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Caries management for institutionalized elders using fluoride and chlorhexidine mouthrinses

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Abstract – *Objectives:* The effectiveness of either a 0.2% neutral sodium fluoride (NaF) solution or a 0.12% chlorhexidine (CHX) solution as a daily mouthrinse for controlling caries was tested against a placebo rinse in this 2-year randomized clinical trial among elders in long-term care (LTC) facilities. *Methods:* At baseline, 369 recruits were examined clinically for caries and allocated randomly to one of the mouthrinse groups. *Results:* After 2 years, 116 participants remained in the trial. The prevalence of caries and the dental status of the groups were similar at baseline and after 2 years. On average, each group lost less than one tooth per person, but the fluoride group compared with the others had significantly less caries and significantly more reversals from carious to sound dental surfaces at the end of the trial. *Conclusions:* We conclude that 0.2% neutral NaF mouthrinse every day does reduce the incidence of caries among elders in LTC facilities.

Key words: caries prevention; chlorhexidine; fluoride; geriatrics; randomized clinical trial

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About 6% of the population older than 65 years in most Western countries live in long-term care (LTC) facilities (1). In general, their oral health is very poor, with dental caries particularly rampant among those who have natural teeth (2). Caries occurs for many reasons in this population but mostly because of excessive sugar consumption, poor oral hygiene, medications that disturb salivary flow, and poor access to dental services (2). The impact of caries in any age group threatens nutrition and overall comfort, but it can be particularly damaging to the systemic health of frail elders (3). Consequently, caries among elders in LTC is a substantial health concern that needs practical methods to control and prevent.

Several strategies have been used to prevent or reduce caries in children, mostly with fluoridated drinking water, mouthrinses or dental varnishes. In young populations, weekly 0.2% NaF rinse has been shown to reduce caries incidence by 47% (4). Similarly, van Rijkom et al. (5) reported a 46% inhibiting effect of chlorhexidine (CHX) on caries incidence. Bader et al. (6) report 'fair' evidence from a review of the literature that fluoridated varnish helps to prevent caries when the risk of the disease is high, but that the evidence is incomplete for other preventive methods. A daily mouthrinse with 0.12% CHX solution reduced the numbers of *Streptococcus mutans* and *Lactobacillus* in the saliva of elders at particular risk to caries (7), but the significance of this reduction to the management or control of caries has not been established. Bader et al. (6) also indicated that the evidence supporting CHX for caries prevention 'is suggestive but not conclusive'. Apparently, most studies have not had the statistical power to show the effectiveness of antimicrobial mouthrinses in populations at high risk to caries (8).

The objective of this double-blind randomized clinical trial was to assess, over 2 years, the clinical effectiveness of a daily mouthrinse with 15 ml of

either 0.2% neutral NaF or 0.12% chlorhexidine gluconate (CHX) compared with a placebo (Pl) for reducing the net incidence of dental caries among institutionalized elders.

Materials and methods

A previous study in LTC facilities found a net incidence of new caries over 2 years in about 80% of the residents (9), and a similar study found at least one new lesion in 59% of community-dwelling elders and in 71% of the elders in LTC after 1 year (10). We aimed to achieve a net reduction of at least 25 percentage points (to 55% or less) in caries incidence as an indication of therapeutic success based on previous reports of 80% caries incidence among institutionalized elders. We determined that 43 subjects per group would provide an 80% probability of detecting such a difference, using a one-sided test for proportions at a 0.05 significance level (11). As we anticipated a drop-out of 65% over 2 years, also based on previous experience (9), we aimed to recruit at least 123 participants for each of three treatment groups at baseline. The treatment groups were prescribed, respectively: 15 ml of a 0.12% CHX solution [chlorhexidine gluconate 20% BP (Medisca Pharmaceutique Inc., St. Laurent, Quebec, Canada)], 4% isopropyl alcohol, 0.04% peppermint essence, and distilled water); and 15 ml of a 0.2% NaF solution (Fluorinse^{TM}; Oral-B Laboratories, Mississauga, Ontario, Canada), or 15 ml of a Pl (4% isopropyl alcohol, 0.04% peppermint essence, and distilled water) rinse.

A letter explaining the trial was sent to the administrators of 39 LTC facilities in Vancouver. The staff in each facility helped to identify and recruit 369 residents with the following inclusion criteria: (i) natural teeth; (ii) at least a 3-year life expectancy; (iii) a tolerance for dental examinations, (iv) an ability to use a mouthrinse; and (v) competence to give consent. After 2 years, 116 (31%) of the recruits remained in the trial – 38 (33%) using NaF; 41 (35%) using CHX; and 37 (32%) using the Pl. Mostly, they were Caucasian (93%) and women (69%), while the mean age of the recruits was 83 years (SD: 9.54; range: 54–101 years). The other 253 subjects lost to follow-up died (39%), were too ill (43%) or refused to comply with the rinse regimen (18%). Noncompliance was similar for all three regimens over the 2 years: CHX (22%), NaF (19%), and Pl (21%).

A dental assistant cleaned soft deposits and extrinsic stains from the teeth of the participants before a dentist examined the teeth of each participant for caries using the National Institute of Dental Research (NIDR) clinical criteria and examination protocol (12). Examinations were performed at baseline and after 1 and 2 years with the participants seated in a portable dental chair under a halogen light. The dentist used an air and water syringe along with suction to dry all dental surfaces and a no. 5 dental explorer with light pressure to identify active carious lesions (12–15). The structure of the teeth, including third molars, was recorded by an assistant as absent, sound, restored or decayed.

After the baseline examination, participants were assigned by a double-blind randomized block design to a CHX group (122 subjects, 33%), a NaF group (128 subjects, 35%), or a Pl group (119 subjects, 32%). Mouthrinses were prescribed as part of daily medication orders of the facility with the cooperation of each participant's physician. A pharmacy delivered a supply of mouthrinse to each facility every month during the trial, and the nursing staff monitored and recorded the use of the mouthrinses.

A random selection of 10 subjects was re-examined after 1 week to determine the examiner's repeatability of the tooth surface scores for coronal and root caries. There were no significant differences between individual coronal surfaces ($t = 0.452$; d.f. $= 9$; two-sided $P = 0.662$), and root surfaces ($t = 0.165$; d.f. $= 9$; two-sided $P = 0.872$) upon re-examination. In addition, one of the authors and the examining dentist independently examined the teeth of 10 subjects for caries; there were no significant differences between the mean scores for either coronal carious surfaces ($t = 1.246$; d.f. $= 9$; two-sided $P = 0.244$) or root carious surfaces ($t = 1.937$; d.f. $= 9$; two-sided $P = 0.085$).

As the primary outcome of the trial was the net incidence of caries in each group, we calculated the surface-by-surface incremental change in the number of new coronal and root surface lesions over the three examination recordings. We calculated the incidence at year 1 and year 2 by subtracting the number of carious surfaces at baseline from the total number of carious surfaces less the number of reversals from carious to sound (healthy) surfaces at subsequent examinations (16). Moreover, we confirmed from our clinical records that carious surfaces identified previously had been neither filled nor extracted. The Root Caries Index (RCI)

indicated the distribution of caries relative to the number of root surfaces at risk to caries (17). We recorded '*filled surfaces*' but we did not include them within the incremental measure because of uncertainty about reasons for filling or extracting teeth.

Contingency table chi-square tests were used to compare groups with respect to categorical and dichotomous outcomes, such as presence or absence of caries. In addition, *t*-tests were used to compare groups with respect to mean values or changes in mean values, such as numbers of carious surfaces.

Results

Descriptive statistics show no substantial difference between the dental status of the 369 subjects recruited for the trial and the status of the 116 participants who remained in the trial for the 2 years. The 69% loss to follow-up was slightly greater than the 65% anticipated. They had on average 17 teeth, four teeth with caries mostly on root surfaces, many surfaces restored with fillings and some with cast crowns (Table 1). Slightly more than three-quarters of the participants had caries at baseline and at year 2 (Table 2).

As reported at baseline, the majority (87%) of subjects did not receive assistance with daily oral hygiene, 12% received help from a care-aide and 1% from a family member. The majority of subjects (339) did nothing more than brush their teeth, eight of those also used a mouth rinse, whereas four of them used a brush and dental floss, but only five subjects used a brush, floss and a mouth rinse every day. Fifteen subjects used no toothpaste; five used nonfluoride toothpaste; while the others used fluoride toothpaste. Of the 55 subjects who used a mouthrinse, 15% used a fluoride rinse; none used a chlorhexidine rinse; and the remainder used rinses without fluoride. Four of the eight subjects using fluoride prior to entering the study were available for the final examination (three in the NaF group, one in the CHX group and none in the Pl group). Thirteen subjects (3.5%) admitted to performing no oral hygiene.

For the combined three treatment groups, there was a small but statistically significant decrease in the mean number of sound coronal surfaces ($P < 0.01$) and an increase in the mean number of

Table 1. Clinical status at baseline and year 2 of the participants who began the trial and those who finished the trial

	Participants		
Clinical status	Began the trial at baseline ($n = 369$)	Finished the trial at baseline ($n = 116$)	Year 2 ($n = 116$)
Teeth	16.4 (7.1)	17.0 (6.8)	16.8 (7.0)
Sound			
Teeth	1.1 (1.8)	1.0 (1.6)	1.1 (1.7)
Surfaces	68.6 (35.4)	70.6 (35.0)	70.3 (36.7)
Coronal surfaces	47.7 (26.6)	49.0 (26.2)***	46.1 (26.8)***
Root surfaces	20.9 (14.7)	21.5 (14.5)	24.2 (14.0)
Teeth with gingival recession	11.4 (5.9)	11.6 (5.4)	13.1 (5.6)
Teeth restored with			
Any restoration	7.2 (5.7)	7.5 (5.5)	7.4 (5.9)
Filling in a coronal	8.8 (6.0)	9.5 (5.8)	9.3 (5.9)
Filling in a root surface	2.8 (3.2)	2.9 (2.8)	3.4 (2.9)
Cast-alloy	2.6 (3.7)	2.4 (3.5)	2.5 (3.6)
Carious			
Teeth	3.8 (4.2)	4.0 (4.4)	4.5 (5.0)
Any surfaces	6.9 (10.0)	6.9 (9.5)*	8.1 (10.7)*
Coronal surfaces	2.0 (3.7)	2.3 (4.6)	2.4 (4.5)
Root surfaces	4.9 (7.9)	4.6 (6.5)**	5.7 (7.2)**
DMFS			
Coronal	112.3 (26.6)	111.0 (26.2)	113.9 (26.8)
Coronal and root	219.7 (35.4)	217.8 (35.1)	218.0 (36.7)
Root Caries Index	30.3 (26.1)	28.4 (22.9)	30.8 (21.9)

Significant changes among participants who finished the two-year trial (paired sample *t*-test, two-sided) *$P \leq 0.05$; **$P < 0.02$; ***$P < 0.01$.
Values are mean (SD).

Table 2. The mean prevalence of caries among participants who began and those who finished the trial

Caries surfaces	Participants (%)		
	Began the trial at baseline ($n = 369$)	Finished the trial at baseline ($n = 116$)	At year 2 ($n = 116$)
Any	80	78	76
Coronal	50	53	47
Root	69	68	72

carious surfaces ($P < 0.05$) especially on root surfaces ($P < 0.02$) during the 2 years (Table 1).

Comparing the treatment groups at baseline, there were no significant differences with respect to their percentage of caries-free participants (Table 3); but the mean number of carious teeth was greater for participants in the NaF group (4.5) compared with the CHX group (2.9) (Table 4; $P < 0.05$). Furthermore, the prevalence of caries increased in the CHX (73% to 85%) and Pl (75% to 81%) groups but decreased in the NaF group (85% to 61%) during the 2-year trial (Table 3), which represents a 12% and 6% increase of caries prevalence in the CHX and Pl groups, respectively, compared with a 24% decrease in the NaF group, over the 2 years. In general, the differences between the Pl and CHX groups were insignificant, apart from a higher incidence in the Pl group over the 2 years of new coronal caries on surfaces that were sound at baseline ($\chi^2 = 5.87$; d.f. $= 1$; $P = 0.02$) (Table 3).

The incidence of caries on one or more coronal or root surface during the trial was significantly less in the NaF group (15%) than in the CHX (50%) or Pl (35%) groups ($\chi^2 = 15.44$; d.f. $= 2$; $P < 0.001$) (Table 5). Comparisons between groups revealed further that differences in incidence were significant between the NaF and Pl groups ($\chi^2 = 11.5$; d.f. $= 1$; $P < 0.001$) and between the NaF and CHX groups ($\chi^2 = 19.3$; d.f. $= 1$; $P < 0.001$) but not between the CHX and Pl groups ($\chi^2 = 1.4$; d.f. $= 1$; $P = 0.49$).

Reversal of carious lesions to sound or healthy surfaces during the trial occurred much more frequently in the NaF group (59%) than either in the Pl (23%) or the CHX (18%) group ($\chi^2 = 21.2$; d.f. $= 2$; $P < 0.001$), whereas a comparison between groups revealed a reversal of one or more coronal or root lesions more frequently ($\chi^2 = 22.6$; d.f. $= 4$; $P < 0.001$) in the NaF group (59%) than in the CHX (18%) or Pl (23%) groups.

The mean increase, over the 2 years, of 0.7 carious surfaces in the NaF group was less ($t = 2.74$, d.f. $= 74$, two-sided $P = 0.008$) than the 2.9 surfaces in the Pl group, or the 3.1 surfaces in the CHX group ($t = 7.75$, d.f. $= 78$, two-sided $P < 0.001$), while most of the new lesions occurred on root surfaces (Table 5). In total, the net incidence of caries was significantly lower in the NaF group.

The effect of the fluoride rinse was most pronounced in reversing and preventing caries on root surfaces (Table 5).

Discussion

We established the sample size for each group with the expectation that there would be adequate statistical power to detect significant ($P \leq 0.05$) differences in caries incidence with an anticipated drop-out rate of 65% of the participants from each group over the 2 years. Although, the drop-out rate was slightly higher than that expected, the large differences observed between the NaF and the other two groups provided shows clearly that NaF reduces the incidence of caries in this population. The dropout of participants was largely because of death or illness; however, one of five participants in each group dropped out from the trial because they did not comply with the regimen. The participants probably differed from the general population of nursing home residents by being physically more independent and cognitively more alert (18). Nonetheless, we believe that our selection process provided a representation of elders in LTC who can use

Table 3. Prevalence of caries at baseline, year 1 and year 2

Caries surfaces	Chlorhexidine completed 2 years ($n = 41$)			Fluoride completed 2 years ($n = 39$)			Placebo completed 2 years ($n = 36$)		
	Baseline (%)	Year 1 (%)	Year 2 (%)	Baseline (%)	Year 1 (%)	Year 2 (%)	Baseline (%)	Year 1 (%)	Year 2 (%)
Any	73	81	85	85	74	61	75	81	81
Coronal	42	49	49	56	54	46	64	61	58
Root	68	78	80	72	69	59	64	78	78

Table 4. Clinical status of the participants completing the trial in each treatment group at baseline, year 1 and year 2

	Treatment groups								
	Chlorhexidine ($n = 41$)			Fluoride ($n = 39$)			Placebo ($n = 36$)		
Clinical status	Baseline	Year 1	Year 2	Baseline	Year 1	Year 2	Baseline	Year 1	Year 2
Teeth	16.1 (8.0)	15.8 (8.2)	15.8 (8.2)	17.4 (5.7)	17.5 (5.8)	17.2 (6.1)	17.6 (6.3)	17.5 (6.5)	17.5 (6.5)
Sound									
Teeth	5.1 (4.1)	4.7 (4.2)	4.5 (4.4)	5.4 (4.0)	4.7 (4.2)	4.5 (4.4)	5.8 (5.0)	5.3 (5.7)	5.1 (4.4)
Surfaces	66.3 (34.8)	66.9 (38.3)	67.1 (38.5)	68.5 (32.4)	69.2 (33.7)	70.1 (34.6)	77.7 (37.7)	74.5 (37.4)	74.3 (37.3)
Coronal surfaces	47.0 (27.5)	45.0 (28.4)	44.4 (28.6)	47.6 (24.7)	46.3 (24.9)	45.3 (25.1)	52.9 (26.6)	49.9 (27.4)	48.8 (27.2)
Root surfaces	19.3 (13.5)	22.0 (14.9)	22.7 (14.4)	20.9 (14.9)	22.9 (13.6)	24.8 (14.2)	24.9 (15.0)	24.6 (14.4)	25.5 (13.6)
Teeth with gingival recession	10.5 (5.2)	11.9 (6.1)	12.3 (6.1)	11.2 (5.4)	11.9 (6.1)	12.3 (6.1)	13.4 (5.2)	13.8 (5.0)	14.3 (5.1)
Teeth with									
Cast restoration	2.2 (3.6)	2.1 (3.5)	1.9 (3.2)	2.3 (2.7)	2.4 (3.1)	2.5 (3.1)	1.5 (2.5)	1.5 (2.5)	1.6 (2.8)
Any restoration	5.9 (5.1)	5.5 (4.9)	5.4 (4.6)	5.1 (4.5)	5.6 (5.4)	5.6 (5.4)	5.5 (4.2)	5.6 (4.6)	5.2 (4.5)
Coronal restoration	8.3 (6.1)	8.4 (6.2)	8.4 (6.2)	9.3 (5.3)	9.4 (5.8)	9.3 (5.9)	7.9 (5.5)	8.0 (5.7)	8.0 (6.0)
Root restoration	1.8 (2.6)	2.1 (2.6)	2.1 (2.7)	1.2 (1.4)	1.9 (2.2)	2.2 (2.3)	2.2 (2.3)	2.4 (2.3)	2.3 (2.5)
Carious									
Teeth[a]	2.9 (3.6)**	3.6 (4.0)	4.1 (4.2)**	4.5 (4.0)*	4.3 (4.5)	3.7 (4.4)*	4.8 (5.5)*	5.3 (5.7)	5.7 (5.7)*
Any surface	5.0 (7.8)**	6.8 (9.2)	7.8 (9.4)**	7.6 (8.2)	7.4 (8.7)	6.2 (8.6)	8.3 (12.1)**	9.3 (12.8)	10.6 (13.6)**
Coronal surfaces	1.9 (4.0)	2.3 (4.5)	2.1 (3.5)	2.2 (4.8)	2.0 (3.4)	1.9 (4.2)	3.0 (4.8)	3.1 (5.0)	3.4 (5.4)
Root surfaces	3.2 (4.5)***	4.5 (5.3)	5.7 (6.2)***	5.4 (6.7)	5.4 (6.6)	4.3 (5.9)	5.4 (8.0)***	6.3 (8.5)	7.3 (8.9)***
DMFS									
Coronal	221.8 (34.7)	221.1 (38.3)	221.0 (38.5)	219.9 (32.3)	219.2 (33.6)	218.4 (34.5)	210.9 (38.1)	213.9 (37.8)	214.1 (37.6)
Coronal and root	113 (27.5)	115.1 (28.4)	115.6 (28.6)	112.4 (24.7)	113.7 (24.9)	114.7 (25.1)	107.1 (26.6)	110.1 (27.4)	111.2 (27.2)
Root Caries Index	27.0 (21.6)	31.4 (23.3)	30.8 (21.9)	28.9 (23.2)	30.3 (21.3)	27.3 (19.6)	29.4 (24.3)	32.0 (22.5)	32.6 (21.8)

*Significant difference with the paired sample t-test: *$P \leq 0.05$; **$P < 0.02$; ***$P < 0.01$.
[a]Difference with the t-test between chlorhexidine and fluoride groups at baseline is significant at $P = 0.05$.
Values are given as mean (SD).

Table 5. Changes in carious surfaces per treatment group over time

Surface	Treatment groups [mean (SD)]		
	Chlorhexidine ($n = 41$)	Fluoride ($n = 39$)	Placebo ($n = 36$)
Incidence			
Baseline to year 1			
Any	1.8 (3.9)	0.2 (4.5)	1.0 (4.3)
Crown	0.5 (2.1)	0.0 (2.6)	0.1 (2.3)
Root	1.3 (3.1)	0.2 (4.3)	0.9 (2.8)
Year 1 to year 2			
Any	1.3 (3.4)	−0.4 (2.9)	1.3 (3.2)
Crown	−0.1 (1.9)	0.1 (1.5)	0.3 (1.3)
Root	1.4 (3.0)	−0.5 (1.9)	1.0 (2.6)
Baseline to year 2			
Any	3.1 (5.8)	0.7 (4.2)	2.9 (4.9)
Crown	0.3 (2.3)	0.4 (2.5)	0.8 (2.4)
Root	2.7 (5.3)	0.3 (3.1)	2.2 (3.8)
Reversals			
Baseline to year 2			
Any	1.9 (2.1)	3.0 (2.0)	1.9 (1.6)
Crown	0.32 (0.76)	0.49 (1.02)	0.42 (0.65)
Root	1.37 (1.39)	2.49 (1.8)	1.44 (1.5)
Net increase (+) or decrease (−) of carious surfaces	+3.4 (5.4) (range −5 to +24)	−1.1 (5.3) (range −5 to +24)	+2.3 (5.3) (range −5 to +24)

a mouthrinse and who are most in need of an effective strategy for managing caries. We determined, in a pilot study, that mouth rinses were used reliably when prescribed on a resident's medication orders (these records also document the daily intake of medications) and monitored by the nursing staff. The use of a prescription within the medical record of each participant, bolstered by a close liaison between our research staff and the nursing staff, which is similar to a preventive protocol for school children used by Ripa et al. (4), probably enhanced the compliance of the participants. We did not hear the complaints reported by others (19) about the bitter taste or dental stains from the CHX, possibly because the participants are accustomed to medications and discoloured teeth.

The oral status of the recruits at baseline (18, 20) was similar to the oral health of other institutionalized elders reported recently by others (21–23). Moreover, the mean increase of 1.5 carious surfaces over the first year in the placebo group was the same as the incidence reported about 10 years ago by MacEntee et al. (10). It is higher than the 0.1 surface increase over 15 months reported by Guivante-Nabet et al. (24), but they reported that an additional 9.4% of the carious teeth were extracted. The relatively high prevalence of caries in the NaF group and to a lesser extent in the Pl group at baseline could have enhanced the possibility of a significant reduction in caries over time, but it is unlikely that an uneven distribution at baseline could alone explain the relatively lower incidence and higher reversals of carious lesions within the NaF group.

Chlorhexidine can reduce *Streptococcus mutans* and *Lactobacillus* in mouths of older subjects, at least over a 6-week period (7), and it does not seem to be dependent on the method of application or the frequency of use (5). It is possible that the effectiveness of CHX as an antibacterial agent, and in caries prevention decreases over time. The benefits of fluoride are easier to explain as an inhibitor of surface demineralization and as a promoter of dental remineralization that become even more effective with time (25). Public health programmes usually administer 0.2% NaF on a weekly basis; however, we chose to test this concentration on a daily basis. Further information is needed now to determine the optimal concentration and frequency of NaF for a maximal dose effect.

A daily oral rinse with 15 ml of 0.2% neutral NaF solution by elderly residents in LTC facilities is significantly better than either a 0.12% of CHX solution or a Pl rinse at reducing the net incidence of caries over 2 years.

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