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Complications associated with surgical treatment for pediatric spine deformities: a single center 10-years' experience

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ABSTRACT

Introduction: The surgical treatment for pediatric spine deformity is complex and often associated with complications, which generates important clinical and economic impact. Herein the authors analyze the prevalence of complications in surgery for pediatric spine deformity, the correlation between complications and several risk factors, and present a preventive algorithm for these events.

Material and methods: We collected for analysis the data regarding pediatric patients with spine deformities surgically treated in our institution through a 10 years' period with 100% revision rate and a 24-month minimum follow-up were included. The statistical analysis was performed using SPSS *Statistics* 23.

Results: 70 complications (33,4%) were identified in 56 patients (26,7%), of which 38 (54,2%) were acute and 32 (45,7%) late complications. Pulmonary complications (7.1%), surgical site infection (6.6%) and junctional kyphosis (4.3%) were the most frequent events. Scoliosis etiology was especially correlated with general complications ($p<0.05$) and early complications ($p<0.01$). A logistic regression model identified preoperative hemoglobin (OR=1.476; p=0.044), fused levels (OR=-0.677; p=0.023) and titanium implants (OR=0.257, p<0.000) as relevant factors for complications. Area under the curve was 0.744, and, when using the best cutting point, the model was capable of predicting absence of complications in 84% of cases, and its occurrence in 56%.

Discussion: Pulmonary complications, surgical site infection and junctional events were identified as the most frequent complications after pediatric scoliosis surgery. By developing high risk protocols to decrease these events, patient safety will be significantly enhanced. Risk assessment makes part of this process and our predictive model by identifying two modifiable factors and including another that relates to procedure invasiveness may help avoiding complications and improve outcomes.

Keywords: Pediatric spine deformities; Complications; Risk factors; Risk assessment.

INTRODUCTION

The surgical treatment for pediatric spine deformities is a considerable technical challenge for any spine surgeon. Due to the progressive increase of this type of surgery in the last years, it has become a major financial burden for the institutions, mainly if complications arise during hospitalization[1].

The notification of perioperative complications in scoliosis or kyphosis surgery varies according to the criteria applied by the different authors[2]. Based on essentially retrospective studies, complication rates range from 5.6% to 23% for idiopathic scoliosis and from 13% to 56% for neuromuscular scoliosis[1-12].

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This study aims to analyze the prevalence of both early and late complications in surgery for the treatment of pediatric spinal deformities. Other goals were to correlate preoperative and operative risk factors with their occurrence and develop an algorithm capable of predicting complications.

MATERIALS AND METHODS

Patients under 21 years of age with a scoliosis or kyphosis operated in our institution between 2006 and July 2016 were analyzed. Data were retrospectively collected until 2013 and prospectively gathered between 2014 and 2016. Inclusion criteria encompassed all deformities requiring posterior instrumentation of five or more levels, regardless of previous anterior or posterior release. Trauma sequelae deformities or deformities caused by spondylodiscitis were excluded.

The study included 209 patients with idiopathic scoliosis (90 patients), Sheuermann's kyphosis (13 patients), and congenital scoliosis (6 patients), syndromic

Table I. Complications associated with treatment of scoliosis in the pediatric population

Total Number of Patients	Total 209	Idiopathic 103	Congenital 6	Neuromuscular 52	Other* 48
Patients with complications	56	18	2	16	20
Death	1	0	0	1	0
Neurological deficit	3	0	1	2	0
Superficial infection	1	0	0	1	0
Deep infection	15	8	0	2	5
Wound dehiscence	5	1	0	1	3
Pulmonary	15	2	0	8	5
Junctional kyphosis	9	5	0	2	2
Related with Implant	7	3	0	3	1
Venous thrombosis	1	0	0	1	0
Epidural hematoma	1	0	0	0	1
Peripheral nerve or plexus lesion	2	1	0	1	0
Other complications	10	0	1	3	6
Total Complications	70	20	2	25	23
Return to operating room	31	16	1	4	10

*Syndromic (Marfans, Ehler´s-Danlos, Down, Rett), Neurofibromatosis, Myelomeningocele, bone dysplasia).

scoliosis (41 patients), neuromuscular scoliosis (40 patients), and scoliosis secondary to muscular dystrophy (19 patients). Recorded data were gender, age at the time of surgery, weight, underlying pathology, deformity location, Cobb angle[13], instrumented levels and preoperative hemoglobin. Surgical indication was based on deformity etiology, severity of the curve, and the need to anticipate complications inherent to progression. All surgical procedures were performed by the same surgeon. Complications arising during hospitalization or within 30 days after surgery were considered early perioperative complications and those occurring after this period as late complications. Length of hospital stay and length of stay in intensive care unit, operative time, estimated blood loss, adverse events, complications and its severity graded between I and V according to Dindo *et al*[14] were analyzed. The rate of new unexpected surgical procedures was also determined, as well as their respective causes. Mean follow up was 47,37 months (min:24 - max:136).

Data were registered in a Microsoft Excel spreadsheet and the statistical analysis was conducted using the IBM SPSS *Statistics* 23 software. All continuous variables were tested for the normality of their distribution, and, when found, linear models were used, being data represented in means +/- standard deviation. D-Cohen was also tested for effect size, which was considered significant when above 0.2. The Mann Whitney U test was used in the absence of normality, with effect size calculated for ODDS adjusted to post-program, where data are represented by medians +/- interquartile interval. Linear regression models and Pearson's correlations were performed for risk factor evaluation for complications. Finally, binary logistic regression models were used for the probability calculation of complications, where ROC curves represent sensitivity and specificity.

RESULTS

We operated on 135 female and 74 male patients, with a mean age of 14.32 years (min:18 months old - max:21 years old). The mean Cobb angle was 74.7° (min:30 - max:150). We performed 28 fixations requiring extension to the pelvis (24 in neuromuscular scoliosis and 4 in syndromic scoliosis). Anterior followed by posterior approach was performed in 36 patients. A mean of 13.33 vertebral fusion levels (min: 5 - max: 17) were instrumented, with a mean operative time of 279.82 minutes (min:155 – max:540). The mean hospital stay was 12.11 days (min:3 - max:104), and the mean stay in intensive care unit was 2.15 days (min:0 – max:10). A total of 70 complications (33,4%) in 56 patients (26,7%) were registered, of which 38 (54,2%) were early and 32 (45,7%) late complications (Table I).

Most perioperative complications (66%) were Dindos's et al. grades I, II and IIIa, and were solved with medical or invasive therapy, with no anesthesia, and with no significant repercussions on the final outcome. Two pneumonias (a grade IVa complication) lead, in a case, to a significant deterioration of previous respiratory function, thus requiring longer assisted ventilation time, and, in the other case, to an unresolved residual lesion with deterioration of the respiratory function. Two spinal cord lesions were recorded. The first referred to a female patient with neuromuscular scoliosis, with paraplegia at time of awakening and the second neurological lesion was of a young woman diagnosed with severe congenital kyphoscoliosis who underwent a vertebral resection awakening with a partial deficit, completely recovered at six post-operative weeks.

A patient with idiopathic scoliosis presented a high brachial plexus lesion, related to ventral decubitus positioning with complete recover at six months.

Regarding frequency, the main complications during the perioperative period were respiratory (15 patients – 7.1%), especially in diagnoses of neuromuscular and syndromic scoliosis. Early wound complications affected seven patients (3.3%). The early deep infection rate was 0.9%, as it occurred only in two patients: one suffering from syndromic scoliosis who underwent surgery with previous *cor-pulmonale* and heart failure, and the other was a myelomeningocele patient with scoliosis. The patient who died had a congenital muscular dystrophy and this fatal event occurred during anesthetic induction before any surgical procedure (Table II).

Regarding late complications (Table III), 13 patients (6.2%) presented infection which required an unplanned operating room return (UORR) for debridement and implant removal. One of these infections, a child with cerebral palsy, ended up conditioning the failure of proximal screw fixation, which migrated to the vertebral canal leading to the development of paraplegia six years after the initial procedure. Two patients returned to the operating room for the second time for spinal re-instrumentation due to deformity progression. Another important cause for operative room returns was junctional failure, with a 3.8% rate (8 patients), proximally in seven cases and distally in one case. Both diagnoses (infection and junctional failure) justified the 67.6% of UORR. Also, three cases of fixation failure were reported, but only one was reviewed. Two thoracoplasties were performed *a posteriori*, for esthetical improvement.

Late infection cases were re-operated after a mean period of 33 months (min: 12 – max: 96), with isolation of the bacterial agent in six of the patients. In 12 cases, stainless steel implants were used, and in only one case was it titanium. Most patients presented a purulent collection around the implants, frequently with peri-implant corrosion. All patients were treat-

Table II. Type of early perioperative complications and respective return to the operating room for treatment of a complication

Complication	Number of cases	Number of returns to operating room
Death	1 *	
Pulmonary	15	
Gastrointestinal	3	
Urinary / Renal	7	
Surgical Wound	7	6
Deep infection	2	2
Superficial infection	1	
Hematoma. dehiscence	4	4
Instrumentation related	1	1
Neurologic	4	
Medullar lesion	2	
Radicular lesion	2	
Total		7

*Congenital muscular dystrophy patient with cardiac arrest during anesthetic induction.

Table III. Type of late complications and respective return to the operating room for treatment of a complication

Complication	Number of cases	Number of returns to operating room
Instrumentation related	-	
Failure	1	
Connection loss Instr./bone	3	1
Prominence	2	1
Pseudarthrosis	3	1
Neurologic	1	
Surgical wound		
Deep infection	13	13
Other Complications		
Adding-on	1	1
Thoracoplasty	2	1
PJF / DJF *	8	6
Total	32	24

*PJF – Proximal junctional Failure; DJF – Distal junctional failure

Table IV. Logistic regression for variables which affect the occurrence of a complication

		Variables					
		B	S.E.	Waid	df	Sig.	Exp(B)
Step 1[a]	Number of spine levels fused	0.389	0.193	4.059	1	0.044	1.476
	Pre-operative Hemoglobin	0.171	0.171	5.177	1	0.230	0.677
	Titanium hardware	0.350	0.350	15.059	1	0.000	0.257

*Step1: Variables entered on step 1: Number of spine levels fused, pre-operative hemoglobine and use of titanium hardware.

ed by means of material removal and antibiotherapy. In regard to junctional failure, seven cases presented hybrid instrumentation with proximal foundation consisting of hooks. An eighth case occurred one year after Sheuermann's kyphosis correction, with rod-screw connection failure at the level of the last instrumented vertebra. Even though asymptomatic, the patient underwent a new surgical procedure.

The re-operation rate was 14.8%, with 31 patients going back to the operating room for one or more unplanned surgical procedures.

In the absence of complications, the global mean hospitalization time was 10.22 (±11.2) days, whereas, when complications occurred, the mean was 17.3 (±14.5) days, ($p<0.01$). As for intensive care unit stay, when no complications were reported, the mean hospitalization time was 1.85 (±0.8) days, and when complications arose, the mean was 2.94 (±1.94) days, ($p<0.01$).

Table I, shows that complications were more frequent in the groups encompassing syndromic and neuromuscular scoliosis. From the 52 patients diagnosed with neuromuscular scoliosis and 48 patients diagnosed with syndromic scoliosis, 16 and 20 patients, respectively, suffered one or more complications, with both groups explaining 68.5 % of all the complications. On the other hand, in idiopathic deformities, from 103 patients, 18 patients had one or more complications explaining 28.5 % of all complications. Correlation between neuromuscular and syndromic etiologies and complications was demonstrated by a linear regression which became statistically relevant for complications in general ($p<0.05$), as well as for early complications ($p<0.01$). Nevertheless, it was not relevant for late complications ($p=0.34$).

In the search for other risk factors, age, weight, Cobb angle, preoperative hemoglobin, length of surgery, vertebral instrumented levels, need for complementary anterior approach, estimated hematic loss and type of implant used were considered. This assessment was primarily carried out independently, and the effects and moderation between all continuous and categorical variables were tested. Based on this previous study, logistic regression models were performed for explaining one complication (one parameter) using the relevant variables which were etiology, instrumented vertebral levels, pre-operative hemoglobin values and type of alloy used. As the variable levels behave very alike etiology and levels being a continuous variable this one was selected for our regression. From the analysis of Table IV we can see that by increasing the instrumented fused vertebral levels it will lead to the possibility of having a complication (OR = 1.476; $p=0.044$). On the other hand, the higher the pre-operative hemoglobin levels, the lower that risk (OR = 0.677; $p=0.023$) and the use of titanium alloy instead of stainless-steel also reduces the risk of a complication (OR = 0.257; $p<0.001$). As we can see in Figure 1 the ROC curve (area = 0.749, $p<0.001$) points to a regular quality of this predictive instrument, with the best cutting point at 0.349. The model with a Pseudo-R^2 is 0.21, which is more specific than sensitive, has a 75% explanatory power, predicting an absence of complications in 84% of the cases, as well as the occurrence of a complication in 56% of the cases.

DISCUSSION

Progress in diagnostic, surgical and anesthetic techniques reflected very positively in spine surgery, leading to a substantial increase in the number of surgical procedures in the last 20 years[15]. Even though the advantages of a successful spine surgery are widely recognized, the fact that a complication may compromise the clinical result, deteriorate the initial condition or even cause the death of a patient is also easily understood.

Most studies on complications are based on a retrospective review of patients. One recent study, which used morbidity and mortality data from the Scoliosis Research Society (SRS), presents a complications rate in scoliosis surgery of 10.2%. In a total of 19,360 patients,

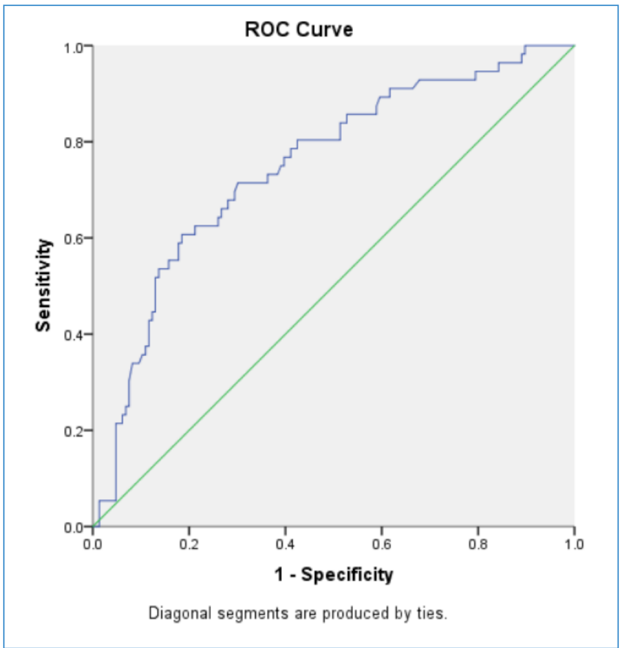

Figure 1. ROC curve for the explanatory model of complications (Area under the curve (AUC) = 0.749, p<0.001)

the deep infection rate was only 1.7%, pneumonia rate was 1%, as was the neurological lesion rate. Moreover, a higher complication rate is observed in neuromuscular (17.9%) and syndromic (14.5%) scoliosis, compared to idiopathic scoliosis, of which only 6.3% of the cases presented complications[16]. The differences regarding our own results and this study by Reames *et al.* are considerable, although we can admit some lack of accuracy in such a database since this is self-reported complication rate from the SRS fellows[16]. This study reports a high rate of early complications, mainly early complications, and these numbers may well be closer to general practice than those extracted from big databases. The prospective and multicenter study of Carreon *et al.* revealed a 15.4% rate of non-neurological complications in a population of 702 patients who consecutively underwent surgery for idiopathic scoliosis. In this study, the risk factors for complications were the presence of renal disease, blood loss, length of surgery and length of anesthesia[17]. According to the systematic literature review of Weiss *et al.*, in seven quality studies, the mean complication rate for idiopathic scoliosis was 8.6% (min:0 – max:37%)[18]. Based on 17 studies, the same review shows a complication rate of 17.4% (min: 0 – max: 39%) for neuromuscular scoliosis, thus highlighting the variability in the occurrence of complications in scoliosis surgery[18].

One of the most feared complications is the neurological lesion, which can take a number of forms, ranging from a mild sensory deficit to paraplegia. Neuromonitoring, has been key in reducing risk by allowing the surgeon to reverse maneuvers which are electrophysiologically compromising the spinal cord through compression, traction or ischemia, thus avoiding a deficit with clinical repercussions[19-21]. A study conducted by the Scoliosis Research Morbidity and Mortality Committee revealed that the incidence of neurological complications in adolescent idiopathic scoliosis surgery was 0.26% for anterior approach, 0.32% for posterior approach, and 1.75% for combined approach[22]. Neurological complications are usually associated to type of procedure, magnitude of the deformity, type of instrumentation, combined anterior and posterior approach, and reduction of blood perfusion due to hypotension and/or hemorrhage[23]. Patients undergoing osteotomy with Cobb angle over 90º and kyphosis have higher incidence of intraoperative events than other patients[24]. Our rate of early neurological lesions was 0.95%, but we were surprised by a late deficit, six years after surgery, due to intracanal migration of implants due to late infection, thus reinforcing the need for long term follow-up on these long spinal instrumentations. A brachial plexus lesion was also registered reminding us that patient positioning is important with careful protection of bone prominences and peripheral nerves.

According to Lipton *et al*. and Hod-Feins *et al* in neuromuscular scoliosis the surgical risk seems to be only enhanced in curves with a Cobb angle above 70º-100º respectively, thus making it advisable to delay surgery, allowing the child to grow and gain weight[25,26]. Although in our series, patients with curves above 90º underwent surgery with no noticeable complications a compromise between growth and weight gain and deformity progression may well be desirable. Zheng *et al*. correlated the length of instrumentation with hospitalization time, hematic loss and length of surgery[27] as well as Guigui P. *et al*. who identified an increased risk in instrumentation length and use of osteotomies[28].

In our study pulmonary complications were recorded in 15 patients (7.1%), of whom 13 were diagnosed with neuromuscular and syndromic scoliosis, representing 40% of early complications. The other two pulmonary complications occurred in two patients with idiopathic scoliosis and were anterior release approach related. Surgical site infection was also one of the major complications of our series. Aleissa *et al*. reported a deep infection rate of 6.2% in a population of 227 patients. These authors refer non-idiopathic diagnosis, length of instrumentation and use of an allograft as risk factors[29]. Other studies highlight neuromuscular scoliosis, cognitive deficit associated to cerebral palsy, sub-nutrition, length of surgery and hematic loss as risk factors for surgical site infection[30-33]. Our deep infection rate was 7,1%, and most of the infections occurred

12 months after the surgery. A large amount of pus associated with metal corrosion was found in almost all patients. Contrary to what might be expected, late infection rate was slightly higher in patients diagnosed with idiopathic scoliosis (7.7%) than in patients with neuromuscular and syndromic scoliosis (7%). One of the possible reasons for this high late infection rate is the use of stainless-steel implants during the first half of the study period, since our logistic regression showed an important correlation between the type of implant used and general complication rate. In fact, the use of titanium was correlated with an inferior number of complications (OR = -0.257; $p<0.05$), very likely due to a drop-in infection rate. Similarly, in a comparative study with a population which underwent surgery with stainless steel and another with titanium, Silvestre *et al*. demonstrated that the late infection rate was clearly inferior in the second group ($p<0.01$)[34]. In a series by Sultanis *et al*., 12% of the patients submitted to surgery with stainless steel developed late infection, whereas only 2% of the patients who underwent surgery with titanium presented the same complication[35].

Regarding junctional failure, these occurred in nine patients (4.3%), of whom eight required surgical reintervention. Radiographically, proximal junctional kyphosis is defined by the increase of kyphosis, measured between the lower endplate of the upper instrumented vertebra (UIV) and the upper plate of the superjacent vertebra. A kyphosis equal to or greater than 10º or a preoperative and post-operative variation greater than 10º should be considered as abnormal occurring in around 30 to 47% of idiopathic scoliosis submitted to surgery[36-39]. Unlike us, Kim *et al*., comparing three populations, one which underwent surgery only with hooks, another with hybrid constructions (proximal hooks and distal screws), and a third with only screws, did not find significant differences regarding the incidence of junctional kyphosis[36]. Preoperative hyperkyphosis, its exaggerated correction, and performance of thorarocoplasty are all considered risk factors for junctional kyphosis. However, in our study, these complications occurred mainly in hybrid constructions, namely proximal hooks and distal screws, which were reviewed with a proximal extension of the respective instrumentation. Apart from deformity progression, the eight patients who were re-operated were referring pain, whether due to lamina fracture or the yielding of posterior soft tissues.

From our data and literature review, any intervention aiming to reduce pulmonary and operative wound complications, as well as junctional failure, will have a relevant impact on outcomes, both for the patients and the safety of the surgical procedure. In this respect Halpin *et al*. presented a protocol for the patient at risk of complications which includes a preoperative multidisciplinary assessment of the child, the use of all the resources during the intraoperative period in order to reduce hematic loss, and an enhanced post-operative surveillance, with significant outcomes in the reduction of complications[39].

Using an original methodology, Boachie *et al*. entered several risk factors of each patient and each deformity into a multivariate analysis. After applying it to a population with very severe spine deformities, the authors conceived a surgical difficulty predictive model, as well as a complication predictive model, thus creating a new risk stratification system (*Score* FOCUS), which allocates resources and more experienced surgeons to higher difficulty Score cases[40].

Considering our series, besides establishing a correlation between scoliosis etiology and complications through logistic regression, we also correlated the higher length of instrumentation, lower preoperative hemoglobin levels and the use of stainless steel as risk factors for complications, each with its own impact. The developed algorithm has an explanatory power of 75%, with a significant area under the ROC curve of 0.74 ($p<001$). By attempting to reach the best explanatory model along the ROC curve the predictive tool became more specific than sensitive, being superior at its ability to determine true negatives rather than at determining the patients who will develop a complication. This methodology, in our opinion can improve patient safety in pediatric scoliosis surgery as when integrated with other modifiable factors and adapted to the reality of each institution, can play a decisive role in reducing surgical complications.

CONCLUSION

Pediatric scoliosis surgery is a complex procedure where patients can present several comorbidities increasing the risk of having a complication. Early complications may be correlated more to diagnosis and invasiveness of the procedure (fused levels) where late complication may be more related with surgical technique and alloy used. According to our predictive tool, using titanium, adapting invasiveness to diagnosis, if needed, and improving pre-operative hemoglobin when requested by this model will help surgeons to decrease the probability of having a complication.

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