

Comparative study on the effects of injectable triamcinolone acetone versus oral prednisolone in the treatment of lepra reactions

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Abstract:

Lepra reactions are very much common in patients suffering from leprosy, may occur in up to 25% of patients with paucibacillary leprosy and 40% in multibacillary leprosy causing significant morbidity and complications. Oral prednisolone is the most frequently used drug to control these reactions. Injectable triamcinolone acetone, if given intra-muscularly once every 3 weeks for 24 weeks can effectively control these reactions. A study was carried in 100 leprosy patients suffering from lepra reactions (57 patients suffering from type 2 and 43 patients from type 1 lepra reactions). Patients were selected by purposive sampling and then randomized into 2 groups. Group A patients were treated by inj. triamcinolone, 40 mg I/M once in every 3 weeks for 24 weeks and group B patients received oral prednisolone, starting 40 mg and then tapering the dose gradually for 24 weeks. Two parameters were used for type 1 reaction- reduction of temperature and pain & two parameters were used for type 2 reaction- reduction of temperature and of the size of the largest tender nodules. Data were collected and statistical analysis was done using SPSS 20. Temperature was significantly reduced in group A patients in comparison with group B patients in both type 1 and type 2 reactions. Significant reduction of pain score in type 1 reaction and that of diameter of largest tender nodule in type 2 reaction in group A patients were found in comparison with group B patients. Inj. triamcinolone acetone showed better efficacy than oral prednisolone in the treatment of lepra reactions.

Key words: Leprosy, lepra reactions, prednisolone, triamcinolone acetone.

Date of Submission: 16-02-2021

Date of Acceptance: 02-03-2021

I. INTRODUCTION

Leprosy (Hansen's disease) is a chronic granulomatous disease affecting skin and nerves, and is caused by *Mycobacterium leprae*, a slow growing mycobacterium which cannot be cultured in vitro. The clinical manifestations are determined by the degree of the patient's cell-mediated immunity (CMI) towards *M. leprae*. High levels of CMI with elimination of leprosy bacilli produces tuberculoid leprosy, whereas absent CMI results in lepromatous leprosy.¹

Three cardinal signs have remained the basis for the clinical diagnosis of leprosy.²

- a. Anaesthetic/hypoanesthetic skin lesion(s)
- b. Thickened peripheral nerve(s) with impairment of sensations in the area supplied
- c. Acid-fast bacilli in the skin smear

Any one of these signs has been regarded as sufficient for the diagnosis of leprosy, so that the sensitivity is high. Each sign is also quite specific in itself, so the specificity is also high.² Elimination of leprosy as a public health problem, defined by a registered prevalence of less than one case per 10,000 populations, was achieved by Bangladesh in 1998, and steady reduction in prevalence is ongoing³. In 2013, the prevalence rate is 20.

Lepra reactions can develop at any time, but can occur-

- a) Onset of disease/before starting treatment,
- b) During treatment &
- c) After completion of treatment

1) Type I reaction: They are also called reversal reactions (RR), can occur in any patient with unstable CMI. These occur in 30% of borderline patients (BT, BB or BL) and are delayed hypersensitivity reactions. Skin lesions become erythematous. Peripheral nerves become tender and painful, with sudden loss of nerve function. These reactions may occur spontaneously, after starting treatment and also after completion of multidrug therapy.

2) Type 2 reaction: Also called erythema nodosum leprosum (ENL). These are partly due to immune complex deposition and occur in BL and LL patients, who produce antibodies and have a high antigen load. They manifest with malaise, fever and crops of small pink nodules on the face and limbs. Iritis and episcleritis are common. Other signs are acute neuritis, lymphadenitis, orchitis, bone pain, dactylitis, arthritis and proteinuria. ENL may continue intermittently for several years.¹

Corticosteroids: The adrenal cortex releases a number of steroids in the circulation. Some have minimum biologic activity and function primarily as precursors, and there are some for which no function has been established. The hormonal steroids may be classified as those having important effects on intermediary metabolism and immune function (glucocorticoids), those having principally salt-retaining activity (mineralocorticoids) and those having androgenic and estrogenic activity.⁴

Glucocorticoids have become important agents for use in the treatment of many inflammatory, immunologic, hematologic and other disorders. This has stimulated the development of many synthetic steroids with anti-inflammatory and immunosuppressive activity.⁴

Some commonly used natural and synthetic corticosteroids in general use⁴

Agent	Activity			
	Anti-inflammatory	Topical	Salt-retaining	Equivalent dose(mg)
Hydrocortisone	1	1	1	20
Prednisolone	4	4	0.3	5
Methylprednisolone	5	5	0	4
Triamcinolone	5	5	0	4
Dexamethasone	30	10	0	0.75

Corticosteroids remain the drug of choice in the treatment of reversal reactions (RRs). According to World Health Organization (WHO), the recommended dose is 40-60 mg daily which is gradually reduced weekly or fortnightly and stopped in 12 weeks duration.¹ The main effect of corticosteroids is to suppress the T-cell driven inflammatory response to *M. leprae* antigen within the skin and nerves. Therefore, the immunosuppressive doses of corticosteroids are required for prolonged periods, as the reaction will persist or recur even whilst the bacillary load gradually falls.⁵

Rose and Walters⁶ Naafs^{7,8} have recommended that most BT patients require prednisolone for 4-9 months, BB patients for 6-9 months and BL patients for 6-18 months or even 24 months. Twelve weeks of prednisolone therapy for RRs in BB/BL patients has been found to be inadequate, with one-third of patients relapsing: however, extension of therapy to 20 weeks resulted in a low recurrence rate.⁹ The existing reports provide conflicting data regarding adequate duration of steroid treatment in RRs.

Damage to the nerve due to influx of inflammatory cells and their mediators is generally responsible for acute NFI.¹⁰ Demyelination occurring as a sequelae to atrophic changes in the axonal component and physiologic damage due to persistence of mycobacterial antigens in the Schwann cells or axons is responsible for more diffuse, insidious and gradually progressive NFI.¹¹ Within what period after the onset of nerve damage should corticosteroid therapy begin and how long to continue remains unanswered. WHO states that neuritis of less than 6 months duration should be treated with the standard 12 weeks regimen of oral prednisolone.¹ Patients with recent NFI of less than 6 months duration, demonstrate greater improvement in nerve function than those with old impairments.^{9,12} However, van Brakel and Khawas noted significant improvement in sensory function after 3 months prednisolone therapy in some patients with NFI of 6 months duration.¹³ It may be argued that NFI treated 'early' should respond better to treatment than when treated 'late', but very little evidence for this could be found in the literature.¹⁴ More studies are needed to define the group of responsive patients, adequate length and dosage of corticosteroids more accurately. Leprosy reactions and new NFI occurred in a third of the study group (TRIPOD 3), emphasizing the need to keep patients under regular surveillance during MDT, and, where possible, after completion of MDT.¹⁵

The biggest problem in the management of leprosy is the nerve damage which occurs along the course of the disease per se, becomes acute during reactions and this results in deformities and disabilities. There is no parameter which can reliably predict what will be the likely nerve damage in a given patient and what dose of steroids, for what duration and instituted when, will give the best results. More studies may provide the answers.

II. Materials And Methods

A randomized clinical trial was done at Medicine ward, indoor and outdoor, and Leprosy clinic, Dermatology & Venereology Department, Chittagong Medical College Hospital (CMCH) from May 2010 to April 2011. All patients of diagnosed as case of leprosy with type 1 and type 2 lepra reactions. Patients were categorized in to two groups. Group A: A total of 50 leprosy patients with lepra reactions were given injectable triamcinolone acetonide. Group B: A total of 50 leprosy patients with lepra reactions were given oral prednisolone. Inclusion criteria were all patients of leprosy with type 1 or type 2 lepra reactions. Exclusion criteria were patient with concomitant febrile illness, acute medical condition like acute MI and acute stroke and patient who are unwilling to be included in the study.

Two parameters were used for type I reaction:

A. Reduction of body temperature and

B. Reduction of pain score using visual analogue scale of pain after giving oral prednisolone and injectable triamcinolone.

Two parameters were used for type II reaction:

A. Reduction of body temperature and

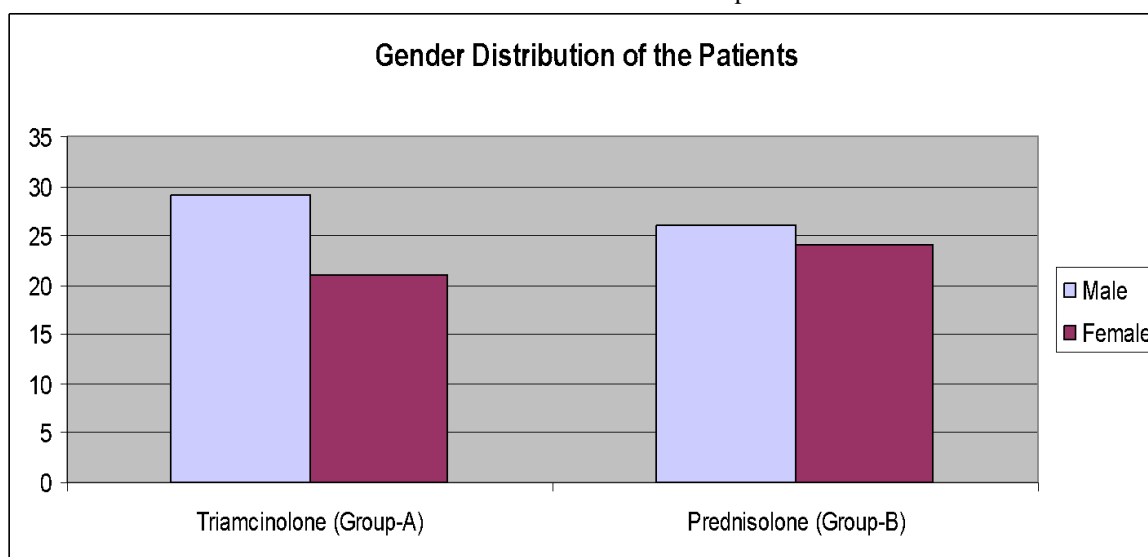
B. Reduction of size of the largest tender nodule after giving both drugs.

Data were processed and analyzed by using computer based software SPSS 20. Different statistical methods were applied for data analysis. P value will be considered as statistically significant when it is less than 0.05.

III. Results

1. Distribution of patients according to gender: Among the 100 patients, male were 55(55%) and female was 45(45%). Male to female ratio was 1.2: 1

Table 1: Gender distribution of the patients



2. Skin findings of the study patients: Common skin findings were skin ulceration (17%), and other different skin lesions were papules (28%), patch (13%), nodule (55%), mixed (4%). Skin anaesthesia was found on 95% patients, skin hypopigmentation, skin redness were found in 36%, nerve abscess were found among 4%, skin necrosis 5%, exaggerated pre-existing skin lesion was 5%, eye involvement in the form of madarosis was 3% and mucosal involvement was found among 3% of total study patients.

Table 2: Skin findings

		Group-A (Triamcinolone)	Group-B (Prednisolone)	Total	P value
Skin ulceration	Present	13	4	17	0.003
	Absent	37	46	83	
Types of skin lesion	Papule	17	11	28	0.21
	Patch	3	10	13	
	Nodule	26	29	55	
	Mixed	4	0	4	
Skin anesthesthesia	Yes	50	45	95	

	No	0	5	5	
Skin hypopigmentation	Present	50	50	100	
Redness of the skin	Present	20	16	36	0.75
	Absent	30	34	64	
Nerve abscess	Present	2	2	4	1
	Absent	48	48	96	
Skin necrosis	Present	3	2	4	0.980
	Absent	47	48	95	
Exaggeration of pre-existing lesion	Yes	3	2	5	0.34
	No	47	48	95	
Eye findings(Madarosis)	Present	2	1	3	0.52
	Absent	48	49	97	
Mucosal involvement	Present	3	2	5	0.087
	Absent	47	48	97	
Total		50	50	100	

3. Neurological findings of study patients: Peripheral nerves were palpable in 72% of patients and among them 65% had tender nerves, nerve abscess were found among 4% of total subjects. Facial nerves were commonly involved (5%), next to it was great auricular nerve (10%)

Table 3a: Pattern of nerve involvement

		Group		Total	P value
		Group-A (Triamcinolone)	Group-B (Prednisolone)		
Peripheral nerves	Involved	35(70)	37(74)	72(72)	0.78
	Not involved	15(30)	13(26)	28(28)	
Tender nerves	Present	34(68)	31(62)	65(65)	0.089
	Absent	16(32)	19(36)	35(35)	
Nerve abscess	Present	2(4)	2(4)	4(4)	0.998
	Abscess	48(96)	48(96)	96(96)	
Total		50	50	100	

Table 3b: Type and pattern of nerves involved

		Group		Total	P value
		Group-A (Triamcinolone)	Group-B (Prednisolone)		
Facial nerves	Involved	2(4)	3(6)	5(5)	0.989
	Not involved	48(96)	47(94)	95(95)	
Great auricular nerve	Present	4(8)	6(12)	10(10)	0.564
	Absent	46(92)	44(88)	90(90)	
Claw hand	Present	2(4)	2(4)	4(4)	0.897
	Abscess	48(96)	48(96)	96(96)	
Wrist drop	Present	3(6)	2(4)	5(5)	0.675
	Absent	47(94)	48(96)	95(95)	
Foot drop	Present	2(4)	3(6)	5(5)	0.938
	Absent	48(96)	47(92)	95(95)	
Total		50	50	100	

4. Distribution of patients according to different systemic manifestations: Constitutional symptoms were present in all 100 patients. 32% patients had testicular involvement, 23% patients had deformity at presentation, swelling of the limbs were present in 65% of patients, eye involvement were present in 5% of patients and 17% patients had lymphadenopathy.

Table 7: Systemic involvement of the study patients.

		Group		Total	P value
		Group-A (Triamcinolone)	Group-B (Prednisolone)		
Systemic features					
Constitutional symptoms	Present	50(100%)	50(100%)	100	1
Testicular involvement	Involved	14(28%)	18(36%)	32(32)	0.78
	Not involved	36(72%)	32(64%)	68(68)	
Deformity	Present	10(20%)	13(26%)	23(23)	0.54
	Absent	40(80%)	37(74%)	77(77)	
Swelling of the limbs	Present	32(64%)	33(66%)	65(65)	0.98
	Absent	18(36%)	17(34%)	35(35)	
Eye involvement	Present	5(10%)	0	5(5)	
	Absent	45(90%)	50(100%)	95(96)	
Lymphadenopathy	Present	7(14%)	10(20%)	17(17)	0.945
	Absent	43(86%)	40(80%)	83(83)	

5. Pattern of lepra reactions of the study patients: Type I lepra reaction was found among 43 patients where 22 patients were in group A and 21 patients were in group B. 57 cases of type II lepra reaction was found where 28 patients were in group A and 29 patients were in group B.

Table 5: Types of lepra reactions

Lepra reaction	Group	Group		Total	P value
		Group-A (Triamcinolone)	Group-B (Prednisolone)		
Type I	Type I	22(44)	21(42)	43	0.45
	Type II	28(56)	29(58)	57	
Total		50	50	100	

6. Temperature changes at different follow-up: Significant change of temperature between group A and Group B in type I and type II lepra reactions was found at day 7, also found significant change in type II reaction at day 180(p<0.05), other follow up findings were not significant among the both groups.

Table 9: Statistics of temperature change among the study groups (with t – test significance)

Lepra reaction	Group	N	Mean	Std. Deviation	P value		
Type I	Temperature at Day 0(*F)	Group-A(Triamcinolone)	22	100.6364	.58109	0.021	
		Group-B(Prednisolone)	21	100.8286	.61412		
	Temperature at Day 7(*F)	Group-A(Triamcinolone)	22	99.3636	.49237		
		Group-B(Prednisolone)	21	99.7143	.46291		
	Temperature at Day 21(*F)	Group-A(Triamcinolone)	22	98.4273	.07025		0.133
		Group-B(Prednisolone)	21	98.4667	.09661		
	Temperature at Day 180(*F)	Group-A(Triamcinolone)	22	98.4000	.00000		0.069
		Group-B(Prednisolone)	21	98.4143	.03586		
Lepra reaction	Group	N	Mean	Std. Deviation	P value		
Type II	Temperature at Day 0(*F)	Group-A(Triamcinolone)	28	101.8643	.57877	0.009	
		Group-B(Prednisolone)	29	101.6759	.55140		
	Temperature at Day 7(*F)	Group-A(Triamcinolone)	28	99.4643	.50787		
		Group-B(Prednisolone)	29	99.7931	.41225		
	Temperature at Day 21(*F)	Group-A(Triamcinolone)	28	98.5714	.27603		0.092
		Group-B(Prednisolone)	29	98.4690	.16280		
	Temperature at Day 180(*F)	Group-A(Triamcinolone)	28	98.4250	.05853		0.025
		Group-B(Prednisolone)	29	98.4000	.00000		

7. Pain score at subsequent follow-up: Significant change of pain score were found between group A and Group B in type I reaction at day 7.

Table 10: Statistics of pain score among the study groups (with t – test significance)

Lepra reaction	Group	N	Mean	Std. Deviation	P value	
Type I	Pain score at Day 0	Group-A(Triamcinolon)	22	10.00	.000 ^a	0.002
		Group-B(Prednisolone)	21	10.00	.000 ^a	
	Pain score at Day 7	Group-A(Triamcinolon)	22	2.00	.309	
		Group-B(Prednisolone)	21	2.43	.507	

8. Change of diameter of largest tender nodule at subsequent follow-up: Diameter of largest tender nodule was found significantly reduced at day 7 in type II lepra reaction.

Table 8: Statistics of change of diameter of largest tender nodule among the study groups (with t – test significance)

Lepra reaction	Group	N	Mean	Std. Deviation	P value	
Type II	Diameter of the largest nodule(mm) at Day 0	Group-A(Triamcinolone)	28	9.71	.713	0.001
		Group-B(Prednisolone)	29	9.93	1.132	
	Diameter of the largest nodule(mm) at Day 7	Group-A(Triamcinolone)	28	4.75	.441	
		Group-B(Prednisolone)	29	5.31	.761	

IV. Discussion

Prednisolone, being the most commonly used drug to treat lepra reactions has to be taken on daily basis and patients frequently fail to adhere to the treatment plan. Moreover, when the dose of prednisolone is tapered (i.e, when the dose is gradually reduced from the starting 60 mg to 15-10mg and less),the lepra reactions frequently flare-up. Considering these short-comings of using prednisolone in the treatment of lepra reactions, a

drug with longer duration of action and favorable outcomes has been sought by the clinicians to manage the troublesome and frequently re-appearing lepra reactions. Triamcinolone acetonide, being a parenteral corticosteroid and having wider dose interval may be a good alternative to prednisolone in this aspect.

In our study regarding common skin findings skin ulceration (17%), and other different skin lesions were papules (28%), patch (13%), nodule (55%), mixed (4%). Skin anaesthesia was found in 95% patients, skin hypopigmentation and skin redness were found in 36%, nerve abscess was found among 4%, skin necrosis in 5%, exaggerated pre-existing skin lesion in 5%, eye involvement in the form of madarosis was found 3% and mucosal involvement was found among 3% of total study patients.

In the present study peripheral nerves were palpable in 72% of patients and among them 65% had tender nerves, nerve abscess were found among 4% of total subjects. Facial nerves were commonly involved(5%), next to it was great auricular nerve(10%).

In our study constitutional symptoms were present in all 100 patients. 32% patients had testicular involvement, 23% patients had deformity at presentation, swelling of the limbs were present in 65% of patients, eye involvement were present in 5% of patients and 17% patients had lymphadenopathy. As leprosy is a multisystem disease this findings are as expected.

In the present study type 1 lepra reaction was found among 43 patients where 22 patients were in group A and 21 patients were in group B. 57 cases of type 2 lepra reaction was found where 28 patients were in group A and 29 patients were in group B. Type 2 lepra reactions are more common than the type 1 lepra reaction. The findings were consistent with the pattern of prevalence of lepra reactions in the community.¹⁶

In type 1 reaction, two parameters were used to compare the effectiveness of injectable triamcinolone with that of the oral prednisolone which were reduction of body temperature and reduction of pain score using visual analogue scale of pain. At day 0, the mean temperature(⁰F) in group A was 100.63±0.58 (mean±S.D) & in group B was 100.82±0.61(mean ± S.D). At day 7, the mean temperature(⁰F) in group A was 99.36±0.49(mean ± S.D) & in group B was 99.71 ±0.46(mean ± S.D). Temperature was significantly reduced in group A (p <0.05) than in group B at day 7. Other follow-up findings at day 21 & day 180 showed no significant change between two groups regarding temperature reduction. As lepra reactions are hypersensitivity reactions (type 1 lepra reaction being type IV hypersensitivity & type 2 lepra reaction being type III hypersensitivity), the anti-inflammatory and immunosuppressive effects of triamcinolone acetonide and oral prednisolone are the mechanisms of action in this regard. Better compliance with injectable triamcinolone acetonide than prednisolone may be an explanation for the significant reduction of temperature at day 7 in group A patients.

Pain score at day 0, in group A was 10.00± 00(mean ± S.D) & in group B was 10.00±00(mean ± S.D) & at day 7, in group A was 2.00 ±0.30(mean ± S.D) & in group B was 2.43±0.50(mean ± S.D). Reduction of pain score using visual analogue scale of pain showed significant change in group A(p<0.005) than in group B at day 7.

In type 2 reactions, two parameters were used to compare the effectiveness of injectable triamcinolone with that of the oral prednisolone which were reduction of body temperature and reduction of the size of largest tender nodule. At day 0, the mean temperature(⁰F) in group A was 101.86 ±0.57(mean ±S.D) & in group B was 101.67 ± 0.55(mean ± S.D). At day 7, the mean temperature (⁰F) in group A was 99.46 ±0.50(mean ± S.D) & in group B was 99.79 ± 0.41(mean ± S.D). At day 180, the mean temperature (⁰F) in group A was 98.42 ±0.05(mean ± S.D) & in group B was 98.40 ± .00(mean ± S.D). In group A, temperature was significantly reduced (p<0.05) than in group B at 7 and day 180. The other follow up finding at day 21, the temperature change was not significant between two groups. Triamcinolone acetonide 40 mg injection has an extended duration of effect which may be sustained over a period of several weeks. Studies indicate that a single dose of 60 mg to 100 mg of triamcinolone acetonide, adrenal suppression occurs within 24-48 hours and then gradually returns to normal, usually in 30-40 days. This finding correlates closely with the expanded duration of therapeutic action achieved with this drug.¹⁷

Regarding reduction of size of the largest tender nodule, at day 0, size(mm) in group A was 9.71 ±0.71 (mean ± S.D) & in group B was 9.93 ± 1.13(mean ± S.D). At day 7, size(mm) in group A 4.75 ± 0.44 (mean ± S.D) & in group B was 5.31 ± 0.76(mean ± S.D).At day 7, size was significantly reduced at day 7 in group A (p<0.005) than in group B.

Type 1 lepra reactions or reversal reactions are associated with the development of *M. leprae* antigenic determinants. They are delayed hypersensitivity reactions and may occur in both paucibacillary leprosy and multibacillary leprosy. In type 1 lepra reactions, there is a high risk of permanent damage to the peripheral nerve trunks. If the reaction is mild and there is no evidence of neuritis (pain, loss of sensation or function), the reaction should be treated with analgesics, such as acetylsalicylic acid or paracetamol.¹⁸

V. Conclusion

Present study was carried out to see the effectiveness of injectable triamcinolone acetonide in the treatment of lepra reactions. From the findings of the present study it can be concluded that injectable triamcinolone acetonide can be a treatment option in the treatment of lepra reactions. Compliance of treatment is expected to be better with triamcinolone acetonide (requiring one injection every three weeks) than that of with oral prednisolone which is to be taken daily.

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Dr. Pranab Kumar Barua, et. al. "Comparative study on the effects of injectable triamcinolone acetonide versus oral prednisolone in the treatment of lepra reactions." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 20(02), 2021, pp. 15-21.