Review article

Ukr Neurosurg J. 2023;29(2):3-10
doi: 10.25305/unj.276584

# Professional and ethical approaches to characterize complications in elective spinal neurosurgery. Never events in lumbar discectomy

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*Received: 03 April 2023*
*Accepted:27 April 2023*

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Any surgical intervention is associated with the possible development of complications. Surgical complications are traditionally an unpopular topic for discussion, but in recent decades they have received increased attention, due to both medical and economic factors. This review discusses the general concepts that characterize the negative consequences of surgical interventions in spinal neurosurgery: complications, adverse events, sentinel events, never events, collateral adverse outcomes. Classifications are given that allow systematizing these negative phenomena.

Surgical treatment of the lumbar disk herniation is the most frequently performed spinal surgery. The true number of lumbar discectomies is difficult to estimate because this procedure is often not an isolated surgical intervention, but a step in a larger one. Being a routine surgical procedure, discectomy, performed in one or another way depending on the preferences of the surgeon and available equipment, is characterized by a rather low relative frequency of adverse events and complications compared to other types of spinal surgery. However, due to the significant number of interventions, the absolute figures may present a medical and economic problem. Most authors refer to the classic triad of "wrong level, wrong side, wrong patient" and foreign bodies in the area of surgical intervention as obvious medical errors. Damage to the intestine or peritoneum, trauma to the great vessels and trauma to the nerve roots are considered serious complications, but not always medical errors. The other most commonly reported adverse events of lumbar discectomy are durotomy, neurological complications, surgical wound complications, recurrent disc herniation, and reoperation.

Until now, no clear classification of the negative consequences of lumbar discectomy, which would allow to verify the relationship between intraoperative adverse events (both surgical and anesthetic) and postoperative complications has been developed. In addition, it is extremely difficult, based on the criteria available in the literature, to identify a medical error in a number of iatrogenic complications, which requires further comprehensive study of the problem, since it has not only medical, but also legal consequences.

**Keywords:** *complication; adverse events; collateral adverse outcomes; lumbar discectomy*

## Introduction

There is no room for error in modern medicine, according to the public. While recognizing the fact that "doctors are only human", every patient has an expectation of perfection, sincerely believing in modern treatment methods which are widely advertised and based on technological innovations and highly accurate laboratory tests. Patients who have an obvious need to see their doctors as infallible with the tacit consent of the latter, subconsciously deny the very existence of an error or complication. Accordingly, any serious deviation from the expected outcome of the treatment performed, actually or hypothetically due to the doctor's actions, is regarded as an anomaly. And the solution to such a problem is usually to identify the culprit and through the imposition of certain penalties to get a promise that "it will never happen again." This approach largely limits the systematic changes that can reduce the number of errors and complications [1]. The analysis of errors and complications caused by certain medical procedures and manipulations remains an extremely unpopular and, therefore, less covered topic, amidst a vast amount of accumulated and systematized clinical material.

Progressively growing demand for medical services, and increasing costs caused by the introduction of more efficient and high-cost diagnostic and treatment methods in practical health care, with actually limited resources, as well as obvious differences in tactical approaches to the therapy of a particular nosology, registered within groups of specialists, have determined the need to evaluate and improve the quality of medical care [2]. Current trends in the availability and openness of

information allow patients and payers (public or private insurance companies) to reasonably demand objective and reliable outcome treatment data to assess both the quality of therapy and the cost of medical care [3, 4]. For a meaningful evaluation, such data should be obtained in a standardized and reproducible way, allowing comparisons between different medical institutions and treatment methods, as well as within the same centre over different periods [5, 6]. Health care policies in most developed countries indicate that the availability of data for comparing the performance of certain hospitals and physicians is a powerful market tool to achieve cost reduction while simultaneously improving quality [2, 7].

**Complications in surgical practice**

In the medical environment, there has long been a policy, if not of denying, then at least of keeping certain adverse effects of treatment quiet. This has led to the transfer of the initiative to analyse and propose methods for reducing the incidence of errors and complications to health care professionals - who, in most cases, are not directly involved in the treatment and diagnostic process [8]. This explains the tendency in recent decades to replace the classic medical term "complication" with the broader concept of "adverse event (AE)". At the same time, complications are defined as "a pathological process or event occurring during a disease, is not a mandatory component of this disease, but can be either its consequence or the consequence of the action of independent factors" [9]. An adverse event is a broader concept, as it does not always lead to a complication. Adverse events are defined as episodes that can affect the outcome of the disease, additional surgery, manipulations, diagnostic tests, or increased duration of follow-up [10]. Thus, AEs increase the duration and/or cost of disease treatment without necessarily resulting in adverse patient outcomes. Regarding spinal surgery, an AE is any unexpected or undesirable event that occurs during or as a result of spinal surgery, whereas a complication is an illness or disorder that, due to the surgery, will negatively affect the patient's treatment outcome. According to several studies, AEs have been reported in about 14% of cases of spinal surgical interventions, of which 76.5% did not result in complications [11].

Considering the concept of AE, one should mention the term "never events", first proposed in 2001 by K.W. Kizer, former chief executive officer of the National Quality Forum, to describe particularly gross medical errors that should never be made. Subsequently, the list of "never events" was expanded. Currently, it includes adverse events that are unambigous, i.e. not susceptible to interpretation of the causal relationship, serious and mostly avoidable [12].

In October 2007, Centers for Medicare & Medicaid Services (CMS), a federal agency within the US Department of Health and Human Services, required all medical facilities to report both primary and secondary diagnoses when applying for reimbursement for patient care. Since 2008, CMS has defined a list of in-hospital "never events" for spinal surgery - serious in-hospital diseases, the costs of which are not reimbursed [13]. These include the presence of foreign bodies in the surgical wound, air embolism, incompatible blood transfusions, grade III and IV bedsores, falls and injuries, clinical manifestations of impaired glycemic control, catheter-associated urinary tract infection, catheter-associated bloodstream infections, infectious-inflammatory complications of postoperative wound. In fact, CMS has imposed limits on reimbursement for the treatment of specified AEs. Financial responsibility is supposed to fall on hospitals and health care providers, not on insurance companies [14]. The concept of "never events" also exists in other countries [15].

There are adverse effects that are expected results of certain procedures and therefore do not require further evaluation or treatment in most patients. Such adverse outcomes should be considered treatment-specific and therefore do not meet the definition of a complication or AEs. Collateral adverse outcomes (CAO) are not the result of mistakes. They are registered frequently. In fact, CAO is a compromise in achieving the intended benefits of surgical intervention. Examples of CAO in lumbar spine surgery can be range of motion limitation, postoperative psychological stress, feeling of numbness in the surgical access area, postoperative pain, paravertebral muscles denervation, degeneration of adjacent levels [16]. Planning any surgical intervention involves an assessment of the ratio of the potential benefits of the chosen treatment option to risk of CAO and AE.

One of the first known attempts to systematise all surgical complications was made only in 1992 [17]. A group of researchers headed by P.-A. Clavien suggested classifying adverse outcomes by differentiating complications (unexpected events not specific to the surgical procedure), sequelae (adverse effects specific to the procedure), and failures (events in which the goal of the procedure is not achieved). Four degrees of surgical complications are distinguished:

- Grade I is a deviation from the ideal postoperative course that is not life-threatening and does not result in permanent disability. Complications of this degree require only bedside procedures and do not significantly increase the length of hospital stay;
- Grade II – potentially life-threatening complications, but without persistent residual functional impairment;
- Grade III is a complication with residual disability, in particular resection of organs or preservation of life-threatening conditions;
- Grade IV is a fatal consequence caused by complications.

In 2004, this classification was revised and modified by D. Dindo et al. [18]. For a long time before the development of highly specialized tools, the option suggested by the authors was actually the standard for ranking complications of all surgical interventions [19, 20] (***Table 1***).

The progressive strengthening of standards of providing medical care and financial costs control has necessiated not only the recording of complications, but also the search for causal relationships between the actions of medical staff and the negative consequences of treatment. This requires narrowly focused assessment tools that take nosological specifics into account. One of the first attempts at internal quality control and

systematization of complications in neurosurgical practice was made at the University of Heidelberg in 2001 [21]. The authors identified 3 main classes of complications:

1) neurosurgical complications are those that occurred in the postoperative period and are not characteristic of the natural course of the disease, technically correctly performed surgery, and the normal postoperative period (20 subclasses);

2) complications of the course of neurosurgical pathology are complications due to the specificity and localization of the pathological process (14 subclasses);

3) somatic complications are non-surgical complications that require additional diagnosis and/or follow-up treatment (13 subclasses).

In 2006, Y.R. Rampersaud et al. proposed a grading system for postoperative complications in spinal surgery depending on the length of hospital stay and the presence of consequences for the patient [11]:

0 – no postoperative complications;

I – minor complications: do not require treatment or require minimal treatment, do not affect the length of hospital stay or increase it by no more than 1 day;

II – moderate complications: require treatment, increase the length of hospital stay by 2–7 days and/or have no long-term (more than 6 months) consequences;

III – significant complications: require intensive treatment, increase the length of hospital stay by 7 days and/or have long-term consequences;

IV - death.

One of the most logical and consistent, in our opinion, AE grading systems in neurosurgical practice is the scheme proposed in 2009 by K. Houkin et al. [22]. They classified all AEs according to three criteria: 1) procedure-related, 2) predictability of the event, and 3) AE avoidability. Five types of adverse events are identified ***(Fig. 1)***. Thus, type I events are not related to the procedure and are incidental events occurring in the perioperative period. Type II events are related to the procedure but are unpredictable even in retrospective analysis. Events referring to types III–V are predictable and related to the procedure. Although type III events are predictable, they cannot be avoided, while type IV events are preventable. For type IV events, a different procedure may be recommended in retrospective analysis to avoid adverse events. However, no clear error is found in these events, whereas type V AEs are events that are clearly the result of negligence or human error.

The analysis of the given scheme gives grounds for a number of non-obvious conclusions. Thus, all adverse events classified as type II–V are iatrogenic, but medical errors account for only a small part of them. Not all of the anticipated adverse events associated with a particular manipulation, as well as prevention of complications, should be considered a medical error. It is natural that the assessment of predictability and the possibility of preventing a complication requires a complex approach and in many cases is challenging, since the same AE arising from a particular type of surgical intervention for a certain disease, depending on the characteristics of the patient, may differ in both predictability, and by the possibility of avoiding it.

The most up-to-date, according to our data, scheme for systematization of adverse events in spinal surgery is the Spinal Adverse Events Severity System, version 2 (SAVES-V2) [23]. The authors suggested dividing AEs into intraoperative and postoperative.

Intraoperative AEs categories:

1. Allergic reaction.
2. AEs anesthesia related.
3. Dislocation of a bone implant requiring revision.
4. Cardiac AEs.
5. Spinal cord injury.
6. Dural tear.
7. Hardware malposition requiring revision.
8. Hypotension (systemic <85 mm Hg for ≥15 min)
9. Massive blood loss (>5 L in 24 hrs or >2 L in 3 hrs).
10. Nerve root injury.
11. Bedsores.
12. Great vessel injury.
13. AEs related to airway/pulmonary ventilation.
14. Visceral injury.
15. Other.

Postoperative AEs categories:

***Table 1.*** Classification of surgical complications (D. Dindo et al., 2004) [18]

| | |
|---|---|
| Grade I | Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed drugs are antiemetics and antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade includes also wound infections opened at the bedside |
| Grade II | Deviations from the normal course of the postoperative period, requiring pharmacotherapy with drugs other than those allowed for grade I complications, as well as transfusion of blood components and total parenteral nutrition |
| Grade III | Complications requiring surgical, particularly endoscopic or radiological intervention |
| IIIa | Intervention not under general anesthesia |
| IIIb | Intervention under general anesthesia |
| Grade IV | A life-threatening complication requiring ICU management |
| IVa | Single organ dysfunction (including dialysis) |
| IVb | Multiorgan dysfunction |
| Grade V | Death of a patient |

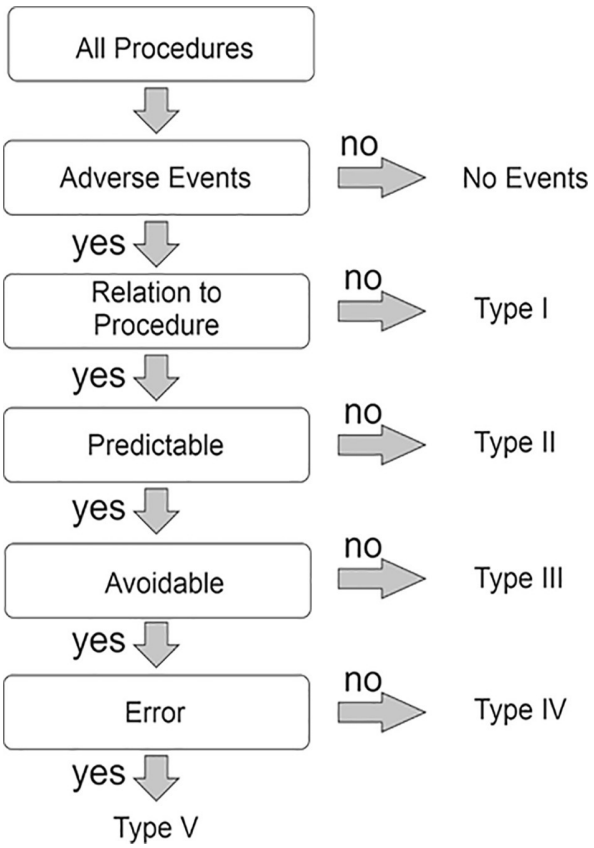


***Fig. 1.*** Algorithm for determining the type of adverse event in neurosurgical practice (according to K. Houkin et al., 2009 [22])

1. Cardiac arrest/heart failure/arrhythmia.
2. Construct failure with loss of correction.
3. Construct failure without loss of correction.
4. CSF leak/meningocele.
5. Deep vein thrombosis.
6. Deep wound infection.
7. Delirium.
8. Dysphagia.
9. Dysphonia.
10. Gastrointestinal bleeding.
11. Hematoma.
12. Myocardial infarction.
13. Neurologic deterioration ≥1 motor grade in the ASIA scale.
14. Nonunion.
15. Pneumonia.
16. Postoperative neuropathic pain.
17. Bedsores.
18. Pulmonary embolism.
19. Superficial wound infection.
20. Systemic infection.
21. Urinary tract infection.
22. Wound dehiscence.
23. Other.

Each of the reported AEs has been proposed to be systematised using a modified Y.R. Rampersaud scale [11]:

1. AE does not require treatment and has no side effects.
2. AE requires minor invasive intervention (Foley catheter, nasogastric tube, etc.) or additional treatment, but has no long-term effects.
3. AE requires invasive (e.g., surgery) or complex treatment and mostly has temporary (<6 months) adverse effects.
4. AE requires invasive or complex treatment and is likely to have long-term (6 months) adverse effects.
5. Significant injury to nerve structures (by ≥1 ASIA score worsening) or serious threat to life or health or any sentinel event.
6. AE resulting in death.

The effect of the amount of reported AEs on the patient's length of hospital stay was suggested to evaluate. Six options are possible: no effect on the length, increases the length by 1-2, 3-7, 8-14, 15-28 and 28 days. The described scheme is an almost universal tool for statistical analysis of AE in spinal surgery, since each type of surgical intervention is characterised by a specific frequency spectrum of the specified categories of adverse events.

Obviously, the list of AE classifications in spinal surgery is not exhaustive. A number of other methods have been proposed for ranking the adverse effects of surgical interventions, based on different principles and developed for different types of surgical interventions or nosological units (24-30). Some of these are still in use in clinical practice. These data allow us to form a common understanding of the concept of "adverse events" and "complications" in modern neurosurgical practice and, accordingly, to take a critical view of the statistical data reported in the specialised literature.

**Complications of lumbar discectomy**

Lumbar disc herniation is the most common cause of sciatica, affecting 1 to 5% of the population annually [31–33]. Primary treatment of sciatica is predominantly non-surgical and usually involves medication, physical therapy, and sometimes epidural steroid injections. Acute sciatica symptoms disappear in most patients regardless of treatment [34]. In cases where initial conservative treatment is ineffective, two options are considered: continuing conservative treatment with a wider range of physiotherapeutic effects and medications, or performing a lumbar discectomy to remove a herniated intervertebral disc resulting in irritation/compression [35]. The feasibility and benefits of each approach are debated [36], but it is generally accepted that surgical treatment provides rapid symptomatic relief compared to conservative therapy [37]. In longer-term follow-up, the differences in efficacy between surgical and conservative treatment are usually leveled out, but invasive treatment methods have some advantage [31]. Results of randomized controlled trials suggest that more than 40% of patients who choose or are prescribed conservative treatment undergo surgery within the first 2 years after the onset of the disease [38, 39].

Since W.J. Mixter and J.S. Barr reported the first successful resection of a lumbar disc herniation accompanied by removal of end plates (1934) [40], surgical treatment methods for degenerative changes of the spine have continually evolved with a general

tendency towards minimizing trauma. In 1951, J.E. O'Connell proposed an extended discectomy technique involving the radical removal of an intervertebral disc with disc herniation resulting in clinical symptoms. The concept behind this procedure is that the remaining part of the disc tends to form re-extrusion, leading to a recurrence of symptoms. The method was considered the gold standard of lumbar hernia surgery until 1977, when the surgical microscope was first used and the microdiscectomy technique was developed [41]. The advantage of the latter is the much smaller surgical access compared to a standard discectomy, which significantly reduces the duration of surgical intervention and the volume of blood loss, shortens the patient's hospital stay, reduces the risks of infectious complications and facilitates a faster return to an active lifestyle [42].

However, additional curettage of the intervertebral space leads to disc height collapse, which can provoke the formation of instability and cause the development of spondylosis ("failed back surgery syndrome") [43, 44]. To prevent these consequences, R.W. Williams and D.M. Spengler proposed sequestrectomy consisting in removal only a disc fragment with no or little invasion into the disc space [45, 46]. Despite the presence of some disadvantages, both techniques (microdiscectomy and sequestrectomy) are widely used in clinical practice.

Advances in science and technology contributed to the development and improvement of medical technologies, making it possible to introduce minimally invasive discectomy techniques. In 1993, H.M. Mayer and M. Brock, and in 1997, K.T. Foley and M.M. Smith described techniques using tubular retractors - endoscopic discectomy, later - microendoscopic discectomy, as well as total endoscopic discectomy with video assistance [47, 48]. Despite the advantages of minimally invasive techniques, the clinical outcomes of using endoscopic techniques and classic microdiscectomy and discectomy have not been shown to be statistically significantly different [49].

Surgical treatment of lumbar spine hernia is currently the most commonly performed intervention in spinal surgery [42, 50]. The ratio of minimally invasive to open surgical manipulations varies considerably depending on the region. Despite an increase in the proportion of minimally invasive interventions, open surgeries still predominate [51]. The actual number of discectomies performed is difficult to estimate, since disc removal is often not an isolated surgical intervention, but a stage of larger operations, ranging from interbody fusion through posterior and lateral approaches (PLIF, TLIF, and XLIF) to major decompressive-stabilization interventions. In recent decades, there has been an increasing trend towards the latter [52–54]. As a routine surgical intervention, discectomy, performed in some modification depending on the surgeon's choice and material and technical support, is characterized by rather low relative AE and complication rates compared to other types of spinal surgical interventions. However, due to a high number of operations, absolute rates can pose a medical and economic problem. Given the fact that all discectomy options (open, minimally invasive, in particular fully endoscopic) are applied to the same anatomical site and they solve the same task, the frequency spectrum of complications for these interventions is very similar [55]. Slight differences are due to both technical features and registration methods.

As mentioned above, the grading of adverse effects of spinal surgical interventions is still not strictly regulated. Most authors refer to the classic triad "wrong level, wrong side, wrong patient" as obvious medical errors, which is the most common in lumbar discectomy, as well as foreign bodies in the area of surgical intervention [56, 57]. However, in most cases, these events are caused not due to a surgeon's error, but largely due to defects in the organization of the care system in general [58, 59]. Injuries to the intestine or peritoneum, injuries to great vessels and nerve roots are considered to be serious complications, but not necessarily medical errors. The specified 5 types of AEs are commonly grouped into a group of so-called sentinel events (SE) that require close attention and priority development of methods for their prevention. SEs are associated with a significantly higher incidence of postoperative cardiac complications, aspiration, deep vein thrombosis, surgical site hematoma, hemorrhagic anemia, neurological complications, pulmonary embolism, re-intubation, urinary tract infection, intestinal obstruction, and postoperative wound infection, which in 20 times increases the mortality rate compared to patients without these complications [60, 61].

Other commonly reported AEs of lumbar discectomy include intraoperative dura mater damage combined with postoperative CSF leak/meningocele in 1.1–6.6% of cases, neurological complications (worsening of preexisting motor or sensory symptoms, and the appearance of new postoperative symptoms) – 1.8–4.9%, complications related to the postoperative wound (superficial and deep wound infections, including spondylodiscitis, hematoma of the surgical site, poor wound healing and suture dehiscence) – 1.2– 3.5%, recurrence of disc herniation – 39.0–51.0%, reoperation – 33.0% [55, 62]. The given list of complications and AEs is not exhaustive, and the data on the frequency of their occurrence are rather indicative and do not reflect the true situation. Some authors have pointed that the frequency of complications is always lower in retrospective analysis than in prospective analysis. Thus, in general, for thoracolumbar spine surgery, the prospective and retrospective complication rates are 20.4 and 17.5%, respectively [63]. In addition, the rate of intraoperative complications declared by surgeons is always lower than that reported by external observers, which also does not contribute to the objectification of the rates [64].

The difficulty in analyzing and interpreting complications in lumbar discectomy, as well as in spinal surgery in general, is that in most publications, AEs are considered as defects in the provision of medical services, and the economic component is considered the basic criterion. In fact, the idea of "complication is bad because it is expensive" is regulated. For example, even SAVES-V2 divides all AEs into intraoperative and postoperative, but does not allow one to single out surgical, anesthetic, etc. for analysis. It is quite

difficult to verify the relationship between postoperative complications and intraoperative AEs.

For a practicing surgeon or anesthesiologist, only the medical component of potential AEs is of interest in terms of their causal relationship, prevention methods, the impact of comorbidities, and other risk factors. Despite the vast clinical experience of lumbar discectomies as the most commonly performed spinal surgical procedure, this issue remains open and requires further comprehensive study.

**Conclusions**

The data presented in the review indicate that surgical complications, as a traditionally unpopular topic for discussion, have received increased attention in recent decades due to medical as well as economic factors. The introduction into practice of the term "adverse event", aimed at streamlining the analysis of adverse effects of the provision of medical care, has not solved the problem of adequate registration, statistical analysis and identification of causal relationships of surgical complications, due to ambiguous interpretation, as well as the lack of clear and generally accepted classification principles.

Lumbar discectomy, being the most frequent spinal surgical procedure, is characterized by relatively low complication rates, but given the number of discectomies performed, the absolute number of these complications may have some socio-economic significance. A number of questions concerning the relationship between AEs recorded intraoperatively and the development of postoperative complications require further investigation.

**Disclosure**

*Conflict of interest*

The authors declare no conflict of interest.

*Ethical approval*

This article contains no studies involving humans or animals.

*Funding*

The research was conducted without sponsorship.

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