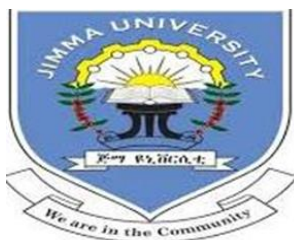


JIMMA UNIVERSITY



**PREVALENCE AND RISK FACTOR OF GASTROINTESTINAL  
ANASTOMOTIC LEAK AMONG ADULT SURGICAL  
PATIENTS AT JIMMA MEDICAL CENTER**

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A RESEARCH PROPOSAL TO BE SUBMITTED TO SCHOOL OF MEDICINE, COLLEGE  
OF HEALTH SCIENCE, DEPARTMENT OF SURGERY IN PARTIAL FULFILLMENT FOR  
A SPECIALTY CERTIFICATE IN GENERAL SURGERY

# Prevalence and risk factors of gastrointestinal anastomosis leaks among adult surgical patients at Jima Medical Center

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## Abstract

**Background:** Gastrointestinal(GI) resection and anastomosis is a common surgical procedure. As reported in most literature, the anastomotic leak is a complication affecting 1.8-26% of patients undergoing GI anastomosis, and once occurred is known to adversely affect the clinical outcome of and economic burden to the patient. There are various factors contributing to the development of a leak. This study was designed to assess the prevalence and associated risk factors for anastomotic leakage over three years retrospectively.

**Objective:** To determine the prevalence, risk factors, and outcomes of GI anastomotic leak among adult surgical patients who had GI anastomosis at JMC, Jima, southwest Ethiopia from October 1, 2019, to October 30, 2022.

**Method:** An institution-based retrospective cross-sectional study was conducted in Jima, southwest Ethiopia, from October 1, 2019, to October 30, 2022, on 186 surgical patients who underwent GI anastomosis and fulfilled the inclusion criteria. Data was collected, cleaned, coded, and analyzed using SPSS 26.0. Statistical analysis including bivariate and multivariate correlational analysis was done to look for associated variables with a p-value of 0.05 taken as significant.

**Result:** One hundred eighty-six patients are included; 74.2% male and 25.8% female, with a mean age of presentation of 41.7 years. Anastomotic leak(AL) occurred in 12(6.5%) of patients. The mean ( $\pm$  SD) time of post-op AL Diagnosis is 7(  $\pm$ 2.6) days. The diagnosis was made clinically with or without evidence of GI content coming through the wound in 77%. Factors found to significantly associate on bivariate analysis include: the urgency of surgery, intraoperative evidence of intraperitoneal contamination and/or peritoneal infection, need for pre or intraoperative blood transfusion, and perioperative use of vasopressor. The multivariate logistic regression model failed to identify any of these factors as an independent predictor. AL was also found to adversely affect the outcome. The odds of having a relaparotomy done increase by 37 times in patients with AL (P value=0.000); Increases likely hood of staying >2 weeks by 2.7 times(P value=0.044); and mortality after the leak is increased by a factor of 12.5 (p-value =0.04).

**Conclusion:** Anastomotic leak continued to be a common complication of GI anastomosis; more importantly, in emergency scenarios where there is a chance of contamination and peritoneal infection, and physiologic derangement in the patient resulting in blood and vasopressor use. It is also found to significantly increase the relaparotomy rate, hospital stay, and in-hospital mortality.

**Keywords:** Anastomotic leak; Risk factors; Prevalence, Ethiopia

## **List of abbreviations**

ASA-American society of anesthesiologist

AL-anastomosis leak

CKD-chronic kidney disease

COPD-chronic obstructive pulmonary disease

DM-diabetes mellites

GI-gastro-intestinal

Hct- hematocrit

HTN-hypertension

IBD-inflammatory bowel disease

JMC-Jima medical center

LBO-large bowel obstruction

OR-operation Room(theater)

RVI-retroviral infection

SBO-small bowel obstruction

SBV-small bowel volvulus

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## **CHAPTER ONE: INTRODUCTION**

### **Background**

Intestinal anastomosis is one of the commonly performed surgical procedures, both in emergency and elective surgeries for benign or malignant lesions of the GI tract. Several complications may occur following anastomosis of which anastomosis leak is the most feared one(1).

An anastomotic leak can be used as an indicator of the quality of surgical care, and comparisons can be made within and between centers, which depends on standard definitions. Moreover, there is no universally accepted definition of an anastomotic leak at any site and The definitions and values used to measure anastomotic failure vary extensively(2). The UK Surgical Infection Study Group defined an AL as ‘a leak of luminal contents from a surgical join between two hollow viscera.’ These contents can exit through wounds or drains or collect at the anastomotic site (3).

To mitigate the sequelae of an AL surgeons may choose to create a defunctioning stoma or to avoid an anastomosis altogether by forming an end stoma. A defunctioning stoma decreases the severity of sepsis due to an anastomotic leak, reduces the need for emergency reoperation, and reduces mortality. However, forming a defunctioning stoma is a difficult decision and one that patients and surgeons, will naturally wish to avoid (4).

There are many factors associated with AL and they include patient-related factors like Age >60 years old, Cardiovascular disease, Malnutrition, Steroid use, male Gender, Diabetes, Alcohol use, Hypertension, ASA fitness score, Tobacco use, Diverticulitis and Leukocytosis and surgical factors which include Poor anastomotic blood supply, Intra-operative sepsis, Peritonitis, Poor colonic preparation, Operative time >3 h, Peri-operative blood transfusion, Pre-operative Anastomotic ischemia or tension, radiotherapy, Emergency resection, and Anastomotic location.(1,5,6)

Most anastomotic leaks usually become apparent between 5 and 7 days postoperatively. As clinical signs and symptoms are nonspecific and overlap normal post-operative inflammatory and physiological responses, clinicians make use of both laboratory tests and radiologic studies

to aid in diagnosing AL.(7). The patients can be managed conservatively, intervention radiologically or endoscopically, or with definitive surgery based on their degree of symptoms on presentation(8).

### **Statement of problem**

Anastomosis leak is the most dreaded complication after GI resection and anastomosis. The incidence is not uncommon as it occurs in 1.8-26% and significantly varies according to the location of the anastomosis along the GI tract and the definition used. Anastomotic leak rate along different parts of GI includes esophageal (9.6-14%), stomach (1.1-3.3%), small intestine (1.0-3.8%), ileocolic (2.0-6.5%), Colo colic (3.0-5.4%), colorectal (4.0-26%), and ileorectal (5.0-19%). there is higher AL associated mortality which exceeds 20% in many series(9).

AL will usually occur when many patient-related factors including Cardiovascular disease, Malnutrition, Steroid use, Diabetes, Alcohol use, Hypertension, ASA fitness score, Tobacco use, Diverticulitis, and Leukocytosis are not actively sought and optimized preoperatively whenever feasible and when a meticulous technique is not followed, and attention not given to every detail during surgery. In addition, meticulous surgical technique and attention to detail as evidenced by large series of carefully followed patients suggest that many leaks may be preventable(1,10).

AL usually occurs early and can have both short-term complications like septic or hemorrhagic complications and long-term consequence. Multiple reoperations and stoma creation are often necessary to control the leak. All these consequences significantly increase morbidity, mortality, length of stay, and overall cost to the patient, significantly affecting the quality of life of the patient. In addition, it also adds a burden to the health facility (11)

The best is to avoid the occurrence of the anastomotic leak by promptly identifying and taking care of associated risk factors, but after AL has occurred failure to detect and manage early will significantly affect overall prognosis and survival. Furthermore, Once AL occurred it will require extensive resources, personnel, and set up both to diagnose and treat. In Ethiopia, as in other Sub- Saharan countries where the resources are very limited, there is limited capability of diagnosing AL using different radiologic or clinical parameters, and there are few options of

management and support to be given to the patient once anastomotic disruption occurred. In addition, in our setup, there is no established assessment of risk factors for AL before surgical treatment and there are no established institutional guidelines for its management. to my knowledge, there is no study conducted on this subject in our institution. This mandates extensive studies to know different risk factors and the way to avoid this devastating complication of GI anastomosis.

### **Significance of the study**

This research will show the magnitude of the problem and its associated factor which will help us to reevaluate our practices to decrease the occurrence of AL in our setup. This study will also be used as valuable data and benchmark for future related research.

## CHAPTER TWO: LITERATURE REVIEW

### 3.1 PREVALENCE

The prevalence of AL after esophagectomy in the literature ranges from zero(12) to 34.1%(13). Factors incriminated for post-esophagectomy AL include the type of anastomosis, esophageal substitute, location of anastomosis (cervical or intrathoracic), whether it is a single or double layer, or whether done manually or with stapling, the stage of the tumor, the distance from the anastomoses line to the tumoral tissue, additional radiotherapy or chemotherapy used in the treatment, anemia, and album(13,14).

There are abundant studies conducted on the AL after colorectal surgery. studies indicate the leak rate ranges from 0.5 to 30 % (15–18). In contrast, there is limited data on small bowel AL. Few studies have reported the AL rate of 1 to 17.2% after small bowel resection and anastomosis, but slightly higher for ileocolic and ileorectal anastomosis(1,19–21).

A multicenter retrospective study done in Ethiopia involving 352 patients showed the overall GI AL rate was 9.9 %. The mean hospital stay was 12 days, with AL associated death rate of 48%. In the same study, AL rate along the GI tract in descending order was entero-enterostomy (17.2%), esophagectomy (16.3%), gastrectomy (10.5%), colorectal anastomosis (10.2%), ileocolic anastomosis (9.1%) and Colo colic anastomosis (4.2%). ileorectal anastomosis did not leak (1). A similar study done in the same country on 157 patients with intestinal anastomosis showed an AL prevalence rate of 10.8 % (5).

### 3.2 DEFINITION, MANIFESTATIONS, AND DIAGNOSIS

Most AL usually become apparent between 5 and 7 days postoperatively although there are also reports of a leak more than 30 days after index surgery(22). Moreover, surgeons clinical judgment failed to accurately predict the occurrence of AL in the specific patients(22–24).

The definitions and values used to measure anastomotic failure vary extensively and there is no universally accepted definition of AL at any site. In a systematic review of ninety-seven studies

measuring the AL rate after GI surgery at different sites, Bruce et al.(2) noted that there was a total of 56 separate definitions of an AL.

Many reports define an AL using clinical signs, radiographic findings, and intraoperative findings. The clinical signs include pain, fever, tachycardia, local or generalized peritonitis, feculent or purulent drainage, sepsis, and organ failure. those are usually nonspecific and may overlap with signs caused by normal post-operative inflammatory and physiological responses. Hence clinicians use a variety of laboratory tests like leucocyte count and CRP (C-Reactive Protein) to aid in diagnosis. In one study it is demonstrated that based on clinical assessments and blood tests 69% of AL patients had a delayed diagnosis which makes those parameters inadequate for identifying high-risk AL patients or for its early diagnosis(7,22).

Although there is still no definitive consensus on which imaging modality should be used for AL diagnosis, Current clinical practices for AL diagnosis rely on abdominal imaging (abdominal ultrasound, computed tomography (CT) scans, or water-soluble contrast enemas, in conjunction with the clinical and biochemical evaluation. Radiologic signs that can be depicted are the presence of extravasation of contrast, and other suggestive signs like extraluminal air and localized para-anastomotic collections. Gross enteric spillage and Anastomotic disruption are the possible intraoperative findings during reoperation(7,22).

### 3.3 RISK FACTOR

Risk factors can be categorized by most authors as patient-specific and surgical factors.

**Patient-specific risk factors** include:- Age >60 years old, Cardiovascular disease, low albumin, Steroid use, male Gender, Diabetes, Alcohol use, Hypertension, ASA fitness score, Tobacco use, Diverticulitis, and Leukocytosis(1,23,25,26).

**American Society of Anesthesiologists (ASA) score:** -Higher ASA score is a strong independent risk factor identified in many series. Comorbid conditions such as diabetes mellitus, hypertension, and cardiac disease as represented by an ASA score of 3, were associated impaired microcirculation required for a healthy anastomosis(5,17,27).

In addition, Patients with pre-operative weight loss, anemia, or low albumin levels are at increased risk of AL. works of literature also have demonstrated that the narrower male pelvis is associated with an increased incidence of AL (6)

**Surgical factors include:** -Poor anastomotic blood supply, Intra-operative sepsis, Peritonitis, Poor colonic preparation, Operative time >3-hour, Peri-operative blood transfusion, Pre-operative Anastomotic ischemia or tension, Emergency resection, and Anastomotic location.

**Anastomotic location:** - A significant AL risk factor is the anatomical location of where the anastomosis is performed in the GI tract. Phillips et al.(9) reported the rate AL as follows; stomach (1.1-3.3%), small intestine(1.0-3.8%), ileocolic(2.0-6.5%), Colo colic(3.0-5.4%), colorectal(4.0-26%), and ileorectal(5.0-19%). Another study involving 224 patients identified a leak in 22.2 % of colonic anastomoses, 9.8 % of small intestinal anastomoses, and 9.6 % of ileocolic anastomoses(28). Studies have also shown that anastomotic position in relation to the anal verge is important; resections performed in the mid/low rectum or <6 cm from the anal verge have been associated with significantly higher AL rates(27).

**Emergent surgery:** a prospective study which included 315 cases that underwent bowel anastomosis for small intestinal and colorectal pathology, showed the percentage of cases with an emergency type of operation was significantly higher in the leakage group (66.7% vs 42.01%). The same study showed serum albumin was significantly lower in the leakage group vs the no-leakage one (2.9 vs 3.9) (6). In a similar study done in Ethiopia, Emergency procedures and low serum albumin was significantly associated with AL(1,5).

**A prolonged operative time:-**prospective study which involved 811 colorectal resections anastomoses showed prolonged (>3 hr.) operative time is associated with increased AL with OR of 3.07 (p=0.02) (27).

Perioperative blood transfusion was described in many pieces of literature as independent risk factor for increased AL(5,28,29). Poor intestinal tissue oxygenation by either iatrogenic surgical disruption of the peri-anastomotic microvascular blood supply or tension at the anastomotic site

can compromise intestinal tissue perfusion leading to peri-anastomotic ischemia and necrosis and hence contribute to AL(29).

**Intra-abdominal infection from fecal contamination or peritonitis:-**The presence of peritonitis from perforated diverticulitis, a perforated colorectal cancer, colorectal trauma, or fecal contamination during colorectal surgery indicates the patient's nutritional and physiologic compromise which increases the rates of AL(1,29).

**Hand-sewn versus stapled anastomosis:-**A systematic review performed comparing outcomes after emergency laparotomy using stapled versus hand-sewn anastomosis failed to show differences in the individual rates of AL, abscess, fistulae, or postoperative deaths between techniques(30).

Postoperatively, the use of vasopressors may cause local tissue ischemia and increase the risk of anastomotic dehiscence. In a recent clinical series, the use of vasopressors increased the AL rate threefold in a dose-dependent manner(31).

### 3.4 CONSEQUENCE

AL in GI surgery is a major complication, often associated with increased postoperative morbidity, mortality, and duration of hospital stay. AL usually occurs early and can have both short-term complications like septic or hemorrhagic complications and long-term consequence. Multiple reoperations and stoma creation are often necessary to control the leak, which significantly increases health risks and health care costs up to 5 times that of patients with no leak(11).

### 3.5 TREATMENT OF ANASTOMOTIC LEAK

Once the diagnosis of AL is established, prompt early management improves the prognosis since it increases the possibility of preservation of anastomoses and reduces the duration of hospital stay. The goal of treatment is to control sepsis irrespective of its severity(8).

Therapeutic options include: conservative medical treatment for asymptomatic patients radiologic or endoscopic interventions for mild symptoms or surgery in severe cases (8,32)

## CHAPTER THREE: OBJECTIVES

### 2.1 General objective

- To determine the prevalence and the risk factors for gastrointestinal anastomotic leak among adult surgical patients who had GI anastomosis at JMC from October 1,2019 to October 30,2022.

### 2.2 Specific objectives

- To determine magnitude of anastomotic leak along parts of GI tract among adult surgical patients who had GI anastomosis at JMC
- To describe factors associated with AL among adult surgical patients who had GI anastomosis at JMC
- To determine mortality after GI anastomosis leak in adult surgical patients who had GI anastomosis at JMC



## CHAPTER FOUR: METHODOLOGY

### 4.1 STUDY AREA AND PERIOD

The study was conducted from October 1,2019 to October 30,2022, at JMC, Jima, Ethiopia. JMC is found in Jima town, which is located 350km southwest of Addis Ababa. It is the biggest teaching and referral hospital in the southwestern part of the country. It is one of the universities in Ethiopia known for its pioneer in community-based education. There are 10 departments (Internal Medicine, Surgery, Orthopedic surgery GYN/OBS, Ophthalmology, Dermatology, Psychiatry, pediatrics, dentistry, and Anesthesia) run by the Hospital.

The surgery department has the following sub-specialty unit; Plastic Surgery, pancreatic hepato-biliary surgery, pediatric surgery, Neurosurgery, and GI Oncology. There are 8 operation tables functional 5 days a week. The Surgical ICU has 8 beds and three functioning mechanical ventilators.

### 4.2 STUDY DESIGN

A retrospective cross-sectional study was used.

### 4.3 POPULATION

#### **Source population**

All Adult ( $\geq 15$  yrs) surgical patient admitted to surgical ward at JMC from October 1,2019 to October 30,2022

#### **Study population**

All adult (age  $\geq 15$  yrs) patients for whom GI resection and anastomosis was done at JMC during the study period who fulfilled inclusion criteria

#### Inclusion criterion

- All adult patients who underwent GI resection and anastomosis during the study period.

#### Exclusion criteria

- All patients who had gastrointestinal primary oversewn bowel without resection
- All Patients for whom gastrointestinal bypass surgery without resection of GI segment was done
- Hepatobiliary anastomosis
- GI anastomosis done outside JMC
- All patients whose charts are missing
- All patients whose charts are incomplete

### 4.5 SAMPLE SIZE

Whole population census sampling was used

## 4.6 STUDY VARIABLES

### Dependent variable

- Anastomosis leak

### Independent variables

- Age
- Sex
- comorbidities
- Primary pathology
- Timing of surgery (elective, emergency)
- Serum albumin level
- Preoperative bowel preparation
- Prophylactic antibiotics
- ASA class
- Perioperative blood transfusion
- Perioperative use of vasopressors
- Duration of surgery
- Location of anastomosis along GI tract
- Layer of anastomosis
- Principal surgeon
- Intra-abdominal infection from fecal contamination or peritonitis

## 4.7 DATA COLLECTION PROCESS

A questionnaire was developed by the principal investigator(PI) after reviewing relevant literatures. Data was collected by trained health professionals from operating room registers and medical records of adult patients who underwent GI resection and anastomosis after retrieval. The PI checked and reviewed the filled questionnaires for completeness to maintain data quality.

During the study period, GI anastomosis was done for 402 patients, Chart number was obtained from OR logbook and charts of 161 patients were missing and are excluded. The remaining 55 patients are excluded by other exclusion criteria, and Charts of 186 patients make the basis for the analysis of this study.

#### 4.8 DATA PROCESSING AND ANALYSIS

Data was coded, cleaned, entered, and analyzed using SPSS version 25. Descriptive data like percentage, mean, median, and bivariate data like chi-square and the odd ratio were calculated and results were presented using tables and figures. Bivariate and multivariate regression was computed from the independent variables to identify factors associated with the GI AL.

#### 4.9 ETHICAL CONSIDERATION

Before starting the research, as per the basic principles of the World Medical Association Declaration of Helsinki, the support and ethical approval letter was received from the ethical review committee of Jima University. Confidential information obtained from patient's medical records was maintained during data collection, analysis, and interpretation of results.

#### 4.10 OPERATIONAL DEFINITION

**Adult:** A patient aged 15 years and above

**Anastomotic leak:** A leak that was diagnosed on imaging, on relaparotomy or after presenting with symptoms; and treated by a primary treating physician

**Incomplete chart** –a chart that can't provide 75% of the required information on the questionnaire

**Anemia:** hematocrit level<35%

**Anemia:** hematocrit level<35%

**hypoalbuminemia:** serum albumin of <3.5gm/dl

## CHAPTER FIVE:RESULT

### DEMOGRAPHIC CHARACTERISTICS AND PRIMARY DIAGNOSIS

One hundred and eighty-six patients were included in this study. Demographic characteristics showed that majority of patients were males (74.2%), and from rural part of the country(75.81%). The mean age(  $\pm$ SD)was 41.74( $\pm$ 14.64)years; with age of presentation ranging from 15-75 years.

Table 1 Demographic distribution and diagnosis of 186 patients with GI Anastomosis at JMC in Jima, October 1,2019 to October 30,2022

Characteristics		Number of patients(N=186)	Percent
Gender	Male	138	74.2
	Female	48	25.8
Age(years) mean ( $\pm$ SD)= 41.74( $\pm$ 14.64)years	15-30	52	28.0
	31-60	114	61.3
	>60	20	10.8
Area of residency	Urban	45	24.2
	Rural	141	75.8
Primary diagnosis	Stoma reversal	59	31.7
	SBO	57	30.6
	Gastric cancer	16	8.6
	Esophageal cancer	15	8.1
	Redundant sigmoid	13	7.0
	Bowel perforation	10	5.4
	Colonic mass(non-obstructing)	8	4.3
	Colonic mass(LBO)	3	1.6
	Both SBO and LBO(compound )	2	1.1
	Other	3	1.6
Total	186	100.	

SBO= Small bowel obstruction, LBO=Large bowel obstruction

The most common indication for GI anastomosis was stoma reversal (31.7%) followed by SBO(30.6%). The rest of the diagnoses, in decreasing order of frequency includes gastric cancer(8.6%), esophageal cancer(8.1%), redundant sigmoid(7%), bowel perforation(5.4%), and colonic mass, which were non-obstructing in 8 patients and obstructing in 3 patients. Other less common diagnosis for which GI anastomosis was done were stricture of small bowel(1 patient),

mesenteric cyst(1), and complicated appendicitis(1). Resection and primary anastomosis for viable sigmoid volvulus was done for only 1 patient during this study period.(Table 1)

Further observation on types of stomas reversed and index surgery indicated that majorities of reversal of stoma were for Hartmann’s colostomy(31/59). Hartmann’s colostomy was done for obstruction of sigmoid colon; by gangrenous(9/31) or viable(2/31) sigmoid volvulus, or when it is part of ileo-sigmoid knotting(6/31). Sigmoid colonic mass was reason of Hartmann’s colostomy in 5 patients. Remaining types of stomas reversed in descending order includes: end distal small bowel(19/31), end proximal colon other than Hartmann’s(5/31), and end proximal small bowel(3/31). The ileostomies were done, for SBV(8/19), for AL management (4/19), and following ileo-ileal knotting(3/19).

Table 2 Bivariate analysis of demographic characteristic and diagnosis with occurrence of AL

Risk factor		Not leaked N(%)	Leaked N(%)	P-value
<b>Age(yrs)</b>	15-30	48(92.3%)	4(7.7%)	.892
	31-60	108(94.7%)	6(5.3%)	
	>60	18(90%)	2(10%)	
<b>Gender</b>	Female	44(91.7%)	4(8.3%)	.707
	Male	130(94.2%)	8(5.8%)	
<b>Area of residence</b>	Rural	133(94.3%)	8(5.7%)	.690
	Urban	41(91.1%)	4(8.9%)	
<b>Primary diagnosis</b>	Bowel perforation	8(80%)	2(20%)	.239
	Colonic mass	8(100%)	0(0%)	
	Esophageal	13(86.7%)	2(13.3%)	
	Gastric CA	16(100%)	0(0%)	
	Colonic mass(LBO)	3(100%)	0(0%)	
	Other	3(100%)	0(0%)	
	Redundant sigmoid	13(100%)	0(0%)	
	SBO	50(87.7%)	7(12.3%)	
	Both LBO and SBO	2(100%)	0(0%)	
	Stoma reversal	58(98.3%)	1(1.7%)	

SBO= Small bowel obstruction, LBO=Large bowel obstruction

The most common cause of SBO in patients who underwent resection and anastomosis was SBV(17/57); followed by small bowel intussusception(11/57) and abdominal wall hernia(10/57). other causes includes: ileo-sigmoid knotting(8/57), obstructing adhesion(5/57) and ileo-ileal knotting(4/57).

Anastomotic leak occurred in 10% in patients >60 years and was lower in younger age group; 7.7% and 5.3% in age range between 15-30 and 30-60 yrs. respectively but was not statistically significant. sex and area of residence is not associated with occurrence of AL. The leak rate was highest following bowel perforation 20% (2/10) followed by diagnosis of SBO 12.3% (7/50).

## PREOPERATIVE AND INTRAOPERATIVE CHARACTERISTICS

The most common comorbidity diagnosed was Hypertension (10.2%). Preoperatively, Hematocrit was determined for almost all but one patient; and anemia (hct < 35%) was prevalent in 17.7%. Nonetheless, albumin was determined only for 51.1% of patients; of which majority (55/95) were hypoalbuminemic (serum albumin < 3.5 gm/dl). (Table 2)

Table 3 preoperative characteristics of 186 patients with GI Anastomosis at JMC in Jima, October 1, 2019 to October 30, 2022

Preoperative characteristics		Patients (N=285)	percentage
urgency of surgery	Elective	108	58.1
	Emergency	78	41.9
comorbidities	No comorbidities	163	87.6
	Hypertension	19	10.2
	COPD	1	0.5
	DM	1	0.5
	Other	2	1.1
ASA class	1	96	51.6
	2	57	30.6
	3	11	5.9
	4	6	3.2
preoperative HCT level	≥35%	152	81.7
	<35%	33	17.7
preoperative serum albumin (gm/dl)	<3.5	55	29.6
	≥3.5	40	21.5
Preop mechanical bowel preparation done	no	114	61.3
	yes	71	38.2
Was prophylactic antibiotics given?	yes	183	98.4
	no	2	1.1

ASA= American society of Anesthesiology , HCT=Hematocrit, COPD=Chronic obstructive pulmonary diseases, DM=Diabetes mellitus

One hundred eight(58.1%) patients were operated as an elective surgery while the remaining 78 (41.9%) of them were operated on emergency basis. ASA status was documented for nearly all of patients; majority are classified as ASA 1(51.6%),followed by ASA2(30.6%), ASA3(5.9%) and ASA 4(3.2%). GI resection and anastomosis was performed in 61.3% of patients without preoperative mechanical bowel preparation. Prophylactic antibiotics was given for almost all(98.4%). (Table 2)

Table 4 Bivariate analysis of preoperative factors of 186 patients with GI Anastomosis at JMC in Jimma, October 1,2019 to October 30,2022

Variables			Leak detected		P-value
			NO	yes	
Hct level	<35%	N(%)	31(93.9%)	2(6.1%)	0.961
	>35%	N(%)	142(93.4%)	10(6.6%)	
Albumin level	<3.5	N(%)	49(89.1%)	6(10.9%)	0.426
	≥3.5	N(%)	40(100%)	0(0%)	
Preop bowel preparation	no	N(%)	103(90.4%)	11(9.9)	0.056
	yes	N(%)	70(98.60%)	1(1.41%)	
ASA category	ASA<3	N(%)	108(96.4%)	4(3.6%)	0.061
	ASA≥3	N(%)	66(89.2%)	8(10.8%)	
Timing of surgery	elective	N(%)	105(97.2%)	3(2.8%)	0.027
	emergency	N(%)	69(88.5%)	9(11.5%)	

ASA= American society of Anesthesiology , HCT=Hematocrit,

There was no association of preoperative anemia with AL, while serum albumin and ASA category showed borderline association with occurrence of anastomotic failure in this study. There was 10.9% prevalence in those with serum albumin level<3.5gm/dl while none of patients whose albumin ≥3.5gm/dl leaked. ASA level≥3 also have leak rate of 10.8% as compared to 3.5% in those <3.



Table 5 Intraoperative characteristics of 186 patients with GI Anastomosis at JMC in Jima, October 1, 2019 to October 30, 2022

Variable		N	Percent
Site of anastomosis	Entero-enterostomy	66	35.5
	Colorectal anastomosis	45	24.2
	Ileo-colic anastomosis	33	17.7
	Gastrectomy and anastomosis	17	9.1
	Esophagectomy and anastomosis	15	8.1
	Colo-colic anastomosis	9	4.8
Technique used	Hand sewn	185	99.5
	Staples	1	0.5
Layers of anastomosis	Two layers	100	53.8
	One layer	40	21.5
Alignment of anastomosis	End-to-end	134	72
	End-to-side	45	24.2
	Side-to-side	2	1.1
Primary operating surgeon	Consultants assisting residents	116	62.4
	Consultants	38	20.4
	Residents alone	32	17.2
Operative time(hour)	3-5	76	40.9
	2-3	58	31.2
	>=5	21	11.3
	1.5-2	15	8.1
	<1.5	1	0.5
Pre- or intra-operative blood transfusion	No	158	84.9
	Yes	28	15.1
Perioperative vasopressor use	No	178	95.7
	Yes	8	4.3

Upon opening the peritoneal cavity, in addition to GI pathology, there was evidence of pus and/or contamination by small bowel content or fecal matter in 9.14% of patients. The most common operative procedure done was entero-enterostomy(35.5%), followed by colorectal anastomosis(24.2%). The remaining procedures include; ileocolic anastomosis(17.7%), gastrectomy and anastomosis(9.1%), esophagectomy and anastomosis(8.1%), colo-colic anastomosis(4.8%), and jejuno-transverse anastomosis(0.54%) in descending order. Majority(62.4%) of surgeries were done by residents being assisted by surgeons. While

surgeons operated themselves in 20.4 % of case; residents operated alone 32 cases. There was no other professional other than mentioned who did GI resection and anastomosis.

Regarding technique of anastomosis, only one was stapled, the rest(99.5) were hand sewn. The layers of anastomosis were documented in 74.3% of operation notes; and was two layered in 53.8% of patients and was one layer in 21.5%. Anastomosis was created in end-to-end fashion in majority(72%). In the remaining it was end to side (24.2%), side to side(1.1%). Operative time was documented in 93.5% of anesthesia sheets; and elapsed 3-5 hr. in most of the surgeries(40.8%). The surgery took: 2-3hr,  $\geq 5$  hr., and 1.5-2 hr.; in 31.2%,11.3%,and 8.1% respectively. Only one patient's surgery was finished in  $< 90$  min. Pre or intra operative blood transfusion was given in 15.1%, and perioperative vasopressor was used in 4.3 % of patients for whom GI anastomosis was done.(Table 3)

The occurrence of AL along GI tract in decreasing order is: esophageal resection and anastomosis (13.3%), ileocolic anastomosis(9.1%), entero-enterostomy(9.1%), and colorectal anastomosis(2.2%). Gastrectomy and anastomosis and Colo colic anastomosis didn't leak in this study.

On bi variate analysis factor found to be significantly associate with AL include emergency surgery, presence of contamination by GI content and/or evidence of peritoneal infection, intra operative blood transfusion and need of perioperative vasopressors. In this study, 11.5% of patients operated as emergency leaked as compared to only 2.8% in elective cases(P-value=0.027). Presence of contamination and peritoneal contamination is also found to significantly affect outcome of GI anastomosis. there was AL in 28.6% of patients with as compared to only 4.7% in without peritoneal contamination with or without pus(p value =0.02). In addition, there were significantly higher anastomotic failure in those transfused with blood (21.4% vs 3.8%, P-value=0.02) and those who received vasopressors(37.5% vs 5.1%, P-value=0.03) compared to patients who are not given.

This study also showed; preoperative mechanical bowel preparation and two layers of anastomosis were found to be associated with lower rates AL but was not statistically significant

Table 6 Bivariate analysis of intraoperative variables

	<b>Variables</b>	<b>N</b>	<b>not leaked</b>	<b>leaked</b>	<b>P-value</b>
Site of anastomosis	Colo-colic	N(%)	9 (100%)	0 (0%)	0.408
	colorectal	N(%)	44(97.8%)	1(2.2%)	
	Entero-enterostomy	N(%)	60(90.9%)	6((9.1%)	
	esophagectomy	N(%)	13(86.7%)	2(13.3%)	
	gastrectomy	N(%)	17(100%)	0(0%)	
	Ileo-colic	N(%)	30(90.9%)	3(9.1%)	
	other	N(%)	1(100%)	0(0%)	
Alignment of bowel ends	end to end	N (%)	126 (94%)	8(6%)	0.551
	end to side	N(%)	42(93.3%)	3(6.7%)	
	side to side	N(%)	3(100%)	0(0%)	
layer of anastomosis	one layer	N(%)	37(92.5%)	3(7.5%)	0.48
	two layers	N(%)	95(95%)	5(5%)	
	not specified	N(%)	42(91.3%)	4(8.7%)	
primary operating surgeon	residents alone	N(%)	30(93.8%)	2(6.3%)	0.929
	surgeon	N(%)	34(89.5%)	4(10.5%)	
	Surgeon assisting residents	N(%)	110(94.8%)	6(5.2%)	
presence of infection or contamination	yes	N(%)	10(71.4%)	4(28.6%)	0.002
	no	N(%)	164(95.3%)	8(4.7%)	
pre or intra operative blood transfusion	no	N(%)	152(96.2%)	6(3.8%)	0.002
	yes	N(%)	22(78.6%)	6(21.4%)	
peri operative use of vasopressors	no	N%)	169(94.9%)	9(5.1%)	0.003
	yes	N(%)	5(62.5%)	3(37.5%)	

Variables which were significantly associated with anastomotic leak on univariate analysis were computed using multivariate analysis to see their strong independent effect on occurrence of AL, and they fell out of range of significance (Table 5).

Table 7 Multivariate analysis of factors significantly associated with occurrence of AL

variable	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I. for EXP(B)	
							Lower	Upper
Urgency of surgery	1.03	0.788	1.707	1	0.191	2.801	0.597	13.129
Intraperitoneal infection and/or contamination	1.557	0.821	3.595	1	0.058	4.745	0.949	23.729
Pre or intraop blood transfusion	1.29	0.729	3.136	1	0.077	3.634	0.871	15.152
Perioperative use of vasopressor	1.821	0.986	3.407	1	0.065	6.177	0.894	42.702
Constant	-4.087	0.678	36.33	1	0	0.017		

#### OUTCOME OF GI ANASTOMOSIS: PREVALENCE OF LEAK, ASSOCIATED MORBIDITY AND MORTALITY

Twelve out of 186 patients (6.5%) have developed anastomosis leak. As shown on figure 1 below, post operative days of leak detection ranged from day 4 to day 13, with mean ( $\pm$  SD) day of post op diagnosis 7 ( $\pm$  2.6) days. In majority (9, 75 %) leak was detected between 5<sup>th</sup> and 8<sup>th</sup> post operative days. The mechanism of leak detection was: clinical signs of fever, abdominal finding of peritonism and laboratory evidence of leukocytosis in 4/12 patients; and GI content through wound in 2/12; or combination of both in 2/12. Leak was also diagnosed on relaparotomy done for complete wound dehiscence in 2/12. Ultrasound was used as adjuvant in diagnosis of AL only in one patient. (Figure 2)

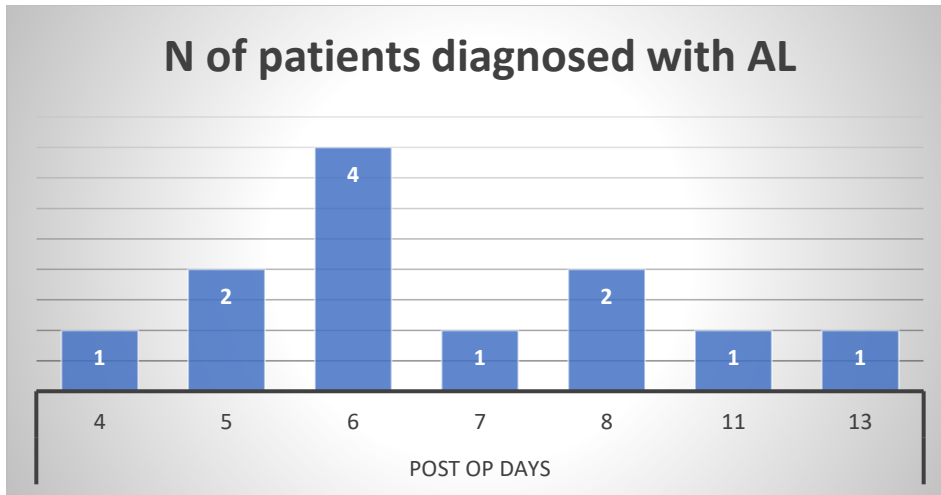


Figure 1 Post op days of Diagnosis of AL patients at JMC in Jima, October 1,2019 to October 30,2022

As per this study, relaparotomy was done in 18(9.7%) of patients who underwent GI anastomosis, which confirmed leak in half (9/18). Following exploration in those with anastomosis failure, stoma was created in 7/9 patients and the remaining were reanastomosed. Three patients were not explored because two refused and were discharged against medical advice while the other one was critical and unfit for anesthesia.(Figure 3)

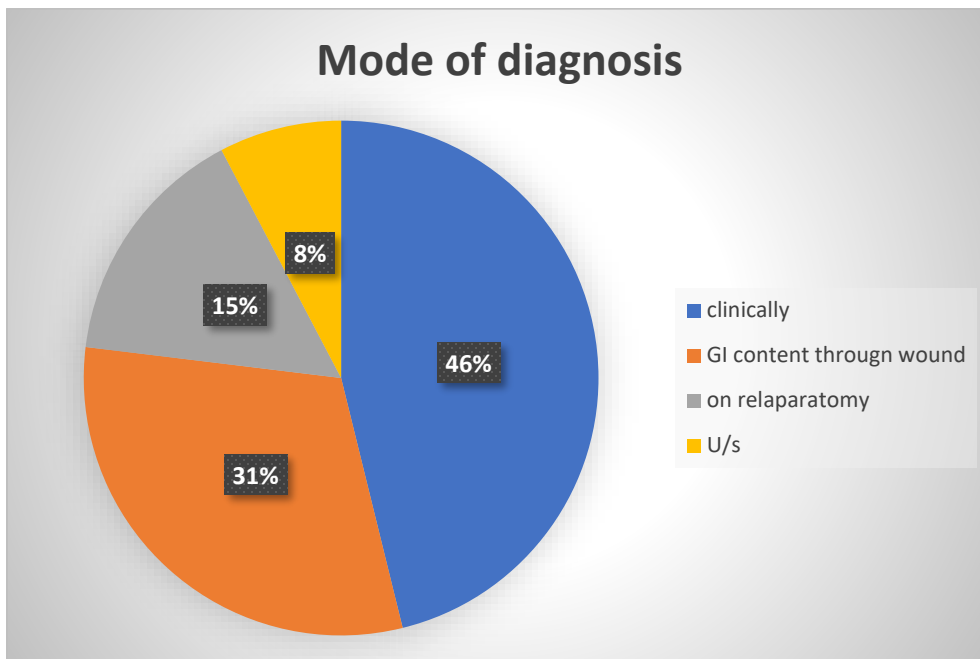


Figure 2 Modes of diagnosis of AL patients at JMC, Jima, October 1,2019 to October 30,2022

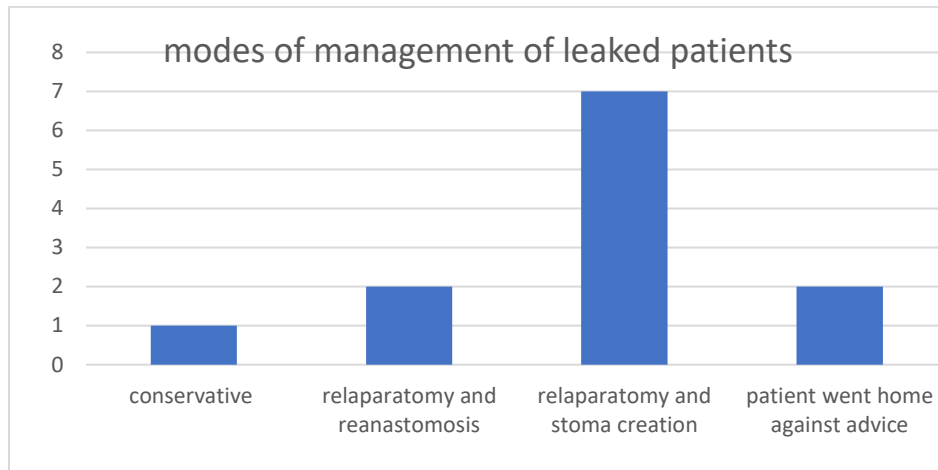


Figure 3 modes of management AL patients at JMC, Jima, October 1,2019 to October 30,2022

Average length of hospital stay after GI anastomosis was 9.9 days, and ranges from 5 to 44 days. The presence of AL is found to independently affect the relaparotomy rate, length of hospital stays and in hospital mortality. Eighty-three percent of patients that leaked stayed one week or longer, and 66.7% stayed more than 2 weeks as compared to only 8% in those patients who did not have leak.

Table 8 Bivariate analysis on Consequence of AL

outcome			not leaked	leaked	P-value
<b>Relaparotomy done</b>	<b>no</b>	N(%)	163(93.7%)	3(25%)	0..000
	<b>yes</b>	N(%)	9(5.2%)	9(75%)	
<b>hospital stay</b>	<b>stayed &gt; 2 weeks</b>	N(%)	14(8%)	8(66.7%)	0.044
	<b>stayed &lt;2 week</b>	N(%)	160(92%)	4(33.3%)	
<b>in hospital death</b>	<b>died in hospital</b>	N(%)	6(3.4%)	3(25%)	0.004
	<b>discharged</b>	N(%)	168(96.6%)	9(75%)	

As depicted in table 6 below, 3/4<sup>th</sup> of patient who leaked underwent relaparotomy as compared to only 5.2 % in those who didn't have a leak, and about 2/3<sup>rd</sup> of them stayed more than 2 weeks as compared to only 8% of patient without AL. There is also associated high mortality; 25% of patients with AL died in the hospital, as compared to 3.4 % of patients without AL.

Table 9 Multivariate analysis of outcome after AL

	<b>B</b>	<b>S.E.</b>	<b>Wald</b>	<b>df</b>	<b>Sig.</b>	<b>Exp(B)</b>	<b>95% C.I.for EXP(B)</b>	
							<b>Lower</b>	<b>Upper</b>
<b>Relaparotomy done</b>	3.616	1.004	12.967	1	0.000	37.199	5.197	266.277
<b>Stay of &gt; 2weeks</b>	0.993	0.912	1.185	1	0.276	2.698	0.452	16.115
<b>In hospital mortality</b>	2.529	1.126	5.041	1	0.025	12.543	1.379	114.098
<b>Constant</b>	-15.321	3.018	25.767	1	0.000	0.000		

## CHAPTER SIX:DISCUSSION

### PREVALENCE OF ANASTOMOTIC LEAK

Anastomosis leak is the most feared complication after a very common surgical procedure, GI anastomosis. The occurrence varies according to definition used, site of anastomosis and risk factors identified(1,2). Its occurrence leads to increased morbidity and mortality, by increasing risk of relaparotomy and stoma formation, prolonged hospital stay; and as a result, increasing total clinical and economic burden(11). Therefore, there is no doubt that knowledge on prevalence, risk factors and associated consequence of AL helps in preventing, early diagnosis and management of this dreaded complication.

Of total 186 patients included in this study, 138(74.2%) were male; with male to female ratio of 2.8:1. This demography is also similar with two studies from Addis Ababa and study from Egypt(1,5,33). Prevalence of AL in this study is 6.5%, which is within the usually acceptable range of AL of 2% to 10%(5). This rate is found to be lower than from Addis Ababa by Mekete et al.(9.9%) and Zemenfes et al.(10.8%(1,5). Prospective study from Egypt on 315 cases showed leak rate of 8.57%(6) while another prospective report from the same country showed higher rate of 15.4%(33). The lower rate observed in our study is probably due to higher chance of doing stoma for at risk cases and for gangrenous Sigmoid volvulus in this setup; evidenced by the most common primary diagnosis for anastomosis found to be stoma reversal(31%) and more than half of them being Hartmann's colostomy. Furthermore, only one case of resection and primary anastomosis was done for viable sigmoid volvulus. Study from Addis Ababa end colostomy accounted for only 9.9% and SBO only 14.8% of cases(1). There could also be major difference on the trends and practices among those institutions which needs further comparative study. Bivariate analysis on demographic factors like; age , gender, area of residence, didn't show any statistically significant association.



## PREOPERATIVE AND INTRAOPERATIVE FACTORS

In General, AL rate varies based on site of anastomosis along GI tract: esophageal (9.6-16.3%), stomach (1.1-3.3%), small intestine (1-2%), ileocolic (1.0-4%), colo colic (2-3%), colorectal (5-19%), and ileorectal (3-7%)(34). The Most common primary diagnosis in our study is stoma reversal in 31.7%, mostly closure of Hartman's colostomy(52%). The next common diagnoses are SBO(30.6%),gastric(8.6% ) and esophageal cancers( 8.1% ). The rate of leak with respect to primary diagnosis varied widely. The leak rate of anastomosis following perforation and SBO was 20%(2/10)and 12.3%(7/50) respectively. This is likely to be due to their emergency nature, the likelihood of presence of peritoneal cavity infection and higher chance of blood transfusion along with use of vasopressor which are found to be significant risk factor for AL in this study group. In addition, patient with SBO is likely to have edematous and dilated loops of bowel which will have potential to have loosening of suture and leaking site after bowel edema subsides. Only one (1.7%) to whom stoma reversal was done had AL. In this study, there is no leak occurred in cases of Gastric ca and colonic masses and in LBO for which primary resection and anastomosis done.

This study also showed variable rates of AL based on type of procedure. The occurrence of AL in decreasing order is: esophageal resection and anastomosis (13.3%), ileocolic anastomosis(9.1%), entero-enterostomy(9.1%), and colorectal anastomosis(2.2%). Gastrectomy and anastomosis and Colo colic anastomosis didn't leak in this study. Mekete et.al.(1) showed AL rates in decreasing order of entero-enterostomy (17.2%), esophagectomy (16.3%), gastrectomy (10.5%), colorectal anastomosis (10.2%), ileocolic anastomosis (9.1%) and Colo-colic anastomosis (4.2%). This result agreed with ours except the rates of leak was lower along all GI tract and gastrectomy and colo-colic anastomosis didn't leak in our study. The reason for lower incidence of leak in tumor cases in this study might be due to a smaller number of surgeries for GI tumor in our center which might have reduced sample size and affected analysis among other factors.

Emergency patients had higher occurrence of AL; 11.5% as compared to 2.8% in elective surgeries which was found to be statically significant. This agrees with report of Mekete et.al.; 17.6% vs 7.5% of emergency vs elective surgery(1). Nair et al.(35) reported Suture line

disruption occurred in 26 of 74(35%) emergency small bowel resection and anastomosis, which is higher than our study. studies by El-Badawy et al. and Awad et al. reported similar finding(33)(6).

Presence of Intraoperative contamination by GI content or fecal matter and presence of intraperitoneal infection evidenced by pus was assessed in this study. There was AL in 28.6% in those who had vs 4.7% who didn't. prospective cohort Study by Sieda et al. on 287 patients showed 14.46% AL in those having evidence of acute intra-abdominal contamination, as compared to only 4.13% who doesn't have(29). this supported our study except the rate is higher in our study(28.6% vs 4.7%). This could be explained by the high possibility of surgery becoming emergency, patient becoming septic and possibility they are going to need transfusion or vasopressor, and the high likely of the bowel to be unfavorable to anastomose and the likely of the patient to have post operative ileus which will all predispose to a chance of leak.

Pre or intra operative blood transfusion is also found to be significantly associated with AL in our study, as 21.4% of those transfused vs only 3.8% which didn't developed AL. zemenfes et al. Got similar result; 31.7% of blood transfused patients developed leak, in contrast to only 7.5% leak rate among non-transfused patients (P-value 0.001, AOR 4.3, CI 1.8-10.3)(5). other similar studies done are also in congruent with our finding(29,31). In its review of literatures, Phillips et al stressed to Limit use of pressors; and when pressors are necessary, to consider proximal diversion or end stoma in colorectal surgery(9). In our study, 3 of 8 patient(37.5%) for whom perioperative vasopressor was used developed leak compared to only 5.10(9/169) who didn't get. This evidence is supported by a similar paper from India which showed 4 times chance of developing AL in those who required ionotropic support(36).

Studies have shown independent predictability of ASA class on occurrence of AL(34). Zemenfes et al. observed AL in 41.7% of patients who had ASA class  $\geq 3$ , in contrast to only 7% in those with ASA class  $< 3$  (P-value 0.025, AOR 1.6, CI 1.1- 2.6)(5). Our work showed borderline significant(p value= 0.061) effect of ASA on AL; with 10.8% AL occurrence in ASA  $\geq 3$  compared to 3.6% in those  $< 3$ . Hypoalbuminemia was also showed as an independent predictive factor by mekete et al(1) and Awad et al(6). In our study, albumin is determined only in 47 % of

patients which might have affected sample size and its possibility to be independent predictor. As a result, 10.9 % of those albumin < 3.5 developed leak and none of those  $\geq 3$  leaked (p value = 0.426).

Bivariate analysis of operative factors like; type of anastomosis (alignment of ends), layer of anastomosis, primary operating surgeon, and patient factor like; comorbidity and Hct level didn't show any statistically significant association. The percentage of leaked patient in the hands of consultants are a bit higher in this study group but it is not statistically significant. This is high likely due to the involvement of consultant almost in every case of critical emergency patients, and likelihood of surgery to be done by themselves to shorten operative time in those case. In addition, complex and demanding surgery like oncology cases are usually done by consultant while straight forward and less complex cases are done by residents.

## DIAGNOSIS AND MANAGEMENT

Mode of diagnosis in our study was mainly clinical signs (46%) and appearance of GI content through wound (31%). Mean ( $\pm$ SD) post operative day of diagnosis of AL was  $7 \pm (2.6)$  days. The odds of having relaparotomy done increases by about 37 times in those who had leak as compared to those who haven't (P value = 0.000). It also increases the chance of staying more than two weeks by about 2.7 times (P value = 0.044) and mortality after leak is increased by a factor of about 12.5 when compared to those who didn't leak (p value = 0.04). The mode of management in AL have 3 options: conservative in asymptomatic; radiologic or endoscopic interventional procedures in those with non-life threatening conditions; and urgent surgery with either refreshing edges and re anastomosis or, stoma creation, when vital prognosis is engaged (8). In our scenario almost all (9/12) are managed surgically, mainly by creating stoma. This is explained by the fact that as most AL are diagnosed after manifesting clinically, they cannot be a candidate for conservative management, and even if they are only presenting with mild non-life-threatening signs and symptoms there is no options of interventional radiology or endoscopy in our setup, so they are left with surgical option only.

## CONSEQUENCE OF ANASTOMOTIC LEAK

Mekete et al.(1) found 71.4% of patients with AL had relaparotomy compared to the 1.9% relaparotomy rate in those without AL. Length of stay wise, compared to a 3.8% of patients without AL, 62.9% of patients with AL stayed more than 3 weeks in hospital. Mortality in the same study was 48.3% in leaked patients compared to the 3.5% in those who did not develop AL(1). This study showed 25% AL associated mortality compared to 3.4% without AL. The mortality comparison with Mekete et al. showed similarity in those without leak but is nearly 2 times higher than ours in those who leaked. Similar report from the same area, Addis Ababa by Zemefes et al.(5) reported even higher mortality of 65% in those who had AL. The report further stated 100% mortality in those with initial diagnosis of gangrenous bowel obstruction(5). Those two papers attributed late detection primary as a reason of increased mortality in leaked patients in addition to poor skill as mortality is found to be higher in cases operated by residents as compared to consultants(82% vs 33%). In our case it might be lower rate and lower mortality b/c of earlier detection b/c the cases are being followed by the same operating team till patient is discharged and slower skill hand over to senior residents near the end of the year which might have increased the curiosity of the residents and involvement of senior consultants in the most difficult cases almost always. There could also be major difference on mode of management of leaked patient, which in general needs comparative study. Other series showed increased morbidity and overall cost and mortality(12-29%) in patient with AL(11)(33). In contrast, although data's from developed countries are available mostly on specific sites of GI tract based on subspecialties, data from UK and Ireland shows lower incidence and Mortality from AL as compared to ours(37,38). This is high likely to be due to improved patient factors including earlier presentation to hospital, better skill and experiences in technique, better perioperative care for patient.

## **CHAPTER SIX: STRENGTH AND LIMITATIONS OF THE STUDY**

Strength of this research are data collection was by surgical residents which make the data standard and reliable.

This study is retrospective in nature and there was problem in getting all charts, and some of the charts were incomplete and many charts are missing, the data may not be representative

## **CHAPTER SEVEN: CONCLUSION AND RECOMMENDATION**

In this study we aimed to know the prevalence and factors associated with development of AL and its consequences, and the objectives are fully meet. The prevalence of AL in our study group is 6.5%, which is slightly lower rate than research done in other parts our country and other countries in Africa but slightly higher than western centers. The rates are also found to vary along different parts of GI tract and types of procedures.

Surgery being emergency, presence of fecal contamination or evidence of puss in the peritoneal cavity, pre or intra operative blood transfusion ,and use of vasopressor are found to be strongly associated with development of leak. Hence b/c of high likely presence of those mentioned factors all together in an emergency patient, consideration of diversion colostomy selectively is plausible in emergency patient with above mentioned characteristics. It is also important to limit the use of vasopressor perioperatively if possible, and if we are going to use better to divert or do end stoma to prevent grave consequence of AL

As clearly evidenced in our work, Anastomotic leak once occurred is going to be disastrous both for the patient and for the resource limited setup. It is going to independently affect relaparotomy rate, length of hospital stays and overall morbidity and mortality. Hence, it is crucial to know factors affecting occurrence of leak both preoperatively, and intra operatively; to closely follow the patient with GI anastomosis; to early detect and have proper plan of management once leak occurred; with final goal of improving both clinical and economic burden both to the patient and the crawling setup like ours.

In addition to prevalence, Mortality rate in our study is found to be significantly lower than other parts of our country and other African countries which need further work as to know what

contributed to the lower incidence of AL and lower associated mortality in comparable resource limited setup.

Further work ,preferably prospective study, need to be done on the different causes, indications, and outcomes of stoma, as they are found to be commonest reason of GI anastomosis in our study.

Finally, based on our challenge of getting charts and significant missing charts, I recommend JMC administration the following: possible installation of electronic medical recording as soon as possible which will solve most of those problems, and allow different personnel to do research on the same patient by multiple investigators. Also, we recommend against chart handling by the patients, and to have strict rules on chart transport in the hospital.

## **CHAPTER EIGHT: DISSEMINATION OF THE RESULT**

The result of this study will be submitted, both in hard and soft copies to the Jima University's postgraduate and research study office. An attempt will be made to present at association meeting like the Ethiopian surgical society meeting. Efforts will also be made to publish in international journals. Further, it will be uploaded and made available on the Website of Jima University.

## **CHAPTER NINE: ASSURANCE OF PRINCIPAL INVESTIGATOR**

The undersigned agrees to accept responsibility for the scientific ethical and technical conduct of the research project and for the provision of required progress reports as per terms and conditions of the Faculty of Public Health in effect at the time of grant is forwarded as the result of this application.

Name of the student: \_\_\_\_\_

Date. \_\_\_\_\_ Signature \_\_\_\_\_

### **APPROVAL OF THE FIRST ADVISOR**

Name of the first advisor: \_\_\_\_\_

Date. \_\_\_\_\_ Signature \_\_\_\_\_

### **APPROVAL OF THE SECOND ADVISOR**

Name of the first advisor: \_\_\_\_\_

Date. \_\_\_\_\_ Signature \_\_\_\_\_

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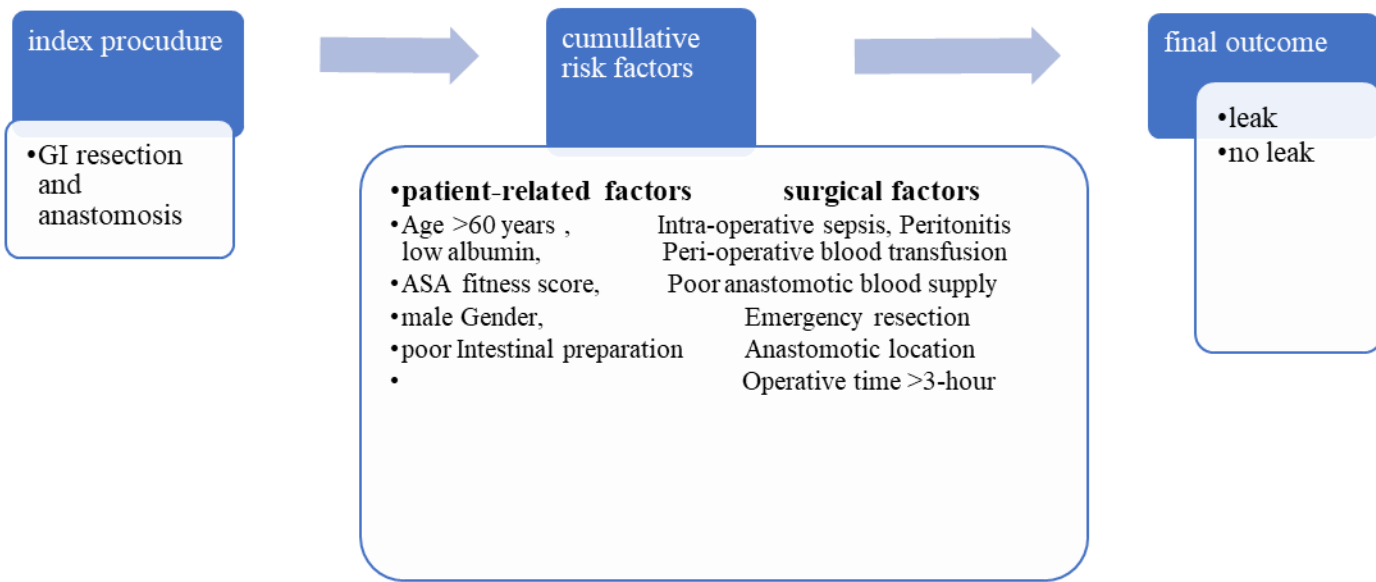
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# ANNEXES

## ANNEX 1: CONCEPTUAL FRAMEWORK



## ANNEX2: DATA COLLECTION FORM

- 1) S.no\**serial number* \_\_\_\_\_
- 2) ID\**medical record number* \_\_\_\_\_

### demographic characteristics

- 3) Age\*(yrs) \_\_\_\_\_
- 4) sex\*  
 male  female
- 5) area of residence  
 urban  rural

### preop characteristics

- 6) **what was primary diagnosis?\****phatology diagnosed*  
 esophageal ca  gastric ca  complicated PUD (GOO)  redundant sigmoid  IBD   
stoma reversal  bowel perforation  SBO  LBO  other  colonic mass, non obstructing
- 7) **If stoma reversal, specify** \_\_\_\_\_
- 8) **If SBO, what was diagnosis** \_\_\_\_\_
- 9) **any comorbidities known\***  
 HTN  DM  cardiac illness  CKD  RVI  COPD  other  none
- 10) **ASA class\***  
 1  2  3  4  5  not available
- 11) **Timing of surgery\***

emergency  elective

### **laboratory characteristics**

#### **12) hct level\***

<35%  >35%  not determined

#### **13) albumin level\**preoperatively***

<3.5  >=3.5  not determined

#### **14) RFT\***

>=1.2  <1.2  not determined

#### **15) prophlactic antibiotics given?**

yes  no  not known

#### **16) preoperative bowel preparation done?\***

yes  no  not known

### **intraoperative characteristics**

#### **17) type of operative procedure done\***

esophagectomy and anastomosis  gastrectomy and anastomosis  entero enterostomy   
ileocolic anastomosis  colocolic anastomosis  ileorectal anastomosis  colorectal anastomosis  
 other

#### **18) what was technique of anastomosis\***

hand sewn  staples  both techniques used

#### **19) layer of anastomosis\***

one layer  two layer  not specified

#### **20) type of anastomosis\***

end to end  end to side  side to side  other

**21) primary operating surgeon\***

surgeon  surgeon assisting residents  residents alone  other professional  no adequate information

**22) intraperitoneal finding\***

reactive fluid  hemorrhagic fluid  frank blood  small bowel content  fecal matter   
evidence of puss or abcess  none /only the bowel pathology  other

**23) operative time\***

<1.5 hr  1.5-2 hr  2-3 hr  3-5 hr  >=5 hr  not documented

**24) pre or intra operative blood transfusion\***

yes  no

**25) peri operative use of vasopressors\***

yes  no

## post operative characteristics

**26) post op leak diagnosed?\***

yes  no

27) If yes,, .leak detected by

- a) Clinical signs (fever, Abdominal pain, Abdominal distension, Abdominal tenderness  
Leukocytosis
- b) Discharge of GI content
- c) Ultrasound
- d) CT scan

**28) If diagnosed on \_\_\_\_\_ post op day**

**29) relaparotomy done\***

yes  no

30) If yes on above, was leak confirmed?

Yes            No

31) Mode of management\_\_\_\_\_

**32) final outcome\***

discharged improved  died in the hospital  discharged against medical advice  referred to  
other hospital  other

33) **length of hospital stay in days\***\_\_\_\_\_