



Society of Interventional Radiology Position Statement: Prevention of Unintentionally Retained Foreign Bodies during Interventional Radiology Procedures

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STATEMENT

There is anecdotal evidence that retained sponges have occurred during interventional radiology procedures. Therefore, the Society of Interventional Radiology (SIR) recommends specific steps that should be taken to avoid unintentionally retained foreign bodies during interventional radiology procedures.

INTRODUCTION

Interventional radiology is a minimally invasive, image-guided, procedure-oriented medical specialty. The interventional radiologist performs procedures through incisions that are seldom larger than a no. 11 blade

stab wound (ie, 5–8 mm). As a result, the likelihood of an unintentionally retained foreign body in interventional radiology is extremely small. No such cases have been reported in the English-language medical literature. Anecdotal reports may or may not be related to interventional radiology procedures. This position statement provides the recommendations of SIR for the prevention of this rare occurrence.

These recommendations apply only to interventional radiology procedures that are performed by interventional radiologists in the interventional radiology suite. Procedures performed in the interventional radiology suite by multidisciplinary teams are likely to involve more extensive wounds than those typical of interventional radiology procedures. Procedures performed in areas of the hospital outside of the interventional radiology suite should be performed in accordance with the standard operating procedures of that area.

RATIONALE

Estimates of the incidence of retained surgical sponges typically vary from one in 1,000 to one in 1,500 surgical procedures (1). Recent retrospective reviews performed in conjunction with malpractice attorneys have revised this estimate to an even lower frequency, between one in 8,801 and one in 18,760 cases (2). Although this number is small, the consequences of an unintentionally retained foreign body can be severe, and appropriate measures are necessary to prevent its occurrence when foreign body retention is possible. Ideally, a retained foreign body incident should never occur (3).

Risk factors for unintentional sponge and instrument retention during surgery are well documented, and include an operative site within a body cavity (ie, chest, abdomen, pelvis, and vagina), procedures performed on patients with high body mass index, emergent procedures, a planned return to the operating room with packing materials left intentionally in place, multiple surgical teams, and an intraoperative change in intended surgical procedure (4,5). Only the second and third of these could apply potentially to interventional radiology practice.

The surgical literature states that catheterization procedures are unlikely to result in a forgotten instrument or sponge (2). There are no published English-language reports of unintentionally retained foreign bodies following interventional radiology procedures. This suggests strongly that this event is extremely rare in interventional radiology. There are no anecdotal reports of which SIR is aware of an unintentionally retained needle or instrument from an interventional radiology procedure. An advisory from the Pennsylvania Patient Safety Authority (6) anecdotally described three cases of unintentionally retained foreign bodies (a guide wire in one case and a sponge in two cases) ascribed to interventional radiology procedures. One of these three cases (a retained vascular guide wire) was stated to have been performed by a vascular surgeon in a

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cardiac catheterization laboratory, and one anecdote included no details on the operator or the location where the procedure was performed. In both cases of a retained sponge, the procedure was placement of an implantable infusion port.

The Association of periOperative Registered Nurses guidelines (7,8) recommend that sponge and instrument counts be performed for procedures in which the possibility of an unintentionally retained foreign body exists. The same guidelines specifically include minimally invasive procedures, and give as justification an example of a case of a retained sponge during endoscopic saphenous vein harvesting augmented with an open surgical technique (9). However, this is an example of a surgical procedure, not of an interventional radiology procedure.

Experienced SIR members who are experts in interventional radiology were polled to determine which interventional radiology procedures could possibly predispose to the occurrence of an unintentionally retained foreign body. All polled SIR experts believe that the only interventional radiology procedure in which an unintentionally retained sponge could possibly occur is the placement of an implantable infusion port, in which a sponge may be used during the procedure to pack the port pocket. As noted earlier, this is the only interventional radiology procedure for which there is even anecdotal evidence of an unintentionally retained foreign body. The opinion of the SIR experts polled is that the size of the skin incision and the pocket, typically no larger than 3–4 cm in any dimension, makes a thorough visual and tactile inspection sufficient to prevent retention of a standard 10-cm × 10-cm surgical sponge (ie, a “4 × 4”) as a result of a procedure to place, revise or remove an implantable infusion port. SIR recommends that sponges smaller than a 4 × 4 not be used during interventional radiology procedures, except as dressings.

Sponge and instrument counts do not guarantee that a foreign body has not been left behind. Indeed, the vast majority of gossypiboma cases have occurred when the sponge count was incorrectly pronounced correct at the end of surgery (5). Also, the count itself may not be a benign process. Christian and colleagues (10) noted that the counting protocol significantly compromised case progression and patient safety.

It is the opinion of SIR that, for essentially all interventional radiology procedures, and specifically for the placement, revision, and removal of implantable infusion ports, a thorough visual and tactile inspection of the operative field is adequate to detect a retained foreign body in those interventional radiology procedures in which an unintentionally retained foreign body could conceivably occur. If a thorough visual and tactile inspection is performed, SIR believes that sponge and instrument counts do not add to the safety of these procedures. Sponge and instrument counts do add time, expense, and additional opportunity for error. SIR recommends that sponge and instrument counts not be performed at the conclusion of an interventional radiology procedure unless the incision and cavity created during the procedure do not permit a thorough and complete visual and tactile examination.

It is the opinion of SIR that some method of identifying sponges is necessary if the incision is such that a thorough and complete visual and tactile examination cannot be performed. This is expected to be a rare event. On these uncommon occasions, only sponges with radiopaque markers should be used for packing, and either fluoroscopy should be performed at the conclusion of the procedure to exclude a retained sponge or a sponge count should be performed at the conclusion of the procedure. If there is any concern of possible retention of a needle or instrument, fluoroscopy should be performed at the conclusion of the procedure unless the required additional radiation for the fluoroscopy is of greater concern.

RECOMMENDATIONS

The following recommendations apply only to interventional radiology procedures performed by interventional radiologists in the interventional radiology suite. Procedures performed in the interventional radiology suite by multidisciplinary teams are likely to involve more extensive wounds than those typical of interventional radiology procedures. Procedures performed in areas of the hospital outside of the interventional radiology suite should be performed in accordance with the standard operating procedures of that area.

1. Sponges smaller than a standard 10-cm × 10-cm sponge (ie, a 4 × 4) should not be used for packing of wounds or incisions. The 4 × 4 sponges should not be cut into smaller pieces for packing of wounds or incisions.
2. Whenever sponges have been used in an incision or cavity, thorough visual and tactile inspections should be performed after sponge removal and again before the incision is closed.
3. If the incision or cavity does not permit a thorough visual and tactile inspection because of its size or shape, only sponges with radiopaque markers should be used for packing, and either fluoroscopy should be performed at the conclusion of the procedure to exclude a retained sponge or a sponge count should be performed at the conclusion of the procedure.
4. If there is any concern of possible retention of a needle or instrument, fluoroscopy should be performed at the conclusion of the procedure unless the additional radiation for fluoroscopy is of greater concern.

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REFERENCES

1. Hyslop JW, Maull KI. Natural history of the retained surgical sponge. *South Med J* 1982; 75:657–660.
2. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med* 2003; 348:229–235.
3. The Joint Commission. Comprehensive accreditation manual for hospitals: the official handbook. CAMH refreshed core, January 2011 edition. Oakbrook Terrace, IL: The Joint Commission, 2011;SE1–SE18.
4. McIntyre LK, Jurkovich GJ, Gunn ML, Maier RV. Gossypiboma: tales of lost sponges and lessons learned. *Arch Surg* 2010; 145:770–775.
5. Wan W, Le T, Riskin L, Macario A. Improving safety in the operating room: a systematic literature review of retained surgical sponges. *Curr Opin Anaesthesiol* 2009; 22:207–214.
6. Pennsylvania Patient Safety Authority. Preventing the retention of foreign objects during interventional radiology procedures. Harrisburg, PA: Pennsylvania Patient Safety Advisory, 2008; 5:24–27.
7. Recommended practices for sponge, sharps, and instrument counts. *AORN J* 2006; 83:418–433.
8. Association of periOperative Registered Nurses. Recommended practices for prevention of retained surgical items. Perioperative standards and recommended practices: for inpatient and ambulatory settings, 2011 edition. Denver: AORN, 2010;263–279.
9. Best practices for preventing a retained foreign body. *AORN J* 2006; 84:S30–S36.
10. Christian CK, Gustafson ML, Roth EM, et al. A prospective study of patient safety in the operating room. *Surgery* 2006; 139:159–173.