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Efficacy of Topical Pomegranate Peel Extract on Burning Sensation in Patients with Oral Lichenoid Lesions: A Randomized Controlled Trial

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Abstract

Objectives: Oral lichenoid lesions (OLL) are successfully treated with various treatment modalities, including corticosteroids. Nevertheless, corticosteroids have side effects which could be overcome with the use of natural remedies such as pomegranate (*Punica granatum* L) peel extract without having adverse effects. Thus, the present study aimed to assess the efficiency of topical pomegranate peel extract (TPPE) in treating OLL as compared to a frequently used topical corticosteroid.

Methods: This randomized controlled trial- double blinding study included 50 patients suffering from OLL. They were equally divided into the experimental group (treated with 10% TPPE) and the control group (treated with topical corticosteroids). Two clinical parameters: 1. Sign score for severity and extent of the lesion, and 2. VAS score for burning sensation were assessed after 15 days and 1 month from initial visit.

Results: The significant reduction was observed in VAS score on the 2nd and 3rd Visits as compared to 1st Visit (baseline) in Experimental group patients. However, comparison of mean VAS score among two groups revealed no difference on 2nd and 3rd Visits, depicting non-significant results, suggesting that both drugs are equally effective in reducing the burning of oral mucosa. Regarding the mean sign score of patients in the experimental group, no significant reduction is found on comparison of mean sign score of 2nd and 3rd Visits with the 1st visit results were statistically nonsignificant.

Conclusions: TPPE, a novel intervention, alleviate the symptoms like burning sensation of OLL which is usually the major concern for the patients.

Keywords: burning, corticosteroid, lichenoid lesion, pomegranate, sign score

Introduction

Oral lichenoid lesions (OLL) or reaction represents a group of oral lesions having common clinical and histologic appearance but having different aetiologies that include oral lichen planus, lichenoid drug eruptions, lichenoid contact reactions or lichenoid reactions of graft versus host disease.⁽¹⁾ Immunity plays a role in etiopathogenesis of these conditions. Whether it be drug induced or contact reactions, delayed hypersensitivity may play a vital role which is associated with immunologic response and may result in the formation of white and red lesions in the oral cavity.⁽¹⁾

OLL presents clinically as white keratotic reticular white patches, papules, or plaques due to increase keratinisation of the affected mucosa and in other cases white lesions maybe mixed with erythematous erosive lesion which may cause irritation and burning sensation to the mucosa.⁽²⁾ Burning of oral mucosa that causes oral discomfort, difficulty in eating is a major concern as it affects quality of life of an individual.

A number of therapeutic options such as corticosteroids, immunomodulatory agents, retinoids, UV irradiation, lasers etc are existing, but none are curative.⁽²⁾ Thus, the management is directed at reducing the symptoms, and to provide comfort to the patient. Usually, corticosteroid is considered as first drug of choice. Localized lesions are treated using topical application whereas widespread lesions are managed by intralesional injections or systemic steroids.⁽²⁾ Nonetheless, a number of side effects are known to be associated with the use of corticosteroids.⁽³⁾ Due to possibility of steroids causing adverse effects various plant-based remedies have been researched for the past years where Pomegranate is one such which is of great interest to researchers. Pomegranate (*Punica granatum* L) belongs to family Punicaceae that is identified by its various health benefits such as immunomodulatory activities, antioxidants, anticariogenic, anti-inflammatory and anti-microbial properties.⁽⁴⁾ These properties that pomegranate possessed is believed to be caused by its constituents such as polyphenol which may include ellagic acid, anthocyanins, Gallo tannins and flavonoids constituents.⁽⁵⁾ Pomegranate and its extracts have been proposed to be helpful in the treatment of OLL mainly due to its immunomodulatory effects, but scanty literature is available related to this.⁽⁶⁾ Thus, the present study evaluated the efficiency of topical pomegranate peel

extract (TPPE), a novel intervention in the management of OLL by comparing with one of the commonly used drugs, that is topical corticosteroid.

Materials and Methods

The present randomized controlled trial- double blinding study was carried out after obtaining Institutional Ethical approval (Reference Number- DMIMS (DU)/ IEC/ 2022/ 1160) and Clinical Trial Registration, India (CTRI/2024/10/075071). The study was conducted in accordance with the ethical guidelines of the Declaration of Helsinki (2000). The patients who were ready to participate were included in the study after obtaining their informed written consent. Statistically derived sample size was total 50 patients.⁽¹⁾ The patients were randomly assigned to either the TPPE or corticosteroid group using computer-generated random numbers, with allocation concealed in sealed opaque envelopes. A double-blind design was implemented, where both patients and outcome assessors were unaware of the treatment allocation to minimize bias.

The justification for sample size calculation is as under.⁽¹⁾

The sample size formulae used are as follows:

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

The notation for the formulae is:

n_1 = Sample size of Group 1

β = sample size of Group 2

σ_1 = standard deviation of group 1

σ_2 = standard deviation of group 2

Δ = difference in group means

K = ratio = n_2/n_1 .

$Z_{1-\alpha/2}$ = two- sided Z value (eg. $Z = 1.96$ for 95% confidence interval).

$Z_{1-\beta}$ = power

Mean sign score in group C = 2

Mean sign score in group P = 1.64 σ_1 = SD of sign score in group C = 0.39

σ_2 = SD of sign score in group P = 0.50

For detecting mean difference of 0.36 i.e. $\Delta = 2 - 1.64 = 0.36$

K = 1

$$N = \frac{(0.39 \times 0.39 + 0.50 \times 0.50)(1.96 + 0.84)^2}{0.36 \times 0.36}$$

$$= 24.32 = 25 \text{ patients needed in each group } (25 \times 2 = 50)$$

Power of the Test: 80%

Level of significance: 5% (95% confidence interval)

The patients in the age range of 18-60 years, having clinical presentation of signs and symptoms of OLL were considered for inclusion in the study while the patients who have taken or taking treatment for the lichenoid lesions, patient with associated malignant lesions, the patient with history of pomegranate allergy, the patients suffering from any systemic disorder and taking treatment for the same were excepted.

Regarding the diagnosis of OLL, there is a diagnostic dilemma between oral lichen planus (OLP) and OLL. However, OLL lacks characteristic bilateral presentation.⁽⁷⁻⁹⁾ While OLP lesions commonly present as asymptomatic white striae with a bilateral symmetrical distribution, predominantly on the buccal mucosa. Unilateral presentation of OLP is atypical. It is reported that, clinically and histologically, it is not possible to distinguish between OLP from OLL as they share common clinical and histological features.⁽⁷⁾ Still based on the modified WHO criteria, the unilateral lesions typical of OLP fall under the category of OLL in spite of being histopathologically typical of OLP.⁽⁷⁾ Therefore, the patients with clinical presentation of unilateral, localized keratotic white patch, papules, or plaque with striations or white lesions may be mixed with erythematous erosive lesion with burning sensation in their oral cavity were diagnosed as OLL and irrespective of the cause for the same were recruited for inclusion in the study.⁽⁸⁾

Two clinical parameters were assessed in this study.

1. Sign score: To see the severity and extent of the lesion using criteria given by Thongprasom *et al.*⁽¹⁰⁾ Depending on the clinical presentation and size of the lesion, score varies from 0 to 5.

- 5 = (white striae with an erosive area > 1 cm²)
- 4 = (white striae with an erosive area < 1 cm²)
- 3 = (white striae with an atrophic area > 1 cm²)
- 2 = (white striae with an atrophic area < 1 cm²)
- 1 = (mild white striae only)
- 0 = (no lesions, normal mucosa).

2. Intensity of burning sensation by Visual Analogue Score (VAS). The assessment of these parameters was performed by a single researcher who was blinded to the type of treatment of the particular patient.

Initially the detailed patient history and detailed clinical examination findings were recorded. Then the patients were explained about the use of the particular drug. Experimental group received 10% TPPE gel and Control group have to use 0.1% Triamcinolone acetonide gel in orabase. Patients were told to apply the gel on the lesion 3 times a day and should not eat, drink or rinse for next 15 minutes. The readings of the first visit were recorded as baseline. Recall visits were done after 14 days and 1 month from the first visit (1st Visit being baseline). Improvement in severity, extent of the lesion and burning sensation was assessed in each patient during every visit. All data were tabulated in excel sheet and subjected for statistical evaluation.

Method of preparation of TPPE

Following the standard protocol the gel was prepared under all aseptic conditions by using an extract of Pomegranate peel. Pomegranate peel is finely minced in a blender. It is then placed in an extractor where alcohol is added and heated to 70 degrees for 1 hour. After 1 hour of heating, alcohol is allowed to evaporate and the residue becomes Pomegranate peel extract. Then 1.8-gram quantity of Carbopol 940 (Lubrizol company, analytical grade) at a concentration of 0.8% is poured in 200 mL distilled water which was used as gel base. One gram of already prepared TPPE was added to Carbopol gel base along with 100 mL glycerin for humectant property and mixed with continuous stirring for 30 min. Triethanolamide is also added to it dropwise which is a thickening agent and having preservative property. The final TPPE gel was dispensed in 10 mL dropper bottles on which the manufacturing and expiry dates of the gel were mentioned. Triamcinolone was used as a commercial preparation, triamcinolone acetonide 0.1%, (marketed by Troikaa Pharmaceuticals Ltd.)

Observations and result

The study patients were 50 in number divided in two equal groups. They were in 18 to 42 years age range. The most of the patients (32 out of 50) were in the third decade. The mean age of patients in Experimental group

was 22.12 ± 8.95 and in Control was 26.08 ± 6.65 . Amongst all patients, 22 (44%) were male, 28 (56%) were female. With reference to oral region, the buccal mucosa was the most common site, while the buccal vestibule, lingual mucosa, retromolar region and labial mucosa were also affected by lichenoid lesion in this study. The parameters recorded on 1st visit (baseline), 2nd visit and 3rd visit were as follows:

The mean VAS score of patients in Experimental group on 1st visit was 2.64 ± 1.33 , 1.28 ± 0.99 on 2nd Visit and 0.14 ± 0.36 on 3rd visit where improvement was observed on the 2nd and 3rd visit) with reduction in VAS score with statistically significant value of 0.001 (Table 1). However, comparison of mean VAS score among two groups revealed no much difference between the two groups with *p* value being 0.15, 0.30 and 0.54 for 1st, 2nd and 3rd visits respectively which is non-significant (Table 2 & Graph 1). This observation shows that both

the drugs are equally effective in reducing the burning of oral mucosa.

The mean sign score of patients in Experimental group was 2.57 ± 0.85 , 2.50 ± 0.75 and 2.42 ± 0.75 in 1st, 2nd and 3rd visit respectively (Table 3). Decrease of the extent of the lesion was not very much evident in 2nd or 3rd visit with *p* value of 0.33 and 0.16 respectively which is non-significant. Similarly, the non-significant results were observed in mean Sign Score on comparison between two groups at 1st, 2nd and 3rd visits, the *p* values being 0.13, 0.08 and 0.09 in 1st, 2nd and 3rd visits respectively. (Table 4 and Graph 2)

Nevertheless, Figures 1 and 2 showing satisfactory response to TPPE in one of the OLL patients. Figure 1 showing OLL with sign score 5 and Figure 2 showing reduction to sign score 1 on 3rd visit treated with TPPE.

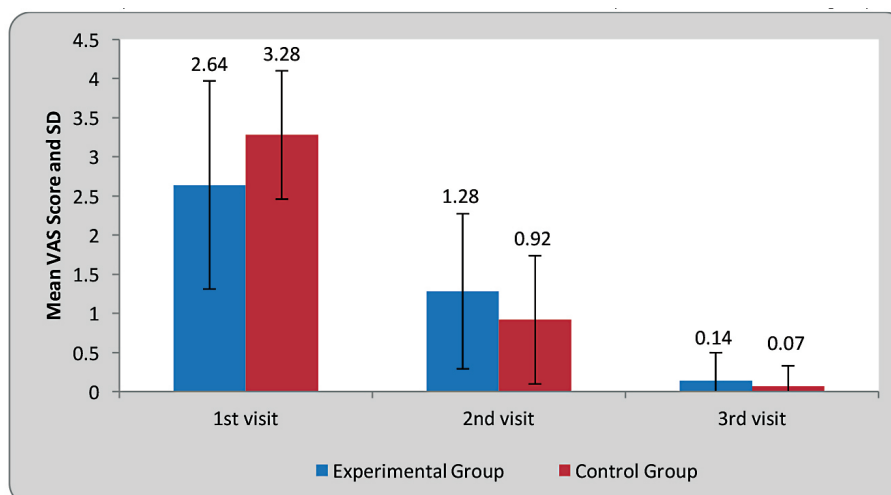
None of the patients reported with the side effect of the drugs Irrespective of the medication used for treating

Table 1: Comparison of mean VAS score at 2nd and 3rd visit compared with 1st visit in experimental group (Wilcoxon Signed Rank Test).

Visit	Mean $\pm$ SD	Mean Difference	z-value	p-value
1 st (Baseline)	2.64 ± 1.33	-	-	-
2 nd	1.28 ± 0.99	1.35 ± 0.92	3.30	0.001, S
3 rd	0.14 ± 0.36	2.50 ± 1.22	3.32	0.001, S

Table 2: Comparison of mean VAS score at 1st, 2nd and 3rd visit in experimental & control Groups (Mann Whitney U Test).

Visit	Visit	Experimental Group	Control Group	z-value	p-value
1 st (Baseline)	1 st visit	2.64 ± 1.33	3.28 ± 0.82	1.42	0.15, NS
2 nd	2 nd visit	1.28 ± 0.99	0.92 ± 0.82	1.01	0.30, NS
3 rd	3 rd visit	0.14 ± 0.36	0.07 ± 0.26	0.60	0.54, NS



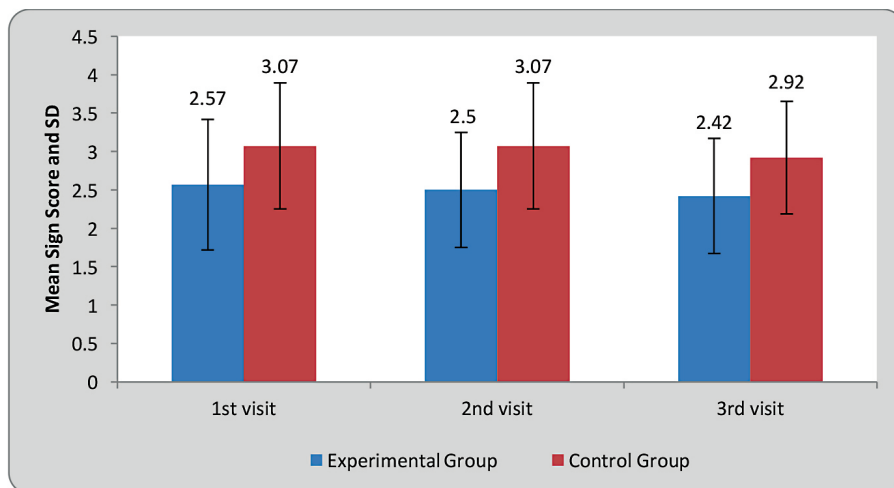
Graph 1: Comparison of mean VAS Score at 1st, 2nd and 3rd visit in experimental and control groups.

Table 3: Comparison of mean sign score at 2nd and 3rd visit with 1st visit in experimental group (Wilcoxon Signed Rank Test).

Visit	Mean±SD	Mean Difference	z-value	p-value
1 st visit	2.57±0.85	-	-	-
2 nd visit	2.50±0.75	0.07±0.26	1.00	0.33, NS
3 rd visit	2.42±0.75	0.14±0.36	1.47	0.16, NS

Table 4: Comparison of mean sign score at 1st, 2nd and 3rd visit in experimental group and control groups (Mann Whitney U Test).

Visit	Experimental Group	Control Group	z-value	p-value
1 st visit	2.57±0.85	3.07±0.82	1.48	0.13, NS
2 nd visit	2.50±0.75	3.07±0.82	1.73	0.08, NS
3 rd visit	2.42±0.75	2.92±0.73	1.68	0.09, NS

**Graph 2:** Comparison of mean sign score at 1st, 2nd and 3rd visit in experimental and control groups.**Figure 1:** OLL presenting as greyish white patch greater than 1 cm² in size with reticular striations and mild erythema (Sign Score 5).**Figure 2:** Mild white striae with marked reduction in sign score of OLL on 3rd visit treated with TPPE (Sign score 1).

the condition, either allopathic or herbal.

Discussion

OLL is an umbrella term which include multiple immune system related disorders.^(9,11) Amongst the therapeutic options, corticosteroid is a drug of choice and depending on the severity of the condition these are used either in topical or systemic forms. However, use of corticosteroid may be associated with side effects. Thus, choosing a treatment with minimal or no side effects is desirable. Natural substitutes in the form of plants constitute many medicinal properties and are side effect free too. In this regard, the utility of TPPE in the management of OLL offers a natural alternative for treatment.

Pomegranate is a commonly consumed fruit which is easily accessible for most families in the country. It plays a vital role in preventing certain diseases like hypertension, hypercholesterolemia, oxidative stress, and inflammatory activities which is mainly due to its components that control the risk factors associated with these diseases.⁽¹²⁾ Pomegranate also possess anticancer effect.⁽¹³⁾

The findings of this study revealed the efficiency of TPPE in treating OLL especially in reducing the burning sensation as significant reduction is found in VAS score in 2nd and 3rd visits as compared to 1st visit. Our findings are matchable with the study by Zakaria *et al.*,⁽¹⁾ as they reported improvement in burning of oral mucosa with the use of topical pomegranate extracts. They have used pomegranate in two forms, seed extracts and peel extracts. Both the preparations they reported to be effective in managing oral lichen planus.⁽¹⁾ Regarding pain reduction, Ghalayani *et al.*,⁽¹⁴⁾ also noticed comparable results in patients with recurrent aphthous stomatitis with the use of 10% pomegranate gel.

The explanation for reduction in burning sensation with the use of TPPE is the role of the key component punicalic acid, which is an efficient anti-inflammatory agent. It reduces pain due to its ability to inhibit secretion of prostaglandin. Pomegranate limits formation of numerous inflammatory mediators and thus control tissue damage. It controls production of interleukin-8 as well as nitric oxide. Moreover, pomegranate plays immunoregulatory role. It can reduce oxidative stress by scavenging free radicals.⁽¹⁵⁾

Similarly, there is strong evidence that PPE is abundant in polyphenols, including punicalagin that has pow-

erful anti-inflammatory activities. It reduces proinflammatory cytokines, modify MAPK signaling, and inhibit COX-2 and iNOS production, all of which provide evidence for their potential as potent anti-inflammatory compounds.⁽¹⁶⁾

With reference to sign score the present study revealed contradictory findings on comparison with previous study as the present study observed no significant difference in sign score on comparison between 2nd and 3rd visit with 1st visit in Experimental Group.⁽¹⁾ Similarly, non-significant observations are noted between present study and the previous study on comparison of Sign Score at 1st, 2nd and 3rd visits in Experimental and Control Groups.⁽¹⁾ The reason for this could be the difference in the doses. In this study, the topical application of the drugs was advised three times per day while in a study by Zakaria *et al.*,⁽¹⁾ it was four times a day. Second possible reason could be weekly recall visits in their study that could assist in improving the patient's compliance.

The presence of significant levels of polyphenols and flavonoids in PPE is responsible for wound healing. Also it is stated that using pomegranate peel strengthens granulation tissues, which aids in wound healing. Therefore, bioactive compounds from pomegranate peel show potential for wound healing by promoting wound contraction, collagen production, and expression of growth factors.^(16,17)

Pomegranate also has the capacity to reduce pathogenic bacteria in oral cavity and also enhance healing of wound by accelerating collagen formation, contraction of wound and tensile strength.⁽¹⁸⁾ A recent study by Potra Cicalău *et al.*,⁽¹⁹⁾ reported useful role of pomegranate in management of gingivitis and periodontitis. Rajan *et al.*,⁽²⁰⁾ mentioned the effectiveness of TPPE for its anti-fungal action. Likewise, the utility of TPPE is reported in candidiasis associated denture stomatitis, gingivitis, periodontitis, caries prevention, plaque control etc.^(14,21-23) Pomegranate have extensive benefits in the management of pre-malignant lesions due to its capability of effecting various signalling pathways which may include inflammation, hyperproliferation, cellular alteration, commencement of tumour formation, formation of new blood vessels and thus suppressing tumor formation and its metastasis.⁽²⁴⁾ They can also be potentially used as an adjuvant in the treatment of oral malignancy due to its anti-angiogenic, anti-proliferative and apoptotic property.⁽²⁴⁾

The observations of the study revealed efficacy of TPPE in relieving the oral burning that reduces oral discomfort. This finding suggests its use on regular basis for improving the symptoms of OLL. Furthermore, PPE is a natural remedy, economical, having negligible adverse effects.

Last but not the least, irrespective of the medication used for treating the condition, might be allopathic or ayurvedic, professional monitoring is required for OLL considering their malignant potential.⁽²⁵⁾ Vital point is deviation from the classic presentation of OLL should be alarmed for thought of biopsy to evaluate for presence of dysplasia or malignancy.

Limitations of the study

The limitations of the study are small sample size, minimal recall visits, follow up for short duration. However, there is a scope to conduct a similar study with larger sample size and the duration would be at least 3 months. Also there is scope to have more valid information about efficacy of the drugs by investigating inflammatory cytokines in saliva

Conclusions

The present study demonstrated that a novel intervention TPPE alone is effective enough to reduce the burning sensation of OLL which is usually the major concern of the patients.

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Conflict of Interest

The authors declare no conflict of interest.

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