The Bone & Joint Journal

West of Scotland Journal club: 27 February 2013

Attendees: Mr ATC Reece, Mr AJ Powell, Mr AS Brydon, Mr OB Murray

Western Infirmary, Glasgow. United Kingdom.

Theme: Spine

1. **Postacchini F, Giannicola G, Cinotti G.** Recovery of motor deficits after microdiscectomy for lumbar disc herniation. *J Bone Joint Surg Br. 2002 Sep;84(7):1040-5.*
2. **Karppinen J, Ohinmaa A, Malmivaara A, Kurunlahti M, Kyllönen E, Pienimäki T, Nieminen P, Tervonen O, Vanharanta H.** Cost effectiveness of periradicular infiltration for sciatica: subgroup analysis of a randomized controlled trial. Spine *(Phila Pa 1976). 2001 Dec 1;26(23):2587-95.*
3. **Delamarter R, Zigler, J.** Five-Year Reoperation Rates, Cervical Total Disc Replacement Versus Fusion, Results of a Prospective Randomized Clinical Trial. *Spine (Phila Pa 1976). 2012 Nov 2. [Epub ahead of print]*

Postacchini F, Giannicola G, Cinotti G. Recovery of motor deficits after microdiscectomy for lumbar disc herniation. *J Bone Joint Surg [Br]* 2002;84:1040-5.

Reviewer: Mr Andrew J Powell

Summary

1. Purpose

To assess the long term results of lumbar microsurgical discectomy with associated muscle weakness quantifying the rate of improvement and degree of weakness post operatively.

2. Methods

This is a prospective study of 116 patients who underwent lumbar microdiscectomy by the same surgeon between 1991 and 1997, all of which had lower limb weakness pre operatively. All deficits were MRC graded pre-operatively by a non-operating surgeon and the diagnosis confirmed by MRI +/- CT which also noted canal size. Variables were also noted - age, sex, smoking, alcohol,

comorbidities, diabetes etc. Intra-operatively both the type of disc herniation and location were noted.

Patients were then followed up at 1, 2, 3, 4 and 6 months. All deficits were MRC graded by both the operating surgeon and the same non-operating surgeon independently using reproducible and consistent clinical examination to test and quantify individual muscle group power. The study group was finally followed up at a mean of 6.4 years post op were subjective satisfaction and Oswestry disability score questionnaires were completed and a final power examination was conducted.

3. Results

Complete recovery of pre operative motor deficit was seen in 88 of 116 patients (76%). Patients that showed partial or complete recovery usually did so within 2 months. Residual end of study muscle weakness (24%) was observed in 16% of patients with pre-op mild weakness and 39% of patients with severe or very severe weakness.

Regarding duration of symptoms until surgery, in those with mild preoperative weakness, the mean duration of weakness pre-op was significantly shorter in those who recovered completely (84 days) compared with those with residual weakness (120 days) p=0.029.

In patients with severe preoperative weakness, the mean duration of weakness pre-op was significantly shorter in those who recovered completely (35 days) compared with those with residual weakness (69 days) p=0.017.

An inverse relationship was found between severity of preoperative muscle deficit and ability to regain full function p=0.0046.

A significant difference was shown between the presence of extruded or sequestrated herniation versus protrusion and the severity of residual muscle weakness p=0.038.

No significant difference was found for post operative weakness against the variables of age, sex, smoking, alcohol, comorbidities or size of spinal canal.

No significant difference between groups was seen on functional scoring post operatively.

4. Conclusions

The authors conclude that in patients with herniation of a lumbar disc which causes mild to severe weakness, a complete or almost complete recovery of strength will be made after microdiscectomy. The chance of recovery is better the less the neural deficit is preoperatively and the less delayed the operation.

5. Critique

This study documents the rate and quantifiable recovery of weakness post lumbar microdiscectomy and arrives at statistically significant conclusions. We had concerns reviewing this as to the lack of a control group of non-operative patients with similar symptoms to assess the natural history of muscle weakness post lumbar disc prolapse.

Strengths

- Prospective study with long term follow up of patients
- Well described methodology to allow consistently of assessment – previously poorly described in the literature
- Statistically significant results

Methodological Concerns

- No mention of the natural history of muscle weakness with lumbar disc prolapse in conservatively managed patients in the authors' patient population.
- No mention of the method of selection of the 508 patients operated on by the study author with lumbar disc prolapse.
- Despite attempts to standardise assessment there will still be considerable scope for inter observer error during MRC weakness testing and during assessment of subjective questionnaires.
- EMG studies for all would provide stronger objective data.

Karppinen J, Ohinmaa A, Malmivaara A, Kurunlahti M, Kyllönen E, Pienimäki T, Nieminen P, Tervonen O, Vanharanta H. Cost effectiveness of periradicular infiltration for sciatica: subgroup analysis of a randomized controlled trial. *Spine (Phila Pa 1976).* 2001;26:2587-95.

Reviewer: Mr Alistair S Brydone

Summary

1. Purpose

To determine the clinical efficacy and cost-effectiveness of peri-radicular infiltration of steroid and anaesthetic (methylprednisilone and bupivacaine) in subgroups of patients with sciatica.

2. Methods

Sub group analysis of a prospective randomized controlled trial

160 patients with sciatica (defined as unilateral pain radiating from back to below knee in a dermatomal distribution, lasting for 1 to 6 months) were given a peri-radicular injection (confirmed by neurogram) by one radiologist with steroid and anaesthetic or saline. This paper follows on from an RCT that had been powered at >90% to identify a 15mm improvement in the leg visual analogue pain score.

Patients were divided into subgroups based on the morphological characteristics of the herniation (bulge, contained herniation or extrusion) and the anatomical level of the lesion (L3-5 or L5/S1). Kappa values were recorded.

The main outcome measures were 100mm visual analogue scale, Oswestry Low Back Disability Questionnaire, Nottingham Health Profile, and medical costs assessed at baseline, 2, 4, 12, 26, and 52 weeks after peri-radicular infiltration. Outcome measures were compared at each follow-up using ANOVA and cumulative scores were assessed using the area under the curve (AUC) method.

Patients were categorised into responders (at least a 75% decrease in leg pain) or non-responders. The effectiveness of each treatment was compared using the number of responders vs. non responders at each time point using Fisher's exact test.

3. Results

When the subgroup of patients with contained herniations were separated out there was a significant reduction in the intensity of leg pain in the steroid group at baseline, and 2 weeks and 4 weeks post injection. The cumulative AUC score up to 3 months also favoured the steroid group ($P = 0.042$). The statistical difference (determined by ANOVA/Kruskal-Wallis) in the baseline intensity of leg pain of patients with contained herniations is shown in table 1, but it is not marked on the graph in figure 1 and is not reported in the methods.

Likewise, the subgroup of steroid patients with a lesion at L3-5 had a significant reduction in leg pain at 2 and 4 weeks and the cumulative AUC score at 3 months. The L5/S1 patients in the steroid group had a significantly poorer outcome in terms of leg pain after one year.

The mean cumulative costs calculated per responder showed a significant decrease in the cost per responder in the steroid group of patients with contained herniations, but there was a significant increase in the cost per responder in steroid group of patients with extrusions.

4. Conclusions

This study supports a short term symptomatic improvement and reduced need for surgery (within one year) for patients within contained broad-based herniations at baseline MRI. Conversely for patients with extrusions (herniations through the posterior longitudinal ligament), peri-radicular infiltration with steroid and anaesthetic seems to be counter-productive.

5. Critique

The main concerns regarding this paper stem from its basis as an addition to an existing study and published paper.[1] Important background introduction and methodologies e.g. enrolment, power analysis, and blinding are lacking and the paper is better read as a follow-on addition to the previous paper.

Strengths

- Describes a prevalent and economically important disease
- A subgroup analysis of a well-designed randomized controlled trial
- Suggests a need for more differentiation of patients with intervertebral disc herniations based on MRI-based morphology

Methodological Concerns

- The decision process to separate the groups based on the morphological characteristics of the herniation is not well described (in either paper).
- Not initially designed and powered for a sub group analysis so the statistics and conclusions should be interpreted with caution.
- The difference in leg pain VAS at 2 and 4 weeks in the steroid group is over-emphasised considering the baseline difference and the large standard deviations.

1. Karppinen J, Malmivaara A, Kurunlahti M, Kyllönen E, Pienimäki T, Nieminen P, Ohinmaa A, Tervonen O, Vanharanta H. Periradicular infiltration for sciatica: a randomized controlled trial. Spine (Phila Pa 1976). 2001 May 1;26(9):1059-67. PubMed PMID: 11337625.

Delamarter R, Zigler, J. Five-Year Reoperation Rates, Cervical Total Disc Replacement Versus Fusion, Results of a Prospective Randomized Clinical Trial. *Spine (Phila Pa 1976).* 2012;Nov 2. [Epub ahead of print]
Reviewer: Mr Odhrán B Murray

Summary

1. Purpose

A Prospective randomized clinical trial, (Level II): Determine the rates of secondary surgical intervention up to 5 years at both the index and adjacent levels in patients treated with cervical total disc replacement (using ProDisc-C) or anterior cervical discectomy and fusion (ACDF).

2. Methods

This study follows on from a previous non-inferiority randomized clinical trial comparing total disc replacement (TDR) to ACDF. The authors review the results of patients randomized to either cervical TDR or ACDF on a 1:1 basis at 13 sites. Inclusion criteria included single-level cervical disc disease causing debilitating radiculopathy from a single vertebral segment between C3 and C7, unresponsive to nonoperative treatment for at least 6 weeks, and a neck disability index score of 15/50 (30%) or more. The patients were blinded until immediately after the surgery and evaluated preoperatively and postoperatively at 6 weeks, 3, 6, and 12 months, and then annually up to 5 years. A standard approach and cervical decompression was preformed in both groups. Thereafter, the cervical TDR group underwent disc arthroplasty using the ProDisc-C implant whereas the ACDF group underwent fusion using allograft (+/- local bone) and anterior plating. Postoperative care was at the discretion of the surgeon. The primary outcome was any reoperation to the cervical spine at any level.

3. Results

At 5 years, 73% (72/99) of patients in the cervical TDR group and 64% (61/96) in the ACDF groups were followed up. Patients who received ProDisc-C had statistically significant higher probability of no secondary surgery at the index and adjacent levels than patients who underwent ACDF (97.1% vs. 85.5%, P = 0.0079).

4. Conclusions

The authors conclude that the mid-term results of patients undergoing cervical TDR with the ProDisc-C "demonstrate a significant sparing effect of TDR on adjacent levels" compared to ACDF. TDR was also show to be durable with no device failures or implant breakages at 5 years.

5. Critique

Strengths

- Clinically relevant study question.
- Part of a blinded, randomized clinical trial
- Medium-term follow up, (5 years).

Methodological Concerns

- Industry funded
- Original trial setup was a 'non-inferiority' trial and the rate of secondary surgical intervention was not a primary outcome measure.
- No explanation for high levels of patients lost to follow up or in the disparity in dropout rates between the groups.
- It could be argued that autograft may have resulted in less secondary surgery in the in ACDF group.
- Statistics preformed by industry.
- By 5 years the trial was underpowered.

Clinical Relevance

The authors are to be congratulated on the publication of this trial. It reassures surgeons and patients that cervical disc arthroplasty is not inferior to ACDF in the medium term. Accepting the aforementioned weakness, it suggests that TDR may also have a sparing effect on adjacent segment disease. However, the involvement of the prosthesis company especially in the statistical analysis may have biased this study.