

Beyond Counting: Current Evidence on the Problem of Retaining Foreign Bodies in Surgery?

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Retained foreign bodies (RFB) are a rare but devastating and preventable complication in surgery. Despite an increasing body of literature over the last decade, it has been difficult even to accurately estimate how frequently these events occur. An estimate based on claims data suggests the incidence is in the range of 1 in 9000 to 1 in 19000.¹ The current approach to the prevention of RFB relies on a standardized counting protocol developed by the Association of PeriOperative Registered Nurses (AORN) and adapted in operating rooms (ORs) across the country.² The counting process is labor-intensive and has been shown to negatively affect case progression and team performance.³ In addition, to date, there is no data regarding the accuracy or reliability of manual counting. Despite this uncertainty regarding the limitations of the current approach, new technologies are being investigated as adjuncts to the manual counting protocol.⁴

The 2 articles published in this issue of *Annals of Surgery* take an important step toward understanding the utility of our current approach to the prevention of RFB. The paper by Egorova et al identifies cases involving count discrepancies through the hospital reporting system at a large academic institution and its affiliates.⁵ By linking these reports to administrative data, they are able to estimate the rate of RFB as well as evaluate the ability of the counting protocol to detect RFB as they occur. Finally, they provide the first cost analysis of miscounts and compare it with another approach, performing universal radiographs in the operating room.

There are several important points to highlight in this study. First, the authors report a RFB rate of 1 in 7000. Most of the previous literature on this topic has been limited to cases that were identified by review of medico-legal cases. Although this study reports a higher rate than those previously published in the literature, this is still likely an underestimate because it relies on voluntary reporting by practitioners.

Beyond just reporting the rate of RFB, the authors estimate the ability of the manual counting protocol to detect and prevent these events. Most practitioners anecdotally lament the limitations of the manual count, but this is the first published estimate of its test characteristics: a sensitivity of 77% and specificity of 99%. Because of the low rate of RFB, this correlates to a low positive predictive value; only 1.6% of discrepant counts was actually associated with a RFB, leading practitioners to frequently disregard the discrepancy or rely on routine postoperative imaging for further evaluations. Disturbingly, they found that one-third of discrepant counts did not prompt an intraoperative x-ray despite this being the standard procedure at the study institution. It is important to note, as the authors point out, that these estimates do not take into account the missing items that are identified on interim counts.

Previous literature reported that 88% of RFB were associated with a correct count¹; however, this is the first report of the likelihood of a RFB given a counting discrepancy. They report a positive likelihood ratio of 113, meaning that the odds of a retained foreign body are increased 100 times if there is a persistent discrepancy between the initial and

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final sponge counts. This suggests that interventions to improve the accuracy of the counting protocol would decrease the rate of RFBs.

Needles were the most commonly miscounted item in Egorova's series, whereas most previous studies suggested that surgical sponges are at highest risk of being inadvertently left in patients. This likely reflects the different methodologies by which cases are identified. Needles are more difficult to locate once they are misplaced, leading to a lower rate of reconciliation and a higher rate of self-reporting. Sponges are more often detected on postoperative imaging and more likely to lead to clinical sequelae, and therefore more likely to result in legal action and identification in malpractice claims series.

Needles are a more complicated clinical issue than surgical sponges. Surgical sponges have been associated with bowel perforation, fistula, obstruction and even death.^{1,6} The risk of retained needles, especially small needles, appears to be significantly lower. However, whether there is no harm or just a lower incidence of harm is unknown. Egorova and colleagues suggest that even small needles can increase patient risk when undergoing magnetic resonance imaging, requiring that the patient be informed of a discrepant count and the potential for a retained needle. The second paper by Ponrartana et al importantly documents the futility in performing x-rays for needles that are smaller than 10 mm in diameter, which approximately corresponds to a suture 6-0 or finer.⁷

Considering these 2 important studies as well as the knowledge amassed over the last decade since the first investigations of RFB were performed, there is now sufficient evidence to suggest some specific approaches to reducing RFB. They include both policy changes as well as direction for research and are as follows:

1. The current manual counting protocol plays an important role in detecting RFB and should be consistently used.
2. The odds of a RFB are increased 100 times if the count is discrepant. All discrepant counts should prompt an x-ray unless the item that is discrepant is a needle less than 10 mm in size (approximately 5-0 or 6-0).

3. The counting protocol can become disabling in certain instances.⁸ Each institution should consider designating other instances where the count should be suspended and an x-ray automatically performed to rule out RFB. Examples include emergency cases or cases requiring an exceptionally large number of sponges.
4. Technological adjuncts such as bar coding and radiofrequency identification should be developed and investigated and where available considered for adoption. Cost must be included in these analyses and compared with the costs reported by Egorova et al.
5. Prospective analyses of the counting protocol should be performed to accurately determine the rate with which discrepancies occur. The study by Egorova et al suggests that they are more common than previously thought but are likely still markedly underestimated.

As a research community, we have made great strides in understanding how and why surgical equipment can be retained following an operation. As technologic adjuncts are developed and implemented, it will be important that we continue to monitor these devastating events and work toward their prevention.

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