ADHESIVE POST OPERATIVE SMALL BOWEL OBSTRUCTION IN ADULT PATIENTS AS SEEN AT THE KENYATTA NATIONAL HOSPITAL.

A DISSERTATION SUBMITTED IN PART FULFILMENTOF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN GENERAL SURGERY OF THE UNIVERSITY OF NAIROBI

PRINCIPAL INVESTIGATOR: DR. OTIENO G. NYAKITI MBChB (U.O.N.)

H58/68504/2011

Department of general surgery,

University of Nairobi.

DECLARATION

I hereby declare that this proposed dissertation is my original work and has not been presented for any degree or other award in any other university.

Signature…… Date…….

SUPERVISORS

This proposal is submitted with our approval as supervisors:

Prof. L.W. NDAGUATHA

MBChB (UON), MMed General Surgery (UON), FRCS (UROLOGY)

Consultant Urologist & Senior Lecturer,

Department of Surgery,

University of Nairobi.

Sign…….. Date……..

Dr. D. Kiptoon

MBChB (UON), MMed (UON)

Consultant General Surgeon and Lecturer,

Department of Surgery,

University of Nairobi.

Sign…….. Date……

DEPARTMENTAL APPROVAL

This research proposal has been presented at the University of Nairobi medical school department of surgery dissertation clinic held on…….

It is hereby submitted for approval to the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee.

Sign……..

THE CHAIRMAN,

Department of Surgery,

School of Medicine,

University of Nairobi.

LIST OF ABBREVIATIONS

- ASBO – ADHESIVE SMALL BOWEL OBSTRUCTION
- NOM – NON OPERATIVE MANAGEMENT
- OM – OPERATIVE MANAGEMENT
- NGT – NASOGASTRIC TUBE
- LT - LONG TUBE
- WJES – WORLD JOURNAL OF EMERGENCY SURGERY
- KNH-KENYATTA NATIONAL HOSPITAL
- SBO-SMALL BOWEL OBSTRUCTION.
- ERC – ETHICS AND RESEARCH COMMITTEE.
- UON – UNIVERSITY OF NAIROBI.
- WSCA-WATER SOLUBLE CONTRAST ADMINISTRATION.

TABLE OF CONTENTS **PAGE**

ABSTRACT

Background:

Adhesions are the leading cause of small intestinal obstruction worldwide. The commonest risk factor to the formation of adhesions has been shown to be previous abdominal surgery.
The degree of peritoneal inflammation and injury by pathological processes or surgery contributes to the type and severity of the adhesions.
A paucity of data exists locally and regionally on adhesive small bowel obstruction. Any delay in intervention and the choice of intervention greatly impact on the morbidity, length of hospital stay, and timing of recurrence.

Objective:

To determine the prevalence of adhesive small bowel obstruction in KNH. The etiologies, modes of presentation and their relationship to the modes of management.

Design:

A descriptive prospective study.

Methodology:

All adult patients with prior history of abdominal or pelvic surgery and presenting with signs and symptoms of intestinal obstruction were included in the study upon consenting.
Their demographic details, previous surgical history, current clinical presentation and modes of management were entered in a structured questionnaire.

Data management and analysis:

A structured questionnaire was used to collect data prior to entry in SPSS version 17 for analysis. Data are presented in the form of tables, pie charts, tables and graphs.

Results

The mean age of patients with ASBO was 36.6 years (SD ± 13.1) and the age range was between 14 and 72 years. There were 31 (62%) male patients with ASBO. During the period of the study there were 50 ASBO cases in a total population of 354 patients undergoing intestinal surgery. This yielded an incidence of 14.1 (95 % CI 10.7 to 18.2) for ASBO in KNH. The etiologies of ASBO were colorectal surgery 28 (48%), upper GIT 10 (20%), small bowel 8 (16%) and pelvic 8 (16%) surgeries. ASBO etiology was not significantly associated with ASBO presentation or its management.

Conclusion

The study has demonstrated that ASBO is common (14.1%) in abdominal surgery in KNH with a male preponderance, occurring before 50 years of age. Common etiologies are surgery involving extensive peritoneal dissection and patients commonly present within 2 years of surgery with high chance of needing operative management.

INTRODUCTION

Intestinal Obstruction is defined as a blockage condition in which intestinal contents are prevented from moving in the usual oral to anal progression[1].

Adhesive small intestinal obstruction occurs when there is a physical barrier narrowing the small bowel lumen preventing free passage of intraluminal contents due to fibrous bands[2] between bowel loops or between bowel surface and peritoneal lining or other solid viscera. Adhesions are fibrous bands of connective tissue that form in response to trauma, surgical manipulation, or inflammation[3].

Adhesive small bowel obstruction can be complete, meaning nothing can pass beyond the point of obstruction, or partial, meaning that transit occurs through a significantly narrowed lumen.

The presence of strangulation implies compromised blood flow to the involved segment with necrosis of the bowel segment[4]

Small bowel obstruction can also be classified according to the degree of occlusion/completeness: Partial vs complete (or high grade vs low grade), according to the etiology: adhesional vs non adhesional; timing of presentation, early vs late (> 30 days) [5]

Abdominal adhesions, which can begin forming within a few hours after an operation, represent the most common cause of intestinal obstruction being responsible for60% to 70% of SBO[6] worldwide.
Data from Kenya and the region on the epidemiology and outcomes of adhesive small bowel intestinal obstruction is sparse. The initial pathologies that led to the surgery that later resulted to formation of adhesions causing SBO may vary from country to country or even among regions within a specific country[7.]

Kuremu et al found males to be more affected than females 62 % vs 38%.[8]

Worldwide, acute mechanical small bowel obstruction is a common surgical emergency [9.] It is estimated that over 300,000 laparotomies per year are performed in the United States for adhesion-related obstructions[10.] The incidence of small-bowel obstruction and other adhesion-related complications is thought to vary significantly with surgery type, with surgery involving the small or large bowel resulting in higher rates of this complication compared with those involving the foregut[11.]

Ischemia, which complicates 7% to 42% of bowel obstruction-significantly increases mortality associated with bowel obstruction and the small bowel is involved in about 80 percent of cases of ischemic mechanical intestinal obstruction [12.]
Drodz et al found the incidence of ASBO has been found to be more or less similar between males and females[13]. In one Polish study of adult patients, the average age of patients with acute obstruction was 64 years, women comprised 60 percent of the group, and the small

bowel was affected in 76%.[13.] Duron et al concluded that post operative adhesive SBO is a clinical entity with a high recurrence rate and specific risk factors of recurrences which when present warrant prophylaxis[14].

Liung et al found that patients less than 60years old were more likely to suffer ASBO and undergo surgery[6].

In our set up (KNH), no specific study on adhesive small bowel obstruction has been carried out to determine the incidence or prevalence of ASBO, patient demographics or the etiologies underlying the formation of adhesive bands and the eventual outcomes of the various modes of management.

No local study has been done to determine the relationship between the modes of management (operative vs non-operative) and recurrence of ASBO.

There is no local data outlining the relationship between the nature (emergent vs elective) and type (laparoscopic vs open) of surgery to the clinical presentation (partial, complete or strangulated) of ASBO.

The aim of this study is to determine the epidemiology, etiologies, clinical presentations and management of ASBO, in KNH.

Literature review:

Musila found that adhesions from previous abdominal surgery were the leading cause of small bowel mechanical obstruction (36.7%) in KNH. The majority of the subjects were aged between 21-40 years, lived around Nairobi (92.3% vs 7.7%) and presented within 3 days of onset of symptoms. The male to female ratio was 3.2:1[15.]

Topazian et al in Tenwek found that there is scarcity of local data on the incidence, epidemiology and outcomes of mechanical intestinal obstruction [7.]

Miller et al found that the incidence of adhesions in living subjects who had not undergone any preceding abdominal surgery to be at 10% while the incidence in patients who had previous abdominal surgery was found to be at 93% of which 20% were inflammatory.[10]

In a review over the last 25 years it has been shown that adhesions accounted for 1% of all surgical admissions in any particular surgical unit. Three percent of which were due to laparoscopic surgery and 97% due to open surgery [10.]

The most important risk factor for adhesive SBO is the type of surgery and extent of peritoneal injury or damage.
The technique of the procedure (open VS laparoscopic) plays an important role in the development of adhesion related morbidity. In a retrospective review of 446.331 abdominal operation, Galinos et al. noticed that the incidence was 7.1% in open cholecystectomies vs 0.2% in laparoscopic; 15.6% in open total abdominal hysterectomies vs 0.0% in laparoscopic; 23.9% in open adnexal operations vs 0.0% in laparoscopic and there was no significant difference between open and laparoscopic appendectomies (1.4% vs 1.3%)[16.]

Duron et al in a prospective multi centre trial found that the cumulative incidence of overall recurrences was 15.9% and for surgically managed recurrence 5.8%. They found the risk factors for overall recurrence as age < 40 yrs, adhesions or matted adhesions and post operative complications and further recommended the prophylactic use of anti-adhesion agents when a risk factor of recurrence is present [14.]

Reshef et al. compared the risk of ASBO in 205 patients who underwent laparoscopic colorectal surgery and 205 who underwent similar open operations, both without any previous history of open surgery. After a mean follow-up of 41 months the authors found that although the rate of admission for ASBO was similar (9% vs 13%, p = 0.3 for the laparoscopic and the open group), the need for operative intervention for ASBO was significantly lower after laparoscopic operations (2% vs 8%, p = 0.006). These data suggest that the lower incidence of adhesions expected after laparoscopic surgery likely translates into long term benefits in terms of reduced SBO [17.]

Other well-known risk factors include surgeries of the colon and rectum (i.e. total colectomy with ileal pouch anal anastomosis), gynecologic surgeries, age younger than 60 years, previous laparotomy within 5 years, peritonitis, multiple laparotomies, emergency surgery, omental resection, and penetrating abdominal trauma, especially gunshot wounds and a high number of prior episodes of ASBO [6].

Massimo et al found that gastrointestinal involvement of endometriosis in 3%-37% of menstruating women and exclusive localization on the ileum is very rare (1%-7%).Endometriosis of the distal ileum is an infrequent cause of intestinal obstruction, ranging from 7% to23% of all cases[18].

Duron et al found that since 1990, adhesive SBO occurs following 3% of all laparotomies with 1% occurring during the first postoperative year. After operating on adhesive postoperative SBO, a risk of recurrence remains and the literature reported a wide ranging rate of overall recurrence (range, 8.7%–53%) at 3 years and more[14]

Postoperative risk factors included medical and surgical complications e.g. DVT, CCF, SSI, ileus which contributed to the recurrence of post operative ASBO. These patients had previously sustained 6 postoperative complications (2 surgical: 1 wound infection, persisting ileus; and 4 medical: 3 pulmonary and 1 diabetic complication) (31.5%) compared with 25 (10%) in the 259 patients who were alive.

The management of ASBO is controversial issue with no clear consensus because it is well known that surgery can induce new adhesions, whereas the application of conservative treatment does not remove the cause of the obstruction [18].This is qualified by Miller G et al who concluded that NOM for adhesions in stable patients results in a shorter hospital stay and similar recurrence and reoperation rates, but a reduced interval to re-obstruction when compared with operative treatment.[19]

Higher number of previous laparotomies appeared to be predictors of the occurrence of inadvertent enterotomy. Patients with three or more previous laparotomies had a 10-fold increase in enterotomy compared with patients with one or two previous laparotomies strongly suggesting more dense adhesion reformation after each reoperation[20].

Historically, laparotomy and open adhesiolysis have been the treatment for patients requiring surgery for small bowel obstruction[21]. Unfortunately, this often leads to further formation of intraabdominal adhesions with approximately 10% to 30% of patients requiring another laparotomy for recurrent bowel obstruction[21].

Conservative treatment involves nasogastric intubation, intravenous fluid administration, and clinical observation. Strangulation of the bowel requires immediate surgery, but intestinal ischemia can be difficult to determine clinically.

Patients without the signs of strangulation or peritonitis or history of persistent vomiting or combination of CT scan signs (free fluid, mesenteric edema, lack of feces signs, devascularized bowel) and partial ASBO can safely undergo non-operative management.
In these patients tube decompression should be attempted, either with NGT or LT [22].
In non-operatively treated patients with ASBO, the drainage volume through the long tube or nasogastric tube on day 3 (cut-off value; 500 mL) was the indicator for surgery [23].

Also in patients with recurrent episodes and many prior laparotomies for adhesions, prolonged conservative treatment (including parenteral nutritional support) may be the wisest choice and helps to avoid the possibility of a complex high-risk procedure [24], but all that said, the use of supplementary diagnostic tools e.g. CT scan might be desirable to find the patients who will need early operative treatment [25].

Patients who had surgery within the six weeks before the episode of small bowel obstruction, patients with signs of strangulation or peritonitis (fever, tachycardia and leucocytosis, metabolic acidosis and continuous pain), patients with irreducible hernia and patients who started to have signs of resolution at the time of admission are NOT candidates for non operative management +/− WSCA administration [26, 27.]

Complete SBO (no evidence of air within the large bowel) and increased serum creatine phosphokinase predicts NOM failure. Free
Intraperitoneal fluid, mesenteric edema, lack of the “small bowel feces sign” at CT, and history of vomiting, severe abdominal pain (VAS > 4), abdominal guarding,
Elevated WBC count and devascularized bowel at CT predict the need for emergent laparotomy at the time of admission.

Schraufnagel et al. in an univariate analysis showed that complications, bowel resections, prolonged hospital length of stay and death are more likely in patients admitted for ASBO and operated on the fourth day or later [28].

Usually NOM, in absence of signs of strangulation or peritonitis, can be prolonged up to 72 hours of adhesive SBO[29]. After 3 days without resolution, WSCA study or surgery is recommended[30.]

If ileus persists more than 3 days and the drainage volume on day 3 is > 500 ml, surgery for ASBO is recommended[31]. With close monitoring and in the absence of signs suggestive of complications, an observation period even longer than 10 days before proceeding to surgical intervention appears to be safe [32].

However at any time, if onset of fever and leucocytosis greater than 15,000/mm3 (predictors of intestinal complications) are observed, then NOM should be discontinued and surgery is recommended. The patients who are non responders to the long-tube or nasogastric tube and conservative treatment within 72 hours have a considerable risk of recurrent ASBO. Risk factors for recurrences are age <40 years, matted adhesion and postoperative surgical complications[32].

BROAD OBJECTIVE:

To determine the incidence of post operative ASBO in adult patients presenting in KNH and to correlate its etiologies to the pattern of presentation and its modes of management in KNH.

SPECIFIC OBJECTIVES:

- To determine the incidence of ASBO in KNH.
- To determine the etiologies of ASBO in KNH.
- To correlate the etiologies to the patterns of presentation of ASBO in KNH.
- To correlate the etiologies to the modes of management of ASBO in KNH.
- To correlate the etiologies and patterns of presentation to the modes of management.

METHODOLOGY

Setting: KNH casualty department, general surgical wards.

Study population: Consenting adult patients and patients between 13 and 18 years with assenting guardians/parents presenting in KNH with previous history of abdominal surgery and diagnosed by the attending clinician to have ASBO.

Study design: Prospective descriptive study.

Sample size:
Fishers formula for estimating sample size in prevalence studies was used with a finite population correction as suggested by Daniels (1999) to estimate the sample size accounting for the limited number of patient with adhesive small bowel obstruction in KNH (maximum N = 55 during study period, assuming 10 admission per month over the five –month data collection period).

$$\boldsymbol{n = \frac{NZ^2P(1-P)}{d^2(N-1)+Z^2P(1-P)}}$$

N = Total population of patients diagnosed with ASBO in KNH during the 5-month study period

P = Prevalence of any of the four main presentations of ASBO estimated at 1% based on a study by Miller G et al[10].

1-P = 1 minus the prevalence of any of the four main presentations of ASBO

Z = Z statistic representing 95% level of confidence (1.96)

d = desired level of precision set to 0.5 %

$$n = \frac{50 \times 1.96^2 \times 0.01(1 - 0.01)}{0.005^2(50 - 1) + 1.96^2 \times 0.01(1 - 0.01)}$$

n = 49

INCLUSION CRITERIA

1. All consenting adult patients (above 18 years) with laparotomy or laparoscopic abdominal surgical scar presenting in KNH and diagnosed by the attending clinician to have ASBO.
2. All patients between the ages of 13 to 18 years with laparotomy or laparoscopic abdominal surgical scar presenting in KNH and diagnosed by the attending clinician to have ASBO.
3. Clients who fall within the time frame of the study.

EXCLUSION CRITERIA

1. Any patient who declines consent.
2. Patients with non-postoperative ASBO.

DATA COLLECTION

All eligible and consenting patients' demographic data and information regarding previous surgery and current presentation and investigations and management were collected by a research assistant with minimum MBChB qualification using a structured questionnaire.

DATA ANALYSIS AND PRESENTATION

The collected data was entered into the statistical package for social sciences version 17.0 (SPSS 17.0). The descriptive analysis of the socio-demographic data was presented using percentages, frequency tables, pie charts and graphs.

The various sub-presentations of the expected outcome and interventions were presented in form of frequency tables, graphs, pie charts and percentages.

ETHICAL CONSIDERATION

Institutional consent was sought from the department of surgery, University of Nairobi (UON) and the Ethics and Research Committee of KNH.

Informed consent was sought from all eligible patients.

Several measures were undertaken to ensure absolute confidentiality of information, these included:

- Limiting access of the research Data to the principal investigator only during the study.
- Secure storage and archiving of data using password protected computers and lockable cabinets.
- Individual names were kept anonymous and their coded number or in-patient numbers used instead.
- Data will be destroyed once the findings are reported and data publication is done.

4.0 RESULTS

4.1 Characteristic of patients with ASBO

The mean age of patients with ASBO was 36.6 years (SD ± 13.1) and the age range was between 14 and 72 years. The most common age groups for presetnation with ASBO were 40-49 years 13 (26%), 30-39 years 12 (24%) and 20-29 years 11 (22%), Figure 1.

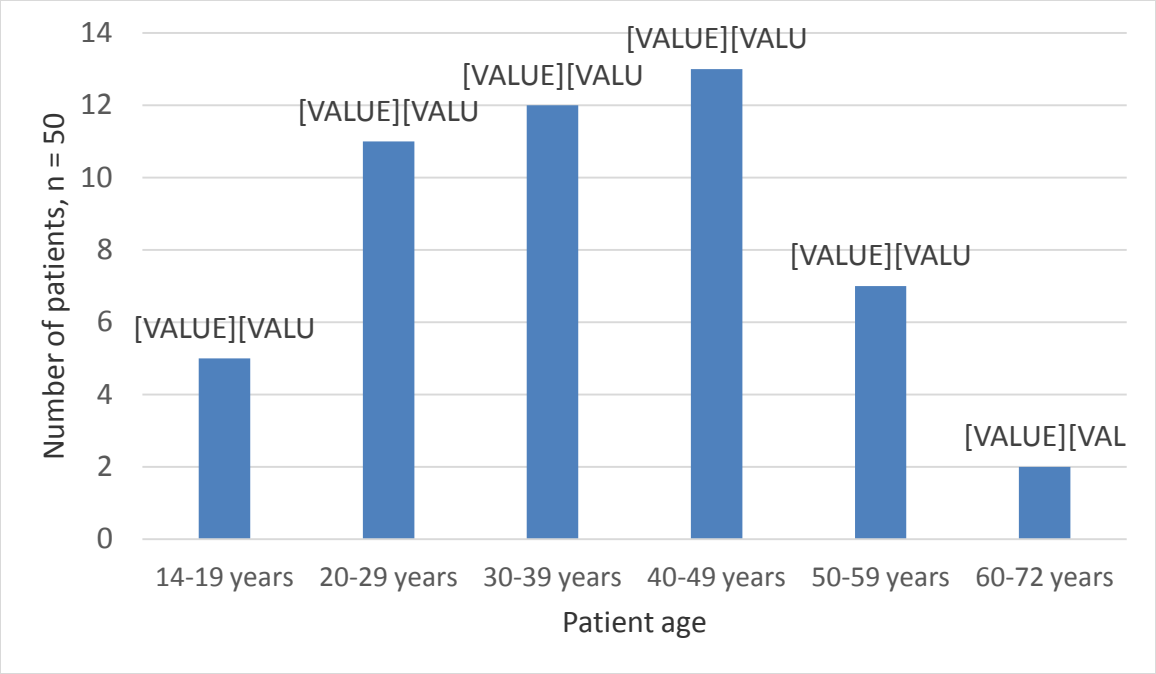

Figure 1: Age distribution of patients presenting with ASBO in KNH

There were 31 (62%) male patients with ASBO (Figure 2), giving a male-to-female ratio of approximately 2: 1. The mean age of male patients was 38.4 years (SD ± 13.2) compared to a mean age of 33.7 years (SD ± 12.7) in females (p = 0.224).

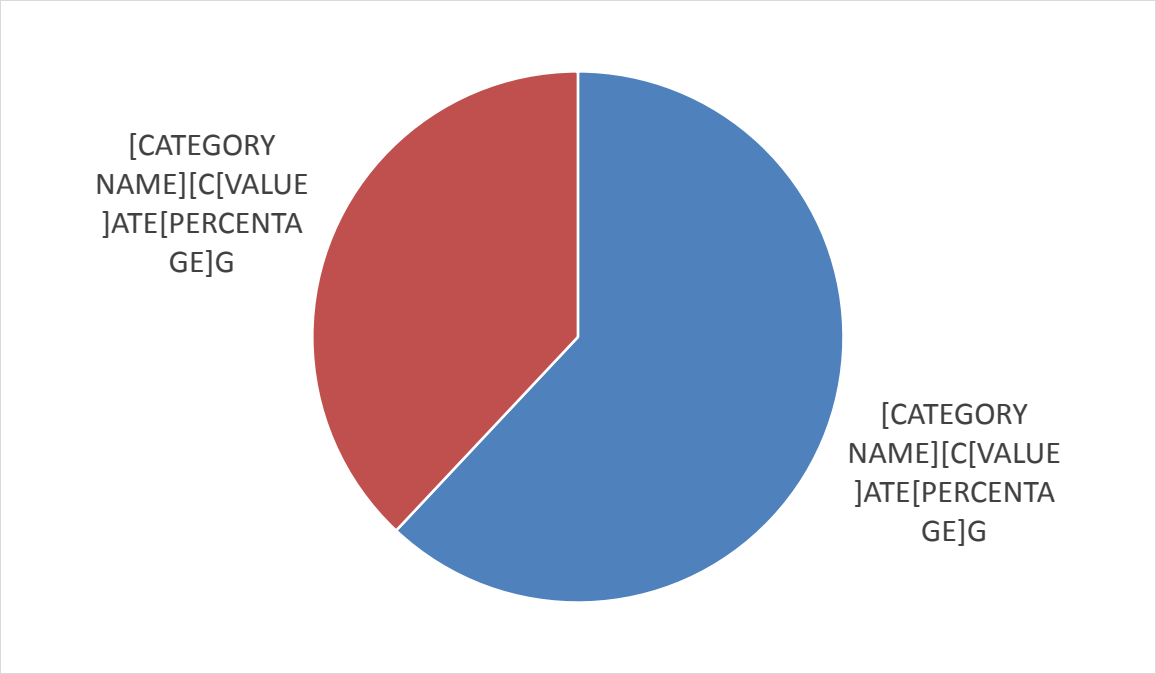

Figure 2: Sex distribution of patients with ASBO in KNH

4.2 History of intestinal obstruction in ASBO

Out of the 50 patients with ASBO, 28 (56%) reported that they had previously been admitted for intestinal obstruction (Table 1). Most 13 (61.9%) previously admitted patients reported that they had a single prior admission. Seven patients had previously been operated for adhesions, with five patients being operated once and a single patient undergoing two operations for adhesions. The median duration between the last operation and the current admission was 2 years (range < 1 year to 20 years). Most 26 (59.1%) patients reported durations between 1 and 2 years since the last operation.

Table 1: History of intestinal obstruction in patients with ASBO in KNH

	Frequency (n)	Percent (%)
Previously admitted for intestinal obstruction (n = 49)		
Yes	28	56
No	22	44
Number of times previously admitted (n = 21)		
Once	13	61.9
Twice	5	23.8
Thrice	3	14.3
Previously operations for adhesions (n = 42)		
Yes	7	16.7
No	35	83.3
Number of times operated for adhesions (n = 6)		
Once	5	83.3
Twice	1	16.7
Duration since last operation (n = 44)		
< 1 years	1	2.3
1-2 years	26	59.1
3-4 years	12	27.3
5 or more years	5	11.4

Previous management of intestinal obstruction

The most commonly employed management following initial admission with intestinal obstruction included conservative management 27 and open (primary) surgical management 16

(Figure 3). Conservative management on initial admissions failed in 4 patients and 2 of these patients were managed through surgery.

Out of the initial admission 12 (42.9%) had one readmission and 1(3.6%) was readmitted twice. During firsts readmission 6 patients were managed through open surgical procedure and 5 through conservative management (Figure 3). The patient who was readmitted twice was managed conservatively on second readmission.

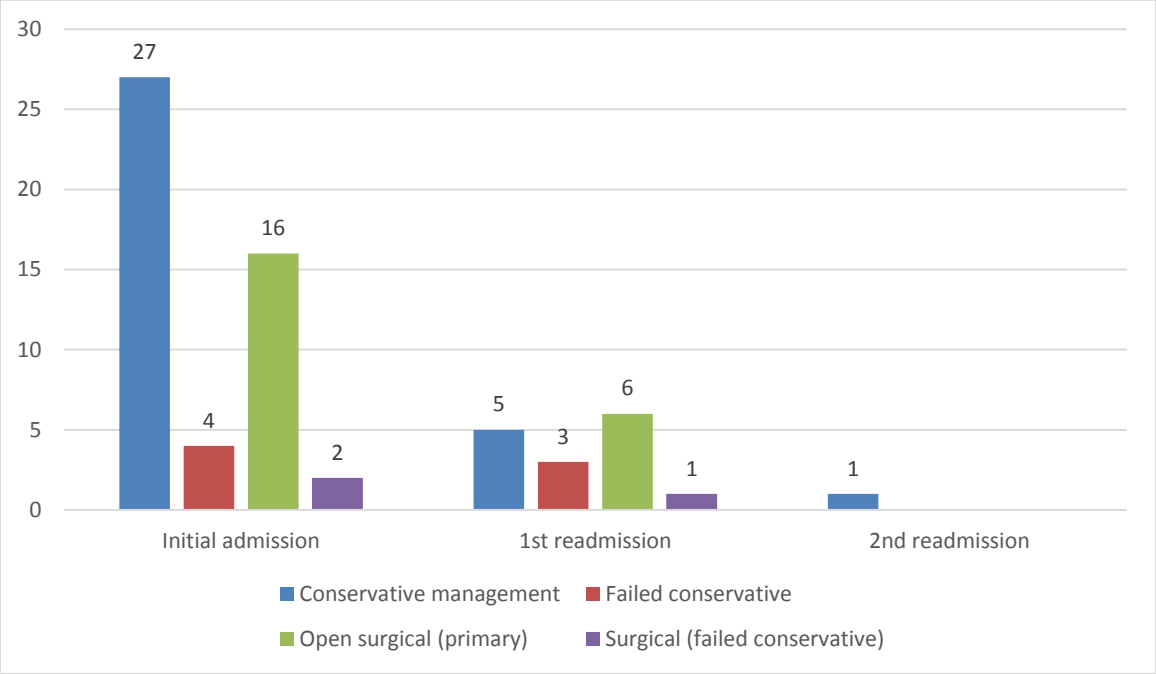

Figure 3: Management of intestinal obstruction in patients with ASBO with previous admission history

4.3 Incidence of ASBO in KNH

During the period of the study there were 50 ASBO cases in a total population of 354 patients undergoing intestinal surgery. This yielded an incidence of 14.1 (95 % CI 10.7 to 18.2) for ASBO in KNH.

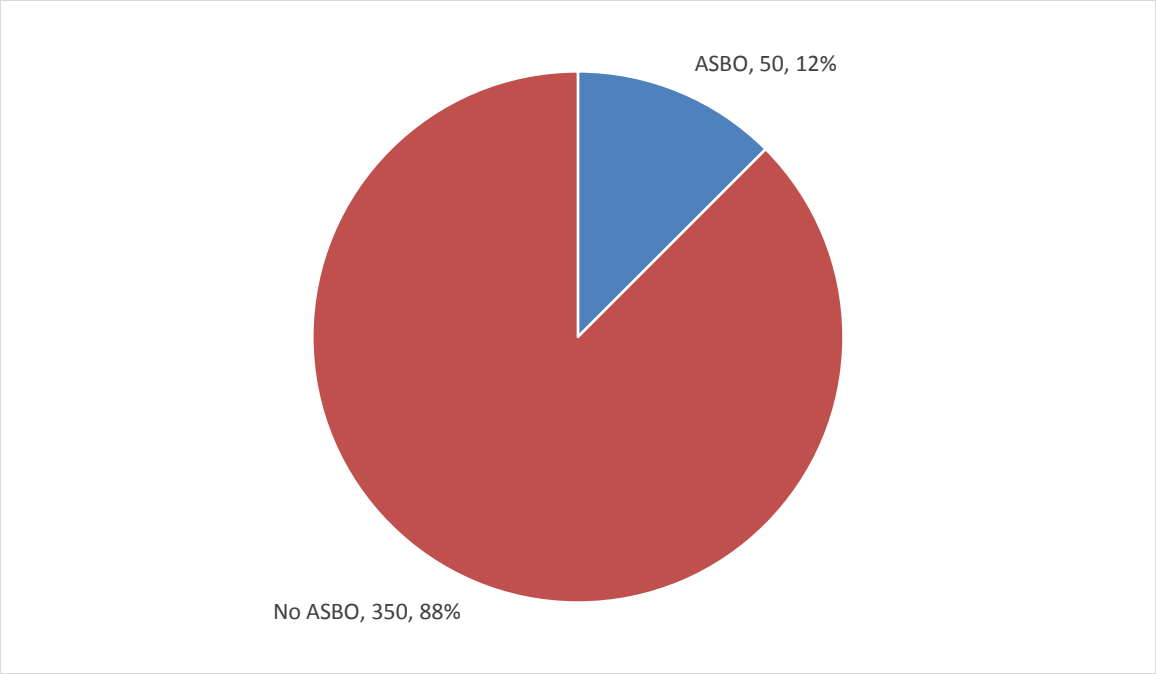

Figure: Incidence of ASBO in patients undergoing abdominal operations in KNH

4.4 Etiologies, patterns and management of ASBO in KNH

4.4.1 Etiologies of ASBO

The most common etiology associated with ASBO in KNH was colorectal surgery in 28 (48%) patients (Table 2). Upper GIT surgery was associated with 10 (20%) cases of ASBO. The remaining cases were attributable to small bowel 8 (16%) and pelvic 8 (16%) surgeries.

Table 2: Etiologies of ASBO in patients at KNH

	Frequency (n)	Percent (%)
Diagnosis leading to first surgery		
Upper GIT surgery	10	20
Small bowel surgery	8	16
Colorectal surgery	24	48
Pelvic surgery	8	16

4.4.2 ASBO etiologies and patterns of presentation

Most patients with ASBO etiologies attributed upper GIT 5 (50%) and colorectal surgeries 14 (58.3%) presented with complete ASBO while conversely most cases attributed to small bowel 6 (75%) and pelvic 5 (62.5%) surgeries presented with partial ASBO (Table 3). There was however no statistically significant association between ASBO etiologies and pattern of presentation (p values > 0.05).

Table 3: ASBO etiologies and patterns of presentation in KNH

	Presentation			
	Complete	Partial	OR(95% CI)	P value
Etiology				
Upper GIT surgery	5(50.0)	5(50.0)	1.00(ref)	
Small bowel surgery	2(25.0)	6(75.0)	0.33(0.04-2.52)	0.287
Colorectal surgery	14(58.3)	10(41.7)	1.40(0.32-6.16)	0.656
Pelvic surgery	2(25.0)	5(62.5)	0.40(0.05-3.12)	0.382

4.4.3 ASBO etiologies and modes of management

The predominant modes of management of intestinal obstruction in upper GIT and colorectal etiologies were surgical procedures performed in 6 (60%) and 15 (62.5%) cases, respectively. Small bowel and pelvic surgery related etiologies were commonly managed using conservative approaches (5[62.5%] and 4[50.0%], respectively). There was however no statistically significant association between ASBO etiologies and modes of management (p values > 0.05).

Table 4: ASBO etiologies and modes of management in KNH

	Management			
	Surgical	Conservative	OR (95% CI)	P value
Upper GIT surgery	6(60.0)	4(40.0)	1.00(ref)	
Small bowel surgery	3(37.5)	5(62.5)	0.40(0.06-2.70)	0.347
Colorectal surgery	15(62.5)	8(33.3)	1.25(0.27-5.77)	0.775
Pelvic surgery	3(37.5)	4(50.0)	0.50(0.07-3.55)	0.488

DISCUSSION

ASBO is commonly seen in local surgical units but there are few Kenyan studies investigating its etiologies, presentation and management. [15] The incidence of ASBO in KNH as estimated in the current study was 14.1%, common etiology was colorectal surgery and open surgery was the predominant management strategy. Based on analysis of patient profile it is apparent that intestinal obstruction among adult patients peaks at between 30 and 40 years and that there is a male preponderance.

The demographics of patients including age [mean 36.6 years (SD ± 13.1)] and sex distribution (62%) was similar to that of patients in previous studies. [15] The mean age of patients presenting with acute intestinal obstruction in a hospital in South Western Kenya was 40.6 years and in common with the present study in KNH, males comprised 68.1% of sample. Kwemu et al, also reported that males were more affected by intestinal obstruction compared to females (62% versus 38%).[8] The major determinants noted were age, sex and the extent of surgery involved. Males are predominantly affected by pathologies such as colorectal tumors which may account for their higher incidence and frequency of recurrence.

On the contrary there are studies that have reported no gender dominance in intestinal obstruction. Drudz et al found the incidence between male to female to be more or less the similar. The average age of patients in one polish study was 64 years with women compromising 60%. In such studies pelvic pathologies which affect women predominate as causes of ASBO.

Incidence and etiologies of ASBO

The incidence of ASBO among all abdominal surgeries during the study period was 14.1% in KNH. Miller et al similarly found that the incidence of adhesions in living subjects who had not undergone any preceding abdominal surgery to be at 10%. In the same series of patients Miller and colleagues reported that the incidence of obstruction in patients who had previous abdominal surgery was 93% of which 20% were inflammatory.[10] In KNH 16.7% of patients had had previous operations for adhesions and 56% had previously been admitted for obstruction confirming the different risk profile in patients with previous related history of abdominal obstruction and its management as suggested by Miller et al.

Musila found that adhesions from previous abdominal surgery were the leading cause of small bowel mechanical obstruction (36.7%) in KNH.[19] In the current analysis colorectal surgery was responsible for 48% of all ASBO and 20% of ASBO cases were attributable to upper GIT obstruction. In Tenwek Hospital, Ooko et al reported that 23% of mechanical obstructions were caused by adhesions. Colorectal and pelvic pathologies requiring surgical intervention were the leading pathologies of ASBO in male and females, respectively.

ASBO etiologies versus pattern of presentation

The two major patterns of presentation were assessed in the current study were partial (53.1%) and complete (46.9%) obstruction. Colorectal and upper GIT related ASBO presented with complete obstruction and pelvic and small bowel surgeries were mostly partial obstructions. The finding that presentation was not significantly associated with etiology was unexpected given that Galinos et al reported that the most important factor for adhesive SBO is the type of surgery and extent of peritoneal damage.[16] this may reflect the effect of both extensive peritoneal irritation and inflammation as major determinants of presentation of ASBO i.e. whether complete or partial.

Etiologies and modes of management

There was no statistically significant association between underlying initial etiology and mode of management. Conservative management is associated with longer hospital stay, cost and less time to recurrence. Historically, laparotomy and open adhesiolysis have been the treatment for patients requiring surgery for small bowel obstruction[21]. Unfortunately, this often leads to further formation of intraabdominal adhesions with approximately 10% to 30% of patients requiring another laparotomy for recurrent bowel obstruction[21].

The implication of this finding is that if the etiology (initial) was PUD or colorectal, this did not influence whether mode of management was either conservative or surgical.

Timing

59% of the patients presented within 2 years of previous surgery and 86% within 4 years.

The initial operation necessitating extensive peritoneal dissection may cause excessive inflammatory reactions resulting in laying down of excessive collagenous material hence denser adhesions.

This affects structures with more peritoneal attachments e.g. colon/rectum/gall bladder and pelvic structures. These patients then present with a higher incidence of ASBO than those with say primary small bowel pathology which is free and translates into fewer incidence and less complete ASBO.

Our findings seem to mirror those of other studies done in other parts of the world with differences being subtle and possibly attributable to variations in populations studied and sampling variation.

Limitations

The main potential limitation of the study was related to possible recall bias introduced by enquiries about previous admissions and surgeries related to the current obstruction. This limitation was overcome by validating information provided by the patients during interviews with information contained in their medical records. However, for patients who had not been previously treated in KNH this verification was not possible to perform but such cases were limited.

Recommendations

Based on the objectives the study makes the following recommendations:

Patients who undergo abdominal surgery or those with history of intestinal obstruction should be followed up and regularly monitored for ASBO because of its high incidence in this group.

Surgeons should apply preventive interventions in patients with known underlying etiologies of ASBO including extensive peritoneal inflammation and previous surgery involving extensive peritoneal dissection.

Conclusion

The study has demonstrated that ASBO is common (14.1%) in abdominal surgery in KNH with a male preponderance, occurring before 50 years of age. The common etiologies are surgery involving extensive peritoneal dissection and inflammation. The patients commonly present within 2 years of surgery with signs of ASBO that is complete and has a higher chance of needing operative management.

REFERENCES

1. Rohovsky S and Ronald Bleday; Oxford textbook of surgery . Oxford University Press; 2nd revised edition (2002) ch.24.

2. Leslie Kobayashi. Trauma Conference 2013. Overview, background. Pathophysiology / Etiology, Diagnosis, treatment and outcomes. Small bowel obstruction (SBO)

3. Becker JM et al. Prevention of postoperative abdominal adhesions by a sodium hyaluronate-based bio-resorbable membrane: a prospective, randomized, double-blind multicenter study. Journal of the American college of Surgeons 1996; vol183: p 297–306.

4. Fischer, Josef E. Title: Mastery of Surgery, 5th Edition 2007 Lippincott. Williams and Wilkins.
5. Orsola S Emergency and Trauma Surgery Unit, Departments of Emergency surgery Maggiore Hospital Trauma Center, Bologna, Italy 2013.
6. Di Saverio et al. World Journal of Emergency Surgery 2013, 8:42 Page 2 of 14 http://www.wjes.org/content/8/1/42

7. Pan African Medical Journal –ISSN: 1937-8688 (www.panafrican-medjournal.com)Published in partnership with the African Field Epidemiology Network (AFENET). (www.afenet.net)

8. Kuremu, Jumbi East African Medical Journal. 2006 Jun; 83(6):333-6.

9. Luciano AA. Laparotomy versus laparoscopy. Programme on clinical Biological Research 1990; 358: 35-44.

10. Miller G, Boman J, Shrier I et al. Natural history of patients with adhesive small bowel obstruction. British Journal of Surgery 2000; 87:1240.

11. Scott FI, Osterman MT, Mahmoud NN, et al. Secular trends in small-bowel obstruction and adhesiolysis in the United States: 1988-2007. American Journal of Surgery 2012; 204:315?

12. Markogiannakis H, Messaris E, Dardamanis D, et al. Acute mechanical bowel obstruction: clinical presentation, etiology, management and outcome. World Journal of Gastroenterology 2007; 13:432.1 ?

13. Drożdż W, Budzyński P. Change in mechanical bowel obstruction demographic and etiological patterns during the past century: observations from one health care institution. Archives of Surgery 2012; 147 (2):175-80:

14. Duron JJ, Silva NJ, du Montcel ST et al: Adhesive postoperative small bowel obstruction: incidence and risk factors of recurrence after surgical treatment: a multicenter prospective study. Ann Surg 2006, 244(5)

15. Musila Gibson a five year retrospective study on pattern of acquired intestinal obstruction adults as seen at Kenyatta national hospital, January 1996 – December 2000

16. Galinos B, Branco BC, Beat S et al: The incidence and risk factors of post-laparotomy adhesive small bowel obstruction. Journal of Gastrointestinal Surgery 2010, 14:1619–1628. doi: 10.1007/s11605-010-1189-8.

17. Reschef A, Hull TL, Kiran RP et al: Risk of adhesive obstruction after colorectal Surgery: the benefits of the minimally invasive approach may extend Well beyond the perioperative period. Surgical Endoscopy 2013, 27:1717–1720. doi:10.1007/s00464-012-2663-z.

18. World J Gastroenterology 2008 June 7; 14(21): 3430-3434wjg@wjgnet.com World Journal of Gastroenterology ISSN 1007-9327doi:10.3748/wjg.14.3430 © 2008 The WJG Press.

19. Miller G, Boman J, Shrier I et al: Natural history of patients with adhesive small bowel obstruction..British Journal of Surgery 2000 Sep; 87(9):1240-7.PMID:10971435

20. Barkan H, Webster S, Ozeran S: Factors predicting the recurrence of Adhesive small-bowel obstruction. Am J Surg 1995, 70:361–365

21.Landercasper J, Cogbill TH, Merry WH et al. Long-term outcome after hospitalization for small-bowel obstruction. Archives of Surgery 1993;8: 765–770. doi: 10.1001/archsurg.1993.01420190059008.

22. Fleshner PR, Siegman MG, Slater GI et al: A prospective, randomized trial of short versus long tubes in adhesive small-bowel obstruction. Am J Surg 1995, 170(4):366–370.

23. Moran BJ: Adhesion-related small bowel obstruction. Colorectal Dis 2007, 9(Supplement 2):39–44.

24. Sakakibara T, Harada A, Yaguchi T et al: The indicator for surgery in adhesive small bowel obstruction patient managed with long tube. Hepatogastroenterology 2007, 54(75):787–790.

25. Fevang BT, Jensen D, Svanes K et al: Early operation or conservative Management of patients with small bowel obstruction? European Journal of Surgery 2002, 168(8–9):475–481.

26. Abbas S, Bissett IP, Parry BR: Oral water soluble contrast for the management of adhesive small bowel obstruction. Cochrane Database Systematic Review 2007, 18(3), CD004651.

27. Branco BC, Barmparas G, Schnüriger B et al: Systematic review and meta-analysis of the diagnostic and therapeutic role of water-soluble contrast agent in adhesive small bowel obstruction. British Journal of Surgery 2010, 97(4):470–478.

28. Schraufnagel D, Rajaee S, Millham FH: How many sunsets? Timing of surgery in adhesive small bowel obstruction: A study of the Nationwide Inpatient Sample. J Trauma Acute Care Surg 2013, 74(1):181–187. doi:10.1097/TA.0b013e31827891a1. Discussion 187–9.

29. Cox MR, Gunn IF, Eastman MC et al: The safety and duration of non-operative treatment for adhesive small bowel Obstruction. Australian and New Zealand Journal of Surgery 1993, 63(5):367–371

30. Diaz JJ Jr, Bokhari F, Mowery NT et al: Guidelines for management of small bowel obstruction. J Trauma 2008, 64 (6):1651–1664.

31. Van Der Krabben AA, Dijkstra FR, Nieuwenhuijzen M. et al. Morbidity and mortality of inadvertent enterotomy during adhesiolysis. Br J Surg. 2000;8: 467–471. doi: 10.1046/j.1365-2168.2000.01394.x.

32. Shou-Chuan S, Kuo-Shyang J, Lin S-C, et al: Adhesive small bowel obstruction: How long can patients tolerate conservative treatment? World Journal Gastroenterology 2003, 9(3):603–605.

APPENDIX 1:

BUDGET

Research fee for KNH-ERC	5000
Statistician fee	30,000
Research Assistant fee	30,000
Stationery, printing and binding	30,000
Contingencies	10,000
Total……	105,000

APPENDIX 2:

TIME FRAME

Time frame	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Proposal writing and ERC approval									
Data collection and dissertation writing									
Dissertation presentation									

APPENDIX 3.

QUESTIONNAIRE

Study subject No…….

1. **Demographic data**
    a) Code…….
    b) Gender ……
    c) Age……

2. **Nature of initial surgery :**
    a) Emergency
    b) Elective

3. **Diagnosis leading to 1st surgery :**

    a) Upper GIT surgery.
    b) Small bowel surgery.
    c) Colorectal surgery.
    d) Pelvic surgery
    e) Urological surgery
    f) Others

4. **Have you been admitted for intestinal obstruction previously?**
    a) Yes
    b) No

5. If yes, how many times?

6. Have you been operated for adhesions before?

7. If yes, how many times?

8. When was your last operation?

9. **What was the management?**

Readmission no	1	2	3	4
Conservative management				
Failed conservative				
Open surgical(primary)				
Surgical(failed conservative)				
Laparoscopic				
Time from admission to surgery.				

10. Presentation :

a) Partial
b) Complete
c) Strangulated
d) Perforated/ peritonitis

11. Vital signs :

B/P	PR	RR	TEMP

12. Investigation requested **YES** **NO**

a) HGM / CBC
b) UEC

c) ABG
d) Plain abdominal X-ray
e) CT scan
f) Abdominal ultra sound

13. Management :

a) Conservative
b) Surgical.

APPENDIX 4.

CONSENT FORM

PREVALENCE, ETIOLOGIES, PRESENTATION AND MODES OF MANAGEMENT OF ADHESIVE SMALL BOWEL OBSTRUCTION AS SEEN IN KNH.

ENGLISH VERSION

This informed consent form is for patients and guardians of patients (below 18 and above 12 yr) who have been admitted with a diagnosis of small intestinal obstruction due to adhesions in KNH.

Principal investigator: Dr. Otieno N. George.

Institution: School of Medicine, Department of Surgery-University of Nairobi.

Supervisors: Prof. Peter L.W Ndaguatha, Dr. Kiptoon.

This informed consent form has three parts:

1. Information sheet (to share information about the research with you)
2. Certificate of consent (for your signature should you agree to take part)
3. Statement by the researcher.

You shall be given a copy of the full informed consent form.

Part I: Information sheet:

My name is Dr. Otieno G. Nyakiti, a post graduate student at the University of Nairobi medical school. I am carrying out a study to determine the prevalence, epidemiology, etiology and modes of management of adhesive small bowel obstruction in KNH.

The study will be conducted by the filling in of data onto a questionnaire at the end of which an analysis will be carried out.

I hereby invite you to participate in my study and are free to choose to decline or participate with no further penalties.

You are free to make inquiries about the study and if not sure at the moment can have time to consider and are free to consult with any individual or professional you are comfortable with. You are also free to seek any further clarification on the study from myself or my research assistant.

If you agree to participate, you will be asked personal information pertaining to your illness and past medical and surgical history which shall all be kept confidential revealed only to the researchers.

All the information you provided shall be coded and the coded identifiable to you by the researchers only.

Your information will not be shared with anyone else unless authorized by the KNH/UON-Ethics and Research Committee.

You are free to stop participating in the study at any at no cost nor will you be denied the right to adequate professional medical/surgical care as a result.

This proposal has been reviewed and approved by the KNH/UON-ERC for the duration of five months. The role of the research committee is to ensure participants like your self are safe. It was submitted to them through the Chairman of the department of surgery, school of Medicine – UON with the approval of my two supervisors whose contact information is availed below should you wish to contact them.

1.Secretary, KNH/UON-ERC

P>O> Box 20723 KNH Nairobi 00202

E-mail: KNHplan@Ken.Healthnet.org

University of Nairobi Research supervisors

3. Dr. Dan Kiptoon

Dept. of Surgery, school of Medicine, UON

Tel:

4. Prof. L.W. Ndaguatha

Dept. of Surgery, school of Medicine, UON

Tel:

P.O> Box 19676 KNH, Nairobi 00202

5. Principle Researcher

Principle Researcher

Dr. Otieno G. Nyakiti

Department of Surgery, UON

Tel No: 0725108819

5. Research Assistant

Part II: Consent certificate by the patient.

I (Name)……..freely consent to take part in the study being conducted by Dr .Otieno G. Nyakiti, whose nature has been explained to me by him/ the research assistant.

I have been informed and have understood that my participation is entirely voluntary and that I am free to withdraw my consent at any time should I so wish without incurring no any penalties or alterations in the level of care due to me.

I also understand that the results of this study may directly benefit me or other patients and more importantly the medical professionals to better understand the prevalence, etiologies, presentations and their relationship to the modes of management of adhesive small bowel obstruction at KNH.

Signature of patient……

Date……Thumb print if illiterate.

Statement by a witness if participant is illiterate:

I have witnessed the accurate reading of the consent form to the participant and the individual has had the opportunity to make inquiries as to the nature of the study and his role in it. I hereby confirm that he has given his consent freely.

Name of witness ……..

Signature of witness ……..

Date ……..

Part III: Researchers Statement

I have accurately read out the information sheet to the participant and to the best of my ability made him/her understand that:

1. Declining to participate or withdrawal from participation after initial consent will not compromise the quality of care due to him.

2. All information he has given will be treated with utmost confidentiality.
3. The results of the study might be published to enhance the knowledge and understanding of the medical professionals regarding the subject of the study.
4. I also confirm that to the best of my knowledge the individual has not been coerced into giving consent and that his consent was given by himself voluntarily.

A copy of this informed consent has been given to the participant.

Name of researcher taking consent ……

Signature ……

Date……

Swahili version

FOMU YA IDHINI

Fomu hii ya idhini ni ya wagonjwa au wasimamizi/wazazi wa wagonjwa (walio kati ya miaka 12 hadi 18) waliolazwa kwa sababu ya matibabu ya ugonjwa wa kufungana kwa matumbo baada ya upasuaji wa matumbo katika hospitali kuu ya KNH.

Mtafiti mkuu: Daktari Otieno N. George.

Chuo: Shule ya Elimu ya Matibabu, Kitivo cha upasuaji-Chuo Kikuu cha Nairobi.

Wahadhiri wasimamizi: Prof. Petero L.W Ndaguatha, Daktari D. Kiptoon.

Fomu hii iko na sehemu tatu:

1. Maelezo ya Daktari mtafiti.
2. Idhini ya mgonjwa.
3. Dhibitisho la mtafiti mkuu.

Utapewa fomu iliyo na sehemu zote tatu.

Sehemu ya kwanza: Maelezo ya Daktari mtafiti:

Majina langu ni Dkt. Otieno G. Nyakiti, kutoka Shule ya elimu ya matibabu Kitivo cha upasuaji.

Ninafanya utafiti kuangalia idadi ya wagonjwa wanaolazwa na ugonjwa wa kufungana matumbo baada ya upasuaji wa matumbo na aina tofauti ya matibabu wanayopewa katika hospitali kuu ya Kenyatta.

Ningependa kuomba ushirikiano wako kwa hiari yako mwenyewe kwa njia ya kujaza fomu maalum ya maswali utakayopewa kwa taarifa yako mwenyewe.

Uko huru kuuliza maswali yeyote kuhusu utafiti huu au kuwasiliana na mtu yeyote unayemwamini kuhusu utafiti huu. Pia uko na uhuru wa kusimamisha uhusiano wako katika utafiti huu bila kuhatarisha matibabu yako katika hospitali kuu ya KNH.

Kuhusika kwako kwenye utafiti huu hakutozwi malipo au hela zozote.

Habari yeyote utakayotupatia mimi ama mtafiti msaidizi wangu ni siri yako na sisi watafiti na haitaenezwa kwa watu wengine. Jina lako halitaandikwa kwenye fomu bali utajulikana kwa kodi.

Unaweza kuuliza maswali yeyote kwangu ama kwa mtafiti msaidizi ama kwa wahadhiri wasimamizi ana kwa ana ama kupitia kwa simu ukitumia nambari zifuatazo;

+

Katibu wa utafiti, Hospitali kuu ya KNH na chuo kikuu cha Nairobi 00202. Nambari ya simu 726300-9

+

Wahadhiri wasimamizi wa chuo kikuu cha Nairobi:

1. Profesa Petero L.W Ndaguatha,
   S.L.P. 19676 KNH, Nairobi 00202,
   nambari ya simu

2 Daktari D. Kiptoon,

Kitivo cha upasuaji, Shule ya elimu ya matibabu, Chuo kikuu cha Nairobi

nambari ya simu

3 Mtafiti mkuu, Dkt. Otieno G. Nyakiti,

Kitivo cha upasuaji, chuo kikuu cha Nairobi.
Nambari ya simu

4 Mtafiti msaidizi, Dkt

Kitivo cha upasuaji, chuo kikuu cha Nairobi
Nambari ya simu

Sehemu ya pili-Idhini ya mgonjwa;

Mimi (jina)……nimekubali kwa hiari yangu mwenyewe na bila shurutisho la aina yeyote kushiriki katika utafiti unaofanywa na Dkt. Otieno G. Nyakiti kulingana na maelezo niliyopewa.

Nimeelezewa ya kwamba ninaweza kuondoa ushiriki wangu wakati wowote nitakao bila kuhatarisha matibabu yangu au ya mgonjwa wangu na pia kwamba matokeo ya utafiti huu yanaweza kuwa na manufaa kwangu ama kwa wagonjwa wengine na hata madaktari kwa jumla kwa kuendeleza elimu juu ya ugonjwa huu hapa KNH.

Sahihi ya mgonjwa…….

Tarehe……..Kidole cha gumba

kwa mgonjwa asiyejua kusoma.

Sehemu ya shahidi wa mgonjwa asiyeweza kusoma:

Nimeshuhudia kusomewa fomu ya idhini kwa mgonjwa naye amepewa nafasi kuuliza maswali kuhusu utafiti na sehemu yake katika utafiti huu. Nashuhudia kuwa amepeana idhini yake kwa hiari bila shurutisho lolote.

Jina la Shahidi ……..

Sahihi ya shahidi ……

Tarehe ……..

Sehemu ya tatu: Dhibitisho la mtafiti mkuu

Hii ni kudhibitisha ya kwamba nimemuelezea mgonjwa au msimamizi wake kuhusu utafiti huu na pia kumpatia nafasi ya kuuliza maswali juu ya utafiti huu.

Nimemueleza ya kuwa:

1. Kushiriki kwake ni kwa hiari bila shurutisho lolote.
2. Kushiriki kwake hakutaleta madhara yeyote ya kiafya kwake.
3. Kujiondoa kwake katika utafiti huu hautahatarisha matibabu anayoyapata katika hospitali kuu ya KNH.
4. Habari zozote atakazopatiana hazitatangazwa hadharani bila ruhusa yake na pia ruhusa kutoka kwa mdhamini mkuu wa utafiti wa hospitali kuu ya KNH na chuo kikuu cha Nairobi.

Appendix 5: Assent form, English version

Study title: Adhesive post operative small bowel obstruction in adult patients as seen at the Kenyatta National Hospital.

Principal investigator: **Dr Otieno G. Nyakiti.**

University of Nairobi, department of general surgery,

P.O. Box 19676 KNH, Nairobi 00202.

Mobile phone: 0725108818

Research supervisors:

Prof. L.W. NDAGUATHA

MBChB (UON), MMed General Surgery (UON), FRCS (UROLOGY)

Consultant Urologist & Senior Lecturer,

Department of Surgery,

University of Nairobi.

P.O. Box 19676 KNH, Nairobi 00202

Dr. D. Kiptoon

MBChB (UON), MMed (UON)

Consultant General Surgeon and Lecturer,

Department of Surgery,

University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202.

Introduction

You are being asked to help us know better about the treatment we are giving you. If you want to know more about helping, you may ask me or my research assistant.

Purpose

Your small intestines have developed some fibrous bands that are blocking food/stool from passing on to the anus. This condition is a result of the previous disease and the surgery you had done on you. You will be managed by the doctors in the ward to which you will be admitted. The management may include pain killers, a tube through your nose to your stomach, fluids into your veins drugs, being kept from feeding through your mouth and even surgery. We want to study how the previous disease and surgery done to you is related to the disease and treatment you are having now.

You do not have to be in this study if you do not want to. If you decide to stop after we begin, that's okay too. Your participation in this study will not influence your treatment in the hospital. Your parents know about the study too.

What we need from you?

We will not be involved in your treatment but will only observe and describe it. We will write down your details like age, sex, previous operations and what was done in your previous admissions and what is being done now.

We will look at this information to see how they are related to each other as far as you are concerned.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

_____ _____
(Sign your name here) (Date)

Assent form, Swahili version

Kichwa cha Utafiti

Mtafiti mkuu: Dkt Otieno G. Nyakiti

Chuo Kikuu cha Nairobi, Kitivo cha upasuaji kwa,

S.L.P 19676 KNH, Nairobi 00202.

Simu ya rununu: 0725108818

Wahadhiri wasimamizi: Dkt. D. Kiptoon, Profesa L.W. Ndaguatha

S.L.P 19676 KNH, Nairobi 00202.

Simu: 0722702716

Utangulizi

Unaulizwa kutusaidia kufahamu zaidi kuhusu matibabu unayopewa kwasababu ya ugonjwa wa kufungana matumbo baada ya operesheni za hapo awali. Kama unataka kujua zaidi kuhusu utafiti huu, unaweza kuniuliza ama mtafiti msaidizi wangu.

Madhumuni

Matumbo yako hayawezi kupitisha chakula/choo kutoka mdomoni unapokula kuelekea sehemu ya kupitisha choo kubwa. Hii ni kwa sababu ya operesheni ulizofanyiwa hapo awali na ugonjwa uliosababisha operesheni hiyo.Utahitaji matibabu ya dawa za kupoza uchungu tumboni, maji kwenye mishipa, dawa za kumaliza maambukizi ya viini vya bacteria, kukaa bila kutia chakula kinywani na pengine hata operesheni nyingine.

Kujiunga na utafiti huu ni kwa hiari yako bila shurutisho lolote. Hata baada ya kuitikia na baadaye ubadilishe uamuzi wako, bado unaruhusiwa na haitahatarisha matibabu utakayopewa katika hospitali hii.Wazazi wako wanajua na wamearifiwa kuhusu utafiti pia.

Ni nini utafanyiwa?

Tutaandika herufi za kukutambua yaani kodi na dalili za ugonjwa zilizokuleta hospitali. Pia matibabu na operesheni ulizofanyiwa hapo mbeleni na ugonjwa amao ulikuwa chanzo cha operesheni hiyo. Pia tutarekodi matibabu yote utakayopokea safari hii lakini watakaokutibu ni madaktari wa wadi utakayokuwa bali siyo mimi binafsi wala mtafiti msaidizi.

Lengo letu ni kutambua jinsi mambo yote haya yanavyohusiana na ugonjwa huu au hata ule wa mbeleni.

Tukimaliza utafiti huu tutaandika ripoti kuhusu matokeo yetu. Ripoti hii haitakuwa na jina lako wala kusema ulishiriki kwa utafiti.

Kama umeamua unataka kuwa katika utafiti huu kwa hiari, tafadhali andika jina na kisha uweke ishara sahihi yako hapa.

Mimi, _____, nimekubali kuwa katika utafiti huu.

_____ _____
(Sahihi) (Tarehe)