A brief pain management program compared with physical therapy for low back pain: results from an economic analysis alongside a randomized clinical 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
The study examined a brief pain management (BPM) programme delivered by physiotherapists and a physical therapy programme (PT) involving spinal mobilisation techniques for the treatment of non-specific low back pain of less than 12 weeks' duration. The interventions consisted of one 40-minute assessment/treatment session, plus up to 6 subsequent 20-minute treatment sessions. The BPM programme focused on known psychosocial risk factors that were not taken into account in the PT programme.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The study population comprised adults aged 18 to 64 years presenting (for the first or second time) with an episode of non-specific low back pain of less than 12 weeks' duration.

Setting
The setting was primary care. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were derived from a study published in 2005. The costs were expressed as 2001/02 prices.

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

Study sample
Power calculations, if performed, were not reported. Of the 544 patients initially assessed for eligibility, 402 (74%) were finally included in the clinical study. There were 201 patients in each treatment group.

Study design
This was a prospective, randomised comparative trial, which was carried out in 28 general practices in North Staffordshire, UK. The length of follow-up was 12 months. The clinical outcomes were collected at baseline and 3 and 12 months by means of self-reported postal questionnaires. The responses were validated by a review of records in a
A randomly selected sample of 10% of the patients. The nurse running the validation was blinded to the self-report questionnaire data. In terms of the response rates, 284 (71%) patients completed the utility questionnaires at baseline and 3 and 12 months, while 329 (82%) patients provided disability scores at baseline and 12 months. There were no differences in response rates between the treatment groups, but non-responders were younger and more likely to be male.

Analysis of effectiveness
The clinical end points used in the analysis were utility values and back-related disability. Utility was measured using the EuroQol (EQ-5D) at baseline and 3 and 12 months. Disability was measured on the Roland and Morris disability questionnaire (RMDQ), a 24-item back pain-specific disability scale with scores ranging from 0 (best health) to 24 (worst health), and was expressed as changes between the baseline and 12-month scores. The authors did not report the baseline comparability of the study groups in terms of their demographics and other characteristics. Baseline EQ-5D and RMDQ scores were not statistically different between the groups, but the authors controlled the 12-month benefit results by baseline scores. The clinical analysis was conducted according to the principle of intention to treat. Missing data were imputed using multiple linear regression models.

Effectiveness results
No statistically significant differences in the two clinical end points were found. For example, the 12-month EQ-5D values were 0.770 (+/- 0.3) in the BPM group and 0.785 (+/- 0.3) in the PT group. The difference was -0.014 (95% confidence interval, CI: -0.08 to 0.05; p>0.05).

The change in RMDQ scores from baseline to 12-month follow-up was 8.709 (+/- 6.6) in the BPM group and 8.730 (+/- 7.3) in the PT group (difference -0.021, 95% CI: -1.39 to 1.35; p>0.05).

Clinical conclusions
The effectiveness analysis showed that the two interventions were similarly effective (not statistically significantly different), although slightly better results were found for the PT group.

Measure of benefits used in the economic analysis
Two summary benefit measures were used in the economic analysis. These were quality-adjusted life-years (QALYs) in the cost-utility analysis and improvements in RMDQ change score in the cost-effectiveness analysis. The two benefit measures were derived directly from the effectiveness analysis. Discounting was not necessary given the 12-month period of the analysis.

Direct costs
The viewpoint of the analysis was that of the health care system, which included both the public and the private sector. The cost categories in the analysis were treatment sessions (physiotherapist time), primary care contacts, inpatient episodes, outpatient attendances and consultations with other health care professionals. A breakdown of the cost items was given. The unit costs and the resource quantities were reported separately. Resource use was estimated from the sample of patients enrolled in the clinical trial. Resource use of the National Health Service (NHS) was costed as national averages, with inpatient and outpatient episodes being costed using the 2002 NHS reference costs. Private care was costed as the NHS equivalent. The British National Formulary was used to cost prescribed medication. Acupuncture costs were assumed to be equivalent to the costs of physiotherapy. Discounting was not relevant as 1-year costs were evaluated. The costs were expressed in 2001/02 prices.

Statistical analysis of costs
Missing data were imputed using multiple linear regression models.
Indirect Costs
Productivity costs were not included, although the number of days off work due to low back pain was recorded (and was similar between groups). However, this represented a secondary outcome of the study and was not costed.

Currency
UK pounds sterling (€).

Sensitivity analysis
CIs were defined for the costs and benefits using conventional parametric methods and bias-corrected and accelerated bootstrapping. The issue of uncertainty was investigated by generating 5,000 bootstrapped replications of mean differences in costs and benefits. An acceptability curve was generated only for the incremental cost-utility ratios, which evaluated the probability that the new intervention (BPM) would be cost-effective at specific cost-per-QALY thresholds. A conventional sensitivity analysis was performed to explore the robustness of the results of the analysis to variations in the cost of private health care, which are likely to exceed those of the NHS.

Estimated benefits used in the economic analysis
The expected QALYs (controlled for baseline values) were 0.755 in the BPM group and 0.777 in the PT group (difference -0.022; 95% CI: -0.07 to 0.02; p=0.35).

The expected RMDQ change scores (controlled for baseline values) were 8.553 in the BPM group and 8.887 in the PT group (difference -0.334, 95% CI: -1.49 to 0.82; p=0.57).

Cost results
The total health care costs per patient for observed data (n=299) were 158.11 (+/- 282.2) in the BPM group and 219.90 (+/- 449.6) in the PT group (difference -61.79; p=0.15).

The total health care costs per patient with imputed data (all patients) were 142.33 (+/- 261.3) in the BPM group and 194.52 (+/- 445.6) in the PT group (difference -52.19; p=0.15).

Synthesis of costs and benefits
An incremental analysis was performed to combine the costs and benefits of the alternative strategies.

The incremental cost per QALY gained with PT over BPM was 2,362.

Using a conservative threshold of 10,000 per QALY gained, the probability that BPM was cost-effective was only 17%. This suggested that there was an 83% chance that PT would be the preferred option.

The cost-effectiveness analysis showed that the incremental cost per additional 1-point improvement in RMDQ change score at 12 months with PT over BPM was 156.

The results of the sensitivity analysis corroborated the base-case findings. Further, increasing prices for private care did not alter the conclusions of the analysis.

Authors’ conclusions
Physical therapy (PT) is a valid and cost-effective approach for patients with low-back pain in the UK. Brief pain management (BPM) administered in fewer sessions might represent a valid alternative strategy.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was appropriate as the new approach for the treatment of low back pain was compared with the conventional approach. Both interventions were accurately described. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness analysis was based on a clinical trial, which was appropriate for the study question. However, as the study had been published elsewhere, little information on the methods of the trial was reported. Nevertheless, the randomised nature of the study and the multi-centre design enhance the internal validity of the analysis. In addition, the analysis was conducted on an intention to treat basis, which represents a further strength of the study. Finally, statistical analyses of the clinical outcomes were appropriately performed and the results were adjusted by baseline differences.

Validity of estimate of measure of benefit
Both summary benefit measures were appropriate. The evaluation of disability scores represents a measure specific to the disease considered in the study. However, it is only comparable with the benefits of similar interventions. The use of QALYs allows more general comparisons. Extensive details of the methods used to derive both measures were given.

Validity of estimate of costs
The cost analysis was consistent with the broad perspective taken in the study, and the categories of costs included were appropriate. Extensive information on the unit costs and quantities of resources used was given. This should help when replicating the analysis in other settings. The sources of data for all items were reported. Statistical analyses were performed for both the quantities and costs. Moreover, the most uncertain cost category (i.e. private sector costs) was investigated in the sensitivity analysis. The price year was reported, which will facilitate reflation exercises in other time periods. Overall, the analysis of the costs was performed credibly. The authors noted that resource use was based on patient recall, which might introduce some bias. However, good data reliability was demonstrated in a validation study. Further, the number of hospitalisations, which represent a substantial cost-driver, was too small for sound statistical analyses to be carried out.

Other issues
The authors stated that comparisons with other studies were difficult given the different patient populations but, in general, their findings were consistent with previous economic evaluations of alternative low back pain treatments. It was pointed out that caution should be exercised when extrapolating the results of the analysis to other health care systems. Extensive sensitivity analyses were performed to address the issue of uncertainty, and appropriate methods (bootstrapping) were used. The results of the analysis were reported clearly.

Implications of the study
The study results suggest that multiple treatment options might be available for the treatment of low back pain. Thus, additional factors such as patient and doctor preferences should be considered when choosing the optimal strategy.

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Bibliographic details

PubMedID
Other publications of related interest

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