Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain

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 compared two treatment options for chronic low back pain, routine care alone and acupuncture in addition to routine care. Acupuncture was only administered using disposable one-time needles and manual stimulation.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised adult patients, aged 18 years or older and with low back pain, who were insured by one of the social health insurance funds participating in the Acupuncture in Routine Care Study. Inclusion criteria included a clinical diagnosis of low back pain with disease duration of more than 6 months and informed consent. Exclusion criteria were patients with protusio or prolapse of one or more intervertebral discs with concurrent neurologic symptoms; prior vertebral column surgery; infectious spondylopathy; low back pain due to inflammatory, malignant or autoimmune disease; congenital deformation of the spine (except for slight lordosis or scoliosis); compression fracture due to osteoporosis; spinal stenosis; and spondylolysis or spondylolisthesis. Physicians who participated in the study had at least an A-diploma representing 140 hours of certified acupuncture education.

Setting
The setting was primary care (general medical practice). The economic study was carried out in Germany.

Dates to which data relate
The clinical data were derived between January 2001 and March 2002. The dates of the cost data and the price year were not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
It appears that the costing has been carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations showed that a sample of at least 366 individuals per group was required to find a difference of 12% (9.36 points) in the back function score (Hannover Functional Ability Questionnaire - HFAQ), assuming a mean score of 78 points and a standard deviation (SD) of 39 in the control/acupuncture group at a significance level of alpha 5%. Patients who met the inclusion criteria were selected for the study (11,630). Of the 3,093 patients randomly allocated to the two groups, 1,549 were assigned to the acupuncture group and 1,544 to the control group. Of these, 252 patients (98 in the acupuncture group and 164 in the control group) were excluded from the study as consent forms were not provided. Patients who refused randomisation (n=8,537) comprised the non-randomised acupuncture group. The study also included 3,486 physicians.

**Study design**
The analysis was based on a multi-centre, randomised controlled trial and a non-randomised cohort. Randomisation was achieved by means of a central telephone randomisation procedure, using blocks of 10 patients. It was performed using SAS software (SAS Institute Inc., Cary, NC). None of the participants was blinded to the intervention. The patients were followed up at baseline, and at 3 and 6 months through standardised questionnaires. At 3 months, data were available for 94% of patients in the randomised acupuncture group, 90.6% in the control group and 91% in the non-randomised acupuncture group. At 6 months, completed questionnaires were available for 91% of patients in the randomised acupuncture group and 86% in the control group. In the non-randomised group, only a random sub-sample of 50% of patients received questionnaires because of the large sample size.

**Analysis of effectiveness**
The analysis appears to have been conducted on the basis of treatment completers only. Statistical analysis demonstrated that the randomised groups were comparable in terms of their demographic and baseline characteristics. However, there were significant differences between the randomised and non-randomised acupuncture groups. Patients in the non-randomised group were more likely to have had more than 10 years of schooling, to have experienced more severe complaints, and the duration of the disease was on average 1 year less in comparison with randomised patients.

The primary health outcome used in the analysis was back function at 3 months, evaluated using the validated HFAQ. In addition, using a combination of the back pain scale and the HFAQ, the authors estimated the percentage reduction of back function loss. Patients with a demonstrated improvement of at least 20% in "back function loss" were considered to respond to treatment. Linear mixed models were used to determine the factors that affected improvement in back function and back pain. Physicians’ and patients' characteristics were also investigated.

**Effectiveness results**
After adjusting for baseline differences, back function improvement at 3 months was greater in the acupuncture group than in the control group. The mean HFAQ scores increased by 12.1 points (standard error, SE=0.4) to 74.5 (SE=0.4) in the acupuncture group and by 2.7 points (SE=0.4) to 65.1 (SE=0.4) in the control group. The difference was 9.4 points (95% confidence interval, CI: 8.3 to 10.5; p<0.0001).

The analysis demonstrated that, at 3 months, patients in the non-randomised acupuncture group experienced greater back function improvement than patients in the randomised acupuncture group. The mean HFAQ scores increased by 12.1 points (SE=0.4) to 74.5 (SE=0.4) in the randomised acupuncture group and by 14.6 points (SE=0.3) to 75.9 (SE=0.2) in the non-randomised acupuncture group. The difference was 1.5 points (95% CI: -2.4 to -0.5; p<0.003).

The authors reported the results of the linear regressions in full, but they are too numerous to be reported in this abstract.

**Clinical conclusions**
The authors concluded that acupuncture in addition to routine care resulted in greater clinical improvement for patients with chronic low back pain.
Measure of benefits used in the economic analysis
Quality-adjusted life-years (QALYs) were used as the measure of benefit in the economic analysis. These were derived from the SF-36 measured at baseline and at 3 months. The SF-36 data were converted to Short Form-6D using a published algorithm (Brazier et al. 1998, see 'Other Publications of Related Interest' below for bibliographic details). It was reported that the cost-effectiveness analysis was conducted only on patients with complete SF-36 data (baseline and 3 months).

Direct costs
Health service costs were included in the analysis. These were the costs of physician visits, hospital stays, medication and acupuncture treatment. The costs and resource use were derived from the participating health insurance funds. The unit costs and resource quantities were not reported. The dates relating to the cost data and the price year were not reported. Since the costs were incurred for only 6 months, discounting was not relevant and was not conducted.

Statistical analysis of costs
The cost data were treated deterministically.

Indirect Costs
It would appear that productivity losses were included in the analysis. Quantities (i.e. number of sick-leave days) were based on data from the participating social health insurance funds. However, the costs and quantities were not reported. As the costs were incurred over a short time, discounting was not relevant and was not conducted.

Currency
Euros (EUR).

Sensitivity analysis
Non-parametric bootstrapping was performed to investigate uncertainty around the estimated incremental cost-effectiveness ratio. The original sample was bootstrapped 1,000 times in order to represent graphically the bootstrapped incremental cost-effectiveness ratios on the cost-effectiveness plane. In addition, a sensitivity analysis was performed to assess the robustness of the effectiveness results regarding the primary outcome measure. Missing data were either replaced using the "last value carried forward" principle or by using various hot deck methods and regression-based multiple imputation.

Estimated benefits used in the economic analysis
Data on QALYs were available for a sub-sample of 2,388 of the 2,841 randomised patients (84%; 1,231 acupuncture and 1,157 control).

At 3 months, acupuncture resulted in a greater number of QALYs than the control group, 0.65 QALYs (SD=0.10) versus 0.62 QALYs (SD=0.10), (p<0.001).

Cost results
The total costs were significantly higher in the acupuncture group than in the control group, EUR 1,062.46 (SD=1,539.74) versus EUR 782.36 (SD=1,728.80), (p<0.001).

The direct diagnosis-specific costs were EUR 557.15 (SD=872.94) in the acupuncture group and EUR 251.91 (SD=1,065.41) in the control group, (p<0.001).

The authors stated that the cost-differences were mainly attributed to the costs of acupuncture.
Synthesis of costs and benefits
An incremental cost-effectiveness analysis was performed.

The incremental cost-effectiveness ratio was EUR 10,526 per QALY gained from a societal perspective and EUR 11,470 per QALY gained from a diagnosis-specific perspective.

The bootstrapping analysis demonstrated that acupuncture in addition to routine care was more effective and more costly than routine care alone.

At a willingness-to-pay threshold of EUR 50,000 per QALY gained, the probability of acupuncture being cost-effective was close to 100%.

Authors' conclusions
"Acupuncture, in addition to routine care, resulted in a clinically relevant benefit and was cost-effective among patients with chronic low back pain from primary care practices in Germany."

CRD COMMENTARY - Selection of comparators
The selection of the comparators was explicitly justified. However, the analysis was restricted to needle acupuncture and other forms of acupuncture (e.g. laser) were not investigated. This means that the study was essentially a partial analysis. You should decide if this represents a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a multi-centre, randomised controlled trial and a non-randomised cohort, which seem to have been appropriate given the study question. The study sample appears to have been representative of the study, characteristics of the patient groups were fully discussed, and power calculations demonstrated that an adequate sample size was used. Appropriate statistical analyses were undertaken to test for any statistically significant differences between the groups. Regression analyses were also undertaken in all study patients to identify factors affecting clinical improvement in back function and to investigate the patients' acceptance of randomisation. The analysis suggests that the internal validity of the study is likely to be good.

Validity of estimate of measure of benefit
The authors used QALYs as the measure of benefit in the economic analysis. Health-related quality of life was measured over 3 months using the SF-36. This was then converted (using an appropriate algorithm) to the SF6-D, which is a utility measure, thus allowing QALYs to be derived.

Validity of estimate of costs
A societal perspective was adopted in the economic analysis. However, the authors reported very limited information on their costing study. Consequently, it was not possible to determine whether all the categories of cost relative to the perspective adopted were included in the analysis, or if all major relevant costs were included. In addition, the resource use quantities and the prices were not reported separately. The costs were derived from German sources, but no sensitivity analysis of the estimates used was performed. These facts will limit the generalisability of the authors' results.

Other issues
The authors compared their findings with those from other studies and, in general, found them to be in agreement. The issue of the generalisability of the results was addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of analysis. A number of further limitations to the study were reported. First, as none of the study participants was blinded to the intervention, biases might have been introduced. Second, as the choice of the patterns of acupuncture treatment and co-interventions depended solely upon the
Physicians, there was great variation in the course of treatment. Third, given the broad inclusion criteria, the patient sample was quite diverse. Finally, the 3-month study horizon was considered to be short.

**Implications of the study**
The authors recommended that acupuncture should be considered as a treatment option for patients with chronic low back pain. No recommendations for further research were made.

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Funded by a number of German social health insurance funds.

**Bibliographic details**

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**Other publications of related interest**
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**Indexing Status**
Subject indexing assigned by NLM

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