Cost effectiveness analysis of a randomised trial of acupuncture for chronic headache in primary care

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
Acupuncture treatment from trained physiotherapists, spread over 3 months, was compared with usual care for the treatment of chronic headache.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients who reported an average of at least two headaches per month and who were recruited from general practices in England and Wales. No specific exclusion criteria were stated.

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

Dates to which data relate
The dates during which the effectiveness data were collected were not reported. The costs were measured in 2002-03 and inflated to 2003 prices.

Source of effectiveness data
The effectiveness data were 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 effectiveness study.

Study sample
The following information was supplemented by a complementary paper, details of which were published elsewhere (see Other Publications of Related Interest). The use of power calculations to estimate the influence of chance on the results was not reported. The patients were recruited from general practices in England and Wales if they reported at least two headaches per month. The authors did not report any further inclusion criteria, or mention any exclusion criteria. This sample was appropriate for the clinical question since it comprised patients in whom acupuncture might be used. In addition, the patients were not selected according to their preference for acupuncture. The base-case cost-effectiveness estimates included only those patients for whom there were complete health-related quality of life
(HRQoL) data. A total of 401 patients were enrolled in the study and 255 gave complete HRQoL data. Of these patients, 136 were in the acupuncture arm and 119 in the control arm. The mean age of the patients was 46.7 (standard deviation, SD=9.7) years in the acupuncture arm and 46.0 (SD=11.0) years in the control arm.

Study design
The basis of the analysis was a randomised controlled trial. The unit and method of randomisation were not reported. The study was conducted at multiple primary care practices across England and Wales. The patients received treatment for 3 months and were then followed for a further 9 months, giving a time horizon of 12 months. A total of 146 patients did not supply complete HRQoL data and this represented the only element of loss to follow-up reported. Blinding was not possible from the perspective of either the patient or acupuncturist. The authors did not report whether the analysts were blinded.

Analysis of effectiveness
The analysis was carried out on an intention to treat basis. The primary health outcomes were contact time with the acupuncturist, and HRQoL at baseline and 3 and 12 months. HRQoL is reported in the “Measure of Benefits Used in the Economic Analysis” section. The authors reported that the baseline characteristics for the patients in the two arms were “similar”.

Effectiveness results
Patients in the acupuncture arm had on average 4.2 hours of contact with the acupuncturist. See ”Estimated Benefits Used in the Economic Analysis” section for a summary of the quality-adjusted life-year (QALY) results.

Clinical conclusions
The authors concluded that there was an improvement in QALYs during the 12 months in the acupuncture group, but not in the control group. This improvement was statistically significant.

Modelling
A linear regression model was used to explore differences between the two study groups in terms of the cost and effectiveness.

Measure of benefits used in the economic analysis
The summary measure of benefit was the QALYs. These were estimated from the SF-36 questionnaire, which was completed by the study sample at baseline and 3 and 12 months, the results of which were transformed into the SF-6D using an algorithm.

Direct costs
The direct costs included both the costs to the health service and patients. Discounting was not required since the time horizon was 12 months. The cost estimation centred on the cost of the acupuncture sessions, other health care professional visits and “other” such as over-the-counter medication. The patients were asked to report unit costs associated with non-prescription drugs and private health care visits. The unit costs for the study intervention were estimated from published sources and multiplied by the quantities observed in the clinical study. The costs were measured for 2002-03 and then inflated to 2003 prices.

Statistical analysis of costs
SDs and confidence intervals (CIs) were reported in order to estimate uncertainty in the total cost estimates and to derive cost-effectiveness acceptability curves.
Indirect Costs
The indirect costs relating to the time off work (a measure of productivity loss) due to morbidity were estimated.

Currency
UK pounds sterling (). 

Sensitivity analysis
Sensitivity analyses were conducted to test the robustness of the results to changes in the base-case assumptions:

- the staff time and grade associated with acupuncture treatment;
- the impact of including productivity loss;
- different strategies to deal with missing data; and
- different time horizons, using discount rates of 6% for costs and 1.5% for QALYs.

Estimated benefits used in the economic analysis
The QALYs were 0.727 (SD=0.119) in the acupuncture arm and 0.708 (SD=0.112) in the control arm. The mean difference was 0.021 (95% CI: 0.001 - 0.040).

Cost results
The cost to the National Health Service (NHS) was 289.65 (SD=165.86) in the acupuncture arm and 88.65 (SD=130.28) in the control arm. The mean difference was 205.34 (95% CI: 169.33 - 241.35).

The cost to the patient was 113.75 (SD=258.24) in the acupuncture arm and 128.56 (SD=426.56) in the control arm. The mean difference was -15.91 (95% CI: -86.24 - 54.42).

The total cost to the NHS and patients was 403.40 (SD=356.69) in the acupuncture arm and 217.20 (SD=486.00) in the control arm. The mean difference was 189.42 (95% CI: 102.24 - 276.61).

Synthesis of costs and benefits
The incremental cost per QALY gained was 9,951 from the NHS perspective, 9,180 from the total cost perspective, and 3,263 from the societal perspective.

The authors reported that, at a ceiling of 30,000 per QALY gained, the probability that acupuncture was cost-effective was 92%. Cost-effectiveness increased with the projection of effects beyond one year. It was reported that inputting values for cases with missing data did not affect the results significantly.

Authors’ conclusions
"Acupuncture led to increases in both QALYs (quality-adjusted life-years) and health service costs”. The results presented in the base-case were conservative estimates.

CRD COMMENTARY - Selection of comparators
The authors compared acupuncture with usual care in the treatment of chronic headache. They do not appear to have asked the control group of patients what constituted usual care (different medication, rest, other relaxation techniques). Nevertheless, usual care is a good comparator in the sense that the trial was a pragmatic study and the results represented true results that would occur in a real situation. Usual care also represented current practice in the authors’ setting at the time of the study.
Validity of estimate of measure of effectiveness
The basis of the analysis was a randomised controlled trial. Although few details about the randomisation process were provided, this type of study helps to reduce systematic differences between the two study groups and increases the internal validity of the results. The study sample was representative of the study population, as it comprised individuals who were suffering from recurrent headaches at the time of entering the study. The authors noted that the baseline characteristics were "similar" for the two groups of patients, but no statistically significant differences were noted. In the base-case, the authors explored a time horizon of 1-year outcomes to avoid having to extrapolate from the trial. Sensitivity analyses were appropriately used to explore longer time horizons.

Validity of estimate of measure of benefit
QALYs were used as the summary measure of benefit. CIs were generated and cost-effectiveness acceptability curves were derived. This promotes confidence in the results presented and their robustness to changes in the assumptions underlying the study.

Validity of estimate of costs
The authors estimated the cost from the NHS and individual perspectives, then combined these to obtain a more societal estimate. This means that the results can be interpreted by health service researchers, as well as lay members of the public who may be interested in such a technology where they can receive private treatment at their own cost. Moreover, this breadth of perspectives gives a more all-round understanding of the technology and its impact on subsets of the economy. All the relevant categories of costs were included. A cost-difference whose 95% CI did not include zero suggests that small omissions in cost are unlikely to have affected the principle results and conclusions. The unit costs were reported separately in the supplementary paper.

Other issues
The authors were unable to compare their results with those from other acupuncture studies as this was the first study of its kind. Nevertheless, they did draw comparisons of the cost-effectiveness results with other technologies approved by the National Institute of Clinical Excellence, and one other anti-migraine intervention. This serves as a useful base on which to assess the results. The issue of generalisability to other settings was not discussed, although the patients were enrolled from across England and Wales. Therefore, the effectiveness results should be generalisable across this setting. The results were not presented selectively and further details of the study, including the sensitivity analyses, were available in the supplementary paper. The conclusions drawn accurately reflected both the scope of the study and the results presented. The limitations of the study were not explicitly discussed, although the authors did highlight ways in which the base-case study was conservative. They also explained how the sensitivity analyses explored less conservative alternatives.

Implications of the study
The authors recommended “clinicians, commissioning, and patients should consider acupuncture for migraine and chronic headache as it seems to reduce the severity of headache and improve HRQoL at a small additional cost”. There were no suggestions for further work on this topic.

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