

Adverse events on the use of interim therapeutic in schoolchildren: Silver diamine fluoride × interim therapeutic restorative – a pilot study

Efeitos adversos de técnicas provisórias em crianças: diamino fluoreto de prata x tratamento restaurador provisório – um estudo piloto

Abstract

Purpose: Silver diamine fluoride (SDF) is a caries prevention and arresting agent that is easy to apply clinically. Interim therapeutic restorations (IRT) are also known to be a simple and effective method for treating caries in children. This study examines whether treatment with 30% silver diamine fluoride (SDF) will cause fewer adverse events than the available interim therapeutic restorations in underprivileged schoolchildren with cavities.

Methods: We conducted a three-month pilot study comparing the adverse effects of IRT using glass ionomer cement (Fuji IX, GC America, Inc.) with those of 30% silver diamine fluoride (Cariostop Biodynamic®, Brazil) in 50 children aged 6 years.

Results: In the SDF group, all caries were arrested and no pain, abscess or fistula was reported. Of the children assigned to the Fuji IX group, 24% reported toothache ($P < 0.05$). There was no significant difference in the occurrence of fistula and abscess in the two groups.

Conclusion: The authors suggest that for underprivileged schoolchildren with caries, the use of SDF when an appropriate clinical setting is not available resulted in fewer adverse effects than did treatment with an interim therapeutic restorative using FUJI IX.

Key words: Dental caries; children; silver diamine fluoride; interim therapeutic restorative

Resumo

Objetivo: O Diamino fluoreto de prata, uma solução de fácil aplicação e que não precisa de um ambiente clínico para o seu uso, é um agente de notável capacidade de paralisar e prevenir cárie. Outro método simples e eficaz para o tratamento da cárie em crianças são Restaurações provisórias. Este estudo examinou o surgimento de efeitos adversos em escolares tratadas com Diamino fluoreto de prata (DFP) comparado com aquelas tratadas com o Tratamento Restaurador Provisório.

Metodologia: Foi realizado um estudo piloto de três meses comparando os efeitos adversos das restaurações provisórias, utilizando cimento de ionômero de vidro Fuji IX (GC America, Inc.), com o Diamino fluoreto de prata a 30% (Cariostop Biodinâmica®, Brasil), em 50 crianças com 6 anos de idade.

Resultados: O grupo DFP teve todas as suas cáries paralisadas e não apresentou dor, abscesso ou fístula. Das crianças tratadas com Fuji IX, 24% delas relataram dor de dente ($P < 0,05$). Para fístula e abscesso, não foi verificada diferença estatisticamente significativa.

Conclusão: Os autores sugerem que, para crianças portadoras de cárie, sem acesso aos serviços de saúde, o DFP apresentou menos efeitos adversos do que o tratamento restaurador provisório utilizando FUJI IX.

Palavras-chave: Cárie; criança; diamino fluoreto de prata; restauração provisória

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Introduction

According to the most recent Brazilian national dental survey, more than 50% of children attending public schools have untreated tooth decay (1). To reduce the incidence of caries in this population, greater financial resources must be devoted to strategies for promoting oral health (2). In very poor regions with limited access to health care, such as northeastern Brazil, action programs aimed at solving the problem of dental caries in children need more attention.

One of the agents for treating decay that has proven effective in community-based programs is silver diamine fluoride (SDF), which is easy to apply, affordable and able to improve access to care for public health purposes. However, because it results in brown spots on the tooth surface after it is application, dentists tend to restrict its use, despite recognizing its therapeutic benefits (3).

A systematic review (4) of the use of SDF revealed that when applied once a year, it is highly successful at preventing new caries and arresting existing ones. Chu et al. (5) compared the effectiveness of silver diamine fluoride applied once a year with that of a fluoride varnish applied twice a year, using water as the control substance. Their sample consisted of 375 children between 3 and 5 years of age with caries in their maxillary anterior teeth. The study's results indicated that SDF was substantially more effective than fluoride varnish in arresting and preventing new caries (96.1% and 70.3%, respectively, for the SDF group and 21.3% and 55.7%, respectively, for the fluoride varnish group). The number needed to treat (NNT) for the SDF group was 0.8 (95% CI=0.5 to 1.0) for caries arrest and 0.9 (95% CI=0.4 to 1.1) for caries prevention. In contrast, the NNT for the fluoride varnish was 3.7 (95% CI=3.4 to 3.9) for caries arrest and 1.1 (95% CI=0.7 to 1.4) for caries prevention. According to the authors of this paper, there was no significant beneficial effect on the anticipated removal of carious tissue.

Llodra et al. (2005) (6) also conducted a longitudinal study to verify the cariostatic and anticariogenic effects of SDF. Their sample consisted of 452 children younger than six years of age with caries in their primary canines and molars and first permanent molars every 6 months for 36 months. A total of 373 children completed the 36-month follow-up. The mean number of new decayed surfaces appearing in primary teeth during the study was 0.29 in the SDF group vs. 1.43 in the controls. The mean of new decayed surfaces in first permanent molars was 0.37 in the SDF group vs. 1.06 in controls. The SDF solution was found to be effective for caries reduction in primary teeth and first permanent molars in schoolchildren.

Another option for improving oral health in large underprivileged communities worldwide is interim therapeutic restorations (IRT). The IRT approach has been largely promoted by the World Health Organization (WHO) and since 1994, it has been applied in several countries (7). This method uses glass ionomer cement (GIC)

to fill cavities because this material reportedly has good chemical adhesion to the tooth structure, good biological compatibility and aesthetics and a coefficient of linear thermal expansion similar to that of teeth, and it releases fluoride (8-10).

Thus, the aim of this study was to compare interim therapeutic restorations using Fuji IX (GC America, Inc.) with silver diamine fluoride (30% Cariestop Biodynamic®, Brazil), with the aim of examining the emergence of adverse effects. The outcome measures of the appearance of adverse events included pain and abscess fistula in the deciduous teeth of 6-year-old children attending municipal schools of the city of Recife, Pernambuco state, Brazil.

Methodology

This study was approved by the Internal Review Board of the University of Pernambuco in accordance with the World Medical Association Declaration of Helsinki and authorized by Recife's Department of Education. Written information explaining the purpose of the study was sent to the participants' parents. In addition to obtaining written consent from the parents, verbal consent was obtained from the children prior to the commencement of the study. The children were at liberty to withdraw from the study at any time, and the parents were allowed the same freedom to withdraw their children. Children with arrested caries and sound dentition were excluded from the sample.

This study was conducted in the city of Recife, Pernambuco, in the northeastern region of Brazil. The city's population is 1,561,659 inhabitants, 18% of the state's population, and it is the poorest part of the country (11). The city is divided into 6 administrative zones. We randomly chose 4 primary schools from the poorest area of Recife, Administrative Zone 2, which is one of the largest slums in the urban area (12).

The sample size was calculated using Episcopo 2.0 using the parameters from previous studies (5,13). For a Type 1 error of 5% and a power of 85%, the calculated sample size was 18 patients in each group. Taking into consideration the possibility of dropouts, we added 20.0% to ensure a sample size that could produce significant results. The final sample size was 25 patients in each group (IRT and SDF). For the data analysis, we used both descriptive and inferential statistical techniques.

This study included children who had primary teeth with active caries lesions involving one or multiple surfaces of the tooth at the dentine level, corresponding to ICDAS 5 for occlusal and smooth surfaces (14) and a shallow average depth, with no pulpal exposure, fistulas or caries in the permanent teeth, and whose parents agreed to their participation in the study.

After the initial examination, the children who met the inclusion criteria were assigned to the SDF experimental group (n=25) or to the IRT control group (n=25). The data were analyzed using the SPSS statistical program

(Version 14.0). Fisher's exact test was used at a 5% level of significance. The intraexaminer reproducibility for caries diagnosis was calculated using Cohen's kappa. The kappa for intraexaminer agreement was 0.86 for caries and 1 for arrested caries.

Before treatment, the children participated in a supervised toothbrushing session, and each child was provided with a toothbrush and fluoridated toothpaste. The children also received healthy eating and oral hygiene instructions. However, because of extreme poverty, diet cannot be controlled in this part of the world, as school meals often consist of sweet biscuits or sweetened maize porridge, and healthy food choices are expensive or not available for those families. Drinking water is not fluoridated, and some schools do not have running tap water.

For the SDF group, no effort was made to remove caries or unsupported enamel in accordance with Chu et al. (5); the same procedure was used for the IRT group based on Niederman et al. (15).

For both techniques, the teeth were isolated from saliva with cotton rolls. For the IRT group, the caries lesions were conditioned with a cavity conditioner (GC Corporation Tokyo, Japan) and filled with the glass ionomer cement GC Fuji IX GP (GC America, Inc.). All participants were advised not to eat or drink for one hour after treatment.

For the 30% SDF (Cariestop Biodynamic®, Brazil) treatment, we applied the solution for 3 minutes, after which the children were asked to rinse their mouths with water from a cup and spit. Vaseline was applied to the soft tissues to prevent contact lesions caused by the caustic nature of the SDF (16).

The criterion used for adverse effects was our clinical judgment of signs of abscess or fistula on the buccal side of the mucosa, manifested by redness or swelling. We also pressed our fingers against the cortical bond to check for signs of injury caused by abscess.

Results

The study sample included 326 schoolchildren aged between 5 and 6 years. Of the participants, 165 (50.6%) were male and 161 (49.4%) were female, 76.96% had the same pattern of carious lesions, 16.49% had teeth requiring extraction and 6.55% had some type of restoration filling. Thus, the mean dmft was 3.8 (Table 1).

The children in the SDF group had no reports of toothache, fistula or abscess. Of the children assigned to the Fuji IX group, 24% reported toothache ($P < 0.05$). There were no statistically significant differences in the reports of fistula and abscess between the two groups (Table 2).

Table 1. Assessment of dfmt at baseline.

	Mean	Standard deviation	Median	Prevalence (%)
Caries	2.94	3.05	2.00	76.96
Indicated for extraction or teeth with pulp exposure	0.63	1.39	000	1.49
Filled	0.25	0.85	0.00	6.55
dmft	3.82	3.68	3.00	

Table 2. Presence of toothache, abscess and fistula at 3-month follow-up (unit of observation per number of children).

Group	Yes		No		Total		P-value	PR and 95% CI
	n	%	n	%	n	%		
Toothache								
IRT	6	24.0	19	76.0	25	100.0	$P^{(1)}=0.022^*$	**
SDF	–	–	25	100.0	25	100.0		
Total	6	12.0	44	88.0	50	100.0		
Abscess								
IRT	1	4.0	24	96.0	25	100.0	$P^{(1)}=1.000$	**
SDF	–	–	25	100.0	25	100.0		
Total	1	2.0	49	98.0	50	100.0		
Fistula								
IRT	1	4.0	24	96.0	25	100.0	$P^{(1)}=1.000$	**
SDF	–	–	25	100.0	25	100.0		
Total	1	2.0	49	98.0	50	100.0		

* Significant differences at 5.0%.

** Not determined due to the null frequency.

⁽¹⁾ Fisher's exact test.

Discussion

This study was conducted in the city of Recife, a very poor city in the northwestern part of Brazil where access to dental care for underprivileged children is not available. This explains the high incidence of untreated caries in this target population. The results of this study compared a group of teeth treated with the IRT FUJI IX with teeth treated with 30% silver diamine fluoride (SDF) (Cariestop Biodynamic®, Brazil). The comparison showed that participants treated with the interim restorative technique were more likely to experience adverse events.

In this study, toothache was the most commonly occurring adverse event in both study groups; however, toothaches occurred twice as frequently in the FUJI IX interim group. The results also indicate that the application of SDF produced not pain, but slight discomfort, which disappeared in few seconds.

One might wonder why dentists would take their time to seal teeth when there is uncertainty about the degenerative process of the pulp tissue and when sealing the cavity would lead to pain and abscess (17). The answer to that question lies in a very obvious situation: there are still very needy communities all over the world where there are no dentists. Furthermore, even when dentists are available, they might lack the resources to apply the preferable diagnosis and treatment. Such situations also raise the issue of shifting the paradigm from sealing or filling cavities to reducing active caries, especially when misdiagnosis can occur more often under these circumstances than in traditional clinical settings.

Given the microbiological effect of the silver in the SDF preparation, one would expect that the use of such an agent would contribute to the arrest of active caries and work as a disinfectant for root canals (16). Therefore, in cases in which there is doubt about the stage of the pulp degradation, SDF appears to be safer than IRT for the target purposes because it is not a sealing material.

A systematic review (4) reported that silver diamine fluoride favors the generation of sclerotic dentin and benefits the germicidal action of the product. The special properties of SDF make it the material of choice for pain and infection control, as reported in this study (18-20).

The need for agents such as SDF should be evaluated in terms of the World Health Organization (WHO) Millennium Development Goals for Health (21), particularly the oral health goals (22), because it is lightly effective, arrests caries and has no major adverse effects.

Simple technologies that improve access to oral health care at a much lower cost are needed. In our study, we used 30% SDF; although 38% SDF is approved by the health authorities for dental use, it is currently not available on the market. We must also emphasize that FUJI IX, the GIC

recommended by the WHO as an IRT, is not available on the market in developing countries, and it costs almost 20 times more than SDF (US\$8.00 vs. US\$150.00). The same applies to the fluoride varnish; the cariostatic agent is commonly used in developed countries but is still very difficult to obtain in poor communities, especially in South America.

Despite the impressive results of this trial, the methodology has a number of limitations that need to be addressed:

- Regarding the study design: For a number of reasons, the authors were unable to perform a randomized control trial. The authors were not able to randomize children because the experimental and control materials produced very different aesthetic results; while SDF stains the teeth black, glass ionomer cement is opaque white.
- The authors were unable to perform a double- or single-blind study; because it was impossible to blind the examiner to the materials because they had quite different appearances.
- The authors also understand that if they had been able to control for diet and fluoridated water, IRT would have produced better results, as caries might have been arrested after the loss of the GIC as a result of avoiding sweet school meals and having fluoridated drinking water. At the same time, the authors recognize that the study could be criticized for not being able to avoid those two important confounding variables. The authors understand that diet and oral hygiene are very important confounding variables that may have interfered with the present results, owing to the inherent socioeconomic issues of the study population. Nonetheless, we believe that these limitations do not invalidate the study because both study groups were similarly poor, lived in the same administrative district, received toothbrushes and fluoridated toothpaste and attended the same kind of schools, which were randomly selected.

Conclusions

The authors suggest that for underprivileged schoolchildren with caries who do not have access to a dental clinic, SDF showed fewer adverse effects than IRT using FUJI IX. SDF presented better results, which may justify a paradigm shift toward its use over IRT in pediatric dentistry for underprivileged communities.

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