

**EARLY POST-OPERATIVE COMPLICATIONS AND  
FACTORS INFLUENCING THEIR OUTCOME, FOLLOWING  
INGUINAL HERNIA REPAIR AS SEEN AT  
KENYATTA NATIONAL HOSPITAL**

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**H58/83914/2012**

**This research proposal was submitted in partial fulfillment for the award  
of Master of Medicine in General Surgery at the University of Nairobi.**

## DECLARATION

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

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This research proposal has been presented at the surgical departmental meeting on...../...../..... and is hereby approved for presentation to the Kenyatta National Hospital Ethics and Research committee.

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## **ACKNOWLEDGEMENT**

My sincere appreciation goes to the Almighty God for keeping me physically and mentally healthy to enable be carry out this research.

Special mention goes to my supervisors Dr. Joseph Githaiga and Prof. Ndaguatha, whose overwhelming support and constant encouragement goes beyond indispensable levels.

Appreciation also goes to my family and friends who offered kind words of encouragement throughout this journey of academic discovery.

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## **ABBREVIATIONS**

<b>KNH-</b>	Kenyatta National Hospital
<b>UoN-</b>	University of Nairobi
<b>ERC-</b>	Ethics Review committee
<b>TAPP-</b>	Transabdominal preperitoneal
<b>TEP-</b>	Totally extra peritoneal
<b>IPOM-</b>	Intraperitoneal Onlay mesh
<b>SOPC-</b>	Surgical outpatient clinic

## **DEDICATION**

This research is dedicated to my wife Judith Mbinya and my two sons, Joshua Msafiri and Caleb Amani, who had to endure my chronic absenteeism from family life in search of knowledge.

# ABSTRACT

## Background

Complications after inguinal hernia repair are relatively common, whose incidence is higher after emergency and recurrent hernia repairs compared with elective repair. With the transition to tension-free repair, hernia recurrence is less frequent while other complications, such as post-herniorraphy neuralgia, have become more prominent.

In our local set-up, these hernia repairs are done by residents at various levels of training and consultant surgeons depending on the complexity of the case. Local data on disease burden and post-operative complications has not been updated.

## Objective

The main objective of the study determined the early post-operative complications and factors influencing their outcome in patients that underwent inguinal hernia repair at Kenyatta National hospital.

## Study Design

A prospective non-randomized descriptive study.

## Study Duration

The study was conducted over a period of 8 months from March 2016 to November 2016.

## Materials and Methods

The study incorporated patients above the age of 12 years admitted to surgical wards for both emergency and elective inguinal hernia repair at KNH main theatres during the period under study. Consenting clients were followed up post-operatively for a 30 day period. Surgical outpatient clinic reviews and phone-calls were utilized during this period for follow-up of patients discharged from the wards post-operatively.

A questionnaire designed for this study was used for data collection, involving the age, sex, occupation, type of hernia, mode of presentation, type of anesthesia, type of surgery, type of herniorraphy, experience level of the surgeon, and use of peri-operative prophylactic antibiotics. Wounds were exposed on the third post-operative day and inspected for any complications. Early complications were considered as: hematoma/seroma formation, morbidity and mortality, scrotal swelling, numbness, recurrence and wound infections.

Data were collected using a predesigned questionnaire and analyzed using Statistical Package for Social Sciences (SPSS) for windows version 21. Data were analyzed by means, median, mode, and standard deviation and subjected to univariate or multivariate analysis for multiple outcomes. Parametric data were analyzed using the paired T-test, while non-parametric data were analyzed using Wilcoxon signed-ranked test.

## **Results**

Mean, median and standard deviation were used to describe the data and presented in form of frequency tables, pie charts and bar graphs.

A p value of  $< 0.05$  was considered significant.

## INTRODUCTION

Hernia repairs are fairly common surgical procedures done at Kenyatta National Hospital (KNH). Patients are admitted and operated either as emergency or as elective basis. Inguinal hernias are the commonest type of hernias seen and operated at KNH. One of the emerging trends in hernia repair is the use of synthetic materials to obliterate hernia defects. The understanding of the science behind this usage is because such synthetic materials elicit a fibrous reaction with body tissues to offer a firm platform upon which body organs cannot herniate. There have been great strides taken in the evolution of inguinal hernia repair from open methods to more advanced laparoscopic and robotic surgery.

Complications after inguinal or femoral hernia repair are relatively common, with the incidence depending upon the clinical circumstance under which the repair was performed as well as the site and type of the hernia<sup>1</sup>.

In multi-institutional reviews and single-center studies,<sup>2-7</sup> complication rates after laparoscopic hernioplasty vary from 5% to 13%. However; the definition of complication differs widely among studies. The incidence of major complications (approximately 1% for experienced surgeons), however, is consistent across these large studies and is similar to that reported for open hernia repairs.

Complications that occur in the peri-operative period include: wound seroma/hematoma, urinary retention, bladder injury, and superficial wound infection<sup>8,9</sup>; while late complications following hernia repair include: persistent groin pain, post-herniorraphy neuralgia, testicular atrophy, deep wound/mesh infection, recurrent hernia, and mesh migration and erosion<sup>10, 11, 12</sup>.

## LITERATURE REVIEW

Hernias are areas of weakness or frank disruption of the fibromuscular tissues of the body wall through which intracavity structures terminate. They are among the oldest recorded afflictions of man, and inguinal hernia repair is the most common general surgical procedure<sup>13</sup>. Surgery is the only effective treatment. Inguinal hernia repair is one of the earliest documented surgeries in literature from the 16<sup>th</sup> century<sup>14, 15</sup>. Over time into the late 19<sup>th</sup> and 20<sup>th</sup> centuries, Lucas- Campionniere 1881<sup>16</sup>, Bassini 1889<sup>17</sup>, McVay 1942<sup>18</sup>, Shouldice 1945<sup>19</sup>, Lichstenstein 1987<sup>20</sup> and Stoppa 1989<sup>21</sup> have immensely contributed to the understanding and change in trends in inguinal hernia repair. Worldwide, there are over 20 million inguinal hernia repairs are performed annually<sup>22</sup>. The surgical management of an inguinal hernias has changed considerably over the past 15 years.

Despite the challenges that the evolution of hernia repair has surmounted over time with respect to changing trends in repair methods, these are not without their attendant complications. Such complications can be due to: operation technique, the skills and experience of the surgeon, choice of procedure and patient risk factors, both local and systemic as discussed below.

### Persistent post-operative pain.

Persistent post-operative pain can be due to nerve entrapment or fixation of nerves by staples during laparoscopic repair. Nerve entrapment is perhaps the most significant complication of inguinal herniorrhaphy. Most nerve entrapment syndromes are self-limited, respond to nonsteroidal analgesics and resolve with time<sup>23</sup>.

Entrapment of the ilioinguinal nerve produces pain in the groin and scrotum; extension of the hip frequently exacerbates the pain. Injury to the genital branch of the genitofemoral nerve can cause hypersensitivity of the groin, scrotum and upper thigh, and can be associated with ejaculatory dysfunction. Injection of a long-acting local anesthetic along the course of these nerves is often helpful for relieving pain from the entrapment<sup>24</sup>.

Another common cause of post-operative pain is fixation of stitch to the periosteum. This is the point of maximum tenderness<sup>25, 26</sup>.

### Infection.

Infections are uncommon postoperative complications. A systematic review done by Sanchez-Manuel FJ et al, of seven randomized trials of antibiotic prophylaxis for open inguinal hernia repair found pooled risks of infection in the prophylaxis and placebo groups of 3.1 and 4.7 %, respectively (odds ratio [OR] 0.61, 95% CI 0.32-1.17)<sup>27</sup>. Odula P in 2000 at Mulago hospital, found out the infection rate after hernia repair to be at 6.7%.<sup>47</sup>

Many surgeons prefer routine single dose pre-operative intravenous antibiotic administration to avert it<sup>27, 28</sup>. However with the increasing number of antibiotic resistance, this practice is not routinely observed.

Patients undergoing mesh repair are at slightly higher risk of developing an infection. Sanabria A. et al, conducted a meta-analysis of six randomized trials involving 2500 patients and found out that patients receiving prophylactic antibiotics had half the number of surgical site infections (1.38 versus 2.89 %, OR 0.48, 95% CI 0.27-0.85)<sup>29</sup>. Most patients, who develop a wound infection, even if polypropylene mesh is present, can be successfully treated by aggressive antibiotic treatment without the need to remove the prosthesis<sup>30</sup>.

#### Seroma and hematoma formation.

Seromas and hematomas are frequent complications after anterior hernia repair. Seroma is a collection of serum in a surgical wound; it contains leukocytes and may also contain some red blood cells<sup>31</sup>. The size of the collection relates to the amount of dissection done between tissue planes and the amount of dead space remaining in the wound<sup>32</sup>.

Hematoma may arise intra-operatively or immediate post-operative period due to inadvertent injury of closely located inferior epigastric vessels.

In a randomized trial of surgery versus watchful waiting, 6.1 % of patients undergoing surgery with an open mesh repair developed a wound hematoma, 4.5 % developed a scrotal hematoma, and 1.6 % developed a seroma<sup>33, 34</sup>.

#### Early recurrence.

Early recurrence following inguinal herniorrhaphy is considered when the hernia reoccurs within 30 days of operation. A Cochrane systemic review done in 2002 by Scott NW et al revealed that this tends to be related to biomaterial breakdown and patient overactivity. Recurrences range from 0.5 to 15 %, with open mesh repair recording lower rates of recurrences. Tension free mesh repair tend to be associated with less recurrence<sup>35</sup>. I. Konate in 2010, reported of a recurrence rate between 4- 7.4 % in Senegal<sup>36</sup> while Adesunkanmi ARK in 2000, reported a figure of 4 % in Nigeria<sup>37</sup>. However these findings were reported after long term follow-up.

#### Morbidity and mortality.

Elective inguinal hernia surgery presents low mortality rates for both sexes at 0.1 %<sup>35,38, 39,41</sup>, but increases significantly when emergency operation is needed ranging from 2.8 to 3.1 %<sup>39, 40</sup>, and even higher when bowel resection is needed<sup>42</sup>. Significant factors associated with increased mortality factors in emergency settings are female gender and increasing age<sup>13</sup>. Arenal JJ et al demonstrated that; mortality after emergency hernia repair increased from 1 % for those 60 to 69 years of age, to 5 % in those 70 to 79 years of age, further increasing to 16 % for those 80 to 89 years of age<sup>40</sup>.

Dahlstrand U et al conducted a study based on a national Swedish Hernia Registry and found increased mortality rates for femoral hernia repairs<sup>42</sup>. Mortality associated with femoral hernias was 0.16 % in elective and 9.8 % in emergency cases. Compared with inguinal hernia, femoral hernias showed an increased 30-day standardized mortality ratio (6.81 versus 1.29 in men and 7.16 versus 2.82 in women)<sup>9</sup>. The higher mortality rate in women is due to

the greater proportion of femoral hernias, emergencies, and older age in women compared with men.

Scrotal numbness and swelling.

Scrotal numbness or local area anesthesia has been described after nerve transection. A study done by Rashid AE Khalil et al in 2011 revealed 11.3% and 10.7% for scrotal numbness and swelling respectively<sup>43</sup>. Khan N et al, in their study also noted a similar figure of 11.3 % for scrotal numbness following inguinal hernia repair<sup>44</sup>. In a Scottish study conducted by Hair A. et al in 2000 that looked at more than 5,500 patients who had undergone inguinal herniorrhaphy found out that about 9 % of them suffered from post-operative scrotal numbness<sup>45</sup>.

**Table 1: Summary of Complications arising from hernia repair**

<b>Open repair</b>	<b>Laparoscopic repair</b>
<b>MAJOR</b> Haemorrhage Testicular atrophy Vas deferens transection Bladder injury Bowel injury	<b>MAJOR</b> Haemorrhage Bowel injury Bladder injury Major vessel injury
<b>MINOR</b> Scrotal ecchymosis Wound infection Urinary retention Recurrence Hydrocele Nerve transection Nerve entrapment	<b>MINOR</b> Urinary retention Trocar site hernia Nerve injury Wound infection Small bowel obstruction



## **Disease burden**

In a retrospective 5 year study conducted by Elijah Mkuzi<sup>46</sup>, 1987, for a period covering 1980-1984 indicated that 302 patients with inguinal hernias were seen and operated at KNH. Despite the increase in the number and types of inguinal hernia repairs that have been done locally, there are no recent data that have been documented on the burden of the disease; hence the present study.

## **STUDY JUSTIFICATION.**

Inguinal hernia repairs are fairly common surgical procedures done at KNH<sup>48</sup>. Despite the repairs, there has been no local data research that has been done to look at the early post-operative complications of herniorraphy as seen in our local set up.

### **MAIN OBJECTIVE.**

The broad objective of the study determined the early post-operative complications and factors influencing their outcome, following inguinal hernia repair in patients operated at KNH.

### **Specific Objectives.**

1. The prevalence of early post-operative complications following inguinal hernia repair was determined.
2. The various types of early post-operative complications following inguinal hernia repair were described.
3. The factors influencing early post-operative hernia repair complications were described.
4. The correlation of early post-operative complications with skills level of the operating surgeon was determined.

# METHODOLOGY

## Study design

This was a prospective descriptive study that was conducted for a period of eight months from March 2016 to October 2016.

## Study site

The study was conducted in KNH surgical wards. Patients were recruited from the surgical outpatient clinics (SOPC) and from the wards. All patients were followed up post-operatively in SOPC.

## Inclusion criteria

Patients aged above 12 years admitted to KNH surgical wards and consented or assented to be enrolled to the study.

## Exclusion criteria

Patients with either of the following: chronic obstructive pulmonary diseases (COPD), obstructive uropathy or recurrent hernias were excluded from this study.

## Sampling method

All consenting patients who met the inclusion criteria were recruited in a consecutive manner and allocated coded numbers for ease of follow up.

Assumptions made were

The estimated prevalence of the commonest type of early post-operative hernia complication (seroma and hematoma formation) is 6.1% of population.<sup>33</sup>

Confidence interval at 95%

For a prospective descriptive, using the formula;

$$n = \frac{Z^2 p (1-p)}{e^2}$$

Where  $n$  = sample size,

$Z$  =  $Z$  statistic for a level of confidence,

$P$  = expected prevalence or proportion

And

$e$  = precision

(In proportion of one; if 5%,  $e = 0.05$ ).

For the level of confidence of 95%, which is conventional, Z value is 1.96.  
 $n = (1.96^2 * 0.061 * 0.939) / 0.0025 = 88$

### **Data collection**

Two research assistants with a minimum of undergraduate medical qualifications were used to help collect data in pre-designed questionnaires. They were briefed on study objectives and methodology. The data collection form was explicitly explained to them. Patients were recruited from casualty and surgical outpatient clinics. The researcher and research assistants then collected data from consenting and/or assenting patients and parents/guardians on a processed data sheet. Patients were followed up in the surgical wards and outpatient clinics once discharged for a period covering 30 days post-operatively.

### **Data handling**

Patient's hospital file number was included into the data sheet to facilitate easy tracing and capture missed information during data collection.

The data sheets were kept safely with the researcher and confidentiality maintained throughout. Electronic data file generated was encrypted with a password only availed to the research team. The collected data were destroyed after completion of the study.

### **Data Analysis**

Data analysis was done using SPSS version 21. Data were analyzed using descriptive statistics (mean, median, standard deviation) and paired sample *T*-test (parametric data) or a Wilcoxon signed-ranked test (non-parametric data) and presented in form of frequency tables, pie charts and bar graphs.

### **Study limitation**

The laparoscopic tower used in KNH developed a mechanical problem halfway during the study period. This therefore partly affected the overall number of laparoscopy cases that were included in the study for analysis. During the study period, I travelled with the some team of surgeons that operate in KNH, to Coast provincial hospital and Moi teaching and referral hospital to operate laparoscopically on a similar profile of patients as those seen at KHN for study consideration purposes.

### **Results dissemination**

Results of this study were disseminated to the head of department of surgery at UoN. Copies were availed to department of surgery, UoN and the College of Health sciences library.

## **Ethical consideration**

This study commenced upon approval from the department of surgery, UoN and the UoN-KNH ERC in March 2016

The parent/ guardian were given a pre-consent counseling on the study after which an informed consent was obtained from them.

With a signed informed consent, the patients were enrolled into the study.

Parents/guardians were not coerced to enroll their children into the study. Participation did not attract extra cost to the medical care of the participants.

Patients' phone numbers were taken down, which I used to make follow up and also remind them of their clinic follow up dates. However some patients did consult me over the phone as regards to the state of their wounds and all phone conversations were kept professional, private and confidential.

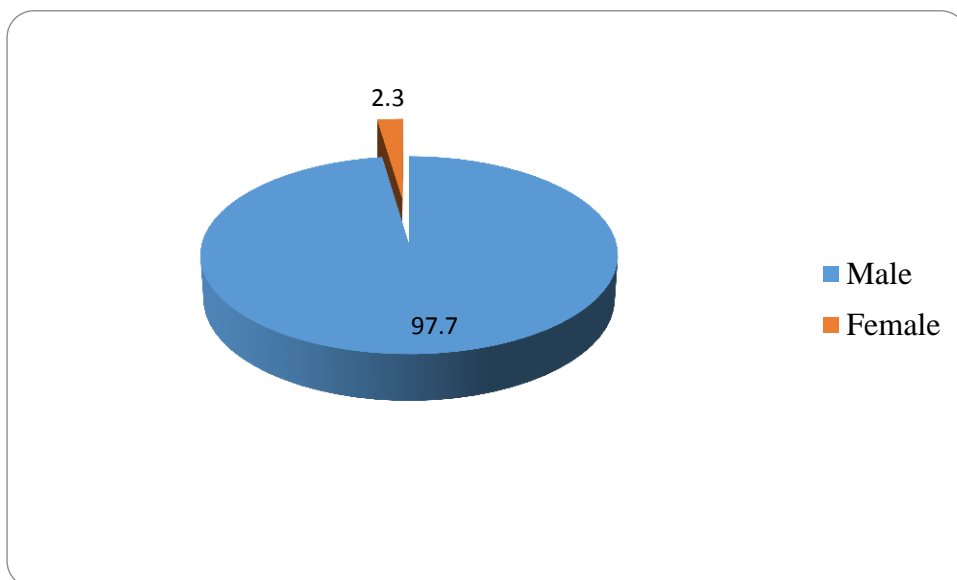
## RESULTS.

### The study population.

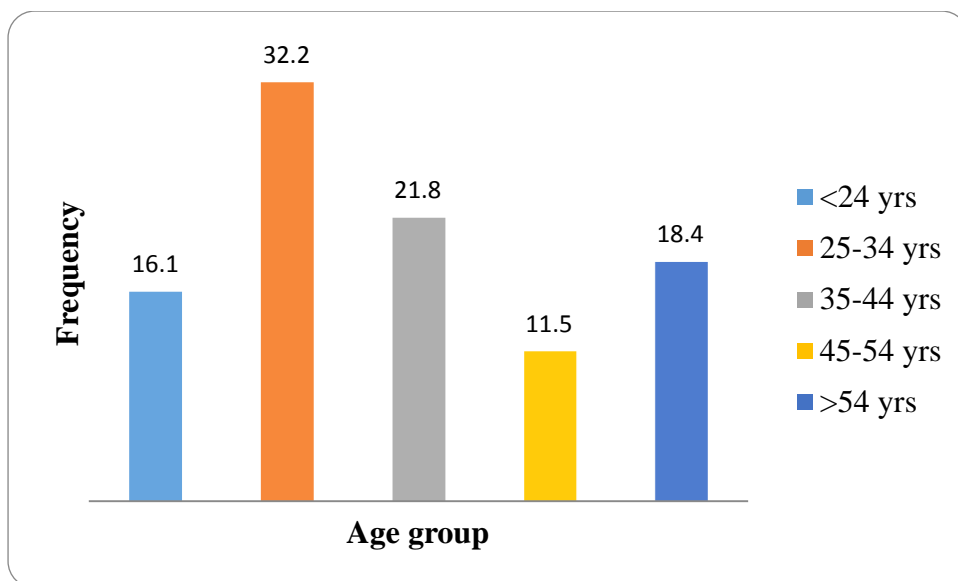
During the study period, ninety three (93) patients were successfully recruited into the study. However over the course of 30 day post-operative follow-up, six (6) patients were lost to follow-up. Some could not be traced through their contacts while some had provided next of kin contacts, making follow-up challenging. We were therefore left with eighty seven (87) patients who had been recruited and fully completed the follow-up process.

Of the eighty seven patients analysed, eighty five (97.7 %) were males (figure 1). The age range of patients under study was between 14 years and 99 years with majority (32.2 %) of the patients in the age bracket of 25-34 years (Figure 2).

Majority of patients (55.2 %) recruited into the study were casual labourers while eight (8) % of the respondents were in the formal sector of employment. Table 1.



**Figure 1: Distribution by gender.**



**Figure 2: The age distribution.**

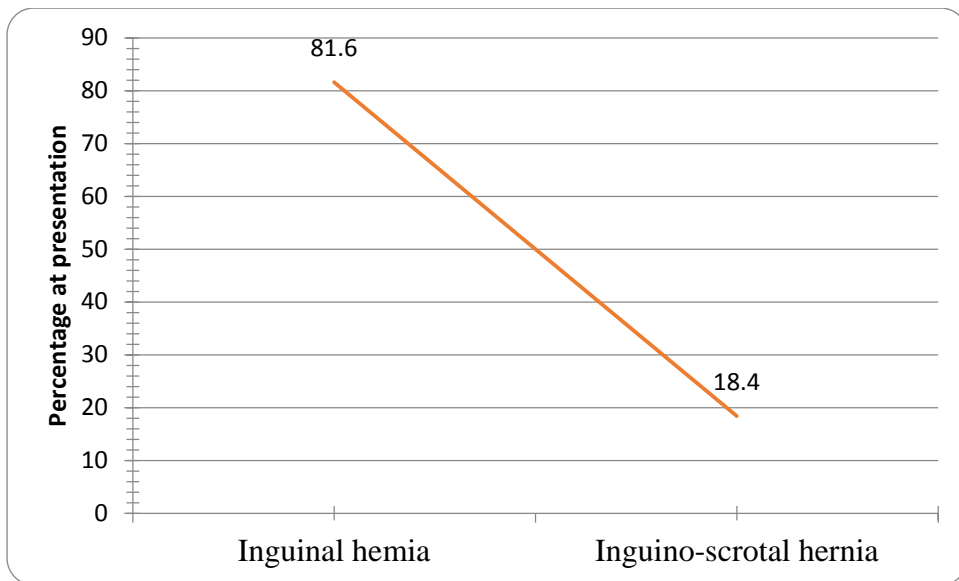
**Table 2: Occupation of respondents.**

Occupation	Frequency	Percent
Casual	48	55.2
Student	6	6.9
Self	21	24.1
Formal	7	8.0
Unemployed	5	5.7
Total	87	100.0

### **The mode of presentation**

At the time of admission, majority of the patients (81.6 %) presented with inguinal swelling. Figure 3. Fifty seven point three (57.3) % of the hernias were reducible and were therefore admitted through our surgery outpatient clinics for scheduled elective operations. Table 2. This figure is slightly higher than the actual number of patients who were operated electively at forty nine point four (49.4) %. The discrepancy in the figures could be explained by the fact that not all patients with reducible hernias were admitted electively. Forty four out of eighty seven (50.1 %) of the patients were operated as emergencies.

Fourteen point six (14.6) % of the patients admitted with irreducible inguinal hernia presented with features of strangulation.



**Figure 3:Diagnosis at admission.**

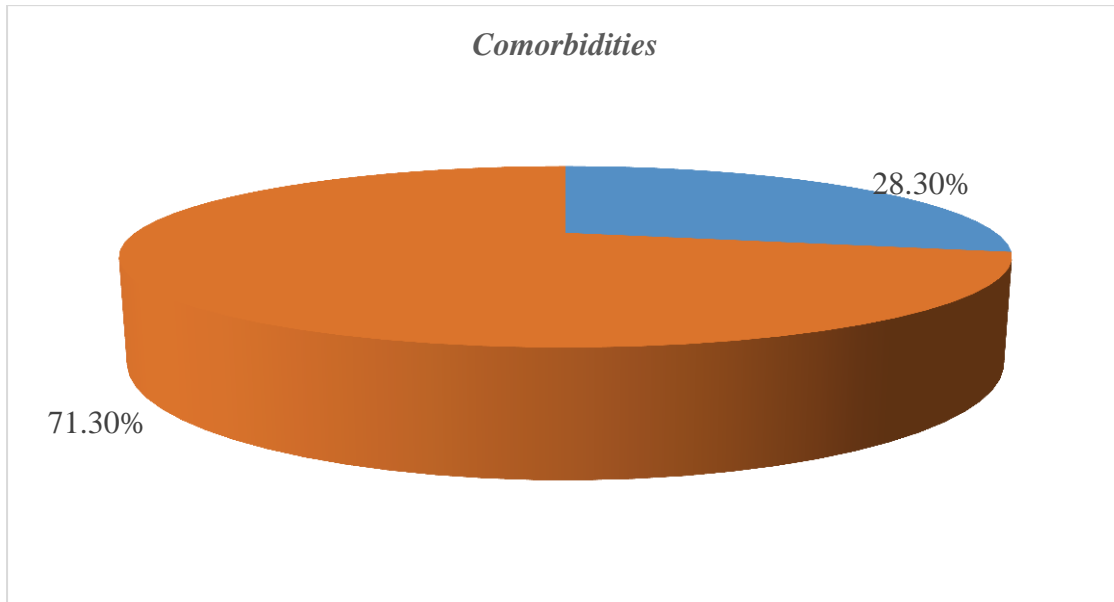
**Table 3:Mode of presentation**

		Responses	
		N	Percent
	Reducible	55	57.3%
	Irreducible	22	22.9%
	Obstructed	5	5.2%
	Strangulated	14	14.6%
Total		96	100.0%

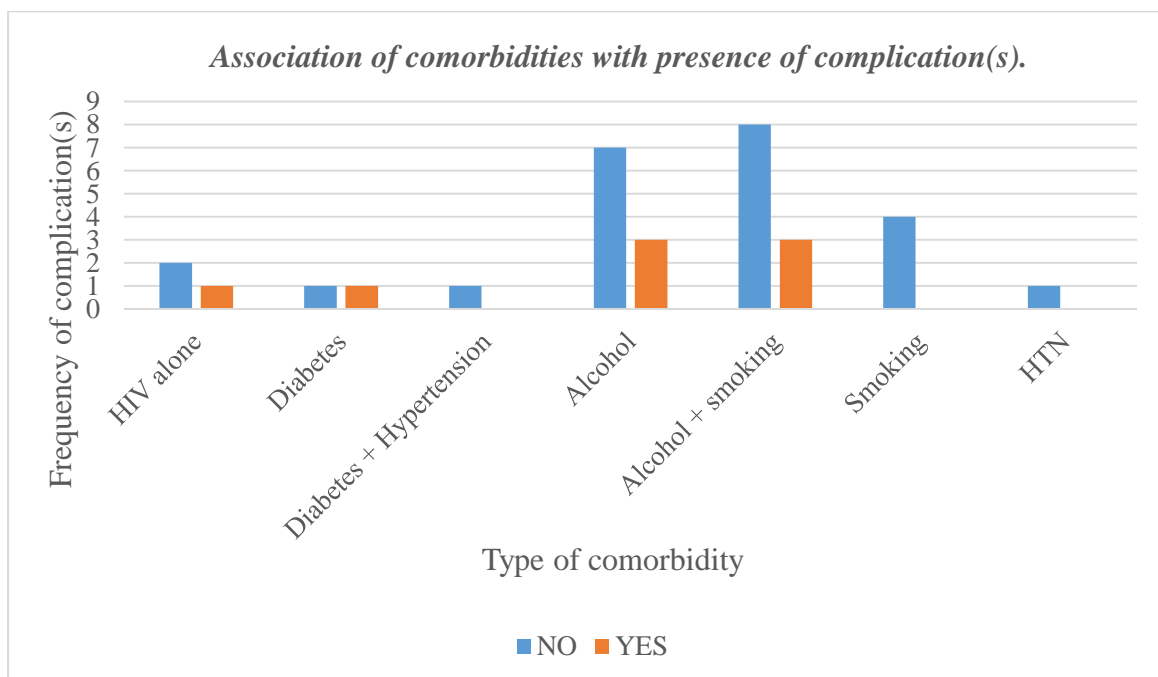


### Association of comorbid factors

Upon evaluation of comorbid factors such as: HIV, diabetes, hypertension, smoking, alcohol consumption or any chronic illness factored in the inclusion criteria, majority (71.3 %) of the patients didn't have. Figure 4. Eight (8) out of twenty five (25) patients with comorbidities developed various complications. Figure 5.



**Table 4: Comorbidities**



**Figure 4: Complications in association with comorbidities.**

## Nature of surgery

Forty- four (51%) of the patients were operated on emergency basis. Figure 6

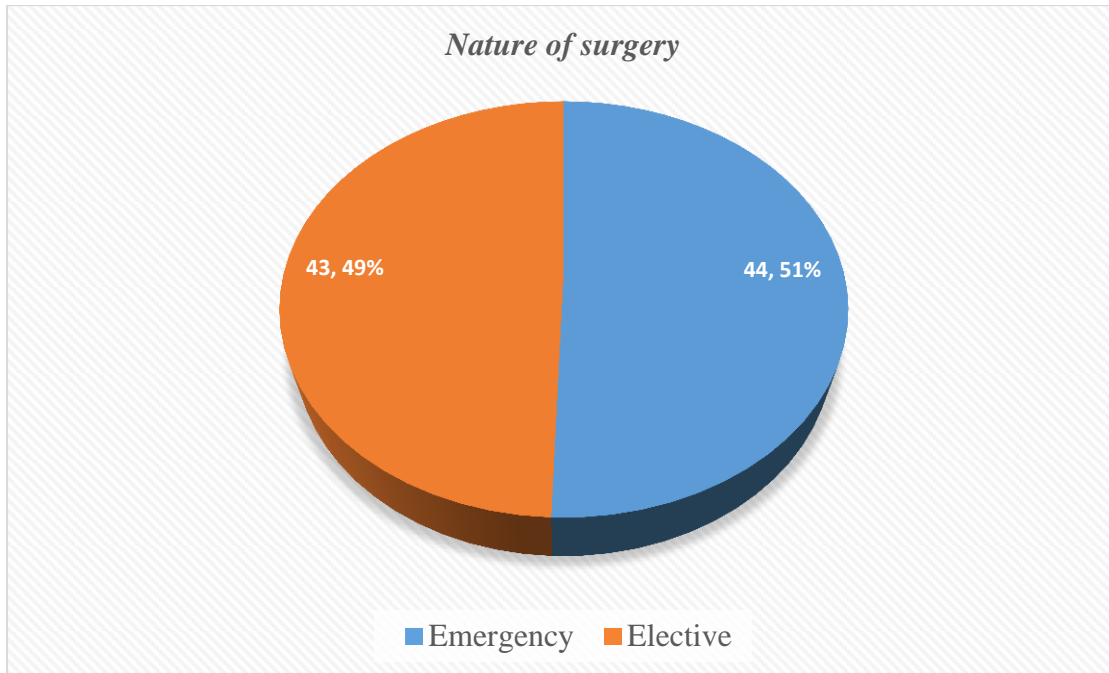
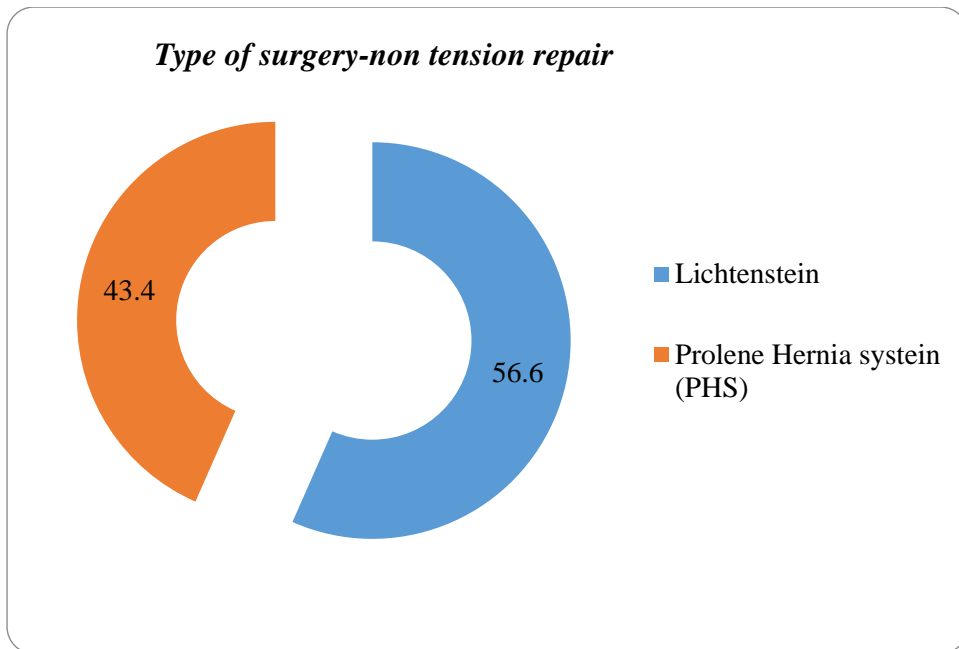


Figure 5:Nature of surgery

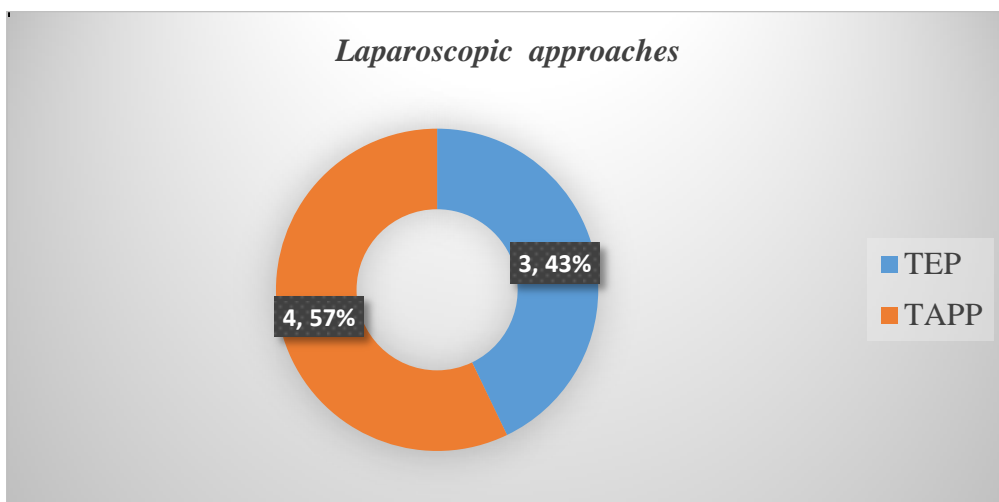
## Types of surgery

Patients were either grouped into tissue based tension repair or non-tension mesh based repair. Under tension repair, the most preferred method was modified Bassini (70.4 %). In the tension free repair category, Lichtenstein hernioplasty (57%) was the most preferred method. Figure 7. Seven (7) patients underwent laparoscopic repair methods. Figure 8.

Overall, we had forty six (52.9 %) patients undergo operation under general anaesthesia. Figure 9. Eight six (98.9%) received antibiotics peri-operatively. Table 3. Majority (36 %) of the clinicians preferred giving intravenous antibiotics for at least forty eight (48) hours. Figure10.



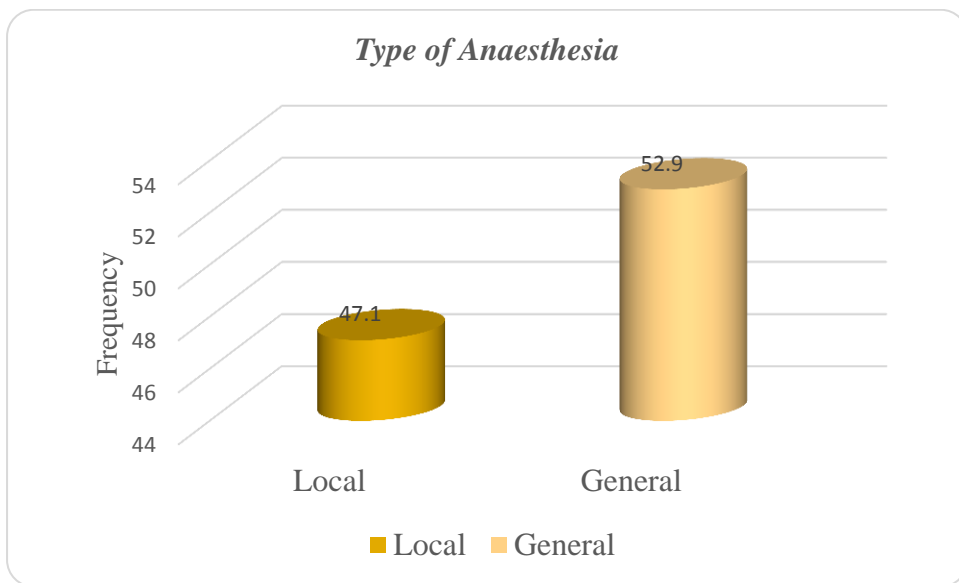
**Figure 6: Type of surgery; non-tension repair.**



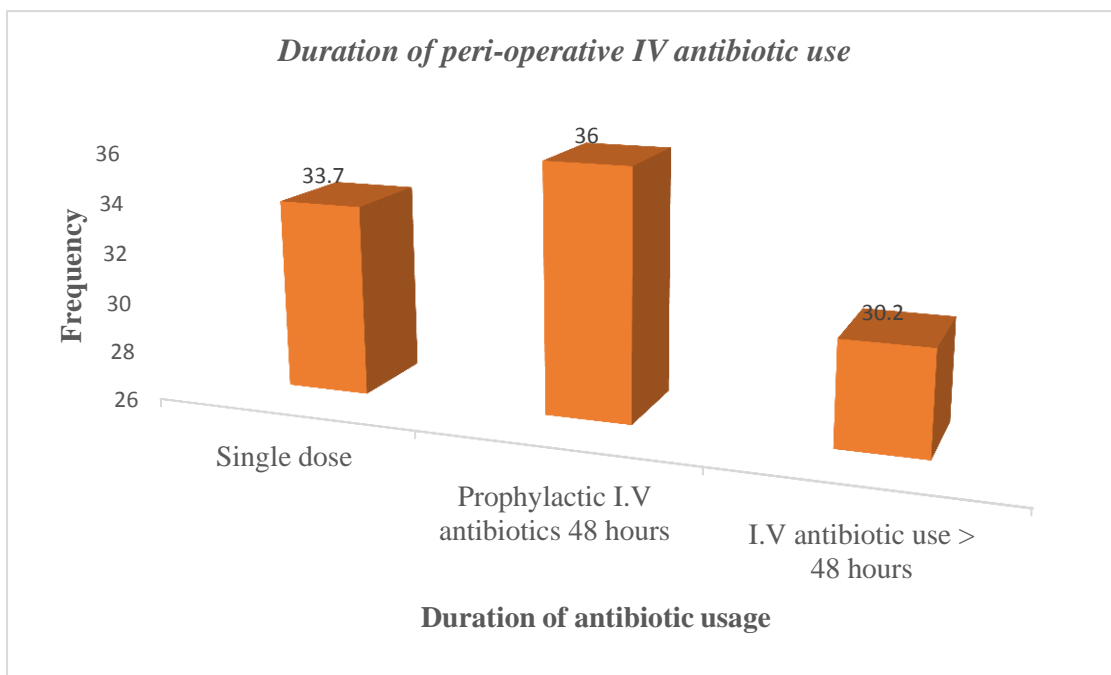
**Figure 7: Laparoscopic approaches.**

**Table 5: Peri-operative antibiotics use.**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	86	98.9	98.9	98.9
	No	1	1.1	1.1	100.0
	Total	87	100.0	100.0	



**Figure 8: Type of anesthesia**



**Figure 9: Duration of peri-operative IV antibiotic use**

## Competence level of surgeons

Seventy three (83.9%) of the operations were done by residents in various levels of training. Figure 11. Whilst it is worth noting that all emergency operations were done by the residents, on the other hand all laparoscopic operations were done by consultants as the primary surgeons.

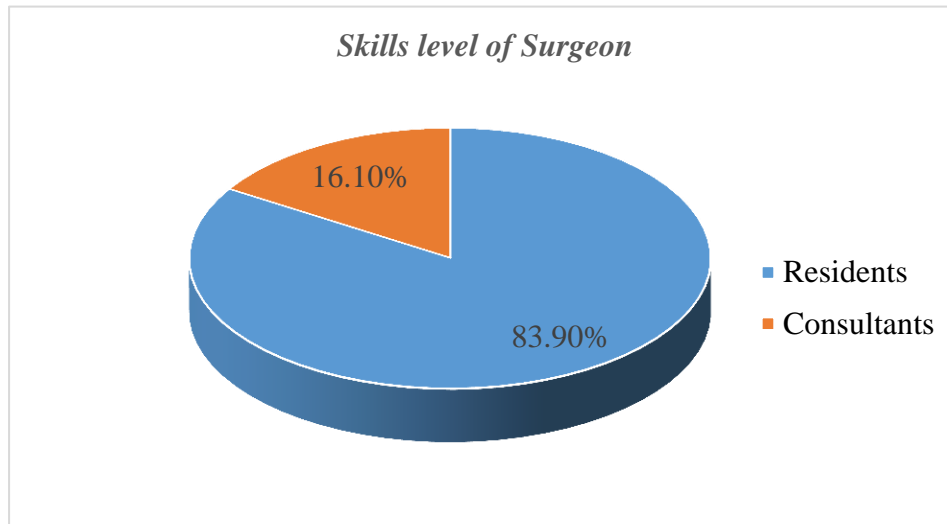


Figure 10:Skills level of surgeon

## Complications

Sixty-four out of the eighty-seven patients (73.6 %) considered under the study did not develop any complication post-operatively. Twenty three (26.4%) patients developed complications which were ranging from minor (e.g. scrotal swelling) to major (e.g. visceral/bladder injury).Table 4. The most common complication (14.1 %) was wound haematoma and seroma formation. Some patients had more than one complication. It is worth noting that most operations were done by residents hence the higher number of complications noted among the residents as compared to consultants. However none of the overall complications were statistically significant in correlation to the level of skills level of the operating surgeon. Nonetheless, haematoma/seroma formation was the commonest complication for both groups. We never had any mortality in all our patients under study.

**Table 6: Types of complications**

<b>Complications</b>	<b>Resident</b>	<b>Consultant</b>	<b>Total</b>	<b>P-Value</b>
Wound infection	2 (2.3%)	0 (0.0%)	2 (2.3)	.53
Hematoma/seroma formation	11 (12.6%)	3 (3.4)	14 (16.1%)	.55
Urine retention	2 (2.3%)	0 (0.0%)	2 (2.3%)	.53
Bladder injury	1 (1.1%)	0 (0.0%)	1 (1.1%)	.66
Wound dehiscence	2 (2.3%)	0 (0.0%)	2 (2.3%)	.53
Scrotal swelling	2 (2.3%)	0 (0.0%)	2 (2.3%)	.53
Scrotal edema	4 (4.6%)	0 (0.0%)	4 (4.6%)	.37
Local numbness	8 (9.2%)	1 (1.1%)	9 (10.3%)	.66
Prolonged ileus	1 (1.1%)	1 (1.1%)	2 (2.3%)	.18
Recurrence	3 (3.4%)	0 (0.0%)	3 (3.4%)	.44

## DISCUSSION

Complications arising from post-operative hernia repair form an important part of recovery and contribute to the overall disease burden. It is with this view in mind that various surgeons have tried to come up with various hernia repair methods in order to reduce or mitigate such occurrences.

Various methods have been deployed for both open and laparoscopic repairs with special emphasis on understanding the pathophysiology of hernia formation with particular meticulous attention to the anatomy. Wound infections in presence of a foreign material (surgical prosthesis/ mesh) and early recurrences are perhaps the most worrisome cases to both the patient and the clinician.

This study delved into looking for the early postoperative complications following hernia repairs in our local set up. Although the complications could be many in overall, the study limited itself to a couple of complications which were relatively common hence are discussed below. However, the study findings were not without very rare complications which are also highlighted.

Our study findings established a 14.1% haematoma and/or seroma formation as the leading complication. This is slightly higher than studies quoted elsewhere of 6.1% and 4.5 % for wound and scrotal haematoma<sup>33</sup> respectively, while that of seroma formation at 1.6%.<sup>34</sup> The discrepancy in our findings could be attributed to the fact that the patients profiles were lumped together for both emergency and laparoscopic surgeries and the various skills of competence of the operating surgeons, which were not controlled. It is understandable that more extensive dissections will most likely lead to haematoma formation if meticulous haemostasis was not achieved. Therefore, our local set up being a learning institution, there was an allowance of learning curve before surgical dexterity was achieved in such operations. At 2% infection rate, our local study findings were comparable to the findings of Sanabria A. et al who conducted a meta-analysis of six randomized trials involving 2500 patients and found out that patients receiving prophylactic antibiotics had half the number of surgical site infections (1.38 versus 2.89 %, OR 0.48, 95% CI 0.27-0.85)<sup>29</sup>. This was markedly lower than the findings of Odula P<sup>47</sup> in his study at Mulago Hospital in 2000, which was at 6.7%. Majority of our patients were subjected to intravenous antibiotics at least for 48 hours. For established infections, the patients were given a full 5 or 7 day course of intravenous antibiotics being guided by culture strains of microorganisms found at wound site. Of the

patients who had mesh placement, none developed infections that necessitated removal of the prosthesis.

Our study established that three (3) % of the patients complained of local numbness post-operatively. This was persistent throughout the period of follow up. However since our study period was limited to 30 days, we did not follow up these patients beyond this period to assess for resolution of symptoms, if any. These findings were significantly lower than those found by Rashid AE Khalil et al in 2011<sup>43</sup> who established local area numbness at 11.3%. Our pool of patients was much smaller compared to large studies done by Hair A. et al in 2000 that looked at more than 5,500 patients who had undergone inguinal herniorrhaphy and found out that about 9 % of them suffered from post-operative scrotal numbness<sup>45</sup>.

At 3.0 %, our study findings of early recurrence rates were comparable with the findings of I. Konate in 2010, who reported of a recurrence rate between 4- 7.4 % in Senegal<sup>36</sup> while Adesunkanmi ARK in 2000, reported a figure of 4 % in Nigeria<sup>37</sup>. However, it is worth noting that there is no local documentation of early recurrences within 30 days. The latter two findings were studies conducted on a long-term follow-up. Our study could therefore perhaps be a pilot reference study for early recurrences in the local set up.

Out of the twenty five (25) patients with comorbidities scrutinized in our study, our findings established a complication rate of thirty two (32) %. The commonest complication in this subgroup pool of patients was haematoma and persistent post-operative pain. Whilst it would be anticipated that patients with comorbid factors will tend to complicate more, in our findings this was not statistically significant. However the rate of complications was higher in emergency operations as compared to elective. Perhaps the planning and optimization of patients for elective procedure negates the propensity to complicate. However our pool of patients was small and perhaps a larger highly powered study can help elucidate the association between comorbid factors and how they influence patient complications.

In our study, we established haematoma/seroma formation as the commonest complication. This was common regardless the skill of the surgeon. There were higher complication rates in the residents group compared to consultants. This cannot be entirely attributed to the level of skills training as our study recorded lower number of overall cases done by consultants, that could have helped mount a statistically objective comparative analysis. Moreover, consultants operated mostly on elective patients as compared to residents who did most of the emergency cases, which could have rendered our study findings biased if the two groups were subjected to comparative analysis at the same tier.



During the course of our study period, we encountered three interesting scenarios which perhaps we thought would be of important to highlight and are thus discussed subsequently. We had one male patient, aged 52 years, with no known comorbid factors. He was diagnosed with right direct inguinal hernia and was thus scheduled for elective repair. The operation was done under spinal anaesthesia after procedural protocols and right inguinal Lichtenstein hernioplasty done. There were no major intra-operative complications. However on the 2<sup>nd</sup> post-operative day, he was noted to have a swelling on the same side of operation as before. The swelling increased over time and a positive cough reflex on examination was elicited. He was taken back to theatre and on second local exploration under general anaesthesia. A recurrent hernia was found sliding beneath the lower edge of the mesh. The mesh had been displaced supero-medially. The hernia was reduced and mesh anchored to the inguinal ligament with non-absorbable suture continuous stitching. Patient had uneventful recovery thereafter.

We had a 28 year old male patient who had presented to our emergency department with painful irreducible right inguinal swelling. A diagnosis of incarcerated right inguinal hernia was made and was therefore taken to theatre for emergency repair. Intra-operatively, there was a gangrenous segment of small bowel which was resected with primary anastomosis done through the inguinal incision. However during the course of recovery in the ward, he was noted to have both inguinal incision swelling and a large expanding scrotal swelling. The scrotal swelling was transluminal on examination and biochemistry results of straw coloured fluid aspirate from the scrotum was consistent with urine. He was taken back to theatre for exploration. Intra-operative findings were iatrogenic bladder injury during the first operation which was leaking urine through the incision site with some tracking through to the scrotum. Bladder repair was done and the patient had uneventful post-operative period.

Lastly, we has a 62 year old male patient who had presented with a reducible right inguinal swelling. A diagnosis of right inguinal hernia was made and he was scheduled for laparoscopic totally extra-peritoneal hernioplasty under general anaesthesia. He had no comorbid conditions. During the intra-operative period, the pre-peritoneal space was developed initially via blunt dissection then sharp dissection towards the inferior edge. There was inadvertent injury of the femoral vein beneath during plane dissection and the laparoscopic operation was abandoned immediately and converted to an open approach. The operation was completed via the open technique, with repair of the venotomy site. No major complications post-operatively and the patient was discharged on the 5<sup>th</sup> post-operative day.

## **Conclusion**

Overall, we had early post-operative complication rates of 26.4%. The complications were higher in the emergency group as compared to the elective group although the ratio of emergency to elective cases was almost 1:1 (51 versus 49) % respectively. The commonest complication was haematoma/seroma formation. Consultants operated mostly on elective patients and all laparoscopic cases while the residents did majority of the emergency cases.

We had twenty five (25) patients with various comorbid factors, out of which eight (8) developed complications. There was no statistical difference in terms of complications occurring in patients with comorbid factors as compared with those without. The skills level of training of the operating surgeon did not majorly influence the burden and type of complications when residents were compared to surgeons. This was partly due to the unequal number of operations done by both groups and the nature of operations.

## **Recommendations**

Hernia repair biomechanics has advanced with age. While in our local set-up we have adopted the newer methods of hernia repair, there is need to improve in our techniques and numbers so as to minimize complications to lower levels like in other international centres of excellence.

There is need to do more laparoscopic hernia operations that can help form a robust leverage for comparative analysis with other hernia repair methods, in terms of early post-operative complications.

Patient optimization peri-operatively, careful tissue handling and perhaps senior surgeon supervision will go a long way in reducing our post-operative morbidities. This can be achieved through more involvement of the more skilled surgeons in technically challenging emergency cases as the skills are passed down to junior surgeons.

A large highly powered study is recommended to evaluate in detail the early post-operative complications of hernia repair and it is the hope of the researcher that this study will form a catalyst for future multicentre studies as the disease burden of hernia is still common in our country and the area of study is just but a national representative sampling region.

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## APPENDICES

### Appendix I: Informed Consent

#### EARLY POST-OPERATIVE COMPLICATIONS AND FACTORS INFLUENCING THEIR OUTCOME, FOLLOWING INGUINAL HERNIA REPAIR AS SEEN IN KNH.

##### **English version.**

This Informed Consent form is for patients with hernia admitted at the Kenyatta National Hospital who need emergency or elective operations. This consent will be administered to the patients or parents/patient's guardians. We are requesting these patients to participate in this research project whose title is "EARLY POST-OPERATIVE COMPLICATIONS AND FACTORS INFLUENCING THEIR OUTCOME, FOLLOWING INGUINAL HERNIA REPAIR AS SEEN IN KNH."

Principal investigator: Dr.Kazimoto M. D.

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

Supervisors:

1. Dr J. Githaiga.
2. Prof. P.L.W Ndaguatha

This informed consent has three parts:

- Information sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)
- 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 Kazimoto Dismas. I am a post graduate student at the University Of Nairobi School Of Medicine, department of general surgery. I am carrying out a study to determine the early post-operative complications and factors influencing their outcome, following inguinal hernia repair in patients admitted to KNH adult surgical unit. This would be possible through data collection by filling in questionnaire and follow up of these patients post-operatively for a period of 30 days.

### **Purpose of the Research.**

Information obtained from this study will reveal to the doctors the magnitude of early surgical complications we have during such treatments in order to be better prepared to handle and indeed avoid them where possible. This study is also a requirement for any doctor who aspires to graduate from our college as a surgeon.

### **Voluntary participation/right to refuse or withdraw.**

An invitation to participate in this study is hereby extended to you. You will have the opportunity to ask questions before you decide on your participation or that of your child's enrollment into the study. You may seek clarification regarding any bit of the study from my assistant(s) or me, should any part be unclear.

### **Confidentiality.**

All the information which you provide regarding yourself or child/kin will be kept confidential; only the researchers will access this information. You will be identified by a number and only the researchers can relate the number to the patient. Your names will not be used anywhere in data handling and processing. All the information you give us will be used for research only.

### **Sharing of the results**

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). This proposal has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm.

### **Risks**

There is no direct risk attributed to participation in this study. Possible operation related risks will be captured in separate consent forms for surgery.



**Cost and compensation**

There will be neither extra cost incurred for participating in this study, nor compensation offered. However your time will be required to participate in the interview.

**Part II certificate of consent**

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this research.

Print Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_

If Illiterate;

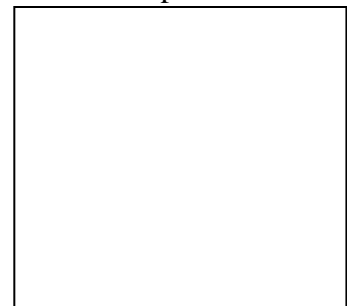
I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of witness \_\_\_\_\_  
participant

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_

Left thumb print of



**Who to contact.**

The contact information is given below if you wish to contact any of them for whatever reason;

Secretary, KNH/UoN-ERC

P.O. Box 20723 KNH, Nairobi 00202

Tel 726300-9

Email: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)

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Principal researcher:

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Mobile phone 0721 580 337

**PART III: Statement by the researcher**

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate knowledge of early complications of hernia repair and their management.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher/person taking consent \_\_\_\_\_

Signature of researcher/person taking consent \_\_\_\_\_

Date \_\_\_\_\_

## **Appendix II: Assent Form for Children 12 Years to 18 Years**

EARLY POST-OPERATIVE COMPLICATIONS AND FACTORS INFLUENCING THEIR OUTCOME, FOLLOWING INGUINAL HERNIA REPAIR AS SEEN AT KENYATTA NATIONAL HOSPITAL.

### **ASSENT FORM FOR CHILDREN 12 YEARS TO 18 YEARS**

My name is Dr. Kazimoto Dismas. I am doing a study on early post-operative complications and factors influencing their outcome, following inguinal hernia repair as seen at KNH.

#### **Purpose of study**

This may help us understand the burden of such problems and enable us improve our outcomes and hence change our patient care, if any improvement on our part, is necessary. If you would like, you can participate in this study.

#### **Voluntariness of participation**

Participation into this study is voluntary and no one can force you to participate. If you decide you want to participate in my study, you will be asked some personal questions and required to go through a questionnaire with me or my research assistant.

#### **Risks**

There are no direct risks involved in this study. However, procedure related complications will be covered in separate consent forms for surgery. Also you will not incur any extra costs for participating in this study.

#### **Right to withdraw from the study**

You can withdraw from the study at any point in time and this will not affect your management at KNH. You will not be denied any service due to your withdrawal

#### **Confidentiality**

Other people will not know if you are participating in this study. Your answers and your progress will be kept private. Your names will not be used anywhere in data handling and processing.

Your parents or guardian have to say it's OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don't want to be in the study, you will not get into any trouble.

You can stop being in the study at any time. In case you have further questions or seeking clarifications, you can contact any of the following below:

Principal researcher:

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Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202

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Email: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)

I will give you a copy of this form in case you want to ask questions later.

Sign this form only if you:

- have understood what you will be doing for this study,
- have had all your questions answered,
- have talked to your parent(s)/legal guardian about this project, and
- agree to take part in this research.

---

Your Signature

Name

Date

---

Name of Parent(s) or Legal Guardian(s)

---

Researcher explaining study

Signature

Name

Date

## **Appendix III: Fomu ya Makubaliano ya Kujiunga na Utafiti**

**Maelezo kwa Kiswahili.**

### **FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI**

**SWALA LA UTAFITI: EARLY POST-OPERATIVE COMPLICATIONS AND FACTORS INFLUENCING THEIR OUTCOME, FOLLOWING INGUINAL HERNIA REPAIR AS SEEN AT KENYATTA NATIONAL HOSPITAL.**

Fomu hii ya makubaliano ni kwa wale wagonjwa wanaolazwa kwa ajili ya upasuaji wa mshipa wa ngiri/ ngiri kokoto au kwa lugha ya utohozi ‘hania’ katika hospitali kuu ya taifa, Kenyatta. Ninakualika kuwa mmoja wa wale watakaofanyiwa uchunguzi huo katika utafiti huu kwa hiari yako.

**Mtafiti mkuu:** Dkt. Kazimoto M.Dismas

**Kituo:** Kitivo cha utabibu, idara ya upasuaji, Chuo Kikuu cha Nairobi.

Fomu hii ya makubaliano ina sehemu tatu:

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

Utapewa nakala ya fomu hii.

### **SEHEMU YA KWANZA: Ukurasa wa habari**

#### **Kitambulizi**

Jina langu ni Dkt. Kazimoto Dismas. Mimi ni daktari ninayesomea uzamili katika idara ya upasuaji Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, “EARLY POST-OPERATIVE COMPLICATIONS AND FACTORS INFLUENCING THEIR OUTCOME, FOLLOWING INGUINAL HERNIA REPAIR AS SEEN AT KENYATTA NATIONAL HOSPITAL”. Dhamira ya utafiti huu itawezekana kupitia kujaza dodoso utakalopewa na kisha kufuatiliwa au mgonjwa wako kufuatiliwa baada ya kufanyiwa upasuaji hadi siku thelathini tangu kupasuliwa.

#### **Nia ya utafiti huu**

Ujumbe utakaopatikana kutokana na utafiti huu utakuwa mwanga kwa madaktari kuelewa uzito wa shida ambazo hutokana na upasuaji wa ‘hania’ na jinsi wanavyoweza kuziepuka au

kuzikabili vilivyo siku za usoni. Aidha, utafiti huu ni mojawapo ya mahitaji anayohitajika mtafiti kuhitimisha katika kiwango cha uzamili kama daktari wa upasuaji.

### **Haki ya kukataa utafiti**

Kushiriki kwako kwa utafiti huu ni kwa hiari yako. Una uhuru wa kukataa kushiriki, na kukataa kwako hakutatumiwa kukunyima tiba. Unayo haki ya kujitoa katika utafiti wakati wowote unapoamua.

### **Taadhima ya siri**

Ujumbe kuhusu majibu yako yatahifadhiwa. Ujumbe kuhusu ushiriki wako katika utafiti huu waweza kupatikana na wewe na wanaoandaa utafiti na wala si yeyote mwingine. Jina lako halitatumika bali ujumbe wowote kukuhusu utapewa nambari badili ya jina lako.

### **Hatari unayoweza kupata**

Hakuna hatari yoyote ambayo yaweza kutokea kwa sababu ya kuhusishwa kwa utafiti huu. Hatari ambazo zaweza tokana na upasuaji wenyewe zitaelezwa katika fomu ya kibali cha upasuaji, tofauti na hii. Aidha, kukataa au kujitoa katika ushiriki wako kwa huu utafiti kwa wakati wowote ule hakutakuletea hatari yoyote ya matibabu.

### **Hifadhi ya matokeo.**

Matokeo ya utafiti huu yatachapishwa kwa nukuu mbali mbali za sayansi kupitia kwa idhini ya mtafiti mkuu. Nakala za chapisho zitahifadhiwa katika idara ya upasuaji, chuo kikuu cha Nairobi na katika maktaba ya sayansi za Afya, kitivo cha utabibu. Hivyo basi, matokeo ya utafiti huu hayatasambazwa kwa umma au jukwaa lisiloidhinishwa kihalali. Ujumbe ulio kwa dodoso hautahifadhiwa baada ya uchanganuzi wa matokeo.

### **Gharama au fidia.**

Utafiti huu hautakugharimu zaidi ya matibabu yako ya kawaida. Vilevile, hakuna malipo yoyote au fidia utakayopokea kutokana na kujiunga kwako katika utafiti huu. Muda wako ndio utakaotumiwa wakati wa mahojiano



**SEHEMU YA PILI: Fomu ya makubaliano**

Nimeelezwa utafiti huu kwa kina. Nakubali kushiriki katika 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 \_\_\_\_\_

Kwa wasioweza kusoma na kuandika:

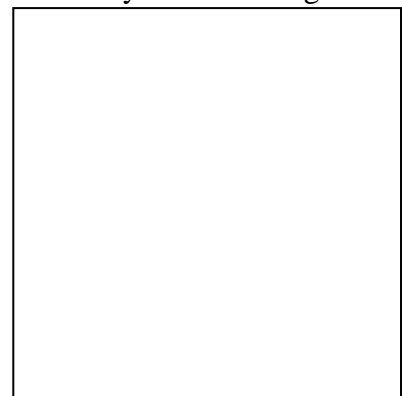
Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nathibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi \_\_\_\_\_  
cha mshiriki

Sahihi la shahidi \_\_\_\_\_

Tarehe \_\_\_\_\_

Alama ya kidole cha gumba



## **Anwani za Wahusika**

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

### **Mtafiti Mkuu:**

#### **Dkt. Kazimoto Dismas**

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

SLP 19676 KNH, Nairobi 00202.

Simu: 0721 580 337

### **Wahadhiri husika:**

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MBCh.B, M.MED (Gen Surg.),

Mhadhiri mkuu,

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

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#### **2. Professa P.L.W Ndaguatha**

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### **SEHEMU YA TATU: Ujumbe kutoka kwa mtafiti**

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

- Kutoshiriki au kujitoa kwenye utafiti huu hakutadhuru kupata kwake kwa matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu yanaweza chapishwa kusaidia utambuzi wa shida zinazotokana na upasuaji wa ‘hania’.

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 \_\_\_\_\_

## **Appendix IV: Fomu ya Idhini ya Watoto Walio na Umri wa Kati ya Miaka 12 hadi 18**

### **EARLY POST-OPERATIVE COMPLICATIONS AND FACTORS INFLUENCING THEIR OUTCOME FOLLOWING INGUINAL HERNIA REPAIR AS SEEN AT KENYATTA NATIONAL HOSPITAL.**

Jina langu ni Dkt. Kazimoto Dismas. Ninafanya utafiti kuhusu shida zinazowaathiri wagonjwa baada ya kufanyiwa upasuaji wa mshipa wa ngiri/ngiri kokoto au kwa lugha tohozi ‘hania’ katika hospitali kuu ya taifa, Kenyatta.

#### **Dhamira ya utafiti.**

Matokeo ya utafiti huu yanaweza saidia kuelewa shida zitokanazo na aina hii ya utabibu na kusaidia kuboresha matokeo na huduma kwa wagonjwa wanaofanyiwa aina hii ya upasuaji. Ikiwa ungependa kushiriki katika utafiti huu, nakusihi ujiandikishe kwa mkataba wa uwiano.

#### **Hiari ya kushiriki.**

Kushiriki katika utafiti huu ni kwa hiari na hamna masharti yoyote ya lazima. Unapokubali kushiriki katika utafiti huu, utaulizwa maswali ya kukuhusu kupitia dodoso hili, aidha nami au mtafiti msaidizi wangu.

#### **Je, kuna hatari ya kushiriki?**

Hakuna hatari wala gharama ya ziada yoyote itakayokukumba kutokana na kushiriki katika utafiti huu. Hatari zitokanazo na upasuaji wenyewe zimezingatiwa katika fomu ya kibali ya upasuaji, tofauti na hii.

#### **Uhuru wa kujiondoa kutoka utafiti.**

Una haki ya kujiondoa kutoka ushiriki wa huu utafiti wakati wowote upendao na uamuzi huo hauwezi dhuru matibabu yako kwa vyovyote vile.

#### **Hifadhi ya siri.**

Hakuna yeyote mwingine atakaye juzwa ushiriki wako katika utafiti huu. Majibu yako na mwelekeo wa matibabu yako yatakuwa ni siri na hifadhi yako. Itwabidi pia wazazi au wadhamini wako kukubali ushiriki wako katika utafiti huu. Watakopoamua, utakuwa nawe uhuru kukubali kwa kushiriki pia. Iwapo hautakubali, hamna madhara yoyote utapata. Una uhuru wa kujiondoa katika utafiti.

Nitakupa nakala ya fomu hii ikiwa ungependa kuuliza maswali zaidi baadaye.

Tia sahihi iwapo;

- Umeelewa ushiriki wako katika utafiti huu
- Maswali yako yote yamejibiwa vilivyo
- Umejadili na wazazi au wadhamini wako kuihusu
- Umekubali kushiriki katika utafiti.

---

Sahihi yako

jina lako

tarehe

---

Jina la mzazi au mdhamini

---

*Mtafiti aliyekupa maelezo ya utafiti*

*Sahihi*

*jina*

*tarehe.*

### **Anwani za Wahusika**

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

Mtafiti Mkuu:

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## Appendix V: Data Collection Sheet

EARLY POST-OPERATIVE COMPLICATIONS AND FACTORS INFLUENCING THEIR OUTCOME,FOLLOWING INGUINAL HERNIA REPAIR AS SEEN AT KENYATTA NATIONAL HOSPITAL.

Data collection Sheet.

Date-----/-----/-----

Patient identification code\_\_\_\_\_

### Socio-demographic data.

Admission date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Age (years) \_\_\_\_\_

Sex\_\_\_\_\_

Occupation\_\_\_\_\_ -

### 1. Diagnosis at Admission.

- a) Inguinal hernia
- b) Inguino-scrotal hernia

### 2. Mode of presentation

- a) Reducible
- b) Irreducible
- c) Obstructed
- d) Strangulated.

### 3. Nature of surgery

- a) Emergency
- b) Elective.

### 4. Co-morbidities (e.g. diabetes, hypertension, AIDS) Smoking, alcohol.

- a) YES
- b) NO

### 5. Type of Surgery

- a) Tension repair
  - i. Modified Bassini
  - ii. Shouldice
  - iii. Desarda

- b) Non-tension repair
  - i. Lichtenstein
  - ii. Prolene Hernia system (PHS)
  
- c) Laparoscopic repair
  - i. Trans abdominal pre-peritoneal approach (TAPP)
  - ii. Totally extra peritoneal approach (TEP)

**5. Type of anesthesia.**

- a) Local
- b) General

**6. Peri-operative antibiotic use**

- a) Yes
  - i. Single dose IV antibiotic at anesthesia induction
  - ii. Prophylactic IV antibiotic for 48 hours
  - iii. IV antibiotic use for more than 48 hours.
- b) No.

**7. Skills level of surgeon.**

- a) Resident
- b) Consultant

**8. Complications.**

- a) Wound infection
- b) Hematoma/seroma formation
- c) Urine retention
- d) Bladder injury
- e) Wound dehiscence
- f) Scrotal swelling
- g) Scrotal edema
- h) Local numbness
- i) Prolonged ileus
- j) Recurrence