A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative
disc disease
Yajun W, Yue Z, Xiuxin H, Cui C

CRD summary
This review concluded that total artificial disc replacement did not show significant superiority for the treatment of lumbar degenerative disc disease when compared with fusion. The authors’ recommended a cautious interpretation of their findings which appeared appropriate given the number of studies and differences between them.

Authors’ objectives
To compare the effectiveness and safety of artificial total disc replacement with fusion for the treatment of lumbar degenerative disc disease.

Searching
Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE were searched up to July 2009 for studies in any language. Keywords were reported. Spine, European Spine Journal and Journal of Bone and Joint Surgery abstracts were searched from 1990. International experts were contacted for additional studies.

Study selection
Randomised controlled clinical trials (RCTs) that compared any type of total disc replacement with fusion of any kind for the treatment of lumbar systematic degenerative disc disease in adults (≥18 years) were eligible for inclusion in the review. Primary outcomes were improvement in pain measured by a validated pain scale, improvement of movement and functioning measured by a disability scale, patient satisfaction with the treatment and risk of complications. Secondary outcomes were clinical success rate, operative level range of motion measured on the flexion/extension films, operation time and blood loss, employment rate and reoperation rate.

Types of total disc replacement assessed in the included studies were ProDisc-L, FlexiCore, CHARITE artificial disc and Maverick. Fusion comparators were: anterior lumbar interbody fusion with BAK cages and posterolateral fusion with autologous bone graft or posterior interbody fusion with two carbon fibre cages; and anterior lumbar interbody fusion with femoral ring allograft plus instrumented posterolateral fusion with autogenous iliac crest bone graft. Included studies assessed mixed gender populations. Mean age ranged from 37.7 to 41 years. Oswestry score was usually at least 40%. Types of degenerative disc disease varied between studies. Participants in all studies except one had back and/or leg pain. Patients in all studies except one had failed at least six months of conservative care with good compliance.

Two reviewers assessed the studies for inclusion; disagreements were resolved through discussion or the involvement of an independent expert.

Assessment of study quality
Two reviewers independently assessed methodological quality of the included studies using criteria developed by Koes et al. Disagreements were resolved through discussion. Each study was awarded a total score up to a maximum of 100 points (criteria were not given equal weighting). Studies were considered to be good quality if they scored more than 50 points. Criteria were: homogeneity; comparability of baseline characteristics; adequacy of randomisation; dropouts described; less than 20% to 10% loss to follow-up; sample size of over 50 and 100; adequate description of intervention; pragmatic study; no cointerventions; use of placebo; patients blinded; use of relevant outcome measures; blinded outcome assessors; use of adequate follow-up; use of intention-to-treat analysis; and adequate description of outcome data for each treatment group.

Data extraction
Two reviewers independently extracted data for the primary and secondary outcomes to enable calculation of either an odds ratio (OR) (dichotomous outcomes) or a mean difference (MD) (continuous outcomes); 95% confidence intervals.
Methods of synthesis

Pooled odds ratios or standardised mean differences (SMD) were calculated using a random-effects model. Clinically important differences were judged to be at least a 20% improvement in pain score or a 25% improvement in the functioning score. Both clinical and statistical heterogeneity were assessed, the latter using $\chi^2$. Statistical pooling was not performed where the level of statistical heterogeneity was judged to be significant ($p>0.05$). Sensitivity analyses were performed to determine the effects of omitting studies that may have had a large influence on the clinical results.

Results of the review

Five RCTs (n=837 participants) were included in the review. Sample sizes ranged from 67 to 304 patients. Follow-up ranged from one to five years. Quality scores ranged from 44 to 69 and four of the five studies were judged to be good quality.

After two years follow-up, patients in the total disc replacement group had statistically significant improved functioning using the Oswestry scale (MD -4.06, 95% CI -7.28 to -0.84, $I^2=0$%; four RCTs) and less back or leg pain using a visual analog scale (MD -4.75, 95% CI -9.14 to -0.35, $I^2=0$%; four RCTs). These differences were not judged to be clinically significant.

In comparison with fusion, total disc replacement patients were judged to have significantly increased patient satisfaction (SMD 0.29, 95% CI 0.05 to 0.53, $I^2=37$%; three RCTs). More total disc replacement patients were willing to undergo the same operation again (OR 2.86, 95% CI 1.41 to 5.77, $I^2=64$%; three RCTs). There were no significant differences between total disc replacement and control groups with respect to complications (three RCTs, $I^2=0$%), patients who returned to full-time/part-time work (three RCTs, $I^2=29$%) and reoperation rate (three RCTs, $I^2=0$%).

After follow-up, there were no significant differences between the two treatment groups with respect to any of the outcomes. Sensitivity analyses showed that some outcomes were highly influenced by one study with BAK cage interbody fusion. When this study was excluded from the two-year analyses, the differences that favoured total disc replacement in terms of functioning, pain and patient satisfaction status were no longer significantly different between the two groups.

Authors’ conclusions

Total artificial disc replacement did not show significant superiority for the treatment of lumbar degenerative disc disease when compared with fusion.

CRD commentary

This review answered a clearly defined research question and carried out literature searches using a number of resources. The risk of language bias was likely to be low as study inclusion was not limited by language. The authors attempted to locate unpublished studies, so the risk of publication bias was likely to be low. Risks of reviewer error and bias were likely to be low as two reviewers independently assessed the studies for inclusion, extracted data and assessed the methodological quality of the studies. Criteria used to assess the methodological quality of the studies appeared appropriate. Four of the five studies were judged to be good quality. Appropriate analyses were performed and took into account both clinical and statistical heterogeneity. The authors attempted to investigate potential sources of heterogeneity.

The authors’ recommended a cautious interpretation of their findings which appeared appropriate given the number of studies and differences between them.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that long-term high-quality studies were required to assess the cost-effectiveness and benefits of motion preservation and the risk of complications associated with total disc replacement versus fusion for...
the treatment of degenerative disc disease.

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