Cost-effectiveness of two forms of circumferential lumbar fusion: a prospective randomized controlled trial

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study compared the cost-effectiveness of titanium cages (TC) with that of femoral ring allografts (FRA) for circumferential lumbar spinal fusion. The authors concluded that FRA were more cost-effective than TC. They cost less, improved QALYs, and also improved work productivity. The methodology of the study appears to have been appropriate and, on the whole, the analysis was clearly and transparently reported. The authors’ conclusions reflected the scope of their analysis.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to compare the cost-effectiveness of titanium cages (TC) with that of femoral ring allografts (FRA) in patients undergoing a circumferential lumbar spinal fusion due to chronic low back pain.

Interventions
The TC were Synthes, from Oberdorf, Switzerland, while the FRA came from the National Blood Service, Edgware, England.

Location/setting
UK/secondary care.

Methods
Analytical approach:
This economic evaluation was based on a single clinical study, which had a two-year time horizon and, as stated by the authors, was conducted from the perspective of the UK National Health Service.

Effectiveness data:
A single-centre randomised controlled trial with a two year follow-up was used to derive the effectiveness data. The trial had a total sample size of 78, with 41 subjects in the TC group and 37 in the FRA group (McKenna, et al. 2005, see ‘Other Publications of Related Interest’ below for bibliographic details). The main clinical outcomes were a Visual Analogue Scale for back pain, the Oswestry Disability Index, and the Short Form (SF)-36.

Monetary benefit and utility valuations:
Patients completed the SF-36 at baseline, 6, 12 and 24 months. The responses were used to derive SF-6D utility scores, using published data from a sample of the UK general population and a modified standard gamble approach.

Measure of benefit:
The measure of benefit was quality-adjusted life-years (QALYs).

Cost data:
Secondary care resource use data were collected at patient level and included surgery time, blood usage, spinal-related inpatient stay, and revision surgery. The main cost source was the local institution. When local specific costs were not available, other published sources were utilised. The costs were presented in 2005 to 2006 UK pounds sterling (£).
Discounting was adequately considered for the costs incurred in the second year. Productivity losses were valued using the human capital approach based on patient occupational status before surgery and at 24 months. These losses were reported separately from the direct costs and were not included in the base-case analysis.

Analysis of uncertainty:
To reflect the study uncertainty the authors reported confidence interval (CI)s for the costs and benefits using non-parametric bootstrapping. In the base-case missing utility scores were imputed. So, some scenarios were run to evaluate the effect of missing data (complete case analysis, available case analysis, and multiple imputation).

Results
FRA dominated (i.e. was more effective and less costly than) TC.

The mean QALYs per patient over 24 months were 0.0522 (standard deviation, SD: 0.0326) for the TC group and 0.1914 (SD: 0.0398) for the FRA group, with a statistically significant difference of -0.1392 (95% CI: -0.2349, -0.0436).

The mean total costs per patient were £9,052 (SD: 3,105) for the TC group and £7,102 (SD: 1,928) for the FRA group, with a statistically significant cost difference of £1,950 (95% CI: 849, 3,145).

Even at large willingness to pay values (£1,000,000) the probability of TC being cost-effective was 0.2%. Compared with FRA, the incremental productivity costs of TC were £185,171. This equates to increased earnings of £5,005 (median) or £6,391 (mean) in the FRA group. In the sensitivity analysis, the scenarios for addressing the missing utility scores had no impact on the overall conclusions.

Authors' conclusions
The authors concluded that FRA were more cost-effective than TC as part of a circumferential lumbar spinal fusion. They had fewer costs, improved QALYs, and also improved work productivity. So, TC should no longer be used. They stated that studies with a broader perspective and a longer time horizon would help to confirm their results.

CRD commentary
Interventions:
The authors clearly reported the interventions. As they stated, this study compared two forms of instrumental spinal fusion. It did not investigate other possible types of fusion, or the value of instrumental fusion, in general or as a comparator for non-instrumental fusion.

Effectiveness/benefits:
The effectiveness data were clearly reported and were based on a good quality randomised trial. It was not clear whether there were other comparative data for FRA versus TC, which could have been considered. As this was a single-centre study, it may not be easily generalisable to other settings.

Costs:
The costs were adequate for the perspective, and followed an suitable methodology. As the authors stated, the exclusion of primary care or other costs would not strongly affect their conclusions. They also acknowledged some limitations in the measurement and valuation of productivity and they reported these separately.

Analysis and results:
The study appears to have been adequately conducted and analysed. The analysis of uncertainty was well handled by performing a stochastic analysis of the global study and evaluating the uncertainty surrounding the significant missing data in the utility scores. The reporting was clear and concise and the authors highlighted and acknowledged the limitations to their study.

Concluding remarks:
The methodology of the study appears to have been appropriate and, on the whole, the analysis was clearly and transparently reported. The authors' conclusions reflected the scope of their analysis.
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