



Oral Health Programme  
Ministry of Health Malaysia

## ORAL HEALTH TECHNOLOGY REVIEW

### SILVER DIAMINE FLUORIDE

#### PURPOSE

To provide scientific evidence on the use, effectiveness, safety and cost-effectiveness of Silver Diamine Fluoride in arresting and prevention of caries.

#### 1.0 INTRODUCTION

Silver diamine fluoride (SDF) is a colourless solution with alkaline pH (pH 8–10) commonly used to help prevent tooth decay in young and special needs children.<sup>1</sup> The main components are silver which is known as an antimicrobial agent, fluoride which aids remineralisation and ammonia which stabilizes the solution.

SDF is one of the options of non-restorative treatment to arrest and prevent carious lesions on primary and permanent teeth.<sup>2</sup> Japan approved the use of SDF more than 80 years ago.<sup>1</sup> Other countries such as Brazil, Argentina, China and Australia have been using SDF since 1970s<sup>3</sup> whilst United States of America started using SDF since 2014.<sup>4</sup>

Silver Diamine Fluoride has been known for its bactericidal effect on cariogenic bacteria, mainly *Streptococcus mutans*. It inhibits the growth of cariogenic biofilms on teeth. SDF treatment has been proven to reduce demineralisation of enamel and dentine. A highly mineralised surface rich in calcium and phosphate was formed on arrested carious lesions.<sup>5</sup>

Several studies have concluded that SDF is a simple and low cost approach in arresting dental caries. SDF do not require caries removal prior to application and it has been proven to be much more successful at reducing cavity growth than varnish.<sup>5</sup>

#### 2.0 METHODS

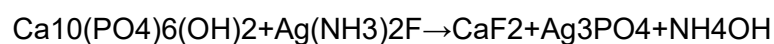
Literature searched was carried out through electronic databases which included Ovid interface: Ovid MEDLINE in process; and other non-indexes citations from 1946 to present;

and Cochrane Database of Systematic Review 2005 to December 2020. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the reference of retrieved articles. The search strategy used these terms either singly or in various combinations: silver diamine fluoride, safety, effectiveness, adverse effects, cost, cost-effectiveness and sodium fluoride. The search was limited to English language, human (in-vivo) and the last search was conducted on 31 March 2021.

### **3.0 ACTION MECHANISMS OF SILVER DIAMINE FLUORIDE**

Dental caries is a continuum process caused by acids from bacterial metabolism diffusing into enamel and dentine and dissolving the mineral. Demineralisation begins at enamel or dentine and can continue unless halted whilst remineralisation is the natural repair process for non-cavitated lesions. The remineralisation process relies on calcium and phosphate ions assisted by fluoride to rebuild new remineralised crystals that are acid resistant and less soluble than the original mineral.<sup>6</sup>

When SDF is applied to the tooth, the following reaction occurs:



(hydroxyapatite+SDF→calcium fluoride+silver phosphate+ammonium hydroxide)

Calcium fluoride and silver phosphate act as a reservoir of fluoride and phosphate that will be released if a pH drop occurs. Meanwhile, fluorohydroxyapatite which is formed when fluoride is incorporated into the hydroxyapatite crystals helps remineralisation and makes the tooth more resistant to further demineralisation.<sup>3</sup>

## **4.0 EFFECTIVENESS**

### **4.1 Caries Arrest and Caries Prevention**

Systematic synthesis of several clinical findings are summarised as follows: -

#### **a. Caries Arrest on Primary Teeth in Children**

- Crystal and Niederman in their systematic review analysis found that SDF is effective in arresting decay in primary teeth. The proportion of caries arrest ranges from 66% to 81% with annual or biannual application.<sup>2</sup>
- Large lesion and lesion with visible plaque had a lesser likelihood of arrest but arrest rate can be increased by increasing the frequency of application.<sup>7</sup>
- Anterior teeth have much higher rates of arrest than posterior teeth.<sup>2</sup>

- SDF at the concentration of 38% was effective in arresting dentine caries in primary teeth among children.<sup>8</sup>
- b. Caries Arrest on Permanent Teeth in Children
    - One clinical trial found that 77% of active caries at baseline became inactive after application of SDF.<sup>2</sup>
  - c. Caries Prevention in Children
    - One clinical trial found that new caries lesion development in primary and permanent teeth was significantly lower in SDF group.<sup>2</sup>
  - d. Caries Arrest and Prevention in the Elderly
    - Subbiah & Gopinathan found that SDF is effective in arresting and preventing root caries in the elderly.<sup>9</sup>

#### **4.2 Silver Diamine Fluoride vs Sodium Fluoride**

Limited studies were retrieved comparing the effect of Silver Diamine Fluoride and Sodium Fluoride (NaF) in arresting caries. Only one systematic review concluded that SDF was statistically more effective in dentine caries arrest of primary teeth. The weighted total effect size of the differences calculated showed nearly double the effectiveness of SDF to NaF at 30 months.<sup>10</sup> Another study suggests that SDF with 5% Fluoride Varnish is an effective approach to the management of early childhood caries.<sup>11</sup> However, if fluoride varnish is to be used post-application of the SDF, the varnish must not be applied to the surfaces where SDF has been placed, as it may reduce the antibacterial action of the SDF.<sup>12</sup> Further clinical research is needed as there is still insufficient evidence to consolidate these findings.

#### **4.3 Silver Diamine Fluoride as indirect Pulp Capping Material**

Several studies have shown positive results to support the use of SDF as an indirect pulp-capping material in deep carious lesions. SDF's ability to arrest dentine caries could reduce iatrogenic pulpal exposures by reducing the amount of tissue removal. However, SDF is not recommended to be used in carious lesions with close proximity to the pulp, due to the potential for silver ion penetration into the pulp complex.<sup>12</sup>

As of today, there is no retrievable evidence investigating the effect of SDF on pulp exposures and direct pulp capping treatments. Therefore, the use of SDF for this purpose is not recommended until further evidence is available.

## **5.0 SAFETY AND CONTRAINDICATIONS**

### **5.1 Safety**

Generally, SDF was found to be an efficient, simple, quick and safe treatment.<sup>12</sup> No serious adverse events have been reported from any of the randomized control trials. Chemical burns to skin and gingival reactions were rare. SDF was reported to be safe even when applied to several carious lesions at the same visit.<sup>13</sup>

The most common concentration of SDF available in the market is 38%, which represents 44,800 ppm of fluoride and 255,000 ppm of silver.<sup>3</sup> However, one drop only contains 2.24mg of fluoride, compared with a typical dose of 5% fluoride varnish which contains 11.3 mg fluoride. The amount of SDF applied is minute and with biannual application, dental fluorosis should not pose a risk in children.<sup>14</sup>

Although there have been no reports of acute toxicity, the high concentration of fluoride and silver has raised some concern, especially with repeated applications on very young children. Investigators have recommended that multiple and frequent applications on young children should be avoided.<sup>2</sup>

### **5.2 Contraindications**

Some studies have suggested that SDF should not be used for the following situations<sup>12</sup>: -

- Silver allergy
- Significant desquamative gingivitis or mucositis
- Pregnancy
- Breastfeeding
- Restorations in the aesthetic zone
- Caries in the aesthetic zone
- Signs or symptoms of periapical pathology
- Radiographic signs or symptoms of periapical pathology.

## **6.0 SIDE EFFECTS / ADVERSE EFFECTS**

### **6.1 Discolouration**

One of the common reported side effects of SDF is discolouration.<sup>12,15,16</sup> The black/dark brown staining is thought to result from silver phosphate ( $\text{Ag}_3\text{PO}_4$ ), which is formed when hydroxyapatite in carious tooth reacts with SDF.

Many studies suggested the use of potassium iodide (KI) after SDF application to reverse the staining effect. KI reacts with the remaining free silver ions to form silver iodide, a creamy white reaction product that after adequate application turns colourless. Although some studies reported a positive effect, there is still insufficient evidence to support the benefit of combining SDF and KI treatment on the tooth staining, mainly due to methodical variations within the current literature.<sup>4,12,15</sup>

## **6.2 Effect of SDF on mucosa and skin**

Mucosal or skin burns may occur post-application as a result of high concentration and high pH of SDF. The burns tend to be small, mildly painful white lesions in the mucosa, which disappear after 48 hours without treatment.<sup>16</sup> SDF can also stain clothes and skin of the body. Though it does not cause pain or damage, SDF skin staining cannot be easily washed away and takes around seven days to disappear. SDF clothes staining however is permanent.<sup>12</sup>

## **7.0 COST / COST-EFFECTIVENESS OF SDF**

### **7.1 Cost of SDF**

According to the supplier, one set of SDI Riva Star which comprised of 1 bottle of Step 1 (1.5ml) and 1 bottle of Step 2 (3.0 ml) cost about ██████. One set will be able to produce 30 drops which is enough for application of 150 sites. Based on rough calculations, one application cost about ██████.

### **7.2 Cost-Effectiveness of SDF**

There is insufficient evidence to conclude the cost-effectiveness of SDF. Only one economic evaluation study in Germany<sup>17</sup> found that SDF is more cost-effective than fluoride rinses and chlorhexidine for the prevention of root-caries in the elderly. In patients with a low number of teeth at risk for caries (16 teeth), SDF was considered most cost-effective compared with no treatment for the prevention of root caries with an Incremental Cost-Effectiveness Ratio (ICER) of 8.30 Euros (RM 40.42) per root caries-free tooth year. Whilst in patients with a high number of teeth (24 teeth) at risk for caries, SDF was considered most cost-effective with an ICER of 0.79 Euro (RM 3.85) per root caries-free tooth year. Chlorhexidine and fluoride rinses were considered more expensive and less effective in both groups.

## **8.0 LEGISLATION**

SDF was approved by the U.S. Food and Drug Administration (FDA) in 2014 for use in the United States. SDF is considered a class II medical device to treat tooth sensitivity.<sup>4</sup> Riva Star is the only brand of SDF supplied in Malaysia. It is registered as a Class B Medical Device (Reg. No GB4791220-49357) which acts as a dental desensitizing agent used by dental professionals to relieve tooth hypersensitivity and indicated for desensitizing cervical tooth hypersensitivity.<sup>18</sup>

## **9.0 CONCLUSION**

SDF promises to be a therapy that could benefit many patients especially patients with extreme caries risk, those who cannot tolerate conventional treatment such as special needs patients, patients who are medically compromised or too frail to be treated conventionally, and those staying in the remote area with little access to care. SDF is a safe, effective and painless alternative to traditional cavity drilling procedures for these patients.

Systematic reviews consistently supported SDF's effectiveness for arresting coronal caries in the primary dentition and arresting and preventing root caries in older adults. However, there is insufficient evidence to draw conclusions on SDF for prevention in primary teeth and prevention and arrest in permanent teeth in children. Clinicians should use their own clinical judgment on the application frequency based on individual caries risk factors, fluoride exposure and patient needs and benefits.

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