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Cluster-randomized xylitol toothpaste trial for early childhood caries prevention

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Abstract

Purpose—We assessed the efficacy of supervised toothbrushing with xylitol toothpaste to prevent early childhood caries (ECC) and to reduce mutans streptococci (MS).

Methods—In this cluster-randomized efficacy trial, 4 Head Start classrooms in the Marshall Islands were randomly assigned to supervised toothbrushing with 1,400ppm/31% fluoride-xylitol (Epic Dental, Provo, UT) or 1,450ppm fluoride-sorbitol toothpaste (Colgate-Palmolive, New York, NY) (N=196 children, ages 4–5 yrs). We hypothesized no difference in efficacy between the two types of toothpaste. The primary outcome was primary molar $d_{2\text{-}3}$mfs increment after 6 mos. A single examiner was blinded to classroom assignments. Two classrooms were assigned to the fluoride-xylitol group (85 children) and 2 classrooms to the fluoride-sorbitol group (83 children). The child-level analyses accounted for clustering.

Results—There was no difference between the two groups in baseline or end-of-trial mean $d_{2\text{-}3}$mfs. The mean $d_{2\text{-}3}$mfs increment was greater in the fluoride-xylitol group compared to the fluoride-sorbitol group (2.5 and 1.4 $d_{2\text{-}3}$mfs, respectively), but the difference was not significant (95% CI:−0.17, 2.37;*P*=0.07). No adverse effects were reported.

Conclusion—After 6 mos, brushing with a low strength xylitol/fluoride toothpaste is no more efficacious in reducing ECC than a fluoride only toothpaste in a high caries risk child population.

INTRODUCTION

Early childhood caries (ECC) is on the rise among U.S. preschool-aged children, especially preschoolers from low-income households.[1] This trend has heightened interest in population-based interventions aimed at prevention.[2]

The American Academy of Pediatric Dentistry (AAPD) endorses the use of xylitol as part of a comprehensive strategy to prevent caries but does not recommend xylitol toothpaste use because the research evidence is inconclusive.[3] There are several xylitol delivery modalities that have been tested in young children including gummy bears, syrup, and gum.[4–6] While a single *in vitro* study suggests that xylitol toothpastes have the potential to prevent tooth decay[7], clinical evidence is conflicting.[8–13] Clinical studies on xylitol toothpastes have

Trial Registration: Controlled-Trials.com; URL: http://www.controlled-trials.com/ISRCTN51682476/icrctn51682476; No. ISRCTN51682476.

focused on permanent teeth in older children and no studies have tested xylitol toothpastes to prevent early childhood caries.

The purpose of this study was to test the efficacy of supervised toothbrushing with xylitol toothpaste among Head Start children. A cluster-randomized design was adopted to avoid contamination of the two interventions and to optimize feasibility of this population-based trial. We hypothesized no difference in efficacy at preventing ECC and reducing MS levels between xylitol toothpaste and an over-the-counter fluoride toothpaste.

METHODS

Design

This was a 6 mos prospective cluster-randomized efficacy trial with 2 arms and 1:1 allocation. During the initial 2 mos of the trial, the children brushed twice per day. After 2 mos, toothbrushing frequency was changed from twice to once daily because Head Start classroom hours of operation were reduced in January 2011.

Participants and Human Subjects

This population-based study included all children in 4 Head Start classrooms on Majuro Atoll in the Republic of the Marshall Islands. We focused on all children ages 4 to 5 yrs enrolled in Head Start during the 2010–2011 school year. This public health evaluation was conducted by the Ministry of Health. A study staff member enrolled subjects and obtained informed consent from the parents. The University of Washington Institutional Review Board approved this study.

Intervention

Children in the experimental arm brushed once-per-day under teacher supervision with a pea-sized amount of 1,400 ppm fluoride/31% xylitol toothpaste (fluoride 0.14 w/v; Epic Dental, Provo, UT). Children in the control group brushed their teeth once-per-day with a pea-sized amount of 1,450 ppm fluoride-sorbitol toothpaste (Colgate Cavity Protection, sodium monofluorophosphate [MFP] 0.76% w/v and sodium fluoride 0.10% w/v; Colgate-Palmolive, New York, NY). Head Start classroom teachers were trained on how to administer a classroom toothbrushing program (e.g., proper toothpaste dose, toothbrushing technique, how long to brush, rinsing, hygienic storage of toothbrushes). Children in both groups also received topical 5% sodium fluoride varnish treatment every 3 mos.

Outcomes

The primary end point was the surface-level primary molar caries increment ($d_{2\text{-}3}$mfs). A single dental examiner was trained according to the NIDCR Early Childhood Caries Collaborative (EC4) Criteria, which is based on the World Health Organization caries classification system, and examined each child visually using a disposable mouth mirror and artificial light. No explorers were used. The examiner demonstrated excellent reliability (intrarater correlation coefficient, 1.00 at baseline dental examination and 0.96 at the end-of-trial examination). Caries data were collected at baseline (post-allocation) and at the end of the 6 mos trial.

A secondary end point was the intraoral MS level at the end of the 6 month trial. MS levels were assessed using the Dentocult SM System (Orion Diagnostica, Espoo, Finland). Plaque and saliva samples were incubated at 37°C for 48 h and dried at room temperature prior to reading. Using the Dentocult SM criteria, each strip was independently read by 2 examiners and assigned a score ranging from 0 to 3. Scores 0 or 1 indicate <100,000 colony forming units (CFU)/mL, 2 indicates 100,000–1,000,000 CFU/mL, and 3 indicates >1,000,000 CFU/mL. Scoring discrepancies were resolved by consensus.

Sample Size

We did not derive sample size estimates because this population-based trial included all children in the 4 Head Start classrooms on Majuro Atoll.

Allocation Sequence Generation and Concealment

We used block randomization to assign the 4 classrooms into 1 of 2 arms. It took 4 attempts to reach balanced groups. Allocation to the experimental or treatment group was based on clusters and was completed by a study coordinator. All examiners assessing primary and secondary outcomes were blinded to study group assignment.

Statistical Methods

The unit of analysis was the child. Any surface-level reversals (e.g., tooth surfaces noted as decayed at baseline but sound at the end of the trial) were classified as decayed. To adjust for clustering by classroom, we calculated revised t critical values using 2-way mixed models, consistency agreement, and intracluster correlation coefficient (ICC) estimates for each measure based on single-rating reliability.[14–15] ICC estimates are used to derive test statistics and p-values that account for clustering. For baseline and end-of-trial $d_{2\text{-}3}$mfs, we compared means using the 2-tailed two-sample t-test (α=0.05). The primary end point, $d_{2\text{-}3}$mfs increment, was estimated by subtracting baseline $d_{2\text{-}3}$mfs from end-of-trial $d_{2\text{-}3}$mfs at 6 mo and compared across the 2 groups using the 2-tailed t-test. For the secondary outcome, the mean MS score at 6 mo was compared using the 2-tailed t- test (for both plaque and saliva). The statistician was blind to group assignment until after the analyses were complete. All data were analyzed using SPSS Version 19.0 for Windows.

RESULTS

Participant Flow

Across the 4 clusters, there were 196 children who were enrolled at the start of the school year and received a baseline caries exam. Of these, 168 children (85.7%) received an end-of-trial caries exam (primary end point) and 145 children (74.0%) were tested for MS (secondary end point) (Figure 1). We were unable to collect data from children who were absent from school on exam and bacterial testing days. The trial ended after 6 mos, corresponding to the end of the school year.

Baseline Data

Table 1 summarizes the characteristics of the children in the final analyses for the primary end point ($d_{2\text{-}3}$mfs increment) by study group. Baseline demographic characteristics were similar for the secondary end points (MS score) (Table 2). There were no significant differences in age or sex between children who remained in the study and those who were absent for the final clinical examination or bacterial sampling. No children switched classrooms. Nearly all children had at least one $d_{2\text{-}3}$mfs at baseline.

Primary End Points

All analyses were conducted by original assigned group. There was no significant difference in mean $d_{2\text{-}3}$mfs at baseline between the xylitol and over-the-counter fluoride toothpaste groups (ICC=0.05; 20.3±9.7 and 23.2±10.4, respectively; $t_{\alpha/2}$=−1.46; df=2; *P*=0.28) (Table 3) nor was there a difference in mean end-of-trial $d_{2\text{-}3}$mfs between the 2 groups (ICC=0.04; 22.8±9.5 and 24.6±10.1, respectively; $t_{\alpha/2}$=−1.03; df=2; *P*=0.41). The mean $d_{2\text{-}3}$mfs increment, after adjusting for clustering, was higher in the xylitol group than in the over-the-counter fluoride group (ICC=0; 2.5±2.8 and 1.4±2.5, respectively), but the difference was not statistically significant (95% CI: −0.17, 2.37; $t_{\alpha/2}$=3.72; df=2; *P*=0.07).

Secondary End Points

There was no significant differences across the xylitol and the over-the-counter fluoride groups in the mean MS level for both plaque (ICC=0.07; 1.6±0.9 and 1.7±1.0, respectively; 95% CI: −1.71, 1.47; $t_{\alpha/2}$=−0.32; df=2; *P*=0.78) and saliva (ICC=0.02; 0.9±0.8 and 0.9±0.9, respectively; 95% CI: −1.13, 0.99; $t_{\alpha/2}$=−0.28; df=2; *P*=0.80) (Table 4).

Harms

There were no adverse outcomes or unintended effects.

DISCUSSION

The trial focused on Head Start children in the Republic of the Marshall Islands – a population that has high caries rates, which makes our findings generalizable to other high-risk pediatric populations.[16] The trial lasted 6 mo and involved 2 mos of twice daily exposure to about 0.16 g xylitol (assuming 0.25 g toothpaste/dose) and 4 mos of once daily exposure to 0.08 g xylitol, both of which were below the recommended daily xylitol dose and frequency.[5] Toothbrushing with a xylitol toothpaste resulted in no therapeutic benefit compared to an over-the-counter fluoride toothpaste, both in terms of early childhood caries prevention or MS reduction. While statistically not significant, there was a tendency for children in the xylitol toothpaste group to have a higher $d_{2\text{-}3}$mfs increment. There are 2 potential explanations. First, the surfactants used in toothpaste may interfere with xylitol uptake.[17] Second, the particular surfactant in the xylitol toothpaste – sodium lauroyl sarcosinate – may interfere with adsorption of fluoride by tooth enamel[18] whereas fluoride adsorption may not have been affected by the sodium lauryl sulfate surfactant in the control toothpaste. Thus, the surfactant used in the xylitol toothpaste may have rendered the xylitol toothpaste chemotherapeutically less active. Consumer safety concerns associated with sodium lauryl sulfate[19] may prompt toothpaste manufacturers to switch to other surfactants

like sodium lauroyl sarcosinate without considering the deleterious health effects. Future studies should continue to investigate how surfactants and other ingredients added to toothpastes can modify toothpaste efficacy.

Our findings of no difference in caries prevention between xylitol and over-the-counter fluoride toothpastes are consistent with a previous 3-y trial that found no difference in permanent tooth decay when 15 mg/g xylitol was added to high fluoride toothpaste (2,500 or 5,000 ppm) and used once daily in a classroom setting.[9] Assuming that each child brushed with 0.25 g of toothpaste, this is less than 0.004 g of daily xylitol exposure, which is one-twentieth the maximum dose to which children in our study were exposed. Contrary to our findings, 2 school-based trials of twice-daily use of toothpastes containing 10% xylitol added to 0.243% sodium fluoride or 0.836% sodium monofluorophosphate reported significant reductions in caries after 3 y.[10,13] Based on 0.25 g of toothpaste use twice daily, children were exposed to 0.05 g xylitol. These findings conflict with a 3-y effectiveness trial comparing twice daily use of 0.8% sodium monofluorophosphate (MFP)+6% sorbitol+3% xylitol toothpaste and 0.8% MFP+6% sorbitol toothpaste that detected no difference in permanent tooth caries.[8] Children would have been exposed to a maximum of 0.015 g xylitol per day. Because the setting was home-based, xylitol exposure may have been even lower because of poor adherence. In the context of previous studies, our findings suggest that once-a-day, short-term exposure to xylitol toothpastes containing low concentrations of xylitol does not reduce caries in the primary teeth.

Our finding of no difference between the two types of toothpaste in regards to controlling mutans streptococci (MS) levels is consistent with a previous 3-mos trial[11] as well as a 3-y xylitol toothpaste trial[8]. In another study, children who brushed twice daily with xylitol toothpaste (0.2 g xylitol/day) had significantly lower levels of salivary and plaque MS after 6 mo[12]. These findings were confounded by the presence of triclosan in the xylitol toothpaste. Extrapolating from other xylitol lozenge and gum studies suggest that higher xylitol doses beyond that available through the fluoride-xylitol toothpaste in our study are needed to reduce mutans streptococci levels.[20–21]

The current community-based public health evaluation had a number of strengths including randomization into 1 of 2 treatment arms, supervised toothbrushing to ensure high treatment fidelity, and 2 clinically relevant end points (caries increment and MS level). However, there are 4 main study limitations. First, the control and experimental toothpastes contained different ionic fluoride concentrations and types. It is unlikely that there is a clinically relevant difference in caries prevention between 1,400 ppm and 1,450 ppm toothpastes.[22] Regarding fluoride type, our over-the-counter fluoride toothpaste contained sodium monofluorophosphate whereas our xylitol toothpaste contained sodium fluoride. Previous studies suggest that sodium fluoride is slightly more effective at preventing caries in children than sodium monofluorophosphate.[23–26] This should have biased our findings in favor of the xylitol toothpaste, but the caries increment was higher in the xylitol toothpaste group, making this unlikely. Future work should ensure identical toothpaste formulations that differ only in the main exposure of interest. Second, because this was a population-based study that included all Head Start classrooms on the Majuro Atoll, we did not calculate sample sizes. Retrospective power analyses were not conducted because this

approach does not provide useful information.[27] Of value are the estimated intracluster correlation coefficients that can be used to help guide sample size calculation in future studies. Third, we were unable to obtain attendance information and to assess how often children missed toothbrushing. The randomization protocol is likely to have addressed this potential problem. Finally, a 6 mos trial length is short. A Consensus Statement by the International Consensus Workshop on Caries Clinical Trials (ICW-CCT) indicates that clinical trials involving anti-caries oral care products should last 2 to 3 years.[28] This allows adequate time for caries to develop in lower-risk populations. In very high-risk populations, however, carious lesions develop quickly, enabling shorter duration trials.[5,29] The caries rate in the population was high (98% of participants had at least one $d_{2\text{-}3}$mfs at baseline), which allowed for a short evaluation time, particularly because $d_{2\text{-}3}$mfs increment was the primary outcome measure. Shorter trials are arguably the most ethical approach in evaluating interventions in populations with high caries rates.

More broadly, our study findings indicate that adding xylitol to fluoride toothpaste does not lead to additional health benefits for children at high risk for caries. Given the small amount of toothpaste that is recommended for daily toothbrushing, it is unlikely that xylitol toothpastes alone can deliver the requisite 8 g of xylitol per day, especially when most high-risk children do not brush regularly. A Cochrane review on fluoride toothpastes reported a 14% increase in the prevented fraction when brushing twice daily with fluoride toothpaste compared to once daily[30], which highlights the importance of implementing a minimum of twice daily brushing in future interventions to optimize outcomes. An additional consideration is cost. The commercially available xylitol toothpaste used in the current study costs 3 times as much per ounce as over-the-counter fluoride toothpastes. A more promising approach is alternative xylitol delivery modalities with known efficacy such as gummy bears, syrups, and gum. In fact, our findings raise questions about all such toothpastes currently on the market. Toothpastes in the U.S. are regulated by the Food and Drug Administration's monograph on anticaries products.[31] Because of the increased availability and marketing of xylitol toothpastes in recent years, future regulation of toothpastes containing additional chemotherapeutic agents such as xylitol may require additional steps to ensure that therapeutic levels of xylitol are present in these products, which will protect consumer safety and health.

CONCLUSION

Brushing with a low strength xylitol/fluoride toothpaste is no more efficacious in reducing caries increment or MS levels than a fluoride only toothpaste in a high caries risk child population. Additional studies are needed to identify alternative modalities of delivering therapeutic xylitol doses to children at high risk for early childhood caries.

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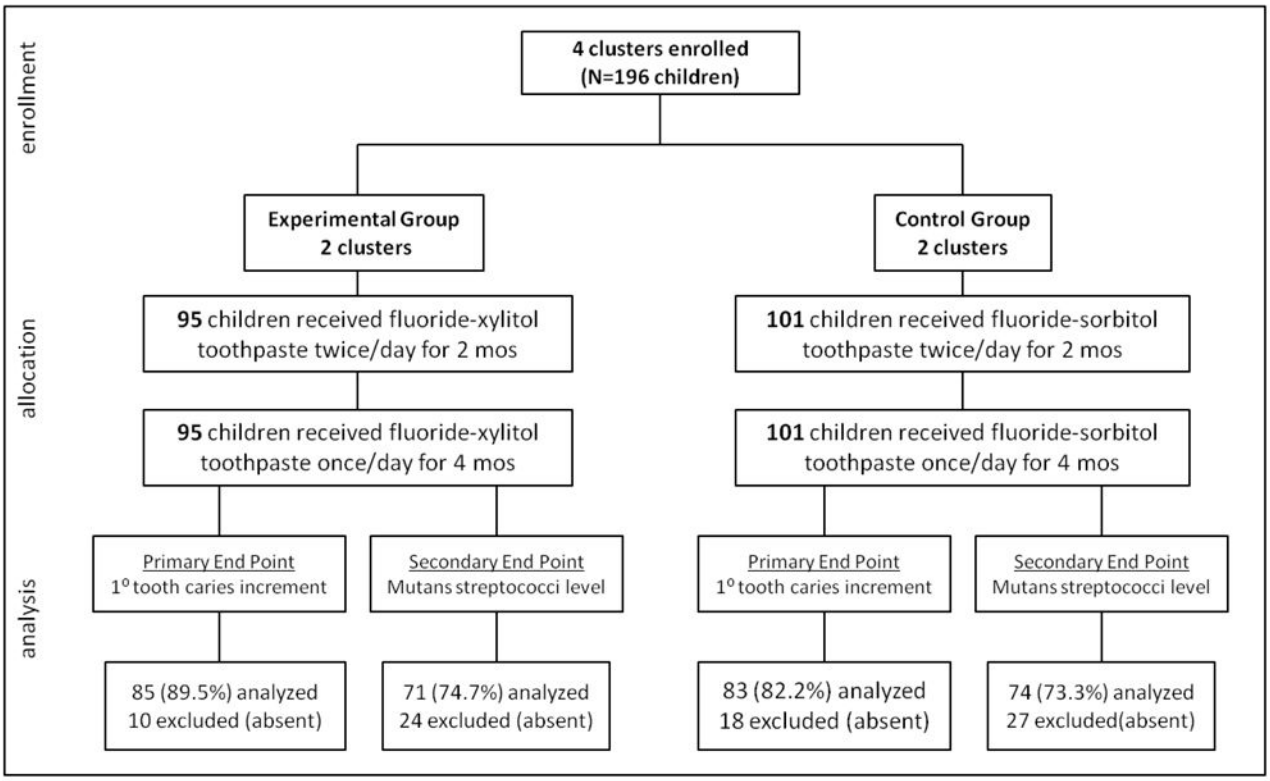

FIGURE 1.

CONSORT flowchart for cluster-randomized trial of fluoride-xylitol toothpaste among 4–5 year old Head Start enrollees in the Marshall Islands.

TABLE 1

Characteristics of subjects included in the final analyses for primary molar caries increment (N=168)

Characteristic	Control Group Over-the-counter fluoride toothpaste n=83	Experimental Group Xylitol toothpaste n=85	Overall N=168
Female sex, N (%)	40 (48.2)	44 (51.8)	84 (50.0)
Age, mean (SD), years	5.4 (0.41)	5.5 (0.61)	5.4 (0.52)
Proportion caries free at baseline (%)	2.4	1.2	1.8

TABLE 2

Characteristics of subjects included in the final analyses for mutans streptococci level (N=145)

Characteristic	**Control Group Over-the-counter fluoride toothpaste n=74**	**Experimental Group Xylitol toothpaste n=71**	**Overall N=145**
Female sex, N (%)	34 (45.9)	35 (49.3)	69 (47.6)
Age, mean (SD), years	5.4 (0.39)	5.5 (0.63)	5.4 (0.53)
Proportion caries free at baseline (%)	2.7	1.4	2.1

TABLE 3

Mean baseline caries, end-of-trial caries, and caries increment in primary molars (primary end points) for children in the final analyses (N=168)

Group	Mean baseline caries (SD)	P-value	Mean end-of-trial caries (SD)	P-value	Mean caries increment (SD)	P-value
Control Group Over-the-counter fluoride toothpaste (n=83)	23.2 (10.4)	*P*=0.28	24.6 (10.1)	*P*=0.41	1.4 (2.5)	*P*=0.07
Experimental Group Xylitol toothpaste (n=85)	20.3 (9.7)		22.8 (9.5)		2.5 (2.8)	

TABLE 4

Mean plaque and salivary mutans streptococci levels (secondary end points) for children in the final analyses (N=145)

Group	Mean plaque mutans streptococci levels (SD)	P-value	Mean salivary mutans streptococci levels (SD)	P-value
Control Group Over-the-counter fluoride toothpaste (n=74)	1.7 (1.0)	*P*=0.78	0.9 (0.9)	*P*=0.80
Experimental Group Xylitol toothpaste (n=71)	1.6 (0.9)		0.9 (0.8)	