



Magnitude and Associated Factors of Anastomotic leak in Colorectal Surgery at a Tertiary Care Hospital in Ethiopia: A five-year retrospective study

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Summary:

Background:

One of the most fatal consequences of intestinal surgery is an anastomotic leak. In the literature, there is no universally acknowledged definition of an anastomotic leak. The magnitude of anastomotic leakage has been observed to range between 0.5% and 21% after colorectal resections. Intraoperative transfusion, prolonged surgery (>3 hours), and emergency surgery are well-known factors for anastomotic leak. The frequency of clinically severe AL after colorectal surgery is much higher, with mortality rates ranging from 12% to 27%.

Objective: is to assess the magnitude and associated factors for anastomotic leak after colorectal surgery.

Methods: A 5-year retrospective cross-sectional study was done at St. Paul's Hospital Millennium Medical College, a teaching institution that also functions as a tertiary referral hospital in Addis Ababa, Ethiopia. All patients who experienced anastomotic leaks following colorectal surgery between 2018 and 2022 were evaluated. Data was gathered from patient charts and the OR log book using a data collection format. SPSS Statistics Version 25 was used to examine the data. The magnitude of leaks was determined, then pre-, intra-, and postoperative associated factors were identified and evaluated.

Result: - A total of 270 patients were evaluated for anastomotic leak in the study period. 68.6% were male and 31.4 were female. The median age of patients were 45 years. Most of the patients 36.5% were from Oromia region. The magnitude of anastomotic leak in this study was slightly higher than the previous study finding in SPHMMC and accounts for 8.1%. A total of 137 patients had initial diagnosis of redundant sigmoid and 65.9% of all pathologies were benign. Sigmoidectomy was the commonest procedure performed on emergency and elective bases. Hypertension was the commonest comorbidity noticed among study group (15.1%). While majority of patients had ASA1 (71.6) it had no significant effect on outcome.

Conclusion: In this study the magnitude of anastomotic leak following colorectal anastomosis was comparable to global and country data, even though malignant pathologies were found to

have influence in AL and majority of patients operated were male, factors such as ASA, comorbidities, age and gender had no noticed effect on AL in our study.

Keyword's: Anastomotic leak, sigmoidectomy, hemicolectomy, colorectal anastomosis.

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ACRONYMS AND ABBREVIATIONS

- **AL:** Anastomotic leak
- **ASA:** American society of anesthesiologists
- **CCI:** Charlson Comorbidity Index
- **CRC:** Colorectal Cancer
- **DC:** Data collectors
- **DM:** Diabetes Mellitus
- **DS:** Data supervisors
- **ECF:** Enterocutaneous fistula
- **GUH:** Gonder University Hospital
- **Hct:** Hematocrit
- **HDU:** High Dependency Unit
- **Hgb:** Hemoglobin
- **IRB:** Institutional Review Board
- **ISREC:** The International Study Group of Rectal Cancer
- **MIIH:** Menilik II Memorial Hospital
- **MRN:** Medical Record Number
- **PI:** Principal investigator
- **PAT:** Penetrating abdominal trauma
- **RVI:** Retroviral infection
- **SPHMMC:** St. Paul's Hospital Millennium Medical College
- **SPSS:** Statistical Package of Social Science
- **TASH:** Tikur Anbessa Specialized Hospital
- **USA:** United States of America
- **WBC:** White blood count

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1. Introduction:

1.1. Background

Colorectal surgery is performed for many conditions benign, malignant or trauma effecting rectum and colon. One of the most serious consequences of colorectal surgery is an anastomotic leak. Anastomotic leak following colorectal surgery contributes to significant morbidity and mortality. The magnitude of anastomotic leak after colorectal surgery was reported to be between 2% and 19% and the mortality related fistula was reported to be between 0.8% and 27%(1). On the other hand, a prospective study conducted in Spain addressing anastomotic leak following only colonic resection revealed a magnitude of 8.7%, and it widely varied between hospitals (2) Prevailing evidence demonstrated that AL is an important cause of delayed postoperative recovery, poorer survival, increased length of hospital stay, and elevated risk of other complications, and accounts for considerable patient suffering and substantial health care costs (3). The majority of literature addresses associated factors for AL after colonic and rectal resection. Typically, AL is higher after rectal resection. The magnitude and associated factors of AL following colonic resection may be masked by mixed studies (2)

Many risk factors for AL following colorectal surgery are identified in the literature. Factors are classified into modifiable or nonmodifiable, pre-, intra- or postoperative and patient, hospital or surgery related(4) Several leakage scores were developed to help surgeons to provide an objective assessment of the risk of AL(5)

1.2. Statement of the Problem

Colorectal surgeries are common procedures done for different pathologies and traumas. One of the most dreadful complications of colorectal surgery is anastomotic leakage. The variation in defining an anastomotic leak has been a dilemma. Following several attempts to develop a standard definition, The International Study Group on Rectal Cancer (ISREC) aimed to solve this in 2010. The definition proposed describes AL as comprising all types of leakage, ranging from an asymptomatic leakage to a leakage resulting in a life-threatening condition. A grading system was also suggested(6). Anastomotic leakage incidence varies significantly between 2.6 % and 19% worldwide(7). In a retrospective study done at SPHMMC, the magnitude of AL was 5.2%;

similar studies in TAH and Gondor resulted in 10.8 and 9.2, respectively (8)(9) which shows a considerable difference compared to the SPHMMC study.

A prospective study was conducted in Valencia, Spain, in 52 hospitals. The number of patients who underwent colonic resection for CRC was 3193. A percentage of 8.7 had anastomotic site leakage postoperatively. The AL rate widely varies between studies. In previous publications, including both colon and rectal resections, it ranged between 3.0% and 15.9%, whereas in publications including only colon resection, the AL rate ranged from 3.0% to 6.4%(2). Male sex was an independent risk factor for AL in both colonic and rectal resections. This can be explained by a narrow pelvis in males when it comes to rectal anastomosis. However anatomical justification is not acceptable with colonic resection.

1.3. Significance of the Study

In Ethiopia, there have been few published studies on this topic. Two years have passed since colorectal surgical services started being provided at St. Paul Millennium Medical College (SPHMMC). A fellowship program in colorectal surgery has been in place for almost a year now. These factors may have helped reduce the incidence of AL. The magnitude of colorectal pathologies is considerable, and there are many colorectal procedures being performed. Despite this, there is a lack of knowledge about factors predicting an anastomotic leak. An anastomotic site leak is a serious and dangerous complication of colorectal surgery that can be fatal. As a result, it should be highly suspected, detected early, and avoided as much as possible.

The goal of this study is to highlight the magnitude of anastomotic leaks in the postoperative period using patients chart review. This study's findings will aid in the prevention of anastomotic leaks. The results of this study will help to improve the quality of surgical care that is being provided by recommending possible means of identifying associated factors of anastomotic leak pre-, intra-, and postoperatively. This will reduce the incidence of postoperative leaks. Hence, it will help to improve patient's quality of life and decrease health care costs as well. The findings of this research will help us develop a protocol for the prevention and management of AL.

2. Literature Review

2.1. Definition of anastomotic leak

There is some variation in the agreed-upon AL definition .According to the 1991 United Kingdom Surgical Infection Study Group, AL was defined as "leak of luminal contents from a surgical join between two hollow viscera" diagnosed (1) radiologically, by a radiographic enema with hydrosoluble contrast or by computerized tomography (CT) with presence of intra-abdominal collection adjacent to the anastomosis; (2) clinically, with evidence of extravasation of bowel content or gas through a wound or drain; (3) by endoscopy; (4)or intraoperatively(10).

The International Study Group of Rectal Cancer (ISREC) made an attempt to solve this variation dilemma in 2010. AL was defined by ISREC as "a communication between the intra- and extra-luminal compartments caused by a defect in the integrity of the intestinal wall at the anastomotic site." Furthermore, even if no communication with the bowel lumen could be proven, a pelvic abscess near to an anastomosis was thought to be the result of a leak(11).

The definition of clinically apparent anastomotic leakage is: 1) fecal fistula to the skin or vagina; 2) fever of more than 38 degrees centigrade or septicemia 3) Radiological or Endoscopic signs of anastomotic leakage 4) Intra-peritoneal abscess or peritonitis in the presence of an anastomotic leak(7).

A proposed clinical grading system by the International Study Group of Rectal Cancer (ISREC). This classification ranks an anastomotic leakage into 1 of 3 grades (grade A, B, or C) according to its impact on clinical management. Grade A anastomotic leakage corresponds to the definition of radiologic leakage'' used by several authors. This grade of AL is not associated with clinical symptoms or abnormal laboratory tests, and no active therapeutic intervention is required. Sometimes turbid or feculent contents may come from the drains. Otherwise, the initial postoperative course is usually uneventful. The leakage is commonly detected by contrast enema studies. While an anastomotic leakage is classified as grade B when the patient's clinical condition requires an active therapeutic intervention that can be managed without operative reintervention, Commonly, administration of antibiotics and/or radiologic placement of a pelvic drain or transanal lavage Patients are in mild to moderate distress, presenting with abdominal and/or pelvic pain and possibly abdominal distension. Turbid or feculent content through the

drain may be seen. Their laboratory tests usually display leukocytosis and/or an increase in serum C-reactive protein. Patients with grade C anastomotic leakage are often ill and require operative re-laparotomy. In the majority of patients, the anastomosis is taken down with the creation of a descending colostomy (Hartmann's procedure). These patients present most often with purulent or fecal drain contents in their drains and markedly increased parameters of infection. They usually have abdominal pain and fever and develop signs of peritonitis (6).

2.2. Magnitude of anastomotic leak

There are significant differences in the magnitude of AL following colonic surgery. The majority of the literature focuses on AL in both colonic and rectal surgery. Considering that AL is usually higher following rectal surgery. This could have resulted in erroneous results.

A prospective study was conducted in Spain on 3193 patients operated on for colonic cancer with primary anastomosis without stoma; 8.7% had AL(12). A similar study was carried out on 1025 patients in France and resulted in 36 (3.5%) cases of AL(13).

Koianka et al. conducted a study on 616 patients in the USA and included both colonic and rectal anastomosis without stoma; 5.7% had leaks(14) In Bosnia and Herzegovina, 23 (14.5) of 159 patients were operated on for CRC and had AL after a retrospective study was conducted(15).

In the Netherlands a retrospective study was carried out on 121 patients diagnosed with left colonic ca. Anastomotic leakage occurred in 10 of 121 cases (8.3%) that did not receive a nonfunctional stoma and in two of 18 cases with a nonfunctional stoma. The magnitude of leak was 4/101 after colonic resection and 8/38 after rectal resection(16).

Krarup et al. published a retrospective study done in Copenhagen, Denmark. The aim was to assess whether comorbidities can predict AL. Total of 8597 patients were included in the study. The magnitude of AL was 6.2% (535 patients)(3). Research on 348 patients in Nigeria was

undertaken to determine the magnitude of anastomotic leak, and 6% of them reported leak from the anastomosis(17).

Kassahun and colleagues conducted research at Gondar University's School of Nursing in Ethiopia. Anastomotic leak was shown to occur in 9.2% of 411 participants in research. The most location of intestinal anastomosis was in large intestine (50.9%), and the magnitude of anastomotic leak vary based on the type of anastomosis with entero-enteric having the lowest leak rate (1–2%) and colorectal/coloanal having the highest (4–26%), Ileocolic (1–4%), colo colic (2–3%), ileorectal (3–7%), and ileoanal pouch (4–7%)(9).

A retrospective study was designed to assess the magnitude and associated risk factors for anastomotic leakage in a period of three years at Tikur Anbessa Specialized Hospital (TASH) and Menilik II Memorial Hospital (MIIMH). Among the patients operated a total of 17 patients developed postoperative anastomotic leakage, which makes the rate of leakage 10.8% (8).

2.3. Associated factors for anastomotic leak

Emily F. Midura et al. conducted a study on 13,684 patients in Ohio, USA. The overall leak rate was 3.8%. Male sex, steroid use, smoking, open approach, operative time (>3 hours), and preoperative chemotherapy were associated with increased anastomotic leaks. An increased length of stay (13 vs. 5 days) and increased 30-day mortality (6.8% vs. 1.6%) were also seen in patients who experienced leaks. These patients also experienced increased readmission rates (43.5% vs. 8.3%) and were 37 times more likely to require reoperation as a complication of their primary procedure (18).

Rencuzogullari et al. carried out a retrospective study in Ohio, USA, on 10,392 people aged 65 or older who underwent elective colectomies. The aim was to study associated factors of anastomotic leak in elderly patients after colectomy. AL occurred in 332 patients (3.2%), among whom 57.8% were men. ASA scores III and IV, chronic obstructive pulmonary disease, smoking history, DM, and open surgery and prolonged operation time were found to be independent factors of AL, with male sex being a significant independent associated factor of AL. The study

agrees with previous studies on considering male sex as a contributing factor for AL in the context of rectal surgery, as the male pelvis is narrower. Additional studies are needed to explain the association with colonic resection. Findings of the current study showed an increased risk for AL in patients receiving corticosteroids before colonic surgery. This knowledge helps when considering the optimal timing of surgery and whether to create a diverting stoma. In terms of nutritional status, the same study found that recent weight loss was an independent associated factor of AL. Preoperative dietary support that results in weight restoration may minimize the magnitude of AL in the elderly (19).

In Spain, a study was designed by Frasson et al. to address associated factors for anastomotic leakage after colon resection for cancer. This study, along with the studies by Krarup et al., Kube et al., and Masoomi et al., all of which included exclusively colon resection, concluded that male sex was an independent factor for AL. However, the reason for leakage in colonic resection is not clear. In an animal model, Ba et al. showed that androgens play an inhibitory role in intestinal endothelial function and established the importance of sex in intestinal microcirculation. No studies carried out on humans prove that yet. Nutritional status is an important factor that contributes to AL. This study's data reveal that a low level of serum total proteins is an independent factor for AL. Other publications corroborate the findings of this study, as they report a correlation between AL after colorectal resection and low levels of serum albumin or total proteins. Several studies have demonstrated the importance of preoperative and perioperative enriched enteral nutrition in diminishing postoperative complications in malnourished oncologic patients. Preoperative enteral nutrition should be recommended for these patients to reduce the magnitude of AL (2).

Previous data on the relationship between AL and comorbidity is contradictory. Several studies have reported associations between the ASA score and anastomotic leak, whereas others found no association. A study from Denmark on the association of comorbidity with AL considered that the divergence is hardly surprising given the fact that the ASA physical status classification was not intended for the prediction of perioperative risk. Associated factors with AL are desirable because patients could potentially be allocated to a tailored surgical treatment, advising

against primary anastomosis in high-risk patients to avoid the immense risk of short-term mortality and inferior oncological outcome following AL (3).

The Charlson Comorbidity Index (CCI) is a grading system reflecting the cumulative likelihood of 1-year mortality and was originally intended for use in longitudinal studies. The CCI is based on 19 disease conditions, each assigned a weighted score. A recent study used both the ASA and the CCI systems to investigate the association between comorbidity and AL. The authors found no association between CCI and AL, whereas a high ASA score was associated with an increased rate of AL. In conclusion, comorbidity failed to predict AL in elective patients with colonic cancer. However, comorbidity increased 30-day mortality and LOS in patients with AL. These findings indicate the importance of including comorbidity in preoperative planning, especially in patients at increased risk of AL (3).

Gutema Wako et al. conducted a 4-year retrospective study at SPHMMC, a tertiary hospital in Addis Ababa, Ethiopia, for which they studied 221 patients. The mean age of patients was 46.44 (SD = 19.1), with a range of 1 to 85 years. Males accounted for 166 (74.8%) of the patients. Anastomotic leakage occurred in 12 (5.2%) of the patients. The mean time to diagnosis was 9.55 days (95% CI, 7.2-11.8) after surgery. Univariate analyses showed high preoperative levels of creatinine, ASA scores III and IV, emergency operations, operative times greater than three hours, and malignant diseases were associated with colorectal anastomosis leaks (7).

A descriptive study was carried out by Zemenfes et al. to assess the magnitude and association of different factors with anastomotic leakage. A total of 157 patients were operated on for whom intestinal anastomosis was done from 2014 to 2016 at TAH and MIIH. An anastomotic leak was detected in 17 of them. There was a statistically significant association between emergency presentation, ASA class (3), and the need for intraoperative blood transfusion with the occurrence of anastomotic leakage. According to this study, the site of anastomosis has no significant association with leakage in the small bowel (5%) or large bowel (12.2%), but mortality was higher in those who leaked after an anastomosis done in the rectum and small intestine. Other factors like sex, age, involved part of the bowel, type of pathology, and serum albumin level did not show a statistically significant association (8).

Kassahun et al. conducted a retrospective analysis at Gondor University that found a similar rates to the TAH study. Clinical anastomotic leak was linked to age groups 0–10, emergency presentation, and concomitant conditions. Patients with an emergency presentation were three times more likely to leak. Those with concomitant illnesses were 7.6 times more likely to develop clinical anastomosis. Clinical anastomosis leakage was 6.8 times higher in the age group 0–10 than in the age group ≥ 61 . This finding contradicted findings from other countries (9).

3. Objectives:

3.1. General Objective:

- To assess the magnitude and associated factors for anastomotic leak after colorectal surgery at SPHMMC.

3.2. Specific objectives:

- To determine the magnitude of anastomotic leak following colorectal surgery at SPHMMC.
- To assess factors associated with the occurrence of anastomotic leak in colorectal surgery at SPHMMC.

4. Methodology:

4.1. Study setting:

This study was carried out at St. Paul's Hospital Millennium Medical College in Addis Ababa, Ethiopia. With 100 surgical beds and 4 HDU beds, St. Paul's Hospital Millennium Medical College serves as a teaching hospital for both undergraduate and graduate study. The study includes all patients who had colonic anastomosis between 2018 to 2022. The surgical department has about 18 actively working consultant general surgeon. There are four colorectal surgery fellows currently training while study is conducted. Significant number of procedures is performed on monthly.

4.2. Study Period:

January 1st, 2018 to December 31st, 2022.

4.3. Study Design:

A retrospective cross-sectional study was conducted to assess the magnitude and factors associated with anastomotic leak in colorectal surgery.

4.4. Study Population:

All adult patients who underwent colorectal surgery at SPHMMC's surgical department and subsequently developed an anastomotic site leak during the study period make up the research populations.

4.4.1. Inclusion criteria:

- All adult patients over the age of 18 who received colorectal surgery at SPHMMC

- Patients who underwent colorectal operations on an emergency and elective basis are included.
- All patients for whom colorectal resection and a single primary anastomosis with no protective stoma was performed.

4.4.2. Exclusion criteria:

- Those charts of patient with incomplete data.
- Patients who had protective stomas
- All patients operated elsewhere and referred to SPHMMC.

4.5. Sample Size:

All patients who underwent colorectal resection at SPHMMC between January 1st, 2018 and December 31st, 2022 fulfills the inclusion criteria.

4.6. Measurement:

4.6.1. Study Variables:

Dependent variable

- Anastomotic leak

Independent variable

- Age
- Gender
- Type of resection

- Anemia
- Co-morbidities and ASA class
- Duration of surgery
- Nutrition
- Urgency of surgery
- Type of pathology: Benign vs Malignant

4.7. Data Collection and Procedures:

Data was collected using a structured data checklist, which was prepared after a thorough literature review on anastomotic leak in colorectal surgery. The checklist was developed in English and used for this investigation. Records from the operation theater registry and ward log books of patients who had colorectal surgery and suffered anastomotic leaks between January 1st, 2018 and December 31st, 2022, were taken for this study and utilized to retrieve individual patient cards from the record room. Socio-demographic information such as gender, age, occupation, and residency were documented. Preoperative, operative, and postoperative information, such as pathology, urgency, duration, and type of surgery performed, including Preoperative creatinine, hemoglobin, and albumin levels were checked and documented in the data collection format.

4.8. Data Quality Control and Management

A team of five data collectors (General Practitioners) were given training on how to collect the data and fill in the data on a computer. The data collected were checked daily by the principal investigator for relevance and adequacy. Epi Info. was used for data entry and validation.

4.9. Data Analysis Plan and Procedures

The data obtained from the completed chart reviews were analyzed on the computer using Statistical Package for Social Sciences (SPSS) version 25.0. Means, standard deviations, and percentages were calculated. Descriptive and inferential statistical methods, which include line

graphs, tables, pie charts, and bar charts was used to analyze this study. Binary and multiple logistic regression analyses was used to assess the association between dependent and independent variables. A P-value of less than 0.05 was considered statistically significant.

4.10. Ethical Consideration:

Ethical clearance was obtained from surgery Department's Research and Publications Committee of St. Paul Hospital millennium medical college. Waiver of consent was obtained from SPHMMC patients Data and registry head office. Data was collected confidentially and was recorded and analyzed with coded instruments, and study subjects' identifiers were excluded.

4.11. Operational definition:

Anastomotic leak: is defined as a communication between the intra- and extra-luminal compartments caused by a defect in the integrity of the intestinal wall at the anastomotic site.

Postoperative complications: are defined as any complication related to colorectal surgery within 30 days of the surgery.

Intraoperative complications: are defined as unexpected adverse events during procedure due to surgery or anesthesia.

5. RESULT:

Socio-demographic characteristics:

The research was done retrospectively in the past 5 years and out of the 310 colorectal surgeries, 30 cards were not found and 10 had incomplete data so 270 were assessed. From these 22(8.1%) patients had anastomotic leak. The median age of patients was 45yr with a range of 19-84 years. About 186(68.6%) patients were male whereas 83(31.4%) were females with male to female ratio of 2.2:1. 28.2% of patients are from Addis Ababa while 36.5%, 5.9%, 1.2%, and 1.2% are from Oromia, Amhara, Tigray, and SNNRP respectively and 27% of patient's addresses were not mentioned. 18.2% of patients were farmers while 26.2% had private job, 17.1% were housewives and 19.4% were students.

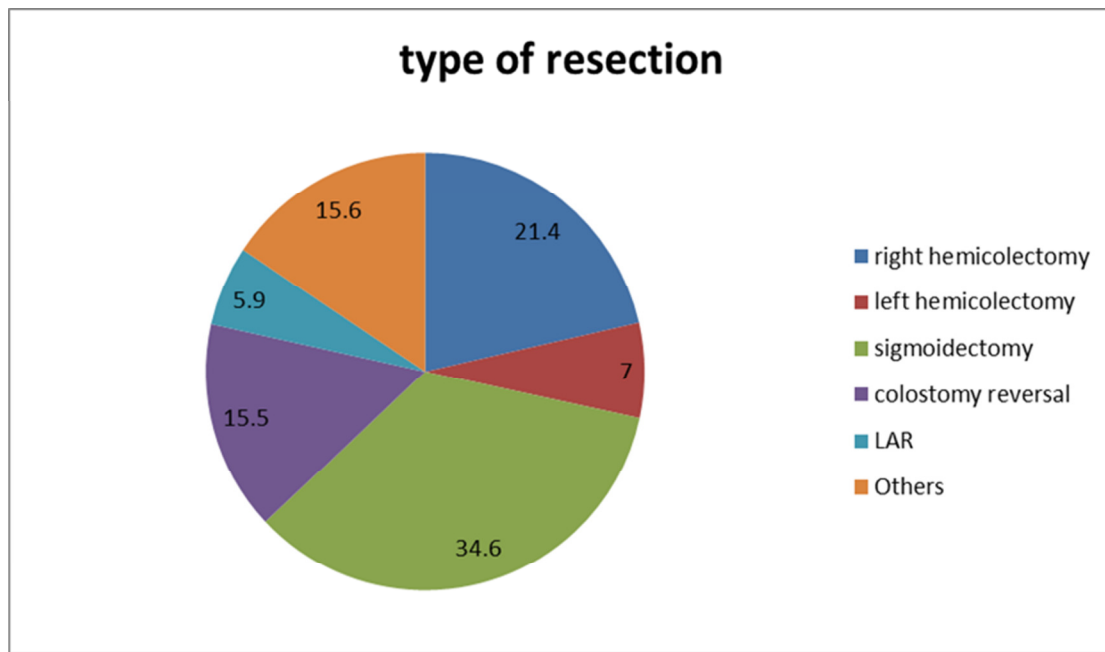
Preop diagnosis and related factors:

Initial diagnosis of most patients is redundant colon and complication (134), colon and rectal cancers (83), intussusception (12), traumatic injury (12), Inflammatory bowel disease (11), Intestinal TB (3), Mesenteric ischemia (3) and others (12). When assessing the condition of the diagnosis 178(65.9%) are benign and 92(34.1%) are malignant. From the malignant 92 cases only 8% took neoadjuvant chemotherapy. 83 patients had tumors which is located at appendix (5) and cecum, (8) hepatic flexure (4), ascending colon (11 patients), transverse colon (3), descending colon (9), sigmoid (19), rectum (16) and splenic flexure (3), Rectosigmoid junction (5). 2.2% of those tumors were found perforated at the time of diagnosis.

Among the surgeries 33.3% (90) were performed by colorectal fellow while 45.6% (123) and 21% (57) were performed by general surgeons and residents only respectively. From the performed operations 224 (83%) are elective while 46(17%) are emergency. Type of surgeries performed were sigmoidectomy, right hemicolectomy and left hemicolectomy which accounts for 34.6 %, 21.4% and 7% respectively. The remaining accounts for other procedures like

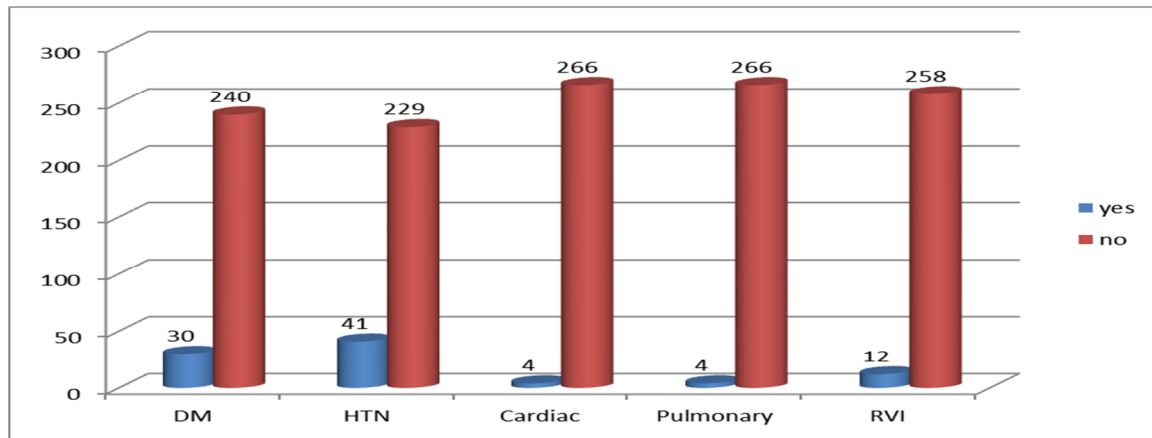
colostomy reversal (15.5%), LAR (5.9%) and others. The mean preoperative WBC is 8.2 with neutrophil of 64.3%, the mean hemoglobin and hematocrit is 13.5 and 35.2%. the mean preoperative albumin and creatinine is 2.5 and 0.94 respectively.

Figure 1: type of resection in percentages



From the co-morbid conditions DM, HTN, pulmonary, cardiac and HIV were assessed and they had response rate of 11.1%, 15.1%, 1.2%, 1.2% and 4.4% respectively. Other comorbid conditions were BPH, CKD, HBV and TB. 20 (7.4%) of patients were found to be smokers. ASA classification of patients includes class I, II, III and IV with rate of 71.6%, 24 %, 3.7% and 0.4% respectively.

Figure 2: number of patients with different comorbidities



Anastomotic leak symptoms, signs and imaging:

The mean onset of symptoms suggesting of anastomotic leak is 5 days with a range of 2-12 days. Among presenting symptoms abdominal pain, fecal/ pussy discharge from incision or drain, fever, abdominal distention and peritonitis has rate of 86.3%, 63.6%, 10.7%, 36.4% and 6.3% respectively. 1.5% had vomiting, 1.9% had diarrhea and 0.7% patient presented with low BP and tachycardia respectively.

31(11.4%) of the patients had documented ultrasound among which 22 patients had echo-debris, multiseptated or complex collection. 1 patient had CT report showing LBO and another 2 patients with erect abdominal X-ray result of LBO.

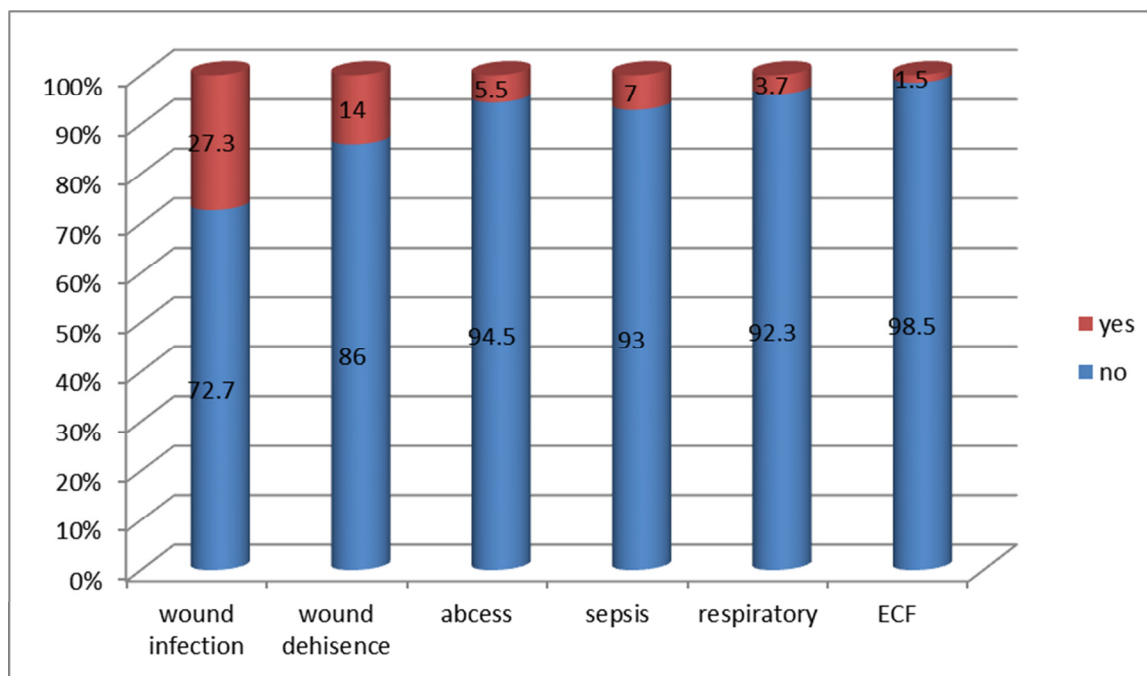
During the study period 33(12.2%) patients underwent re-laparotomy for post-operative complications. From which 22 patients had anastomotic leak ,15(5.5%) patients intrabdominal abscesses. A number of 10(3.7%) required conservative management with daily wound care and 82.6% required no interventions. Among patients that underwent re-laparotomy 33, (16 patients) had diverting stoma, (1 patient) had resection and anastomotic and (2 patient) had anastomotic site reinforcement. 3 patients were unfit for surgery form the complication of the leak.

The mean time of the procedure is 150 minutes with a range of 60-360minutes. 206 (76%) of patients' operation time was less than or equal to 3 hours while for 65(24%) of patient operation last more than 3 hours. 28 patients required intra op transfusion (22 required 1 unit and 2 patients required 2 units of PRBC). 15(5.5%) of patients had Intra-op/post-operative shock.

12(4.8%) patients had intra-op surgical complication where 7 patients had fecal matter spillage, 4 had iatrogenic injury and 2 patients had poor bowel preparation. 4 patients had anesthesia complication (low BP). 8 patients were admitted to ICU where they stayed 3 _ 16 days.

After the procedure complications like wound infection, wound dehiscence, intra-abdominal abscess, sepsis, respiratory and ECF were tried to asses and it was found 27.3%, 14%, 5.5%, 7%, 3.7% and 1.5% of patients had them respectively. 35 patients had post-operative ileus and 5 patients had moderate anemia. 20 patients required post op transfusion with 13 patients took 1 unit and 3 patients took 2unit of PRBC and 4 patient required 1 PRBC and FFP. Mean length of hospital stay is 18day with a range of 3-84 days. Among the patients 13(4.8%) have died in hospital with main cause is sepsis of GI focus or Massive PE. Among those patients 94.5% were discharged improved, 4.8% of them died in hospital and 0.4% went against medical advice. 19.6%(53 patients) were re admitted for indication of colostomy reversal (44), wound closure (4) and hernia repair (5). Among the patients, 257 had follow up among which 247 were improved, 4 were found on same condition and 6 patients were worse.

Figure 4: percentages of patient with different post op complications



Anastomotic leak and associated factors:

The relationships between procedural features, comorbidity, and demographic traits to AL were assessed. In univariate analysis, 5 associated factors were linked to AL: tumor location ($p=0.025$), condition of tumor ($p=0.015$), duration of the procedure ($p=0.031$), type of resection ($p=0.147$) and emergency operation ($p=0.000$). After being added to the multivariate logistic regression, emergency operation, duration of the procedure and nature of the tumor were found to be statistically significant. Patients who underwent emergency surgeries were 9.41 times higher chance of developing AL ($p=0.00$, AOR=9.41, CI=3.76-23.67). Operation that took more than 3 hours were 2.8 times higher chance of developing AL risk than less than 3 hour procedures ($p=0.031$, AOR=2.8, CI=1.123-7.234). Patients with malignant tumors have 3.9 times higher risk of developing AL ($p=0.03$, AOR=3.9, CI=1.564-9.54).

Between AL and age, gender, co morbidity and ASA classification no statistically significant correlation was found with p value of 0.79, 0.98, 0.86 and 0.471 respectively. Among the anastomotic leak patients 12 were male and 10 were female. In relation to surgery among patients with leak 13 were emergency and 9 was elective. In terms of ASA classification among the patients with AL, 14 were class I, 7 were class II and 1 were class III. 3 patients who had AL also had HTN, 2 had RVI and 1 had cardiac, and 1 also had pulmonary conditions.

Table 1: Anastomotic leak and associated factors

variables	Number and percentage		COR	AOR	CI	P value
Type of tumor	Malignant	83(31%)	0.256	3.912	1.501-9.541	0.03
	Benign	187(69%)				
Type of surgery	Emergency	46(17%)	0.187	9.41	3.721-23.75	0.000
	Elective	224(83%)				
Duration of the procedure	More than 3 hours	65(24%)	0.675	2.82	1.121-7.232	0.031
	Less than/equal to 3 hours	206(76%)				

6. Discussion

The records of 270 patients who underwent colorectal anastomosis throughout the study period were examined in total. Male to female ratio is 2.2:1, with roughly 186(68.6%) of patients who had anastomotic leak and this is comparable to that a global study where the rate of AL ranges from 0.5 – 21% (8) (9) (20) and comparable to previous study done in our country(7) Unlike the study carried in Spain that showed significant relationship between gender and AL(2) (3) In our study there was no statistically significant relation between AL and gender (7)(8) (9) Twelve of patients with anastomotic leaks were male, and ten of them were female and it shows no significant difference.

In our study, CRC anastomosis was performed on patients in all age categories, with a median age of 45 and a range of 19–84 years. Nine of the AL cases were over 65, while 10 were between 30 and 60 and three patients were younger than 30. The result doesn't show significant effect of age on AL, which coincides with studies done in most countries(1) (2) (7)(8).Our report was inconsistent with the findings of Kassahun et al. who included pediatric group and reported association between age and AL(9).

The majority of patients accounting for 134(49.6%), were found to have redundant sigmoid. Whether the initial presentation was gangrenous or viable. Followed by 30.7% of colorectal tumors, traumatic injuries (4.4%), and intussusception (4.4%). Making benign pathologies the leading cause of colorectal anastomosis at a rate of 178 (65.9%)(7). On the other hand, 92(34.1) % were malignant tumors, with left colonic tumors being higher (38%) followed by right colon tumors. When it comes to AL, eleven were operated for tumors, three for penetrating abdominal trauma, three for redundant colon, three for colostomy reversal and two for intussusception. 2.2% of patients presented with tumor perforation at the time of diagnosis. This shows the malignant nature of disease has affected the outcome of surgery and contributed to AL.

About 83% of colorectal surgeries, including tumor resection, sigmoid resection, and stoma reversal, were performed as elective procedures. The remaining 17% percent were emergency cases. AL risk was shown to be increased in patients who underwent emergency surgery. This is study has found 15 out 22 patients who leaked were operated as emergency. Which support the previous SPHMMC research regarding contribution urgency of procedure to AL(7).

The average albumin level among the 270 people was 2.62, and creatinine was 0.8/ mg/dl. Two patients with AL experienced acute renal injury. This study showed no significant association between AL and preoperative AKI. Unlike the study conducted in Denmark by Krarup et al.(3)(7) which found an association when the AKI is moderate to severe.

The majority of patients lacked recent serum albumin levels so it was difficult to assess the relationship. The commonest comorbidity in this study, accounting for 15.1% of cases, was hypertension, followed by DM at 11%. One patient with anastomotic leak was known to have high blood pressure. Not one was RVI. However, there was no significant association found between these conditions and the leaks in our research.

Arron et al. conducted a nine-year retrospective analysis in the Netherlands to analyze changes in rates and risk factors of AL (7)(20). The study indicated an association between ASA classification (≥ 3) and AL in CRC. Wako et al. noted that it was due to increased comorbidity rate (e.g., cardiovascular or pulmonary disorders), which could affect tissue perfusion and oxygenation. Our findings were inconsistent with those reported, and the majority of patients (71.6%) were ASA class 1(2).

This analysis shows that the mean preoperativeHgb was 13.5g/dl, and the hematocrit was 41.2%. Thirty percent of the patients who leaked needed a blood transfusion due to preoperative or intra operative shock. While the mean duration of operations in our sample was 150 minutes, or less than three hours, eleven of the patients who had AL underwent long surgeries >3 hr. In our study, 13/22 who had leaked required intraoperative or postoperative blood transfusion. Four of the patients who leaked had pre- and intraoperative hypotensive records and were started on vasopressors. They were admitted to the ICU. Two of them died of refractory septic shock. Intraoperative blood transfusion was a significant contributor to AL in this study. This finding supports the research from Spain(2).

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7. Conclusion:

In our study the magnitude of anastomotic leak following colorectal anastomosis was comparable to global and country data, even though malignant pathologies were found to

influence anastomotic leak and majority of patients operated were male factors such as ASA, comorbidities, age and gender had no noticed effect on AL in our study.

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9. Annex

9.1. Annex I: Information Sheet

Research Title: Retrospective study on Magnitude and associated factors of anastomotic leak in colorectal surgery at SPHMMC; 2018-2022

Principal Investigator (PI): Akwon Lwal (MD, General Surgery Resident)

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Gelan Gebremichael (MD, General Surgeon, Assistant Prof. of Surgery & colorectal surgery fellow).

Binyam Yohannes (MD, General Surgeon, Assistant Prof. of Surgery& colorectal surgery fellow)

Sponsor: St. Paul's Hospital Millennium Medical College

9.2. Annex II: Data Collection Format

Data Collection Format		
MRN _____	Age _____	Sex Male ☐ Female ☐
Location of primary residence	Region _____ Town _____	Occupation
Initial diagnosis	_____	
Nature of the condition	Benign Yes ☐ No ☐ Type of condition _____	Malignant Yes ☐ No ☐ If YES , any history of neoadjuvant chemotherapy? Yes ☐ No ☐
Related to the tumor		
Tumor localization	Right colon ☐ Hepatic flexure ☐ Transverse colon ☐ Splenic flexure ☐	Splenic flexure ☐ Left colon ☐ Synchronous tumors ☐
Tumor perforation	Yes ☐ No ☐	
Recurrent tumor	Yes ☐ No ☐	
Type of resection	Right hemicolectomy ☐ Extended right hemicolectomy ☐ Left hemicolectomy ☐ Sigmoidectomy ☐ Others _____	Type of surgeon Colorectal fellow ☐ General surgeon ☐ Residents alone ☐
Type of surgery	Elective ☐ ☐	Emergency ☐

Preoperative Labs	WBC	Hgb/Hct	Serum Albumin	Serum creatinine
Co-morbid conditions	DM	Yes ☐ No ☐	RVI Yes ☐ No ☐ Unknown ☐	
	Hypertension	Yes ☐ No ☐	Others	
	Pulmonary disease	Yes ☐ No ☐		
	Cardiac disease	Yes ☐ No ☐		
Addictions	Smoking Yes ☐ No ☐			
ASA Class	I ☐ II ☐ III ☐ IV ☐ V ☐			
Anastomotic leak symptoms, signs and imaging findings				
Onset of symptoms Postoperatively	_____ days			
Symptoms and signs	Abdominal pain	Yes ☐ No ☐	Abdominal distention Yes ☐ No ☐	
	Fever	Yes ☐ No ☐	Fecal or pusy discharge from laparotomy incision or drain Yes ☐ No ☐	
	Signs of peritonitis	Yes ☐ No ☐	Others	
Imaging findings	Abdominal US	Yes ☐ No ☐	Comment:	
	Abdominal CT	Yes ☐ No ☐	Comment:	
	Other		Comment:	
Operative Procedures, Postoperative Complications, and Mortality				

Management options	Re-laparotomy Yes ☐ No ☐		
	Percutaneous drainage Yes ☐ No ☐		
	Conservative management Yes ☐ No ☐		
	If re-laparotomy was the choice. Was intraoperative diagnosis? Same ☐ Changed ☐ if changed specify _____		
Operation performed	Diverting stoma (ileostomy/colostomy) Yes ☐ No ☐	Resection and anastomosis Yes ☐ No ☐	
	Other _____		
Preop/intraoperative shock	Yes ☐ No ☐		
Length of procedure	_____in minutes	Intraoperative transfusion?	Yes ☐ No ☐ If yes, how many units _____
Intraop surgical complication?	Yes ☐ No ☐	If yes, mention the complication _____	
Intraop anesthesia complication?	Yes ☐ No ☐	If yes, mention the complication _____	
ICU admission	Yes ☐ No ☐	If yes, length of ICU Stay _____ (in days)	
Post-operative complications	Yes ☐ No ☐	Wound infection Yes ☐ No ☐ Wound dehiscence Yes ☐ No ☐ Intra-abdominal abscess Yes ☐ No ☐ ECF Yes ☐ No ☐	Sepsis Yes ☐ No ☐ Cardiovascular Yes ☐ No ☐ Respiratory Yes ☐ No ☐ Others _____
Post-operative transfusion	Yes ☐ No ☐	If yes, how many units _____	
Re-exploration?	Yes ☐ No ☐	IF yes, reason and outcome _____	

Total hospital stay	_____ in days	In hospital death? Yes ☐ No ☐ If yes, cause of death _____		
Condition on discharge	Improved ☐	Same ☐	Worse ☐	Death ☐
Readmission?	Yes ☐ No ☐	If yes, reason _____		
Follow up visit	Yes ☐ No ☐	If yes, Improved ☐ Same ☐ Worse ☐ If new complaint, specify _____		

9.3. Annex III: Assurance of Investigator

I the undersigned resident agree to accept all responsibilities for the scientific, ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the Research and Publication Directorate and /or Department of Public Health of St. Paul's Hospital Millennium Medical College.

Name of the Resident: Dr. Akwon Lwal

Signature: _____

Date: _____

Approval of Advisors

Name of Clinical Advisor: Dr. Mulugeta Kassahun

Signature: _____

Date: _____

Name of Clinical Advisor: Dr. Gelan Gebremichael

Signature: _____

Date: _____

Name of Clinical Advisor: Dr. Binyam Yohannes

Signature: _____

Date: _____