A 15-year follow-up retrospective study on 959 spine surgeries : what can we learn from real-world data?

Abstract

Study design: Retrospective study

Objective: The aim of this study was to investigate the patients flow and need for additional surgery after first low back surgery. Next we analysed the patients who developed chronic LBP and were treated with SCS.

Summary of Background data: Low back pain (LBP) has a lifetime prevalence of 84% and imposes a high economical burden. Treatment is focused on preventing chronic pain. Research has shown the efficacy of treatment options. However, less is known about who benefits the most from which therapy and when they should be positioned in the treatment algorithm.

Methods: In this retrospective study, data of all patients who underwent first time surgery from 2000 to 2004 were included. After 10-15 year patients were contacted about their quality of life (EuroQol-5D) and life and heath perception (EQ-VAS).

Results: 959 patients underwent surgery at the lower back area. Follow-up time ranged from 13 to 17 years. 225 patients (23.5%) underwent a second surgery.
In total 20 patients (2,1%) developed chronic neuropathic back pain and received SCS therapy. Ten years post-surgery, 438 (45,7%) patients completed the QoL and low back pain questionnaires. The health-related quality of life and health situation were significantly lower in patients with multiple surgeries ($p<0,001$).

Conclusion: The study results indicate that large data sets, with multiple outcome measurements and long-term follow-up are necessary to improve our knowledge and to optimize the therapeutic pathway. In that way we might learn how to select a patient for the right treatment or treatments at the right moment and shorten the circulation in our health-care system

Keywords: low back surgery, patient flow, circulation in healthcare, chronic low back pain, neuropathic pain, spinal cord stimulation, decompression surgery, fusion surgery, microdiscectomie, PLIF, ALIF

Introduction

Background

Low back pain (LBP) has become a major public health problem worldwide. The lifetime prevalence of LBP is reported to be as high as 84%, and the prevalence of chronic LBP is about 23%. [1,2] LBP affects general well-being and performance at work, with 11-12% of the population being disabled. It imposes a high economic burden on individuals and governments. [1-3] In Belgium, the global cost for the management of LBP is estimated to be 187 million euro each year.[4]

In the acute phase, LBP is mainly treated with self-management and analgesics [1,5]. When surgery is indicated, it has been shown an effective treatment. [6] Patients should be selected carefully for surgery because the clinical outcome is highly correlated with patient selection [7]. Patients can have a combination of attributable causes, which has major implications on the outcome of the surgical intervention. [8,9] True remission is rare, and many patients continue to have symptoms and/or disability.[10] Research has shown that for low back surgery, 40% of the patients will develop chronic pain. [11] Moreover, in case the first surgery did not resolve the complaints, the chances of success are lower for the next back surgeries. [12]

One of the most important goals in treating LBP is to prevent the pain to become chronic, since treatment outcomes of chronic LBP are less favourable [13-15]. Chronic LBP is a complex entity. It can both have nociceptive and, often underdiagnosed and undertreated, neuropathic characteristics. [16] Neuropathic pain can be treated with medication, with results varying between 30% and 40%. [15] However, 50% of patients are intractable to this treatment. [17-19] A highly effective treatment for the neuropathic component is spinal cord stimulation (SCS).[20] SCS has shown to be more effective if started within 3 years following their initial back surgery. The results of SCS seem to be good, with a majority of the FBSS patients reporting a reduction in pain of at least 50%. [21,22]

Objective

This paper focusses on treatment of degenerative spinal pathologies. Since spinal degeneration is a continuous process, the ideal treatment strategy remains unclear. [15,20,23] Much research has been performed to show efficacy of treatments in Randomized Controlled Trials (RCTs). [24] However, less is known about which patients with chronic LBP will benefit most from the treatments and 'when and where' to position these in the treatment algorithm.

Methods

Study population and types of surgery

This study is designed as a retrospective study. Data of patients who underwent first time surgery at the lower back area from 2000 to 2004 at the Department of Neurosurgery, were included in the study. General and demographic information, the type of initial surgery and type, level and timing of additional surgeries were collected. Patients were divided in three groups, based on their first surgical intervention: 1) microdiscectomy (MD); 2) decompression surgery, which include laminectomy; 3) fusion surgery (anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion PLIF, and direct lateral interbody fusion (DLIF)). MD was performed in case of sciatica and laminectomy for neurogenic claudication. Discogenic degeneration and/or neuroforaminal stenosis and spondylolisthesis with back and leg pain were indication for fusion surgery. 15 years after initial surgery, all patients were contacted to provide details about their quality of life (QOL) (EuroQoL-5D) and self-rated health status (EQ-VAS). [25,26] Approval of the Internal Review board was obtained. Patient consent wasn't needed for the retrospective data collection.

Statistical methods

All statistical analyses were performed using SPSS (version 19; SPSS for windows; SPSS Inc., Chicago, IL). Continuous variables are reported as mean value ± standard deviation or number (percentage). In the absence of normality, the Mann Witney U test was used instead of student t-tests. Linear regression statistics were used to analyse the influencing factors on the perceived QOL (EQ5D) and EQ VAS scores. Statistical results were considered significant if $p<0.05$.

Results

Participants

A total of 959 (524 male and 435 female) patients who underwent spine surgery for the treatment of LBP with or without radicular pain, between January 2000 and December 2003, were included. General characteristics are summarized in table 1.
What follows is a summary of the most important findings from these data. Detailed results can be consulted in the supplemental digital content.

1. *Patient flow and follow-up time*

The median time from the first surgery until the second surgery was 1481 days. This median time was 541 days for 'same level' surgery and 1911 for 'other level' surgery. Patient flow characteristics for the different surgical treatments are summarized in table 2. Of the 225 patients who needed a second surgery, 69 (30.6%) had a third surgical intervention of whom 31 (13.8%) at the same level.

The flow of patients after a first MD is shown in figure 1. The majority of patients (110 or 74,3%) had the second surgery after one year from the initial surgery. A complete overview of the timing of the second surgery after a first MD can be seen in figure 2.
The second largest group was the laminectomy group (n=179). Within the first year, 17 patients (38,6 %) underwent a second surgery of which 5 were due to complications. The flow of patients after a first laminectomy is illustrated in figure 3.
In the group of patients who first received fusion surgery, visualized in figure 4 (n=115), 32 had a second surgery.

2. *Spinal fusion following non-fusion surgery*

In the MD group, a total of 72 patients (10,9%) had at least one fusion surgery after the initial MD. 52 fusion surgeries were performed as a second intervention after initial MD. Of these, 48 on the same level and 4 on a different level. 13 fusion surgeries were performed within the first year after the initial MD. After the initial laminectomy, 15 patients (8,4%) had at least one fusion surgery. Fusion surgery was performed 12 times (8 same level and 4 other level) as second and 5 times (4 same level and one other level) as a third intervention.

3. *Spinal cord stimulation therapy*

In total, 20 patients (2,1%) developed chronic neuropathic back pain and received SCS therapy. Two patients received SCS as a 2nd surgical treatment, 11 as 3rd surgical treatment and 7 as 4th surgical treatment.

15 SCS patients originated from the MD group. For these patients SCS was the 2nd, 3rd and 4th intervention for respectively 1, 7 and 5 patients. One patient received SCS as 6th intervention after the initial MD. In the laminectomy group 2 patients received SCS as 3rd intervention. From the initial fusion surgery group, 5 patients developed chronic LBP and received SCS. For one patient SCS was offered as 5th intervention.

The average time between the first diagnosis of chronic LBP and SCS was 3.36 years. The timing of SCS implantation after the initial MD surgery is illustrated in figure 5. None of the patients started SCS within the first year and 4 started 10 years after initial MD.

4. Quality of life

Ten years post-surgery, 438 (45,7%) patients completed the questionnaires on QoL and LBP problems. The overall median QoL was 0,773 and median perceived health situation was 70. Mean QoL and perceived health situation are summarized in table 3.

The health-related QoL and health situation were significantly lower in patients with multiple surgeries ($p<0,001$). Linear regression indicated that an increase in the number of surgeries is correlated with a decrease in the QoL ($p=0,002$, ß= -0,064, R-Square=0,41) and health situation (EQ VAS) ($p=0,004$, ß= -4,8, R-Square=0,34). Furthermore, both variables are significantly different depending on the initial surgery ($p< 0,001$). The initial MD surgery group has the best score for health-related QoL and health situation at long term follow-up. The EQ-5D and EQ VAS questionnaires were completed by 10 of the 15 SCS patients after initial MD (66%). Linear regression did not show an association between the time between initial surgery and SCS implantation and the QoL ($p=0,17$) or perceived health situation ($p=0,61$). A non-significant trend was observed between a higher number of surgeries before the SC and a lower EQ5D.

5. Complications

The complications in these patient flows are solely complications for which a second surgery was deemed necessary. In the MD group (figure 1), only 2 patients (0,3% of the MD group) underwent surgery for complications. There were no complications observed on the long-term. For the laminectomy group, 5 complications (2,8% of the laminectomy group) were observed and resolved by the second intervention. For the fusion surgery group no complication interventions were recorded.

Discussion

This retrospective long-term follow-up study investigated the patient's trajectories after initial spinal surgery for LBP. The trajectory of patients treated for LBP has not been investigated in recent years. The papers that have been published, describe a 'spaghetti pathway'. The average

time spend in the healthcare system was shown to be between 6 months and 6 years. It's important to improve the pathway and learn to position which treatment should be provided to which patient at which time. In that way we might shorten the path to optimal treatment by excluding unnecessary treatments.

The importance of long-term follow-up

Our retrospective study revealed that a long-term follow-up is essential to understand the evolution of the outcomes of surgical interventions. In 76.6% of patients the LBP problems resolved with the first surgery. Within the mean follow-up time of 15 years, 23.4% of patients needed a second surgical intervention.

In the MD group, 5,7% of patients needed a second surgery in the first year, but an additional 16,6% underwent surgery within 15 years. When comparing these results with literature, we notice a large variation in reported outcomes. Hence the cut-off for follow-up time has a big influence on the reported outcomes. In the prospective study of Ryang et al. on microdiscectomy, 10% of the patients underwent reoperation in a mean follow-up period of 16 months [27]. Kim et al. reported a reoperation rate of 6.2% in a follow-up between 18-36 months [28]. Son et al. performed a retrospective assessment with follow-up ranging from over 10 to more than 25 years. The reoperation rate was 13.9% during a mean follow-up period of 15.3 years [29] This confirms that results are highly influenced by the follow-up duration of the study.

For patients who underwent a laminectomy (179), 24,5% of patients had at least a second surgery, with 17 within the first year. This is a relatively low number, which is in accordance with literature [30]. Sato et al. observed a high reoperation rate for patients undergoing laminectomy (33.8%) compared with those treated with decompression and fusion in a follow-up period of 5-10 years [31].

For the 115 fusion surgeries we recorded 14 (12%) reoperations within one year from which 12 at the same level. However, an additional 14% of patients had a second surgery at another level after one year. This may mean that fusion surgery does have a higher incidence of adjacent level progression, which has also been described in literature. In a recent retrospective study of patients who underwent a first-time PLIF, 26.51% had a reoperation, of which 9.1% within a 3-year follow-up period [32]. In a recent systematic review and meta-analysis of anterior lumbar spine surgery (such as ALIF), reoperation rate ranged from 0% to 4%. [33] In the study of Sato et al., patients were followed for at least 5 years after the initial surgery. Reoperation rate for the

patients who had a PLIF was 14.4% at the final follow-up (between 5 and 10 years) [31]. This again stresses the importance of long-term follow-up from large patient groups.

One of the main concerns after an initial microdiscectomy or laminectomy is the potential need for a future fusion surgery, since this is considered to be more invasive. In our data set 10,9% of patients, which underwent a microdiscectomy, had one or more fusion surgeries after the initial surgery. In the laminectomy group, 8,4% underwent additional fusion surgery. Kao at al. reported fusion surgeries in 11,25% after MD and 12,08% after laminectomy within a follow-up period of 5 years. A comparable fusion surgery rate of 12,5% after microdiscectomy was reported by Castillo et al [34]. Our data is in line with these reports.

Neuropathic pain and SCS.

It is well known that the results in the treatment of chronic pain are less successful in comparison to acute pain. One reason is that patient might develop neuropathic pain. [15] Neuropathic pain can be treated successfully with medication. However, a part of these patients will become intractable to this treatment[17-19] and can be offered SCS.[11] The chance to develop neuropathic pain after spine surgery is about 30% [21,35] In our dataset 20 patients underwent a treatment with SCS. These patients could represent the pharmacological therapy-resistant patients with neuropathic pain. This resembles a total of 2.1% of the studied patient population. Linear regression showed no significant difference in outcome for the number of surgeries or the timing before SCS. However, there seems to be a trend for a higher QoL in patients with less surgical interventions prior to SCS. One could hypothesize that for certain patients a fusion of the lumbar back may not be a solution. These patients would benefit from SCS at an earlier time in their treatment trajectory. Hence, the success rate of SCS is associated with the interval between the onset of chronic pain and the implantation. The efficacy exceeds 85% if implanted within 2 years of the initial onset. [36] One of the major questions for the future of SCS is to identify its position in the treatment algorithm. Our data suggests that SCS could be considered earlier.

Quality of life

The overall life quality (QOL) is somewhat lower for patients suffering from spinal pathology (mean EQ-5D 0.773, VAS 70) in comparison with the mean perceived QOL in Belgium (mean EQ-5D 0,94, VAS 80) [37].

Both the perceived health situation and the overall QOL is better for the group with only one operation compared to those with several interventions (table 2). Possible explanations are the lower success rate of following treatments, the inevitable progression of spinal degenerative disease and the overall duration of pain since the first complaints.[23]. Interestingly, we saw that the initial surgery type is related to the longterm EQ-5D outcome. The microdiscectomy group had the best score, followed by the laminectomy group and then the fusion surgery group (table 1).

Study limitations

This study was a retrospective study, results should be validated before we can state firm conclusions. Only the pathway of the patient of reoperations and type of operations were identified. Overall outcome after 15 years was measured. No distinct outcomes after the surgeries, nor over time were collected. The response rate of 51% for this questionnaire was very reasonable. Finally, it's unknown if patients have been treated elsewhere.

Conclusion

Although this paper is a retrospective paper, it still points out some important findings, which can only be found on large data sets with a long-term follow-up.

1. Long-term follow-up is necessary to have a real-world vision on the effects and outcomes of spine surgery. Our data reveals that the majority of same-level surgeries and adjacent level surgeries occur in the years after the 1-year follow-up period.

2. Fusion surgery occurs in approximately 10% after disc herniation surgery in our data set and 8.4% in the laminectomy group.

3. The amount of patients with intractable neuropathic pain resulting in neuromodulation is 20 out of 959 (2.1%). Prospective research should investigate the positioning of neuromodulation in the treatment paradigm of neuropathic pain.

4. The QOL of patients which underwent surgery at the lower back is slightly lower in comparison to the general population (after a 15-year period). Multiple surgeries do decrease the overall long-term life quality, which underlines the importance of choosing the right treatment at the right moment for the right patient.

These conclusions point out that big data sets, with multiple outcome measurements and long-term follow-up are necessary to improve our knowledge and to optimize the therapeutic pathways. This data should be collected in daily clinical practice and should offer a bird's eye perspective in order to oversee the multidisciplinary collaborations. In that way we might learn how to select a patient for the right treatment or treatments at the right moment and shorten the circulation in our health-care system. This can result in better clinical outcomes, less economic burden and improved QOL.

Legends:

Fig 1: Patient flow after initial MD.

Fig 2: Timing of the second surgery after initial MD.

Fig 3: patient flow after initial decompression surgery

Fig 4: patient flow after initial fusion surgery

Fig 5: time between first surgery and spinal cord stimulating therapy

Table 1: patient characteristics

Table 2: patient flow characteristics

Table 3: mean quality of life and health situation.

Supplemental digital content 1: Detailed results. The Supplemental Digital Content expands on the results of this retrospective study.

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