Randomized osteopathic manipulation study (ROMANS): pragmatic trial for spinal pain in primary care

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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

A practice-based osteopathy service for subacute spinal pain was examined. Patients received three or four sessions of spinal manipulation from a general practitioner (GP) who was a registered osteopath, at intervals of 1 to 2 weeks. The intervention consisted not only of spinal manipulation, but also of advice about keeping active, exercising regularly and avoiding excessive rest. In patients with persistent symptoms, tender ligaments or peripheral joints were injected with corticosteroids.

Type of intervention

Treatment.

Economic study type

Cost-effectiveness analysis.

Study population

The study population comprised patients aged between 16 and 65 years, presenting with mechanical pain in the neck or upper or lower back of 2 to 12 weeks' duration, as either the first episode or a recurrence. Patients likely to have serious spinal pathology, and those with features of nerve root pain, prior spinal surgery or major physiological disorder, were excluded.

Setting

The setting was primary care. The economic study was carried out in Northwest Wales, UK.

Dates to which data relate

The effectiveness and resource use data were gathered from September 1997 to March 2001. The prices related to 1999 to 2000.

Source of effectiveness data

The effectiveness evidence was 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

Power calculations were performed in the preliminary phase of the study. These suggested that a sample of 200 patients was required to give a power of 80% for detecting a change of 6 points (equivalent to a standardised difference of 0.4)

in the main outcome measure, at a 5% significance level. The patients were identified by their GPs and were then referred to the trial office. Of an estimated 2,000 potentially eligible patients, 201 agreed to participate. There were 109 patients in the control group and 92 in the intervention group. The demographics of the patients were not reported.

Study design

This was a prospective, randomised controlled trial, which was carried out by 54 GPs in 14 practices in Northwest Wales. Randomisation was stratified according to symptom location, the referring GPs' perception of symptom severity, and whether the pain was a first episode or a recurrence. The basis of the method was random number tables kept secure from all participants. The unit of randomisation was the patient. The length of follow-up was 6 months, although the outcomes were also assessed after 2 months. At the final assessment, medical data were available for 101 control patients (93%) and for 86 intervention patients (95%). However, the 6-month questionnaire return rate was 66% in the control group and 70% in the intervention group. The assessment was not carried out blind.

Analysis of effectiveness

The analysis of the clinical study was conducted on an intention to treat basis. The primary health outcome was the Extended Aberdeen Spine Pain Scale (EASPS), which comprised several condition-specific measures for spinal pain and disability. The secondary health outcome measures were the Short-form McGill Pain Questionnaire (SMPQ), the SF-12 health profile, and the EuroQol (EQ-5D) index of health utility. The authors stated that, at baseline, the study groups were comparable in terms of their sociodemographic characteristics, baseline outcome scores, or treatment activity and health service costs.

Effectiveness results

At 2 months, the mean change in the EASPS score was 8.6 (+/- 14.2) in the control group and 13.9 (+/- 12.8) in the intervention group. The difference was 5.3 (95% confidence interval, CI: 0.7 - 9.8; p=0.02).

Although both groups reported improvements, no statistically significant differences were generally observed in the SMPQ, EQ-5D and SF-12 scores. The exception was the SF-12 mental score, which was significantly better in the intervention group.

No adverse events were observed.

At 6 months, only the SF-12 mental score was significantly better in the intervention group, 1.14 (+/- 11.3) versus 6.8 (+/- 13.6) in the control group. The difference was 5.5 (95% CI: 1 - 9.9; p=0.02).

Clinical conclusions

The effectiveness analysis showed that the osteopathy service improved both short-term physical outcomes and long-term psychological outcomes.

Measure of benefits used in the economic analysis

The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. The authors stated that a cost-consequences analysis was conducted.

Direct costs

Discounting was not relevant because the costs were incurred during less than 2 years. The unit costs and the quantities of resources used were presented separately. The health services included in the economic evaluation were primary care consultations, investigations, prescribing and referrals. The cost/resource boundary of the NHS was adopted. Resource use was estimated from actual individualised data, which were derived from the sample of patients involved in the effectiveness study. Data were estimated for the 6 months before and 6 months after randomisation. The costs were estimated from national sources and 1999/2000 prices were used.

Statistical analysis of costs
The costs were presented as mean values with standard deviations. As the costs were skewed, bootstrapping was applied for 1,000 replications.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
UK pounds sterling ().

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean costs for spinal pain were 64 (+/- 90) in the control group and 129 (+/- 283) in the intervention group. The difference was 65 (95% CI: 32 - 155; p<0.05).

The mean total costs were 307 (+/- 687) in the control group and 328 (+/- 564) in the intervention group. The difference was 22 (95% CI: -159 - 142; p>0.05).

Synthesis of costs and benefits
The costs and benefits were not combined because a cost-consequences analysis was performed.

Authors' conclusions
The osteopathy service resulted in small improvements in the patients' health and was cost-neutral in comparison with standard care provided to patients with spinal pain.

CRD COMMENTARY - Selection of comparators
The choice of the comparator (standard care) was appropriate since it reflected the routine care provided to patients with spinal pain. The authors reported the characteristics of the standard approach. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a randomised trial, which was appropriate for the study question. The study groups were comparable at baseline and power calculations were performed to justify the sample size. Further, the methods of sample selection and randomisation were described. The analysis of the clinical study was conducted on an intention to treat basis, but a substantial group of patients in both groups were lost to follow-up. The study sample was representative of the study population. These issues enhance the internal validity of the analysis. The choice of the effectiveness measures was appropriate for capturing the impact of the study interventions on the patients' health. However, as the authors noted, only 10% of potentially eligible patients were enrolled into the trial. Finally, the lack of blinding might have led to some observer bias.

Validity of estimate of measure of benefit

No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

Validity of estimate of costs

The authors stated explicitly which perspective was adopted in the study. A detailed breakdown of the cost items was provided and it appears that all the relevant categories of costs have been reported. Data on resource use were presented separately from the unit costs. This would enable the study to be replicated in other contexts. The cost data were derived from official sources and appropriate statistical tests were carried out to deal with skewed data. However, the cost estimates were specific to the study setting and sensitivity analyses were not carried out. The price year was reported, which makes reflation exercises possible. However, the economic study may have been underpowered to detect statistically significant differences in the estimated costs. Finally, the inclusion of the indirect costs would have been relevant.

Other issues

The authors did not compare their findings with those from other studies. They acknowledged that the generalisability of the study results to other settings was low due to the fact that the trial involved a single practitioner in a single location. Further, sensitivity analyses were not performed. This reduces the external validity of the analysis. The study referred to patients with spinal pain and this was reflected in the authors' conclusions.

Implications of the study

The study results suggested that small improvements could be obtained by an osteopathy service for the treatment of spinal pain, at little extra cost. However, as the authors noted, further studies should be conducted to confirm the results of the current analysis.

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Bibliographic details

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Other publications of related interest

Williams N, Wilkinson C, Russell I. Extending the Aberdeen back pain scale to include the whole spine: a set of outcome measures for the neck, upper and lower back. Pain 2001;94:261-74.

Indexing Status

Subject indexing assigned by NLM

MeSH

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