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UNIFORM-MDT IN PAUCI AND MULTI BACILLARY LEPROSY PATIENTS –AN OBSERVATIONAL STUDY

Dermatology

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ABSTRACT

OBJECTIVES: To determine the efficacy of U-MDT regimen with regard to relapse rate and acceptability of the patients in pauci and multi bacillary cases.

METHODS: 106 leprosy patients aged between 14-60 years attending department of Dermatology, Venerology and Leprosy at RIMS, RANCHI between May 2011 and October 2012 were included in the study and they were allocated U-MDT . Patients were followed up for 12 to 18 months for periodic clinical, bacteriological and histopathological assessment.

RESULTS: In histopathological assessment of PB cases, after 6, 12 and 18 months, UPB group showed 91%, 100% and 100% improvement . Among multi bacillary cases, after 12 months 32% of UMB group of patients became smear negative. In histopathological assessment after 12 months, in UMB group, 94% patients showed good improvement.

CONLUSIONS: In conclusion, U-MDT was observed to be an effective and useful regimen to treat PB and MB patients of leprosy.

KEYWORDS

U MDT, PAUCIBACILLARY LEPROSY, MULTIBACILLARY LEPROSY

INTRODUCTION

Leprosy is a chronic disease caused by Mycobacterium Leprae affecting peripheral nervous system, skin and nerves. The Ridley-Jopling classification is based on clinical, histological, bacteriological and immunological parameters.[1] For treatment purposes, the WHO study group, in 1982, classified leprosy into two types: paucibacillary (PB) and multibacillary (MB) on the basis of number of patches on the skin and number of nerves involved. PB patients have five or less than five patches and up to one nerve trunk involvement. WHO recommended a MDT regimen of two drugs and a MDT regimen of three drugs for PB and MB patients respectively.[2] The WHO Technical advisory group (TAG), in its third meeting in 2002 proposed that a uniform MDT regimen (U-MDT) containing three drugs (dapsone, clofazimine and rifampicin) should be considered for six months to treat all types of leprosy.[3] The group felt that with WHO MDT being widely implemented with very low relapse rates and complete absence of emergence of M.leprae resistance, further shortening of and simplification of the MDT regimen by introducing Uniform MDT would lead to better sustainability of services after integration. To overcome the classification process in the field setup at times, Uniform MDT has been advocated. Clofazimine containing regimen has an added advantage that the same drugs may be given for varying durations depending upon the clinical classification. Benefits of the regimen are simpler information system, reduced training needs and better sustainability and compliance of the patient.

MATERIALAND METHODS

106 leprosy patients (77 male and 29 female) aged between 14-60 years attending department of Dermatology, Venerology and Leprosy department at RIMS between May 2011 and October 2012 were included in the study. Patients of PB and MB leprosy were allocated into UPB and MPB. Both PB and MB patients were given U-MDT drug regimen for six months. Patient information and details of clinical examination were recorded and body charting done at initial registration and at the end of the study. Patients were followed up for a minimum period of 12 months and maximum period of 18 months after enrolment and periodic clinical assessment for changes in disease activity were made at specific intervals. Skin smears were taken from all three sites in all patients at entry, 6 and 12 months and stained with Zeihl Nelson's stain. AFB was looked for and Bacterial Index (BI) were graded by Ridley's scale. Patients with Lepra reaction (I and II) were hospitalized whenever necessary and treated appropriately.

STATISTICALANALYSIS

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 20.0.1 and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. Univariate analysis was performed by logistic regression method for calculation of risk factors. Explicit expressions that can be used to carry out various t-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a t-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test.

RESULTS

Incidence of leprosy in my study was 0.7%. Maximum numbers (40.05%) of patients were found in age group 31-40 years and most of them were males. At the time of entry, total 106 numbers of patients were included out of which 62 were in MB and 44 were in PB group. When patients under study were clinically typed based on Ridley - Joplin's classification, BT patients were 27 out of 44 in UPB group. At each interval, the number of patients with higher scores went on decreasing in each group and number of patients with lower scores was more in UPB group. At all intervals, histopathological improvement was found to be good in UPB group (as shown in **Table 1**).

Table 1 clinical, bacteriological and histopathological assessment of pauci-bacillary cases of leprosy patients who were treated with U-MDT and WHO-MDT regimen

		UPB
At admission	Clinical score	
	0-3	2
	4-6	3
	7-9	6
	10-12	8
	13-15	3
At 3 months	0-3	5
	4-6	6
	7-9	10
	10-12	1
	13-15	0

At 6 months	0-3	6
	4-6	9
	7-9	7
	10-12	0
	13-15	0
At 12 months	0-3	8
	4-6	11
	7-9	3
	10-12	0
	13-15	0
At 18 months	0-3	12
	4-6	8
	7-9	1
	10-12	0
	13-15	0
At entry	CELLULARITY	Lymphocytes++ Epitheloid cells+++ Giant cell+ BI 2+, >1+
At 6 months (improvements)	good	20/22
	No change	1/22
	poor	1/22
At 12 months (improvements)	good	22/22
	No change	0
	poor	0
At 18 months (improvements)	Good	22/22
	No change	0
	poor	0

In UMB group, 48% patients were of BL type. BL and LL type constituted the maximum number of patients. At entry, total 42 patients were smear positive, all in MB group, with 19 in UMB group (61.2%). All PB group patients were AFB negative. The difference in the number of patients with AFB positive in BL group was statistically significant. The BI ranged from 1+ to 6+ with maximum patients with BI 3+ in both UMB (31.6%). none of the patients with negative smears at entry showed positive smears subsequently.

As shown in **Table 2**, during clinical assessment after 6 months none of the patients showed good improvement in UMDT. After 12 months, 4.5% patients in UMB group showed good improvement.

Table 2 clinical, bacteriological and histopathological assessment of multi bacillary cases of leprosy patients who were treated with U-MDT and WHO-MDT regimen

		UMB
At entry	No. Of skin lesion	20 to numerous
	Infiltration	+
	Size of lesion	variable
At 6 months (improvement)	Good	none
	moderate	16/31
	poor	17/31
At 12 months (improvement)	good	2/31
	moderate	10/31
	poor	19/31
At 18 months (improvement)	good	3/30
	moderate	7/30
	poor	20/30
At admission		19/31
At 6 months		16/31
At 12 months		9/31
At 18 months		14/30
At entry	Cellularity	Lymphocytes +, macrophages++, epitheloid cells+++, giant cell-
At 12 months	Good	29/31
	No change	1/31
	poor	1/31
At 18 months	good	15/30
	No change	-
	poor	15/30

These differences were statistically significant. After 18 months, only 10% patients of UMB group showed good improvement. 67% of patients in UMB group showed poor improvement. At the time of bacteriological assessment, after 12 months, UMB group showed 32% improvement. But after 18 months, in UMB group, 5 more patients became AFB positive. In histopathological assessment, after 12 months, in UMB group, 94% patients showed good improvement.

DISCUSSION

Number of patients attending RIMS dermatology OPD in 18 months span was 50445, out of which new leprosy cases were 363. As leprosy is a chronic illness and initially symptoms are less marked, leprosy patients present before clinician very late. Low incidence in Jharkhand was due to lack of conveyance, seasonal variation, low socio-economic status and unawareness about the diseases. It was consistent with studies done by Dharmendra et al (1985), Das et al (1996) and M. Arora et al (2008).[4] Most of the patients were male. It may be due to high chances of contact among male due to social gathering and they are more active in reporting to health facility for seeking treatment. In the present study it was found that the number of cases were maximum (58.5%) in multibacillary group and BT patients were more than TT group of patients. It was consistent with Mahajan VK, Sharma NL, Rana P, Sood N. et al (2003).[5] and Directorate of Health service, National Leprosy Eradication Programme Chhattisgarh (2004) report. It was observed that at the time of admission maximum number of patients in UPB (36.3%) had scores in the range of 10-12.

After 3 months, in score range 0-3 and 4-6, there was 14% increase in number of patients in UPB. In score range 7-9, there was 18% increase in number of patients in UPB. After 6, 12 and 18 months of follow up, it was seen that the number of patients with higher scores went on decreasing in each group and number of patients with lower score was continuously increasing.

Among multibacillary cases 90% patients belonged to BL and LL type. After 12 months 32% of UMB group of patients became smear negative. After 18 months, in UMB group, 5 patients deteriorated and AFB positive at the end of the study. Kaur I, Dogra S et al in 2002 reported that at the end of 2 years, 39.7% patients became smear negative with bacillary index 4+ or more and 84.8% patients became smear negative with bacillary index 3+ or less.[6] Vara N, Marfatiya Y et al in 2005 reported that at the end of 2 years of MDT, 61.8% patients with bacillary index <3+ before treatment, became smear negative. J. Sen et al in 2012 showed that after taking 6 months of UMDT, at 18 months 39.8% patients became smear negative and after 42 months of follow up, 73.5% patients became smear negative. The UMB group did not have a single good grade at 6 months. More importantly, the percentage of poor grades in the study group was 49%, 64% and 67% at 6, 12 and 18 months respectively. P. N. Rao et al in 2009 showed that the numbers of moderate and good responses were 78% and 61% at 6 months, 86% and 94% at 18 months and 82% and 100% at 24 months in WPB and UPB respectively.[7] In histopathological assessment after 6, 12 and 18 months, UPB group showed better improvement.[8]

Clinical improvements grades in UMB group did not have a single good response at 12 and 18 months with poor response being 50%, 67% and 75% at 12, 18 and 24 months.[9] In histopathological assessment after 12 months, in UMB group, 94% patients showed good improvement.[10]

CONCLUSIONS

PB patients on U-MDT in the present study showed good clinical improvement. The addition of clofazimine to the PB treatment regimen is an improvement over the available treatment schedule and it has the added advantage of being operationally more easily administered in the field. With the PB study group on U-MDT containing clofazimine showing better grades overall and continued higher response at 12 and 18 months. This continued favourable response could be attributed to the depot action of clofazimine in the tissues. In the present study, it was observed that MB patients on U-MDT, showed a significantly poor response at all period of clinical assessment at 12 and 18 months in follow up. Clearly there are grounds

for concern regarding the reduction of the duration of treatment for MB patients from 24 to 12 months. As there are several reports of relapses in MB patients on MDT-MB of 12 and 24 months duration, further shortening of duration to 6 months should be considered with great caution and only if it is found to as effective as the present regimen of 12 months.

In conclusion, U-MDT was observed to be an effective and useful regimen to treat PB patients of leprosy, but in MB patients it was not found to be very effective.

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