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Clinical evaluation of chlorhexidine for the control of dental biofilm in children with special needs

A.C.R. Chibinski[1], M.T. Pochapski[2], P.V. Farago[3], F.A. Santos[1] and G.D. Czlusniak[1]

[1] Department of Dentistry, Ponta Grossa State University, School of Dentistry, Ponta Grossa, Paraná, Brazil; [2] Department of Pharmacology, Anesthesiology and Therapeutics, Piracicaba Dental School, University of Campinas, Piracicaba, SP, Brazil; [3] Department of Phamarcy, Ponta Grossa State University, School of Dentistry, Ponta Grossa, Paraná, Brazil

Objective: The aim of the present study was to assess two vehicles and forms of the in-home administration of chlorhexidine for the control of dental biofilm in children with special needs. ***Basic Research Design:*** Twenty-nine children aged seven to 12 years (mixed dentition phase) participated in the study. A double-blind, placebo-controlled, cross-over clinical trial was carried out with the following treatment groups: 1 - 0.12% chlorhexidine gel (CG); 2 - placebo gel (PG); 3 - 0.12% chlorhexidine spray (CS); 4 - placebo spray (PS). Ten-day experiment periods were separated by 15-day washout intervals. ***Main Outcome Measures:*** The parameters evaluated were plaque, gingival bleeding, and preferences of parents/caregivers. ***Results:*** The initial conditions were similar in each phase of the experiment ($p>0.05$). The treatments with chlorhexidine (gel and spray) achieved a significant reduction ($p<0.0001$) in plaque and bleeding. The placebo treatments did not achieve significant differences ($p>0.05$). The parents/caregivers preferred the administration of chlorhexidine in spray form. ***Conclusions:*** The topical administration of chlorhexidine associated to tooth brushing led to a reduction in dental biofilm and gingival bleeding in children with special needs. Administration in spray form proved easier and was preferred by parents/caregivers.

Key words: *Plaque control; Gingivitis; Oral hygiene; Special care; Clinical Trials*

Introduction

The maintenance of dental biofilm levels under conditions that are compatible with the oral health of patients with special needs is not an easy task. Due to the motor and cognitive limitation inherent to these patients, the mechanical control of dental biofilm may not be adequate even when performed by parents/caregivers (hereafter referred to as caregivers). Thus, high rates of oral disease are reported for this population. This difficulty can be addressed with the use of chemical agents (Choi and Yang, 2003, de Abreu *et al.*, 2002, Teitelbaum *et al.*, 2009).

Chlorhexidine is considered the gold standard among the currently available antimicrobial products for control of dental plaque and gingivitis. Its use has been extensively studied and shown to improve oral hygiene in individuals with special needs (Bozkurt *et al.*, 2005; Francis *et al.*, 1987a,b; Kalaga *et al.*, 1989b).

The most common form of chlorhexidine administration is a mouthwash solution, which is contra-indicated for patients with special needs. Thus, alternative methods have been researched, such as gels, varnishes, dentifrices and sprays (Ankola *et al.*, 2008; Bozkurt *et al.*, 2005; Kalaga *et al.*, 1989a; Pizzo *et al.*, 2006; Stoeken *et al.*, 2007; Teitelbaum *et al.*, 2009). It should be pointed out that, in most studies, the administration of chlorhexidine is carried out by dental professionals (dentists, dental hygienists or dental assistants) or nurses (Chikte *et al.*, 1991; Kalaga *et al.*, 1989a; Shapira and Stabholz, 1996; Stabholz *et al.*, 1991; Steelman *et al.*, 1996). However, the availability of such professionals in the daily lives of children with special needs is unlikely. The ideal situation requires a simple regimen that can be provided by caregivers and accepted by the patients. It is therefore necessary to design effective, broad-scoped, preventive/therapeutic protocols for the control of dental biofilm that are easy to execute and suitable to their daily needs (Francis *et al.*, 1987a; Kalaga *et al.*, 1989b; Pannuti *et al.*, 2003; Shapira and Stabholz, 1996; Stabholz *et al.*, 1991).

The aim of the present study was to clinically assess two vehicles for the administration of chlorhexidine (gel and spray) for the control of dental biofilm in children with special needs, taking into account the opinion of caregivers. The two hypotheses tested were: 1, that there would be no difference in clinical findings after short-term chlorhexidine administration using gel or spray; and 2, caregivers/parents would express a preference regarding the delivery method of the agents being tested.

Method

The present study received approval from the Ethics Committee of the Ponta Grossa State University (Process #05408). All the caregivers were invited to an initial meeting with the clinical researcher and they were informed of the nature of the study. After that, they signed a consent form, according to the Helsinki Declaration (version 2002) and the Dentistry Ethical Code (CONEP/MS, Brazil).

The sample was made up of 30 children with special needs (12 patients with Down syndrome, 6 with cerebral

Correspondence to: Dr F.A. Santos, Department of Dentistry, Ponta Grossa State University, Ave. Carlos Cavalcanti, n.4748, CEP- 84030-900, Uvaranas, Ponta Grossa PR, Brazil. E-mail: fasantos11@gmail.com

palsy and 12 with idiopathic cognitive impairment). The sample size of 30 subjects was estimated for this research based on a previous study (by the same authors) using a similar project design (Teitelbaum *et al.*, 2009). The inclusion criteria were: medical diagnosis of cognitive impairment; moderate degree of retardation ("trainable" category, intelligence quotient between 40 and 55); age between seven and 12 years, in the phase of mixed dentition, with elements 11, 31, 41, 16, 26, 36 and 46 erupted (2/3 of the crown or more). The exclusion criteria were: numerous cavities; residual roots; dental-alveolar abscesses; the use of antibiotic, anti-inflammatory or anticonvulsant drugs in the six months prior to the study; and a history of allergic reaction to the chemical agent being tested.

A cross-over, double-blind clinical trial was employed, using two vehicles: 1, chlorhexidine gel (0.12%), applied with gauze; 2, chlorhexidine solution in spray form (0.12%). The test and placebo gels were placed in coded plastic receptacles, with a capacity for 30g. The same procedure was used for the solutions. Pharmaceutical equivalence tests between the gel and solution were carried out using a pycnometer and precision digital scale in order to ensure the equivalence of mass, volume and density between the vehicles. Thus, 2.27g was established as the adequate amount of gel and 24 squirts (2.26mL) was established as the adequate amount of solution, indicating that each dental arch should receive 1g of gel or 12 squirts of spray per application.

The subjects were then submitted to four treatments (cross-over design, Figure 1): 1, chlorhexidine gel (CG: chlorhexidine, essence of peppermint, green dye, hydroxyethylcellulose); 2, placebo gel (PG: essence of peppermint, green dye, hydroxyethylcellulose); 3, chlorhexidine spray (CS: chlorhexidine, essence of peppermint, green dye, distilled water); 4, placebo spray (PS: essence of peppermint, green dye, distilled water). Experiment periods lasted 10 days with 15-day washout intervals.

The caregivers and subjects were asked to participate in four sessions (coinciding with the beginning of each phase of the experiment) to receive instructions for administering the agents being tested. The set of materials necessary for the oral hygiene of the patients was offered in four different kits that contained a child's toothbrush, placebo dentifrice (5% propylene glycol, 25% glycerin, 0.1% methylparaben, 0.2% sodium saccharin, 0.1% menthol, 0.5% essence of mint, 2.5% hydroxyethylcellulose, red dye) and the agents to be tested. All materials were furnished by an assistant, without the participation of the main researcher. All treatments included three daily toothbrushings with the placebo dentifrice. The agents tested were administered in the morning and after the last meal of the day. The caregivers were unaware whether they were administering the active product or the placebo. During the washout phases, the caregivers received instructions to return to the normal dental hygiene habits with a fluoridated dentifrice.

For the initial and final evaluations, the vestibular and lingual surfaces of elements 11, 31, 16, 26, 36 and 46 were examined. The plaque index was determined using the method described by Quigley and Hein (1962), with scores ranging from 0 to 5 (0 no plaque; 1 separate flecks of plaque at the cervical margin of the tooth; 2 a thin continuous band of plaque (up to 1mm) at the cervical margin of the tooth; 3 a band of plaque wider than 1mm but covering less the one-third of the crown of the tooth; 4 plaque covering at least one-third of the crown of the tooth but less than two-thirds of the crown of the tooth; 5 plaque covering two-thirds or more of the crown of the tooth). The gingival conditions were determined by the presence or absence of marginal bleeding upon probing (WHO 621, Seffiro Stainless, Lascod, SpA, Italy) (Ainamo and Bay, 1975). At the end of each clinical session, the patients had their teeth brushed by a dental assistant resulting in the complete removal of the plaque disclosing agent. All evaluations

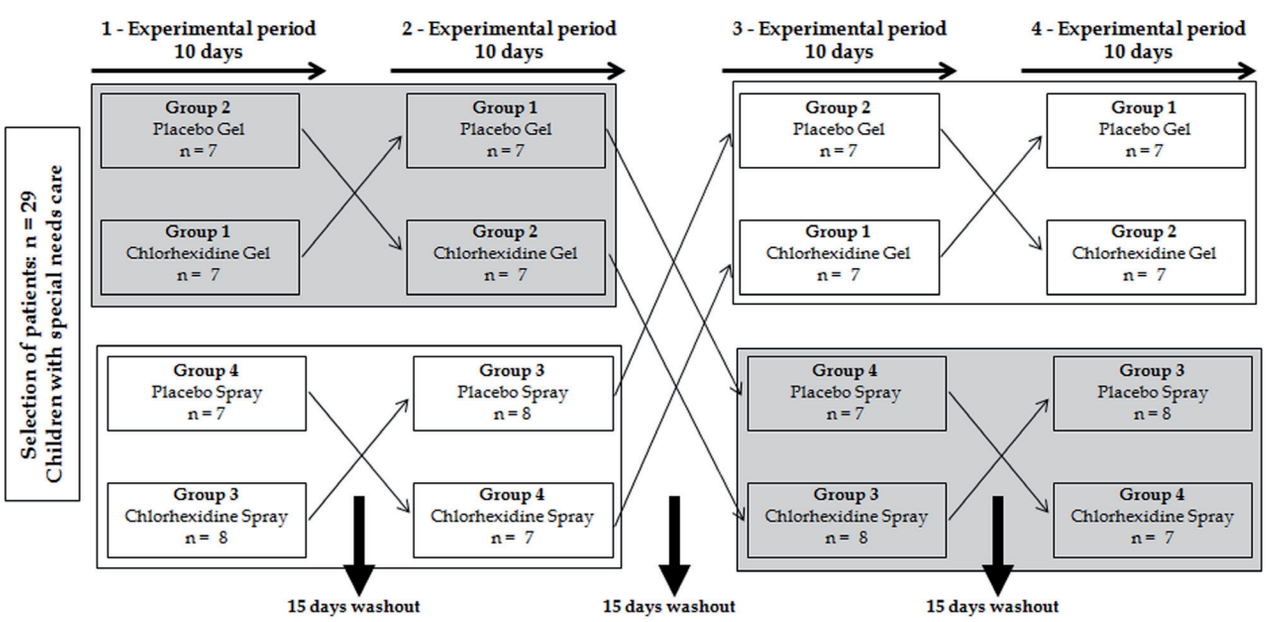

Figure 1. *Experimental design of the cross-over clinical trial*

Table 1. Mean and standard deviation of initial and final plaque index values for the four different treatments: chlorhexidine gel (CG), placebo gel (PG), chlorhexidine spray (CS) and placebo spray (PS)

	Mean Plaque Index (sd)		
Treatment	*Before treatment*	*After treatment*	
chlorhexidine gel (CG)	3.61 (0.45)	2.75 (0.40)	*p<0.0001
placebo gel (PG)	3.75 (0.34)	3.82 (0.31)	
chlorhexidine spray (CS)	3.62 (0.46)	2.60 (0.56)	*p<0.0001
placebo spray (PS)	3.73 (0.32)	3.91(0.29)	

* Significant difference between initial and final plaque index values in CG and CS groups by paired t-test.
Intra-group comparison: Significant difference final plaque index among groups (p<0.0001) "versus" PG and PS (ANOVA with Bonferroni post hoc test).

Table 2. Percentage Gingival Index (absence of bleeding) before and after the four treatments: chlorhexidine gel (CG), placebo gel (PG), chlorhexidine spray (CS) and, placebo spray (PS)

	Gingival Index		
Treatment	*Before treatment*	*After treatment*	
chlorhexidine gel (CG)	75.6%	99.7%	*p<0.0001
placebo gel (PG);	79.6%	77.0%	
chlorhexidine spray (CS)	71.8%	96.0%	*p<0.0001
placebo spray (PS)	71.8%	65.8%	

* Significant difference between initial and final gingival index values by McNemar Test.

and procedures were made in a dental office based in a school for children with special needs.

The clinical exams were performed by a single examiner (ACRC), blinded to which vehicle for chlorhexidine administration (gel or spray; placebo or active) was used and having achieved a Kappa index of 0.89 for the plaque index. For the gingival index, training was carried out with clinical photos and a discussion regarding the parameters with a second examiner (10 patients with the same conditions as those in the study). At the end of the experiment, the caregivers were asked about compliance with prescribed protocols, the ease of application, and their preference regarding the treatments used.

The Statistical Package for Social Sciences (SPSS®, v.11.5.1, Chicago, Illinois) program was used for statistical analyses with the significance level set at 0.05. Comparisons between the initial and final results of the plaque and gingival indices were carried out using analysis of variance (ANOVA) for repeated measurements with Bonferroni post hoc test and Cochran's Q statistic, respectively. The initial and final plaque values in a single treatment were compared using the paired Student's t-test. McNemar's test was used for the comparisons regarding gingival bleeding, application ease and preference of use.

Results

A total of 29 individuals (16 boys, 13 girls) completed the study. One volunteer was excluded during the study for the use of an antibiotic. There were no significant differences in mean initial values for the plaque and gingival indices between groups (Tables 1 and 2).

Table 3. Percentage of caregivers stating ease of use and preference for use of the gel and spray formulations

Formulation	*Ease of Use*	*Preference*
Gel	38.0%	34.0%
Spray	79.0%	62.0%
	*p<0.0001	*p=0.021

* Significant differences by McNemar test

The treatments with chlorhexidine (gel and spray) achieved a reduction (p<0.0001) in plaque and gingival bleeding. A 24% and 28% reduction in plaque was achieved in the CG and CS groups, respectively. A reduction in gingival bleeding from 24.4% to 0.3% was achieved in the CG group and a reduction from 728.2% to 4% in the CS group. The placebo treatments showed little change in the plaque index and the gingival index (Tables 1 and 2).

There were differences (p<0.0001) between the chlorhexidine and placebo treatments regarding the clinical parameters assessed (Tables 1 and 2). There was no difference between the two active vehicles tested. All caregivers affirmed their total compliance with prescribed protocol. They found it easier to administer the chlorhexidine in spray form and preferred this mode of application (Table 3).

Only one patient presented dental staining after the application of chlorhexidine gel. No other adverse reactions were reported for any treatments used.

Discussion

In the present study, chlorhexidine administered in both vehicles tested achieved significant reductions in plaque and gingival bleeding. The Quigley and Hein (1962) index is widely used in the literature and was chosen to quantify the build-up of dental biofilm (Bozkurt *et al.*, 2005; Pizzo *et al.*, 2006; Stoeken *et al.*, 2007). Like other indices, this assessment tool involves a certain degree of subjectivity. Therefore, in order to ensure the reliability of the index, assessments were carried out by a single, previously calibrated examiner who achieved a Kappa index of 0.89, for which scores above 0.75 are considered adequate for clinical trials.

The gingival condition was assessed through marginal bleeding upon probing, which is the criterion employed by a number of previous studies involving patients with special needs (Francis *et al.*, 1987a, 1987b; Kalaga *et al.*, 1989a,b; Teitelbaum *et al.*, 2009). This index was chosen because it is based on a clinical finding (marginal bleeding). However, gingival probing makes calibration unachievable, as the second exam could cause additional bleeding, thereby masking the result. Thus, clinical training alone was performed, with no previous calibration of the examiner.

For both assessment criteria, the decision was made to examine specific teeth. The erupted permanent teeth in the age groups analyzed were selected for this purpose. The limited number of teeth examined also allowed for carrying out repeated clinical exams in a population where this practice is normally severely lacking (Chikte *et al.*, 1991, Stabholz *et al.*, 1991, Teitelbaum *et al.*, 2009).

At the beginning of the four periods of the experiment, the sample had a high plaque index and more than ¼ of the sites presented bleeding. These findings agree with the literature relating to special needs children (Choi and Yang, 2003, Teitelbaum *et al.*, 2009). Lower values were achieved on both indices following the administration of chlorhexidine (gel or spray). The comparison of these findings with those described in the literature should be carried out with caution due to the different methods employed (de Abreu *et al.*, 2002, Steelman *et al.*, 1996, Kalaga *et al.*, 1989a,b; Pannuti *et al.*, 2003).

An understanding of the actual influence of the chlorhexidine-administration vehicle was established as one of the aims of the present study. For this reason, the concentration was maintained at 0.12% in both the gel and spray forms. Other conditions capable of influencing the final clinical result were also standardised, such as mass and density of the vehicle and the amount used per application. Therefore, the only variable related to the physiochemical conditions of the products used was centered on its pharmaceutical form.

Another variable that makes comparisons more complex is the age group of the sample. There are studies carried out on either adults (Kalaga *et al.*, 1989b, 1989a; Pannuti *et al.*, 2003) or children (Stabholz *et al.*, 1991; Teitelbaum *et al.*, 2009) as well as samples that include children, adolescents and adults (de Abreu *et al.*, 2002; Chikte *et al.*; 1991, Francis *et al.,* 1987a,b; Steelman *et al.*, 1996). Although all subjects in these studies have special needs, the dental characteristics inherent to each age group should be considered. There is a tendency toward a worsening of oral health conditions as patients with special needs enter adolescence and adulthood (Choi and Yang, 2003). Judging this tendency to be relevant, the study sample comprised exclusively children aged 7- 12 years. Nonetheless, there is a consensus in the literature regarding the potential of chlorhexidine for the control of dental biofilm in both adults and children (de Abreu *et al.*, 2002; Pannuti *et al.*, 2003; Shapira and Stabholz, 1996; Stabholz *et al.*, 1991).

In the present study, the use of chlorhexidine with the different treatments (gel and spray, administered by the caregivers) led to a significant reduction in plaque. There are reports in the literature of greater reductions. However, it should be stressed that the administration of chlorhexidine in those cases was by nurses or trained caregivers on institutionalized special needs patients (de Abreu *et al.*, 2002; Chikte *et al.*, 1991; Kalaga *et al.*, 1989b; Pannuti *et al.*, 2003; Steelman *et al.*, 1996).

The administration of the gel with gauze could contribute to a reduction in the clinical parameters assessed, as gauze could exercise a mechanical action on the removal of biofilm. However, the caregivers were instructed to only use gauze to spread the gel onto the tooth surfaces, without friction. The effectiveness of the methods employed was proven, as the use of the placebo (gel or spray) did not lead to a reduction in plaque or gingival bleeding.

Habitual toothbrushing was maintained throughout the experiment to avoid altering the oral hygiene routine. Daily brushings were performed by the caregivers, regardless of the degree of dexterity or autonomy of the child. This, associated with the use of the placebo, proves the effectiveness of chlorhexidine as a complement to mechanical means of biofilm removal, as special needs children generally have poor oral hygiene, even when aided by a parent or caregiver (Ankola *et al.*, 2008, Christensen, 2005).

The systematization of the hygiene procedure, in which the caregivers were instructed to administer the gel or spray following a predetermined sequence, could increase the amount of care directed at the child during the experiment, thereby improving the standard of hygiene. The experimental model (cross-over trial) contributed toward minimizing the effect of uncontrollable variables among the groups, such as the degree of learning during the study, the "Hawthorne" effect or the receptivity of the child to the treatment.

The caregivers reported difficulties administering the gel, as it required two steps: first wrapping gauze round the finger, then applying the gel to each dental arch. By contrast, the application of the spray depended solely on counting the number of squirts and so was the caregivers preferred method. Previous studies have also demonstrated this preference (Francis *et al.*, 1987a,b).

Within the limits of the present study, it was concluded that the topical application of chlorhexidine used as part of thrice-daily toothbrushing led to a significant reduction in dental biofilm and gingival bleeding for children with special needs. Parents/caregivers preferred to administer the chlorhexidine in spray form.

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