Original Article

Preventing Early Childhood Caries through Oral Health Promotion and a Basic Package for Oral Care: A Pragmatic Trial

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Abstract

Introduction: Untreated caries in mothers is one of the common risk factors for early childhood caries (ECC). **Aim:** The aim of the study was to investigate the impact of an oral health promotion program on ECC. **Methodology:** We conducted a pragmatic trial at 12 primary health centers in a rural community of India with 311 pregnant women using fluoride toothpaste, oral health information through pamphlets, and referral to urgent dental care or atraumatic dental treatment as the test intervention. Data were collected through structured interviews at baseline and oral examination of the children at 2 years of age. **Results:** Of the 311 women who participated, 274 children were followed up with at 2 years of age. ECC was low and comparable in both groups. When compared with the control group, significantly, more children from the intervention group were breastfed for over 6 months of age ($P = 0.012$) and consumed less sugar ($P < 0.001$). The number of mothers' decayed teeth ($P = 0.01$), children's sweet scores ($P < 0.001$), and the age at which brushing commenced for children ($P = 0.04$) increased the likelihood of tooth decay in children. **Conclusion:** The oral health promotion program had some beneficial effects in preventing caries in children when provided to pregnant women.

Keywords: *Basic package of oral care, early childhood caries, pragmatic trial, pregnant women*

Introduction

Early childhood caries (ECC) is one of the significant public health problems affecting both developed and developing countries.[1,2] Fluoride use has shown promising outcomes in decreasing caries.[3,4] However, in the absence of a community-based approach to deliver fluoride to the most susceptible individuals with limited access to dental care services, controlling ECC remains a significant challenge.[5]

Parents are important stakeholders in caries control as they are the ones who make the most oral health-related decisions for their children including oral hygiene practices, dietary intake, and treatment decisions.[6] Pregnancy seems to be a suitable time to provide oral health intervention as the benefits can be applied to individuals during the prenatal periods, beyond their pregnancies, and to their soon to be born children by preventing the initiation of caries.[7] Studies that were conducted with pregnant women using a variety of interventions to control ECC-reported positive outcomes.[7-13]

The health-care infrastructure and access to care play a significant role in the prevalence of oral diseases. In India, the Public Health Services cater to vast, far-flung rural areas of the country, while the private health-care organizations provide services primarily to the urban population. A limited number of public–private partnerships and nongovernmental organizations try to fill the gap between governmental and private health-care organizations and make significant contributions to the health-care milieu of India. The public health system in India is generally managed by the state governments, although they do receive policy guidelines, technical assistance, and additional resources from the central government. At the peripheral level, the public health system consists of the Community Health Center (CHC), which oversees the Primary Health Center (PHC), which in turn oversees about 6–8 subcenters catering to a population of approximately 30,000 people. Dental

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clinics are almost nonexistent in the PHCs. There exist a few dental care facilities in the CHCs, but they are not adequately equipped and do not meet the standards and specifications required for the practice of conventional dentistry.[14]

Given the near-total lack of oral care and dental facilities provided by the public health system in rural India, our overarching goal was to introduce an oral health program at a rural community in Dakshina Kannada, a district of Karnataka, which is situated in the southwestern region of India. Through this program, we aimed to inform the community and to create oral health awareness and provide them with access to essential, basic dental care services. Pregnant women are a vulnerable population group because any conditions that affect them can affect their children.[15] In the absence of optimum access to care for these pregnant women, we introduced an oral health promotion program in conjunction with an evidence-based Basic Package of Oral Care (BPOC)[16] at primary health-care centers to control the incidence of ECC in the community. In this paper, we are reporting the impact of this program on the incidence of ECC.

Methodology

We conducted a pragmatic trial in Mangalore with pregnant women and their unborn children.[17] Ethical approval was obtained through the Institutional Ethics Committee of the Manipal College of Dental Sciences, Mangalore (Protocol no-11069).

Sample

The sample size was estimated using the prevalence of ECC in India,[15] 80% statistical power, and a two-sided significance level of 5%. To detect a difference of 40% in the odds of ECC incidence between intervention and control groups by the age of 2 years, we were required to recruit a sample of 127 mothers in each group. To compensate for 10% attrition, we decided to recruit 140 participants. Of the total 16 PHCs in Mangalore, 12 study sites were chosen randomly by referring to random number table. The participants were pregnant women in their first trimester of pregnancy, visited the participating PHCs, and were living within the area of coverage of the PHCs.

Subject recruitment and allocation

Potentially eligible participants were identified at the selected 12 PHCs, met in person, and were informed of the study. Those who expressed interest in participating were recruited by obtaining written informed consent and assent for their unborn children. The recruited participants were randomly assigned into two groups, an intervention and control group, by a dentist who was not involved in the analysis using computer-generated block randomization technique by a block of two.

Test intervention

The test intervention included a comprehensive oral examination of the participants (pregnant women) by a licensed dentist, oral health education using verbal and print material, and the BPOC as described below.

1. Comprehensive oral examinations were conducted by a licensed dentist to assess the oral health status of the intervention group participants and to make appropriate referrals to the dentists depending on the normative oral treatment needs of the participants
2. Oral health education was delivered to the intervention group of mothers using an oral health information pamphlet that was created for the study at baseline and verbal information by the first author, a dentist with a specialization in dental public health. The participants in the intervention group were followed up with twice (during their 3rd trimester, and postnatally, until the child reached 1 year of age) to render oral health education. The oral health education included information about how to maintain good oral health during pregnancy and beyond as well as for their unborn children. The information included the selection of appropriate toothpaste and toothbrushes, the importance of fluoride content in toothpaste, feeding practices for the child, sugar intake, oral hygiene practices, and the importance of seeking dental care
3. The BPOC included the following three components:[16]

Oral urgent treatment

The oral urgent treatment (OUT) is an on-demand service that provides basic emergency oral care with the main goal to relieve pain, to administer first aid for oral infections, and to treat traumatic dental injuries or any issues requiring immediate attention.

Affordable fluoride toothpaste

Fluoride toothpaste with 1000 ppm of sodium monofluorophosphate as the main component was supplied to last during the entire pregnancy period.

The atraumatic restorative treatment

The atraumatic restorative treatment (ART) is a minimally invasive approach to provide dental care in nondental settings.

Control intervention

The control group participants were also given a comprehensive oral health examination by the same dentist and were referred to tertiary care facilities to receive the needed dental care for their normative dental treatment needs. In addition, the same investigator from the intervention group provided them with one-time information verbally about how to maintain good oral health for themselves through their pregnancy and beyond for their unborn children.

Data collection

Mothers

Data were collected from the participants using a self-reported questionnaire and the oral exams that were performed at the baseline to make the referral to the normative oral care needs. All participants completed self-reported questionnaires that were designed to collect their demographic details, brushing habits, and dental visit behavior. The sugar exposure in their diet was assessed with the help of sweet scores that were calculated using information obtained through a 24-h diet chart, which tracked the consumption of different forms of sugary food and its frequency [Table 1]. For example, sugar intake in the form of liquid would receive a score of 5, in the solid and sticky form would receive a score of 10, and in the slowly dissolving form, it would receive a score of 15 per the frequency of the intake behavior.[17] Oral examinations were carried out by a single examiner under natural light using a mouth mirror and a probe for detecting caries and gingival health using the community periodontal Index (CPI).[18] The periodontal scoring ranges from 0 to 4, where Code 0 means healthy periodontal health, Code 1 indicates the presence of gingival bleeding on probing, Code 2 means the presence of calculus and bleeding on probing, Code 3 indicates shallow pockets (≤5 mm), and Code 6 indicates deep periodontal pockets (≥6).

Children

The data were collected from the children who were born from the pregnant participants when they reached 2 years of age. The child's feeding history, diet history, and oral hygiene practices were collected using the self-reported surveys completed by their mothers, and the child's oral status was evaluated through an oral examination. All oral exams were performed by the same dentist, with the child laying on a table or sitting on the mother's lap, under natural light, using a mouth mirror and probe. The teeth were dried using sterile gauze, and all dental surfaces were inspected for caries and decayed surfaces. The data were recorded on the WHO Oral Health Assessment.[18] For the purpose of the study, we defined caries in children as any white spot/lesion or cavity on the teeth.[19] Children with at least one or more carious lesions on the surface of any of their teeth were considered ECC.[11,19]

Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 16.0 (SPSS Inc., Chicago, IL, USA), with the two-sided significance level set at $P < 0.05$. First, we tested the normality assumption of the data using the Shapiro–Wilk test. Since our data were not normally distributed, we performed the Mann–Whitney U-test to investigate the differences in outcomes between the intervention and control groups for the continuous variables (number of decayed, filled, and missing teeth surfaces) and Chi-square tests for categorical variables. Then, we performed bivariate correlations to understand which of the mother's factors were associated with that of the child's tooth decay. The factors that are important based on existing literature, and those factors that had significant associations, were used in the binary logistic regression analyses to ascertain the effect of the selected variable on the child's caries status.

Results

Of the total of 311 participants in the study (intervention group = 155 and control group = 156), 274 were followed up with when their children reached 2 years of age. The intervention and control group mothers did not vary from each other in their age, educational, and socioeconomic levels. About 42% had an income (INR) between 10,000 ($ 133.71) and 15,000 ($ 200.31), and the majority (74.74%) were semi-skilled workers. The sociodemographic characteristics, oral health statuses, and dental care-seeking behaviors of the mother participants are presented in Table 2. A small proportion of the participants (7.7% of the intervention and 5.7% of the control group) had regular dental visits, and another small proportion never had a dental visit (11.8% from the intervention group and 14% of the control group). The remaining vast majority of the participants visited a dentist when needed. All participants, including those in the control group, were using fluoride toothpaste during the study. Caries experience was highly prevalent in the sample, affecting 94% of them.

Although the intervention group had access to the OUT, none had any dental emergencies and thus did not utilize the OUT. About 35 (22.43%) were referred for ART. Of them, five declined to receive the treatment due to fear or discomfort during dental treatment. Tooth decay (Decayed teeth, Filled teeth, Decayed, Missing, and Filled Teeth, and severity of dental caries) significantly varied between the intervention and control group mothers ($P < 0.05$). Although the periodontal status (CPI scores) did not vary between groups, the 59% of the mothers had CPI codes 2, indicating supra- and subgingival calculus, and a small proportion (6% of the intervention and 4% of the

Table 1: Sweet score calculation

Form	Type of sugar	Points
Liquids	Soft drinks, fruit drinks, sugar in beverages, ice creams	Frequency * 5
Solid and sticky	Cake, cupcake, sweet rolls, pastries, chocolates, caramel, jelly, jam	Frequency * 10
Slowly dissolving	Hard candies, breath mints	Frequency * 15

*Multiplied by, ≤5: Excellent, 10: Good, and≥15: Watch out zone

Table 2: The characteristics of the mother participants

	Intervention group (*n*=155), *n* (%)	Control group (*n*=156), *n* (%)	*P*
Age	24.06±2.0§	24.51±2.12§	0.29
Education level			
No education	54 (34.83)	42 (26.92)	0.12
Primary	54 (34.83)	52 (33.33)	
High school	54 (34.83)	44 (28.2)	
College	8 (5.16)	18 (11.53)	
Skill level			
Skilled workers	22 (14.19)	22 (14.10)	0.56
Semi-skilled workers	133 (85.81)	134 (85.90)	
Income	13503±5667	14025±5386	0.40
Socioeconomic class			
Upper lower (5-10)	110 (70.91)	95 (60.9)	0.07
Lower middle (11-15)	45 (29.03)	61 (39.1)	
Dental visiting pattern			
Never visited	26 (16.77)	22 (14.10)	0.562
Once in 3 months	0	2 (1.28)	
Once in 6 months	12 (7.74)	9 (5.77)	
Once a year	11 (7.10)	10 (6.41)	
Visited only when there was a problem	106 (68.39)	113 (72.44)	
Sweet score			
Excellent	52 (33.54)	54 (34.61)	0.29
Good	56 (36.12)	69 (44.23)	
Watch out zone	47 (30.32)	33 (21.15)	
Tooth decay			
People who experienced caries	148 (95.48)	144 (92.30)	0.24
People with untreated caries	121 (78.06)	127 (81.41)	
MT	73 (47.10)	63 (40.38)	
FT	99 (63.87)	72 (46.15)	
Mean DT	2.42±2.24	3.16±2.58	0.01
Mean MT	1.07±1.60	0.87±1.62	0.26
Mean FT	3.14±3.86	1.62±2.62	<0.001
Mean DMFT	6.63±4.58	5.67±4.07	0.05
Caries severity			
One surface filling	107 (69.03)	128 (82.05)	0.009
Two or more surface filling	50 (32.26)	35 (22.44)	
Pulp care	21 (13.55)	42 (26.92)	
Extraction	43 (27.74)	35 (22.44)	
Periodontal health (CPI scores)			
Code 0: healthy periodontal condition	18 (11.61)	20 (12.82)	0.88
Code 1: gingival bleeding present	15 (9.68)	19 (12.18)	
Code 2: calculus and bleeding present	92 (59.35)	92 (58.97)	
Code 3: shallow pockets (4-5 mm)	24 (15.48)	21 (13.46)	
Code 4: deep pockets (≥6 mm)	6 (3.87)	4 (2.56)	

§Mean±SD. SD: Standard deviation, MT: Missing teeth, DT: Decayed teeth, FT: Filled teeth, DMFT: Decayed, Missing, and Filled Teeth, CPI: Community periodontal index

control group mothers) had a score of 4, which means ≥6 mm periodontal pockets requiring periodontal care.

A total of 274 children (intervention = 139 and control = 135) born to the mother participants were followed up with at 2 years of age. The main reason for dropout was the migration of the participants to some other place and the inability to trace their new addresses. The general characteristics of the children participants are presented in Table 3. The majority were full-term births in both the intervention and control groups. Feeding methods were comparable between the intervention and control groups, with a vast majority of breastfed children in both groups. However, a significantly larger proportion of the intervention group children were breastfed for over 6 months of age (P = 0.012). The sweet scores significantly differed between the intervention and control

Table 3: The general characteristics of the child participants

	Intervention group (*n*=139), *n* (%)	Control group (*n*=135), *n* (%)	*P*
Gender			
Female	81 (58.27)§	66 (48.89)§	0.08
Birth weight			
Preterm	14 (10.07)	16 (11.85)	0.48
Full term	125 (89.92)	119 (88.14)	
Sweet score			
Excellent	54 (38.84)	11 (8.15)	<0.001
Good	58 (41.73)	29 (21.48)	
Watch out zone	27 (19.42)	95 (70.37)	
Cleaning teeth			
Once	86 (61.87)	87 (64.44)	0.75
Twice	44 (31.65)	41 (30.37)	
More than twice	9 (6.47)	7 (5.19)	
Feeding method			
Breast	86 (61.87)	78 (57.78)	0.69
Bottle	6 (4.32)	9 (6.67)	
Both	47 (33.81)	48 (35.56)	
Feeding duration (months)			
<6	21 (15.10)	35 (25.93)	0.012
>6	118 (84.89)	100 (74.07)	
Bottle content			
Milk without sugar	30 (21.58)	28 (20.74)	0.45
Formula and sugar	23 (16.55)	29 (21.48)	
Age at which brushing started			
When the first tooth erupted	90 (64.75)	80 (59.26)	0.80
Before the child's first birthday	27 (19.42)	21 (15.56)	
After the child's first birthday	22 (15.83)	34 (25.19)	

§Mean±SD. SD: Standard deviation

groups ($P < 0.001$). For instance, 39% of the intervention group children had excellent sweet scores when compared with a small proportion of the control group children (8%) who had excellent sweet scores. Over 70% of the control group participants were in the watch out zone for sweet scores, whereas only 19% of the intervention group children were in the watch out zone. Oral hygiene practices did not differ in both the intervention and control group children.

There was no significant difference in ECC in both the intervention and control groups. In other words, ECC affected 21 children (13.46%) in the intervention group and 22 children (14.19%) in the control group. The prevalence of ECC was low in both the intervention and control groups. Ninety-nine percent of the children born to the mothers who received the ART had no tooth decay. Logistic regression was performed using the following variables: tooth decay, preterm status, gender, sweet score, cleaning teeth, feeding methods, feeding duration, feeding bottle content, and the age at which brushing commenced. Increase in the number of decayed teeth in the mother ($P = 0.01$), sweet scores of the children ($P < 0.001$), and the age at which brushing commenced for children ($P = 0.04$) increased the likelihood of tooth decay in children [Table 4].

Discussion

In this study, we investigated the impact of delivering oral health education and providing access to oral care services to women during their pre- and post-natal periods on their children's caries. Our results indicate that the mothers' caries status, children's sweet scores (measured by dietary intake), and the time at which tooth cleaning commenced were significantly associated with the children's caries status. To our knowledge, this is the first study of its kind to provide oral health education and access to dental care services using BPOC to pregnant women in India within the existing PHC setup and to investigate its impact on children's tooth decay. None of the PHCs included in this study provided dental care. Thus, this study simulates a real-world situation and hence has better practical implications.[20]

Although we randomly allocated the participants in the intervention and control groups, the intervention group mother participants had significantly fewer decayed teeth when compared with the control group mother participants at baseline. However, the incidence of caries in their children at age 2 did not vary. Significantly a greater number of children from the intervention group had excellent sweet scores indicating lesser exposure to sugar

Table 4: Logistic regression outcomes with the dependant variable as the incidence of early childhood caries among children

Variables in the equation	*B*	SE	Wald	Df	Significance	Exp (*B*)	95% CI for Exp (*B*)	
							Lower	Upper
Number of decayed teeth in mothers	0.163	0.063	6.656	1	0.010*	1.178	1.04	1.333
Birth weight	−0.846	0.605	1.956	1	0.162	0.429	0.131	1.404
Gender	0.254	0.292	0.76	1	0.383	1.289	0.728	2.284
Sweet score (excellent)	3.356	0.416	65.014	1	0.000*	28.66	12.678	64.79
Sweet score (good)	2.201	0.327	45.319	1	0.000*	9.034	4.76	17.146
Cleaning teeth once a day	0.751	0.661	1.293	1	0.256	2.119	0.581	7.733
Cleaning teeth twice a day	0.588	0.686	0.735	1	0.391	1.8	0.469	6.902
Feeding method	−0.041	0.157	0.068	1	0.795	0.96	0.705	1.306
Feeding duration	−0.613	0.377	2.64	1	0.104	0.542	0.259	1.135
Bottle content	−0.144	0.183	0.615	1	0.433	0.866	0.605	1.24
Age when brushing commenced	0.357	0.174	4.232	1	0.041*	1.43	1.017	2.01
Constant	−1.463	1.291	1.284	1	0.257	0.232		

SE: Standard error, CI: Confidence interval, Df: Degree of freedom, *Statistically significant

than the children in the control group. It is possible that our follow-up and verbal information session may have reminded the intervention group mothers about restricting dietary sugar intake, impacting their sweet scores positively.

Despite the intervention group participants having access to urgent needs (through the OUT), none of them reported any urgent oral treatment (OUT). Although the intervention group participants were provided with a fluoride toothpaste supply to last through their prenatal period, we observed that the control group participants were also using fluoride toothpaste. This may have dissipated some of the intervention effects.

We noted that the incidence of ECC in intervention and control groups was lower when compared to the existing literature.[15] This could be because we educated both groups. Even the control group received oral health information, although it was verbal. They were provided with information about the importance of fluoride toothpaste and when and how to use it for their children's oral hygiene practices. This is in line with the results of a review conducted by Twetman, who investigated the impact of using fluoride toothpaste in controlling ECC.[21] Our study findings are in accordance with a few community-based trials that were carried out in preschool children in China using fluoride toothpastes as the intervention for reducing the risk for ECC.[22,23] Another important predictor for ECC in our study was the time at which toothbrushing commenced. In addition to eliminating the plaque and debris from toothbrushing, the topical effect may have played a role in decreasing the incidence of caries. This finding is in line with the study conducted by Wigen and Wang with the Norwegian mother and children.[12] Past studies have reported that toothbrushing with the fluoridated toothpaste by mothers of the children is essential for maintaining good oral hygiene as well as reducing the level of caries causing bacterial and caries themselves.[13]

Of the total thirty mothers who received the ART, 29 (99%) children from these mothers did not show ECC at 2 years of age. This implies that providing ART to the mothers is crucial for the prevention of caries in their offspring. Providing restorations decreases the *Streptococcus mutans* count and thus decreases the chance of transmission of *S. mutans* from mother to child.[24,25] The findings in this study are in line with the past literature that investigated the impact of a preventive oral health program that targeted pregnant women in controlling caries in their children.[10] Past research suggests that every pregnant woman should have an oral evaluation, be counseled on proper oral hygiene, and referred for restorative and preventive care.[26,27] Given the nature of the natural experiment that we conducted, our program has an advantage of sustainability in the existing setup and is effective for routine and everyday practice as recommended.[28]

It is essential to reflect on the following study limitations while interpreting the study findings. First, those who participated in our study could be the ones who were interested in maintaining the oral health of their unborn children. Furthermore, the study was conducted in a specific location of India, and thus this population could be unique and may have limited generalizability to other populations. Thus, the findings that we observed may not reflect all the pregnant women in the region. Second, caries is a disease of multifactorial etiology, and addressing all potential caries risk factors for ECC was beyond the scope of the study. Third, although we provided the intervention group with the fluoride toothpaste, it was not new to them. In fact, both the intervention and control groups used it before participating in our study and this may have interacted with our study outcomes. In addition, there might have been contamination as the intervention group participants may have shared the information with the control group participants. Furthermore, the participating mothers from both groups may have used dental services outside of our

program, and we have no information on that. Finally, we used self-reports, and thus, their responses may have been exaggerated.

Conclusion

The results suggest providing oral health information, access to oral care, and BPOC during the pre- and post-natal period to women could reduce the incidence of ECC in their children. In other words, the preventive program that targeted pregnant women early in their pregnancies and continued to do so during the prenatal period seems effective in preventing or delaying the development of caries in children. While these findings are interesting, they need to be confirmed with larger samples. Furthermore, the intervention program that we used in this study showed that it was feasible to provide dental care services in a rural setup to prevent tooth decay in target populations.

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Conflicts of interest

There are no conflicts of interest.

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