Cost effectiveness of interventions for lateral epicondylitis: results from a randomised controlled trial in primary care

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
Three interventions for the treatment of lateral epicondylitis in adult patients were examined. These were corticosteroid injections, physiotherapy and wait-and-see. With corticosteroid injections, patients were given a single local corticosteroid injection of 1 mL triamcinolone (10 mg/mL) and 1 mL lidocaine 2% on up to three separate occasions. The patient was injected until free of pain, with a maximum of 2 mL per injection. Physiotherapy consisted of treatment with pulsed ultrasound (2 W/cm², applied for 7.5 minutes), deep friction massage and an exercise programme, over a 6-week period. Treatment sessions of approximately 30 minutes were scheduled twice a week, with a maximum of nine treatment sessions. Under a wait-and-see policy, patients visited their general practitioner (GP) once during the 6-week intervention period. During this visit, the GP discussed with the patient any activities that caused pain and disability. Medication (paracetamol or non-steroidal anti-inflammatory drugs) was prescribed, if necessary.

Type of intervention
Treatment.

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

Study population
The study population comprised patients aged between 18 and 70 years with pain at the lateral side of the elbow for at least 6 weeks, and with pain increasing with pressure on the lateral epicondyl and during resisted dorsiflexion. Patients were excluded if they had received physiotherapy or corticosteroid injections for lateral epicondylitis in the last 6 months, surgery of the elbow, or had bilateral elbow symptoms. They were also excluded if there were contraindications for corticosteroid injections, or if there was evidence of any specific pathology (e.g. malignancy, fracture or inflammation).

Setting
The setting was primary care. The economic study was carried out in The Netherlands.

Dates to which data relate
Patients were enrolled between September 1997 and October 1998, during which time the effectiveness and resource use data were presumably gathered. The price year was 1999.

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 not reported. A sample of 185 patients was enrolled. There were 62 patients in the injection group, 64 patients in the physiotherapy group, and 59 patients in the wait-and-see group. There was no information on either the characteristics of the patients or patients who refused to participate in the study.

Study design
This was a randomised clinical trial that was carried out at 85 primary care centres in two cities in The Netherlands. The length of follow-up was one year. Only two patients in the injection group were lost to the follow-up assessment. Thus, the rate of complete follow-up was 99%.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The four clinical measures used in the analysis were general improvement, pain during the day, elbow disability, and utility. Patients rated their general improvement on a 6-point ordinal scale, ranging from "much worse" to "completely recovered". Success was defined as "much improved" or "completely recovered". The patients rated their pain during the day, in the week preceding their periodic assessment, on an 11-point numerical scale (0 indicating no pain). Elbow disability was measured using the modified Pain Free Function Questionnaire (PFFQ), which consists of common situations that might cause elbow pain (0 indicating no pain). All outcome values for the pain scale and the modified PFFQ were transformed into a 100-point scale to facilitate interpretation. Quality of life was measured with the EuroQol and expressed as utility values ranging from 0 to 1, where 1 represented perfect health. All outcomes were assessed using self-reported patient questionnaires at baseline and 3, 6, 12, 26 and 52 weeks. The baseline comparability of the study groups was not discussed.

Effectiveness results
The success rate after 52 weeks was 91% in the physiotherapy group, which was significantly higher compared with that in the injection group (69%) but not compared with that in the wait-and-see group (83%).

The difference in success rates between the wait-and-see policy and injections did not reach statistical significance.

General improvement was 0.90 with physiotherapy, 0.83 with the wait-and-see policy, and 0.71 with corticosteroid injections.

The pain during the day was 39 (+/- 26) in the wait-and-see group, 35 (+/- 26) in the injection group, and 46 (+/- 28) in the physiotherapy group.

The values of elbow disability were 35 (+/- 21) in the wait-and-see group, 27 (+/- 23) in the injection group, and 40 (+/- 22) in the physiotherapy group. These differences were statistically significant in favour of physiotherapy compared with injections, but not for physiotherapy versus the wait-and-see policy or injections versus the wait-and-see strategy.

The utility values were 0.81 (+/- 0.12) in the wait-and-see group, 0.78 (+/- 0.14) in the injection group, and 0.82 (+/- 0.14) in the physiotherapy group. Differences in the utility values were not statistically significant between groups.

Clinical conclusions
The effectiveness analysis showed that physiotherapy was the most effective strategy. Physiotherapy was in general significantly more effective than corticosteroid injections, while the trend in better outcomes compared with wait-and-see did not reach statistical significance.
Measure of benefits used in the economic analysis
The summary benefit measures used were the four clinical end points that were estimated from the clinical trial (i.e. general improvement, pain during the day, elbow disability, and utility).

Direct costs
The analysis took the viewpoint of society and included direct medical and non-medical costs. The direct medical costs referred to the interventions (i.e. number of sessions with a physiotherapist or visits to a GP, number of corticosteroid injections), additional visits to a health care provider (GP, physiotherapist, medical specialist or outpatient care, other healthcare professionals), prescribed medications, professional home care, diagnostic interventions and hospitalisations. The direct non-medical costs included out-of-pocket expenses (i.e. over-the-counter medication) and the costs of paid and unpaid help. The unit costs were presented separately from the quantities of resources used for all items. The resource use data were derived from the sample of patients included in the clinical trial using standardised forms and cost diaries. The costs came from multiple sources, including published Dutch guidelines, tariffs of the Dutch Central Organisation for Health Care Charges, fees charged by professional organisations, and the Royal Dutch Society for Pharmacy. Travel costs were estimated using shadow prices. Discounting was not relevant since the costs per patient were incurred during one year. The price year was 1999.

Statistical analysis of costs
Bootstrapping (2,000 replications) was used for pair-wise comparison of the mean costs. Confidence intervals for differences were calculated.

Indirect Costs
The indirect costs (i.e. productivity losses associated with absenteeism paid and unpaid labour) were included in the analysis since a societal perspective was adopted. The unit costs were presented separately from the quantities of resources used. Resource consumption came from the sample of patients included in the clinical trial. The costs of paid work were estimated using mean income of the Dutch population, according to age and gender of employees, on the basis of the friction cost method. Unpaid work was estimated using a shadow price. As in the analysis of the direct costs, discounting was not applied and the price year was 1999.

Currency
Euros (EUR). The exchange rate from Euros into US dollars ($) was EUR 1 = $0.90.

Sensitivity analysis
Sensitivity analyses were carried out using bootstrapping (5,000 replications) for cost-effectiveness and cost-utility ratios, which were represented on cost-effectiveness planes. Cost-effectiveness acceptability curves were then generated to determine the probability that a treatment is cost-effective given a specific ceiling ratio.

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

Cost results
The cost analysis showed that there were no statistically significant differences in the consumption of resources among treatment groups.

The direct health care costs were EUR 56 (+/- 100) in the wait-and-see group, EUR 143 (+/- 187) in the injection group, and EUR 214 (+/- 92) in the physiotherapy group.

The direct non-health care costs were EUR 57 (+/- 182) in the wait-and-see group, EUR 125 (+/- 379) in the injection
group, and EUR 96 (+/- 101) in the physiotherapy group.

The indirect costs were EUR 518 (+/- 1,549) in the wait-and-see group, EUR 164 (+/- 507) in the injection group, and EUR 612 (+/- 2,456) in the physiotherapy group.

The total costs were EUR 631 (+/- 1,627) in the wait-and-see group, EUR 430 (+/- 872) in the injection group, and EUR 921 (+/- 2,468) in the physiotherapy group.

The mean total costs in the injection group were 53% (EUR 491) lower than in the physiotherapy group. This difference was statistically significant.

The mean total costs in the wait-and-see group were 47% (EUR 201) higher than in the injection group and 31% (EUR 290) lower than in the physiotherapy group, but none of these differences reached statistical significance.

**Synthesis of costs and benefits**

Incremental cost-effectiveness and cost-utility ratios were calculated to combine the costs and benefits of the alternative treatments.

The additional cost per additional 1-point improvement on the ordinal General Improvement Scale was EUR 2,035 with wait-and-see over injections, EUR 4,675 with physiotherapy over wait-and-see, and EUR 3,089 with physiotherapy over injections.

The additional cost per additional 1-point improvement in pain during the day was EUR 43 with wait-and-see over injections, EUR 64 with physiotherapy over wait-and-see, and EUR 53 with physiotherapy over injections.

The additional cost per additional 1-point improvement on the PFFQ was EUR 29 with wait-and-see over injections, EUR 72 with physiotherapy over wait-and-see, and EUR 46 with physiotherapy over injections.

The additional cost per additional utility gain was EUR 6,807 with wait-and-see over injections, EUR 34,461 with physiotherapy over wait-and-see, and EUR 12,158 with physiotherapy over injections.

The cost-effectiveness acceptability curve showed that with a ceiling ratio of EUR 20,000 per improvement in outcome, the probability that physiotherapy was cost-effective in comparison with injection was approximately 80%. Less clear indications for the comparison between injections versus wait-and-see and physiotherapy versus wait-and-see were observed.

**Authors’ conclusions**

Physiotherapy showed better clinical effects, whereas a wait-and-see strategy was less costly but still produced clinical benefits in comparison with corticosteroid injections. Therefore, no strong conclusion could be reached on the optimal strategy for the treatment of lateral epicondylitis.

**CRD COMMENTARY - Selection of comparators**

The rationale for the selection of the comparators was clear. Wait-and-see was the treatment option recommended by the Dutch College of General Practitioners, while physiotherapy and corticosteroid injections were also commonly used for the treatment of lateral epicondylitis in adult patients. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**

The effectiveness evidence came from a published clinical trial, thus limited information on the design and other characteristics of the study was provided. In general, the use of a randomised trial has a high internal validity, owing to the reduced impact of selection bias and confounding factors. An intention to treat analysis of the clinical study and the limited loss to follow-up enhance the robustness of the effectiveness study. However, the reader is referred to the
primary trial to assess the validity of the clinical estimates.

Validity of estimate of measure of benefit
The summary benefit measures were specific to the disease considered in the study. They are not comparable with the benefits of other health care interventions. They were derived directly from the effectiveness study. The impact of the interventions on quality of life was investigated.

Validity of estimate of costs
The adoption of a societal point of view was appropriate as all relevant categories of costs were considered. Both paid and unpaid work lost was considered, which represents a strength of the analysis. The unit costs and the quantities of resources were appropriately reported, which aids replication of the cost analysis in other settings. The source of the data was reported for all items. The costs were specific to the study setting, but extensive sensitivity analyses were carried out to deal with the distribution of cost data and their variability. The price year was reported, which enables reflation exercises to be conducted.

Other issues
The authors did not compare their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. The extensive use of bootstrapping enhances the robustness of cost-effectiveness estimates. The study referred to adult patients with lateral epicondylitis and this was reflected in the authors' conclusions.

Implications of the study
The study results suggested that there is no reason to update or amend the clinical guidelines for GPs in The Netherlands, which recommend a wait-and-see strategy for the management of lateral epicondylitis.

Source of funding
Funded by the Health Insurance Council for Investigative Medicine, and the Netherlands Organisation for Scientific Research.

Bibliographic details

PubMedID
14871165

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

**MeSH**
Adolescent; Adrenal Cortex Hormones /economics /therapeutic use; Adult; Aged; Anesthetics, Local /economics /therapeutic use; Cost of Illness; Cost-Benefit Analysis; Health Care Costs; Health Services Research; Humans; Injections, Intradermal /economics /utilization; Lidocaine /economics /therapeutic use; Middle Aged; Netherlands; Observation; Physical Therapy Modalities /economics /utilization; Primary Health Care /economics /methods; Tennis Elbow /economics /therapy; Treatment Outcome

**AccessionNumber**
22004008180

**Date bibliographic record published**
31/05/2006

**Date abstract record published**
31/05/2006