A Comparison of Economic Aspects of Hospitalization Versus Ambulatory Care in the Management of Neuritis Occurring in Lepra Reaction¹

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ABSTRACT

Neuritis is one of the important causes of deformities and disabilities in leprosy. Neuritis has been managed both in the field and in hospital. This study was done to compare the economic aspects of cost of ambulatory vs in-patient management of neuritis in leprosy. The quality of life of the affected patients and the clinical improvement in the 2 groups were also studied. Twenty six patients fulfilling the study criteria were randomized into the ambulatory and in-patient group (13 in each group). The primary outcome examined was cost, in various categories; the secondary outcomes included pre- and post- treatment comparison of Quality of Life (QOL) scores and tests of sensory and motor function.

The direct and indirect medical costs incurred by patients in the hospitalized group were higher than those patients in the ambulatory group. The difference in the direct medical costs between the two groups was Rs. 9110.5, and the extra direct non medical costs incurred by patients in the hospitalized group was Rs. 888.50 because of more frequent visits of family members. A greater percentage of ambulatory than in-patients returned to work in ≤15 days (53.8% vs 15.3%), and the mean duration before returning to work was 19.5 days ambulatory patients compared to 66.8 days for in-patients group. The QOL scores and motor and sensory function tests showed no significant difference between groups. Although the sample size was small, these preliminary results suggest that substantial cost minimization by ambulatory care is possible without significantly affecting the quality of life or peripheral nerve function.

RÉSUMÉ

Les névrites sont une des causes importantes de difformités et de handicap de la lèpre, qui peuvent être traitées à la fois sur le terrain et à l'hôpital. Cette étude fut entreprise afin de comparer les aspects économiques du coût des soins ambulatoires *versus* hospitaliers des névrites lépreuses. La qualité de vie des patients et l'amélioration clinique fut aussi étudiée dans les 2 pratiques. Vingt-six patients remplissant les conditions de l'étude furent assignés au hasard soit au groupe ambulatoire, soit au groupe hospitalisé (13 par groupe). Le paramètre principal étudié fut le coût pour chaque catégorie; les résultats secondaires ont inclus la comparaison avant et après le traitement des scores de qualité de vie (QDV) et des tests de fonction sensorielle et motrice.

Les coûts directs et indirects incombant aux patients hospitalisés furent plus élevés que ceux du groupe ambulatoire. La différence entre les coûts directs de chaque groupe a été de Rs. 9110,5 et les frais directs non médicaux des patients hospitalisés ont été de Rs. 888,50, dû aux visites plus fréquentes des membres de la famille. Un plus grand pourcentage de patients ambulatoires est retourné au travail dans les 15 jours (53,8 *versus* 15,3%) et la durée moyenne avant de retourner au travail a été de 19,5 jours pour les patients ambulatoires comparée à 66,8 jours pour les patients hospitalisés. Les scores QDV et les tests fonctionnels sensoriels et moteurs n'ont pas révélé de différence significative entres les deux groupes de patients. Bien que la taille de l'échantillon étudié ait été faible, ces résultats préliminaires

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suggèrent que la diminution substantielle de coût des soins ambulatoires soit possible, sans pour autant af fecter de façon significative la qualité de vie et la fonction des nerfs périphériques des patients hanséniens atteints de névrites.

RESUMEN

La neuritis es una causa importante de deformidad y discapacidad en la lepra. La neuritis se ha manejado tanto a nivel de campo como de hospital. El presente estudio se realizó con el fin de comparar los aspectos económicos del tratamiento de la neuritis en la lepra en el paciente ambulatorio y en el paciente hospitalizado. También se estudió la calidad de vida de los pacientes afectados y la evolución clínica de los pacientes en los dos grupos. Los veintiséis pacientes que cumplieron con los criterios del estudio se asignaron, aleatoriamente a los grupos ambulatorio (N = 13) y hospitalizado (N = 13). El primer parámetro estudiado fue el costo, en varias categorías; los parámetros secundarios incluyeron la comparación de la calidad de vida antes y después del tratamiento, y la evaluación de las funciones sensitiva y motora.

Los costos médicos directos e indirectos en el grupo hospitalizado fueron mayores que en el grupo ambulatorio. La diferencia en los costos médicos directos entre los dos grupos fue de Rs. 9119.5, y los costos extra directos, no médicos, en los pacientes hospitalizados ascendieron a Rs. 888.50 debido a las visitas más frecuentes de los familiares. Un mayor porcentaje de pacientes ambulatorios regresaron a trabajar en <15 días (53.8% vs 15.3% en los hospitalizados), y la duración promedio antes de regresar a trabajar fue de 19.5 días en los pacientes ambulatorios y de 66.8 días en los pacientes hospitalizados. Los niveles de calidad de vida y de función motora y sensorial no mostraron diferencias significativas entre los grupos. Aunque el tamaño de la muestra fue pequeño, estos resultados preliminares sugieren que es posible abatir substancialmente el costo del tratamiento de los pacientes ambulatorios, sin afectar significativamente ni su nivel de vida ni la función de sus nervios periféricos.

The economic aspects of the management of neuritis in leprosy have received scant attention. A recent paper by Naik and Ganapathy highlighted the need for such studies in the present declining phase of leprosy endemicity (9). Leprosy causes a variety of impairments both primary and secondary. The significant, serious, and more common primary impairments resulting from leprosy are mostly related to the consequences of nerve damage secondary to neuritis. There have been many studies (3, 4, 6, 8, 12) on the effect of steroids on neuritis of leprosy conducted both in the field and in hospitals but none comparing the implications of the cost of the two modes of treatment i.e., hospitalization and ambulatory management. Along with the study on cost, quality of life and motor and sensory functions were also studied. There are only a few studies done on the psychological impact of the disease and quality of life in patients with leprosy (5,7,11). The aim of the present study was to compare the economic aspects of ambulatory and in-patient management of neuritis in leprosy. The impact of these two modes of management on the quality of life scores and the motor and sensory functions were also looked at.

MATERIALS AND METHODS

The study was conducted at the skin and leprosy department of a tertiary level teaching hospital in Tamilnadu from October 1999 to March 2001 incorporating a multidisciplinary team of dermatologists, neurologists, and a health economist. All patients presenting with neuritis, as a part of either type 1 or type 2 reactions, of less than 6 months duration, were included. Neuritis was defined as tenderness of the nerve and/or deterioration in sensory or motor function. Patients with a nerve abscess, pustular or ulcerating erythema nodosum leprosum (ENL), and those on oral or parenteral steroids during the month prior to entering the study were excluded. Children below the age of 12 yrs were also excluded.

Patients, who were willing to enter the study after informed consent, were randomized into ambulatory and in-patient (patients who received treatment in hospital) groups. A computerized random numbers table was used for randomization in blocks of two. These patients were classified based on findings of clinical examination and skin smears, using the Ridley-Jopling classification.

Sample size. The sample size was calcu-

lated based on the primary outcome. The assumption was that 5% of the patients being managed in the admitted group would return to work in 15 days, whereas 45% of patients being managed on an ambulatory basis would return to work in 15 days. Two weeks are the period of admission for the in-patient group and stipulated period of rest in the ambulatory arm. With a type 1 error of 5% and type 2 error of 20% the estimated sample size was 18 in each group.

Outcome measures. Primary outcome: Day of return to work after the stipulated period of rest/admission. Secondary outcomes: (i) Estimation of mean cost/patient; (ii) Improvement in the score of QOL; (iii) Improvement in sensory and motor scores.

Protocol for management. Patients in the in-patient group were admitted for 2 weeks and were monitored in the ward for complications of steroid therapy. Those in the ambulatory group were educated regarding the complications of steroids and advised rest at home 2 weeks. Patients in both groups were given prednisolone at 1 mg/kg/day. Follow-up was done every 2 weeks during the first month and monthly thereafter, until the end of steroid treatment. The dose of steroids was reduced by 10 mg every visit. The day of return to work was recorded. A detailed clinical examination, sensory and motor assessment was done as a baseline, at the end of 2 weeks and then monthly till the end of treatment.

All patients underwent a pre-steroid work up which included hemoglobin, complete blood count, urine routine, random blood sugar, and a chest X-ray to rule out tuberculosis.

Sensory assessment. Sensory examination was done using Semmes-W einstein graded nylon filaments. Palms were tested with filaments of 0.2 gm (blue) and 2 gm (purple), and the soles with 4 gm (red) and 10 gm (orange).

Protective sensation was detected by using purple filaments for the palms and orange for the soles. Sensation was tested on 10 standard points on the palms and soles. One point was given to each area with misreferred or absent sensation. The maximum score for each ulnar nerve was 4, median nerve was 6 and posterior tibial was 10. Each site with absent sensation was scored and the mean sensory score for each nerve

before and after treatment was calculated in both groups.

Motor power. 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. The mean motor score prior to and after treatment was calculated.

Cost analysis. A detailed proforma was filled with regard to direct medical costs, direct non-medical costs and indirect costs (Annexure 1) (All Annexures for this article are available in the online issue of the JOURNAL at www.leprosy-ila.org). Direct costs are the costs incurred by the health sector and the patient. The direct medical costs include cost of medications, tests and hospitalization. The direct non-medical costs include cost of transport and food. Indirect costs include the wages lost on account of illness (1,2). The details of unit cost of each item used for the estimation of the direct medical costs is given in Annexure 1.

Quality of life assessment (QOL). Quality of life is defined as an individual's perception of their position in life in the context of the culture and the value systems where they live, and in relation to their goals, expectation, standards and concerns (13).

The QOL questionnaire was filled out for patients in both groups before starting steroids and at the end of treatment. The questionnaire adopted for this study was modified from the WHO Quality of life Global pool of questions (Annexure 2) (see online JOURNAL). These include information on 5 domains-physical, psychological, level of independence, environment, and social (Table 1). Each question had a maximum score of 5 except the question on pain in the physical domain, which had a maximum score of 6. The total maximum score was 106. A higher score meant a better quality of life. The total and I mean scores of each of the domains were calculated and the improvement in the score was compared among the 2 groups. The mean score for the sub-groups with and without deformities was calculated and compared.

Data analysis. Intention to treat analysis was done using the EPI INFO package. Since sample size was small and not normally distributed non parametric tests (Kruskhal-Wallis H test) were done to determine the statistical significance of ob-

Domains	Facets		
Physical	Pain, discomfort, energy, fatigue, sleep rest.		
Psychological	Positive feelings, thinking, learning, memory, concentration, self-esteem, bodily image and appearance, negative feelings.		
Level of independence	Mobility, activities of daily living dependence on medication or treatments, working capacity.		
Social relationships	Personal relationships, social support, sexual activity.		
Environment	Physical safety and security, home environment, financial resources, health and social care: availability and quality. Opportunities for acquiring new information and skills. Participation in and opportunities for recreation/leisure. Physical environment (pollution, i.e, traffic, climate) transport.		
Spiritual	Spirituality/religion/personal beliefs.		

Table 1. Domains and facets in the instrument for quality of life assessment.

served differences in costs, QOL scores and motor and sensory scores in the 2 groups. Chi-square test was done to test the difference in proportion of patients who returned to work.

RESULTS

Demographic and clinical data. Five hundred and eleven leprosy patients were examined during the study period. Of them, 53 (10.37%) were diagnosed as having reactions. Twenty-six patients were found eligible and willing for the study and were randomized into the ambulatory and inpatient group (13 in each). The baseline characteristics of the two groups were comparable with respect to age, sex, presenting complaints, reaction type, deformity and the spectrum of leprosy. (Table 2) Twentythree nerves in 13 patients of the ambulatory group and 28 nerves in 13 patients in the in-patients group were involved. The ulnar nerve was the most common nerve involved in both groups. There were 4 defaulters: two from the ambulatory group and one from the in-patient group were lost to follow-up after the first visit, and one other patient from the in-patient group was lost to follow-up after 3 months

Cost analysis. (Table 3) Considering return to work as the outcome, patients in the ambulatory group, on an average, returned to work is 19.5 days (0 to 60 days, median = 13) as compared to 66.8 days (0 to 180 days, median = 47) taken by patients in the in-patient group. This difference was statistically significant (p = 0.02).

The proportion of patients who returned to work in ≤ 15 days in the ambulatory

group was 7 (53.8%) as compared to 2 (15.3%) in the in-patient group. The difference was statistically significant (p = 0.04).

The mean direct medical cost in the ambulatory group was Rs.2341.30 and of the in-patient group was Rs.11451.80. This difference of Rs.9110.50 was statistically significant (p = 0.001). This extra cost incurred for the hospitalized patients is mainly because of bed, investigations, diet and professional char ges of the doctor and the nurse. The average direct non-medical costs were Rs.348.30 and Rs.1236.80, respectively in the ambulatory and in-patient group. The extra cost of Rs.888.50 incurred by the patients in the in-patient group was mainly because of more frequent visits of the family members. The total extra cost to the hospitalized patient incorporating both medical and non medical cost was on an average Rs.9999.00.

The indirect cost was estimated on an average, as Rs.4544.30 and as Rs.13051.10, respectively for the ambulatory and inpatient group. The difference of Rs.8506.80 is the economic gain in the ambulatory group.

Total cost for a patient including direct and indirect cost was Rs.7233.90 and Rs.25,739.70, respectively for the 2 groups (ambulatory and in-patient). The total extra direct and indirect cost per patient in the hospitalized group was Rs.18505.80. The overall difference between the ambulatory and inpatient groups ranged from Rs.2655–34,356 based on the estimates of 95% CI for the mean cost of ambulatory care together with inpatient care. This is the money lost per case if we have a policy of

TABLE 2. Shows the baseline characteristics of patients in the ambulatory and inpatient group.

Characteristics	Ambulatory $(N = 13) \%$	Inpatient (N = 13) %	
Age in years (Range)	31.3 (15 to 49)	40.7 (19 to 60)	
Sex: Male:Female	11:2	12:1	
Presenting symptoms			
Skin lesions	7 (53.8)	7 (53.8)	
Neural			
Pain	3 (23.07)	3 (23.07)	
Sensory impairment	1 (7.6)	2 (15.3)	
Motor deficit	5 (38.4)	6 (46.1)	
A combination of the above 3 symptoms	4 (30.7)	2 (15.3)	
Reaction in relation to period of treatment with MDT			
0 to 6 months	6 (46.1)	9 (69.2)	
6 months	5 (38.4)	3 (23.07)	
Post MDT	2 (15.3)	1 (7.6)	
Recurrence of reaction	4 (30.7)	4 (30.7)	
Reaction	, ,	` '	
Type 1	12 (92.3)	12 (92.3)	
Type 2	1 (7.6)	1 (7.6)	
Neuritis			
Ulnar	11 (47.8)	11 (37.9)	
Median	3 (13.04)	5 (17.2)	
Common peroneal	4 (17.3)	8 (27.5)	
Posterior tibial	5 (21.7)	3 (10.3)	
Facial 0		2 (6.8)	
Deformity			
Grade 0	3 (23.07)	1 (7.6)	
Grade 1	6 (46.1)	5 (38.4)	
Grade II	4 (30.7)	7 (53.8)	
Diagnosis			
BT	6 (46.1)	6 (46.1)	
BL	3 (23.07)	4 (30.7)	
LL	1 (7.6)	1 (7.6)	
Subpolar LL	0	1 (7.6)	
Pure neuritis	3 (23.07)	1 (7.6)	
Socioeconomic status			
high	8.3% 8.3%		
low	91.7%	91.7%	

hospitalization for all cases of mild to moderately severe neuritis.

Analysis of quality of life in the 2 groups. Seventeen patients, 9 in the ambulatory group and 8 in the in-patient group were available for assessment of pre- and post-treatment QOL scores.

The sum and mean of pre- and posttreatment scores of all the domains in both groups are shown in Table 4 and 5, respectively. The mean pre-treatment scores in the ambulatory and inpatient group were 61.3 and 68.0, respectively. The mean post-treatment scores in both groups were 77.7 and 78.8, respectively. The overall mean difference in pre and post treatment scores for ambulatory and inpatient groups was 10.8 (95% CI 6.7 to 14.4) and 16.4 (95% CI 12.2 to 20.6), respectively . The difference was not statistically significant (p = 0.42).

Patients with and without deformity were compared. The mean score before treatment was 65 in patients with ulnar claw hand and 62.3 without it. The score for patients with

Categories of cost	Ambulatory	Inpatient	p value	Extra
Direct medical cost				
Mean 2,341.30		11,451.80		
Median 1,526		9,086.5		
Range	(566.65 to 11,546.55)	(6,505.25 to 27,128.69)	0.001	9,110.5
Direct non-medical cost				
Mean	348.30	1,236.8		
Median	287	705		
Range	(45.4 to 960)	(49 to 6500)	0.07	888.5
Indirect cost				
Mean	4,544.3	13,051.1		
Median	3,900	4,695		
Range	(560 to 11,200)	(1,800 to 72,100)	0.12	8,506.8
Total cost				
Mean	7,233.90 25,739.70		18,505.80	
Median	3,702.5	10,905.9		
Range	2,638.2 6,293.3			
95% CI	(3,638.2 to 10,829. 5) (6,29	of to 45,186) < 0.0	1	(2,655-34,356)

TABLE 3. Shows the different categories of costs in rupees in the two groups.

and without foot-drop were 61.2 and 63.25. None of the differences reached statistical significance.

Assessment of sensory function in the 2 groups of the study. The mean sensory scores of the ulnar, median and posterior tibial nerves improved with treatment in both groups. The difference in improvement seen was however not statistically significant (Table 6).

Assessment of motor function in the 2 groups of the study. The mean motor scores of the ulnar nerve of the patients in the ambulatory group and ulnar, median and common peroneal nerves of patients in the in-patient group improved with treatment (Table 7). Only the difference in improvement of the median nerve scores in the in-patient group reached statistical sig-

nificance (p = 0.01). There was deterioration of the mean motor scores of the median and common peroneal nerves of patients in the ambulatory group as compared to the in-patient group, but this was not statistically significant.

DISCUSSION

This is a preliminary study on the comparative economic analysis of the treatment of neuritis in hospitalized and ambulatory patients. The results of this study need to be viewed with caution in view of the small sample size which is a major drawback. However, the study does provide some interesting data which are discussed below since there is paucity of studies relating to the economic aspects of treatment policies for neuritis. Return to work was considered

Table 4. Shows the distribution of sum of quality of life scores according to domains among patients in both groups.

Domain	Ambulatory (N = 9)		Inpatients (N = 8)	
	Pre- treatment treatment	Post-	Pre- treatment treatment	Post-
Physical	127	184	122	162
Independence 138		159	119	141
Environment	143	145	137	139
Psychological 96		143	95	128
Social 27		3	30	33
Total	531	663	503	603

TABLE 5. Shows the results of pre- and post-treatment quality of life scores in both groups.

Category	Ambulatory	Inpatients	
Pretreatment Mean	61.3	68.0	
S.D.	8.6	9.4	
Median	61	65	
Post-treatment Mean	77.7	78.8	
S.D.	6.4	7.0	
Median	76	78.5	
Difference			
Pre- and post-(mean)	10.8	*16.4	
95% CI	(6.7 to 14.4)	(12.2 to 20.6)	

p = 0.42.

to be a sound surrogate marker for effectiveness of treatment and well being of the patient. A statistically significant number of patients in the ambulatory group returned to work early (p = 0.04). The time taken to return to work was also significantly shorter among patients in the ambulatory group. This implies a significant gain in productivity.

The patients in the in-patient group returned to work later. Some patients continued to stay away from work after discharge from hospital. It is possible that hospitalization, which has a known negative effect on the patient's view of the disease, influenced this outcome (11). The direct medical costs were significantly higher in the hospitalized group. The difference in costs were due to the bed and nursing char ges, doctors' professional fees and diet in the hospitalized group. The mean overall cost for ambula-

tory group was Rs.7,233.9 (95% CI 3638.2 to 10829.5) and for hospitalized group Rs.25739.7 (95% CI 6293 to 45186). economic gain reflected by the differences of these two costs was Rs.18505.8. lower and upper estimates of this mean cost difference was calculated from the difference of the lower and upper limits of the 95% CI. This ranged from Rs.2655 to 34,356. This reflects the range of economic gain possible if the policy of ambulatory care of patients with neuritis is adopted. The high cost of hospitalization and the loss in productivity following this, were the main disadvantages experienced by opting for this mode of management for neuritis. Thus the results of our study suggests that it is economically more advantageous to adopt the ambulatory management of neuritis, especially in resource poor countries.

In a study published earlier on the impact of leprosy on the QOL, it was seen that the mean score of QOL was lower in cases than controls in all domains except spiritual Vs 101.5 for controls). (94.5 for cases Males with visible deformities had a significantly lower score than those without deformity (91.4 vs. 99.2). There was a positive correlation between the socio-economic status and quality of life scores (5). In our study physical, psychological and levels of independence showed an improvement. However, there was no dif ference in the pretreatment mean QOL among patients with and without physical deformities (63.1 vs. 62.5). One of the reasons for the apparent lack of impact of deformity in the QOL score could be the small sample size stud-

Table 6. Shows the mean and total sensory scores of patients in both groups pre- and post-treatment.

Nerves	Ambulatory (Total score)(N = 13)		Inpatients (Total score)(N = 13)		
	Pre- treatment treatm	Post- ment treatment treatment	Pre- ment	Post-	p value
Ulnar					
*0.2 g	4.4(58)	2.2(29)	6.3(82)	3.9(51)	0.9
*2 g	2.8(38)	1.1(15)	4.2(55)	3.1(41)	0.6
Median					
*0.2 g	5.2(68)	2.4(32)	7.4(97)	5.0(66)	0.8
*2 g	3.8(51)	1.5(20)	5.0(65)	2.3(30)	0.6
Post tibial	` '	` ′		` ´	
*4 g	10.8(135)	8.3(108)	15.9(207)	13.07(170)	0.7
*10 g	10.2(129)	7(91)	14.3(186)	12.1(158)	0.6

Table 7. <i>Shows the med</i>	n and total motor	scores of patients i	n both groups.

Nerves	Ambulatory (Total score)(N = 13)		Inpatients (Total score)(N = 13)		m volvo	
	Pre- treatment treat	Post- ment treatment treatm	Pre-	Post-	p value	
Ulnar 91.46(1	189)	92.6(1204)	72.9(948)	84.8(1103)	0.41	
Median	34.84(453) 32.2	2(419) 29.0(378)		34.07(443)	0.01	
Radial 10		10	10	10	_	
CPN	25.23(328) 23.	8(310) 20.6(269)		25.15(327)	0.1	
		Muscle	es tested			
Ulnar nerve:		interosssei, abductor	~	ctor pollicis, medial		
Median nerve:		Abductor pollicis, opponens pollicis and lateral 2 lumbricals.				
Radial nerve:		Extensors of the wrist				
Common perone	al nerve: Tibialis anterior, extensor hallucis and extensor digitorum					

ied. It is also possible that the questionnaire was not sensitive enough to detect the impact of deformities on the QOL in leprosy patients. It has been reported that patients with grade 1 disability face less discrimination in the family and at work compared to those with grade 2 disabilities (¹⁰). In our study, 58% of patients had either no deformity or grade 1 deformity. In another study done in Tamilnadu it was seen that caste status influenced the nature and the extent of handicaps experienced by leprosy patients (7). This in turn could have influenced the QOL. Thus the impact of deformities on the patient's well being and attitude to the disease is multi-factorial and was probably not adequately addressed by the questionnaire used. However, since there is no significant difference in the quality of life between the ambulatory and hospitalized group it may be concluded that status of hospitalization did not contribute significantly to improvement in the QOL.

This study is the first to throw light on the economic aspects of management of neuritis. As stated earlier, no major inferences can be drawn due to the relatively small sample size studied. It is, however, apparent that in resource poor countries it is more advantageous economically to adopt the ambulatory management in patients with mild to moderately severe neuritis. It is often the fear of the complications of moderately high doses of steroids that causes physicians to admit patients especially at tertiary levels of care. The fact that none of our patients in either arm experienced any significant steroid induced complications suggest that ambulatory care on a moderately high dose of steroids is safe.

In conclusion, it may be said that the burden of disease in leprosy has not received adequate attention. Large multicenter studies are required to address the economic and other non medical aspects of the management of the leprosy.

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