



Factors affecting the stability of transpedicular fixation in patients with neglected osteoporotic vertebral fractures

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Abstract

Introduction With increasing life expectancy and an aging population, vertebral fractures are one of the most common fractures associated with low bone mineral density. The problem of vertebral fractures associated with low bone mineral density is becoming increasingly common. Despite a variety of treatment methods, the risk of transpedicular fixation instability in the postoperative period remains.

The **objective** was to identify risk factors for unstable spondylosynthesis in patients with osteoporotic spinal fractures to substantiate an individualized approach to the surgical treatment.

Material and methods This A retrospective single-center study was based on the findings of 82 patients who underwent surgical treatment at the R.R. Vreden National Medical Research Center for Trauma and Orthopedics between 2019 and 2023. Patients were divided into a case group of patients who developed unstable fixation, $n = 8$) and controls (who had no hardware instability, $n = 74$). Potential risk factors included age, body mass index, fixation length, a screw placed in the involved vertebra, screw diameter, the presence and type of bone cement augmentation, the amount of decompression, the presence of local kyphosis and correction technique (Schwab vertebroto my), duration of surgery and blood loss.

Results A screw placed into the involved vertebra was the only statistically significant ($p < 0.05$) difference between the groups. A logistic regression model was used to identify factors that could improve the hardware stability including intermediate fixation, augmentation of the fractured vertebra, screw augmentation and a larger screw diameter. Laminectomy, facetectomy, advanced age, and excess body weight were identified as factors negatively affecting the stability of the metal construct.

Discussion Patients with osteoporotic vertebral fractures are heterogeneous in age and medical status which complicates selection of optimal surgical approaches. Laminectomy and facetectomy are the main factors impacting stability in case of facet joint resection. Larger-diameter screws and bone cement augmentation are practical for better stability and associated with a risk of specific complications. The screw placed in the broken vertebra is a significant positive factor, as confirmed by other biomechanical and clinical studies. Limitations of the study included the retrospective design, small sample size and cohort heterogeneity, which reduce the statistical power and generalizability of the results.

Conclusion Unstable transpedicular fixation after stabilization is multifactorial in patients with chronic osteoporotic vertebral fractures. Surgical factors are most significant. Laminectomy and facetectomy increase the risk of instability with the screw placed in the broken vertebra and bone cement augmentation helps maintain the stability. The length of fixation, the extent of kyphosis correction and residual kyphosis had no significant effect in the study sample. These results support the need for individualized surgical approaches in osteoporotic patients.

Keywords: osteoporosis, spinal fracture, transpedicular fixation, instability

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INTRODUCTION

Vertebral compression fractures (VCFs) affect many individuals worldwide. Approximately 1.4–1.5 million VCFs occur annually in the general population, of which about a third are caused by systemic osteoporosis [1, 2]. In the Russian Federation, more than 14 million people suffer from osteoporosis, which is approximately 10 % of the country's population, and osteopenia has been diagnosed in 20 million residents. Population studies in Russia show that low bone mineral density, characteristic of osteoporosis, was detected in 33 % of women and 27 % of men over 50 years of age in 2013. The global incidence of fractures related to osteoporosis is expected to increase dramatically in the next few decades and are projected to exceed 21 million cases by 2050 [3].

The majority of fractures (60 to 75 %) are localized in the Th12–L2 which is considered the most vulnerable site. The zone is characterized by a biomechanical transition from the more rigid thoracic spine to the relatively mobile lumbar spine [4]. Based on biomechanical studies on stability three-column concept proposed by Francis Denis, divides a spinal segment into three parts: anterior, middle, and posterior columns [5]. Osteoporotic compression fractures predominantly affect the anterior and middle columns of the vertebra, including the anterior longitudinal ligament and the vertebral body. Preserving the integrity of the posterior column is essential for stability of the spinal motion segment preventing neurological deficiency. Neurological disorders in osteoporotic fractures are relatively rare with no fracture fragments migrating into the spinal canal and causing compression [6, 7]. However, neurological symptoms may develop with the progressing deformity, fracture instability and compression of neural structures which would require timely surgical intervention.

Compression fractures of the spine in systemic osteoporosis constitute a significant proportion of spinal pathology in elderly patients due to biomechanical characteristics of the thoracolumbar junction and requires an adequate clinical approach, considering complications of prolonged immobilization and the risk of cascade fractures.

Literature review has shown that there is no unified and standardized approach to the treatment of patients with pathological fractures of the thoracic and lumbar spine caused by osteoporosis, especially in the absence of neurological symptoms. Patients with osteoporotic vertebral fractures caused by low-energy trauma require a more differentiated and balanced choice of treatment strategy, considering age, concomitant somatic diseases and the severity of bone tissue changes. Surgical treatment with the use of metal fixators can be indicated for some patients [8]. With the variety of techniques, there is no consensus on the indications for surgery in osteoporotic patients. Patients with acute neurological deficit would require surgical management. Somatic risks and condition of the spinal column, including the extent of compression and vertebral deformity, duration of pain and location of the fracture would be essential to consider indications for surgery [9, 10].

The choice of fixation method is complicated by the need to ensure reliable implant stability in the affected bone, the optimal approach and extent of the procedure. Anterior approaches are often associated with greater trauma and do not demonstrate significant advantages over posterior approaches. There is also a high risk of interbody implant instability with use of MESH meshes or expandable implants such as vLift. The use of wide-base implants and proper implant positioning can reduce the risk of implant migration and instability in some cases [11–13].

Surgical interventions performed through a posterior approach carry a risk of instability, when there is no way to create a supporting bone block. Age and comorbidities may increase the risk of complications during revision surgery.

Therefore, the challenge of determining the optimal surgical strategy for osteoporotic patients lies in the choice of a minimally invasive surgical approach maximizing the stability of the implant during the postoperative period.

The **objective** was to identify risk factors for unstable spondylosynthesis in patients with osteoporotic spinal fractures to substantiate an individualized approach to the surgical treatment.

MATERIAL AND METHODS

Study design

The study was a retrospective comparative analysis of the results of surgical treatment of patients with osteoporotic spinal fractures of types OF4 and OF5 who received medical care at the Vreden National Medical Research Center of Traumatology and Orthopedics from 2019 to 2023.

Inclusion criteria:

- patients of either sex over 50 years of age;
- diagnosis of systemic osteoporosis, confirmed by medical documentation;
- the presence of single-level osteoporotic fractures of the thoracic and lumbar spine types OF4 and OF5 according to the AO Spine DGOU classification;
- the period of time since the injury at least six weeks [15];
- surgical intervention including reduction and stabilization performed at the Vreden National Medical Research Center of Traumatology and Orthopedics with use of transpedicular fixation systems;
- the minimum follow-up period of six months.

Non-inclusion criteria:

- scoliotic spinal deformity in the frontal plane with a Cobb angle greater than 10° that developed prior to the fracture;
- peri-implant infection;
- previous surgical interventions on the operated segment;
- fractures of adjacent vertebrae types OF4 and OF5 seen before the intervention;
- patients who were not allowed to undergo surgery due to the severity of the physical status as evaluated with the ASA (American Anesthesiological Association) grading system (ASA IV, ASA V) [16].

Participants

Data from 82 patients were reviewed with the majority being females ($n = 70$, 85 %). The mean age was 68.99 (SD = 7.12), body mass index (BMI) was 26.53 (SD = 5.10). Most patients ($n = 55$, 67 %) had ASA third status. Hypertension (ICD 10 code I11.9) and type 2 diabetes mellitus (ICD 10 code E11) were most common comorbidities. Most patients ($n = 64$, 78 %) had not received treatment for osteoporosis. Preserved neurological function (ASIA classes D and E) was observed in 76 patients (93 %).

Patients were grouped depending on the surgical outcome:

- Control group ($n = 74$) included patients without signs of fixation instability;
- Case group ($n = 8$) consisted of patients who developed unstable fixation or fracture of adjacent vertebrae.

Seven patients (88 %) in the Case group had resorption around the screws, and one patient (12 %) had a fracture of the fixation screw. Anthropometric data are presented in Table 1. The two groups were similar in terms of the parameters explored and showed no statistically significant differences.

Table 1

Anthropometric indices of the study cohort

Description	Total (<i>n</i> = 82), M (SD)	Control group (<i>n</i> = 74), M (SD)	Case group (<i>n</i> = 8), M (SD)	<i>P</i>
Age (years)	68.99 (7.12)	69.03 (6.98)	68.67 (8.46)	0.8923
BMI (kg/m ²)	26.63 (5.10)	26.42 (4.89)	28.57 (7.03)	0.2623
Weight (kg)	70.51 (12.88)	70.01 (12.21)	75.06 (18.44)	0.2950

The patients showed signs of decreased BMD according to densitometry (T-score of 2.80 (SD = 0.64)) and CT (HU 80.78 (SD = 25.31) with the VBQ index measuring 2.34 (SD = 0.02). The characteristics of the groups by type and location of vertebral fractures are presented in Table 2.

Table 2

Distribution of vertebral fractures by type and location

Fracture type and vertebra	All patients (<i>n</i> = 82)		Control group (<i>n</i> = 74)		Case group (<i>n</i> = 8)		<i>P</i>
	abs.	%	abs.	%	abs.	%	
Ranking by fracture type (DGOU)							
OF4	72	87.8	65	87.8	7	87.5	0.2932
OF5	10	12.2	9	12.2	1	12.5	0.4241
Ranking by fracture location							
Th12	25	30.9	22	29.7	3	37.5	0.6812
L1	23	28.4	20	27	3	37.5	0.6657
L2	11	13.6	10	13.5	1	12.5	1.000
L4	6	7.4	6	8.1	0		
Th11	5	6.2	5	6.7	0		
L3	4	4.9	4	5.4	0		
Th8	3	3.7	3	4	0		
Other segments	4	4.9	4	5.4	0		

The thoracolumbar junction was most common segments involved. A segmental comparison of fracture types between the Case and Control groups revealed no statistically significant differences.

The criteria and parameters examined

Clinical characteristics:

- age;
- gender;
- BMI;
- risk of surgical treatment evaluated with the ASA grading system;
- history of osteomodifying therapy.

Imaging:

- DXA scans were performed within 12 months;
- BMD (bone mineral density) in Hounsfield units, calculated from the average density of the cross-section of the cancellous bone of the L3 vertebral body [17];

- VBO (Vertebral Bone Quality): MRI bone quality index, calculated as the ratio of the average T1-weighted signal from the bodies of the L1, L2, L3, L4, L5 vertebrae (broken segments were excluded from the analysis) to the cerebrospinal fluid signal value at the L3 level [18];
- localization and nature of the fracture according to DGOU;
- the angle of local kyphosis calculated as the Cobb angle between the upper endplate of the overlying vertebra and the lower endplate of the underlying vertebra; the formation of the bone block was assessed according to the classification of F. Chistensen [19].

The stability of the construct was assessed by the presence of:

- resorption zones greater than 1 mm around the screws;
- signs of dissociated elements in the construct;
- pain;
- fractures of the upper and lower vertebrae relative to the fixation zone no less than six months after the intervention.

Characteristics of surgery:

- length of fixation;
- diameter;
- size of screws;
- the presence and type of bone cement augmentation used;
- decompression volume;
- the presence and method of correction of local kyphosis (Schwab vertebrotomy) [20];
- duration of operation;
- blood loss;
- postoperative stay;
- complications as classified by Calvien-Dindo [21].

Statistical analysis

The mean and median values, standard deviation (SD), and interquartile range (IQR) were used for descriptive statistics. ROC AUC, accuracy, and sensitivity metrics were used to assess risk factors for the accuracy of the logistic regression model. Statistical processing and multivariate regression analysis were performed using the pandas, numpy, scikit-learn, statsmodels, and matplotlib packages for the Python programming environment.

Ethical Approval

The study was exempt from ethics review because it did not address issues requiring ethical approval. The study does not violate the principles of the Declaration of Helsinki or the requirements of Russian legislation on scientific research ethics.

RESULTS

The characteristics of the interventions performed according to the compared criteria are presented in Table 3.

Table 3

Characteristics of the interventions performed

Description		All patients (<i>n</i> = 82)	Control group (<i>n</i> = 74)	Case group (<i>n</i> = 8)	<i>P</i>
Invasiveness of the operation					
Duration (min), M (SD)		119.10 (48.00)	118.75 (48.84)	123.33 (39.71)	0.8239
Blood loss (mL), M (SD)		276.50 (259.60)	268.51 (248.90)	375.00 (384.38)	0.3371
Length of fixation					
Short-segmented (3 segments)	abs.	42	39	3	0.6564
	%	51.2	52.7	37.5	
Long-segmented (≥ 4 segments)	abs.	39	35	4	1.0000
	%	47.6	47.3	50.0	
Surgical techniques					
Screw placed into the involved vertebra	abs.	36	36	0	0.0377*
	%	44.4	48.6	0.0	
Augmentation of screws	abs.	37	36	1	0.1146
	%	45.1	48.6	12.5	
Vertebral augmentation	abs.	14	14	0	0.3918
	%	17.1	18.9	0.0	
Laminectomy	abs.	20	17	3	0.6344
	%	24.4	23.0	37.5	
Facetectomy	abs.	25	22	3	0.9607
	%	30.5	29.7	37.5	
Screw diameter (mm)	M	6.60	6.60	6.58	0.9267
	SD	0.35	0.35	0.38	

A comparative analysis of the Case and Control groups in terms of intervention invasiveness revealed one statistically significant difference between the groups: screw placed in the involved vertebra. The Case group included only one patient, who underwent cemented vertebral augmentation.

An analysis of surgical invasiveness revealed a large standard deviation in blood loss and operative time due to the wide variability of surgical techniques, ranging from minimally invasive percutaneous fixation as the most gentle method to extensive corrective vertebrotomies with vertebral and intervertebral disc resection.

None of the patients in the study sample experienced complications early post-op.

Schwab corrective vertebrotomies (Table 4) were used to correct local kyphotic deformity, with the exception of types 2 and 5.

Table 4

Comparison of local kyphotic angles and methods of deformity correction

Description		All patients (<i>n</i> = 82)	Control group (<i>n</i> = 74)	Case group (<i>n</i> = 8)	<i>P</i>
Angles of local kyphosis					
Baseline (°) M, SD		22.83 (10.68)	22.51 (10.97)	25.77 (7.29)	0.4162
Residual (°) M, SD		14.48 (9.66)	14.23 (9.88)	18.14 (4.38)	0.3848
Corrected (°) M, SD		7.18 (10.66)	7.33 (10.84)	5.80 (9.27)	0.7028
Correction technique					
No correction produced	abs.	71	64	7	1.0000
	%	86.6	86.5	87.5	
Type 1	abs.	6	5	1	1.0000
	%	7.3	6.8	12.5	
Type 3	abs.	1	1	0	1.0000
	%	1.2	1.4	0.0	
Type 4	abs.	3	3	0	1.0000
	%	3.7	4.1	0.0	

No statistically significant differences in radiographic findings were found between the groups in terms of the angles of baseline and residual (postoperative) kyphosis, or the extent and method of correction of local kyphotic deformity.

A multivariate regression analysis was performed to identify factors predicting fixation instability. The logistic regression model demonstrated high predictive ability: ROC-AUC of 0.924, accuracy of 91.5 %, and sensitivity of 98 %. The model results are visualized as odds ratios (Fig. 1).

The length of fixation and residual kyphosis had no effect on the construct stability in the sample.

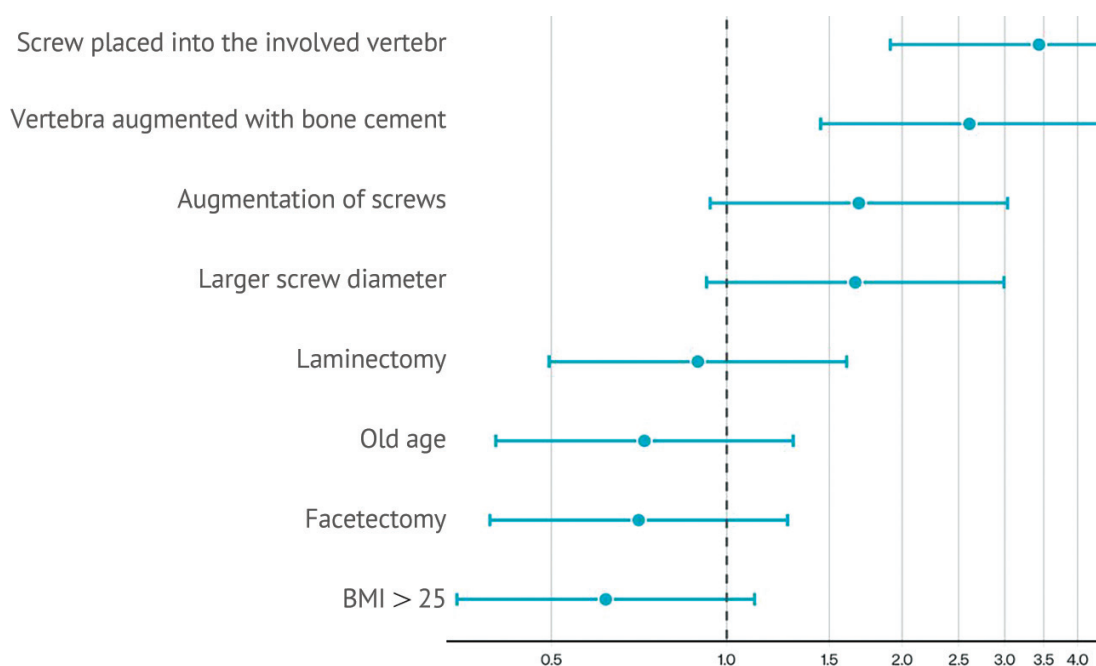


Fig. 1 Odds ratio of maintaining fixation stability

Clinical instance

A 82-year-old (at the time of surgery) patient presented with pain in the thoracolumbar spine, VAS scored 7, without radiating to the legs. The patient reported pain developed acutely after an awkward movement within the bed approximately six months prior to admission, with no significant improvement from conservative treatment. Her medical history included hypertension, coronary artery disease, and renal failure. Radiograph showed unstable compression fracture of the T11 vertebra. Densitometry revealed osteoporosis ($T_{cr} = -3.0$). Minimally invasive short-segment fracture fixation without augmentation was performed considering the patient's physical status and the nature of the fracture, (Fig. 2).

The patient stayed at the hospital for six days. Seven months after the procedure, the patient reported a deterioration in her condition, with pain similar to preoperative pain but of lesser intensity. A follow-up CT scan revealed signs of osteolysis around the screws (Fig. 3, red arrow). The patient declined revision surgery.

Based on the study results, it can be hypothesized that the absence of protective factors (vertebral augmentation) and intermediate fixation, which would improve the stability could cause postoperative instability. The posterior supporting structures of the vertebrae were completely preserved in this case. The bone cement reinforcing pedicle screws and the screw placed into the fractured vertebra had a greater impact on stability than the effects on the posterior bony structures of the spinal column; however, this hypothesis requires further investigation.

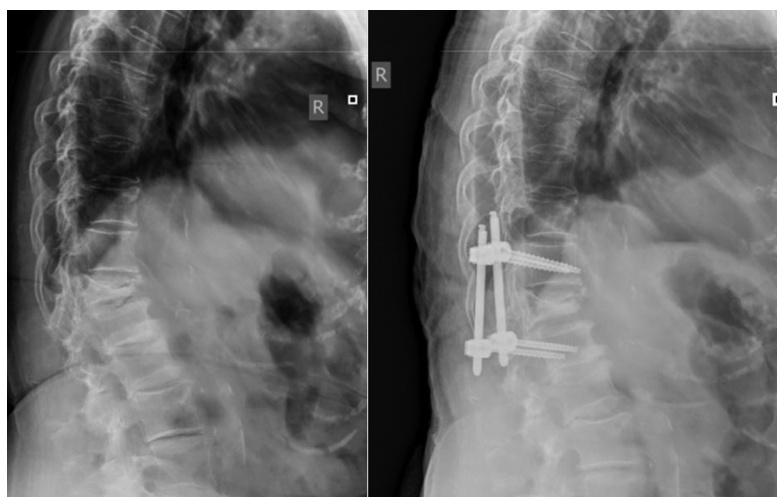


Fig. 2 Preoperative and postoperative radiographs of the patient from the Case group



Fig. 3 CT scan of a patient in the Case group seven months after surgery

DISCUSSION

Patients with osteoporotic fractures represent a highly heterogeneous group in terms of age and physical status, making it difficult to select the optimal surgical strategy. The cohort of patients was predominantly females and had no history of antiresorptive therapy. Elderly and overweight patients are the most vulnerable group in terms of implant stability. Treatment strategies for these patients require further study.

Preservation of the neurological status of the group allowed for stabilizing surgical interventions without decompression and extensive resection of the posterior bone structures and had a positive effect on maintaining the stability of the metal construct. Laminectomy and facetectomy are the most significant surgical factor negatively affecting the maintenance of fixation. This can be caused by greater destabilization of the spinal motion segment and is confirmed by the results of other clinical studies [22, 23]. Interestingly, resection of the facet joints has a greater impact on the onset of instability than laminectomy alone.

An Urban wedge, a fragment of the vertebral body protruding into the spinal canal, is a most common cause of neural compression in vertebral fractures. Decompression through an anterior approach and transpedicular fixation would be the optimal surgical treatment strategy to restore the anterior supporting column. Some authors recommend the use of a wide-based interbody implant to improve support [11]; however, this may pose a high risk of interbody implant migration and subsidence [13].

Screws of a larger diameter are practical to improve the primary stability of the construct and maximize the filling of the vertebral pedicle. Biomechanically, this is due to screw fixation in the denser cortical portion of the pedicle and uniform load distribution [24, 25]. The use of large-diameter screws is associated with a high risk of malposition. A mismatch between the implant and pedicle sizes can lead to a fracture of the pedicle and segment destabilization. The length of fixation in the study group had no significant impact on stability. However, with the advent of cement fixation and other screw augmentation techniques, the length of fixation no longer has a significant impact on maintaining stability [26].

Active use of bone cement (augmentation of a fractured vertebra, screws) has a significant effect on the maintenance of structural stability in the postoperative period; in this regard, our results are consistent with literature data [27, 28]. However, the use of bone cement cannot be considered

a safe surgical technique; its use is associated with a greater risk of fractures of adjacent vertebral segments, especially in the case of cement leakage into the intervertebral discs. There are known cases of cement embolism of the cardiac vessels and pulmonary artery, which can lead to death [29, 30]. Cases of compression of neural structures and neurological deficit in patients due to cement leakage into the spinal canal have been reported, and can result in revision surgery [31, 32].

Intermediate fixation with a screw placed into the fractured vertebra was found to be the most significant factor influencing the maintenance of fixation stability in the present series. The surgical technique may be biomechanically justified by the presence of a fixation point preventing rotational and translational deformity of the segment [33]. Our findings are consistent with those of other authors, who also report the positive effect of intermediate fixation maintaining structural stability [22].

The issue of deformity correction in patients with osteoporotic fractures is controversial. Our findings suggest that correction of spinal deformity and restoration of the sagittal axis have no significant effect on maintaining the fixation integrity, but this is inconsistent with other studies [34–36]. This discrepancy may be due to the low level of local kyphosis at baseline and the sample size. Residual kyphosis may have a negative impact on the quality of life, but we did not explore this indicator in the present series.

The study has several limitations. First, the retrospective design, relying on existing documentation, increases the risk of selection bias and information bias. We were unable to standardize the observation protocol and the timing of instability onset. Second, the small sample size and the small number of instability cases (eight patients) limit the power of the multivariate analysis, increasing the risk of overfitting the logistic regression model, and do not allow for a reliable assessment of the influence of rare factors. Third, the heterogeneity of the cohort (age, physical status, degree of osteoporosis, comorbidities, lack of standardized osteomodifying therapy, a variety of surgery types) makes it difficult to isolate the effect of individual surgical techniques reducing the generalizability of the results. Furthermore, the minimum follow-up period of six months may be insufficient to detect late mechanical complications and assess the impact of residual deformity on long-term clinical and functional outcomes, which was not specifically reviewed.

CONCLUSION

Instability of transpedicular fixation in patients with chronic osteoporotic vertebral fractures types OF4–OF5 was shown to be multifactorial. Among the variables explored, surgical factors including laminectomy and facetectomy were most significant increasing the risk of fixation instability. In contrast, a screw placed in the broken vertebra and bone cement augmentation contribute to the maintenance of metal construct stability and can be considered biomechanically practical elements of osteosynthesis. The length of fixation, the extent of kyphotic correction and residual kyphosis do not significantly affect the stability of the construct. The findings suggest the need for individualized surgical approaches in the treatment of patients with chronic vertebral fractures and osteoporosis.

Conflict of Interest Statement None of the authors has any potential conflict of interest.

Funding The authors received no specific funding for this work.

Ethical Approval The study does not raise ethical issues and does not violate the principles of the Declaration of Helsinki or the requirements of Russian legislation in the field of research ethics.

Informed Consent Given the retrospective nature of the study (review of medical records), informed consent from patients was not required.

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