Retained Surgical Sponges: Findings from Incident Reports and a Cost-Benefit Analysis of Radiofrequency Technology

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BACKGROUND: Retained surgical items (RSIs) are serious events with a high potential to harm patients. It is estimated that as many as 1 in 5,500 operations result in an RSI, and sponges are most commonly involved. The adverse outcomes, additional medical care needed, and medico-legal costs associated with these events are substantial. The objective of this analysis was to advance our understanding of the occurrence of RSIs, the methods of prevention, and the costs involved.

STUDY DESIGN: Incident reports entered into the University HealthSystem Consortium (UHC) Safety Intelligence database on incorrect surgical counts and RSIs were analyzed. Reported cases of retained surgical sponges at organizations that use radiofrequency (RF) technology and those that do not were compared. A cost-benefit analysis on adopting RF technology was conducted.

RESULTS: Five organizations that implemented RF technology between 2008 and 2012 collectively demonstrated a 93% reduction in the rate of reported retained surgical sponges. By comparison, there was a 77% reduction in the rate of retained sponges at 5 organizations that do not use RF technology. The UHC cost-benefit analysis showed that the savings in x-rays and time spent in the operating room and in the medical and legal costs that were avoided outweighed the expenses involved in using RF technology.

CONCLUSIONS: Current standards for manual counting of sponges and the use of radiographs are not sufficient to prevent the occurrence of retained surgical sponges; our data support the use of adjunct technology. We recommend that hospitals evaluate and consider the use of an adjunct technology. (J Am Coll Surg 2014;219:354–364. © 2014 by the American College of Surgeons)

Retained surgical items (RSIs) are serious reportable events with a high likelihood of harming patients.[1] Adverse outcomes include pain and suffering, readmission (30% to 59%), reoperation for removal (69% to 83%), infection or sepsis (43%), intra-abdominal abscess, intestinal fistula or obstruction (10% to 22%), visceral perforation (7%), and death (up to 2%).[2,3] More current studies show that RSIs occur at a rate of 1 in 5,500 to 1 in 7,000 operations.[4-6] Surgical items are most commonly retained in the abdomen or pelvis, thoracic cavity, and vagina,[2,3,7] and most often involve surgical sponges.[2-4,6,8] Tissue reaction to retained sponges is much more serious than it is to metal objects and may result in adhesions, encapsulation, and granuloma. More serious reactions involve an inflammatory response, with formation of abscesses and fistulas. This tissue response has led to having sponges migrate into the gastrointestinal tract, bladder, and respiratory tract.[9]

Risk factors associated with RSIs include emergency surgery,[2] high body mass index,[2,6] an unexpected change in the procedure,[2,6] number of major procedures performed,[3] a longer duration of surgery,[6] and incorrect counts.[3,6] Other factors contributing to RSIs include

Disclosure Information: Dr Steelman has received honoraria for speaking engagements paid by RF Surgical Systems, Inc. The University of Iowa has received research grant money from RF Surgical Systems, Inc. All other authors have nothing to disclose.

University HealthSystem Consortium (UHC) created a publication of this analysis for dissemination to its member organizations. Tables 1 and 2 and Figures 1 and 3 are contained within the UHC manuscript. The UHC presented the findings of this analysis in a UHC webinar to its members in August of 2013. A poster was presented at the NPSF Annual Conference in May 2014 which displayed Figures 1 to 3.

Received January 24, 2014; Revised March 21, 2014; Accepted March 24, 2014.

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http://dx.doi.org/10.1016/j.jamcollsurg.2014.03.052
ISSN 1072-7515/14

Abbreviations and Acronyms
CMS = Centers for Medicare and Medicaid Services
OR = operating room
PSO = Patient Safety Organization
RF = radiofrequency
RFID = radiofrequency identification systems
RSI = retained surgical item
RSS = retained surgical sponge

noncompliance with protocols,[6] poor standards or wound examination,[10] low-quality x-rays,[4,10] unmarked sponges or towels,[10] and poor communication.[4,7,10]

Mandatory reporting and refusal by the Centers for Medicare and Medicaid Services (CMS) to pay for care associated with RSI removal prompted the need for improvement.[11] The medical and legal costs associated with RSIs can be substantial. In 2007, CMS estimated the average cost of removing an RSI at $63,631 per hospital stay.[11] Medical malpractice claims data vary widely, with the larger settlements in the $2 million to $5 million range.[12-14] Depending on the source of the data and the region from which the information was obtained, average indemnity costs in more recent years have ranged from $150,000 to $500,000,[14-16] and the average legal defense costs for physicians are approximately $30,000.[14]

The objective of this analysis was to advance our understanding of why and how RSIs occur, how they can be prevented, and what they cost. Our specific aims were:

1. To describe data entered into the UHC® Safety Intelligence™ incident report tool on incorrect surgical counts and RSIs;
2. To compare the trend in reporting unintentionally retained surgical sponges (RSSs) in organizations that use radiofrequency (RF) technology vs those that do not; and
3. To determine the costs and benefits of adopting RF technology as an adjunct method for preventing RSSs.

There are a number of recommended practices and other technologies for detecting RSIs, including a methodic wound exploration before closure, manual counting, intraoperative radiography, and other technologies used as adjuncts to manual counting. These technologies are not intended to replace manual counting, but rather should be used as a check. These practices, their effectiveness, and their advantages and disadvantages will be described next.

Manual counting procedures

For years the primary intervention for preventing RSSs has been manual counting. Sponges are counted by 2 people before surgery, when they are dispensed onto the sterile field, when wound closure is beginning, and when wound closure is being completed.[17] Counting is time intensive, occupying up to 14% of operative time.[8,15,18] Standard protocols for manual counting are necessary, but are prone to human error. As many as 57 potential failures have been identified in sponge counting,[19] and count discrepancies most often involve a misplaced item, followed by documentation and counting errors.[20,21]

Count discrepancies are common, occurring as often as once in every 8 cases,[5,21] and the odds of an RSI increase by more than 100-fold when a count is discrepant.[5] Perhaps even more important is the evidence showing that correct counts are frequently not reliable. In 62% to 88% of RSI cases, the counts were correct at the end of the procedure.[2,4,6] The sensitivity of counting has been shown to be 77.2%; the specificity, 99.2%; and the positive predictive value, only 1.6%.[5] Resolving a count discrepancy, including radiography when the count cannot be reconciled, can take 13 to 23 minutes, depending on the study.[21,22]

Intraoperative radiography

Radiography has been the primary method of screening for RSI, and best practices include the use of radiopaque (x-ray–detectable) surgical items[16] to facilitate visualization. Although some organizations obtain radiographs on all patients undergoing an open-cavity operation, most use radiography only when the count is incorrect.[2] Radiographs can be expensive and time consuming, they expose the patient to radiation, and they are not always reliable, especially for needles and sponges.[4,8,15] The sensitivity of intraoperative radiographs for detecting a retained item has been found to be 67%,[4] and 10% of radiographs have been found to be falsely negative for radiopaque sponges.[23] The cost of performing routine intraoperative radiography to prevent RSIs is estimated to be $11.5 million for every clinically harmful object detected.[15,24]

Bar-coded counting systems or data-matrix–coded sponges

This computer-assisted counting system consists of 2-dimensional matrix-labeled sponges and a scanning device that reads the labels. Each sponge is individually identified by scanning 1 at a time onto and off of the sterile field. The sponges must be removed from the patient because the scanner cannot read through or detect the presence of a sponge inside the patient.[10,20] Randomized controlled trials have shown that bar coding significantly increased the detection of misplaced and miscounted sponges.[20,25] This technology is reported to be