Addition of choice of complementary therapies to usual care for acute low back pain: a randomized 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
The study examined the addition of complementary therapies (i.e. acupuncture, chiropractic or massage therapy), as selected by the patient, compared with usual care in patients with acute low back pain (LBP).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 18 years and older who were presenting for an initial evaluation of back pain. There were many initial exclusion criteria. For example, pain not in the low back, pain lasting longer than 21 days, back or neck surgery in the past 5 years, history of vertebral fracture or dislocation, pregnancy, treatment with systemic corticosteroids, prior treatment for this episode of back pain, involvement in litigation, and a number of specific co-morbidities (current or historical). Patients who were not excluded underwent a second screening. This required a score of 3 or higher on a 0 - 10 pain scale, an ability to communicate in English, and availability for the 5-week treatment period.

Setting
The setting was outpatient care. Treatment was provided at 4 clinical practice sites of a large multi-speciality group practice (usual care) and at the private offices of alternative medical providers (complementary therapies) in the Boston area (USA). The economic study was carried out in the USA.

Dates to which data relate
Recruitment occurred between April 2001 and July 2003. The effectiveness data were collected for each patient over a total of 52 weeks, with primary outcomes relating to the initial 5-week treatment period. The cost data were collected for 12 weeks before and after study enrolment. The price year was 2003.

Link between effectiveness and cost data
The costing was performed retrospectively on a sub-set (approximately 61%) of patients included in the effectiveness study. The sub-set comprised patients who were continuously enrolled with a particular insurer for 12 weeks before and after study enrolment. These patients were similar to the full sample of patients, with the exception that they were significantly older (mean of 45.7 years versus 38.7 years).

Study sample
The authors estimated that 444 patients would provide 80% power to detect a difference in the outcome of interest. Patients with LBP were identified and initially screened, according to self-reported reasons for attending the participating clinics (n=3,308). Of these, 2,313 (69.9%) were ineligible at the first screening, primarily due to the pain not being in the low back (n=1,188; 51.4%), LBP present longer than 21 days (n=592; 25.6%), or prior treatment for that episode (n=135; 5.8%). A further 310 (31.2%) patients were found to be ineligible at the second screening, primarily due to an inability to enrol within 24 hours (n=177), an inability to attend treatment due to travel (n=54), or prior treatment for that episode (n=24). Of the remaining 685 eligible patients, 235 declined to participate, primarily because they were not interested (n=218), or the distance to alternative providers was too great (n=14).

Four hundred and fifty patients finally entered the study. These were randomised in a ratio of 1:2 to usual care versus choice, that is, 150 patients in the usual care group versus 300 patients in the choice group. Post randomisation, 2 patients from the usual care group and 4 patients from the choice group withdrew.

Study design
The study was a multi-centre RCT. It involved 4 sites offering usual care and a number of selected separate sites providing alternative therapies (11 acupuncturists, 9 chiropractors and 12 massage therapists); these were selected from 100 applicants, partly according to a credential process. Randomisation was conducted using sealed, opaque, sequentially numbered envelopes, containing treatment assignments generated by computerised stratified permuted-block randomisation. Blinding was not feasible during the study period and was not applied to the data collectors (telephone interviewers) during follow-up, but these interviewers were not involved in the data analysis or interpretation. The patients were interviewed by telephone at 2, 5, 12, 26 and 52 weeks. The response rates were high at 92.1%, 90.8%, 87.4%, 82.4% and 80.4%, respectively, with no significant differences between the two groups.

Analysis of effectiveness
The analysis was conducted only for the 444 patients who completed the study. Patients in the choice group had a higher expectation of improvement in 6 weeks than those assigned to the usual care group, but no other significant differences in the baseline characteristics were found. The primary outcomes were changes from baseline to week 5 in:

- symptom relief (measured as bothersomeness of the worst symptom of LBP, sciatica or numbness, over the previous 24 hours, on a scale of 0 - 10);
- functional status (measured using the modified Roland-Morris Disability Questionnaire about daily activities, on a scale of 0 - 23); and
- satisfaction with care (measured using a rating scale).

Additional outcomes were:

- adverse effects;
- difficulty performing three important self-identified activities (measured on a scale of 0 - 10);
- worry about one’s back problem (measured on a scale of 0 - 10); and
- overall mental and physical health (measured with the Medical Outcomes Study Short Form, SF-12).

It was noted that the minimal clinically important difference for the Roland score was 2.5 points.

Effectiveness results
At week 5, choice patients had a statistically, but not clinically, significant 1-point improvement in symptom relief. The median change from baseline was -4 (interquartile range, IQR: -7 to -2) for usual care and -5 (IQR: -7 to -3) for choice, (p=0.002). There was no significant improvement in Roland score (-8, IQR: -13 to -2) for usual care or for choice (-9, IQR: -15 to -4), (p=0.15). By week 12, there were no differences for either end point.
Despite similar scores at baseline, choice patients were significantly more likely to rate their care as excellent at each time point throughout the trial.

The only significant difference among other outcomes was a greater decrease in worry at 5 weeks. The median change from baseline was -2 (IQR: -5 to -2) for usual care and -4 (IQR: -6 to -1) for choice, (p=0.004).

**Clinical conclusions**

The authors concluded that the trial failed to identify any clinically significant benefit to the choice group for either of the primary outcomes of symptoms or function. A persistent, significant difference in perceived satisfaction with care was observed in the choice group, but the authors suggested that this might be partially explained by the non-blinding of all participants to their care allocation.

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

A summary measure of benefit was not derived. The authors believed that they had demonstrated therapeutic equivalence in their chosen outcomes, so only costs were considered in the economic analysis.

**Direct costs**

Secondary data on the numbers and types of provider visits, laboratory tests and prescription drugs were obtained from electronic medical records, pharmacy and claims databases at the study sites and at the primary insurer (only patients enrolled with this insurer were analysed for cost). Only the quantities and costs of alternative provider visits were reported separately. Since the categorisation of back-pain specific costs using retrospective claims data was not reliable, all medical costs were included in the analysis. The costs were assigned using Medicare reimbursement for encounters and average wholesale prices (Red Book) for prescription medicines in 2003. Alternative providers were paid at different rates for first and subsequent visits, and 50% patient co-payments were applied beyond the first 10 visits (marginal costing). Discounting was irrelevant given the short timeframe of the study.

**Statistical analysis of costs**

The costs over 12 weeks were examined via a 2-stage model, separately modelling the log odds of incurring any costs and the log of costs amongst those who incurred a cost. Duan's smearing estimator was used to calculate appropriate error estimates when the data were re-transformed from the log scale. Mean and median total costs were reported pre- and post-study, and the costs were disaggregated into usual care and additional therapy costs for the choice group post-study.

**Indirect Costs**

Productivity costs were not included.

**Currency**

US dollars ($).

**Sensitivity analysis**

The study cost results were adjusted for the patients' pre-study costs.

**Estimated benefits used in the economic analysis**

See the 'Effectiveness Results' section.

**Cost results**
In the pre-study period, the mean total cost was $393 (median $126, IQR: 30 to 373) in the usual care group and $247 ($131, IQR: 19 to 333) in the choice group, \( (p=0.68) \).

Post-study, the mean total cost was $521 (median $207, IQR: 62 to 727) for usual care and $476 (median $185, IQR: 37 to 599) for usual care only within the choice group, \( (p=0.20) \).

After controlling for pre-study costs, the costs of usual care only within the choice group were $99 lower.

The mean costs for alternative therapy within the choice group was $343 (median $300, range: 0 to 675), resulting in total incremental costs for the choice group of $244 per person.

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors' conclusions**
Despite increased satisfaction among patients, the care model tested in this study, which included alternative therapies for acute low back pain (LBP), did not demonstrate superior clinical outcomes and resulted in increased costs of care.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the comparator used. It represented usual practice within the authors' setting. You should decide whether this represents a relevant alternative in your own setting.

**Validity of estimate of measure of effectiveness**
The study used an RCT design, which was appropriate for the study question. The study sample was representative of the study population and was shown to be comparable at baseline across the two groups. The reasons for exclusion from the study were clear. Power calculations were reported and an appropriate sample size was used. The method of randomisation, length of study and loss to follow-up were all reported, suggesting that the internal validity of the study was good.

The analysis was conducted for treatment completers only, rather than the intention to treat population. Appropriate statistical analyses were undertaken to take potential biases and confounding factors into consideration. However, several of the outcomes were measured using non-validated scales newly designed for the study, which implies that the results may not easily be interpreted or generalised outside of this study. Another limitation to the results stems from the fact that participants were permitted to use alternative therapies outside of the study. This might have led to an overestimation of the effectiveness of usual care: the proportion of those doing so in the usual care group (n=18; 12%) was higher than in the choice group (n=14; 5%).

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of benefits. In effect, a cost-consequences analysis was performed. As the authors determined that their analysis demonstrated no significant differences in effectiveness between therapies, only costs were analysed further.

**Validity of estimate of costs**
The perspective adopted was that of a medical insurer. All the relevant categories of costs, as well as relevant costs, appear to have been included. However, only limited disaggregated unit cost and quantity data were reported (only costs and mean numbers of visits to alternative providers). The sources of the cost data were appropriate and the price year was reported. Statistical modelling was undertaken to fully examine the cost data. Given the data, the methods and models used appear to have been appropriate.
Other issues
The authors made appropriate comparisons of their findings with those from other studies. They acknowledged potential variation in the cost data in a setting where referrals and prescriptions are less closely managed, but did not explore this via sensitivity analyses. The authors presented almost all their results, but appear to have avoided presenting the total mean costs in the choice group and comparing this figure with the total mean costs in the usual care group. The large incremental cost ($244 per patient) implies that the difference is likely to have been statistically significant. The authors' conclusions reflected the scope of the study

The authors acknowledged several limitations. First, the choice model did not include all available alternative or complementary therapies. Second, the therapies included might not have been the most effective sub-set of therapies available. Third, other financial models for reimbursement of alternative care may exist. Finally, additive or synergistic effects among therapies were not tested.

Implications of the study
The trial examined a particular model of care within a particular financial framework and did not find that additional alternative therapies are more effective. However, the approach used may be usefully applied in future evaluations of models of care delivery. The authors suggest that such trials should focus on common chronic conditions that are costly and for which conventional medical care is of limited effectiveness.

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