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Comparison of anti-candidal efficacy of *green tea*, *triphala* and *nystatin* in the treatment of denture stomatitis: a randomised control trial

Dental Science

KEYWORDS: Denture Stomatitis, Oral Candidiasis, Green Tea Extract, Triphala, Medical Plants.

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ABSTRACT

Context: The last few decades have witnessed an upsurge in the geriatric population and consequent upward shift in prevalence of age related changes in the oral cavity. Edentulous state followed by denture usage remains the most prevalent condition seen in aged patients. Denture stomatitis associated with fungal infection is one prime area of concern among these patients. With an idea to introduce natural, readily available and economical treatment for denture stomatitis which might be helpful for financially dependent elderly patients, the following study was planned. **Aim:** to evaluate the efficacy of green tea extract, triphala extract compared with nystatin in the treatment of denture stomatitis. **Methodology:** This concurrent parallel study included 120 patients in three groups; 40 patients received triphala mouthwash, 40 patients received green tea mouthwash and the remaining ones received nystatin drop. All the patients were instructed to use mouthwash 4times in a day and refrain from eating or drinking for next 30 minutes. The baseline values of amount of palatal inflammation and mycological samples were recorded and assessed at day 7th and 14th. Data collected was statistically analysed using version 16.0 of SPSS software. **Results:** The amount of palatal inflammation and candida colony count as compared with baselines was significantly reduced in all the groups. ($p<0.05$)However, no statistically significant difference was seen between the groups at the same visits. ($p>0.05$) **Conclusion:** Green tea mouthwash or triphala mouthwash can serve as efficacious and economical substitute in the management of denture stomatitis associated with candidiasis.

BACKGROUND

Throughout the globe, a demographic revolution in proportion of the geriatric population is underway. The count of people with advanced age is growing faster than ever. The result of current surveys depict that approximately 600 million people are aged more than 60 years and this number is expected to double in next ten years.[1] Concurrently the prevalence of age related dental problems liketooth loss, dental caries, periodontal disease and xerostomia are also experiencing an upward shift. In India, 19% of population aged between 65-74years is edentulous.[2]Petersen PE etal and Randolph WM et al conducted multicentre surveys and reported that one-third to half of the older people wear full dentures while up to three-quarters wear removable full and/or partial dentures.[3,4]. In a clinical study of 463 randomly selected geriatric denture wearers, denture stomatitis was found in 6.5%. [5] The prevalence rate of stomatitis is reported within the range of 11–67% in complete denture wearers. [6] Mubarak S etal reported that 16.3% cases of denture stomatitis were associated with chronic atrophic candidiasis.[7]High prevalence rates of disease among economically dependent elderly population provides a scope for research to explore natural and easily available remedies. Hence the aim of this study was to compare the anticandidal efficacy of green tea extract, triphala with nystatin oral drop in the treatment of denture stomatitis.

Materials and methods

Study design

This double blind randomised control trial included patients who were referred to the department of oral medicine in Daswani dental college and research centre, Kota for evaluation of denture induced lesions. All these patients were examined and cross checked for the presence of denture stomatitis by a dental surgeon specialised in oral medicine (JA). One hundred forty two patients were eligible to be included in this study. Based on pilot study results and using the following formula, 120 subjects were divided randomly into three parallel groups; keeping power of study at 80% and 5% level of significance.

$$N=\frac{(Z\alpha+Z\beta)\,\hat{}\,2\,(S)\,\hat{}\,2}{2(d)\,\hat{}\,2}$$

(Where N= sample size; Zα= value for α error; Zβ= value for β error;S: Standard deviation; d= difference from mean value to be detected.)

Inclusion criteria: Participants whohad a complete acrylic maxillary denture and were willing to participate in the study

Exclusion criteria: Participants with partial maxillary dentures or mandibular dentures; those who were using or who had used a denture cleanser within the previous 2 weeks; participants taking antifungal agents or antiseptic mouthwashes; those with systemic diseases or conditions making them prone to Candida infections.

Prior to start of the study, an ethical clearance was taken from the institutional ethical committee. All patients gave an informed written consent to participate in the study. At the first visit, a thorough case history was recorded in customised Performa and the palatal mucosa was examined for presence of inflammation and graded (Table1).

Table 1: Grading on the basis of palatal inflammation and count of candida colonies

Grade	Amount of palatal inflammation	Number of candida colonies
1	0-4cm^2	0
2	5-9cm^2	0-9
3	10-14cm^2	10- 49
4	15-19cm^2	50-100
5	20-24cm^2	100-1000
6	≥25cm^2	≥1000

Samples were collected by running a swab over palatal mucosa which were then cultured and examined histologically for candidiasis.

Drug: In this study, Nystatin, green tea extract and triphala extract was used as mouthwash. Nystatin was purchased as Mystation OS from Savorite pharmaceuticals (Vadodara, India). Unflavoured and fresh (date of packaging<1 month) Green tea was purchased from La Plant Pure Green tea.2% green tea was prepared with 2grams of

green tea bag dipped in 100ml water for five minutes. For the preparation of triphala mouthwash, 10 gm of commercially available triphala powder (Organic triphala from Nirogam) containing equal quantities of T. bellirica, T.chebula and E.officinalis was added to 10 ml of boiled distilled water.

The drugs were poured in identical bottles of 10 ml each and labelled as A, B and C. Neither the examiner, nor the patient knew about the content of the bottle.

Sampling and implementation

This was a randomized, controlled, experimental double blind concurrent parallel study with 40 patients in three groups. Using random allocation rule, patients were divided into Group A, B and C. Cards with group names were kept folded and all patients were asked to pick up one card. These cards were opened by the investigator once the name of the participant had been written over it.The patients were instructed to use mouthwash 4 times a day using 15 - 20 drops 5 minutes and refrain from eating/drinking for 30 minutes. Patients were evaluated on day 0, 7 and 14.Amount of palatal inflammation was measured using divider and ruler and graded before and after the treatment in each session. Mycological samples were taken from the palatal mucosa and cultured on YGC medium (yeast extract glucose chloramphenicol agar), then incubated at 37°C. After 2 days, colonies were counted and expressed in terms of densities.

Statistical Analysis

Statistics Analysis of data was done using Version 16.0 SPSS software considering = 0.05 and = 0.2. Chi-square test was used to check the randomness of data.Intragroup comparison was done using pairedt test. Turkey'spost hoc test was used for intergroup comparison. P value of less than or equals to 0.05 was statistically significant. Cohen's Kappa statistics was applied to standardise the inter/intra-examiner error variability.

RESULTS

One hundred twenty patients (77 males and 43 females; Male: Female ratio is 1.79:1)with denture stomatitis referred to the Department of Oral Medicine, Daswani Dental College and Research Centre, Kota were included in this study.No statistically significant difference was seen in age or gender of subjects in each group. The mean age of patients was 67.97 years with standard deviation of 6.65 years. Table 2 shows the demographic profile of the patients.

Table 2: Demographic profile of the patients

AGE (in years)	GROUP A		GROUP B		GROUP C	
	Males	Females	Males	Females	Males	Females
≤60	5	2	4	2	4	0
61 - 70	12	3	7	8	11	5
71-80	10	8	8	7	7	7
≥81	0	0	4	0	5	1
Total	27	13	23	17	27	13

$\chi^2_{(calculated)} = 26.034$; $\chi^2_{(tabulated)} = 5.99$; df=2; $\alpha = 0.05$

Intra-group comparison

The follow-up visits revealed a statistically significant reduction in palatal inflammation (table 3)

Table 3 showing difference between area of palatal inflammation

GROUP	N	BASELINE	14TH DAY	p value
A	40	3.65±0.802	1.45±0.749	0.031
B	40	4.01±0.908	1.72±0.654	0.042
C	40	4.79±0.874	1.53±0.530	0.039

and colony forming units of candida (table 4) in all three groups.

Table 4 showing mean reduction in total candida count(colony forming units/4 cm^2

GROUP	N	BASELINE	14TH DAY	p value
A	40	325 X 10^2	68 X 10^2	0.003
B	40	295 X 10^2	54 X 10^2	0.004
C	40	287 X 10^2	72 X 10^2	0.009

Intergroup comparison

Turkey test was employed to compare the efficacy of three different groups. It was found that no statistically significant difference was seen among three groups (table 5).

Table 5: Turkey's test showing intergroup comparison

Group	P value(mean reduction in CFU)	P value (mean reduction in area of palatal inflammation)
A	0.84	0.21
B	0.92	0.54
C	0.97	0.32

DISCUSSION

The prevalence of candida-associated denture stomatitis is 60-65% in denture wearers.[8]The actual number is expected to be even higher considering that all subjects do not manifest clinical signs of inflammation. The etiopathogenesis is elaborate but the main one is the accumulation of microbial plaque on the surface of the denture that contacts mucosa. Present day therapy includes the meticulous removal and control of the plaque through use of topical and systemic antifungal drugs. In this study, we have compared the anti-candidial efficacy of three different mouthwashes.

Green tea is a readily available evergreen shrub native to Southeast Asia. It is derived from the leaves of plant: *Camellia sinensis.*[9]Review of literature suggests multiple miraculous properties of green tea like antioxidant, anti-carcinogenic, antibacterial, antiviral, anticandidal and anti-allergic but its application as denture cleanser has not been established.[9,10]The antifungal property of both activity of both green and black tea catechins against Candida albicans has also been proved.[11,12]Aladag et al. showed in vitro antifungal activity of methanol extracts of green tea leaves (Camellia sinensis L.) in different harvest times.[13]In our study, the green tea mouthwash was efficacious in reducing the inflammation and candidalcount.Theantibacterial, antiseptic and antiseptic properties of triphala or three fruit are well established since early times.[14]Desai et al conducted a clinical trial and reported that triphala mouthwash in combination with scaling and root planing resultedin significant reduction in plaque index, oral hygiene index and calculus stain. The added benefit of using triphala is absence of stains.[15] Bajaj et al compared the efficacy of 0.6% triphala and 0.1% chlorhexidine and reported similar reduction in plaque score except lactobacillus count where triphala showed better results.[16] The results of clinical study conducted by Srinagesh et al conclude that 6% triphala twice daily reduced oral streptococci count by 17% and 44% compared to 0.2% chlorhexidine group which showed 16% and 45% reduction at the end of 2nd day and 7th day respectively.[17]Shetty et al reported significant reduction of total candida count on using triphala as denture cleansing tablet.[18] These results are in accordance with our study.

CONCLUSION

Nature based products like green tea and triphala are equally efficacious as commercially available nystatin to treat candida associated denture stomatitis. Because of their non-toxicity, cost effectiveness and easy availability they can serve as excellent anticandidal therapy.

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Legends for tables

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