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Original Research Article

To study the effectiveness of Methotrexate as a steroid sparing agent in Type 2 Lepra reaction

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Abstract:

Background & Method: The aim of the study is to study the effectiveness of Methotrexate as a steroid sparing agent in Type 2 Lepra reaction. A thorough clinical history, examination, blood counts, urine routine/microscopy, liver and renal function test, chest radiograph, abdominal-, and/or pelvic- sonography, Urine pregnancy test (if required), anti HIV antibodies (if required) were done in all the study participants.

Result: In the study overall, there were 34 patients who were undergoing treatment and 18 patients had completed their treatment. In group A the number of patients undergoing treatment was greater than in group B whereas the number of patients who had completed their treatment was more in group B than group A. The mean duration of MDT treatment was greater in group B as compared to group A. The mean number of episodes was greater in group B as compared to group A. Similarly, Reaction severity scores and total duration of episodes were also more in group B participants as compared to group A.

Conclusion: Methotrexate can serve as a steroid sparing agent in the treatment of T2LR where it may reduce the severity, duration and recurrences of T2LR. Methotrexate is a miraculous drug known since long with tremendous familiarity especially to dermatologists .It serves as a safe and comparatively cheaper therapeutic option.

Keywords: Methotrexate, steroid & Type 2 Lepra.

Study Designed: Observational Study.

1. INTRODUCTION

The accepted definition of leprosy as per the 7th WHO Expert Committee on Leprosy (WHO, 1998), is a person having one or more of the following features, and who is yet to complete the full course of treatment: hypopigmented or reddish skin lesion(s) with definite loss of sensation[1], nerve thickening with sensory impairment and skin smear positive for acid fast bacilli[2].

The use of the biological TNF alpha blocker infliximab has also emerged as an option for treatment of T2LR but its high cost is a limiting factor in its usage especially in developing countries like ours[3]. Thus, all currently available treatment modalities have many drawbacks and are not effective for all patients[4]. Therefore there exists a need to look for

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alternative drugs for efficient treatment of patients with Type 2 Lepra reaction and/or ENL[5].

Most cases occur in the developing world; 83% of registered cases have been concentrated in only 6 countries: India, Brazil, Burma, Indonesia, Madagascar, and Nepal[6]. Currently, seven States in India, namely, Bihar, Uttar Pradesh, Chhattisgarh, Jharkhand, Maharashtra, Odisha and west Bengal contribute almost 3/4th of the total leprosy burden (74.9% new leprosy cases detected) [7].

2. MATERIAL & METHOD

Present study was conducted at Shrimant Rajmata Vijayaraje Scindia Medical College and Hospital, Shivpuri, M.P. from July 2022 to June 2023. A thorough clinical history, examination, blood counts, urine routine/microscopy, liver and renal function test, chest radiograph, abdominal-, and/or pelvic- sonography, Urine pregnancy test (if required), anti HIV antibodies (if required) were done in all the study participants. Other investigations as directed by clinical history and examination were performed.

- GROUP A(CASES)-Included 30 patients who received Corticosteroids + Methotrexate
- GROUP B(CONTROLS)- 30 patients received the conventional course of corticosteroids + corticosteroids

INCLUSION CRITERIA

- Confirmed cases of T2LR
- Subjects who have completed their family

EXCLUSION CRITERIA

- Non consenting participants
- Chronic alcoholics

A reaction severity scores play an important role in making clinical decisions about reactions, the choice of treatment and monitoring progress. Reaction severity assessment can be calculated more accurately using reaction severity scale formulated and tested by van Brakel and his team.

This group assessed 21 items as the basis for a reaction severity scale. These included assessment of skin signs, fever, edema and forms of neuritis plus changes in sensory and motor function assessed using monofilaments (200 mg, 2 g, 4 g, 10 g and 300 g) and voluntary muscle testing (VMT) respectively. Monofilament assessment at each test point is scored 0 where the 200 mg monofilament is felt through to 5 where the 300 g is not felt. Muscle testing is scored using the standard Medical Research Council grading, normal (5), full range of movement but reduced resistance (4), full range of movement but no resistance (3), movement but reduced range (2), muscle flicker (1) and paralyzed (0).

3. RESULTS

Table 1: Description of age (in years) of study participants in two groups

	Number of participants (N)	Mean	SD	Minimum	Maximum
Group A (Cases)	30	48.0667	6.59198	36	60
Group B (Control)	30	43.0000	8.78337	26	59

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The mean age of study participants was greater in group A as compared to group B. The minimum age as well as maximum age of the participant also was more in group A than group B. Male: Female Ratio Group A - 2:1 & Group B - 1.5:1

Table 2: Description of MDT status in group A and group B

	No. of patients with already ongoing MDT	**No. of patients with MDT Completed**	**Number of patients with MDT not yet started**	**Mean Duration of MDT (in months)**
Group A (Cases)	18	08	05	6.9000
Group B (Control)	16	10	05	8.133
Total	34	18	08	

In the study overall, there were 34 patients who were undergoing treatment and 18 patients had completed their treatment. In group A the number of patients undergoing treatment was greater than in group B whereas the number of patients who had completed their treatment was more in group B than group A. The mean duration of MDT treatment was greater in group B as compared to group A.

Table 3: Description of duration (in months) of MDT status

	Group A (Cases)		**Group B (Control)**	
	Mean	**SD**	**Mean**	**SD**
Duration (in months)	6.7328	6.23293	9.1169	6.71672

SD – Standard Deviation

Table 4: Total duration of episodes, past episodes of T2LR during study period with scores

	Group A (Cases)		**Group B (Control)**	
	Mean	**SD**	**Mean**	**SD**
Number of episodes	5.6023	1.14019	9.0281	1.41245
#*Cumulative Reaction Severity scores	67.1627	18.05673	111.3268	10.06721
*Cumulative Duration of episodes(in days)	65.2383	9.67430	122.98130	19.59119

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The mean number of episodes was greater in group B as compared to group A. Similarly, Reaction severity scores and total duration of episodes were also more in group B participants as compared to group A.

4. DISCUSSION

In this study we evaluated our patients primarily for duration, severity and number of episodes of T2LR [8]. We also prepared a home assessment chart for episodes of T2LR for patients who could not come for follow up which they could use for recording reaction episodes at home. However, all of our patients came to us every time they had a reaction and the home assessment chart could not be utilized by any of them [9].

To the best of our knowledge this is the first study evaluating effectiveness of methotrexate as a steroid sparing agent in patients with T2LR [10]. We found that low dose methotrexate can reduce the severity of T2LR .We also observed that methotrexate can be used as a steroid sparing agent in the treatment of T2LR. The drug was able to reduce the duration ($p<0.05$), severity ($p<0.05$) and recurrences of episodes ($p<0.05$) of T2LR[11].

5. CONCLUSION 44

Methotrexate can serve as a steroid sparing agent in the treatment of T2LR where it may reduce the severity, duration and recurrences of T2LR. Methotrexate is a miraculous drug known since long with tremendous familiarity especially to dermatologists. It serves as a safe and comparatively cheaper therapeutic option.

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