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ORIGINAL ARTICALE

THE EFFECTIVENESS OF TRIAMCINOLONE ACETONIDE (0.1%), AMLEXANOX (5%) AND CLOBETASOL PROPIONATE (0.05%) IN TREATING ORAL LICHEN PLANUS

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ABSTRACT

Background: Oral lichen planus (OLP) is a potentially malignant mucocutaneous condition. The present research done was to evaluate the efficiency of 0.1% triamcinolone acetonide, 0.05% clobetasol propionate, and 5% amlexanox in treating OLP.

Methods: Three equal groups of sixty participants with OLP were treated with topical medications: 5% amlexanox (Group III), 0.1% triamcinolone acetonide (Group II), and 0.05% clobetasol propionate (Group I). The visual analogue scale (VAS) was used to evaluate the patients' level of pain. On Days 1, 7, and 15 of the trial, their erosive area and ulcerative lesion type were also assessed.

Results: In every investigated group, the VAS pain scale score decreased statistically significantly between Day 1 and Day 15. In comparison to the other two groups, Group B's pain score was lower. Additionally, on the fifteenth day, the erosive region on the left and right buccal mucosaon decreased with all three of the studied medications. In comparison to 0.05% Clobetasol Propionate and 5% Amlexanox, triamcinolone acetonide (0.1%) was efficient in improving the erosive lesions on the buccal mucosa on the right and left sides. Of the three groups, Group II had the highest healing ratio (37 cases), Group I had the second-highest (32 cases), and Group III had the lowest (30 cases).

Conclusion: All medicines utilised in this trial –triamcinolone acetonide, clobetasolpropionate andamlexanox–were beneficial in managing OLP patients; consequently, it can be considered as substitute.

Keywords: Erosive, management, mucosa, oral lichen planus, visual analogue scale

INTRODUCTION

One mucocutaneous condition that has the potential to be malignant is oral lichen planus (OLP). People in their 40s and 50s are primarily affected.[1] Compared to men, women are more likely to have OLP. OLP is thought to be a cell-mediated immunological effect to basal keratinocytes, despite the fact that its exact cause is uncertain. Atrophic, reticular, bullous, plaque, ulcerative, erosive and popular is a few of the prevalent types of OLP. [2]

Stomatitis, vesiculation, ulceration and a burning feeling while ingesting spicy meals and hot beverages are some of the symptoms of OLP, which differ from patient to patient. The thigh, flexor surfaces of the arms, forearms, and buttocks are the most typical locations for OLP to occur. Any area of the oral cavity may be impacted in the mouth.[3] The soft palate, gingiva, lips, tongue, and buccal mucosa are the most often impacted regions. The defining feature of this illness is bilateral presentation. Wickham striae, which are whitish keratotic radiating striations, are frequently seen diagnostic features, particularly in the reticular type. [4]

OLP has been treated with a variety of medications, with differing degrees of success. Among the specific drugs currently on the market are corticosteroids (intralesional, topical, or systemic), cyclosporine, retinoids, psoralen plus UVA light, hydroxychloroquine, griseofulvin and dapsone. [5]

Steroids have been effective in treating symptomatic OLP because they reduce pain and inflammation. Corticosteroids, such as clobetasol propionate, fluticasone propionate, and triamcinolone acetonide, in both local and systemic formulations, can be used to treat OLP; atrophic-erosive OLP was found to be cured by topical clobetasol and 0.01% triamcinolone acetonide. Clobetasol is an active corticosteroid that has anti-inflammatory effects on the skin, reducing inflammation-causing chemical messengers such as swelling, redness, and itching. Candida, or the excess of the normal oral flora that results in candidiasis, is the only side effect of topical corticosteroid therapy. [6] Amlexanox is a non-steroidal anti-inflammatory and anti-allergic medication that is typically prescribed as an oral paste at a concentration of 0.5%. Reducing the release of histamine from mast cells, neutrophils, and basophils is the primary mode of action. [3]

Present study compares topical 0.1%triamcinolone acetonide, 5% amlexanox, and 0.05% clobetasol propionate in the management of OLP.

MATERIAL AND METHOD

Study design and Setting

Total of 60 individuals having oral lichen planus were included for this observational cross sectional study. The research was carried out between March 2022 and January 2023. Following patient permission and an ethical clearance certificate from higher authorities, the study was carried out. (Ref no.IEC.KIIT/2016-016).

Study Population

Patients diagnosed with OLP of both genders in ages ranged from 40 to 70 and those who gave their consent were included for the study. Patients using immunosuppressive medications within the previous three months and having a history of consuming antibiotics and pregnant women were excluded from the study.

Methodology

A case history recording followed by a comprehensive oral examination was undertaken for all patients. The lottery approach was used to randomly assign patients into three groups, each of which had forty patients. Group II was given 0.1% triamcinolone acetonide (Cortorawyn 0.1% oral 5Gm paste, Wyn Clark, India), while Group I was given 0.05%W/W clobetasol propionate (Topinate Gel 30 gm, Systopic Laboratories PVT LTD, India).Topical 5% amlexanox (Lexanox Oral paste, Macleods Pharmaceuticals Pvt Ltd, India) was administered to Group III. For 15 days, the participants were instructed to apply the prescribed medications to the lesions three times a day (after meals), with the first application being done under supervision and observed for 20 minutes. After 15 days, the patients were asked to cease taking the medication and undergo examinations to determine whether the pain had decreased and whether the erosive lesions had completely healed.

Evaluation

The visual analogue scale (VAS) was used to evaluate the patients' discomfort and the extent of the erosive area. The greater diameter (cm) and greater width (cm) were multiplied to determine the erosive area (cm2). The erosive region and pain were noted on Days 1, 7, and 15. We measured the higher width and greater diameter perpendicular to the maximal diameter of individual erosive lesions using a calibrated dental probe. Maximum width (cm) times maximum diameter (cm) equals erosive area (cm2). Pain or burning sensations were measured using the VAS, which use a 10 cm horizontal line on a 0–10 scale, where 1 denotes no pain and 10 denotes severe pain. Three categories of ulcerative lesions were assessed: healed, somewhat healed, and unhealed.

Statistical analysis

The collected data were tabulated and statistically assessed; a P value of lesser to 0.05 was deemed considerable, and the results were compiled and statistically assessed using the Mann–Whitney U test.

RESULTS

Group I consist of 14 males and 26 females, Group II consist of 12 males and 28 females and Group III consist of 16 males and 24 females. Inter group and intra group evaluation was considerable at day 1 to 15 (Table 1).

Table 1. Distribution of participants

Groups	Group I	Group II	Group III
Medicine used	0.05% clobetasol propionate	0.1% triamcinolone acetonide	5%amlexanox
Male–Female ratio	14:26	12:28	16:24

Table 2. VAS pain scores were compared between the groups.

Day	Group I	Group II	Group III	p value
1	6.5±1.124	7.1±1.132	6.3±1.153	0.05
7	5.2±1.067	6.4±1.073	4.2±1.083	0.03
15	0.6±0.453	0.3±0.326	0.4±0.572	0.04
p value	0.02	0.02	0.01	

The VAS pain scores in Groups I, II and III on Day 1 were6.5±1.124,7.1±1.132 and 6.3±1.153 respectively; on Day 7 they were 5.2±1.067, 6.4±1.073 and 4.2±1.083 respectively, and on Day 15 they were 0.6±0.453, 0.3±0.326 and 0.4±0.572 correspondingly. The variation observed was considerable (P< 0.05) (Table 2). In every investigated group, the VAS pain score decreased statistically significantly between Day 1 and Day 15. In comparison to the other groups, Group II had the lowest pain score. Comparisons between and among groups were significant from day 1 to day 5 (Table 2).

Table 3. Erosive areas in the right buccal mucosa among the groups

Day	Group I	Group II	Group III	p value
1	1.42±1.345	1.45±1.366	1.32±1.475	0.91
7	0.32±1.056	0.51±1.043	0.69±1.474	0.05
15	0.021±0.678	0.002±0.431	0.011±0.568	0.01
p value	0.01	0.01	0.02	

On Day 1, the erosive region on the right buccal mucosa was 1.42±1.345 cm^2 in Group I, 1.42±1.345 cm^2 in Group II and 1.32±1.475 cm^2 in Group III. On Day 7, it was 0.32±1.056 cm^2in Group I, 0.51±1.043 cm^2 in Group II and 0.69±1.474 cm^2 in Group III. On Day 15, it was 0.021±0.678 cm^2in Group I, 0.002±0.431 cm^2in Group II and 0.011±0.568 cm^2 in Group III. The variation was considerable (P< 0.05). When it came to reductions in erosive lesions, the intragroup comparison from day 1 to day 15 was significant, but the intergroup comparison was not (Table 3).

Table 4. Erosive regions in the left buccal mucosa of the groups are compared.

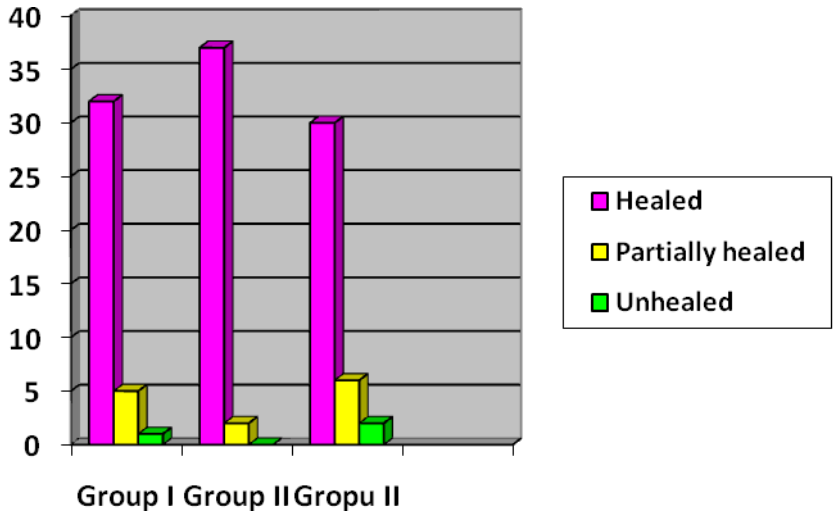
Day	Group I	Group II	Group III	p value
1	1.46±1.476	1.43±1.345	1.32±1.435	0.84
7	0.34±1.045	0.43±1.064	0.47±1.086	0.05
15	0.024±0.067	0.018±0.364	0.007±0.821	0.01
p value	0.09	0.02	0.04	

The erosive area on the left buccal mucosa on Day 1 was 1.46 cm^2 in Group I, 1.43 cm^2 in Group II and 1.32

cm^2 in Group III. On Day 7, it was 0.34 cm^2in Group I, 0.43 cm^2in Group II and 0.47 cm^2 in Group III. On Day 15, it was 0.024 cm^2in Group A, 0.018 cm^2in Group II and 0.007 cm^2in Group III. The variation was considerable (P< 0.05). Inter group comparison was significant at day 7 and 15 but intra group association was significant at day 1 to 15 (Table 4).

For all three of the tested medications, the erosive regions on the right and left buccal mucosa decreased statistically significantly between Day 1 and Day 15 (Tables 3 and 4).When compared to clobetasol propionate and 5% amlexanox, triamcinolone acetonide (0.1%) was more successful in minimising the erosive lesions on the buccal mucosa's left and right sides.

Graph 1. Healing of ulcers in the groups



The three groups' ulcer healing statuses are shown in Figure 1. Group II (37 instances) had a greater healing ratio than Group I (32 cases) and Group III (30 cases).

DISCUSSION

T cell-mediated chronic inflammatory oral mucosal disease is known as oral lichen planus. Although its exact cause is uncertain, it is believed to be the consequence of an aberrant T cell-mediated immune response in which the basal epithelial cells' altered cell surface antigenicity leads to an incorrect identification of them as foreign particles. According to estimates, 0.5–2.0% of the general population is thought to be affected by this relatively common disorder. [5]

OLP affects women more frequently than it does men. One risk factor is stress. Both erosive and atrophic variants of OLP frequently cause a burning sensation.[7] The reticular form of OLP is the most prevalent kind. In order to prevent relapse and remission, the majority of patients are prescribed topical and systemic steroids, even if they experience side effects.[8] When used to treat OLP, a variety of steroids have been shown to yield notable outcomes. The anti-inflammatory medication amlexanox is available topically. [8] It inhibits the breakdown of mast cells by influencing the behaviour of other leukocytes in the afflicted area. This, in turn, inhibits the production of histamine, TNF, and leukotrienes, which raise vascular permeability and result in swelling and inflammation of the affected tissues. [9]

For the treatment of OLP, we compared topical doses of triamcinolone acetonide, 5% amlexanox, 0.1% and 0.05% clobetasol propionate.

Topical clobetasol propionate (0.05%), triamcinolone acetonate (0.1%), and tacrolimus orabase (0.03%) were used to treat OLP in a research by Sivaraman et al. They discovered that clobetasol propionate 0.05% ointment was more efficient than tacrolimus ointment 0.03% and triamcinolone acetonide 0.1%.[5] This contrasts with the findings of this investigation. Furthermore, no negative reactions or side effects were noted in any of the groups. [10]

After seven days of treatment, Fu J et al. found that both topical amlexanox and topical dexamethasone significantly reduced the erosive regions and VAS pain levels in their patients. [11]

Hettiarachchi PV et al. compared the success of clobetasol and tacrolimus in the treatment of 86

cases diagnosed with OLP. There was a substantial reduction in the VAS pain score and erosion score after the use of medicaments. The authors revealed that all tested drugs were effective and 5% amlexanox exhibits promising results .[12] Walia et al. assessed the efficiency of topical administration of TA orabase and Tacrolimus ointment in conjunction with intralesional triamcinolone acetonide (injection TA) for symptomatic patients of OLP. They found improvement in pain and burning sensation after the treatment.[13] Verma et al. assessed the effectiveness of the topical application of 0.1% Triamcinolone Acetonide oro-mucosal paste and 5% Amlexanox oral paste in the treatment of OLP. They concluded that the treatment of OLP is best managed by the topical application of 0.1% triamcinolone acetonide rather than the topical application of 5% Amlexanox. [14] Kavita et al. evaluated the effectiveness of 0.1% topical triamcinolone acetonide and 5% topical amlexanox in the treatment of recurrent aphthous stomatitis. It was discovered that the aforementioned medications helped patients with recurrent aphthous stomatitis heal faster with less pain, erythema, and ulcer size. In comparison to amlexanox, triamcinolone acetonide produced better results. [15] Kavita et al. observed that 90% of patients using triamcinolone acetonide experienced complete improvement whereas only 65% of patients using amlexanox experienced complete improvement. [15] Similarly, in this study, better results and healing of lesions with triamcinolone acetonide compared to amlexanox, and 0.05% clobetasol propionate were observed. Lokesh Kumar et al. compared the effectiveness of Nigella sativa (75% v/v) cream and clobetasol propionate (0.05% w/w) gel for the treatment of OLP. It was discovered that Nigella sativa cream was equally as effective as clobetasol propionate 0.05% gel.[16] Bioactive constituents in plants exhibit pharmacological activities, such as antioxidant, anti-inflammatory, anti-fibrotic and immuno-modulatory benefits.[17] Various herbal medicaments shows antibacterial and anti-inflammatory benefits which can be used in for different oral conditions. [18]

All of the medications evaluated in this trial were found to be successful in treating OLP; however, when compared to other medications, 0.1% triamcinolone acetonide was the most effective. One limitation of this study is that just three medications were chosen for comparisons, and there were only a small number of patients recruited for the trial.

Limitations

The study's limitations included comparing only three medications and having a smaller sample size. To confirm the findings, more investigation is required.

CONCLUSION

From day 1 to day 15, all groups in the current study experienced a decrease in the VAS pain score and the erosive area on the left and right buccal mucoa. Triamcinolone acetonide had a greater healing ratio than clobetasol propionate and 5% amlexanox. Since 5% amlexanox, 0.1% triamcinolone acetonide, and 0.05% clobetasol propionate were all successful in treating OLP patients, it is recommended that these medications be taken into consideration as alternatives.

DECLARATION

Conflict of interest

Nil

Source of funding

Self

Ethical approval and consent to participate and publication

The present study was approved by the ethics committee

Competing of interest

The authors declare there is no conflict of interest

REFERENCES

1. Shennawy ME. Efficacy of topical use of amlexanox and fluocinolone acetonide gels in the treatment of oral lichen planus. *Egypt Dent J.* 2001, 47:367-74.
2. Khandwala A, Van Inwegen RG, Alfano MCl. 5% Amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: II. Pharmacokinetics and demonstration of clinical safety. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.*1997, 83:231-8. 10.1016/s1079-2104(97)90010-x.
3. Bhat S, Sujatha D. A clinical evaluation of 5% amlexanox oral paste in the treatment of minor recurrent aphthous ulcers and comparison with the placebo paste: A randomized, vehicle controlled, parallel, single center clinical trial. *Indian J Dent Res.* 2013, 24:593-8. 10.4103/0970-9290.123382.
4. Katti G, Darshan DD. Amlexanox in the treatment of recurrent minor aphthous ulcers. *Int J Dent Clin.* 2011, 3:23-6.
5. Sivaraman S, Santham K, Nelson A, Laliytha B, Azhalvel P, Deepak JH. A randomized triple-blind clinical trial to compare the effectiveness of topical triamcinolone acetonate (0.1%), clobetasol propionate (0.05%), and tacrolimus orabase (0.03%) in the management of oral lichen planus. *J*

Pharm Bioallied Sci. 2016, (Suppl 1):S86-S89. 10.4103/0975-7406.191976.

6. Thongprasom K,Dhanuthai K. Steriods in the treatment of lichen planus: a review. Journal of Oral Science.2008, 50(40): 377-385.
7. Rozycki TW, Rogers RS 3rd, Pittelkow MR, McEvoy MT, el-Azhary RE, Bruce AJ,et al. Topical tacrolimus in the treatment of symptomatic oral lichen planus: A series of 13 patients. J Am Acad Dermatol. 2002, 46:27-34. 10.1067/mjd.2002.119648
8. Kiyani A, Sohail K, Saeed MHB. Efficacy of 0.1% tacrolimus in long-term management of erosive lichen planus. *J Dermatolog Treat.* 2021, 32:367-71. 10.1080/09546634.2019.1654072.
9. Tsushima F, Sakurai J, Uesugi A, , Oikawa Y, Ohsako T, Mochizuki Y et al. Malignant transformation of oral lichen planus: A retrospective study of 565 Japanese patients. *BMC Oral Health.* 2021, 21(1):298.10.1186/s12903-021-01652-7.
10. Seth V, Patil RG, Moger G, Singh U, Sharma A, Saxena S. Comparative evaluation of the efficacy of topical Amlexanox 5%, Triamcinolone Acetonide 0.1%, and Tacrolimus 0.03% in the treatment of oral erosive lichen planus – A double-blinded randomized clinical trial. *J Indian Acad Oral Med Radiol.* 2022, 34:136-40.10.4103/jiaomr.jiaomr_16_21
11. Fu J, Zhu X, Dan H, Zhou Y, Liu C, Wang F, et al. Amlexanox is as effective as dexamethasone in the topical treatment of erosive oral lichen planus: A short-term pilot study. *Oral Surg Oral Med Oral Pathol Oral Radiol.* 2012, 113:638-43.10.1016/j.oooo.2011.10.013
12. Hettiarachchi PV, Hettiarachchi RM, Jayasinghe RD, SitheequeM. Comparison of topical tacrolimus and clobetasol in the management of symptomatic oral lichen planus: A double-blinded, randomized clinical trial in Sri Lanka. *J Investig Clin Dent.* 2017, 8(4):1-5.10.1111/jicd.12237.
13. Walia C, Rallan NS, Premkumar A, Roy S. Clinical evaluation of efficacy of triamcinolone acetonide with tacrolimus in the management of oral lichen planus: A pilot prospective observational study. Contemp Clin Dent. 2022, 13: 236-41. 10.4103/ccd.ccd_899_20
14. Verma S, Sonali P, Choudhary A. Evaluation of efficacy of topical application of 5% amlexanox oral paste and 0.1% triamcinolone acetonide oromucosal paste in the treatment of oral lichen planus. *Global Journal for Research Analysis.* 2020, 9(10):104-108.10.36106/gjra
15. Kavita K, Singh R, Singh R, Gonuguntla S, Maniangat Luke A, Jois HS. Assessment of efficacy of 5% topical amlexanox and 0.1% topical triamcinolone acetonide in management of recurrent aphthous stomatitis. *J Pharm Bioall Sci.* 2020, 12:S444-7. 10.4103/jpbs.JPBS_133_20
16. Lokesh Kumar S , Zameera Naik , Arun Panwar , Sridhar M , Keluskar V, Surath Kumar R.Comparative evaluation of the efficacy of Nigella sativa (75% v/v) cream and clobetasol propionate (0.05% w/w) gel in oral lichen planus-a double-blinded randomized control trial. *Oral Maxillofac Surg.* 2022, 22. 10.1007/s10006-022-01130-6.
17. Bahadur S, Santosh T, Altaher Mohammed OB , Salma F , Deepak TS , Agrawal B et al. Efficiency of turmeric, triphala and aloe vera in the treatment of oral submucous fibrosis. *Bioinformation.* 2025, 21(4): 630-634. DOI: 10.6026/973206300210630
18. Vathsala N, Bahadur S, Sharma A, Gupta N, Ahmed Almuntashiri AA, Rajan R et al. Antibacterial effect of various herbal root canal irrigants. *Bioinformation.* 2025;21(2):165-168. doi: 10.6026/973206300210165