

# Comparison Outcomes of Discover Total Disk Arthroplasty and Anterior Cervical Discectomy with Fusion in Surgical Treatment of Cervical Disk Degenerative Disease: a Meta-Analysis of Randomized Trials

V.A. Byvaltsev<sup>1,2,3,4</sup>, I.A. Stepanov<sup>1</sup>, M.A. Aliyev<sup>1</sup>, B.M. Aglakov<sup>1</sup>,  
B.R. Yussupov<sup>1</sup>, V.V. Shepelev<sup>1</sup>

<sup>1</sup> Irkutsk State Medical University, Irkutsk, Russian Federation

<sup>2</sup> Railway Clinical Hospital on the station Irkutsk-Passazhirskiy of Russian Railways Ltd., Irkutsk, Russian Federation

<sup>3</sup> Irkutsk Scientific Center of Surgery and Traumatology, Irkutsk, Russian Federation

<sup>4</sup> Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation


## Abstract

**The purpose** — to compare the effectiveness of Discover cervical disk arthroplasty (CDA) and anterior cervical discectomy with fusion (ACDF) in the surgical treatment of cervical intervertebral disk (IVD) degenerative disease. **Study design** — a meta-analysis of randomized clinical trials. **Materials and Methods.** Randomized clinical trials were conducted in the PubMed, EMBASE, ELibrary and Cochrane Library databases published from 2008 to October 2018, which compared the results of Discover CDA and ACDF techniques in the surgical treatment of cervical IVD degenerative disease. For dichotomous variables, the relative risk and 95% confidence interval were calculated, standardized difference of mean values and their 95% confidence interval were used for continuous variables using the random effects model. **Results.** This meta-analysis included 9 randomized controlled clinical trials, including the results of surgical treatment of 513 patients with degenerative disease of the cervical IVD. In the CDA group, the operation time was significantly shorter, in contrast to the group of patients who underwent ACDF ( $p < 0.0001$ ). The values of blood loss ( $p = 0.89$ ), levels of quality of life for patients according to the Neck Disability Index (NDI) ( $p = 0.22$ ), severity of pain in the cervical spine ( $p = 0.50$ ) and upper limbs on a visual analogue scale (VAS) ( $p = 0.16$ ), as well as the prevalence of secondary surgical procedures ( $p = 0.68$ ) and adverse events ( $p = 0.40$ ) between the compared groups did not have significant differences. At the same time, significantly large values of the range of motion at the operated level were noted in the CDA group ( $p < 0.00001$ ). **Conclusion.** Discover CDA in comparison with ACDF has a significantly large values of range of motion at the operated level. At the same time, there were no statistically significant differences in the NDI scores, VAS pain scores in cervical spine and upper limbs, and the prevalence of secondary surgical procedures and adverse events between the compared groups of respondents were not identified.

**Keywords:** cervical intervertebral disk, degenerative disease, Discover total disk arthroplasty, anterior cervical discectomy and fusion, meta-analysis, randomized controlled trials.

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 **Vadim A. Byvaltsev;** e-mail: vadimabyvaltsev@gmail.com

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## Introduction

Anterior interbody fusion (ACIF) is the golden standard in surgical treatment of patients with degenerative diseases of cervical intervertebral discs (IVD). According to various authors ACIF is a highly efficient method allowing to level present clinical and neurological symptoms in patients with degenerative cervical IVDs [1, 2]. Nevertheless ACIF is associated with some adverse events like hypermobility, pseudarthrosis, dysphagia and degeneration of adjacent spinal motion segments [3]. At the end of the last century a method of total arthroplasty (TA) of cervical IVDs [4] was developed and introduced into the clinical practice.

Currently TA of cervical IVD is widespread in many neurosurgical clinics of the world [5]. Some researchers have the opinion that TA procedure has a high clinical efficiency in patients with degenerative diseases of cervical IVDs, allows to maintain physiological range of motion in the operated segment and to prevent degeneration of adjacent segments [5, 6].

Global medical industry developed a variety of prostheses for TA of cervical IVDs. Every prosthesis is featured by a special design, biomechanical parameters, implantation technique, clinical and roentgenological efficiency. Some promising randomized clinical studies were discovered during search through literature in the PubMed, EMBASE and eLibrary databases presenting outcomes of Discover prosthesis (DePuy Spine, USA) application for TA in patients with degenerative diseases of cervical IVDs [7–12]. The outcomes turn to be controversial to a large extent which stimulated the authors to conduct the present meta-analysis.

**Purpose of the study** — to compare the efficiency of TA by Discover prosthesis and anterior cervical interbody fusion (ACIF) in

surgical treatment of degenerative diseases of cervical intervertebral discs (IVD).

**Study design** — meta-analysis of randomized clinical studies which compare methods of TA by Discover prosthesis and anterior cervical interbody fusion (ACIF) in surgical treatment of degenerative diseases of cervical intervertebral discs (IVD).

## Material and Methods

### *Strategy of search and selection of literature*

The authors performed search of randomized clinical studies in PubMed, EMBASE, eLibrary and Cochrane Library databases published in the period from 2008 to October 2018 where authors compare outcomes of TA methods by Discover prosthesis and ACIF in surgical treatment of degenerative diseases of cervical IVDs. Search of literature was conducted by two researchers. In case of disputes related to inclusion of studies into the meta-analysis the decision was made collectively by the whole group of authors. The search was done in accordance with international recommendations on preparing the systematic reviews and meta-analysis PRISMA [13].

The first stage included the search of literature using keywords «Discover cervical disk arthroplasty», «Discover cervical total disk replacement», «anterior cervical discectomy and fusion», «cervical spine degeneration», «cervical intervertebral disk degeneration» in English-language systems; and similar combination of words in Russian — in the National Russian Electronic Library. The second stage included review of abstracts to exclude publications not corresponding to such criteria. The third stage included review of full texts of publications to confirm correspondence to criteria and lists of references to see if those contain relevant studies (Fig. 1).

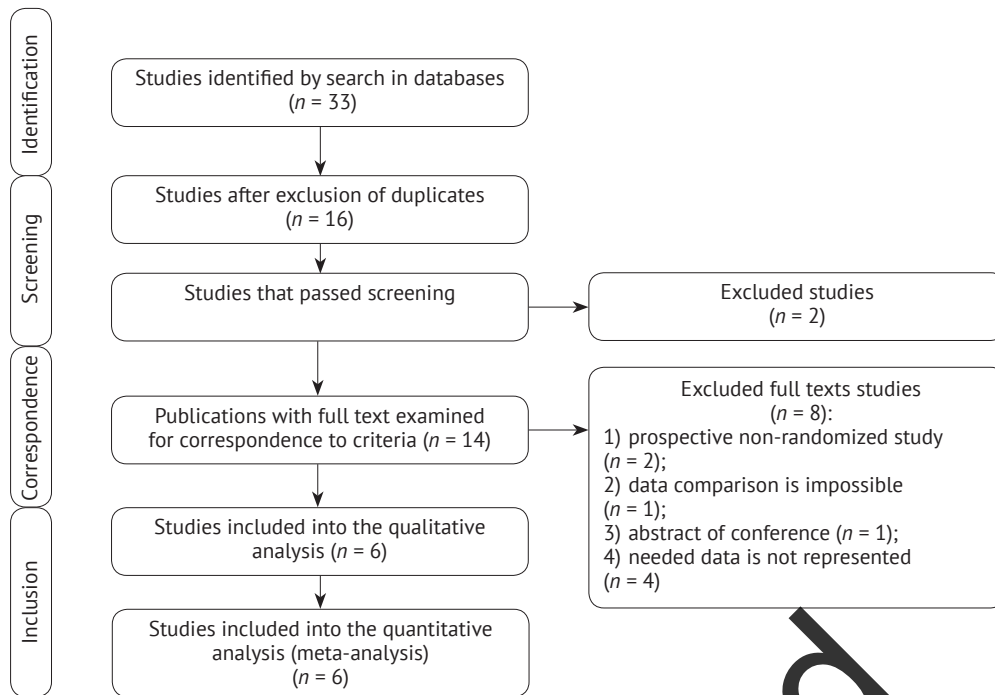


Fig. 1. Flow chart showing search strategy

### Correspondence criteria

To compare efficiency of two mentioned surgical procedures the following correspondence criteria were defined:

1) included studies: randomized clinical studies examining outcomes of TA by Discover prosthesis and ACIF in adult patients with degenerative diseases of cervical IVDs along with clinical and neurological symptoms (radiculoneuragia, radiculoneuritis, radiculopathy);

2) types of surgical procedures: studies comparing TA of cervical IVDs by Discover prosthesis and ACIF with various implants;

3) outcomes: studies analyzing clinical and instrumental outcomes of described procedures; life quality of patients related to limitation of motions in cervical spine by NDI (Neck Disability Index); severity of pain syndrome in cervical spine and upper limbs on VAS scale; frequency of adverse events and degeneration of adjacent spine motion segments; as well as rate of revisions;

4) study design: randomized clinical studies with methodology quality evaluation no less than 3 on Jadad scale [14] were included into the analysis.

### Valuation of risk of bias

Each study included into the meta-analysis was evaluated using a Risk of bias tool under Review Manager 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014, Denmark) on the following parameters:

- 1) data sequence generation;
- 2) hiding of study data;
- 3) use of blinding;
- 4) incomplete list of obtained data;
- 5) selective presenting of study outcomes;
- 6) other bias (table 1).

Total valuated risk of bias for all studies were distributed for “low”, “uncertain” and “high” (Fig. 2).

Table 1

Valuation of risk of bias for studies included into the meta-analysis

Studies	Bias parameters					
	data sequence generation	hiding of study data	use of blinding	incomplete list of obtained data	selective presenting of study outcomes	other parameters
Chen Y. et al., 2013	+	?	?	+	+	+
Luo C. et al., 2015	+	?	?	+	+	+
Rozankovic M. et al., 2017	?	?	?	+	+	+
Shi S. et al., 2016	?	?	?	+	+	+
Skeppholm M. et al., 2015	+	+	+	+	+	+
Sun Q. et al., 2016	+	?	?	+	+	+

+ – low risk; ? – uncertain risk.

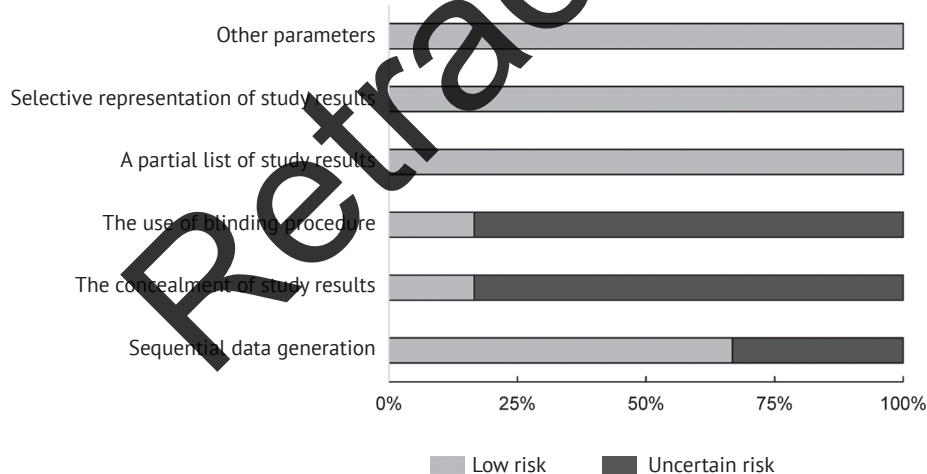


Fig. 2. Risk of bias assessment for all included studies

Statistical data analysis

The authors calculated a relative risk (RR) and 95% confidence interval (CI) for dichotomized variable. Standardized difference of average values (SDA) and 95% confidence interval (CI) with the random effects model (REM) was used for continuous vari-

able. Coefficient I2 was used for evaluation of heterogeneity. With I2 coefficient value less than 25% the studies were considered homogeneous, from 25 to 50% – low rate of heterogeneity, from 50 to 75% – moderate heterogeneity, over 75% – high heterogeneity. Skewness of the study was analyzed

by plotting a funnel diagram and linear regressive Egger’s test. Tree diagrams were plotted with Review Manager 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014, Denmark). Differences were considered statistically significant with  $p \leq 0,05$ .

**Results**

*Search of literature*

Based on correspondence criteria the present meta-analysis includes 6 randomized controlled clinical studies with outcomes of surgical treatment of 513 patients with degenerative diseases of cervical IVDs. Overall characteristics of included studies are present in table 2.

All studies reflect the main clinical, instrumental and intraoperative parameters; contain information on application of an artificial Discover cervical IVD as well as cages and bone autografts for ACIF.

*Time of surgical procedure*

Three randomized clinical studies present information on time of operative procedures [10–12]. Cumulative analysis of obtained data indicates that in the group of TA for cervical IVDs the time of procedure was statistically significantly less as compared to the group of patients who underwent ACIF (SDA = -0.71, 95% CI: -1.07, -0.36,  $p < 0.0001$ ; I2 = 49%) (Fig. 3).

*Blood loss volume*

The authors included three randomized clinical studies which compared volume of blood loss after TA procedure and ACIF [10–12]. Meta-analysis of studies outcomes demonstrated the absence of statistically significant differences in volumes of blood loss in compared procedures (SDA = -0.02, 95% CI: -0.33, -0.20,  $p = 0.89$ ; I2 = 87%) (Fig. 4).

**Overall characteristics of studies included into the meta-analysis**

Table 2

Study	Year	Country	Number of operated segments	Number of patients		Average age, years		Gender (male/female)		Time of follow up, months
				TA	ACIF	TA	ACIF	RA	ACIF	
Chen Y. et al. [7]	2013	China	1	16	16	43.2	46.5	9/7	8/8	24
Luo C. et al. [8]	2015	China	1	34	37	47.2	46.3	18/16	20/17	48
Rozankovic M. et al. [9]	2017	Croatia	1	51	50	41.3	41.9	25/26	25/25	24
Shi S. et al. [10]	2016	China	1	60	68	46.5	47.4	36/35	24/33	24
Skeppholm M. et al. [11]	2015	Sweden	2	81	70	45.3	46.7	40/41	33/37	24
Sun Q. et al. [12]	2016	China	2	14	16	46.7	48.1	9/5	11/6	32.4

TA — total arthroplasty of intervertebral disc; ACIF — anterior cervical interbody fusion.

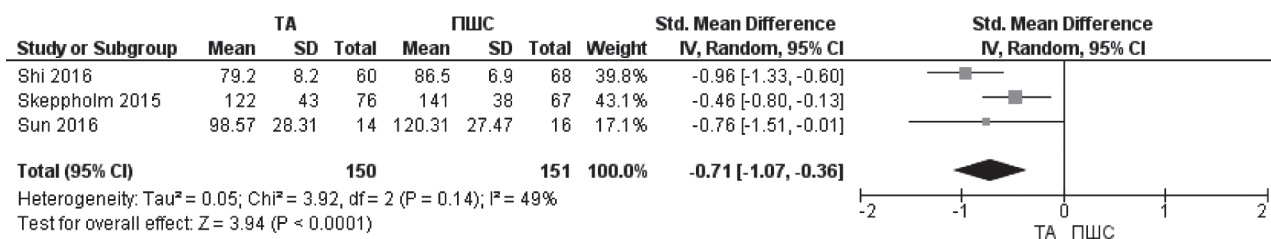


Fig. 3. Forest plot for operation time

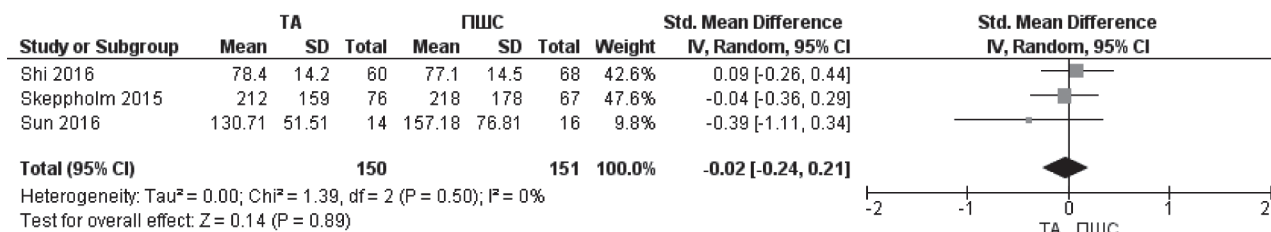


Fig. 4. Forest plot for blood loss

*Life quality according to NDI*

All studies included into the meta-analysis present information on life quality of the patients by NDI after procedures of TA and ACIF. High values of patients' life quality by NDI were verified in group of TA for cervical IVDs as well as in the group of patients who underwent ACIF (SDA = -0.33, 95% CI: -0.86, 0.20, p = 0.22; I<sup>2</sup> = 87%) (Fig. 5).

*VAS pain severity in cervical spine*

Information on pain syndrome severity by VAS in cervical spine and upper limbs after TA of cervical IVDs and ACIF was reported in three studies [8, 9, 12]. No statistically significant differences in VAS pain severity values in cervical spine were observed between the groups (SDA = -0.37, 95% CI: -1.845, 0.70, p = 0.50; I<sup>2</sup> = 95%) (Fig. 6).

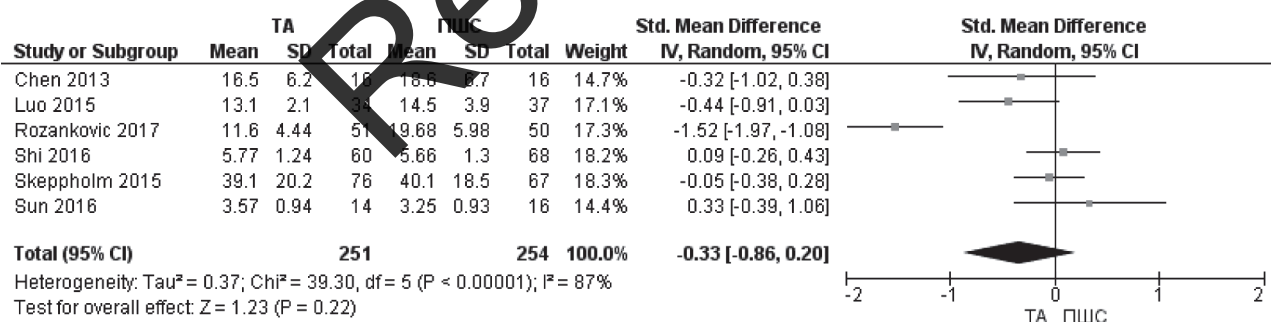


Fig. 5. Forest plot for NDI score

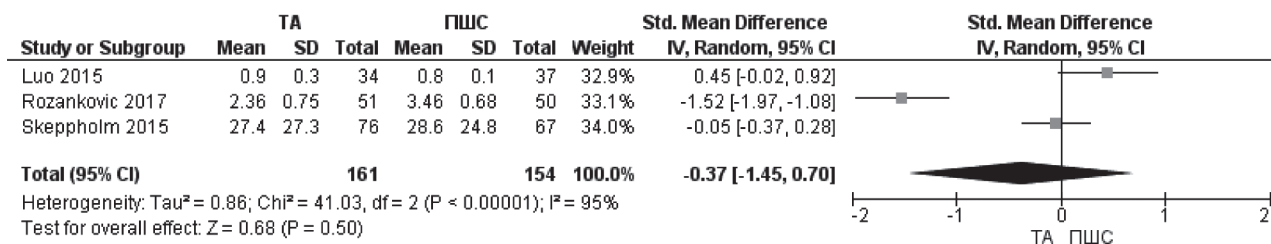


Fig. 6. Forest plot for VAS neck pain score

*VAS pain severity in upper limbs*

No statistically significant differences in VAS pain severity values in upper limbs were observed between the groups (SDA = -0.47, 95% CI: -1.12, 0.18,  $p = 0.16$ ;  $I^2 = 87%$ ) (Fig. 7).

*Range of motion in operated spine segment*

Two perspective clinical studies presented information on range of motion values in operated spinal segments in patients who underwent TA of cervical IVDs and ACIF [8, 10]. Meta-analysis of studies evidently demonstrated significantly larger values of range of motion in operated spinal segments in TA group (SDA = 5.28, 95% CI: 4.69, 5.88,  $p < 0.00001$ ;  $I^2 = 0%$ ) (Fig. 8).

*Revision procedures*

Revision rates were present in three studies [8, 9, 11]. Cumulative analysis of outcomes of these studies demonstrated the statistically significant differences in prevalence of revisions between groups of TA and ACIF (RR = 0.69, 95% CI: 0.11, 4.14,  $p = 0.68$ ;  $I^2 = 68%$ ) (Fig. 9).

*Adverse events*

Information on revision rates after TA and ACIF procedures was present in all studies included into meta-analysis [8–12]. No significant differences were observed (RR = 0.80, 95% CI: 0.48, 1.34,  $p = 0.40$ ;  $I^2 = 39%$ ) (Fig. 10).

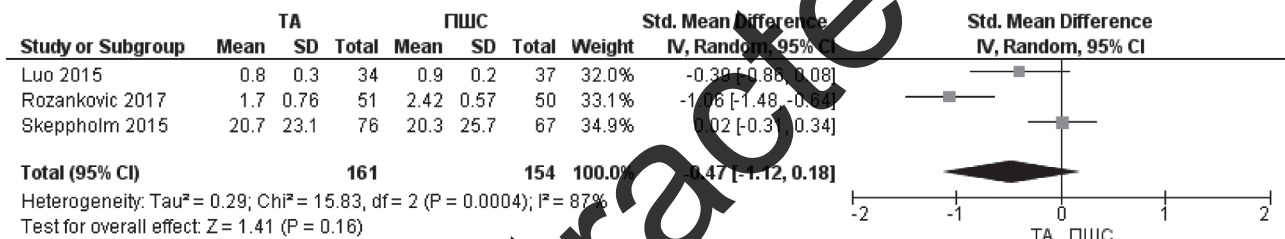


Fig. 7. Forest plot for VAS arm pain score

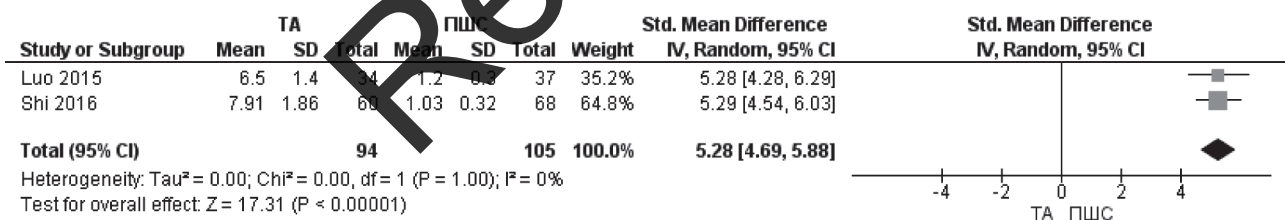


Fig. 8. Forest plot for range of motion at operated level

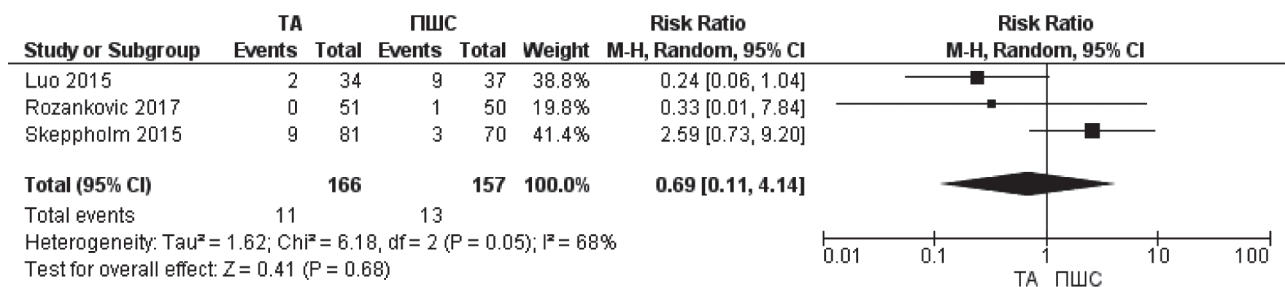


Fig. 9. Forest plot for secondary surgery

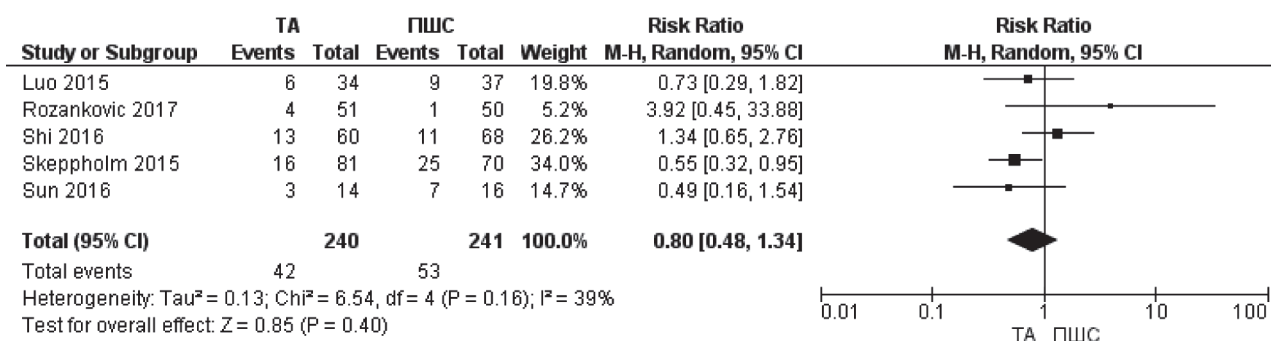


Fig. 10. Forest plot for adverse events

### Discussion

Search of literature in databases revealed several meta-analyses comparing efficiency of TA and ACIF procedures in surgical treatment for degenerative diseases of cervical IVDs. Thus, L. Xie et al in his work demonstrated that TA is more efficient method for treatment of patients with degeneration of cervical IVD [15]. S. Zou et al [16] proved that TA method allows to obtain statistically significantly better clinical outcomes than ACIF in patients with two-level degenerative disease of cervical IVD [16]. With that the authors of mentioned papers consider that clinical efficiency of TA for cervical IVDs in patients with degenerative disease of discs depend at large on type of the prosthesis. Undoubtedly each artificial IVD has peculiarities of design, geometry of its components and biomechanics. For this reason the research on comparison of efficiency of various prostheses remains one the most important tasks of the current spine surgery.

The present meta-analysis demonstrates that time of procedure during TA is statistically significantly less as compared to ACIF. This data contradicts previous research [17–19]. Nevertheless some researchers consider that longer times of TA procedure can be due to specifics of implantation of artificial IVDs using many instruments in contrast to ACIF procedure. On the other hand use of implants during ACIF procedure also means use of additional instruments [20]. The au-

thors of the present meta-analysis would like to note that data obtained on time of operative procedure in compared groups of patients is not convincing while various implantation techniques in included randomized studies and their high level of heterogeneity.

Some authors demonstrated that ACIF procedure allows to gain statistically significant improvement of patients' quality of life by NDI as compared to TA [21, 22]. It's worth noting that meta-analyses confirming significant improvement of life quality by NDI in ACIF group had a series of methodological disadvantages in the study design which doesn't allow to objectively assess the outcomes. According to the present meta-analysis no statistically significant differences in life quality by NDI were observed between the groups of patients.

As is known one of the adverse events after ACIF is the degeneration of adjacent spinal motion segment [23]. R. Davis et al consider that after ACIF procedure the range of motion in the operated segment is sharply decreased which is compensated by a significant increase in range of motion in adjacent spinal motion segments [24]. In contrast to ACIF the TA procedure allows to preserve normal biomechanics in the operated segment and the whole cervical spine, thus preventing degeneration of adjacent segments [25]. S. Yin et al report that TA of cervical IVDs allows to preserve a physiological range of motion in operated segment which is confirmed by re-



sults of the present meta-analysis. However for a more objective evaluation of the status of operated and adjacent spinal motion segments further research is needed to study biomechanical and kinematic features of those segments.

Conducted meta-analysis of prospective randomized studies did not reveal the differences in rate of adverse events in studies groups of patients. The data obtained by the authors is consistent with results of meta-analysis of S. Lei et al [27], S. Yi et al [28] and M. Qi et al [29]. The most frequent adverse event in both groups of patients was dysphagia.

### Study limitations

The present meta-analysis has a series of disadvantages. Firstly, meta-analysis includes 6 prospective randomized clinical studies with minor number of respondents which had an impact on results of statistical data processing. Secondly, Major part of included studies had a short follow up period which significantly decreases validity of results. Lastly, only one randomized study had a low risk of bias on all parameters which also could impact the results of meta-analysis.

### Conclusion

The present meta-analysis evidently demonstrated that procedure of TA for cervical IVDs by Discover prosthesis as compared to ACIF procedure provides for statistically significantly greater range of motion in the operated spinal motion segments. With that no statistically significant differences were observed in compared groups of respondents on values of life quality by NDI, pain severity by VAS in cervical spine and upper limbs, by revision rate and by frequency of adverse events. Undoubtedly we need further conducting of meta-analysis which would include methodologically high-quality randomized clinical studies with long term follow

up of patients who underwent TA and ACIF of degenerative diseases of cervical intervertebral discs.

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INFORMATION ABOUT AUTHORS:

*Vadim A. Byvaltsev* — Dr. Sci. (Med.), head of Neurosurgery and Innovative Medicine Department at Irkutsk State Medical University; chief of Neurosurgery in the JSC «Russian Railways»; head of Neurosurgical Center at Road Clinical Hospital at «Irkutsk-Passazhirskiy» Station; vice-president of Irkutsk Scientific Center of Surgery and Traumatology; professor of the Department of Traumatology, Orthopaedics and Neurosurgery, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

*Ivan A. Stepanov* — postgraduate student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

*Marat A. Aliyev* — doctoral student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

*Bakhyt M. Aglakov* — postgraduate student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

*Bobur R. Yussupov* — postgraduate student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

*Valerii V. Shepelev* — doctoral student, Irkutsk State Medical Academy of Continuing Education, Irkutsk, Russian Federation

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