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(Accepted 24 March 2005)

doi 10.1136/bmj.38441.620417.8F

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

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Abstract

Objective To determine whether from a health provider and patient perspective, surgical stabilisation of the spine is cost effective when compared with an intensive programme of rehabilitation in patients with chronic low back pain.
Design Economic evaluation alongside a pragmatic randomised controlled trial.
Setting Secondary care.
Participants 349 patients randomised to surgery (n = 176) or to an intensive rehabilitation programme (n = 173) from 15 centres across the United Kingdom between June 1996 and February 2002.
Main outcome measures Costs related to back pain and incurred by the NHS and patients up to 24 months after randomisation. Return to paid employment and total hours worked. Patient utility as estimated by using the EuroQol EQ-5D questionnaire at several time points and used to calculate quality adjusted life years (QALYs). Cost effectiveness was expressed as an incremental cost per QALY.
Results At two years, 38 patients randomised to rehabilitation had received rehabilitation and surgery whereas just seven surgery patients received had both treatments. The mean total cost per patient was estimated to be £7830 (SD £5202) in the surgery group and £4526 (SD £4155) in the intensive rehabilitation arm, a significant difference of £3304 (95% confidence interval £2317 to £4291). Mean QALYs over the trial period were 1.004 (SD 0.405) in the surgery group and 0.936 (SD 0.431) in the intensive rehabilitation group, giving a non-significant difference of 0.068 (−0.020 to 0.156). The incremental cost effectiveness ratio was estimated to be £48 588 per QALY gained (−£279 883 to £372 406).
Conclusion Two year follow-up data show that surgical stabilisation of the spine may not be a cost effective use of scarce healthcare resources. However, sensitivity analyses show that this could change—for example, if the proportion of rehabilitation patients requiring subsequent surgery continues to increase.

Introduction

The first UK based trial comparing surgical stabilisation of the spine with a programme of intensive rehabilitation, has shown a significant difference in the Oswestry disability index,[1] at two years in patients randomised to spinal fusion surgery compared with intensive rehabilitation.[2] This statistical difference between treatment groups in only one of the two primary outcome measures was marginal and only just reached the predefined minimal clinical difference. The potential risk and additional cost of surgery also need to be considered. No clear evidence emerged that primary fusion was any more beneficial than intensive rehabilitation. We report an economic evaluation of this trial. We employ a cost utility framework to determine whether any net health gain from using surgery would be sufficient to justify a likely increase in the costs of treatment. The chosen form of analysis will facilitate comparisons between the cost effectiveness of surgery and that of other healthcare interventions competing for healthcare resources.

Methods

Full details of the randomised controlled trial are published in parallel with this paper.[2] We recruited 349 patients who met trial eligibility criteria from 15 centres around the UK between June 1996 and February 2002. Of these patients, 176 were ran-

See also *Editorial* by Koes and p 1233

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BMJ 2005;330:1239–43

Additional details of the costing method, the participating units, and the members of the MRC steering committee are on bmj.com

This is the abridged version of an article that was posted on bmj.com on 23 May 2005: http://bmj.com/cgi/doi/10.1136/bmj.38441.429618.8F

domised to spinal fusion surgery and 173 to intensive rehabilitation.

For surgery patients, the local operating surgeon decided the type of spinal stabilisation used. Rehabilitation patients attended a paced exercise and education programme based on principles of cognitive behaviour therapy of about 75 hours' duration in total. We followed patients and collected back pain related NHS data and data on use of resources by patients to 24 months after randomisation. Patients who considered that their allocated treatment for chronic low back pain had failed could have further treatment including surgery. At baseline, six, 12, and 24 months, patients completed the EuroQol EQ-5D questionnaire, a generic health outcome instrument used to estimate utility scores[3] and quality adjusted life years (QALYs).

Resource use

Patient specific data on the use of NHS resources included initial treatments, other back pain related hospital inpatient and outpatient visits, primary care contacts, and prescribed items of medication. We also collected data on over the counter medications purchased and visits made to private practitioners. Unless otherwise indicated, we used national average unit costs. All costs calculated are expressed in 2002-3 pounds sterling, inflated to this base year where appropriate.[4]

Spinal fusion surgery

A "micro" approach to the costing of surgery used patient specific data itemised by use of resources. We costed duration spent by each patient in the operating theatre to allow for the time of staff involved and use of the theatre.[4 5] We used unit costs obtained from the lead investigating centre to value types and numbers of surgical implants and intraoperative spinal x rays.

We calculated costs for anaesthetic agents and blood products administered during each patient's surgery. Finally, we costed each patient's surgery related inpatient stay in hospital.[6]

Intensive rehabilitation

For each patient, we collected information on the number of half day rehabilitation sessions attended and applied staff costs per session.[4] Patients had one hydrotherapy session per day, valued by using a unit cost from the lead investigating centre. We costed exercise equipment, and use of the hospital gym and a meeting room by adding 15% (the overhead rate employed by the lead investigating centre) to staff, hydrotherapy, and equipment costs. Finally, we costed overnight accommodation at either a private bed and breakfast (paid for by the NHS) or on a hospital ward.

Other back pain related NHS contacts

Patients reported attendances at hospital outpatient clinics for spinal surgery, physiotherapy, and other back pain related care at six, 12, and 24 months, which we then costed. We used the mean cost of the initial fusion procedures (calculated as described above) to cost hospital admissions for unplanned spinal fusion surgeries. Admissions for investigations included the cost of the evaluative procedure (provided by the lead investigating centre) plus overnight hotel costs on a general medical ward. We costed visits to and home visits from general practitioners and practice nurses.[4] We used the average cost of a rehabilitation programme (calculated as described above) to cost any additional intensive rehabilitation.

Patients' costs

Patients reported contacts with private complementary practitioners, for which we obtained costs from relevant national organisations. Patients also documented items of medication prescribed, and the cost of over the counter medication purchased for back pain (see bmj.com for more details of costing methods).

Paid employment

Patients reported their employment status, occupation, and hours worked at baseline, six, 12, and 24 months. We calculated and costed total hours worked by each patient.[7]

Health related quality of life and quality adjusted life years

We used the EuroQol EQ-5D social tariff, estimated from a representative sample of the UK population, to convert patients' responses to the EuroQol EQ-5D questionnaire at baseline, six, 12, and 24 months into single utility levels.[8] We then constructed patient specific utility profiles, assuming a straight line relation between each of the patient's utility levels. We calculated the number of QALYs experienced by each patient from baseline to 24 months as the area beneath this profile.

Discounting

We discounted costs and effects at an annual rate of 3.5%.

Statistical analysis

A small amount of trial data (12% of follow-up resource use items, 10% of utility scores, and 14% of work status data) were missing between baseline and 24 months. We used multiple imputation to replace missing values (see bmj.com).

We carried out incremental analysis, with the mean cost difference between surgery and rehabilitation divided by the mean QALY difference to give the incremental cost effectiveness ratio (ICER) and the non-parametric percentile method for calculating the confidence interval around this ratio. We used the cost effectiveness acceptability curve to show the probability that surgery is cost effective at two years for different values of the NHS's willingness to pay for an additional QALY.

Results

Surgery—Procedures were divided into three different groups: posterolateral fusion (n = 57), 360° fusion (n = 57), and Graf stabilisation (n = 25). Table 1 presents data on use of surgical resources and cost, averaged across all 139 patients who had surgery. The mean total cost of a spinal operation was estimated at £7610 (SD £2643). Zero surgery costs were assigned to the 37 patients who did not have spinal fusion and an average treatment cost of £6011 (SD £3896) calculated across all surgery patients.

Intensive rehabilitation—Table 1 shows a breakdown of the mean total cost of intensive rehabilitation among the 151 patients who attended rehabilitation. The total cost was estimated to be £1615 (SD £644). Including zero rehabilitation programme costs for the

Table 1 Breakdown of resource use and costs associated with initial treatments (in 2002-3 pounds sterling)

	Mean (SD) resource use per patient*		Mean cost per patient (SD)*	
Resource use item	**Surgery (n=139)**	**Rehabilitation (n=151)**	**Surgery (n=139)**	**Rehabilitation (n=151)**
Surgical stabilisation				
Duration in theatre in minutes	182 (76)	N/A		
Costs related to theatre duration				
Cost of theatre per se			£204 (£85)	N/A
Cost of theatre personnel			£2635 (£1409)	N/A
Cost of anaesthetics†			£24.07 (£29.55)	N/A
Radiography‡	0.69 (1.06)	N/A	£18.39 (£24.48)	N/A
Surgical implants used	96%§	N/A	£1703 (£1589)	N/A
Blood products used	18%§	N/A	£77.79 (£241)	N/A
Surgery related inpatient hospital stay in days	7.70 (3.13)	N/A	£2933 (£1192)	N/A
Mean total cost of a surgical stabilisation operation¶			£7610 (£2643)	N/A
Intensive rehabilitation				
Number of half day rehabilitation sessions attended	N/A	26.32 (6.94)		
Costs related to session attendance				
Cost of programme personnel			N/A	£513.79 (£135.51)
Cost of hospital gym or exercise rooms			N/A	£223.70 (£59)
Cost of hydrotherapy sessions			N/A	£526.36 (£138.82)
Accommodation required	N/A	36.5%§	N/A	£350.81 (£506.99)
Mean total cost of a course of intensive rehabilitation**			N/A	£1615 (£644)
Mean total cost of interventions			£6011 (£3896)††	£1410 (£808)††

N/A=Not applicable.
*Calculated for 139/176 surgery patients and 151/173 rehabilitation patients receiving allocated therapy.
†Includes cost of administering and monitoring anaesthetics.
‡Includes cost of radiography plus a 30 minute allocation of radiographer time.
§Proportion of patients consuming resource.
¶Includes low cost items not shown in the table—that is, use of image intensifier and post-operative pain control costing £0.20 and £14.82 per patient, respectively.
** Includes low cost item not shown in table—that is, exercise equipment (chair and mat) at £0.74 per patient.
††Calculated across all 176 surgery patients and all 173 rehabilitation patients.

22 patients who did not attend, averaging across all 173 patients generated a cost estimate of £1410 (SD £808). Intensive rehabilitation was substantially less costly than surgery (cost difference £4601, 95% confidence interval £4013 to £5189, $P<0.001$).

Other back pain related NHS costs

Forty eight patients randomised to rehabilitation underwent surgical stabilisation of the spine—10 instead of rehabilitation, 38 in addition to rehabilitation. These unplanned surgery costs averaged £2128 per patient across the rehabilitation group (see bmj.com). This was greater than the corresponding cost of £451 in the surgery group, which was primarily attributable to 11 patients who required spinal re-operations.

Fourteen surgery patients underwent unplanned intensive rehabilitation (seven instead of surgery, seven as well as surgery). These costs amounted to £162 per patient. The overall mean cost per patient of follow-up back pain related NHS contacts was £1302 lower in the surgery group (95% confidence interval −£1999 to −£605, $P<0.001$).

Patient costs

Patient costs related to back pain were similar in both arms (see bmj.com).

Overall costs

Table 2 shows costs at two years, with the cost difference favouring intensive rehabilitation.

Return to work

See bmj.com for comparisons of paid employment, hours worked and gross earnings between the surgery group and rehabilitation group; differences were all non-significant.

Utility

We found no significant differences in utility at any of the follow-up points (fig 1). A notable difference in utility existed at baseline (0.35 for surgery, 0.41 for rehabilitation). Adjusting for such a difference produced a mean QALY difference in favour of surgery of 0.068 (−0.02 to 0.156, $P=0.13$; mean 1.004 (SD 0.405) for surgery and 0.936 (SD 0.431) for rehabilitation).

Cost utility

The incremental cost per QALY of using a policy of immediate surgery was estimated to be £48 588 (−£279 883 to £372 406). Figure 2 shows the cost effectiveness acceptability curve. If decision makers are willing to pay £30 000 for a QALY (the value above which the National Institute for Clinical Excellence is less likely to accept a technology as cost effective[9]), at

Table 2 Summary of initial treatment and 24 month follow-up costs (2002-3 pounds sterling)

	Surgery group (n=176)	Rehabilitation group (n=173)	Mean cost difference (95% parametric CI)
Cost category	**Mean (SD) cost per patient**	**Mean (SD) cost per patient**	
Initial treatment cost	£6011 (£3896)	£1410 (£808)	£4601 (£4013 to £5189)*
Other back pain related NHS contacts at 24 months	£1707 (£2451)	£3009 (£4001)	–£1302 (–£1999 to –£605)*
Total NHS cost	£7718 (£5138)	£4419 (£4026)	£3299 (£2322 to £4267)*
Back pain related patient costs at 24 months	£112 (£350)	£107 (£502)	£5 (–£86 to £96)
Total cost of care	£7830 (£5202)	£4526 (£4155)	£3304 (£2317 to £4291)*

*P<0.001.

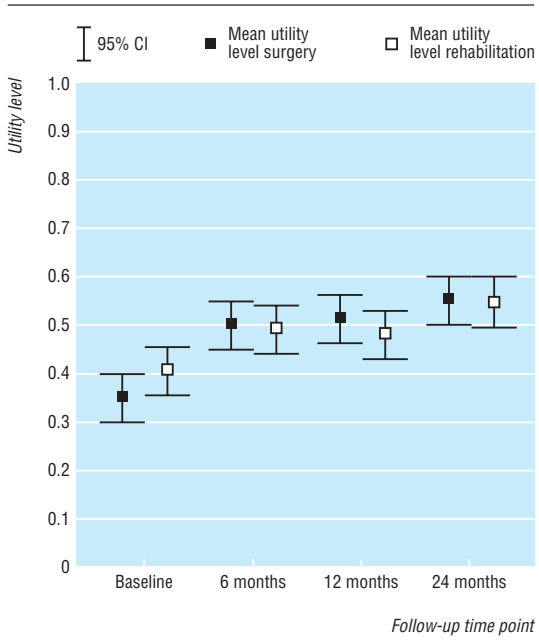

Fig 1 Mean utility levels (with 95% confidence intervals) generated by applying the EuroQol EQ-5D social tariff to patients' self reported health state descriptions

What is already known on this topic

An economic evaluation of surgery for chronic low back pain that used unspecified physical therapy as the comparator indicated that surgery may be cost effective

A small trial reported that an intensive rehabilitation programme including cognitive behaviour therapy produced similar clinical benefits to spinal fusion surgery

The cost effectiveness of surgery compared with such a programme has not been assessed

What this study adds

In the short term, compared with intensive rehabilitation, surgical stabilisation of the spine as first line treatment for chronic low back pain patients who have already failed standard non-operative care seems not be cost effective

If the number of rehabilitation patients observed having surgery continues to increase beyond two years, or the small treatment benefit at two years continues, this conclusion may change

two years, the chance that surgery will be cost effective is less than 20%.

Sensitivity analysis

We used sensitivity analysis to examine uncertainty surrounding the use of different surgical techniques for spinal stabilisation. Assuming any patient in the trial receiving surgery underwent posterolateral fusion, the least costly technique at £6170, the incremental cost per QALY would fall to £35 338 (−£188 876 to £410 404). Alternatively had all patients undergone 360° fusion, the most costly technique at £9279, the incremental cost per QALY would rise to £60 765 (−£420 210 to £617 081).

If the difference in utility observed at 24 months (0.566 for surgery and 0.532 for rehabilitation after adjustments for baseline) was maintained for a further two years, the incremental cost per QALY at four years would fall to £25 398 (£13 121 to £75 916).

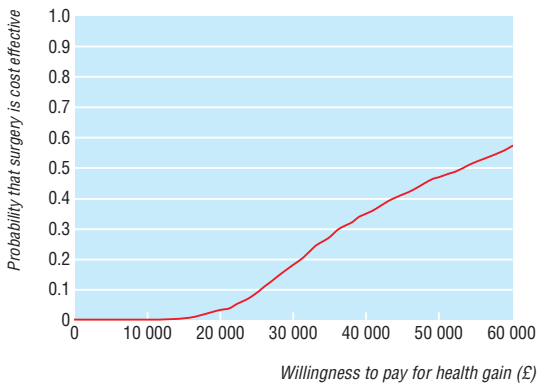

Fig 2 Cost effectiveness acceptability curve showing the probability that surgery is cost effective for different ceilings of willingness to pay

We also examined the impact of patients receiving other treatments subsequent to their allocated therapy. At two years, 45 patients had received both treatments. Holding all else constant and assuming 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 difference is reduced to £1144 (−£312 to £2600) and the cost per QALY to £16 824 (−£156 358 to £138 911). If the trend continued but at half the rate observed in years one and two, the excess cost of the surgery arm at five years would fall to £2165 (£904 to £3425) and the cost per QALY to £31 838 (−£407 056 to £283 783).

Discussion

A policy in which patients receive spinal fusion surgery as first line therapy for their chronic low back pain seems not to be a cost effective use of healthcare resources at two year follow-up.

Strengths of the study

The main strength lies in the pragmatic approach adopted by the randomised controlled trial. Patients were not denied alternative healthcare interventions for chronic pain of the low back, so treatment patterns observed are likely to reflect those prevailing in routine practice.

At 24 months, the numbers of patients receiving both trial interventions differed significantly between the two arms. It is possible that this difference will increase beyond the two year follow-up point, and sensitivity analyses have shown that this could substantially affect the cost effectiveness of surgery.

Only one other economic evaluation has compared operative and conservative treatment,[10] but rehabilitation included in that study focused primarily on routine physiotherapy.

Conclusion

Although a policy of spinal fusion surgery as first line therapy for chronic low back pain seems not to be a cost effective use of healthcare resources at two year follow-up, our analyses have shown that this conclusion could alter if the number of rehabilitation patients subsequently receiving surgery continues to increase in the future.

We thank the patients who permitted a difficult decision to be made for them, physiotherapists and surgeons both inside and outside the trial who helped develop the protocol and made the study possible, Anthony Morton for provision of unit costs, the Medical Research Council for supporting the study, and the NHS R&D programme (especially Richard Lilford) for supporting and promoting the study.

Contributors: See bmj.com

Funding: This study was supported by the UK Medical Research Council. The NHS (326) or private patient insurance (23) funded the treatment of patients. The Health Economics Research Centre is partly funded by the National Coordinating Centre for Research Capacity Development. JF and JW-M receive funding from Synthes for a spinal fellow.

Competing interests: None declared.

Ethical approval: Granted by 15 local research ethics committees and one multicentre research ethics committee.

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(Accepted 29 March 2005)

doi 10.1136/bmj.38441.429618.8F

Systematic review and meta-analysis of studies of the timing of tracheostomy in adult patients undergoing artificial ventilation

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Abstract

Objective To compare outcomes in critically ill patients undergoing artificial ventilation who received a tracheostomy early or late in their treatment.
Data sources The Cochrane Central Register of Clinical Trials, Medline, Embase, CINAHL, the National Research Register, the NHS Trusts Clinical Trials Register, the Medical Research Council UK database, the NHS Research and Development Health Technology Assessment Programme, the British Heart Foundation database, citation review of relevant primary and review articles, and expert informants.
Study selection Randomised and quasi-randomised controlled studies that compared early tracheostomy with either late tracheostomy or prolonged endotracheal intubation. From 15 950 articles screened, 12 were identified as "randomised or quasi-randomised" controlled trials, and five were included for data extraction.
Data extraction Five studies with 406 participants were analysed. Descriptive and outcome data were extracted. The main outcome measure was mortality in hospital. The incidence of hospital acquired pneumonia, length of stay in a critical care unit, and duration of artificial ventilation were also recorded. Random effects meta-analyses were performed.
Results Early tracheostomy did not significantly alter mortality (relative risk 0.79, 95% confidence interval 0.45 to 1.39). The risk of pneumonia was also unaltered by the timing of tracheostomy (0.90, 0.66 to 1.21). Early tracheostomy significantly reduced duration of artificial ventilation (weighted mean difference −8.5 days, 95% confidence interval −15.3 to −1.7) and length of stay in intensive care (−15.3 days, −24.6 to −6.1).
Conclusions In critically ill adult patients who require prolonged mechanical ventilation, performing a tracheostomy at an earlier stage than is currently practised may shorten the duration of artificial ventilation and length of stay in intensive care.

Introduction

Tracheostomy is among the most commonly conducted procedures in critically ill patients. However, the procedure is not without risk, and the effect of its timing on outcome is not clear.[1–3]

Evidence to guide practice has been limited. In 1989 the National Association of Medical Directors of Respiratory Care recommended that a tracheostomy should be placed in patients who still require artificial ventilation 21 days after admission.[4] Although this recommendation is based only on expert opinion,

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BMJ 2005;330:1243–6

ELPS *This is the abridged version of an article that was posted on bmj.com on 18 May 2005: http://bmj.com/cgi/doi/10.1136/bmj.38467.485671.E0*