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ORIGINAL ARTICLE

Change in dental caries status on provision of high fluoridated tooth paste; A triple blind randomized clinical trial.

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ABSTRACT… Objective: To investigate the change in dental caries status on provision of high fluoridated tooth paste after 24 months. **Study Design:** Triple Blind Randomized Clinical and Controlled Trial. **Setting:** Private School of Gulshan Town, Karachi. **Period:** January 2018 to January 2020. **Material & Methods:** A cohort of regular school children aged 12-15 years studying in classes 6-9 were included. Through simple random sampling, 412 subjects were purposively allocated to Group A (n=202, intervention group) and Group B (n=210, control group). A pre-trial market survey was conducted to identify the fluoridated toothpastes available followed by the laboratory testing of fluoride concentration through Atomic Absorption Spectrometry. Dental examination was performed by a single examiner on mobile dental units under sunlight in the school ground using sterilized dental mirror, probe and tweezers at baseline and then after 8, 16 and 24 months employing the World Health Organization recommended Decayed Missing Filled Teeth index. **Results:** The mean age of the recruited participants was 12.91±0.82 having 209 males and 203 females. The mean DMFT scores observed over 24 months were 1.25 in group A and 1.42 in group B. At baseline it was 1.10 ±1.50 and 1.11±1.43 which gradually increased to 1.32±1.57 and 1.59±1.96 in group A and B respectively at last follow-up examination. **Conclusion:** This trial has identified no significant change in the overall dental caries status; however, the mean decayed score in both the interventional groups decreased on provision of high fluoridated tooth paste.

Key words: Dental Caries, Fluoride, Prevention.

INTRODUCTION

High prevalence and incidence of the oral diseases throughout the world recognize them as a major public health problem, although most of them are highly avertable.[1,2] During previous few decades a common agreement reported worldwide was a significant decline in the dental caries burden among different populations. The dental community has prided itself on struggles that has reduced the burden of dental caries including the practice of systemic and topical fluorides, toothpastes, sealants, improvements in diet, oral health education and dental care.[3] The prevalence of dental decay has shown a declining trend in developed countries[1] while it is still radically rising in some developing countries.[2,4] The last globally weighted Decayed, Missing, Filled Tooth (DMFT) value for 12-years old was estimated to be 1.61[4], whereas, in the same year and similar age group, recorded DMFT score in Pakistan was 1.38 (urban-1.23, rural-1.59) with decayed component of 1.06. That is, at least one tooth on an average was found to be decayed in local children population.[3] Although, this mean DMFT score was in fact below the weighted global value but the reality that should be focused was the escalating trend of DMFT score in Pakistan from 0.9 to 1.38 over 4 years.[5-7]

Use of fluorides has been the most imperative caries-preventive way. Over the years, the topical use of fluorides (e.g., fluoride toothpastes, mouth rinses, gels, and varnishes) has reported to be superior to the systemic use of fluorides (e.g., fluoride tablets and the addition of fluoride to drinking water), with fluoride toothpastes being the

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most extensive form of topical fluoride practice.[8,9] Anti-caries benefits of topical fluoride are generally recognized by dental researchers and practicing dental specialists worldwide. Previous clinical and epidemiological data suggests that fluoride implements its topical preventive action against caries primarily through reducing the rate of enamel demineralization and remineralization of the initial caries lesions.[4,10]

Fluoride toothpastes are the most convenient, ethnically accepted and cost-effective methods towards the accomplishment of the goal for prevention.[2] "Fluoride dentifrice is a wise investment, as an ounce of prevention is worth a pound of cure"[11] Review from Cochrane database show that in the developed countries, amplified use of fluoridated tooth pastes has reduced the prevalence of dental caries and so has been anticipated as the method of choice for dental caries prevention.[12]

In developed countries, well-controlled clinical trials have investigated the desirable data in relation to the caries controlling efficacy of tooth pastes but there has been no such data reported in our part of the world indicating that this topic remains unexplored.[14] The ultimate evidence behind the efficiency of fluoride toothpaste is the decline in dental caries increment in a controlled clinical trial. But as these trials require a huge sample, long study duration and immense financial support, initiatives were never taken. Therefore, this study was carried out to investigate the change in dental caries status on provision of high fluoridated toothpaste; a randomized clinical trial.

MATERIAL & METHODS

This Triple Blind Randomized Controlled Trial spanned over twenty four months (January 2018 to January 2020) was conducted in a private school of Gulshan town, Karachi, Pakistan. Current trial has also followed the ethical standards of World Medical Association for human experimentation 2008 version of Helsinki Declaration.[13] The present study was composed in line with the Consolidated Guidelines for Reporting Clinical Trials (CONSORT) [14] and is registered at www.clinicaltrial.gov (NCT No. 02016001). Permission to conduct the study was obtained from the parent Institutional Review & Ethical Board (IRB/-MDC/-09), Multan Medical & Dental College and from the school administration. Individual written consent for the dental examination was taken from the respective child's parents before the baseline phase of examination.

A cohort of regular school children aged 12-15 years studying in classes 6-9, residing in the same vicinity of school (Gulshan Town), consuming drinking water supplied by the government and not on mineral water and having at least four permanent molars were included in the trail. However, children who are medically and/or physically compromised, taking any medication, under any kind of parallel fluoride regime, with rampant caries and all filled molars, having any oral infection, undergoing orthodontic/ prosthodontics treatment and non-consenting subjects were excluded.

Sample size for the present study was calculated to be 412. This was attained referring a similar Indian study[15] using the statistical formula and a computer software program Epi-info 6.[16] Simple Random Sampling was employed for which the first sample selection was done on 664 enrolled school students out of which 583 students revealed the eligibility for the trial. From these eligible students, the required sample size for this trial (n=412) was obtained using electronically generated simple random number table. Later these 412 students were purposively allocated to two study groups, 202 to Group A (intervention group) and 210 to Group B (control group). Those subjects who self-reported the use of a single famous brand of toothpaste (during pre-trial situation analysis) having 1000 ppm of labeled fluoride concentration were allocated to a positive control group 'B' while, the rest of the participants were assigned to intervention group 'A' and were provided monthly with a toothpaste of highest labeled fluoride concentration that is1400 ppm. In order to have a possible control over this trial, the participants of both the groups were provided with a daily record chart, having questions regarding the use of recommended toothpaste, brushing

technique, amount of toothpaste, frequency and time spent (duration) on tooth brushing. These charts were being collected from each participant every month by the class teacher.

A pre-trial market survey was conducted before the commencement of the trial. For this a single biggest departmental store of Karachi city was visited to identify the local brands of non-medicated (recommended for regular use) toothpastes available for the local population. All these brands were observed for the presence or absence of fluoride labeled by the manufacturer, the fluoride concentrations in ppm and type fluoride compound in the active ingredient list printed on the toothpaste commercial pack.

Next, the toothpastes which were intended to be provided in the trial were priory tested for the exact total concentration of fluoride present in parts per million (ppm) through Atomic Absorption Spectrometry (AAS). This test was performed at Industrial Analytical Centre, H.E.J Research Institute of Chemistry, University of Karachi.

Prior to the commencement of the trial a demonstration workshop was conducted and all the participants were recommended to strictly comply with the following instructions, particularly during the trial period:

- Toothbrush with the appropriate and demonstrated brushing technique (Bass method)[17]
- Apply toothpaste on full length of tooth brush (practically demonstrated and pictures provided)
- Brush twice daily (after breakfast and before going to bed)
- Perform tooth brushing for 2 minutes

The participants, single examiner and the outcome assessor (trial statistician) were all blind to the treatment allocation (fluoride concentrations in tooth pastes given to each interventional group). Only the research supervisor was not masked to the group assignment. The participants were blind as they were not aware of the exact fluoride concentration they were using. The single examiner was not known that the subject she was examining was actually belonging to either control or intervention group. No concentration of fluoride was mentioned in the data which was provided to the statistician and therefore in this way he was also blind to the treatment allocation.

The single dental examiner was trained, calibrated and supervised by an experienced oral epidemiologist. Dental examination was performed by properly gloved and masked single dental examiner on the permitted dates by the school administration. Mobile dental units were utilized with the child supine, under the day time sunlight in the school ground. Sterilized and autoclavable instruments (dental mirror, probe and tweezers) were used to execute the examination. The children were examined at the beginning of the trial (baseline) and then after 8, 16 and 24 months. A structured proforma was used to record the readings and same proforma was utilized during all the follow ups. The dental caries status of the participants was recorded employing the World Health Organization recommended Decayed Missing Filled Teeth (DMFT) index.[18] DMFT in permanent teeth, is actually the summation of the number of Decayed, Missing due to caries, and Filled Teeth present. The mean value of DMFT is obtained by summing the individual values of DMFT divided by the sum of population. All the teeth (except third molars) are included; therefore the final value ranges from zero to 28 in whole numbers.

Data collected was subjected to statistical analysis using Statistical Package for Social Sciences (SPSS) Version 21 software. Descriptive analysis (frequencies and percentages), Repeated-Measure Analysis Of Variance (to see the time related difference between subject and within subject effect in the mean DMFT scores of the two groups at baseline and follow-ups) and Two sample independent t-tests were applied to compare these differences in the mean DMFT scores of the two groups at baseline, 8 months, 16 months and 24 months of examination. Inter-examiner and intra-examiner reliability were calculated using Cohen's Kappa. The p-value of <0.05 was considered as statistically significant at 95 % confidence level while the power of the

test was kept at 80%.

RESULTS

A total of 412 participants were recruited (202 in Group A and 210 in Group B). The overall mean age was 12.91±0.82 (13.04±0.87 of Group A and 12.78±0.73 of Group B), whereas, 302 (72.90%) and 110 (27.10%) were from age 12-13 and 14-15 years respectively. Out of these recruited participants 209 (50.89%) were males and 203 (49.10%) were females.

In the present study inter examiner reliability between the single examiner and the research supervisor for dental caries detection using DMFT index was found to be 92% (0.86), while the intra-examiner reliability of the single examiner was attained as 96% (0.94). A total of 24 (5.82%) participants lost to follow up during the total trial span of 24 months.

In the pre-trial market survey, a total of 23 non-medicated local brands of toothpastes were identified out of which 15 were labeled with a presence of fluoride (mentioned in the active ingredient list on the packet). Among these 15, two toothpastes had a labeled fluoride concentration of 1400 ppm, 5 had 1000 ppm while remaining 8 had no particular fluoride concentration mentioned.

For pre-trial laboratory testing, a total of 3 samples of toothpastes were sent for confirmation of fluoride concentrations through Atomic Absorption Spectrometry (AAS). The two samples which were found to have the maximum labeled fluoride concentration (labeled 1400 ppm) in the pre-trial market survey revealed a presence of 1330 and 1212 ppm of fluoride respectively on AAS. The third sample showed the presence of 766 ppm on AAS. This sample was the one which was labeled with 1000 ppm of total fluoride in the pre-trial market survey and was already in use by more than 50% of the participants before the commencement of the trial.

Table-I describes the separate mean scores for Decayed, Missed and Filled Teeth, whereas; mean DMFT scores observed over 24 months in group A and B are appreciated in Figure-1.

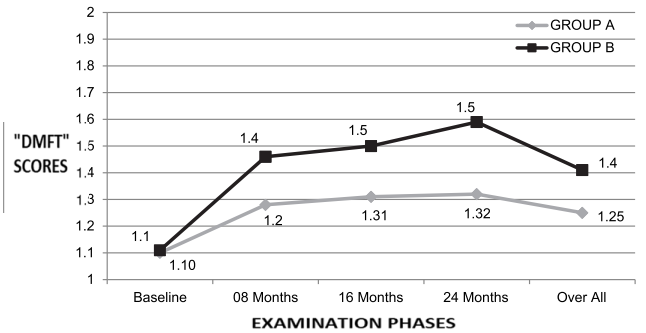

Figure-1. Mean DMFT scores at baseline and follow-ups

DISCUSSION

This experimental study was conducted to assess the change in dental caries status on provision of high fluoridated tooth paste under strict standardizations; however, after 24 months of this triple blind randomized controlled trial, no significant difference was identified in the mean DMFT scores of the two interventional groups. The participants, single examiner and the outcome assessor (trial statistician) were all blind to the group allocation.

Trial duration and specifications of this research were obtained from the American Dental Association Guidelines.[19] Also Federation Dentaire Internationale (FDI) recommendations were followed observing a two year caries

Examination Phases	Mean Decayed Teeth Scores (SD)		Mean Missing Teeth Scores (SD)		Mean Filled Teeth Scores (SD)	
	Group A (n=202)	Group B (n=210)	Group A (n=202)	Group B (n=210)	Group A (n=202)	Group B (n=210)
Baseline	0.95(1.43)	0.99(1.39)	0.12(0.45)	0.10(0.39)	0.01(0.16)	0.02(0.14)
08 Months	0.81(1.11)	1.14(1.44)	0.23(0.54)	0.24(0.54)	0.18(0.46)	0.05(0.22)
16 Months	0.79(1.20)	1.08(1.46)	0.25(0.68)	0.25(0.55)	0.12(0.41)	0.17(0.51)
24 Months	0.78(1.05)	1.25(1.44)	0.25(0.64)	0.27(0.70)	0.28(0.74)	0.31(0.85)

Table-I. Mean decayed, missing & filled teeth scores at baseline and follow-ups

clinical trial for proving the efficacy of fluoridated toothpaste.[20,21] The DMFT index was felt suitable for this trial as compared to other newly established caries recording indices because many of the already conducted similar comparable trials have used DMFT index as a measuring tool. [22-24]

Literature proposes that promotion of fluoride toothpaste must go hand in hand with quality regulator methods on its efficacy, for this valuation of fluoride availability in the toothpaste is of prior importance.[25] In Pakistan, just a couple of descriptive studies have been reported so far, describing the labeled concentrations of fluoride, tested (laboratory) fluoride concentrations in toothpastes and their relationship with dental caries status.[26-28] However, the present trial has filled this gap providing evidences on these three unexplored domains of fluoride prevention.

This trial has reported the anti-carious efficacy of a much wider range of age group, which is also an indexed age group by World Health Organization that is, 12-15 years. This group is particularly important to be incorporated as most of these children have the full set of permanent teeth and the DMFT index can easily be applied. Also, as teeth at this stage are no more in the development stage, there is minimal risk of fluorosis in case of ingestion. Furthermore, school going children are supposed to be more responsive towards following instructions as they are under administrative control. Literature also provides sufficient evidence both global and local that caries attack was found to be extensive in this age group and so abundant research data is present providing the previous DMFT scores of this age group. Therefore, the results of this trial may be easily compared, reported and disseminated.[5,6,29]

In the current trial, the recorded mean DMFT scores at baseline were 1.10±1.50 in group A, while 1.11±1.43 in group B. These scores were recorded before the provision of the interventions and were close enough to eliminate any bias at this stage that may have been caused because of the difference in mean scores at the initial phase of the trial. These baseline DMFT scores of the two respective groups in this study are almost similar to those reported in the previous literature. In 2011, a study performed in private school of Pakistan reported the mean DMFT score of 1.27±1.59 among 11-12 years old students[29] whereas, the score was 1.26 in another local study of school children belonging to age 12 -15 years.[30,31]

An increase in mean DMFT scores was observed in all the three follow up examinations. This increase is may be attributed to the fact that the DMFT index gives equal weight to Decayed, Missed and Filled Teeth and therefore, if the score of one component decreases while the score of other component increases, the overall DMFT score still remains the same. Similarly, in this trial, the mean decayed score in both the interventional groups decreased over time, but the mean DMFT score was not affected as it was counterbalanced by the increase in missed and filled scores in both the groups. Furthermore, it may be stated that numerous formerly documented decayed lesions may now have endured extractions or any restorative management. Also, the emerging decayed lesions which were not extended to a cavity (at the previous phase of examination) were not recorded as decayed that time, may have elevated the decayed score in the ending phase. Correspondingly, the upsurge in filled and missed scores is may be because of the extractions and newer restorations throughout the trial duration of 24 months.

This study might have underestimated the caries experience in the defined population as the dental caries examination in this trial was entirely visual and lacked radiographic proof to second the visual findings because of shortage of capital resources. DMFT index, the measuring tool used in this trial inheritably gave equal weight to untreated decayed, missed and restored teeth and was unable to record the development of early enamel carious lesions during the trial. DMFS index over a much longer duration may also be recommended for future studies for reporting proximal caries. However, a pertinent and ample sample size of 412 subjects in present trial helped to depict more reliable results. Also, the

trend of conducting such experimental research of hierarchical study designs (triple randomized controlled trials) has been promoted through this study in the world of preventive dentistry of Pakistan.

CONCLUSION

This trial has identified no significant change in the overall dental caries status; however the mean decayed score in both the interventional groups decreased on provision of high fluoridated tooth paste after 24 months of this trial.

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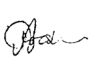
AUTHORSHIP AND CONTRIBUTION DECLARATION

No.	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Aeeza Malik	Basic conception, designing, data collection and write-up.	
2	Basil Khalid	Basic conception, designing, data collection and write-up.	
3	Rohana Rehman	Basic conception, designing, write-up.	
4	Fahad Dogar	Data entry, data analysis, literature search, write-up, gave final approval.	
5	Ayesha Ishfaq	Data entry, data analysis, literature search, write-up, gave final approval.	
6	Malik Saleem	Data analysis, results interpretation, critically reviewed the manuscript, gave final approval.