

**INCIDENCE, TYPES AND THE OUTCOME OF SURGICAL
MANAGEMENT OF PERFORATED PEPTIC ULCERS AS
SEEN AT KENYATTA NATIONAL HOSPITAL**

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**A Dissertation Submitted In Partial Fulfillment for the Award of
Master's of Medicine Degree In General Surgery,**

University of Nairobi

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DECLARATION

I declare that this Dissertation is my own original work and has not been presented for a degree in any other University.

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DEDICATION

I dedicate this book to my family especially to my wife Happiness, and my son Austin. Without their love, support, understanding and unceasingly prayers and encouragement, completion of this book would not have been possible. May our Lord Jesus Christ protect you and bless you abundantly. I love you.

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ABBREVIATIONS

DUs	–	Duodenal Ulcers
GIT	–	Gastrointestinal tract
GUs	–	Gastric Ulcers
KNH	–	Kenyatta National Hospital
NSAIDs	–	Non-Steroidal Anti -inflammatory Drugs
PPI	–	Proton Pump Inhibitors
PPUD	–	Perforated Peptic Ulcer Disease
PPU	–	Perforated peptic Ulcers
PU s	–	Peptic Ulcers
SPSS	–	Statistical Package for Social Sciences
SSI	–	Surgical site infection
UON	–	University of Nairobi

ABSTRACT

BACKGROUND:

Perforated Peptic Ulcer disease (PPUD) is believed to be less common and less severe as the result of modern medical treatment of peptic ulcer disease (PUD). Management of PUD has improved over the past few decades; however the widespread usage of non-steroidal anti-inflammatory drugs (NSAIDs) means that the burden of PUD and PPUD remains relevant issue. In the past several decades the pharmacologic and endoscopic treatment of PUD had shown dramatic improvement, however perforated peptic ulcers (PPUs) have been observed to be the leading cause of generalized peritonitis and hence their management have continue to be a challenging task in our environment. Literature reviews from western countries indicate that there are increasing rates of perforated PU in chronically ill and elderly patients unlike our local observations in younger patients. Further literature reviews demonstrate that delayed treatment after peptic ulcer perforations increase complication rates, prolonged hospital stay as well as mortality. Complications following ulcer perforations are associated with delayed presentation, surgical techniques, immune status of the patients, and others; however, the incidence and complications associated with the size of perforations has been scarcely discussed in our set up.

OBJECTIVE: The aim of this study is to determine the incidence, types and the outcome of surgical management of perforated peptic ulcers as seen at Kenyatta National Hospital.

METHODS: 9 months prospective Descriptive cross-sectional hospital based study carried out at Kenyatta National Hospital (KNH) Casualty, Theatre and the General surgery wards. All patients who presented with clinical features of perforated PUD, those who agreed and had signed informed consent, and intraoperative were found to have perforation were recruited for the study. Data collected through structured questionnaires, analysis of the variables i.e. the incidence, types of perforation in terms of anatomical location and the size, surgical technique used and its outcome were done using the statistical program for social sciences (SPSS) version 13. Data presented in form of graphs, tables and pie charts.

RESULTS: All 22 cases recruited were males with age ranging from 22 to 76 years. Most of the cases, 45%, were operated within the first 24hrs after the onset of severe acute symptoms of abdominal pain, 27% within 48hrs, 14% within 72hrs, and 14% were operated >72hrs after the onset of severe symptoms of abdominal pain. The incidence of perforated peptic ulcer was found to be 19 per 1000years. Common site of perforation was at first part of duodenum

64% with small perforation (<1cm) 36% and large perforations (1 - 3cm) 64%. All cases underwent upper midline laparotomy and repair was done using Graham's omental patch. The outcome was 62% of all cases had no complications while 19% had surgical site infection, 10% intraabdominal abscess, 5% wound dehiscence and 5% leaking. 50% were discharged home within the first week post surgery, 31.82% on second week 4.54% on third week and 9.08% on fourth week. Mortality was 4.54%.

In this study all perforations were found to be anterior perforations predominant duodenal perforations with large perforation size. Graham's omental patch remained the main surgical procedure in all cases.

CONCLUSION: The earlier the presentation of the patient to the hospital resulted in good outcome. The small and large perforations are easily repaired by Graham's omental patch.

1.0 Introduction

Burning epigastric pain exacerbated by fasting and improved by meals is a symptom complex associated with Peptic Ulcer Disease (PUD). The decrease in the incidence of elective surgery is due to the decline in incidence of peptic ulcers as a result of availability of H₂ receptor antagonists and proton pump inhibitors in recent years¹, however the incidence of peptic ulcer perforation has not changed remarkably since the introduction of H₂-blockers and proton pump inhibitors as shown elsewhere^{2,3}.

Perforated Peptic Ulcer Disease (PPUD) is the second most frequent abdominal emergency requiring surgical treatment⁴. Delay in diagnosis and delayed initiation of surgical management of PPUD has clearly shown to be associated with high morbidity and mortality after surgery for PPUD^{5,6}. Early recognition, prompt diagnosis and aggressive resuscitation and early surgical intervention clearly aid in keeping the morbidity and mortality low⁷. Studies of ulcer mortality and ulcer perforation show a cohort pattern, which means that these ulcer manifestations are particularly common in certain high-risk generations^{8,9}; however, ulcer death and ulcer perforation represents only minor groups of subjects with peptic ulcer disease. Peptic ulcer disease follows a cohort pattern and that the susceptibility to peptic ulcer is established early in life¹⁰. Published reports on perforated peptic ulcers indicate increasing perforations for the elderly, those chronically ill and females, however our local observations are at variance¹¹. Retrospective review of patients operated for peptic ulcer perforations at Kenyatta National Hospital (KNH) in Nairobi from January 2005 to December 2006 concluded that perforated peptic ulcer disease is a disease of young males¹¹. Therefore, this study focused prospectively to look at incidence, types of perforated peptic Ulcer disease and outcome of their surgical management outcome as seen at Kenyatta national hospital.

2.0 LITERATURE REVIEW

2.1 Epidemiology

PUD encompasses both gastric and duodenal ulcers and other ulcers related to pepsin production located anatomically from the stomach and the duodenum. Ulcers are defined as breaks in the mucosal surface >5 mm in size, with extension to the submucosa. Duodenal ulcers (DUs) and gastric ulcers (GUs) share many common features in terms of pathogenesis, diagnosis, and treatment, but several factors distinguish them from one another¹². The rise and fall of peptic ulcer disease in the 20th century is still a riddle, even though the immediate understanding of the disease increased greatly with the discovery of the role of *H. pylori*¹³. Studies of ulcer mortality and ulcer perforation show a cohort pattern, which means that these ulcer manifestations are particularly common in certain high-risk generations^{8,9, 14}

The incidence of DUs declined steadily from 1960 to 1980 and has remained stable since then. The death rates, need for surgery, and physician visits have decreased by >50% over the past 30 years. GUs tend to occur later in life than duodenal lesions, with a peak incidence reported in the sixth decade. More than half of GUs occur in males and are less common than DUs, perhaps due to the higher likelihood of GUs being silent and presenting only after a complication develops¹². Autopsy studies suggest a similar incidence of DUs and GUs¹². Lifetime prevalence of PUD in the United States is ~12% in men and 10% in women. Moreover, an estimated 15,000 deaths per year occur as a consequence of complicated PUD. The financial impact of these common disorders has been substantial, with an estimated burden on direct and indirect health care costs of approximately \$10 billion per year in the United States¹². The incidence of perforated peptic ulcer disease in western countries is 7 – 9 per 100,000 population per year¹⁵. Perforation is one of the most catastrophic complications of PUD and it occurs in approximately 5% - 10% of PU patients^{16, 17, 18}. In Ethiopia, incidence of perforated peptic ulcer account for 3.4% of the adult emergencies³. The previous local experience has shown almost similar findings^{11, 19, 20}

2.2 Pathology and Clinical presentation

All perforated peptic ulcers are consequent to *H. pylori* infection, use of non steroidal anti-inflammatory drugs, and massive acid hypersecretions^{12,18,21}, the most common being the *H.pylori* and the NSAID, though there are other factors that include psychological, behavioral such as cigarette smoking. Not only have smokers been found to have ulcers more

frequently than the nonsmokers, but smoking appears to decrease healing rates, impair response to therapy, and increase ulcer-related complications such as perforation¹².

Perforated gastric ulcers are considered to be contaminated at time of perforation while duodenal ones are considered sterile within 12 hours of perforation, which could be one of the factors that lead to delayed presentation and therefore surgical intervention²².

There are three distinct types of perforations of duodenal ulcers that are encountered in clinical practice. The first, are the 'small' (<1cm in diameter) perforations that are easy to manage and have low morbidity and mortality. The second are the 'large' (1cm – 3cms in diameter) perforations, that are also not uncommon, and omental patch closure gives the best results even in this subset of patients. The third are 'giant' perforations that exceed 3cms in diameter and are extremely uncommon²³.

The results of omentopexy in small and large sized perforations give statistically similar results²³. The leak rates and mortality of the two groups after omentopexy remain comparable, thereby suggesting that this may be considered as the procedure of choice in all perforations up to a size of 3cms²³. Giant gastric ulcers are associated with failure on primary closures, therefore when one encountering such perforation one may be required to do partial gastrectomy with gastrojejunostomy²⁴.

Delayed treatment for peptic ulcer perforations poses significant consequences to individual patients as far as morbidity and mortality are concerned²⁵. Survival of patient depends on the time of perforation to the time of operation. Studies from Western countries have shown that there is an increase in time from perforation to operation²⁶. Other studies showed that the main presenting clinical features in patients with perforated PU were severe upper abdominal pain, severe nausea and vomiting, abdominal distension, abdominal tenderness, shock and generalized peritonitis²⁷.

2.3 Investigations

The clinical diagnosis of a patient with PPUD is mainly on history taking and physical examination, imaging and laboratory investigations. Imaging include plain abdominal and chest radiographs, abdominopelvic ultrasonographic scans, gastrointestinal (GIT) gastrografen, diagnostic laparoscopy and laboratory blood test⁵. In a study done in Nigeria, 42 patients who had plane abdominal and chest radiographs, 66.7% (28cases) demonstrated air under the diaphragm while 30 patients who had abdominopelvic ultrasonographic scans, 93.3% (28cases) showed free fluid into the peritoneal cavity²⁷. Routine blood count

examination may show leukocytosis and biochemical assays may depict serious electrolyte derangements such as metabolic acidosis¹¹. In questionable cases gastrografen can be introduced through Reyes tube to determine whether or not there is perforation¹¹. Laparoscopy is useful diagnostic tool and it offers advantage in that it can be therapeutic in same setting. Some of the perforations may seal spontaneously and patient continues to improve therefore explorative laparotomy is often necessary to confirm diagnosis in such scenario¹⁹.

2.4 Treatment of perforated peptic ulcers

Surgical intervention in PUD can be viewed as being either elective(for treatment of medically refractory disease) or as emergency¹²(for the treatment of an ulcer-related complication such as perforation).

The operative management of PPUD has hitherto been varied²⁸,but recently there is a definite shift from the traditional definitive peptic ulcer surgery to simple closure of the perforations with omental (Graham's) patch²¹. This is followed up postoperatively with *H. pylori* eradication and administration of proton pump inhibitors therapies. This approach is even more pertinent here, where patients present late with gross and fulminating peritonitis and therefore not suitable for definite peptic ulcer surgery^{4, 27}. The local study was limited to omental Graham patch repair¹¹, although this procedure has been associated with ulcer recurrence rates of up to 40%, the significant side effects of definitive ulcer surgery (dumping in 50% and diarrhea in 10%)²⁹ and the advent of efficacious medical treatment (proton pump inhibitors, H₂ receptor blockers *H. pylori* eradication), and triple therapy, the patch repair will remain popular. In Giant perforations provided patients' haemodynamically are stable and no other co morbidities partial gastrectomy and gastrojejunostomy has better outcome compared to primary closure with omental pedicle or free patch. In this series, 86% of cases recovered well while complications occurred to 10% and mortality of 5%. They concluded that partial distal gastrectomy and gastrojejunostomy is a better option, even in an emergency setting if the expertise is available²⁴.

2.5 Treatment complications

Early complications of treatment noted include pneumonia, haematemesis, atelectasis, diarrhea, iodine burns to the scrotal sac following preoperative prepping of the patient³⁰. Vagotomy and drainage techniques are safe and relatively effective in stopping bleeding but

have significant ulcer recurrence rates (10% to 15%)³¹. In contrast; vagotomy and resections such as antrectomy have a lower incidence of recurrence (less than 1%)³² but higher associated overall morbidity and mortality³³. Ugochukwu et al reported in his series post-operative complications 63.2%. The most frequent complication was surgical site infection 39.5%, pulmonary infection 13.2%, and continuing peritonitis 10.5%. Re-perforation 6.6% necessitated re-exploration and re-closure; of these patients few developed intra abdominal abscess and one a duodenal fistula. Overall 9.2% developed postoperative intra abdominal abscess. Cardiopulmonary arrest was recorded in 7.9% all of whom died. The cardiopulmonary arrest occurred a few minutes to a few hours after surgery either in the recovery room or Critical Care Unit. Continuing septic shock was recorded 7.9%, some of these developed acute renal shutdown and electrolyte imbalance, which led to their demise. Prolonged paralytic ileus was recorded 3.9% one of whom developed wound dehiscence. Overall 5.3% developed wound dehiscence or burst abdomen. Incision hernia occurred 3.9% at follow up²⁷.

3.0 STUDY JUSTIFICATION

Management of perforated peptic ulcer disease is Surgical. PPU is the second most frequent abdominal emergency requiring surgical treatment⁴. Delay in diagnosis and delayed initiation of surgical management of PPUD has clearly shown to be associated with high morbidity and mortality after surgery for perforated peptic ulcer disease^{5,6}. Early recognition, prompt diagnosis and aggressive resuscitation and early surgical intervention clearly aid in keeping the morbidity and mortality low⁷. Studies of ulcer mortality and ulcer perforation show a cohort pattern, which means that these ulcer manifestations are particularly common in certain high-risk generations^{8,9}, however, ulcer death and ulcer perforation represents only minor groups of subjects with peptic ulcer. Peptic ulcer disease follows a cohort pattern and that the susceptibility to peptic ulcer is established early in life¹⁰. Types of perforated peptic ulcer are small <1cm; large 1cm – 3cms; and Giant >3cms located either on stomach or duodenum²⁴. Retrospective series of patients who underwent emergency laparotomy at KNH following PPU from Jan 2005 to Dec 2006, 31.6% of the cases developed complications after treatment¹¹. Various complications were mentioned including deaths. In the series mentioned above they could not describe the types and the size of perforations. Therefore there is a justification of finding out the descriptive incidence; types and size of perforated peptic ulcers and their surgical management outcomes since there is no local studies so far that describe types of ulcer perforation and their surgical management outcome.

3.1 OBJECTIVES

3.1.1 Main objective

The main objective of this study was to determine the incidence, types and the outcome of surgical management of perforated peptic ulcers as seen at Kenyatta National Hospital

3.1.2 Specific Objectives

1. To determine duration of onset of severe symptoms of perforated PU to surgical intervention
2. To determine the incidence of perforated peptic ulcer disease
3. To describe the site and size of perforation intra operatively
4. To identify surgical technique used intra operatively
5. To determine the outcome of the surgical intervention

3.2 MATERIALS AND METHODS

3.2.1 Study design

This was a 9months prospective descriptive cross-sectional hospital based study

3.2.2 Study Area and population

The study was conducted at KNH. Patients were followed up from Accident and Emergency department to Main theatres, General surgical wards and later on in surgical outpatient clinics.

3.2.3 Inclusion criteria

- All patients who presented with signs and symptoms of acute perforated peptic ulcer disease in which intra operative findings confirmed perforations of the stomach or duodenum.

3.2.4 Exclusion criteria

- All patients whom intra-operative findings did not confirm perforation of peptic ulcers.
- All patients who had other perforations apart from stomach and Duodenum
- All patients who had traumatic or stab perforations.
- All patients who refused to be enrolled into the study despite of meeting inclusion criteria

3.2.5 Sampling method

Consecutive sampling method was employed. Patients and their next of kin (close relative) were informed about the study. Those who signed informed consent were enrolled.

3.2.6 SAMPLE SIZE ESTIMATION

Formulae for sample size calculations for a cross sectional descriptive study

$$n_0 = \left[\frac{1.96^2 p (1 - p)}{(d)^2} \right]$$

n_0 = Is the sample size (56)

p = Incidence of perforation 3.8%

d = level of precision ($\pm 5\%$)

1.96 is the z - score

Since patients admitted for peptic ulcer perforations in KNH are few (estimated average of 4 cases per month), the formula below is applied to adjust this for a finite population;

$$n = \left[\frac{n_0}{1 + \frac{n_0 - 1}{N}} \right]$$

n = is the sample size (22)

N = Number of patient in KNH undergoing the perforations in 9 months (36)

3.2.7 Data collection

Data was collected using pretested questionnaire.

Every patient who met the set criteria and signed informed consent for the study was enrolled for the study. Principle investigator sought informed consent from the participants who have been already diagnosed to have PPUD at accident and emergency department at time of admission to surgical wards. For those who were unable to read and write, informed consent administered under eyewitness who then justified that the patient has understood everything pertaining the study and has accepted to be enrolled into the study. Eyewitness and the patient both will sign on the consent. Patient put a thumbprint and the eyewitness a signature of his/her own. Standard ruler that is present in theatre laparotomy set measured the size of perforation. All emergency surgical management of the patients was done by the registrars under the close supervision of the two senior consultant surgeons appointed to supervise the

surgical management intra-operatively by principal researcher. These were competent, qualified Consultant Surgeons, lecturers at the University of Nairobi.

The study was conducted for a period of 9 months.

3.2.8 Ethical consideration

The study commenced after approval by UON/KNH Ethics and Research Committee. Informed consent obtained by principle investigator from each participant after explaining purpose of study, risks and benefits to the patient immediately after the diagnosis of PPUD is made at accident and emergency department. Those who declined participation were not denied the surgical management they deserved.

No extra costs incurred for participants in the study. Confidentiality maintained at every stage.

3.2.9 Data management

Data from questionnaires were entered into Epi-data software and then exported to the SPSS for analysis. Data editing and reconciliation including coding and cross tabulation were undertaken before analysis was done.

3.2.10 Study Limitation

1. Short duration of the study compared to number of cases found.
2. Small sample size due to low rate of cases attributed to the short duration of the study.
We would like to combine the prospective and retrospective data in this study but unfortunately ethically the information we were to look in retrospective cases would not tally with the prospective cases therefore the retrospective cases were not included in the study hence small sample size
3. Small sample size statistically may not prove everything.

4.0 RESULTS

Data collection began August 2014. A total number of cases recruited were 22 cases in a period of 9 months (August 2014 to April 2015).

The study involved 1165 cases seen in medical outpatient clinic (MOPC), who were being followed for peptic ulcer disease, or chronic gastritis secondary to chronic use of NSAIDs due to rheumatoid arthritis (total population at risk). The cumulative incidence (CI) therefore for the past 9 months of this study was calculated as follows:

$$CI = \frac{\text{number of new cases of a disease during a given period of time}}{\text{Total population at risk}}$$

Note:

$$\text{Number of new cases} = 22$$

$$\text{Total population at risk} = 1165$$

Therefore;

$$CI = 22/1165$$

$$CI = 0.019 \text{ (estimated in nearest 3 decimal places)}$$

$$CI = 19/10^3 \text{ person-years}$$

The cumulative incidence CI was 19 per a thousand person-years

Table 1: The age distribution of the patients were as shown below

Age group	Frequency	Percent
20 - 24 yrs	4	18%
25 - 29 yrs	5	23%
30 - 34 yrs	3	14%
35 - 39 yrs	2	9%
40 - 44 yrs	3	14%
45 - 49 yrs	2	9%
60 - 64 yrs	2	9%
75 - 79 yrs	1	4%
Total	22	

It was noted that ages of participants were as low as 22 years and as high as 76 years old, whom were categorized in age groups of interval of 5 years. The common age group found

was between 25 to 29 years, which has 23% (5cases) followed by 18% of age group of between 20 to 24 years. See the graph below;

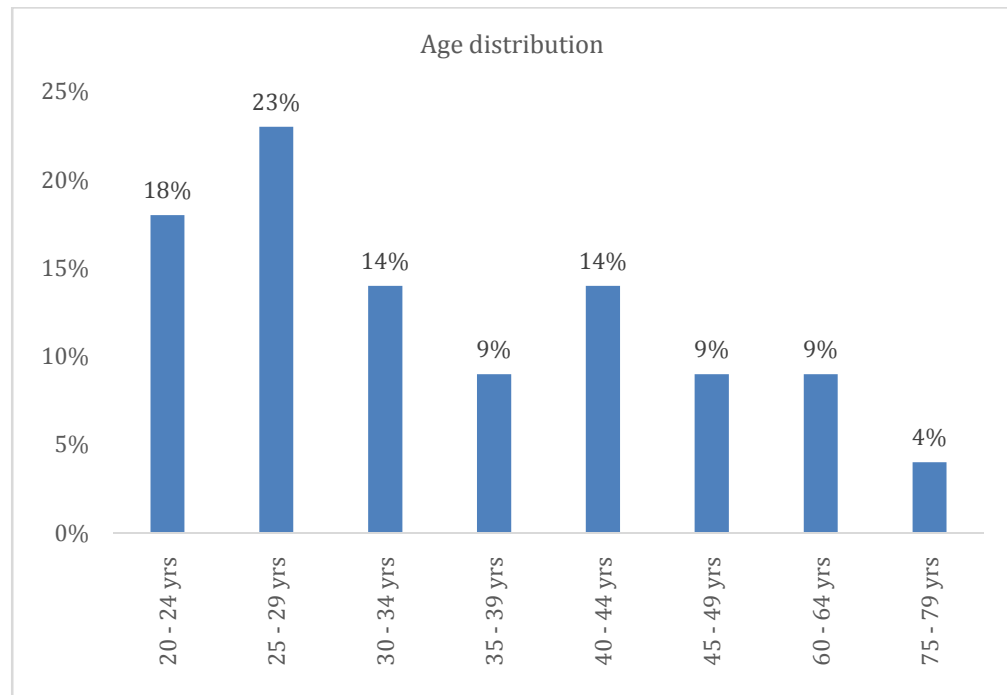


Figure 1: shows age distribution of the patients

Table 2 reflected the frequency distribution table of symptoms of acute onset of pain to Surgical intervention.

Estimated time	Frequency	Percentage
0-12hrs	2	9%
12 - 24 hrs	8	36%
25 - 48 hrs	6	27%
49 - 72 hrs	3	14%
>72hrs	3	14%
Total	22	100%

45% (10 cases) of patients presented at accident and emergency department with symptoms of severe sudden onset of the abdominal pain were operated within 24hours of the onset of severe symptoms. Among them 9% were operated within the first 12hours while 36% were operated within 12 to 24hours. 55% (12cases) were operated 24hours, 48hours and some even after 72 hours post onset of severe symptoms. This means that, 27% were operated

between 25 – 48hours after severe symptoms started, 14% were operated between 48 – 72hours after severe symptoms and 14% were operated 72hours after the sudden onset of severe symptoms.

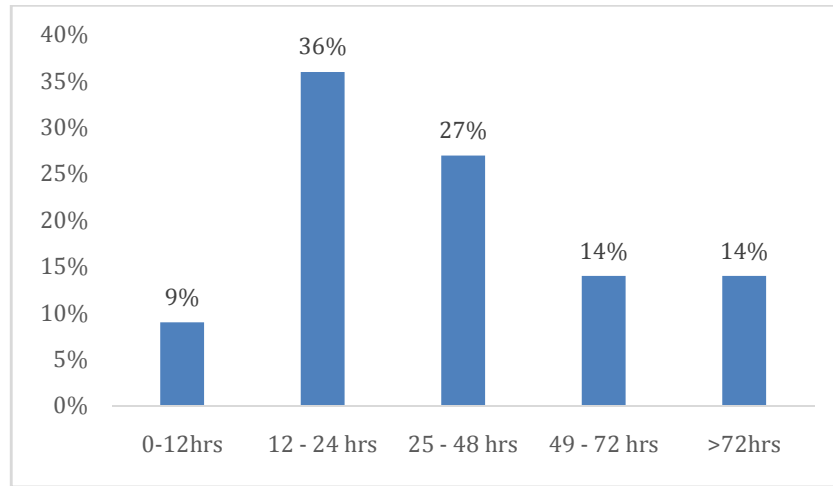


Figure 2: Bar chart showing estimated time of acute onset of pain to surgical intervention

Table 3: frequency distribution table of location of perforation shown below

Where was the perforation located	Freq.	Percent	Cum.
Anterior stomach	1	4.54	4.54
Anterior antral	3	13.64	18.18
1 st part of duodenum anterior	18	81.82	100.00
Total	22	100.00	

Three anatomical locations of perforations have been seen in this study. These include; anterior part of the stomach, anterior antral area, and first part of duodenum anteriorly with the percentage of 4.54%, 13.64% and 81.82% respectively. This shows that the commonest site of perforation in this study is the first part of duodenum anteriorly.

Table 4; different type of perforation in terms of size, percentage and cumulative percentage

Size	Frequency	Percentage
<1cm	8	36%
1cm- 3cms	14	64%
Total	22	

In this study, we found two types of perforations. 36% were perforations that were less than 1cm in diameter, while others were large perforations (1-3cms) comprised of 64% of all cases found.

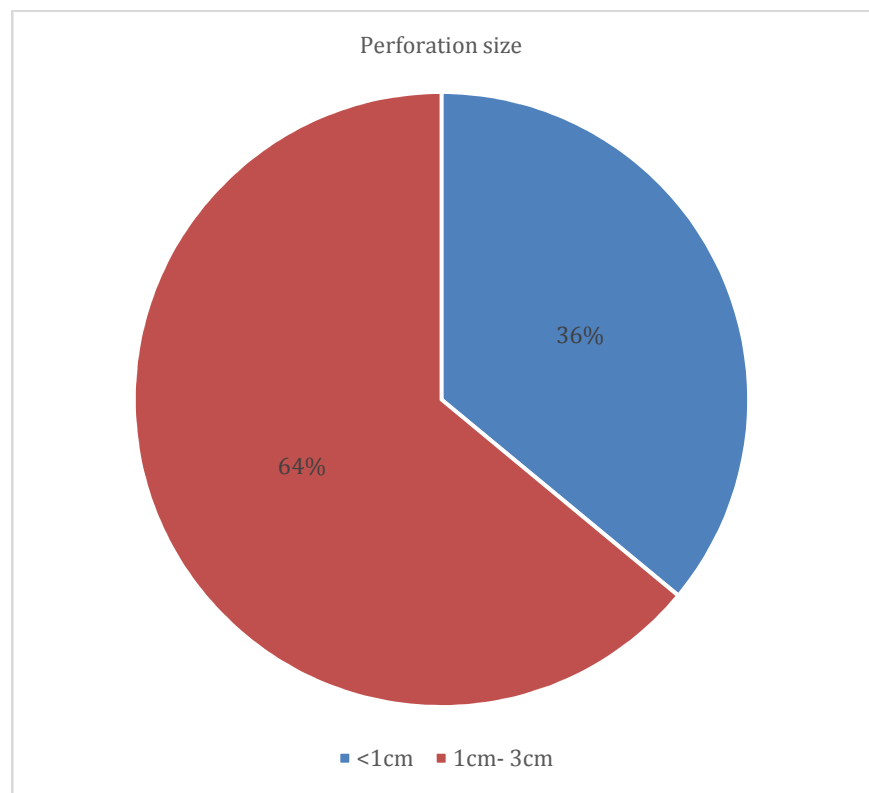


Figure3: pie chart showing percentage of the perforations sizes found

Table 5; surgical technique used to treat perforation

Technique used to treat Perforation	Freq.	Percent	Cum.
Primary closure with omental patch	22	100.00	100.00
Total	22	100.00	

All cases that were seen regardless of their size of perforation, they were all undergone primary closure with omental patch, famous known as Graham’s patch

Table 6; outcome of surgery assessed as number of days spent in the hospital / death

Outcome of Surgery(hospital stay)	Freq.	Percent	Cum.
0-7 days	11	50.00	50.00
8-14 days	7	31.82	81.82
>22 days	3	13.64	95.46
Died (0 - 7 days)	1	4.54	100.00
Total	22	100.00	

50% were discharged home within the first week postoperative day, 31.82% were discharged home following the second week postoperative and 13.64% were discharged home after third week postoperative day. Mortality was 4.54% (1case) that occurred on the first week postoperative.

Table 7: The table below shows frequency of complications noted after surgical intervention.

	Frequency	%
No complications occurred	13	62%
Surgical site infection	4	19%
Burst abdomen	1	5%
Intra abdominal abscess	2	10%
Leaking	1	5%
Total	21	100%

The table above shows 21 cases that were analysed; there was mortality of 1 case that died within 2days post operative hence excluded from the analysis table above.

Out of 21 cases, 62% Of all cases had no complications. 19% had surgical site infection, 5% developed burst abdomen, and 10% had intrabdominal abscess while 5% leaked post graham’s patch.

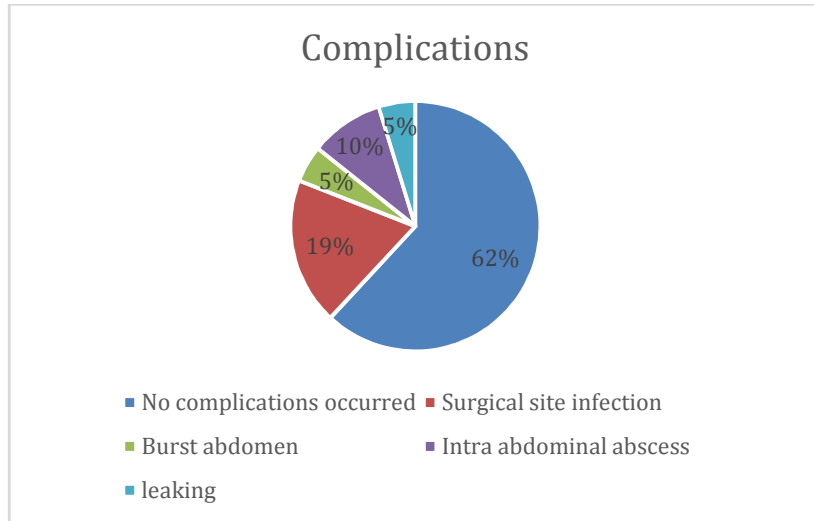


Figure 4: Pie chart showing percentage of the complications found

Table 8. The table below shows association between anatomical location of perforation and the complication noted

Location of perforation	Complications noted (freq/percentage)					Total
	No complication	Surgical site infection	Burst abdomen	Intra abdominal abscess	Others	
Anterior stomach	1	0	0	0	0	1
	100.00	0.00	0.00	0.00	0.00	100.00
Anterior antral	1	0	0	0	1	2
	50.00	0.00	0.00	0.00	50.00	100.00
1st part of duodenum anterior	12	4	1	2	0	19
	63.16	21.05	5.26	10.53	0.00	100.00
Total	14	4	1	2	1	22
	63.64	18.18	4.55	9.09	4.55	100.00

Fisher's exact test = 0.448

Total number of cases analyzed was 22. Out of these cases 63.16% (12cases out of 19 cases) who had perforation at the first part of duodenum had no complications, while 21.05% (4cases) had surgical site infection (SSI), 10.53% (2cases) had intra abdominal Abscess, and

5.26% (1case) had burst abdomen. 50% of the cases that presented with anterior antral perforation had no complications while the remaining 50% had other complications including death.

100% (1 case) of the cases presented with anterior stomach perforations had no complications.

In a nut shell, out of 22 cases, 63.64% had no complications while the remaining 36.36% had various complications such as SSI 18.18%, Burst abdomen 4.55%, Intra abdominal abscess 9.09%, and 4.55% other complications including death post surgery.

There is no statistical significance in association between site of perforation and complication that arisen among the study group, Fisher’s Exact test of 0.448

Table 9: comparison between the locations and the complications noted shown on the table below

	Overall (all patients) N = 21			
	Anterior stomach n = 1	Anterior Antral n = 2	First part of duodenum n= 18	P – value
Complication				
No complication:	1 (8)	1 (8)	11 (84)	0.205
Surgical site infection:	0 (0)	0 (0)	4 (100)	
Burst abdomen:	0 (0)	0 (0)	1 (100)	
Intra-abdominal abscess:	0 (0)	0 (0)	2 (100)	
Leaking:	0(0)	1 (100)	0 (0)	

Table 9 shows a comparison between the locations and the complications noted before discharge. There was no statistically significant difference in the development of complications and the location of the perforation (p =0.205). 1 case could not be analyzed. Patient died second postoperative day and the cause of death was not established.

Table 10: comparison between the size of perforation and the outcome (hospital stay)

	Overall (all patients) N = 21		
	<1cm N = 8	1 – 3 cm N = 13	P – value
Outcome (hospital stay)			
Discharged after 0-7 days:	3 (27)	8 (73)	0.214
Discharged after 8 -14 days:	3 (43)	4 (57)	
Discharged after 15 -21 days:	0 (0)	1 (100)	
Discharged after 21 days:	2 (100)	0 (0)	

Table 10 shows a comparison between the size of perforation and the outcome. There was no statistically significant difference in the outcome in the two groups (p =0.214).

Table 11: comparison between the size of perforation and the complications noted

	Overall (all patients) N = 21		
	<1cm N = 8	1 – 3 cm N = 13	P – value
Complication			
No complication:	5 (39)	8 (61)	0.618
Surgical site infection:	1 (25)	3 (75)	
Burst abdomen:	1 (100)	0 (0)	
Intra-abdominal abscess:	1 (5)	1 (50)	
Leaking:	0 (0)	1 (100)	

Table 11 shows a comparison between the size of perforation and the complications developed prior to discharge of patients from KNH. There was no statistically significant difference between the developed complications and size of perforation noted (p =0.618).

Table 12: comparison between the outcome (hospital stay) and the estimated time from the onset of severe abdominal pain to surgical intervention has shown below.

	Overall (all patients) N = 21				P value
	Discharged after 0-7 days n = 11	Discharged after 8 -14 days n = 7	Discharged after 15 -21 days n = 1	Discharged after 21 days n = 2	
Estimated time					0.013
0 – 12 hrs:	2 (100)	0 (0)	0 (0)	0 (0)	
12 – 24 hrs:	4 (50)	3 (37)	1 (13)	0 (0)	
25 – 48 hrs:	4 (67)	2 (33)	0 (0)	0 (0)	
49 – 72 hrs:	1 (33)	2 (67)	0 (0)	0 (0)	
>72hrs:	0 (0)	0 (0)	0 (0)	2 (100)	

Table 12 shows the comparison between the outcome (hospital stay) and the estimated time (hrs) from the onset of severe abdominal pain to surgical intervention. There is significant difference between the outcome and the estimated time from the onset of abdominal pain P (0.013).

The earlier the better outcome while those who came late stayed more days in the hospital

Table 13: comparison between the estimated time (in hours) from the onset of severe abdominal pain and complications noted.

	Overall (all patients) N = 21					
	No complication n = 13	Surgical site infection n = 4	Burst abdomen n = 1	Intra abdominal abscess n = 2	Leaking n = 1	P – value
Estimated time						
0 – 12 hrs:	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0.070
12 – 24 hrs:	4 (50)	2 (25)	0 (0)	1 (12.5)	1 (12.5)	
25 – 48 hrs:	6 (100)	0 (0)	0 (0)	0 (0)	0 (0)	
49 – 72 hrs:	1 (33)	2 (67)	0 (0)	0 (0)	0 (0)	
>72hrs:	0 (0)	0 (0)	1 (50)	1 (50)	0(0)	

Table 13 shows the comparison between the estimated time (hrs) from the onset of severe abdominal pain to surgery and the complications noted. There is no statistically significant difference between the two variables $p= 0.070$.

5.0 DISCUSSION

Incidence of perforated peptic ulcers differs from one geographic location to another. Incidence of PPU in the western countries is different from developing countries such as Kenya. Thors et al looked at the incidence of PPU during the period 1962 - 1990 and found that the incidence to be $11/10^3$ per year. This incidence was fairly similar among men and women³⁴. Jani et al reported 65 cases of perforated peptic ulcers in duration of 64 months (January 1980 – April 1985)²⁰. Chalya L.P et al reported 17cases of PPU per year in northwestern Tanzania³⁵ while Ugochukwu A.I et al reported 15cases of PPU per year in southeast Nigeria²⁷. The two studies above are similar in findings as Schein et al in South Africa who retrospectively analysed 99 cases in a period of 6years³⁶. Nasio et al reported a total number of 44 cases of PPU disease in a period of 2years¹¹. In this study, the incidence of PPU is found to be $19/10^3$ person years in a period of 9 months and recruited cases were all male patients. This finding shows that males are more affected by the disease than female.

The observations of current study indicate predominant male gender is more associated with perforated peptic ulcer disease; this observation is similar to the previous study done by Nasio et al¹¹. In this current study there was no single female patient recruited in the past 9 months of the study conducted.

Buck et al reported in their study that 26.5% of cases died within the 30 days of surgery, and this was attributed by the delay of patients from admission to surgery. They reported that every hour delay from admission to surgery was associated with an adjusted 2.4% decrease in probability of survival compared with previous hour³⁷.

In the current study, 45% of all patients who presented in the hospital were operated within the first 24hrs unlike the similar study done on the same setting 10yrs ago whereby 23.8% who presented with severe symptoms were operated on the first 24hrs¹¹.

In this study, 27% of patients presented on the second day post onset of severe symptoms and were operated within the same time (25 – 48hrs), while the remaining 28% presented after 48hrs and were operated within similar time (*ref. figure 2*). In this study we did not explore for the reason(s) of the delayed presentation to the hospital.

The late presentation of the patients to the hospital and from admission to surgery was associated with complications that either lead to an increase of hospital stay or death of the patients. In the current study, the late presentation of the patients has shown to have

significant impact on the hospital stay with the p value of 0.013. This finding is tallying with several other studies that were carried out within the same setting, region, and as well as the western countries^{5,11,20,35,37}.

Gupta S et al in 2001 - 2003 described three major group of perforation depending on the size of perforations, the small perforations (< 1cm), the large perforations ($\geq 1\text{cm} \leq 3\text{cms}$), and giant perforations (>3cms)²³. Chalya et al, Ugochukwu et al found that the sizes of perforations were ranging from 2mm to 2cms with the mean size of perforation being 5.4mm^{27,35}. In the current study we have found only two types of perforations, the small and the large perforations. Due to the shortest period of time we could not manage to find any of the giant perforations in this study.

Several studies have reported commonest site of perforation to be on the anterior duodenum, followed by gastric perforation, which may be antral, or body of stomach, and posterior duodenal perforation^{23,24,35}. In the current study we have noticed three main perforation sites; first part of the duodenum anteriorly (anterior aspect of duodenal bulb), anterior antral area and the body of stomach anteriorly with percentage 81.82%, 13.64% and 4.54% respectively. These findings are nearly similar to the previous studies mentioned above.

There are several techniques employed in the management of perforated peptic ulcer disease. These surgical techniques depend on the size of perforation found. In a small perforations (<1cm) can generally be closed primarily and buttressed with a well-vascularized omentum. For larger perforations ($\geq 1\text{cm} \leq 3\text{cms}$), a Graham patch repair with tongue of healthy omentum is performed. For very large perforations (>3cm) control of the duodenal defect can be difficult and so therefore the defect should be closed by the application of the healthy tissue such as omentum or jejunum-serosal, with placement of duodenostomy tube and wide drainage. In this situation there is a likelihood of leakage of gastric contents into the drainage tube but in most cases the sepsis will resolve. An alternative to these difficult situations is antrectomy and a Bilroth II reconstruction for the stable patients or when symptoms are controlled after damaged control surgery³⁸. Onur et al reported 3 cases of giant perforations (>3cm) that were managed successful with tube duodenostomy instead of complex procedures such as Bilroth II reconstructions. In their series several techniques employed including pylorus exclusion with gastro-jejunostomy in order to avoid leak from the repaired duodenum. In some occasion they have even restored feeding jejunostomy and tube gastrostomy to avoid leak from the duodenostomy tube. Pawanindra et al also reported 100%

success in managing giant duodenal perforations using tube duodenostomy compared to the 30% control of the convention management of duodenal ulcer perforations^{39, 40}.

Studies have shown different surgical techniques that are done when encountering different sizes of perforations. Small and large perforations are easily managed with simple omental patch famous known as Graham's patch^{5, 10, 11, 19, 22, 23, 27, 34, 35}, while giant perforations requires partial gastrectomy and gastrojejunostomy in either emergency setting provided that patients' status is stable and expertise are available or under elective procedures²⁴. In our study all patient fell under small and large perforations that were sorted out by Graham's omental patch alone. No other surgical techniques used such as tube duodenostomy, Billroth I&II, pylorus exclusion, jejuno-serosal patch and others employed throughout the study period to deal with the sizes of perforation noted. In this study there was no single patient that was operated under laparoscopic procedure but laparotomy through upper midline incision.

The surgical outcome depends on the individual patient presentation to the hospital. Hospital stays and complications developed were the main factors, which were looked at in many studies. Late presentation of the patients was associated with prolonged morbidity and even mortality after surgical intervention. Some studies reported the following complications; SSI, wound dehiscence, continuing sepsis and septic shock, intra-abdominal abscess, pulmonary infection, cardiopulmonary arrest, duodenal and gastric fistulas or leaking of enterocontents, acute renal shut down, paralytic ileus, acute renal failure, enterocutaneous fistula, peritonitis, incisional hernia, re-perforation and many others^{11, 27, 35}.

In this study, surgical outcome was measured by, the number of days patients spent in the hospital, and the complications developed. 50% of the patients were discharged home in \leq 7days, 31.82% discharged home in the following week \leq 14 days, 4.54% in \leq 21days, 9% \geq 21days, and we had mortality of 4.54% that occurred within the first week after surgical intervention.

In this study 59% of the cases had no complications noted and therefore were discharged home in the first 10 days. The complications noted were; SSI was noted in 18.18%, wound dehiscence/burst abdomen in 4.54%, and intraabdominal abscess 9%, leaking was noted in 4.54% and mortality was 4.54%.

Comparison between onset of severe symptoms to surgical intervention and hospital stays has shown that there was statistical significant (P value 0.013). Late presentation to hospital after

the onset of severe symptoms leads to the poor outcome, (table 12). Like wise in comparing estimated time from the onset of severe symptoms to surgery against the complications noted shows that there was no statistical significant (P value 0.07).

6.0 CONCLUSION

The incidence of perforated peptic ulcer disease is low in our set up. Most of these cases present at first time in an emergency department without a warning of previous history of peptic ulcer disease. It is the disease that occurs predominantly in young males between 20 and 40 years.

Majority of the cases in this study presented early and therefore favors the good outcome. The commonest encountered perforations in our set up are the anterior duodenal bulb perforations followed by anterior gastric perforations.

The size of perforations ranged from 5millimeters to 30millimeters and these types of perforations are best treated with simple Graham's omental patch.

Common complications encountered were SSI, wound dehiscence/burst abdomen, intraabdominal abscess, and leaking that cause increase duration of hospital stay

6.1 RECOMMENDATION

- Small to large perforation may be sorted out by a simple procedure that is safe and takes shorter time to perform. Therefore Graham's omental patch is the ideal procedure recommended than the definitive ulcer surgery in an Emergency setting.
- The cases that present early and are haemodynamically stable require surgery within the first twelve hours in order to achieve good surgical outcome.
- There should be either large similar study within KNH or a multi centered study that may take more time to recruit larger sample size so as to give the trends of perforated peptic ulcer morbidity and mortality in Kenya.

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APPENDICES

APPENDIX I A: CONSENT INFORMATION SHEET (ENGLISH VERSION)

This informed consent is for patients planned to undergo emergency surgeries following Perforated peptic ulcer disease in the study titled; “INCIDENCE, TYPES AND THE OUTCOME OF SURGICAL MANAGEMENT OF PERFORATED PEPTIC ULCERS AS SEEN AT KENYATTA NATIONAL HOSPITAL”

Principal Researcher; **Dr Alpha Ajuaye Kinghomella**

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

This informed consent has three parts

1. Information about the research
2. Certificate of consent
3. Statement by the researcher

You will be given a copy of the full informed consent in either English version or Kiswahili version.

PART 1

Introduction

My name is Dr. Alpha Ajuaye Kinghomella, a postgraduate student at the University of Nairobi, school of medicine department of surgery, pursuing masters of medicine in general surgery. I am carrying out a study to determine the INCIDENCE, TYPES AND THE OUTCOME OF SURGICAL MANAGEMENT OF PERFORATED PEPTIC ULCERS AS SEEN AT KENYATTA NATIONAL HOSPITAL

Purpose of the study

Perforated peptic ulcers are one of the encountered complications of peptic ulcer disease. It is one of the common surgical emergencies seen frequently at KNH. Studies have shown that perforated peptic ulcer disease has been constant throughout the past three decades despite the introduction of drugs such as H₂receptor antagonists and proton pump inhibitors. Therefore the purpose of this study is to determine the incidence, types and the outcome of surgical management of perforated peptic ulcers as seen at KNH.

This information I am sharing with you as I invite you to participate in this study. Any information, which is not clear, you're allowed to ask for clarification.

Type of research intervention

This study will involve preoperative intra-operative and postoperative follow-up. All the patients presenting with features of perforated peptic ulcer disease that are seen at casualty (accident and emergency) will be advised to participate in the study as soon as the diagnosis of perforated PUD is made. The principle investigator will ask you or the next of kin or close relative a series of questions. These questions will be directly concerning your (patient's) disease from the onset of illness to the time of surgery as well as during recovery and post-surgical management.

Confidentiality and dignity

The information obtained will be treated with confidentiality and will be available to the principle investigator and authorized medical fraternity. Your name will not be used; instead you will be assigned a number on your response as per questionnaire.

You are entitled to be treated with dignity and respect.

Sharing the results

The analyzed data from this study will be shared with clinicians and other relevant health care workers, policy makers within KNH/UON and ministry of health.

Cost

There will be no extra cost incurred for participating in this study.

Study approval

This Research proposal has been reviewed and approved by UON/KNH ethics committee.

This is a committee tasked with making sure that research participants are protected from harm.

For any further enquiry about the study, you may contact the following;

- Principal Researcher:

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Mobile no. 0713082384

- University of Nairobi Supervisors:

- **Prof. Jani Pankaj G**

M.B.Ch. B, M. Med (Surg), F.R.C.S (Glasgow), Sub-Speciality:
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- **Prof. Ndaguatha Peter L. W,**

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Professor of General Surgery and Urology

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

P.O. Box 19676 KNH, Nairobi 00202.

Mobile no. 0722 314533

- If you have any ethical concerns, you may contact:
 - **Secretary,**
KNH/UoN-ERC,

P.O. Box 20723 KNH, Nairobi 00202

Tel +254-020-2726300-9 Ext 44355

Email: KNHplan@Ken.Healthnet.org

Part 2

CERTIFICATE OF CONSENT

If able to read and write

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it which been answered to my satisfaction. I consent voluntarily to participate as a study participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date

If unable to read and write

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

Thumbprint of participant

Print Name of witness _____

Signature of witness _____

Date _____



PART 3

STATEMENT BY 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 shared with medical fraternity as well as policy makers and also published in relevant medical journals.

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

Signature of researcher

Date.....

**APPENDIX I B: CONSENT INFORMATION SHEET (KISWAHILI VERSION)
FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI**

Fomu hii ya makubaliano inahusisha wagonjwa ambao wanahudumiwa kwenye kitengo cha upasuaji katika hospitali ya KNH. Wamealikwa kujiunga Na utafiti “INCIDENCE, TYPES AND THE OUTCOME OF SURGICAL MANAGEMENT OF PERFORATED PEPTIC ULCERS AS SEEN AT KENYATTA NATIONAL HOSPITAL”

Mtafiti: Dkt Alpha Ajuaye Kinghomella

Kituo: Shule ya Utabibu, Idara ya Upasuaji, Chuo Kikuu cha Nairobi

Fomu hii ya makubaliano Ina sehemu tatu;

1. Habari itayokukusaidia kukata kauli
2. Fomu ya makubaliano(utakapo weka sahihi)
3. Ujumbe kutoka kwa mtafiti

Utapewa nakala ya fomu hii.

SEHEMU YA KWANZA

Utambulisho (kitambulizi)

Kwa jina ninaitwa Dkt Alpha Ajuaye Kinghomella, niko katika chuo kikuu cha Nairobi, shule ya utabibu, idara ya upasuaji ambapo nasomea upasuaji. Utafiti wangu wahuu “INCIDENCE, TYPES, AND THE OUTCOME OF SURGICAL MANAGEMENT OF PERFORATED PEPTIC ULCERS AS SEEN AT KENYATTA NATIONAL HOSPITAL”

Nia ya Utafiti Huu

Vidonda vya tumbo hutoboa matumbo. Hii ni mojawapo ya hatari zinazoletwa na vidonda vya tumbo. Upasuaji wa dharura hufanywa mara kadhaa hapa katika hospitali kuu ya Kitaifa ya Kenyatta. Mahali pengine duniani utafiti umeonesha kuwa kwa takribani miaka thelathini sasa kupita ugonjwa huu umebakia kuwa kama hapo awali japokuwa kuna madawa ya kutibu ugonjwa huu kama H₂receptor antagonists na proton pump inhibitors (PPIs). Hivyo basi, nia kubwa ya utafiti huu ni kujua “matukio (incidence), aina, na matokeo ya upasuaji wa dharura wa vidonda vya tumbo vilivyotoboa matumbo hapa katika hospitali ya Kitaifa ya Kenyatta”

Matokeo ya utafiti huu yatachangia kujua incidence, types, and the outcome of surgical management of perforated peptic ulcers kama wanavyoonekana katika Hospitali ya Kitaifa ya Kenyatta. Habari ambayo nawasiliana nawe kushiriki kwenye utafiti. Una uhuru wa kuuliza maswali na ufafanuzi mahali ambapo hujaelewa.

Aina ya utafiti

Utafiti huu utahusisha kumchunguza mgonjwa kabla, wakati wa upasuaji (ndani ya chumba cha upasuaji), na baada ya upasuaji (wodini). Wagonjwa wote wanaogundulika kuwa na tatizo hili na ambao wameonekana katika idara ya wagonjwa waliozidiwa (casualty) wanaalikwa kushiriki na utafiti huu.

Mtafiti mkuu atahojiana na wewe mgonjwa ama ndugu wa karibu (next of kin) kupitia dodoso (questionnaire) lililo na maswali juu ya ugonjwa wako.

Usiri na hadhi

Habari ambayo tutapata kutoka kwa utafiti huu ni ya siri na itakuwa wazi kwa mtafiti mkuu na wadhamini (supervisors) wake. Jina lako halitatumikiwa ila nambari maalumu juu ya majibu katika dodoso (questionnaire).

Kwa wakati wa utafiti utashughulikiwa kwa hadhi na heshima.

Ugavi wa matokeo

Matokeo ya utafiti itasambazwa kwa madaktari na wahusika wengine kwenye kitengo ya afya. Habari hii pia itasambazwa kwa wapanga sera kwenye hospitali na wizara ya afya.

Kuhusu Gharama

Hakuna gharama zaidi katika kushiriki katika utafiti huu.

Kuhusu Pendekezo la Utafiti

Pendekezo la Utafiti huu limechunguzwa na kupewa kibali na kamati Utafiti ya chuo kikuu cha Nairobi ikishirikiana na hospitali ya Kenyatta. Kamati ina jukumu ya kuhakikisha ya kwamba washiriki wote kwenye utafiti huu, haki yao imelindwa.

Kwa taarifa zaidi waweza wasiliana nasi kupitia anuani zifuatazo;

Wasiliana na

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SEHEMU YA PILI

Fomu ya Makubaliano

Wanaojua kusoma na kuandika

Nimeelezwa utafiti huu kwa kina. Nimekubali kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumuuliza mtafiti mkuu au watafiti waliotajwa hapo awali.

Jina la Mshiriki.....

Sahihi ya mshiriki.....

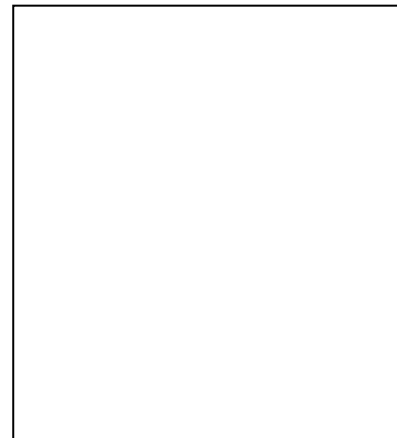
Tarehe.....

Kwa wasioweza kusoma na kuandika:

Nimeshuhudia kusomewa 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 hautamzuia kupata matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu inaweza chapishwa kutoa habari kuhusu maambukizi katika upasuaji wa tumbo wadharura.

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

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti _____

Sahihi ya Mtafiti _____

Tarehe _____

APPENDIX II : RESPONDENT QUESTIONNAIRE

IDENTIFICATION NUMBER

A: DERMOGRAPHIC DATA

101. Gender.....M/F

102. Age (in full years).....

B: SYMPTOMS PRESENTED

201. History of peptic Ulcer Disease (a) YES (b) NO

If YES, for How long / Duration

202. History of epigastric pain (a) YES (b) NO

If YES, for how long/ Duration.....

203. History of Obstruction (a) YES (b) NO

If YES, give duration.....

204. History of sudden onset of severe abdominal pain. (a) YES (b) NO

If YES, Estimate time / Duration from Onset of severe symptoms to surgery.....

Give reason(s) for the delay coming to the hospital.....

D: INTRAOPERATIVE FINDINGS AND POSTOPERATIVE FINDINGS

301. What was the operation?

- i. Exploratory laparotomy
- ii. Laparoscopy

302. Where was perforation located?

- i. Anterior stomach body
- ii. Anterior antral area
- iii. Posterior stomach body
- iv. Posterior Antral area
- v. First part of duodenum anterior
- vi. First part of duodenum posterior
- vii. First part of duodenum lateral
- viii. Second part of duodenum anterior
- ix. Second part of duodenum posterior
- x. Second part of duodenum lateral
- xi. Lesser curve at incisura
- xii. High on lesser curve
- xiii. Prepyloric

303. Size of perforation noted intraoperatively i) <1cm ii) 1cm – 3cms iii) >3cms

304. What technique used to treat perforation?

- i. Resection of edges and primarily closure with tube duodenostomy
- ii. Resection of edges and primarily closure with omental patch (Graham's patch)
- iii. Resection of edges and primary closure with jejunum-serosal patch
- iv. Billroth I partial gastrectomy
- v. Billroth II gastrectomy
- vi. Pylorus exclusion with gastrojejunostomy

305. Outcome of surgery,

- i. Discharged home after 0 – 7days
- ii. Discharged home after 8-14days
- iii. Discharged home after 15 – 21days
- iv. Discharged home 22days and above
- v. Died (specify time from surgery)

306. Complication(s) Noted prior to discharge

- i. No complications occurred
- ii. Surgical site infection
- iii. Burst abdomen
- iv. Enterocutaneous fistula
- v. Intra abdominal abscess
- vi. Leak
- vii. Others (mention)

LETTER OF APPROVAL FROM KNH/UON -ERC



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Ref: KNH-ERC/A/350

Link: www.uonbi.ac.ke/activities/KNHUoN

23rd October 2014

Dr. Alpha A. Kinghomella
Dept. of Surgery
School of Medicine
Kenya University

Dear Dr. Kinghomella

Research proposal- Incidence, types and the outcome of surgical management of perforated peptic ulcers as seen at Kenyatta National Hospital (P378/06/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 23rd October 2014 to 22nd October 2015.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN.

Protect to discover



Yours sincerely

PROF. M.L. CHINDIA
SECRETARY, KNH/UON-ERC

- c.c. The Principal, College of Health Sciences, UoN
- The Deputy Director CS, KNH
- The Chair, KNH/UoN-ERC
- The Assistant Director, Health Information, KNH
- The Dean, School of Medicine, UoN
- The Chairman, Dept. of Surgery, UoN
- Supervisors: Prof. Jan Fankaj, Prof. Ndaguatha

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