Reducing Inadvertent Particulate Contamination in the Cath Lab

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Foreign Materials

Embolization of a variety of materials can occur during cardiovascular interventions:

- gauze
- glove powder (starch)
- polymers for drug delivery
- hydrogel coatings
- plastic sheath

Complications occur as a result of embolization of foreign materials.

Mehta RI et al., Mod Pathol 2010; 7: 921-30
Problem: Transmission of Cellulose

- Products manufactured from cotton plants such as Gauze, Telfa Pads, Towels, etc. contain Cellulose
- Cellulose is not digested by tissue macrophages; therefore, a cascade of inflammatory reactions occurs, causing foreign body granuloma formation.
Potential Complications from Products Manufactured Using Cotton

- Inflammation/Granuloma formation
- Thrombus Formation – myocardial infarction and stroke
- Adhesions
- Restenosis
- Infection
- Necrosis
Public Enemy Number One!

Cotton Gauze

EM of Cotton Gauze
Cotton Fiber Embolization

Coronary Embolization of a Gauze Fragment: A Cautionary Case Report

Michael Fisch, MD, and Craig R. Narins, MD
Example of:
Foreign Body Transmission

Gauze fiber lodged on a stent strut from handling with sterile glove.
Example of: Foreign Body Transmission

Cotton Gauze found on Glide Wire
Example of: Cotton Fiber Embolization

Distal Embolization: A Threat to the Coronary Artery?
Glenn Van Langenhove, Leonidas Diamantopoulos, Evelyn Regar, David P. Foley, Jan Tuin, Stephane G. Carlier and Patrick W. Serruys
Clinical Imperative

• Embolism -- “Unintentional foreign body emboli remain common in modern angiographic practice and are probably underappreciated clinically. Particulate embolization, which is usually a cotton fiber, is present in as many as 25% of resected arteriovenous malformations....”

Foreign body contamination during stent implantation in porcine

Whelan D.M. et al., Catheterization and Cardiovascular Diagnosis 1997; 40:328–332

Percentage of starch and textile fiber contamination

<table>
<thead>
<tr>
<th>Animal group</th>
<th>%starch contamination</th>
<th>%textile fiber contamination</th>
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</thead>
<tbody>
<tr>
<td>Total (n=46)</td>
<td>19.6</td>
<td>6.5</td>
</tr>
<tr>
<td>Short-term follow up (n=12)</td>
<td>41.6</td>
<td>0</td>
</tr>
<tr>
<td>Long-term follow up (n=34)</td>
<td>11.8</td>
<td>8.8</td>
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</tbody>
</table>
What Happens When Cotton Fibers Get Into Patients?
Problem:
Cotton Fiber Induced Arterial Thrombosis

• Embolization of cotton fibers during coronary and neuro interventional procedures has been shown to cause arterial thrombosis leading to myocardial infarction and stroke.
Clinical Imperative

- Stent Thrombosis -- 1997 study of coronary stent implants found: “42% of patients with stent thrombosis had particulate (glove powder and lint fibers) enmeshed within the thrombi”

Whelan D, Van Beusekron H, Van Der Giessen W. Foreign body contamination during stent implantation Catheterization and Cardiovascular Diagnosis 1997; 40 (3): 328-332
A 62-year-old woman presented with subarachnoid hemorrhage. Following angiography, the patient developed an attenuated left hemiplegia. CT was showed a large cerebral infarction.
Transmission in the Procedure Is Due To:

- Cleaning and wiping medical devices with cotton based products (Gauze or Telfa Pads).

- Soaking cotton based products into procedure bowls and drawing up the flush into a syringe and injecting it into catheters or sheaths to clear or to flush the catheter lumen.

- Medical device contact with cotton towels and procedure drapes.

- Particulate contamination from handling cotton based products with sterile gloves with subsequent transfer of fibers from gloves to medical device.
Telfa is No Better!

EM of Telfa Pad with >100 um Particle
Product Comparison Data

**SWIPER Versus Cotton Gauze and TELFA® Pad**

- **Cotton Gauze**
  - Magnification 30X

- **TELFA Pad**
  - Magnification 30X

- **SWIPER**
  - Magnification 30X

**Testing by Independent Laboratory Proves SWIPER has Lower Particulate**

<table>
<thead>
<tr>
<th>Product</th>
<th>≥10 μm</th>
<th>≥25 μm</th>
<th>≥50 μm</th>
<th>≥100 μm</th>
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<tbody>
<tr>
<td>Cotton Gauze</td>
<td>29809*</td>
<td>937*</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>TELFA</td>
<td>27884*</td>
<td>2401*</td>
<td>111*</td>
<td>15*</td>
</tr>
<tr>
<td>SWIPER</td>
<td>6692</td>
<td>70</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

*Test performed by submerging and squeezing product in 80 ml of filtered water and then analyzing sample of water with light obscuration particle counting equipment. Counts expressed as average number of particles within micron (μm) size range per 80 ml of fluid.

* Denotes particle count significantly greater than SWIPER (p<0.05).

Data on file at Syntervention, Inc.
Alternatives to Cotton Products

**SWIPER**

**SEM of SWIPER**

**SWASHER**

**SEM of SWASHER (Ultra Low Lint Surgical Towels)**
SWIPER vs. Cotton Gauze

35 Cotton Gauze = > 1 million cellulose fiber / particulate

1 SWIPER = < 7000 Particulate (No Cellulose)
Example of:
Foreign Body Transmission

Gauze fibers adhered to a guide wire between the tip of a balloon catheter and the Y-adapter. (Courtesy of Nick Cavros, MD)
Literature Review

18. Truscott W. Lint and Particle Contamination During Diagnostic and Interventional Procedures in the Cardiac Catheterization Lab. Cath Lab Digest (2006), online.
Summary

• Cotton fiber embolization occurs during cardiovascular, neurovascular and peripheral vascular interventions and can result in significant complications

• To increase the safety of our interventional procedures, we need to evolve (and modernize) and work to eliminate cotton based products from the procedural work flow