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Original Research Article

Comparative evaluation of efficacy of Darolac, Arimedadi oil and chlorhexidine mouthwash on salivary pH in special children: a randomized control trial

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ABSTRACT

Background: Children with special healthcare needs often have trouble keeping their teeth clean because of cognitive and physical problems, increasing their risk of oral diseases. While chlorhexidine effectively maintains salivary pH, it has lot of side effects. Hence an alternative mouthwash to chlorhexidine is required. The aim of this study was to compare the efficacy of chlorhexidine, Darolac (a probiotic) and Arimedadi oil (an herbal formulation) on salivary pH in special children.
Methods: Randomized controlled trial was conducted comprising of 45 special children of age 9-12 years from a special School from Rishikesh were randomly assigned to three groups i.e., group I Chlorhexidine (n=15) group II Darolac (n=15) and group III (n=15) Arimedadi Oil. A pre intervention saliva swab was taken priorly to evaluate the salivary pH. Following a standardized oral hygiene regimen, participants were instructed to use their respective mouthwash twice daily for a duration of 7 days. Salivary pH measurements were taken at the end of the intervention period using pH paper. Statistical analysis was performed to compare the changes in salivary pH among the three groups.
Results: After 15 days of intervention, intragroup comparison showed a significant increase in salivary pH compared to baseline with $p<0.05$ ($p=0.00$). The intergroup comparison of three groups when compared to mouthwashes containing chlorhexidine and Darolac, Arimedadi oil caused a modest increase in salivary pH after 15 days.
Conclusions: Chlorhexidine, Darolac and Arimedadi oil mouthwashes were found to be effective in increasing the salivary pH in special children, indication their potential in maintaining oral health. Arimedadi Oil showed superior efficacy compared to Chlorhexidine and Darolac mouthwashes in this population.

Keywords: Arimedadi oil, Chlorhexidine, Darolac, Mouthwash, Oral health, Salivary pH, Special children

INTRODUCTION

According to American academy of pediatric dentistry children with special healthcare needs are defined as "children with any physical, developmental, mental, sensory, behavioral, cognitive or emotional impairment or limiting condition that requires medical management, healthcare intervention and use of specialized services or programs.".[1] The national sample survey organization estimates that 18.49 million people in India are disabled, making about 1.8% of the country's overall population. In India between 6 to 10% of newborns are born with disability and these children make up to one third of the total population with disability.[2] Maintaining optimal oral health in special children is very important. However, these individuals often face challenges in performing

adequate oral hygiene practices due to sensory sensitivities, motor impairments, communication difficulties and behavioral issues. Consequently, they are at increased risk of dental caries, gingival inflammation and other oral health problems.[3] Furthermore, it becomes challenging for their parents or caretakers to follow regular dental hygiene procedures. They are more concern with the medical care of these children.[4] A balanced oral environment is vital aspect in preventing dental caries and promoting pediatric oral health which is a critical aspect of overall well-being. Dental caries is the most common chronic disease affecting children. It can be managed by limiting tooth demineralization, modifying dietary habits, altering pH and buffering capacity of saliva.[3]

The normal range of salivary pH is 6.2-7.6. Tooth decay begins when the pH of saliva drops below 5.5 also known as critical pH. The low salivary pH provides an acidogenic environment for the growth of aciduric bacteria leading to dental caries. Thus, the use of mouthwash as a preventive measure in children has gained significance importance due to its potential to modulate salivary pH and decreasing the risk of dental caries.[5]

Mouthwashes are commonly used as adjuncts to mechanical oral hygiene practices such as toothbrushing and flossing. They offer benefits such as reducing plaque accumulation, controlling oral malodor and providing antimicrobial effects. Among the various types of mouthwashes available, Chlorhexidine, a widely used antimicrobial agent, is known for its efficacy in balancing the pH in the oral cavity. But long-term use of chlorhexidine has various detrimental effects on dental tissues such as tooth staining, unpleasant taste, altered taste sensation etc, so there is a need of alternate mouthwashes that could give similar results with minimal side effects.[6]

Darolac, a probiotic-based mouthwash and Arimedadi oil an herbal formulation, may harness natural antimicrobial properties and maintain pH thus reducing plaque formation and dental caries. Understanding the comparative impact of these mouthwash agents on salivary pH is essential for tailoring effective oral care strategies for special children as they often face unique challenges in maintaining optimal oral health due to various physical, cognitive or behavioral conditions.[6,7]

The Objective of this study were to evaluate and compare the effectiveness of three different mouthwashes i.e., Chlorhexidine, Darolac (a probiotic) and Arimedadi oil (an herbal formulation) on salivary pH levels in children with special healthcare needs.

METHODS

The present study was a double blinded randomized controlled trial. A sample of 45 special children aged 9-12 years were included in the study. The study was conducted over a period of 15 days (18 January 2024–31 January 2024) at Jyoti Special School, Rishikesh, Uttarakhand. Ethical clearance was obtained from the institutional review board. Informed oral and written consent was obtained from the parents of the children and permission was sought from the principal of the respective school.

Inclusion criteria

Inclusion criteria was (a) special children aged 9 to 12 years; (b) medically diagnosed with special needs/ special children; and (c) consent obtained from parents/guardians.

Exclusion criteria

Exclusion criteria was (a) patient with IQ above 70; (b) children with severe systemic conditions affecting salivary pH.; and (c) parents not willing to participate in the study

A principal investigator packed the mouthwashes in three identical opaque bottles for each mouthwash. Participants were blinded and randomly divided into three groups I, II and III with 15 participants in each group. Group I was given chlorhexidine mouthwash, while group II was given Darolac and group III was given Arimedadi oil. Participants were guided by a second investigator who didn't know about the mouthwashes to spit the saliva into a disposable container. 2-3 ml of unstimulated saliva was collected and termed as baseline sample. Then they were guided by the second investigator to swish for 30 seconds twice daily for 15 days. The second investigator supervised the dosage of mouth wash being used to ensure proper mouthwash use. Then after 15 days salivary pH was measured again and was sent for statistical analysis.

Salivary pH measurements

A volume of saliva samples was collected before the commencement of mouth rinsing, baseline and after 15 days rinsing. Unstimulated whole saliva samples were collected in a disposable container sitting in an upright position. Children were informed not to eat or drink anything (except water) 1 h before saliva collection to minimize possible food debris and stimulation of saliva. Salivary pH was measured using pH strips. A single sheet was dipped into the saliva till it is fully wet and removed immediately.

After 30 s, the acid produced reacts to these pH indicators, thus leading to colorimetric change which was compared with color code chart and the pH value was noted. After the baseline recording of salivary pH, the designated mouth rinse was dispensed to the respective groups. Group I received chlorhexidine mouthwash, group II received Darolac mouth rinse and group III

received Arimedadi oil. They were instructed to swish with the 10 ml of mouth rinse for 30 sec continuously for 15 days and post intervention salivary pH was measured using pH strips following 15 days and comparisons were done.

The collected data was entered and analysed using IBM SPSS Statistics for windows, version 20.0 (IBM Corp., Armonk, NY). Descriptive statistics such as frequencies and percentages were used to summarize demographic data and response distributions. Paired t test analysis was employed to the comparisons at baseline and after intervention. A p-value of <0.05 was considered as statistically significant.

RESULTS

The statistical analysis was carried out using paired t test for all the three groups and the mean value is represented in Table 1.

The mean pH value at baseline for Group I Chlorhexidine group was 6.07 which was increased to 7.93 after administration for 15 days which was clinically significant. For the Group II Darolac group the mean pH value at baseline was 5.80 which increased to 7.93 after administration for 15 days which also showed clinically significant result and for the Arimedadi oil it increased from 5.87 to 8.33 after 15 days which was also clinically significant.

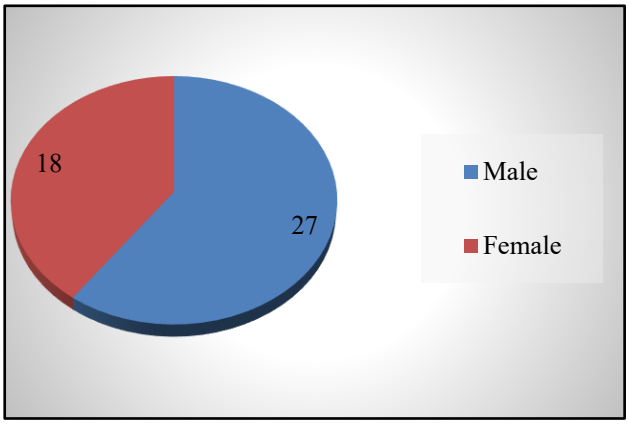

Figure 1: Gender distribution of study population.

The statistical analysis showed that there was a significant increase in the pH of all the 3 groups with group III (Arimedadi oil) showing maximum increase in salivary pH.

Table 1: Comparison of salivary pH among the three groups (aired t test).

Mouthwash	pH of saliva	N	Mean	SD	P value
Chlorhexidine	Pre intervention	15	6.07	0.884	0.0003*
	After 15 days	15	7.93	0.704	
Darolac	Pre intervention	15	5.80	0.775	0.0001*
	After 15 days	15	7.93	0.704	
Arimedadi oil	Pre intervention	15	5.87	0.743	0.0001*
	After 15 days	15	8.33	0.617	

*Paired t Test. P value≤0.05–Statistically significant. SD-Standard Deviation.

DISCUSSION

Children with special healthcare needs also deserve the same level of good oral hygiene as other children. However, oral hygiene and dental disorders are often neglected due to their clinical status and lack of understanding which leads to undesirable outcomes and increased need for dental care over the course of the patient's life.[3] Dental caries is one of the biggest issues among children in India.

The WHO oral health report from 2003 states that among 12-years-old children in India, the mean DMF value ranged from 1.2 to 2.6.[8] Due to their weak muscles and poor motor coordination, children with special healthcare needs may be more susceptible to dental caries and may find it more difficult to maintain good oral hygiene habits. According to previous studies, visually impaired children were more susceptible to dental caries followed by hearing and speech impaired group whereas orthopedically handicapped children were the least susceptible to dental caries.[9] Traditional mechanical plaque control techniques are used across the world, yet it is inadequate.[10,11] Given the challenges associated with traditional oral hygiene practices in special children, the effectiveness of mouthwashes in altering salivary pH helps in improving oral health outcomes.

Chlorhexidine is the mouthwash that has been studied the most. Chlorhexidine inhibits the glycosyltransferase enzyme, which causes bacteria to accumulate on the surface of teeth and has an impact on the movement of sugar and the formation of acid by oral bacteria.[12] But Long-term use of chlorhexidine has various detrimental effects on dental tissues such as tooth staining, unpleasant taste, altered taste sensation etc. Both Arimedadi oil and Darolac mouthwash emerge as a promising option. Additionally, the comparable efficacy of both suggests that natural, alternative mouthwash formulations may be suitable for special children, offering a potentially safer and more tolerable option.

The present study aimed to assess the effectiveness of Chlorhexidine, Darolac and Arimedadi mouthwashes in

altering salivary pH among special children. A commercially available probiotic Darolac and an herbal mouthwash Arimedadi oil were used as experimental mouthwash and chlorhexidine mouthwash was used as a control. The age group ranged from 9 to 12 years of age because it becomes difficult for younger children to rinse.[13] The participants were all kind of children with special health care needs. The participants were informed not to eat or drink anything (except water) 1 h before saliva collection to minimize possible food debris and stimulation of saliva.

The baseline pH was more towards acidic side and no significant difference was noticed between the three groups at pre intervention stage. A 15 days trial duration was selected for the mouthwash rinse because prolong use of chlorhexidine can discolor teeth.[13] The adverse effects of herbal mouthwash are not known.[14]

The results of this study indicate that all three mouthwashes led to a significant increase in salivary pH levels compared to baseline. Group I (chlorhexidine mouthwash) showed that the pH level after 15 days of follow up was higher (7.93±0.704) compared to baseline (6.07±0.884). It suggests that the salivary pH shifted towards neutral pH which is in accordance with similar study done by Badri et al.[9] We also found that group II (Darolac mouthwash) showed higher level of pH after 15 days of follow up (7.93±0.704) as compared to pre intervention (5.80±0.775). A study done by Jindal et al.[15] in which they found that using probiotic powder containing a mixture of bacteria as a mouth rinse for 14 days resulted in a statistically significant decrease in the number of mutans streptococcus bacteria in saliva.

Arimedadi oil mouthwash (group III) showed increased salivary pH after 15 days follow up (8.33±0.617) than the baseline (5.87±0.743). Similar findings were noted in research by Mali et al, in which they came to the conclusion that, when used in conjunction with mechanical plaque control to prevent plaque accumulation and gingivitis, Arimedadi Oil is just as efficient as chlorhexidine gluconate.[16,17] Patil et al, showed that Arimedadi oil is effective in reducing gingival index and gingival bleeding index.[11]

Notably, Arimedadi oil exhibited the highest increase in salivary pH followed by Darolac and Chlorhexidine mouthwashes. This finding aligns with existing research highlighting the properties of Arimedadi oil in enhancing salivary buffering capacity and modulating oral microbiota.[18] The observed increase in salivary pH with Arimedadi oil suggests its potential to create a less acidic oral environment.[19] Kandaswami et al, did a study comparing the effectiveness of probiotic, chlorhexidine and oil pulling therapy on plaque accumulation and gingival inflammation in 10 to 12-years-old school children and concluded that all the three remedies were equally effective in reducing plaque and in improving the gingival status of children.[15] The superior efficacy of Arimedadi oil and Darolac in elevating salivary pH suggests its potential as a beneficial adjunctive therapy for oral health maintenance in special children.

The study is relatively short in duration and the small sample size may limit the generalizability of the findings. Additionally, the study focused solely on salivary pH as an outcome measure overlooking other important parameters of oral health. Further studies with larger sample sizes and longer follow-up periods are required to validate these findings and explore additional outcomes.

CONCLUSION

Both Darolac and Arimedadi oil emerges as a promising option due to its equal efficacy to chlorhexidine and presents itself as a viable alternative to chlorhexidine as it is associated with the side effects when used for the prolonged period of time. So, these findings highlight the importance of natural oral care approaches for special children and offer avenues for further research to optimize oral health outcomes in this vulnerable population.

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