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Clinical Evaluation of Topical Applications of Clotrimazole & Punica Granatum Peel Extract in Management of Type I & Type II Denture Stomatitis

By Shreya Dange

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Material & Method: Total of 30 patients suffering from denture stomatitis type I and type II were selected in the study. They were divided randomly into in two groups of 15 each.

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Group B - Patients treated with topical Punica granatum peel extract.

All patients were treated for 7 days. All patients were evaluated for the lesion size of denture stomatitis on 1st, 7th, 15th & 30th day.

Statistical Analysis: Statistical analysis was done using SPSS Software Version 13.

Results: The mean reduction in lesion size of denture stomatitis on 30th day in-group A & group B were 32.71mm² & 31.69 mm² respectively.

Conclusion: Topical application of clotrimazole & Punica granatum peel extract both were found to be equally effective in reducing the lesion size of denture stomatitis type I and type II.

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I. INTRODUCTION

Denture stomatitis indicates an inflammatory process of the mucosa especially the denture bearing area, which affect both maxillary and mandibular arches, which bear a complete or partial removal denture. Denture stomatitis is frequently asymptomatic. Some patients may complain of halitosis, slight bleeding, swelling in the involved area, burning sensation, or taste alterations. Clinically the lesions of denture stomatitis range from subtle erythematous macule to severe form of papillary projection^[1]. Candida-associated denture stomatitis is a very common inflammatory process affecting about 35-50%

of persons who wear complete dentures. The prevalence of denture stomatitis is less in partial dentures wearer as compared to complete denture wearers. No racial or sex predilection exists, although some authors have described a higher prevalence among women^[2]

The etiology is multifactorial, but prolonged denture wearing, especially when worn during the night. *Candida albicans* seems to be the major pathogen involved in the oral candidiasis.^[3,4] Patients with denture stomatitis show higher intraoral concentrations of fungi than individuals without this disorder and the lesions objectively improve after antifungal drug administration^[5]. However, the role of this organism as the sole etiologic factor remains ambiguous^[6,7].

Punica granatum is one of the phytoplant with considerable medicinal value. It's therapeutic properties such as antifungal and antibacterial are often used as a remedy in folk medicine for curing several diseases such as cardiovascular diseases, cancer, diabetes, gastritis, ulcers^[8-12]. Different parts of this plant have numerous phytochemical compounds (flavonoids, polyphenols, tannins, organic acids) amid of which peel has surpassing phytochemical compounds. Several in vitro studies and in vivo experiments have demonstrated the potential health benefits of pomegranate polyphenols. Polyphenols such as condensed tannins, anthocyanins, and minor flavonoids are also present in pomegranates. Particularly, the intake of polyphenols has been shown to be associated with an increased antioxidant potential in plasma and vascular protection^[13-18].

Punica granatum has proved its antifungal efficacy against the *Candida* species. A two-week study by Vasconcelos LC et al demonstrated improvement in symptoms & total recovery of denture stomatitis with 1.25% gel of *Punica granatum* fruit extract. Moreover, authors suggested that this extract gel could be used as topical antifungal agent. The tannins and polyphenols present in the fruit extract are considered to have antifungal property. Tannins affect the cell membranes of yeast due to the precipitation of protein, but the exact effect on *C. albicans* is currently not known^[19,20].

Author: e-mail: shreyadange05@gmail.com

According to Newton (1962), the classification of Candida-associated denture stomatitis [2]

- Type I: Localized simple inflammation or pin-point hyperemia
- Type II: Diffused erythema and edema of the palatal mucosa covered by the dentures
- Type III: Granular surface or inflammatory papillary hyperplasia of the central palate.

The treatment objectives for denture stomatitis are removing the etiologic agent, which is the candidal overgrowth, eliminating erythematous patch, and burning sensation on denture bearing edentulous ridges. Predisposing factors and underlying disease should also be corrected. Treatment should begin locally, maintaining oral hygiene, dealing with the defects in the denture such as irregular surfaces, ill-fitting dentures and broken dentures contribute to the candida like growth [21, 22]

A number of synthetic substances including antifungal drugs have been used in the management of denture stomatitis with varying degree of success. However, the success achieved with these antifungal drugs is not flawless. Recolonization of the oral mucosa by the fungi after completion of therapy & an array of side effects (comparatively more with systemic therapy) are the two major concerns with antifungal drugs. [23-28]

Hence, this comparative study was undertaken with the aim of determining the effects of Punica granatum peel extract on the size of lesion of denture stomatitis. Since clotrimazole is one of the commonly used antifungal agents, it was decided to compare the effects of Punica granatum peel extract with that of clotrimazole.

II. AIM

To compare the efficacy of topical Clotrimazole with topical Punica granatum peel extract in reducing the lesion size of type I & type II denture stomatitis.

III. OBJECTIVES

- To measure the Pre-treatment & post treatment lesion size of denture stomatitis treated with commercially available topical clotrimazole.
- To measure the Pre-treatment & post treatment lesion size of denture stomatitis treated with topical application of punica granatum peel extract.
- To compare the reduction in size of lesion in both treatment groups.

IV. MATERIALS AND METHODS

This study was conducted in the Oral Medicine & Radiology department of a dental institute in the city of north Maharashtra, India. Thirty patients suffering from denture stomatitis with clinical signs [type I & type II] were selected for the study. Study was conducted

abiding by all human ethical principles as per the WMA (world medical association) - Declaration of Helsinki and the Guidelines of Good Clinical Practice (ICMR- Indian council of medical research) was followed. Ethical clearance was obtained (MGV/KBH/DC/1082/2019-20) from the institutional ethical committee. Patients were divided by simple random sampling into in two treatment groups. Patients were informed prior regarding the study. A Signed informed consent was obtained from all participants. Detailed case history was taken with information regarding the use, duration, frequency and hygiene of denture.

Inclusion Criteria:

- Clinically diagnosed cases of denture stomatitis type I and type II.
- Patients willing to participate and cooperate for the study.
- Patients who have not received any treatment for denture stomatitis in last 3 months.

Exclusion Criteria:

- Patients with systemic disease, like diabetes, HIV, immunosuppression etc.
- Patients allergic to any content of punica granatum and/or clotrimazole.
- Patients currently receiving any other treatment for denture stomatitis.

Patient Withdrawal Criteria:

- Patients not following the study protocol.
- Patients willing to receive treatment at other hospitals/ clinics.

Group A (n=15)- Patients treated with commercially available clotrimazole

Candid mouth paint (clotrimazole- 1%w/v to be applied 3 times a day for 7 days over the lesion with sterile cotton tip after meals.

Group B (n=15)- Patients treated with punica granatum peel extract.

A solution containing 100 µl/ml concentration of punica granatum peel extract (prepared by the local pharmacy laboratory) to be applied 3 times a day for 7 days over the lesion with sterile cotton tip after meals.

Both group patients were instructed not to eat/drink anything for 30 minutes after application.

All the patients in both the treatment groups were evaluated for the size of lesion on day 1(pre-treatment) & thereafter on 7th, 15th & 30th day. The lesion size was measured with geometric divider & scale.

V. PREPARATION OF EXTRACT [8, 27]

The Punica granatum (pomegranate) fruits for the study were obtained from the local market. The fruits were washed & cleaned thoroughly. The pericarp of punica granatum was removed carefully, dried for 2

days, and then it was powdered using a grinder. About 100 grams of powdered peel sample was soaked in 99.9% ethyl alcohol for four days and filtered by using Whitman filter paper. The obtained filtrate was subjected to rotary evaporator at a temperature of 70°C and 120 rpm and crude extract was obtained. The crude extract of 10 gm was dissolved in 20 ml of distil water and was distributed in 20 ml bottle each.

VI. STATISTICAL ANALYSIS

Data were entered into the computer and frequency tables were generated using SPSS Software Version 13. To evaluate if there is any significant reduction in the mean size of lesion in the single treatment group, statistical analysis was done using paired 't' test. To evaluate if there is any significant difference between the mean reduced size of lesions treated with 2 different medicine, unpaired 't' test was applied at 95% confidence of level and 4 degree of freedom. P value less than 0.005 was considered as statistical significant.

VII. RESULT

The demographic distribution shows more numbers of males were affected as compared to females by denture stomatitis (Table 1). Patient's age ranges from 61-70 years were comparatively more affected (shows in Table 2). Most common affected site was the maxillary arch as compared to mandibular arch (Table 3). There is no significant difference in mean pretreatment lesion size in both the groups (Table 4). Although the progressive reduction in lesion size in both the treatment groups from day 1 to day 30 is observed (Table 5).

Pre-treatment (Day1) & Post-treatment (Day30) shows the lesion size in Group A. The difference in Pre-treatment & Post-treatment lesion size is significant (Table 6). Similarly, Pretreatment (Day1) & Post-treatment (Day30) shows the lesion size in Group B. The difference in Pre-treatment & Post-treatment lesion size is significant (Table 7). Although the mean reduction in size of lesion appears more for group A as compared to group B, the difference is statistically insignificant (Table 8).

It can be concluded that there is no significant difference between the average reduction in the lesion size for both the groups treated with commercially available Clotrimazole and Punica granatum peel extract. Thus, both medicines Punica granatum peel extract and commercially available Clotrimazole are equally effective in reducing lesion size.

VIII. DISCUSSION

Various animal trials & in-vitro studies showed antifungal activity of Punica granatum. Certain studies even claimed that the antifungal activity of Punica

granatum extract is equivalent to antifungal drugs.^[8, 17, 19, 20, 22- 26, 30,31] The success of antifungal drugs is not however irrefutable. Re-colonization of the oral mucosa by the fungi after completion of therapy & certain mild to severe side effects (comparatively more with systemic therapy) are the two major concerns with antifungal drugs.^[21]

In this present study, it has been observed that the maxillary arch is more frequently involved than mandibular arch. This finding is in accordance with previous literature.^[1, 2]

This study denotes that after starting the therapy, there is gradual decrease in lesion size in both the groups. This result is analogous to an animal trial where *C. albicans* infected Immuno-suppressed wistar rats showed a gradual cure in 5, 10 & 15 days after treatment with pomegranate peel extract & nystatin.^[24]

We found significant improvement (i.e. reduction in lesion size) with clotrimazole group. This finding is similar to the findings of Madugula P et al.^[8] A similar result was also observed in another study carried out with miconazole.^[19] However, there is one study showing a little different finding. A study done by Sholapurkar A. et al showed 78.57 per cent clinical resolution rates with clotrimazole mouth paint. The reason for these differences may be attributed to different compositions of study samples. In their study, Sholapurkar A. et al included extensive fungal lesions & even incorporated immune-compromised patients.^[26]

In this study, even the Punica granatum group showed significant improvement (i.e. reduction in lesion size). This finding is in line with an animal trial,^[24] an in-vitro study^[8, 32, 33] and with a randomized clinical trial.^[18] The present study denotes that there is no significant difference in efficacy of Clotrimazole and Punica granatum peel extract in the management of denture stomatitis. This finding is analogous to previous in vitro study by Madugula P et al.^[8]

The previous studies & the results of present current clinical trial signify that Punica granatum peel extract is decidedly effective in management of candidal infections.^[34-37] However, A Systematic Review by Gabriela Lacet et al. demands more scientific evidences and precisely designed clinical trials affirming the existence of scientific evidence for the use of natural products in the treatment of oral candidiasis.^[22]

There were certain limitations in this study. It was not double-blinded which could have led to some bias. Secondly, along with clinical evaluation Pre and post mycological response should also have been calculated. Thirdly, Patients were not followed-up after 30 days for any possibility of recurrence & fourthly, sample size was small, further studies should be conducted with large sample size.

IX. CONCLUSION

Within the scope of our study, we conclude that Punica granatum peel extract has antifungal, anticariogenic, antioxidant properties responsible of healing effect of fungal infection. Topical application of clotrimazole & Punica granatum peel extract both were found beneficial. Topical application of clotrimazole & Punica granatum peel extract were equally effective in reducing the lesion size of denture stomatitis type I and type II.

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Demographic Data

Table 1: Gender Distribution

Denture Stomatitis	Male	Female
Type I	10	8
Type II	6	6
Total	16	14

Table 2: Age-wise Distribution

Age	50-60 yrs.	61-70 yrs.	71-80 above yrs.
Number	09	12	09

Table 3: Involvement of Arch

Denture Stomatitis	Maxilla	Mandible
Type I	16	07
Type II	07	0
Total	23	07

Table 4: Mean Pre-treatment Lesion Size in Both Groups (Unpaired t test)

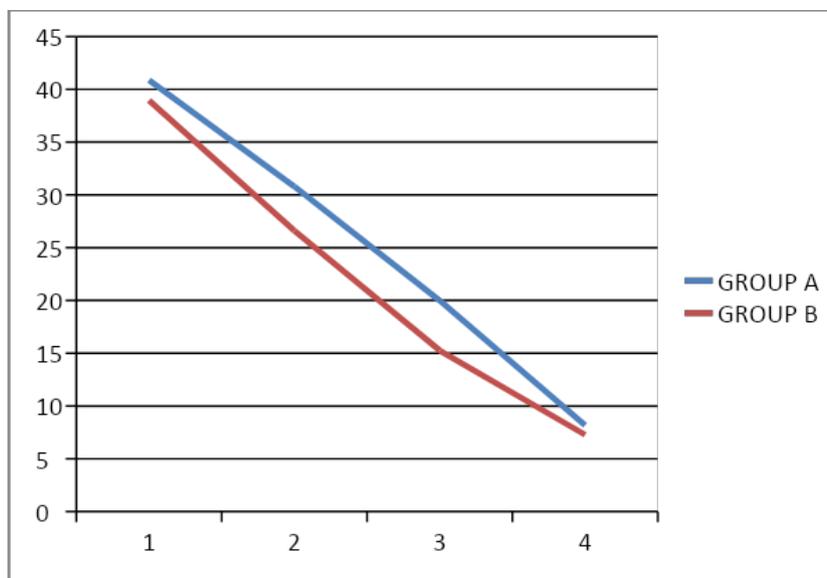
Group	Mean Pre-treatment Lesion Size (sq.mm.) (Day 1)	S.D	P value	Significance
A	40.87	4.0037	0.27402	Not Significant
B	38.96	5.2870		

Table 5: Shows mean lesion size (sq.mm.) in both groups on day 1, 7, 15, & 30

Group	Day 1	Day 7	Day 15	Day 30
A	40.87333	30.79333	19.98	8.16
B	38.96	26.6	15.26	7.273333

Table 6: Mean Reduction in Size of Lesion in Group A (paired t test)

Day	Size of Lesion	S.D	Mean Difference	P Value	Significance
Pre-treatment (Day1)	40.873	4.0037	32.72	<0.005	Significant
Post-treatment (Day30)	8.16	2.6365			



Graph no.1: Graphic representation of mean lesion size (sq.mm.) in both groups on day 1, 7, 15 & 30. Graph illustrates gradual reduction in the lesion size in both the treatment groups from day 1 to day 30. Here group A: represent patients treated with clotrimazole and group B: represent patients treated with punica granatum peel extract.

Table 7: Mean Reduction in Size of Lesion in Group B (paired t test)

Day	Size of Lesion	S.D	Mean Difference	P Value	Significance
Pre-treatment (Day1)	38.96	5.2870	31.69	<0.005	Significant
Post-treatment (Day30)	7.273	3.570			

Table 8: Mean Reduction in the Lesion Size for Group A & B (unpaired t test)

Group	Mean reduction in size of lesion	S.D	P value	Significance
A	32.72	3.30	0.3885	Not Significant
B	31.69	3.12		