Clinical efficacy of 0.5% clobetasol propionate and 0.1%triamcinolone acetonide in the treatment of oral lichen planus

Mehrunnisa [1], Bushra [2], Surwaich Ali Channa [3,*], Zunair Akbar Memon [4], Shuja Hamid [5], Qaimuddin Shaikh [6].

ABSTRACT:

Objectives: To compare the efficacy and short-term safety profile of clobetasol propionate 0.05% ointment and triamcinolone acetonide 0.1% orabase adhesive in moderate to severe oral lichen planus (OLP) in terms of pain, burning sensation, and lesion extension.

Methodology: A quasi-experimental study conducted on 42 adult patients with moderate to severe OLP. All subjects were equally divided into two groups for receiving either clobetasol or triamcinolone for four times in a day for four weeks. The clinical severity was assessed by an ordinal four-point scale (no disease= 0; severe disease= 3) at the start, week four, and two weeks after treatment completion (week six). Differences between groups were analyzed using the Mann-Whitney U test, while differences within groups were analyzed using Wilcoxon signed rank test.

Results: Significant higher rates of complete remission of triamcinolone were found in all domains at week four (pain = 66.7% vs 4.8%; burning = 95.2% vs 0%, mucosal extension = 57.1% vs 0%, all $p < 0.001$). At week six, remissions of burning sensation and lesion extension were found in the triamcinolone group, but in clobetasol group all domains showed significant rebound of disease symptoms ($p< 0.05$).

Conclusion: Triamcinolone acetonide 0.1% orabase was significantly more efficacious than clobetasol propionate 0.05% ointment in moderate to severe OLP cases.

Keywords: Oral Lichen Planus; Clobetasol Propionate; Triamcinolone Acetonide; Topical Corticosteroids; Orabase; Oral Mucosal Disease.

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Introduction:

Oral Lichen Planus (OLP) is an autoimmune mediated, chronic disease of the oral mucosa which has a clear predilection towards middle-aged females, and occurs in around 0.5%-2% of the general population.[1,2] While distinct from Lichen Planus in terms of its clinical manifestations and symptoms, it has one common characteristic feature – that of being hard to treat. Indeed, OLP tends to recur, persists, and can become a pre-cancerous condition, hence classifying itself as a potentially malignant disorder of the oral mucosa.[3] Clinical manifestations include asymptomatic reticular forms to painful atrophic and erosive forms causing significant discomfort while speaking and eating. Pathogenesis of OLP involves auto-immune mediated T-cell activities targeting the basal keratinocytes in the oral mucosa. In particular, CD8+ T-lymphocytes, activated by antigen presenting cells and expressing perforin, granzyme B and Fas/Fas Ligand, cause the death of basal keratinocytes. [4,5] The CD4+ mediated response, meanwhile, causes chronic inflammation.[6] Thus, OLP is characterized by its immunological pathogenesis which makes the use of immunosuppressants a necessary part of therapy. Among such agents, corticosteroids have been demonstrated to be highly effective, and have been used as first-line treatment of symptomatic OLP for decades due to their inhibitory effect on nuclear factor-kB (NF-kB) activity.[7,8]

A review of the existing literature regarding comparative analysis of both of these drugs demonstrates that a large number of studies compare the effectiveness of each agent alone with other treatments such as tacrolimus, amlexanox, and biologics, but the comparison of the effects of clobetasol 0.05% and triamcinolone 0.1% on OLP using an appropriate OLP severity grading scale before and after cessation of treatment remains rare.[9-12]

Against this backdrop, the present study sought to examine the therapeutic effectiveness of topical application of clobetasol propionate 0.05% cream in comparison with triamcinolone acetonide 0.1% orabase in treating patients with histopathologically proven OLP.

Objectives:

To compare the efficacy and short-term safety profile of clobetasol propionate 0.05% ointment and triamcinolone acetonide 0.1% orabase adhesive in moderate to severe oral lichen planus (OLP) in terms of pain, burning sensation, and lesion extension.

Methodology:

This comparative study was conducted at the Department of Oral Medicine Bhitai Dental & Medical College Mirpurkhas for a period of one year (from 3 January 2023

1. Department Periodontology. Bhitai Dental & Medical College Mirpurkhas.
2. Assistant Professor. Department Of Oral Medicine; Isra Dental College. Isra University Hyderabad.
3. Associate Professor. Department of Oral Pathology, Bhitai Dental and Medical College Mirpurkhas.
4. Assistant Professor. Department of Oral Medicine; Isra Dental College. Isra University Hyderabad.
5. Assistant Professor. Department of Oral Medicine; Bhitai Dental and Medical college Mirpurkhas.
6. Prof. Department of Oral and Maxillofacial Surgery; Bibi Aseefa Dental College. Shaheed Mohtarma Benazir Bhutto Medical University Larkana.

*=corresponding author:
Email: surwaichchanna6@gmail.com

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to 2 January 2024) after taking approval from research department (ref: BDMC/R&D/ERC/2023-14 dated 2nd January 2023).The informed consent of patients was taken in writing after thoroughly informing them about the details of the study, the possible risks associated with the procedure, and withdrawal of consent anytime during the trial. A sample of minimum size of 42 patients was taken on the assumption that at least 50% remission of pain is expected in each group by week 4. With an assumed alpha of 0.05 and desired power of 90%, taking into account the remission rates of previous corticosteroid trials done in OLP 13-15 the sample size needed was minimum of 19 per group. To allow for the estimated 10% drop-out, the sample size of 21 patients per group (total of 42) was chosen.

Subjects included adults aged ≥18 years with a clinical/histopathological diagnosis of OLP. Moderate-severe symptomatology (baseline scores of 2-3 in two domains out of pain, burning, or lesion extension) was the criterion for inclusion. Patients who had received any corticosteroids or immunomodulators within the last 4 weeks, had any hypersensitivity to study drugs, were pregnant/lactating women, had concurrent oral candidiasis or systemic conditions with lichenoid mucocutaneous reaction (e.g., graft vs host disease or drug induced lesions) were excluded from the study.

In the clobetasol group 0.05% ointment, and in triamcinolone group 0.1% orabase four times daily for four weeks was used. Application method for maximum mucosal exposure was followed. Clinical evaluation was made at baseline (week 0), endpoint of therapy (week 4) and after 2 weeks of treatment discontinuation (week 6).

Statistical Analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). The changes in parameters within a group were analyzed using Wilcoxon Signed Rank Test. The comparisons between groups were analyzed using Mann Whitney U test. Categorical variables like complete remission and adverse effects were compared using chi square test or Fisher's exact test as appropriate. P value < 0.05 was considered significant.

Results:

The study groups had an equal number of males (8 patients each representing 38.1%) and females (13 patients each representing 61.9%). The average age in both groups was nearly same, that is, 43.7 ± 18.2 and 43.6 ± 19.3 in the clobetasol and triamcinolone groups, respectively. The two groups were statistically similar at baseline. Severe pain (score = 3) was observed in 16 patients (76.2%) in each group while 5 patients (23.8%) experienced moderate pain (score = 2). In each group, severe burning sensation was observed in 14 patients (66.7%) while moderate burning sensation was observed in 7 patients (33.3%). Mucosal involvement was either severe in 17 patients (81%) or moderate in 4 patients (19%) in each group.

The intra-group comparison based on the Wilcoxon signed rank test considered complete remission as a severity score of 0. In all domains, triamcinolone acetonide 0.1% proved to be more effective than clobetasol propionate 0.05%. Complete remission was observed in 14 out of 21 (66.7%) patients in pain with triamcinolone at Week 4 compared with 1 out of 21 (4.8%) patients in pain with clobetasol (p<0.001). The patients who did not experience complete remission had mild pain. Complete remission in burning was noted in 20 out of 21 (95.2%) patients treated with triamcinolone compared with zero out of 21 patients treated with clobetasol (median scores were 0 and 1 respectively, p<0.001).

Table No 1. Baseline Demographic and Clinical Characteristics of Study Participants.

Characteristic	Clobetasol 0.05%	Triamcinolone 0.1%	p-value
Male, n (%)	8 (38.1%)	8 (38.1%)	
Female, n (%)	13 (61.9%)	13 (61.9%)	
Mean Age ± SD (years)	43.7 ± 18.2	43.6 ± 19.3	
Pain score 3 (severe), n (%)	16 (76.2%)	16 (76.2%)	1.000
Burning score 3 (severe), n (%)	14 (66.7%)	14 (66.7%)	1.000
Burning score 2 (moderate), n (%)	7 (33.3%)	7 (33.3%)	1.000
Mucosal score 3 (severe), n (%)	17 (81.0%)	17 (81.0%)	1.000
Mucosal score 2 (moderate), n (%)	4 (19.0%)	4 (19.0%)	1.000
Median pain score (range)	3 (2-3)	3 (2-3)	0.999
Median burning score (range)	3 (2-3)	3 (2-3)	0.999
Median mucosal score (range)	3 (2-3)	3 (2-3)	0.999

Table No 2: Primary Efficacy Outcomes Complete Remission Rates and Median Severity Scores at Week 4 and Week 6

Outcome Measure	Clobetasol 0.05%	Triamcinolone 0.1%	p-value
Pain Week 4			
Complete remission, n (%)	1 (4.8%)	14 (66.7%)	< 0.001
Mild residual pain, n (%)	13 (61.9%)	7 (33.3%)	
Moderate residual pain, n (%)	7 (33.3%)	0 (0%)	
Median score (range)	1 (0-2)	0 (0-1)	< 0.001
Within-group p-value vs. baseline	< 0.001	< 0.001	
Pain Week 6			
Complete remission, n (%)	0 (0%)	9 (42.9%)	< 0.001
Mild residual pain, n (%)	9 (42.9%)	12 (57.1%)	
Moderate residual pain, n (%)	12 (57.1%)	0 (0%)	
Median score (range)	2 (1-2)	1 (0-1)	< 0.001
Within-group p-value vs. Week 4	< 0.05	< 0.05	
Burning Week 4			
Complete remission, n (%)	0 (0%)	20 (95.2%)	< 0.001
Mild residual burning, n (%)	20 (95.2%)	1 (4.8%)	
Moderate residual burning, n (%)	1 (4.8%)	0 (0%)	
Median score (range)	1 (1-2)	0 (0-1)	< 0.001
Within-group p-value vs. baseline	< 0.001	< 0.001	
Burning Week 6			
Complete remission, n (%)	0 (0%)	20 (95.2%)	< 0.001
Mild residual burning, n (%)	12 (57.1%)	1 (4.8%)	
Moderate residual burning, n (%)	9 (42.9%)	0 (0%)	
Median score (range)	1 (1-2)	0 (0-1)	< 0.001
Within-group p-value vs. Week 4	< 0.05	0.999	
Mucosal Extension Week 4			
Complete remission, n (%)	0 (0%)	12 (57.1%)	< 0.001
Mild residual involvement, n (%)	18 (85.7%)	9 (42.9%)	
Moderate residual involvement, n (%)	3 (14.3%)	0 (0%)	
Median score (range)	1 (1-2)	0 (0-1)	< 0.01
Within-group p-value vs. baseline	< 0.001	< 0.001	
Mucosal Extension Week 6			
Complete remission, n (%)	0 (0%)	12 (57.1%)	< 0.001
Mild residual involvement, n (%)	9 (42.9%)	9 (42.9%)	
Moderate residual involvement, n (%)	12 (57.1%)	0 (0%)	
Median score (range)	2 (1-2)	0 (0-1)	< 0.001
Within-group p-value vs. Week 4	< 0.05	0.999	

Table No 3:Full Severity Score Distribution Across All Timepoints Both Treatment Groups.

Domain	Clobetasol W0	Clobetasol W4	Clobetasol W6	Triamcinolone W0	Triamcinolone W4	Triamcinolone W6
Pain						
Score 3 Severe	16 (76.2%)	0 (0%)	0 (0%)	16 (76.2%)	0 (0%)	0 (0%)
Score 2 Moderate	5 (23.8%)	7 (33.3%)	12 (57.1%)	5 (23.8%)	0 (0%)	0 (0%)
Score 1 Mild	0 (0%)	13 (61.9%)	9 (42.9%)	0 (0%)	7 (33.3%)	12 (57.1%)
Score 0 Absent	0 (0%)	1 (4.8%)	0 (0%)	0 (0%)	14 (66.7%)	9 (42.9%)
Median (range)	3 (2-3)	1 (0-2) *	2 (1-2) *†	3 (2-3)	0 (0-1)*	1 (0-1) *†‡
Burning						
Score 3 Severe	14 (66.7%)	0 (0%)	0 (0%)	14 (66.7%)	0 (0%)	0 (0%)
Score 2 Moderate	7 (33.3%)	1 (4.8%)	9 (42.9%)	7 (33.3%)	0 (0%)	0 (0%)
Score 1 Mild	0 (0%)	20 (95.2%)	12 (57.1%)	0 (0%)	1 (4.8%)	1 (4.8%)
Score 0 Absent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	20 (95.2%)	20 (95.2%)
Median (range)	3 (2-3)	1 (1-2) *	1 (1-2) *‡	3 (2-3)	0 (0-1) *	0 (0-1) *
Mucosal Extension						
Score 3 Severe	17 (81.0%)	0 (0%)	0 (0%)	17 (81.0%)	0 (0%)	0 (0%)
Score 2 Moderate	4 (19.0%)	3 (14.3%)	12 (57.1%)	4 (19.0%)	0 (0%)	0 (0%)
Score 1 Mild	0 (0%)	18 (85.7%)	9 (42.9%)	0 (0%)	9 (42.9%)	9 (42.9%)
Score 0 Absent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	12 (57.1%)	12 (57.1%)
Median (range)	3 (2-3)	1 (1-2) *§	2 (1-2) *†‡	3 (2-3)	0 (0-1) *	0 (0-1) *

Fisher's Exact test was used for all categorical variables. AE: adverse events; N/A: not applicable. Both treatment regimens were well-tolerated throughout the four weeks of treatment and two weeks of post-ceasing observation, as shown in Table 4 below.

Table No 4: . Safety and Adverse Event Profile Both Treatment Groups

Safety Parameter	Clobetasol	Triamcinolone	p-value
Transient oral burning (first 48 h), n (%)	0 (0%)	0 (0%)	1.000
Oral candidiasis (any timepoint), n (%)	0 (0%)	0 (0%)	1.000
Hematological abnormalities, n (%)	0 (0%)	0 (0%)	1.000
Biochemical abnormalities, n (%)	0 (0%)	0 (0%)	1.000
Detectable serum drug levels (Week 4)	Not detected	N/A	
Severe adverse events, n (%)	0 (0%)	0 (0%)	1.000
Treatment withdrawal due to AE, n (%)	0 (0%)	0 (0%)	1.000
Protocol completion, n (%)	21 (100%)	21 (100%)	1.000

Discussion:

In conclusion, triamcinolone acetonide 0.1% orabase proved to be significantly superior compared to clobetasol propionate 0.05% ointment concerning complete remission from pain, burning and mucosal lesions in moderately severe OLP at Weeks 4 and 6. Pain, burning and lesion extension complete remission in patients receiving triamcinolone reached 66.7%, 95.2% and 57.1% respectively, compared to 4.8%, 0% and 0% in the control group.[13]

It seems reasonable that relatively low-potency of corticosteroid can outweigh superpotent counterpart due to differences in pharmacokinetics. Triamcinolone orabase containing carboxymethylcellulose adhesive gel ensures constant mucosal contact, thus maintaining maximal local bioavailability of drug delivery to mucosa damaged by CD8+ T cell mediated mechanisms.[14] Clobetasol ointment is rapidly displaced by salivary flow and oral motility resulting in limited mucosal penetration despite higher binding affinity to glucocorticoid receptors. Such vehicle dependent clinical outcome had already been described before in other OLP trials.[15]

Durability of response was particularly evident at week 6 when patients in the triamcinolone orabase group maintain symptoms remission while patients in the control group experienced significant worsening ($P<0.05$) in all investigated parameters. This fact indicates that sustained local administration could lead to interruption of local inflammation cycle better than temporary relief achieved with conventional ointments.[16-19]

Overall results are congruent with those found previously about efficacy of topical corticosteroids in OLP patients. Polizzi et al. [20] revealed that adhesive formulations provided more effective relief of symptoms than conventional ointments, in line with our results. Network meta-analysis by Leong et al. [12] also noted an importance of delivery system in achieving high clinical success rates with orabase or gel preparations often surpassing stronger potent ointments. Unlike previous studies, this trial included assessment of response persistence after cessation of the treatment at week 6, where triamcinolone demonstrated sustained effect while clobetasol led to worsening of all studied parameters. Both treatment regimen and clinical outcomes indicate that potency and form of preparation play important roles in effectiveness of treatment of OLP. [17]

Neither therapy led to any serious side effects such as oral candidiasis or systemic complications. Such results are consistent with previous experiences regarding safety of short-term use of topical corticosteroids in OLP.[18]

Despite the fact that this study provides convincing evidence about superior effect of orabase-delivered triamcinolone, it should be noted that some limitations exist. They include insufficient sample size, short treatment and follow-up period, single-center design, lack of placebo comparison and exclusion of histopathological classification for subgroup efficacy analysis.[1,6] Future RCTs comparing triamcinolone orabase, clobetasol bio adhesive ointment and non-steroidal agents like tacrolimus should shed light on optimal first-line treatment of moderate-to-severe OLP.

Conclusion:

In this study, 0.1% TA in orabase has been found to be better than 0.05% CP ointment in treating moderate to severe OLP, as complete remission in terms of pain (66.7%), burning sensation (95.2%) and lesions in the mucosa (57.1%) was observed as compared to 4.8%, 0%, and 0% with CP. This improved efficacy could be attributed to the prolonged contact of the orabase formulation with the mu-

cosa and increased local availability, despite the increased potency of CP. The safety and tolerability of both formulations were good, without any incidence of oral candidiasis, systemic absorption and side effects.

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Author's Contribution	
Mehrunnisa	Methodology; Writing – Original Draft. And co supervision
Bushra	Methodology; Validation;
Surwaich Ali Channa	Validation, Critical appraisal, final approval
*Zunair Akbar Memon	Methodology; Visualization
Shua Hamid	Writing – Review & Editing
Qaimuddin Shaikh	Re-Analysis and drafting