Chapter 15. Prevention of Surgical Items Being Left Inside Patient: Brief Update Review

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Introduction

Leaving surgical items inside patients is a rare but potentially deadly mistake. The most common such item is a surgical sponge. Researchers at the Mayo clinic found that during the four-year period from 2003 to 2006, the rate of retained foreign objects was 1 in every 5,500 operations, and 68 percent of the retained objects were sponges. The greatest subsequent risk to the patient is infection, which can be fatal. Other risks include perforations and granulomas.

Risk factors for such incidents were explored by Gawande and colleagues (2003), who examined factors surrounding 42 retained sponges and 19 retained instruments. The majority required reoperation, and one patient died. Compared with control incidents, item retention was more likely to occur in the context of emergency surgery, an unexpected change in surgical procedure, high body-mass index (an x-ray is recommended), and the lack of item counts.

A review of the literature on the topic of retained surgical sponges conducted for the original report identified only one study (a case series) that attempted to assess the use of sponge and instrument counts to prevent retention. The goals of the present review were to identify interventions implemented since the previous review and to report on studies assessing their effectiveness. We conducted a review of the literature from 2001 to 2011 and reviewed all studies relevant to methods used to prevent surgical items from being left inside patients during surgical procedures.

What Are the Practices Aimed at the Prevention of Leaving Surgical Items Inside Patients?

To prevent leaving surgical items inside patients, the Association of periOperative Registered Nurses (AORN) recommends counting all sponges, sharps, and related miscellaneous items at five different times: (1) before the procedure to establish a baseline, (2) before closure of a cavity within a cavity, (3) before wound closure begins, (4) at skin closure, and (5) at the time of permanent staff relief of either the scrub person or the circulating nurse. In addition, specifically for surgical instruments, AORN recommends counting only at times 1, 3, and 5 above. AORN also recommends all counts be documented in the intraoperative record. If a discrepancy occurs between counts, surgical staff must search for the lost item (usually a sponge). If it is suspected in the OR that an item was left inside the patient, a radiograph may be necessary.

For comparison, the Surgical Safety Checklist of the World Health Organization requires a post-procedure count, but the checklist suggests neither pre-procedure counts nor intraoperative counts.

What Supplementary Methods Have Been Used To Improve Counts of Surgical Items?

Three technologies can enhance the accuracy of the count, thereby further lowering (theoretically) the risk of leaving items inside patients: (1) bar coding, (2) radiofrequency tagging
without unique item ID numbers (abbreviated RF), and (3) radiofrequency tagging with unique item ID numbers (RFID). Bar coding is an established and low-cost technology, but a direct line of sight between the bar code scanner and the item’s bar code label is needed in order to scan it, and blood-soaked items may be difficult to scan accurately. The RF technologies (a penny-sized or smaller chip implanted into the device) allow items to be detected by a specialized wand that is waved over the patient’s body during and after the procedure. This scan can prevent the need for a radiograph, which itself can increase surgical risk because of the added time on the operating table and under anesthesia. RFID represent an advance from the simpler RF technologies because if each item is assigned a unique ID number, then the manual count can be checked against the RFID system’s baseline count.

The FDA has cleared four products relevant to the above technologies for marketing in the United States (U.S.):

1. Safety-Sponge™ System, (SurgiCount Medical, Temecula, California).6 This system comprises bar-coded sponges.
2. RF Surgical Detection System™ (RF Surgical, Bellevue Washington). This technology permits detection of devices but does not provide a count, because items do not receive unique ID numbers. The detection wand is single use. The system can be used with sponges, laparotomic pads, gauze, and towels, but not surgical instruments or sharps.
3. SmartSponge™ System (Clear Count Medical, Pittsburgh Pennsylvania). This system assigns a unique ID for each device, so it is used for both detection and counting. As the procedure progresses and staff remove sponges or other items, they put the items into a specialized bucket fitted with an antenna that detects and counts the RFID items. If a discrepancy occurs between the baseline counts and the final counts, it notifies the OR team with auditory and visual warnings, thereby initiating a search for the lost item(s) using a detection wand. This system also can be used with sponges, laparotomic pads, gauze, and towels, but not surgical instruments or sharps.
4. ORLocate™ (Haldor, Boston, Massachusetts).7 This system also assigns a unique ID for each device, so it is used for both detection and counting. Unlike the two systems described above, it can be used for instruments and sharps as well as sponges and other non-metallic items

What Have We Learned About Methods To Improve Counts of Surgical Items?

Greenberg and colleagues (2008)8 randomized 298 patients to undergo operations involving either manual counting (148 patients) or bar-coded sponges (150 patients). Twice as many sponge count discrepancies were detected in the bar-coded group (24 operations) as in the manual counting group (12 operations). This difference was mostly explained by miscounted sponges (nine operations in the bar-code group vs. one operation in the manual counting group) rather than by misplaced or retained sponges (17 in the bar-code group vs. nine in the manual counting group). Interestingly, in these same operations, no difference was seen between the groups in count discrepancies for non-bar-coded surgical instruments (11 in the bar-code group vs. ten in the manual counting group).

A 2009 systematic review by Stawicki and colleagues9 on risks and measures to prevent retention of surgical items that considered a variety of case reports, case series, registry reports, and position papers concluded that “the most important preventive measure is to accurately count all the pieces of surgical gauze and surgical instruments used during an operation.” Authors also
listed additional factors that could help minimize this type of mistake: (1) Knowledge of risk
factors, (2) Use of modern technology, (3) Improved perioperative patient processing systems.

**Methods May Be Time Consuming and Present Technical Challenges**

In the 2008 study by Greenberg and colleagues, \(^8\) 17 incidents of technological difficulties
occurred because of the bar-code system (2.04 per 1000 sponges counted), issues that would not
have arisen with manual counting. Further, of 150 operations with bar-coded sponges, the
surgical team abandoned the bar-code system in five operations (3%) due to the extra time
required. However, the authors concluded that the use of the bar-code technology was well
tolerated by staff members. The amount of time needed to count items can potentially cause
harm to patients if other key surgical steps are missed or rushed as a result of counting.
Greenberg and colleagues\(^8\) found that the bar-code-sponge method required more than twice as
much time to count sponges as the manual method (5.3 minutes vs. 2.4 minutes).

**Other Implementation Issues May Arise**

One consideration for hospitals regarding the use of RF and RFID technologies is that if only
a portion of the hospital’s surgical devices are RF-enabled, confusion might result. Staff may
mistakenly assume that all devices are RF-enabled, and a post-procedural scan would miss any
non-RF-enabled device inside the patient. Thus, it is recommended that RF-adoption be all or
none. \(^10\) Also, wand technique can be important when using RF devices, because scanning too far
away from the body, or too early—the surgeon may need to use additional tagged items—can
fail to locate all items. Also, because adipose tissue can increase the distance between the wand
and tagged items, some items may be missed when scanning obese patients.

In the 2008 study of bar-coded sponges by Greenberg and colleagues\(^8\), a post-study survey of
41 providers found moderately high ratings for ease of use (average rating 7.3 on a 0-10 scale)
and confidence in the ability of the system to track sponges (average rating 7.5 on a 0-10 scale).
Opinions on whether the bar-code system benefitted the counting protocol were mixed but
slightly positive (on a scale from -5 to +5, the average was +1.6). Authors stated that “some
providers felt that the system was especially useful in large operations with high blood loss and
many sponges, whereas others felt that the system was difficult to use in these types of
operations.” \(^8\)

**Questions About Cost-Effectiveness**

The medical and liability costs of a surgical item left inside a patient can exceed $200,000. \(^11\)
In 2009, Regenbogen and colleagues \(^11\) performed a cost-effectiveness analysis of six strategies to
prevent this type of incident. In their simulation, manual counting prevented 82 percent of the
simulated incidents at a cost of $1,500. In comparison, the other five strategies performed as
follows:

- Bar-coding the sponges raised the effectiveness to 97.5 percent, and the cost-per-
  prevented-retained-sponge was $95,000.
- RF-enabling the sponges (without a unique ID for each sponge) raised the effectiveness
to between 97.5 percent and 100 percent, and the cost-per-prevented-retained-sponge was
  between $620,000 and $720,000.
- Three radiographic strategies were dominated by the two bar code strategies with respect
to cost and effectiveness: 1. Do not count but always X-ray before closure; 2. Count, and
always X-ray before closure; 3. Count, and also X-ray before closure only for high-risk operations).

Conclusions and Comment

To prevent leaving items (typically sponges) inside patients during surgery, manually counting all items is widely recommended. Although several supplementary technologies exist, their use must remain limited to that of supplementing or aiding counting. These technologies include bar coding and radiofrequency tagging (with or without unique ID numbers). For each of these technologies, specific institutional hurdles (e.g., cost, confusion with older non-tagged devices, and wand technique with RF and RFID systems) must be overcome before their use can be considered both reliable and cost effective. A summary table is located below (Table 1).

Table 1, Chapter 15. Summary table

<table>
<thead>
<tr>
<th>Scope of the Problem Targeted by the PSP (Frequency/Severity)</th>
<th>Strength of Evidence for Effectiveness of the PSPs</th>
<th>Evidence or Potential for Harmful Unintended Consequences</th>
<th>Estimate of Cost</th>
<th>Implementation Issues: How Much do We Know?/How Hard Is it?</th>
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<tr>
<td>Rare/Low</td>
<td>Low</td>
<td>Negligible</td>
<td>Low if it simply involves more frequent manual counting; high if RFID is used</td>
<td>Little</td>
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References


