



### RESEARCH ARTICLE

## A COMPARATIVE CLINICAL EVALUATION OF MULTI-HERBAL AND 0.2% CHLORHEXIDINE MOUTH WASH ON PLAQUE AND GINGIVITIS CONTROL : A RANDOMIZED CLINICAL TRIAL

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### Manuscript Info

### Abstract

#### Manuscript History

Received: 30 November 2019

Final Accepted: 31 December 2019

Published: January 2020

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### Introduction:-

Dental Plaque is the main etiological factor in gingival inflammation and has been found to be associated with the initiation and progression of periodontal diseases. Various epidemiological and clinical research studies concluded that plaque-induced gingivitis precedes Periodontitis<sup>1, 2</sup>. So that the periodontal diseases are mainly prevented by control of supra gingival plaque.

Supra gingival plaque can be controlled by mechanical and chemical methods. The mechanical plaque control is the most effective oral hygiene measure but acceptable plaque removal requires time, motivation and manual dexterity<sup>3</sup>. This, in turn, has led to exploring additional benefits from chemotherapeutic anti-plaque agents. These agents can decrease the rate of new plaque accumulation, decrease or remove existing plaque, suppress the growth of pathogenic microflora or inhibit the production of virulence factors<sup>4</sup>. Various modes of delivery for these anti plaque agents include tooth pastes, chewing gums, irrigators, sprays, varnishes and mouth washes<sup>5</sup>.

Mouthwashes have proved to be simple, safe and effective delivery system and play a major role in plaque reduction<sup>6</sup>. The first reference to mouth rinsing around 2700 B.C. is credited to Chinese medicine literature for treatment of gingival diseases by rinsing with urine of the child. We have come a long way since then to the use of Chlorhexidine (CHX) now for over three decades.

Chlorhexidine (CHX) is the most well-known anti-plaque agent. Its molecules inhibit bacterial adhesion, bacterial growth and biofilm formation, and are bactericidal at higher concentration as they damage the bacterial cell membrane<sup>7,8,9,10,11</sup>. However, due to undesirable effects after prolonged use, such as pigmentation and taste disturbance<sup>12,13</sup>, herbal agent had been researched recently showing encouraging results<sup>13,14,15,16,17</sup>.

Herbal mouthwash has been considered to be a more advantageous option to their chemical counterparts, for a long term use. Himalaya complete care mouth wash contains an active combination of Miswak, Pomegranate and Neem. Miswak inhibits the build-up of dental plaque and is therefore beneficial in the prevention of gingivitis. It reduces gingival inflammation, prevents gingival bleeding and has an astringent property which strengthens gums. Pomegranate fruit rind has astringent, antibacterial and antioxidant properties. Studies showed that pomegranate helps to combat dental plaque<sup>18</sup>. Neem is a herb for total oral hygiene. Neem bark possesses phenolic and antioxidant activity and also has anti-inflammatory and antimicrobial properties.

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Taking into consideration the side effects of Chlorhexidine and the liking or faith of people for herbal/natural products, the present study was conducted with an aim to compare the anti-plaque efficacy of 0.2% Chlorhexidine mouthwash and the herbal mouthwash (Himalaya complete care mouthwash).

### **Materials and Methods:-**

The present study was an examiner-blinded, randomized parallel designed clinical trial carried out in Department of Periodontics, Lenora Institute of Dental Sciences, Rajamahendravaram, Andhra Pradesh, India. The sample size was determined using (SPSS version 20.0, IBM Corporation) software-based means obtained from a previous study. The calculated sample size was 40 per Group and was allocated to Two Groups respectively.

Total of 80 subjects (age range of 18 to 35 years) were randomly divided into two Groups (40 in each) using lottery method with different ages to define the various strata. The primary investigator was involved in the random allocation sequence and enrolment of participants to the assigned groups. This lottery method randomization process ensured that there was no selection bias in the recruitment and allocation of study participants to the intervention groups, which can be considered as the strength of the present study. The ethical clearance for the study was obtained from the Institutional Ethical Committee. Informed consent was taken from all the subjects of the study.

Materials used were diagnostic instruments including mouth mirror, probes, explorers, scalers, polishing cups, abrasive paste, disclosing agent, 0.2% Chlorhexidine mouthwash, herbal mouthwash.

### **Inclusion criteria:**

Systemically healthy subjects with a dentition of  $\geq 20$  teeth with a minimum of 5 teeth per quadrant having mild to moderate gingivitis were enrolled in this study.

### **Exclusion criteria:**

Subjects with severe mal-alignment of teeth, orthodontic appliance, removable partial denture, tobacco consumers, pregnant and lactating women and subjects with the medical or pharmacological history that could compromise the conduct of the study were excluded.

### **Study design:**

In all the selected subjects oral hygiene status was assessed by Plaque index – (Turskey et al. modification of Quigley Hein index), Gingival index (Loe and Silness 1964) and Sulcus bleeding index – (Muhlemann and Son, 1971). 1% erythrosine solution was used to disclose plaque and base line plaque index, gingival index and sulcus bleeding index score were recorded. Through scaling and polishing with rubber cups and an abrasive paste were done. Then the subjects were assigned randomly into two groups. GROUP 1: 0.2% Chlorhexidine mouthwash (n=40), GROUP 2: Multi-herbal mouthwash (n=40, Himalaya complete care mouth wash).

After the initial examination, a personal kit containing a new tooth brush and 0.2% CHX or herbal mouth rinse (600 ml) was given in Bottles of identical appearance to each subject who was blinded to the mouth wash received. All the subjects were instructed to brush their teeth with a fluoridated dentifrice two times a day for 1 min using their habitual technique. After 30 min, the participants were instructed to rinse for 1 min with one of the mouth rinses and then expectorate it. Verbal and written instructions about the correct use of mouth wash were given to all subjects. After 30 days plaque index, gingival index, sulcus bleeding index were recorded and the teeth were polished with abrasive paste. In addition, the hard and soft tissues of the oral cavity were visually inspected for the presence of any adverse effect. All clinical recording was done by single examiner.

### **Statistical analysis:**

The data were carried out using a computer software program (SPSS version 20.0, IBM Corporation). Comparison of clinical findings in both groups from base line and after 1 month were evaluated by Wilcoxon sign rank test. Comparison of all clinical findings between two groups from base line and after 1 month were evaluated by Mann-Whitney U test.

### **Results:-**

All the subjects sincerely followed the protocol of the study, none of them showed any adverse reaction with different formulations.

Table 1 explains the highly significant reduction of clinical parameters including plaque index, gingival index and sulcus bleeding index from base line to 1 month in group 1 subjects.

Table 2 explains the highly significant reduction of clinical parameters including plaque index, gingival index and sulcus bleeding index from base line to 1 month in group 2 subjects.

When comparison of clinical parameters including plaque index, gingival index and sulcus bleeding index between the groups were done from base line to 1 month there was no statistically significant difference were observed as shown in Table 3, 4 & 5.

**Table 1:-** Comparison of Clinical parameters from baseline to 1 month in Group 1.

|          | Plaque index   | Gingival index | Sulcus Bleeding index |
|----------|----------------|----------------|-----------------------|
| Baseline | 1.73±0.64      | 1.52±0.5       | 1.85±0.74             |
| 1 month  | 0.79±0.16      | 0.78±0.23      | 1.8±0.76              |
| Z value  | -3.921         | -3.924         | -4.041                |
| P value  | <0.0001** (HS) | <0.0001** (HS) | <0.0001** (HS)        |

Test applied: Wilcoxon sign rank test HS: Highly- significant

**Table 2:-** Comparison of Clinical parameters from baseline to 1 month in Group 2.

|          | Plaque index | Gingival index | Sulcus Bleeding index |
|----------|--------------|----------------|-----------------------|
| Baseline | 1.71±0.57    | 1.54±0.47      | 1.8±0.76              |
| 1 month  | 0.74±0.2     | 0.8±0.18       | 0.4±0.25              |
| z value  | -3.921       | -3.923         | -4.045                |
| P value  | <0.0001 (HS) | <0.0001 (HS)   | <0.0001 (HS)          |

Test applied: Wilcoxon sign rank test HS: Highly- significant

**Table 3:-** Comparison of Plaque index between Group 1 and Group 2

|          | Group 1   | Group 2   | Mann Whitney U value | P value   |
|----------|-----------|-----------|----------------------|-----------|
| Baseline | 1.73±0.64 | 1.71±0.51 | 186.5                | 0.714(NS) |
| 1 month  | 0.79±0.16 | 0.74±0.2  | 157.5                | 0.248(NS) |

Test applied: Mann-Whitney U test NS- Not-significant

**Table 4:-** Comparison of Gingival index between Group 1 and Group 2

|          | Group 1   | Group 2   | Mann Whitney U value | P value   |
|----------|-----------|-----------|----------------------|-----------|
| Baseline | 1.52±0.5  | 1.54±0.47 | 195.5                | 0.902(NS) |
| 1 month  | 0.78±0.23 | 0.8±0.18  | 192.5                | 0.838(NS) |

Test applied: Mann-Whitney U test NS- Not-significant

**Table 5:-** Comparison of sulcus Bleeding index between Group 1 and Group 2

|          | Group 1   | Group 2  | Mann Whitney U value | P value   |
|----------|-----------|----------|----------------------|-----------|
| Baseline | 1.85±0.74 | 1.8±0.71 | 200.00               | 1(NS)     |
| 1 month  | 0.4±0.25  | 0.4±0.25 | 192.00               | 0.816(NS) |

Test applied: Mann-Whitney U test NS- Not-significant

## Discussion:-

Periodontitis starts with inflammatory lesion of the gingiva which, if left untreated, with time may progress and eventually involve and compromise the entire periodontal attachment apparatus of the affected teeth. This fact suggests that the prevention of periodontal disease should be based on measures of supra gingival plaque control which prevents gingivitis<sup>19</sup>. Ideally, supra gingival plaque control should prevent periodontal tissue inflammation and break down. However, since complete plaque removal is unrealistic, prevention may be achieved by both mechanical and chemical plaque control methods.

In this scope, Chlorhexidine is considered the gold standard anti-plaque and anti-gingivitis agent. It is a cationic bis-biguanide and most widely used the member of the class of broad-spectrum antiseptics. It is effective against an array of micro-organisms and exhibits anti-bacterial properties. It acts by altering the integrity of cell membrane of bacteria. However, several side effects associated with its use have stimulated the search for alternative agents. Herbal agents have been researched recently showing encouraging results<sup>13,14,15,16,17</sup>. So the present study was

carried out to assess the clinical effectiveness of 0.2% chlorhexidine and Himalaya complete care herbal mouth wash.

Himalaya complete care herbal mouth wash contain Miswak, Pomegranate and Neem. Miswak contains salvadorine, trimethylamine, vitamin C and tannins which helps in remarkable antimicrobial and astringent effects<sup>20</sup>. Polyphenolic molecules of pomegranate aid in inhibition of the three main periodonto pathogens including *P. intermedia*, *P. gingivalis* & *A. a* and an improvement in the level of anti-oxidant concentration. So the mouthwash consisting of pomegranate will be able to fight against plaque and tartar formation because it prevents microorganisms from attaching to the tooth surface. They have been able to bring about the significant reduction in the activity of the enzyme aspartate aminotransferase and increased activity of the antioxidant enzyme ceruloplasmin<sup>21,22</sup>. *Azadirachta indica* (Neem) is found to be beneficial in reducing the plaque index and salivary bacterial count comparatively better than chlorhexidine mouthwash<sup>23</sup>.

In our study there was highly significant reduction in clinical parameters including Plaque index, Gingival index and Sulcus bleeding index from baseline to 1 month in both groups. This is because of anti-plaque and anti-gingivitis effect of both 0.2% CHX and herbal mouth wash. Results were in accordance with studies done by Irwin D et al, Chatterjee A et al, and A M Khalessi et al<sup>24,25,26</sup>.

The clinical parameters (PI, GI and SBI) between two groups from base line to 1 month, no statistically significant difference was observed. This means that anti-plaque and anti-gingivitis properties of chlorhexidine and herbal mouthwash are similar. This is in accordance with studies conducted by Faris Yahya I Asiri et al and Bagchi S et al<sup>27,28</sup>. Therefore the herbal mouthwash can be considered to be used as an alternative to Chlorhexidine and can be prescribed for longer duration without any side effects for management of periodontal diseases.

### Conclusion:-

The emergence of antimicrobial resistance is currently posing a major global challenge, with an increasing number of microorganisms becoming resistant to commonly used antibiotics. Hence new approaches for the control of plaque-associated periodontal disease are the need of the hour. Our study concluded that multi - herbal mouth wash has an efficacy which is comparable to the anti-plaque agent 0.2% Chlorhexidine mouth wash. Considering side effects associated with Chlorhexidine, herbal mouth wash (Himalaya complete care) can be considered as a viable alternative. However, studies with long term rinsing period should be carried out to delineate the advantages and disadvantages associated with this herbal mouth wash.

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