Lumbar Decompression Versus Spinal Fusion in a Private Outpatient Setting: A Retrospective Study with Three Years of Follow-up*

Descompressão lombar versus fusão espinhal em ambiente ambulatorial privado: Um estudo retrospectivo com três anos de acompanhamento

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Abstract

Objective To compare pain, function, quality of life and adverse events of lumbar decompression and spinal fusion in patients with degenerative spinal pathologies who participated in a second opinion program for spinal surgeries with a 36-month follow-up.

Methods The data for this retrospective cohort were withdrawn from a private healthcare system between June 2011 and January 2014. The study sample consisted of 71 patients with a lumbar spine surgical referral. The outcomes for the comparisons between lumbar decompression and spinal fusion were quality of life (evaluated through the EuroQoL 5D), pain (measured by the Numerical Rating Scale) and function (assessed through the Roland Morris Disability Questionnaire) measured at baseline, and at 12 and 36 months after the surgical procedures. The definitions of recovery were established by the minimal clinically important difference (MCID). The baseline differences between the groups were analyzed by non-paired *t*-test, and the differences in instrument scores between time points, by generalized mixed models. The results were presented as mean values adjusted by the models and 95% confidence intervals.

Results Concerning the surgical techniques, 22 patients were submitted to spinal fusion and 49 patients, to lumbar decompression. As for the comparisons of the findings before and after the surgical interventions, the MCID was achieved in all outcomes regarding quality of life, pain and function at both time points when compared to baseline scores Moreover, concerning the complication rates, only lumbar

Keywords
- outcome assessment, health care
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- spine
- surgical interventions

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decompression presented a surgical rate of 4% ($n = 3$) for recurrence of lumbar disc hernia.

Conclusion Patients with degenerative spinal pathologies present improvements in long-term outcomes of pain, function and quality of life which are clinically significant, no matter the surgical intervention.

Resumo

Objetivo Comparar a dor, a função, a qualidade de vida e os eventos adversos da descompressão lombar e da fusão espinhal em pacientes com patologias degenerativas da coluna vertebral que participaram de um programa de segunda opinião para cirurgias de coluna com acompanhamento de 36 meses.

Métodos Os dados desta coorte retrospectiva foram obtidos de um sistema de saúde privado entre junho de 2011 e janeiro de 2014. A amostra do estudo foi composta por 71 pacientes encaminhados para cirurgia de coluna lombar. Os desfechos para comparações entre a descompressão lombar e a fusão espinhal foram qualidade de vida (avaliada pelo questionário EuroQoL 5D), dor (medida pela Escala Numérica de Classificação de Dor) e função (avaliada pelo Questionário de Incapacidade de Roland Morris) no início do estudo e aos 12 e 36 meses de acompanhamento pós-cirúrgico. As definições de recuperação foram estabelecidas pela diferença mínima clinicamente importante (DMCI). As diferenças basais entre os grupos foram analisadas por teste *t* não pareado, e as diferenças nas pontuações dos instrumentos entre os momentos, por modelos mistos generalizados. Os resultados foram apresentados como valores médios ajustados pelos modelos e intervalos de confiança de 95%.

Resultados No total, 22 pacientes foram submetidos à artrodese, e 49 pacientes, à descompressão lombar. Quanto às comparações de achados antes e depois das intervenções cirúrgicas, a DMCI foi alcançada em todos os desfechos de qualidade de vida, dor e função nos dois pontos de acompanhamento em relação aos escores basais Em relação às complicações, apenas a descompressão lombar apresentou 4% ($n = 3$) de taxa cirúrgica de recidiva da hérnia de disco lombar.

Conclusão Pacientes com patologias espinhais degenerativas apresentam melhoras nos desfechos de dor, função e qualidade de vida em longo prazo que são clinicamente significativas e independentes da intervenção cirúrgica.

Palavras-chave

- avaliação de resultados em cuidados de saúde
- doenças musculoesqueléticas
- dor nas costas
- coluna vertebral
- intervenções cirúrgicas

Introduction

Degenerative joint disease is the leading cause of chronic disability worldwide, and is usually associated with pain, joint blockage, and stiffness.[1] The increase in spinal surgeries nowadays is most frequently associated with degenerative processes of the lumbar spine; in recent years, the rate of lumbar procedures grew ten times faster than that of other orthopedic procedures, such as total hip or knee replacement.[2]

One of the consequences of spinal degeneration was first described by Verbiest in 1954, and is defined by the narrowing of the spinal canal, which causes compression of the spinal cord.[3] According to the author[4], the symptoms of nerve root compression due to hypertrophy of the articular processes occurred when the patient was in the upright position, especially during gait. Further studies have described that the compression of nerve structures is due to other components, such as hypertrophy of the ligamentum flavum, synovial cysts adjacent to the facet, and loss of height of the intervertebral disc.[5]

Symptomatic patients should initially be treated conservatively with physical therapy and medication, but, during patient assessment, it is possible to detect a small proportion of serious spinal pathologies, as well as those with compromised nerve root, and refer these patients to surgery.[6] The second opinion program was proposed to analyze the risks of unnecessary surgical procedures, as well as the costs, promoting a more ethical and beneficial practice for the patients, and a standard service for the treatment of low back pain.[7]

Surgical decompression is indicated in the following situations: when the conservative treatment fails, or when the patient develops cauda equina syndrome or presents progressive motor deficit.[8] On the other hand, lumbar fusion is indicated in cases of instability of the lumbar spine, and it can be performed through posterolateral (PL) fusion, in which the bone graft is placed between the transverse processes, or through the interbody (IB) fusion technique, in which the bone graft is placed between the vertebral bodies.

The use of IB fusion is indicated once the source of the pain is the intervertebral disc; regardless of its current widespread use, there is little evidence confirming its superiority.[9] Despite being technically more demanding, IB fusion provides better support for the anterior spine, indirect

foraminal decompression, lordosis restoration, and better removal of the intervertebral disc, which is an important pain factor.[10] The PL fusion is indicated when the source of the pain is the facet joint.[11] This technique is easier to perform and has a lower rate of complications, but could lead to more pain due to the need for greater exposure and damage to paravertebral muscles.[12] In regard to the outcomes, such as pain and dysfunction, the literature is inconclusive, because it has not been determined whether one approach offers any gains compared with the other.[13,14]

Despite these data, there is a controversy concerning which is the more appropriate intervention: isolated fusion or decompression.[11,15] Therefore, the aim of the present study is to compare pain, function and quality of life after lumbar decompression or spinal fusion in patients with degenerative spinal pathologies who participated in a second opinion program for spinal surgeries with a 36-month follow-up.

Methods

Study Design

Data for this retrospective cohort were withdrawn from a program of second opinion in spinal surgeries conducted in a private healthcare system, which includes patients with health insurance who had received an indication for surgery from a private practice spinal surgeon, and were offered a second opinion by their health insurers in Brazil.

The patients were assessed for eligibility between June 2011 and January 2014, and were followed up for 36 months. The eligibility criteria included: having an indication for spinal surgery due to degenerative lumbar spine conditions, such as intervertebral disc disease, degenerative spondylolisthesis, lumbar canal stenosis, facetary low back pain and lumbar instability; no contraindication to general anesthesia; ability to understand Portuguese; and agreeing to participate in the study. Patients with spinal fractures, scoliosis >20 degrees, congenital deformities, spinal tumors, confirmed or suspected pregnancy, and those who could not complete the follow-up were excluded from the study.

Surgical Interventions

Surgical procedures were performed or supervised by 14 senior surgeons (neurosurgeons or orthopedic surgeons) with more than 15 years of expertise. All patients underwent decompression or fusion. Decisions on which procedure to perform and on which levels were based on clinical practice guidelines, considering the findings on the clinical exam, instability criteria, and spinal stenosis.

Data Collection and Follow-up

Baseline data such as sociodemographic characteristics, general health, and any associated disease were collected at the hospital right before the surgical procedure by a research assistant (blinded to the aim of the study) as well as all outcome measurements. Long-term follow-up data were collected by telephone 12 and 36 months after surgery. The data were checked by two study coordinators, and, in case of any missing data, the databases were crosschecked in order to retrieve the information.

Outcomes

The outcomes for this study were: pain, function and quality of life measured at baseline, and at 12 and 36 months after surgery by specific questionnaires. All instruments have been translated and cross-culturally adapted into Brazilian Portuguese, and have had measurement properties tested.[16–18] Moreover, complications and relapse rates were assessed by the study coordinators through the hospital database and the medical records of the patients.

The participants were asked to classify their average pain over the previous week, and its intensity was measured by the pain Numerical Rating Scale (NRS), an 11-point numerical scale, which ranges from 0 to 10 (with 0 representing "no pain" and 10 representing "the worst pain the patient could ever experience").[19]

Also, self-rated back pain related function was measured by the Roland Morris Disability Questionnaire (RMDQ), in which each question is worth 1 point, and the scores range from 0 (no disability) to 24 (severe disability).[17]

Health-related quality of life was measured by the EuroQoL (EQ-5D), an assessment tool which uses five dimensions (5D: mobility, self-care, usual activities, pain/discomfort and anxiety/depression) to generate a score from 0 to 1 (worst to best).[17]

The minimal clinically important difference (MCID), which assigns a specific value of variation between follow-ups to define a clinically significant change in a patient's outcome (NRS: 2 points; RMDQ: 5 points; EQ-5D: 0.03 points) between the baseline and the follow-up periods is used as a definition of recovery.[20–22]

Sample Size

Since the present study is a retrospective cohort, the sample size is limited to the number of eligible patients who completed the treatment between June 2011 and January 2014.

Based on a previous study,[21] we estimated the mean pain score of 5.8 and the standard deviation of 2.0. Considering the main objective of comparing groups with different treatments regarding the level of pain and assuming that the standard deviation of the pain scale in the present study is similar to that observed in the study by Childs et al.,[21] the sample is sufficient to reach a power $>95\%$ for the detection of a difference of 1 point in the pain scale if we use the repeated measures design with a correlation structure, assuming that the correlation between measurements of the same patient over time is of ,0.5 and the significance level is 5%. The calculations were performed using the Power Analysis and Sample Size 14 (PASS 14, NCSS, LLC, Kaysville, UT, US) software package.

Statistical Analysis

Data were described as absolute and relative frequencies for the categorical variables, and, for the numerical variables, as means and standard deviations (SDs) or medians and

Table 1 Demographic and clinical characteristics of the study sample in values expressed as mean (standard deviation or percentage)

	Spinal fusion ($n = 22$)	Lumbar decompression ($n = 49$)	Total (n = 71)
Gender, male*	11 (50%)	27 (55.1%)	38 (53.5%)
Age, years*	59.14 (15.65)	44.51 (15.15)	62.47 (8.66)
Body mass index, kg/m^{2*}	28.96 (2.97)	27.19 (4.91)	27.7 (4.4)
Smoking, yes*	5 (22.72%)	9 (18.36%)	14 (19.7%)
Commorbities*			
Hypertension, yes	5 (22.72%)	12 (24.48%)	17 (23.9%)
Diabetes, yes	2 (9.09%)	2 (4.08%)	4 (5.6%)
History of cancer, yes	1 (4.54%)	1 (2.04%)	2 (2.8%)
Diagnosis			
Radiculopathy/Disc herniation/Disc protrusion	7 (31.81%)	37 (75.51%)	44 (62.0%)
Lumbar canal stenosis	4 (18.18%)	3 (6.12%)	7 (9.9%)
Mechanical low back pain	3 (13.63%)	2 (4.08%)	5 (7.0%)
Spondylolysis/Spondylolisthesis	3 (13.63%)	1 (2.04%)	4 (5.6%)
Intervertebral disc disease	3 (13.63%)	2 (4.08%)	5 (7.0%)
Unknown	2 (9.09%)	4 (8.16%)	6 (8.5%)
Reoperations	0	3 (4%)	3 (4%)

Note: *$p > 0.05$ for every characteristic analyzed.

quartiles, as well as minimum and maximum values. Generalized mixed models were adjusted to investigate differences in scores between follow-up periods, in order to consider the dependence between evaluations of the same patient. Baseline differences between groups were analyzed by non-paired *t*-test and the differences in instrument scores between the moments of assessment were investigated using generalized mixed models. Differences were found on multiple-comparison tests corrected by the sequential Bonferroni method, evaluating the effects between the baseline and the follow-up periods, as well as the interaction between time points. The results were presented as mean values adjusted by the models and 95% confidence intervals. The analyses were performed using the Statistical Package for the Social Sciences (SPSS, IBM Corp., Armonk, NY, US) software, considering a significance level of 5%.

The present study has been approved by the local Research Ethics Committee (under CAAE 59736016.0.0000.0071). All participants signed a consent form agreeing to participate in the spine program.

Results

The study sample consisted of 71 patients aged $\geq$ 18 years, with an indication of surgery (referred by the health care provider) for the treatment of degenerative diseases of the lumbar spine. All of them participated in the second opinion in spinal surgeries program, conducted at a tertiary hospital with access to supplemental health care, and were treated surgically and followed up for 36 months. The baseline demographics and clinical characteristics of the patients are presented in ►**Table 1**, according to the surgical procedure. Comparing the two types of surgical procedures, we observed significant differences in the demographics, clinical characteristics and diagnosis of the patients in each group ($p > 0.05$). A higher prevalence of lumbar decompression (69%) was observed; moreover, the groups presented statistically significant differeces ($p > 0.05$) in all characteristics analyzed. Concerning the rates of reoperation, only lumbar decompression presented a surgical rate of 4% (n = 3) for lumbar disc herniation.

Regarding the comparisons of the findings before and after the surgical interventions, ►**Table 2** presents outcome measurements of quality of life, pain and function, showing that the MCID was achieved in all outcomes, at both time points, when compared to the baseline scores ($p < 0.001$; ►**Table 2**).

However, when analyzing the postoperative time points without considering the surgical procedure, we did not observe differences or a specific value of variation between follow-ups to define a clinically significant change in a patient's outcome reached between the 12-month and 36-month follow-ups regarding quality of life, pain and function (►**Table 2**).

Discussion

Surgical interventions are frequently considered an option for the treatment low back pain, despite the divergences concerning the choice of technique.[2,3,5] Therefore, the aim of the present study was to compare long-term outcomes of quality of life, pain and function after lumbar decompression

Table 2 Mean adjusted values and 95% confidence intervals for the instrument scores for quality of life, pain and function at baseline and follow-ups according to surgical intervention.

Instruments	Baseline(N = 71)	12-month follow-up (N = 68)	36-month follow-up (N = 67)	*p*-value
EuroQoL-5D				
Spinal fusion	0.39 (0.28–0.49)	0.72 (0.61–0.82)	0.69 (0.58–0.80)	
Lumbar decompression	0.37 (0.30–0.44)	0.77 (0.70–0.84)	0.83 (0.76–0.91)	
Total	0.38 (0.32–0.44)	0.75 (0.69–0.81)	0.79 (0.73–0.85)	< 0.001
Minimal clinically important difference	–	0.37	0.41	0.356†
Numerical Rating Scale				
Spinal fusion	7.8 (6.8–9.0)	4.5 (3.7–5.4)	4.0 (3.2–5.1)	
Lumbar decompression	8.2 (7.5–9.0)	4.5 (3.9–5.1)	4.4 (3.8–5.1)	
Total	8.1 (7.5–8.7)	4.5 (4.0–5.0)	4.3 (3.8–4.8)	< 0.001
Minimal clinically important difference	–	3.6	3.8	0.559†
Roland Morris Disability Questionnaire				
Spinal fusion	14.8 (11.8–18.5)	6.4 (4.5–9.0)	5.9 (4.0–8.6)	
Lumbar decompression	16.4 (14.2–18.9)	5.8 (4.5–7.4)	4.8 (3.7–6.3)	
Total	15.9 (14.1–17.9)	6.0 (4.9–7.3)	5.1 (4.1–6.4)	< 0.001
Minimal clinically important difference		9.9	10.8	0.200†

Note: †*p*-values corrected by the sequential Bonferroni method.

and spinal fusion in patients with degenerative spinal pathologies who participated in a second opinion program for spinal surgeries.

Our results support the current evidence concerning clinically significant improvements after surgery,[23] and highlight the information that the scores did not differ between patients operated by spinal fusion or lumbar decompression, but they changed between time points (p <0.001), since the mean preoperative score was higher than the mean values (p <0.001) of the follow-ups at 12 and 36 months.

On the other hand, it is already known that the positive outcomes, the low rates of complications and reoperation, as well as the cost-effectiveness, are associated to the selection of patients for specific surgical techniques, which is often made based on patient profile and specific comorbidities, such as age and body mass index (BMI).[24] Likewise, recent evidence suggests that fusion provides no additional benefits compared to the traditional decompression surgery.[25] In addition, evidence shows that spine reoperation has an incidence of 5% to 16%, depending on the risk factors,[26,27] which means that the present study showed positive outcomes and a minimal rate of recurrence for lumbar disc hernia (4%), which were only observed on the lumbar decompression group.

Moreover, the patients of the present study are part of a second opinion program which can be considered an alternative to perform a shared decision-making approach to validate or not the decision of having surgery for back pain in the first place.[28] This interaction between the patient and the health care professional has been already proven to improve patient compliance and reduce healing time and functional deficits.[29]

Descriptive and administrative data concerning outcomes have been presented by researchers in an attempt to report population-based procedure rates, surgical safety outcomes, and costs regarding the diagnosis and management of conditions related to back pain.[15,30] Our results contribute to current body of evidence by demonstrating that patients with degenerative spinal pathologies present clinically significant long-term outcomes for pain, function and quality of life, regardless of the surgical intervention.

In addition, given the heterogeneity of symptoms and pathology, it is wise to state that there are no standardized criteria to refer patients to clinically meaningful groups based on surgical indication.[31] The present study points out a higher rate of lumbar decompression in a spinal-surgery program, but this could be linked to many reasons, such as the surgeons' discretionary use of operative techniques, hospital management and shared decision-making approaches.

The surgical treatment is highly controversial, and many techniques have been developed and performed worldwide. Spinal fusion and lumbar decompression are the top-two most performed low back surgeries overall, and have been associated with poor outcomes in 20% to 40% of the patients.[30,31] In the present study, we observed a variety of diagnosis with the same surgical indication, which leads to the urge to conduct further studies in order to sharpen the indication criteria, reduce the reoperation rates, and improve the quality of the health care.

Conclusion

In conclusion, patients with degenerative spinal pathologies present long-term outcomes for pain, function and quality of

life which are clinically significant, regardless of the surgical intervention. However, further studies must be conducted in order to better understand the factors which contributed to these outcomes, as well as also the economic impact associated with each intervention.

Authors' Contributions

All authors conceived the study. IOO chose the study design, and ML, EA and MF helped with the final version of the manuscript. IOO and EA were involved in the statistical analysis. All authors contributed to the refinement of the study and approved the final manuscript.

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Conflict of Interests

The authors have no conflict of interests to declare.

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