



**Clinical characteristics and short-term outcome of surgically managed
inflammatory bowel disease patients: an experience from SPHMMC, Addis Ababa
Ethiopia**

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Clinical characteristics and short-term outcome of surgically managed inflammatory bowel disease patients in SPHMMC: a 3-year cross-sectional study

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Executive Summary

Background: Inflammatory bowel disease (IBD) is a chronic inflammatory condition of the gastrointestinal tract (GI), which is characterized by a disrupted mucosal structure, altered gut microbial composition, and systemic biochemical abnormalities. The two main diseases of inflammatory bowel disease are Crohn's disease and ulcerative colitis. The pathogenesis of inflammatory disease is that abnormal intestinal inflammations occur in genetically susceptible individuals according to various environmental factors. The consequent process results in inflammatory bowel disease. Most common clinical presentation include diarrhea, rectal bleeding, abdominal pain, fatigue and weight loss. Medical treatment consists of the induction of remission in the acute phase of the disease and the maintenance of remission. Patients with Crohn's disease finally need surgical treatment in 70% of the cases. The overall 1, 5, 10 years risk of surgery is 18.7%, 28.0%, and 39.5% respectively [*]. The main surgical options for Crohn's disease are divided into two surgical procedures. The first is strictureplasty, which can prevent short bowel syndrome. The second is resection of the involved intestinal segment. Simultaneous medico-surgical treatment can be a good treatment strategy. Ulcerative colitis is a diffuse nonspecific inflammatory disease that involves the colon and the rectum. Patients with ulcerative colitis need surgical treatment in 30% of the cases despite proper medical treatment. Similarly, the overall 1, 5, 10 years risk of colectomy was 4.0%, 8.8% and 13.3% respectively [*]. The reasons for surgical treatment are various, from life-threatening complications to growth retardation. The total proctocolectomy (TPC) with an ileal pouch anal anastomosis (IPAA) is the most common procedure for the surgical treatment of ulcerative colitis. Medical treatment for ulcerative colitis after a TPC with an IPAA is usually not necessary.

Objective: to evaluate the clinical characteristics and short-term outcome of surgically managed inflammatory bowel disease (IBD) patients at SPHMMC, Addis Ababa Ethiopia.

Methods: This is a cross-sectional study to examine the data of individuals with Inflammatory bowel disease who are managed surgically. A questionnaire will be used to collect data, and SPSS version 28 will be used to compute descriptive statistics, correlation, and regression analysis to test for the rate of surgery for IBD and short-term outcome including complication rate after surgery. P-values of less than 0.05 shall be considered statistically significant.

Timeframe: February 2021 to March 2024.

Estimated Budget: The estimated budget required to conduct this study is **28,200** ETH Birr.

Keywords: Inflammatory bowel disease, ulcerative colitis, Crohn's disease, short-term surgical outcome

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Abbreviation

SPHMMC: Saint Paul's Hospital Millennium Medical College

IBD: Inflammatory bowel disease

HLQ: health related quality of life

TPC: total proctocolectomy

IPAA: ileal pouch anal anastomosis

UC: Ulcerative colitis

CD: Crohn's disease

SBO: small bowel obstruction

SSSI: superficial surgical site infection

HAI: hospital acquired infection

1. Introduction and Literature review

1.1 Background

– Inflammatory bowel disease (IBD) is a chronic inflammatory condition of the gastrointestinal tract (GI), which is characterized by a disrupted mucosal structure, altered gut microbial composition, and systemic biochemical abnormalities. Inflammatory bowel disease (IBD) is comprised of two major disorders: ulcerative colitis and Crohn's disease. Ulcerative colitis and Crohn's disease have distinct pathologic and clinical characteristics but their pathogenesis remains poorly understood. [1]

Ulcerative colitis: is a chronic inflammatory condition characterized by relapsing and remitting episodes of inflammation limited to the **mucosal layer of the colon**. It almost invariably involves the rectum and may extend in a proximal and continuous fashion to involve other portions of the colon. [1]

Crohn's disease: is characterized by **transmural** inflammation and by **skip lesions**. The transmural inflammatory nature of Crohn's disease often leads to fibrosis and to obstructive clinical presentations that are not typically seen in ulcerative colitis. The transmural inflammation can also result in sinus tracts that burrow through and penetrate the serosa, giving rise to micro perforations and fistulae. It may involve the entire gastrointestinal tract from mouth to perianal area. [1]

EPIDEMIOLOGY: Multiple studies have evaluated the epidemiology of inflammatory bowel disease (IBD) in various geographic regions.

In North America, incidence rates range from 2.2 to 19.2 cases per 100,000 person-years for ulcerative colitis and 3.1 to 20.2 cases per 100,000 person-years for Crohn's disease [2]. The prevalence of ulcerative colitis in adults in the United States was 238 per 100,000 population and the prevalence of Crohn's disease was 201 per 100,000 population [4]. The incidence and prevalence of Crohn's disease and ulcerative colitis appear to be lower in Asia and the Middle East [3].

Geographic variation in the incidence of IBD has also been observed [5]. The incidence of IBD may have changed over time. Ulcerative colitis was more common than Crohn's disease in northern Europe and America throughout the first several decades of the 20th century. While the incidence of ulcerative colitis remained essentially stable from the 1950s through the 1980s.

the comprehensive Global Burden of Diseases, Injuries and Risk Factors Study (GBD) 2019 data showed the reported prevalence of IBD for 2017 was 11.2 per 100 000 population in western sub-Saharan Africa, 9.9 per 100 000 population in eastern sub-Saharan Africa, and 10.2 per 100 000 people in central sub-Saharan Africa. [6]

In Ethiopia, study done by Fekade, Amir sultan et al. published in 2022, showed total of 102 IBD patients (29 UC, 73 CD and a ratio of 2.5:1) with female predominance, 57% (n = 58) were identified. The mean age at diagnosis was 26.4 years for CD and 33 years for UC. Only 5.9% of patients had a family history of IBD, and 18.6% of patients had a history of bowel resection. [7]

RISK FACTORS: Although the pathogenesis of inflammatory bowel disease (IBD) remains unclear, a number of risk factors have been identified.

Age and gender: The age of onset of most cases is between 15 and 40 years. Many studies suggest a bimodal age distribution for both disorders with a second peak between 50 and 80 years [8]. There appear to be small differences in IBD incidence by gender. In general, there is a slight female predominance in Crohn's disease, although in some low incidence areas a male predominance exists. The female predominance, especially among women in late adolescence and early adulthood, suggests that hormonal factors may play a role in disease expression. In contrast, there may be a slight male predominance in ulcerative colitis [8].

Racial and ethnicity: Both ulcerative colitis and Crohn's disease are more common in Jews than non-Jews [9,10]. The incidence of IBD is lower in black and Hispanic populations compared to whites [11].

On study done by Basu, Dhiman M.D1; Lopez, Ivelisse M.D in 2005 to assess Impact of Race and Ethnicity on Inflammatory Bowel Disease found, African Americans and whites predominantly had CD, whereas Mexican Americans predominantly had UC. [12]

A study by I. C. Dos Santos Marques, L. Theiss, L. Wood on Dec 7, 2022 reported of 23,901 patients with IBD, the racial/ethnic makeup were: 88.7% White, 7.6% Black, 2.4% Hispanic and 1.4% Asian. Showed disparity in post-op complication rate in different ethnic group. Overall mean LOS was 8 days (SD 8.2) and significantly varied between groups (8d for White, 10d for Black, 8.5d for Hispanic, and 11.1d for Asian; $p < 0.001$). Hispanic patients had the highest odds of readmission (OR: 1.4; 95% CI 1.1-1.8). Black patients had increased odds of renal insufficiency (OR: 1.8; 95% CI 1.1-2.9), bleeding requiring transfusions (OR: 1.7; 95% CI 1.4-1.9), and sepsis (OR: 1.7; 95% CI 1.4-2.02) compared to White patients. [13]

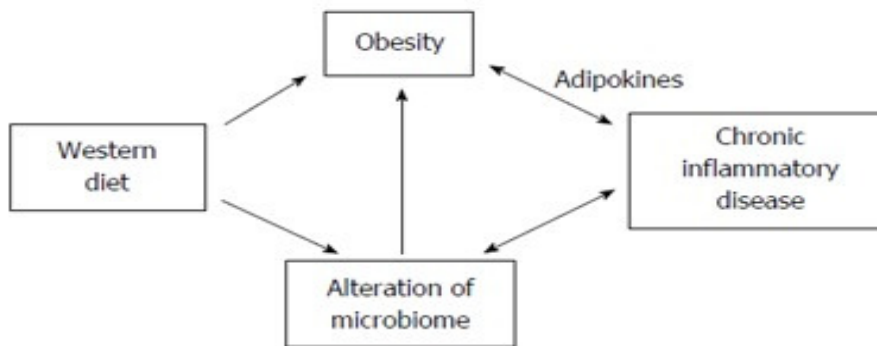
Genetic susceptibility: Approximately 10 to 25 percent of individuals with IBD have a first degree relative with either Crohn's disease or ulcerative colitis [14,15].

Smoking: has different effects on ulcerative colitis and Crohn's disease [16]. Nicotine and/or smoking byproducts may directly affect mucosal immune responses, smooth muscle tone, gut permeability, and microvasculature. A study done by Suhal S. Mahid MRCS, PhD a et al. on Smoking and Inflammatory Bowel Disease: A Meta-analysis found evidence of an association between current smoking and CD (OR, 1.76; 95% confidence interval [CI], 1.40-2.22) and former smoking and UC (OR, 1.79; 95% CI, 1.37-2.34). Current smoking had a protective effect on the development of UC when compared with controls (OR, 0.58; 95% CI, 0.45-0.75). [17]

Diet: Food antigens are thought to trigger an immunologic response resulting in the development of IBD. However, specific pathogenic antigens have not been identified. While studies attempting to associate specific diets with the development of IBD have had inconsistent results, the data suggest that a "Western" style diet

(processed, fried, and sugary foods) is associated with an increased risk of developing Crohn's disease, and possibly ulcerative colitis. [18]

Obesity: Accumulation of intra-abdominal fat may contribute to mucosal inflammation thereby affecting the clinical course in patients with established IBD [19].



Inflammatory bowel disease (IBD) treatment options are quite limited due to its complicated and unknown etiology and are focused on disease induction and maintenance in remission rather than on a cure. This lack of an appropriate treatment accounts for the high burden of IBD. Commonly recommended standard therapies for IBD patients are corticosteroids, amino-salicylates, and immunosuppressive agents. In addition, biological agents such as infliximab and tacrolimus have been used. [20]

Inflammatory Bowel Disease (IBD), sometimes requires surgical intervention when medical treatments are insufficient or complications arise.

- Crohn's Disease: Up to 80% of patients with Crohn's disease may require surgery during their lifetime. Common reasons include strictures, fistulas, abscesses, free perforation, and refractory disease. [21]
- Ulcerative Colitis: Around 25-40% of patients with ulcerative colitis may eventually need surgery. Reasons include severe disease not controlled by medications, dysplasia or cancer, and complications like toxic megacolon. [22]

In some clinical settings, surgical resection may be the most efficient means to restore health and improve quality of life, particularly in patients with short-segment stricturing or fistulizing disease [23]. Because of the risk of recurrent disease after intestinal resection, as much bowel as possible should be preserved.

OPERATIVE MANAGEMENT OF CROHN'S DISEASE

Conservative resection: The surgical resection of diseased bowel should be conservative, resecting only the sections causing symptomatic complications, such as obstruction, bleeding, or perforation. [24].

The type of anastomosis (eg, side-to-side, side-to-end) after ileocolonic resection: A meta-analysis of eight comparative studies found that a side-to-side anastomosis was associated with fewer anastomotic leaks and postoperative complications, a shorter hospital stays, and lower peri-anastomotic recurrence rates compared with end-to-end anastomosis [25].

Strictureplasty: can relieve obstruction, and can be performed with or without a synchronous small bowel resection [26]. Strictureplasty involves creation of a longitudinal incision through the narrowed area while closing transversely, which widens the lumen. Strictureplasty is particularly well-suited for patients who have short, localized areas of chronic stenosis, and who are at increased risk for short bowel syndrome due to previous intestinal resection [27].

Strictureplasty has been associated with excellent results, including relief of obstruction, the ability to withdraw steroids, and improvement in symptoms [28-30]. The risk of fistula or recurrent stricture formation is low and comparable to resection.

Balloon dilation: Another method to dilate intestinal strictures is with a hydrostatic balloon [31]. A meta-analysis of 13 studies including 347 patients with Crohn's disease reported overall technical success in 86 percent of cases and long-term efficacy in 58 percent, with up to 33 months of follow-up [31]. On multivariate analysis, a stricture length of ≤ 4 cm was associated with better surgery-free outcomes. The outcome of balloon dilatation to relieve obstruction from intestinal strictures in Crohn's disease is not influenced by the type of concomitant medical therapy [32].

An illustrative report included 55 patients with 59 ileocolonic strictures who underwent 78 dilation procedures [33]. The procedures were performed endoscopically with patients under general anesthesia. Seventy procedures (90 percent) were technically successful. Perforation occurred in six patients (11 percent), two of whom required surgery and four of whom recovered with medical treatment. Obstructive symptoms were relieved in 62 percent of patients up to 11 months after the procedure.

Balloon dilation may be useful in situations in which it is desirable to postpone surgery. However, the significant risk of perforation, which substantially increases morbidity, must be considered; hence, strictureplasty is preferred approach.[33].

Stenting: Placement of an expandable metal stent within colonic strictures has been described, but experience is limited, and the safety of this approach is uncertain [34]

The **optimal procedure** depends in part upon the extent of the disease and the clinical setting:

Segmental colectomy may be adequate for isolated areas of colonic involvement. An Ileorectal anastomosis can be carried out if the rectum is spared. However, approximately one-half of such patients require a subsequent proctectomy. The presence of perianal disease and an anastomosis increases the risk of relapse and reoperation. Both procedures segmental colectomy and total colectomy with ileorectal anastomosis, appear to be equally effective as treatment options for colonic Crohn's disease. However, patients undergoing segmental resection may have earlier recurrence. The choice of operation depends upon the extent of colonic disease; there

may be better outcomes with ileorectal anastomosis in those who have two or more involved colonic segments.[35]

Total proctocolectomy is indicated for patients with extensive, diffuse colorectal disease. Subtotal colectomy with ileostomy is usually performed in emergent situations [35].

An abdominoperineal resection with a permanent end-colostomy is appropriate for patients with severe Crohn's disease confined to the anorectum. An intersphincteric proctectomy is recommended to minimize the risk of a nonhealing wound and sexual or urinary dysfunction [36]. In one series using this technique, postoperative retrograde ejaculation and impotence occurred in only 4 percent of patients [36]. A low Hartmann procedure should be considered in the presence of severe anorectal disease and ongoing sepsis. A perineal proctectomy can be performed in select patients with minimal or no perianal disease [37].

POSTOPERATIVE MONITORING — Patients undergoing a resection of small or large intestine for Crohn's disease require vigilant monitoring for recurrent disease and/or malignancy.

Recurrence: The postoperative recurrence rate for patients undergoing a resection and anastomosis is high [38]. Endoscopic recurrence approaches 80 percent at one year, while the clinical recurrence rate is 10 to 15 percent per year [40]. However, in most series, up to 20 percent of patients will not have a clinical recurrence even at 15 years after resection [39]. Those with severe endoscopic or radiologic findings are at increased risk to have or develop symptoms (72 versus 42 percent in those with minimal disease) [40]. An increased risk for reoperation has been associated with perforating disease and smoking [41].

The recurrence rate is lower in patients with Crohn's colitis who undergo a total colectomy and ileostomy compared with those with disease involving other segments of the digestive tract. Such patients have only a 10 percent recurrence rate in the small intestine at 10 years [35]. Total proctocolectomy in properly selected patients is associated with low morbidity, a decreased risk of recurrence, and a long interval to recurrence [38].

Patients with severe Crohn's colitis requiring a colectomy are at increased risk of developing dysplasia and adenocarcinoma in the retained rectum. In a retrospective review of 222 patients who required operative intervention for Crohn's colitis, there were five cases of dysplasia (2.3 percent) and six cases of adenocarcinoma (2.7 percent). In this small cohort, the risk factors for the development of dysplasia or adenocarcinoma included longer disease duration (over 17 years), extensive disease, and older age at diagnosis (38 years of age or older). These findings support colonoscopic screening and surveillance of patients with Crohn's colitis.[42].

❖ OPERATIVE MANAGEMENT OF ULCERATIVE COLITIS

It is estimated that approximately 20 to 30 percent of patients with ulcerative colitis will eventually require a surgical resection [43]. The development of continence-preserving procedures such as the ileal pouch-anal anastomosis has made surgery a more attractive option in patients for whom medical therapy has been unsuccessful in controlling symptoms or is undesirable.

A range of 15 to 50 percent of patients in an emergent clinical setting will require operative intervention during admission; [43].

Emergent clinical settings

Acute fulminant colitis with acute abdomen: is a potentially life-threatening condition and, therefore, an absolute indication for immediate surgical treatment. An acute abdomen in this setting can be caused by toxic megacolon, perforation, or hemorrhage. Toxic megacolon, which may be triggered by the administration of narcotic, antidiarrheal, anticholinergic and antidepressant medication, occurs in approximately 5 to 10 percent of patients with acute fulminant colitis [43].

A total abdominal colectomy is the operation of choice for management of acute fulminant ulcerative colitis with or without toxic megacolon. A temporary ileostomy is constructed. The completion proctectomy or ileal pouch-anal anastomosis is performed electively.

Free perforation is rare and usually represents the end result of an untreated toxic megacolon. The frequency of severe hemorrhage ranges from 0 to 4.5 percent [44].

Elective clinical settings:

The clinical settings that warrant strong consideration of a total colectomy in an elective setting include:

Risk reduction for colon and rectal cancer: In the clinical setting of no detectable precancerous lesions, a prophylactic total colectomy is an option for patients with long-standing ulcerative colitis. The risk of developing colon or rectal cancer during the first 8 to 10 years after a diagnosis of colitis is low, but the risk of developing cancer steadily increases with an incidence of 0.5 to 1 percent per year after the first decade of disease [45]. The extent of colitis (ie, pancolitis versus left sided colitis) but not the severity of colitis does not appear to increase the cancer risk.

In population-based research done by Ekholm, M.D., Charles Helmick, M.D. to assess Ulcerative Colitis and Colorectal Cancer, Colorectal cancer was diagnosed in 91 patients during the follow-up period (1958 through 1984), 5.7 times the expected number of cases (16.0; 95 percent confidence interval, 4.6 to 7.0) [46].

Precancerous lesions: Patients with precancerous lesions such as dysplastic lesions and tubular or villous adenomas of the colon should be offered a proctocolectomy to prevent the development of a malignancy.

Cancer risk in the presence of a low-grade dysplasia is approximately 10 to 30 percent, for high-grade dysplasia the risk is 30 to 40 percent, and when dysplasia is associated with a lesion or mass (DALM), the risk of concomitant carcinoma approximates 80 percent [47].

Study done by Gorfine, Stephen R. M.D.; Bauer, Joel J. M.D on Dysplasia complicating chronic ulcerative colitis, is immediate colectomy warranted? Concluded Colonoscopy evidence of low-grade dysplasia has a higher positive predictive value than either dysplasia associated mass or lesion or high-grade dysplasia. Dysplasia grade does not predict tumor stage. Because advanced cancer can be found in association with dysplastic changes of any grade, confirmed dysplasia of any grade is an indication for colectomy [48].

Intractable disease: The most common indication for elective surgery and should be considered intractable when it or its treatment is associated with severe and persistent impairment in the quality of life [49].

Extra intestinal manifestations: For example, patients with life threatening thromboembolic complications, erythema nodosum, massive hemolytic anemia (including a splenectomy), and arthralgia of the small and large joints appear to benefit the most from proctocolectomy [50].

SHORT TERM SURGICAL OUTCOME OF INFLAMMATORY BOWEL DISEASE

An institution based research done by A de Buck van Overstraeten, E J Eshuis, S Vermeire to assess Short- and medium-term outcomes following primary ileocaecal resection for Crohn's disease, defined short term operative outcome as postoperative 30-day morbidity in terms of overall complication rate (anastomotic leak; fever of more than 38 °C; prolonged postoperative ileus, defined as inability to tolerate oral diet for 4 days or more; surgical-site infection; acute postoperative renal failure; etc), found the overall 30-day morbidity rate was 22.5 per cent. Anastomotic leakage occurred in 15 of 507 patients, and a deep abscess was diagnosed in 13 patients (2.4 per cent). Prolonged postoperative ileus occurred in 33 patients (6.1 per cent) and 29 (5.4 per cent) developed postoperative fever [51].

Accordingly, in another study assessing short and long-term outcomes of surgery for inflammatory (uncomplicated) ileocecal Crohn's disease: Multicenter retrospective analysis of 211 patients done by Nicolas Avellaneda a b and Annalisa Maroli, median follow-up was 36 (17–70) months. The endoscopic recurrence-free survival proportion at 24, 48, 72, 96, and 120 months was 56%, 52%, 45%, 38%, and 33%, respectively. The clinical recurrence-free survival proportion at 24, 48, 72, 96, and 120 months was 83%, 79%, 76%, 74%, and 74%, respectively. Concluded Surgery in patients with primary inflammatory ileocecal CD is associated with good postoperative outcomes, low postoperative morbidity with reasonable recurrence rates.[52]

In study published in 2021 by South African Journal of Surgery, A fourteen-year audit of surgery for inflammatory bowel disease reported, the most commonly performed elective procedure was proctocolectomy & ileal pouch anal anastomosis (IPAA) and the most commonly performed emergency procedure was total colectomy & ileostomy [53].

In the same study, the postoperative complication rate was 19.8% for CD and 41.2% for UC. Patients with CD had a 30-day mortality rate of 3.5% and patients with UC had 20% mortality following abdominal surgery [53].

1.2. STATEMENT OF THE PROBLEM

Traditionally, IBD has been regarded as a disease of high-income nations, but a shift in the epidemiological pattern has been reported, indicating stabilizing incidence in high-income countries with a high burden and prevalence, and a rapid rise in newly industrialized countries in South America, eastern Europe, Asia, and Africa [2]. Even with the introduction of biological drugs and corticosteroids that had a radical shift in patient management, surgery should be considered as another option in sequential treatment of IBD patients. Some studies had showed improved quality of life after and 50% of operated patients remain in clinical remission for 8-10 years after surgery [54]

However, Previous studies reported an incidence of early post operative complication for Crohn's disease patients to be 15-30% [55] and for ulcerative colitis, pelvic sepsis is the most serious early complication of UC

surgery (20%) followed by bowel obstruction (30% at 10years) and anastomotic stricture (8-14% at 10 years) [56].

In Ethiopia there is no research been done in this perspective and this study will act as base line for future researches on both surgical short and long-term outcomes.

2. SIGNIFICANCE OF THE STUDY

As experience in surgically managing patients with IBD for complications arising from the disease itself or from drugs used or as refractory to medical treatments showed increment in the past decade, there is only few researches to address proportion of the patients who were managed surgically for IBD and their post-operative outcome in sub-Saharan context which are mostly from South Africa and few in north African countries like Algeria, and in case of Ethiopia, specifically at SPHMMC, with establishment of department of colorectal Surgery 03 years back, there is increased trend of cases seen and operated for IBD but their short-term surgical outcome hasn't been assessed yet, which might have a significant role in the care of such patients and for future researches.

3. OBJECTIVES OF THE STUDY

3.1 General objectives

- To evaluate clinical characteristics and short-term outcome of surgically managed inflammatory bowel disease at SPHMMC, Addis Ababa, Ethiopia from February 8,2021 to march 9,2024.

3.2 Specific objectives:

- To evaluate proportion of IBD patient who required surgical intervention
- To assess type of surgery done for IBD patients
- To assess the short-term outcome following surgery for IBD

4. OPERATIONAL DEFINITION:

- ✓ Surgical complication for IBD surgery: incudes SSSI, bleeding, anastomotic leak, wound dehiscence, DVT/PTE, and stoma complications (for stoma patients)
- ✓ Surgical out-come: includes surgical complication and post-op hospital stay, re-operation rate, in-hospital mortality and 30-days re-admission.
- ✓ Short-term surgical outcome: - surgical out-come of IBD patients from surgery up to 12 months follow up

5. METHODS

5.1 study setting:

The study setting for this research includes one prominent medical institutions in Addis Ababa, Ethiopia: Saint Paul's Hospital Millennium Medical College (SPHMMC).

- SPHMMC, founded in 1968 G.C, by the late Emperor Haile Selassie. It offers a range of academic programs, including undergraduate and postgraduate medical education. The college is dedicated to excellence in medical education, research, and patient care. It boasts state-of-the-art infrastructure, a skilled faculty, and a focus on advancing healthcare practices and improving health outcomes in Ethiopia. It's indeed one of Ethiopia's largest hospital, with 750 inpatient beds at the moment. Annually, approximately 500,000 patients (inpatient and outpatient) are serviced, with a catchment population of 5 million. There are about 50 beds in the surgical department, and on average, 5000 procedures are performed each year. There are 05 Gastroenterologist and 04 colorectal surgeons who work in Multi-disciplinary fashion to improve health related quality of care in inflammatory bowel disease patients. By selecting SPHMMC as the study setting, this research will benefit from the expertise, resources, and patient population of the institution.

5.2 study period: The study will be conducted from February 8,2021 to march 9,2024.

5.3 Study Design

- Retrospective cohort study design will be used

5.4 Source population: all patients who were seen at referral clinics (GI and CRC), and EOPD of SPHMMC with diagnosis of IBD during study period.

5.5 Study population: All Patients from referral clinics, emergency OPD and wards whom are surgically managed during study period with the diagnosis of IBD.

5.6 INCLUSION AND EXCLUSION CRITERIA

- Inclusion criteria: -All patients with IBD treated and discharged at SPHMMC during the study's period
- Exclusion criteria: - IBD patients below age 14.
 - IBD patients with indeterminate colitis
 - IBD patients with incomplete medical record available for review
 - IBD patients who underwent surgery for malignancy

5.7 SAMPLING TECHNIQUE AND SIZE:

All patients treated for IBD at SPHMMC in the study period of February 8, 2021 – March 9, 2024, satisfying the inclusion criteria make up the sample size trend study. The sample size is calculated using single population proportion; Daniel equation $N = \frac{z^2 p (1-p)}{d^2}$

N= sample size required

z= 1.96 (normal deviate corresponding to 95% confidence interval)

d= degree of precision 5%

P= prevalence of rate of surgery for IBD at 18.6 % Addis Ababa (from study done by Fekade, Amir sultan et al (2022)).

N =232

6. MEASUREMENTS

6.1 Study Variables

- Dependent variables: short-term outcomes of IBD surgery
- Independent variables: Demographic data,
 - type of surgical intervention,
 - functional status of the patient,
 - nutritional status
 - pre-operative type of medication used.
 - clinical presentation type of inflammatory bowel disease

7. DATA COLLECTION INSTRUMENTS AND METHODS

Patient cards from referral clinics, emergency OPD and OR registry with a diagnosis of IBD and was operated during study period will be traced and data will be collected from patient card using structured questionnaire by principal investigator and residents

8. DATA QUALITY CONTROL

The data collection instrument will be pretested on 10 % of IBD patients from referral clinic and emergency OPD prior to actual data collection to check missed information so as to make possible amendments. Selection and training of data collector will be done. Checking for completeness and consistency of collected data at the end of each day will be done throughout data collection period.

9. DATA PROCESSING AND ANALYSIS

After checking the completeness of data, it will be analyzed using SPSS version 28 will be used to compute descriptive statistics, correlation, and regression analysis to test for the rate of surgery for IBD and short -term outcome Finally, the data is presented in tables and graphs as necessary and cross tabulation with statical test for association.

10. ETHICAL CONSIDERATION

Prior to data collection a formal letter of permission was collected from SPHMMC, department of surgery and forwarded to SPHMMC, administrative office to get permission for the study. Purpose and procedure of study was explained to SPHMMC, administrative office and other concerned body to avoid ambiguity. Patient's record will be kept confidential

11. DISSEMINATION OF THE RESULT

After analyzing data, conclusion and recommendation will be made and the result will be submitted to SPHMMC, department of surgery and possible publication on local and regional journals.

12. LIMITATION OF THE STUDY: The data source is secondary data, some data may be incomplete.

- The study is retrospective study.
- Since the study is institution based it may not completely reflect the overall status of the problem in Ethiopia.

5. Work plan

Nº	Activities	Responsible person	Miazia 2016	Sene 2016	Hamle 2016	Meskerem 2017	Hidar 2017	Tahsas 2017
1	Submit research topics	PI						
2	Topic approval and advisor assignment	PI						
3	Draft proposal submission to advisors	PI						
4	Proposal submission to the department	PI						
5	Proposal Defense	PI						
6	Final proposal submission to department & college research directorate	PI						
7	Data collection and analysis and Thesis writing	PI						
8	Draft research paper submission to Advisors	PI						
9	Research paper Submission to research office	PI						
10	Research paper defense							
11	Final paper submission (as a research manuscript)							

KEY: PI- Principal Investigator

6. Estimated cost of the research

Budget Justification:

We expect total study population of 140 patients to be enrolled in this small scale study. Patients' charts shall be searched by assigned collectors from HMIS and Card room and shall be paid 50birr per chart (50X140= 7000ETB).

Data collectors will be trained on how to make the clinical and demographic data entry to the structured questionnaire for one day and shall be paid 500 ETB each (1000 X 5=5000ETB).

Latter after the patient charts are collected ,5 professionals shall receive the data collection sheet daily and will make demographic and clinical data entry to the approved structured questionnaire for whom they will be paid 100 birr each for 3 days (100 birr X 140 chart =14,000ETB).For stationary 2700. Data extraction to the questionnaire, data checkups for completeness and overall supervision of the data as well as data clearance and entry shall be made by the authors and shall not be included in compensation payment.

Lists		Unit costs	Multiplying factor	Total cost(in birr)
Collecting Charts		50 ETB	140	7000ETB
Five Data collectors Training		1000	5	5000 ETB
Data extraction to the questionnaire		100 ETB	140	14000 ETB
Stationary	copy	10	140	14000
	pencil	20	10	200
Subtotal				26,200 ETB
Overhead cost for institution (10% of the subtotal)				2620 ETB
Grand Total:				28,820

7. References

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Annex: Data Collection Format

patient characteristics, associated disease, presenting symptom, and preoperative laboratory data

MRN _____	Age _____		Sex: Male · Female ·	
Location of primary residence	Region _____ Town _____		Occupation _____	
Referred from	Regional hospital · Zonal hospital ·		District hospital · self-referral · private center · other ·	
Type of IBD	Crohn's disease · Ulcerative colitis ·		Age at diagnosis _____	
Presenting symptom	Abdominal pain yes · no ·	Diarrhea Yes · no ·	Blood in stool yes · no ·	Weight loss yes · no ·
Duration of illness	_____ in months	Previous treatment yes · no ·	Smoking history: Yes · No ·	
Preoperative disease medication	Corticosteroids ·	Immunomodulators · (Azathioprine or methotrexate)	Anti-TNF · (Infliximab)	Amino salicylate · (sulfasalazine)
Co-morbid condition	DM Yes · No · RVI Yes · No · Unknown ·	Hypertension Yes · No · Obesity Yes · No · others	Family history Yes · No · If yes, 1st degree · 2nd degree ·	
ASA level	I · II · III · IV ·	Preoperative Labs	WBC	
			HGB	
			Serum albumin	
			Electrolytes	
Imaging findings		Endoscopy Yes · No · colonoscopy Yes · No · CT- Scan Yes · No ·	Comment: Comment: Comment:	
Operative Procedures, Postoperative Complications, and Mortality				
Intraoperative diagnosis	Same · Changed · if changed specify _____		Length of procedure: _____in minutes	
Operation Performed	Iliocolic resection · (right hemicolectomy)	SB · resection	Segmental/total · Colectomy	Stoma creation · proctocolectomy +/- ileal pouch ·

