Silver Nitrate for Caries Arrest

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First Choice Community Healthcare

A mouth without teeth is like a mill without a millstone, and a tooth is much more to be prized than a diamond. – Don Quixote
How did I get interested?

Medical Management of Caries

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to

Enjoy a free article from the Nov. 2012 Journal of the California Dental Association

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Silver Nitrate

- What is silver nitrate?
- What is the Duffin protocol?
- Does it work? – my clinical experience
- What are the indications?

- Is it safe?
- Is it legal?
- What about silver diamine fluoride?
History of Silver Nitrate

• Silver nitrate discovered in the 13\textsuperscript{th} century
  – Nitric acid used to dissolve silver out of a silver/gold alloy
  – Noted that it could blacken skin

• 1881 – first used for newborns to protect eyes from transmission of gonorrhea from mothers during birth (concentrations $\leq 1\%$)

• 1920 – GV Black wrote about technique for caries arrest with silver nitrate
History of Silver Nitrate

• Common in the dental literature into the 1950’s
  – Howe’s solution
• Articles up to the 1970’s
• Eventually went out of style in dentistry
  – Increased focus on fluoride
  – Local anesthesia lead to shift from medical to surgical management of caries
• Silver nitrate sticks still used in medicine for hemostasis and chemocautery today
What is the Duffin Protocol?
What is the Duffin Protocol?


• Reports the results of 5 years of clinical experience and over 5000 pediatric patients

• Dramatic drop in hospital cases

• 98% effective in long term carious lesion arrest based on clinical chart review
What is the Duffin Protocol?

• Obtain written informed consent
• Dispense 1-2 drops 25% silver nitrate (aq) into a disposable dappen dish and **recap the bottle**
• De-plaque the lesion and dry with reasonable isolation
• Wet the lesion with silver nitrate solution using micro brush
• Immediately cover with 5% fluoride varnish to **seal in the silver nitrate**
What is the Duffin Protocol?

• Continue for all lesions to be treated
• Afterwards soak up any remaining silver nitrate in the dappen dish with a cotton roll
• Then peel off glove onto dappen dish and cotton roll and immediately throw away
• Total procedure time < 5 minutes
What is the Duffin Protocol?

• For definitive caries arrest, re-eval and repeat application every 2 weeks until complete arrest is achieved – up to 6 times
• Wait 4-6 more weeks before placing restorations – often no anesthesia needed
• Many lesions may not need operative therapy
• Combine with prophylaxis, fluoride varnish, motivational interviewing to address home care, diet, other risk factors
How can I get it?

- Item code 3018890
- $100.22 per 1 oz bottle
- 591 drops per oz
- $0.10 per drop
Does it work?

My clinical experience
Patient MK

24 year old male. Heavy smoker

Seen by a cosmetic dentist for exam on 10-22-12. Rampant decay.

Over the next year teeth #2, #4, #5, #12, #13 extracted.

Presented with pain on LL on 10-18-13. Teeth #18 and #19 were extracted.

Patient referred to me for restorative treatment at that time.
Patient MK – Exam 10-22-13

• 4 days after ext of #18, #19 and less than 2 weeks after ext of #4, #5
• Rampant decay, poor hygiene, “all my teeth hurt”
• Treatment plan: caries control
• Oral hygiene instruction given
• Caries risk assessment / motivational interviewing
  – Change from sweet tea to water or unsweetened tea
  – Baking soda mouthwash after meals and snacks
  – Brush 5 minutes 2x daily with ClinPro 5000
Patient MK – Treatment

- 10-22-13: Exam and OHI
- 11-1-13: Prophy, F⁻ varnish, OHI reinforced
- 11-21-13: Ops and AgNO₃
  - Oral hygiene is very good
    - patient drinking mainly water
    - using ClinPro 5000 toothpaste
    - baking soda mouthwash after meals and snacks
  - Restored #8(F) and #9(F) with GC Equia
  - Placed AgNO₃ and F⁻ varnish on all other carious lesions
Patient MK – Treatment

• 12-12-13: GC Equia restorations #3(B), #6(DFM), #7(DFLMI) – all arrested

• 1-9-14: GC Equia restorations #10(F), #11(F), #14(B). Repeated AgNO₃ and F⁻ varnish on all remaining lesions.

• 3-4-14: Restored deep buccal caries (arrested) #30 and extracted #31.

• 3-13-14: Restored arrested caries #20(B) and #21(B).
  – #15, #28, #29(B) remain unrestored
  – Photographic documentation
Patient MK 3-13-14

#29

#28
Which looks like a simpler restoration?

10-22-12

3-13-14
Which looks like a simpler restoration?

10-22-12

3-13-14
What about this tooth?
What about this tooth?

#15
Patient NM

- 38 year old female
- Oral hygiene is fair
- High sugar frequency diet. History of soft food diet for ~1 year after jaw dislocation
- Fully erupted 3\textsuperscript{rd} molars
- Caries
  - pits and fissures of 2\textsuperscript{nd} and 3\textsuperscript{rd} molars
  - along gumline facial to #9, #10, #29 and also #1.
Patient NM

• Must always have a pillow under her neck
• Won’t lean back in the chair for fear of her jaw locking open
• Even upright, can’t stay open more than ~2 minutes at a time
• Moans and kicks during any treatment—eg. placement of topical anesthetic
Patient NM

Treatment

• 3-14-13
  – Fuji IILC facial class V of #9, #10

• 5-9-13
  – Fuji Triage sealant #17(O)
  – Silver Nitrate / F⁻ varnish #1(B), #29(B)

• 5-23-13
  – Fuji Triage sealants #15(OL), #16(O)
  – Silver Nitrate / F⁻ varnish #1(B), #29(B)
Patient NM

Treatment

- 6-20-13
  - Fuji Triage sealant #1(OL)
  - Lesions on #1, #29 are inactive
  - Silver Nitrate / F- varnish #1(B), #29(B)

- 7-9-13
  - Fuji Triage sealants #30(OB), #31(OB), #32(O)
  - Silver nitrate lesions are arrested
  - Silver Nitrate / F- varnish #1(B), #29(B)
Patient NM

Results of AgNO$_3$ and F$^-$ varnish #1 (DB) and #29 (B)
Patient NM
Recall Exam
3-24-14
Patient AS

#17

#18
Caries Arrest

3/13/14  4/3/14  8/7/14

#17

#18

• 3-13-14 – Silver nitrate and varnish
• 4/3/14 – Repeat
• 8/7/14 – #17 out ~ 2 weeks; #18 ready to restore
Restoration of Arrested Caries
One Last Case
One Last Case
CC: “I want a cleaning.”

- a 62 year old male
- Arthritis
- Hepatitis C
- History of drug and alcohol abuse
- Severe dry mouth
Treatment

• 4 applications of silver nitrate and fluoride varnish over 6 week period
  – Gave Rx toothpaste
  – Gave OHI
  – Discussed needed diet changes

• Scheduled to start ops, pt failed appointment

• Did not see patient again for over a year
Recall – 1 year later

• Using Rx toothpaste? No
• Improved OH? No
• Diet changes? No
• Received dental care anywhere else? No
• Mouth still very dry? Yes
Recall FMX
What are the indications?

• Caries control / initial disease management
• Definitive caries arrest
  – True minimally invasive dentistry
• Adjunct to restorative dentistry
  – Easier, more predictable restorations
  – Slow or stop disease progression for non-compliant patient
  – Allow time for completion of operative treatment plan with less concern for endodontic complications
What are the indications?

- Any patient with limited ability to cooperate for operative dentistry
  - children, elderly, phobics, disabled
- General anesthesia referral patients
- Rampant caries
- Difficult to access carious lesions
- Non-compliant patients
- Anyone with cavitated carious lesions
Is it safe?

• The dose makes the poison
• Ingestion of large quantities of silver nitrate can be fatal (2g possibly – 10g likely)
  – Silver nitrate reacts rapidly with dissolved chloride to precipitate highly insoluble AgCl.
  – This results in a fatal electrolyte imbalances
Is it safe?

- 25% AgNO₃ (aq) = 7.5 g AgNO₃ per 1 fl oz bottle
  - Don’t chug the bottle!
- 1 fl oz = 591 drops
- \((7.5 \text{ g } \text{AgNO}_3 / 1 \text{ fl oz}) \times (1 \text{ fl oz} / 591 \text{ drops})\) = 13 mg AgNO₃ / drop
- A 2 drop treatment dose represents 0.65% of a fatal dose
Is it safe?

Other things that would be bad to ingest 1 fluid ounce of...
Is it safe?

• The silver nitrate sticks are very caustic
  – Mistaken use of these in the eye rather than 0.5% solution has caused blindness through burns or opacification of the cornea

• Solutions of silver nitrate > 1% are known to cause discoloration of the cornea

• Patients and staff must wear eye protection
Is it safe? Site Specific Exposure

• Skin contact results in a painless brown stain that fades over 2-3 weeks as stained cells slough off
• Spills can permanently stain countertops
  – Tarn-X can help some
Is it safe? Chronic Exposure
Is it safe? Chronic Exposure

- 13 mg AgNO₃ / drop of 25% aqueous soln
- Atomic weight of AgNO₃ = 169.9
- Atomic weight of Ag = 107.9
- 107.9 / 169.9 = 63.5% of AgNO₃ is Ag
- (13mg AgNO₃) / drop * (107.9 mg Ag / 169.9 mg AgNO₃) = 8.3 mg Ag / drop
Is it safe? Chronic Exposure

- **10 g** of silver is the human lifetime No Observable Adverse Effect Level according to WHO
- **8 mg per drop** = .083% of lifetime cumulative safe dose
- **1205 drops** to reach lifetime exposure limit for no observable effect
- **Drink 1 drop per day** for 3.3 years and you might start to turn a little blue
Is it legal?

• 25% Silver Nitrate (Gordon Laboratories)
• “Human Prescription Drug”
• “escharotic, dehydrating and sclerosing agent”
• “THIS DRUG HAS NOT BEEN FOUND BY FDA TO BE SAFE AND EFFECTIVE, AND THIS LABELING HAS NOT BEEN APPROVED BY FDA.”
Is it legal?

“THIS DRUG HAS NOT BEEN FOUND BY FDA TO BE SAFE AND EFFECTIVE” ≠

“This drug has been found by the FDA to be Unsafe or Ineffective”
Is it legal?

Drug Efficacy Study Implementation (DESI)

• FDA program begun in the 1960s
• Goal was to certify that all drugs are safe and effective (previously only needed to be safe)
• All pre-1962 drugs that were already on the market were to be classified as either effective, ineffective, or needing further study.
• This retrospective review is still ongoing
  – Many products grandfathered if no changes to labeling
Is it legal?

• Effectively, the manufacturer is in a legal gray area with the FDA to market and sell the 25% silver nitrate solution.

• Gordon Laboratories has been reporting their product and their labeling to the FDA for decades without any FDA action.

• However, dentists are perfectly within their prescribing authority to use a prescription labeled drug they are able to acquire. Can be either according to the label or off label.
Off-label Rx – limiting liability

• Made with the patient’s knowledge that a drug is being prescribed for an off-label use
• Principally motivated by a desire to diagnose, treat and directly benefit the patient for whom a drug is prescribed (versus experimental research)
• Based on the doctor’s own expert medical opinion
• Supported by reputable peer reviewed literature reflecting sound scientific evidence
• Generally supported by the opinions of the physician’s local colleagues

Silver Diamine Fluoride

- 30+ years of research showing efficacy for caries arrest
- Had not been FDA approved or commercially available in the US
- 2014 - FDA decision classified SDF as simply a fluoride treatment
  - Indication is for treatment of dentin hypersensitivity
- 2015 First commercially available product

Elevate Oral Care
Silver Nitrate

- 100+ years history of use in dentistry
- Varnish taste
- Not FDA approved
  - Grandfathered
  - Off label usage for caries arrest

Silver Diamine Fluoride

- 30+ years research for caries arrest
- Metallic taste
- FDA approved
  - As desensitizer
  - Off label usage for caries arrest
Silver Nitrate

- Simple protocol
  - Dry and deplaque
  - Apply silver nitrate
  - Coat with fluoride varnish

Silver Diamine Fluoride

- Numerous protocols
  - Dry and deplaque
  - Apply and evaporate
  - Rub in for 1-3 minutes
    - Wash off
    - Apply a reducing agent
      » Tannic Acid
      » Potassium Iodide
Silver Nitrate

- 25% AgNO₃N
  - 16% Silver
- $100.22 / 1 fl oz
- 590+ drops / bottle
- $0.17 / drop
- $0.82 / dose varnish
- $0.99-$1.16 per application

Silver Diamine Fluoride

- 38% Ag(NH₄)₂F
  - 24% Silver
  - 5% Fluoride
- $124.95 / 8 ml
- 160-250 drops / bottle
- $0.50-$0.78 / drop
- $0.50-$1.56 per application
Can it be delegated?

• Dental Hygienist
  – “applying fluorides and other topical therapeutic and preventive agents”
  – Neither silver nitrate nor SDF are on the prescribing formulary for hygienists
• Expanded Functions Dental Auxillary – nothing specific
• Community Dental Health Coordinator
  – “dispense and apply medications on the specific order of a dentist”
• Dental Assistant
  – “apply fluoride and pit and fissure sealants without mechanical alteration of the tooth”
  – “perform such other related functions that are not expressly prohibited by statute or rules of the board”
Questions?

Please feel free to contact me if you have any questions: jeremiah_dye@fcch.com