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Three years evaluation of retained foreign bodies after surgery in Iran

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ABSTRACT

Background: Medical errors such as retained foreign bodies (RFB) during surgery are not well studied. To define risk factors associated with this type of error, we performed retrospective study.
Methods: We reviewed medical records for unintentional foreign object remaining in the body during surgery such as gender, age, surgery ward, and incident reports referred to several forensic medicine administrations as well as adverse effects of retained foreign bodies and methods for detection of them over a 3-years period from January 2008 through May 2011.
Results: Thirty eight patients were involved in the study to have retained foreign bodies (73% sponges and 27% other instruments including 7 (18.42%) cases of other bandages, 2 cases (5.26%) of scissor and 1 case (2.63%) of forceps). The general surgery ward was most commonly involved (47%) followed by the gynecology surgery ward (34%). Men (58%) were more involved with RFB than women (42%).
Conclusion: Considering the most frequent type of retained foreign bodies and also more frequent involved surgery wards besides detection methods for RFB, a mixed of preventing protocols such as regular counting of devices, post-operative X-ray with radiopaque markers and exact evaluation of surgery site should be employed to reduce the occurrence of retained foreign bodies and its complications.

1. Introduction

Surgical cases where instruments or sponges are left behind following a surgical procedure are fortunately uncommon, but potentially dangerous medical errors [1]. The literature reports an estimated 1:1000 to 1:1500 intra-abdominal surgeries result in a retained foreign body (RFB) [1,2]. In a systematic review study, the median incidence estimate for retained surgical items was 1.32 events per 10000 surgical procedures [3]. However, the magnitude of the problem is most likely underestimated because of the reluctance on the part of clinicians and hospitals to disclose these types of errors [2].

Although a rare event, one of the most common and poorly understood medical errors in surgery involves leaving sponges or instruments inside patients after surgery [4]. Furthermore, publishing RFB data are often hampered by the confidentiality requirements of insurance and legal claims [5]. However, retained foreign body cases are avoidable, frequently injurious, and are associated with a high likelihood of litigation [1]. Surgical sponges are usually the most commonly reported retained items [6,7]. Incidence estimates varied widely and ranged from no retained sponges 30 to 3.04 retained guidewires 34 per 10000 procedures [3]. In some studies, it was stated that events were discovered even when surgical counts were recorded as correct and/or routine radiographic imaging was performed [8–11]. Objects can be recognized incidentally during the postoperative period, manifest themselves clinically through symptoms or complications, or lay dormant for years [12]. Clinical morbidity resulting from RFB includes persistent inflammation, obstruction, or septic

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complications [7,13]. Operations should include counts of soft goods, needles, miscellaneous items, and instruments, and efforts should be made to prevent retention of fragments of broken devices. If a count discrepancy occurs, the perioperative team should follow procedures to locate the missing item. Perioperative leaders may consider the use of adjunct technologies such as bar-code scanning, radio-frequency detection, and radio-frequency identification [14].

For these reasons, identifying risk factors associated with this type of medical error is important and could lead to changes in operating room policy intended to reduce the errors. We performed a retrospective study to evaluate different aspects of RFB.

2. Materials and methods

In a retrospective study, all cases referred to Iranian forensic medicine administrations for unintentional retained foreign body during 3 years from January 2008 through May 2011 were involved.

In a case series study, the cases were referred to forensic medicine administrations of Iran for compliance about medical errors and malpractice with the focal point of retained foreign bodies. The patients lacking date from their files or incorporative for this study were not included in this study. Totally 43 cases of RFB were referred to legal medicine organization while only 38 cases obtained needed criteria to be involved in the study.

Variables were identified including operating room circumstances, and operating room staff involvement, patients' age, gender, type of retained foreign body, surgery wards, time to discovery of RFB, side effects of RFB and methods of finding RFB.

2.1. Statistical analysis

The data were analyzed using SPSS version 20.0. Descriptive data were presented in Mean ± SD and frequency (%) and non-parametric data were compared using Chi-square test. P values < 0.05 were considered as statistically significant.

3. Results

We identified 38 cases including 22 males (57.89%) and 16 (42.10%) females with the average age of 29.47 ± 6.7 that met our entry criteria to be included in this study. Of the 38 retained foreign body cases, 28 (73.68%) involved sponges and 7 (18.42%) involved other bandages, 2 cases (5.26%) of retained scissor and 1 case (2.63%) of retained forceps (Graph 1). Frequency of sponges were significantly more than other types of RFB. ($P = 0.031$).

The mean time to discovery of RFB was 76 days, with the minimum time of 12 days and longest discovery time of 8.5 years after surgical operation. The retained objects were discovered by either physical exam (12: 31.57%) or radiological evaluation (26: 68.42%). No death was attributable to RFB; however, all of the cases did require a reoperation. The patients experienced morbidity from the RFB including pain (84.32%), fever (51.32%), sepsis (44.73%), intra-abdominal abscess (23.68%) as well as bowel obstruction and bowel perforation (2.63%). There was no case of accidental finding of the retained foreign body and all of them had compliance about fever, pain and, etc.

There were several patients with RFBs presenting as intra-abdominal mass (gossypiboma) whom were reported with retained sponges and bandages, but no case of fistula was reported.

The retained foreign bodies had occurred at different departments including 18 cases (47.36%) at general surgery wards, 13 cases (34.21%) at gynecology surgery wards, 5 cases (13.15%) at orthopedics surgery wards and, 2 cases (5.26%) at cardiac surgery wards (Graph 2). There was no data about surgery place for 5 cases.

Statistical comparison of different surgery wards showed that general surgery was significantly more involved compared with other surgery wards. ($P = 0.023$).

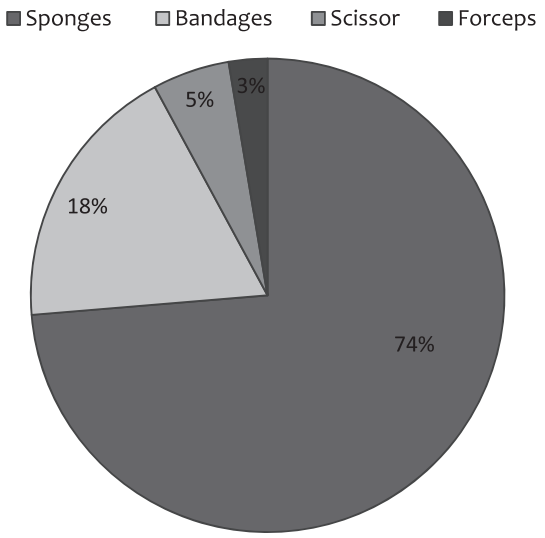

Fig. 1. Frequency of the type of retained foreign bodies referred to forensic medicine administration.

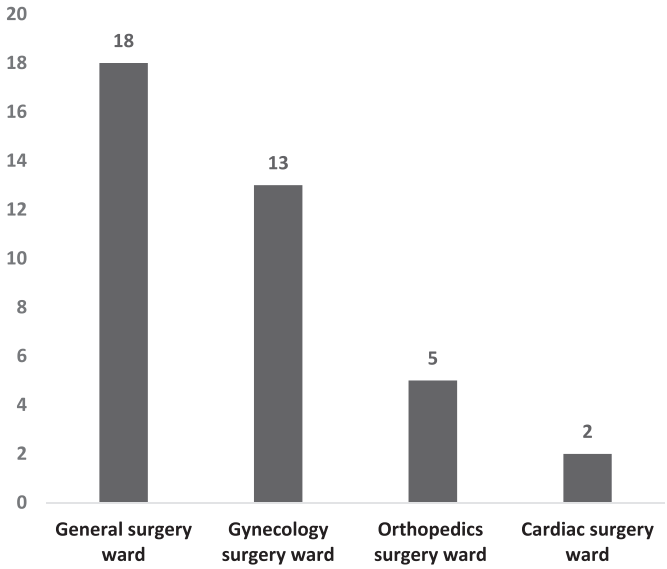

Fig. 2. Involvement of different surgery wards for incidence of retained foreign bodies referred to forensic medicine administration.

Foreign objects were left behind in all body cavities including peritoneal cavity, pleural cavity, gastrointestinal tract, urogenital system, facial area, pelvic cavity with the majority abdominal and peritoneal cavity (55.26%) and thoracic or pleural cavity (18.42%)

Table 1
Involved anatomical area for retained foreign bodies referred to forensic medicine administration.

Anatomical Area	Frequency (%)	P-Value
Peritoneal cavity	21 (55.26%)	0.012
Pleural Cavity	7 (18.42%)	
Gastrointestinal tract	2 (5.26%)	
Urogenital System	3 (7.89%)	
Facial Area	1 (2.63%)	
Pelvic cavity	4 (10.52%)	

areas (Table 1).

4. Discussion

Medical errors have become a focal point for media coverage since the publication of the Institute of Medicine's report on medical errors such as forensic medicine [15]. Despite this negative publicity, the continued medico-legal implications and, more importantly, the remaining patient safety issues, medical errors during surgery have not been well studied [5,16]. Although a rare event, one of the most common and poorly understood medical errors in surgery involves leaving sponges or instruments inside patients' bodies after surgery [1,17].

The natural history of objects left in the body during surgery is highly variable. Objects can be recognized incidentally during the postoperative period, manifest themselves clinically through symptoms or complications or lay dormant for years [16]. Clinical morbidity resulting from RFB includes pain, persistent inflammation obstruction, or septic complications [18]. The current study used a retrospective attempt to identify risk factors that led to the retention of foreign bodies after surgery. Our findings showed that pain, inflammatory fever, sepsis, intra-abdominal abscess and bowel complications were clinical consequences of RFB.

Methodologies for identifying RFB reported previously may have introduced selection bias. Specifically using malpractice insurance files and incident reports alone may underestimate rates of RFB [1,19]. RFB was most frequently observed at general surgery ward followed by women surgery ward and it may be because of patients overload. On the other hand, the most frequent RFB was sponges. The variable rate of RFB in different surgery wards can be related to different amounts of surgery operations performed e.g. general surgery wards usually have the most amounts of surgical operations. Here in Iran, usually no surgery operation is performed in emergency ward and all heavy operations are performed in related surgery rooms, thus, no case of RFB was reported to be from there. Also, as this study was a retrospective study, it was not possible to clarify exactly weather which type of surgery caused RFBs in the patients after orthopedic surgery nor for facial soft tissues.

The present study did not covered BMI, emergency surgery or unexpected changes in operative procedure as significant predictors of RFB. Most objects were discovered via physical exam, X-ray or reported symptoms with discovery time ranging from immediately to 8.5 years after the surgery. Although there were no reported deaths because of the RFB, all of the patients required reoperation and a small proportion of patients experienced complications including sepsis, intra-abdominal abscess, and bowel complications. Universally standardizing and adhering to OR safety protocols should reduce the incidence of RFB. These protocols should include pre-operative and multiple post-operative counts of sponges and other surgical instruments [1,5,19]. Surgeons should routinely inspect the operative field and body cavities for objects before closing [5,16]. All sponges should have radiopaque markers for easy detection during radiography [1,2,20]. Routine radiography in the setting of emergency cases or when multiple major procedures are being performed involving multiple surgical teams have also been suggested.

Ultrasonography, computed tomography (CT) scan, and magnetic resonance imaging are the diagnostic tools available for identifying surgical objects not detected through visual inspection of the operative field and are not usable routinely [21,22]. Body cavity location and the type of missing surgical object should both be considered when choosing an appropriate diagnostic tool. For example, although CT scans are optimal for detecting intra-abdominal retained foreign sponges (i.e., gossypiboma) [23,24], while there can be difficulty in detecting intra-thoracic gossypibomas using CT scans [25,26]. The optimal X-ray technique for detecting lost needles is a mobile image intensifier, however, it should be noted that lost needles smaller than 13 mm will not be detected using any type of scan and the true clinical significance is debatable [27]. Finally, radiographic screening of high-risk cases, regardless of count, ought to be considered [1,2,19,25]. In high-risk cases, radiographic screening may be warranted regardless of count. Based on these data, it is suggested that multiple films be shot so that the entire abdomen can be visualized to reduce the rates of missed objects. The incidence of RFB could be further reduced by changing OR protocols. Counting surgical devices is a with only 77% sensibility [28] and routine surgical postoperative X-ray needs a radiopaque marker and to expose the whole surgical field for maximum efficacy [28]. Electronic dispositive based on barcode detection and other technological adjuncts for counting sponges are being developed [29,30]. However, none of these preventing systems are reliable when used alone [28].

4.1. Limitations of the study

One of the limitations of this study was lack of data about total number of surgery operations for estimation of the frequency of RFB. So, we could not present the frequency of RFB. Our results showed that sponges are the most frequent retained foreign body. One other limitation of this study was small sample size of the study and it can be because of low rate of RFB occurrence. Lacking data about time of the surgery, complexity of the surgery as well as involved surgical teams were other limitations of the study.

5. Conclusion

Retained foreign objects after surgery are associated with multiple major surgical procedures being performed at the same time and an incorrect instrument or sponge count. Identification of these risk factors using case-control analysis may influence operating room policy and reduce these types of errors. Finally, considering the most frequent type of retained foreign bodies as well as most frequent involved surgery wards besides detection methods for RFB, a mixed of preventing protocols such as regular counting of devices, X-ray with radiopaque markers and exact evaluation of surgery site should be employed to reduce the occurrence of retained foreign bodies and its complications.

Conflict of interest

The authors declare no conflict of interest.

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