Early outcome and cost-effectiveness of endoscopic versus open carpal tunnel release: a randomized prospective trial


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
Patients with carpal tunnel syndrome (CTS) were given either single portal endoscopic carpal tunnel release (ECTR) or open carpal tunnel release (OCTR). ECTR was performed according to the extrabursal technique described by Agee et al. (see ‘Other Publications of Related Interest’ for bibliographic details) using the MicroAire CTRS single-portal system. OCTR used a standard open approach with a 2-cm palmar incision. Both kinds of surgery were performed using local anaesthetic and tourniquet control.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with CTS who were aged at least 16 years old. CTS was diagnosed clinically and, when in doubt, nerve conduction tests were carried out. Patients were excluded if they had had wrist fractures in the past, surgery, rheumatoid arthritis, or other inflammatory conditions. Patients were also excluded if they had a suspected mass lesion, or if they required additional procedures such as biopsy.

Setting
The setting was secondary care. The economic study was carried out in Norwich, UK.

Dates to which data relate
The effectiveness evidence related to 1998 to 2001. The indirect costs related to 2002. No dates or price years were given for the direct costs.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same patients who provided the effectiveness evidence. However, some of the costing was theoretical rather than being based on the costs actually incurred.

Study sample
No power calculations were reported. There was no sample selection as all eligible patients were included. A total of
162 patients were invited to participate in the study, and 123 gave their informed consent. After enrolment, 74 patients (28% male) received ECTR and 76 patients (25% male) received OCTR. The mean age of the patients was 54 (+/-15) years in the ECTR group and 50 (+/-15) years in the OCTR group. Patients with bilateral CTS underwent releases sequentially starting with the more affected hand. Once these patients felt that they could use the operated hand normally they underwent the second procedure. The minimum time between operations was 7 months. Nine of the patients originally allocated to ECTR were eventually moved to OCTR as they did not meet the criteria laid down for the surgeons, which permitted them to continue with ECTR.

**Study design**
This was a randomised controlled trial (RCT) that was performed in two hospitals. The patients were randomised using block randomisation and sealed envelopes. The assessor was blinded to the procedure by placing a stockinet over the wrist of the patient. The patients were followed up for 12 weeks.

**Analysis of effectiveness**
The basis of the analysis was intention to treat. Patients were analysed as randomised to the study and not according to the surgical procedure actually used. The primary health outcome assessed was the number of days off work. The dates of surgery and return to work, as reported by the patient in their sick notes, were used to calculate this outcome. The secondary health outcomes assessed were:

- the operation time;
- preoperative severity, assessed using Levine's Symptom Severity and Functional Scales questionnaires (Levine et al., see 'Other Publications of Related Interest' for bibliographic details);
- the subjective response to surgery and its impact on activities of daily living;
- the subjective anterior carpal tenderness in the heel of the hand, assessed using a visual analogue scoring;
- grip strength, measured using a Jamar Hand Dynamometer (Clifton); and
- the incidence of adverse events.

Patients were assessed for comparability at baseline but no statistical tests were reported. The patients in the ECTR group were, on average, 5 years older than those in the OCTR group and were more likely to have their left hand operated on. Apart from these differences, the two groups appeared similar preoperatively.

**Effectiveness results**
Forty three patients (58%) in the endoscopic group and 42 (55%) in the open group were in employment at the time of the study. An analysis of the primary end point could only be carried out on these individuals.

Patients in the endoscopic group returned to work, on average, 8 days (95% confidence interval: 2 - 13) quicker than the open group, (p=0.005; two-sample t-test).

A general linear model was constructed to test for a between-group difference in the number of days taken to return to work whilst adjusting for age, side of hand operated (left or right) and occupation (manual and non-manual), but these adjustments made no difference to the results.

The mean operation time was 15.8 minutes (standard deviation, SD=3.5) in the ECTR group and 13.4 minutes (SD=3.4) in the OCTR group, (p<0.001).

Patients were evaluated at 1, 3, 6 and 12 weeks. The values below are described as an area under the curve analysis (a way of averaging the values over time).
The mean score for anterior carpal tenderness (11 is painless and 55 is severe pain) was 22 (SD=7) in the ECTR group and 24 (SD=6) in the OCTR group, (p=0.176).

The mean grip strength was 253 kg (SD=121) in the ECTR group and 231 kg (SD=102) in the OCTR group, (p=0.213).

The median Levine functional score was 109 (S-IQR 22) in the ECTR group and 108 (S-IQR 24) in the OCTR group, (p=0.984).

The median Levine symptom score was 120 (S-IQR 21) in the ECTR group and 119 (S-IQR 19) in the OCTR group, (p=0.701).

There was no statistically significant difference between the results in the two groups.

In terms of adverse effects, no patients suffered from permanent neurovascular injury.

One patient in the ECTR group had transient numbness in the index finger which disappeared after 3 weeks. One patient in the OCTR group had hyperaesthesia over the scar area which had improved by 3 months. One patient in each group had a superficial wound infection. One patient in the ECTR group needed open surgery after 3 months because there had been no improvement in symptoms, and one patient in the OCTR group had no improvement in symptoms.

Clinical conclusions
Both kinds of carpal tunnel release produced similar outcomes in terms of improvements in symptoms and in terms of incidence of adverse effects. However, ECTR led to a quicker return to work, with an average reduction in sick leave of 8 days.

Measure of benefits used in the economic analysis
No summary measure of benefit was produced. As such, the authors carried out a cost-consequences analysis.

Direct costs
No discounting was carried out as the costs were incurred during less than 2 years. Only the marginal cost of ECTR was estimated. This was the cost of the capital equipment used for each patient and the cost of the non-reusable blade used for each patient. The costing of each technique was predicated on the assumption that resource use in terms of the surgeon, theatre staff, anaesthetic and theatre equipment was the same for both procedures, except for the cost of the endoscopic equipment. In addition, the authors reported that they were unable to perform more than eight of either procedure per day-case list. Therefore, they assumed that the time taken for both procedures was similar. The costs were derived from actual data from the hospital and were broken down into prices and quantities. However, it was not the actual cost incurred by the patients, but a theoretical cost based on the authors’ knowledge of the two kinds of surgery and their estimation of the marginal cost. No price year was given.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
No discounting was carried out, which was appropriate as the costs were incurred during less than 2 years. The costs were estimated from actual data given by the patients and data from the Confederation of British Industry. The cost of family and friends staying off work was estimated, but it turned out to be zero. The cost of being off work was measured, and the quantities and costs were analysed separately. The price year was not stated clearly, but it was likely to have been 2002.

Currency
UK pounds sterling () and Euros (Euro). No conversion rate was reported.

**Sensitivity analysis**
No sensitivity analysis was carried out.

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

**Cost results**
The marginal cost per case of ECTR due to extra equipment was 98 (Euro147).

The cost saving to industry from the earlier return to work was 536 (Euro805) per patient.

Therefore, ECTR resulted in a net saving of 438 (Euro658) per patient for those in employment.

For those unemployed, there was nothing to offset the incremental cost of 98 (Euro147) since no input was required.

The costs were calculated for 12 weeks.

The costs of adverse effects and of ECTR patients converting to OCTR were not included.

**Synthesis of costs and benefits**
The costs and benefits were not combined as the study was, in effect, a cost-consequences analysis.

**Authors’ conclusions**
Endoscopic carpal tunnel release (ECTR) saves society resources in comparison with open carpal tunnel release (OCTR), as patients are able to return to work earlier after surgery. The benefit of ECTR more than outweighs the extra cost.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparators was justified as they were well-established treatments for CTS. You should decide if they are widely used health technologies in your own setting.

**Validity of estimate of measure of effectiveness**
The source of the effectiveness data was a single study. The study design, an RCT, was appropriate for the study question. No power calculations were reported and, therefore, the study might have had insufficient power to detect statistical differences in secondary outcomes. As there was no strict sample selection, the reader should decide whether the exclusion criteria make the study sample representative of the study population of patients with CTS. The patients were shown to be comparable in most, but not all, baseline characteristics at analysis. However, a linear regression analysis was conducted to account for those differences and no effect was found. The analysis of effectiveness was handled credibly in many respects, but the large number of patients moved to OCTR (12%) limits the value of the effectiveness evidence.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefits. The health benefits were therefore those associated with the effectiveness outcomes.
Validity of estimate of costs
From the cost perspective adopted (i.e. society), the authors included all relevant costs if they were accurate in their estimation of the marginal costs of ECTR. However, the authors did not calculate the actual costs incurred by the patients. They also did not include the OCTR costs for patients who started ECTR and were then switched. Thus, it is likely that the authors have underestimated the marginal cost of ECTR. Also 58% of the ECTR group and 42% of the OCTR group were in employment, thus the social gain of the early return to work did not apply to all patients with CTS. However, the authors’ overall conclusions that ECTR is less costly will not be affected by the population they studied. Some, but not all, of the unit costs were reported separately from the resource quantities, which will increase the generalisability to other settings. The resource use quantities were taken from a single study, while the prices were taken from the authors’ setting and from a published source. No statistical or sensitivity analyses of the quantities or prices were carried out. These facts limit the interpretation of the results. No price year was given, which will prevent any possible inflation exercises.

Other issues
The authors made appropriate comparisons of their results with the findings from other studies. The issue of generalisability to other settings was addressed, particularly as the study showed an unusually high conversion rate from ECTR to OCTR. The authors did not present their results selectively, but their conclusions on costs are stronger than their results can justify.

The authors acknowledged that their results are subject to several limitations. First, they only examined surgery on one hand at a time. Second, the follow-up period was short. Third, although OCTR took 2 minutes less than ECTR, they were unable to operate on more patients in a single day for organisational reasons, which could change in the future and would result in an increase in the marginal direct cost of ECTR. Finally, they did not consider whether ECTR results in a higher recurrence rate of CTS, or the impact of any major nerve injury that results in permanent disability. These facts may have a major impact on cost-effectiveness.

Implications of the study
The authors recommended that ECTR should be considered a cost-effective procedure, but perhaps not in the general population as a whole. Further research should attempt to obtain a more accurate estimate of the marginal cost of ECTR and to confirm the results over a long-term period.

Source of funding
None stated.

Bibliographic details

Other publications of related interest


Subject indexing assigned by NLM

**MeSH**
Activities of Daily Living; Carpal Tunnel Syndrome /economics /surgery; Cost-Benefit Analysis; Employment; Endoscopy /adverse effects /economics; Female; Humans; Male; Middle Aged; Orthopedic Procedures /adverse effects /economics; Pain Measurement; Prospective Studies; Questionnaires

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