A comparison of economic aspects of hospitalization versus ambulatory care in the management of neuritis occurring in lepra reaction


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
Ambulatory versus inpatient treatment of neuritis in leprosy was examined.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients presenting with neuritis, as a part of either Type 1 or Type 2 reactions, of less than 6 months’ duration. Patients with a nerve abscess, pustular or ulcerating erythema nodosum leprosum, and those on oral or parenteral steroids during the month prior to entering the study, were excluded. Children younger than 12 years of age were also excluded.

Setting
The setting was a hospital or outpatient department, depending on the treatment modality. The economic study was carried out in India.

Dates to which data relate
The effectiveness and resource use data were gathered from October 1999 to March 2001. The price year was not reported.

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 clinical study.

Study sample
Power calculations were performed in the preliminary phase of the study. These were based on the assumption that 5% of patients being treated in the admitted group would return to work in 15 days, compared with 45% of patients being treated on an ambulatory basis. Thus, a sample size of 18 in each group was required for a Type 1 error of 5% and Type 2 error of 20%. Of the 511 leprosy patients that were examined during the study period, 53 (10.37%) were diagnosed as having reactions, but only 26 patients were found eligible and agreed to participate. There were 13 patients in each
The mean age was 31.3 (range: 15 - 49) years in the ambulatory group and 40.7 (range: 19 - 60) years in the inpatient group. The gender ratio (male:female) was 11.2 in the ambulatory group and 12:1 in the inpatient group.

Study design
This was a prospective, randomised clinical trial that was carried out at the skin and leprosy department of a tertiary level teaching hospital in Tamilnadu, India. A computerised random numbers table was used to allocate patients to the study groups in blocks of two. Fifteen days was the period of admission for the inpatient group, and the stipulated period of rest in the ambulatory arm. Follow-up was done every 2 weeks during the first month and monthly thereafter, until the end of steroid treatment. Four patients were lost to the follow-up assessment. Of these, two were lost from the ambulatory group and one from the inpatient group after the first visit, and one other patient from the inpatient group was lost after 3 months. No blinded assessment of the outcome was performed.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary outcome measure was the number of days to return to work after the stipulated period of rest or admission. The secondary outcomes were improvements in the QOL score and sensory and motor scores. Sensory function was examined using Semmes-Weinstein graded nylon filaments (the detailed procedure was described). Motor power of the muscles of hands and feet were tested and graded according to the Medical Research Council scale on a score of 0 to 5. QOL was assessed using a specific questionnaire (higher score reflected better QOL), which was filled out for patients in both groups before starting steroids and at the end of treatment. The questionnaire was a modified version of the World Health Organization Quality of life Global pool of questions, which considered five domains (physical, psychological, level of independence, environment and social). Only 17 patients, 9 in the ambulatory group and 8 in the inpatient group were available for the assessment of QOL scores.

At baseline, the study groups were comparable in age, gender, presenting complaints, reaction type, deformity and the spectrum of leprosy.

Effectiveness results
On average, patients in the ambulatory group returned to work after 19.5 days (range: 0 - 60; median 13) compared with 66.8 days (range: 0 - 180; median 47) for patients in the inpatient group, (p=0.02).

The proportion of patients who returned to work in 15 days or less was 53.8% in the ambulatory group and 15.3% in the inpatient group, (p=0.04).

In the ambulatory group, the pre-treatment mean QOL was 61.3 (+/- 8.6) (median 61) and the post-treatment mean QOL was 77.7 (+/- 6.4) (median 76). The difference was 10.8 (95% confidence interval, CI: 6.7 - 14.4). The corresponding scores in the inpatient group were 68.0 (+/- 9.4) (median 65) and 78.8 (+/- 7.0) (median 78.5), and the difference was 16.4 (95% CI: 12.2 - 20.6). The overall mean difference in pre- and post-treatment scores for ambulatory and inpatient groups did not reach statistical significance. The analysis was replicated in the sub-group of patients without deformity and similar results were achieved.

Sensory function improved in both groups but was not significantly different between groups.

For motor function, significant differences were only achieved for median nerve scores in the inpatient group, where the score improved from 29.0 to 34.07.

Clinical conclusions
The effectiveness analysis showed that return to work was significantly shorter for patients in the ambulatory group compared with those in the inpatient group. No significant differences in QOL and sensory functions were observed, although inpatients improved some aspects of motor scores.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.

Direct costs
A societal perspective was adopted in the cost analysis. Direct medical and non-medical costs were considered, such as the costs incurred by the health sector and the patient. The direct medical costs included the costs of medications, tests and hospitalisation, while the direct non-medical costs included the costs of transport and food. The unit costs and the quantities of resources used were not reported. The authors noted that most of the details were reported in an appendix ((which was not available) on the journal website. The resource use data was estimated alongside the clinical trial from October 1999 to March 2001. No information on the source of the costs was provided. Discounting was not relevant because of the short timeframe of the analysis. The price year was not reported.

Statistical analysis of costs
The costs were presented as mean (median) values with CIs. Non-parametric tests (Kruskal-Wallis H test) were used to test for statistical differences in the costs.

Indirect Costs
The indirect costs (i.e. wages lost on account of illness) were included in the economic analysis since a societal perspective was adopted. The days of work lost were estimated in the clinical trial. However, details of the unit costs and data sources were not reported. As in the analysis of the direct costs, discounting was not relevant because of the short timeframe of the analysis and the price year was not reported.

Currency
Indian rupees (Rs).

Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
The average direct medical costs were Rs 2,341.30 (median 1,526; range: 566.65 - 11,546.55) in the ambulatory group and Rs 11,451.80 (median 9,086.5; range: 6,505.25 - 27,128.69) in the inpatient group (difference 9,110.5; p=0.001).

The average direct non-medical costs were Rs 348.30 (median 287; range: 45.4 - 960) in the ambulatory group and Rs 1,236.8 (median 705; range: 49 - 6,500) in the inpatient group (difference 888.5; p=0.07).

The average indirect costs were Rs 4,544.3 (median 3,900; range: 560 - 11,200) in the ambulatory group and Rs 13,051.1 (median 4,695; range: 1,800 - 72,100) in the inpatient group (difference 8,506; p=0.12).

The average total costs were Rs 7,233.90 (median 3,702.5; 95% CI: 3,638.2 - 10,829.5) in the ambulatory group and Rs 25,739.70 (median 10,905.9; 95% CI: 6,293 - 45,186) in the inpatient group (difference 18,505.80; 95% CI for the difference: 2,655 - 34,356; p<0.01).

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was carried out.

**Authors' conclusions**
Compared with inpatient care, the ambulatory treatment of neuritis from leprosy led to a shorter return to work and lower costs in a resource poor country such as India. The authors pointed out that this was a preliminary study, the conclusions of which must be interpreted with caution given the small sample size.

**CRD COMMENTARY - Selection of comparators**
A justification for the choice of the comparators was provided. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness analysis was based on a clinical trial, which was appropriate for the study question. Details on the process of patient selection and random allocation to the study groups were provided. The use of a random design reduces the potential impact of selection bias and confounding factors. The two groups of patients were well matched at baseline. The size of the sample was small, although it was based on statistical calculations which strengthen the robustness of the comparison. An extensive description of the outcome assessment tools was provided. The use of intention to treat and the partial sub-group analysis represent further strengths of the analysis. The length of follow-up appears to have been appropriate. These issues tend to enhance the internal validity of the study. The evidence came from a single institution and some patients were lost to follow-up. This might limit how representative the study sample was. Further, return to work was considered as a surrogate marker for effectiveness.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The cost analysis was performed from a societal perspective, thus all the relevant categories of costs were included. The authors stated that most of the details of the analysis were presented in a technical appendix, which was unavailable. However, the cost items considered in the analysis were clear, although the unit costs and the quantities of resources used were not presented. The period during which the resource use data were gathered was reported but the price year was not stated. This might limit the possibility of replicating the cost analysis and conducting reflation exercises in other settings and time periods. Statistical analyses of the costs were appropriately performed. However, the cost estimates were specific to the study setting and were not varied in the sensitivity analysis.

**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. No sensitivity analyses were carried out, which limits the external validity of the study. The analysis referred to patients with neuritis occurring in lepra reaction and this was reflected in the authors’ conclusions.

**Implications of the study**
The study results suggested that the ambulatory treatment of neuritis from leprosy was safe and effective as inpatient care. However, significant cost-savings may be achieved with the outpatient approach. The authors noted that large studies should be carried out to corroborate the results of the current study.

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