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Original Article

Comparative efficacy of dentifrice containing sodium monofluorophosphate + calcium glycerophosphate and non-fluoridated dentifrice: A randomized, double-blind, prospective study

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ABSTRACT

Background: The efficacy of fluoridated dentifrices in caries prevention has been well documented and research into various formulations continues for a more effective dentifrice. This study evaluated the anti-caries and anti-plaque efficacy of a dentifrice containing sodium monofluorophosphate (1000 ppm) and calcium glycerophosphate, and compared it with a non-fluoridated dentifrice.
Materials and Methods: A total of 595 school children (12–15 years) were divided into test (302 children) and control (293 children) groups. The test group used the dentifrice containing sodium monofluorophosphate (1000 ppm) and calcium glycerophosphate, whereas the control group was given a placebo dentifrice. Oral examination for dental caries and plaque assessment was carried out at the start of the study and the children were followed up semiannually up to 18 months. Data were analyzed using repeated-measure analysis of variance (ANOVA) followed by one-way ANOVA.
Results: The values for decayed missing filled teeth (DMFT) increased from baseline to 18 month examination from 4.43±2.03 and 4.67±2.25 (P=0.175) to 5.84±2.29 and 5.13±2.30 (P=0.001) for control and test groups, respectively. Similarly, the increase in decayed missing filled surface (DMFS) values were from 6.42±4.10 and 7.06±4.77 (P=0.082) to 8.64±4.51 and 7.92±5.07 (P=0.095) for test and control groups, respectively. The mean DMFT and DMFS values increased for both the groups; however, the increase was less in test group as compared to control group. The baseline plaque score reduced from 2.94±0.72 and 2.91±0.72 (P=0.679), respectively, for control and test groups to 1.33±0.46 and 0.91±0.38 (P<0.001), respectively, at 18 month examination.
Conclusion: Results revealed that the test dentifrice was effective in inhibiting the progression of plaque and control of dental caries as compared to the placebo dentifrice.

Key Words: Dentifrice, sodium monofluorophosphate, calcium glycerophosphate

INTRODUCTION

Dental caries is a major public health problem and the reason of considerable social and economic burden. This widespread and devastating disease has still not been conquered. Judicious use of fluoride through different ways has a great impact on the arrest of initial carious lesion as well as the severity of dental caries.[1-3] Extensive clinical and epidemiological research has been carried out to explore the multifaceted nature of the preventive roles of fluoride. The effectiveness of fluoridated dentifrices is an integral part of caries preventive strategy. Fluoride dentifrices have been accepted as the most practical and effective approach toward prevention of dental caries, simultaneously providing the benefits associated with improved oral hygiene.[4]

Since the introduction of fluoride dentifrices, varieties of changes in formulations have taken place resulting

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in improved anti-caries efficacy. The forms of fluoride used in dentifrices have been sodium fluoride, sodium monofluorophosphate, and amine fluoride. One such innovation has been the addition of calcium glycerophosphate and sodium monofluorophosphate to dentifrices. Literature reveals that very few studies have been conducted using this formulation, especially in developing countries like India.[5-7] Therefore, the present study was carried out with the dentifrice containing sodium monofluorophosphate and calcium glycerophosphate against a placebo dentifrice.

MATERIALS AND METHODS

Study protocol

This project was as an 18 month, randomized, double-blind clinical study registered with the Director, Indian Council of Medical Research, Government of India, New Delhi, India. The present study was conducted using dentifrice containing sodium monofluorophosphate (1000 ppm) and calcium glycerophosphate as the active ingredients in comparison with placebo dentifrice. No commercial brand of toothpastes was used. Since it was a blind study, both toothpastes were specially formulated, labeled by the Pharmacologist/Chemist at the Pharmacology Department as Tube A and Tube B and handed over to the examiner for the study. Both pastes (50 g each) were prepared using common ingredients of commercial non-fluoridated toothpaste with sodium monofluorophosphate and calcium glycerophosphate as additives in Paste A (revealed after the study).

Area of study and the participants

The study was designed and carried out in schools situated in Mumbai, India. The necessary approval for the study was taken from the school board and ethical committee clearance was obtained from the concerned authorities. A written consent from parents of the children participating in this study was obtained. The fluoride content of drinking water in schools was estimated to be 0.09 ppm. The total number of participants was 595 (271 girls and 324 boys) school children in the age group of 12–15 years, who had at least one carious tooth. Selected children were divided into two groups according to the dentifrice given and were randomly assigned to the two groups (the participants were allotted numbers, and thereafter a table of random numbers was used for allocation into either control or test group). Simple random sample was utilized. Care was taken to have the proper representation of the age groups in both the groups (i.e. control and test). The control group had 293 children and the test group had 302 children. The control and test dentifrices were prepared and packed in white tubes of 50 g each by the chemist of the Pharmacology Department and handed over to the examiners blinded to the ingredients, coded as "A" and "B," respectively. The active ingredients in test dentifrice were sodium monofluorophosphate (1000 ppm) and calcium glycerophosphate. The control dentifrice was placebo (placebo had all characteristics and ingredients of test toothpaste but without active fluoride content). Participants (both control and test groups) consumed drinking water with negligible fluoride content at 0.09 ppm. Also, no systemic/topical fluoridation program had been undertaken in the study area. Further, the participants (both groups) habitually used toothpastes without fluoride as it was more economical. The children and parents were motivated to comply with the conditions and schedule of the study, i.e. no other household member would use the assigned dentifrice and children would brush with pea-sized toothpaste twice daily (after breakfast and before going to bed) for 2 minutes. Medically/physically compromised patients and those undergoing orthodontic treatment were not included in the study. (None of the participants were on fluoride regime, either systemic or topical.)

In the present study, the diet diary revealed that the children consumed their customary diet which was not different from routine dietary practices.

Clinical examination and data collection

Oral examination was done and findings were recorded as per the criteria specified by WHO (Oral Health Assessment Form – 1997).[8] Dental plaque was disclosed with the plaque disclosing solution in dilutions of 1:50 with deionized distilled water (PLAK-SEE; ICPA Health Products, Mumbai, India) and recorded as per Turesky modification of the Quigley-Hein Plaque Index.[9] Brushing technique (Bass method)[10] was demonstrated to the children and they were asked to follow it. The children were examined at the beginning of the study and then after every 6 months till 18 months of the study. Since in these studies immediate results are not seen, a time period of 18 months was kept.

Reliability of the recording procedure

The chief examiner performed all examinations and recordings of the sample. Intra-examiner reliability

of the recorded data was assessed by re-examining a small percentage of the sample the next day.

Data analysis

Data collected were subjected to statistical analysis using repeated-measure analysis of variance (ANOVA) followed by one-way ANOVA to see the time related difference between the DMFT, DMFS and plaque scores of control and test groups at baseline and reviewed at every 6 months up to 18 months of examination.

RESULTS

At baseline, in control group and test group, the mean DMFT values were 4.43±2.03 and 4.67±2.25 (P=0.175), respectively. On examination at 6 and 12 months for control and test groups, the values were 4.88±2.18 and 4.83±2.34, and 5.34±2.17 and 4.96±2.27, respectively. At the end of 18 months, the mean DMFT values were recorded as 5.84±2.29 and 5.13±2.30 (P=0.001), respectively, which were statistically significant [Figure 1].

The mean DMFS values in control and test groups were 6.42±4.10 and 7.06±4.77 (P=0.082), respectively, at baseline examination. On examination at 6 and 12 months for control and test groups, the values were 7.20±4.47 and 7.44±4.99, and 7.88±4.36 and 7.61±4.87, respectively. At the end of 18 months, the mean scores were 8.64±4.51 and 7.92±5.07 (P=0.095), respectively, which was found to be statistically insignificant [Figure 2].

The mean plaque score of the control and test group subjects declined from 2.94±0.72 and 2.91±0.72 (P=0.679), respectively, at baseline (statistically insignificant) to 1.33±0.46 and 0.91±0.38 (P<0.001), respectively, at 18 months, which was statistically significant. The values upon examination at 6 and 12 months for control and test groups also decreased from 2.16±0.62 and 2.09±0.64 to 1.49±0.58 and 1.35±0.56, respectively [Figure 3].

The attrition rate for the study was 17.98% (statistically not significant). The results of the study for the children who completed the study from starting to completion at end of 18 months were as follows:

On comparison between mean DMFT values of control and test groups at baseline to 6 months, the values were 0.47±0.66 and 0.17±0.38 (P<0.001), respectively, which was significant. There was an

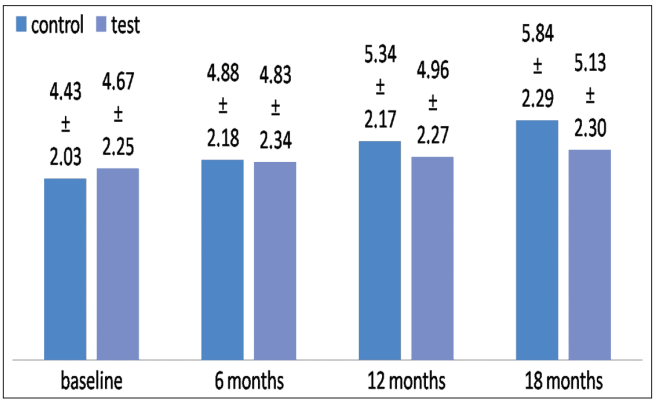

Figure 1: DMFT scores of control and test group from baseline to 18 months examination

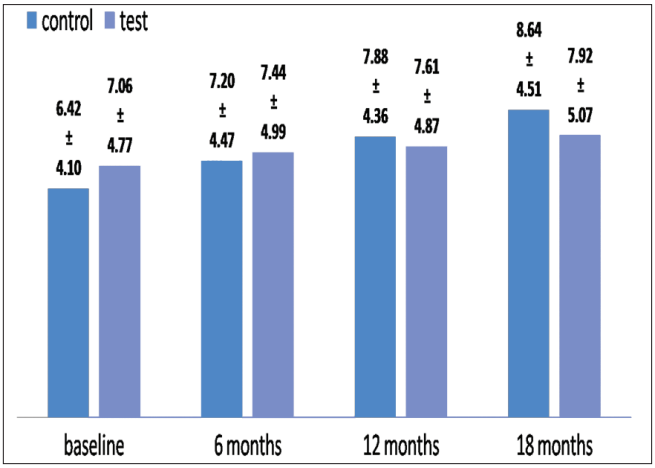

Figure 2: DMFS scores of control and test groups from baseline to 18 months examination

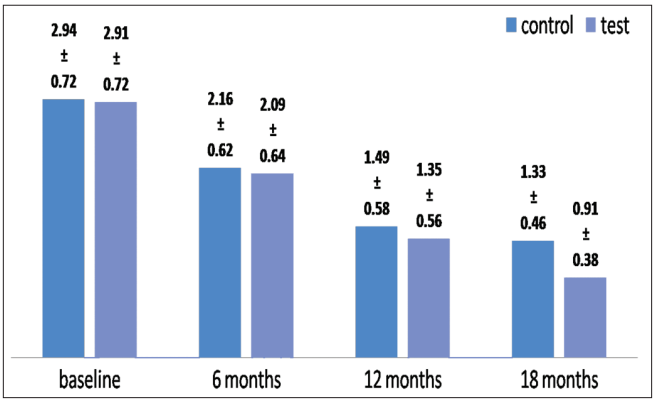

Figure 3: Plaque scores of control and test groups from baseline to 18 months examination

increase in the comparative values of both the groups from baseline to 12 months, which were 0.93±1.19 and 0.28±0.67 (P<0.001), respectively, and in the scores from baseline to 18 months, which were 1.42±1.09 and 0.45±0.87 (P<0.001), respectively, and was found to be highly significant [Table 1].

There was increment in the values of mean DMFS for both the control and test groups from baseline to 6 months: 0.83±1.39 and 0.60±1.22 (P=0.056), respectively; from baseline to 12 months: 1.63±1.73 and 0.78±1.68 (P<0.001), respectively; and from baseline to 18 months: 2.43±2.14 and 1.16±1.94 (P<0.001), respectively, which were statistically significant at 12 month and 18 month comparison between both the groups [Table 2].

The comparative mean plaque scores were 0.77±0.76 and 0.82±0.80 (P>0.05) in the control and test groups, respectively, from baseline to 6 months, and further these values were 1.45±0.86 and 1.59±0.82 (P>0.05) at baseline to 12 months comparison, but were not statistically significant among the groups. However, at the baseline to 18 months comparison, the values were 1.66±0.80 and 2.05±0.79 (P<0.001), respectively, which was statistically significant [Table 3].

DISCUSSION

The first fluoride dentifrice, which was demonstrated to have significant cariostatic activity, contained stannous fluoride. Later on, NaF was incorporated by Finn and Jamison.[11] They reported that the effectiveness of NaF was higher than that of stannous fluoride due to its compatibility with wider variety of ingredients including alumina and calcium abrasives.[12] Several additional approaches were designed to increase the cariostatic activity of sodium monofluorophosphate dentifrices, one being the addition of calcium glycerophosphate.

In the present study, out of 595 children enrolled, only 488 could complete the study in accordance with the protocol. The overall attrition rate was 17.98%. Although this was not statistically significant, there were bound to be variations within the groups when examinations were carried out and results compared from baseline to 6 months, from baseline to 12 months and from baseline to 18 months [Tables 1-3]. Results of children in control and test groups who participated from the beginning till completion at 18 months were as follows: the mean DMFT values were seen to increase from 0.47±0.66 and 0.17±0.38, respectively, at baseline to 1.42±1.09 and 0.45±0.87, respectively, at 18 months, which was found to be highly significant [Table 1]. The mean DMFS value for control and test groups had increased from 0.83±1.39 and 0.6±1.22, respectively, at baseline to 2.43±2.14 and 1.16±1.94, respectively, at 18 months [Table 2].

Table 1: Comparison of DMFT scores between control and test groups on examination from baseline to 6 months, 12 months and 18 months

Time period	Groups	Values		*P* value	Significance
		Mean	SD		
Baseline to 6 months	Control group	0.47	0.66	*P*<0.001**	HS
	Test group	0.17	0.38		
Baseline to 12 months	Control group	0.93	1.19	*P*<0.001**	HS
	Test group	0.28	0.67		
Baseline to 18 months	Control group	1.42	1.09	*P*<0.001**	HS
	Test group	0.45	0.87		

**Significant, HS: Highly significant, NS: Not significant. DMFT: Decayed missing filled teeth, SD: Standard deviation

Table 2: Comparison of DMFS scores between control and test groups on examination from baseline to 6 months, 12 months and 18 months

Time period	Groups	Values		*P* value	Significance
		Mean	SD		
Baseline to 6 months	Control group	0.83	1.39	*P*=0.056	NS
	Test group	0.60	1.22		
Baseline to 12 months	Control group	1.63	1.73	*P*<0.001**	HS
	Test group	0.78	1.68		
Baseline to 18 months	Control group	2.43	2.14	*P*<0.001**	HS
	Test group	1.16	1.94		

**Significant; HS: Highly significant; NS: Not significant. DMFT: Decayed missing filled teeth, SD: Standard deviation

Table 3: Comparison of plaque scores between control and test groups on examination from baseline to 6 months, 12 months and 18 months

Time period	Groups	Values		*P* value	Significance
		Mean	SD		
Baseline to 6 months	Control group	0.77	0.76	*P*>0.05	NS
	Test group	0.82	0.80		
Baseline to 12 months	Control group	1.45	0.86	*P*>0.05	NS
	Test group	1.59	0.82		
Baseline to 18 months	Control group	1.66	0.80	*P*<0.001**	HS
	Test group	2.05	0.79		

**Significant; HS: Highly significant; NS: Not significant. DMFT: Decayed missing filled teeth, SD: Standard deviation

At the 6-monthly oral examinations of children (at baseline, 6 months, 12 months, 18 months) in control group and test group, the mean DMFT values were 4.43±2.03 and 4.67±2.25, respectively. At the end of 18 months, there was increase in mean DMFT values of both the groups to 5.84±2.29 and 5.13±2.30, respectively [Figure 1]. The mean DMFS values in control and test groups were 6.42±4.10 and 7.06±4.77, respectively, at baseline examination. At the end of 18 months, the mean scores were 8.64±4.51 and 7.92±5.07, respectively [Figure 2].

The mean DMFT and DMFS values increased in both test and control groups throughout the study duration. However, the increases in mean DMFT and DMFS values were greater in the control group as compared to the test group. This increase in mean DMFT and DMFS values was statistically significant which was indicative of the efficacy of the test dentifrice.

These results are in accordance with the findings reported by Naylor *et al*.,[5] Murray *et al*.,[13] Mainwaring *et al*.[7] and Andlaw *et al*.[14] Leo Hanachowicz[15] reported a reduction of 26% in DMFT and 27% in DMFS values, on using 1.2% sodium monofluorophosphate dentifrice for a duration of 3 years. Studies carried out in naturally fluoridated areas by Lind *et al*. using sodium monofluorophosphate dentifrice reported a 30% reduction in dental caries increments and 27.9% and 28.2% reduction in DMFT and DMFS values, respectively.[16] The results of the study are in accordance with the results reported by Leo Hanachowicz, Lind and Anlow.

The mean increments in DMFT and DMFS values of the present study are comparable with the results of a study carried out by Conti *et al*.[17] who used 1.14% sodium monofluorophosphate dentifrice for a duration of 3 years. They reported 20.9% reduction of DMFT and 24.3% reduction of DMFS values. A study conducted by Curnow *et al*. in 2002[18] using l000 ppm sodium monofluorophosphate and 0.13% calcium glycerol phosphate in comparison with a placebo dentifrice had reported a mean caries increment of 0.81 and 1.19 on the first permanent molars in test and control groups, respectively.

The greater reduction in dental caries increment might be attributed to the anti-caries effect of fluoridated dentifrice.[19] Dental caries, being a multifactorial disease, the composition of saliva and oral hygiene status can play a vital role in its etiology.

The mean plaque score of the control group reduced from 2.94±0.72 at baseline to 1.33±0.46 at 18 months, whereas in the test group, the value was 2.91±0.72 at baseline which declined to 0.91±0.38 at 18 months. The plaque score reduction was statistically significant in both the groups from baseline to 12 months and 18 months, but a numerically higher reduction of plaque score was seen in test group [Figure 3]. This may be attributed to the improved brushing efficacy of the children due to repeated demonstration of brushing technique.

CONCLUSION

The present double-blind prospective study conducted over an 18-month period confirmed that the dentifrice containing sodium monofluorophosphate and calcium glycerophosphate was effective in inhibiting the progression of dental caries as compared to the placebo dentifrice, reinforcing the cariostatic effect of fluorides and their beneficial effects among children, with improved oral health status.

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