Providing sealants at the general anaesthetic assessment visit for children requiring caries-related dental extractions under general anaesthetic

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TITLE

Providing sealants at the GA assessment visit for children requiring caries related dental extractions under GA: pilot RCT

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In brief points:

- Following caries related extractions under GA, children remain at high risk of caries in other, sound permanent molars.
- Sealant placement during the pre-GA assessment visit is feasible and may reduce caries incidence.
- High-risk families can be reliable trial participants.

Abstract

Introduction: Children experiencing a caries related dental general anaesthetic (GA) are at high risk of developing new caries. It is thus important to maximise opportunities for prevention.

Aim: To undertake a pilot randomised controlled clinical trial (RCT) to assess the feasibility of delivering and evaluating the effectiveness of sealing sound permanent molars at the pre-GA assessment appointment in children needing caries related extractions under GA.

Methods: Children (5 to 15 years) scheduled for GA extractions at Birmingham Dental Hospital (BDH), were randomised to control or sealant groups. At the pre-GA assessment appointment, sound permanent molars were sealed. Participants were followed up at 2 years.

Results: 132 children were assessed for eligibility and 100 randomized (50 control, 50 sealant). 49 children in the intervention group had sealants applied.
At 2 years, 82 children returned for follow-up at (43 control, 39 sealant). Sealants were retained on 93.5% (244/261) of surfaces sealed at baseline. 42% (n=18) of control-group participants had dentine caries in at least one permanent molar that was sound at baseline compared with none in the sealant-group.

Conclusion: Following caries related extractions under GA, children are at high-risk of developing new caries in permanent molars that were sound at the time of the GA. Sealant placement during the pre-GA assessment visit is feasible and may reduce caries incidence in this vulnerable group. High risk families were found to be reliable study participants.

INTRODUCTION

Since the late 1990's, use of general anaesthesia (GA) for dental treatment in children in the United Kingdom (UK) has steadily increased[1, 2] with highest rates amongst 5 to 9 year olds, for whom hospital admissions in England in 2017-18 were over 26, 000.[3] The frequency of a repeat dental GA is also relatively high, with rates reported ranging from10 to almost 40% .[4, 5, 6, 7, 8]

Children with experience of dental treatment under GA are at high risk of further caries and a repeat GA, so prevention is clearly paramount.[8, 9, 10, 11] Previous research has helped identify challenges parents face in supporting their child's oral health[10, 12, 13], but also suggests the GA experience does not appear to have a significant impact on long term preventive behaviours.[14] Many high-risk families are irregular attenders and this includes attendance for follow-up appointments after the GA.[10, 15, 16, 17, 18, 19]

Furthermore, preventive support (including use of fluorides and fissure sealants) by referring practitioners and GA providers also appears to be inadequate.[9, 10, 11, 13, 20] A service evaluation of preventive care by dentists referring children for GA in Birmingham identified an unmet need for sealants, with 77% of 6 to 8 year olds having at least one caries-free 'sealable' first permanent molar at the time of the GA.[20] Of those that could be followed up two years later, only 5% had sealants in first permanent molars but a third had untreated dentine caries in at least one first permanent molar that was previously sound.[20] Barriers to promotion of oral health by general dental practitioners (GDP) include poor patient compliance, parents' attitudes and behaviours with respect to oral health and insufficient time and remuneration for preventive activity.[11]

However, evidence based pro-active interventions are required to address the preventive needs of these high-risk children and given poor levels of dental attendance, it would seem appropriate to make better use of opportunities offered by the GA encounter.[7, 20] One option is to provide sealants at the GA assessment appointment. Fissure sealants are efficacious and cost-effective[21, 22] and recommended for high caries-risk children.[23, 24] Unlike oral health counselling, they do not depend on positive behaviour change by families and compared to topical fluoride, can be delivered in a single appointment. Furthermore, sealants target the

most caries susceptible (occlusal) surfaces of the most caries prone teeth (first permanent molars) in the age group (5-9 years) most often requiring a dental GA.[1, 2, 25, 26] Clearly, sealants don't protect all surfaces and have less scope to benefit younger children with a primary dentition, as pit and fissure caries accounts for only 40% of total caries experience in primary teeth and evidence for sealing primary molars is less robust.[27]

Thus, the aim of this research was to undertake a pilot randomised controlled clinical trial (RCT) to assess the feasibility of delivering and evaluating the effectiveness of sealing sound permanent molars at the pre-GA assessment appointment in children needing caries related extractions under GA.

OBJECTIVES:

To evaluate,

1. The ability to recruit based on failure to meet exclusion criteria, declining to participate or other reasons and retention rates based on subsequent withdrawals.
2. Feasibility and acceptability of placing sealants in this setting, based on compliance with the intervention.
3. Sealant retention rates based on the proportion of sealants that were fully intact, partially intact or lost after 24 months.
4. Two-year incidence of caries in permanent molars that were sound and suitable for sealants at the time of the pre-GA assessment, based on the proportion of children with:
    a. Experience of caries into dentine in at least one permanent molar
    b. Untreated caries into dentine in at least one permanent molar
5. Oral health related Quality of Life (OHRQoL) two years following caries related extractions under GA, based on the Child-Oral Impacts on Daily Performances (Child-OIDP) scale and separate questions relating to specified oral symptoms.
6. Oral health support provided by referring practitioners, within the 2 years following the dental GA, based on,
    a. Structured interview questionnaire to record parents' experience of preventive advice and treatment received, following the GA extractions
    b. Sealants identified at follow up that were not present at baseline or provided as part of the study

METHODS

Ethics approval and registrations:

Ethics approval was obtained from South Birmingham National Research Ethics Service, NRES Committee (West Midlands) in June 2014. REC reference: 14/WM/1007, IRAS project ID: 148667 and amendment number: SA#01
Local NHS permissions (Research and Development approval) were obtained from the National Institute of Health Research (NIHR) Clinical Research Network (West Midlands Consortium) and Birmingham Community Healthcare, BCHC NHS Trust and the study was also registered on a publicly accessible database (ClinicalTrials.gov), registration number NCT02443896.

Design:

We conducted a two-arm two-year non-blinded pilot RCT to compare sealant versus no sealant, placed on sound permanent molars, at the GA assessment visit, in children scheduled for caries related dental extractions under GA. This served to evaluate: recruitment and retention of participants, feasibility and acceptability of placing sealants in this setting, sealant retention rates and caries incidence in permanent molars (that were 'sound and sealable' at the time of the GA), along with oral health related quality of Life (OHRQoL) and oral health support provided by referring practitioners, within the 2 years following the GA.

Setting and subjects: The background to the paediatric dental GA service at BDH was described in an earlier paper.[20] The exodontia (extractions only) service, often referred to as the short 'chair' GA accounts for most of this activity and treats around 1600 children (under 17 years) each year. According to activity data based on age, almost 65% of children attending for a chair GA in 2017-18, were 6 years or older and thus potentially suitable for sealants.

Children (age 5 to 15 years) with a Birmingham postcode, who were referred to BDH for caries related extractions under a chair GA were considered eligible for inclusion if they had at least one caries free (sound and sealable) permanent molar at the GA assessment appointment. They had to be co-operative to a clinical dental examination and accompanied by an adult with legal capacity to give informed consent to take part in the study. Children with signs of a systemic illness or oral symptoms (e.g. pain, swelling) that might preclude

placement of sealants at the GA assessment visit were excluded as too were any whose parents were not confident about being able to attend for review at 2 years.

The Assessment visit

***Recruitment and randomisation**:*

Recruitment was carried out over a total period of 8 months. However, during this time, the study investigator (AR) was only available to recruit participants on ad hoc dates. Therefore, to facilitate recruitment, referral letters were triaged to identify children that were likely to be eligible (based on age, postcode and reason for GA referral) so they could be scheduled on these dates.

Study information (including separate leaflets for parents and children) was posted a few weeks before the GA assessment appointment.

At this visit, clinicians responsible for completing the GA assessment, also screened children to identify those that had potentially sealable permanent molars, and they were then invited to see the investigator on the same day. Further to this, eligibility to take part in the study, based on the full list of inclusion criteria was confirmed following full verbal and written consent.

A baseline clinical dental examination was undertaken by a single examiner (AR). A 3 in 1 syringe was used to wash and dry teeth and a ball ended probe used to remove soft debris and check for presence of sealants. Caries and caries related treatment (including evidence of sealants) were recorded using the International Caries Detection and Assessment System (ICDAS).[28, 29] Radiographs were not taken for study purposes but any available as part of the GA assessment, were referred to.

Sample size, randomisation and allocation concealment:

For this feasibility study, no formal sample size calculation was performed. A sample size of 100 children (50 per group) was considered sufficient to address the specific aims of this study. Eligible participants were randomised using an online randomisation service ('sealedenvelope.com')[30] immediately prior to the provision of the intervention.

Sealant group intervention:

Where possible, occlusal fissures of all caries free, sound and erupted permanent molars were sealed. Where appropriate, buccal pits and palatal fissures were also sealed. A resin-based sealant (Helio-seal F) was used as the first-choice material. When compliance was compromised and/or moisture control more challenging, a glass ionomer (GI) sealant (Fuji triage) was placed. The same products were used throughout the study to minimise variation related to different materials. All sealants were applied by a single operator (AR) and in accordance with manufacturer's instructions and recommended techniques.

Control group procedures and management of carious teeth not earmarked for extraction:

Children in the control group did not receive fissure sealants as part of the study but were subject to the current standard of preventive care in the secondary and primary sectors. For both groups, carious teeth not earmarked for extraction were managed as per the routine standard of practice: parents were offered treatment on under-graduate student clinics and/ or patients referred to their dental practitioner for completion of any outstanding restorative treatment.

All demographic and clinical data were recorded on case report forms.

Follow up - 24 months

Participants were reviewed (at BDH) 24 months after randomisation. Appointment letters were where possible, supported by telephone reminders. A further appointment was sent if the first was failed. If possible, non-attendees were telephoned (by AR), to establish the reason. Shopping vouchers were provided to reimburse travel expenses for parents attending the review.

Clinical Examination at Follow up Appointment:

The procedure for clinical examination was identical to that used at baseline and completed by AR: caries status was assessed using the ICDAS and radiographs taken if clinically justified (but not for study purposes). Retention of sealants was reported as fully intact, partially intact or lost. All data were recorded on follow-up case report forms.

Questionnaires:

Structured interview questionnaires were used to collect information on parents' experiences of dental services for their children, following the GA. Oral Health Related Quality of Life (OHRQoL) was assessed using the Child-Oral Impacts on Daily Performances (Child-OIDP) scale[31, 32] along with separate questions relating to specified oral symptoms. The Child-OIDP is a widely used self-reported measure, which has been validated for use in children in the UK and was also used for the most recent Child Dental Health Survey. [31, 32, 33] Both questionnaires were delivered by AR.

***Dental treatment and prevention activity at 24-month review*:**

Preventive advice and if appropriate, preventive interventions (sealants and/ or topical fluoride) were offered to all participants. This included sealants on teeth that may have erupted since the baseline examination. In the sealant group, lost or defective sealants were, if necessary, replaced. Preventive interventions (and if appropriate, any outstanding dental treatment) were managed through under-graduate student clinics and/ or patients were referred to their usual dental practitioner for ongoing care.

***Statistical analyses*:**

Summary statistics were calculated as appropriate. Baseline differences between children who did and did not attend follow-up were compared using two-sided t tests for continuous variables and Pearson's chi squared tests for categorical data at alpha=0.05. No formal hypothesis testing was performed to compare clinical outcomes between intervention and control groups as this was a feasibility study not designed to demonstrate efficacy.

RESULTS

Recruitment was undertaken from August 2014 to March 2015 and 24 month reviews completed between August 2016 and May 2017 (Figure 1).

Although the recruitment period extended over 8 months, as explained earlier, the study investigator was only available to undertake enrolment on a limited number of ad hoc sessions throughout this time. Based on these, 132 children were assessed for eligibility.

Baseline characteristics: (Table 1):

The average age of the sample was 7.7 years (range 5-14 years). Most (76%) participants were 6 to 8 years old, with a comparable number of boys (56%) and girls (44%). Asian children (mostly Pakistani) were, as a collective ethnic group, the most widely represented (45%), followed by White children (mostly British), who accounted for almost one-third (30%). Sixty percent of participants were resident in the poorest areas of Birmingham and none were in the most affluent decile.

All children were registered with a dentist, mostly (95%) with a GDP and all referrals had been made through primary dental care. Most (91%) had no follow-up appointment booked to see their dentist after the GA and 12% had previous experience of a caries related GA.
Most patients were scheduled for extraction of primary teeth. Based on the inclusion criteria, all participants had at least one caries free permanent molar, and most of these were first permanent molars (FPMs). Six to eight year olds were most likely to have four sound FPMs (88%, 67/ 76). Notably, no children at baseline had evidence of sealants.
Patient characteristics were generally well balanced between the control and sealant groups (Table 1).

A total of 82 (82%) of children attended the follow-up visit after 24 months: 43 (86%) of the control group and 39 (78%) of the sealant group. Boys (78%, n=14), children from a White ethnic background and children with permanent molars with caries into dentine at baseline, were more likely to be lost to follow up (online supplementary material – Table A).

Sealants applied at baseline (Table 2):

Forty-nine (out of 50) children in the intervention group had sealants applied but one was not compliant. The mean number of teeth sealed in each child was 3.6. Most (90%) had resin sealants but the remainder GI, due to insufficient co-operation to achieve adequate moisture control. No participant had both types of sealants. The procedure time was 12-29 minutes depending on the number of teeth sealed, although the average time required to seal four molars was around 20 minutes.

Follow-up at 24 months

***Sealants at 24 months (Table 3)*:**

Almost 12% of children in the control group had evidence of at least one sealant at the 24-month review and almost 95% of participants in the study intervention group, still had at least one sealant in situ.

Of the sealants retained (244) in the intervention group, 82% (201) were fully retained (compared to 42% of sealants identified in the control group). For sealants provided as part of the study, resin sealants were better retained than GI. Sealant retention on occlusal and smooth (buccal and palatal) surfaces was comparable.

***Caries prevalence in permanent molars at 24 months (Table 3)*:**

When reporting on all permanent teeth (which includes teeth present but not sound at baseline and any that had erupted within the 2 year study period), the control group had more experience of caries in dentine: almost 42% (n=18) of control group children had a DMFT of greater than zero, compared to 15% (n=6) in the sealant group. All experience of caries affecting dentine in permanent teeth, was confined to permanent molars. The control group also had higher levels of untreated dentine caries than the sealant group (35%, n=15 children in control group and 5%, n=2 children in sealant group). When limiting analyses to permanent molars that were present and sound at baseline (i.e. no experience of caries, restored or unrestored), none of the sealant group had experience of dentine caries in a permanent molar compared to 42% (n=18) of the control group (33%, n=14 had untreated caries in dentine). However, 64% of children in the sealant group and 77% of children in the control group had any caries (ICDAS > 0), which includes early caries confined to enamel. Overall, most caries affected occlusal surfaces, with 90% (29/32) of untreated dentine lesions involving occlusal fissures, compared to only 6% (n=2) of interproximal surfaces.

***Caries in primary teeth at 24 months (Table 4)*:**

At 24 months, 31% of children in the sealant group and 44% in the control group had experience of dentine caries in primary teeth and this affected only primary molars. Of the surfaces with experience of caries in dentine, one third (33%) were interproximal.

Oral symptoms, OHRQoL and experience of oral health support provided by referring practitioners, within the 2 years following the GA

Prevalence of oral symptoms in children followed up after 2 years was high, with 88% of children questioned, reporting at least one problem and just over half (52%) experiencing at least one negative impact of oral problems on their quality of life.
Most (85%) children had been back to see a dentist within the 2 years following the GA; three-quarters (76%) reported receiving oral hygiene instruction and two-thirds (66%) dietary advice, 17% of children had fluoride varnish applied and 7% had received sealants.

Please refer to online supplementary material (Tables B, C, D, E) for further details on findings relating to oral symptoms, OHRQoL and families' experiences of oral health support provided by referring practitioners, within the 2 years following the GA.

DISCUSSION

There is an unmet need for sealants in children requiring caries related dental extractions under GA and they remain at high risk of caries in permanent molars that were sound at the time of the GA. Findings from this pilot study show that sealant placement as part of the pre-GA assessment visit is feasible and well received by most children and may reduce caries incidence in this susceptible group. Furthermore, high risk families were found to be reliable study participants.

Most children were 6 to 8 years old, which supports the national picture[1] and the ethnic profile reflects the general ethnic pattern of school children in Birmingham.[35] Significantly more Asian children returned for follow up, which contradicts traditional perceptions of poor attendance within ethnic minority families.[36] Deprivation was high supporting higher rates of dental GA in children from deprived areas[16, 37, 38]. However, a tenth of children were from the more affluent half of society, indicating children from wealthier backgrounds were also susceptible to a dental GA.[39] Twelve percent had previous experience of a dental GA, which reflects repeat GA rates reported by other centres in the UK.[6, 8]

Sealants were well received by most children and compliance was higher than expected, given these children had been referred for dental treatment under GA. Clearly, extractions are more challenging than sealants, but this suggests some patients might manage treatment with conscious sedation or possibly only local anaesthesia (with appropriate behaviour

management techniques). This supports recommendations for other methods of delivering treatment to be considered.[40]

Sealants identified in the control group at follow-up serve as the most appropriate measure of the overall prevalence of sealants, in children that have experienced a dental GA. On this basis, 12% had at least one sealant after 2 years, which were assumed to have been placed in primary care. Sealant rates in the pilot sample were slightly higher than the national average (7% of 8 year olds in England)[41] but still too low, considering the high risk status of the study group. Retention of sealants applied as part of the study was high and analogous to those reported in other sealant trials.[21] Glass ionomer sealants were poorly retained, compared to their resin counterparts but were equally effective in terms of preventing caries.[21, 42, 43]

Given this was a pilot study, differences in caries experience between the intervention and control groups at follow-up are interpreted with caution: two years after the GA, a third of children in the control group had untreated dentine caries in at least one permanent molar that was caries free at baseline, compared to none in the intervention group. Nine percent of 8 year olds in the UK have experience of dentine caries in permanent teeth[44]: the pilot results thus highlight the very high-risk of caries in children experiencing a dental GA and demonstrate the potential benefits achievable through sealants. The susceptibility of occlusal surfaces to caries was confirmed.[25] Fourteen percent of children in the control group had evidence of 'severe' caries affecting a permanent molar, which compares with 15% of 15 year olds nationally[45]: the extent of severe disease in the pilot sample was of concern given the children affected were much younger. Children not returning for follow-up had higher levels of dentine caries in permanent molars at baseline: irregular attenders are more likely to experience caries relapse following a GA[46] as well as require a repeat GA[8] so prevention in this sub-group is clearly a priority.

Caries levels in the primary dentition at 24 months in sealant and control groups were comparable, supporting the benefit of sealing permanent molars in the intervention group. In primary molars, interproximal surfaces have been shown to be more vulnerable, with pit and fissure caries only accounting for around 40% of the total caries experience.[27] However, in the pilot sample, two-thirds of caries in primary molars affected occlusal, buccal or palatal surfaces, indicating these could also be sealed.

Considering the strengths and limitations of this study, it was encouraging that only a fifth of exclusions at the outset related to parents declining to take part in a study. Most were due to time constraints on the day caused by only one investigator being available to recruit families and provide the intervention. This calls for multiple examiners and operators in any future trials. The retention rate also compares favourably with other trials involving high-risk participants[47]. Shopping vouchers are presumed to have encouraged attendance.

Moving forwards, a definitive multi-centre trial to evaluate the effectiveness of this intervention is recommended, as we recognise the favourable outcomes observed in the pilot study might be less readily achievable by different clinicians working in varied operating conditions. The intervention could be extended to include sealants on premolars and primary molars and differences between GI and resin could be further evaluated by means of a 3-arm trial with 2 intervention groups (resin sealant or GI sealant) and the control group. Assessment of the health economics and cost effectiveness of the intervention proposed is also recommended.

CONCLUSIONS

Further to caries related extractions under GA, children are at high-risk of developing new caries in permanent molars that were sound at the time of the GA. Provision of fissure sealants by practitioners falls short of what would be expected for susceptible patients. Placing sealants at the GA assessment visit is feasible, well received by parents and most children and may reduce the incidence of caries in this group. Recruitment and retention for this pilot study were good, suggesting high-risk families can be reliable trial participants, which should facilitate development of appropriately tailored interventions, to help address the specific challenges associated with delivering prevention to this notoriously high-risk group.

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