

**THE CLINICAL CHARACTERISTICS OF PATIENTS DIAGNOSED
WITH ACQUIRED BENIGN ANORECTAL CONDITIONS AT MNH
FROM JUNE 2016 TO JUNE 2020.**

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October, 2021**

**MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
DEPARTMENT OF SURGERY**



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By

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**A Dissertation Submitted in (Partial) Fulfilment of the Requirements for the
Degree of Master of Medicine (General Surgery) of
Muhimbili University of Health and Allied Sciences
October, 2021**

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance of a dissertation entitled: "***The characteristics of patients diagnosed with acquired benign anorectal conditions at MNH from June 2016 to June 2020.***" in fulfillment of the requirements for the degree of Master of Medicine (General Surgery) of Muhimbili University of Health and Allied Sciences (MUHAS), Dar es Salaam, Tanzania.

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Date: _____

Prof. Mabula D Mchembe

(Co - Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I, **Dr. Boaz Mwasambili Yonah**, **declare** that this dissertation is my original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature.....

Date.....

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DEDICATION

To my parents, Mr. Yonah M Mwasambili and Mrs. Tabu M Mwasambili, and My Wife, Dr. Lightness Amani Gelakwila.

ABSTRACT

Background: Acquired benign anorectal disorders are common in the general population worldwide and largely underestimated in surgical practice. Few studies have been conducted globally to establish its prevalence and they have shown variation in its predominance, symptoms, and management offered. The Prevalence of these conditions in our setting is lacking hence a true burden of disease is unknown.

Objectives: To describe the characteristics of patients diagnosed with acquired benign anorectal disorders and operated at Muhimbili National Hospital.

MATERIAL AND METHOD: This was a retrospective study involving a total of 226 patients operated on due to acquired benign anorectal conditions from June 2016 to June 2020 at Muhimbili National Hospital, Dar es salaam Tanzania. The presenting symptoms, preoperative diagnosis, investigations done, post-operative diagnosis, and type of Surgery done were recorded together with their demographic data were obtained from both patient's files and Hospital electronic database.

RESULTS: A total of 226 patients operated on due to acquired benign anorectal conditions were studied. Hemorrhoids (46.9%) were the most frequent condition followed by a fissure in ano (24.9%) and fistula in ano (23.3%). 62.4% of patients were males and 37.6% were females. The age group of 30–40 years was most commonly affected by benign anorectal diseases accounting for 29.6% of all patients with a median age of 41 (ranging from 18 to 83 years). Common presenting symptoms, in general, were Painful defecation, mass protrusion per anus and around the anal verge, discharge around the perianal region, blood in the stool. Closed hemorrhoidectomy was commonly performed (92.6%) among patients with hemorrhoid, 60% of patients with fissure in anal underwent lateral internal sphincterotomy and 66.1% underwent fistulectomy among patients with Fistula in ano.

Conclusion: Acquired benign anorectal conditions are common hemorrhoids being the common condition followed by a fissure in ano and fistula in ano.

Recommendation: Presenting symptoms of acquired benign anorectal condition can easily be picked by patients themselves hence emphasis on early health-seeking behavior is important and addressing preventive measures and proper selection of treatment options in our settings is of great importance. Community-based studies to determine the true burden of disease, risk factors and other comparative studies on treatment options available are highly recommended.

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ABBREVIATIONS

1. **CT**-computed tomography
2. **HKMU**-Hubert Kairuki Memorial University
3. **IRB**- Institutional Review Board
4. **LIFT**-Ligation of the inter-sphincteric fistula tract
5. **MNH**-Muhimbili National Hospital
6. **MoHCDEC**-Ministry of Health, Community Development, Gender, Elderly and Children
7. **MRI**-Magnetic Resonance Image
8. **MUHAS**- Muhimbili University of Health and Allied Sciences
9. **SPSS**- Statistical Package for Social Sciences

DEFINITION OF TERMS

- Anal verge:** is an external opening or visible part of the anus and its entry into the anal canal.⁵
- Anal canal:** is further classified into;
- Surgical anal canal:** the anal canal extends from the anal verge distally to the anorectal ring proximally.⁷⁰
- Anatomical anal canal:** It begins at the anorectal junction and terminates at the anal verge (2-4cm long).⁴
- Anorectal ring:** is defined as the junction where the anal canal meets the rectum.⁷⁰
- Benign:** contains abnormal cells that closely resemble, and function like normal cells.⁷¹
- Anorectal:** a combination of anal verge, anal canal, and rectum.⁴

1.0 INTRODUCTION

Anal verge, canal, and part of the rectum as other parts of the gastrointestinal tract are associated with the development of malignant or benign lesions¹. The most common conditions arising in this area are benign but may be debilitating and interfere with the daily quality of life of patients². A clear understanding of its anatomy is important in the proper diagnosis and treatment of these conditions³. Moreover, these disorders are frequently misdiagnosed or poorly treated, leading to devastating consequences.⁴

Among acquired benign anorectal disorders; hemorrhoids, anal fissures, fistula in Ano, pruritus ani, and abscesses account for the majority of anal conditions for which patients will see a healthcare provider.⁵ With good history, and a thorough physical examination, these common problems are not difficult to diagnose or treat.⁶ Hemorrhoids being the most common among all benign anorectal disorders, majority of patients will present complaining of it even if it is another disorder, and here is where a thorough history taking and physical examinations are of paramount importance.⁶

Several obstacles prevent proper diagnosis and treatment of non-neoplasm anorectal disorders, including miseducation and embarrassment of health care providers and patients, and can lead to long time complications and suffering to the patient.^{7, 8} Several Studies of accurate diagnosis of anorectal problems, indicate accuracy rates of 50% to 61% among primary care physicians⁹⁻¹². Two other studies found that 52% to 82% of patients presenting to their primary care physicians with anorectal problems received no rectal examination^{10, 12}. Some management options have been proposed and practiced ranging from conservative options, medical to surgical options depending on the patient's presentation.¹³

Muhimbili National Hospital serves several patients with anorectal non-neoplasm disorders by both surgical interventions and conservative interventions. (Appendix 1) A monthly mortality and morbidity audit was done at the surgery department;

the leading disorders are hemorrhoids followed by fistula in ano and ano fissure being the third (attached appendix 1)

1.1.1 Hemorrhoids

Hemorrhoids are cushions of submucosal tissue containing end vessels both venules, arterioles, and smooth muscle fibers that are located in the anal canal⁴⁹. Hemorrhoids are thought to function as part of the continence mechanism and aid incomplete closure of the anal canal at rest hence are a normal part of anorectal anatomy, treatment is only indicated if they become symptomatic^{2,17}. Increased abdominal pressure, excessive straining, and hard stools increase venous engorgement of the hemorrhoidal plexus and cause symptomatic prolapse of hemorrhoidal tissue which may result in bleeding and thrombosis.¹⁸ They are classified broadly as external hemorrhoids (below the dentate line) and internal hemorrhoids (above the dentate line).^{19,20}. The internal hemorrhoids have four grades depending on the severity of prolapse which guides its management.^{1, 2,20} Grade one is when internal hemorrhoids don't prolapse but may bleed and project into the canal.⁶¹ In grade two there is a prolapse of internal hemorrhoids but they reduce spontaneously.⁵ When hemorrhoids prolapse and are reduced manually it's grade three.¹² Grade four is not reducible when prolapsed.¹⁶

1.1.2 Fistula in ano

Fistula in Ano is the communication between two epithelial linings of the ano canal and perianal skin.²³ They develop from anorectal abscess inadequately drained accounting for 50% of all anorectal abscesses¹. The fistula usually originates in the infected crypt (*internal Opening*) and tracks to the *external opening*.²⁴ Depending on where does the track curves to and opens, they are classified into 4 main types (Park's classification), inter-sphincteric (the common one accounting for more than 45%), Trans-sphincteric, supra-sphincteric, and extra-sphincteric fistula.^{24,26}

1.1.3 In Ano fissures

The third common is ano fissures, a tear in the anoderm distal to the dentate line.^{29,43} The pathophysiology of an anal fissure is thought to be related to trauma from either the passage of hard stool or prolonged diarrhea or anal sex.²⁹ A tear in the anoderm leads to spasm of the internal anal sphincter, which results in severe pain, increased tearing, and decreased flow of blood to the anoderm.^{29,30} The pain, spasm, and ischemia (cycle) contribute to the development of a poorly healing wound that becomes a *chronic fissure*.^{2,43} The vast majority of anal fissures occur in the posterior midline. 10%- 15% occur in the anterior midline.³⁰ Less than 1% of fissures occur off midline.³¹

1.1.4 Rectal prolapse

Rectal prolapse refers to a circumferential, full-thickness protrusion of the rectum through the anus.³⁴ Mucosal prolapse is a partial-thickness protrusion often associated with hemorrhoidal disease and is usually treated with banding or hemorrhoidectomy.^{2,34}

1.1.5 Anal warts

Anal warts mainly condyloma acuminata are implicated with human papillomavirus type 6 and 1 (more than 90%) with no reported possibility of malignancy transformation in contrast to warts secondary to HPV type 16 and 18 which are associated with squamous intraepithelial lesions and squamous cell carcinoma.³⁸

1.1.6 Anorectal abscess

The majority of anorectal abscesses result from infections of the anal glands found in the inter-sphincteric plane.³⁹ Infection of the anal gland results in the formation of an abscess that enlarges and spreads in the perianal and perirectal spaces.^{39,40} Anorectal abscesses are classified into; *Perianal abscess*, the most common which appears as a painful swelling at the anal verge.³⁹ *Ischiorectal abscess* results from the spread through the external sphincter.⁴⁰ Intersphincteric abscesses occur in the inter-sphincteric space and are difficult to diagnose.² *Pelvic* and *supralevator abscesses* are uncommon and may result from ischiorectal abscess

upward or extension of an inter-sphincteric or extension of an intraperitoneal abscess downward.^{2,6,40}

There are many other non-neoplasm anorectal conditions like, pruritus ani, disorders of defecation, and congenital malformations like imperforate anus in neonates or Hirschsprung disease^{1,2} which some of them will be analyzed in this research and others are not going to be covered in this research due to age group involved which is excluded like congenital anorectal malformations.

1.2 LITERATURE REVIEW

1.2.1 Prevalence

The prevalence of acquired benign anorectal diseases in the general population has been difficult to establish, either because the individual diseases themselves have been difficult to characterize in surveys or because of bias in the selection of the survey population¹⁴. Under-reporting of symptoms, which patients can find embarrassing and difficult to disclose and challenge to distinguish between different anorectal disorders which present with similar symptoms can also explain the difficulty to establish its prevalence¹⁵. Few studies have been done globally and locally on the actual prevalence or incidence of non-neoplasm anorectal disorders. But a significant number of studies on the comparison of surgical modalities currently advocated in different disorders have been done.²

In an observational prospective study conducted by the surgical clinic hospital in Nasik, Maharashtra, India for benign anorectal diseases, a total of 160 patients who reported to the surgical clinic with benign anorectal diseases were included in the study. Fissure-in-ano (32.5%) was the most frequent condition for which the patients consulted followed by hemorrhoids (22.5%), fistula in ano, and perianal abscess being the least.⁴⁶ this shows a variation in epidemiology worldwide as in other regions like the US the leading is Hemorrhoids.^{47, 48} The prevalence of symptomatic hemorrhoids is estimated at 4.4% in the general population.⁴⁹ whereas both symptomatic and asymptomatic have been estimated as 50-85% of the total population.^{50,51}

Another prospective study done in Austria 2008-2009 in colorectal cancer screening, of 976 participants, 380 patients (38.93%) suffered from hemorrhoids. In 277 patients (72.89%), hemorrhoids were classified as grade I, in 70 patients (18.42%) as grade II, in 31 patients (8.16%) as grade III, and in two patients (0.53%) as grade IV. 170 patients (44.74%) complained about symptoms associated with hemorrhoids, whereas 210 patients (55.26%) reported no symptoms⁵³.

Anal fissure cases are common, but no population studies have explored their exact incidence.⁴² In a study done in Unani Hospital India in 2015 it was shown that in patients with anorectal complaints, 15.62% had a fissure in ano.⁴³ The cumulative lifetime incidence is estimated at 11% as reported in a study done in north America.⁴⁴

The true prevalence of fistula-in-ano globally like other non-neoplasm anorectal conditions is unknown.⁵⁴ One study done in the city of Helsinki showed that the prevalence of fistula-in-ano is 8.6 cases per 100,000 population⁵⁴. In men, the prevalence is 12.3 cases per 100,000 population, and in women, it is 5.6 cases per 100,000 population^{51, 52}. However, another study was done in the United Kingdom and showed that the standardized prevalence of anal fistula was 1.8 per 10000 patients and general prevalence in Europe was estimated to be 1-2 per 10000 patients, 8.6, and 2.32 in Finland Spain, and Italy respectively. A recent systematic review estimates the prevalence in Europe to be 1.69 per 10000 patients. The highest prevalence being in patients with Crohn's disease.⁵⁴

Rectal prolapse like other benign anorectal conditions, its global prevalence or incidence is unknown.⁵⁸ In a hospital-based retrospective and prospective cross-sectional study which was done in Jyväskylä Central Hospital in Finland showed the annual incidence of rectal prolapse to be 2.5 per 100 000 population.⁵⁸ The annual incidence of perianal abscesses is estimated between 14 000 and 20 000 people in the UK, resulting in about 12 500 operations in the National Health Service each year.⁵⁹ A recent Swedish cohort study estimated the incidence of 16.1 per 100 000. Many patients in the community are treated with antibiotics and it has been reported that some abscesses spontaneously regress or discharge, the true incidence may be higher.⁵⁹

A systematic review of the incidence and prevalence of genital warts done between 2001 and 2012 using the official databases and additional screening of abstracts from relevant sexual health and infectious disease conferences from

2009 to 2011 showed that the overall prevalence based on retrospective administrative databases or medical chart reviews or prospectively collected physician reports ranged from 0.13% to 0.56%, whereas it ranged from 0.2% to 5.1% based on genital examinations.⁶⁰

1.2.2 Demographic characteristics and risk factors

The demographic characteristics and risk factors of acquired benign conditions vary depending on the type of the presenting disorder as shown in several studies below.

In a hospital-based cross-sectional study carried out at a tertiary care hospital in the department of general Surgery among 100 patients who presented with symptoms suggestive of hemorrhoids during the study period from 1st January 2017 to 31st October 2018 in a Government Medical College, Ambajogai, Maharashtra, India; Majority of the patients (41%) were in the age group of 35-45 years followed by 33% in the age group of 46-55 years. As the age increased the number of patients decreased from 41% in the age group of 35-45 years to only 11% in the age group of 66-70 years.⁵¹

Fissures occur in all age groups, but appear to be more common in young and otherwise healthy people.⁴² Whereas fistula in ano and ischiorectal abscesses are more common in men and their incidence peaks around age 20-40 years.⁶⁶ On the other hand, Rectal prolapse was found to be distributed as follows; ten men (10%) and 89 women (90%). The median age of the patients was 69 (range, 21-91) years in a study done in Scandinavian countries.⁵⁸ Constipation and low fiber diet were statistically significant associated with it.⁴³

The female to the male ratio of fistula in ano has been reported to be 6:1 with a peak age of 7th decade.^{35,2} However this varies with a study done in Helsinki showing the male-to-female ratio is 1.8:1 and the mean patient age is 38.3 years.^{54, 55} Low immunity, ischiorectal abscesses, trauma, Crohn's diseases, and pelvic surgeries have been reported to be the risk factors of fistula in ano.²

1.2.3 Presentation, examination, and investigations

Acquired benign anal conditions can easily be diagnosed with good history taking and physical examination, rarely further investigations are needed.⁵

A study of 198 physicians from different specialties, found the rate of correct identification for 7 common benign anal pathologies was greatest in condylomata and rectal prolapse and lowest in hemorrhoids, thus emphasizing proper history taking and physical examination to improve the accuracy in diagnosis. The investigators found the overall diagnostic accuracy among the physicians to be 53.5%, with the accuracy for surgeons being 70.4% and that for the rest of the doctors being less than 50%.⁴⁹

Studies show that in adolescents with rectal prolapse, common symptoms are tenesmus, anorectal pain, and passage of blood and mucus.⁷² Whereas in children, rectal prolapse is typically detected by the patient's parents. A dark red mass with or without mucus and blood that protrudes from the rectum during straining is common, but again it is usually spontaneously resolved on itself.⁷²

Severe anal pain is the most common presenting complaint of the rectal abscess and a mass is often detected by inspection of the perianal area or palpated during a digital rectal examination.⁴⁰ Occasionally, patients will present with fever, urinary retention, or life-threatening sepsis.⁴⁰ As stated earlier, some of these conditions will necessitate imaging investigations like in complex case scenarios, CT or MRI can be indicated to confirm the diagnosis.⁴¹

Condylomata acuminata presents as flesh-colored grouped papules and sometimes proliferating as cauliflower-like plaques.⁷³ In men the coronal sulcus of the penis and prepuce are mostly affected ⁷⁴ while in women lesions mainly appear at the labia minora, Majora, and the introitus vaginae.⁷⁵ Perianal or intra-anal manifestations, just as lesions in the oral cavity and pharynx depend on sexual practices.⁷⁵

Anal fissures present with complaints of anal pain that is worse during defecation. At times, there is associated bleeding during defecation but usually not massive hemorrhage. The pain usually persists for hours after defecation.⁷⁶ Often, acute

anal fissures may be misdiagnosed as external or internal hemorrhoids. Therefore, a thorough physical exam should be performed to delineate between the two.⁷⁶

1.2.4 Treatment

Management of these acquired benign anorectal conditions depends on the type, severity, and comorbidity presented by a patient.^{50,80} Below are some of the management options for some of these conditions;

Hemorrhoids are managed by conservative modalities like dietary and lifestyle modification or the use of laxatives.²² Again, it can be treated by rubber band ligation, sclerotherapy, and infrared photocoagulation. Surgical options are excision of thrombosed hemorrhoid, open or closed hemorrhoidectomy, whitehead's hemorrhoidectomy, and stapled hemorrhoidectomy.^{21,22} The surgical interventions are advocated in hemorrhoid cases where there is the persistence of symptoms not responding to conservative or minimally invasive procedures.⁵⁰ Apart from this, Surgery is the main choice of patients presenting with grade III, IV hemorrhoids, and strangulated or thrombosed hemorrhoids.^{62, 63}

Management of anal fissures starts with conservative modalities like the use of stool softeners, food rich in fibers, sitz baths, and topical analgesics per rectum. Stool softeners and analgesia together will heal 8-51% of fissures, with most studies showing healing rates of 16-31% in both acute and chronic fissures.⁶⁴ lateral sphincterotomy, fissurectomy, fissurotomy, and local flap advancement has been some of the modality of surgical treatment advocated for decades.⁴² Lateral internal sphincterotomy is the treatment of choice to a failed conservative modality.³¹ Healing is achieved in more than 95% of patients using this technique, and most patients experience immediate pain relief.³³

Anorectal abscesses are treated by incision and drainage and many of them will develop into a fistula.^{39,67} Following drainage, antibiotics are highly recommended for patients who are septic or immunocompromised or have significant cellulitis.^{40,41,42} If a fistula is present, initial drainage and fistulotomy of a concomitant fistula shows an 83% lower incidence of abscess recurrence compared to drainage alone, but with an increased risk of fecal incontinence.⁶⁸

Fistula in Ano modality of management depends on the complexity of the fistula ranging from one stage fistulotomy, staged fistulotomy using seton suture, lateral internal sphincterotomy, fistulectomy, fecal diversion by colostomy placement, or by ligation of inter-sphincteric fistula tract (LIFT).^{2,24,25,27} The primary therapy for rectal prolapse is Surgery, and many procedures have been described to treat this condition.³⁶ Surgical approaches can either be abdominal or perineal.³⁶ Aimed at; (a) reduction of the perineal hernia and closure of the cul-de-sac (Moschowitz repair) (b) fixation of the rectum, either with a prosthetic mesh or fascia lata sling (Ripstein and Wells rectopexy; ventral rectopexy) or by suture rectopexy or (c) resection of the redundant sigmoid colon. In some cases, resection is combined with rectal fixation (resection rectopexy).^{1,2,34-36}

The treatment of anal warts depends on the location and extent of the disease ranging from medical to surgical excision of warts.³⁸ Medical options are like the use of bi-chloroacetic acid or podophyllin topical applications or the use of immunomodulator (Imiquimod).³⁷ As the number and size of warts increase the more the need for surgical excision.³⁷

1.2.5 Morbidity and Mortality

Few studies have been done to show the mortality rates of acquired benign anorectal conditions with a good number of reported morbidities as part of surgical outcomes or untreated life-threatening cases. Studies show that rectal or perineal abscesses if left untreated can advance unto necrotizing fasciitis which carries mortality as high as 50%.³⁹ However the overall mortality if treated is very low.⁶⁹

Another study done in India in 2008 showed the commonest surgical complications after surgical hemorrhoidectomy was the pain (the leading), urine retention with an estimated incidence of up to 34 %. Anal stenosis incidence was 0.6% and up to 28% presented with defecation control problems both stool and flatus, Tenesmus, frequency, and fecal urgency are variably associated with hemorrhoid surgery and are usually transient and self-limiting⁵².

A Cochrane review of 27 studies comparing the surgical treatment of fissures, included a total of 2056 patients, found that lateral internal sphincterotomy was

less likely to result in treatment failure compared to fissurectomy, however, both had a similar risk of incontinence.⁶⁵ Overall a recurrence occurs in less than 10% of patients, and the risk of incontinence (usually to flatus) ranges from 5% to 15%.^{32,33}

Following incision and drainage of the anorectal abscess, studies show that the rate of recurrence requiring repeat drainage is 3-44%.⁶⁷ Rectal prolapse is associated with anal incontinence and constipation in the majority of patients mostly before surgical intervention.⁶⁸ Fistula in ano is the commonest acquired benign condition associated with devastating outcomes of recurrence.^{28,56}

Some of the acquired benign anorectal conditions have got the potential to turn to malignancy, that's why excised warts and other tissues surgically removed from anorectal lesions should be sent for pathologic examination to rule out dysplasia or malignancy.^{2, 37,38}

1.3 PROBLEM STATEMENT

Acquired benign anorectal disorders are among common disorders in a population and some of them when left untreated or poorly treated leads to the devastating outcome and miserable discomfort to patients for lifelong ^{1,2} Studies done globally have shown that the pattern of acquired benign anorectal disorders varies in different regions and nations.^{47, 48, 54, 56.}

In the year 2019, a pilot study was done at MNH in the general surgery department, among 650 patients operated by one general surgery firm, and found that more than 60 patients were documented to have been operated on due to non-neoplasm anorectal conditions accounting for approximately 10%. Taking into account that these disorders are manageable at primary and secondary health care facilities, it shows that the magnitude of the disease might be large in our settings even though there is no statistical evidence yet to support this fact.

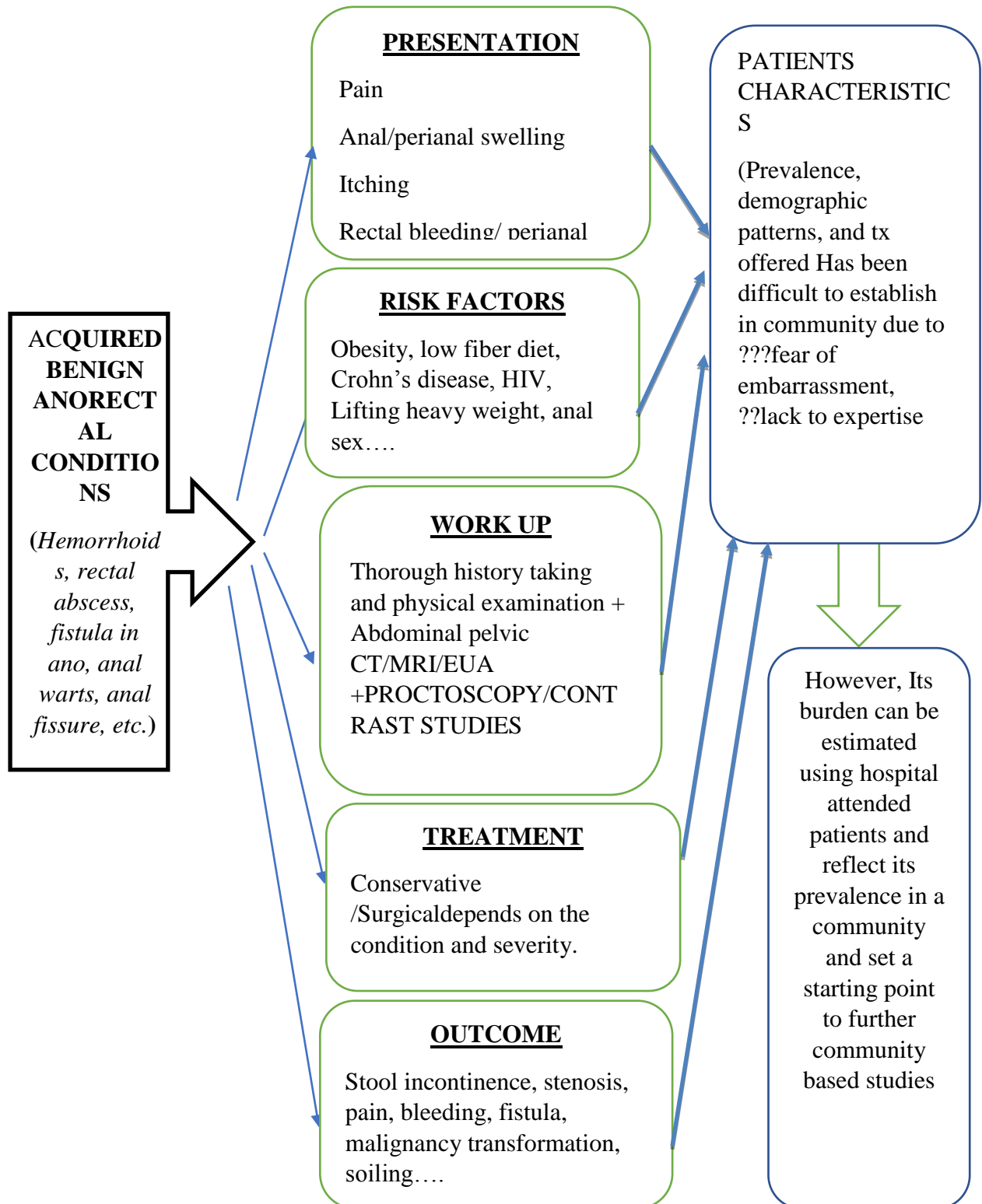
1.4 RATIONALE

There was a need to describe the pattern and patients' characteristics of acquired benign anorectal disorders in our local settings following the fact that its prevalence varies among regions as shown in the literature review. This will help in establishing a true burden of disease in our settings and ensure a proper diagnosis, and care of the patients presenting with these conditions.

This study will serve as a starting point to know the true population prevalence of these conditions and open a way for further research on treatment modalities offered and their outcomes.

1.5 THE CONCEPTUAL FRAMEWORK

Figure 1: The conceptual framework



The conceptual framework above shows common presentations, a summary of workups, risk factors, treatments, and the outcomes expected when these conditions are treated or left untreated. Further, it shows how the patient characteristics including its prevalence in the community have been difficult to find. However, it ends by narrating the possibility of setting a starting point towards community-based studies by using patients operated due to these conditions to at least know the burden of these conditions in our local regions as there is a paucity of studies in the matter in our local regions.

1.6 RESEARCH QUESTION;

What are the clinical characteristics of patients operated to surgical wards of MNH due to acquired benign anorectal disorders?

1.7 OBJECTIVES**1.7.1 Broad Objective;**

To describe the characteristics of patients diagnosed and operated on due to acquired benign anorectal disorders at MNH.

1.7.2 Specific Objectives

- 1 Describe the clinical presentation among patients with acquired benign anorectal disorders at MNH.
- 2 To determine the proportions of each acquired benign anorectal disorder among all cases operated due to acquired benign anorectal conditions.
- 3 To analyze the surgical managements offered to patients presented with acquired benign anorectal disorders at MNH.

2.0 METHODOLOGY

2.1 STUDY DESIGN

A retrospective cross-sectional hospital-based study.

2.2 STUDY DURATION

From June 2016-June 2020

2.3 STUDY SETTINGS

The study was conducted at Muhimbili National Hospital, located in Dar es Salaam- Ilala region in Upanga along United Nations road. MNH is the national referral hospital receiving patients from the district and regional referral hospitals within the country, and it serves as a City hospital by receiving more patients from the three designated regional referral hospitals in the city (Amana, Temeke, and Mwananyamala) and nearby district hospitals of Pwani Region due to its geographical location. The hospital is a teaching hospital for MUHAS students and other affiliated universities like St Joseph University, HKMU, and Aghakhan University. General surgery (Firm 1 & Firm 11) wards, clinics, and Medical records for retrieving old files are expected to be the areas where the study will be done.

2.4 STUDY POPULATION

All patients operated in general Surgery aged 18 years and above due to acquired benign anorectal conditions from June 2016 to June 2020.

2.5 INCLUSION AND EXCLUSION CRITERIA

2.5.1 Inclusion Criteria

All patients operated in general surgery wards age 18 and above and operated due to acquired benign anorectal conditions from June 2016 to June 2020.

2.5.2 Exclusion Criteria

All cases whose files were unable to be retrieved.

2.6 SAMPLING TECHNIQUE

A convenience non-probability sampling technique was used, whereby all patients operated due to acquired benign anorectal conditions and operated on were included in the study.

2.7 SAMPLE SIZE CALCULATION

Convenience non-probability sampling technique was used hence sample size depended much on the number of years included in the review. The sample size was calculated to justify a minimum of 4 years of review of cases operated due to benign anorectal conditions. (Per year at least 60 patients are operated on as per a pilot study done with an attachment in appendix 1).

The following formula is used;

$$n = \frac{z^2 p(100-p)}{\varepsilon^2} \quad n = \frac{z^2 p(100-p)}{\varepsilon^2}$$

$$\frac{z^2 p(100-p)}{\varepsilon^2}$$

Where

n= minimum required sample size

z= level of confidence (1.96 for 95% confidence level)

□=marginal error/ maximally accepted error (5%)

P= expected proportion with the characteristic of interest in percentage (In a study done in Unani Hospital in India 2015 (Tertiary hospital) showed a prevalence of anal fissure estimated at 15.62%)

$$n \square \frac{1.96 \times 1.96 \times 15.62(100-15.62)}{5 \times 5}$$

$$\frac{1.96 \times 1.96 \times 15.62(100 - 15.62)}{5 \times 5}$$

$$\frac{1.96 \times 1.96 \times 4.8(100 - 4.8)}{5 \times 5}$$

= 203 patients

Adjusting for Non-response rate

-A response rate (accurately retrieved files) of more than 90% was selected.

Total n \square $203 \times 1/0.9$

\square 225 patients

Therefore, the study required a minimum of 225 cases operated due to non-neoplasm anorectal conditions hence a 4years period was enough to have an adequate number of cases.

2.8 VARIABLES

Independent Variables; Age, Sex, Marital status, level of education, occupation.

Dependent variables; Post-operative Diagnosis, presenting symptoms.

2.9 DATA COLLECTION

All patients operated due to acquired benign anorectal conditions (hemorrhoids, anal fissures, fistula in ano, rectal prolapse, anal warts, pruritus ani, anorectal abscess, anal tags, Disorders of continence, and others) were identified using a hospital electronic database and the file numbers of the patients (not their names) were filled in a checklist.

Again, using admission books in all general surgery wards and other subsidiary wards like private wards, all file numbers of patients operated due to benign anorectal conditions were identified and recorded in a separate checklist other than used while recording the cases from the electronic database.

Using theater analysis books, in another separate checklist the hospital file numbers were recorded of all patients operated due to the mentioned non-

neoplasms anorectal disorders. The hospital file numbers of the patients from the above named three sources were entered into an excel document/ SPSS direct to confirm the missed patients, avoid repetition of patients, and easy identifying the cases readmitted due to recurrence or other surgical conditions.

Using the above-obtained file numbers sheet, the files of the patient were retrieved from the medical records department and all demographic data was recorded from the patient's files including the type of anorectal condition he/she presented with and management offered as per the research checklist. Data was codified and entered into SPSS, whereas frequencies of all variables were run to ensure completeness of the data.

2.10 DATA ANALYSIS

Data collected in a checklist was codified then entered in the statistical package for social science (SPSS) 26 version where the analysis was done. Proportions were calculated for all categorical data like age, sex, and occupations. Histograms, pie charts, and bar charts have been used to summarize the collected data. Chi-square and t-tests for both categorical variables and one-sample test for the significance level. The results are of statistical significance if the P-value is <0.05 .

3.0 ETHICAL ISSUES

3.1 IRB AND ETHICAL CLEARANCE

- Ethical clearance was sought from Muhimbili University of Health and Allied Science, Ethics, and Research Committee. Permission was sought from Muhimbili National hospital ethical clearance committee before the study was carried out.

3.2 CONFIDENTIALITY AND SECURITY

- No extracted information from the patient's files will be shared without approval from the MUHAS IRB and MNH ethical clearance committee.
- Confidentiality has been highly maintained by using file numbers instead of the names of patients in data collection and entry.
- The researcher had no conflict of interest.

3.3 RISKS AND BENEFITS

- There are no direct benefits to the participant but the study will have a positive impact on the institution and community in addressing the burden of disease and setting a starting point towards further studies on common acquired anorectal disorders individually in our local settings.

3.4 DATA DISSEMINATION

- The results and reports of this study will be deposited in the MUHAS repository, published in local and international journals, and presented at scientific conferences. The manuscript for this study is being prepared, for submission and subsequently published in the journal of East and Central African Journal of Surgery.
- A report will be presented to the MNH Research and Training department.

3.5 STUDY LIMITATIONS AND MITIGATIONS

3.6.1 LIMITATIONS

- Lack of some important findings in the retrospective collection of data is expected due to poor documentation.

3.6.2 MITIGATIONS

- Retrieved files with poor documentation or missing information were excluded in the analysis of a particular missing aspect.
- All cases unable to retrieve their files were excluded from the study.
- Both theatre register books and wards admission books were used to reduce the number of undocumented patients in either of the books.

4.0 RESULTS

Table 1: Characteristics of patients with acquired benign anorectal conditions at MNH

VARIABLE	FREQUENCY	PERCENTAGE (%)
SEX		
Male	141	62.4
Female	85	37.6
Age group		
<20	2	2.7
21-30	38	16.8
31-40	67	29.6
41-50	41	18.1
51-60	41	18.1
>61	33	14.6
Marital Status		
Married	168	74.3
Single	58	25.7
Common presenting symptoms		
Painful defecation	137	60.6
Mass protrusion per anus	133	58.9
Bleeding per rectum	90	39.8
Discharge at perianal region	58	25.7
Constipation	40	17.7
Fever	2	0.9
Stool incontinence	1	0.4

VARIABLE	FREQUENCY	PERCENTAGE (%)
Proportions of each Acquired benign anorectal condition		
Hemorrhoids	118	46.6
Fissure in ano	63	24.9
Fistula in ano	59	23.3
Rectal prolapse	3	1.2
Perianal Sinus	3	1.2
Rectal Polyp	3	1.2
Perianal abscess	2	0.8
Anal Warts	1	0.4
pilonidal sinus	1	0.4

A total of 226 patients operated due to acquired benign anorectal conditions were identified out of 5,908 patients operated in general surgery firms. The majority of patients were males (72%) (table 1 and Chart 1). 73% of patients were married (Table 1). Most patients aged between 31-40 years (29.6%) with a median age of 41years (range of 18-83 years) followed by 18.1% in the age group of 41-50 and 52-60years Table 1. Hemorrhoids were most common in the age group of 31-40years (26.2%). Fissure in ano and fistula in ano most commonly occurred in the same age group of 31-40years 32.2% and 34.5% respectively.

Among all benign anorectal conditions, the most common presenting symptoms were Painful defecation and mass protrusion per anus accounting for 60.6% and 58.80% respectively. Only 25.7% has a history of discharge around the perianal region (25.7%) and a history of passing hard stool was encountered in 17.7% of the patients. **Table 1.**

The pre-operative diagnosis was missed by some of the patients. Out of 122 patients labeled as having Hemorrhoids, only 118 had hemorrhoids and the rest had another diagnosis including anal fissures, rectal prolapse and others had

hemorrhoids that didn't need Surgery concomitantly with other acquired benign conditions which necessitated Surgery.

The proportions of each acquired benign anorectal condition among all cases operated on are shown in table 1 above. Hemorrhoid was the leading diagnosis accounting for 46.9% followed by a fissure in ano (24.9%) and fistula in ano (23.3%). Rectal prolapse accounted for 1.2 % the least being anal warts, pilonidal sinus, and anal abscesses which accounted for less than 1 % each.

Figure 2: Shows common symptoms with respective acquired benign anorectal conditions operated at MNH.

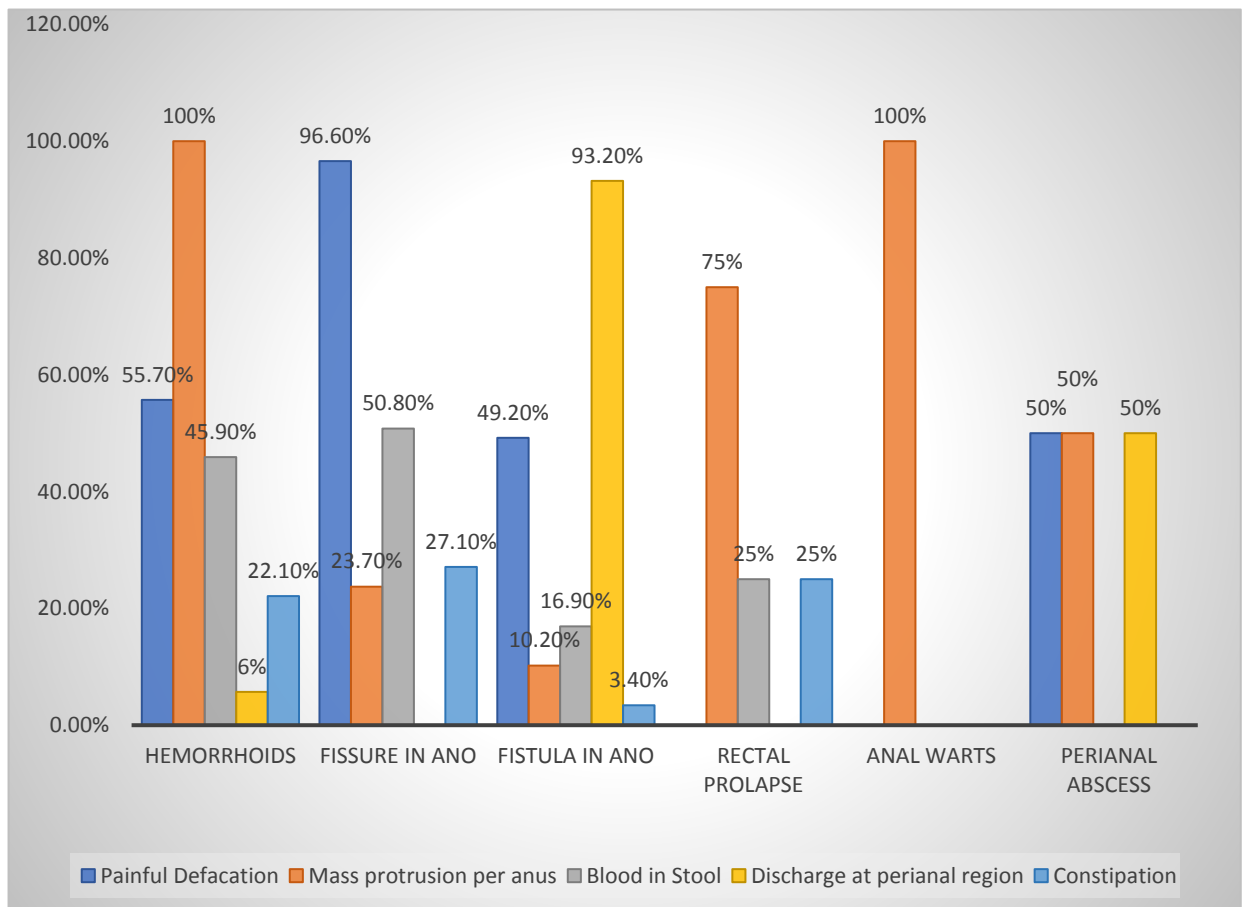


Figure 1 above enumerates common presenting symptoms concerning each acquired anorectal condition. Among patients with hemorrhoids, all patients presented with mass protrusion per anus followed by 55.7% of patients who presented with painful defecation. 22.1% had complaints associated with constipation. Whereas 96.6% of patients with fissures in ano presented with painful defecation. Majority of patients with fistula in ano (93.6%) presented with perianal discharge and painful defecation in 49.2% of patients. Mass protrusion per anus was the leading complaint in rectal prolapse and anal warts accounting for 75% and 100% respectively. Among patients with anal abscesses, 50% presented with painful defecation with the same proportion presenting with mass protrusion per anus and discharge per anus.

Figure 3: Type of Surgery done to each common acquired benign anorectal condition

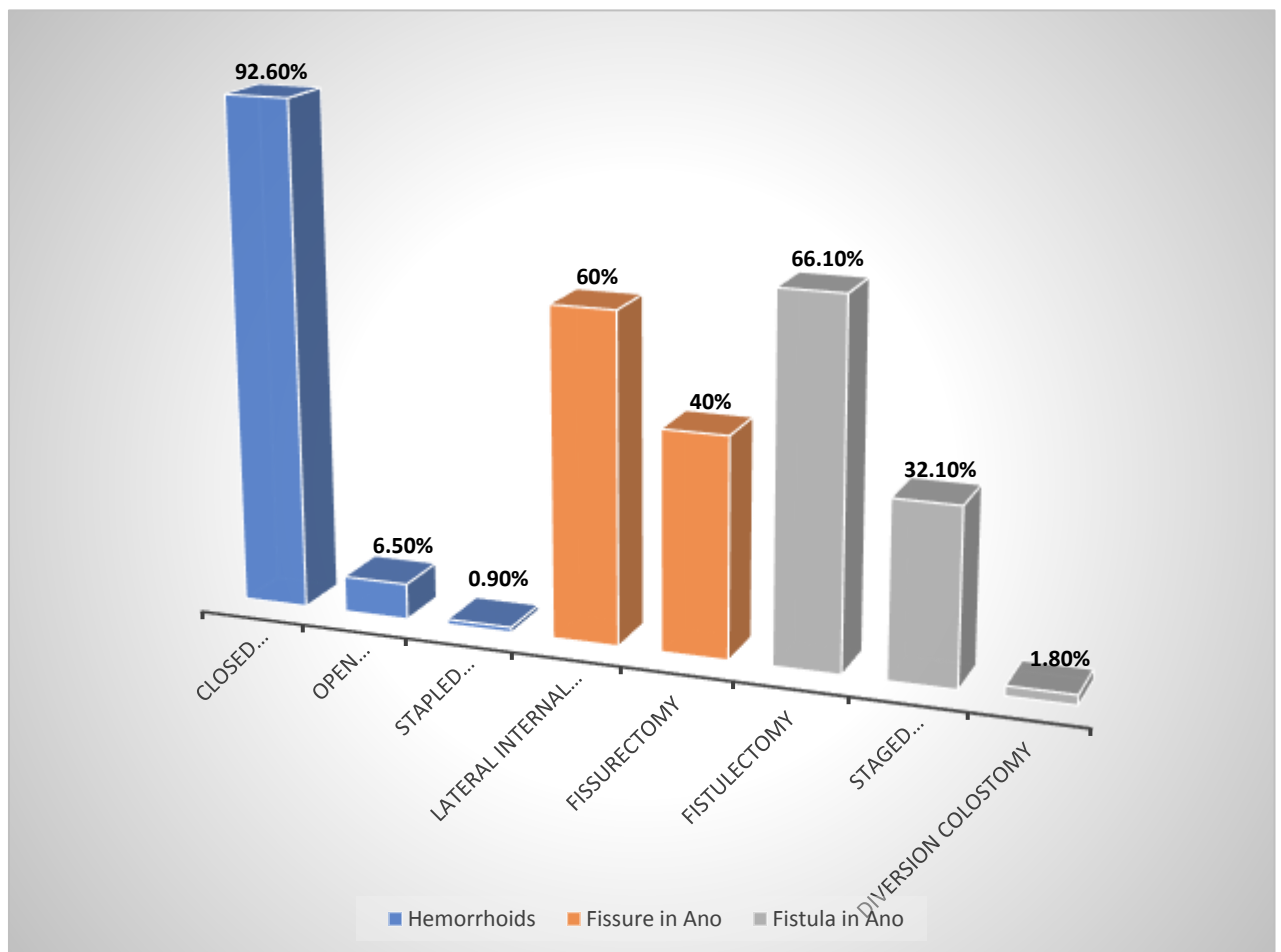


Figure 2 above represents the type of operations done to major three leading diagnoses of benign anorectal conditions in this study. About 92.6% underwent closed hemorrhoidectomy with diathermy and suturing technique. Whereas 6.5% underwent open hemorrhoidectomy via the Milligan Morgan technique and only one patient was documented to have undergone stapled hemorrhoidectomy. 60% of patients with fissure in ano underwent lateral internal sphincterotomy and fissurectomy was done to the remaining 40%. Among patients with fistula in ano, 66.10% underwent fistulectomy, 32.1% staged fistulotomy using improvised seton suture and one patient with complex fistula underwent diversion colostomy.

5.0 DISCUSSION

Acquired benign anorectal conditions accounted for 3.8% of all cases operated at MNH among adults in the General surgery department which is close to the general population estimate of the majority of individual conditions like hemorrhoids, ano fissures, and fistulas. are bothersome conditions that require awareness and the surgeon's attention. Among all 226 patients, only a few patients with fistula in ano did fistulogram as an investigation to confirm the diagnosis however other condition's diagnoses were clinically diagnosed. However, misdiagnosis is still possible despite accuracy in history taking and physical examinations and some conditions necessitating contrast imaging studies like fistulogram, CT Scan or MRI⁵. The majority of patients with benign anorectal conditions are males (62.4%) compared to females which is similar to the findings reported in a study done in Maharashtra, India, and several other studies done globally.⁴⁶ The age group of 30-40 years was much affected which is the same as the same findings in the previous named study.⁴⁶

Presentation of acquired anorectal conditions varies depending on the type of the presenting condition, however, the majority of symptoms overlap between two or more of the conditions. In this study, it was found that the leading common symptoms were painful defecation followed by mass protrusion per anus or swelling at the perianal region, bleeding during defecation, and discharge at the perianal region which resembles studies from midland Michigan and Castellon General Hospital, europe.^{15, 17,80}

Hemorrhoids are among common acquired benign anorectal conditions where mass protrusion per anus has been the leading complaint followed by painful defecation and passage of blood in stool in our study which corresponds to other studies done globally, ^{48,78}. However, this has been the case because almost all cases of hemorrhoids in our study were of grades 3 and 4.

Similar studies quoted above show in earlier grades the main presenting symptoms are painless blood in stool for internal hemorrhoids and painful mass or swelling for external hemorrhoids ^{48,49, 57}.

Patients with fistula in ano presented with discharge at perianal region (93%) as the leading complaint followed by painful defecation (50%) but also majority was preceded by a history of perianal abscess or previous similar Surgery which is similar to the study done at the Government Medical College, Rajnandgaon, Chhattisgarh, India.⁷⁹ Another study done in Gandhi Medical College, Bhopal, Madhya Pradesh, India showed that 91% of patients with fistula in ano presented with pus discharge at perianal region followed by 82% with pain and 31% of swelling at the perianal region.

In this study, fissure in ano presented with pain during defecation in 96.6% of all patients with ano fissure followed by 50.8% of patients complaining of blood in the stool. These findings are similar to those reported in a study done at Nium Hospital in India showing out of 65 patients with fissure in ano, all 65 had severe pain as the leading complaint followed by blood in stool in about 37 patients. The same findings have been reported in a review article published by startpearls.⁷⁶

Other acquired anorectal conditions presented with similar complaints in addition to other symptoms enumerated in this study like the history of passing hard stool. Among the patients with rectal prolapse, both presented with a mass protrusion per anus which was the same presentation in patients with anal warts. These presentations or findings resemble findings found in a study done by Kairaluoma MV in India.⁵⁸

Hemorrhoids, fissure in ano, and fistula in ano are the major leading conditions noted in this study which corresponds to findings in the study done in Maharashtra, India, and Castellon General Hospital^{5, 46}. Even though the prevalence of these conditions in the general population has been difficult to ascertain¹⁴, this study as other studies in different regions will give a foundation and estimate of its proportions out of all cases reviewed.

Findings in this study show the leading condition was hemorrhoid which accounted for 49% of all cases followed by a fissure in ano (24%) and fistula in ano (24%) which is slightly different compared to the study done in surgical clinic hospital in

Nasik, Maharashtra, India for benign anorectal diseases were fissure in ano was the leading followed by hemorrhoids and fistula in ano⁴⁶. Another study done in the Institute of Unani Medicine again showed fissure in ano was the leading condition by 36.2% followed by hemorrhoids and fistula in ano. All these findings cement the fact that the distribution of these disorders varies globally.

The proportion of hemorrhoids in this study is close to the reported global estimates of its prevalence ranging from 50-80%.^{50, 51} However varying prevalence globally has been reported like Australia (38.93%), Egypt (18%), Israel (16%), and Korea (14.4%).⁷⁷⁻⁸⁰ Fissure in ano proportion of 24% in our study was higher compared to the one reported in a study done in Unani Hospital India in 2015 which showed a prevalence of 15.62%.⁴³ And it was again higher compared to the cumulative lifetime incidence which was estimated to be at 11% as reported in a study done in North America.⁴⁴ In a study done in Tirunelveli Medical College, Tirunelveli, Tamil Nadu, India revealed a prevalence of fissure of 30.7% which was higher compared to the findings of our studies. The Prevalence of fistula in ano reported in America shows a range of 26-38%^{82, 83} which is close to the proportion found in our study of 24%.

Although rectal prolapse, anal warts, and perianal sinuses accounted for small proportions in our studies, these proportions are similar to the prevalence reported in the following studies. A study which was done in Jyväskylä Central Hospital in Finland showed the prevalence of rectal prolapse to be 2.5%,⁵⁸ another Systematic review of the incidence and prevalence of genital warts by Wagner in 2013 reported a prevalence of anal warts to be ranging from 0.13% to 0.56%.⁶⁰ In a study done at General Regional Hospital' George Papanikolaou'.

Thessaloniki, Greece revealed a prevalence of 0.26% which is close to the one found in this study of 0.3%.

Although not all benign anorectal conditions necessitate surgical intervention, Surgery has remained a mainstay treatment option for the majority of conditions after failed conservative treatment and recurrences.

6.0 CONCLUSION

From this study, it has been shown that acquired benign anorectal conditions are common in our settings (3.8%), hemorrhoids being the most common of all followed by fistula in ano and ano fissure. Taking into account that MNH serves patients from all parts of Tanzania and the majority of patients with these conditions are conservatively and surgically treated at other tertiary hospitals and others not at all seeking health care; the true prevalence of acquired benign anorectal conditions might be higher than what has been found in this study. They commonly occur between 30-40years with a median age of 41. Their presentations overlap between different conditions and investigations are not needed for many patients in diagnosing these conditions. Surgery has remained a mainstay of treatment in recurrence, advanced diseases, and failed conservative management. However further community-based studies are needed to establish the true burden of disease in each condition.

7.0 RECOMMENDATIONS

Awareness should be created to community members on the presenting symptoms of these conditions and encourage early healthcare-seeking behavior as the majority of these conditions in early stages are treated conservatively and reduce complication rates.

Despite the majority of conditions being surgically managed as described in the results above, in the presence of advancement in technology and vast proves of the superiority of some surgical procedures over the other like in fistula in ano which studies have shown that fistulectomy has been associated with a significant recurrence rate, there is a need of opting on other surgical interventions or recommend further comparative studies between the main techniques practiced at our settings and its outcome.

Emphasis is to be directed in advocating primary preventive measures as the majority of studies show these conditions are preventable by lifestyle modification and timely treatment of underlying conditions like anal abscess treatment in the prevention of fistula in ano. Prevention of secondary complications like recurrence depends much on the proper choice of treatment modalities and timely intervention.

Further community-based studies are recommended to establish a true burden of disease in a general population, risk factors and address the respective measures in the prevention of these conditions.

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APPENDICES

Appendix 1: MNH GENERAL SURGERY DEPARTMENT (FIRM ONE MIN SURVEY)

		2017	2018	2019
1	LATERAL SPHINCTEROTOMY	9	6	10
2	FUSSURECTOMY	2	3	3
3	FISTULECTOMY	14	22	16
4	SETTON SUTURE PLACEMENT AND ADJUSTMENT	3	8	2
5	HEMORRHOIDECTOMY*	35	32	31
6	PERIANAL SINUS EXPLORATION	2	1	1
	TOTAL	65	62	62

Appendix II: DATA COLLECTION CHECKLIST

1. Serial Number.....
2. Hospital Reg No.....
3. Demographic data
 - i. Sex
 - a) FEMALE ()
 - b) MALE ()
 - ii.Age.....
 - iii.Occupation.....
 - iv.Marital status.....
 - v.Residence/ Address.....
4. Any known history of
 - i.DM (YES/NO)
 - ii.HIV (YES/NO)
 - iii.Pregnancy (YES/NO)
5. Presenting symptoms
 - i.Painful defecation (YES/NO)
 - ii.Mass at the anal verge (YES/NO)
 - iii.Mass protrusion per Anus (YES/NO)

If YES above. a) Goes back on itself (YES/NO) b) manual reduction (YES/NO) c) doesn't go back (YES/NO)
 - iv.Bleeding per rectum (YES/NO)
 - v.Discharge around the perianal region (YES/NO) specify.....
 - vi.Fever (YES/NO)
 - vii.Stool incontinence (YES/NO)
 - viii.History of Hard stool (YES/NO)
 - ix.Others.....
6. Pre operative diagnosis.....
7. Investigations.....

- 8. Intra-operative findings and diagnosis.....
- 9. Grade (if applicable e.g. HEMORRHOID)
- 10. Surgical management offered.....
- 11. History of previous Surgery or recurrence and Time-lapse.....

Appendix III Surgical procedures offered to major anorectal conditions depicted in this study.

Closed hemorrhoidectomy → Also known as The Parks or Ferguson hemorrhoidectomy involves resection of hemorrhoidal tissue and closure of the wounds with absorbable suture. In prone or lithotomy position under local, regional, or general anesthesia, the anal canal is examined and an anal speculum inserted. The hemorrhoid cushions and associated redundant mucosa are identified and excised using an elliptical incision starting just distal to the anal verge and extending proximally to the anorectal ring. The apex of the hemorrhoidal plexus is then ligated and the hemorrhoid excised. The wound is then closed with a running absorbable suture. All three hemorrhoidal cushions may be removed using this technique; however, care should be taken to avoid resecting a large area of perianal skin in order to avoid postoperative anal stenosis.

Open Hemorrhoidectomy → Also known as the Milligan and Morgan hemorrhoidectomy, follows the same principles of excision described in closed technique, but the wounds are left open and allowed to heal by secondary intention.

Stapled Hemorrhoidectomy → Best suited for patients with second- and third-degree hemorrhoids, this outpatient procedure uses a stapling device similar in appearance and mechanism of action to an end-to-end anastomotic. It provides relief for internal hemorrhoids by pexying the redundant hemorrhoidal tissue, ligating the venules feeding the hemorrhoidal plexus and fixing redundant mucosa proximal to the dentate line.

Lateral internal sphincterotomy → aim of the procedure is to relieve or decrease spasms at the internal sphincters by dividing a portion of the muscle. Approximately 30% of the internal sphincter fibers are divided laterally by using either an open or closed technique.

Fissurectomy → a fissure is identified and excised followed by primary closure of the mucosa or its left open to heal by secondary intention.

Fistulectomy → it involves excision of fistulous tract and left open to heal by secondary intention or alternatively closed using fibrin glues and other alternatives like glaciis patches.

Staged Fistulotomy (seton suture) → consist of a suture or a rubber band that is placed through the fistula and intermittently tightened in the office. Tightening the seton results in fibrosis and gradual division of the sphincter, thus eliminating the fistula while maintaining continuity of the sphincter.

Diversion Colostomy → Placement of a defunctioning distal colon stoma to allow complicated perianal or anorectal fistulas to heal spontaneously or to protect contamination from surgical fistula closure.

Appendix IV Ethical clearance letter

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Ref. No.DA.282/298/01.C/

Date: 05/08/2020

MUHAS-REC-08-2020-326
Dr Boaz Mwasambili Yonah
School of Medicine
MUHAS

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED:
Patient's characteristics of acquired benign anorectal conditions at MNH from
October 2016 to October 2020**

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 05/08/2020
EXPIRATION DATE OF APPROVAL: 04/08/2021

STUDY DESCRIPTION:

Purpose:

The purpose of this retrospective cross-sectional hospital-based study is to describe the patient's characteristics of acquired benign anorectal disorders among patients admitted and operated at MNH.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
<https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2061.pdf> and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
8. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website <https://dr.muh.ac.tz/>



Dr. Bruno Sungu
Chairman, MUHAS Research and Ethics Committee

