EVALUATION OF OUTCOMES OF SURGICAL TREATMENT FOR DEGENERATIVE DISEASES OF THE SPINE

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The paper presents a review of the current literature devoted to estimation of outcomes of surgical treatment for degenerative changes in the spine using scales, tests and questionnaires. The literature search in domestic and foreign bibliographic databases has been carried out, and the use of scales, tests and questionnaires in spinal surgery was analyzed. The review presents requirements for scales, tests and questionnaires, examines the evaluation of clinical and patient-reported outcomes, and describes the advantages of multifactorial outcome evaluation. The multifactorial evaluation of outcomes is illustrated by the example of degenerative changes in the cervical spine, and includes a clinical case of surgical treatment for cervical myelopathy. The limitations of scales, tests and questionnaires are also discussed.
Key Words: outcome assessment, spinal surgery, degenerative spine disease.

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Medicine is not merely a science but an art.
Paracelsus (1493–1541)

Evidence-based medicine aimed at optimization of the quality of medical care has been rapidly developed in recent decades. For this purpose, only those prevention, diagnosis, and treatment methods are implemented in clinical practice, whose effectiveness and safety have been tested in clinical studies with a high level of evidence [2, 3, 5, 19, 23].

Objective evaluation tools used in clinical studies include rating scales, tests, and questionnaires. Evaluation of treatment outcomes using these tools in surgery is important for several reasons, including the need for objectification of surgical outcomes, analysis of safety, efficacy, and cost-effectiveness of the treatment. All these factors can make adjustments to the treatment strategy and/or surgical technique in order to achieve the best treatment outcomes [5, 6, 9, 10].

According to the WHO definition, which came into force in 1948, the term "health" is commonly understood as a state of complete physical, mental, and social wellbeing and not merely the absence of disease or infirmity [15]. This implies that health is characterized not only by the severity of a pathological process, but also social and adaptive capacity of an individual. Scales, tests, and questionnaires are basic measurement tools to assess the effect of the disease on patient's self-care and social activity. This evaluation is based on the measurement of certain parameters that reflect functional capabilities of an individual. The International Classification of Functioning, Disability and Health Disorders (ICF) shows the relationship between health components as well as their interaction [13]. Furthermore, this classification for the first time considered life activity disorders in the context of social or environmental factors [2, 3]. However, this classification does not include and does not assess patient's quality of life and satisfaction with the quality of life. To date, tests determining health-related quality of life, such as a 36-point brief questionnaire assessing the health status (SF-36), Sickness Impact Profile (SIP), European questionnaire of the quality of life (EuroQol) are widely used for this purpose [3, 19, 24–26].

In recent years, there are increasingly more published studies focusing on the application of scales, tests, and questionnaires in spinal surgery. Researchers are aiming to find out, which of the available scales can best describe the results of surgical treatment and most accurately assess patient's quality of life after surgery. Evaluation using scales, tests, and questionnaires is mainly used in clinical trials in order to report the results to the medical community in the form of publication or oral presentation. However, implementation of surgical outcome assessment in the routine clinical practice is of high importance, since the scales are easy to use and interpret both surgical outcomes and patients' subjective assessment of their condition. It is an easily available and easily applicable tool for objectification of treatment outcomes, which can unify the criteria of clinical studies and enable comparing treatment outcomes by specialists from different countries.

Requirements to scales

Scales, tests, and questionnaires are designed to measure subjective data in order to produce objective data. This conversion is achieved due to compliance with specific requirements (standards) that were originally developed in psychometry for psychometric tests [3]. Correct measurements are very important to obtain the result forming the basis for conclusions about treatment effectiveness. It should be noted that scales, tests, and questionnaires are the main tools to assess disorders of life activity and biosocial functions rather than pathological process, which is determined using diagnostic methods.

Basic requirements for scales, tests, and questionnaires are as follows: comparability of treatment methods (conservative or surgical), efficacy, reproducibility, validity, reliability, sensitivity, and data completeness [3, 5, 19, 24, 34].

Comparability. Methods of treatment should be comparable to each other. Depending on the study design, groups of patients receiving different types of treatment are compared. Outcomes after conservative and surgical treatment are often assessed separately because of different criteria for patient inclusion in the groups of conservative and surgical treatment. However, the results of conservative and surgical treatment may be compared.

When using scales, outcomes are assessed in two stages, before and after treatment. Pain is usually assessed throughout the treatment. In some cases, immediate and long-term surgical outcomes are evaluated. Immediate postoperative period means the next day after surgery, the day of discharge, and day 10 after the operation. Long-term outcomes should be evaluated in 1, 3, 6, and 12 months. When using the relative evaluation scales (MacNab, Nurick), evaluation of the results is started before the treatment [5].

Reproducibility is the similarity of the results of studies conducted using identical methods under identical conditions by different research groups in different centers. Therefore, application of questionnaires and scales by specialists of different medical centers in patients with identical pathology and after identical treatment is appropriate.

Validity is a measure of concordance between test scores and the nature of the property, quality, or parameter measured using these scores [3], i.e. the relevance and applicability of the assessment tool (in this case, test) under specific conditions for the specific purpose. The test must comply with its intended purpose and be adequate. In fact, validity characterizes the level of accuracy.

Reliability is the characteristic of test precision and stability and the level to which the result is free from random errors. The results obtained using reliable methods can be considered as accurate.

Sensitivity. A doctor should identify the presence or absence of a disease or condition in a patient, as well as the dynamics of the studied parameters using a test or questionnaire. The sensitivity of the test characterizes the probability of identification of such a state. If the test is highly sensitive, then it is capable of identifying patients with minimal abnormalities and describing more accurate dynamics of disease progression or regression.

Data completeness is the measure of sufficiency of the available data to make conclusions.

The aforementioned requirements are standard in the evidence-based medicine. Compliance with these requirements can guarantee the accuracy of the results obtained in the research.

Evaluation of treatment outcomes in spinal surgery

The interim results of the study focusing on the evidence level of outcome assessment in spinal surgery were published in 2015 [29]. The authors of the study reviewed the main types of treatment outcome assessment in the spinal surgery and classified surgical interventions into two main groups, decompression and stabilization methods and surgical neuromodulation methods. Surgical neuromodulation is a surgical treatment for chronic neuropathic pain, which includes chronic neurostimulation and intrathecal therapy. The use of validated scales and questionnaires in the diagnosis of chronic neuropathic pain is a standard [11]. Hereinafter we will discuss assessment of the outcomes of surgical treatment for degenerative spine disease (DSD).

Evaluation of clinical outcomes after stabilization operations. Outcomes are evaluated for fusion effectiveness and postoperative complications.

Historically, radiographic techniques are used to evaluate the outcomes of stabilization operations. Until recently, effectiveness of spinal fusion was determined as a complete union of operated segments as assessed by postoperative radiography [29]. However, plain radiography without functional tests is quite an unreliable method for determining cervical spine fusion, since the presence of trabeculae is considered as a fusion criterion, while changes in X-ray exposure time can affect the degree of trabecula imaging [33]. Besides imaging modes, the accuracy of outcome assessment using radiographic procedures is affected by spinal implants, as reported by Blount et al. [21]. Schoenfeld and Bono [31] pointed to other limitations of radiographic techniques, which lies in the fact that researchers mostly ignore the available modern tools for outcome evaluation and assess low fusion efficacy on the basis of local kyphosis, although it is observed in less than a half of cases and believed to be a non-permanent sign of instability [16]. Thus, the recommendations are currently changed and the effectiveness of stabilization operations should be evaluated based on the solid fusion rate, non-union rate and levels of fusion. Evaluation of the outcomes of minimally invasive surgery, such as endoscopic removal of disc herniation of the lumbosacral spine it still relevant [1].

About 20 % of patients have complications after spinal surgery [29]. Retrospective study [29] showed that the incidence of severe neurological deficit due to injury to the spinal cord or cauda equina in patients who underwent spinal surgery account for approximately 0–2 %. At the same time, 7 % of patients undergo revision surgery, including 5 % due to infection, 1 % due to cerebrospi-

nal fluid leakage or stabilizing system displacement. Importantly, the rate of favorable outcomes of stabilizing operations should exceed the risk of complications [21]. The scale for evaluation of the severity of complications is the best designed classification of spinal surgery complications [29]. It is a 5-stage scale for assessment of the severity of complications (0 — no complications, 4 — death) with allowance for the effect of intraoperative complications on the prolongation of hospital stay. It can be concluded that assessment of spinal surgery complications is quite a challenge and only limited number of tools are available for this purpose. Therefore, it was proposed to evaluate complications as the percentage of patients with complications and the number of complications [21, 29].

Outcomes as assessed by patients. The most significant factors affecting the patient's quality of life after surgery include the severity of pain, functional status, and the possibility to return to the usual household and professional activity [23, 28].

The visual analog scale (VAS), numeric rating scale (NRS), and verbal rating scale (VRS) are the most common pain assessment scales. Patient's functional status is usually assessed using the SF-36 and Oswestry disability index (ODI).

There is no special scale determining patient's ability to return to professional activity. However, Prolo economic status scale is being used for this purpose for the past 20 years [29]. Many researchers are skeptical about the reliability of the Prolo scale. Thus, V.N. Bikmullin et al. [4] investigated the reliability of this scale compared to that of the Watkins scale and concluded that the latter is more reliable. Watkins scale consists of three domains. Two of them assess the economic and functional status and match the same domains of the Prolo scale. These scales differ in the presence of pain assessment domain in the Watkins scale. The presence of only two domains in the Prolo scale makes it impossible to assess its internal consistency. It was also shown that the competitive consistency of the Watkins scale is higher as well. The possibility to assess pain together with economic and functional status is an advantage and the use of other scales and questionnaires can be avoided.

Assessment of the quality of life is one of the most important indicators of surgical outcomes. According to the WHO WHO's project to develop the WHOQOL (World Health Organization Quality of Life), quality of life questionnaire should meet the following requirements:

– the test should have sections assessing five major areas (physical health, psychological health, the level of independence in daily activities, social relations, security);

– emphasis should be placed on the patients' subjective perception of their health;

– the results of objective research are not included;

– questionnaires are filled by patients themselves.

The European quality of life questionnaire (Euro Quality of Life – 5D dimensions) meets these requirements, it is relatively simple to fill and evaluate its parameters [18, 35].

The role of multifactorial evaluation. Spinal surgery is a complicated procedure resulting in various outcomes, and therefore multifactorial evaluation should be carried out along with self-assessment of outcomes by patients. [29] It includes the assessment of clinical outcomes, i.e. the surgical outcomes and complication rate, as well as the outcomes evaluated by patients themselves, which include the general condition, disability level, pain severity, the possibility to return to professional activity, satisfaction with the results of treatment, and the use of analgesics. The trend towards multifactorial evaluation of the effectiveness of surgery originates from the suggestion made by Graver et al. [27] in 1998 on the calculation of the total clinical score consisting of the following components: pain intensity, physical symptoms, functional capabilities, and the use of analgesics. Table 1 shows the basic tools for multifactorial assessment of outcomes.

Several types of outcome assessment are described by Vavken et al. [34], who proposed classification shown in Table 2.

Pain assessment

Reduction of pain severity is the main goal of surgical treatment for the DSD. Pain is characterized by numerous aspects (severity, intensity, durability) and each of them can be evaluated using a proper tool. For example, the severity of pain includes pain intensity and negative impact of pain on daily activities.

ODI, Roland-Morris Disability Questionnaire (RDQ), and the SF-36 are the three most commonly used tools for assessment of the impact of pain on daily activities. They all meet the requirements of validity, reliability, and sensitivity. It should be noted that ODI is more suitable to assess the state of disabled patients, while RDQ can be used in the case of mild or temporary limitations of working ability. SF-36 questionnaire is a generalized questionnaire and it is less sensitive compared to the scales specific to a particular disease. Furthermore, SF-36 cannot determine the relationship between the overall patient's condition and pain in a particular area.

VAS, NRS, and VRS are the universal scales measuring pain intensity. Despite the fact that pain is the most pronounced symptom of the disease, this characteristic is subjective and depends on the patient's psycho-emotional personality characteristics. Quantitative assessment of the vertebral syndrome and extravertebral manifestations is advisable in order to obtain an objective picture. To this end, several simple but informative test have been developed, for example, "pouring water out of a kettle" test and "hand on the neck" test [3].

According to the US National Health and Nutrition Examination Survey as of 2009—2010, pain is chronic in 14 % of patients suffering from pain in the lumbar spine [32]. According to ICF, 26—33 % of the adult population in Russia suffer from chronic back pain. Chronic pain reduces the quality of life, psychological and social adaptation, and working ability [11]. Evaluation of chronic pain must necessarily include assessment of patient's mental condition, since chronic pain syndrome is often accompanied by severe psychological maladjustment

and emotional-volitional disorders in the form of depression [3, 11].

Multifactorial analysis of surgical treatment outcomes as exemplified by spondylogenic cervical myelopathy

DSD accounts for about 90 % of all cases of illness [9, 12, 14, 21]. This pathology is closely related to the living standards of the population and it is more common in developed countries, where people lead a sedentary lifestyle. DSD may lead to disability, significantly reduces quality of life, and affects patient's psychoemotional state. It is a multifactorial disease and its pathogenesis is still unknown. The ubiquity and chronisation of the process result in significant economic losses [17].

Progression of the DSD in the cervical spine results in cervical spondylogenic myelopathy (CSM). Pathogenesis of this condition includes the following two major mechanisms: degenerative changes in the cervical spine and ischemia. CSM is characterized by narrowing of the spinal canal due to degenerative processes in the intervertebral discs and joints, osteophyte formation, thickening and ossification of the ligamentous apparatus. This results in compression of the spinal cord and roots, which causes secondary circulatory disorders due to compression of the anterior and posterior spinal arteries. Ischemic disorders contribute to formation of the clinical presentation of the CSM [12].

It is advisable to use scales to assess the severity of CSM when diagnosing this pathology [9]. The Nurick scale based on the assessment of gait disorders is used to determine the stage of the process. The Japanese Orthopedic Association scale (JOA) is used to evaluate patient's clinical status with allowance for the level of postoperative neurologic recovery. Convenience of the scale lies in the possibility of calculating the recovery rate according to the formula:

$$K_R = \frac{K_2 - K_1}{17 - K_1} \times 100\ \%$$

where K_R is recovery rate; K_1 — preoperative index; K_2 — postoperative index [3, 6, 7].

In neurosurgical practice, these scales are successfully used to assess the severity of myelopathy [6—8, 10]. The JOA and Nurick scales can also be used to estimate of the effectiveness of a particular surgical treatment method. Thus, the studies demonstrated the effectiveness of laminoplasty compared to corporectomy in the case of CSM [8, 10]. The evaluation criteria of clinical symptoms included preoperative and postoperative JOA and Nurick scores. The JOA scale was used for objective assessment of neurological symptoms in both groups of patients (after laminoplasty and corporectomy) (Table 3). Analysis using the Nurick scale provided an idea of how patients change from one stage to another. The results are shown for the group of patients who underwent laminoplasty (Table 4).

Below we report a case of successful surgical treatment of multilevel cervical myelopathy with underlying degenerative compression [7].

Patient M., 66 years old, was admitted to the hospital with complaints of weakness in the left arm, gait disorders (dragging of the left leg), urination problems, and dizziness when walking.

Neurological status: clear consciousness; correct understanding of the place,

Table 1
Core Set of Instruments for Multidimensional Measurement of Spinal Surgery Outcome [29]

Outcomes	Recommended Measure
Patient-Reported	
General health status	SF-36 or SF-12
Back specific disability	Oswestry Disability Questionnaire (ODI)
Pain level	Visual analogue pain scale (1—10) for back or lower limb; or neck for cervical fusions
Return to work	Prolo Economic Scale
Patient Satisfaction	North American Spine Society Patient Satisfactio Index
Medication use	Patients taking narcotics, non-narcotic analgesics and no analgesics; patients with significant reduction in analgesics use (>50 %) measured post-operatively
Surgical	
Fusion status	Radiographic assessment of solid fusion, nonunion rate, levels fused
Complications	A generalized complication rate to include percentage of patients with a complication and breakdown of complications by number

Table 2
Types of outcome measures [34]

Type of measures	Description
Dimension-specific	Focus is on a particular aspect of health
Disease/population-specific	Measures several health domains and focuses on aspects of health that are relevant to particular health problems
Generic	Measures outcomes across diseases and different patient populations
Individualized	The importance of certain aspects of the respondent's life are measured and weighted to produce a single score
Role-specific	A more specific generic tool that captures aspects of working life
Utility	Developed for economic evaluation, entails preferences for health status, and yields a single index

time, self-perception. There are no meningeal signs. Cranial innervation without significant abnormalities. Left-sided hemiparesis with mild decrease in muscle strength in the proximal parts of the left hand, moderate — in the distal parts of the left hand and left leg; strength of the other groups of muscles is normal. There is pyramidal increase in muscle tone in the left extremities. Tendon reflexes of the hands are higher on the left than on the right; knee reflexes are increased, Achilles reflexes are intact. There is unstable Babinski sign on the left. There is carpal Rossolimo's sign on both sides, more pronounced on the left. There is no clonus. Mild hypotrophy of the left thenar. Conductive decrease in pain sensitivity on the left. The patient satisfactorily performs the finger-to-nose test. Romberg's test is negative. The patient controls the functions of the pelvic organs. There is no sensation of completely emptied bladder. The patient can walk independently without support, dragging his left leg.

Clinical status was assessed preoperatively, postoperatively (on day 7), and in 4 months using VAS, JOA, Nurick, and ODI scores (Table 5).

Preoperative preparation plan included MRI (Fig. 1) and additional diagnostic methods to assess functional changes in conductivity, such as investigation of somatosensory evoked potentials, transcranial magnetic stimulation, and electroneuromyography.

Discectomy, autologous fusion with cage at the level of C2—C3 vertebrae, C5 corporectomy, fusion with bone allograft and Atlantis ventral plate at the level of C4—C6 vertebrae were carried out (Fig. 2).

As the first stage, disc herniation at the level of C2 and C3 vertebra was removed using longitudinal dissection along the medial edge of the sternocleidomastoid muscle in the projection of C2 and C6 vertebrae under X-ray control followed by fusion with a cage. As the second stage, we carried out approach to C4 and C6 bodies, inserted distractor system, and performed C5 corporectomy followed by preparation and insertion of an allograft, which was fixed by Atlantis plate after final decompression of the neural structures.

Limitations of existing scales, tests, and questionnaires

Validation of scales, tests, and questionnaires is increasingly more common in the field of neurology and neurosurgery, since the need for adherence to objective assessment methods in medicine is well understood. Validation process includes not only professional linguistic translation of the scale from the original language, but also its cultural adaptation [20]. According to Beaton et al. [20], cross-cultural adaptation includes work of independent translators, direct and reverse translation, participation of original language speakers in translation, multiple editions of the scale before its initial testing on a limited population. Ambiguity may occur even at the stage of translation, leading to inaccurate interpretation and, therefore, incorrect assessment of treatment effectiveness, which is absolutely unacceptable as far as human life and health are concerned. This was demonstrated by V.N. Bikmullin et al. [4] as exemplified by Prolo scale and Renc et al. [30], who tested the SF-36 questionnaire translated to Chinese in the Chinese living in the United States. Even English-language scales require adaptation, when it comes to applying them in the UK and US [22].

It is important to take into account the level of adequacy of understanding the scale of the questionnaire depending on patient's intellect and education [11]. Difficulties can arise even with relatively simple scales, such as VRS and NRS, although it is believed that the level of understanding of both scales by patients is high. VRS may be unsuitable for patients with limited vocabulary, since its filling requires the use of adjectives that adequately describe patient's condition. Since the intervals between mild, moderate, and severe pain on the scale are equal, the problem may arise when describing the severity of pain within the intermediate scale divisions. However, this scale has an undeniable advantage, since a patient can score the severity of pain from 0 to 10 points even by phone, which can be applied to all three pain assessment scales.

Scales, tests, and questionnaires should be highly reliable. It should be kept in mind that, in the case of well-defined and well-controlled inclusion criteria, the study can often lose its external validity, i.e. generalizability and reliability of the results.

Improvement of medical techniques resulted in significant improvement of treatment outcomes. However, since the proportion of successful outcomes is high, further improvements are less noticeable, i.e. so-called saturation effect has been reached [30]. While improvement of clinical parameters still reflect significant changes, slight increase is considered as unimportant.

Table 3
Analysis of recovery of patients with myelopathy using the JOA scale depending on the medical history

Operation type	Medical history	JOA index		Recovery factor
		Preoperative	Postoperative	
Laminoplasty	over 2 years	8.27 ± 1.4	11.18 ± 2.4	28.2 ± 11.3
	less than 1 years	11.3 ± 1.2	13.8 ± 1.5	46.2 ± 19.2
Corporectomy	over 2 years	10.0 ± 2.4	14.7 ± 0.6	44.7 ± 16.4
	less than 1 years	12.4 ± 1.5	15.4 ± 1.5	58.8 ± 18.1

Average values are given; $p < 0.05$.

Table 4
Neurological status distribution in patients as assessed on the Nurick scale, n (%)

Stage	Before laminoplasty	After laminoplasty
1	3 (8.8)	6 (17.6); +3 from stage 2
2	7 (20.5)	9 (26.4); +5 from stage 3; –3 to stage 1
3	18 (52.9)	16 (47.0); +3 from stage 4; –5 to stage 2
4	4 (11.7)	1 (2.9); –3 to stage 3; +1 from stage 4; –1 to stage 5
5	2 (5.8)	2 (5.8); –1 to stage 4; +1 from stage 4

Conclusion

DSDs are widespread throughout the world. However, the methods of treatment of this pathology may vary depending on the medical center and specialist. In recent years, surgeons master increasingly more novel methods and techniques. When assessing treatment outcomes, it is necessary to make sure that the chosen tool reflects the expected end point [34]. Endpoint is the term adopted in the evidence-based medicine characterizing the disease and evaluating the clinical outcome of the treatment. It is also advisable to take into account generalizability of the end points and the possibility of comparing with the results of outcome evaluation by other instruments and the results obtained by other researchers. It should be kept in mind that questionnaire design affects end point distribution and the ratio of successful and unsuccessful surgical outcomes [4].

Although we cannot state that one scale is superior to another, it is easy to notice that some scales and questionnaires are used more often than others. When choosing the scale or questionnaire, one should be guided by high reliability and availability of a version validated for the use in a particular country. The following three most important goals of the surgery for spinal pathology formulated by McCormick, Werner, and Shimer should be kept in mind: improvement of patient's quality of life, functional recovery, and pain relief [28].

Table 5
Monitoring of the values obtained using scales and questionnaires for patient M., 66 years old

Scale	Preoperative	Day 7 after the surgery	4 months after the surgery
VAS: 0–10 points; normal value – 0	6	4	4
JOA: 0–17 points; normal value – 17 (recovery rate: 0–100 %; normal value – 100 %)	9	12 (37.5 %)	12 (37.5 %)
ODI: 0–100 %; normal value – 0 %	54	48	45
Nurick: 0–5 points; normal value – 0	Stage 3	Stage 2	Stage 2

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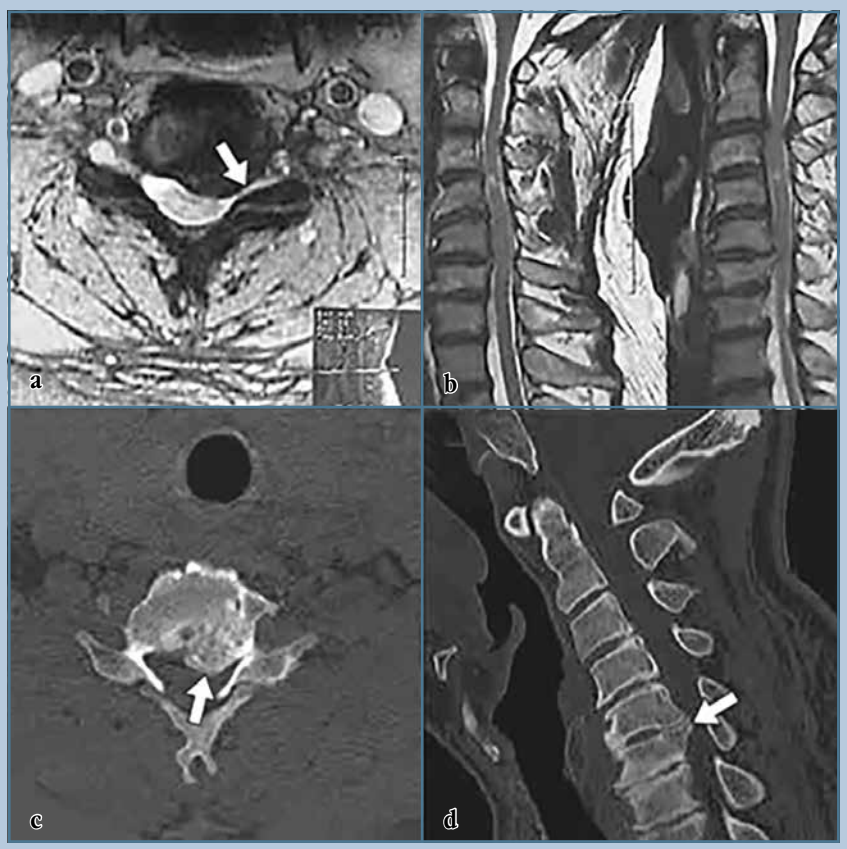

Fig. 1
Preoperative imaging data of Patient M., 66 years old (axial and sagittal view): **a** – MRI shows a left-sided paramedian herniation of the intervertebral disc at the level of C5–C6 vertebrae (arrow); **b** – MRI shows the lack of the anterior subarachnoid space at the level of C2–C7 vertebrae; **c** – MSCT shows ossified disc herniation at the level of C5–C6 vertebrae (arrow); **d** – MSCT shows hyperlordosis at this level (arrow)

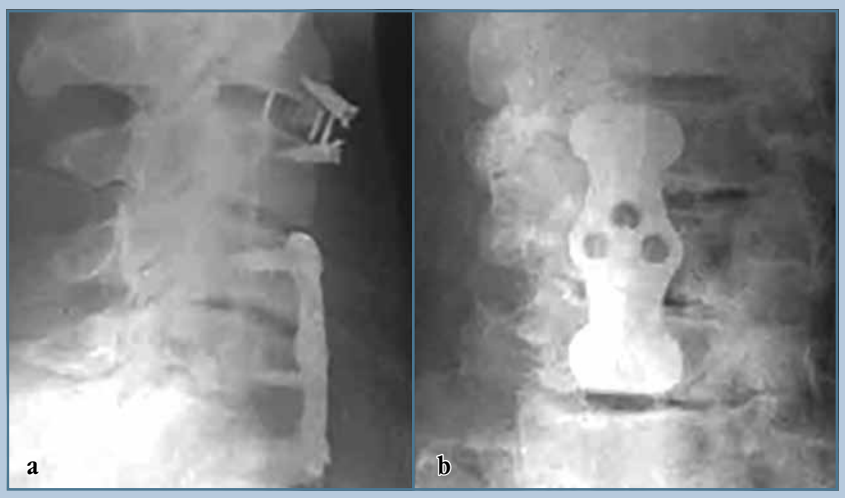

Fig. 2
Postoperative radiographic image of patient M.: lateral **(a)** and frontal **(b)** projections

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