Cost-effectiveness analysis of adjuvant physical or occupational therapy for patients with reflex sympathetic dystrophy

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
Adjuvant physical therapy (PT) and occupational therapy (OT) alongside medical treatment in the treatment of patients with reflex sympathetic dystrophy (RSD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study investigated patients with RSD in one upper extremity, who had experienced the symptoms for less than a year.

Setting
The setting was hospital. The economic analysis was carried out in The Netherlands.

Dates to which data relate
Effectiveness and resource use data were collected during a 12-month period, but the date was not specified. The price date was 1996.

Source of effectiveness data
The evidence for final outcomes 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
It was not stated whether power calculations were used to determine the sample size. 145 consecutive patients fulfilling the clinical inclusion criteria were asked to participate and 10 (6.8%) refused, thus 135 patients were randomised, 44 to physical therapy, 44 to occupational therapy, and 47 to the control group.

Study design
The study was a twelve-month two-centre randomised controlled trial. The patients were seen 5 times during this
period. Detailed information was not provided on the method of randomisation to the different arms of the study. The patients could not be blinded for this intervention but the introduction of bias was handled to some extent by choosing a control treatment that provided close attention to the patients, rather than doing nothing. Centre effects on the outcomes were explored and no difference was found. 15 patients (11% of total patients) were lost to follow-up, 7 in the physical therapy group (16% of PT group), 7 in the occupational therapy group (9% of OT group) and 4 in the control group (8.5% of CT group). It was not stated whether the investigators were blinded to the treatments received by the patients.

**Analysis of effectiveness**
The results were analysed on the basis of intention to treat and of treatment completers. Of the PT patients, 3 could not complete the treatment protocol but did attend the measuring sessions. 14 patients switched adjuvant therapy: 9 from CT to PT, 3 from CT to OT, and 2 from OT to PT. No relevant differences in patient characteristics were found at enrollment. All patients received identical medical treatment during the study. Three measures of effectiveness were used: the Impairment-level Sum Score (ISS), the modified Greentest and the Sickness Impact Profile (SIP). The ISS reflects the level of impairment caused by RSD (scores from 5 to 50 points), the modified Greentest measures the disability caused by RSD and the SIP measures health-related functional status (score between 0 and 100).

Effectiveness was reported in terms of the mean difference between the baseline scores and the end scores for each instrument.

**Effectiveness results**
The mean gain in effectiveness for PT was as follows:

- Greentest, 15.8;
- ISS, 22; and
- SIP, 6.8.

The mean gain in effectiveness for OT was as follows:

- Greentest, 14.2;
- ISS, 46; and
- SIP, 7.7.

The mean gain in effectiveness for CT was as follows:

- Greentest, 10.7;
- ISS, 38; and
- SIP, 9.7.

The mean gain in score for the modified Greentest and the SIP did not significantly differ in a pairwise comparison for the three groups. For the ISS a significant positive difference occurred for the comparison of PT with CT and for the comparison of OT with CT.

**Clinical conclusions**
The adjuvant physical therapy results in clinically relevant improvement in RSD regarding the level of impairment as measured with ISS and is more effective than occupational therapy and control treatment. On the level of general health, differences between the groups using the SIP could not be found, probably because this instrument is not able to measure the subtle differences between the adjuvant treatment regimens.
Measure of benefits used in the economic analysis
No summary health benefit was used in the economic analysis. Benefits were measured in terms of points gained between baseline and the 12-month follow up, on three different assessment instruments, the SIP, the Greentest and the ISS. The reader is referred to the effectiveness results reported above.

Direct costs
Costs were not discounted, which was appropriate given that the duration of the study was one year. Cost prices were reported but not quantities. Medical costs for adjuvant therapy, other medical costs (hospital stay, usage of transcutaneous electrical nerve stimulation apparatus, GP visits, outpatient visits, other treatments), help at home, non medical costs (travelling costs and out of pocket costs) were recorded. Resources used were measured using a case record form to register hospital admissions and using cost diaries given to the patients, for two week periods at each of the five follow up meetings. Costs incurred over 12 months were then estimated using the area under the curve method. Costs for PT, OT and CT were estimated using employee costs, costs for materials and depreciation costs. Real costs, as opposed to charges, were used from one of the participating hospitals. Missing values (due to missing diaries) were assumed to be random and a weighted mean of the measured value for that period was used. Costs were measured for one year but the date was not specified. The price date was 1996.

Statistical analysis of costs
For the costs recorded continuously over the 12 month period, the difference between the different costs categories of the three groups was statistically tested by the non-parametric Mann-Whitney U Test. For the costs recorded in the diaries, the area under the curve method was used to estimate 12 months costs and because of missing values, only group means could be calculated. For these, the standard error of the costs per treatment group was calculated using the jackknife method.

Indirect Costs
Patients recorded the number of days of absence from work or inability to carry out daily activities in the cost diaries. The method used to estimate these costs was not stated.

Currency
Dutch guilders (Dfl).

Sensitivity analysis
A sensitivity analysis was performed on the cost prices for adjuvant treatment and hospital admission, although it is not clear whether this was a one-way or multi-way analysis.

Estimated benefits used in the economic analysis
The reader is referred to the effectiveness results reported above.

Cost results
Based on the intention-to-treat analysis (per protocol analysis is also reported), the mean total medical costs were Dfl 8,692 for PT, Dfl 13,023 for OT and Dfl 7,888 for the control treatment. Non-medical costs and indirect costs were not included in the analysis, because the shown to be differences between the three groups were not statistically significant.

Synthesis of costs and benefits
Incremental cost-effectiveness ratios were calculated pairwise for the three interventions. Effectiveness was measured as the mean difference between baseline scores and end scores on the three different instruments and costs were mean total medical costs. Based on the intention to treat analysis (per protocol analysis is also reported), for the ISS, PT was
dominant over OT (i.e. more effective and less costly), PT had an incremental cost-effectiveness ratio of Dfl 157 per point compared to CT. OT had an incremental cost-effectiveness ratio of Dfl 1,467 per point compared to control therapy. Confidence intervals for the cost-effectiveness ratios were not reported. Sensitivity analysis on cost prices and hospital admission showed that varying these parameters had a marginal effect on the findings.

Authors' conclusions
PT results in clinically relevant improvement in RSD regarding the level of improvement as measured with ISS. Thus, compared to both OT and the control treatment, PT seems to be a cost-effective treatment.

CRD COMMENTARY - Selection of comparators
The authors make a good case for selecting a control treatment (follow-up by the department of social work) that is different to usual practice (doing nothing), in order to avoid effects arising simply from more attention being provided to the treatment groups (the placebo effect).

Validity of estimate of measure of benefit
The randomised study design and thoroughness of the statistical analyses (for example both intention to treat and per protocol analyses were performed) suggest that the validity of the benefit measures is high. The lack of information on the randomisation process and the blinding of the investigators may however, hamper the validity of the estimate of measure of benefit to some extent.

Validity of estimate of costs
The estimation of costs was handled thoroughly and real costs at one of the participating hospitals were used rather than charges. The differential analysis of costs allowed the authors not to include non-medical costs and indirect costs in the cost-effectiveness ratios, since these cost categories were not found to be significantly different in each of the three groups.

Other issues
The authors raise the issue of whether these results are only valid for the complete application of the treatment programme or whether the same effectiveness gains could be obtained from partial application of the programme, which is the underlying assumption of cost-effectiveness decision rules. An extensive literature review was conducted using MEDLINE and reviewing economic evaluations to find similar studies for the treatment of RSD, but none were found. This made it impossible to assess the findings with other possible interventions for RSD.

Implications of the study
The results of the study suggest that compared to OT and CT, PT would appear to be more cost-effective.

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