THE EFFECTS OF AN ALCOHOL-FREE 0.12% W/V CHLORHEXIDINE GLUCONATE MOUTHRINSE ON ORAL HEALTH

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Original Article

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ABSTRACT

Chlorhexidine gluconate, a dicationic bisbiguanide agent, contains anti-plaque properties. Most chlorhexidine gluconate mouthrinses presently available contain alcohol in varying concentrations. The role of alcohol in these mouthrinses is to act as a preservative and solvent although it may have deleterious effects on the oral epithelium on long term usage. Recently, an alcohol-free 0.12% w/v chlorhexidine gluconate mouthrinse (Oradex®) has become available in Malaysia. This clinical study is aimed at determining the effects of this alcohol-free product compared to a placebo. A group of 60 meticulously screened subjects were assigned into two groups of 30 each. The first group started using the test product for 2 weeks followed by a washout period of 4 weeks. After this duration, this group used the placebo for a further 2 weeks. The 2nd group underwent similar protocol as the 1st except that this group started with the placebo. Measurements consisting of the following scores were recorded at baseline and after 2 weeks for each group: Plaque, Gingivitis, Papillary Bleeding, Stain and Calculus. Full mouth prophylaxis was carried out for all subjects after measurements at baseline as well as after the 2-week period. They were told to rinse with 15 ml of the designated mouthrinse twice daily for thirty seconds each after toothbrushing. The results of this study indicated that there was significant improvement in the plaque, gingival and papilla bleeding scores compared to the placebo. Stain and calculus scores were significantly increased for the test product when compared to the placebo. In conclusion, this study showed that alcohol-free 0.12% w/v chlorhexidine gluconate mouthrinse is effective in reducing plaque and gingivitis but causes staining and calculus formation.

Key words: Chlorhexidine, mouthrinse, alcohol, plaque, gingivitis, papilla bleeding, calculus and stain.

INTRODUCTION

Dental plaque accumulation is the prerequisite for the development of gingivitis (1). Current opinion favours the concept that plaque-induced gingivitis always precedes periodontitis (2,3) although not all gingivitis proceeds to periodontitis (4). Indeed, the long-term success of periodontal treatment is dependent on satisfactory oral hygiene practices by individuals to maintain plaque levels compatible with gingival health (5,6). Periodontal treatment is also directed towards eliminating subgingival plaque which itself is derived from supragingival plaque (7).

Supragingival plaque control is largely the responsibility of the individual, using toothbrushes and interdental cleaning devices and remains the most widely accepted method of oral disease prevention (8). Chemical agents have increasingly been used as adjuncts to mechanical plaque control (9). They are however intended to augment and not to replace mechanical plaque control (10). Given the microbial nature of plaque, antimicrobial agents such as chlorhexidine have so far been the mainstay of chemical plaque control and have been used in the prevention and treatment of gingivitis and periodontitis (11, 12).

Rationale for supragingival plaque control

Dental plaque occupies a central role as the major aetiological factor in the pathogenesis of dental caries and periodontal disease (1). The conceptual framework for these oral diseases, like other infectious diseases, is that of a balance between host response on the one hand and microbial pathogenesis on the other. In health, host immune responses are sufficient to hold in check the pathogenic potential of both the normal resident microbial flora or exogenous microbial pathogens (13). Infectious diseases such as dental caries and periodontal disease occur when this equilibrium is disturbed. Consequently, these two diseases may be prevented or successfully controlled by the complete, regular removal of plaque from tooth surfaces (14).

Periodontal disease is global in distribution and as such, control of the disease in all its forms must cross all socioeconomic barriers (12). In some countries, virtually 100% of the population is affected to some degree by gingivitis at some time (15). For more severe periodontal disease in which tooth longevity is at risk, prevalence figures of approximately 5-15% of the population have been quoted and this is much higher than some other diseases (16, 17).

It is widely accepted that the cornerstone for prevention of periodontal disease is that of prevention and/or removal of dental plaque and inhibition of gingivitis and supragingival plaque control still remains the mainstay of controlling gingivitis and therefore the occurrence or recurrence of periodontitis (12). Research shows that the time spent on toothbrushing procedure and the frequency of toothbrushing are key factors in determining the efficiency of supragingival plaque removal (18). In addition, patient dexterity, motivation and awareness of the benefits of good ora hygiene are important (19, 20). However, the dedication and motivation required to achieve or maintain such control is not the norm for most individuals (18). A typical response to prophylaxis, toothbrushing instructions and motivation is a temporary improvement in gingival health, which is lost in the absence of further motivation (21). Furthermore, population surveys suggest that high proportions of adults are affected by early periodontal disease (22, 23) suggesting that mechanical plaque control is insufficient to ensure periodontal health in most individuals.

These observations have provided a compelling rational for the introduction of chemical agents as adjuncts to mechanical oral hygiene procedures to control supragingival plaque formation (24). Indeed, antimicrobial therapy has become established as a part of the armamentaria for the reduction of plaque and gingivitis (25).

Alcohol in Mouthrinses

One of the features of mouthrinses that is of concern to dental public health workers and which could lead to oral tissue damage, is their alcohol (ethanol) content (26). The amount of alcohol in some mouthrinses equaled or exceeded that contained in many alcoholic beverages and if used over a long term, could be a contributory factor in oral cancer (27). Concerns over the possible association of alcohol intake and oral and pharyngeal cancer have been extended to include alcohol-containing mouthrinses, although the scientific validity of these concerns has not been established todate (7).

Chlorhexidine

The dental profession has used chlorhexidine for more than two decades and it is recognized as the primary agent for chemical plaque control (28). Chlorhexidine is a dicationic chlorophenyl biguanide with outstanding bacteriostatic properties (14). The drug was synthesized and first reported by Imperial Chemical Industries, England in 1954, following extensive investigations of the biological properties of polybiguanide compounds (29). Chlorhexidine is well-tolerated and long-lasting antiseptic which is not neutralized by body fluids or other organic compounds (30) and this compound was introduced for medical use in 1953 as an antiseptic cream for wounds. Its later applications included those of a pre surgical skin cleanser, a surgical scrub, an obstetric cream and an instrument sterilization fluid (29). The application of chlorhexidine as an antiplaque agent was suggested by Schroeder in 1969 (31). Most of the chlorhexidine mouthrinses available in the market today contain alcohol (mainly ethanol) in varying concentrations.

The aim of the study is to ascertain the effects of an alcohol-free chlorhexidine mouthrinse (Oradex ®) on plaque, gingivitis, papilla bleeding, stain and calculus formation in subjects compared to a placebo.

MATERIALS AND METHODS

A group of 60 subjects (48 females, 12 males; age range 22 to 46 years), were recruited from the staff of the University Hospital. Prior to their participation, they were meticulously screened to ascertain if they conformed with the criteria for the study. They were given written and verbal explanation and instructions pertaining to the study. Consent forms were signed by all participants.

The trial design was a placebo-control, double-blind, crossover type consisting of two 14-day test periods separated by a washout period of 4 weeks. During the entire study the participants continued to exercise their regular non-supervised, self-performed oral hygiene measures. They were each provided with a Oral B toothbrush and toothpaste.

The participants were assigned into two groups, those receiving the mouthrinses in the order active/placebo (Group A) and those in the order placebo/active (Group B). The mouthrinses were dispensed through a staff of the Department who held a sealed code-breaker. Due to the double-blind design, all solutions had the same colour and were kept in the same kind of bottle.

Subject selection criteria

Inclusion criteria

1. Subjects should have reasonable standard of oral hygiene with no severe gingivitis (score of not > 2 on the Gingival Index).
2. Subjects should have probing depths of not more than 3mm.
3. Subjects should have a minimum of 20 natural teeth.
4. Subjects should have no physical limitations or restrictions that might preclude normal oral hygiene procedures such as toothbrushing.
5. Subjects should have no history of adverse reactions to mouthrinses.
6. Subjects should consent to participate in the clinical trial after being given adequate information pertaining to the study.

Exclusion criteria

1. Subjects with severe gingivitis or who have probing depths exceeding 3mm and alveolar bone loss.
2. Subjects who have consumed antibiotics in the past 6 months.

3. History of rheumatic fever, congenital heart disorders, prosthetic heart valves or any other conditions requiring antibiotic cover prior to dental treatment.

4. Subjects with systemic disorders such as hypertension, diabetes mellitus, blood dyscrasia and infectious diseases eg. Hepatitis and Acquired Immune Deficiency Syndrome (AIDS).

5. Subjects who are pregnant.

6. Subjects who smoke.

7. Subjects whose manual dexterity is compromised eg. handicapped or post-stroke patients.

Clinical measurements

Plaque

Assessment was done after disclosing the supragingival plaque with erythrosine dye. Four surfaces (mesiobuccal, mesiolingual,distobuccal and distolingual) on four teeth (incisor, canine, premolar and molar) in each quadrant were scored according to the criteria of the Turesky et al. (1970) (32) modification of the Quigley and Hein (1963) (33) Plaque Index.

Gingivitis

Gingivitis was scored on four surfaces (mesiobuccal, mesiolingual, distobuccal and distolingual) of four teeth (incisor, canine, premolar and molar) in each quadrant according to the criteria of Loe and Silness (1963)(34).

Papilla Bleeding

The interdental papilla of four teeth (incisor, canine, premolar and molar) in each quadrant were scored following gentle probing according to the criteria of Saxer & Muhlemann (1975) (35).

Calculus

Scoring was done on the lingual surfaces of the lower anterior teeth according to the criteria of the Volpe-Manhold Index (1965) (36). The greatest area of calculus is measured in milimeters using a periodontal probe through the mesio-incisal and disto-incisal angles of the teeth.

Stain

The Shaw & Murray Index (1977) (37) was used to score stain on four surfaces of four teeth in each quadrant. This index evaluates the intensity of stain in four grades: no staining, slight, moderate and heavy staining.

Methodology

Pre-treatment phase

All subjects were rendered prophylaxis prior to commencement of the study. This was because some of the subjects had dental check-up with scaling done only recently and thus presented with minimal stain and calculus whereas some others had not had scaling since the past few years and presented with heavy deposition of stain and calculus. A period of four weeks was then allowed to elapse before the first test period.

First test period

Baseline measurements of plaque, gingivitis, papilla bleeding, calculus and stain were recorded. Plaque was scored last after disclosing it with erythrosine dye. This was followed by ultrasonic scaling and polishing of all teeth with a rubber cup and prophylaxis paste.

The subjects were each given a medium-soft toothbrush (Oral B) and a tube of toothpaste (Oral B). They were instructed to continue with their routine toothbrushing methods. The designated mouthrinses were dispensed according to the groups of the subjects. Group A started with the active product whereas Group B with the placebo. They were instructed to rinse twice daily about 30 minutes after toothbrushing so as to avoid interference between sodium lauryl sulphate in the toothpaste and chlorhexidine in the mouthrinse. The subjects were told to rinse for sixty seconds, followed by expectoration of residual mouthrinse. On day 14, all subjects returned for clinical measurements. This was followed by scaling and polishing of all teeth.

Washout period

An interval of four weeks was given after the first test period so that the effects from the previous mouthrinse did not carry over into the next test period. During the washout period the subjects exercised toothbrushing as they are used to but refrained from using any mouthrinse.

Second test period

The baseline measurements were repeated and followed by prophylaxis. The subjects were allotted the alternative mouthrinse and instructed to use it exactly as they did the previous product. They returned two weeks later for clinical measurements. All the subjects were then offered full-mouth prophylaxis.

Evaluation of scores

In the case of plaque, gingivitis and papilla bleeding, the data obtained were studied for the highest scores before and after using the products. The particular mouthrinse was deemed effective if the subject exhibited a reduction in this highest score after two weeks of utilizing the rinse. If the score was found to have increased or remained the same, the mouthrinse is considered ineffective. However, if prior to using the rinse, the particular subject had started with an initial highest score of 0 (for plaque and gingivitis) or 1 (for papilla bleeding) ie. the minimum score for these indices, and maintained this as the highest score, then the rinse was still considered effective.

As for calculus and stain, the data obtained before and after using the products was evaluated to determine any increment in the highest scores. The mouthrinse is considered to have caused staining or calculus formation

if there is an increase in the highest score two weeks after the rinse was employed. However, if the score had remained the same, it is considered to have had no effect.

Data management and analysis

The data collected was analysed to determine if usage of the products had any effect on the parameters observed compared to the placebo. The percentage of subjects where the test product and placebo was effective/not effective was tabulated and these categorical variables were cross tabulated using the Pearsons chi-square test for statistical significance. Level of significance was set at $p = 0.05$. Data was analysed using the SPSS version 9.0 programme.

Null Hypothesis

There is no difference with regards to effect on plaque, gingivitis, papilla bleeding, calculus and stain when subjects rinse with Oradex® or placebo during a 2-week period.

RESULTS

All subjects satisfactorily completed both rinsing regiment and presented for examination on the respective days.

1. **Plaque**
   Higher percentage of subjects were found to have improved plaque status when they rinsed with the test product compared with the placebo (71.7% VS 35%) (Table 1). The difference was found to be statistically significant ($p < 0.05$).

2. **Gingivitis**
   Higher percentage of subjects exhibited improved gingival status when they rinsed with chlorhexidine compared to the placebo (85% Vs 28.3%) (Table 2). The difference was found to be statistically significant ($p < 0.05$).

3. **Papilla Bleeding**
   Higher percentage of patients had improved papilla bleeding status when they rinsed with chlorhexidine compared with the placebo (90% Vs 45%) (Table 3). The difference was found to be statistically significant ($p < 0.05$).

4 **Calculus**
   Higher percentage of subjects exhibited increased calculus deposition when they rinsed with chlorhexidine compared to the placebo (86.7 % Vs 23.3%) (Table 4). The difference was found to be statistically significant ($p < 0.05$).

5 **Stains**
   Higher percentage of subjects had increased stain formation when rinsing with chlorhexidine compared to the placebo (95% Vs 18.3%) (Table 5). The difference was found to be statistically significant ($p < 0.05$).

Table 1. Effect on Plaque

Type of Mouthrinse	Effect					
	Effective		Not Effective		Total	
	n	%	n	%	N	%
Chlorhexidine	43	71.7%	17	28.3%	60	100
Placebo	21	35%	39	65%	60	100

Table 2. Effect on Gingivitis

Type of Mouthrinse	Effect					
	Effective		Not Effective		Total	
	n	%	n	%	N	%
Chlorhexidine	51	85%	9	15%	60	100
Placebo	17	28.3%	43	71.7%	60	100

Table 3. Effect on Papilla Bleeding

Type of Mouthrinse	Effect					
	Effective		Not Effective		Total	
	N	%	n	%	N	%
Chlorhexidine	51	85%	9	15%	60	100
Placebo	17	28.3%	43	71.7%	60	100

Table 4. Effect on Calculus

Type of Mouthrinse	Effect					
	Effective		Not Effective		Total	
	n	%	n	%	N	%
Chlorhexidine	52	86.7%	8	13.3%	60	100
Placebo	14	23.3%	46	76.7%	60	100

Table 5. Effect on Stain

Type of Mouthrinse	Effect					
	Stain		No Stain		Total	
	n	%	n	%	N	%
Chlorhexidine	57	95%	3	5%	60	100
Placebo	11	18.3%	49	81.7%	60	100

DISCUSSION

Bacterial plaque is firmly implicated in the initiation of gingivitis and in its progression towards periodontitis. The most widely accepted method of plaque removal is by mechanical cleansing . Chemical plaque control remains only as an adjunct because many individuals are unable to perform proper mechanical plaque removal.

Mouthrinses have been available for a long time and with the recent proliferation of varieties, their mass marketing and their sale to the public with restriction has led to substantially increased use. With this increased usage, the monitoring and assessment of any potential adverse effect is paramount, no matter how insignificant they may seem. One of the features of mouthrinses that is of concern to dental public health workers and which could lead to oral tissue damage is their alcohol content (26). The concept of alcohol-free mouthrinses is relatively new (38). The findings of this study is similar with those of the only other clinical study done on alcohol-free chlorhexidine mouthrinse by Eldridge which concluded that alcohol-free chlorhexidine mouthrinse was as effective in reducing plaque and gingivitis (38) The results of the present study were also similar to several other studies done on alcohol-containing 0.12% chlorhexidine mouthrinses which concluded that 15ml of 0.12% chlorhexidine mouthrinse was significantly clinically better than a placebo when used alongside tooth brushing.

Chlohexidine is a dicationic anti plaque agent often described as gold standard in its antiplaque activity and its excellent retentive action on oral tissues (substantivity). The availablility of an alcohol-free 0.12 % chlorhexidine mouthrinses in Malaysia can overcome any shortcomings in mechanical plaque control and also allay fears of any side effects of alcohol which is so often used in these products. Short to medium term usage of this product can also overcome other side effects like staining.

CONCLUSION

In conclusion, this alcohol-free product is effective in improving plaque, gingivitis, papilla bleeding but causes calculus and stain formation in comparison to the placebo. The results of this study indicate that alcohol-free chlorhexidine mouthrinses are worthy of further clinical investigation. This would be particularly useful to individuals who are averse to alcohol.

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