

Comparative efficacy of aloe vera mouthwash and chlorhexidine on periodontal health: A randomized controlled trial

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ABSTRACT

The use of various herbal and natural products for the treatment of different oral diseases and ailments has become more popular. Many plant-based solutions have been used quite successfully as anti-microbials and tooth cleaners. These goods can provide an effective substitute for antibiotics and antimicrobials used for the same purpose. Another benefit of utilising herbal medicines is that they have a lower risk of adverse effects when used over a lengthy period of time. Periodontal disease is one of the primary causes of tooth loss, as is well known. Gingivitis is the most frequently seen condition among the several periodontal disease disorders. A combination of oral hygiene instructions and mechanical professional tooth cleaning at proper intervals can almost completely prevent the development of both gingivitis and periodontitis

Aim: To compare the efficacy of Aloevera and Chlorhexidine mouthwash on Periodontal Health.

Materials and methods: The present study was done to compare the efficacy of aloevera mouthwash and chlorhexidine on periodontal health: A randomized controlled trial. It is a thirty days randomized controlled trial which was conducted among 45 dental students. The students were randomized into two intervention groups namely Aloe Vera (AV) chlorhexidine group (CHX) and one control (placebo) group. Sample selection for the present study was done by simple random sampling (Lottery method) from Babu Banarsi Das College of Dental Sciences Lucknow, Uttar-Pradesh. Plaque index and gingival index was recorded for each participant at baseline, 1 day and 15 day. Training of the investigator was done for conducting the pilot study.

Result: At base line and 15 day the difference between the groups was statistically significant when analyzed using One Way ANOVA (p=0.001). There was a reduction in plaque index values at 30 days follow up but difference in the decrease in scores between aloevera and Chlorhexidine group was not statistically significant.

Conclusion: Aloe Vera mouthwash is equally effective as chlorhexidine in reducing plaque and gingivitis. There was no statistical difference between 0.2% chlorhexidine gluconate mouthwash and Aloe vera mouthwash. Keywords:- Dental students, Aloe-vera mouthwash, Chlorhexidine mouthwash

INTRODUCTION

The use of various herbal and natural products for the treatment of different oral diseases and ailments has become more popular. Many plant-based solutions have been used quite successfully as anti-microbials and tooth cleaners. These goods can provide an effective substitute for antibiotics and antimicrobials used for the same purpose. Another benefit of using herbal medicines is that they have a lower risk of adverse effects when used over a long period of time.¹

Dental plaque plays a major role in the aetiology of periodontal disease. The mainstay of preventing periodontal disease is the control of plaque and thus the prevention of plaque induced gingivitis.² Periodontal health is clearly demonstrated to be important for both an individual's oral and general health.³

Plaque control normally means preventive measures aimed at removing dental plaque and preventing it from recurring. This can be accomplished either mechanically or chemically.⁴ The prevalence of periodontitis in developed countries was about 48% among the age group between 18 and 55 years of old patients. In India, there appears to be an increase in the prevalence of periodontitis figures varying from 50-79%.⁶



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There are many commercially available products for mechanical (tooth brushing and flossing) and chemical plaque reduction techniques. It is generally known that mouthwashes with active ingredients such cetylpyridinium chloride, triclosan, and chlorhexidine are clinically beneficial. Long-term use also had well-documented negative consequences, including changes in taste perception, tooth discoloration, and desquamation or discomfort of the oral mucosa.⁷ Mouthwashes have proved to be a simple, safe, and effective delivery system, and in popularity are next only to toothpastes; mouthwashes have proven to play a vital role in plaque reduction.⁹

MATERIAL AND METHODS

The present study was done to Compare the efficacy of aloevera mouthwash and chlorhexidine on Periodontal Health: A randomized controlled trial. It is a thirty days randomized controlled trial which was conducted among 45 dental students. The students were randomized into two intervention groups namely Aloe Vera (AV) chlorhexidine group (CHX) and one control (placebo) group.

Study Population

The study population consisted of 18-25 years old Dental students (undergraduate) from Babu Banarsi Das College of Dental Sciences Lucknow, Uttar-Pradesh.

Study Design

A Randomized Control Trial was done to Compare the efficacy of aloevera mouthwash and chlorhexidine on periodontal health in Babu Banarsi Das College of Dental Sciences Lucknow, Uttar-Pradesh.

Sampling Technique

Sample selection for the present study was done by simple random sampling (Lottery method) from Babu Banarsi Das College of Dental Sciences Lucknow, Uttar-Pradesh.

Pilot Study

A pilot study was conducted in Babu Banarsi Das College of Dental Sciences in the Department of Public Health Dentistry, in the month of November 2022. 15 Dental Students were selected from Babu Banarsi Das College of Dental Sciences, for the pilot study to check the constraints, feasibility and size of the study without hampering there clinics and lectures and the subjects who were included in the pilot study were excluded from the final result of the study. All the Dental students were randomized into two intervention groups namely Aloe Vera (AV) chlorhexidine group (CHX) and one control (placebo) group and examination is carried out during lunch time. Plaque index and gingival index was recorded for each participant at baseline, 1 day and 15 day. Training and calibration of the investigator was done for conducting the pilot study.

This was done to determine the feasibility of the study, the applicability and accuracy of the study, and to determine the amount of time required for study.

A pilot study saves precious time, identify potential difficulties and prompt modifications that may be necessary before the actual start of the study.

Sample Size Estimation

The sample size determination was carried out using the previous literature by using formula,¹ Sample size was calculated by keeping Power of study $(1-\beta) = 80$, After conducting the pilot study, the Effect size was set at 0.353, and Confidence interval 0.05

Sample came out to be 13 each group and was rounded to 15 in each group.

Calibration And Training

Prior to the start of study, Two examiners were trained and calibrated in the Department of Public Health Dentistry to record plaque and gingival index.

Selection Of Study Participants

Clinical Examination Type III Clinical Examination

The examination was carried in the BBD College of Dental Sciences with a source of light and by wearing surgical gloves gown and face shield.

Subjects were examined seated in the chair with a head supported on the chair examiner standing by the side of the chair.



A study specific proforma was used to record demographic details, & dental history of each participant. Clinical Assessment of gingival health was seen by using gingival index given by Loe H and Silness J in 1963 and plaque index by Silness j and Loe H in 1964 at baseline, 15 and 30 days which formed the dependent variables.

Gingival index was recorded using mouth mirror and probe based on degree of inflammation score 0,1,2,3 was allotted to all index teeth and subsequently final score was allotted for individual participant. Similarly plaque index was recorded for each index teeth and score 0,1,2,3 was given to each index tooth and final score was calculated for each participant.

All 45 students fulfill the inclusion criteria.

Inclusion Criteria

- ✓ Plaque Index score more than 1.9,
- ✓ Gingival Index score more than 1.1, with no ongoing dental treatment, antibiotic or anti-inflammatory drug therapy for the past 3 months.

Exclusion Criteria

- ✓ History of systemic diseases/conditions,
- ✓ fibrotic gingival enlargement were excluded from the study.
- ✓ Those subjects who had used antibiotics or mouthwash for 5 consecutive days or corticosteroids in the past 30 days and who had a history of sensitivity to any mouthwash or used removable prosthesis or an orthodontic appliance were excluded from the study.

Blinding

It was a Triple blind clinical trial. The study subjects remained blind to procedures after collection of the data.

All three types of mouthwashes were kept in similar container after preparation and same flavour of spearmint was added to each solution to blind the subjects in which group they fall (single blinding).

All mouth rinse bottles were coded and was handed over to study participants by an investigator-1 not participating in the clinical examination and data analysis. (Double blinding).

Investigator-2 too was unaware of the mouthwash allotted, who recorded plaque and gingival index scores (Triple Blinding).

Ethical Consideration

The ethical clearance was obtained from the Institutional Ethical committee (IEC) of Babu Banarsi Das College Of Dental Sciences, Lucknow Uttar pradesh

The required official permission to select and collect the relevant data from selected subjects was solicited and obtained from the Principal of the Babu Banarsi Das College Of Dental Sciences, Lucknow.

Consent

The purpose of the study was explained and written informed consent was obtained from each participants who was included in the study and fulfilled the inclusion criteria.

Schedule Of The Survey

The study was conducted between February - April 2023

Sterilization

The instruments which was used for clinical examination was sterilized in the Department of Public Health Dentistry Babu Banarsi Das College of Dental Sciences.

Intervention

None

All the participants reverted back after 15 & 30 days

Materials and Equipments

For clinical Examination

Mouth mirror, Probe, Tweezer, Kidney tray, Mouth mask, Gloves, Headcap, Hand sanitizer, Cotton & cotton holder

DATA ANALYSIS

The data were analyzed using SPSS version 23.0. ANOVA followed by Tukey post-hoc were used for analysis. P-Value of 0.05 was taken to be significant.



Table 1. Mean Values of plaque and Palque Index of three groups (AV, Chlorhexidine and placebo) at different time intervals.

	Baseline	15 Days	30 Days
Aloevera	2.47±0.45	2.01±0.40	1.77±0.23
Chlorhexidine	2.41±0.36	1.99±0.32	1.73±0.39
Placebo	2.39±0.32	2.31±0.31	2.20±0.35
P value	0.887	0.852	0.001 (Sig)

Post Hoc Analysis

		Baseline	15 days	30 Days
Aloevera	VS	P=0.875	P=0.986	P=0.873
Chlorhexidine		(Non-Significant)	(Non-Significant)	(Non-Significant)
Aloevera vs Placebo		P=0.786	P=0.046	P=0.001
		(Non-Significant)	(Significant)	(Significant)
Chlorhexidine	VS	P=0.935	P=0.039	P=0.001
Placebo		(Non-Significant)	(Significant)	(Significant)

At the baseline the mean plaque score was 2.47 in the aloevera group, 2.41 in the Chlorhexidine group and 2.39 in the placebo group. The difference between the groups was statistically non-significant when analyzed using One Way ANOVA .At the 15 days time interval the mean plaque score was 2.01 in the aloevera group, 1.99 in the Chlorhexidine group and 2.31 in the placebo group. The difference between the groups was statistically significant when analyzed using One Way ANOVA (p=0.001). There was a progressive reduction in plaque index values at s15 days Follow ups but difference in the decrease in scores between aloevera and Chlorhexidine group was not statistically significant as shown in by post-hoc test, hence showing both Chlorhexidine and Aloe Vera equally efficient However, the difference between Aloe vera and the placebo group and Chlorhexidine and the placebo group was statistically significant (P < .05

Table 2. Intragroup comparison of Mean Values of plaque Index of three groups (Aloe-vera chlorhexidine and placebo) between different time intervals.

	Baseline	15 Days	30 Days	P values
Aloevera	2.47±0.45	2.01±0.40	1.77±0.23	0.001 (Sig)
Chlorhexidine	2.41±0.36	1.99±0.32	1.73±0.39	0.001 (Sig)
Placebo	2.39±0.32	2.31±0.31	2.20±0.35	0.289 (Non-Sig)

In the aloevera group at the baseline the mean plaque score was 2.47, 2.01 at the fifteen days time interval and further reduced to 1.77 at the 30 days time interval. The progressive reduction in the plaque score was statistically significant from baseline to 15 days and 30 days. In the Chlorhexidine group at the baseline the mean plaque score was 2.41, 1.99 at the fifteen days time interval and further reduced to 1.71 at the 30 days time interval. The progressive reduction in the plaque score was statistically significant from baseline to 15 days and 30 days. In the Chlorhexidine group at the 30 days time interval. The progressive reduction in the plaque score was statistically significant from baseline to 15 days and 30 days. In the placebo group at the baseline the mean plaque score was 2.39, 2.31 at the fifteen days time interval and further reduced to 2.30 at the 30 days time interval. The progressive reduction in the plaque score was statistically non-significant from baseline to 15 days and 30 days.

Table 3. Mean Values of Gingival Index of three groups (Aloe-vera, Chlorhexidine and placebo) at different time intervals.

	Baseline	15 Days	30 days
Aloevera	2.06±0.44	1.66±0.29	1.34±0.35
Chlorhexidine	2.01±0.39	1.64±0.30	1.27±0.32
Placebo	2.04±0.41	1.93±0.31	1.71±0.35
P value	0.946	0.012	0.008 (Sig)

At the 30 days time interval the mean plaque score was 1.77 in the aloevera group, 1.73 in the Chlorhexidine group and 2.20 in the placebo group. The difference between the groups was statistically significant when analyzed using



One Way ANOVA. There was a reduction in plaque index values at 30 days follow up but difference in the decrease in scores between aloevera and Chlorhexidine group was not statistically significant as shown in by posthoc test, however, the difference between Aloe Vera and the placebo group and Chlorhexidine and the placebo group was statistically significant (P < .05)

Table 4. Intragroup comparison of Mean Values of Gingival Index of three groups (Aloe-vera, Chlorhexidine and placebo) between different time intervals.

	Baseline	15 Days	30 days	P value
Aloevera	2.06±0.44	1.66±0.29	1.34±0.35	0.001 (Sig)
Chlorhexidine	2.01±0.39	1.64±0.30	1.27±0.32	0.001 (Sig)
Placebo	2.04±0.41	1.93±0.31	1.71±0.35	0.056 (Non-Sig)

In the aloevera group at the baseline the mean gingival score was 2.06, 1.66 at the fifteen days time interval and further reduced to 1.34 at the 30 days time interval. The progressive reduction in the gingival score was statistically significant from baseline to 15 days and 30 days. In the Chlorhexidine group at the baseline the mean gingival score was 2.01, 1.64 at the fifteen days time interval and further reduced to 1.27 at the 30 days time interval. The progressive reduction in the gingival score was statistically significant from baseline to 15 days and 30 days. In the Chlorhexidine group at the baseline to 15 days and 30 days In the progressive reduction in the gingival score was statistically significant from baseline to 15 days and 30 days In the placebo group at the baseline the mean gingival score was 2.04, 1.93 at the fifteen days time interval and further reduced to 1.71 at the 30 days time interval. The progressive reduction in the gingival score was statistically non-significant from baseline to 15 days and 30 days

Statistical Analysis

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation .The intragroup comparison for the different time intervals was done using Repeated Measures ANOVA to find the difference between the individual time intervals. The level of the significance for the present study was fixed at 5%.

The intergroup comparison for the difference of mean scores between independent groups was done using the One Way ANOVA

The Shapiro–Wilk test was used to investigate the distribution of the data and Levene's test to explore the homogeneity of the variables. The data were found to be homogeneous and normally distributed. Mean and standard deviation (SD) were computed for each variable.

DISCUSSION

The present trial was conducted for 30 days to compare the efficacy of Aloe Vera and Chlorhexidine in preventing plaque accumulation and gingival inflammation.¹² The combination of *S. persica* ethanol extract and *Aloe vera* gel extract in mouthwash formula acts better than chlorhexidine in reducing the GI Improvement in GI of hospitalized patients is one of the most important factors which can protect the patients from pathogenic microorganisms.¹²

Triphala is an esteemed drug in India which has been prescribed for centuries to cure a wide range of ailments. Triphala is a polyherbal formulation and the mechanism of action of polyherbals/herbal drugs and their extracts differ in many aspects from that of the synthetic drugs or single substances. Triphala controls dental plaque, gingival inflammation and microbial growth caused by Streptococcus mutans and Lactobacillus.¹³

Triphala controls plaque from baseline and its activity is comparable to commonly available mouthwash Chlorhexidine.¹⁴ Ayurvedic formulations like Triphala Mashi exhibit antimicrobial activity attributed to phenolic compounds and tannins in triphala. The activity is comparable to that of triphala. It inhibits dose dependent growth of gram positive and gram negative bacteria.¹⁵ Chlorhexidine, sodium hypochlorite, amine fluoride and cetylpyridinium chloride are widely used as mouthwashes and irrigating agents that can inhibit the growth of potentially pathogenic oral bacteria. Although these antimicrobial agents are widely used, side effects such as immediate hypersensitivity reactions, toxicity, tooth staining and other side effects have been reported. Moreover, it has been reported that chlorhexidine and sodium hypochlorite possess cytotoxicity toward human periodontal ligament cells, inhibit protein synthesis, and affect mitochondrial activity, thus having detrimental effects on oral tissues (Chang et al).¹⁶

The natural phytochemicals isolated from medicinal plants used in traditional medicine have been considered useful alternatives to traditional allopathic drugs. Many medicinal plants and their products are widely used for prevention



and treatment of oral conditions, and among them Aloe Vera is of particular interest and has been used therapeutically. ¹⁷⁻¹⁹

The low plaque index observed in study subjects could be explained by the fact that Aloe Vera is a good antibacterial against a range of bacteria particularly against Streptococcus mutans, which account for its anti-plaque action.¹⁹ Heggers et al. showed its antimicrobial properties against Candida albicans, Streptococcus pyogens, Streptococcus fecalis.²⁰ Noskova used Aloe Vera to treat early stages of periodontitis and got good results.²¹

Aloe vera mouthwash has shown its efficacy in reduction of plaque, which was in accordance with an in vitro study done by Lee et al. which demonstrated the anti-bacterial effects of Aloe vera on Streptococcus mutans, Streptococcus sanguis and A. viscous. Furthermore, a significant reduction in plaque scores was evidenced in a 4-day plaque regrowth model in studies conducted by Manasa and Aniruth (2014). Chlorhexidine proved to be effective in reducing all the three indices when compared to Aloe Vera and the results are consistent with the results of (Karim et al).²²

Both Chlorhexidine and Aloe Vera mouthwashes had reduced plaque scores significantly but the difference between the groups was statistically non-significant. The results of present study are in accordance with Karim et al. and Gupta et al ²³ who found significant reduction in plaque scores after using Aloe Vera and chlorhexidine mouthwash but the non-significant difference between the groups . Studies done by Chhina et al.⁹ concluded that there was a significant reduction of plaque scores at the 4th day on the usage of Aloe vera mouthwash and was as equally effective as a 0.2% chlorhexidine mouthwash

In the present study there was significant reduction in the plaque scores from baseline to 15 days and 30 days. In a study done by Chandrahas et al.²⁴ and Villalobos et al.²⁵ and a significant reduction in plaque, gingival and bleeding scores on using A. vera mouthwash for 7, 14 and 22 days interval was evident

In the present study there was a significant reduction in the gingival scores at 15 days and 30 days time interval in both aloe vera and chlorhexidine group but the intergroup comparison between aloe vera and chlorhexidine was statistically non-significant. The reduction in gingival index scores can be attributed to components of Aloe Vera. Aloe Vera extracts have shown inhibition of the cyclo-oxygenase pathway and reduces prostaglandin synthesis form arachidonic acid, thus reducing inflammation. Vitamin C present in Aloe vera is involved in collagen synthesis, increases concentration of oxygen at the wound site because of dilation of blood vessels.²⁶ The results of this study were in agreement with those presented by Bhat et al.¹⁹ who used sub gingival delivery of Aloe Vera gel in chronic periodontitis treatment. There was a significant reduction in gingival index, plaque index²⁵. In a study done by by Gupta et al.²¹, a significant improvement in the gingival and plaque scores after 4 days was evident with the usage of A. vera mouth rinse and was in par with that of the chlorhexidine mouthwash group

In a study done by Vangipuram et al.¹ when the efficacy of chlorhexidine and A. vera were compared at 15 and 30 days, both the groups were equally effective in reducing the clinical parameters. Also, de Olivera et al^{27.} found that both dentifrices containing Aloe Vera and dentifrice containing fluoride resulted in significant reduction of plaque and gingivitis, but no statistical significant difference was observed between them . The results were also consistent with Pradeep et al²⁸. who found toothpaste containing Aloe Vera showed significant improvement in gingival and plaque index compared with placebo dentifrice

The present study showed that Aloe Vera mouthwash is equally effective as chlorhexidine in reducing plaque and gingivitis Chlorhexidine is the most widely investigated and used oral product. Short-term trials predominantly demonstrate the superior efficacy of Chlorhexidine on plaque regrowth and numerous other outcome measures.²⁹ Plaque reductions of 16%-45% and gingivitis reduction from 27%-80% have been demonstrated in six-month trials.³⁰ Based on the accumulation of positive clinical research findings, Chlorhexidine rinses are often used as a benchmark control, meaning a product already in use and/or evaluated, thus providing information regarding another agent's relative activity. Chlorhexidine rinses are used similarly as a positive control, meaning that they are accepted as effective, the most effective, or the "gold standard".³¹ It promises to be a better preventive home care therapy in developing countries like India where accessibility, affordability, availability and sustainability are important issues.

CONCLUSION

Chemical plaque control is considered to be corner stones of periodontal health maintenance in adjunct with mechanical plaque control. Although chlorohexidine is considered to be gold standard agent for chemical plaque, various herbal preparations are in demand to overcome the side effects associated with chlorohexidine.

There was no statistical difference between 0.2% chlorhexidine gluconate mouthwash and Aloe vera mouthwash. Therefore, in low socio-economic status population, presently tested Aloe vera mouthwash can be a better



alternative to 0.2% chlorhexidine gluconate mouthwash. Thus, when socio-economic factors, side effects of chlorhexidine and/or preference of the population for natural products need consideration, presently tested herbal mouthwash may be considered as a good alternative.

Aloe Vera mouthwash is equally effective as chlorhexidine in reducing plaque and gingivitis. It promises to be a better preventive home care therapy in developing countries like India where accessibility, affordability, availability and sustainability are important issues. Further studies should be carried out with larger samples, varying time period of trial to establish its efficacy in prevention of periodontal problems and open new doors in the field of research in oral health care.

Limitations

The limitations of the present study are small sample size and Short period of the study As results cannot be generalized as the study population include patient attending to the dental college More number of the people from the different institutions should be there in the study for the generalizability

Recommendation

Further studies should be carried out with larger samples, varying time period of trial to establish its efficacy in prevention of periodontal problems and open new doors in the field of research in oral health care

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