Evaluating the clinical effectiveness and cost-effectiveness of foot orthoses in the treatment of plantar heel pain: a feasibility 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
The study investigated the use of accommodative orthoses compared to functional orthoses to treat plantar heel pain. Functional foot orthoses were full-length orthoses made of ethyl vinyl acetate (70 Shore A) with a 25 Shore A top cover and a 4 degree medial rear foot ethyl vinyl acetate post. Accommodative foot orthoses were full-length orthoses made of low-density ethyl vinyl acetate (20 Shore A) with a polyurethane heel pad. All orthoses were manufactured by the same company (Talar Made Orthotics Ltd, Chesterfield, UK).

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with plantar heel pain. The inclusion criteria for the study were: (1) at least 2 month's experience of unilateral plantar heel pain; (2) a history of night time or early morning pain that decreased after walking and increased after exercise or prolonged periods of standing; (3) heel pain severe enough to bring about a reduction in physical activity, a visit to a health professional, or the use of medication specifically for plantar heel pain; and (4) good general health. Individuals were excluded if they met any of the following criteria: previous foot surgery, recent abrupt foot trauma, congenital lower extremity defects, diabetes mellitus, corticosteroid injection in the heel in the previous 3 months, and a history of systemic disease with manifestations similar to those of plantar heel pain, including rheumatoid arthritis and sero-negative arthritis.

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

Dates to which data relate
Effectiveness and resource data dates were not reported by the authors. Costs were reported in 2001-2002 prices.

Source of effectiveness data
The effectiveness data 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 study.
Study sample
No power calculations to determine the sample size were reported and no specific sample size was planned. A convenience sample of 48 patients was recruited from North Tyneside Healthcare Trust. The patients were recruited from Podiatry services, and by means of referrals from physicians and physiotherapists. Out of the 48 patients, 22 patients received accommodative orthoses and 26 received functional orthoses. The mean age of patients in the accommodative group was 58.3 (+/- 12.6) years and in the functional group was 61.2 (+/- 14.4) years.

Study design
The study was a randomised trial carried out in a single centre. Patients were randomly assigned to one of the two groups by the use of randomised tables by an independent observer. Patients were followed-up for a period of eight weeks. Thirteen patients were lost to follow-up, an attrition rate of 27.1%. Out of the thirteen patients, 9 patients were given an accommodative orthosis and 4 were issued with a functional orthosis. No significant difference was noted between the two dropout groups.

Analysis of effectiveness
It would appear that the analysis of the clinical study was based on treatment completers only. The outcome used in the study was health status. Health status measures were obtained using the Foot Health Status Questionnaire (FHSQ) and the EuroQol (EQ5D) questionnaire. The FHSQ is a disease-specific questionnaire that captures foot health-related quality-of-life data, and has 13 key items spanning four domains of foot health: foot pain, foot function, footwear, and general foot health. A maximum score of 100 signifies optimal foot health. The EQ5D is a generic questionnaire used to measure health status. It comprises five dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension comprises three levels (some problems, moderate problems, and extreme problems), generating 243 theoretically possible health states. These two questionnaires were given to patients at baseline, at 4 weeks and at 8 weeks. Both groups were shown to be comparable in terms of age, weight, height, body mass index, and duration of plantar heel pain.

Effectiveness results
Using the FHSQ, no significant differences were found for either orthosis at the time intervals for the general foot health and footwear domains.

The foot pain domain demonstrated a significant difference at all time intervals for the functional orthosis (p<0.05). At baseline the FHSQ foot pain score was 39 (+/- 18.7), at 4 weeks was 54 (+/- 21.9) and at 8 weeks was 74 (+/- 25.3).

The accommodative orthosis demonstrated a significant difference between baseline and 4 and 8 weeks (p<0.05) but not between 4 and 8 weeks (p=0.53). At baseline the FHSQ foot pain score was 30 (+/- 23.7), at 4-weeks was 62 (+/- 24.1) and at 8-weeks was 62 (+/- 26.1).

Significant differences were noted in the FHSQ foot-function domain for the functional orthosis group between baseline and 4 and 8 weeks (p<0.05). At baseline the FHSQ foot-function score was 54 (+/- 24.7), at 4 weeks was 71 (+/- 19.3) and at 8 weeks was 74 (+/- 25.4).

No significant differences were observed for the accommodative orthosis group during the 8-week trial (p>0.05).

No significant differences in EQ5D scores at the different time intervals were found for the accommodative orthosis group. However, significant differences (p<0.05) were observed for the functional orthosis group between baseline and 8 weeks and between 4 and 8 weeks. At baseline the EQ5D score was 0.62 (+/- 0.25), at 4 weeks it was 0.68 (+/- 0.19) and at 8 weeks was 0.79 (+/- 0.11).

Clinical conclusions
The results of this feasibility study indicated that there was an improvement over time in the FHSQ foot-pain and foot-function domain scores and the EQ5D scores following the intervention of functional orthoses over a 2-month period.
The accommodative foot orthoses demonstrated a significant reduction in foot pain only at 4 weeks.

**Measure of benefits used in the economic analysis**
The measure of benefits used in the economic analysis was quality-adjusted life-years (QALYs) gained. Results from the EQ5D scores at baseline and at 4 and 8 weeks were converted to a utility score, based on a "tariff" derived from interviews with 3,395 members of the UK public. The two orthosis groups were compared in terms of mean changes in QALYs during the 8-week period by plotting the EQ5D utility scores at baseline and at 8 weeks and calculating the area under the curve to estimate QALYs gained/lost for each patient.

**Direct costs**
Resource quantities and costs were not reported separately. However, the authors did provide unit costs for each item of resource use. The direct costs included in the analysis were those to the National Health Service and those accrued by the patient and the family. These included the following items: the cost of the orthoses to the NHS; clinician costs; the travel and time (from the clinician's base of work to the patient's residence) costs of the clinician; patient's cost of travel time to and from appointments; patient's time; patients' travel expenses; other expenses incurred by the patient as a direct result of treatment; and the costs to any other NHS departments, including use of physician or physiotherapy services during the study. Data on resource use for the economic analysis were obtained from patient and staff questionnaires (both distributed at baseline and at 4 and 8 weeks). Discounting was not relevant, as all costs were incurred over a period of two months and it was, appropriately, not performed. The study reported average costs. Costs were inflated to a 2001-2002 price base using the National Health Service Cost Index.

**Statistical analysis of costs**
The overall total mean cost per patient was analysed using the Mann-Whitney U test. Statistical significance was set at p<0.05.

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

**Currency**
UK pounds sterling (£). The conversion rate to US dollars was reported as 1 = $1.82.

**Sensitivity analysis**
No sensitivity analyses were conducted.

**Estimated benefits used in the economic analysis**
The mean QALY gain was represented as a monthly difference. The mean QALY gain per month was 0.0488 for the functional orthosis group and 0.0379 for the accommodative orthosis group. The authors noted that these differences were small and did not approach conventional level of statistical significance.

**Cost results**
There was a significant difference in mean total costs for the accommodative orthosis group versus the functional orthosis group: 16.18 (+/- 5.54) versus 34.17 (+/- 5.18), (p<0.05). The 95% confidence intervals (CIs) demonstrated that the mean difference was between 21.79 and 14.17 per patient.

**Synthesis of costs and benefits**
A synthesis of costs and benefits was carried out by calculating a cost-utility ratio (i.e. the additional cost required per
QALY gained. The use of functional orthoses over accommodative orthoses resulted in an incremental cost per QALY gained of 1,650.

Authors’ conclusions
The authors concluded that their study demonstrated that the functional orthosis, although initially more expensive, resulted in a better quality of life and was more cost-effective than the accommodative orthosis in the treatment of plantar heel pain.

CRD COMMENTARY - Selection of comparators
A justification was given for using accommodative orthoses as the comparator, namely that they are commonly used in clinical practice for the treatment of plantar heel pain. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised trial which was appropriate for the study question. The study sample was representative of the study population, and patient groups were shown to be comparable at analysis. However, this might have been due to the small sample size, and to the study not being sufficiently powered to detect any differences between the two groups. Although a randomised trial was conducted, it would appear that the outcomes were analysed for treatment completers only. The authors did not, however, find any significant differences between the two dropout groups, so this limitation may well not affect the results. All differences in health status were appropriately tested for statistical significance using appropriate statistical tests.

Validity of estimate of measure of benefit
The estimation of benefits was derived from the EQ5D responses obtained from the effectiveness analysis. The use of QALYs as the measure of benefit was justified.

Validity of estimate of costs
Although the authors reported that costs were estimated from a societal perspective, indirect costs (i.e. productivity costs due to mortality and/or morbidity) were not included. The authors included the costs to the NHS and the direct costs to the patient and family. All relevant direct costs appear to have been included in the analysis. Even though total costs and quantities were not reported separately, which will limit the generalisability of the authors’ results, the authors did provide all unit costs for each category of resource use. The authors derived unit costs from their own organisations and other published sources. Cost differences between the two treatment groups were tested for significance using appropriate statistical techniques. Since all costs were incurred over one year, discounting was unnecessary. The price year was reported, which will assist any inflationary exercises.

Other issues
The authors did not make any comparisons of their cost-effectiveness results with those from other studies, because a comprehensive review of the literature indicated no research evaluating the cost-effectiveness of foot orthoses. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors reported no limitations to their study.

Implications of the study
The authors recommended future studies to evaluate the clinical effectiveness and cost-effectiveness of orthoses during a 12-month period using a randomised controlled trial. Future studies should also include, according to the authors, not only cost-effectiveness analysis but also a cost-benefit analysis, i.e. the willingness of patients to pay.
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Bibliographic details

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
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