

Chapter 22. The Retained Surgical Sponge

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Background

Although less likely to garner public notoriety, errors relating to the failure to remove surgical instruments at the end of a procedure, (ie, needles, knife blades, electrosurgical adapters and safety pins) or sponges (known as gossypiboma; *gossypium*: Latin, cotton; *boma*: Swahili, place of concealment) are no less egregious than the better known mishaps such as “wrong-site surgery” (see Subchapter 43.2).

Retained materials may cause an acute foreign body reaction with local or systemic signs that prompt investigation and reoperation. Alternatively, a fibrinous response may be elicited, and the retained instrument or sponge may become apparent some time after the original surgical procedure either serendipitously, or via fistulization into local structures.¹ The medical literature is scattered with reports of presentations of retained sponges found days, months, or even years after the original surgery.²⁻⁵ While many cases of retained foreign body do not cause harm, some clearly do. Nevertheless, the Joint Commission on Accreditation for Healthcare Organization’s (JCAHO) sentinel event policy specifically mentions that “unintentionally retained foreign body without major permanent loss of function” do not require reporting.⁶ Although JCAHO’s decision suggests that it considers these events less egregious than reportable sentinel events (eg, wrong patient surgery), retained foreign body events are far more common. This chapter reviews the problem and the scanty literature regarding safety practices to reduce the incidence of retained sponges and instruments.

Practice Description

Surgeons and operating room teams rely upon the practice of *sponge, sharp and instrument counts* as a means to eliminate retained surgical instruments. Counts are also a method of infection control and inventory control, and a means to prevent injury from contaminated sharps and instruments. Four separate counts have been recommended⁷: the first when the instruments are set up or the sponges unpackaged, a second before the surgical procedure begins, a third as closure begins, and the final count performed during subcuticular or skin closure.

Use of this simple preventative measure is not universal. In fact, the process by which counts are performed is not standardized and is often modified according to individual hospital policy. Even when present, counts are frequently omitted or abbreviated in emergency or transvaginal surgeries, or for vaginal deliveries.⁸ An adjunctive procedure to the count, used when the count could delay care and jeopardize patients’ lives or when an incorrect count is established, is an x-ray examination to detect radiopaque objects.^{1,7} Since this practice is not routinely used it will not be discussed here.

Prevalence and Severity of the Target Safety Problem

A literature search revealed few data to describe population or even hospital-level information regarding the prevalence of retained surgical materials. One study from a medical malpractice insurance company reported 40 cases in a 7-year period,⁹ or about 1% of all claims. Because this estimate is based on malpractice insurance claims, it is sure to be a gross underestimate of the actual incidence. A recent unstructured review cited “a prevalence ranging from 1/100 to 1/5000,” and an associated mortality ranging from 11 to 35%, citing non-English language medical references.¹ Other reports are based on case series or descriptions of unusual presentations, as described above. Surgeons may not report these events for a variety of reasons, not the least of which is fear of litigation

Opportunities for Impact

Without accurate prevalence information, the true magnitude of the opportunity for impact is unclear.

Study Designs and Outcomes

Only one study provided even indirect evidence of the effectiveness of sponge and instrument counts. Kaiser et al, using a retrospective review of medical malpractice claims data from a statewide insurer in Massachusetts, reviewed 67 cases where retained sponges or surgical materials were the primary reason for the claim.⁹ This study is a case series without any controls (Level 4 design, Level 2 outcomes) which reported only the outcome of retained sponges, rather than the clinical consequences of these errors.

Evidence for Effectiveness of the Practice

The Kaiser et al study reported that 55% of retained sponges were found after abdominal surgery and 16% after vaginal delivery. In cases with retained sponges, sponge counts had been falsely correct in 76% of non-vaginal surgeries; in 10% no sponge count had been performed at all. Falsely correct sponge counts were attributed to team fatigue, difficult operations, sponges “sticking together,” or a poor counting system. Incorrect sponge counts that were accepted prior to closure resulted from either surgeons’ dismissing the incorrect count without re-exploring the wound, or nursing staff allowing an incorrect count to be accepted. Interestingly, in 3 of 29 cases in which intraoperative x-rays were used to detect radiopaque sponges, the radiograph was falsely negative.⁹

Comment

Although literature describing the incidence of iatrogenic foreign bodies is highly limited in quantity and quality, it is unlikely that these events are as rare as other iatrogenic complications that have drawn considerable national attention. The existing system of sponge and instrument counts probably works well, but we have no evidence to describe its actual failure rate. The little existing evidence suggests that it fails due to human-related factors (ie, the count is not performed, or is ignored, and that ancillary methods such as x-rays are also fallible. Although some have advocated CT or ultrasonography as additional methods to reduce rates of these adverse events, it is possible that other technologies (eg, inventory control devices used in retail stores and libraries, possibly including bar coding (Subchapter 45.1)) may prove to be useful adjuncts. However, there are obvious logistical challenges that make such technologies too impractical at the present time. For now we are left with a paucity of data regarding the

prevalence of this error and the effectiveness of preventative measures. Use of anonymous reporting systems may reduce the fear of litigation associated with iatrogenic foreign bodies, and may allow for more accurate assessment of the incidence and causes of these events.

References

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