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Comparative Evaluation of Anti- Plaque Efficacy of Commercially Available Herbal and 0.2% Chlorhexidine Gluconate Mouthwash: A Randomized Clinical Trial

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Abstract: ***Introduction*: Anti-microbial mouth rinses limit the accumulation of dental plaque with a primary objective of controlling the development and progression of periodontal diseases. Chlorhexidine is regarded as gold standard anti- plaque agent with certain side effects. Nowadays, herbal medicines with their 'naturally occurring' active ingredients offer a gentle and enduring way for restoration of health by the most trustworthy and least harmful way. *Objective*: To Compare the Anti-Plaque Efficacy of an Herbal Mouthwash With 0.2% Chlorhexidine Gluconate Mouthwash and Normal Saline. *Methodology*: It is a Double-blinded, randomized clinical trial in which 90 students were divided into 3 groups – Group A – Chlorhexidine, Group B – Herbal, and Group C – Normal saline. Subjects with GI &PI < 1 were included in the study. These students were refrained from their regular mechanical oral hygiene measures and were asked to swish the mouthwashes given to them for 4 days.GI & PI scores were then re-evaluated on the 5th day and the differences were compared statistically by ANOVA & Student 't'-test. *Results*: Least post-rinsing GI scores were observed with Herbal mouthwash whereas least PI scores with Chlorhexidine. Highest scores were observed with Normal Saline. The difference in post-rinsing PI scores between groups A & B was statistically non-significant (p value – 0.076). *Conclusion*: With in the limitations of the study, it was concluded that 0.2% Chlorhexidine mouthwash remains the best anti-plaque agent. Herbal rinse may be considered as a good alternative.***

Keywords: Anti – plaque efficacy, Gingivitis, Chlorhexidine, Herbal rinse

1. Introduction

There is a growing interest throughout the oral health care profession in therapeutic agents that complement and enhance the mechanical removal of biofilms in the oral cavity. Bacterial metabolites released from the biofilm induce gingival inflammation, which lead to periodontitis [1]. Periodontal diseases are among the most common infectious diseases affecting humankind and can lead to destruction of the periodontal ligament, cementum, gingiva, and alveolar bone [2]. In India, nearly 60-65% of the child population is affected by dental caries and 10% has periodontitis [3]. Plaque is known to be an initiating factor in the development of gingivitis when in contact with the gingival tissues and, therefore, plaque control represents the cornerstone of good oral hygiene practice [4]. The concept of plaque control is broadly based on mechanical plaque control and chemical plaque control [5]. The tools most used in mechanical supragingival plaque control are the toothbrush (manual or electric), floss, wood sticks, and interdental brushes [4]. Chemical plaque control approach is desirable to deal with the potential deficiencies of daily self-performed oral hygiene in handicapped and elderly patients [4]. Mouth rinses treat all accessible surfaces of the oral cavity and may reduce the number of bacteria accumulating on mucosal surfaces [6]. Dental plaque could be modified by rinsing with chemotherapeutic agents as diverse as Chlorhexidine, Tetracycline, Vancomycin and Bacitracin [7]. Most products in current use or under study are antiseptics. Vehicles with anti-plaque/anti-gingival action are toothpastes, mouthwashes, spray, irrigators, chewing gum, and varnishes. Mouthwashes are a simple and widely accepted method to deliver the anti-microbial agent (after toothpastes), which can be used by the patient as an oral hygiene aid [8].

Chlorhexidine is regarded as the "Gold Standard" anti-plaque agent. However, it is not a "Magic Bullet" due to certain side effects like taste disturbance[9], brownish discoloration, parotid swelling, enhanced supra gingival plaque[3], and less commonly, desquamation of the oral mucosa[4]. Chlorhexidine has long been recognized as the primary agent for chemical plaque control. Alternatives to mouth rinse, sprays and chewing gums could also be beneficial [10]. Chlorhexidine was developed in 1940's by Imperial Chemical Industries, England. Later, Davis et al. 1954 in a study on polyguanides found that certain bisbiguanides had a broad anti-microbial spectrum. By structural variation they arrived at the agent with the greatest bacteriostatic and bactericidal features 1, 6 bis-4 chlorophenyl diguanidohexane, a synthetic cationic detergent usually referred as Chlorhexidine [11].Initially in dentistry, it was used for presurgical disinfection of mouth and in Endodontics.[11] Plaque inhibition by Chlorhexidine was first investigated in 1969, but the definitive study was performed by Loe and Schiott. The study showed that rinsing for 60 sec twice daily per day with 10ml of 0.2% (20 mg dose) Chlorhexidine gluconate solution inhibits plaque re-growth and development of gingivitis in the absence of normal tooth cleansing [11].

However, today's dentists are practicing in an era where the patients are more concerned about both their oral health and their overall medical wellbeing. Thus, in the midst of

growing evidence of the connection between oral health and whole body health, herbal medicines with their 'naturally occurring' active ingredients offer a gentle and enduring way for restoration of health by the most trustworthy and least harmful ways [4]. These herbal mouthwashes are gaining popularity as they contain naturally occurring ingredients called as Phytochemicals that achieve the desired antimicrobial and anti-inflammatory effects [2]. The major strength of these natural herbs is the absence of any side effects. Hiora is an herbal mouthwash, with Miswak (Salvadora persica) as an active herbal ingredient. (Each gram of HiOra mouthwash consists of Pilu (Salvadora persica)- 5.0 mg, Bibhitaka (Terminalia bellerica)-10mg, Nagavalli (Piper betel)-10 mg, Gandhapura taila-1.2 mg, Ela-0.2 mg, Peppermint satva-1.6 mg, Yavanisatva-0.4 mg). It has been demonstrated that extracts of S.persica improved gingival health and inhibited growth of carcinogenic bacteria [3].

So, the main objective of our study is to compare the Anti-plaque efficacy of an herbal mouthwash with 0.2% Chlorhexidine gluconate mouth wash.

2. Material and Methods

The present study was a double blinded, randomized clinical trial carried out in Department of Periodontics, Govt Dental College and Hospital, Kadapa which included a total of 90 BDS students (age of 18 to 23 years). The ethical clearance was obtained from the Institutional Ethical Committee (IEC), and informed consent was taken from all the participants of the study.

Inclusion Criteria

- Systemically healthy subjects with GI≤1 (as a mean value for all tooth surfaces scored),
- Minimum of 20 teeth should be present in the dentition,
- Patients who had not received any periodontal therapy for the past 6 months.

Exclusion Criteria

- Subjects with severe malalignment of teeth, orthodontic appliances,
- Fully crowned teeth, Removable partial dentures,
- Patient with a known history of allergy to herbal or any chemical products,
- Smokers,
- Subjects with medical or pharmacological history that could compromise the conduct of the study were excluded.

Materials Used

Materials used were Diagnostic instruments, Ultrasonic scalers, 0.2%Chlorhexidine Gluconate mouthwash, Herbal mouthwash (HiOra), Normal Saline, Sterile dispensing bottles, measuring cups, and plaque disclosing agent. HiOra Mouthwash Regular- Manufactured by the Himalaya Drug Company Makali, Bangalore (India).

Group Distribution

Subjects were randomly assigned to Group A, Group B and Group C. Each group included 30 subjects.
Group A- Subjects were treated by scaling along with the usage of 0.2% Chlorhexidine gluconate mouthwash,
Group B- Subjects were treated by scaling along with the usage of Herbal mouthwash (HiOra),
Group C- Subjects were treated by scaling along with the usage of Normal Saline.

Clinical Parameters

Prior to scaling, subjects were evaluated for the following clinical parameters:

Gingival Index (Loe and Silness, 1963) [13].

Plaque Index (Turesky et al. 1970), which is a modification of the Quigley and Hein Plaque Index (1962) [14].

GI and PI were recorded and brought to "0" by professional prophylaxis. Intra-oral colored photographs were taken. Then, subjects were assigned randomly after fitting into inclusion and exclusion criteria. The recording of clinical parameters was carried out by the main investigator and treatment was carried by co-investigators. Side- effects of mouthwashes were evaluated from subjects of all the 3 groups by means of a questionnaire as well as by means of clinical examination. The clinical parameters were assessed on day "0" and day "5".

In the questionnaire, subjects were requested to mention Yes/No for pain, dryness of mouth, burning sensation, taste disturbance, itchiness/pruritis, discoloration of teeth and tongue surfaces, feeling of bitter taste in the mouth after a 4-day use of the 3 mouthwashes. They were asked to rate the severity of side effects as none, mild, moderate, or severe. With respect to the taste disturbance side-effect, the subjects were also asked to specify which taste (i.e., salt, bitter, sweet, or sour) had altered in perception.

By means of clinical examination, following side-effects were evaluated:

(a) The severity of soft tissue irritation, rated as none, change in color, desquamation, or presence of aphthae.
(b) Discolorations were recorded as Present/Absent and if present, further classified as none, mild, moderate, or severe.

Usage of Mouthwash

These students were refrained from their regular mechanical oral hygiene and were asked to swish the respective mouthwash of 10 ml twice daily for 4 days.

Statistical Analysis

Post-rinsing GI and PI scores of groups A, B, and C were then compared statistically by ANOVA and Student 't'-tests.

3. Results

Participants sincerely followed the protocol of the study, and no systemic side effects were observed in these subjects. There was no significant difference in the mean age (20± 2) of subjects in the 3 groups. Table 1 and Figure 1 shows ANOVA test for difference between pre- rinsing GI scores of the 3 groups. Though there was significant difference between mean GI and PI of the 3 groups at pre-rinsing stage, both were brought to 0 by professional prophylaxis. Table 2 and Figure 2 shows ANOVA test for difference between pre-rinsing PI scores of the 3 groups. Mean GI at post-rinsing stage was least with group B subjects (0.71), followed by group A subjects (0.73) and then group C subjects (1.23). Similarly, mean PI at post-rinsing stage was least with group A subjects (2.46), followed by group B subjects (2.76) and then group C subjects (3.65).

Differences between post-rinsing GI and PI scores were also evaluated by ANOVA test [Tables 3 and 4]. Table 3 shows a very highly significant difference for post-rinsing GI scores between the 3 groups at probability value 0.0001 and F value 28.456. Table 4 shows that there was a very high significant difference for post-rinsing PI scores between the 3 groups at probability value 0.0001 and F value 32.362. Furthermore, the differences in GI and PI scores between the 3 groups at post-rinsing stage were also evaluated by't'-test [Tables 5 and 6]. Table 5 and Figure 3 shows the difference of post-rinsing GI scores between the group A and group B was non-significant at probability value 0.806 and 't' value 0.247, this difference was highly significant between groups A and C at probability value

0.000 and 't' value 6.212, and the difference between groups B and C was also highly significant at probability
0.000 and 't' value 6.801.

Table 6 and Figure 4 shows the difference of post-rinsing PI scores between the groups A and B was non-significant at probability value 0.076 and 't' value 1.807, this difference was highly significant between groups A and C at probability value 0.000 and 't' value 8.417, and the difference between groups B and C was highly significant at probability 0.000 and 't' value 5.891.

Subjective opinions of the participants were evaluated after 4 days of mouthwash use. Staining (mild brown discoloration of teeth) was found in 9 subjects in group A (estimated visually). 16 subjects in group A reported an unpleasant taste (mild alteration in taste for salty foods/drinks). 11 subjects in group B experienced mild/slight bitter taste. Staining was not observed in group B subjects.

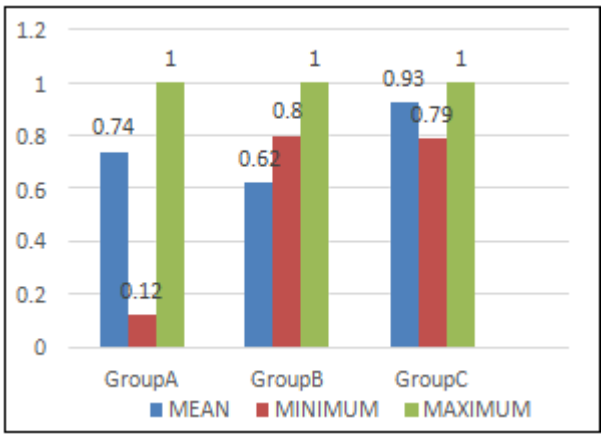

Figure 1: Pre-rinsing Gingival Index scores of different groups

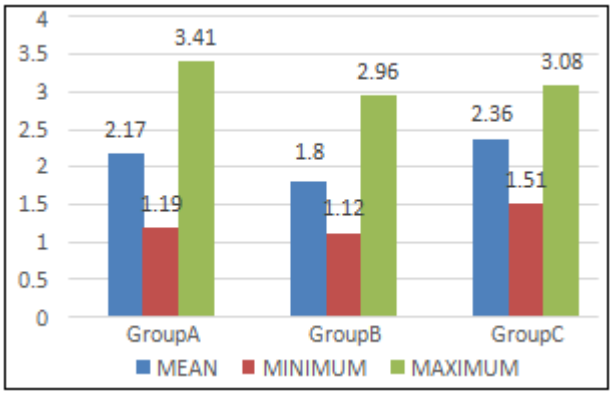

Figure 2: Pre-rinsing Plaque Index scores of different groups

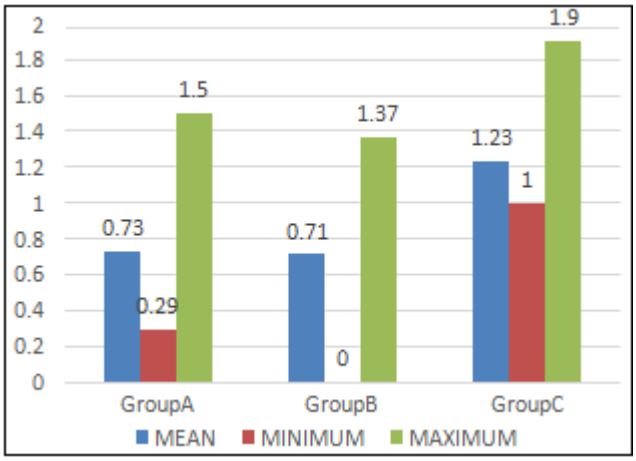

Figure 3: Post –rinsing Gingival Index scores of different groups

Table 4: ANOVA for post-rinsing plaque index scores of different groups

Source of variation	Sum of squares	Degrees of freedom	Mean square	F	P Value
Between groups	23.082	2	11.541	32.362	<0.0001 VHS
Within groups	31.026	87	0.357		
Total	54.108	89			

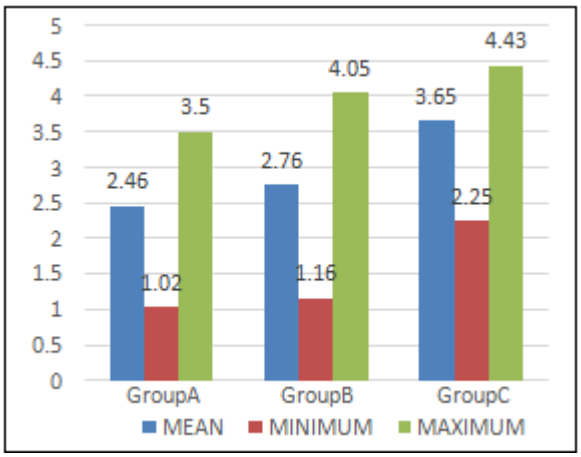

Figure 4: Post-rinsing Plaque Index scores of different groups.

Table 1: ANOVA for pre-rinsing gingival index scores of different groups

Source of variation	Sum of squares	Degrees of freedom	Mean square	F	P Value
Between groups	1.449	2	0.725	14.083	<0.000 1 VHS
Within groups	4.477	87	0.51		
Total	5.926	89			

Table 2: ANOVA for pre-rinsing plaque index scores of different groups

Source of variation	Sum of squares	Degrees of freedom	Mean square	F	P Value
Between groups	4.736	2	2.368	9.441	<0.000 1 VHS
Within groups	21.884	87	0.252		
Total	26.620	89			

Table 3: ANOVA for post-rinsing gingival index scores of different groups

Source of variation	Sum of squares	Degrees of freedom	Mean square	F	P Value
Between groups	5.351	2	2.676	28.456	<0.000 1 VHS
Within groups	8.181	87	0.094		
Total	13.532	89			

Table 5: 't' values for post-rinsing gingival index score of the different groups

Groups	Mean	Mean	't' Value	Probability	Significance
Group A & B	0.73	0.71	0.247	0.806	NS
Group A & C	0.73	1.23	6.212	0.000	VHS
Group B & C	0.71	1.23	6.801	0.000	VHS

Table 6: 't' values for post-rinsing plaque index scores of the different groups

Groups	Mean	Mean	't' Value	Probability	Significance
Group A & B	2.46	2.76	1.807	0.076	NS
Group A & C	2.46	3.65	8.417	0.000	VHS
Group B & C	2.76	3.65	5.891	0.000	VHS

*NS- Not significant *VHS- Very highly significant

4. Discussion

Dental plaque is one of the ecosystems in which a maximum number of microorganisms are observed. The plaque biofilm has been attributed to as one of the main etiological agents for periodontitis [9]. Chemical inhibitors of plaque play an important role in plaque control. A variety of approaches have been considered for chemical plaque control among which mouthwashes are widely accepted [8]. Though a wide array of allopathic anti-plaque agents are available, nowadays, interest has been developed towards the traditional system of medicine in India – Ayurveda, due to the cost and adverse effects of allopathic agents on long term usage [9]. Because of its unique combination of herbs, herbal mouthwashes possess various beneficial properties like antiseptic (due to the presence of tulsi, neem), antibiotic (due to the presence of khadirchaal), analgesic (by virtue of tulsi, ajwain, clove oil), astringent (by virtue of bakulchaal, khadirchaal) and anti- inflammatory and immunity booster (due to the presence of triphala) [4]. Chlorhexidine was developed in 1950, which is considered as gold standard till date and most common anti plaque agent. However, long-term use of Chlorhexidine is limited by altered taste perception and staining of tooth [15].

Present study was designed to evaluate the antiplaque efficacy of herbal and 0.2% Chlorhexidine gluconate mouth wash. As evident from the results of the study, there was no significant difference between GI and PI scores of the 3 groups at pre-rinsing stage. Furthermore, there was no significant difference in the mean age of subjects in the 3 groups indicating the sample was homogenous. Mean GI at post-rinsing stage was least with group B subjects (0.71), followed by group A (0.73) and then group C (1.23). Similarly, mean PI at post-rinsing stage was least with group A subjects (2.46), followed by group B(2.76) and then group C (3.65).Differences between post-rinsing GI (p value-0.968) and PI scores (p value-0.125) were also evaluated by ANOVA test and shows that no statistical significant difference between group A and B, whereas this difference was highly significant between group A and C (P value-< 0.005) and between B and C (P value- < 0.005).

The current study findings revealed that the anti-plaque and anti-gingivitis effects of Herbal mouth rinse were like that of 0.2% Chlorhexidine and significantly better than rinsing with Normal Saline. The findings of the present study were similar to the studies conducted by **Malhotra R et al**.in 2011 [4] and **Prashant R Shetty**etal.in 2013 [19] with respect to anti-plaque efficacy, that Chlorhexidine has the best anti-plaque effect compared to the Herbal mouth rinse whereas these studies are contradictory in relation to the anti-gingivitis effect, as the Herbal mouth rinse has better anti-gingivitis effect when compared to that of Chlorhexidine in the present study.

Among Group C subjects using Normal Saline, no improvement was seen in mean plaque and gingival scores which was similar to the study conducted by **Parwani *et al***.[8] in 2008 who found that least post- rinsing GI and PI scores were demonstrated with 0.2% Chlorhexidine gluconate mouthwash, followed by herbal mouthwash compared to normal saline.

Khalessi et al.[16] in 2004 compared the oral health efficacy of PersicaTM mouthwash (containing an extract of Salvadora persica) with that of a placebo, for a three- week period and concluded that the use of PersicaTM mouthwash resulted in improved gingival health and lower carriage rate of cariogenic bacteria. Neither the Persica nor the placebo reduced the accumulation of dental plaque.

Aspalli S et al. [20] in 2014 evaluated the efficacy of herbal mouthwash on reduction of plaque and gingivitis and concluded that herbal mouth wash is effective in treatment of plaque induced gingivitis and can be effectively used as an adjunct to mechanical therapy with lesser side effects.

Almas K et al. [17] in 2005 assessed the anti-microbial activity of eight commercially available mouth rinses and 50% miswak extract against seven microorganisms and concluded that mouth rinses containing chlorhexidine was with maximum antibacterial activity, all of which are in agreement with the present study.

Waghmare PF et al.[18] in 2011 compared the efficacy of turmeric mouthwash and chlorhexidine gluconate mouthwash in prevention of gingivitis and plaque formation and concluded that Chlorhexidine gluconate has been found to be more effective when anti-plaque property was considered which was in agreement with the anti-plaque efficacy of the present study.

Chlorhexidine, till date is the proven most effective anti-plaque agent. However, its prolonged usage is limited due to discolorations, taste disturbances etc. On the other hand, Herbal mouthwash due to its natural ingredients has no reported side effects and serves as a good alternative [9].

5. Conclusion

Within the limitations of this 4-day “de novo” plaque formation study, it was concluded that 0.2% Chlorhexidine rinse has a better anti-plaque efficacy, while Herbal rinse has better anti-gingivitis effect. But, owing to the side effects and cost efficacy of Chlorhexidine, Herbal rinse can be used as an alternative because of its biocompatibility and acceptance by the patient. However, further studies with a large sample size and long-term follow-up are needed to extrapolate the advantages and dis-advantages of this herbal product.

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