

Comparing the Efficacy of Gel Containing Aloe Vera (25%) with Chlorhexidine Gluconate (1% W/W) In Treatment of Gingivitis Amongst Blind Children: A Triple Blind, Parallel Group, Placebo Controlled Randomized Control Trial

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ABSTRACT

Background: Aloe vera is a natural product exhibiting anti-inflammatory and antibacterial action. The oral health of blind children is compromised, since they are unable to adequately apply the techniques necessary to control plaque. Very few in vivo studies were available showing the effect of Aloe vera gel on gingival health. The purpose of the study was to compare the efficacy of gel containing Aloe Vera (25%) with Chlorhexidine (1% w/w) and Placebo gel on gingivitis.

Materials and Methods: A triple blind, randomized placebo controlled trial with parallel design, was conducted among 72 blind children with mild to moderate gingivitis, using gels containing Aloe Vera, Chlorhexidine and Placebo. Modified Gingival Index and Modified Quigley Hein Plaque index were used to measure the gingival and plaque scores. Kruskal-Wallis test and Mann Whitney U test was used for inter-group comparison and Friedman test was used for within-group comparison at different time intervals.

Results: Aloe vera and Chlorhexidine reduced gingival ($p=0.00$) and plaque scores ($p=0.00$) when used for a period of 6 months. However, there was no statistically significant difference between the two groups.

Conclusion: Aloe Vera gel showed promising results in the reduction of gingivitis.

Keywords: Aloe Vera, Chlorhexidine, Placebos, Gingivitis, Dental plaque.

INTRODUCTION

The prevention of gingivitis by daily and effective supragingival plaque control is necessary to arrest its progression into periodontitis. Although mechanical plaque control methods have the potential to maintain adequate levels of oral hygiene, clinical experience and population based studies have shown that such methods are not being employed as accurately as they should be by a large number of people. Several chemotherapeutic agents

have been developed to control bacterial plaque, to improve the efficacy of daily hygiene control measures.⁽¹⁾ Oral health is an important aspect of health for all children, and is all the more important for children with special health needs. The oral health of children who are visually impaired is compromised, as they are unable to adequately apply the techniques necessary to control plaque.⁽²⁾ Aloe vera is a natural product exhibiting anti-

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inflammatory, antibacterial, antioxidant, antiviral and antifungal actions.^(3,4) Aloe vera plant is normally found in the Indian household. Recently, many scientists have studied the effect of aloe vera gel for dental use in vitro ⁽³⁾ and in vivo ⁽⁵⁾ and have shown its action against oral bacteria. However, studies undertaken were of short duration and it was not tested against the gold standard nor was a gel formulation used. Hence, the present study was conducted to compare the efficacy of gel containing Aloe Vera with Chlorhexidine in treatment of gingivitis for six months.

MATERIALS AND METHODS

Trial registration:

Clinical Trial Registry- India: - REF/2013/07/005429

A triple blind, randomized placebo controlled trial with parallel design was conducted among 72 blind children in a residential school in Bhosari, Pune, with mild to moderate gingivitis using gel containing Aloe Vera (25%) ,Chlorhexidine(1% w/w) and Placebo. Allocation ratio was 1:1. Blind children were selected as the study participants, as gingivitis and poor oral health was noticed among these children during a routine dental camp which was conducted as part of outreach programme of the Department of Public health dentistry. Demographic details like name, age of the participant was collected at the time of examination. Oral prophylaxis of all the participants was done prior to start of the study and those who needed restorations were treated through the mobile dental van. Referral of participants needing specialized dental care was done.

Based on a study by Pradeep A R et al, on effect of tooth paste containing aloe vera in treatment of gingivitis, sample size was estimated as 19 in each group. Mean and standard deviation for plaque scores at 24th week for group 1 (placebo toothpaste); group 2 (toothpaste containing aloe vera); and group 3 (toothpaste with polymer and fluoride containing triclosan) was 3.012 ± 0.794 , 2.348 ± 0.666 , 2.593 ± 0.690 respectively.⁽⁷⁾ The sample size was increased to account for loss to follow up. A total of 72 participants were part of the study, out of which 24 participants were included in each group. Sample size was calculated using

nMaster 1.0 (Biostatistics resource and training centre, Christian medical college, Vellore, India) with the power of 80% and alpha error of 5%.

Participants were randomly allocated into three groups by random allocation sequence generated using the online website, www.randomization.com by the colleague and then the products were distributed accordingly after scaling of the teeth.

Group 1 (Code A): Aloe vera gel. (25%)

Group 2 (Code B): Placebo gel

Group 3 (Code C): Chlorhexidine gel.(1%w/w)

Gels were matched for colour and smell by the manufacturer (Arjun Healthcare Company, Mumbai, India). Non-fluoridated toothpaste and soft toothbrush was distributed to all the participants and tooth brushing technique was demonstrated to the caretakers. The Caretakers were instructed to monitor the children daily to obtain a good compliance. Compliance of gel application on gums in participants was checked after every 15 days by the principal investigator. Follow-up was done at the end of 3 and 6 months.

The Participants, Principal investigator and data analyzer were blinded in the study. Modified Gingival Index (Lobene et al. 1986) and Modified Quigley Hein Plaque index (Turesky et al. 1970) was used to measure the gingival and plaque scores respectively at baseline, three and six months.⁽⁶⁾

The collected data was compiled and normality of the data was tested using Kolmogorov Smirnov test. Data was found to be not normal. Hence, Kruskalwallis test was used to compare the gingival and plaque scores among the three groups. Friedman's test was used to compare the gingival and plaque scores within the groups. All the statistical data was analyzed by using SPSS (Statistical Package for the Social Sciences acquired by International Business Machines) version 17.

Ethics:

Procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation i.e from institutional review board and ethical committee.

RESULTS

Table 1: Distribution of Study Participants.

Age Groups of study participants	Number
12-15 years	43
16-18 years	29
Total	72

Table 2: Modified Gingival Index Score (Lobene et al. 1986) Of Participants In Aloe vera, Placebo And Chlorhexidine Group.

Group	Baseline	3 months	6 months	Friedman
Group 1(Aloevera)	0.35 ±0.23	0.41±0.30	0.22±0.21	P= 0.00
Group 2(Placebo)	0.46±0.47	0.41±0.44	0.94±0.43	P= 0.00
Group 3 (Chlorhexidine)	0.40±0.32	0.413±0.228	0.27±0.224	P= 0.00
Kruskal-Wallis	P= 0.847	P= 0.442	P= 0.00	
Mann Whitney	Group 1Vs Group 2	P= 0.00		
	Group 3 Vs Group 2	P= 0.00		
	Group 1Vs Group 3	P= 0.336		

*Friedman test used for within -group comparison at different time intervals.

†Kruskal-Wallis test and Mann-Whitney test used for inter-group comparison at different time intervals

Table 3: Modified Quigely Hein Plaque Index Score (Turesky et al. 1970) Of Participants In Aloe Vera, Placebo And Chlorhexidine Group.

Group	Baseline	3 months	6 months	Friedman
Group 1	2.16±0.49	2.05±0.23	1.69±0.53	P= 0.00
Group 2	1.93±0.68	1.89±0.37	2.43±0.24	P= 0.00
Group 3	2.18±0.35	2.00±0.30	1.64±0.36	P= 0.00
Kruskal-Wallis	P= 0.471	P= 0.265	P=0.00	
Mann Whitney	Group 1Vs Group 2	P=0.00		
	Group 3 Vs Group 2	P=0.00		
	Group 1Vs Group 3	P=0.142		

‡Friedman test used for within -group comparison at different time intervals.

§Kruskal-Wallis test and Mann-Whitney test used for inter-group comparison at different time intervals.

A total of 72 male, blind school children aged 12 to 18 years from a residential school were recruited in the present study. This trial was conducted for a period of 6 months from March-October 2013. Table 1 shows distribution of study participants. Table 2 shows the inter-group and intra group comparison of Modified Gingival Index scores in group 1, group 2 and group 3 at 1, 3 and 6 months of intervention. Gingival scores among participants showed a significant reduction from baseline scores to 6 months in group 1 and group 3. There was

statistically significant reduction in gingival score from baseline to 6 months (p=0.00) for both the groups. But there was no statistically significant difference between the two groups at the end of six months (p=0.33).The participants of group 2 showed a significant increase in the gingival scores from baseline scores to 6 months. There was statistically significant difference in gingival scores of group 1 and group 3 when compared with group 2 (p=0.00) at the end of the trial.

Table 3 shows the inter-group and intra group comparison of Modified Quigley Hein Plaque Index scores in group 1, group 2 and group 3 at baseline, 3rd month and 6th month of intervention. Plaque scores among participants showed a significant reduction from baseline scores to 6 months in group 1 and group 3. There was statistically significant reduction in gingival score from baseline to 6 months ($p=0.00$) for both the groups. But there was no statistically significant difference between the two groups at the end of the sixth month ($p=0.14$). There was statistically significant difference in plaque scores in group 1 and group 3 when compared with group 2 ($p=0.00$).

In the present study, staining of teeth was seen at the end of 6 months in few participants using chlorhexidine gel, while no side effects were seen in participants using aloe vera gel. A very small number of participants (4%) had calculus at the end of 6 months.

DISCUSSION

This study was carried out to compare the efficacy of gel containing Aloe vera with well known gold standard i.e. Chlorhexidine on gingivitis amongst 72 male blind school children aged 12 to 18 years from a residential school. Oral health is compromised because these children practice unsupervised brushing which may account for ineffectively removed plaque.⁽³⁾ The plant of Aloe vera and its usage as drug dates back to 6000 years B.C. Aloe vera is similar to Cactus but belongs to Lily family of Aloe barbadensis group. Aloe vera has 300 species but just 2 species; *A. barbadensis* and *A. aborescens* are used for trade in the world.⁽¹⁾

Use of gel containing Aloevera (Group 1) showed a significant reduction in gingival and plaque scores when used for six months by the participants. Similar results were seen by Bhat G et al who found that subgingival administration of aloe vera gel resulted in improvement of periodontal condition.⁽⁵⁾ Pradeep AR et al found that a toothpaste containing aloe vera showed significant improvement in gingival and plaque index scores.⁽⁷⁾ Oliveira et al found that the dentifrice containing aloe vera did not show any additional effect on plaque and gingivitis control compared to the fluoridated dentifrice over a period of 1 month. However, the author also concluded that the experimental period

of 30 days may not be sufficient to show the superiority of the aloe vera dentifrice over the fluoridated toothpaste.⁽⁸⁾ So it can be concluded that gel containing Aloevera used over a long period of time can be used in the treatment of gingivitis.

Pannuti CM et al in Brazil in 2003 showed that the Chlorhexidine gel reduced gingival bleeding by 33% when compared to a placebo gel among handicapped children.⁽⁹⁾ In the present study, it was seen that participants using gel containing Chlorhexidine (Group 3) showed a significant reduction in gingival and plaque scores over a period of six months. But there was no statistically significant difference in the gingival and plaque scores of participants in Group 1 and group 3 at the end of six months. However, there was statistically significant difference in gingival and plaque scores in Group 1 and group 3 when compared with group 2 at the end of six months.

The gel containing aloe vera which was commercially available in the market was expensive. The products used in this study, were specially manufactured by the pharmaceutical company. Aloe vera gel was comparatively cheaper, widely accepted and was palatable by all the participants. No itching, burning or other adverse effects on oral mucosa were reported in the participants using aloe vera gel. It can be concluded that gel containing natural product i.e. Aloe vera is efficacious in the reduction of gingivitis.

In the study, an attempt was made to reduce the drop-outs, as the children from residential school who had showed signs of dental neglect as seen from their poor oral health status were made part of the study.

Aloe vera considerably brought down the gingival and plaque scores in the participants when used for the period of six months. Hence, it can be concluded that Aloe vera gel can be used in treatment of gingivitis. Gold standard "Chlorhexidine" also reduced the gingival and plaque scores in participants. Staining of teeth was observed in the participants of chlorhexidine group at the end of six months, while no such side effect was noticed in participants of aloe vera group. So, Aloe vera gel can be used for treatment of gingivitis and it may be more acceptable as it is a herbal product.

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CONFLICTS OF INTEREST

The authors declare they have no potential conflict of interests regarding this article.

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