

EVALUATION AND COMPARISON OF EFFICACY OF TRIPHALA MOUTHWASH WITH CHLORHEXIDINE MOUTHWASH ON DENTAL PLAQUE AND GINGIVITIS: A RANDOMISED CLINICAL TRIAL

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ABSTRACT:

Rationale: Triphala is a combination of three medicinal plants, extensively used in Ayurveda since ancient times. Triphala mouthwash is used in the treatment of periodontal diseases because of its proven antimicrobial and antioxidant properties.

Aim: The objective of this study is to evaluate clinically the efficacy of Triphala mouthwash on dental plaque and gingival inflammation and to compare the effect of Triphala mouthwash with commercially available Chlorhexidine mouthwash.

Methods: In this randomized, clinical trial, 72 patients were selected according to strict inclusion criteria and subsequently randomized into two groups with equal patients in each group. Patients in Group A were instructed to rinse their mouth with 15ml of 6% Triphala mouthwash twice daily and Group B with 15ml of 0.2% Chlorhexidine mouthwash twice daily. Clinical parameters Gingival Index, Plaque Index (Silness&Loe) were recorded at baseline and at 21 days.

Results: There was no statistically significant difference ($p > 0.05$) when the anti-plaque and anti gingivitis efficacy of Triphala was compared with 0.2% chlorhexidine.

Discussion: The Triphala mouthwash (herbal) is equally effective anti-plaque and anti gingivitis agent as 0.2% Chlorhexidine. Triphala mouthwash is well tolerable with no reported side effects.

Keywords: periodontal diseases; antiplaque; gingival inflammation; anti gingivitis

INTRODUCTION

Periodontal diseases appear to occur when pathogenic microbial plaque acts on a susceptible host.^[1] Dental plaque is a complex mixture of bacteria with representatives from more than 500 species enmeshed in a tightly adherent biofilm. Plaque control is fundamental to the prevention and management of periodontal diseases,^[2] either mechanically or by means of different

chemical agents. Mechanical plaque control is a challenge in hospital admitted medically compromised patients (partial paralysis and old patients) who do not give control over their faculties and orthodontic patients respond better to chemical plaque control. Thus, an adjunctive use of chemical agents is advisable and practiced. Chlorhexidine (CHX), a cationic bisbiguanide, is a gold standard among

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all mouthwashes, particularly because of its substantivity and broad-spectrum antibacterial activity.^[3] However, CHX has been reported to have a number of side effects like brown discoloration of teeth, and alteration of taste perception in regards to salty food, oral mucosal erosions, and enhanced supragingival calculus formation which limits its long-term use.^[4] Therefore, research has been focused in recent years on herbal medicines, owing to their wide range of biological and medicinal activities, ease of availability, higher safety margins and lower cost (Cowan, 1999).^[5] Hence, now a days, herbal drugs are preferred to synthetic antibiotics.^[6] One such herbal remedy is Triphala, an equi-proportional mixture of

Hiritaki or Black myrobalan (*Terminalia chebula*) Hindi name: Harre, Harad.

Bibhitaki: (*Terminalia bellerica*) Hindi name: Bahera, Baherha

Amalaki: (*Emblicus officinalis*) Hindi name: Awala, Amla, Aonla.^[7]

It has been used extensively in the Indian system of medicine as a potent anti-inflammatory (Jagadish et al, 2009)^[8], antioxidant (Asmawi, 1993)^[9] and antimicrobial agent against a wide spectrum of microbes (Biradar, 2008)^[10]. Hence the current study was conducted to evaluate clinically the efficacy of Triphala mouthwash on dental plaque and gingival inflammation and to compare the effect of Triphala mouthwash with commercially available Chlorhexidine mouthwash.

MATERIALS AND METHODS

This was a randomized clinical trial designed to evaluate and compare the effect of Triphala extract mouth rinse and chlorhexidine on dental plaque and gingivitis. All the subjects selected were from the outpatient clinics of the Department of Periodontics and Oral Implantology, SudhaRustagi College of Dental Sciences and Research, Faridabad, Haryana where this study was conducted. Ethical clearance and approval from Institutional ethical committee was obtained before initiating the study. The study took place from Dec 2014 to Feb 2015. Informed and written consent was obtained from the study volunteers.

Sample size estimation:

Sample size estimation was done by using **G Power software**. In G Power, a priori sample size estimation was performed. Then, a Wilcoxon-Mann Whitney test was chosen. A minimum total sample size of 72 with a 1:1 allocation ratio (Triphala gr: 36; CHX gr: 36) was found to be sufficient for an alpha of 0.05, power of 80% and a large effect size of 0.69 (judged from a similar type of study). To compensate for any dropouts, the sample size was inflated up to additional 10%. Thus, the final total sample size decided was 80 with equal allocation in both the groups i.e., 40 in each group. Both males and females were selected in the study. At the end of trial 4 subjects dropped out of the chlorhexidine group, and 4 subjects from the Triphala group. A total of 72

subjects remained in the study with 36 subjects in each group at the end of trial.

Inclusion Criteria:

- Age group : 20-60 years
- Both genders males and females were selected.
- Mild to moderate gingivitis
- Minimum 20 teeth with plaque and calculus.

Exclusion Criteria:

- Subjects who have undergone periodontal therapy.
- Subjects already using any mouth rinse.
- Subjects allergic to mouthwash used in study.
- Subjects with any systemic diseases, allergy or infectious disease.
- Subjects who had taken antibiotic therapy in last 3 months, or on anti-inflammatory therapy.
- Subjects using orthodontic appliances or removable partial denture.

Group Distribution:

The subjects were divided into two groups:

Group I (n=40): using Triphala mouthwash (6%)

Group II (n=40): using Chlorhexidine mouthwash (0.2%)

Baseline assessment:

Plaque scores (PI) were recorded using the methodology given by Silness and Loe (1964). The Gingival index (GI) was calculated according to the method given by Loe and Silness (1963). All these clinical parameters were recorded at baseline and after 21st day.

Preparation of 6% Triphala mouthwash:
[11]

- 60 gm of Triphalachurna dissolved in 1000 ml of water brought to a boil and filtered. Triphala has a flavor of a raw fruit
- To mask this flavor and improve patients compliance, 2ml of glycerin (sweetening agent) and 1 ml of pudinhara, a commercially available mint extract, was added.
- Solution was cooled and 100 ml was measured and dispensed in bottles.

STUDY DESIGN:

A total of 80 patients in the age group 20-60 years both males and females were selected in the study. Only the subjects with mild to moderate gingivitis were included in the study. To follow these strict inclusion criteria [12], first the gingival index (Loe&Silness 1963) of each patient was recorded and then patient was categorized into mild, moderate and severe gingivitis. Only the patients with mild and moderate gingivitis were included in the study and rest were excluded. The subjects were then divided into two groups: Group I (n=40):

using Triphala mouthwash (6%) and Group II (n=40): using Chlorhexidine mouthwash (0.2%). The patients were instructed to rinse their mouths with 15 ml of the assigned mouthwash for 1 minute twice daily for two weeks. The patients were instructed to continue with their routine oral hygiene measures and to keep a gap of 30 minutes between tooth brushing and rinsing. The plaque index (PI) and the gingival index (GI) were assessed in each patient at baseline and after 21st day.

STATISTICAL ANALYSIS

All data were entered into Excel spreadsheet, checked for entry errors and analyzed with a statistical package, Statistical Package for Social Sciences (IBM) ver. 21.0. Continuous variables i.e., Age, Plaque Index and Gingival Index were summarized as Means and categorical variable i.e., gender was summarized as frequencies. The normality of the data distribution was checked using Shapiro Wilk test. Both parametric and non-parametric tests were used for inferential statistics. Independent Student's t test was used to compare the mean age of subjects in Triphala group with that of CHX group. Chi square test was used to compare the gender wise distribution of subjects among both the groups. As the data related to PI and GI failed to achieve the normality, non-parametric tests of significance were used for their comparison. For intergroup comparison of plaque and gingival scores, Wilcoxon signed ranks test was used while for

intergroup comparison Mann Whitney U test was used. The level of significance was set at 0.05. The data was presented in both forms i.e., tables and graphs. No drop-out analysis was performed because some subjects that dropped out at the end of trial did not affect the power of the study, since more subjects were recruited in each group to compensate for attrition.

RESULTS

Table 1 depicts the mean (SD) age of subjects and gender wise distribution of subjects among two groups. Difference in the mean age of subjects among both the groups was not found to be statistically significant. Gender wise distribution of subjects among both the groups was also failed to reach the level of statistical significance.

Table 2 depicts the intra-group (pre & post) & intergroup comparison of mean Plaque Index and mean Gingival Index of group 1 & group 2, at baseline & 3 weeks. Intragroup comparison shows that a statistically significant reduction ($p < 0.001$) from baseline to 3 weeks in both mean PI and mean GI, among both the groups was found. Intergroup comparison shows that baseline mean PI scores were significantly different between Triphala and CHX groups. While baseline mean GI scores and post intervention scores (i.e. 3 weeks score) of both mean GI & PI were not significantly different among both the groups. Comparison of percent reduction (from baseline to 3 months) in Plaque Index scores and Gingival Index scores

between Triphala group & chlorhexidine group using Mann-Whitney U test is depicted in Table 3. Differences in mean percent reduction of PI and GI among Triphala and CHX group failed to reach the level of statistical significance.

DISCUSSION

The present study was conducted to evaluate clinically the efficacy of Triphala mouthwash on dental plaque and gingival inflammation and to compare the effect of Triphala mouthwash with commercially available Chlorhexidine mouthwash. The formation of dental plaque at the microscopic level can be divided into three phases: formation of the pellicle coating on the tooth surface, initial colonization by bacteria, and secondary colonization and plaque maturation. The initial colonizers such as *A. viscosus* and *S. sanguis* adhere to the pellicle^[13,14] through specific molecules, termed adhesins, on the bacterial surface that interact with receptors in the dental pellicle. Then secondary colonizers including *P. intermedia*, *P. loescheii*, *Capnocytophagaspp.*, *F. nucleatum*, and *P. gingivalis*^[15] adhere to cells of bacteria already in the plaque mass through a process called co-aggregation. Triphala has been shown to inhibit growth of primary colonizers like *S. sanguis*.^[16]

Various microbiological studies have already been done proving the anti-microbial efficacy of Triphala. Thomas et al 2011 conducted a study to assess the antimicrobial properties of Triphala in comparison with commercially available

toothpastes and found that Triphala showed Minimal Inhibitory Concentration / Minimal Bactericidal Concentration at 6.25% for Microbial type culture collection (MTCC) strain of *S. mutans* and 3.12% for clinical isolate of *S. mutans*.^[11] So, we did not conduct the microbiological study and decided to prepare the Triphala mouthwash with a concentration of 6%. Patients in Group A were instructed to rinse their mouth with 15ml of 6% Triphala mouthwash twice daily and Group B with 15ml of 0.2% Chlorhexidine mouthwash twice daily. They were instructed not to rinse their mouth with water or drink anything for half an hour because the retention of chlorhexidine in the oral cavity is dependent on a number of factors as is stated by Walton & Thomson.^[17] The effectiveness of Triphala mouth rinse was intended to be studied in a real-life situation and hence no oral prophylaxis was performed. CHX rinses are often used as a benchmark control and a positive control, meaning that they are accepted as effective, the most effective, or the "gold standard".^[18] Short-term trials predominantly demonstrate the superior efficacy of CHX on plaque regrowth and numerous other outcome measures.^[19] According to the *Sushruta Samhita*, Triphala can be used as a gargling agent in dental diseases.^[20] It is also recommended to be used for cardiovascular disorders, high blood pressure, serum cholesterol reduction, ophthalmic problems, liver dysfunction, inflammation and complications of the large intestine.^[21,22] It is also used as a

blood purifier, to improve the mental faculties and is reported to possess anti-inflammatory, analgesic, anti arthritic, hypoglycemic and anti-aging properties.^[23] Several authors have used Triphala as a mouth rinse in healthy gingivitis patients.^[24] Triphala presented an antiplaque efficacy similar to that of CHX and was more effective in inhibiting plaque formation with lesser or no side effects^[25]. *Sushruta Samhita* has emphasized that Triphala has haemostatic, anti-inflammatory, analgesic, and wound-healing properties. Haritaki is the most efficacious for bleeding gums and gingival ulcers as well as carious teeth.^[20] Side effects such as loss of taste, burning sensation of the oral mucosa, subjective dryness of the oral cavity and discoloration of teeth and tongue were reported with 0.2% chlorhexidine.^[26] Resistance of pathogens to synthetic drugs is posing an ever increasing therapeutic problem⁽²⁷⁾ and increased MICs of chlorhexidine for *S. mutans* have been reported.^[28] In the present study, a 0.2% chlorhexidine mouth rinse was found to be effective in reducing the plaque and gingival index score to a statistically significant level ($p < 0.001$).

Our study was in accordance with results obtained by Desai et al.^[29] Furthermore, 6 % Triphala extract showed a statistically significant reduction in plaque and gingival scores ($p < 0.001$) when compared to the baseline parameters. This is in conformity with the study conducted by Bajaj et al (2011), who concluded that there was no

significant difference between the Triphala and the chlorhexidine mouthwash. The results obtained in the current study can be attributed to the antimicrobial and antiplaque activity of Triphala, as also found by Jagadish et al (2009) who studied the effect of Triphala on dental biofilm. Biradar et al (2008) chemically analyzed Triphala, and reported tannic acid, chebulic acid and Flavenoids as its major constituents. The presence of tannins in Triphala during the early stages of plaque formation could effectively reduce the number of bacteria available for binding to the tooth surface by increasing their physical removal from the oral cavity through aggregate formation. Alternatively, the tannins could be associated with surface lipoteichoic acid, as in the case of salivary acidic glycoproteins, resulting in bacterial aggregation.^[10] Kaikuchi et al (1986) reported that the galloyl radical of the tannins was important for inhibition of glucan activity and the antiplaque activity of the tannins.^[30] Peroxidation of the biological membrane occurs at the tissue level during gingival inflammation. A decrease in the oxidation of the host tissues may resolve inflammatory changes (Firatli et al, 1994).^[31] Triphala exhibits a strong antioxidant property, as confirmed by Jagadish et al (2009)^[8]. This might explain the significant reduction in the gingival score reduction in the Triphala group. Group 1 showed reduction in gingivitis scores from baseline (1.05) till the end of 21 days (0.56) which was significant ($p < 0.001$). However, Group 1

and Group 2 did not differ significantly suggesting that both the mouthwashes have same effect on gingival health. Thus, it could be suggested that Triphala mouthwash was comparable to Chlorhexidine in maintaining the healthy status of the gingiva. Similar observation was noted in a study by Gupta et al.^[32]

CONCLUSION

Chlorhexidine has been considered the best antiplaque and antigingivitis agent, but now, it is time to acknowledge the value of natural herbs like Triphala, known to have many useful properties

and no side effects. The major advantages of using herbal alternatives are low toxicity, increased shelf life and lack of microbial resistance reported so

far. More studies are required to further emphasize the effect of Triphala on gram-negative anaerobes, the microorganisms responsible for causing periodontitis, and to determine the sustained release capacity (Substantivity) of Triphala for plaque control for the prevention of periodontal disease and maintenance of good oral health. This trial highlights that Triphala (herbal) mouthwash is as efficient an antiplaque agent as 0.2% CHX.

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TABLES:

Table 1: AGE WISE & GENDER WISE DISTRIBUTION OF SUBJECTS AMONG TWO GROUPS

Group	Male		Female		Mean Age (SD)	P ^a value, Significance
	N	%	N	%		
Triphala gr N= 36	21	58.3%	15	41.7%	32.92 (7.86)	0.680 [#]
CHX gr N= 36	19	52.8%	17	47.2%	33.72 (8.64)	
Total=72	40	55.6%	32	44.4%	33.32(8.21)	
P ^b value, Significance	0.635 [#]					

[#] Non-significant difference (p-value >0.05)

^aIndependent Student's t test & ^bChi square test

Table 2: INTRA & INTERGROUP COMPARISON OF MEAN PLAQUE INDEX AND MEAN GINGIVAL INDEX OF GROUP 1 & GROUP 2, AT BASELINE & 3 WEEKS

	PI			GI		
	Triphala gr Mean (SD)	CHX gr Mean (SD)	P ^b value of Inter group comparison	Triphala gr Mean (SD)	CHX gr Mean (SD)	P ^b value of Inter group comparison
At baseline	0.99 (0.09)	0.94 (0.09)	0.036, S	1.05(0.08)	1.04(0.13)	0.817 [#]
At 3 weeks	0.54 (0.13)	0.50 (0.18)	0.23, NS	0.56(0.15)	0.50(0.15)	0.082 [#]
P ^a value of Intra group comparison	<0.001*	<0.001*		<0.001*	<0.001*	

[#] Non-significant difference (p-value >0.05)

*Significant difference(p-value ≤ 0.05)

^aWilcoxon Signed Ranks Test; ^bMann-Whitney U test

Table 3 : COMPARISON OF PERCENT REDUCTION (FROM BASELINE TO 3 MONTHS) IN PLAQUE INDEX SCORES & GINGIVAL INDEX SCORES BETWEEN TRIPHALA GROUP & CHX GROUP

	PI			GI		
	Percentage Reduction in Triphala group Mean (SD)	Percentage Reduction in CHX group Mean (SD)	P ^b value of Inter group comparison	Percentage Reduction in Triphala group Mean (SD)	Percentage Reduction in CHX group Mean (SD)	P ^b value of Inter group comparison
From baseline to 3 months	44.98(13.72)	46.38(20.61)	0.367, NS	46.71(14.00)	50.82(16.9)	0.230, NS

[#] Non-significant difference (p-value >0.05)

^bMann-Whitney U test

ABBREVIATIONS:

CHX

Chlorhexidine

MIC

Minimum Inhibitory Concentration

Tri

Triphala