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ЭКО • ВЕКТОР

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30 ЛЕТ ЖУРНАЛУ «ТРАВМАТОЛОГИЯ И ОРТОПЕДИЯ РОССИИ»

Дорогие читатели!

Тридцать лет назад, в июне 1993 г., вышел в свет первый выпуск научно-практического журнала «Травматология и ортопедия России».

Единственный в СССР журнал по нашей специальности «Ортопедия, травматология и протезирование» издавался в Харькове, но после распада Советского Союза в 1991 г. российские травматологи и ортопеды остались без своего периодического издания. Поэтому выпуск российского специализированного журнала стал большим событием для отечественной ортопедической науки. О его значимости говорит тот факт, что авторами первого выпуска стали директора научно-исследовательских институтов травматологии и ортопедии, а с приветствием к журналу обратился министр здравоохранения России Э.А. Нечаев.

В условиях отсутствия общедоступного Интернета печатная версия журнала стала единственной платформой, где могли обменяться опытом и обсудить актуальные проблемы российские травматологи-ортопеды. Этим объясняются большие тиражи (2000 экз.) и постоянно растущее число подписчиков. К сожалению, в конце 1990-х – начале 2000-х гг. в связи с финансовыми трудностями журнал стал выходить нерегулярно, а в 1999 и 2001 гг. не вышло ни одного выпуска.

Новый этап развития журнала начался в 2004 г. вместе со сменой главного редактора и редакционной команды. Был взят курс на переход к международным стандартам научной периодики, изменены требования к оригинальным статьям. К рецензированию, которое стало многоступенчатым, были привлечены самые квалифицированные и признанные специалисты в своей области, что позволило достаточно быстро повысить качество научных публикаций. Обязательным этапом рассмотрения рукописей стала их статистическая экспертиза, что обеспечило достоверность результатов и выводов в оригинальных статьях. Надо признать, что авторы не сразу привыкли к новым требованиям, переходный период занял несколько лет. Но если сравнить качество публикаций 20 лет назад и в настоящее время, то отчетливо видно, какая огромная работа была проделана и как повысился уровень журнала.

В последние годы к статьям, посвященным наиболее актуальным или дискуссионным темам, публикуются редакционные комментарии или мнения читателей.

Вместе с повышением качества научных статей постепенно возрастал и рейтинг журнала в Российском индексе научного цитирования (РИНЦ). Сейчас наш журнал занимает 45-е место из 528 научных медицинских журналов и является лидером среди журналов по травматологии и ортопедии. Постоянными читателями на сайте журнала являются 1528 пользователей. Двухлетний импакт-фактор с учетом цитирования из всех источников составляет 1,224. Средний индекс Хирша авторов журнала вырос за 10 лет более чем в два раза и составил 7,3 в 2021 г.

Свидетельством высокого качества издания и его соответствия мировым стандартам стало принятие журнала в 2016 г. в самую престижную международную базу данных Web of Science. Журнал включен также в Directory of Open Access Journals (DOAJ) – крупнейший онлайн-каталог высококачественных рецензируемых журналов открытого доступа, объединяющий более 19 тысяч журналов из 134 стран мира.

С 2001 г. журнал «Травматология и ортопедия России» постоянно входит в список периодических изданий, рекомендованных ВАК РФ для публикации основных научных результатов диссертаций на соискание ученой степени доктора и кандидата наук.

За всю историю журнала нашими авторами стали 1935 специалистов из более чем 200 медицинских организаций. География публикаций охватывает практически все регионы Российской Федерации и 15 зарубежных стран, в том числе США, Германию, Канаду, Норвегию, Италию, Польшу, Чехию, Индию, страны СНГ.

Сейчас, спустя 30 лет, перед редколлегией журнала и редакцией стоят новые задачи. Мы планируем расширить географический охват авторов и научных организаций, сделать журнал привлекательным для зарубежных специалистов, организовать дискуссии по наиболее спорным проблемам специальности на страницах журнала.

С уважением,
главный редактор журнала
«Травматология и ортопедия России»
член-корреспондент РАН профессор Р.М. Тихилов

Original Article
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Long-term Outcomes and Effectiveness of Treatment Methods for Vertebral Osteomyelitis With Different Types of Lesions According to the E. Pola Classification

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Abstract

Background. Treatment of vertebral osteomyelitis (VO) is accompanied by a number of organizational and tactical problems related to the multidisciplinary nature of the disease. Therefore, the use of classifications determining treatment tactics is necessary. The evaluation of treatment outcomes and efficacy should be conducted in accordance with the classification type of the lesion and decisions made based on the tactical algorithm.

Aim of the study — to identify the dependence of long-term treatment outcomes of vertebral osteomyelitis on the type of lesion according to the modified Russian version of the E. Pola classification and the methods of treatment used.

Methods. The study analyzed the treatment results of 266 patients with vertebral osteomyelitis from 2006 to 2019. Type A lesions accounted for 24.1% (n = 64), type B — 47.0% (n = 125), type C — 26.3% (n = 70), and lesions of vertebral processes — 2.6% (n = 7). Neurological disorders were detected in 53 observations (type C). Conservative treatment, debridement, and reconstructive surgeries were performed. The evaluation of results was carried out a year or more after discharge.

Results. The maximum effectiveness of conservative treatment was noted in uncomplicated courses and minor bone destruction. Conservative treatment of type A lesions led to recovery in 97.4% of cases compared to reconstructive operations (p = 0.002) and recurrences (p = 0.034). Mortality was higher after reconstructive interventions (p = 0.001). The highest number of fatal outcomes after debridement of the focus was observed in type B lesions — 15.8% (p = 0.022). Analysis of type C lesions did not reveal significant differences between the methods of treatment used. The maximum number of unsatisfactory results was registered in patients with sepsis: mortality was 17.4%, and in its absence — 4.9% (p = 0.039), recurrences — 21.7% versus 7.8% (p = 0.043), recovery — 56.6% versus 83.5% (p = 0.004), respectively. There were no significant differences in the assessments according to the ODI, NDI, SF-36 scales in the long term. The overall survival rate was 84.4%, and the long-term one was 90.4%, which increased with conservative treatment compared to reconstructive interventions (p = 0.045).

Conclusion. Conservative treatment and extra-focal fixation of the spine showed maximum effectiveness in low-destructive and uncomplicated lesions (type A). Reconstructive interventions lead to an increase in the number of recurrences and fatal outcomes. Debridement of the focus in septic course of type B lesions leads to an increase in hospital mortality. There were no statistically significant differences between the results of different treatment methods for type C lesions.

Keywords: vertebral osteomyelitis, spondylitis, spondylodiscitis, classification of vertebral osteomyelitis.

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Отдаленные результаты и оценка эффективности методов лечения остеомиелита позвоночника при различных типах поражений по классификации E. Pola

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Реферат

Актуальность. Лечение гематогенного остеомиелита позвоночника (ГОП) сопровождается рядом организационных и тактических проблем, связанных с мультидисциплинарным характером заболевания. При этом абсолютно необходимо использование классификаций, определяющих тактику лечения. Оценку результатов и эффективности методов лечения целесообразно проводить в соответствии с классификационным типом поражения и решениями, принятыми на основании тактического алгоритма.

Цель исследования — выявить зависимость отдаленных результатов лечения гематогенного остеомиелита позвоночника от типа поражения по модифицированной русскоязычной версии классификации E. Pola и использованных методов лечения.

Материал и методы. Выполнен анализ результатов лечения 266 больных гематогенным остеомиелитом позвоночника за 2006–2019 гг. Поражения типа А составили 24,1% (n = 64), В — 47,0% (n = 125), С — 26,3% (n = 70), поражения отростков позвонков — 2,6% (n = 7). Неврологические нарушения выявлены в 53 наблюдениях (тип С). Выполнялись консервативное лечение, санирующие, стабилизирующие и реконструктивные вмешательства. Оценка результатов проводилась через год и более после выписки.

Результаты. Отмечена максимальная эффективность консервативного метода при неосложненном течении и незначительной костной деструкции. Консервативное лечение поражений А привело к выздоровлению в 97,4% наблюдений в сравнении с реконструктивными операциями (p = 0,002) и рецидивами (p = 0,034). Летальность была выше после реконструктивных вмешательств (p = 0,001). При поражениях типа В отмечено максимальное количество летальных исходов после санации очага — 15,8% (p = 0,022). Анализ поражений типа С не выявил значимых различий между использованными методами лечения. Максимальное количество неудовлетворительных результатов зарегистрировано у больных с сепсисом: летальность составила 17,4%, а при его отсутствии — 4,9% (p = 0,039), рецидивы — 21,7% против 7,8% (p = 0,043), выздоровления — 56,6% против 83,5% (p = 0,004) соответственно. Различий в оценках по шкалам ODI, NDI, SF-36 в отдаленном периоде не выявлено. Общая выживаемость составила 84,4%, отдаленная — 90,4% с ее повышением при консервативном лечении в сравнении с реконструктивными вмешательствами (p = 0,045).

Заключение. Консервативное лечение и внеочаговая фиксация позвоночника показали максимальную эффективность при малодеструктивных и неосложненных поражениях (тип А). Реконструктивные вмешательства приводят к повышению количества рецидивов и летальных исходов. Санация очага при септическом течении поражений типа В приводит к увеличению госпитальной летальности. Не выявлено статистически значимых различий между результатами различных методов лечения поражений типа С различными методами лечения.

Ключевые слова: остеомиелит позвоночника, спондилит, спондилодисцит, классификация остеомиелита позвоночника.

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BACKGROUND

Increasing life expectancy, the presence of comorbidities in the older age group, a significant increase in the volume of planned surgical care for the population, and the proportion of patients with immunodeficiency have led to a significant rise in inflammatory spinal disorders [1, 2, 3, 4]. In the general population, there has been an increase in the incidence of vertebral osteomyelitis (VO) from 2.2 per 100,000 population per year in 2008 to 11.3 in 2019. This rate reaches 21.6 per 100,000 population per year in the age group over 70 and 25.1 in the age group 80 and above [5, 6, 7].

The International Classification of Diseases, 10th Revision (ICD-10) is the primary classification used in most studies for documentation purposes and does not influence the choice of treatment [5, 7]. Guidelines and recommendations are used to determine treatment strategies [8, 9, 10, 11, 12], but a systematic evaluation of treatment outcomes based on the classification used is not provided. E. Pola et al. proposed a new classification for spondylodiscitis, the New Classification of Pyogenic Spondylodiscitis (NCPS), in 2017, with an inter-expert agreement among trained specialists of 67% [14]. The classification provides general data on treatment outcomes, including the proportion of recoveries, recurrences, fatal outcomes, and residual back pain based on the type of lesion, but an analysis of the effectiveness of treatment methods is not provided, and ventral interventions are absent from the treatment algorithm [13].

The aim of this study was to determine the relationship between long-term treatment outcomes of vertebral osteomyelitis and the type of lesion according to the modified Russian version of E. Pola's classification and the treatment methods used.

METHODS

Study design

A retrospective observational study was conducted.

The medical records of 266 patients with VO who underwent treatment from 2006 to 2019 at the State Budgetary Healthcare Institution Tyumen Regional Clinical Hospital No. 2, Tyumen, Russia, were analyzed.

Inclusion Criteria: all patients with nonspecific spinal osteomyelitis.

Exclusion Criteria:

– specific spondylitis (tuberculosis, brucellosis);

– postoperative spondylitis;

– lack of follow-up for one year or more since discharge;

– age under 18 years.

Patients

To determine the type of lesion, a modified Russian version of E. Pola's classification was used [15, 16]. The distribution of patients by types and subtypes is presented in Table 1.

Neurological disorders developed in 53 observations in patients with type C lesions. Acute and subacute forms of the disease were present in 160 (60.2%) patients, while chronic forms were present in 106 (39.8%) patients. The level of involvement was localized in the cervical spine in 20 (7.5%) observations, thoracic spine in 90 (33.8%), lumbar spine in 144 (54.1%), and multi-level processes were identified in 12 (4.5%) patients.

Table 1

Distribution of patients by types and subtypes of lesions, n (%)

Lesion type	Lesion subtype				Total
A	A.1 0 (0.0)	A.2 44 (68.8)	A.3 16 (25.0)	A.4 4 (6.2)	64 (100.0)
B	B.1 65 (52.0)	B.2 42 (33.6)	B.3.1 17 (13.6)	B.3.2 1 (0.8)	125 (100.0)
C	C.1 8 (11.4)	C.2 15 (21.4)	C.3 21 (30.0)	C.4 26 (37.2)	70 (100.0)
Lesions not classified according to NCPS*	7 (100.0)				7 (100.0)

* Lesions of posterior structures without involvement of the spinal-motor segment (n=6) and CI-CII articulation (n=1).

Conservative therapy was performed in 88 (33.1%) patients, while 178 (66.9%) patients underwent surgery. Debridement, stabilization, and reconstructive surgeries were applied (Table 2).

Ventral interventions were performed in 108 patients, with transpedicular fixation added in 75 (69.4%) cases. Anterior 360° spondylodesis, including reconstruction, was performed in 29 (26.8%) patients. The duration of hospital stay was 30.01±16.42 days.

Outcome assessment

Outcome assessment was conducted one year after discharge from the hospital. In the long-term period, the following were evaluated: pain severity using the Visual Analog Scale (VAS), functional status of the cervical spine using the Neck Disability Index (NDI), and the lumbar spine using the Oswestry Disability Index (ODI), severity of neurological di-sorders using the Frankel scale, and data from the SF-36 questionnaire.

Table 2

Distribution of patients by treatment methods and lesion type, n (%)

Treatment method	Lesion type			Lesions not classified according to NCPS * 7 (2.6)	Total 266 (100.0)
	A 64 (24.1)	B 125 (47.0)	C 70 (26.3)		
Conservative	38 (59.4)	42 (33.6)	7 (10.0)	2 (28.6)	89 (33.4)
Debridement	12 (18.7)	19 (15.2)	24 (34.3)	5 (71.4)	60 (22.6)
Stabilization	11 (17.2)	33 (26.4)	6 (8.6)	0 (0.0)	50 (18.8)
Reconstruction	3 (4.7)	31 (24.8)	33 (47.1)	0 (0.0)	67 (25.2)

* Lesions of the posterior structures without involvement of the spinal motion segment (n = 6) and the CI–CII articulation (n = 1).

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics 21 software package.

The distribution of quantitative variables was assessed using the Kolmogorov-Smirnov test. For normally distributed variables, the results are presented as the mean (M) and standard deviation (SD), while for non-normally distributed variables, the results are presented as the median (Me) and interquartile range (25^{th} and 75^{th} percentiles). Student's t-test was used for comparing variables between two groups with normal distribution, and the Mann-Whitney U test was used for non-normally distributed variables. One-way analysis of variance (ANOVA) or the Kruskal-Wallis test with Bonferroni correction was used for comparing variables among more than two groups. The Wilcoxon signed-rank test was used for comparing variables over time. Categorical variables in independent groups were compared using the chi-square test or Fisher's exact test, and in paired groups using McNemar's test. When comparing more than two groups, the significance level was adjusted using the Bonferroni correction by multiplying the original p-values by the number of performed comparisons. Survival analysis was performed using the Kaplan-Meier method with survival curves and the log-rank test for comparing survival between groups. Differences were considered significant at $p<0.05$.

RESULTS

All patients received inpatient treatment at the Traumatology and Orthopedics or Neurosurgery department of Hospital No. 2 in Tyumen. In most cases, the length of hospital stay was determined by the duration of the course of antibiotic therapy (ABT) for conservative treatment and the postoperative period. The average duration of ABT was 1.8-3.8 weeks during hospitalization and 4.0-7.2 weeks on an outpatient basis. An increase in the duration of antibiotic treatment was observed from mono-segmental lesions to poly-segmental and multi-level lesions, which amounted to 1.8-3.8 and 1.6-4.2 weeks during the hospital stage, and 3.9-7.2 and 4.2-7.2 weeks during the outpatient stage.

Surgical treatment methods were divided into three main types: debridement, stabilization, and reconstructive. The effectiveness of these me-thods was assessed based on the main types of lesions according to E. Pola's classification with co-authors. A statistically significant increase in

the number of stabilization procedures was noted for type A lesions compared to more severe forms of the disease (p<0.001). In these cases, transpedicular fixation was performed in a minimally invasive manner without intervention at the infectious-inflammatory focus, which eliminated the need for prolonged wearing of a rigid brace and improved the quality of life. The proportion of reconstructive interventions increased for type B (p = 0.036) and type C (p<0.001) lesions compared to lesions without bone destruction, neurological disorders, and epidural abscess (type A).

The distribution of outcomes based on the type of lesion and treatment method is presented in Table 3. When analyzing the data presented in Table 3, some statistically significant differences were found for different types of lesions.

For type A lesions: the highest number of recovered patients was observed with conservative treatment (97.4%) and stabilization surgeries (90.9%), while the lowest was observed with reconstructive interventions at 33.3% (p = 0.002). Performing reconstructive interventions for these lesions resulted in a 66.7% mortality rate, whereas the mortality rate for conservative therapy was 2.6% (p = 0.001).

For type B lesions: conservative treatment remains highly effective for subtypes B.1 (82.8%) and B.2 (85.7%), which decreases with increasing severity of bone destruction. After extrafocal instrumental fixation for mild-destructive lesions, the recovery rates were 82.4% for B.1 and 100% for B.2. Bone-destructive processes with objective signs of segmental instability were an indication for reconstructive surgeries, including the use of ventral approaches. Overall, in-hospital mortality for type B lesions was 4.0%, and an increase in mortality was observed after debridement interventions to 15.8% (p = 0.022), with the indication for surgery being the patient's overall severe condition.

For type C lesions: conservative treatment was only used in the absence of neurological disorders and/or in the presence of absolute contraindications for surgery. Extrafocal stabilization was performed exclusively for subtypes C.1 and C.2 in neurologically intact patients. Focal lesion drainage and decompression via ventral or dorsal access were the preferred methods in cases of acute neurological deficit or sepsis when reconstruction was not possible due to the severity of the patient's condition. Stable hemodynamics and compensation of

Table 3

Disease outcomes according to lesion type and treatment method, n (%)

Lesion type	Treatment outcome*	Treatment method				*p*
		Conservative	Surgical			
			Debridement	Stabilization	Reconstruction	
A	Recovery	37 (97.4)	10 (83.3)	10 (90.9)	1 (33.3)	0.002
	Recurrence	0 (0.0)	2 (16.7)	1 (9.1)	0 (0.0)	0.089
	Fatal	1 (2.6)	0 (0.0)	0 (0.0)	2 (66.7)	0.001
	Total	38 (100.0)	12 (100.0)	11 (100.0)	3 (100.0)	
B	Recovery	35 (83.3)	12 (63.2)	30 (90.9)	26 (83.9)	0.087
	Recurrence	3 (7.1)	3 (15.8)	3 (9.1)	4 (12.9)	0.720
	Fatal	2 (4.8)	3 (15.8)	0 (0.0)	0 (0.0)	0.022
	Progression	2 (4.8)	1 (5.3)	0 (0.0)	1 (3.2)	0.641
	Total	42 (100.0)	19 (100.0)	33 (100.0)	31 (100.0)	
C	Recovery	5 (83.3)	17 (68.0)	5 (83.3)	23 (69.7)	0.795
	Recurrence	1 (16.7)	5 (20.0)	0 (0.0)	1 (3.0)	0.137
	Fatal	0 (0.0)	2 (8.0)	0 (0.0)	5 (15.2)	0.490
	Progression	0 (0.0)	1 (4.0)	1 (16.7)	4 (12.1)	0.520
	Total	6 (100.0)	25 (100.0)	6 (100.0)	33 (100.0)	

* One patient with a fatal outcome in monovertebral lesion (not classified according to NCPS) is not included in the table.

vital functions were the basis for reconstructive interventions for subtypes C.2-C.4. We did not find statistically significant differences in the number of cases of recovery, recurrence, and in-hospital mortality depending on the treatment method, which suggests a correct tactical approach in the treatment of type C lesions. The treatment outcomes of HOP based on the type of lesion, regardless of the treatment method, are presented in Table 4.

When analyzing the data presented in Table 4, a statistically significant decrease in the number of recovered patients was observed with increasing severity of spinal cord lesions ($p = 0.016$). The severity of neurological disorders was higher in patients after debridement ($p = 0.002$) and reconstructive interventions ($p<0.001$) both before and after treatment ($p = 0.001$, $p<0.001$, respectively). A statistically significant decrease in the severity of neurological deficit in the postoperative period was observed after debridement and reconstructive interventions ($p = 0.004$), while no such relationship was found after stabilization surgeries ($p = 0.180$). The dynamics of neurological deficit before and after treatment depending on the method are presented in Table 5.

In the conservative and surgical treatment groups, the severity of neurological disorders was significantly lower in the long-term period ($p<0.001$).

Significant differences in treatment outcomes were observed in patients with sepsis, which occurred in 26.1% (n = 6) of type A lesions, 34.8% (n = 8) of type B lesions, and 39.1% (n = 9) of type C lesions. The treatment outcomes depending on the presence of sepsis are presented in Table 6.

The analysis revealed a statistically significant increase in the proportion of in-hospital mortality by 12.5% ($p = 0.039$), recurrence by 13.9% ($p = 0.043$), and a decrease in the number of recovered patients by 27% ($p = 0.004$) in the presence of sepsis compared to the group of patients without this complication.

The long-term results were evaluated no earlier than one year after discharge from the hospital. The main criteria were the severity of pain syndrome assessed by VAS, the functional status of the spine assessed by ODI and NDI, and the overall health status of the patient assessed by SF-36. A statistically significant decrease in the severity of pain syndrome was observed after one year or more after discharge ($p<0.001$). The treatment results depending on the method are presented in Table 7.

No statistically significant differences were found when comparing the results between the comparison groups. The indicators reflecting the long-term treatment outcomes depending on the type of lesion are presented in Table 8.

When analyzing the intensity of pain depending on the main types of lesions according to E. Pola, a decrease in pain intensity was also observed in the long-term period ($p < 0.001$) in all comparison groups. No differences in the severity of pain syndrome were found depending on the type of lesion ($p>0.05$).

Survival analysis was conducted based on data from 198 patients, which accounted for 74.4% of the total cohort. The follow-up period for the patients was 47.50 [25.00; 82.00] months.

The overall survival rate for all types of lesions over the entire follow-up period was 84.4%. No statistically significant differences were found between the types of lesions, but in absolute numbers, this indicator decreased with increasing severity of the disease: 92.1% for type A, 86.8% for type B, and 76.0% for type C. There was a tendency towards higher survival rates in type A compared to type C ($p = 0.080$). Analysis of the proportion of surviving patients in conservative treatment and the

Table 4

Distribution of patients according to treatment outcomes based on lesion type regardless of treatment method, n (%)

Criterion	Lesion type			*p*
	A	B	C	
Recovery	57 (89.0)	103 (82.4)	50 (71.4)	0.016
Recurrence / Progression	4 (6.3)	17 (13.6)	13 (18.6)	0.106
Hospital mortality	3 (4.7)	5 (4.0)	7 (10.0)	0.207
Total	64 (100.0)	125 (100.0)	70 (100.0)	—

Table 5

Neurological deficit before and after treatment based on treatment method, n (%)

Neurological deficit by Frankel grade	Treatment method			
	Conservative		Surgical	
	Before treatment	After treatment	Before treatment	After treatment
A	0 (0.0)	0 (0.0)	12 (6.7)	7 (3.9)
B	0 (0.0)	0 (0.0)	9 (5.1)	2 (1.1)
C	1 (1.1)	0 (0.0)	20 (11.2)	16 (9.0)
D	1 (1.1)	0 (0.0)	10 (5.6)	19 (10.7)
E	86 (97.8)	88 (100.0)	124 (69.7)	134 (75.3)
R*	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)

* R - Radicular syndrome; $p<0.001$.

Table 6

Treatment outcomes based on the presence of sepsis, n (%)

Criterion	Sepsis		*p*
	Absent	Present	
Recovery	203 (83.5)	13 (56.5)	0.004
Recurrence	19 (7.8)	5 (21.7)	0.043
Progression*	9 (3.8)	1 (4.3)	0.602
Hospital mortality	12 (4.9)	4 (17.4)	0.039
Total	243 (100.0)	23 (100.0)	—

* Progression against the background of complex treatment.

Table 7

Long-term treatment outcomes based on treatment method

Criterion	Treatment method		*p*
	Conservative	Surgical	
VAS before treatment. Me [25%; 75%]	9.0 [8.00; 10.00]	9.0 [8.00; 10.00]	0.790
VAS after treatment, Me [25%; 75%]	2.0 [0.00; 4.00]	2.0 [0.00; 3.00]	0.425
NDI, Me [25%; 75%]	–	12.17 [9.00; 17.00]	–
ODI, Me [25%; 75%]	16.0 [4.00; 26.00]	12.67 [2.00; 31.10]	0.626
PH (SF-36), M±SD	40.33±10.04	41.00±10.57	0.824
MH (SF-36), M±SD	47.00±11.62	47.28±10.71	0.776

When comparing the intensity of pain syndrome before treatment and in the long-term period, a statistically significant reduction was observed within the comparison groups ($p<0.001$).

Table 8

Long-term treatment outcomes based on lesion type

Criterion	Lesion type			*p*
	A	B	C	
	Me [25; 75%]	Me [25; 75%]	Me [25; 75%]	
VAS before treatment, Me [25%; 75%]	9.0 [8.00; 10.00]	9.0 [8.00; 10.00]	10.0 [8.00; 10.00]	0.640
VAS after treatment, Me [25%; 75%]	2.0 [0.00; 4.00]	2.0 [0.00; 2.00]	2.0 [0.00; 4.00]	0.260
NDI, Me [25%; 75%]	–	–	12.17 [9.00; 17.00]	–
ODI, Me [25%; 75%]	16.0 [0.00; 20.00]	13.33 [4.00; 28.00]	29.40 [4.00; 36.00]	0.223
PH (SF-36), M±SD	39.26±9.10	41.59±10.23	39.69±11.29	0.578
MH (SF-36), M±SD	47.55±8.14	46.98±11.28	47.37±12.37	0.973

When comparing the intensity of pain syndrome before treatment and in the long-term period, a statistically significant reduction was observed within the comparison groups ($p<0.001$).

main types of surgical interventions revealed the following differences: survival rate in conservative treatment reached 92.1%, in stabilization surgeries — 88.9%, in debridement — 84.2%, and in reconstructive interventions — 74.3%.

Statistically significant differences were found between conservative treatment and 360° spinal fusion (log rank = 4.028; p = 0.045). The highest survival rate was observed in the absence of surgical intervention and decreased with increasing volume and invasiveness.

Long-term survival (after discharge from the hospital) was 90.4%, and no statistically significant differences were found between the conservative and surgical treatment groups — 95.5% and 88.4% respectively (log rank = 1.286; p = 0.257) (Fig. 1).

DISCUSSION

Evaluation of the treatment outcomes of pyogenic spondylodiscitis (PSD) in most publications is traditionally conducted through comparisons of the localization of the pathological process, presence of complications, effectiveness of treatment methods, and types of surgeries [17, 18, 19, 20, 21, 22, 23], or it is justified by the necessity of surgical treatment in the absence of adequate progress with conservative therapy [24]. The need for a multidisciplinary approach to PSD treatment is acknowledged by many researchers [25, 26]. The initial experience of applying tactical classifications and algorithms aims to prove the validity of this approach, and authors present general treatment outcomes based on the different variants of the pathological process without providing evidence of the effectiveness of the proposed treatment options [10, 11, 13].

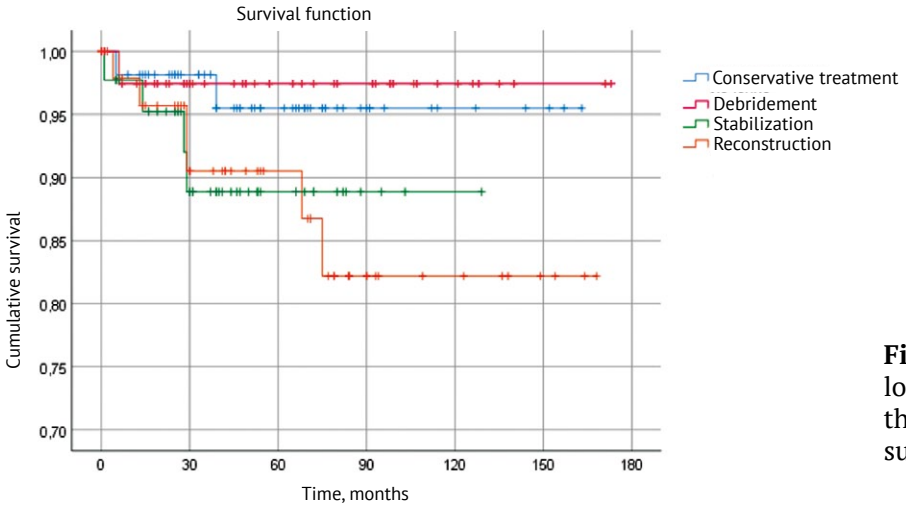

Fig. 1. Patient survival in the long-term period depending on the treatment method and type of surgery

While the development of a tactical classification is considered the first step in the treatment of multidisciplinary conditions [10, 27], and the validation of its accuracy is the second step [14, 16], the third step undoubtedly should be the evaluation of the effectiveness of the proposed algorithm, which involves matching the type/subtype of the lesion to the chosen treatment method. The use of the aforementioned classifications in clinical practice allows for better consideration of the various disease progressions, as demonstrated in the New Classification for the Treatment of Pyogenic Spondylodiscitis by E. Pola et al. [13], without increasing the complexity of its application. Although the use of this classification in Russia is currently recommended, it is actively applied in specialized institutions where patients with spinal osteomyelitis are treated [16].

The original paper by E. Pola et al. presented three main types of lesions: Type A, without bone destruction; Type B, with bone destruction; and Type C, with epidural abscess and/or neurological deficit. The criteria, such as the degree of involvement of paravertebral tissues, instability of the affected spinal segment, and presence of neurological deficit, allow for the selection of the optimal treatment approach for patients [13]. However, there are some limitations to the use of this classification, including specific etiology of the disease, postoperative spondylodiscitis, and localization in the cervical spine [16]. Additional considerations, such as accounting for the presence of systemic inflammatory response syndrome and sepsis, as well as treatment options for cervical spine involvement, are necessary for the development of an algorithm that takes into account lesions in all segments of the spine and the most significant complications [28].

The results presented in our study are based on three main types of lesions. Conservative treatment is the primary method for Type A lesions, compared to Types B and C, where the proportion of surgical interventions significantly increases ($p<0.01$). Laminectomy was performed more frequently for Type C lesions than for Type B ($p<0.001$). The use of posterior approaches with bone resection elements for Types B and C can only be justified for lesions involving the vertebral arches or processes or for reconstruction using a posterior approach. The frequency of anterior debridement and/or reconstruction increases for Type C lesions compared to Types A ($p = 0.012$) and B ($p<0.001$). Thus, the extent of surgical intervention correlates strictly with the type/subtype of the lesion (severity of the disease), while maintaining the high effectiveness of conservative treatment in uncomplicated cases.

Considering the lack of data on the effectiveness of treatment methods in the work by E. Pola et al., we conducted a comparative analysis of the main outcomes, taking into account a comparable number of patients in both studies — 250 and 259 observations, respectively — classified according to the New Classification for the Treatment of Pyogenic Spondylodiscitis (NCPS). The comparative analysis of our own treatment outcomes for PSD with the data from E. Pola et al. is presented in Table 9.

The studies presented here show differences in the disease structure, diagnostic timelines, and consequently, treatment outcomes, due to the predominance of Type C lesions in the work by E. Pola et al. and Type B lesions in our study. It is important to note that comparing the total number of patients without analyzing the subtypes, considering the severity of neurological deficit, extent of paravertebral abscesses, and instability of the affected spinal segment, does not allow for a direct comparison of the results obtained. These differences may be attributed to differences in the timing of diagnosis, age composition of the studied cohorts, comorbidities, and organization of patient care. It is crucial to emphasize that adherence to tactical classifications and treatment algorithms must be consistent with the basic principles of PSD treatment, including appropriate composition and duration of antibiotic therapy and immobilization of the affected spinal segment [9, 24, 29, 30].

Further investigation into the effectiveness of treatment methods for spinal osteomyelitis, specifically in relation to lesion types and the justification of tactical algorithms, should be conducted in a multicenter prospective study. This would help address various organizational and practical challenges in the treatment of this multidisciplinary condition.

CONCLUSION

A systemic approach to treatment using a tactical classification and treatment algorithm allows for the assessment of the effectiveness of the utilized methods for different types of spinal osteomyelitis. For minimally destructive and non-septic Type A and Type B lesions, conservative treatment and focal stabilization achieve 97.4% and 90.9% of recoveries, respectively ($p = 0.002$). The use of reconstructive interventions leads to an increase in recurrence rate and mortality ($p = 0.001$). The mortality rate for Type B lesions after debridement procedures reaches 15.8%

Table 9

Distribution of treatment outcomes for hematogenous spondylodiscitis based on lesion type compared to the data from E. Pola et al. [13], n (%)

Treatment outcome	Lesion type					
	A		B		C	
	E. Pola et al.	Own research	E. Pola et al.	Own research	E. Pola et al.	Own research
Recovery	81 (96.43)	57 (89.06)	43 (93.48)	103 (82.40)	108 (90.00)	50 (71.43)
Recurrence	8 (9.52)	4 (6.25)	2 (4.35)	17 (13.60)	4 (3.33)	13 (18.57)
Mortality	3 (3.57)	3 (4.69)	3 (6.52)	5 (4.00)	6 (5.00)	7 (10.00)
Total	84 (33.60)	64 (24.10)	46 (18.40)	125 (47.00)	120 (48.00)	70 (26.30)

(p=0.022), which is attributed to the presence of sepsis in operated patients. No statistically significant differences were found in the results of the presented treatment methods for Type C lesions. A significant reduction in pain syndrome in the long-term period was observed in all patient groups (p<0.001), as well as a decrease in the severity of neurological deficits in the postoperative period (p<0.001). No differences in treatment outcomes were found in the long-term period based on ODI, NDI, and SF-36 scales. The overall survival rate was 84.4%, and the long-term survival rate was 90.4%, with a significant increase in survival observed with conservative treatment compared to reconstructive interventions.

DISCLAIMERS

Author contribution

Bazarov A.Yu. — the conception and design of the study, the analysis and interpretation of data, the writing of the article.

Sergeev K.S. — the analysis and interpretation of data, the drafting of the article.

Tsvetkova A.K. — data collection and processing.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Anterior Dynamic Versus Posterior Transpedicular Spinal Fusion for Lenke Type 5 Idiopathic Scoliosis: A Comparison of Long-term Results

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Abstract

Background. Despite the active implementation of dynamic correction in case of idiopathic scoliosis, there are no comparative studies of results of posterior and anterior dynamic correction in patients with completed and near-completed growth.

Aim of the study — to compare clinical and radiological results of anterior dynamic correction and conventional posterior transpedicular correction of Lenke type 5 scoliotic deformities in patients with completed or near-completed growth.

Methods. Eighty-six patients with Lenke type 5 scoliotic deformities were enrolled in the study. The first group (54 patients) underwent deformity correction via posterior approach using a rigid transpedicular system; the second group (32 patients) — using dynamic correction system. Mean patients' age was 22.6±12.8 and 27.3±10.9 years, respectively. We studied radiological data before surgery, immediately after surgery, and 2 or more years after surgery. Blood loss volume, duration of hospital stay, and duration of narcotic analgesics intake in the early postoperative period were analyzed. Functional results were assessed using SRS-22 questionnaire.

Results. Preoperative Cobb angle in the first group was 65.5°, and 27.5° at the long-term follow-up. Junctional kyphosis of T10-L2 before surgery was 21.0° and 13.2° at the long-term follow-up. Preoperative Cobb angle of the initial curve in the second group was 52.5° and 24.5° at the long-term follow-up. Junctional kyphosis of T10-L2 before surgery was 19.5°, and 19.0° at the long-term follow-up. Nash and Moe apical vertebral rotation in the first group before surgery was 1.62 and 0.17 at the last follow-up; in the second group, it was 1.80 and 0.81, respectively. Mean number of fixed levels was 6.4±1.0 in the first group and 5.6±1.5 in the second group. Mobility of the thoracolumbar/lumbar curve was higher in the second group, 28.2±9.1°, compared with 36.0±7.2° in the first group. Preoperatively, lumbar lordosis in the second group was 42.5°, in the long-term period — 43.5°, and in the first group — 43.4° and 44.3°, respectively.

Conclusion. Both posterior rigid and anterior dynamic correction in case of Lenke type 5 idiopathic scoliosis can provide satisfactory radiological results with initially similar thoracolumbar deformities in patients with completed or near-completed growth. However, dynamic approach can reduce blood loss, duration of hospital stay, duration of narcotic analgesics intake after surgery, and improve quality of life in the long-term period.

Keywords: lumbar scoliosis, spinal fusion, Lenke type 5, anterior dynamic fusion, transpedicular fusion..

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Вентральная динамическая или дорсальная транспедикулярная коррекция и фиксация при хирургическом лечении идиопатического сколиоза типа Lenke 5: сравнение отдаленных результатов

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Реферат

Актуальность. Несмотря на активное внедрение динамической коррекции при идиопатическом сколиозе, отсутствуют сравнительные исследования результатов дорсальной и вентральной динамической коррекции у пациентов с завершенным и завершающимся ростом.

Цель исследования — сравнить клинические и рентгенологические результаты вентральной динамической коррекции и традиционной дорсальной транспедикулярной коррекции сколиотических деформаций типа Lenke 5 у пациентов с завершенным или завершающимся ростом.

Материал и методы. В исследование было включено 86 пациентов со сколиотическими деформациями типа Lenke 5. В первой группе (54 пациента) выполняли коррекцию деформации из дорсального доступа с использованием ригидной транспедикулярной системы, во второй группе (32 пациента) — с применением системы для динамической коррекции. Средний возраст пациентов составил 22,6±12,8 и 27,3±10,9 лет соответственно. Изучали рентгенологические данные до операции, сразу после операции и через 2 и более года после операции. Анализировали объем кровопотери, сроки пребывания в стационаре, длительность приема наркотических анальгетиков в раннем послеоперационном периоде. Функциональные результаты оценивали с использованием опросника SRS-22.

Результаты. В первой группе угол Кобба до операции составил 65,5°, при отдаленном наблюдении — 27,5°. Переходный кифоз Th10–L2 до операции составил 21,0°, при отдаленном наблюдении — 13,2°. Предоперационный угол Кобба основной дуги во второй группе 52,5°, а в отдаленные сроки — 24,5°. Переходный кифоз Th10–L2 до операции — 19,5°, в отдаленные сроки — 19,0°. Ротация апикального позвонка по Nash — Moe в первой группе до операции составила 1,62, при последнем осмотре — 0,17, во второй группе — 1,80 и 0,81 соответственно. Среднее количество фиксированных уровней составило в первой группе — 6,4±1,0, во второй — 5,6±1,5. Мобильность грудопоясничной/поясничной дуги была выше во второй группе — 28,2±9,1° по сравнению с первой группой — с 36,0±7,2°. До операции поясничный лордоз у пациентов второй группы составил 42,5°, в отдаленные сроки — 43,5°, у пациентов первой группы — 43,4° и 44,3° соответственно.

Заключение. Как задняя ригидная, так и вентральная динамическая коррекция при идиопатическом сколиозе Lenke 5 могут обеспечить удовлетворительный рентгенологический результат при изначально схожей величине грудопоясничных деформаций у пациентов с завершенным или завершающимся ростом. Однако динамический подход позволяет сократить объем кровопотери, срок пребывания в стационаре, длительность приема наркотических анальгетиков после операции, а также улучшить качество жизни в отдаленном периоде.

Ключевые слова: поясничный сколиоз, коррекция сколиоза, Lenke 5, вентральная динамическая коррекция, транспедикулярная фиксация.

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BACKGROUND

One of the frequent problems faced by spine surgeons managing idiopathic scoliosis is the choice of treatment tactics for patients with completed growth who have radiological indication for a surgery and moderate degree of deformity with asymptomatic course of disease. Patients and their families discuss and evaluate the benefits of surgical treatment and search for alternative (both surgical and nonsurgical) methods, especially if there is no pain, pulmonary dysfunction, or other problems associated with the spinal deformity [1]. In addition, surgical correction in patients with completed growth often raises concerns about possible various complications, especially palsy. Therefore, studies comparing the results of surgical treatment of scoliosis in adolescents and adults have begun to appear in order to prove the advantages of performing surgical correction at a younger age.

Patients who undergo surgical treatment of idiopathic scoliosis via posterior approach at a younger age have less fixed segments, lower blood loss, shorter duration of surgery, and fewer complications in comparison with adults who had natural history of scoliosis and its progression and sought medical attention later, although X-ray data of correction are similar and improvement in quality of life after surgery is observed in both cohorts [2]. However, methods of surgical treatment of idiopathic scoliosis remain controversial. In particular, there is no agreement upon the choice of approach (anterior or posterior) [3], optimal points of fixation [4, 5], prevention of complications [6], and, importantly, the choice of instruments in case of surgical treatment of scoliosis with main curve in the lumbar or thoracolumbar part (Lenke type 5). According to Lenke classification, type 5 deformity is optimal for anterior correction [7]. When hooks were used in posterior surgery, anterior approach provided better results, since screws enabled to improve derotation effect [8, 9]. However, with the beginning of use of transpedicular screws, the situation changed: efficacy of posterior correction increased and became comparable to the anterior one. Most surgeons in the world began to use posterior transpedicular correction and fixation because they are technically easier to be performed [10, 11]. In general, no difference was found in radiological and clinical outcomes in patients after anterior or posterior correction with the use of rigid fixation for Lenke type 5 scoliosis [12]. However, risks and advantages of each approach are considered by the surgeon and the patient individually [12].

Since recently, surgeons have begun to use dynamic correction systems, first in pediatric patients to modulate growth [13, 14, 15] and later in patients with completed or near-completed growth as an option [6, 16]. Using dynamic correction system preserves mobility in the area of fixation, as confirmed by biomechanical studies [17]. Dynamic correction also allows patients to return to their usual physical and sports activities in a short period of time [18].

Despite active implementation of dynamic correction systems in the treatment of idiopathic scoliosis, there are few reports on the results of using this method in patients with completed or near-completed growth, as well as comparative studies concerning the use of posterior correction (spine fusion) and anterior dynamic correction.

Aim of the study — to compare clinical and radiological results of anterior dynamic correction and conventional posterior transpedicular correction of Lenke type 5 scoliotic deformities in patients with completed or near-completed growth.

METHODS

Study design

A retrospective non-randomized cohort comparative study was performed basing on data analysis of patients with Lenke type 5 idiopathic scoliosis who underwent deformity correction via posterior approach using rigid transpedicular system (with spine fusion) and dynamic correction system (without spine fusion).

Inclusion criteria:

1) Lenke type 5 idiopathic scoliosis;

2) one-stage surgery for Lenke type 5 scoliosis via posterior approach with transpedicular fixation and spine fusion or dynamic fixation using transcorporal screws connected by a flexible polyethylene terephtholate cord;

3) follow-up period of more than 2 years.

Exclusion criteria:

1) non-selective fixation;

2) incomplete radiological data.

The study enrolled 86 patients operated between 2013 and 2021 by the same surgeon who

had experience in both anterior and posterior scoliosis correction.

The first group included 54 patients with lumbar or thoracolumbar idiopathic scoliosis aged 16 to 41 years: 48 women and 6 men. Classic posterior correction with the use of transpedicular screws was performed in this group. Posterior approach with stripping of the posterior vertebral elements was performed, transpedicular screws were inserted using the free-hand method with subsequent X-ray examination, and posterior release (Ponte osteotomy at several levels) was carried out in some patients. Three-plane correction using rods and posterior spine fusion were performed (Fig. 1).

The second group consisted of 32 patients aged 14 to 44 years: 29 women and 3 men. Thoracophrenolumbotomy without rib resection was performed in this group. Two screws with staples (buttress plates) were inserted into the vertebral bodies, and correction was performed using two cords (Fig. 2). Zimmer Dynesis system was used in this group.

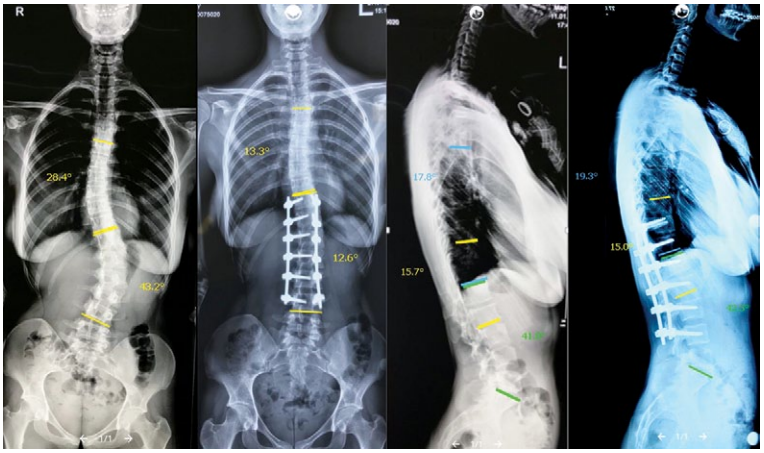

Fig. 1. X-rays of a 31-year-old patient with left-sided lumbar scoliosis before and 2 years after posterior correction and T11-L4 fixation. Satisfactory result was achieved. No loss of correction was observed at the long-term follow-up

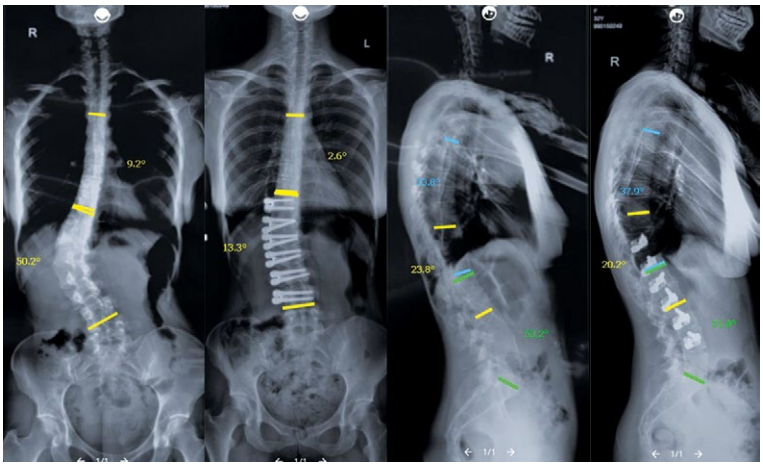

Fig. 2. X-rays of a 32-year-old patient before and 2 years after posterior correction and T11-L4 fixation. No loss of correction was observed. No signs of bone block formation were noted

Both groups included only patients who had undergone a single-stage surgical intervention for correction of deformity without the use of preoperative halo-traction. In both groups, indication for surgical treatment was the deformity of more than 40°.

Type of deformity was assessed according to Lenke classification. Lenke type 5 includes deformities in which the apex of the main (structural) curve is between T12 and L4 vertebrae, i.e. T12, L1, L2, and L3. Thoracic and upper thoracic curves are not structural. This means that their magnitude is less than that of the initial main curve, which are corrected by less than 25° on lateral tilt X-rays.

End vertebrae were included in the area of fixation according to radiological data. The lower point of fixation of L3 was selected if the L3-L4 disc was parallel or "open" on the concave side; neutral; with a tilt to the opposite side on X-rays;

and L3 was centered above the sacrum. In the remaining cases, L4 was selected as the most distal fixed vertebra. In one case, L2 was selected as the lower point of fixation. If two lower vertebrae were parallel, the more caudal vertebra was chosen as the most distal instrumented vertebra.

Evaluation methods

Preoperative, postoperative, and final (at the time of the last examination) spine X-rays in the standing position were analyzed using Cobb method in the frontal and sagittal planes. X-rays with left and right tilt, traction test (spinal traction along the axis with a load of 40% of the patient's weight, but not more than 30 kg), magnitude of lumbar lordosis and thoracic kyphosis before and after surgery, spinal derotation using Nash-Moe method were used to assess spinal flexibility before surgery [19].

Due to no access to postural X-rays at the time of preoperative examination and surgery in patients with rigid constructs, we had to refuse to assess sagittal parameters in the groups. X-ray parameters were measured as follows: T5-T12 thoracic kyphosis; T10-L2 thoracic-lumbar junctional kyphosis; L1-S1 lumbar lordosis; fixed segmental angle (frontal Cobb angle between the upper fixed vertebra and the lower fixed vertebra); Risser staging. Radiological measurement was performed by one and the same expert, who was independent of the surgical team.

Blood loss volume, duration of hospital stay, and duration of narcotic analgesics intake in the early postoperative period were analyzed.

Functional results were assessed using SRS-22 (Scoliosis Research Society) questionnaires. Loss of correction was considered as an increase in the fixed curve by more than 5° for all methods of fixation.

Statistical analysis

Statistical analysis was performed using SPSS Statistics software package. Data on the variables were presented using descriptive statistics (mean value, standard deviation) to assess differences between the groups at baseline and during two years of follow-up. Pearson's chi-squared test was used to compare groups according to qualitative variable (gender).

Normality of distribution of quantitative variables was assessed using Kolmogorov-Smirnov one-sample test. After testing, a decision was made whether to use parametric or nonparametric methods of comparison.

Distribution of all variables was nonparametric (except for T5-T12 thoracic kyphosis, number of fixed segments, and SRS-22 questionnaire values obtained 2 years after the surgical intervention). Differences between the groups for all relevant variables were analyzed using Mann-Whitney test. Data with parametric distribution were analyzed using Student's t-test. Comparability of gender distribution of patients in the groups was assessed using Pearson's chi-squared test.

RESULTS

Characteristics of patients in both groups are presented in Table 1. Magnitude of the main curve deformity in the lumbar or thoracolumbar spine, thoracic compensatory curve, and sagittal parameters were comparable between the groups. Radiological parameters are presented in Table 2.

Mean number of fixed segments was 6.4±1.0 in the first group and 5.6±1.5 in the second group (p = 0.047). Comparable number of segments were fixed in both groups, but slightly fewer in the anterior correction group. In the dynamic correction group, fixation ended at the L3 segment in 13 pa-

Table 1

Characteristics of patients in the groups

Parameter	First group	Second group	*p*
Age, y. o.	22.6±12.8	27.3±10.9	0.744
Risser test, grade	4.4±1.2	4.2±1.7	0.556
Observation period, mos.	46.4±23.2 (24–84)	39.2±14.1 (24–42)	0.377

tients (40.7%) and at the L4 segment in 19 (59.3%) patients; in the posterior correction group, fixation ended at the L3 segment in 29 patients (53.7%) and at L4 in 25 patients (46.3%). Mobility of the thoracolumbar/lumbar curve was higher in the group with dynamic correction — 28.2±9.1° compared to the rigid fixation — 36.0±7.2°.

Thoracic kyphosis increased during the long-term follow-up in both groups, both immediately after surgery and in the long-term period (see Table 2).

Patients in both groups demonstrated no significant loss of deformity correction during the follow-up period.

Blood loss in the first group was (Me and Q1-Q3, respectively): 382 (249; 503) mL; in the second group 156 (102.3; 204) mL (p = 0.023).

Patients in the second group spent less time in the hospital after surgery, and there was also a decrease in duration of narcotic analgesics intake to 2 days after the intervention, which is reflected in Table 3.

Table 2

Radiological parameters in the groups, deg.

Observation period	First group	Second group	*p*
Cobb angle in the frontal plane (main curve), Me (95% CI)			
Before surgery	65.5 (50.4; 79,5)	52.5 (43.2; 63.1)	0.259
After surgery	24.0 (11.4; 37.2)	29.0 (17.5; 41.2)	0.039
Two years after surgery	27.5 (22.4; 32.9)	24.5 (18.6; 32.8)	0.046
T10-L2 junctional kyphosis angle, Me (95% CI)			
Before surgery	21.0 (15.3; 29.0)	19.5 (13.5; 24.2)	0.289
After surgery	15.3 (13.8; 17.1)	18.5 (16.4; 21.1)	0.048
Two years after surgery	13.2 (11.8; 15.1)	19.0 (18.6; 19.7)	0.032
Apical vertebral rotation (Nash-Moe method), Me (95% CI)			
Before surgery	1.62 (1.41; 1.89)	1.80 (1.52; 2.08)	0.369
After surgery	0.15 (0.01; 0.63)	0.83 (0.51; 1.12)	0.013
Two years after surgery	0.17 (0.01; 0.53)	0.81 (0.49; 1.19)	0.028
Lumbar lordosis, Me (95% CI)			
Before surgery	42.5 (36.7; 50.1)	43.4 (31.8; 53.2)	0.548
After surgery	43.5 (35.8; 55.9)	42.3 (34.10; 52.03)	0.396
Two years after surgery	43.5 (32.4; 51.8)	44.3 (32.7; 55.3)	0.569
T5-T12 thoracic kyphosis, M±σ*			
Before surgery	19.0±5.8	21.2±7.0	0.249
After surgery	17.4±8.3	20.2±4.6	0.070
Two years after surgery	18.6±6.5	22.3±6.8	0.375

* Given the normality of data distribution, results are presented as M±σ, where M — the mean value, σ — the standard deviation.

There were no complications such as infection, damage of vessels, and deterioration of neurological status in both groups. Among early complications, hematoma of the postoperative wound was revealed in 5 patients of the first group, which required additional treatment and prolongation of hospital stay. Three patients with dynamic correction had pneumothorax - the pleural cavity was drained according to Bülau. No complications, such as cord rupture during dynamic correction, screw instability, or fractures of the elements of rigid constructs, were observed. Neuropathic pain syndrome was diagnosed in two patients in the first group and in four patients in the second group. There was a correlation with the patients' age: neuropathy developed at an older age. This problem was solved with the use of gabapentin 300 mg twice a day for 2-3 months, after which the condition was resolved. In the first group, 3 patients had a rod fracture more than a year after surgery, which required its replacement, but the functional outcome was not significantly affected by revision surgery.

Results of SRS-22 questionnaire 2 years after the intervention are presented in Table 4.

Table 3

Duration of hospital stay and narcotic analgesics intake

Parameter	First group	Second group	*p*
Postoperative bed day, days	8.2 (6.4; 10.3)	5.0 (4.1; 6.5)	0.017
Narcotic analgesics intake, days	3.5 (2.1; 5.2)	2.5 (1.5; 3.7)	0.043

Table 4

Results of SRS-22 questionnaire in the groups

Parameter	First group	Second group	*p*
Function	3.9±0.5	4.8±0.3	0.038
Pain syndrome	4.6±0.4	4.2±0.7	0.041
Mental function	4.0±0.7	4.4±0.4	0.049
Satisfaction with the result	3.8±0.5	4.3±0.8	0.021
Self-assessment	4.3±0.5	4.6±0.4	0.034

DISCUSSION

According to the literature and our own experience, there is still insufficient objective data proving the advantages of dynamic correction in case of idiopathic scoliosis compared to standard spine fusion [6, 20]. The question of indications remains to be debated: what type of deformity, its magnitude, mobility of the main curve, or age of patients would be the best indications for dynamic approach, in particular in conditions of completed growth [16, 21]. In addition, patients with completed growth usually have more rigid deformities than growing patients. Therefore, growth modulation is not possible. On the other hand, during modulation, it is difficult to predict the response of the growing spine to a dynamic implant, while in case of completed growth, spine correction is more predictable, because the surgeon attempts to perform it as efficiently as possible.

Although dynamic correction has become an innovative strategy for managing scoliosis without spine fusion, it has not been clearly defined how and when to use dynamic or rigid fixation in case of completed growth either [22].

It is known that posterior rigid correction is efficient but is associated with blood loss and does not allow to preserve motions in operated segments, which negatively affects the functional state of the spine [23, 24]. Peak of publication

activity on the problem of posterior scoliosis correction using transpedicular fixation only was observed in 2010-2013. At the same time, there was an increase in publications on anterior scoliosis correction with the use of rigid systems as well, and later, the interest in anterior approach in case of lumbar/thoracolumbar idiopathic scoliosis among spine surgeons decreased a lot. This is due to the proven lack of significant differences between radiological and functional results of anterior and posterior approaches [3, 11, 12, 24].

Currently, there are studies evaluating the results of dynamic scoliosis correction in adults, where the authors suggest that the radiological results of ASC (Anterior Scoliosis Correction) in patients with completed or near-completed growth are better than those of VBT (Vertebral Body Tethering) due to aggressive surgical techniques applied during surgery to achieve satisfactory correction [6]. These studies evaluate the lower point of fixation for anterior scoliosis correction [26, 27], but there are no data on the choice of the upper point. The same situation is observed for dynamic fixation.

Posterior transpedicular correction in our study gave results similar to anterior dynamic correction, but required a longer surgery duration and was associated with significantly greater intraoperative blood loss. This was due to more traumatic nature of the surgery and the necessity to perform posterior release and sometimes posterior Ponte osteotomy, while dynamic correction involved only nucleotomy at the apex of deformity. Mean angle of the main curve in rigid fixation was 64.4° and was corrected to 26.9° at the long-term follow-up, and in dynamic correction, from 52.4±9.6° to 24.2±12.3°. Preoperative deformities in this group were more mobile by about 10%. There was also a certain improvement in the long-term period comparing with the postoperative data, apparently due to the preserved growth potential in some patients of the second group. However, it should be noted that the degree of correction in both groups depended on the initial deformity angle and spine mobility; the degree of correction with rigid and dynamic correction was identical for angles up to 50-55°. For more severe deformities, it depended on the spine mobility.

In 2021, P.D. Trobisch and A. Baroncini published the data on patients who underwent dynamic correction at the thoracolumbar/lumbar level with satisfactory results, but the incidence of rupture was quite high. This confirms the hypothesis that lumbar VBT is indeed associated with a higher incidence of rupture than thoracic VBT [27]. This may be due to the use of the first cord and aggressive derotation manipulations, as well as to the greater mobility of the lumbar spine compared to the thoracic spine, which may affect the strength of the construct. Spine growth is also not taken into account. In our dynamic correction group, there were no cases of cord rupture, which is common in growing patients. This is probably due to the routine use of double cords, which provides greater tensile strength and prevents material wear. However, there are no biomechanical studies to assess the strength of single and double cords nowadays, although such suggestion was made by A. Baroncini et al. [29]. Recent biomechanical study showed that surgical constructs with one or two cords insignificantly limited global and L1-L2 spinal movements in flexion or extension (<10%) of the left or right axial rotation (<14%) [18]. In addition, intervertebral discs and facet joints did not change degeneratively when dynamic fixation was used after an average of 29 months of follow-up [28].

Lumbar lordosis was one of evaluated parameters that changed significantly after surgery in the group with rigid fixation. Anterior correction appears to have a certain kyphosogenic effect, but provides a harmonious sagittal profile while preserving the back muscles and posterior ligaments, which explains the low incidence of PJK (proximal junctional kyphosis) development with this method [27, 29, 30]. Although the importance of assessing, interpreting and restoring the "ideal" parameters of global balance in dynamic correction is not entirely clear, since unlike rigid systems, the dynamic approach implies preserving certain mobility in the fixation and amortization area. This, in turn, should reduce the risk of adjacent segment disease, fatigue fractures of implants, and other implant-dependent complications that are observed in rigid fixation in conditions of severe spinal balance disorders. In addition, correction loss, pseudarthrosis, and

fractures of implants are rare in adolescence when using posterior transpedicular rigid systems, but the risk of these complications increases at an older age [22, 31].

According to our data, the use of double cord in the lumbar spine had no kyphosogenic effect on lumbar lordosis. This supports the hypothesis that lumbar VBT is indeed associated with a higher incidence of ruptures than the thoracic one [28, 32]. However, dynamic compression has lesser derotating effect compared to rigid systems according to Nash and Moe assessment of apical vertebral rotation (see Table 1). Improvement of T10- L2 junctional kyphosis was achieved in both groups.

In the study on functional outcome of Lenke type 5 scoliosis correction performed by F. Tao et al., all SRS-22 domains were significantly higher in the group with rigid anterior scoliosis correction compared to posterior correction [33]. Still, there is some evidence that there are no significant differences between these approaches [25, 34]. Nevertheless, dynamic correction provides better functional outcome according to the results of SRS-22 questionnaire in our patients. There were no significant differences between two groups in terms of patients' perception of function, pain, self-assessment, mental function, or satisfaction. However, functional scores, satisfaction with surgery, and mental health were higher in the anterior dynamic correction group, indicating that this method of treatment met the patients' expectations (see Table 3).

Limitations

Sample size was limited by retrospective type of the study. Outcome assessment tool was not used consecutively to allow comparisons with clear preoperative and postoperative intervals, and randomization was not applied.

CONCLUSION

Both posterior rigid and anterior dynamic correction in Lenke type 5 idiopathic scoliosis can provide satisfactory radiological results with initially similar thoracolumbar deformities in patients with completed or near-completed growth. However, dynamic approach is characterized by lower blood loss, shorter hospital stay, shorter duration of postoperative narcotic analgesics intake, and better quality of life in the long-term period.

DISCLAIMERS

Author contribution

Pereverzev V.S. — the conception and design of the study, the analysis and interpretation of data, the writing of the text.

Kolesov S.V. — the analysis and interpretation of data, the drafting of the text.

Kazmin A.I. — data collection and processing.

Morozova N.S. — the statistical analysis of results, the drafting of the article.

Shvets V.V. — the search and analysis of literature sources, the analysis and interpretation of data, the drafting of the article.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Prevalence of Osteoporosis and Its Correlation With Common Secondary Risk Factors in Population from Rural Areas of South India

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Abstract

Background. Osteoporosis is a common metabolic disorder characterised by decreased bone mass and weakened micro-architecture of bone tissue. After 50 years of age, one in three women and one in five men experience osteoporotic fractures. This is projected to cause a yearly loss of 5.8 million healthy life years to disability. The number of patients who attend the outpatient clinic and emergency department of Sanjay Gandhi Institute of Trauma and Orthopaedics with fragility fractures has been increasing, hence to know the prevalence of osteoporosis in the general population who were asymptomatic, we decided to conduct a study in the rural areas of south India.

Aims: 1) to estimate the prevalence of osteoporosis among the population above 50 years in rural areas of south India; 2) to determine the correlation between common secondary risk factors for osteoporosis like tobacco consumption, alcohol, diabetes, and hypertension.

Results. The prevalence of osteoporosis in the rural population was more in females at 42.2%, whereas the males had a prevalence of 32.5%. Among the population with habits of tobacco consumption and alcohol consumption, the prevalence was 78% and 30.6% respectively. 20.2% of non-smokers and 39.7% of non-alcoholics were osteoporotic. Among the population with comorbidities, 53.6% of diabetes and 55.4% of hypertensives were osteoporotic. 33.7% of non-diabetics were osteoporotic, and 29.5% of hypertensives were osteoporotic. The correlation between osteoporosis and the individual risk factors ranged between weak negative to moderately positive ($r = -0.2$ to 0.5). The correlation between the combination of all the four risk factors and osteoporosis is weakly positive ($r = 0.339$), which is highly significant ($p<0.001$).

Conclusion. Overall, the findings of this study suggest that addictive habits such as tobacco and alcohol consumption may have a significant impact on bone health, with a higher prevalence of osteopenia and osteoporosis observed in individuals with these habits. Comorbidities such as diabetes and hypertension were also found to be associated with a higher prevalence of osteoporosis. These findings emphasize the importance of early detection and prevention of addictive habits and comorbidities to reduce the risk of osteopenia and osteoporosis. Furthermore, the study highlights the need for further research to fully understand the complex relationships between sociodemographic factors, addictive habits, comorbidities, and bone health.

Keywords: osteoporosis, alcohol, tobacco consumption, diabetes, hypertension.

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Распространенность остеопороза в сельских районах Южной Индии и его связь с общими вторичными факторами риска

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Реферат

Актуальность. Остеопороз — распространенное метаболическое расстройство, характеризующееся уменьшением массы костной ткани и ослаблением микроархитектуры костей. После 50 лет каждая третья женщина и каждый пятый мужчина сталкиваются с остеопоротическими переломами. Это приводит к ежегодной потере 5,8 млн лет здоровой жизни (HLY) из-за инвалидности. Количество пациентов, обращающихся в поликлинику и отделение неотложной помощи Института травматологии и ортопедии им. Санджая Ганди с патологическими переломами, из года в год увеличивается. Чтобы определить распространенность остеопороза среди населения, не имеющего симптомов данного заболевания, мы решили провести исследование в сельских районах Южной Индии.

Цели исследования: 1) оценить распространенность остеопороза среди населения старше 50 лет в сельских районах Южной Индии; 2) определить связь между общими вторичными факторами риска остеопороза, такими как употребление табака и алкоголя, диабет, гипертония.

Результаты. Распространенность остеопороза в сельских районах была выше у женщин и составила 42,2%, в то время как у мужчин распространенность составила 32,5%. Среди лиц, употребляющих табак и алкоголь, распространенность составила 78,0% и 30,6% соответственно. Остеопороз был выявлен у 20,2% некурящих и у 39,7% не употребляющих алкоголь. Среди лиц с сопутствующими заболеваниями остеопороз выявлен у 53,6% диабетиков и 55,4% гипертоников. Связь между остеопорозом и отдельными факторами риска колебалась от слабо отрицательной до умеренно положительной (r = -0,2 до 0,5). Связь между комбинацией всех четырех факторов риска и остеопорозом была слабо положительной (r = 0,339) и имела высокую значимость (p<0,001).

Заключение. Результаты данного исследования свидетельствуют о значительном влиянии вредных привычек, таких как употребление табака и алкоголя, на здоровье костей, с более высокой распространенностью остеопении и остеопороза у лиц с этими привычками. Сопутствующие заболевания, такие как диабет и гипертония, также связаны с более высокой распространенностью остеопороза. Эти свидетельствует о важности раннего выявления сопутствующих заболеваний и отказа от вредных привычек для снижения риска развития остеопении и остеопороза. Необходимы дальнейшие исследования для полного понимания сложных взаимосвязей между социодемографическими факторами, привычками, сопутствующими заболеваниями и здоровьем костей.

Ключевые слова: остеопороз, остеопения, алкоголь, табакокурение, диабет, гипертония.

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INTRODUCTION

Osteoporosis is a common metabolic disorder characterised by decreased bone mass and weakened micro-architecture of bone tissue. This makes the bone highly prone to pathological fractures [1, 2]. It is only after the fracture that the condition is diagnosed more often, and measurement of Bone Mineral Density (BMD) can diagnose "osteoporosis" and identify the population at risk for fractures [1, 3].

The global burden of osteoporosis is enormous. It has been recognised as a worldwide epidemic. In 2014 journal "Osteoporosis International" estimated osteoporosis to be one of the leading causes of disability, depression, and early mortality in the elderly. After age 50, one in three women and one in five men experience osteoporotic fractures. This is projected to cause a yearly loss of 5.8 million healthy life years to disability. There is about a 30 % rise in mortality in the first year after fracture, which remains high for up to 5 years.

The economic burden has been 37 billion EUR in the EU and 19 billion USD in the USA [4]. In 2014, it was reported in Europe that socioeconomic status and poverty have a bearing on the prevalence of Osteoporosis [5].

Having a different landscape, India has a different socio-economy and lifestyle. Even within the country, there is much diversity between urban and rural life. In 2012 C. Rex estimated that osteoporosis would affect half of the Indian population by 2022 [6].

The USA and Europe have been significant contributors to research in osteoporosis, with 27,0% and 8.2% of global publications, respectively. India could merely contribute 2% of the world's research on osteoporosis [7]. An article in 2015 reviewed a few sporadic studies on Osteoporosis in Indian women and noted a high prevalence of the disease in postmenopausal women.8

Sanjay Gandhi Institute of Trauma and Orthopaedics is a tertiary care hospital. The number of patients who attend the outpatient clinic and emergency department of Sanjay Gandhi Institute of Trauma and Orthopaedics with fragility fractures has been increasing, hence to know the prevalence of osteoporosis in the general population who were asymptomatic, we decided to conduct a study in the rural areas of south India.

Aims: 1) to estimate the prevalence of osteoporosis among the population above 50 years in rural areas of south India; 2) to determine the correlation between common secondary risk factors for osteoporosis like tobacco consumption, alcohol, diabetes, and hypertension.

METHODS

Design

A cross-sectional study on the prevalence of osteoporosis was planned over one year (i.e., September 2021 to august 2022) as there was an increased incidence of fragility fractures in the population attending the outpatient clinic and emergency department. Ten random villages were selected by cluster sampling in villages from Karnataka, Andhra Pradesh, and Tamilnadu. In each village, 100 people aged 50 years to 100 years were enrolled on the study.

Inclusion criteria: men and women aged 50 and above.

Exclusion criteria: patients having other causes affecting bone strength like malignancy; Paget's disease; congenital disorders; osteomyelitis etc.

Consenting participants were interviewed and examined. The tools used in this study were a two-part proforma and BMD measuring portable SONOST 3000 Ultrasound machine.

The Sonost 3000 bone densitometer uses ultrasound technology to measure bone density, transmitting high-frequency sound waves through the bone and measuring how much of the wave is absorbed; it is a portable and lightweight machine, weighing only about 4 pounds, and can be operated with a rechargeable battery, making it convenient for use in remote or mobile settings. A quality assurance test for the device was performed on each screening day. The measurements were carried out in a room by a single technician to complete the entire test on all the subjects.

Those subjects with low BMD were classified accordingly as Osteopenia (BMD -1 to -2.5) or Osteoporosis (BMD -2.5 or less).

Statistical analysis

The data was analysed using SPSS 28 software. Pearson correlation coefficient test examined the correlation between variables. $P<0.05$ was used as the threshold to determine statistical significance, meaning that results with a p-value less than 0.05 were considered statistically significant. This methodology allows for identifying relationships and trends within the data and determining the statistical significance of these relationships.

RESULTS

Socio-demographic factors

The total number of subjects considered in the study was 1000: 536 males (53.6%) and 464 females (46.4%). Most of the people who participated in the study were 50-60 years old, accounting for 52.9%, followed by 60-69 years (22.6%), 70-79 years (19.7%), 80-89 years (3.7%), and 90-99 years (1.1%).

Addictive habits and comorbidities

Habits that were considered in the study: tobacco consumption (smoking/smokeless), alcohol.

Comorbidities considered in the study: diabetes, hypertension.

In this study 29.1% (n = 291) of the population consumes tobacco, of which 82% are males and 18% are females; 29.7% (n = 297) of the population drinks alcohol: 91.95% of males and 8.05% of females. In the study population, 16.8% of people had diabetes: 9.2% of men and 7.6% of women; 28.9% people suffered from hypertension:16.2% of men and 12.7% of women.

Osteopenia

Out of the total population considered for this study, 512 were osteopenic: 45.5% of males and 57.8% of females. Among the people suffering from osteopenia, 65.7% were between 51-60 years. Among the population with addictive habits, 2.7% of tobacco consumers and 69.4% of alcoholics were osteopenic. This suggests that there may be a stronger association between alcohol consumption and osteopenia than tobacco consumption and osteopenia, despite the fact that a higher percentage of the overall population consumes tobacco.

One possible explanation for this discrepancy is that alcohol consumption may have a greater impact on bone health than tobacco consumption. Studies have shown that excessive alcohol consumption can interfere with the body's ability to absorb calcium and can also reduce bone density, which can lead to osteopenia and osteoporosis. On the other hand, while tobacco use is a well-known risk factor for several health problems, including lung cancer and cardiovascular disease, its impact on bone health is less clear. Another possibility is that there may be other factors at play that are affecting the relationship between addictive habits and osteopenia. For example, people who consume more alcohol may also be more likely to have poor diets or engage in other behaviours that increase their risk of osteopenia. Additionally, there may be differences in the demographics of the tobacco-consuming and alcohol-consuming populations that could be influencing the results. Overall, it's important to remember that studies like these can only show associations between variables and cannot prove causation. More research would be needed to fully understand the relationship between addictive habits and osteopenia and determine the best prevention and treatment strategies.

Among the population with comorbidities, 13.1% of people with diabetes and 44.6 % with hypertension were osteopenic.

The correlations between gender and tobacco consumption, gender and alcohol consumption, and alcohol consumption and hypertension are all statistically significant at the 0.01 level (two-tailed), with correlation coefficients of 0.362, 0.241, and 0.339, respectively. These coefficients indicate a weak to a moderate positive correlation between these variables.

The correlations between tobacco consumption and diabetes, tobacco consumption and hypertension, and opsteopenia and tobacco consumption are also statistically significant at the 0.01 level (two-tailed), with correlation coefficients of 0.566, 0.378, and -0.621, respectively. These coefficients indicate a moderate to a strong positive correlation between these variables.

The correlations between diabetes and alcohol consumption and hypertension and opsteopenia are statistically significant at the 0.01 level (two-tailed), with correlation coefficients of -0.105 and -0.084, respectively. These coefficients indicate a weak negative correlation between these variables.

Finally, the correlation between gender and diabetes, gender and hypertension, and diabetes and opsteopenia are not statistically significant at the 0.01 level (two-tailed), with correlation coefficients of 0.010, 0.031, and -0.343, respectively. These coefficients indicate a very weak to weak positive or negative correlation between these variables (Table 1).

Table 1

Correlation between secondary risk factors and osteopenia

Parameters		Gender	Tobacco consumption	Alcohol consumption	Diabetes	Hypertension	Opsteopenia
Gender	pearson correlation	1					
	p						
	n	1000					
Tobacco consumption	pearson correlation	0.362	1				
	p	0.000					
	n	1000	1000				
Alcohol consumption	pearson correlation	0.241	0.056	1			
	p	0.000	0.078				
	n	1000	1000	1000			
Diabetes	pearson correlation	0.010	0.566	-0.105	1		
	p	0.741	0.000	0.001			
	n	1000	1000	1000	1000		
Hypertension	pearson correlation	0.031	0.378	0.339	-0.027	1	
	p	0.321	0.000	0.000	0.396		
	n	1000	1000	1000	1000	1000	
Osteopenia	pearson correlation	-0.122	-0.621	0.236	-0.343	-0.084	1
	p	0.000	0.000	0.000	0.000	0.008	
	n	1000	1000	1000	1000	1000	1000

Osteoporosis

In this study, out of the total study population, 370 people were osteoporotic. In this population, 53.0% who were osteoporotic were between 50-60 years. The prevalence of osteoporosis in the rural population was more in females at 42.2%, whereas the males had a prevalence of 32.5%.

Among the population with the habit of tobacco consumption, 78% were osteoporotic, and in those with the habit of consuming alcohol, 30.6% were osteoporotic, while 20.2% of non-smokers and 39.7% of non-alcoholics were osteoporotic.

Among the population with comorbidities, 53.6% of people with diabetes and 55.4% of hypertensives were osteoporotic, while 33.7% of non-diabetics were osteoporotic, and 29.5% of hypertensives were osteoporotic.

Statistical analysis of the data shows Pearson correlation between osteoporosis and tobacco usage shows a moderately positive correlation ($r = 0.544$), which is highly significant ($p<0.001$). Correlation between osteoporosis and alcohol consumption is weakly negative ($r = -0.086$), which is highly significant ($p = 0.007$). It is important to note that correlation does not imply causation. Therefore, while there may be a negative correlation between alcohol consumption and osteoporosis, it does not necessarily mean that drinking alcohol prevents osteoporosis. Other factors may be at play that influence both alcohol consumption and the risk of developing osteoporosis, such as diet, exercise, smoking, or genetics. Furthermore, the significance of the correlation ($p = 0.007$) indicates that the observed relationship between alcohol consumption and osteoporosis is unlikely to be due to chance. However, statistical significance does not necessarily mean practical significance or clinical relevance. In other words, a significant correlation may not necessarily have a large enough effect size to be of practical importance.

Correlation between osteoporosis and diabetes is weakly positive ($r = 0.154$), which is highly significant ($p<0.001$). Correlation between osteoporosis and hypertension is weakly positive ($r = 0.242$), which is highly significant ($p<0.001$) (Table 2).

The correlation between osteoporosis and the individual risk factors ranged between weak negative to moderately positive. The correlation between the combination of all the four risk factors and osteoporosis is weakly positive ($r = 0.339$), which is highly significant ($p<0.001$).

Table 2

Correlation between secondary risk factors and osteoporosis

Parameters		Tobacco	Alcohol	Diabetes	Hypertension	Osteoporosis
Tobacco	pearson correlation	1				
	p					
	n	1000				
Alcohol	pearson correlation	0.056	1			
	p	0.078				
	n	1000	1000			
Diabetes	pearson correlation	0.566	-0.105	1		
	p	0.000	0.001			
	n	1000	1000	1000		
Hypertension	pearson correlation	0.378	0.339	-0.027	1	
	p	0.000	0.000	0.396		
	n	1000	1000	1000	1000	
Osteoporosis	pearson correlation	0.544	-0.086	0.154	0.242	1
	p	0.000	0.007	0.000	0.000	
	n	1000	1000	1000	1000	1000

DISCUSSION

Osteoporosis is a skeletal disease characterised by decreased bone mass per volume associated with microarchitectural deterioration of the bone tissue resulting in bone fragility and increased risk of fracture [1]. Another variant of low bone mass density is osteopenia, which is defined as a condition with low BMD but of less severity when compared to that of osteoporosis. Osteoporosis is most commonly seen in the elderly, with females being most commonly affected compared to males [2]. Whereas osteopenia is seen in younger age groups with no gender inequality [3].

The burden of osteoporosis in the India population is around 40% as the population living in India is mainly from a rural background and has low BMD compared to the western population of the same age and gender. The maximum loss of bone density is observed in the fourth decade of life and early postmenopausal years [4].

Chronic bone pain, disability, and peritrochanteric and vertebral fractures are common among the osteoporotic elderly population, leading to severe functional limitations and decreasing the quality of life [5]. Pneumonia, urinary tract infections, pressure sores (mainly nonhealing ulcers), and deep vein thrombosis contribute to worsening the prognosis among the osteoporotic elderly population. The common sites of osteoporotic fractures following minimal trauma are vertebra, distal radius, and peritrochanteric fractures due to lack of osteoid in sufficient quantity that leads to rapid bone loss [6]. Osteoporosis is mostly asymptomatic; on the other hand, in symptomatic patients, vague, diffuse low backache is the most common symptom [7].

Recent studies have indicated that even low-level exposure to cadmium could increase the risk of osteoporosis and fractures [8]. Women are four times more prone to osteoporosis and two times more prone to osteopenia [9]. Diabetes mellitus increases osteoclast function but decreases osteoblast function, leading to accelerated bone loss, osteopenia and osteoporosis [10]. In hypertension patients, excess urinary calcium secretion induces secondary parathyroidism to increase the serum calcium level by calcium release from bone, which may accelerate osteoporosis [11]. Alcohol use decreases bone density and weakens bones mechanical properties [12].

Diagnosing osteoporosis is a significant step in its management. Diagnosing osteoporosis at the gross root level is far better to avoid the consequences like fractures and deterioration of life quality among the rural population [13]. Despite being the most common problem among the rural and urban population in India, there is no Cohesive National Policy on screening and prevention policy and programs.

Various tools are available nowadays for diagnosing osteoporosis, like DEXA scan, India-specific FRAX tool, etc. [1, 3, 4, 14]. Among all India-specific FRAX tool is gaining popularity in risk prediction of 10-year probability of osteoporotic fracture. Due to a lack of awareness on health education, lack of internet facilities, etc., it is still of limited use.

Age. Our study found that the prevalence of osteoporosis and osteopenia increases with age, consistent with other studies. A study by N.S. Kadam et al. reported a similar finding, where the prevalence of osteoporosis is more prevalent in 50-60 years age group [15].

Gender. Our study found that females had a higher prevalence of osteoporosis and osteopenia compared to males, consistent with other studies. A study by N.S. Kadam et al. reported that females had a higher prevalence of osteoporosis than males [15].

Tobacco and alcohol consumption. Our study found that tobacco and alcohol consumption were associated with an increased risk of osteoporosis and osteopenia, consistent with other studies. A study by A.M. Al-Bashaireh et al. showed that smoking tobacco has been associated with reduced bone mass and increased risk of fracture through its direct or indirect effects on osteoblast and osteoclast activities. The RANKL-RANK-OPG pathway plays a vital role in the mechanisms by which smoking may result in poor bone health [16].

Chronic excessive alcohol consumption has deleterious effects on bone and results in low bone mass which may predispose to fragility fractures leading to increased morbidity [17].

Comorbidities. Our study found that comorbidities such as diabetes and hypertension were associated with an increased risk of osteoporosis and osteopenia, consistent with other studies. Similarly a study by A.G. Asokan et al. found that prevalence of osteoporosis was higher among diabetics [18]. Another study by R. Khinda et al. showed that hypertension causes severe loss of bone minerals including calcium and its metabolism, resulting in accelerated bone resorption [19].

Overall, these findings highlight the importance of managing these risk factors to prevent the development of osteoporosis and osteopenia.

Limitations

In this study, we have used only one tool for assessing the bone mass density for grading the patient depending on feasibility.

The study did not consider different types of alcohol, such as toddy, wine, and beer, which may have different effects on bone health. For example, some studies suggest that moderate consumption of red wine may have a beneficial effect on bone density due to its high levels of polyphenols, while heavy alcohol consumption has been linked to decreased bone density.

The study did not consider different methods of tobacco use, which may have different effects on bone health. For example, smoking has been linked to decreased bone density due to its negative impact on calcium absorption, while smokeless tobacco has been linked to increased bone density due to its high nicotine levels.

It is important to acknowledge these limitations when interpreting the study's findings and to consider the potential impact of these factors on bone health. Future studies may benefit from considering the effects of different types of alcohol and tobacco use on bone health in more detail.

CONCLUSION

Overall, the findings of this study suggest that addictive habits such as tobacco and alcohol consumption may have a significant impact on bone health, with a higher prevalence of osteopenia and osteoporosis observed in individuals with these habits. Comorbidities such as diabetes and hypertension were also found to be associated with a higher prevalence of osteoporosis. These findings emphasize the importance of early detection and prevention of addictive habits and comorbidities to reduce the risk of osteopenia and osteoporosis. Furthermore, the study highlights the need for further research to fully understand the complex relationships between sociodemographic factors, addictive habits, comorbidities, and bone health.

DISCLAIMERS

Author contribution

Pothuri Rishi Ram — the design of the study, data collection and analysis, writting the first draft of the manuscript.

Praveen Narayan — the statistical analysis and the interpretation of the results, critical feedback on the manuscript.

Pavith Janardhan — data collection and management, the literature review and discussion, revising the manuscript for submission.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Заявленный вклад авторов

Потури Риши Рам — разработка проекта исследования, сбор и анализ данных, написание статьи.

Правин Нараян — статистический анализ и интерпретация результатов, редактирование статьи.

Павит Джанардан — обзор литературы и обсуждение, редактирование статьи.

Surya Sri Karun Ch. — the study design, expertise on methodological approach, revising the manuscript for submission.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Все авторы прочли и одобрили финальную версию рукописи статьи. Все авторы согласны нести ответственность за все аспекты работы, чтобы обеспечить надлежащее рассмотрение и решение всех возможных вопросов, связанных с корректностью и надежностью любой части работы.

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Fixation Techniques for Intraarticular Proximal Humeral Fractures

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Abstract

Background. The most severe type of injuries of the proximal epiphysis of the humerus are intraarticular fractures. One of the main complication is the development of avascular osteonecrosis, which is caused by the peculiarities of blood supply of the humeral head and its compromised vascularization as a result of trauma. Current osteosynthesis techniques for intraarticular fractures of the proximal humerus (PH) do not reduce the risk of avascular osteonecrosis of the humeral head (AONHH) and do not reduce the risk of nonunion. To prevent ischemic changes in the humeral head, osteosynthesis with reparative osteogenesis stimulation is recommended.

Aim of the study — to specify indications for various fixation techniques of intraarticular fractures of the proximal humerus.

Methods. The study enrolled 48 patients with AO/ASIF type 11C1 and 11C2 intraarticular PH fractures requiring surgical treatment. All patients were allocated into 2 groups. Retrospective (control) group included 25 patients who were treated using locking plate osteosynthesis or intramedullary locking osteosynthesis with proximal humeral nails. Prospective (main) group included 23 patients who were additionally treated with a vascularized musculoskeletal graft from the coracoid process of the scapula transplanted to the fracture area.

Results. Functional treatment results of patients who underwent surgery using vascularized musculoskeletal grafts from the coracoid processes of the scapula (71.50% were excellent and 14.3% were good) were better than those of the control group (35.28% were excellent and 17.64% were good). Consolidation of the fracture in the control group occurred in 92% of cases (23 patients); the remaining 8% (2) of patients had pseudoarthrosis of the anatomical or surgical neck of the humerus developed within 6 months after the surgery. In the main group, the fractures consolidated in all patients.

Conclusion. Fractures with no damage to the bicipital groove should be considered an indication for performing plate osteosynthesis without vascularized musculoskeletal grafting. Locking osteosynthesis in case of intraarticular PH fractures makes it much more difficult to reduce the humeral head and the tubercular area. Locking osteosynthesis decreases the rigidity of fixation of fragments, which may contribute to their secondary displacement.

Keywords: proximal humerus fracture, plate osteosynthesis, stimulation of reparative osteogenesis, vascularized musculoskeletal graft, humeral osteonecrosis.

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Выбор метода остеосинтеза при внутрисуставных переломах проксимального эпифиза плечевой кости

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Реферат

Актуальность. Наиболее тяжелой категорией переломов проксимального эпифиза плечевой кости являются внутрисуставные повреждения. Одним из основных осложнений является формирование аваскулярного некроза, причиной которого служат особенности кровоснабжения головки плечевой кости и нарушение ее васкуляризации вследствие травмы. Существующие в настоящее время способы остеосинтеза внутрисуставных переломов проксимального отдела плечевой кости (ПОПК) не снижают риска развития асептического некроза головки плечевой кости (АНГПК) и не уменьшают риск несращений. Для профилактики ишемических изменений головки плечевой кости рекомендуется использовать метод остеосинтеза с элементом стимуляции репаративного остеогенеза.

Цель исследования — уточнение показаний к применению различных методов хирургического лечения внутрисуставных переломов проксимального отдела плечевой кости.

Материал и методы. В исследование включено 48 наблюдений пациентов с внутрисуставными переломами ПОПК типов 11-С1 и 11-С2 по классификации AO/ASIF, нуждающихся в оперативном лечении. Из общего количества пациентов были сформированы две группы. В ретроспективную (контрольную) группу вошли 25 пациентов, которых лечили с использованием накостного остеосинтеза пластиной с угловой стабильностью или интрамедуллярного блокируемого остеосинтеза проксимальными плечевыми штифтами. В проспективную (основную) группу вошли 23 пациента, при лечении которых дополнительно выполняли пересадку несвободного костно-мышечного трансплантата из клювовидного отростка лопатки в зону перелома.

Результаты. Функциональные результаты лечения пациентов, оперированных с использованием несвободных костно-мышечных трансплантатов из клювовидного отростка лопатки (71,5% отличных и 14,3% хороших результатов), лучше результатов контрольной группы (35,28% отличных и 17,64% хороших результатов). В контрольной группе консолидация перелома произошла в 92% случаев (23 пациента), у остальных 8% (2) пациентов отмечен исход в виде ложного сустава области анатомической или хирургической шейки плечевой кости в течение 6 мес. после операции. В основной группе у всех пациентов переломы консолидировались.

Заключение. Показанием для выполнения накостного остеосинтеза без несвободной трансплантации костно-мышечного лоскута следует считать переломы без нарушения целостности межбугорковой борозды. Применение блокирующего остеосинтеза при внутрисуставных переломах ПОПК значительно затруднено необходимостью репозиции головки и бугорковой зоны. При блокирующем остеосинтезе снижается жесткость фиксации отломков, что может способствовать их вторичному смещению.

Ключевые слова: внутрисуставной перелом проксимального отдела плечевой кости, накостный остеосинтез, стимуляция репаративного остеогенеза, несвободный костно-мышечный трансплантат, асептический некроз проксимального эпифиза плечевой кости.

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BACKGROUND

Fractures of the proximal humerus (PH) account for about 6% of all fractures, with a peak incidence in the age group of 60 to 90 years [1]. Among patients over 65 years old, these fractures are the third most common after the injuries of osteoporosis critical areas [2]. Despite many studies proving the inefficiency of conservative methods of PH treatment, the comparison of surgical and conservative methods is constantly under study. Currently, the prevailing opinion is that the conservative treatment of unstable comminuted fractures of the proximal humerus leads to unsatisfactory results in the majority of cases [3]. Their surgical treatment is represented by three main techniques: osteosynthesis with angular stable locking plates, intramedullary locking osteosynthesis with different modifications of proximal humeral nails (PHN) and shoulder arthroplasty. There are also original fixators of limited use. External fixation of PH fractures is not widespread due to its technical complexity and the need for regular control of fixator's state.

Despite the developed clinical guidelines for treatment, the choice of osteosynthesis method for intraarticular PH fractures remains a relevant problem, primarily due to a high incidence of postischemic changes in the humeral head.

Aim of the study — to clarify indications for various techniques of surgical treatment of intraarticular fractures of the proximal humerus.

METHODS

Study design

A single-center retrospective prospective cohort non-randomized controlled (active control) study was performed and included 48 cases of patients with intraarticular PH fractures who were treated on an inpatient basis and subsequently followed up on an outpatient basis.

Inclusion criteria: patients aged 20 to including 80 years with AO/ASIF type 11C1 and 11C2 fractures [4] (excluding fracture dislocations) or with the consequences of PH fractures requiring surgical treatment.

All patients were allocated into 2 groups. Retrospective (control) group included 25 patients who were treated using locking plate osteosynthesis or intramedullary locking osteosynthesis with proximal humeral nails. Prospective (main) group included 23 patients who were additionally treated with a vascularized musculoskeletal graft from the coracoid process of the scapula transplanted to the fracture area.

Examination of patients

All patients underwent clinical and radiological examinations. Clinical examination included history and complaints intake, as well as assessment of patients' *status localis*. Radiological examination consisted of shoulder X-rays in two or three views, MRI and multispiral computed tomography (MSCT) and aimed to assess the degree of osteosclerosis and associated dystrophic changes and/or damages to the shoulder rotator cuff tendon and the severity of the secondary omarthritis. Radiological dynamics of changes in the fracture area and bone structure of the humeral head were studied.

Assessment of results

Clinical outcomes were assessed using the ASES questionnaire: intensity of pain syndrome (PS) and level of activities of daily living (ADL). The grade of avascular osteonecrosis of the humeral head (AONHH) was assessed using the radiological data.

Statistical analysis

Distributions of the samples of continuous variables of age, postoperative examination time, ASES, abduction, flexion, internal and external rotation were tested for agreement with the law of normal distribution using Shapiro-Wilk test; equality of variance in the compared groups was tested using Fisher's criterion. Most distributions were non-normal and heteroscedastic. Therefore, continuous variables were compared using the nonparametric Mann-Whitney U-criterion. Pseudomedian of differences (PM) and standardized mean difference (SMD) were calculated to assess the difference between the groups. Continuous variables were described as median [first quartile; third quartile] (M [Q1; Q3], minimum and maximum values (min-max).

Binary variables of consolidation and elevation were described as the number of events and incidence with 95% confidence interval (CI) using Wilson's formula (n, % [95% CI]). Risk difference (RD) and odds ratio (OR) with 95% CI

were calculated to assess group differences. The number of patients and detection rate (grade — n (%)) were calculated for the grades of categorical AONHH. Binary and nominal variables were compared using two-tailed Fisher's exact test. Comparing grades in nominal variables, the multiple comparison error was corrected by Benjamini-Hochberg criterion.

Statistical hypotheses were tested at the critical level of significance p = 0.05, i.e. the difference was considered statistically significant at p<0.05. Statistical analysis was performed using the Rstudio software (version 2022.07.2+576, 2022-09-06) in the R language (version 4.1.3).

RESULTS

Results were evaluated 12-24 months after the surgery (Table 1).

The distribution of grades of AONHH in the main and control groups differed statistically significantly (p = 0.010): grade 0 in 12 (48.0%) and 20 (87.0%) patients, respectively (p = 0.018), grade 4 in 10 (40%) and 2 (8.7%) patients, respectively (p = 0.028). No differences in grade 3 were found (p = 0.610) (Fig. 1).

Range of active motions in the groups was comparable: in the main group it was on average 5-10° lower (p = 0.483-0.532) (Fig. 2).

Table 1

Comparison of values of parameters between the main group and the control group

Parameter	Control group *n* = 25	Main group *n* = 23	Evaluation of differences	*p*
Age, y.o. M [Q1; Q3] (min–max)	67 [55; 70] (33–77)	65 [62; 76] (46–81)	ПМ: 4 [-3; 9] СРС: 0.43	0,296
Term of postoperative examination, mos. M [Q1; Q3] (min–max)	48 [24; 48] (12–68)	18 [11; 24] (6–36)	ПМ: 24 [12; 36] СРС: 1.52	<0,001*
Bone union, number (%) [95% CI]	23 (92) [75%; 98%]	23 (100%) [86%; 100%]	PP: 8% [3%; 19%]	0,491
PS, points M [Q1; Q3] (min–max)	45 [35; 50] (5–50)	45 [45; 50] (35–50)	ПМ: 5 [0; 10] СРС: 0.83	0,017*
ADL, points M [Q1; Q3] (min–max)	37 [22; 45] (12–50)	33 [29.5; 42] (22–50)	ПМ: 0 [-6; 10] СРС: 0.18	0,877
ASES, total score M [Q1; Q3] (min–max)	80 [62; 88] (27–100)	80 [77; 88.5] (68–95)	ПМ: 4 [-5; 16] СРС: 0.54	0,535

* — statistically significantly different values.

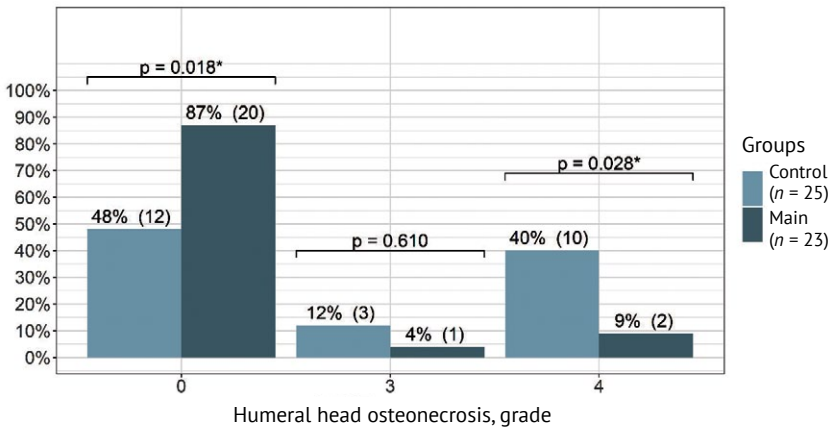

Fig. 1. Distribution of grades of avascular osteonecrosis of the humeral head in the groups

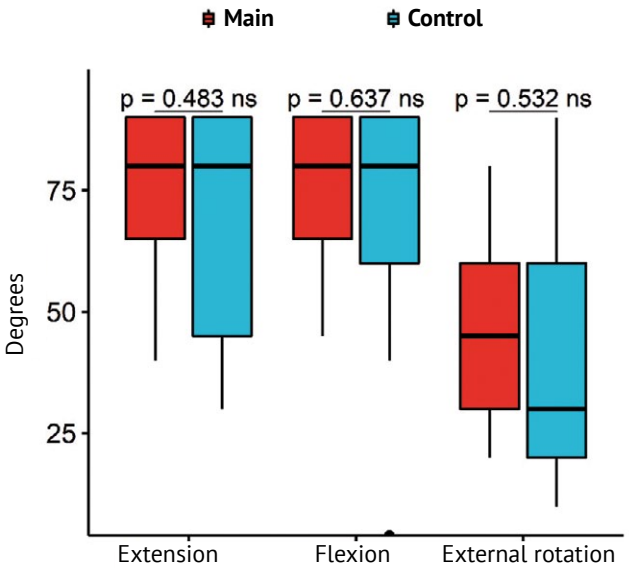

Fig. 2. Range of active motions in the shoulder in the groups

Median PS values in the main and control groups were 45 [35; 50] and 45 [45; 50] points, respectively. In the main group, PS was statistically significantly greater by an average of 5 points (p = 0.017). Median ADL values were 37 [22; 45] and 33 [29; 42] points. In the main group, ADL was statistically significantly greater by an average of 3 to 5 points (p = 0.088) (Fig. 3).

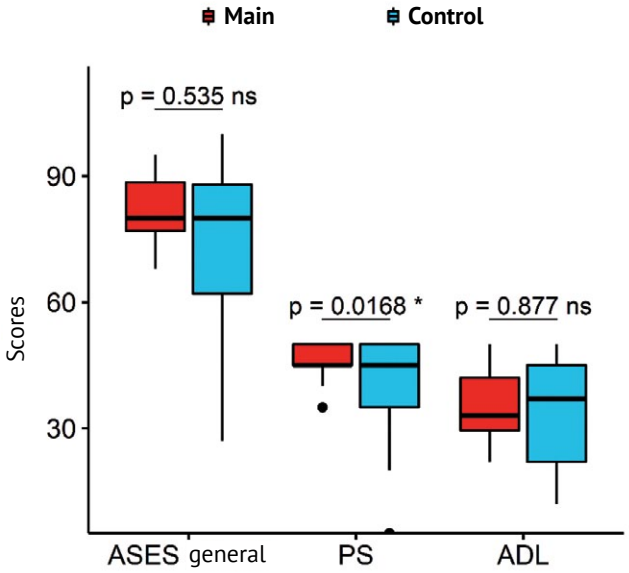

Fig. 3. PS and ADL values in the groups

In the control group, bone union occurred in 92% of cases (23 patients) (p = 0.491); the remaining 8% (2) of patients, developed pseudoarthrosis of the anatomical or surgical neck of the humerus within 6 months after surgery. There were no cases of pseudoarthrosis in the main group; fractures in all patients healed.

DISCUSSION

When choosing a method of osteosynthesis for intraarticular fractures of the proximal epiphysis of the humerus, the practicing surgeon is faced with the problem of minimizing the surgical trauma and preserving the blood supply of the fragments, on the one hand, and ensuring accurate reduction and stable rigid fixation, on the other. Intramedullary osteosynthesis is widely used in the treatment of type C fractures mainly due to advanced screw locking system and is considered to be the method of choice in elderly patients because it provides sufficient stability of fragments [5]. Angular stable locking fixation systems have higher internal stability values, so they maintain better reduction at the stage of postoperative functional treatment [6]. In 2013, P.G. Kogan et al. considered intramedullary osteosynthesis to be one of the most promising methods of treatment of comminuted fractures of the proximal epiphysis of the humerus [7]. However, with the development of minimally invasive techniques, some studies have appeared revealing negative aspects of closed fracture reduction.

C. Rajasekhar et al. reported 59 complications in 115 patients. Screw migration accounted for the largest number (26 out of 59). Authors draw attention to the necessity of more accurate fixation of the tubercles and improvement of screw placement technique to prevent this complication [8]. Similar complication rate, which was 39% (26 of 61 patients), was noted by C. Witney-Lagen et al. Impingement syndrome accounted for the largest number of complications (7 out of 26), requiring nail removal [9].

Due to some technical difficulties in restoring the anatomical relationships in the joint in case of closed reduction, reduction methods using mini-open approach with soft tissue stabilization of the tubercles [10] or their fixation with single

implants have been being developed. The screw-in-screw technique, in addition to PH fragments stabilization, to some extent solves the problem of their secondary displacement, but it is less reliable than the osteosynthesis with the use of LCP plates.

Primary shoulder arthroplasty is considered to be the method of choice for comminuted PH fractures. Most recent studies show that early arthroplasty is usually preferable to arthroplasty in the long-term period, since the primary surgery is technically easier to be performed [11]. Nevertheless, U. Prakash et al. found no difference between the primary and delayed arthroplasty more than 30 days after the injury [12]. Recently, there are more and more reports on poor outcomes of shoulder arthroplasty for PH fractures. In 2010, D. den Hartog et al. published the results of meta-analysis of 33 studies that included 1096 patients with three- and four-fragment PH fractures. Patients who underwent arthroplasty showed worse functional outcomes compared to non-operated patients, with a difference of 10.9 points according to the Constant-Murley 100-point score [13]. Comparative study of long-term consequences of arthroplasty revealed moderate and severe limb dysfunction in 30% of cases [14]. Despite the ambiguity of obtained results of shoulder arthroplasty in case of fractures, current prevailing opinion is that intraarticular PH fractures are an indication for primary arthroplasty of the joint [15]. In addition to technical difficulties, long-term results of osteosynthesis of intraarticular PH fractures are always uncertain due to its impaired vascularization at the time of the injury and surgery, which then leads to head osteonecrosis and collapse, taking place in 30-100% of cases [16]. Thus, one of the main factors influencing the choice of surgical management in case of intraarticular fractures of the proximal humerus is the probability of damage to the main sources of blood supply to the humeral head.

Studies of the vascular network of the proximal humerus have shown that the blood supply to the humeral head is mainly through the arcuate artery, which branches from the ascending branch of the anterior circumflex humeral artery. When the arcuate artery is damaged, the blood supply to the humeral head cannot be compensated by other sources, which leads to AONHH [17].

Crucial significance of the damage to the arcuate artery was confirmed by C.H. Brooks et al. who studied the anatomy of PH arteries and the impact of four-fragment fractures on the blood supply to the humeral head. In most cases, simulated four-fragment fractures interrupted the perfusion of the humeral head. However, if the fracture line passed distally below the articular surface and medially, some perfusion of the head was preserved due to the posteromedial vessels. These vessels play an important role in the treatment of comminuted PH fractures [18]. Therefore, it is necessary to stimulate reparative osteogenesis in case of intraarticular fractures to reduce the time of bone union and prevent ischemic changes in the humeral head. Using vascularized grafts to stimulate osteogenesis appears to be the most promising.

Blood supply of the osteotomized fragment of the coracoid process was verified in the anatomical and morphological study performed by R. Khundkar et al. Experimental cadaveric and clinical studies demonstrated the presence of a previously unidentified direct arterial branch from the second (middle) part of the axillary artery feeding the anterior 2-3 cm of the coracoid process of the scapula [19]. A. Hamel et al. performed postmortem arteriography of the upper limb. Results were as follows: the vertical part of the coracoid process was supplied by the suprascapular artery, and the horizontal part — by branches of the axillary artery [20]. Another study of the blood supply of the coracoid process by Z. Deng et al. revealed that the coracoid process is supplied by the suprascapular artery, the thoracoacromial artery, and a branch from the second part of the axillary artery. Moreover, there is a possibility that the vessels derived from *m. biceps* fed the inferior side of the coracoid process [21].

Modern methods of stimulation of reparative processes that are most feasible for execution in a general hospital are considered. The use of free cancellous bone autografts from the wing of the iliac bone is considered exclusively for the replacement of PH defects arising due to osteoporotic bone collapse at the moment of injury [1]. This option of bone grafting is optimal due to many factors, including the absence of immune response and the presence of live osteogenic cells. The main disadvantages of autografting are well known to every trauma practitioner: ad-

ditional trauma to the donor site, increased surgery duration, emergence of additional infection portals of entry. Some sources indicate the possibility of using allogeneic and synthetic materials for this purpose [22]. Unfortunately, these materials cannot in any way stimulate osteogenesis in the ischemic zone of bone tissue, except in cases of saturation of the allograft bone structure with osteostimulating substrates. The study of osteostimulation by the graft from the preparation of the head, neck and part of the diaphysis of the cadaver fibula, saturated with collagen solution can be an example. According to study results, the developed combined allogeneic graft from the head of the fibula, saturated with type I collagen, is nontoxic, has no immunogenicity and has more pronounced osteoconductive properties in comparison with native bone allografts, which contributes to its colonization by cells [22].

Wide application of autologous platelet-rich plasma, autologous human platelet lysate and autologous human bone marrow aspirate is limited as it requires special expensive equipment. The most promising method for stimulation of osteogenesis appears to be the vascularized autografts, preserving the blood supply of the parafracture area from an additional source. Along with our proposed technique, the method of vascularized bone grafting for the treatment of pseudoarthrosis in the upper third of the humerus proposed by Tikhilov R.M. et al. [23] attracts attention. The idea of this method is to form a musculoskeletal graft, including a fragment of the lower angle of the scapula, which is transferred to the reconstruction area in the upper third of the shoulder.

CONCLUSION

Intraarticular PH fractures with displacement of fragments along the bicipital groove of more than 2 mm are indications for osteosynthesis. Fractures with no damage to the bicipital groove should be considered an indication for performing osteosynthesis without vascularized musculoskeletal grafting. The use of locking osteosynthesis for intraarticular PH fractures is significantly complicated due to the need of reduction of the head and tubercular area. Locking osteosynthesis decreases the rigidity of fixation of fragments, which may contribute to their secondary displacement. Given the closed reduction of fragments, the probability of damage to the arcuate branch of the anterior circumflex humeral artery increases.

DISCLAIMERS

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Ethics approval. The study was approved by the local ethics committee of Novosibirsk Research Institute of Traumatology and Orthopedics n.a. Ya.L. Tsivyan, protocol No 001/23, 17.01.2022.

Consent for publication. The author obtained written consent from patients to participate in the study.

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Эффективность современных пероральных форм нестероидных противовоспалительных препаратов для обезболивания после тотального эндопротезирования коленного сустава

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Реферат

Введение. Тотальное эндопротезирование коленного сустава (ТЭКС) характеризуется выраженным болевым синдромом в послеоперационном периоде с тенденцией к медленному снижению.

Цель исследования — оценить эффективность и безопасность применения таблетированных форм кеторолака и кетопрофена для купирования послеоперационной боли у пациентов с гонартрозом после ТЭКС.

Материал и методы. Сто пациентов с гонартрозом терминальной стадии (80 женщин и 20 мужчин, средний возраст 66,6 лет), последовательно госпитализированных для планового первичного неосложненного ТЭКС, были перспективно рандомизированы в основную (49 пациентов) и контрольную (51 пациент) группы. В основной группе для послеоперационного обезболивания использовали перорально Кеторол Экспресс 10 мг (4 раза в сутки), в контрольной группе – Кетонал 100 мг (2 раза в сутки). Для оценки результатов лечения использовались цифровая рейтинговая (NRS) и визуальная аналоговая шкалы (ВАШ), дневники боли, опросник коморбидности, шкала Oxford Knee Score-12, опросники выявления нежелательных эффектов и побочных действий. Дополнительно анализировали переносимость препаратов, удобство применения и общую удовлетворенность лечением по балльным категориальным шкалам. Половозрастные, клинико-рентгенологические, функциональные и интраоперационные характеристики пациентов в обеих группах не имели статистически значимых отличий.

Результаты. Динамика боли по шкалам NRS и ВАШ в обеих группах демонстрировала одинаковую тенденцию: средние значения достигали пика уровня умеренной боли в первые сутки после операции, снижаясь к 4-му дню вдвое. Средний, минимальный и максимальный уровни боли в течение дня как в покое, так и при движениях, а также продолжительность умеренной/сильной боли в течение дня значимо не отличались в обеих группах, также как и скорость наступления обезболивающего эффекта в течение первого часа после приема препарата. В обеих группах выявлено сравнимое число пациентов, которым дополнительно к пероральному приему потребовалось парентеральное введение анальгетиков: в среднем 3,57 инъекции в основной и 4,41 — в контрольной группах. Однако на 3-и и 4-е сут. после операции среди пациентов, получавших кеторолак, необходимость в дополнительном обезболивании была примерно на треть ниже к 3-м сут. (p<0,05) и почти вдвое — к 4-м сут. (p<0,05) по сравнению с принимавшими кетопрофен. Частота нежелательных явлений была схожа в обеих группах пациентов, но об отличном уровне удовлетворенности проводимым лечением среди пациентов, принимавших кеторолак, сообщило вдвое больше больных.

Заключение. Пероральные формы кеторолака и кетопрофена демонстрируют сопоставимую высокую эффективность при купировании боли после ТЭКС и хорошо переносятся пациентами, поэтому могут быть адекватной альтернативой их парентеральному применению в раннем послеоперационном периоде.

Ключевые слова: эндопротезирование коленного сустава, послеоперационный болевой синдром, аналгезия, нестероидные противовоспалительные препараты.

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Efficacy of Novel Oral Non-Steroid Anti-Inflammatory Drugs for Pain Management After Total Knee Arthroplasty

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Abstract.
Background. Total knee arthroplasty (TKA) typically associated with moderate to severe post-operative pain that resolves quite slowly. Therefore, injectable forms of non-steroid anti-inflammatory drugs became the key element of multi-modal analgesia in early post-operative period.
Aim of the study — to evaluate the effectiveness and safety of ketorolac vs. ketoprofen for relief of postoperative pain in patients after TKA.
Methods. 100 end-stage osteoarthritic patients (mean age 66,6 years, 80 women and 20 men) that consecutively admitted for primary uncomplicated TKA were randomized in two groups. Ketorol Express (10 mg oral, 4 times per day) used for post-op pain management in the first (49 patients) while Ketonal (100 mg oral, twice a day) — in the second (51 patients). The outcomes assessed by numeral rating scale (NRS), visual analog scale (VAS), pain diaries, comorbidities, peri-operative characteristics, knee function (Oxford Knee Score — 12), adverse effects, drug tolerance and usability, overall satisfaction of treatment. Both groups had no significant gender, age, clinical, radiological, functional or intra-operative differences.
Results. The NRS and VAS ratings showed the similar tendency in both groups: the next day after surgery the pain increased up to moderate, followed by 2 times reduction at day four. There were no differences in average, minimal and maximal pain both in rest and movement as well as amount of daily moderate to severe pain and speed of analgesic effect after oral drug intake. The similar number of patients needed additional analgesics in both groups: on average 3,57 and 4,41 injections correspondently. However, in ketorolac group at day 3 & 4 the percentage of such patients was significantly lower: by 30% at day 3 ($p<0,05$) and 50% at day 4 ($p<0,05$). Reported side effects were comparable in both groups but the high level of overall satisfaction was two times more in the patients who took ketorolac.
Conclusion. Oral administration both of ketorolac and ketoprofen proved to be highly effective for pain management after TKA with appropriate tolerance therefore could be used instead of injections since early post-op period.

Keywords: knee arthroplasty, post-operative pain, non-steroidal anti-inflammatory drugs.

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ВВЕДЕНИЕ

Тотальное эндопротезирование коленного сустава (ТЭКС) сопровождается развитием выраженной боли в послеоперационном периоде, которая имеет тенденцию к снижению в течение недель, а у некоторых пациентов — даже месяцев [1]. Это обусловлено, с одной стороны, сложностью иннервации данной анатомической области [2], а с другой стороны, тем, что после ТЭКС формируются новые биомеханические и кинематические условия функционирования всей нижней конечности в целом.

Одним из достижений технологий артропластики крупных суставов в XXI в. стало научное обоснование и клиническое внедрение мультимодального подхода к анальгезии, неотъемлемым элементом которого являются нестероидные противовоспалительные препараты (НПВП) [3, 4]. В настоящее время в РФ зарегистрировано около 30 молекул, относящихся к этой группе, которые представлены как оригинальными препаратами, так и дженериками. Выбор НПВП осуществляется эмпирически и в основном определяется наличием у пациента индивидуальных факторов риска, среди которых наиболее значимыми являются сердечно-сосудистая патология и заболевания органов желудочно-кишечного тракта [5]. Отдельные молекулы обладают более выраженным анальгетическим, нежели противовоспалительным/жаропонижающим эффектом, что может быть клинически значимым в раннем послеоперационном периоде. Тем не менее исследований, напрямую сравнивающих клиническую эффективность различных НПВП после ТЭКС, как в зарубежной, так и отечественной научной литературе встречается мало [6, 7]. Следует отметить и то, что в РФ для послеоперационного обезболивания традиционно применяются парентеральные формы НПВП, хотя за рубежом, в силу трансформации в последние два десятилетия артропластики крупных суставов в «хирургию одного дня», предпочтение отдается пероральным формам [8].

Цель исследования — сравнительная оценка эффективности и безопасности применения таблетированных форм кеторолака и кетопрофена для купирования послеоперационной боли у пациентов с гонартрозом после тотального эндопротезирования коленного сустава.

МАТЕРИАЛ И МЕТОДЫ

Дизайн исследования

Выполнено открытое наблюдательное проспективное рандомизированное сравнительное.

Пациенты

В исследование вошли 100 пациентов (80 женщин и 20 мужчин, средний возраст 66,6 лет) с терминальной стадией гонартроза (3 ст. по классификации Н.С. Косинской или IV ст. по классификации Kellgren – Lawrence). Все пациенты были госпитализированы в НМИЦ ТО им. Р.Р. Вредена для планового первичного неосложненного ТЭКС с апреля по ноябрь 2022 г.

Критерии включения:

– варусная деформация не более 25°;

– ограничение объема движений не более 60°;

– ИМТ менее 36;

– отсутствие противопоказаний к использованию максимальных доз НПВП, местных анестетиков, гемостатического жгута;

– отсутствие костных дефектов, требующих восполнения.

Критерии невключения:

– корригирующие остеотомии бедренной или большеберцовой кости в анамнезе;

– посттравматический гонартроз;

– анкилоз коленного сустава;

– системные заболевания соединительной ткани;

– предшествующее эндопротезирование контралатерального коленного сустава;

– наличие клинически значимых внесуставных источников боли (дегенеративно-дистрофические заболевания позвоночника, коксартроз, невропатии и т.п.);

– гиперчувствительность к кеторолаку и кетопрофену;

– наличие серьезной сопутствующей патологии, затрудняющей интерпретацию результатов лечения;

– злокачественные новообразования; застойная сердечная недостаточность (NYHA класс II–IV); почечная недостаточность (креатинин более 0,18 ммоль/л);

– лихорадка;

– нарушения сердечного ритма;

– неспособность пациента понять процедуру, незнание русского языка.

Критерии исключения из исследования: любые периоперационные осложнения, требующие изменения стандартного протокола ведения пациента (в том числе имплантация систем повышенной связанности), либо нарушение пациентом протокола исследования (отказ от приема обезболивающих препаратов, невозможность заполнения инструментов оценки и т.п.).

Пациенты были рандомизированы методом случайных чисел в две группы. В основной группе (49 пациентов) для обезболивания после ТЭКС использовали новую таблетированную форму кеторолака 10 мг (1 диспергируемая таблетка Кеторол Экспресс 4 раза в сут.). В контрольной группе (51 пациент) с той же целью применяли таблетированную форму кетопрофена 100 мг (1 таблетка Кетонала 2 раза в сут.). Из исследования не было исключено ни одного пациента.

Оценка результатов

Оценка результатов лечения в обеих группах производилась по балльным шкалам-опросникам, прошедшим культурную адаптацию и валидацию в РФ, перед операцией и ежедневно со дня операции (день 0) до 4-х сут. после ее выполнения (день накануне выписки):

1. Цифровая рейтинговая шкала (NRS) предназначена для измерения интенсивности боли и измеряется в баллах от 1 до 10, где 1 — отсутствие боли и 10 — сильнейшая боль, какую можно только представить [9]. После операции первый раз пациенты отмечали уровень боли до приема препарата (Прием 1), а затем фиксировали интенсивность боли через каждые 15 мин. в течение часа.

2. Визуальная аналоговая шкала (ВАШ) также предназначена для измерения интенсивности боли и представляет собой отрезок прямой длиной 10 см, начало которого соответствует отсутствию боли, а конечная точка — максимально возможной «невыносимой» боли. Расстояние между началом отрезка («боли нет») и сделанной пациентом отметкой измеряли в сантиметрах и округляли до целого: каждый сантиметр на линии соответствовал 1 баллу. Частота измерений по ВАШ была такой же, как и NRS.

3. Дневник боли (Pain Diary — PD) предложен для ежедневной оценки болевого синдрома. Опросник отражает шесть различных аспектов боли: наименьшую, среднюю и наивысшую силу болевых ощущений в течение суток и, кроме этого, уровень и продолжительность боли как в покое, так и при движениях в коленном суставе. Для градации используется NRS в пределах от 0 (нет боли) до 10 (максимальный уровень боли). Длительность болевых ощущений определяется количеством часов в день.

4. Опросник коморбидности (The Self-Administered Comorbidity Questionnaire — SACQ) предназначен для анализа сопутствующей патологии, которая является прогностическим фактором исходов лечения и возможных осложнений, а также функциональных результатов и продолжительности пребывания в ортопедическом стационаре [10].

5. Шкала Oxford Knee Score-12 (OKS) характеризует боль и функцию коленного сустава у пациентов с гонартрозом до и после ТЭКС, обладая высокой специфичностью и чувствительностью [11, 12].

Оценка нежелательных эффектов и побочных действий проводилась с использованием оригинального опросника, составленного на основе побочных действий кеторолака*/кетопрофена**, которые описаны в утвержденных инструкциях к препаратам с пометками «часто» и «менее часто».

Кроме этого, изучали:

1) переносимость препарата по четырехбалльной категориальной шкале: 1 балл — плохая переносимость, 2 — удовлетворительная, 3 — хорошая, 4 — отличная;

2) удобство применения формы препарата: да/нет (приятный вкус, удобство применения, быстрота развития эффекта);

3) общую удовлетворенность лечением по пятибалльной категориальной шкале: 1 — состояние ухудшилось, 2 — состояние не изменилось, 3 — состояние частично удовлетворительное, 4 — состояние удовлетворительное, 5 — состояние значительно улучшилось.

Половозрастные, клинико-рентгенологические, функциональные и интраоперационные характеристики пациентов в обеих сравниваемых группах не имели статистически значимых отличий (табл. 1). Сравнение проводилось с помощью χ^2-критерия Пирсона для качественных признаков и критерия Манна–Уитни для количественных признаков.

Таблица 1

Характеристика пациентов в группах сравнения, *n* (%), Me [Q1;Q2]

Параметр	Основная группа (кеторолак) *n* = 49	Контрольная группа (кетопрофен) *n* = 51
Женщины	43 (87,7)	37 (72,5)
Мужчины	6 (12,3)	14 (27,5)
Возраст, лет	65 [59;73]	65 [59;70]
Длительность заболевания, лет		
менее 5	29 (59,3)	33 (64,3)
более 5	17 (34,7)	15(29,4)
Время операции, мин.	60 [55;65]	60 [55;70]
Кровопотеря, мл	50 [50;85]	50 [50;65]
с гемостатическим жгутом	38 (76,6)	41 (80,4)
без гемостатического жгута	11 (22,4)	10 (19,6)

* https://www.rlsnet.ru/drugs/ketorolak-21188#pobocnye-deistviia.

** https://www.rlsnet.ru/active-substance/ketoprofen-642.

Окончание таблицы 1

Параметр	Основная группа (кеторолак) $n = 49$	Контрольная группа(кетопрофен) $n = 51$
Продолжительность использования жгута, мин.	60 [50;60]	60 [50;70]
Имплантат с сохранением ЗКС	43 (87,8)	48 (94,1)
Имплантат с замещением ЗКС	6 (12,2)	3 (5,9)
Модель эндопротеза		
AGC (Zimmer Biomet)	18 (36,7)	26 (51,1)
Sigma (Johnson & Johnson, DePuy)	23 (46,9)	21 (41,2)
NexGen (Zimmer Biomet)	3 (6,1)	3 (5,9)
Anthem (Smith & Nephew)	3 (6,1)	1 (1,9)
Triathlon (Stryker)	2 (4,1)	–
NRS до операции	5 [3;6]	5 [3;7]
OKS до операции	33 [29;39]	34 [27;40]
Наличие сопутствующей патологии	36 (73)	39 (76)

Во всех наблюдениях была использована спинномозговая анестезия с внутривенной седацией. ТЭКС выполнялось обоими авторами стандартизировано с применением техники измеряемой резекции и восстановлением нейтральной механической оси конечности с симметрией сгибательного и разгибательного промежутков, с использованием ограниченного срединного доступа с переднемедиальной артротомией [13]. Синовэктомия, эндопротезирование надколенника и дренирование раны не применялись. Во всех случаях осуществляли локальную инфильтрационную анальгезию по методике, описанной нами ранее [14].

Обе группы исследования были сравнимы по количеству пациентов с коморбидностью, среди которой лидировали сердечно-сосудистые заболевания (62 или 81,6%) и боли в позвоночнике (52 или 68,4%), в то время как патология желудочно-кишечного тракта была более редкой (17 или 22,4%).

Статистический анализ

Применялись следующие статистические методы для обработки данных:

– описательные статистики (математическое ожидание, среднеквадратичное отклонение, медиана, квартили, минимум/максимум) для обобщения первичных результатов, полученных из индивидуальных регистрационных карт пациентов;

– доверительная оценка параметров (математическое ожидание, стандартное отклонение (SD)), позволяющая оценивать исследуемые параметры с заданной надежностью.

Качественные переменные описывались абсолютными и относительными частотами (процентами).

При сравнении качественных показателей использованы методы статистического анализа: χ^2-критерий Пирсона, парный и непарный t-критерии Стьюдента. Для параметров, распределение которых отличалось от нормального, использовали непараметрические тесты: при сравнении двух групп использовали критерий Манна – Уитни, критерий Вилкоксона. Различия считались статистически значимыми при $p<0,05$.

Статистическая обработка данных проводилась на персональном компьютере с помощью программы IBM SPSS Statistics 25. Статистический анализ данных проводился на выборке пациентов, имеющих данные об анализируемом параметре.

РЕЗУЛЬТАТЫ

Динамика уровня боли по шкалам NRS и ВАШ в обеих группах демонстрировала одинаковую тенденцию: средние значения достигали пика уровня умеренной боли в 1-е сут. после операции, снижаясь затем к 4-м сут. вдвое (рис. 1).

С помощью критерия Вилкоксона выявлено значимое снижение боли для обоих препаратов между днем операции и 4-м сут. наблюдения ($p = 0,000$). В каждой из точек наблюдения значимого различия на основе критерия Манна – Уитни по шкале NRS между группами не выявлено ($p>0,05$) (табл. 2).

Средний, минимальный и максимальный уровни боли в течение дня как в покое, так и при движениях, а также продолжительность умеренной/сильной боли в течение дня значимо не отличались. Как кеторолак, так и кетопрофен позволяли эффективно контролировать уровень боли после ТЭКС: суточная динамика снижения боли представлена на рисунке 2.

В каждой из точек наблюдения значимых различий по шкале ВАШ на основе критерия Манна – Уитни между группами не выявлено ($p>0,05$) (табл. 3).

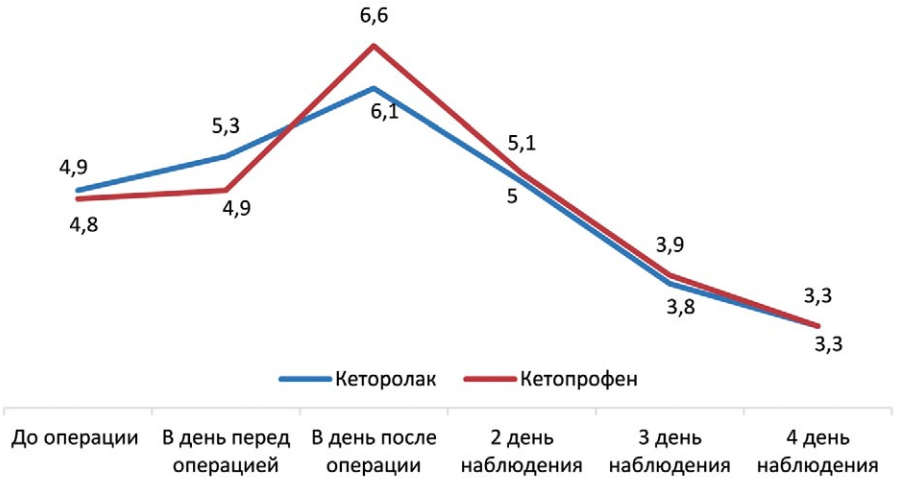

Рис. 1. Оценка боли по шкале NRS

Fig. 1. Pain severity ratings according NRS from admission trough discharge from the clinic

Таблица 2

Оценка боли по шкале NRS на основе критерия Манна – Уитни, Me [Q1;Q2]

Срок наблюдения	Основная группа (кеторолак)	Контрольная группа (кетопрофен)	*p*
До операции	5 [3;6]	5 [3;7]	0,789
В день перед операцией	5 [4;7]	5 [4;6]	0,169
В день после операции	6 [5;7]	7 [5;8]	0,144
2-й день наблюдения	5 [4;6]	5 [3;6]	0,957
3-й день наблюдения	4 [3;5]	4 [3;5]	0,808
4-й день наблюдения	3 [2;4]	3 [2;4]	0,946

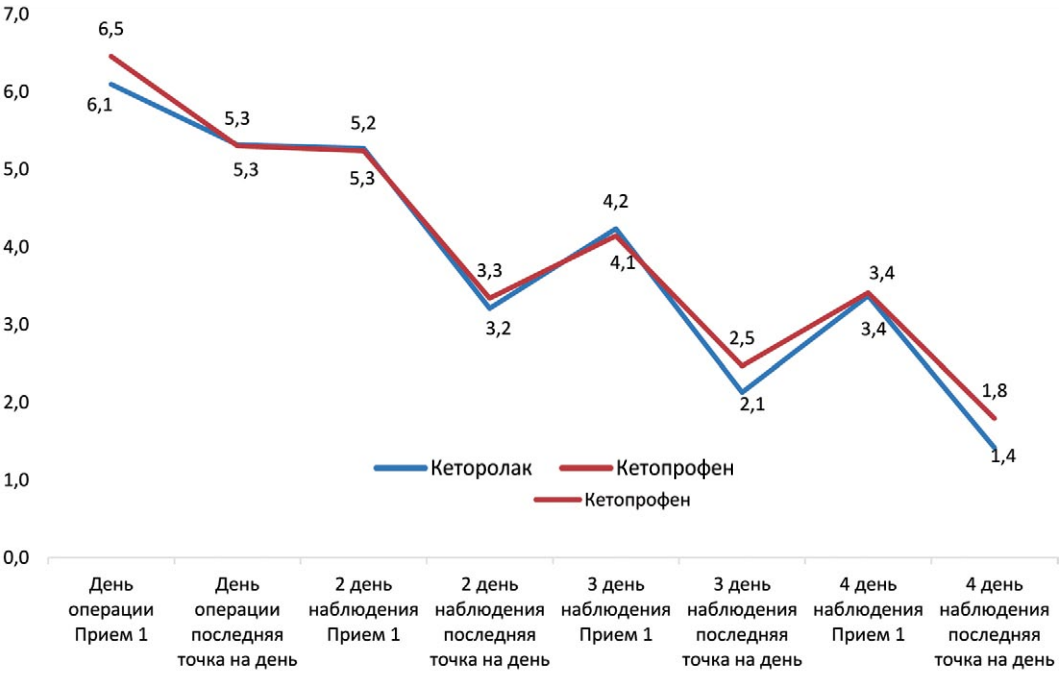

Рис. 2. Суточная динамика снижения боли по ВАШ

Fig. 2. Daily dynamic of pain from the day of surgery trough discharge from the clinic according VAS

Таблица 3

Суточная динамика снижения боли по шкале ВАШ на основе критерия Манна – Уитни, Me [Q1;Q2]

Срок наблюдения	Основная группа (кеторолак) *n* = 49	Контрольная группа (кетопрофен) *n* = 51	*p*
День операции Прием 1	6 [5;7]	7 [5;8]	0,402
День операции, последняя точка на день	5,5 [4;7]	5 [4;7]	0,908
2-й день наблюдения Прием 1	6 [4;7]	5 [4;6]	0,700
2-й день наблюдения Последняя точка на день	2,5 [1;5]	3 [2;5]	0,531
3-й день наблюдения Прием 1	4 [3;5]	4 [3;5]	0,666
3-й день наблюдения Последняя точка на день	2 [1;3]	2 [1;3]	0,349
4-й день наблюдения Прием 1	3 [3;4]	3 [3;4]	0,916
4-й день наблюдения Последняя точка на день	1 [1;2]	1 [1;2]	0,395

Скорость наступления обезболивающего эффекта в течение первого часа после приема препарата статистически значимо не отличалась в обеих группах пациентов.

В обеих группах выявлено сравнимое число пациентов, которым дополнительно к пероральному приему потребовалось парентеральное введение анальгетиков: в среднем 3,57 инъекции в основной группе и 4,41 — в контрольной. Однако на 3-и и 4-е сут. после операции среди пациентов, получавших кеторолак, необходимость в дополнительном обезболивании была статистически значимо ниже: примерно на треть к 3-м сут.и почти вдвое — к 4-м сут. (рис. 3).

Наркотические анальгетики (трамадол 2 мл в/м одно-двукратно) и ненаркотические (р-р парацетамола — 500 мг / 50 мл в/в одно-двукратно) рутинно применялись только в 1-е сут. после операции

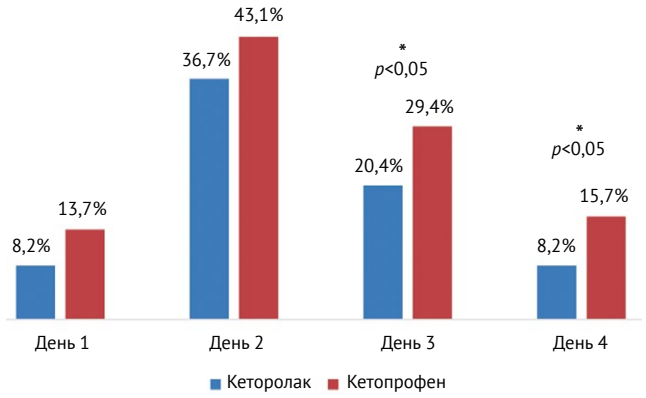

Рис. 3. Количество пациентов, нуждающихся в дополнительном парентеральном обезболивании

Fig. 3. Percentage of patients who need additional parenteral analgesia from the day of the surgery trough discharge from the clinic

по требованию пациента при условии недостаточной анальгезии. В дальнейшем доля пациентов, нуждающихся в их использовании, была крайне низкой, значимо не отличаясь между обеими группами.

Среди пациентов, принимавших Кеторол Экспресс, начиная со 2-го дня после операции, некоторые снижали кратность его приема в течение суток в связи с минимальным уровнем болевых ощущений, в отличие от контрольной группы (рис. 4). В итоге к 4-м сут. после операции около трети пациентов не нуждались в четырехкратном приеме этого препарата. При этом среди пациентов, уменьшавших кратность приема до трех, двух или даже одного раза, к 3–4-м сут. боль продолжала оставаться на низком уровне: 0,6–1,8 по NRS. Среди пациентов, принимавших Кетонал, на однократный прием со 2-го дня перешли двое (3,9%), с 3-го дня трое (5,9%), и с 4-го дня — двое (3,9%).

Частота нежелательных явлений была схожа в обеих группах пациентов — 47% (22) и 44% (22) соответственно. Их распределение представлено на рисунках 5 и 6. Анализ наличия или отсутствия связи отмеченных нежелательных явлений с используемыми препаратами не проводился, изменения протокола лечения или дополнительной коррекции не потребовалось. Следует подчеркнуть, что ни у одного из находившихся под наблюдением пациентов не развилось серьезное нежелательное явление или реакция по критериям ВОЗ.

Более 2/3 пациентов отметили переносимость обоих препаратов как хорошую и отличную. Однако об отличном уровне удовлетворенности проводимым лечением среди пациентов, принимавших кеторолак, сообщило вдвое больше, чем среди получавших кетопрофен (рис. 7).

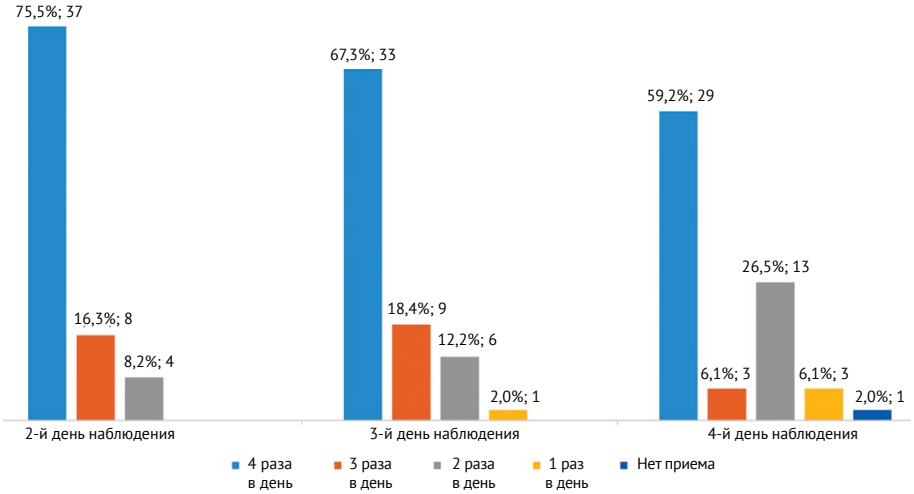

Рис. 4. Кратность приема кеторолака со 2-го дня до выписки

Fig. 4. Frequency of ketorolac intake from the second day after surgery trough discharge from the clinic

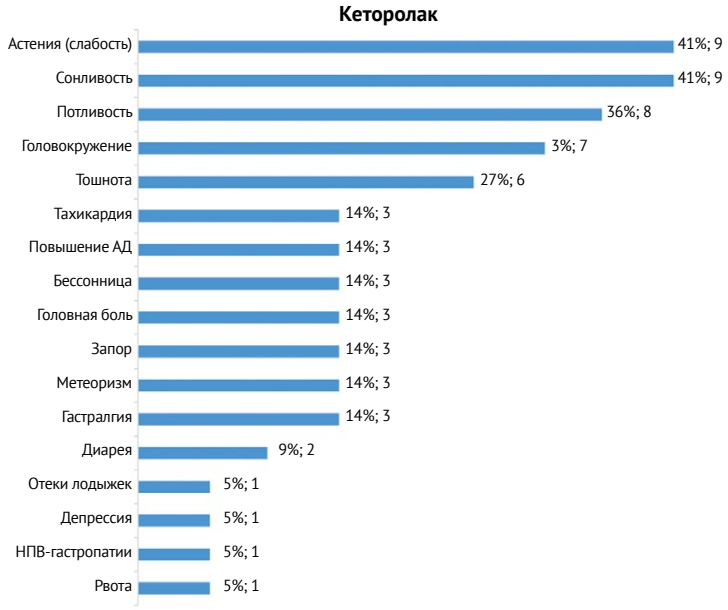

Рис. 5. Распределение побочных эффектов на фоне приема кеторолака

Fig. 5. Frequency of adverse events in ketorolac cohort

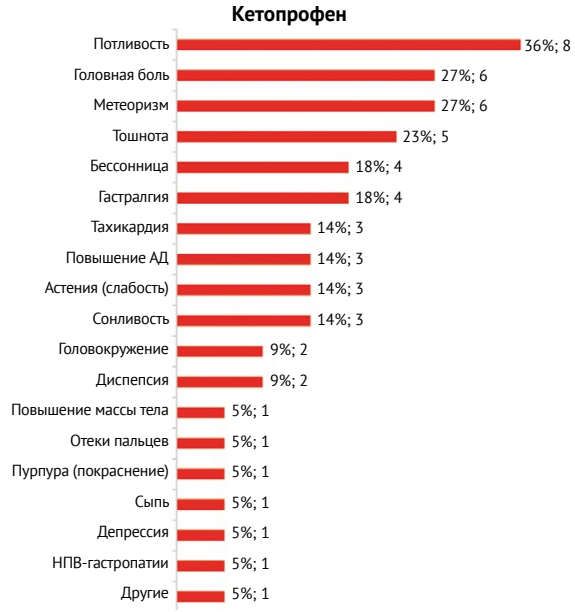

Рис. 6. Распределение побочных эффектов на фоне приема кетопрофена

Fig. 6. Frequency of adverse events in ketoprofen cohort

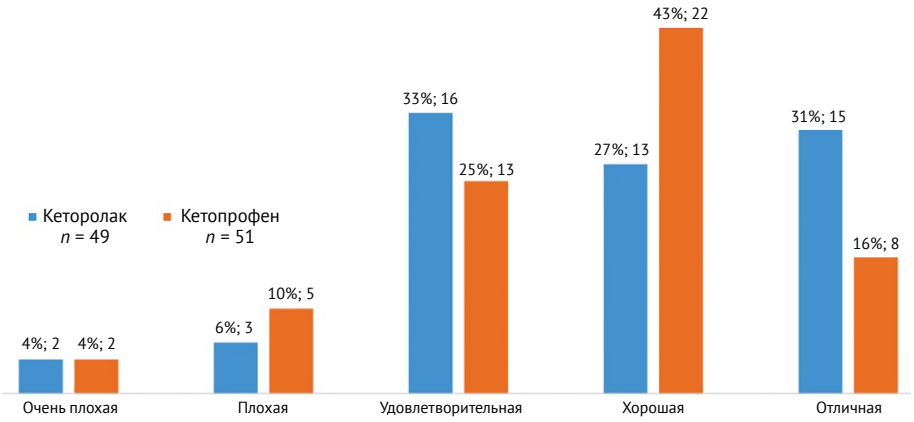

Рис. 7. Удовлетворенность пациентов лечением в обеих группах

Fig. 7. Patients' satisfaction with the treatment in both groups

Большинство пациентов оценили вкус кеторолака как приятный — 37 (78,7%), а также отметили возможность его применения без воды — 42 (89,4%).

ОБСУЖДЕНИЕ

Во-первых, полученные результаты свидетельствуют о том, что пероральное применение современных форм НПВП после ТЭКС позволяет добиться адекватного уровня анальгезии на протяжении всего периода, пока пациент находится в стационаре, тем самым снизив нагрузку на средний медицинских персонал. В проведенном нами ранее исследовании, посвященном изучению траекторий боли после ТЭКС, в котором НПВП применяли парентерально, абсолютные величины и динамика среднего, минимального и максимального уровней боли в течение дня (в покое и при движениях), а также количество часов умеренной/сильной боли в течение суток даже несколько превышали значения, продемонстрированные при использовании таблетированных форм [14]. Парентеральное введение ненаркотических и наркотических аналгетиков остается востребованным в 1-е сут. после хирургического вмешательства, когда использование пероральных форм может быть затруднено из-за заторможенного или возбужденного состояния пациента [15]. При этом НПВП в сочетании с опиоидными анальгетиками являются моделью мультимодальной анальгезии [16, 17]. Тем не менее, учитывая, что большинству пациентов после ТЭКС прием НПВП может быть необходим до 3 мес. после операции, важным является подбор схемы эффективной пероральной аналгезии еще в период стационарного лечения, так как умеренная/сильная боль, сохраняющаяся к 3-м сут. после вмешательства, является значимым прогностическим фактором риска развития хронического послеоперационного болевого синдрома [18].

Во-вторых, оба сравниваемых препарата (кеторолак в форме диспергируемой таблетки и кетопрофен в таблетированной форме) не показали значимых отличий по переносимости в сопоставимых группах пациентов, у которых лидирующим фактором коморбидности была патология сердечно-сосудистой системы [19]. Зафиксированные нежелательные явления среди пациентов обеих групп не потребовали дополнительной терапии или отмены НПВП и купировались самостоятельно. Учитывая, что пациенты в раннем послеоперационном периоде, кроме НПВП, получают лекарственные средства для профилактики инфекционных и тромбоэмболических осложнений, а также терапии сопутствующих заболеваний, размер проанализированной выборки недостаточен для выявления корреляционных взаимосвязей между конкретным НПВП и побочным эффектом. Полученные нами данные об относительной эффективности и безопасности НПВП соответствуют выводам системного метаанализа 25 РКИ, посвященного применению НПВП у пациентов после тотальной артропластики коленного и тазобедренного суставов и рекомендациям рабочей группы PROSPECT (PROcedure SPEcific Postoperative Pain ManagemenT), которая представляет собой глобальное сотрудничество хирургов и анестезиологов, формулирующих рекомендации по лечению боли после распространенных операций [20, 21]. Относительно клинически значимых осложнений со стороны желудочно-кишечного тракта, применение НПВП после подобных хирургических вмешательств характеризуется низким риском (0,6%), однако если и развивается, то приводит к существенному удлинению пребывания в стационаре и повышению внутрибольничной смертности [22, 23]. Поэтому перед эндопротезированием крупных суставов конечностей обоснованным является проведение фиброгастродуоденоскопии для скрининга пациентов со скрытыми гастропатиями. Таким образом, результаты исследования подтверждают актуальность тезиса, отраженного в отечественных клинических рекомендациях, о возможности эмпирического подхода к выбору НПВП для послеоперационной анальгезии, но с учетом имеющейся у пациента соматической патологии [24].

В-третьих, если у пациента после операции достигнут низкий уровень боли, стабильно сохраняющейся и в периоды двигательной активности, например при ходьбе и занятиях лечебной физкультурой, суточная доза препарата может быть снижена. С одной стороны, это оптимизирует расход лекарственных средств, а с другой — является профилактикой развития нежелательных явлений, для некоторых из которых характерен дозозависимый эффект.

Ограничения исследования

К ограничениям исследования следует отнести неравномерное гендерное и смешанное этническое распределение пациентов в изучаемой выборке, что, хотя и отражает реальную клиническую практику работы НМИЦ ТО им. Р.Р. Вредена, требует взвешенной трактовки полученных результатов. При сложных случаях первичного ТЭКС или ревизионных вмешательствах степень хирургической агрессии, включая продолжительность и кровопотерю, могут отражаться как на уровне послеоперационной боли, так и на эффективности обезболивания, что требует отдельного изучения.

ЗАКЛЮЧЕНИЕ

Пероральные формы кеторолака и кетопрофена демонстрируют сопоставимую высокую эффективность при купировании боли после ТЭКС и хорошо переносятся пациентами. К 3–4-м сут. после операции в группе пациентов, получавших кеторолак, на 30% сокращается количество нуждающихся в его четырехкратном приеме, а также снижается доля больных, добровольно на фоне низкого уровня боли отказывающихся от дополнительного парентерального обезболивания. Таким образом, таблетированные формы НПВП являются адекватной альтернативой парентеральному применению препаратов данной группы в раннем послеоперационном периоде после ТЭКС.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Заявленный вклад авторов

Сараев А.В. — сбор клинического материала, редактирование статьи.

Корнилов Н.Н. — дизайн исследования, анализ литературы, написание и редактирование статьи.

Все авторы прочли и одобрили финальную версию рукописи статьи. Все авторы согласны нести ответственность за все аспекты работы, чтобы обеспечить надлежащее рассмотрение и решение всех возможных вопросов, связанных с корректностью и надежностью любой части работы.

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DISCLAIMERS

Author contribution

Aleksandr V. Saraev — data collection and processing, the drafting of the article.

Nikolai N. Kornilov — design of the study, the search and analysis of literature sources, the writing and the writing of the article.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Evaluation of Biocompatibility of New Osteoplastic Xenomaterials Containing Zoledronic Acid and Strontium Ranelate

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Abstract

Background. The problem of improving the functional characteristics of implanted devices and materials used in traumatology and orthopedics is a topical issue.

Aim of the study — to study biocompatibility of bovine bone matrix xenomaterials modified by zoledronic acid and strontium ranelate when implanted into the bone defect cavity.

Methods. The study was performed on 24 male rabbits of the Soviet Chinchilla breed. Test blocks of bone matrix were implanted into the cavity of bone defects of the femur. Group 1 animals (n = 8, control group) were implanted with bone xenogenic material (Bio-Ost osteoplastic matrix). Group 2 animals (n = 8) were implanted with bone xenogenic material impregnated with zoledronic acid. Group 3 animals (n = 8) were implanted with bone xenogeneic material impregnated with strontium ranelate. Supercritical fluid extraction technology was used to purify the material and impregnate it with zoledronic acid and strontium ranelate. Radiological, pathomorphological, histological and laboratory (hematology and blood biochemistry) diagnostic methods were used to assess biocompatibility. Follow-up period was 182 days after implantation.

Results. It was found out that on the 182nd day after implantation the median area of the newly-formed bone tissue in the defect modeling area in Group 1 was 79%, in Group 2 — 0%, in Group 3 — 67%. In Group 2 the maximum area by this period was filled with connective tissue — 77%. Median relative area of implanted material fragments in Group 1 was 4%, in Group 2 — 23%, in Group 3 — 15%. No infection or material rejection was observed in animals of all groups. There were no signs of intoxication or prolonged systemic inflammatory reaction. Laboratory parameters did not change significantly over time. One animal in each group experienced one-time increase in C-reactive protein level against the background of leukocytosis. Two animals in Group 1 had a slight migration of implanted material under the skin, one animal developed arthritis of the knee joint.

Conclusion. Osteoplastic materials based on bovine bone xenomatrix and filled with zoledronic acid and strontium ranelate have acceptable values of biocompatibility including their safety profile.

Keywords: osteoplastic material, xenograft, zoledronic acid, strontium ranelate, bone defect, biocompatibility.

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Оценка биосовместимости новых костнопластических ксеноматериалов, содержащих золедроновую кислоту и ранелат стронция

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Реферат

Актуальность. Улучшение функциональных характеристик имплантируемых изделий и материалов, используемых в травматологии и ортопедии, является актуальной проблемой.

Цель исследования — изучить биосовместимость модифицированных золедроновой кислотой и ранелатом стронция ксеноматериалов из костного матрикса крупного рогатого скота при их имплантации в полость костного дефекта.

Материал и методы. Исследование выполнено на 24 кроликах-самцах породы советская шиншилла. В полость дефектов бедренной кости имплантировали тестируемые блоки костного матрикса. Животным группы 1 (n = 8, группа контроля) имплантировали костный ксеногенный материал «Матрикс остеопластический “Bio-Ost”». Животным группы 2 (n = 8) имплантировали костный ксеногенный материал, импрегнированный золедроновой кислотой. Животным группы 3 (n = 8) имплантировали костный ксеногенный материал, импрегнированный ранелатом стронция. Для очистки материала и импрегнации в его объем золедроновой кислоты и стронция ранелата использовали технологию сверхкритической флюидной экстракции. Для оценки биосовместимости использовали рентгенологический, патоморфологический, гистологический и лабораторный (гематология и биохимия крови) методы исследования. Срок наблюдения составил 182 дня после имплантации.

Результаты. На 182-е сут. после имплантации площадь новообразованной костной ткани в области моделирования дефекта у животных группы 1 по медиане составила 79%, в группе 2 — 0%, в группе 3 — 67%. В группе 2 к данному сроку максимальную площадь занимала соединительная ткань — 77%. Относительная площадь фрагментов имплантированного материала у животных группы 1 составила 4% по медиане, в группе 2 — 23%, в группе 3 — 15%. У животных всех групп инфицирования и отторжения материала не отмечали. Признаков интоксикации, длительной системной воспалительной реакции не наблюдали. Лабораторные показатели в динамике существенно не изменялись. Во всех группах у одного из животных отмечали разовый рост уровня С-реактивного белка на фоне лейкоцитоза. В группе 1 у двух животных наблюдалась незначительная миграция имплантируемого материала под кожу, у одного развился артрит коленного сустава.

Заключение. Костнопластические материалы на основе ксеноматрикса из костей крупного рогатого скота, насыщенные золедроновой кислотой и стронция ранелатом, имеют приемлемые значения биосовместимости, включая показатели безопасности.

Ключевые слова: костнопластический ксеноматериал, золедроновая кислота, ранелат стронция, костный дефект, биосовместимость.

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BACKGROUND

Nowadays, the problem of improving biological and functional characteristics of implanted devices and materials used in traumatology and orthopedics is rather relevant [1, 2, 3, 4]. The main direction of studies on this topic is the use of material/device not only as a matrix for bone tissue formation, but also as a system of delivery of additional biologically active substances to implantation area [5, 6, 7]. It is demonstrated that the most acceptable carrier is the bone tissue itself, both of allogenic and xenogenic nature [8, 9, 10]. In this context, the main directions of bone material modification are focused on enhancing osteoinductive and osteogenic effects. Thus, the bone matrix is impregnated with: cells [11, 12], including platelet-rich plasma [13]; growth factors and cytokines [14, 15, 16]; non-collagen proteins [17]; messenger RNA (mRNA) [18, 19]; drug substances, including antibacterial drugs [20, 21, 22, 23]. To improve the biological features of bone material, technologies of its physical treatment are modified [24]. Recently, it has become obligatory to preserve the mechanical features of bioresorbable implants to provide structural support to the bone until a complete regenerate is formed. This can be achieved by impregnating implants with substances that modulate resorptive effect, including zoledronates and strontium ranelate [25, 26, 27]. In our opinion, impregnation of these substances into xenogenic bone has certain prospects as it is the most accessible in terms of raw material and possibilities of its modification [28, 29, 30].

Aim of the study — to study biocompatibility of bovine bone matrix xenomaterials modified by zoledronic acid and strontium ranelate when implanted into the bone defect cavity.

METHODS

Study design

The study was performed on 24 male rabbits of the Soviet Chinchilla breed (PAO Sintez farm), aged from 8 to 16 months with body weight from 3.0 to 4.5 kg. Bone tissue defects of 4×4×6 mm were simulated in the animals. Xenomaterial (XM) test blocks of the same size were implanted into the cavities of the defects.

Group 1 animals (n = 8, control group) were implanted with bone (unmodified) xenogenic material ("Bio-Ost" Osteoplastic Matrix, (Roszdravnadzor 2015/3086) (raw material — bovine cancellous bone). Group 2 animals (n = 8) were implanted with bone xenogenic material impregnated with zoledronic acid. Group 3 animals (n = 8) were implanted with bone xenogenic material impregnated with strontium ranelate. Bone blocks of 20×15×5 mm (Bio-Ost), polylactide (Poly[D,L-lactide] IV dl/g, acid-terminated, molecular mass 30 kDa), zoledronic acid monohydrate (Sigma-Aldrich, USA) and strontium ranelate (Sigma-Aldrich, USA) were used to obtain the modified bone marrow (BM).

Impregnation procedure

Crushed polylactide weighing 1 g (for zoledronate) and 0.5 g (for ranelate) were dissolved in 20 ml of ethyl alcohol and incubated for 3 hours at 60°C. Next, 50 mg of zoledronic acid were dissolved in 10 ml of 0.1N NaOH solution. Strontium ranelate was dissolved in 10 ml of distilled water. These solutions (zoledronic acid and strontium ranelate) were mixed with the polylactide solution. Then, the blocks (10 pieces) were immersed in the obtained solution. Next, the solution with immersed blocks was placed in Waters supercritical fluid extraction reactor, carbon dioxide was injected and medium parameters were adjusted to P = 250 atm, T = 32°C [31]. After setting up the static mode in the reactor, the blocks were incubated for 30 min, then the carbon dioxide supply was turned off and the pressure was being reduced during 30 min. Extracted blocks were lyophilized and subjected to gas sterilization in ethanol oxide medium, followed by vacuuming and aeration for 2 days. Materials were obtained at the premises of OOO MedInzhBio (Penza, Russia).

Simulation of bone tissue defects of the distal femoral metaphysis and proximal tibial metaphysis

The surgery was performed under general anesthesia (premedication: dimedrol 1% solution (0.02 mg/kg), atropine sulfate 0.1% solution (0.02 mg/kg), meditin 1% (0.35 mg/kg); for anesthesia: sodium thiopental 5% (10 mg/kg). Initially, surgical approach to the lateral surface of the distal femoral metaphysis was carried out. Then, the metaphyseal bone tissue was sampled

with a dental bur, forming a part-through defect 4 mm wide, 4 mm long and 6 mm deep. After that an implant was inserted into the defect cavity by light hammering. Next the surgical wound was sutured layer-by-layer with Vicril 4/0 suture material (Ethicon, USA). Surgical approach to the proximal metaphysis of the tibia was performed on the medial surface of the lower leg. Defect formation, implant installation and surgical wound suturing were performed as described above. To prevent septic postoperative complications, a single injection of cephalosporin antibacterial drugs (cefazolin 200 mg) and nonsteroidal anti-inflammatory drugs (ketoprofen 0.05% 0.5 ml) was administered on the day of the surgery. Surgical suture dressing was not performed.

Four implantations were performed in each animal: distal femoral metaphysis and proximal tibial metaphysis on both limbs.

To prevent complications of postoperative hypothermia of anaesthetic sleep, after the surgery the rabbits were heated under an infrared lamp for 1-3 hours at 25-28°C on the body surface until the they were completely awakened. The period of planned euthanasia was day 84 and day 182 after implantation (when choosing the period of observation of animals after implantation, we were guided by GOST ISO 10993-6-2011. Medical devices. Biological evaluation of medical devices. Part 6. Tests for local effects after implantation).

Animal management

Animals were kept in individual 0.5 m² cages, one-by-one with permanent access to food and water, in the vivarium of the research center. Hay was used as bedding. Feeding was carried out according to standard nutrient-balanced diet including mixed rabbit feed (PZK 90, Bogdanovichskii Feed Mill), oat grain, fresh carrot and hay. Clean drinking water was provided without restrictions.

Before enrolling in the experiment, the animals were quarantined for 15 days. While they were in the quarantine unit, their general condition was monitored daily by examining in the cage. Animals with unsatisfactory general condition were excluded from the process of group formation. Animals were randomized into groups.

Each animal in the group was identified by an individual three-digit number. Marking method was tattooing the individual three-digit number on the inner surface of the auricle and putting a tag with the same number on the cage.

In order to assess biocompatibility, including the safety of the tested materials, methods of intravital observation, radiological, pathological, histological and laboratory methods of examination were used.

Intravital observations

Deviations in the general condition of rabbits, their behavior in the cage, and the presence of lameness were monitored every day. Food and water intake, coat color, and visible mucous membranes were evaluated. When examining the implantation area, attention was paid to the surgical wound condition, appearance of oedema, exudate effusion, painfulness.

X-ray examinations

X-ray examination was performed on the day of the surgery, on the 14th, 28th, 56th, 84th, 112th, 140th, and 182nd days of observation. X-rays of implantation zones were taken in the AP, axial and lateromedial projections on TOSHIBA (Rotanode) Model E7239. N: 10G749 X-ray machine (Japan). Current strength — 2.5-3.2 mA, voltage — 43-44 kV, focal distance 90 cm, automatic exposure.

Post-mortem studies

Planned euthanasia of animals was performed under premedication (dimedrol 1% (0.02 mg/kg), rometar 2% (5 mg/kg) by barbiturate overdosing. At autopsy, examination of internal organs and implantation sites was performed. Relative weight of parenchymatous organs was determined. Macroscopic examination of implantation areas was carried out.

Histological studies

Tubular bone metaepiphyses, including the surgical site, were fixed for 3 days in 10% formalin for histology (Labiko, Russia) at pH 6.8-7.4. After acid decalcification in solution containing 10% concentrated hydrochloric acid and 8% concentrated formic acid, the bone blocks were degreased in acetone and dehydrated in ethanol with ascending concentration of 70% to 100%. Decalcified samples were embedded in celloidin-paraffin and sectioned on the HM-450 sledge microtome (Thermo Fisher, United Kingdom). Obtained sections up to 7 μm thick were stained with hematoxylin and eosin and Masson's trichrome. Histological samples were scanned in the Pannoramic Midi II microscope (3DHISTECH

Ltd., Hungary) with 40× Corr/NA 0.95 plan-apochromat objective. Morphological examination of digital histological samples, histomorphometry of cellular and tissue components was performed using Pannoramic Viewer software (3DHISTECH Ltd., Hungary).

Histomorphometric study was performed on digital samples obtained using the hardware and software complex for digital technologies mentioned above. Cellular composition and vascularization of the bone organ in the implantation area were evaluated on digital images of histological sections stained with hematoxylin and eosin. The number of cells and vessels was counted in the field of vision of 0.01 mm^2 with 100× digital objective. Percentage of areas of newly-formed cancellous bone substance, connective tissue and osteoplastic material were determined on digital images of Masson's trichrome stained histological specimens using 20× digital objective. Lamellar and woven bone tissue as well as xenogeneic bone matrix were identified on the basis of fibroarchitectonic features, morphology of bone cells (osteoblasts and osteocytes) and signs of osteonecrosis. Percentage of trabecular bone area was determined in the cancellous bone substance of the implant bed. At least 30 fields of vision were analyzed for each material at each stage of experiment. Basing on obtained quantitative data, the degree of irritating effect of biodegradable materials was determined according to GOST ISO 10993-6-2011.

According to a four-point scale, the absence of any type of cells in the field of vision was scored as 0 points, the presence of 1-5 cells (1-2 for multinucleated phagocytes) as 1 point, 5-10 (3-5 for multinucleated phagocytes) as 2 points, abundant infiltrate as 3 points, dense arrangement as 4 points. The sample was considered: non-irritant (≤0.0 to 2.9 points), mild irritant (3.0 to 8.9 points), moderate irritant (9.0 to 15.0 points), severe irritant (>15).

Tissue reaction to implanted materials was also assessed using a four-point scale. Neovascularization degree was determined by the number of capillaries in the field of vision: 1-3, 4-7, wide and abundant band with fibroblast structures. Intensity of fibrosis was assessed by the width of connective tissue layer. Intensity of fatty infiltration was determined in a similar way, differentiating fat interlayers in connective tissue with red and yellow bone marrow. Sum of all parameters in points was also used to calculate the irritating effect of implantation materials.

The final value was the total score of interim assessment of cellular and tissue reactions to intraosseous implantation of samples. Degree of irritation was determined according to the total score (irritating effect (IR) = cellular reaction (CR) + tissue reaction (TR)) and the difference between the values of the control and experimental groups for the corresponding term of experiment (RD Gr1 - RD GrN1,2,3). The negative value corresponded to zero points. The sample was considered: non-irritant (≤0.0 to 2.9 points); mild irritant (3.0 to 8.9 points); moderate irritant (9.0 to 15.0 points); severe irritant (>15).

Laboratory tests

Laboratory tests (hematology and blood biochemistry) were performed before the surgery, on the 14^{th}, 30^{th}, 84^{th} and 182^{nd} days after implantation. Hematological blood test included determination of white blood cell count on ProCyte Dx automated blood cell counter (IDEXX Lab, USA). Biochemical blood test showed the concentrations of total protein, urea, C-reactive protein (CRP), creatinine, glucose, total calcium, and inorganic phosphate. Activity of alkaline (ALP) and tartrate-resistant (bone) acid phosphatase (TRACP), aspartate aminotransferase (AST), alanine aminotransferase (ALT) was determined. Enzyme activity and substrate concentration in blood serum were determined on Hitachi/BM 902 automated biochemical analyzer (Japan) using reagent kits from Vital Diagnostic (St. Petersburg, Russia) and Vector-Best (Novosibirsk, Russia).

Statistical analysis

Results of quantitative signs are presented in tables as median, 1-3 quartiles (Me; Q1-Q3). Normality of samples was determined using Shapiro-Wilk test. Statistical evaluation of significance of differences between parameters within the studied groups (before/after implantation) was performed using Wilcoxon W-criterion. Mann-Whitney T-test was used to assess statistical significance (of differences?) of values between the groups. The minimum level of significance (p) was taken as 0.05. AtteStat 12.0.5 data analysis program was used for calculations.

RESULTS

Intravital observation

Postoperative period in animals of all experimental groups was similar. General condition of the animals after the surgery was satisfactory. Animals had subfebrile body temperature between 39.5-39.7°C from day 1 to day 3, appetite was slightly reduced, water was accepted. The mucous membranes of the conjunctivae and oral cavity were pink. In the following days, body temperature returned to mean values, appetite restored. During the first 5-7 days, hyperemia of the skin and slight swelling of subcutaneous fatty tissue were noted in the area of implantation, pain on palpation was moderate. There were no signs of soft tissue inflammation later on. Surgical incisions healed by primary intention. The animals used their limbs during the whole experiment, motor and support functions were fully preserved.

X-ray examinations

The implantation zones in animals of all groups were well visualized on X-rays on the day of the surgery (Fig. 1).

On day 84 of the experiment in Group 1, the interface between the implanted material and the host bone was diffuse in 50% of cases. Xenomaterial was only visible in the proximal metaphysis of the tibia. In Group 2, the implant was well visualized in 90% of cases and the contour of the host bone defect was well defined by that date. In Group 3, the material was completely resorbed in 33% of cases and the borderline of the host bone defect was not visible by that date.

At day 182 of the experiment, traces of implanted material were visible in Group 1. In Group 2, the first X-ray signs of BM remodeling appeared only by that time. We noted the reduction of implanted material volume, blurring of the borderline of the bone defect. However, high density of the implant was preserved. In Group 3, the borderlines of the bone defect were not visible by that time (Fig. 2).

Thus, it can be noted that X-ray signs of material replacement in Groups 1 and 3 were comparable and appeared by day 182 after implantation. There was no complete material replacement by the last day of the follow-up in Group 2.

Results of post-mortem studies

All animals were subjected to elective euthanasia (on the 84th and 182nd days after implantation). There were no unplanned animal deaths. At the time of euthanasia, no injuries of the skin and internal organs were noted in the animals of all groups during external examination. The relative weight of the organs in the animals of Groups 2 and 3 did not differ statistically significantly from the animals of Group 1.

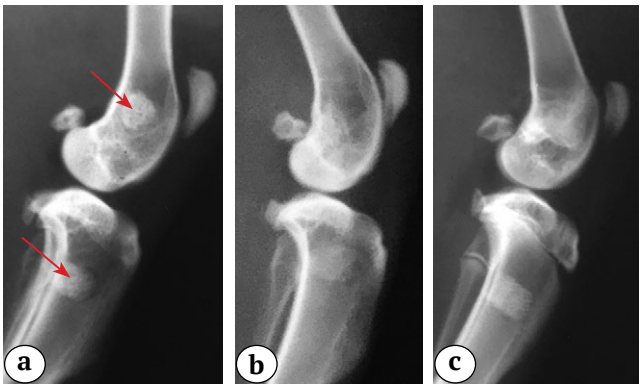

Fig. 1. X-rays of the implantation area on the day of the surgery:
a — Group 1 (arrows indicate the implantation area); b — Group 2; c — Group 3

Fig. 2. X-rays of the implantation area on the 182nd day after implantation:
a — Group 1; b — Group 2; c — Group 3

In Group 1, the implantation site was poorly visible at day 182 of the experiment. The border with the host bone was smoothed. Implant surface was covered with transparent, shining thick tissue, through which an irregular (cancellous) implant structure was visible. There were no fistulas in the implant-bone contact zone.

In Group 2 at day 182, the border with the host bone was clearly visible in the majority of animals (80%), the implant surface was slightly tuberous. The implant was tightly bound to the host bone along the entire perimeter. Focal space-occupying chondral beddings were observed on the lateral surface of the femoral metaphysis.

In Group 3 at day 182, all animals had a tight junction of the host bone and the implant, its border was defined, the implant surface was rough, partially covered by cartilage tissue. The lateral surface of the femoral metaphysis was covered with diffused thin chondral beddings.

In all groups of animals, the implantation site in the tibial metaphysis was covered by a thick white layer of superficial fascia. There were no fistulas or instability in the area of contact with the host bone.

Histological studies

Eighty-four days after implantation in animals of Group 1, active osteogenesis in the area of defect simulation was observed both in the spaces between the BM trabeculae and on the border with the cancellous bone substance of maternal bed (Fig. 3).

Xenogenic implantation material showed osteoconductive properties, being a basis for osteogenic cells adhesion and formation of bone matrix. In some fields of vision 1-2 attached or detached osteoclasts were detected on the surface of bone structures. Both newly-formed bone matrix and BM trabeculae were resorbed. The areas between xenomatrix fragments and bone trabeculae were filled with well vascularized loose areolar connective tissue. Its cellular composition included fibroblast-like cells, monocytes, macrophages. Elements of cellular inflammation were represented by eosinophilic granulocytes. Lymphocytes were found in single fields of vision. Plasma cells, neutrophil granulocytes, and necrotized cells were almost absent. Cancellous bone substance of the implant bed was represented by a sparse net of lamellar bone trabeculae with fatty bone marrow in the intertrabecular spaces. The surface of trabeculae was covered by resting cells; there was no resorption by osteoclasts.

In Group 2, the fibrous layer separated the implant from the border of the bone defect. Trabeculae of the BM were found surrounded by vast areas of poorly vascularized loose areolar connective tissue. Its cellular composition included fibroblast-like cells, monocytes, a large number of eosinophilic granulocytes. Lymphocytes, plasma cells, neutrophil granulocytes, and necrotized cellular elements were singular. Osteogenesis was observed only appositively on the surface of the host bone bed trabeculae. Resorption of osteoplastic material, as well as cancellous bone substance trabeculae, was not registered.

In Group 3, active osteogenesis was noted along the periphery of the bone defect and in the cancellous bone substance of the graft bed. Red bone marrow with inclusion of adipocytes was found in the intertrabecular spaces of the newly-formed bone substance. BM trabeculae were surrounded by interlayers of vascularized loose areolar connective tissue with high cell density. Fibroblast-like cells and elements of monocyte-macrophage lineage prevailed in connective tissue composition. Lymphocytes, plasma cells, polymorphonuclear leukocytes including eosinophils, necrotized cellular elements were present in insignificant amount. In the central part of the implant separate newly-formed woven bone trabeculae, partially contacting with the implant trabecular net were found. Implant material was resorbed by osteoclasts. Up to 3-5 attached, but more often detached multinucleated phagocytes were observed in some fields of vision.

One hundred eighty-two days after implantation, Group 1 showed organotypic restoration of cancellous bone substance in the defect simulation area with preservation of microfoci of fibrosis and neoosteogenesis. Increased concentration of eosinophils was noted in the foci of fibrosis. Implantation material biodegraded, being replaced by cancellous bone substance with a sparse net of lamellar bone trabeculae and red or yellow bone marrow in the intertrabecular spaces. The newly-formed bone trabeculae included BM microfragments. Implantation area was surrounded by yellow bone marrow with rare hypoplastic bone trabeculae without signs of remodeling.

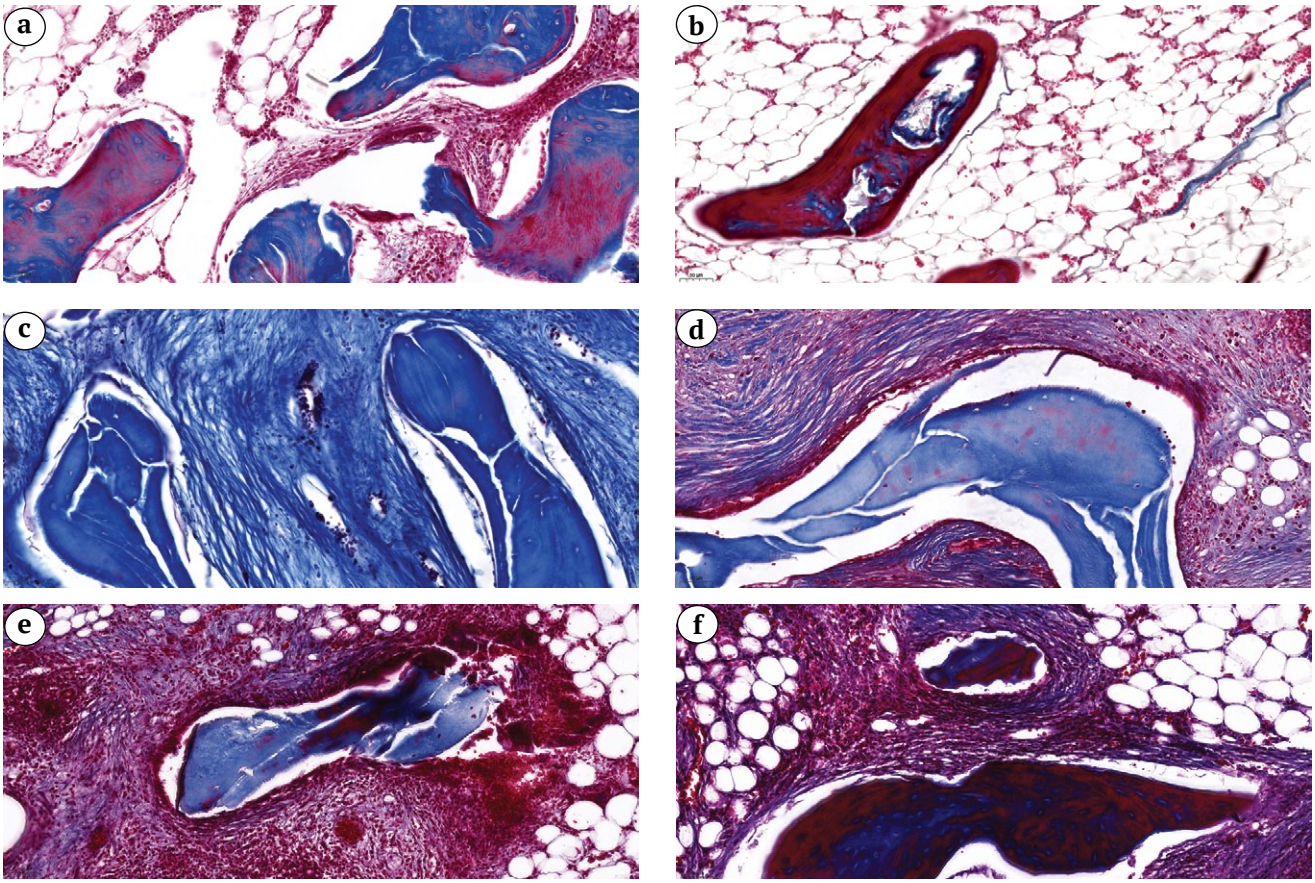

Fig. 3. Histostructure of the xenomaterial implantation area on the border with the bone bed. Day 84 (left column) and day 182 (right column) after implantation. Group 1 — xenomaterial is partially resorbed and surrounded by a narrow band of fibrous tissue (a) and cancellous bone substance (b). Group 2 — xenomaterial is encapsulated by fibrous tissue, signs of bone formation and resorption are not pronounced (c, d). Group 3 — xenomaterial trabeculae are surrounded by wide fibrous tissue bands, weak resorptive activity prevails on the 84th day (e), osteoconduction, neoosteogenesis — on the 182nd day (f). Paraffin sections. Masson's trichrome stain. Mag. ×20. Scale bar = 50 μm

In Group 2, the implantation area was filled with poorly vascularized fibrous tissue, completely surrounding the BM structural elements, with no signs of osteogenic activity. There was no resorption of BM by multinucleated phagocytes. Intensive eosinophilic infiltration of the defect area was still present. Trabecular net of the bone bed was compacted on the border with the implantation site. There was yellow bone marrow with numerous foci of hematopoiesis in the intertrabecular spaces. No osteoclast-osteoblastic remodeling of lamellar bone trabeculae was noted.

In Group 3, the area of bone defect simulation was filled with cancellous bone substance and tracts of well vascularized connective tissue encapsulating BM fragments. Fibroblast-like cells, monocytes, macrophages dominated in the cellular composition of connective tissue. Cells of leukocytic and lymphoid lineage, necrotized cells were almost absent. Tight junctions of BM fragments and individual bone trabeculae were observed without integration of implantation material into the bone matrix. Numerous resorption lacunae were preserved on the surface of BM fragments, but attached osteoclasts were rare. Massive newly-formed bone trabeculae at the border with the cancellous substance of the bone bed were lined by active osteoblasts. Few resorption lacunae and attached osteoclasts were found on their surface.

The described phenomena were statistically confirmed by the results of the histomorphometric study (Table 1). There was a significant predominance of osteoblasts/osteocytes and capillaries in the implantation area in the animals of

Group 1 on day 84 and Group 3 on day 182 of the experiment. Osteoclasts prevailed in Group 3 on day 84 of the experiment. Fibroblasts/fibrocytes and monocytes/macrophages were present in a significant amount in the implantation area in Group 3 animals. Elements of cellular inflammation were represented exclusively by eosinophilic granulocytes and were consistently present in the tissues of the implantation area of Group 2 animals. In Group 3, tissue eosinophilia was completely suppressed.

Analysis of the quantitative ratio of the area of tissue components and BM structural elements in the implantation area also revealed statistically significant differences between the groups (Table 2). The area of newly-formed bone tissue in the defect simulation area in the animals of Group 1 and Group 3 significantly increased by day 182 after implantation (up to 70%), whereas in Group 2 the maximum area by this time was occupied by connective tissue (significantly exceeding that of Groups 1 and 3). Relative area of BM fragments on histological samples at day 182 after implantation was maximal in the animals of Group 2 and minimal in the animals of Group 1.

Density assessment of the cancellous bone substance of the implant bed by calculating the total share of trabecular bone tissue showed that the impregnation of both zoledronic acid and strontium ranelate increased the value of this parameter many times. Appearance of this effect was statistically significant both on day 84 and day 182 of the experiment and more pronounced in the group where zoledronic acid was used (Table 3).

Cell reaction index in Group 2 on day 182 after implantation was significantly higher than in Groups 1 and 3 (Table 4). Tissue reaction index was the highest in Group 2 throughout the experiment. Analysis of the total score of irritant effect of studied materials showed that on the 84th day after implantation BM exhibited the properties of a moderate irritant, but its effect weakened by the 182nd day of the experiment for all groups. At the same time, impregnation with zoledronic acid significantly increased the irritant effect of BM throughout the experiment. In contrast, the combination with strontium ranelate significantly reduced the irritant effect of BM, putting it in the category of light irritants by day 182 of the experiment.

Table 1

Number of cells and vessels in the implantation area (field of vision area 0.01 mm^2), Me (Q1-Q3)

Assessment parameter	84th day after implantation			182nd day after implantation		
	Group 1	Group 2	Group 3	Group 1	Group 2	Group 3
Osteoblasts/osteocytes	6 (4–8)	**0 (0–0)**	**0 (0–1)**	1 (0–1)*	**0 (0–0)**	**2 (1–3)***
Fibroblasts/fibrocytes	23 (19–31)	23 (19–26)	**41 (34–52)**	15 (14–16)*	**20 (18–22)***	**29 (27–31)***
Osteoclasts	0 (0–1)	**0 (0–0)**	**1 (0–1)**	0 (0–0)*	0 (0–0)	0 (0–0)*
Monocytes/macrophages	12 (9–14)	**8 (7–9)**	**21 (17–24)**	5 (4–6)*	5 (4–6)*	**13 (12–14)***
Eosinophils	7 (6–10)	**11 (9–12)**	**0 (0–0)**	7 (5–9)	**11 (9–13)**	**0 (0–0)**
Capillaries	2 (2,0–2,5)	**1 (0–1)**	**1 (1–2)**	2 (1–2)*	2 (1–2)	**5 (4–6)***

* — statistically significant differences in comparison with the day 84 at p<0.05.
Statistically significant differences in comparison with Group 1 are shown in bold at p<0.05.

Laboratory tests

Statistically significant increase of leukocyte counts relative to preoperative values was observed on the 14th day of the experiment in the animals of Group 3 (Table 5).

Decrease of erythrocyte counts relative to preoperative values on day 14 of the experiment was observed in animals of all groups. Group 2 animals showed a significant increase in CRP level by day 30 of the experiment. There was a significant decrease in the activity of ALP at certain periods of experiment in the animals of Group 2 relative to preoperative values and values of Group 1. Activity of TRACP at certain times of experiment was lower than in the control group of rabbits of Group 2. Statistically significant changes in concentrations of total calcium, inorganic phosphate, total protein, creatinine and urea, as well as transaminase activity in blood serum of animals of all groups were not observed during the experiment.

Thus, there were no significant shifts in the laboratory blood tests values of rabbits during the study, the nature of which would indicate a long-term adverse effect of the drugs used to saturate the bone blocks.

Summary data on adverse events observed during the experiment are presented in Table 6. There was a minor migration of one sample of implanted material under the skin in the area of implantation in the femoral metaphysis in two animals of Group 1. Migration occurred because prepared implant was smaller than the formed defect, which did not allow the implant to be firmly fixed in the bone. One rabbit developed knee arthritis. One animal in each group showed an increase in CRP levels accompanied by leukocytosis on the 14th-30th days after implantation.

Table 2

Percentage of area of tissue components and xenomaterial in the defect simulation area, Me (Q1-Q3), %

Component	84th day after implantation			182nd day after implantation		
	Group 1	Group 2	Group 3	Group 1	Group 2	Group 3
Cancellous bone tissue	14 (14–14)	**0 (0–0)**	**27 (25–31)**	79 (56–73)*	**0 (0–0)**	67 (57–65)*
Connective tissue	73 (72–74)	**73 (71–75)**	**53 (48–63)**	17 (15–19)*	**77 (75–78)***	**23 (19–28)***
BM	13 (12–14)	**27 (24–29)**	15 (12–20)	4 (2–5)*	**23 (22–25)***	**15 (12–17)**

* — statistically significant differences in comparison with the day 84 at p<0.05.
Statistically significant differences in comparison with Group 1 are shown in bold at p<0.05..

Table 3

Percentage of trabecular bone area in the cancellous bone tissue of the implant bed, Me (Q1-Q3), %

84th day after implantation			182nd day after implantation		
Group 1	Group 2	Group 3	Group 1	Group 2	Group 3
5 (3–14)	**36 (38–44)**	**17 (8–25)**	3 (0–14)	**26 (14–33)***	**15 (7–28)**

* — statistically significant differences in comparison with the day 84 at p<0.05.
Statistically significant differences in comparison with Group 1 are shown in bold at p<0.05.

Table 4

Assessment of irritating effect of implant material, Me (Q1-Q3), points according to GOST ISO 10993-6-2011

Parameter	84th day after implantation			84th day after implantation		
	Group 1	Group 2	Group 3	Group 1	Group 2	Group 3
Cellular response						
Eosinophils	2 (2–2)	3 (2–3)	0 (0–0)	2 (2–2)	3 (2–3)	0 (0–0)
Lymphocytes	1 (0–1)	1 (0–1)	1 (0–1)	1 (0–1)	1 (0–1)	1 (0–1)
Other leukocytes (polymorphonuclear granulocytes, plasma cells)	0 (0–1)	0 (0–1)	0 (0–1)	0 (0–1)	0 (0–1)	0 (0–1)
Monocytes/macrophages	3 (2–3)	2 (2–2)	3 (2–3)	1 (1–2)	2 (2–2)	3 (2–3)
Multinucleated phagocytes	0 (0–1)	0 (0–0)	0 (0–1)	0 (0–0)	0 (0–0)	0 (1–0)
Necrosis	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
Tissue response						
Neovascularization	1 (1–1)	1 (0–1)	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)
Fibrosis	2 (2–2)	4 (4–4)	1 (1–1)	1 (0–1)	3 (3–3)	0 (1–0)
Fatty infiltrate	0 (1–0)	0 (0–0)	0 (1–0)	0 (1–0)	0 (0–0)	0 (1–0)
Indicators of irritant action (IA)						
Cell reaction (∑×2)	12 (12–14)	12 (10–12)	**8 (6–8)**	8 (8–8)*	**12 (10–12)**	**8 (6–8)***
Tissue reaction	3 (2–3)	**5 (5–5)**	2 (2–3)	2 (1–2)*	**4 (4–4)**	**1 (1–1)***
Irritant action (cell reaction + tissue reaction)	15 (15–17)	**17 (15–17)**	**10 (9–10)**	10 (9–10)*	**16 (14–16)**	**9 (7–9)***
IA Gr1–IA Gr1,2,3	0	2	-5	0	6	-1

* — statistically significant differences in comparison with the day 84 at p<0.05.
Statistically significant differences in comparison with Group 1 are shown in bold at p<0.05.

DISCUSSION

During our studies on assessment of biocompatibility of osteoplastic BMs containing pharmacological substances in their composition, including radiological, pathological, histological, and laboratory studies it was found that the biocompatibility of all tested materials can be evaluated as acceptable: no immunological rejection of xenogenic material involving lymphocytes as well as cytotoxic effects were observed. At the same time, materials containing zoledronic acid and strontium ranelate showed better fixation in the defect, and no implant migration was recorded, in contrast to the control group. Similar peculiarity was noted earlier for allomaterials containing zoledronic acid [32].

Tissue and cellular composition of the area of implantation of xenogeneic bone matrix impregnated with antiresorptive agents was different and differed significantly from the control group. Bone tissue implant was not completely immunologically neutral, producing local moderately irritating effect expressed by weak eosinophilia and monocytic-macrophage infiltration of connective tissue in intertrabecular spaces of osteoplastic material. This reaction is due to the typical immunological response to xenotransplantation and is the key to both the development of non-responsiveness and successful survival of foreign material [33].

Table 5

Post-implantation laboratory parameters of rabbits. Me (Q1-Q3)

Parameter	Group	Before surgery	14th day	30th day	84th day	182th day
Leukocytes. 10^9/l	1	7.7 (7.1–8.0)	7.8 (7.4–7.9)	7.4 (6.8–7.8)	7.6 (6.9–9.3)	7.1 (6.6–7.4)
	2	7.6 (7.2–9.3)	8.2 (7.9–8.3)	7.0 (6.6–7.4)	8.2 (8.1–9.5)	7.0 (5.8–8.1)
	3	7.6 (6.6–8.4)	10.6* (9.9–12.9)	8.9 (8.2–11.6)	8.8 (8.0–10.4)	7.0 (6.9–8.0)
Erythrocytes. 10^{12}/l	1	6.4 (6.1–6.9)	5.7* (5.3–6.0)	6.6 (6.1–6.7)	6.6 (6.3–7.0)	6.8 (6.4–6.9)
	2	6.4 (5.6–6.8)	5.6* (4.7–6.0)	6.0 (5.9–6.3)	6.5 (5.4–6.9)	6.4 (6.1–7.1)
	3	6.1 (4.8–6.9)	5.4* (5.9–6.3)	6.9 (6.1–7.0)	6.3 (6.0–6.9)	6.7 (6.3–7.0)
Thrombocytes. 10^9/l	1	379 (303–465)	509 (476–542)	446 (425–497)	438 (392–461)	387(370–448)
	2	397 (326–466)	464 (388–490)	464 (388–490)	308 (290–410)	369 (346–471)
	3	343 (330–393)	410 (389–435)	464 (408–490)	390 (360–470)	359 (316–400)
CRP. mg/l	1	0.0 (0.0–0.9)	0.0 (0.0–2.4)	0.4 (0.0–2.5)	0.0 (0.0–1.9)	0.0 (0.0–1.0)
	2	0.0 (0.0–0.2)	0.9 (0.0–5.8)	**3.6 (2.1–4.6)***	0.0 (0.0–0.2)	0.0 (0.0–0.0)
	3	0.0 (0.0–0.8)	0.0 (0.0–0.3)	0.0 (0.0–0.8)	0.0 (0.0–1.0)	0.0 (0.0–0.0)
ALP. u/l	1	55 (43–67)	55 (50–57)	40 (37–49)	41 (33–48)	53 (50–57)
	2	57 (49–68)	**36 (22–48)***	**24 (20–34)***	31 (23–39)*	65 (55–71)
	3	62 (50–68)	67 (55–75)	57 (41–68)	50 (39–58)	59 (53–62)
TRACP. u/l	1	26 (23–27)	23 (22–25)	23 (21–25)	20 (17–25)	18 (16–19)*
	2	26 (22–28)	**14 (11–18)***	**12 (9–14)***	13 (11–19)*	14 (11–17)*
	3	27 (24–30)	27 (24–29)	27 (22–29)	25.8±3.6	21 (20–21)*

* — statistically significant differences in comparison with the day 84 at p<0.05.
Statistically significant differences in comparison with Group 1 are shown in bold at p<0.05.

Table 6

Adverse events observed in experimental groups, number of observations

Adverse event	Group 1 (*n* = 8)	Group 2 (*n* = 8)	Group 3 (*n* = 8)
Implant migration under the skin	2/32*	0	0
Knee arthritis	1	0	0
Increased CRP and leukocytosis	1	1	1
Total	4 (50%)	1 (13%)	1 (13%)

* — calculated relative to the number of implantations.
In parentheses is the percentage of total number of animals or of number of implantations.

Impregnation with zoledronic acid had a prolonged antiresorptive effect both on the xenogeneic bone matrix itself and on the cancellous bone tissue of the graft bed, which resulted in an increase in their trabecular density comparing to the control group. The same effect was found earlier when impregnating bone allografts and titanium implants with zoledronic acid. At the same time, ability of zoledronic acid to affect the osteogenic potential in the implant area appears to be dose-dependent and is currently up for discussion [34, 35].

Zoledronic acid also increased local irritant effect of xenogenic matrix, expressed in increased eosinophilia and fibrosis of transplantation area. According to the data obtained earlier, this effect could be due to the M1 phenotype acquired by macrophages under the influence of zoledronic acid [36], which led to imbalance of macrophage polarization between proinflammatory (M1) and anti-inflammatory (M2) phenotypes, and as a result — to activation of eosinophil regulatory function and local fibrosis.

It is known that the distinctive feature of strontium ranelate in case of systemic and local application is not only inhibition of bone resorption but also stimulation of osteogenesis [37]. Therefore, impregnation of xenogenic bone matrix with strontium ranelate expectedly increased the share of newly-formed bone tissue in the area of transplantation and the density of trabecular net of the bone bed. Decrease in values of irritant effect index of implanted material in this group of experiments can be related to previously studied influence of strontium ranelate on macrophages' polarization in the direction of anti-inflammatory M2 phenotype. However, presence of strontium ranelate in the area of transplantation also led to imbalance of M1 and M2 macrophage phenotypes, which could induce moderate fibrosis in the area of implantation [38].

Due to the reasons mentioned above, the recovery of organotypic structure of the bone defect with degradation and remodeling of the implanted material with complete defect replacement occurred in different groups with different rate. Both zoledronic acid and strontium ranelate showed the ability to increase the density of the cancellous bone substance of maternal graft bed, more pronounced when using zoledronic acid. However, bone matrix impregnated with strontium ranelate at the end of experiment showed no statistically significant change in resorption rate in relation to the control material (pure matrix), and the material with zoledronic acid demonstrated delayed graft resorption and its replacement with bone tissue.

The latter observation should be evaluated in the context of described experience in the clinical application of osteoplastic materials. Thus, in the publication of Y. Fillingham, J. Jacobs it is pointed out that the direct contact of the graft with the host bone as well as the presence of mechanical load on it are necessary conditions for successful bone graft functioning [39]. Therefore, the requirement for the bone implant to preserve the biomechanical properties in order to support the bone structure is an important feature, but is the opposite of the requirement for its bioresorbability rate. In this regard, some studies show, for example, that failures in clinical practice when using allomaterials are caused by rapid and complete material degradation [40]. In this regard, there is a whole range of studies in which zoledronates are used as modifiers preventing excessive resorption of osteoplastic material containing promoters of osteogenesis (growth factors, as a rule) [41, 42].

In general, experimental studies show that the anti-osteoresorptive features of zoledronates can be used to improve the osseointegration of implanted devices and materials (both metal and natural) [43, 44]. Areas of clinical application of osteoplastic materials containing zoledronate are indicated in the early study of M. Sørensen et al. who noted that such material could be useful in providing early stability of prostheses in case of revision arthroplasty without any adverse effect on bone formation [34]. Moreover, increased resistance of osteoplastic materials to resorption can be applied to replace large defects when preservation of biomechanical characteristics of implanted graft matrix is required for a longer period of time [45].

Additional point when analyzing the resorption time of materials can be the fact that, as the experience of clinical use of allomaterials shows, the allografts can persist and not be completely resorbed many years after implantation [46].

According to our data, safety and acceptability of studied materials can also be assessed as acceptable. In particular, it was observed that implantation of all the materials did not cause any signs of rejection, intoxication (both local and systemic), or long-term systemic inflammatory reactions in the animals during the entire follow-up period, although single irritating local effect was observed up to 182 days after implantation of material impregnated with zoledronic acid. There were also no material infections or other serious adverse reactions to the tested materials. This observation is a positive point, because in

other studies the applicability of BM is limited by the increased immune response to its implantation [47].

All in all, our study and available literature show that there are prospects for the use of zoledronate-modified xenogenic osteoplastic material. Such enhancement of properties of osteoplastic materials can be quite legitimate, as it increases the opportunities for a surgeon to choose the material [48].

Impregnation of strontium ranelate into the material did not cause significant differences comparing to the control group, that can be attributed to its low bioavailability from xenomatrix. In this regard, we might have found the effects of using strontium ranelate in case of a longer follow-up period after implantation. However, available literature data demonstrate that acceptable bioavailability of strontium ranelate is achieved when it is implanted into the matrix of artificial materials [25, 49].

In general, strontium ranelate- and zoledronic acid-impregnated BM can be recommended for restoration of bone defects located outside the joint cavity. Due to their longer period of remodeling, they can also be used to restore bone defects in segments with high bearing load.

Limitations

The limitation of this study is the sample size of experimental animals, but obtained results can be used to develop indications for the use of osteoplastic materials impregnated with studied substances.

CONCLUSION

Osteoplastic materials based on xenomatrix from bovine bones saturated with zoledronic acid and strontium ranelate have acceptable biocompatibility values, including safety profile. Taking into account the discovered biological properties of developed materials, their further application in cases of restoration of large bone defects and revision arthroplasty seems possible.

DISCLAIMERS

Author contribution

Stogov M.V. — concept or design of the study, collection and processing of a material, the interpretation of the data, the drafting of the manuscript.

Dyuryagina O.V. — concept or design of the study, collection and processing of a material, the interpretation of the data.

Silant'eva T.A. — concept or design of the study, collection and processing of a material, the interpretation of the data, the drafting of the manuscript.

Shipitsyna I.V. — concept or design of the study, collection and processing of a material, the interpretation of the data, critical revision of the manuscript.

Kireeva E.A. — concept or design of the study, collection and processing of a material, the interpretation of the data, critical revision of the manuscript.

Stepanov M.A. — concept or design of the study, collection and processing of a material, the interpretation of the data, critical revision of the manuscript.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Ethics approval. The study was conducted in compliance with the principles of humane treatment of laboratory animals in accordance with the requirements of the European Convention for the Protection of Vertebrate Animals used for Experiments and other Scientific Purposes and Directive 2010/63/EU of the European Parliament and the Council of the European Union of September 22, 2010 on the protection of animals used for scientific purposes. The study was approved by the local ethics committee of National Ilizarov Medical Research Centre for Traumatology and Ortopaedic, protocol No 2 (57), 17.05.2018.

Consent for publication. Not required.

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Анализ региональных особенностей переломов плато большеберцовой кости в Ростовской области

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Реферат

Введение. Распространенность переломов плато большеберцовой кости (код 41-A, B OA/ATO, МКБ-10 S82.1) достигает 51,7 на 100 тыс. населения в год, составляя примерно 1% от переломов других локализаций, и осложняется развитием гонартроза у 25–45% травмированных.

Цель исследования — изучить региональные особенности переломов плато большеберцовой кости: частоту, структуру, исходы.

Материал и методы. Обработана обезличенная выборка из базы данных ТФОМС по кодам МКБ-10 S82.1, Z47.0, M17.2, M17.3 за 2017–2021 гг. Применены принципы и программное обеспечение Data Science.

Результаты. Получены 14 705 записей. Средняя распространенность переломов в области составила 24 на 100 тыс. населения в год. Частота переломов максимальна среди трудоспособных пациентов, соотношение М:Ж = 1,02:1,00. Для гонартроза выявлен сдвиг в возрастную группу старше 60 лет. С 2018 г. наблюдается снижение количества переломов у лиц пожилого и старческого возраста. Госпитализированы 1017 пациентов, у которых выполнено 1752 операции. Доля открытых травм — 1,9%, частота осложнений — 5,3%. Выявлены корреляции умеренной силы между открытыми переломами, осложненным течением, затратами на стационарное лечение ($0,42>r>0,3$).Вероятность развития гонартроза в пятилетнем периоде составила 0,0161. Возраст мужчин с развившимся гонартрозом — 51±7 лет, женщин — 60±7 лет. Более молодой возраст возникновения артроза у мужчин, возможно, связан с преобладанием более тяжелых переломов. Средняя стоимость стационарного лечения возросла с 26 533 руб. в 2017 г. до 34 682 руб. в 2021 г. и кратно превышает стоимость поликлинического этапа лечения.

Заключение. Переломы S82.1 преобладают у экономически активных мужчин. Снижение доли пострадавших пожилого возраста в 2019–2021 гг., возможно, объясняется уменьшением количества пожилых людей в регионе и особенностями пандемических ограничений. Система ОМС несет наибольшие затраты на этапах оказания стационарной помощи. Целесообразно внести в базы данных классификационные признаки переломов по OA/OTA, что позволит точнее планировать и дифференцировать расходы на лечение.

Ключевые слова: переломы плато большеберцовой кости, эпидемиология, осложнения лечения, посттравматический гонартроз, методы Data Science.

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Analysis of Regional Features of Tibial Plateau Fractures in the Rostov Region

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Abstract

Background. The prevalence of tibial plateau fractures reaches 51.7 per 100,000 population per year, accounting for approximately 1% of all fractures, and is associated with the development of post-traumatic knee osteoarthritis in 25-45% of cases.

The aim of this study was to investigate the regional features, including frequency, structure, and outcomes, of S82.1 fractures.

Methods. An anonymized sample was obtained from the region's database, covering the period from 2017 to 2021, using the ICD-10 codes S82.1, Z47.0, M17.2, and M17.3. Data Science principles and software were applied for analysis.

Results. A total of 14,705 records were obtained. The average prevalence of tibial plateau fractures in the region was 24 per 100,000 population per year. The frequency of fractures was highest among the working-age population, with a male-to-female ratio of 1.02:1.00. There was a shift in the age group of knee osteoarthritis occurrence to individuals over 60 years old. Since 2018, a decrease in the number of fractures has been observed among elderly individuals. Out of the total sample, 1,017 patients were hospitalized, and 1,752 operations were performed. Open injuries accounted for 1.9% of cases, and the complication rate was 5.3%. Moderate correlations were found between open fractures, complicated course, and inpatient treatment costs (0.42>r>0.3). The probability of developing knee osteoarthritis within a five-year period was 0.0161. The average age of men with knee osteoarthritis was 51±7 years, while for women, it was 60±7 years. The younger age of osteoarthritis onset in men may be associated with a higher prevalence of severe fractures. The average cost of inpatient treatment increased from 26,533 rubles in 2017 to 34,682 rubles in 2021, significantly exceeding the cost of outpatient treatment.

Conclusion. Tibial plateau fractures (S82.1) predominantly occur among economically active men. The decrease in the proportion of elderly individuals with fractures in the years 2019-2021 may be explained by a decrease in the elderly population in the region and the impact of pandemic-related restrictions. The compulsory health insurance system incurs the highest costs during inpatient care. It is advisable to include classification features of fractures according to the OA/OTA system in databases to facilitate more accurate planning and differentiation of treatment expenses.

Keywords: tibial plateau fractures, prevalence, treatment complications, post-traumatic knee osteoarthritis, Data Science methods.

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ВВЕДЕНИЕ

Переломы плато большеберцовой кости представляют собой сложную проблему из-за возрастающей частоты и тяжести ближайших и отдаленных осложнений. Частота таких переломов колеблется от 17,0 до 51,7 на 100 тыс. населения в год [1, 2, 3], что составляет примерно 1% от всех переломов, достигая 8% у пожилых людей [4, 5]. В 10–54% случаев такие переломы сопровождаются неудовлетворительными результатами лечения, чаще всего нарушением конгруэнтности суставных поверхностей и быстрым прогрессированием посттравматического гонартроза. Стойкая инвалидность является следствием подобных повреждений у 5,9–9,1% пострадавших [6, 7]. В долгосрочной перспективе посттравматический гонартроз развивается у 25–45% пациентов, а вероятность тотального эндопротезирования коленного сустава через 10 лет составляет 3–7%, что увеличивает общие расходы на лечение [8].

Изложенное подтверждает актуальность изучения региональной структуры переломов плато большеберцовой кости. Для планирования работы отделений травматологии и ортопедии представляют интерес частота и популяционные особенности переломов: зависимость от времени года и социальных характеристик населения. Результаты анализа обзоров, посвященных эпидемиологическим характеристикам внутрисуставных повреждений большеберцовой кости в европейских странах, показывают, что вышеназванные зависимости существуют [1, 9, 10, 11]

Цель работы — изучить региональные особенности переломов плато большеберцовой кости в Ростовской области: частоту, структуру, исходы.

МАТЕРИАЛ И МЕТОДЫ

Информация для анализа получена из баз данных Территориального фонда обязательного медицинского страхования Ростовской области (ТФОМС РО), Территориального органа Федеральной службы государственной статистики по Ростовской области, справочного портала по здравоохранению и медицине.

Объектом исследований явились внутрисуставные переломы проксимального отдела большеберцовой кости (AO/OTA 41) [12, 13]. Идентификаторами интересующих групп переломов и их последствий являются коды МКБ-10:

– S82.1 — перелом проксимального отдела большеберцовой кости;

– Z47.0 — удаление пластинки после сращения перелома, а также другого внутреннего фиксирующего устройства;

– M17.2, M17.3 — посттравматический гонартроз двусторонний, другие посттравматические гонартрозы.

Экспорт записей в формате xls за период с 01.01.2017 по 30.12.2021 происходил с фильтрацией по указанным кодам. Получена первичная информация о возрасте, поле, датах обращения за медицинской помощью, видах и количестве проведенных операций, длительности пребывания в стационаре, осложнениях и исходах лечения.

Персональная информация о пациентах из выходных данных исключалась, однако с учетом поставленной задачи отслеживания перемещения пациентов между лечебными учреждениями и территориями в пределах области СНИЛС рассматривался как наиболее удобный признак. С целью соблюдения норм Федерального закона от 27 июля 2006 г. № 152-ФЗ «О персональных данных» в процессе экспорта данных СНИЛС зашифровывался. Шифрование производилось группировкой записей с одинаковыми значениями СНИЛС и перестановкой цифр по единому случайному для данной группы алгоритму. Таким образом сохранялась возможность отслеживать пациента при недостижимости его идентификации. Новый идентификатор обозначен как PID (Patient ID — идентификатор пациента).

Стоимость лечения определялась по коду стоимости случая в соответствии с тарифом ТФОМС РО*. Сведения о численности населения Ростовской области по муниципальным образованиям получены из открытых источников [14, 15].

Информация обрабатывалась в соответствии с алгоритмами подготовки, принятыми в Data Science [16]:

– сбор данных и выгрузка в формате csv;

– разметка, очистка и классификация;

– генерация признаков и преобразование;

– проверка гипотез на основании анализа данных.

Первичная обработка и классификация информации осуществлялась в Excel Office 365. Подготовленные данные преобразовывались в Pandas DataFrame. Группировка, агрегирование, статистический анализ и графическая визуализация осуществлялись средствами пакетов Python NumPy, Pandas, Matplotlib [17]. Данные в формате csv, описание структуры и Jupiter Notebook для их обработки доступны по адресу: https://cloud.mail.ru/public/63cg/GXgWu4ZYU.

Поскольку пациенты могли перемещаться из стационара на амбулаторное лечение, вновь госпитализироваться для лечения осложнений или гонартроза как среднесрочного последствия трав-

* Тарифы на оплату медицинской помощи для ТФОМС других субъектов РФ [Электронный ресурс]. URL: https://rostov-tfoms.ru/dokumenty/tarify/tfoms.

мы, PID использован в качестве идентификатора для отслеживания изменений статуса пациентов. Для поиска случаев развития посттравматического артроза был применен следующий алгоритм:

– пациенты сгруппированы по кодам S82.1 (группа 1) и M17.2 (группа 2);

– методом поиска пересечений множеств PID в группах 1 и 2 получено множество совпадающих кодов;

– записи сгруппированы по PID и кодам МКБ-10, датам обращения за стационарной или амбулаторно-поликлинической помощью;

– интервал между датой госпитализации по поводу перелома и первым обращением с установлением диагноза M17.2 считали периодом развития посттравматического артроза.

Статистический анализ

Для непрерывных переменных вычислялись средние значения и среднеквадратические отклонения (SD). Частоты и проценты использовались для категориальных данных. Проверка соответствия результатов нормальному распределению осуществлялась с использованием теста Колмогорова – Смирнова. Критерий суммы рангов Уилкоксона – Манна – Уитни использовался для сравнения показателей, распределение которых не соответствовало нормальному.

Проанализированы корреляции между различными факторами: возраст, пол, место жительства (городские и сельские муниципальные образования), предоперационные и послеоперационные осложнения, сезонность травм.

РЕЗУЛЬТАТЫ

Получены 14 705 записей. Из дальнейшего анализа были исключены 1610 записей, не имевших идентификатора PID и, следовательно, не удовлетворявших задачам исследования. В выборке за анализируемый период преобладают пациенты, получавшие амбулаторно-поликлиническое лечение и лечение в дневном стационаре (рис. 1).

Ежегодная динамика числа обращений по группам МКБ-10 и количества пациентов приведена в таблице (табл. 1). Из приведенных данных следует, что в посттравматическом периоде пациенты не менее двух раз наблюдались специалистом.

С переломами S82.1 госпитализированы 1017 пациентов. В этой группе незначительно преобладали женщины — Ж:М = 536:481.

Различия в среднем возрасте в группах S82.1 и M17.2 были статистически значимыми (t = -49, df = 14 540; p<0,0001). Между группами S82.1 и Z47.0 статистически значимые отличия в среднем возрасте отсутствовали (t = 1, df = 73, p = 0,1). Во всех группах МКБ-10 средний возраст женщин превышал средний возраст мужчин: S82.1 : Z47.0 : M17.2 = 51,0±20,0(Ж), 39,0±18,0(М):49,0±16,0(Ж), 34,0±16,0(М):61,0±14,0(Ж), 54,0±17,0(М). Однако значимые отличия в среднем возрасте выявлены только в группе S82.1 (t = -29, df = 7888, p<2e-16) и M17.2 (t = -17, df = 3080, p<2e-16). Распределение пациентов по возрасту в зависимости от принадлежности к группе МКБ показаны рисунке 2.

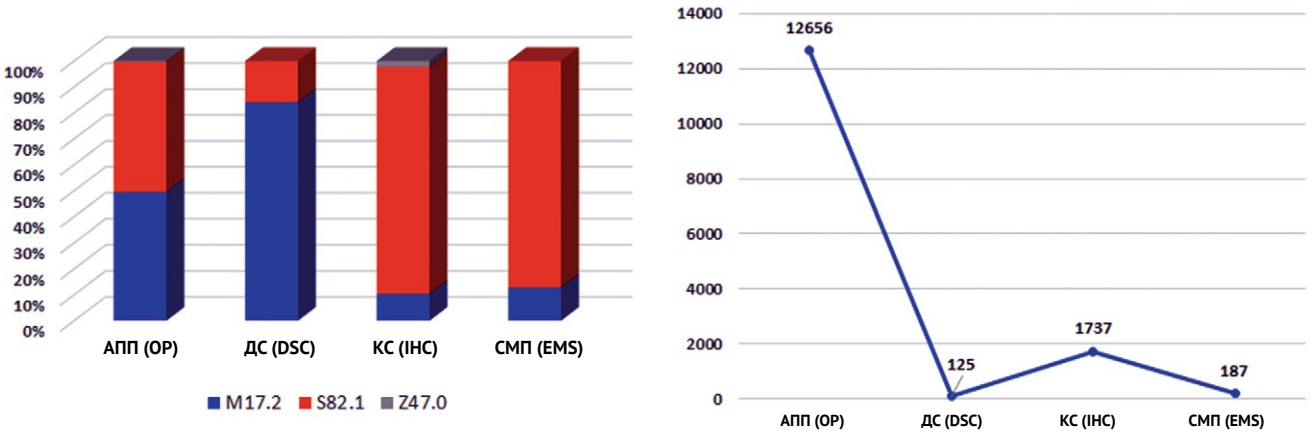

Рис. 1. Распределение пациентов по группам МКБ-10 и видам оказания помощи:
АПП — амбулаторно-поликлиническая помощь; ДС — дневной стационар; КС — круглосуточный стационар; СМП — скорая медицинская помощь

Fig. 1. Distribution of patients by ICD-10 groups and types of medical care:
OP — outpatient care; DSC — day hospital care; IHC — inpatient hospital care; EMS — emergency medical services

Таблица 1

Среднее количество обращений и количество пациентов по группам МКБ-10 в год

Год	M17.2			S82.1			Z47.0			Всего	
	Обращения	Пациенты	Среднее количество обращений	Обращения	Пациенты	Среднее количество обращений	Обращения	Пациенты	Среднее количество обращений	Обращения	Пациенты
2017	1670	1328	1,3	1392	631	2,2	6	3	2,0	3068	1962
2018	1995	1708	1,2	1584	758	2,1	35	29	1,2	3614	2495
2019	1181	958	1,2	1344	607	2,2	20	16	1,3	2545	1581
2020	870	718	1,2	1202	554	2,2	3	3	1,0	2075	1275
2021	573	475	1,2	1215	597	2,0	4	3	1,3	1792	1075
Итого	6289	5187	–	6737	3147	–	68	54	–	13094	8388

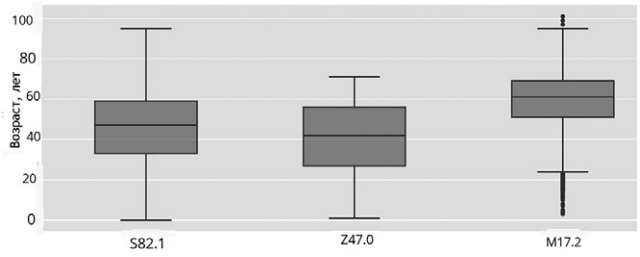

Рис. 2. Распределение пациентов по возрасту и группам МКБ-10

Fig. 2. Distribution of patients by age and ICD-10 groups

Распространенность переломов в области составила 24 на 100 тыс. населения в год с максимальным значением в портовом городе Таганроге (более 100) и минимальным в сельских районах (1,5 на 100 тыс. населения). Распределение обращений пациентов с переломами S82.1 и их последствиями по годам наблюдения приведено на рисунке 3.

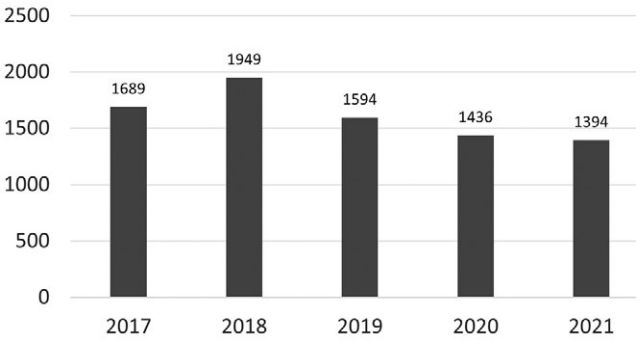

Рис. 3. Число ежегодных обращений по поводу переломов S82.1 и их последствий в Ростовской области

Fig. 3. Annual cases of S82.1 fractures and their consequences in the Rostov region

Плотность распределения переломов в различных возрастных группах в интервале от 5 до 90 лет (шаг — 5 лет) показана на рисунке 4a. Частоты имеют несколько пиков, приходящихся на активный «спортивный», а также на трудоспособный возрасты. Распределение обратившихся в этот же период для лечения по поводу гонартроза является скошенным в направлении старших возрастных групп (рис. 4b).

Оценка зависимости количества переломов от изменений численности населения области и количества жителей в возрасте старше 60 лет осуществлена нормированием величин годовой численности населения, численности лиц в возрасте старше 60 лет и годового количества лиц пожилого возраста, находившихся на стационарном лечении с переломами S82.1 (рис. 5).

С 2018 г. произошло снижение количества переломов у лиц пожилого и старческого возраста. Скорее всего, такое явление связано с уменьшением общего количества переломов у мужчин и женщин всех возрастов в том же периоде (рис. 6), а также с более жесткими ограничениями для пожилых в связи с пандемией коронавируса.

Анализ плотности распределения переломов S82.1 по месяцам позволяет заключить, что ее увеличение приходится на весенний и летний периоды (рис. 7).

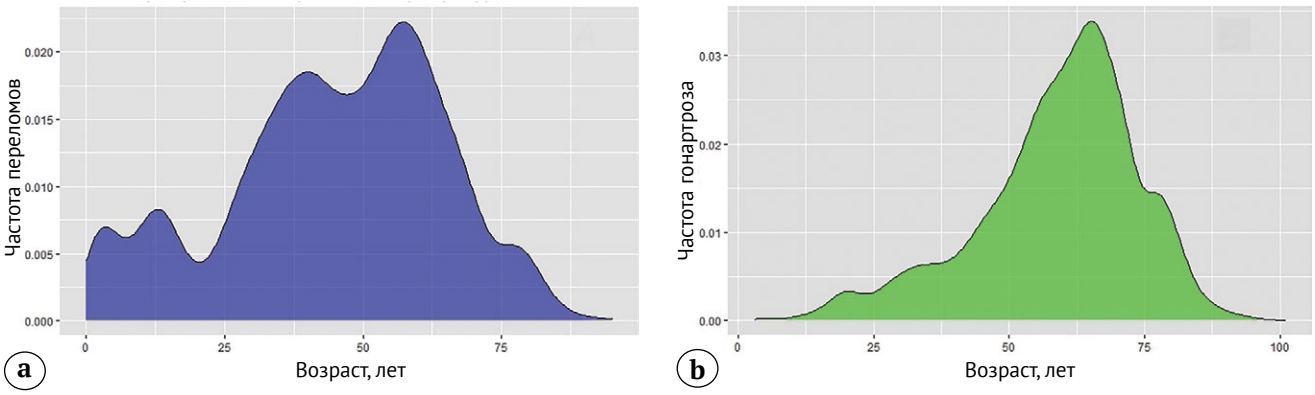

Рис. 4. Плотность распределения пациентов с переломами S82.1 (a) и гонартрозом M17.2 (b) по возрастным группам
Fig. 4. Density distribution of patients with S82.1 fractures (a) and M17.2 osteoarthritis (b) by age groups

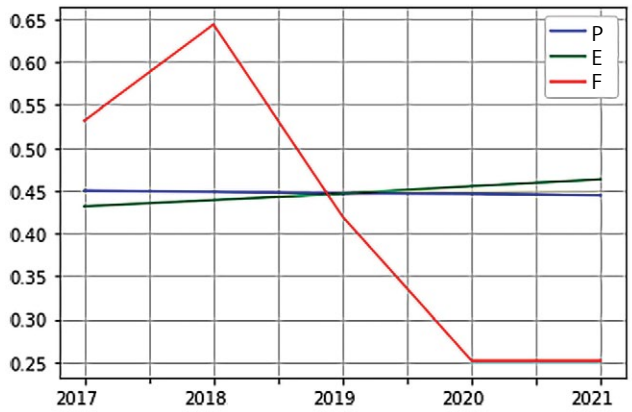

Рис. 5. Нормированные данные:
P — население; E — количество пожилых;
F — количество переломов у пожилых

Fig. 5. Normalized data:
P — population; E — elderly population;
F — number of fractures in the elderly

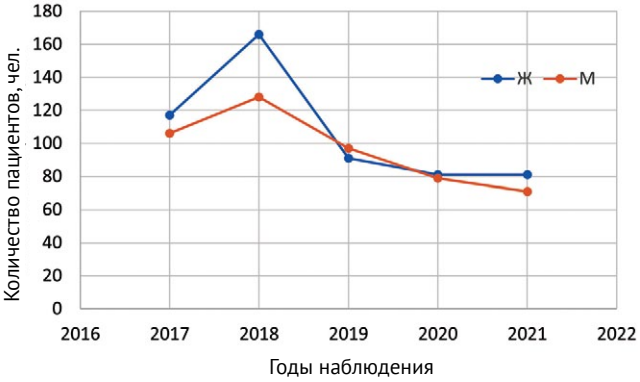

Рис. 6. Распределение переломов S82.1 среди мужчин и женщин в 2017–2021 гг.

Fig. 6. Distribution of S82.1 fractures among men and women in 2017-2021

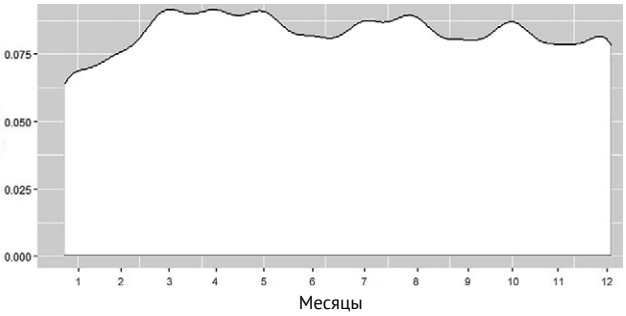

Рис. 7. Плотность распределения случаев госпитализации по МКБ-10 S82.1 по месяцам (2017–2021)

Fig. 7. Monthly distribution of hospitalization cases with ICD-10 S82.1 (2017-2021)

В таблице 2 показано распределение пациентов в зависимости от вида полученной помощи и кода МКБ-10. Очевидно, что доля амбулаторно-поликлинической помощи преобладает во всех группах МКБ-10. Минимальное количество обращений в службу скорой помощи в сельской местности позволяет сделать предположение либо о недостаточной обеспеченности службы в этих регионах, либо о предпочтении пациентов самостоятельно добираться до лечебного учреждения. Косвенным подтверждением этого предположения является пятикратно меньшее количество обращений в СМП в сельской местности по поводу переломов S82.1 (город:сельская местность = 157:30)

Экстренно были госпитализированы 1017 пациентов с переломами, оперированы 748 из них — выполнено 1752 операции. По неотложным и плановым показаниям в интервале 24–72 ч. с момента поступления у большинства пациентов выполнялась предоперационная подготовка скелетным вытяжением с последующим погружным остеосинтезом (рис. 8). Названия операций приведены в соответствии с классификатором*.

* Министерство_здравоохранения_Российской_Федерации. Приказ от 13 октября 2017 г. N 804н «Об утверждении номенклатуры медицинских услуг» (с изменениями на 24 сентября 2020 г.). 2020. Режим доступа: https://docs.cntd.ru/document/542609980.

Таблица 2

Распределение пациентов по годам, видам помощи и группам МКБ-10

Год	M17.2				S82.1				Z47/0				Итого
	АПП	ДС	КС	СМП	АПП	ДС	КС	СМП	АПП	ДС	КС	СМП	
2017	1677	21	33	4	1309	2	343	35	5	–	2	–	3431
2018	1989	40	72	4	1478	10	426	35	12	–	25	–	4091
2019	1185	24	35	6	1292	4	276	22	9	–	12	–	2865
2020	859	9	18	8	1137	4	262	33	3	–	–	–	2333
2021	552	11	21	2	1144		212	38	4	–	–	–	1984
Всего	6262	105	179	24	6360	20	1519	163	33	0	39	0	14704

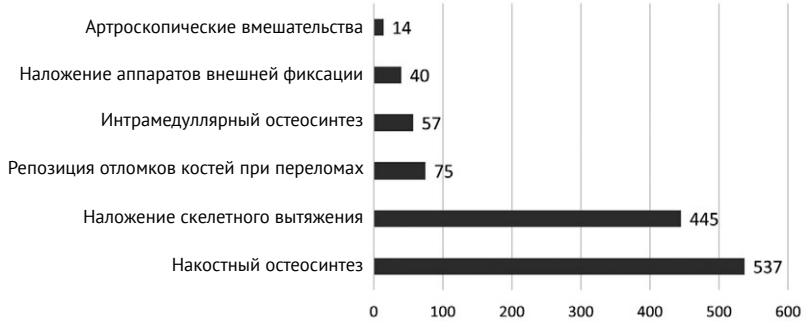

Рис. 8. Наиболее частые оперативные вмешательства, выполнявшиеся по неотложным и плановым показаниям в группе S82.1

Fig. 8. Most frequent surgical interventions performed for emergency and planned indications in the S82.1 group

Распределение пациентов с переломами по количеству проведенных у них операций показано на рисунке 9.

Преобладали пациенты с одним-двумя вмешательствами, однако у пациента PID № 20-887-821 469 за период 92-дневной госпитализации проведено 25 операций.

Отсутствие в исходных данных сведений о характере переломов (открытый или закрытый) потребовало выполнить анализ сочетаний оперативных вмешательств у пациентов в первые сутки госпитализации. Количество пострадавших, для которых были указаны действия, характерные для обработки открытых травм, составило 22 (1,9%) среди госпитализированных с кодом S82.1 (табл. 3).

В записях базы данных ТФОМС РО описаны осложнения у четырех пациентов, находившихся на стационарном лечении по поводу переломов проксимального эпиметафиза большеберцо-

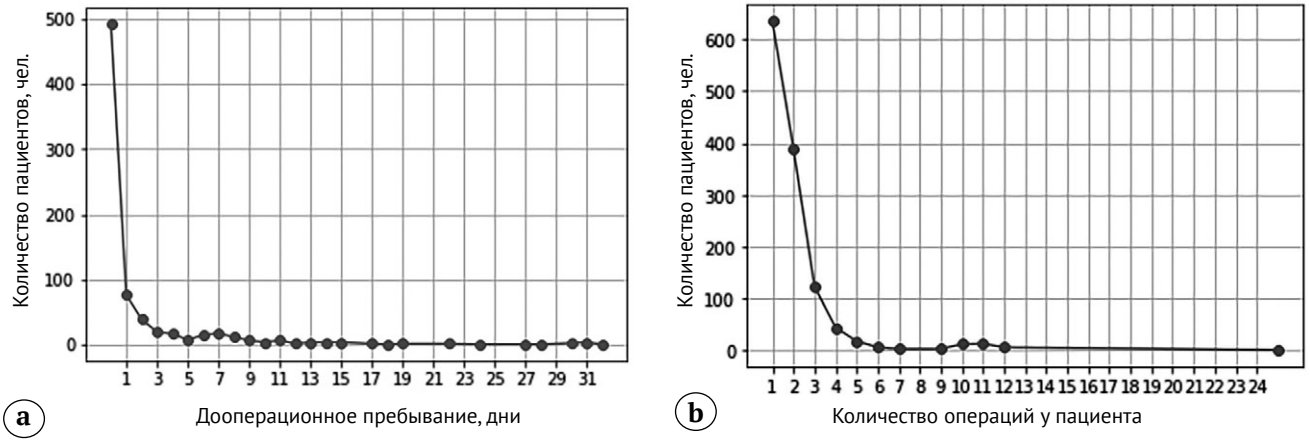

Рис. 9. Распределение пациентов по длительности дооперационного койко-дня (a) и количеству проведенных операций (b)

Fig. 9. Distribution of patients by preoperative hospital stay duration (a) and number of surgeries performed (b)

вой кости. Выделение из когорты пострадавших, у которых в период первой госпитализации было проведено более одной операции, позволило установить, что оперативные вмешательства, обычно выполняемые по поводу осложнений, проведены у 54 человек (табл. 4).

Таким образом, частота осложнений при хирургическом лечении переломов S82.1 оставила 5,3%.

Рассчитаны коэффициенты корреляции между количественными показателями для оценки взаимосвязи факторов, которые могут влиять на исход лечения. Из исходной корреляционной матрицы размерностью 15×15 удалены показатели с величинами коэффициентов менее 0,1 (табл. 5).

Как следует из представленной корреляционной матрицы, большинство факторов не связаны между собой. Сильные корреляции выявлены между:

– стоимостью лечения и фактом проведения оперативного лечения;

– фактом проведения оперативного лечения и оценкой результата лечения при выписке.

Прослеживаются корреляции средней силы между:

– характером перелома (открытый или закрытый) и осложненным течением;

– длительностью пребывания в стационаре и фактом проведения операции.

Таблица 3

Вмешательства, возможные при открытых переломах

Вмешательство	Число пациентов	Код
Хирургическая обработка раны или инфицированной ткани	12	A16.01.004
Ушивание открытой раны (без кожной пересадки)	1	A16.01.009
Открытое лечение перелома (без внутренней фиксации)	1	A16.03.027
Установка дистракционного аппарата	3	A16.03.048
Удаление свободного или инородного тела сустава	3	A16.04.003
Дренирование полости сустава	2	A16.04.048
Всего	22	–

Таблица 4

Количество пациентов, перенесших операции по поводу осложнений

Наименование операции	Число пациентов	Код операции
Некрэктомия	3	A16.01.003
Хирургическая обработка раны или инфицированной ткани	37	A16.01.004
Наложение вторичных швов	1	A16.01.008.001
Вскрытие и дренирование флегмоны (абсцесса)	2	A16.01.012
Фасциотомия	1	A16.02.001.003
Иссечение пораженной кости	1	A16.03.016
Обработка места открытого перелома	3	A16.03.031
Остеонекрэктомия	1	A16.03.058
Краевая резекция кости	3	A16.03.059
Дренирование полости сустава	2	A16.04.048
Всего	54	–

Таблица 5

Корреляции между учтенными факторами для переломов S82.1

Параметр	Возраст	Количество операций	Количество койко-дней	Результат при выписке	Пол	Пациент оперирован	Длительность предоперац. койко-дня	Стоимость лечения	Открытый перелом	Осложненное течение
Возраст	**1**	-0,07	0,02	0,02	0,32	0,04	0,01	-0,04	0,01	0
Количество операций	-0,10	**1**	0,26	-0,02	-0,10	-0,06	0,14	0,27	-0,08	0,06
Количество койко-дней	0,02	0,26	**1**	-0,13	-0,10	-0,33	0,22	0,25	-0,03	0,17
Результат при выписке	0,02	-0,02	-0,13	**1**	0,03	**0,79**	-0,02	**-0,83**	-0,12	-0,2
Пол	0,32	-0,06	-0,06	0,03	**1**	0,05	-0,03	-0,04	0	-0,01
Пациент оперирован	0,04	-0,06	-0,33	**0,79**	0,05	**1**	0,09	**-0,79**	-0,15	-0,25
Длительность предоперац. койко-дня	0,01	0,14	0,22	-0,02	-0	0,09	**1**	0,07	0,04	-0,03
Стоимость лечения	-0	0,27	0,25	**-0,83**	-0	**-0,79**	0,07	**1**	0,06	0,15
Открытый перелом	0,01	-0,08	-0,03	-0,12	0	-0,15	0,04	0,06	**1**	0,34
Осложненное течение	0	0,06	0,17	-0,20	-0	-0,25	-0,03	0,15	0,34	**1**

Сильные корреляционные связи между признаками выделены жирным шрифтом.

Корреляции между иными показателями, приведенными в таблице, слабые или отсутствуют.

Особый интерес представляет вероятность возникновения посттравматического гонартроза у пациентов, перенесших внутрисуставные переломы типа 41. По коду PID идентифицированы 24 пациента, у которых в течение посттравматического периода наблюдения был диагностирован гонартроз. В этой группе было 6 мужчин (средний возраст 51±7 лет) и 18 женщин (средний возраст 60±7 лет). Вероятность обращения пострадавших для лечения артроза в 5-летнем периоде составила 0,0161. Более молодой возраст возникновения артроза у мужчин, возможно, связан с тяжестью травмы, однако отсутствие информации о классификационных признаках переломов по AO/OTA и доступа к рентгеновским изображениями не позволяет утверждать это.

Динамика расходов на стационарное лечение пострадавших приведена на рисунке 10. Пиковое значение расходов на лечение одного пациента было в 2019 г.: 121285,71 руб., 92 дня пребывания в стационаре для снятия аппарата внешней фиксации, 13 дней предоперационного пребывания. Видимо, это связано с возникшими осложнениями или коморбидностью, однако уточняющие сведения в базе отсутствуют.

Сравнение годовых расходов региона на лечение переломов S82.1 и гонартроза M17.2 приведено в таблице 6.

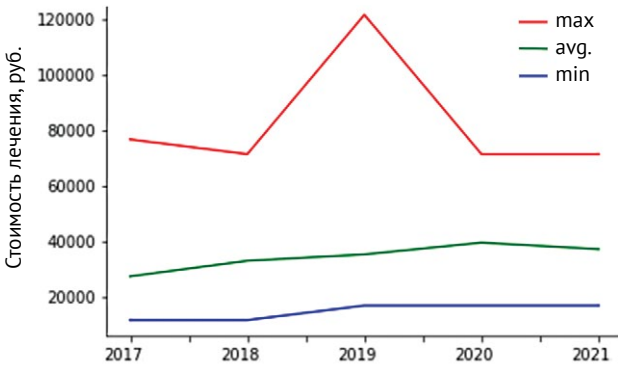

Рис. 10. Годовая динамика расходов на стационарное лечение переломов S82.1: max — максимальная стоимость лечения одного пациента; avg. — средняя стоимость лечения; min — минимальная стоимость лечения

Fig. 10. Annual dynamics of expenses for inpatient treatment of S82.1 fractures: max — maximum treatment cost per patient; avg. — average treatment cost; min — minimum treatment cost

Таблица 6

Ежегодные региональные затраты на лечение переломов S82.1 (стационарное и амбулаторно-поликлиническое) и гонартроза M17, руб.

Год	M17.2	S82.1 стац.	S82.1 АПП	Итого
2017	1 387 610,36	5 916 872,13	375 124,67	7 679 607,16
2018	2 565 307,83	9 505 274,37	462 205,62	12 532 787,82
2019	1 317 467,84	5 844 432,84	537 118,98	7 699 019,66
2020	681 396,62	5 578 510,14	449 114,37	6 709 021,13
2021	718 993,67	5 271 670,17	474 240,06	6 464 903,90
Всего	6 670 776,32	32 116 759,65	2 297 803,70	41 085 339,67

В таблице 6 выделяется 2018 г., когда сумма расходов почти вдвое превысила среднегодовые, что связано с количеством переломов в анализируемом периоде. Относительно небольшие затраты на лечение гонартроза можно объяснить тем, что пациенты обращались в основном за амбулаторно-поликлинической помощью с невысокой стоимостью оплаты визита, не включающей оплату медикаментов.

Сведения об исходах лечения приведены в таблице 7.

Таблица 7

Исходы лечения в зависимости от группы МКБ-10, число случаев

Исход лечения	Код МКБ-10			Всего	
	M17.2	S82.1	Z47.0	Абс.	%
Без перемен	3748	3352	23	7123	54,40
Выздоровление	989	1432	13	2434	18,59
Ремиссия	681	5	–	686	5,24
Улучшение	869	1911	32	2812	21,48
Ухудшение	2	37	–	39	0,30
Итого	6289	6737	68	13094	100,00

ОБСУЖДЕНИЕ

Целью исследования была оценка региональных особенностей распространенности переломов плато большеберцовой кости, оказания помощи, размеров финансовых потерь, вероятности развития посттравматического гонартроза. Предполагалось, что база данных ТФОМС предоставляет репрезентативный набор сведений о частоте и лечении переломов в регионе.

Данные о заболеваемости 24 на 100 тыс. человек в год, полученные в настоящем исследовании, соответствуют интервалам значений от 10,3 на 100 тыс. [2] до 51,7 на 100 тыс. [3] по сведениям регистров европейских стран.

Сильных корреляций между учтенными показателями, кроме стоимости лечения, не выявлено. Объяснением этому является тот факт, что использованный источник ориентирован на оценку затрат, составлен и контролируется финансовыми органами. Особенность базы данных не позволяет анализировать сведения, представляющие интерес для хирурга-травматолога (открытые или закрытые, вид переломов, временные интервалы и характер возникающих осложнений и т.д.).

В ходе выполнения настоящего ретроспективного исследования установлено, что частота переломов МКБ-10 S82.1 имеет тенденцию к снижению. В литературе существуют диаметрально противоположные данные. Ряд европейских публикаций сообщают о росте числа остеопоротических переломов S82.1, которые выявляются благодаря качественным методам визуализации — КТ и МРТ [2, 3, 18]. Такие переломы часто являются минимально смещенными и не обязательно требуют оперативного лечения. Несмотря на то, что в данном исследовании выявлено полимодальное распределение частоты переломов по возрасту с одним из пиков, приходящихся на возраст более 60 лет (см. рис. 4), нет логичного объяснения отмеченному снижению ежегодного количества переломов у пациентов пожилого и старческого возраста.

Меньший наклон кривой снижения частоты переломов получен у мужчин (см. рис. 6). Такой результат сопоставим и согласуется с популяционными исследованиями переломов плато большеберцовой кости [3, 10, 19]. Напротив, в исследовании V. Vestergaard с соавторами показан рост количества переломов S82.1 при сопоставимом с нашими данными о количестве переломов на 100 тыс. населения [20].

Специфический набор данных в базе ТФОМС не позволяет полноценно анализировать причины и типы переломов, объединяемых кодом S82.1.

В публикациях, посвященных особенностям переломов плато большеберцовой кости, подчеркивается, что преобладание типов по AO/OTA или J. Schatzker с соавторами [12] значительно отличаются в разных странах. В Дании и Бразилии самой распространенной конфигурацией являются переломы 41-B3, вторыми по частоте являются переломы 41-C3 [2]. В Сингапуре наиболее распространенным вариантом переломов был 41-B1, вторым по частоте — перелом 41-B3 [19]. Причем только 50,5% пациентов нуждались в хирургическом вмешательстве, что намного ниже, чем в исследовании R. Elsoe с соавторами, которые указывают, что у 92,1% пациентов проведены различные хирургически вмешательства [2]. В анализированном нами массиве хирургические вмешательства выполнялись у 73,6% пациентов.

В нашем исследовании 1,9% переломов классифицированы как открытые, что ниже, чем в публикациях, где открытые переломы плато большеберцовой кости составляют 9,9–12,8% [21, 22]. Возможно, это связано с неполнотой регистрируемых в базе данных сведений. Бактериальное загрязнение поврежденных тканей сустава определяется как важнейший неизменяемый фактор риска послеоперационных нагноений. Избираемая стратегия лечения переломов с использованием внешней фиксации в большинстве случаев позволяет предотвратить неблагоприятные исходы, включая остеомиелит и последующую ампутацию [23, 24, 25].

В базе ТФОМС РО найдены сведения только о четырех случаях инфекционных осложнений. Однако их истинное количество, выявленное путем анализа видов оперативных вмешательств, проведенных в период госпитализации, оценено в 5,3%, что согласуется с результатами многоцентрового исследования результатов оперативной фиксации переломов плато большеберцовой кости в травматологических центрах 1-го уровня, продемонстрировавшего частоту нагноений в 7,4%. При многофакторном анализе причин послеоперационных осложнений единственным значимым фактором риска авторы назвали чрезмерное, более 14 единиц (420 мл) в неделю, употребление крепкого алкоголя. Другие параметры, такие как курение, сахарный диабет, ожирение и уровень ASA, не оказывали влияния на частоту нагноений [23].

Отсутствие прямых сведений о типе перелома по AO/OTA или по Schatzker, данных о характере перелома — открытый или закрытый, детальных сведений о причинах осложнений требует поиска дополнительных источников для более точного анализа и сравнения региональных особенностей переломов с данными других областей и стран. Внесение в базы данных ТФОМС признаков «тип перелома по AO/OTA», «открытый/закрытый перелом» может повысить их научную и клиническую ценность. Тем не менее, применение технологий Data Science позволяет получать полезную информацию из баз ТФОМС, содержащих много эксклюзивной информации и представляющих ценный источник сведений для анализа.

Расходы системы ОМС Ростовской области на лечение пациентов с переломами S82.1 и их последствиями с 2017 по 2021 г. превысили 34 млн руб. и были связаны преимущественно со стационарным этапом лечения — более 32 млн руб. Средняя стоимость стационарного лечения составила 34 289,21 руб., максимальная — 121 285.71 руб. Исследование показало, что переломы S82.1 поражают экономически активное население*, преимущественно мужчин. Такие результаты в сочетании с увеличением количества переломов в весенне-летние месяцы могут быть объяснены более высокой подверженностью молодых мужчин дорожно-транспортным происшествиям.

Экономический ущерб не исчерпывается только прямыми затратами на лечение пострадавших. Неоднократные обращения за амбулаторно-поликлинической помощью, возникновение хронического поражения суставов снижают трудоспособность пациентов и увеличивают расходы, связанные с инвалидностью и реабилитационным лечением.

Возникновение посттравматического гонартроза коррелирует с тяжестью разрушения суставных поверхностей, их дисконгруэнтностью, изменением механической оси ноги, посттравматической нестабильностью, перестройкой метаболизма хондроцитов [26, 27, 28]. Оценка частоты гонартроза после переломов плато большеберцовой кости варьирует в долгосрочных наблюдениях от 19,6% у молодых пострадавших [32] до 83% у лиц среднего и пожилого возрастов [29]. Прогрессирование гонартроза также связано с послеоперационными инфекционными осложнениями [28].

Рентгенологические признаки гонартроза в интервале 42–130 мес. были выявлены у 73,34% пациентов, из которых у 56,67% был гонартроз 1-й и 2-й степеней, частота гонартроза 3-й и 4-й степеней составила 11,66% и 5,00% соответственно [30].

В нашем исследовании развитием посттравматического гонартроза считалось обращение пострадавших с регистрацией кода M17.2 в течение

* Классификация статистических данных о составе рабочей силы, экономической активности и статусу в занятости [Электронный ресурс]. Режим доступа: https://www.gks.ru/bgd/free/b99_10/isswww.exe/stg/d000/i000080r.htm.

периода наблюдения. Вероятность развития артроза составила 0,0161 с соотношением мужчины/женщины = 1/3.

Нет оснований утверждать, что все пациенты, получившие переломы плато большеберцовой кости, обращались для последующего наблюдения. Кроме того, исключение из рассмотрения 525 пациентов с переломами S82.1, не имевших СНИЛС, также могло повлиять на конечные оценки. Возможно, с этим связана низкая расчетная вероятность развития гонартроза, оказавшаяся меньшей, чем в зарубежных многоцентровых исследованиях.

Большинство дегенеративных изменений происходит в первое десятилетие после первоначальной травмы. Вероятность их значительно возрастает с увеличением возраста на момент травмы. Несмотря на гетерогенность факторов, приводящих к прогрессированию гонартроза, переломы плато большеберцовой кости остаются важной причиной заболеваемости. Функциональный исход травмы и возникновение посттравматического гонартроза напрямую связаны с достигнутой конгруэнтностью суставов и анатомическим выравниванием конечностей, а также с предотвращением инфекции области хирургического вмешательства [31, 32].

ЗАКЛЮЧЕНИЕ

В Ростовской области распространенность переломов плато большеберцовой кости составляет 24 на 100 тыс. населения в год. В основном страдают мужчины трудоспособного возраста. Отмечено снижение доли пострадавших пожилого возраста в 2019–2021 гг., объяснением чему могут служить уменьшение количества пожилых в популяции региона и ряд особенностей, связанных с пандемическими ограничениями. Доля открытых переломов составляет 1,9%, инфекция области хирургического вмешательства осложнила посттравматический период у 5,3% пострадавших.

Внутрисуставные переломы плато большеберцовой кости, их лечение в специализированных травматологических центрах должны рассматриваться с точки зрения выбора методов, гарантирующих восстановление конгруэнтности суставной поверхности, а также возможность начала ранних движений в суставе.

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Заявленный вклад авторов

Голубев Г.Ш. — концепция исследования, проект обработки данных и их графического представления, написание текста статьи.

Андриенко С.Г. — сбор и интерпретация данных, написание и редактирование текста статьи и его критический анализ, утверждение окончательной версии с принятием ответственности за все аспекты публикации.

Хади Р.А. — разработка алгоритмов обработки данных, проектирование и написание кода, редактирование статьи.

Все авторы прочли и одобрили финальную версию рукописи статьи. Все авторы согласны нести ответственность за все аспекты работы, чтобы обеспечить надлежащее рассмотрение и решение всех возможных вопросов, связанных с корректностью и надежностью любой части работы.

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Author contribution

Georgy Sh. Golubev — research concept, drafting of data processing and their graphical representation, text writing.

Stanislav G. Andrienko — data collection and clinical interpretation, text writing.

Roman A. Khadi — development of data processing algorithms and writing of code, drafting the text.

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The Effect of Nationwide Lockdown in India on the Epidemiology of Injuries During the First Wave of COVID-19

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Abstract

Background. The pattern of hospital admissions and medical care changed during the COVID pandemic.

The aim of the study — to describe the nature of patients attending the orthopedic emergency department of a level 1 trauma center in terms of number and proportion based on demographic characteristics and the nature of the injury before the lockdown, during the lockdown, and during the unlocking period of the nationwide lockdown for controlling the COVID-19 pandemic in India.

Methods. We conducted a longitudinal study from 01.01.2020 to 31.12.2020. Patients attending the orthopedic emergency were grouped based on cause, type, and site of injury. The median number observed each day with IQR. The distribution of the same was compared between the prelockdown with lockdown period and the lockdown period with a phased unlocking period.

Results. A total of 10513 patients were included. There was a statistically significant reduction in the proportion of patients needing inpatient care between the prelockdown phase and lockdown phase ($p = 0.008$). However, this was not seen between lockdown and postlockdown periods ($p = 0.47$). The proportion of road traffic accidents dropped from 26% to 15% during this time ($p<0.001$). The proportion of contusions was reduced and that of soft tissue injuries increased ($p<0.001$). The proportion of lower limb injuries decreased from the prelockdown phase to the lockdown phase, and that of spinal injury patients increased ($p = 0.007$). The proportion of patients with contusions increased and soft tissue injuries decreased during this period ($p<0.001$). Lower limb injuries and road traffic accidents increased, and spinal injuries were reduced ($p<0.001$).

Conclusion. The lockdown for controlling the spread of the pandemic affected the demographic and epidemiological aspects of injuries attending the orthopedic emergency department of a level 1 trauma center in a developing country. There was a decrease in the proportion of females and children attending the ED during the lockdown. The number of road traffic accedents s decreased during the lockdown. The number of patients with contusions attending the trauma center during the lockdown decreased, but there was an increase in the number of patients with spine injuries. We suggest that improvement in triage facilities, wider use of telemedicine, and increasing the stock of PPEs are essential for tackling such situations in the future.

Keywords: COVID-19, SARS-CoV-2 infection, pandemic, epidemiology of injury, orthopedic emergency department.

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Влияние национального локдауна на эпидемиологию травм во время первой волны COVID-19 в Индии

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Реферат

Введение. Во время пандемии COVID-19 изменилась структура госпитализаций и оказания медицинской помощи.

Цель — проанализировать эпидемиологию и тип травм, полученных пациентами, обратившимися в травмоцентр 1-го уровня во время пандемии и локдауна в Индии.

Материал и методы. Мы провели лонгитюдное исследование с 01.01.2020 по 31.12.2020 г. Пациенты, обратившиеся за неотложной травматологической помощью, были сгруппированы в зависимости от причины, типа и места повреждения. Среднее число ежедневных обращений было расчитано с помощью IQR (интерквартильного размаха). Было проведено сравнение распределений среднего числа наблюдений между периодами до и во время локдауна, а также во время локдауна и после его снятия.

Результаты. Всего в исследование было включено 10 513 пациентов. Наблюдалось статистически значимое снижение доли пациентов, нуждающихся в госпитализации, между периодами до и во время локдауна (p = 0,008). Однако этого не наблюдалось между периодами локдауна и постлокдауна (p = 0,47). Доля дорожно-транспортных происшествий снизилась с 26% до 15% между периодами до и во время локдауна (p<0,001). Доля ушибов уменьшилась, а мягкотканных повреждений увеличилась (p<0,001). Доля травм нижних конечностей уменьшилась между периодами до и во время локдауна, а доля травм позвоночника увеличилась (p = 0,007).

Заключение. Национальный локдаун повлиял на демографические и эпидемиологические показатели травм в травмоцентре 1-го уровня в Индии. Наблюдалось снижение доли женщин и детей, обратившихся в отделение неотложной помощи. Количество ДТП сократилось во время локдауна. Количество пациентов с ушибами, обратившихся в травматологический центр во время локдауна уменьшилось, а количество пациентов с травмами позвоночника увеличилось. Мы рекомендуем улучшить медицинскую сортировку, расширить использование телемедицины и увеличить запасы средств индивидуальной защиты для борьбы с подобными ситуациями в будущем.

Ключевые слова: COVID-19, инфекция SARS-CoV-2, пандемия, эпидемиология травм, травматологическое отделение скорой помощи.

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INTRODUCTION

The COVID-19 pandemic has greatly burdened the healthcare system. It has emerged as a medical threat to mankind, with a serious disruption of lifestyle in 2020-2021. This has not only changed the way we live and work but has also changed the pattern of hospital admissions and medical care [1]. The majority of patients with SARS-CoV-2 infection require hospitalization. The care of trauma patients in our region is mainly performed by a network of hospitals. Our hospital is a level 1 trauma center in our region. During the pandemic, many healthcare workers from the orthopedic department were reassigned to care for COVID patients. Moreover, some of them were posted exclusively for the care of orthopedic patients with SARS-CoV-2 infections. Many peripheral hospitals were unable to admit orthopedic patients due to the burden of COVID-19 patients. Our department has 150 beds for orthopedic patients. The majority of our beds, including beds in intensive care units, were taken over for the care of COVID-19 patients. The nonemergency admissions were stopped. There were no elective or nonemergency surgeries performed in the orthopedics department.

Many pandemics have affected mankind. They are rare occasions to study various aspects of health care delivery. Increased global travel and integration, urbanization, and greater exploitation of the natural environment have increased the likelihood of pandemics over the past century [2]. The nationwide lockdown to control the COVID-19 pandemic was a new experience for us. The fear of contracting the disease, fewer outpatient and inpatient facilities for non-COVID patients, and the lack of transport facilities prevented many patients from attending orthopedic clinics. People are urged to stay at home and only seek medical services if they experience an emergency [3, 4]. A reduction in public mobility and outdoor activities during lockdown led to a decrease in motor vehicle accidents, sport-related traumas, and work-related traumas. The number, demography, and type of injuries sustained by the patients attending the orthopedic emergency department can vary during the pandemic and lockdown. There can be many waves of COVID-19 before it can be controlled. Universal immunization and the development of effective treatment take a long time [5]. There is a dearth of literature reporting the effect of lockdown on the epidemiology of patients attending the orthopedic emergency department (ED) during lockdown.

The aim of the study — to describe the nature of patients attending the orthopedic emergency department of a level 1 trauma center in terms of number and proportion based on demographic characteristics and the nature of the injury before the lockdown, during the lockdown, and during the unlocking period of the nationwide lockdown for controlling the COVID-19 pandemic in India.

METHODS

We conducted a longitudinal study. All patients attending the orthopedic emergency department (ED) of our institution from 1 January 2020 to 31 December 2020 were included in the study. Our institution is a tertiary care teaching institution with a level 1 trauma center. We have not included those patients referred to our ED from other departments for consultations. Patients attending the COVID section with orthopedic injuries were also excluded.

We collected the demographic characteristics of all the patients. The patients were divided into three groups based on their ages: <20 years, 20 to 50 years, and >50 years. The modes of injuries were divided into falls, road traffic accidents, assault, and other causes. The injuries were categorized as contusions, closed fractures, soft tissue injuries, open fractures, and others. The injuries were recorded according to the region and site. Upper limb injuries, lower limb injuries, and spine and pelvic injuries. The total number of patients attending the ED was collected. The number of patients treated as outpatients and inpatients was recorded separately.

Statistical analysis

The data collected were entered into Microsoft Excel software 2013 version. The entered data were rechecked for any errors by adding up the subgroups and checking whether the sums matched.

The total number of patients presenting to the ED and each subgroup of patients based on sex, nature of treatment provided, and age group were summarized as the median number per day with interquartile range (IQR) in each period. Injuries were grouped based on cause, type, and site and summarized as the median number observed each day with IQR. For comparison between different times, the total number of patients and injuries of the subgroups were added up, and proportions were calculated in each period. The distribution of the same was compared between the prelockdown with lockdown period and the lockdown period with the phased unlocking period with the chi-square test. The significance was calculated with a 95% confidence level and a power of 80%.

RESULTS

A total of 10513 patients attended the orthopedic emergency department during the study period. A total of 1194 patients attended during the lockdown. The maximum number of patients attended during the unlocking period (Fig. 1). Male patients predominate in ED attendance during this period. The proportion of females attending the ED was

27%, 31%, and 29% during the prelockdown, lockdown, and unlocking periods, respectively. There was no significant difference in the proportion of female patients attending the ED between the lockdown period and the unlocking period (Fig. 2). The age group of the patients attending the emergency department varied significantly during the prelockdown, lockdown, and postlockdown periods. The proportion of patients in the age group <20 years decreased from 20% to 17%, and those between 20 and 50 years increased from 52% to 55% from the prelockdown to lockdown period (p = 0.008). During the unlocking phase, the proportion of patients <20 years increased from 17% to 18%, and the proportion of patients >50 years decreased from 28% to 27%, but these changes were not statistically significant (p = 0.44) (Fig. 3).

There was a statistically significant reduction in the proportion of patients needing inpatient care between the prelockdown phase and lockdown phase (p = 0.008). Comparing the proportion of patients requiring inpatient care between lockdown and postlockdown periods did not vary significantly (p = 0.47) (Fig. 4). There were significant changes in the proportion of various modes/causes of injury between the prelockdown and lockdown periods. The proportion of road traffic accidents (RTAs) dropped from 26% to 15% during this time (p<0.001). The proportion of contusions decreased from 32% to 26%, and that of soft tissue injuries increased from 12% to 17% (p = <0.001) (Fig. 5). The sites of injury also varied significantly during these three phases. The proportion of lower limb injuries decreased from 45% to 41% during the prelockdown phase to the lockdown phase, and the proportion of spinal injury patients increased from 9% to 12% (p = 0.007) (Fig. 6).

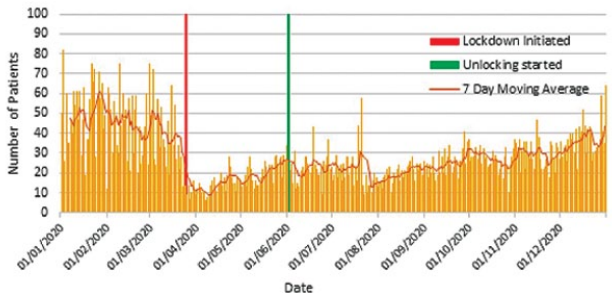

Fig. 1. Line chart of the total number of patients presented each day with a 7-day moving average

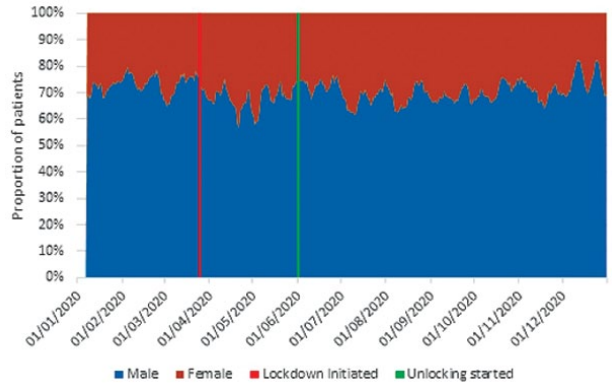

Fig. 2. Component area chart of a 7-day moving average of males and females presenting to casualty each day

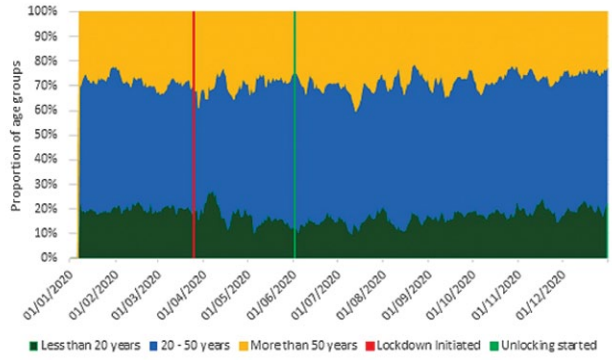

Fig. 3. Component area chart of the proportion of the 7-day moving average of the number of patients of different age groups presenting to casualty each day

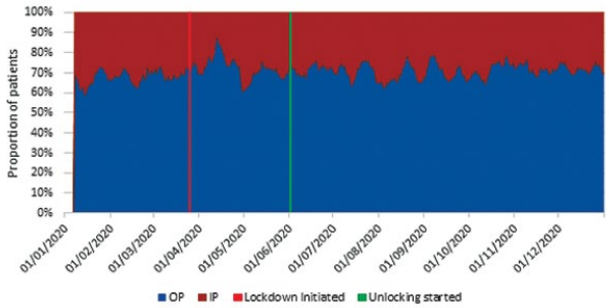

Fig. 4. Component area chart of the 7-day moving average of the proportion of patients needing OP/IP care each day

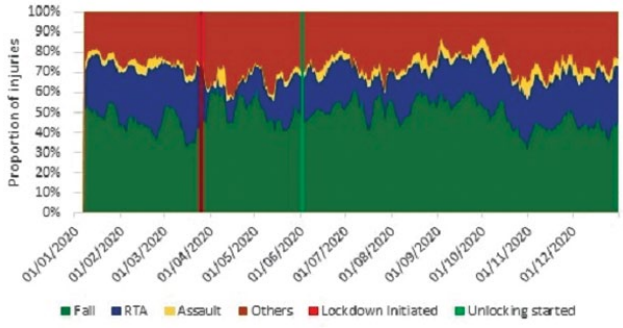

Fig. 5. Component area chart of the 7-day moving average of the proportion of different causes of injuries encountered each day

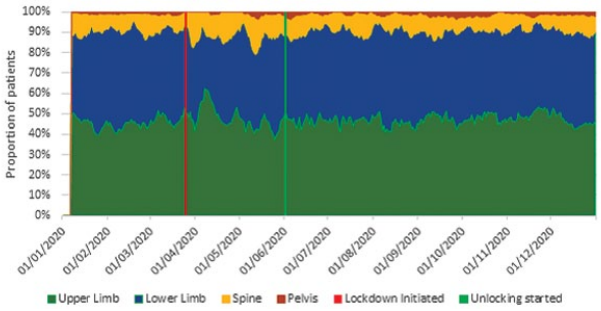

Fig. 6. Component area chart of the 7-day moving average of the proportion of different sites of injuries encountered each day

There was a significant alteration in the modes of injuries of patients attending the ED between the lockdown phase and the unlocking phase. The proportion of RTAs significantly increased from 15% to 22% between the lockdown period and the unlocking period ($p<0.001$). The proportion of patients with contusions increased from 26% to 33%, and those with soft tissue injuries decreased from 17% to 14% during this period ($p<0.001$). There was a significant difference in the proportion of the sites of injury of patients attending the ED between the lockdown phase and the unlocking phase.

The proportion of patients with lower limb injuries increased from 41% to 43%. The proportion of spinal injuries decreased from 12% to 8% during this time. Both of these differences were statistically significant ($p<0.001$).

When we checked the association of the total number of outpatients and inpatients during the first wave of the pandemic with the total number of COVID-19 patients in a day in our district and different phases of lockdown in our country, the number of COVID cases did not affect the outpatient and inpatient admission of emergency patients, but during the lockdown, there was a reduction in cases and a gradual increase during the unlocking period (Fig. 7).

DISCUSSION

The first case of a COVID patient in our country was reported on 27 January 2020. The WHO declared coronavirus infection a global health emergency and called for a combined international effort to suppress the outbreak. Various countries have adopted aggressive mitigation and containment measures such as a complete lockdown. We tried to contain it by quarantine, contact tracing, screening, and isolation. However, that was ineffective. The number of cases started to rise exponentially in different parts of the country. To curtail the rapid spread of the coronavirus and to buy time for the healthcare system to assimilate the necessary infrastructure for fighting the pandemic, a strict nationwide lockdown was enforced from 25 March 2020 by the government of India. There was a complete lockdown until May 31, 2020. Resumption of services in a phased manner was declared from 1 June, which has been termed “unlock”. This process was completed by October 30, 2020 (Table 1). On 25 March 2020, our government legalized telemedicine practice in our country in the wake of the COVID pandemic. Many patients might have utilized this facility to avoid attending hospitals [6].

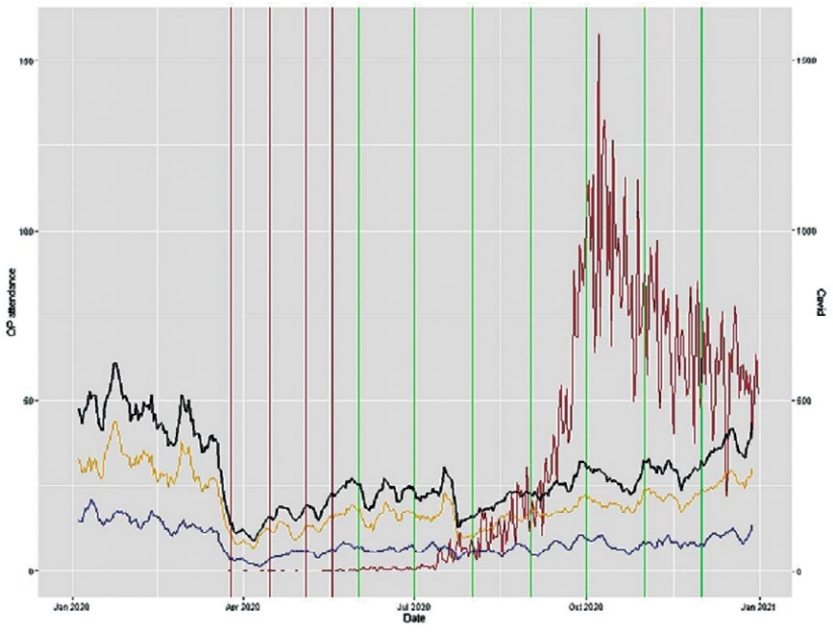

Fig. 7. The association of the total number of outpatients and inpatients during the first wave of the pandemic with the total number of COVID-19 patients in a day in our district and different phases of lockdown in our country. The red line chart is the new COVID cases reported in a day in our district. blackline — total patients, orange — outpatients, blue — inpatients. vertical lines — red — lockdown phases, green — unlock phases

Table 1

Different phases and durations of nationwide lockdown and lockdown in India

Lockdown	Dates and days	Unlocking	Dates and days
Phase 1	25-3-2020 – 14-4-2020 (21 days)	Phase 1	1-6-2020 – 30-6-2020 (30 days)
Phase 2	15-4-2020 – 3-5-2020 (19 days)	Phase 2	1-7-2020 – 31-7-2020 (31 days)
Phase 3	4-5-2020 – 17-5-2020 (14 days)	Phase 3	1-8-2020 – 31-8-2020 (31 days)
Phase 4	18-5-2020 – 31-5- 2020 (14 days)	Phase 4	1-9-2020 – 30-9-2020 (30 days)
		Phase 5	1-10-2020 – 31-10-2020 (31 days)

From our study, we found that the daily number of COVID-19 patients in our district did not have much effect on either outpatient or inpatient attendance at the orthopedic ED. The nationwide lockdown and its lockdown had a definite effect on patients attending orthopedic EDs. The fewest patients (1194) attended the ED during the lockdown (68 days). There were 3728 patients before the lockdown (83 days), and the number rose to 5591 during the unlocking period (153 days). The proportion of female patients increased during the lockdown period and remained the same throughout the unlocking phase compared to the prelockdown period. The proportion of patients requiring inpatient care increased from the prelockdown period to the lockdown and remained the same during the unlocking phase. These demographic variations are due to the unavailability of emergency facilities in the primary and secondary centers; hence, they were forced to attend the tertiary care center. As expected, the proportion of road traffic accidents decreased during the lockdown and increased during the unlocking phase. There was no significant alteration in other modes of injuries. There was a significant drop in the proportion of patients attending the ED with contusions during the lockdown. We think the economic factors and fear of contracting coronavirus from the hospital and lack of transport facilities might prevent patients from attending the hospital during the peak of coronavirus infection. The reduction in motor vehicle accidents caused a reduction in lower limb injuries during the lockdown. However, the nonavailability of beds in the peripheral hospital caused an increase in spine injury patients during the lockdown. The closure of schools and confinement to home led to a reduction in the proportion of the pediatric population attending the orthopedic ED during the lockdown.

We have compared the results of our study with similar studies conducted in different parts of the world. There is not much difference in the epidemiology of patients attending the emergency department during the COVID pandemic. However, the lack of strict implementation and regional differences in lockdown have changed the modes and patterns of injuries in different countries (Table 2).

Table 2

A comparison of the results of our study with similar studies conducted in different parts of the world

No.	Reference	Conclusion	Comparison with our study
1	Giudici R. et al., 2021 [7]	The COVID-19 outbreak affected the epidemiology of severe trauma patients. An increase in trauma patient admissions to a few designated facilities with a high level of care obtained satisfactory results, while COVID-19 patients overwhelmed the resources of most other hospitals	The majority of the peripheral hospitals were designated for the care of COVID patients. So trauma centers like our hospital had to manage most of the injured patients
2	Kuo L. et al., 2021 [8]	The limited COVID-19 outbreak in Taiwan has led to a decreased incidence of trauma patients, and the reduction is mostly attributed to the decline in workplace injuries	We had a major outbreak in our country leading to lockdown it affects the number of patients with trauma, especially motor vehicle accidents

End of table 1

No.	Reference	Conclusion	Comparison with our study
3	Khak M.et al., 2020 [9]	The cessation of sports activities resulted in a reduction in ligamentous injuries of sports origin. Women better implemented the stay-at-home strategies shown by a sudden increase in the men to women ratio of risk-taking traumatic injuries. The decreased number of patients with soft-tissue injuries and a high rate of self-discharge must inform the authorities of the fear of in-hospital contamination	The majority of patients who attended the ED were males. There was an increase in the number of female patients attending the ED during the lockdown period.
4	Johnson M.A. et al., 2021 [10]	We observed an over fivefold reduction in presentation for common pediatric musculoskeletal injuries typically associated with sports	We also observed a reduction in the number of injured patients <20 years during the lockdown period
5	Sabbagh R.S et al., 2022 [11]	ED visits in the United States for injuries sustained while participating in an organized team or individual sport underwent a decrease after the beginning of the COVID-19 pandemic in 2020, especially during the lockdown period	There was a reduction in sports-related injuries during the lockdown
6	Huang W. et al., 2021 [12]	Under the impact of COVID-19, the total number of RTIs in Suzhou from January to May 2020 decreased	There was reduction in the injuries due to motor vehicle accidents
7	Nabian M.H. et al., 2020 [13]	In Iran, overall trend of pediatric trauma has been decreasing during the outbreak; but the lack of reduction in proportion of accidents may pose an alarm that an effective lock-down has not been imposed	We did not observed an increase in motor vehicle accidents as we have a strict lockdown
8	Rajput K. et al., 2021 [14]	Trauma continues during lockdown, our MTC has continued to provide a full service during lockdown. However, trauma patterns have changed and departments should adapt to balance these alongside the COVID-19 pandemic. As the U.K. starts its cautious transition out of lockdown, trauma services are required to be flexible during changes in national social restrictions and changing trauma patterns. COVID-19 and lockdown state were found to have no significant impact on survival outcomes for trauma	Situations were similar in our place also
9	Abhilash K.P.P. et al., 2021 [15]	A significant reduction in the incidence rate of trauma victims, especially RTA and geriatric trauma was seen during the gruelling lockdown period of the COVID 19 pandemic	Our results are comparable
10	Wong J.S.H. et al., 2020 [16]	Demand for orthopedic care remains, despite weekly reductions of 351 orthopedic operations, 974 hospital admissions, and 3,432 clinic attendances	We also noticed that there were not much changes in the outpatient and inpatient attendance of patients in ED during COVID

On 13 March 2020, the American College of Surgeons recommended either postponing or canceling all elective surgeries. The British Orthopedic Association and NHS England issued guidelines to manage urgent orthopedic and trauma conditions. Many orthopedic emergencies are managed nonoperatively if surgery is avoidable [17]. The pandemic has affected emergency management in orthopedic and trauma cases. Reduced supply of surgical materials, limited availability of recommended operation theatres, redeployment of staff for the care of COVID patients, coronavirus infection among staff members, lack of ICU facilities, and trained anesthesiologists are some reasons for this [18]. To practice safely in the ED, it is essential to prevent nosocomial infection with coronavirus [19]. The changes in clinical patterns in an orthopedic entry in Milan, Italy, showed that elective surgeries declined to zero, outpatient admissions were restricted only to cases that could not be postponed, and the number of emergencies increased during the pandemic [20]. There was an overall decline in pediatric orthopedic cases, but the emergency admissions for musculoskeletal conditions in children did not change [21]. A nationwide web-based survey conducted in the US among people above 18 showed that an overall 40.9% of adults avoided medical care during the pandemic. Of these, 12% avoided emergency care, and 31.5% avoided routine medical care [22]. The deployment of human and material resources for fighting the pandemic has resulted in the cancellation, delay, and postponement of nonessential and emergency surgical management in low- and middle-income countries. These factors lead to higher morbidity and mortality in these countries in addition to the COVID-19 toll [23]. Many orthopedic procedures are either limb-saving or lifesaving. A classification system for performing medically necessary surgical procedures during the COVID-19 pandemic with recommendations for the safety measures to be taken was developed by C. Benjamin et al. [24]. Healthcare workers are organized in such a manner that a high standard and quality of care should be provided to trauma and orthopedic patients during the pandemic [25].

The first case of novel coronavirus infection was reported in Wuhan, China, in December 2019. Later, the spread of the virus across the globe grew into a pandemic. On 23 March 2020, the government of Britain implemented a national curfew (lockdown) to contain the spread of the virus. Many countries followed this lockdown policy to curtail the spread. This resulted in a reduction in face-to-face consultations with doctors, increasing telemedicine consultations [26]. A nationwide survey among ophthalmologists in India during the lockdown showed that there were no face-to-face consultations and complete cessation of elective surgeries, and 27.5% were attending emergencies [27]. Ninety percent of patients underwent major surgery during the lockdown compared to 47% in the nonlockdown period for bone sarcoma [28]. A single-center observational cohort study to investigate a possible 'lockdown' effect on the volume and severity of surgical admissions showed fewer surgical admissions and only acutely ill patients attending the ED [29]. People with serious surgical pathologies remained in their homes untreated or were treated in the community during the pandemic [30]. There was a reduction in RTA to 42.6% from 46.6% with more accidents involving bikes and a reduction in all trauma-related injuries from 37.6% to 30% during the lockdown in northwest England [31].

An observational analysis of 17591 ED access from 3 trauma centers in Italy to assess the effect of lockdown on the patient characteristics and incidence of traumatological emergencies showed 3163 trauma visits. There was a 59.8% reduction in ED trauma visits. There was a reduction in road traffic accidents and sports-related injuries [32]. A comparative study to assess the demographic data, injury type, location, mechanism of injury, and surgical logistics during social restriction and lockdown during the same period in the previous year in a level 1 trauma center in Sydney found a 30.8% reduction in orthopedic admissions and a 15.6% reduction in emergency operations. Road accidents remain the same, but bicycle injuries have increased [33]. Acute referral of trauma patients was reduced to 50%, and there was a reduction in isolated limb injuries and emergency operations compared to the previous year in the golden month of the pandemic in a trauma center in London [34]. There was a 30% reduction in operations due to a reduction in RTA and sports-related injuries during the early phase of the lockdown in the UK. The number of hip fractures and minor injuries remains the same [35]. An experience from a hospital in Nepal showed a total of 1077 trauma patients in the ED. There was an 82.21% reduction in outpatient consultations and a 56% reduction in surgeries during the lockdown [36]. During the first 12 weeks of lockdown, there was a 35.3% reduction in the number of referrals received. There was an increase in the proportion of pushbike-related injuries and a reduction in operations. The proportion of fractures of the neck femur and ankle injuries remained similar to that in the previous year [37].

This was a rare opportunity for us to learn about the epidemiological changes occurring in the hospital visits of emergency and trauma patients to orthopedic EDs. The black death of the plague in Europe (1347 to 1670) and the Spanish flu (1918) were some of the previous pandemics [38, 39]. However, similar data were not available. The lack of vaccines, unhygienic envi-

ronment, and scarcity of sanitization and disinfection to prevent the transmission of the disease during those days were the major reasons for higher mortality during those days [40]. Our study is unique in that no previous study had performed a complete survey comparing prelockdown patient status with the lockdown and unlocking phases. The majority of previous studies were either for a short duration or a comparison between COVID time and a similar period in the past. Our study is the first longitudinal study comparing the pre-COVID and COVID periods over a year. It covers the entire first wave of the COVID pandemic in developing countries.

Our results will help healthcare workers and officials plan and mobilize resources adequately during further waves of the COVID pandemic and other epidemic calamities requiring lockdowns.

CONCLUSION

The lockdown for controlling the spread of the pandemic affected the demographic and epidemiological aspects of injuries attending the orthopedic emergency department of a level 1 trauma center in a developing country. There was a decrease in the proportion of females and children attending the ED during the lockdown. The number of RTAs decreased during the lockdown. The number of patients with contusions attending the trauma center during the lockdown decreased, but there was an increase in the number of patients with spine injuries. We suggest that improvement in triage facilities, wider use of telemedicine, and increasing the stock of PPEs are essential for tackling such situations in the future.

DISCLAIMERS

Author contribution

Balaji Zacharia — conception and design of study, data collection and analysis, writing and editing the manuscript.

Harshitha Hayavadana Udupa — data collection and analysis, writing and editing the manuscript.

Rahul Chandran — data collection and analysis, writing and editing the manuscript.

Arun Prakas — data collection and analysis, writing and editing the manuscript.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Tenosynovitis of the Flexor Digitorum and Flexor Carpi Caused by *Mycobacterium Tuberculosis*: Case Report and Review

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Abstract

Background. Mycobacterial tenosynovitis of the hand and forearm is an extremely rare form of extrapulmonary tuberculosis, which can lead to permanent disability of patients.

Case presentation. We present a rare clinical case of generalized tenosynovitis of the tendons of all hand and finger flexors of the right upper extremity caused by *Mycobacterium tuberculosis*. Patient complained of a lump on the palmar surface of the right hand with periodic spontaneous discharge in the form of rice grains. MRI revealed a peritendinal synovial cystic mass on the volar surface of the hand and wrist joint with the presence of multiple chondromal bodies, tendinitis and tenosynovitis of the flexor of IV and V fingers. Removal of the neoplasm, pathological tissues, and total synovectomy were performed. Intraoperative material was tested using PCR. DNA of *Mycobacterium tuberculosis* complex was detected.

Conclusion. Presented case report demonstrates the importance of preoperative MRI examination in tenosynovitis of unknown etiology and the necessity of histological and bacteriological examination of intraoperative material. Transportation of obtained tissues for examination should be performed without the use of formalin in order to exclude false negative results. One should be vigilant against nonspecific infections, including *Mycobacterium tuberculosis*, when treating patients with immunocompromising diseases. The presence of limb neuropathy, instrumental signs of the second or the third stage of tuberculous tenosynovitis according to Kanavel classification are indications for surgical treatment.

Keywords: mycobacterial tenosynovitis, *Mycobacterium tuberculosis*, carpal tunnel syndrome, synovectomy, synovial hypertrophy, tendinitis.

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Клинический случай
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Теносиновит сгибателей пальцев и кисти, вызванный *Mycobacterium tuberculosis*: клинический случай и обзор литературы

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Реферат

Актуальность. Теносиновит кисти и предплечья микобактериальной этиологии является крайне редкой формой внелегочного туберкулеза и может приводить к стойкой инвалидизации пациентов.

Описание случая. Представляем редкий клинический случай распространенного теносиновита сухожилий всех сгибателей кисти и пальцев правой верхней конечности, вызванного *Mycobacterium tuberculosis*. Пациент обратился с жалобами на наличие образования по ладонной поверхности правой кисти, из которого периодически самопроизвольно возникало отделяемое в виде рисовых зерен. По результатам МРТ выявлена картина перитендинального синовиального кистозного образования по волярной поверхности кисти и лучезапястного сустава с наличием множественных хондромных тел, тендинит и теносиновит сгибателей IV и V пальцев кисти. Выполнено удаление новообразования, патологических тканей и тотальная синовэктомия. Интраоперационный материал отправлен на ПЦР-исследование, выявлена ДНК микобактериального туберкулезного комплекса.

Заключение. Представленный клинический случай демонстрирует важность выполнения МРТ исследования при теносиновите неясной этиологии до операции и необходимость гистологического и бактериологического исследования интраоперационного материала. Транспортировка полученных тканей для исследований должна осуществляться без использования формалина с целью исключения ложноотрицательных результатов. При лечении пациентов с имуннокопрометирующими заболеваниями должна быть настороженность в отношении неспецифических инфекций, в том числе *Mycobacterium tuberculosis*. Наличие у пациента нейропатии конечности, инструментальных признаков второй или третей стадии туберкулезного теносиновита по классификации Kanavel является показанием к хирургическому лечению.

Ключевые слова: теносиновит микобактериальной этиологии, *Mycobacterium tuberculosis*, микобактерия туберкулеза, синдром карпального канала, синовэктомия, гипертрофия синовиальных оболочек, тендинит.

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BACKGROUND

Despite the advances in public healthcare, tuberculosis remains one of the top ten causes of death worldwide [1]. In 2018, there were about 7 million new and recurrent cases of tuberculosis. Extrapulmonary forms of tuberculosis occur in 15% of 7.0 million reported cases [1].

Tuberculosis of bones and joints accounts for up to 10% of all forms of extrapulmonary tuberculosis and can lead to sustained disability of patients [1]. Mycobacterial tenosynovitis of the hand and forearm is an extremely rare form of extrapulmonary tuberculosis. This nosology occurs in 5% of cases of musculoskeletal tuberculosis [2].

Patients with tenosynovitis of the upper extremity of mycobacterial etiology suffer from increasing pain, swelling, limited range of active and passive motions in the joints of the affected extremity, further joined by symptoms of neuropathy, such as hyperesthesia, hypoesthesia, paresthesia. Instrumental methods of examination (ultrasound, MRI) reveal the presence of hypertrophied synovia, increased tendon volume compared with the healthy side. Rice body symptom can also be visualized. However, these data are typical for dozens of other diseases, such as seronegative arthritis, rheumatoid arthritis, systemic lupus erythematosus, oncological diseases, etc. [3]. Thus, the clinical manifestation of disease is not specific, which leads to errors in diagnosis and subsequently to wrong treatment tactics [4].

Original study on a relatively large group of patients was conducted by M. Yushan et al. Authors studied clinical features and functional outcomes of the upper extremity tuberculosis in 84 patients [3]. Other publications of different authors mainly describe single clinical cases of this disease. In the Russian literature, there are no studies on tenosynovitis of mycobacterial etiology.

Identification of mycobacterial tenosynovitis represents a diagnostic problem, taking into account its low incidence, latent onset, and lack of specific signs of disease.

Aim of the study — to demonstrate and analyze a rare clinical case of generalized tenosynovitis of the tendons of all hand and finger flexors of the right upper extremity caused by Mycobacterium tuberculosis (Mtb).

Case presentation

Patient (45 years old, height 163, weight 69, BMI 25), first contacted the consulting and diagnostic department of the Vreden National Medical Research Center of Traumatology and Orthopedics on 15.06.2022 complaining of a lump on the palmar surface of the right hand with periodic spontaneous discharge in the form of "rice grains". Limb swelling had been observed since 2014, and the patient attributed the swelling to an injury caused by repeated blows on a glass door with his right hand. He did not seek medical care and did not receive conservative or surgical treatment. Since April 2022 the above mentioned symptoms began to bother him, so that the patient applied to the City Clinical Oncology Center, from which he was referred with the diagnosis of a synovial cyst of the right hand for further examination and consultation to the Vreden National Medical Research Center of Traumatology and Orthopedics, where he was routinely admitted and treated from 20.09.2022 to 03.10.2022.

Main diagnosis according to ICD-10: D 21.1 Benign neoplasm of connective and other soft tissue of upper limb, including shoulder. Soft tissue neoplasm of the right hand and right forearm.

From his life history it is known that the patient had a long period of intravenous drug abuse (heroin) at a young age. Since 1998, he has been diagnosed with HIV infection and chronic hepatitis C infection, that is why he is registered at the Center on Prevention and Control of AIDS and Infectious Diseases. Currently, the patient has stage 4B HIV infection (remission with ART). Since 2014, he has been receiving continuous specific antiretroviral therapy and has been undergoing regular examinations (once every 6 months). At the time of examination, he was receiving the following therapy: elpida 20 mg, 1 tablet once a day; lamivudine-advansd 150 mg, 2 tablets 2 times a day; virfoten 300 mg, 1 tablet once a day. At admission the patient had the following comorbidities in addition to the above mentioned: mild thrombocytopenia, moderate neutropenia, non-acute chronic bronchitis, RF 0. Analysis of lung X-rays revealed no pathological changes typical for tuberculosis, including calcinates of the Ghon's focus type.

On examination, the right hand, fingers, and lower third of the forearm were significantly enlarged compared with the healthy left upper extremity (+3.0 cm). Volar surface was lumpy, skin was thin and mulberry (Fig. 1). In addition, there was a pronounced subcutaneous oval neoplasm on the palmar surface of the hand, 3.0 x 2.0 cm in size, over which the skin was tense, shiny, hyperemic. In the center there was a 0.5 cm diameter wound under a scab. No discharge from the wound was observed (Fig. 1).

On palpation, the segments are densely elastic on the palmar surface, the skin is slightly displaceable, the palpation is insignificantly painful. Blood supply to fingers is compensated, innervation is not impaired. Range of motions in finger joints: in I finger IPJ (interphalangeal joint) flexion is 30°, extension corresponds to the norm; in II finger MPJ (metacarpophalangeal joint) flexion is 60°, PIPJ (proximal interphalangeal joint) flexion is 40°, DIPJ (distal interphalangeal joint) flexion corresponds to the norm; In II-V fingers, MPJ flexion is 60°, PIPJ, DIPJ flexions are in full volume; opposing of I finger is preserved. Range of motions in the wrist joint is in full volume, extension of the hand is slightly painful in extreme position.

MRI was performed on June 26, 2022 (Magnetom Skyra 3T, examination protocol: T2 COR, T1 COR, T1 COR FS, PD COR FD, PD TRA FS, PD SAG FS). Detected: MR image of peritendinous, synovial, cystic formation along the palmar surface of the hand, wrist joint with the presence of multiple cartilage flaps. The above mentioned changes were most typical for the manifestation of synovial chondromatosis. Edematous changes in the surrounding soft tissues, tendinitis, tenosynovitis of the flexors of IV, V fingers of the hand were also observed. In addition, peritendinous synovial cyst of the hand was found, located subcutaneously, in the area of IV finger, communicating with the synovial sheath (Fig. 2).

The patient underwent standard preoperative examination, was consulted by a therapist, underwent echocardiography, laboratory blood tests.

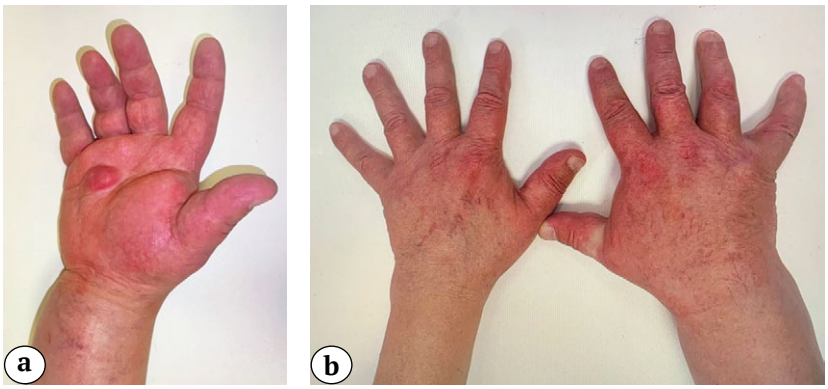

Fig. 1. Volar surface of the hand and forearm:
a — "draining sinus" in the projection of the IV ray;
b — dorsal surface of both upper extremities, increased right hand and forearm circumference

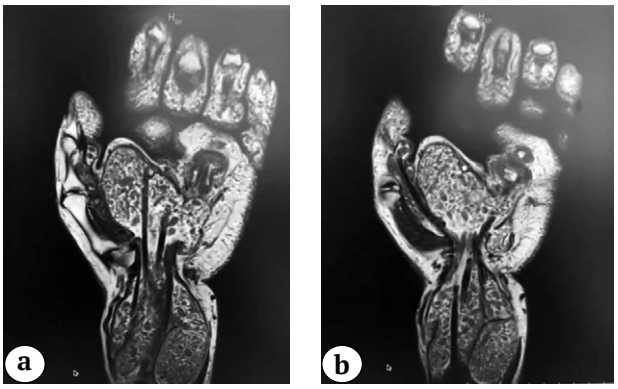

Fig. 2. MRI scans of right upper extremity:
a — masses on the volar surface of the hand and wrist joint with multiple chondromal bodies, "rice grains" inclusions;
b — peritendinal synovial cyst, located subcutaneously in the IV ray area, communicating with the flexor channels

In a dressing room, the scab was removed from the surface of the wound on the palmar surface of the right hand, the wound edges were expanded, observing aseptic measures. When pressing on the wound, a dense liquid transparent content of yellowish tinge with solid masses similar to rice - small (up to 0.4 cm long and 0.2 cm in diameter), oval and spindle-shaped with a smooth surface, white in color, transparent, in an amount of 8 pieces was discharged from the wound. Wound discharge (2.0 ml in volume) was sent for inoculation to detect deep mycosis, identify the bacterial pathogen, and determine antibiotic sensitivity. Bacteriological examination of biopsy samples on 25.09.2022 revealed the following pathological flora: *Enterococcus faecalis, Staphylococcus epidermidis*.

No contraindications for surgical treatment were found. Surgical intervention was performed on September 28, 2022 and consisted of removal of a soft tissue neoplasm of the right forearm and hand, excision of II finger superficial flexor, dissection of the transverse carpal ligament, fasciotomy of the anterior and lateral muscle compartment.

The surgery was performed in supine position with the right upper extremity abducted and placed on a side table. After standard treatment of the operative field with antiseptic solutions under a tourniquet, a shaped incision was made along the volar surface of the right forearm and a Y-shaped incision along the palmar surface of the right hand. The antebrachial fascia and the ligament of the carpal tunnel were dissected. Revision surgery revealed the following changes: the superficial flexor muscles of the fingers and hand were hypertrophied, pale pink and gray with yellow flecks, the median nerve was flattened, its sheaths were pale, local narrowing was revealed, being a sign of chronic nerve compression mentioned in modern literature as a phenomenon of focal median nerve hourglass-like constriction.

Synovial sheaths of the finger flexors are hypertrophied, thickened, gray, and there are saccular thickenings filled with transparent yellowish fluid (Fig. 3). Suspended structures in the form of yellow and white grains with a smooth surface are visualized in the fluid in large numbers, varying in size from 5.0 mm to 2.0 cm in length (Fig. 3). On palpation, white formations are stiff and elastic, yellow formations are soft, and all are homogeneous on section. Sheaths of flexor tendons are changed throughout. Vascular and nerve bundles are intact, not fused with the formation and underlying tissues. The superficial flexor tendon of the second finger is altered, and there is a rupture with a defect of up to 3 cm. Taking into account the extent of the process and complexity of the segment anatomy, the formation was removed fragmentarily within healthy tissues, the altered tendon of the superficial flexor of the second finger was resected, and total synovectomy was performed. After tourniquet removal, thorough hemostasis was performed, the wound was sutured with interrupted sutures and drained with passive drains (polyethylene half-tubes).

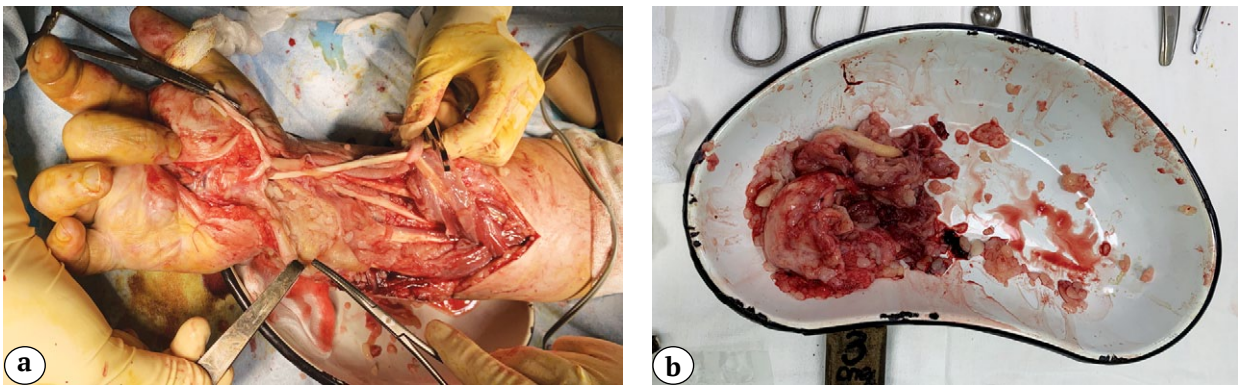

Fig. 3. View of the limb after fasciotomy of the anterior and lateral muscle compartments (a); removed abnormal tissues — hypertrophic synovial sheath, grain-like structures of various sizes in large numbers (b)

Removed soft tissues were placed in physiological solution (NaCl 0.9%) and sent for histological examination to the AP department of the Vreden National Medical Research Center of Traumatology and Orthopedics, for Mtb detection — to the St. Petersburg Research Institute of Phthisiopulmonology. On 03.10.2022 the result from the St. Petersburg Research Institute of Phthisiopulmonology was received: DNA of Mycobacterium tuberculosis complex was detected.

On 07.10.2022 the results of histological examination were obtained. Macrodescription: soft tissue fragments of 100 cm^3 of whitish color, densely elastic consistency. Eight histological specimens stained with hematoxylin and eosin revealed the following changes: multiple foci of hyalinosis with caseous necrosis surrounded by a bank of lymphocytes with rare multinucleated giant cells. In places, cell-free foci of hyalinosis, located in loose areolar connective tissue, richly infiltrated by lymphocytes, plasma xanthocytic cells, histiocytes, macrophages. Fibrosis of necrosis foci and their localized infiltration can be seen periodically (in some places). Fibrous tissue of different density, rich in cells of the described composition was detected in the rest of the area. Conclusion: inflammatory process of a specific nature (tuberculosis?), combined with chronic soft tissue inflammation (Fig. 4).

After surgery, the patient received the following therapy: ampicillin + sulbactam 1500 mg (3.0 g) intravenously 3 times a day for 5 days; ketonal 2.0 intramuscularly 2 times a day for 2 days; tramadol 2.0 intramuscularly once. For 5 days, daily dressings were administered, and laboratory tests were performed according to internally approved protocols.

Dynamics in the early postoperative period: analgesics were required for two postoperative days; part of the drains were removed in 24 hours, completely — on the second day after surgery; the wounds healed by primary intention. There were no neurogenic complaints, range of motions in the fingers of the right hand and wrist joint corresponded to the initial ones before surgery, with no negative dynamics.

At the outpatient stage, the patient followed the following recommendations: immobilization of the right upper extremity with a splint for two weeks after surgery; compression underwear of class 1 compression for 6 months after surgery for the right upper extremity from the distal phalanges to the upper third of the shoulder; amoxicillin + clavulanic acid 1000 mg 1 tablet 2 times a day for 2 months after discharge from the hospital; ciprofloxacin 500 mg 1 tablet 2 times a day for 2 months after discharge from the hospital.

When examined 2.5 months later, the patient had no complaints. The function of the left hand almost corresponded to the healthy side (Fig. 5). When measured with a tape measure, the circumference of the right upper extremity decreased by 2 cm compared with the preoperative values. The patient continued rehabilitation treatment under the supervision of a physiotherapist, underwent examination at the Research Institute of Phthisiopulmonology, where the diagnosis was confirmed.

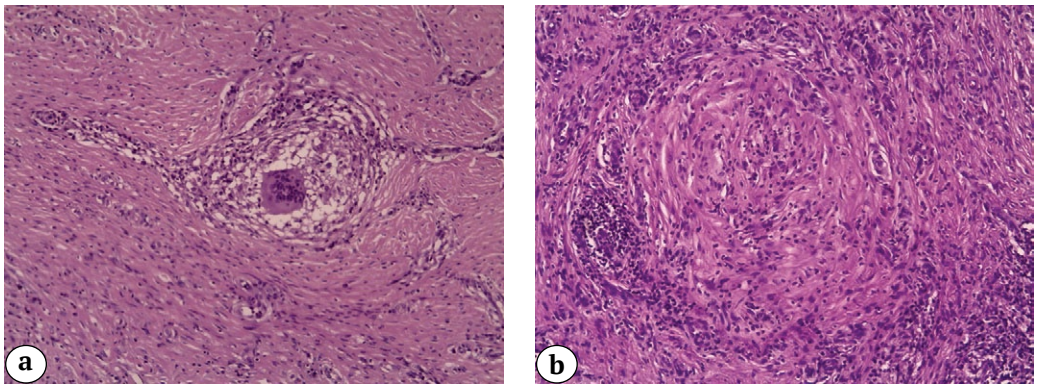

Fig. 4. Histological specimens of soft tissue fragments:
a — cell-free foci of hyalinosis are located in loose areolar tissue richly infiltrated by lymphocytes;
b — multiple foci of hyalinosis with caseous necrosis surrounded by a bank of lymphocytes with rare multinucleated giant cells. Hematoxylin and eosin staining. Mag. ×280

Fig. 5. Results 2.5 months after surgical treatment: a — maximal range of flexion in the finger joints of both hands, sagittal view; b — maximal range of extension in the finger joints of both hands; c — maximal range of flexion in the finger joints of both hands, frontal view

DISCUSSION

Mycobacterium tuberculosis is a facultative intracellular parasite and has the appearance of a thin, straight or slightly curved bacillus, measuring 1-10 x 0.2-0.6 μm. Despite its simple prokaryotic structure, the microorganism has plasmids that ensure its autonomous replication, genome variability, and as a consequence commitment to mutation. Specific properties of the bacterium have evolutionarily resulted in a variety of molecular mechanisms that allow it to evade detection by host immune system and eventually multiply, causing persistent, difficult-to-treat disease [5, 6].

Risk factors for disease development include: older age, low social standing of a patient, nutritional deficiency, a history of tuberculosis or contact, immunosuppression, alcohol abuse, permanent residence in endemic areas, and injections of steroids [7]. Our case report illustrates several risk factors for diseases of tuberculosis etiology, namely, a history of intravenous drug injection, presence of immunocompromising diseases such as stage 4B HIV infection and chronic hepatitis C. However, the patient denied any contact with tuberculosis patients and use of steroids.

Mycobacterium tuberculosis is mainly aerosol-transmitted pathogen and has a discernible tropism to lung tissue. Penetration into the musculoskeletal system is possible in several ways. During primary infection, bacteremia (bacillemia) can occur, which is normally inhibited by cell-mediated immunity. In patients with hereditary and acquired immunodeficiency states, cell-mediated immunity is dysfunctional, and bacillemia leads to hematogenous spread of the microorganisms. Lymphogenous dissemination of the bacteria into the musculoskeletal system is also possible [8].

The absence of a primary focus in the body does not exclude the possibility of extrapulmonary tuberculosis. Contact way of transmission of the pathogen is realized through injury, when the microorganism gets on the damaged skin with soil or water contaminated with the bacterium. Similarly, vector-borne transmission is also possible. Cases of extrapulmonary musculoskeletal tuberculosis following the injection of intravenous forms of drugs have been reported in the literature [9]. There are also cases of iatrogenic infection, the number of which is increasing due to the spread of medical tourism [10, 11]. I. Cheung et al. report a clinical case of extrapulmonary tuberculosis after total knee arthroplasty [12]. K.L. Winthrop et al. identified an outbreak of mycobacterial infection among clients of a nail salon [13].

In our clinical case, at the stage of preoperative preparation, X-rays analysis did not reveal calcinates of the Ghon's focus type in the lungs (primary tuberculosis complex), which excludes the presence of a primary lesion in the lungs and hematogenous and/or lymphogenous dissemination of the bacteria. Thus, the contact mechanism of infection is more likely.

After Mtb penetration into the patient's body, tendon sheaths are affected with the formation of a cold abscess, which extends to the surrounding anatomical structures (joint capsule, muscles, tendons and synovial membranes) through the interstitial spaces. Then the hypertrophy of

synovial membranes, formation of granulomas and zones of focal necrosis of periarticular soft tissues occur [3].

Histological and clinical changes in the tissues are dynamic and correspond to the three stages described by A.B. Kanavel in 1923 [14]. The first stage is characterized by the production of serous exudate with thickening of synovial sheaths, at the second stage granulation tissue is formed, consisting of "rice bodies", then at the third stage of the disease massive caseous necrosis occurs along with adhesion of tendons and their synovial sheaths with formation of draining sinuses (fistulous tracts) and "cold" abscess [15, 16, 17]. All of the above stages occur without causing pronounced clinical symptoms, as Mtb do not produce endo- and exotoxins. Only as Mtb multiplies and the tissues become hypersensitive to tuberculoproteins do the first signs of infection appear (positive reaction to tuberculin). This makes it difficult to diagnose tuberculous tenosynovitis at the early stages of the disease [18].

In our clinical observation, disease course was unobvious and slow. The patient first came to the medical institution already at the third stage of the disease according to Kanavel classification. By this time, a draining sinus had formed on the palmar surface of the hand, and an increase in the hand circumference and tendon adhesion restricted full range of fingers' motion.

There are several classic manifestations of tuberculous tenosynovitis: hygroma (ganglion) on the palmar surface of the hand and lower third of the forearm, carpal tunnel syndrome, and isolated tenosynovitis of one finger (the term "Sausage finger" often appears in the literature) [19, 20, 21, 22].

Initially, patients with tuberculous tenosynovitis complained on a painless increase in the volume of the fingers or hand compared to the contralateral limb. Classical symptoms of inflammation (erythema, hyperthermia, tenderness) of the affected segment are not observed, and there are no general symptoms of the infectious process (increased body temperature, hypodynamia, etc.). As tenosynovitis progresses and the space for the neurovascular bundles decreases, the first signs of neuropathy appear [7, 23].

Patients most often refer to a doctor with the clinical picture of compression neuropathy of the median nerve [7]. S. Hassanpour et al. reported 12 cases of tuberculous tenosynovitis of the flexor tendons out of 1180 patients operated for carpal tunnel syndrome. Large "rice bodies" in the hypertrophic synovial membranes were observed intraoperatively in 10 cases, in 2 patients the affected synovial membranes were filled with yellow exudate, no direct involvement of the median nerve was noted in any of the cases. Full recovery was achieved in all patients after surgical treatment in combination with anti-tuberculosis therapy [24].

The nature of "rice bodies" is still a subject of discussion. Some authors consider this phenomenon as a result of chronic tissue inflammation. There is also a theory according to which "rice bodies" are formed as a result of fragmentation and disjunction of the synovial membrane due to repeated local microinfarcts along its length [3, 25, 26, 27].

It takes about two years from the contamination to the development of above-mentioned morphological changes in the tissues. On average, after three years, damage to the tendons occurs, leading to their degenerative rupture with clinical manifestations in the form of impaired joint function in the fingers of the hand. One of the symptoms of the third stage of the disease is the formation of a "draining sinus", which is a slit-shaped opening in the skin of the limb (often on the palm surface of the hand), communicating with the tendon sheath, through which the contents of synovial membranes ("rice bodies", synovial fluid) are spontaneously evacuated. In the absence of treatment, the process spreads to the bones of the extremity with the development of secondary osteomyelitis [23].

Clinical and biochemical blood tests for diagnosis of this disease are often non-specific: the parameters may be normal, in some cases there is leukopenia, a moderate increase of erythrocyte sedimentation rate (ESR) [20, 28].

X-ray, CT, MRI examinations, and ultrasound of the limb are most commonly used to clarify the diagnosis. The first two instrumental methods are most effective in case of bone tuberculosis, but X-rays can reveal indirect signs of tenosynovitis in the form of increased soft tissue volume. The most informative in the diagnosis of this pathology is MRI examination, which confirms hypertrophy of synovial membranes, granulomatous changes of tendons in the intermediate signal of T1 weighted tomograms with contrast enhancement of gadolinium drugs and hyperintense signal of T2 weighted tomograms.

Abscess and destruction of the underlying bone can also be detected, as well as the symptom of "rice bodies" [20, 28].

The presented clinical case, apart from being extremely rare, is also interesting because described clinical manifestations are not typical for any of the above mentioned classical forms of the disease (hygroma, carpal tunnel syndrome, sausage finger). Upper extremity disease involved all finger and hand flexor channels from the distal phalanges to the upper third of the forearm, but did not manifest itself as a striking picture of median or ulnar neuropathy, even despite the already existing area of focal hourglass-like constriction of the median nerve, which was found intraoperatively. Rice body symptom was the only indirect sign of tuberculous tenosynovitis, which was detected by MRI at the preoperative examination stage. Despite the involvement and complete damage along the length of the superficial flexor tendon of the second finger, the patient did not complain of its dysfunction, apparently due to the preservation of the deep flexor tendon.

Tenosynovitis of tuberculous etiology can only be confirmed by microbiological and histological examination. The material is obtained by fine-needle aspiration biopsy, targeted biopsy of the affected area, and intraoperative excision of altered tissue. Acid-fast bacilli test, inoculation, as well as molecular genetic testing (PCR), histological examination, and determination of adenosine deaminase levels in synovial fluid are performed using the obtained sample [5]. Difficulties in diagnosis are the following: histological examination reveals non-caseous granuloma, which can be wrongly interpreted as sarcoidosis. Transportation of biopsy material for inoculation in formalin almost excludes the possibility of detecting bacilli in the sample [5, 23].

In addition, the diagnosis of tuberculous tenosynovitis is complicated by the presence of numerous differential diagnoses, including: other atypical mycobacterial infections, syphilis, systemic lupus erythematosus, pyogenic infections, brucellosis, osteoarthritis and rheumatoid arthritis, etc. [2].

The most dangerous is the misinterpretation of tuberculous tenosynovitis as a rheumatologic disease whose therapy protocols include steroid drugs. Administration of corticosteroids accelerates the process of soft tissue damage due to Mycobacterium tuberculosis infection [17, 29].

Our clinical case demonstrates the diagnostic value of PCR, with the help of which the causative agent was identified and the final diagnosis was made. At the same time, the results of histological examination confirmed the pattern of chronic tissue inflammation, which can be interpreted as a manifestation of several dozens of other diseases.

Treatment of patients with tenosynovitis of tuberculosis etiology includes thorough radical synovectomy of all altered synovial membranes. If tendons are involved, they must be excised. Immediately after the surgical treatment the following combination of drugs should be taken, corresponding to the standard antituberculosis therapy: isoniazid, rifampicin, ethambutol and pyrazinamide for 2 months, then isoniazid and rifampicin for 4 months [19]. A number of studies recommend a longer course of drug therapy, which sometimes lasts up to 18 months from the time of surgery [6, 30].

P.P. Kotwal et al. reported on the successful isolated conservative treatment without surgical intervention of 75% of patients and their return to full activity in an average of 5 months after the start of the therapy [31]. Treatment of tuberculosis of rare localization remains a controversial issue. Predominantly, the authors recommend surgical treatment if conservative treatment is ineffective, as well as at the second or the third stage of the disease according to Kanavel classification. [15,19]. Some studies demonstrate that the combination of surgical treatment with antituberculosis therapy guarantees persistent remission and satisfactory clinical outcome [5, 19, 23].

CONCLUSION

Tenosynovitis caused by Mtb is a rare disease that requires careful perioperative management for timely diagnosis and selection of proper treatment tactics for the patient.

This clinical case demonstrates the need to be cautious regarding extrapulmonary tuberculosis. Identification of risk factors in the patient's medical history (presence of immunocompromising diseases, long-term immunosuppression, unfavorable social standing, drug and alcohol abuse) should alert orthopedic surgeons when detecting tenosynovitis of unknown etiology.

At the stage of clinical data collection, if tenosynovitis of unknown etiology is detected, an MRI examination should be prescribed. Detection of rice body symptom is an indication for biopsy in order to identify the causative agent before surgical treatment. If tuberculosis etiology of the disease is suspected, the patient should be consulted and examined by a phthisiatrician. In addition to lung X-rays, CT examination of the chest should be performed to analyze the condition of the lymph nodes, to detect or exclude primary tuberculosis complex in the lungs and lymph nodes. The presence of the limb neuropathy in patient, instrumental signs of the second or the third stage of tuberculous tenosynovitis according to Kanavel classification are indications for surgical treatment.

DISCLAIMERS

Author contribution

All authors made equal contributions to the study and the publication.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Case Report
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Progressive Calcification of Supraspinatus Tendon in Patients With Calcific Tendinitis: Two Case Reports

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Abstract

Background. Calcific tendinitis (CT) is a common disease characterized by the presence of calcific deposits in the tendons of the rotator cuff. CT has a wave-like course, and the formed calcification tends to be resorbed. The lysis of the calcium deposits is characterized by a strong pain syndrome, and the site of the calcification is replaced by collagen.

The aim — to demonstrate clinical observations in which the deposited calcification in the rotator cuff did not resorb but increased over time.

Cases presentation. We report on two rare clinical cases of an increase in calcification of the rotator cuff in patients aged 51 and 50 years old. Calcific tendinitis occurred with periods of remission and exacerbation. During exacerbations, conservative treatment was carried out, including courses of massage, physiotherapy, and pain relief therapy. In one case, a single injection of a hormonal drug was performed. Control X-rays and MRI during one of the exacerbations showed an increase in the size of the calcifications. Due to the lack of effect from conservative treatment and the detected increase in calcifications, a decision was made to perform surgical treatment. Arthroscopic removal of calcifications with re-fixation of the supraspinatus tendon and elimination of internal damage was performed on both patients. Good results were noted on the follow-up examination according to the ASES orthopedic score, as well as clinical examination data.

Conclusion. The presented case reports illustrate the possible increase in calcification, unlike the standard course of the disease, in which the calcification is resorbed. Further study of this pathology is necessary to establish the causes and mechanisms of calcification increase over time and its dependence on the phase of the disease.

Keywords: calcific tendinitis, rotator cuff, calcification of the rotator cuff.

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Клинический случай
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Увеличение кальцината сухожилия надостной мышцы: два клинических случая

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Реферат

Актуальность. Кальцинирующий тендинит (КТ) является распространенным заболеванием, характеризующимся отложением депо кальция в сухожилиях вращательной манжеты плечевого сустава. КТ свойственно волнообразное течение, а сформированный кальцинат имеет тенденцию к рассасыванию. Лизис депо кальция характеризуется сильным болевым синдромом, а место кальцината замещается коллагеном.

Целью данной работы было продемонстрировать клинические наблюдения, в которых депонированный кальцинат вращательной манжеты не рассасывался, а увеличивался со временем.

Описание случаев. В работе приведены два редких клинических случая увеличения кальцината вращательной манжеты у пациенток 51 и 50 лет. Кальцинирующий тендинит протекал с периодами ремиссии и обострений. Во время обострений проводилось консервативное лечение, которое включало курсы массажа, физиотерапии, обезболивающую терапию. В одном случае однократно выполнялась инъекция гормонального препарата. На контрольных рентгенограммах и МРТ во время одного из обострений было отмечено увеличение размеров кальцинатов. Ввиду отсутствия эффекта от консервативной терапии, а также выявленного увеличения кальцинатов принято решение о хирургическом лечении. Обоим пациенткам выполнено артроскопическое удаление кальцинатов с рефиксацией сухожилия вращательной манжеты и устранением внутренних повреждений. На контрольном осмотре отмечены хорошие результаты по ортопедической шкале ASES, а также данным клинического осмотра.

Заключение. Представленные клинические случаи иллюстрируют возможное увеличения кальцината в отличие от стандартного течения заболевания, при котором кальцинат рассасывается. Необходимо продолжить изучение данной патологии для установления причин и механизмов увеличения кальцината с течением времени и его зависимости от фазы заболевания.

Ключевые слова: кальцинирующий тендинит, вращательная манжета, кальцинат вращательной манжеты.

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BACKGROUND

Calcific tendinitis (CT) is a common disease characterized by the presence of calcific deposits in the tendons of the rotator cuff of the shoulder joint [1]. CT is more common in women (up to 79%) at an average age of 55 years (range 31-87 years) [2].

Calcific deposition predominantly occurs in the supraspinatus tendon (51-90%) [2, 3], but can also occur in other tendons of the rotator cuff. Histological analysis of the deposits has revealed carbonate apatite [4, 5]. Complications of CT include adhesive capsulitis, rotator cuff tear, and humeral head osteolysis [2, 6].

CT is the most common cause of acute shoulder pain without preceding trauma [1, 6]. Three stages of CT are recognized. The first stage is the precalcific stage, where cellular changes predispose tissues to calcium deposition. The second stage is the calcific stage, where calcium is extruded from cells and then consolidated into deposits. Following the formation of calcification, a resting phase begins, which can last for different periods and is painless. The most painful phase follows the resting phase, which is the resorptive phase. The third stage is the postcalcific stage, where calcium deposits are resorbed and replaced by connective tissue [1].

The duration of clinical symptoms varies considerably, as the duration of the disease cannot be predicted. Some patients suffer from recurring symptoms, sometimes for many years, while others experience spontaneous recovery after a single episode of pain [7, 8].

CT is a self-limiting condition [5, 7, 9]. A systematic review by M. Loew et al. showed that deposited calcium tends to dissolve within 1-3 years [7]. Cases of migration of calcification to muscle and the humeral head, as well as progression of humeral head degeneration against the background of calcification, have been described [10, 11]. At present, there is no single concept for treating patients with this pathology, and both conservative and surgical methods are used [12].

The aim of this study was to present clinical examples in which deposited calcification in the rotator cuff did not dissolve over time, but increased.

Case 1

In 2016, a 51-year-old female patient presented to the European Clinic of Sports Traumatology and Orthopedics (ECSTO) with pain syndrome in her right shoulder joint. After examination by a trauma and orthopedic surgeon, she was referred for further tests. CT of the supraspinatus tendon was detected. Conservative treatment was recommended: rehabilitation therapy, NSAIDs, and orthopedic regime. During the treatment, the patient reported improvement with a decrease in pain from 0-1 points on the VAS. The next exacerbation occurred in May 2022, with a gradual progression of pain up to 7-8 points on the VAS.

After clinical examination and analysis of the results of control studies due to an increase in calcium deposition and progression of clinical symptoms, the patient was recommended for surgical treatment.

The dynamics of the increase in calcinate in patient 1 is shown in Figure 1.

The size of the calcinate according to X-ray data in 2016 was 9.2 x 2.7 x 10.0 mm, and in 2022, it was 31.4 x 6.3 x 10.1 mm. According to MRI data in 2016, it was 10.1 x 4.2 x 9.6 mm, and in 2022, it was 25.1 x 3.0 x 1.1 mm.

According to the X-ray classification of B.M. Bosworth [13], the calcinate increased from medium size (up to 1.5 cm) to large (> 1.5 cm). According to the X-ray classification of J. Gärtner and A. Heyer [14], the calcinate corresponded to type 1, which is limited, dense calcinate. According to the MRI classification of M. Loew et al. [15], the CT corresponded to type B — dense, separated, with clean contours.

In May 2022, under general anesthesia, the patient was placed on her nonoperative side, and arthroscopic examination of the shoulder joint was performed through standard portals. Narrowing of the subacromial space, rupture of the upper fibers of the subscapularis tendon, subluxation of the long head of the biceps tendon, and osteophyte of the humeral head were detected.

Thorough bursectomy was performed with visualization of the tendinous-muscular transition of the rotator cuff. Under visual control, signs of the presence of calcinate in the supraspinatus tendon were determined. The location of the calcinate was confirmed under the control of the C-arc.

In the area of the calcinate, incision of the fibers of the supraspinatus tendon was performed from the subacromial space over a length of 10 mm. A cluster of white, paste-like substance was visualized. Aspiration was performed, and the removed material was sent for histological and biochemical analysis. In addition, the lesion was treated with a laser. According to the results of histological and biochemical studies, a degenerative-destructive calcifying tendinosis of the supraspinatus tendon was diagnosed. During the postoperative period, the patient underwent a course of physiotherapy, massage, and rehabilitation exercises. Calcific deposit removal was performed. The residual deficit of the tendon measured 15x10 mm. Tendon refixation was carried out using a single-row suture. Due to additional joint changes detected, subluxation decompression, coracoplasty, subscapularis tendon refixation, biceps tendon tenodesis, subacromial decompression, acromioplasty, and tuberoplasty of the right shoulder joint were performed (Fig. 2).

In the postoperative period, the patient used an abduction brace for 6 weeks. Passive shoulder joint range of motion exercises were allowed starting from the 4th week.

The dynamics of the shoulder joint condition according to the validated ASES scale [16] are presented in Figure 3.

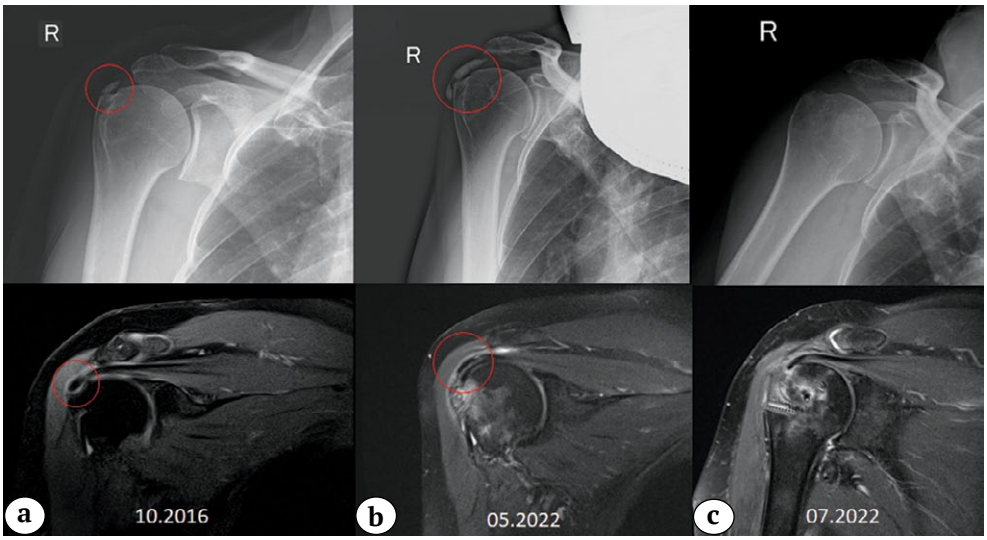

Fig. 1. Case 1. Dynamics of the increase in calcification of the rotator cuff according to X-ray and MRI in the PD mode:
a — initial visit: calcification of the supraspinatus tendon; b — increase in calcification after 6 years; c — shoulder joint after removal of the calcium deposit and refixation of the rotator cuff.
Red circle — location of the calcification

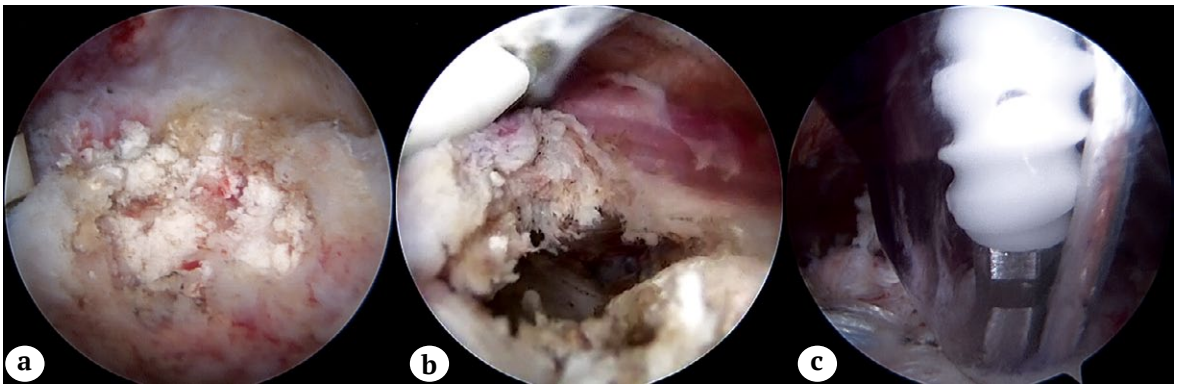

Fig. 2. Case 1. Arthroscopic removal of calcification with subsequent refixation of the rotator cuff; a — calcium deposit in the supraspinatus tendon; b — calcium deposit removed, partial tear of the supraspinatus tendon; c — installation of a fixing anchor

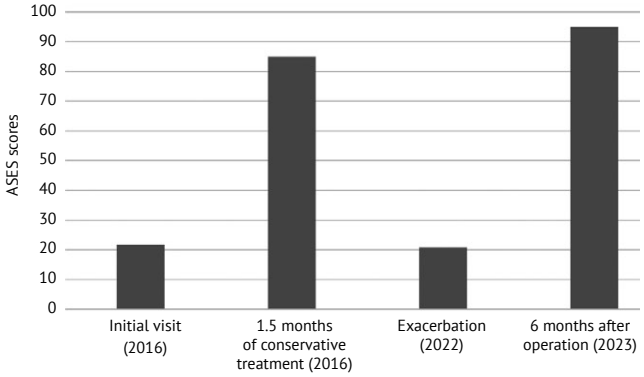

Fig. 3. Case 1. Dynamics of indicators according to the ASES

Case 2

A 50-year-old female patient presented to the European Clinic of Sports Traumatology and Orthopedics (ECSTO) in 2016 with complaints of pain (8 points according to the VAS) in the right shoulder joint. A positive effect was observed for 6 months against the background of conservative treatment (rehabilitation therapy, NSAIDs). A recurrent exacerbation and the reappearance of pain occurred in May 2018. A positive effect was achieved with repeated conservative treatment and the intra-articular and subacromial injection of Diprophos, which lasted for 4 years. The dynamics of the calcification progression are shown in Figure 4. The calcinate's dimensions according to the X-ray in 2016 were 7.9x5.3x9.6 mm; in 2018, 9.6x4.2x10.5 mm; and in 2022, 16.5x6.1x17.9 mm.

According to the X-ray classification of B.M. Bosworth, the calcinate's size increased from medium (up to 1.5 cm) to large (>1.5 cm). According to the X-ray classification of J. Gärtner and A. Heyer, the calcinate corresponded to type 1 — limited and dense calcinate. According to the MR-classification of M. Loew et al., it corresponded to type B — dense, separated, with clear contours. The calcinate's dimensions according to the MRI in 2016 were 9.7x3.8x8.2 mm; in 2018, 12.4x4.7x7.7 mm; and in 2022, 17.3x4.1x16.4 mm.

Due to the recurrence of pain and the increasing calcium deposit, the patient was recommended for surgical treatment.

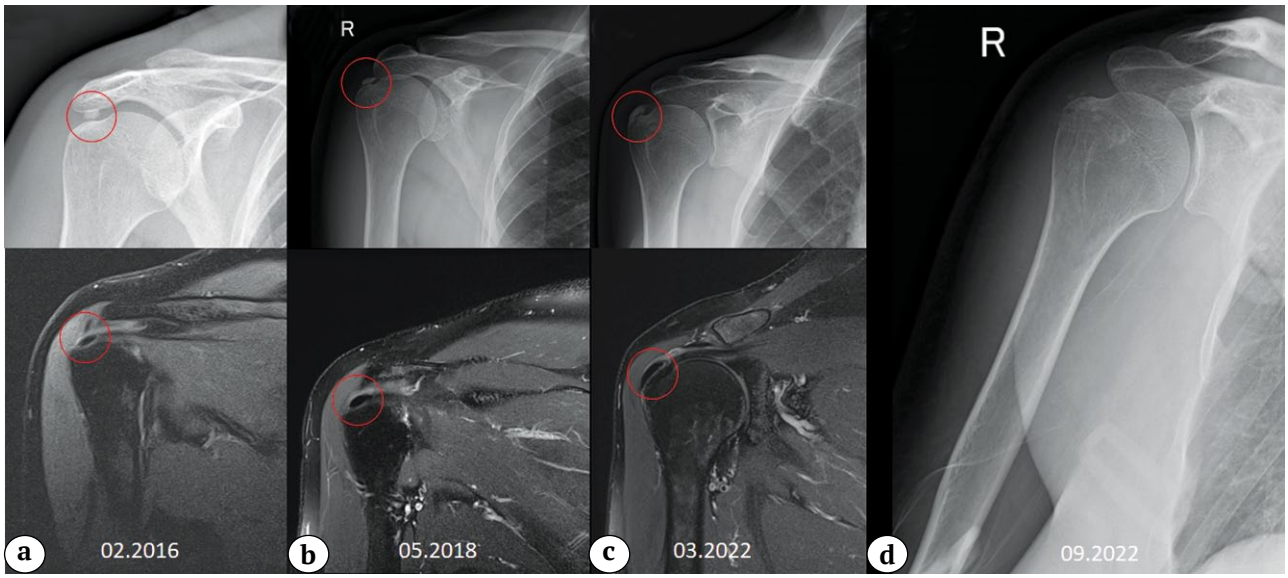

Fig. 4. Case 2. Dynamics of the increase in calcification of the rotator cuff according to X-ray and MRI in the PD mode:
a — at the initial visit (calcification of the supraspinatus tendon);
b, c — increase in calcification;
d — X-ray of the shoulder joint after removal of the calcium deposit.
Red circle — location of the calcification

Under general anesthesia, the patient was placed on her nonoperative side, and arthroscopic revision of the right shoulder joint was performed. Subluxation of the long head of the biceps tendon and a rupture of the upper fibers of the subscapularis muscle were detected. Removal of the calcinate and its visualization were performed using the method described in the previous clinical case. Due to the incomplete layer defect of the rotator cuff after the calcium deposit removal, the supraspinatus tendon was refixed with a single-row suture. Due to the additional changes found in the joint, a tenodesis of the long head of the biceps tendon of the shoulder was performed in the proximal areas of the intertubercular sulcus, refixation of the subscapularis tendon (one P-shaped suture), and subacromial decompression of the right shoulder joint (Figure 5).

The postoperative protocol was similar to the one described in the first clinical case. The dynamics of ASES score indicators in patient 2 are shown in Figure 6.

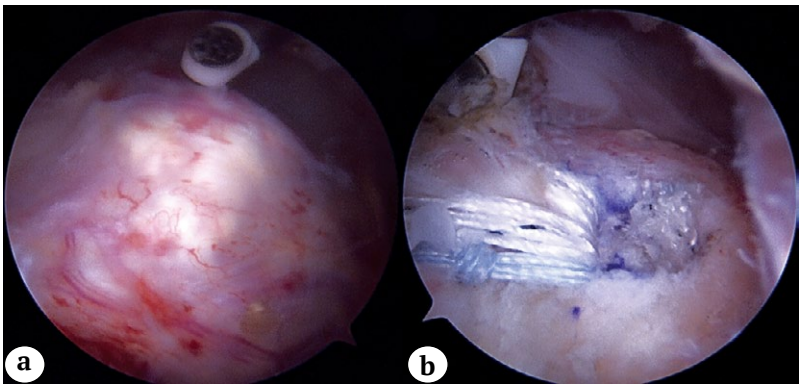

Fig. 5. Case 2. Calcific tendinitis of the supraspinatus tendon:
a — calcification;
b — refixed supraspinatus tendon after removal of the calcium deposit

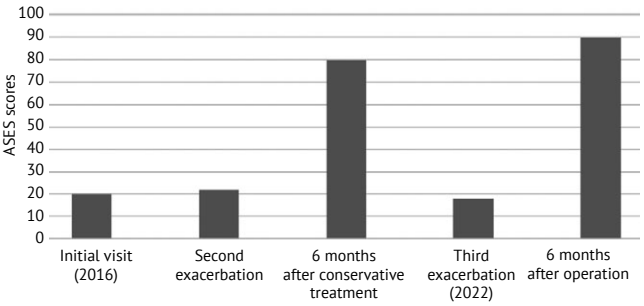

Fig. 6. Case 2. Dynamics of indicators according to the ASES

DISCUSSION

Calcific tendinitis (CT) of the rotator cuff is a common disease and is the main cause of shoulder pain without a preceding traumatic factor [1, 2, 3, 7]. For example, the incidence of rotator cuff tear with CT in Korean residents is up to 15% [2]. The mechanism and causes of CT are currently unknown [17]. Several possible causes are identified, such as microtrauma to the tendon and various metabolic disorders.

In the world literature, there is a lot of data indicating that CT has a wavy course and the formed calcification tends to dissolve [1, 5, 7, 8, 9, 17]. Calcium deposit lysis is characterized by severe pain syndrome, and the site of calcification is replaced by collagen [5].

In our report, we present two clinical cases of increased calcification of the rotator cuff. The disease progressed with periods of exacerbation and pronounced pain syndrome. According to the literature, some patients with CT require surgical treatment due to a pronounced pain syndrome and a lack of effect from conservative treatment [7, 8]. Perhaps, it is the increase in calcification over time that leads to exacerbation of pain sensations.

Arthroscopic removal of calcification is the optimal treatment method in the absence of effect from conservative treatment [18, 19]. Surgical treatment of CT within 1 to 5 years of observation shows good long-term results with a low number of complications [20].

In both clinical cases described by us, after the removal of calcification, a partial-thickness tear of the supraspinatus tendon was revealed, which was then repaired.

The long-term results of treatment of patients in the clinical cases described by us are similar to those published in the literature. For exam-

ple, in the study by C.H. Cho et al., ASES scores increased by more than 75% after 6 months of treatment [18]. In the work of J.J. Ernat et al., an improvement in ASES scores from 59.4 to 88.0 points was noted during the observation period of at least 2 years [21].

CONCLUSION

Calcific tendinitis is a multifactorial disease with a phase character of the course. We presented two clinical cases of an increase in the calcification of the rotator cuff. In the absence of effect from conservative treatment, surgical removal of the calcification is recommended, which shows good results. Further study of this pathology is necessary to establish the causes and mechanisms of an increase in calcification over time and dependence on the phase of the disease.

DISCLAIMERS

Author contribution

All authors made equal contributions to the study and the publication.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Case Report
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Migration of a Kirschner Wire Into the Urinary Bladder: A Case Report

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Abstract

Background. Migration of Kirschner wires is a dangerous complication of osteosynthesis, especially when they displace into adjacent anatomical areas. Preventive measures do not eliminate the possibility of this complication.

Aim of the study — to draw physicians' attention to the possibility of asymptomatic migration of a Kirschner wire into the bladder after osteosynthesis of a femoral neck fracture with a bundle of wires

Case presentation. We present a case report of a 70-year-old patient with asymptomatic migration of Kirschner wires into the bladder and hip joint cavity, which occurred 5 years after the primary surgery for the fracture of the left femoral neck. To manage the complication, a combination of endoscopic removal of the foreign body from the bladder and open removal from the hip joint followed by total hip replacement were used simultaneously. The surgical intervention was performed without any complications. The patient began rehabilitation the next day after the surgery.

Conclusion. Osteosynthesis should be supplemented with preventive measures against the fracture of fixator and its migration. The patient must be dynamically followed up during the treatment period with all necessary monitoring methods (X-ray, CT scan, ultrasound, etc.). In case of wire fracture and/or migration, it must be removed immediately. Once the fracture has healed or the period of fixation of the dislocation is over, the wires should also be removed. Preventive measures can avoid the migration of Kirschner wires and related complications.

Keywords: femoral neck osteosynthesis, Kirschner wires, migration of wires, pseudoarthrosis of the femoral neck.

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Клинический случай
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Миграция спицы Киршнера в мочевой пузырь: клинический случай

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Реферат

Актуальность. Миграция спиц Киршнера является опасным осложнением остеосинтеза, особенно при их смещении в смежные анатомические зоны. Предпринимаемые меры профилактики не исключают возникновения этого осложнения.

Цель исследования — обратить внимание врачей на возможность бессимптомной миграции спицы Киршнера в мочевой пузырь после остеосинтеза перелома шейки бедренной кости пучком спиц.

Описание случая. Мы представляем клинический случай лечения 70-летней пациентки с бессимптомной миграцией спиц Киршнера в мочевой пузырь и полость тазобедренного сустава, наступившей через 5 лет после первичной операции по поводу перелома шейки левой бедренной кости. Для лечения осложнения симультанно использовали комбинацию эндоскопического удаления инородного тела из мочевого пузыря и открытого удаления из тазобедренного сустава с последующим тотальным эндопротезированием. Оперативное вмешательство прошло без осложнений. На следующие сутки после операции пациентка приступила к реабилитационным мероприятиям.

Заключение. Выполнение остеосинтеза необходимо завершать мерами профилактики переломов фиксатора и его миграции. Требуется динамическое наблюдение за пациентом в течение периода лечения с проведением всех необходимых методов контроля (рентгенография, КТ, ультразвуковое исследование и т.д.). В случае перелома спицы и/или ее миграции необходимо незамедлительно удалить спицу. После сращения перелома или окончания сроков фиксации вывиха также спицы следует удалять. Профилактические мероприятия позволяют предупредить миграцию спиц Киршнера и связанные с ней осложнения.

Ключевые слова: остеосинтез шейки бедренной кости, спицы Киршнера, миграция спиц, ложный сустав шейки бедренной кости.

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BACKGROUND

Kirschner wires are widely used in modern trauma surgery for fixation of fractures of various localizations. They are used both as independent fixators and as an auxiliary tool: guide wire, temporary fixation, etc. Due to their technical properties (small diameter and smooth surface), wires are easy to use, but fatigue fractures and migration often occur. Cases of K-wires migration after osteosynthesis of the clavicle [1, 2], humerus [3], sternum [4], femur [5, 6], and reconstruction of the acromioclavicular joint [7, 8, 9, 10, 11] are described in the literature. Localization of displaced fixator varies from the subarachnoid space to the abdominal cavity: migrations to the heart, lungs, mediastinum, aorta, spinal canal, and bladder have been described [12, 13, 14, 15, 16, 17]. Often a displaced foreign body resulted in fatal injuries of internal organs.

We also have some experience in managing this complication. In our case report, migrated wire has not disturbed the patient for many years and has been detected accidentally.

Aim of study — to draw physicians' attention to the possibility of asymptomatic migration of a Kirschner wire into the bladder after osteosynthesis of the femoral neck fracture with a bundle of wires.

Case presentation

A 70-year-old patient presented to the Ural Clinical Therapeutic and Rehabilitation Center named after V.V. Tetyukhin (Nizhnii Tagil) with complaints of pain and limited movements in the left hip joint. Her medical history showed that five years ago she had undergone osteosynthesis of the neck of the left femur with a bundle of wires at the local central district hospital in Perm region. Three years later, a progressive pain syndrome in the area of intervention occurred. On presentation to the health care facility where the primary surgery had been performed, femoral neck pseudarthrosis and K-wire fracture and migration were diagnosed. Patient was admitted to the hospital, and elective surgery for removal of fixators was performed. However, the broken wire could not be removed for technical reasons. Wound having been healed, the patient was discharged for outpatient treatment. During the next two years, a mild pain syndrome persisted, but the patient was not followed up by an orthopedic traumatologist. Over the past 6 months, the pain increased, which was the reason for the patient's reapplication for medical care. Plain X-ray of the pelvis was performed and showed wire migration into the abdominal cavity (Fig. 1 a). At the time of examination, there was no evidence of abdominal organ damage. The patient was urgently referred to the admission department of the Ural Clinical Therapeutic and Rehabilitation Center named after V.V. Tetyukhin, where a CT scan of the abdomen was performed and the localization of the foreign body was determined (Fig. 1b). The wire was located in the bladder. After preoperative planning, it was decided to perform a two-stage surgery to remove two foreign bodies simultaneously: the first stage was cystoscopy and removal of the wire fragment from the bladder; the second stage was K-wire removal from the hip joint and total hip arthroplasty.

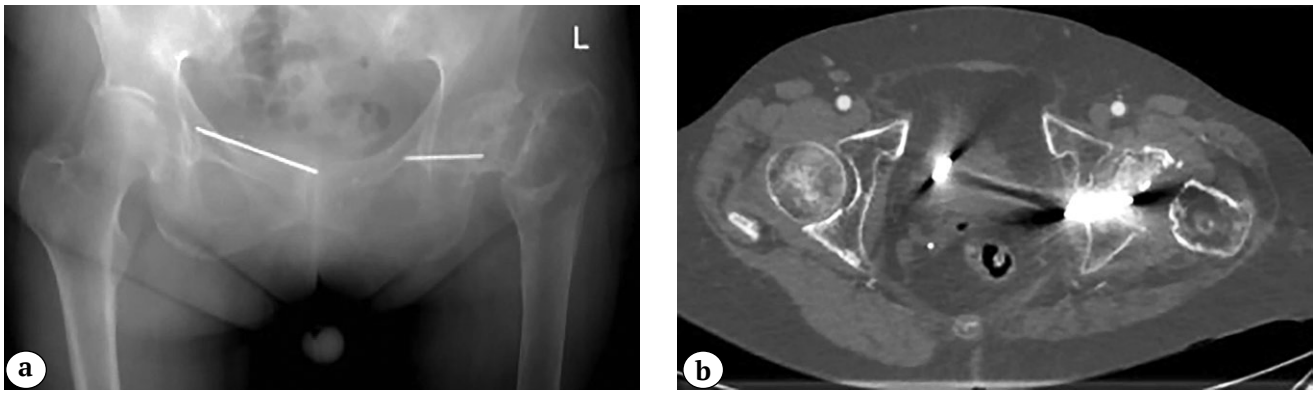

Fig. 1. Plain X-ray of the pelvis (a) and CT scan (b) at admission to hospital: fracture and K-wire migration

With the patient in supine position under endotracheal anesthesia, the operative field was treated with antiseptic solutions. No leakage of the contrast agent from the bladder cavity was registered (Fig. 2 a, b). Cystoscopy revealed migrated K-wire in the bladder cavity. The foreign body was removed using endoscopic forceps (Fig. 2 c, d). Control contrast-enhanced fluorography showed no contrast leakage (Fig. 2 e). Control X-ray was performed, in which a remainder of the wire was visible in the hip joint area (Fig. 3 a, b).

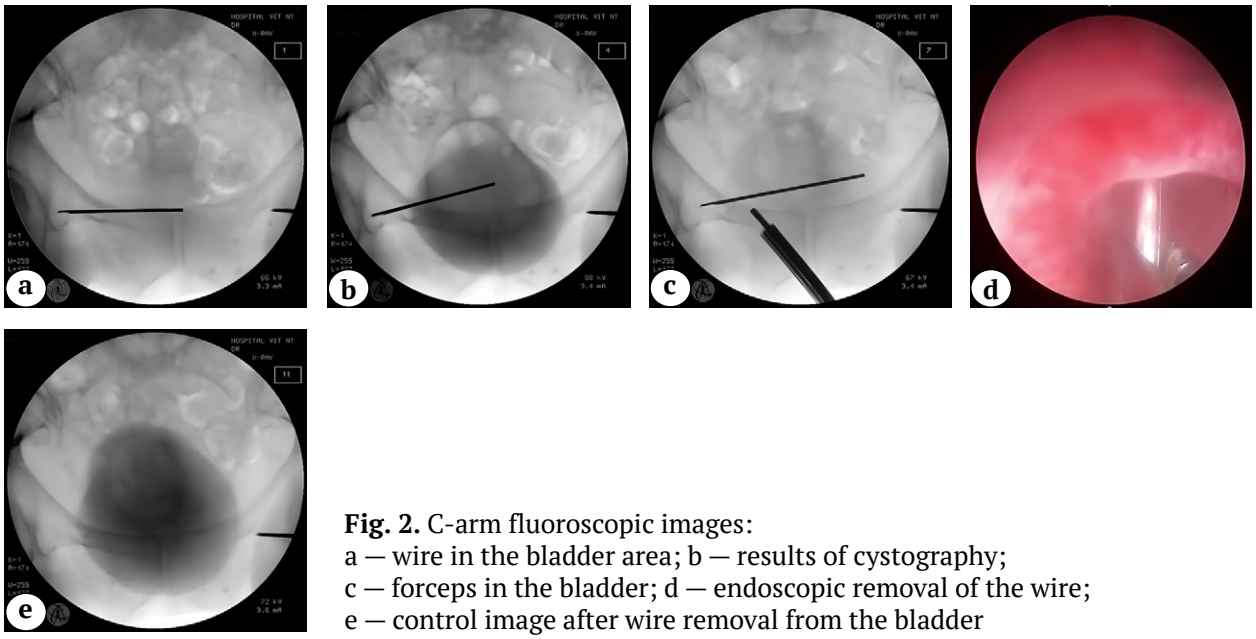

Fig. 2. C-arm fluoroscopic images:
a — wire in the bladder area; b — results of cystography;
c — forceps in the bladder; d — endoscopic removal of the wire;
e — control image after wire removal from the bladder

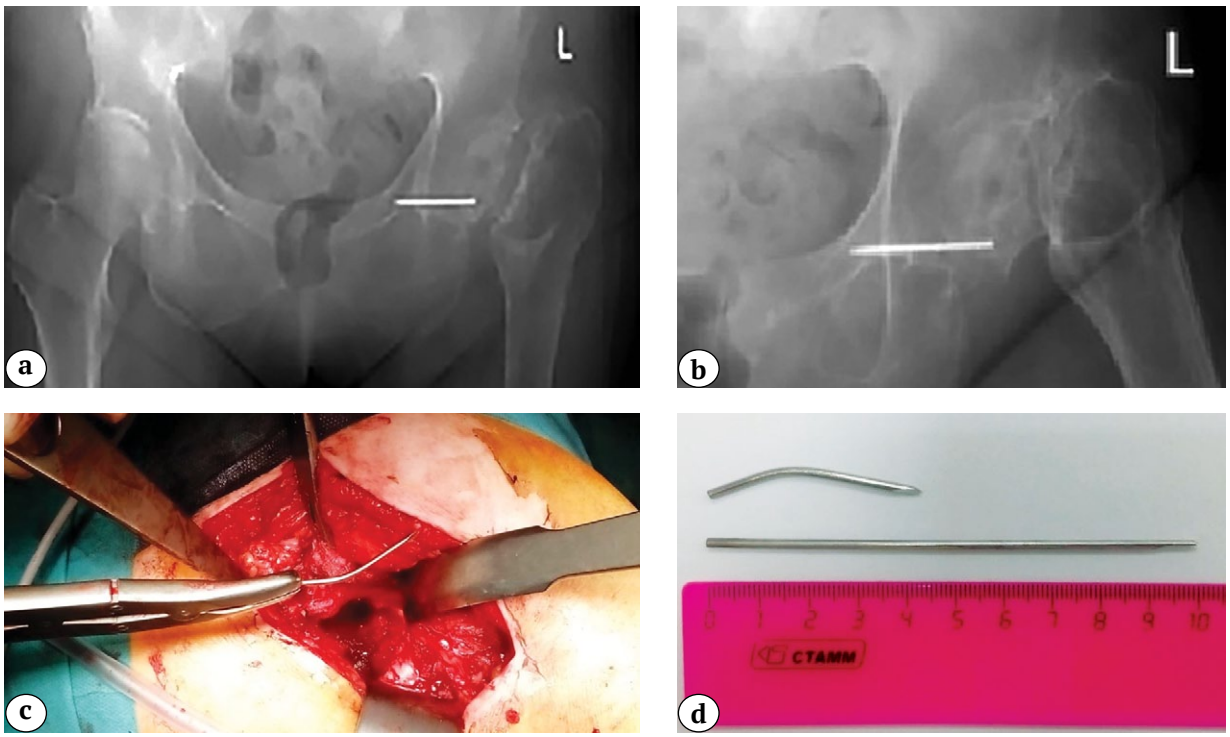

Fig. 3. X-rays of the pelvis in AP (a) and axial (b) views;
K-wire is located in the area of left femoral head and acetabulum; the wire is removed from the joint cavity (c); removed foreign bodies 4 and 10 cm long (d)

The patient was put on the right side, the operative field was treated, and Harding approach to the left hip joint was performed. After removal of the femoral head, the wire fragment was found in the joint cavity and was removed (Fig. 3 c, d). Cemented left hip arthroplasty was performed (Fig. 4).

Rehabilitation procedures started on the second day after the surgery. The wound healed with primary intention, and there were no complaints at the time of discharge. At 3-month follow-up examination and subsequent check-ups the patient could walk without additional support and had no complaints.

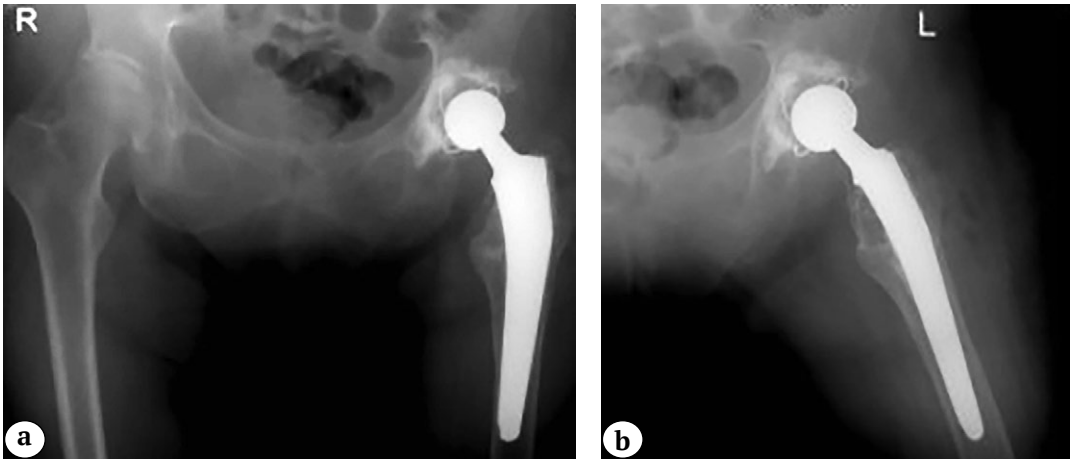

Fig. 4. X-rays of the pelvis in AP (a) and axial (b) views after wire removal and total left hip replacement

DISCUSSION

Despite a large number of modern implants, Kirschner wires are still widely used in trauma surgery for fracture fixation. This is primarily due to their ease of use, no need for special instruments, and low cost of implants. However, this apparent simplicity hides serious complications. H. Matsumoto et al. reported on the damage of the intestine caused by a K-wire located in the pelvic cavity [13]. The literature also presents data on bladder and ureter perforation [14], perforation of abdominal aorta and iliac arteries [15], of descending vena cava [16, 17], as well as heart [18], lung [19] and spinal cord [20] damage.

In 1977, M. Cohen et al. reported on the treatment of a 57-year-old man with bladder perforation with a Knowles pin after osteosynthesis of the femoral neck fracture. Similarly to our case, the patient had no clinical manifestations, but there was microhematuria in the common urine analysis. Laparotomy, cystotomy, bladder revision, verification and removal of the broken pin were performed under endotracheal anesthesia. Postoperative period was without complications [5].

Hardware migration can lead to severe complications, up to lethal outcome [21], and occur years after the surgical treatment [21, 22, 23]. S.V. Sivakon' et al. observed a case of iatrogenic foreign body migration 12 years after the surgery [24].

There is a large number of theories of wire migration. M.D. Romanov et al. consider the lack of reliable fixation of the distal part of a wire, as well as untimely fixator removal to be the main causes of wire migration [2]. Some authors associate the development of complications with constant movements in the joints and muscle work; others associate it with bone resorption [20, 25].

To determine the localization of migrated wire fragment, the most frequently used radiological methods are X-ray and CT, including contrast-enhanced [1, 14, 17, 23]. Once the localization of displaced wire is determined, the problem of its removal arises. In most cases, both open [2, 5, 9] and endoscopic interventions were equally used [26]. Thus, M. Cohen

et al. used laparotomic approach to remove a wire from the bladder [5]. A number of authors discuss in their studies the advantages of endoscopic methods [14, 26, 27].

The possibility of K-wire migration, as well as its severe consequences, prompted us to study this complication and the ways of its prevention [2, 6, 9]. First of all, it is necessary to limit the use of Kirschner wires as a definitive fixation method and give preference to modern implants with minimal probability of migration. In cases when the wires are indispensable to perform the surgery, it is necessary to use threaded ones [26], or bend their end, which will significantly decrease the possibility of migration [1]. D.B. Tuliaganov et al. consider that in the postoperative period it is obligatory to use external immobilization to reduce joint mobility [20]. When the time of bone union is reached and the fracture consolidation is confirmed radiologically, K-wires must be removed [3, 7]. According to W. Mamane et al., periodic radiological monitoring enables early detection of fixator migration and, if this occurs, its immediate removal [28]. B. Zacharia et al. also emphasize that if migration of wire is revealed, it must be removed immediately even if there are no clinical manifestations [29].

In our study, the patient suffered only from the hip joint pain, and the wire migration was diagnosed during elective preoperative examination. We used a combination of open and endoscopic methods to remove the migrated fixators depending on their localization and planned surgical volume.

CONCLUSION

This case has taught us to be cautious when performing osteosynthesis of bone fractures with K-wires due to their frequent fatigue fractures and migration. Osteosynthesis should be supplemented with preventive measures against fractures and migration of fixators. The patient must be dynamically followed up during the treatment period using all necessary monitoring methods (X-ray, CT, ultrasound, etc.). In case of wire fracture and/or migration, it must be removed immediately. Once the fracture has healed or the fixation period of the dislocation is over, the wires should also be removed. Preventive measures allow to avoid migration of K-wires and associated complications.

DISCLAIMERS

Author contribution

All authors made equal contributions to the study and the publication.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Ethics approval. Not applicable.

Consent for publication. Written consent was obtained from the patient for publication of relevant medical information and all of accompanying images within the manuscript.

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Editorial
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Editorial Comment on the Article by A.O. Farion et al. “Migration of a Kirschner Wire Into the Urinary Bladder: A Case Report”

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Abstract

The article “Migration of a Kirschner Wire into the Bladder: Case Report” describes a rather rare but serious complication after osteosynthesis of a medial femoral neck fracture performed with wires, that is a fatigue fracture of a Kirschner wire with migration of its proximal fragment into the bladder. It is stated in the commentary that such complications do occur and the results of their successful treatment have been published in the modern scientific literature. The author of the commentary draws attention to the tactical and organizational aspects of treating patients with femoral neck fractures related to this case. It is pointed out that there are standard replicable osteosynthesis techniques for fractures of a number of localizations that provide good clinical results. Proximal femur is one of these localizations, and the methods of surgical treatment of its fractures are described in details in current clinical guidelines. Possible reasons for the long-term persistence of pseudarthrosis of the femoral neck are also analyzed. Conclusions: when choosing a method of surgical treatment, it is necessary to follow the approved clinical guidelines to reduce the risks of nonunion of femoral neck fractures. Hip arthroplasty should be performed without delay in cases of fracture nonunion after osteosynthesis.

Keywords: osteosynthesis, K-wire, migration of wires, failure of osteosynthesis, femoral neck fracture.

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Редакционный комментарий к статье А.О. Фарйона с соавторами «Миграция спицы Киршнера в мочевой пузырь: клинический случай»

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Реферат

В комментарии к статье «Миграция спицы Киршнера в мочевой пузырь: клинический случай», описывающей достаточно редкое, но серьезное осложнение после остеосинтеза медиального перелома шейки бедренной кости, выполненного спицами: усталостный перелом спицы Киршнера с миграцией проксимального ее фрагмента в мочевой пузырь, констатируется наличие подобных осложнений с публикацией результатов успешного их лечения в современной научной литературе. Автор комментария обращает внимание на связанные с этим случаем тактические и организационные аспекты оказания помощи пациентам с переломами шейки бедренной кости. Отмечается, что при переломах ряда локализаций существуют стандартные тиражируемые методики остеосинтеза, дающие хорошие клинические результаты. К числу таких локализаций относится и проксимальный отдел бедренной кости, методики оперативного лечения переломов которого подробно изложены в действующих клинических рекомендациях. Анализируются также возможные причины длительного существования ложного сустава шейки бедренной кости. Выводы: для снижения риска несращений переломов шейки бедренной кости при выборе метода оперативного лечения необходимо следовать утвержденным клиническим рекомендациям, а в случаях несращения переломов после остеосинтеза без задержек выполнять эндопротезирование тазобедренного сустава.

Ключевые слова: остеосинтез, спицы Киршнера, миграция спиц, несостоятельность остеосинтеза, перелом шейки бедренной кости.

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Certainly, presented case is quite interesting from the clinical point of view. Nevertheless, we would like to draw attention to the tactical and organizational aspects of treating patients with femoral neck fractures.

Osteosynthesis with wires as a method of definitive fixation is currently most commonly used as a part of the tension band with a wire loop for patella fractures [4], olecranon fractures [5] and less frequently for fractures of other localizations as an independent fixator, in particular for fractures of the proximal humerus [6] and the distal radius [7]. Not long ago, different types of wire osteosynthesis were also used for femoral neck fractures. However, there were cases of wire migration. To improve the quality of fixation and prevent wire migration, in 1997, a method of osteosynthesis of the proximal femur was proposed using three bundles of mutually orthogonal wires in the form of pins (Method of surgical treatment of fractures of the proximal femur. Patent of invention RU 2139002 C1, 10.10.1999). However, later, the same authors who proposed this technique did not even mention it when analyzing the results of treatment of patients with femoral neck fractures [8].

When using wires as guides for insertion of cannulated constructs as well as when performing definitive osteosynthesis with wires to prevent their migration, it is common to use threaded wires (Method of surgical treatment of fractures of the pubic ring bones via osteosynthesis with a threaded fixing wire. Patent of invention 2727895 C1, 24.07.2020).

When discussing the tactics of surgical treatment of proximal femur fractures, we should say that in case of intracapsular fractures (type B fractures according to the AO classification), we can choose between osteosynthesis or arthroplasty. When deciding to perform arthroplasty, one can debate the choice between different modifications and methods of fixation of prosthetic components. The situation is completely different when deciding upon performing osteosynthesis of a femoral neck fracture. Considering the choice of osteosynthesis technique, we should note that there are standard replicable techniques for fractures of several localizations that give good clinical results. Proximal femur is one of these localizations. Most of unsolved issues related to osteosynthesis of these fractures today are organizational ones [9]. Technically, in case of femoral neck fractures, osteosynthesis can be performed with parallel cannulated screws, dynamic hip screw system, or dynamic parallelly inserted screws locked in a plate. These methods are approved in the current clinical guidelines for the treatment of proximal femur fractures. It also states there that the methods of osteosynthesis with a three-blade nail and angled blade plate, which have been widely used not so long ago, are not recommended [10]. The lack of even a mention of osteosynthesis with wires in the clinical guidelines demonstrates that this technique is extremely rare nowadays.

There is another fact in the article that cannot be overlooked. The patient sought hospital care only three years after the osteosynthesis and had the wires removed. Obviously, at that time there were all indications for arthroplasty, which was performed only two years afterwards. We can only theorize about the reasons. Perhaps, there were some organizational problems related to the paperwork associated with performing a high-tech surgical intervention. However, it is most likely that the patient was fine with the decrease in her quality of life and decided to undergo arthroplasty only when her pain syndrome increased. Nevertheless, after reviewing this article, the following conclusions can be made: when choosing a method of surgical treatment, it is necessary to follow the approved clinical guidelines to reduce the risks of nonunion of femoral neck fractures. Hip arthroplasty should be performed without delay in cases of fracture nonunion after osteosynthesis.

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Review Article
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Current Concepts in Diagnostics and Treatment of Patellar Instability: Review

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Abstract

Background. Patellar instability is one of the most common pathologies of the musculoskeletal system, predominantly observed in physically active young individuals. It ranks third in the structure of knee joint injuries after anterior cruciate ligament and meniscal injuries.

The aim of this review — to present modern perspectives on the diagnosis, principles, and surgical treatment techniques for patients with patellar instability based on an analysis of the literature.

Methods. Publications were searched in the PubMed/MedLine and eLIBRARY databases. A total of 112 foreign articles published between 1984 and 2023 and 12 domestic publications from 2011 to 2022 were found. During the analysis, 68 articles were selected, which had full texts or abstracts containing sufficient information on diagnostic methods, commonly used standard and modified surgical correction methods for patellar instability, and treatment protocols considering patient age structure, instability characteristics, and functional demands.

Results. A qualitatively new stage in the reconstructive and restorative surgery of patellar instability is the in-depth examination of patients to determine the extent of damage to the medial retinaculum and the presence of dysplastic changes in anatomical structures that provide normal biomechanics of the knee extensor apparatus. A strictly individual approach to the selection of surgical treatment methods considering risk factors contributing to the development of chronic patellar instability becomes of particular importance.

Conclusion. Precise restoration of the medial patellofemoral ligament, supplemented by the correction of identified dysplastic changes in anatomical formations of the knee joint area, allows for better functional outcomes in patients with acute and chronic patellar instability.

Keywords: patellar dislocation, patellar instability, medial patellofemoral ligament reconstruction, trochlear dysplasia.

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Современные подходы к диагностике и лечению нестабильности надколенника: обзор литературы

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Реферат

Актуальность. Нестабильность надколенника — одна из наиболее часто встречающихся патологий опорно-двигательного аппарата, наблюдающаяся преимущественно у физически активных молодых людей, которая занимает третье место в структуре повреждений области коленного сустава после травм передней крестообразной связки и менисков.

Цель обзора — на основании анализа данных литературы представить современные взгляды на диагностику, принципы и методики хирургического лечения пациентов с нестабильностью надколенника.

Материал и методы. Поиск публикаций осуществлялся в базах данных PubMed/MedLine и eLIBRARY. Всего было найдено 112 иностранных статей, опубликованных в период с 1984 по 2023 г., и 12 отечественных публикаций за 2011–2022 гг. В ходе анализа публикаций было отобрано 68 статей, для которых были доступны полные тексты или рефераты, содержащие достаточную информацию по методам диагностики и наиболее часто применяемым стандартным и модифицированным способам хирургической коррекции нестабильности надколенника, а также протоколы лечения рассматриваемой патологии с учетом характера нестабильности, возрастной структуры и функциональных запросов пациентов.

Результаты. Качественно новым этапом развития реконструктивно-восстановительной хирургии нестабильности надколенника является углубленное обследование пострадавших с определением степени повреждений медиального ретинакулюма и диспластических изменений анатомических структур, обеспечивающих нормальную биомеханику разгибательного аппарата коленного сустава. Особое значение приобретает строго индивидуальный подход к выбору метода хирургического лечения с учетом факторов риска, способствующих развитию хронической нестабильности надколенника.

Заключение. Прецизионное восстановление медиальной пателло-феморальной связки, дополненное по показаниям коррекцией выявленных диспластических изменений анатомических образований области коленного сустава, позволяет получить лучшие функциональные результаты у больных с острой и хронической нестабильностью надколенника.

Ключевые слова: вывих надколенника, нестабильность надколенника, реконструкция медиальной пателло-феморальной связки, дисплазия блока бедренной кости.

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BACKGROUND

Patellar instability is one of the most common pathologies of the musculoskeletal system, primarily observed in physically active young individuals [1]. It ranks third in the incidence of knee joint injuries after meniscal tears and anterior cruciate ligament ruptures, accounting for 3.3% [2].

Primary patellar dislocation mostly occurs as a result of acute trauma. According to M. Moiz et al., conservative treatment of traumatic patellar dislocations leads to the development of chronic instability in one-third of the affected patients (31%) [3]. A study by R.A. Magnussen et al. showed that only 26.4% of patients regain knee joint function to the level of their previous physical activity after conservative treatment [4]. L.S. Huntington et al. confirmed that conservative treatment of primary patellar dislocations is accompanied by recurrence of instability in 33.6% of cases, significantly affecting the patients' quality of life [5]. E.E. Salonen et al. demonstrated that chronic patellar instability is associated with a high risk of early development of patellofemoral joint osteoarthritis due to constant cartilage trauma in the patellar joint and the femoral block [6]. A.K. Orletsky et al. reported a lower risk of patellar dislocation recurrence after operative treatment compared to conservative treatment, but a higher risk of developing osteoarthritis of the patellofemoral joint following surgery [7].

Currently, the question of selecting indications for operative treatment in patients with primary patellar dislocation remains debatable. In the last decade, special attention has been given to the biomechanical aspect of instability development [8]. The conducted studies have demonstrated that anatomical features of the knee joint extensor apparatus, such as tibial tuberosity dysplasia, lateralization of the tibial tuberosity, high patellar position, excessive femoral anteversion, and torsion of the tibia, significantly influence the biomechanics of the patellofemoral joint. These factors should be taken into account when choosing treatment strategies for both acute and chronic instability [9, 10, 11, 12].

The aim of this review is to present contemporary views on the diagnosis, principles, and surgical treatment techniques for patients with patellar instability based on an analysis of the literature.

METHODS

The search for publications was conducted in the PubMed/MedLine and eLIBRARY databases. The search keywords and phrases included: patellar dislocation, patellar instability, medial patellofemoral ligament, tibial tuberosity dysplasia, medial patellar retinaculum, tibial tubercle, trochleoplasty, patellar instability, recurrent patellar instability, patellar dislocation, medial patellofemoral ligament reconstruction, MPFL, tibial tubercle osteotomy, trochlear dysplasia, femoral osteotomy, trochleoplasty.

A total of 112 foreign articles published from 1984 to 2023 and 12 domestic publications from 2011 to 2022 were found. During the analysis of the publications, 68 articles with full texts or abstracts containing sufficient information about diagnostic methods, commonly used standard and modified surgical correction techniques for patellar instability, as well as treatment protocols considering patient age, type of instability, and functional demands were selected.

RESULTS

Diagnostic features

The diagnosis of patellar instability, in addition to clinical examination, is based on determining numerous indicators that characterize the individual anatomical features of the knee joint extensor apparatus. The characteristics of the morphology of the femoral block and patella, the height of the patella relative to the femur, and the lateralization of the tibial tuberosity are the main interrelated signs that define the diagnosis of "patellar instability." In addition to their diagnostic value, indicators such as the tibial tuberosity-trochlear groove distance (TT-TG), the angle of the femoral trochlear groove, and the height ratios of the patella and the type of femoral block structure assist in choosing the surgical treatment approach [13].

Assessment of patella height

The most straightforward and surgically correctable anatomical anomaly of the knee joint is the high patella position relative to the femoral block. The higher the patella is positioned, the greater the flexion angle at which it engages with the femoral trochlear groove, and the less stable the patella becomes. According to Ch. Huber

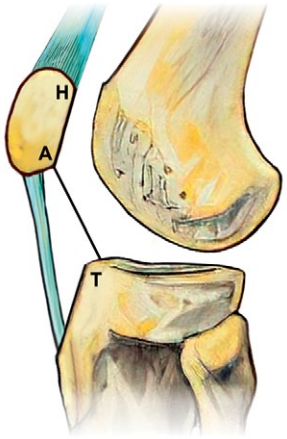
et al., if the patella fails to engage with the trochlear groove at a flexion angle greater than 30°, it indicates a potentially high risk of instability [14]. Usually, the assessment of patella height is performed using a lateral radiograph of the knee joint at a 30° flexion position [9, 15].

According to most authors, the Caton-Deschamps index is the most informative, with a normal range of 0.6-1.3 [13, 14, 15] (Fig. 1). R. Neyret et al. found this anomaly in 48% of patients with patellar instability and only 12% of individuals in the control group without a history of patellar dislocation [16].

Different opinions on the magnitude of the Caton-Deschamps index can be found in the literature. An index range of 1.2-1.3 is considered mild, while 1.3-1.4 is considered severe. Until now, most authors have followed the recommendations of H. Dejour et al. and performed surgical correction when the index exceeds 1.2 [9]. In the last decade, publications have emerged suggesting that surgery is indicated when the index is above 1.4 or 1.3 [13, 17, 18]. However, the patella height index alone, increased to 1.2 or even 1.3, is not a direct indication for surgical correction since patella lowering in cases of instability is rarely considered as an isolated procedure and is usually performed in combination with correction of other extensor apparatus anomalies that can affect this indicator's change.

Lateralization of the tibial tuberosity

The distance from the center of the femoral block to the attachment site of the patellar ligament on the tibial tuberosity in the frontal plane significantly influences the magnitude of lateralizing forces on the patella during flexion-extension movements of the knee joint. Lateralization of the tibial tuberosity is an external, easily detectable sign of excessive rotation of the proximal portion of the tibial tuberosity. This anomaly has long been known, but it was only with the widespread clinical use of CT and MRI that precise measurements and discussions of the quantitative aspect of this indicator became possible. These measurements are performed on axial MRI and CT scans and are referred to as the TT-TG (tibial tubercle-trochlear groove) distance or index. A commonly accepted indication for surgical correction is a distance of 20 mm or more [19] (Fig. 2).



CDI = HA/AT

Fig. 1. Calculation of the Caton-Deschamps index: AT — line connecting the lower edge of the patellar articular facet to the anterior edge of the tibial plateau; HA — line corresponding to the articular surface of the patella; CDI — Caton-Deschamps index, the ratio of the length of the AT line to the HA line

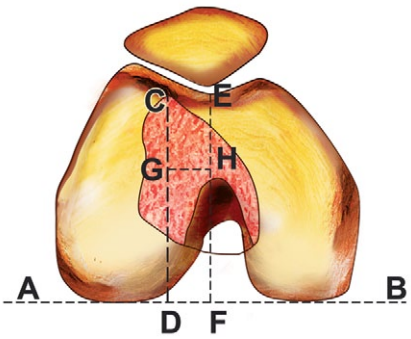


Fig. 2. Scheme for calculating the TT-TG index in the axial plane: AB — tangent line to the femoral condyles; CD — perpendicular from the center of the tibial tuberosity to the line of the femoral condyles; EF — perpendicular from the center of the articular surface of the femoral block to the line of the femoral condyles; GH — distance between the center of the articular surface of the femoral block and the center of the tibial tuberosity

According to S. Tan et al., the measurement of the TT-TG index significantly differs between CT and MRI. Their analysis showed that for the same patients with patellar instability, the average index measured on MRI was 15.3 mm, while on CT, it was 18.3 mm. However, measurements performed on CT are considered more reliable [20].

Objective measurement of the TT-TG distance is an important step in diagnosing and planning the surgical correction of patellar instability. However, this method presents significant challenges in cases of block dysplasia, especially type D, when determining the position of the tibial tubercle on its flat or asymmetrically convex surface.

To improve the accuracy of this measurement, G. Seitlinger et al. proposed using the attachment point of the posterior cruciate ligament on the lateral wall of the medial femoral condyle as a more constant reference point on the distal femoral epiphysis, which is independent of the degree of block dysplasia. They named this indicator the TT-PCL (tibial tubercle-posterior cruciate ligament) index and established its upper normal limit at 24 mm [21].

Z. Xu et al. recommended a different modification of this indicator, replacing the point of the trochlear groove with a point located at the apex of the "Roman arch" on the posterior surface of the intercondylar fossa of the femur. This yields the TT-RA index, with a normal value of less than 26 mm [22].

A comparative analysis conducted by T.J. Kim et al. found that the accuracy of calculations for the TT-TG and TT-PCL indices is influenced by the consideration of femoral anteversion, medialization of the intercondylar groove, and the specific anatomical structure of the proximal tibial tuberosity, which is not always taken into account in their determination. The authors noted that the parameters of the TT-RA index are not affected by anatomical variations of the tibial tuberosity, thereby minimizing the margin of error, and this method can be an alternative for assessing lateralization of the tibial tuberosity, especially when TT-TG measurement is inconclusive [23]. However, Z. Xu et al. argue that, compared to other parameters, the TT-TG distance still has the greatest diagnostic value when considering all the anatomical features of the knee joint extensor apparatus [24].

Diagnosis of types of femoral block dysplasia

The most important and commonly observed manifestation of knee joint dysplasia, which predisposes to patellar instability and creates difficulties in its correction, is the anomalous shape of the articular surface of the femoral block. This pathology is specifically understood as "knee joint dysplasia" in the narrow sense. The diagnosis of this anatomical feature is based on the analysis of knee joint X-rays in the strictly lateral projection [9, 16, 25, 26] (Fig. 3).

In 2010, D. Dejour and P. Saggin proposed a classification of femoral block dysplasia, which is an improved version of N. Dejour's classification and forms the basis of modern surgical treatment schemes for patients with patellar instability. The classification identifies four main types of block dysplasia, characterized by deformations of its articular surface [27] (Fig. 4).

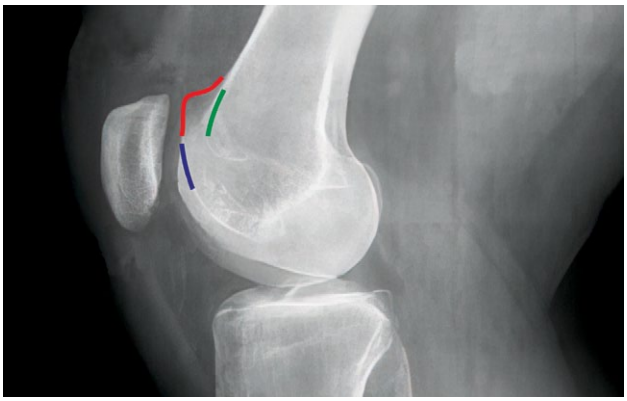


Fig. 3. X-ray of the knee with signs of trochlear dysplasia in the lateral projection:
blue line — «crossing sign», representing the deepest point of the trochlear groove crossing the anterior border of the femoral condyles; red line — «supratrochlear spur», the prominence of the trochlea on the anterior side of the femoral cortex; green line — «double contour», hypoplastic medial facet located behind the lateral facet

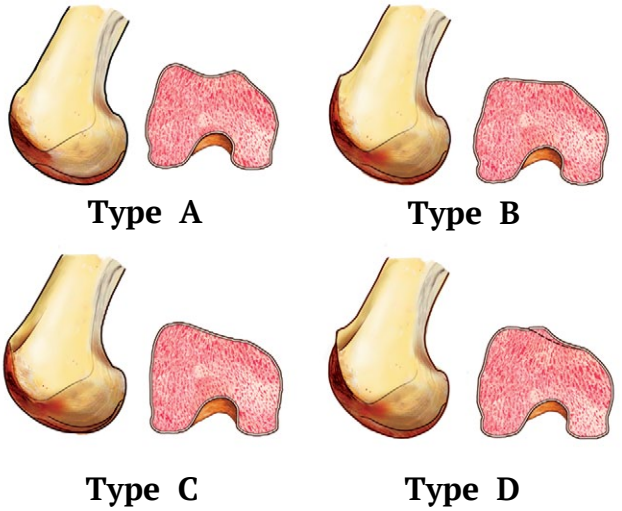


Fig. 4. D. Dejour classification of trochlear dysplasia

In practice, D. Dejour's classification places the main emphasis on the analysis of tomograms in the axial plane, which can be easily obtained during standard CT or MRI scans, unlike X-rays in the strictly lateral projection. However, these tomograms do not have such clear quantitative criteria, making it difficult to objectively analyze the results of surgical patellar stabilization. The presence of severe dysplasia types B, C, and D complicates the surgical correction of patellar instability due to the pathological biomechanics in the femoral-patellar joint of the knee [28, 29, 30].

The severity of the dysplasia type also influences the condition of the patellar cartilage. Progressive hypoplasia of the lateral femoral condyle, together with the incompetence of the medial retinaculum, leads to more pronounced traumatic damage to the patellar articular facet and, consequently, the development of early patellofemoral arthritis [31].

Risk factors and specifics of surgical correction

Restoration of the Medial Patellofemoral Ligament (MPFL)

The leading anatomical factor contributing to the development of chronic patellar instability is the functional insufficiency of the medial patellofemoral ligament (MPFL), which provides more than 60% resistance against lateral dislocation of the patella during stress loads within a limited range of knee joint motion. Currently, the restoration of the MPFL, which contributes to the elimination of frontal patellar instability, is the goal of surgical treatment for this condition [32, 33, 34].

According to anatomical and biomechanical studies, the knee joint's medial retinaculum, in addition to the MPFL, has another capsular ligament called the medial patellotibial ligament (MPTL). The MPTL acts as an auxiliary static stabilizer of the patella when the leg is flexed beyond 30°, where the influence of the MPFL physiologically weakens. Combined reconstruction of these two ligaments is considered an option for additional reinforcement during MPFL restoration in cases of increased risk of patellar instability recurrence, caused by high patellar positioning and abnormal lateralization of the tibial tubercle, and as an alternative to tibial tubercle transposition [35, 36, 37].

Anatomical ligament reconstruction has an undeniable priority over primary suture or local tissue plastic repair [38, 39, 40]. The success lies in the anatomical placement of the graft [39]. The key aspect of the reconstruction is the correct selection of the fixation point on the medial surface of the medial femoral condyle, located in the posterior-upper segment of the area where the damaged native ligament was attached. Such positioning, while maintaining normal knee joint range of motion, results in less than 4% change in graft length. The resulting graft anisometry ensures proper biomechanics and reliable stabilization of the patella at its most vulnerable position during the initial flexion of the leg, when the graft experiences maximum traction forces, serving as the only structure preventing lateral dislocation until it enters the femoral trochlear groove [15, 38]. Typical anatomical anomalies of the knee joint, based on its dysplasia, as well as incorrect placement of the fixation point on the femoral condyle, hinder the proper functioning of the graft and greatly increase the load on it, creating conditions for the formation of persistent contractures and recurrent instability.

Currently, the Schöttle method is used for intraoperative X-ray video control to determine the fixation point of the graft in the area of the medial femoral condyle. This technique significantly improves accuracy, reduces invasiveness, and shortens the operation time [41] (Fig. 5).

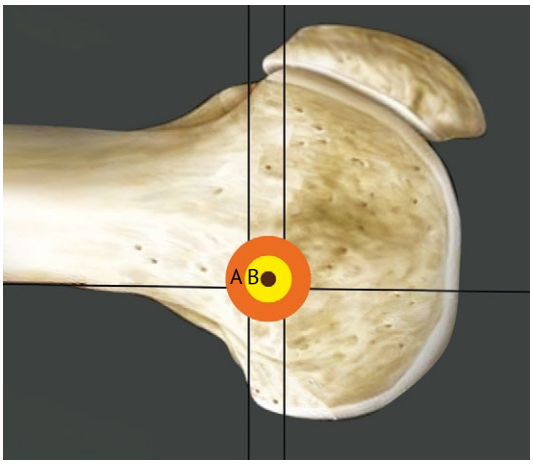


Fig. 5. Scheme of tunnel formation for fixation of the MPFL graft in the femoral condyle:
A — satisfactory tunnel positioning;
B — correct tunnel location

For severe degrees of femoral block dysplasia (Types C and D according to D. Dejour), the use of X-ray methods may alter the spatial positioning of landmarks and lead to serious errors in calculations. To avoid this, it is advisable to combine radiographic and traditional anatomical landmarks, complementing them with a functional test aimed at evaluating the tension of the MPFL graft at different angles of knee joint flexion [30].

Meticulous calculations for the correct selection of the graft fixation point in the femoral tunnel, which make up the majority of technical errors in MPFL reconstructions, can result in changes in graft tension in different knee joint positions and anomalies in the patellar motion trajectory [34]. Typical deviations from the anatomical attachment point of the MPFL on the medial femoral condyle (Schöttle point) proximally and anteriorly during flexion beyond 50-60° lead to significant graft tension and the formation of persistent extension contracture. During rehabilitation, with the forced restoration of motion amplitude through aggressive physical therapy, chondromalacia of the patella and femoral trochlea can occur, ultimately leading to graft damage, plastic elongation, or complete rupture with recurrent instability [39, 42, 43]. According to Th. Neri et al., errors in femoral tunnel placement during MPFL reconstructions can reach up to 33% [44].

The anatomical fixation of the graft on the proximal half of the medial border of the patella restores its ability to simultaneously act on the quadriceps tendon. There are two main methods of fixation: placing the graft in bony tunnels or in a bone trough along the edge of the patella, secured with interference screws, anchors, or transosseous sutures. The main requirements in this regard are the strength of graft fixation in the early postoperative period and minimizing the risk of fractures of the patella at the tunnel sites in the future [35]. V.A. Raoulis et al. did not find significant differences among the three aforementioned methods of graft fixation in the patellar area, although the use of interference screws showed a higher degree of graft fixation stiffness, and patients reported less pronounced pain in the anterior aspect of the knee joint when using anchor or suture-button fixators [45].

Failures in restoring the proper trajectory of patellar motion during MPFL reconstruction can also be associated with excessive graft tension, leading to medial subluxation. In most cases, the occurrence of this complication is provoked by an extensive release of the lateral retinaculum with resection of the lateral patellofemoral ligament and detachment of a portion of the lateral quadriceps tendon [46]. In cases of isolated MPFL reconstruction, it is generally recommended to avoid this procedure. If it is not possible to avoid lateral release due to persistent contracture of the lateral retinaculum, it is advisable to perform an elongation plasty of the lateral patellofemoral ligament rather than simple resection [47, 48].

The stability and normal kinematics of the patella are the result of the complex interaction between muscles, the capsuloligamentous apparatus, normal bone geometry of the femorotibial joint surfaces, and a stable supportive limb balance. However, a significant factor that influences the outcomes of patellar instability treatment, even with impeccable MPFL reconstruction, is the frequently encountered anatomical anomaly of the femoral block and the knee extensor apparatus, which have a dysplastic nature [49].

Currently, it is widely accepted that anatomical MPFL reconstruction generally leads to good anatomical and functional results with a relatively low rate of complications, especially for

patients with low functional demands [18, 29, 50, 51, 52]. However, the outcomes of such surgeries largely depend on the correct positioning of the graft and, most importantly, on risk factors associated with anatomical anomalies of dysplastic origin. Several authors note that without considering these factors, simple isolated MPFL reconstruction provides acceptable restoration of knee joint function in less than 40% of cases, with a recurrence rate of patellar instability ranging from 30% to 35% [43, 49, 53, 54]. M.J. Feucht et al. reported that after isolated MPFL reconstruction, the main complications leading to revision surgery were recurrent instability (35.6%) and persistent joint contracture (22.2%) [55].

Bone plastic surgeries

In 1994, N. Dejour et al. identified four risk factors for the development of patellar instability: femoral trochlear dysplasia, quadriceps dysplasia with a lateral tilt of the patella greater than 20°, a high-riding patella with a Caton-Deschamps index greater than 1.2, and excessive lateralization of the tibial tubercle with a TT-TG index greater than 20 mm. They classified femoral trochlear dysplasia based on lateral radiographic signs, including "crossing sign," "trochlear spur," which protrudes more than 3 mm above the anterior surface of the femoral diaphysis, and shallow trochlear groove with a depth reduction of 4 mm or more (see Figure 3). They also associated anatomical anomalies predisposing to lateral patellar instability with changes in the rotational profile of the lower limbs, such as excessive internal rotation of the femoral condyles more than 25° and external torsion of the tibia more than 35° [8, 9, 28, 56].

The complexity of assessing the degree of various dysplastic manifestations in the structures of the knee extensor apparatus and their impact on surgical outcomes arises from the fact that some authors consider Type A dysplasia as pathology, while others classify it as a borderline condition or even a conditional norm. R.N. Steensen et al. found that dysplastic anomalies of the knee joint were present in 58.3% of patients with patellar instability, compared to only 1.7% in the control group. Femoral trochlear dysplasia was observed in 68.3% of patients and 5.8% of individuals in the control group, high-riding patella in 60% and 20.8%, and increased TT-TG distance in 42% and 3.2%, respectively. They emphasized the significance of spatial deformations of the lower limb at the knee joint level in the frontal plane (valgus deviation of the tibia) and horizontal plane (internal torsion of the femur, external torsion of the tibia) [57].

Some authors note that typically, patients present a combination of these two types of anatomical lower limb changes, and an increased TT-TG index, pronounced valgus deformity of the lower limb, and dysplasia of types B, C, and D correlate with an increased risk of "hidden" torsional deformations of the limb [55, 58].

Correction of lateralization of the tibial tubercle

Surgical treatment of patients with an increased TT-TG index involves its reduction through medial transposition of the tibial tubercle along with the attachment site of the patellar ligament, according to the Elmslie-Trillat procedure [59] (see Figure 6).

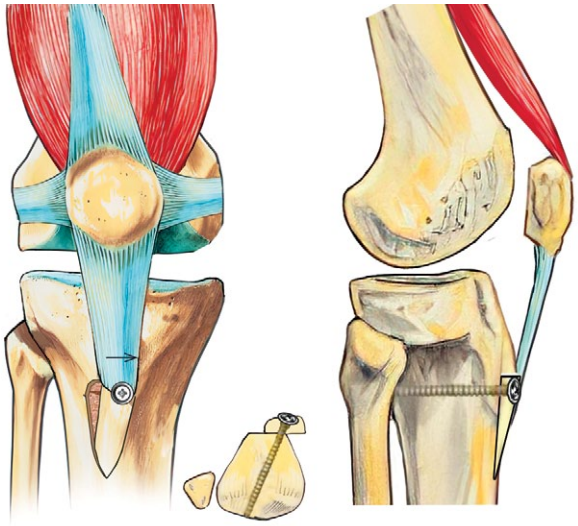


Fig. 6. Scheme of medializing transposition of the tibial tuberosity according to Elmslie-Trillat

The technical simplicity and biomechanical effect of tibial tubercle transposition in cases of increased TT-TG index in correcting dysplastic patellar instability explain the popularity of this versatile surgical method in modern comprehensive treatment of this pathology. C.E. Franciozi et al. suggest that in addition to MPFL reconstruc-

tion, medialization or anteromedialization of the tibial tubercle according to Fulkerson should be performed when the TT-TG index exceeds 17 mm, achieving a tubercle position of 10-12 mm [60].

Usually, not only medialization but also medialization with distalization is performed, as excessive lateralization of the tubercle is often associated with a high-riding patella. In the context of pronounced dysplasia of types B, C, and D, the possibility of accompanying rotational and frontal deformations at the knee joint level, which can influence the true value of the TT-TG index, should be considered [48]. According to L. Jud et al., during high tibial tubercle derotational osteotomy, each degree of internal detorsion is accompanied by a decrease in the TT-TG index by 0.68 mm [61].

It is believed that additional surgical procedures, primarily tibial tubercle transposition, increase the duration of the rehabilitation period and may impact the final outcomes [39]. One challenging combination for choosing the surgical treatment approach is type D dysplasia combined with a TT-TG index greater than 20 mm [62]. L. Hiemstra et al. explain the increased risk of recurrence associated with type B and especially type D dysplasias, characterized by a pronounced trochlear bump exceeding 5 mm [63]. In such cases, trochleoplasty is recommended, and an alternative option is medialization-distalization transposition of the tibial tubercle, which allows restoring the anatomical and biomechanical relationship between the patella and the femoral trochlea without directly correcting the femur [30, 64] (see Figure 7).

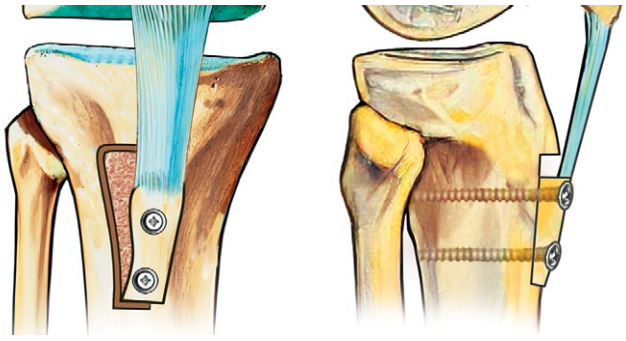


Fig. 7. Scheme of distalization and medialization of the tibial tuberosity (DMTT)

Correction of femoral bone anatomical changes

Data on the frequency of femoral trochlear dysplasia of different types are quite inconsistent, which is likely due to the subjective nature of their assessment. According to several authors, through detailed CT and MRI examinations, femoral trochlear dysplasia is detected in 65-85% of patients with symptomatic patellar instability and in 2-10% of individuals in control groups [5, 16]. A study by J.N. Liu et al. showed that 92% of patients undergoing surgery for patellar instability exhibited signs of trochlear dysplasia, including type A (8%), B (23%), C (26%), and D (43%) [50]. In 2020, a group of authors from the Technical University of Munich reported that all examined patients with patellar instability (151 patients) had anatomical signs of trochlear dysplasia. Mild type A dysplasia was observed in 33% of cases, while severe dysplasia of types B, C, and D was present in 67% [58].

According to A. Geierlehner et al., the majority of orthopedic surgeons, including those specializing in general reconstructive knee surgery, avoid patients with complex dysplastic anomalies or limit their treatment to a set of simpler and typical procedures such as MPFL reconstruction combined with lateral retinaculum lengthening and tibial tubercle transposition [51].

Modern pathogenetically justified surgical treatment of trochlear dysplasia involves a subchondral reconstruction of the deepened femoral trochlea (trochleoplasty), which is technically complex and invasive, thus having limited indications primarily for severe dysplasia (types B and D) with an abnormal trajectory of the unstable patella. Therefore, in practice, these procedures are mostly indicated for severe dysplasia, especially in revision stabilizations of the knee joints. The main goal of such surgeries is the resection of the wedge-shaped prominence characteristic of the most severe form of trochlear dysplasia (type D), resulting in the formation of an anatomically concave surface that normalizes the patellar trajectory and stabilizes the patella [28, 64, 65] (see Figure 8).

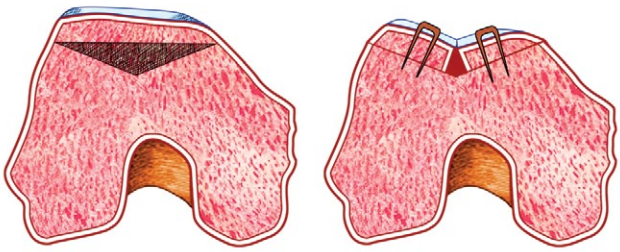


Fig. 8. Scheme of trochleoplasty according to D. Dejour (2010)

According to several authors, for patients with patellar instability rarely accompanied by significant femoral trochlear dysplasia, it is more reasonable to limit the treatment to MPFL reconstruction combined with tibial tubercle transposition. In cases of pronounced valgus deformity of the limb at the knee joint level, varus osteotomy of the femur or derotational osteotomy may be performed. In cases of rigid lateral retinaculum, this combination can be supplemented with lengthening plastic surgery of the lateral patellofemoral ligament, eliminating rotational stress on the extensor apparatus of the knee joint. If this condition is not feasible, additional external fixation of the patella with a special brace can be considered [66, 67, 68].

S. Zaffagnini et al. also note that performing unjustified trochleoplasty in cases of relatively simple dysplasia types A and C does not lead to a significant reduction in the recurrence of instability. For such patients, traditional MPFL reconstruction, either in isolation or combined with tibial tubercle transposition, is appropriate. However, for severe forms of dysplasia (types B and D), a combination of trochleoplasty with MPFL reconstruction contributes to real improvements in outcomes in both revision and primary surgeries [66].

CONCLUSION

The foundation of modern organ-preserving surgery for patellar instability, regardless of the timing of the procedure, lies in an individualized approach to selecting the method and extent of intervention. In all cases, the restoration of the integrity of the MPFL as a key element of the medial retinaculum is mandatory. The indications for additional correction of anatomical features of the extensor apparatus of the joint are determined by the degree of dysplasia and associated biomechanical abnormalities, patient age, and functional demands.

DISCLAIMERS

Author contribution

Khominets V.V. — the design, the writing and the drafting of the article.

Konokotin D.A. — the conception, data collection and processing, the writing of the article.

Rikun O.V. — data collection and processing, he writing and the drafting of the article.

Fedotov A.O. — he conception, the writing of the article.

Grankin A.S. — the writing and the drafting of the article.

Vorobiev A.S. — data collection and processing.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Анатомо-биомеханические особенности латерального отдела коленного сустава и связанные с ними технические аспекты одномыщелкового эндопротезирования: лекция

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Реферат

Частота выполнения латерального одномыщелкового эндопротезирования коленного сустава оценивается, по данным современной литературы, в 1% от всего объема артропластик коленного сустава. Современные исследования показывают, что, если данная операция выполнена по показаниям и технически корректно, она столь же эффективна и безопасна, как и тотальное эндопротезирование. Потенциальными преимуществами частичного замещения сустава являются меньшая травматичность по сравнению с тотальным, меньшая периоперационная кровопотеря, более быстрая реабилитация пациента и возможность сохранить нативную проприорецепцию сустава. В то же время важно помнить, что для успешного проведения данного вида частичного эндопротезирования коленного сустава, кроме корректного отбора пациентов, необходимо учитывать техническую сложность выполнения данного вмешательства, высокие требования к материальной оснащенности операционной и к прецизионной хирургической технике, осуществляемой опытным хирургом. Несоблюдение этих условий будет нивелировать все потенциальные преимущества и способно привести пациента к ревизионному вмешательству уже в краткосрочной перспективе. Одномыщелковое эндопротезирование не является половиной операции тотального замещения сустава, а парциальная артропластика латерального отдела коленного сустава имеет лишь общее сходство с гораздо более популярной и отработанной операцией медиального одномыщелкового эндопротезирования. Данные различия кроются в первую очередь в сложной анатомии и биомеханике латерального отдела коленного сустава, имитировать которые даже с использованием анатомичных современных имплантатов является непростой задачей. Развитие роботизированной хирургии, использование персонифицированных имплантатов поможет решить эту задачу более эффективно, но в настоящее время в рутинной практике мы можем рассчитывать лишь на конвенциональные инструменты и оптимизировать свою работу с ними. Перед авторами данной статьи стояла задача сформулировать основные современные представления об анатомии и биомеханике латерального отдела коленного сустава и связанных с ними узкоспецифичных технических аспектах хирургической техники парциальной латеральной артропластики с использованием имплантата с фиксированной тибиальной платформой.

Ключевые слова: латеральный отдел коленного сустава, одномыщелковое эндопротезирование коленного сустава, анатомия коленного сустава, биомеханика коленного сустава.

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Anatomical and Biomechanical Features of the Lateral Compartment of the Knee and Associated Technical Aspects of Unicompartmental Knee Arthroplasty: Lecture

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Abstract
The frequency of lateral unicompartmental knee arthroplasty is estimated at 1% of the total volume of knee arthroplasties, according to contemporary literature. Recent studies analyzing this type of surgical intervention indicate that when performed with proper indications and technical accuracy, it is equally effective and safe as total knee arthroplasty. Potential advantages of partial knee replacement include reduced invasiveness compared to total knee arthroplasty, lower perioperative blood loss, faster patient rehabilitation, and preservation of native joint proprioception. However, it is important to consider that successful implementation of lateral unicompartmental knee arthroplasty requires not only appropriate patient selection but also technical proficiency, advanced operating room equipment, and precise surgical techniques performed by experienced surgeons. Failure to meet these conditions can negate the potential benefits and may lead to early revision surgery. It is evident that unicompartmental knee arthroplasty is not simply a half-operation of total joint replacement, and the lateral compartment's partial arthroplasty only shares general similarities with the more popular and established medial unicompartmental knee arthroplasty. The differences lie primarily in the complex anatomy and biomechanics of the lateral compartment, which present a challenging task even with the use of modern anatomically designed implants. The development of robotic surgery and personalized joint implants may help overcome these challenges more effectively. However, in our current routine practice, we rely on conventional instruments and strive to optimize our techniques. The authors of this article aim to provide an overview of the contemporary understanding of the anatomy and biomechanics of the lateral compartment of the knee and the specific technical aspects related to partial lateral arthroplasty using a fixed tibial platform implant.

Keywords: lateral unicompartmental knee arthroplasty, knee anatomy, knee biomechanics.

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ВВЕДЕНИЕ

«Вся эта книга об одном только протезе коленного сустава, и более того, только о половине протеза…», — писали P.R. Aldinger с соавторами в своем руководстве по одномыщелковому эндопротезированию, несколько иронизируя над высокой степенью специализации современной ортопедии [1]. В то же время, если какое-то специфическое хирургическое вмешательство является эффективным и безопасным, пусть и для небольшой группы пациентов, стоит ли от него отказываться?

Так, в настоящее время в структуре артропластики коленного сустава в разных ортопедических клиниках частичная артропластика составляет от 5 до 40%. Но если отдельно проанализировать количество операций по замещению латерального отдела коленного сустава, то окажется, что их число не превышает 1% от общего числа вмешательств данного профиля [2]. Это обусловлено рядом причин, из которых наиболее важными являются меньшее число пациентов с вальгусной деформацией в популяции, большая разнородность частоты выполнения частичного эндопротезирования в мире от страны к стране, противоречивые результаты ранних исследований, оценивавших эффективность и безопасность данной операции, а также технические трудности, связанные с хирургическим вмешательством и обусловленные уникальностью анатомо-функционального строения латерального отдела коленного сустава. Освещению технических путей преодоления проблем, специфичных для частичного замещения латерального отдела коленного сустава, и посвящена данная статья.

Анатомические и биомеханические особенности латерального отдела коленного сустава

С точки зрения анатомии и биомеханики латеральный отдел коленного сустава значительно отличается от медиального, что делает хирургическую технику его парциального замещения искусственным суставом высокоспецифичной. Анатомические различия медиального и латерального отделов коленного сустава включают ряд важных аспектов: различия в задних наклонах (slope) латерального и медиального мыщелков большеберцовой кости, а также разную величину их переднезаднего размера [3, 4]. Несмотря на то, что костные ориентиры латерального и медиального отделов большеберцовой кости во фронтальной плоскости расположены примерно на одном уровне, за счет хрящевой ткани латеральное плато имеет более выпуклую форму и расположено несколько проксимальнее, чем медиальное плато. Также немаловажно отметить, что латеральный мениск имеет О-образную форму, более подвижен, шире и толще С-образного медиального мениска [5]. Обращая внимание на данную особенность, O.C. Brantigan и A.F. Voshell писали: «Медиальный мыщелок бедренной кости является осью вращения коленного сустава» [6]. Под этим авторы, очевидно, понимали то, что при сгибании медиальный мыщелок бедренной кости, имея выпуклую форму и практически не смещаясь, скользит в углублении медиального мыщелка большеберцовой кости, в то время как латеральные мыщелки бедренной и большеберцовой костей имеют выпуклую форму, в связи с чем смещения наружных мыщелков костей, образующих коленный сустав, друг относительно друга, более значительны. Также важно отметить, что при сгибании медиальный мениск практически недвижим, в то время как латеральный мениск, особенно в крайних углах сгибания, значительно транслируется кзади [7] (рис. 1).

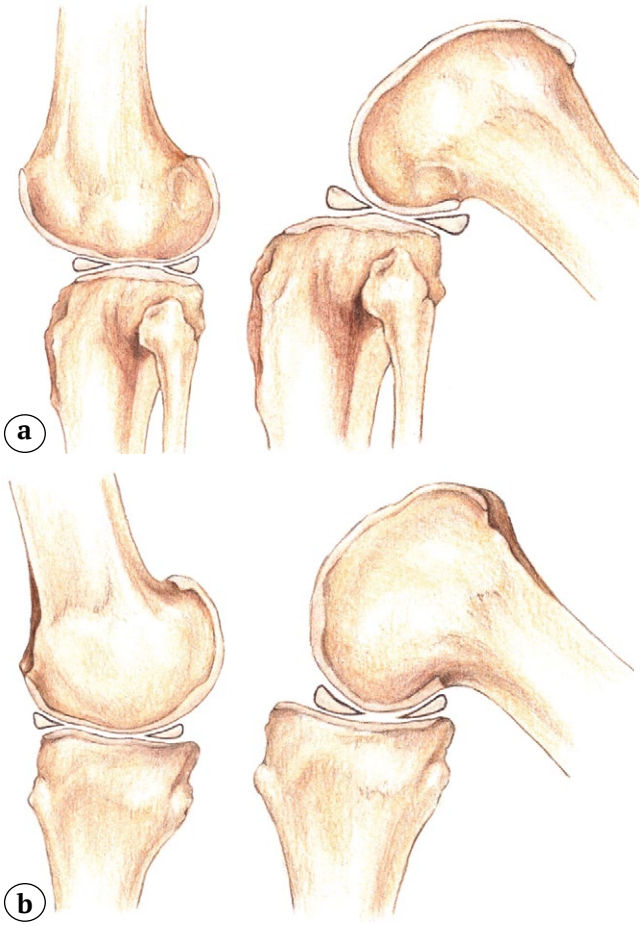

Рис. 1. Различия в мобильности латерального (a) и медиального (b) менисков коленного сустава

Fig. 1. Differences in mobility of the lateral (a) and medial (b) menisci

Движение мыщелков бедренной и большеберцовой костей является сложным биомеханическим процессом, в основе которого лежат качение и скольжение. При сгибании нижней конечности в коленном суставе суставные поверхности бедренной и большеберцовой костей в переднезаднем направлении движутся неравномерно: из положения полного разгибания в первые 10–15° сгибания происходит качение мыщелков бедренной кости по мыщелкам большеберцовой кости, далее в медиальном отделе начинается скольжение, в то время как в латеральном отделе продолжается качение примерно до 20° сгибания. Данное обстоятельство объясняет, почему расстояние, проходимое латеральным мыщелком, больше, чем медиальным (рис. 2).

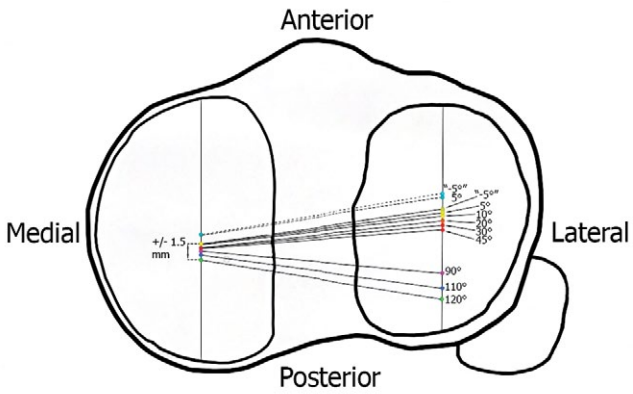

Рис. 2. Разница в длине треков мыщелков бедренной кости относительно плато большеберцовой кости на различных уровнях сгибания/разгибания коленного сустава

Fig. 2. The difference in track lengths of the femoral condyles relative to the tibial plateau at different levels of knee flexion/extension

При дальнейшем сгибании соотношение качения и скольжения значительно меняется, так что при максимальном сгибании происходит только скольжение. Качение при первых 20° сгибания обеспечивает коленному суставу максимальную стабильность, в то время как дальнейшее скольжение делает сустав более мобильным и дает больше возможности для ротации. Данные особенности объясняют наибольшую подвижность латерального отдела.

Еще одна важная особенность латерального отдела КС состоит в том, что мыщелки бедренной кости асимметричны и разновелики: медиальный мыщелок примерно на 1,3–1,5 см длиннее в переднезаднем направлении, чем латеральный. Но, несмотря на это, площадь контакта артикулирующих поверхностей мыщелков латерального отдела больше, чем медиального, ввиду описанных ранее анатомических и биомеханических особенностей. Когда бедренная кость движется по большеберцовой при последних 20° разгибания, осуществляется реализация так называемого screw home mechanism (screw locking mechanism), или «механизма доворачивания винта». Его суть заключается в том, что при последних 15–20° разгибания в коленном суставе происходит «доворачивание» голени, т.е. ее наружная ротация, становящаяся максимальной при полном разгибании голени за счет натяжения передней крестообразной связки и вектора действия четырехглавой мышцы бедра [8]. Наружная ротация голени приводит к натяжению передней крестообразной связки и глубокой порции поверхностной медиальной коллатеральной связки, что образует «замок коленного сустава», обеспечивая ему ротационную устойчивость [9, 10, 11]. Понимание данной особенности функционирования коленного сустава очень важно для латерального одномыщелкового эндопротезирования. Чтобы добиться максимально приближенной к нативной биомеханики движения, хирургу необходимо сохранить этот механизм, ориентировав бедренный компонент одномыщелкового эндопротеза в положение наружной ротации, а большеберцовый компонент — в положение внутренней ротации, чтобы при реализации screw home mechanism не происходило импиджмента между компонентами и сохранялась достаточная рабочая площадь для артикуляции компонентов (см. ниже описание хирургической техники).

Показания и противопоказания к латеральному одномыщелковому эндопротезированию

Показания:

- изолированный идиопатический гонартроз с полнослойной потерей хряща в латеральном отделе сустава, подтвержденный с помощью МРТ и рентгенограмм (в т.ч. с нагрузкой) (рис. 3);
- асептический некроз латерального мыщелка бедренной или большеберцовой кости;
- посттравматический латеральный гонартроз вследствие внутрисуставных переломов наружных мыщелков бедренной или большеберцовой костей.

Критерии отбора пациентов:

- интактные медиальный и пателлофеморальный отделы коленного сустава;
- функционально состоятельные крестообразные и коллатеральные связки коленного сустава;
- мануально корригируемая до нейтральной оси вальгусная деформация.

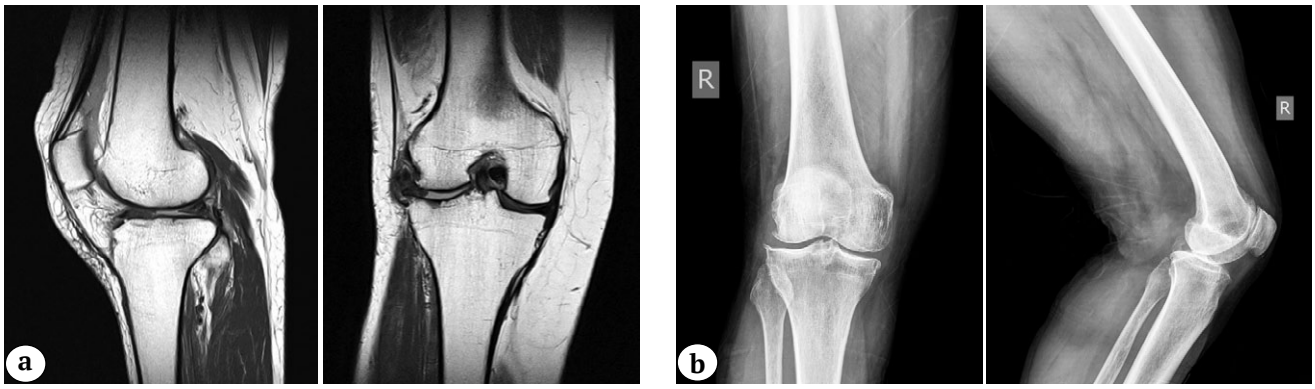

Рис. 3. Признаки локального поражения суставного хряща латерального отдела коленного сустава:
a — магнитно-резонансная томограмма латерального отдела коленного сустава;
b — рентгенограммы коленного сустава в прямой и боковой проекциях

Fig. 3. Signs of local cartilage damage in the lateral knee compartment:
a — MRI images;
b — X-rays images in anterior-posterior and lateral projections

Противопоказания

Общие противопоказания для выполнения частичного эндопротезирования являются сходными для любого планового ортопедического вмешательства: наличие активного воспалительного процесса, как локального, так и генерализованного, либо острых или декомпенсированных хронических заболеваний.

Среди частных противопоказаний необходимо выделить следующие:

• распространенный гонартроз с поражением медиального и/или пателлофеморального отделов коленного сустава;

Рис. 4. Телерентгенограмма пациента с латеральным гонартрозом перед выполнением парциальной артропластики

Fig. 4. Full-length X-ray of a patient with lateral knee osteoarthritis prior to partial arthroplasty

• несостоятельность крестообразных или коллатеральных связок коленного сустава;

• фиксированная сгибательная/разгибательная контрактура или вальгусная деформация.

Предоперационное обследование пациентов

Параметры, оцениваемые в ходе клинического обследования пациента:

• степень выраженности хромоты;

• потребность в использовании дополнительной опоры при ходьбе;

• тяжесть деформации нижней конечности на уровне коленного сустава во фронтальной и сагиттальной плоскостях;

• амплитуда пассивных и активных движений;

• степень фронтальной и сагиттальной связочной нестабильности;

• наличие контрактуры коленного сустава, ее тип и выраженность;

• возможность пассивной коррекции фронтальной деформации.

Рентгенологические исследования, выполняемые в предоперационном периоде:

• рентгенография коленного сустава в двух проекциях в положении лежа;

• рентгенография коленного сустава в прямой проекции с нагрузкой (в положении стоя со сгибанием на уровне коленного сустава 20–30°);

• телерентгенография (панорамный снимок) обеих нижних конечностей (рис. 4).

Параметры, оцениваемые в предоперационном периоде:

• стадия деформирующего артроза;

• характер деструктивных изменений костей, формирующих коленный сустав;

• выраженность фронтальной деформации конечности и локализация ее вершины [11].

Особенности одномыщелкового эндопротезирования латерального отдела коленного сустава на примере имплантата с фиксированным полиэтиленовым вкладышем

Укладка пациента

Операцию выполняют в положении пациента на спине, оперируемая нижняя конечность фиксируется держателем. Используют пневмотурникет с давлением в манжете 250–300 мм рт. ст. в зависимости от объема мягких тканей бедра либо с использованием формулы: систолическое давление пациента + 150 мм рт. ст.

Анестезиологическое пособие

Выполняется спинномозговая анестезия с внутривенной седацией, если соматическое состояние пациента не требует иного вида обезболивания.

Тромбопрофилактика

- низкомолекулярный гепарин (дозировку подбирают с учетом возраста, веса и коморбидности пациента) за 12 ч до операции;
- компрессионный эластический трикотаж I степени компрессии;
- низкомолекулярный гепарин с переводом на пероральные антикоагулянты до 21-го дня послеоперационного периода либо пероральные антикоагулянты с первого дня после операции в зависимости от уровня рисков пациента.

После проведенного клинического и рентгенологического обследований должны быть уточнены показания и противопоказания, а также возможность выполнения операции одномыщелкового эндопротезирования у данного пациента. В то же время необходимо предусмотреть возможность интраоперационного перехода на систему для тотальной артропластики.

Пациентам выполняют переднелатеральный мини-инвазивный доступ к коленному суставу (рис. 5).

Кожный разрез длиной 7–10 см осуществляют по краю надколенника от его верхнего края до латеральной поверхности бугристости большеберцовой кости. В этих же пределах производят латеральную артротомию, обходя надколенник снаружи и формируя при этом несвободный жировой лоскут из тела Гоффа. При этом ножка жирового лоскута остается фиксированной к переднелатеральной части капсулы сустава, что позволяет не нарушать кровоснабжение лоскута за счет сохранения латеральной нижней артерии (рис. 6).

Во время выполнения хирургического доступа при необходимости может быть выполнена парциальная резекция латеральной фасетки надколенника. Данный хирургический прием улучшает визуализацию латерального отдела коленного сустава и устраняет латеральный остеофит, формирующий гиперпрессию надколенника и мыщелка бедренной кости.

В ходе оперативного доступа субпериостально отслаивают часть волокон большеберцовой мышцы и передний край прикрепления подвздошно-большеберцового тракта к большеберцовой кости в объеме, достаточном для адекватного позиционирования большеберцового резекторного блока (рис. 7).

Рис. 5. Предоперационная разметка анатомических ориентиров и схема доступа к коленному суставу

Fig. 5. Preoperative marking of anatomical landmarks and access scheme to the knee joint

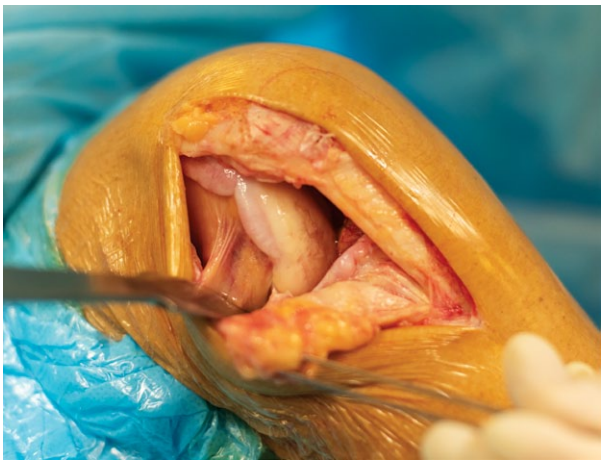

Рис. 6. Вид коленного сустава после выполнения латеральной артротомии. Пинцетом отведен жировой лоскут, который будет использован для укрытия дефекта в капсуле сустава, формирующегося после коррекции вальгусной деформации

Fig. 6. View of the knee joint after a lateral arthrotomy. The fatty flap is retracted with forceps and will be used to cover the capsule defect that occurs after correction of valgus deformity

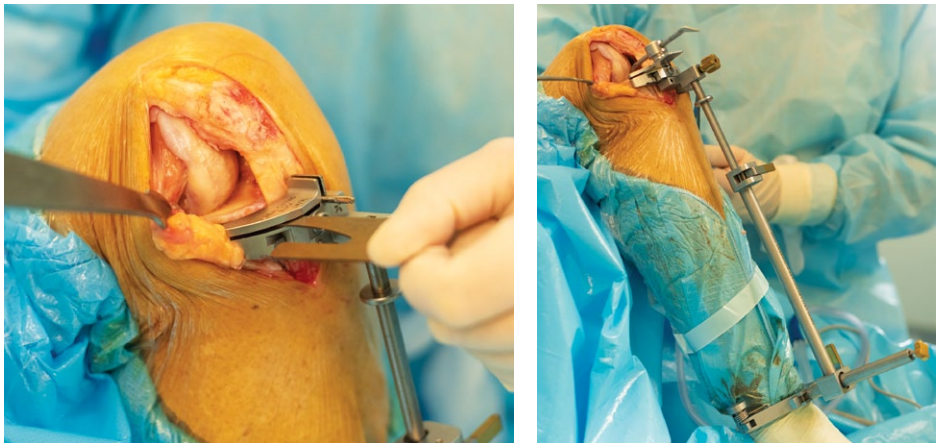

Рис. 7. Позиционирование большеберцового резекторного блока

Fig. 7. Positioning of the tibial resection block

Резецируют краевые остеофиты с латерального мыщелка большеберцовой кости, при этом оставляя краевые костно-хрящевые разрастания на латеральном мыщелке бедренной кости, которые в последующем послужат опорой для бедренного компонента эндопротеза ввиду необходимости его латерализации. Осуществляют ревизию полости коленного сустава, убеждаясь в изолированности гонартроза, оценивают глубину и характер износа суставных поверхностей латеральных мыщелков бедренной и большеберцовой костей, сохранность медиального отдела, в том числе мениска; состоятельность передней крестообразной связки; состояние пателлофеморального сочленения; наличие остеофитов на надколеннике; сохранность хрящевого покрова на его суставной поверхности. Убедившись в том, что пациент соответствует критериям имплантации одномыщелкового эндопротеза, приступают к выполнению опилов большеберцовой кости. Опилы латерального отдела плато осуществляют, располагая резекторный блок таким образом, чтобы сагиттальный опил создавал внутреннюю ротацию формируемого ложа для большеберцового компонента относительно оси голени (рис. 8).

Внутренняя ротация большеберцового компонента позволяет определить его адекватный размер, который при эндопротезировании латерального отдела коленного сустава, как правило, выбирают из первых двух размеров в линейке. При выполнении сагиттального опила большеберцовой кости по краю связки надколенника и позиционировании большеберцового компонента с внутренней ротацией даже начальные размеры тибиальных компонентов будут велики. Для обеспечения корректности данного опила его необходимо выполнять через связку надколенника, предварительно расслоив ее волокна продольно. Лезвие реципрокной пилы располагается таким образом, чтобы плоскость резекции проходила через латеральный бугорок межмыщелкового возвышения (рис. 9).

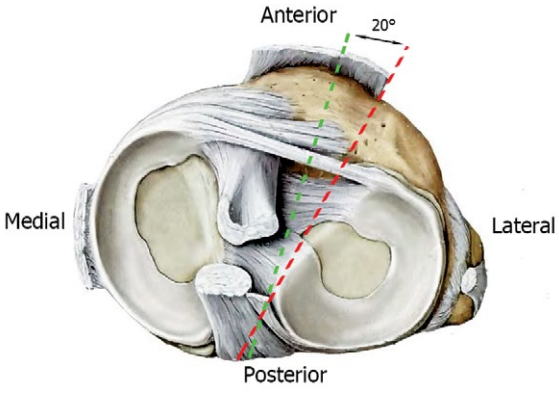

Рис. 8. Схема, демонстрирующая направление корректного выполнения сагиттального опила большеберцовой кости через связку надколенника

Fig. 8. The correct direction for performing the sagittal cut of the tibial plateau through the patellar ligament

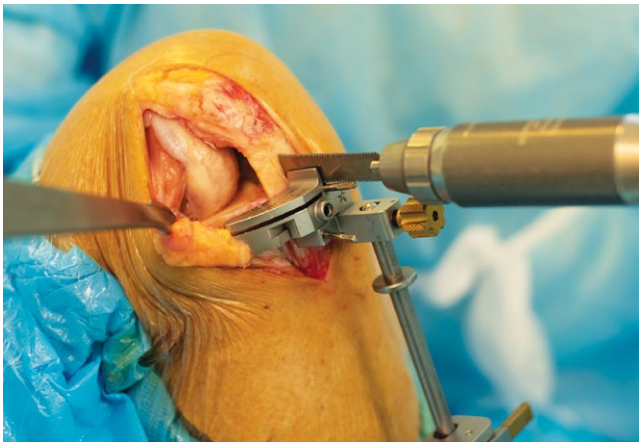

Рис. 9. Выполнение сагиттального опила большеберцовой кости через связку надколенника

Fig. 9. Performing the sagittal cut of the tibial plateau through the patellar ligament

В горизонтальной плоскости позиционируют резекторный тибиальный блок таким образом, чтобы глубина резекции была минимальной, не выходя за пределы «костной эрозии» мыщелка, не превышала 1 мм в центральной части мыщелка большеберцовой кости, чтобы был сохранен нативный наклон суставной поверхности кзади, составляющий для латерального мыщелка большеберцовой кости условные 0° (рис. 10).

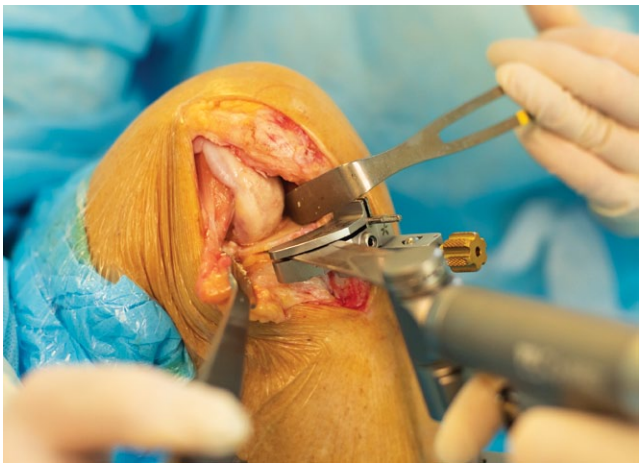

Рис. 10. Выполнение опила большеберцового плато в горизонтальной плоскости

Fig. 10. The horizontal cut of the tibial plateau

После выполнения опилов большеберцового плато в двух плоскостях необходимо извлечь костный фрагмент, желательно не фрагментируя его, чтобы оценить размеры компонента и локализацию износа (рис. 11, 12).

J. Weidow с соавторами, подчеркивая различия анатомических и биомеханических особенностей медиального и латерального отделов коленного сустава, установили, что при изолированном медиальном артрозе изнашивание хряща на большеберцовой кости локализовано преимущественно в передних отделах, в то время как при латеральном гонартрозе износ больше в центральной и задней частях наружного мыщелка [13].

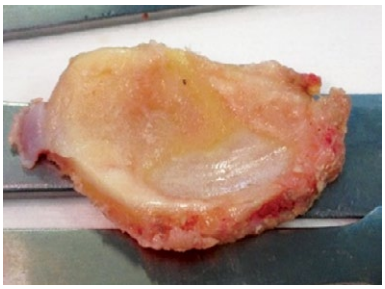

Рис. 11. Морфологическая картина опила латерального мыщелка большеберцовой кости при латеральном идиопатическом гонартрозе

Fig. 11. Morphological image of the lateral tibial plateau cut in lateral idiopathic

После выполнения резекции большеберцовой кости определяют предварительный размер сформированных разгибательного и сгибательного промежутков: убеждаются в том, что минимальный по толщине спейсер-блок не приводит к гиперкоррекции вальгусной деформации. Но при этом спейсер-блок туго вводится в положении полного разгибания конечности в коленном суставе, а в положении сгибания в коленном суставе 20° при осуществлении варизирующего усилия открывается щель в 2–3 мм. В положении легкого сгибания нивелируется натяжение задней капсулы коленного сустава между спейсер-блоком и бедренной костью. При соблюдении данного условия оценивают ориентировочную толщину примерочного вкладыша. Задав выбранным вкладышем, фиксированным в резекторном блоке для дистального опила бедренной кости необходимое натяжение разгибательного промежутка, производят фиксацию блока. Через прорезь резекторного блока производят дистальную резекцию латерального мыщелка бедренной кости (рис. 13).

Удаляют остатки латерального мениска и выполняют окончательную оценку величины разгибательного промежутка и предварительную оценку величины сгибательного промежутка в положении 90° сгибания в коленном суставе (рис. 14).

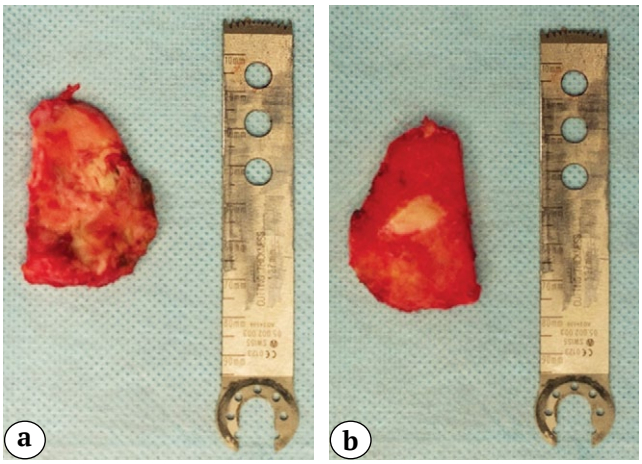

Рис. 12. Морфологическая картина опила латерального мыщелка большеберцовой кости при латеральном посттравматическом гонартрозе:
a — вид сверху; b — вид снизу. Консолидированный с деформацией перелом латерального мыщелка большеберцовой кости

Fig. 12. Morphological image of the lateral tibial plateau cut in lateral post-traumatic knee osteoarthritis:
a — view from above;
b — view from below.
Consolidated lateral tibial plateau fracture with deformity

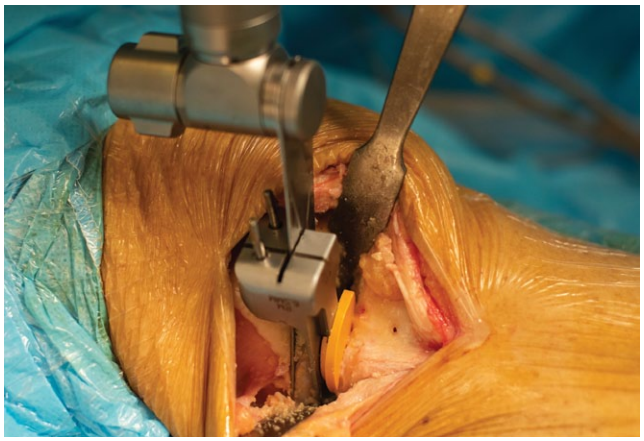

Рис. 13. Установка дистального резекторного блока и осуществление резекции бедренной кости

Fig. 13. Installation of the distal resection block and resection of the femur

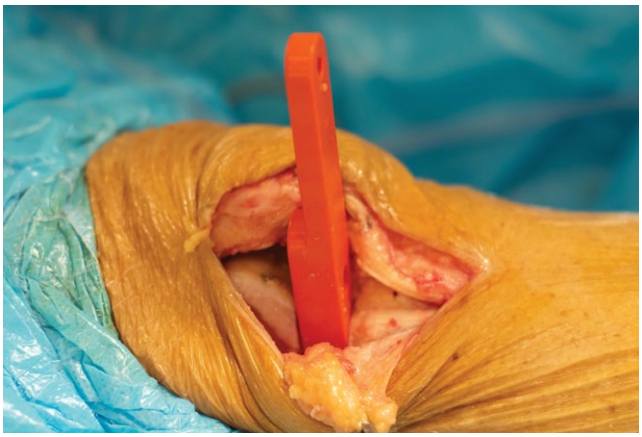

Рис. 14. Оценка разгибательного промежутка спейсер-блоком

Fig. 14. Assessment of the extension gap using a spacer block

При обеспечении адекватного мягкотканного баланса приступают к завершающим опилам латерального мыщелка бедренной кости: позиционируют резекторный блок по периферии сохраненного краевого остеофита, смещая его максимально латерально, повторяя положение латерального мыщелка, анатомически отклоненного на 10–20° относительно медиального. В заданном положении наружной ротации выполняют косой и задний опилы бедренной кости (рис. 15).

Положение наружной ротации бедренного и внутренней ротации большеберцового компонентов эндопротеза обусловлено сложной биомеханикой латерального отдела коленного сустава и позволяет реализовать механизм полицентрической ротации латерального мыщелка бедренной кости относительно латерального мыщелка большеберцовой кости. Такое позиционирование компонентов позволяет обеспечить максимально возможную площадь для их опоры на кости и препятствует импинджменту компонентов друг о друга.

После выполнения финальных опилов бедренной и большеберцовой костей и формирования отверстий под ножки компонентов эндопротеза осуществляют пробную сборку эндопротеза и оценивают кинематику протезированного сустава (рис. 16).

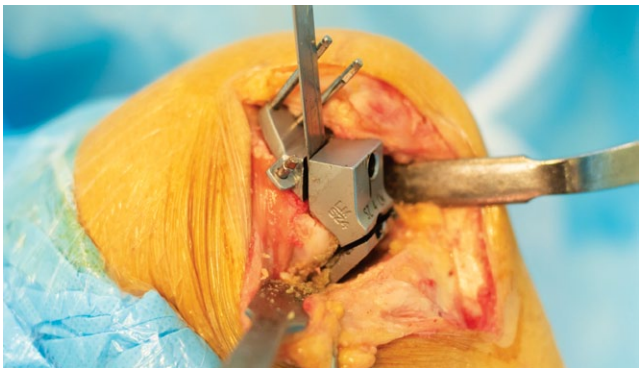

Рис. 15. Позиционирование бедренного резекторного блока перед выполнением опилов

Fig. 15. Positioning of the femoral resection block prior to performing the cuts

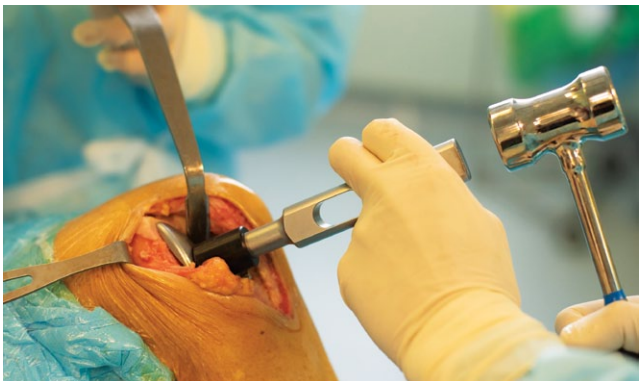

Рис. 16. Вид коленного сустава после имплантации примерочных тибиального и бедренного компонентов эндопротеза

Fig. 16. View of the knee joint after implantation of the trial tibial and femoral components

После пробной сборки определяют степень восстановления оси конечности (недопустимой является гиперкоррекция вальгусной деформации), отсутствие импинджмента бедренного компонента о край сагиттального опила большеберцовой кости и межмыщелкового возвышения, соосность скольжения бедренного компонента по поверхности большеберцового компонента с восстановлением screw-home механизма, восстановление нативного натяжения латеральных связочных структур на протяжении всей амплитуды движений в коленном суставе (корректным считают формирующееся при варусном стресс-тесте коленного сустава пространство между компонентами эндопротеза в 2–3 мм).

При адекватном позиционировании компонентов эндопротеза выполняют окончательную имплантацию (рис. 17).

Операционную рану ушивают послойно без дренирования полости коленного сустава, на следующий день выполняют рентгенологический контроль положения компонентов эндопротеза (рис. 18).

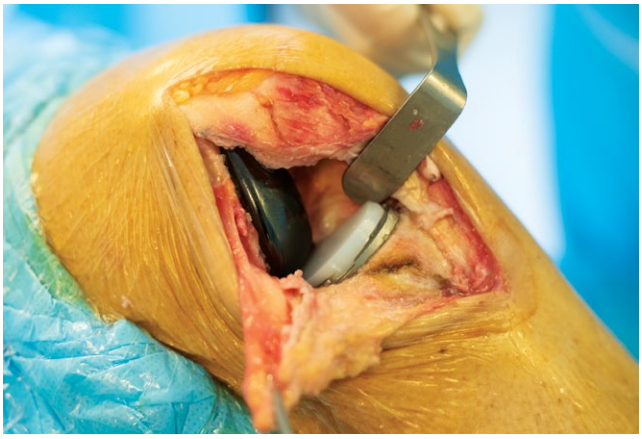

Рис. 17. Вид коленного сустава после имплантации компонентов эндопротеза

Fig. 17. View of the knee joint after implantation of the endoprosthesis components

Послеоперационное ведение и реабилитационная программа пациентов после латерального одномыщелкового эндопротезирования не отличается от реабилитации после частичной артропластики медиального отдела. Внешняя иммобилизация (гипсовая повязка, тутор, шарнирный брейс) не применяется, пациенты начинают ходить с дополнительной опорой на костыли с 1-го дня после операции. В это же время начинается разработка движений в прооперированном коленном суставе в пределах, лимитированных болевыми ощущениями.

ОБСУЖДЕНИЕ

В настоящее время одномыщелковое эндопротезирование латерального отдела коленного сустава в структуре современной артропластики выполняется примерно в 10 раз реже, чем эндопротезирование медиального отдела [14]. Это можно объяснить тем, что изолированный латеральный гонартроз является довольно редкой ситуацией, встречающейся примерно у 1% людей с деформирующим артрозом коленного сустава [14]. Несмотря на подобную «эксклюзивность», тема парциальной замены коленного сустава остается предметом повышенного интереса в современной ортопедической литературе. Известно, что ранние исследования, изучавшие данную проблему, показали большое количество неудовлетворительных результатов данной операции. Однако изменившийся подход к отбору пациентов, более совер-

Рис. 18. Рентгенограммы после выполненного одномыщелкового эндопротезирования латерального отдела коленного сустава в прямой (a) и боковой (b) проекциях; телерентгенограмма (c)

Fig. 18. X-ray images after performing lateral unicompartmental knee arthroplasty in anterior-posterior (a) and lateral (b) projections; full-length X-ray (c)

шенная хирургическая техника, а также конструкция современных имплантатов позволили сделать данное вмешательство более прогнозируемым и успешным [15, 16, 17, 18, 19].

Последние исследования, изучающие частичное эндопротезирование коленного сустава, показали ряд его преимуществ перед тотальным: менее инвазивный доступ, меньшие по объему резекции костей и мягкотканные релизы, малая кровопотеря и сохранение нативной проприорецепции прооперированного сустава [20, 21, 22, 23, 24]. Кроме того, сокращается процент случаев ранней перипротезной инфекции и риск тромбоэмболических осложнений, уменьшается болевой синдром в раннем послеоперационном периоде, а амплитуда движений в коленном суставе увеличивается [22, 24]. Стоит также отметить более короткий срок пребывания больных в стационаре и значительно более раннюю активизацию пациентов, перенесших одномыщелковое эндопротезирование по сравнению с тотальной артропластикой [25, 26].

Несмотря на вышеуказанные преимущества малоинвазивной хирургии, в случаях, когда показано выполнение лишь одномыщелкового эндопротезирования латерального отдела коленного сустава при сохранном медиальном отделе, большинство оперирующих травматологов-ортопедов предпочитают выполнение тотального эндопротезирования коленного сустава. Так, S. Campi с соавторами отмечают, что только 10% хирургов, занимающихся эндопротезированием коленного сустава, владеют техникой парциальной артропластики [27].

Изучая историю одномыщелкового эндопротезирования коленного сустава, S. Johal с соавторами отмечают, что одномыщелковое эндопротезирование латерального отдела коленного сустава выполняется примерно в 10 раз реже, чем медиальное, объясняя это недостаточностью имеющихся литературных данных о данном типе артропластики, что также является весомым аргументом для практикующего ортопеда, который стоит перед вопросом: какой тип вмешательства будет оптимальным для данного пациента? Анализируя исторические успехи и неудачи данной операции, авторы подчеркивают, что для одномыщелкового эндопротезирования тщательный отбор пациентов и опыт хирурга имеют важнейшее значение [14]. Хотя в рамках дискуссии можно заметить, что данные факторы являются абсолютно базовыми и облигатными для любого ортопедического вмешательства.

T. Bonanzinga с соавторами, проанализировав 47 научных работ на тему парциальной артропластики латерального отдела коленного сустава, пришли к выводу, что выживаемость имплантатов при пятилетнем наблюдении и удовлетворенность пациентов результатами операции сравнимы с таковыми при частичном эндопротезировании медиального отдела и тотальном эндопротезировании коленного сустава. Тем не менее авторы отмечают недостаточное количество и качество исследований, посвященных данному типу парциальной артропластики [28].

E. Deroche с соавторами, оценив в своем метаанализе 268 случаев одномыщелкового эндопротезирования латерального отдела коленного сустава, пришли к выводу, что данный тип вмешательства показал отличные результаты выживаемости имплантатов и удовлетворенности пациентов при сроках наблюдения от 5 до 23 лет. Стоит отметить, что основной причиной ревизионных вмешательств авторы считают прогрессирование артроза в других отделах коленного сустава, подчеркивая важность соблюдения строгих показаний к данной операции и требований к прецизионной хирургической технике [29].

Обзор S.D. Buzin с соавторами также показывает, что одномыщелковое эндопротезирование латерального отдела коленного сустава демонстрирует превосходные долгосрочные клинические результаты и выживаемость имплантатов при выполнении данного типа эндопротезирования у тщательно отобранных пациентов. Причем, эти выводы применимы ко всем типам имплантатов: с мобильным и фиксированным вкладышем, а также к протезам с металлическим тибиальным компонентом (metal-backed tibial component) или полностью полиэтиленовых (all-poly tibial component). Такие причины ревизий, как перелом бедренного компонента, перелом большеберцового компонента и остаточная вальгусная деформация коленного сустава, отмечались в более ранних работах и для более «старых» типов имплантов [30]. Основными причинами ревизионного вмешательства после парциального латерального эндопротезирования являются прогрессирование остеоартрита других отделов коленного сустава (медиального и пателлофеморального) и асептическое расшатывание компонентов эндопротеза. И все же, несмотря на редкие случаи необходимости ревизионного вмешательства, частота ревизий при одномыщелковом эндопротезировании латерального отдела коленного сустава вполне сравнима с парциальной артропластикой медиального компартмента и тотальным эндопротезированием коленного сустава [30].

Однако не все авторы согласны с мнением, что разные типы дизайна одномыщелкового эндопротеза одинаково хороши. Так, например, говоря о системах с мобильным вкладышем, T. Walker с соавторами в своем метаанализе отмечают, что его использование при парциальном латеральном эндопротезировании коленного сустава у большой группы пациентов в 15% случаев привело к ревизионному вмешательству в течение первых

пяти лет после первичного эндопротезирования, при этом основной причиной стал вывих мобильного вкладыша [31].

J.A. Kennedy с соавторами также отметили, что частота вывиха подвижного вкладыша при одномыщелковом эндопротезировании латерального компартмента случается примерно в 4% случаев. Авторы советуют интраоперационно оценивать стабильность мобильного вкладыша в искусственном суставе и при невозможности создать достаточное натяжение латеральных связочных структур — использовать тибиальный компонент с фиксированным вкладышем.Относительно молодой возраст, высокий ИМТ, износ хряща в пателло-феморальном отделе и высокий уровень физической активности не должны рассматриваться как абсолютные противопоказания для парциального эндопротезирования латерального отдела коленного сустава [32].

Говоря об одномыщелковых эндопротезах с фиксированным вкладышем, стоит упомянуть об имплантатах с полностью полиэтиленовым большеберцовым компонентом. Первые модели эндопротезов были представлены all-poly тибиальными компонентами, и ряд исследователей рассматривали такой вариант дизайна как золотой стандарт парциальной артропластики [33]. E. Deroche с соавторами в своем анализе, рассмотрев 54 случая парциального эндопротезирования латерального отдела коленного сустава, также пришли к выводу, что использование полностью полиэтиленового большеберцового компонента показало отличные результаты. Степень износа полиэтилена, частота ревизий и удовлетворенность пациентов операцией были сопоставимы с эндопротезами с металлической платформой и фиксированным или мобильным вкладышем [34].

Однако последние обзоры, посвященные эндопротезированию латерального отдела коленного сустава, демонстрируют, что частота ревизий при использовании эндопротеза с металлической платформой и фиксированным вкладышем (0,8%) гораздо меньше по сравнению с моделями протезов с полностью полиэтиленовым большеберцовым компонентом (8,6%) и одномыщелковыми эндопротезами с мобильным вкладышем (7,1%) [27]. Прогрессирование артроза в смежных отделах коленного сустава, некорректное выравнивание механической оси нижней конечности и асептическое расшатывание явились основными причинами ревизионных вмешательств после одномыщелкового эндопротезирования латерального отдела коленного сустава [35]. Полученные данные в очередной раз подтверждают, что точная коррекция механической оси нижней конечности, сохранение баланса сгибательного и разгибательного промежутков во время операции, тщательный отбор пациентов и использование проверенных временем имплантатов позволят значительно уменьшить риск вышеупомянутых осложнений [27, 35].

Использование компьютерной навигации и робот-ассистированной хирургии на сегодняшний день являются перспективными направлениями. Технологический прогресс в одномыщелковом эндопротезировании в настоящее время направлен на оптимизацию точности механического выравнивания оси нижней конечности, баланса промежутков и позиционирования компонентов эндопротеза, контролируемых в традиционной хирургической технике органами чувств хирурга и заметно влияющих на результат — срок выживаемости эндопротеза [36].

Так, ряд авторов, говоря в своих исследованиях об одномыщелковом эндопротезировании коленного сустава, отмечают, что как при медиальной, так и при латеральной частичной артропластике коленного сустава, выполненной с помощью роботизированной системы, отмечаются лучшие результаты по сравнению со стандартной техникой операции (преимущественно касающиеся позиционирования компонентов эндопротеза). Роботизированное одномыщелковое эндопротезирование позволяет добиться выравнивания механической оси нижней конечности, максимально приближенной к нативной, более точного ориентирования компонентов эндопротеза, что, в свою очередь, снижает частоту ревизионных вмешательств после первичной артропластики [37, 38, 39, 40].

F. Zambianchi с соавторами, исследуя робот-ассистированную хирургию латерального отдела коленного сустава, показали 100% трехлетнюю выживаемость у 67 пациентов после проведенной роботом операции [41]. R. Canetti с соавторами в своем ретроспективном исследовании продемонстрировали, что робот-ассистированное одномыщелковое эндопротезирование латерального отдела коленного сустава обеспечивает более быстрое возвращение к спорту в сравнении со стандартной хирургической техникой (4,2 мес. и 10,5 мес. соответственно) [42].

Компьютерная навигация, по мнению D. Chona с соавторами, так же, как и роботическая система, позволяют добиться более точного позиционирования компонентов одномыщелкового эндопротеза, что особенно актуально для хирургов, только начинающих осваивать парциальную артропластику [43]. По результатам последних исследований, протезирование латерального отдела коленного сустава с использованием вспомогательных компьютерных технологий показывает сопоставимые результаты со стандартной хирургической техникой. Так, C.N. Carender с соавторами в своем метаанализе установили, что одномыщелковое

эндопротезирование латерального отдела коленного сустава с использованием компьютерной навигации в среднем длится на 8 мин. дольше, чем без нее. Однако не было обнаружено достоверных различий в частоте краткосрочных послеоперационных осложнений, частоте ревизионных вмешательств и среднем времени пребывания пациентов в стационаре между парциальной артропластикой с компьютерной навигацией и прецизионной хирургической техникой [44].

Важно понимать, что, несмотря на вышеуказанные преимущества, робот-ассистированные технологии, используемые для одномыщелкового эндопротезирования латерального отдела коленного сустава, остаются достаточно дорогостоящими, имеют большое количество технических и организационных ограничений, используются в крупных хирургических клиниках и не являются общедоступной опцией [31].

ЗАКЛЮЧЕНИЕ

Потенциальными преимуществами эндопротезирования латерального отдела являются возможность сохранить естественную кинематику коленного сустава и добиться высокой степени удовлетворенности пациентов результатами перенесенной операции. Необходимы дальнейшие исследования, направленные на изучение этого сложного, но эффективного хирургического вмешательства, для того чтобы сформировать адекватные критерии отбора пациентов и оценить, какие из технических опций являются ключевыми для получения оптимального клинического результата.

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Author contribution

All authors made equal contributions to the study and the publication.

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