Gossypiboma

Tales of Lost Sponges and Lessons Learned

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Objective: To review the details surrounding cases of patients found to have retained laparotomy sponges after surgical procedures and share policy changes that have led to process improvements at one academic medical center.

Design: Retrospective medical record review as part of a quality improvement process.

Setting: Single academic medical center.

Patients: Patients identified through the quality improvement process as having had retained foreign bodies after surgery.

Conclusions: Sentinel events such as retained foreign bodies after surgery require intensive review to identify systems problems. This can lead to protocol changes to improve the process. After a series of incidents, protocol changes at our institution have led to no further incidents of retained foreign bodies.

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Retained surgical sponges and instruments are an unacceptable and entirely preventable surgical complication. They are considered “always wrong” errors by the Leapfrog initiative, mandating acknowledgment, direct apology to the patient, and hospital payment for all costs incurred as a result.1 Retained sponges can result in significant complications for patients and costly legal proceedings for caregivers. While there are many articles that describe isolated cases of retained surgical instruments and sponges, multiple reviews of the literature have demonstrated the problem to be a rarity and, as such, little has been written as to how to avoid this complication. We describe 3 cases of retained sponges at our institution during a 2-year period and the policy changes implemented to prevent further occurrences, including a link to our current teaching tutorial.

Harborview Medical Center is a busy level 1 trauma center that serves as a regional resource for a 4-state region. In 2006, there were more than 6000 admissions and 300 in-hospital trauma deaths. More than 12,000 surgical procedures were done in that year, with 818 laparotomies, 522 of which were nonelective. Owing to the severity of illness in our patients, approximately 20% of initial nonelective laparotomies at our institution are performed in a damage-control fashion, resulting in an open abdomen that requires planned repeated operations prior to eventual definitive closure. In addition, we performed more than 500 radical debridements for necrotizing soft tissue infections, many leading to amputations and/or large open wounds, frequently in morbidly obese patients.

Harborview Medical Center is also an integrated teaching institution of the University of Washington, with medical students, residents, and fellows participating on the trauma service. Many of the residents and fellows are from other institutions and may spend only a few weeks or months at Harborview, and thus are often unfamiliar with local practice patterns. The perioperative staff also provides oversight for surgical scrub technician and operating room (OR) nursing trainees.

Owing to the need for repeated explorations and the complexity of procedures, frequent hand-offs and multidisciplinary teams can be required in the care of a patient. This often involves several attending surgeons and resident teams who may be variably present for subsequent procedures.

Many emergency cases use several instrument sets and more than 100 sponges.
Also, there are frequent changes in personnel during these complicated cases, either owing to shift change or break time. In addition, given the 80-hour work week limitation set forth by the American College of Graduate Medical Education and surgical Residency Review Committee, a different resident frequently operates each time a patient has a repeated operation. Hand-offs and sign-out among residents and attendings can be inconsistent or incomplete. Finally, owing to the multiple clinical, teaching, and administrative demands of each attending surgeon, the attending surgeon at the initial operation may not be the attending surgeon at subsequent operations, further compromising continuity of care.

All perioperative policies at Harborview abide by the guidelines set forth by the Association of PeriOperative Registered Nurses, and any proposed changes to the policies are presented to and approved by our multidisciplinary surgical council. Issues relating to patient safety and quality of care are reported to our hospital medical staff quality assurance committee and are subject to intensive review meetings involving affected disciplines and risk management. In addition, sentinel events such as inadvertent retention of foreign bodies after surgery undergo root cause analyses, as required by the Washington State Department of Health and the Joint Commission.2

Prior to 2005, the occurrence of retained instruments or sponges at our institution was rare. At the time, our perioperative policy for instrument, needle, and sponge accountability had included routine surgical postoperative x-rays (SPOX) for abdominal, thoracic, spinal, and gynecological procedures after final closure of wounds, primarily to account for retained instruments. Sponges were accounted for with a counting system used by the circulating nurse and the scrub technician before and after incision and closure. There were no specific modifications to the policy for emergency cases. We then had a series of cases that challenged our existing policies.

REPORT OF CASES

CASE 1

A 56-year-old man was transferred from another institution after having 2 operative debridements for Fournier’s gangrene. He arrived with signs and symptoms of sepsis and persistent areas of undrained abscesses. He was taken to the OR on the day of transfer and had drainage of purulent collections as well as extensive debridement of his genitalia, perineum, left groin, and left anterior abdominal wall. His pelvic musculature was also involved and, in debriding this area, bleeding was encountered and controlled by packing with laparotomy pads. He was left packed and taken to the intensive care unit for resuscitation. He returned to the OR the next day with a different surgical team and, on removal of the packs, further bleeding occurred, leading to ligation of the internal iliac vein and more packing. He returned again to the OR the following day with the original surgical team for pack removal, this time with bleeding controlled. All wounds were then packed open with Kerlix rolls. He required no further operative debridement, and his wounds eventually granulated in. He had split thickness skin grafting about 3½ weeks after his last operation and was discharged a week later. He returned to the clinic 6 weeks after discharge with all wounds nearly healed except for a small area in his perineum that continued to drain a small amount of purulence. Investigation using computed tomography revealed a retained laparotomy pad in his left retroperitoneum; this was removed in a subsequent operation, and the patient recovered without further incident.

Discussion

This patient’s first 2 operations at Harborview Medical Center were done in a damage-control fashion, given the difficulties with hemorrhage control. He did not receive a SPOX after these procedures, ostensibly because of hemodynamic instability and need for expedient return to the intensive care unit. A SPOX was also not obtained after the third debridement, as his wound was still left open with packing; definitive wound closure was planned for a future procedure. However, a definitive procedure was not performed, and healing occurred by secondary intent. For the first case, nursing documentation recorded correct “initial, first and final counts”; however, on further investigation, elsewhere in the chart, “3 packs left in abdomen...” was noted. At the second procedure, initial and first counts were recorded as correct; the final count was left blank. There was a separate notation, “...the patient came to the OR with 2 laps left in...” For the third operation, the areas listing the sponge counts were all filled in with “N/A.”

Action

A root cause analysis and intensive review were held, and 2 issues were determined to be contributory. First, there was inconsistency as to how to document and account for packs intentionally left behind in the nursing OR record. Second, there was no policy in place for obtaining a SPOX when definitive closure of a wound is not done. As a result, the OR policy was revised to say

An X-ray will be taken...after any procedure in which a body cavity is opened or when the wound is considered large enough to retain an instrument or sponge. This film will be taken regardless of whether a final closure has occurred, intentional packing left in or an additional surgery is planned.

In addition, “The circulator will document any sponges packed and left in the wound on the OR record...An X-ray must be taken to confirm the removal of all packs, regardless of whether the wound is to be left open...”

A little more than a year after this policy change was enacted, a second incident occurred.

CASE 2

A 38-year-old man was crushed between a forklift and a wall. He was transferred to Harborview Medical Center after a computed tomographic scan at an outside facility demonstrated hemoperitoneum and he became hypo-
tensive. He was taken to the OR immediately after arrival. Initially, all 4 quadrants in the abdomen were packed, then sequentially removed, demonstrating vigorous bleeding from several branches of the superior mesenteric artery. These were repaired or ligated, and the intervening devitalized small bowel was resected but not anastomosed, given the potential for further bowel ischemia. The sponge counts were correct, and a SPOX film demonstrated no retained foreign body. He was then transferred to the intensive care unit and completed his imaging studies for complete evaluation of potential injuries. This included a computed tomographic scan of the abdomen that demonstrated a retained laparotomy sponge near the spleen. He was taken back to the OR the next day as planned, his bowel anastomosis performed, and the sponge removed. He had an uncomplicated hospital course and was discharged a week later.

Discussion

All components of the policy were followed in this case. However, on review of the SPOX after the first operation, it was clear that this film was taken off center and that the left side of the patient’s abdomen was incompletely imaged (Figure 1). This patient was obese (body mass index [calculated as weight in kilograms divided by height in meters squared], 35.8) and likely should have received 2 films to completely survey his abdomen. This film was read by the surgery resident, not the attending surgeon, as the attending surgeon was required at another emergent case. Also, this case reinforced what has been previously reported, that the counting process was not reliable.

Action

Another root cause analysis and intensive review was held. The policy was again revised to account for cases in which there is clipped anatomy on the SPOX:

If the SPOX image does not cover the entire surgical field ("Clipped Anatomy") the RT [radiology technician] will return to the room and inform the surgeon the film has clipped anatomy. The SPOX is to be retaken . . .

It was also a concern that many junior residents do not have experience in identifying retained sponges on imaging studies. To account for this, the policy modification included, “. . . the operating surgeon, third year resident or more senior resident, will read this film in the room and the results and reading surgeon recorded in the OR record.” An important component of the improved policy was that a tutorial was also developed by our radiology department to aid in teaching our residents how to identify sponges on plain films and computed tomography scans.

Finally, the sponge count procedure involving the circulator and the scrub was more rigidly outlined including guidelines for when personnel change during cases:

Relief counts will be done if the scrub and/or circulator is relieved for shift change or meal break . . . a case cannot be turned over to relief personnel unless all participating staff members are satisfied with counts and relief count documentation is completed.

Four months after this policy revision, we were appalled to find yet another case of a retained sponge.

CASE 3

A 19-year-old woman was a passenger in a motor vehicle collision. She arrived hemodynamically unstable from an outside institution. An abdominal ultrasound done in the emergency department was positive for fluid, and she was taken emergently to the OR. On laparotomy, a large liver laceration was found and partially repaired. However, she had required multiple blood transfusions and had a significant coagulopathy. Her liver lacerations were packed to control persistent bleeding, and she was taken to the intensive care unit for resuscitation. It was unknown how many packs were left in her abdomen given the emergent nature of her operation and the difficulty controlling the hemorrhage.

She was taken back to the OR 2 days later by the same surgical team; all packs were thought to have been removed, and her fascia was closed. The sponge counts were correct for that procedure, and the SPOX was read by the attending surgeon as negative for retained sponges and felt to be an adequate visualization of the entire abdomen.

Three days later, on an abdominal radiograph taken following feeding tube placement, a sponge was noted in the left upper quadrant. The patient was taken back to the OR that day, and the sponge was removed without incident.

Figure 1. Postoperative radiograph depicting “clipped anatomy.” The surgical sponge is viewed in the left upper quadrant (arrow).
Discussion

This was again a case of “clipped anatomy,” though the SPOX taken after the second procedure appeared to show the entire abdominal cavity. On close inspection of this radiograph, the very tip of the tail of the retained sponge can be visualized (Figure 2), although this finding was not obvious to subsequent blinded reviewers. This case also demonstrated the potential problem with omitting sponge counts prior to use in “crash” cases; in these situations, the number of intentionally left sponges is unknown, and it is impossible to ascertain this number at the completion of the case if counts are not performed beforehand.

Action

After another intensive review and root cause analysis, the policy was revised to address the issue of inconsistent and unreliable sponge counts. First, it was mandated that all cases, including crashes, will have a baseline count of sponges. Prior to this, some emergent “crashes” were deemed too rushed to provide adequate time for baseline sponge counts. Second, whenever a sponge is placed within a wound, the surgeon will announce to the team both the type of sponge and the number placed; this number will be recorded by the circulator. When the sponges are removed, the surgeon will again announce it to the team. The number of retained sponges, if any, is formally documented and will then be in the operative record for referral at subsequent cases.

To account for the more subtle examples of “clipped anatomy,” the policy revision says, “In cases where the abdominal cavity was explored, landmarks from the diaphragm to symphysis should be visualized, utilizing multiple films if needed.”

COMMENT

The term gossypiboma is derived from the Latin gossypium meaning “cotton” and the Swahili boma meaning “place of concealment.” While retained sponges are ubiquitous, reporting is inconsistent. Previous studies from decades ago estimated their incidence as occurring in 1 in 1000 to 1 in 1500 inpatient operations; more recent reviews based on malpractice claims found a 1 in 8801 to 1 in 18760 rate. Given the legal implications, cases of retained sponges are probably grossly underreported, making true estimates of their incidence difficult.

The clinical presentation of a patient with a retained sponge varies widely, often depending on the time elapsed between operation and detection. Cases of intestinal obstruction, intestinal perforation, intra-abdominal abscesses, and fistulae have been described; other presentations are more vague and include abdominal distention and pain. Many patients are asymptomatic, and the sponges are found during evaluation of other problems. Time to detection from operation varied from the same day to years in some reports. In our series, 2 of our patients had their retained sponges detected incidentally within days of their last operation. The third presented with a persistent draining wound and had the sponge removed nearly 4 months after the operation when it was most likely left behind.

Previous larger reviews of cases with retained sponges have identified some risk factors. In one large case-control analysis, emergency surgery and unexpected changes in surgical procedure were associated with a higher risk of retained sponges. Bani-Hani and colleagues likewise found emergency surgery as a risk factor in their series. In addition, morbid obesity was noted as a risk factor in their patients with retained sponges. Other studies have identified cases in which there were multiple major procedures done in a single operation or cases in which multiple surgical teams were involved as being associated with a higher rate of retained sponges. All of the cases presented in this current article involved these recognized high risk factors as major contributors to the problem.

In cases in which sponges are retained, the issue of whether the sponge counts were correct or incorrect is interesting. In a retrospective review of medical malpractice claims data from a statewide insurer in Massachusetts, Kaiser et al reviewed 67 cases in which retained sponges or instruments were the primary reason for the claim. They found that sponge counts were falsely correct in 76% of nonvaginal cases of retained sponges; in 10%, no sponge count had been performed at all. The current standards of the Association of PeriOperative Registered Nurses specify routine counting of sponges and instruments both preoperatively and postoperatively. If counts are incorrect or inconsistent, the guidelines further recommend the routine use of ra-
diography. Despite these guidelines, the process by which counts are performed and documented is neither standardized nor universal; often the process is modified to accommodate individual institutional policies. The use of complete body cavity radiographs either as routine or when counts are incorrect is even less consistent across the country. When radiography is used, retained sponges can still occur, as demonstrated by our series and also in Kaiser and colleague’s review in which postoperative films had been read as negative in 3 cases of retained sponges.

The 3 cases presented in this article highlight the difficulties in prevention of this complication as a result of both human error and breaches in the system process. Despite strict policies, sponges were retained, and each case had a unique reason why it occurred. Based on our experience, we recommend that all hospitals adhere to strict preprocedure and postprocedure counting of sponges, especially in “crash” cases. We also recommend a strict policy regarding how counts are documented on the operative record, how intentionally left sponges should be reported, and what the protocol should be when personnel changes occur during a case.

The use of SPOX should be routine to add another layer of safety, especially at institutions where emergent cases are often performed. The efficacy of the use of radiographs in the identification of retained surgical foreign bodies has never been evaluated but their routine use has been suggested. Nevertheless, obtaining abdominal radiographs while the patient is on the operating table presents challenges, and radiographs are often of suboptimal quality, with a restricted field of view. For this reason, particular attention should be paid to the periphery of the images, and the reader of the radiograph should be aware of cases of clipped anatomy, especially in obese patients. With most recent estimates of overweight US adults (body mass index, 25-29) reaching 66%, with 32% being frankly obese (body mass index, ≥30), the possibility of clipped anatomy is a very real concern. Because larger films are not currently available, most obese patients require 2 radiographs to adequately survey the abdomen. Readers of radiographs should be given a tutorial or other educational interventions to enhance reliability in recognizing sponges on a radiograph, particularly for residents during training. Our tutorial has greatly improved resident comfort and ability to identify indicators of sponge retention (http://depts.washington.edu/uwerad/spox/postopxray.html).

While the routine use of SPOX films may seem costly and unnecessary, prevention of even 1 case of a retained sponge makes it worthwhile. The average indemnity payment in both Gawande’s and Kaiser’s reviews of claims involving retained sponges was about $52,000. It is difficult to quantify the cost to the institution of the routine use of SPOX—technician time, cartridge and processing fees, and OR minutes spent waiting for the results need to be considered. At our institution, the cost to the hospital of 1 SPOX film is about $64.47. There were approximately 990 SPOX films taken in the last year, at a total cost of $63,825 to the hospital. The 3 cases within the last 2 years could potentially cost our institution $156,000. But in addition to the dollar amount in cost to the hospital or surgeon, cases of retained sponges have additional, immeasurable negative effects such as unwanted scrutiny in the press. Most importantly, the potential risk of significant harm to the patient by a retained sponge is real and must be avoided if at all possible.

Although the literature describing cases of retained foreign bodies is scarce in both quality and quantity, it is likely not as rare a phenomenon as previously reported. With the Institute of Medicine’s report, To Err Is Human: Building a Safer Health System, the risks of medical care in the United States have been at the forefront of public awareness. In response to this report, in 2006, the National Quality Forum released a list of 28 defined events that should never occur within a health care facility, with the retention of foreign bodies after surgery included in this list. The Leapfrog Group endorses hospitals that are willing to acknowledge these never events, with steps that include full disclosure and apology to the patient and/or family, reporting of the event to the Joint Commission on the Accreditation of Healthcare Organizations or a similar agency, root cause analysis, and waiving of all costs directly related to the event. Leapfrog also strongly supports Center for Medicare and Medicaid Services plan to eliminate payments for “never events.” Given the current climate, it is clear that health care facilities that do not take steps to reduce iatrogenic complications will face significant financial consequences. To reduce the number of complications such as retained sponges, it is broadly endorsed that more complete reporting of such events with root cause analysis is necessary. However, as suggested by Gibbs and Auerbach, use of an anonymous reporting system may lead to more diligent reporting without fear of litigation, and this may allow for a more accurate assessment of the incidence and causes of these events. Steps can then be made toward reducing their incidence and monitoring the efficacy of these prevention programs.

In the 18 months since our perioperative policy was last revised, Harborview has performed more than 20,000 surgical cases including nearly 600 nonelective laparotomies. We have not had any further incidences of retained sponges.

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REFERENCES


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