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Original

Adverse events related to foreign body retention

Eventos adversos relacionados à retenção de corpo estranho

Eventos adversos relacionados con la retención de cuerpo extraño

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Abstract

Objective: to analyze events related to foreign body retention recorded in a healthcare institution and to describe the process of reformulating the prevention protocol. **Methodology:** observational, descriptive, and retrospective study based on all adverse event notifications between 2021 and 2022. The outcomes of the change in the institutional protocol on the incidence of foreign body retention in a large, private, philanthropic hospital were analyzed. Data were extracted and analyzed with a focus on notified adverse events, observing possible changes in the number of occurrences after the implementation of the new protocol. **Results:** in the year 2021, 14,370 surgical procedures were performed, with four cases of retention notified, a rate of 0.02%. In the year 2022, 17,920 surgical procedures were performed, with five cases of retention, maintaining the same rate of 0.02%. The cases involved needles, gauzes, and instruments, without evidence of reduction after the implementation of the new protocol. **Conclusion:** despite the low incidence observed, retention is an adverse event with serious consequences for patients and significant losses for institutions. It is essential to carefully analyze the causes of failure to adhere to the protocol and invest in continuous training to strengthen safety culture.

Descriptors: Near miss, healthcare; Time out, healthcare; Sentinel surveillance; Patient safety; Guideline adherence.

Whats is already known on this?
Foreign body retention, classified as a "never event," has serious consequences for patients, including further surgery and longer length of stay.

What this study adds?
This study highlights the need for detailed protocols, active supervision, enhanced adherence, and continuous training to consolidate safety culture and prevent foreign body retention in the surgical environment.

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Resumo

Objetivo: *analisar eventos de retenção de corpo estranho registrados em uma instituição de saúde e descrever o processo de reformulação do protocolo de prevenção.* ***Método:*** *estudo observacional, descritivo e retrospectivo, baseado em todas as notificações de eventos adversos ocorridas entre 2021 e 2022. Foram analisados os desfechos da alteração no protocolo institucional sobre a incidência de retenção de corpo estranho em um hospital privado, filantrópico e de grande porte. Os dados foram extraídos e analisados com foco nos eventos adversos notificados, observando-se possíveis alterações no número de ocorrências após a implementação do novo protocolo.* ***Resultados:*** *em 2021, foram realizados 14.370 procedimentos cirúrgicos, com quatro casos de retenção notificados, uma taxa de 0,02%. Em 2022, foram realizados 17.920 procedimentos cirúrgicos, com cinco casos de retenção, mantendo a mesma taxa de 0,02%. Os casos envolveram agulhas, gazes e instrumentais, sem evidência de redução após a implementação do novo protocolo.* ***Conclusão:*** *apesar da baixa incidência observada, a retenção é um evento adverso com consequências graves para o paciente e prejuízos significativos para a instituição. É fundamental analisar cuidadosamente as causas da falha na adesão ao protocolo e investir em treinamentos contínuos para o fortalecimento da cultura de segurança.*

Descritores: *Near miss; Time out na assistência à saúde; Vigilância de evento sentinela; Segurança do paciente; Fidelidade a diretrizes.*

Resumén

Objetivo: *analizar eventos de retención de cuerpo extraño registrados en una institución de salud y describir el proceso de reformulación del protocolo de prevención.* ***Método:*** *estudio observacional, descriptivo y retrospectivo, basado en todas las notificaciones de eventos adversos ocurridos entre 2021 y 2022. Se analizaron los resultados de la modificación del protocolo institucional sobre la incidencia de retención de cuerpo extraño en un hospital privado, filantrópico y de gran tamaño. Los datos se extrajeron y analizaron con enfoque en los eventos adversos notificados, observando posibles cambios en el número de ocurrencias después de la implementación del nuevo protocolo.* ***Resultados:*** *en 2021, se realizaron 14,370 procedimientos quirúrgicos, con cuatro casos de retención notificados, una tasa del 0.02%. En 2022, se realizaron 17,920 procedimientos quirúrgicos, con cinco casos de retención, manteniendo la misma tasa del 0.02%. Los casos involucraron agujas, gasas e instrumental, sin evidencia de reducción tras la implementación del nuevo protocolo.* ***Conclusión:*** *a pesar de la baja incidencia observada, la retención es un evento adverso con consecuencias graves para el paciente y pérdidas significativas para la institución. Es fundamental analizar cuidadosamente las causas de la falla en la adhesión al protocolo e invertir en entrenamientos continuos para el fortalecimiento de la cultura de seguridad.*

Descriptores*: Potencial evento adverso; Pausa de seguridad en la atención a la salud; vigilancia de guardia; Seguridad del paciente; Adhesión a directriz.*

INTRODUCTION

The Joint Commission International (JCI) classifies foreign body retention (FBR) as a never event, i.e., a serious and preventable event that should never occur, given its association with significant data for patients and healthcare institutions. Although the estimated incidence is low – 0.02% in North American hospitals between 2005 and 2017 –, FBR remains one of the leading causes of sentinel events reported to JCI, especially in gastrointestinal, thoracic, and multi-cavity surgeries.[1-3]

Defined as the unintentional retention of objects inside the patient's body after closure of the surgical incision, even if detected while still under anesthesia or in the operating room, FBR can lead to severe complications such as sepsis, pulmonary infections, and the need for a new intervention. These events result in increased length of stay, hospital costs, and significant emotional impact on patients and their relatives.[3-5]

It is estimated that each case of FBR can generate expenses of up to US$ 200,000, considering medical and legal costs. Despite its severity, subnotification, variability in notification systems, and multifactorial complexity make it difficult to accurately measure its occurrence.[4-5]

By recognizing this need, the World Health Organization (WHO), through the World Alliance for Patient Safety, launched the second global challenge focused on surgical safety in the year 2008. Among its objectives, we can cite: standardization of practices for infection prevention, safe anesthesia, and safety of surgical teams, with a focus on implementing the WHO Surgical Checklist.[7]

This list consists of three critical moments: sign in (before anesthetic induction), time out (before incision), and sign out (before the patient leaves the room). The sign out stage, in particular, is crucial in preventing FBR, as it involves counting and checking the materials used.[8]

The leading role of nursing team members in this process is widely recognized, as they are responsible for conducting surgical countings and identifying failures in protocol compliance. Nonetheless, the effectiveness of these practices depends directly on the engagement of the multidisciplinary team and systematic adherence to institutional standards.[9-12]

Despite international guidelines, there are still gaps regarding the practical effects of institutional updates on protocols and safety, mainly in Latin American contexts. This study seeks to contribute to this

field by analyzing institutional data related to FBR before and after the update of the sign out protocol, carried out in the year 2022, with a focus on computerization and adaptation to the reality of the sector.

Accordingly, the objective of this study is to analyze events related to FBR recorded in a healthcare institution and describe the process of reformulating the prevention protocol, aiming to strengthen safe practices in the surgical environment.

METHODS

This is an observational, descriptive, and retrospective study, typified as before-after, which analyzed all notifications of adverse events related to FBR recorded at a large private and philanthropic hospital located in the city of São Paulo. The institution has a surgical center with 22 operating rooms and 30 beds in the Post-Anesthesia Care Unit (PACU), where low, medium, and high complexity surgeries are performed, totaling an average of 1,600 procedures per month and approximately 20,000 surgical patients per year.

This study was approved by the Research and Ethics Committee of the institution, under Opinion n. º 7.294.756, in December 2024.

The notifications related to FBR are made through an institutional electronic system, accessed via the hospital intranet. The study sample consisted of all records available in this system in the years 2021 (before the protocol update) and 2022 (after the update). The inclusion criteria covered all records related to FBR notified during the period, and the exclusion criteria were those with incomplete data that made descriptive analysis impossible.

Data collection was performed by exporting the notification system records to a Microsoft Excel® spreadsheet, which contained the following variables: patient name, service, responsible medical team, bed of origin, location of the event, notifying agent, type and description of the event, and its classification. The data were treated using simple descriptive analysis, with presentation of absolute frequencies, averages, and proportions. Inferential statistical tests were not applied due to the small number of cases.

The institutional Safe Surgery protocol, in force since the year 2007, is structured in three main stages: sign in (before anesthetic induction), time out (before surgical incision), and sign out (before closing the cavity). Each stage includes specific verification items focused on patient safety. At sign in, information related to the patient and the procedure is checked; at time out, the surgical procedure, the anticipated risks, and the sending of specimens for pathological anatomy are confirmed; and, at sign out, surgical materials (compresses, gauzes, and needles) are counted, the specimens removed are checked, and the patient's destination is determined.

Until August 2022, the surgical counting routine involved checking, conducted by the nursing technician in the room, the number of open compress and gauze packages on the surgical table, comparing them with the items discarded in the hamper. The initial counting depended on manually checking the contents of each package at the time of opening. In case of discrepancy, a second counting was performed by another professional. If the inconsistency persisted, an imaging examination (C-arc X-Ray) was performed for investigation, with the images analyzed by the medical team and recorded in the medical chart.

In August 2022, this protocol was reviewed and updated, with computerization of the process and adjustments to the operationalization of the sign out stage, aiming at greater standardization, traceability, and safety in the final conference.

The results of the analysis are presented descriptively, highlighting the frequency of notifications related to FBR before and after the protocol review, as well as the main characteristics of the cases. The institutional experience is also shared as a resource for clinical practice and for improving surgical safety.

RESULTS

In the year 2021, 14,370 surgical procedures were performed at the institution, with four cases related to FBR recorded, corresponding to a rate of 0.02%. Of these cases, three involved the use of gauzes or surgical compresses and one involved the use of needles. In the year 2022, with 17,920 surgical procedures performed, five cases related to FBR were notified, maintaining the same proportional rate of 0.02%. Of these, two cases were related to gauze retention, two to surgical instrument retention, and one to needle retention.

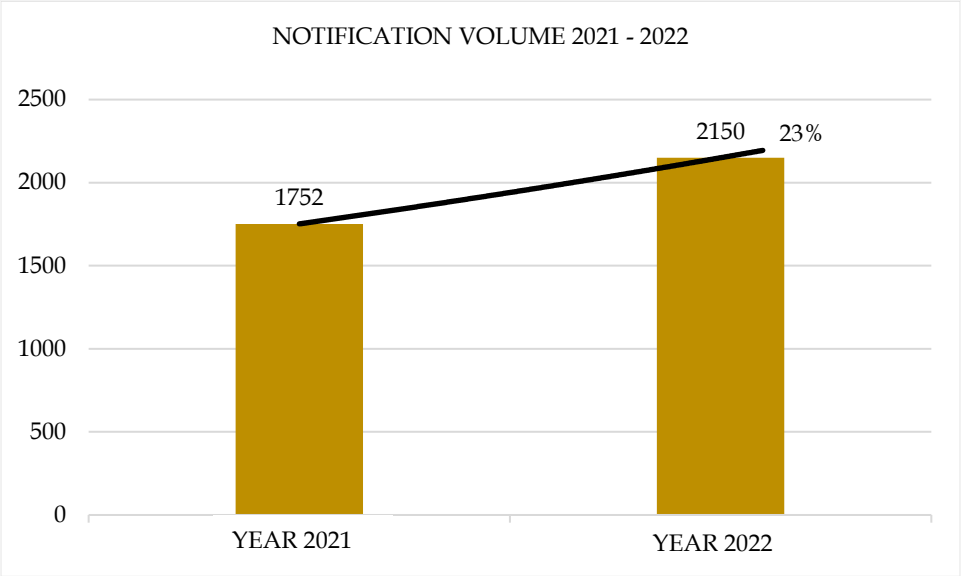
Regarding the surgical profile, the events in 2021 occurred mainly in abdominal surgeries (three cases) and one in orthopedics. In 2022, the five cases occurred in different specialties: abdominal surgery,

plastic surgery, orthopedics, otorhinolaryngology, and gynecology. Gauze retention was identified in plastic and otorhinolaryngological surgeries; needle retention occurred in abdominal surgeries; and cases of retained instruments involved a uterine manipulator (gynecological) and a wire passer (orthopedic).

In cases involving gauzes and needles, the current counting protocol was followed. Discrepancies were identified during the surgical procedure, allowing for recounting and intraoperative C-arc X-Ray, with removal of the material before the patient left the operating room. These cases show the effectiveness of the protocol as a safety barrier. On the other hand, cases involving instruments revealed an institutional weakness, as there is no structured and formalized protocol for counting instruments by the medical team. Currently, this step is limited to a verbal consultation at the end of the procedure about the possibility of retained instruments.

In addition to the variation in the absolute number of surgeries performed, there was a 23% increase in the total volume of notifications related to adverse event between the years 2021 and 2022, as displayed in Graph 1.

Graph 1 – Comparison of the volume of notifications between 2021 and 2022. São Paulo-SP, Brazil, 2022.

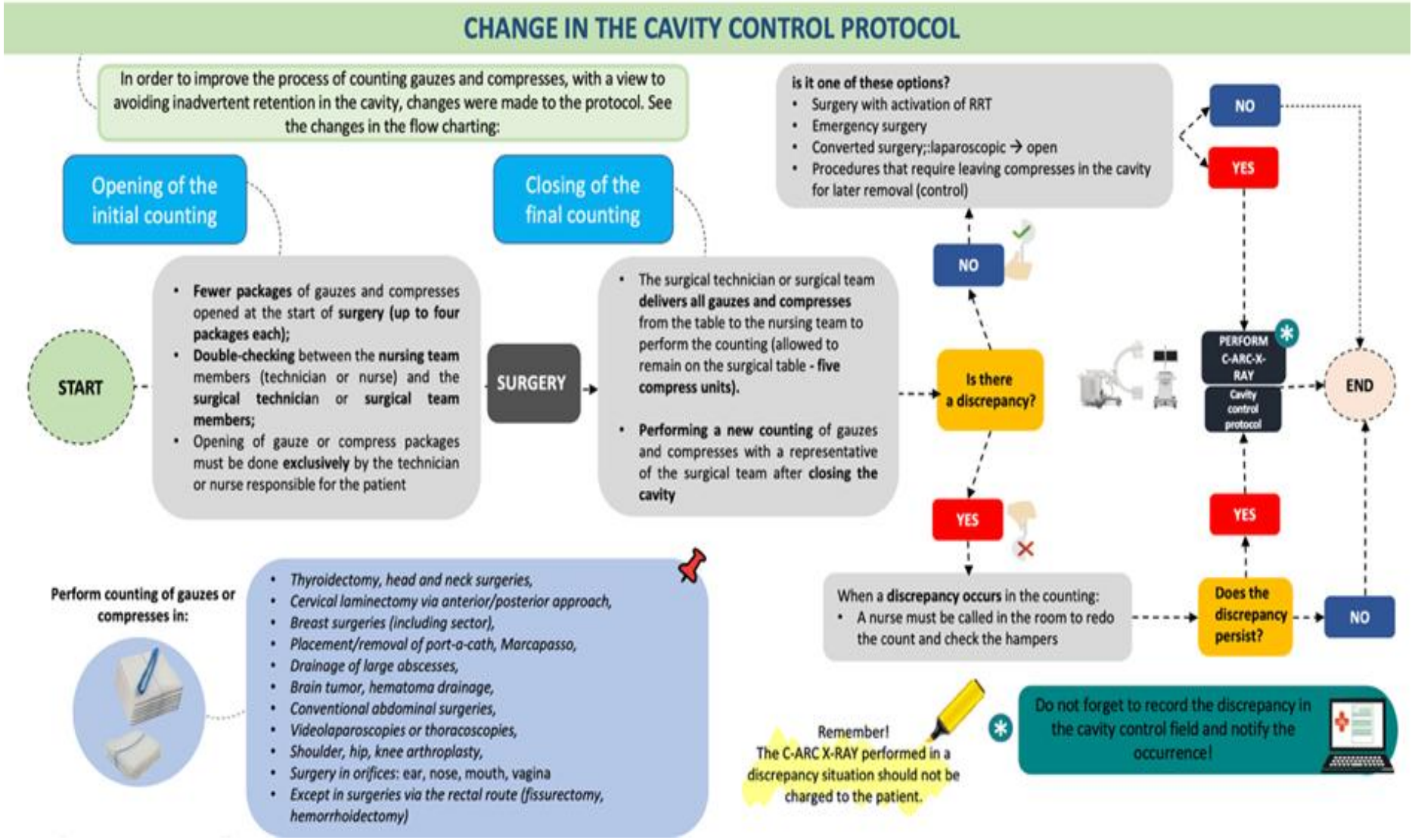


Source: Adverse Events System of the Syrian-Lebanese Hospital.

Reformulation of the protocol and practical implications

Following a case of a compress being retained in an abdominal cavity in August 2022, the institutional protocol was reviewed. The new guideline was developed by nurses from the development team, in conjunction with nursing coordination and surgical center technicians, and was pilot tested with medical teams and officially implemented in September 2022 (Figure 1).

Figure 1 – Change in the protocol for counting gauzes and compresses. São Paulo-SP, Brazil, 2022.



Source: Institutional Protocol of the Syrian-Lebanese Hospital.

The main changes implemented in the gauze and compress counting protocol include:

- Limitation on opening packages: a maximum of four packages of gauzes and compresses are allowed on the instrument table, under the sole responsibility of the nursing technician or nurse in the room.
- Organized waste disposal: at the end of surgery, all material must be discarded in the hamper, except for five compresses, which remain on the table for final counting.
- Hamper segregated by type of material: use of colored bags, separated by large compresses, small compresses, and gauzes, with a view to facilitating conference.
- Supervised final counting: the conference is performed by two professionals – the nursing technician and a surgical team member.
- Additional criteria for performing C-arc X-Ray: in addition to count discrepancies, X-Ray became mandatory in cases of conversion from laparoscopic to open surgery, emergency surgeries, and activation of the Rapid Response Team (RRT), even when the counting was considered correct.

The needle counting protocol remained unchanged, providing for final conference and storage in a magnetic box with a counter. In case of discrepancy, intraoperative X-Ray must be performed for visual confirmation by the medical team. A comparative of the versions (before-after) of the protocol changes is displayed in Table 1.

Box 1 – Comparative between the previous protocol and the reformulated protocol for counting gauzes and compresses. São Paulo-SP, Brazil, 2022.

Aspect	Previous protocol (until August 2022)	Reviewed protocol (from September 2022)
Responsible for opening packages	Any member of the surgical team could open and count the contents of packages	Only the nursing technician or nurse in the room can open them
Limit on opening packages	No limitation	Up to four packages may be opened on the instrument table before the start of surgery
Waste disposal organization	Compresses and gauzes discarded without standardized segregation	Hamper separated by colored bags, specific for gauzes, small compresses, and large compresses
Final counting	Performed by the nursing technician in the room	Performed in pairs (nursing technician + surgical team member)
Remaining material on the table	Some materials remained on the table until the end	Only five compresses may remain on the table, with a view to facilitating counting
Instrument counting	Verbal questioning at the end of the procedure regarding the perception of any missing items	No change in this regard (verbal questioning at the end of the procedure remains unchanged)
Criteria for intraoperative C-arc X-Ray	Performed only in case of discrepancy in terms of counting	Performed in case of discrepancy or if there is: activation of RRT, conversion from laparoscopy to open surgery, or in emergency surgeries, even with correct counting
Record	In medical charts	No change in this regard (the record remains in the medical chart)
Protocol adherence	Investigative control after adverse event notification	No change in this aspect (adverse event monitoring and fact-finding investigation remain unchanged)

After the implementation of the new protocol, a case related to FBR involving the use of needles was recorded, which occurred in November 2022.

DISCUSSION

Although the events were classified as "never events" and the occurrence rate was low, the consequence for patient safety is high. A descriptive study of 308 events reported retention of instruments

(102) and needles/blades (33), among other items related to surgical procedures. Many of the instruments were used in minimally invasive or orthopedic surgeries. The items were most often retained in the abdomen or vagina. A total of 1,156 contributing factors were identified, most frequently in the categories of human factors, leadership, and communication,[13] which, on average, corresponds to 51 events per year, an occurrence higher than that recorded in our institution, but with similar items and procedures.

Another study related to gynecological surgeries shows a lower incidence, with 45 cases in the last 19 years. The most common items were vaginal sponges (53.33%). Items retained less frequently involved broken instruments (20.20%). Most cases consisted of laparoscopic hysterectomies or vaginal deliveries. In addition, 75 contributing factors were identified, consisting mainly of preconditions for unsafe acts (communication challenges, coordination failures, and problems with tool/technology design) and unsafe acts (errors).[14]

In a study focused on outpatient surgeries, inadequate intraoperative surgical counting was the most commonly identified contributing factor as a sentinel event (12/20; 60%). This category was assigned to cases where surgery was completed before a comprehensive counting of instruments, needles, or compresses was completed. This category also included cases where a foreign object was retained, but there was no documentation that a surgical counting had occurred.[15]

In a Swiss study, pressure for productivity and a strong emphasis on economic efficiency in operating rooms were perceived as detrimental to safety culture – considered essential for preventing FBR, especially among professionals working in this environment. FBR were described as "maximally minimized", although admittedly not entirely preventable. Despite the fact that most experts considered that the published incidence of FBR warranted a thorough analysis of the data, there was little agreement on who was responsible for initiating new preventive measures.[4]

Several factors increase the risk of FBR: intraoperative blood loss, longer duration of surgery, more subprocedures, lack of (or incorrect) surgical countings, more than one surgical team, and unexpected intraoperative factors. Unclear policies regarding counting responsibility, surgical specimen handling, involvement of two surgical teams, and inadequate handover with a surgical technician shift represent other important contributing factors.[16]

Despite few notifications, this type of event may be subnotified, as the surgeon may remove the device during the procedure and not inform the nursing team. A survey conducted in the year 2012 by the School of Medicine of the University of São Paulo analyzed a questionnaire administered to 2,872 surgeons, where 43% reported having left a foreign body behind and 73% reported having removed a foreign body in one or more situations.[17]

We do not have records of the causes of the incidents that occurred, because these issues are handled confidentially by the safety committee. Nevertheless, studies strongly suggest a relationship with human factors (communication, leadership, incorrect records, counting errors, medical errors, and lack of records in medical charts),[4,13-15] factors inherent to the surgical procedure, intraoperative complications, and procedures involving more than one surgical team.[16]

In another study conducted in Turkey, the causes were divided into three categories: institutional factors, individual factors, and factors specific to the perioperative environment. Institutional factors are related to employees not following institutional protocols, the nursing team members feeling like they are the doctor's "secretary" and problem solver, the expectation on the part of nursing team members that doctors will fulfill their tasks, staff shortages, excessive workload, and lack of motivation. As for Individual factors, we can cite: conflict between medical teams and nursing team members, aggressiveness, and inappropriate dynamics. As for specific factors related to the perioperative environment, the fast dynamics of services stands out.[18]

In clinical practice, we can observe that these causes are present in our daily lives. There is a lack of adherence to institutional protocols by nursing and medical teams, which, despite recent changes and training, are sometimes ignored. The nursing team often has to clash with the medical team in order to carry out routine tasks, which discourages correct compliance with the protocol. In addition, work overload, reduced team numbers, and communication failures can also be observed.

With regard to the established protocol, when compared to the AORN's Guideline for Retained Items, published in the year 2022, the American proposal is more detailed concerning issues that may arise in the operating room and provides guidance on the necessary actions at each stage of the item counting.[19] Therefore, in our protocol, there is a lack of detailed procedures, which can generate doubts and favor the definition of procedures by the operating room team.

As for recording information, JCI studies corroborate our results. More than 80% of gauzes or compresses retained in patients reported to JCI occurred when the counting was recorded as correct. Consequently, in some countries, such as the US, radiofrequency is already used to detect gauzes and compresses in patients at the end of surgical procedures, regardless of whether the counting was correct.[20] In Brazil, this technology is not yet available, but it is a major step forward in terms of maintaining patient safety.

The review of the protocol, combined with the active participation of the nursing team in its development and implementation, reflects an institutional advance toward strengthening patient safety culture. The centrality of nursing in the counting and checking process, especially during the sign out stage, highlights its strategic role as an integrative link among surgical team members and reinforces the empowerment of the nursing team as a leadership agent.

However, weaknesses remain, especially regarding the lack of a formalized protocol for counting surgical instruments. In response to this gap, the institution's management acquired traceability software for the Central Supply Sterile Department (CSSD) in the year 2022, with technology for scanning instruments at the end of procedures and automated recording of items used. During the period analyzed, the solution was in the development and integration phase with the Information Technology (IT) team, with future implementation planned. The expectation is that this tool will contribute to increasing the traceability of surgical materials and mitigating the risks associated with FBR per instrument.

This study has important limitations that should be considered when interpreting the results. The first of these relates to the possible subnotification of events related to foreign body retention, since not all occurrences may have been recorded due to communication failures or ethical issues.

In addition, the absolute number of cases analyzed was very small, which makes inferential statistical analyses impossible and limits any generalization of the findings to other institutions or healthcare contexts. The data reflect only the reality of a single hospital, with its own protocols, institutional resources, and specific organizational culture, which restricts extrapolation to services with other characteristics.

Another relevant limitation was the absence of qualitative data on the factors involved in counting errors and events related to FBR. The records available in electronic systems are essentially descriptive and do not include the teams' perceptions of the difficulties encountered in complying with the protocol, the relational dynamics among professionals, or concrete operational obstacles. This prevents an in-depth understanding of the organizational, cultural, or relational barriers that contribute to the occurrence of these events.

From a methodological point of view, the retrospective observational design, typified as before-after, without a control group, prevents any inference of causality or assessment of the direct impact of the protocol change. The findings only allow us to describe the time trend of the events notified and discuss possible associations with institutional changes, but there is no control of confounding variables or standardization of exposure to risk factors.

Finally, although the institution invested in the acquisition of a computerized system for the traceability of surgical instruments in the year 2022, with automatic beeping and recording of the items used, this technology was still in the development and integration phase and had not been implemented during the period analyzed. This highlights a persistent weakness in terms of instrument counting, thus constituting a critical point for future improvement actions.

Therefore, strengthening safety culture requires not only well-structured technical protocols, but also continuous investment in supporting technologies, ongoing education processes, and recognition of the nursing team as an essential agent in terms of leading safe surgical practices.

CONCLUSION

Although the incidence of foreign body retention was low in the period analyzed, it is a serious adverse event that poses significant challenges for healthcare institutions. This study highlighted the importance of well-structured protocols, with clear steps, detailed procedures, and active supervision, as essential elements for preventing this type of occurrence. In addition, it emphasized the relevance of continuous training and the consolidation of a safety culture in the surgical environment.

Despite technological limitations, such as the absence of radiofrequency detection systems, the institutional experience analyzed shows that adjustments to processes, continuous review of protocols, and investments in developing technologies are promising strategies for mitigating risks and ensuring safer

and more efficient patient care. Improving practices, combined with active clinical governance, is essential for building a safer and more resilient surgical environment.

CONTRIBUITIONS

Contributed to the conception or design of the study/research: Palos, LC, Kageyama, ES, Espindola, CD, Rinaldi LC, Correa, RP, Sousa, CS. Contributed to data collection: Palos, LC, Kageyama, ES. Contributed to the analysis and/or interpretation of data: Palos, LC, Kageyama, ES. Contributed to article writing or critical review: Palos, LC, Kageyama, ES, Espindola, CD, Rinaldi LC, Correa, RP, Sousa, CS. Final approval of the version to be published: Sousa, CS.

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