Preventing Retained Surgical Items During Endovascular Procedures: Bridging the Gap Between Guidelines and Practice

PODCAST

Kendal M. Endicott, MD; Rebekah Friedrich, MS, RN, CCRN; Jason W. Custer, MD; Rajabrata Sarkar, MD, PhD; Lisa Rowen, DNSc, RN; Megan G. Anders, MD, MS, CPPS

ABSTRACT

A retained surgical item (RSI) can be a devastating and costly procedural complication. Although the current incidence of RSIs is unknown, perioperative personnel routinely perform surgical counts according to their facility's policies and procedures to prevent this sentinel event. The American College of Surgeons, The Joint Commission, and AORN emphasize the importance of communication and standardized protocols for the counting of surgical items. However, there is a lack of current evidence to support specific recommendations for the counting of items during endovascular procedures. After the occurrence of RSIs during endovascular procedures at our facility, we convened an interdisciplinary workgroup, conducted an analysis of root causes, reviewed the available literature, and revised the existing policy. This article reviews the available literature on RSIs, describes root causes, discusses recommendations from national organizations, and describes the process that we used to create the policy changes at our facility.

Key words: *retained surgical item (RSI), endovascular procedures, unintended retention of a foreign object (URFO), sentinel event, guidewire.*

A retained surgical item (RSI) can be a devastating and costly procedural complication. To prevent sentinel events involving RSIs, perioperative personnel routinely perform surgical counts of soft goods, sharps, instruments, and miscellaneous items according to their facility's policies and procedures. Despite these practices, 60 (12.8%) of 436 sentinel events reported to The Joint Commission during the first half of 2019 were RSIs (ie, unintended retention of foreign bodies, unintended retention of foreign objects).[1] Researchers at The Joint Commission reviewed 308 RSI sentinel event reports between 2012 and 2017 and determined that human factors, inadequate policies and procedures, and poor communication were the most frequently cited contributing factors.[2] Although the researchers excluded guidewires, 15 (4.8%) of the 308 reports related to intravascular catheters or lines.

Clinicians routinely insert central venous catheters in critically ill patients who may experience rare—but not insignificant—guidewire retention events.[3] At a facility in Singapore, health care personnel observed three instances of guidewire retention in 120 ultrasound-guided central venous catheter insertions in an intensive care unit, and initiated an improvement project to address the concern.[4] Operator error,[5] kinking or fracturing of the wire,[6] or fracture and subsequent embolization[7] can cause guidewire loss or retention of catheter fragments during insertion. Researchers suggest that guidewires may warrant a safer design; however, most prevention strategies focus on standardizing insertion policies, providing additional education, and increasing awareness.[8]

There are many strategies for preventing RSIs in different settings; however, practices to prevent fragmented

http://doi.org/10.1002/aorn.13250

endovascular catheters and sheath retention in the OR are either absent or only vaguely defined. Endovascular procedures are increasingly performed in a variety of practice settings, including office-based laboratories, cardiac catheterization and interventional radiology suites, ORs, and hybrid rooms. Although many of these settings are dedicated to percutaneous procedures, surgeons and perioperative team members often perform a variety of emergent and complex open and endovascular procedures in ORs and hybrid rooms after regular working hours. In our experience, leaders in office-based laboratories and cardiac catheterization and interventional radiology suites routinely schedule the same staff members to participate in catheter-based interventions during routine hours. In contrast, nurses who may have received only minimal education on endovascular procedures may provide patient care during emergent endovascular procedures in ORs and hybrid rooms, especially after the routine hours of operation.

At our facility, there are more than 18 different catheters and a variety of lengths and sizes of sheaths and stents available for insertion. Adding to the complexity, these products may change according to supply availability and purchasing agreements. Stents often appear visually different after deployment, further complicating the identification of device integrity (Figure 1). We believe that the increasing number of complex hybrid procedures performed in environments in which expertise of perioperative personnel may vary puts the patient and treatment team at risk for unintentionally retained fragmented catheters and sheaths. Using a standardized catheter tip design to improve recognition of nonintact catheters at the point of removal may be a possible safety improvement.[9] However, manufacturers use a variety of sizes, shapes, and materials when producing catheters and sheaths; therefore, standardization appears to be an unlikely solution in the near future.

EVOLUTION OF GUIDELINES FOR PREVENTING RSIs

In 2008, the US Food and Drug Administration issued a public health advisory that aimed to reduce complications from unretrieved medical device fragments and included recommendations for inspecting devices before use and after removal and using devices as instructed, particularly during insertion and removal.[10] This advisory also reviewed the reporting requirements for medical device events and provided recommendations on counseling patients and assessing the risks and

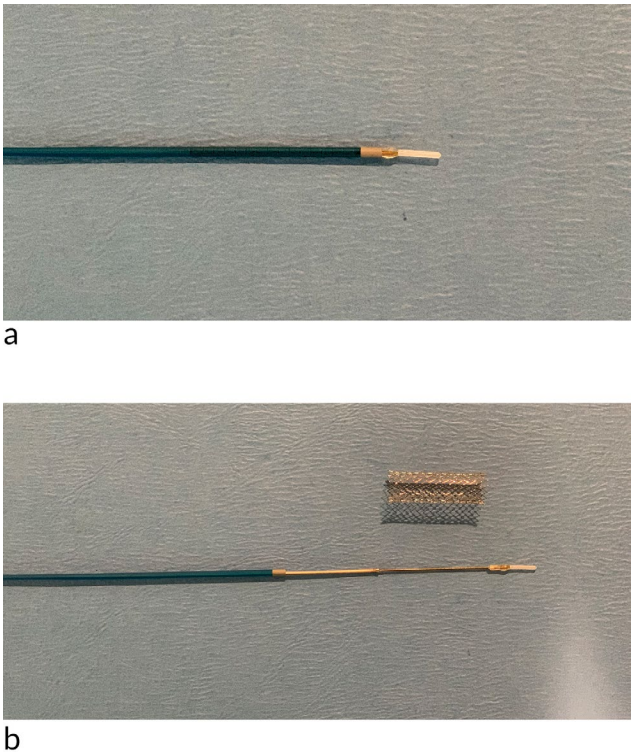

Figure 1. Endovascular stent catheter before *(a)* and after *(b)* deployment of stent.

benefits of fragment retrieval. If a device becomes damaged, personnel should retain the item to assist with the root cause analysis.

In 2011, the Society of Interventional Radiology published a position statement entitled "Prevention of unintentionally retained foreign bodies during interventional radiology procedures."[11] Most of the document focuses on sponges, with a brief recommendation to perform fluoroscopy at the conclusion of the procedure "[i]f there is any concern of possible retention of a needle or instrument."[11(p1562)]

In 2013, The Joint Commission issued a sentinel event alert that highlighted 772 unintentionally retained foreign object incidents from 2005 to 2012 and identified their root causes.[12] The alert indicated that the absence of policies and procedures, failure to comply with existing policies, hierarchy and intimidation, communication failures, and inadequate or incomplete education of staff members were contributing factors to these events. After identifying the root causes of the RSIs, The Joint Commission specifically recommended possible strategies for improvement in hospitals and ambulatory surgery centers, including implementing effective processes, procedures, and communication techniques; appropriate documentation;

and safe technology.[12] The alert also encouraged highly reliable and standardized counting systems to prevent RSIs and emphasized the need for key components for the counting procedure (eg, require two staff members to perform counts audibly and visibly); wound opening and closing procedures; and use of intraoperative radiographs when a procedure is at high risk for an RSI, or when the surgical count is incorrect or unreconciled. However, The Joint Commission did not specifically address any recommendations for catheter- and wire-based endovascular procedures in the alert.

In response to the sentinel event alert from The Joint Commission,[12] the American College of Surgeons (ACS) published a bulletin describing the recommendations for ambulatory surgery centers and hospitals "to take a fresh look"[13] at how to avoid RSIs. Two years later, the ACS published a follow-up statement, indicating that the "[p]revention of unintentionally retained surgical items after surgery requires good communication among perioperative personnel and the consistent application of reliable and standardized processes of care."[14] According to the ACS, "Policies and procedures for the prevention of retained foreign bodies should be developed, reviewed periodically, revised as necessary, and available in the practice setting."[14] As with the sentinel event alert, the ACS bulletins did not contain language specific to endovascular devices.

The AORN "Guideline for prevention of retained surgical items"[15] provides detailed guidance regarding accountability for soft goods (eg, sponges, towels), sharps, instruments, and miscellaneous items during procedures and under a variety of different circumstances. The guideline includes recommendations on accounting for catheter sheaths and guidewires under miscellaneous items—a grouping that includes electrosurgery scratch pads, cervical cups, trocar sealing caps, and umbilical tapes.

The guideline includes a section on device fragments and acknowledges the limitations of the evidence because of the lack of published reports on the topic in the peer-reviewed literature. AORN recommends inspecting items used in the surgical wound for breakage or fragmentation when they are removed from the surgical site. AORN also recommends that perioperative personnel "[t]ake measures to prevent intravascular device (ie, catheter, guidewire, sheath) fragments."[15(p781)] Perioperative personnel should

- insert and remove devices according to the manufacturers' instructions for use,
- inspect all devices before use to identify any defects,
- avoid withdrawing catheters and guidewires through a needle,
- replace bent guidewires immediately, and
- "account for intravascular devices in their entirety by inspection for breakage immediately on removal from the patient."[15(p781)]

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AORN recommends that perioperative teams document RSI-prevention activities and that an interdisciplinary team comprising perioperative nurses, surgeons, anesthesia professionals, sterile processing personnel, risk managers, and leaders complete a risk analysis; the team should then develop policies and procedures for RSI prevention at their facility based on the outcomes. In addition, facility personnel should implement an interdisciplinary process improvement program related to RSIs.[15]

DESCRIPTION OF PROCESS IMPROVEMENT STRATEGY

After a series of RSI events, our facility's leaders formed an interdisciplinary workgroup that included senior leaders and experts in nursing, vascular surgery, anesthesiology, patient safety, and human factors to examine the in-house policies and practices regarding endovascular procedures.[16] Although facility leaders initially addressed these sentinel events with nursing education, a focused root cause analysis identified multiple opportunities for process improvement.

After recognizing a lack of standardization in accountability for and handling of endovascular items in the OR, our interdisciplinary workgroup proposed a process to redefine the policies at our regional and national academic referral center and included the following steps.

- Review existing external facilities' policies and national guidelines.
- Identify relevant questions that were unanswered in existing counts policy and national guidelines.
- Use interdisciplinary group member input to develop new procedures.
- Revise the facility's policy and educate the workforce.

For potential guidance, we began the review process with an informal survey of local and national hospital clinicians regarding their current protocols. Representatives for 20 different hospitals responded to our query, and we learned that none of those facilities had a formal OR protocol specific to wire, catheter, and sheath counts or for inspecting device integrity. Furthermore, none of the respondents reported that they had a formal protocol for documenting device integrity.

Guideline and Policy Gap Analysis

To aid the quality improvement process at our facility, the interdisciplinary workgroup performed a gap analysis and identified critical questions that were not addressed in sufficient detail in our existing facility policy and for which there were no specific evidence-based recommendations in national guidelines (Table 1). The first topic that the workgroup addressed involved accounting for catheters, sheaths, and guidewires in a method similar to the process that perioperative personnel use for counting easily recognizable soft surgical goods, sharps, miscellaneous items, and instruments during a postprocedure count. Surgical technologists (STs) and perioperative nurses at our facility are familiar with these items and will include in the count any additional items that are added to the sterile field during a procedure. As a result, the postprocedural counts include all added items, and there are well-defined facility protocols if the counts are incorrect.

However, endovascular items such as catheters, sheaths, and guidewires are quite variable in appearance. These items can be several feet long with a large variety of tip designs. Endovascular items can become bent or misshapen during use and may be designed to appear different after deployment, which further complicates postprocedural identification. Surgical technologists and perioperative nurses involved in emergency endovascular procedures may be unfamiliar with specific endovascular devices. Because of the variable and dynamic nature of these devices, we believe that endovascular items should be treated fundamentally differently than other items used during surgical procedures.

Verifying device integrity

The interdisciplinary workgroup members then considered which individuals should be responsible for verifying device integrity. After an in-depth review of processes at our facility, the workgroup members realized that perioperative nursing staff members accounted for needles, sponges, and instruments during endovascular procedures; however, they were not routinely inspecting endovascular sheaths, catheters, or guidewires. Many perioperative nurses, especially those without cardiovascular education and experience, expressed that they were unable to identify a sheared or compromised endovascular catheter or sheath consistently

Table 1. Current AORN Guideline Recommendations for the Prevention of Retained Surgical Items and Subsequent Questions Generated

Current AORN Recommendation	Outstanding Questions
"Account for miscellaneous items, including catheter sheaths … [and] guidewires."[1(p775)]	• Should catheters, sheaths, and guidewires be accounted for via a postprocedural count in the same manner as soft surgical goods?
"Insert and remove intravascular devices in accordance with the manufacturer's instructions for use."[1(p781)]	• Who is responsible for ensuring personnel follow the instructions for use for intravascular devices?
"Replace bent guidewires immediately."[1(p781)]	• Who is responsible for inspecting guidewires?
"Account for intravascular devices in their entirety by inspection for breakage immediately on removal from the patient."[1(p781)]	• Who is responsible for inspecting intravascular devices? • When should intravascular devices be inspected? • How should intravascular device integrity be verified? • Who should document intravascular device integrity?

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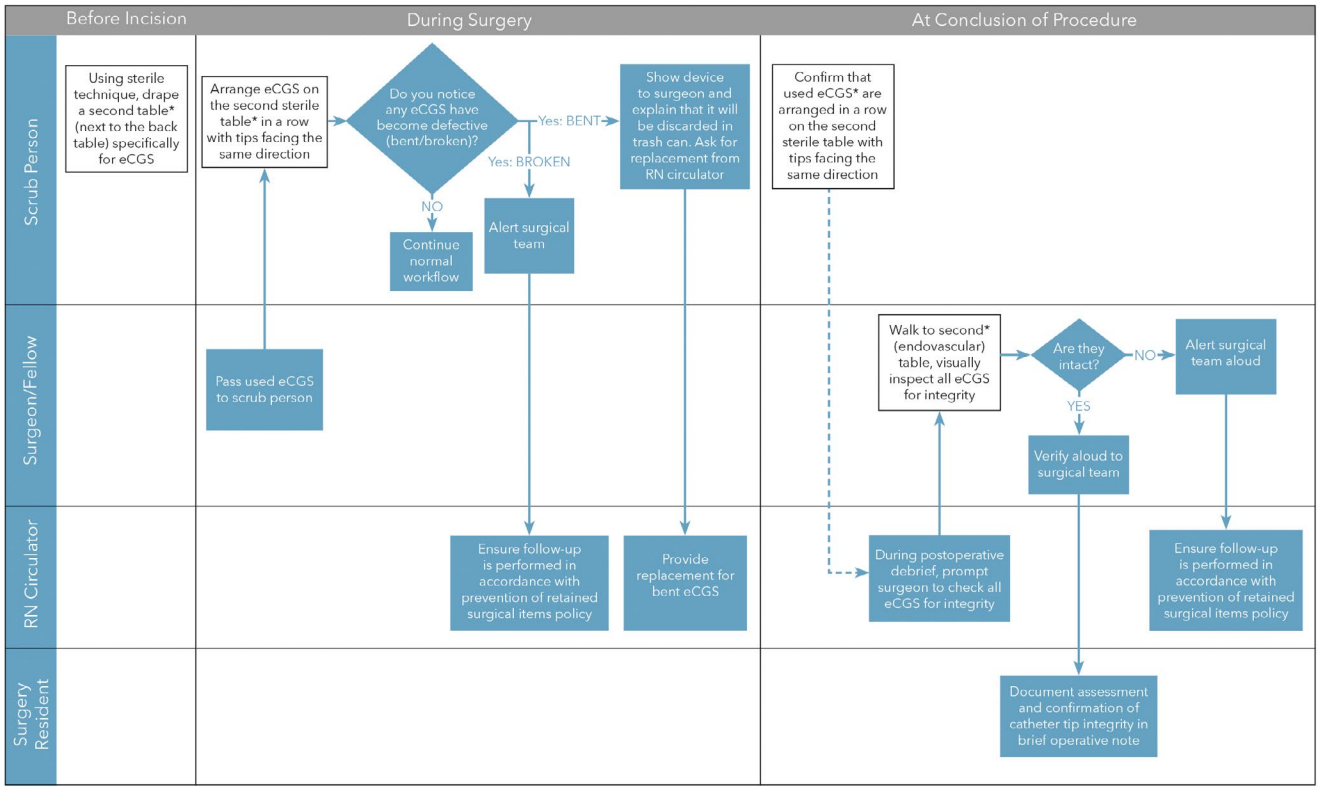
1. *Guideline for prevention of retained surgical items. In*: Guidelines for Perioperative Practice. *Denver, CO: AORN, Inc; 2020:755-806.*

and correctly. After reviewing relevant human factors and failure modes, workgroup members concluded that a reliable process should include assigning responsibility for the visual inspection and verification of endovascular device tip integrity to the team member most likely to identify a lack of tip integrity. Because many endovascular procedures are emergent and often require the participation of team members without cardiovascular experience, the workgroup determined that the attending surgeon or senior fellow should be responsible for verifying device integrity.

Next, the workgroup members considered when and how the surgeon should perform the device integrity verification. Ideally, he or she would perform this check as soon as the device is removed from the patient.[15] In practice, however, scrubbed team members often remove endovascular catheters and sheaths from the surgeon's operative field of reach and sight and guidewire ends often rest several feet from the access site. Further, guidewires and devices may be reinserted several times, including when the operating surgeon's visual focus is elsewhere, such as on the original insertion site or imaging displays. Generally, the RN circulator lowers the ambient lighting in the vicinity of the operative field to facilitate optimal viewing of fluoroscopic imaging. As a result, the surgeon often cannot verify device integrity in real time upon removal. In light of these considerations, the workgroup determined that surgeons should inspect all catheters and sheaths at the conclusion of a procedure during a defined pause designed explicitly for this purpose (Figure 2). However, this practice should not deter perioperative team members from inspecting devices during the procedure and bringing any concerns about device integrity to the immediate attention of the operating surgeon. During surgery, the ST can arrange the endovascular devices on a back table, facilitating the surgeon's visual inspection at the conclusion of the procedure (Figure 3).

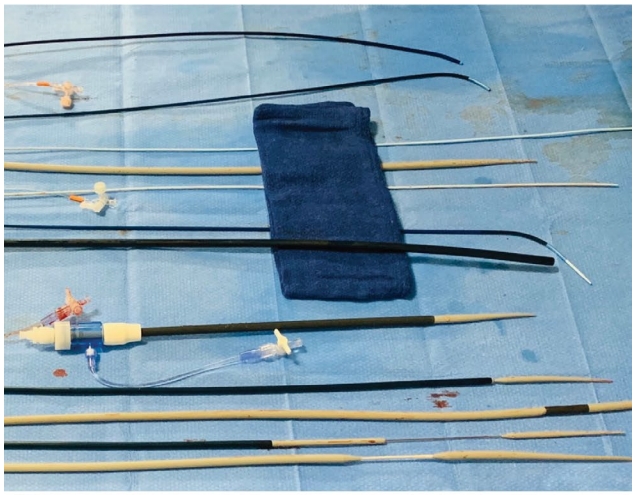
Completing device integrity documentation

The interdisciplinary workgroup also addressed device integrity documentation. At our facility, perioperative nursing staff members regularly document the outcome of surgical counts that they personally perform. Because of the complexity of many endovascular procedures and the wide variety of catheter and sheath tips, the workgroup concluded



*In procedures with only one instrument tray, a second sterile table is not needed and the catheters are aligned and inspected on the back table.

Figure 2. Flowchart of the intraoperative procedure for endovascular catheter inspection. eCGS = endovascular catheters, guidewires, and sheaths.



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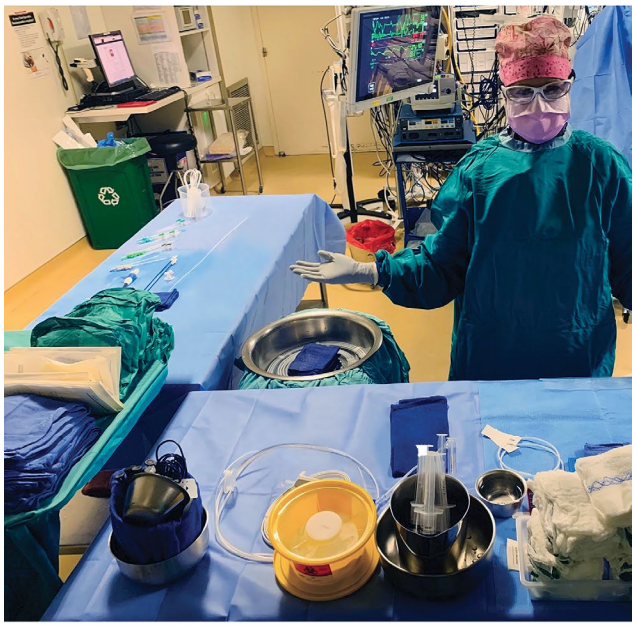

b

Figure 3. Proposed back table setup for endovascular device examination. Catheters and sheaths are lined up for ease of viewing tips *(a)*. An additional back table *(b)* may be necessary for procedures involving multiple endovascular devices.

that the perioperative nursing staff members may document that the surgical inspection process step occurred, but the operating surgeon is responsible for documenting the visual confirmation of a device's integrity. The workgroup also determined that the surgeon should include this documentation in both the brief operative note that he or she completes at the conclusion of the procedure and in the dictated (ie, final) surgical operative report. To facilitate this change, the workgroup created a hard stop in the templated procedure notes for endovascular procedures that includes a statement indicating that the surgeon followed the inspection procedure and that all devices were intact.

Managing special circumstances

The interdisciplinary workgroup also identified special circumstances that surgeons and nursing staff members should consider. Some patients who are transferred to tertiary referral centers have open surgical wounds, in situ endovascular devices supporting ongoing clinical care, or retained endovascular device fragments as the indication for transfer. Our existing policy specified indications for preoperative imaging to identify planned or unplanned retained objects in open body cavities, but it did not contain guidance for patients transferred with sheaths, catheters, or guidewires in place.

Finally, the interdisciplinary workgroup considered how a team should proceed after identifying an RSI. When perioperative team members identify that a device is damaged or retained during a procedure, additional decisions and tasks may include

- ascertaining the best way to handle the incident clinically,
- arranging to prolong the procedure and anesthesia for additional imaging and possible interventions,
- confirming compliance with the surgical count policy and RSI procedures, and
- completing the clinical and safety documentation of the event.

There are circumstances in which surgeons may complete a clinical assessment and determine that the risk of retrieval (either immediate or delayed) outweighs the benefit. Our institutional experience with RSIs highlighted a need for definitive instructions regarding the expected actions when the surgeon determines that immediate retrieval is not advisable. Specifically, our existing policy did not provide teams with direction for the required documentation to facilitate moving from RSI identification to postoperative care of the patient.

SPECIFIC POLICY AND PROCEDURE CHANGES FOR REDUCING RSIs

After reviewing the concerns related to the identified questions, the interdisciplinary workgroup carefully considered

Key Takeaways

- To prevent retained surgical items (RSIs), perioperative personnel routinely perform surgical counts of soft goods, sharps, instruments, and miscellaneous items according to their facility's policies and procedures.
- There are many strategies for preventing RSIs in different settings; however, practices to prevent fragmented endovascular catheters and sheath retention in the OR are either absent or vaguely defined. Endovascular devices are complex, and supplies may change because of availability and purchasing agreements.
- After a series of RSI events occurred during endovascular procedures at their facility, an interdisciplinary workgroup comprising surgeons, nursing leaders, and patient safety professionals at a university medical center reviewed current literature, accrediting agency requirements, and national organization recommendations. They determined the available literature and recommendations lacked specificity for endovascular procedures.
- The interdisciplinary workgroup addressed the outstanding questions they had identified related to the recommendations. The workgroup revised the facility policy to define team members' roles and improve communication, processes, and documentation for surgical counts and preventing RSIs.

national guidelines, safety goals, and facility policies and procedures, and sought advice from regulatory experts (eg, representatives from The Joint Commission) as needed before revising our facility's policy and procedures for surgical counts and preventing RSIs. The policy and procedure revision addressed the following categories.

- Procedure
  - All items should be inspected for integrity before the procedure begins and immediately after the procedure is completed. The RN circulator and ST should inspect all sheaths, catheters, and guidewires when opened and presented to the field; the ST should inspect items before use.
  - After the procedure, the attending surgeon or fellow is responsible for examining all removed catheters, sheaths, and guidewires for integrity and notifying the RN circulator of the findings.
- Documentation
  - The RN circulator will document the surgeon's visual inspection of the devices.
  - The surgical team will document the results of the postprocedure device integrity inspection in the postoperative notes.
- Special circumstances
  - When a patient is transferred, the accepting team will document the presence of all known guidewires, sheaths, or catheters. The accepting team will send all removed items to surgical pathology and document them as sent using the current surgical pathology form.
  - In the event that a device fragment is retained, the surgeon must weigh the clinical risks and benefits of retrieval. The surgical team must appropriately document the immediate or future plans related to the retained fragment.
  - The surgeon should inform the patient of the presence of any retained fragment that is not removed.

RECOMMENDATIONS

After participating in the interdisciplinary workgroup at our facility, we recommend that current national guidelines be expanded and strengthened to account for the increasing and evolving complexity of endovascular procedures. As outlined in our workgroup's experience, the current guidelines for specific handling of endovascular devices and accounting for device failure lack definition. At a facility level, we have addressed guideline shortcomings with protocols to improve communication, processes and procedures, and appropriate documentation. Our protocols clearly define team member roles, including the surgeon's role in verifying device integrity. This approach presents a cultural shift in current standard OR procedures, in which the RN circulator and ST usually complete a visual inspection of materials.

Looking forward, although strategies for prevention of RSIs can improve effective processes and procedures, standardization of devices across manufacturers might assist perioperative personnel in preventing RSIs. Visual cues, such as a colored indicator on the tip of every catheter, might facilitate more reliable identification of device integrity and education of personnel about the devices.[9] This approach negates differences in catheter appearance and accounts for device evolution. In addition, when perioperative team members are able to recognize a sheared device promptly, the surgeon can address the situation in a timely manner and retrieve the device fragment or treat the patient as indicated. This approach may create a safer system that facilitates early recognition of device failure.

As part of a medical community, surgeons and perioperative personnel have an obligation to demand better design of medical devices that may facilitate safer patient care. While surgeons and perioperative personnel wait for improved designs, national organizations should define safer protocols and procedures to help prevent the unintended consequences of retained endovascular devices.

CONCLUSION

The Joint Commission considers RSIs an ongoing sentinel event. After a series of RSIs occurred during endovascular procedures at our facility, leaders formed an interdisciplinary workgroup to perform a gap analysis on RSIs and identify practice changes to prevent them. The workgroup members reviewed the existing literature to identify recommendations for improvement in our facility's policy and identified a gap between the existing recommendations and endovascular practice environments. The complexity, variability, and evolution of endovascular items requires a different procedural approach than that used for soft goods, sharps, instruments, and miscellaneous items. The workgroup assessed the available literature and recommendations and revised the counting policy to address the gap. The goal was to define team members' roles and improve communication, processes, and documentation. The workgroup's approach addressed these concerns and included the surgeon's role in verifying device integrity. As a result, the revised counting policy incorporates the available guidance from national organizations and addresses staff members' concerns specific to our facility.

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Kendal M. Endicott, MD, is a vascular surgery fellow in the Department of Surgery, Division of Vascular Surgery at the University of Maryland School of Medicine, Baltimore. *Dr Endicott has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.*

Rebekah Friedrich, MS, RN, CCRN, certified professional in patient safety (CPPS), is a senior performance improvement leader for the Division of Quality & Safety at the University of Maryland Medical Center, Baltimore. *Ms Friedrich has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.*

Jason W. Custer, MD, is an associate professor of pediatrics in the Division of Pediatric Critical Care Medicine at the University of Maryland School of Medicine, Baltimore, and medical director of the pediatric intensive care unit at the University of Maryland Medical Center, Baltimore. *Dr Custer has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.*

Rajabrata Sarkar, MD, PhD, is the Barbara Baur Dunlap Professor in Surgery and Physiology and head of the Division of Vascular Surgery at the University of Maryland School of Medicine, Baltimore. *Dr Sarkar has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.*

Lisa Rowen, DNSc, RN, certified in executive nursing practice (CENP), FAAN, is the chief nurse executive for the University of Maryland Medical System, Baltimore, and an adjunct professor at the University of Maryland School of Nursing, Baltimore. *Dr Rowen has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.*

Megan G. Anders, MD, MS, CPPS, is an assistant professor of anesthesiology and the associate chair for safety and quality in the Department of Anesthesiology at the University of Maryland School of Medicine, Baltimore. *Dr Anders has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.*