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Radio-frequency identification of surgical sponges in the abdominal cavity of pigs

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ABSTRACT

Background: Counting the sponges is an important step in surgical procedures. A miscount may impact the patient's health, and it also has legal implications for the surgeon. This is an experimental study evaluating radio-frequency technology used in the perioperative period to identify surgical sponges left in the peritoneal cavity of swine.
Methods: Radio-frequency labeled-disc identification tags were sewn into 40 surgical towels. Twenty labels had the ability to emit radio-frequency waves, and 20 labels were inert to radio-frequency identification. Twenty adult pigs that underwent laparotomy and randomly received two surgical sponges were scanned by a radio-frequency identification antenna.
Results: This method presented a positive predictive value of 100% and 100% specificity and sensitivity, as all of the tagged surgical sponges were detected.
Conclusion: Radio-frequency identification has been proved to be a useful method for the identification of surgical sponges within the abdominal cavities of swine.

1. Introduction

Counting sponges is an important step in surgical procedures, as miscounting may impact the patient and the doctor.

The first study of postoperative findings of foreign bodies was conducted by Wilson (1884) with 30 cases registered in the U.S. and Europe. Following that report, the number of cases and their complications continued to increase, with Crossen in 1940 reporting 307 cases of retained sponges in the abdominal cavity after surgery and 153 cases of foreign bodies in other sites [1].

The actual incidence of foreign body retention in the abdominal cavity is not well elucidated, and data for this type of event are reported as "unusual". Each study reports a different number of cases, ranging from 1 in 100 operations to 1 in 18,000 laparotomies [2–7]. These results are probably related to the low number of reports regarding this matter and the scant literature addressing this subject.

The study, "Risk Factors for Retained Instruments and Sponges after Surgery", published in The New England Journal of Medicine, aimed to assess the risk factors arising from the presence of foreign bodies in various body cavities. Approximately 69% of the 54 foreign bodies found corresponded to surgical dressings, and 54% of the foreign bodies were found in the abdominal or pelvic cavity [2]. In this same study, 61 cases of retained foreign bodies related to surgical procedures were identified, and a multivariable analysis presented three factors that were significantly associated with a greater risk that surgical materials will be left in the body: emergency procedures, unexpected situations during the surgical procedure and an elevation in the Body Mass Index [2].

Even though the clinical presentation of retained foreign bodies is highly variable and often asymptomatic [8], the most common features are intestinal obstruction (present in approximately 67% of cases), fever, weight loss, vomiting, and abdominal pain [9].

Invariably, during a trial, the verdict is favorable to the patient [10]. The surgeon is responsible for the observation of the surgical field and the identification of possible foreign bodies retained in a cavity, independently of whether another member of the team is directly responsible for accurately counting the dressings.

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The first Radio-frequency Identification patent was filed by Mario W. Cardullo for an active Radio-frequency Identification tag with rewritable memory on January 23, 1973 [11]. Since that date, Radio-frequency Identification has been applied in different aspects of our lives. Another application of Radio-frequency Identification is in its form as small labels, also called "tags," that can be applied to objects, people and animals. These tags contain a silicon chip and an antenna that responds to the radio signals sent by a transmitter [12].

2. Methods

This study was performed at the experimental surgery laboratory of the Faculdade Evangélica do Paraná in Curitiba, Brazil. Sterile active waterproof electronic oval-shaped tags composed of ABS/EPOXY (Daily RFID Co., Limited, Guanzhou City, Guangdong Province, China), measuring 2 cm in diameter and 0.3 cm in thickness were sewn into 20 surgical towels measuring 23 × 25 cm. The tags meet all of the essential requirements for heat, pressure and chemical resistance used for the contactless tracking of garments in the textile rental and dry cleaning industries. The tags have an operating frequency of 125 KHz or 13.56 MHz, an operating temperature of −25 °C to +85 °C, a storage temperature of −25 °C to +185 °C and can be read up to 100,000 times. Additionally, 20 inactive electronic tags, with the same size and shape, were sewn into another 20 surgical towels.

Twenty adult pigs (Sus scrofus domesticus) of the landrace breed, after general anesthesia and antisepsis, underwent laparotomy with manipulation of the bowel. After the peritoneal cavity was opened, the animals randomly received two surgical sponges in the following regions: right upper quadrant (RUQ), left upper quadrant (LUQ), left lateral paracolic gutter (LPG), right lateral paracolic gutter (RPG), right subphrenic space (RSS) and left subphrenic space (LSS). The surgical dressings were divided into two groups, Radio-frequency Identification and non-Radio-frequency Identification, numbered from 1 to 40, and distributed at random.

With the abdominal cavity exposed, the animals underwent scanning using the radio frequency detector for the Medium Range UHF Reader DL930 (Daily RFID Co., Limited, China) in the 920 MHz range, sequentially from the cranial caudal sternal notch to the iliac wing, and from the left and right of the midline to the pubic region. The scanner was kept in the proximity of the animal's skin, at a distance of approximately 30–50 cm. This scanner was connected to a computer (Apple Macbook Pro 15″ 3.3 GHz), equipped with software that was specially designed to recognize the electronic tags placed in the pigs' abdomens.

The ethical committee of Faculdade Evangelica do Parana, in accordance with the standards previously established by the Brazilian Society of Science in Laboratory Animals (SBCAL), approved this study under the number 129259/2012-8.

The data for the tests that were positive for the identification of radiofrequency waves into the abdominal cavity were collected. The animals were killed with an intravenous lethal dose of thiopental.

We observed a positive predictive value, a negative predictive value, and sensitivity and specificity of the test for the detection of radiofrequency tagged surgical dressings.

3. Results

The 40 sponges, 20 tagged and 20 non-tagged, were distributed randomly into seven predetermined spaces: the right upper quadrant (RUQ), left upper quadrant (LUQ), left lateral paracolic gutter (LPG), right lateral paracolic gutter (RPG), right subphrenic space (RSS) and left subphrenic space (LSS). The surgeon who conducted the distribution of the surgical towels was not the same surgeon who scanned the operative field so that the person who performed the scans was unaware of which of the surgical towels were tagged.

The abdomen of each animal was scanned with the electronic reader. When it emitted a beeping sound it indicated the presence of a tagged sponge. The presence of a tagged sponge was later confirmed by manually searching for the sponge in the area indicated and ensuring that the sponge contained a Radio-frequency Identification chip.

All 20 of the surgical sponges that were reactive to Radio-frequency Identification scanning were detected correctly in all of the tests. All 20 of the non-tagged sponges showed negative readings. Therefore, this method presented a positive predictive value of 100% and 100% specificity and sensitivity because all of the tagged surgical sponges were detected in each of the seven spaces.

In addition, the scanner, representing a negative predictive value of 100%, did not detect the other 20 non-tagged surgical sponges. This result is important for verification of whether the scanner reacts with non-tagged sponges.

4. Discussion

The first report of using radiofrequency identification technology to detect surgical gauze sponges was published in 2006 [13]. In this initial evaluation, 28 RFID sponges and eight untagged sponges in eight patients who were undergoing abdominal or pelvic surgery were used. The results were similar to the present study, with a sensitivity and specificity of 100% (Table 1).

Another similar study was performed at the University of Nebraska and published in 2007 [14]. However, this study first aimed to test if the radiofrequency technology could be safely used within body fluids. Then, the RFID sponges were located in porcine cavities, which resulted in an accuracy of 100%. In a recent study published in 2012, Kranzfelder and cols used a stationary RFID system for real-time surgical sponge monitoring in vitro, and all of the 20 sponges used were detected [15].

The count discrepancies occur because of human error. Up to 88 percent of retained foreign body cases occur when the sponge and instrument count have been declared to be correct [2]. The initial count at the beginning of the procedure may be wrong, or an interim count may have been rushed while nursing teams were changing shifts, or in some cases, the count is omitted altogether as it may occur during an emergency laparotomy or in complex surgical procedures. Other factors related to the operating room environment that contribute to count discrepancy include incomplete, interrupted, or absent sponge counts, absence of a clear standardized count policy, and using non-radiopaque sponges [6].

The errors related to sponge counts also implies a greater time investment by the surgical team, as the risks of retained foreign bodies in human cavities are well elucidated and a frequent concern for surgical teams. In a study that detailed the activities during nine complex general surgery cases performed in an academic hospital, counting was an auxiliary task that was in direct competition with the primary patient-centered activities [16]. An average of 35 min per case was dedicated to counting, representing

Table 1
Results of the scanning of RFID-tagged surgical sponges in 20 swine; positive predictive value and negative predictive value.

	Radio-frequency identification reactive	Radio-frequency identification non-reactive	Predictive values
Surgical sponges +	20	0	100%
Surgical sponges −	0	20	100%

14.5 percent of the nurses' time during the operation. Despite the time involved, 17 count discrepancies were observed, 11 of which disrupted the activities of the surgical team. The observational team identified two events that it labeled as "safety-compromising" that occurred when attempts were being made to reconcile an inconsistent count.

In the U.S., the 2002 National Quality Forum listed retained items among a group of completely preventable medical errors that should never happen to patients, the so-called "never events." Retained surgical materials are also considered "always wrong" by the Leapfrog initiative, mandating acknowledgment, a direct apology to the patient, and the hospital's payment for all costs incurred as a result.

When a retained sponge is identified in a symptomatic patient, it should be removed [2,17,18]. However, the operative removal of retained sponges, particularly those present for a prolonged time, can be difficult and are associated with high complication rates. The mortality associated with retained sponges ranges from 11 to 35 percent [18]. Most intra-abdominal retained foreign bodies require laparotomy for removal; however, laparoscopic removal has been described for both retained instruments and sponges [19,20].

The differential aspect of our research is the use of a non-stationary device that allows the identification of tagged surgical sponges in real time. During our experiment, it was observed that the reading of the tagged surgical sponges was approximately less than 1 s, which did not represent any delay in the procedure. In addition, the reading was indicated by a sound emitted from the reader and was confirmed by the software. This software It not only indicates which surgical sponge was identified but also how many times the tag could be read. Many times, a surgical sponge may be in a place that is difficult to access with a stationary device, which requires moving the patient or the equipment.

We tested our tagged sponges randomly in the primary anatomical spaces of swine (the right upper quadrant, left upper quadrant, right subphrenic space, left subphrenic space, right lateral paracolic gutter and left lateral paracolic gutter) that could easily correspond to the anatomical structures in a human body. Before placing the sponges into the cavities, they were soaked in saline to simulate body fluids. The primary objective was to identify whether an organ would deflect the Radio-frequency Identification wave emanating from the tag and prevent the scanner from finding a sponge, but it was discovered later that Radio-frequency Identification waves are not deflected in this scenario.

It is also important to clarify that the time spent locating the tagged sponges by scanning the swine's cavities was approximately 15 s, representing a reduced time for a surgical operation. When the scanner locates a tagged sponge, a digital or audio alarm is triggered that indicates the precise placement of the sponge. All of the other 20 non-tagged sponges were inert to the scanner and did not trigger the audio alarm.

Another crucial aspect of this work was the cost involved in our RFID system. The scanner costs approximately $400.00, and each electronic tag costs approximately $0.50. Considering that one scanner can be used multiple times and that the electronic tags can be read up to 100,000 times, there is a great cost-benefit because the medico-legal aspects of retained foreign bodies represent a greater cost to the hospital.

Our study showed that RFID tags have high sensitivity and specificity rates. The RFID scanning system can be used by anyone in the OR, and its size does not compromise the sequence of the surgical procedure.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.amsu.2014.03.002.

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