Surgical stabilisation of the spine compared with a programme of intensive rehabilitation for the management of patients with chronic low back pain: cost utility analysis based on a randomised controlled trial


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
This study examined surgical stabilisation of the spine (SSS) and intensive rehabilitation (IR) for the management of patients with chronic back pain (CBP). The surgical approach consisted of spine fusion surgery.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with CBP. More detailed inclusion and exclusion criteria might have been reported in the primary clinical trial.

Setting
The setting was secondary care and a hospital. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered from June 1996 to February 2002. The costs were expressed using 2002-2003 prices.

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

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the clinical study.

Study sample
The authors stated that the primary study was powered to detect a 4-point difference on the main outcome measure (changes in activities of daily living, ADL). Limited information on the method of sample selection was reported. An overall sample of 349 patients who met the eligibility criteria was enrolled. There were 176 patients in the SSS group and 173 patients in the IR group. The proportion of male patients was 44.9% in the SSS group and 53.8% in the IR group. Most of the patients were in the age groups 30 to 39 years (SSS group 35.8%; IR group 38.7%) and 40 to 49 years (SSS group 31.8%; IR group 38.1%).
Study design
This was a prospective, randomised clinical trial that was carried out in 15 centres across the UK. Details of randomisation and the method of outcome assessment were not reported. The patients were followed for 24 months, with clinical outcomes evaluated at baseline, 6, 12 and 24 months. No clear information on the loss to follow-up was provided, but it would appear that utility data were missing for 10% of the sample (and were estimated using a multiple imputation approach).

Analysis of effectiveness
It was not stated whether the analysis of the clinical study was conducted on an intention to treat basis. The main outcome measures used in the current study were the Oswestry disability index (a questionnaire designed to assess limitations of various ADL) and utility scores. The baseline comparability of the study groups was not stated.

Effectiveness results
The results of the analysis of effectiveness were not reported.

Clinical conclusions
The authors did not draw any specific conclusions from the clinical analysis.

Measure of benefits used in the economic analysis
The summary benefit measure used was the quality-adjusted life-years (QALYs). The EuroQol EQ-5D social tariff (estimated from a representative sample of the UK population) was used to convert patients’ responses to the EuroQol EQ-5D questionnaire at follow-up assessments into single utility levels. An annual discount rate of 3.5% was applied.

Direct costs
Discounting was relevant since the costs were incurred during two years, and an annual discount rate of 3.5% was applied. The quantities of resources used were presented, whereas details of the unit costs were not. The health services included in the economic evaluation were SSS, IR and other back pain-related contacts. SSS covered the operating theatre, surgical implants, and intra-operative spinal X-rays. IR covered staff, hydrotherapy sessions, exercise equipment, hospital gym, meeting room and overnight accommodation. Other back pain-related contacts covered attendances at hospital outpatient clinics, and visits to and home visits from general practitioners and practice nurses. Paid employment was also considered, but was not included in the cost analysis since the differences between the groups were not statistically significant. Patient costs (i.e. those associated with private complementary practitioners and over-the-counter medications) were also included. The cost/resource boundary of the National Health Service (NHS) was adopted. Resource use was estimated using patient-level data derived from the sample of patients included in the clinical trial. The costs came mainly from national average rates, with local data being used for some items. The costs were expressed using 2002-2003 values.

Statistical analysis of costs
Statistical analyses were carried out to test the statistical significance of differences in costs between the groups. A multiple imputation method was used to assess missing resource use data. Arithmetic means and confidence intervals (CIs) were presented. The authors stated that skewness in the cost data was modest, thus conventional parametric CIs were reported.

Indirect Costs
The indirect costs were not considered in the economic evaluation.
Currency
UK pounds sterling (\).

Sensitivity analysis
Univariate sensitivity analyses were carried out to examine the robustness of the cost-utility ratios to variations in the unit costs, discount rate, utility values, surgical approaches and long-term management of patients. A bootstrapping approach with 1,000 iterations was used to derive the CIs around the cost-utility ratios.

A cost-effectiveness acceptability curve was constructed to show the probability that surgery was cost-effective at two years for different values of the NHS's willingness-to-pay for an additional QALY.

Estimated benefits used in the economic analysis
The average estimated QALYs were 1.004 (+/- 0.405) with SSS and 0.936 (+/- 0.431) with IR. The difference was 0.068 (CI: -0.02 - 0.156; p=0.13) in favour of SSS.

Cost results
The total NHS costs were 7,718 (+/- 5,138) with SSS and 4,419 (+/- 4,026) with IR. The difference was 3,299 (CI: 2,322 - 4,267; p<0.001).

Back pain-related costs were 112 (+/- 350) with SSS and 107 (+/- 502) with IR. The difference was 5 (CI: -86 - 96; p not significant).

The total costs of care were 7,830 (+/- 5,202) with SSS and 4,526 (+/- 4,155) with IR. The difference was 3,304 (CI: 2,317 - 4,291; p<0.001).

Synthesis of costs and benefits
An incremental cost-utility ratio was calculated to combine the costs and benefits of the two strategies under examination.

The incremental cost per QALY with SSS over IR was 48,588 (CI: -279,883 - 372,406). The cost-effectiveness acceptability curve showed that at two years, the probability that SSS would be cost-effective (NHS's willingness-to-pay of 30,000 per QALY) was less than 20%.

The sensitivity analysis showed that the base-case results were robust to variations in the unit costs and discount rates. Under the assumption that any patient in the trial receiving surgery underwent posterolateral fusion (the least costly technique), the incremental cost per QALY fell to 35,338 (-188,876 - 410,404).

If the difference in utility observed at 24 months was maintained for a further two years, the incremental cost per QALY at four years would fall to 25,398 (13,121 - 75,916). Under the assumption that patients in each arm would continue to receive both treatments in years three, four and five at the rates observed in years one and two, the cost per QALY fell to 16,824 (-156,358 - 138,911).

Authors' conclusions
A strategy of using spinal fusion surgery as first-line therapy for patients with chronic back pain (CBP) was not cost-effective at the 2-year follow-up. However, the analysis showed that surgical stabilisation of the spine (SSS) might be cost-effective if the proportion of rehabilitation patients requiring subsequent surgery continued to increase.

CRD COMMENTARY - Selection of comparators
The authors did not provide a specific justification for the choice of the comparators, which were the two strategies...
being evaluated in the primary clinical trial. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**

The clinical evidence came from a clinical trial, which was appropriate for the study question. There were limited data on the design of the trial and characteristics of the patient sample since the clinical trial had already been published. Thus, it was difficult to assess the validity of the primary study. However, the use of a randomised and multi-centre design should ensure the robustness of the study. Further, the study was powered to detect statistically significant differences between the groups with respect to one outcome measure. The results of the clinical end point assessment were not reported. The authors stated that the main strength of the analysis lay in the pragmatic approach adopted in the clinical trial.

**Validity of estimate of measure of benefit**

The summary benefit measure (QALYs) was appropriate because it considers the impact of the interventions on both quality of life and survival. Discounting was applied, as UK guidelines recommend. The utility weights were derived from the sample of patients included in the clinical analysis, and were then transformed into more generalisable measures using values from a representative sample of the UK population. No information on the survival component in the calculation of QALYs was provided.

**Validity of estimate of costs**

The costs included were consistent with the perspective adopted in the analysis. A detailed breakdown of the cost items was given. The source of the data was provided, and typical NHS sources were used. The unit costs were not reported, but extensive details on resource consumption were given. This should help in the replication of the cost analysis in other settings. Statistical analyses were performed and the cost estimates were varied in the sensitivity analysis. The price year was reported, which aids reflation exercises in other settings.

**Other issues**

The authors stated that other economic evaluations of interventions for CBP had been published. However, only one compared SSS with conservative treatment, and rehabilitation focused primarily on routine physiotherapy. The issue of the generalisability of the study results to other settings was implicitly addressed in the sensitivity analysis. The study referred to patients with CBP and this was reflected in the authors’ conclusions. A great variability in study results was observed, as reflected in the wide CIs for the estimated costs.

**Implications of the study**

The study results did not support the use of SSS for the management of patients with CBP. However, the availability of reliable long-term follow-up data could permit a more precise estimate of the cost-effectiveness of SSS.

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