Addition of acupuncture and self-care education in the treatment of patients with severe angina pectoris may be cost beneficial: an open, prospective study

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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 and self-care education in addition to standard treatment of patients with severe angina pectoris.

Type of intervention
Treatment and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with severe angina pectoris.

Setting
Institution (private outpatient research clinic). The study was carried out in Denmark.

Dates to which data relate
Effectiveness and resource data were collected for a five year period prior to 15 May, 1997. The medical expenses were calculated from 1997 costs in Denmark. For medical treatment alone the data relate to 1995. No single price year was used.

Source of effectiveness data
A single study provided information for the intervention and a review of the literature (for risk of MI and/or death) provided information for the comparator groups.

Link between effectiveness and cost data
Costing was undertaken both prospectively and retrospectively for the patient group assigned to the intervention.

Study sample
105 consecutive patients with severe angina pectoris were treated with acupuncture and self-care education in additional to the standard treatments. The median age was 62 years and 71% were male. 73 patients were candidates for invasive treatment, whereas 32 were rejected because of high operative risk (6), high reoperative risk (7), operation not technically possible (5), reoperation not technically possible (7) and second reoperation not possible (7). No patients were excluded from the study. It was not stated whether power calculations determined the sample size.
Study design
The study was a case-series with reference (control) groups being derived from the literature. The study was carried out in a single centre. The patients received 12 acupuncture treatments within a 4-week period according to Traditional Chinese theory. No electrical or mechanical stimulation was given. Patients were also informed about adjustment of lifestyle and attitudes, stress coping techniques, daily relaxation exercise, daily physical exercise, and diets. Patients were followed for a median of 34 months (range: 3-106) until one of the following end points: MI, death, invasive treatment or end of observation period. The follow-up data were based on hospital reports, supplemented by reports from the general practitioner (GP) and questionnaires. As there was no regular control group, the results were compared with recently published results (see review details below).

Analysis of effectiveness
The method of analysis (intention to treat or completers only) was not stated. The main health outcomes were accumulated risk for MI or cardiac death, health status as measured by the NYHA scale (a satisfactory health status was defined as NYHA 0-I and/or no antianginal medication), degree of disease according to a visual analogue scale and quality of life according to a visual analogue scale. Demographic and health data were provided for the intervention group only and as such it is not possible to assess overall comparability with the chosen reference groups. The authors indicated, however, that the reference group taken from the Danish population matched the intervention group by age and sex. The average age of the reference group with angina pectoris was 63 and 66% were men.

Effectiveness results
Accumulated risk for MI or cardiac death was 4%, 10% and 13% after 1, 3 and 5 years respectively for the intervention group. Compared to 8% before treatment, 53% of patients achieved NYHA 0-I after 1 year, 36% after 3 years and 69% after 5 years. Before treatment, 4% were without antianginal medication which increased to 12% after 1 year, 35% after 3 years and 34% after 5 years. Before treatment median degree of disease was 71mm on a 100mm scale (interquartile range 48-90mm) compared with 24mm, 25mm and 26mm after 1, 3 and 5 years, respectively (interquartile ranges 11-39mm, 9-40mm and 15-39mm (all p<0.0001)). Median quality of life improved from 64mm before treatment (interquartile range 45-83mm) to 21mm, 23mm and 24mm after 1,3 and 5 years respectively (interquartile ranges 12-35mm, 9-38mm, 14-39mm (all p<0.0001).

Clinical conclusions
Compared to the reference group in the Danish population with angina pectoris no increased risk of MI or cardiac death was observed (not tested statistically). The intervention group was associated with improvements in medical status and quality of life, and a reduction in disease status when examined from a before intervention/after intervention perspective.

Outcomes assessed in the review
Health outcomes assessed from the literature were accumulated risk of MI and cardiac death for the chosen reference groups: medication, CABG (and PTCA), general population and those in the general population (based on a sample of 211 patients) with angina pectoris.

Study designs and other criteria for inclusion in the review
Not stated. The data for medication and surgery were based on a published review of randomized trials over a 10 year period. Data for the general population were derived from a large-scale heart study of the Copenhagen population.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
1 study (medication), 1 study (surgery), 1 study (general population and reference group with angina pectoris).

Methods of combining primary studies
Not stated (single source for each group/s).

Investigation of differences between primary studies
Not stated.

Results of the review
The accumulated risk of MI or cardiac death for conventional treatment is 8-15% for 1 year, 18-23% for 3 years and 24-31% for 5 years. In the Danish reference groups the figures were 1%, 3% and 5% for the general population and 4%, 13% and 19% for the reference group in the Danish population with angina pectoris.

Measure of benefits used in the economic analysis
The measures of benefit were medical status, degree of disease and quality of life. Additionally, avoided surgery was reported. Visual analog scales were used to evaluate degree of disease and quality of life. The behavioural patterns and emotional states (anxiety and depression) of the patients were evaluated using Jenkins Activity Survey and Aaron Bech rating scale of mood disorders.

Direct costs
The perspective adopted was that of the health care system. Direct medical costs included GP visits, cardiologist visits, ambulatory treatment and hospitalization treatment per day, the 5-year cost of PTCA and CABG, annual cost of medication alone and the cost of the 12 acupuncture treatments. The source of cost data for PTCA and CABG was a study reported in 1997 and the source for medical management was a study reported in 1995. Discounting, although relevant, was not applied. Costs and quantities were reported separately. The price year was 1997 for all data except medical treatment alone, which was given in 1995 prices.

Statistical analysis of costs
Not undertaken.

Indirect Costs
Although referred to in the paper, indirect costs were not included in the cost analysis.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analysis was not carried out.
Estimated benefits used in the economic analysis
Compared to 8% before treatment, 53% of patients achieved NYHA 0-I after 1 year, 36% after 3 years and 69% after 5 years. Before treatment, 4% were without antianginal medication which increased to 12% after 1 year, 35% after 3 years and 34% after 5 years. Before treatment median degree of disease was 71mm on a 100mm scale (interquartile range 48-90mm) compared with 24mm, 25mm and 26mm after 1, 3 and 5 years, respectively (interquartile ranges were 11-39mm, 9-40mm and 15-39mm (all p<0.0001)). Median quality of life improved from 64mm before treatment (interquartile range 45-83mm) to 21mm, 23mm and 24mm after 1, 3 and 5 years respectively (interquartile ranges were 12-35mm, 9-38mm, 14-39mm (all p<0.0001)). Avoidance of surgery occurred in 52 (71%) of patients in the intervention group.

Cost results
The cost results were calculated by comparing resource usage one year before the intervention with resource usage in the 5 year period after the study commenced. The estimated savings per patient receiving the intervention were $32,000. This was mainly due to a 90% reduction in hospitalization and avoided surgery. For the 32 patients who were rejected for surgery, healthcare costs were $8,800 per patient before the intervention. During the first year these reduced to $2,300, $1,700 in the second year and $1,200 for the remaining three years. For patients who were candidates for invasive treatment the costs 1 year before treatment were $3,500 which reduced to $1,100, $800 and $900 1, 2 and 3-5 years after the intervention, respectively.

Synthesis of costs and benefits
Not undertaken.

Authors' conclusions
The study suggests that the combined treatment with acupuncture and self-education may be effective in improving medical status and cost beneficial for patients with advanced angina pectoris. However, the results require confirmation in further, preferably randomized studies.

CRD COMMENTARY - Selection of comparators
rationale for the choice of comparators was clear. The comparators used were traditional alternatives for managing this population of patients. The intervention belongs to the category of alternative medicine.

Validity of estimate of measure of benefit
validity of estimate of effectiveness (reduction of MI and cardiac death) and health benefits (disease status, medical status and quality of life) should be treated with caution due to the study design adopted by the authors. No concurrent control group was used for accumulated risk assessments (reference groups were derived from the literature), and the before and after approach used in assessing the health benefits is likely to contain a number of potential biases (for example recall bias and the placebo effect of the intervention). Additionally, the authors acknowledge that the intervention may contain separate effects (acupuncture and self-care education) which could be analysed separately in order to determine true etiologic relations. In order to improve the validity of quality of life estimates, a more sophisticated utility instrument could be adopted in preference to the visual analogue scales used here which only allow one overall assessment. The fact that several patients died during the period of follow-up may bias the health benefit results in favour of the intervention if the fitter patients were surviving longer.

Validity of estimate of costs
the economic analysis is based on the estimates of effectiveness and health benefits they also need to be treated with a degree of caution. By using a one year assessment period prior to commencement of the intervention, and a variable patient follow up within a five year period, a number of potential limitations exist. Due to the method of analysis, the authors were not able to subject the results to either statistical or sensitivity analyses. The use of concurrent controls
within a prospective design would clearly be needed to validate the estimated economic benefits of the intervention.

**Other issues**

Results may not be generalisable to other settings or countries due to the use of country-specific data. Although the authors classified their study as a cost-benefit analysis it more accurately fits a cost-effectiveness classification (more precisely cost-consequences because a cost-benefit analysis would convert health outcomes to monetary values using instruments such as willingness to pay or human capital). However, an experimental study design which more closely and prospectively links the cost and effectiveness (benefits), perhaps by means of a summary benefit measure, for this intervention and standard comparators is clearly called for.

**Implications of the study**

The study findings suggest that acupuncture and self-care education brings about health benefits and is cost saving to the health care system in Denmark. However, due to the concerns expressed above confidence for decision-makers at the policy level in adopting this intervention may be low and further evidence-based research is needed to confirm these results.

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