

Topical antimicrobial therapy in the prevention of early childhood caries

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Abstract

Purpose: Early childhood caries (ECC) is microbiologically characterized by heavy infection of mutans streptococci (ms) on dental surfaces. Accordingly, it is reasonable to speculate that suppression of dental ms levels would decrease risk for ECC. On this basis, a randomized double blind, placebo controlled pilot study was performed to test this concept.

Methods: The study population consisted of 31 subjects (age: 12 to 19 mos; sex: 18F/13M) who were clients of a Women, Infants, and Children (WIC) clinic in Puerto Rico. Inclusion criteria included: (1) unremarkable medical history; (2) presence of 4 maxillary primary incisors (PMI) with no visible defects; (3) clinically caries free; (4) use of a nursing bottle at naptime and/or bedtime which contained a cariogenic substrate; (5) two consecutive ms positive cultures (utilizing Mitis-Salivarius-Bacitracin (MSB) agar) from pooled PMI plaque. The subjects were randomized into 2 groups. The 15 subjects in the experimental group and the 16 subjects in the control group were evaluated every 2 months during the study period. At each evaluation, the subjects had 10% povidone iodine (experimental group) or placebo (control group) applied to their dentition. The placebo was commercial instant tea (without lemon or sweetener) and deionized water. Treatment failure was defined as the appearance of a white spot lesion(s) on any of the PMI during the study period.

Results: The mean duration of observation to treatment failure was 155 days; the mean duration of observation for treatment success was 217 days. Five of the 16 control subjects and 0 of the 15 experimental subjects experienced treatment failure (Fisher's exact test: $P=0.04$). The Kaplan-Meier estimate for incidence of treatment failure in the placebo group was 48% over 357 days ($P=0.02$).

Conclusion: These observations suggest that topical antimicrobial therapy reduces risk for the development of ECC in high-risk children. (*Pediatr Dent* 21:9-11, 1999)

Early childhood caries (ECC) is a disease of infants, toddlers, and young preschool children that may devastate the primary dentition. Microbiologic studies indicate that ECC is characterized by heavy infection of mutans streptococci (ms) on dental surfaces.¹ Accordingly, it is reasonable to conclude that suppression of dental ms populations to non-pathogenic levels would decrease risk for ECC. In this regard, human^{2,3} and animal^{4,5} model studies indicate that topical iodine agents can significantly suppress dental levels of ms. Collectively, this information supports the concept that topical application of an iodine agent to dental surfaces of children at risk for ECC should reduce risk for the development of ECC. On this basis, a randomized double blind placebo controlled pilot study was performed to test this concept.

METHODS

Population

The study population consisted of 31 babies who were clients of a Women, Infants, and Children (WIC) clinic in Puerto Rico. This population was composed of 18 females and 13 males who were 12 to 19 months of age at their time of entry into the study. Inclusion criteria were as follows: (1) unremarkable medical history; (2) presence of 4 primary maxillary incisors (PMI) with no visible defects; (3) clinically caries free; (4) use of a nursing bottle at naptime and or bedtime which contained a liquid other than water (NB+); (5) two consecutive positive ms cultures (separated by an 8 week interval) from pooled PMI plaque.

Medical history was confirmed by the WIC clinic's consulting pediatrician. The presence of 4 PMI with no visible defects and caries free status was established by examining the subjects. Caries diagnosis was based on the criteria of Radike (1972) with the modification that enamel was not scraped from white spot lesions.⁶

NB+ status was assessed by interviewing the subject's mother. Nursing bottle contents included cow's milk (N=16), cow's milk + powdered sweetening agents such as sucrose, Ovaltine and Quick (N=9), cow's milk + cereal (N=4) and juice (N=2). A pooled plaque sample was obtained by swabbing the gingival 1/3 of the 4 PMI with a cotton swab. The samples were placed into vials containing 2 ml of reduced-Transport-Fluid (RTF) with glass beads and transported to the laboratory for processing within 4 h of collection. The samples were dispersed and plated onto Mitis-Salivarius-Bacitracin (MSB) agar as previously described.⁷ They were incubated at 37°C for 48 h under anaerobic conditions and then placed for 24 h under aerobiosis. Representative colonies with morphological characteristics of ms were isolated⁸ and biochemically confirmed to be ms utilizing mannitol and sorbitol fermentation tests.⁹

Design

The study was designed as a randomized double blind placebo controlled clinical trial. Treatment failure was defined as the appearance of a white spot lesion(s) on any of the PMI during the study period. The subjects were randomized into 2 groups. The 15 subjects in the experimental groups and the 16 subjects in the control group were evaluated every two months during the study period. At each evaluation they were examined for dental caries and had a 10% povidone iodine solution (experimental group) or placebo solution (control group) applied to their dentition. The placebo was commercial instant tea (without lemon or sweetener) and deionized water. These agents were placed into coded vials by the laboratory technician so the examiners would be blinded. The agents were applied by swabbing the dentition with a small sterile cotton ball that was saturated with the respective agent and held in a locking cotton plier. In addition, the mothers were questioned at each evaluation to verify the NB+ status of their baby.

Statistical Analysis

Baseline comparisons of the two groups were done to assess the randomization process. The number of subjects in each group to experience treatment failure was compared using Fisher's exact test. The incidence of treatment failure was compared in the two groups using Kaplan-Meier estimation techniques for survival functions. Statistical comparisons of the survival functions were done using the log rank test. Differences were considered statistically significant if two-sided P-values were at or below 0.05. The mean episode duration to treatment failure was compared to the mean episode duration of treatment success using a 2 sample t-test. Subjects that were lost to follow up (N=3), non-compliant (N=11), or discontinued their NB+ feeding habit (N=1) contributed observation time until they were statistically censored.

RESULTS

There were no statistically significant differences in the age or gender distribution of the subjects in the two study groups. The 16 placebo subjects were observed for a mean of 192 days (range: 47-352 days) and the 15 experimental subjects were observed for a mean of 224 days (range: 63-359 days). Five of the 16 control subjects and none of the 15 experimental subjects experienced treatment failure ($P=0.04$). The Kaplan-Meier estimate for incidence of treatment failure in the placebo group was 48% over 357 days ($P=0.02$). The mean duration of observation to treatment failure was 155 days (range: 47-306 days); the mean duration of observation for treatment success was 217 days; (range: 63-359 days). These differences were not significant ($P=0.26$).

DISCUSSION

The data from the placebo group in this study allowed estimation of the incidence of white spot lesions in children 12-19 months old who have ms in their oral flora and are NB+. The Kaplan-Meier estimate was 48 per 100 children per year. This is the first longitudinal study that we are aware of to estimate incidence of white spot lesions in children at high risk for ECC.

Earlier studies indicate that ECC is microbiologically characterized by dense dental infection with ms.¹ Animal studies indicate that accumulation of ms are associated with frequent and prolonged consumption of cariogenic substrates and precede the onset of dental caries.^{10,11} These experimental observations support the notion that infants who are colonized by ms and who have feeding habits characterized by frequent and prolonged oral exposure to cariogenic substrates, are likely to have a drastic increase in their oral ms populations. Such an increase is associated with a high risk for rampant dental caries. On this basis, it is reasonable to speculate that suppression of ms to non-pathogenic levels may decrease risk for ECC. In this regard, iodine solutions are well known for their ability to suppress ms dental populations when topically applied to the teeth.²⁻⁵ Collectively, the preceding narrative suggests that periodic topical application of an iodine solution to the dentition of children at high risk for ECC should suppress dental ms levels and in turn reduce risk for the development of ECC. The findings of this study provide evidence to support this concept. Stated differently, the experimental results of this clinical trial suggest that topical antimicrobial therapy significantly reduces the incidence of ECC in high-risk children. This preliminary finding has potential clinical significance and underscores the rationale for initiating larger and more in-depth clinical trials.

Current oral health policy of the American Academy of Pediatric Dentistry states that infants should

be weaned from the bottle at 12-14 months of age.¹² Most clinicians support this recommendation and will accept water substitution as a reasonable alternative. On this basis, the inclusion criterion of NB+ was formulated. However, recent and compelling data indicate that cow's milk is not cariogenic in a desalivated rat model.¹³ Accordingly, we parenthetically assessed the cariogenic potential of cow's milk in the study population of this report. It is of interest that 8 experimental and 8 control subjects had cow's milk as the only substrate placed in their nursing bottles. None of these 16 subjects experienced treatment failure (Fisher's exact test: $P=0.02$). This human observation supports the concept that cow's milk is not cariogenic.

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