

Comparison of a commercially available herbal and 0.2% chlorhexidine mouthrinse for prevention of oral malodor: A clinical trial

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Abstract

Objectives: Despite the adverse effects of chlorhexidine (CHX) in the oral cavity, it is still the most commonly prescribed mouthrinse for halitosis control due to its excellent results. The purpose of this study was to compare the efficacy of a mouthrinse with herbal formulation for halitosis control with 0.2% CHX gluconate containing rinse and to simultaneously assess adverse effects caused by the herbal mouthrinse if any. **Materials and Methods:** Ninety-six systemically healthy subjects with chronic generalized gingivitis were recruited in the study and divided into three groups receiving 0.2% CHX gluconate mouthrinse, herbal mouthrinse, or negative control, respectively as Group A, B, and C. The halimeter scores and organoleptic scores were recorded for each subject at baseline and after scaling. Others parameters recorded were plaque index and gingival index. All scores were reassessed on the 7th and 14th day, respectively. Statistical analysis was performed using Kruskal–Wallis ANOVA, Mann–Whitney U–test, and Wilcoxon matched pairs test. **Results:** There was an overall reduction in the halimeter scores both in Group A and B subjects which were not statistically significant within the groups; this was in accordance with the decrease in the mean organoleptic scores. Reduction in Group C scores was the least and differed statistically from both Group A and B scores. **Conclusions:** The results indicate an equivalent reduction in breath odor by both the herbal mouthrinse and CHX. Furthermore, side effects were less, and patient compliance was more with the herbal mouthrinse, which can thus be prescribed more safely and with predictable outcomes for oral malodor.

Key words: Chlorhexidine, clinical trial, herbal, malodor, mouthrinses

INTRODUCTION

At present, where a lot of research is directed toward more sophisticated procedures for treatment and diagnosis of periodontal diseases, the research directed toward prevention is receiving much less attention. Oral halitosis is a common complaint which has been

recognized since ancient times but has only recently come forward as it can be a significant social handicap in this increasingly sophisticated world. This study was thus directed toward the prevention of oral malodor. The term “oral halitosis” is specific and is used to define halitosis with an origin within the oral cavity. Clinical

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surveys have shown that around 90% of all breath odors originate inside mouth.^[1]

Information on the prevalence of oral halitosis; however, is less due to the lack of epidemiological studies. In a study,^[2] it was found that up to 25% people of the population have volatile sulfur compounds (VSC) in the breath in amounts higher than what is considered to be the socially acceptable limit.

Various means for the reduction of oral malodor can be mechanical agents, chemical agents,^[3] rendering malodorous gases nonvolatile, and masking the malodor. Because of its strong antibacterial effects^[4] and substantivity in the oral cavity chlorhexidine (CHX) gluconate provides a significant reduction in the VSC levels and organoleptic ratings.^[5] Rosenberg *et al.*, 1991^[6] showed that a 0.2% CHX regimen produced a 43% reduction in VSC values and a more than 50% reduction in the organoleptic ratings. However, the beneficial effects of CHX come with an array of adverse effects of which change in taste perturbation^[7] and staining of teeth^[8] can produce discomfort to the patient and can also affect patient compliance. A chemical agent with an efficacy equivalent to that of CHX and less adverse effects will thus be of clinical significance. Sood *et al.* conducted a similar study where they compared the efficacy of oil pulling with sesame oil with that of 0.2% CHX for the reduction of malodor and found it to be equally effective.^[9] Although oil pulling may not be as palatable and acceptable for all the individuals, and a commercial formulation with such products may be more acceptable.

Thus, this study was conducted to compare the efficacy of a mouthrinse having herbal formulation with 0.2% CHX gluconate mouthrinse in the reduction of oral malodor, and adverse effects caused by the herbal mouthrinse if any was noted.

MATERIALS AND METHODS

Participant selection

Plaque scores were taken for sample size calculation for the study. The power of the test was set at 80% with two-sided 5% significance level. The formula used for sample size calculation was $n = \frac{2(S^2)}{d^2} [z_{\alpha/2} + z_{1-\beta}]$. Following which a total of 96 subjects with chronic generalized gingivitis were taken with 32 subjects in each group.

The study was in accordance with guidelines of the Helsinki Declaration as revised in 1975. A written informed consent was taken for each participant after giving detailed information and explanation about the study, and the study was approved by the Institutional Review Board Committee of the Institute. The subjects were included by the following criteria, (1) age range 15–55 years, (2) having chronic gingivitis, and (3) systemically healthy. Whereas the following were excluded from the study: (1) Subjects using any mouth rinse, (2) if they got scaling done in previous 6 months, (3) the ones who used antibiotics in previous 3 months, (4) smokers, and (5) the ones who were not willing to participate in the study.

The study procedure

Parameters noted for each subject at baseline, day 7th and day 14th were (1) gingival index (GI)^[10] (2) plaque index (PI)^[11] (3) organoleptic scores^[12] where a score of 0–5 was given after sniffing the breath odour (4) Halimeter (interscan co-operation)* scores, by a single trained examiner. It was ensured that the patient did not consume anything in the previous 1 h as both the organoleptic and halimeter scores can get influenced by that. To record the organoleptic score, criteria and methodology by Rosenberg and McCulloch were followed.^[12] Halimeter score was recorded as per the manufacturer's instructions. Before recording the subject had to keep his/her mouth closed for 3 min after which a disposable plastic straw connected to the halimeter was placed 2 cm inside the patients' mouth without touching any other part of the oral cavity, the patient was refrained from breathing, and the maximum reading shown by the halimeter was recorded.

The selected subjects underwent baseline scaling procedure to avoid wide variations in scores and also because the mouthrinse acts only after an already formed biofilm is removed.^[13] After 15 min of scaling procedure, the organoleptic and halimeter scores were re-recorded, and these were considered as the baseline values. The subjects were then randomly and equally assigned into any of the three groups Group A - positive control-received 0.2% CHX mouth rinse; they were asked to use 10 ml mouthrinse twice daily after brushing and were told to avoid eating or drinking for 20 min after the use of mouthrinse. Group B - test-received commercially available herbal mouthrinse, they were asked to use 15 ml of mouthrinse twice daily as per the dosage and were given no other set of instructions, unlike Group A subjects. Group C - negative control - were given placebo containing distilled water. They were instructed to use

10 ml twice daily. The subjects were told to report back at the 7th and 14th day, respectively. During this period, they were called once in a week to reinforce the instructions and to ensure that they continued using the mouth rinse. They were also instructed to report back with the empty bottles to check the compliance. On the return visit, all four parameters were re-recorded. Furthermore, patients were asked for any discomfort that they experienced and were examined for adverse effects if any.

The statistical analysis was carried out using SPSS 20 software (SPSS 20, IBM, Armonk, NY, USA). Kruskal–Wallis ANOVA, Mann–Whitney U-test, and Wilcoxon matched pairs test were applied for performing the analysis.

RESULTS

Baseline scores were matched for all the subjects, and there was no statistically significant difference between the baseline values as mentioned in Table 1.

Plaque and gingival index scores

A significant decrease in both the scores was seen in all the groups after scaling [Tables 2, 3 and

| Table 1: Baseline scores | | | |
|---------------------------|--------------|--------------|--------------|
| Demographic | Group A | Group B | Group C |
| Age (in years) | 26.59 | 25 | 27.23 |
| GI | 1.21±0.43 | 1.30±0.40 | 1.13±0.39 |
| PI | 1.74±0.53 | 1.86±0.56 | 1.71±0.55 |
| Halimeter scores (in ppb) | 119.13±11.50 | 118.44±23.49 | 117.22±21.54 |
| Organoleptic scores | 2.85±0.45 | 2.84±0.43 | 2.56±0.47 |

PI=Plaque index, GI=Gingival index.

Figures 1, 2]. PI showed a slightly greater reduction in Group B when compared to Group A on the day 7, but the overall reduction was more in Group A on the 14th day although both the above-observed differences were not statistically significant. GI, on the other hand, was reduced slightly more in Group A at both the recall intervals, but it was of no statistical significance when compared to Group B. The least reduction in scores was shown by Group C for both indices.

Organoleptic and halimeter scores

On the day 7, Group B, which received the herbal mouthrinse showed slightly more reduction in organoleptic (difference 0.03) and halimeter scores (difference 0.10 ppb) than Group A, but it was not of any statistical significance, whereas Group C showed the least reduction in both the values. On the day

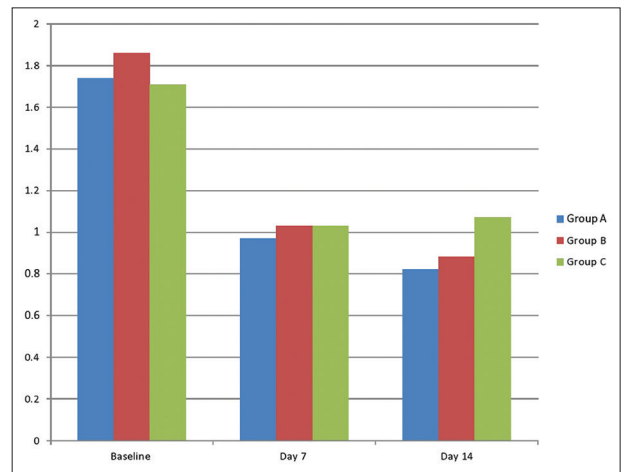


Figure 1: Intergroup comparison of plaque index at all-time intervals

| Table 2: Plaque index | | | | | | | |
|----------------------------------|-----------|---------------------|----------------------|------------------------|-------------------------|------------|--|
| | Mean±SD | | | | | | |
| | Baseline | 7 th day | 14 th day | BL-7 th day | BL-14 th day | 7-14 days | |
| A | 1.74±0.53 | 0.97±0.18 | 0.82±0.20 | 0.78±0.50 | 0.92±0.51 | 0.15±0.17 | |
| B | 1.86±0.56 | 1.03±0.12 | 0.88±0.13 | 0.83±0.54 | 0.98±0.56 | 0.14±0.07 | |
| C | 1.71±0.55 | 1.03±0.17 | 1.07±0.14 | 0.68±0.45 | 0.64±0.46 | -0.03±0.08 | |
| Total | 1.77±0.55 | 1.01±0.16 | 0.93±0.19 | 0.76±0.50 | 0.85±0.53 | 0.09±0.14 | |
| Percentage of change in A | | | | 44.44 | 52.87 | 15.16 | |
| Percentage of change in B | | | | 44.80 | 52.52 | 13.98 | |
| Percentage of change in C | | | | 39.60 | 37.59 | -3.32 | |
| H | 1.1254 | 2.0498 | 31.2386 | 0.7091 | 8.7549 | 42.8935 | |
| P | 0.5697 | 0.3588 | 0.0000 | 0.7015 | 0.0126 | 0.0000 | |
| Pair wise by Mann–Whitney U-test | | | | | | | |
| A versus B | 0.3600 | 0.1970 | 0.1390 | 0.6080 | 0.8560 | 0.6510 | |
| A versus C | 0.9570 | 0.2370 | 0.0000 | 0.7200 | 0.0160 | 0.0000 | |
| B versus C | 0.3590 | 0.9950 | 0.0000 | 0.4130 | 0.0070 | 0.0000 | |

Kruskal–Wallis analysis of variance, Mann–Whitney U-test, Wilcoxon matched pairs test. *P<0.05. BL=Baseline, SD=Standard deviation

Table 3: Gingival index

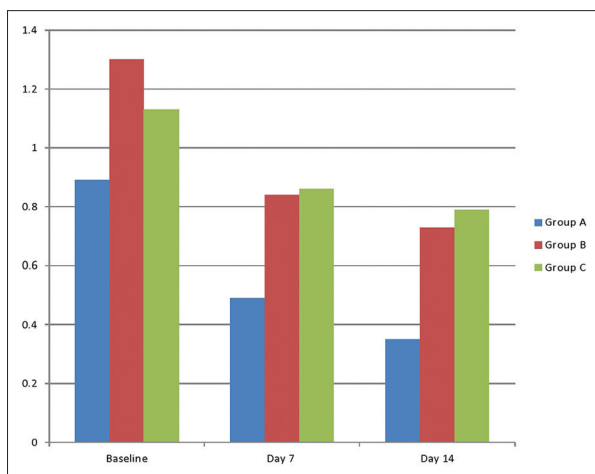
| Groups | Mean±SD | | | | | |
|----------------------------------|-----------|---------------------|----------------------|------------------------|-------------------------|-----------|
| | Baseline | 7 th day | 14 th day | BL-7 th day | BL-14 th day | 7-14 days |
| A | 0.89±0.48 | 0.49±0.35 | 0.35±0.27 | 0.41±0.21 | 0.55±0.26 | 0.14±0.15 |
| B | 1.30±0.40 | 0.84±0.18 | 0.73±0.15 | 0.45±0.25 | 0.56±0.29 | 0.11±0.10 |
| C | 1.13±0.39 | 0.86±0.25 | 0.79±0.14 | 0.27±0.22 | 0.34±0.28 | 0.07±0.15 |
| Total | 1.11±0.45 | 0.73±0.32 | 0.63±0.28 | 0.38±0.24 | 0.48±0.29 | 0.10±0.14 |
| Percentage of change in A | | | | 45.63 | 61.19 | 28.62 |
| Percentage of change in B | | | | 34.94 | 43.37 | 12.96 |
| Percentage of change in C | | | | 24.03 | 29.83 | 7.64 |
| H | 11.6680 | 18.9140 | 42.8760 | 13.2250 | 13.9940 | 5.5900 |
| P | 0.0030 | 0.0000 | 0.0000 | 0.0010 | 0.0010 | 0.0610 |
| Pair wise by Mann-Whitney U-test | | | | | | |
| A versus B | 0.0010 | 0.0000 | 0.0000 | 0.5400 | 0.7610 | 0.6020 |
| A versus C | 0.0480 | 0.0000 | 0.0000 | 0.0010 | 0.0020 | 0.0330 |
| B versus C | 0.0800 | 0.7480 | 0.1540 | 0.0020 | 0.0010 | 0.0600 |

Kruskal-Wallis analysis of variance, Mann-Whitney U-test, Wilcoxon matched pairs test. *P<0.05. BL=Baseline, SD=Standard deviation

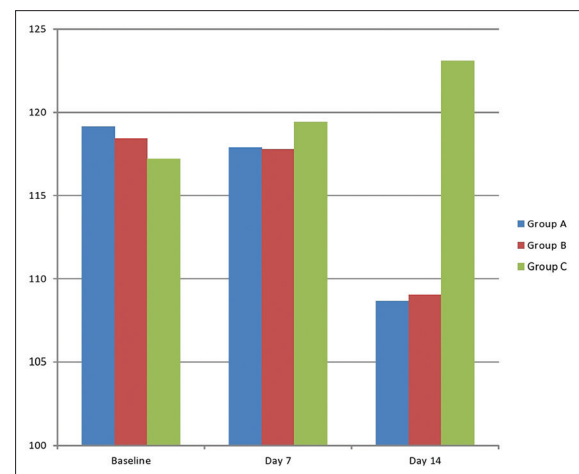
Table 4: Halimeter scores (in ppb)

| Groups | Mean±SD | | | | | |
|-------------------------------|--------------|---------------------|----------------------|------------------------|-------------------------|------------|
| | Baseline | 7 th day | 14 th day | BL-7 th day | BL-14 th day | 7-14 days |
| A | 119.13±11.50 | 117.88±15.94 | 108.66±15.47 | 1.25±14.04 | 10.47±16.19 | 9.22±14.10 |
| B | 118.44±23.49 | 117.78±21.61 | 109.06±26.89 | 0.66±20.77 | 9.38±26.34 | 8.72±14.14 |
| C | 117.22±21.54 | 119.41±15.63 | 123.09±18.34 | -2.19±12.61 | -5.88±15.12 | -3.69±8.63 |
| Total | 118.26±19.37 | 118.35±17.76 | 113.60±21.66 | -0.09±16.10 | 4.66±21.04 | 4.75±13.80 |
| Percentage of change in A | | | | 1.05 | 8.79 | 7.82 |
| Percentage of change in B | | | | 0.55 | 7.92 | 7.40 |
| Percentage of change in C | | | | -1.87 | -5.01 | -3.09 |
| F | 0.0779 | 0.0828 | 4.9960 | 0.4117 | 6.7659 | 10.8407 |
| P | 0.9251 | 0.9206 | 0.0087 | 0.6638 | 0.0018 | 0.0001 |
| Pair wise by Tukeys HSD tests | | | | | | |
| A versus B | 0.9893 | 0.9998 | 0.9967 | 0.9883 | 0.9737 | 0.9862 |
| A versus C | 0.9198 | 0.9379 | 0.0182 | 0.6738 | 0.0041 | 0.0003 |
| B versus C | | 0.9303 | 0.0225 | 0.7629 | 0.0079 | 0.0005 |

One-way analysis of variance, Tukeys honest significant difference, paired t-test). *P<0.05. HSD=Honest significant difference, BL=Baseline, SD=Standard deviation

**Figure 2:** Intergroup comparison of gingival index at all-time intervals

14th Group A showed the maximum reduction in both the scores but this was not of any statistical significance when compared to the test Group B. Group C subjects

**Figure 3:** Intergroup comparison of halimeter scores (in ppb) at all-time intervals

showed least reduction in the scores at both the point intervals [Table 4 and Figure 3].

Test agents

- CHX mouthrinse (positive control): Commercially available nonalcoholic 0.2% CHX mouthrinse (Rexidin; Warren pharmaceuticals Pvt., Ltd., India)
- Herbal mouthrinse (Test): Containing (i) Extracts: Bhibitaka (*Terminalia bellerica*, 10 mg), Nagavali (*Piper betle*, 10.0 mg) Pilu (*Salvadora persica*, 5.0 mg) (ii) Powders: Peppermint satva (*Mentha* spp., 1.6 mg), Yavani satva (*Trachyspermum ammi*, 0.4 mg) and (iii) Oils: Gandhapura taila (*Gaultheria fragrantissima*, 1.2 mg), Ela (*Elettaria cardamomum*, 0.2 mg). (HiOra; Himalaya Herbal Healthcare, Bengaluru, India)
- Placebo mouthrinse (negative control): Distilled water.

DISCUSSION

Subjects using CHX showed maximum reductions in the halimeter and organoleptic scores at the end of the 14th day which were the primary outcomes of the study, whereas the group which was using herbal mouthrinse showed slightly lesser and nonstatistically significant difference in scores than the positive controls.

Secondary outcomes of the study including the plaque and GI were also in accordance with the primary outcomes. The control group showed least changes in all the parameters of the study which also varied statistically with both the positive control and the test group.

The reduction in all the parameters in Group A was due to 0.2% CHX gluconate which has been set as the gold standard chemical in the reduction of breath odor.^[8] The almost equivalent reduction in the scores shown by the herbal mouthrinse can be attributed to its various constituents such as, *S. persica*, *Piper betel*, Peppermint satva, *E. cardamomum*, and *G. fragrantissima* all of which have been shown to have an anti-inflammatory and antibacterial action against various aerobic and anaerobic microorganisms.^[14-17] Furthermore, these constituents help to increase the salivary secretion in the mouth and thus in the reduction of oral malodor.^[18,19] Herbal agents have been compared with CHX mouthrinses in the past with similar antibacterial effects.^[20]

In this study, a single examiner performed all the tests and also dispensed the mouth rinses, and there were no dropouts although a double-blind, randomized control trial as opposed to this could have been performed for stronger evidence.

The significant reductions as obtained by both the formulations in this study can be compared to studies with individual agents done in the recent past where the authors could attain a significant reduction in breath malodor using green tea and chlorine dioxide.^[21,22] The evidence of the efficacy of such chemical agents in a mouthrinse or dentifrice formulation on the control of oral malodor can be derived from the systematic reviews; Slot *et al.*, and Blom *et al.* in their independent reviews have concluded beneficial effects of active chemical containing mouthrinses. Although they state that the efficacy varies with the ingredient added.^[23,24] Cochrane review in 2008 pointed that mouth rinses containing some antibacterial agents can reduce oral malodor to some extent, but the CHX containing mouth rinse resulted in noticeable but temporary staining of the tongue and teeth.^[25]

In accordance with the evidence of both the active ingredient containing mouthrinses showed a significant reduction in the breath malodor on the day 14. Thirty-four percent subjects using CHX reported of a change in taste perturbation and stains on teeth by the end of the study.^[7,8] The set of instructions given to the subjects in Group A to use it half an hour after brushing was due to the cationic nature of the compound which tends to interact with the anionic detergent in the tooth paste and thus is not effective if used immediately.^[26] Furthermore, they were told to refrain from eating and drinking for 20 min after its use which was to avoid staining of the teeth as CHX reacts with colored components in food items. Subjects who were working/college students found it difficult to follow these instructions in the morning when they had limited time and thus, they presented with staining. Since no such interactions of the herbal mouthrinse have been reported no specific instructions of usage were given to the Group B subjects, which was thus more convenient to use as reported by the subjects of this group. Furthermore, none of them showed staining or altered taste perturbation at the end of the 14th day. Although 97% of these subjects reported of burning sensation on using the mouth rinse for the initial 3 days. This can be attributed to some specific constituents in the mouth rinse such as the essential oils.

Use of chemical agents for the reduction of oral malodor or as a breath freshener has an effect for a shorter duration and thus, a long-term prescription of these agents is needed. With the adverse effects and reduced patient compliance, due to the strict instructions, which come with CHX it may be less preferred despite of its superior effects.

Although no significant adverse effects were reported by this study with the use of the herbal mouth rinse long-term studies need to be conducted to monitor the same, also since none of the systematic reviews provide a considerable evidence for the use of agents with an active herbal ingredient for reduction of oral malodor as opposed to CHX long-term studies, and further evidence needs to be reported.

CONCLUSIONS

Within the limitations of the study, it can thus be concluded that the herbal mouth rinse which showed an equivalent reduction in the breath odor as seen by no statistically significant difference between Group A and Group B can be prescribed more safely and with predictable outcomes in patients with oral malodor.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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