# **RESEARCH ARTICLE**

# Prolonged operative time significantly impacts on the incidence of complications in spinal surgery

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# Abstract

**Background** In spinal surgery adverse events (AE) and surgical complications (SC) significantly affect patient's outcome and quality of life. The duration of surgery has been investigated in different surgical field as risk factor for complications. The aim of this study is to analyze the correlation between operative time and adverse events in spinal surgery.

**Methods** We retrospectively analyzed data collected prospectively in a cohort of 336 patients surgically treated for spinal diseases of oncological and degenerative origin in a single center, between January 2017 to January 2018. Demographics and clinical data were collected. Adverse events were classified using Spinal Adverse Events Severity System version 2 (SAVES-V2) capture system. Focusing on degenerative patients, bivariate analysis and univariate logistic regression were used to determine the association between operative time and complications.

**Results** A total of 105/336 patients experienced an AE related to surgery, respectively 38% in the oncological group and 28% in the degenerative group. The average age at surgery was 60.3 years (SD 17.1) and the mean operative time was 164.8 ± 138 min. A total of 206 adverse events (30 intraoperative, 135 early postoperative and 41 late postoperative AEs) were recorded. Early post-operative complications accounted for the most recorded AEs (55.5% in the oncological group and 73.2% in the degenerative group). Univariate logistic regression analyses confirmed that operative time correlated with increased risk of intra-operative (p-value = 0.0008), early post-operative (p-value < 0.001) and late post-operative (p-value < 0.001) adverse events.

**Conclusions** This study highlights the strong correlation between the occurrence of adverse events in spinal surgery and prolonged operative time and suggests that efforts should be made to minimize the duration of surgical procedures while prioritizing patient's safety, without compromising the technical achievement of the procedure.

Keywords Spinal surgery, Adverse events, Complications, Operative time

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# Introduction

As the number of spinal surgical procedures has rapidly increased worldwide, concerns have arisen regarding elevated rate of complications that can lead to prolonged length of stay, poor outcomes, high rate of readmission and reintervention, severe and permanent disabilities, with a relevant impact on patients' quality of life and on the healthcare system [1-4].

The duration of surgery is an often-studied risk factor for complications following surgical procedures. Different studies have shown that operative time is independently associated with adverse events in a variety of settings, including cardiac surgery, neurosurgery, bariatric surgery and urological procedures [5]. Orthopedic surgeons have also shown interest in this potentially modifiable risk factor, with studies mentioning its association with short-term complications in different types of surgery ranging from total hip arthroplasty to anterior cervical discectomy and fusion [6, 7].

Indeed, longer operative time has been associated with increased rates of both surgical and medical complications (e.g. surgical site infection, sepsis, pneumonia) [4]. Furthermore, a longer surgical time was correlated with a longer duration of anesthesia, which contributes to the development of complications [8]. Previous research in these fields suggest that a 15-minute increase in operative duration is associated with proportional increase in surgical site infection, wound dehiscence, venous thromboembolism risk, extended length of hospital stay and readmission [6, 8].

To our knowledge, the role of operative time throughout its entire range as a continuous variable has not been still examined in spinal surgery. Similarly, it is not known which category of AEs are impacted by prolonged operative time and which are not [4].

The purpose of this study is to analyze the correlation between operative time and specific intra and post-operative adverse events captured through Spinal Adverse Events Severity System, version 2 (SAVES-V2) [9, 10] among patients treated in our tertiary reference center for spinal surgery.

# Methods

This is a retrospective analysis of data collected prospectively from patients undergoing spinal surgery between January 2017 to January 2018 at a single, tertiary orthopedic spine department. The present study was approved by the local Ethics Committee (protocol number #0022814, 15/12/2016). This study was conducted following the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [11].

The study population included a total of 336 patients surgically treated for degenerative spine disease and oncological spinal disease. Patients under the age of 18 were also included. The investigation was conducted in accordance with the ethical principles of the latest version of the Declaration of Helsinki.

Patients were classified in two groups, Degenerative and Oncological patients. Patients' characteristics including sex, age, comorbidities (according to Charlson Comorbidity Index) and American Society of Anesthesiology (ASA) score were recorded. Information on the type of surgical procedure and on its duration were collected from electronic health records. All surgeries were performed by four surgeons who have more than 20 years of experience and who have been working in the same team for 25 years.

SAVES-V2 system (including SAVES V2 severity grades, categories of intraoperative AEs, categories of post-operative AEs) [9, 10] was used to record and classify retrospectively all the adverse events. Postoperative AEs were differentiated in "early postoperative", occurring in the first 30 days after surgery, and "late postoperative", occurring more than 30 days after surgery.

Using as threshold operative time  $\geq$  3 h the categories of AEs in the two groups were further analysed in detail.

## Statistical analysis

A descriptive analysis was executed for patients' demographics and surgical data in our cohort. The normality of all parameters was tested through the Shapiro-Wilk test. The analysis confirmed a non-normal distribution of data for operative time only in the tails where occasional surgeries with very short or very long operative time were represented. Data were summarised using mean±standard deviation or median and range value for continuous variables, and by absolute and relative frequency for categorical variables. Bivariate analysis and univariate logistic regression models were created to determine the association between operative time and complications as continuous variable. All analyses were performed using R version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria). A significance threshold value of 0.05 was used throughout.

# Results

# Patients' population description

223 patients were treated for degenerative conditions while 113 had primary or metastatic spinal tumors requiring surgical intervention.

The overall mean age was 60.3 years (range 6–91, SD 17.1) and most patients were female (58.9%, n=198). Comorbidities were evaluated as summarized using the Charlson Comorbidity Index (CCI); in the global population the mean value of CCI index was 3.2 and a mean ASA classification of 2.2 was recorded. The mean operative time for all the surgeries was 164.8±138 min.

A total of 206 adverse events (30 intraoperative AEs, 135 early postoperative AEs and 41 late postoperative) were retrospectively recorded using SAVES-V2 system. One hundred and five patients (31%) experienced an adverse event related to surgery, respectively 38% in the oncological group and 28% in the degenerative group (Table 1).

### Adverse events in oncological patients

The oncological population (113 patients) had a mean age 52.4 (range 6–83), a mean CCI index of 4.7 (SD 3.2) and a mean ASA score of 2.3 (SD 0.7). The mean operative time was  $213\pm161$  min. A total number of 90 adverse events were collected (Table 1).

According to surgical duration, patients were stratified in two subgroups: 56 had an operative time less than 3 h and 57 had an operative time more than 3 h.

AEs for oncological patients are reported in Table 2. Twenty patients (17%) had intra-operative complications of which 4 patients experienced more than one. Of the total 23 intra-operative AEs, twenty-two (95.6%) adverse events occurred during an operative time longer than 3 h. The most common complication was dural tear 9/22 (40.9%), followed by massive blood loss 4/22 and vascular injury 4/22 (18% each other).

Early post-operative AEs account for most of the recorded AEs (50/90, 55.5%) and occurred in 30 patients. In particular, 13 AEs were recorded with an operative time (OT) less than 3 h and 37 AEs (74%) with an OT longer than 3 h. The most common AEs were included in the category "others" (18/37, 48.6%): fever and pleural effusion were the most frequent. Other common early post-operative AE were pneumonia (4 cases), followed by neurological deterioration and urinary tract infection.

9 patients experienced 17 late post-operative complications (4 patients with more than one AEs) and 15 out of 17 (88.2%) adverse events occurred after surgeries lasting more of 3 h. Category "others" (including pleural effusion, anemia, hydrocephalus and disease recurrence) represented the most frequent complications with an incidence of 33.3% (5/15), followed by deep wound infection (26.7%).

#### Adverse events in degenerative patients

Degenerative population, comprehensive of a total of 223 patients, had a mean age 64.2 (range 13–91), a mean CCI index of 2.4 (SD 1.7) and a mean ASA score of 2.2 (SD 0.6). The mean operative time was 138±115 min. A total number of 116 adverse events were collected (Table 1).

Sixty-two patients had an operative time less than 3 h and 161 patients had an operative time longer or equal to 3 h.

AEs for degenerative patients are reported in Table 3. Intra-operative AEs were less common in the degenerative group and 6 out of 7 (85.7%) complications were recorded in the subgroup with operative time longer than 3 h; dural tear represented the most common complication (4/6 with a incidence of 66.7%).

As for the oncological patients, also for the degenerative group early post- operative adverse events accounted for the major category of complications (85/116, 73.2%) and 61 out of 85 (71.7%) complications occurred when OT was longer than 3 h. Many adverse events filled the category "others" (75.4%) of which fever and anemia were the more frequent. The same category "other" with an incidence of 62.5% was recorded in the subgroup with operative time less than 3 h.

Late post-operative adverse events affected 15 patients and 5 of them had more than one complication for a total of 21 adverse events: 21 out of 24 (87.5%) AEs were collected with an operative time longer than 3 h; the most frequent complications were construct failure (14/21, 66.6%) and deep wound infection (3/21, 14.2%).

## Correlation between operative time and complications

Considering that the group of degenerative patients was more homogenous for diagnosis, comorbidities and type of surgery performed, we analyzed the correlation between operative time and complications in this group of patients.

	General Population	Oncological group	Degenerative group
Total	336	113	223
Female	198	49	149
Male	138	64	74
Age	60.3 (range 6–91)	52.4 (range 6-83)	64.2 (range 13–91)
Mean CCI Index	3.2 (SD 2.5)	4.7 (SD 3.2)	2.4 (SD 1.7)
Mean ASA score	2.2(SD 0.6)	2.3 (SD 0.7)	2.2 (SD 0.7)
Operative Time	164.8±138 min	213±161 min	138±115 min
Operative time < 3 h	118	56	62
Operative time≥3 h	218	57	161
Complicated patients	105 (31%)	43 (38%)	62 (28%)
Adverse events	206	90	116

#### Table 1 Data collection

Intra-operative Adverse Events				
Operative Time < 3 h		Operative Time $\geq$ 3 h		
	Ν		Ν	%Tot
Massive Blood loss	1	Massive Blood Loss	4	21.7
		Dural tear	9	39.1
		Vascular injury	4	17.4
		Visceral injury	3	13
		Hardware malposition	2	8.7
Total	1		22(95.6%)	
Early post-operative Adverse Ev	vents			
	Ν		Ν	%Tot
CSF leak	1	CSF leak	3	8
Deep vein thrombosis	1	Deep vein thrombosis	2	6
Neurological deterioration	1	Neurological deterioration	3	8
Other	4	Other	18	44
Deep wound infection	2			4
		Hematoma	3	6
Delirium	1			2
		Dysphagia	1	2
Superficial wound infection	1			2
		Pulmonary embolism	1	2
Urinary tract infection	1			2
		Pneumonia	4	8
Wound dehiscence	1			2
		Systemic infection	1	2
		Cardiac arrest	1	2
Total	13		37(74%)	
Late post-operative Adverse Ev	ents			
	Ν		Ν	%Tot
Wound dehiscence	1	Wound dehiscence	2	17.6
Deep wound infection	1	Deep wound infection	4	29.4
		Construct failure without loss	1	5.8
		Construct failure with loss	1	5.8
		Neurologic deterioration	1	5.8
		Post-op neuropathic pain	1	5.8
		Other	5	29.4
Total	2		15 (88.2%)	

 Table 2
 Adverse events in oncological patients

We previously observed that CCI and ASA score were not associated with complications in our population [3]. As reported in Table 4A, in the present study a preliminary comparative analysis has showed a significant difference between the two-patient population (operative time < 3 or  $\geq$  3 h), indicating that patients with operative time less than 3 h are older (p-value=0.00039) with a higher CCI index (p-value=0.00007) and ASA (p-value=0.0301) score than patients with longer surgeries. Likewise analyzing operative time as a continuous variable, the bivariate analysis corroborated that a longer operative duration was associated with CCI  $\leq$ (p-value<0.0001), ASA score  $\leq$  (p-value=0.0434) and age < 60 years old (p-value = 0.007922). Moreover, we confirmed that operative time was associated with the rate of complicated patients (p-value < 0.001) (Table 4B).

Dividing operative time into 2-hours intervals, we observed a progressive increase of complicated patients: we registered a 2.4% rate of complicated patients (3/123) for surgical time less than 2 h, 44.5% (28/63) for 2–3.59 h, 69.5% (16/23) for 4–5.59 h and 85.7% (12/14) for operative time longer than 6 h (Table 5; Fig. 1).

Univariate logistic regression analyses showed that longer operative time correlated with increased risk of intra-operative (p-value=0.0008), early post-operative (p-value<0.001) and late post-operative (p-value<0.001) adverse events (Table 6). Indeed, 113 adverse events occurred in 100 surgeries lasting more than 2 h, as shown in Table 5; Fig. 2. In particular, all the intra-operative AEs (7/7, 100%) and all the late post-operative AEs (24/24, 100%) occurred in surgeries longer than 2 h; also 82 out of 85 (96.4%) early post-operative AEs occurred

Intra-operative Adverse Events				
Operative Time < 3 h		Operative Time≥3 h		
	Ν		Ν	%Tot
Dural tear	1	Dural tear	4	71.4
		Cardiac	1	14.2
		Visceral injury	1	14.2
Total	1		6 (85.7%)	
Early post-operative Adverse Ev	ents			
	N		Ν	%Tot
Cardiac arrest/ failure/ arrythmia	1	Cardiac arrest/ failure/ arrythmia	3	4.9
Neurological deterioration	3	Neurological deterioration	3	7.4
Pneumonia	1	Pneumonia	2	3.7
Urinary tract infection	2	Urinary tract infection	1	3.7
Other	15	Other	46	75.3
		Hematoma	3	3.7
		Pulmonary embolism	1	1.2
		CSF leak	1	1.2
Total	24		61 (71.7%)	
Late post-operative Adverse Eve	ents			
	N		Ν	%Tot
Construct failure without loss	1	Construct failure without loss	6	29.1
Deep wound infection	1	Deep wound infection	3	16.7
Other	1	Other	2	12.5
		Construct failure with loss	8	33.3
		Systemic infection	1	4.1
		Hematoma	1	4.1
Total	3		21 (87.5%)	

Table 3 Adverse event in degenerative patients

Table 4 A comparative analysis of demographic and clinical factors related to operative time in degenerative patients

	Operative Time < 3 h	Operative Time ≥ 3 h	<i>p</i> -Value
Variables			
Age	65.9	60.2	0.00039
CCI	2.71	1.76	0.00007
ASA	2.27	2.05	0.0301

in surgeries longer than 2 h. More interestingly, only 37 surgeries (16.5% of all surgeries for degenerative disease) lasted more than 4 h and they accounted for 61 out of 116 (52.5%) AEs (Table 5; Fig. 2).

We also divided the operating time in increasing intervals of 30 min and observed an increase of the complication rate, even if a nonlinear increase of risk is observed across increasing time intervals (Fig. 3).

Table 5 Distribution of adverse events in different operative intervals for degenerative patients

	Opera	Operative time intervals			
	<2 h	2–3.59 h	4–5.59 h	≥6 h	
					Tot.
Complicated patients	3/123	28/63	16/23	12/14	223
Ν	2.4%	44.5%	69.5%	85.7%	
%					
N°of AEs	3	52	35	26	116
Intra operative AEs	0	2	2	3	7
Early post-operative AEs	3	45	21	16	85
Late post-operative AEs	0	5	12	7	24

# Discussion

Surgical complications occur more frequently, often are more preventable, and their consequences can be more

Table 4 B Bivariate analysis of correlation between continuous operative time and different baseline variables for degenerative patients

	95% CI		
Variables	Upper	Lower	p-Value
Age < 60	12.17079	79.12593	0.0079
Sex	4.191885	68.901882	0.0271
CCI≤2	33.14331	91.74727	< 0001
ASA≤2	0.9795844	64.5588064	0.0434
Complicated	-177.7758	-111.5200	< 0001



Fig. 1 Distribution of patients who experienced AEs within each operative time interval (2 h)

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	OR	95% CI		
Variables		Upper	Lower	p-Value
Intra-operative AEs	1.009	1.003894056	1.014971534	0.0008
Early post-operative AEs	1.008	1.006025914	1.012232538	< 0.0001
Late post-operative AEs	1.008	1.004943075	1.013274889	< 0.0001



Fig. 2 Distribution of total adverse events and subcategories (intra-operative, early and late post-operative) across increasing operative time

severe than other types of complications. Thus, predictive factors for surgical complications have been extensively studied. In a recent systematic review addressing predictive factors for the development of operative complications in adult patients undergoing gastrointestinal, vascular, or general surgery, Visser et al. [12] identified, categorized, and ranked various patient- and surgery-related risk factors for complications: prolonged operative time was considered among the top three surgery-related factors.

This evidence was confirmed by Cheng et al. [5] who reported on the association between operative duration



Fig. 3 Distribution of the number of adverse events compared to the number of surgeries at increasing operating time intervals of 30 minutes.

and complications across various surgical specialties and procedure types, showing that likelihood of complications increased significantly with prolonged operative duration, approximately doubling with operative time thresholds exceeding 2 or more hours. Meta-analyses also demonstrated a 14% increase in the likelihood of complications for every 30 min of additional operating time.

In recent years, spine surgery has emerged as a critical intervention for addressing a myriad of spinal conditions; however, the complexity of these procedures often accompanies a risk of complications that can significantly impact patients' outcomes and quality of life. In general, the complication rate after spinal surgery ranges between 7 and 20% [2, 13, 14]while orthopedic surgery generally has a mean rate of complications of 5% [2].

We recently classified adverse events occurring in a tertiary reference center for spinal surgery according to SAVES v2 system [9, 10] and analysed risk factors for surgical complications and prolonged length of hospital stay [3], highlighting the prevalent role of operative time longer than 3 h as risk factor for complications. Our population included patients affected by oncological and degenerative spinal diseases mainly located at thoracic and lumbar level, but the same results were achieved by Ondeck et al. [6] on a population undergoing a 1-level anterior cervical discectomy and fusion and by Hersey et al. [15] who identified that longer operative duration was associated with more complications among patients  $\geq 65$  years undergoing posterior lumbar fusion procedures.

In the present study we proposed to further investigate on the relationship between surgical duration and adverse events via logistic regression models. In order to reduce the impact of other variables on surgical complications, we analyzed a population of patients surgically treated for degenerative spinal diseases in a single center, where confounding factors (diagnosis, comorbidities, type of surgery) were minimized. Although previous studies have noted that increased operative time (as a binary variable) is associated with the total rate of adverse events, most of them have not attempted to quantify the increased risk associated with greater operative duration across the entire range of operative times or been specific about which categories of adverse events are increased.

In our population surgical time was considered as continuous variable and was confirmed as a relevant risk factor for the occurrence of any complication across the spectrum of operative times.

At univariate analysis both CCI and ASA score did not result as risk factors for complications in our population of degenerative patients [3], in contrast with Withmore et al. [16] who previously reported the association of increasing CCI and ASA grade with complications and societal costs in spinal surgery.

We observed here that lower scores of CCI ( $\leq 2$ ) and ASA ( $\leq 2$ ) and age less than 60 years old were associated with an increased surgical time (Table 4A-B). In fact, the age-related medical comorbidities affect not only the decision to undertake a surgical procedure but also the magnitude of the procedure and consequently its duration. In our study complicated and elderly patients were eligible for less complex and invasive surgeries, while healthier and younger patients usually underwent to longer surgical procedure in order to improve their overall survival and outcomes. Likewise, procedural times are often reflective of case complexity, another factor heralded as influential in the risk of complications. We observed that the rate of complicated patients

increased with increasing operative time (Table 5; Fig. 1) and almost all the intra-operative and post-operative adverse events occurred in surgeries lasting more than 2 h (Table 6; Fig. 2). As we found a significantly lower age, CCI and ASA score in the group of patients who underwent surgeries longer than 3 h with respect to patients undergoing surgeries with OT less than 3 h (Table 4A-B), the relevant increase of AEs can be attributed to increasing operative time and not to other possible influencing factors. We show that an increase of 30 min in operating time can increase the complication rate, even if a nonlinear increase of risk is observed across increasing time intervals (Fig. 3). Ondeck et al. [2] previously observed that each additional 15 min of operating time raised the risk for having any adverse events after anterior cervical discectomy and fusion by an average of 10%. In our population, patients were affected by degenerative spine diseases, mainly localized at thoracic and lumbar levels, and posterior stabilization with or without decompression was the most frequent surgery.

We observed that intra-operative complications as well as early and late post-operative complications were associated to prolonged operating time. Concerning intra-operative AEs, the most common was dural tear (6.7%). In spinal surgery, accidental dural tears have been documented as a noteworthy adverse event, with an incidence ranging from 0.4-15.8% [17]. Interestingly, centers conducting a substantial number of surgical procedures tended to report lower rates of dural tears, while those with fewer procedures reported higher incidence rates [3, 17, 18]. In our cohort 9 out of 14 dural tears occurred in operative time longer than 6 h; this could be partially explained with an increase of the operative time due to the additional procedure of dural tear's repair. In fact, Weber et al. [19] investigated dural tears after elective spinal surgery and they reported that the operative time significantly increased from 116 min to 153 min when they occurred (P<.0001). Moreover, the occurrence of dural tear has been associated to other perioperative complications in spinal surgery [20]. When assessing operative time some intra-operative complications may not be the consequence of increased duration, but instead may be one of the contributing factors to increase time, and this is difficult to be quantified, as for massive blood loss intra-operative AE. "Major" or "massive" blood loss is defined as the loss of 1 volume of the patient's total blood (60mL/kg in adults) in <24 h [21]. In our study this complication was recorded in 18.1% of patients with  $OT \ge 3$  h in the oncological group. Generally, the first reason that can cause surgical blood loss is a hypervascularized tumor even if treated with a pre-embolization. In spinal procedures that require decompression, laminectomy can result in epidural bleeding.

Even if intra-operative complications could be a contributing factors for increasing operative time, numerous studies described a putative relation between longer operative time and post-operative complications, with an increased risk both for surgical and medical complications [1, 22]. Kim et al. [23], focusing on single-level lumbar fusion/instrumentation procedure, analyzed the effect of operative duration on postoperative adverse event showing that most postoperative complications exhibited a nonlinear increase in risk across the increasing groups. Similar to the findings by Kim et al., the current descriptive analysis showed that the risk of postoperative complications raised through surgical duration: early post-operative AEs were more common where OT was between 2 and 3.59 h, while late post operative AEs were more frequent in OT interval times longer than >4 h. Thus, the surgical duration results to be strictly related to post-operative complications, that increase the length of hospital stay [3] and impair the clinical outcomes and the patient's quality of life in the follow period, while impairing on healthcare system expenditure.

Early post- operative adverse events represent the most frequent category of complications in our cohort (135/206, 65.5%). Even if we used SAVES-V2 capture system to collect AEs, 83 out of 135 early post-operative complications fitted into the category "other", comprehensive of a large variety of medical complications. Fever represented 11/83 early post operative adverse events with an onset of 2-3 days post-surgery. Seo et al. [24] showed in their study that post-operative fever without infection in long operative or trauma surgery is a normal medical sequalae, caused by a greater degree of tissue inflammation. Oncological group showed several pulmonary complications (pneumonia and pleural effusion) into "other" category. As reported, the incidence of pulmonary complications following spine surgery for metastases ranged from 1 to 18% [25] and, this AE has been related to the prolonged anesthesia procedure.

Concerning late post-operative adverse events identified in this patients' cohort, they result to be similar to those previously identified in elderly spine patients [26] and all patients undergoing spinal fusion [23]. For the oncological group deep wound infection represented 28.5% of adverse events associated with longer operative time. Operative time has also been cited as a risk factor for surgical deep wound infection in abdominal surgery. In spinal surgery, the correlation between deep wound infection and prolonged operative duration can be attributable to various time-related factors such as prolonged microbial exposure, diminished efficacy of antimicrobial prophylaxis over time, increased tissue retraction leading to tissue ischemia, necrosis, and desiccation, and increased opportunities for violations in sterile technique [5, 27]. Common mechanisms for construct failure, with or without loss of correction, registered in degenerative patients were rod breakage, pedicle screw pull-out, proximal junctional kyphosis (PJK) and proximal junctional failure (PJF). These types of complications occurred in particular in long spinal instrumentation.

Despite limitations due to the retrospective analysis and the small sample size, this study highlights the relevant problem of complications in spinal surgeries and its strong correlation with prolonged operative time, focusing on a homogenous cohort of patients treated in the same tertiary center by the same surgeons.

# Conclusion

Considering the significant impact of surgical complications on clinical outcomes, patient's quality of life and costs for the healthcare system, the results of this paper suggest that efforts should be made by hospitals and surgeons to minimize the duration of surgical procedure while prioritizing patient's safety, without compromising the technical achievement of the procedure.

#### Author contributions

Conceptualization: Giovanni Barbanti Brodano, Annalisa Monetta, Cristiana GriffoniMethodology: Annalisa Monetta, Cristiana GriffoniValidation: Gisberto EvangelistiFormal analysis: Annalisa Monetta, Luigi Emanuele Nolilnvestigation: Luigi Falzetti, Carlotta CavallariResources: Alessandro Gasbarrini, Stefano Bandiera, Silvia Terzi, Giovanni Barbanti Brodano, Riccardo Ghermandi, Giuseppe Tedesco, Marco Girolami, Valerio PipolaWriting -Original Draft: Annalisa Monetta, Cristiana GriffoniWriting - Review & Editing: Luigi Falzetti, Luigi Emanuele Noli, Giovanni Barbanti BrodanoSupervision: Alessandro Gasbarrini.

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#### Data availability

No datasets were generated or analysed during the current study.

#### Declarations

#### **Competing interests**

The authors declare no competing interests.

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