Retained Radiofrequency Tag Despite Normal Count

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Background	Notwithstanding the best practice guidelines and the stigma attached to the retained surgical items, these events continue to haunt health care personnel. Current guidelines and institution policies to prevent such an occurrence are focused on the importance of correct surgical counts and aims to overcome distraction, especially with multiple teams involved in lengthy and time-sensitive procedures.
Summary	We present an intriguing case review of a 49-year-old-female. An encapsulated RF tag used on a surgical RAY-TEC gauze, an innovation to prevent such sentinel events from happening, was displaced from the gauze and lost in the body cavity during a robotic cholecystectomy. We believe it is essential to emphasize the possibility of such an eventuality, as this is an example of a retained surgical item not included in the surgical counts at many institutions.
Conclusion	This case review underscores the value of using a sensor to account for cases where RF-tagged items are used. We advocate performing a separate count for the tags used in the surgical procedure. This event also calls for improvement in the industry product, where we can reinforce the RF tags to surgical items to prevent future occurrences.
Keywords	Retained surgical items, RF tag, RFID surgical gauze

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Case Description

Retained surgical items (RSI) are preventable sentinel events with an incidence of approximately 1 per 10,000 surgical procedures.[1] RSI can lead to serious adverse effects, including infection/sepsis, reoperation, readmission, and visceral injury. The National Quality Forum has listed RSI as "never events."[2] Since 2008, the center for Medicare and Medicaid Services has stopped reimbursing for patient care due to RSI. We report a case report of retained encapsulated radio frequency (RF) tag of a surgical Ray-Tec gauze, without the gauze being retained, and means to prevent this mishap in the future.

We describe a case of a 49-year-old-female with a past medical history of class II obesity and granulomatosis with polyangiitis complicated by extensive sinusitis. The patient required a gastrostomy tube for feeding access after her sinus surgery and developed an incisional hernia at the site of the previous open gastrostomy procedure. She suffered an episode of acute cholecystitis while awaiting hernia repair. A cholecystostomy tube was placed at an outside hospital, and she was referred to us for cholecystectomy. She remained symptomatic and urgent cholecystectomy was scheduled. Her liver function test was within range. She was scheduled to undergo robotic-assisted cholecystectomy as well as the removal of the cholecystostomy tube' utilizing the da Vinci Xi® system (Intuitive Surgical, Sunnyvale, CA, USA) platform.

There were significant acute and subacute inflammatory adhesions around the gallbladder and cholecystostomy access site. The gallbladder had perforated into the liver. A single RF-tagged (4 x 4 in.) gauze was used during dissection to aid in hemostasis and visualization (Figure 1).

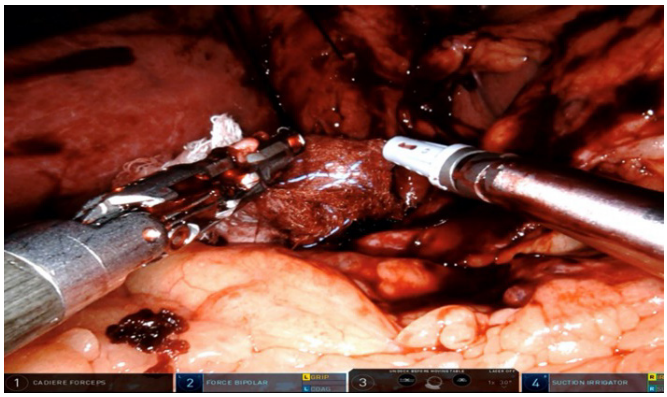

Figure 1. The intraoperative use of RF-tagged Ray-tec gauze.

The robot was undocked after confirmation of manual count for surgical items, and ports were removed. The skin was closed, and 2-octyl cyanoacrylate (Dermabond; Ethicon, Somerville, NJ) was applied. As per our hospital policy, we used the wand and surgical sponge/gauze detection system RF Assure (RF Surgical Systems, Inc., Bellevue, WA) to confirm the surgical count before orotracheal extubation. The use of the wand was consistent with a retained surgical object.

This procedure was followed by a repeat manual count, which again confirmed the correct surgical count. A detailed examination of the used cotton gauze demonstrated that an RF tag was missing from the retained gauze as also a small hole in the green cloth used to secure the tag. A portable X ray of the abdomen was obtained, revealing a radiopaque object similar to a tag in the upper-right quadrant (Figure 2A). The pneumoperitoneum was reestablished, the ports were replaced, and standard laparoscopy was initiated. The encapsulated RF tag was not visualized on an initial inspection with a 300 camera. Intraoperative fluoroscopy was then used to localize the tag (Figure 2B). Triangulation with a laparoscopic instrument and intraoperative fluoroscopy revealed the tag in hepatic flexure mesentery (Figure 3). The tag was retrieved, and the count was again confirmed manually and with the RF Assure surgical sponge detection system (Figure 4).

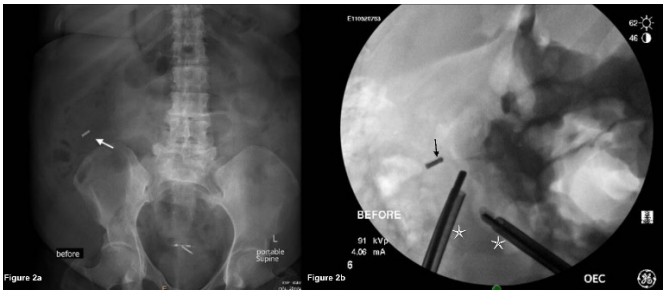

Figure 2. A) Portable on-table abdomen X ray, antero-posterior view. Arrow showing dislodged RF tag in the right upper quadrant; B) Use of intraoperative fluoroscopy to triangulate the precise location of RF tag. Arrow is showing the RF tag and white stars point to surgical instruments.

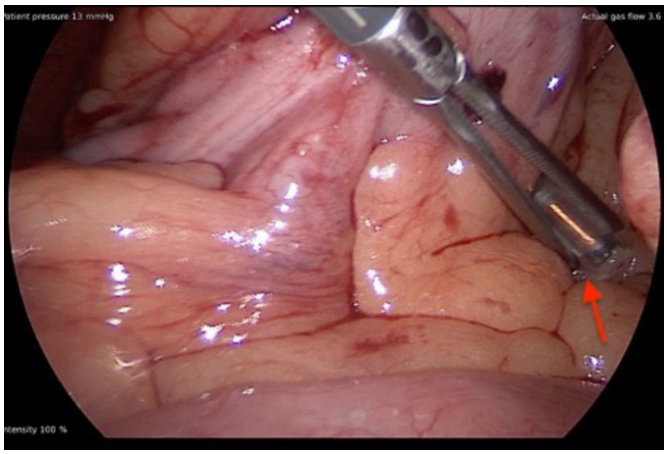

Figure 3. Intraoperative picture with an arrow showing RF tag being retrieved.

Figure 4. The retrieved RFID tag next to the gauze with a small hole visible in the gauze pocket.

A confirmatory abdominal X ray was performed. The ports were then removed, and the skin was closed. The patient was then extubated and moved to the recovery area in a stable condition. The surgical team disclosed the event in detail with the family and with the patient once she was fully awake. She was discharged home the same day.

Discussion

A review of 7.45 million hospital discharges from the Agency for Healthcare Research and Quality (AHRQ) database noted that foreign bodies left during a procedure increased the average length of hospital stay by 2.08 days and added $13,325 to the hospital cost.[3] The abdominal cavity is involved in most RSI cases (46 percent to 55 percent), and surgical gauze account for half of the patients.[4] There are specific guidelines by the Association of periOperative Registered Nurses (AORN) to prevent this sentinel event.[5] However, the incongruity in surgical counts continues to occur in more than 10 percent of cases and require on average 13 minutes to resolve.[6]

Radiofrequency identification (RFID) technology initially developed during World War II for an aircraft radar system has been improvised to detect surgical items, especially surgical gauze and sponges. Tags are encapsulated in a shell with an integrated circuit (IC) for protection. Radiofrequency waves from the scanning device activate the electrical energy-generating passive RF tags, activating the IC. The activated IC sends a signal back to the scanning device to be interpreted by the receiver.

For gauze/sponges, low-frequency (less than 0.300 MHz) RF tags are used; they are meant to conduct even inside body fluid.[7] RFID technology is finding increasing health care applications (e.g., preventing mismatched blood transfusion, labeling pathology specimens, and tagging medications). It is an improvement on the barcode as it does not require a direct line of sight, is encapsulated, automated, and can provide three-dimensional position tracking.

Moreover, an IC linked with the transponder also provides detailed information about the tagged product. The RFID tag is a useful adjunct to manual surgical counting, which has a sensitivity of only 77 percent.[8] This has important implications as 62 to 88 percent of RSI occurs when the count has been reported as correct. In their study of 210 patients and 840 readings, Steelman et al. reported no false positive or false negative recording while using RF tags to detect surgical gauze and sponges.[9] This report also demonstrated 100 percent sensitivity and specificity, even in morbidly obese patients. RFID technology has also been found to significantly decrease operating room (OR) time when the count is not congruent, especially in long, complex cases involving multiple surgical specialties or in emergent procedures.

We believe this is the first reporting of an RF tag getting dislodged from a surgical item and left inside the body cavity. The operating team was alerted due to a positive detection signal on the system receiver. The tag's highly metallic content makes it radiopaque, which helped confirm our findings with X ray. Radiopacity allowed the use of intraoperative fluoroscopy with instrument triangulation for localization. Detection of the missing RF tag and its safe retrieval before weaning the patient from the ventilator prevented the event from becoming more complicated.

As per our institution's policy, timeouts are an integral part of every surgery. During a timeout, we confirm the patient's identity using the name, medical record number, and date of birth. We verify the procedure, identify the surgical site, the operating surgeon, other OR team members, and their roles. We verify allergies, need for blood products and presence of type and screen, anticipated blood loss, type, and dose of antibiotics, if any, patient positioning, patient disposition after surgery, fire risk, and any other concerns. Nurses maintain a record of gauze/sponges, instruments, implants, and needle counts. After completion of the surgery, before the closure starts, the first count is done. It includes counting sponges/gauze, instruments, needles, implants, and specimens, if any. After closure, a second similar count is done before removing the drapes. Wanding for RFID tags was done before the patient is weaned off anesthesia in the operating room. Since this event, we have modified our institution policy to include wanding for RFID tags just before skin closure.

We do not know the long-term implications of a lost RF tag in the abdominal cavity. The transponder and IC are nonradioactive and in passive mode unless electromagnetic signals activate them. Nevertheless, our case report's finding is pertinent as it brings attention to the possibility of a missing RF tag. Given this, we recommend that a tag count be performed in addition to a manual gauze/sponge count if RF-tagged surgical items are used during a procedure. The scope of improvement in the final industry product cannot be overstated. Attachment of the tag to the surgical gauze could be reinforced or altered to prevent this mishap, as it has the potential to increase OR time and expose the patient to an additional invasive procedure.

Conclusion

Safety protocols in the operating room are under constant scrutiny in most hospitals. In addition to patient safety concerns, the cost and legal implications mandate that issues such as wrong-site surgery and retained instruments, gauze, and sponges be taken very seriously and be "never" events. There was no retained gauze or instrument in this situation, but rather the failure of a device. The only purpose of it was to avoid the exact situation that developed. An astute surgical team recognized the issue and gauze tag's failure in real-time before any injury to the patient.

Prompt teamwork by the surgical, anesthesia, and radiology support teams enabled retrieval of this device and led to a successful outcome. The small size of the object made the retrieval challenging. Our protocol for the RFID gauze/sponge now includes confirmation of the tag's presence at the initial gauze/sponge count and proof that when a sponge or a piece of gauze is retrieved from a body cavity, the tag is still present in the gauze or sponge. The tags are palpable in the pockets of the gauze/sponge. This case report shows ana RF tag becoming dislodged from the surgical gauze/sponge, which emphasizes the importance of counting RF tags and the manual count of the surgical items.

Lessons Learned

We describe the possibility of RF tags getting dislodged in the body cavity during a procedure. Reporting missing RF tags is pertinent as RFID technology is a crucial adjunct finding increasing application in health care.

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