

# Leaving a foreign object in the body of a patient during abdominal surgery: still a current problem

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## ABSTRACT:

**Introduction:** Leaving a foreign object (retained surgical item, or RSI) during surgery involving the abdominal cavity and pelvis minor is a relatively frequent, underestimated phenomenon which is dangerous to the health of the patient and the legal security of the medical personnel. These adverse events are easy to avoid through the use of appropriate means of prevention. The aim of the present paper is the collection of epidemiological data and determination of risk factors, symptomatology, health effects, and prevention methods associated with RSIs.

**Material and methods:** Analysis of global scientific publications in the databases PubMed, ClinicalKey, Google Scholar, ScienceDirect, and Scopus related to the subject of RSIs.

**Results:** The frequency of RSI incidents ranges from 1 to 10 in 10,000 surgeries, which results in at least one case in an average multispecialty hospital on a yearly basis. The items most frequently left behind include soft foreign objects, such as swabs and bandages (90%). Risk factors include emergency surgical procedures, high patient BMI, significant loss of blood during surgery, and neglect in counting the material and surgical tools. The postoperative course, although in many cases asymptomatic, may be complicated by inflammation, bleeding, or perforation, leading to the necessity of a second operation and, in 2 to 4% of cases, even ending in death. Imaging tests are effective diagnostic tools. Effective methods of preventing RSIs are based on checklists and systems for counting and monitoring the location of material and tools.

**Conclusions:** The globally occurring problem of RSIs requires education of the operating block personnel regarding risk factors and identification with elimination of adverse events of this type. Diagnostics based on imaging should take into account non-specific complaints resulting from a possible oligosymptomatic course. An RSI should not be regarded as a medical error. Changes in the perception of the phenomenon aim aimed at minimising the legal liability of the staff in the event of leaving a foreign object in a patient's body.

## KEYWORDS:

adverse event, foreign object, gossypiboma, never event, retained foreign object

## INTRODUCTION

Unintentionally leaving a foreign object in the body of a patient in the course of surgical procedures involving the abdominal cavity and the pelvis minor, although statistically not very frequent, arouses many emotions in doctors as well as in patients and their relatives. It can be considered by lawyers to be a contributing factor to both criminal and civil liability. From the point of view of the culture of security in the provision of health services, however, it is a typical adverse event, which, although it should not occur, does occur all over the world. The frequency of this phenomenon is underestimated; this is related to the lack of a proper system of monitoring the equipment used during procedures, the lack of reporting (for fear of legal liability), and also a sometimes-asymptomatic postoperative course. The problem is therefore a challenge for those wishing to improve the quality of medical procedures through the introduction of effective remedial methods rather than repression [1–3].

In the literature on the subject, we usually use the term retained surgical item (RSI), indicating any object inadvertently left inside a patient's body during surgery [4]. The phenomenon has been classified under the ICD-10 system under number T81.5 as 'a foreign object accidentally left in a body cavity or surgical wound following surgery'; whereas its consequences have been classified as T81.6, an 'acute reaction to a foreign object accidentally left [in a patient's body] during a procedure' [5]. An

RSI is counted as a so-called never event, i.e. an adverse event in the healthcare system which can easily be avoided and which in principle should not occur, but which, if it does occur, may have tragic consequences for the patient. The aim of the present paper is the determination of the frequency of RSIs in surgery involving the abdominal cavity and the pelvis minor as well as systematisation of current knowledge about the type of foreign objects left behind, surgical procedures during which such objects are left behind, relevant risk factors, symptomatology, potential health effects, legal consequences, and analysis of solutions whose implementation would enable reduction of the risk of occurrence of this event.

## MATERIALS AND METHOD

An analysis of global scientific publications in the medical databases PubMed, ClinicalKey, Google Scholar, ScienceDirect, and Scopus concerning foreign objects left in the body of a patient in the region of the abdominal cavity and pelvis minor was conducted from the viewpoint of the epidemiology of the phenomenon, risk factors, and typical health consequences. The following keywords were used to search the publications: retained surgical items, retained foreign object, gossypiboma, never event, and textiloma. The most recent publications were selected from the available literature, along with those concerning large groups of patients or reporting interesting cases (e.g. unusual locations).

## EPIDEMIOLOGY

Data on RSI frequency should be treated with great caution, due to the nature of the adverse event being described, possible legal consequences, and the great negative media furor. This situation, combined with a potential asymptomatic course of such events, means that some events are not disclosed or noticed at all. In the United States, according to the data from the National Quality Form, 2,000–4,000 cases of RSI occur each year [6]. A 5-year analysis of the collections of the Agency for Healthcare Quality and Research (AHRQ, USA) conducted by Elsharydah et al. (2016) showed this frequency at a level of 13 events per 100,000 cases-years, and persisting at a similar level [4]. According to most publications, the frequency of incidents of foreign objects left in patients' bodies ranges from 1 to 10 cases per 10,000 surgeries. This means that at least one RSI incident can be expected in each typical multispecialty hospital on a yearly basis [1–3, 7–13]. There is no data on the frequency of this phenomenon in Poland.

Among the factors influencing the frequency of this type of adverse event are, first and foremost, the type and mode of surgery being performed, operational conditions, patient's condition, level of experience of the surgeon and the staff of the operating block, internal procedures of a given centre with respect to the handling of materials and tools, and the system of reporting adverse events. Although it is not possible to eliminate human error completely, strict adherence to specific rules and guidelines governing intra- and perioperative procedures may contribute to a significant reduction in the incidence of RSI-related complications [14]. In contrast to the American studies quoted above, in recent years a drop in the incidence of RSIs has been observed in Great Britain (in the 1980s, according to Hariharan et al., 1 incident in 1,000–1,500 abdominal procedures, as opposed to current ratios of 1:5,500–18,760). The differences in these values are attributed to, inter alia, the retrospective model of scientific research, the reluctance of hospitals to disclose sensitive data on adverse events, the asymptomatic course of many cases of RSI, and potential legal consequences [15]. It is believed that at least 1 or 2 RSI incidents will occur [9] during the professional life of an average surgeon. In a survey conducted by Birolini et al., where the respondents were surgical specialists, 43% of respondents admitted to having left a foreign object in a patient's body during their professional career, and 73% had at least once conducted a resection of an RSI that had been left behind previously [16]. Foreign objects are most frequently left behind in the following surgical departments: general (18%), gynaecological (13%), orthopaedic (5%), and cardiac (2%) [10].

## TYPES AND LOCATIONS OF RSIS

Foreign objects left in the bodies of patients can be divided into soft (textiles, synthetics) such as surgical swabs, gauze, and bandages, and hard (needles, steel clips, surgical tools, e.g. retractors, scissors, Pean forceps). Soft objects most often left behind include large swabs (42.01%), small swabs (26.11%), and bandages (22.10%); hard objects include surgical tools (5.21%) and needles (2.84%) [16]. Among hard foreign objects, we also count incomplete surgical tools, as well as their fragments [17]. Since swabs and surgical gauze are left behind most frequently, they are referred to in the literature as gossypibomas, from Latin gossypium (i.e. cotton and boma, which means 'hiding place' in Swahili), gauzomas,

or muslinomas (from muslin) [18]. According to statistical data, foreign objects are usually left behind during medical procedures performed in the abdominal cavity and pelvic area [16]; therefore, the authors of the present paper have focused on these locations. RSI cases also apply to other areas, including the cranial cavity, maxillary sinuses, neck, chest, axillary fossa, vagina, paraspinal area, and pericardium [1, 19–22]. The most frequent locations, apart from the peritoneal cavity (55.26%), include the pleural cavity (18.42%), pelvis minor (10.52%), urinary tract (7.89%), subdiaphragmatic part of the gastrointestinal tract (5.26%), and cranial cavity (2.63%) [10]. According to other sources, the foreign object is left behind in 54% of cases in the abdominal cavity or uterus, in 22% in the vagina, in 7.4% in the chest, and in 17% in other locations (the spinal canal, face, or brain) [2].

## COMPLICATIONS

Every foreign object triggers defensive reactions by the body. Depending on the type of foreign object left behind, its location, and patient's condition, clinical manifestations may differ. In many cases involving abdominal surgery, leaving a foreign object in the patient's body may not cause any symptoms; in others, where bacterial colonisation occurs, a local or general inflammatory reaction may develop. In a study conducted by Styskel et al., involving 1,100 RSI cases, mortality due to complications from leaving a foreign object in the patient's body was estimated at 4.5% [9]. In 78.1% of cases, an event of this type was associated with permanent and in 16.3% of cases with temporary physical damage to health. Meanwhile, 1.1% of cases were related to psychological consequences [23]. The average mortality rate, according to various studies, varies from 2 to 4% [2, 9].

We distinguish two classic reactions of the patient's body to a retained foreign object: an acute inflammatory response (with or without formation of a secondary abscess) and a chronic inflammatory process with fibrosis and formation of a pathological tumour [1]. The first of these reactions occurs early, undergoing a gradual progression. Fibrosis is characterised by the formation of granulation tissue [1]. A chronic response to the presence of a foreign body may manifest itself clinically as nonspecific pain, sitophobia, or weight loss. Due to an unclear clinical picture, a lack of extensive diagnostics may erroneously suggest systemic diseases, functional disorders, or cancer [1]. Discomfort felt by a patient in connection with a retained foreign object is usually difficult to differentiate from complications associated with the procedure, including: pains in the location where the foreign object was left behind (which often corresponds to the area operated on), fever, nausea, vomiting, and post-operative healing disorders [1, 24]. The consequences of leaving a foreign object in the patient's body may include peritonitis, fistulae, abscesses, strictures of the intestinal lumen, and obstructions [25, 26]. Less common complications include bleeding and perforations. The most common consequence of complications is the necessity of removing the foreign object (69%) and of re-hospitalisation (59%) [2]. Reoperations are not inevitably required; any decision takes the risks and benefits into account, especially in cases of mild symptoms, or none.

The usual reaction to sterile swabs and surgical gauze, similar to the reaction to sterile surgical needles (90%), involves minor symptoms (71% of cases) associated with nonspecific abdominal discomfort

or the presence of a palpable mass in palpation tests. Textiles may, in some cases (according to the cited study, 17%), lead to acute inflammatory reactions. Interestingly, decontaminated surgical instruments, in two of every three cases, produce no symptoms (67%) [16]. Sterile hard foreign objects, which are left behind less frequently than soft ones, may remain in the body for a long time without any clinical symptoms, or may cause nonspecific pain with or without an inflammatory component. Infection is usually caused by normal bacterial colonisation.

## DIAGNOSTICS

Diagnosis of a foreign object left behind in the abdominal cavity consists of differentiating among the symptoms reported by the patient [27]. Some asymptomatic foreign objects are detected accidentally during tests carried out for other purposes. Discovery of an RSI is usually made thanks to imaging diagnostics (68%), as well as, less frequently, by physical examination (31%) [10]. The patient most frequently reports to his or her primary care physician due to nonspecific pain in the abdominal cavity or pelvis minor, loose stools, fevers, or general malaise. In the first place, performance of an abdominal ultrasound examination is recommended. Hard and metallic foreign objects are easily identified in radiographic images due to the difference in their densities and to their characteristic shapes [28, 29]. A computed tomography (CT) examination is usually performed to detect non-textile materials and hard foreign objects made of plastic or metal materials. In cases of poor patient preparation, diagnostics may be impeded by intestinal gauze obscuring images in both X-ray and CT exams, leading to a long-term failure to diagnose RSI [30]. Notwithstanding the use of imaging diagnostics, foreign objects may go undetected (in 13 of 27 cases in a study by Stawicki et al.) [3].

The average time elapsed between a foreign object being left in the body to its detection varies greatly, ranging from about two weeks to several years. According to a study by Zarenezhad et al., which analysed 38 RSI cases (including 28 involving swabs, 7 other textile materials, 2 scissors, and 1 forceps), the average time was 76 days [10]. In another study, the average time elapsed from surgery to detection was 1,225 days (3 years and 4 months); in half of the cases, the object was located within the first year [31]. In an analysis by Birolini et al., of 4,547 cases, in 42% of patients the foreign object was detected within the first two months following surgery; in 36%, within 10 months; in 78%, within a year; 14% of patients were diagnosed within 5 years [16]. Such a discrepancy in terms of time may be explained by the fact that patients tend to undergo imaging examinations in the postoperative period, and thus some of the foreign objects are detected then. Moreover, within this period, foreign objects that do not remain asymptomatic provoke an exudative response from the body, mandating a search for the source of inflammation. Late-detected RSIs usually remain asymptomatic. Foreign objects consisting of textiles cause fibrosis (which is oligo- or asymptomatic). There have also been cases of RSI detection after 12 years [32].

The absorptive properties of textile materials introduced into body cavities are conducive to their being left behind in the operating room, and make diagnostics difficult. This explains the statistics cited above: the items left behind most frequently, consisting of surgical gauze, are difficult to detect. These items, soaked and

saturated with bloody matter, tangled and balled up, with altered dimensions, and moved from place to place within the operating room, are difficult to distinguish from anatomic structures.

Treatments involving a high risk of a foreign object being left behind include caesarean section (18%), transabdominal hysterectomy (16.3%), exploratory laparotomy due to diagnosis of an acute abdomen (13.5%), exploratory laparotomy following an injury (7.3%), classic cholecystectomy (6.6%), colectomy (4.1%), and appendectomy (3.6%) [16]. The main factors, irrespective of the type of procedure, include emergency procedures, unplanned changes in the mode and scope of operations, and high BMI values in patients [2]. Other risk factors include operations consisting of several sub-procedures (especially when performed by changing operating teams), significant loss of blood (> 500 mL), and treatments performed at smaller centres [4, 33]. Birolini et al. distinguished the following risk factors: sudden surgery (26%), failure to count instruments following a completed procedure (25%), difficult operational conditions (12%), patient obesity (11%), unexpected changes in the operational protocol (11%), fatigue and overwork on the part of the medical staff (9%), a change of the operating team during a procedure (5%), and a multi-speciality team working at the operating table (2%) [16].

## DISCUSSION: PREVENTION

Currently classified as a never event, leaving a foreign object in a patient's body during an operation, though a rare phenomenon, is potentially dangerous for the patient [2, 9, 17]. The first publication reporting an RSI incident, by C. P. Wilson, dates from 1884 and refers to surgical gauze left behind after a laparotomy [34]. The problem, even though it has been known for a long time, is still current, despite the implementation of preventive measures. What is more, it is likely to persist, and thus the only thing we can do is to take action to reduce its frequency. It is, therefore, worth considering briefly whether RSI should be treated as a complication that may occur in spite of due diligence, as a medical error generating legal consequences, or as (in accordance with the spirit of the 'culture of security') an adverse event requiring thorough case analysis and introduction of, or monitoring of the efficiency of, preventive methods. Most lawyers, without taking operational realities or the results of such analyses into account, treat foreign objects left behind in the bodies of patients as 'gross negligence', rejecting any definition of such a case as a medical error (in accordance with the definition thereof as a substantively improper procedure). Any discussion on the validity of this approach would be beyond the scope of consideration of the present analysis. Legal doctrine resulting from judicial decisions seems largely to share this view, sometimes indicating an organisational error or non-compliance with procedures on the part of operating block personnel [35]. In almost every case, the consequences of an RSI may include an effective civil claim, taking into account harm (including material harm, impaired health, pain, suffering, negative psychological experiences, etc.) to the patient. In Poland, in the majority of such cases, the verdicts of the courts recognise such claims as legitimate; however, data is lacking regarding the range of compensation awarded; such awards may vary significantly depending on the case [35]. Compensation costs in the USA, as cited by Hariharan et al., even in cases where the patient did not suffer much harm as a result of the occurrence of an RSI, range from about \$37,000

to \$2,350,000, averaging \$95,000 [15]. In most cases in Poland, a country dominated by a 'culture of repression,' causing a detriment to health due to a foreign object left in the body of a patient may lead to criminal liability, or, more infrequently, to charges of exposing the patient to the danger of death, causing a severe detriment to health, or manslaughter. Whereas the defendant in a civil liability case may be the unit where the procedure was performed, in the case of criminal proceedings it is necessary to indicate a specific individual responsible for the offence in question. This has sparked a dispute as to whether this individual is always the first surgeon to review the operating room, or the surgical nurse who inventories the material, or whether we are dealing here instead with a case of collective responsibility. However, this problem, in terms of legal principles, can have no influence on effective methods of preventing RSIs.

The literature on the subject includes many case studies and review papers identifying the causes and risk factors associated with leaving a foreign object in a patient's body, as well as suggestions concerning practices designed to prevent such events [13, 36–40]. Despite many global studies, the scale of the phenomenon in Poland is unknown and there are no papers on this subject. Reporting of adverse events is carried out within the framework of quality control procedures, but is neither obligatory nor monitored. In 2015, the Quality Monitoring Centre issued recommendations concerning the prevention of adverse events, including leaving foreign objects in patients' bodies [40]. In the same year, an ordinance of the Minister of Health introduced the obligation to use a Perioperative Checklist (in Polish, OKK), based on the surgical checklist used by WHO, as described in publications by Atul Gawande, consisting of an inventory of material along with a statement of compliance [41]. Research on the effectiveness of the checklist, such as that cited above, proved that its conscientious use enables, at a low cost, the achievement of a significant result in the form of a reduction in the number of adverse events, including RSIs. The introduction of the checklist as an obligatory document in Poland constitutes an opportunity to cut down on this phenomenon in the future, even if this effect depends to a great extent on the discipline of the personnel and on understanding and acceptance of the idea behind the introduced changes.

From the point of view of the 'culture of security,' the key to avoiding RSI is widespread knowledge on the part of all personnel about the essence of the problem, the identification of risk factors, and local and global assessment of the phenomenon. In an extensive review of the literature, Hempel et al. pointed to certain behaviours of the operating team as a potential contributing factor to leaving a foreign object in a patient's body, including lack of communication between members of the operating team during surgery and the omission or incomplete implementation of an inventory of surgical instruments [13]. An interesting observation, as pointed out by Stawicki et al., is that the presence of a doctor in training at the operating table is associated with a lower risk of RSIs. This is probably due to the traits characterising doctors in training (vigilance, tendency to ask questions about the legitimacy of certain practices, inquisitiveness) [3]. The most common practice known to prevent the RSI phenomenon is the counting of all equipment and materials used prior to, during, and following surgery. This indicates the key role of surgical nurses in avoiding RSIs. In particular situations, such as sudden emergency operations, consumption of materials in large amounts, or a change of

nursing staff during surgery, this task may be difficult. According to the literature on the subject, in 76–80% of RSI cases, the number of surgical instruments and textiles used after the surgery was reported as complete [6, 42]. While conducting an inventory is an easy way to avoid the RSI phenomenon, it is always subject to human error, which is facilitated by difficult conditions during arduous procedures. Errors in counting or in documentation constitute a predisposing factor for the occurrence of RSIs [13]. Research indicates the usefulness of various systems and protocols aimed at avoiding such errors [13, 43–46]. One of these is 'Sponge ACCOUNTing,' which involves the handling of swabs during the operation based on three steps. In the first of these, the main role is played by the nursing staff, whose job is to place 10 swabs in plastic packs, then to arrange 10 packages prepared in this way in holders, from which they are given to surgeons. The second step is to conduct a thorough review of the wound prior to the final closure of the integument by the operating surgeon. The final stage is the replacement of the used swabs by the surgical nurses in the same holders as prior to the operation. The key element of this step is reciprocal monitoring by the surgeon and nurses. The operating surgeon should, at this point, ask to be shown the holders and should check whether the numbers of packages and of swabs is consistent with the corresponding numbers prior to surgery [6]. Other systems use modern technology to monitor material. The Mayo Clinic (Rochester, USA) applies a system involving continuous scanning of the position of the swabs, which are marked with special labels. Radio wave detection systems, using small (4 × 12 mm) transmitters placed in textile materials, are also used [47]. Post-surgical imaging diagnostics (X-rays) of the operating area helps to detect foreign objects left behind, although as a rule it is applied only when the inventory shows discrepancies [15]. The biggest problem is swabs without tags. As indicated by the authors of the commentary to the article by Hariharan et al., the sensitivity of post-operative X-rays in the operating room in discovering foreign objects left behind in patients' bodies is 67%; however, the study did not take tagged swabs into account [48]. The use of radio-tagged swabs reduces the risk of leaving them behind, as they are easily detected by routine imaging diagnostics [45].

Despite the application of costly technological solutions to reduce the risk of RSIs, such factors as appropriate communication between members of the operating team, properly understood assertiveness, conscientious counting of tools and materials, and a sufficiently-staffed operating team capable of calmly carrying out all tasks assigned to it still lie at the core of prevention.

## CONCLUSIONS

Leaving a foreign object in a patient's body during surgery of the abdominal cavity and pelvis minor is a worldwide problem. In Poland, the scale of this phenomenon remains unknown due to the lack of a relevant system of records. Preventing RSIs requires the education of the operating block personnel concerning the risk factors contributing to their occurrence and the ability to identify and eliminate them. Effective prevention can be guaranteed by introducing systems of work organisation that ensure appropriate communication, sufficient staffing of the operating team, conscientious compliance with procedures (OKK, or Perioperative Checklist), and modern technological solutions (monitoring of the material used). Diagnostic imaging, the most effective tool

for the detection of RSIs, should always be carried out in case of doubt regarding agreement in the inventory of material and tools used during the operation, or following the occurrence of non-specific symptoms not necessarily associated with the procedure.

An RSI is an adverse event which should not be treated as a medical error but rather (apart from some exceptions) as gross negligence. A change in the perception of the phenomenon is expected to reduce the legal liability of the staff in the event of leaving a foreign

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