THE PRACTICE OF INTERVENTIONAL GASTRO INTESTINAL ENDOSCOPY AT KENYATTA NATIONAL HOSPITAL.

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A dissertation submitted in part fulfillment of the requirements for the award of the degree of master of medicine in general surgery of the University of Nairobi.

DECLARATION.

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

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ABBREVIATIONS.

APC – Argon Plasma Coagulation.

ASGE – American Society for Gastrointestinal Endoscopy.

BSG – British Society of Gastroenterology.

CBD – Common Bile Duct.

EFTR – Endoscopic Full Thickness Resection.

EMR – Endoscopic Mucosal Resection.

ERCP – Endoscopic Retrograde Cholangio Pancreatography.

ESD – Endoscopic Sub Mucosal Dissection.

ESGE – European Society of Gastrointestinal Endoscopy.

EUS – Endoscopic Ultrasound.

EVBL – Endoscopic Variceal Band Ligation.

GERD – Gastro Esophageal Reflux Disease.

GI – Gastro Intestinal.

HIV – Human Immunodeficiency Virus

KNH – Kenyatta National Hospital.

NOTES- Natural Orifice Transluminal Endoscopic Surgery

OGD – Oesophago Gastro Duodenoscopy (EGD).

OGIB - Obscure Gastro Intestinal Bleeding.

PEG – Percutaneus Endoscopic Gastrostomy.

PUD – Peptic Ulcer Disease.

RFA – Radio Frequency Ablation.

SAGES Society of American Gastrointestinal and Endoscopic surgeons.

SEMS – Self Expandable Metal Stents.

UoN – University of Nairobi.

ABSTRACT.

Background: The gastrointestinal system contributes a large proportion of diseases encountered in daily clinical practice. Interventional endoscopy allows diagnosis and treatment of gastrointestinal diseases with added benefits of minimally invasive therapy. Available interventional GI endoscopy procedures and their outcomes remain unknown in our set up.

Objective: To describe the practice of interventional GI endoscopy at Kenyatta National Hospital.

Study design: This was a prospective descriptive study.

Study setting: The study was carried out at Kenyatta National Hospital endoscopy unit.

Study population: Patients offered interventional GI endoscopic treatment at the endoscopy unit.

Study period: The study duration was six months.

Methodology: Informed consent was obtained from the patient or the guardian and assent obtained from patients below 18yrs. Consecutive sampling was used. Preformed data sheets were used to fill in collected variables. Main outcome measures were interventional procedure offered, sedation modalities and immediate outcome of the procedure. The data was stored in a data base using SPSS® for windows v21.0 (Chicago, Illinois). Analysis was done using frequencies and descriptive statistics.

Results; Interventional endoscopy accounted for 21.7% of endoscopies done. The male; female ratio was 1:0.9. The median age group was 45 years. Variceal band ligation, ERCP and oesophageal stenting were the three most common procedures (respectively 36.9%, 16.1% and 12.8%). Majority of patients (56.4%) received midazolam and pethidine for conscious sedation. Pulse oximetry and pulse rate were used as the sole monitoring variables in 74.9% of patients. ERCP had the highest rate of non-completion at 20.6%. Over sedation and post procedural bleeding were recorded as complications. There were no luminal perforations or mortalities that were recorded during the period of study.

Conclusion: Interventional GI endoscopy offers minimally invasive therapy at diagnosis in a variety of gastroenterology diseases with minimal complications. There is still a gap in the variety of interventions available locally compared to other countries.

INTRODUCTION.

Gastrointestinal system pathologies present a large number of diseases encountered in general clinical practice [1]. Gastrointestinal endoscopy is the visual inspection of the digestive canal through a fibre optic camera passed through the mouth or the anus [2]. Endoscopy is a valuable tool in investigating diseases of gastrointestinal origin. Anecdotally endoscopy began in Kenya in the 1960s with rigid endoscope. Flexible endoscopes came into use in the 1980s, about three decades after the invention of fibre optic technology. Early publications on diagnostic endoscopy by Lule and Ogutu *et al* were with regard to peptic ulcer disease, *Helicobacter pylori* and GERD at KNH [3-5]. Recently, endoscopic diagnosis of jejuno-gastric intussusception has been reported by Mwachiro *et a*l of Tenwek, Kenya [6]. Basic diagnostic endoscopy is now available in cities and major towns in Kenya and there is increased need for interventional endoscopy services. Advances in endoscopic technology and devices have led to a wide variety of new and exciting applications for endoscopy and minimally invasive endoscopic surgical procedures. Interventional endoscopy allows one-time diagnosis and treatment, with added benefits of minimally invasive surgery [7]. While innovative technology continuously improves and updates diagnosis and treatment of GI diseases in the developed countries, interventional endoscopy has remained at infancy level in developing countries [8]. Majority of patients in third world countries are treated with open surgeries after endoscopic diagnosis which has increased morbidity and cost. The cost of the endoscope and its accessories may be an impediment in developing countries. However, paucity of data on available interventional gastrointestinal endoscopic procedures is a major setback in utilisation of interventional endoscopy in gastroenterology. The knowledge of their existence remains with the practising endoscopist and therefore not utilised by other clinicians practising gastroenterology. There is little advocacy in health policy decision making and therefore little funding is allocated to interventional endoscopy. Research on current interventional endoscopy in a tertiary centre may increase awareness among clinicians, promote more training and advocacy in health policy therefore, increasing the service output and lower the cost with the sole aim of improving standards of healthcare in developing countries.

LITERATURE REVIEW.

The development of the endoscope.

Endoscopy is a medical procedure that uses an endoscope to view inside the body through natural body orifices [2]. For millennia, clinicians have endeavoured to view the interior of the gastrointestinal tract in order to diagnose and treat gastrointestinal diseases. Greek, Roman, and Egyptian scholars are all known to have created specula with which body orifices were viewed [9].

The term endoscope was first used in 1853 by Antonin Jean Desormeaux (1844–1894), a French surgeon working in Hôpital Necker in Paris. The instrument was used mainly in urology, but also served as a rigid oesophagoscope (polyscope). Early endoscopes were rigid instruments and depended on natural light. Examinations were uncomfortable, incomplete and biopsy facilities were poor [10].

In the mid-twentieth century, the development of fibre optic technology permitted the invention of flexible manoeuvrable endoscopes that transmitted light through a fibre optic bundle from external source. As light returns through the endoscope, each fibre carries a parcel of the image [11].

Earlier endoscopes had eye piece to view into the lumen through the scope. Newer devices convert the image into digital format that can be displayed on a computer or television screen. This improves ergonomics during the procedure and enhances training of endoscopy.

The need of endoscopy in general.

Endoscopy has been incorporated in almost all medical specialities. Gastrointestinal endoscopy is the visual inspection of the digestive canal through a fibre optic camera passed through the mouth or the anus [2]. Furthermore, the endoscope can be passed through a stoma fashioned on the abdominal surface.

Gastro intestinal endoscopy has been defined further according to the section of the tract being examined. Oesophagogastroduodenoscopy (OGD) affords an excellent view of mucosal surfaces

of the oesophagus, stomach, and proximal duodenum. Colonoscopy allows examination of the entire colon and rectum and frequently the terminal ileum.

Standard diagnostic functions include inspection, biopsy, photography, and video recording. Diagnostic observations are made concerning focal benign or malignant lesions, diffuse mucosal changes, luminal obstruction, motility, and extrinsic compression by contiguous structures. Flexible sigmoidoscopy uses a flexible instrument to examine the rectum, sigmoid, and a variable length of more proximal colon.

Interventional endoscopy.

Advances in endoscopic technology and devices have led to a wide variety of new and exciting applications for endoscopy and minimally invasive endoscopic surgical procedures.

Variceal haemorrhage is a major cause of upper gastrointestinal bleeding in the local set up. Portal hypertension secondary to schistosomal fibrosis is common in Kenya since schistosomiasis is endemic in both Nyanza and Eastern provinces [12]. Endoscopic therapy plays a major role in the management of patients with variceal haemorrhage. In Kenya, endoscopic variceal haemostasis began in the early 1990s. Sclerotherapy was the first endoscopic modality followed by endoscopic variceal band ligation (EVBL) [13]. Lodenyo *et al* reported successful endoscopic injection sclerotherapy in 112 patients at Kenya Medical Research Institute (KEMRI) in 2007 [14]. Sclerosant commonly used was 5% ethanolamine oleate. Two mls are injected into each varix to a maximum of 10-15 millilitres each session [14]. Endoscopic Variceal Band Ligation (EVBL) uses an endoscopic rubber band ligator that is slipped into a loop of the varix. Jani reported the first eight cases of EVBL in 1997 [13]. In his series of 43 patients who underwent EVBL, Jani in 2004 described better results with EVBL regarding variceal kill time, transfusion requirement and risk of re-bleed [15]. Recent data on endoscopic variceal haemostasis is missing.

Percutaneous Endoscopic Gastrostomy (PEG) is the insertion of a feeding tube into the stomach through the anterior abdominal wall by use of an endoscope. Ponsky & Gauderer first described percutaneous endoscopic placement of gastrostomy tubes in 1980 [16]. The

gastroscope is passed into the stomach and anterior abdominal wall illuminated to site the incision site. Guide wire is passed through the abdominal incision into the stomach and held by endoscope forceps that pulls it out through the mouth. Through the push technique, the feeding tube can be passed over the guide wire or tied to it and pulled down through the incision site. Anchoring is done by affixing two bumpers, from within and outside. It is currently the preferred route of feeding and nutritional support in patients with a functional gastrointestinal system who require long-term enteral nutrition. The most common indications for PEG placement are impaired swallowing because of neurological events, oropharyngeal or esophageal, dysphagia, severe facial trauma and poor volitional intake [17]. The procedure is cheap, less invasive and no need for general anaesthesia in most cases which is a challenging factor in debilitated patients, to whom gastrostomy tubes are most commonly placed [17]. PEG offers superior access to the GI system compared to open surgical methods. PEG is now recommended as the gold standard for enteral feeding tube fixation by the ASGE. No local experience with PEG has been reported despite being carried out in several tertiary centres.

Endoscopic ultrasound (EUS) is a technique whereby an ultra sound transducer is incorporated into the tip of the endoscope or a probe is passed through the channel of the endoscope [18]. This provides high-resolution images of the GI wall and adjacent structures. Endoscopic Ultrasound is now the most accurate imaging technology for staging tumours of the gastrointestinal tract, retroperitoneum, and mediastinum [19]. Instruments can be passed under US guidance to obtain tissue samples and perform therapy both intraluminal and extraluminal. Endoscopic ultrasound fine needle aspirate (EUS-FNA) of pancreatic tumours and celiac plexus neurolysis to obliterate malignant abdominal pain are feasible endoscopically. Theodoros and Nikolaides reported a case in the African journal of paediatric surgery, of EUS cystogastrostomy in a 5- year -old boy with pancreatic pseudocyst [20]. However, this was done in Athens, Greece and local experience with EUS has not been reported.

Endoscopic Retrograde Cholangio Pancreatography (ERCP) uses duodenoscopy to identify the major and minor papillae. The biliary and pancreatic ductal systems are cannulated and opacified with contrast material to provide diagnostic information. Other diagnostic tools may be used in conjunction with ERCP including brush cytology, biopsy, intraductal ultrasound (US),

cholangioscopy, and pancreatoscopy [18]. Therapeutic manoeuvres performed during ERCP include endoscopic sphincterotomy with or without stent placement, removal of choledocholithiasis, and other ancillary techniques for the treatment of pancreatic and biliary duct disease [19]. Malignant biliary obstruction is often caused by pancreatic carcinoma, cholangiocarcinoma and metastatic disease. The majority of these patients will require non-surgical treatment because of the advanced nature of the disease. Wagner et al in 1993 reported the effectiveness of endoscopic biliary stent placement in relieving jaundice and improving quality of life in inoperable malignant biliary obstruction [21]. There is inadequate reporting of ERCP carried out in our setup.

Endoscopic gastrointestinal stenting is the use of luminal tubes (Stents) to maintain or restore the lumen of hollow organs. Current stents available include self-expandable metal stents (SEMS) for esophageal, gastroduodenal, and colonic malignant obstruction and self-expandable plastic stents (SEPS) for benign or malignant esophageal strictures [22]. Endoscopic placement of self expanding metal stents (SEMS) has evolved as a main alternative minimally invasive option for palliation of the malignant dysphagia [23]. Ndonga *et al* in 2008 reported a series of a hundred endoscopies SEMS insertion at St. Mary's hospital (Nairobi) for oesophageal cancer [24]. All patients were able to swallow immediately after and over half of the patients (54%) had an objective weight gain before stabilizing or reducing as other tumour effects set in. They found endoscopic stenting to be an affordable and effective minimally invasive outpatient procedure for palliation of dysphagia in non-resectable disease [24]. Duodenal and colonic stents are also fixed locally but local experience has not been reported.

Endoscopic Mucosal Resection (EMR) and endoscopic sub mucosal dissection (ESD) offers the potential for an exciting alternative to endoscopic treatment of early neoplastic lesions of the luminal GI tract as well as difficult colonic sessile lesions [25]. Endoscopic Mucosal Resection (EMR) involves using an electrified wire to snare and remove the abnormal portion of the oesophageal lining. Patients often first receive an injection underneath the lining of the oesophagus that causes it to lift away from the deep muscle layer so unwanted tissue can be more easily and safely removed [26].

Radio Frequency Ablation (RFA) uses thermal energy to burn a thin layer of tissue on the surface of the esophagus. CryoSpray Ablation uses liquid nitrogen, also delivered via endoscope, to freeze off unwanted tissue [18]. Endoscopic colonic polypectomy is carried out for large sessile polyps in the colon.

Foreign body retrieval from the GI system has been employed using the endoscope. Bane and Bekele [27] have reported their experience of gastrointestinal foreign body extractions under light conscious sedation using flexible video endoscopes in children and adults at Adera Medical centre in Addis Ababa, Ethiopia. They undertook a retrospective survey of 25 patients, 10 children and 15 adults who had accidental ingestion of foreign body. All of the foreign bodies were removed successfully without any complication. They concluded that flexible endoscopy is a very safe and efficient method of timely diagnosis and removal of ingested foreign bodies in children and adults in trained hands to prevent life threatening complications.

Confocal Laser Endomicroscopy (CLE) is a cutting-edge technology, often referred to as the "world's smallest microscope," which allows for a small probe to be passed via the endoscope imaging through the gastrointestinal tract [28]. It can be used in ERCP to image the bile duct. It can be passed through a needle during EUS – FNA of pancreatic lesions or in standard gastroscopy and colonoscopy to image the gastrointestinal mucosa. Also, early stage cancers can be diagnosed both accurately and instantly without the need for a biopsy, allowing treatment to be delivered immediately during the endoscopy [28]. These newer technologies may not be available in our set up currently but may begin with advocacy in health policy.

Safety of interventional endoscopy.

Any interventional procedure is aimed to be successful, safe and comfortable to the patient. Most patients are offered conscious sedation during the procedure using a benzodiazepine and an opioid analgesic [29]. The BSG has recommended a consent process represented by acronym **EMBRACE** [30] (**E**xplanation in full on procedure, **M**otivation or reasoning behind the medical recommendation, **B**enefits, **R**isks involved, **A**lternatives available, **C**omplications and side **E**ffects particularly of sedation to be given). However, interventional endoscopy is not without its risks and endoscopists need to be aware of possible procedure related complications and

should strategize to minimize them [31]. Cotton et al [32] have graded these complications as mild (simple and manageable intra procedural), moderate (requiring in patient admission), severe (requiring open surgery) and fatal complications. Complications may be sedation related, leading to cardiorespiratory failure or related to endoscope and its accessories [33]. The most common endoscope related complications are perforation, bleeding and aspiration [34]. Co morbidities involving the cardiorespiratory system and the brain are associated with high risk of complications [35]. It is important to monitor vital signs throughout the procedure or get formal anaesthetic assistance when necessary.

Local status and challenges.

Diseases which afflict both western and developing countries are often seen in more florid forms in poorer countries [36]. Innovative techniques continuously improve and update gastroenterological practice. However, advances in interventional endoscopy which are commonplace in the West, have yet to reach many developing countries [37]. Basic diagnostic endoscopy is currently a growing practice while interventional endoscopy is in its infancy in developing countries [38, 39]. This may be explained by the poor social economic status in most African countries. However, despite these challenges of poor equipment and training in a resource poor setting, endoscopy can be performed competently with good outcomes [40]. Interventional endoscopy should be promoted in developing countries to achieve standard of healthcare. Majority of studies done in our locality show little practice of interventional endoscopy. The commonly done procedure is variceal ligation and esophageal stenting for malignancy. No studies have reported on therapeutic ERCP, biliary stenting, percutaneous endoscopic gastrostomy and endoscopic mucosal dissection. While these procedures among others are often practised in tertiary centres, their reporting have widely remained anecdotal without any scientific publications. Due to lack of similar local research, comparison with other parts of the world in this field has been impossible without published data. Our local experience and variety of disease conditions remains unknown therefore left behind in contributing to evolution of interventional endoscopy.

STUDY JUSTIFICATION

Developing countries lag behind in standards of gastroenterology despite having the largest burden of disease. There is a gap in the practice of interventional endoscopy between developed countries and our local set up. Majority of studies done in our locality show little practice of interventional endoscopy. Inadequate reporting in our local practice is a major setback in bridging this gap besides skill and facility limitations. Knowledge on variety of diseases, interventions carried out and their immediate outcomes in a tertiary centre, may increase awareness among clinicians and patients, promote policy advocacy in training and healthcare institutions with the aim of promoting interventional endoscopy and gastroenterology practice to world standards.

RESEARCH QUESTION.

What are the gastrointestinal pathologies treated by interventional endoscopy at Kenyatta National Hospital?

MAIN OBJECTIVE.

To describe the practice of interventional gastrointestinal endoscopy at Kenyatta National Hospital.

SPECIFIC OBJECTIVES.

I. To determine the incidence of GI diseases undergoing interventional gastrointestinal endoscopy at KNH endoscopy unit.
II. To determine the variety of interventional gastrointestinal endoscopic procedures carried out at KNH endoscopy unit.
III. To determine the pre-medications, intra-procedural monitoring and the immediate outcome of interventional endoscopic procedures carried out at KNH endoscopy unit.

METHODOLOGY.

Study design

This was a prospective descriptive study conducted in the endoscopy unit of Kenyatta National Hospital, over a period of six months.

Inclusion criteria

1. All patients twelve (12) years and above undergoing gastrointestinal therapeutic procedures.

Exclusion criteria

1. Patients who did not consent.
2. Patients below twelve years.
3. Patients undergoing interventional endoscopy other than gastrointestinal.

Sample size calculation

For a descriptive study assumptions made included:

The estimated incidence of patients requiring endoscopic interventional procedure is **3.7** %. [40].

Confidence level set at 95%

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

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.

$$n= (1.96^2*0.037*0.963)/0.0025=55$$

Method

Research assistant recruitment; Two Research assistants for data collection were recruited from the nursing personnel in the endoscopy unit and trained on patient recruitment and data collection procedure.

Patient recruitment and consenting; Informed consent was obtained from the patient or the guardian and assent obtained from patients below 18yrs.Consecutive sampling of patients who came for interventional endoscopy was used. All patients who fulfilled the criteria and gave informed consent were recruited in the study before the intervention was carried out.

Clinical examination and questionnaire administration; Each recruited patient was assigned a serial number that was filled at the top of the data collection form. The age and sex was filled in. Neither the name nor the patient number was used for confidentiality purposes. The patients were requested to submit if present, any prior radiological or histopathology reports regarding the relevant gastrointestinal disease. The radiological or pathology reporting was recorded in the data form. Enquiry on medical history and drug history was made to pick any co morbidities of interest as per the data form.

Clinical intervention procedures; Each recruited patient was followed through the procedure room. Medications given for sedation and peri procedural monitoring done were recorded. Interventional procedure carried out was recorded also.

Immediate outcome procedures; safe and successful completion of intervention was aimed. However, any complications intraprocedural or during recovery were looked for and treated accordingly.

Confidentiality and privacy; All data was recorded in MS Excel (version 2013) data sheets that were saved under password protection only accessed by personnel involved in the project.

Ethical consideration; The study commenced upon approval by the department of surgery (UON) and KNH Ethics and Research committee. A pre-consent counselling of the participants was carried out, and then an informed consent obtained from each of the participant prior to enrolment in the study. There was no extra cost incurred by the patient for participating in this study.

Data analysis

The data was analyzed using Statistical Package for Social Sciences (SPSS) for Windows Version 21. The incidence of interventional endoscopy was calculated from total GI endoscopies done. Sex and age distribution among the different procedures were analysed using frequency statistics. Failure of procedure completion either due to technical difficulties or patient unpreparedness e.g. inadequate colonic bowel preparation were analysed as such in the results. A p value <0.05 was considered significant.

RESULTS

Prevalence of interventional endoscopy.

The number of interventional GI endoscopies was 211(21.7%) out of the 972 endoscopies done. The median age group was 41-50 years with a range of 13 to 86 years. The male: female ratio was 1:0.9. There were more interventional endoscopies for the upper tract than the lower tract (23.1% and 5.2% respectively).

Upper GI bleeding Haemostasis.

Variceal band ligation, ERCP and esophageal stenting were the three common procedures respectively (37.0%, 17.1% and 12.8%), Figure 1. The least done procedures were argon plasma coagulation, adrenaline injection and endoscopic haemostatic clip application for GI bleeding. Variceal haemostasis was the commonest procedure carried out up to the age of sixty years, after which ERCP and oesophageal stenting were commonest (41.6% and 27.7%) respectively.

ERCP, Biliary stenting and other ancillary procedures.

ERCP was twice frequently done in female as compared to males (M: F = 1:2). ERCP patients were the only group done as in-patient procedure. These patients were investigated for haemoglobin level, coagulation tests, liver and renal function tests. Thereafter they were admitted a day before the procedure for hydration and six hours fasting. Intravenous ceftriaxone 1 gram was given before the procedure. Obstructive biliary disease was the sole indication for ERCP. The commonest cause of obstructive biliary disease was distal CBD stricture (35.3%) followed by cholangiocarcinoma (23.5%) and cholelithiasis (17.6%). Adjunct procedures done during ERCP were sphincterotomy of the ampulla, brush cytology of biliary tract, bile stone extraction and biliary stenting. Distal common bile duct stricture was the commonest indication for ERCP, Table-1.

Enteric stenting and PEG fixation.

Palliative stenting was done for malignant esophageal disease with dysphagia (n=27). Self-expandable metallic stents were inserted under direct endoscopic visualisation with scope and

stent insitu or through blind metric deployment over guide wire. Two centimetre overlap of the stent beyond tumor margins was ensured proximally and distally. These patients were thereafter sent for radiotherapy. Dilation only was done in benign esophageal strictures in 9 patients. Pyloric balloon dilation was carried out in two patients with alkali ingestion however they later underwent surgery for gastric outlet obstruction. Severe head injury (n=12) was the commonest cause of poor volitional intake requiring PEG fixation.

Sedation and monitoring during interventional endoscopy.

Majority of patients (59.2%) received two combinations of medications for conscious sedation which were midazolam and pethidine, Figure-2. Propofol and ketamine were used infrequently as sedatives. Intravenous fluids and oxygen via nasal cannula were other supplemental therapies given during the procedures. Pulse oximetry and pulse rate were used as the sole monitoring variables in 74.9% of patients, table-2. Blood pressure monitoring was commonly done during ERCP. ERCP had the highest rate of non completion at 33.3% (n=12). Failed ampullary cannulation and pyloric obstruction were among the technical difficulties encountered. Over sedation and continuous bleeding were recorded as complications. There were no luminal perforations and no mortalities that were recorded during the period of study.

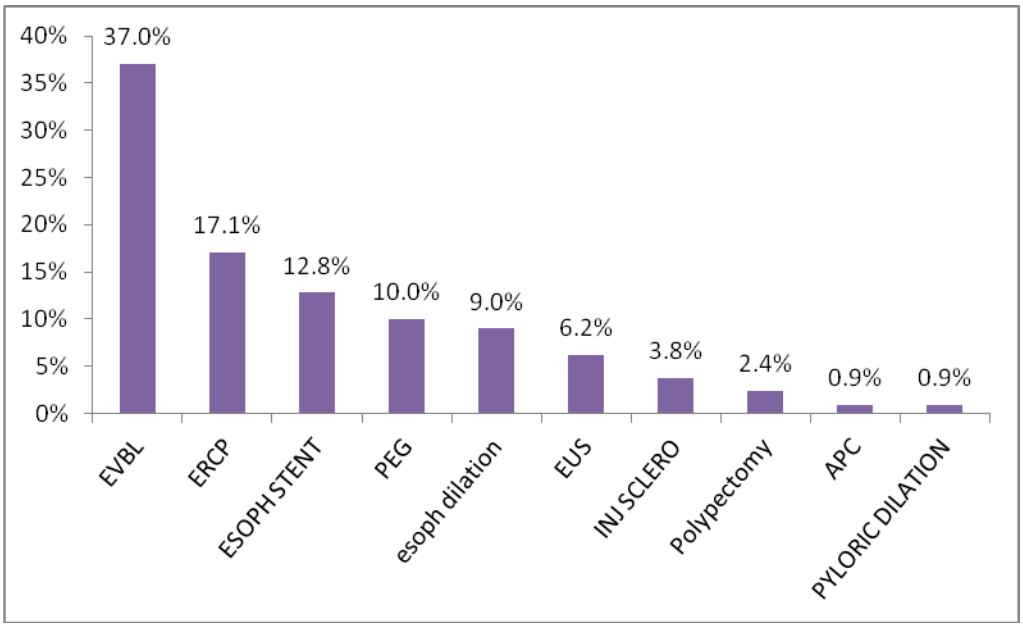


Figure 1: Variety of interventional GI endoscopic procedures

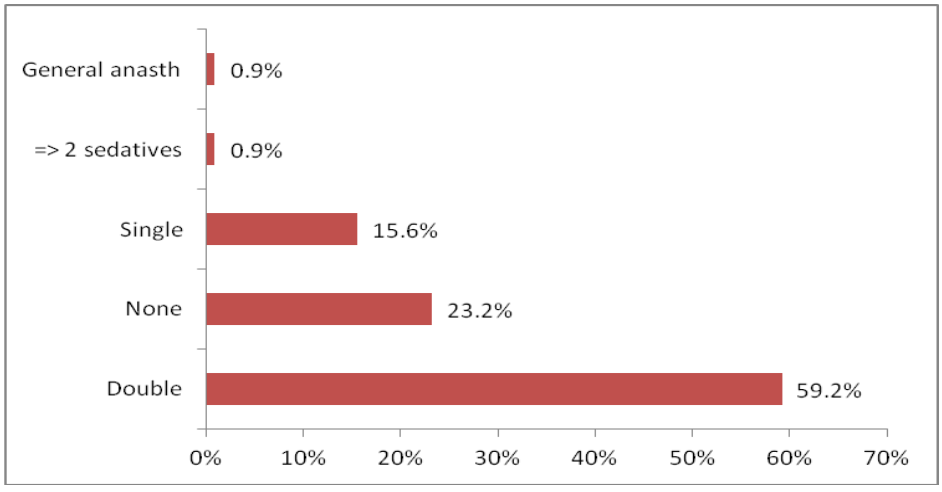
Table 1: Causes of obstructive biliary disease.

Cause.	No. of patients	Percentage
Distal CBD stricture	12	35.3%
cholangiocarcinoma	8	23.5%
Choledocholithiasis	6	17.6%
Pancreatic head tumor	6	17.6%
Peri ampullary tumor	1	3.0%
Primary sclerosing cholangitis	1	3.0%

Table 2: Intra procedural monitoring.

	Monitoring methods			
Procedures	None	Sat/PR	Sat/PR/BP	Sat/PR/BP/RR
EVBL	13(16.7%)	64(82.1%)	1(1.3%)	0
INJ SCLERO	1(12.5%)	6(75.0%)	1(12.5%)	0
ERCP	1(2.8%)	10(27.8%)	20(55.6%)	5(13.9%)
Polypectomy	1(20.0%)	1(20.0%)	1(20.0%)	2(40.0%)
ESOPH DILATION	0	16(84.2%)	2(10.5%)	1(5.3%)
EUS	0	12(92.3%)	0	1(7.7%)
PEG	2(9.5%)	16(76.2%)	3(14.3%)	0
ESOPH STENT	1(3.7%)	22(81.5%)	4(14.8%)	0
APC	0	0	2(100%)	0
PYLORIC DILATION	0	2(100%)	0	0

Sat- saturation, PR – pulse rate, BP- blood pressure, RR- respiratory rate.



Single = midazolam or pethidine. Double = midazolam and pethidine

Figure 2: Mode of sedation.

DISCUSSION

The average number of endoscopies done every month is 175 with a projected annual rate of 2,100 procedures. This is below expected work load considering the population that KNH serves, as compared to developed countries with an annual workload of approximately 3000 examinations in a District General Hospital serving a population of 250,000 [41]. This may be due to inadequate endoscopy services in our locality commensurate with population. The percentage of interventional procedures was 21.7% among endoscopies done. This is a higher proportion than what has been recorded in other previous studies in Africa [40]. Interventional procedures are carried out in a separate unit from screening endoscopy in developed countries [42]. Interventional upper endoscopy was more common than interventional colonoscopy. This can be attributed to the relatively large number of upper GI diseases as compares to lower GI diseases in the study population. Patients were commonly diagnosed and treated endoscopically during their fifth decade in life. This may inform on age at screening for GI disorders for our population.

Variety of interventional endoscopy procedures.

1. Upper GI bleeding haemostasis.

Our study shows that the commonest indication for interventional GI endoscopy is upper GI bleeding secondary to esophageal or gastric varices. Portal hypertension secondary to schistosomal fibrosis is still common in Kenya complicating into upper GI bleeding [12]. Evolution of endoscopic variceal haemostasis from injection sclerotherapy to endoscopic variceal ligation is portrayed in our findings as well as other studies [15]. All patients with oesophgeal varices underwent variceal band ligation. Injection sclerotherapy was reserved for gastro-oesophageal junction and fundal varices where banding was impractical. Butyl cyanoacrylate (histocryl) was used as the sclerosant agent which has been shown to achieve variceal haemostasis faster with fewer re-bleed [43] as compared to what had been earlier reported by Lodenyo *et al* with ethanolamine oleate [14].

2. Percutaneous endoscopic gastrostomy.

PEG offers superior access to the GI system compared to open surgical methods and is well tolerated with fewer complications [17]. Prolonged enteral feeding in Severe Head injured patients was the commonest indication (57.1%) for percutaneous endoscopic gastrostomy in our set up. The greater proportion of PEG tube fixation may be explained by management of severe head injury patients in intensive care unit necessitated assisted enteral feeding beyond two weeks. All cases of PEG fixation were done using the pulsion technique as described by Ponsky & Gauderer in 1980 [16]. Studies have shown no difference between pulsion and traction techniques [17].

3. Endoscopic retrograde cholangiopancreatography.

ERCP was twice as common in females than males (M:F=1:2). This may reflect the female preponderance of cholelithiasis one of the commonest cause of biliary obstruction [18]. However, distal biliary stricture was the commonest indication for ERCP followed by cholangiocarcinoma and cholelithiasis. This difference in our study may be explained by referral bias of malignant biliary disease to this tertially facility. ERCP was technically challenging and had the highest rate of non-completion at 33.3% as compared to other interventional procedures. This may be explained by the fact that ERCP was started not long ago in 2013 a few years before commencement of this study. The long learning curve and the larger proportion of malignant biliary obstruction may explain the lower ERCP success rate of 66.3% in our study than what is quoted in the literature of 90% [21]. Failed ampullary cannulation and pyloric obstruction were among the technical difficulties encountered. Periampullary tumors were found to be compressing the duodenum making cannulation of ampulla difficult. We recommend routine straight viewing endoscopy to patients planned for ERCP for malignant disease to confirm patency of duodenal channel before proceeding with side viewing duodenoscopy.

4. Enteral stenting and dilation.

Esophageal cancer was the sole indication for esophageal stenting in our study. Other studies have described stenting for benign conditions like esophageal fistulas [23]. Esophageal cancer is common in our set up and commonly presents in advanced stages necessitating palliative stenting [24]. Partially covered self-expanding metal stents (SEMS) were routinely used and have been shown to have superior outcome as compared to plastic stents [23]. Local studies have shown advantages of endoscopinc stenting regading ability to swallow immediately after and over half of the patients (54%), an objective weight gain before stabilizing or reducing as other tumour effects set in. They found endoscopic stenting to be an affordable and effective minimally invasive outpatient procedure for palliation of dysphagia in non-resectable disease [24]. Benign esophageal strictures underwent bouginage or balloon dilation as preffered by the endoscopist. Pyloric balloon dilation was carried out in two patients with alkali ingestion however they later underwent surgery for gastric outlet obstruction. Colonic stents were not deployed during the period of our study. This may be due to un awareness of the role of colonic stents among referring clinicians.

5. Endoscopic ultrasonography.

Endoscopic ultrasound was newly introduced in the facility soon after commencement of this study. Endoscopic Ultrasound is now the most accurate imaging technology for staging tumours of the gastrointestinal tract, retroperitoneum, and mediastinum [19]. In our study, EUS was used for diagnosis of pancreatic disease and staging early upper GI tumors. Endoscopic ultrasound guided-fine needle aspiration was carried out in four patients with pancreatic mass. This was useful where histological diagnosis was not confirmed in patients who required palliative biliary drainage followed by palliative chemotherapy. In one patient with chronic abdominal pain due to advanced pancreatic tumor, celiac plexus neurolysis was demonstrated to obliterate afferent pain sensory fibres at the celiac ganglion.

Complications and outcome.

Complications may be sedation related, leading to cardiorespiratory failure or related to endoscope and its accessories [33]. Over sedation and continuous bleeding were recorded as complications in our study. Cotton et al [32] have graded these complications as mild (simple and manageable intra procedural), moderate (requiring in patient admission), severe (requiring open surgery) and fatal complications. Over sedation occurred in patients who received multiple doses of two or more sedatives and were managed by oxygen supplementation until fully awake. One patient had continuous bleeding from duodenal ulcer. Argon plasma coagulation and adrenaline injection were employed with haemostasis. Later in the ward the patient had continued hematemesis and was taken to theatre for laparotomy where the bleeding vessel was over sewn. There were no luminal perforations and no mortalities that were recorded during the period of study as reported in other similar studies [35]. With adequate skill and preparation, interventional endoscopy has minimal complications that can be managed with good outcome.

CONCLUSION

There is still a gap in the variety of interventions available locally compared to developed countries. Our report on interventional endoscopy in a tertiary centre may increase awareness among clinicians, promote more training and advocacy in health policy therefore, increasing the service output and lower the cost with the sole aim of improving standards of gastroenterology healthcare in our local set up.

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APPENDIX 1: PATIENT CONSENT:

THE PRACTICE OF INTERVENTIONAL GASTRO INTESTINAL ENDOSCOPY AT KENYATTA NATIONAL HOSPITAL.

ENGLISH VERSION.

This Informed Consent form is for patients being offered interventional endoscopic services at KNH endoscopy unit. I am requesting patients to participate in this research project whose title is "The practise of interventional gastro intestinal endoscopy at Kenyatta national hospital".

Principal investigator: Dr. James M. Waweru.

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

Supervisors: Professor Pankaj Jani and Dr. Daniel Ojuka.

This informed consent has three parts:

1. Information sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)
3. Statement by the researcher

You will be given a copy of the full Informed Consent Form.

PART I: INFORMATION SHEET.

Introduction; My name is Dr James M. Waweru, a post graduate student at the University of Nairobi's School of Medicine. I am carrying out a study to describe the practise of interventional endoscopy at Kenyatta National Hospital. **Voluntariness of participation;** I am inviting you to participate in my study and you are free to either agree immediately after receiving this information or later after thinking about it. You will be given the opportunity to ask questions before you decide and you may talk to anyone you are comfortable with about the research before making a free decision.

Compensation; There will be no compensation for participating in the study.

Alternatives to participate in the study; You should feel free to choose not to be included in the study. Your treatment will not be affected in anyway and no explanations will be needed.

Risks and benefits; Following your consent to participate in this research, we will record your age, sex and the problem your doctor is about to treat you for. We will follow you through the procedure and record the preparation done to you, monitoring during the procedure, the interventional endoscopic procedure carried out and the final outcome of the procedure. However, we will not participate per se to your treatment and we will only be observers. However, we may be requested by your doctor to assist him/her in your treatment. There are no added risks for participating in your study. The information recorded will help the doctors to improve treatment offered at the unit.

Confidentiality; This information will be strictly confidential to the researcher only. No names nor patient numbers or any information that can trace you in anyway will be recorded. 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).

- **Secretary, KNH/UoN-ERC**

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- **University of Nairobi research supervisors**

  1. Professor Pankaj Jani.

     Department of Surgery, School of Medicine, University of Nairobi

     P.O. Box 19676 KNH, Nairobi 00202

  2. Dr Daniel Ojuka

     Department of Surgery, School of Medicine, University of Nairobi

     P.O. Box 19676 KNH, Nairobi 00202

- **Principle researcher:**

  Dr. James M. Waweru.

  Department of Surgery, School of Medicine, University of Nairobi

  P.O. Box 36153, 00200 Nairobi.

  Mobile phone 0735966577

PART II.: CONSENT FORM FOR THE RESEARCH ON THE PRACTISE OF INTERVENTIONAL GASTROINTESTINAL ENDOSCOPY AT KNH ENDOSCOPY UNIT.

Informed Consent for inclusion in the above study is hereby given by Mr./ Mrs/ Miss……. Having being explained to myself of the aim, benefits and risks associated with my inclusion in the study.

Participant's signature……. Date……

Name of witness……...……

Signature……Date……

Name of research assistant taking consent……

Signature……Date……

Principal investigator: Dr. James M. Waweru.

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

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 the following:

- Refusal to participate or withdrawal from the study will not in any way compromise the quality of care and treatment given to the patient.
- All information given will be treated with confidentiality.
- The results of this study might be published to enhance knowledge and to help improve interventional gastrointestinal endoscopy at the KNH endoscopy unit. 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 taking consent……

Signature……Date……

KISWAHILI VERSION.
FOMU YA IDHINI.

SEHEMU YA KWANZA: MAELEZO YA DAKTARI MTAFITI.

Kitambulisho cha mtafiti; Mimi ni daktari James Waweru, kutoka shule ya Elimu ya Afya idara ya upasuaji Chuo Kikuu cha Nairobi. Ninafanya utafiti kuhusu matibabu inayotekelezwa kwa njia ya vifaa vya endoscopy badala ya upasuaji. **Kujitolea kwa hiari yako;** Nakukaribisha kushiriki katika utafiti huu baada ya kuelewa vyema maelezo ya utafiti. Unaweza kubali sasa hivi au wakati mwingine. Una uhuru wa kuuliza jamaa wako kuhusu kusajiriwa katika utafifti huu. Pia unaweza kutuuliza maswali yoyote kabla ya kukubali.

Fidia ya kushiriki katika utafiti; Hakuna malipo yoyote utakayopokea kwa kushiriki katika utafiti huu.

Chaguo la kutoshiriki katika utafiti; Matibabu yako yataendelea vyema utakapochagua kutoshiriki katika utafiti huu. Hakuna maelezo zaidi utatakiwa kueleza kwa chaguo la kutoshiriki.

Hasara na faida ya utafiti huu; hakuna madhara yoyote imeongezwa katika matibabu yako kwa kushiriki utafiti huu. Matokeo ya utafiti huu yatawasaidia madaktari kuendeleza matibabu haya kwa ufanisi zaidi na kwa kuendeleza elimu.

Siri ya utafiti; Habari zote zitakazokusanywa zitashughulikiwa kwa siri na hazitasambazwa ila tu kwa ruhusa kutoka kwa mkurugenzi mkuu wa utafiti wa chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta. Kuhusika kwako, mwanao au jamaa wako kwenye utafiti huu hakuna malipo yoyote ila ni kwa hiari yako mwenyewe na pia unaweza kujiondoa kushiriki katika utafiti wakati wowote bila kuhatarisha matibabu ya mwanao/jamaa wako katika Hospitali Kuu ya Kenyatta. Naomba mimi ama wasaidizi wangu katika utafiti wakuulize maswali ambayo yatajibiwa kwa fomu maalum. Habari yote ambayo utatuarifu ni ya siri kati yako nasi watafiti na haitaenezwa kwa watu wengine. Jina la mwanao/jamaa wako halitaandikwa kwenye fomu yoyote wala kwenye vipimo vyovyote.

Unaweza kuuliza maswali yeyote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini iliyopo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu kwa mtafiti mkuu ama mkuu wa idara ya upasuaji katika chuo kikuu cha Nairobi ama walimu wasimamizi wa utafiti ukitumia nambari za simu zifuatazo;

- Katibu wa utafiti, Hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi. Sanduku la Posta 20723 KNH, Nairobi 00202. Nambari ya simu 726300-9.

Walimu wakuu wa Chuo kikuu cha Nairobi:

1. Mhadhiri mkuu Pankaj Jani.

   MBChB,M.Med, FRCS (Edinburg)F.C.S (ECSA)

   Sanduku la Posta 19676 KNH, Nairobi 00202.

2. Daktari Daniel Ojuka,

   MBChB (U.o.N), M.Med Surgery (U.o.N).

   Sanduku la Posta 19676 KNH, Nairobi 00202.

- Mtafiti: James Waweru.

  Idara ya Upasuaji ya Shule ya Afya – Chuo kikuu cha Nairobi,

  Sanduku la Posta 36153 - 00200.

  Nambari ya simu 0735966577

SEHEMU YA PILI – IDHINI YA MGONJWA.

Mimi (Jina)…… nimekubali kushiriki katika utafiti huu unaofanywa na Daktari James Waweru kutokana na hali ambayo nimeelezwa na sio kwa malipo ama shurutisho lolote.

Nimeelewa kwamba ninaweza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu yangu au mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwangu ama kwa wagonjwa wengine kwa jumla na hata madaktari wenyewe na kwa kuendeleza elimu ya matibabu ya endoscopy.

……

Sahihi/ama alama ya kidole cha gumba katika sanduku →

Tarehe…….....

Siku/Mwezi/Mwaka

Jina la shahidi…….

Sahihi……Tarehe……

Kidole cha gumba kwa Yule asiyeelewa

Kuandika.

Jina la anayesimamia mtafiti ……

Sahihi…….....Tarehe…….....

SEHEMU YA TATU – DHIBITISHO LA MTAFITI.

Hii nikuidhinisha ya kwamba nimemueleza msimamizi wa mshiriki(mgonjwa) kwenye utafiti kuhusu utafiti huu na pia nimempa nafasi yakuuliza maswali. Nimemueleza yafuatayo;

- Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo.
- Kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.
- Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu anayoyapata katika hospital kuu ya Kenyatta.
- Habari ambazo atapeana hazita tangazwa hadharani bila ruhusa kutoka kwake (mshiriki) na pia kutoka kwa mdhamini mkuu wa utafiti wa hospital kuu ya Kenyatta na chuo kikuu cha matibabu.

Jina la anayesimamia mtafiti ……

Sahihi……..

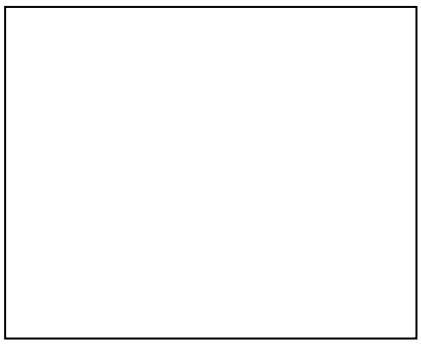
Tarehe…….

ASSENT FORM FOR UNDER AGE PATIENTS.

I……, have agreed to be included in the interventional endoscopy study. I have been explained that the study will not affect my treatment in anyway. The information will help the doctors to improve on the treatment services of interventional endoscopy. My assent is hereby given with the informed consent of my parent/ guardian.

Signature ……...

Left thumb print.

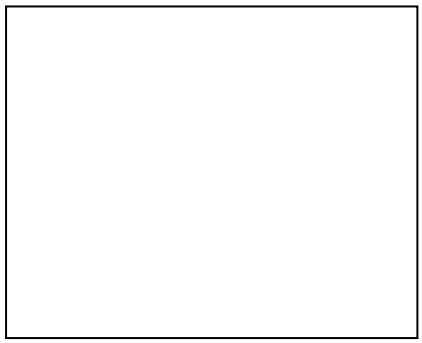


IDHINI YA WALIO CHINI YA MIAKA KUMI NA MINANE.

Mimi ……, nimekubali kusajiriwa katika utafiti huu wa matibabu ya endoscopy. Nimeelezwa kuwa utafiti hautakuwa na madhara kwa matibabu yangu. Matokeo ya utafiti itawasaidia madaktari kuendeleza ujuzi wa matibabu ya endoscopy. Idhini yangu imefuata kubali la mzazi/ Jamaa wangu nisajiriwe katika utafiti.

Sahihi…….

Kidole cha kushoto cha gumba.



APPENDIX 2: DATA COLLECTION FORM.

THE PRACTICE OF INTERVENTIONAL GI ENDOSCOPY AT KNH.

Serial No……

1. AGE (YRS)……..... SEX; ☐ Male ☐ hale

2. Gastrointestinal disease……

3. Co morbidities.
   - ☐ None
   - ☐ Heart diseases
   - ☐ Lung diseases
   - ☐ Renal diseases
   - ☐ Retroviral disease
   - ☐ Diabetes.
   - ☐ Others (specify)……

4. Sedation drugs.
   - ☐ None.
   - ☐ Benzodiazepines (midazolam/diazepam).
   - ☐ Opioid analgesics (pethidine /fentanyl).
   - ☐ Other drugs (specify)…….

5. Peri -procedural Patient Monitoring;
   - ☐ None.
   - ☐ Respiratory rate.
   - ☐ Blood Pressure.
   - ☐ Heart/pulse rate.
   - ☐ Pulse oximetry.
   - ☐ Electrocardiography.
   - ☐ Capnography

6. Endoscopic intervention undertaken;
   - ☐ Variceal hemostasis.
   - ☐ Injection sclerotherapy

☐ Endoscopic variceal band ligation.

☐ Entral stenting
- ☐ Esophageal stenting
- ☐ Duodenal stenting.
- ☐ Colonic stenting.

☐ Interventional ERCP
- ☐ Billiary stenting
- ☐ Bile stone retrieval

☐ Foreign body retrieval
- ☐ Esophageal foreign body.
- ☐ Gastric foreign body.
- ☐ Colonic foreign body.

☐ Percutaneus Endoscopic Gastrostomy.

☐ Colonic polypectomy.

☐ Endoscopic ultrasound.

☐ Other interventional procedures (specify);

……

7. Failure of completion of procedure
   - ☐ Technical difficulties.
   - ☐ Patient unpreparedness.

8. Sedation related complications;
   - ☐ None.
   - ☐ Post procedural pain
   - ☐ Respiratory depression.
   - ☐ Hypotension.
   - ☐ Myocardio ischaemia.

9. Endoscope & accessories related Complications;

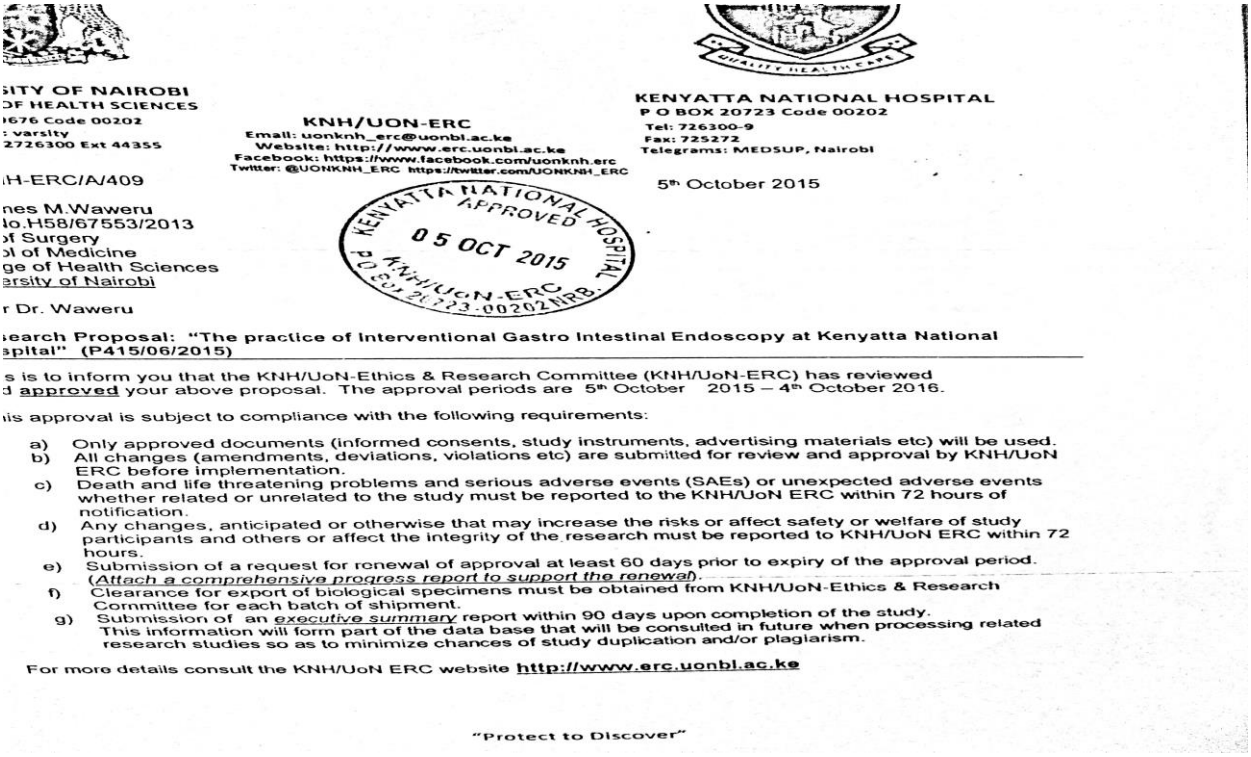
- ☐ None.
- ☐ Bleeding.
- ☐ Luminal perforation.
- ☐ Aspiration.
- ☐ Others (specify)……

10. Management of complications;

- ☐ Intra procedural treatment.
- ☐ In ward treatment.
- ☐ Open surgery treatment.
- ☐ Fatal.

……The end……...

APPENDIX 3: KNH-UON ETHICS AND RESEARCH COMMITTEE APPROVAL LETTER.



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5th October 2015

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KENYATTA NATIONAL HOSPITAL APPROVED 05 OCT 2015 KNH/UoN-ERC P.O. Box 20723-00202 NRB.

r Dr. Waweru

earch Proposal: "The practice of Interventional Gastro Intestinal Endoscopy at Kenyatta National spital" (P415/06/2015)

s is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed d approved your above proposal. The approval periods are 5th October 2015 – 4th October 2016.

iis approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and serious 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.
d) 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.
e) 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*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) 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 **http://www.erc.uonbi.ac.ke**

"Protect to Discover"

STUDY BUDGET.

Budget Item	Amount (K.shs.)
Research fee for KNH-ERC	1,500
Statistician consultation fee	30,000
Stationery;(a) Printing (b)photocopying (c)binding (d)pens	5,000 2,000 10,000 500 Total=17,500
Research assistants fee @15000 each (two assistants)	30,000
Contingency fund	10,000
Total	100,000

TIME FRAME.

ACTIVITY	2015 FEB/ MARCH	2015 APRIL /MAY	2015 JUNE/ JULY	2015 AUG/ SEPT	2015 OCT/ NOV	2016 DEC/ JAN	2016 FEB/ MARCH	2016 APRIL/ MAY	2016 JUNE/ JULY	2016 AUG/ SEPT
PROPOSAL DEVELOPMENT										
DEPARTMENTAL APPROVAL										
ETHICAL APPROVAL										
DATA COLLECTION										
DATA ANALYSIS										
PRESENTATION										