Surgical versus non-surgical treatment of chronic low back pain: a meta-analysis of randomised trials

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Abstract We performed a meta-analysis of randomised controlled trials to investigate the effectiveness of surgical fusion for the treatment of chronic low back pain compared to non-surgical intervention. Several electronic databases (MEDLINE, EMBASE, CINAHL and Science Citation Index) were searched from 1966 to 2005. The meta-analysis comparison was based on the mean difference in Oswestry Disability Index (ODI) change from baseline to the specified follow-up of patients undergoing surgical versus non-surgical treatment. Of the 58 articles identified, three studies were eligible for primary analysis and one study for sensitivity analysis, with a total of 634 patients. The pooled mean difference in ODI between the surgical and non-surgical groups was in favour of surgery (mean difference of ODI: 4.13, 95%CI: -0.82 to 9.08, $p=0.10$, $I^2=44.4\%$). Surgical treatment was associated with a 16% pooled rate of early complication (95%CI: 12–20, $I^2=0\%$). Surgical fusion for chronic low back pain favoured a marginal improvement in the ODI compared to non-surgical intervention. This difference in ODI was not

statistically significant and is of minimal clinical importance. Surgery was found to be associated with a significant risk of complications. Therefore, the cumulative evidence at the present time does not support routine surgical fusion for the treatment of chronic low back pain.

Résumé Méta-analyse randomisée pour étudier la réalité de la fusion chirurgicale pour lombalgies chroniques comparée à l'évolution sans chirurgie. Plusieurs fichiers électroniques (Medline, Embase, Cinahl et Science citation index) ont été étudié de 1996 à 2005. La comparaison était basée sur les modifications de l'index d'Owestry (ODI) après traitement chirurgical ou non chirurgical. Trois études sur 58 articles étaient utilisables pour une première analyse et une étude pour une analyse fine, avec un total de 634 patients. Les différences de l'index mesuré étaient en faveur de la chirurgie (différence moyenne de l'index ODI: 4,13; IC de 95%: -0,82 à 9,08; $p=0,10$; $I^2=44,4\%$). Le traitement chirurgical s'accompagnait de 16% de complications précoces (IC de 95%: 12–20%, $I^2=0\%$). La fusion chirurgicale pour lombalgies chroniques améliore de façon non significative l'index de Oswestry par rapport au traitement non chirurgical et elle a un risque plus grand de complications.

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Introduction

Low back pain is a common symptom affecting 70–85% of the population at some stage in their life [1]. When it persists for longer than three months, it is classified as chronic. Chronic low back pain is prevalent in 23% of the population [2] and is the most common cause of activity limitation in people younger than 45 years of age [1]. In addition to the physical symptoms endured by these patients, chronic low back pain poses a major economic problem due to their frequent use of health services and absence from work.

The management of chronic low back pain remains controversial with a variety of treatment options available [14, 26]. The traditional approach is non-surgical treatment combining physiotherapy and analgesia. Failure of the non-surgical treatment leads to alternative options, such as a variety of surgical approaches to achieve spinal fusion [15, 18] with various results [5, 22, 29].

The indications for spinal fusion and how it should be performed for the relief of chronic low back pain remain unclear. The aim of surgical fusion is to reduce pain and decrease disability, and the underlying rationale is that the pain arises from a degenerative motion segment and, consequently, fusion should eliminate motion and subsequent pain [5, 13, 26].

During recent decades, surgical fusion of the lumbar spine for chronic low back pain has been increasingly performed on patients [4]. In 2001, over 122,000 lumbar fusions were performed in the United States for degenerative conditions of the lumbar spine. This represents a 220% increase in fusions per 100,000 since 1990 [7]. These increases were not associated with clarified indications or improved efficacy, suggesting a need for better data on the efficacy of various fusion techniques for various indications. The lack of consensus on whether surgical or non-surgical treatment should be offered to patients has prompted several randomised controlled trials (RCTs) [3, 8, 9, 12, 19, 24].

In order to investigate the effectiveness of fusion as a treatment for chronic low back pain, we carried out a systematic review of the literature and a meta-analysis of RCTs and compared our findings to those of non-surgical intervention following the Quality of Reporting of Meta-analyses (QUOROM) [23] guidelines.

Methods

Identification of relevant literature

A literature search to identify all published randomised controlled trials comparing surgical fusion and non-surgical intervention for the treatment of chronic low back pain was performed with the help of an experienced medical librarian. The databases that were searched included MEDLINE (1966–October 2005), EMBASE (1980–October 2005), CINAHL (1982–October 2005), Science Citation Index (1970–October 2005) and the Cochrane registry of clinical trials.

The following key words were used for the search: low back pain, physical therapy, physiotherapy, rehabilitation, cognitive therapy, surgery, spinal fusion, spinal stabilisation, randomised controlled trial, random allocation, randomisation and clinical trial.

Two authors independently reviewed abstracts of all the references identified. Any study that could be relevant based on findings that were described in the respective abstract was reviewed in full text. Bibliographies and review articles were reviewed manually for additional citations. There was no restriction to the language of the publication. We did not seek unpublished investigations.

Inclusion criteria

Only RCTs comparing surgical and non-surgical treatments for chronic low back pain were considered for inclusion. The types of treatment included surgical (spinal fusion with or without instrumentation) and non-surgical (physical therapy with or without cognitive therapy) interventions. The trials must have reported an Oswestry Disability Index (ODI) as an outcome measure. The ODI has ten questions on pain and pain-related disability in activities of daily life and social participation and is patient-administered. The sum is calculated as a percentage, with 0% representing no pain and disability and 100% representing the highest level (worst) of possible pain and disability. The ODI is a valid condition-specific outcome measure of spine-related disability [10]. We excluded RCTs with unique primary outcomes where the pooling of results was not possible [19].

Data collection

A data collection form was developed and used to retrieve information on relevant features and results. Two authors independently extracted data. The data retrieved included the following items: study characteristics, intervention, outcome definition, sample size, mean difference in ODI change from baseline to follow-up of patients undergoing surgery versus those undergoing non-surgical treatment with a respective standard error or 95% confidence interval (CI) and the number of patients with early complications (within two weeks) from surgery. The two authors independently assessed the methodological quality of the selected studies, and any disagreement that arose was discussed and resolved by consensus.

Statistical analysis

The meta-analytic comparison was based on the mean difference in ODI change from baseline to follow-up of patients undergoing surgery versus those undergoing non-surgical treatment. The mean difference in ODI with the 95%CI were extracted from studies in all of the papers [3, 9, 12]. One study included in the sensitivity analysis did not report the mean change from baseline to follow-up [8]. Pooled estimates of the mean difference in ODI were obtained by combining the separate estimates of inverse

variance-weighted log mean difference estimates from each study. We performed sensitivity analyses by repeating the meta-analysis using the imputed mean difference in ODI change in the study by Fairbank et al. [9] that had >15% loss to follow-up. Additional sensitivity analyses were repeated by including the study by Ekman et al. [8] since it involved a different patient population (patients with adult isthmic spondylolisthesis). For this study [8], we used the mean difference in ODI at follow-up between the surgical and non-surgical groups. In a randomised trial, mean differences based on changes from baseline can usually be assumed to be addressing exactly the same underlying treatment effects as analyses based on final measurements [21].

We also pooled the early complication rates among patients undergoing spinal fusion surgery. Complications rates and their 95%CI were obtained by dividing the number of patients developing complications by the total number of patients undergoing surgery. Pooled estimates of the complication rates were then obtained by combining the separate estimates of inverse variance-weighted log complication rates from each study. All meta-analyses were performed using a random-effect model [6].

Between-study inconsistency was quantified by means of $I^2 = [(Q-df)/Q] \times 100\%$, where Q is the chi-squared statistic and df is its degrees of freedom [16]. I^2 defines the variability percentage in effect estimates that is due to heterogeneity rather than to sampling error (chance). A value >50% represents substantial heterogeneity. All analyses were performed with REVMAN ANALYSES ver. 4.2.7 (2004, the Cochrane Collaboration).

Results

Studies meeting inclusion criteria for analysis

Figure 1 summarises the process of identifying eligible studies. The search resulted in identifying six studies, three of which were found to be eligible for primary analysis. The fourth [8] was included in the sensitivity analysis and the fifth [24] study was a duplicate study reporting on the same set of patients with isthmic spondylolisthesis. The sixth study did not report an ODI as an outcome measure [19]. The kappa statistics for interobserver agreement on study eligibility was 1.0.

Study characteristics

Table 1 summarises the characteristics of the four studies included in our primary and sensitivity analyses. Taken together, the studies included a total of 634 patients, with individual sample sizes ranging from 61 to 289 patients.

Fig. 1 Flow diagram of eligible studies. ODI Oswestry Disability Index

One of the studies recruited patients with a history of low back pain that had persisted for more than 12 months [3], and two of the studies had recruited patients with low back pain persisting at least two years [9, 12]. Ekman et al. [8] recruited patients with isthmic spondylolisthesis. All of the patients were adults. Surgical treatment involved surgical fusion with or without instrumentation or flexible stabilisation, and non-surgical treatment involved exercise programs with or without cognitive therapy. The primary outcome in all studies was assessed using the difference in ODI from baseline to follow-up. In the study by Ekman et al. [8], only the ODI at follow-up was reported.

Quality assessment

We assessed the quality of the studies in two ways. Firstly, randomised controlled trials were judged according to the key validity components that address biases in selection, performance, detection and sample attrition [17]. Table 2 summarises the different domains of study quality. The kappa statistics for interobserver agreement on these quality domains was 1.0.

Secondly, we assessed quality by using ten criteria taken from the Cochrane Back Review Group [30]. All studies

Table 1 Characteristics of the randomised controlled trials included in this study

Source, year, country	Age of patients: range in years	Number of patients at follow-up	Type of surgery	Type of non-surgical treatment	Follow-up period	Outcomes other than ODI
Fairbank et al. [9], 2005, UK (Multi-centre)	18–55	284	Spinal fusion with some cases of flexible stabilisation	Intensive rehabilitation and Cognitive therapy	2 years	Shuttle Walking Test; Short Form 36 (SF-36). No significant difference in shuttle walking test and SF-36
Fritzell et al. [12], 2001, Sweden (Multi-centre)	25–65	289	Posterolateral fusion (PLF) or PLF with pedicle screws or circumferential fusion	Physical therapy	2 years	Visual Analogue Scale (VAS); Million Visual Analogue Scale (MVAS); General Function Score (GFS); Zung Depression Scale (ZDS); Overall Assessment; Work Status. No significant difference in ZDS. Significant difference in VAS, MVAS, GFS, overall assessment and work status in favour of surgical group
Brox et al. [3], 2003, Norway	25–60	61	PLF with pedicle screws	Physical and Cognitive therapy	1 year	General Function Score (GFS); Back Pain; Lower Limb Pain; Emotional Distress; Life Satisfaction; Fear-avoidance physical activity; Fear-avoidance work; Fingertip-floor distance; Patient Overall Rating; Work Status. No significant difference in GFS, back pain, lower limb pain, emotional distress, life satisfaction, patient overall rating and work status. Significant difference in fear avoidance, physical and work and fingertip-floor distance in favour of non-surgical group
Ekman et al. [8], 2005, Sweden	18–55	106	PLF with or without pedicle screws	Physical therapy	2 years	Pain Index; Disability Rating Index (DRI). Significant difference in pain index and DRI in favour of surgical group

scored greater than four points, with a score of four points or less indicating poor quality. Table 3 summarises the different criteria of study quality. All studies were prone to performance bias and detection bias since the intervention cannot be concealed and the outcome was a patient-administered questionnaire (ODI).

Quantitative results of the meta-analysis

Figure 2 displays the cumulative meta-analytic comparison. The mean overall difference in the ODI between the surgical and non-surgical groups was 4.13 in favour of surgery, but this difference was not statistically significant (95%CI: -0.82 to 9.08, $p=0.10$). There was evidence of

Table 2 Quality assessment^a of randomised controlled trials

Source					
Type of bias	Item	Fairbank et al. [9]	Fritzell et al. [12]	Brox et al. [3]	Ekman et al. [8]
Selection	Was allocation adequate? ^b	Yes	Yes	Yes	Yes
	Was an adequate method of randomisation described?	Yes	Yes	Yes	Yes
Performance	Were the patients/caregivers blinded to the intervention? ^c	No	No	No	No
Detection	Was the outcome ascertained blindly? ^d	No	No	No	No
Attrition	What percentage was lost to follow-up?	19	2	3	5
	Were all patients analysed in the group to which they were assigned (intention-to-treat analysis)?	Yes	Yes	Yes	Yes

^a Adapted from Juni et al. [17]

^b Adequate” means the use of a central site, numeric code, opaque envelopes, drugs prepared by pharmacy and other appropriate procedures.

^c Unable to blind patient or caregiver due to nature of treatment

^d Outcome was a patient-administered questionnaire (ODI)

Table 3 Quality assessment^a of randomised controlled trials

Source				
Criteria	Fairbank et al. [9]	Fritzell et al. [12]	Brox et al. [3]	Ekman et al. [8]
Was there a randomisation method using an adequate procedure?	Yes	Yes	Yes	Yes
Was the treatment allocation concealed?	Yes	Yes	Yes	Yes
Was the care provider blinded to the intervention? ^b	No	No	No	No
Was there control for co-interventions?	No	No	No	No
Were co-interventions reported for each group separately?	Yes	No	No	No
Was the patient blinded to the intervention? ^b	No	No	No	No
Was the outcome assessor blinded to the intervention? ^c	No	No	No	No
Was the withdrawal and drop-out < 20% short-term?	Yes	Yes	Yes	Yes
Was the timing of the outcome assessment in both groups similar?	Yes	Yes	Yes	Yes
Was the analysis done according to intention-to-treat?	Yes	Yes	Yes	Yes
Score ^d	6	5	5	5

^a Adapted from van Tulder et al. [30]

^b Unable to blind patient or caregiver due to nature of treatment

^c Outcome was a patient-administered questionnaire (ODI)

^d A score of 4 points or less indicates poor quality.

moderate heterogeneity between the studies, and the I^2 was 44.4%.

Figure 3 displays the cumulative early complication rate. Surgical treatment was associated with a 16% pooled rate of early complication (95% CI: 12–20). No between-study heterogeneity was present, $I^2=0\%$. The study by Ekman et al. [8] had a lower complication rate of 4%. The pooled rate of early complications following surgical treatment, including the Ekman et al. [8] study, was 13% (95%CI: 6–20, $I^2=66.9\%$).

Results of sensitivity analyses

Sensitivity analyses were performed to examine the effect of the imputed results from Fairbank et al. [9] and the inclusion of the study by Ekman et al. [8] in the analysis. Analysis using imputed results from Fairbank et al. [9] showed a mean overall difference in the ODI of 4.34 in favour of surgery, but this difference was not statistically significant (95% CI: -0.48 to 9.17, $p=0.08$, $I^2=44.0\%$).

Further analyses were carried out that included the study by Ekman et al. [8]. This latter study recruited patients with chronic low back pain caused by isthmic spondylolisthesis and was the only study to do so. Analyses including this

study, using available or imputed results by Fairbank et al. [9], showed a mean overall difference in the ODI of 3.9 (95% CI: 0.17–7.62, $p=0.04$, $I^2=21.4\%$) and 4.11 (95% CI: 0.46–7.76, $p=0.03$, $I^2=22.1\%$) in favour of surgery, respectively.

Discussion

Our systematic review identified three randomised controlled trials that compared surgical fusion and non-surgical treatment for chronic low back pain and looked at the short-term outcome. An additional study recruited a different patient group with isthmic spondylolisthesis and was included in the sensitivity analysis. All studies were of good methodological quality. The pooled results showed a trend in favour of surgery with a mean ODI difference of 4.13 ($p=0.10$; 95%CI: -0.82 to 9.08). The results were consistent across different assumptions. Analysis using imputed results from Fairbank et al. [9] caused minimal changes in the ODI mean difference between the groups (ODI difference=4.34, $p=0.08$, 95%CI: -0.48 to 9.17). Sensitivity analyses that included the study of Ekman et al. [8] showed only minimal changes in the ODI mean

Fig. 2 Forest plot: mean difference in ODI and 95% CI for surgical versus non-surgical treatment

Fig. 3 Forest plot: early surgical complication rate and 95% CI

difference (3.9) between the groups, which was statistically significant ($p=0.04$, 95%CI: 0.17–7.62).

All studies used a condition-specific validated patient-administered outcome measure – the ODI [10]. There is currently no consensus on what should be considered to be the clinically significant difference in the ODI from baseline to end point. Mead et al. [20] showed that a minimum ODI difference of four indicates clinical improvement, whereas Taylor et al. [28] suggested that a mean difference of 18 indicates clinical improvement. The upper level of the 95%CI of the ODI difference in the pooled analysis was only 9.08. Surgical treatment was associated with a 16% pooled rate of early complication (95%CI: 12–20). From a clinical perspective, the overall complication rate of surgery outweighs this minimal clinical benefit.

The cost effectiveness of surgical versus non-surgical treatment of chronic low back pain has been reported for two of the studies in our meta-analysis. Fritzell et al. [11] found that the societal and health care costs for the surgical fusion patients was significantly higher than those for the non-surgical group. However, all treatment effects were better after surgical fusion. Rivero-Arias et al. [27] showed that surgical treatment cost twice as much as non-surgical intervention in the Fairbank et al. [9] study and that there was no statistical significance in the quality-adjusted life years between the groups.

The inclusion criteria and treatment modalities of each study were different, and these are potential sources of heterogeneity. In the Ekman et al. [8] study, the study population consisted of patients with isthmic spondylolisthesis. Möller et al. [25] reported similar clinical patterns and functional disabilities in patients with adult spondylolisthesis and low back pain of non-specific origin, while Fairbank et al. [9] used uncertainty of outcome as the eligibility criteria. The other two studies used pain for different time intervals: Fritzell et al. [12] recruited patients with back pain for at least 24 months, whereas Brox et al. [3] recruited patients with back pain for at least 12 months. The non-surgical intervention groups consisted of different treatment modalities. Fairbank et al. [9] and Brox et al. [3] used both physical therapy together with the principles of cognitive therapy, whereas Fritzell et al. [12] and Ekman et al. [8] used physical therapy alone. The compliance of

physical therapy is also difficult to calculate and is likely to be different between the patient groups according to the intensity of the particular regime. Surgical treatment modalities also differed between the included trials. The fusion techniques used in the Fairbank et al. [9] study was left to the discretion of the surgeon. Several techniques must have been used, and this could be a potential source of heterogeneity.

Our analysis has limitations due to the paucity of studies addressing this pivotal issue. First, there were only three eligible published studies. Although there was moderate between-study heterogeneity, we chose to perform the meta-analysis to provide more generalisable results on the effect estimate. Second, the only outcome measure examined in this meta-analysis was the ODI. This is a reliable and clinically relevant outcome. Other important outcomes, such as patient satisfaction and return to work, were not included in all the original studies and thus were not considered for our meta-analysis. This may have limited our conclusions because it may not be possible to know whether patients achieved greater general health or higher satisfaction with or without surgery. The possibility that the observed improvement in the ODI between the surgical fusion and non-surgical groups was due to bias should be considered. It could be argued that this difference, although difficult to prove, could be due to the placebo effects of surgery following a procedure to treat a chronic symptom. Publication bias is also possible in our review. The small number of studies limits our ability to assess for (for instance, using a funnel plot) or draw conclusions regarding publication bias. Nevertheless, the expected direction of both placebo effect and publication bias towards the null effect strengthen our conclusion that currently available evidence does not support the routine use of surgery for the treatment of chronic low back pain.

Conclusion

We found that surgical fusion may improve the ODI compared to non-surgical intervention at the two-years follow-up for chronic low back pain. This improvement in the ODI was not statistically significant and is of minimal

clinical importance; consequently, surgeons should recommend spinal fusion cautiously to patients with chronic low back pain. Further long-term follow-ups of the studies reviewed in this meta-analysis are required to provide more conclusive evidence in favour of either treatment.

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