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Case Report

# Retained surgical sponge: Medicolegal aspects

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ABSTRACT

Retained surgical sponge events continue to occur despite the implementation of preventive surgical count policies, procedures, and adjunct technologies to manual counting. Such intraoperative mistakes can cause chronic nonspecific symptoms during the early postoperative period. When discovered years after surgery, they raise thorny medicolegal questions. We describe two cases from our practice that illustrate the need to identify the responsibility of the surgical team, as delineated in ministerial directives and the current legal framework, as well as the difficulty in evaluating clinical actions taken at different times and in different settings, with regard to the permanent health damage incurred by sponge retention. Finally, we discuss prevention actions operating room staff should take to reduce the risk of retained surgical sponges.

## 1. Introduction

There is ample literature on the risk of retained sponges, instruments, and miscellaneous small items in patients after surgery. The majority of retained surgical items (RSI) are surgical sponges [1–4] inadvertently left behind in the abdominal cavity [5–7]. Such intraoperative mistakes occur most often during emergency procedures, unplanned changes in operative procedures during surgery, and in patients with high body-mass index [8–10]. The time to discovery of retained surgical sponges varies considerably: they may be detected at control examination during the early postoperative period [7] or weeks to years after surgery when patients present with gastrointestinal symptoms, including abdominal bloating and pain. In severe cases, intestinal occlusion may be caused by the transmural migration of surgical sponges into the intestinal wall [11–18]. In some cases, however, surgical sponges retained in the abdominal cavity may produce no or few symptoms for years until discovered incidentally [19–24].

The authors report two cases of retained surgical sponge that came to their attention during medico-legal assessment of liability for medical error. The cases illustrate the main characteristics of this persistent yet avoidable problem and the difficulties in assessing the responsibility of surgical team members and operating room (OR) staff for its occurrence.

## 2. Case no. 1

A 55-year-old woman underwent laparoscopic cholecystectomy via right transrectal incision for gallstones and was discharged after an uneventful postoperative course. Over the next 32 years, treatment for recurrent dyspeptic episodes thought to be related to gallbladder removal brought temporary relief. Symptoms gradually worsened with increasing frequency of vomiting. Diagnostic procedures were performed. Laboratory tests showed elevated liver enzyme levels (gamma-glutamyltransferase [gamma-GT] and glutamic-oxaloacetic transaminase/glutamate pyruvate transaminase [GOT/GPT]); imaging studies (ultrasound and computed tomography of the liver and bile ducts) revealed in the pericholecystic area and adjacent to the right lobe of liver, a well-defined, round hypodense solid mass (50 mm in greatest diameter) containing calcifications. The mass was surgically removed with minimal resection of the fifth liver segment. Histology demonstrated a pseudocystic structure with a foreign body giant-cell granulomatous reaction surrounding filamentous inorganic debris referable to textile fibers. In addition to suffering the stress of undergoing liver surgery and compromised aesthetics subsequent to surgery, the patient developed a reactive psychoneurotic disorder.

## 3. Case no. 2

A 49-year-old woman with a history of hysterectomy underwent appendectomy. During the following months, fever, pain, and worsening abdominal bloating developed. An ultrasound procedure was performed. During the procedure, she experienced an acute colic attack and spontaneously evacuated a fragment of the retained surgical sponge. She was immediately transferred to the hospital where the appendectomy had been performed. The remaining sponge fragment was removed via a transanal approach and her previous symptoms

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resolved. The patient believed the retained sponge was due to an intraoperative error that had occurred during her recent appendectomy; however, the more likely cause was that it was left behind during the hysterectomy since the time between the appendectomy and evacuation of the sponge was too short for it to have completely migrated from the abdominal cavity to the intestinal wall. Indeed, migration of the retained sponge might have been suspected from the preoperative computed tomography report which stated, "imaging finding of a tubuliform structure approximately 10 cm in length, with markedly thickened walls medial to the cecum."

## 4. Discussion

Retained surgical sponge cases continue to occur despite the implementation of surgical count policies and procedures to prevent them. Recognizing this problem, the World Health Organization (WHO) launched the World Alliance for Patient Safety program in 2004, followed in 2008 by the Second Global Patient Safety Challenge: Safe Surgery Saves Lives. The problem area selected for the second initiative was the safety of surgical care. Among the objectives this agenda set was the prevention of inadvertent retained sponges or other instruments in the surgical wound (Objective 7). To meet this objective, OR staff are required to follow a procedure checklist before the patient leaves the OR: the scrub or circulating nurse must verbally confirm the correct sponge count with the OR team; before leaving the OR the team must verify the final count so that all sponges have been accounted for. This procedure was later included in the WHO Surgery Safety Checklist (2009) and the WHO Surgery Checklist Implementation Manual (2009) which states that the OR nurse must alert the team in cases of sponge count discrepancies "..so that appropriate steps can be taken (such as examining the drapes, garbage, and wound or, if need be, obtaining radiographic images)…". In addition, Objective 7 specifies that "The team will prevent inadvertent retention of instruments and sponges in surgical wounds" by accounting for such items through documentation of the baseline count and final count and the procedures in place to resolve discrepancies, for example, by means of methodical wound exploration before surgical closure as an alternative to monitoring and manual counting.

About the same time, the Italian Ministry of Health issued recommendations and guidelines for the protection of patient safety. To reduce the risk of retained instruments or other items in the surgical site, defined as a "reviewable sentinel event" (Recommendation No. 4), in July 2006 the Ministry issued Recommendation No. 2, which provides an operative model[1] of standardized processes of care that healthcare institutions must apply in their OR and healthcare personnel must consistently follow. A successive version issued in March 2008, entitled Recommendations for the Prevention of Retained Surgical Sponges, Instruments, and Other Material in the Surgical Site, and received by the Regional and Autonomous Provincial Coordinating Committee for Patient Safety, was later taken up in the Manual for Operating Room Safety: Recommendations and Guidelines issued by the Ministry in October 2009.[2] Some ten years earlier, in 1999, the Association of periOperative Registered Nurses (AORN) published its recommended practices for sponge, sharp, and instrument counts, according to which four separate counts should be performed: "the first when the sponges are unpacked, a second before the surgical procedure begins, a third as closure begins, and the final count performed during subcuticular or skin closure" [25].

Alongside methodical wound exploration before closure of the surgical site, sponge counting is a key patient safety practice surgical teams have routinely adopted to reduce the probability of adverse events after exposure to an invasive procedure. Nevertheless, unaccounted for sponges and instruments figure among the main causes of foreign object retention in the surgical site [26–28]. Most often, counting errors occur with changes in the surgical team during a procedure, during lengthy or after-hours surgery, and in proportion to the higher number of nurses on the OR team [9]. Other factors adding to the risk of incorrect surgical counts include inappropriate medical staff behavior, a chaotic environment, and communication gaps [29,30]. Since counting errors are preventable, nurse training courses and initiatives to develop collaborative count policies have been implemented to improve counting practices [29,31,32].

As an adjunct to manual counting, automated systems using bar coding or other technologies have been experimented with varied success [3,33–37]. Safer than intraoperative radiography, because of the potential harm to patients from exposure to ionizing radiation and because it is not always reliable or practical, low-energy radiofrequency identification (RFID) enabled systems are being increasingly used to keep track of surgical tools and ensure that no surgical sponges have been left behind at the final count before and after closing of the patient (Table I).

Finally, sentinel event reporting (art. 14 of the Ethical Code of May 2014) of RSI cases by healthcare operators holds importance for understanding why counting errors occur and how to improve safety practices to prevent their occurrence. It may also encourage new ways of thinking about human error by promoting a culture of learning from mistakes rather than create fear of punishment.

## 5. Medicolegal aspects

Retained surgical item (RSI) events after surgery raise numerous medicolegal questions regarding the legal responsibility of the OR team, the methodological approach to assigning responsibility, and the medicolegal evaluation of damage related to such events. Retention of surgical sponges in patients following surgical procedures is usually defined as an inexcusable error when the sponges have been left behind after a routine procedure or are exceptionally large or have not been counted or have been miscounted or the count has been incorrectly communicated between the OR team members at shift changes. Retention may be defined as an excusable error if many sponges have been used to manage major bleeding or in emergency procedures requiring prompt response to intraoperative complications, including anesthesia complications during surgery, or when fragments cannot be detected.

From an analysis of our series and reported cases, the major criticalities are identifying the surgical actions responsible for retained sponges in patients with a history of multiple surgeries. Potentially useful clues may be gained from the site of the retained sponge, the type

[1] The Recommendation describes in detail the steps in systematic counting of surgical items and their integrity and identifies the OR nurses as being directly responsible for performing surgical item counts. The Recommendation expressly states that two OR team members, the instrument nurse and the OR nurse or the scrub nurse, together count the number of surgical items and check their integrity. Counting should be performed verbally, paying particular attention to the baseline count and items as they are added to the field, documenting the counts on a specific form to be attached to the patient's clinical chart.

[2] Objective 2, Section 4.2 describes the procedure for preventing the occurrence of RSI in the surgical site. It specifies that "[…] counting and control of the integrity of surgical items must be performed by nurses (instrument nurse or OR nurse) or scrub nurse assigned the counting activity. The surgeon will verify that the count has been performed and that the final count of used and unused sponges equals the baseline count and the additional number of sponges used during the case. The count must be recorded, (*footnote continued*) including the name and role of the team member who conducted it, and state whether the counts are concordant or discrepant. These results must be clearly communicated to the entire OR team […]". Furthermore, Objective 12, which establishes the duty to communicate and inform all team members about material count and control, states "[…] the information recorded by the nurses must include at least the following elements: counts of sponges, needles, sharps, and surgical items used during the various stages of the case; name and role of the staff that carried out the count; surgical items or sponges intentionally left inside the patient; procedures to reconcile count discrepancy; eventual reasons for not having performed a count […]."