Treating dyspepsia with acupuncture and homeopathy: reflections on a pilot study by researchers, practitioners and participants

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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
Homeopathy and acupuncture were compared with normal general practitioner (GP) care for the treatment of dyspepsia. Homeopathy was provided for up to 6 months by a non-medical homeopath that practised classical homeopathy. Acupuncture was provided for up to 6 months, by a professional (non-medical) acupuncturist within the system of Chinese medicine.

Type of intervention
Primary care (complementary therapy).

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised people suffering from dyspepsia. Patients were excluded from the study if they had dyspepsia symptoms of less than 2 weeks, were younger than 16 years old, or were pregnant or unable to attend the surgery for care. Those who required specialist referral for investigation or treatment of serious diseases, and those who had received complementary therapy for the presenting condition in the last 3 months, were also excluded.

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

Dates to which data relate
Recruitment into the study took place in 1999 and took 8 months. After that, the patients were followed for 26 weeks. The price year was 1998/1999.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
The sample size was not determined in the planning phase of the study. However, power calculations were performed retrospectively. These suggested that a full-scale trial would require at least 60 patients in each group. The calculation specified a difference in Measure Yourself Medical Outcome Profile (MYOP) scores, and assumed a standard
The recruitment strategy in the study was very intensive. Thirty-two patients attending a particular general practice for routine consultations with their GPs were found to have dyspepsia, of which 2 were ineligible for the study. Of the 141 patients found with repeat prescriptions for dyspepsia, 4 were already in the trial and 13 were ineligible. The investigators sent 121 letters to all those on repeat prescriptions asking them to participate in the study, but only 22 patients were willing to join. Weekly computer searches identified patients who may have been eligible to enter but who had possibly been missed. GPs contacted those identified by letter. Of the 76 patients found by this method, 47 were ineligible and 11 were already in the study. Only one patient responded to the publicity in the waiting room of the general practice.

In total, 71 eligible patients were identified, of whom 11 decided not to take part after they were provided with full information on the trial. Thus, 60 eligible patients consented to take part in the study. From these, 20 patients received acupuncture, 19 received homeopathy and 19 received normal GP care (control group). The homeopathy group had a 6:15 male-to-female ratio, with a mean age of 56 years (range: 29 - 79). The acupuncture group had a 7:13 male-to-female ratio, with a mean age of 56 years (range: 29 - 79). The control group had a 9:10 male-to-female ratio, with a mean age of 54 years (range: 30 - 78).

Study design
This was a pilot, randomised controlled trial incorporating the patients' preference for treatment. The participants expressed their preference for homeopathy or acupuncture or, if they had no preference, were randomised to one of the groups. All the patients were then randomised to receive their preference or to be in the control group. The method of randomisation was block randomisation in blocks of four. Serially numbered opaque envelopes were used to achieve concealed allocation. The ratio between receiving the intervention or the normal GP care was 2:1. The groups were followed for 26 weeks. Only 2 patients (both in the homeopathy group) did not begin their therapy. Of the 20 primary outcome questionnaires given to those in the acupuncture group, 19 (95%) were completed at 6 weeks, 20 (100%) at 12 weeks and 20 (100%) at 26 weeks. Of the 19 primary outcome questionnaires given to those receiving normal GP care, 14 (74%) were completed at 6 weeks, 16 (84%) at 12 weeks, and 16 (84%) at 26 weeks. Of the 21 questionnaires given to those receiving acupuncture, 19 (90%) were completed at 6 weeks, 19 (90%) at 12 weeks, and 16 (76%) at 26 weeks.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The participants were asked to complete the SF-36 health survey, MYMOP, and General Well Being Index (GWBI) outcome questionnaires at baseline and 6, 12 and 26 weeks. The primary health outcomes were the changes in MYMOP (a 7-point scale with positive changes meaning improvement) and GWBI (scale from 22 to 110, with positive changes meaning improvement) at 6 and 12 weeks, and 6 and 8 months. The groups were shown to be comparable at analysis in terms of their age, gender and prognostic features. No difference was found between the MYMOP score of those recruited by their GP and those recruited from repeat prescriptions. Feedback and views from participants and practitioners was obtained at the end of the study in a focus group meeting, which the authors organised to generate ideas for future work.

Effectiveness results
The changes in MYMOP and GWBI scores at 6 weeks were characterised by small mean changes and wide confidence intervals (CIs).

The mean change in the MYMOP scores at 6 weeks were 0.53 (SD=1.76) in the control group, 0.28 (SD=1.34) in the acupuncture group and 0.44 (SD=1.41) in the homeopathy group. This translates into a mean difference between the control and treatment groups of -0.24 (95% CI: -1.33 - 0.83) for the acupuncture group and -0.09 (95% CI: 1.19 - 1.01) for the homeopathy group.

The mean change in the GWBI scores at 6 weeks were 2.14 (SD=14.33) for the control group, 0.05 (SD=7.78) for the acupuncture group and -1.63 (SD=9.22) for the homeopathy group. This translates into a mean difference between the control and treatment groups of -2.09 (95% CI: -10.0 - 5.82) for the acupuncture group and -3.77 (95% CI: -12.13 -
4.58) for the homeopathy group.

An unpaired t-test of the mean change in both treatment groups versus the control showed no significant differences between the groups. This was also confirmed by an analysis of co-variance. The mean MYMOP change scores at 12 weeks, 6 and 8 months showed all three groups improving up to month 6, at which time a plateau was reached. No significant differences or trends were observed between the groups. The SF-36 and GWBI scores revealed little change over time.

**Clinical conclusions**
This pilot study provided high-quality data on preferences and outcome scores. However, the study sample was not sufficiently large to detect significant differences in outcomes between the groups.

**Measure of benefits used in the economic analysis**
No summary health benefit measure was used in the economic analysis. A cost-consequences approach was therefore adopted.

**Direct costs**
The resource quantities and the costs were reported separately. The direct costs included in the analysis were those of the NHS primary care system. These were for GP consultations (17 per consultation, telephone consultations included), prescribed drugs (British National Formulary prices, March 1999) and nurse consultations (8.80). The NHS primary care costs during follow-up were calculated from counts of prescriptions and consultations on the practice computer records. Referral costs were reported, but they were not included in the analysis since referrals to hospital were rare and would have required a large sample size for their evaluation. The study reported the mean costs. Discounting was not relevant, as all the costs were incurred in less than one year, and was not conducted. 1998/1999 prices were used.

**Statistical analysis of costs**
Descriptive statistics were given, with costs and resource use being provided as mean values with their respective SDs. Statistical tests (unpaired t-tests and analysis of co-variance) were performed to test for statistically significant changes in the total costs between the three groups. The study was not powered to detect any differences.

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
UK pounds sterling ().
**Synthesis of costs and benefits**
The costs and benefits were not combined since a cost-consequences approach was undertaken.

**Authors' conclusions**
The pilot study provided high-quality data on patient preferences, the number and costs of treatments, outcome scores and NHS costs. However, the authors also concluded that, with such a small sample, they were unable to determine any significant differences between the groups and nor were they able to determine any trends.

**CRD COMMENTARY - Selection of comparators**
The use of usual GP care as the comparator was justified on the grounds that it represented current practice in the authors' setting. You should decide if the comparators represent current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis used a randomised trial incorporating patient preference for treatment, with either acupuncture or homeopathy, and a control receiving GP care. This was appropriate for the study question. Due to the exhaustive and intensive recruitment strategy, the study sample was representative of the study population. However, the authors admitted that such a heterogeneous study sample, coupled with a small sample size, resulted in a wide range of change scores and CIs, with no statistically significant results being derived. The patients were shown to be comparable at analysis in terms of their age, gender, prognostic features and baseline MYMOP and GWBI scores. The analysis of effectiveness was handled in a credible manner. The loss to follow-up was clearly stated, randomisation was carried out in a completely random and concealed fashion, and the outcomes were analysed on an intention to treat basis.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
Although the authors reported at the beginning of the study that a NHS perspective was adopted, secondary care costs were not included in the analysis. The authors justified this by stating that referrals to hospital were rare, thus their evaluation would require a large sample. Hence, they reported the total NHS costs for primary care only. All the costs relevant to this new perspective appear to have been included. The costs and the quantities were reported separately, which will enhance the generalisability to other settings. The resource use data were derived directly from the study. The resource use quantities were reported with their SDs, to account for variability in the results. The unit costs were derived from the authors' setting and the British National Formulary. The total costs were also reported with their SDs, and appropriate techniques were used to determine statistical significance. Since all the costs were incurred in less than one year, discounting was unnecessary and was not performed. The dates to which the prices related were given, which will facilitate reflation exercises.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies, although they noted that there was little evidence relating to the treatment of dyspepsia with homeopathy and acupuncture. One of the few studies found (Sodipo et al., see Other Publications of Related Interest) found significant reductions in gastric acid secretion and markedly reduced symptoms in patients who had received acupuncture for 6 weeks. The authors addressed the issue of generalisability to other settings. The heterogeneous study sample, and the fact that the authors reported the prices and resource use separately, greatly enhances the generalisability to other settings. The authors did not present their results selectively. Apart for the fact that the only NHS costs included in the analysis were those in primary care and not for the NHS as a whole, the authors’ conclusions reflected the scope of the analysis.

The authors reported a further limitation in that the traditional presentation of results with means and SDs did not
demonstrate the individual's response to treatment. It also did not help answer vital questions such as how can one predict who will benefit from what intervention, and which patients will respond to drugs, acupuncture or/and homeopathy?

**Implications of the study**
The authors stated that a full-scale trial would be needed due to the small sample study size and the heterogeneity in the study sample. They also stated that this full-scale trial may need to exclude more patients (e.g. those taking more than 3 or 4 regular drugs) to make the study sample more homogenous. They also implied that qualitative methods could be used to obtain a better understanding of individual experiences of patients’ illnesses and their treatment. The authors suggested, with some reservation, that crossover study designs and n-of-1 trials should be considered.

**Source of funding**
Funded by a NHS South and West R&D project grant. Warwick House Medical Centre receives support funding. The Somerset Health Authority funded the treatments.

**Bibliographic details**

**PubMedID**
12801492

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Acupuncture Therapy; Adult; Aged; Aged, 80 and over; Dyspepsia /economics /therapy; Female; Health Status Indicators; Homeopathy; Humans; Male; Middle Aged; Pilot Projects; Treatment Outcome

**AccessionNumber**
22003000962

**Date bibliographic record published**
30/04/2004

**Date abstract record published**
30/04/2004