The influence of comorbidity on the risks and benefits of spine surgery for degenerative lumbar disorders

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Received: 1 December 2013 / Revised: 8 January 2014 / Accepted: 9 January 2014 / Published online: 24 January 2014
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Abstract

Purpose The ageing of the population will see a growing number of patients presenting for spine surgery with appropriate indications but numerous medical comorbidities. This complicates decision-making, requiring that the likely benefit of surgery (outcome) be carefully weighed up against the potential risk (complications). We assessed the influence of comorbidity on the risks and benefits of spine surgery.

Methods 3,549/4,053 patients with degenerative lumbar disorders, undergoing surgery with the goal of pain relief, completed the multidimensional Core Outcome Measures Index (COMI; scored 0–10) before and 12 months after surgery. At 12 months postoperatively, they also rated the global treatment outcome and their satisfaction with care. Using the Eurospine Spine Tango Registry, surgeons documented surgical details, American Society of Anesthesiologists comorbidity (ASA) grades and perioperative surgical and general complications.

Results 29.0 % patients were rated as ASA1 (normal healthy), 45.7 % as ASA2 (mild/moderate systemic disease), 24.9 % as ASA3 (severe), and just 0.4 % as ASA4 (life-threatening). In going from ASA1 to ASA3 (ASA4 group too small), surgical complications increased significantly from 5.0 to 14.5 % and general complications increased from 2.9 to 15.7 %; 12-month outcomes showed a corresponding decline, with a good global outcome being reported by 79 % ASA1 patients, 76 % ASA2, and 68 %

ASA3. Satisfaction with treatment was 87, 85, and 79 %, respectively, and reduction in COMI was 4.2 ± 2.9 , 3.7 ± 3.0 , and 3.4 ± 3.0 points, respectively. Multiple regression analysis revealed a significant ($p < 0.0001$) independent effect of ASA grade on both complications and outcome.

Conclusion The negative impact of comorbidity on the outcome of spine surgery has not been well investigated/quantified to date. The ASA grade may be helpful in producing algorithms for decision-making and preoperative counselling regarding the corresponding risks and benefits of surgery.

Keywords Comorbidity · Spine surgery · Complications · Outcome

Introduction

The United Nations Population Division reports that in mid-2010 there were 523 million people in the world who were aged 65 years or more [1]. It has been estimated that this will rise to 601 million in 2015 and to 714 million in 2020, such that for the first time in human history there will be more people in the world over age 65 than under age 5. This profound population transformation will affect society in many fundamental ways, not least in relation to the health-care costs associated with the treatment of degenerative diseases.

The changing demographic of the population will undoubtedly result in a growing number of older patients who present for spine surgery with appropriate indications but with numerous medical comorbidities. The prevalence of comorbidities increases with advancing age, with estimates of 60–88 % of the population aged ≥ 65 years

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having at least one comorbidity in addition to their index disease [2].

The surgical treatment of spinal disorders is always associated with a certain risk of intraoperative and perioperative complications, and these generally increase with age and comorbidity [3]. These factors complicate decision-making, requiring that the likely benefit of surgery (outcome) using the chosen approach be carefully weighed up against the potential risk (complications). Many studies have focused on the complications associated with increasing comorbidity, but few have evaluated the corresponding patient-centred treatment outcomes. Whilst some studies in the field of orthopaedics have shown that comorbidity impacts on the absolute scores of function or quality of life recorded preoperatively [4] or at follow-up [5], only few studies have addressed its influence on changes in health-related outcomes after surgery, and these have produced conflicting results. In patients undergoing total hip replacement, Imamura et al. [6] showed that there is no influence of comorbidity on the change in health status as measured by functional, recreational, and social activities of daily living. In contrast, Slover et al. [7] showed that increasing comorbidity was associated with a generally poorer outcome, assessed as either the change in back-related disability (Oswestry Disability Index) or in SF36 physical function. Whether the negative impact of comorbidity represents an association between comorbidity and outcome per se, or is simply a reflection of the increased complications in patients with greater comorbidity, has not been well investigated. Indeed, to date, the influence of comorbidity on the balance between complications and outcome—or the risks and benefits—of spine surgery has received very little attention in the literature.

The aim of the present study was to perform an evaluation of both the risk and benefit of lumbar spine surgery in a given population of patients stratified by comorbidity level and type of surgery.

Methods

Inclusion criteria

The study was carried out using the framework of the Eurospine Spine Tango Registry together with our own in-house spine surgery outcomes database. It included the prospectively collected data of consecutive patients who had undergone surgery by qualified, specialised spine surgeons in our own spine centre (part of an orthopaedic hospital) from 2005 to 2011. To be included, patients had to: have a good understanding of written German or English or (after 2006) French, Spanish, Italian or Portuguese; be at least 1 year postoperative; and fulfil the study's

surgical admission criteria. The latter made use of the options ticked in relation to the given fields on the Spine Tango surgery form and were as follows: surgery in the lumbar or lumbosacral region of the spine; degenerative disease as the main pathology; pain relief as at least one of the goals of surgery.

Questionnaires

Before and 12 months after surgery, patients were requested to complete the Core Outcome Measures Index (COMI) questionnaire [8, 9]. On each occasion, the questionnaires were sent to the patients to complete at home, to ensure that the information given was free of care provider influence. The COMI is a multidimensional index consisting of validated questions covering the domains of pain (leg/buttock and back pain intensity, each measured separately on a 0–10 graphic rating scale), function, symptom-specific well-being, general quality of life, and social and work disability. In addition to the above questions, at the 12-month follow-up there was a further question inquiring about the global treatment outcome: “How much did the operation help your back problem?”, with five response categories: (1) helped a lot, (2) helped, (3) helped only little, (4) did not help, and (5) made things worse. The global treatment outcome was dichotomised into “good” (1 and 2) and “poor” (3, 4 and 5) for the purposes of subsequent analyses. A second item at follow-up inquired about the patient's overall satisfaction with the treatment of the back problem in our hospital, also with five response categories: (1) very satisfied, (2) satisfied, (3) neither satisfied nor dissatisfied, (4) dissatisfied, and (5) very dissatisfied. These were similarly dichotomised into “satisfied” (1 and 2) and “dissatisfied” (3, 4 and 5) for subsequent analyses.

Comorbidity was assessed using the American Society of Anesthesiologists Physical Status Score (ASA) grade. Though not formally a comorbidity instrument, the ASA grade is widely used to assess the overall health status of patients and has been shown to be useful in assessing the risk of intraoperative and postoperative complications as well as morbidity, cost, and length of hospital stay [10]. It rates patients in five categories based on the severity of their comorbid diseases (1 no disturbance, normal healthy patient; 2 mild/moderate disturbance; 3 severe disturbance that limits activity but is not incapacitating; 4 life-threatening, incapacitating disturbance; 5 moribund and not expected to survive 24 h with or without treatment) [10].

The ASA grade was documented by the surgeon on the Spine Tango Surgery form (the grade was based on evaluation of the patient by the anaesthetist, following interview with the patient and review of the patient records) as were the surgical procedures used and the surgical and

general complications occurring during the hospital stay in the time period from admission to discharge. The latter were recorded by means of multiple choice options of the most common complications given on the Tango form. For surgical complications, these included wrong level surgery, nerve root damage, cauda equina damage, spinal cord damage, bleeding in the spinal canal, bleeding outside the spinal canal, malposition of the implant, dural tear, wound infection, implant failure, and other. Options for general complications included anaesthesiological, cardiovascular, pulmonary, cerebral, kidney/urinary, liver/GI, death, or other.

Statistical analyses

Descriptive data are presented as means $\pm$ standard deviations (SD). The differences between comorbidity (ASA grade) groups were analysed using analysis of variance (ANOVA) (with post hoc Fisher's PLSD tests) for continuous data and contingency analyses with Chi-squared/Fisher's exact *P* test for categorical variables.

Multivariable logistic regression analyses were used to examine the influence of age, comorbidity, and other factors on the following dichotomised variables: surgical complications (y/n), general complications (y/n), global treatment outcome at 12 months (good/poor), satisfaction (satisfied/not satisfied), and achievement of Minimal Clinical Important Change score of ≥ 2.2 points [11] for COMI (yes/no).

Statistical significance was accepted at the $p < 0.05$ level.

Results

Patients and follow-up rates

In relation to the registry data collected from our spine centre, the average compliance rate for the surgeons' completion of the surgical forms after the initial work-in phase was 85 % (i.e. 85 % of all spine surgeries carried out in the spine centre had an accompanying Spine Tango Surgery). Hence, potentially, up to 15 % of eligible patients were not included in the present study (the exact number is unknown, because a completed Tango surgery form was a prerequisite for identifying patients who fulfilled the study's surgical inclusion criteria).

Of all the patients in our local spine surgery database, 4,053 satisfied the study's admission criteria. A patient-rated questionnaire was completed by 3,807 of these (94 %) at baseline and 3,763 (93 %) at 12 months' follow-up; 3,549 (88 %) returned a questionnaire at both time points.

Table 1 Baseline demographic, comorbidity, and self-reported clinical data (mean $\pm$ SD, or % values) for the study group

Variable	
Age (years)	61.2 $\pm$ 15.3
Gender	2,057 (51 %) F 1,996 (49 %) M
Comorbidity, ASA grade (%) ^a	
1	1,175 (29.0 %)
2	1,850 (45.7 %)
3	1,006 (24.9 %)
4	14 (0.4 %)
Back pain intensity (0–10 scale)	5.5 $\pm$ 2.9
Leg pain intensity (0–10 scale)	6.5 $\pm$ 2.7
Intensity of worst pain, back/leg (0–10 scale)	7.3 $\pm$ 2.0
COMI summary score (0–10 scale)	7.8 $\pm$ 1.7
% additional pathology other than degenerative disease ^b	1,063 (26 %)
Most severely affected segment	
L2/3	271 (6.7 %)
L3/4	800 (19.7 %)
L4/5	1,823 (45.0 %)
L5/S1	989 (24.4 %)
Other	170 (4.2 %)
Extent of lesion	
1 segment	1,922 (47.4 %)
2–3 segments	1,853 (45.7 %)
4–5 segments	250 (6.2 %)
>5 segments	28 (0.7 %)
Decompression	3,905 (96.3 %)
Fusion/stabilisation	1,365 (33.6 %)

^a Not recorded in eight patients

^b Most commonly, deformity or spondylolisthesis

The baseline data of the patients are shown in Table 1.

Comorbidity and complications

The comorbidity scores were distributed as follows: 29.0 % patients were rated as ASA1 (normal healthy), 45.7 % as ASA2 (mild/moderate systemic disease), 24.9 % as ASA3 (severe), and just 0.4 % as ASA4 (life-threatening).

In the entire group, there were 352 patients (8.7 %) for whom a surgical perioperative complication had been registered. These complications comprised (more than one option possible in a given patient) dural tears ($N = 216$ patients), implant failure ($N = 37$), wound infection ($N = 27$), bleeding outside of the spinal canal ($N = 32$), nerve root damage ($N = 15$), bleeding in the spinal canal ($N = 12$), malposition of implant ($N = 1$) and others

Fig. 1 Surgical and general complication rates stratified by ASA grade

Fig. 2 Increase in general complication rate with more complex surgery (no fusion/stabilisation vs. fusion/stabilisation) stratified by ASA grade

($N = 42$). There were 332 patients (8.2 %) for whom a general complication had been registered. These comprised (more than one option possible in a given patient) kidney/urinary problems ($N = 101$), cardiovascular ($N = 100$), pulmonary ($N = 38$), liver/GI ($N = 33$), cerebral ($N = 30$), anaesthesiology ($N = 13$), or other problems ($N = 70$).

In going from ASA1 to ASA3, surgical complications increased significantly from 5.1 to 14.7 % and general complications increased from 3.0 to 15.8 % (Fig. 1). The ASA4 group was very small, but surgical complications were present in 2/14 (14 %) patients and general complications in 5/14 (36 %).

The use of fusion/stabilisation was associated with a significantly higher rate of surgical complications (7.9 % for no fusion/stabilisation vs. 10.2 % for fusion/stabilisation; $p = 0.016$) and general complications (5.8 and 13.0 %, respectively; $p < 0.0001$). The influence of the use of fusion/stabilisation on general complications stratified by ASA grades is shown in Fig. 2. For surgical complications, the influence of the more extensive surgery was less marked, especially at the higher ASA grades: for ASA

Table 2 Output of multiple logistic regressions to evaluate the effect of age and comorbidity (graded 1–5) on five dichotomised outcomes

Dependent variables (outcomes)	Independent variable: odds ratio (OR; with 95 % confidence intervals) and significance (p value) in multivariable model	
	Age (years)	Comorbidity (ASA grade)
Surgical complications	OR 1.01 (1.00–1.02) $p = 0.007$	OR 1.56 (1.29–1.88) $p < 0.0001$
General complications	OR 1.03 (1.02–1.04) $p < 0.0001$	OR 1.78 (1.47–2.17) $p < 0.0001$
Poor global treatment outcome at 12 months postoperatively	$p = 0.46$	OR 1.37 (1.20–1.55) $p < 0.0001$
Not achieving MCIC in COMI score at 12 months postoperatively	$p = 0.31$	OR 1.31 (1.17–1.48) $p < 0.0001$
Not satisfied with care at 12 months postoperatively	$p = 0.31$	OR 1.32 (1.14–1.53) $p = 0.003$

1, 2 and 3 groups, respectively, surgical complication rates were 4.6, 7.1, and 14.3 % with no fusion/stabilisation and 6.9, 8.6, and 15.3 % with fusion/stabilisation.

Multiple logistic regressions showed a significant unique effect of both comorbidity and age on surgical and general complications (Table 2).

Comorbidity and patient-rated outcome

All 12-month outcomes were significantly ($p < 0.0001$) worse with increasing ASA grade (Fig. 3).

Comorbidity, but not age, had a significant unique effect on all types of patient-rated outcomes: the greater the ASA grade, the lower was the likelihood of reporting a good global outcome, being satisfied with treatment, and achieving the MCIC score for COMI (Table 2).

This effect of ASA on outcome was retained in the multivariable model, even when general and surgical complications and the type of degenerative disease were added as independent variables. In other words, ASA grade remained a significant independent predictor of outcome even when controlling for the presence/absence of surgical and general complications (which may be considered confounders, since they themselves may influence outcome) and the type of degenerative disease (which may be considered a confounder since some types may have more favourable outcomes than others). An example of such a multivariable model output for the “global treatment outcome” is shown in Table 3.

Fig. 3 12-Month outcome stratified by ASA grade (change in COMI score in points; all other measures are in %)

Table 3 Output of multiple logistic regression to evaluate the effect of age, comorbidity (graded 1–5), type of degenerative disease, and surgical and general complications on global treatment outcome

Independent variable entered into the multivariable model	Odds ratio (OR; with 95 % confidence intervals) and significance (<i>p</i> value) in predicting global treatment outcome
Age (years)	OR 1.00 (0.99–1.00), <i>p</i> = 0.125
Comorbidity (ASA grade)	OR 1.29 (1.13–1.47), <i>p</i> < 0.0001
Surgical complications (1 = yes)	OR 1.38 (1.08–1.77), <i>p</i> = 0.011
General complications (1 = yes)	OR 1.39 (1.07–1.80), <i>p</i> = 0.014
Disc herniation ^a (1 = yes)	OR 0.77 (0.64–0.92), <i>p</i> = 0.005
Spinal stenosis ^a (1 = yes)	OR 1.00 (0.82–1.21), <i>p</i> = 0.97
Adjacent segment degeneration ^a (1 = yes)	OR 1.08 (0.76–1.52), <i>p</i> = 0.68
Disc degeneration ^a (1 = yes)	OR 0.95 (0.80–1.13), <i>p</i> = 0.57
Spondylarthrosis ^a (1 = yes)	OR 0.87 (0.72–1.05), <i>p</i> = 0.14

^a More than one type of degenerative disease can be indicated in the Spine Tango form. Those shown here were the most commonly indicated types of degenerative disease in the current study, each simply categorised as present or absent

Discussion

A comorbid disease is a condition that is unrelated in aetiology to the condition of interest [10]. Clinical and health services research has rarely taken comorbidity into account when evaluating the effectiveness of health-care interventions [6]. We showed that comorbidity, as stratified by the ASA grade, was significantly associated not only with the incidence of complications arising during spine surgery, but also with a poorer treatment outcome.

The latter was not just an age effect, since age explained no unique variance in any of the outcome measures, in accordance with previous findings [11]. Moreover, it was

not a coincidental finding arising solely due to the association between diagnosis, ASA grade, and outcome (e.g. discectomy is usually associated with a good outcome and is also more common in patients with a lower ASA grade). Having a herniated disc was indeed associated with an improved outcome, but the significant unique influence of comorbidity on patient-rated outcome was still evident, over and above this effect.

It is well established that comorbidity is associated with higher complication rates during spine surgery. However, its significant negative impact on the patient-rated outcome has not been well investigated. Notably, the influence of comorbidity on outcome was independent of (i.e. additional to) any influence mediated via the increase in complications. This suggests that, when it comes to assessing the balance between risks and benefits of surgery, comorbidity exerts a “doubly detrimental” influence—increasing complication rates and also reducing treatment effectiveness—necessitating extra caution when indicating surgery.

It is not immediately apparent why condition-specific outcomes should be poorer in patients with high levels of comorbidity. However, this is not a finding unique to the present study. Slover et al. [7] reported that, contrary to assumptions regarding condition-specific outcomes, medical and psychosocial comorbidities negatively affected the generic SF-36 and the condition-specific Oswestry Disability Index to a similar extent. A surgical intervention likely represents a burden to the patient that causes a decline in function to varying extents; on top of existing systemic conditions influencing function and quality of life, it may require greater time and effort for patients with high comorbidity to recover, and in some patients full recovery may never be achieved.

The influence of ASA grade on outcome has various implications. First, given the increasing reliance on self-rated outcome scores in spine surgery, a better appreciation of factors that can affect the scores—independent of the technical success of the surgery—is necessary. In any studies comparing treatment outcomes in non-randomised studies (registries/observational studies), it is essential to consider comorbidity as a confounding variable or mediator in the statistical analyses, to improve internal validity. The ASA grade is a simple rating, routinely available for all surgical patients, and may be helpful in producing algorithms for use in the decision-making and preoperative consent processes regarding the risks and benefits of surgery. As far as setting realistic expectations is concerned, patients with a higher ASA grade should be informed that they should expect smaller improvements in health status/outcome. Otherwise, inappropriate expectations of treatment may be elicited, leading to subsequent dissatisfaction with the outcome [12]. To this end, the large volumes of data collected in spine registries could be utilised for the

development of accurate predictive algorithms for estimating the likely risks and outcomes associated with different spine procedures, based on various risk factors including ASA grade.

In an increasingly competitive environment, clinical outcomes assessment of health-care providers is an important issue [13]. In relation to this, benchmarking and clinical quality indicators must adjust for differences in clinical risk factors, to allow meaningful comparisons of performance. Finally, in attempting to improve outcomes, further studies are required to ascertain whether potentially modifiable comorbidities that negatively impact outcome can be addressed/treated preoperatively.

The strengths of the present study include the large numbers of consecutive patients assessed, the high rates of compliance with follow-up, and the uniform and systematic manner in which both the complications and outcomes data were collected. Weaknesses include the potential for under-reporting of complications. The accuracy, honesty, and thresholds for reporting complications are often questioned, especially when data are entered into a registry. To counteract this potential bias, the data reported, based on input to the Spine Tango, were all cross-checked and where necessary corrected/updated with the information collected on a routine basis for morbidity and mortality analyses by our hospital's medical documentation department. Another limitation is that we were unable to evaluate separate comorbid diseases and their relative influence. It may have been more accurate to evaluate comorbidity using self-rated comorbidity scales as opposed to simply the ASA grading. The latter was chosen because every patient is routinely categorised by the anaesthetist using this system and the information is documented in Spine Tango; whilst recommended as a comorbidity instrument for routine clinical use, there are, however, some uncertainties surrounding its reliability [13]. Nonetheless, given the fact that ASA grading is routinely available in many hospitals, any new or more detailed measure must be shown to outperform it sufficiently to make the extra effort worthwhile [6].

The impact of comorbidity on the outcome of spine surgery has not been well investigated in the literature to date. We showed that the ASA grade at the time of operation was predictive of both perioperative complications and patient-rated outcome 1 year after surgery. The ASA grade is simple and routinely available for all surgical patients. A measure such as the ASA grade should be included in any observational or benchmarking study investigating patient-rated outcomes of spine surgery, to allow statistical adjustment of outcome data. The ASA grade should be incorporated into predictive algorithms, along with other known predictors, for decision-making

and preoperative counselling regarding the corresponding risks and benefits of surgery.

Conflict of interest None.

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