



Morbidity and mortality following degenerative spine surgery in a prospective cohort of 1687 consecutive surgical procedures

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Abstract

Study design Prospective, observational cohort study.

Objective To determine the true incidence of adverse events (AEs) in European adults undergoing surgery for degenerative spine diseases.

Summary of background data The majority of surgeries performed for degenerative spinal diseases are elective, and the need for adequate estimation of risk-benefit of the intended surgery is imperative. A cumbersome obstacle for adequate estimation of surgery-related risks is that the true incidence of complications or adverse events (AEs) remains unclear.

Methods All adult patients (≥ 18 years) undergoing spine surgery at a single center from February 1, 2016, to January 31, 2017, were prospectively and consecutively included. Morbidity and mortality were determined using the Spine Adverse Events Severity (SAVES) system. Additionally, the correlation between the AEs and length of stay (LOS) and mortality was assessed.

Results A total of 1687 procedures were performed in the study period, and all were included for analysis. Of these, 1399 (83%) were lumbar procedures and 288 (17%) were cervical. The overall incidence of AEs was 47.4%, with a minor AE incidence of 43.2% and a major of 14.5%. Female sex (OR 1.5 [95% CI 1.2–1.9], $p < 0.001$) and age > 65 years (OR 1.5 [95% CI 1.1–1.7], $p = 0.012$) were significantly associated with increased odds of having an AE.

Conclusion Based on prospectively registered AEs in this single-center study, we validated the use of the SAVES system in a European population undergoing spine surgery due to degenerative spine disease. We found a higher incidence of AEs than previously reported in retrospective studies. The major AEs registered occurred significantly more often perioperatively and in patients > 65 years.

Keywords Degenerative spine surgery · Complications · Adverse events · Prospective

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Abbreviations

AEs	Adverse events
ASA	American Society of Anaesthesiologists
CI	Confidence interval
LOS	Length of stay
OR	Odds ratio
SAVES	Spine Adverse Events Severity system
SD	Standard deviation

Introduction

Degenerative spine disease has been the leading cause of loss of functional health (years lived with disability) during the last three decades [25]. The majority of surgical procedures for degenerative disease is elective, and the need for adequate estimation of risk-benefit of the intended surgery is imperative

both in patient counseling and when deciding to perform surgery. However, the true incidence of complications or adverse events (AEs) following spine surgery remains unclear. This is in large part due to inconsistencies in defining surgery-related complications [10, 14, 15, 24]. Furthermore, the majority of previous studies are retrospective and based on hospital registries or large national databases. The completeness and accuracy of these registries and databases have not been established [28]. In addition, retrospective studies are susceptible to underestimation of the incidence of complications [15]. Definitions for major complications often vary between studies and are often limited to describing risks of specific procedures or etiologies, resulting in limited general applicability. Rampersaud et al. addressed this issue by presenting a comprehensive, clinically relevant, and simple classification system for evaluating AEs related to spine surgery—the Spine Adverse Events Severity system (SAVES) [16–18]. Their intent was to propose a system for quantitative comparison across centers and procedures. Street et al. used this system to report the incidence of AEs in 942 consecutive adult patients undergoing spine surgery, both emergency and elective, at an academic quaternary referral center [10]. Karstensen et al. validated the SAVES system in a European population undergoing more complex spine surgeries (including surgery for deformity, major revisions, trauma, metastatic medullary cord compression, and infectious conditions) by comparing their results with that of Street et al. [5].

The primary purpose of this study was to use the SAVES system to determine the true incidence of adverse events (AEs) in European adults undergoing spine surgery for purely degenerative spine diseases both acute and elective, in efforts to further validate the SAVES system. The secondary purpose was to assess the correlation between the AEs and length of stay (LOS) and mortality.

Materials and methods

This study was performed at an academic tertiary referral center serving a population of approximately 2.5 million people.

All adult patients (≥ 18 years) undergoing spine surgery from February 1, 2016, to January 31, 2017, were prospectively included. The SAVES system V2 was used to record all intra- and perioperative AEs. This version contains 14 predefined intraoperative AEs, 29 predefined perioperative AEs, and categories for “other” (miscellaneous) intra- or perioperative AEs [10, 16, 20]. All AEs were categorized as major AE if the AE leads to intensive care, prolonged hospital stay, prolonged poor outcome (> 6 months), or death. AE grading was adopted from the original article by Rampersaud et al. [16], according to a previously published article by Bari et al. [1]. Individual SAVES forms were filled out

prospectively for each included patient by a research coordinator. Written informed consent was obtained from all individual participants included in the study. The research coordinator was not involved in the treatment of the patients. Once a week, all admitted patients were reviewed for additional AEs by the surgical staff, and questions raised by the research coordinator were clarified. All forms were concluded on the day of discharge. Extended LOS was defined as LOS exceeding the mean with one standard deviation (SD) and obesity as having a BMI > 30 kg/m².

Data

Patient characteristics, type of admission, and surgical data were registered for all. LOS and in-hospital, 30-day, and 90-day mortality was also recorded. Procedures were classified as lumbar (foraminotomy or laminotomy and discectomy, laminectomy, anterior stand-alone fusion, percutaneous minimal invasive posterior instrumentation, non-instrumented fusion, posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF) with pedicle screw instrumentation) or cervical (anterior cervical discectomy and fusion (ACDF) with or without anterior plating, posterior decompression with or without fusion and instrumentation, corpectomy).

Statistical analysis

Data analysis was performed using SPSS version 27 (SPSS Inc., IBM Corp., Armonk, NY, USA). Normality was determined using histograms, qq plots, and Kolmogorov-Smirnov tests. Incidences were compared using Fischer’s exact test. Continuous, normally distributed data were compared using the Student *t* test. The Mann-Whitney *U* test was applied when assumptions of normality were not met. Logistic regression was performed to assess the correlation of the registered AEs to LOS and mortality while adjusting for clinically relevant confounders such as sex, age, and surgical subgroup. $p < 0.05$ was considered statistically significant. Results were reported with 95% confidence intervals (95% CI) and standard deviations (SD).

Results

A total of 1687 procedures were included in the study period representing 100% of eligible patients. Mean (\pm SD) age was 60.4 ± 14.9 , and 55.1% ($n = 930$) of patients were female. The majority of procedures were lumbar 1399 (82.9%), and the most common surgical spine procedure was lumbar foraminotomy or laminotomy and discectomy ($n = 545$, 32.3%), followed by lumbar laminectomy ($n = 389$, 23.1%) and posterior fusion (PLIF or TLIF) with pedicle screw

instrumentation ($n = 325$, 19.3%). There was a total of 288 cervical procedures of which ACDF with or without anterior plating was the most common procedure ($n = 246$, 14.6%). Table 1 shows patient characteristics.

The overall incidence of AEs was 47.4%. Minor AEs were recorded in 43.2% of cases and major AEs in 14.5%. During the prospective study period, there were 1144 perioperative AEs and 144 intraoperative AEs resulting in an overall rate of 67.8% and 8.5%, respectively. Perioperative AEs were more common in older patients (> 65 years) compared with younger patients (mean AEs per patient 0.86 ± 1.09 vs 0.54 ± 0.79 , $p < 0.001$). There was no significant difference comparing intraoperative AEs (mean AEs per patient 0.08 ± 0.30 vs 0.09 ± 0.29 , $p = 0.474$). When examining major AEs only, these were more common perioperatively than intraoperatively (11.9% vs 4.1%, $p < 0.001$).

Stratified by surgical procedure, we saw the highest mean AE per patient among patients undergoing non-instrumented posterior lumbar fusion (1.4, SD ± 1.2) and PLIF or TLIF with pedicle screw instrumentation (1.4, SD ± 1.3). The mean AE per patient in patients undergoing lumbar laminotomy due to disc herniation or foraminotomy due to lateral spinal stenosis was significantly lower (0.4, SD ± 0.6 , $p < 0.001$) (Table 2).

Patient characteristics were assessed for correlation to the occurrence of any AE (Table 3). Univariable analysis showed several parameters with significantly increased odds (OR [95% CI]) of an AE (Table 3). In the multivariable model, female sex (1.5 [1.2–1.8], $p < 0.001$) and age > 65 years (1.4 [1.1–1.7], $p = 0.012$) remained significant.

Table 1 Patient characteristics

	Cohort ($n = 1687$)
Demographics	
Female	937 (55.1%)
Male	757 (44.9%)
Age (years)	60.4 (± 14.9)
Range (years)	19–92
Length of stay (days)	3.0 (± 3.3)
Type of admission	
Elective (n)	1570 (93.1%)
Acute (n)	117 (6.9%)
Comorbidity	
CCI (mean)	2.9 (± 1.6)
ASA score (mean)	1.9 (± 0.7)
BMI (kg/m^2)	27.1 (± 5.0)

Data is presented as numbers (proportions) or means (\pm standard deviation)

CCMI Charlson Comorbidity Index, ASA American Society of Anaesthesiologists, BMI body mass index

Length of stay

The overall mean \pm SD LOS was 3.0 ± 3.3 days (range 1–67 days). Patients ≥ 65 years had significantly longer LOS compared with younger patients (3.6 ± 3.5 vs 2.5 ± 3.1 days, $p < 0.001$).

Univariable logistic regression showed that age > 65 years, American Society of Anaesthesiologists' (ASA) score, and surgical procedure were significantly associated with increased odds of extended LOS (Table 4). These parameters, in addition to sex and emergency surgery, were then included in a multivariable model. We found that emergency surgery (4.0 [2.1–7.7], $p < 0.001$) and ASA score (1.9 [1.4–2.5], $p < 0.001$) remained significantly associated with increased odds of extended LOS.

Looking at specific types of intraoperative AEs, dural tear (1.6 [1.2–2.3], $p = 0.004$) and implant malposition requiring revision (7.1 [1.1–44.0], $p = 0.036$) were significantly associated with increased odds of extended LOS. Regarding perioperative AEs, anemia (OR 3.2 [1.5–6.9], $p = 0.003$), fever of unknown origin (OR 3.4 [2.5–4.5], $p < 0.001$), hematoma (OR 3.2 [2.0–5.3], $p < 0.001$), electrolyte imbalance (OR 1.8 [1.2–2.7], $p = 0.004$), urinary tract infection (OR 3.0 [2.0–4.5], $p < 0.001$), and nausea/vomiting (OR 1.6 [1.1–2.2], $p = 0.019$) were significantly associated with increased odds of extended LOS in our multivariable model (Table 4).

Mortality

The in-hospital mortality rate was 0.1% ($n = 2$). The causes of death were sepsis with subsequent multiorgan failure and a central nervous system (CNS) infection. The patients were 68 and 80 years old, and both were electively admitted. Both patients had one minor perioperative AE and no intraoperative AE. The 80-year-old patient with the CNS infection also had one major perioperative AE (urinary tract infection).

Discussion

In the present study, we prospectively examined AEs in a consecutive cohort of patients undergoing spine surgery for lumbar or cervical degenerative diseases. In 1687 procedures, we found an overall AE rate of 47.4%. A previous review of retrospective studies reported complication rate between 5.0 to 19.3% in 7 cervical and 3.7 to 12.8% in 11 lumbar spine studies [6]. Nasser et al.'s review (80% were retrospective) found an overall complication rate of 16.4% in 105 studies, varying between 19.9% in the prospective and 16.1% in the retrospective studies [15]. In the studies included in both reviews, there was no consensus or consistent definition of AEs

Table 2 Incidence of any adverse event per surgical procedure

	Number of patients	Number of patients with any adverse event
Cervical procedures		
Anterior discectomy and fusion (ACDF) with or without anterior plating	246	92 (37.4%)
Corpectomy	11	6 (54.5%)
Posterior decompression with or without fusion and instrumentation	31	12 (38.7%)
Lumbar procedures		
Foraminotomy or laminotomy and discectomy	545	172 (31.6%)
Laminectomy	389	191 (23.9%)
Anterior discectomy and fusion (ALIF)	20	8 (40.0%)
Percutaneous minimal invasive instrumentation	18	12 (66.7%)
Posterior fusion (TLIF and PLIF) with pedicle screw instrumentation	325	229 (70.5%)
Non-instrumented posterior fusion	102	78 (76.5%)
Total	1687	800 (47.4%)

Data is presented as numbers (incidence)

AEs adverse events, *ACDF* anterior cervical discectomy and fusion, *ALIF* anterior lumbar interbody fusion, *TLIF* transforaminal lumbar interbody fusion, *PLIF* posterior lumbar interbody fusion

or complications. The majority of the studies were retrospective which, as indicated in the study by Nasser et al., tended to underestimate the rate of complications.

In contrast, Street et al. reported the incidence of AEs in a prospective cohort of 942 patients using the SAVES system [20]. They found that AEs were more common, occurring at a mean rate of 0.1 intraoperative and 2.0 perioperative AEs per patient. In the present study, the mean rate per patient was similar for intraoperative AEs, although less frequent for perioperative AEs. However, the cohort presented by Street et al. consisted of patients undergoing more complex spine surgery, and procedures for degenerative diseases amounted to only 20% of procedures with a subsequent expected higher AE rate. Similarly, Karstensen et al. assessed AEs in a prospective cohort of 679 patients undergoing mainly complex spine procedures, using the same SAVES system [10]. Results were similar to the study by Street et al. (0.2 intraoperative and 2.1 perioperative AEs per patient) [20].

LOS was markedly shorter in the current study (3.0 days) compared with the studies by Street et al. [20] (13.7 days) and Karstensen et al. [10] (7.4 days), again presumably due to the difference in etiology and complexity of the surgery [8, 11, 19].

Female sex was significantly associated with having an AE. Previous studies have reported inconsistent results on being female and association with a higher occurrence of complications [5, 7, 9, 12, 22]. AEs were also more common in elderly patients (> 65 years). Age and the effect on AEs and complications have previously been inconsistently reported, and one should be careful of putting too much emphasis on age alone without any stratification in the risk-benefit estimation when contemplating spine surgery [2, 12, 13, 21].

Length of stay

Reducing LOS is important in a patient perspective, in efforts to minimize risk of AEs (e.g., infections and deep vein thrombosis) and in reducing costs related to treatment [8, 23, 26]. Therefore, identifying potentially modifiable factors affecting LOS is crucial when developing preventative customized protocols as enhanced recovery after surgery (ERAS).

We found that emergency surgery co-morbidity (increasing ASA score), and surgical procedures were all associated with extended LOS. These are not modifiable factors but should be allocated added attention in efforts to reduce the risks related to extended LOS. Turning to potentially modifiable factors, electrolyte imbalance and nausea/vomiting were also associated with extended LOS. These are often regarded as minor AEs and not given much attention in previous studies related to complications despite being easily avoidable. The present results warrant future validation.

Length of stay can potentially be influenced by several different factors, and we therefore performed logistic regression analysis to adjust for clinically relevant patient characteristics and surgical variables when examining the effect of recorded AEs both intraoperatively and perioperatively on extended LOS. We recognize that there may be factors influencing LOS that were not included in our analysis. However, there is not a clear consensus in the literature regarding which factors that do significantly influence LOS [8, 19, 29]. We therefore hope our results can contribute to the body of knowledge.

Table 3 Patient characteristics' effect on any adverse event. Univariable and multivariable logistic regression

	Univariable model OR (95% CI)	<i>p</i> value	Multivariable model OR (95% CI)	<i>p</i> value
Age > 65 years	1.6 (1.3–1.9)	< 0.001†	1.4 (1.1–1.7)	0.012†
Sex (female)	1.7 (1.4–2.0)	< 0.001†	1.5 (1.2–1.9)	< 0.001†
Emergency surgery	0.6 (0.4–0.9)	0.010†	1.0 (0.6–1.5)	0.979
ASA-score	1.3 (1.1–1.5)	0.003†	1.0 (0.9–1.2)	0.846
Obesity (BMI>30kg/m ²)	1.4 (1.1–1.7)	0.005†	1.2 (1.0–1.6)	0.074
Surgical procedure				
Lumbar foraminotomy or laminotomy and discectomy	Ref.	Ref.	Ref.	Ref.
Cervical procedure				
Anterior discectomy and fusion (ACDF) with or without anterior plating	1.3 (0.9–1.8)	0.107	1.4 (1.0–1.9)	0.068
Corpectomy	2.6 (0.8–8.6)	0.118	2.6 (0.8–8.8)	0.126
Posterior decompression with or without fusion and instrumentation	1.4 (0.7–2.9)	0.408	1.2 (0.6–2.7)	0.576
Lumbar procedure				
Laminectomy	2.1 (1.6–2.7)	< 0.001†	1.8 (1.3–2.4)	< 0.001†
Anterior discectomy and fusion (ALIF)	1.4 (0.6–3.6)	0.429	1.4 (0.5–3.5)	0.500
Percutaneous minimal invasive instrumentation	4.3 (1.6–11.7)	0.004†	4.4 (1.6–12.1)	0.004†
Posterior fusion (TLIF and PLIF) with pedicle screw instrumentation	5.2 (3.8–7.0)	< 0.001†	5.0 (3.7–6.8)	< 0.001†
Non-instrumented posterior fusion	7.0 (4.3–11.5)	< 0.001†	5.6 (3.3–9.4)	< 0.001†

OR odds ratio, CI confidence interval, ASA score American Society of Anaesthesiologists, BMI body mass index, ACDF anterior cervical discectomy and fusion, ALIF anterior lumbar interbody fusion, TLIF transforaminal lumbar interbody fusion, PLIF posterior lumbar interbody fusion

†*p*<0.05

Mortality

The mortality rate was low as expected since the majority of cases were elective and therefore underwent preoperative risk assessment. The number of deaths was too low for meaningful logistic regression analysis.

Strength and limitations

The prospective and systematic registration of AEs more accurately describe the true incidence [10, 15, 20]. The 100% cohort completeness minimizes the risk of selection bias and adds to the external validity. This was a single-center study performed at a dedicated surgical department for degenerative spine disease which is the only public hospital serving 2.5 million. The patient population, therefore, represents an appropriate cross section of the total population. In addition, the short study period of 1 year reduces the risk of significant changes in treatment principles.

The types of AEs used in the SAVES system are often monitored and recorded in the clinical setting at our hospital, and implementation did therefore not cause added staff strain or require specific added instructions. AEs were registered prospectively and coordinated by a research administrator not involved in clinical treatment, which further

minimizes the effect of recall bias as when reported by the surgeon [4]. The prospective nature and the use of predefined AEs in the SAVES system allowed for a more objective assessment and data aggregation in efforts to more thoroughly understand the complexity of factors associated with outcome. Both minor and major complications have previously been associated with increased costs of care in spine surgery [3, 10, 27].

However, despite exhaustive efforts to detect every predefined AE, all AEs may not have been captured. Although the SAVES system incorporates a category for miscellaneous AEs, there may be subtypes of relevance not included in the predefined categories. Furthermore, as the decision to operate was at the surgeon's discretion, although in accordance with relevant guidelines, an extent of selection bias may be present by excluding patients with severe comorbidities from surgery.

Conclusion

Based on prospectively registered AEs in this single-center study, we validated the use of the SAVES system in a European population undergoing surgery due to degenerative spine disease. We found that AEs were more common than

Table 4 Assessment of adverse events and the effect on extended length of stay. Univariable and multivariable logistic regression

	Univariable model OR (95% CI)	<i>p</i> value	Multivariable model OR (95% CI)	<i>p</i> value
Age (> 65 years)	2.4 (1.8–3.2)	< 0.001†	1.3 (0.9–2.0)	0.184
Sex (female)	1.0 (0.8–1.3)	0.926	0.8 (0.6–1.2)	0.352
Emergency surgery	1.3 (0.8–2.2)	0.269	4.7 (2.4–9.5)	< 0.001†
ASA score	2.2 (1.7–2.7)	< 0.001†	2.0 (1.4–2.7)	< 0.001†
Obesity (BMI > 30 kg/m ²)	1.5 (1.1–2.0)	0.010†	1.2 (0.8–1.8)	0.368
Surgical procedure				
Lumbar foraminotomy or laminotomy and discectomy	Ref.	Ref.	Ref.	Ref.
Cervical procedure				
Anterior discectomy and fusion (ACDF) with or without anterior plating	2.3 (1.3–4.2)	0.004†	2.9 (1.4–6.1)	0.004†
Corpectomy	4.8 (1.0–23.6)	0.052	2.8 (0.4–19.5)	0.292
Posterior decompression with or without fusion and instrumentation	23.2 (10.3–52.3)	< 0.001†	35.2 (13.8–89.9)	< 0.001†
Lumbar procedure				
Laminectomy	2.8 (1.7–4.7)	< 0.001†	1.7 (0.9–3.2)	0.112
Anterior discectomy and fusion (ALIF)	1.1 (0.1–8.9)	0.899	1.1 (0.1–13.6)	0.955
Percutaneous minimal invasive instrumentation	6.2 (1.9–4.7)	0.003†	4.7 (1.1–20.9)	0.042†
Posterior fusion (TLIF and PLIF) with pedicle screw instrumentation	7.7 (4.8–12.4)	< 0.001†	3.8 (2.0–7.0)	< 0.001†
Non-instrumented posterior fusion	9.0 (5.0–16.3)	< 0.001†	4.0 (1.9–8.7)	< 0.001†
Intraoperative AE				
Anesthesia related	0.8 (0.1–5.1)	0.839		
Dural tear	2.0 (1.6–2.6)	< 0.001†	1.8 (1.3–2.5)	< 0.001†
Implant malposition requiring revision	10.0 (1.9–53.1)	0.007†	6.5 (1.0–43.1)	0.055
Major blood loss	10.2 (1.3–80.1)	0.027†	0.7 (0.1–5.4)	0.727
Airway/ventilation	3.2 (0.3–35.0)	0.348		
Postoperative AE				
Anemia	10.7 (5.0–22.0)	< 0.001†	4.6 (2.1–10.1)	< 0.001†
Cardiac arrhythmia/arrest	3.6 (1.1–11.9)	0.038†	0.8 (0.1–5.5)	0.856
CSF leakage/meningocele	1.8 (0.5–5.9)	0.348		
Delirium	6.1 (1.9–19.7)	0.003†	2.8 (0.8–10.3)	0.122
Dysphagia	2.4 (1.3–4.4)	0.005†	2.2 (0.9–5.4)	0.087
Dysphonia	1.2 (0.4–3.0)	0.762		
Fever of unknown origin	3.7 (2.9–4.8)	< 0.001†	3.4 (2.5–4.5)	< 0.001†
Hematoma	3.8 (2.6–5.6)	< 0.001†	3.2 (2.0–5.3)	< 0.001†
Electrolyte imbalance	5.8 (4.4–7.8)	< 0.001†	1.8 (1.2–2.7)	0.004†
Neurological deterioration (< 1 motor grade ASIA scale)	2.0 (0.5–7.3)	0.309		
Pneumonia	3.4 (1.9–6.0)	< 0.001†	1.4 (0.7–2.9)	0.348
Superficial wound infection	10.2 (1.3–80.1)	0.027†	5.1 (0.5–49.7)	0.158
Urinary tract infection	4.4 (3.2–6.1)	< 0.001†	3.0(2.0–4.5)	< 0.001†
Wound dehiscence	2.3 (0.5–10.2)	0.260		
Nausea/vomiting	1.8 (1.4–2.3)	< 0.001†	1.6 (1.1–2.2)	0.019†
Medication related	2.4 (1.7–3.4)	< 0.001†	1.6 (1.0–2.6)	0.057

OR odds ratio, CI confidence interval, ASA American Society of Anaesthesiologists, BMI body mass index, ACDF anterior cervical discectomy and fusion, ALIF anterior lumbar interbody fusion, TLIF transforaminal lumbar interbody fusion, PLIF posterior lumbar interbody fusion

†*p* < 0.05

previously reported in retrospective studies. Major AEs occurred more frequently perioperatively than intraoperatively, and in patients > 65 years. We believe that this study adds

significantly to our understanding of the AE burden in degenerative spine surgery and may prove important in both patient counseling and when deciding to perform surgery.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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