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EFFICACY OF HERBAL AND NON-HERBAL ANTIBACTERIAL DENTIFRICES ON DENTAL PLAQUE AND GINGIVITIS- A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

BACKGROUND: Plant based formulations have gained rapid interest recently as they are safer to use with minimal side effects. Aim of the present study was to evaluate and compare the efficacy of herbal based dentifrice (Sudanta) having bakul as its major ingredient with chlorhexidine containing dentifrice (Elgydium) on gingival inflammation and plaque scores.

METHODS: Based in the inclusion and exclusion criteria, 50 Participants were included in the study and were randomized using random number table method into two groups (Group A- Sudanta; Group B- Elgydium) having 25 participantseach. Plaque index (PI), gingival index (GI), modified sulcus bleeding index (mSBI) and pH were recorded at the baseline and after 3 weeks. Data was analysed using Mann-Whitney U test and Wilcoxon Signed Rank test wherever appropriate.

RESULTS: There were 8 dropouts at the end of the study. Mean age of 42 participants was 27.33 ± 7.62 years. In Group A, significant improvement in the mean PI ($p=0.028$), GI ($p=0.008$) and mSBI ($p<0.001$) scores were observed from baseline to 3 weeks. Similarly, significant decrease in the mean PI ($p=0.005$), GI($p<0.001$) and mSBI ($p<0.001$) scores were also observed in group B. However, no significant difference in the pH changes were noted in both groups($p>0.05$). Although the values in both groups were comparable to each other, no significant difference was observed in the intergroup comparisons between groups ($p>0.05$).

CONCLUSION: Although not superior, the effectiveness of herbal formulations like bakul was similar to chlorhexidine in reducing plaque scores and gingival inflammation.

KEYWORDS: bakul, chlorhexidine, herbal dentifrice, gingival index, plaque score,

INTRODUCTION

An esthetic smile can be achieved by maintaining good oral hygiene with practices such as regular brushing and flossing. Poor oral hygiene in the form of constant deposition of plaque on the tooth surfaces and gingival crevices, causes irritation and inflammation of gingiva leading to gingivitis, periodontitis and subsequent tooth loss.^[1] Gingivitis is regarded as the second most commonly occurring oral malady, affecting more than 75% of the population worldwide.^[2] Optimal plaque control with the help of good mechanical cleansing aids such as toothbrush (manual or electric), floss, and interdental brushes with a good dentifrice prevent plaque related diseases. However, plaque formed in the stagnation areas such as proximal areas, gingival margins, and defects in the teeth are difficult to access and most subjects lack the compliance and dexterity required for adequate tooth brushing and flossing.^[3] To overcome this, first dentifrice with a chemotherapeutic agent triclosan with antiplaque activity was introduced in early 1990s. Till date, various anti plaque dentifrices with chemotherapeutic agents such as stannous fluoride, sodium hexametaphosphate, and zinc lactate, chlorhexidine have been introduced in the market which are effective in reducing plaque and gingivitis in an adult population.^[4]

Chlorhexidine Gluconate (0.004% w/w) is a cationic antiseptic with action against a wide array of bacteria including Gram-positive and Gram-negative bacteria, dermatophytes and some lipophilic viruses. It causes disruption of the bacterial cell membrane, thereby increasing its permeability and subsequent cell lysis. Although previous studies have shown significant decrease in the plaque score; however, due to the associated adverse effects including staining of teeth, loss of taste sensation and parotid swelling with its overzealous use and because of its possible interaction with anionic ingredients contained in toothpaste and gels, it gained less attention amongst its peers. Therefore, limited data is available on the evaluation of the clinical efficacy of dentifrices containing chlorhexidine.^[5,6] With the undesirable effects of the conventional dentifrices surpassing the benefits, lately, the focus is shifting towards herbal toothpastes with its natural ingredients that provide long lasting and complete oral care similar to conventional dentifrices.

Mimusops elengi Linn. (*M. elengi*) known as Bakul in Hindi, is an evergreen ornamental tree of the family Sapotaceae with pleasant fragrant flowers. Various parts of the plant or the

whole plant itself has many therapeutic implications with proven efficacy in diseases including odontopathy, gingival inflammation and bleeding. Similar to chlorhexidine, *M elengi*s effective against the common oral pathogens including, *Staphylococcus aureus*, *Streptococcus mutans*, *S. salivarius*, *S. sanguis*, *Lactobacillus acidophilus* and *Candida albicans*.^[7] Many clinical trials have been conducted to evaluate the efficacy of commercially available herbal dentifrices with variable contents including, chamomile, Echinacea, sage, neem, basil, clove, mint, etc. have shown positive effect on plaque control.^[8-10] However, limited studies are available on the comparison of herbal dentifrices with chlorhexidinecontaining dentifrice. Hence, the present study was undertaken with an aim to evaluate and compare the efficacy of herbal based dentifrice (Sudanta) having bakul as its major ingredient with chlorhexidinecontaining dentifrice (Elgydium) on gingival inflammation and plaque scores.

MATERIALS AND METHOD

The present single blinded randomized controlled trial was carried out among 50 subjects at Triveni Institute of Dental Sciences, Hospital and Research centre, Bilaspur. The Clinical trial was carried out in accordance to Declaration of Helinski (DoH) of 1975, as revised in 2013.^[11] Institutional ethical clearance was obtained prior to the study (TIDSHRC2018SS0001 dated 31/07/2018) and the trial was registered under Clinical Trial Registry of India (Ref No.- CTRI/2018/08/015544).

A sample size of 50 was determined based on previous studies. Patients visiting the departments of Periodontology, Oral Medicine and Radiology and Public Health Dentistry between the age group of 18-50 years were screened for the following inclusion criteria. Patients with a minimum 20 teeth (excluding third molars) and those with a minimum of 1.0 for Gingival Index (GI) as per Loe and Silness (1963)^[12] and mean Plaque Index (PI) Of 1.5 as per Turesky's modification of Quigley-Hein PI (1970)^[13] were included in the study. Patients with partial dentures, orthodontic bands or advance periodontal disease; patients with systemic diseases, pregnancy, smoking and history of allergy to the toothpaste; patients with antibiotic intake in the last one month; and those having used mouth rinse in last 3 months period were excluded from the study. Randomization was done by using random number table method and participants were divided into two

groups having 25 subjects each by a second examiner who was not involved in recording of clinical parameters.

The study was explained in detail to the participants and an informed consent was obtained prior to the trial. Before the initiation of clinical trial, ultrasonic scaling was performed in all participants followed by a washout period of 2 days (according to Newcombe et al., 1995)^[14] wherein, the subjects were asked to clean the teeth only with water to rule out any possible carryover effect of previously used oral hygiene products. At the end of washout period, a thorough clinical examination of oral cavity under adequate light was carried out using a mouth mirror and UNC 15 Probe. Baseline scores of (day 0) plaque index using two-tone disclosing solution and Turesky's (1970) modification of the Quigley, Hein (1962) index (PI),^[13] gingival index (Loe and Silness -1963),^[12] Gingival bleeding (Modified Sulcus Bleeding Index (mSBI))^[15] were recorded at six sites on each tooth. Baseline salivary pH was also recorded using a litmus paper as per the manufacturer instructions.

Each participant was provided with a soft bristle toothbrush and the respective dentifrice to be used for a period of three weeks. Participants of Group A were given commercially available herbal dentifrice- Sri Sri Tattva's Sudanta™, composed of Bakul bark (*Mimusops elengi*) (5mg/g) as the main ingredient, along with Lavanga (Clove), Maricha (*Piper nigrum*), Mayaphal (*Quercus infectoria*), Dalchini (*Cinnamomum zeylanicum*), Sodium benzoate in smaller proportions. Participants of group B received dentifrice Elgydium (Win-medica Pvt Ltd) consisting of Chlorhexidine gluconate (0.004%w/w). All participants were instructed to brush twice daily for 3 minutes using modified bass brushing technique, and refrain from any other oral hygiene practices (mouthwashes) throughout the study duration. At the end of 3 weeks, the participants were re-examined by the same investigators, and all the clinical parameters as well as adverse reactions were recorded. Dentifrices were collected back from the participants and weighed to measure the quantity used.

There were 8 drop outs at the end of follow up; therefore, final analysis was performed with scores of 42 subjects (Figure 1). The collected data was entered in Microsoft excel and analysed using SPSS (Statistical Package for Social Sciences) software,

Version 20.1 (IBM Corporation, Chicago, USA). Shapiro- Wilk test was used to test the normality of data; since the data did not follow normal distribution, the non-parametric tests were used for the analysis. The Mann-Whitney U test and Wilcoxon Signed Rank test was used to check differences in mean scores between groups wherever appropriate. A p value of <0.05 was considered statistically significant.

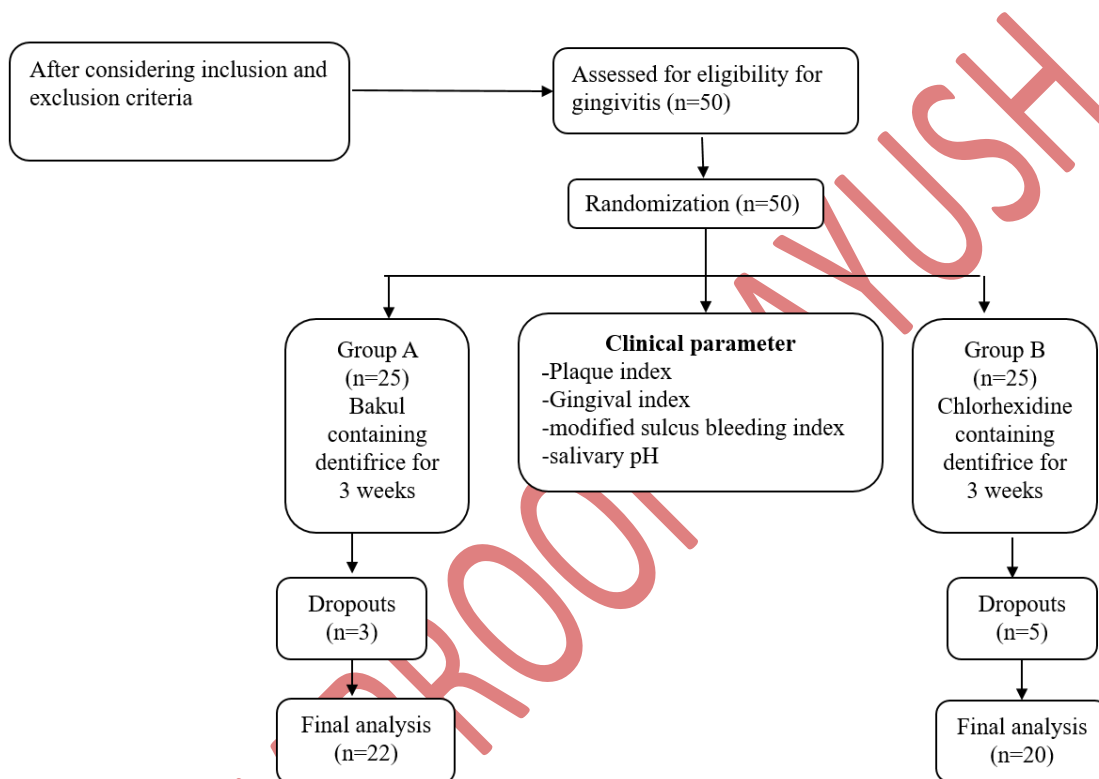


Figure 1: Flowchart depicting the study design

RESULTS

At the end of follow up, out of 50 participants recruited for the trial, 8 participants were lost to follow up. At the end analysis, the mean age of 42 participants was 27.33 ± 7.62 years. Mean age of participants in group A and group B was 27.27 ± 8.36 and 27.40 ± 6.93 years respectively ($p=0.116$). Of the 42 participants, 22 (52.4%) were male and 20(47.6%) participants were female. The difference in the sex distribution between both groups was not statistically significant ($p=0.537$) (Table 1).

Table 1: Demographics of the study population

Variables		Group A (n=22)	Group B (n=20)	Total	p-Value
Age in years (Mean \pm S.D)		27.27 \pm 8.36	27.40 \pm 6.93	27.33 \pm 7.62	0.116
Sex n (%)	Male	10 (45.5%)	12 (54.5%)	22 (52.4%)	0.537
	Female	11 (55.0%)	9 (45.0%)	20 (47.6%)	

Participants' PI, GI, mSBI scores and pH were recorded at baseline and at the end of 3 weeks. Intragroup comparisons of the means of these variables using Wilcoxon Signed Rank test are summarized in Table 2. In group A, mean PI score at baseline was 2.58 ± 0.48 which significantly reduced after 3 weeks (2.28 ± 0.48 ; $p=0.028$). Similar improvement in the GI score ($P=0.008$) and mSBI scores ($P<0.001$) were observed between baseline and after 3 weeks of using the dentifrice. Mean pH of the participants was 6.50 ± 0.51 at baseline which improved to 6.59 ± 0.50 after 3 weeks; however, the difference was not statistically significant ($p=0.157$). In group B, mean PI, GI and mSBI scores at baseline were 2.48 ± 0.33 , 1.88 ± 0.40 , 1.36 ± 0.36 respectively which significantly decreased to 2.18 ± 0.50 ($p=0.005$), 1.47 ± 0.28 ($p<0.001$) and 0.81 ± 0.36 ($p<0.001$) respectively after 3 weeks of trial. No significant difference was observed in the mean pH at baseline (6.60 ± 0.75) and after 3 weeks (6.60 ± 0.50 ; $p=1.000$).

Table 2: Intra-group comparisons of the study variables

Variables		Baseline (Mean \pm S.D)	3 Weeks (Mean \pm S.D)	P-Value*
Group A (n=22)	PI	2.58 ± 0.48	2.28 ± 0.48	0.028
	GI	1.79 ± 0.37	1.58 ± 0.32	0.008
	mSBI	1.35 ± 0.31	0.91 ± 0.30	<0.001
	pH	6.50 ± 0.51	6.59 ± 0.50	0.157
Group B (n=20)	PI	2.48 ± 0.33	2.18 ± 0.50	0.005
	GI	1.88 ± 0.40	1.47 ± 0.28	<0.001
	mSBI	1.36 ± 0.36	0.81 ± 0.36	<0.001
	pH	6.60 ± 0.75	6.60 ± 0.50	1.000

*Wilcoxon Signed Rank test

Table 3 summarizes the intergroup comparison between group A and group B at baseline and at 3 weeks analyzed using Mann-Whitney U test. There was no difference observed between the Mean scores of PI ($p=0.256$), GI ($p=0.571$), mSBI ($p=0.850$) and pH ($p=0.876$) at baseline suggesting that the values were comparable with each other at the start of study. Similarly, after 3 weeks of using dentifrice, individual improvement observed in the clinical parameters were comparable with each other and no statistically significant difference was observed in the mean PI ($p=0.338$), GI ($p=0.246$), mSBI ($p=0.290$) and pH ($p=0.953$) scores between both groups.

Table 3: Comparisons of the study variables between group A and Group B

Variables		Group A (n=22)	Group B (n=20)	P-Value*
Baseline	PI	2.58 ± 0.48	2.48 ± 0.33	0.256
	GI	1.79 ± 0.37	1.88 ± 0.40	0.571
	mSBI	1.35 ± 0.31	1.36 ± 0.36	0.850
	pH	6.50 ± 0.51	6.60 ± 0.75	0.876
After 3 weeks	PI	2.28 ± 0.48	2.18 ± 0.50	0.338
	GI	1.58 ± 0.32	1.47 ± 0.28	0.246
	mSBI	0.91 ± 0.30	0.81 ± 0.36	0.290
	pH	6.59 ± 0.50	6.60 ± 0.50	0.953

*Mann-Whitney U test

DISCUSSION

With an understanding of the relationship between the oral and systemic health, there is an upsurge in the awareness of oral health and hygiene. However, despite practicing effective

mechanical tooth cleaning, bacterial colonization on the tooth surface, around the gingival margin and interdental spaces can be missed out.^[4] Thus, dentifrices with myriad of interesting ingredients having antimicrobial properties have been formulated and tested by various researchers and lately, the recent shift in paradigm has led to a growing interest for herbal oral health care products globally.^[16] Natural herbs used either as whole single herb or in combination have been scientifically proven to be safe and effective medicine against various oral health problems like bleeding gums, halitosis, mouth ulcers and preventing tooth decay.^[1]

Sudanta dentifrice used in our study consists of Bakul/*M. elengi* as a major constituent. It is known to have anti-viral, anti-inflammatory, antimicrobial antioxidant, analgesic, and astringent properties. Similarly, other constituents like *Cinnamomum zeylanica*, Piperine, *Quercus infectoria* and *Cinnamomum camphora* are also known for their antimicrobial and anti-inflammatory properties.^[16] It is well known that chlorhexidine effectively reduces the anaerobic bacterial counts, supragingival plaque, gingival inflammation and bleeding. Hence, it was used as a control dentifrice in our study.^[17-20] To the best of our knowledge, this is the first randomized controlled clinical trial in a subset of Indian population assessing the efficacy of bakul based dentifrice with chlorhexidine-based dentifrice.

In our study, efficacy of dentifrices were assessed by using GI, PI and mSBI; which are standard indices to assess gingival health. Bhopale et al.,^[6] in their study observed a 24.5% and 5% reduction of GI and PI after 3 months of using chlorhexidine based dentifrice. Similarly, we observed a significant decrease in the mean PI ($p=0.005$), GI ($p<0.001$) and mSBI ($p<0.001$) scores between baseline to after 3 weeks of chlorhexidine based dentifrice usage. Similar improvement in the mean PI score ($p=0.028$), GI score ($p=0.008$) and mSBI scores ($p<0.001$) were also observed between baseline and after 3 weeks of using the herbal dentifrice in Group A patients. These results are in agreement with the studies carried out by Srinivasa et al.,^[2] Tatikonda et al.,^[21] Howshigan et al.,^[10] and Jayashankar et al.,^[22] which showed significant improvement in plaque, gingivitis, and bleeding indices using similar constituents as that of the test dentifrice used in our study. Similarly, studies using dentifrice containing Chamomile, Sage, Myrrh, Rhatany, Echinacea and Peppermint oil have also found a significant reduction of PI and GI within group.^[23] On the

contrary, Pannuti et al.,^[9] during a 21 day home use clinical trial found no significant difference in mean plaque indices with either test (herbal dentifrice) or control dentifrice.

There was no difference observed between the mean scores of PI ($p=0.256$), GI ($p=0.571$), mSBI ($p=0.850$) and pH ($p=0.876$) at baseline between groups, suggesting that the values were comparable with each other at the start of study. At the end of 3 weeks although there was significant improvement was observed in PI, GI and mSBI within groups, no statistically significant difference was observed in the mean PI ($p=0.338$), GI ($p=0.246$), mSBI ($p=0.290$) and pH ($p=0.953$) scores between both groups. The results of our study were in partial agreement with other studies,^[4,8,9,2,23] which reported a significant intragroup reduction in the plaque index and gingival index scores but no significant difference on intergroup comparison. This suggests that herbal dentifrices containing Bakul are as effective as the chlorhexidine based dentifrices in the reduction of plaque and gingivitis. It is possible that results of our study might also been affected by the Hawthorne effect, where in the awareness of the sheer participation in the trial might have inadvertently lead to improvement in brushing technique, thus affecting the plaque and gingival score in both groups.^[9]

Herbal dentifrice is known to improve the bleeding index and plaque index within 1 week of its usage due to the anti-inflammatory and astringent properties present in the herbal products along with supervised toothbrushing.^[3] Radafshar et al.,^[23] in their study conferred that herbal toothpaste acts better on lingual surfaces of molar-premolar teeth in both jaws, which are the most vulnerable sites to early plaque regrowth. Farzi et al.,^[24] reported that increased periodontal disease is associated with reduced salivary flow rate causing supersaturation of saliva with calcium and phosphate salts leading to increased salivary pH which changes to alkaline form after using herbal dentifrices. Pentapati et al.,^[16] observed a shift towards more alkaline in the salivary pH from the baseline in both control and test group. However, no significant difference was seen between them. Similar to study by Hosadurga et al.,^[8] we did not observe significant change in the salivary pH levels in both groups.

Although the herbal toothpaste is safe and no adverse effects have been reported so far, however there can be a possibility of hypersensitivity to few ingredients. In our study, no

adverse reactions were reported during the study period which is in accordance with the studies by Tatikonda et al.,^[21] de Oliveira et al.,^[25] Singh et al.,^[4] and Ozaki et al.,^[26] High vascularization of the epithelium, protective role of saliva and the shorter duration of brushing might have reduced the incidence of such allergy as compared to longer contact period in chewing gums.^[16] Tatikonda et al.,^[21] de Oliveira et al.,^[25] observed a significant reduction of dentifrice tube weights between days 0 and 30 in both the groups which shows that the volunteers had actually used the toothpastes. Although dentifrice were examined at the end of the study from the participants; however, we cannot rule out the possibility of sharing of the dentifrice by the family members which is a common practice in an Indian household. Additionally, short duration of study and smaller sample size limits the generalizability of the results. Further studies are recommended to use more detailed plaque indices for a longer duration in a more diverse study group to validate the effects of these dentifrices.

CONCLUSION

Although, chlorhexidine is considered the gold standard in plaque control; however, is associated with certain side effects including staining of teeth, loss of taste sensation, parotid swelling with its overzealous use. With the results of our study we conclude that herbal dentifrice containing Bakul is as effective as chlorhexidine in reducing plaque scores and gingival inflammation. These findings suggest that the herbal dentifrice could be an effective alternative to conventional formulations for individuals with an interest in naturally based products.

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