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Original Article

Evaluation of long-term clinical outcomes and the incidence of adjacent proximal segment degenerative disease with algorithmic transforaminal interbody fusion: A multicenter prospective study

ABSTRACT

Study Design: This was a prospective multicenter study.

Background: Adjacent segment degenerative disease (ASDd) is a common complication of open transforaminal lumbar interbody fusion (O-TLIF), the leading cause of which is initial adjacent segment degeneration (ASD). To date, various surgical techniques for the prevention of ASDd have been developed, such as, simultaneous use of interspinous stabilization (IS) and preventive rigid stabilization of the adjacent segment. The use of these technologies is often based on the subjective opinion of the operating surgeon, or on the assessment of one of the predictors of ASDd. Only sporadic studies are devoted to a comprehensive study of risk factors of ASDd development and personalized performance of O-TLIF.

Purpose: The purpose of this study was to evaluate long-term clinical outcomes and the incidence of degenerative disease of the adjacent proximal segment using clinical-instrumental algorithm for preoperative planning to O-TLIF.

Materials and Methods: The prospective, nonrandomized, multicenter cohort study included 351 patients who underwent primary O-TLIF, and the adjacent proximal segment had initial ASD. Two cohorts were identified. The prospective cohort included 186 patients who were operated by using the algorithm of personalized O-TLIF performance. The control retrospective cohort consisted of patients (n = 165), from our own database who had been operated on previously without the algorithmized approach. Treatment outcomes were analyzed by Visual Analog Scale (VAS) assessment of pain syndrome, Oswestry Disability Index (ODI) scores, physical component score (PCS) and mental component score (MCS) scores of the Short Form 36 questionnaire, frequency of ASDd was compared between studied cohorts.

Results: Thirty-six months after follow-up, the prospective cohort had better SF36 MCS/PCS outcomes, less disability according to ODI, and lower pain level according to VAS ($P < 0.05$). The incidence of ASDd in the prospective cohort was 4.9%, which was significantly lower than in the retrospective cohort (9%).

Conclusions: The prospective use of a clinical-instrumental algorithm for preoperative planning of rigid stabilization, depending on the biometric parameters of the proximal adjacent segment, significantly reduced the incidence of ASDd and improved long-term clinical outcomes compared with the retrospective group.

Keywords: Adjacent segment degenerative disease, degenerative disease, lumbar spine, open transforaminal lumbar interbody fusion, prognosis, risk factors

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INTRODUCTION

Lumbar spine degenerative diseases are characterized by degeneration of the intervertebral discs (IVDs), the facet joints (FJs), and the ligamentous system, with various neurological, orthopedic, and visceral disorders, which are the leading causes of medical consultation and disability worldwide.[1] Up to 10% of lumbar spine degenerative diseases are accompanied by the development of functional spinal unit (FSU) instability, spondylolisthesis, and other deformities that cause spinal-pelvic imbalance.[2] In case of persistent pain syndrome and clinical and neurological deficits tolerant to conservative therapy, the question arises about surgical treatment of these pathological conditions,[3] with dorsal decompressive and lumbar interbody fusion being an effective method of treatment.[4] Currently, open transforaminal lumbar interbody fusion (O-TLIF) is a widespread method of decompression and stabilization.[5] This technique allows to create conditions for bone block formation and provide adequate and safe decompression of neural structures.[6] Despite its obvious advantages, accumulated experience has shown that biomechanical changes in the spine occurring after O-TLIF cause the overloading of adjacent segments, which leads to the development of adjacent segment degenerative disease (ASDd).[7] In most cases, the proximal segment is affected by ASDd; the incidence of this complication is 5.2%–20% according to a number of sources.[8-12] ASDd is a polyethylogic disease, the main role in the development of which is played by the presence of initial asymptomatic adjacent segment degeneration (ASD), and the performance of rigid fusion in turn leads to its acceleration.[9] To date, various surgical techniques for the prevention of ASDd have been developed, such as, simultaneous use of interspinous stabilization (IS) and preventive rigid stabilization of the adjacent segment.[10,11] Nevertheless, the use of these technologies is often based on the subjective opinion of the operating surgeon, or on the assessment of one of the predictors of ASDd.[12,13] Only sporadic studies are devoted to a comprehensive study of risk factors of ASDd development and personalized performance of O-TLIF.[14] Therefore, we conducted a retrospective study of treatment outcomes in patients who underwent O-TLIF between 2005 and 2014 [Figure 1], who had initial preoperative degeneration of the adjacent proximal FSU. Depending on the severity of the degeneration, the decision was made to expand the volume of stabilization using either IS device or preventive rigid fixation of the adjacent FSU. The decision on the tactics for the adjacent FSU was based on the opinion of an experienced operating surgeon. Correlation and regression analysis was used to determine the main preoperative parameters and their absolute values influencing the long-term clinical

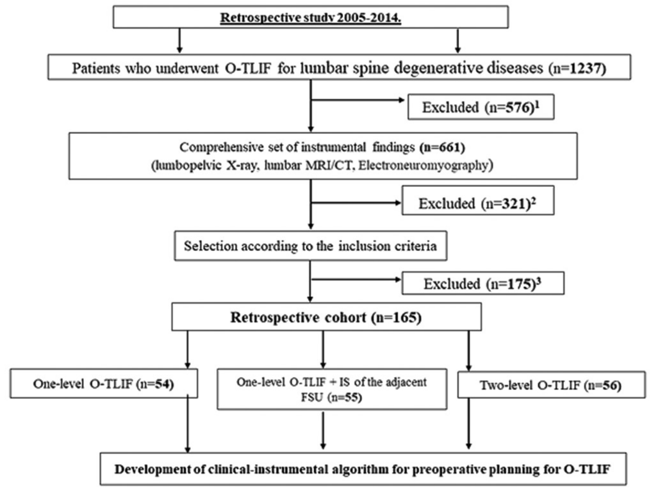

Figure 1: Flowchart characterizing the structure of the retrospective part of the study. Note. (1) Excluded due to postoperative follow-up period <36 months, (2) excluded with incomplete set of radiological data, (3) excluded according to inclusion/exclusion criteria, MRI - Magnetic resonance imaging, CT - Computer tomography, O-TLIF - Open transforaminal lumbar interbody fusion. FSU - Functional spinal unit, IS - Interspinous stabilization

outcome and the development of ASDd. These were pelvic incidence and lumbar lordosis difference (PI-LL),[15] segmental LL of the adjacent FSU,[16] changes of the adjacent IVD according to Pfirrmann,[17] its measured apparent diffusion coefficient (ADC), FJ according to Fujiwara,[18] and body mass index (BMI).[19]

Thus, it was found that one-level O-TLIF satisfactory results were obtained with the following clinical and instrumental parameters: PI-LL 4.8°–10°, segmental LL adjacent FSU 10.5°–15°, changes of adjacent IVD I-II grade by Pfirrmann and its ADC 1250–1450 mm^2/s, FJ I grade by Fujiwara, and BMI <25 kg/m^2.

After simultaneous one-level O-TLIF and IS of the proximal adjacent FSU, satisfactory results were obtained with parameters: PI-LL 10.5°–15°, segmental LL of the adjacent FSU 6.5°–10.5°, changes in the adjacent IVD II-III grade according to Pfirrmann and its ADC 1050-1220 mm^2/s, FJ I-II grade according to Fujiwara, and BMI <25 kg/m^2.

Satisfactory results of preventive rigid stabilization of the adjacent proximal FSU were obtained with the following parameters: changes in IVD according to Pfirrmann IV-V grade and its ADC 850–1050 mm^2/s, FJ III-IV grade according to Fujiwara, segmental LL of the adjacent FSU 5.5°–10.5°, PI-LL 15.2°–20°, and BMI 25.1–35 kg/m^2. Because of the obtained data, an algorithm for differentiated O-TLIF performance aimed at improving long-term outcomes and reducing the incidence of ASDd was developed and introduced into clinical practice in 2015 [Figure 2].

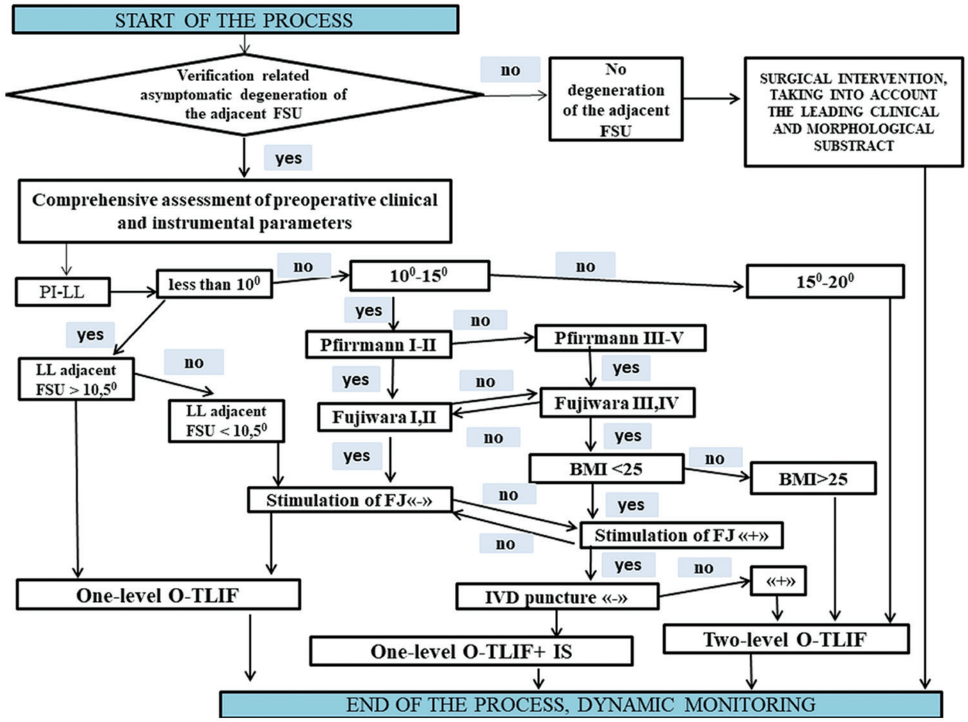

Figure 2: Clinical-instrumental algorithm for preoperative planning for O-TLIF. Note* FSU - Functional spinal unit, BMI - Body mass index, FJ - Facet joint, IVD - Intervertebral disc, O-TLIF - Open transforaminal lumbar interbody fusion, LL - Lumbar lordosis, PI-LL - difference of pelvic incidence and lumbar lordosis

The purposes of this study were to evaluate long-term clinical outcomes and the incidence of degenerative disease of the adjacent proximal segment using clinical-instrumental algorithm for preoperative planning to O-TLIF.

MATERIALS AND METHODS

Study design

This was a prospective multicenter, nonrandomized cohort study. The work was approved by the local ethical committee of the Irkutsk State Medical University dated on November 27, 2015. Written informed voluntary consent to participate in the study was taken from each study participant. We developed an algorithm for personalized O-TLIF performance. This technique was based on the comprehensive assessment of biometric and radiological parameters and further determination of the tactics for the associated FSU [Figure 2]. The prospective study was conducted from 2015 to 2018 based on three neurosurgery departments in Hospital 1, Hospital 2, and Hospital 3. To minimize subjective error, a comprehensive protocol of examination and surgical treatment was developed. All patients participating in the study were included in their own register of patients with lumbar spine degenerative diseases.[20] This led to a unified clinical-instrumental algorithm for preoperative planning for O-TLIF, which was agreed by the operating surgeons and implemented in all three departments of neurosurgery. The operating surgeons were the heads of these structural units. Prior to the development of this protocol, none of the neurosurgery departments used an algorithmic approach. All decisions about tactics for the adjacent segment were based on the subjective decision of the operating surgeon. The use of the clinical-instrumental algorithm for preoperative planning for performing O-TLIF was expected to improve the long-term results.

The results obtained were compared with the control retrospective cohort whose patients were treated without any algorithmic approach at the Department of Neurosurgery in Hospital 1. To minimize the influence of surgeon's experience on the long-term outcome in the prospective cohort, the experience of the operating spine surgeon was more than 20 years, in the retrospective cohort – at least 15 years.

Inclusion criteria

The prospective study included patients who were scheduled for O-TLIF for the following indications:

1. Long-term or recurrent pain syndrome tolerant to conservative therapy and persistent neurological deficit
2. Radiological signs of instability at the level of the "symptomatic" FSU: vertebral displacement relative to each other more than 15%, dynamic instability with vertebral displacement more than 4.5 mm, and hypermobility of the FSU with angular deformity more than 20° at L4-L5 and more than 25° at L5-S1, as revealed by functional X-ray.[21]

3. Asymptomatic ASD at the adjacent FSU of varying severity.

Exclusion criteria

Patients with BMI >35 kg/m^2, several spinal-pelvic disorders (PI-LL >20°), infectious diseases, injuries, tumors, severe morbid background, signs of ASD at the level of the distal adjacent FSU, and those previously operated on the lumbar spine were excluded. In addition, patients with formed interbody fusion against the background of pronounced degenerative changes at the level of the "symptomatic" FSU, who required only decompression without interbody fusion, were excluded from the study.

Surgical technique

All surgical interventions were performed in the prone position, under general anesthesia, using optical magnification, C-arm, and neurophysiological monitoring. The surgical intervention was performed at the level of the FSU L3-S1. We used O-TLIF and transpedicular fixation. U-shaped titanium implants were used for IS of the adjacent FSU.

Outcomes of the study

In the preoperative period, patients studied the following instrumental parameters: PI-LL,[15] segmental LL of the adjacent FSU,[16] changes of the adjacent IVD according to Pfirrmann,[17] its ADC, and FJ according to Fujiwara[18] and BMI.[19]

To measure the ADC of the adjacent IVD, preoperative studies were performed on a magnetic resonance imaging (MRI) machine with a field strength of at least 1.5 TL. Diffusion-weighted imaging (DWI) MRI with SE-echo-planar imaging, 160 × 128 matrix, TR - 7500, TE - 83, NEX - 6, slice thickness - 4 mm, FOV - 30 × 30 were used. The following values were applied: 400 and 800 mm2/s, scan time 6 min 30 s. Diffusion coefficient was calculated on T2-weighted images using OsiriX Lite software, and the obtained values were transferred to functional DWI maps.

In the long-term postoperative period clinical data and frequency of ASDd were analyzed. Outcomes were assessed by studying the Oswestry Disability Index (ODI), physical component score (PCS) and mental component score (MCS) of the Short Form 36 (SF-36) questionnaire, and intensity of pain syndrome according to the Visual Analog Scale in the lumbar spine and in the lower extremities in the remote period.

Statistical analysis

Data were processed using Microsoft Excel and Statistica-13.5. The test for normal distribution was performed using the Shapiro–Wilk (p_W), Kolmogorov–Smirnov (p_D), Cramer–von Mises ($p_{W\text{-}sg}$), and Anderson–Darling ($p_{A\text{-}Sq}$) tests. Given the presence of significant differences in these tests ($P < 0.05$), the distribution was considered to be different from normal; therefore, the significance of differences between the samples was evaluated using nonparametric statistical tests. The $P < 0.05$ level was considered the lower confidence limit. Data were represented by median and interquartile range Me (25%; 75%). Hypothesis testing for equality of group mean values and variance for quantitative characteristics: age (year), BMI (kg/m^2), bone mineral density (T-criterion), disease duration (from debut to the moment of surgery/months) was performed by pairwise comparison between retrospective and prospective groups using the Mann–Whitney *U*-test.

Comparison of treatment outcomes between prospective and retrospective cohorts was performed by pairwise comparison of distant clinical outcomes in groups with the same volume of surgical intervention using a two-sample Student's *t*-test. The incidence of ASDd was compared between prospective and retrospective cohorts.

RESULTS

A total of 351 patients were included in the study. The median follow-up was 36 (28, 42) months. In the prospective cohort, 186 patients were available for the study out of 210 planned [Figure 3]. The surgical tactics for the adjacent proximal FSU were determined according to the developed algorithm [Figure 2]. After a comprehensive assessment of instrumental, biometric parameters, provocative disco-puncture tests,[22] and periarticular stimulation of FJ[23] on the adjacent FSU, one-level O-TLIF was performed in 64 cases; in 62 cases, O-TLIF was performed simultaneously with IS of adjacent proximal FSU; and in 60 cases, two-level O-TLIF was performed, with preventive rigid fixation of adjacent proximal FSU.

The retrospective cohort included 165 cases from our own database[20] who had previously undergone O-TLIF and had underlying degeneration on the adjacent proximal FSU. The decision to extend the scope of surgery to the adjacent distal FSU was based on the clinical experience of the operating surgeons. Thus, in 54 cases, a one-level O-TLIF was performed; in 55 cases, a simultaneous one-level O-TLIF with IS of the proximal adjacent FSU was performed. In 56 cases, two-level O-TLIF with stabilization of the adjacent proximal FSU was performed.

In prospective and retrospective cohorts, there was a nonnormal distribution for all quantitative characteristics ($P < 0.05$).

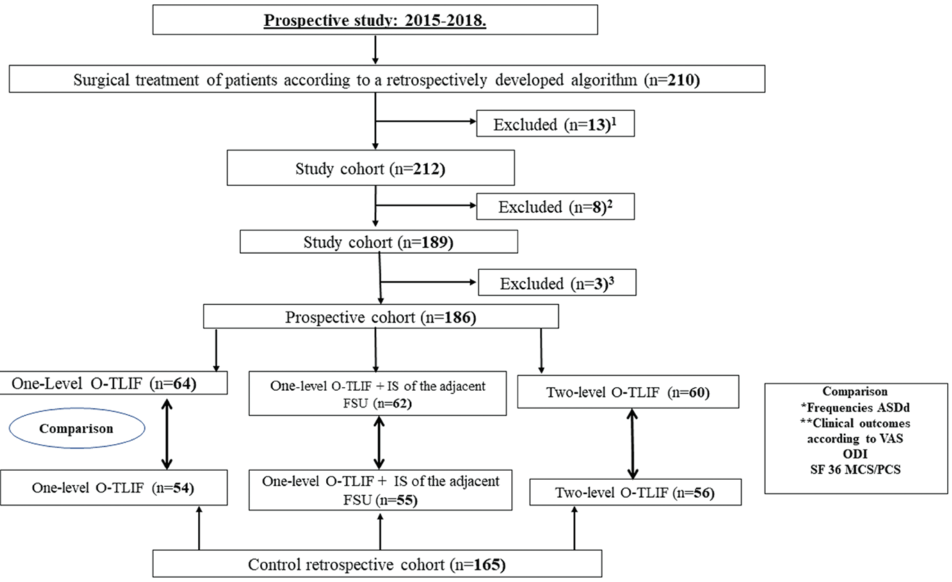

Figure 3: Flowchart characterizing the prospective part of the study: (1) Loss of communication with the participant, (2) postoperative refusal, (3) death in the postoperative period not related to hospitalization and surgery. * The frequency of ASDd was compared between prospective and retrospective cohort, ** Distant clinical outcome was compared between the groups operated on in the same volume. *O-TLIF - Open transforaminal lumbar interbody fusion, ASDd - Adjacent segment degenerative disease

When assessing the group and mean values within each cluster, we found that there were no differences in gender, age, comorbidities, and the number of FSU operated on in both cohorts ($P > 0.05$). In groups where it was performed two-level O-TLIF with stabilization of the adjacent proximal FSU of both cohorts, patients with BMI over 25 kg/m^2 predominated ($P < 0.05$).

A paired comparison between the groups operated on in the same volume [Figure 3] in prospective and retrospective cohorts showed that the intensity of pain syndrome in the lower extremities and lumbar spine was lower in the long-term period in all three prospective cohort patients. Furthermore, patients' prospective cohort had a less disability on ODI and a higher level of quality of life according to SF-36 MCS/PCS scales [Table 1]. The incidence of ASDd in prospective cohort patients was 4.9% ($n = 9$), which was significantly lower than in retrospective cohort 9% ($n = 15$), ($P < 0.05$). No complications during minimally invasive puncture diagnostic tests were reported in the prospective cohort.

We applied a clinical-instrumental algorithm for preoperative planning for O-TLIF in this study, aimed at reducing the incidence of ASDd and improving the long-term clinical outcomes after O-TLIF. This technique is based on a step-by-step analysis of the main preoperative clinical and instrumental parameters influencing the development of ASDd. Thus, the first stage is to determine PI-LL and LL of the adjacent FSU; then, the grade of IVD dystrophy according to Pfirrmann and FJ according to Fujiwara is assessed. The BMI is also necessarily considered. To detect hidden clinical symptomatology and increase the validity of this decision-making system, after instrumental diagnostic methods, invasive diagnostics was performed, namely periarticular stimulation of FJ[23] and disco puncture test.[22] After a comprehensive algorithmized assessment, a personalized method of performing O-TLIF was proposed based on the combination of the above parameters [Figure 2].

DISCUSSION

ASDd is a long-term complication that occurs against the background of biomechanical changes after lumbar interbody fusion with a frequency of 5%–20%[5,7,8] and is the leading cause of revision interventions and unsatisfactory outcomes in the long-term period.[12] The basis for the development of ASDd is the presence of asymptomatic degeneration of adjacent FSU. The term ASD is multifaceted and includes morphological changes in adjacent IVD, FJ, and local spino-pelvic disorders. In addition to ASD, the risk factors for the development of ASDd include overweight.[19]

The main value characterizing the spino-pelvic relationship is the PI-LL. Senteler *et al*.[16] proved that an increase in the PI-LL difference correlates with the amount of load on the FJ and IVD in the FSU L3-L4 and L4-L5. In another study, Rothenfluh *et al*.[5] described those patients with a PI-LL difference of more than 10° are at risk of developing ASDd in single- and dual-segment fixation due to the presence of decompensation of the spino-pelvic relations. The authors recommend a detailed follow-up examination of these patients and measures for intraoperative correction of the

Table 1: Results of a pairwise comparison of long-term clinical results between groups of prospective and retrospective cohorts operated on at the same volume using a two-sample Student's test

Parameters	One-level O-TLIF (*n*=54) retrospective cohort	One-level O-TLIF (*n*=64) prospective cohort	*P*-test (student's *t*-test)	One-level O-TLIF + IS (*n*=55) retrospective cohort	One-level O-TLIF + IS (*n*=62) prospective cohort	P-test student's *t*-test	Two-level O-TLIF (*n*=56) retrospective cohort	Two-level O-TLIF (*n*=60) prospective cohort	*P*-test (student's *t*-test)
VAS* (mm)	10 (8; 12)	7 (5; 9)	0.0223	11 (9; 13)	7 (5; 9)	0.0232	13 (7; 14)	8 (7; 11)	0.0142
VAS** (mm)	13 (9; 15)	4 (2; 8)	0.0135	15 (10; 17)	5 (3; 9)	0.0235	16 (11; 18)	7 (4; 11)	0.0341
ODI	20 (15; 22)	14 (8; 17)	0.0392	21 (16; 23)	16 (7; 18)	0.0132	22 (18; 24)	17 (8; 20)	0.0341
SF-36 MCS	47 (43; 54)	53 (48; 66)	0.0245	45 (41; 52)	52 (47; 65)	0.0336	43 (40; 51)	50 (41; 59)	0.0236
SF-36 PCS	46 (42; 53)	55 (48; 69)	0.0271	47 (42; 54)	53 (45; 67)	0.0362	43 (41; 52)	51 (44; 62)	0.0272

*Lumbar spine, **Lower extremities. O-TLIF - Open transforaminal lumbar interbody fusion; VAS - Visual Analog Scale; ODI - Oswestry Disability Index; SF-36 - Short Form 36; MCS: Mental component score; PCS - Physical component score; IS - Interspinous stabilization

LL angle. Speaking about the follow-up examination of these patients, much attention should be paid to the adjacent FJ. Several reports confirm that the presence of baseline grade II-IV FJ degeneration according to Fujiwara is a factor in the development of ASDd.[12,13] Lee *et al*.[12] in a study with more than 1,000 respondents who underwent O-TLIF found that 3.6% of revision interventions were performed due to persistent clinical and neurological deficits associated with severe degeneration of the FJ adjacent FSU. Yoshiiwa *et al*.[13] proved that the presence of arthrosis of adjacent FJ ≥ grade II Fujiwara is the cause of adjacent FSU stenosis, which supports the above findings. Evaluation of the adjacent IVD also has an important role in the prediction of ASDd. In a study involving 1258 respondents who underwent O-TLIF, Ye *et al*.[8] found that in the group of patients with ASDd, patients with grade III, IV IVD degeneration according to Pfirrmann prevailed, explaining this by the fact that these stages are characterized by the maximum loss of disc hydrophilicity and cartilage failure. At the grade V of Pfirrmann IVD degeneration, the degenerative cascade ends and the processes of spontaneous fusion begin. Several studies also note that a significant cause of ASDd development is an increased BMI, more than 25–30 kg/m^2.[19] Thus, Seicean *et al*.[24] noted that when BMI is more than 25 kg/m^2, the risk of ASDd after fixation remains high, regardless of the degree of instrumental degeneration of the adjacent FSU.

The development and implementation of algorithms aimed at reducing the number of various surgical complications and improving distant clinical outcomes in spinal surgery today have gained wide significance.[3] Experience accumulated over the past decades has shown that many unsatisfactory outcomes directly correlate with irrational preoperative tactics based on the subjective opinion of surgeons.[1] In turn, the development of decision support systems is aimed at reducing their frequency. Thus, Masevnin *et al*.[14] in their work offers an algorithm for the choice of posterior LIF tactics based on the assessment of such sagittal balance parameters as PI-LL, sagittal vertical axis (SVA), and degree of adjacent IVD degeneration according to Pfirrmann. Depending on the severity of the deviations, the authors suggest correcting the PI-LL difference either by a one-level interbody fusion or by additional adjacent FSU fixation with spondylotomy according to the Smith–Petersen technique,[25] at the level of the "symptomatic" and adjacent FSU. In case of adjacent FSU degeneration ≥ grade IV according to Pfirrmann, the author recommends to perform radiofrequency ablation of adjacent FJ simultaneously with posterior stabilization. The incidence of ASDd in this study was 16.7%. The study is based on a comprehensive analysis of the main instrumental parameters influencing ASDd. The disadvantages of this algorithm include the fact that it requires the measurement of SVA, and the X-ray telemetry method is not available in every clinic. Application of Smith–Petersen technique[25] is a rather traumatic method and requires high surgical skills. It should also be noted that the study is based on a small sample ($n = 39$), with postoperative follow-up of 36 months.

The algorithm we have developed and implemented in clinical practice is based on a comprehensive analysis of the leading clinical and instrumental risk factors for the development of ASDd in patients scheduled for O-TLIF. Its effectiveness was confirmed by comparing the results with a retrospective control cohort. The disadvantages of the developed methodology include the absence of a few values that can have a significant impact on the effectiveness of the prognostic model. For instance, the work did not assess the height of the adjacent interbody interspace, which is an important point in planning the insertion of an interbody implant as well as the correction of the local angle of lordosis.[6,7] In addition, the above algorithm cannot be applied to the distal adjacent FSU.

This study showed that the main risk factors for the development of ASDd are preoperative degeneration of the adjacent IVD, and FJ, local spino-pelvic disorders, and an increase in BMI over 25 kg/m^2. The obtained results are comparable with the world literature data.[6-8] It should be noted that the above studies are based on the assessment of one[15,16,19] or two of the listed features,[12] are retrospective in nature, and do not suggest any surgical tactics. Moreover, these publications did not use minimally invasive perioperative provocative puncture tests, which is an effective method for detecting latent symptomatology.[22,23] In this study, we performed a comprehensive assessment of clinical and instrumental predictors of ASDd with the determination of their absolute values and suggested tactical options for performing O-TLIF. The method of surgical treatment in this study was O-TLIF, and only two methods – installation of a dynamic U-shaped IS and preventive rigid fixation of the adjacent FSU – were used as prophylaxis. These facts are a significant limitation of this work, since many technologies have been developed for the treatment of o-listhesis, segmental instability, and spine-pelvic deformities in lumbar spine degenerative diseases. These include lateral minimally invasive approaches (extreme lateral interbody fusion [XLIF], direct lateral interbody fusion [DLIF],[26,27] and anterior lumbar interbody fusion [ALIF]).[28] In addition to the above approaches, minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) is currently widely used in practice. This technology allows minimizing surgical trauma and preserving the integrity of the lumbar multifidus muscle, which is the basis of stability of the lumbar spine.[3] The above facts allow to improve the long-term clinical results, and indicate the advantages of MI-TLIF, despite the longer learning curve. Speaking about instrumental spinal systems used for the prevention of ASDd, it should also be noted that dynamic transpedicular fixation systems[29] as well as IVD prostheses[3] are currently introduced and widely used. The use of these devices makes it possible to preserve the range of motion in the operated FSU and thus prevent ASDd without extending surgical intervention to the adjacent FSU.

The use of algorithms in the practical work of surgeons, as well as any other specialists, helps to solve highly specialized tasks and is an important step in the creation of artificial intelligence and machine learning systems. For example, a study by Lee *et al*.[2] proved the effectiveness of using algorithms to predict spino-pelvic compensation after spondylodesis to reduce the risk of proximal kyphosis formation. A prospective evaluation[3] of the results of introducing the decision support system during O-TLIF, MI-TLIF, and lumbar total disk arthroplasty based on the assessment of individual biometric parameters of lumbar segments showed its high efficiency and advantages compared to the control retrospective study group.

Thus, the introduction of algorithms makes it possible to increase the efficiency of care due to the leveling of "subjective" error, also to reduce the time and number of examinations, save money, and minimize the burden on medical institutions. Certainly, their application requires long-term testing and deep learning on many respondents, in order to prevent undesirable phenomena, which may occur against the background of a system error, or due to the presence of individual patient characteristics.

Limitations of the study

The study has several limitations that should be noted. First, the study was not randomized and was conducted only in three clinics in one country. It is possible that if more patients from different institutions and different countries were included in the study, the results may differ significantly from our findings. Second, the median follow-up was 36 (28, 42) months. This may not be enough, since according to some literature sources, the follow-up period was 48 months.[5-8,12,28] Third, only O-TLIF was analyzed and only two methods of surgical prevention of ASDd were studied. Comparisons with techniques such as MI-TLIF, ALIF, XLIF, and DLIF were not performed. Fourth, a comparative analysis of preoperative clinical data was not performed due to the retrospective nature of the study in a retrospective cohort. Fifth, we compared the prospective cohort formed because of three neurosurgery departments, while the control retrospective cohort was recruited from only one department, which may be a reason for the heterogeneity of the data and affect the reliability of the results. Sixth, in the study conducted, the retrospective cohort was recruited between 2005 and 2014, whereas the prospective study was conducted between 2015 and 2018. Therefore, by the beginning of the prospective study, the operating surgeons could have gained experience, and the operating equipment and instrumentation could have been updated, which can also improve the long-term outcome. Objectivization requires a prospective study in a similar period without using a systematic approach to determine the tactics of performing O-TLIF, but having an algorithm that has already been clinically tested and has high efficiency, it would be unethical not to use it. Finally, sixth, the multiplicity of studied parameters does not allow to fully study the degree of influence of each of the algorithm components on the clinical outcome.

CONCLUSIONS

Based on this study, we developed and tested a clinical-instrumental algorithm for preoperative planning aimed at preventing ASDd [Figure 2]. Its use significantly reduced the incidence of ASDd and improved long-term clinical outcomes compared with the retrospective control cohort. The use of this methodology is a convenient and simple way to obtain recommendations on the prevention of ASDd in patients with planned O-TLIF and reduces the probability of "subjective" error and can also be used to develop a decision-making system on the tactics of surgical management of patients with lumbar spine degenerative diseases.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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