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Community trial of silver fluoride treatment for deciduous dentition caries in remote Indigenous communities

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ABSTRACT

Background: Silver fluoride 40% followed by 10% stannous fluoride (AgF) has been used in dental practice in some parts of Australia for many years. This study compared the effectiveness of application of AgF with atraumatic restorative technique (ART) in managing cavitated carious primary molars.
Methods: The study was a community effectiveness trial in two remote Aboriginal communities where AgF has been used for some time. Children between 4 and 8 years of age with caries on primary molars were randomized by birth date to receive AgF or ART. There were 210 children who were included in the study with 384 eligible teeth. Children were followed up for periods between 9 months and 4 years. Negative outcomes such as dental pain, extraction, use of antibiotics and more extensive restorative treatment were considered as the primary outcomes of the study.
Results: Those negative outcomes were infrequent in both treatment groups. The prevalence ratio of negative sequelae for children treated with AgF compared with those treated with ART was lower at 0.18.
Conclusions: Silver fluoride was well accepted, easy to use and at least as effective a treatment as ART for dental caries in primary molars in young Aboriginal children in remote areas.

Keywords: Community effectiveness trial, primary teeth, silver fluoride.

Abbreviations and acronyms: AgF = silver fluoride (40%) + stannous fluoride (10%); ART = atraumatic restorative technique; PR = prevalence ratio; SDF = silver diamine fluoride.

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INTRODUCTION

Active caries in the primary dentition is a strong predictor for caries in the permanent dentition and for poorer general health. Untreated dental disease in children has been related to delayed speech development, poor dietary choices, dental pain and poorer oral health-related quality of life.[1] Furthermore, active caries in young children has a significant impact on their oral health-related quality of life.[2] Caries is highly prevalent in young Aboriginal children in remote areas and is increasing both in prevalence and severity.[3,4] Among children aged 5–6 years, 69% have caries experience[5] most of which is untreated. Jamieson and others noted in 2006 that remote-living Aboriginal children had 1.5 times the admission rate of their counterparts in major cities or regional areas ($P < 0.001$), and 1.4 times the admission rate of remote-living non-Aboriginal children for receipt of hospital-based dental services under general anaesthesia.[6]

Providing atraumatic dental care for young children is difficult. Conventional dental treatment to manage dental caries is not feasible in very young children particularly Aboriginal children in remote communities. This is due to the requirement for local anaesthesia for pain and moisture control in conventional dentistry, as well as child management issues. In many communities, the lack of dental infrastructure is an additional issue. The more acceptable 'conventional' dental treatment in the remote environment is atraumatic restorative treatment (ART) which has been endorsed by the World Health Organization (WHO).[7] ART requires fewer resources and is more acceptable than traditional dentistry in remote areas and for young children. However, even ART might be problematic and regarded as too intrusive for some Indigenous children. In addition, the materials required for ART require constant refrigeration which might not be feasible in some remote locations.

Simple effective methods applicable in the remote environment are needed to manage the caries process

in children with single or multiple caries lesions. This could either delay the need for treatment until the child is old enough to have conventional dental care within their community, be simple enough to be undertaken by non-dental health professionals and/or reduce the need for dental extractions and thus dental care under general anaesthetics.

Silver fluoride 40% followed by 10% stannous fluoride (AgF) is suggested as a treatment to inhibit caries progression or even to arrest the disease completely, and has been evaluated in cohort studies.[8,9] While application of this technique has had variable support within the public and private dental sectors, it is currently used in a number of remote communities for the treatment of caries in the primary dentition. One reason for this treatment is to avoid discomfort of more invasive treatment for the children receiving care. Aboriginal children in remote areas generally have high rates of respiratory and skin infections. These are frequently treated with intramuscular antibiotics; hence, children are often very wary of needles. Use of silver fluoride avoids many behavioural problems as there is no need for use of local anaesthetic often required in standard dental care. In addition, silver fluoride is widely accepted by the community and a number of caries lesions can be readily treated at the same visit.

A second reason is that child rearing practices in remote communities have an emphasis on autonomous behaviour[10] and children can accept or refuse treatment at a very young age. Having a non-invasive treatment used along with gentle handling of children by dental staff further encourages attendance.

The ART technique was developed as a treatment of dental caries which could be used in areas where dental equipment and dentists were in short supply. It is a relatively pain-free method for treating dental caries.[11] The ART approach includes both prevention and treatment of dental caries. ART procedure is based on excavating and removing soft diseased dentine using hand instruments only and then restoring the tooth with an adhesive glass ionomer material. ART has been widely accepted as an alternative treatment modality with outcomes similar to other treatments[12] where success rates of retention of between 55% and 80% have been obtained in primary teeth.

Use of silver diamine fluoride (38%) (SDF) has been reported from international studies. Chu *et al.*[13] found that silver diamine fluoride applied annually was more effective in arresting dental caries in the anterior teeth of 4 year old Chinese children than fluoride varnish applied 3- monthly and more effective than no treatment. Two further studies[14,15] and two reviews[16,17] supported these findings. However, silver diamine fluoride has an odour which is less well tolerated by young children.[18]

The disease management approach with AgF (silver fluoride 40% and stannous fluoride 10%) (Creighton Pharmaceutical formulation) used in this study was a different formulation than that used in the silver diamine fluoride studies and has not been formally evaluated. However, it has been part of the armentarium for dentists in remote Aboriginal communities since the 1980s.

This study compared the effectiveness of silver fluoride with ART in the management of caries lesions in posterior primary teeth among children residing in remote Aboriginal communities in Australia. The null hypothesis was that there would be no difference between the outcomes of the two treatments.

METHODS

The study was designed as a clustered randomized control trial with two arms: silver fluoride or atraumatic restorative treatment (ART). Recruitment began in 2011 and follow-up continued until 2016.

Target population

All children aged between 4 and 8 years under two remote Aboriginal Health Councils were invited to participate. In both communities, oral health screening is undertaken for all children. Children with active cavitated caries lesions in their posterior primary teeth which were asymptomatic and had no signs of pulpal involvement were included. Consent was sought from carers/parents for children to participate in the trial with clear explanations on randomization. Children were randomly assigned by birthdate to receive one of the two interventions. It was difficult to blind the children and parents as the interventions are quite different. Similarly, clinicians applying the treatments were not blinded. Data were collected on optical mark reader forms and from case notes. Children were examined by an independent examiner at completion of the study.

Intervention

Two groups were formed in the randomization procedure. Children in one group received standard ART management of the lesions in their caries-affected posterior primary teeth. Lesions in children in the second group were treated with a maximum of one drop of silver fluoride per child per visit, applied by micro brush for at least 1 min to caries lesions, followed by a microbrush moistened with 10% stannous fluoride and sealed with a small piece of gelatin adhesive wafer or gelatin paste (Orabase TM). The protocol for the AgF component of the study was a single application. Children in both groups participated in

regular dental examinations over the period of the study. Data were collected for each visit.

Outcome variables

The primary outcome, failure of treatment was analysed at tooth level. Any of the following noted on treated teeth was regarded as a failure of treatment – dental pain, extraction, further restorative treatment, evidence of pulpal infection (abscess, evidence of pulpal exposure, premature hypermobility, abnormal colouring), use of antibiotics for management of a dental problem by the medical clinic or referral for treatment under general anaesthesia related to the treated tooth. AgF-treated teeth were regarded as having no problem and not requiring further treatment if the lesions were arrested. Retreatment with AgF was considered necessary if there was any sign of loss of black pigmentation.

Control variables were age, baseline caries, sex, community, and time since ART or AgF application.

Ethics approval was obtained from the Human Ethics Committee, The University of Adelaide (approval number H-018-2011) and from the relevant Health Councils following a meeting of the researchers with Council members and local dental personnel. Community and individual parental consent was obtained by bilingual Aboriginal Health Workers prior to any examination for the study. The authors declare that they have no conflicts of interest in relation to the work reported in this study.

RESULTS

There were 210 children who were included in the study (Fig. 1) with 384 eligible teeth. Of 210 children, 133 were randomly allocated to AgF and 77 were randomly allocated to ART. Of 384 teeth, 380 teeth were followed up at later clinical appointments. The baseline characteristics of the children in the treatment group (AgF) and the control group (ART) were compared as shown in Table 1. No differences were seen between the children in the treatment group and in the control group, although there was a tendency for a higher proportion of the children in the treatment group to be younger (30.3%) compared with the ART group (18.4%).

Table 2 shows the distribution of the outcomes at a tooth level in both groups. In both the treatment and the control groups, the vast majority of teeth had no problems; however, more teeth needed retreatment in the AgF treatment group.

Table 3 shows the percentage of teeth with any additional treatment needed by age and caries severity at baseline. Although not statistically significant, a higher proportion of teeth in the AgF treatment group required some form of additional treatment, which was a reapplication of AgF in almost all cases.

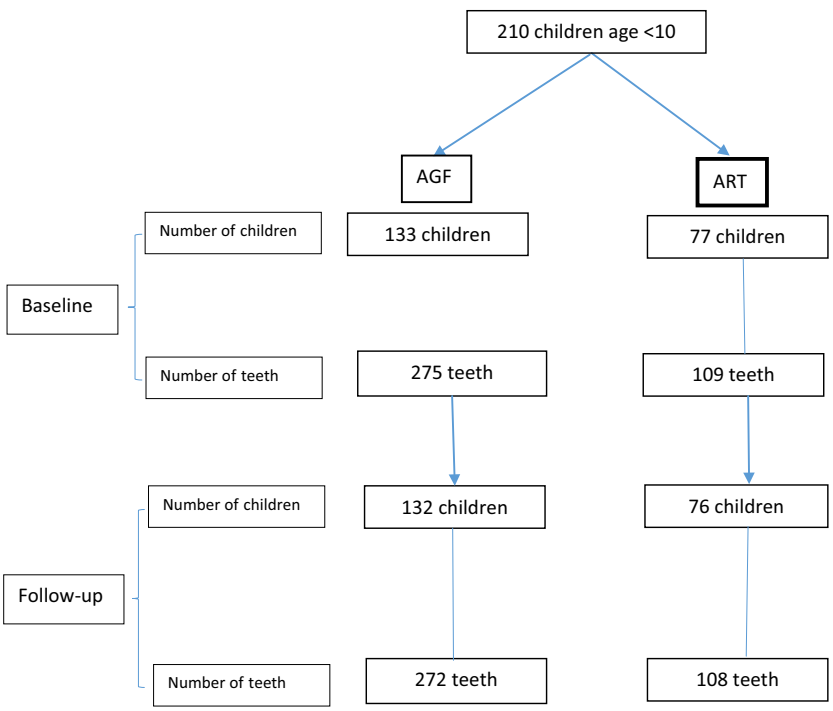

Fig. 1 Recruitment and follow-up.

Table 1. Comparing baseline characteristic between treatment and control group (person level)

Baseline characteristics	AGF group		ART group	
	% or mean	95% CI	% or mean	95% CI
Number of participants (n)	133		77	
Age (years, mean)	5.4	5.2–5.7	5.9	5.6–6.3
Age group (column %)				
3–4 year olds	30.3	22.6–38.9	18.4	10.5–29.0
5 year olds	21.2	14.6–29.2	25.0	15.8–36.3
6 year olds	22.7	15.9–30.8	23.7	14.1–33.2
7–10 year olds	25.8	18.5–33.2	32.9	22.3–43.5
Sex (column %)				
Boys	54.4	47.7–60.9	54.0	43.0–64.8
Girls	45.6	39.0–52.3	46.0	35.2–57.0
Time between first and last examination (months)	23.3	21.4–25.2	25.8	23.4–28.3
Caries severity (mean)				
Decay surfaces	3.5	2.6–4.3	3.0	2.0–3.9
Missing surfaces	0.3	0.1–0.5	0.2	0.0–0.4
Filled surfaces	1.1	0.8–1.5	1.4	1.0–1.9
dmfs	4.9	4.0–5.8	4.6	3.5–5.6
dmft	3.4	3.0–3.9	3.2	2.6–3.8

AgF, silver fluoride + stannous fluoride; ART, atraumatic restorative technique.

Table 2. Outcome distribution (tooth level)

Outcome	Number of teeth	
	AGF group	ART group
No problem	195	87
Extraction	1	0
Self-reported pain	1	0
Abscess	0	0
Retreat	68	20
GIC added elsewhere	6	0
Swelling	0	0
Pulpotomy	1	1
Total number of teeth involved in the study	272	108

AgF, silver fluoride + stannous fluoride; ART, atraumatic restorative technique.

Similarly, there was a tendency in the youngest age group for a higher proportion of teeth in the ART group to need additional care, although that was reversed among 5-year-olds and in the oldest age group with the AgF group tending to require additional care. A higher percentage of teeth in children with 1–<4 carious surfaces needed additional treatment.

Table 3. Percentage of teeth requiring treatment including retreatment, additional GIC or with problems of pain, abscesses, extraction or pulpotomy by treatment group and baseline characteristics*

Baseline characteristics	AGF group		ART group	
	% teeth with problems	95% CI	% teeth with problem	95% CI
Total	28.3	23.0–34.1	19.4	12.5–28.2
Age group				
3–4 year olds	20.4	12.9–29.7	33.3	16.5–54.0
5 year olds	46.0	33.4–59.0	15.4	4.4–34.8
6 year olds	25.0	13.6–39.6	23.1	9.0–43.7
7–10 year olds	25.4	15.3–37.9	6.9	0.9–22.7
Caries severity at baseline				
1–<4 surfaces	23.3	15.9–32.0	4.1	0.0–13.9
4–<8 surfaces	25.8	17.0–36.5	42.9	24.5–62.8
8+ surfaces	39.4	28.0–50.8	22.5	7.8–37.3

AgF, silver fluoride + stannous fluoride; ART, atraumatic restorative technique.
Model adjusted for time since treatment.
*This table only includes teeth treated at baseline.

Table 4. The multivariable regression model of children who were most likely to develop problems after treatment (included pain, abscesses, extraction, retreatment, GIC added or pulpotomy)

	Unadjusted PR	95% CI	PR	95% CI
Treatment group				
AGF	1.70	1.05–2.75	1.77	1.09–2.87
ART	REF		REF	
Age group				
3–4 year olds			1.05	0.57–1.92
5 year olds			2.01	1.12–3.60
6 year olds			1.25	0.65–2.41
7–10 year olds			REF	
Caries severity at baseline				
1–<4 surfaces			0.43	0.26–0.72
4–<8 surfaces			0.74	0.45–1.22
8+ surfaces			REF	

AgF, silver fluoride + stannous fluoride; ART, atraumatic restorative technique; PR, prevalence ratio.
Model also adjusted for length of time to follow-up.

In a multivariable regression model of children requiring any additional treatment, including the need for retreatment (Table 4) adjusted for length of time of follow-up, the prevalence ratio for children with AgF-treated teeth was higher (PR, 1.77) compared with children with teeth treated with ART. Five year old children had twice the prevalence of requiring additional treatment as children aged 7–10 years. Children with 1–<4 carious lesions had a lower prevalence ratio (0.43) than those with eight or more lesions.

Table 5. The multivariable regression model of failure of treatment* in child (pain, abscesses, extraction or pulpotomy)

	Unadjusted PR	95% CI	PR	95% CI
Treatment group				
AGF	0.20	0.09–0.43	0.18	0.08–0.40
ART	Ref		Ref	
Age group				
3–4 year olds			3.55	0.96–13.11
5 year olds			2.73	0.72–10.29
6 year olds			1.98	0.49–7.97
7–10 year olds			Ref	
Caries severity at baseline				
1–<4 surfaces			0.56	0.18–1.72
4–<8 surfaces			2.39	0.97–5.90
8+ surfaces			Ref	

AgF, silver fluoride + stannous fluoride; ART, atraumatic restorative technique; PR, prevalence ratio.
Model also adjusted for length of time to follow-up.
*This table accounts for retreatment for AGF as routine practice but not a failure of treatment but retreatment of ART as a failure of treatment.

If retreatment with AgF is regarded as part of routine treatment, then the prevalence ratio of negative sequelae for children treated with AgF compared with those treated with ART was lower at 0.18 (Table 5), with no differences by age group or caries severity at baseline.

DISCUSSION

This study found that use of the formulation 40% silver fluoride with 10% stannous fluoride was as effective as ART in treating dental caries among young children in a real-life clinical setting in remote Australia. Both types of treatment resulted in very few complications. The null hypothesis was supported.

Retention of primary teeth is an important goal of treatment of caries in young children as is reduction in dental pain and avoidance of extensive treatment. Acceptance of such treatment by the young child also has implications for future dental care.

The strength of this study included the use of a silver fluoride formula, one which has been more commonly used in Australia and does not have an ammonia smell. Treatment was undertaken in the posterior teeth of the primary dentition, whereas most studies of silver diamine fluoride have treated anterior teeth.[13–15] Other strengths were the comparison with an existing treatment (ART) and the evaluation of AgF in routine clinical practice. This meant that the results show effectiveness of the AgF rather than efficacy.

The limitations were difficulties in recruitment in one community due to multiple changes of staff and an overall difference in the numbers of children between the treatment and control groups for which the reasons were unclear. As this difference was seen predominantly in the youngest age group, it is likely that a clinical decision was made based on the cooperation of the child.

This study used a different formula than silver diamine fluoride but which gave results similar to SDF. The need for retreatment was regarded as a disadvantage in one result in this study but is recognized that it might be required as part of the treatment regime with AgF. Recent studies of silver diamine fluoride have suggested that biannual treatments are necessary to produce the best results with that agent.[19] The use of the silver fluoride stannous fluoride combination enabled the maintenance of the primary dentition as well as ART.

This AgF treatment is simple and could be used by oral health therapists and hygienists. It was well accepted by children in this study. The black staining which results was not mentioned as a problem by the children in the study or by their parents, and is clinically useful as an indicator of caries arrestment. Studies *in vitro* have raised the possibility that staining with SDF might be minimized with potassium iodide[20] which could be investigated for AgF. AgF could also be used beneath glass ionomer cement fillings to reduce the appearance of staining or if the possibility of food packing was considered an issue.

In recent years, the Hall Technique using preformed stainless steel crowns has been widely used to treat primary caries. This is also a treatment which does not require local anaesthetic and which reduces risk of major failure or pain compared to fillings.[21] Research comparing use of silver fluoride with preformed stainless steel crowns would be useful. It would also be useful to conduct a cost-effective analysis regarding number of dental general anaesthetics prevented due to provision of AgF.

CONCLUSIONS

Silver fluoride treatment for cavitated carious lesions in primary molars was as effective as the ART technique in this remote Indigenous population. It is an acceptable technique on very young and/or apprehensive patients and does not have the ammonium odour of SDF.

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DISCLOSURE

None declared.

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