

## COMPARISON OF THE ANTIGINGIVITIS AND ANTIPLAQUE EFFICACY OF THE HERBORAL (HERBAL EXTRACT) MOUTHWASH WITH CHLORHEXIDINE AND LISTERINE MOUTHWASHES: A CLINICAL STUDY

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### ABSTRACT

*The study was done to compare the anti gingivitis and antiplaque efficacy of Herboral with CHX and Listerine and to assess the side effects of the mouthwashes, if any.*

*It was a single-centre, double-blind, parallel group and oral hygiene controlled clinical trial. 60 participants were equally divided into 3 groups: Herboral, CHX, and Listerine. These groups were asked to rinse with their respective mouthwash 2 times daily for 15 days. Gingivitis was evaluated by using Loe and Silness index (1963), and plaque was evaluated by using the Turesky modification of the Quiely Hein index (1970). The evaluation was carried out at the end of 15 days, 1 month, and 3 months.*

*Intragroup comparison for plaque and gingival scores was done using “t” test. Intergroup comparison was done using ANOVA and Tukey test.*

*At the end of 15 days, all three mouth rinses were effective in reducing the mean scores [gingivitis / plaque]: Herboral [0.34 / 1.0], Chlorhexidine [0.22 / 1.18] and Listerine [0.86 / 1.67]. At the end of 30 and 90 days the plaque and gingival scores had increased in all the three groups, more in the Listerine group. The use of CHX showed brown staining, whereas Listerine gave a burning sensation.*

*As an antiplaque and antigingivitis agent, the Herboral mouthwash is as effective as Chlorhexidine (CHX) and more effective than Listerine.*

**Key Words:** *Plaque, gingivitis, herbal extract, Herboral mouthwash.*

### INTRODUCTION

In Ayurveda, dental health (*dantaswasthya*) is determined by two factors, the constitution (*prakriti*) of each person and the climatic changes resulting from the solar, lunar, and planetary influences (*kala-*

*parinama*).<sup>1</sup> In dental sciences, it is believed that dental plaque is the main etiological factor that causes caries, gingivitis and periodontal disease. Although brushing the teeth is considered the most effective method of cleaning the teeth<sup>2</sup> and controlling plaque, mouthwashes are widely used as adjuncts to tooth-brushing and in delivering active agents to the teeth and gums.<sup>3</sup> Chlorhexidine (CHX) and Listerine are the two very popular brands of mouthwashes that have always been prescribed by clinicians.

Chlorhexidine (CHX) is regarded as the ‘gold standard’ antiplaque treatment and is particularly effective against gingivitis. This mouthwash is widely used as an adjunct treatment for periodontitis.<sup>4</sup> However, most practitioners do not recommend the long-term and daily use of CHX as a mouthwash. This is mainly

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**Received for Publication:** December 18, 2012

**Revision Received:** January 22, 2013

**Revision Accepted:** January 28, 2013

because of its side effects, such as objectionable taste, tooth discoloration, desquamation, and soreness of oral mucosa.<sup>5</sup> The activity of this mouthwash is pH-dependent and is greatly reduced in the presence of organic matter.<sup>5</sup> The side effects caused by this mouthwash limit the acceptability to users and the long-term use of a 0.2% CHX antiseptic in preventive dentistry. Manufacturers have tried to modify the taste of their mouthwashes, but the bitter taste of CHX is evidently difficult to mask.

Listerine (List) is an essential oil containing mouthwash that is available over the counter. Listerine (List) has been reported since the 1890s.<sup>6</sup> Short-term and long-term clinical studies have indicated that the daily use of List (Pfizer), a mouthwash that contains phenolics such as thymol, eucalyptol, menthol, and methyl salicylate, may retard plaque buildup and reduce gingivitis.<sup>5,7-14</sup> The effect of List on plaque was ascribed to its bactericidal properties that were documented in-vitro and in-vivo.<sup>11,15,16</sup> Phenolic compounds, however, are also known to interfere with the inflammatory process.<sup>17,18</sup> Therefore, it was observed that when List was used as a mouthwash two times daily for 6 weeks, it had limited influence on plaque, but was effective in reducing gingival inflammation similar to CHX.<sup>19</sup> Other studies with a similar study design<sup>16,20</sup> showed that the regular use of List failed to retard plaque-associated gingivitis.

With the continuous need to counter the adverse effects, improve the antiplaque and antigingivitis potential, and to reduce the increasing microbial resistance to conventional antiseptics and antibiotics, attention is now turning to the use of natural antimicrobial compounds (herbal extracts). In 1989, a patent had been filed at the European Patent Office (#0341795A1) stating that the combination of herbal extracts leads to the synergistic reduction of both dental plaque and gingival bleeding.

Herbal products are being used in India since ancient times for the treatment of various ailments. Of late, the commercial use of these products in toothpaste and for oral irrigation delivery has increased manifold. Some of the natural or herbal products and their extracts, such as guava, pomegranate, neem, propolis, tulsi, green tea, cranberry, and grapefruit, when used in mouthwashes have shown significant advantages over the chemical ones.<sup>3</sup>

Herboreal is a herbal liquid gargle prepared by M Tech Innovations (India),<sup>21</sup> claims to act as an oral antiseptic and prevent tooth decay. It also claims to prevent bad breath and mouth ulcers and help in gum tightening. It does not contain alcohol and sugar and is prepared with time-tested active ingredients like:

Bakul Chaal (*Mimusops Elengi*), Neem Paan (*Azadirachta Indica*), Clove oil (*Caryophyllus Aromaticus*), Tulsi Patra (*Ocimum Sanctum*), Triphala (*Three Myrobalans*), Pudina Ke Phool (*Metha Spicata*), Khadir Chaal (*Acacia catechu*), Jyeshthiamadh (*Glycyrrhiza Glabra*), Ajivan ke Phool (*Apium Gracilens*) and Maypal (*Quercus Infectoria*). This mouthwash consists of substances that are mentioned in the ayurvedic science for care of teeth (*Dantadhavana*).<sup>22</sup>

With the background that CHX has various adverse effects and Listerine has a limited antiplaque effect, the current study was designed to evaluate if Herboreal can be a better choice. The aim of the study was to compare the antigingivitis and antiplaque efficacy of Herboreal (herbal extract mouthwash) with the CHX (bis-biguanide) and Listerine (phenolic compound) mouthwashes and to assess the side effects of these mouthwashes, if any. The null hypothesis of the study was that the Herboreal, CHX, and Listerine mouthwashes have the same antiplaque and antigingivitis efficacy.

## METHODOLOGY

It was a single centre, double blind, parallel group, oral hygiene controlled clinical trial. 60 subjects in the age group 18 to 54 years (mean age 44.6 ± 10.5 years) participated in the study. Of the 60 subjects, 39 were females and 21 were males. The selection criteria was that the subjects should have a minimum of 20 teeth with a Loe and Silness<sup>23</sup> gingival index score of more than 2 and Turesky modification of Quiely Hein index,<sup>24,25</sup> score of more than 1.8. Subjects who had destructive periodontal disease or who had undergone a periodontal surgery in the past three months were excluded from the study.

The screening and clinical examinations were carried out at the department of Periodontics, Dental College and Hospital. All subjects signed an informed consent form. They were also given a patient information sheet that detailed the procedure of the study and included instructions. The study design (Fig 1) was approved by the Institutional Ethics Committee.

## STUDY PROCEDURE

**Day 0:** The subjects received a complete prophylaxis, including scaling and professional tooth cleaning, to minimize the existing gingivitis prior to using the mouthwash.

**Day 16 (Baseline):** 15 days after oral prophylaxis, the subjects were called. The baseline scores of plaque and

gingivitis were recorded. They were then randomly allocated to one of the following three groups:

- Group H: Herbal mouthwash [20 ml of Herboral mouthwash to be rinsed for 30 seconds]
- Group C: Chlorhexidine (CHX) mouthwash [10 ml of Hexidine to be rinsed for 30 seconds]
- Group L: Listerine [20 ml of Listerine to be rinsed for 30 seconds]

Each subject was identified by a code. The label indicating the name of the mouthwash was removed. At no point in time did the subjects of the 3 groups interact with one another. The subjects from the 3 groups were called on separate days for examination. They rinsed with their respective mouthwash 2 times daily for 15 days. They were given written instructions on how to use the mouthwash. To check for compliance, the subjects were asked to note the times at which they rinsed. They were instructed to refrain from using any other commercial mouthwash during the study period. They were advised to use a non-therapeutic, low abrasive dentifrice (Colgate Dental Cream) and a soft nylon

toothbrush (Colgate brand). The mouthwashes were commercially purchased from the market.

**Day 31 (15 days follow up):** The subjects were called at the end of the mouth rinsing phase. The plaque and gingivitis index scores were recorded. The subjects were instructed to follow the routine plaque control measures with the recommended toothbrush and paste for the next 3 months.

**Day 46 (1 month follow up) and day 106 (3 months follow up):** The subjects were called and the gingival and plaque indices were recorded.

A blinded examiner recorded the indices scores. The subjects were instructed to refrain from eating or drinking 2 hours prior to the examination. The plaque scores were recorded by using the Turesky modification of Quiely Hein index<sup>24,25</sup> and the gingival scores were recorded by using the Loe and Silness index.<sup>23</sup>

The side effects of the mouthwashes were assessed by visually examining the labial surfaces of the 12

TABLE 1: THE MEAN AND STANDARD DEVIATION OF GINGIVAL INDEX SCORES FOR HERBORAL, CHX AND LISTERINE GROUP AND THE RESULTS OF ANOVA ,TUKEY TEST AND ‘T’ TEST

	<b>Herboral Group Mean±SD</b>	<b>CHX Group Mean±SD</b>	<b>Listerine Group Mean±SD</b>	<b>ANOVA F value (p-value)</b>	<b>Tukey test</b>
Baseline	1.88±0.26	1.87±0.25	1.90±0.14	0.0609 (0.94)	
15 days	0.34±0.44	0.22±0.39	0.86±0.76	7.3884 (0.00*)	Hvs C=NS Hvs L=S*
30 days	1.03±0.49	0.71±0.60	1.26±0.48	5.3032 (0.00*)	HvsC=NS HvsL=NS
90 days	2.09±0.14	2.09±0.15	2.23±0.30	2.6713 (0.46)	
<b>Intra group comparison "t" test value (p-value)</b>					
Baseline-15 days	14.61 (0.00*)	17.37 (0.00*)	6.19 (0.00*)		
15 -30 days	-4.55 (0.00*)	-3.49 (0.00*)	-2.09 (0.00*)		
30-90 days	-9.58 (0.00*)	-9.63 (0.00*)	-7.25 (0.00*)		
Baseline-96 days	-2.86 (0.00*)	-3.13 (0.00*)	-4.18 (0.04*)		

\*statistically significant . Tukey test performed where ANOVA was statistically significant.

TABLE 2: THE MEAN AND STANDARD DEVIATION OF PLAQUE INDEX SCORES FOR HERBORAL, CHX AND LISTERINE GROUP AND THE RESULTS OF ANOVA , TUKEY TEST AND ‘T’ TEST

	<b>Herboral Group</b> Mean±SD	<b>Chlorhesidine Group</b> Mean±SD	<b>Listerine Group</b> Mean±SD	<b>ANOVA F value</b> (p-value)	<b>Tukey test</b>
Baseline	2.89±0.31	2.91±0.51	2.96±0.32	0.1444 (0.86)	
15 days	1.00±0.12	1.18±0.21	1.67±0.13	91.042 (0.00*)	Hvs C=NS HvsL=S*
30 days	1.71±0.14	1.84±0.37	1.87±0.16	2.2179 (0.11)	
90 days	2.31±0.21	2.10±0.30	2.37±0.22	6.1847 (0.00*)	Hvs C=S* HvsL=NS
<b>Intra-group comparison ‘t’ test value (p-value)</b>					
Baseline-15 days	26.95 (0.00*)	14.98 (0.00*)	17.44 (0.00*)		
15 -30 days	-18.25 (0.00*)	-7.84 (0.00*)	-6.68 (0.00*)		
30-90 days	-14.83 (0.00*)	-3.14 (0.00*)	-8.12 (0.00*)		
Baseline-90 days	10.54 (0.00*)	7.21 (0.00*)	8.53 (0.00*)		

\*statistically significant . Tukey test performed where ANOVA was statistically significant.

anterior teeth for extrinsic stains at 15 days and at the end of 3 months. The subjects were interviewed about the taste of the mouthwash (agreeable or disagreeable), altered taste sensation, and presence of any burning sensation in the mouth.

**STATISTICAL ANALYSIS**

Intragroup comparison of the plaque and gingival scores were done using the “t” test and intergroup comparison was done using the ANOVA and Tukey tests. The level of significance was fixed at 5%.

**RESULTS**

59 subjects completed the study (one drop out from CHX group) . At the end of the mouthrinsing phase, the lowest gingival score of 0.22 was recorded for the CHX group and the lowest plaque score of 1.0 was recorded for the Herboral group. The comparison of scores is explained in Table 1 and Table 2.

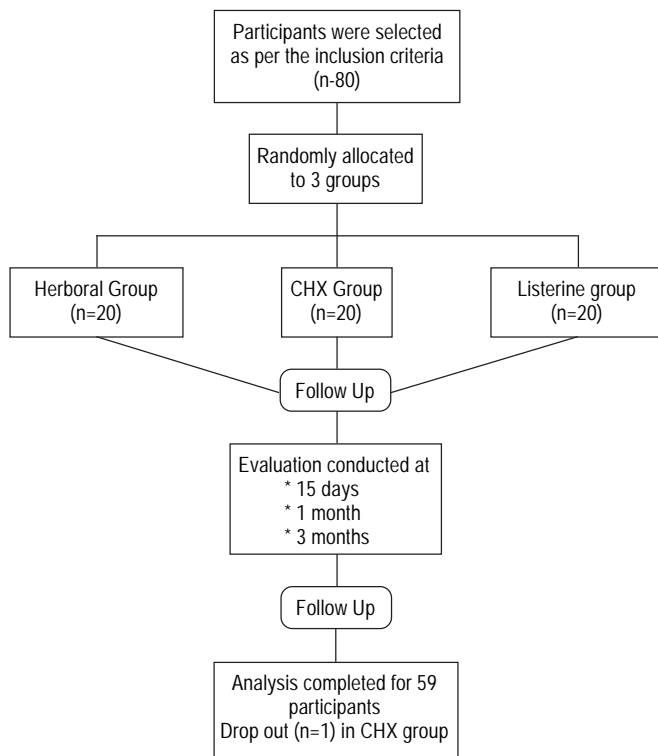
Table 1: At baseline, the 3 groups were similar. At the end of 15 days, there was a significant reduction in the gingival scores in all the 3 groups. Statistically, the Herboral group (0.22) presented a significantly lower

mean gingival score than the Listerine group (0.86). At the end of 30 days, the scores in all 3 groups had significantly increased. At the end of 90 days, the index score had increased, the score was similar in the Herboral (2.09) and CHX groups (2.09), but more in the Listerine group (2.23), although the difference was not statistically significant. Intra-group comparison showed that, as compared to the baseline mean scores, there was a marked reduction at the end of 15 days, but from then on, the mean scores had increased when recorded at the end of 30 days and 90 days. This phenomenon was observed in all the 3 groups.

Table 2: At baseline, the 3 groups were similar. At the end of 15 days, the Herboral group (1.0) presented a statistically significant lower mean plaque score than the Listerine group (1.67). At the end of 30 days, the scores had increased in all the 3 groups. At the end of 90 days, the index scores had increased. The mean score in the Herboral group (2.31) was significantly more as compared to the CHX group (2.10). Intragroup comparison showed that, as compared to the baseline mean plaque scores, there was a marked reduction at the end of 15 days. But from then on, the means score had increased when recorded at the end of 30 days and

90 days. Similar to the gingival mean scores, this phenomenon was again observed in all the 3 groups.

With regards to the side effects of the mouthwashes, extrinsic stains (n=8) and altered taste sensation (n=2) was reported by the subjects in the CHX group only. However, only 1 subject in the Herbal group and 19 subjects in the Listerine group reported of burning sensation in the mouth.



**DISCUSSION**

The trial demonstrated that the use of the Herbal mouthwash resulted in a significant reduction of gingivitis and plaque at the end of the mouthrinsing phase. At the end of the study, half of the null hypothesis was accepted. This half stated that the Herbal and CHX mouthwashes had a similar antigingivitis and antiplaque efficacy. The second part of the null hypothesis, which stated that Herbal and Listerine have similar efficacy, was rejected. This is because Herbal proved to be superior in the antigingivitis and antiplaque action as compared to Listerine.

Herbal remedies traditionally used to help combat gum bleeding and gingivitis include mouthwash, dental oils and herbal supplements.<sup>22</sup> Herbal is a herbal preparation that is made from 10 natural herbs. Malhotra R et al (2011),<sup>26</sup> in his study, has explained the action of the combination of these herbs in the Herbal mouthwash. It possesses various beneficial properties: antiseptic (because of the presence of *tulsi*

and *neem*), antibiotic (because of the presence of *khadirchaal*), analgesic (by virtue of *tulsi*, *ajwain*, and *clove oil*), astringent (by virtue of *bakulchaal* and *khadirchaal*), and anti-inflammatory and immunity booster (because of the presence of *triphala*). In addition, *maypal* that is present in Herbal can be used to cure gum diseases and whiten teeth. *Jyestiamadh* can be used against mouth ulcers. Apart from these, Herbal is a non-alcoholic preparation, with no added sugar, no artificial preservatives, no artificial flavors and colors, and absolutely no side effects.

CHX is considered the gold standard because of its superior antiplaque effects, which is a result of its superior degree of persistence on the tooth surface. As compared to this benchmark, Herbal was equally effective. CHX rinsing can cause a number of local side effects, such as extrinsic tooth and tongue brown staining, taste disturbance, and enhanced supragingival calculus formation. CHX rinsing can also cause desquamation of the oral mucosa<sup>26</sup>, but this is less common. On the other hand, because of its natural ingredients, Herbal does not cause any side effects. Therefore, Herbal can be safely considered for long-term use.

Only one study in the literature can be traced. This study was conducted by Malhotra R et al (2011),<sup>26</sup> which evaluated the antiplaque effectiveness of Herbal and CHX mouthwashes by using a 3-day *de novo* plaque accumulation model with no brushing of the teeth among dental students. The results showed that the Herbal mouthwash was a potent plaque inhibitor, but less effective than CHX. This was contrary to the results of the study.

In the current study, the Herbal mouthwash was found superior to Listerine as an antiplaque and antigingivitis agent. However, no studies in the literature can be retrieved to support or refute this finding. Singh A et al(2012),<sup>27</sup> studied the effect of a new herbal, an essential oil mouthwash and the CHX mouthwash on *de novo* plaque formation. The results indicated that CHX was more efficacious than the new herbal and essential oil mouthwash. In other studies,<sup>28,29</sup> when the essential oil mouthwash was compared to the 0.05% cetylpyridinium chloride mouthwash, the former was more superior in reducing plaque and gingivitis. Although Listerine fulfills the consensus criteria for an effective antigingivitis or antiplaque product, because of the ethanol content, the concern over its safety for long-term use remains to be clarified.<sup>30</sup>

Many studies,<sup>26,31-34</sup> use the 3-day *de novo* plaque accumulation and non-brushing model to assess the effect of various mouthwashes. The results drawn from such studies indicate that the assessment was

carried out under experimental conditions. However, in the current study, the mouthwash was used as an adjunct to tooth brushing. Such a study design assesses the actual effectiveness of the mouthwash in a real-life situation.

An important auxiliary finding that is worth the mentioning is that, after the mouth rinsing had stopped, the plaque and gingival index scores increased reaching close to the baseline scores and further rising beyond this limit (Table 1 and 2). This suggests that there is no carryover effect of the mouthwash after rinsing stops. Therefore, while conducting any cross-over clinical trial with mouthwashes, 15 days can be safely considered as the washout period.

The Herbal mouthwash is easy to use and has better after taste as compared to CHX.<sup>26</sup> Given the fact that subjects of the current study reported burning sensation with Listerine and showed brown staining and complained of bitter taste with CHX, it is advisable that clinicians must safely prescribe the Herbal mouthwash to their patients.

This being a short-term study, the results can be used as a baseline data for future studies with similar study design.

## CONCLUSION

Within the limits of the study, it can be concluded that, as an antiplaque and antigingivitis agent, the Herbal mouthwash is as effective as Chlorhexidine (CHX) and more effective than Listerine.

## Acknowledgement

The authors would like to thank the Medilinkers Research Consultancy for providing help during statistical analysis and preparation of the manuscript.

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