Cost effectiveness of brace, physiotherapy, or both for treatment of tennis elbow
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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 examined three treatments for tennis elbow (lateral epicondylitis). These were physiotherapy, brace, or a combination of both physiotherapy and brace. Physiotherapy comprised a 6-week intervention period during which patients received nine sessions, consisting of three, two, one, one, one and one session(s) per week. Every session consisted of 7.5 minutes of pulsed ultrasound treatment and a friction massage. The patients were also instructed in a strengthening and stretching protocol to be performed at home. With the brace intervention, patients provided with the brace were instructed in its application and use, and were asked to visit a participating physiotherapist once during the first week of the intervention period. With the combined intervention, patients received both the brace and physiotherapy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The study population comprised patients who had suffered from elbow complaints for at least 6 weeks and had clinically diagnosed lateral epicondylitis. This comprised pain on the lateral side of the elbow, aggravated with both pressure on the lateral epicondyle of the humerus and resisted dorsiflexion of the wrist. The exclusion criteria were bilateral complaints, a clear decrease in pain in the preceding 2 weeks, and any form of treatment for the lateral epicondylitis episode in the 6 months before inclusion.

Setting
The setting was an outpatient clinic. The economic study was carried out in the Netherlands.

Dates to which data relate
The clinical data and information on resource use were gathered between January 1999 and May 2001. The price year was not reported.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the analysis of effectiveness.

Study sample
Power calculations were not performed. Patients were recruited for inclusion by general practitioners (GPs) and physiotherapists. Overall, 180 patients were included in the study, of which 56 (48% men) were in the physiotherapy group, 68 (53% men) in the brace group and 56 (50% men) in the combined intervention group. The mean age of the
patients was 43 (+/- 8) years in the physiotherapy group, 46 (+/- 11) years in the brace group and 47 (+/- 9) years in the combined intervention group. It was not stated whether some patients refused to participate or were excluded, for any reasons, from the study sample.

**Study design**
This was a prospective RCT that was carried out at the authors' institution. A blinded researcher performed the randomisation process using a computer program. The length of follow-up was 12 months. The outcomes were evaluated at 6 and 52 weeks after randomisation. At 1 year, follow-up data were available for 168 (93%) patients, of whom 63 (93%) were from the brace group, 52 (93%) from the physiotherapy group and 53 (95%) from the combined intervention group. A researcher, blinded to patient allocation to treatment group, evaluated the clinical end points.

**Analysis of effectiveness**
The primary clinical end points were:

- a global measure of improvement on a 6-point scale (1 - completely recovered; 6 - much worse);
- severity of the patients' complaints on an 11-point scale (0 - no complaints; 11 - serious complaints);
- pain intensity of the patient's most serious complaint on an 11-point scale (0 - no pain; 11 - severe pain); and
- quality of life (assessed using the EuroQol).

The analysis of the clinical study was conducted on an intention to treat basis. At baseline, the study groups were comparable in terms of the demographic and clinical characteristics.

**Effectiveness results**
At the 1-year follow-up assessment, all clinical end points were comparable between the groups. Differences between the groups did not reach statistical or clinical significance.

For example, the values of quality of life (utilities) were 0.12 (+/- 0.16) in the physiotherapy group, 0.17 (+/- 0.29) in the brace group and 0.18 (+/- 0.30) in the combined intervention group. Similarly, the success rate (i.e. the percentage of patients with improvement) was 89% in the physiotherapy group, 86% in the brace group and 87% in the combined intervention group.

**Clinical conclusions**
The effectiveness analysis showed that the three treatments of tennis elbow were similarly effective.

**Measure of benefits used in the economic analysis**
The summary benefit measures used were the clinical end points estimated in the RCT. No discounting was performed, which was appropriate given the short time horizon of the analysis.

**Direct costs**
The analysis of the costs was carried out from a societal perspective. The direct costs included were for GP visits, physiotherapy visits, medical specialist visit in the outpatient setting, hospital stay, professional home care, acupuncture, brace and chiropractor. Both medical and non-medical direct costs were included. The unit costs and the resource quantities were presented separately. Resource consumption was collected from the sample of patients enrolled in the clinical trial, using standard forms for physiotherapists and questionnaires filled out at 6, 26 and 52 weeks' follow-up. The costs were estimated using typical Dutch sources, such as the Dutch guidelines for cost analysis in health care research, the tariffs of the Dutch Central Organisation for Health Care Charges, professional organisations and the Royal Dutch Society for Pharmacy. Discounting was not relevant as the costs were incurred during a 12-month
timeframe. The price year was not given.

**Statistical analysis of costs**
The costs in the different groups were compared using bootstrapping for pair-wise comparisons and generating 95% confidence intervals (CIs). Missing cost data were replaced by the mean of the measured costs as less than 5% of the total data were missing.

**Indirect Costs**
Productivity costs were included in the analysis, which was appropriate given the societal perspective used. Both paid and unpaid labour, and help from partners/friends, was taken into account. The unit costs and the quantities of resources used were reported separately. Resource use was derived from actual data in the RCT. The cost of unpaid labour was based on a shadow price. The cost of paid labour was estimated using the friction cost approach. As in the analysis of the direct costs, no discounting was performed and the price year was not explicitly reported (although it might have been 2004).

**Currency**
Euros (EUR). The exchange rate to US dollars ($) at February 2004 was EUR 1 = $1.26.

**Sensitivity analysis**
The issue of uncertainty was implicitly addressed by calculating bootstrapped CIs around cost-effectiveness and cost-utility ratios. A sensitivity analysis was carried out in which two alternative scenarios for costs were considered. In one scenario the cost of sick leave was based on a patient’s true salary versus the mean income of the Dutch population by age and gender. In the other scenario, the influence of labour intensity (light or heavy) on work absenteeism was considered.

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

**Cost results**
The direct costs were EUR 417 (+/- 386) in the physiotherapy group, EUR 564 (+/- 1,173) in the brace group and EUR 518 (+/- 802) in the combined intervention group.

The indirect costs were EUR 557 (+/- 1,851) in the physiotherapy group, EUR 1,416 (+/- 2,890) in the brace group and EUR 739 (+/- 2,072) in the combined intervention group.

The total costs were EUR 975 (+/- 1,989) in the physiotherapy group, EUR 1,980 (+/- 3,673) in the brace group and EUR 1,258 (+/- 2,403) in the combined intervention group.

None of the differences between groups reached statistical significance, although physiotherapy was the cheapest intervention.

The direct costs were comparable between groups, but the indirect costs were significantly higher in the brace only group compared with the physiotherapy group.

**Synthesis of costs and benefits**
Incremental cost-effectiveness ratios and cost-utility ratios were calculated in order to combine the costs and benefits of the alternative strategies. The authors also calculated incremental ratios in many cases of dominance, although these are meaningless.
In general, the incremental analysis revealed the following results:

the comparison between physiotherapy and brace favoured the physiotherapy strategy, which was less costly and had similar clinical profiles (dominant when the measure of benefit was success rate, severity of complaint or pain for the most serious complaint);

the comparison between brace and the combined therapy favoured the combined intervention, which was also less costly and had similar benefit results (dominant when measure of benefit was success rate, severity of complaint and quality of life);

in the comparison between physiotherapy and the combination therapy, physiotherapy was less costly and had similar benefit results.

However, all the incremental cost-effectiveness ratios showed very large confidence intervals around the mean estimates, ranging from dominance to very high values.

The base-case results were confirmed in the two sensitivity analyses that considered alternative cost scenarios.

Authors’ conclusions
The three therapies for tennis elbow were similarly effective and costly from a societal perspective, although there was a trend towards a better cost-effectiveness profile associated with physiotherapy alone.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. Three commonly used treatments for tennis elbow were considered. The authors stated that these were the most frequently used strategies in their setting. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a clinical trial, which was appropriate for the study question. The use of an RCT is usually associated with a high internal validity given the randomised nature of its design. Moreover, a researcher blinded to treatment allocation assessed the outcomes, which represents a further strength of the analysis. The length of follow-up appears to have been appropriate. Further advantages of the study were the baseline comparability of the study groups, which enhances the robustness of the analysis, and the use of intention to treat analysis. There was little information on the sample selection process. Finally, since no power calculations were performed, it is not clear whether the sample size was sufficiently large to detect statistically significant differences in the clinical end points.

Validity of estimate of measure of benefit
The summary benefit measures were specific to the disease considered in the study (except for the values of quality of life) and will not be easily compared with the benefits of other health care interventions. Utility values would be more generalisable. The use of the EuroQol to estimate patient quality of life appears to have been appropriate.

Validity of estimate of costs
Extensive information on the cost analysis was provided and the economic side of the study was carried out satisfactorily. The perspective was appropriate as both direct and indirect costs were taken into account. This is an important aspect of the analysis given the relevance of indirect costs (both paid and unpaid work). A breakdown of the cost items was provided, and all details of the quantities of resources used and unit costs were reported. The sources of the data were explicitly reported and represented typical national sources in the authors’ setting. Statistical analyses of the costs and quantities were performed. A sensitivity analysis was carried out to consider different assumptions in the cost analysis. However, it was unclear whether the economic analysis had sufficient power to detect statistically significant differences between groups, as the authors acknowledged. Another limitation of the analysis was the fact that the price year was not reported. Moreover, high standard deviations of mean costs per patient were observed, suggesting a large variability in costs among patients.
Other issues
The authors stated that their findings were similar to those reported in a previous study. The issue of the generalisability of the study results to other settings was not explicitly addressed. Further, the limited use of sensitivity analyses reduces the external validity of the analysis. The study referred to patients suffering from tennis elbow and this was reflected in the authors’ conclusions. In general, the main limitation of the study was the possible lack of power to detect differences in costs between the groups, as stated already.

Implications of the study
On the basis of the current findings, none of the treatments can be recommended as the optimal approach in the treatment of tennis elbow. However, given the similar success rate of the three strategies, the (non significantly) cheapest strategy, namely physiotherapy, could be selected. The authors stated that future studies should investigate two areas of research. Specifically, the treatment of patients whose complaints have not resolved after a wait-and-see policy, and the identification of sub-groups of patients who might favour certain specific interventions.

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MeSH
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