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ORIGINAL ARTICLE

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No difference in clinical outcome after posterolateral lumbar fusion between patients with isthmic spondylolisthesis and those with degenerative disc disease using pedicle screw instrumentation: a comparative study of 112 patients with 4 years of follow-up

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Abstract We compared the clinical outcome after spinal fusion between patients with isthmic spondylolisthesis and those with degenerative disc disease of the lumbar spine, using multiple logistic regression analysis. A questionnaire describing medication, pain, vocational status and patient satisfaction was mailed to all the patients at a median interval of 4 years after their operation. Fusion was evaluated on plain radiographs at a minimum of 12 months after surgery, and patients were classified as fused or not fused. The overall satisfaction rate was 70%. The results of the present study showed no difference in the outcome after spinal fusion between the two groups of patients. The factors that significantly increased the likelihood of an optimal result – defined as patient satisfaction, return to work, and reduced medication – were male gender, being in work prior to surgery, and being a non-smoker. Since spinal fusion is an expensive treatment with potentially serious risks, and leaves one-third of the patients with an unsatisfactory result, we believe that more studies focusing on the indications for surgery should be performed.

Keywords Spine surgery · Clinical outcome · Spondylolisthesis · Degenerative disc disease · Comparative

Introduction

Over the years, a number of instrumentation systems have been developed to obtain high fusion rates in spinal arthrodesis [7, 21, 22, 28, 31]. As a consequence, most reports on spinal fusion have concentrated on the advantages and disadvantages of arthrodesis obtained with or without the use of spinal implants [30, 36].

Two diagnoses of major interest treated by lumbar spinal fusion procedures are isthmic spondylolisthesis and degenerative disc disease. Only few studies, however, have focused on the relationship between the preoperative diagnosis and the clinical outcome after spinal fusion. Patients with isthmic spondylolisthesis at the L5-S1 level are often considered as a separate clinical entity in the evaluation of results after lumbar spinal fusion, whereas patients with degenerative disc disease, including degenerative spondylolisthesis at the L4-L5 level, are considered as a much more heterogeneous group with a higher risk of unfavorable results after fusion procedures [8, 16, 24]. Turner et al. [32] concluded in a meta-analysis that any difference in outcome between patients with isthmic or degenerative spondylolisthesis couldn't be assessed due to the small number of studies where all patients had a single diagnosis. We have therefore found it of relevance to compare the clinical outcome of spinal fusion in patients with isthmic spondylolisthesis with that in patients with degenerative disc disease of the lumbar spine, using multiple logistic regression analysis.

Materials and methods

A total of 127 patients were operated; 53 women and 73 men, with a median age at time of operation of 45 years (range 18–69 years). Group A consisted of 71 patients with isthmic spondylolisthesis at the L5-S1 level [35]. All the patients had a grade 0-II slippage according to the classification by Meyerding [23]. Group B consisted of 56 patients with degenerative disc disease of the lumbar spine. Degenerative disc disease was defined as the presence of decreased signal intensity of the intervertebral disc on T2-weighted magnetic resonance (MR) images, combined with a loss of height of the disc space according to Boden et al. [5] or as a slippage between L4 and L5 accompanied by a decrease in vertebral disc space according to Herkowitz [12] as seen in degenerative spondylolisthesis. Only levels with disc degeneration grade III–V were fused [25].

Twenty-one of the patients had been operated before because of disc herniation. None of these patients, however, had undergone fusion procedures.

All the patients were subjected to posterolateral fusion of the lumbar spine using pedicle screw technique. In patients with isthmic spondylolisthesis, fusion was carried out, with minor repositioning. In every case the indication for surgery was prolonged back pain not responding to conservative treatment, and/or back pain resulting in work incapacity. None of the patients underwent anterior fusion, and the same two surgeons operated all the patients. Cotrel-Dubousset and Roy-Camille implants were used in 91% of the cases.

A questionnaire containing items on medication, pain, vocational status and patient satisfaction was mailed to all the patients. All patients were also asked to fill out a pain drawing depicting their symptoms on a silhouette of the human body using a number of predefined symbols. Only patients with pain classified as organic on the basis of the pain drawings were included in the study [27, 33]. Fusion was evaluated on plain radiographs at a minimum of 12 months after surgery, and patients were classified as fused or not fused. Fusion was considered solid when bone could be identified between the involved transverse processes, or when oblique views showed fusion of the facet joints [18].

Statistics

Statistical analysis was performed using forward stepwise logistic regression analysis according to Hosmer and Lemeshow [15]. Outcome was assessed selecting three dependent variables in turn: patient satisfaction, return to work and reduced medication. In every case, the dependent variable was dichotomous, with a value of 0 or 1. As independent variables, the following were used: sex, age, smoking, follow-up period, fusion (fused vs not fused), re-operation, number of levels fused, previous spine surgery, type of implant, preoperative job status and diagnosis (isthmic spondylolisthesis vs degenerative disc disease).

Each variable was initially assessed in sex- and age-adjusted logistic regression models. Additional variables were subsequently entered into the model to obtain independent risk estimates for single variables controlled for the effect of possible confounders and other risk factors [1]. The risk estimates for the three outcome variables were expressed as odds ratios (ORs), and were derived from the model using the following equation:

$$\mathrm{OR} = \mathrm{e}^{\beta}$$

where β is the coefficient of the fitted model and e is the exponential function. The 95% confidence intervals were derived from the standard errors (SEs) of the final model using the following equation:

$$\mathrm{CI} = \mathrm{e}^{\beta \pm 1{,}96\ \mathrm{SE}(\beta)}$$

where β is the coefficient for the fitted model.

In each case, the ORs of the independent variables express the likelihood of a "positive" versus a "negative" outcome:

- Satisfied versus not satisfied
- Working versus not working, and
- Reduced medication versus no reduction of medicine

A P-value of <0.05 was considered significant. To give an impression of the statistical power of the study, the ORs and the 95% confidence intervals for all the independent variables in the logistic regression models are shown in Table 1. A 95% confidence interval including the value of 1 corresponds to a P-value of >0.05.

Results

The median follow-up was 4 (range 2–8) years. All patients had a follow-up of minimum 2 years, including patients who were re-operated. Of the total 127 patients, 112 (88%) returned the questionnaire, with no difference

Table 1 Odds ratios (OR) and 95% confidence intervals (CI) indicating the likelihood of the outcome for the "compared" versus the "reference" category. An OR >1 indicates *increased likelihood* of the outcome for the compared category; an OR <1 indicates *decreased likelihood* of the outcome for the compared category. Where the OR = 1, there is an *identical likelihood* of the outcome for the compared versus the reference category (*CD* Camille-Dubousset instrumentation, *RC* Roy-Camille instrumenatation)

Independent variables (reference vs compared category)	Dependent variables OR (95% CI)		
	Satisfied	Working	Reduced medication
Age[a]	–	–	1.13 (1.02–1.24)*
Sex (woman vs man)	0.26 (0.04–1.64)	87.32 (2.56–2972.54)	
Diagnosis (isthmic spondylolisthesis vs degenerative disc disease)	–	6.67 (0.59–75.94)	
Fused (not fused vs fused)	–	–	11.47 (0.67–196.7)
Implant (CD vs RC)	–	–	–
Re-operated (no vs yes)	0.32 (0.04–2.73)	–	–
Follow-up	–	–	–
In work prior to surgery (yes vs no)	–	0.03 (0.002–0.30)	0.29 (0.07–1.14)
Smoking (no vs yes)	–	0.04 (0.003–0.60)	–

Table 2 Patient characteristics increasing the likelihood of an "optimal" outcome (i.e. satisfied, in work and reduced medication)

Variables (reference vs compared category)	Optimal outcome OR (95% CI)
Sex (woman vs man)	7.2 (1.03–51)*
In work prior to surgery (no vs yes)	8.5 (1.5–49)**
Smoking (no vs yes)	0.18 (0.04–0.9)***

*P=0.015; **P=0.012; ***P=0.023

in response rate between the two groups. Non-responders did not deviate from the baseline characteristics of the responders. There was an overall satisfaction rate of 70%, with no difference between the two groups.

The results of the logistic regression analysis are shown in Table 1, for the three outcome variables: satisfied, working and reduced medication. In Table 2 the result of the logistic regression analysis for the "optimal outcome" is shown. The optimal result was defined as the combination satisfied *and* working *and* reduced medication.

Reoperations

Twenty-three of the 127 patients were reoperated, giving a reoperation rate of 18%. Three reoperations were done because of local problems with the implant. In the remaining cases, pseudarthrosis was suspected, but it was only verified in five cases by the reoperation. In these five cases, autologous bone transplant was applied at the location of the pseudarthrosis after decortication. At follow-up 12 months after their second operation, all five patients were classified as fused. There were no deep infections and no cases of deep venous thrombosis.

Discussion

From a preoperative diagnostic point of view, comparison between the two groups is of interest because isthmic spondylolisthesis is a well-defined diagnostic entity affecting about 5% of the Caucasian population [23, 35]. In contrast, radiographic evidence of degenerative processes can be demonstrated in the majority of people older than 40 years, including in persons without back pain [3, 20]. Also, about 30% of asymptomatic individuals may have abnormal findings on myelograms [13], discography [14] and computer-assisted tomography [34]. Therefore, a number of patients undergoing lumbosacral fusion due to degenerative diseases of the spine are operated primarily because of pain. It could be argued that pain alone is a sufficient indication for surgery. It should be remembered, however, that pain is a combination of personal, social and economic factors [9, 11]. Therefore, it is unlikely that a surgical solution can resolve such a complex problem. In theory, this should make the outcome better in patients with spondylolisthesis, since the surgical indication in these patients is based on the clinical presentation combined with a specific radiographic finding.

The overall satisfaction rate of 70% in the present study is comparable to most other studies on spinal fusion obtained with implants based on pedicle screw techniques [7, 22, 26, 29, 30]. Being an expensive treatment with potentially serious risks, which leaves one-third of the patients with an unsatisfactory result, the indications for surgery require a thorough examination. An analysis of the three outcome parameters – patient satisfaction, return to work and reduced medication – did not reveal any significant difference between the two groups. As can be seen from Table 1, patients operated on for degeneration of the lumbar spine have an increased likelihood of being in work compared to patients operated on for isthmic spondylolisthesis. The OR, however, is not significant, with a 95% confidence interval from 0.6 to 76.

Although most studies on the outcome after spinal fusion have included patients with both degenerative disease of the lumbar spine and those with isthmic spondylolisthesis, surprisingly few have focused on any possible difference in outcome between these two groups of patients. Pihlajamäki et al. [26] reported a series of 63 consecutive patients undergoing lumbosacral fusion with pedicle screw technique. They concluded that the best clinical results were obtained in patients operated for isthmic spondylolisthesis compared to patients operated for degeneration. This finding was in accordance with the results found by Axelsson et al. [2]. We find, however, that there are some statistical problems with these studies, since the authors used multiple chi-square tests in their analyses, with the risk of mass significance. We therefore entered the raw data of the study by Pihlajamäki et al. [26] into a logistic regression analysis. Choosing the same outcome parameters as the ones used in our study, no difference between the two diagnostic groups was found.

The issue of whether return to work should be used as an outcome parameter after spinal surgery has been debated. Keller et al. [19] pointed out that work status depends on several factors such as motivation and the socioeconomic conditions in the society, which affect the availability of work. Gallagher et al. [10] also addressed this aspect of chronic low back pain. Therefore it has been suggested that return to work should not be the primary parameter in studies evaluating the outcome after spinal fusion procedures. We included return to work in the present study for comparative reasons. Table 1 illustrates that the selection of the outcome variable has a major influence on the independent variables identified as predictors of a successful outcome. For none of the outcome variables did all three independent variables fit into the logistic model. This is why the term "optimal outcome" was defined. The result of the analysis is shown in Table 2, and shows that being in work prior to surgery has the greatest impact on the "optimal outcome".

Several studies have demonstrated the inability of radiographs to accurately predict spinal fusion. This includes flexion/extension films, computed tomography, and tomograms [4, 6, 18]. Furthermore the clinical relevance of radiographically demonstrated pseudarthrosis remains unclear. In the present study, the fusion rate was comparable to other studies [22, 30]. The statistical analysis, however, did not reveal any relation between fusion rate and the three outcome parameters studied. This is in accordance with the findings of Pihlajamäki et al. [26], who found no correlation between radiographically confirmed fusion and either clinical outcome or return to work.

Radiographically it could be argued that a minimum follow-up of 1 year is too short. However, Johnsson et al. [17], using roentgen stereophotogrammetric analysis (RSA), showed that the fusion mass became rigid within 1 year after surgery. The definition of "rigid" was an intervertebral translation of less than 1 mm. From this study it can be concluded that, if used, plain radiographic assessment at more than 12 months after surgery offers no advantages compared to a 12-months control, since it is unlikely that intervertebral translation can be determined more accurately with plain radiographs compared to RSA.

In general, controlled randomized studies on spinal fusion are limited [22, 36]. One important contribution of retrospective studies could be to identify possible variables to include in future randomized studies. It is, however, a fact that grouping of various diagnoses, different surgical techniques, and a number of surgeons hampers the retrospective studies. Additionally, most of these studies use statistical analysis in ways that increase the risk of mass significance. This risk is reduced by the use of multiple logistic regression, comparing all the selected parameters in one statistical process. This technique increases the possibility of identifying confounding factors affecting the outcome. We are, however, aware that a study of the present nature, with relatively few patients in each group, holds limited statistical power. Consequently, there is a risk of falsely accepting the null hypothesis that there is no difference in clinical outcome between the two diagnostic groups. The power of a study can also be defined as the probability of rejecting the null hypothesis, concluding that there is a statistically significant difference between the assessed groups, if one truly exists. Since the confidence interval of risk estimates reflects the power of the analysis, separate power calculations have not been performed in the present study. We are, however, fully, aware that the sample size could explain the fact that no difference in clinical outcome was found between the two groups. Until controlled trials are performed, we find that retrospective studies are justified, provided that the correct statistical method is used with cautious interpretation of the results. Also, the results from properly conducted retrospective studies could serve as guidelines for future controlled trials.

With these considerations in mind, we conclude that the present study did not demonstrate any difference in the outcome after spinal fusion between patients with isthmic spondylolisthesis and those with degenerative disc disease of the lumbar spine. The factors that significantly increased the likelihood of an optimal result – defined as patient satisfaction, return to work, and reduced medication – were male gender, being in work prior to surgery, and being a non-smoker. Since spinal fusion is an expensive treatment with potentially serious complications, leaving one-third of the patients with an unsatisfactory result, we think that more studies focusing on the indications for this kind of surgery should be performed.

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