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Diagnosis of Deep Periprosthetic Infection of the Hip

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Periprosthetic infection (PJI) is one of the most frequent and devastating complications of total hip arthroplasty (THA). Early and accurate diagnosis of PJI allows timely initiation of treatment. Various diagnostic tools and algorithms for hip PJI diagnosis are described. The available serum (ESR, CRP, D-dimer, etc.) and synovial (alpha-defensin, leukocyte esterase, D-lactate) biomarkers are listed, as well as their combinations for the purpose of PJI verification. Combined serum and synovial tests can significantly improve the efficiency of PJI hip diagnosis.

Keywords: deep periprosthetic infection of hip, laboratory diagnosis of hip periprosthetic infection, synovial biomarkers, serum biomarkers.

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Диагностика глубокой перипротезной инфекции тазобедренного сустава

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Перипротезная инфекция (ППИ) является одним из наиболее частых и разрушительных осложнений эндопротезирования тазобедренного сустава (ТБС). Ранняя и точная диагностика ППИ позволяет своевременно начать лечение. Описаны различные диагностические инструменты и алгоритмы диагностики ППИ ТБС. Перечислены имеющиеся сывороточные (СОЭ, СРБ, D-димер и др.) и синовиальные (альфа-дефенсин, лейкоцитарная эстераза, D-лактат) биомаркеры, а также их комбинации с целью верификации ППИ. Объединение сывороточных и синовиальных тестов позволяет значительно повысить эффективность диагностики ППИ ТБС.

Ключевые слова: диагностика перипротезной инфекции тазобедренного сустава, синовиальные биомаркеры, сывороточные биомаркеры.

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BACKGROUND

Annually registers of total hip arthroplasty (THA) reported an increasing number of primary hip arthroplasty surgeries [1, 2, 3, 4]. Hence, the number of complications increases, of which the most dangerous is periprosthetic joint infection (PJI). The same registries of arthroplasty reported that PJI ranks one of the first among the reasons for revision procedures on the hip joint following primary arthroplasty. PJI ranked second in the structure of the causes of revision THA at 40.8%, following the aseptic loosening of the components, according to the Vreden Russian Scientific Center of Traumatology and Orthopedics in 2007-2020 [1].

Ahmed et al. revealed that the need of the population for THA will increase by 400% in 2030. Hence, PJI will rank first among the reasons for revision interventions after primary THA due to a decreased frequency of revisions for aseptic loosening of components and revisions for wear of bearings [2].

Nowadays, PJI is the most life-threatening complication, requiring repeated revision interventions and long courses of systemic antibacterial drugs in some cases, which cause quality of life deterioration in patients, bone and muscle tissue deficiencies, and an extensive cicatricial adhesion in the operated joint area. Postoperatively, patients with PJI require long-term follow-up, as well as prolonged antibacterial, symptomatic, and infusion therapy. hence, the duration of inpatient treatment increases, which entails additional financial treatment and rehabilitation costs. The treatment and rehabilitation process greatly affects the quality of life of patients, often causing mental and psychological disorders. Moreover, a long hospital stay may result in the growth of resistant flora and an increased risk of severe complications, such as systemic inflammatory response syndrome, pulmonary embolism, and sepsis [3, 4, 5]. The mortality rate after two-stage revision intervention for PJI was 4.22% at 1-year follow-up and >21% at 5-year follow-up [6].

To date, several algorithms are used to determine, diagnose, and treat PJI, each of which has its advantages and disadvantages. The search for new diagnostic tools continues, as well as further study of existing ones. However, no single algorithm is generally accepted for diagnosing PJI [7, 8].

The most complete and clear criteria for determining PJI were presented at the Second International Consensus Meeting on Musculoskeletal Infection (ICM) held under the leadership of J. Parvizi in 2018. According to them, a joint with at least one of the proposed main criteria, and/or a joint whose sum of the minor criteria scores is ≥6 is considered infected [9].

Considerably, this definition, as well as all ICM results, exclusively represents recommendations for PJI diagnostics and treatment for healthcare professionals in different countries. Therefore, the use of these recommendations, as a single generally accepted standard for diagnostics and treatment of PJI, cannot guarantee 100% efficiency in all possible clinical cases [9].

Nowadays, the most modern and accurate algorithms for diagnosing and determining PJI are World Association against Infection in Orthopaedics and Trauma, The European Bone and Joint Infection Society (EBJIS) 2018, and ICM 2018. The work by Kazantsev et al. presented the main characteristics of these algorithms [10].

CLASSIFICATION

According to the PJI classification proposed by Coventry and Tsukayama, the infection has four types depending on the time of manifestation of symptoms and the infection penetration manner in the operated joint area:

type I — early postoperative (up to 4 weeks);

type II — late chronic (4 weeks and more);

type III — acute hematogenous (after 1 year or more);

[1] Swedish Hip Arthroplasty Register Annual Report 2019. Available from: https://registercentrum.blob.core.windows.net/shpr/r/VGR_Annual-report_SHAR_2019_EN_Digital-pages_FINAL-ryxaMBUWZ_.pdf

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[4] The National Joint Registry 18th Annual Report 2021 [Internet]. London: National Joint Registry; 2021 Sep. Available from: https://www.ncbi.nlm.nih.gov/books/NBK576858/

type IV — positive intraoperative culture (in case of positive intraoperative inoculation results in 2-6 tissue samples).

The main manifestations of early postoperative infection (type I) may be the emergence of a fistula, edema, local hyperemia, and hyperthermia in the surgical area, as well as systemic reactions, such as an increased leukocytosis in the general blood test, and fever. This type of infection is established within 4 weeks after hip arthroplasty [11].

The DAIR (debridement, antibiotics, implant preservation) algorithm is used for an early postoperative infection [12]. Articular debridement is performed with preservation of endoprosthesis components, mandatory replacement of modular components (head/neck/liner), and microbiological examination of periprosthetic tissues (determining the sensitivity of microorganisms) to prescribe further targeted antibiotic therapy. Empirical antibiotic therapy is prescribed, followed by a transition to drugs according to the inoculation results, before obtaining the microbiological study results [13].

Late chronic infection (type II) has a much less typical clinical presentation and a different period of manifestation; most often, the first symptoms (moderate pain in the area of the operated hip joint with irradiation to the inguinal region, aggravated by axial load) start to manifest themselves in patients on week 4 postoperatively [11]. Treatment for this type of PJI involves one-stage or two-stage revision arthroplasty with prolonged antibiotic therapy. Specialists perform exarticulation of the joint or even amputation of the limb in severe cases [12].

Type III PJI develops in association with bacteriemia after infectious diseases of the urinary system, oral cavity, or respiratory tract in ≥1 year postoperatively [12]. Attention should be paid to existing foci of chronic infection if the diagnostic biomarker levels of inflammation do not decrease after PJI treatment initiation or in cases of acute symptoms of PJI during the rehabilitation phase [14]. The primary foci of acute hematogenous infection can be identified in most cases [15], and the treatment algorithm corresponds to the timing of symptom development postoperatively and is aimed at the sanitation of the focus of infection and prescribing antibacterial drugs for a long time [11].

Type IV PJI is first established in the case of microbial growth in two or more intraoperative samples of periprosthetic tissues during revision surgeries. A course of high-dose antibiotic therapy is prescribed according to the microbiological inoculation results during the revision intervention, considering the sensitivity of the identified pathogen, when type IV infection is detected [12], while specific surgical interventions are not required [11].

DIAGNOSTICS

The diagnostics include physical examination, instrumental methods (X-ray, computed tomography, etc.), laboratory methods (determination of serum/synovial biomarkers), polymerase chain reaction (PCR) study, and microbiological and cytological studies of the synovial fluid and samples of periprosthetic tissues of the joint under study to rule out the hip joint PJI.

Physical examination

Clinical evaluation, based on a combination of symptoms and risk factors for infection, is important to determine the most appropriate diagnostic strategy. The diagnosis of PJI can be established already at the initial examination of the patient in some cases. Establishing PJI is not difficult in cases of fistula, erythema, and edema in the investigated hip joint area, as well as in the presence of systemic inflammatory reactions, such as fever, algidity, and general malaise. However, chronic PJI is clinically difficult to distinguish from aseptic loosening of endoprosthesis components because clinical signs of infection may be completely absent [12]. The clinical presentation of PJI depends on the virulence of the involved etiological agent, the nature of the infected tissue, the route of infection, and the illness duration. The possibility of PJI should always be considered even in the absence of obvious evidence of infection [16]. Careful collection and assessment of the patient's history, as well as clinical examination, are important tools to screen for PJI and perform a correct diagnostic search [17].

Instrumental diagnostic methods

The main method of visualization in diagnosing PJI is standard radiography, namely plain radiographs of the pelvis and the hip joint under study. Plain radiographs are especially useful in the assessment of the pathological process that changes over time, compared to previous images. Signs indicating the development of a pathological process include a radiolucent line (osteolysis) at the cement-bone interface (when using cement fixation) or at the metal-bone interface (uncemented use), which are associated with bone destruction [18]. However, osteolysis and implant migration may be present on patient radiographs and in case of aseptic loosening of endoprosthesis components [19].

Positron emission tomography with intravenous administration of 18F-fluorodeoxyglucose provides a higher spatial resolution of the image zones, which imparts a significant advantage to this method compared with other X-ray diagnostic methods. However, clearly differentiating the pathological process etiology is not possible because neutrophilic granulocytes and tissue macrophages that absorb the contrast agent can be present in both septic and aseptic processes [20].

The use of magnetic resonance imaging (MRI) and computed tomography (CT) in PJI diagnostics is limited due to their high cost and low specificity. However, specialists use MRI to assess the soft tissue condition and the neurovascular formation location and identify fistulous tracts and fluid accumulations in the hip joint area. Additionally, various modes of metal artifact suppression in modern magnetic tomographs enable to further improve the image quality [21]. The obtained data from CT examination of the affected joint can be extremely useful within determining the extent of revision surgery [22].

Notably, imaging diagnostic methods are not included as recommended diagnostic criteria according to ICM (2018) [9, 17].

Laboratory diagnostics

Serum markers

Serum biomarkers represent a fast and affordable tool for diagnosing PJI both in hospital and outpatient settings [23]. However, the time elapsed from the surgery when interpreting their indicators, and comorbidities should always be considered, as well as other factors affecting the result [24]. Importantly, PJI may exist in cases with normal serological test values [25].

Erythrocyte sedimentation rate and C-reactive protein

Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) determinations are currently recommended as first-line screening tests for PJI and are part of the diagnostic criteria proposed by ICM (2018). However, CRP and ESR may not be effective in detecting PJI in patients with a history of systemic inflammatory diseases, as well as in the early postoperative period [24]. The level of ESR and CRP reaches a peak value on postoperative days 2-3. CRP values return to normal values 1 month postoperatively, and ESR values become normal only after 3 months [26]. Dugdale et al. determined the optimal threshold values for diagnosing PJI, including a CRP of >100 mg/l and ESR of >46 mm/h up to 6 weeks, and CRP of >33 mg/l and ESR of >47 mm/h from 6 to 12 weeks. The authors note that laboratory studies, conducted from 6 to 12 weeks postoperatively, are more effective and veracious [27].

D-dimer

D-dimer is a fibrin breakdown product formed when plasmin dissolves a fibrin clot. Thus, the fibrinolytic system is activated in the body with the development of an infectious process, which, in turn, leads to an increase in the blood D-dimer level [28]. D-dimer is promising as a diagnostic serological marker in PJI with a sensitivity of 89% and a specificity of 93% [29]. Blood D-dimer determination is an effective and accurate tool for diagnosing PJI, especially in patients without a history of coagulopathy [30, 31]. Elevated D-dimer levels may indicate the presence of an inflammatory process not associated with infection (thrombosis, oncological diseases, etc.) [28]. Conversely, the diagnostic efficiency of D-dimer determination does not exceed ESR and CRP [32]. Additionally, the absence of a single D-dimer threshold value, different laboratory systems of determination, and other factors require further study of the possibility of using serum D-dimer as a marker for diagnosing PJI [31].

Interleukin-6

Interleukin-6 (IL-6) is produced by immune cells and induces the production of major proteins in the acute phase of inflammation, including CRP and B- and T-lymphocytes, in the presence of bacterial infection [33]. The blood serum IL-6 level reaches its peak values on day 2 after uncomplicated joint arthroplasty and acquires quickly the normal values [34]. Serum IL-6 is a valuable and accurate marker with greater diagnostic accuracy than ESR or CRP in chronic PJI diagnostics. In particular, the diagnostic odds ratio for IL-6 was 314.7 compared to 13.1 and 7.2 for CRP and ESR, respectively [34]. Joint determination of IL-6 and CRP in the blood serum enables PJI detection in 100% of cases [35]. Elgeidi et al. revealed the method sensitivity, specificity, and accuracy as 100%, 90.9%, and 92.5%, respectively, at a threshold value of blood IL-6 of >10.4 pg/ml [36].

Some authors used a combination of serum and synovial IL-6 to more accurately determine PJI [37, 38]. The obtained data revealed a 96.77% accuracy of diagnosing PJI when determining the combination of serum and synovial IL-6, which is higher than when using serum (84.95%) and synovial (93.55) IL-6 separately [37].

The method disadvantages are elevated IL-6 levels in patients with chronic inflammatory diseases of other organs (urinary tract, lungs, and heart), Paget's disease, and immunodeficiency syndromes [38].

Synovial markers

With all their advantages, a significant disadvantage of serum tests is their low specificity. Thus, some biomarkers may increase in response to inflammatory reactions associated with other diseases. Hence, the attention of specialists involved in PJI has recently been focused on the assessment of synovial fluid biomarkers as a possible breakthrough in diagnosing complicated PJI cases [17, 37]. Synovial biomarkers provide high accuracy in diagnosing PJI, including in patients with systemic diseases, as well as in patients taking antibacterial drugs [39].

Alpha-defensin

Alpha-defensin is a pro-inflammatory biomarker secreted by human neutrophils in response to the presence of microbial pathogens [40]. Alpha-defensin is detected using an enzyme-linked immunosorbent assay (ELISA) or a test strip kit for the rapid detection of alpha-defensin in synovial fluid [41]. The rapid test is a convenient and fast alternative to laboratory analysis (ELISA) and allows intraoperative PJI detection. The qualitative result of the rapid test is available in just 10 min, which is noticeably faster than the ELISA test (quantitative result within 24 h). The alpha-defensin rapid test was recently approved in the United States of America and commercialized specifically for diagnosing PJI after large joint endoprosthesis replacement [17]. The undoubted advantage of the method is the possibility of diagnosing PJI in patients with a history of systemic inflammatory diseases, as well as in patients who continue to take antibacterial drugs [42, 43]. However, the probability of false-positive results increases if the aspirated synovial fluid is contaminated with associated blood, as well as in cases of pronounced metallosis or polyethylene debris formation in the periprosthetic tissues [44].

Leukocyte esterase

Leukocyte esterase (LE) is an enzyme that is produced by neutrophils at the bacterial infection site. LE detection has traditionally been used to diagnose urinary tract infections. LE is detected in synovial fluid using inexpensive colorimetric test strips. LE is a fast and inexpensive method for diagnosing PJI with high specificity and sensitivity [45]. Importantly, the assessment and interpretation of the changes in the test strip colors depend on the specialist performing the study. Some experts recommend centrifuging the obtained synovial fluid for 2 min, if it is contaminated with associated blood or metal or polyethylene debris products, to perform a study of pure synovial fluid [46].

D-lactate

D-lactate is a specific marker for the presence of a bacterial infection and is the predominant form of lactic acid produced by various types of

bacteria and fungi. This biomarker has been used by specialists for diagnosing bacterial infections for a long time [47]. The studies by Yermak et al. and Karbysheva et al. are particularly valuable, considering the small number of studies on the use of D-lactate for PJI verification. The presented results revealed that the D-lactate level in the synovial fluid, which enables us to consider the joint as infected, is 1.3 mmol/l with a sensitivity of 94.3% and specificity of 78.4% [48]. Additionally, the method sensitivity and specificity are 86.4% and 80.8%, respectively, at a threshold value of 1.263 mmol/l [49]. Synovial D-lactate determination enables us to verify PJI in a short time (result within 1 h) and with high sensitivity [50].

Synovial fluid viscosity

Some authors propose to determine the synovial fluid viscosity to verify PJI. Fu et al. demonstrated that synovial fluid viscosity determination is a potentially important method for diagnosing PJI. According to their data, the synovial fluid viscosity in patients with PJI is significantly lower (7.93 mPa/s) than in patients with non-infectious loosening of endoprosthesis components (13.11 mPa/s). The obtained results are comparable in terms of the accuracy of diagnosing PJI with the indices of serum biomarkers CRP, ESR, and D-dimer (sensitivity 93.33% and specificity 66.67%). The authors note that their study is currently the only one in the available literature that determines the synovial fluid viscosity as a marker of PJI and states the need for further research on the use of this method for diagnosing PJI [51].

Cytological examination of synovial fluid

An increased synovial fluid of leukocytes of >3000 in 1 μl associated with a neutrophilic shift (>80%) may be a sign of PJI of the joint under study [9]. The study of the cellular composition of the synovial fluid in patients with fistulous tracts communicating with the joint cavity, which is accompanied by profuse discharge, should be considered. The synovial fluid may be completely absent due to an active fistula, and the cytological data validity may be reduced in case of its presence. This fact is confirmed by the guidelines for a rapid test system that determines the presence of alpha-defensin proteins in the aspirate from the joint cavity with a functioning fistula due to the increased risk of false-negative results [10].

Zahar et al. determined the sensitivity and specificity of the method depending on the accepted threshold value. The best diagnostic accuracy was achieved at a level of 2582 leukocytes/μl (sensitivity of 80.6%; specificity of 85.2%) and 66.1% of polymorphonuclear neutrophils (sensitivity of 80.6%; specificity of 83.3%). The indicators have 83.6% sensitivity and 82.2% specificity at a threshold value of 1630 leukocytes/μl, and 80.3% sensitivity and 77.1% specificity with 60.5% of polymorphonuclear neutrophils [52].

Diagnostic joint aspiration

Diagnostic aspiration of synovial fluid followed by microbiological and cytological analyzes is an invasive method for diagnosing PJI. Its success depends on the specialist performing the study [53]. Various imaging techniques, including ultrasound and fluoroscopic navigation, are used to accurately perform joint cavity aspiration. Duck et al. revealed an 87% accuracy of the method using ultrasound navigation; the method sensitivity and specificity were 83% and 89%, respectively [54]. Kanthawang et al. evaluated the efficiency of fluoroscopic (roentgenoscopic) navigation. The method accuracy in diagnosing PJI was 78.5% and the sensitivity index was 64%, according to the ICM criteria (2018) [55].

Randelli et al. conducted a comparative analysis between ultrasound navigation and fluoroscopic navigation and revealed that ultrasound navigation had higher diagnostic values at a lower cost compared to fluoroscopic navigation, with a sensitivity of 89% compared to 60% and specificity of 94% compared to 81%. Additionally, the cost at the time of the study was 125.30 € versus 343.58 € per study [56].

A specialist may be faced with obtaining only associated blood or with a complete absence of fluid (dry joint) when performing a diagnostic hip joint cavity aspiration. Some authors suggest injecting 10 ml of 0.9% saline solution into the joint cavity and immediately aspirating it in the case of a dry joint, and they recommend diluting the resulting aspirate with 0.9% sa-

line solution when obtaining associated blood [7, 54]. Considerably, distortions in the test results are possible when diluting the punctate [57]. Thus, the accuracy of diagnostics is 69% when obtaining a hemorrhagic aspirate and 60% when rinsing a dry joint compared with 87% in studies with obtaining synovial fluid [54]. Barker et al. analyzed and determined the mean joint aspiration volume for infected and non-infected joints (6 ml [2–36 ml] and 11 ml [1–200 ml], respectively) [58]. An important condition for performing diagnostic aspiration is the abolition of antibiotic therapy at least 14 days before the puncture, because this may contribute to obtaining unveracious results of microbiological examination [59]. The use of bacteriostatic solutions when rinsing the joint and the use of local anesthesia of deep tissues in the joint area under study should also be excluded [54, 55].

Methods of molecular diagnostics

The PCR technique is a simple and automated method for analyzing a biomaterial sample, which does not require an incubation period. A new generation of multiplex PCR for PJI diagnostic demonstrates a fast and accurate result, making it possible to identify the pathogen within 5 h, which enables us to prescribe timely targeted antibiotic therapy in comparison with the standard microbiological study (5–14 days) [60].

Li et al. demonstrated the combined sensitivity and specificity of the method of 70% and 92%, respectively [61]. Lausmann et al. believe that PCR diagnostics can detect even culture-negative infections, including in patients taking antibacterial drugs [60].

The disadvantages of PCR are related to the type of study, as multiplex PCR enables specific organism identification depending on the primers used, in contrast to broad-spectrum PCR, which can detect DNA from many types of cultures but not microbial associations. The disadvantages also include the high cost of the study (¥1200) [62, 63]. However, PCR diagnostics can become a fast and accurate test that complements traditional microbiological examination [64].

Microbiological examination

To date, the gold standard for diagnosing PJI is the microbiological examination of the synovial fluid, as well as intraoperative samples of periprosthetic tissues [9]. Qu et al. revealed the method sensitivity and specificity of 70% and 94%, respectively, which indicates a high diagnostic value of the method [65].

Strictly following the rules for collecting, processing, and transporting biomaterial is necessary to obtain accurate microbiological examination results [10]. An important requirement for microbiological examination is the abolition of antibiotic therapy for at least 14 days [66]. The probability of false-positive (contamination during sampling) and false-negative (culture-negative infections/microorganisms in biofilms/low-virulent strains) results, together with the time for obtaining the result up to 14 days, constitute significant disadvantages of this method [67, 68].

Sonication

Sonication (ultrasound treatment of the removed components of the endoprosthesis) is actively used within the intraoperative diagnostics of PJI, followed by a microbiological examination of the obtained fluid. Some authors revealed that this enabled us to improve the accuracy of diagnosing PJI due to the destruction of biofilms under the action of ultrasonic waves and the dispersion of microorganisms in the sonic fluid and to establish a diagnosis in situations previously treated as aseptic loosening [20]. The sensitivity score for sonication is significantly superior to the standard microbiological examination of tissue samples, namely 97% vs. 57% for synovial fluid and vs. 70% for periprosthetic tissue samples. However, the sonication method specificity is comparable to that of a standard microbiological study (90% and 100%, respectively) [69]. The sensitivity index was 96.3% when combining the methods of sonication and microbiological examination [70].

Aspects of compliance with the algorithm for preoperative diagnostics of periprosthetic infection

A specialist may encounter some difficulties when performing a diagnostic algorithm. Thus, obtaining liquid during the hip joint aspiration is not always possible. Hence, the use of synovial biomarkers is not possible when diagnosing PJI.

Christensen et al. believe that paying special attention to the result interpretation is necessary when diagnosing PJI in "dry joints" [71].

Strictly adhering to the chosen algorithm for diagnosing and determining PJI is worthy in cases of obtaining ambiguous microbiological study results, as well as serological and synovial tests. Observing the stages of diagnostic measures and performing a comprehensive preoperative diagnostic study, two or even three times with an interval of 14–30 days, is important [7].

Notably, Charette and Melnic revealed that the incidence of culture-negative infections varies from 2% to 18% despite all possible diagnostic measures [72].

CONCLUSION

PJI diagnostics remain a difficult task, which can be solved using a multidisciplinary approach, as well as additional training of outpatient doctors and hospital specialists to be alert to PJI. Existing scientific studies revealed that the combination of the serum and synovial test results, as well as the use of a multidisciplinary approach, improves the speed and accuracy of diagnosing PJI.

The development and research of new diagnostic methods with greater accuracy, simplicity, convenience, and low cost will increase the efficiency of diagnosing PJI, thereby avoiding possible adverse consequences.

DISCLAIMERS

Author contribution

Murylev V.Yu. — design of the study, literature review, analysis and statistical processing of data, writing the draft, editing.

Rudnev A.I. — design of the study, literature review, writing the draft, editing.

Kukovenko G.A. — design of the study, literature review, collection and processing of material, writing the draft.

Elizarov P.M. — design of the study, analysis and statistical processing of data.

Muzychenkov A.V. — collection and processing of material.

Alekseev S.S. — collection and processing of material.

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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