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Clinical Study

Clinical implication of complications on patient perceived health status following spinal fusion surgery

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ABSTRACT

Approximately 2% to 16% of patients undergoing spinal surgery suffer adverse events or complications. There is a paucity of studies evaluating the impact of complications on long-term outcomes. The purpose of this study was to assess the long-term effects of surgical complications on patient functional improvement and overall health status, using a multi-institutional, prospective spine outcomes registry. A total of 1498 patients undergoing primary lumbar fusion for low back pain and/or radiculopathy between January 2003 and December 2010 were enrolled. All patients completed the Oswestry Disability Index (ODI), Medical Outcome Study Short Form 36 (SF-36), and back and leg pain numerical rating scores (Visual Analog Scale [VAS]) before surgery and at 1 and 2 years post-operatively. Patients were stratified based on the occurrence of a peri or post-operative complication, and by major *versus* minor complications. Baseline and 2 year clinical outcome scores were compared between cohorts. Both groups were similar at baseline. Complications occurred in 115 (7.68%) patients. The most common complications were cerebrospinal fluid leak (49.18%), bleeding requiring transfusion (13.11%) and nerve root injury (9.83%). Compared to baseline, there was no significant difference in the extent of functional improvement (ODI, VAS, SF-36) between both patient groups at 1 and 2 years post-operatively. Furthermore, there was no significant difference in outcome scores between patients with minor *versus* major complications. Within the context of an ongoing debate on the consequences of complications, we observed no lasting effect of complications on the patient's interpretation of overall health status and functional improvement at 1 and 2 years following elective lumbar spine surgery.

1. Introduction

Despite advances in technology and operative techniques, the incidence of complications during spinal surgery remains high, with reported rates ranging from 2% to 16% [1–5]. Factors such as patient age [2], underlying spinal pathology [2,6], pre-operative health status [7], duration of surgery, psychiatric illness [8] and obesity [9,10] have been associated with increased incidence of complications. Notwithstanding the prevalence of complications during spinal surgery, there is a paucity of studies assessing the long-term effects of complications on patient reported health outcomes and patient interpretation of overall health status. Whether complications influence long-term patient reported outcome measures is currently poorly defined.

The purpose of this study was to assess, using validated patient reported outcomes measures, the long-term effects of surgical complications on patient interpretation of their functional improvement and overall health status, using a large and multi-institutional prospective registry.

2. Methods

2.1. Patient selection

This was a retrospective study utilizing a prospectively maintained data registry. This study included patients aged 18–70 years who met the following inclusion criteria: (i) low back pain and/or radiculopathy; (ii) MRI evidence of degenerative disc disease, or Grade I spondylolisthesis with central or foraminal stenosis; (iii) failure of at least 6 weeks of non-surgical treatment; (iv) lumbar spinal fusion (including pedicle screw fixation, transforaminal

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lumbar interbody fusion, extreme lumbar interbody fusion, anterior lumbar interbody fusion); and (v) available patient reported outcomes data at baseline then at 1 and 2 year time points following surgery.

We excluded patients who had (i) prior lumbar spine surgery, (ii) severe co-existent pathology that could confound the assessment of operative outcome (such as rheumatoid arthritis, osteoarthritis, metabolic bone disease), or (iii) patients lacking comprehensive 1 and 2 year outcomes data.

2.2. Immediate post-operative complications

We assessed post-operative complications for each patient included in the study. Complications were divided into those likely or possibly associated with the surgery, including nerve root injury, surgical site drainage or infection, bleeding requiring transfusion and cerebrospinal fluid leak. Other complications known to be associated with lumbar spinal fusion surgery included pulmonary embolism (PE)/deep vein thrombosis (DVT), hardware failure, non-union, adjacent segment disease and genitourinary or gastrointestinal-related complications. Patients were then split into two cohorts based on the presence or absence of post-operative complication(s). Patients within the complications cohort were further stratified into major *versus* minor complications, as outlined by Glassman and colleagues [11].

2.3. Patient reported outcomes

Back pain was assessed using the Back Pain Visual Analog Scale (VAS), while leg pain was assessed using the Leg Pain VAS [12,13]. Functional status was assessed using the Oswestry Disability Index (ODI) questionnaire [14,15]. These questionnaires have been validated and are used widely in the spine surgery literature, with several studies showing their relevance to actual clinical practice. The questionnaires were administered before surgery and then re-administered at 1 and 2 years following surgery.

2.4. Statistical analysis

We compared patient and surgical variables, pain measures and functional status measured at 1 and 2 years post-operatively between the cohort of patients with complications and those without. Patients with major and minor complications were also compared. Demographic variables included patient age, body mass index and sex. Surgical variables evaluated included surgical indications, number of levels treated, spinal diagnosis and type of fusion performed. Clinical outcome variables included severity of back and leg pain at baseline, change in patient reported outcomes at the 1 and 2 year time points, functional status at baseline and the change in functional status at the 1 and 2 year time points.

Parametric data were expressed as means ± standard deviation and compared via Student's *t*-test. Nonparametric data were expressed as median [interquartile range] and compared via the Mann–Whitney U test. Nominal data were compared with the chi-squared test. All tests were two sided and were statistically significant if the p value was less than 0.05. We used SAS 9.3 (SAS Institute, Cary, NC, USA) for all data preparation and analysis.

3. Results

From January 2003 to December 2010, 1498 patients were enrolled in the study. We included patients between 18–70 years old who had both clinical and radiographic indications for lumbar spinal fusion, with available 1 and 2 year follow-up data. We excluded patients who had prior lumbar spine surgery, severe pathologies that could confound the assessment of potentially operative back pain, or an active medical or workman's compensation lawsuit.

Of the 1498 patients in the study, 115 (7.68%) experienced complications. The study population was 43.43% male (complications group 45.90% *versus* no-complications 43.21%, $p = 0.59$). Patients with complications had a mean age of 60.48 ± 12.17 years *versus* 55.18 ± 13.74 years in the no-complications cohort ($p = 0.06$). The mean body mass index of the complications groups was 30.40 ± 6.64 kg/m^2 compared to 29.52 ± 5.96 kg/m^2 in the no-complications group ($p = 0.11$). There was no significant difference in the median number of levels fused between the complications group (2 [interquartile range 1–4] levels) and no-complications group (2 [interquartile range 1–2]; $p = 0.67$).

The most common indications for surgery were degenerative disc disease (complications group 39.65% *versus* no-complications 44.80%; $p = 0.15$), spondylolisthesis (complications group 33.57% *versus* no-complications 30.10%; $p = 0.03$), and spinal stenosis (complications group 13.56% *versus* no-complications 13.74%; $p = 0.81$). Demographic characteristics for both cohorts, including indications for and type of surgery, are included in Table 1.

3.1. Post-operative complications

Of the 115 patients evaluated with complications, the most common complications were cerebrospinal fluid leak (49.18%), bleeding requiring transfusion (13.11%) and nerve root injury (9.83%). Other complications included surgical site infection (9.28%), genitourinary or gastrointestinal-related complications (6.01%), hardware failure (5.46%) and PE/DVT (4.91%) (Table 2).

3.2. Baseline patient reported outcome

There was no statistically significant difference between patient cohort scores for Back Pain VAS (complications group 7.09 ± 2.40 *versus* no-complications 6.99 ± 2.56; $p = 0.63$), Leg Pain VAS (complications group 6.71 ± 2.70 *versus* no-complications 6.76 ± 2.79; $p = 0.81$), ODI (complications group 47.18 ± 15.49 *versus* no-complications 48.22 ± 15.05; $p = 0.43$), Short Form 36 (SF-36) Physical Component Summary (complications group 27.96 ± 9.25 *versus* no-complications 27.37 ± 9.67; $p = 0.45$) or SF-36 Mental Component Summary (complications group 40.30 ± 16.27 *versus* no-complications 39.16 ± 15.95; $p = 0.41$) (Table 3).

3.3. Patient reported outcome measures at 1 and 2 years

Overall, there was a statistically significant improvement in patient reported outcome measures at 1 and 2 years after surgery. At 1 and 2 years post-operatively, there was no statistically significant difference in pain, disability or quality of life between patients with complications compared to the patients without complications (Table 4). Moreover, with further stratification of patients in the complications cohort into minor *versus* major complications, our study showed no significant difference in the extent of functional improvement at 1 and 2 years post-operatively (Fig. 1).

4. Discussion

In this 2 year longitudinal cohort study, we demonstrated that the occurrence of complications during spine surgery had no durable effect on long-term patient reported outcomes or patient interpretation of their overall health status. There was no difference in patient reported outcome measures of pain and functional disability between both patient groups at 1 and 2 years after index