Betamethasone Oral Mini-Pulse Therapy in the Treatment of Lichen Planus

Muhammad Munir Rashid, MD[1]
Uzire Azam Khan, MD, M Phil[2]
Md Akramullah Sikder, DDV[1]
Eakub Ali, DDV[1]
Nargis Akhtar, DDV[1]

1. Department of Dermatology and Venereology, Bangabandhu Sheikh Mujib Medical University, Shahbag Dhaka, Bangladesh
2. Department of Physiology, Dhaka Medical College, Dhaka, Bangladesh

Corresponding author:
Muhammad Munir Rashid, MD
Sheikh Mujib Medical University,Shahbag Dhaka, Bangladesh
Email: munir@dhaka.net

Received: August 26, 2008
Accepted: November 11, 2008

Abstract

Background: Lichen planus is a common dermatological condition. Many treatment options have been discussed in literature, each with its own risk profile. Betamethasone pulse therapy is one of the effective therapies mentioned.The objective of this study was to find out whether oral betamethasone mini pulse therapy is effective in lichen planus.

Methods: A total of 40 patients were enrolled in the study. Twenty patients received 5mg of oral betamethasone daily for two consecutive days in a week for 6 weeks along with loratadine and the other twenty patients received a loratadine tablet daily for the same period.

Results: The flattening of the existing lesions, appearance of the new lesions and persistence of itching were considered as the parameters of clinical evaluation. It was clearly observable that the number of lichen planus lesions were drastically decreasing in group A and only slightly increasing in group B during the follow-ups.

Conclusion: Betamethasone oral mini-pulse therapy was found to be more effective than loratadine in the treatment of lichen planus. *(Iran J Dermatol 2008;11:99-102)*

Keywords: lichen planus, betamethasone, mini pulse therapy

Introduction

Lichen planus is an inflammatory pruritic muco-cutaneous condition with characteristic violaceous polygonal flat-topped papules and plaques[1]. It most commonly affects middle-aged adults and involves glabrous skin, mainly of extremities, oral and genital mucous membranes, hair and nails. Although the exact prevalence of lichen planus is unknown, the overall prevalence is believed to be somewhat less than 1% of the general population with a slight predominance in women with no racial predilection[2].

The etiology of lichen planus is not known, but there are several hypotheses involving both endogenous-genetic and exogenous-environmental components such as drugs or infections[3]. The disease is supposed to be the result of a cell mediated immune reaction in which Langerhans cells, keratinocytes and activated T lymphocytes are involved[4].

Lichen planus is an unpredictable disease that typically persists for 1 to 2 years, but may follow a chronic, relapsing course over many years. The duration of lichen planus varies according to the extent and site of involvement and morphology of lesions. Lichen planus may cause atrophic cicatricial alopecia and nail dystrophy with the involvement of scalp and nail respectively[5]. Skin lesions of lichen planus may be disfiguring and involvement of the oral mucosa and genital mucosa in severe cases may be debilitating. Oral lichen planus may predispose to the development of squamous cell carcinoma within the lesion[1].

The treatment of lichen planus is often disappointing and controversial[6]. Many treatment options have been discussed in literature, each with its own risk profile. Systemic corticosteroids are of great value in treating those severe cases with severe irritation, where ulcerative mucous membranes have occurred or where there is progressive nail destruction. They greatly relieve the symptoms and the lesions may clear entirely during the treatment[5]. A short course of oral prednisolone in moderately high dose and without gradual reduction of the dose has been shown to be a effective and safe treatment for mild or moderately severe lichen planus[7]. Although the use of systemic steroid in lichen planus causes quick and often dramatic relief of symptoms, it is related with many possible side-effects including hyperglycemia, proximal myopathy, osteoporosis, central obesity,

peptic ulcer disease and growth retardation in children[8].

To minimize the side effects a novel approach has been suggested to give corticosteroid in a weekly pulse form (5 mg betamethasone in a single morning dose after breakfast on 2 consecutive days of a week) till the arrest of disease as well as amelioration of the signs and symptoms. This form of weekly pulse therapy with low dose steroid is known as oral mini-pulse therapy (OMP)[9]. OMP with corticosteroids has many advantages over daily or alternate day steroid therapy such as less frequent dosing and thus ensuring compliance and deceased risk of short and long term side effects associated with corticosteroid therapy[10]. Oral mini-pulse therapy has been reported to be an effective, safe and better therapeutic approach for the treatment of lichen planus[11].

Patients and Methods

Type of study: It was a prospective clinical trial.

Place of study: Department of Dermatology and Venereology, Bangabandhu Sheikh Mujib Medical University, Shahbag, Dhaka 1000.

Study population: Patients with cutaneous lichen planus with or without the involvement of other sites and fulfilling the inclusion criteria were selected. Diagnosis of lichen planus was based on clinical features. Severity of itching was determined by categorically asking the patients whether that was mild, moderate or severe.

Sample size: Forty adult patients of both sexes. They were divided into groups: A(case) and B (control).

Group A: 20 participants (9 males and 11 females, age ranging from 20 to 56 years). Group B: 20 participants (10 males and 10 females, age ranging from 22 to 67 years).

Study period: November 2004 to November 2005.

Sampling technique: Simple Random sampling

Inclusion criteria:

1. Patient of cutaneous LP with or without involvement of other sites.
2. Patients of both sexes.
3. Any age over 18 years.
4. Willing to give consent.

Exclusion criteria:

1. Patients of lichen planus co-existing with diabetes mellitus, hypertension, active peptic ulcer disease, glaucoma, epilepsy and osteoporosis.
2. Pregnancy and lactation
3. Age less than 18 years
4. Documented hypersensitivity to betamethasone
5. Patients suffering from hepatic or renal diseases.
6. Unwilling to give informed consent.

Ethical consideration: All the patients were informed of the nature of study in detail including the possible risks and benefit of it and then a consent was taken before enrollment into the study.

Treatment regimen: Participants of group A were advised to take 5 mg betamethasone (10 tablets of 0.5 mg betamethasone) as a single dose in the morning after breakfast for two consecutive days followed by 5 days off every week for a period of 6 weeks along with loratadine. Tapering of the dose of betamethasone was done by 0.5 mg every week over the next 10 weeks. To prevent drug induced hyper-acidity omeprazole 20 mg was given two times a day for the whole period of treatment. The group B was given loratadine, a second generation anti-histamine, 10 mg daily to alleviate itching.

Follow-up: Clinical assessment was done at baseline, on days 14, 28, and 42

Data collection: Data were collected by a structured questionnaire.

Data processing and analysis: All data were checked and edited after collection. Then the data was analyzed with SPSS Ver.12 software programme.

Results

The present study has been undertaken to assess the efficacy of betamethasone oral mini pulse therapy and its compliance in terms of side effects and dose. The mean (±SD) ages of group A and group B were 37.7 (±10.79) and 38.9 (±12.62) years, respectively. This difference between group A and group B was not statistically significant ($p > 0.05$). The ratio between the male and female in both group A and group B were 1:1 and 9:11 respectively. This difference was not also statistically significant ($p > 0.05$). So, the participants in group A and group B were age and sex matched and their occupations and socioeconomic conditions were similar as well.

Out of 20 patients of group A, 16 (80%) showed complete remission of lichen planus 6 weeks after mini pulse therapy. Among 20 patients of group B, 1(5%) showed complete remission of lichen planus after use of loratadine ($p < 0.05$).

The severity of itching also reduced considerably in patients treated with betamethasone (Tables 1,2; $p < 0.05$).

Table 1: *Frequency distribution of itching on 1st day*

Variable	Characteristic	Betamethasone	Loratadine	p value
Severity of itching	Mild	8 (40%)	8 (40%)	.841
	Moderate	8 (40%)	9 (45%)	
	Severe	4 (20%)	3 (15%)	
	Total	20 (100%)	20 (100%)	

Table 2: *Frequency distribution of itching on different follow-up days*

Itching on	Characteristic	Betamethasone	Loratadine	p value
1st day	Present	20 (100%)	20 (100%)	1
	Absent	0	0	
14th day	Present	17 (85%)	18 (90%)	.633
	Absent	3 (15%)	2 (10%)	
28th day	Present	4 (20%)	12 (60%)	.010
	Absent	16 (80%)	8 (40%)	
42nd day	Present	1 (5%)	10 (50%)	.001
	Absent	19 (95%)	10 (50%)	

Discussion

Among the total affected,47.5% were males and 52.5% were females which is similar to the report made by Katta that lichen planus has a slight predominance in women.

Along with skin involvement, the most common other site of involvement was mucous membrane in both the case (40%) and control (55%) groups. However, these findings are not consistent with Daoud et al (2003) who reported that oral involvement occurs in approximately 60 to 70% of patients with lichen planus. Rashmi & Manchanda had 1 patient with mucous membrane involvement out of 10 cases. A smaller sample size does not give a conclusive epidemiological result.

The number of lesions in lichen planus were drastically decreasing in group A and only slightly increasing in group B during the follow-up visits. The result was statistically significant from the 28th day of follow-up and onward ($p < 0.05$). This result is consistent with a study undertaken by Rashmi & Manchanda. They achieved an excellent response in 6 of their 10 patients and a good response in 4 patients[10]. Al-Mutairi et al. also reported flattening of lesions achieved within 3 weeks with the same treatment.

Remission of itching was noticed in betamethasone group from the first follow-up (14th day) but it was significant on the 28th and 42nd day ($p < 0.05$). Complete remission of itching within 3 weeks of treatment in all the 10 patients was reported by Rashmi and Manchanda. Al-Mutairi et al. reported that itching subsided completely with the first pulse. This was possible, probably due to the fact that they have used topical momentosone furoate 1% cream as well.

No new lesion appeared on 6 (30%), 14 (70%) and 18 (90%) patients in group A and 1 (5%), 3 (15%) and 4 (20%) patients in group B on the subsequent follow up on the 14th, 28th, and 42nd day, respectively. Cessation of appearance of new lesions observed on all follow-ups was statistically significant. This result is consistent with the result reported by Rashmi & Manchanda and Al-Mutairi et al.

At the end of the present study, 16 (80%) patients in group A and 1 (5%) patient in group B achieved complete remission. The remission in group A was highly significant ($p<0.05$) in comparison with the group B.

References

1. Katta R. Lichen planus. Am Fam Physician 2000 ; 61: 3319-24.
2. Boyd AS, Nelder KH. Lichen planus. J Am Acad Dermatol 1991; 25:593-619.
3. Pittlekow MR, Daoud MS. Lichen planus. In: Freedberg I, Eisen AZ, Wolf K, et al (eds). Fitzpatrick's dermatology in general medicine. New York: McGraw-Hill;2008: 244-55.
4. Italiano G. Epidemiological evidence of the association between lichen planus and immune-related diseases, Arch Dermatol 1991; 127: 688-91.
5. Breathnach SM, Black MM. Lichen planus and lichenoid disorders. In: Champion RH, Burton JL, Burns DA, et al (eds). Rook's text book of dermatology. Oxford: Blackwell Science Ltd; 2004:42.17.
6. Cribier B, Frances C, Chosidow O. Treatment of Lichen planus: An evidence-based medicine analysis of efficacy. Arch Dermatol 1998;134:1521-30.
7. Kellett JK, Ead RD. Treatment of lichen planus with a short course of oral prednisolone. Br J Dermatol 1990;123:550-51.
8. Waller DG, Renwick AG, Hillier K. Corticosteroids (glucocorticoids and mineralocorticoids). In: Medical

pharmacology and therapeutics. Edinburgh: WB Saunders ; 2001.
9. Al-Mutairi N, Joshi A, Zaki A, et al. Acute generalized lichen planus treated with weekly betamethasone 5 mg oral mini-pulse therapy. J Drugs Dermatol 2005;4:218-20.
10. Rashmi M, Manchanda Y. Lichen planus treated with betamethasone oral mini pulse therapy. Indian J Dermatol Veneral Leprol 2000;66:34-5.
11. Pasricha JS, Khaitan BK. Oral mini pulse therapy with betamethasone in vitiligo patients having extensive or fast-spreading disease. Int J Dermatol 1993;32:753-57.