

Unintentionally retained foreign bodies after surgical procedures. Analysis of 4547 cases

Retenção inadvertida de corpos estranhos após intervenções cirúrgicas. Análise de 4547 casos

DÁRIO VIANNA BIROLINI¹; SAMIR RASSLAN²; EDIVALDO MASSAZO UTIYAMA³

A B S T R A C T

Objective: this study aims to explore the experience of Brazilian surgeons on Unintentionally Retained Foreign Bodies (RFB) after surgical procedures. **Methods:** A questionnaire was sent to surgeons by electronic mail, between March and July 2012. The questions analyzed their experience with foreign bodies (FB), foreign bodies' types, clinical manifestations, diagnoses, risk factors and legal implications. **Results:** in the 2872 eligible questionnaires, 43% of the surgeons asserted that they had already left FB and 73% had removed FB in one or more occasions, totalizing 4547. Of these foreign bodies, 90% were textiles, 78% were discovered in the first year and 14% remained asymptomatic. Among doctors with less than five years after graduation, 36% had already left a FB. The most frequently surgical procedures mentioned were the elective (57%) and routine (85%) ones. Emergency (26%), lack of counting (25%) and inadequate conditions of work contributed (12.5%) to the occurrence. In 46% of the cases patients were alerted about the FB, and 26% of them sued the doctors or the institution. **Conclusions:** challenging medical situations, omission of security protocols and inadequate work conditions contributed to RFB. However, RFB occurs mostly in routine procedures such as cesarean or cholecystectomy, and at the beginning of the professional career, highlighting, particularly in poorest countries, the need for primary prevention. Textiles predominated causing clinical repercussions and they were diagnosed in the first postoperative months. Surgeons were sued in 11.3% of the RFB cases.

Key words: Foreign Bodies. Postoperative Complications. Surgical Instruments.

INTRODUCTION

Unintentionally Retained Foreign Bodies (RFB) causes 70% of reinterventions¹, reaching 80% morbidity and 35% mortality^{2,3}, in addition to significant medical and legal costs^{4,5}. However, RFB still represents a problem without solution⁶.

The sporadic nature of this event (1:1000 to 1:2000)⁷⁻⁹, as well as the stigma of medical malpractice that follows it, still hinder its report and understanding, which is based on case-control studies and limited series. In order to make progress in understanding their occurrence, covering a greater number of cases, this study will examine the experience of surgeons with RFB, assessing some of their characteristics and consequences.

METHODS

The project was approved by the Ethics in Research Committee of the University de São Paulo Medical School under number 493/11. It is a cross-sectional,

observational study carried out by means of a survey developed with the help of the Jotform tool (www.jotform.com) and sent over the Internet to the members of Brazilian societies related to the specialties of Urology, Gynecology, Obstetrics, General, Oncologic and Thoracic Surgery, Coloproctology, and Surgery of the Digestive Tract and Trauma. The responses were voluntary, confidential and anonymous.

In March 2012 those societies began to send e-mails to their members. The forms could be completed for a period of up to three months. Since there were overlapping email addresses between those doctors who participate in more than one society, the site blocked answers coming from the same e-mail and/or Internet Protocol (IP) number, in order to avoid duplicated answers.

Doctors without a specialist title, completed residency or without electronic addresses were excluded from the project. Members with specialist titles in other areas, such as mastology, vascular surgery, head and neck surgery and plastic surgery, were also excluded.

The questionnaire was divided into four parts. The first concerned the information about the doctor's

1. Serviço de Cirurgia de Emergência, Hospital de Clínicas, Faculdade de Medicina, Universidade de São Paulo (HCFMUSP), SP, Brasil; 2. Disciplina de Cirurgia Geral e Trauma, Hospital de Clínicas, Faculdade de Medicina, Universidade de São Paulo (HCFMUSP), SP, Brasil; 3. Serviço de Cirurgia Geral Eletiva, Hospital de Clínicas, Faculdade de Medicina, Universidade de São Paulo (HCFMUSP), SP, Brasil.

experience, such as graduation time and if he/she had already removed, or unintentionally left, some FB. In the second part, in those cases in which RFB had occurred, we verified the information directly related to the FB, as type of surgical instrument, retention time and clinical manifestations. The third part assessed the triggering factors of RFB and analyzed the surgeries that had a higher prevalence. The last part focused on how doctors and patients dealt with ethical issues of RFB and if there were legal implications.

None of the answers was mandatory, although some questions depended on the previous one's affirmative answer. Thus, the percentage of each item was calculated based on the number of responses for each question, which were not always coincident.

RESULTS

We received 2,885 answers. Thirteen forms were discarded since they were incomplete or duplicate, leaving 2,872 questionnaires for analysis.

The respondents comprised 1,021 general surgeons (36%), 1,613 gynecologists and obstetricians (56%) and 238 urologists (8%). Concerning graduation time, 20% of them had less than 10 years; 27% from 11 to 20 years; 28% from 21 to 30 years and 25% more than 30 years.

When asked if they had already removed a FB left by another colleague, 46% of the surgeons graduated for less than five years answered positively, as well as 69% of those graduated up to 10 years, 74% up to 30 years and 78% more than 30 years. On average, 73% of the participants had already removed some FB.

Among those surgeons with less than five years of practice, 36% had already left some FB. This index

amounted to 40% in the group with 11 to 20 years experience and reached 51% in the group with more than 30 years. On average, 43% had left some FB and, of these, 36% more than once.

Of the 4,547 foreign bodies reported, textiles accounted for 90% (Table 1). The retention was diagnosed in the first two months after the procedure in 42% of the cases, and within the 10 consecutive months in 36 % of them, totalizing 78% during the first year. The remaining 14% were diagnosed between one and five years, and 8%, after this period.

Regarding the clinical picture, 14% of the patients were asymptomatic, 61% reported mild symptoms such as unspecific abdominal discomfort or palpable mass, and 25% developed severe manifestations such as peritonitis, fistula or intestinal obstruction.

When we correlated the time for FB diagnosis to the clinical picture, we found that 96% of patients had some symptom two to six months after surgery, whereas 23% were asymptomatic in the period of more than five years after the procedure. Severe manifestations appeared in the first two months in 20% of the patients, decreasing to 11% up to sixty months, and to 23% after this period.

The relation of the clinical picture and the type of FB is shown in table 2. When we analyzed the severe manifestations in relation to the type textiles, we found 6.3% for gauze, 12.2% for small sponge and 29.9% for large sponge.

The majority of RFB occurred in open surgical procedures (94%) and elective surgeries (54%), which the surgeons classified as usual (85%) but complex (57%). Among the operations in which the surgeons left any FB, we identified 115 types of procedures, showing the seven most frequent in table 3.

Table 1 - Distribution of Foreign Bodies according to type.

Type of Retained Foreign Body	Percentage (%)
Large Sponge	42.01
Small Sponge	26.11
Gauze	22.10
Surgical Instrument	5.21
Needle	2.84
Others	1.74

Table 2 - Clinical manifestations according to Foreign Body type.

Type of Clinical Manifestation	Foreign Body		
	Textiles	Surgical Instrument	Needle
Asymptomatic	12%	67%	10%
Oligosymptomatic	71%	33%	90%
Severe manifestations	17%	-	-

When asked about which single factor has contributed more to RFB, respondents most frequently pointed emergency situations, not counting the sponges and inadequate work conditions. They highlighted difficulties related to incomplete and unprepared surgical teams, excess work, inappropriate operating rooms, and unprepared and undersized nursing staff table 4.

In the group of surgeons who had already left FB, 54% of their patients were not informed about the incident. Among those who were aware of the fact, 26% sued the doctor and/or the Institution. In the group of surgeons who had not left FB, only 26% would inform the patient if there had been a RFB.

DISCUSSION

The incidence of unintentionally Retained Foreign Bodies (RFB) is underestimated^{10,11}. The explanation for those occurrences are, in addition to difficulties in making the diagnosis^{11,12}, potential legal repercussions^{1,5} and difficulty in reporting the malpractice and dealing with its consequences^{13,14}. This study decided to explore the issue from the point of view of the surgeons who have already left and/or removed FB. Therefore, we needed a project that would reduce the discomfort caused by the matter and that would reach a large number of doctors of the main specialties involved on it, preserving their anonymity.

Table 3 - Distribution of RFB reports among the procedures. Seven most frequent types.

Procedure	Percentage
Cesarean	17.96%
Abdominal Hysterectomy	16.33%
Exploratory Laparotomy for Acute Abdomen	13.54%
Exploratory Laparotomy for Trauma	7.26%
Cholecystectomy via subcostal incision	6.62%
Colectomy	4.12%
Appendectomy	3.60%

Table 4 - Factors that contributed to RFB.

Factors	Percentage (%)
Urgency / Emergency	26
Not counting the sponges	25
Inadequate work conditions	12
Patient's Obesity	11
Unexpected change of plans or surgical accident during surgery	11
Fatigue	9
Change of medical team during surgery	5
Teams of different specialties acting simultaneously	2

As, according to Scriven *et al.*, the internet provides distance and makes it easier to answer to delicate issues or to less socially desirable ones¹⁴, we asked to medical Brazilian societies to send the questionnaire to their members by e mail. In this way, were excluded surgeons who were in the basic years of residence or with an insufficient technical preparation.

As it was a voluntary research, we obtained a convenience sample. Some questions, such as the percentage of surgeons that have already left some FB or been sued, shall be analyzed taking this limitation into consideration. Nevertheless, the method allowed us to examine the experience of 2,872 professionals with 4,547 cases of RFB, representing approximately 7% of all general surgeons, urologists, gynecologists and obstetricians registered by the Federal Council of Medicine in Brazil (most of these doctors are not associated to the participating medical societies)¹⁵. We believe that it is an expressive number since Wan *et al.*, in the major review of cases published since 1963, collected 254 cases of retained sponges¹⁶.

When analyzing when RFB could have happened, we found that the peak incidence was at the beginning of the surgeons' career. Thereafter, the number slowly increased until it reached half of the interviewed among those with more than thirty years of practice. These data suggest that RFB happens more often than we think, and that doctors in training should receive more attention, so that they could learn techniques to prevent their own failures before they happen.

Of the 4,547 FB reported, 90% of them were textiles and, among these, large sponges were the most common. We had only 129 cases of needles, surpassed even by 237 surgical clamps, seldom mentioned in the medical literature. The most widespread RFB preventive measure is the instrumental counting, which, in many surgical centers, is not standardized or uses only textiles counting¹⁷⁻¹⁹. Even in the places that follow all recommendations of the Association of Perioperative Registered Nurses (AORN), needles represent the most discrepancies in counting²⁰. So, considering these data, we asked ourselves why were the textiles, not the needles or clamps, the most retained items²¹.

These data support the explanation for the majority of RFB cases, that is, only FB intentionally inserted, released inside the cavity and then forgotten by the surgical team would be retained in surgeries. Since doctors, even temporarily, must not release a scalpel, anatomical tweezers or a needle and suture thread in the cavity, those instruments are hardly retained.

Taking into account the levels of diseases prevention that Leavall *et al.* popularized in 1965²², the same emphasis given to techniques for detecting something placed in the cavity should be given to disseminate methods to not release anything in the cavity. For example, in order to prevent a myocardial infarction, primary measures as avoiding sedentary lifestyle and overweight are more important than secondary measures, such as performing a periodic coronary tomography. In the same way, it might be more important to use sponge holding forceps than to count the sponges.

Other primary measures should also be used such as to always fix gauze to a clamp, or keeping the malleable valve extremity outside during the incision closure. The same concept can also be applied when, for example, a tired surgeon with an incomplete team chooses to postpone a complex surgery that is not urgent.

Regarding the time of FB detection, the peak incidence had usually occurred in the first two months, as was expected^{11,16,23}. Those numbers can be explained by the fact that patients undergo more imaging examinations in the early post-operative period and by the greater tendency of the textiles to evolve to exudatives and symptomatic processes at this stage⁷. In late detection, the fibrotic reaction predominates, usually minimizing clinical manifestations²⁴⁻²⁶. Although 8% of the cases were detected after five years from the initial surgery, 23% of these patients developed serious complications, justifying the surgical removal though being asymptomatic²⁴. On the other hand, the FB type should also be taken into consideration. After all, the rate of serious complications doubled according to the increase in the size of the textile, being 6% for gauze, 12% for small sponge and 24% for large sponge.

Brazilian surgeons highlighted the same risk factors emphasized in the studies of Gawande *et al.*¹, Lincourt *et al.*¹⁰ and Stawicki *et al.*^{6,27}. Exploratory laparotomies usually include these risk factors, being urgent/emergency and complex surgeries performed in unstable patients, with unplanned changes in the surgical procedure, needing textiles to hemostasis and, often, performed by tired medical teams and in improper environments. For these reasons, it was not a surprise that exploratory laparotomies were in our list of surgeries with FB (20.8%). According to Cima *et al.*²¹, the majority of RFB occurred in routine and elective open surgeries. Although the 115 listed interventions may share these characteristics, there was a significant number of Cesarean sections, Hysterectomies and Cholecystectomies (40.91%). Perhaps, that may be explained by their high prevalence (350,000 Cesareans,

61,000 Cholecystectomies and almost 45,000 hysterectomies from October 2011 to March 2012) in Brazil²⁸. However, the most important fact is that, in these interventions, sponges are routinely inserted in cavities to expose the operative field. Their removal depends on secondary prevention mechanisms, exposing their fallibility²⁹⁻³¹. Eventually, in these cases, some RFB could be prevented by using sponge holding forceps. In addition to the previously mentioned factors, many interviewees reported structural and procedural failures, revealing worrisome workplaces frequented by many Brazilian and third world surgeons¹⁹.

Some important studies on RFB came from the registry of legal processes^{1,5}. If this methodology were applied to that sample, we would be assessing only 11% of the cases and underestimating their occurrence. Furthermore, claiming to be an inherent risk in surgery, with possible legal and professional implications, 74% of surgeons stated that they would not tell the patient about the removal of a FB left by another colleague. Therefore, some paradigms need to be broken in order to better understand this phenomenon.

Unfortunately, despite all advances, the doctrines of "res ipsa loquitur" (the thing speaks for itself) and "captain-of-the-ship" (that blame mainly the surgeon), are still in force³². The focus on a forgotten FB would need to be changed to that on the safety in surgery. The RFB should be approached as a system failure and not as the product of negligence or incompetence of a specific professional^{33,34}.

Despite not always having high technology, there are accessible and simple measures that must be disclosed and followed^{6,35-37}. Among these, it is worth emphasizing the primary prevention and an appropriate work environment, so that professionals act in a dignified and safer manner. Although some of these results have not been based on a statistical risk analysis, they suggest some reflections.

In conclusion, the challenging medical situations, the omission of security protocols and inadequate working conditions contributed to RFB. However, inadvertent retentions occurred mainly in routine operations such as Caesarean sections and cholecystectomy, especially early in the medical career, highlighting, especially in poorer countries, the need for primary prevention. Textiles predominated, leading to clinical manifestations and being diagnosed in the first months after the postoperative. Doctors were sued in 11.3% of RFB cases.

Acknowledgments

We thank the Brazilian College of Surgeons, the Brazilian Society of Coloproctology, the Brazilian Society of Laparoscopy, the Brazilian College of Digestive Surgery, the Brazilian Society of Thoracic Surgery, the Brazilian Society of Integrated Care on Trauma, the Brazilian Federation of Gynecology and Obstetrics, the Brazilian College of Oncologic Surgery and the Brazilian Society of Urology.

R E S U M O

Objetivo: avaliar a experiência de cirurgiões brasileiros com a retenção inadvertida de corpos estranhos (RICE) após procedimentos cirúrgicos. **Métodos:** foi enviado por correio eletrônico um questionário para cirurgiões, de março a julho de 2012. As questões avaliavam a sua experiência com RICE, os tipos de corpos estranhos, suas manifestações clínicas, diagnósticos, fatores de risco e implicações jurídicas. **Resultados:** 2872 questionários foram analisados. Destes, 43% dos cirurgiões já teriam deixado algum corpo estranho (CE) e 73% removido um CE em uma ou mais ocasiões. De um total de 4547 CE, 90% eram têxteis, 78% foram descobertos dentro do primeiro ano, e 14% assintomáticos. No grupo dos médicos graduados há menos de cinco anos, 36% já havia deixado um CE. Os procedimentos operatórios mais relacionados eram eletivos (54%) e rotineiros (85%). Emergência (26%), ausência de contagem (25%) e condições inadequadas de trabalho também contribuíram com a ocorrência (12,5%). Em 46% dos casos os pacientes tomaram ciência da retenção e 26% deles processaram os médicos ou as instituições. **Conclusão:** situações médicas desafiadoras, omissão de protocolos de segurança e condições inadequadas de trabalho contribuíram com a RICE. Entretanto, as RICE ocorreram principalmente em operações de rotina, como cesarianas e colecistectomias, principalmente no início da carreira profissional, ressaltando, principalmente em países mais pobres, a necessidade de prevenção primária. Os têxteis predominaram, acarretando repercussões clínicas e sendo diagnosticados nos primeiros meses de pós-operatório. Os médicos foram processados em 11,3% dos casos de RICE.

Descritores: Corpos Estranhos. Complicações Pós-Operatórias. Instrumentos Cirúrgicos.

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Received: 18/05/2015

Accepted for publication: 14/10/2015

Conflict of interest: none.

Funding source: none.

Mailing address:

Dairio Vianna Birolini

E-mail: drdario78@hotmail.com