

# Evaluation of the Effectiveness of Amlexanox in the Treatment of Erosive Oral Lichen Planus: A Clinical Experience from a Tertiary Care Center

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## ABSTRACT

**Aim:** This comparative study evaluated the effectiveness and safety profile of topical amlexanox and triamcinolone for the management of erosive oral lichen planus (EOLP). **Materials and Methods:** This prospective, observational study included 21 patients diagnosed clinically and histopathologically with EOLP and categorized into two groups. Subjects in the two groups were prescribed topical amlexanox and triamcinolone, respectively, for 4 weeks. The area of the erosive lesion and burning sensation was measured at baseline, at the end of the first, 2second, and fourth week. These outcome measures were documented and statistically analyzed. The statistical analyses were performed using the IBM SPSS Statistics version 22. Analysis for age distribution was done by independent sample *t* test. Analysis of sex distribution was done by chi-square test. Variations within a single group for both the outcome parameters were calculated by Wilcoxon signed rank test. ( $P < 0.05$  statistically significant).

**Results:** A total of 30 erosive sites were evaluated in 21 patients over a 4-week duration. The most common site was the buccal mucosa in both groups (23 of 30; 76.67% of total lesions assessed), followed by the tongue (5 of 30; 16.67% of total lesions assessed), the palate (1 of 30; 3.33% of total sites assessed), and the maxillary attached gingiva (1 of 30; 3.33% of total sites assessed). Group 1 (amlexanox) was comprised of 11 subjects, whereas Group 2 (triamcinolone) was comprised of 10 subjects. Pre and posttreatment comparison revealed no statistically significant difference ( $P = 0.756$ ;  $0.512$ , respectively), for the area of the erosion and burning sensation. Intragroup analysis showed that in Groups 1 and 2, there was a statistically significant reduction in the measures posttreatment ( $P < 0.05$ ). **Conclusions:** Amlexanox provides an earlier onset of pain relief in the treatment of EOLP, whereas providing a comparable reduction in the erosive area compared with triamcinolone. Topical amlexanox appears to be as effective as triamcinolone and is a promising alternative in the management of the erosive lichen planus with minimal adverse effects.

**KEYWORDS:** Amlexanox, erosive, erosive oral lichen planus, triamcinolone, visual analog scale

## INTRODUCTION

Lichen planus (LP) is an autoimmune disease known for its chronic nature that affects oral mucosa and cutaneous surfaces of the scalp and

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genitalia. It has been observed that 65% of patients with cutaneous LP will demonstrate concurrent oral lesions.<sup>[1]</sup> The most common type is the reticular variant, which is mostly asymptomatic followed by the erosive type, which is associated with oral discomfort and burning. The erosive variant has the potential for malignant transformation (1%–2% of the cases).<sup>[2–5]</sup>

World Health Organization (WHO) clinical criteria for the diagnosis of oral LP and lichenoid reactions include “Presence of bilateral, more or less symmetrical lesions; Presence of a lace-like network of slightly raised gray-white lines (reticular pattern) Erosive, atrophic, bulbous and plaque-type lesions are only accepted as a subtype in the presence of reticular lesions elsewhere in the oral mucosa; In all other lesions that resemble OLP but do not complete the aforementioned criteria, the term ‘clinically compatible with’ should be used.”<sup>[2]</sup>

Management remains palliative with pain reduction being the primary objective. Triamcinolone, a medium-potency corticosteroid, is one of the first-choice medications and possesses anti-inflammatory, antipruritic, and vasoconstrictive properties. These chronic lesions necessitate its prolonged use, which has been implicated in causing unwanted effects, such as oral candidiasis, xerostomia, burning sensation, and bleeding.

Amlexanox (5%), as an oral mucoadhesive paste has been tested for patients with recurrent aphthous ulceration (RAU)<sup>[6–8]</sup> due to its potent anti-inflammatory properties. It works by inhibiting the formation and release of inflammatory modulators with a membrane-stabilizing effect on cellular structures. Additionally, its use is not associated with any known adverse reactions like topical corticosteroids. Amlexanox works by the mechanism of inhibiting the histamine release, tumor necrosis factor- $\alpha$ , and leukotriene release from the mast cells by increasing intracellular cyclic adenosine monophosphate content and has membrane stabilizing effects.<sup>[9]</sup>

Therefore, this study was conducted to evaluate the effectiveness and safety profile of topical amlexanox for the management of erosive lesions of lichen planus and compare it with triamcinolone acetonide.

## MATERIALS AND METHODS

### STUDY DESIGN

This is a single-center, single-blinded, prospective, observational study with a follow-up period of 1 month at the Department of Oral Medicine & Radiology, Manipal, Karnataka, India, for one and a half years. Institutional Ethics Committee

approved the conduct of this project (IEC 708/2015). Patients with clinical and histopathological features consistent with erosive oral LP (EOLP) were enrolled in the study. They have explained the nature of the study and the need to come for subsequent follow-ups. Signed informed consent was taken from all the study participants.

### STUDY PARTICIPANTS

Each participant was provided with a subject information sheet and the details of the study were explained.

The inclusion criteria of the study subjects were as follows:

- presence of single/multiple erosive lesions of clinically and histologically confirmed EOLP by WHO criteria<sup>[10]</sup>;
- patients aged above 18 years;
- patients with hematological results (complete blood picture) within physiological limits before the commencement of this study; and
- patients who have been prescribed amlexanox/triamcinolone following the histopathological diagnosis of oral LP

The exclusion criteria for this study were as follows:

- subjects with other comorbidities;
- presence of coexisting oral mucosal diseases (lichenoid reactions etc.);
- subjects who had a history of antibiotic therapy and immunomodulators in the past 3 months;
- pregnant and lactating women;
- history of recent usage of steroid-based contraceptives;
- psychological diseases; and
- patients who denied compliance with the therapy offered in this study

### SAMPLE SIZE ESTIMATION

The following formula was used to determine the adequate sample size for the study:

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2}{d^2}$$

where  $n$  is the number of participants,  $\sigma = 1.25$  (standard deviation),  $d = 0.5$  (clinically significant difference);  $Z_{1-\alpha/2} = 1.96$  ( $\alpha = 5\%$  level of significance; probability of type I error);  $Z_{1-\beta} = 0.84$  for 80% power (probability of type II error);  $n = 2 \times (1.96 + 0.84)^2 \times (1.25)^2 \div (0.5)^2 = 60.46$ .

The overall sample size of this study was determined as 60. Thus, 30 study participants were to be included in each group.

#### METHODOLOGY

Subjects with typical clinical lesions of oral LP were enrolled for this study. They have explained the nature of the study and the need to come for subsequent follow-ups. Demographics along with personal and medical history were recorded in a proforma specially designed for this study. The clinical parameters of OLP lesions including the location, extent, size, shape, surface texture, consistency, and tenderness were noted. Pretreatment photographs of these lesions were taken to serve as a baseline reference record.

An incisional biopsy of the lesion was done using a biopsy punch under local anesthesia. The tissue sample was then placed in a calibrated labeled bottle containing 10% formalin and sent for histopathological examination. Patients with a histopathological diagnosis consistent with OLP were recruited into the study.

#### STUDY OUTCOMES

The study outcomes are as follows:

1. The area of the erosive lesion was measured by William's probe or a measuring scale, whichever was feasible/accessible to the lesion. It was the multiple of two greatest dimensions of the lesion.
  - Erosive area size (mm<sup>2</sup>) = maximum diameter (mm) × maximum width (mm); multiple of maximal cross-sectional dimensions).
2. The burning sensation was quantified using a Visual Analog Score (VAS) scale, a 10-cm horizontal line with no markings, each terminal end indicating 0—No pain and 10—Maximum pain. Patients were asked to mark the point, which best represented their intensity of pain or burning sensation. This mark was then quantified by measuring it from 0 and assigning a score.

#### STUDY INTERVENTIONS

To avoid any bias in the treatment strategies, patients were allocated to two groups and the medications of these respective groups were prescribed along with instructions. This method ensured that the principal investigator was blinded, thus making the study single-blinded.

- Group 1 was assigned to the amlexanox group. These patients were prescribed Gel Lexanox in a 5-g tube containing 50mg amlexanox at 5% concentration (Macleods Pharmaceuticals

Limited, Andheri (East), Mumbai, Maharashtra, India).

- Group 2 was assigned to the triamcinolone group. These patients were prescribed Gel Tess in a 5-g tube containing 0.1% w/w triamcinolone (Troikaa Pharmaceuticals Ltd., Ahmedabad, Gujarat, India).

The patients were instructed to apply the medication at the lesion site, thrice daily application (after meals) for 4 weeks. They were advised to swish their oral cavity with distilled water properly and apply these medications for 15 min, during which they were asked to avoid intake of any edible agent that could contaminate the area of application. Upon having any adverse reactions, they were asked to note it down and to report on follow-up visits.

#### FOLLOW-UPS

Each patient was instructed to report for follow-ups at the end of the first week, second week, and posttreatment assessment in the fourth week. Clinical photographs of the erosive lesion were taken at each follow-up visit. Evaluation of treatment outcome was done on the specially designed proforma under two parameters, namely area of the erosive lesion and intensity of pain or burning sensation at each follow-up visit. Other details, such as drug compliance as well as adverse drug reactions, if any, were also noted in this proforma. A per-protocol analysis was employed for the analysis of results.

#### STATISTICAL METHODS

The statistical analyses were performed using the IBM SPSS Statistics version 22 for Windows (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0; IBM Corp., Armonk, NY, USA) Analysis for age distribution was done by independent sample *t* test. Analysis of sex distribution was done by chi-square test. Variations within a single group for both the outcome parameters were calculated by Wilcoxon signed rank test. Variations across the groups were calculated by Mann–Whitney *U* test. A  $P \leq 0.05$  was considered to be statistically significant.

#### RESULTS

A total of 25 subjects (9 males and 16 females) met the eligibility criteria. Three patients declined to participate and 21 subjects were included. They were assigned to amlexanox therapy (Group 1) and triamcinolone therapy (Group 2). Although 12 patients were recruited in Group 1, 1 patient failed to report for follow-up at the end of the second week and was subsequently excluded from the clinical assessment.

Hence, Group 1 (amlexanox) was comprised of 11 subjects, whereas Group 2 (triamcinolone) was comprised of 10 subjects.

**DISTRIBUTION OF PATIENTS ACCORDING TO AGE AND SEX**

Table 1 shows the demographic characteristics of Groups 1 and 2. The age of patients in Group 1 ranged from 23 to 66 years (mean: 48.18 years). The age of patients in Group 2 ranged from 25 to 75 years (mean: 44.10 years). There was no difference in the age distribution between the groups ( $P = 0.545$ ). There was a total of 13 females and 8 males. Group 1 had 11 subjects, of which there were 7 females and 4 males of total subjects. Group 2 had 10 subjects, of which there were 6 females and 4 males. There was no difference in gender distribution among the two groups ( $P = 0.864$ ).

**DISTRIBUTION OF PATIENTS ACCORDING TO SITE**

A total of 30 erosive sites were evaluated in 21 patients over a 4-week duration. Buccal mucosa was the most common site of erosive lesions in both groups (23 of 30; 76.67% of total lesions assessed), followed by the tongue (5 of 30; 16.67% of total lesions assessed), the

palate (1 of 30; 3.33% of total sites assessed), and the maxillary attached gingiva (1 of 30; 3.33% of total sites assessed).

**EVALUATION OF STUDY OUTCOMES**

*Area of the erosive lesion*

Table 2 shows a comparison of the area of the erosive lesion and the intensity of the burning sensation between the two groups. In Group 1, the mean area at the pretreatment (baseline) stage was  $49.91 \pm 79.70 \text{ mm}^2$ . Posttreatment, the mean area was  $11.82 \text{ mm}^2 \pm 20.064$  with an area reduction of  $38.09 \pm 59.642 \text{ mm}^2$  (76.31%). There was a statistically significant difference ( $P = 0.008$ ) noted in the values of the mean area at pretreatment (baseline) and posttreatment. In Group 2 (triamcinolone), the mean area recorded at the pretreatment stage was  $88.50 \text{ mm}^2 \pm 131.758$ . Posttreatment, the mean area was  $21.90 \text{ mm}^2 \pm 44.792$  with an area reduction of  $66.60 \pm 86.966 \text{ mm}^2$  (76.31%). There was a statistically significant difference ( $P = 0.005$ ) in the values of the mean area at pretreatment (baseline) and posttreatment. On comparison between Group 1 and Group 2, the area of the erosive lesion showed no statistically significant difference at baseline and

**Table 1: Demographic characteristics of Groups 1 and 2**

Characteristic:	Group 1 (n = 11)	Group 2 (n = 10)	P value
Mean age in years (range)	48.18 ± 13.69	44.10 ± 17.19	0.545*
Gender			0.864**
Male	4	4	
Female	7	6	

Values are given as mean (SD).

\*Independent t test.

\*\*Chi-square test

**Table 2: Comparison of the area of erosive lesion and Intensity of pain or burning sensation between the two groups**

Stage	Area of erosive lesion (mm <sup>2</sup> ) Mean ± SD					Intensity of pain or burning sensation using VAS score Mean ± SD				
	Group 1 (n = 11)	Difference in %	Group 2 (n = 10)	Difference in %	P value	Group 1 (n = 11)	Difference in %	Group 2 (n = 10)	Difference in %	P value **
Pretreatment (baseline)	49.91 ± 79.706	—	88.50 ± 131.758	—	0.756**	5.55 ± 1.916	—	5.30 ± 2.111	—	0.512**
At first week	41.81 ± 60.909	16.26	75.1 ± 114.725	15.14		4.181 ± 1.778	24.66	4.4 ± 2.170	16.98	
At second week	22 ± 28.224	47.38	35.7 ± 55.948	52.46		3.636 ± 1.689	13.03	3.7 ± 2.54	15.90	
Posttreatment (at fourth week)	11.82 ± 20.064	46.27	21.90 ± 44.792	38.65		3.09 ± 1.514	15.01	2.70 ± 1.947	27.02	
Difference	38.09 ± 59.642	76.31	66.60 ± 86.966	75.25		2.46 ± 0.402	44.32	2.6 ± 0.164	49.05	
P value	0.008*	0.005*		0.003*	0.004*					

\* $p \leq 0.05$  significant compared with other groups (wilcoxon signed rank test)

\*\*Mann Whitney U test

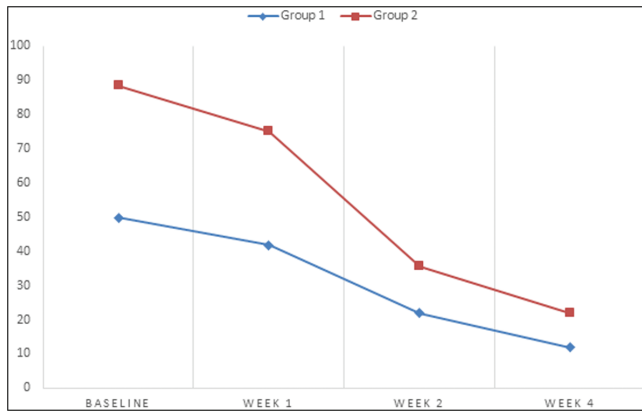


Figure 1: Mean erosive area of Groups 1 and 2

following treatment ( $P = 0.756$ ). Figure 1 depicts the mean erosive area of Group 1 and Group 2.

#### The intensity of pain or burning sensation

In Group 1 (amlexanox), the mean VAS score at the pretreatment (baseline) stage was  $5.55 \pm 1.916$ . Posttreatment, the mean VAS score was  $3.09 \pm 1.514$  with a reduction of  $2.46 \pm 0.402$  (44.32%). On the comparison between the pretreatment (baseline) and posttreatment values of mean VAS scores, there was a statistically significant difference ( $P = 0.003$ ). In Group 2 (triamcinolone), the mean VAS score before treatment (baseline) stage was  $5.30 \pm 2.111$ . After treatment, the mean VAS score was  $2.70 \pm 1.947$  with a score reduction of  $2.6 \pm 0.164$  (49.05%). On the comparison between the pretreatment (baseline) and posttreatment values of the mean VAS score, there was a statistically significant difference ( $P = 0.004$ ). In comparison between Group 1 and Group 2, the intensity of the burning sensation showed no statistically significant difference before and after treatment ( $P = 0.512$ ).

#### Adverse effects of medications among groups

In Group 1, one patient experienced a burning sensation and discontinued the medication, thus reducing the sample size ( $n = 11$ ). All patients in Group 2 tolerated their medications well with no burning sensation or any other adverse effects reported. Interobserver agreement was calculated for 25% of observations in both groups for the area parameter by using Pearson's intraclass correlation coefficient. It revealed a near-perfect agreement ( $\rho = 0.95$ ). In Group 1 (amlexanox), the mean reduction in the area of erosive lesion was  $38.09 \pm 59.642 \text{ mm}^2$ . The maximum reduction was seen between first week and second week (47.38%), whereas the minimum reduction was seen between the pretreatment (baseline) and first week (16.26%). The mean reduction in the intensity

of pain or burning sensation measured using the VAS score was  $2.46 \pm 0.402$ . The maximum reduction was seen in between the second week and fourth week (27.02%), whereas the minimum reduction was seen in between the first week and second week (15.90%). On comparison between before and after treatment values, there was a statistically significant difference in the area of erosive lesion ( $P = 0.008$ ) and intensity of pain or burning sensation ( $P = 0.003$ ).

In Group 2 (triamcinolone), the mean reduction in the area of erosive lesion was  $66.60 \pm 86.966 \text{ mm}^2$ . The maximum reduction was seen in between the first week and second week (52.46%), whereas the minimum reduction was seen in between the pretreatment and first week (15.14%). The mean reduction in intensity of pain or burning sensation measured using the VAS score was  $2.46 \pm 0.402$ . The maximum reduction was seen in between baseline (pretreatment) and first week (24.66%), whereas the minimum reduction was seen in between the first week and second week (13.03%). On comparison between before and after treatment values, there was a statistically significant difference in the area of erosive lesion ( $P = 0.005$ ) and intensity of pain or burning sensation ( $P = 0.004$ ).

The comparison of before and after treatment values between the groups for the area of erosive lesion and burning sensation revealed no statistically significant difference ( $P = 0.756$ ;  $0.512$ , respectively).

## DISCUSSION

Erosive LP is potentially malignant, does not resolve, and requires medical intervention. Patients with EOLP present with pain and burning sensation leading to loss of appetite and deterioration in the quality of life.<sup>[11]</sup> Bandyopadhyay *et al.* reviewed cases of OLP with malignant transformation and observed that 1.4% of the lesions exhibited malignant transformation observed for 3.5 years.<sup>[12]</sup>

Various treatment strategies have been proposed for the management of EOLP with a primary focus on reduction in symptoms of pain or burning sensation; however, no standard modality exists. Several studies have evaluated the efficacy of topical corticosteroids for this condition.<sup>[13]</sup> A recent systematic review showed comparable effects for dexamethasone, amlexanox, thalidomide, and photodynamic therapy for oral LP.<sup>[14]</sup> AlMutairi<sup>[15]</sup> *et al.* recommended the use of 5% amlexanox, 0.1% triamcinolone acetonide, and 0.03% tacrolimus for the management of oral LP. Thongprasom *et al.*<sup>[16]</sup> found increased efficacy of triamcinolone compared to cyclosporine while

Didona *et al.*<sup>[17]</sup> found equal efficacy of both drugs. Siponen *et al.*<sup>[18]</sup> found equal efficacy of triamcinolone compared to tacrolimus. Amlexanox has been widely employed in the treatment of RAU.<sup>[18]</sup> Studies done by Khandwala *et al.*<sup>[19]</sup> Murray *et al.*,<sup>[20]</sup> and Greer *et al.*<sup>[21]</sup> proved the effectiveness of amlexanox for reducing the size of RAU. The study was done by Fu *et al.*<sup>[22]</sup> have compared amlexanox and dexamethasone for the treatment of erosive OLP. Seth *et al.*<sup>[23]</sup> recommended the local application of 5% amlexanox, which was as effective as 0.1% triamcinolone acetonide and 0.03% tacrolimus paste in the treatment of such lesions.

In the present study, 13 subjects were females and eight subjects were males (F:M = 1.62:1). This gender distribution is following other studies.<sup>[10,12,15]</sup> However, the study done by Malhotra *et al.*<sup>[19]</sup> reported a male preponderance. The age of subjects in our study ranged from 23 to 75 years with the mean age being 48.18 years (amlexanox group) and 44.10 years (triamcinolone group). Although OLP is known to occur in any age group, the typical age of presentation is 30–60 years of age.<sup>[19,20]</sup> The age range and mean age in our study were in concurrence with all the previous studies.<sup>[10,12,15,18,22]</sup> OLP has been known to have a bilaterally symmetrical presentation of lesions, which accounts for the increase in lesion sites when compared with the number of subjects.<sup>[2]</sup> This finding was in concurrence with various studies where the number of assessed lesions exceeded the number of subjects.<sup>[6,10,12,15,22]</sup> However, Fu *et al.*<sup>[22]</sup> in their study included patients with a single erosive lesion.

## STUDY OUTCOMES

### Area of the erosive lesion

The reduction in the area of the erosive lesion in both groups posttreatment was statistically significant. It was maximal between the first and the second week for both groups. This implies that the effects of both medications became more pronounced after the first week of application. Overall, Group 1 (amlexanox) showed a reduction in area compared to Group 2 (triamcinolone) post-treatment (76.31% vs. 75.25%). The study done by Fu *et al.*,<sup>[22]</sup> which assessed the efficacy of topical amlexanox in the treatment of EOLP and compared it with dexamethasone over an 1-week duration showed a better area reduction in the dexamethasone group compared to the amlexanox group (77.38% vs. 72.51%), which is not following the present study. In both studies, the inter-group comparison did not show a statistically significant difference.

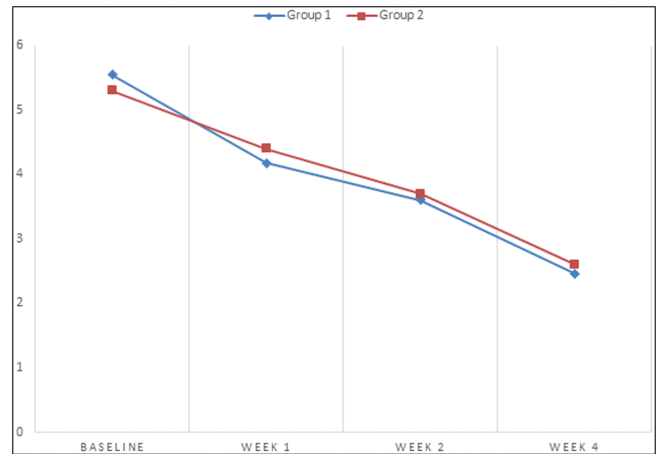


Figure 2: Mean of Visual Analog Scale score of Groups 1 and 2

### Intensity of pain or burning sensation

The analysis of pain or burning sensation using VAS score revealed that both the groups (amlexanox group and triamcinolone group) showed a significant reduction in score over the 1-month follow-up period. In Group 1, the reduction in VAS score was maximum between pretreatment and the first week. In Group 2, the maximum reduction was noted between the second week and posttreatment (fourth week). This implies that the patients in the amlexanox group reported an earlier onset of symptomatic relief. Overall, triamcinolone showed a better overall reduction in VAS score compared to amlexanox post-treatment (49.05% vs. 44.32%). Figure 2 depicts the mean of the VAS score of Group 1 and Group 2. On the contrary, Fu *et al.*<sup>[22]</sup> observed a better reduction in the amlexanox group compared with dexamethasone (77.38% vs. 72.51%) between the pre and posttreatment period. In both studies, the inter-group comparison did not show a statistically significant difference. Therefore, the results of the present study are in concurrence with the study by Fu *et al.*<sup>[22]</sup>

### Safety profile

We also assessed the safety of the medications over one month. A total of 22 subjects were initially recruited. One patient in Group 1 ( $n = 12$ ), developed a burning sensation to amlexanox between the first and second follow-up (first and second week) and discontinued the use of medication. He was excluded from clinical assessment, thus reducing the sample size to 11. All subjects in Group 2 tolerated the medications well, with none reporting burning sensations or any other adverse reaction. Posttreatment period, no adverse events were noted in any subjects. Fu *et al.*<sup>[22]</sup> reported mild adverse effects in the form of a burning sensation, dry mouth, and bleeding to amlexanox.

The shortcomings of this study are the small sample size and long-term evaluation, which is essential for chronic autoimmune conditions, which are characterized by periods of exacerbations and remissions. Owing to the fewer side effects and safety profile of amlexanox, larger clinical trials may offer amlexanox as a potential alternative to conventional steroid therapy.

## CONCLUSIONS

Topical amlexanox can be considered as a potential alternative for erosive LP. It is generally well tolerated; however, sometimes it may be associated with a burning sensation. Amlexanox and triamcinolone are equally effective in the reduction of the area of erosion and burning sensation. However, clinical trials with a larger sample size and long-term evaluation are warranted to establish the efficacy and long-term safe usage of amlexanox.

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## FINANCIAL SUPPORT AND SPONSORSHIP

Nil.

## CONFLICTS OF INTEREST

There are no conflicts of interest.

## AUTHORS CONTRIBUTIONS

SR, YC, and SA designed the study. SR and YC performed data collection and investigation. SR and MS performed the analysis of the samples. SR and YC performed the statistical analysis. SR, YC, and MK wrote and reviewed the manuscript to be published. SR designed the study and performed the data collection, data analysis, and interpretation. YC and MK wrote the manuscript. SR, YC, MK, SA, SC, and MS reviewed the manuscript to be published.

## ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

All procedures have been performed as per the Declaration of Helsinki (revised in 2008). Approval to conduct the study was obtained from the Institutional Ethical Committee (IEC 708/2015) was obtained before the start of the study.

## PATIENT DECLARATION OF CONSENT STATEMENT

All procedures have been performed as per the Declaration of Helsinki (revised in 2008).

## DATA AVAILABILITY STATEMENT

The additional data of this study are available on request from Dr. Yogesh Chhapparwal at [yogesh.chhapparwal@manipal.edu](mailto:yogesh.chhapparwal@manipal.edu).

## List of Abbreviations

LP: Lichen planus  
 OLP: Oral lichen planus  
 EOLP: Erosive oral lichen planus  
 VAS: Visual Analog Scale  
 WHO: World Health Organization  
 RAU: Recurrent aphthous ulceration  
 cAMP: Cyclic adenosine monophosphate  
 TNF- $\alpha$ : Tumour necrosis factor-alpha

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