

Keeping the Room Out of the Patient

Reducing the risk of foreign body embolization during interventional procedures.

BY JOHN R. LAIRD, MD, FACC, FACP, FSCAI

Embolization of a variety of materials can occur during cardiovascular, cerebrovascular, and other endovascular procedures. Cotton fibers, glove powder (starch), polymers for drug delivery, hydrogel coatings, and fragments of catheters/wires can find their way into patients and cause significant harm.¹⁻³ One underemphasized and underrecognized source of contamination is cotton fibers/lint from gauze 4 X 4 sponges, Telfa pads, and cotton surgical towels that are so ubiquitous in cardiac catheterization laboratories and endovascular suites around the world (Figure 1).

Gauze 4 X 4 sponges are the most commonly employed product in the cardiac catheterization laboratory for wiping catheters and guidewires and for absorbing blood. Unfortunately, the loosely woven structure of gauze combined with cotton's fibrous nature makes it susceptible to fiber shedding and/or separation of the woven structure (Figure 2).

When introduced into the body, cotton fibers/lint can lead to a variety of complications including inflam-

mation/granuloma formation, thrombus formation, adhesions, infection, and tissue necrosis.⁴⁻⁹ These cotton fibers can find their way into patients after they are transferred onto catheters/guidewires after direct contact with towels or gauze, after handling with a sterile glove contaminated with fibers, from fibers floating in the air around the cath table, or from fibers in the flush materials (Figure 3).

There is particular potential for harm during percutaneous coronary interventions or neurovascular interventions where the introduction of cotton fibers can lead to thrombus formation and myocardial infarction or stroke.¹⁰⁻¹² Case reports of coronary embolization of gauze fragments during the process of flushing catheters have increased the awareness regarding the inappropriateness of soaking gauze in the bowl from which saline is aspirated and injected into catheters.¹⁰ Not enough attention is directed, however, to the potential for introduction of fibers into the patient during other routine procedural tasks.



Figure 1. Typical setup for a diagnostic or interventional procedure (A). High-lint cotton towels commonly used in cardiac cath labs and endovascular suites (B).



Figure 2. Cotton fiber shedding from the edge of a 4 X 4 gauze.

SCOPE OF THE PROBLEM

The exact incidence of cotton fiber embolization during diagnostic and interventional procedures is unknown because these events may not lead to clinically recognizable complications or overt symptoms. Shannon et al reported the prevalence of cotton fiber embolization during cerebral angiography.¹² A 5-year retrospective study was done on all available postmortem cases to systematically assess the prevalence of particulate embolization in patients with arteriovenous malformations. Particulate embolization, primarily due to cotton fiber, was present in 25% of the cases. These cotton fiber emboli were found to be mixed with thrombus. In a couple of instances, the foreign particulate emboli produced catastrophic results.

One can get a sense of the possible frequency of foreign body contamination during diagnostic and interventional coronary procedures from animal studies in which the hearts are harvested and sent for pathologic

examination. In a porcine coronary stent model, textile fabric contamination was present in 6.5% of cases.¹³ Hematoxylin and eosin staining from myocardial sections of these pig hearts showed birefringent foreign material with associated granulomatous changes and giant cell arteritis. Although many cases of coronary stent thrombosis can be explained by inadequate stent expansion and stent wall apposition, or insufficient antiplatelet therapy, some cases of stent thrombosis occur without clear explanation. One possible precipitating factor is foreign body contamination at the time of stent implant. Whelan and colleagues demonstrated that 42% of cases of coronary stent thrombosis had evidence of lint and glove powder on pathologic examination.¹³ Lint fibers were found incorporated into the neointimal layer, and particulate covered with inflammatory cells were found occluding capillaries.

Hydrophilic coatings on catheters and guidewires increase the risk of introducing cotton fiber/lint into the patient. As these hydrophilic coatings hydrate and swell, they have the potential to hold on to fibers with greater affinity. On the other end of the spectrum, as hydrophilic catheters and guidewires dry out, they become sticky, and cotton fibers readily adhere to these devices (Figure 4).

This is particularly common and problematic during peripheral vascular interventions, where the use of hydrophilic guidewires is routine and the cases are often long, resulting in prolonged contact between the hydrophilic guidewires and 4 X 4 gauze or cotton towels.

OPPORTUNITIES FOR IMPROVEMENT

There is significant opportunity for improvement in cardiac catheterization laboratories, endovascular suites, and operating rooms around the world. Despite what is known about the harmful effects of foreign

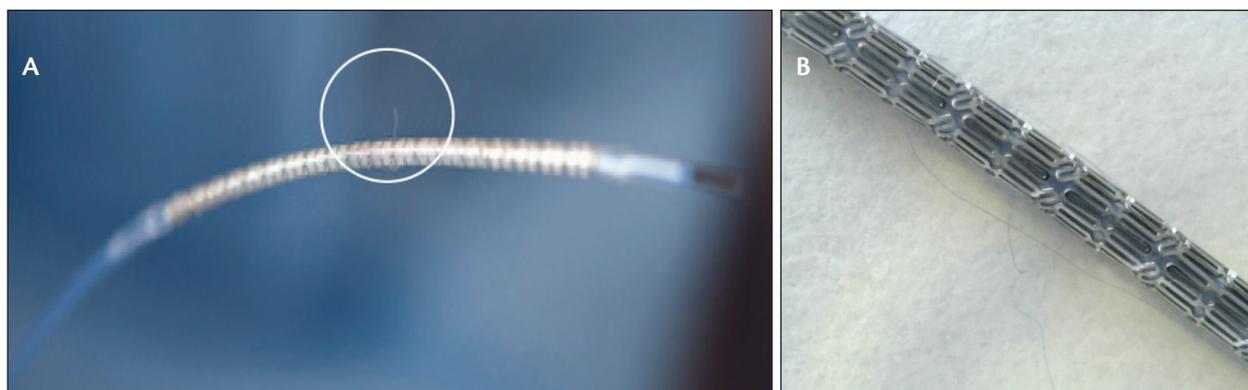


Figure 3. Gauze fiber lodged on a stent strut from handling with a sterile glove (A). Cotton towel fiber trapped on a stent after laying the stent on towel (B).

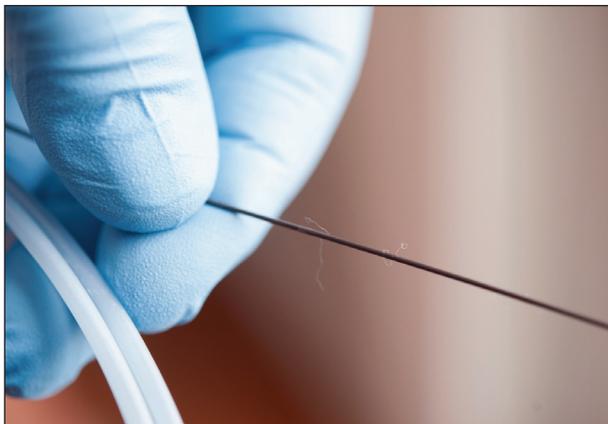


Figure 4. Cotton fibers adherent to a hydrophilic guidewire.

body contamination, most facilities cling to the traditional practice of using high-lint drapes and high-lint cotton towels, high-lint “lap sponges,” and cotton gauze. This is particularly remarkable in light of the fact that manufacturing plants for medical devices and clean rooms would never entertain the thought of using cotton-based products during the manufacture, cleaning, and packaging of medical devices, yet right at the point of entry into the patient’s body, there is a high likelihood these devices will come in contact with these high-lint cotton products.

A strategy to reduce the likelihood of foreign body contamination during interventional procedures should include the use of powder-free gloves and the use of low-lint patient drapes, low-lint towels, and fiber-free wipes. The highest priority should be given to eliminating the practice of wiping catheters and guidewires with 4 X 4 gauze. In addition, frequent cleaning of gloves to remove particulate/fiber, frequent wiping of guidewires with fiber-free wipes, and meticulous attention to prevent contact between stents/permanent implants and cotton towels will ultimately prove very beneficial. Appropriate air filtration and positive air flow in the operating room or endovascular suite will also reduce the likelihood of airborne particulate.

There are a variety of low-lint products available for clinical use. These products undergo special laundry processes to remove lint, fiber, and particulate and must meet strict specifications for particulate, residue levels, and absorbency. The Swiper foam wiper (Syntervention, Inc.) is one of the first of these products being provided in sterile form for medical procedures. 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 (Figure 5).

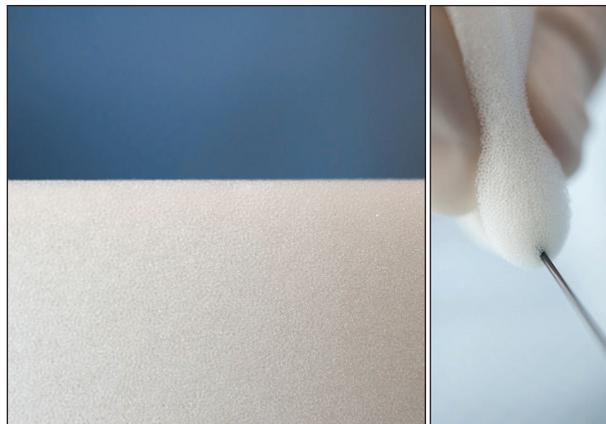


Figure 5. Fiber-free foam wiper (Swiper).

Low-lint surgical towels are also available and have the potential to reduce lint by > 99%. These towels are often lighter than standard cotton towels while retaining equivalent absorbency. They have the potential to reduce medical waste costs due to their lower wet weight. The Swasher ultra-low-lint surgical towel (Syntervention, Inc.) is composed of rayon for absorbency and polyester for strength (Figure 6). Replacing cotton towels with low-lint towels in the standard patient setup (Figure 1) will offer the potential for reduced transfer of cotton fibers onto catheters and guidewires during their introduction into the patient.

SUMMARY

Medical device manufacturers are required to follow strict quality system regulations as mandated by the US Food and Drug Administration.¹⁴ Once sterile medical devices are opened for use in the sterile field, they are exposed to a number of elements during a procedure. The requirements met to market the device no longer benefit the patient when the device is exposed to foreign body contaminants in the operating room or interventional lab. Cotton fiber embolization occurs



Figure 6. Low-lint surgical towels (Swasher).

during cardiovascular, neurovascular, and peripheral vascular interventions and can result in serious 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. The same standards used in the manufacture and packaging of our medical devices should be applied to the use of these devices for the care of our patients. ■

John R. Laird, MD, FACC, FACP, FSCAI, is Professor of Medicine and Medical Director of the Vascular Center, University of California, Davis Medical Center in Sacramento, California. Dr. Laird is a consultant/scientific advisory board member for Abbott Vascular, Boston Scientific, Bard Peripheral Vascular, Covidien, and Medtronic. He receives research support from Gore & Associates. He is a board member and has an equity investment in Syntervention, Inc. Dr. Laird may be reached (916) 734-2028; john.laird@ucdmc.ucdavis.edu.

1. Dimmick JE, Bove KE, McAdams AJ, Benzing III G. Fiber embolization—a hazard of cardiac surgery and catheterization. *Med Intel.* 1975;292:685-687.
2. Walley VM, Stinson WA, Upton RT, et al. Foreign materials found in the cardiovascular system after

instrumentation or surgery (including a guide to their light microscopic identification). *Cardiovasc Pathol.* 1993;2:157-185.

3. Glasgow D, Sommers J. Lint shedding cannot be overlooked. *Clin Services J.* 2003;28-30.
4. Von Glahn WC, Hall JW, Sun S. Arteritis in guinea pigs, produced by emboli of cotton, resembling the arteritis of hypersensitivity. *Am J Pathol.* 1954;30:1129-1139.
5. Heath D, Mackinnon J. Case reports: cotton-wool granuloma of pulmonary artery. *Brit Heart J.* 1962;24:518-520.
6. Ramot Y, Amir G, Willenz EP, Nyska A. Foreign body granulomas within intramyocardial arteries in a transcatheter safety assessment in pigs. *Toxicol Pathol.* 2008;36:385-387.
7. Janoff K, Wayne R, Huntwork B, et al. Foreign body reactions secondary to cellulose lint fibers. *The Am J Surg.* 1984;147:598-600.
8. Sturdy JH, Baird RM, Gerein AN. Surgical sponges: a cause of granuloma and adhesion formation. *Ann Surg.* 1967;165:128-134.
9. Bookstein JJ, Arun K. Experimental investigation of hypercoagulant conditions associated with angiography. *J Vasc Interv Radiol.* 1995;6(2):197-204.
10. Fischl M, Narins CR. Coronary embolization of a gauze fragment: a cautionary case report. *Catheter Cardio Interv.* 2005;66:570-572.
11. Silberman J, Cravioto H, Feigin I. Foreign body emboli following cerebral angiography. *Arch Neurol-Chicago.* 1960;3:119-126.
12. Shannon P, Bilbao JM, Marotta T, Terbrugge K. Inadvertent foreign body embolization in diagnostic and therapeutic cerebral angiography. *Am J Neuroradiol.* 2006;27:278-282.
13. Whelan DM, van Beusekom HMM, van der Giessen WJ. Foreign body contamination during stent implantation. *Catheter Cardio Diag.* 1997;40:328-332.
14. 21 CFR 820. Available at [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/CFRSearch.cfm?CFRPart=820&showFR=1&utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=21 CFR 820&utm_content=1](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/CFRSearch.cfm?CFRPart=820&showFR=1&utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=21%20CFR%20820&utm_content=1). Accessed June 24, 2012.