Preventive strategies to improve periodontal health in people with Down syndrome

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Abstract

Aims and objectives: This study was designed to investigate the effects of different application of chlorhexidine as a gel (1%) and varnish (1% and 40%) on the periodontal health of a group of individuals with Down syndrome.

Design: The study was a single blind, crossover, randomised trial in a group of 27 people with Down syndrome conducted over 24 months in the Dublin Dental University Hospital. Two different concentrations of chlorhexidine varnish (1% and 40%) applied 3-monthly and 6-monthly, respectively were tested. A positive control phase received no chlorhexidine varnish although all regimes were supplemented with professional prophylaxis 6-monthly and chlorhexidine gel (1%) applied at home on a daily basis. Standard periodontal indices were applied at baseline, at 3-monthly or 6-monthly intervals and after cessation of the interventions. A questionnaire to carers was used to compare attitudinal and quality of life measures between the different regimes.

Results: There were significantly lower mean pocket probing depths and modified gingival indices for the control phase compared to those who received 3-monthly application of chlorhexidine varnish (1%). There was a significantly lower mean gingival bleeding index for those who received 6-monthly applications of chlorhexidine varnish (40%), compared to the control phase. Those receiving 6-monthly chlorhexidine varnish (40%) described statistically significantly higher eating scores, on the quality of life assessment, than during the control phase.

Conclusions: In this group of people there were few, significant differences between concentration, formulation or frequency of application of chlorhexidine on clinical measures of periodontal disease. Chlorhexidine gel (1%) applied at home daily (along with 6-monthly professional prophylaxis) may be as effective and efficient a means of maintaining periodontal health in individuals with Down syndrome. Chlorhexidine varnish (40%) applied 6-monthly may offer some additional benefit however this regime may cause some eating difficulties.

Key words: Chlorhexidine, Down syndrome, periodontal disease, quality of life

Introduction

Down syndrome is caused by a chromosomal abnormality and is characterised by certain physical, intellectual and medical features. A number of these features, such as learning disability, cardiac anomalies and an altered immune system, can have a profound effect on oral health and the delivery of oral care (Fiske and Shafik, 2001). The incidence of Down syndrome in Ireland is 1:540 live births (Johnson et al., 1996).

It is recognised that people with Down syndrome are more likely to develop periodontal disease than the general population (Bagic et al., 2003; Cheng et al., 2007). The age of onset of periodontal disease is also likely to be younger than the general population, which may lead to premature tooth loss (Amano et al., 2000). The severity and rapid progression of periodontal disease, often seen in people with Down syndrome, has been attributed to a combination of inadequate oral hygiene measures (Kao and Chou, 1991; Cichon et al., 1998), altered immune response (Tsilingaridis et al., 2003), including an alteration in the phagocytic activities of neutrophils, and early colonisation of periodontal pathogens (Amano et al., 2000).

Individuals with Down syndrome are often further disadvantaged by poor preventive dental health practices and should be targeted for increased preventive dental care (Randell et al., 1992). Supervised, preventive programmes have been shown to be very effective in reducing plaque and gingival scores in people with Down Syndrome (Yoshihara et al., 2005). Professional tooth cleaning is known to be effective in reducing probing depths, number of sites with bleeding and visible debris but this is operator intensive and impractical in day to day living (Shapira and Stabholz, 1996; Mori et al., 2000). Oral health and the delivery of oral care can have a huge impact on social acceptance and quality of life. The ideal management of the oral health of an
individual with Down syndrome is achieved via a multiprofessional approach that involves the members of the dental team from an early age with the potential to enhance quality of life (Stiefel et al., 1995).

It can be difficult to maintain compliance with oral hygiene regimes in patients with special oral health care needs. Any procedure that reduces the reliance on carers, whilst at the same time optimising health for the individual, is desirable. The control of periodontal disease in an individual with Down syndrome requires a regime that is simple, easy for patient or carer to use, acceptable to both patient and carer and sparing of resources.

It is acknowledged that chemical adjuncts may potentially simplify plaque control routines however, the way in which they are delivered may be critical to a successful outcome (Matthijs and Adriaens, 2002). There are a vast number of chemical adjuncts available currently in the market, both over the counter and those only available to oral health care professionals. This study focused specifically on chlorhexidine digluconate. Chlorhexidine is a biguanide with cationic properties. It has been shown to decrease plaque bacteria by up to 62% (Gusberti et al., 1988; Stabholz et al., 1991) and can be useful in controlling dental biofilm and in the reduction of gingival bleeding (Teitelbaum et al., 2009). It is bacteriostatic in low concentrations and bacteriocidal in high concentrations and is effective against gram positive and gram negative bacteria, including Staphylococcus Aureus, fungi and yeasts (Emilson, 1977; Scannapieco et al., 2009). Various concentrations of chlorhexidine varnishes have been proven effective in reducing oral pathogens, including streptococci, in vivo and in vitro (Petersson et al., 1992; Ogaard et al., 1997). Chlorhexidine gels have proven to be successful to a limited degree, in improving markers of periodontal health (Cutress et al., 1977; Pannuti et al., 2003; Cheng et al., 2008). Side effects of topical chlorhexidine include extrinsic staining (Ellingsen et al., 1982; McCoy et al., 2008), offensive taste and altered taste sensation (Grossman et al., 1996; Guimaraes et al., 2006). Staining is, however, removable by brushing, with a powered toothbrush being the most effective (Gent et al., 2002). Both the associated offensive taste and altered taste sensation are considered transient if used in moderation (Marinone and Savoldi, 2000; Gent et al., 2002; Guimaraes et al., 2006).

The vast array of formulations and concentrations of chlorhexidine make it difficult for oral health professionals to decide upon the best way to utilise this product to help maintain periodontal health in patients with Down syndrome. This study tested the impact of chlorhexidine at different formulations, concentrations and frequency of application, alongside regular oral prophylaxis, on periodontal health in a group of people with Down syndrome. The authors examined the effects of different application of chlorhexidine in gel form (1%) and varnish form (1% and 40%), on periodontal health using standard periodontal indices for assessment at baseline, at 3-monthly intervals and after cessation of the interventions. In addition, a questionnaire was used to determine user acceptability, perceptions of oral well-being and quality of life, as a consequence of the different regimes.

Materials and methods

This study was carried out over the course of 24-months from 2008-2009 in the Dublin University Hospital, a national referral centre. The study was a single blind, crossover, randomised trial in a group of people with Down syndrome which tested two different concentrations of chlorhexidine varnish (1% and 40%), applied 3-monthly and six monthly, respectively. Outcomes were measured against chlorhexidine gel (1%) used at home as a positive control. Twenty-seven subjects were included, having been recruited from referrals through Down Syndrome Ireland and the Dublin Dental University Hospital patient database.

Ethical approval was obtained from the Trinity College Faculty of Health Sciences Research Ethics Committee. Assent/consent from parents or significant caregiver were obtained at the outset of the study.

Subjects were stratified according to age, systemic disease and ability to maintain oral cleanliness either unaided or assisted by carers. Exclusion criteria included those for whom no consent/assent to take part had been given, subjects who were unable to comprehend what the study was about and/or who were unable to sit still for the duration of treatment, subjects who were taking medications that may have modified salivary form and function or subjects who had dental care, to include sub-gingival scaling, within the preceding two months. Subjects who had a congenital heart defect were not excluded from the study but were given appropriate antibiotic cover as indicated for periodontal prophylaxis and application of chlorhexidine varnish. The decision to provide such cover was based on the Dublin Dental University Hospital infective endocarditis prophylaxis protocol at the time of the study and applied to eight individuals.

Subjects entered the programme incrementally and were randomly allocated to a group; phase one, phase two or the positive control phase. This allocation, and subsequent movement between phases, was made by the treating dental hygienist. The assessing clinician was blinded to the phase. All three phases were subjected to a basic regime of topical application of chlorhexidine gel (1%) at home on a daily basis along with six-monthly professional prophylaxis. Phase one was supplemented with chlorhexidine varnish (1%) (Cervitec®) applied to all gingival margins along with professional prophylaxis at every three-month visit, beginning with the initial visit. Phase two had chlorhexidine varnish (40%) (EC40®) applied to all gingival margins along with professional prophylaxis at every 6-month visit, beginning with the initial visit. Patients, parents and carers were instructed on oral hygiene measures and at-home topical application of the chlorhexidine gel (1%). Subjects and parents/
carers were instructed that the chlorhexidine gel was to be used at a different time to the use of fluoridated toothpaste, in order to avoid the interaction with the foaming agents contained in conventional toothpaste ingredients. This advice was reinforced at each visit. The first phase lasted for 9-12 months after which groups crossed-over for the final 12 months. This was followed by a final examination after three months of no interventions other than at-home, daily application of chlorhexidine gel (1%). There was a minimum washout period of three months. Figure 1 provides a clinical flow diagram detailing the timeline of the groups.

The hygienist who was recruited specifically for the trial undertook non-blinded varnish applications over the range of visits according to the schedule. This operator also undertook the professional prophylaxis. Upon completion of the study, each participant was referred to either their primary dental carer or to the Dublin Dental University Hospital undergraduate teaching clinic for continued care with a dental hygienist or dental science student.

A number of clinical assessments were documented in order to accurately assess periodontal status. These assessments were recorded at each visit. Gingival health was evaluated using the Modified gingival index (Lobene et al., 1986). The presence of bleeding was assessed using the Gingival-bleeding index (Gibbs et al., 1988). The presence of plaque/calculus was investigated using the Calculus index (Manhold et al., 1965) and the Plaque index (Dababneh et al., 2002). Pocket probing depths were measured at index sites 1.6, 1.1, 2.6, 3.6, 4.1, 4.6 (Barmes, 1994). Where there were missing teeth, adjacent tooth types were substituted. Dentition status and caries prevalence, using the dmft/DMFT indices, were assessed at baseline and on completion of the study.

In order to investigate attitudinal and quality of life measures, a questionnaire to carers was designed based on that described by Allison & Hennequin (2000). This was designed to reflect the subject and the carers’ views on the acceptability of the different regimes, the likely compliance with the different regimes, side effects and the impact that the use of the different preventive approaches were perceived to have on the subjects’ quality of life. The carer completed this questionnaire at each visit. The questionnaire is divided into four sections: communication, eating, parafunction and symptoms. In each section there were between four and six questions. A final questionnaire was distributed to parents/carers at the end of the study to ascertain their preference for the various regimes. Parents/carers were also given the opportunity to comment at this point on anything else they thought relevant to the study. The assessments of periodontal health and the four sections of the questionnaire were each compared between phase one, phase two and the control phase using a student’s t-test with matched pairs.

Results

Twenty-seven subjects were included in this study, 12 males and 15 females. The mean age of the total group was 25.4 (range 9.2-43.1). The mean total number of visits was 5 (range 3-8). The average number of retained primary teeth of the total group was 2.3 (range 1-9). The mean DMFT at baseline was 0.44 (range 0-5) and the mean DMFT at finish was 0.48 (range 0-5). The mean DMFT at baseline and finish was 0.0.

Tooth brushing was carried out by a parent or family member in 11% of the total group, solely by the patient in 74%, and by a combination for 19% of the subjects; 85% of patients who brushed were right handed brushers and 15% were left handed brushers; 66% of the sample used a manual toothbrush, 34% used an electric toothbrush; 89% of the sample brushed their teeth using fluoride toothpaste.

There were significantly lower mean pocket probing depths (P=0.026) and modified gingival indices (P=0.029) for the control phase (1% chlorhexidine at home daily) (0.33, SD 0.60, and 1.03, SD 0.43, respectively) compared to phase one (1% chlorhexidine varnish applied 3-monthly) (0.49, SD 0.67, and 1.38, SD 0.14, respectively) (Table 1, Figures 2 and 3). There was no significant difference between phase one and the control phase with regard to any of the other markers of periodontal health measured, i.e. gingival bleeding index, calculus index and plaque index.

There were significantly lower mean gingival bleeding indices (P=0.028) for phase two (0.13, SD 0.14) compared to the control phase (0.16, SD 0.14) (Figure 3). There was no significant difference between phase two and the control phase with regard to any of the other markers of periodontal health measured, i.e. modified gingival index, probing pocket depth, calculus index and plaque index.

The quality of life questionnaire was completed at each visit. When the means of each of the four sections were compared between phase one, phase two and the control phase, phase two demonstrated a statistically significantly higher eating score (where eating was described as more difficult) (P=0.034) than the control phase (2.24 and 1.50 respectively).

Qualitatively, when the mean initial-visit score for each of the four sections for the total group was compared to the mean scores obtained at the final visit, both parafunction and symptoms sections lowered; 3.81-3.48 and 3.37-2.56, respectively. Conversely, for communications and eating, mean scores increased, i.e. they were seen to be more difficult from the initial visit to the final visit, 3.11-3.78 and 1.70-1.89, respectively.

The final questionnaire distributed to parents/carers revealed that 56% of parents/carers preferred attending the Dental Hospital in three-monthly intervals as opposed to six-monthly. The vast majority of the patients found the taste of 40% chlorhexidine intolerable however, this was only anecdotal evidence.
Figure 1. Clinical flow diagram detailing the timeline of the groups
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Diagram: Flowchart of study design.

**Beginning of clinical phase**

**Stage 1**
- Phase 1: 1% chx varnish clinically every 3-months (beginning with first visit), 3-monthly prophylaxis, 1% chx gel at-home daily
- Phase 2: 40% chx varnish every 6-months (beginning with first visit), 6-monthly prophylaxis, 1% chx gel at-home daily

**Crossover**

**Stage 2**
- Phase 1: 1% chx varnish clinically every 3-months (beginning with first visit), 3-monthly prophylaxis, 1% chx gel at-home daily
- Phase 2: 40% chx varnish every 6-months (beginning with first visit), 6-monthly prophylaxis, 1% chx gel at-home daily

**Safety**
- Report Progress - protocol amendments
- None necessary

**Audit**

**End of trial July 2009**
- Plans for continued oral care of subjects
  - Each subject referred back to primary caregiver or to undergraduate teaching clinics within the Dublin Dental School and Hospital.
- Data analysis
  - Student’s t-test with matched pairs
  - Reports within one year of trial ending
  - Dissemination of results
  - Archiving

Key: chx = Chlorhexidine Digluconate
*Random allocation by dental hygienist to maintain blinding
Discussion

This study was designed to determine whether there is an optimum concentration, formulation and frequency of application of chlorhexidine that maintains periodontal health in a group of people with Down syndrome and yet is acceptable to patients and carers.

In this study, there were significantly lower mean pocket probing depths (P=0.026) and modified gingival index (P=0.029) for the control phase (1% chlorhexidine at home daily) compared to group one (1% chlorhexidine varnish 3-monthly) (Figures 2 and 3). There was no significant difference between group one and the control phase with regard to any of the other markers of periodontal health measured, i.e. gingival bleeding index, calculus index and plaque index. This suggests that the basic regime of chlorhexidine gel (1%) applied topically on a daily basis, together with six-monthly professional prophylaxis, may offer a greater improvement on markers of periodontal disease in individuals with Down Syndrome than when this basic regime is supplemented with the application of chlorhexidine varnish (1%) as well as prophylaxis every three months. This finding implies that there is no benefit in supplementing periodontal regimes with three-monthly professional prophylaxis and application of chlorhexidine varnish (1%), despite evidence from the literature (Ogaard et al., 1997). However as it was, for each individual participating in phase one, there were only four occasions of professional prophylaxis and application of the chlorhexidine varnish (1%) within the twelve month time slot, which may have been insufficient to effect resulting improvements in periodontal health. Also, the control phase did not include a placebo varnish so perhaps the at-home compliance with oral hygiene measures as well as application of the chlorhexidine gel (1%), reduced slightly in phase one when the individuals were aware that something was being placed on their gums intended to help their oral health. This may explain the higher pocket probing depths and modified gingival index seen in phase one compared to the control phase. However, there were no significant differences between phase one and the control phase regarding any of the other markers of periodontal health measured, i.e. gingival bleeding index, calculus index and plaque index. This reinforces the fact that supplementing the basic regime of six-monthly prophylaxis and at-home, daily application of chlorhexidine gel (1%) with three-monthly professional prophylaxis and application of chlorhexidine varnish (1%) is unlikely to afford additional improvements in the major markers of periodontal health, in this study at least.

There was a significantly lower mean gingival bleeding index (P=0.028) for phase two (40% chlorhexidine varnish applied 6-monthly) compared to the control phase (1% chlorhexidine gel at home daily). This suggests that the addition of chlorhexidine varnish (40%) in

Table 1 Mean values (standard deviations) for the various markers of periodontal health across the three study phases. *Statistically significant difference between phases for that index (student’s t-test, matched pairs (p < 0.05))

<table>
<thead>
<tr>
<th></th>
<th>Phase 1 (SD)</th>
<th>Phase 2 (SD)</th>
<th>Control Phase (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculus index</td>
<td>0.38 (0.38)</td>
<td>0.23 (0.33)</td>
<td>0.25 (0.37)</td>
</tr>
<tr>
<td>Pocket probing depths</td>
<td>0.49* (0.67)</td>
<td>0.52 (0.52)</td>
<td>0.33* (0.60)</td>
</tr>
<tr>
<td>Gingival bleeding index</td>
<td>0.13 (0.14)</td>
<td>0.13* (0.14)</td>
<td>0.16* (0.15)</td>
</tr>
<tr>
<td>Modified gingival index</td>
<td>1.38* (0.14)</td>
<td>1.33 (0.55)</td>
<td>1.03* (0.43)</td>
</tr>
<tr>
<td>Plaque index</td>
<td>1.89 (0.25)</td>
<td>1.88 (0.30)</td>
<td>1.70 (0.34)</td>
</tr>
</tbody>
</table>

Figure 2. Description of the three study phases

Phase 1: 1% chlorhexidine varnish applied 3-monthly plus 3-monthly professional prophylaxis (plus 1% chlorhexidine gel applied at home daily)

Phase 2: 40% chlorhexidine varnish applied 6-monthly plus 6-monthly professional prophylaxis (plus 1% chlorhexidine gel applied at home daily)

Control phase: (1% chlorhexidine gel applied at home daily plus 6-monthly professional prophylaxis)
six-monthly increments may offer some improvement for markers of periodontal disease compared to the basic regime of six-monthly prophylaxis and at-home, daily application of chlorhexidine gel (1%) alone. There was no significant difference between phase two and the control phase with regard to any of the other markers of periodontal health measured, i.e. modified gingival index, probing pocket depth, calculus index and plaque index, which suggests any benefit to be minimal. However, again due to the short-term nature of the study, the results obtained may not be a truly accurate representation of the effect of the higher concentration of chlorhexidine as it was only applied twice in the allocated twelve months. If the study had been carried out over a longer term, further improvements in the other markers of periodontal health may have been evident. The results of this study suggest that the addition of a high concentration chlorhexidine varnish (40%) every six-months to the basic regime of six-monthly prophylaxis and at-home, daily application of chlorhexidine gel (1%), may afford a slight additional improvement in periodontal health.

The quality of life questionnaire was completed at each visit. When the means of each of the four sections were compared between phase one, phase two and the control phase, phase two demonstrated a statistically significantly higher eating score (2.240) than the control phase (P=0.034). This suggests a greater eating difficulty associated with the addition of chlorhexidine varnish (40%) six-monthly along with six-monthly prophylaxis to the basic regime. Chlorhexidine has been associated with poor taste and altered taste sensation and so it is feasible that the parents/carers perceived some eating difficulties around the time of application of the higher concentration varnish. Anecdotally, most patients complained of the foul taste of this varnish after application. However, it is generally accepted that any altered taste or taste sensation is transient so it is unlikely that six-monthly application of the chlorhexidine varnish (40%) afforded long-term eating difficulties. Parents/carers may have been reporting on specific times, i.e., on the day of the varnish application rather than describing an ongoing difficulty with eating. There were no statistically significant differences between phase one, phase two and the control phase regarding the other three sections of the quality of life questionnaire, namely communication, parafunction or symptoms, which implies that there is no major difference between the impact of the three phases on quality of life.

This study did not address the side effects often seen with topical application of chlorhexidine. It would be useful for further studies to compare the efficacy of various regimes of topical chlorhexidine against the experience of poor taste, altered taste sensation and extrinsic enamel staining. It was difficult to properly gauge the compliance with the at-home care, i.e. the basic oral hygiene measures as well as the daily application of chlorhexidine gel (1%). This should be noted when considering the significance of the findings of this study.

Over half of parents/carers (56%) preferred attending the Dental Hospital at three-monthly intervals as opposed to six-monthly. This implies a high level of interest and motivation amongst the study sample but may be a reflection of the difficulty some parents reported in accessing dental care. It also suggests a greater perceived, if not actual, benefit and oral health improvement from more frequent dental visits. However, the cost efficiency...
and practicalities of such frequent visits are yet to be assessed.

Conclusions

Individuals with Down Syndrome are often further disadvantaged by poor preventive dental health practices and should be targeted for increased preventive dental care (Randell et al., 1992). Supervised preventive programmes have been shown to be very effective in reducing plaque and gingival scores in people with Down Syndrome (Yoshihara et al., 2005). Regular, professional tooth cleaning is known to be effective in reducing probing depths, number of sites with bleeding and visible debris but it is operator intensive and impractical in day to day living (Shapira and Stabholz, 1996; Mori et al., 2000).

In this study there were few significant differences between concentration, formulation or frequency of application of chlorhexidine on clinical measures of periodontal disease or quality of life measures. Of the various regimens investigated in this current study, chlorhexidine gel (1%) applied at home daily, along with six-monthly professional prophylaxis, may be the most effective and efficient way of maintaining periodontal health in individuals with Down syndrome. This regime is sparing of resources and acceptable to patients and carers although compliance with the at-home measures in this study sample was difficult to determine. Higher concentration chlorhexidine varnish (40%) applied six-monthly may offer some additional benefit although this regime may lead to some, possibly transient, eating difficulties. There was no advantage to be found with the addition of chlorhexidine varnish (1%) along with a higher frequency of professional prophylaxis (three-monthly) other than the fact that parents and carers seem to prefer this frequency of visits.

References


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