Microscopic Foreign Body Contamination During Interventional Procedures

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NEW CARDIOVASCULAR HORIZONS 2012
DISCLOSURES

- SYNTERVERVENTION, INC.
  MEDICAL ADVISORY BOARD MEMBER
Microscopic Foreign Body Contamination in Interventional Procedures

- **The Problem**: Microscopic foreign body contamination is the entry of materials not intended to enter the body, that can result in benign changes to severe complications.

- **The Cause**: Commonly used cotton-based materials, such as gauze pads and sponges, deposit particles on interventional tools and in saline, thereby causing inadvertent introduction of the particles into the patient.
Microscopic Foreign Body Contamination in Interventional Procedures

1929
Werner Forssman, MD 1st discovered how to access heart with a catheter through the arm

1949
Pulmonary artery reaction to cotton fiber emboli
Von Glahn et al. Amer J Pathol

1958
1st Selective coronary angiogram by Dr Mason Sones at Cleveland Clinic

1960
Silberman reports cotton foreign body emboli following cerebral angiography

1964
Charles Dotter, MD, Interventional radiologist at Univ. of Portland, OR working with Melvin Judkins, MD, perform 1st PTA

1977
1st Angioplasty performed by Andreas Gruentzig in Zurich, Switzerland; 1st in US: Lenox Hill Hospital (NYC) and St. Mary's Hospital (SFO)

1979
1st Balloon expandable stent

1986
1st Coronary Self-expanding Stent Procedure

1989
1st Balloon expandable stent

1997
Foreign Body Contamination In Stent Implantation
Whelan et al. CCI

2002 / 2003
1st Sirolimus eluding stent approved for sale in EU / US

2012
Address Microscopic Foreign Body Contamination in the interventional lab
Microscopic Foreign Body Contamination in Interventional Procedures

- **Impact on Clinical Outcomes:**
  
  **Embolization** - Particulate embolizes and causes a thrombus to form at the site where the foreign body becomes lodged ultimately blocking flow;

  Fisch and Narins (2005) reported coronary embolization of a gauze fragment in a coronary artery causing thrombus formation in the LAD after leaving the cath lab. A thrombectomy was performed and it revealed a gauze fragment from the coronary artery.
Impact on Clinical Outcomes:

**Infection** - Foreign bodies, or particulate, carry bacteria that can cause infection.

**Foreign Body (Granulomatous) Reaction** - Studies have shown intravascular foreign bodies can cause inflammation, increased neointimal formation and granuloma formation; all contributors to the restenosis process.
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- **Hypothesis**: We hypothesized that a new fiber-free product, the Swiper™ (Syntervention Inc, Rocky Mount, NC) would shed less particulate than the currently used products, gauze (Covidien, Mansfield, MA) and Telfa™ (Covidien, Mansfield, MA).

The SWIPER™ is a sterile, biocompatible, fiber-free, foam wiper designed for the removal of blood, contrast and other contaminants from sterile instruments and medical devices.
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- **Testing Methodology***:

  Individual samples were hydrated in filtered water (80ml) and squeezed under water 3 times.

  The product remained in the water for 2 minutes, absorbed water was squeezed back into bowl, then the product was discarded.

  A sample of the water was aspirated and injected into a light obscuration particulate counter. Particles measuring ≥10, ≥25, ≥50, and ≥100 microns (μm) in size were counted for each of the products.

*Independent testing by: Nelson Laboratories, Salt Lake City, Utah
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- Results:

<table>
<thead>
<tr>
<th>Product</th>
<th>≥10 µm</th>
<th>≥25 µm</th>
<th>≥50 µm</th>
<th>≥100 µm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gauze (n=5)</td>
<td>29809†</td>
<td>937†</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Telfa (n=5)</td>
<td>27884†</td>
<td>2401†</td>
<td>111†</td>
<td>15†</td>
</tr>
<tr>
<td>Swiper (n=5)</td>
<td>6692</td>
<td>70</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

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

*Independent testing by: Nelson Laboratories, Salt Lake City, Utah
Many medical devices are manufactured to strict requirements concerning cleanliness, particulate and fiber content.

- It should be noted that once the sterile medical devices are opened in the lab, they are exposed to a number of foreign bodies or contaminating elements.

- The manufacturing requirements no longer benefit the patient when the device is subjected to microscopic foreign body contaminants in the operating room or the interventional lab.
Conclusions:

- Complications from microscopic foreign body contamination are under-reported and the cause may go unrecognized.

- Severe complications may occur even after achieving an optimal interventional result.

- A fiber-free material is a viable option to reduce microscopic foreign body contamination in the interventional lab.

- We reduced the ergonomic risks by developing better shielding and lead protection...so...
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We MUST do ALL we can to prevent this!

It is all about the patients... anyway and all ways we can reduce the risk... we need to do it.