



# PERIOPERATIVE AND EARLY COMPLICATIONS OF EXTENDED INSTRUMENTAL FIXATION FOR SPINAL DEFORMITY IN CHILDREN: WHAT DOES THE APPLICATION OF THE CLAVIEN – DINDO CLASSIFICATION REVEAL AND WHAT QUESTIONS DOES IT RAISE?

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**Objective.** To analyze complications of extended posterior instrumental fixation for spinal deformity in children in accordance with the Clavien – Dindo classification and to assess its information content and limitations.

**Material and Methods.** A retrospective single-center cohort study included 136 patients aged from 1 year to 17 years 11 months consecutively operated in 2020–2023 for thoracic and lumbar spine deformities associated with congenital, neuromuscular, syndromic, idiopathic scoliosis and Scheuermann's kyphosis. At least four spinal motion segments were included in the zone of posterior instrumental fixation. All perioperative events and postoperative complications noted in the medical records were registered in accordance with the Clavien – Dindo classification. An analysis of factors influencing the development of complications of grade IIIB and higher was carried out.

**Results.** With a total apparent high number of complications/events (55 or 40.4 % of the number of operations), the vast majority of them correspond to grade I–II (41; 30.1 %) and do not affect the tactics and outcome of treatment. Complications of grade III and IV were noted in 13 (9.6 %) cases, and of grade V – in 1 (0.7 %) case. The influence of deformity etiology, gender, age or underweight on the risk of grade IIIB and IVA complications was not revealed, which may be due to the limited number of observations. The installation of more than 18 transpedicular screws, which correlated with surgery duration and blood loss volume, was significant for the development of such complications. The results obtained were compared with those presented in the literature, the information content and limitations of the use of the Clavien – Dindo classification in spine surgery were discussed.

**Conclusion.** A significant part of the complications of spinal deformity correction in children is conventionally not taken into account in domestic practice and, accordingly, cannot be prevented. The use of the Clavien – Dindo classification allows estimating the frequency of complications that potentially do not affect (grade I–II) and affect (grade III–IV) the tactics of postoperative treatment and outcomes. The installation of 18 or more supporting elements of instrumentation is directly related to surgery duration, intraoperative blood loss volume and the risk of developing grade IIIB and IVA complications. Larger data sets are needed for a more objective analysis of the risk of severe complications for each nosology.

**Key Words:** spine; deformities; children; scoliosis; kyphosis; complications; infection; transpedicular fixation; halo-traction.

Please cite this paper as: Mushkin AY, Petukhova VV, Pershin AA, Maletin AS, Malamashin DB, Kuklina SA, Evseev VA, Kostik MM. Perioperative and early complications of extended instrumental fixation for spinal deformity in children: what does the application of the Clavien – Dindo classification reveal and what questions does it raise? *Russian Journal of Spine Surgery (Khirurgiya Pozvonochnika)*. 2024;21(3):36–46. In Russian.

DOI: <http://dx.doi.org/10.14531/ss2024.3.36-46>.

The perioperative events/complications is not only a clinical and statistical but also a management issue, since some of them may be planned, and their analysis and identification determine the possibility of appropriate prevention.

The risk and incidence of complications in spine surgery are usually evaluated in relation to a specific clinical eti-

ological group (deformities, infections, injuries, tumors, etc.) or surgical technique (conventional open or minimally invasive), with reported complication rates in surgical treatment of scoliosis ranging from fractions (for congenital deformities) to tens of percent (for neuromuscular scoliosis, NMS) [1–7]. The research design may be one of the

reasons for the considerable differences within the nosological category: it has been proven that surgeons usually record fewer perioperative events/complications than independent researchers whose data is considered to be more objective [8]. It remains controversial to compare local asymptomatic conditions that are immediately diagnosed and elim-

inated intraoperatively with the conditions that arise after surgery but are not associated with spinal pathology, as well as planned and unplanned revision procedures [9, 10].

Currently, the Clavien-Dindo classification of perioperative complications [11, 12] has recently been used in spine treatment [13] and for spinal deformities in children only in recent years [14–16].

The objective is to analyze complications of extended posterior instrumental fixation for spinal deformity in children in accordance with the Clavien – Dindo classification and to assess its information content and limitations.

Study design: a retrospective single-center cohort study.

#### *Methodology for data collection*

1. One of the authors, who was not on the hospital staff on time of surgery, analyzed surgical records and case histories with the registration of complications. The events that were documented have been confirmed and evaluated by other authors.

2. The concept of Extended Posterior Instrumented Fixation accepted in the Russian literature was selected as the best-fitting to English term the Long Segmental Spinal Fixation (LSSF) used when at least two segments above and below the deformity apex are included in the instrumentation zone [17].

## Material and Methods

The study cohort was composed according to the following criteria.

#### *Inclusion criteria:*

- patients under 18 at the time of surgical treatment;
- unity of surgical treatment place (clinic of pediatric surgery and orthopedics, Saint-Petersburg Research Institute of Phthisiopulmonology);
- time of surgery: from January 1, 2020, to December 31, 2023;
- first-time spinal instrumentation for deformity correction with inclusion of the thoracic and lumbar spine (from T1 to L5);
- open-approach surgery;

- etiology of deformity: idiopathic, syndromic, neuromuscular, congenital scoliosis/kyphoscoliosis and Scheuermann's kyphosis;

- inclusion of at least four spinal motion segments in the instrumentation zone;

- use of entirely transpedicular or hybrid (screws + hooks) fixation systems with at least four anchor elements;

- intraoperative neurophysiological monitoring of motor evoked potentials;

- not using self-saver technology;
- wound suturing after hemostasis without additional drainage and without local antibiotics;

- recording of complications developed intraoperatively and in the first 30 days after surgery.

#### *Exclusion criteria:*

- spinal deformities due to injuries, tumors, infectious and inflammatory processes, consequences of spinal hernias and syndromic kyphosis (achondroplasia, spondylo-meta-epiphyseal dysplasia, etc.);

- inclusion of the cervicothoracic (C7/T1 and above) or lumbosacral (L5/S1) spine in the area of instrumental fixation;

- fully laminar fixation or application of Luque fixation.

In cases of rigid spinal deformities, Schwab-grades II to IV vertebroplasty [18] was performed. The duration of surgery, blood loss, number of anchor elements, neurophysiological monitoring data, and neurological changes were recorded.

#### *Examination techniques*

All patients suffering from NMS and Scheuermann's kyphosis were examined according to the guidelines approved by the Russian Ministry of Health [19, 20] with a complex of imaging examinations (radiography, CT, MRI) and additional study if indicated; patients with idiopathic scoliosis underwent radiography with bending test. All patients were examined by the same neurologist.

#### *Assessment techniques*

All identified perioperative events/complications were evaluated according to the Clavien – Dindo classification (Table 1).

Considering the particularities of spinal surgery, complications are categorized as follows:

- grade I: hematomas not requiring drainage, limited marginal necrosis, as well as asymptomatic screw malposition found on postoperative CT scan;

- grade II: pain that persists for more than four days and requires systemic administration of analgesic drugs; drained hematomas not requiring suturing, marginal necrosis complicating inpatient treatment, as well as postoperative substitution blood transfusions; transient neurological disorders with complete regression by the time of discharge;

- grade IIIA: hemopneumothorax requiring puncture or drainage; cases of secondary wound suturing;

- grade IIIB: surgical site infections (SSIs), as well as neurological complications associated with malposition of anchor elements or compression of bone structures;

- grade IVA: cerebrovascular disorders, hemodynamic instability, respiratory dysfunction, malabsorption, etc.;

- grade IVB: any combination of grade IVA complications.

The following factors were identified during statistical study:

- non-modifiable risk factors: etiology of deformity, gender and age of patients, circulating blood volume (CBV), and body weight (due to the difficulty in interpreting BMI in children, weight below the 3rd percentile for age, height, and gender was considered insufficient);

- modifiable risk factors: surgery duration, blood loss volume, number of anchor elements, surgical technique, incl. simultaneous or staged surgery with discectomy and halo-traction performed 1–2 weeks before the main surgery.

Statistical processing was performed in Microsoft Excel and Statistica 10 software. Quantitative variables were tested for normality of distribution using the Kolmogorov-Smirnov test. Due to non-normal distribution, the results were expressed as medians (Me) and extreme values (min; max) for quantitative variables; absolute values and fractions (%) were used for categorical variables. Independent categorical and binary variables were compared using the Chi-square test or Fisher's exact test if the expected frequency was less than 5. Differ-

ences between two independent quantitative variables were determined using the Mann – Whitney U test. Thresholds for quantitative variables were determined using ROC analysis, followed by the determination of odds ratio, relative risk, sensitivity, and specificity. Statistical hypotheses were tested at a critical significance value of  $p = 0.05$ . The correlation between parameters was calculated using Spearman's correlation coefficient.

## Results

The inclusion/exclusion criteria were met by 136 patients (47 boys, 89 girls) who underwent surgery between the ages of 1 year and 17 years 11 months (mean age  $11.7 \pm 4.6$  years). Discectomy in the thoracic spine and pre-op halo-femoral traction for 10–14 days were performed in 14 patients, and halo-femoral traction was performed intraoperatively in 4 ones.

The distribution of patients by etiology of deformity is given in Fig. 1: there were a comparable number of congenital, as well as idiopathic and syndromic scoliosis, together accounting for 86%; other pathologies accounting for 14 % only.

Since the number of patients with Scheuermann's kyphosis, neuromuscular, and syndromic scoliosis (the latter represented by neurofibromatosis in all cases) was small, they were combined with idiopathic scoliosis in the general description of the study. The distribution by age and number of transpedicular anchor elements placed is shown in Fig. 2 and Fig. 3. The minimum number of pedicle screws noted in Fig. 3 do not contrast with the inclusion criteria, where the minimum number of anchor elements, including hooks, is 4. The number of screws was selected in the following analysis because their malposition is usually attributed to the risk of neurological complications.

It became obvious by the time the outcomes were evaluated that all children after polysegmental spinal fixations required prolonged anesthesia and had local hematomas of varying severity; for this reason, it was decided to combine complications of grades I and II in further analysis as not affecting the course of inpatient treatment.

The adverse effects/complications were reported in 55 (40.4 %) from 136 operated patients; the distribution according to Clavien – Dindo classification is summarized in Table 2.

Grade IIIB included 4 stability failures of anchors, 4 early SSIs, and 3 neurological deteriorations, including their combination in one observation.

Grade IVA included a case of massive intraoperative blood loss with hemodynamic impairments that required termination of surgery and treatment in the intensive care unit. The surgery in complete volume was performed several months later.

One lethal outcome was associated with the development of massive pulmonary embolism in the early postoperative period in a patient with syndromic scoliosis.

Complications of grades III and IV are of highest interest for analysis and are the focus of subsequent attention. The staged factor analysis indicated that the risk of their development was influenced by the surgery duration, the volume of intra-op blood loss, and the number of placed anchor elements, whereas no statistical relationship was proved with respect to the etiology of the deformity, gender and age of the patients, underweight, and two-stage treatment (Tables 3, 4).

ROC-analysis was used to identify threshold values of predictors of com-

plications development: blood loss more than 950 mL or more than 20.6 % of CBV, surgery duration more than 365 min and number of anchor screws more than 18 (Table 5).

The number of anchor elements greater than 18 that had the strongest association with the development of complications correlated with the surgery duration and intraoperative blood loss in all cases, which does not give an opportunity to assess the influence of each factor separately. In addition to having etiological peculiarities (5 congenital scoliosis, 41 other deformities; 10.9 % and 89.1 %, respectively), patients with more than 18 anchor elements were also 2 years older – 14 (11; 17) and 12 (2; 17) years; they weighed 10 kg more – 49 (28; 97) and 39 (11.9; 95) kg; and they were 8 cm taller – 161 (131; 178) and 153 (86; 199) cm in comparison to patients with fewer pedicle screws. The mean surgery duration in these subgroups was 400 min (280; 540) and 280 min (120; 590), respectively, and blood loss was 28.5 % (7.4; 55.7) and 16.1 % (4.0; 60.1) of CBV or 1,000 mL (350; 1,600) versus 445 mL (50; 2,100), respectively. It is obvious that the development of grade III and IV complications imminently increased the length of hospital stay ( $p = 0.00001$ ).

There were not surgical site infection (SSIs) in congenital scoliosis, while their incidence in other pathologies was 5.3% ( $p < 0.001$ ).

Table 1

Clavien – Dindo classification of surgical complications [11, 12]

Grade	Definition
I	Any deviation from the normal course without the need for pharmacological, surgical, endoscopic, or radiological treatment
II	Requiring pharmacological treatment, postoperative blood transfusion and parenteral nutrition
III	Requiring surgical treatment/procedures
IIIA	Interventions without general anesthesia
IIIB	Interventions under general anesthesia
IV	Life-threatening complications (including CNS complications) requiring treatment in intensive care units
IVA	Single organ dysfunction
IVB	Multi-organ failure
V	Death

The study did not identify any factors significantly influencing the risk of neurological complications.

## Discussion

The peculiarity of the Clavien – Dindo classification is, in our opinion, its comprehensiveness from the administrative as well as organizational and analytical points of view. Since its occurrence, the need to adapt it for each separate section of surgery has been consistently noted [27], and this has taken more than 20 years for pediatric spinal deformity surgery [14–16]. Nevertheless, we would like to deal not only with the analysis of the results obtained during the study but also with additional issues that inevitably arise.

It is highly unexpected that there is an almost complete shortage of domestic articles directly focusing on the problem of complications in pediatric spine surgery. Consequently, the results of our study which, at first glance, should have triggered a negative reaction due to the high number of adverse effects, had to be compared with other papers, providing a slightly different perspective on the issue.

In a single-center observational analysis of 450 spinal surgeries in children, Lambert et al. [22] reported implant-associated SSIs in 5.8 %, including 2.4 % in idiopathic scoliosis and 12.3 % in NMS. Revision surgeries were performed in all cases, including repeated revision in 8 %.

Practically at the same time, Mallet et al. [23] indicate the possibility of reducing the incidence of SSIs in adolescents with idiopathic scoliosis from 5.1 % to 1.3 % due to preoperative decontamination of the nasopharynx from *Staph. Aureus*, yet 4 years later, after assessing a mean SSI rate of 3 %, they note that despite the local application of vancomycin, the infection still developed in 5.4 %, while massive povidone-iodine wound irrigation resulted in 1.1 % [24].

According to a multicenter study by Lake and Gordon [25], the fluctuating incidence of implant-associated SSIs ranges from 0.5 % to 3.0 % in adolescents with idiopathic scoliosis and from 4.0 % to 13.0 % in those with NMS. Meanwhile,

the Harms Study Group [26] estimated the total number of major complications in scoliosis at 9.9 % in a 10-year follow-up; infectious complications were reported in one third of cases, and neurological complications in every ninth case.

Another interesting data on 27 % of complications in surgery of NMS in children, 81 % (!) of which are major complications; their predictors are inability of patients to walk, overweight, myelomeningocele, lumbar hyperlordosis, and pronounced pelvic torsion, as well as intraoperative blood loss, surgery duration, and pulmonary complications [27].

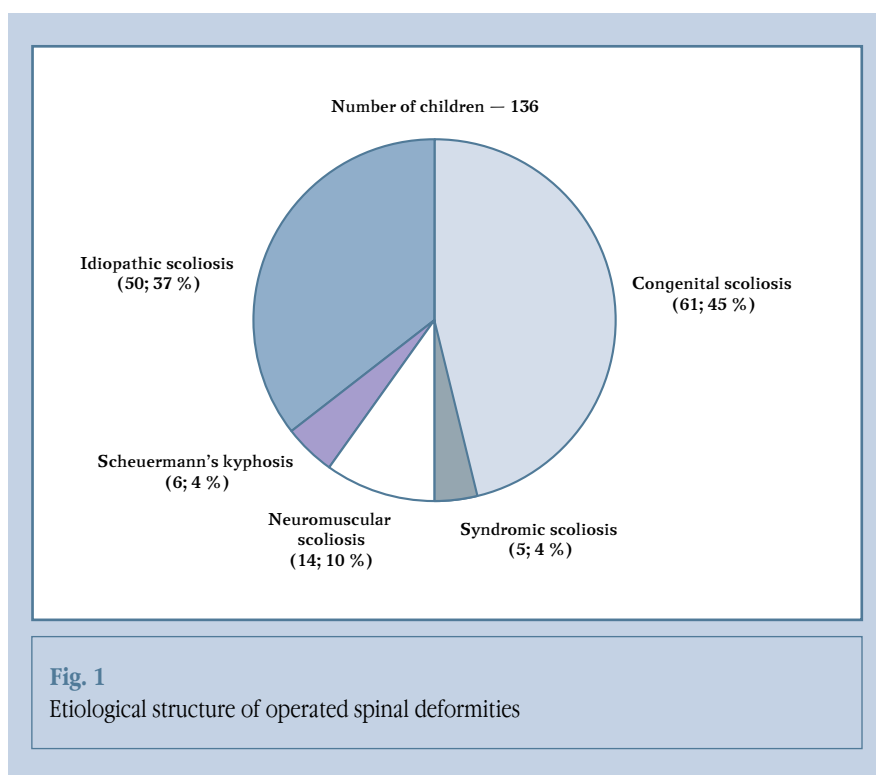
Besides the efficacy of halo-traction for severe spinal deformities, in recent years, attention has been focused on its complication rate of 23.3 %; 16 % of these complications are neurological, and almost half (46 %) are associated with infection in the cranial screw site [28]. The relation of the technique to complications of the main stage has not been analyzed, presumably because the technique itself is used only in an intraoperative manner.

The overall complication rate of spinal deformity correction in children is reported to range from 5.1 % to 22.3 %,

according to the US national database. In turn, the incidence of neurological complications is 0.9 % [29], but other studies show that it ranges from 0.3 % to 4.0 % [30–31]. Interestingly, one-third of them are considered nonreversible [32] even after revision surgery, which is explained by the predominance of spinal cord ischemia rather than compression [33].

The incidence of all, including long-term major complications in Scheuermann kyphosis surgery is reported to be 16.3 %, three times higher than idiopathic scoliosis with a comparable incidence of neurological complications [34]. Each additional level of instrumentation increases the risk of complications by 37 %, primarily because of SSIs, pseudarthrosis, and contact segment pathology. It is particularly noted that additional anterior column release, increasing the time and injury rate of surgery, does not provide advantages for deformity correction compared to posterior vertebrotomy [35].

The reasons for prolonged hospital stay of patients with idiopathic scoliosis include training purpose (!), comorbidity, fixation of nine or more spinal segments, massive blood loss, low epidural anesthesia efficacy, and major



postoperative complications (the last factor enhances the risk of prolonged hospital stay by 3.14 times). Moreover, the authors refer to the mean duration of the hospital stay as 4 days and to prolonged hospital stay as more than 6 days [7, 36].

The identification of the correlation between the risk of severe complications and interrelated factors (number of anchor elements, surgery duration, blood loss volume) has to influence the technique of deformity correction, the use of perioperative blood saving tech-

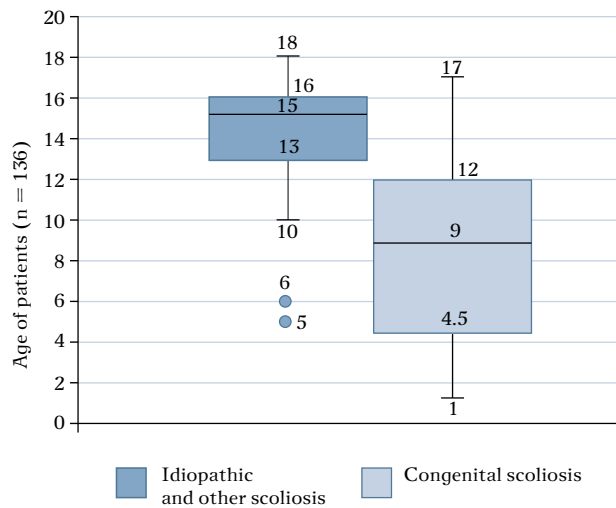
niques, the calculation of the adequate number and options of anchor elements, etc. Intraoperative neuromonitoring, rejection of preliminary halo-tractions, etc. are of equal significance. [37–41]. Although our results are comparable to those described above, it is the small number of cases that explains the lack of evidence in our cohort of the effect of the deformity etiology on the risk of complications.

While favorably evaluating the use of the Clavien-Dindo classification, first of all, to register complications in spine surgery and to build a strategy for their prevention, we would like to draw attention to the challenges associated with its use as a tool for comparative studies.

For example, compressive myelopathy, one of the reasons for which is intracanal position of the screw, usually regresses after revision surgery, but it may be less important for the patient than persistent ischemic disorders that require conservative neurotropic and vascular treatment, given the pathogenesis. However, the first corresponds to grade IIIB, and the second must be rated as grade II.

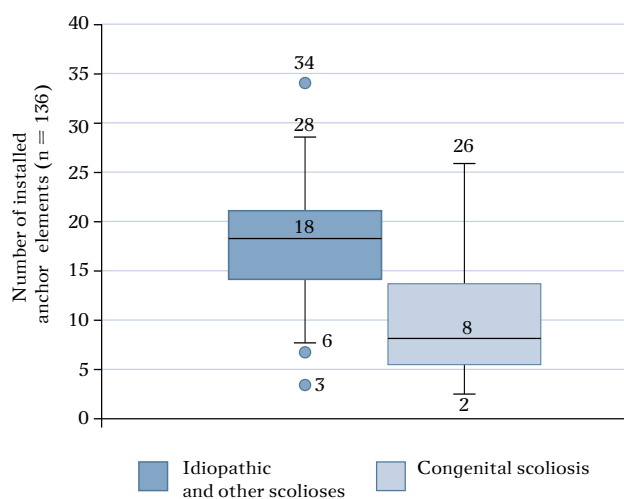
Some systemic complications of grade IVA (e.g., manageable transient respiratory and hemodynamic impairments) may be less crucial for the prediction of the patient's quality of life than nonreversible neurological complications (grade II).

Should asymptomatic (including intracanal) pedicle screw position be considered a complication? Are revision procedures reasonable in these cases, given that they are often justified by the potential for future complications? However, every spine surgeon is aware of the spinal cord's reserve spaces and, with sufficient experience, has seen intracanal malpositions that had no clinical manifestations in the long-term follow-up and were associated with a change in the preoperative neurological deficit obviously associated with the elimination of spinal cord kinking/compression during deformity correction (while posing this question, we do not compromise the expediency of the most correct placement of pedicle screws).



**Fig. 2**

Distribution of patients by age



**Fig. 3**

Distribution of patients by the number of transpedicular anchor elements



Table 2

Distribution of peri-/postoperative complications/events according to the Clavien – Dindo classification [11, 12]

Complication grade	Number of complications		
	n	% of surgeries	% of complications
I + II	41	30.1	74.5
IIIA	2	1.5	3.6
IIIB	10	7.3	18.2
IVA	1	0.7	1.8
IVB	—	—	—
V	1	0.7	1.8

How should the conversion of endoscopic to open surgeries, which complications according to the categorization under discussion fall into class IIIB, be compared to primary open surgeries?

We believe that the Clavien – Dindo classification's application in our field is constrained by the absence of solutions to these kinds of issues. Its undoubted advantages of the systematization of complications, therefore, can justify orga-

nizational decisions and, consequently, determine the real costs of treatment that is invaluable for any health care system.

## Conclusion

Application of the Clavien – Dindo classification to a selective group of children, who underwent extended (more than four spinal motion segments) instrumental correction of spinal deformities, allowed to determine that the use of more than 18 transpedicular anchor elements correlates with an increase in the surgery duration and intraoperative blood loss relevant for the development of grade III and IV complications.

Given that the apparently high rates of complications are in line with those documented in international literature,

Table 3

Analysis of potential quantitative risk factors for grade III and IV complications

Attribute	Entire group, Me (min; max)	No complications of grade III and IV, Me (min; max)	Development of complications of grade III and IV, Me (min; max)	p
Age, years	13 (1; 18)	13 (1; 18)	14 (1; 17)	0.653
Weight, kg	42 (10.5; 104.5)	39.7 (10.5; 97.0)	48.5 (12.9; 104.5)	0.200
Height, cm	152 (82.0; 199.0)	152 (82.0; 199.0)	161 (89.5; 178.0)	0.215
BMI	18.3 (9.54; 37.19)	18.2 (9.54; 37.19)	18.8 (16.10; 33.36)	0.157
Circulating blood volume, mL	2940 (735; 7315)	2779 (735; 6790)	3395 (903; 7315)	0.200
Surgery duration, minutes	309 (100; 600)	300 (100; 590)	397 (255; 600)	0.001
Blood loss, mL	510 (20; 2100)	500 (20; 2100)	1000 (340; 2000)	0.012
Screw number, n	14 (0; 34)	14 (0; 27)	21 (5; 34)	0.014

Table 4

Analysis of potential qualitative risk factors for grade III and IV complications

Attribute	No complications of grade III and IV, n (%)	Development of complications of grade III and IV, n (%)	p	Total number, n (%)
Etiology (congenital scoliosis)	57 (93.4)	4 (6.6)	0.291	61 (44.9)
Etiology (other forms, except congenital scoliosis)	66 (88.0)	9 (12.0)	0.291	75 (55.1)
Gender (m)	40 (85.1)	7 (14.9)	0.124	47 (34.6)
Gender (f)	83 (93.3)	6 (6.7)	0.124	89 (65.4)
Underweight	25 (92.6)	2 (7.4)	0.873	27 (21.1)
Halo-traction before and during surgery	14 (77.8)	4 (36.4)	0.062	18 (16.5)
Halo-traction before surgery	10 (78.6)	4 (21.4)	0.114	14 (10.4)

Table 5

Analysis of predictors of grade III and IV complications development

Predictor	Se	Sp	AUC (95 % CI)	OR (95 % CI)	RR (95 % CI)	p
Halo-traction before surgery	36.4	85.7	—	3.5 (0.9; 13.3)	2.9 (0.9; 8.9)	0.062
Blood loss over 950 mL	58.3	79.3	0.721 (0.614; 0.797)	4.8 (1.5; 15.6)	4.0 (1.4; 10.9)	0.005
Blood loss over 20.6% of CBV	83.3	58.9	0.702 (0.614; 0.871)	5.6 (1.5; 21.3)	4.8 (1.4; 16.5)	0.005
Surgery duration over 365 min	61.5	76.4	0.715 (0.631; 0.789)	5.2 (1.6; 17.1)	4.3 (1.5; 12.3)	0.003
Screw number over 18	69.2	75.2	0.715 (0.631; 0.789)	7.0 (2.0; 24.3)	5.6 (1.8; 17.1)	0.0008

it is legitimate to wonder how fairly they are regarded in domestic practice and, consequently, how sensible the preventative strategies are.

*Limitations of the integrity.* The authors fully understand the limitations of the integrity. The most relevant, in our opinion, are the following:

– the extreme complexity in real-world conditions to analyze complications with full consideration of the principles of independent audit;

– lack of analysis of grade I and II complications, appropriate multimodal analgesia, and timely discharge of wound hematoma are essential for early rehabilitation, but they are not severe complications causing organizational and cost loading;

– limited 30-day postoperative follow-up;

– the limited number of cases in such groups as Scheuermann's kyphosis, NMS, and syndromic scoliosis does not provide its independent analysis.

The authors hope that this article will encourage national pediatric spine surgeons to conduct pooled multicenter studies.

*The study had no sponsors. The authors declare that they have no conflict of interest.*

*The study was approved by the local ethics committees of the institutions. All authors contributed significantly to the research and preparation of the article, read and approved the final version before publication.*

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Received 01.07.2024

Review completed 12.08.2024

Passed for printing 19.08.2024



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