Adjuvant physical therapy versus occupational therapy in patients with reflex sympathetic dystrophy/complex regional pain syndrome type I

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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
Three approaches were compared for the treatment of patients with reflex sympathetic dystrophy (RSD): physical therapy, occupational therapy and social work. RSD is also called complex regional pain syndrome Type I.

Type of intervention
Rehabilitation.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with RSD, excluding those with a peripheral nerve lesion. RSD was diagnosed according to the criteria published by Veldman et al. (see Other Publications of Related Interest. Patients were included if they met the following inclusion criteria:

they had RSD of one upper extremity with a duration of less than 1 year;
complete treatment could be administered in one of the two study sites; and
they were aged at least 18 years.

Patients were excluded on the grounds of the following: impairment of a contralateral extremity, relapse of RSD, pregnancy, lactation, and prior sympathectomy of the affected extremity.

Setting
The setting was an out-patient department in tertiary care. The study was conducted in Nijmegen and Amsterdam, The Netherlands.

Dates to which data relate
The effectiveness evidence and resource use data were gathered between 1 June 1994 and 18 February 1998. The price year was not reported.

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

Link between effectiveness and cost data
The effectiveness and cost data were collected from the same sample of patients.

**Study sample**
The required sample size (n=150) was determined using a power calculation. This assumed an 80% power, based on a mean difference of 6 or 7 points on the Impairment Level Sumscore (ISS). The study achieved a sample size of 135, which gave a 72% power to detect a significant treatment effect with each group. The authors did not report how the sample was selected. A total of 135 patients were included in the study. There were 44 patients in the physical therapy group, 44 in the occupational therapy group, and 47 in the social work group. A further 10 patients refused to take part because of the travelling distance and/or lack of time, or because they were unwilling to leave their physiotherapist or participate in a research project.

**Study design**
The study was a two-centre, prospective, randomised, single-blinded controlled trial. The patients were assigned to groups using allocation lists established by the Department of Medical Statistics (University of Nijmegen). Randomisation was stratified according to the duration of illness (0 to 6 months or 7 to 12 months), and the skin temperature of the affected extremity on enrolment (warm or cold). The patients were followed for 12 months. Eighteen patients were lost to follow-up: 7 in the physical therapy group, 4 in the occupational therapy group, and 7 in the social work group. A further 14 patients switched therapies: 12 switched from social work to physical therapy (9 patients) or occupational therapy (3 patients), and 2 switched from occupational to physical therapy.

The study was initially single-blind because the assessors did not know how the patients were allocated to the treatment arms. However, this was disrupted after the baseline visit because patients either wore splints or had evidence of having worn splints, or showed evidence of connection to the transcutaneous electrical nerve stimulation equipment. In addition, the investigators saw the patients making their way to the various departments for treatment.

**Analysis of effectiveness**
The study was analysed on the basis of per protocol (PP) and intention to treat (ITT). The PP analysis excluded patients who were lost to follow-up or who switched groups (protocol violators). The results of the treatment were documented for impairment, disability and handicap. Impairment was assessed using the ISS, where a change of 5 points in the ISS score was rated as clinically relevant. Disability was assessed using the Radboud Skills questionnaire, the modified Greentest and the Radboud Dexterity test. Handicap was assessed using the Sickness Impact Profile (SIP) index. The patients in the three treatment groups had similar characteristics at enrolment.

**Effectiveness results**
Physical and occupational therapies resulted in greater improvements in ISS scores than the control group (social work).

When using the PP analysis, the mean ISS scores were 16.4 (standard error, SE=1.7) for the physical therapy group, 14.4 (SE=1.3) for the occupational therapy group, and 9.6 (SE=1.7) for the social work group, (p=0.006 for physical therapy and p=0.024 for occupational therapy).

When using the ITT analysis, the mean ISS scores were 15.8 (SE=1.6) for the physical therapy group, 14.2 (SE=1.2) for the occupational therapy group, and 10.7 (SE=0.5) for the social work group, (p=0.023 for physical therapy and p=0.07 for occupational therapy).

The Radboud Skills questionnaire and Greentest did not reveal any significant differences in the overall results between the groups when using either the PP or ITT analysis. When the individual components of the Greentest were analysed, both the ITT and PP analyses revealed significant differences in favour of occupational therapy in 3 of the 7 components. The ITT and PP analyses showed that occupational therapy had a significantly better effect on the overall score on the Radboud Dexterity test than social work.

The ITT and PP analyses showed that the results and improvements over time for the SIP scores were similar in all...
Clinical conclusions
The authors concluded that physical therapy, and to a lesser extent occupational therapy, had a clinically relevant effect on impairment. The physical therapy groups scored 6 points on the ISS, whilst the occupational therapy group scored 4 points. On a disability level, a positive trend was found in favour of occupational therapy. There were no differences between the groups in terms of the level of handicap.

Measure of benefits used in the economic analysis
The measures of benefit used in the economic analysis were the ISS, the modified Greentest and the SIP index. These were compared at baseline and at 12 months.

Direct costs
The resource quantities and costs were not reported separately. The direct costs were for treatment, travelling, and other medical and non-medical costs. No further details of the type of direct costs included were reported. The source of the direct cost data or the unit costs was not reported. Discounting was irrelevant due to the short timeframe (1 year) of the study. The price year was not reported.

Statistical analysis of costs
The authors reported that non-parametric tests were used to analyse the costs statistically. However, they did not report any results of this analysis.

Indirect Costs
The authors reported that the indirect costs, classified as "productivity" costs, were included in the analysis. However, they did not provide a rationale for including these costs. The authors did not state whether the productivity gains or losses were measured. In addition, they did not report the source of the quantity or unit cost data. The quantities and costs were not analysed separately. It was not reported whether the indirect costs were estimated from actual data or by guesswork. Discounting was irrelevant due to the short timeframe (1 year) of the study. The price year was not reported.

Currency
Dutch guilders (Dfl). No currency conversion rate was reported.

Sensitivity analysis
The authors reported that a sensitivity analysis was conducted, but they did not report any details of this.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section. The authors reported that there was no statistical difference in the Greentest and SIP index. Physical therapy was superior to the occupational therapy in terms of the ISS score.

Cost results
The total medical costs were depicted graphically, whereas the actual values were not reported. The approximate values, as obtained from the graph, were Dfl 13,000 for the occupational therapy group, Dfl 8,700 for the physical therapy group, and Dfl 8,000 for the social work group.
Synthesis of costs and benefits
The incremental cost-effectiveness ratio of physical therapy compared with social work was Dfl 186 per ISS point. The value for occupational therapy compared with social work was Dfl 1,467 per ISS point.

The authors reported that the sensitivity analysis showed the cost parameters had a moderate influence on the incremental cost-effectiveness ratios. However, they did not report any values.

Authors’ conclusions
Physical therapy was shown to have an advantage over occupational therapy with regards to the cost-effectiveness ratio.

CRD COMMENTARY - Selection of comparators
The choice of physical therapy and occupational therapy as the comparators was explicitly justified. The use of the social work group was not explicitly justified. You should decide if this is a widely used approach in your own setting.

The authors did not provide adequate details about the type of occupational and physical therapies provided during this study. They only referred to the fact that the therapy was standardised using a treatment protocol.

Validity of estimate of measure of effectiveness
The study was designed as a randomised, single-blind controlled trial, which was appropriate for the study question. In practice, it was not possible to blind the assessors to the assessment of the outcome. This may have resulted in a bias because the study investigators knew the treatment strategy allocated to each patient. The study sample was representative of the study population. The groups of patients were shown to be comparable at analysis. The analysis was conducted on both a PP and an ITT basis. Power calculations were reported. The study achieved a power of 72% rather than 80%, based on the ISS score. The study was not powered to detect a statistical difference for the other effectiveness measures. It was, therefore, not possible to determine whether the lack of statistical difference observed between the groups was due to actual equivalence or inadequate power.

Validity of estimate of measure of benefit
The benefits were estimated directly from the effectiveness analysis. The study used the primary measure of effectiveness, upon which the study was powered, as the main summary measure of health benefit. The choice of the measure of benefit seemed appropriate and was justified by the authors.

Validity of estimate of costs
The authors reported that all the categories of cost relevant to the perspective adopted were included in the analysis. However, from the information reported, it was not possible to determine whether all the costs relevant to each category were included. The costs and quantities were not reported separately. The authors did not report the source of the prices or unit costs, or the actual values for medical, non-medical and indirect costs. Discounting was irrelevant since all the costs were incurred over one year. The price year was not reported.

The authors referred to a statistical analysis of the costs, but they did not provide details concerning the p-values reported in the paper. In addition, they did not provide details of the input parameters used for the sensitivity analysis, or the results.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not adequately addressed for two reasons. First, there was insufficient justification for the comparators. Second, there was a lack of information on the methods used for the sensitivity analysis. The authors reported that they valued medical, non-medical and indirect costs. However, they only presented values for the medical costs graphically, and they did not explain which costs were used to calculate the incremental cost-effectiveness ratio. The actual data used for the statistical and sensitivity analyses were not reported. These omissions made it difficult to
critically appraise the study’s findings, and to translate the findings to other settings.

The study enrolled patients with RSD of less than one years’ duration and this was reflected in the conclusions. The authors reported that the physical and occupational treatment protocols were specially constructed for this research, but that they could be improved.

**Implications of the study**
Adjuvant physical therapy, and to a lesser extent occupational therapy, made a valuable contribution to the relief and cure of signs and symptoms of RSD in patients with RSD of the upper extremity. The authors summarised that physical therapy and occupational therapy each contributed to the recovery of RSD of the upper extremity, albeit in different ways. They went on to suggest that further studies were needed to examine the type of physical and occupational therapies used. Also, to identify appropriate measures to judge treatment progress and outcome.

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**Other publications of related interest**

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