ORIGINAL ARTICLE

Assessment of Radiofrequency Device Sensitivity for the Detection of Retained Surgical Sponges in Patients With Morbid Obesity

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Hypothesis: Retained surgical sponges are serious medical errors that result in negative patient outcomes. A radiofrequency (RF) mat for the operating room bed has recently been introduced to detect the presence of a retained surgical sponge. The study objectives were to evaluate the sensitivity and specificity of the RF mat for the detection of surgical sponges through the torso of individuals with varying body habitus and to compare the sensitivity of the RF mat with that of the RF wand. We hypothesized that the sensitivity and specificity of the RF technology would be comparable to published findings of the manual sponge count by operating room personnel.

Design: A prospective, crossover, double-blinded study design was used. Participants served as their own controls.

Setting: Large Midwestern academic medical center.

Participants: In total, the first phase of the study enrolled 203 participants, including 129 (63.5%) with morbid obesity. One hundred seventeen of 203 participants were also enrolled in the second phase of the study.

Main Outcome Measures: The study participants reclined in a supine position on top of an RF mat. Four surgical sponges were sequentially placed on top of the torso in locations approximating the abdominal quadrants. The torso was scanned for sponges. In a subset of participants, 4 surgical sponges were sequentially placed underneath the torso, and an RF wand was passed over the abdomen.

Results: Overall, 812 readings were obtained with the RF mat, and 468 readings were obtained with the RF wand. Twelve false-negative readings were obtained with the RF mat, exclusively in participants with super morbid obesity (body mass index [calculated as weight in kilograms divided by height in meters squared] >50.0). Overall, the sensitivity of the RF mat was 98.1%, and the specificity of the RF mat was 100.0%. In the subset of 117 participants in whom the RF wand was also used, the sensitivity and specificity of the wand were each 100.0%.

Conclusions: The sensitivity and specificity of RF device technology are much higher than those of surgical sponge counts or published findings on the use of intraoperative radiographs to identify retained surgical sponges. The RF wand is more sensitive than the RF mat in individuals with morbid obesity.

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RETAINED SURGICAL ITEMS (EG, sponges, needles, and instruments) were the most frequently reported sentinel events in a 2011 report,[1] and they occur in an estimated 1 case per 5500 surgical procedures.[2] These serious adverse events result in negative patient outcomes, including reoperation (in 69%-83% of retained surgical items),[3,4] readmission or prolonged hospital stay (in 30%-59%),[3,4] infection or sepsis (in 43%),[3] fistulas or bowel obstructions (in 15%),[3] visceral perforation (in 7%),[3] and death (in 2%).[3]

Sponges account for 48% to 69% of retained surgical items.[2-4] Cotton gauze causes a more serious tissue reaction than metal items. Although surgical items have been inadvertently retained in all body cavities, studies[2,4,5] have consistently found that the abdomen is the most frequently involved location (representing 46%-55% of retained surgical items).

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In recent years, a national focus on patient safety and prevention of adverse events in health care has increased tremendously. The National Quality Fo-

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rum[6] now considers retained surgical items to be serious reportable events. The Joint Commission[7] requires that these sentinel events be investigated thoroughly and corrective action taken. At least 27 states and the District of Columbia require public reporting of these events.[8] The Centers for Medicare & Medicaid Services[9] will no longer reimburse for the additional patient care required to treat patients who sustain a retained surgical item. Negative patient outcomes, coupled with public awareness and financial incentives, provide impetus for the surgical team to evaluate current practices and to consider additional options for preventing retained surgical sponges.

Current standards for the prevention of retained surgical sponges rely heavily on manual counting by operating room personnel, an ongoing process requiring attention throughout the procedure.[10] A 2011 study[11] identified 57 potential failures during this process, perhaps explaining why the surgical counts do not adequately prevent retained sponges. A retrospective review[12] of adverse events between 2000 and 2004 in a New York City hospital system found the sensitivity of surgical counts to be 77.2% and the specificity to be 99.0%; the positive predictive value was 1.6%. In another large study,[2] 62% of retained surgical items were detected by postoperative radiography after the surgical count was reported as being correct.

If the surgical count is incorrect, it is common practice to obtain an intraoperative radiograph to rule out retention of a surgical item. This process requires extended time in the operating room, and the accuracy of these radiographs is suboptimal. In a large study,[2] intraoperative imaging failed to detect 33% of retained items.

Radiofrequency (RF) technology is available for the detection of retained surgical sponges. An RF chip is imbedded into the fabric of the sponges. A wand, connected to a detection console, is used to scan the patient. If a sponge is detected, the console triggers an alarm. In a study[13] of 210 individuals, including 101 with morbid obesity, the sensitivity, specificity, and positive predictive value of this technology were each 100.0%. However, this technology requires reliable use by the surgical team. Scanning too far from the torso could lead to false-negative results.

Recently, an RF mat has been introduced to automate the scanning process. The mat is placed under the patient's torso before the surgical procedure. On completion of surgery, a button is pushed on the console, and the mat scans the patient for a retained sponge. This technology avoids the potential for most human error during scanning. A systematic evaluation of this technology is needed to determine its sensitivity and specificity, particularly in patients with morbid obesity, a known risk factor for retained items.[3]

METHODS

This study had the following objectives: (1) to evaluate the sensitivity and specificity of the RF mat for the detection of surgical sponges through the torso of individuals having varying body habitus, including those with morbid obesity, and (2) to compare the sensitivity of the RF mat with that of the RF wand.

STUDY DESIGN

A prospective, crossover, double-blinded study design was used, with participants serving as their own controls. The study was conducted in a large Midwestern academic medical center. The protocol was approved by the university's human research institutional review board, and participants gave written informed consent.

Patients and visitors in a bariatric clinic were invited to participate in the study. Inclusion criteria were adult status, ability to give informed consent, and competency in reading and understanding English. Exclusion criteria were current pregnancy, infection control isolation, inability to lie in a supine position, or the presence of an implanted electronic medical device.

Participants served as their own controls. Using a random number generator (http://www.random.org/integers), sponges were randomly assigned to the abdominal quadrants in an overall ratio of 3 RF sponges to 1 plain (control) sponge. Each participant could receive zero to 4 RF sponges, and the remaining sponges were controls. This ratio was based on the assumption that knowing that a sponge has been retained is more important to surgeons than correctly identifying that a sponge is not present. Sponges were sealed in opaque bags, and the persons performing the scanning were blinded to the type of sponge.

The RF mat (RF Assure Detection System) was placed on top of the mattress of a transport cart and was connected to an RF detection system console (RFS Assure Detection System model 200; both from RF Surgical Systems Inc). The RF mat and detection console were calibrated as specified by the manufacturer. Participants were weighed and measured using a self-calibrating scale. Next, they were interviewed to obtain demographic data (age, sex, and self-identified race/ethnicity). These data were considered important because they might influence body habitus. Participants were asked to empty their pockets and to remove electronic devices (eg, cell phones) before being assisted into a supine position on top of the RF mat. Abdominal height was measured from the mat to the highest point of the abdomen in the supine position. An initial RF reading was performed to verify the absence of any electrical interference. Next, a sponge was placed on top of the participant's torso in a location approximating an abdominal quadrant. After the sponge was placed, the participant was scanned using the RF mat. The outcome was a positive or negative response. A positive response was defined as an audible and visual alarm from the console. A negative response was defined as the absence of an alarm. The sponge was removed, and the process was repeated with the other 3 abdominal quadrants. Data were recorded manually and were verified with electronic data downloaded from the console.

SAMPLE SIZE

The sample included 203 participants. This sample size was determined using a power analysis based on a study by Li and Fine.[14] Individuals with morbid obesity likely pose the greatest challenge to the sensitivity of the measurement because of the greater distance between the sponge and the RF mat. These participants were the focus of the power analysis. In total, 200 readings from 50 participants with morbid obesity allowed for testing 95.0% sensitivity vs 99.0% sensitivity, with 90.0% power and a .05 type I error rate. This sample size was sufficiently powered to test the difference between 95.0% specificity and 99.0% specificity. The enrollment of 203 individuals from locations where patients with morbid obesity are treated was projected to include 50 individuals (25%) with morbid obesity after allowing for the possible withdrawal of 3 participants.

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Table 1. Detection of Surgical Sponges Using the Radiofrequency Mat in 203 Study Participants

Variable	Without Morbid Obesity (n = 74)	With Morbid Obesity (n = 129)	Overall (N = 203)
No. of readings			
Total	**296**	**516**	**812**
True-positive result[a]	228	378	**606**
False-positive result[a]	0	0	**0**
True-negative result	68	126	**194**
False-negative result	0	12	**12**
% (95% CI)			
Sensitivity	100.0 (98.3-100.0)	96.9 (94.7-98.2)	98.1 (96.6-98.9)
Specificity	100.0 (94.7-100.0)	100.0 (97.0-100.0)	100.0 (98.1-100.0)
Positive predictive value	100.0 (98.3-100.0)	100.0 (99.0-100.0)	100.0 (99.4-100.0)
Negative predictive value	100.0 (94.7-100.0)	91.3 (85.4-95.0)	94.2 (90.1-96.6)

[a] A positive response was defined as an audible and visual alarm from the console. A negative response was defined as the absence of an alarm.

STATISTICAL ANALYSIS

Data were analyzed using commercially available software (SAS version 9.3; SAS Institute, Inc). Descriptive statistics were used to analyze the participants' demographics (age, sex, and race/ethnicity) and body size (height, weight, and body mass index [BMI, calculated as weight in kilograms divided by height in meters squared]). Sensitivity was determined by the proportion of correctly identified positive responses (true positives) to the sum of the numbers of true positives and incorrectly identified negative responses (false negatives). Specificity was determined by the proportion of correctly identified negative responses (true negatives) to the sum of the numbers of true negatives and incorrectly identified positive responses (false positives). The positive predictive value was calculated by dividing the number of true positives by the sum of the numbers of true positives and false positives. A 95% CI was estimated using the Wilson score method.[15]

RESULTS

FIRST PHASE

In total, 203 participants (median age, 44 years; age range, 18-76 years) completed the first phase of the study. The demographics of participants reflect the population served in the study setting: 183 (90.1%) were of white race/ethnicity, and 153 (75.4%) were female. The height of participants varied (median [SD], 167.5 [9.1] cm; range, 145.0-200.5 cm), as did their abdominal height (median [SD], 30.5 [5.3] cm; range, 16.5-50.0 cm) and weight (median [SD], 121.9 [37.3] kg; range, 57.0-251.1 kg). Their BMIs ranged from 20.9 to 78.8. The BMI distributions among 203 participants in the study cohort were 20 individuals with a BMI of 20.0 to 29.9, 54 with 30.0 to 39.9, 74 with 40.0 to 49.9, 36 with 50.0 to 59.9, 14 with 60.0 to 69.9, and 5 with 70.0 to 79.9. Overall, 183 participants (90.1%) were obese, with a BMI exceeding 30.0. One hundred twenty-nine participants (63.5%) were morbidly obese, with a BMI exceeding 40.0. Fifty-five participants (27.1%) were super morbidly obese, with a BMI exceeding 50.0. The largest participant had a BMI of 78.8.

Participants had various internal metal implants that did not activate the RF alarm. Likewise, jewelry (including numerous body piercings with adornments and bullets) did not interfere with the RF readings. Implants and prostheses included the following: pin, staple, aortic graft, cardiac stent, breast implant, joint prosthesis, plate and screw, dental prosthesis, radiation makers, fallopian tube clip, intrauterine device, and spinal fusion hardware. Adornments included a watch, bracelet, necklace, facial ring, finger ring, tongue ring, and cervical ring. Other items included a bullet, gunshot, gastric tube, and urinary catheter with clamp.

Four measurements were obtained per participant with sponges on top of the torso, approximating each of 4 abdominal quadrants. Of 812 RF readings obtained with the mat, 606 were true positives, zero were false positives, 194 were true negatives, and 12 were false negatives, with the latter exclusively in participants with morbid obesity. Using the RF mat to detect sponges, the overall sensitivity was 98.1% (**Table 1**), and the overall specificity was 100.0%. In participants without morbid obesity, the sensitivity and specificity of the RF mat were each 100.0%. In participants with morbid obesity, the sensitivity was 96.9%, and the specificity was 100.0%.

The BMIs of 10 participants with 12 false-negative readings ranged from 50.2 to 78.8 (median [SD], 65.2 [8.4]), and their abdominal heights ranged from 33.0 to 50.0 cm (median [SD], 38.7 [5.1] cm). Their heights ranged from 165.0 to 191.5 cm (median [SD], 184.8 [8.3] cm), and their weights ranged from 180.1 to 251.1 kg (median [SD], 214.9 [23.5] kg). The false-negative readings were in the right upper quadrant (n = 4), right lower quadrant (n = 6), and left lower quadrant (n = 2). There were no false-negative readings in the left upper quadrant.

SECOND PHASE

A preliminary review of our findings showed that the sensitivity of the RF mat was less than that in a previous study of the RF wand. To provide a more comprehensive evaluation, we added a second phase to the study to compare the sensitivity of the RF mat with that of the RF wand in a subset of the same individuals. After scanning the participant using the RF mat, 4 additional scans were performed using an RF wand (Blair-Port Wand model 0020; RF Surgical Systems Inc). The RF wand was used as calibrated by the manufacturer. A sponge, sealed in an opaque

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Table 2. Comparison of the Detection of Retained Sponges Using the Radiofrequency (RF) Mat vs the RF Wand in 117 Participants

Variable	Without Morbid Obesity (n = 32)		With Morbid Obesity (n = 85)	
	RF Mat	RF Wand	RF Mat	RF Wand
No. of readings				
Total	**128**	**128**	**340**	**340**
True-positive result[a]	93	93	250	262
False-positive result[a]	0	0	0	0
True-negative result	35	35	78	78
False-negative result	0	0	12	0
% (95% CI)				
Sensitivity	100.0 (96.0-100.0)	100.0 (96.0-100.0)	95.4 (92.2-97.4)	100.0 (98.6-100.0)
Specificity	100.0 (93.1-100.0)	100.0 (93.1-100.0)	100.0 (95.3-100.0)	100.0 (95.3-100.0)
Positive predictive value	100.0 (96.0-100.0)	100.0 (96.0-100.0)	100.0 (98.5-100.0)	100.0 (98.6-100.0)
Negative predictive value	100.0 (90.1-100.0)	100.0 (90.1-100.0)	86.7 (78.1-92.2)	100.0 (95.3-100.0)

[a] A positive response was defined as an audible and visual alarm from the console. A negative response was defined as the absence of an alarm.

bag, was placed behind the right upper quadrant of the participant's torso. The RF wand, connected to the RF detection console, was passed over the abdomen parallel to the abdominal surface, from right thorax to right groin, right groin to sternum, sternum to pubis, pubis to left thorax, and left thorax to left groin for each sponge. The presence of an audible and visual alarm indicated a positive test result and the detection of a sponge. The absence of an alarm indicated a negative test result. The sponge was removed, and the procedure was repeated with sponges over the remaining 3 abdominal quadrants.

A subset of 117 participants who completed the first phase of the study also completed the second phase; 85 (72.6%) were morbidly obese (**Table 2**). In total, 468 readings (355 true positives and 113 true negatives) were obtained using the RF wand and were compared with 468 readings previously obtained in the same participants using the RF mat. The sensitivity and specificity of the RF wand were each 100.0%. In participants with morbid obesity, the negative predictive value was 100.0% for the RF wand compared with 86.7% for the RF mat in the same individuals. In all 10 participants with false-negative readings using the RF mat, the RF wand correctly identified all sponges and did not issue an alarm for any sponges that were not present.

COMMENT

To our knowledge, this is the first published systematic evaluation of the RF mat for the detection of surgical sponges. In an earlier study[13] that included individuals with morbid obesity, the sensitivity, specificity, and positive predictive value of the RF wand were each 100%. However, the adoption of this technology has been met with some resistance, in part because of concerns about the potential for human error in the scanning process. The use of the RF mat eliminates the potential for human error during scanning, yet we found no published report on the accuracy of the technology.

To determine the appropriate use of the RF mat in an operating room, we needed to know the size of patients for whom the technology is sufficiently sensitive to detect sponges. This information is essential because higher BMI has been identified as a risk factor for retained surgical items.[3] We targeted our recruitment of participants to include individuals with morbid obesity and enrolled a sufficient sample size to determine the sensitivity and specificity in persons with varying body habitus. We show herein that the use of the RF mat is not as accurate as the use of the RF wand in patients with supermorbid obesity. The findings of this study are generalizable to the broad range of body habitus among patients undergoing surgical procedures.

The results of the study provide patient size parameters for the appropriate use of the RF mat. The RF mat is narrower than the operating room bed, and the abdominal cavity of patients with morbid obesity can exceed the width of the mat. This likely explains the false negatives that were found with the use of the RF mat in 10 participants with a BMI exceeding 50.0. Because the RF wand was able to scan closer to all parts of the participant's abdomen, all readings with the RF wand in these individuals were accurate. Therefore, the use of the RF wand is preferable to the use of the RF mat in patients with a high BMI.

Our study findings support the results of an earlier study[13] that found that metal implants and jewelry often seen on surgical patients do not interfere with the detection of retained RF sponges. This is reassuring because of the increasing number of patients with implants or body jewelry.

RF DEVICE VS SURGICAL COUNT

The RF device technology was much more sensitive than the manual surgical counts as reported in a previous study.[12] The surgical count, developed by the Association of Perioperative Registered Nurses with representation from the American College of Surgeons, has been widely used for decades.[10] In a 2008 study,[13] the sensitivity of surgical counts was 77.2%. This leaves a wide margin for counts to be reported to the surgeon as correct, when in fact a sponge may remain in the wound. Studies have found in 62%[2] and 88%[16] of instances that retained surgical items remained when the count was reported as correct.

Count discrepancies occur in 1 of 8 surgical cases.[17] These disagreements require additional time searching the wound, trash and linen receptacles, and the operat-

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ing room for the surgical item. This can easily add more than 15 minutes to the operating time.

Technology has been developed to enhance the accuracy of the surgical count. A pocketed bag system is available to separate sponges. A dot matrix (bar coded) sponge counter is also available. However, this technology does not evaluate for the presence of a retained sponge.

In contrast, the RF scanning procedure to detect the presence of a sponge took less than 1 minute. When a sponge was detected, the alarm sounded in less than 30 seconds. The RF wand can also be used to locate a sponge in a linen or trash receptacle. Therefore, the use of the RF device technology can save significant time and additional operating room costs associated with resolving a count discrepancy.

RF DEVICES VS OTHER TECHNOLOGY TO IDENTIFY A RETAINED SPONGE

Other technology is available to rule out the presence of a retained surgical sponge, namely, radiography and RF identification technology. The sensitivity of intraoperative radiography has been found to be 67%.[2] A study[5] of closed insurance claims found that 10.3% of retained sponges were falsely reported as negative on radiography results. Intraoperative imaging is time-consuming and exposes the patient to unnecessary irradiation. Using radiography to rule out the presence of a retained sponge in the abdomen of a patient with morbid obesity often requires 2 overlapping radiographs, potential contamination of the surgical drapes, and an estimated 30-minute extension to the operating room time. The cost of an intraoperative radiograph to rule out a retained surgical sponge has been reported to be $705.[18]

Radiofrequency identification technology is different from RF detection technology and identifies the type of sponge. Each sponge is imbedded with a chip coded with an identification number that can be detected by a scanner. An initial clinical evaluation of this technology in 8 individuals found that the technology correctly located RF identification sponges in all participants; however, the study[19] was underpowered to determine the sensitivity and specificity, and the body habitus of the participants was not described.

LIMITATIONS

A limitation of our study is that sponges were placed outside of, rather than in, the abdominal cavity. This may not accurately approximate intra-abdominal assessment. However, placing the sponge a greater distance from the RF mat or RF wand actually poses a greater challenge for detection than with the use of intra-abdominal locations; the distance between the scanning device and the sponge is significantly greater, particularly in individuals with morbid obesity. So, the sensitivity and specificity of the RF mat in clinical use may be greater than reported in this study.

In conclusion, this is the first published study of the sensitivity and specificity of the RF mat for the detection of retained surgical sponges. The sensitivity, specificity, and positive predictive value of the RF mat were each 100.0% in individuals with a BMI of less than 40.0. In participants with morbid obesity (BMI >40.0), the sensitivity was 96.9%. This level of accuracy far surpasses that found in previous studies of manual surgical counts (77.2%)[12] and intraoperative radiography (66.7%).[2] The sensitivity of the RF wand was 100.0%, consistent with a previous study.[13] Therefore, both the RF mat and the RF wand are appropriate options to consider when implementing changes to promote patient safety. The higher sensitivity of the RF wand in individuals with morbid obesity indicates that its use is preferable in patients with a high BMI. Additional longitudinal studies are needed to determine the effect of the implementation of this technology on the incidence of retained sponges.

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