Function after spinal treatment, exercise and rehabilitation (FASTER): cost-effectiveness analysis based on a randomised controlled trial

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STRUCTURED ABSTRACT

Study design Cost-effectiveness analysis alongside a factorial randomized controlled trial.

Objective To assess the cost-effectiveness of a rehabilitation [\(rehab\)](#) program and/or an education booklet each compared with usual care for the postoperative management of patients undergoing discectomy or lateral nerve root decompression surgery.

Summary of Background Data There is little knowledge about the cost-effectiveness of postoperative management of patients following spinal surgery.

Methods Three hundred and thirty-eight patients were recruited into the study between June 2005 and March 2009. Patients were randomized to rehab only, booklet only, rehab plus booklet, or usual care only. Interactions between booklet and rehab were non-significant, hence we compare booklet versus no booklet and rehab versus no rehab. We adopt an English National Health Service (NHS) and personal social services perspective. Data on outcomes and costs are based on patient level data from the trial. A one year time horizon was used. Outcomes were measured in terms of quality-adjusted life years (QALYs). Health-related quality of life was reported by patients using the EQ-5D. A comprehensive range of health service contacts were included in the cost analysis.

Results There were no significant differences in costs or outcomes associated with either intervention. Mean incremental costs and mean QALYs gained per patient of booklet versus no booklet were -£87 (95% CI, -£1221 to £1047) and -0.023 (95% CI, -0.068 to 0.023), respectively. Figures for rehab versus no rehab were £160 (95% CI, -£984 to £1304) and 0.002 (95% CI, -0.044 to 0.048), respectively. Neither intervention was cost-effective when compared with the threshold range commonly used to judge whether or not an intervention is cost-effective in the English NHS.

Conclusions

Cost-effectiveness evidence does not support use of booklet over no booklet or rehab over no rehab for the postoperative management of patients following spinal surgery.

KEY WORDS

Cost-effectiveness; postoperative management; rehabilitation; education; spinal surgery; factorial design; randomized controlled trial

KEY POINTS

- There is little knowledge about the cost-effectiveness of postoperative management of patients following spinal surgery.
- We undertook a cost-effectiveness analysis of a rehabilitation programme and an education booklet for the postoperative management of patients undergoing spinal surgery.
- We found that there were no significant differences in costs or benefits associated with either intervention compared with not receiving that intervention.
- Neither intervention was cost-effective when compared with the threshold range commonly used to judge whether or not an intervention is cost-effective in the English NHS.

MINI ABSTRACT

We undertook a cost-effectiveness analysis of a rehabilitation programme and an education booklet for the postoperative management of patients following spinal surgery. There were no significant differences in costs or benefits with either intervention, and neither was cost-effective when compared with the cost-effectiveness threshold commonly used in the English NHS.

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INTRODUCTION

There is considerable variation in the use, type and intensity of rehabilitation after spinal surgery.¹ This may be due to the small evidence base, which has led to clinical uncertainty about appropriate practice.¹ For example, while there have been several clinical trials of postoperative rehabilitation in patients undergoing spinal surgery it remains unclear as to what the exact components of such a rehabilitation programme ought to be.²

While a lack of efficacy data has led to calls for further clinical trials, it has also been suggested that further research is required to assess the cost-effectiveness of rehabilitation after surgery.² A small number of studies have investigated this issue. A brief review of the National Health Service (NHS) Economic Evaluations Database³ undertaken by the authors revealed several studies investigating the cost-effectiveness of rehabilitation for back pain patients, but few that considered postoperative management.^{4,5}

In a multicentre factorial randomized controlled trial – Function after spinal treatment, exercise and rehabilitation (FASTER) – we compared the effectiveness of a rehabilitation program and/or an education booklet for the postoperative management of patients undergoing discectomy or lateral nerve root decompression surgery each compared with usual care. The study found that neither intervention had a statistically significant impact on functional outcomes at 12 months. In resource-constrained health care systems considerations of cost-effectiveness are relevant,⁶ even when an intervention does not show significant improvements in outcomes.⁷ For instance, an intervention may be no more or less effective than an alternative but it may be less costly, and thus represent good value for money. The aim of this study was therefore to assess the cost-effectiveness of the rehabilitation program and the education booklet based on data from the FASTER trial.

METHODS

The FASTER trial compared the effectiveness of a rehabilitation program (hereafter “rehab”) and an education booklet (“booklet”) for the postoperative management of patients undergoing discectomy or lateral nerve root decompression surgery, each compared with usual care, using a 2x2 factorial design. Patients were randomized to one of four groups: rehab only; booklet only; rehab plus booklet; and, usual care only. The primary outcome measure was the Oswestry Disability Index (ODI, v2.1a).^{8,9} The trial was powered to detect a between-group difference of 8 points in ODI at one year after surgery. We recruited 338 patients into the study who met the trial eligibility criteria from seven centers in London, UK between June 2005 and March 2009.

The education intervention consisted of [an](#) educational booklet,¹⁰ which was given to patients on discharge from hospital following surgery. The rehab intervention consisted of an exercise program that began six to eight weeks after surgery. The program comprised 12 one hour classes run twice weekly by an experienced physiotherapist. The classes were standardized to a set agreed protocol with clear exercises and progression. They included general aerobic fitness work, stretching, stability exercises, strengthening and endurance training for the back, abdominal and leg muscles, ergonomic training, advice on lifting and setting targets, and self-motivation along with an open group discussion at the end of each class where problems and concerns could be discussed with the therapist. Patients receiving usual care were managed according to the relevant surgeon’s usual practice. Patients receiving rehab and/or the booklet also received usual care. Previous work has shown that usual care varies considerably, and is typically limited.^{1,11}

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The study found that neither intervention had a statistically significant impact on functional outcomes at 12 months. Since the study was not powered to show equivalence it is inappropriate to conduct a cost-minimization analysis.⁷ Hence, we undertook a cost-effectiveness analysis of both interventions, measuring outcomes in terms of quality-adjusted life years (QALYs) and cost-effectiveness in terms of the incremental cost per QALY gained.

We found no evidence of statistically significant interactions between booklet and rehab (McGregor, Doré, Morris et al, submitted). Utilising the factorial design, we therefore calculated the cost-effectiveness of booklet versus no booklet and rehab versus no rehab. For the main analysis we adopt an English National Health Service (NHS) and personal social services perspective to measure costs and outcomes. We also calculate private (patient) costs. Evidence on outcomes and costs was based on patient level data from the trial. Health-related quality of life was reported directly by patients in the trial using the EQ-5D.¹² A one year time horizon was used, corresponding to the length of follow-up in the trial. Given the time horizon discounting was not applied. All costs are presented in UK£2008/9 (UK£1=US\$1.58205=€1.15295).¹³

Measuring health-related quality of life and quality adjusted life years

None of the patients died during the trial. Health-related quality of life described using the EQ-5D was reported directly by patients in the trial pre-operatively (baseline) and then at six weeks, three months, six months, nine months and 12 months post surgery. EQ-5D states were converted to utility scores using an EQ-5D social tariff estimated from a representative sample of the UK population.¹⁴ Using these values we constructed patient specific utility profiles, assuming a straight line relation between each of the patient's utility levels at each time point. We calculated the number of quality-adjusted life years (QALYs) experienced by each patient from baseline to 12 months as the area beneath this profile.

Measuring costs

The intervention costs included the cost of the booklet and staff costs for the rehab classes, which did not vary by patient.

The following NHS contacts were included in the cost analysis: inpatient stays; day cases; outpatient attendances; A&E attendances; GP surgery visits; GP home visits; GP telephone calls; nurse home visits; nurse surgery visits; nurse telephone calls; physiotherapy sessions. We ~~also~~—included the use of prescribed medications. We ~~also~~—measured private contacts (physiotherapy sessions, osteopathy sessions, chiropractor sessions), as well as the use of over the counter medications.

The number of NHS and private contacts related to the patients' back surgery were collected via five sets of resource diaries, which were prospectively completed by patients and collected at each follow-up point. They covered weeks 1-6 and 7-12, and months 3-6, 7-9 and 10-12 post surgery. Patients ~~also~~—recorded details of the quantities of medications they took that related to their back surgery, including the name of the drug taken, the dosage, the amount consumed per day, the number of days the drug was taken, and whether the drug was prescribed by their doctor or bought over the counter. Patients were ~~also~~—invited to record any other contacts over the period that related to their back surgery. The most common of these were acupuncture (recorded by 4 patients), hydrotherapy (3 patients) and occupational therapy (2 patients); due to small numbers these contacts were not included in the analysis.

Unit costs were obtained from standard published sources supplemented with previous published estimates.¹⁵⁻²⁰

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No costs were assumed to be incurred for usual care over and above those included in the NHS and private contacts.

We summed the number of contacts at each follow-up period, applied unit costs, and calculated mean contacts and costs per patient in each of the four study groups (usual care, booklet, rehab, booklet & rehab) to 12 months post surgery. ~~We identified medications taken and their quantities from the patient diaries and applied unit costs using the lowest recorded prices where more than one was available. We multiplied the quantities of medications recorded by patients by their published unit costs, using the lowest price where a range was available.~~

Statistical analysis

There were missing data at each follow-up point (EQ-5D data, 1%, 24%, 27%, 29%, 31% and 8% of patients had missing data at baseline, 6 weeks, and 3, 6, 9 and 12 months, respectively; contacts, 34%, 30%, 32%, 35% and 23%, for weeks 1-6 and 7-12, and months 3-6, 7-9 and 10-12, respectively 23%–35%). Multiple imputation by chained equations²¹ was used to deal with missing values. For EQ-5D data the imputation model included baseline and follow up values, intervention group, recruiting centre, type of surgery, weight, height, sex and age. Values were imputed 10 times. QALYs were calculated from the imputed EQ-5D data. For contacts data the imputation model included values for each contact at other time points. The model also included total contacts over the 12 month period, which were imputed as a function of contacts at each time point plus age, gender, economic activity status and primary and secondary study outcomes. Values were imputed 100 times; the number of imputations was higher than for the EQ-5D data because there were a higher proportion of missing values. Means of the imputed values for each patient were calculated and analyzed. Complete cases were analyzed to verify

Comment [a1]: Slight confused by the 2 rates, I guess this is because EQ5-D was completed more often than cost sheet should we mke this clearer?

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that imputed values were consistent. Standard errors around the mean imputed values were calculated accounting for the additional uncertainty in the patient level data arising from the use of imputed values.²²

We tested for mean differences in EQ-5D score at each time point, QALYs at 12 months, and 12 month costs for each cost component using ordinary least squares regression. We regressed each variable against treatment group (booklet versus no booklet and rehab versus no rehab simultaneously; an interaction term for booklet and rehab was ~~originally~~ initially included but statistical tests indicated that this was non-significant), adjusting for type of surgery and surgeon.

Cost-effectiveness was measured in terms of the incremental cost per QALY gained of booklet versus no booklet and rehab versus no rehab. This was calculated as the difference in adjusted mean costs between booklet versus no booklet and rehab versus no rehab (the incremental cost) divided by the difference in adjusted mean QALYs (the incremental effectiveness). See Supplemental Digital Content for further explanation.

We represented uncertainty due to sampling variation in the cost-effectiveness ratios using non-parametric bootstrapping, presented graphically on the cost-effectiveness plane. We generated 1,000 bootstrap replications of the cost-effectiveness ratios and used these to construct 95% confidence ellipses.²³ We also constructed cost-effectiveness acceptability curves, based on the proportion of the replications that had positive net benefit values as the cost-effectiveness threshold was increased from £0-£50,000.²³ We did not calculate confidence intervals around the base case cost-effectiveness estimates because the bootstrapped cost-effectiveness ratios were spread over all four quadrants of the cost-effectiveness plane and the cost-effectiveness ratio has discontinuities at the boundaries between different quadrants.²⁴

RESULTS

The mean costs per patient of the booklet and rehab interventions were £3.50 and £131, respectively (see Supplemental Digital Content). Mean NHS and private contacts and costs per patient to 12 months post-surgery by treatment group are in Table 1. Mean EQ-5D scores and QALYs per patient by treatment group are in Table 2.

Differences in NHS and private costs, EQ-5D at each time point and QALYs per patient to 12 months post-surgery for each intervention compared with no intervention are in Table 3. The interaction tests (final column) indicate no statistically significant interactions between booklet and rehab for any of the variables. We therefore calculated the cost-effectiveness of booklet versus no booklet and rehab versus no rehab. There are no significant differences in mean costs between booklet and no booklet and-or between rehab and no rehab with respect to any of the types of contact, nor were there any differences with respect to EQ-5D scores at each time point.

There were no significant differences in mean NHS costs or mean QALYs per patient associated with either intervention. The mean incremental NHS cost per patient of booklet versus no booklet was -£87 (95% CI -£1221 to £1047); while non-significant the point estimate was *negative* indicating that booklet was *less* costly than no booklet. The mean QALYs gained per patient were -0.023 (95% CI -0.068 to 0.023); booklet was *less* effective than no booklet. Analogous figures for rehab versus no rehab were £160 (95% CI -£984 to £1,304), (rehab was *more* costly than no rehab) and 0.002 (95% CI -0.044 to 0.048) (rehab was *more* effective than no rehab), respectively.

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The incremental costs per QALY gained of booklet versus no booklet and rehab versus no rehab were £3,852 ($= -£87/-0.023$) and £82,817 ($=£160/0.002$), respectively. ~~Both interventions are not cost-effective when compared with the £20-£30,000 threshold range judged by the National Institute for Health and Clinical Excellence in England to be acceptable for use in the NHS.⁶ This is because rehab is more costly and more effective than no rehab and the cost-effectiveness ratio is higher than the threshold; booklet is less costly and less effective than no booklet and the cost-effectiveness ratio is lower than the threshold.~~

While there is uncertainty surrounding some of the cost variables included in the analysis, varying the values within plausible limits does not change the results appreciably. If the costs of the booklet and rehab interventions are both increased by 50% then the incremental costs per QALY gained of booklet versus no booklet and rehab versus no rehab were £3,775 and £116,719, respectively. If the intervention costs are reduced by 50% then the incremental costs per QALY gained were £3,930 and £48,914, respectively. If the costs of the NHS contacts are all increased by 50% then the incremental costs per QALY gained were £4,853 and £77,034, respectively, and if they are all reduced by 50% then they were £2,852 and £88,600, respectively.

The bootstrapped incremental cost effectiveness ratios and 95% cost-effectiveness ellipses are in Figure 1. In the analysis of booklet versus no booklet, the 1,000 bootstrap replications fall mainly in the bottom left quadrant of the cost-effectiveness plane (booklet is less costly and produces fewer QALYs than no booklet; 45% replications) and the top left quadrant (more costly, fewer QALYs; 39% replications), with 2% in the top right quadrant (more costly, more QALYs) and 14% in the bottom right quadrant (less costly, more QALYs) (Figure 1(a)). For rehab versus no rehab analogous figures are: bottom left quadrant, 8% replications; top left

quadrant, 34% replications; top right quadrant, 36%; and, bottom right quadrant, 23% (Figure 1(b)).

Based on the cost-effectiveness acceptability curves (Figure 2), and reading off the height of the curves on the y-axis at the desired threshold values on the x-axis, if the English NHS was willing to pay an extra £20,000–£30,000⁶ for an additional QALY then booklet would be cost-effective relative to no booklet in 25%–29% of situations in this patient group (Figure 2(a)) and rehab would be cost-effective relative to no rehab in 43%–47% of situations (Figure 2(b)).

DISCUSSION

There is little knowledge about the cost-effectiveness of postoperative management of patients following spinal surgery.² We investigated the cost-effectiveness of a rehabilitation program and an education booklet for the postoperative management of patients undergoing discectomy or lateral nerve root decompression surgery, both compared with usual care, using data from a factorial randomized controlled trial.

Our main finding is that neither intervention is cost-effective when compared with the £20-£30,000 threshold range judged by the National Institute for Health and Clinical Excellence in England to be acceptable for use in the NHS.⁶ are, in the case of booklet versus no booklet, that the mean incremental NHS cost per patient was -£87 and the mean QALYs gained per patient were -0.023; neither of these differences was statistically significant. The incremental cost per QALY gained was £3,852. Based on the cost-effectiveness acceptability curves, if decision makers in the English NHS were willing to pay an extra £20,000-£30,000 for an additional QALY then the chance that booklet would be cost-effective relative to no booklet is less than 30%. These findings suggest that booklet does not represent value for money

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1 compared with no booklet in the English NHS. Note that since booklet is *less* costly and *less*
2 effective than no booklet then for it to be considered good value for money it is necessary that
3 the cost-effectiveness ratio is *higher* than the cost-effectiveness threshold range, so that
4 reductions in effectiveness are achieved at the gain of relatively large reductions in costs. We
5 assume by applying the cost-effectiveness threshold in this way that it is not 'kinked', i.e., ~~we~~
6 ~~assume~~—that individual preferences for equal gains and losses are symmetrical— the cost-
7 effectiveness threshold in situations where incremental costs and effects are both negative (less
8 costly, less effective) is no different to the threshold in the more usual situation where they are
9 both positive (more costly, more effective). Some have suggested, based on empirical studies of
10 consumer's willingness to pay and willingness to accept, that the threshold is kinked, reflecting
11 different cost-effectiveness thresholds in different quadrants of the cost-effectiveness plane.²⁵
12 Others have rejected the validity of such preferences.²⁶

13
14 In the case of rehab versus no rehab the mean incremental NHS cost per patient was £160 and
15 the mean QALYs gained per patient were 0.002; as with booklet, neither of these differences
16 were statistically significant. The incremental cost per QALY gained was £82,817. The likelihood
17 that rehab would be cost-effective relative to no rehab is higher than for booklet versus no
18 booklet, but is still less than 50%. Since rehab is *more* costly and *more* effective than no rehab
19 then for it to be considered good value for money it is necessary that the cost-effectiveness ratio
20 is *lower* than the threshold, which it is not, suggesting that rehab does not represent good value
21 for money compared with no rehab in the English NHS.

22
23 Even though there are missing data the main strength of our cost-effectiveness analysis is the
24 quality of the cost and outcomes data. We collected patient level EQ-5D data at frequent
25 intervals during the trial, and we prospectively collected detailed patient level cost data for a
26 wide range of contacts. Further, the pragmatic approach adopted in the trial meant that patients

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were not denied health care interventions relating to their back surgery, and consequently the treatment patterns observed are likely to reflect those prevailing in routine practice.

A possible limitation of our analysis is that we take a 12 month time horizon only, based on the duration of follow-up in the trial. Had we shown significant differences in EQ-5D scores at 12 months, QALYs over the 12 month period, or costs over the 12 month period then limiting the analysis to a 12 month time horizon might have led us to over- or underestimate the cost-effectiveness of the interventions. However, since this was not the case we did not extend the time horizon beyond the end of the follow-up period of the trial. This assumes that no differences in costs or benefits will be observed after 12 months, which seems plausible given

that no differences were observed during the within-trial period. Another issue is that while our findings do not support the use of either intervention, we acknowledge that it may be the case that in sub-groups of patients the interventions are cost-effective. Given the number of patients in the study and the extent of missing data sub-group analyses of cost-effectiveness were not appropriate. Finally, while we investigated the cost-effectiveness of rehab versus no rehab, there are a number of approaches to postoperative rehabilitation following spinal surgery including individual physiotherapy sessions, group sessions encompassing self-directed approaches, and home-based self management interventions (McGregor, Doré, Morris et al, submitted). We investigated the cost-effectiveness of a six-week program based on group sessions led by a physiotherapist. In addition to having different impacts on outcomes, the cost implications may also differ between these types of rehabilitation. Thus, care must be taken in drawing conclusions about the cost-effectiveness of postoperative rehabilitation generally based on the findings presented in this study.

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- 1 Bearing these caveats in mind, our conclusion is that cost-effectiveness evidence does not
- 2 support use of booklet over no booklet or rehab over no rehab for the postoperative
- 3 management of patients following spinal surgery from the perspective of the English NHS.

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