GOSSYPIBOMA: A PREVENTABLE CONTINUING SURGICAL ERROR

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Abstract -

Background: Inadvertent retention of gauze and sponge material after surgery is a preventable error that still persists despite laid down protocols for best practice in the theatre suite to eliminate gossypiboma.

Aim: To present twelve cases of gossypiboma managed at the Korle-Bu Teaching Hospital (KBTH) to emphasise the frequency at which gossypiboma is occurring in Accra, highlight the risk factors that contributed to the development of gossypiboma and then stress the importance of strict adherence to theatre protocol to help prevent its occurrence.

Methods: A register to record and follow-up cases of gossypibomas that reported to KBTH was maintained by the authors and these cases were followed throughout their admission and treatment. The surgeons, the theatre nursing staff who treated these patients and the patients themselves were interviewed by the authors. The Patients' case notes, the theatre and autopsy registers were also consulted for information.

Results: There were nine females and three males aged

between 26 and 75 years. Seven of the index operations were performed at the Korle-Bu Teaching Hospital, two each at Municipal and private hospitals and one in a para-statal hospital.

Ten followed intra-abdominal operations, six of which were pelvic procedures; four being gynaecological.

The contributing factors to the gossypiboma were lack of instrument count (all cases), operating in deep surgical fields (seven cases), operating without the full complement of operating staff (seven cases), extensive surgery (seven cases), excessive bleeding (six cases), emergency procedures done at night, change in part of the operating team without proper handing over and unexpected change in the surgical procedure.

Conclusion: Gossypiboma is not an uncommon condition in the developing world but possibly underreported. The presence of risk factors for its occurrence should prompt the surgeon to take extra precautions in high risk patients and to always insist on strict adherence to operating room protocols especially when the operation is in a body cavity.

Key Words: Gossypiboma, Textiloma, Sponge material, Pseudo-tumour.

Introduction

Inadvertent retention of gauze material in the body, gossypiboma, textiloma, gauzoma or muslinoma, is not an uncommon serious surgical complication that is preventable. It continues to be reported from both the developed and developing world and its occurrence is unrelated to the pathology for which the surgery was done nor the surgical technique itself, rather a lack of diligence in adherence to basic theatre protocol in ensuring accurate instrument count and documentation. It is most frequently reported to occur in the abdominal cavity, however, no body space where surgery has been performed seems to be spared^{1.4}.

The true incidence of gossypiboma is not known and may never be known due to under reporting because of the embarrassment and the medicolegal issues that could arise therefrom. It is estimated to occur in 1 out of 100 to 300 surgical interventions and

Author for Correspondence: Dr. Jonathan CB Dakubo Department of Surgery University of Ghana Medical School Korle Bu E mail: jdakubo@yahoo.com Conflict of interest: None declared 1 in 1000 to 1500 intra-abdominal operations⁵.

A number of factors have been cited as contributing to the occurrence of gossypiboma including obesity, emergency operations, change in the surgical team, laparoscopic procedures and inaccuracy of instrument count and documentation during surgery.

Over a ten year period, 2003 to 2012, twelve cases of gossypiboma were managed at the general surgery unit of the department of surgery at Korle-Bu Teaching Hospital (KBTH) and these form the basis of this communication to highlight the factors that contributed to their occurrence and the importance of the time honoured practice of strict adherence to operating room protocols.

Materials and Methods

Following their encounter of the first case of gossypiboma in 2003 the authors created a register to record and follow-up cases of gossypibomas that reported to KBTH and this has been maintained to date. Just at that same time a backward search in the theatre register, up to 1996, was done for earlier cases but did not yield any results.

For each case of gossypiboma that was treated at the KBTH the patient's case notes as well as the theatre records were reviewed. Additionally the surgeons who performed the index surgery, and the theatre and/or the scrub nurses were interviewed to ascertain technical challenges during surgery. For those cases that occurred outside KBTH the authors contacted the administrators of the hospitals and with permission studied the patients' case notes similarly as well as interviewing the surgeons and the theatre and/or scrub nurses.

Data recorded included the patients' demography, the indication for the index surgery, the procedure performed, intra-operative blood loss, documentation of instrument/swab count and any other issue that in the opinion of the surgeon could have contributed to the gauze retention. The duration of the gossypiboma, the type of gauze material that was retained, the presentation of the gossypiboma, the method of recovery of the foreign body and the treatment outcome were also noted. Those patients who were informed about the incident by their doctors were interviewed to ascertain any emotional stress they experienced and if they intended to pursue the matter any further.

The total number of major surgeries performed in the general surgery unit from January 2003 to December 2012 was extracted from the theatre register. The cause of deaths that occurred was obtained from the autopsy register at KBTH.

Results

Tables 1 and 2 summarize the twelve cases that were seen at the KBTH over the ten years 2003 to 2012. The patients were made up of nine females and three males. Seven of the index surgeries were performed at the KBTH, two at Municipal hospitals, one in a para-statal hospital and two in private hospitals

Case N <u>o</u>	Date	Sex	Age (Years)	Hospital of 1 st Operation	Indication for operation	Operation done	Contributing factor(s)
1	2003	М	26	KBTH	GOO, Corrosive ingestion	Feeding Gastrostomy	Emergency, No scrub Nurse, No instrument count
2	2005	М	58	KBTH	Pre-sacral tumour	Laparotomy and excision	Bleeding, obscured surgical field. No instrument count
3	2007	F	43	KBTH	Left Breast Cancer	Mastectomy and Axillary Clearance	Large Breast, Bleeding in Axilla. No instrument count
4	2007	М	53	KBTH	Rectal Cancer	ARR and Hartmann's Procedure	Bleeding. No instrument count
5	2008	F	44	Private	Uterine Fibroids	ТАН	Bleeding. No instrument count
6	2009	F	36	Private	Appendix Abscess	Laparotomy, Pelvic Exploration, Appendicectomy	Emergency, Change in the surgical team and change in procedure, No instrument count
7	2009	F	75	KBTH	Obstructing Rectal cancer	Sigmoid Colostomy	Emergency, use of free Gauze in the abdomen. No instrument count
8	2010	F	45	Parastatal hospital	Uterine Fibroids	TAH and Appendicectomy	Bleeding. No instrument count
9	2011	F	36	Municipal Hospital	Uterine Fibroids	ТАН	Change in half of the Operating Team. No instrument count
10	2011	F	36	КВТН	Gunshot to abdomen and chest	Exploratory laparotomy and repair of multiple organ injuries	Extensive surgery with deep wounds that were packed for a long time, obscured field
11	2012	F	44	KBTH	Goitre	Thyroidectomy	No instrument count
12	2012	F	45	Municipal Hospital	Uterine fibroids	ТАН	No instrument count

Table 1: Patient's demography and clinical characteristics at index operation

Legend

GOO: Gastric outlet obstruction ARR: Anterior resection TAH: Total Abdominal Hysterectomy

Table 2:	Patient's	clinical	data	after	the	Gossypiboma
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Case	Duration of	Type of	Presentation/	Recovery of	Outcome
N <u>o</u>	Gossypiboma	Material	diagnosis	foreign body	
1	Two weeks	Abdominal	Copious discharge from	Re-laparotomy	Died of
		sponge	Abdominal wound		sepsis
2	Two months	Abdominal	Discharging surgical wound	Re-laparotomy	Uneventful
		sponge			recovery
3	One month	Gauze	Unremitting discharge of	Wound	Uneventful
			pus from wound	exploration	recovery
4	One month	Abdominal	Peritonitis	Re-laparotomy	Uneventful
		sponge			recovery
5	Four years	Abdominal	Constipation and extruding	Extruded sponge	Uneventful
		sponge	sponge through rectum	through the	recovery
			which got impacted	rectum	
6	Two months	Abdominal	Extruded sponge completed	Extruded sponge	Uneventful
		sponge	through rectum	through rectum	recovery
7	Six months	Gauze	Intestinal Obstruction	Re-laparotomy	Died from
					hypostatic
					pneumonia
8	Four months	Abdominal	Extensive anterior	Re-laparotomy	Uneventful
		sponge	Abdominal wall fasciitis		recovery
9	Four months	Abdominal	Extruded sponge through	Re-laparotomy to	Uneventful
		sponge	vagina which created an	close fistula	recovery
			Entero-vaginal fistula		
10	Four months	Abdominal	Severe epigastric pain.	Re-laparotomy	Uneventful
		sponge	Sponge revealed at		recovery
			Gastroscopy		
11	Three months	Gauze	Non-healing discharging	Wound	Uneventful
			wound. Ultrasound	exploration	recovery
12	Four months	Abdominal	Abdominal mass, fever,	Re-laparotomy	Uneventful
		sponge	anaemia. CT scan		recovery

all in Accra. Twenty seven thousand, eight hundred and thirty nine major operations were performed in the period, out of which 1554 deaths occurred (mortality rate of 5.6%) in the general surgery unit of the Korle-Bu Teaching Hospital. This gives a gossypiboma rate of 2.5 per 10,000 major general surgery operations.

Ten gossypibomas followed intra-abdominal operations, six of which were pelvic procedures; four being gynaecological. The remaining two cases were extra-abdominal procedures; thyroidectomy and mastectomy.

The contributing factors to the gossypiboma were lack of instrument count (all cases), operating in deep surgical fields (7 cases), operating without the full complement of operating staff (seven cases), extensive surgery (7 cases), excessive bleeding (6 cases), emergency procedures done at night (4 cases), change in part of the operating team without proper handing over (2 cases), and unexpected change in the surgical procedure (1 case).

The longest duration of gossypiboma was four years. The majority of cases presented in three to four months. The abdominal sponge which was the foreign body retrieved in ten patients was the most frequent offending material.

In all except the last two cases (case numbers 11 and 12) the diagnosis was not suspected or confirmed

before the second surgery. There was however enough reason in these patients for a second surgery during which the gossypiboma was diagnosed incidentally. In case 11 an ultrasound and plain X-Ray of the neck that were done including an oesophagoscopy were not helpful in making a diagnosis and this delayed exploration of the wound, figure 1, for another two weeks. In case 12 both an abdominal ultrasound and plain abdominal X-Ray were not useful in making a diagnosis as abdominal sponges



Figure 1: A gauze being removed from the neck of Case 11 in whom the material was left after a thyroidectomy.

and gauze used locally do not have radio-opaque material impregnated in them. The diagnosis was made by abdominal CT scan that demonstrated a pseudo-tumour, figure 2.



Figure 2: Abdominal CT-Scan image of Case 12 showing the pseudo-tumour with the enhanced fibrosed wall (Arrowed)

Ten patients underwent surgery to recover the foreign body. Two patients extruded their sponges completely through the rectum, figure 3. There were two deaths among those who underwent surgery to recover the foreign body giving a mortality rate of 16.7%. One death was from overwhelming sepsis from protracted peritonitis in a background of severe malnutrition and the second from respiratory failure, the consequence of hypostatic pneumonia from prolonged hospitalization in bed.



Figure 3: A sponge impacted as it was being extruded through the rectum by Case 8 and being extracted manually by the surgeon

The diagnosis of gossypiboma was divulged to four of the patients after they were retrieved at surgery and the two patients who extruded the material through the rectum were aware of it naturally. Besides one of the patients who extruded the sponge through the rectum who threatened a legal suit and had her hospital bills refunded to her none of the remaining considered litigation. They considered it "the will of God since they were alive after all that had happened", which in their view was beyond the power of man. They therefore did not find it necessary to indulge in "what will not yield anything more than the wrath of the doctors whose intention it was to save their lives".

Discussion

Dr. Henry P.C. Wilson made the first report of a Gossypiboma in the literature in 1884⁶ and the first suit on gossypiboma was reported in 1933 in the medical literature, however a diligent search of court records by some authors revealed that judgements were made as far back as 1897 on this condition⁷. Following these well over 300 cases have been reported to date in the English medical literature mostly now from the developing world⁸.

Reports on the incidence of Gossypiboma is varied because of under-reporting and also the patient populations used to determine the incidence rates, and this makes it difficult to compare the rates. For example, estimates based on malpractice claims suggest that it occurs in 1 in 9000 to 19,000 inpatient operations⁹. The rate was also estimated to be as high as 2.4 per 10,000 surgical admissions among a representative national sample, in the United States, of inpatient administrative claims data¹⁰. We find that it occurs in 2.5 per 10,000 major general surgical operations at the KBTH in this study. This incidence rate is unacceptably high and urgent strict measures to enforce adherence to standard operative room practices must be taken to help reduce it.

Gossypiboma brings about medical issues; infection, intestinal obstruction, fistula formation, and can have medico-legal consequence involving liability of the surgeon^{5,6}. For fear of the latter gossypiboma is infrequently divulged to the patient as evidenced by the silence of these issues in the many reports of gossypiboma found in the literature. In this study all but one of the surgeons who treated the patients were made aware of their error resulting in the condition and six of the patients were informed about their gossypiboma.

The surgeons who performed the seven cases at the KBTH were aware of the condition since they were the same surgeons who retrieved the foreign bodies. The surgeon who performed one of the cases in a municipal hospital also retrieved the foreign body from the patient when it was being extruded through the vagina. He subsequently referred the patient to KBTH for repair of an entero-vaginal fistula it caused. The patient who extruded the foreign body completely through the rectum reported this to the gynaecologist at the private hospital where she was treated and was referred to the KBTH for further management for fear she might develop another complication. Formal communication, and later an interview, was made to the two other surgeons; one in a private hospital from where the patient with abdominal wall fasciitis came and the surgeon in the second municipal hospital who treated case 12. Hence only in one case, the case which presented after four years, was the surgeon not informed, because he had died.

It is encouraging that four of the surgeons dutifully informed the patients of the error. Patients here are frequently considerate and allow such mishaps to pass as long as they regain their health. Being a strong religious community people have always attributed developments in their lives to the making of God. They receive solace in this and it is helpful since, as noted in this study, the patients who knew of the error did not consider legal redress. It is also because people are largely ignorant on their medical rights and on how to seek redress. Things will not last this way forever. It will also not always be peaceful this way with everybody as noted in one of the patients who thought a legal redress was her due. In communities where patients know their rights and insist on them, which have resulted in high rates of medical litigation, hospital staff including, those in the theatres, are firmly on their guard to avoid such negligence; the consequence of which is dire.

The possible causes of sponge retention are emergency surgery, unexpected change in the surgical procedure, disorganization (e.g. poor communication), hurried sponge counts, long operations, unstable patient condition intra-operatively, inexperienced staff, inadequate staff numbers, obesity, operating in more than one body cavity, damage control and complex surgical procedures^{5, 11}.

Gawande et al performed a retrospective case control study involving 54 cases pooled from ten hospitals and reported that the factors associated with a significantly increased risk of retention of a foreign body were emergency surgery (risk ratio, 8.8 [95 percent confidence interval, 2.4 to 31.9]), unplanned change in the operation (risk ratio, 4.1 [95 percent confidence interval, 1.4 to 12.4]), and body-mass index (risk ratio for each one-unit increment, 1.1 [95 percent confidence interval, 1.0 to 1.2]).⁹

The patients in this study were not obese. Only four of the surgeries were emergencies. Bleeding was a most frequent reason for the Gossypiboma. A worrying observation in this study is the absence of documented instrument count in all cases. In two cases there was a change in the nursing staff without adequate handing over. Operating in deep surgical fields (pelvis and upper abdomen) was significant in this study and should prompt surgeons to be more vigilant when operating in such areas. Damage control surgery was performed in one case who sustained gunshot wounds. The multiple operations and frequent packing of the deep wounds could account for the condition. A case of appendix abscess was misdiagnosed as an infected right ovarian cyst. Intra-operatively and following exploration of the pelvis this diagnosis was found to be wrong, rather a mass involving the caecum was identified and the general surgeon called in. A diagnosis of an appendix mass was made. appendicectomy was done following which the gynaecologist was left to close the abdomen. The two factors of change in surgical procedure and surgeons are significant.

The presentation of gossypiboma can be protean and vague. Up to a third of gossypibomas remain asymptomatic and found incidentally at radiology^{12, 13}. Intra-abdominal Gossypibomas have been extruded completely through the rectum without consequence. They have also caused severe complications including intestinal obstruction, intestinal fistulae, peritonitis and intra-abdominal abscesses and excruciating lumbar pain³.

Asymptomatic cases are frequently identified by the radiologist who may face challenges in making a diagnosis of the lesion. Numerous X-Ray, ultrasound and CT scan features have been described to be diagnostic of a Gossypiboma yet these may not be available because of the long duration of the gossypiboma. False negative rates in detecting retained sponges using radiography varied between 3% and 25% depending on the type of sponge¹⁴. These and the general lack of suspicion of the condition frequently lead to misdiagnosis and often unnecessary radical surgical procedures are performed¹⁵. In the current series it was in only two cases that attempts were made to diagnose the condition, one of which was successful. In the other cases in which surgery was performed there were urgent and compelling indications (septic complications) for the procedure to save life.

The worst complication of Gossypiboma is death. Mortality rate for gossypiboma has been reported as 15 $-22\%^{16}$. There were two deaths out of the twelve cases (17%) reported in this study.

Although human errors cannot be completely avoided continuous medical training and strict adherence to theatre protocol should reduce retention of foreign material after surgery to the minimum. To this end accurate instrument and sponge count and documentation as well as thorough exploration of the surgical field for retained material cannot be overemphasized. While it may be understandable and possibly pardonable when a gossypiboma occurs in a difficult and bloody surgery in a deep cavity, forgetting a gauze material in superficial small surgical fields as in thyroidectomy and mastectomy border on surgical negligence. Failure to account for all sponges and instruments after a surgical procedure should prompt a thorough search of the operating field before wound closure. Appropriate radiological investigations should then be undertaken postoperatively if the sponge or instrument could not be found.

The standards of many operating room nurse associations worldwide, namely, the Association for Peri-operative Practice (United Kingdom), the Association of Peri-operative Registered Nurses (United States), the Australian College of Operating Room Nurses, Operating Room Nurses Association of Canada and the South African Theatre Nurse, require that only sponges detectable on radiography be used and that they be counted once at the start and twice at the conclusion of all surgical procedures. These standards also recommend that instruments be counted in all cases involving an open cavity and if a count is incorrect, that is, not all materials are accounted for, then radiography or manual re-exploration is to be performed. When a count cannot be performed, an Xray should be taken before the patient leaves the operating room, if the patient's status permits, or as soon as possible thereafter¹⁷. These recommendations notwithstanding, counts are clearly not always sufficient, however. Of the many cases of retained foreign bodies in which counts were performed, between 76% and 88% involved a final count that was erroneously thought to be correct^{8,9}. These findings suggest that simple radiological screening of high risk patients at the end of operations should be considered even when counts are documented as correct. These are inexpensive yet for logistical constraints surgical sponge material in many theatres in the developing world do not have radio-opaque material in them.

Newer techniques are currently in use to detect retained sponge by automated counting and tracking of sponges in the theatre to increase the accuracy of counting and detection of inadvertently retained sponges. Bar-coded sponges and sponges with radiofrequency are in use. In a randomized controlled trial, Greenberg CC, et al demonstrated a threefold increase in the detection of miscounted or misplaced sponges with the bar-coded sponges even though they could not determine whether the bar-code system could decrease the rate of retained sponges. These techniques and technology will be beyond the budgets of many theatres in the developing world for a long time to come. Compared to the very inexpensive radio-opaque impregnated sponges it is within the rights of surgeons in the developing world to insist on these materials from hospital administration.

Conclusion

Gossypiboma is not an uncommon preventable surgical error especially in the developing world. A third of cases are asymptomatic and in the remainder the symptoms are varied. The risk factors for its occurrence as noted should alert the surgeon to take extra precautions in high risk patients and to always insist on strict adherence to operating room protocols. Retention of gauze material in superficial small surgical fields is unpardonable just as it is unacceptable the general unavailability of radio-opaque impregnated sponges in many theatres in the developing world that would help in the early detection of inadvertently retained sponges.

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