INCIDENCE AND RISK FACTORS OF POST-OPERATIVE ILEUS IN ADULT PATIENTS AT KENYATTA NATIONAL HOSPITAL

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2020

STUDENT’S DECLARATION

I declare that this proposal for a dissertation is my original work and has not been presented for a degree in any other university.

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SUPERVISORS' APPROVAL

This proposal for a dissertation has been submitted for examination with my approval as a university supervisor.

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List of Abbreviations

COX2	CycloOxygenase-2
ENS	Enteric nervous system
IL	Interleukin
iNOS mRNA	inducible nitric oxide synthetase
KNH	Kenyatta National Hospital
MMC	Migrating motor complex
NO	Nitric monoxide
POI	Post-operative ileus
ROT	Return of transit
T1H	T1 Helper lymphocytes
TPN	Total parenteral nutrition
UON	University of Nairobi

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I also acknowledge the Kenyatta National Hospital management having allowed me conduct my study at this great teaching facility.

Shout out to the online teachers and content creators on research and statistical methods. You are the real ‘Most Valuable Players’!

Dedication

I dedicate this to my parents who have ensured that I got a proper education and sober upbringing. My sibling, Eric, for challenging me through research and giving a hand when the going got tough. To Jemimah for always ensuring my head was in the right place.

I thank you all!

Abstract

Background

Ileus is a state of hypomotility of the intestines that impairs propulsion of intestinal contents when there is lack of mechanical obstruction. It leads to intestinal contents (i.e. gas and fluids) building up within the bowel.

Postoperative ileus (POI) is an often anticipated state of transient bowel hypomotility after abdominal surgery. Perioperative circumstances may change the intestinal equilibrium leading into disorganized electrical activity and paralysis of intestinal segments. This state is self-limiting with recovery of regular bowel motor function within 3-5 days after surgery.

In some incidences this recovery of bowel function may extend beyond the anticipated duration causing considerable frustration for patients and their caregivers. These frustrations arise from adverse clinical sequelae such as nosocomial infections, pulmonary complications and escalation of medical bills.

Previously, variations amongst clinicians around the world were a big challenge for validation of prior studies. This has recently been addressed in research developing standardised terms to evaluate this clinical entity. Locally there had been no reports on the incidence of POI nor its risk factors. This study aimed to fill this gap and in doing so stimulate better practice within our setup and thus improve our patient outcomes.

Objectives

The main objective of the study was to determine the incidence and risk factors of postoperative ileus amongst adult patients undergoing abdominal surgery at the Kenyatta National Hospital (KNH).

Study Design

This was a cross-sectional study conducted at the Kenyatta National Hospital.

Methodology

Participants were recruited in the post-operative period after undergoing abdominal surgeries in the surgical units at KNH by convenient sampling. This was carried out from December 2019 to May 2020. A structured data collection sheet was utilised for data collection. Data was derived from both the patient and their medical records in the file. This data was then used to determine patients who develop POI based on defined clinical endpoints and thereafter a determination of the risk factors for POI in those patients who fulfilled the clinical criteria.

Data Management

The data was analysed using the Statistical Package for the Social Sciences (SPSS) version 26 and analyzed for proportion and associations and the results presented in form of means, median or standard deviation for continuous variables. Categorical data was presented as frequencies and percentages with the use of graphs and pie charts where applicable. Chi-square test was used to test bivariate relationships.

Results

A total of 243 patients undergoing abdominal surgery were recruited. The mean age of the study population was 38.7 years. 67.8% were female and 32.2% male. The study population underwent various elective and emergency abdominal procedures of general surgical, obstetric and gynaecological indications. The incidence of postoperative ileus in adult patients undergoing abdominal surgery at KNH was 10.7%. There were positive associations of POI occurrence with several risk factors such as history of prior abdominal surgery, abdominal soiling, intestinal surgery and high grade complications. Of the risk factors evaluated, the most significant identified was high grade complications with a Clavien Dindo score ≥ 2 with an odds risk ratio 28.8 (1.6 – 518.1) at 95% CI (p=0.001)

Conclusions

The incidence of POI within our setup as described in this study is 10.7%. The most significant risk associated with POI was high grade complications as per the Clavien Dindo scale.

We need to place an emphasis on our principles of surgery to minimise our postoperative complications and thus reduce the risk of POI in those patients who develop postoperative complications. Possibly future studies inclusive of broader risk factors could enable us derive a predictive index for POI within our setup so we may anticipate and better manage the patient.

Chapter 1: Introduction

Postoperative ileus (POI) is a widespread complication after abdominal surgery despite advances in patient care around the world and can be quite exasperating to the patient and the surgical team in the early period after abdominal surgery. It causes the patient great unease through nausea and abdominal distension and further apprehension due to the unpredictability of its duration as well as the consequential nosocomial infections and prolonged hospital stay and treatment costs.

Some studies have been conducted on the incidence of postoperative ileus as well as others looking into various risk factors. Most of these studies have been based on abdominal, colorectal and even urological surgeries. These have utilised various clinical manifestations with significant variations in the definitions and clinical endpoints for POI hence hindering the validation of their results.

To surmount that, a consensus update released in 2006, defined POI as 'the period from surgical until passage of flatus or stool and until initiation of enough oral intake tolerated and maintains hydration throughout 24 h' (1). Through further review by various interest groups following the above consensus update, the development of standardized definitions of POI allows for a more uniform description of this clinical entity for reporting on its incidence. (2) An acceptable working definition of POI is "the time from surgery until the passage of flatus or stool while tolerating oral feeds, if appropriate." The modifier "if appropriate" is requisite for patients who may not be given oral feeds due to the type of procedure undertaken or those prescribed total parenteral nutrition (TPN). Elsewhere "tolerance of feeds" is construed as "tolerance of part or all of 3 successive meals without nausea or vomiting suggestive of POI." Some risk factors for POI have been repeatedly delineated, such as biologic characteristics of the patient, comorbidities; surgical factors and pharmacologic agents prescribed.

There are no local studies on the incidence or risk factors for POI within our setup. With no tangible convenience of POI, it would of interest to know the occurrence and the risk factors for POI in our setup. This study sought to fill this gap and in doing so stimulate better practice to improve postoperative outcomes for our patients.

Chapter 2: Literature Review

2.1 Definitions

There was previously a non-existent, universally validated clinical definition for POI. There was lack of congruence in the descriptive terms used for POI undermining the consistent estimation of its incidence and identification of the risk factors.

A systematic review by Vather et al sought to resolve this by reviewing the terminology in various randomised trials scrutinizing POI after abdominal surgeries between 1996 and 2011. Their review of some 52 identified trials was capped by a global survey inviting input form authors who have published in the same field. (2)

Through amalgamation of the data they define POI as "Period from surgical intervention up to movement of flatus or stool while tolerating oral feeds, with these occurrences before the fourth postoperative day".

They also defined Prolonged POI as featuring two or more of nausea or vomiting, intolerance of oral feeds over twenty four hours, no flatus over twenty-four hours, distended abdomen, radiological corroboration on or after the fourth postoperative day without prior resolution of POI"; Congruence of this terminology with the global survey was 80%, with majority of invited authors acknowledging two or more of the criteria as essential.

2.2 Incidence

The current literature on incidence of POI arises mainly from studies on colorectal and urological procedures. A study by Venara et al found variations between authors and sub specialities but stated that the incidence of POI is between 10 and 30% for abdominal surgeries. (3)

2.3 Risk Factors

The literature identifies a variety of predisposing factors whose validation is undermined by the prior variable definitions of interval to return of transit (ROT) used for data analysis in the various studies in the past.

Despite this challenge authors have severally identified advanced age, male gender, and loss of blood significantly as predisposing factors. One such paper by Kronberg et al. analysed the prognosticative appraisal of age ≥60 years, previous abdominal surgery and preoperative narcotic use. Their observation was that up to 18.3% of their study population having two or three risk factors developed POI, compared to only 2.7% of those who did not have any risk factors. (4)

Surgical approach also counts towards time to ROT, with a longer shorter duration for laparoscopic as compared to laparotomy approach. It is hypothesised that this is due to the reduced tissue trauma in laparoscopic surgery relative to open approaches. Murine studies have reached similar conclusions after laparoscopic versus open colonic resection. To possibly explain this, Leung et al studied the levels of inflammatory markers comparing surgical approaches. They observed significantly lower expression of cytokines and C-Reactive protein for minimally invasive approaches relative to open colonic resection. (5) (6).
The site of surgery also factors i.e. intestinal surgery versus non-intestinal surgery. One study demonstrated a higher incidence of 10-30% for colorectal procedures versus non-intestinal surgery e.g. pancreatic and gastric operations at 8-13%. (3)
Other factors have been classified as secondary POI such as the occurrence high grade complications e.g. anastomotic leaks, fistulas and intra-abdominal infections.
Morphine has particularly been evaluated for association with incidence of POI with findings of a predisposition to POI with perioperative opioid use. Evidence strongly suggests that its inhibitory effect on bowel motility is dose dependent.(7)

Other factors anecdotally captured are emergency surgery, length of abdominal incision and prior open abdominal surgery.

2.4 Pathogenesis

While the exact mechanism of POI is unknown, it is believed to arise due to multiple factors. These beliefs arise from studies on animal models which are distantly relatable to human beings. (3)

POI mechanism unfolds in three progressive steps

- **a)** Neurological processes (via the sympathetic nervous system)
- **b)** Hormonal and inflammatory mechanisms.
- **c)** Parasympathetic nervous activation (anti-inflammatory role for resolution of ileus).

2.4.1 Neurological Phase

Mediated via sympathetic nervous apparatus which signal distally to the enteric nervous system (ENS). Animal studies show that the surgical incision as well induction of anaesthesia can prompt stimulation of presynaptic noradrenergic B receptors. Nevertheless, it appears that intestinal handling does not activate this pathway

Found within the inflamed muscularis mucosae are Alpha-2 adrenergic receptors which are theorised to augment production of messenger RNA of the inducible nitric oxide synthetase (iNOS mRNA) which releases nitrogen monoxide (NO). NO then activates CycloOxygenase-2 (COX2).

A study by Zhang et al demonstrated the relation of enhanced COX2 activity and haemorrhagic shock in induction of intestinal dysmotility. (8)

2.4.2 Inflammatory Phase and Intestinal Manipulation

Intestinal manipulation causes an inflammatory reaction in the third hour of a laparotomy in the next stage. Inflammatory cells are increased in the intestinal wall and these secrete pro-inflammatory molecules. This response does not arise with laparoscopic procedures possibly accounting for the relatively reduced incidence of POI compared to open procedures (9).
Handling of bowel stimulates interleukin 12 (IL) from dendritic cells which then stimulates T1 helper lymphocytes (T1H) to traverse to distant non-manipulated areas where they effect inflammation via the secretion of alpha interferon (IFN alpha) which also recruits macrophages. This "field effect" can account for the phenomenon of a drain say in the pouch of Douglas causing local inflammation can prolong POI in the rest of the digestive tract.
The inflammatory process is further propagated by the translocation of bacteria across the increasingly permeable epithelial barrier of the intestines.
Also, activation of calcium channels in conjunction with in potassium concentration may contribute to POI. This can explain the role of fluid over-resuscitation and the benefits of minimising the volumes of crystalloid in resuscitation to maintain "natural homeostasis".

2.4.3 Phase of Resolution of Ileus and Vagal Activation

In this phase the inflammatory process diminishes as vagal tone increases. Increase in vagal tone is via nicotinic alpha 7 acetylcholine receptors (alpha7-nAChR) and 5-hydroxytryptamine 4 receptors (5-HT4R). The latter's activation increases acetylcholine release by myenteric cholinergic neurons, thus allowing activation of alpha7-nAChR on monocytes and macrophages and which lessens the inflammatory reaction.
Chewing gum and early mobilisation have proven beneficial in reducing POI by their stimulation of the vagal tone for this anti-inflammatory phenomenon. (10)

2.5 Return of Transit

Enteric nervous system controls motility patterns of the bowel under intrinsic control; a move that is extrinsically influenced by the autonomic nervous system that may increase or decrease the basic intestinal motility patterns. If left untreated, POI can persist up to 4-5 days after major abdominal surgical procedures before resolution to allow the patient pass flatus and tolerate oral feeds.

A physiologic study conducted by Livingstone found that the various anatomical bowel sections have different transit responses to ileus. The fastest was the small bowel recovering its peristaltic motions within twenty-four hours; the stomach at 24–48 hours; lastly the large intestines needing up to 120 hours for normal motility. (11)

Under normal physiological conditions, the myoelectric circuitry of the intestines controls distinct patterns of contractions in the presence or absence of luminal contents. In a state of fasting, these migrating motor complexes (MMC) commence in the stomach then progress to the distal small bowel in some two hours. Another MMC is initiated at the stomach just as the previous one diminishes.

These MMC demonstrate three phases: firstly a period of inertia usually 30-60 minutes; the second a gradual increase of contractions over some 60 minutes; lastly intestinal contractions at their maximal rate for some 10 minutes. A meal changes this predictable MMC replacing it with random contractions

In the colon, no MMCs are observed in starvation. The ascending colon demonstrates retrograde contractions that enhance water re-absorption while the descending colon has ante-grade movements for propagation of stool. The colonic movements are increased by food producing propulsive movements over long segments i.e. mass movements. (12)

As important as the return of intestinal electrical activity is that the activity is coordinated to allow it function normally. Even in the small bowel, recent findings show that despite an

earlier return of contractile activity, the coordination and motility are abnormal for several days. As example, decreased jejunal activity for up to 3 days is commonly demonstrated after open colectomy. (13)

Likewise, following trans-peritoneal aortic surgery, there are abnormal MMCs for some 3 days.

2.6 Clinical Endpoints

Van Bree *et al*. tasked themselves with establishing reliable endpoints for clinical use in determining POI. They paralleled colon transit time with various clinical endpoints in their study. (14). Their results showed the highest correlation in the point to tolerance of feeds and passing of stools (area under curve=0.9). On retrospective analysis of their database using this endpoint, they found it capable of capturing a previous recovery of bowel function in comparison of laparoscopic and open surgery which was previously no discernible by conventional endpoints.

Van Bree also demonstrated presence of bowel sounds in six out of seven patients with ileus during the first three days after surgery thus discrediting the previous clinical adage that return of bowel sounds was adequate as a clinical endpoint.

In addition, Waldhausen *et al*. showed that return of functional colonic electrical response motions took 5.9 days on average after open surgical procedures. On correlation, Waldhausen showed that this was much prolonged than the return of bowel sounds at average 2.4 days yet parallel to the average time to passage of flatus and stool. (15). Postoperative gastrointestinal symptoms such as abdominal distension, vomiting, nausea were found to be inadequate to inform on differential diagnosis. Laboratory studies as well were limited to investigation for metabolic or infectious anomalies.

2.7 Impact of Post-Operative Ileus

POI causes unwelcome patient discomfort and lengthened hospital stays. More fearful consequences are intestinal perforation, malnutrition, nosocomial infections. Extension of hospital stay increases exposure to nosocomial infections with can further raise treatment costs as demonstrated in various studies. (16) In the United States one study demonstrated an increased length of hospital admission by some 4.8 to 5.7 days when compared to similar patients without ileus; and in increase in personal healthcare costs up to $4000 (United States Dollars) for those who developed POI. (7).

Chapter 3: Methodology

3.1 Research Questions

i. What is the incidence and risk factors of Postoperative ileus (POI) in adult patients undergoing abdominal surgery in KNH?

ii. What are the risk factors of Postoperative ileus (POI) in adult patients undergoing abdominal surgery in KNH?

3.2 Objectives

3.2.1 Main Objectives

- To determine the incidence of post-operative ileus in adults undergoing abdominal surgery at KNH
- To determine the risk factors for post-operative ileus in patients undergoing abdominal surgeries at KNH

3.2.2 Specific objectives

- To identify patients with symptoms of POI
- To determine the time from surgery to passing flatus/stool while tolerating oral feeds
- To determine the relationship of POI and various risk factors in those patients identified to have POI.

3.3 Materials and Methods

3.3.1 Study Design

This was a cross-sectional study.

3.3.2 Study Setting

The study was carried out at the Kenyatta National Hospital which is Kenya's National Teaching and Referral Hospital with an inpatient bed capacity of up to 2000 beds. The hospital is the largest training facility in the East African region with more than 500 annual abdominal surgeries performed in the general surgical units alone.

The study took place in the surgical wards through which more than 500 abdominal surgeries are performed each year.

3.3.3 Patient selection

All patients who underwent abdominal surgery between December 2019 and May 2020 and fulfilled the inclusion criteria were enrolled in the study.

3.3.4 Inclusion Criteria

- Patients undergoing abdominal surgery within the general surgical, orthopaedic, cardiothoracic, obstetrics and gynaecology and ENT wards were recruited.
- Those who were 13 years of age and above were included.
- Elective and emergency abdominal surgical cases
- Open and laparoscopic abdominal surgery patients.

3.3.5 Exclusion Criteria

- Patients who declined participation in the study.
- Patients who were offered an oral diet where appropriate owing to the type of surgery they undergo i.e. those offered total parenteral nutrition.

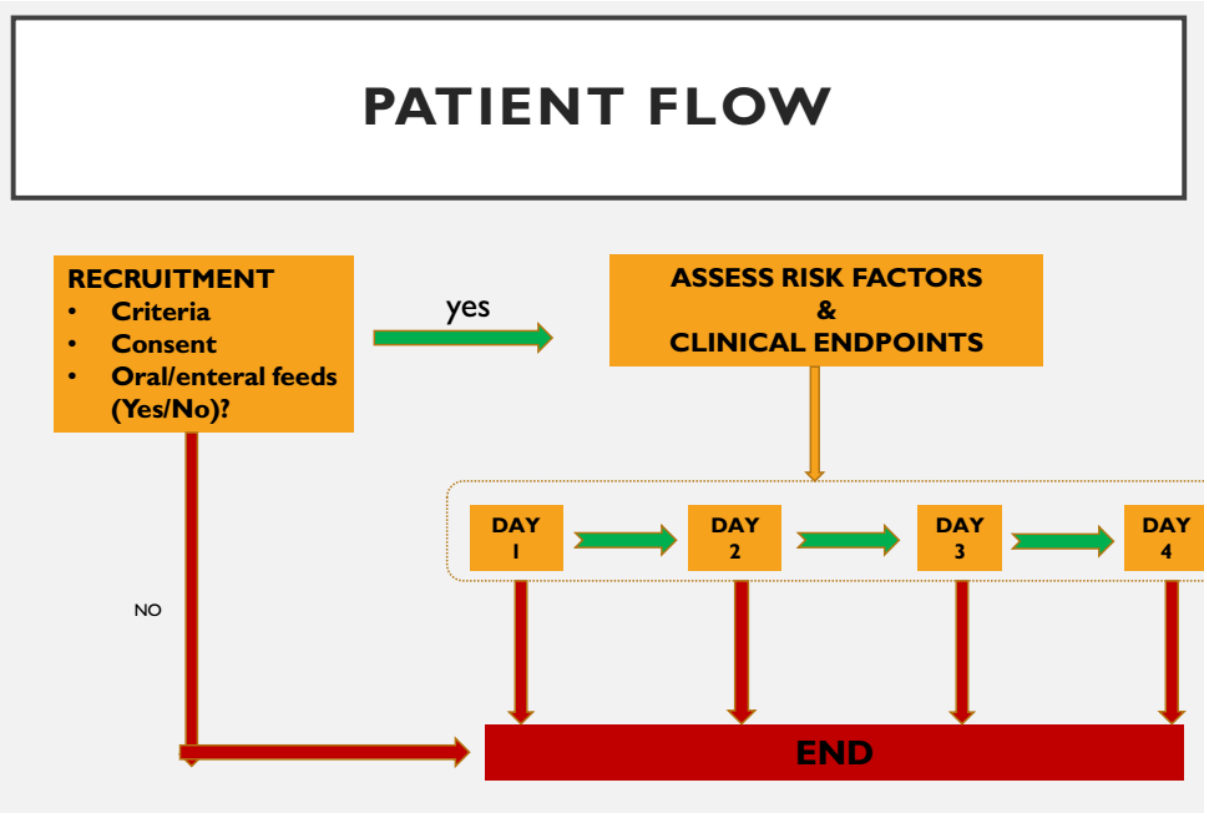
- Patients nil per oral due to planned re-entry into the abdomen
- Patients with ileus occurring preoperatively as evidenced by electrolyte derangements plus absence of bowel sounds.

3.3.6 Method

Convenience sampling was used to recruit patients in the postoperative period. Patients meeting the criteria were recruited. Recruitment was verbal, and participants were informed of the nature and purpose of the study. Those patients who agreed to take part in the study had written informed permission obtained and then were subsequently enrolled in the study. A structured data sheet was used to capture the details broadly described as “Biodata, Risk factors and Clinical endpoints.

The patients were then evaluated daily for the clinical endpoints and until exiting the research upon demonstrating tolerance of feeds as determined by the outlined clinical endpoints in the literature.

Figure 1: Patient flow diagram



3.4 Sample Size Calculation

Fischer's formula was used to calculate our sample size;

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (taken as 20% which is the mean of the incidence reported in the literature as ranging between 10%-30% in other studies)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.20(1-0.20)}{0.05^2} = 245$$

3.5 Data Management

3.5.1 Data Collection

The data collected included:

- Biodata i.e. Patient reference number, age, gender
- Risk factors
    - Nature of surgery i.e. Elective or Emergency; Intestinal or Non-intestinal
    - History of perioperative narcotic use
    - Presence of abdominal soiling
    - Presence of hemodynamic instability necessitating fluid resuscitation and/ or blood transfusion

    - High grade complications
- Assessment of clinical endpoints
    - Time of surgery
    - Time of tolerating meal and passing flatus

3.5.2 Data Handling

Data was collected by principle researcher using a data collection sheet (Appendix I: Data collection sheet). These data collection sheets were kept is a secure locker accessible solely to the principal investigator. The data was then entered into the Statistical Package for Social Sciences (SPSS) version 26 on a secure, password protected computer accessible solely to the principal researcher. SPSS was used to analyse data; mean, median and standard deviation were be used for data description. Correlation of risk factors and POI was analysed and presented as frequencies and proportions.

3.6 Ethical Considerations

The study was commenced in December 2019 upon authorization by the Department of Surgery (UON) and KNH Ethics and Research Committee (Ref: KNH-ERC/A/456).

Considerations to maintain ethical integrity included:

- A pre-consent counselling of all patients prior to obtaining of a written consent.
- Patients allowed free will to accept or decline participation. It was further explained to the patient population that those who declined involvement would not be denied treatment they deserve due to their choice not to participate. That there would be no extra cost incurred for participating in the study.
- Patients reassured that all personal information would be protected by the principal investigator solely, that confidentiality and privacy would be observed and the data sheets destroyed on completion of the study.

3.7 Study Limitations

The study relied heavily on pre-recorded information within the participant files. The major limitation was that some participants' files were either missing from the filing area leading to difficulties in obtaining all the necessary information.

As pertains to surgical approach, there no similar surgeries performed to allow for comparison of say a particular surgery performed either laparoscopically or via open approach.

More time would have allowed for inclusion of a multitude of other risk factors for their analysis.

Chapter 4: Results

4.1. Participant selection

A total of 255 participants were initially recruited by convenient sampling. Out of these 243 were selected having met the inclusion criteria. Reasons for exclusion of the others were patients in Intensive Care Unit admission who were not able to sign consent as well as subjects <18 years who did not have a present guardian to consent to their inclusion at the time of data collection.

4.2. Characteristics of patients undergoing abdominal surgery

4.2.1. Age characteristics

The mean age of the study population was 38.7 years. The youngest subject being 16 years, while the eldest was 71 years. 74.1% of patients were aged < 50 years, the remaining 24.9% aged > 50 years. (Fig1 &2)

Figure 2: Pie chart showing distribution per age grouping

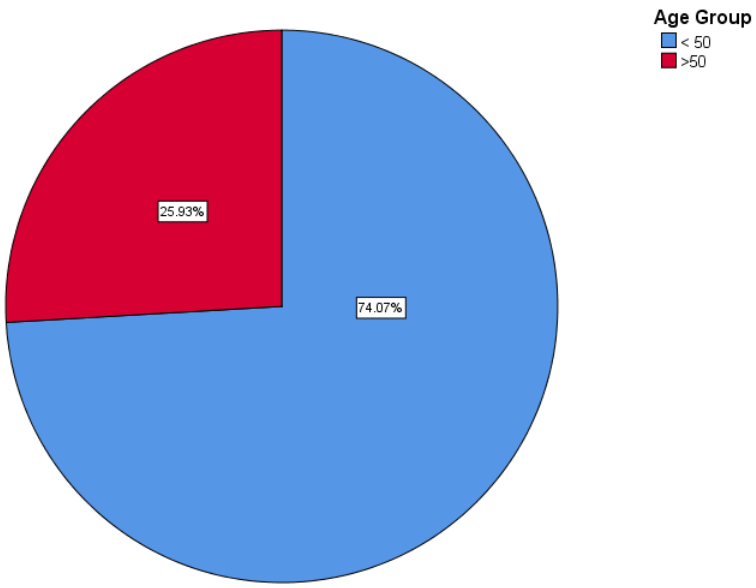
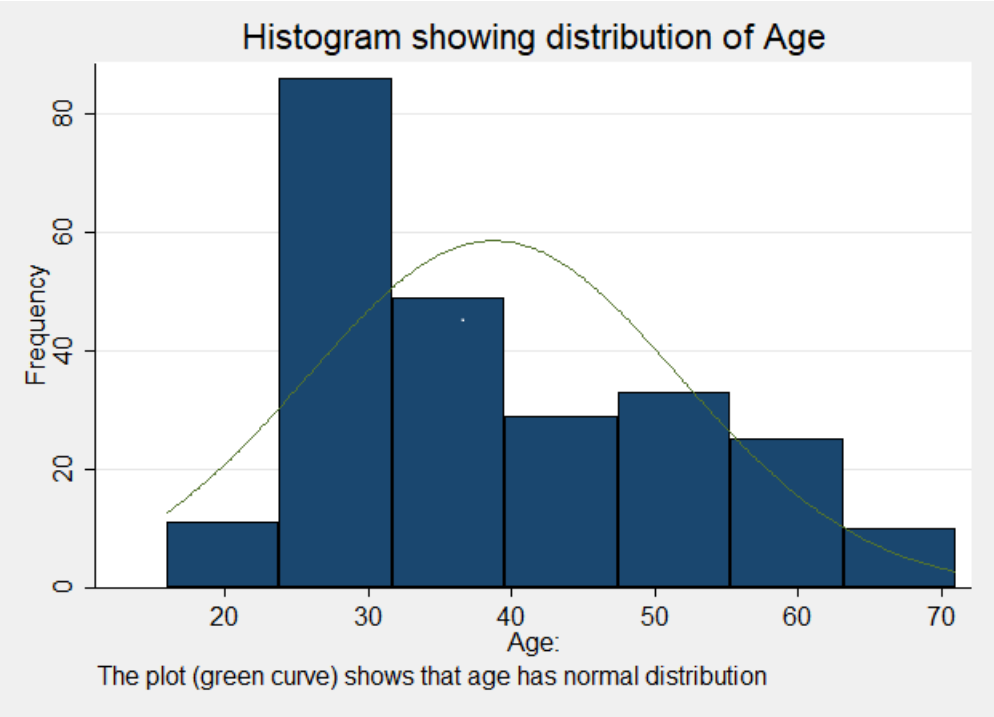


Figure 3: Histogram showing age distribution

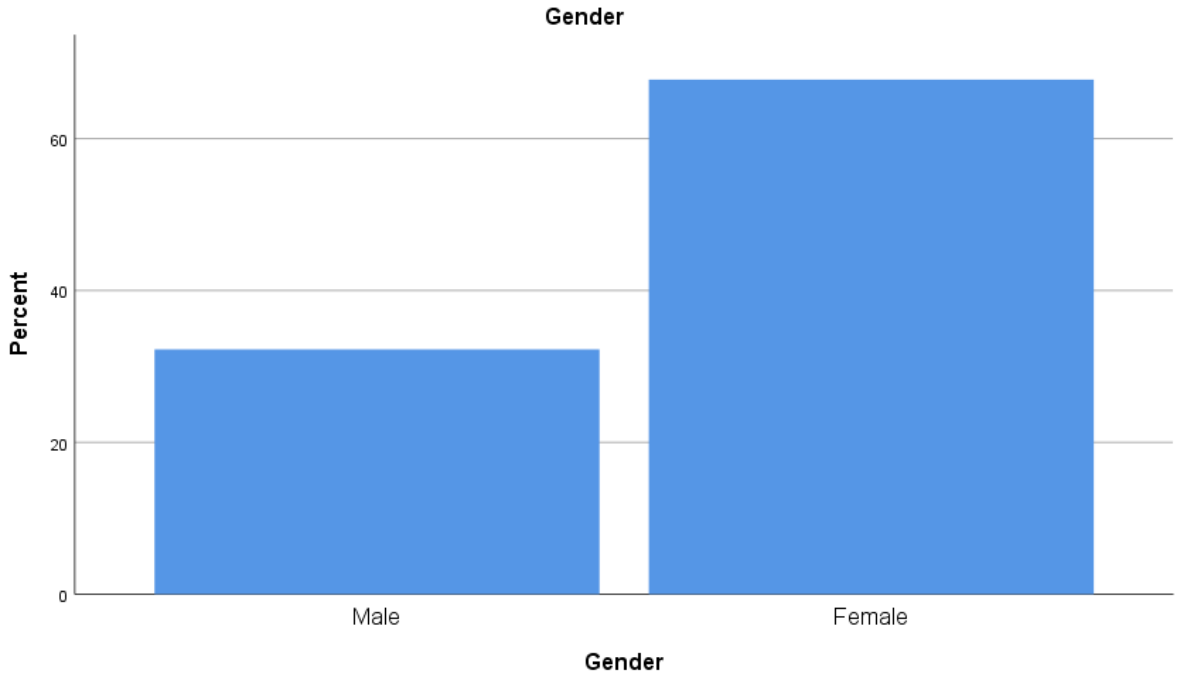
Figure 4: Histogram showing age distribution



4.2.2. Sex characteristics

There was a female preponderance with 165 out of 243 (67.8%) patients being female versus the remaining 78 patients (32.2%) being male.

Figure 5: Bar graph showing gender distributions

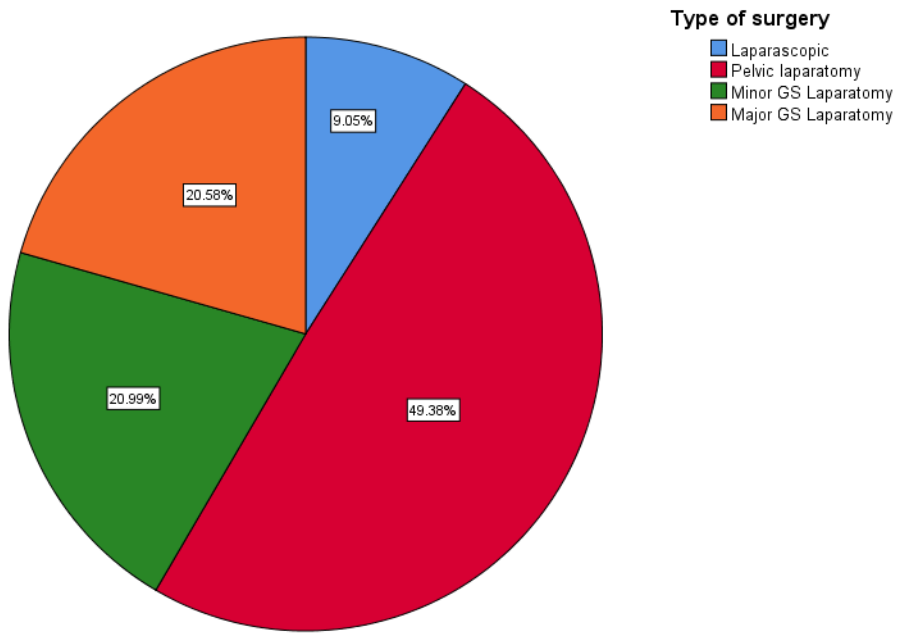


4.2.3. Types of abdominal surgeries

As already stated, the patients undergoing abdominal surgery were recruited from a variety of surgical specialities. For ease of discussion these were grouped into:

- Laparoscopic abdominal surgery
- Laparotomy for pelvic surgery i.e. those undergoing open abdominal surgery for caesarean sections, myomectomy, hysterectomy, ectopic pregnancy and pelvic abscess.
- Laparotomy for Minor General Surgery i.e. open surgery for minor procedures such as epigastric hernia repair, surgical gastrostomy insertion, uncomplicated appendicitis via lanz or gridiron incisions.
- Laparotomy for major General Surgery i.e. open surgery via formal extended midline incisions for intestinal obstruction, blunt and penetrating abdominal trauma, peritonitis, complicated appendicitis, gastrectomy, whipple's procedure, oesophagectomy, liver resection, enteric bypass, stoma reversal, perforated peptic ulcer disease.

Figure 6: Pie chart showing distribution of types of surgery



4.2.4. Time to return of transit

The mean time to return of transit was 46.97 hours for this study population. The shortest time noted for return of transit was 24 hours while the longest duration was 110 hours. 89.3% demonstrated a return of transit in <72 hours while some 10.7% had a time to return of transit > 72 hours.

This is further explored in comparison for surgical approach.

4.2.5 Summary of patient characteristics

Characteristics	Frequency	Descriptive statistic
Age <50 >50	 74.1 % 25.9 %	Mean = 38.7 years, Youngest: 16 years, Eldest: 71 years
Sex Male Female	 32.2 % 67.8 %	Male: Female ratio 1 : 2.1
Type of surgery Laparoscopic Open Major Pelvic surgery Open Minor General Surgery Open Major General Surgery	 9.1 % 49.4 % 21.0 % 20.6%	
Time to return of transit < 72 hours > 72 hours	 89.3 % 10.7 %	Mean = 46.97 hours Shortest : 24 hours Longest 110 hours

4.3. Analysis of demographic characteristics and occurrence of POI

Analysis was run to determine any associations between our demographic characteristics and the occurrence of POI.

4.3.1 Age and occurrence of POI

For bivariate analysis the patients were grouped into two groups to enable determination of age association with the outcome of POI. The basis of the grouping was a cut-off age of 50 years:

- Patients aged < 50 years
- Patients aged > 51 years.

The data suggests that age does not influence the outcome of POI (p=0.308).

4.3.2. Sex and occurrence of POI

For this a comparison of male and female sex was straightforward.

On bivariate analysis, our results suggest that gender does not influence outcome of POI (p=0.825).

4.3.3 Type of surgery and POI

Table 2: Table showing summary of analysis for type of surgery

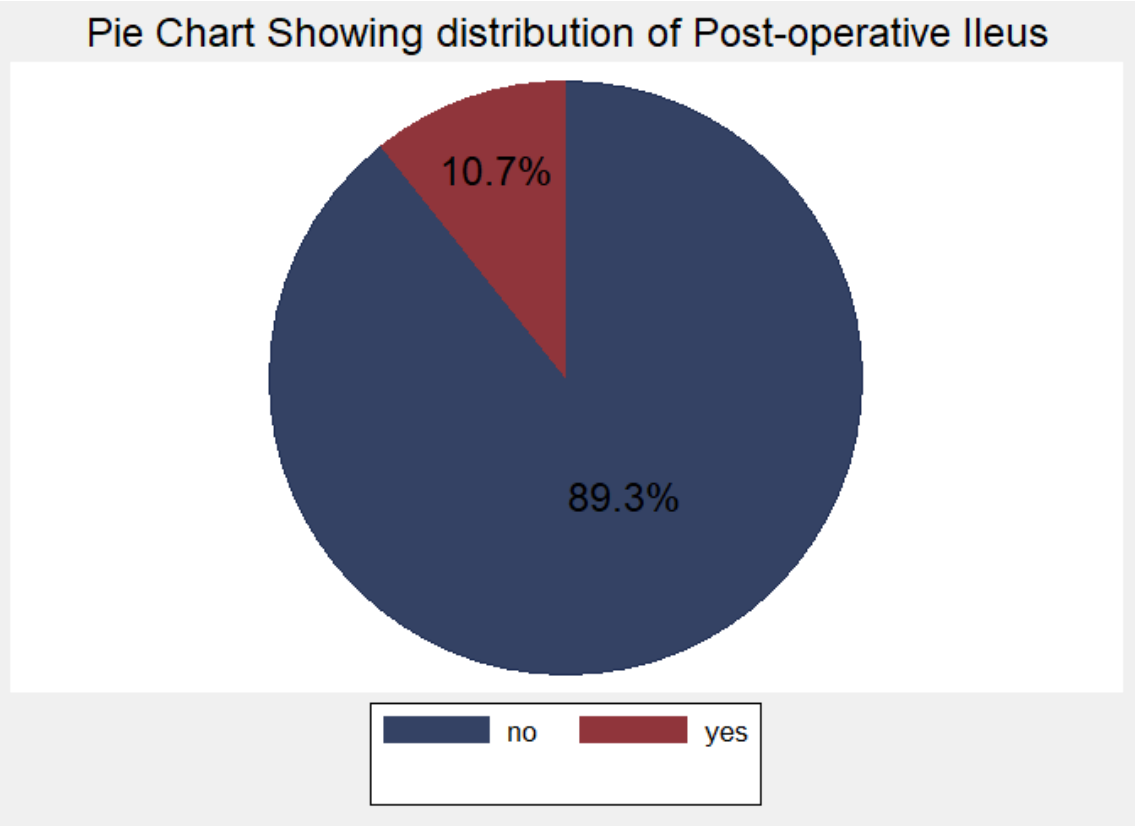
Type of surgery	**P value**
Laparoscopic	0.288
Minor General surgery laparotomy	0.173
Major General surgery laparotomy	0.000
Major Pelvic surgery	0.015

The analysis does suggest some significance in the undergoing major general and major pelvic surgery with occurrence of POI.

4.4. Incidence of POI

The proportion of study participants who developed POI was 10.7%.

Figure 7: Pie chart showing distribution of POI



4.5. Correlation of risk factors and POI

Bivariate analysis was carried out to see whether patient exposure variables would influence the occurrence of POI.

Our interest value is the Pearson's Chi square and Fishers exact if some cells in a table have a value of 5 and below.

4.5.1. Surgical approach and POI

A total of 221 subjects underwent open abdominal surgery while 21 underwent laparoscopic abdominal surgery.

Patients undergoing laparoscopic approach generally demonstrated earlier time to return of transit compared to those undergoing open approach. The mean time to return of transit by open group was 48.27 hrs while for laparoscopic group was 33.91 hrs.

From 221 subjects who underwent open abdominal surgery 25(2.2%) developed POI as compared to 1 out of 21(4.8%) that underwent laparoscopic abdominal surgery.

Comparison of outcomes as pertains to open abdominal surgery versus laparoscopic surgery suggest no positive correlation between choice of one approach over the other in terms of outcome of POI ($p=0.484$).

4.5.2. Clavien Dindo Score and POI

Each subject was assigned a Clavien Dindo score based on postoperative complications encountered. 97% were assigned a score of 1, while 1.6% and 0.8% a score of 2 and 3 respectively.

Bivariate analysis was then performed to determine for an association between score and the development of POI. Towards this goal the patients were divided into two groups:

- Patients with a score ≤ 1 taken as low grade complications
- Patients with a score ≥ 2 taken as high grade complications

The analysis suggest a positive association between a Clavien Dindo score ≥ 2 and the development of POI.

4.5.3. Comparing Intestinal Versus Non-Intestinal Surgery

Patients who underwent abdominal surgery either had intestinal or non-intestinal indications for the surgery. As such is prudent to evaluate and compare the two for associations with POI.

8 (5.3%) out of 150 patients who non-intestinal surgery developed POI while 18 (19.4%) out of 93 who had intestinal surgery did develop POI.

Bivariate analysis suggest a positive association between a patient having intestinal surgery and occurrence of POI (p=0.001).

4.5.4. Contamination of Abdomen and POI

Evaluation of the association of abdominal contamination and POI was done. Contamination was defined as findings of gross perioperative abdominal soiling, intraabdominal purulence or gangrenous viscera.

207 patients did not have gross contamination of their abdomen and of these 15(7.2%) developed POI. For the 36 subjects who had documented contamination of the abdomen, 11(30.5%) developed POI.

From bivariate analysis there is a suggested positive association between soiling of the abdomen and the occurrence of POI (p=0.00).

4.5.5. Urgency of Surgery and POI

Urgency of surgery was assigned to either elective or emergency surgery. 99(40.3%) out of 243 subjects underwent elective surgery with the remaining 141(58%) undergoing emergency surgery.

9 (9%) of those who had elective surgery developed POI, compared to 17 (12%) of those whose surgeries were emergent.

Bivariate analysis was then performed to determine any association with the occurrence of POI.

Analysis suggest no positive association between the urgency of surgery and the occurrence of POI ($p=0.667$).

4.5.6. Hemodynamic Instability and POI

34 of our study subjects were documented to have fulfilled criteria for hemodynamic instability, defined as hemodynamic instability requiring transfusion of blood or fluid resuscitation to restore hemodynamic parameters.

7(25.9%) out of 27 who met the criteria developed POI, while 19(9%) out 209 that did not have hemodynamic issues developed POI.

On bivariate analysis there was no suggested positive association between hemodynamic instability and the occurrence of POI (p=0.67).

4.5.7. Use of Narcotics and POI

Subjects in the study may or may not have been prescribed narcotics in the perioperative period following abdominal surgery.

79 patients (32.5%) were not prescribed perioperative narcotics, while 164 patients (67.4%) had narcotics prescribed.

Of the 79 who had prescribed narcotics, 11 (13.9%) developed POI while 15 (9.1%) of those who did not receive perioperative narcotics did develop POI.

Bivariate analysis finds no positive association between the perioperative use of narcotics and occurrence of POI (p=0.273).

4.5.8. Summary of bivariate analysis

In summary the following factors were positively associated with post-operative ileus (P value of less than 0.05). Note we are referring to the Pearson chi square.

Table 4: Summary of bivariate analysis p values

Characteristic	**P value**
History of prior surgery	0.001
Contamination level	0.000
Intestinal vs non-intestinal	0.001
Clavien Dindo score of 2 and above	0.001
Hemodynamic instability	0.044

4.5. Multivariate Model Using Logistic Regression with Corresponding Odds Ratios for Values that are Significant in the Bivariate Analysis

This is the logistic model for the factors that were significantly associated with falls in the bivariate analysis.

Table 5: Summary of Odds ratios for positively associated risk factors

Characteristic	**Odds Ratios with 95% CI**
Prior surgery	0.4 (0.2 – 0.8)
Hemodynamic instability	0.2 (0.1 – 0.7)
Clavien Dindo score	28.8 (1.6 – 518.1)
Intestinal vs non-intestinal	0.2 (0.1 – 0.4)

From this data, for the variables of Prior surgery, hemodynamic instability and intestinal/non-intestinal surgery, the direction of association is negative i.e. Having not had prior surgery, having hemodynamic stability and having had a non-intestinal surgery were protective of not getting ileus since their odds ratios and corresponding limits of CI were less than 1.

While a Clavien Dindo score of 2 and above were risk of having post op ileus because the odds ratio have CI limits greater than one.

Chapter 5: Discussion

Post-operative ileus (POI) is a common perioperative event of considerable nuisance to both the patient and the caregiver and thus stimulating various researchers to attempt to device tactics in which to reduce the occurrence of this event. In order to do so we must know our incidence of POI in our setup as well as understand our risk factors.

The mean age was 38.7 years. The subjects were grouped into two groups based on a cut-off age of 50 years and for comparison. In our setup there was no observed positive association for age and the occurrence of POI (p=0.228). In one study conducted by Svatek et al a group of patients were followed up post radical cystectomy for occurrence of POI. On multivariate analysis adjusted for the influence of competing variables, increasing age were significantly associated with the presence of POI (hazard ratio 1.09, 95% confidence interval 1.02-1.16, P = .008). (17) Of consideration is that in their study most of the patients were older since the indications for radical cystectomy were malignancy for which the occurrence increases with age hence an older population in their study. Also, their cases could be considered major pelvic surgery whereas in our setup the study population did include a mixture of major and minor general surgical procedures. For comparison, our study did find some association between major pelvic surgery and occurrence of POI.

There were 78 Males (33.1%) 165 Females (67.9%) in this study population. There was no observed association of gender with occurrence of POI (p=0.825). In a study by Chapuis et al regarding risk factors for POI after resection of colon cancer they observed a statistically significant risk of male gender for ileus (OR: 1.7, P < 0.001). (18) This is the only such finding in the literature. Possibly male patients were at risk in their study due to their higher predisposition to colon cancer due to lifestyle of habitual smoking which is not as common in women.

In this study, as regards the occurrence of POI amongst adult patients undergoing abdominal surgeries at KNH, the proportion was 10.7% of those patients who fulfilled the inclusion criteria. The present study considers POI after abdominal surgery only where there are variations in the published references although our figure falls within the range in these references. Venara et al in their review in 2016 did report on a variation of the incidence amongst different authors and specialities, although further adding that it did fall within 10-30% for abdominal surgery.(3) Based on 1999-2000 data reported by the Health Care Financing Administration (HCFA) that included more than 161,000 major intestinal surgical procedures performed in 150 US hospitals, the overall incidence of POI that was diagnostically coded in the medical records was 8.5%. (1) This wide range of variation in the literature could be attributed to the different clinical endpoints used for POI in the different research.

In comparison of outcomes as pertains to open abdominal surgery versus laparoscopic surgery the mean time to return of transit by open group of 48.27 hrs while for laparoscopic group was 33.91 hrs suggestive of a difference in time to return of transit between the two groups. As pertains to surgical approach, there no similar surgeries performed to allow for comparison of say a particular surgery performed either laparoscopically or via open approach. There was no observed positive correlation between choice of one approach over the other in terms of outcome of POI ($p=0.484$). The most likely explanation for the difference in risk association is that in our setup our laparoscopic procedures are shorter, non-intestinal unlike the colorectal patients in the compared meta-analysis. In the literature we find only one study that compared the two approaches based on a common surgery. This is a meta-analysis of short-term outcome of laparoscopic surgery versus conventional open surgery on colorectal carcinoma. (5) Postoperative time to flatus in laparoscopic surgery group was earlier than that in open surgery significantly (95% CI: 1.53 to 0.91, $P<.01$).

A second patient variable of importance is a high-grade complications as measured by the Clavien Dindo score. Our patients were distributed as high-grade (score ≥ 2) and low-grade complications (score ≤ 1). It was observed that high-grade complications had a positive association with occurrence of POI. A low-grade Clavien Dindo score appears to promote return of transit however, a clearer picture can be obtained by having more patients with a poorer scores. These findings are consistent with a study by Kim et al that analysed the risk factors for POI in patients undergoing urologic laparoscopic surgery. In their study, multiple linear regression analysis showed that the modified Clavien Dindo classification was an independent risk factor for postoperative ileus (odds ratio, 5.372; 95% confidence interval, 2.084 to 13.845; P = 0.001). (19)

The same study by Kim et al also found a positive association for blood loss and POI (p=0.004). Similarly, the study by Chapui et al also found an increased risk for POI with perioperative transfusion (OR: 1.6, P < 0.010). But in our setup, there was no observed positive association (p=0.44; odds 0.2 (0.1 – 0.7)). Possibly this can be explained by the type of surgeries in these reference studies which were colorectal solely unlike our study where majority of the transfusions were in caesarean sections being much shorter duration procedures, possibly suggesting routine transfusions in more stable patients hence lower incidence of hemodynamic instability.(19)

Narcotics are scientifically proven to slow bowel motility. As such one would expect a positive association with perioperative opioid use and occurrence of POI. Several studies have demonstrated this, some such as a study by Tong et al on the impact of postsurgical opioid use and ileus. POI was identified through ICD-9 diagnosis codes and postsurgical morphine equivalent dose (MED) determined. (7) They found that patients with ileus received significantly greater MED than those without (median: 285 vs. 95 mg, p=50.0001) and were twice as likely to have POI. In our setup there is no observed positive association

between the perioperative use of narcotics and occurrence of POI (p=0.273). Of note is that this is not an isolated finding as Petros et al in their study found no significant relationship between the type or amount of analgesia used postoperatively. (20)

A study by Kronberg et al that aimed to generate a predictive score for POI run an analysis on the risk of POI in patients who had undergone prior abdominal surgery. They found that more patients in the POI group had undergone previous abdominal surgery within the established limits defined for this study (66.7% vs 47.9%; P = 0.024; OR, 2.17). (4) In our setup there was a suggested positive relationship between a history of prior surgery and the occurrence of POI (p=0.001; Odds with 95% CI 0.4 (0.2 – 0.8)).

Lastly, the findings as concerns the urgency of operation, either elective or emergency surgery, there was no suggested association between the urgency of surgery and the occurrence of POI (p=0.667). A study by Vaughan-Shaw et all showed that oedema is associated with clinical outcome following emergency abdominal surgery. On multivariate analysis, oedema was independently associated with gastrointestinal recovery (B=6.91, p=0.038). (21) Chapuis et all also demonstrated an increased risk in intestinal surgery with resection at urgent operation (OR: 2.2, P < 0.001). (18)

Chapter 6: Conclusions and Recommendations

The incidence of POI within our setup as described in this study is 10.7%. The most significant risk associated with POI was high grade complications as per the Clavien-Dindo scale.

Recommendation include an emphasis on our principles of surgery to minimise our postoperative complications and thus reduce the risk of POI in those patients who develop postoperative complications. Possibly future studies inclusive of broader risk factors could enable us derive a predictive index for POI within our setup so we may anticipate and better manage the patient.

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Appendices

Appendix I: Data Collection Form

(To be completed ONLY for patients on offered oral or enteral feeds in the post-operative period)

SECTION I: BIODATA

Patient serial number: …….

Patient initials: ……

Ward: …….. Room & Bed number: ……

Age: ……..

Gender: ……..

SECTION II: CLINICAL ENDPOINTS

Is the patient cleared for feeding? ☐ (*if NO then no further assessment needed*)

Postoperative Day 1

Is the patient exhibiting any of vomiting, abdominal distension and pain? ☐

Has the patient passed stool or flatus? ☐

Time when the patient passed stool or flatus ……

Postoperative Day 2

Is the patient exhibiting any of vomiting, abdominal distension and pain? ☐

Has the patient passed stool or flatus? ☐

Time when the patient passed stool or flatus ……

Postoperative Day 3

Is the patient exhibiting any of vomiting, abdominal distension and pain? ☐

Has the patient passed stool or flatus? ☐

Time when the patient passed stool or flatus ……

Postoperative Day 4

Is the patient exhibiting any of vomiting, abdominal distension and pain? ☐

Has the patient passed stool or flatus? ☐

Time when the patient passed stool or flatus ……

Postoperative Day 5

Is the patient exhibiting any of vomiting, abdominal distension and pain? ☐

Has the patient passed stool or flatus? ☐

Time when the patient passed stool or flatus ……

Conclusions

Time of completion of surgery: ……

Time to passage of stool and/or flatus while tolerating feeds: ……

Is the interval to passage of stool and/or flatus more than 72 hours ……..

SECTION III: RISK FACTORS ***(To be filled for those who are determined to have POI as determined in SECTION II)***

(Tick or cross for yes or no respectively)

Surgery description …….

Nature of surgery:

Elective ☐ or Emergency ☐

Intestinal ☐ or Non-intestinal ☐

Clean ☐ or Contaminated ☐

Open approach ☐ or Minimally invasive approach ☐

History of prior abdominal surgery ☐

History of perioperative narcotic use ☐

Hemodynamic instability necessitating fluid resuscitation and/ or blood transfusion ☐

High grade complications ☐

Appendix II: Consent Form (English version)

INCIDENCE AND RISK FACTORS OF POST OPERATIVE ILEUS IN ADULT PATIENTS AT KENYATTA NATIONAL HOSPITAL

This Informed Consent form is for patients participating in this study at Kenyatta National Hospital.

We are requesting these patients to participate in this research project whose title is **"**INCIDENCE AND RISK FACTORS FOR POSTOPERATIVE ILEUS AT KENYATTA NATIONAL HOSPITAL"

Principal Investigator: Dr Fredrick Chege Mbuthia

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

Supervisors: Dr Ojuka, Dr Kiptoon

This informed consent has three parts:

1. Information sheet (to share information about the research with you)

2. Certificate of Consent (for signatures if you agree to take part)

3. Statement by the researcher

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

Part I: Information sheet

Introduction

My name is Dr Fredrick Chege Mbuthia, a postgraduate student at the University of Nairobi's School of Medicine. I am carrying out a study to determine the incidence and risk factors of Post-Operative Ileus in adult patients at the Kenyatta National Hospital.

This will be determined by data collection through filling a questionnaire and patient examination.

Purpose of the research

Information obtained from this study will reveal to the doctors the incidence and risk factors of Post-Operative Ileus at the Kenyatta National Hospital.

This study is also a requirement for any doctor who aspires to graduate from our college as a general surgeon.

Voluntary Participation/Right to Decline or Withdraw

I extend an invitation to participate in this study. You will have the opportunity to ask questions before you decide on your child's enrollment into the study. You may seek clarification regarding any bit of the study from myself or my assistant(s) should any part be unclear. The decision to participate in this study will be entirely voluntary after you have comprehensively understood the details herein. By refusing to participate in the study, you will not be denied medical care. Furthermore, you may stop participating at any time with no consequences whatsoever.

Confidentiality

If you agree to participate, you will be asked to provide personal information and other details related to your medical condition. All the information which you provide will be kept confidential and no one but the researchers will access it. Your names will not appear in any document. The information about the participant will be identified by a number and only the

researchers can relate the identification number to the said participant. The information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC).

Risks

Your involvement in this research will be through clinical evaluation after surgery and there are no additional risks if you consent to participate in this research.

Cost and Compensation

There will be no extra cost incurred by you (or your kin) from participation in this study. There is also no compensation or any other inducement to participate in this study.

Sharing of information

Following authorization by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC), which is a committee whose work is to make sure research participants are protected from harm, relevant medical information yielded from this study may be shared with fellow doctors through scientific seminars, workshops and publications. Personal information will not be disclosed whatsoever.

Who to contact

This proposal has been reviewed and approved by the KNH/UoN-ERC, for the duration of one year. The responsibility of this committee is to make sure research participants are protected from harm. It was submitted to them through the Chairman of the Department of Surgery at the School of Medicine of the University of Nairobi with the approval of university supervisors. The contact information of these people is given below if you wish to contact any of them for whatever reason;

The Secretary, KNH/UON-ERC

P.O. Box 20723 KNH,

Nairobi 00202

Tel 726300-9

Email: KNHplan@Ken.Healthnet.org

Principal Researcher:

Dr. Fredrick Chege Mbuthia

Resident, Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 22906 00400, Nairobi

Mobile No. 0732921074 /0720

Supervisors

Dr. Kiptoon Dan

MBChB, M.Med Surgery (UON),

Lecturer, Department of Surgery,

University of Nairobi.

Tel: 0202726300

Dr. Daniel Kinyuru Ojuka

MBChB, M.Med Surgery (UON),

Lecturer, Department of Surgery,

University Of Nairobi.

Tel: 0202726300

Part II: Consent certificate by patient

I……..freely give consent for my (my dependant's) recruitment in the study conducted by Dr. Fredrick Chege Mbuthia, the nature of which has been explained to me by him/ his research assistant. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care given to myself(or dependant). The results of the study may directly be of benefit to myself or other patients and to the medical professionals in order to understand better the incidence and risk factors of post-operative ileus at the Kenyatta National Hospital.

Signature of Patient ……..

Signature of Guardian (*where applicable*) ……...

Date (Day/Month/Year) ……..

Statement by the 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 ask questions. I confirm that the individual has given consent freely.

Name of witness……

Signature of witness……..

Date……

Left thumb

Part III: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability and made sure of the following;

- That the participant consent has been given voluntarily and free of duress.
- That all information given will be treated with confidentiality.
- That refusal to participate or withdrawal from the study will not in any way compromise the quality of care and treatment given to the patient.
- That the results of this study might be published to enhance the knowledge of the subject of research.
- That I have answered all the questions asked by the participant to the best of my ability and knowledge.
- That a copy of this Informed Consent Form has been provided to the participant.

Name of researcher taking consent ……

Signature of researcher taking the consent ……

Date ……Day/Month/Year

Appendix III: Consent Form (Swahili Version)

FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

Fomu hii ya makubaliano ni ya wale wagonjwa ambao wanahudumiwa kwenye kliniki upasuaji ya watu wazima katika hospitali ya KNH na wamealikwa kujiunga na utafiti **"**MATUKIO NA HATARI ZA ILEUS KATI YA WAGONJWA WAZIMA BAADA YA UPASUAJI WA TUMBO**"**

Mtafiti mkuu: Dkt. Fredrick Chege Mbuthia

Kituo: Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi.

Fomu hii ya makubaliano ina sehemu tatu:

- Habari itakayo kusaidia kukata kauli
- Fomu ya makubaliano (utakapo weka sahihi)
- Ujumbe kutoka kwa mtafiti

Utapewa nakala ya fomu hii.

SEHEMU YA KWANZA: Ukurasa wa habari

Kitambulizi

Jina langu ni Dkt. Fredrick Chege Mbuthia. Mimi ni daktari ninayesomea upasuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, **"MATUKIO NA HATARI ZA ILEUS KATI YA WAGONJWA WAZIMA BAADA YA UPASUAJI WA TUMBO"**

Lengo kuu la utafiti.

Ujumbe utakaodhihirika kutokana na utafiti huu utasaidia madaktari kutadhimini matukio na hatari za ileus kati ya wagonjwa wazima baada ya upasuaji wa tumbo katika Hospitali ya Taifa ya Kenyatta. Utafiti huu utasidia katika matibabu ya wagonjwa watakao fanyiwa upasuaji wa tumbo.Utafiti huu pia ni mojawapo wa mahitaji ya kuhitimu kwa stashada ya upasuaji.

Ushiriki wa Hiari/Haki ya Kukataa

Ningependa kukualika ushiriki katika utafiti huu. Utapata nafasi ya kuuliza maswali kuhusu utafiti huu, aidha kutoka kwangu au kutoka kwa wasaidizi wangu. Baada ya kuelewa kabisa undani wa maelezo ya utafiti, ushiriki wako utakuwa wa hiari. Iwapo utaamua kutoshiriki katika utafiti, mtoto wako hatanyimwa matibabu. Isitoshe, ukishaamua kushiriki, ni haki yako kukataa kuendelea na ushiriki huo wakati wowote ule bila madhara yoyote.

Taadhima ya Siri

Ujumbe wote utakaotokana na utafiti huu utahifadhiwa kwa siri, na utatumika tu na wahusika wa utafiti kwa malengo ya utafiti pekee. Jina lako au la mtoto wako halitaorodheshwa popote katika utafiti huu; nambari spesheli itatumika katika utambulizi.

Utumizi wa Matokeo ya Utafiti

Nakala za matokeo ya utafiti huu zitahifadhiwa kwa siri katika maktaba ya Idara ya Upasuaji, Chuo Kikuu cha Nairobi. Kwa minajili ya kuendeleza ujuzi wa Sayansi ya Utabibu, huenda haja ya kuarifu matabibu wengine kuhusu utafiti huu itokee. Cha muhimu ni kwamba, ruhusa itaombwa kutoka kwa Afisi ya Maadili ya Utafiti inayosimamia utafiti katika Hospitali kuu ya

Kenyatta na Chuo Kikuu cha Nairobi, kabla ya kutumia matokeo ya utafiti huu katika warsha za Sayansi au kuyachapisha katika majarida ya Sayansi. Nyakati hizo, ujumbe wa kibinafsi hautafichuliwa kamwe.

Madhara

Utafiti huu hauna madhara yoyote kwa mtoto wako.

Gharama/Malipo

Hakuna gharama ya ziada wala malipo utakayopata kutokana na kushiriki kwako katika utafiti.

Anwani za Wahusika

Ikiwa uko na maswali ungependa kuuliza baadaye, unaweza kuwasiliana na:

Mtafiti Mkuu:

Dkt Fredrick Chege Mbuthia,

Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

SLP 22906 00400 Nairobi.

Simu: 0720921074.

Wahadhiri wahusika:

Dkt. Dan Kiptoon

Idara ya Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202

Simu: 0202726300

Dkt. Daniel Ojuka

Idara ya Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202

Simu: 0202726300

Wahusika wa maslahi yako katika Utafiti:

Karani,

KNH/UoN-ERC

SLP 20723 KNH, Nairobi 00202

Simu: +254-020-2726300-9 Ext 44355

Barua pepe: KNHplan@Ken.Healthnet.org

Sehemu Ya Pili: Fomu ya makubaliano

Nimeelezewa utafiti huu kwa kina. NakubaIi kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki ……..

Sahihi ya mshiriki ……..

Tarehe ……

Jina la Mlezi ……...

Sahihi ya Mlezi ……..

Tarehe ……

Kwa wasioweza kusoma na kuandika:

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nathibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi_____ Alama ya kidole cha mshiriki

Sahihi la shahidi_____

Tarehe _____

Sehemu Ya Tatu: Ujumbe kutoka kwa mtafiti

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo:

- Kutoshiriki au kujitoa kwenye utafiti huu hautadhuru mtoto wake kupata matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.

- Matokeo ya utafiti huu yanaweza chapishwa ili kuwezesha kuzuia na kutibu matatizo yanayosababishwa na uchungu baada ya upasuaji katika watoto wachanga.

Ninathibitisha kuwa mshiriki alipewa nafasi ya kuuliza maswali na yote yakajibiwa vilivyo. Ninahakikisha kuwa mshiriki alitoa ruhusa bila ya kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti _____

Sahihi ya Mtafiti _____

Tarehe_____