



The Journal of Bone & Joint Surgery

Journal Club: 1 December 2011

Attendees: Mr A. Khan, Mr A. Frost, Mr T. Goff, Mr J. Messner, Mr B. Haughton, Mr S. Jain, Miss K. Shepherd, Mr S. Harrison, Mr W. Chellam.

Leeds General Infirmary, Great George Street, Leeds, United Kingdom

Theme: Spine - Degenerative spondylolisthesis

Presented Papers:

1. **HN Herkowitz, LT Kurz.** Degenerative Lumbar Spondylolisthesis with Spinal Stenosis – A Prospective study comparing decompression with decompression and intertransverse process arthrodesis. *J Bone Joint Surg [Am]* 1991;73-A:802-8.
2. **Timo J et al.** Postoperative Rehabilitation does not improve functional outcome in lumbar spinal stenosis: a prospective study with 2-year postoperative follow-up. *Eur Spine J* 2011;20:1331-40.
3. **Yan D-L, Pei F-X, Li J, Soo C-L.** Comparative study of PILF and TLIF treatment in adult degenerative spondylolisthesis. *Eur Spine J* 2008;17:1311-16.
4. **Seong, YJ et al.** Posterior decompression and fusion in patients with multilevel lumbar foraminal stenosis: A comparison of segmental decompression and wide decompression. *Asian Spine Journal* 2011;5:100-6.
5. **Weinstein JN et al.** Surgical versus Nonsurgical Treatment for Lumbar Degenerative Spondylolisthesis. *N Engl J Med* 2007;356:22.

Paper 1

Reviewers: Mr T Goff & Mr B Haughton

Summary

1. Purpose

To determine the indications for concomitant arthrodesis with decompressive laminectomy in the operative management of patients who have degenerative lumbar spondylolisthesis and spinal stenosis.

2. Methods

50 consecutive patients with single level spinal stenosis were enrolled in this prospective study. Patients were alternately assigned to one of two treatment groups: decompressive laminectomy or decompressive laminectomy with bilateral lateral intertransverse-process arthrodesis. Inclusion criteria were patients unresponsive to an adequate trial of non-operative treatment with a single level of degenerative lumbar spondylolisthesis (and spinal stenosis at that level only).

Preoperative and follow-up xrays were analysed with respect to the amount ofolisthesis (translation - mm), angular motion (degrees) between the adjacent vertebrae, the development of a pseudarthrosis (lack of continuity in the fusion mass at any point), and the height of the disc space at the level of the arthrodesis (by the farfan method). Back pain and lower limb pain was subjectively rated before and after surgery on a scale of 0 (no pain) to 5 (severe pain).

Operative results were graded Excellent/Good/Fair/Poor based on resumption of daily activities and relief from pain symptoms (including to what extent analgesia was required).

3. Results

25 patients in each treatment group, average age for each group was 63.5 years (range 52-84) with arthrodesis, and 65 years (range 53-83) without arthrodesis. The mean duration of follow-up for both groups was 3 years (range 2.4 to 4 years).

- *Overall* = 11 excellent, 13 good, 1 fair, and no poor results in the arthrodesis group, compared with 2 excellent, 9 good, 12 fair, and 2 poor results in the no arthrodesis group. (Fisher exact test $P=0.0001$)
- *Pain* = Significantly more residual back pain was reported by the patients who had not had an arthrodesis (mean pain score, 1.3 points vs. 2.5 points for those who had not). Similarly, the scores for lower limb pain revealed significantly more residual pain in the patients who had not had an arthrodesis (mean pain score, 1.0 point vs. 1.7 points for those who had not).
- *Olisthesis* = Significant increase in olisthesis in patients who had not had arthrodesis (96% vs 25%).
- *Vertebral angulation* = Significant increase in angular motion in patients who had arthrodesis.
- *Pseudarthrosis* = 36% of arthrodesis patients, however all had either excellent or good outcomes.

4. Conclusions

This prospective study demonstrates that decompressive lumbar laminectomy with intertransverse process arthrodesis is the operative procedure of choice for patients who have spinal stenosis associated with degenerative lumbar spondylolisthesis at a single level. The age and sex of the patient and the height of the disc space did not influence the outcome of the operation. The development of a pseudarthrosis did not preclude a successful result.

Critique

Strengths

- Sample demographics reflect the population affected by this condition
- Majority of outcome measures clearly defined
- Patients blinded to treatment

Methodological Concerns

- This study was conducted without oversight/approval of the local research ethics board.
- Inclusion / exclusion criteria could be more clearly defined
- Adequate non-operative treatment was poorly defined
- Did any patients have pre or post operative neurology
- No power calculations to rationalise the sample size
- No randomisation process, instead consecutive assignment
- No validated measures for outcomes relating to pain and function

- No mention of postoperative complications
- No insight into the strengths and weaknesses of this study is included

Paper 2

Reviewer: Mr W Chellam

Timo J et al. Postoperative Rehabilitation does not improve functional outcome in lumbar spinal stenosis: a prospective study with 2-year postoperative follow-up. European Spine journal (2011) 20:1331-1340

Summary

1. Purpose

To determine if supervised post-operative physiotherapy influenced outcome following surgery for lumbar spine stenosis.

2. Methods

- 102 patients selected for lumbar decompression on the basis of radiculopathic symptoms and an MRI scan confirming degenerate stenosis (cauda equina, flavum, facets, foramina or disc).
- Randomization into “normal treatment” and supervised physiotherapy pools
- Oswestry disability index, pain, satisfaction, objective walking distance, depression scale at 3,6,12,24 months

3. Results

- Apparent but not statistically significant benefit to post-operative physiotherapy

Critique

Post-operative physiotherapy can be resource intensive and inconvenient for patients, determining whether it influences outcome following common spinal procedures is a valid goal with obvious service provision and cost implications.

Strengths

- Representative inclusion criteria – only patients physically incapable of undergoing the diagnostic criteria or performing the rehabilitation were excluded
- ODI is a well validated outcome measure for spinal surgery
- Good period of follow-up and meaningful intervals of follow-up chosen

Methodological Concerns

- A number of conclusions referencing data not presented in the paper i.e. comparisons to baseline ODI which is not presented for the two groups
- A larger sample size may have differentiated a statistically significant difference between the groups.
- The ‘control’ group was not strictly controlled – patients could seek physiotherapy if they chose
- Power and odds-ratio results are not shown for anything other than the primary outcome measure

Because of the lack of protocol governing the 'control' group and limited sample-size it is hard to draw statistically significant conclusions from the data presented. A larger sample size would allow sub-strata analysis of the control group to ascertain any difference between 'no-physiotherapy' and 'routine-treatment'. There seems little point in collecting and presenting the secondary outcome measure data when no statistical analysis or interpretation is applied to it.

Paper 3

Reviewer: Mr S Harrison

Summary

1. Purpose

To compare the therapeutic effects of posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF) with pedicle screw fixation for the treatment of adult degenerative spondylolisthesis

To identify procedure specific complications and pre-operative factors that predict them

2. Methods

Retrospective study

Patient identification:

1. L5/S1 slip or L4/L5 slip
2. Single level slip (grade I/II)
3. 176 participants allocated to two groups (PLIF vs TLIF) (11 patients lost to follow-up)
4. Excluded if slip was pathological

Patients were reviewed pre-operatively and at two-year follow assessing:

1. Pain with visual analogue score
2. Functional disability with Japanese Orthopaedic Association Score (JOA)
3. Fusion with plain radiographs and CT

Statistical analyses performed by a single observer.

1. T-test
2. Chi-squared test

3. Results

Groups were well matched for age and gender

No deaths identified

85 patients underwent a PLIF and 91 had a TLIF

No significant reduction in pain on VAS between groups

Functional disability didn't identify notable differences between groups

Approximately 75% reduction in spondylolisthesis in both groups from pre-op to 2-year follow-up

No difference in disc height or foramen height at 2 years between groups

PLIF group – all fused, no cage extrusion, three cases of cage subsidence

TLIF group – one case of revision

Each group identified cases of radiculitis

4. Conclusions

No significantly significant difference in outcomes between two groups

Highlights that TLIF is a shorter operation

Performing a PLIF and therefore increasing operating time may put the patient at risk of further complications

Critique

This paper aims to suggest which method of surgical treatment is more suitable in the treatment of adult degenerative spondylolisthesis. It describes two surgical treatment options for Grade I/II spondylolistheses. It compares a TLIF, a novel method over a well established PLIF. It aims to identify the factors that could predict complications but does not really highlight this.

Strengths

- Inclusion and exclusion criteria identified
- Groups appear well matched
- States the aims of the study clearly
- The procedures compared are suitable for the population being studied
- Statistical tests identified
- Numbers all add up

Methodological Concerns

- The authors do not appear to assess patient co-morbidities
- If co-morbidities were taken into account, perhaps a multi-variate analysis should have been performed. This therefore questions the results
- How many surgeons performed the surgery?
- Did they change their practice at all?
- Within the three year collection period, did all surgeons use the same kit?
- No mention as to what bony substitute was used
- The follow-up is short. Already identified cases of subsidence and need for revision
- Did patients receive physiotherapy and if so for how long – did this help improve the outcome scoring
- The conclusions do not identify factors to predict complication as they have not identified any!

From this study it would seem that neither procedure has an improved outcome over the other. The benefits of shorter operating times would suggest that a TLIF is better (no mention as to average operating time for this group of surgeons). However, PLIF is well established and has a good success rate, if only given by this study. It would therefore be best for the surgeon to perhaps stick to his/her strengths in what procedure is chosen.

Paper 4

Reviewer: Mr J Messner

Summary**1. Purpose**

To compare the outcome of segmental vs. Wide decompression in patients with multilevel lumbar spinal stenosis and associated back pain. Decompression of multilevel foraminal stenosis is a high risk surgical procedure, wide decompression and fusion is associated with a high rate of complications, particularly in the elderly patient. The authors' hypothesis is that segmental decompression and fusion reduces operation time, blood loss and risk of infection.

2. Methods

Prospective study with 100 patients and minimum of 2 year follow up, inclusion criteria: back and leg pain with MRI confirmed moderate to severe central and foraminal lumbar spinal stenosis, one surgeon, randomisation: sealed envelope with surgical procedure type was opened before incision, procedure: group 1:segmental decompression: 1/3 laminectomy superior and inferior, total

foraminotomy and facetectomy vs. Group 2: wide decompression: total laminectomy, foraminotomy and facetectomy, posterolateral pedicle screw/rod fixation (instrumented) in all patients. Endpoints: back and leg pain (visual analogue scale), disability score, blood loss, operating time, complications, radiological fusion.

3. Results

Significant reduction in leg and back pain in both groups

Significant improvement in disability score for both groups

Significantly less blood loss and shorter operating time in group 1

Similar overall complication rate in both groups: 13/45 (29%) vs. 16/42 (38%)

Major complication rate (2/45 vs. 4/42) similar in both groups

Similar radiographic fusion rate in both groups

Both groups were similar regarding age, sex, co-morbidities.

4. Conclusions

Segmental decompression and fusion offers a promising surgical alternative reducing blood loss and operating time with similar clinical and radiological outcome. Authors's view on limitations of study: number of patients, short follow up.

Critique

Strengths

Prospective study

Methodological Concerns

No power analysis of study performed

Randomisation procedure not fully explained, single blinded or not blinded

Ethical approval not mentioned in paper

Complication rate/ outcome not explained in context with current literature

Paper 5

Reviewers: Miss K Shepherd, Mr S Jain

Summary

1. Purpose

Management of degenerative spondylolisthesis with spinal stenosis is controversial. Surgery is widely used, but its effectiveness in comparison with that of nonsurgical treatment has not been demonstrated in controlled trials.

2. Methods

Surgical candidates from 13 centers in 11 U.S. states who had at least 12 weeks of symptoms and image-confirmed degenerative spondylolisthesis were offered enrolment in a randomized cohort or an observational cohort. Treatment was standard decompressive laminectomy (with or without fusion) or usual nonsurgical care. The primary outcome measures were the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) bodily pain and physical function scores (100-point scales, with higher scores indicating less severe symptoms) and the modified Oswestry Disability Index (100-point scale, with lower scores indicating less severe symptoms) at 6 weeks, 3 months, 6 months, 1 year, and 2 years.

3. Results

We enrolled 304 patients in the randomized cohort and 303 in the observational cohort. The baseline characteristics of the two cohorts were similar. The one-year crossover rates were high in the randomized cohort (approximately 40% in each direction) but moderate in the observational cohort (17% crossover to surgery and 3% crossover to nonsurgical care). The intention-to-treat analysis for the randomized cohort showed no statistically significant effects for the primary outcomes. The as-treated analysis for both cohorts combined showed a significant advantage for surgery at 3 months that increased at 1 year and diminished only slightly at 2 years. The treatment effects at 2 years were 18.1 for bodily pain (95% confidence interval CI, 14.5 to 21.7), 18.3 for physical function (95% CI, 14.6 to 21.9), and -16.7 for the Oswestry Disability Index (95% CI, -19.5 to -13.9). There was little evidence of harm from either treatment.

4. Conclusions

In non-randomized as-treated comparisons with careful control for potentially confounding baseline factors, patients with degenerative spondylolisthesis and spinal stenosis treated surgically showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically.

Critique

The aim of this paper was to compare surgical intervention with nonsurgical/conservative management for a common condition – spondylolisthesis, leading to spinal stenosis. The data presented in this paper was collected and analysed as part of the large Spinal Patient Outcomes Research Trial (SPORT), a large, multicentre trial in the USA.

Strengths

- Randomised controlled trial leading to level 1 evidence
- Prospective
- Strong, validated primary research tools; (SF-36) and the Oswestry Disability Index
- Long-term & regular follow up
- Large sample size
- Acknowledgement given to the weaknesses of the study

Methodological concerns

- Significant cross-over between allocated randomisation and observational cohorts
- Range of surgical approaches/techniques employed with different surgeons (although the large numbers of patients recruited should reduce this effect)
- Despite the large numbers recruited the study was not case controlled/matched
- Blinded by statistical science and so on the whole could not critique to any reasonable level the statistical approaches utilised

In summary this research article could be considered a seminal one, especially when considered alongside the additional SPORT trial data. However, its main methodological weakness of the cross over between the cohorts and practical weakness of poor readability fail the authors and trial researchers is their noble aim.