Medical Management of Caries Using Silver Nitrate and Fluoride Varnish Two Year Findings- Kalona Trial

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Background of the study

• 2013 Hood River Symposium on Caries in the Primary Dentition in American Indian and Alaska Native Children

• Learned about Dr. Steve Duffin’s protocol for arresting caries in the Primary dentition
  • 25% Silver Nitrate / cover with fluoride varnish
  • Applications at time 0, 2, 4, 8 and 12 weeks

• Talked with Pediatric Dentists using a modified protocol
  • 3 applications one month apart / cover with FV
Purpose of the Study

• To compare (a) the conventional approach of restoring caries in the primary dentition to (b) medically managing caries using silver nitrate and fluoride varnish.
Study Population

• Amish children living in Kalona, IA.
• Settlement established 1845
• Average family has 8 children
• High caries rate
• Low exposure to fluoride
• Oral hygiene often insufficient
• Limited access and utilization of regular dental care
Timing of Study

- Oct, 2014 – IRB approval (201406792)
- Nov, 2014 – Subject recruitment, enrollment, random assignment, treatment began (rolling admissions)
- Nov, 2015 – 12 month recalls began
- Nov, 2016 – 2 yr. recalls began
Eligibility Criteria

- Ages 2-11 years
- Otherwise healthy
- Untreated caries into dentin in at least one primary tooth
- Teeth with caries encroaching on the pulp not included in the study
Materials & Methods

• Subjects randomized into two groups:
  • Conventional group (CON)
    • Restorations (composites, glass ionomers, stainless steel crowns)
  • Silver nitrate group (SN)
    • Medical management of carious lesions using silver nitrate and fluoride varnish
• Both groups received “best practice” prevention
  • Oral hygiene instruction
  • Fluoride varnish application
  • Diet counseling
• Subjects were randomized 2:1 (SN:CON)
Materials & Methods

• Recall interval for both groups is 6 months
• New BW radiographs made each recall
• SN group receives application of silver nitrate to study teeth at each recall
Flow Chart for the Silver Nitrate Study

Assessed for eligibility (n=103)

- Excluded (n=28)
  - Not meeting inclusion criteria (n=28)
  - Declined to participate (n=0)
  - Other reasons (n=0)

Randomized (n=85)

- Allocated to Silver Nitrate Group (n=59)
  - Received allocated intervention (n=59)
  - Did not receive allocated intervention (n=0)

- Allocated to conventional Group (n=26)
  - Received allocated intervention (n=23)
  - Did not receive allocated intervention (parent request to receive silver nitrate) (n=3)

Follow-up

- Lost to follow-up (give reasons) (n=0)
- Discontinued intervention (give reasons) (n=0)

Analysis

- Analysed for baseline demographics (n=60)
  - Excluded from analysis (give reasons) (n=0)

- Analysed for 24 month follow-up (n=42)
  - Excluded from analysis (not due for the 24 month recall) (n=18)

- Analysed for baseline demographics (n=25)
  - Excluded from analysis (give reasons) (n=0)

- Analysed for 24 month follow-up (n=22)
  - Excluded from analysis (not due for the 24 month recall) (n=3)
### Outcome Clinical Criteria at the 2-Year Recall

#### Table 1a: Outcome Criteria: Clinical Assessment in the 2 Treatment Arms

<table>
<thead>
<tr>
<th>Silver Nitrate Group</th>
<th>Conventional Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome: Successful</strong></td>
<td><strong>Primary Outcome: Successful</strong></td>
</tr>
<tr>
<td>• Caries arrested (hardness/softness; lesion feels hard on gently probing the dentin),</td>
<td>• Restoration appears satisfactory (intact tooth surface adjacent to restoration, stained margins consistent with noncarious lesions)</td>
</tr>
<tr>
<td>• No clinical signs or symptoms of pulpal pathology, or</td>
<td>• No clinical signs or symptoms of pulpal pathology, or</td>
</tr>
<tr>
<td>• Tooth exfoliated without minor or major failure</td>
<td>• Tooth exfoliated without minor or major failure</td>
</tr>
</tbody>
</table>
### Table 1b: Outcome Criteria: Clinical Assessment in the 2 Treatment Arms

<table>
<thead>
<tr>
<th>Silver Nitrate Group</th>
<th>Conventional Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome: Minor Failure</strong></td>
<td></td>
</tr>
<tr>
<td>• Caries progression that required abandonment of SN protocol and placement of a restoration</td>
<td>• Secondary caries (visible dentin in the interfacial space with signs of caries requiring intervention)</td>
</tr>
<tr>
<td>• Signs or symptoms of reversible pulpitis treated without requiring pulpotomy or extraction</td>
<td>• Restoration loss, fracture or wear requiring intervention</td>
</tr>
<tr>
<td></td>
<td>• Signs or symptoms of reversible pulpitis treated without requiring pulpotomy or extraction</td>
</tr>
</tbody>
</table>
## Outcome Clinical Criteria at the 2-Year Recall

### Table 1c: Outcome Criteria: Clinical Assessment in the 2 Treatment Arms

<table>
<thead>
<tr>
<th>Silver Nitrate Group</th>
<th>Conventional Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome: Major Failure</strong></td>
<td></td>
</tr>
<tr>
<td>• Irreversible pulpitis (history of spontaneous pain or precipitated pain caused by thermal or other stimuli) or dental abscess requiring pulpotomy or extraction.</td>
<td>• Signs or symptoms of reversible pulpitis requiring pulp therapy</td>
</tr>
<tr>
<td></td>
<td>• Signs or symptoms of irreversible pulpitis or dental abscess</td>
</tr>
<tr>
<td></td>
<td>• Restoration loss and tooth is unrestorable</td>
</tr>
</tbody>
</table>
24 month Results - Major & Minor Failures

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Major and Minor Failures at 24 Months*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Silver Nitrate Group</td>
</tr>
<tr>
<td></td>
<td>Major Failure</td>
</tr>
<tr>
<td>17 / 237</td>
<td>7.2%</td>
</tr>
<tr>
<td>7.2%</td>
<td>2.1%</td>
</tr>
</tbody>
</table>

*Reported at the tooth level

- 7.2 % of SN lesions experiences major failure
- 3.2 % of CON lesions experiences major failure

- Numbers presented are teeth, not subjects
- Major failure includes all failures that necessitate extraction of the tooth
- Minor failures includes lost fillings that required replacement, pulp therapy, but not extraction
### 24 month Results – New carious Lesions

<table>
<thead>
<tr>
<th></th>
<th>Silver Nitrate Group</th>
<th>Conventional Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=59</td>
<td>N=25</td>
<td>N=84</td>
</tr>
<tr>
<td>Subjects w/ new lesions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N (%)</td>
<td></td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>23 (47.5)</td>
<td>31 (52.5)</td>
<td>13 (52.0)</td>
<td>12 (48.0)</td>
</tr>
</tbody>
</table>

*Reported at the child level*
### Location of New Carious Lesions

<table>
<thead>
<tr>
<th></th>
<th>Interproximal (M,D)</th>
<th>NOT Interproximal (O,F,B,L)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Silver Nitrate Group</strong></td>
<td>43 (70.5%)</td>
<td>18 (29.5%)</td>
<td>61 (100%)</td>
</tr>
<tr>
<td><strong>Conventional Group</strong></td>
<td>20 (90.9%)</td>
<td>2 (9.1%)</td>
<td>22 (100%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>63 (75.9%)</td>
<td>20 (24.1%)</td>
<td>83 (100%)</td>
</tr>
</tbody>
</table>
Despite failures, most teeth are doing well

• 90.7 % Silver Nitrate group carious teeth are doing fine
• 96.8% Conventional group carious teeth are doing fine
Lessons Learned*

Kanellis, Owais, Warren et al. Managing Caries in the Primary Dentition With Silver Nitrate: Lessons Learned from a Clinical Trial.
Journal of the California Dental Association. Accepted August, 2017

* with this population
Successful Outcome

• MB is a 6 year 7 month old (at baseline) female subject from the SN group.

• DMFT (at Baseline): 3
• DMFT (at 2 years): 3
Successful Outcome

- Multiple deep interproximal carious lesions medically managed with silver nitrate over 24 month period.

- CK is a 9 year 4 month old (at baseline) male subject with deep lesions.

- DMFT (at Baseline): 8 (A,B,I,J,K,L,S,T)
- DMFT (at 2-years): 8 (A,B,I,J,K,L,S,T)

- Despite the extent of the decay, this subject showed no signs or symptoms of caries progression or irreversible pulpitis throughout the course of the study.
Silver nitrate doesn’t stop all caries progression

- Decay can continue to progress following silver nitrate application
  - Food impaction
  - Cariogenic diet
  - Poor oral hygiene
  - Lower fluoride exposure
- New lesions in other unaffected teeth/teeth surfaces that were not treated with SN
Location and size of lesions matter

• Anterior teeth do better after SN treatment than posterior teeth

• All major failures have occurred on posterior teeth

• Lesions that pack food do not do as well as other lesions
“Collateral benefit” from silver nitrate
SN “bleeds” and stains decalcified enamel

• 1 month following SN treatment

• Following rubber cup prophy

• Following polish with finishing bur
Interproximal application of SN is a challenge
Thank you