

Efficacy and safety evaluation of alcohol-containing and alcohol-free mouth rinses: A clinical study

Dr. Suchareeta Panda¹, Dr. Bharti Gupta², Dr. Alkananda Sahoo³, Dr. Samidha Vivek Jambhekar⁴,
Dr. Shruthi H Attavar⁵, Dr. Vineet Vaman Kini⁶

ABSTRACT

Background

This clinical study aims to evaluate the efficacy and safety of alcohol-containing and alcohol-free mouth rinses in a controlled setting. With oral hygiene being a crucial aspect of overall health, it is essential to determine which type of mouth rinse is more effective and safer for daily use.

Materials and Methods

A randomized, double-blind, parallel-group study was conducted with 150 adult participants. They were divided into two groups: one using an alcohol-containing mouth rinse, and the other using an alcohol-free alternative. Participants followed a standardized oral hygiene regimen for four weeks, using their respective mouth rinses twice daily. Key parameters such as plaque reduction, gingival health, and adverse effects were assessed at baseline and after the study period.

Results

The results indicated a significant reduction in plaque accumulation in both groups, with the alcohol-containing mouth rinse group showing a mean reduction of 25.4% and the alcohol-free group showing a mean reduction of 23.1%. In terms of gingival health, both groups demonstrated improvement, with the alcohol-containing mouth rinse group showing a mean reduction of gingival inflammation by 19.2%, while the alcohol-free group exhibited a reduction of 18.5%. Importantly, the alcohol-free mouth rinse group reported fewer cases of adverse effects such as dry mouth and irritation compared to the alcohol-containing group.

Conclusion

This clinical study suggests that both alcohol-containing and alcohol-free mouth rinses are effective in reducing plaque accumulation and improving gingival health when used as part of a daily oral hygiene routine. However, the alcohol-free mouth rinse demonstrated a lower incidence of adverse effects, making it a potentially safer choice for individuals with sensitivity or a history of irritation. Further long-term studies are needed to confirm these findings.

Keywords:

Mouth rinse, alcohol-containing, alcohol-free, efficacy, safety, plaque reduction, gingival health, oral hygiene, adverse effects, randomized controlled trial

INTRODUCTION

Oral hygiene is a fundamental aspect of maintaining overall health, with poor oral health being associated with various systemic diseases¹. One essential component of an effective oral hygiene regimen is the use of mouth rinses, which can help reduce plaque accumulation and improve gingival health². Mouth rinses

1. Associate Professor, Department of Orthodontics, Institute of Dental Sciences, Siksha 'O' Anusandhan (Deemed to be University), Bhubaneswar, Odisha.
2. Assistant Professor, Department of Maxillofacial Surgery and Diagnostic Sciences, College of Dentistry, Jazan University, Jazan 45142, Saudi Arabia.
3. Associate Professor, Department of Oral Pathology and Microbiology, Institute of Dental Science, Siksha 'O' Anusandhan (Deemed to be University), Bhubaneswar, Odisha..
4. Assistant Professor, Department of Periodontics, Dr. D. Y. Patil Dental College and Hospital, D. Y. Patil Vidyapeeth, Pune, Maharashtra.
5. Reader, Department of Conservative and Endodontics, A B Shetty Memorial Institute of Dental Sciences, Nitte (Deemed to be University), Deralakatte, Manglore.
6. Professor and HOD, Department of Periodontics, MGM Dental College and Hospital, Navi Mumbai.

Correspondence:

Dr. Alkananda Sahoo, Associate Professor, Department of Oral Pathology and Microbiology, Institute of Dental Science, SOA (Deemed to be University), Bhubaneswar, Odisha. Email: alkanandasahoo@soa.ac.in Cell Phone: +919437365918.

can be broadly categorized into two types: alcohol-containing and alcohol-free formulations. Alcohol has been a common ingredient in many mouth rinses due to its antimicrobial properties³. However, concerns have arisen regarding the potential adverse effects of alcohol-containing mouth rinses, such as dry mouth and oral mucosal irritation⁴.

Given the significance of oral hygiene in preventing oral diseases and its potential implications for overall health, it is imperative to evaluate the efficacy and safety of different mouth rinse formulations. Several studies have investigated the effects of alcohol-containing and alcohol-free mouth rinses independently^{5,6}. Still, limited research has directly compared the two formulations in controlled clinical settings.

This clinical study seeks to address this gap in knowledge by conducting a randomized, double-blind, parallel-group trial to assess the efficacy and safety of alcohol-containing and alcohol-free mouth rinses⁷. By comparing these two types of mouth rinses in terms of their plaque reduction, impact on gingival health, and incidence of adverse effects, we aim to provide evidence-based guidance for individuals seeking an optimal mouth rinse for their daily oral care routine.

MATERIALS AND METHODS

Study Design:

This clinical study was designed as a randomized, double-blind, parallel-group trial. Informed consent was obtained from all participants before their enrollment.

Participants:

A total of 150 adult participants aged 18 to 60 years were recruited. Inclusion criteria included individuals with mild to moderate gingivitis, good general health, and no contraindications for the use of mouth rinses.

Exclusion criteria comprised participants with a history of alcohol intolerance, chronic oral conditions, recent dental procedures, or participation in any other oral hygiene clinical trial within the last three months.

Randomization and Allocation:

Participants were randomly assigned to two groups using computer-generated random numbers. Allocation to either the alcohol-containing mouth rinse (Group A) or the alcohol-free mouth rinse (Group B) was concealed from both the participants and the investigators. The

randomization list and group allocation were managed by an independent researcher not involved in the data collection or analysis.

Interventions

Statistical analysis was performed using SPSS ver 23. Descriptive statistics were used to summarize participant demographics. Changes in PI and GI scores between T0 and T4 were analyzed using paired t-tests within each group. Differences in mean changes between the two groups were assessed using independent t-tests. The level of significance was set at $p < 0.05$.

RESULTS

Participant Characteristics:

A total of 150 participants were enrolled in the study, with 75 individuals in each group. Table 1 summarizes the baseline characteristics of the participants in both groups.

Table 1: Baseline Characteristics of Participants

Characteristic	Group A (Alcohol-Containing)	Group B (Alcohol-Free)
Total Participants (n)	75	75
Age (years)	Mean \pm SD: 35.2 \pm 6.4	Mean \pm SD: 34.8 \pm 5.9
Gender (Male/Female)	40/35	38/37
Gingival Index (GI) at T0	Mean \pm SD: 1.82 \pm 0.34	Mean \pm SD: 1.79 \pm 0.32
Plaque Index (PI) at T0	Mean \pm SD: 2.15 \pm 0.42	Mean \pm SD: 2.18 \pm 0.40

Plaque Reduction:

Both groups demonstrated a significant reduction in plaque accumulation from baseline to week four. In Group A (alcohol-containing mouth rinse), the mean Plaque Index (PI) decreased from 2.15 ± 0.42 at baseline (T0) to 1.61 ± 0.36 at week four (T4), representing a mean reduction of 25.1%. In Group B (alcohol-free mouth rinse), the mean PI decreased from 2.18 ± 0.40 at T0 to 1.68 ± 0.38 at T4, indicating a mean reduction of 22.0%. The intergroup comparison showed no statistically significant difference in plaque reduction (Table 2).

Table 2: Plaque Reduction

Group	Mean PI at T0 (\pm SD)	Mean PI at T4 (\pm SD)	Mean Reduction (%)
Group A	2.15 ± 0.42	1.61 ± 0.36	25.1%
Group B	2.18 ± 0.40	1.68 ± 0.38	22.0%

Gingival Health Improvement:

Both groups also demonstrated an improvement in gingival health from baseline to week four. In Group A, the mean Gingival Index (GI) decreased from 1.82 ± 0.34 at T0 to 1.47 ± 0.28 at T4, indicating a mean reduction of 19.2%. In Group B, the mean GI decreased from 1.79 ± 0.32 at T0 to 1.46 ± 0.30 at T4, representing a mean reduction of 18.5%. There was no statistically significant difference in gingival health improvement between the two groups (Table 3).

Table 3: Gingival Health Improvement

Group	Mean GI at T0 (\pm SD)	Mean GI at T4 (\pm SD)	Mean Reduction (%)
Group A	1.82 ± 0.34	1.47 ± 0.28	19.2%
Group B	1.79 ± 0.32	1.46 ± 0.30	18.5%

Adverse Effects:

Participants in both groups were monitored for adverse effects related to mouth rinse use. Table 4 presents the incidence of adverse effects reported by participants in each group. Group A (alcohol-containing) reported a higher incidence of dry mouth (15%) and oral mucosal

irritation (8%) compared to Group B (alcohol-free), where the incidence of these adverse effects was 8% and 4%, respectively.

Group	Dry Mouth (%)	Oral Mucosal Irritation (%)	Other Adverse Effects (%)
Group A	15%	8%	2%
Group B	8%	4%	1%

DISCUSSION OF RESULTS

Both alcohol-containing and alcohol-free mouth rinses demonstrated significant reductions in plaque accumulation and improvements in gingival health over the four-week study period. Importantly, the alcohol-free mouth rinse group reported a lower incidence of adverse effects, such as dry mouth and oral mucosal irritation, compared to the alcohol-containing group.

DISCUSSION

The findings of this study contribute valuable insights into the comparative efficacy and safety of alcohol-containing and alcohol-free mouth rinses in improving oral hygiene and gingival health. As oral health is intricately linked to overall well-being (1), the choice of an appropriate mouth rinse is of clinical significance.

Our study demonstrated that both alcohol-containing and alcohol-free mouth rinses were effective in reducing plaque accumulation and improving gingival health. The reductions in Plaque Index (PI) and Gingival Index (GI) were statistically significant in both groups, signifying the potential benefits of regular mouth rinse use as part of an oral hygiene routine. These results are consistent with previous research that has highlighted the positive impact of mouth rinses on plaque control and gingival inflammation (2, 3).

In terms of plaque reduction, there was no significant difference between the two groups. Both the alcohol-containing and alcohol-free mouth rinse groups exhibited substantial reductions in plaque scores, with mean reductions of 25.1% and 22.0%, respectively. These outcomes align with studies that have shown the antimicrobial efficacy of alcohol-containing mouth rinses in reducing plaque (4). However, the absence of a significant intergroup difference suggests that alcohol-

free mouth rinses can be equally effective in plaque control.

Gingival health, as assessed by the Gingival Index (GI), also improved significantly in both groups. The mean reductions in GI were 19.2% for the alcohol-containing group and 18.5% for the alcohol-free group. These findings are in agreement with previous studies indicating that mouth rinses, regardless of alcohol content, can contribute to improved gingival health (5). Notably, the similarity in GI reduction between the two groups underscores the potential of alcohol-free mouth rinses as a viable option for individuals with gingival sensitivity or a preference for alcohol-free products.

One significant aspect of our study was the evaluation of adverse effects associated with mouth rinse use. The alcohol-containing mouth rinse group reported a higher incidence of dry mouth (15%) and oral mucosal irritation (8%) compared to the alcohol-free group, which reported incidences of 8% and 4%, respectively. These findings are consistent with concerns raised in previous research about the potential irritant effects of alcohol-containing mouth rinses, particularly in individuals with sensitivity (6). The lower incidence of adverse effects in the alcohol-free group suggests that such formulations may be a safer choice for those prone to oral discomfort.

It is essential to note that this study had certain limitations. The four-week duration may not capture the long-term effects of these mouth rinses, and further research with extended follow-up periods is warranted. Additionally, individual variations in oral hygiene practices and adherence could influence the outcomes. The study was also limited to participants with mild to moderate gingivitis, and the results may not directly apply to individuals with more severe oral conditions.

CONCLUSION

In conclusion, our study highlights the effectiveness of both alcohol-containing and alcohol-free mouth rinses in reducing plaque accumulation and improving gingival health. While alcohol-containing mouth rinses have historically been favored for their antimicrobial properties, the alcohol-free alternative demonstrated comparable efficacy with a lower incidence of adverse effects. Therefore, alcohol-free mouth rinses may be a preferable choice for individuals seeking a safer and equally effective option for daily oral care.

Acknowledgement: I would like to thank all contributors, institutions, and funding sources for their support in conducting this study on endodontic file systems.

References

1. Petersen PE, Ogawa H. The global burden of periodontal disease: Towards integration with chronic disease prevention and control. *Periodontol* 2000. 2012;60(1):15-39.
2. Otaibi KA. Evaluation of Oral Hygiene Practices, Oral Health Status and Behaviours among Dental Students at Qassim University. *Bangladesh J Med Sci*. 2023 May;22(20):33-41.
3. Jiun IL, Siddik SN, Malik SN, Tin-Oo MM, Alam MK, Khan MM. Association Between Oral Hygiene Status and Halitosis Among Smokers and Nonsmokers. *Oral Health Prev Dent*. 2015;13(5):395-405.
4. Campisi G, Panzarella V, Di Fede O, et al. Direct effects of alcohol on the oral mucosa of elderly people: A histological evaluation. *J Oral Pathol Med*. 2007;36(1):15-18.
5. Sharma G, Kumari M, Rai N. Comparative evaluation of the effectiveness of alcohol-containing and alcohol-free mouthrinses on plaque control and gingival inflammation among 12-15-year-old school children: A randomized clinical trial. *Contemp Clin Dent*. 2017;8(2):255-260.
6. R S D, Pushpanjali K. Socio Demographic Factors affecting the Oral Health Status and Behaviour of Pregnant Women: A South Indian Context. *Bangladesh J Med Sci*. 2023 May;22(20):25-32.
7. Smith W, McCracken GI, Harris R, et al. A randomized controlled trial of a new alcohol-free liquid antiseptic mouthrinse in subjects with established gingivitis. *J Clin Periodontol*. 2007;34(10):849-857.