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Experience of a Tertiary-Level Urology Center in the Clinical Urological Events of Rare and Very Rare Incidence. I. Surgical Never Events: 2. Intracorporeally-Retained Urological Surgical Items

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Key Words

Intracorporeal foreign bodies • Never events • Retained surgical items • Textiloma

Abstract

Objective: Presentation of our center's experience in the management of intracorporeally-retained urological surgical items. ***Materials and Methods:*** Retrospective search of our center's data for cases of retained surgical items during the period July 2006 to June 2016. Each case was studied for the demographic and clinical variables including types, presentation, and management. ***Results:*** Out of more than 55,000 different urological interventions, only 39 cases (28 males and 11 females) had retained surgical items. Urolithiasis-related urological subspecialties were more involved than others. Forgotten items and technically-retained items occurred in 38.5 and 61.5% of cases, respectively, and were immediately discovered or discovered up to 10 years later. Material types were textiles, biosynthetics, and metallics in 31, 51, and 18%, respectively. Possible predisposing factors included complex surgeries, emergent intraoperative events, and extra approaches. Occurrences of retained surgical items before and after implemented corrective actions were 74.6 and 25.4%, respectively. All the final outcomes were either short- or long-term harm without deaths, organ losses, or permanent disabilities. ***Conclusion:*** Retained urological surgical items are surgical never events that result from forgetfulness or technical surgical human errors. Their sequels can be potentially fatal, but they are preventable and can be significantly reduced.

Introduction

Surgical never events are subjects of concern among all patients, healthcare providers, and the public [1, 2]. Many classifications have been reported, but none of them are convincing for the interested personnel. However, the retained surgical items category has been reported as the commonest in a 3-category classification including wrong-site surgery and surgical fires [3]. The term "retained surgical item" is defined according to the National Quality Forum's report as a foreign object which is unintentionally retained inside a patient following surgery [1]. This surgical item is intentionally used by the operator for surgical purposes, but is subsequently

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and unintentionally left within the patient [4]. Although they are foreign bodies in all criteria, retained surgical items have their own special introduction modes to be within patients during surgical interventions [4, 5], especially open cavity surgeries [6]. This should be correlated to urological surgery where the urological procedures represent significant proportions of abdominal surgery. The terms retained and missed foreign bodies or objects are used interchangeably in the literature. However, the most acceptable term is "retained surgical items" [4].

Although the category of retained surgical items resembles other categories of never events in the occurrence of a human error as a cause, it differs from them in the detectability of the foreign object within the body with its subsequent sequels [4]. Also, while the term "missed surgical items" involves mostly missing surgical tools and instruments during open surgeries, the scope of the subject was widened in the current study to include retained catheters and broken instruments during minimally-invasive techniques and outpatient maneuvers. Accordingly, this study separately targeted retained urological surgical items in order to evaluate the situation in our center and take a step forward in management of surgical never events.

Materials and Methods

A retrospective search and collection of the data of patients who were operated upon in the Assiut Urology and Nephrology Hospital, Assiut University, Egypt in the period from July 2006 to June 2016 was done to study intracorporeally retained surgical items. A retained surgical item can be defined according to the National Quality Forum's definition as a foreign object that is unintentionally retained inside a patient as a sequel of surgical interventions. Also, this definition fulfills the criteria for inclusion in surgical never events [1]. Inclusion criteria included surgical intervention for a urological disorder, occurrence of a human error that resulted in the intracorporeal retention of a surgical item, and detection of this item by physical examination, imaging, interventional diagnosis, or surgery.

Each case was studied for its demographic and clinical variables including age, gender, primary diagnosis, primary procedural approach (open or endoscopic surgery) and level (minor, intermediate, or major), urological subspecialty, surgical item material [textile, biosynthetic (such as latex rubber, polyurethane, and sutures), or metallic], clinical presentations, diagnostic methods, extra procedures and approaches needed (open or endoscopic procedures), major sequels and complications, and final outcomes (short- or long-term harm, organ loss or permanent disability, and death). According to the cause of retention, retained urological surgical items were classified into missed items due to forgetfulness such as textile items and technically-retained items due to surgical technical errors such as catheter fixation by stitches or instrumental disuse such as detached catheters and broken instruments. Retained catheters due to non-human errors (such as balloon non-deflation) represented a different subject where they did not fulfill the criteria of never events to be included in this study.

Proposed underlying predisposing factors were studied such as long duration surgery, missed counting policies (implementation and methods such as checklists and manual counting), complex surgeries (doing more than 1 procedure in the same surgical session on single or multiple organs), emerging intraoperative events (hemorrhage, extensive adhesions, employing multiple approaches, or anatomical abnormalities), and an inappropriate surgical qualification level (low for residents and non-urologists, intermediate for assistant lecturers, and high for lecturers and higher academic positions).

Chronological correlation was done between the occurrences of these events and the corrective policies taken in technical (encouraging the use of endoscopic interventions against open surgery and strict demarcations between the urological subspecialties) and administrative (legal punishment rules of the involved personnel) axes before and after the year 2010.

Results

Our urological interventions in the time period from July 2006 to June 2016 included more than 55,000 interventions which varied between minimally-invasive procedures such as insertion of a percutaneous nephrostomy tube and advanced surgery such as kidney transplantation. Of them, 39 cases (0.07%) involved missed or retained urological surgical items. Age ranged from 4 to 70 years (mean 42.79 ± 14.78 years) with only one involving a child and included 28 males and 11 females.

Most of the urological subspecialties were involved with a predominance of urolithiasis-related interventions and general urology (fig. 1). Approaches of primary procedures were open in 71.8% cases and endoscopic in 28.2% of cases. Their levels were minor, intermediate, and major in 12.8, 43.6, and 43.6%, respectively. The main surgeon's qualification levels were low, intermediate, and high in 5 (12.8%), 7 (18%), and 27 (69.2%) of cases, respectively. Primary procedure/urologist qualification levels were proportional in 36 (92.3%) and disproportional in 3 (7.7%) cases.

Anatomical spaces of location of the retained surgical items included the abdominal cavity in 14 cases (36%) (12 items were in the retroperitoneal space and only 2 items in the intraperitoneal space), the pelvic cavity in 12 cases (30.7%) (8 items were in the extraperitoneal spaces and 4 items in the intraperitoneal space), penile subcutaneous plane in 1 case (2.6%), genitourinary tract lumens (intraluminal) in 12 cases (30.7%), 10 items were inside the urinary tract (ureter, bladder, and urethra in 5, 4, and 1 cases, respectively), and 2 items were inside the vagina.

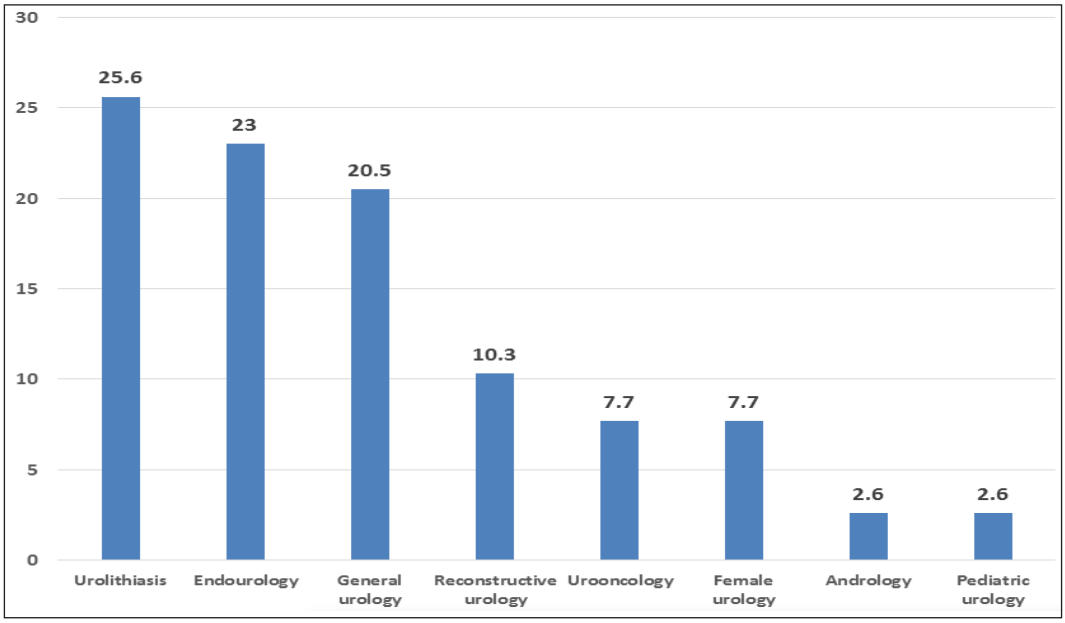

Fig. 1. Percentages of urological subspecialties involvement in retained surgical items.

The material type of the retained surgical items included 3 categories (fig. 2); textile (table 1), biosynthetic, and metallic materials. Surgical items were retained due to forgetfulness in 15 cases which were mainly textile materials (towels and gauzes), and due to technical errors in 24 cases which were mainly synthetic materials (catheters and sutures) followed by metallic materials.

The direct causes were counting mistakes in 8 cases (20.5%), negligence in 5 cases (12.8%), technical error in 17 cases (43.6%), and instrument malfunctioning in 9 cases (23.1%). The former 2 causes were mainly the cause in missed surgical items, while the latter 2 causes occurred mainly in technically-retained surgical instruments. Operative time was more than 1 hour in most of the cases (fig. 3).

Possible underlying predisposing factors were encountered in 22 cases (56.4%). Of them, complex surgeries were encountered in 12 cases (54.5%), emerging intraoperative events in 6 cases (27.3%) (including hemorrhage in 7 cases, extensive adhesions in 2 cases, and needing an extra-approach in 1 case). Four cases (18.2%) had complex surgery (multiple procedures) besides at least one emerging intraoperative event.

The duration of intracorporeal retention of the surgical items were immediate discovery group in 9 cases (23%) and the later discovery group in 30 cases (77%) which varied from 3 days up to 10 years.

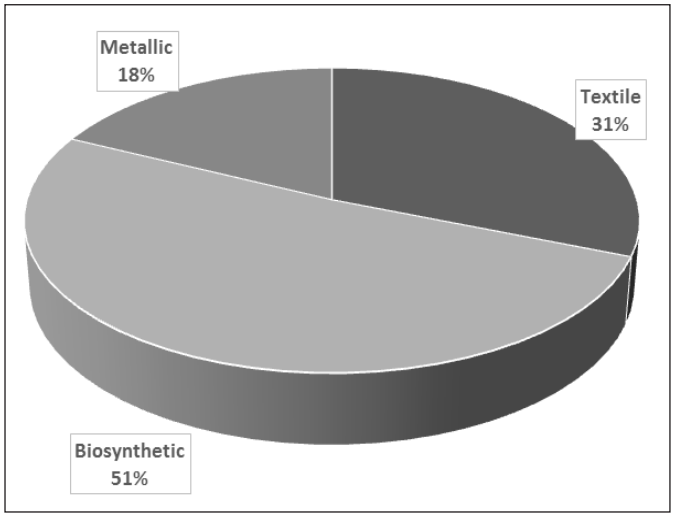

Fig. 2. Percentages of material types of the retained surgical items.

Major sequels and complications occurred in 14 cases (36%) and included septic peritonitis in 1 patient, abscesses in 2 patients, urinary fistulas in 3 patients, sinuses in 2 patients, renal obstruction in 3 patients, and stone formation on the missed or retained item in 3 patients.

Table 1. Surgical features of retained textile surgical items

Retained surgical item	Anatomical space	Approach of primary procedure	Duration of retention	Diagnostic tools	Approach of removal	Significant complications
Surgical towel	pelvis: extraperitoneal	open	10 years	CT	open	vesicocutaneous fistula
Surgical towel	pelvis: intraperitoneal	open	6 months	CT	open	vesicovaginal fistula
Surgical towel	pelvis: intraperitoneal	open	1 week	CT	open	septic peritonitis
Surgical towel	abdomen: intraperitoneal	open	immediate	none	open	none
Surgical towel	abdomen: intraperitoneal	open	immediate	none	open	none
Surgical gauze	abdomen: retroperitoneal	open	2 weeks	CT	open	abscess
Surgical gauze	abdomen: retroperitoneal	open	1 month	CT	open	flank sinus
Surgical gauze	abdomen: retroperitoneal	open	3 weeks	CT	open	abscess
Surgical gauze	urinary bladder	open	2 weeks	US, cystoscopy	endoscopic	LUTS
Surgical gauze	urinary bladder	open	1 week	US, cystoscopy	open	LUTS
Vaginal pack	vagina	open	1 week	physical examination	manual	vaginal discharge
Vaginal pack	vagina	open	4 days	physical examination	manual	vaginal bleeding

CT = Computed tomography; LUTS = lower urinary tract symptoms; US = ultrasonography.

Thirty-one patients (79.5%) needed one extra procedure for treatment of the retained items and only 1 case (2.5%) needed 2 procedures. They included 19 open surgeries and 14 endoscopic procedures. Manual extraction was successfully employed in 7 cases (18%). This approach was found possible in superficially retained items or some of those with extracorporeal extensions such as catheters.

Regarding the final outcome, no deaths, permanent disabilities, or organ losses occurred as a direct result of missed or retained surgical items. Most of cases experienced short-term harm (72%) including 1 case of septicemia and few cases (28%) of long-term harm including 4 urinary fistulas and 2 sinuses. All the cases had their retained surgical items removed with complete resolution of the effects of the event and its sequels or complications.

Only 3 cases (7.7%) had legal disputes with the involved surgical teams or the institutions.

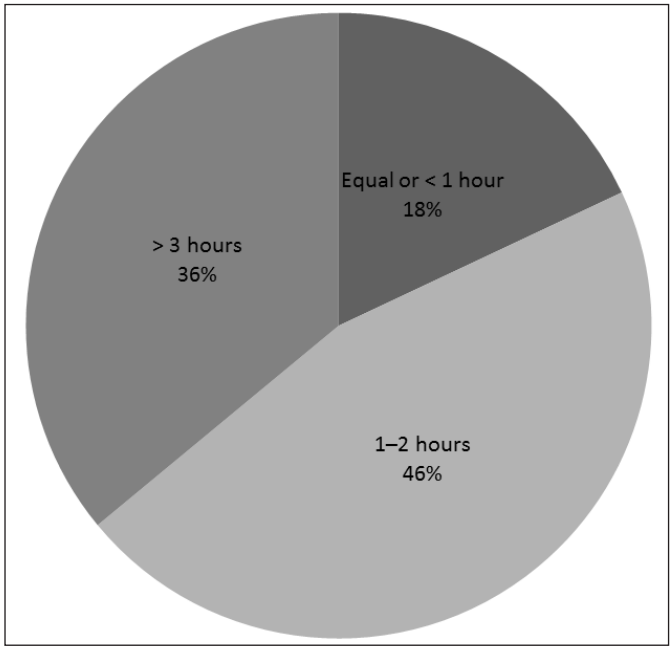

Fig. 3. Percentages of time duration categories of urological surgeries involved in retained surgical items.

Discussion

Retained surgical items are a well-known preventable category of never events which is associated with open surgical as well as minimally-invasive procedures. The term "never event" refers to a human error that involves medical practice, but optimally, it should not occur under any circumstances. The result of human error as a retained surgical item is illustrated by imaging and gross detectability on surgery [4]. Accidentally-retained foreign bodies are introduced into the human body via wounds and natural orifices. However, in spite of the similarity to those accidental foreign bodies in the mode of introduction, retained surgical foreign bodies are originally surgical items used for therapeutic purposes before being retained as foreign bodies due to forgetfulness or technical errors. So, they are definitely different and deserve to be named as "retained surgical items".

The median estimate for retained surgical items was reported as 1.32 events per 10,000 procedures. However, the estimates are variable by single items and procedures [3]. The incidence in the current series was higher than this value, where it could be attributed to inclusion of the technically-retained items such as catheters. Although the male gender is more involved in retained surgical items, they occur in both genders.

No certain urological subspecialty is spared from the involvement in these events. However, their rare incidence may not allow real chances to estimate the true incidence in each subspecialty. In the current study, urolithiasis and related urological subspecialties had the majority of events. This could be attributed to the high prevalence of urolithiasis in Egypt involving all age groups as one of the Afro-Asian stone-forming belt countries with variable therapeutic interventions including open surgeries [7].

Open primary procedures were encountered in the majority of cases. This proportion may explain why many retained surgical items are associated with open cavity surgeries. The abdominal cavity with its continuations including the pelvic and retroperitoneal spaces represent the common site of occurrence of the retained surgical items [4, 8]. Moreover and typically, urological interventions are approached mainly through the abdomino-pelvic cavity, especially, the retroperitoneum. In the current study, the majority of retained surgical items (66.7%) were in the abdominal and pelvic cavities with 20 items (51.3%) in the abdominal retroperitoneal and pelvic extraperitoneal spaces. Intraluminal retained surgical items could be due to missing gauzes after urinary bladder surgeries [9]. Two cases with intravesical gauzes were found after transvesical prostatectomy in the current series. Also, minimally-invasive surgeries contribute to retained surgical items [10]. The current results correlate to these findings.

In regards to the natural history, the major proportions of the retained surgical items are shortly detectable after intervention, either as immediate discovery or after development of acute symptoms such as peritonitis which may require emergent surgical removal. However, a small proportion of them may pass unnoticed for a long time to be incidentally detected or confused with other entities such as tumors or chronic abscesses [4, 11, 12]. The duration of intracorporeal retention is variable from immediate discovery up to decades [12]. One of the current cases presented with a suprapubic vesicocutaneous fistula after open prostatectomy due to a towel retained for 10 years. Possibly, fistulas may complicate retained surgical items due to associated inflammations and erosive effects.

Textile items have been reported as the most common material type of retained surgical items with surgical sponges being the most common among them. They may form masses which are known in the literature as gossypibomas, textilomas, or pseudo-tumors. Reported textilomas with renal surgeries are scarce [12–15]. However, they could have higher rates when all the genitourinary organs are considered [9]. Accordingly and although the retained surgical items are heterogeneous in material types, they were differentiated into textile and non-textile categories [4]. This differentiation was believed to affect the retention risk profile [8]. However, for more specification, we differentiated them into textile, metallic, and biosynthetic materials (such as latex rubber) on the basis of including the technically-retained items, in this study, which mainly belong to the latter material type.

Retained surgical items have predisposing factors such as emergency surgeries, simultaneous multiple major surgical procedures, and incorrect counting of surgical items or instruments [5, 16]. In the current study, the possible underlying factors included incorrect surgical counts, long duration procedures, bloody surgeries, multiple surgeries in the same surgical session, and intraoperative emergent surgical events. In contrast, the procedure level and surgeon qualification level were proportional in the most of the cases, where this finding could exclude disproportionation as a major risk factor for retained surgical items.

Concerns about non-immunity of minimally-invasive procedures against retained surgical items are raised [10]. However, our regulatory technical and administrative actions represented by the marked shift from open surgical approaches to endoscopic approaches in management of urolithiasis and some general urological disorders such as benign prostatic hyperplasia were associated with a marked reduction in the occurrences of retained surgical items, especially forgotten textile items.

As a well-known entity in surgical never events, retained surgical items have the same concerns of financial and psychosocial burdens on both the patient, the involved medical personnel, and health care systems. Extra procedures for extraction of the retained item or correction of its sequels and paid claims mandate extra financial resources [2]. Involved medical personnel are prone to stresses of self-blame, administrative actions, and medico-legal responsibilities. In the current study, few cases had legal disputes against the medical teams or institutes. This could be attributed to many factors

such as free treatment policies, traditional compensation means, and sociocultural factors.

The current study analyzed a large series of urological operations in a single tertiary-level urology center to study these very rare events. The magnitude of the problem may be outlined by the current results. Moreover, exposure of our experience may motivate other researchers to make more efforts in studying for better development of improvement quality systems. This study targeted the retained surgical items due to urological surgeries which is not a common issue in the literature.

Critically, the current study is a retrospective one which could be a limiting methodological factor. However, it may be the only way to consider this subject. Its results represent only the situation in a single tertiary-level urology center in Egypt. So, they should be cautiously extrapolated when the problem is discussed at a national level due to expected less generalizability and until other national studies can optimally evaluate the whole situation.

Conclusion

Retained urological surgical items are rare and unique surgical never events. They involve open surgeries more than endoscopic interventions, where textile items are primarily related to the former approach. They may be classified into forgotten and technically-retained surgical items. Predisposing factors may include complex surgeries, emergent intraoperative findings, and multiple surgical approaches. The sequels are potentially fatal and could be durable for decades, but they are commonly correctable. Also, although the occurrences of retained surgical items appear inevitable, their reduction could be effectively attempted.

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