The retained surgical sponge or gauze after surgical intervention or a birth can have serious consequences for patients and poses a challenging problem for clinicians. Although the true incidence of the problem, formally called gossypiboma, is probably underreported, one estimate suggests it occurs as often as 1 in every 7000 procedures.\(^1\) That translates to approximately 2000 cases of retained surgical items occurring annually in the United States.\(^2\) The median time to discovery of these retained items is 21 days,\(^3\) with 40% detected within 1 year and 50% within 5 or more years after surgery.\(^4\,5\) Although there are common sense ways to improve these statistics, the Joint Commission has also suggested that organizations explore the use of assistive technologies to augment manual counting procedures.\(^6\) The Situate™ Delivery System, from Medtronic, is among the options worth considering. The Situate™ Delivery System combines a RadioFrequency (RF) sensor and a detector that can detect objects in a patient’s abdominal cavity or birthing canal.

Both the Joint Commission and the National Quality Forum (NQF) consider retained surgical sponges to be significant impediments to quality patient care. NQF’s list of 29 events that should never occur includes “unintended retention of a foreign object in a patient after surgery or other procedure.”\(^7\) Similarly in a 2013 Sentinel Event Alert, the Joint Commission specifically includes vaginal sponge retention as a reportable sentinel event that is a violation of patient safety and quality of care.\(^8\)

Among 394 events reported to the Joint Commission between January and June 2014, unintended retention of a foreign body was at the top of the list of sentinel events based on the number of occurrences.\(^9\) Other sentinel events on the list included delays in treatment, operative and postoperative complications, and medication errors.

The possible complications associated with gossypiboma are patient morbidity and excess cost burden to the health system. Published reports describe patients presenting with a mass, abdominal pain, or small bowel obstruction from weeks to years post incident.\(^4\) Forgotten sponges have also been associated with fistulas, walled-off abscesses, and passage of the foreign body through intestinal walls with spontaneous evacuation.\(^7\) Other clinical sequelae reported in the literature include refractory urge incontinence and a urinary bladder stone when proximity to the GU tract exists.\(^4\)

Retained surgical objects are among many other medical errors that have contributed to complications and deaths in US hospitals. In 1999, the Institute of Medicine issued the well-publicized To Err is Human report, which estimated that annual deaths from medical errors ranged between 44,000 to 98,000.\(^9\) A Harvard report by Leape et al suggested that this estimate may be too low, contending about 140,000 deaths were due to medical errors.\(^10\)

The latest analysis, from Makary et al, estimated that medical errors comprise the third leading cause of death in the United States.\(^11\) That study concluded that these errors are underreported in part because medical error is not listed in cause of death rankings nor included on death certificates.\(^11\) In addition, this analysis concluded that previous underestimates have occurred because death certificates rely on the assignment of an ICD code. Since many human and systemic factors that cause medical errors are not related to ICD codes, these deaths are not taken into account.\(^11\)
While the errors discussed above are generally applicable to the operating room suites, the labor and delivery arena is not immune. Physician fatigue, blood filling the vaginal cavity, and lack of sufficient counting policies are all contributors to the occurrence of the retained vaginal sponge postpartum. The retained, postpartum textile can result in potential infection, discomfort, and the need for further antibiotic therapy, which increases patient and health care system overall costs.  

Understanding the Causes of Sponge Retention

Unintended retention of surgical sponges has been associated with several risk factors and contributing causes, such as emergency operations, procedures that require an unexpected change, an increased body mass index, and a failure to perform accurate sponge and instrument counts. Research also suggests that even when intraoperative imaging is used to reconcile miscounts, it identifies only 67% of misplaced foreign objects.  

One publication documented 35 surgical item miscounts among 2285 patients, including missed items at the surgical site, within the operative suite, and hidden in surgical drapes. That translates into a rate of 1.53%. A model has been created to help clinicians understand what contributes to potential failures in sponge management. Referred to as a Healthcare Failure Mode and Effect Analysis (HFMEA), this model includes practitioner distraction, multi-tasking, time pressure, emergencies, and systemic breakdowns in following procedures.  

In light of the many ways that sponge management can be thwarted, it is no surprise to find a Minnesota Department of Health Spotlight on Patient Safety concluded that retained foreign objects (RFOs) were among the most frequently reported events in the 5 years that adverse health events information was collected. The report goes on to explain that 83% of the cases reported an accurate count despite the presence of an RFO. Such statistics may be one of the reasons the Joint Commission is encouraging institutions to consider looking at adjunct technology to double check sponge counts. The same Minnesota Health Department analysis found that, among the root causes of retained surgical items during labor and delivery, were problems with communication (43%), training (26%), fatigue/scheduling (11%), and rules/policies (97%). The report also found that obstetrical procedures accounted for 25% of retained foreign objects, compared to 13% for musculoskeletal and 11% for cardiovascular procedures.  

An analysis by Gawande et al sheds light on the risk factors that contribute specifically to retained instruments and sponges after obstetric/gynecologic (ob/gyn) procedures. They found 54% of these foreign items were located in the abdomen and 22% in the vagina. Concerns about the specific risk of RFOs in ob/gyn units are reflected in a 2012 protocol from The Institute for Clinical System Improvement (ICSI) called Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries. This protocol aims to measure and reduce the number or rate of unintentionally retained foreign objects left following a vaginal delivery.  

Retained Foreign Objects and Medical Liability

RFOs in obstetrics and gynecology have also raised concerns about the risk of malpractice lawsuits. A 2010 paper published in Obstetrics and Gynecology concluded that 87% of the quality problems in labor and delivery, which included objects retained in the vagina, were preventable. The same analysis reviewed 90 closed medical liability claims related to obstetrical care and found that 78% had a preventable cause. An earlier analysis from the Annals of Surgery found that in a closed-case series of medical malpractice claims, RFOs in the vagina comprised approximately 28% of cases. These RFOs can be expensive for hospitals and physicians. Among 307 cases involving RFOs from 2007 to 2011, 46% required paid indemnity, with an average payout of $473,022.  

Preventive Tools

Stawicki et al discuss 3 basic factors that could help minimize retained surgical items:  

- Knowledge of the risk factors  
- Improved perioperative patient processing systems  
- The use of modern technology  

The Situate Delivery System, from Medtronic, addresses the last factor. This system is designed to detect surgical sponges in vivo through dense tissue, blood, bone, and near metal, as well as in the surrounding operating room (Figure 1). It combines a sensor and a detector that can detect objects in a patient’s abdominal cavity or birthing canal, even if it is blocked visually by blood, bone, or other materials.  

The Situate Delivery System has 3 parts: a touch screen console, a handheld scanner that sends out a radiofrequency (RF) signal, and a detection sensor that recognizes the RF signal, located in each tagged surgical sponge. The nonintrusive design enables a postdelivery vaginal scan and takes into account the angle and depth of the birthing canal.
The system is equipped with dual scanning capability, sensing RF tags in both the birth canal and surrounding area. Because the console is portable, the system can be moved from room to room.

Scanning is a 3-step process. With the system in static mode, the scanner is positioned within 1 inch of the pubic bone. The operator presses start on the touch screen console, and within 15 seconds, a confirmation scan is registered. If the scan is negative, a confirmation code appears, which can then be transcribed into the electronic medical record. If it detects a tagged sponge, it delivers a red X, at which point the operator needs to take action.

The Situate™ Delivery System also has a room scan feature, referred to as dynamic mode. Its purpose is to locate missing tagged sponges around the L&D Suite, which includes the trash can. In order to use this feature, hospital staff need to move the scanner around the labor and delivery suite to search for missing objects. The scan will alert users to the presence of a tagged object within 8 inches of the scanner.

**Evidence Supporting Assistance Technology**

There is peer-reviewed evidence to demonstrate that RF-tagged surgical supplies can reduce the incidence of retained foreign objects. A prospective trial of 2285 patients found that the Situate™ Detection System, when used in conjunction with manual sponge counting, detected 1 sponge that was missed by manual counts and assisted in the resolution of 35 surgical sponge miscounts. Importantly, there were no false negatives or false positives reported during the investigation.

In a prospective, crossover study that enrolled 210 subjects, nearly a quarter of which were morbidly obese, 4 surgical sponges were placed behind each subject's torso in locations that approximated their abdominal quadrants. The investigators then took 840 readings using RF scanning to detect the “missing” items, concluding that there was 100% sensitivity and specificity of RF detection through subjects’ torsos.

**Patient Safety Must Come First**

The benefit of assistance technology, such as the Situate™ Delivery System, extends beyond its ability to reduce the rate of retained foreign objects. While the damage to a hospital's reputation from publicity surrounding a retained sponge is hard to calculate fiscally, it is surely considerable. Andrew Webber, the President and CEO of the National Business Coalition of Health recently stated that “it is very clear that...
for a hospital institution, community reputation is critically important to their branding, to their image, and they will respond if that information is transparent." In fact, it is estimated that 97% of consumers would choose a hospital based on its safety, regardless of cost.22 Organizations like the Leapfrog Group publish hospital safety scores, allowing patients to choose hospitals with the best safety records and avoid those that fall short. The group’s scoring system rates facilities with a letter grade from A to F, using a methodology that includes the rate of retained surgical items. Retained surgical items comprise 4.7% of the total score.23

**CONCLUSION**

In conclusion, data demonstrate that while counting surgical sponges is an important way to reduce the likelihood of leaving one in the surgical site, counting is probably not enough. By combining state-of-the-art sensors and a detector that can find objects in a patient’s abdominal cavity or birthing canal, the Situate™ Delivery System can help reduce the incidence of gossypiboma, which is responsible for approximately 2000 cases of retained surgical items each year in the United States. Using such assistive technology to locate overlooked foreign items left after vaginal delivery will likely improve the quality of care offered to patients and support patient safety.

**REFERENCES**


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