



EFFICACY OF CLOBETASOL PROPIONATE 0.05%- AS A TOPICAL ORABASE IN SYMPTOMATIC ORAL LICHEN PLANUS

Oral Medicine

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ABSTRACT

Oral lichen planus is a complex and poorly understood clinical condition which cannot be cured. Symptoms and complications are common and challenging but may be managed with a variety of therapies including orally administered and systemic medications as well as lifestyle alterations and reduction of precipitating factors. Topical steroids are the mainstay management which are easier, more effective than systemic therapy with no to minimal adverse effects. 20 patients included in the study who were clinically diagnosed with symptomatic oral lichen planus were instructed to apply clobetasol propionate (0.05%) orabase thrice daily for a week. Data was analyzed by statistical software and used Boneferri Post hoc test for multiple comparison tests.

Results: using clobetasol propionate 0.05% orabase showed to be effective with an early healing time.

KEYWORDS

oral lichen planus, clobetasol propionate, topical orabase.

INTRODUCTION: Oral lichen planus (OLP) is a chronic inflammatory condition due to abnormal T-cell mediated immune response in which basal epithelial cells are recognized as foreign because of changes in the antigenicity of their cell surface. The cause of this immune-mediated basal cell damage is unknown. The etiopathogenesis of OLP includes infectious agents, genetic variables, environmental influences, and lifestyle elements [1].

The OLP lesions like plaque, papular and reticular are often asymptomatic but the atrophic as well as erosive forms of OLP are symptomatic, often associated with burning sensation to severe pain, leading to difficulty in oral related functions and possess a risk for squamous cell carcinoma [2].

Numerous treatment strategies have been tried in past, including topical, systemic, and intra-lesional corticosteroids, topical cyclosporine, topical and systemic retinoids, azathioprine, tacrolimus, photochemotherapy and surgery [3]. Although a wide range of treatment modalities which are palliative are in practice, like topical application of steroids to laser therapy. Steroids are most commonly employed drugs for the treatment of OLP. The rationale behind their usage is their ability to modulate inflammation and immune response. They act by reducing the lymphocytic exudate and stabilizing the lysosomal membrane.

Various topical corticosteroids serve as a main stay in the treatment of OLP, systemic therapy is advocated where the condition is unresponsive to topical steroids such as severe refractory, numerous or widespread and those with acute exacerbation [4].

Among topical steroids, triamcinolone acetonide ointment which is mildly potent used to improve patients symptoms but no specific information is provided on the resolution of symptoms with this therapy. Fluocinolone acetonide 0.1% in orabase is highly potent which has been shown more effective results than a similar triamcinolone acetonide 0.1% preparation with no serious side effects. Clobetasol which is super potent can result in more effective improvement of the condition than fluocinonide, as it exerts anti-inflammatory, immunosuppressive and antimetabolic effects influencing the growth, differentiation and function of various cells and inhibition. The greater advantage of clobetasol is that it counteracts the production of phospholipase A2 and sub products such as lipooxygenase and cyclooxygenase.

Although there are some reports of systemic absorption and adrenal

suppression from super-potent topical steroids in the treatment of chronic skin disorders, adrenal suppression has not been found in long-term oral application of topical clobetasol 0.05% [5].

Therefore the present study was aimed to evaluate the efficacy of 0.05% clobetasol propionate orabase in management of oral lichen planus lesions.

The objective was to check the efficacy of clobetasol propionate in terms of alleviating burning sensation on visual analog scale.

MATERIALS AND METHODS: The present study was carried out in the department of oral medicine and radiology, SVS Institute of Dental Sciences, Mahabubnagar during a period of January 2016 to April 2016 with a chief complaint of burning sensation in oral cavity. An informed consent in their respective vernacular languages was obtained from the subjects enrolled for the study adhering to the institutional ethical committee protocols. 20 patients who were clinical diagnosed with erosive, reticular lichen planus with erosive component and atrophic lichen planus were included in the study. Patients having poor oral hygiene and uncontrolled diabetes and under systemic steroid therapy were excluded from the study.

Clobetasol propionate orabase constituting clobetasol propionate 0.05%, sodium carboxymethyl cellulose as base, gelatin, pectin were used (gelling and thickening agent to bind cells together and to regulate water) to facilitate adhesion to tissue in the treatment of OLP. Patients were instructed to apply a thin layer of prescribed topical corticosteroid 0.05% clobetasol orabase thrice daily, after meals and advised to expectorate excess saliva after the application and not to swallow for at least 1 hour. All the patients will be periodically subjected to hematological investigations. They were also mentioned about the use, duration and tapering of the doses.

Data was analyzed by statistical software using SPSS version 16.0. Data was described by Mean \pm SD for continuous data, Median \pm IQR for ordinal data and percentages for categorical data. The comparison between weeks was done with one way repeated analysis of test and followed by Boneferri Post hoc test for multiple comparison tests. P-values less than 0.05 were considered as statistically significant.

RESULTS: In all the cases the administration of the corticosteroid was effective in producing remission of symptoms in each group of patients. Reticular LP lesions regressed within 2 weeks; 3 erosive LP showed complete recovery of the lesion within 3 weeks [Figure 1] and

atrophic LP showed regression in 3 weeks and a tapering dose application was advised. None of the patients developed any adverse reactions due to clobetasol propionate orabase. VAS score was obtained during every follow up in these patients. There is significant difference between 0, 2, 4, 6 weeks for the parameter lesion. That means significantly reduction from 0 to 2 to 4 to 6 weeks [Table 1 and Figure 2].

Figure 1: Series of pictures depicting improvement in erosive form of lichen planus



Statistical significance was noticed in the pain score along with an early healing time. There is significant difference between 0 and 2, 0 and 4, 0 and 6, 2 and 4, 2 and 6; 4 and 6 is not significant [Table 2]. Close follow-up of the patient was carried out, starting on a monthly basis for three months and every three months, thereafter Special emphasis was placed to oral hygiene, because dental plaque often aggravates the symptoms of the lesions. Hence the need for proper oral physiotherapy should constantly be reinforced to the patient and periodontal treatment should be instituted whenever necessary.

Table-1: The VAS score among symptomatic oral lichen planus lesion 0, 2, 4, 6 weeks.

Weeks	N	Range	Median	IQR	P-value
0	20	6 to 10	8	7 to 8	<0.0001
2	20	1 to 5	2	2 to 3	
4	20	0 to 3	0	0 to 0	
6	20	0 to 1	0	0 to 0	

Note: IQR means Inter-Quartile Range.

Figure-2: The simple median bar diagram for the comparison of VAS score between 0, 2, 4, 6 weeks

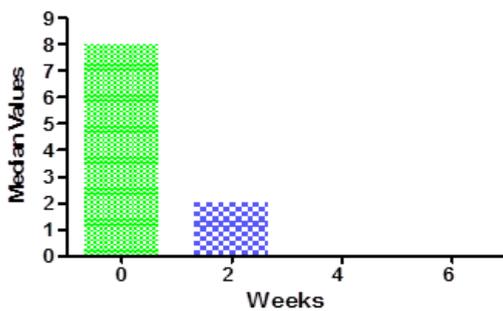


Table-2: The multiple comparison between 0, 2, 4, 6 weeks for the parameter Lesion

Multiple Comparison	Mean Difference	Significant? P < 0.05?	Summary
0 vs. 2	5.15	Yes	***
0 vs. 4	7.30	Yes	***
0 vs. 6	7.60	Yes	***
2 vs. 4	2.15	Yes	***
2 vs. 6	2.45	Yes	***
4 vs. 6	0.30	No	NS

DISCUSSION: Oral lichen planus is a complex and poorly understood clinical condition which cannot be cured. A definitive diagnosis and careful, conscientious follow-up are imperative. Symptoms and complications are common and challenging but may be managed with a variety of therapies including orally administered and systemic medications as well as lifestyle alterations and reduction of precipitating factors.

Rodstorm et al in 1994 compared the effect of clobetasol propionate ointment and triamcinolone acetonide in the treatment of erosive oral lichen planus in the double-blind clinical trial. The results

was similar with the present study demonstrate that clobetasol propionate compared with triamcinolone acetonide provides a more immediate clinical response in OLP [6].

Conrotto in 2006 stated the effectiveness of Clobetasol (0.025%) and cyclosporine (1.5%) compared on 40 subjects in terms of long term remission of symptoms and cost effectiveness for 2 months and presented that Clobetasol is more effective than cyclosporine in inducing clinical improvement and gives less stable results with higher incidence of side effects in a follow up of 2 months [7].

Thongprasom in 2007 conducted a study among 13 subjects to compare the effectiveness of cyclosporine solution with triamcinolone acetonide 0.1% in orabase for 8 weeks and concluded that topical cyclosporine was not effective than triamcinolone acetonide and more side effects were noticed in patients receiving cyclosporine [8].

Passeron (2007) study stated Efficacy of 1% pimecrolimus for 4 weeks on 12 subjects and concluded that pimecrolimus seems to be effective and well tolerated treatment but with minimal side effects and relapse of the treatment was seen in 1 month follow up [9].

Forty subjects were evaluated to compare the efficacy and safety of pimecrolimus 1% cream with triamcinolone acetonide 0.1% for 2 months by Gorouhi (2007) drawing to a conclusion that both the drugs were effective in the management but with minimal side effects noticed with pimecrolimus in 2 months of follow up [10].

A study conducted by Carbone et al (2009) suggested that clobetasol propionate in 4% hydroxyethyl cellulose gel, independent of the concentration used, would appear to be a treatment of choice for patients with atrophic-erosive OLP, providing comparable clinical efficacy, being safe and well-tolerated [11].

Sonthalia (2012) piloted an 8 week study on 40 subjects, to relate the efficacy of clobetasol propionate 0.05% with tacrolimus 0.1%. The results disclosed that the latter is effective and can be considered as first line of therapy with no adverse effects [12].

A study conducted by Siva Raman (2016) compare the effectiveness of topical triamcinolone acetonide (0.1%), clobetasol (0.05%) and tacrolimus Orabase (0.03%) in the management. Thirty subjects were included in this study which concluded that clobetasol propionate has higher efficacy when compared to triamcinolone acetonide and tacrolimus with no side effects. It was also inferred that triamcinolone acetonide 0.1% has better effects than tacrolimus 0.03% [13].

CONCLUSION: The results suggest that topical application of clobetasol propionate 0.05% as a muco-adhesive orabase is an effective drug for symptomatic relief of oral lichen planus.

The rationale for treatment is to provide oral comfort for the patient if the lesions are symptomatic, to improve function (eating, speaking, sleeping, wearing dental prostheses etc.), as well as to prevent or prolong the frequency and severity of exacerbations.

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