Retained Vaginal Foreign Body in Minimally Invasive Gynecological Surgeries

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ABSTRACT

Background: Retention of a surgical object in a patient's body is a preventable human error that is rare but can cause serious clinical complications, lead to malpractice lawsuits, and be a devastating event both for the patient and the care provider. Although the incidence of retained foreign bodies in the abdomen tends to decrease with the rise in minimally invasive surgery, a retained surgical object in the vagina is a possible adverse outcome of which the surgical team should be aware.

Cases: We describe 2 cases of minimally invasive surgeries that were complicated by a retained surgical object in the vagina and occurred within 2 consecutive years at the same institution. The first case describes a retained Asepto bulb (Xodus Medical, New Kensington, Pennsylvania) after a robot-assisted total laparoscopic hysterectomy, and the second describes a retained surgical sponge after a laparoscopic ovarian cystectomy. Both patients did well after removal of the foreign body, without major complications.

Conclusion: The counting system and radiographic screening for high-risk cases are not reliable methods to prevent retained foreign objects. Communication is always important, and standardization of the language in the operating room is essential. The surgical team should be aware of a retained foreign body as a possible adverse outcome, and specific steps should be taken to ensure that all objects are removed from the patient at the completion of the surgery.

Key Words: Retained foreign bodies, Minimally invasive surgical procedures, Surgical error.

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INTRODUCTION

Retention of a surgical sponge or instrument in a patient's body is a preventable human error that is rare but can result in major injury. This has long been a subject of interest and, given the seriousness of the problem, many guidelines and recommendations have been issued by the Association of periOperative Registered Nurses (AORN) and the American College of Surgeons (ACS) in an effort to decrease the incidence of such events.[1–4] Yet these errors persist. Although the incidence has not been determined, it is estimated that such events occur in 1 of every 1000 to 1500 abdominal operations.[3,4] The actual rate is believed to be higher due to underreporting of those cases because most studies are based on either malpractice claims filed or hospital records.[3,4]

Retained surgical items can cause serious clinical complications including sepsis, fistula or bowel obstruction, visceral perforation, and sometimes death.[3,5] In cases of retention in the abdomen, they often lead to reoperation for removal of the object and management of complications[3,5] In addition, such events attract wide critical press coverage and frequently lead to malpractice lawsuits. In the report by Gawande et al, 87% of retained surgical item cases resulted in malpractice litigation.[3,5] Regardless of the clinical outcome, this is a psychologically devastating event both for patients and health care providers.[5]

Sponges are the most frequently retained foreign object during surgery, and the abdomen is the most common location. Sponges retained in the vagina are also problematic[3,6]; the vagina is the second most common location in which a foreign body has been retained.[3] According to the Minnesota Adverse Health Events Reporting system, obstetrical procedures—mainly vaginal deliveries—account for 25% of retained surgical objects,[5,7] and they reported

that sponges used during vaginal births were retained more often than all other types of retained objects combined.[8] In a study of the Medical Professional Mutual Insurance Company in Boston, of the 40 patients with retained surgical sponges, 22 (55%) had undergone abdominal surgery, 11 of which were obstetric or gynecologic in nature. In addition, 11 of those 40 cases (27%) involved vaginal deliveries.[2]

With the rise of minimally invasive surgery, incidents of retained surgical sponges and instruments in the abdomen tend to decrease, as shown by Gawande et al, who did not find any incidence of a retained surgical item in any laparoscopic, endoscopic, or catheterization procedures.[3,6] Nevertheless, a retained foreign object in the vagina is a possible adverse outcome of which the surgical team should be aware.

We describe 2 cases of minimally invasive surgeries that were complicated by retained surgical objects in the vagina and occurred within 2 consecutive years at our institution.

CASE 1

A 33-year-old patient underwent a robot-assisted total laparoscopic hysterectomy with bilateral salpingo-oophorectomy, appendectomy, and cystoscopy for severe endometriosis and chronic pelvic pain that had been unresponsive to medical treatment. A RUMI uterine manipulator and KOH ring colpotomizer (both from CooperSurgical, Trumbull, Connecticut) were used. After the colpotomy was performed, the uterus and cervix were removed transvaginally. An Asepto bulb that was detached from its syringe was used with an 11-mm trocar and inserted into the vagina to maintain a pneumoperitoneum and to provide access to the abdomen. The vaginal cuff was then closed and the robot was undocked. The operative note stated that the Asepto bulb and trocar were removed from the vagina and all counts were correct. The procedure was uneventful and the patient was discharged home the next day.

On postoperative day 4, the patient presented to the emergency department with abdominal pain, nausea and vomiting, fever, and chills. Her white blood cell count (17,000 cells/mcL) and positive urinalysis results were suggestive of pyelonephritis. A computed tomography scan done in the emergency department to rule out ureteral lithiasis did not show any stones but showed a small ringlike object within the vagina, suggestive of a pessary **(Figure 1)**. The abdomen was soft and nontender on palpation. A vaginal examination was done, and the foreign object was removed: it was the Asepto bulb that had been used as a vaginal occluder. There was no purulent discharge noted, and the vaginal cuff was intact.

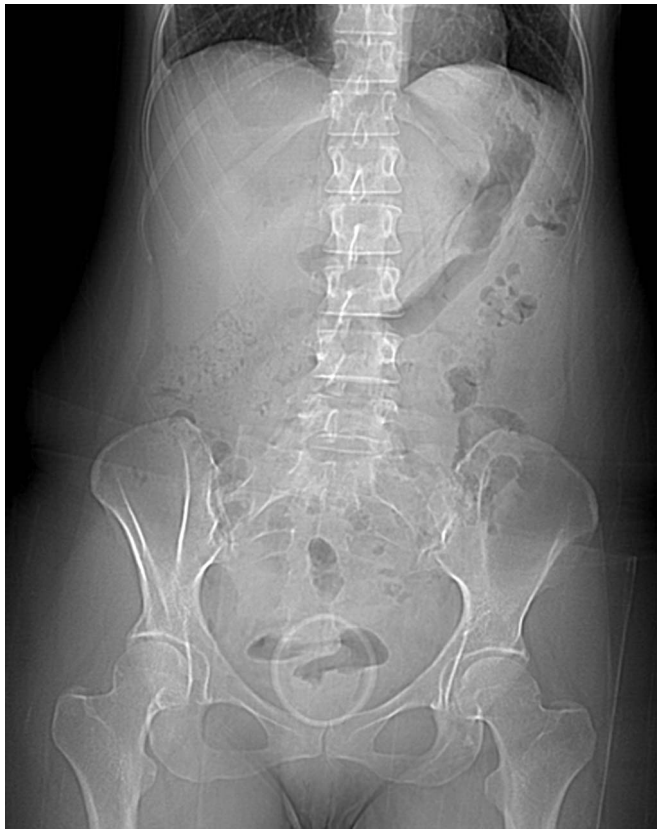

Figure 1. The retained Asepto bulb seen on radiograph.

The diagnosis was discussed with the patient and her husband, and the object was shown to them. The patient was then discharged home with a 14-day prescription for ciprofloxacin.

The next day, the patient presented again to the emergency department with nausea, vomiting, and complete intolerance of oral intake. She was afebrile, and her white blood cell count was 15 000 g/L. Her symptoms remained unresolved with intravenous hydration and symptomatic treatment with antiemetic medication; thus, a general surgery consultation was requested. The diagnosis was postoperative ileus likely caused by a urinary tract infection that was precipitated by partial bladder obstruction from pressure to the bladder neck by the retained vaginal foreign body. Surgical intervention was judged unnecessary, and the patient was treated conservatively with intravenous hydration, no oral intake, and electrolyte correction. Significant improvement was noted by the end of the second hospital day, and she was discharged home on the

third hospital day after she was able to tolerate an oral diet and all of her symptoms had resolved. She followed up at the clinic 1 month later, with normal recovery and no complications noted.

CASE 2

This patient was a 20-year-old nulligravida who presented to the emergency department with a sudden onset of intense right lower quadrant abdominal pain and was noted to have an enlarged right ovarian cyst that was suspicious for possible ovarian torsion. She underwent a diagnostic laparoscopy with a right ovarian cystectomy. A Harris-Kronner Uterine Manipulator Injector (HUMI) (CooperSurgical) was used for uterine manipulation, and the right ovarian cystectomy was performed without complications. The HUMI catheter was removed and the patient taken to recovery in stable condition. The counts of sponges, needles, and laps were reported as being correct at the end of the procedure. The patient was discharged home on the same day.

The postoperative course was complicated by suprapubic pain requiring continuous narcotic use, persistent vaginal bleeding, and foul-smelling vaginal discharge. On postoperative day 13, the patient called to state that "a roll of gauze is coming out of [her] vaginal area" and that she had a foul smell coming from "her body." She was instructed to present to the emergency department, where she was evaluated. On presentation, the patient had already removed the reported roll of gauze. She was afebrile and hemodynamically stable. An abdominal examination noted suprapubic tenderness but no acute abdomen. A vaginal examination revealed a foul-smelling discharge as well as a friable cervix with left-sided abrasion and scant blood. She was treated empirically with ceftriaxone and azithromycin and discharged home with prescriptions for metronidazole and fluconazole. The patient was seen in the clinic as a follow-up and was doing well with no problems reported.

DISCUSSION

Retention of a surgical object in a patient's body is a rare event that can cause adverse clinical complications and major distress to both the patient and the provider. Its publicity can attract wide local press coverage, and it is an important source of litigation as well.[3,5] Guidelines for surgical counting have been issued by AORN to prevent retained surgical items,[1,6] and both AORN and the ACS recommend a methodical wound exploration before wound closure.[6] Despite all guidelines and performance of proper procedures, these human errors still occur.[2,3]

Unfortunately, most of the cases of retained foreign bodies erroneously reported a final count of surgical instruments and material to be correct..[3,6] Studies have shown that in 88% of patients with retained objects, the count was reported as correct.[3,6] Thus the suggestion was made by Gawande et al to screen the high-risk cases at the end of surgeries, even when the final count seems to be correct.[3] The main screening method currently available is radiographic screening.[3] AORN recommends intraoperative radiographs if an incorrect count cannot be resolved,[1,6] but some institutions require intraoperative radiographs for all trauma and emergency cases, regardless of the count.[6] However, there are significant data that show radiography is not a reliable technique for ensuring that there is not a retained surgical item, especially for sponges and needles.[2,6,9] In a 2008 study by Cima et al, only 67% of confirmed retained objects were identified on intraoperative radiography.[9]

Risk factors for retained surgical objects in order of importance include emergent procedures, unplanned changes in procedure, more than one surgical team involved in the case, change in the nursing staff during the procedure, and patients with a high body mass index.[3] It is more likely that multiple factors contribute to the unfortunate event of leaving a surgical item in a patient's body.

Although retention of vaginal objects can still carry the same outcomes and complications as retention of items in the abdomen, it does not warrant a reoperation for removal because objects can be removed with a simple vaginal examination. Hence it may be viewed as a low-risk adverse event. In addition, because of a perceived noninvasive resolution of the problem, there is a potential for nondisclosure of the error, which can account in part for those events being underreported. The ethics code of the American Medical Association states that when a significant medical complication may have resulted from a physician's mistake, the physician is ethically required to fully disclose that event to the patient.[10] Research demonstrates that disclosure of adverse events is associated with higher ratings of physician quality by patients, an improved rate of recovery, a decrease in the number of malpractice suits, and a decrease in the average settlement amount.[10]

With the increasing use of minimally invasive procedures, the incidence of retained surgical objects in the abdomen is decreasing, but retention of surgical objects in the vagina is a possible adverse outcome that should be avoided

by the surgical team. The use of new techniques intended to fix the loss of a pneumoperitoneum that occurs during laparoscopic and robotic-assisted hysterectomies might be a risk factor for a retained foreign object in the vagina. In both our first case and the case described by Sakhel and Hines,[4] an Asepto bulb that had been placed in the vagina to maintain the pneumoperitoneum during the laparoscopic closure of the vaginal cuff was forgotten. A major reason these errors happen is because of a breakdown in communication between the surgeon and the other team members in the operating room. Standardization of the language used in the operating room and clarification of the steps taken by each individual may help overcome the barriers to effective communication. We suggest that the placement of an Asepto bulb or any other object in the vagina, as well as its removal, should be clearly declared by the person who removes it and then noted by the circulating nurse.

Separation between the instruments of the vaginal table and the instruments of the abdominal procedure and performance of 2 different counts for the vaginal and abdominal instruments might be helpful in decreasing the risk of retaining a foreign body. All of the instruments used for the vaginal work including vaginal cleaning, manipulation, sponges, and Asepto bulb should belong to the vaginal table and be included in the vaginal count. Both vaginal and abdominal instruments would then be added to the final count.

A final suggestion is the time-tested systematic digital vaginal examination at the end of each procedure to make sure no sponges or instruments are left behind. There should be a mandatory documentation of this check by both the circulating nurse and the physician in the operative note. Because both AORN and the ACS recommend a methodical wound exploration before wound closure, a methodical vaginal exploration at the end of the procedure and before waking the patient might be warranted.

In conclusion, a retained foreign object in the vagina amounts to a breach in patient safety. In view of the rising incidence of minimally invasive surgery in gynecology, all efforts should be made to actively develop protocols aiming to eliminate the rare but preventable medical error of retaining a foreign object in a patient's body.

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