TITLE OF STUDY

A REVIEW OF THE CLINICAL PRESENTATION, DIAGNOSTIC CHALLENGES OF RETAINED ABDOMINAL SWABS AND THE MEDICO-LEGAL IMPLICATIONS OF GOSSYPIBOMA.

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THESIS SUBMITTED TO THE UNIVERSITY OF KWAZULU NATAL (UKZN) FOR THE DEGREE OF MASTER OF MEDICINE (SURGERY)

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Student: Dr R Naidoo Date: _____

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ACKNOWLEDGEMENTS

Thank you to Ms Sumayyah Ebrahim for her assistance and guidance with this project. Thank you to my mother Mrs Anusuyia Naidoo for her assistance with the capturing of data.

Thank you to Professor B Singh for the endless words of encouragement and motivation. Thank you for the supervision, assistance and unwavering support.

ABBREVIATIONS

- C/S – Caesarean Section
- TAH – Total Abdominal Hysterectomy
- BSO – Bilateral salpingo – oophorectomy
- RO – Right oophorectomy
- X – ray – radiograph
- CT Scan – Computer tomography scan
- ERCP – endoscopic retrograde cholangio-pancreaticogram
- MRI – Magnetic resonance imaging
- MRCP – Magnetic resonance cholangio-pancreaticogram
- HPCSA – Health Professionals Council of South Africa

FIGURES, TABLES AND GRAPHS

CONTENTS

CHAPTER ONE

1.1 Introduction

Gossypiboma is a term used to describe a retained surgical swab following any surgical procedure. The term originates from the Latin word ‘gossypium’ which means cotton and the Swahili word ‘boma’ which means place of concealment. The synonyms for this word includes textiloma, gauzoma and muslinoma (1, 2). Although a relatively rare occurrence it has been present since the beginning of surgical practice and still continues to happen today despite advances in theatre practice. The consequences of this mistake can be life altering or even fatal. The myriad of clinical presentations associated with a retained abdominal swab often mimicking other clinical entities makes this a difficult diagnosis. This review is set to highlight the predisposing factors, clinical presentation and diagnosis of retained abdominal swab by reviewing all reported cases in the English literature from 1990 to 2012. A total of 100 such reports were reviewed. Reports of 1 or 2 cases per report were included in the data analysed. Reports with 3 or more cases were considered a series and used as comparisons for the results found in this study.

A retained surgical swab is a surgeon’s and scrub nurse’s worst nightmare. It is fraught with legal consequences regarding clinical practice as well as financial consequences. It also impacts on the professional standing of these clinicians. These reasons, coupled with the consequences for the patient, make a compelling argument to find a way to avoid this disaster, prompting a review of good surgical practice. Presently, this topic leaves many unanswered questions and a paucity of guidelines regarding diagnosis, treatment and prevention; a review of the literature will attempt to address these challenges.

Medico legal implications remains an important aspect of this topic for both surgeon and scrub nurse. The law pertaining to the retained swab in different countries approaches this misfortune differently. Some look upon it with a harsh hand deeming it negligence while some believe it to be a mistake. The responsibility may lie with different parties in different legal systems as well. This review will endeavour to explore these differences with a special emphasis on the South African legal stance.

1.2 Problem Statement

The retained surgical swab, although rare, remains a persistent complication following open abdominal surgery. Despite this, there are no clear guidelines for its diagnosis and management.

1.3 Significance of the study

The study provides a comprehensive update regarding the incidence, pathogenesis, presentation, varied complications and challenges in diagnosis and treatment of the retained swab. The current international literature regarding the responsibility of such a misadventure, as well international surgical guidelines aimed at preventing such mishaps, will be reviewed.

1.4 Aim of the study

The study aimed to provide a comprehensive review of the current literature with respect to the symptoms and signs that a patient with a retained abdominal swab may exhibit, as well as the radiological appearance of a retained swab and the legal implications for the operating team.

1.5 Specific objectives

- To describe the pathogenesis of a retained swab

- To summarize the various complications and clinical presentations of a retained abdominal swab.
- To review radiological features of a retained abdominal swab
- To review the South African and international medico – legal guidelines on retained swabs as well as standard operating room practice.

CHAPTER TWO

2.1 Ethical Considerations

Ethical approval for this study was waived by the University of KwaZulu-Natal (UKZN) Biomedical Research Ethics Committee (BREC).

2.2 Study Design

The study consisted of a literature review of relevant published material.

2.2.1 Search Strategy and Data collection methods

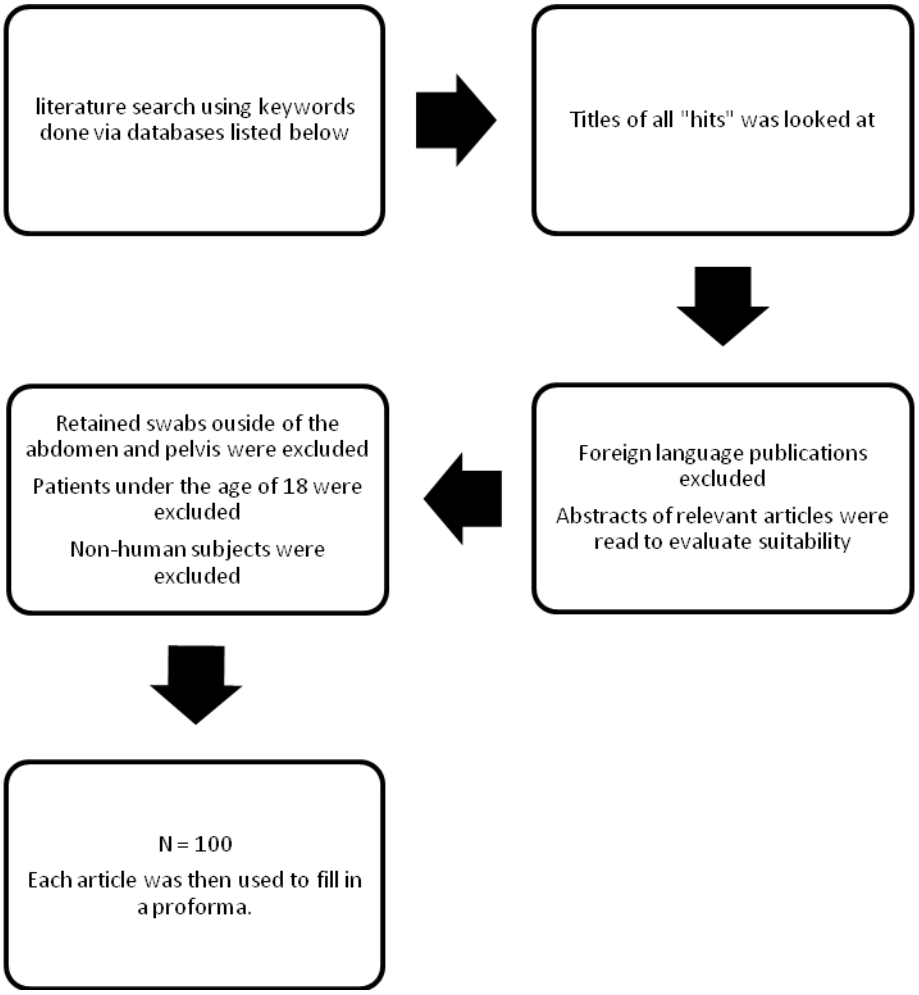


Figure 1 is a diagrammatic representation of the method used for obtaining the data used in this study.

Search strategy*:* A collective review of the literature using the relevant search engines and search terms (as listed below) was done.

Search engines and electronic databases

Science Direct; Cochrane library; EBSCO host research databases; Google scholar; MD consult; Medline/ Pubmed

Relevant search terms will include the following keywords and MeSH terms as applicable:

Gossypiboma abdomen ; Textiloma abdomen ; Retained swab/sponge abdomen ; Medico – legal retained swab or sponge; Medico – legal gossypiboma; Operating room / theatre guidelines

2.2.2 Inclusion and exclusion criteria

The inclusion criteria:

- Human subjects
- Retained abdominal swab
- English language text
- Period- Year 1990 to 2012
- Studies from both developed and developing countries

The exclusion criteria:

- Swabs retained outside the abdomen and pelvis
- Literature published before 1990
- Foreign language reports

An experienced medical librarian was consulted to improve general approaches for conducting a comprehensive search of the above databases.

2.3 Data abstraction and analysis

Case reports of 1 or 2 per report were added into the cohort. Reports of 3 or more cases were reserved to allow comparison of results. A review of all the titles and abstracts was done. Full text articles were sourced if appropriate. The content from the literature was reviewed by a single author to eliminate bias in extracting information. The information was quantified under the following headings:

- Clinical presentation
- Radiological imaging
- Initial surgery
- Time between surgery and presentation

2.4 Limitations to the study

- Reliance on reported data only.
- The sole use of electronic sources for the literature search.
- Exclusion of literature prior to 1990 as well as exclusion of foreign language publications.

CHAPTER THREE

3.1 Epidemiology

Accurate incidence of this misfortune is hampered by the reluctance to report these cases by medical staff as well confidentiality agreements following legal settlements (3). The complication may sometimes remain asymptomatic or realised many years later or diagnosed at a different institution which also impacts on the accuracy of incidence.

Recent statistics based on malpractice claims puts the incidence of retained foreign bodies at 1 in 18760 surgical procedures to 1 in 8801 surgical procedures; however these figures are likely to be an underestimate because a large number of minor procedures such as laparoscopic, endoscopic and catheterisation procedures have been included and these are unlikely to result in retained swabs (4). The most common retained foreign body are surgical swabs, likely due to their frequent use, small size and, once blood soaked, maybe easily missed (3, 5). The most common site involved is the abdominal cavity followed by the thoracic cavity (3).

An incidence of 1 in 1000 abdominal surgeries to 1 in 1500 abdominal procedures have been commonly described in the literature; however accuracy is hampered by under-reporting and late presentation, presentation at a different institution as well as patients who are completely asymptomatic(2, 6). A third world study showed a much higher incidence of 1 in 677 surgical procedures. This has been attributed to the lower risk of legal consequences resulting in a less diligent medical staff, more difficult working conditions in poorer countries, as well as a lack of proper resources such as radio-opaque swabs and intra-operative radiographic resources (7). Further reasons for under reporting maybe to protect the reputation of the

surgeon as well as the fear of being labelled a “whistle blower” should the swab be found by a second neutral surgeon (2).

Some studies suggest that this complication occurs more commonly in females (4, 8). This has been ascribed to gynaecological procedures being added to the list of causative procedures, thus increasing the total number of females compared to males having surgery. There is no specific risk being female.

The incidence of retained surgical swabs, both in general as well as specific to abdominal procedures, varies greatly between retrospective reviews. This may be attributed to the small numbers in the sample size, patients presenting after extended periods and presentation to a different institution (5). The type of surgical procedures performed also varies amongst hospitals.

CHAPTER FOUR

4.1 Pathogenesis

Cotton surgical swabs are inert and do not undergo spontaneous decomposition within the body (9). The swabs are also without impurities and without the electrical potential. They are also easy to sterilise (10).

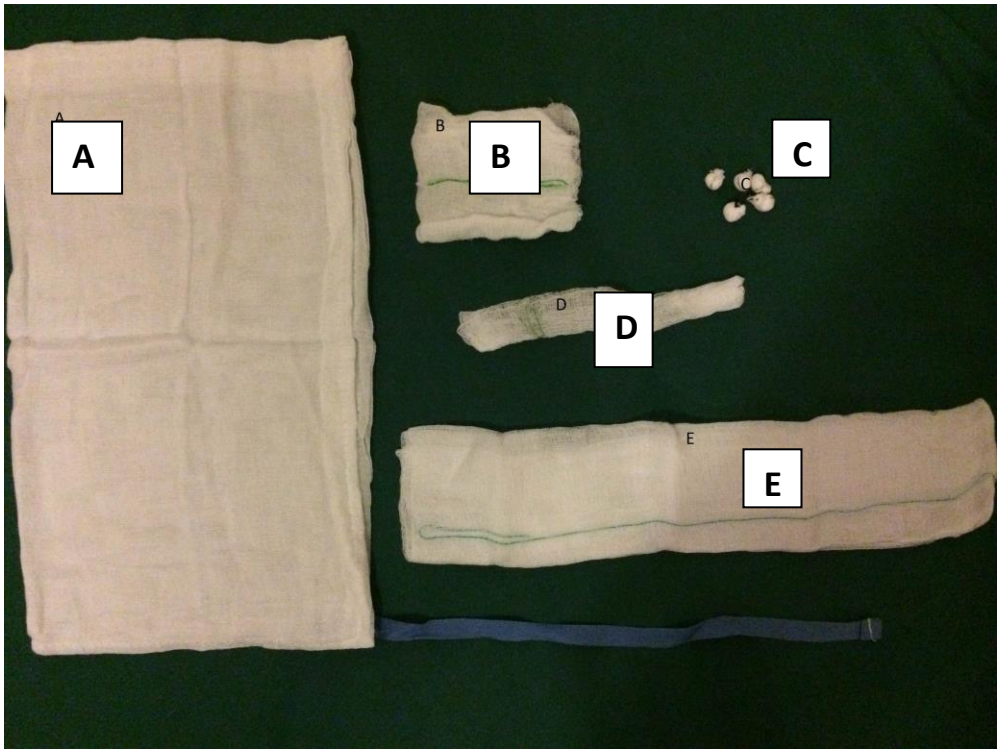


Figure 2 the different types of gauze swabs used during surgical procedures.

A: Taped abdominal packing swab

B: Gauze swab

C: Peanut swab

D: Tonsil Swab

E: Dissecting swab

Swabs used in surgical procedures come in array of sizes as pictured in Figure 1, above. The different shapes and sizes facilitate different intraoperative manoeuvres such as clearing the field of blood, packing away organs to expose the relevant area more clearly and blunt dissection. Different swabs are used in different areas of the body as well because some operative fields are limited compared to others. Abdominal procedures usually involve the use of the abdominal packing swab, the dissecting swab, gauze swabs mounted on an instrument and "peanut' swabs which are also mounted on an instrument.

Two reactions have been outlined for retained surgical swabs. Both reactions are foreign body reactions, and between them help to explain the variety of clinical presentations.

The first type of reaction is an aseptic fibrous tissue reaction that involves fibroblast reaction, adhesion formation (resulting in either complete or incomplete encapsulation), and granuloma formation (11).

The second type of reaction is an exudative inflammatory response which results in abscess formation or chronic internal or external fistulae, which may eventually result in transmural migration (12). The inflammatory reaction elicited by the swab initiates a process of self-extrusion, because the human body has the capability to recognise the sponge as a foreign body and its natural instinct is to eliminate the foreign body (10). Extrusion may be external and occur via a sinus or the abdominal incision itself or it may be internal by eroding and perforating the intestinal wall, the vagina or the urinary bladder. The swab then migrates into the viscus aided by peristalsis. When complete, the swab may extruded; if the migration is incomplete, the patient may present with intestinal obstruction or a fistula, or urinary obstruction depending on the viscus entered (10, 13)

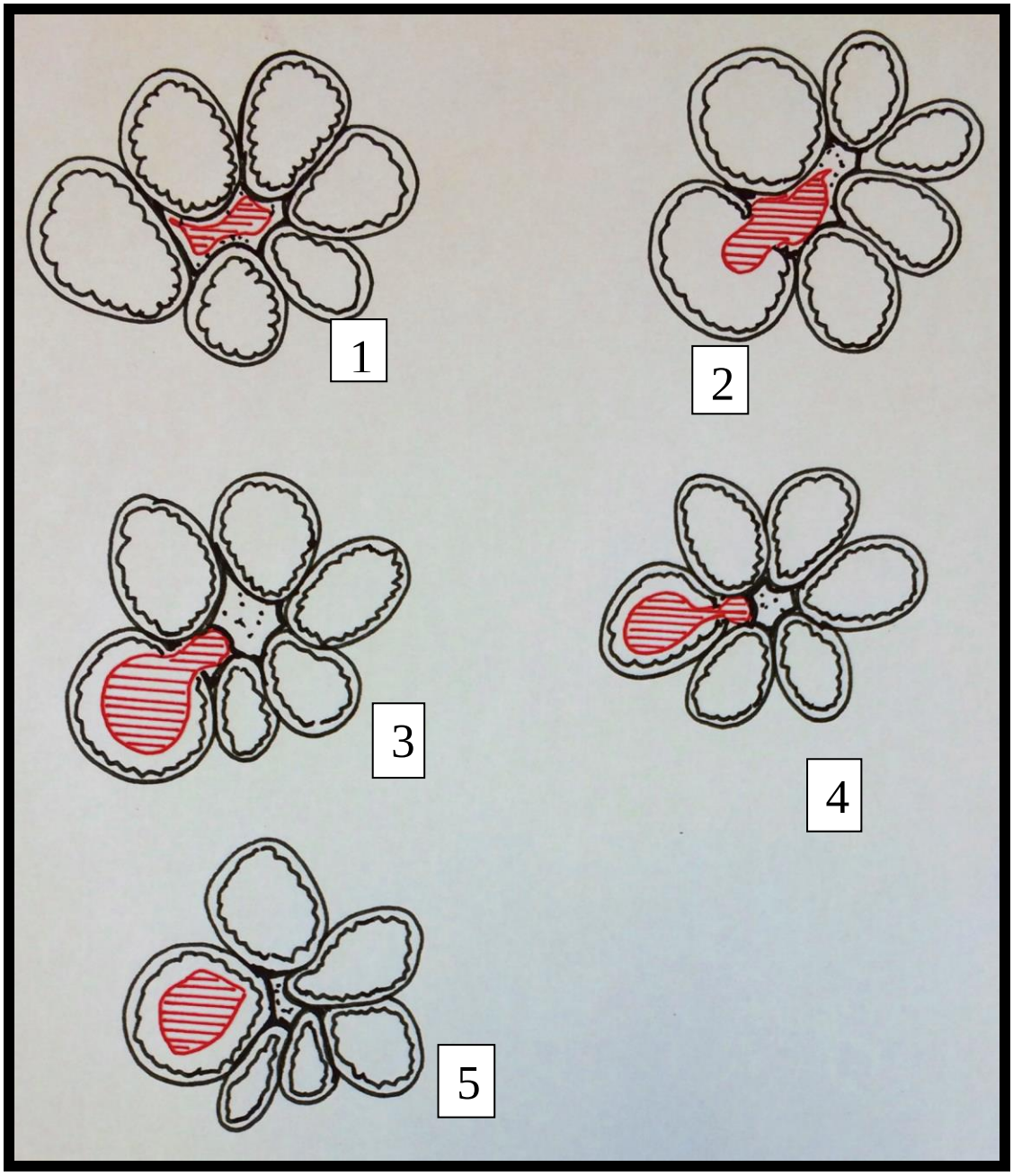


Figure 3 : Diagrammatic representation of various stages of movement (labelled 1 to 5) of sponge from the peritoneal cavity into the intestine lumen (10). In 1, the swab is in a cavity encircled by bowel loops; in 2, the swab making entry into the bowel by eroding through the wall. In 3 the swab moves further into the bowel lumen; in 4, the swab is almost completely within the bowel lumen with the cavity decreasing in size; however there is still communication between the bowel lumen and the cavity. In 5, the cavity which contained the

swab is more or less collapsed, with the swab entirely with the bowel lumen with no loss of bowel wall integrity.

These two types of reactions account for the varied timing in presentation. The aseptic type results in a protracted course with less severe symptoms while the exudative reaction usually prompts an earlier more acute response (14, 15)

4.2 Clinical Vignette

The following clinical vignette is an example of this type of reaction:

An 18 year old male underwent a laparotomy for an abdominal stab. At surgery no visceral injury was noted. The patient recovered and was discharged home. The patient subsequently presented repeatedly over the next 18 months with abdominal pain and sub-acute intestinal obstruction. He was managed as an adhesive bowel obstruction at his local hospital and responded to non-operative management each time. The patient eventually presented greatly distressed having defaecated a swab. The patient's distress was surpassed by the attendant doctor's perplexity. On retrospective review of the abdominal radiographs from previous admissions it was noted that the radio-opaque marker of a swab was overlooked on the several presentations to the hospital.

Figure 4 The swab defaecated by the patient described in 4.2 Clinical vignette (above).

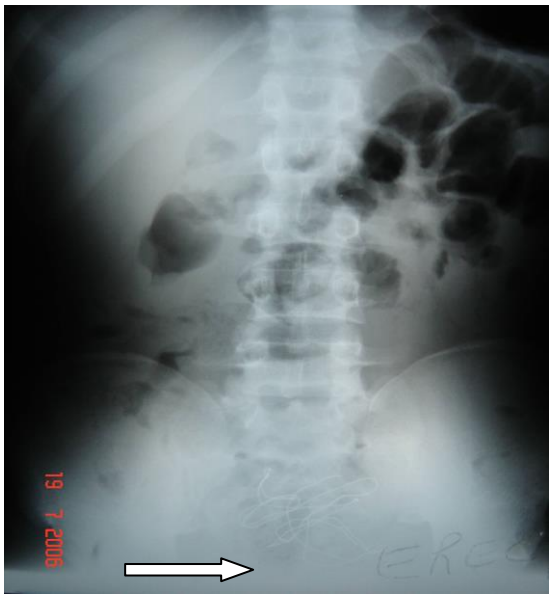


Figure 5 shows the abdominal x-ray of patient described in 4.2 Clinical vignette (above). Note the opacity indicated by the arrow.

CHAPTER FIVE

5.1 Clinical Presentation

5.1.1 Overview

The clinical manifestation of a retained swab shows vast variation which relates to the location of the material within the abdomen, the extent of bacterial contamination (5) as well the type of reaction the body has to the foreign material. The presentation may be acute and severe or chronic and vague. Some of the commonest presenting symptoms are abdominal masses, fistulae or sinuses, intestinal obstruction, intra-abdominal abscesses and pain. The septic complications may also be influenced by the degree of intra-abdominal spillage and contamination during surgery (11) . The foreign material may n be extruded from the body via the gastrointestinal or urinary tract.

5.1.2 Results

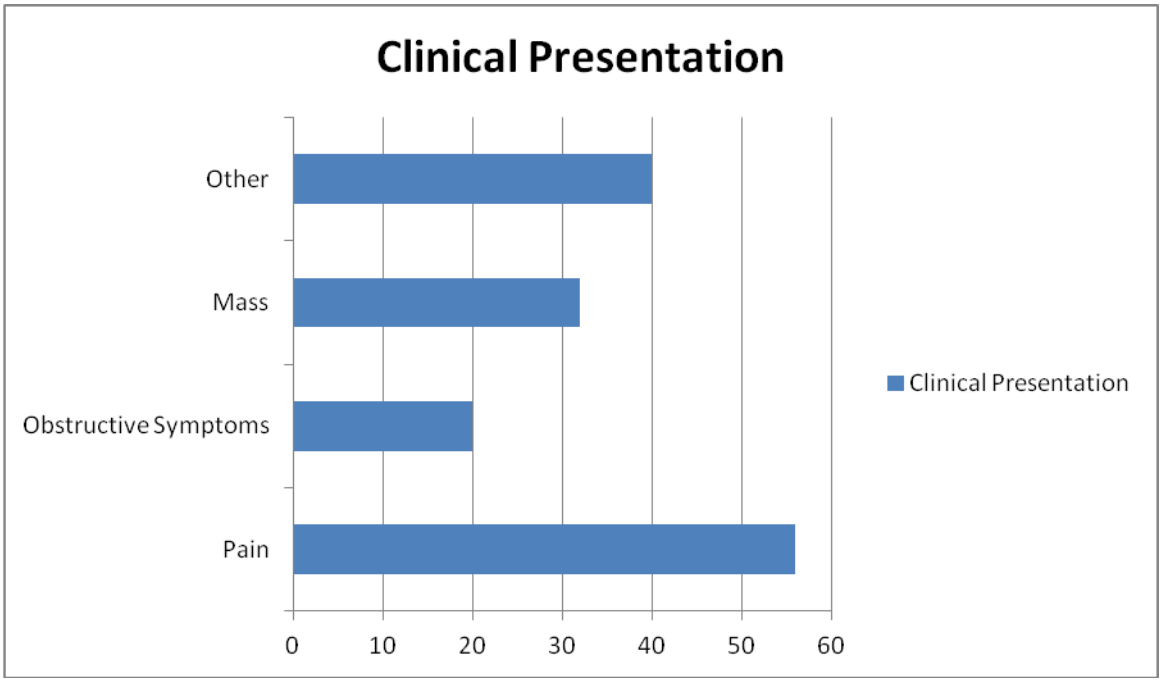
In this dissertation all cases documented in English literature between 1990 and 2012 were reviewed. One hundred cases were found on review of the literature. Reports that have more than 3 cases in their series were used for comparison of outcome (Table 1, Figure 4).

TABLE 1: Clinical presentation of patients with retained abdominal swabs as reported in literature from 1990 to 2012.

AUTHOR	MASS	OBTRUCTION	PAIN	OTHER
Huston (16)				Fistula
Jebbin (17)	1		1	Fever Abscess
Mohammed (18)	1		1	Extrusion
Iqba (19)				Extrusion
Aziz (20)	1		1	
Sirjani (21)				Jaundice
Yeung (22)	1		1	

AUTHOR	MASS	OBTRUCTION	PAIN	OTHER
Asuquo (23)		1		
Dewachter (24)				Abscess
Dash (25)		1	1	
Lu (26)	1		1	
Shyung (27)			1	
Sugano (28)	1		1	
Malik (29)	1		1	
Lin (30)				Extrusion
Doles (31)			1	
Bindapersad (32)			1	
Gogia (33)		1	1	
Anjum (9)			1	
Bhandari (34)			1	
Cerwenka (35)			1	
Rajagopal (36)	1			
Kansakar (37)				Urinary tract infection
Dux (38)		1	1	
Sharma (39)		1		
Marcy (40)			1	Dysparunia
Jouini (41)	1		1	
Al Thubaity (42)		1		
De Campos (15)			1	Iron deficiency anaemia
Lourenco (43)		1		Fever
Akbulut (44)		1	1	
Haegeman (45)			1	
Mohammadi (46)			1	
Kansakar (47)			1	Diarrhoea
Dakubo (14)			1	
Cheon (48)		1	1	
Kawamura (49)			1	
Yamamura (50)	1			
Ramdass (51)	1		1	
Abeygunasekera (52)				Enteric fistula
Mylarappa (53)				Haematuria
Gencosmanoglu (54)		1	1	
Kiernan (55)	1		1	Urinary Tract infection
Veena (56)	1		1	
Cimsit (57)			1	Jaundice
Rajput (58)	1		1	
Saji (59)	1		1	Diarrhoea
Arpit (60)		1		Enteric fistula
Kaplan (61)	1			Fever
Aminian (62)	1		1	
Grassi (63)			1	
Akbulut (44)		1	1	
Cevik (64)				Hypertension
Malhotra (65)			1	

AUTHOR	MASS	OBTRUCTION	PAIN	OTHER
Yakan (66)	1		1	
Brylka (67)				Asymptomatic
Dane (68)	1		1	
Alayo (69)			1	Fever
Agras (70)			1	
Sun (71)	1			Urinary tract infection
Patil (72)		1	1	
Paramythiotis (73)		1	1	Fever
Keymeulen (74)			1	
Ibrahim (75)				Upper GI bleeding
Ali (76)			1	
Dash (25)	1		1	Menorrhagia
Tandon (77)			1	
Erdil (78)				Upper GI bleeding
Godara (79)				Extrusion
Sharma (80)				Foreign body in urethra
Adu-Aryee (81)	1	1 1	1 1	
Cekirge (82)				Enteric fistula
Choi (83)		1	1	
Furukwa (84)			1	Incidental
Ivica (85)			1	Fever
Duman (86)	1			
Ozkan (87)				Extrusion
Quaraishi (88)	1	1	1	Fever
Saidi (89)	1		1	
Skandalos (90)	1			
Shahi (91)				Asymptomatic
Sankhe (92)		1	1	
Ray (93)	1		1	
Masqood (94)	1	1	1	
Prasad (95)		1		Fever
			1	
Sagili (96)	1		1	
Kadian (97)	1		1	Fever
Yaycioglu (98)				Fistula
Kubota (99)	1			
Nieves (100)	1			
Govarijn (101)			1	Enteric fistula
Mousavi (102)				Incidental
Kohli (103)	1	1		
	1	1		
Moslemi (104)			1	
Zbar (105)	1		1	



Graph depicting the prevalence of clinical presentation of retained abdominal swabs

5.1.3 Discussion

The most common presenting symptom was pain. Fifty six percent of patients complained of significant pain as part of their symptom complex; however only 22% complained of pain only. Pain was usually coupled with one of the other common symptoms, an abdominal mass or symptoms of vomiting and or constipation which have been grouped together as obstructive symptoms. These findings are consistent with the pathogenesis of the foreign body being walled off with fibrosis creating a mass or the foreign body migrating into the lumen to be extruded but causing luminal obstruction instead.

Seven percent presented with signs of sepsis which suggests that the exudative pathological process is less common.

Six percent of patients presented with a fistula which accentuates the remarkable way in which the body seals off the swab without allowing a loss in gastro-intestinal continuity.

A remarkable 6% of patients presented with complete extrusion of the swab via a normal orifice which further amplifies the sentiment above.

In comparison Jaffary et al (106) reported the following results in their review of 14 patients with a retained swab: 50 % of patients presented with an abdominal mass, 28.6% presented with subacute intestinal obstruction 14.3% with acute intestinal obstruction and 1% with a discharging sinus. It is likely that pain was considered part of the presentation complexes above, however abdominal mass and intestinal obstruction continually feature as common clinical presentations. This is in keeping with findings in our review.

CHAPTER SIX

6.1 Initial surgical procedure and time to presentation

6.1.1 Overview

The first surgical procedure is varied and a swab can be left behind after the exploration of any anatomical region; thus swabs may be retained in sites as varied as the thorax, the cranium, the abdomen and the pelvis. Retained swabs have even been described following spinal and neck surgery. This review is limited to swabs retained following abdominal and pelvic surgery. Factors associated with a higher risk of retained swabs include emergency surgeries, patients with a raised Body Mass Index and when the initial procedure changes unexpectedly (4). Mefire et al found in their review that 85,7% of affected patients were involved in emergency procedures and the patients most affected were obstetrics patients (7).

6.1.2 Results

TABLE 2 : The initial operations and time to presentation of 100 patients reported with retained abdominal swabs in published literature from 1990 to 2012.

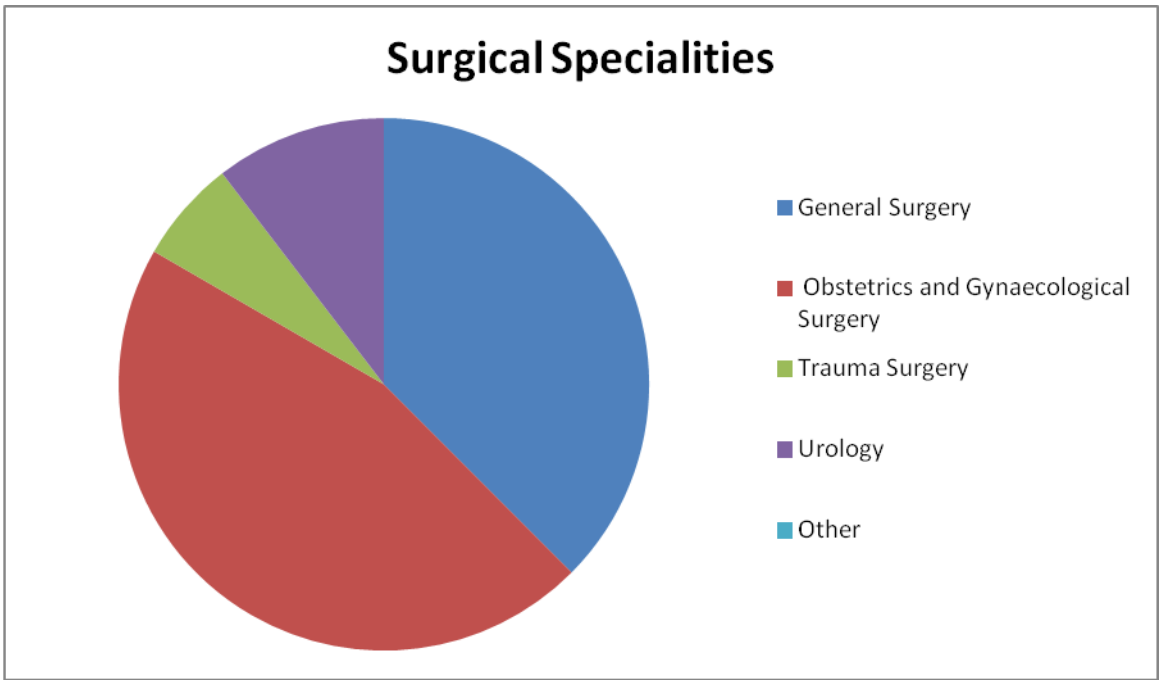
AUTHOR	INITIAL PROCEDURE	TIME TO PRESENTATION
Huston (16)	Abdominoplasty	1 yr
Jebbin (17)	Incisional hernia repair	1yr 9mo
Mohammed (18)	Trauma laparotomy	6yrs
Iqbal (19)	Trauma Laparotomy	5 days
Aziz (20)	Caesarean section	23 yrs
Sirjani (21)	Cholecsytectomy	5yrs
Yeung (22)	Hysterectomy	15 yrs
Asuquo (23)	Laparotomy Caesarean section	Unknown 9days
Dewachter (24)	Gastric surgery	12 yrs
Dash (25)	Tubectomy	5 yrs
Lu (26)	Appendicectomy	20yrs
Shyung (27)	Colectomy	Unknown
Sugano (28)	Cholecystectomy	4 yrs

AUTHOR	INITIAL PROCEDURE	TIME TO PRESENTATION
Malik (29)	Total abdominal hysterectomy	18 days
Lin (30)	Appendicectomy + ovarian cyst marsupulization	2 yrs
Doles (31)	Prostatectomy and inguinal hernia repair + orchidectomy	4 yrs
Bindapersad (32)	Trauma laparotomy	3 yrs
Gogia (33)	Caesarean section	3 yrs
Anjum (9)	Open nephrolithtotomy	6 yrs
Bhandari (34)	Cholecystectomy	10 yrs
Cerwenka (35)	Cholecsytectomy	30 yrs
Rajgopal (36)	Caesarean section	12 weeks
Kansakar (37)	Open cystolithotomy	1 yr
Dux (38)	Open cholecystectomy	10 months
Sharma (39)	Open cholecystectomy	2 months
Marcy (40)	Total abdominal hysterectomy	8months
Jouini (41)	Trauma Lap	9 yrs
Al Thubaity (42)	Caesarean section	1 yr
De Campos (15)	Total abdominal hysterectomy	16 yrs
Lourenco (43)	Aneurysm repair	4 yrs
Akbulut (44)	Laparotomy	28 yrs
Haegeman (45)	Abdominal Aortic Aneurysm	9 yrs
Mohammadi (46)	Trauma Lap	5 yrs
Kansakar (47)	Cholecystectomy	14 yrs
Dakubo (14)	Total abdominal hysterectomy	4yrs
Cheon (48)	Partial gastrectomy	30 yrs
Kawamura (49)	Caesarean section	3 yrs
Yamamura (50)	Distal gastrectomy	15 yrs
Ramdass (51)	Ruptured ectopic	9 yrs
Abeygunasekera (52)	Pyelolithotomy	Unknown
Mylarappa (53)	Total abdominal hysterectomy	15 yrs
Gencosmanoglu (54)	Cholecystectomy + umbilical hernia repair	3 yrs
Kieman (55)	Total abdominal hysterectomy	4 yrs
Veena (56)	Subtotal hysterectomy LSO	4 yrs
Cimsit (57)	Cholecystectomy + drainage of hydatid cyst	4 yrs
Rajut (58)	Total abdominal hysterectomy + bilateral salphingo-oophorectomy	30 yrs
Saji (59)	Myomectomy – fibroid	6 months
Arpit (60)	Laparotomy for ischaemic bowel	3 months
Kaplan (61)	Peptic Ulcer Disease	32 yrs
Aminian (62)	Caesarean section	5 yrs
Grassi (63)	Abdomino-perineal resection	3 yrs
Akbulut (44)	Splenectomy	4 yrs
Cevik (64)	Nephrectomy	32 yrs
Malhotra (65)	Total abdominal hysterectomy + Cholecystectomy	Unknown

AUTHOR	INITIAL PROCEDURE	TIME TO PRESENTATION
Yakan (66)	Peptic Ulcer Disease	23 yrs
Brylka (67)	Caesarean section	Unknown
Dane (68)	Caesarean section	5 yrs
Alayo (69)	Cholecystectomy	6 months
Agras (70)	Nephrolithotomy	38 yrs
Sun (71)	Vaginal hysterectomy	18 yrs
Patil (72)	Caesarean section	3 months
Paramythiotis (73)	Incisional hernia repair	8 yrs
Keymeulen (74)	Nephrectomy	38 yrs
Ibrahim (75)	Total abdominal hysterectomy	2 weeks
Ali (76)	Caesarean section	2 yrs
Dash (25)	Caesarean section	9 yrs
Tandon (77)	Caesarean section	2 yrs
Erdil (78)	Cholecystectomy	1 yr
Godara (79)	Defaecation of swab	16 months
Sharma (80)	Total abdominal hysterectomy	18 months
Adu-Aryee (81)	Caesarean section Trauma laparotomy	10 months 5 months
Cekirge (82)	Left hemicolectomy	3 weeks
Choi (83)	Caesarean section	3 months
Furukawa (84)	Cholecystectomy Cholecystectomy	8 yrs 7yrs
Ivica (85)	Extrauterine pregnancy	40 yrs
Duman (86)	Cholecystectomy	8 yrs
Ozkan (87)	Myomectomy	1 yr
Quarishi (88)	Caesarean section	1 month
Saidi (89)	Caesarean section	1 yr
Skandalos (90)	Nephrectomy	13yrs
Shahi (91)	Cholecystectomy	2 yrs
Sankhe (92)	Caesarean section	10 months
Ray (93)	Cholecystectomy	2 yrs
Masqood (94)	Cholecystectomy	5months
Prasad (95)	Caesarean section	15 days
	Nephrectomy	2 days
Sagili (96)	Total abdominal hysterectomy	8 yrs
Kadian (97)	Myomectomy	8 months
Yaycioglu (98)	Ureterolitotomy	4 yrs
Kubota (99)	Gastrectomy	24 yrs
Nieves (100)	Gynaenocological surgery	16 yrs
Govarjin (101)	Caesarean section	5months
Mousavi (102)	Total abdominal hysterectomy	4yrs
Kohli (103)	Total abdominal hysterectomy	13yrs
	Open cholecystectomy	2 months
Moslemi (104)	Bilateral orchidopexy	5 yrs
Zbar (105)	Caesarean Section	6months

Speciality	Number of cases
General surgery	36
Obstetrics and gynaecological surgery	44
Trauma surgery	6
Urology	10
Other	4

Table 3 Summary of the distribution of retained swabs among surgical specialities reported in the literature (1990-2012)



Graph 3 Summary of the distribution of retained swabs among surgical specialities

6.1.3 Discussion

The commonest implicated speciality in this review was Obstetric and Gynaecological surgery. The most common operations performed were caesarean section and abdominal hysterectomy. A theory for the high number of mishaps in this group of patients is that by nature caesarean section tends to be an emergency operation. A proposed reason for the

increased risk during gynaecological procedures maybe the technical difficulty of working in a deep small cavity such as the pelvis where a bloody swab maybe easily missed.

An important repeat offender is the open cholecystectomy. This may be attributed to the limited operating space and the use of packing swabs to improve exposure. Appendicectomies were also commonly implicated. This again is likely due to the limited incision and the use of packing swabs to improve exposure. Appendicectomies are usually done as emergency surgery, sometimes late at night. Interestingly trauma surgery accounts for only 6% percent of patients, despite repeated reports that it is a risk factor for swab miscounts.

Jaffary et al reported that 8 of 11 patients had either Obstetric or Gynaecological procedures initially(106).

Bani – Hani reported that 4 of 11 patients had either Obstetric or Gynaecological procedures initially and 4 of 11 patients had general surgical procedures initially(8).

The mean time to presentation was 7yrs 5 months and 9 days. The interval to presentation range was 5 days to 37 years.

The interval to presentation has significant legal implications. There is a statute of limitations from time of injury to pressing of charges (107). It can also confound diagnosis, because such a long time after surgery one may not expect to be still experiencing complications from it. Jaffary et al reported a mean interval of 8 months and an interval to presentation range of 1week to 2 year(106).

CHAPTER SEVEN

7.1 Radiological Investigation

7.1.1 Overview

An array of radiologic investigations have been described in the investigation of patients with a retained swab, as evidenced by the case reports reviewed in this study. The reason for this is that a diagnosis is not easily forthcoming and the clinical presentation is varied, mimicking diseases involving any of the intra-abdominal organs.

The reports include the use of plain radiographs, ultrasound, computed tomography and magnetic resonance imaging most commonly; however the use of contrast studies of the bowel(60, 77), intravenous pyelogram (27), magnetic resonance cholangio pancreatogram (34), endoscopic retrograde cholangio pancreatogram (57), conventional angiography (84) and endoscopy (48, 50) have been used as part of the investigative imaging of these patients.

The array of investigations used demonstrates how difficult it is to make a diagnosis pre-operatively with certainty. Because of its relatively non-specific appearance this entity has been mistaken for tumours of the retroperitoneum (70), pancreas (34), and spleen (12) as well as gastrointestinal stromal tumours (48). Diagnosis such as hydatid cysts (76) as well as bezoars (24) has also been entertained in the differential diagnosis.

However, the literature reviewed does offer some consistent appearance in the common investigations. Plain X-ray is the commonest investigation performed. The common findings noted were (108, 109):

- Radio opaque mass
- Radio opaque string like appearance
- Calcified mass
- Mottled or sieve like mass (may also be mistaken for faecal matter)

- Features of intestinal obstruction such as dilated loops of bowel, air fluid levels and a paucity of air in the rectum.

A significant number of cases reported no abnormalities on plain x-ray which suggests that a normal x-ray does not exclude the diagnosis of a retained swab. Most swabs have a radio-opaque marker; however some poorer countries are still not using these. A further confounding factor in the acute setting when plain films are taken in the operating theatre is the difficulty in positioning the bed side unit around the theatre equipment. This may result in inadequate coverage of the body cavity involved and may result in a false negative study (110). Patients may present after many years which may also explain the lack of evidence on plain film (109). The diagnosis of a retained swab may be made easily on plain film if the radio opaque marker is intact; however this may be broken over time or disintegrate. It may also become bound or folded (111). Radio opaque markers may also be misinterpreted as calcifications, intestinal contrast material, or surgical clips. Even in optimal situations the plain x-ray shows a 10-25% false negative rate (11).

Figure 6 Plain X-ray showing the radio opaque marker of the swab. (112)

The second most commonly used investigation is the ultrasound. This is a cheap non-invasive investigation which is a suitable second step in the diagnostic algorithm. The features of a retained swab on ultrasound are consistent (108, 110) :

- Encapsulated complex cystic or solid mass
- Usually a hypoechoeic and heterogeneous mass
- Dense acoustic shadows

This appearance is not very specific and almost always mandates further imaging either by CT Scan or less commonly by magnetic resonance imaging as demonstrated by most cases in the review. Ultrasound in the immediate post-operative period may also be limited by intestinal gas due to a post-operative ileus or a physiological response to surgery and may also be limited by painful incision sites and dressings over the incisions (11).

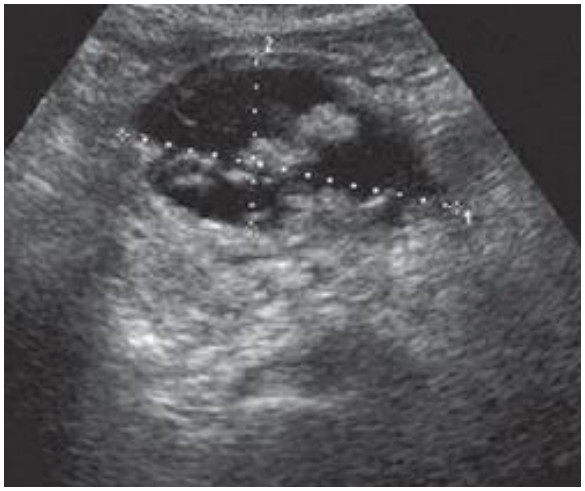


Figure 7 Ultrasound showing a mass with echogenic foci. (108)

The features on CT scan tend be consistent and appear to be the most accurate at making a pre-operative diagnosis. The features include (112, 113) :

- Thick walled enhancing mass
- Fluid and air bubbles trapped within the mass
- A foreign metallic body maybe seen within the mass (radio-opaque marker)
- Calcified mass
- Spongiform mass
- Fat stranding

These features collectively will strongly suggest a retained swab. However, if they are not all present the diagnosis may still be elusive until exploratory laparotomy. It is suggested that CT scan is the best imaging modality to diagnose a retained swab (114).

Figure 8 CT Scan showing a mass with hyper dense whirl pattern within. (112)

Magnetic resonance imaging (MRI) is often used in the investigation of the soft tissue tumours and consequently becomes a significant investigation in patients with a retained swab. The features of a retained swab on MRI include the following(111):

- A well-defined mass that showed a peripheral wall of low signal intensity at T1- and T2-weighted imaging and enhancement at contrast-enhanced T1-weighted imaging
- Whorled stripes within the central portion were characteristically shown as low signal at T2-weighted imaging and
- Serrated contour in the inner border of the peripheral wall was shown at contrast-enhanced T1-weighted imaging (111).

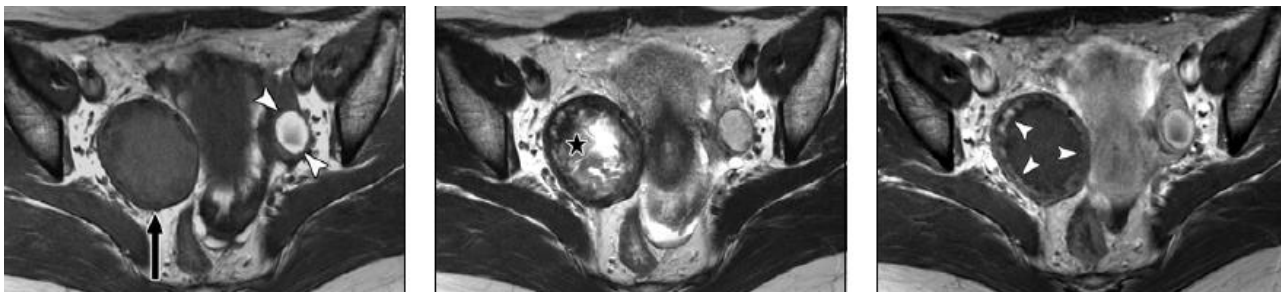


Figure 9 MRI scan showing a low intensity mass with a hyper dense central portion and serrated edges. (111)

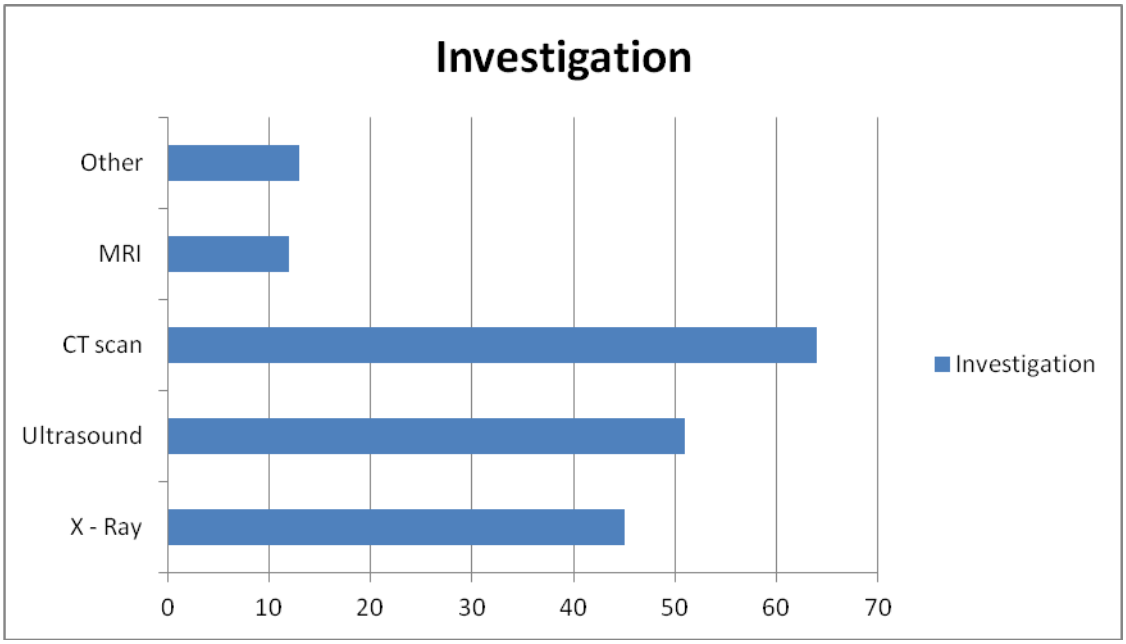
7.1.2 Results

TABLE 4: Shows the radiological investigations undertaken in 100 patients with a retained abdominal swab reported in published literature from 1990 to 2012.

AUTHOR	X-RAY	ULTRASOUND	CT SCAN	OTHER
Huston (16)			X	
Jebbin (17)		X		
Mohammed (18)	X			
Iqbal (19)	X	X		
Aziz (20)			X	MRI
Sirjani (21)				MRI
Yeung (22)	X	X	X	
Asuquo (23)	X X	X		
Dewachter (24)			X	
Dash (25)	X	X		
Lu (26)	X		X	IVP#
Shyung (27)	X	X		
Sugano (28)		X		
Malik (29)	X	X	X	
Lin (30)	X		X	
Doles (31)	X	X	X	
Bindapersad (32)			X	
Gogia (33)	X			
Anjum (9)		X		
Bhandari (34)		X	X	MRCP*
Cerwenka (35)		X	X	MRI
Rajagopal (36)	X	X	X	
Kansakar (37)	X	X		
Dux (38)	X	X	X	
Sharma (39)			X	
Marcy (40)		X	X	MRI
Jouini (41)	X	X	X	
Al Thubaity(42)	X		X	
De Campos (15)		X	X	
Lourenco (43)	X	X	X	
Akbulut (44)	X		X	
Haegeman (45)	X		X	
Mohammadi (46)	X	X	X	
Kansakar (47)		X	X	
Dakubo (14)	-	-	-	-
Cheon (48)		X	X	endoscopy
Kawamura (49)			X	MRI
Yamamura (50)			X	MRI / endoscopy
Ramdass (51)	X			

AUTHOR	X-RAY	ULTRASOUND	CT SCAN	OTHER
Abeygunasekera (52)			X	
Mylarappa (53)	X			
Gencosmanoglu (54)	X		X	
Kieman (55)		X	X	MRI
Veena (56)		X		MRI
Cimsit (57)				MRCP*/ERCP+
Rajput (58)			X	
Saji (59)		X	X	sigmoidoscopy
Arpit (60)	X		X	barium enema
Kaplan (61)		X	X	
Aminian (62)	X		X	
Grassi (63)	X		X	
Akbulut (44)	X	X		
Cevik (64)		X		Voiding cystogram
Malhotra (65)	X			
Yakan (66)	X		X	
Brylka (67)		X		
Dane (68)		X		
Alayo (69)			X	
Agras (70)		X	X	MRI
Sun (71)		X	X	
Patil (72)	X		X	
Paramythiotis (73)	X	X	X	colonoscopy
Keymeulan (74)			X	
Ibrahim (75)	X		X	
Ali (76)		X		
Dash (25)		X		
Tandon (77)		X		barium enema
Erdil (78)				endoscopy
Godara (79)		X	X	
Sharma (80)	-	-	-	-
Adu-Ayree (81)	X X	X		
Cekirge (82)	X		X	
Choi (83)	X		X	
Furukawa (84)		X X	X X	angiogram
Ivica (85)	X	X	X	
Duman (86)			X	
Ozkan (87)			X	
Quarishi (88)			X	
Saidi (89)		X	X	
Skandalos (90)			X	MRI
Shahi (91)		X		
Sankhe (92)			X	
Ray (93)	X		X	

AUTHOR	X-RAY	ULTRASOUND	CT SCAN	OTHER
Maqsood (94)	X	X		
Prasad (95)		X	X	
			X	
Sagili (96)		X	X	
Kadian (97)	X	X	X	
Yaycioglu (98)				
Kubota (99)		X	X	MRI
Nieves (100)				
Govarjin (101)	X			fistulogram
Mousavi-Bahar (102)	X		X	
Kohli (103)	X	X	X	MRI
	X	X	X	
Moslemi (104)			X	
Zbar (105)		X		



Graph 3 depicts the array of radiological investigations used

X – Ray	8
Ultrasound	13
CT Scan	18
X- Ray + Ultrasound	8
X- Ray + Ultrasound + CT Scan	13
X- Ray + CT Scan	16
No investigation	4

Table 5 Summary of spectrum of investigations used in diagnosis of retained swabs

Discussion

Forty five percent of patients had a plain abdominal x-ray. Plain X-ray of the abdomen is the most basic of investigations and is usually a starter investigation for most complaints involving the abdomen. It is interesting to note however that only 8% of patients had no further investigation done, which suggests that plain x-ray may not be as helpful in diagnosing a retained swab confidently as initially thought. The reasons for the plain x-rays shortcomings have been proposed above.

Ultrasound seems a valuable tool with 21% of patients being successfully investigated with ultrasound and x-ray only. It should be strongly considered as it is a cheap, readily available and low risk procedure that can be used to make a pre-operative diagnosis.

Sixty four patients had a CT scan with only 9 of them also having an MRI. Eighteen patients had only a CT scan. This information is in keeping with the literature which suggests that a preoperative diagnosis of a retained swab is likely best made with CT scan.

Cheng et al (112) proposed that plain x rays were unhelpful in the diagnosis of retained abdominal swabs, and proposed that CT scan was a practical tool for accurate diagnosis. Jaffery et al (106) and Custovic et al (6) also advocate CT scan as the best radiological intervention.

CHAPTER EIGHT

8.1 Prevention of the Retained Swab

Prevention is always deemed better than cure and avoiding this catastrophic error is no exception. Ever since surgery was first undertaken retained foreign bodies have been a problem. The first report was by Wilson in 1884 (115) and since then there has been constant development of techniques and protocols to decrease its incidence. Although greatly improved the *Holy Grail* has not been found. Despite many modern innovations human error cannot be completely extinguished.

One of the earliest strategies for prevention was the counting of swabs. This has become the standard of care in theatre practice. The counting is to be done when swab packs are opened and when the surgical wound is being closed. In some countries a routine double count is done at the end of an operation. This is the case in South Africa. Each count should also be by at least 2 attending members of staff (116). Multiple counts intra-operatively have also been advocated.

The routine checking of the body cavity by the surgeon specifically checking for retained foreign bodies has been advocated, and is perhaps one of the best ways of guarding against this problem (116).

Rotating nurses and scrub nurses are also advised to record all swabs placed inside the body, for haemostasis or exposure, while the surgery is taking place.

Radio opaque marked swabs are used almost routinely in theatre practice today, although some countries may not be using them because of financial constraints. In South Africa they are the norm in surgical practice (116). Radio opaque markers are helpful in the identification

of retained swabs using plain x-ray. They may be helpful when a swab count is incongruent. An x-ray is taken on table and reviewed prior to wound closure. Pitfalls of this include incorrect positioning due to theatre equipment obstructing proper positioning.

The labelling of individual swabs with numbers or letters of the alphabet may assist in counting as it more likely that a missing swab will be noticed if the numerical or alphabetic sequence is interrupted.

Poor communication and an imbalance of authority between the scrub nurse and the surgeon may also lead to the nurse not alerting the surgeon of an incongruent swab count. The nurse fears the wrath of the doctor for causing a delay in the conclusion of the operation. It has been suggested that equal accountability for mishaps and an improvement in relations may remedy this problem (116).

Time management has been implicated in the omission of proper swab counting protocol as well as a lack of staff. The strain on staff to complete multiple emergency surgeries with no rest is great and although not an excuse for poor theatre practice, it is a reason for this occurring. The only solution to this problem is fewer surgeries or more staff and equipment and to run more theatres, which is not always practical (116)

One of the more recent developments is radio nucleotide marked swabs. A gamma counter is used to locate lost swabs. This technique is helpful by allowing the team to exclude whether or not a missing swab is within the body cavity, because this is the concern of the surgical team. By sweeping the operative field the gamma counter a swab within 5 centimetres of the counter can be excluded. This will mean that the missing swab is unlikely to be in the patient and the search for swab can continue within the theatre while the surgeon continues to complete the operation (117).

Electronic article surveillance (known as magneto-mechanical technology) which is widely used in the prevention of shoplifting has also been applied to the detection of retained swabs. The swabs are tagged and at the end of the surgery an electronic detection device is passed over the operative field set up to detect the signal emitted by the tags, and should alarm if the tag which is attached to a swab is still in the body cavity. This method is still very much in the experimental phase, and bears with it the possibility of mechanical failure. (118).

Emergency surgery, with multiple surgical teams and unexpected intra-operative changes is another important risk factor implicated in swab retention. (3). In this case a routine post-operative on table x-ray maybe prudent. A study showed that routine post-operative x-ray in these circumstances was cost effective when comparing the cost of an x-ray to the legal costs following a retained surgical swab (119)

Higher risk is also associated with a change in nursing team mid-procedure because of shift changes (120). Some hospitals prohibit this practice and compensate the nursing staff either monetarily or by repaying time. This however varies between institutions in South Africa.

Obesity has been implicated as a risk factor (8); however Lincourt et al did not find obesity to be a risk factor in their review. Other factors implicated where haemorrhagic operations, and difficult to reach anatomic areas such as the pelvis (120).

CHAPTER NINE

9.1 Medico – Legal Consequences

In the past the nobility of the medical profession and the deep trust of patients in their physicians protected medical professionals from legal accountability for their professional conduct (121). The revered position in society held by doctors cemented the belief that doctors would not intentionally make decisions that negatively affect the clinical condition of the patient. This blind faith has changed in modern day medicine and the fallibility of medical professionals is now recognised. This trend started in western countries and has crept into developing societies as people become more knowledgeable and empowered. Notwithstanding this, there appears to be a paucity of established laws pertaining to medical error.

Medical misdemeanours are viewed differently throughout the world. In some countries, such as Turkey and Italy medical cases are harshly judged (122). They are viewed as criminal offences and are commenced as manslaughter or personal injury charges. While in contrast in other countries medical misdemeanours usually belongs to the category of civil law. Civil law obligations are of 2 types, Law of Contract and Law of Tort. When a medical professional undertakes to treat a patient an informal but legally valid contract is undertaken. The implied agreement is that the doctor will diagnose the patient's complaint and treat in the normal manner according to generally accepted medical practice. In the private sector this contract is between the practitioner and the patient, in a state hospital it is between the patient and the hospital (10). A breach of this contract occurs when a clinician fails to provide the standard care expected of another clinician with similar training and in similar circumstances. This failure may be viewed as illegal, negligent or unethical (10). Tort is a civil wrong for which

an action can be filed in court to recover damages for personal injury resulting from a negligent act. Medical negligence is recognised under the Law of Tort(10).

When these cases are heard in court the onus is on the plaintiff (patient) to prove that the treatment provided by the medical professional did indeed cause injury or harm and was in fact negligent. This view tends to favour the medical professional as it is exceptionally difficult for the plaintiff (given the fact they are not medically trained) to prove that the medical professional was intentionally negligent (10).

To appreciate the legal consequences one first has to understand what constitutes medical negligence. So what then is negligence? Negligence refers to failure to diagnose a pre-existing disease allowing it to progress with harmful effects, or not treating a diagnosed disease using conventionally accepted methods resulting in a deleterious outcome for the patient. When considering the harmful effects one has to take into account the pre-existing condition and then consider the chance of cure which is most likely not 100% depending on the progression of the pre-existing disease (27).

Negligence also occurs when a doctor fails to take proper care and damage may result. It has been held, in India, that negligence is to be determined according to British Common Law (10). The essential components are :

- The doctor (defendant) owed a duty of care to the patient (plaintiff).
- That there was failure to attain that standard of care prescribed by the law, thereby committing a breach of such duty.
- That the plaintiff suffered damage.
- That the damage was caused by the breach of duty of care

It is appropriate to define acceptable standard of care. This emphasises that the care needed to be given by a medical doctor is the same as other medical doctors would have given in the same situation and under the same labour conditions.

In some cases the burden of proof may not rest upon the shoulders of the plaintiff. This is true for cases of obvious misconduct and fall under the "*Res Ipsa Loquitur*" Law. This law is relevant in cases of retained abdominal swabs because in some countries this error does not need proof, the act in itself is indefensible. So what is "*Res Ipsa Loquitur*" ? The accident speaks for itself or tells its own story. This law is often used in everyday cases of negligence resulting in injury where any reasonable person may see the negligence. The literature refers to a scenario dating back approximately one hundred and fifty years. A person was walking along a wharf in England, next to a warehouse, when he was hit on the head by two sacks of sugar that had fallen from the building. The individual did not know what had happened or why it happened, nor could he identify who did the wrong. It was however obvious that in the chain of work a mistake was made and the victim deserved compensation. When he explained the facts to the judge, the judge said *"res ipsa loquitur"* in Latin which translates as the thing speaks for itself. As such, the law was born. This law may sometimes be applied to medicine especially in cases like retained foreign objects from surgery where the misdemeanour seems obvious. This is upheld in countries like the United States of America and the United Kingdom. In South Africa this rule is not applied because of the unique skill and knowledge required in the decision making process of medicine (10).

Medical practice in South Africa is primarily regulated by a number of statutory enactments. The most important statute governing medical practice is the Health Professions Act. The act provides for the establishment of the Health Professionals Council of South Africa (HPCSA), the statutory regulatory body responsible for, inter alia, controlling and exercising "authority in respect of all matters affecting the training of persons in, and the manner of the exercise of

the practices pursued in connection with, the diagnosis, treatment or prevention of physical or mental defects, illnesses or deficiencies in human kind." Briefly, the act provides for control over the education, training, registration and practices of a variety of health professionals. There are different boards within the HPCSA governing different disciplines, but all ultimately fall under the umbrella of the HPCSA. No medical professional may practice in the country without being registered practioner with the council. This board has wide power under the Health Professionals Act which includes the removal and restoration of names to and from the register. As such cases of medical negligence may be settled by the HPCSA resulting in a doctor being unable to practice medicine. This may be contested in High Court by the doctor (123).

The relationship between the doctor or hospital and the patient is not governed directly by criminal law. There are however various common law crimes that the doctor may conceivably commit in the course of medical practice. These include murder, culpable homicide, assault, criminal defamation, crimen injuria, fraud, perjury, and contempt of court.

When cases are taken to court, in South Africa the law regarding medical negligence where a retained foreign object following surgery is concerned seems to follow protocol set by the precedent setting case "Van Wyk versus Lewis" case(123). The findings in this case indicated that the mere fact that the swab was left in situ does not imply negligence, because the circumstances surrounding the case should be taken into account. A second landmark case is "Goliath versus the Minister of Health in the Eastern Cape". Both cases found in favour of the defendant, citing difficult intra-operative conditions with a medically unstable patient thus not allowing for extended operative time under anaesthesia.

Further considerations include the statute of limitations. In Texas, United States of America there were 2 patients who had retained swabs discovered 10 years after surgery. The law in

Texas does not allow a claim to be commenced after 2 years or a liability claim to be instituted more than 10 years after the initial procedure or hospitalisation (107). This brings in a new light to the problem of retained foreign bodies following surgery as a significant number of these cases are discovered many years after surgery.

The debate regarding which person should shoulder the blame for this unfortunate incident also rages on. Some countries such as the United States of America use the "Captain of the ship theory". The surgeon is said to be the leader in theatre and therefore should shoulder the responsibility of any mishap, while others say that the surgeon is not involved in the counting of swabs. The scrub nurse and rotating sister are in charge of the correct swab count while the surgeon busies himself with the task of operating. One could argue that the surgeon does the final cavity sweep to look for any foreign bodies and should therefore be responsible. The culpability of the surgeon alone in South Africa remains a debatable issue.

To conclude, the legal aspects of this disaster are not consistent globally. South Africa seems to have a much more lenient stance than some other countries, especially in the first world where resources and working conditions play less of a role.

CHAPTER TEN

10.1 Conclusion

The retained foreign body following surgery has always been a complication since the conception of surgery and despite many modern advances attempting to alleviate this particular misfortune; it continues to be an error today. This is accounted for by the fact that it is impossible to completely obliterate human error, and operative surgery as well as the condition of the individual patient is dynamic and unpredictable. It follows then that this complication will always plague the surgeon.

The nature of this disease entity does not allow for absolute guidelines to be drafted because it is almost exclusively a retrospective diagnosis often made following exploratory laparotomy. The extensive scouring of the literature suggests that a strong clinical suspicion for this complication should be maintained by all clinicians because of the varied clinical presentations, especially in patients who have had abdominal surgery and more especially those that have had pelvic surgery and surgery through limited incisions.

Radiological investigations are usually directed by the presenting complaint of the patient. However in this review the plain x – ray has been shown not be as helpful as one had initially considered, although when positive is diagnostic. It is evident that abdominal ultrasound may be valuable in suspecting this complication, however the features on CT Scan are far more convincing in making a pre-operative diagnosis.

It cannot be stressed enough that preventing this disaster is the gold standard. Stringent theatre protocols with excellent compliance from the theatre staff will no doubt curb this problem to a minimum. The nursing team should be diligent and truthful and the medical team should address the concerns of the nursing staff regarding missing equipment with the respect that it deserves. A thorough search should be carried out until both parties are

satisfied. Whilst new advances in the tracking of swabs during surgery show promise in curbing this misdemeanour, they have not as yet found a routine placement in theatre protocol. One can only hope that as technology progresses and minimal access surgery increases this disaster will become extinct.

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