Silver Nitrate Study

The University of Iowa
Dr. Michael Kanellis
Dr. Arwa Owais
8/26/2016
Medical Management of Caries in the Primary Dentition Using Silver Nitrate

This study is enrolling participants by invitation only.

**Sponsor:**
University of Iowa

**Collaborator:**
Delta Dental of Iowa

Information provided by (Responsible Party):
University of Iowa

ClinicalTrials.gov Identifier:
NCT02604134

First received: October 28, 2015
Last updated: November 10, 2015
Last verified: November 2015

**Purpose**

This pilot trial compares conventional restorations with a new strategy based on the medical management of caries using silver nitrate and fluoride varnish with no restorations.
Funding

• Delta Dental of Iowa Foundation
• Dow’s Institute for Dental Research
• Department of Pediatric Dentistry
Research Team

• M Kanellis
• A Owais
• D Dawson
• J Warren
• G Wehby
• D Drake
• W Liu

• A Gasparoni
• R Oweis
• C Stokowski
• M Akers
• M Geneser
• K Weber-Gasparoni
• Dental Students
Purpose of the Study

To compare the conventional approach of restoring caries in the primary dentition, to medically managing caries using silver nitrate and fluoride varnish.
Study Population

• Amish children living in Kalona, IA.
• Settlement established 1845
• Ave. family has 8 children
• High caries rate
• Low exposure to fluoride
• Limited access and utilization of regular dental care
Current Progress of the Study

• Oct, 2014 – IRB approval (201406792)
• Oct & Nov, 2014 – Informational sessions
• Nov, 2014- May, 2015 – Recruitment, enrollment, random assignment, treatment
• July, 2015 – Recalls began
• July, 2016- 18 Month recall began
Materials & Methods

• This is a two-arm, parallel group, patient-randomized controlled pilot trial. Healthy children with at least one primary tooth where caries extends into dentin but not encroaching on the pulp were included in the study.

• Children were randomized and treated according to one of two treatment approaches: conventional caries management with best practice prevention or medical management of caries using silver nitrate and fluoride varnish with best practice prevention.
Baseline & Outcome Measures

- Direct reporting by parents, children and operator
- Clinical examination including blinded radiograph assessment,
- Child/parent questionnaires.
- Incidence of caries (clinical and radiographic)
- Pain or infection
- Patient quality of life
- Cost-effectiveness, and
- Acceptability of treatment strategies.
Assessment of Caries

• EC4 Criteria
• Clinical Examination
• Radiographic Examination
Radiographic Assessment (Each tooth with Caries)

R0: Sound
RF: Radiographically Filled
R1: Caries in the outer half of enamel
R2: Caries in the inner half of enamel
R3: Caries in the outer half of dentin
R4: Caries in the inner half of dentin not encroaching on the pulp
R5: Caries encroaching on the pulp
Q: Unable to assess
Silver Nitrate Application Protocol

• Study teeth are cleaned and dried, isolated with cotton roll/ dry angle isolation
• 25% Silver Nitrate (SN) applied to the carious lesions using a microbrush for open lesions and super floss/interproximal aid for closed radiographic lesions then covered with Fluoride varnish
• Application time of SN is 5-10 seconds
• Application Frequency: once every 4 weeks for three months (a total of 3 applications)
• Fluoride varnish is applied to all teeth every 6 months and on study teeth only on the follow up visits for SN application
## Children Demographics in The SN Study Based Upon Intention-to-treat Analysis

<table>
<thead>
<tr>
<th></th>
<th>Silver nitrate treatment group (n=50 children)</th>
<th>Conventional treatment group (n=24 children)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Child’s age in year</strong></td>
<td>Mean (standard deviation) 7.1 (2.2)</td>
<td>Median (minimum, maximum) 6.9 (3.1, 11.4)</td>
<td>Mean (standard deviation) 7.7 (2.0)</td>
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<tr>
<td><strong>dmft score</strong></td>
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<tr>
<td><strong>dmft score</strong></td>
<td>4.4 (2.8)</td>
<td>4.0 (0, 10.0)</td>
<td>5.1 (3.3)</td>
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</tr>
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<td>8.0 (3.8, 11.0)</td>
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<td>9.2 (8.6)</td>
<td>12.1 (11.3)</td>
<td>0.5133</td>
</tr>
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<td></td>
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<td></td>
</tr>
<tr>
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<td>7.0 (0, 41.0)</td>
<td>9.5 (0, 36.0)</td>
<td></td>
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</tbody>
</table>
Children’s Age at the Baseline by Treatment Group

![Box plot showing children's age at baseline by treatment group. The box plot compares two groups: 1. Silver Nitrate and 2. Conventional Treatment. The y-axis represents the child's age in years, ranging from 4 to 10. The median age is indicated by a diamond symbol within the box.](image-url)
Distribution Of Children’s dmft at the Baseline (EC4 Criteria)

1. Silver Nitrate
2. Conventional Treatment

Group

Child’s dmft

0 2 4 6 8 10

1. Silver Nitrate 2. Conventional Treatment

Group
Distribution of Maxillary Teeth by Tooth Number Based Upon Intention-to-treat Analysis (N=74 Children)

![Bar chart showing percentage of treated primary teeth for different tooth numbers. The chart compares conventional group and silver nitrate group.](chart.png)
Distribution of Mandibular Teeth by Tooth Number Based Upon Intention-to-treat Analysis (N=74 Children)
Distribution of Children by Number of Treated Primary Teeth (N=74 Children)

Percentage of children

Conventional Treatment | Silver Nitrate
## 18-month Recall Results- New Caries Lesions

<table>
<thead>
<tr>
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<th>Silver Nitrate Group</th>
<th>Conventional Treatment Group</th>
<th>Total N = 46</th>
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<tr>
<td></td>
<td>N = 30</td>
<td>N = 16</td>
<td>N = 46</td>
</tr>
<tr>
<td>New Lesions* N (%)</td>
<td>17 (56.7)</td>
<td>5 (31.3)</td>
<td>22 (47.8)</td>
</tr>
<tr>
<td>No New lesions* N (%)</td>
<td>13 (43.3)</td>
<td>11 (68.8)</td>
<td>24 (52.2)</td>
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*Numbers presented by subject, not all subject had the 18 month recall as of August, 2016

Numbers presented here by teeth.
The additional numbers provided are all-inclusive, and include subjects enrolled since analysis was run.
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<table>
<thead>
<tr>
<th></th>
<th>Interproximal (M,D)</th>
<th>NOT Interprox. (O,F,B,L)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silver Nitrate</td>
<td>24</td>
<td>8</td>
<td>32</td>
</tr>
<tr>
<td>Conventional Treatment</td>
<td>6</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>8</td>
<td>38</td>
</tr>
</tbody>
</table>

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### Major & Minor Failures Throughout the Study Period

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<th>Silver Nitrate Group</th>
<th>Conventional Treatment Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Failure *</td>
<td>8</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Minor Failure *</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

* Numbers presented by subject, failures vary by time.

Major failure includes all failures that necessitates extraction of the tooth
Minor failures includes lost fillings that required replacement, pulp therapy, etc but not extraction.
Lessons Learned
Edwin M- Tooth #19 (Collateral Effect of SN)
Food Impaction is Your Enemy
Silver Nitrate bleeds and stains Incipient Lesions
Lessons Learned

1. Open lesions that pack food are not good lesions for silver products alone.

2. Lesions that are encroaching on the pulp are not good lesions for silver products.

3. Silver nitrate “bleeds” onto other surfaces. This can lead to “black” white spot lesions on permanent teeth.

4. Interproximal application is a challenge. Using “picks” and “superfloss” are problematic.

5. Our findings challenge the concept that silver application on affected teeth prevents caries in the rest of the mouth.

6. It is important to not view silver products as “either/or”.
Questions