Clinical and radiographic evaluation of disc excision for lumbar disc herniation with and without posterolateral fusion
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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
Two different techniques for lumbar disc herniation were considered: disc excision alone and disc excision with posterolateral fusion.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with lumbar disc herniation who were eligible for surgery. Patients were eligible if they met the following criteria:

- they were aged younger than 60 years;
- this was their first operation;
- the surgical disc was limited to one level;
- the symptoms were compatible with a diagnosis of lumbar disc herniation; and
- they were unaffected by lumbar canal stenosis or spondylolisthesis.

Setting
The setting was a hospital. The economic study was carried out in the Tondabayashi Hospital, Japan.

Dates to which data relate
The effectiveness evidence and the resource use data were gathered between January 1986 and December 1992. 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 prospectively on the same patient sample as that used in the effectiveness analysis.
Study sample
Power calculations were not performed to determine the sample size. From January 1986 to December 1992, 115 patients undergoing surgery at the Tondabayashi Hospital were considered eligible for the study. Twenty patients could not participate in the study and were excluded. Thus, 95 patients were included. Of these, 44 patients underwent disc excision alone. The average age in this group was 38 (+/-11.2) years and 28 of the participants were men. The remaining 51 patients underwent disc excision and fusion. The average age in this group was 40 (+/-10.2) years and 35 of the participants were men.

Study design
This was a prospective case-control study carried out in a single centre. The average duration of follow-up was 6.6 (+/-2.1) years in the non-fusion group and 7.4 (+/-1.8) years in the fusion group. The patients underwent water-soluble contrast myelography and concomitant lumbar computed tomographic scanning before the operation, at 1 and 5 years after the intervention, and at the final follow-up.

Analysis of effectiveness
All 95 patients included in the study were accounted for in the analysis. The main health outcome used in the analysis was the rate of improvement after surgery. This was assessed using the Japanese Orthopaedic Association back scores, then classified according to a four-grade-scale:

- excellent, which represented an improvement of greater than 90%;
- good, which represented an improvement of 75 to 89%;
- fair, which represented an improvement of 50 to 74%; and
- poor, which represented an improvement of below 49%.

The other primary outcomes assessed were:

- intraoperative blood loss;
- the length of the operation and the duration of hospital stay;
- clinical symptoms before and after surgery, including lower-back pain, leg pain, ability to walk, straight leg raising, sensory abnormality, and motor weakness;
- the number of major complications;
- the level of spinal motion; and
- disc height, as assessed by a radiological analysis.

Statistical analyses were also conducted to show the comparability of the groups with respect to age, gender and preoperative instability.

Effectiveness results
The rate of improvement was satisfactory (excellent or good) in 73% of the patients in the non-fusion group and in 83% of those in the fusion group. However, this difference was not statistically significant.

The average intraoperative blood loss was 71 mL in the non-fusion group and 235 mL in the fusion group.

The average length of the operation was 76 minutes in the non-fusion group and 150 minutes in the fusion group.
The mean hospital stay was 48 days in the non-fusion group and 59 days in the fusion group. These differences were stated to have been statistically significant at the 0.05 level.

Among the clinical symptoms before and after surgery, lower-back pain after the intervention was found to be significantly higher in the non-fusion group (61%), compared with the fusion group (35%). Disc hernia at the same level was significantly more recurrent in the non-fusion group (11%) than in the fusion group (0%).

None of the patients in the groups experienced major complications. In the non-fusion group, there was only a slight decrease in the segmental range of motion at the level of surgery, from 9.3 (+/− 4.8) degrees before surgery to 8.7 (+/− 4.1) degrees at the follow-up. No segmental motion was seen in the fusion group. This difference between the non-fusion and fusion groups was statistically significant.

Five years after the operation, there was a significant difference between the two groups in terms of the disc height. The disc height was 0.19 in the non-fusion group versus 0.21 in the fusion group.

**Clinical conclusions**

The effectiveness analysis indicated that disc excision alone was more effective in terms of intraoperative blood loss, the length of the operation, the duration of hospital stay, and the disc height. However, disc excision with fusion was more effective with respect to postoperative lower-back pain, disc hernia recurrence, and motion of surgical segment.

**Measure of benefits used in the economic analysis**

The authors did not use a summary measure of benefit and left the health outcomes disaggregated. A cost-consequences analysis was therefore carried out.

**Direct costs**

Discounting was not carried out, although it would have been relevant as the costs were incurred over a period of time greater than 2 years. The quantities and the unit costs were not reported separately, and only the total costs for each procedure were given. The resource/cost boundary was not reported. The source of the cost and resource data was not reported. The costs appear to have been estimated from the actual data derived from the patients’ charts. The resource use data were gathered between January 1986 and December 1992. The price year was not reported.

**Statistical analysis of costs**

A statistical analysis of costs was reported.

**Indirect Costs**

The indirect costs were not included.

**Currency**

US dollars ($).

**Sensitivity analysis**

No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**

See the ‘Effectiveness Results’ section.
Cost results
The total procedural costs were $9,300 in the non-fusion group and $14,800 in the fusion group. The authors highlighted that this difference was statistically significant.

Synthesis of costs and benefits
Not applicable since a cost-consequences approach was adopted.

Authors' conclusions
Both of the techniques were associated with pros and cons in terms of the effectiveness and the costs. It was therefore impossible to draw precise indications on whether to recommend disc excision with or without posterolateral fusion for lumbar disc herniation.

CRD COMMENTARY - Selection of comparators
The reason for the selection of the health technologies was clear. The interventions represented the most commonly practised techniques in Japan from 1986. You should consider whether they are widely used in your own setting.

Validity of estimate of measure of effectiveness
The main limitation to the internal validity of the study was the lack of randomisation in the study design. However, a statistical analysis was performed in order to show the comparability between the study groups with respect to demographics and preoperative clinical characteristics. It would have been interesting to have taken into account the impact of the techniques on the patients' quality of life, had the primary health outcomes been aggregated and a summary benefit measure adopted.

Validity of estimate of measure of benefit
There was no summary measure of benefit.

Validity of estimate of costs
The analysis of the costs was somewhat limited. There were no details on the resources and the cost items. In addition, the price year and the perspective of the study were not reported. Finally, sensitivity analyses were not performed and the costs were not discounted.

Other issues
The generalisability of the study was limited and the robustness of the results was not addressed through sensitivity analyses. However, the authors made appropriate and interesting comparisons of their findings with those of other studies.

Implications of the study
The main implication of the study, according to the authors, was that "there is seldom an indication for primary fusion for lumbar disc herniation". However, the statement does not seem to be justified given the ambiguity of the effectiveness results, where fusion was associated with greater effectiveness on some measures, most importantly pain.

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