Comparison of lumbar interbody fusion techniques using ray threaded fusion cages and pedicle screw fixation systems
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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.

Health technology
Three different types of lumbar interbody fusion surgery were examined:

- anterior lumbar interbody fusion using Ray threaded fusion cages (ALIF/TFC),
- posterior lumbar interbody fusion with Ray threaded fusion cages (PLIC/TFC), and
- posterior lumbar interbody fusion with concomitant posterior stabilisation (PLIF/Plate).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with lower-back pain (with or without sciatica) caused by degenerative disc disease that had failed non-operative treatment programmes. The exclusion criteria were patients aged less than 18, obesity, insulin-dependent diabetes, alcohol abuse, abnormal spinal or osteoporotic conditions, and the use of glucocorticoid medication.

Setting
The clinical setting was a hospital (division of Neurosurgery). The economic study was performed in Norfolk (VA), USA.

Dates to which data relate
The effectiveness evidence and resource use data were gathered between January 1996 and August 1998. The clinical outcomes were obtained during the patient follow-up (2 years). The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as that used in the effectiveness study.
Study sample
Power calculations, if performed, were not reported. A total of 46 patients who consented to participate in the study were included in the analysis. Ten patients underwent ALIF/TFC (group 1), 22 patients received PLIF/TFC (group 2) and 14 received PLIF/Plate (group 3). The same surgeon operated on all patients. The mean age was 51.6 (+/- 11.7) years in group 1, 47.0 (+/- 16.0) years in group 2 and 45.4 (+/- 18.9) years in group 3. The proportion of men was 40% in group 1 and 50% in the other two groups. The proportions of smokers and workers were approximately 40% in all groups. Approximately 70% of the individuals in all groups had undergone prior surgery. It was not stated whether some patients refused to participate or were excluded from the initial study sample for any reason.

Study design
This was a retrospective cohort study (with three groups) that was performed in a single centre. The patients were followed for up to 24 months. Data during the follow-up period were available at 6 weeks and 6, 12 and 24 months. No patient was lost to follow-up. The charts of all patients were reviewed independently.

Analysis of effectiveness
All patients included in the initial sample were used for the effectiveness analysis. The clinical outcomes assessed in the analysis were economic and functional capability (Prolo scale), fusion success, hospital length of stay and complications. On the Prolo scale, economic and functional capabilities are each divided into five categories. The categories range from "complete invalid" to "working without restrictions" for economic status, and from "total incapacity from pain" to "complete recovery" for functional status. Each of the economic and functional components is associated with a numeric value from 1 (worse state) to 5 (best state). A final score of 9 - 10 indicates perfect health, 7 - 8 good health, 5 - 6 fair, and 2 - 4 poor health. The scores were based on patient-reported health states. Fusion success was achieved in the case of absence of less than 3 degrees on flexion-extension radiographs, absence of any dark halo around the device, and the presence of persistent bone mass inside the cage (or within the interbody space for PLIF/Plate).

The three groups were similar (not statistically different) in terms of their age, gender, degree of pain, number of surgeries, and other economical and descriptive characteristics at the baseline.

Effectiveness results
The results of the Prolo scale were:

- after 6 weeks, 5.4 (+/- 1.5) with ALIF/TFC, 6.1 (+/- 1.5) with PLIF/TFC, and 5.9 (+/- 1.1) with PLIF/Plate;
- after 6 months, 6.0 (+/- 2.2) with ALIF/TFC, 7.0 (+/- 1.9) with PLIF/TFC, and 7.1 (+/- 1.8) with PLIF/Plate;
- after 1 year, 6.4 (+/- 2.3) with ALIF/TFC, 7.7 (+/- 2.2) with PLIF/TFC, and 7.0 (+/- 1.7) with PLIF/Plate; and
- after 2 years, 6.3 (+/- 2.2) with ALIF/TFC, 7.5 (+/- 2.2) with PLIF/TFC, and 7.8 (+/- 1.9) with PLIF/Plate.

All three groups showed significant increases in clinical outcomes at 1 and 2 years after surgery, (p<0.0001).

At 24 months, in terms of the Prolo scale scores, there was a trend in favour of PLIF/TFC and PLIF/Plate in comparison with ALIF/TFC. However, this difference was not statistically significant, (p=0.0877).

All patients achieved fusion success after 1 year from surgery. Subsequently, 2 patients in the ALIF/TFC group, 1 in the PLIF/TFC group and 1 in the PLIF/Plate group reported lower-back pain that required revisional surgery.

The length of stay was 3.7 (+/- 0.7) days in group 1, 4.0 (+/- 1.3) in group 2 and 4.1 (+/- 1.4) in group 3, (p=0.1954).

Only minor complications occurred (3 cases).
Clinical conclusions
The authors concluded that there were no statistically significant differences in the clinical outcomes among the 3 treatments, although there was a trend in favour of PLIF/TFC and PLIF/Plate in comparison with ALIF/TFC.

Measure of benefits used in the economic analysis
No summary benefit measure was used. The study may be classified as a cost-minimisation analysis (CMA).

Direct costs
Discounting was not applied, which was appropriate since the costing was performed over a short time horizon. The quantities of resource use and the unit costs were not reported separately. No information on the unit costs was given. The quantity/cost boundary was that of the third-party payer. The cost categories included in the analysis were length of hospital stay, operative blood loss, surgeon's fees, operative time and instrumentation. Resource use and costs were obtained from the patients' charts and billing records provided by insurance carriers and workers' compensation data. The quantities of resources were measured between January 1996 and August 1998. The price year was not reported.

Statistical analysis of costs
The mean costs were compared using statistical tests (Tukey-Kramer multiple comparison procedure).

Indirect Costs
The indirect costs were not included in the analysis

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The median total costs were $12,040 (+/- 299) for ALIF/TFC (95% confidence interval, CI: 11,826 - 12,254), $13,657 (+/- 1,576) for PLIF/TFC (95% CI: 12,958 - 14,356) and $15,432 (+/- 2,008 for PLIF/Plate (95% CI: 14,273 - 16,591).

The total costs for PLIF/TFC and PLIF/Plate were significantly higher than those for ALIF/TFC, (p<0.01). These differences were mainly due to the significantly lower operative time and anaesthesia time for ALIF/TFC in comparison with the other two procedures.

ALIF/TFC also showed a lower variability of costs when compared with the other two treatments.

Synthesis of costs and benefits
Not relevant as a CMA was performed.

Authors' conclusions
The three treatments showed similar results in terms of the clinical outcomes. Both ALIF/TFC (anterior lumbar interbody fusion using Ray threaded fusion cages) and PLIF/TFC (posterior lumbar interbody fusion with Ray threaded fusion cages) were significantly less costly than PLIF/Plate (posterior lumbar interbody fusion with concomitant posterior stabilisation). Consequently, PLIF/Plate cannot be considered a cost-effective strategy for patients with lower-back pain (from a fiscal point of view).

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. In the USA there is still a debate on which interbody technique should be preferred for patients suffering from lower-back pain, therefore the authors compared three procedures currently in use. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness analysis used a cohort study. This can present some limitations in terms of the internal validity of the results. However, the authors performed several statistical analyses to assure the comparability of the three groups. The main limitation of the effectiveness analysis appears to have been the small sample size, which may have created problems in detecting statistically significant differences in the results. The clinical outcomes were based on patient-reported health states, which is appropriate for the type of disease. The study sample appears to have been representative of the study population.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. Given that the results obtained in the clinical outcomes among the three procedures were not statistically significantly different, the study was categorised as a CMA.

Validity of estimate of costs
All the categories of costs relevant to the perspective of the analysis were included. The authors performed statistical analyses to investigate the significance of the difference in the costs. No details were given on the unit costs and only the total costs were reported. No sensitivity analyses were performed, thus reducing the transferability of the results. The cost estimates were specific to the study setting.

Other issues
The authors compared the results of their study, in terms of the clinical outcomes, with those found in published literature. However, no comparison was made on the cost side. In addition, the lack of sensitivity analyses limits the generalisability of the results. The authors' conclusions were drawn on the basis of there being no significant difference in the effectiveness results among the three treatments. However, this could have been due more to the small sample size than to a real similarity in the results. In fact, there was an evident trend in favour of PLIF/TFC and PLIF/Plate in the majority of the clinical outcomes.

Implications of the study
The results of this study suggested that, compared with PLIF/Plate, ALIF/TFC and PLIF/TFC should be considered as the most cost-effective strategies for patients with lower-back pain. However, further studies should be performed to confirm these results, possibly with a different study design (randomised clinical trial) and larger sample size.

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