Are 2 cages needed with instrumented PLIF: a comparison of 1 versus 2 interbody cages in a military population
Molinari R W, Sloboda J, Johnstone F L

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
The study compared the use of either one or two nonthreaded interbody cages in patients undergoing instrumented posterior lumbar disc excision and interbody fusion (PLIF). All patients were treated with instrumented 1-level PLIF using an autogenous iliac crest bone graft. The cages used were Brantigan or Harms. A 4-pedicle screw/rod instrumentation construct and a concomitant posterolateral fusion were performed in all patients, as well as a bilateral diskectomy. A morselised autogenous bone graft was placed anteriorly and laterally in the disc space before the insertion of each cage. When only a single cage was used the bone graft was inserted from a bilateral approach. No physical therapy or brace was prescribed postoperatively.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised active-duty and retired US military male personnel from the three branches of service (Army, Navy and Air Force) who suffered from chronic back pain. All patients had a history totalling at least one year of chronic back pain complaints due to single-level lumbar disc degeneration, either an isolated degenerative lumbar disc or low-grade isthmic spondylolisthesis at the affected level. All patients had been treated unsuccessfully during the year before referral with some form of conservative measure.

Setting
The setting was tertiary care (Madigan Army Medical Centre). The economic study was carried out in Washington, USA.

Dates to which data relate
The effectiveness evidence and resource use data related to August 1998 to June 2001. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study.
Study sample
The study sample included 35 consecutive patients who were referred to the same spinal surgeon for chronic back pain from August 1998 to June 2001. The average age of the patients was 36 years (range: 22 - 54), and 19 had an isolated degenerative lumbar disc and 16 a low-grade isthmic spondylolisthesis. Of the 35 patients, 19 (54%) patients received PLIF using one nonthreaded interbody fusion cage (Group 1), while the remaining 16 (46%) patients received PLIF using two nonthreaded interbody fusion cages (Group 2). Power calculations were not reported.

Study design
This was a single-centred, non-randomised controlled trial. The average follow-up time was 15 months (range: 3 - 36).

Analysis of effectiveness
It was not stated whether the analysis was conducted on an intention to treat basis or on treatment completers. The primary health outcomes used were:

- the estimated blood loss;
- the rates of implant complications, dural tear, neurologic deficit, and wound complications;
- functional outcomes;
- radiographic assessment of fusion; and
- the length of hospitalisation.

The functional outcomes included function, pain and satisfaction measures, These were assessed using a standardised 17-question functional-outcomes instrument consisting of combined questions from the American Academy of Orthopaedic Surgeons Modems and the Scoliosis Research Society outcomes instrument. The authors reported preoperative function and pain for each group. However, they did not report any statistically significant differences between the two groups. Adjustments for confounding factors were not reported.

Effectiveness results
The average estimated blood loss was 1,050 mL for Group 1, and 1,100 mL for Group 2 (range for both groups: 700 - 2,500).

The average length of stay was 4 days (range: 3 - 5) for both groups.

No implant complications such as interbody cage misplacement, postoperative cage migration, pedicle screw loosening or breakage, were observed.

Dural tears occurred and were treated in 4 (11%) of the 35 patients (11%), 1 (5%) in Group 1 and 3 (19%) in Group 2. No patients had postoperative symptoms related to dural tears.

The incidence of new postoperative radiculopathy was 0% in Group 1 and 6% in Group 2 (1 of 16 patients). There were no permanent neurologic complications.

One patient (5%) in Group 1 (n=19) and one patient (6%) in Group 2 (n=16) had wound seromas postoperatively that required operative treatment. No patient in either group developed deep infection.

Both groups reported an increase in function after treatment. The preoperative score was 9.7 (standard deviation, SD=2.3) for Group 1 and 9.8 (SD=2.4) for Group 2, while the postoperative scores were 13.1 (SD=2.8) and 13.4 (SD=2.6), respectively. Increases in function were 35% in Group 1 and 37% in Group 2. The difference in post-treatment function between the groups was not statistically significant.
After treatment, 18 patients (95%) in Group 1 (n=19) and 15 patients (93%) in Group 2 (n=16) reported decreased pain. The preoperative score was 8.2 (SD=1.8) for Group 1 and 7.9 (SD=1.1) for Group 2, while the postoperative scores were 2.5 (SD=2.1) and 2.1 (SD=2.3), respectively. The difference in post-treatment pain between the groups was not statistically significant.

The average satisfaction score was 13.5 out of 15 (SD=2.0) for Group 1 and 13.0 out of 15 (SD=1.7) for Group 2. The difference in satisfaction scores between the groups was not statistically significant.

In total, 17 patients (89%) in Group 1 (n=19) and 14 patients (87%) in Group 2 (n=16) demonstrated radiographic evidence (bridging bone) of anterior fusion. Posterior fusion (grade A or B) was observed in 14 (74%) Group 1 patients and 11 (69%) Group 2 patients. Evidence of posterior and/or anterior fusion was observed in 33 (94%) of the 35 patients.

Clinical conclusions
The authors did not report a synthetic clinical conclusion. Instrumented PLIF procedures performed with either 1 or 2 non-cylindrical interbody cages, in addition to autogenous anterior and posterolateral bone grafting, had similar low rates of complications and high rates of radiographic fusion. The incidence of dural tear was higher with the use of 2 interbody cages. Outcomes with respect to pain, function, and satisfaction were good in most cases, but did not differ between the groups.

Measure of benefits used in the economic analysis
No summary measure of benefit was used. The cost and effects were left disaggregated and the study was, in effect, a cost-consequences analysis.

Direct costs
The direct costs reported were for the cage and interbody implant. Discounting was, appropriately, not carried out because of the short time horizon studied. The quantities and the costs were not reported separately. The quantities and costs were both estimated from actual data. The sources reported were government costs. All other cost categories were excluded as the rates of fusion and complications were similar between the groups. The price year was not reported.

Statistical analysis of costs
No statistical tests were reported. Descriptive statistics were given. The authors reported the mean values for each group but no variability estimate (e.g. SD or interquartile range).

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.
Cost results
A single Harms titanium mesh cage cost $1,010, while a single carbon fibre Brantigan cage cost $2,195.

Interbody implant costs averaged $2,070 in Group 1 and $3,798 in Group 2. The average difference in interbody cage costs between the groups was $1,728.

The lowest interbody implant costs were observed in Group 1 patients in whom a single Harms cage was placed ($1,010; n=2). The highest costs occurred in Group 2 patients in whom two Brantigan cages were placed ($4,390; n=12). The maximum difference in interbody implant costs between patients in the two groups was $3,380.

Synthesis of costs and benefits
Not applicable since the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Instrumented posterior lumbar disc excision and interbody fusion (PLIF) procedures performed with either one or two non cylindrical interbody cages, in addition to autogenous anterior and posterolateral bone grafting, had similar low rates of complications and high rates of radiographic fusion. The incidence of dural tear was higher with the use of two interbody cages. Outcomes pertaining to pain, function, and satisfaction were good in most cases, but did not differ between the groups. The treatment costs were lower in those patients receiving only one structural interbody cage.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. Instrumented PLIF performed with two interbody cages is a potential treatment for chronic back pain. You should judge whether this procedure is relevant in your own setting, or whether other comparators from other techniques and implant modalities could also have been relevant, for example, PLIF with pedicle screw instrumentation.

Validity of estimate of measure of effectiveness
The analysis was based on a non-randomised controlled trial. This design might have resulted in biases and may also limit the validity of the comparison of the two groups. The study sample appears to have been representative of the study population. The fact that there were no statistically significant differences in outcomes between the two groups might have been due to the small sample size and the resulting lack of statistical power. Since no patient characteristics were reported, is not possible to assess whether there were any differences between the two groups which might have impacted on the study results. The authors did not report the statistical methods used. Hence, it is unclear whether appropriate statistical analyses were undertaken to ensure the comparability of the patient groups. The study represents a single surgeon's experience, and this limits the possible extrapolation of the results to other settings.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was, in effect, a cost-consequences study.

Validity of estimate of costs
The perspective adopted was unclear, but it was likely to have been that of a single provider. Although it was not explicitly stated, some relevant costs (e.g. laboratory and radiographic costs, or other inpatient costs) were omitted from the analysis. If clinical effects and side effects were similar between the groups, the omission of these costs is unlikely to have affected the authors' conclusions. The costs and the quantities were not reported separately, thus the results of the analysis could not be easily extrapolated to other settings. The resource use quantities were derived from the study, while the unit costs were derived from the authors' settings. No statistical or sensitivity analyses of the quantities or prices were performed, hence the uncertainty in the authors' results was not examined. The price year was not reported, which will hinder any future reflation exercises.
Other issues
The authors compared their findings with those from other studies, generally finding them to be in agreement. The issue of generalisability was not addressed explicitly. The authors carefully chose diagnoses that would limit the generalisability of the results to other disorders. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors did not report any additional limitations.

Implications of the study
The authors did not make any recommendations for changes in policy or practice, and/or the need for further research, other than those stated in their conclusions. The conclusions of the study should be taken as preliminary. Evidence from randomised studies and a larger sample is needed to confirm the clinical results.

Source of funding
None stated.

Bibliographic details

PubMedID
12892278

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Blood Loss, Surgical; Humans; Intervertebral Disc Displacement /surgery; Low Back Pain /surgery; Male; Middle Aged; Military Personnel; Patient Satisfaction; Spinal Fusion /economics /instrumentation /methods; Spondylolisthesis /surgery; Treatment Outcome; Washington

AccessionNumber
22003006494

Date bibliographic record published
30/06/2005

Date abstract record published
30/06/2005