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COMPARISON OF ABDOMINAL ULTRASOUND AND ABDOMINAL COMPUTED TOMOGRAPHY FINDINGS WITH COLONOSCOPY FEATURES IN THE DIAGNOSIS OF INFLAMMATORY BOWEL DISEASE AT TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA.

A RESEARCH THESIS SUBMITTED TO ADDIS ABABA UNIVERSITY, CHS-SOM; DEPARTMENT OF INTERNAL MEDICINE FOR THE PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR A SPECIALTY CERTIFICATE IN INTERNAL MEDICINE.

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ADDIS ABABA, ETHIOPIA

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March, 2024

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Abstract

Background: *Inflammatory bowel disease (IBD) is a chronic inflammatory disease of the gastrointestinal tract. It mainly includes ulcerative colitis and Crohn's disease. The mainstay for the diagnosis of inflammatory bowel disorders is currently colonoscopy. Nevertheless, colonoscopy is a costly, time-consuming, and invasive procedure that patients might not always tolerate. As a result, there is increased interest in non-invasive diagnosing and monitoring techniques such as ultrasonography and computed tomography. However, there is a lack of studies on the comparison between abdominal ultrasound and Computed tomography scan findings with colonoscopy in the diagnosis of inflammatory bowel disease in Ethiopia. The study aims to investigate the correlation between abdominal Ultrasound and Computed tomography scan findings with colonoscopy in diagnosing inflammatory bowel disease among patients who presented with signs and symptoms suggestive of inflammatory bowel disease at TASH, Addis Ababa, Ethiopia.*

Objective: *to assess the comparison of abdominal ultrasound and abdominal computed tomography findings with colonoscopy in diagnosing inflammatory bowel disease among patients who presented with symptoms suggestive of inflammatory bowel disease at TASH, Addis Ababa, Ethiopia.*

Method: *A 6 year retrospective cross sectional study was employed from May 2023 to March 2024 among 120 patients who presented with symptoms suggestive of inflammatory bowel disease at TASH. The data was collected using a standardized questionnaire from the medical records starting from January 01, 2018 to December 30 2023 of patients who underwent abdominal ultrasound, abdominal computed tomography and colonoscopy for suspected IBD. The collected data was entered after checked for completeness, then using SPSS 26, descriptive analysis was applied through frequency, percentage mean and standard deviation. Statistical analysis was employed to see the each test's diagnostic accuracy through sensitivity, specificity, positive and negative predictive values and accuracy for both ultrasound and computed tomography in comparison to colonoscopy which was used as a gold standard reference for IBD diagnosis. Finally the result was presented using tables, charts and bars.*

Result: *IBD was finally diagnosed in 79.2% of the total cases. Sensitivity, specificity, accuracy, PPV, and NPV were used to evaluate the diagnostic accuracy of each test. The results of our final analysis indicated that Abdominal CT scan had the following values for sensitivity, specificity, accuracy, PPV and NPV: 73.4%, 44.0%, 67.5%, 83.3%, and 30.6%; while Abdominal US had these values at 55.8%, 72.0%, 59.2%, 88.3%, and 30.0%, respectively. The degree of agreement was as follows: for abdominal US, kappa=0.183, there was a significant association and slight agreement; for Abdominal CT scan, kappa=0.152, there was no significant association and slight agreement.*

Key words: *ultrasound, computed tomography, colonoscopy, inflammatory bowel disease, diagnostic accuracy, correlation, Ethiopia*

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Abbreviation and acronym

AAU-Addis Ababa University

BUS-Bowel ultrasonography

CD- Crohn's disease

CDI- Color Doppler Imaging

CEUS-Contrast enhanced ultrasonography

CHS-College of health Science

CT- Computed tomography

CTC- Computed tomography colonography

CTE- Computed tomography enterography

ECCO- European Crohn's and Colitis organization

ESGAR- European society of Gastrointestinal and abdominal Radiology

GI- Gastrointestinal

HUS- Humanitas Ultrasound Criteria

IBD- Inflammatory bowel disease

IBS- Irritable bowel syndrome

IUS- intestinal ultrasound

MRI- magnetic resonance imaging

NPV- Negative predictive value

PPV- positive predictive value

PET- positron emission tomography

Se- Sensitivity

SICUS- Small intestine contrast ultrasonography

SOM- School of medicine

TASH- Tikur Anbesa Specialized hospital

US- Ultrasound

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CHAPTER ONE

1. Introduction

1.1. Background

Inflammatory bowel disease (IBD) is defined as non-infectious chronic inflammation of the gastrointestinal tract. It is mainly composed of ulcerative colitis, which affects only the colonic mucosa and Crohn's disease, which can affect any part of the gastrointestinal tract from the mouth to the anus(1). Abdominal pain and diarrhea are common symptoms of ulcerative colitis and Crohn's disease. Patients with Crohn's disease typically experience weight loss and perianal disease, however rectal bleeding is more common in ulcerative colitis patients(2).

Since colonic involvement is present in a significant number of IBD patients, objective measurement of colonic inflammation is critical for diagnosis, monitoring and clinical therapy(3). To manage patients with inflammatory bowel disease (IBD), objective proof of intestinal inflammation is essential because clinical-based assessment is insufficient to determine appropriate treatment decisions(4).

The gold standard for diagnosing inflammatory bowel disorders is currently endoscopy and biopsy. Despite this, the limited scope of common endoscopy to the colon and distal small bowel makes small bowel disease diagnosis challenging. Moreover, endoscopic examinations, which include biopsies, can be painful for patients and are not always readily available.

In contrast, Computed Tomography (CT) imaging is widely available and provides a non-invasive method for the evaluation of the entire GI tract including extra intestinal manifestations and complications, which are not visible by endoscopy. In order to further aid in the efficient classification of therapies, CT may offer image-based biomarkers for the inflammatory activity of IBDs(5).

Nevertheless, endoscopy is a costly, time-consuming, and invasive procedure that patients may not always tolerate. As a result, there is increased interest in non-invasive monitoring techniques such as intestinal ultrasonography (IUS). IUS is a commonly used imaging technique that has a low cost, a good safety record, and little training(6). It is becoming more widely acknowledged as a reliable method for diagnosing inflammatory bowel disease (IBD), as well as for determining the severity and course of the illness, identifying complications, and tracking the effectiveness of treatment(7). In addition, IUS can be used in a point-of-care context, which enables prompt therapy optimization, permits recurrent assessments to track lesions over time,

and can even take the place of invasive tests like endoscopy(8). Furthermore, in skilled hands, IUS can replace other cross-sectional imaging modalities like computerized tomography (CT) or magnetic resonance imaging (MR) because of its low radiation, good availability, and ease of use for both patients and physicians(9). The use of IUS in the diagnosis and treatment of IBD patients is supported by new ECCO-ESGAR guidelines, which make it evident that this non-invasive monitoring technique is necessary(9).

1.2.Statement of the problem

IBD is now a worldwide phenomenon as a result of its rising occurrence in recent decades. Globally, the epidemiology of IBD is evolving quickly; in Western nations, the estimated prevalence of IBD (>0.3%) is still rising, with North America, Oceania, and Europe having the highest IBD burdens(10). Similar to the rising incidence of IBD seen in Western countries in the 1990s, the prevalence is also rising in newly industrialized countries in Africa, Asia, and South America as a result of urbanization and rapid socioeconomic growth(11).

From 1990 to 2017, there was a rise of 85.1% in the global prevalence of IBD cases, from 3.7 million to over 6.8 million people(12). IBD currently affects 0.5% of people in North America, and by 2030, it is expected to impact about 4 million people(13). While the typical diagnostic findings are widely recognized, none of the particular items are unique to IBD. As a result, the combination of clinical symptoms, serology, imaging, appearance during an endoscopy, and histopathology always forms the basis of the diagnosis(14).

A colonoscopy is regarded as the best procedure. However, 5% of individuals, on average, cannot visualize their entire colon during a colonoscopy. Furthermore, advancements in endoscopic methods have made it feasible to employ it for GI tract interventions in certain illnesses in recent years. Due to its invasiveness, the challenge of investigating small intestines, and the inability to visualize potentially involved extra-intestinal structures, colonoscopy does have certain limits(15). Furthermore, because a colonoscopy can only go in one direction, there could be blind zones where many lesions go unnoticed. While complications from colonoscopy are more likely during therapeutic procedures, there are numerous potentially fatal consequences from colonoscopy, including severe bleeding, perforation, and bacteremia(16). Moreover, 0.9% of colonoscopies result in serious cardiopulmonary problems as a result of anesthetic delivery(17).

The diagnostic approach to the GI tract has altered in the recent few decades due to the advent and advancement of non-invasive cross-sectional imaging techniques such as computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and ultrasound (US)(18).

Computed tomography (CT) and ultrasonography (US) are two examples of non-invasive imaging techniques that are commonly used to measure small bowel inflammation because they are widely accessible, well tolerated(19), and require less thorough intestinal preparation(20).

Rapid image acquisition is a benefit of CT, which is generally accessible. One drawback of CT is radiation exposure, especially for patients who are having multiple examinations(21).

Patients accept and tolerate ultrasonography since it is non-invasive, inexpensive, and readily available. This is especially true since it doesn't involve ionizing radiation(22). One benefit of ultrasonography is that it can be used to quickly assess intestinal wall stratification in both CD and UC, as this immediately reflects changes in histology. The second benefit is that color Doppler sonography allows for the direct visualization of the vascularization of the colon. Contrast-enhanced ultrasonography (CEUS) has the potential to increase intestinal wall vascularization and improve diagnostic precision. The ability to see motility directly is the third benefit. Ultrasonography is the most sensitive imaging method for observing small bowel movements(23,24).

Although clinically, many conditions can resemble IBD, thorough and repeated tests, when required, can significantly reduce the chance of misdiagnosis. In most situations, the proper diagnosis can be established by carefully evaluating the clinical, radiological, endoscopic, and histopathologic aspects of the patient(25).

Ethiopia is a developing country with a growing burden of IBD cases. However, there is a lack of studies on the correlation between abdominal US and CT scan findings with colonoscopy in the diagnosis of IBD. The study aims to investigate the correlation between abdominal US and CT scan findings with colonoscopy features in diagnosing IBD on patients presenting with signs and symptoms suggestive of IBD at TASH, Addis Ababa, Ethiopia. The study will also assess the accuracy of each test in diagnosing of IBD.

1.3. Significance of the study

The significance of this study lies in its potential to improve the diagnosis and management of IBD in Ethiopia by providing more accurate and reliable diagnostic tools. This, in turn, can lead to better outcomes for patients with IBD, including earlier detection, appropriate treatment, and improved quality of life.

Our findings could be useful for health service planners and policy makers to justify and priorities resource allocation to be able to respond to the growing number of patients with IBD. This study will motivate health planners to develop cost-effective and simple community-based interventions for implementation by health-care professionals at the primary-care level.

The study's findings may also have broader implications for the use of abdominal CT scans and ultrasonography as a diagnostic tool for IBD worldwide, as it could help to identify any potential limitations or drawbacks of using this tool, as well as its potential benefits.

The study contributes to the existing knowledge on IBD diagnosis and provides valuable information for healthcare providers and researchers in this field.

Additionally, the study can provide a foundation for future research on IBD in Ethiopia and other similar settings.

CHAPTER TWO

2. Literature review

2.1. Diagnostic accuracy of abdominal ultrasound for detecting of IBD

A comparative study was carried out on the accuracy of intestinal US in conjunction with colonoscopy in assessing CD among 60 adult patients. The outcome was performed to assess the BUS's accuracy in several classifications: localization, enhancement, disease activity, stricture, fistula, and abscess. Indicate the accuracy of each categorization based on the following factors: accuracy, positive and negative predictive values, specificity, and sensitivity. The disease activity accuracy value was 92% in terms of sensitivity, 100% in terms of specificity, 96% in terms of accuracy, and 100% and 94% in terms of positive and negative predictive values, respectively(26).

In Italy, a cross-sectional study was conducted on 53 consecutively chosen patients between 2015 and 2017 to evaluate the accuracy of intestinal ultrasonography (BUS) using Humanitas US criteria. Colonoscopy used as gold standard diagnostic examination of inflammatory bowel disease (IBD). Every patient had a UC diagnosis; 16% had pancolitis, and 56% had left-sided colitis. Colonic wall thickening, colonic wall flow at the power Doppler, colonic wall pattern, and the presence of a lymph node were among the BUS characteristics that were assessed. The Humanitas Ultrasound Criteria (HUC) was used to determine BUS, and the Mayo endoscopic sub-scale was utilized to evaluate the endoscopic activity findings. The results revealed a substantial level of accuracy in establishing the presence of disease activity; the overall sensitivity and specificity were 71% and 100%, respectively(27).

The results of the systematic review, which examined the accuracy of US for the assessment of colorectal segments in patients with IBD, revealed that the pooled sensitivity and specificity were 86.4% and 88.3%, respectively. Only in the rectum were the accuracy 69.5% specificity and 74.5% sensitivity, respectively. Seven studies (84 patients with CD and 420 with UC) were included in the systematic review(28).

Similarly, 63 papers were examined in another systematic review of studies on the use of intestinal ultrasonography in the treatment of CD. The results showed that there was 89% sensitivity and 94.3% specificity for the initial assessment in established patients with CD, in contrast to 79.1% sensitivity and 96.7% specificity for suspected cases. In the case of segments

with 81.8% and 95.3% sensitivity and specificity for colon CD and 92.7% sensitivity and 88.2% specificity for ileal CD. There have been reports of lower detection accuracy in the proximal lesion. Nevertheless, the use of an oral contrast agent increases the sensitivity and specificity of identifying CD lesions and evaluating the locations and severity of the disease(7).

The results of the meta-analysis on IBD in the US revealed that out of the 33 included studies, the mean sensitivity of the US to identify the illness was 89.7%, and the mean specificity was 95.6% per patient. Per-bowel segment sensitivity was found to be 73.5%, while specificity was reported to be 92.9%(29).

A study was carried out to investigate the diagnostic accuracy of small US for the extent and activity of CD in 233 newly diagnosed and relapsed patients. The results showed that the accuracy of the activity or presence of the disease was 92% and 84% in terms of sensitivity and specificity, respectively, while the sensitivity and specificity of the disease's extent were 70% and 81%(20).

Between 2019 and 2020, a study was conducted at a tertiary referral center in Milan, Italy, with 43 patients to evaluate the precision of the US in determining UC disease activity. Patients were chosen consecutively from a referral center located in Milan; the results showed that the specificity was 95% and the sensitivity was 85%(30).

180 adult patients at a tertiary hospital participated in a study to investigate the function of an IV contrast agent in the sonography assessment of CD activity. Wall thickness, color Doppler imaging (CDI), contrast enhancement US (CEUS), and wall thickness (Wall Thickness) were the three US assessment methods employed in the study to monitor the effectiveness of US. The outcome additionally displayed, according to US evaluation methods, that wall thickness alone had an 80.9% sensitivity, 61.5% specificity, 88.4% PPV, 47.1% NPV, and 76.1% accuracy. For CDI alone, the corresponding values were 67.6%, 92.1%, 97%, 43.2%, and 72.8% for sensitivity, specificity, PPV, NPV, and accuracy. The reported PPV and NPV were 90.4% and 95.8%, while the sensitivity and specificity of CEUS alone were 99.3%, 60.5%, and 91.1%, respectively. All three measurement methods, wall thickness, CDI, and CEUS, had accuracy levels of 91.1%, sensitivity of 100%, specificity of 59%, and NPV and PPV of 100% and 89.8%, respectively(31).

According to a study done on 160 patients at the University of Calgary's IBD and general gastroenterology clinic between 2010 and 2013, the accuracy of a simple US score for identifying inflammatory activity in CD was investigated. The results showed that the accuracy, PPV, NPV, specificity, and sensitivity were, in order, 93.3%, 76.8%, 88.2%, 86.3%, and 87.5%. When it came to the identification of colonic illness as opposed to ileal disease, the US was modestly more sensitive and specific. The colon's sensitivity and specificity were 94.6% and 81.3%, respectively, while the ileum's were 91.7%, 75%, and 84.1% (32).

An investigation into the diagnostic efficacy of intestinal US was conducted on 313 patients who came to the gastroenterology clinic with complaints of bowel dysfunction and abdominal pain. Of the patients who underwent examination, 236 (75%) had IBS, 61 (20%) had CD, and 16 (5%) had UC. The following is a report on the accuracy of the intestinal US: sensitivity (74%), specificity (98%), PPV (92%), and NPV (92%). Additionally, the results demonstrated that 38% of UC patients, 2% of IBS patients, and 84% of CD patients had positive US tests (33).

A study among IBD patients was carried out to determine the clinical relevance of trans-abdominal ultrasonography in patients with IBD of the large bowel and terminal ileum. The results revealed that the procedure had 82% sensitivity, 97% specificity, 96% PPV, 84% NPV, and 89% accuracy. In patients with UC, the accuracy was higher than in patients with CD; for UC, it was 95%, but for CD, it was 81%. 89% of cases could detect an illness extension. Segmental analysis showed that in patients with CD, the US recognized active involvement of the terminal ileum most reliably (specificity 100% and sensitivity 96%). However, in patients with UC, the accuracy of detecting active involvement of the cecum, ascending colon, and sigmoid colon was 100% (34).

A study among 487 patients who were admitted under the care of gastroenterology from 1999 to 2002 was conducted in Milan, Italy. The study aimed to assess the role of early US detection of inflammatory intestinal diseases and anatomical location. The results showed that sensitivity was 85%, specificity was 95%, PPV was 98%, and NPV was 75%. For specific diseases, sensitivity for CD was 88.2% and 87.5% for UC (35).

A prospective study was conducted in Rome, Italy, with 148 patients who received treatment as outpatients for symptoms or signs that would suggest small intestinal pathology. The results revealed that for trans abdominal US, the sensitivity and specificity were 57% and 100%, and for small intestine contrast US (SICUS), they were 94.3% and 98% (36).

A prospective study consisting of 38 patients, ranging in age from 4 to 18, was carried out to evaluate the accuracy of US versus ileocolonoscopy in the diagnosis of IBD in children. Of the 38 individuals, 21 had CD, 9 had UC, and 8 had normal endoscopic results. Overall, 88% and 93% of the data were sensitive and specific(37).

Another prospective study that examined 156 patients in five healthcare facilities to determine the value of trans abdominal US for UC assessment found that the accuracy was 78.9% and 63.8% for sensitivity and specificity, respectively(38).

To determine the utility of the US in the diagnosis of CD extension, activity, and complications, a systemic review was conducted. The findings showed that the US had an overall accuracy of 84% in terms of sensitivity and 92% in terms of specificity for disease activity. Its accuracy was reduced for diseases proximal to the terminal ileum, but it is still a useful tool for evaluating disease activity and diagnosing suspected CD. The US had a pooled result about the disease's location that had a sensitivity of 86% (83%–88%) and a specificity of 94% (93%–95%)(39).

2.2.Diagnostic accuracy of abdominal computed tomography detecting of IBD

A comprehensive analysis was conducted to examine the significance of CT in the diagnosis of CD extension, activity, and complications. The overall findings of the study demonstrated that CT was accurate in identifying disease activity, with a sensitivity of 81% (77%–86%) and a specificity of 88% (82%–91%). The accuracy of CT in detecting disease extension was 88% in terms of sensitivity and 88% in terms of specificity. However, the sensitivity of 38% in identifying lesions in colonic segments, specifically in the ascending colon, was much lower than that of the ileum(39).

In a follow-up investigation comparing CT colonography (CTC) and conventional colonoscopy performed on twenty UC patients, CTC demonstrated 81.0% sensitivity and 73.8% specificity in detecting granular appearances and 82.1% sensitivity and 84.5% specificity in detecting pseudo polyps²¹.

A study comparing the accuracy of CT with colonoscopy on 99 randomly chosen individuals was conducted. The finding revealed that the accuracy of CT in detecting polyps was 57.8% in terms of sensitivity, 92.6% in terms of specificity, and 86.7% in terms of positive predictive value(40).

To evaluate CT colonography in IBD patients, a multi-center study including 21 patients was carried out. Out of all the patients, 15 had CD and 6 had UC. The overall sensitivity for endoluminal lesion identification was 100%. For both acute and chronic IBD, sensitivity was 75% and specificity was 100%. The accuracy of the specific disease was subsequently analyzed: the sensitivity of CD (acute-75% and chronic-100%) and UC (acute-33.3% and chronic-100%), the specificity of CD (acute-50% and chronic-100%), and the specificity of UC for both acute and chronic 100% of specificity. The positive predictive value of CD and UC was 85.7% and 100%, respectively, whereas the negative predictive value of CD was 33.3% and 100% for both acute 50% and chronic 100% of UC(41).

According to a meta-analysis of 33 studies on CT accuracy, the overall sensitivity was found to be 84.3%, with a specificity of 95.1% per patient. The outcome of identifying each segment's disease presence was lower, with a 67.4% sensitivity and a 90.2% specificity(29).

The results of a study that was conducted among 70 IBD patients to assess the efficacy of the CT enterography equipment revealed that the sensitivity was 74%. As colonic distention increased, so did the sensitivity for identifying IBD; at excellent distention, the sensitivity rose to 89%. 93% of patients with moderate or severe colitis were effectively identified, indicating that sensitivity was highest for identifying this stage of the disease. In terms of specificity, poorly distended colons had the highest specificity of 95%. Excellent distended had a specificity of 86%, whereas good distended had 89%. The degree of disease activity also affected the sensitivity for detecting colon IBD at CTE; for example, the sensitivity for mild disease was 67%, whereas the sensitivity for severe illness was 100%(42).

CHAPTER THREE

3. Objective

3.1.General objective

To assess the comparison of abdominal ultrasound and abdominal computed tomography findings with Colonoscopy in diagnosing inflammatory bowel disease among patients who visited Gastroenterology clinic with symptoms suggestive of inflammatory bowel disease from January 2018 to December 2023 at Tikur Anbesa Specialized hospital

3.2.Specific objectives

- To assess the diagnostic accuracy (sensitivity, specificity, accuracy, positive and negative predictive values) of abdominal ultrasound with the comparison to colonoscopy among patients who presented with symptoms suggestive of IBD
- To assess the diagnostic accuracy (sensitivity, specificity, accuracy, positive and negative predictive values) of abdominal CT-scan with comparison to colonoscopy among patients who presented with symptoms suggestive of IBD
- To assess the level of agreement between abdominal US and colonoscopy among patients who presented with symptoms suggestive of IBD
- To assess the level of agreement between abdominal CT scan and colonoscopy among patients who presented with symptoms suggestive of IBD

CHAPTER FOUR

4. Methods and materials

4.1. Study area and period

The study was conducted at Tikur Anbesa specialized Hospital in Addis Ababa, Ethiopia during the period from May 2023 to March 2024 G.C. TASH is a tertiary care teaching hospital. It is the largest public hospital in Ethiopia and serves as a referral center for patients from all over the country. The hospital provides a range of medical services including general medical care, emergency medicine, surgery, and specialized care in areas such as cardiology, neurology, and gastroenterology. The study was conducted in the gastroenterology department of the hospital. The data was collected from the medical records of the patients who underwent colonoscopy, abdominal US and abdominal CT-scan from January 01 2018 to December 30, 2023 G.C.

4.2. Study design

An institutional based retrospective cross sectional study was conducted.

4.3. Population

4.3.1. Source of population

All patients who presented with symptoms suggestive of IBD and sought medical care at TASH from January 01, 2018 to December 30, 2023 G.C.

4.3.2. Study population

All patients who presented with symptoms suggestive of IBD and Underwent abdominal Ultrasound, abdominal CT-scan and colonoscopy for suspected IBD at TASH during the study period.

4.4. Eligibility Criteria

4.4.1. Inclusion criteria

All adult patients who presented with symptoms suggestive of IBD and underwent Abdominal US, Abdominal CT scan and Colonoscopy for suspected IBD were included.

4.4.2. Exclusion criteria

Patients who had incomplete medical records related to the study topic were excluded. Patients who were treated for IBD before undergoing either Colonoscopy or Abdominal CT scan or US were also excluded.

4.5. Sample Size Determination

Convenience sampling method was used. The predicted number of patients attending GI referral clinic during the study period is less than 10,000. A total of 150 patients with an established diagnosis of IBD (UC or CD) were seen at the GI clinic over 12 month's period. The required sample size for the study will be calculated by considering 50% as sensitivity and specificity of imaging studies for IBD diagnosis since there are no previous similar studies done in the same area. A margin of error of 5%, confidence interval of 95% and non-response rate of 10% is considered. The required sample size (n) will be calculated as follows:

$$n = \frac{(Z_{\alpha/2})^2 p (1-p)}{d^2} = \frac{(1.96)^2 * 0.5 * (1-0.5)}{(0.05)^2} = 384$$

Where

n- Sample size

p- Sensitivity and specificity of imaging studies for IBD diagnosis (0.5).

d- The maximum margin of sample error tolerated (5%)

$Z_{\alpha/2}$ - is the standard normal distribution at 1-a% confidence level (95%=1.96)

The sample size will be n=384. But since our sample population is less than 10,000, the required minimum sample size will be calculated as $(384/(1+384/150))=108$. Adding 10% non-response rate, the final sample size will be 120..

4.6. Sampling Procedure

Non-probability sampling methods; Convenience sampling was used

4.7. Study Variables

4.7.1. Dependent Variables

- Diagnosis of IBD using US, CT-scan and Colonoscopy
- Location and Extent of US, CT-scan and Colonoscopy findings
- Level of agreement between Abdominal US and CT-scan with colonoscopy

4.7.2. Independent Variables

- Socio demographic variables; Age, Sex
- Clinical Characteristics

4.8. Operational definition

Abdominal Computed Tomography (CT scan) with oral contrast: A diagnostic medical imaging test that uses X-rays and contrast material, typically ingested orally, to produce detailed

images of the abdominal region, including the liver, pancreas, kidneys, and intestines. The oral contrast helps to highlight the digestive tract in the images and improve visualization of any abnormalities.

Diagnostic ultrasound is a non-invasive diagnostic technique used to image inside the body. Ultrasound probes, called transducers, produce sound waves that have frequencies above the threshold of human hearing (above 20KHz), but most transducers in current use operate at much higher frequencies (in the megahertz (MHz) range).

Colonoscopy: A medical procedure that uses a flexible, lighted tube with a camera on the end (colonoscope) to examine the lining of the large intestine (colon) and rectum. The procedure can detect inflamed tissue, ulcers, and abnormal growths, such as polyps, and is commonly used to screen for colorectal cancer.

Inflammatory Bowel Disease: - will be considered when the diagnosis of CD and UC is made by a gastroenterologist based on the following:

Crohn's Disease: diagnosed when endoscopy has done by a senior gastroenterologist reveals suggestive endoscopic features (like skip lesions, mucosal ulcerations, cobblestone appearance, aphthous ulcers,) with or without supportive histologic findings (including deep inflammation or chronic terminal ileal inflammation) in a patient with typical clinical symptoms.

Ulcerative Colitis: diagnosed when endoscopy done by a senior gastroenterologist reveals suggestive endoscopic features (like a diffuse mucosal disease of colon with different proximal extensions from the rectum, superficial inflammation, and rectal involvement without any evidence of small bowel involvement other than backwash ileitis) with or without supportive histologic findings (vascular congestion, crypt abscesses, cryptitis, and crypt branching) in a patient with typical clinical symptoms.

4.9. Data Collection Procedures and tools

A database of medical chart records was searched from 01 January 2021-30 December 2023. Then a total of **120** patients' medical records with suspected diagnosis of IBD (chief complaint with signs and symptoms suggestive of IBD) were reviewed. Data was collected from the medical records by well-trained residents using standardize chart review checklist.

4.10. Data Quality

A well-trained data collectors and supervisor carefully collected data based on the inclusion criteria of the chart review checklist. The collected data was reviewed and checked for completeness.

4.11. Data Analysis Procedure

The collected data was re-checked for completeness before the analysis process begins. Incomplete data was cleaned and removed. The completed data was entered into SPSS version 26. The socio demographic and other variables were presented by using tables, charts, and graphs. The comparison of diagnostic test was determined. Parameters of diagnostic accuracy; sensitivity, specificity, positive predictive value, negative predictive value, and accuracy also were determined.

4.12. Ethical clearance

Ethical clearance was obtained from the Ethical Review Board of AAU-CHS-SOM. The officials at different levels in the study area were communicated with through letters from AAU-CHS-SOM. Confidentiality of the Collected data in this study was maintained.

4.13. Dissemination of the result

After completion of the study, the results will be submitted to AAU-CHS-SOM; Department of Internal Medicine. Manuscripts will be submitted for publication in peer-reviewed scientific journals and results will be presented at scientific conferences for better communication of the results.

CHAPTER FIVE

5. Result and discussion

5.1.Result

Socio-demographic characteristics of respondents

The study included 120 patients in total, indicating a 100% response rate. The mean age of respondents was 39.7 + 16.64 years, with the age group between 18 and 30 years old comprising the biggest number of respondents, followed by the age group of 31–45 years old. 64 respondents, or 53.3% of the total, were female.

Table 1 Age and Sex distribution of respondents

Ser.no	Variables	Category	Frequency	Percentage
1	Age	< 18 years	6	5.0%
		18-30 years	40	33.3%
		31-45 years	35	29.2%
		46-60 ears	20	16.7%
		>60 years	19	15.8%
2	Sex	Female	64	53.3%
		Male	56	46.7%

Clinical characteristics of respondents

During their hospital visits, the patients displayed the following symptoms: Abdominal pain, diarrhea (bloody, mucoid, or watery), rectal bleeding, constipation, and weight loss were the five primary symptoms that were recorded. About 91 (75.8%) of the respondents reported having abdominal pain, 74 (61.7%) reported having diarrhea, 72 (60.0%) reported having weight loss, and 36 (30.0%) reported constipation. Only 10 (8.3%) suffered rectal bleeding, though.

In addition to the primary symptoms, the respondents also reported experiencing various other symptoms. Out of the 120 patients who were included in the study, 44 (or 36.7%) had additional symptoms. The most common additional symptom was tenesmus, which was reported in 16 cases (36.4%), followed by vomiting in 14 cases (31.8%), and the least common symptoms were fatigue, abdominal distention, and swelling, umbilical discharge, and inguinal swelling, each with 1 case (2.2%).

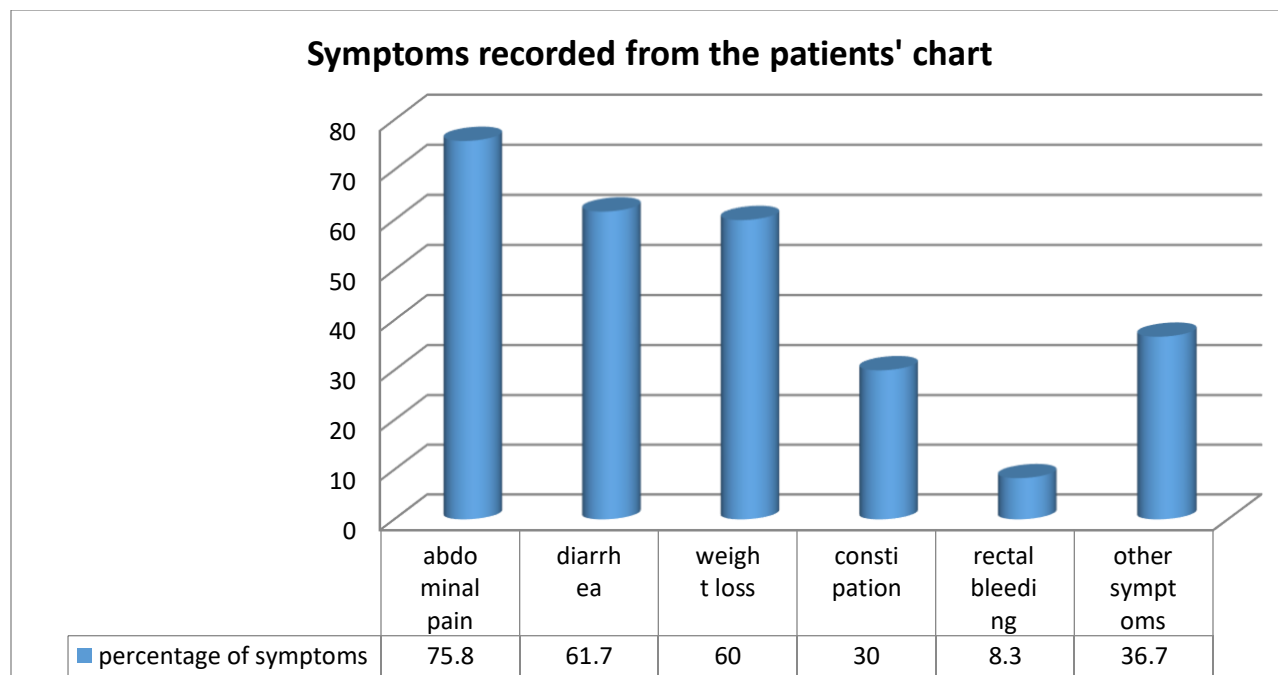


Figure 1 symptoms recorded from patients' chart at TASH,

About 16 patients (13.3%) had extra-intestinal manifestations, and their medical records indicated the presence of extra-intestinal symptoms. Lower back pain and iron deficiency anemia ranked highest among the them, with 3 (18.7%) for each. Skin tags and fatty liver ranked second, with 2 (12.5%) for each.

Table 2 Extra intestinal manifestations of the study patients at TASH

Ser.no	Extra intestine manifestations	Frequency	Percentage
1	Anemia	3	18.7
2	Lower back pain	3	18.7
3	Skin tag	2	12.5
4	Fatty liver	2	12.5
5	Anal fissure	1	6.2
6	Recurrent kidney stone	1	6.2
7	Cholelithiasis	1	6.2
8	Fecal discharge per urethra	1	6.2
9	Fecal discharge per vagina	1	6.2
10	Multiple joint pain	1	6.2
11	Peripheral arthropathy	1	6.2

12	PSC	1	6.2
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PSC-

Duration of symptoms of the patients

Out of all the patients who were part of the study, 46 (38.3%) had symptoms that persisted for more than a year, while 38 (31.7%) and 35 (29.2%) had symptoms that persisted for 6–12 months and less than 6 months, respectively.

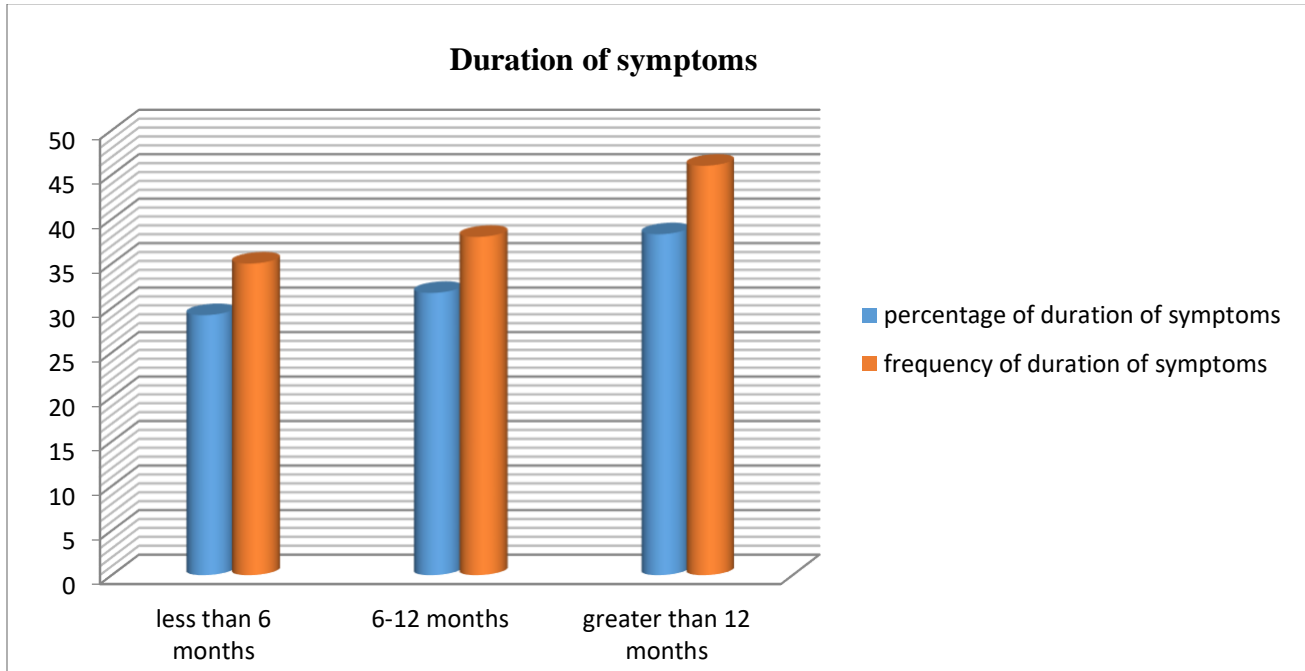


Figure 2 Frequency and percentage of duration of symptoms of patients at TASH, Ethiopia, 2024

IBD diagnosis in patients using colonoscopy, abdominal US, and CT scans

IBD Diagnosis using abdominal US examination

Of all the patients who had abdominal ultrasonography exams, sixty (or 50%) had positive results for IBD, and the remaining 50% had negative results.

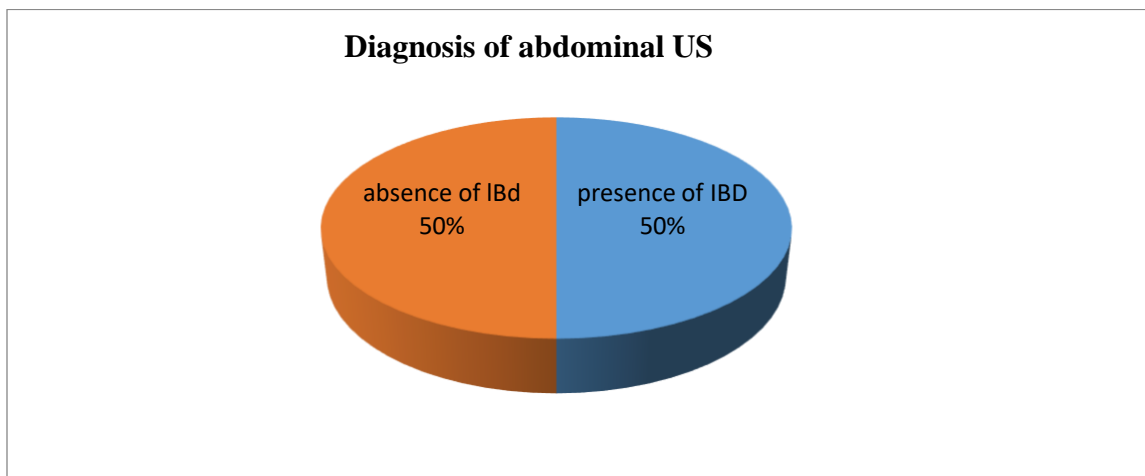


Figure 3 Abdominal US examination Result of study samples at TASH

Among the patients who underwent examination utilizing the US, 60 patients received an IBD diagnosis. In their US findings, 57 patients (47.5%) had bowel wall thickening, 4 patients (3.3%) had mesenteric fat stranding, 10 patients (8.3%) had bowel stratification, 12 patients (10.0%) had mesenteric lymphadenopathy, and 13 people (10.8%) experienced complications. Other than the five key findings listed above five out of sixty (4.1%) patients with IBD were found to have other US findings.

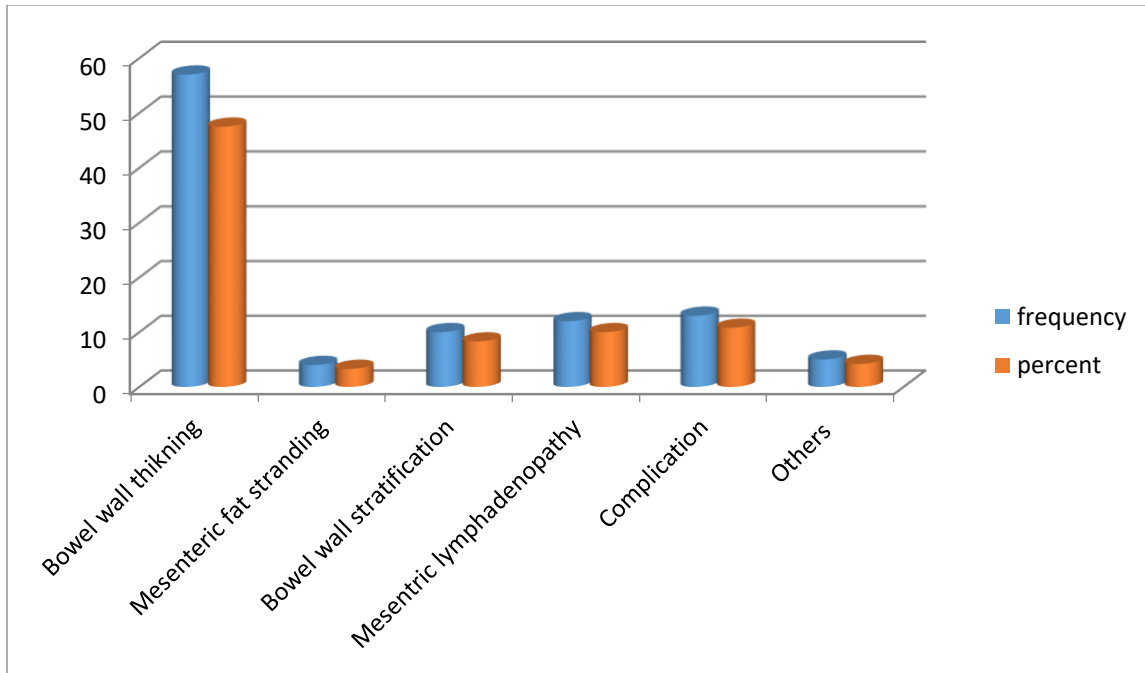


Figure 4 Features of US among patients who underwent abdominal US examination

Location and extent of lesions in abdominal US examination

The US findings or lesions in the patients with IBD were located in various parts of the gastrointestinal tract. The greatest percentage of lesions—45, or 37.5%—were found in the terminal ileum, with the least amount found in the rectum (7.8%), right colon (28, or 23.3%), and left colon (15, or 12.5%). In addition to the GIT segment mentioned above, lesions were seen in the remaining small intestine in 4 cases.

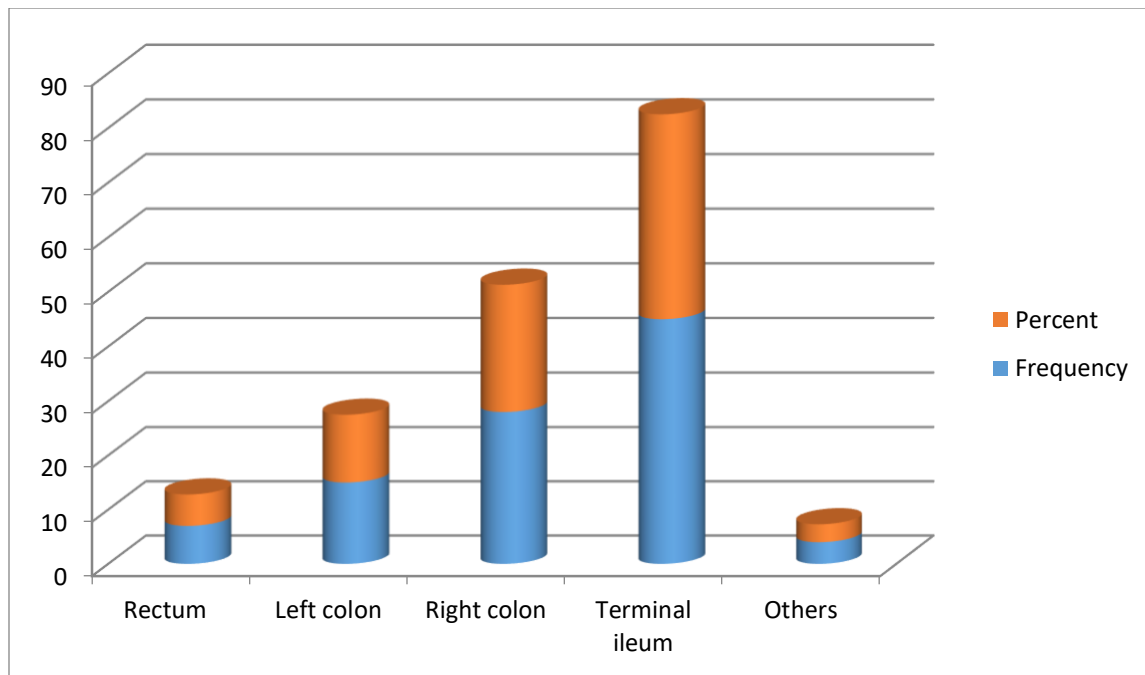


Figure 5 Locations and extent of lesions based on abdominal US result among study patients

In addition to the main features, other findings were found in the US.

Table 3 Additional US findings/features among study patients at TASH

Ser.no	US findings	Frequency	Percent
1	Peritoneal fluid collection	8	30.8
2	Fatty liver	3	11.5
3	Hepatic hemangioma	2	7.7
4	Left lower quadrant mass	1	3.8
5	Pelvic collection and ovarian cyst	1	3.8
6	Cholelithiasis	1	3.8
7	Budd-chair syndrome	1	3.8
8	Matted bowel loop	1	3.8
9	Liver mass	1	3.8
10	Hepatic abscess	1	3.8
11	Abdominal lymphadenopathy	1	3.8
12	Asymmetric colonic wall thickening	1	3.8
13	Splenic mass	1	3.8
14	CBD dilation	1	3.8
15	Hydronephrosis	1	3.8
16	Hepatosplenomegaly	1	3.8

CBD;

Diagnosis of IBD using abdominal CT scan

Of the 120 patients, 84 (or 70%) had an abdominal CT scan that resulted in an IBD diagnosis. Features from the CT scan were noted while the abdomen CT scan was examined. 78 (94.0%) patients with IBD had thickening of the bowel wall, 25 (30.1%) had enhancement of the bowel wall, 26 (31.3%) had mesenteric fat stranding, 17 (20.5%), and 24 (28.1%) had mesenteric lymphadenopathy and complications, respectively. Beyond the findings listed here, just one patient had additional abdominal CT features.

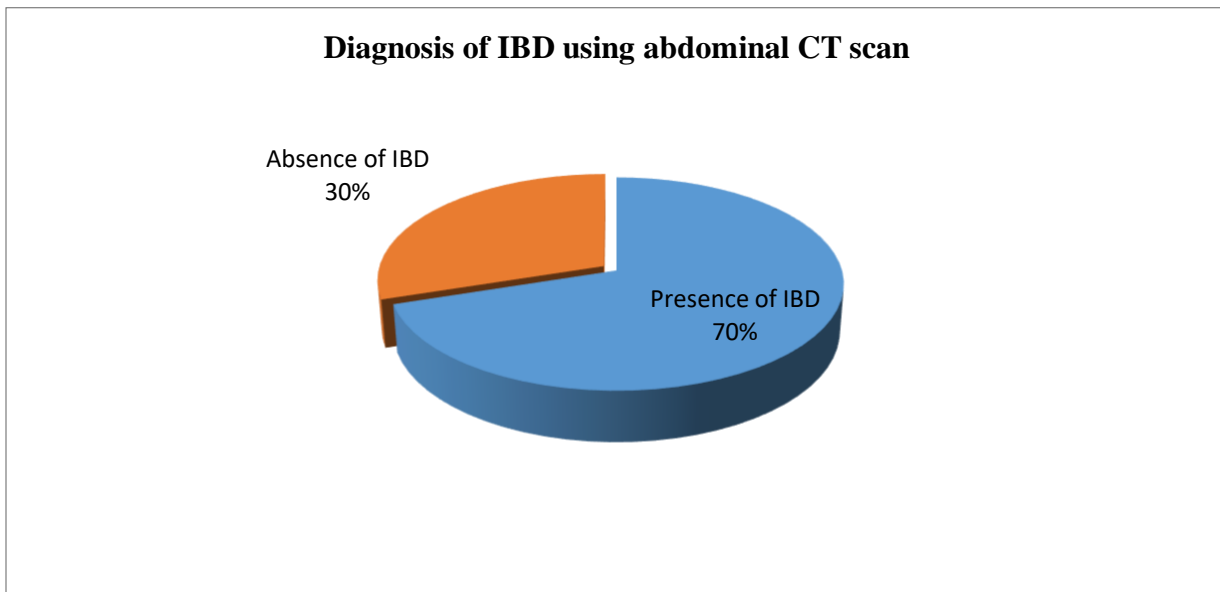


Figure 6 Diagnosis of IBD using abdominal CT scan among study patients at TASH

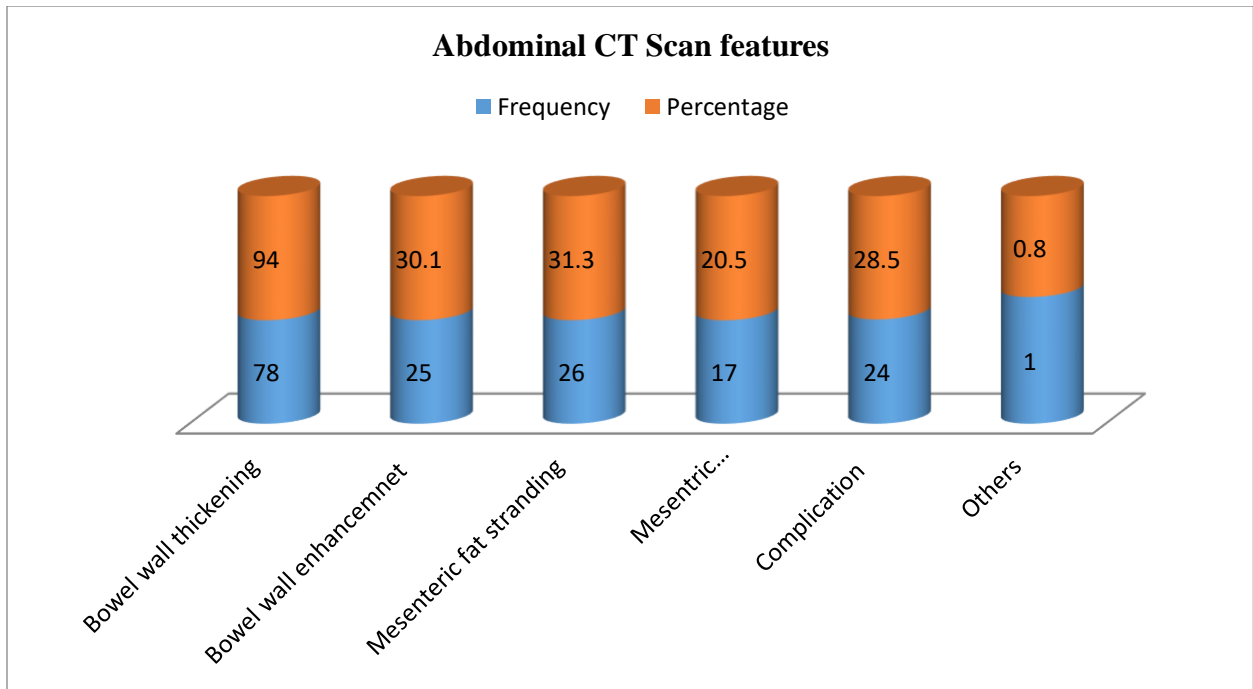


Figure 7 Abdominal CT scan features of the study patients at TASH
Others:

Location and extent of abdominal CT scan findings

Seventy percent of the patients who received abdominal CT scans showed positive results. Sixteen (19.3%) of the 84 patients who had positive abdominal CT scans had findings in the rectum, seventeen (20.5%) in the left colon, thirty-one (37.3%) in the right colon, and the remaining fifty-nine (71.1%) in the terminal ileum. Furthermore, 1 (0.8%) and 6 (5.0%) were in the perianal and small intestine, respectively.

Table 4 Location and extent of abdominal CT scan findings of the study patients

Ser. No	Location	Frequency	Percentage
1	Rectum	16	19.3
2	Left colon	17	20.5
3	Right colon	31	37.3
4	Terminal ileum	59	71.1
5	Others		
	Small intestine	6	5.0
	Perianal region	1	0.8

Diagnosis of IBD using Colonoscopy

The results of the colonoscopy revealed that 95 people, or 79.2%, had an IBD diagnosis. 60 patients (62.5%) with Crohn's disease, 28 patients (29.5%) with non-specific/indeterminate colitis, and 7 patients (7.34%) with ulcerative colitis were diagnosed with IBD.

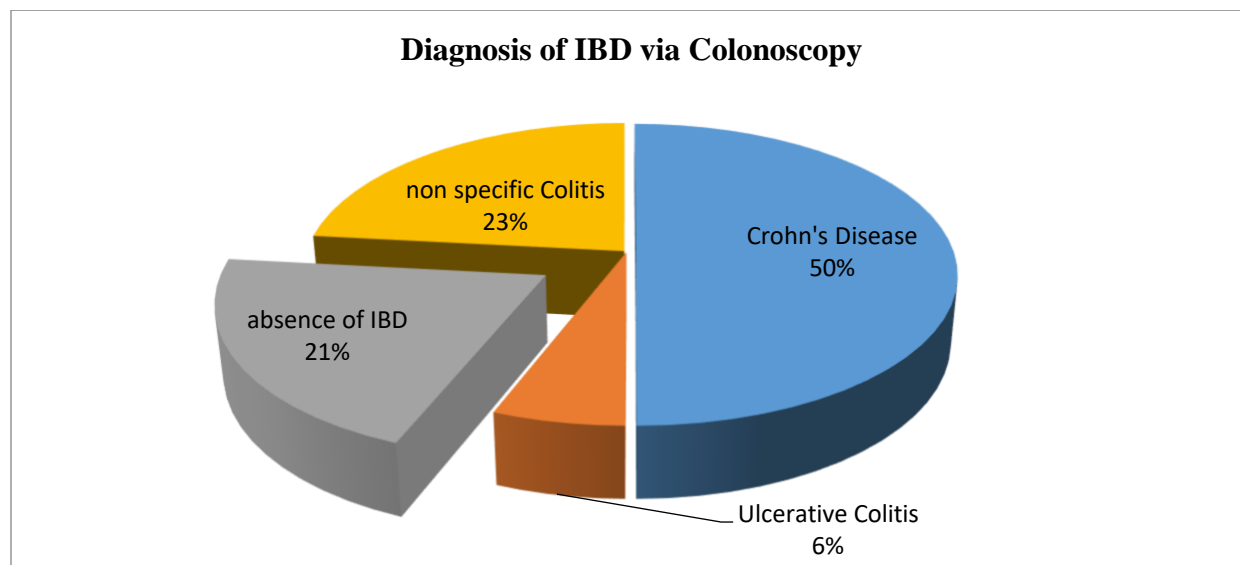


Figure 8 Diagnosis of IBD using colonoscopy of the study patients at TASH

Colonoscopy features of patients

After undergoing a colonoscopy examination, 45 patients (37.5%) had ulceration or erosion, 7 patients (5.8%) had cobblestone appearance, 5 patients (4.2%) had skip lesions, and 67 patients (55.6%) had mucosal inflammation. Mucosal friability or bleeding, loss of vascular marking, and complications were reported in 42 (35%), 7 (5.8%), and 5 (4.2%) cases, respectively. In addition to the features mentioned above, 3 patients (2.5%) had additional colonoscopy findings.

Table 5 Colonoscopy features distribution within sub type diagnoses of IBD

Ser. no	Colonoscopy features	Category	IBD sub types		
			CD N (%)	UC N (%)	Nonspecific colitis N (%)
1	Ulceration or erosion	No	27(54.0)	3(6.0)	20(40.0)
		Yes	33(73.3)	7(17.8)	4(8.9)
2	Cobblestone appearance	No	53(60.2)	7(8.0)	28(31.8)
		Yes	7(100)	0(0)	0(0)
3	Skip lesions	No	55(61.1)	7(7.8)	28(31.1)
		Yes	5(100)	0(0)	0(0)
4	Mucosal inflammation	No	18(64.3)	2(7.1)	8(28.6)

		Yes	42(62.7)	5(7.5)	20(29.9)
5	Loss of vascular markings	No	59(65.6)	4(4.4)	27(30.0)
		Yes	1(20.0)	3(60.0)	1(20.0)
6	Mucosal friability or bleeding	No	57(64.8)	3(3.4)	28(31.8)
		Yes	3(42.9)	4(57.1)	0(0)
7	Complications	No	26(49.1)	6(11.3)	21(39.6)
		Yes	34(81.0)	1(2.4)	7(16.7)

CD- Crohn's Disease, UC-Ulcerative Colitis

Location and extent of colonoscopy findings

Colonoscopy revealed that 40 patients (42%) had terminal ileum lesions, with 25 patients (31.7%) having right colon lesions.

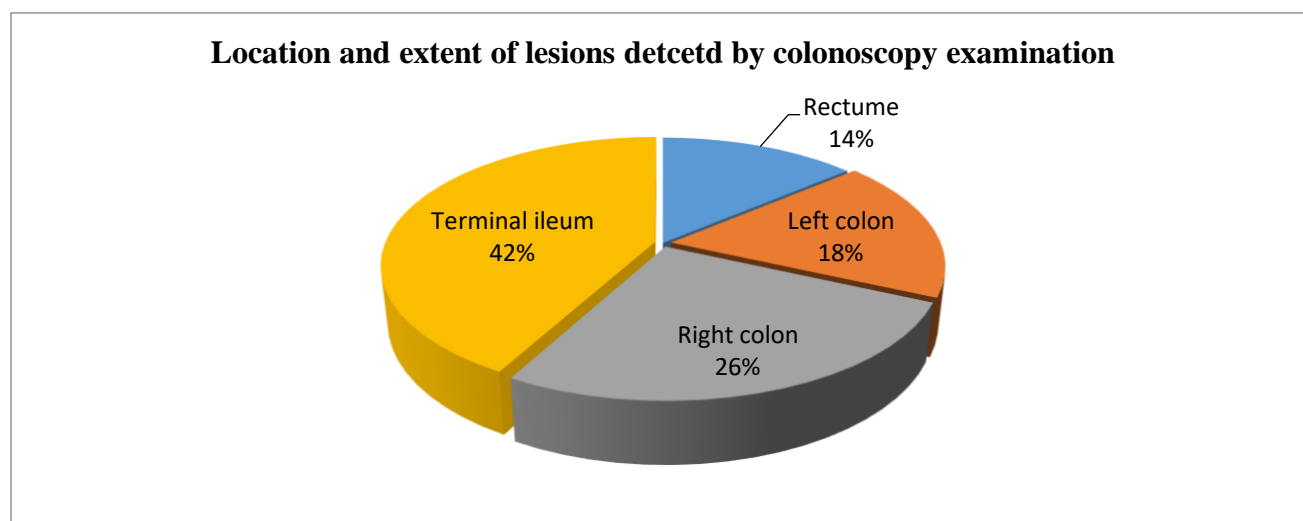


Figure 9 Location and extent of lesions detected by colonoscopy

Diagnostic accuracies of US and CT scan and their discrepancy from the gold standard diagnostic test

1. Agreement level and discrepancy of abdominal CT-scan and Gold standard test (colonoscopy)

According to the data taken from the patient's chart, 95 patients had the gold standard test (a colonoscopy) to confirm their diagnosis of IBD, and 70 of those patients also had an abdominal CT scan, which confirmed their diagnosis of IBD (70 true positives). Eleven patients (eleven true negative values) tested negative for IBD on abdominal CT-scan. Abdominal CT scan identified 14 people as having IBD, although the gold standard test found them to be negative for the disease (14 false positives). Whereas, the scan missed 25 cases even though the gold standard test found them

to be positive (25 false negatives). Based on the above data, the diagnostic accuracy analysis showed that the abdomen CT scan had sensitivity and specificity values of 73.7% and 44.0%, respectively.

Abdominal CT scan accuracy, positive and negative predictive values, and 67.5%, 83.3%, and 30.6%, respectively. There was a 0.15 (kappa = 0.15) degree of agreement between the gold standard colonoscopy and the abdominal CT scan, indicating a slight agreement with no statistical significance (p = 0.085).

2. Agreement level and discrepancy of abdominal US and Gold standard test (colonoscopy)

According to the current study, 53 patients underwent abdominal US examinations and tested positive for IBD; however, 95 cases tested positive for IBD using the gold standard test (53 true positives). Merely 18 of the 25 individuals who were found to be negative for IBD by the gold standard test had negative abdominal ultrasound results (18 of which were true negatives). In 7 patients, the abdominal US test revealed IBD, although the colonoscopy revealed 7 false positives. Although 42 patients tested negative in the US, the gold standard test revealed positive results (42 false negatives).

The results of the diagnostic accuracy analysis showed that the positive and negative predictive values were 30.0% and 88.3%, respectively, and the sensitivity was 55.8% and the specificity was 72.0%. The accuracy percentage was 59.2%. Along with having a slight agreement with the gold standard, the degree of agreement was 0.18, and there is a significant association (p = 0.013) between the two tests.

Table 6 Diagnostic accuracy values of abdominal US and CT scan

Ser. no	Variables	US	CT scan
1	Sensitivity	55.8%	73.3%
2	Specificity	72.2%	44.0%
3	Accuracy	59.2%	67.5%
3	Positive predictive vale	88.3%	83.3%
4	Negative predictive value	30.0%	30.6%
5	Kappa (k)	0.18	0.15
6	Association (p)	0.013*	0.085

*- < 0.05, significant association, US- Ultrasound, CT - Computed Tomography

5.2. Discussion

Considering several parameters such as bowel wall thickening and stratification, mesenteric fat stranding and lymphadenopathy, and the existence of complications, this retrospective study attempts to evaluate the diagnostic accuracy of US and CT in diagnosing IBD in comparison to colonoscopy.

According to the results, the majority of patients who were included in the study were between the ages of 18 and 30, and the highest percentage of patients (68.6%) who were between the ages of 31 and 45 had positive abdominal US results for IBD. The age group of 18 to 30 years old had the highest number of IBD patients identified by abdominal CT scan, whereas the age group of less than 18 years old had the lowest number of IBD patients. Every patient in the under-18 age group who had a colonoscopy examination tested positive for IBD. The percentage of IBD cases that tested positive for all diagnostic tests was greater in women. However, in all three diagnostic methods, more men than women were negative for having IBD.

A colonoscopy revealed that 79% of patients had IBD. 50% of the patients in the current study were diagnosed with IBD on an abdominal US examination. Of all the cases that had abdominal CT scans, 84 (or 70%) had positive results for IBD.

The results of our investigation showed that five US features were used for diagnosing IBD by the abdominal US. Bowel wall thickening was the most common feature among the features, accounting for 47.5% of the total, whereas mesenteric fat stranding was the least common, accounting for 3.3%. The rectum was the last part to have 5.8% of the total lesions found by the US, with the terminal ileum having the greatest percentage of lesions present (37.5%).

According to the study's findings, mesenteric lymphadenopathy was the least common type of CT scan detection, while bowel wall thickness was the most frequently observed feature in the evaluation of the abdomen CT scan. The majority of patients—about 49%—had a lesion placed in the terminal ileum, while only 13.3% of patients had lesions found in the rectum after an abdominal CT scan examination.

The abdominal US had a sensitivity, specificity, and accuracy of 55.8%, 72.0%, and 59.2%, respectively. A different cross-sectional study that was carried out in Italy with 53 patients also revealed sensitivity and specificity of 71.0% and 100%, which were significantly higher than the results of the current study(27). Another study found that the sensitivity, specificity, and accuracy were 92%, 100%, and 96%, respectively; these results were much higher than the current study(26). Similar findings were reported by another study carried out in Milan, Italy, which revealed 85% sensitivity and 95% specificity(30).The basis for the significant discrepancy between the above mentioned studies and our study lies mainly upon the type of US used which was usually contrast enhanced and color Doppler US.Furthermore, those studies were done prospectively with Uniform expert radiologists for all patients whereas in our study retrospective US reading was used from all levels of expertise of radiologist from junior residents to expert radiologists in our institution.

Our analysis also revealed that US had positive and negative predictive values of 88.3% and 30.0%, respectively. The PPV and NPV of 160 patients in the University of Calgary investigation were 76.8% and 88.2%, respectively. The PPV was substantially similar to the current study, but the NPV was much higher(32). Another study likewise found that the NPV and PPV were greater, at 92% each(33). Similar comparative research conducted in Italy revealed 75% NPV and 98% PPV(35).The same reasons apply for this differences too in addition to variety of US criteria used and population groups.

According to the results of the current investigation, abdominal CT had the following values for sensitivity, specificity, and accuracy: 73.7%, 44.0%, and 67.7%, respectively. The sensitivity of another study, which involved 21 patients, was comparable to the current study, but the specificity

was significantly greater at 75% and 100%, respectively(41). It could be the variation in sample sizes between the two studies. In a different study involving 99 IBD patients, the sensitivity (57.8%) was lower than the present value, but the specificity (92.4%) was higher(40).

The results of this investigation showed that the CT scan's positive and negative predictive values were, respectively, 83.3% and 30.6%.

The discrepancy between our study and similar other studies also is implied in the difference between the technique used in other studies which usually is CT- enterography and enterociclysis as compared to conventional CT in our study.

Based on the results of our investigation, the degree of agreement between the US and colonoscopy was 0.183 (kappa = 0.183), which was low and had a significant association (p = 0.013). Similarly, there was no significant association (p = 0.085) despite a slight level of agreement (kappa = 0.152) between the abdominal CT scan and colonoscopy.

Chapter six

6. Conclusion and Recommendation

6.1. Conclusion

- The purpose of our study was to evaluate the diagnostic accuracy of abdominal US and CT scans compared colonoscopy as the gold standard . IBD was finally diagnosed in 79.2% of cases. Sensitivity, specificity, accuracy, PPV, and NPV were used to evaluate the diagnostic accuracy of each test. The results of our final analysis indicated that abdominal CT scan had the following values for Sensitivity, specificity, accuracy, PPV, and NPV respectively; 73.4%, 44.0%, 67.5%, 83.3%, and 30.6% while, abdominal US had these values at 55.8%, 72.0%, 59.2%, 88.3%, and 30.0%, respectively. The degree of agreement was as follows: for the US, kappa=0.183, there was a significant association and slight

agreement; for the CT scan, kappa=0.152, there was no significant association and slight agreement. Abdominal US and CT-scan, despite showing only modest diagnostic sensitivity, specificity and accuracy in our current study due to different confounding factors, are very useful adjunctive tests to colonoscopy in order to confirm diagnosis, not to miss complications and see parts of the bowel that are not accessible by colonoscopy..

6.2.Recommendations

For health professionals

- These two imaging tests are relatively non invasive compared to colonoscopy which makes them the entry points for suspicion of IBD in patients newly presenting with suggestive symptoms. Further test can be done afterwards. We would recommend starting the investigation of IBD suspects with both US and CT-scan as long as they are accessible, affordable and available to the patient These tests are also pivotal for monitoring of patients in addition to their diagnostic application.
- We would also recommend better, clear and detailed medical recording practice for future research endeavors.

For further researchers

- To further verify the results of our study, future prospective, multicenter designs with larger sample size, standardized criterias, designated expert radiologists and enhanced uniform imaging techniques should be applied in order assess the factors influencing the specificity and sensitivity of the abdominal US and CT scan results.

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Annex I

Data Collection Format

Addis Ababa University, CHS-SOM

The Purpose of this study is to Correlate Abdominal Ultrasound and Abdominal CT scan findings with Colonoscopy in the diagnosis of Inflammatory Bowel disease at TASH, A.A, Ethiopia.

I kindly request your willingness to perform these reviews. The information gathered will be used confidentially.

Code	Question	Response	Remark
Part one: Socio-demographic factors			
SD1	MRN(code)	_____	
SD2	Age (yrs)	_____	
SD3	Sex	Male	
		Female	

Part two: Clinical Characteristics			
CC1	Symptoms	Abdominal pain	
		Diarrhea(watery,Mucoid,Bloody)	
		Rectal bleeding	
		Constipation	
		Weight Loss	
		Other (specify)	
CC2	Duration of Symptoms	< 6months	
		6-12 months	
		>12months	
CC3	Extra intestinal manifestations (eye, skin, musculoskeletal, liver and biliary tree, AS, PSC)	Yes, specify	
		No	
Part Three: Abdominal Ultrasound Findings			
US1	Presence of Abdominal Ultrasound findings indicating IBD (Yes/No)	Yes	
		No	
US2	If Yes, specify Type (check all that apply)	Bowel wall thickening	
		Mesenteric Fat stranding	
		Bowel wall stratification	
		Mesenteric lymphadenopathy	
		Complications(stricture,fistula,mass,abscess)	
		Other (specify)	
US3	Location and extent of Abdominal ultrasound finding	Rectum	
		Left colon	

	(check all that apply)	Right colon
		Terminal ileum
		Other (specify)
US4	Other findings (specify)	

Part Four: Abdominal CT-Scan Findings		
CT1	Presence of Abdominal CT scan findings indicating IBD (Yes/No)	Yes
		No
CT2	If yes, Specify Type (check all that apply)	Bowel wall thickening
		Bowel wall enhancement
		Mesenteric Fat stranding
		Mesenteric Lymphadenopathy
		Complication(stricture,fistula,mass,abscess)
		Other (specify)
CT3	Location and extent of Abdominal CT scan findings (check all that apply)	Rectum
		Left colon
		Right colon
		Terminal ileum
		Other (specify)
CT4	Other findings (specify)	
Part Five: Colonoscopy Findings		
CO1	Presence of Inflammatory Bowel Disease (IBD) (Yes/No)	Yes
		No

CO2	If Yes, specify Type	Crohn's disease
		Ulcerative colitis
		Non -specific/Indeterminate colitis
CO3	Type of Lesions (check all that apply)	Ulcerations or Erosions
		Cobble Stone Appearance
		Skip lesions
		Loss of Vascular Markings
		Mucosal Friability or Bleeding
		Mucosal Inflammation
		Complications(Stricture, Fistula, Mass)
		Others (specify)
CO4	Location and extent of Lesions (check all that apply)	Rectum
		Left colon
		Right colon
		Terminal ileum
		Other (specify)
CO5	Other findings (specify)	
Part six: Correlation with Colonoscopy		
CR1	Agreement between Abdominal ultrasound findings and colonoscopy in IBD diagnosis (Yes/No)	Yes
		No
CR2	Agreement between Abdominal CT scan findings and colonoscopy in IBD diagnosis (Yes/No)	Yes
		No

Assurance of Principal Investigator

I agree to accept all responsibilities for the scientific and ethical conduct of the research project. I will provide a timely progress report to my advisor and seek the necessary advice and approval from my primary advisors in the course of the research. I will communicate timely to my advisors and all stakeholders involved in the study including any source of funding for this research.

Name of the resident: _____

Signature: _____

Date: _____

Approval of the Primary Advisor

Name of the primary advisor: _____

Signature: _____

Date: _____

Approval of the Co-Advisor

Name of the primary advisor: _____

Signature: _____

Date: _____