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Arresting active carious dentine lesions and quality of life among a group of preschool children: A randomized controlled clinical trial

Basma Elsayed Hamza

Assistant Lecturer, Public Health Department, Faculty of Medicine, Mansoura University, Mansoura, Egypt.

Corresponding author email: bsmahamza@mans.edu.eg

Nasr Mohamed Attia

Lecturer, Public Health Department, Faculty of Medicine, Mansoura University, Mansoura, Egypt.

Email: nasrattia@mans.edu.eg

Salwa Adel Hegazy

Professor, Public Health Department, Faculty of Medicine, Mansoura University, Mansoura, Egypt.

Email: salwahegazy@mans.edu.eg

Abstract---The aim of this clinical trial was to investigate the efficacy of 38% silver diamine fluoride (SDF) in the arrestment of dentine caries in primary molars of preschool children. The time required for treatment, anxiety, adverse events, parental aesthetic perception and oral health related to quality of life (OHRQoL) were also assessed. Sixty, 3–5 years old children, were assigned randomly to SDF test group or atraumatic restorative treatment (ART) control group. The ICDAS criteria determined the presence of caries and its activity. The treatment time was recorded, and the child's anxiety was evaluated using the facial image scale before and after treatment. The caregivers were asked about any adverse events and the questions regarding esthetic perception were addressed to them. The OHRQoL was evaluated through the A-ECOHIS questionnaire before and 3 months after treatment. The overall success rates of SDF and ART after 12 months were 86.7% and 80%, respectively. There was no significant difference in arrestment of caries between SDF and ART (P value > 0.05). The time required to treat with SDF was significantly shorter (p < 0.001). The percentage of adverse events revealed no significant difference (p=0.604). Anxiety levels were significantly lower in the SDF group (p= 0.003). There was a statistically significant reduction in mean scores of the total A-ECOHIS after 3 months. It was concluded that 38% SDF has similar results as ART in arresting caries lesion,

anxiety levels, adverse effects and aesthetic perception. It requires much less chair-time and shows similar impact on quality of life.

Keywords---Silver Diamine Fluoride, Early Childhood Caries, Quality of Life.

1. Introduction

Early Childhood Caries (ECC) has been defined by the American Academy of Pediatric Dentistry as ‘the presence of one or more decayed, missing due to caries, or filled tooth surfaces in any primary teeth in children under 6 years of age. Any evidence of smooth-surface caries in children younger than 3 years of age, is an indication of the severe form of the early childhood caries (S-ECC)(AAPD and AAP, 2016).

Caries in preschool children remains a major problem in both developed and developing countries despite the reduction in the prevalence of dental caries in children in western countries, A review of the literature suggests that in most developed countries the prevalence rate of ECC is between 1 and 12% (Masumo et al., 2012). In less developed countries, the prevalence has been reported to be as high as 70% (Congiu et al., 2014). In Egypt, the prevalence of ECC was found to be 61.4% (Shalan and Abo Bakr, 2018).

The etiology of ECC is multi-factorial. It is the product of the interaction of factors that include cariogenic bacteria, fermentable carbohydrates through incorrect feeding habits and a variety of social variables (De Grauwe et al., 2004). Primary dentition is essential for proper mastication, phonetics, esthetics, maintenance of space and for prevention of habits. ECC has its impact on the children’s oral health related quality of life (OHRQoL) as it may delay their physical development, may cause loss of school days and reduce children’s ability to learn (Chu et al., 2012).

Prevention of the progression of the ECC can be achieved with the aid of restorative measure, diet modification, parents’ education regarding decay, maintaining good oral hygiene, promoting feeding behaviors, and the use of preventive agents like topical fluorides. If initial strategies of prevention fail, management will be needed to halt the disease and minimize the negative influence of caries. The management of ECC is expensive and usually requires extensive restorative treatment and extraction of teeth at an early age. Since young children may not be able to cope with the extensive treatment procedures, general anesthesia or deep sedation may be required (Duangthip et al., 2016).

As it is well accepted by children, does not require electricity and running water and has shown efficient caries control, atraumatic restorative treatment (ART) is a low-cost substitute to allow the access to restorative care to these children. In disadvantaged communities, the use of ART has increased gradually and remains high. It involves hand excavation of caries, then restoration using high viscosity glass ionomer cement (GIC) (Holmgren et al., 2013).

In preschool children, silver diamine fluoride (SDF) has been proposed as an option for controlling dental caries because it is safe, easy and effective in arresting tooth decay (Duangthip et al., 2017, Oliveira et al., 2019). SDF may influence community and pediatric dentistry in a positive way and may be a cheaper innovatory dental product of this century. Although SDF causes black discoloration of teeth, the advantages of having no pain and dental abscesses can overcome this negative factor, especially in areas where the access to dental care is limited (Hu et al., 2018).

Knowing that there is no study performed among preschool children In Egypt comparing the efficacy of 38% SDF with ART in carious dentine lesions of primary molars, this randomized, controlled clinical trial was carried out to compare arrestment rate of caries lesions treated with SDF and ART. The aim of the study was to investigate the following outcomes: arrestment of caries lesion, oral health related quality of life (OHRQoL) of children and their families, parental aesthetic perception, adverse events, children's anxiety and time required for treatment.

2. Materials and Methods

This was a randomized paralleled controlled trial, with a 1:1 allocation ratio following the CONSORT recommendations (Moher et al., 2001).

Study sample

Between January and November 2020 at the Pediatric Dental Clinic, 60 preschooler children with primary molars having active occlusal caries lesions were recruited by one trained examiner. Eligibility criteria included: 3 to 5 years old healthy children having at least one untreated cavitated active caries lesion involving only the occlusal surface of a primary molar. Children were excluded if their parents refused to be involved in any of the treatment approaches; if children were medically compromised or had silver allergy; children from families planning to move from Mansoura during the study period; and molars with clinical signs of pulpitis. The activity of the carious lesions included was diagnosed according to ICDAS II criteria and received scores 5 or 6 (Shivakumar et al., 2009).

The approval of the ethical committee of the faculty of Dentistry, Mansoura University was firstly obtained with the code A22080120. Written informed consents were signed by the parents prior to examination and treatment of their children. Parents/caregivers were assured that all given data will be anonymous.

Intra-examiner calibration

Before the beginning of the study, 20 children were examined and diagnosed according to ICDAS criteria, twice, with a week interval to ensure intra-examiner consistency and reliability. The results of the two examinations were compared and the agreement Kappa value was higher than 0.85 which indicated very good agreement.

Sample size calculation

The sample size was calculated considering the difference of proportion of the clinical success observed in a previous similar study ([Dos Santos et al., 2012](#)) and using the Biostat 5.3 program,

Study procedures:

Sixty children were randomly allocated into 2 equal groups: the test group (receiving 38% SDF, Advantage Arrest™, Elevate Oral Care, LLC, West Palm Beach, FL), and the control group (receiving ART). Allocation of the children into the groups was achieved by block randomization of eight in the Excel program, by a researcher different from the operator. Concealment of the allocation was achieved with sequenced sealed envelope each having a number and containing the treatment allocation cards.

Baseline data such as oral hygiene, eating routine, previous dental visits, socioeconomic and socio-demographic information were also collected. Oral health related to quality of life (OHRQoL) was also inquired into by interviews with parents, using the Arabic version of the Early Childhood Oral Health Impact Scale (A-ECOHIS) questionnaire ([Farsi et al., 2017](#)).

A facial image scale (FIS) ([Buchanan and Niven, 2002](#)) was shown to the children immediately before treatment to measure the children's anxiety. Children were asked to choose the facial expression that described their feelings accurately at that moment (very happy, happy, neutral, unhappy and very unhappy). Immediately after the procedure, they were asked to repeat the test. Children of the test and control groups received 38% SDF varnish biannually and ART, respectively, according to previously mentioned protocols ([Horst and Ellenikiotis, 2016](#), [Frencken et al., 1996](#)).

Follow up and outcomes

The different treatment approaches were followed up at 3, 6 and 12-month intervals. The primary outcome was the caries arrestment. After the patients brushed their teeth, the same examiner performed a similar clinical examination as that performed at baseline. Data about dental examination and presence or absence of pain were recorded in a pre-prepared form. The information from the baseline examination is then compared to those from the second one and accordingly the teeth could be classified as success or failure. The tooth was considered a success when caries was classified as inactive according to ICDAS ([Shivakumar et al., 2009](#)) criteria; and failure when caries was classified as active according to ICDAS ([Shivakumar et al., 2009](#)) criteria and/or when there is spontaneous pain or signs of pulp involvement.

Regarding the control group, the treatment was considered successful if the restoration was intact and present, without exposed dentin, or if the exposed dentine was arrested/inactive. The treatment was considered a failure if the glass ionomer was partially or totally lost or when the exposed dentine was classified as

active by ICDAS (Shivakumar et al., 2009) criteria and/or when there is spontaneous pain or signs of pulp involvement

Information about oral health related quality of life was registered via face to face meetings with the parents of all children before and 3 months after treatment. The A-ECOHIS (Farsi et al., 2017) questionnaire was applied by the same examiner at both times. In the two moments, the same parent answered the questions. The total A-ECOHIS scores and each subscale scores were calculated as a summation of the response codes. A more negative impact on the oral health-related quality of life is expressed by higher scores, and vice-versa.

Statistical analysis and data interpretation:

Data were fed to the computer and analyzed using IBM SPSS Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Qualitative data were described using number and percent. Quantitative data were described using median (minimum and maximum) and mean, standard deviation for parametric data after testing normality using Shapiro-Wilk test. Significance of the obtained results was judged at the (0.05) level.

Data analysis

Qualitative data:

Chi-square test for comparison of 2 or more groups.

Quantitative data between groups:

Parametric tests:

Student t-test was used to compare 2 independent groups.

Non-Parametric tests:

- Mann-Whitney U test was used to compare 2 independent groups.
- Wilcoxon signed Rank test to compare between 2 studied periods.

3. Results

This study included 60 preschoolers, with a mean age of 3.9 ± 0.74 (standard deviation) years old (minimum equals two and maximum equals five), divided into two treatment groups: ART (n=30) and SDF (n=30). The group treated with SDF consisted of 30 preschoolers, as well as 30 in the group treated with ART. No losses occurred throughout the entire duration of the study. The recruitment and flow of the participants are represented in a CONSORT flow chart (Figure 1).

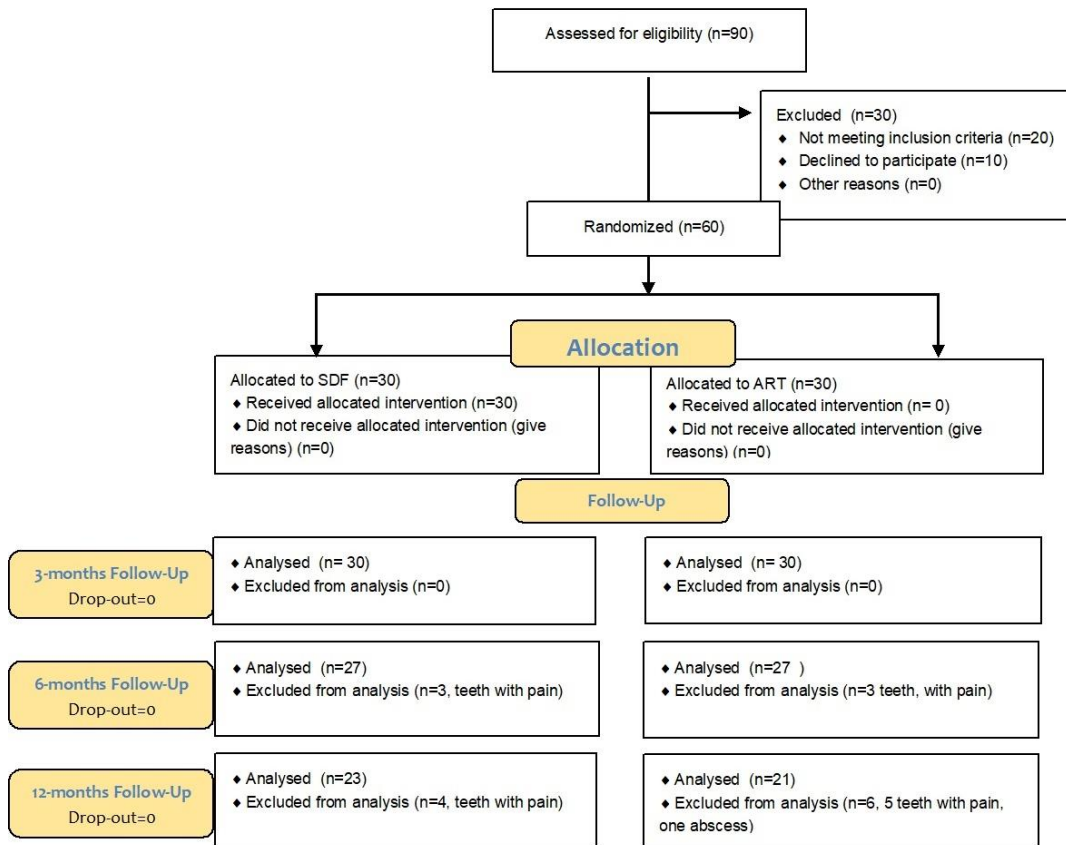


Figure (1): CONSORT flow diagram of the trial

Data regarding the socio-demographic characteristics of all participants and their respective treatment groups are shown in Table 1. There was no any statistically significant difference between the two groups regarding the age, gender, socioeconomic class and parent's education.

Regarding the caries arrestment in both study and control groups, Table 2 shows that at 3 months follow up, all teeth were successful (100%). At 6 months, three teeth failed in each of the SDF and ART groups resulting in 90% success in both groups. At 12 months follow up four and six teeth failed in the SDF and Art groups respectively, resulting in 86.7% and 80% success rates respectively. There was no significant difference in arrestment of caries between SDF and ART at 3, 6 and 12 months follow up (P value > 0.05).

The mean procedure duration for SDF ($n=30$) was 3.9 ± 1.35 minutes with the median of 4 (3.5-5). For ART ($n=30$), the mean time was 7.5 ± 3.45 minutes with the median of 8 (7-10). Thus, there was a significant difference between the time needed for treatment of the groups. ($p < 0.05$) (Table 1). Considering the anxiety of the children before and after treatment with SDF and ART, all participants were evaluated using a facial image scale¹⁶ with a high significant difference between the groups ($p=0.003$) (Table 1).

Before treatment (T0), all caregivers (n equals 60) answered the A-ECOHIS questionnaire. After 3 months 60 questionnaires were answered again by the same parent/caregiver. There was no significant difference between the two treatment groups at baseline (P value >0.05). After 3 months (T3), there was a reduction in the mean scores of each question of the ECOHIS for SDF and ART groups compared to 'T0'. Similar to the situation at T0, there was still no significant difference between the two treatment groups after 3 months (P value > 0.05).

Table (1): Baseline socio-demographic characteristics of the studied groups

	SDF group n=30	ART group n=30	Test of significance
Age/years mean±SD	3.90±0.74	3.90±0.74	t=0.0 p=1.0
Gender n(%)			
Boys	13(43.3)	16(53.3)	x ² =0.601
Girls	17(56.7)	14(46.7)	p=0.438
Socioeconomic Class n (%)			
Middle	20(66.7)	25(83.3)	x ² =2.22
Low	10(33.3)	5(16.7)	p=0.136
Educational level n(%)			
College education	27(90)	27(90)	
Less than college	3(10)	3(10)	p=1.0

t:Student t test , x²=Chi-Square test

Table (2): Comparison of carries arrestment, time required for treatment and facial image scale between SDF and ART groups

Variables		SDF n(%)	ART n(%)	Test of significance
Caries Arrestment	months 3			
	Success	30(100)	30(100)	
	Failure	0	0	
	months 6			
	Success	27(90)	27(90)	x ² =0.0
	Failure	3(10)	3(10)	p=1.0
	12 months			
	Success	23(85.2)	21(77.8)	x ² =0.490
	Failure	4(14.8)	6(22.2)	p=0.483
Total	Success	23(76.7)	21(70)	x ² =0.341
	Failure	7(23.3)	9(30)	p=0.559
Time required (Median) (Mean)		4 (3.5) 3.9	8 (7-10) 7.5	z=6.87 p<0.001*
FIS	treatment-Pre (max-Median (min	1.5 (1-5)	2 (1-5)	z=0.880 p=0.379
	treatment-Post max-Median (min	1 (1-2)	2 (1-5)	z=3.01 *p=0.003
	Wilcoxon signed rank test	Z=3.53 P<0.001*	Z=1.28 P=0.201	

x²:Chi-Square test Z:Mann Whitney U test *statistically significant, FIS: Facial image scale.

After 48 hours, the operator interviewed all 60 parents by telephone. The parents reported that 11 children reported 11 adverse events. The adverse events reported were discoloration to the gingiva, black staining of the arrested lesions and bitter/metallic taste. According to the interviews, the rate of the adverse events per child was 20% (n=6) in the SDF group and 16.7% (n=5) in the ART group (p=0.738). During the time of treatment, the operator recorded 23 adverse events; 13 in the SDF group thus 43.3% of children and 33.3% of children in the ART group (p=0.604) showing no significant difference.

Table 3 shows P value with the Wilcoxon test showing significant difference at child impact section (CIS), family impact section (FIS) and the total A-ECOHIS score for both the SDF and ART groups between T0 and T3. However, no difference was observed between SDF and ART groups at T3 (P value > 0.05).

Table (3): Comparison of CIS, FIS & Total A-ECOHIS between SDF and ART and within group change from zero to 3 months

		SDF group n=30	ART group n=30	Test of significance
CIS	T0	7.87±2.47	8.13±2.54	Z=0.425 p=0.671
	T3	1.93±1.31	2.27±1.53	Z=0.871 p=0.384
Wilcoxon signed rank test (comparison between zero & 3 months)		Z=4.82 P<0.001*	Z=4.82 P<0.001*	
FIS	T0	4.77±1.59	4.73±1.79	Z=0.023 p=0.982
	T3	0.533±1.07	1.07±1.31	Z=1.83 p=0.07
Wilcoxon signed rank test (comparison between zero & 3 months)		Z=4.80 P<0.001*	Z=4.81 P<0.001*	
Total	T0	12.63±3.67	12.87±4.06	Z=0.290 p=0.772
	T3	2.47±2.19	3.33±2.68	Z=1.15 p=0.249
Wilcoxon signed rank test (comparison between zero & 3 months)		Z=4.79 P<0.001*	Z=4.79 P<0.001*	

Parameters described as mean±SD, Z: Wilcoxon signed rank test & Mann Whitney U test

*Statistically significant

4. Discussion

This randomized clinical trial analysis provides data about the short and long-term efficacy of 38% SDF in arresting carious dentine lesions in primary molars of preschooler children compared to conventional atraumatic restorative treatment and their effect on the oral health related quality of life.

The short-term average caries arrest rate in the present study was 100%. This is higher than previous ones using 38% SDF which reported 72% (Milgrom et al., 2018) and 98% (Clemens et al., 2018) of arrested caries in 21-days and 3-month follow-up, respectively. When comparing with 6 and 12-months studies, the

results of this study showed increased rates of caries arrestment than former ones, which reported 84.7% (Shivakumar et al., 2009) and 43.3% (Zhi et al., 2012) in 6-months and 66.9% (Shivakumar et al., 2009) in 12-months follow-up. In this study, teeth were dried and isolated before SDF application which may explain the higher success rates. This comes in accordance with previous studies (Shivakumar et al., 2009, Clemens et al., 2018).

Biannual SDF application was performed since it shows higher arrestment rates (Zhi et al., 2012, Llodra et al., 2005). This may be a disadvantage as it requires seeing the patient to every six months. However, it is still superior to the disadvantages of ART cases which are subjected to fractures and need to be fixed. In this study, at 6 months, a single restoration had to be fixed and two at 12-months. The need for repair was like that found in a previous study (Vollú et al., 2019).

This study reported that there is no difference between SDF and ART regarding caries arrestment and that they are both equally effective. This came in accordance with studies that have shown that treating dentin carious lesions with SDF in preschoolers is as effective as treatment with ART (Zhi et al., 2012, Vollú et al., 2019).

In the present study, a significantly shorter operation time was registered for the test group. This is a great advantage as it is understood that treatments requiring longer time can initiate poor behaviors in children. The chair time recorded in this study was quite shorter than the one registered in other studies using SDF (Vollú et al., 2019, Johnson et al., 2019, Mattos-Silveira et al., 2015), but in one of these studies²⁵ the author used rubber dam which may have increased the treatment time.

For many years, children's dental anxiety has been considered as a problem in patient management. Moreover, its effects have been shown to continue into adulthood and often lead to avoidance of dental treatment and the subsequent decline of oral health (Buchanan and Niven, 2002). Children who had positive dental experiences when needed dental services are known to convert into preventively minded symptoms free adult dental attenders (Milsom et al., 2003). In this study, there was a significant difference between the two treatment groups in favor of SDF over ART which was more accepted by the children probably due to absence of pain or sensitivity during teeth excavation. This finding was in contrast with Vollu et al. (2019), whose results showed no difference in anxiety between the groups.

In this study, few adverse events were reported after the treatments; immediately or after two days, without difference between the groups. This goes in agreement with similar studies which investigated the possible adverse events after treatment and also reported some discoloration (Chu et al., 2002), black staining on the arrested lesion (Zhi et al., 2012, Fung et al., 2018, Duangthip et al., 2016) and metallic taste (Horst and Ellenikiotis, 2016).

No children had avoided smiling after treatment and only two parents were concerned by the appearance in this study. These results went to the same

direction of other studies which investigated the parent's satisfaction with appearance (Zhi et al., 2012, Chu et al., 2002). It is believed that the undesirable dark staining of the carious lesions of SDF are overcome by its favorable qualities in the majority of cases. This finding has also been reported by Crystal et al. (2017).

In pediatric dentistry, an effective treatment should possess other features as important as its clinical efficacy. By adding the results of the primary outcome, to the secondary outcomes and the procedural and cost characteristics, the treatment with SDF can be suggested as a better treatment option to the ART in halting carious lesions. Accordingly, it may be summarized that some advantages of SDF, such as the shorter treatment time, the lower cost (Johhnson et al., 2019), requiring less operator skills and better acceptance by the children and their parents.

The influence of oral problems and their required treatments on the quality of life of preschooler children and their families is now well known and understood. Therefore, the outcome of dental treatment can be assessed by the OHRQoL (Abanto et al., 2015). In this study, at baseline, when each A-ECOHIS question was evaluated, it was observed that the most prevalent impacts of the present study, which are pain in the teeth/ mouth/jaws and guilty/upset parents, are among the most frequent impacts reported by Duangthip et al. (2019), who evaluated the impact of SDF treatment on children's and families' OHRQoL.

The changes of the mean pre- and post-treatment total A-ECOHIS scores of children reflect how their oral health has been improved after treatment. This study shows a reduction in all sections and subscales in both groups, which illustrated the positive influence of both treatments. This finding is the same as the one reported by Vollu et al. (2019) and Rodrigues et al. (2020).

Conclusion

The arrestment rate of carious dentine lesions observed in both SDF and ART groups was similar. No differences were verified regarding adverse events and OHRQoL between SDF and ART. SDF application required less chair-time and caused lower levels of anxiety in the children receiving the treatment. Taking in consideration that SDF is cheaper, requires less operator skills and consumes nearly half of the time needed for ART, it can be suggested that SDF should be the treatment of choice, at least in areas where the access to treatment is difficult.

Limitations

The difficulty of evaluating the OHRQL in preschool children, since it was the guardians who answered the questions about their children, Thus, further studies must use instruments based on the opinions of children as well as parents.

Strength points

1. This study was able to investigate the long-term efficacy of both 38% SDF and ART (12 months follow up).

2. The participation of 100% of the patients (no dropouts), despite dealing with young and uncooperative children.

Ethical Compliance

Sources of funding:

This study was funded by the researcher.

Potential Conflict of interest

The authors declare that they have no conflict of interest.

Informed Consent

Informed consent was obtained from each individual participant involved in this study.

Statement of Human Rights

This study was conducted in accordance with the 1964 Declaration of Helsinki and its subsequent amendments.

Data availability

Datasets related to this article can be found at www.clinicaltrials.gov under the ID: NCT05314660.

Authors Contribution

All authors have substantially contributed to designing of the work, the acquisition and analysis of data for the work. They were also responsible for drafting the work and revising it critically for important intellectual content and for approval of the version to be published. They agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. They actively participated in discussing the manuscript's findings and have revised and approved the final version of the manuscript.

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