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Original Article

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A Comparison of Mortality and Morbidity Between Complex and Degenerative Spine Surgery in Prospectively Collected Data From 2,280 Procedures

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Objective: The reported incidence of complications and/or adverse events (AEs) following spine surgery varies greatly. A validated, systematic, reproducible reporting system to quantify AEs was used in 2 prospective cohorts, from 2 spine surgery centers, conducting either complex or purely degenerative spine surgery; in a comparative fashion. The aim was to highlight the differences between 2 distinctly different prospective cohorts with patients from the same background population.
Methods: AEs were registered according to the predefined AE variables in the SAVES (Spine AdVerse Events Severity) system which was used to record all intra- and perioperative AEs. Additional outcomes, including mortality, length of stay, wound infection requiring revision, readmission, and unplanned revision surgery during the index admission, were also registered.
Results: A total of 593 complex and 1,687 degenerative procedures were consecutively included with 100% data completion. There was a significant difference in morbidity when comparing the total number of AEs between the 2 groups ($p < 0.001$): with a mean number of 1.42 AEs per patient (n = 845) in the complex cohort, and 0.97 AEs per patient (n = 1,630) in the degenerative cohort.
Conclusion: In this prospective study comparing 2 cohorts, we report the rates of AEs related to spine surgery using a validated reproducible grading system for registration. The rates of morbidity and mortality were significantly higher following complex spine surgery compared to surgery for degenerative spine disease.

Keywords: Prospective study, Complications, Adverse events, Complex spine surgery, Degenerative spine surgery

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INTRODUCTION

The reported incidence of complications and/or adverse events (AEs) following spine surgery varies greatly.[1-7] This is in large part due to the fact that there is no clear consensus of what a complication entails, and that they are often arbitrarily defined by investigators; which makes comparisons between studies difficult.[6,8-11] Furthermore, the retrospective nature of the majority of previous studies is vulnerable to bias and has been shown to underestimate the incidence of complications.[6] This has led to a limited general applicability of the results.

A difference in the occurrence of complications or AEs between complex and degenerative spine surgery is intuitive given the greater invasiveness of surgery and frailty among the patients undergoing complex spine surgery. However, there have been inconsistencies in the reporting,[12-19] and this difference has not previously been examined in large prospective cohorts from the same patient population using a validated registration system that is ideal for reproducibility.

The primary objective of the present study was to quantify and compare the occurrence of AEs in 2 prospective cohorts undergoing either complex or purely degenerative spine surgery. In this way, we would highlight the differences from these 2 distinctly different prospective cohorts with patients from the same background population. A validated, systematic, reproducible reporting system was used to register all AEs and the complex groups was also stratified into major diagnostic groups for more nuanced comparison.

The secondary objectives were to compare length of stay (LOS), wound infection requiring revision, readmission at 30 and 90 days, revision surgery during the index admission and mortality.

With the design of the study, we also hope to facilitate further studies utilizing a systematic reporting system and by so doing contributing to data aggregation that could lessen the disparities in the reporting on the incidence of AEs in spine surgery.

MATERIALS AND METHODS

1. Patient Selection

This study was a prospective observational analysis performed at 2 academic tertiary referral centers serving the same population of approximately 2.5 million people. All adult patients (≥18 years old) undergoing spine surgery at the 2 centers from February 1, 2016 to January 31, 2017, were prospectively and consecutively included.

The surgical procedures have been allocated and divided between these 2 centers. Longer fusion procedures for deformities, major revision surgery, surgery due to trauma, removal of primary tumors and decompression for metastatic cancer lesions, and surgery due to infections are classified as complex and performed at the center for complex spine surgery. Surgery for purely degenerative cervical or lumbar spine diseases, such as decompression surgery with or without arthrodesis for radiculopathy/myelopathy and spinal stenosis; is performed at the center for degenerative spine surgery. The centers are part of the same organization—Rigshospitalet—but are located at different hospitals within the same region. Both centers have postoperative care facilities as well as an intensive care unit and a ward for admittance pre- and postoperatively. Since both centers are a part of Rigshospitalet which is a university hospital the surgeons performing the procedures are both consulting specialists and residents under specialization. Both centers employ both neurosurgical and orthopedic specialists.

2. Data Collection

Demographic, surgical, and postoperative data were registered for all in addition to in-hospital, 30- and 90-day mortality. Additionally, the number of unplanned revision surgeries during the index admission and unplanned readmissions within 90 days postoperatively were also recorded. Procedures were classified as elective or emergency and into major diagnostic subgroups: elective (deformity, degenerative, oncology, infection, and other) and emergency (degenerative, oncology, trauma, infection, and other). The surgical etiology was classified as deformity rather than degenerative if it involved instrumented fusion of more than 5 consecutive spinal levels, more than 3 levels of interbody fusion, or involved any type of osteotomy due to the corrective nature of the procedure. These cases were performed at the center for complex spine surgery. Elective infection included planned biopsy and decompression surgery for infectious conditions. Emergency oncology cases were primarily metastatic lesions causing medullary cord compression, whereas elective oncology cases predominantly were spinal tumors of bone or the neural elements.

Informed written consent was obtained from all patients participating in the study. Since written informed consent was obtained and the study exclusively concerned information obtained by patient journals and did not involve biological materials; under Danish law no approval from the Danish Research Ethics Committee was required. The study was approved by the Danish Data Protection Agency (approval number: 2014-41-2820).

3. Spinal AdVerse Events Severity System Version 2

The Spinal AdVerse Events Severity (SAVES) system version 2 is a validated registration tool for the prospective registration of AEs in spine surgery. A detailed description of the center for degenerative spine surgery study cohort has been published previously in a study further validating the SAVES system in a European population.[20] This system was used to record all intra- and perioperative AEs in the current study and contains 14 predefined intraoperative AEs, 29 predefined perioperative AEs and categories for "other" (miscellaneous) intra- or perioperative AEs.[3,10,21] All AEs was categorized as major if the AE lead to intensive care, prolonged hospital stay, prolonged poor outcome (> 6 months), or death.[21,22] Individual SAVES forms were filled out prospectively for each included patient by a research coordinator. The research coordinator was not involved in the treatment of the patients. Once weekly, all forms 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.

4. Statistical Data Analysis

Statistical data analysis was performed using IBM SPSS Statistics ver. 25.0 (IBM Co., Armonk, NY, USA). Normality was determined graphically by histogram and qq-plot as well as the Kolmogorov-Smirnov test. Incidences were compared using Fischer exact test. Continuous, normally distributed data were compared using the Student t-test or 1-way independent analysis of variance. Mann-Whitney U-test was applied when assumptions of normality were not met. We used multivariable logistic regression to analyze the effect of undergoing complex spine surgery compared to degenerative spine surgery on AEs and mortality, adjusted for patient characteristics (sex and age), comorbidities (American Society of Anesthesiologists [ASA] physical status classification), type of admission (elective or emergency), and length of surgery. Stepwise backward multivariable logistic regression as well as examination for multicollinearity with Pearson bivariate correlation was performed in order to evaluate the results of the regression. A p-value of < 0.05 was considered statistically significant. Results were reported as odds ratios (ORs) with 95% confidence intervals (95% CIs) and/or standard deviation (SD).

Table 1. Patient characteristics

Characteristic	Complex cohort (n = 593)	Degenerative cohort (n = 1,687)	p-value
Sex			
Female	309 (52.1)	930 (55.1)	0.204
Male	284 (47.9)	757 (44.9)	
Age (yr)			
Mean ± SD	58.4 ± 18.0	60.4 ± 14.9	0.186
Range	18-95	19-94	
Length of stay (day)	6.6 ± 8.7	3.0 ± 3.3	< 0.001*
Type of admission			
Elective (n)	254 (42.8)	1,570 (93.1)	< 0.001*
Age (yr)	55.1 ± 19.1	61.0 ± 14.7	< 0.001*
Emergency (n)	339 (57.2)	117 (6.9)	< 0.001*
Age (yr)	60.9 ± 16.7	52.9 ± 15.8	< 0.001*
Comorbidity, ASA PS classification			
I	130 (21.9)	433 (25.7)	0.054
II	261 (44.0)	961 (57.0)	< 0.001*
III	188 (31.7)	291 (17.2)	< 0.001*
IV	14 (2.4)	2 (0.1)	< 0.001*
ASA PS classification	2.1 ± 0.8	1.9 ± 0.7	< 0.001*
Mortality			
Total in-hospital deaths (n)	12	2	< 0.001*
Overall mortality rate	2.0%	0.1%	

Values are presented as number (%) or mean ± standard deviation (SD) unless otherwise indicated.
ASA PS, American Society of Anesthesiologists physical status.
*p < 0.05, statistically significant difference.

Table 2. Incidence of most common adverse events

Variable	Complex cohort (n = 593)	Degenerative cohort (n = 1,687)	p-value
Intraoperative adverse events			
Dural tear	31 (5.2)	120 (7.1)	0.086
Nerve root injury	9 (1.3)	2 (0.1)	< 0.001*
Hardware malposition requiring revision	6 (1.0)	6 (0.4)	0.058
Major blood loss	6 (1.0)	4 (0.2)	0.014*
Cord injury	4 (0.7)	1 (0.1)	0.006*
Visceral injury	4 (0.7)	0 (0)	< 0.001*
Anesthesia related event	4 (0.7)	8 (0.5)	0.563
Airway/ventilation	3 (0.5)	3 (0.2)	0.179
Perioperative adverse events			
Electrolyte imbalance	269 (45.5)	279 (16.5)	< 0.001*
Nausea and vomiting	111 (18.7)	435 (25.8)	< 0.001*
Fever of unknown origin	80 (13.5)	108 (6.4)	< 0.001*
Anemia	67 (11.3)	30 (1.8)	< 0.001*
Cardiac arrest/failure/ arrhythmia	52 (8.8)	3 (0.2)	< 0.001*
Urinary tract infection	17 (2.9)	64 (3.8)	0.260
Hematoma	17 (2.9)	57 (3.4)	0.540

Values are presented as number (%).
*p < 0.05, statistically significant difference.

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RESULTS

We included 2,280 procedures in the 2 cohorts combined—593 in the complex spine surgery cohort and 1,687 in the degenerative cohort—with 100% completion of AE forms using the SAVES system. A comparison of the 2 cohorts regarding patient characteristics and surgical data (Table 1) showed that the complex cohort had longer mean (±SD) LOS (6.6±8.7 days vs. 3.0±3.3 days), more frequently underwent emergency procedures (57.2% vs. 6.9%) and had higher comorbidity burden (mean ASA PS classification grade 2.1±0.8 vs. 1.9±0.7). There were no significant differences in age or sex.

When comparing age across major groups; patients in the trauma (55.5±18.7) and deformity group (55.7±20.1) were younger than the patients in the degenerative (60.3±15.0), oncology (61.7±16.1), and infection groups (62.2±13.2).

1. Adverse Events

AEs affected overall 382 patients (64%) in the complex cohort compared to 800 patients (47%) in the degenerative and the mean number of AEs per patients were also higher in the complex 1.4±1.7 vs. 0.8±1.0 ($p<0.001$) with a total of 844 AEs vs. 1,288 AEs. When examining mean AE per patient among the major groups in the complex cohort we found no significant difference among infection (1.5±2.0, 58 AEs in 38 patients), oncology (1.4±1.6, 309 AEs in 219 patients), deformity (1.4±1.7, 172 AEs in 124 patients), and trauma (1.4±1.7, 183 AEs in 136 patients). Table 2 summarizes the most common AEs. Following multivariable analysis (Table 3), the odds of having any AEs remained significantly increased in the complex cohort (OR, 1.6; 95% CI, 1.3–2.1; $p<0.001$).

There was a higher number of perioperative AEs per patients in the complex group (1.3 vs. 0.7, $p<0.01$) with 18.4% of patients being affected compared to 14.5% in the degenerative cohort. The difference remained significant in multivariable analysis (OR, 1.6; 95% CI, 1.4–1.9; $p<0.001$) (Table 3). When comparing the number of perioperative AEs per patient among the major groups in the complex cohort we found no significant difference among infection (1.4±1.7, 52 AEs in 38 patients), oncology (1.3±1.5, 285 AEs in 219 patients), deformity (1.3±1.6, 155 AEs in 124 patients), and trauma (1.2±1.5, 166 AEs in 136 patients) ($p=0.971$).

Intraoperative AEs were more frequent in the complex cohort (12.5% [n=74] vs. 8.5% [n=144], $p=0.024$). This difference was however, not significant in subsequent multivariable analysis (OR, 1.1; 95% CI, 0.7–1.6; $p=0.804$) (Table 3). Across the major groups in the complex cohort, we found no difference in the frequency of intraoperative AEs: infection (15.8% [n=6]), deformity (13.7% [n=17]), trauma (12.5% [n=17]), and oncology (11.0% [n=24]) ($p=0.927$).

Further subanalysis of patients undergoing either emergency or elective surgery was performed for the complex and degenerative cohort separately. We found no significant difference in the incidence of AEs in either cohort when comparing emergency and elective patients.

Continuing subanalysis in the 2 respective cohorts, multivariable regression models revealed increased odds of AEs associated to ASA PS classification (OR, 1.3; 95% CI, 1.0–1.6) in the complex cohort, whereas sex (female) (OR, 1.7; 95% CI, 1.4–2.1) was associated to increased odds in the degenerative cohort (Table 4). Increasing length of operation was associated with a modest increase in the likelihood of having an AE in both cohorts. Additionally, age was associated with a modest increase in the likelihood of having an AE in the degenerative cohort.

2. Length of Stay

Mean LOS was longer in the complex cohort (6.6±8.7 days vs. 3.0±3.3 days) and significantly associated to increased odds of overall, intraoperative, and perioperative AEs in both cohorts ($p<0.001$). We found no significant difference in mean LOS comparing the major groups in the complex cohort: oncology (6.8±10.2), deformity (6.8±8.8), infection (6.5±9.4), and trau-

Table 3. Univariable and multivariable logistic regression analysis and the risk of adverse events

Complex surgery compared to degenerative surgery	Univariable analysis			Multivariable analysis		
	OR	95% CI	p-value	Adjusted† OR	95% CI	p-value
Total AE	2.1	1.7–2.6	<0.001*	1.6	1.3–2.1	<0.001*
Intraoperative AE	1.4	1.0–1.9	0.028*	1.1	0.7–1.6	0.804
Perioperative AE	2.3	1.9–2.8	<0.001*	1.8	1.4–2.3	<0.001*

OR, odds ratio; CI, confidence interval; AE, adverse event; ASA PS, American Society of Anesthesiologists physical status.
*$p<0.05$, statistically significant difference. †Adjusted for age, sex, type of admission (elective/emergency), comorbidity (ASA PS classification), and length of operation.

Table 4. Multivariable logistic regression analysis showing the effect of patient characteristics on the occurrence of AEs overall, perioperatively and intraoperatively

Variable	Complex cohort			Degenerative cohort		
	OR	95% CI	p-value	OR	95% CI	p-value
Overall AEs						
Sex (reference male)	1.164	0.820–1.653	0.396	1.690	1.378–2.073	< 0.001*
Age	1.006	0.996–1.016	0.232	1.015	1.007–1.023	< 0.001*
Length of operation	1.003	1.001–1.005	0.005*	1.012	1.010–1.014	< 0.001*
ASA PS classification	1.279	1.025–1.598	0.030*	1.013	0.853–1.202	0.886
Type of admission (reference elective)	1.389	0.961–2.007	0.080	1.286	0.854–1.937	0.229
Perioperative AEs						
Sex (reference male)	1.123	0.793–1.590	0.514	1.842	1.499–2.264	< 0.001*
Age	1.005	0.996–1.015	0.279	1.013	1.005–1.021	< 0.001*
Length of operation	1.003	1.001–1.005	0.004*	1.011	1.009–1.013	< 0.001*
ASA PS classification	1.304	1.046–1.626	0.018*	1.032	0.869–1.225	0.723
Type of admission (reference elective)	1.343	0.933–1.934	0.113	1.332	0.877–2.024	0.179
Intraoperative AEs						
Sex (reference male)	1.058	0.474–2.361	0.891	0.918	0.642–1.313	0.639
Age	1.056	0.624–1.787	0.839	1.025	1.011–1.040	< 0.001*
Length of operation	1.011	0.996–1.026	0.167	1.009	1.006–1.011	< 0.001*
ASA PS classification	1.004	1.001–1.007	0.005*	0.882	0.656–1.187	0.408
Type of admission (reference elective)	1.222	0.717–2.082	0.462	1.058	0.474–2.361	0.891

AE, adverse events; OR, odds ratio; CI, confidence interval; ASA PS, American Society of Anesthesiologists physical status.
*p < 0.05, statistically significant difference.

ma (6.2 ± 6.9) (p = 0.788).

Mean LOS was significantly longer for patients who underwent unplanned revision surgery in both the complex cohort (23.8 ± 19.4 days vs. 6.1 ± 7.8 days, p < 0.001) and in the degenerative cohort (9.0 ± 4.9 days vs. 2.8 ± 3.1 days, p < 0.001).

3. Infections Requiring Revision

There were 12 cases (2.0%) with postoperative wound infections requiring revision surgery within the follow-up period of 90 days; 4 of these occurred during the index admission. Only 1 of the cases (0.06%) was seen in the degenerative cohort. The distribution for the 12 cases among the major diagnostic subgroups was: 7 emergency oncology (58%), 3 elective deformity (25%), 1 emergency deformity (8%), and 1 elective trauma (8%) patient (originally operated electively due to pain after previous trauma fusion surgery).

4. Readmissions

The overall incidence of readmission in the study period was significantly higher in the complex spine cohort (8.6% vs. 4.8%, p = 0.001) (Table 5). This difference remained significant in terms of 30-day readmission but not in 90-day readmission. The most common reason for readmission within 30 days was surgical site infection in the complex cohort; which was the second most common in the degenerative cohort. In the degenerative cohort, pain issues were the most common reason for readmission; which was seldom seen in the complex cohort (Table 5). In the degenerative cohort, mean AEs per patient were significantly higher in patients with an unplanned readmission with 1.2 ± 1.0 vs. 0.7 ± 1.0 AEs (93 AEs in 81 patients vs. 1195 AEs in 1,606 patients) (p < 0.001) compared to the nonreadmitted. The difference was not significant in the complex cohort with 1.4 ± 1.7 versus 1.3 ± 1.5 AEs (p = 0.818) (779 AEs in 542 patient vs. 65 AEs in 51 patients).

5. Unplanned Revision Surgery

When comparing rates of unplanned revision surgery during the index admission, we found no significant difference between the complex cohort (2.5%) and the degenerative cohort (2.8%). The mean number of AEs per patient undergoing revisions was

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Table 5. Summary of most frequent unplanned readmissions

Variable	Complex cohort (n = 593)	Degenerative cohort (n = 1,687)
30-Day readmissions	45 (88%)	59 (73%)
Incidence of unplanned readmission	7.6%	3.5%
Reason for unplanned readmission		
Pain issues	1	19
Surgical site infection	26	12
Hardware revision	5	1
CSF leak	5	1
Wound dehiscence	0	4
90-Day readmissions	6 (12%)	22 (27%)
Incidence of unplanned readmission	1.0%	1.3%
Reason for unplanned readmission		
Pain issues	0	7
Surgical site infection	4	2
Hardware revision	1	3
CSF leak	0	2
Unsatisfactory decompression	0	2
Total unplanned readmissions	51	81

Values are presented as number (%) and incidence.
CSF, cerebrospinal fluid.

Table 6. Reasons for unplanned revision surgery during index admission

Cohort	No. (%)
Complex cohort (n = 593)	
Infection	4 (27)
Unsatisfactory decompression	3 (20)
Hardware malposition requiring revision	2 (13)
Postoperative hematoma	2 (13)
Supplemental fixation	2 (13)
Suture esophageal tear	1 (7)
CSF leakage	1 (7)
Total	15 (2.5)
Degenerative cohort (n = 1.687)	
Postoperative hematoma	20 (43)
Recurrent disc herniation	9 (19)
Residual disc herniation	5 (11)
Unsatisfactory decompression	4 (9)
Hardware malposition requiring revision	3 (6)
CSF leakage	2 (4)
Construct failure without loss of correction	1 (2)
Surgery performed at wrong level	1 (2)
Infection	1 (2)
Drainage equipment was accidentally sutured to the muscle	1 (2)
Total	47 (2.8)

CSF, cerebrospinal fluid.

significantly increased in both the complex and degenerative cohort (4.2 ± 2.3 vs. 1.4 ± 1.6 and 2.2 ± 1.7 vs. 0.7 ± 1.0, $p < 0.001$). Unplanned revision surgeries are further detailed in Table 6.

6. Mortality

There were 12 in-hospital deaths (2.0%) in the complex cohort and 2 (0.1%) in the degenerative cohort. Of the 12 in-hospital deaths in the complex cohort, 1 was in the elective group, and the remaining were emergency admissions. The 2 mortalities in the degenerative cohort were both electively admitted.

DISCUSSION

The main findings of this study were the significantly increased incidences of AEs and mortality in the complex cohort. LOS, infections requiring revision surgery and readmission rates were also significantly increased in the complex cohort. Rates of unplanned revision during the index admission were not significantly different. When examining the occurrence of AEs in the major groups within the complex cohort such as infection, trauma, deformity, and oncology, we found no difference either overall nor when sub analyzing peri- or intraoperative AEs. There was also no significant difference in mean LOS across the aforementioned groups.

Complications in complex and degenerative spine surgery have previously been described in the literature; as well as with proposed associated risk factors. The expected concomitant injuries in the trauma patient, the frailty of patients suffering from ongoing infection or malignancy and the greater invasiveness of deformity surgery with prolonged anesthetic time should arguably be associated with a higher risk of AEs compared to patients undergoing mainly elective surgery for purely degenerative conditions. This intuitive understanding has been challenged by inconsistencies in the reporting, and previous studies have been conflicting.[12-19] We believe that this study because of its prospective design with a validated registration system that contains predefined variables, on a large number of patients from the same population reflects a more realistic measure of the occurrence of AEs. Further it provides evidence in support of the intuitive understanding that complex spine surgery is associated with more AEs and therefore contribute to the body of evidence in the literature that can be used for evaluation regarding allocation of different procedures across spine disease and severity within regions or countries.

1. Adverse Events

Perioperative AEs were, as expected, more frequent in the complex cohort. We found no significant difference in the occurrence of perioperative AEs between the major diagnostic groups within the complex cohort. The mean perioperative AE per patient in these groups were similar to that found by Karstensen et al.[10]

When examining the cohorts separately (Table 4), increasing ASA-score was the predictor associated with the highest OR of having any perioperative AE in the complex cohorts. This corresponds well with the notion that the higher frailty and/or concomitant injuries across the patients in complex cohort should contribute to a higher occurrence of perioperative AEs. The ASA-score is however more of an indicative measure than an exhaustive measure of the higher frailty and/or concomitant injuries, and this study was not set up for a definitive evaluation of this effect; therefore, further studies are warranted.

Electrolyte imbalance, nausea, and vomiting were the most prevalent perioperative AEs in both cohorts; in agreement with previous studies using the SAVES system.[3,10,21] In contrast to the studies by Rampersaud et al.[21] and Street et al.,[3] the prevalence of the "medication-related" AEs was less apparent in our 2 cohorts. Our results were, however, comparable to the rates reported by Karstensen et al.,[10] who validated the SAVES system in a European population undergoing complex spine surgery.

A significantly higher incidence of intraoperative AEs in the complex cohort was also expected, although not apparent in multivariable analyses, possibly due to unknown confounders. As with the perioperative AEs, we could not find a statistically significant difference when comparing the major groups of infection, oncological, trauma, and deformity within the complex cohort.

Analyzing the cohorts separately (Table 4), increasing ASA PS classification was associated to increased odds of intraoperative AEs in the complex cohort whilst the same applied for age and length of operation in the degenerative cohort. When doing a stepwise backward regression removing the variable length of operation led to being in the complex cohort compared to the degenerative cohort becoming statistically significant. When comparing the mean length of surgery, we saw a significant longer surgery time in the complex cohort (149 ± 85 minutes vs. 91 ± 55 minutes, $p < 0.001$). The length of surgery is often used as a surrogate for the extent, and thus the invasiveness, of surgery which subsequently contributes to the significant higher occurrence of intraoperative AEs in the complex cohort. By adjusting the multivariable model for surgical invasiveness, a major trait differences between the cohorts are thus removed, possibly explaining the diminishing effect seen in the OR.

2. Length of Stay

We found significantly longer LOS in the complex cohort, comparable to the previous study by Karstensen et al.[10] We found no significant difference between the major groups within the complex cohort. It is reasonable to argue that patients undergoing deformity or tumor surgery undoubtedly need longer time to mobilize, and that the frailty of patients undergoing tumor surgery or the concomitant injuries of a trauma patient can result in medical complications requiring further intervention which extends LOS compared to patients undergoing surgery on the basis of degenerative spine disease. The significantly longer LOS for patients undergoing unplanned revisions surgery in both cohorts underlines the added burden on patients and increased costs to the healthcare provider.

3. Infections Requiring Revision

A significant higher incidence of infections requiring revision surgery in the complex cohort was in accordance with our expectations as there previously has been shown an association with larger procedures with greater invasiveness.[23]

4. Readmissions

The 30-day readmission rate was higher in the complex cohort corresponding well with significantly higher incidence of AEs and a more morbid patient population. However, the effect diminished when looking at 90-day readmission.

An unexpected finding was that there was no difference in the occurrence of AEs of readmitted patients in comparison to nonreadmitted patients in the complex cohort. A possible explanation could be that since patients in the degenerative cohort were primarily elective patients their main active illness was related to the operation and hence also their main hospital admission. Whereas, patients in the complex cohort had competing morbidities. In addition, patients in the major diagnostic subgroups such as infection, trauma, and oncology were often transferred to a different department following discharge for further treatment and; therefore, did not require readmission to

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the spine surgery department for minor complications that could be addressed by their respective departments. The significantly increased rate of AEs in the complex cohort—hence the more even distribution of AEs—could also contribute to balance the difference in AEs in patients who were readmitted and those who were not.

5. Unplanned Revision Surgery

The rate of unplanned revision surgery during index admission was similar in both cohorts, in contrast to expectations. It is important to note that recurrent and residual disc herniation made up 30% of the unplanned revisions in the degenerative cohort, but then again, the occurrence of postoperative hematoma was threefold in the degenerative cohort compared to the complex. The reasons for unplanned revisions in the degenerative cohort were also more varied, and the frequency too low for further subanalysis. Additional assessment of 2-year revision might reveal a difference between patients undergoing either complex or degenerative surgery; however, beyond the scope of this study.

6. Mortality

We found significantly increased in-hospital mortality in the complex cohort (2.0%) compared to the degenerative (0.1%). This was to be expected due to the greater invasiveness of deformity surgery, concomitant injuries in trauma patients, and frailty of patients with ongoing infection or malignancy.

7. Strength and Limitations

Prospective and systematic registrations of AEs more accurately describes the true incidence.[3,6,10] Both cohorts were 100% complete, thus minimizing selection bias and adding to the external validity. All AEs were registered by a team of healthcare providers and a research coordinator, which further minimizes the effect of recall bias as has been previously shown when AEs are reported by the surgeon.[24] The variables in the SAVES system are commonly registered variables in a clinical setting at our 2 hospitals and we did therefore not need to train the staff specifically for this project which in turn was beneficial for the validity of the prospective collection of data. The prospective nature and the use of the predefined categories in the SAVES system allow for a more objective assessment and aggregation of data to more thoroughly understand the complexity of factors that determine outcome. Both minor and major complications have previously been associated with increased costs of care in spine surgery.[10,25,26] Thus, this study adds to our understanding of the occurrence of AEs in both a wide array of complex and degenerative spine surgery and facilitates the possibility for future comparative studies.

This study also has its weaknesses. 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, this was an observational cohort study, and therefore, the decision to operate was at the surgeon's discretion in accordance with relevant guidelines. Therefore, an extent of selection bias may be present by excluding patients with severe comorbidities from undergoing surgery. Complex spinal pathologies often necessitate surgical treatment despite severe comorbid conditions. Finally, although both cohorts are large, there is a risk of type II errors in negative findings which warrants future validation. The differences in main and secondary outcomes could possibly be more nuanced within the degenerative cohort and in comparison, if stratified by cervical and lumbar procedures as well as fusion and/or decompression alone, of interest for future studies.

CONCLUSION

In this study, we prospectively included 2 complete cohorts of patients undergoing either complex or degenerative spine surgery, consisting of 2,280 consecutive patients. In a comparative fashion, using the SAVES system, we found increased morbidity related to complex spine surgery not previously demonstrated in a prospective study. The results warrant further studies, hopefully using the same registration system, for additional validation and comparison.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES

1. Yadla S, Malone J, Campbell PG, et al. Early complications in spine surgery and relation to preoperative diagnosis: a single-center prospective study. J Neurosurg Spine 2010;13:360-6.
2. Boakye M, Patil CG, Ho C, et al. Cervical corpectomy: complications and outcomes. Oper Neurosurg 2008;63(suppl_4): ONS295-302.
3. Street JT, Lenehan BJ, DiPaola CP, et al. Morbidity and mortality of major adult spinal surgery. A prospective cohort anal-

ysis of 942 consecutive patients. Spine J 2012;12:22-34.
4. Dea N, Versteeg A, Fisher C, et al. Adverse events in emergency oncological spine surgery: a prospective analysis. J Neurosurg Spine 2014;21:698-703.
5. Kalanithi PS, Patil CG, Boakye M. National complication rates and disposition after posterior lumbar fusion for acquired spondylolisthesis. Spine (Phila Pa 1976) 2009;34: 1963-9.
6. Nasser R, Yadla S, Maltenfort MG, et al. Complications in spine surgery. J Neurosurg Spine 2010;13:144-57.
7. Dekutoski MB, Norvell DC, Dettori JR, et al. Surgeon perceptions and reported complications in spine surgery. Spine (Phila Pa 1976) 2010;35(9 Suppl):S9-21.
8. Vincent C, Moorthy K, Sarker SK, et al. Systems approaches to surgical quality and safety. Ann Surg 2004;239:475-82.
9. Mirza SK, Deyo RA, Heagerty PJ, et al. Towards standardized measurement of adverse events in spine surgery: conceptual model and pilot evaluation. BMC Musculoskelet Disord 2006;7:53.
10. Karstensen S, Bari T, Gehrchen M, et al. Morbidity and mortality of complex spine surgery: a prospective cohort study in 679 patients validating the Spine AdVerse Event Severity (SAVES) system in a European population. Spine J 2016;16: 146-53.
11. Ratliff JK, Lebude B, Albert T, et al. Complications in spinal surgery: comparative survey of spine surgeons and patients who underwent spinal surgery. J Neurosurg Spine 2009;10: 578-84.
12. Deyo RA, Cherkin DC, Loeser JD, et al. Morbidity and mortality in association with operations on the lumbar spine. The influence of age, diagnosis, and procedure. J Bone Joint Surg Am 1992;74:536-43.
13. Carreon LY, Puno RM, Dimar JR, et al. Perioperative complications of posterior lumbar decompression and arthrodesis in older adults. J Bone Joint Surg Am 2003;85:2089-92.
14. Cassinelli EH, Eubanks J, Vogt M, et al. Risk factors for the development of perioperative complications in elderly patients undergoing lumbar decompression and arthrodesis for spinal stenosis: an analysis of 166 patients. Spine (Phila Pa 1976) 2007;32:230-5.
15. Raffo CS, Lauerman WC. Predicting morbidity and mortality of lumbar spine arthrodesis in patients in their ninth decade. Spine (Phila Pa 1976) 2006;31:99-103.
16. Schoenfeld AJ, Carey PA, Cleveland AW, et al. Patient factors, comorbidities, and surgical characteristics that increase mortality and complication risk after spinal arthrodesis: a prognostic study based on 5,887 patients. Spine J 2013;13: 1171-9.
17. Reis RC, de Oliveira MF, Rotta JM, et al. Risk of complications in spine surgery: a prospective study. Open Orthop J 2015;9:20-5.
18. Yadla S, Malone J, Campbell PG, et al. Obesity and spine surgery: reassessment based on a prospective evaluation of perioperative complications in elective degenerative thoracolumbar procedures. Spine J 2010;10:581-7.
19. Shamji MF, Parker S, Cook C, et al. Impact of body habitus on perioperative morbidity associated with fusion of the thoracolumbar and lumbar spine. Neurosurgery 2009;65:490-8.
20. Solumsmoen S, Bari TJ, Woldu S, et al. Morbidity and mortality following degenerative spine surgery in a prospective cohort of 1687 consecutive surgical procedures. Acta Neurochir (Wien) 2021;163:281-7.
21. Rampersaud YR, Anderson PA, Dimar JR, et al. Spinal Adverse Events Severity System, version 2 (SAVES-V2): inter- and intraobserver reliability assessment. J Neurosurg Spine 2016;25:256-63.
22. Bari TJ, Karstensen S, Sørensen MD, et al. Revision surgery and mortality following complex spine surgery: 2-year follow-up in a prospective cohort of 679 patients using the Spine AdVerse Event Severity (SAVES) system. Spine Deform 2020; 20:717-29.
23. Baker GA, Cizik AM, Bransford RJ, et al. Risk factors for unintended durotomy during spine surgery: a multivariate analysis. Spine J 2012;12:121-6.
24. Chen BP, Garland K, Roffey DM, et al. Can surgeons adequately capture adverse events using the Spinal Adverse Events Severity System (SAVES) and OrthoSAVES? Clin Orthop Relat Res 2017;475:253-60.
25. Whitmore RG, Stephen J, Stein SC, et al. Patient comorbidities and complications after spinal surgery: a societal-based cost analysis. Spine (Phila Pa 1976) 2012;37:1065-71.
26. Calland JF, Guerlain S, Adams RB, et al. A systems approach to surgical safety. Surg Endosc 2002;16:1005-14.