



The long-term outcome of lumbar fusion in the Swedish lumbar spine study.

<https://arctichealth.org/en/permalink/ahliterature282366>

Author: Rune Hedlund
Christer Johansson
Olle Hägg
Peter Fritzell
Tycho Tullberg

Source: Spine J. 2016 05;16(5):579-87

Date: 05-2016

Language: English

Publication Type: Article

Keywords: Adult
Female
Humans
Low Back Pain - surgery
Lumbar Vertebrae - surgery
Male
Middle Aged
Physical Therapy Modalities - adverse effects
Postoperative Complications
Prospective Studies
Randomized Controlled Trials as Topic
Spinal Fusion - adverse effects
Surveys and Questionnaires
Sweden
Treatment Outcome

Abstract: Current literature suggests that in the long-term, fusion of the lumbar spine in chronic low back pain (CLBP) does not result in an outcome clearly better than structured conservative treatment modes.

This study aimed to assess the long-term outcome of lumbar fusion in CLBP, and also to assess methodological problems in long-term randomized controlled trials (RCTs).

A prospective randomized study was carried out.

A total of 294 patients (144 women and 150 men) with CLBP of at least 2 years' duration were randomized to lumbar fusion or non-specific physiotherapy. The mean follow-up time was 12.8 years (range 9-22). The follow up rate was 85%; exclusion of deceased patients resulted in a follow-up rate of 92%.

Global Assessment (GA) of back pain, Oswestry Disability Index (ODI), visual analogue scale (VAS) for back and leg pain, Zung depression scale were determined. Work status, pain medication, and pain frequency were also documented.

Standardized outcome questionnaires were obtained before treatment and at long-term follow-up. To optimize control for group changers, four models of data analysis were used according to (1) intention to treat (ITT), (2) "as treated" (AT), (3) per protocol (PP), and (4) if the conservative group automatically classify group changers as unchanged or worse in GA (GCAC). The initial study was sponsored by Acromed (US\$50,000-US\$100,000).

Except for the ITT model, the GA, the primary outcome measure, was significantly better for fusion. The proportion of patients much better or better in the fusion group was 66%, 65%, and 65% in the AT, PP, and GCAC models, respectively. In the conservative group, the same proportions were 31%, 37%, and 22%, respectively. However, the ODI, VAS back pain, work status, pain medication, and pain frequency were similar between the two groups.

One can conclude that from the patient's perspective, reflected by the GA, lumbar fusion surgery is a valid treatment option in CLBP. On the other hand, secondary outcome measures such as ODI and work status, best analyzed by the PP model, indicated that substantial disability remained at long-term after fusion as well as after conservative treatment. The lack of objective outcome measures in CLBP and the cross-over problem transforms an RCT to an observational study, that is, Level 2 evidence. The discrepancy between the primary and secondary outcome measures prevents a strong conclusion on whether to recommend fusion in non-specific low back pain.

Notes: Comment In: Spine J. 2016 May;16(5):588-9027261844

PubMed ID: 26363250 [View in PubMed](#) 