INDICATION AND OUTCOME OF ULTRASOUND-GUIDED PERCUTANEOUS CATHETER DRAINAGE OF INTRA-ABDOMINAL COLLECTIONS AT KENYATTA NATIONAL HOSPITAL

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2021

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LIST OF ABBREVIATIONS AND DEFINITIONS

ACR American College of Radiology

APACHE II: Acute Physiology, Age, Chronic Health Evaluation II

CC: Centimeter cubic

CRP: C-reactive protein

CT: Computed tomography

DIRM: Department of Diagnostic Imaging and Radiation Medicine

ERCP: Endoscopic Retrograde cholangiopancreatography

F: French (size of catheter diameter)

G: Gauge

Hb: Haemoglobin

IBD: Inflammatory bowel disease

INR: International normalized ratio

IV: Intravenous

KNH: Kenyatta National Hospital

PCD: Percutaneous catheter Drainage

PTT: Partial thromboplastin time

DEFINITION OF TERMS

Short Term Outcome: The result of the PCD technique within six weeks duration

SIR: Society of Interventional Radiology

SPSS: Statistical Package for the Social Sciences

Technical Success Rate: The adequacy of the drainage of the target collections after successful catheter placement without surgical intervention.

UON: University of Nairobi

US: Ultrasound

WBC: White blood cells count

ABSTRACT

Percutaneous ultrasound-guided catheter drainage (PCD) is an effectual and commonly used interventional procedure to diagnose and treat patients with intra-abdominal collections. It is a standard minimal invasive and appropriate technique for critically ill patients with no other indications of surgery. It is a placement of a catheter using images to provide constant drainage of collections by use of a percutaneous access pathway. It entails localization of collection, placement and maintenance of a catheter which could either be an alone session or staged procedure in numerous sessions. It has a diagnostic role of sampling the collection using a catheter or a needle throughout a sole imaging session. Despite the procedure is effective and minimal invasive, it has complications of haemorrhage, septicemia, super infection and bowel perforation. Abscess and post-operative fluid collections are the main indications of percutaneous ultrasound-guided drainage. Pre-procedural case workup and appropriate preventive measures reduce the risk of complications. There are no absolute contraindications of ultrasound-guided drainage of intra-abdominal collections. Uncorrectable coagulopathy and the absence of a safe percutaneous access pathway are relative contraindications. Continuous observation of clinical status is given to the patients who underwent ultrasound-guided drainage procedures to determine the short and long outcomes of the technique. Locally, it's accepted and is a safe and very valuable procedure for all patients with intra-abdominal collections.

Aim

The main aim of this study is to determine the indication and outcome of the percutaneous ultrasound-guided drainage procedure of patients with intra-abdominal collections performed at Kenyatta National Hospital.

Methodology

Study design: Prospective cross-sectional descriptive study.

Study site*:* Kenyatta National Hospital, Department of Interventional Radiology

Study duration*:* The study was carried out for a period of six months from March 2019 to June 2020.

Study population: All patients in all age groups were referred for ultrasound-guided drainage of intra-abdominal collections.

Ethical considerations: Approval for ethics and permission was obtained from the KNH-UON Ethics Review Board.

Statistical analysis: Data was collected and analyzed using Statistical Package for the Social Sciences (SPSS program 24.0). Results were presented in a tabular and graphical format.

CHAPTER ONE: INTRODUCTION/BACKGROUND

1.1 Introduction

The intra-abdominal collection is a pathological fluid collection in the abdomen. The undrained intra-abdominal abscess has a mortality rate between 45-100%. The morbidity and mortality rate of the intra-abdominal abscess has declined due to widely practice of image-guided percutaneous drainage techniques (1).

Ultrasound-guided percutaneous catheter drainage is defined as placement of catheter using ultrasound guidance to provide continuity of a fluid collection using an access pathway of a percutaneous approach (2). The purpose of percutaneous procedure in a collection is to obtain a fluid sample for diagnosis, completely drain a collection or treat a recurrent collection by instilling a sclerosing agent. Percutaneous catheter drainage is now standard management for patients with intra-abdominal collections without signs of open intervention. Safety, efficacy and ease of the procedure have revolutionized the treatment of an intra-abdominal abscess. The majority of the intra-abdominal collections can be treated with appropriately sized and positioned catheters. Indications include post-operative, inflammatory and traumatic collections.

Table 1: Indications for US Guided Drainage of Abdominal Fluid Collections (3)

1- Abdominal abscess
2- Postoperative fluid collection
3- The consequence of acute inflammatory conditions like cholecystitis, appendicitis.
4- Due to traumatic hematoma
5- Diagnostic purpose or fluid characterization
6- Others: Cysts, pseudocysts, bilomas, urinomas, and lymphocele
7- Temporizing manoeuvre to stabilize the patients' condition before definitive surgery

Most abscesses result from post-operation, consequences of intra-abdominal inflammatory processes (cholecystitis, appendicitis, diverticulitis, and inflammatory bowel disease), abdominal trauma and tuberculosis. PCD cannot be taken into consideration if an abscess size is less than 4cm (as it may resolve with conservative treatment) except the patient is in septic condition attributable to the collection. The open procedure is preferred in multiloculated or multiple abscesses(2). The mortality rate of the untreated intra-abdominal abscess is 100% (3). Locally, most of the patients with intra-abdominal collections are post-operative abscess formation. There is no local study emphasizing this.

The peritoneal space of the collection is related to the anatomically affected organ; right sub-phrenic collections are linked to gastro-hepato-biliary surgical procedures and bile leaks, left subphrenic collections are attributed to gastric, colonic, pancreatic and splenic pathology and procedures while paracolic collections are connected to intestinal(Crohn' s or diverticular disease)

or appendiceal pathologies. Retroperitoneal collections are a result of pancreatic, duodenal, ureteric, renal, bowel, para-aortic or paraspinal pathologies (4). Collections tend to settle to dependent sites i.e. posterior sites in supine point and lower abdominal sites in the upright position. Awareness of these sites' predilections helps to identify the collection and peritoneal compartments it occupies (5).

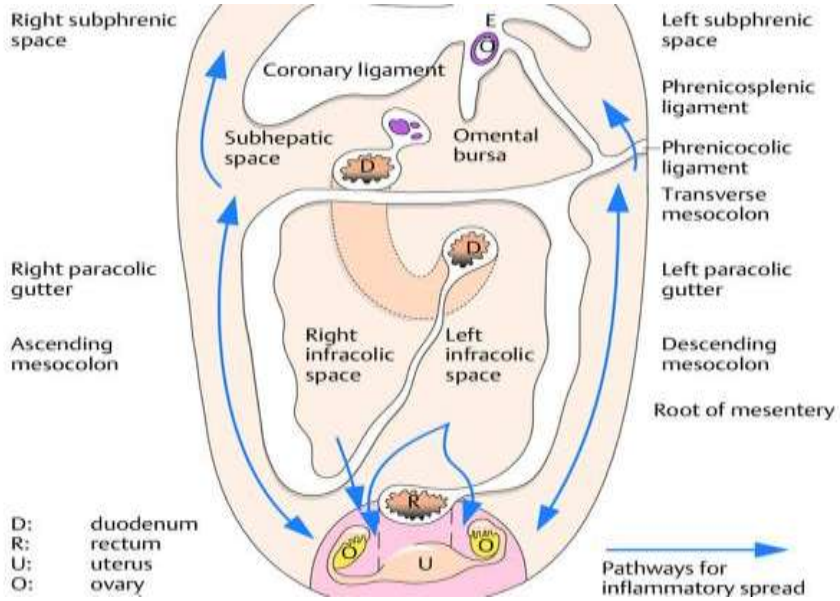


Figure 1: Compartments in Peritoneal Cavity

Peritoneal Space Anatomy

Familiarity with the anatomy of peritoneal reflections and potential spaces is very vital. The depressing hydrostatic pressure at the time of inspiration permits transcoelomic passage to the right perihepatic space because it's the most dependent space during the supine position. Perihepatic peritoneal spaces are divided into compartments by peritoneal ligaments (coronary, triangular and falciform ligaments). The presence of collateral vessels should be considered in portal hypertension (4).

Contra-indication of percutaneous US-guided drainage of abdominal collections

There is no absolute contraindication of PCD; however, there are relative contraindications and advantages over the risk of the evaluation procedure. The relative contraindications of percutaneous drainage generally include; severe refractory coagulopathy, hemodynamic instability or severe cardiopulmonary compromise and uncooperative patient (4).

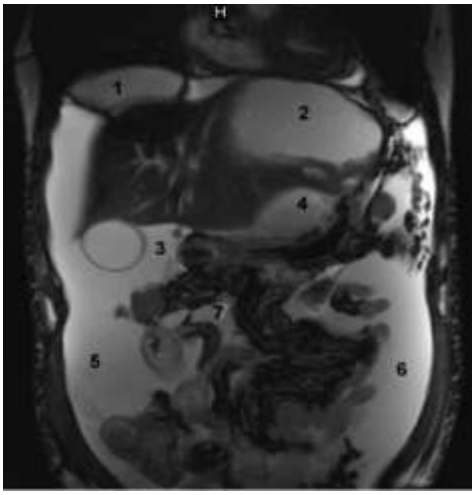


Figure 2: Peritoneal Spaces where Intra-Abdominal Collections Ocur

The right (1) and left (2) subphrenic spaces are divided by the falciform ligament. The right (3) and left (4) subhepatic spaces correspond with the respective subphrenic spaces superiorly and the right (5) and left (6) paracolic spaces inferiorly. Interloop abscesses gather between intraperitoneal bowel loops (7). Note the slight difference in signal strength in this patient with acute pancreatitis between free fluid (1

Technique

Pre-procedural Assessment

The success rate and safety of percutaneous drainage of the abdominal collection depend on the adequate pre-procedural workup. The danger of post-procedural haemorrhage from PCD is stratified by the patient's coagulation and the location of the collection. Intra-abdominal collections are modest risk procedures, therefore, pre-procedural testing ought to comprise of the international normalized ratio (INR=/<1.5), activated partial thromboplastin time (aPTT<30s) and platelets >50000[4]. The selection of imaging guidance for draining of intra-abdominal collections varies with body habitus, presence of adjacent structures, size, site and presence of bowel gas (6),(7).

CT is the preferred choice to detect intra-abdominal abscess due to its detailed anatomical collection localization about adjacent structures. It also has the advantage of visualization of retroperitoneal and posterior intra-abdominal structures covered by overlying bowel gas on ultrasound (6),(7). Drainage of abdominal collection under US guidance is commonly used and accepted because, it is cheaper, faster, and avoids radiation effects and can characterize the composition of a complex collection. Decisions for the choice of imaging modality are based on how easy the collection can be visualized, the route of access, size and location of the collection (6),(8). Imaging of intra-abdominal collection, CT and US are widespread used modalities to diagnose and guide percutaneous drainage of intra-abdominal collections. The US offers a detailed evaluation of complex collections and solid organs with the benefit of real-time imaging. In this case, US-guided interventions are quicker than CT guided interventions (9). Percutaneous ultrasound-guided drainage is a minimally invasive procedure and fast procedure alternative to surgical drainage. It can be done bedside technique. Numerous studies provide advantages of percutaneous catheter drainage of abdominal collections over surgical drainage. They come with a less patient hospital stay, avoidance of anaesthesia risks and the postponement of surgery in critically ill patients (10).

Percutaneous catheter drainage is the first-line treatment for symptomatic or infected abdominal and pelvic collections in the absence of emergency indications of surgery (10). It is seen to be a safe and effective procedure for the treatment of intra-abdominal abscess in children (11).

Percutaneous catheter drainage becomes the best option of treatment to manage ruptured amoebic hepatic abscess complications. The status of PCD is the optimal procedure to manage multiloculated liver abscess and is generally used. The advantages of PCD compared to open

surgical drainage are lower cost, increased patient acceptance, and fewer problems that need only local anaesthesia (11)(12))(13).

Percutaneous US-guided drainage of abdominal collections is safe and effective in draining collections in lesser sac space due to its transhepatic approach for catheter drainage of lesser sac collections (14).

PCD has replaced endoscopic ultrasound drainage of pancreatic pseudocysts. Transgastric percutaneous drainage of pancreatic pseudocysts is similar to standard internal surgical drainage in efficacy. Preliminary results of 6 patients who underwent transgastric approach showed no major complications. Percutaneous transgastric catheter drainage is recommended as a pancreatic pseudocyst of more than 5cm in diameter. Its failures do not compromise subsequent surgical intervention (15).

Percutaneous US-guided drainage can be done with or without diagnostic aspiration. Locally both diagnostic and therapeutic aspiration is performed according to the content and volume of the collection. Therapeutic aspiration is an evacuation of collection without placement of the catheter. Percutaneous catheter drainage and needle aspiration of intraabdominal abscesses have similar mortality rates; however, recurrence and requirement of surgical operation are high in needle aspiration alone (16).

At the Kenyatta National Hospital, most patients with abdominal collections undergo US-guided drainage with good clinical outcomes. Due to the safety of the procedure, some clinically stable patients with the non-infected collection are discharged the same day of the procedure after a few hours of observation and follow up abdominal US scans are recommended. There is no local study emphasizing the technical success rate of US-guided PCD.

Special consideration should be given to the following factors: the shortest pathway to the collection, easiest angulation, avoidance of adjacent structures and reproducibility of the designed move and the correct position for the comfort of the patient. The collection should be in a solid organ when draining and the access route transverse the nominal amount of a normal organ to minimize bleeding (6). Independent drainage should be as dependent as possible i.e. if the patient is in a supine position, posterior and lateral approaches are preferable (15).

Supplies

Pigtail draining catheter is made up of kink-resistant polyurethane material with a hydrophilic coating to help deploy numerous side holes. Large catheters (12-14F) are normally preferred and located inside the loop to boost its flow. When carrying out drainage procedure, chiba needle/ kellet, guide wires, dilators, US sterile cover, connector, draining bag. 20 ml syringe, skin securing devices, local Lidocaine, sterile pack, scalpel, US machine, dilators, 20CC syringe and guidewire are all vital equipment (17)(5).

Figure 3: Draining Catheters and Stylet

Figure 4: Draining Vaccum

Planning an Access Route

Select the shortest, straightest and safest path to the widest area of the collection by placing the catheter in the very reliant part of the collection. Ensure that there is a possibility of removing the catheter to drain the superficial part of the collection. Approach the long axis of the collection and angle the approach as required as possible. At the access, displace the bowel loops with gentle US probe compression and use colour Doppler scan to avoid damage of blood vessels. At this point, the previous surgical drain tract can be useful as access. Subcostal access is preferable during subphrenic collections to evade the risk of pleural transgression (8). It is recommended to use a transhepatic or transgastric approach at the time of life-threatening subhepatic, gall bladder bed, paraduodenal and lesser sac collections. Several studies emphasize that transgastric or transhepatic access is safe (18). Damage to dilated bile ducts, large hepatic vessels, and gallbladder and perigastric vessels should be carefully avoided. During inaccessible interloop collection, consider aspirating the collection by transgressing the bowel segment with a 20G needle to give a sample (19). The transpleural approach in post-splenectomy collections is the only route that avoids bowel transgress and has a high success rate (8).

Complications of percutaneous drainage are approximately less than 10% while the success rate of percutaneous drainage and aspiration is above 95% (20). The Society of Interventional Radiology (SIR) formalized the threshold for appropriate criteria of carrying out percutaneous drainage (21).

Table 2: Complications of PCD of Intra-Abdominal Collections (17).

1- Peritonitis or peritoneal infection	2%
2- Sepsisorsepticemia	2-5%
3- Bleeding due to vascular injury	2-10%
4- Pneumothorax	2-10%
5- Embyaema	2-10%
6- Pleural effusion	2-10%
7- Bowel injury	1%

Recognizing and management of complications

Even the most talented interventional radiologist will encounter complications of collection drainage, including sedation complications, drug allergy complications, infectious complications, non-target access and bleeding (20)(22).

Infection

This is usually related to catheter placement during abscess drainage. If the fistula is suspected abscessogram is performed after antibiotic coverage. Clinical features of acute sepsis related to the

drainage procedure include fever with chills and shock. Immediate management of blood pressure and oxygen saturation monitoring with intravenous antibiotic treatment should be established. Preventive measures of infection related to fluid drainage are to avoid non-sterile routes of drainage and diagnostic aspiration of the collection before catheter placement (22)(14).

Bleeding

Vascular injury can occur during drainage of a collection adjacent to the vascular organ or blood vessels. Bleeding due to injury of small blood vessels is self-limiting and conservative management with IV fluid or transfusion of blood has always satisfactory results. Persistent bleeding or fistula formation transcatheter embolization should be considered. In cases of large vessel laceration resulting in cardiopulmonary collapse surgical intervention should be recommended. During cases with a high tendency of bleeding, a Seldinger technique drainage procedure is preferred (9).

Non- target Puncture

Subcapsular or intraperitoneal bleeding is seen during puncturing or placement of the catheter in solid parenchymal organs. Tract embolization using gel form and catheter removal is performed. Puncturing of small bowel with small-sized needles has minimal risk. Bowel content and high output are seen in the catheter drainage. Transenteric drainage of the colon has the risk of sepsis will require surgical consultation (22).

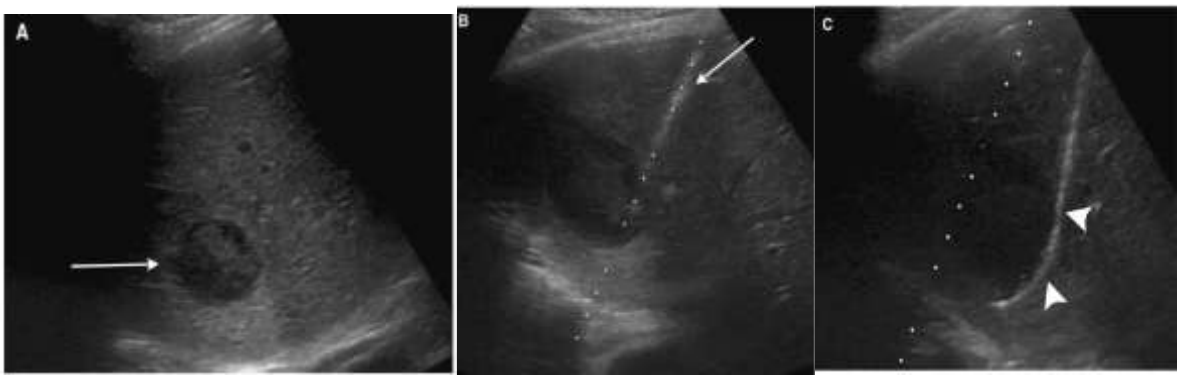


Figure 5: Ultra-Sound Guided Liver Abscess Drainage

Longitudinal images of the liver discover a complex fluid collection with internal echoes to represent debris (white arrow) (**A**). A subcostal approach was applied to get into the collection (white arrow) (**B**) and the wire was documented within the collection (over arrows heads) (**C**).

Specific Needs of Children with abdominal collection undergoing ultrasound-guided drainage.

PCD is currently recognized as the optimal safe procedure for neonatal liver abscess and the long-time study reported that PCD for neonatal liver abscess drained with PCD has a high success rate (23). Young children need sedation (mild, moderate or deep sedation). This sedation process is planned for preprocedural assessment. Intraprocedural monitoring of vital signs and the airway is performed by the attending anesthesiologist (24). Any possible complications related to general anaesthesia will be managed with the KNH resuscitation guideline.

The short outcome of ultrasound-guided drainage of the intra-abdominal collection

Technical success in short term outcome is defined as the adequacy of the drainage of the target collections after successful catheter placement without surgical intervention. It's based on CT or US findings that confirmed the complete absence of collection and clinical improvement. The

draining catheter is removed after the resolution of fever and leukocytosis in abscess cases and daily drainage of less than 20, mL/day and or complete absence of the collection seen in imaging (17).

The success rate of the PCD depends on the type of collection and physiological condition of the patient. IR radiologists strive to achieve perfect results. ACR reviewed a guideline of the success rate of both aspiration and drainage with the collaboration of the Society of Interventional Radiology (SIR) and recommended a success rate of more than 95% of the PCD procedure (21).

Table 3: Success Rate and Threshold of PCD and Aspiration (18).

Outcome	Suggested threshold
Successful diagnostic fluid aspiration	95%
Successful drainage Curative and partial drainage	95% 85%

Curative drainage is a full resolution of infection that does not need more operative intervention, while partial success is sufficient drainage of abscess with surgery consequently done to repair a fundamental cause (21). A technical failure in the short term outcome is defined as the need for elective interval surgery or emergency after PCD (below). There are potential factors in short term outcomes: 1. Age of the patient, the underlying cause of the intra-abdominal collection (post-surgery, IBD, pancreatitis, diverticulitis, appendicitis or liver abscess). 2- Lab data of the patient (WBC, Hb and CRP). 3- Site, number and type of the collection (abscess, fistula formation, fungal superinfection, and presence of phlegm on). 4. Type of procedure draining procedure: concomitant

use of antibiotic therapy, type and duration of antibiotic therapy. There are predictors of the short term result of PCD (25)

Locally US-guided drainage procedure can be successfully done on intra-abdominal collections cases with very few minimal complications. No local published studies have shown the technical success rate and short term outcomes. The duration of the follow up depends on the type of collection drained. The indwelling pigtail catheter is removed based on the criteria of removal; however, the clinical status (fever during an abscess) and less volume of drainage (less than 20ml/day) should be considered. Most postoperative abscesses or non-infected fluids often demonstrate post- drainage successful results with a single drainage procedure. While collections with fistula or infected will require more than a single drainage procedure with a longer duration (25).

Locally, the short term follow-up of post-ultrasound-guided drainage flow up of the patients is up to six weeks. There is no local study supporting this duration. Some patients remain in hospital wards for further assessment and observation while others get discharged on the same day of the procedure. This is based on the clinical condition of the patient and the size of the collection. Most of the small collections (<3cm) are managed with antibiotics. Follow up imaging with ultrasound is essential with consideration of needle aspiration if the collection is resolved.

Some collections (cysts, lymphoceles, and seromas) are persistent and require a long period of catheterization. Several studies reported intracavitary instillation of sclerotherapy agents (ethanol, tetradecyl sulfate) can shorten the period of catheterization. For cases, fistulization of the abscess cavity intestine, genitourinary, pancreatic or biliary system, percutaneous ultrasound-guided drainage may be successful with prolonged catheterization (5)(6). The thick vicous collection is easily drained with large size pigtail catheters with effective results (23). Locally, Short term

follow up of six weeks duration is performed in patients drained percutaneously with good clinical outcomes. In the local scene, catheter fallout, obstruction or displacement is the most common complication encountered. The catheter is repositioning or a new catheter replacement is established. Care of the indwelling catheter is important. Catheter patency is monitored with a regular flush of 5-10mL normal saline. If the catheter is patent but the collection persists, a large size catheter should be replaced (5)(11).

Refractory Collections

The persistence of collection after PCD might be related to fistula formation with the bowel or with the lymphatic system. fibrinolysis of multiseptated fluid refractory to PCD is recommended. Several studies emphasized the intracavitary instillation of sclerotherapy agents has a high success rate of drainage in sterile collections such as cysts, lymphocele and seromas (20)(9).

1.2 Literature Review

Image-guided percutaneous drainage was described by Gronvel et al in the late 1970s and 1981. Gerzof et al formalized the technique for percutaneous catheter drainage using combined US and CT guided drainage of an intra-abdominal abscess in 29 patients with a success rate of 86 %(10). The mortality and morbidity of postoperative intra-abdominal collections (abscess) declined with the advances of US-guided percutaneous intra-abdominal collection drainage which provided an effective and safe alternative to open(surgical) intervention(8). Image-guided percutaneous drainage and broad-spectrum antibiotics changed the treatment of intra-abdominal collections that previously needed an urgent operation (26).

Several studies reported that the most common indication or use of percutaneous ultrasound-guided drainage is an abscess or infected intra-abdominal collection in post-surgery conditions which is aimed for palliation of a septic condition associated with the infected fluid collection

(27)(10). Most percutaneous catheter drainage at Kenyatta National Hospital is a result of abscess or infected fluid and always after alimentary surgical procedure. The Department of Radiology at Massachusetts General Hospital and the University of California, San Diego conducted a study of 250 procedures of percutaneous catheter drainage of an intra-abdominal collection in two hundred and nine (209) patients. Most of the collections were pyogenic abscess (139 cases), amoebic abscess (12 cases) abscesses and secondarily infected tumours (5cases). There were ten non-infected hematomas, nine pancreatic pseudocysts, nine bile collections, seven urinomas, four lymphoceles and four serinomas. Sites of drainage were subphrenic, pancreas and lesser sac and paracolic gutter. Cures and successes totalled 227/250(90.83%). There were reported twenty-one (21) failures and twenty (20) recurrences of previously drained collections (13).

Catheter drainage of abdominal collections is as efficient as surgical drainage. In this regard, a review of four years of studies of 83 patients with intra-abdominal abscesses was done; forty- (41) of these patients went through surgical drainage, while 42 patients were treated with percutaneous catheter drainage. The two groups were grouped according to age, abscess location, aetiology and evaluation of the APACHE II scoring system. The rate of success of percutaneous drainage was recorded at 93% with two complications of enteric fistulas due to catheter placement. Both of these, however, were resolved with the reposition of the catheter. There was reported a higher rate of fistula formation in a surgically drained group which had two deaths and a 5% of wound dehiscence rate. The study signified the value of percutaneous catheter drainage that offers advantages to patients with diverticular abscesses who could benefit from preoperative percutaneous catheter drainage for a consequent single- procedure (28).

Percutaneous catheter drainage offers significant therapeutic benefits to critically ill patients with complex abscesses before surgical procedures. Complex abscess in critically ill patients

(postoperative patients) with complex inaccessible abscesses or underlying fistula can be managed by two-stage percutaneous catheter drainage and combined surgical reparative therapy, this is in addition to the benefits of the safety of PCD (26). Risk factors contributing to death in patients with complex abscesses include septicemia, organ failure, persistence or recurrence of an abscess, positive blood culture and over 50 years of age. In this situation, appropriate temporizing percutaneous catheter offers benefits of the partial evacuation of the abscess, guidance for the surgeon, correct selection of antibiotics and elective rather than emergency operation. Several studies listed several valuable functions of temporizing the percutaneous catheter approach, stabilizing the patients with unstable vital signs, improvement of other clinical parameters, reducing abscess volume, defining the cause of abscess and improving the overall condition of the patient (nutritional status and subjective comfort (10).

The technical success rate of PCD is over 95%. Reviews of many kinds of literature reported PCD under ultrasound guidance as to safe non-operative procedures. PCD is a widely accepted standard therapy for abdominal collections in the absence of surgical indications (26). From October 2013 to November 2014, an assessment study of PCD effectiveness in 41 patients with abdominal collections was carried out in Iraq. Intra-abdominal collections were detected with the US in 30 patients; while 11 patients needed abdominal CT. Thirty-four (34) patients had postoperative abdominal collections due to cholecystectomy, laparotomy, hydatid cyst and appendicectomy, while six (6) patients had primary intra-abdominal collections largely pyogenic liver abscess. Twenty-eight (28) patients (70%) improved clinically after drainage without morbidity. Seven (7) patients with bile leaks required further interventional procedures (sphincterotomy and ERCP). Five (5) patients did not improve and needed an open operation. One (1) patient with peritoneal mucinous carcinomatosis died after 6 months (29).

US-guided PCD of abdominal collections is safe and a less invasive procedure but rare complications may be encountered by even the most talented compulsive interventional radiologists. In this case, infection related to inadvertent puncture of the colon during catheter placement and local skin infections is secondary to prolonged catheterization. Proper image-guided localization of the collection, aspiration of the collection to characterize and avoidance of non-sterile routes can minimize this complication. Bleeding complications is an inherent risk of catheter drainage of an abscess. It includes pseudoaneurysm, vascular fistula formation and vessel laceration since collection can be found within, adjacent to or behind vascular organs (liver, spleen). Premature exclusion from large vessels may lead to massive bleeding; therefore, follow up images are important to be obtained before moving or removing the instrument to be introduced. The minimal small vessel is self restricted and can be managed with IV fluids or blood transfusion due to shock and observation at the intensive care unit. In the case of laceration of a large vessel, urgent surgical consultation should be obtained. Temporary capping, upsizing or reposition of the catheter may sufficiently end severe bleeding, but constant bleeding from small vessels, pseudoaneurysms, and fistulae may need trans-catheter embolization. If the clinical conditions of the patient or technical aspects are connected with the danger of bleeding regardless of preventive measures in place, the Seldinger technique is the most preferable way of obtaining early access by use of a small needle. A small catheter (6 – 8 French) is recommended during initial drainage if sufficient drainage can be obtained. Using Doppler ultrasound for imaging guidance is always important as an adjuvant to CT guided drainages to evade puncturing closest structures or vessels. In this case, complications are rarely reported (< 5%) (30).

There are potential deterministic factors for the short outcome of PCD. This includes the age of the patent, the postoperative clinical status of the patient, type of the collection (multiloculated,

fistula formation), secondary fungal infection, concomitant antibiotic therapy. To determine the predictors of PCD, a retrospective study of 137 postoperative drainages in 96 patients with multivariate regression analysis was done. Most of the post-operative abscess drainage was successful (82%) except patients with the intra-abdominal collection due to pancreatitis or fungal infection. In multivariate regression analysis, variables included age, the clinical status of the patient, number of the abscess, presence of the organism in the collection (the type of bacteria or fungi and the number), number of the drainage technique(single or multiple sessions) and pancreatic origin of the collection. The postoperative abscess was the only independent of a successful outcome (P=0.4), negative predictors of a successful outcome was the presence of fungal infection (P<.001) and pancreatic origin of the collection (P=.002) (25). The success rate of PCD of the abdominal collection is limited in collection with fistula and the presence of fungal infection. Many studies concluded that such collections will need multiple sessions of drainage and the recurrence rate of collection is high (31). Locally, proper care and pre-procedural assessment are given to the patients with the intra-abdominal collection and or with fistula. Surgical consultation is done accordingly. There is no local guideline for the management of the cases with predicted low success rates in PCD.

CHAPTER TWO: STUDY RATIONALE AND JUSTIFICATION

Percutaneous catheter drainage of abdominal collection under ultrasound guidance is a safe, less invasive and efficient procedure with a higher success rate of (95%) and a lower complication

morbidity rate. There are no local recorded studies on the outcome of ultrasound-guided percutaneous drainage of intra-abdominal collections. To share and build knowledge on our experience, local reference study and local publications are significant. This study aimed to fill the above-mentioned gap. In addition to this, a local audit of complications arising from this procedure was utilized to identify any avoidable adverse occurrences to improve patient management with the abdominal collection and the outcome. Establishing our local accuracy rate to carry out diagnostics and therapeutic ultrasound-guided percutaneous drainage of the intra-abdominal collection would be important reference information going forward to build local expertise as well as improve patient outcomes. Ultimately, this data is fundamental by forming our local reference guidelines to standardize the practice of US-guided percutaneous drainage of intra-abdominal collections. On a larger scale, findings from this study build a local database and reference for National audit purposes in the future.

This study standardizes and allows the US-guided PCD procedure of intra-abdominal collections to be the basic, optimal and locally accepted procedure for all post-operative infected and non-infected collections intra-abdominal collections. It also increases the general awareness of our surgeons on the efficacy and the safety of US-guided percutaneous drainage of postoperative intra-abdominal abscess which has been globally accepted but not fully utilized locally. In addition to that, the data of the study substantiates the effectiveness of the locally performed PCD technique, determining the accurate technical success rate, the major complications encountered, and the short term outcome of the PCD procedure and the selection criteria of the patients to be drained percutaneously. This will eventually lead to the establishment of local guidelines of PCD which plays a major role in the proper management and follow up care of patients with intra-abdominal collections.

2.1 Objectives

2.1.1 Broad Objective

The main objective of the study was to determine the indications and the outcomes of the percutaneous drainage procedure of intra-abdominal collections performed under ultrasound guidance at Kenyatta National Hospital.

2.1.2 Specific Objectives

i. To determine the various indications of percutaneous ultrasound-guided drainage of patients with intra-abdominal collections at the Kenyatta National Hospital.

ii. To determine the technical success rate and complications of percutaneous ultrasound-guided drainage.

iii. To determine clinical short term progress for admitted patients who undergo percutaneous drainage of intra-abdominal collections at Kenyatta National Hospital.

CHAPTER THREE: METHODOLOGY

3.1 Study Design and Methodology

The study adopted a prospective cross-sectional descriptive study design

3.1.1 Study Area

The study area was Kenyatta National Hospital Interventional Radiology Department

3.1.2 Study Population

All patients in all age groups (adults and children) undergoing percutaneous ultrasound-guided drainage of intra-abdominal fluid collections at the Kenyatta National Hospital. Data was collected and analyzed as planned.

3.1.3 Sample Size

The sample size was calculated using Fisher's formula (31);

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

Where, n = Desired sample size

Z = value from standard normal distribution corresponding to the desired confidence level (Z=1.96 for 95% CI). P = expected true proportion (estimated at 90.8%, from a study conducted in 2016 USA (Image-guided percutaneous drainage: a review Tracy A. Jaffe, Rendon C. Nelson found 90.8% of them were cured or had partial success (5).

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.908(1-0.908)}{0.05^2} = 128$$

The sample size of **128** patients was ideal for the study.

3.1.4 Sampling Technique

The convenience sampling method was applied until the sample number was reached.

3.2 Statistics and Data Analysis

Data was analyzed using the statistical model SPSS program (Statistical Package for the Social Sciences, (24.0). Results spectrum was analyzed in form of percentage of complications, short term outcome of the PCD technique and most common of the collection drained.

Patient characteristics were calculated by age, proportions for sex, diagnosis, and pre or post-operative drainage and type of drainage.

Results were presented in the tabular and graphical format while frequencies and frequency distribution was calculated and correlated between variables.

To determine the accuracy of the collections seen in imaging before the drainage procedure, diagnostic aspiration of the fluid was conducted and the collection sample sent to the laboratory for microbiological or biochemical analysis.

3.3 Inclusion Criteria

All patients in all age groups with intra-abdominal collections are recommended for US-guided percutaneous drainage at Kenyatta National Hospital Interventional Radiology Department. Written consent was provided to all study participants that included parents or guardians in case of a child participant who were willing to provide written informed consent.

3.4 Exclusion Criteria

1. Important coagulopathy that could not be adequately corrected.
2. Strictly compromised cardiopulmonary function or hemodynamic instability.
3. Absence of a safe pathway to the abscess or collection
4. Patients who refused to give permission

3.5 Methodology

A prospective study was done on all patients (all age groups) undergoing percutaneous ultrasound-guided drainage of the intra-abdominal collection at the Kenyatta National Hospital.

Selection of patients was done at the Intervention Radiology Clinic at Kenyatta National Hospital, at clinical round of the consultant interventional radiologist or radiology registrar in the ward where procedural details, potential complications and pre-procedure appropriateness criteria were reviewed and discussed. Pre-procedural work-up includes image review of the collection, site of the access, diagnosis of the patient, assessment of the surgical wound status in post-operative patients and routine clotting profile (full blood count, prothrombin time, prothrombin time index and international normalized ratio -INR).

Table 4: Coagulation Profile

Coagulation Parameter	**Reference Range**
INR	<1.5
PT	20 seconds (<5 seconds than control)
Platelet count	>100,000/ml

Impaired coagulation profile can be managed by transfusion of fresh frozen plasma for elevated INR or platelets for low platelet count. Relative contraindications to the procedure may include mild coagulopathy, uncooperative patient and ascites. Absolute contraindications are severe uncorrected coagulopathy, uncooperative patient, severe cardiopulmonary compromise. The correct approval and moderate sedation administration should be part of routine PAD and must

strictly follow the parameters of the procedure. Empirical pre-procedural broad-spectrum antibiotic treatment is recommended for patients with clear signs and symptoms of infection (6). Written informed assent was obtained since the procedure was done under real-time ultrasound guidance to minimize the risk of complications. Five personnel participated in the procedure in addition to the benefits of the safety of PCD for a number done by an interventional radiologist or a radiology registrar under the supervision of the interventional radiologist with the assistance of a registered nurse and a radiographer.

Performing the Procedure

After consent was obtained, the patient was placed in a supine position with hemodynamic monitoring put in place. A preliminary abdominal scan using a G.E systems ultrasound machine 5MHz transducer was used to localize the collection adjacent to the transducer as well as plan the access for the safest and shortest pathway. The selected skin site was prepared and draped in an aseptic manner. To maintain sterility of the procedure, the ultrasound transducer was draped in a sterile sheath and betadine solution was used between the skin and the transducer in place of the coupling gel. Lidocaine (1 to 2% up 20mL) was applied at the site of the skin and along the tract. The addition of 10mL of sodium bicarbonate in each millilitre of Lidocaine decreases the pain of the infiltration of the Lidocaine solution. The patient was encouraged to breathe gently and advised to avoid coughing while local anaesthesia is infiltrated in a transhepatic and transgastric draining approach. A small skin incision was then done using a number 15 scalpel and the aspiration of the collection content is made with an 18G trocar needle (17) ((5).

Commonly used Techniques

One-step Technique

This technique is used for large and superficial collections. After aseptic preparation and infiltration of local anaesthesia under the guidance of ultrasound, the draining catheter is put on a stiffener or stylet and central sharp needle and directly inserted into the anterior wall of the collection. The sharp needle is then detached and a small amount of fluid is aspirated to verify the entry. The outer catheter is moved further in the collection with a pigtail locking device whilst the stylet is held in place. This method is faster than Seldinger and is mainly used for endocavitary drain placement (6).

Two-step/ Seldinger Technique

This is a commonly used normal practice after diagnostic aspiration is performed under the guidance of the US. An 18 gauge sharp needle is used to pierce the rim of the collection. Once a pierced style is removed, fluid is aspirated through the trocar needle for confirmation and complete, decompression of the collection is avoided before the catheter is placed. Depending on the size of the access needle, 0.035 or 0.018 guidewires is advanced through a trocar and the needle is then withdrawn leaving the distal tip of the wire coiled inside the collection. The image is made at this point to document the right placement of the guidewire before track dilatation. Facial dilators are advanced further over the wire with stepwise add to the diameter in widening the track of the anticipated catheter. During this process, the kinking of the guidewire is avoided whilst using stiff dilators (17).

The draining catheter with a stiffener is advanced along the wire without trocar once the tract is dilated. Once in the collection, the draining catheter is fed off and the metal cannula into the collection and the pigtail is created. To protect the draining catheter, a string locking method is used to fix the pigtail in the coiled position; it is then cut and fed into a stopcock. The catheter must be secured to the skin with an adhesive-backed locking device or suture. A lot of care ought

to be taken to enable the drain and tube cover conveniently. Blood aspirate may indicate the opposition of walls (19),(6).

Data collected on each patient included bio-data (age and sex), clinical indication for drainage, type of the fluid aspirated, post-procedural complication, associated diagnosis, post-operative procedure and the type of techniques used. The aspirated sample was sent to the pathology laboratory and results were obtained by direct follow up at the University of Nairobi pathology laboratory using the patient's hospital number.

Figure 6: Chiba Needle Insertion under Ultra-Sound Guidance

Figure 7: Tip of Needled Placed in the Collection

Figure 8: Cather Placed in the Collection

Post-procedure care

The period was limited to one hour whereby patients had their vital signs monitored every 30 minutes and for any signs of complications. Care was offered to make the patient comfortable by providing analgesics and allow the drain to be dependent. In case of any complications, emergencies would be managed according to the Kenyatta National Hospital emergency protocols.

3.6 Study Limitations

1) Lack of randomized studies to allow reaching consensus on the use of PCD in conditions of an intra-abdominal abscess with fistula.

2) Late recognition of post-operative complex intra-abdominal multilocular abscess especially patients referred from other hospitals.
3) Patients with intra-abdominal collections drained with surgical interventions**.**

3.7 Ethical Consideration

The study took into account several considerations by sending an official request to Kenyatta National Hospital Ethics and Research Committee (KNH-UoN ERC) for approval. The study commenced as soon as the approval by the ethics and research committee was granted.

To uphold confidentiality, the patient's personal information e.g. names were not used in the study, the acquired information was not used for any other purpose besides the clinical management of patients and academics.

No examination was done on the patients apart from the one requested by the primary physician.

Informed consent was obtained from all patients/ or guardians enrolled in this study.

Permission was obtained from the Kenyatta National Hospital administration.

3.8 Confidentiality

All information was treated with confidentiality and any relevant medical information on the result of the aspirated sample performed during the drainage procedure and the data collected was accessible to the researcher. Supervisors were also permitted to access the study information. At the end of the study, all collected information was destroyed.

No records of names of the patients/ relatives were kept when data was collected.

3.9 Participants of the Study

A Researcher (Registrar), Research Assistant and Nurse were employed to assist with the documentation process and two consultant radiologists carried out Supervisory duties.

CHAPTER FOUR: RESULTS

The results of the study are presented in this chapter. The main objective of the study was to determine the therapeutic role and complications of the percutaneous drainage procedure of intra-abdominal collections performed under ultrasound guidance at Kenyatta National Hospital.

A total number of 128 patients were recruited during the study period (from June 2018 to July 2020). Most patients (96%) were referred from the KNH wards and few patients from other clinics.

4.1 Demographic Information

This subsection presents the demographic information of the patients which included the age and

Table 1: Age of the patients

Age (Years)	Frequency (N)	Percentage (%)
<18	3	2.3
18-25	15	11.7
26-35	17	13.3
36-45	22	17.2
46-55	25	19.5
56-65	17	13.3
>65	29	22.7

The mean age of the patients was 48.8 (SD=18.3) years, while the median age was 48.5 (IQR=30) years. The minimum age was 11 years while the maximum age was 90 years.

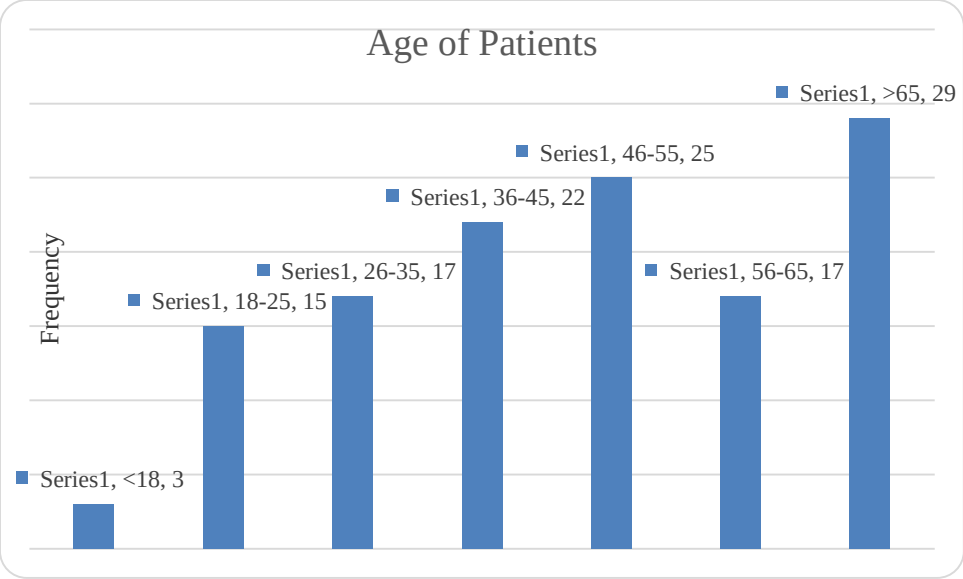
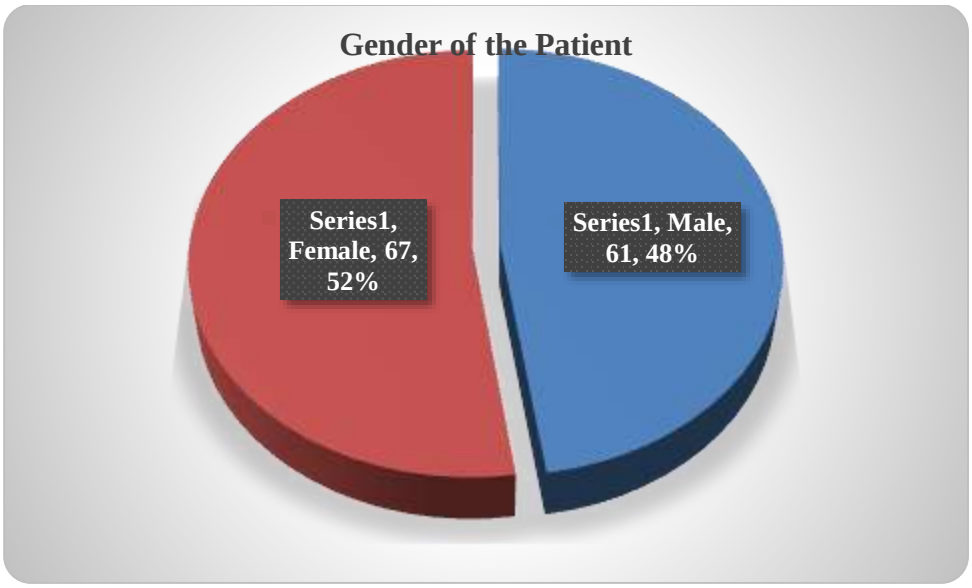


Table 2: Gender of the patient

Gender	Frequency (N)	Percentage (%)
Male	61	47.7
Female	67	52.3

Out of the 128 patients, 67 (52.3%) were female, while 61 (47.7%) were male.



4.2 Indications of Percutaneous Ultrasound-guided Drainage

The first objective of the study was to determine the indications of percutaneous ultrasound-guided drainage of patients with intra-abdominal collections at Kenyatta National Hospital.

4.2.1 Pre/Post-Operative Status of the Abdomen

The patient's pre/post-operative status of the abdomen is as shown in Table 3.

Table 3: Pre/Post-operative status of the abdomen, other non-operative-abdominal procedure

	Frequency (N)	Percentage (%)
Others	92	71.9
Postoperative	33	25.8
Preoperative	3	2.3

The pre/post-operative status indicates that 33 (25.8%) were post-operative, while only 3 (2.3%) were pre-operative, and 92 (71.9%) were others.

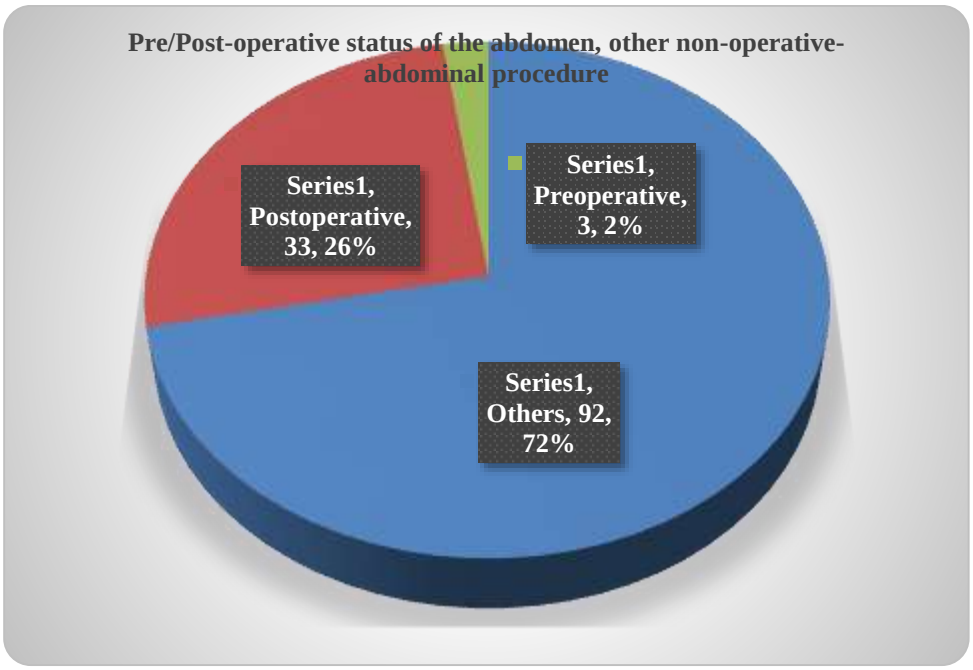


Table 4: Main categories of intra-abdominal collection

	Frequency (N)	Percentage (%)
Peritoneal abscess or infected collection	37	28.9
Ascites	54	42.2
Parenchymal abscess(liver, spleen and pancreas)	13	10.2
Cyst and pseudocyst(pancreas, spleen and liver)	9	7.0
Post traumatic intra-abdominal haematoma	10	7.8
Others	5	3.9

The most common type of intra-abdominal collection was ascites (42.2%), followed by peritoneal abscess or infected collection.

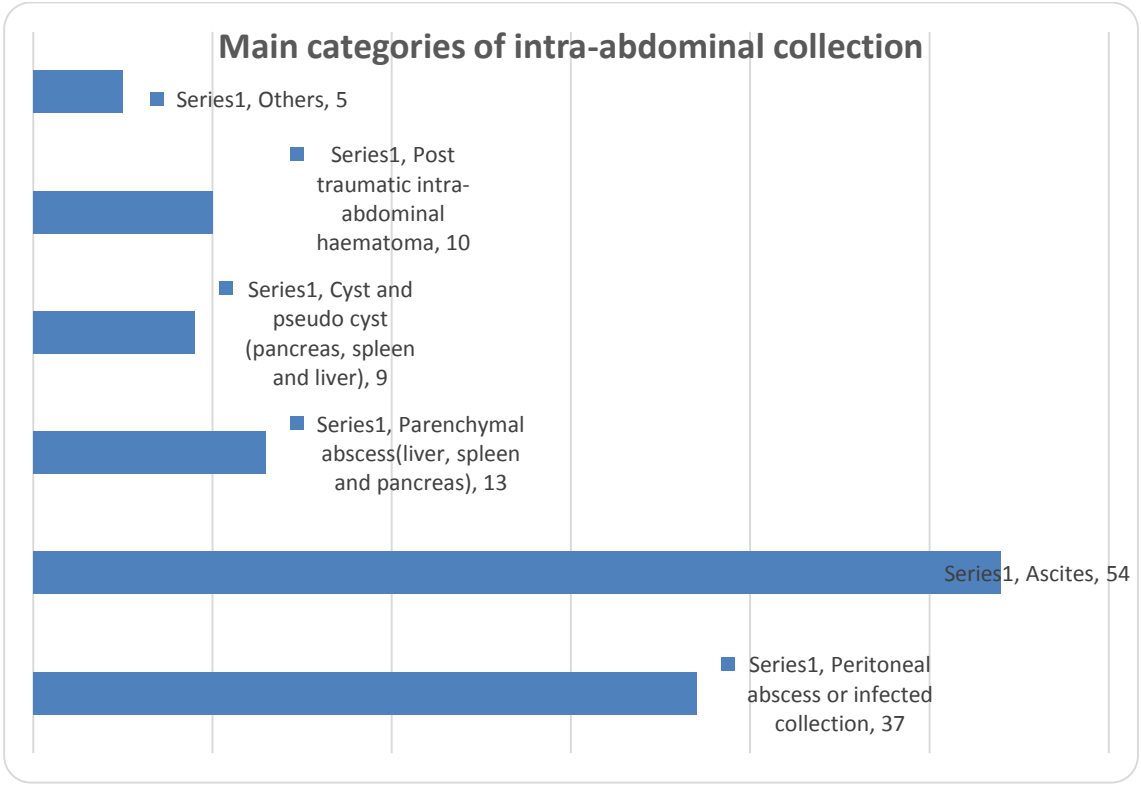


Table 5: Location wise categorization of intra-abdominal collection

	Frequency (N)	Percentage (%)
Intrahepatic	27	21.1
Splenic	9	7.0
Pancreatic	1	0.8
Intraperitoneal	74	57.8
Retroperitoneal	17	13.3

The location with the most intra-abdominal collection was the intraperitoneal (57.8%), and this was followed by intrahepatic (21.1%).

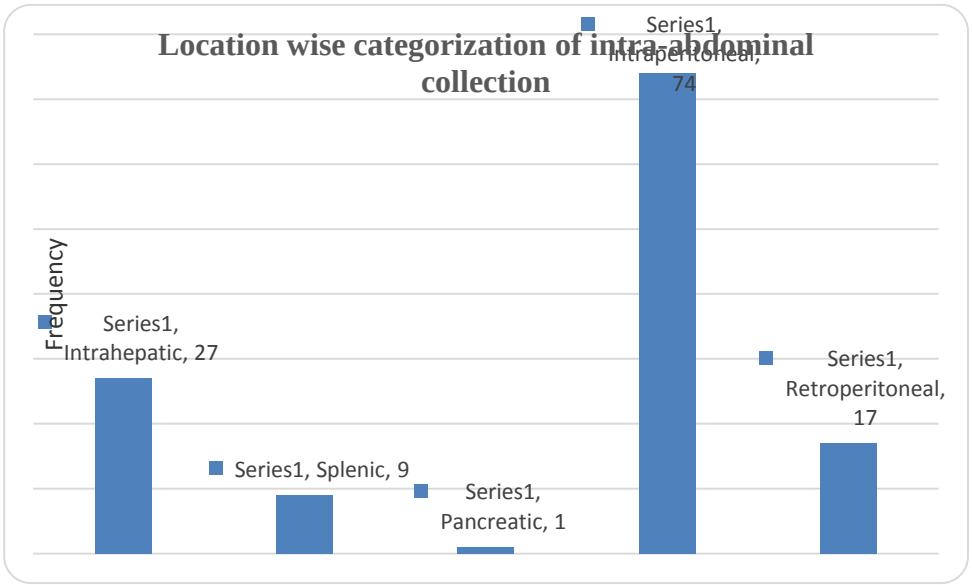


Table 6: Type of fluid drained

	Frequency (N)	Percentage (%)
Serous fluid	41	32.0
Pus	41	32.0
Blood	8	6.3
Infected fluid	21	16.4
Tumour cells	8	6.3
Others: seroma, bilomas, urinomas, lymphocele	9	7.0

The type of fluid that was mostly drained were serous fluid (32.0%) and pus (32.0), this was followed by infected fluid (16.4%).

Table 7: Number of the catheter inserted

	Frequency (N=128)	Percentage (%)
Single	118	92.2
Multiple	10	7.8

There were 118 (92.2%) of the patients who had a single catheter inserted while only 10 (7.8%) had multiple insertions of the catheter.

Table 8: First intra-abdominal drainage procedure

	Frequency (N=128)	Percentage (%)
First	125	97.7
Second	3	2.3

This was the first intra-abdominal drainage procedure for most of the patients (97.7%), while only 2.3% it was their second intra-abdominal drainage procedure

The size of the draining catheter that was mostly used was the 10 French (60.9%), while the 8 French was used on only 37.5% of them.

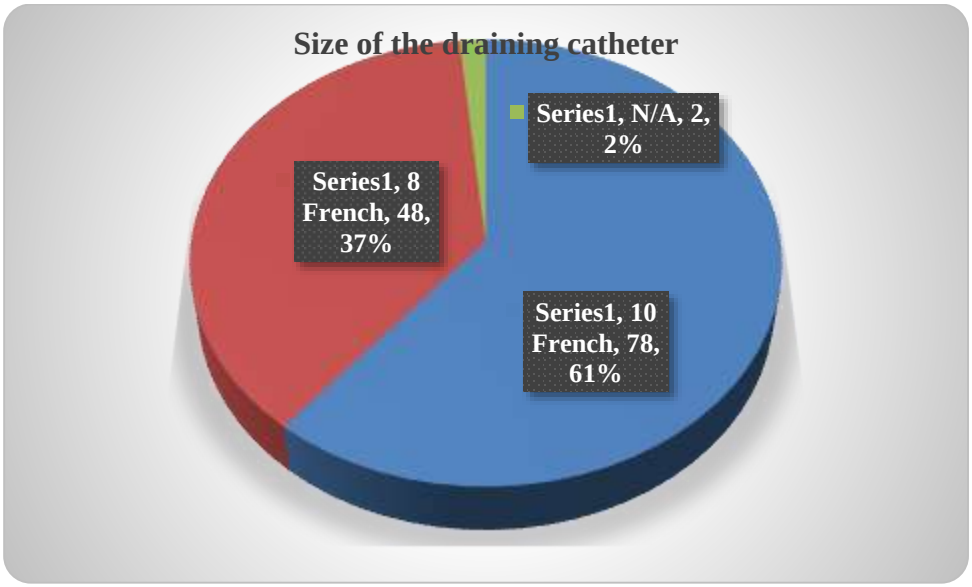


Table 10: Antibiotic treatment (intravenous or oral form) for infected collections

	Frequency (N=128)	Percentage (%)
Yes	93	72.7
No	35	27.3

There were 93 (72.7%) patients who received some form of antibiotic treatment either intravenously or orally.

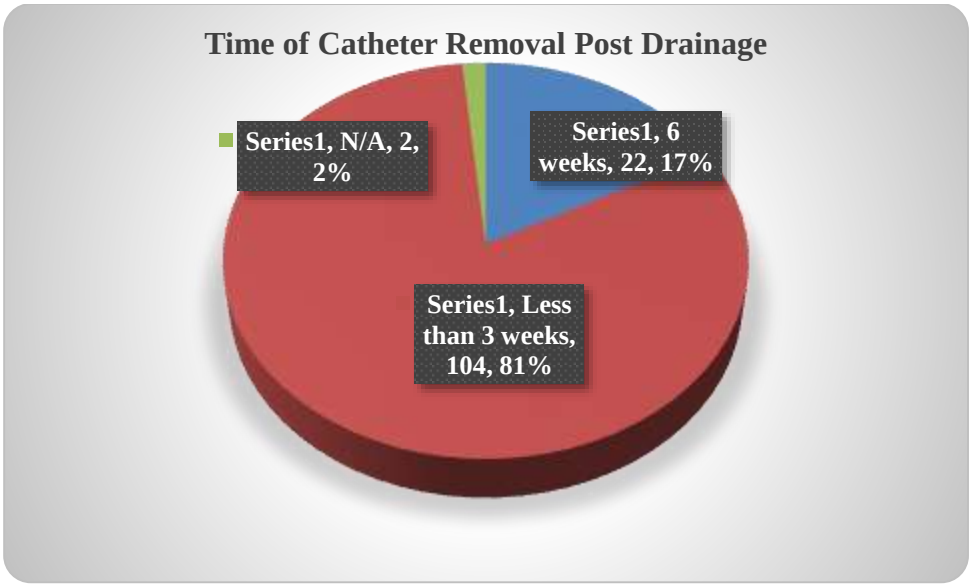
Table 11: Blood test (white blood cell count)

	Frequency (N=128)	Percentage (%)
Elevated WBC	50	43.1
Normal WBC	26	22.4
Not done	52	34.5

Fifty (43.1%) of the patients had elevated white blood cell count, 26 (22.4%) had normal, while the rest of the 52 (34.5%) did not have a white blood cell count done.

Table 12: Time of catheter removal post drainage

	Frequency (N=128)	Percentage (%)
6 weeks	22	17.2
Less than 3 weeks	104	81.3
N/A	2	1.6



4.3 Technical Success Rate of Percutaneous Ultrasound-guided Drainage

The second objective of the study was to determine the technical success rate of the percutaneous ultrasound-guided drainage procedure.

Table 13: Adequacy of drainage technique

	Frequency (N=128)	Percentage (%)
Adequate	126	98.4
Inadequate	2	1.6

Almost (98.4%) of all the patients had adequate drainage, except 2 who had inadequate drainage.

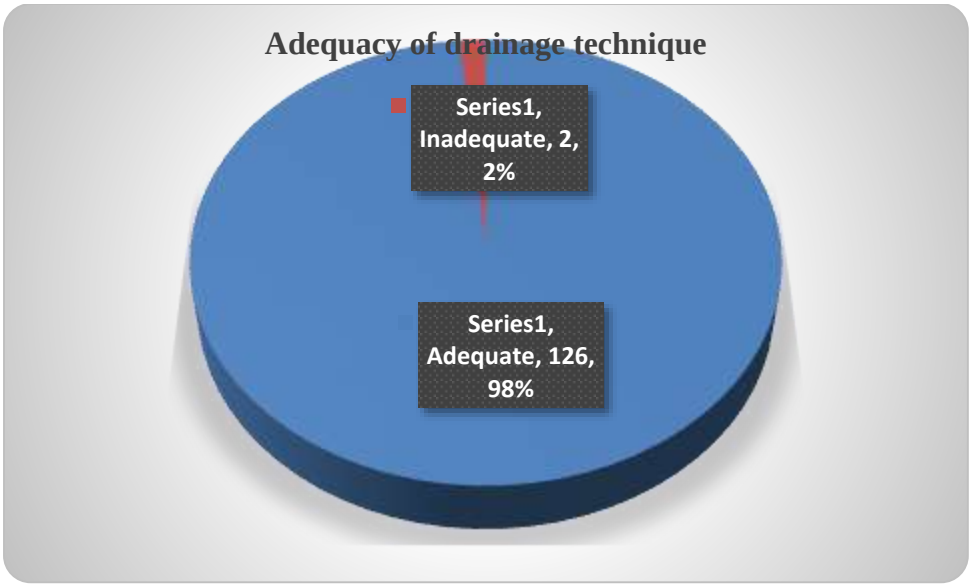


Table 14: Post drainage technique need for surgical drainage

	Frequency (N=128)	Percentage (%)
Yes	1	0.8
No	127	99.2

The majority of patients did not require post drainage for surgical operation drainage and only 1 (0.8%) did require.

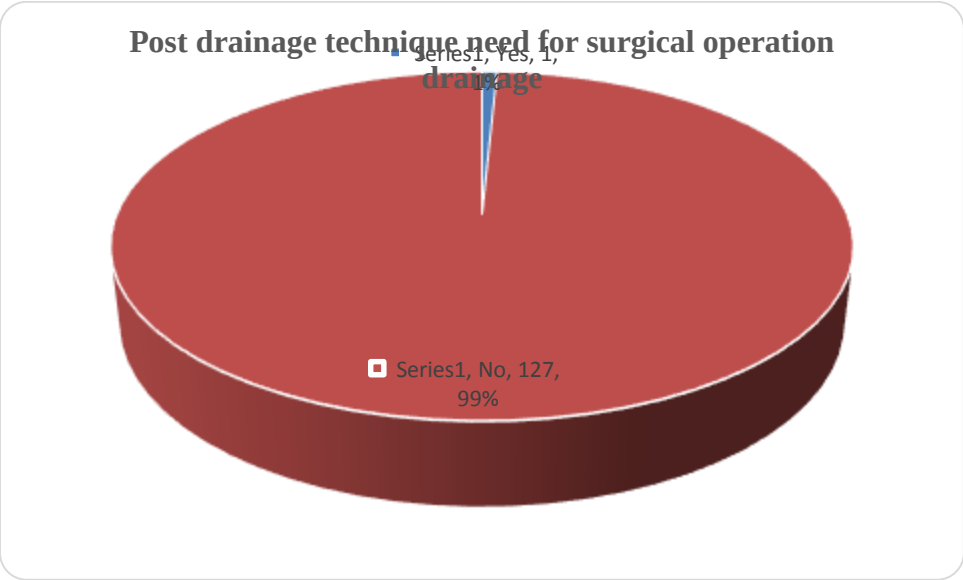


Table 15: Post drainage intervention

	Frequency (N=128)	Percentage (%)
Intravenous fluids	3	2.3
None	123	96.1
Other	2	1.6

A total of 123 (96.1%) of the patients did not require further surgical drainage while 3 (2.3%) had intravenous fluids, and only 2 (1.6%) had other post drainage intervention.

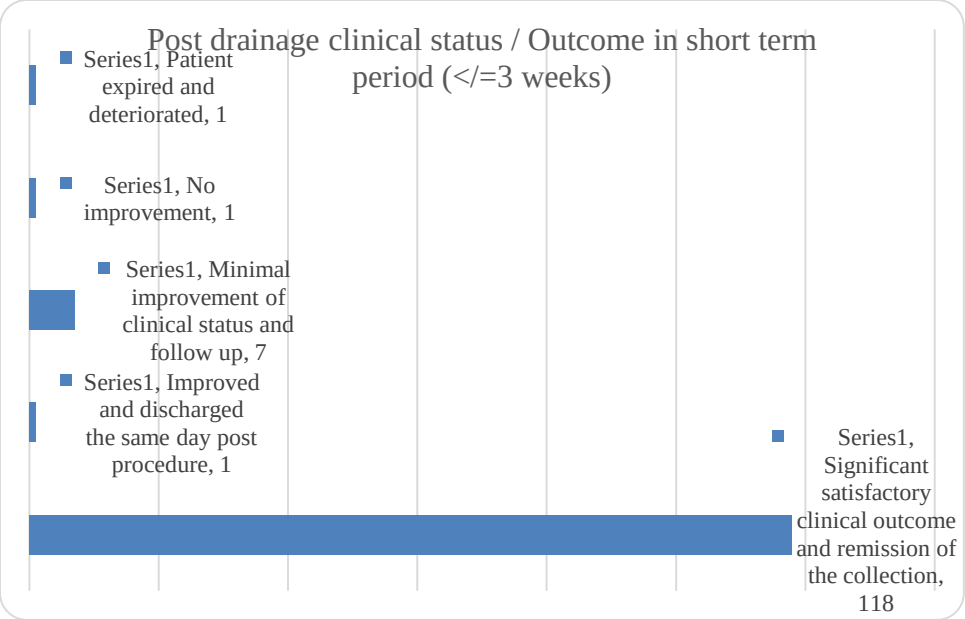
4.4 Short-term Outcomes for Patients Drained Percutaneously

The third objective of the study was to determine short-term outcomes for patients drained percutaneously.

Table 16: Post drainage clinical status / Outcome in short term period (</=3 weeks)

	Frequency (N=128)	Percentage (%)
Significant satisfactory clinical outcome and remission of the collection	118	92.2
Improved and discharged the same day post-procedure	1	.8
Minimal improvement of clinical status and follow up	7	5.5
No improvement	1	0.8
The patient expired and deteriorated	1	0.8

There was a significant satisfactory clinical outcome and remission of the collection from 118 (92.2%) of the patients, and minimal improvement of clinical status and subsequent follow up for 7 (5.5%) of the patients. There was 1 patient who on improvement was discharged on the same day of the procedure, while 1 patient showed no improvement, with only 1 other deteriorating and expiring.



4.5 Spectrum of Complications for Patients Drained Percutaneously

The fourth objective of the study was to determine the spectrum of complications related to ultrasound-guided drainage of intra-abdominal collections at Kenyatta National Hospital

Table 17: Complications resulted from the drainage procedure

	Frequency (N=128)	Percentage (%)
None	122	95.3
Haemorrhage	5	3.9
Raised BP	1	0.8

For 122 (95.3%) patients no complications were arising from the draining procedure, however, there were 5 (3.9%) who had haemorrhages and only 1 (0.8%) who had elevated blood pressure.

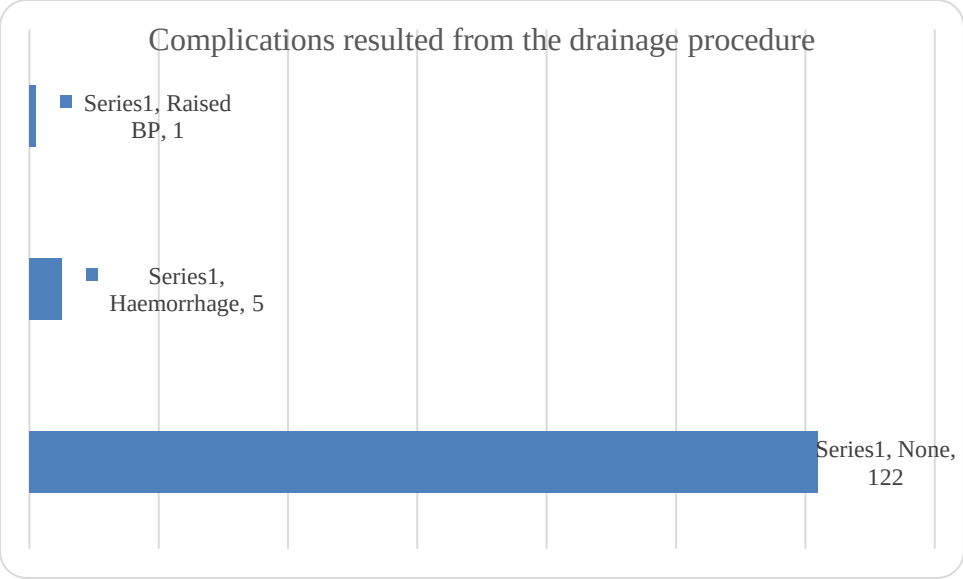


Table 18: Catheter blockage or dislodge

	Frequency (N=128)	**Percentage (%)**
Yes	14	10.9
No	112	87.5
N/A	2	1.6
If yes, **(N=14)**		
Blockage	7	
Dislodge	7	

On catheter blockage or dislodge, 112 (87.5%) did not experience any blockage or dislodge, while 14 (10.9%) did experience, of which 7 had a blockage and the other 7 having a dislodge.

CHAPTER FIVE: DISCUSSION

5.1 Summary and Discussion of Results

The first objective of the study was to determine the indications of percutaneous ultrasound-guided drainage of patients with intra-abdominal collections at Kenyatta National Hospital. The results of this objective indicated that ascites (42.2%) as a category for main intra-abdominal collection had the highest number of patients, and location-wise, the intraperitoneal (57.8%) had the majority of the cases. From the literature, most studies report that the most common indication for percutaneous ultrasound-guided drainage is an abscess or infected intra-abdominal collection in post-surgery conditions which is aimed for palliation of the septic condition associated with the infected fluid collection (19). The type of fluid that was mostly drained were serious fluid (32.0%), pus (32.0%), and infected fluid (16.4%). There was 9.4% of the patients who had a history of trauma, 40.0% who had a history of fever, and 23.0% who mentioned that had a history of liver disease. Most patients had only one single catheter inserted (92.2%), and for the majority, it was their first intra-abdominal drainage procedure (97.7%). For the size of the draining catheter, the most commonly used was the 10 French (60.9%). Almost three-quarters of the patients received antibiotics intravenously or in oral form. Elevated WBC was observed in 43.1% of the patients, and time of catheter removal post drainage was less than 3 weeks for 81.3% of the patients.

The second objective of the study was to determine the technical success rate of the percutaneous ultrasound-guided drainage procedure. The results of this objective indicated that the drainage technique was adequate in 98.4% of the patients, and further to this, almost all the patients except 1 did not require post drainage for their surgical operation. About 96% of the patients had no post drainage intervention.

The third objective of the study was to determine the short-term outcomes for patients who were drained percutaneously. The results for the objective indicate that there was a significant satisfactory clinical outcome and remission of collection in about 92% of the patients. There were 7 patients (5.5%) who had minimal improvement of clinical status, while there were 3 patients, of which 1 had improved and discharged the same day of the procedure, another which showed no improvement, while 1 other whose condition had deteriorated and died.

The fourth and final objective was to determine the spectrum of complications for patients drained percutaneously. Results indicated that 95.3% of the patients had no complications. Out of the 14 patients who had catheter blockage of dislodging, 7 had experienced a blockage, and the rest had dislodged. Vital signs for all the patients were stable pre-drainage and post-drainage.

Percutaneous drainage of abdominal collection under US guidance is safe and less invasive procedure alternative to surgical intervention with a technical success rate of over 95% (13). A review of literature reports that PCD under ultrasound guidance is safe as compare to non-operative procedures (16, 17). PCD is a widely accepted standard therapy for abdominal collections in the absence of surgical indications.

In this study, there was a single case of aspiration that was discharged on the same day. The ultrasound machine was the sole imaging machine, and all the retroperitoneal collection was drained without the need for CT guidance. There was no organ transgresses, bleeding and fistula formation that was encountered during the study. The use of 8 and 10 French catheters were effective even in the setting of thick collections. The study was as comprehensive as all types of drainage procedures of the intra-abdominal collection were performed with a 99% success rate.

5.2 Study Limitations

Due to the Covid-19 pandemic, there was delayed collection of data, and this was compounded by a temporary cessation of elective abdominal collection drainage. Most of the post-operative non-multifocal abdominal abscesses are treated either in the surgery ward or at the theatre due to lack of local written protocol and unawareness of the surgeons about PCD effectiveness.

5.3 Recommendations

It is recommended that there be continuous capacity building of radiology registrars to do all drainage procedures from their first year. The study also recommends that there should be the development of a local protocol for drainage of abdominal abscess that should be done by image guidance, and also have a separate space for image-guided drainage procedures.

5.4 Conclusion

Percutaneous ultrasound-guided drainage of intra-abdominal collection at Kenyatta National Hospital is safe as the procedure is less invasive with a high success rate.

There are no major complications following the procedure and the most common but minor complication is catheter blockage or dislodge.

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APPENDICES

Appendix A: Consent Form to Participate in the Study

This consent form has three parts:

- Information sheet
- Consent certificate
- Statement by the researcher/research assistant

Information Sheet

Background

Percutaneous catheter drainage of intra-abdominal collections under ultrasound guidance is a safe, minimally invasive and effective interventional procedure. This procedure will have a therapeutic and diagnostic role in the management of the patient.

Study Purpose

The study aims to determine the outcomes of percutaneous ultrasound-guided drainage of intra-abdominal collections at Kenyatta National Hospital, specifically the spectrum of complications, type of drainage and success rate of the procedure.

Risks and Benefits

There is a low risk of complications occurring during and after this procedure. The most common complaint is the infection of the peritoneum (peritonitis). The procedure will be carried out under the supervision of an experienced consultant radiologist and in the occurrence of these adverse effects; you will be promptly managed by the KNH emergency protocol. There will be no additional harm or risk for participating in this study. No additional tests will be requested other than the routine for the management of your condition. There will be no extra cost for participating in the study.

Voluntariness of Participation

Participation in this study is voluntary and you will not be denied medical care in case you refuse to participate. You are free to withdraw from participating in the study at any time with no consequence whatsoever.

Confidentiality

All information will be treated with confidentiality and any relevant medical information regarding the result of the aspirated sample performed during the drainage procedure and the data collected will be accessible to the researcher.

Information that may be looked at by his supervisors were relevant to the study.

All information collected will be destroyed at the end of the study.

No records of names of the patients/ relatives will be kept in the data collection.

Compensation

There will be no any form of financial compensation or otherwise for the participants, no preferential treatment, gift or reward for participants will be awarded during the above study.

Contact Information

Shall you need any further clarification regarding this study please feel free to contact the principal researcher

1. **Dr Abdirashid Yussuf Omar ((MBCHB)**

   UON Postgraduate Radiology Resident

   Cell phone number 0790829947

2. **Supervisor:**

Dr Magabe Chacha

Vascular Intervention Radiologist at KNH and a Lecturer in the Department of Radiology, University of Nairobi

Cell phone number 072229104

cmagabe@yahoo.co.uk

If you have any questions on your rights as a research participant you can contact the Kenyatta National Hospital Ethics and Research Committee whose task is to ensure research participants are protected from harm.

3. Secretary, KNH-UoN Ethics and Research Committee, P O. Box 20723, 00200, Nairobi, Tel. No.2726300, Ext. 44102, email.uonknh_erc@uonbi.ac.ke

Consent Certificate

I hereby confirm that the doctor has explained to me about the above study and I understand fully. I have been allowed to ask questions which have been adequately answered.

I understand that my participation is voluntary and that I have not been forced to participate. I understand that I can decline without giving any reason, without my medical care or legal rights being affected.

I understand that I will not receive any compensation either financial or otherwise, and will not receive any preferential treatment, gift or reward, for participating in the above study.

I understand that my personal information will be kept confidential, but that any relevant medical information regarding the results of my scans and the data collected will be accessible to the researcher, and maybe looked at by his supervisors who were relevant to the study. I permit them to have access to this information.

I hereby consent to take part in the above study

Respondent's Signature ….. …….

Date ……

Consent Certificate of a Parent or a Guardian

I hereby represent and confirm that the doctor has explained to me about the above study and I understand fully. I have been allowed to ask questions which have been adequately answered.

I understand that the participation of my child is voluntary and that I have not been forced to participate. I understand that I can decline without giving any reason, without my medical care or legal rights being affected.

I understand that my child will not receive any compensation either financial or otherwise, and will not receive any preferential treatment, gift or reward, for participating in the above study.

I understand that my child's personal information will be kept confidential, but that any relevant medical information regarding the results of my scans and the data collected will be accessible to the researcher, and maybe looked at by his supervisors who were relevant to the study. I permit them to have access to this information.

I hereby consent on behalf of my child to take part in the above study

Respondent's Signature ….. …….

Date ……

Statement by the Researcher/ Research Assistant

I hereby confirm that I have accurately read out the contents of the information sheet to the participant. To the best of my ability, I have made sure the participant understands the following;

- Participation in this study is voluntarily and no compensation will be given.
- Refusal to participate or withdraw from the study at any point will not in any way compromise the quality of care accorded to the patient.
- All the information that shall be given will be treated with confidentiality.

Name ……

Signature……

Date ……..

Appendix B: Fomu ya Idhini ya Kushiriki Katika Utafiti

Mimi ninathibitisha ya kwamba daktari amenielezea kuhusu utafiti huu na ninaelewa kikamilifu. Nimepewa fursa ya kuuliza maswali ambayo yamekuwa ya kutosha kujibiwa. Mimi ninaelewa ya kwamba ushirika wangu ni wa hiari na kwamba mimi sijalazimishwa kushiriki. Naelewa ya kwamba ninaweza kukataa kushiriki bila kutoa sababu yoyote, bila ya uangalizi wangu wa matibabu au haki za kisheria kuathirika. Ninaaelewa vilevile ya kwamba mimi sitapokea fidia yoyote ama fedha au vinginevyo, na wala kupokea chochote cha upendeleo wa matibabu, zawadi au tuzo, kwa ajili ya kushiriki katika utafiti huu. Ninaelewa kwamba maelezo yangu ya kibinafsi yatakuwa siri na taarifa yoyote muhimu ya matibabu kuhusu matokeo ya ukaguzi yangu na takwimu zilizokusanywa zinaweza kufikiwa na mtafiti, na kuangaliwa na wasimamizi wake ambapo ni muhimu kwa utafiti. Mimi nimewapa ruhusa yangu kwa kupata taarifa hii.

Mimi nimekubali kushiriki katika utafiti huu

Sahii ya Mjibu…….

Tarehe ……..

Ridhaa Hati ya Mzazi au Mlezi

Mimi ninawakilisha na kuthibitisha kuwa daktari amenieleza kuhusu utafiti huu na nimeelewa kikamilifu. Nimepewa fursa ya kuuliza maswali ya kutosha na kujibiwa kikamilifu. Ninaelewa kwamba ushiriki wa mtoto wangu ni wa hiari na mimi/mtoto hakulazimishwa kushiriki. Ninaelewa kwamba ninaweza kukataa bila kutoa sababu yoyote, bila ya uangalizi wangu wa matibabu au haki za kisheria kuathirika. Ninaelewa kwamba mtoto wangu hatapokea fidia yoyote ama fedha au vinginevyo kama, upendeleo wa matibabu, zawadi au tuzo, kwa ajili ya kushiriki katika utafiti huu. Naelewa kwamba taarifa binafsi ya mtoto wangu itakuwa siri, lakini yoyote yanayohusiana na maelezo ya matibabu kuhusu matokeo ya ukaguzi wangu na takwimu zilizokusanywa zinaweza kufikiwa na mtafiti, na kuangaliwa na wasimamizi wake ambapo ni muhimu kwa utafiti. Mimi nimetoa ruhusa yangu kwa kuzipata taarifa hizi.

Mimi nimetoa ridhaa kwa niaba ya mtoto wangu kushiriki katika utafiti huu

Sahii ya Mjibu .....

Tarehe ……

Assent Form

Project Title: The Indication and Outcome of Ultrasound-Guided Percutaneous Catheter Drainage of Intra-Abdominal Collections at Kenyatta National Hospital

Principal Investigator: Dr Abdirashid Omar, postgraduate student, Dept. of Diagnostic Imaging and Radiation Medicine, UON

My name is Dr Abdirashid Omar, a postgraduate student, Diagnostic Imaging and Radiation Medicine, UON

I am doing a research study involving the removal of fluid collected in the abdomen using a small tube with aid of ultrasound images to improve patient management.

If you agree to be part of this study, you will be requested to take part in a procedure of abdominal fluid drainage under the guidance of ultrasound. This procedure will take about thirty (30) minutes. There are no risks involved in your taking part in the study. There are also no benefits to you for participating in the study.

If you do not want to be in this study you can do it before we begin the procedure and it is okay. Your parents know about the study too.

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

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

_____ _____

(Sign your name here) (Date)

Fomu ya Kukubali

Kichwa cha Mradi: Dhibitisho na Matokeo ya Udhibiti wa Toni ya Ultrasound iliyoongozwa na Mafuta ya Makusanyo ya ndani ya tumbo katika Hospitali ya Kitaifa ya Kenyatta.

Mpelelezi mkuu: Dk. Abdirashid Omar, mwanafunzi aliyehitimu shahada ya kwanza, Dhana ya Utambuzi wa Utambuzi na Tiba ya Mionzi, UON.

Jina langu ni Dk. Abdirashid Omar, mwanafunzi wa Uzamili, Utambuzi wa Utambuzi na Dawa ya Mionzi, UON

Ninafanya utafiti wa kuhusisha kuondolewa kwa maji yaliyokusanywa ndani ya tumbo kwa kutumia bomba ndogo kwa msaada wa picha za ultrasound kuboresha usimamizi wa mgonjwa.

Ikiwa unakubali kuwa sehemu ya utafiti huu, utaombewa kushiriki katika utaratibu wa mifereji ya maji ya tumbo chini ya mwongozo wa ultrasound. Utaratibu huu utachukua kama dakika thelathini (30). Hakuna hatari zinazohusika katika kushiriki kwako kwenye utafiti. Hakuna faida pia kwako kwa kushiriki katika utafiti.

Ikiwa hutaki kuwa katika utafiti huu unaweza kusema kabla ya kuanza utaratibu na ni sawa. Wazazi wako wanajua kuhusu masomo haya pia.

Ukiamua unataka kuwa katika utafiti huu, tafadhali saini jina lako.

Mimi, _____, nataka kuwa katika utafiti huu.

_____ _____

(Saini jina lako hapa) (Tarehe)

Appendix C: Data Collection Tool

Pre-procedure Status	
Patient characteristics	
1-Age	
2-Sex	1= Male 2 = Female
3-Pre/post-operative status of the abdomen Other-non-operative-abdominal procedure	1- Preoperative 2- Postoperative 3- 3-Others
4-Preliminary diagnosis/ Final diagnosis	
5-History of trauma	1- Yes 2- No
6-Other-systemic-disease	

7-Site of fluid collection	
8- History of fever	1- Yes 2- No
9- First intra-abdominal drainage procedure	1- First 2- Second 3- Multiple
10- If the second or multiple drainages are done, specify the date of the drainage	
11-Type of drainage(fluid)	1- Pus 2- Fluid 3- Blood 1- Others
12- Antibiotic treatment(intravenous or oral form) 13-Blood test(white blood cell count)	1- Yes 2- No
Post Procedure status	
14- History of liver disease	1- Yes 2-No
15-Imaging modality	1- Ultrasound 2-CT scan. 3-Both
16- Session technique	1- Single session 2- Multiple sessions
17-Number of the catheter inserted	2- Single 2- Multiple

18- Post drainage technique need for surgical intervention	1- Yes 2- No
19- Complications resulted in the drainage procedure	1 =Haemorrhage 2 = Puncture of liver 3=Puncture of bowel 4=Puncture of gallbladder 7=Puncture of other organ, specify _____
20-Post drainage observation period	_____minutes _____hours
21- Care of catheter education	1- Yes 2- No
22-Post drainage intervention	1=None 2= Intravenous fluids 3=Blood transfusion 4= Laparotomy

	5= Any other, specify
23-Lab investigation of aspirated fluid	1 = Yes 2 = No
24- Diagnosis based on the lab investigation	
25-Follow up of catheter care duration	
26-Adequacy of drainage technique	1- Adequate 2- Inadequate
27-Time of catheter removal post drainage	1- Less than 3 weeks 2- 6 weeks 3- More than 6 weeks 4- More than 6 months
28-Catheter blockage or dislodge	1- Yes 2- No

29-Size of the draining catheter	1- 8 French 2- 16 French
30-Pre-drainage vital signs	Blood pressure= Temperature= Pulse rate=
31-Post drainage Vital signs at 20 minutes	Blood pressure= Temperature= Pulse rate

Appendix D: Budget

ITEM	Quantity	Unit Price (Ksh)	Total(Ksh)
Writing Pens	1box	200 .00	200 .00
Notebooks	5pcs	60.00	300.00
Files	8pcs	50 .00	400 .00
Printing Paper	5rims	400 .00	2 000 .00
Cartridge	1pc	6 000 .00	6 000 .00
Internet Surfing	28GB	428 .60 per GB	12,000 .00
Telephone follow up	1440 minutes	4 .00 per minute	5 760.00
Flash discs	2pcs	2 000 .00	4 000 .00
Thermometer	1piece	3 000.00	3 000.00
Blood pressure machine	1piece	10 000.00	10 000.00
Printing drafts and final proposal	10 copies	500 .00	5 000 .00
Photocopies of data collection tool	200 copies	8 .00	1600 .00
Photocopies of final proposal	6 copies	100 .00	600 .00
Binding copies of proposal	6 copies	60 .00	3600 .00
Ethical review fee	1	1 000 .00	1 000 .00

Subtotal	**55,460 .00**

Personnel

Nurse	1		10 000 .00
Research Assistant	1		20 000.00
Biostatistician	1	30 000 .00	30 000 .00
Subtotal			**60 000 .00**

Data Collection, Data Analysis and Thesis Development

Printing of thesis drafts	10 copies	1 000 .00	10 000 .00
Printing final thesis	6 copies	1 000 .00	6 000 .00
Binding of thesis	6 copies	300 .00	1 800 .00
Dissemination cost			10 000 .00
Subtotal			**27 800 .00**
Contingency (10% of total budget)			**8950 .00**
Grand Total			**162 210 .00**