

**EARLY OUTCOME OF OPEN VERSUS CLOSED LATERAL INTERNAL
SPHINCTEROTOMY IN THE TREATMENT OF CHRONIC ANAL FISSURES
AT KENYATTA NATIONAL HOSPITAL**

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DECLARATION

Candidate

A certify that this dissertation is my original work and has not been presented to any other university for a degree

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DEDICATION

This work is dedicated to:

- i) My parents Kamau and Wambui for taking me to school.
- ii) My wife Sarah and our two daughters Joyce and Hope for their unwavering support.

ACKNOWLEDGEMENT

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ABBREVIATIONS

(C.L.I.S):	Closed lateral internal sphincterotomy
GSW :	General Surgical Wards
KNH/ERC: Committee	Kenyatta National Hospital Ethics and Review Committee
KNH :	Kenyatta National Hospital
(O.L.I.S):	Open lateral internal sphincterotomy
SPSS:	Statistical package for social sciences
SSK	Surgical Society of Kenya
UON:	University of Nairobi
VAS :	Visual Analogue Score
MARP :	Maximum anal resting pressure

ABSTRACT

Background

Chronic anal fissures to the general surgeon presents as a common cause of morbidity. Lateral internal sphincterotomy is the gold standard method of intervention. Closed and open techniques at surgery have both been employed. Previous outcome studies have supported closed technique. However, current studies show some evidence in support of open technique. At Kenyatta National Hospital, no study has been done in order to rationalize use of either method of surgery for chronic anal fissures. This study compares the early surgical outcomes of the two methods within six weeks after operation of lateral internal sphincterotomy.

Objective

This is a prospective randomized clinical study comparing the early outcomes of closed versus open lateral internal sphincterotomy in patients with chronic anal fissures in the first six weeks after operation.

Study design

A prospective single blinded randomized trial.

Setting

The general surgical wards theatres and surgical outpatient clinics at Kenyatta National Hospital

Patients and methods

Two treatment groups of patients meeting the inclusion criteria were randomly assigned to either undergo open or closed lateral internal sphincterotomy by the principle investigator just before surgery. Eighty consecutive patients presenting with chronic anal fissure and scheduled for lateral internal sphincterotomy were recruited. They were randomly assigned to two groups, one undergoing open sphincterotomy and the other closed sphincterotomy. Randomization was done using a computer-generated table of random numbers. The operating surgeon was informed of the group designation just before surgery. Data on post-operative outcomes was collected using a formatted questionnaire and analyzed using statistical package for social sciences version 17.0 (SPSS 17.0).

Main outcome measures

Post-operative outcomes were amount of bleeding at surgery, haematoma formation, post-operative pain, peri-anal sepsis (abscess), incontinence to flatus and /or stool within six weeks of operation.

Results

Pain was the commonest presenting symptom (100%). The median age at presentation was 34 years, most anal fissures were located posteriorly (85%) with females reporting more anteriorly placed fissures than men (11% compared to 4% respectively). Most patients (95%) reported no pain 6 hours post-operatively, compared to those reporting no pain at 96 hours (80%). Overall, the post-operative pain score in the closed and open group shows no scientifically significant differences with P values >0.05. At 6 hours, 37 patients who

underwent closed procedure had no pain compared to 38 patients in the open group (P=0.556). Only a small number of patients reported bleeding (5 in closed group compared to 6 in open group, p=0.555). There was only one case of reported flatus incontinence at six weeks in the open group. 3 patients in the closed group had peri-anal abscesses compared to only 1 in the open group at two weeks after surgery. Seroma formation was more in the open group compared to closed group (3 cases versus 0). Cases of haematoma formation were reported more in the open group (5 cases) compared to those in the closed group (2 cases) (P= 0.249). In the two groups, the average hospital stay was 2 days. There was no case of reported fissures recurrence within the six weeks follow up period in the two arms.

Conclusion

There was no difference in the early surgical outcomes after closed or open lateral internal sphincteromy in the treatment of chronic anal fissure(s).

INTRODUCTION

Anal fissures are common causes of morbidity in the surgical units. The severe pain during and after defecation greatly impacts on the quality of life of many patients. Chronic anal fissures respond poorly to medical treatment and are therefore best managed using surgical methods. Lateral internal sphincterotomy is the gold standard in the treatment of chronic anal fissures (1). Two methods are currently employed in lateral internal sphincterotomy: open or closed techniques. At Kenyatta National Hospital (KNH), no protocol is present on choosing the surgical approach in management of chronic anal fissures. Proponents of the closed method argue that this approach has fewer cases of reported incontinence to stool though incontinence to flatus is reported in both methods (2). Proponents of the open method argue that this technique gives a direct visualization of the internal sphincter fibres and therefore controlled sphincter release made possible. In addition, it gives the surgical trainees a golden opportunity for learning and therefore they recommend it in Teaching Hospitals (3). This study aims to find out whether there is a difference in the early surgical outcome when one uses either closed or open internal sphincterotomy technique in accessing the internal anal sphincter muscle in treating chronic anal fissure.

LITERATURE REVIEW

Anal fissure is a common proctological problem, which presents with pain in the anal region during and after defecation. An anal fissure, also called a fissure in ano, is a traumatically induced longitudinal split or ulcer in the squamous epithelium of the distal anal canal. It typically extends from the anal verge cephalad towards the dentate line. It most commonly occurs in the midline posteriorly, but it can also occur in the midline anteriorly. It can occur at any age, but is usually a condition of young adults. They are commonly found in the midline posteriorly in both genders. However anterior fissures are more common in women than men, occurring in 10% of women with fissures compared with 1% of men with fissures. (4)

Anal fissure can be primary / idiopathic or secondary. It can be divided into two clinical subtypes depending upon the duration of disease, the acute and chronic fissures. Fissures failing to heal within six weeks despite straightforward dietary measures are designated as chronic (5). Chronic anal fissure is characterized by skin tag and hypertrophied anal papilla.(6)

The symptoms of anal fissure are so characteristic as to be nearly diagnostic(7). Patients complain of severe intense pain initiated by the passage of stool, which lasts for a variable period of time after defecation. In addition they complain of anal bleeding, which appears as a bright streak on the sides of stool. Pain and irritation results in spasm of the internal anal sphincter muscle which then fails to relax during defecation thus further aggravating the condition. (7,8)

History and clinical examination is always diagnostic. The presence of a sentinel tag is highly suggestive of a chronic anal fissure. Digital palpation of the anus is usually not possible as it causes severe pain. If at all possible, gentle retraction of perianal skin reveals not only the fissure but also the characteristic spasm of the internal anal sphincter muscle(7,8).An atypical appearance should prompt consideration of other diagnoses. Lateral location, extension onto the anal verge or above the dentate line, and extension of the base of the ulcer through the internal sphincter are all atypical features. Sexually transmitted diseases, leukemia, tuberculosis, Crohn's disease, and squamous cell carcinoma should be excluded in such patients by appropriate testing. (7)

ETIOLOGY AND PATHOGENESIS

The pathogenesis of this condition is still not fully explained, but the widely accepted theory regarding the etiology of anal fissure is that it results from the mechanical forces imposed on the anal canal during the passage of stool. Hard stools are most commonly implicated, but explosive liquid stools can produce the same results. (7) The explanation for this phenomenon is both anatomic and functional.

The posterior commissure of the anoderm is less well perfused than other anodermal regions. The branches of the inferior rectal artery course perpendicularly through septa of the internal anal sphincter before reaching the anoderm. Thus, flow through these arterioles is threatened by elevated pressure of the internal anal sphincter, exceeding the intra-luminal pressure of arterioles. Therefore, increased internal anal sphincter tone compromises perfusion of the anoderm, particularly in the posterior midline by compressing arterioles

of the inferior rectal artery resulting in ischemia that prevents small mechanical tears from healing in a timely fashion; the tears then progress to clinically significant anal fissures. (1,9,10)

In addition, the anal spasm is a defense mechanism to prevent further stretching of the anal canal and worsening of the tear. A vicious cycle ensues whereby the anal spasm exacerbates the ischemia and prevents the fissure from healing, which in turn sustains the anal spasm to prevent further tearing. Once this cycle sets in, the likelihood of spontaneous healing decreases and the edges of the fissures become more fibrosed leading to a chronic fissure.(11)

Many acute anal fissures heal spontaneously. Those that do not, develop secondary changes to the surrounding tissues that signal the long-standing nature of the condition. Over time, the skin distal to the fissure becomes edematous and enlarged, and may form a fibrous skin tag (the sentinel pile). Similarly, the anal papilla cephalad to the fissure can undergo parallel changes and become enlarged. These changes are attributed to chronic low-grade infection. The edges and the base of the fissure becomes fibrotic and one sees the characteristic whitish fibers of the exposed internal sphincter in the base of the fissure. In patients with chronic anal fissure, anorectalmanometry studies have documented increased maximum anal resting pressure (MARP)(7). Ultra slow waves are also found more commonly in patients with fissures than in normal subjects. (12) All these abnormalities resolve after lateral internal sphincterotomy(7).

Schouten et al used a combination of anal manometry and Doppler laser flowmetry to study the relationship between MARP and anodermal blood flow. They demonstrated that blood flow to the posterior commissure was decreased compared with flow in other quadrants, and that MARP was inversely related to blood flow. Further, they demonstrated that lateral internal sphincterotomy in patients with chronic fissures produces decreased MARP and increased anodermal blood flow(13).

MANAGEMENT

Medical treatment has been shown to be effective in acute anal fissure but is known to have high failure rates in chronic anal fissures. (7). Surgical therapy is reserved for patients with refractory anal fissures. The surgical procedures involves the partial disruption of the internal sphincter. The lateral internal sphincterectomy has become the treatment of choice for refractory anal fissures.(14)

Several complications have been reported following internal sphincterotomy. The majority of studies have demonstrated that unhealed and recurrence rates and alterations in continence are lower with lateral internal sphincterotomy than with these other procedures(15). Unhealed or recurrence rates are reported in 1% to 6% of patients in large series(1,9,10). Incontinence to flatus has been reported in 1.5% to 15% of patients, and fecal soilage in 0% to 11% of patients, with most series reporting rates in the lower end of the range (1,9,10). Postoperative complications of prolapsed thrombosed hemorrhoids, hemorrhage, perianal abscess, and fistula-in-ano are each reported in approximately 1% of patients(7).

There is a controversy on whether lateral internal sphincterotomy should be performed in an open or closed fashion. Proponents of the closed technique suggest that alterations in continence may be less frequent after closed sphincterotomy. (2). Ahmad et al found a higher fecal and flatus incontinence rate in the open (32%) versus closed (24%) with similar rates of perianal abscesses and recurrences (16). Perkins et al also reported higher cases of faecal incontinence complication in the open approach than in the closed approach(17). Proponents of the open technique suggest that complication rates may be fewer and unhealed fissures and recurrence rates may be lower after open sphincterotomy. (3,16,17). However, Nelson et al have demonstrated that both methods are equally effective (18,19).. In addition, the American society of colon and rectal surgeons assert that there is no difference in outcomes between properly performed open and closed sphincterotomy.(14).

Local practice at Kenyatta National Hospital has not been well documented and therefore difficult to rationalize which approach is best suited in patients who present with chronic anal fissures. This study aims to determine which method either closed or open offers a better outcome and thus help to rationalize local practice in surgical care.

The purpose of this study is therefore to determine the outcome of chronic anal fissures treated using either of the two surgical methods and the impact either have on the quality of life of the patients.

RATIONALE/JUSTIFICATION

Anal fissures are common causes of morbidity in the surgical units. Lateral internal sphincterotomy is the gold standard in the treatment of chronic anal fissures. However there is a controversy on whether to opt for a closed approach vis a vis an open approach. (7) At KNH, there is no local data on the outcomes following either open or closed lateral internal sphincterotomy in chronic anal fissures management. Alushula D. O., in a local study on outcome of lateral internal sphincterotomy as compared to manual anal dilatation, recommended use of the former but did not show which surgical approach gives better results(20). This study is aimed at comparing the early outcomes depending on method used in our set up. The results of this study may then be used to recommend the method to be used in managing anal fissures at KNH.

NULL HYPOTHESIS

There is no difference in the early surgical outcome after open or closed lateral internal sphincterotomy in the treatment of chronic anal fissure(s).

STUDY QUESTION

Is there a difference in the early surgical outcome when one uses either closed or open lateral internal sphincterotomy technique in treating chronic anal fissure(s).

BROAD OBJECTIVE:

To compare the early outcome of closed versus open lateral internal sphincterotomy in chronic anal fissures.

SPECIFIC OBJECTIVES:

- a) To profile the anatomical sites of chronic anal fissures in the study group.
- b) To compare the post-operative pain pattern among patients undergoing closed versus open lateral internal sphincterotomy.
- c) To compare the risk of developing incontinence to flatus and / or stool in patients undergoing lateral internal sphincterotomy in the two groups..

METHODOLOGY

SAMPLE SIZE CALCULATION

SAMPLE SIZE= 76 patients, (38 in each arm of study).

Let p_i be the proportion of subjects in group i having the outcome of interest, $\bar{p} = (p_1 + p_2)/2$ and $\bar{q} = 1 - \bar{p}$.

$$H_0: p_1 - p_2 = 0$$

$$H_1: p_1 - p_2 = d$$

The sample size per group is

$$n' = \frac{\{z_{\alpha/2}\sqrt{2\bar{p}\bar{q}} + z_{\beta}\sqrt{p_1q_1 + p_2q_2}\}^2}{d^2}$$

n=sample size to be determined

Z=Standard error from mean (Z_{1-a/2}= 1.96]

a=level of significance (Z_{1-a}=1.645)

b=level of significance <80=.842, >90=1.282

P1= proportion of developing complication with closed method (20%).

P2=proportion of developing complication with open method (15%).Alushula O.

Daniel (2006)

Taking into consideration a 10% chance of loss of patients during the study for any

reason, actual sample size = 2(calculated sample size +10% loss)

$$= 2 (38 + 4) = 84$$

Study Design: RandomizedProspective study.

Setting: Kenyatta National Hospital surgical wards and surgical outpatient clinics

Study Population: Adult patients with chronic anal fissures.

Recruitment Process

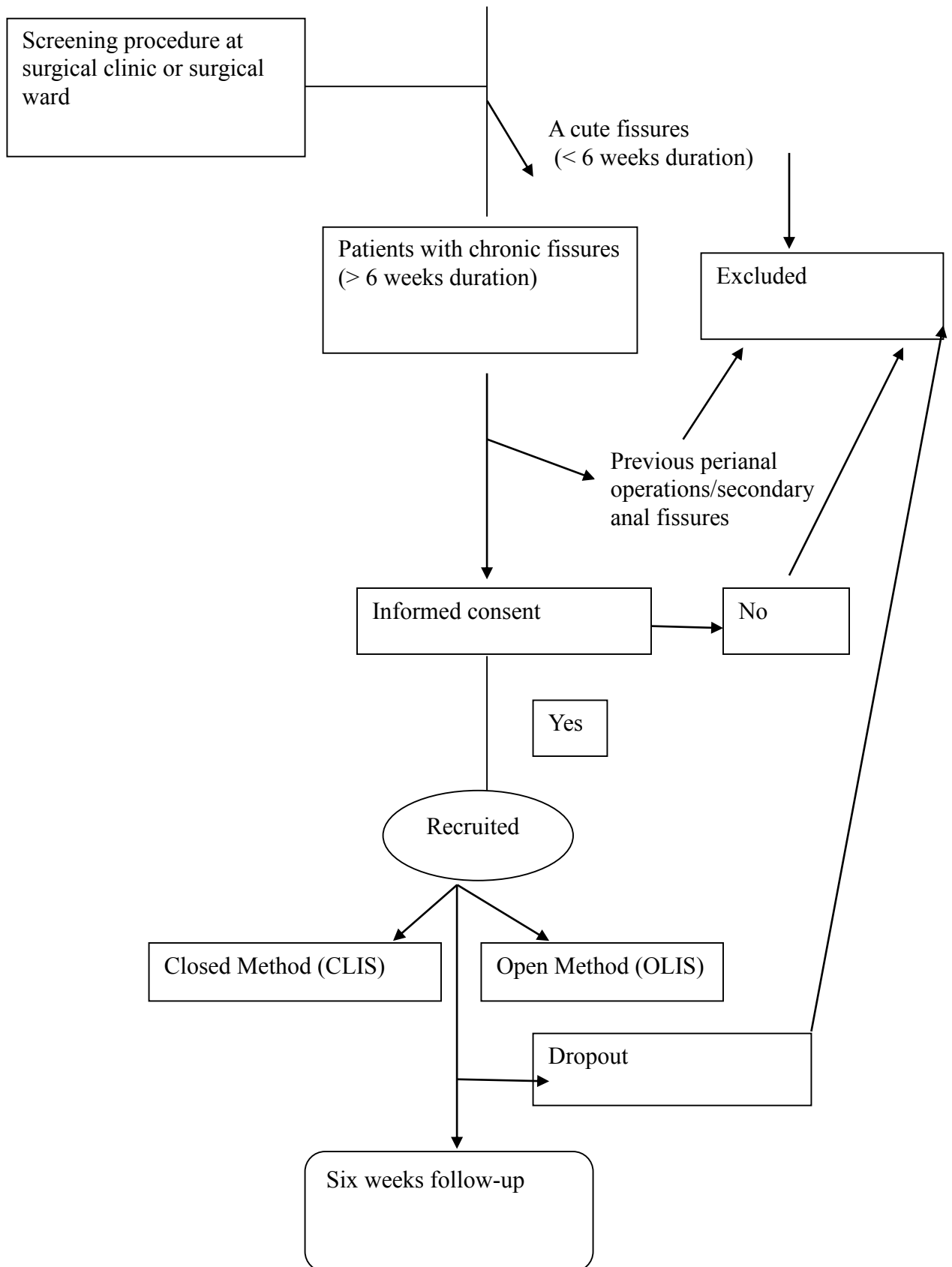
A total of eighty four patients with chronic anal fissures were randomly selected by the principal investigator from the surgical wards after meeting the inclusion criteria from among elective cases admitted for operative management from the surgical outpatient clinics. Informed consent was obtained. Those opting not to consent were excluded from the study. Patients were randomly assigned into two groups, A and B, using computer generate numbers. Group A underwent closed lateral internal sphincterotomy (CLIS) while group B patients underwent open lateral internal sphincterotomy (OLIS). Randomization was done by the principle research in pre-operative room in theatre. Two coloured stickers of different shapes and colors were used to identify each group in the patient file as well as in the data collection sheet as shown below:

Patient	Method	Stickers on file and data collection sheet	
		Colour	Shape
Group A	Closed (CLIS)	Dark green	Rectangular
Group B	Open (OLIS)	Light green	Circular

Only patients were blinded in the study, hence this was a single blinded randomized study. Patients were assessed for early surgical outcomes over a total period of six weeks. This was accomplished by filling in the necessary surgical outcome parameters of post-operative pain, and continence to flatus and/or stool, haematoma formation or perianal wound infections/abscess. This data was then analyzed using appropriate statistical methods.

FLOW CHART

PATIENTS WITH ANAL FISSURES AT CLINIC



Patients biodata (Age, gender, residence) and presenting symptoms was captured in a questionnaire. {Appendix i}

Pre-operative preparation included,

Complete blood count, fasting blood sugar, urea & electrolytes. Patients were given spinal anaesthesia. Positioned in the lithotomy on the operating table. Skin preparation with iodine then appropriate drappings. Using the operating surgeon index finger, palpation of the tight distal internal sphincter and intersphincteric groove was done.

Closed Technique

SURGICAL blade no. 11 was introduced through the perianal skin at the left lateral aspect of the canal sandwiched parallel between the anoderm and internal sphincter.

When tip of blade reached the dentate line, blade was turned outwards to divide the sphincter. A “give” sensation felt when fibres were divided defined adequate release. Blade was removed and gentle pressure applied for 5 minutes to control bleeding. Skin tag was then excised.

Open Technique

Preparation of skin in lithotomy position as above. Radial incision made lateral at the lower border of the internal sphincter into the intersphincteric groove. Then the distal internal sphincter was grasped with Allis forceps and bluntly freed. The lower third or half of the fibres were divided.

All operations were done by qualified and practicing general surgeons in the three firms/units at KNH wards 5A, 5B and 5D. In each of the three wards, specific surgeons recruited were as follows:

5A: Dr. Githaiga/Dr. Nyaima/ Prof. Oliech

5B: Dr. Khaisa/Dr. Musila/ Dr. Njogu/Prof.Jani

5D: Dr. Kiptoon/Dr. Khan/Dr. Kiraitu/Prof Ndaguatha

2 research assistants were recruited into the study. Their main role was compiling data in the data collection sheet during the outpatient clinic follow-up at two and six week's interval. Each was assigned a specific firm during the follow-up period. The research assistants also liaised with the main researcher in case of untoward complication was noted during the follow-up period in order to offer immediate corrective measures. Minimal qualification for research assistant was Diploma in Clinical Medicine and Surgery (commonly referred to as clinical officers)

Eligibility Criteria

- Patients above 18 years with primary chronic anal fissure, with or without blood in stools
- Patients giving informed consent.

Exclusion Criteria

- Patients who had previous surgery for anal fissure.
- Patients with fissures secondary to other diseases like Crohns disease, ulcerative colitis, tuberculosis or anal warts.
- Any co-morbid condition (Diabetes Mellitus, malignancies)

Outcome Parameters

ANAL PAIN: A visual analogue pain score (1-10) during hospital stay and in the Outpatient department follow up period was used.

Complications

Complications such as anal bleeding, perineal abscess, incontinence to flatus or stool, recurrence were noted and captured in the data collection sheet

Post-Operative Care

Included metronidazole 500mg three times a day, cephalosporin 1gm twice a day, diclofenac 50mg three times a day for five days and sitz baths twice daily. Incase of intractable anal pain morphine was used.

DAY 1 CHECKLIST (IN WARD):haematoma, bleeding,, anal pain.

DAY 14 & DAY 28 CHECKS IN CLINIC: Incontinence to flatus and/ or stool, anal pain.

Data Collection

Patient's demographic data will was entered in a pre-prepared data sheet by the principal researcher or his assistant(s) in the wards after admission.

Findings of anal fissure anatomical site were entered in the data sheet in theater during examination under anaesthesia (E.U.A).

Data Handling and Management

Data captured in the structured questionnaire (data sheet) was entered into the statistical package for social sciences version 17.0 (SPSS 17.0).

Descriptive univariate analysis of socio-demographic characteristics (such as age and gender) was analysed and presented using percentages, pie charts, frequency tables and graphs. In addition, analyses on functional outcomes was presented using measures of distribution like frequency distribution tables, central tendency (mean, median and mode.), dispersions (range and standard deviation). Chi-square test or Fishers exact test shall be used to determine the level of significance.

ETHICAL CONSIDERATIONS

This study subject was approved by Kenyatta National Hospital ethical and research committee.

All patients recruited in this study were informed of the study and treatment protocol, expected side effects and treatment options. Patients who agreed to participate signed a consent form (appendix).

The investigator then completed a questionnaire for each patient. All patient details were stored by the principal investigator and kept confidential. Patient hospital numbers were used to identify each patient and not their names.

The information gathered was used for the disclosed purpose of the study only. In addition there was strict confidentiality to safeguard patients' privacy.

Raw Data

This will be stored under encrypted lock and key for a maximum of three (3) years after publication or public release of the work of the research. During this time, the records will be available to the research community. Destruction of raw data/records will be done in accordance with all legal, ethical, University of Nairobi policy requirements and with particular concern for confidentiality and security. Again, we emphasize that the destruction of raw data will only be done after approval by KNH-UON ethical research committee.

LIMITATIONS OF THE STUDY

It is a single centre study limiting the catchment area.

Expected drop out of some patients due to economic constraints for patients not from Nairobi.

DELIMITATIONS OF THE STUDY

This was minimized by making early telephone contacts with patients/relatives before clinic days. In addition, in rare instances, the principal investigator travelled to the nearest hospital that the patient can make follow-up visits.

DATA ANALYSIS AND PRESENTATION OF RESULTS

In this study carried out at Kenyatta National Hospital for six months between May and October 2014 both months inclusive, 80 patients presenting with chronic anal fissure were evaluated.

Table1. Age and sex Distribution

		Overall (all patients) N = 80
		n (%) IQR
Age (yrs)	Less than 30 years	25 (33)
	30 – 40 years	28 (37)
	>= 40 years	23 (30)
Sex	Female:	31 (39)
	Male:	49 (61)
Group	closed:	40 (50)
	open:	40 (50)
Median age (yrs)		34 (26 – 45)

Table 2. Symptoms and Location of Fissure

Symptoms	Anal pain:Yes	80 (100)
	Blood in stool:Yes	59 (74)
	No	21 (26)
	Mucoiddischarge:Yes	40 (50)
	No	40 (50)
	Anal skin tag:Yes	60 (75)
	No	20 (25)
	Perineal swelling:Yes	3 (4)
	No	77 (96)
Location	Posterior:	68 (85)
	Anterior:	9 (11)
	Both:	3 (4)

Table 2 shows the characteristics of the study patients. There was an equal representation of the number of patients who underwent either the closed or open surgery. The median age of the participants was 34 years of age with the male having a higher representation

(61%) than the female. All patients reported to have had anal pain while only 4% had perineal swelling. A majority of the patients (85%) had the fissure located at the posterior. More than half of the patients 51% underwent the CLIS procedure.

Figure 1: Presence of the various symptoms

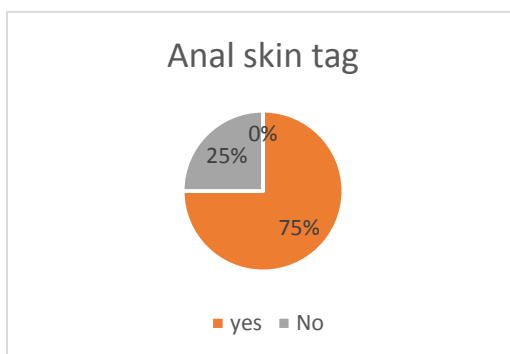
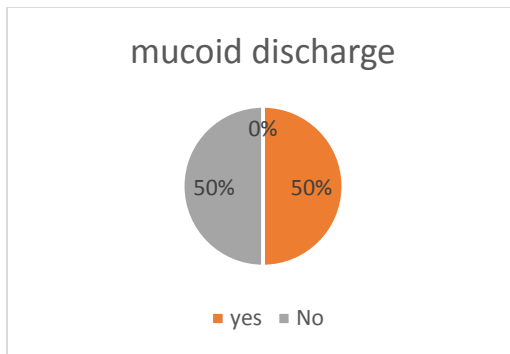
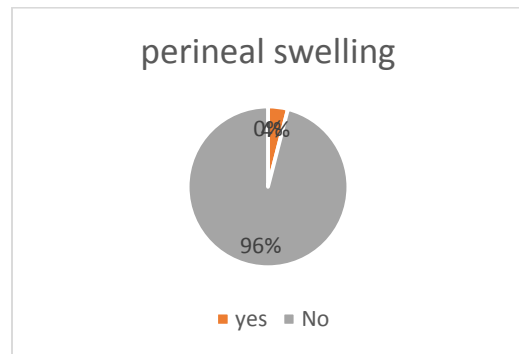
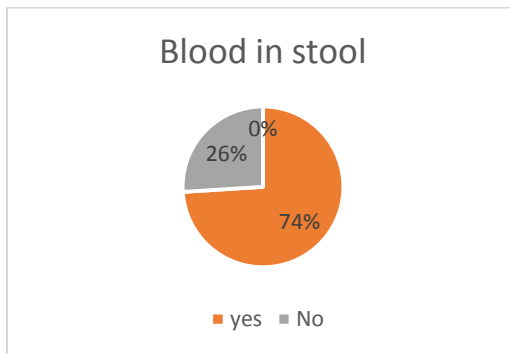


Figure 2: Patient's Age Distribution

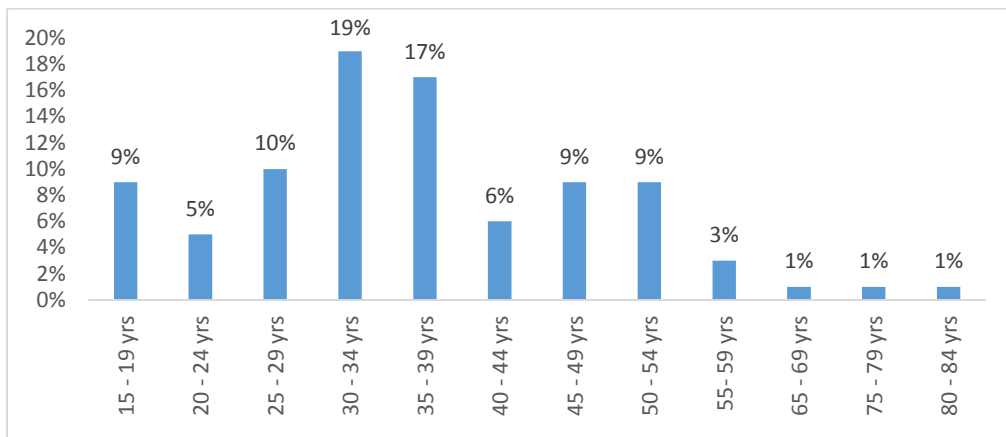


Figure 2 shows the age distribution for the patients in the study. The age group between 30 – 34yrs had the highest number patients in the study.

Figure 3: Fissure location

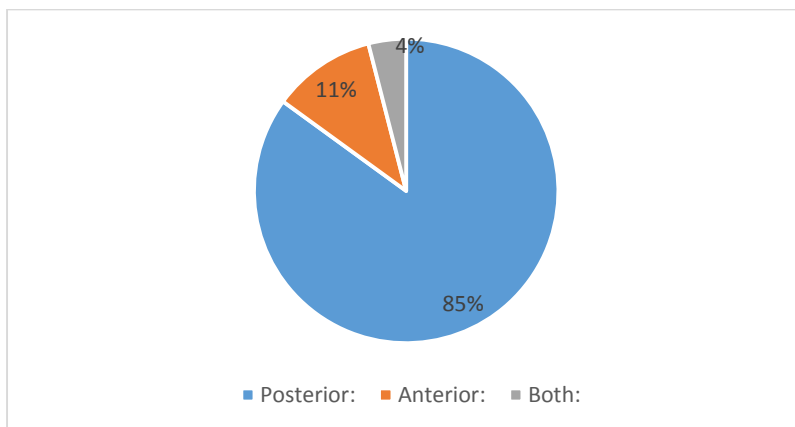


Figure 3 shows the location of the fissure. Most of the patients, 85% had the fissure at the posterior.

Figure 4: Fissure location by gender

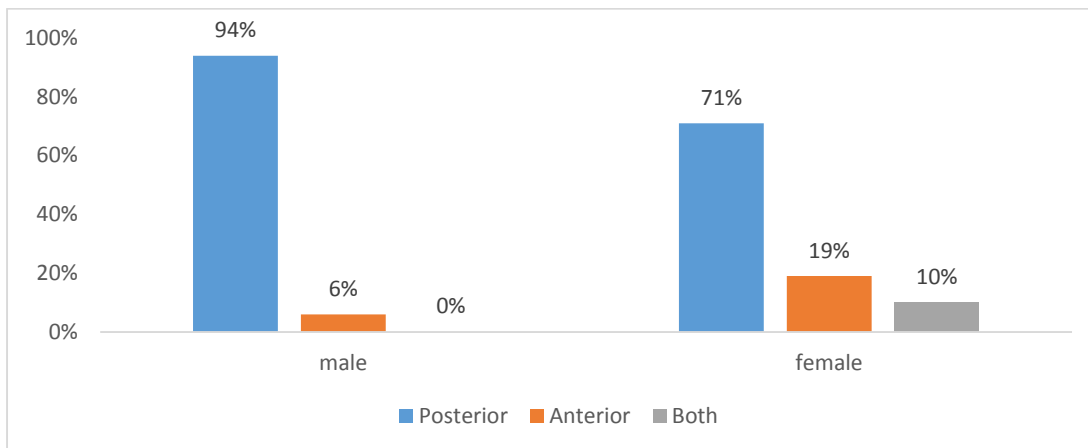


Figure 4 shows the fissure location by gender. In Both genders, the fissure was commonly located at the posterior. Only the female had the fissure located both at the posterior and the anterior.

Table 3: Patient’s post-operative outcomes

	Overall (all patients) N = 80
	n (%) IQR
6 hrs postoperative pain score	
No pain:	74 (95)
1:	1 (1)
Annoying pain:	3 (4)
12 hrs postoperative pain score	
No pain:	66 (84)
1:	1 (1)
Annoying pain:	6 (7)
3:	6 (7)
24 hrs postoperative pain score	
No pain:	43 (54)
Annoying pain:	13 (17)
3:	14 (18)
Uncomfortable:	9 (11)
36 hrs postoperative pain score	
No pain:	22 (28)
Annoying pain:	20 (25)
3:	32 (41)
Uncomfortable:	5 (6)
48 hrs postoperative pain score	
No pain:	13 (17)
Annoying pain:	33 (42)
3:	25 (32)
Uncomfortable:	6 (8)
5	2 (2)
60 hrs postoperative pain score	
No pain:	12 (15)

Annoying pain:	32 (41)
3:	29 (37)
Uncomfortable:	3 (4)
5	2 (3)
72 hrs postoperative pain score	
No pain:	20 (27)
Annoying pain:	25 (34)
3:	21 (29)
Uncomfortable:	6 (8)
5	1 (1)
96 hrs postoperative pain score	
No pain:	16 (80)
Annoying pain:	2 (10)
3:	1 (5)
Uncomfortable:	1 (5)
Bleeding	
Yes:	11 (14%)
No:	68 (86%)
Haematoma	
Yes:	7 (9%)
No:	72 (91%)
Seroma	
Yes:	3 (4%)
No:	76 (96%)
*Perineal abscess	
No:	79 (100%)
*Flatus incontinence	
No:	79 (100%)
*Stool incontinence	
No:	79 (100%)
*Recurrence	
No:	30 (100%)
Hospital stay duration	2 (2-3)
2 weeks Bleeding	
Yes:	1 (1%)
No:	78 (99%)
2 weeks perinealabcess	
Yes:	4 (5%)
No:	75 (95%)
2 weeks seroma	
Yes:	3 (4%)
No:	76 (96%)
6 weeks flatus incontinence	
Yes:	1 (1%)
No:	76 (99%)

Table 3 shows the various outcomes of the procedure. A majority of the patients reported the absence of the following post-operative outcomes, bleeding, haematoma, Seroma, perinealabcess& flatus incontinence at 86%, 91%, 96%, 100% and 100% respectively. The median number of days in the hospital were 2 days.

Figure 5: Percentage patients with no pain

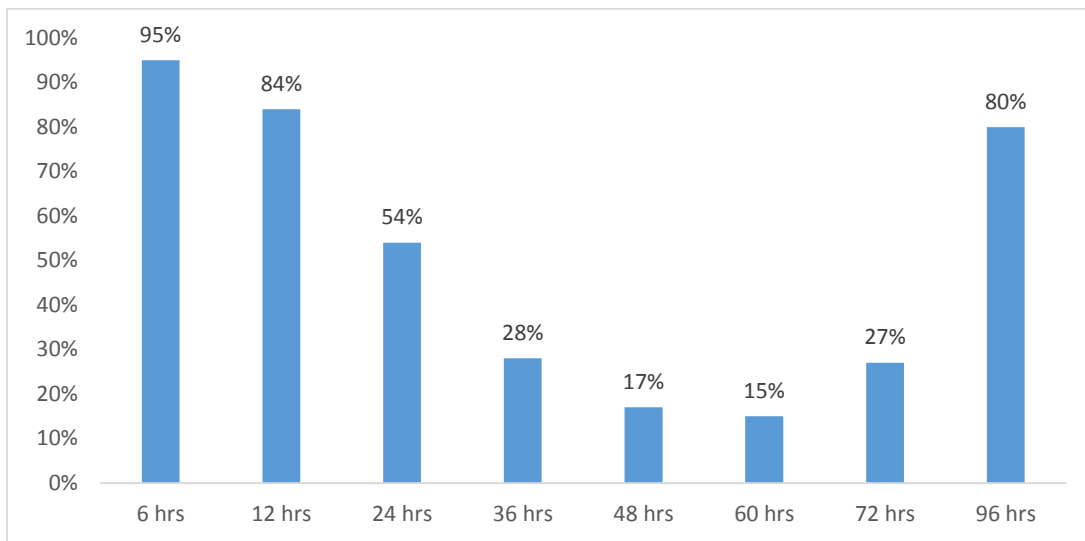
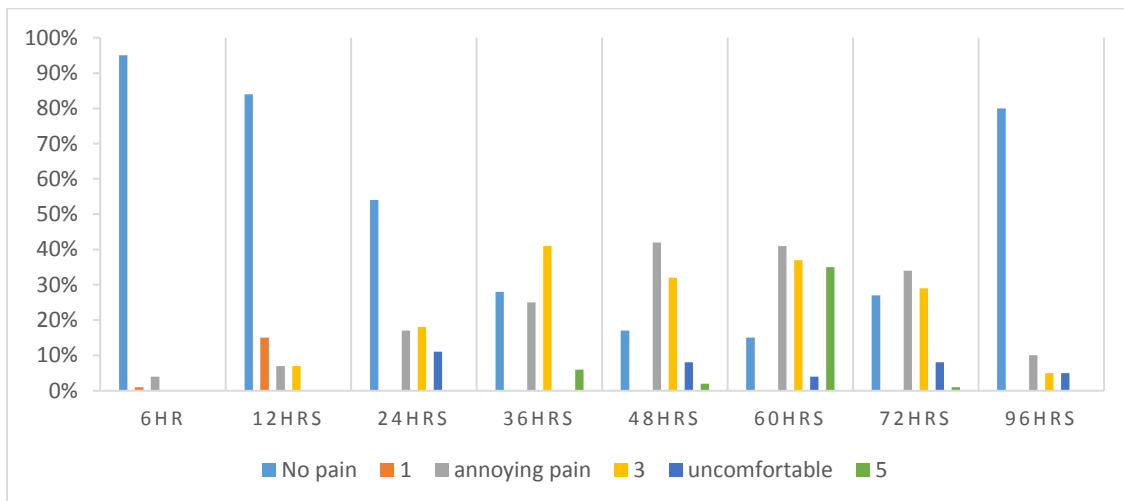


Figure 5 shows the % number of patients who reported having no pain at the various time intervals. However, this number reduced as the number of hours increased.

Figure 6: Pain at Various Time Intervals



Please select another colour as it is difficult to differentiate the shades of blue

Figure 6 shows the pain scale at the different time intervals. Between 6hrs – 24hrs most of the patients reported to have no pain. Sometime between 36hrs – 72 hrs, some patients reported to experience some pain which ranged between the annoying pain and uncomfortable pain. This however changed at 96hrs with most of the patients reporting no pain.

Figure 7: Surgical Outcome of Bleeding/Seroma/Abcess

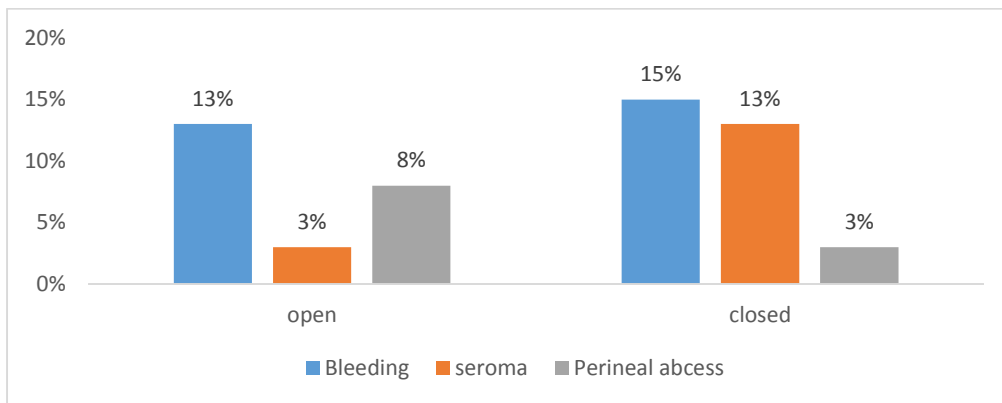


Figure 7 shows the comparison between the various outcomes between the two study groups. Bleeding was the most common outcome among the two groups with 13% and 15% for the open group and the closed group respectively.

Table 4: CLIS versus OLIS Outcomes

		Overall (all patients) N = 80		
		Closed N = 40	Open N = 40	P – value
Age (yrs)	Less than 30 years	13 (52)	12 (48)	0.108
	30 – 40 years	10 (36)	18 (64)	
	>= 40 years	15 (65)	8 (35)	
Sex	Male:	27 (55)	22 (45)	0.251
	female:	13 (42)	18 (58)	
Blood in stool	No:	8 (38)	13 (62)	0.204
	Yes:	32 (54)	27 (46)	
Mucoid discharge	No:	21 (53)	19 (47)	0.204
	Yes:	19 (47)	21 (53)	
Perineal swelling	No:	38 (49)	39 (51)	0.556
	Yes:	2 (67)	1 (33)	
Location	Posterior:	34 (50)	34 (50)	0.801
	Anterior:	5 (56)	4 (44)	
	Both:	1 (33)	2 (67)	

Table 4 shows a comparison between the two groups and the patient characteristics. There was no significant difference between the patient characteristics in the two randomized groups.

Table 5: Group Versus the Outcomes

	Overall (all patients) N = 80			
		Closed N = 40	Open N = 40	P – value
6 hrs pain	None Annoying	37 (49) 2 (67)	38 (51) 1 (33)	0.556
12 hrs pain	None Annoying	35 (52) 4 (33)	32 (48) 8 (67)	0.228
24 hrs pain	None Annoying uncomfortable	25 (58) 11 (41) 3 (33)	18 (42) 16 (59) 6 (67)	0.217
36 hrs pain	None Annoying uncomfortable	10 (45) 25 (48) 4 (80)	12 (55) 27 (52) 1 (20)	0.359
48 hrs pain	None Annoying uncomfortable	6 (46) 30 (52) 3 (38)	7 (54) 28 (48) 5 (62)	0.729
60 hrs pain	None Annoying uncomfortable	5 (42) 32 (53) 2 (40)	7 (58) 29 (47) 3 (60)	0.711
72 hrs pain	None Annoying uncomfortable	10 (50) 22 (48) 4 (57)	10 (50) 24 (52) 3 (43)	0.898
96 hrs pain	None Annoying uncomfortable	8 (50) 1 (33) 0 (0)	8 (50) 2 (67) 1 (100)	0.898
Bleeding	Yes No	5 (46) 34 (50)	6 (54) 34 (50)	0.556
Haematoma	Yes No	2 (29) 37 (51)	5 (71) 35 (49)	0.249
Seroma	Yes No	0 (0) 39 (51)	3 (100) 37 (49)	0.081
2 weeks Bleeding	Yes No	1 (100) 39 (50)	0 (0) 39 (50)	0.320
2 weeks perinealabsess	Yes No	3 (75) 37 (49)	1 (25) 38 (51)	0.317
2 weeks Seroma	Yes No	1 (33) 39 (51)	2 (67) 37 (49)	0.541
6 weeks flatus incontinence	Yes No	0 (0) 38 (50)	1 (100) 38 (50)	0.320

Table 5 shows the comparison of the two groups by the various outcomes. There is no significant difference between the various outcomes of the two study groups.

Figure 8: Percentage of Patients with no Pain at the Various Time Points

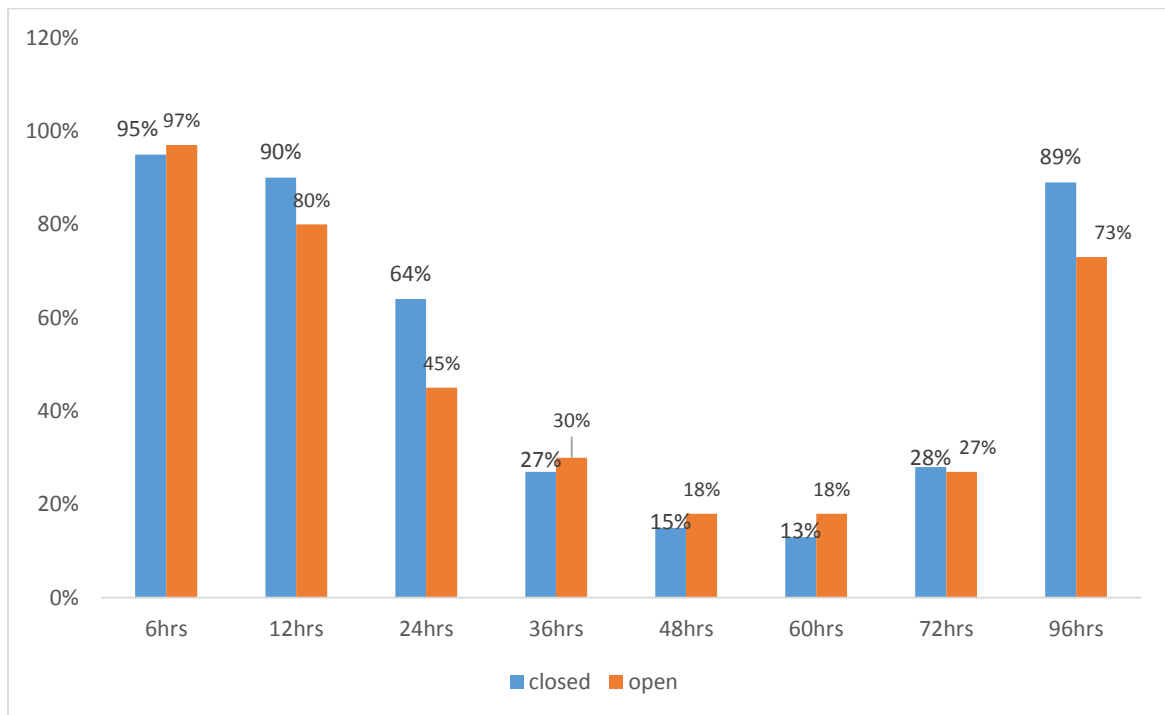


Figure 8 shows the % number of patients who reported to have been experiencing no pain at the various time points across the two groups. At each time point, the number of patients experiencing pain were almost similar. With increase in time for both groups, the number of patients who reported to be experiencing pain increased. The highest level of pain reported was the uncomfortable pain as per the pain scale.

DISCUSSION

(i) Characteristics of study patients

Eighty (80) patients underwent lateral internal sphincterotomy at Kenyatta National Hospital during the study period. 40 (50%) underwent closed lateral internal sphincterotomy (CLIS) while a similar number underwent open lateral internal sphincterotomy (OLIS). The median age at presentation was at 34 years which compares with other studies (4,7,9,12).

The commonest symptom at presentations was anal pain during and after defecation (100%), followed by anal skin tag (75%) and blood in stool (74%). This triad of symptoms constitutes a fairly accurate clinical assessment of chronic anal fissure before a patient is examined to confirm the same. Thus a high index of suspicion would spare the patient the excruciating pain experienced during digital rectal exam in the clinics which would then be confirmed in theatre when anaesthesia is given.

Most fissures were located at posterior anal mucosa (95%) with a small proportion being in the anterior and mucosa (11%). This can be explained both anatomically and physiologically. The posterior commissure of the anoderm is less perfused than other anodermal regions. The branches of the inferior rectal artery course perpendicularly through septa of the internal anal sphincter before reaching the anoderm. Thus, flow through these arterioles is threatened by elevated intramuscular pressure of the internal sphincter exceeding the intra-luminal pressure of arterioles. Therefore increased internal anal sphincter tone compromises perfusion of the posterior midline anoderm resulting in ischaemia that prevents small mechanical tears from healing which then progresses to clinically significant anal fissures [7,8,9].

Overtime, the skin distal to the fissure becomes edematous and enlarged and may form a fibrous skin tag as seen in 75% of the patients in this study. Similarly, the anal papilla cephalad to the fissure can undergo parallel changes and become enlarged. These changes are attributed to chronic low grade infection. The edges and the base of the fissure becomes fibrotic and one is able to see the characteristic whitish fibres of the exposed internal sphincter in the base of the fissure at operation. Fissures occurring at both anterior and posterior sites were uncommon (4%) and were only encountered in female patients (Table 2).

(ii) Post-operative outcomes

All patients were given spinal epidural block in theatre before surgery. Therefore in first 6 hours post operation, 95% reported no pain. This trend was seen upto 24 hours post theatre. In the subsequent 48 hours only a small proportion complained of annoying pain (34%). In the visual pain score this type of pain has a score of 2. This is significant given that at presentation all patients complained of dreadful pain with a mean visual pain score of 6. Hence lateral internal sphincterotomy worked well to relieve pain and therefore significantly improved the quality of life of the patients (Figure 5).

Bleeding was encountered in 14% of patients intra-operatively. This was easily managed by applying constant thumb pressure on surgical site for 5 minutes. Only in one patient was clamping and ligation of vessel necessary. Haematoma formed in 9% of patients and was not significant to require surgical evacuation. Majority of patients had no seroma formation (96%) (Figure 7).

Orroyo A et al in a prospective randomized study of open versus closed lateral sphinterotomy, had reported flatus incontinence rates of 15%. [9] In this study only 11% of patients reported

flatus incontinence and this significantly reduced to 1% at six weeks follow up period. (Table 5). Peri-anal sepsis was uncommon (5%) and this can be explained by the aseptic approach used during surgery as well as use of prophylactic antibiotic (Floxapen 1.5g) intra-operatively. In addition, all patients were trained on personal hygiene and correct use of warm sits baths both in hospital and at home.

(iii) Group versus surgical outcome

Pain was assessed at various timeliness after surgery in the open and closed groups in order to profile the pattern (Figure 8). This was done at 6 hours, 12 hours, 24 hours, 36 hours, 48 hours, 60 hours and 72 hours. At the early hours (24 ours), no significant variation in pain score was noted in the two groups. ($p=0.556$). At 36 hours, the p value had reduced to 0.359 but was again not statistically significant. Overall, there is no significant difference in the pain scores in the two groups being studied. This compares to what Ram et al Meftcalfe A. M. et al reported in their series [4,6,7].

Seroma formed more in the open group (3 patients compared to non in closed group), with $p=0.081$. At the end of the study period, only one patient in this group still had flatus incontinence $p=320$.

Conclusion

From this study, there appears to be no difference in the early surgical outcomes between closed and open lateral internal sphinterotomy.

Recommendations

- i) We recommend routine use of intra-operative prophylactic antibiotic (Floxapen 1.5 gms) as well as sitz baths post operatively as evidenced by low rates of peri-anal sepsis in our study.
- ii) The open approach to lateral internal sphincterotomy is good in teaching hospitals as the trainee surgeons get good exposure compared to the closed technique where exposure to the student is minimal.
- iii) The closed technique is fast and simple in experienced hands and therefore recommended for use in our hospitals especially where time is limited.
- iv) Long term follow up of patients is required to profile cases of recurrence of anal fissure in either group (minimum 12 weeks). This was not assessed in this study as the follow up period was limited to six weeks after surgery.

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21. Medical Records Department KNH 25/8/2012

APPENDIX I
DATA COLLECTION SHEET

Group A Closed Group B.....Open

1.Pre-surgery

(i) Demographic information:

Study number.....

Age.....

Gender: Male..... Female.....

(ii) Presenting symptoms

Pain in anal area.....

Blood in stool.....

Mucoid discharge.....

Anal skin tag.....

Perineal swelling.....

Others (specify).....

(iii) Duration of symptoms prior to presentation (weeks)

(iii) Date of recruitment into study-----/-----/-----

2.Intra-operative

(i) Location of fissure

(a) posterior

(b) Anterior

(c) others(specify)

(ii) Type of procedure

(a) CLIS

(b) OLIS

3.Postoperative follow-up

(i) Average pain score for patient as per VAS:

6hrs.....12hrs.....24hrs.....36hrs.....

48hrs.....60hrs.....72hrs.....96hrs.....

(ii) Bleeding.....YES .NO

(iii) Haematoma..... YES NO

(iv) Seroma..... YES NO

(v) Perineal abscess..... YES NO

(vi) Flatus incontinence..... YES NO

(vii) Stool incontinence.....YES NO

(viii) Recurrence..... YES NO

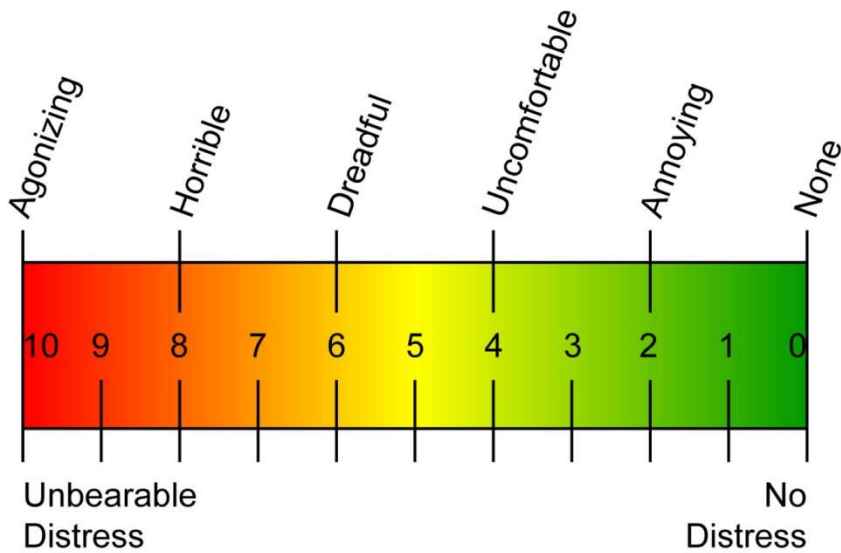
4. Duration of hospital stay (days).....

5. Follow-up at surgical clinic

2 weeks	i. Bleeding Yes <input type="checkbox"/> NO <input type="checkbox"/> ii. Perineal abscess Yes <input type="checkbox"/> No <input type="checkbox"/> iii. Seroma Yes <input type="checkbox"/> NO <input type="checkbox"/>
6 weeks	i. Flatus incontinence Yes <input type="checkbox"/> No <input type="checkbox"/> ii. Recurrent Yes <input type="checkbox"/> No <input type="checkbox"/>

APPENDIX II

VISUAL PAIN SCALE/ANALOGUE SCORE



Task _____

Date _____ Start _____ End _____

APPENDIX III

CONSENT STUDY – LATERAL INTERNAL SPHINCTEROTORY SURGERY

Study No.....

Hospital No.....

Purpose of the study

The purpose of this study is to determine the surgical practice in the management of chronic anal fissures at Kenyatta National Hospital. The information gathered will be used to improve the management of patients undergoing lateral internal sphincterotomy.

Risks and benefits

This study will provide surgeons with necessary information on which surgical approach will yield least complications in patients undergoing lateral internal sphincterotomy. This will mean improved surgical outcome for the patients. There is no harm or risk anticipated from participating in the study. However, during the study if a researcher identifies a complication on you, he will recommend/ refer you appropriately. No additional tests outside the usual ones for treatment will be carried out and no extra costs to you will be incurred in the study.

Voluntary participation

Participation in this study is out of your own will. Medical care will not be denied in case you decline to participate in the study. You may terminate participation at any time with no consequences whatsoever.

Randomization

There will be two arms of treatment option available to you in this study. Both treatment options have been used before to treat chronic anal fissures, but there has been no local studies comparing early surgical outcomes. Please note that the surgeon will randomly select you in either arm at the time of operation as explained to you earlier.

Confidentiality

All information will be treated with utmost confidentiality. Your identity will not be published whatsoever.

I the undersigned have been explained to and now understand the above and voluntarily accept to participate in the study.

Follow-up:

This will occur for six weeks from time of surgery. First review after two weeks and final evaluation at six weeks in the surgical clinic(s).

Signature/ Thumb print.....

Dr. Kihara P. Kamau 0722871543 Chairman KNH/UON-ERC-----020-272300,
Ext. 44355.

APPENDIX IV

KIBALI CHA RUHUSA

Nambariyautafiti..... NambariyaHospitali.....

Sababuyautafiti

Sababuyautafitihuunikuthibitishamanufaayamtindowakutibushindazinazitokananakupasukak
wanjiayamwishoyakinyesikupitiaupasuanji. Utafitihuuutafanyikakatikahospitalikuuya
Kenyatta
namatokeyakeyatatumiwakuboshamatibukwawagonjwaambaowanafanyiwaupasujawamk
undu.

Hatarinamanufaa

Utafitihuuutaimarishaujuziwamadatarikwamatibabuyawagonjwaambaowanafanyiwaupasua
njiwamukundu. Hatutarajiihatarizozotezilekwakounposhiriki.Iwapowakatiwautafiti
,mtafitiatagunduashidakatikamatibabuyako, basiatapendekeza au
kukutumakwamatibabuyanaofaa. Vilevile, utafitihuuhautakugharimufedhazaidi.

Uhusikakwahiari

Kuhusikakwautafitihuunikwahiariyakomwenyewenahauzikushurutishwa.
Utahudumiwahatakamautakataakuhusika.
Unauhurukutamatishakuhusikawakatiwowoteulebilamadharayoyote.

Usiri

Habarizozoteutakazotoazitawekwakwasirinajianlakohalitachapishwapopote.
Nithibitishayakwabanimefahamuyalenimeelezwanamtafitinanimekubalikwahiariyangumwen
yewekuhusikakatikautafitihuu.

Sahihi/Kidole cha gumba(kushoto).....

DR.Kihara P. Kamau.....0722871543 Mwenyekiti KNH/UON-ERC...020-2726300

Ext.44355.

APPENDIX V
ETHICAL APPROVAL



UNIVERSITY OF NAIROBI
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Link: www.uonbi.ac.ke/activities/KNHUoN



KENYATTA NATIONAL HOSPITAL
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Telegrams: MEDSUP, Nairobi

19th June 2014

Dr. Peter K. Kamau
Dept. of Surgery
School of Medicine
University of Nairobi

Dear Dr. Kamau

Research proposal: Early outcome of Open versus Lateral Spinctorotomy in the Treatment of Chronic Anal Fissures at Kenyatta National Hospital (P616/012/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 19th June 2014 to 18th June 2015.

This approval is subject to compliance with the following requirements:

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

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

Protect to Discover

Yours sincerely



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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH/UoN-ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chairman, Dept. of Medicine, UoN
Supervisors: Prof. Ndaguatha P.L.W, Dr. Githaiga J.W.

INFORMED CONSENT : LATERAL INTERNAL SPHINCTEROTORY

Lateral internal sphincterotomy is surgery performed at the anal canal to release muscle spasms in order to relieve pain and allow for adequate wound healing. In order to access to the internal and muscle causing spasms the doctor may use either closed or open technique which will be randomly selected at time of operation. Every surgery involves a certain amount of risk. Although majority of patients have no complications, the following can occur in some patients; perineal bleeding, abscess formation, flatus incontinence and rarely stool incontinence. In addition this procedure involves administration of anaesthesia, and therefore, certain anaesthetic risks though rare may be encountered.

I have authorized the doctor(s) to perform the surgery of sphincterotomy and any other procedure that the doctor may deem necessary and desirable.

I consent to the administration of anaesthesia.

I consent that the procedure, its risks and benefits have been well explained to me by the doctor.

Patient name/signature

Date

Witness name/signature

Date