THE VALUE OF PERITONEAL DRAINS IN
PERFORATED APPENDICITIS AT KENYATTA
NATIONAL HOSPITAL.

A DISSERTATION SUBMITTED IN PART FULFILMENT
FOR THE DEGREE OF MASTER OF MEDICINE
(SURGERY) UNIVERSITY OF NAIROBI.

BY

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DECLARATION

CANDIDATE
This dissertation is my original work and has not been published elsewhere or presented for award of a degree in any other university.

Signed

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M,B,ChB.(NBI)

SUPERVISOR.

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

Signed

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Dedications

I succeeded this far because I was supported by giants. Without the unwavering support, encouragement, criticism and knowledgeable guidance of my supervisor Professor P. Jani this work would never have been completed. My sincere thanks to you professor.

The department of surgery and its lecturers have transformed me through knowledge, and may the lord bless you abundantly.

My family and friends who supported me throughout the journey I dedicate this work to you. The great sacrifices will not be in vain.
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SUMMARY

Introduction

Unlike simple acute appendicitis, complicated appendicitis is challenging in management and outcome unpredictable. Controversies surround some aspects of its management like the right timing and type surgical intervention, the antibiotics use and peritoneal drainage. This study focuses on use of peritoneal drains post appendectomy.

Objective

To evaluate the management of complicated appendicitis at Kenyatta national hospital and determine the value of peritoneal drains post appendectomy in patients with various stages of complicated appendicitis.

Methodology

Patients suspected to have acute appendicitis were recruited from casualty and admitting surgical wards. In theatre those with complicated acute appendicitis were stratified according to the degree of peritoneal contamination. All those with complicated acute appendicitis without generalized peritonitis were randomized to two comparison groups; drains or no drains. All patients received similar treatment in all other aspects; they were followed up for complications, duration of antibiotic use and length of hospital stay. Statistical analysis was used to compare the two groups.

Results

Over one year period, 216 patients were evaluated. 97 had various stages of complicated acute appendicitis, 90 were randomized. Two patients died; one of them had severe sepsis and the other developed pulmonary complications post operation.

18 patients had wound sepsis, 6 patients had other complications including fecal fistulae, abdominal abscess, and paralytic ileus. Out of those with wound sepsis, 83% were of the drain group and 17% of the no drain group. All patients with other complications were of the drain group. The patients in the drain group had significantly longer duration of antibiotic use and hospital stay.

Conclusions

Immediate surgical intervention, after resuscitation and with antibiotics is the main mode of management of complicated appendicitis at Kenyatta national hospital. The findings in this study do not lend any support for use of drains post appendectomy in some stages of advanced appendicitis. The management and role of drains in perforated acute appendicitis with generalized appendicitis needs further review.
INTRODUCTION

Patients presenting with complicated acute appendicitis are common and challenging in management. Controversy exists on particular aspects of management of this condition, such as the need and best timing of surgical intervention, the best choice and length of antibiotic use, and whether or not to use peritoneal drains.(1, 2, 3.)

Roland et al showed that non surgical approach in patients with appendicular abscess or phlegmon was associated with lesser morbidity than immediate surgery. However, this systemic review was based on mainly retrospective studies and still reported serious complications in 19% of the cases (1). On the other hand, Jonathan et al recommended drainage and delayed appendectomy in patients with abscess or right quadrant lower phlegmon. The study included only children.(2)

There is no consensus on the use of peritoneal drains, while established collections are the indication for therapeutic drains; prophylactic drains are placed in anticipation of complications, they are expected to signal leakages or hemorrhage early. These drains are also anticipated to prevent further collections in the cavity. Opinions on the practice are divided, some believe peritoneal drains are useless and do not work while others insert drains routinely, sometimes as safety valves (3).

Harlan et al on a study focused on abdominal drainage following appendectomy and cholecystectomy; showed no difference in outcome when drains were used on simple appendectomy, but significantly higher infectious complications in gangrenous or perforated appendicitis. In this study, penrose drains were used and all stages of appendicitis were included with some drains exteriorlized through the main incision wound.(4)

The practice of using peritoneal drains in complicated acute appendicitis is common at Kenyatta national hospital. Anangwe(1985) found that 22% of all patients with acute appendicitis at Kenyatta National hospital had prophylactic drains fixed post operatively. The indications included all forms of acute appendicitis. This was a retrospective study and all the drains were corrugated rubber drains (5).
In a similar study Sundeep (2002) showed that approximately 30% of patients with acute appendicitis had drains, again all complications of acute appendicitis were included. Although this was a prospective study, the type of drain, their efficiency in function, the duration of use and complications in patients with drains were not evaluated (6).

A systemic review and meta-analysis by Henrik et al showed that many gastrointestinal operations can be performed safely without use of prophylactic drainage. They did not find evidence for use of drains in any stage of appendicitis. However, some of the studies included in the review did not report on their exclusion criteria, others excluded patients with severe intraperitoneal sepsis and appendiceal abscesses. Recognizing these limitations the reviewers called for well designed randomized controlled studies to clarify the value of prophylactic drainage (7).

The purpose of this study is to evaluate the efficiency and the value of peritoneal drainage in patients with complications of acute appendicitis at Kenyatta National hospital.
LITERATURE REVIEW

COMPLICATIONS OF ACUTE APPENDICITIS

(a) Diagnosis

The clinical presentation of complicated appendicitis can not be clearly separated from that of acute appendicitis. It is believed that delay in diagnosis or inappropriate treatment of acute appendicitis leads to complications. Hence, the acute disease may advance to gangrenous appendicitis, appendiceal phlegmon, perforate to form either local abscess or generalized and sometimes formation of mucocele (8). Presenting symptoms and signs are mostly non specific and difficult to elucidate earlier in the course of disease but attention to detail, appropriate investigations and astute clinical acumen are required both in early and advanced disease. Efforts towards early accurate diagnosis have resulted in development of clinical scores, use of imaging and various laboratory markers (9,10,11).

Diagnostic clinical scoring

In an attempt to improve accuracy in the confusing clinical picture of acute appendicitis, several authors have developed clinical scoring systems. These have been found to be useful in complicated appendicitis as well.(9, 11, 12,13, 14, 15.) Alvarado score was formulated from statistical analysis of patient’s signs, symptoms and laboratory findings. The findings were weighted and given numerical values depending on their calculated discriminative and predictive power.

Diagnostic weight was given to localized tenderness in the right lower quadrant, leucocytosis, migrating pain, shift to the left, temperature elevation, nausea vomiting and rebound pain.

It was found that the score was consistently high with perforated and gangrenous appendicitis. These findings have been validated by other studies. The original Alvarado score was modified by substituting left shift with neutrophil percentage count and temperature by tender right iliac fossa to make it more widely applicable. (9,11,12)
Modified Alvarado score (9)

<table>
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<th>component</th>
<th>score</th>
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<tr>
<td>Migrating pain</td>
<td>1</td>
</tr>
<tr>
<td>Anorexia</td>
<td>2</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>1</td>
</tr>
<tr>
<td>Tender right iliac fossa</td>
<td>1</td>
</tr>
<tr>
<td>Rebound tenderness</td>
<td>2</td>
</tr>
<tr>
<td>Leucocytosis &gt;10000</td>
<td>2</td>
</tr>
<tr>
<td>Neutrophils &gt;75%</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
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Appendicitis presents more diagnostic difficulties in the female patients owing to a constellation of differential diagnoses. Eskelinen et al devised a score that is sex specific but it requires use of computer programs that might not be universally available (13). Scoring systems such as fenyo- linberg and Christian, have been utilized other centers (14,15).

In complicated appendicitis, the question of diagnosis might be easy but plan of management must take into account the likely differential diagnosis and therefore, imaging might be required to further define the clinical findings or rule out differentials (16).
The role of imaging in acute appendicitis has been in the cases where the clinical diagnosis is in doubt. Plain radiographs and barium enema have a modest role in diagnosis of appendicitis, where a radio-opacity in the right iliac fossa suggests a calcified fecolith. (16) The ultrasonic scan, the computed tomographic scan, and the magnetic resonance imaging have been shown to have a role in selected patients (16). Normal white blood counts have been encountered in complicated acute appendicitis. It is in this group of patients, with normal counts or upper normal limits and high clinical suspicion that imaging plays a vital role (17).

Ultra sound

Ultra sonographic finding of increased diameter (>6mm), and incompressibility are diagnostic of appendicitis. In complicated acute appendicitis, the finding of mixed echogenic mass, sometimes fluid collection and debris suggests abscess formation. In the best of hands ultra sound has been reported to have sensitivity of up to 80% and specificity of above 90%. It is less costly and confers no radiation risk to the patient. Color Doppler sonography is useful when blood supply is compromised (19,20). However, the reliability of ultra sound is limited in obese patients and in presence of bowel gas and distension. It is user dependent and there are many other conditions that mimic appendicitis in sonographic imaging (18, 19, 20).
Computed tomographic scan

Computed tomographic scan (CT) has been utilized in occasions of diagnostic dilemma especially in complications of acute appendicitis. It has relative operator independence; higher diagnostic accuracy, allows delineation of extent of disease in complicated appendicitis. CT scan has been shown to reduce the incidence of negative appendectomy without increase in rate of perforations. (21) This modality has sensitivity and specificity of 92-94% and 87-90% respectively. Gregory et al showed a reduction in negative appendectomy rate from 14% to 7% by selective use of CT scan.(21) The main disadvantage remains the radiation exposure, limiting its use in pregnancy and children.
The cost and unavailability hampers its routine utilization. However indiscriminate requesting of CT scan for all patients with suspicious abdominal pain was shown to erode its discriminatory power, prolong the pre-operative delay, and increase the cost of treatment in appendicitis. CT scan should only be requested after expert surgical opinion has been sought but not by emergency room physicians. Therefore, CT scan has been reserved for patients with high clinical index of suspicion with inconclusive laboratory markers, indeterminate sonographic findings and in cases of complicated appendicitis (21, 22).

Magnetic resonance imaging-(MRI)

The M.R.I modality is not routinely utilized in the diagnosis of any stage of appendicitis. This modality of investigation has the distinct ability of great anatomical delineation and lack of radiation exposure. Noting that appendicitis is the commonest non obstetric surgical procedure, and complications of appendicitis led to pre- mature labor, fetal or maternal mortality; Lodewisk et al studied the use of M.R.I in evaluation of expectant mothers with clinical suspicion of appendicitis. They found that it is helpful in the situation where the ultra sound is non conclusive.(23) The M R I finding of enlarged appendix with diameter >6mm and signal changes of the peri-appendicular fat were considered diagnostic. This study showed 100% concordance between MRI and histopathology findings (23).
Diagnostic laparoscopy

The capability to combine investigation with therapeutic interventions makes laparoscopy a technique of choice in appendicitis especially in women. Previously complicated acute appendicitis was a contra-indication to laparoscopy but this has gradually changed, however, there are concerns over high incidence of post operative complications with laparoscopic approach in complicated appendicitis. (24,25.) Other abdomino-pelvic conditions causing right iliac pains can be diagnosed. The principle disadvantage is the requirement for general anesthesia and its invasive nature that raises its risk profile to that of operation.

Histology

Clinicians have always regarded histology as the standard of diagnosis while among pathologists debate ranges on the standard histological changes that should warrant the diagnosis of appendicitis.(26) Differences arise on the level of inflammatory cell infiltration; some authors believe that involvement of mucosa and sub mucosa is sufficient to give a report of appendicitis. Others argue that these are transient changes that do not contribute to clinical signs and hence, trans-mural inflammation should be the standard.(38) Carr et al reviewed histology reporting and argued that neutrophils in the lumen, mucosa or sub mucosa should raise the possibility of incidental findings and warrant the search of pathology elsewhere. The presence of a fecolith without inflammation has no significance and the terms “early appendicitis” are speculative and are better avoided. In complicated appendicitis necrosis of the wall and perforation are cardinal features. These may be obvious grossly but difficult to demonstrate by histology. However, serosal involvement and surrounding tissue inflammation suggest advanced disease. Other specimen collected in complicated appendicitis should be reported.(26,38).
(b) Management

Conservative approach - interval appendectomy

The management of complicated appendicitis has traditionally been that of 'wait and see.' This approach initiated by Oschner in 1901, is based on the premise that the acute inflammatory stage will resolve and interval appendectomy will be performed later. This has been the practice for over 100 years. (1, 27, 28)

The argument has been that immediate operations are much more challenging technically and are associated with higher morbidity. The tendency to perform ileal-cecal resection is higher due to difficulty in differentiating between inflammatory changes and malignancy. (27)

Interval appendectomy is much easier, usually performed 8 weeks to three months later. The shortcomings of this approach are noted when there is a possibility of malignancy or other important benign disease like tuberculosis in the appendicular mass (27).

However, there is little evidence-based data for determining the best management of complicated appendicitis (1, 28). Systemic review and meta-analysis of this approach has led Roland et al to recommend that the interval appendectomy is not necessary. They reviewed mostly retrospective studies published in the period 1965-2005, and found that malignancy was in 1.2% of the patients with appendicular mass, and other benign disease in 0.7% of the patients. The incidence of recurrent appendicitis was 7%. It is interesting to note that 19% of the patients still underwent surgery in the initial admission due to failure of non-surgical management. (1)

Since routine interval appendectomy has associated surgical complications; their recommendation was that it was unnecessary in the remaining 93% of the cases. (1)

In centers where dedicated ultra sonography, contrast enhanced CT scan and if need be MRI is available the anatomy of appendicular mass can be elucidated and inform the decision to treat conservatively. (1, 28).
DECISION FOR EMERGENCY SURGERY.

In another review, Abdul-wahed et al, noted that the published studies consist of small sample sizes and no prospective randomized studies exist, hence, the difficulties in drawing conclusive recommendations. However, he suggested that immediate surgery was safe, feasible and with shorter over all hospital stay; especially in consideration of the need for re-admission. The conclusion was that there is no need for interval appendectomy in patients initially treated non-surgically; and early surgery has more benefits than the conservative approach. He called for properly designed randomized controlled prospective studies to generate conclusive evidence. (28)

Proponents of immediate surgery quoted the arguments about incidental malignancy, finding of unsuspected benign disease like tuberculosis; post conservative-management disease progression and more severe infectious complications associated with "watchful-waiting". Furthermore, there is dilemma when a previously non palpable mass becomes obvious after induction of anesthesia. Operations proceeding in that situation have been found be easy with outcomes no different from those in simple appendicitis. (27,28).

Moreover, the development of laparoscopic approach has shown very promising results in immediate surgery for complicated acute appendicitis.

Laparoscopic surgery in complicated acute appendicitis

In a study to evaluate post operative factors after laparoscopic appendectomy for complicated appendicitis, Ball et al compared outcome in terms of analgesia use, length of hospital stay, return to activity, and complication rates (25).

In that study, Ball et al defined complicated appendicitis as acute appendicitis in which perforation had occurred or an intra abdominal abscess had formed. They found better results in the mentioned outcome measures for the laparoscopic group. (25) A similar study, Bannon et al, focusing on pediatric patients showed higher incidence of intra abdominal abscesses in the laparoscopic group. (29)

In the above studies, all the other complications were statistically similar between the laparoscopic and immediate surgery group. A study analyzing the cost of laparoscopic care showed higher cost than the immediate open surgery approach. The conclusion was laparoscopic approach could be applied if the required expertise is available (24, 25, 29).
Percutaneous drainage of abdominal abscesses

Abdominal abscess is associated with a high mortality in the range of 45-100%.

With advancements in medical technology interventional radiologists have successfully drained intra abdominal abscesses with image guidance. Using various approaches drainage catheters are placed in the abscess cavity and the contents are evacuated under image guidance. It is the approach that is widely practiced, and is currently recommended in draining of abdominal abscesses. (30)

However, the approach has limitations in terms of high technical input requirements, and expense. There are also difficulties in draining organized abscesses especially those enclosed by inflamed loops of gut. (31, 32.)

Whatever approach is utilized; after the abscess cavity has been drained further accumulation has to be prevented. It is for this reason that prophylactic peritoneal drains have been utilized since the advent of the surgery of cavities. In complicated acute appendicitis the presence of formed pus or anticipated accumulation after mobilization of an appendicular mass has been taken as an indication for peritoneal drainage.

Use of peritoneal drains

Whether the abscess is drained via the open, laparoscopic or under image guidance, drain catheters are occasionally placed in the peritoneal cavity to offer a low resistance route for conduction of any collections to the exterior. (3)

The drains are supposed to remove all pus collections, necrotic or infected tissue; prevent further accumulation, alleviate symptoms in case a fistula forms and assist in monitoring patient’s progress by characterizing the effluent content. (33)

For proper function the drain should be soft so as not to damage tissue, firm to remain in position, smooth and easily removable. Furthermore, the drain should not be irritant to cause more exudation or provoke florid foreign body reaction. It must remain patent and not allow infection into the cavity that being emptied. That is the ideal drain and currently none exists (3, 33).
Drain materials
Different materials have been utilized in making drain tubes and systems, the most inert and widely used is silicon, others include latex, polyvinyl chloride and polyurethane. Any inert material can be used if appropriately prepared. (31)

Drain systems
The drainage systems are also varied; the passive systems depend on gravity for function and the active systems have an inbuilt suction mechanism to facilitate flow. (32 a)
The variety of drain systems in the market is wide, but none is suited for universal use and each has its advantages and disadvantages. Their applications, efficiency and utility are most contested when used prophylactically in the abdomen. The low suction systems are more useful in the abdomen. (32b)

Peritoneal drains in perforated appendicitis
Magarey et al carried out a study to determine the effects of peritoneal drains after appendectomy. The study was a nine month prospective randomized controlled trial. The patients were stratified as per appendiceal pathology. Thus, simple acute (indurated or purulent). Gangrenous (part or whole wall necrotic) and perforated appendix, normal appendix was excluded. Study subjects were randomized to drain and no drain groups. The study revealed that the drain group had longer post operative fever, and increased rate of wound infection with delayed healing. The main limitation was the draining method; where, a corrugated rubber drain was fixed from the stump to through the main incision. There was no benefit of drains to patients and fecal fistula developed in the drained group only (34).

Greenall et al studied patients with perforated appendix only. Patients with appendicular abscess and appendicular mass were excluded. Hence, limiting the application of the study findings to a wider population of patients. In patients randomized to drain group; corrugated rubber drains either through
the wound or a separate incision. They found no difference in complication rates between the two groups. (37)

Moreover, they noted that none of the patients who had post operation intra abdominal abscess drained through the drain but rather all burst through the main incision wound. The research showed that the drain does not prevent any post operative complication in perforated appendix and hence, finding no support to proponents of prophylactic drains (37).

Harlan et al investigated the same subject and showed higher infectious complications in the drain arm. Further, the study revealed that more patients with drains had higher incidence of hospital acquired pathogens in the wounds. The drain was thought to be the nidus for infection. Corrugated rubber drain used in this study has subsequently been found to have very high capillary action, hence, association with high infection rates. (4).

Whether to drain or not is a dilemma that faces every surgeon on completion of evacuation of intraperitoneal collection. Meticulous surgical technique; with minimal tissue damage, avoiding dead spaces and adequate hemostasis have been advocated as strategy to prevent post operation infectious complications. (3,38)

Drains and appendectomy at Kenyatta National hospital.

The previous studies by Anangwe and Sundeep on appendectomy at the Kenyatta national hospital have shown an approximate of 30% of patients with acute appendicitis at various stages had drains. This is against the background of approximately 40-50% complicated appendicitis found at operation.

The gross pathology in those drained was: generalized peritonitis, appendicular abscess, appendicular mass, suppurative appendicitis and some who turned out to have normal appendix on histology. (5,6)

In a prospective observational study on use of drains in general surgery by Kavuludi; it was established that 66% of all emergency surgery procedures and 33% of all electives had prophylactic drains. Fifteen percent of all drains were on appendectomy patients (35). It is not clear the criteria used as indication for drainage.
It is common practice to base surgical decisions on experience rather than published evidence. A survey carried out by the French society of digestive surgery among its members found that half of their practice was against evidence (36).

However, every surgeon should have an idea of complications arising from the surgical intervention that is applied.

(c) Post operative complications in complicated appendicitis and drains.

The complications of appendectomy are much more common in perforated appendicitis. These include infectious complications such as wound sepsis, intra-abdominal abscess, paralytic ileus, fecal fistula, urinary tract infection and pneumonia which may occur early. Intermediate to late complications include adhesion related intestinal obstruction, incisional hernia and stump appendicitis (27, 38).

Rare complications include pyelophlebitis or portal vein thrombosis in which patient presents with jaundice, hepatic abscess and fever. A computed tomograph scan reveals gas or emboli in the portal vein. This is thought to arise from unrecognized seeding of the portal vein with *escherichia coli* (38).

These complications are associated with increased morbidity and in some cases mortality. In mitigation against these complications antibiotics have a definite role. In a systemic Conchrane review; antibiotics have been proven to be beneficial and are recommended. No combination was found to be superior as far as broad spectrum agents with adequate anaerobic cover were utilized. (39).

The use of peritoneal drains has been associated with complications. The body reacts to drains like any other foreign material. Case reports show drains are implicated in causing perforation, delayed wound healing, provoking haemorrhage, breaking anastomosis, and herniation (40, 41 42).
STUDY JUSTIFICATION

The challenge of management in perforated appendicitis lies in reducing post operative complications and morbidity. The outcome of management is significantly worse once perforation and associated complications occur. Studies from other centers suggest an increase in post operative complications and morbidity when intra peritoneal drains are utilized in complications of acute appendicitis (4, 7, 36, 37).

Previous studies at Kenyatta national hospital show that about 75% of patients with complicated appendicitis had peritoneal drains fixed. (5, 6, 37) In these studies there was no analysis to determine whether the drains served the intended purpose efficiently or added to patient’s post operative complications and morbidity.

Does the addition of peritoneal drains in some patients with perforated acute appendicitis in our center increase their post operative complications and morbidity making their outcome worse?

This study is intended to answer that question by evaluating the management of complicated appendicitis with focus on peritoneal drains; their efficiency and influence on outcomes in our set up. It is hoped that this work will be used as evidence to guide the use of drains in perforated appendicitis at our center.
THE OBJECTIVES

MAIN OBJECTIVE

To determine the value of peritoneal drains on patients with perforated appendicitis at Kenyatta National hospital and establish their influence on outcome.

Specific objectives

1. To establish the presentation of patients with complicated appendicitis as determined by modified Alvarado score.

2. To determine the co-morbid conditions in patients with perforated appendicitis

3. To quantify the amount of drain effluent in patients with complicated appendicitis and peritoneal drains.

4. To compare the post operation wound sepsis and or other complications rates between patients with peritoneal drains and those without drains.

5. To compare the duration in hospital antibiotic use between the two groups

6. To establish and compare the length of hospital stay between the groups.
Sample size SAMPLE SIZE

Calculated using the following formula
Assuming Ho: \( p_1 \neq p_2 \)

\[
N = \left\{ z_{1-\alpha} \sqrt{2p(1-p)} + z_{1-\beta} \sqrt{p_1(1-p_1) + p_2(1-p_2)} \right\}^2 / (p_1 - p_2)^2
\]

Where \( N \) = minimum possible sample per group
Using data from a previous study; where patients with perforated and gangrenous appendix were randomized to drain and no drain groups:
\( P_1 \) = complication rate in drains group = 45%
\( P_2 \) = complication rate in no drains group = 15% (4)
\( P = p_1 + p_2 = 30\% \)
\( z_{1-\alpha} = 1.96 \) with level of significance being 0.05.
\( z_{1-\beta} = 1.282 \) with the power of the study being 95%

The calculated sample size per group is 45 patients.

Inclusion criteria

All patients operated in the general surgical wards for complicated appendicitis.
Age >13 years

Exclusion criteria

Complicated appendicitis where patients declined or randomization was not possible.
Age < 12 years
Laparoscopic appendectomy
Private wing managed patients
Simple non perforated appendix
ETHICAL CONSIDERATION

The study proposal was presented to the ethical and research committee of the hospital and approved. All the data was collected prospectively after signed consent from the patient or guardian, carefully coded with study numbers and confidentially stored for final analysis. The data was used for the purpose of the study only.

STUDY SCOPE AND LIMITATION

This study was limited to patients as seen and managed at the Kenyatta National Hospital. This is a tertiary care center that serves as the national referral hospital and teaching hospital for the university of Nairobi. Therefore, the study group represents a selected group of patients. There was further selection as detailed in the inclusion and exclusion criteria.

The operations were performed by different surgeons and some difference may exist in surgical technique, though, overall the practice of the operation was similar as per the operation methods below.

DURATION OF THE STUDY

The study lasted fifteen months from the presentation of proposal to the ethical committee in July 2007, to writing of the final report in November 2008. The data collection, follow up and analysis lasted one year. November 2007 to October 2008.

CONSENT

The purpose of the study and procedures involved were explained to the patients or their guardians and informed consent was signed before recruitment into the study. A specimen form is appended at the end of this dissertation.
PATIENTS AND METHODS

Patients were recruited from casualty or admitting general surgical ward. The procedures were explained and informed consent signed by the patient or guardian.

A note was made of patient’s demographic profile, presenting symptoms and duration of symptoms prior to presentation to hospital. The patients known co-morbidities were also noted.

Prior treatment received especially antibiotics were recorded. Also noted were any investigations done before arrival and during clinical work up. The patient was examined and further investigations ordered the most important being total WBC count and differential counts. A modified Alvarado score table was then completed or filled as per information available and relevant antibiotics were prescribed.

All operations were done by registrars in the senior part two of their training in general surgery and majority by the investigator.

In theatre, acute appendicitis was classified into four groups depending on gross pathological findings.

1. Perforated appendix with exudates or early adhesions.
   An appendix that was edematous, perforated with localized cloudy / turbid exudates and/or early adhesions.

2. Perforated appendix with localized abscess
   Where an edematous, perforated appendix with gross pus limited to right iliac fossa and or pelvis.

3. Appendicular mass or phlegmon
   The appendix was grossly edematous with inflammatory reaction in the walling omentum, surrounding viscera and peritoneum.

4. Perforated appendix with generalized peritonitis
   Perforated appendix with pus in three or more quadrants of the abdominal cavity. This group was not randomized; drains were fixed in all of them, and they were excluded from further comparative analysis.
Appendectomy was carried out, the specimen taken to laboratory. All patients had appendectomy specimen were followed and their reports noted.

Intra operative finding of perforated appendicitis confirmed the inclusion in the study. Patients with intra operative gross finding of inflamed appendix without perforation, with otherwise clean peritoneal cavity were excluded. Normal appendix was excluded as well as those patients found with other surgical pathology.

**Randomization**

All patients with perforated appendicitis were grouped randomly into two groups. Raffle tickets were numbered from one to ninety one. Numbered raffle tickets were marked drains or no drains. All odd numbers were for drain and even numbers for no drains. All tickets were folded and put into a small paper basket from where they were picked at random to assign patients found to have complicated appendicitis at operation.

The raffle ticket number was then indicated on the questionnaire as the study number. The study number was used instead of the patient’s name or inpatient number during data tallying and analysis.

All the patients with perforated appendicitis had evacuation of all gross pus, exudates and thorough warm saline lavage until the effluent was clear of contamination and the operation bed clean.

Just before closure a drain tube was fixed from the appendectomy site through a separate incision anchored with a stitch and connected to a sterile urine bag that acted as drain reservoir. The drain exit incision was dressed separately from main incision wound. This was in patients in the drain group.

The main incision wound was closed with interrupted stitches to the fascia and skin in both groups and dressed. Wound dressing were soaked in povidone 10% solution and held in place by strapping.

All patients had antibiotics prescribed post operation. Various combinations were used depending on availability in the hospital at the time.
The regimens were meant to cover both gram negative and positive pathogens plus added cover for anaerobes. The drugs used include cefuroxime, and metronidazole combination; penicillin, gentamicin and metronidazole combination and amoxicillin-clavulinate and metronidazole combination. Which ever was available was used. Both groups received similar antibiotics in dosage and class. All antibiotics were administered intravenously for the period the patient was in the hospital. All patients were discharged when fever settled or white blood cell count normalized and were feeding orally. Antibiotics were stopped earlier if patient recovered quickly or were changed on basis of culture and sensitivity. At times they were extended when septic complications occurred.

Antibiotics used.

<table>
<thead>
<tr>
<th>combination</th>
<th>Prescribed regimen (dosage and period)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Crystapenicillin 2 Mu qid x5/7</td>
</tr>
<tr>
<td></td>
<td>Gentamicin 80mg tidx5/7</td>
</tr>
<tr>
<td></td>
<td>Metronidazole 500mg x5/7</td>
</tr>
<tr>
<td>2</td>
<td>Cefuroxime 750 mg x5/7</td>
</tr>
<tr>
<td></td>
<td>Metronidazole 500mg x5/7</td>
</tr>
<tr>
<td>3</td>
<td>Amoxicillin-clavulinc acid 1.2gm x5/7</td>
</tr>
<tr>
<td></td>
<td>Metronidazole 500mg x5/7</td>
</tr>
</tbody>
</table>

**Post operative follow up**

Patients were admitted and treated in the general wards. The active management and clinical decisions were made by the primary firm. The investigators followed and recorded patient progress in the questionnaire to discharge.

In the daily visits the consistency and amount in the drain reservoir (which is marked with volume in mls graduations on the side.) were estimated and recorded,( all volumes were estimated to the nearest 50 ml mark)The wounds were inspected and their status noted.

The total duration of drain activity was noted and recorded in days. Those who had further investigations e.g abdominal ultrasonographic scans were noted and also other complications such as fistula formation.

Infected wounds had the growth from pus swab noted.

The types and duration of antibiotics were recorded.

All the patients had the histopathology followed up and their reports noted.

Finally the length of hospital stay was recorded.
Assessment

Pre-operative ultrasound was considered positive if the radiologist report concluded: acute appendicitis, ruptured appendicitis, appendicular mass, or suggestive of acute appendicitis.
In cases where the conclusion was: appendicitis cannot be ruled out, clinical correlation required, normal abdominal /pelvic scan, acute appendix not visualized were considered negative for acute appendicitis.

Modified Alvarado score
This score was computed in all the patients, however at times the laboratories were either closed or machines were not functioning. Hence, in some patients the score was incomplete due to lack of laboratory back up.
The score was analyzed as complete for those who had full parameters and incomplete when there was no laboratory back up. While a score allows the clinician to decide on when to operate; all the patients in this series were operated.

Operation wound assessment.

Incision that appeared clean and well healed; those that had a minimal serous or blood stained discharge were considered non- infected and not included as septic.
A wound that had pus along the incision; superficial stitch abscess, discharging pus, developed dehiscence or had stitches removed to release pus, was considered as infected.
Abdominal abscess.
Diagnosed by ultra sound scan.

Fecal fistula
When the discharge from the wound or drain had gross consistency of fecal matter. Assessed by primary team of doctors and seen by the investigator.
Paralytic ileus
Diagnosis was on time and clinical circumstances. When there was no bowel sounds or passage of flatus beyond 72 hours, with abdominal distension.
DATA ANALYSIS

Data was collected in questionnaires and tallied into tables. The distributions of all continuous data in the tables are reported as mean, median and range (minimum and maximum).

Analysis was done using STATA version 9.2. Statistical analysis comparing drain group and no drain group was calculated using the Fisher’s exact test for categorical variables and Student’s t-test for continuous variables. Statistical significance was accepted when p < 0.05. Logistic regression was used to assess the probability of occurrence of various outcomes between the two groups. Continuous variables were further dichotomized for analysis.
RESULTS

Over the study period 226 patients were diagnosed with acute appendicitis, 216 were operated and 26 had normal findings at histology. 97 patients had various complications of perforated appendicitis. Two patients died during post operative follow up.

The histology reports showed 26 normal appendix, 93 simple suppurative or acute appendicitis, 96 with necrosis and gangrene of the wall to serosa but one deceased patient had their report misplaced. The negative appendectomy rate was 12%, the complication rate 43% and mortality was 0.9%.

93 patients: acute appendicitis /non perforated. 96 patients: complicated appendicitis. 26: suspected appendicitis/normal on histology. 1 patient : undetermined pathology

Fig 1: the pie chart showing the total number of patients distributed as per the encountered pathology
Complications of acute appendicitis

Patients were stratified into four groups as per the encountered gross pathology at operation. Seven patients with generalized peritonitis were not randomized but had drains and were followed up prospectively to determine their outcome.
The remaining patients were randomized; grouped into two, either drain or no drain with a total number of ninety.

Gender distribution.

A total of forty female and fifty male patients were included and distributed as shown below.

<table>
<thead>
<tr>
<th>Sex</th>
<th>No drain</th>
<th>Drain</th>
<th>Total (n)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>55.00</td>
<td>45.00</td>
<td>40</td>
<td>0.396</td>
</tr>
<tr>
<td>Male</td>
<td>46.00</td>
<td>54.00</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Gender distribution

Out of the 40 female patients with complicated appendicitis who were randomized, 55% were in the no drain group, while 45% were in the drain group. The 50 males were distributed 46%: 54% in the no drain and drain groups respectively

There was no significant difference in gender distribution between the groups with a p-value 0.396.
AGE DISTRIBUTION

The study group comprised of patients with age distribution as shown below.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>No Drain</th>
<th>Drain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Maximum</td>
<td>52</td>
<td>52</td>
</tr>
<tr>
<td>Mean</td>
<td>27</td>
<td>27.8</td>
</tr>
<tr>
<td>Median</td>
<td>26</td>
<td>27</td>
</tr>
</tbody>
</table>

Table 2: Age characteristics of patients with complicated appendicitis

In both groups the age ranged between 13 and 52 years with mean of 27 years in the drain group and 27.8 years in the non drain group. The percentage contribution of age groups to the comparison groups are as shown below.

<table>
<thead>
<tr>
<th>Age group</th>
<th>% no drain</th>
<th>% of the drain</th>
<th>Total number</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>13 - 26</td>
<td>52.27</td>
<td>47.73</td>
<td>44</td>
<td>0.673</td>
</tr>
<tr>
<td>27 - 52</td>
<td>47.83</td>
<td>52.17</td>
<td>46</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: The age-group distribution in the study.

There were forty four patients in the age group 13-26 years, of these; 52.3% were in the no drain group, while 47.7 % were in the drain group. The age
group 27-52 years had 47.8% in the no drain group while 52.2% were in the drain group. There was insignificant bias in age group distribution after randomization with p-value 0.673.

**Duration of pre-hospital symptoms**

Delayed presentation was assessed and the duration of symptoms (in days) before presentation to hospital was as follows.

<table>
<thead>
<tr>
<th></th>
<th>No drain</th>
<th>Drain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Maximum</td>
<td>14</td>
<td>21</td>
</tr>
<tr>
<td>Days of Pre-hospital stay</td>
<td>Mean 3.8</td>
<td>4.6</td>
</tr>
<tr>
<td></td>
<td>Median 3</td>
<td>4</td>
</tr>
</tbody>
</table>

**Table 4: The duration of symptoms in days among the comparison groups**

Among the patients with perforated acute appendicitis, the earliest to present to hospital came after one day of their symptoms and the most delayed patient came after 21 days of symptoms. The mean duration of pre hospital stay was 3.8 days in those randomized to drains and 4.6 days in those in drain group.

Analysis of this data reveals no significant difference in duration of illness between the comparison groups as shown below (p-value 0.126)
Table 5: Duration of symptoms before presentation to the hospital as a factor in distribution of patients among the comparison groups

<table>
<thead>
<tr>
<th>Pre-hospital stay</th>
<th>% no drain</th>
<th>% drain</th>
<th>Total number of patients</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;=4</td>
<td>56.14</td>
<td>43.86</td>
<td>57</td>
<td>0.126</td>
</tr>
<tr>
<td>&gt;=5</td>
<td>39.39</td>
<td>60.61</td>
<td>33</td>
<td></td>
</tr>
</tbody>
</table>

The duration of symptoms before presentation to hospital was categorized for analysis. Out of the 57 patients who had less than 4 days of symptoms 56% were in the no drain group and 44% were in the drain group. Patients with symptoms for more than 5 days were distributed as 39% to no drain and 61% to the drain group.

This classification ensured that the pre hospital duration of illness was not significantly different between the study groups as shown by the p value calculation.
The modified Alvarado score.
The figure below shows the score against the total number of patients per score. The majority of patients had high scores of more than 7. The patients with 5-7 scores did not have the laboratory indices. 67% of the patients had complete scores. In 33% of the patients the score was incomplete due to missing laboratory services at the time of patient preparation.

![Gender and Alvarado Score by group](image)

Figure 2: patients total Alvarado score regardless of missing laboratory data and distribution to both groups

The patients were distributed into study groups regardless of the score completeness. P-values were calculated to determine whether there was any significant difference in the distribution.
THE MODIFIED MODIFIED ALVARADO SCORE CATEGORIES

<table>
<thead>
<tr>
<th>Alvarado Score</th>
<th>% no drain</th>
<th>% drain</th>
<th>Total number</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 - 7</td>
<td>54.05</td>
<td>45.95</td>
<td>37</td>
<td>0.520</td>
</tr>
<tr>
<td>8 - 10</td>
<td>47.17</td>
<td>52.83</td>
<td>53</td>
<td></td>
</tr>
</tbody>
</table>

Table 7: The Alvarado score ranges.
Thirty seven patients had score between 5 and 7, and were distributed as 54%:46% to no drain and drain respectively. The majority had scores between 8 and 10 and distributed as 47:53%. These scores show complicated appendicitis was associated with high scores which were distributed evenly across the study groups.

Table 6: The completeness of the Alvarado score.

<table>
<thead>
<tr>
<th>Score Completeness</th>
<th>% no drain</th>
<th>% drain</th>
<th>Total number</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>complete</td>
<td>49.12</td>
<td>50.88</td>
<td>57</td>
<td>0.827</td>
</tr>
<tr>
<td>incomplete</td>
<td>51.52</td>
<td>48.48</td>
<td>33</td>
<td></td>
</tr>
</tbody>
</table>
Table 8: Prevalence of co-morbidities in patients with complicated appendicitis.

<table>
<thead>
<tr>
<th>Pre op co-morbid condition</th>
<th>drain</th>
<th>No drain</th>
<th>total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PUD</td>
<td>7</td>
<td>3</td>
<td>10</td>
<td>(11%)</td>
</tr>
<tr>
<td>ASTHMA</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>(2.2%)</td>
</tr>
<tr>
<td>FIBROIDS</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>(1.1%)</td>
</tr>
<tr>
<td>HODGEKINS LYMPHOMA</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>(1.1%)</td>
</tr>
<tr>
<td>HYPERTENSION</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>(2.2%)</td>
</tr>
<tr>
<td>HIV</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>(2.2%)</td>
</tr>
</tbody>
</table>

Majority of patients did not have other conditions. Only 20% had co-morbid conditions.

The majority of patients had peptic ulcer disease which accounted for 11% overall, 16% of the patients in the drain group and 7% in the no drain group. The others include asthma, fibroids, hodgekins lymphoma, hypertension and HIV disease.
Other investigations

These include investigations (not the full blood count included in the Alvarado score) that were used in the assessment of the patient.

<table>
<thead>
<tr>
<th>investigation</th>
<th>No drain</th>
<th>drain</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra sound</td>
<td>28</td>
<td>17</td>
<td>45</td>
</tr>
<tr>
<td>electrolytes</td>
<td>45</td>
<td>45</td>
<td>90</td>
</tr>
<tr>
<td>Widal test</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>HIV</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>LFT</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Ct scan</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>urinalysis</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 9: Other investigations and the distribution among groups.

Majority of patients had ultra sound done at 45% overall. Forty five percent of patients in no drain and 40 % of the drained group had sonographic scanning. 26 female patients had ultra sound and 19 males.

The sonographer missed the diagnosis of complicated appendicitis in 44% of the female patients and in 26% of the male patients.

Other tests done include electrolytes which were mandatory for theatre; occasional widal test, liver function tests, urinalysis and C.T scan screening for patients.
Intra-operative gross pathological findings.

Patients with in the study group were stratified by the operation findings into four groups. The following chart shows the numbers in each category. The fourth category was not randomized.

1 perforated appendix with localized abscess
2 perforated appendix with exudates and adhesions
3 appendicular mass/ phlegmon
4 perforated appendix with generalized peritoniti

Figure 3: pie chart showing the gross pathology at operation and the number of patients in each group.
After randomization, the patients were distributed in the two study groups as shown in the table below.

<table>
<thead>
<tr>
<th>Gross pathology</th>
<th>%No drain</th>
<th>% Drain</th>
<th>Total number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforated appendicitis with exudates/adhesion</td>
<td>46.88</td>
<td>53.13</td>
<td>33</td>
</tr>
<tr>
<td>Perforated appendicitis with Localized abscess</td>
<td>54.35</td>
<td>45.65</td>
<td>46</td>
</tr>
<tr>
<td>Appendix with phlegmon/mass</td>
<td>36.36</td>
<td>63.64</td>
<td>11</td>
</tr>
</tbody>
</table>

Table 11: Percentage distribution of patients by gross pathology

The thirty three patients with edematous perforated appendix with turbid exudates and adhesions were distributed 47% : 53% in the no drain and drain group respectively.
The patients with perforated appendicitis with localized abscess were forty six; they were distributed 54% to the drain group and 46% to the no drain group. In the last category the patients were distributed 36% to 64% into both groups as shown.
This distribution shows insignificant difference in terms of gross pathology in the two study groups
Figure 4
The distribution of patients among the study groups by gross pathology.
DRAIN FUNCTION
In the drain group, the volumes of effluent were recorded daily. There were 45 patients in this group. The table below shows the drain volumes collected in day to day three. The number of patients is expressed as a percentage of the total group and the volumes drained are as shown.

<table>
<thead>
<tr>
<th>days of drain use</th>
<th>200mls</th>
<th>150mls</th>
<th>100mls</th>
<th>75mls</th>
<th>50mls</th>
<th>0mls</th>
</tr>
</thead>
<tbody>
<tr>
<td>day 1</td>
<td>82.2%</td>
<td>6.6%</td>
<td>4.5%</td>
<td>4.5%</td>
<td>1.1%</td>
<td>1.1%</td>
</tr>
<tr>
<td>day 2</td>
<td>55.5%</td>
<td>11.2%</td>
<td>33.3%</td>
<td>4.4%</td>
<td>3.3%</td>
<td>3.3%</td>
</tr>
<tr>
<td>day 3</td>
<td>24.4%</td>
<td>11.1%</td>
<td>44.4%</td>
<td>7.7%</td>
<td>11.1%</td>
<td>11.1%</td>
</tr>
</tbody>
</table>

On day one, 82.2% (37/45) of patients had 50mls of effluent in the drain reservoir, 6.6% (3/45) had 100mls, 4.5% had 150mls and a similar proportion had 75mls. Only one patient drained 200mls. It is notable that only 13.3% of the patients had drain effluent of more than a hundred mls on 1st day post operation.
On the second day, 55.5% (25/45) had 50mls, 11.2% (5/45) had 100mls and the rest had inactive drains, hence approximately 90% of the drains were not useful by the second day.
On the third day 24.4% had drain effluent of 50mls all the rest were inactive. Therefore 100% of the drains were not functionally useful by 3rd day.
Table 12: the range and average of drain volumes per day.

<table>
<thead>
<tr>
<th>day</th>
<th>Maximum volume. (mls)</th>
<th>Minimum volume (mls)</th>
<th>Average volume (mls)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>200mls</td>
<td>50ml</td>
<td>74.4mls</td>
</tr>
<tr>
<td>Day 2</td>
<td>100mls</td>
<td>0</td>
<td>37.7mls</td>
</tr>
<tr>
<td>Day 3</td>
<td>50mls</td>
<td>0</td>
<td>13.5mls</td>
</tr>
</tbody>
</table>

It was found that drains in these patients were most active on the 1\textsuperscript{st} day post operative but the average amounts drained were all below 100mls.
COMPLICATIONS
The overall complication rate in this series was 25.5%. Twenty three patients in the series had complications.
The most common complication was wound sepsis that occurred in 18 patients. Two patients got fecal fistulae and a similar number got intra abdominal abscess. Two patients had paralytic ileus post operatively. No patient in this series was re-operated but two were readmitted due to wound sepsis. One of them; known to have immunosupression from HIV, was readmitted with wound sepsis having developed a fecal fistula and wound sepsis at the index admission.
The patients with drains had more wound sepsis than the non drained group, stayed longer in hospital and had longer use of in-hospital use of antibiotics post operation. Wound sepsis was the only complication in the non drain group. All the other complications occurred in the drain group.

<table>
<thead>
<tr>
<th>Wound infection</th>
<th>% no drain</th>
<th>% drains</th>
<th>Total number of patients</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>16.67</td>
<td>83.33</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>58.33</td>
<td>41.67</td>
<td>72</td>
<td>0.002</td>
</tr>
<tr>
<td>Other Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0</td>
<td>100</td>
<td>6</td>
<td>0.026</td>
</tr>
<tr>
<td>No</td>
<td>53.57</td>
<td>46.43</td>
<td>84</td>
<td></td>
</tr>
</tbody>
</table>

Table 13: the percentage distribution of complications among the study groups

42
The percentage distribution of wound sepsis and other complications among the study subjects were as shown on the chart below.

Figure 5: The wound sepsis occurred predominantly in the drain group. The other complications were observed only in the drained group.

The septic complications were significantly higher in the drain group as shown by the p-value calculations above.
The use of antibiotics post operatively.

Forty six patients used intravenous antibiotics for up to three days post operative; 24 patients for 4 days, 20 patients for 5 days or more. Among those who had antibiotics for 4 days 58% had drains and 42% no drains. Similarly, 85% of those who were on antibiotics for longer than 5 days in the hospital had drains while 15% did not have drains. In addition all patients were discharged home on oral antibiotics for a period of 5 days. Overall; patients in the drain group had longer use of in-hospital antibiotics.

<table>
<thead>
<tr>
<th>Duration post op. antibiotic(days)</th>
<th>no drains %</th>
<th>drains %</th>
<th>Total patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;=3</td>
<td>69.6</td>
<td>30.4</td>
<td>46</td>
</tr>
<tr>
<td>4</td>
<td>41.7</td>
<td>58.3</td>
<td>24</td>
</tr>
<tr>
<td>&gt;=5</td>
<td>15.0</td>
<td>85.0</td>
<td>20</td>
</tr>
</tbody>
</table>

Table 14: use of antibiotic in days and % distribution among study groups

<table>
<thead>
<tr>
<th>Post-Op. antibiotic</th>
<th>no drain %</th>
<th>Drain %</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;=3 (days)</td>
<td>69.57</td>
<td>30.43</td>
<td>0.000</td>
</tr>
<tr>
<td>&gt;=4(days)</td>
<td>29.55</td>
<td>70.45</td>
<td>44</td>
</tr>
</tbody>
</table>

Table 15: the difference in post operative in hospital antibiotic use among the study groups.
The patients in the drain group had significantly longer use of antibiotics as shown by the p-value calculation.
Length of hospital stay

A similar trend was observed on length of hospital stay, the minimum stay being 3 days for no drains and 4 days for drain group. The maximum stay was 7 days for no drain group and 12 days for drain group. The average hospital stay was 4 days in the no drain group and 6 days for the drain group as shown in the table below.

<table>
<thead>
<tr>
<th>Length of hospital stay</th>
<th>No drains</th>
<th>Drains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Maximum</td>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td>Mean</td>
<td>4</td>
<td>6.1</td>
</tr>
<tr>
<td>Median</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 14: The length of hospital stay in days.
The length of hospital stay was categorized and p value was calculated as shown below.

<table>
<thead>
<tr>
<th>Length of hospital stay</th>
<th>No drain</th>
<th>Drain</th>
<th>Total</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;=4</td>
<td>78.26</td>
<td>21.74</td>
<td>46</td>
<td>0.000</td>
</tr>
<tr>
<td>&gt;=5</td>
<td>20.45</td>
<td>79.55</td>
<td>44</td>
<td></td>
</tr>
</tbody>
</table>

Table 15: The difference in hospital stay.
The patients in the drain group stayed significantly longer in the hospital as shown by the p-value.
The significance of the outcome measures

|                     | Odds Ratio | Std. Err. | P>|z|   | [95% Conf.] |
|---------------------|------------|-----------|-----|----|-------------|
| Hospital stay       | 14.0       | 7.24      | 0.000 | 5.08 | 38.58       |
| Wound infection     | 7.0        | 4.73      | 0.004 | 1.86 | 26.34       |
| Post op antibiotics | 5.5        | 2.51      | 0.000 | 2.21 | 13.43       |

Table 16: The odds ratio and the confidence interval for the outcomes.

The odds ratio for prolonged hospital stay in patients with drains was 14.0, with wound sepsis and antibiotics odds ratios as shown.

It is clear that from this study that fixing a drain in a patient with complicated appendicitis almost certainly ensures that they will have a prolonged hospital stay, predispose the patient to wound sepsis and hence, prolonged antibiotics use as shown by the high odds ratio and the confidence intervals calculated at 95%.
Complicated appendicitis with generalized peritonitis

There were seven patients in this category. Five of these patients were male aged between 16 and 32 years. The two female patients were 38 and 14 years. Their pre hospital duration of symptoms ranged between 3 and 7 days; two of the males had associated peptic ulcer disease.

They all had at least a stat dose of broad spectrum antibiotics and all were found to have perforated appendix with generalized peritonitis. They all had drains fixed at the end of operation. The drains in this group were more active; the maximum draining 600mls of effluent on the first day, the least active on day one collecting 100mls with an average collection on day one being 228.5mls.

However, most were inactive by day 3.

Notable still, was that three out of the seven had serious complications; one patient developed intra abdominal abscess despite the use of drain, confirmed by sonographic scan but managed conservatively till resolution. He was discharged after 12 days.

One patient developed serious peritonitis with wound discharge; had an active drain, was scheduled for re-operation but succumbed on third post operation day.

Another developed wound sepsis that easily resolved on daily dressing.

Table 16: The amount drained and complications in generalized peritonitis.

<table>
<thead>
<tr>
<th>Day/study number</th>
<th>A</th>
<th>B*</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>27yr/m</td>
<td>32yr/m</td>
<td>25yr/m</td>
<td>16yr/m</td>
<td>38yr/f</td>
<td>14yr/f</td>
</tr>
<tr>
<td>1</td>
<td>200mls</td>
<td>600mls</td>
<td>200mls</td>
<td>100mls</td>
<td>150mls</td>
<td>200mls</td>
</tr>
<tr>
<td>2</td>
<td>200mls</td>
<td>500mls</td>
<td>100mls</td>
<td>100mls</td>
<td>100mls</td>
<td>100mls</td>
</tr>
<tr>
<td>3</td>
<td>100mls</td>
<td>100mls</td>
<td>50mls</td>
<td>50mls</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>50mls</td>
<td>-</td>
<td>50mls</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>average</td>
<td>137.5mls</td>
<td>150mls</td>
<td>100mls</td>
<td>65mls</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>complication</td>
<td>Died/ sepsis</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Mortalities

In this series two patients died. The first, a 32 year old man who came after five days of symptoms at home, presented with clinical features of generalized peritonitis. At operation was found to have a necrotic appendix, with foul smelling pus in all the peritoneal recesses. The appendectomy was done and thorough peritoneal lavage followed by closed drainage.

The drain was active with purulent effluent collected in the reservoir. However, his general condition did not improve; on the second day post operation the wound started oozing pus as well, his abdominal signs were not resolving. A re-exploration for presumed intra-abdominal abscess pockets was scheduled, he died before theatre.

The second patient a 28 year old male who presented after a week of abdominal pains at home, on assessment his Alvarado score was seven, he had a history of cough two weeks prior to admission that had resolved. At operation; the appendix was inflamed but not perforated, the peritoneum was clean. He was not considered further for the study. On the third post operative day he became restless and breathless and started coughing blood he died while being resuscitated.
DISCUSSION

Appendectomy is recognized worldwide as the commonest surgical emergency. In the western world; the rate of appendicitis is estimated at 10/10000, with a lifetime risk of 7%. The disease presents at a more advanced states in Africa as opposed to the western world. (46) The incidence of appendicitis in Kenya has been reported to be higher than the rest of the world at 428/10000 (6). Awori found that appendectomy contributed 63% of all abdominal emergencies at Kenyatta national hospital. (44). The management becomes more challenging when the patient presents with perforated appendicitis.

In this study we evaluated 226 patients 97 of whom had perforated acute appendicitis and its complications. This gives a complicated acute appendicitis rate of approximately 43%. This is comparable to other studies in that showed rate between 39-43% (6,48). The situation in the district hospitals could be different. A study from a rural Kenyan hospital showed a 50% presentation with perforated appendicitis. (49).

The management of acute appendicitis is aimed at attaining a low negative appendectomy rate without increasing the complication rates. In this study the negative appendectomy rate was 12%, a significant drop since the previous study showed a rate of 23% in 2002. Internationally, a negative appendectomy rate of 7-25% has been reported. There have been changes in management in our set up including use of modified Alvarado score, increased availability of ultrasound and involvement of surgical registrars in evaluation of patients in casualty. The increased diagnoses of complicated acute appendicitis could be related to delay of presentation to hospital.

There was a mortality rate of 0.9% in this study. A review of papers from the African continent showed the mortality rate to range from 0.9-4%. (46) Perforated acute appendicitis that presents with generalized peritonitis is associated with higher mortality. One of our patients succumbed to severe sepsis despite surgical intervention; the other was thought to be a case of post operative pulmonary complications after a relatively successful appendectomy for non perforated appendicitis, highlighting the risks associated with surgery at the extremes of the disease pathology.
The study subjects in the perforated appendicitis group were 44% female to 56% male with a male to female ratio of 1.3:1. They were in the age brackets 13-52 years with children below 13 years having been excluded. Age and gender distribution was comparable to many other studies showing appendicitis as predominantly a condition in the young. (6,38,46,48). Some authors have argued that the characteristics of those who rapidly progress to complicated are different from others who have simple appendicitis a position that cannot be verified in this study.

The delay to intervention has been shown to increase the rate of perforation. A study from India calculated that perforation in the majority of their patients occurred after 36 hours. The delay to presentation in that study was 2.5 days in those who were found to have perforated appendicitis (45). Our study concentrates on complicated acute appendicitis and hence, it is not surprising the mean duration of pre-hospital stay was 4.3 days. One patient arrived after 21 days with a localized appendiceal abscess.

**The modified Alvarado score** was developed with a goal to reduce the negative appendectomy rate. The score was initially targeted at non complicated acute appendicitis. It was found to be useful in perforated appendicitis as well. It has been shown that no patient with perforation had a score of less than six and patients with complicated appendicitis had scores of 7 and above. (9,12.) Moreover, in a study like ours a simple score like this could be used to indicate the preoperative condition of the patient. In this study, the intention was to use modified Alvarado score in all patients but this was not possible because the hematology laboratory was not functional 24 hours and there were instances when the full blood could not be done. This was mainly at night, weekends and when the necessary equipment had broken down.

The patients with full scoring (67%) showed a score of more than 7. This is in keeping with other studies which have showed the higher the score the higher the chance of complications. (9,12)

Though, modified Alvarado score is useful in guiding the surgical decision, it cannot be the only criteria; the overall clinical picture of the patient is the main determinant. This is the situation in some centers like ours where laboratory back up is not available round the clock. The clinical signs in patients with complicated acute appendicitis are much more discernable. (47) Hence, in our case the patients could be diagnosed
with incomplete but high scores of 5 - 6 based on clinical examination without laboratory indices.

Further investigations in our patients showed a preference for ultra sound scan. Where clinical diagnosis is clear very little else is done in terms of diagnostic work up. The ultrasound scan has a role in those patients whose diagnosis is in doubt. It is particularly useful in the female and child patient (18,19,20).

There were 45 patients who had ultra sound. More females than males had scans; perhaps indicating the difficulties in clinical diagnosis of acute appendicitis in the female. The utility of the scan in this setting was unclear noting that almost half were false negatives in the female patient. In the male where diagnosis is usually easier, 11 out 19 scans were true positives. Still in 8 patients the scan was false negative in patients with complicated acute appendicitis.

However, in this study all the ultrasound reports available were reviewed regardless of where they were done. Some of them were of suspect quality and the time duration between the scan and operation was not quantified.

In the co-morbidity profile, the finding of high prevalence of peptic ulcer disease is important since there could be an overlap of symptoms in these two conditions. However this pattern conforms with other studies previously done in our set up (5,6.)

After randomization; patients were distributed into two groups which were comparable in all aspects as shown by the statistical analysis. Age, gender, pre hospital duration of symptoms, co-morbidities and pre operative use of antibiotics showed no significant difference between the groups. This is important since significant differences in the results could be attributed to the use of drains.

The modified Alvarado score was also comparable between the groups whether it was incomplete or completed.

The patients were put through the similar management except in the aspect of the peritoneal drain use.
The use of antibiotics has been shown to reduce the incidence of postoperative infectious complications in appendicitis.\textsuperscript{(8,36,37,47,48)} In complicated acute appendicitis full therapeutic regimen should be given till the resolution of fever and normalization of white blood count.

The debate rages on the regimen, the dosing and the duration of these antibiotics. In our study, it was not possible to standardize the regimens due to fluctuations in availability. However, adequate drugs were available for broad spectrum and anaerobic infection coverage. The drugs used were in various combinations, \textit{cefuroxime and metronidazole, amoxy-clavullin and metronidazole and penicillin, gentamicin with addition of metronidazole}.

Intravenous antibiotics were used till the patient was discharged. This phase of antibiotics varied between three and five days. Fever resolved early, patients had bowel function returning faster and they ambulated quicker when no drain was used, despite similar disease state and management. Both groups had similar antibiotics treatment prescribed and administered. It is obvious that septic complications were higher in the drain group despite adequate antibiotic cover. A drain tube encourages formation of a biofilm of pathogenic organisms on its surface that cannot be eliminated until the drain is removed.\textsuperscript{(4)} Two or more extra days of intravenous antibiotics were administered in the drain group before resolution of fever or wound discharge. This contributed to more antibiotic use and prolonged hospital stay in the drain group despite similar management in all other aspects. All patients were discharged after resolution of fever. Furthermore, a five day regimen of oral antibiotic was prescribed on discharge.

There is need for a structured study and policy on use of antibiotics in acute appendicitis in our center.
The peritoneal drains were used in patients with perforated appendix with adhesions and inflammatory exudation, localized abscess, appendicular phlegmon in similar fashion they had been used previously in our set up (5,6,36).

Unlike in those previous studies, there was a control group and strict follow up of patients. In the use of drains in the peritoneal cavity it has been the practice to remove the drain when the collected effluent is between 50 and 100mls. On the first day only 12.8% of the drains had collected more than 100mililitres, hence, 87.2% of the drains were not functional or there was nothing to drain. Only one of ten drains in this group was useful to the patient. All the drains did not serve any function on the second and third day.

During the operation, a thorough peritoneal lavage was performed until the effluent was clear, there was no gross fluid left in the operation field and the little that could have remained was reabsorbed by the body since normal saline was used. In addition, broad spectrum antibiotics were administered. In the group that had no drains this seems to have been adequate treatment. The presence of the drain tube in the operation field in this case therefore seems either to encourage persistence of infection or reduce efficiency of antibiotics. Drains appear to be an over-treatment in the group of patients with perforated appendicitis and no generalized peritonitis.

The infectious complications were encountered in both groups, this mirrors the findings by Harlan et al and others who had previously done randomized studies in this subject but in other centers (4, 33,36,37.)

The average age in the study by Harlan et al was 26years, pretty similar to our mean of 27 yrs. In advanced appendicitis the surgical incision infection rate was higher but not statistically different from the non drained group. In contrast our study shows a higher and significant difference in wound sepsis of patients with drains. The drain group contributed 83% of patients with wound infection in our study as opposed to 17%in the no drain group. Harlan et al found a very high incidence of intra abdominal abscess formation in the drain group where 45%of the patients with drains had intra abdominal abscesses as opposed to 15% in those without drains.

Though, the incidence is very different the trend is similar; since in our study, the intra abdominal abscess formation and fistula were observed only
in the drain group. A drain tube could act as an irritant to friable gut and lead to fistula formation. The formation of intra abdominal abscess suggests that the drain failed to function as expected.

The finding of higher infectious complications in the drain group contrasts other studies that found no difference between the groups(33, 34, 37.) It could have been due to the exclusion criteria in those studies, since patients with appendix abscess and phlegmon were excluded.

After review of the studies on drainage in gastrointestinal surgery, Petrowsky et al noted that intra abdominal infections were not reduced, wound infections and fistulae were increased in the drain subjects and recommended no drains in perforated or any stage of appendicitis.(7)

Our study adds to this body of evidence, however caution is required in appreciation of this data, since all other studies seem to exclude patients with generalized peritonitis secondary to perforated appendix. Patients with drains are more prone to developing post operative sepsis as shown in our study. A drain tube, being a foreign body tends to harbor infecting organisms.

Drains also require frequent handling during dressing, emptying of the reservoir, and mobilization of the patient. The presence of a drain provokes inflammatory reaction that encourages infection especially in presence of gut contaminants in complicated appendicitis. all these activities promote infectious complications post operatively.

Seven patients in our study had generalized peritonitis but had similar demographic characteristics to the others. However, duration of pre-hospital delay was a mean of 5 days, while the rest of the group was 4.3 days.

Studies have stated that severe sepsis and peritonitis occurs in extremes of age.(9, 26, 49) While we excluded children in our study; the elderly did not form a significant portion of our patients. Only one patient was above 50 years and he did not have generalized sepsis. This suggests that beyond the common epidemiological factors like age, gender, and diet, the capability to mount an aggressive inflammatory reaction to contain the ruptured appendix is limited in patients who develop generalized peritonitis. Therefore, the issue of draining or not draining the peritoneum may be secondary in infectious complications in this subset of patients.

Moreover, it has been argued that the drain is a foreign body that provokes some inflammatory reaction in the peritoneum leading to its encapsulation.
and blockage within hours of operation. This was propagated by Yates and other earlier investigators (3). Our patients with generalized peritonitis had significantly higher volumes, than those with other stages of appendicitis in our study. This could have resulted from either increased exudation from the larger surface area involved or their drain tubes remaining patent for longer. This group needs to be studied further.

There was significant difference in length of hospital stay. Patients in the drain group had an average of 6.1 days in hospital, and they continued to use antibiotics. It was a common observation that on removal of the drain, there was a self limiting serous exudation from the drain site and pain in most of the patients. Sometimes a sterile dressing was placed on the site for an extra day or so. If the treating team discharged the patient in this state, most patients would not leave and the nursing team would continue with the antibiotics. This practice; though not contested, contributed to the length of hospital stay in patients with drains without other septic complications.

There is a concealed cost implication that was not analyzed in this study, but becomes apparent on consideration of the added days and antibiotics in the patients with drains.

Patients who stay longer in the hospital have longer delay to return to work or school. Our study reveals high odds ratio for increased hospital stay and use of in-hospital antibiotics suggesting that use of drains in these patients adds to the patients disease burden and delays their return to normal activities.
Conclusions

1. Perforated appendicitis and its complications is common among patients with acute appendicitis in our set up, contributing 43% of patients with appendicitis in the past one year. More males than females were involved and the majority were in the young age group.

2. The diagnosis remains largely clinical; with significant but inconsistent support the laboratory and diagnostic imaging departments. The modified Alvarado score is a useful tool in guiding surgical decisions in this scenario.

3. The management is largely immediate surgery after resuscitation and antibiotics. Delayed surgery and radiological drainage are not routinely utilized in our set up in management of complicated appendicitis in our set up.

4. The use of peritoneal drainage post appendectomy in advanced appendicitis; where a perforation associated inflammatory turbid exudates/adhesions, or a localized abscess, or appendicular phlegmon, is found; is associated with higher post operative septic complications, prolonged use of antibiotics and hospital stay.

5. The patients with perforated appendix and generalized peritonitis have similar demographic characteristics to the other forms of complicated appendicitis but drains seem to evacuate more effluent and may be beneficial. The need for drains in this subset of patients needs further evaluation.
Ref: KNH-ERC/ 01/ 226

Dr. Nyaga Patrick Njeru
Dept. of Surgery
School of Medicine
University of Nairobi

Dear Dr. Nyaga

RESEARCH PROPOSAL: "UTILITY OF PERITONEAL DRAINS IN PERFORATED APPENDICITIS"
(P200/7/2007)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and approved your revised research proposal for the period 5th March 2008 - 4th March 2009.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimen must also be obtained from KNH-ERC for each batch.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF. A N GUANTAI
SECRETARY, KNH-ERC

cc. Prof. K.M. Bhatt, Chairperson, KNH-ERC
The Deputy Director CS, KNH
The Dean, School of Medicine, UON
The Chairman, Dept. of Surgery, UON
Supervisor: Prof. Pankaj G. Jani, Dept. of Surgery, UON