UNIVERSITY OF NAIROBI

FACTORS ASSOCIATED WITH THE TIMING OF INTESTINAL STOMA REVERSAL AND OUTCOMES IN ADULT PATIENTS AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

I hereby declare that this dissertation is my original work and has therefore not been presented for a degree in any other institution. Whenever I have used another's work I have acknowledged and referenced accordingly

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SUPERVISORS APPROVAL

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DEPARTMENTS APPROVAL

This research proposal was submitted at the Department of Surgery meeting held on 29th September 2022 at the University of Nairobi. It was subsequently approved by the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee (KNH/UON ERC) on 14th March 2023 ref **P789/10/2022**. The dissertation is hereby submitted for examination with my approval as the chairman of the Department of Surgery.

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To the almighty God, giver of life and who enables me to do all things

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LIST OF ABBREVIATIONS

ASBO	Adhesive Small Bowel Obstruction
BMI	Body Mass Index
CI	Confidence Interval
DM	Diabetes Mellitus
ECF	Enterocutaneous Fistula
GI	Gastrointestinal
HOS	High Output Stoma
IBS	Irritable Bowel Syndrome
KNH	Kenyatta National Hospital
MTRH	Moi Teaching and Referral Hospital
OR	Odds Ratio
QOL	Quality of Life
RCTS	Randomized Control Trials
SSI	Surgical Site Infections
UoN	University of Nairobi

OPERATIONAL TERMS

Intestinal Stoma: Surgically created opening of either the small intestine or the large intestine onto the anterior abdominal wall

Timing of reversal: time period it takes from the date of stoma creation to the date of stoma reversal.

ABSTRACT

BACKGROUND: Intestinal stoma creation is done as either an emergency surgery or elective surgery to divert the flow of fecal matter in order to relieve obstruction or protect distal anastomosis. It involves bringing out part of either the small intestine or the large intestine through the skin. This can be as a permanent conduit or temporary measure that requires reversal and restoration of normal bowel continuity. Creation and management of intestinal stoma has significant morbidity and cost implications which increases with the duration the stoma is in place. There is no established protocol on the timing of stoma reversal. Timing of the reversal influences post reversal complication. There is paucity of data locally on factors associated with the timing of stoma reversal and immediate complications.

OBJECTIVES: To determine the factors that are associated with the timing and outcome of stoma reversal in adult patients with intestinal stoma at KNH.

METHODOLOGY: This was a retrospective cohort study.

Data was collected using a data collection tool from records of patients managed with intestinal stoma and reversed who met the inclusion criteria in the time period between February 2023 and February 2016. Details of the patient's demographic data, type and indication of stoma, complications, timing of reversal, technique of reversal and immediate post-reversal complications were noted and tabulated. Data was then filtered and entered into Stata version 17 for analysis.

DATA ANALYSIS: Data analysis was done using both descriptive and inferential statistics. Demographic and clinical characteristics were summarized descriptively. Categorical data was summarized using frequencies and percentages. Continuous data was summarized using Mean, Median and Interquartile range (IQR). Indications for stoma creation were analyzed descriptively using frequencies and percentages. Binary logistic regression was conducted to investigate indications associated with timing of stoma (emergency vs elective). Odds ratios were computed to explain the extent of the existing association. The timing of stoma reversal

was analyzed descriptively using median (Interquartile range). A histogram was also utilized to illustrate the distribution of timing of stoma reversal. Factors associated with stoma reversal were investigated using binary logistic regression. In investigating demographic and clinical characteristics associated with time to reversal, independent samples t -test and one-way analysis of variance were used. Binary logistic regression was also used to investigate the association between time to reversal and presence of stoma reversal complication. The significance was assessed at 95% confidence level where variables with a $p<0.05$ were considered to be statistically significant.

RESULTS: A total of 286 patients with intestinal stoma were included in this study. Out of these, 173 (60.5%) had stoma reversal within the study period. The median age of the patients with stoma was 41 years. The most common indication for stoma creation was neoplasm (30.1%) followed by intestinal obstruction (25.5%). Double barrel stoma was the most common type (31.1%) with sigmoid colon being the most common site (52%). The most common complication of stoma was surgical site infection (16%) occurring within 18 days of stoma creation. The average time of stoma reversal was 157.3 days. Surgical site infection was the most common complication after stoma reversal (13.2%). Those who had neoplasm as an indication were 87% less likely to have stoma reversal, OR 0.13, 95%CI:0.07 – 0.23, $p<0.001$. Presence of comorbidities, neoplasm and adjuvant treatment prolonged time to stoma reversal. The results also showed that the likelihood of stoma reversal complications was six times higher among those with late time to reversal (>90 days) compared to those with early time to reversal, Odds Ratio (OR) = 5.89, 95%CI: 1.96 – 17.75, $p<0.001$.

CONCLUSION: Stoma creation is a lifesaving surgical procedure associated with various complications and significant morbidity. Early reversal within 90 days reduces the morbidity and post reversal complications.

KEY WORDS: Intestinal stoma, timing, reversal, complications.

CHAPTER 1

1.1INTRODUCTION

Stoma creation is a common surgical procedure that was first fashioned in 1979 in Germany by Baum to divert stool in a patient with obstructing colon cancer. It is a surgically created opening of the small or large intestine onto the anterior abdominal wall. The exact number of patients living with stomas is hard to quantify because stoma is created and reversed quite frequently [1] – [4].

Creation of stoma can be done as an emergency procedure or as an elective surgery. It is fashioned from either the small intestine (Jejunostomy/ ileostomy) or the large intestine (colostomy) and with different configurations such as loop, end, double barrel or divided stoma. It can function either as a permanent conduit or a temporary diversion that will require reversal at a later date. Various indications for stoma creation include decompression of obstructed gut, evacuation of stool, diversion of fecal stream in trauma or to protect distal anastomosis and perianal wounds. In pediatric patients, stoma is used in the management of Hirschsprung disease and anorectal malformations [1] [2] [12] – [19].

Stoma creation comes with attendant morbidity and maintenance cost. Early complications include bleeding/ hematoma, edema, ischemia/ necrosis and fluid and electrolyte imbalance. Late complications include stoma prolapse, retraction, stenosis and parastomal hernia. Skin irritation, lowered quality of life and high cost of maintenance are other inherent complications of stoma. These are more likely to occur with the longer duration of existence of stoma [21]- [32].

Intestinal stoma should therefore be reversed as soon as possible. Reversal of ileostomies as early as two weeks has been shown to be feasible. Certain factors such as type of stoma, indication, sociodemographic factors, comorbidities and stoma complications have been shown to influence the timing of closure of stoma. There is great variability in timing of closure between institutions since stoma closure is not considered an emergent procedure. In addition, there is no existing protocol on reversal of stoma. Patients may therefore have to endure the burden of stoma longer than necessary [46]- [52].

Stoma reversal also comes with complications such as anastomotic leak, ileus and bowel obstruction, enterocutaneous fistula and surgical site infection. Rates of these complications vary widely and are influenced by timing of closure, comorbidities, surgical technique and qualification and experience of the surgeon.

Factors influencing the timing of stoma closure have not been evaluated locally. Moreover, there is paucity of data on ileostomies done locally. This study aims to bridge this knowledge gap and guide in establishment of protocol for reversal of stoma.

CHAPTER 2

2.1 LITERATURE REVIEW

Introduction

“ostomy” comes from the Greek word “Stoma” which means mouth. Stoma/ostomy refers to a surgically created opening of a hollow organ on the surface of the body to enable excretion of waste products. When the created opening involves the intestine then it is called enterostomy. When it involves the urinary tract then it becomes a urostomy. Enterostomies can further be named depending on the part of the bowel that is brought out: thus, jejunostomy involves the jejunum, ileostomy involves the jejunum, colostomy involves the colon and cecostomy involves the cecum. Other than the above stomata, ostomy can also be created to aid in feeding such as in the case of gastrostomy and jejunostomy [1].

In history, German surgeon Baum in 1879 was first to fashion a stoma to divert stool in colonic cancer causing obstruction. Over time different techniques have been developed in fashioning effective stoma including the advent of Brookes ileostomies in the 1950s [2].

In the United States of America, its estimated 130,000 stomas are created each year with approximately 750,000 people living with stoma [3]. In Germany approximately 100,000 people live with stoma whereas in Japan it is estimated that approximately 25,000 new stomata are created each year. Locally the actual numbers of ostomates is not known [4]. The exact numbers of patients living with stoma is difficult to estimate since stoma creation and reversal is a common surgical procedure.

Anatomy and physiology

Intestinal stoma can be created from any point in the length of the small or large intestine. The naming and physiological function of the stoma is determined by the portion of the bowel that is brought through the stoma.

Anatomically, the small intestine is a 6 meters long hollow tube that extends from the pylorus of the stomach to the ileocecal valve. Duodenum is the proximal fixed part, measures about 25 cm long and is retroperitoneal. It transitions at the ligament of Treitz into a distal longer part that is freely mobile, thrown into folds and suspended from the posterior abdominal wall by mesentery. The mesentery provides a great degree of mobility and transmits blood vessels that supply the intestine. Jejunum constitutes the upper two-fifths of the mobile part while the remaining three fifths is the ileum. There is no clear demarcating boundary between the jejunum and the ileum. However, the number of arterial arcades, vasa recta as well the relative size and location may help in differentiation of the segments. The jejunum generally has a robust blood supply with 2 rows of vasa recta compared to the thinner, single row of vasa recta seen in the ileum. Small intestine is supplied by the jejunal and ileal branches of the superior mesenteric artery while the terminal ileum is supplied by the ileal branches of the ileocolic branch of the superior mesenteric artery. These blood vessels form arterial arcades which give off vasa recta that supplies the bowel from the mesenteric side. Small intestine receives partially digested food from the stomach and mixes with pancreatic and biliary secretions in the duodenum. The extensive surface area of approximately $200m^2$ in the small intestines aid in digestion and absorption of nutrients.

The large intestine is about 150cm long extending from ileocecal valve to the anus. It consists of the caecum (6cm x7cm), ascending colon (12.5cm), transverse colon (45cm), descending colon (25cm), sigmoid colon (37.5cm) and rectum (12cm). The transverse colon and sigmoid colon are suspended by mesentery and are mobile whereas the rest of the large intestine is fixed and is partially retroperitoneal. The colon is supplied by superior mesenteric artery through ileocolic, right colic and middle colic artery branches and inferior mesenteric artery through left colic, sigmoid and rectal branches. These arteries form a circumferential anastomotic arterial channel called marginal artery of Drummond. This is sometimes deficient in the region of splenic flexure and is augmented by an anastomotic arc of Riolan. The main function of the large intestine is absorption of water and electrolytes, storage and lubrication of stool and absorption of some B complex vitamins.

Stoma can be created from any of the mobile parts of the intestine. The fixed parts of the colon can also be used after careful mobilization from the posterior abdominal wall.

Stoma creation is associated with physiological changes since there is decreased surface area for absorption as well as loss of continence provided by the physiological sphincters. This leads to fluid and electrolyte loss as well as nutritional disturbance. The degree of disturbance is influenced by how high the stoma is located in the gastrointestinal tract with jejunostomy (considered less than 200 cm of bowel from the ligament of Treitz) being the most prone to fluid and electrolyte imbalance. The consistency and odor of the effluent also depends on how high the stoma is with proximal stomas producing thin fluid output while distal stoma producing well-formed stool associated with foul smell [1].

Classification

Stoma can be classified based on:

1. Anatomy: based on the part of the bowel that is brought out as stoma: in this classification we have jejunostomy involving the jejunum, ileostomy involving the ileum, colostomy involving the colon and cecostomy involving the caecum. Colostomy can further be specified by the exact part of the bowel involved as either descending, transverse, descending or sigmoid colostomy.
2. Function as temporary or permanent: temporary stoma is created for with an aim of reversal after its role has been accomplished. Permanent stoma is not reversed.
3. Number of openings and nature of bowel brought out: this includes loop, end, double barrel or divided stomas.

Loop ileostomy/ colostomy involves bringing out a loop of bowel through the skin. The anterior antimesenteric wall of the bowel is then opened. The end result is stoma with 2 openings, the proximal functional stoma and the distal mucous fistula.

End ileostomy/colostomy involves dividing the bowel and bringing out the proximal end through the skin as stoma. The distal end is closed and anchored within the abdominal cavity.

Hartman's colostomy is a type of end stoma created from a descending colon with the rectum sealed and left in the abdomen (Hartman's pouch) after proctosigmoidectomy.

End loop stoma involves remote segments of bowel created by resection of intervening bowel to be brought out as stoma through a single opening on the skin. For instance, following right hemicolectomy, the terminal ileum and the transverse colon can be brought out as end loop ileocolostomy.

Double barrel stoma involves dividing the bowel and the two loops brought out through the same opening on the skin, the proximal one being the stool exit and the distal limb being the mucous fistula. In a divided stoma, the two loops of bowel are brought out through different openings.

Ileostomies tend to be fashioned in the right side of the abdomen while colostomies tend to be on the left side. Ileostomy output is usually about 600mls/ day (500-700mls/day). Colostomy contents are semi-solid well-formed stools [5].

Creation of stoma

Stoma creation ideally requires adequate planning and patient preparation. Unless in emergency circumstances, preoperative teaching and site marking should be duly undertaken. It has been established that pre-operative site marking and education reduces early stoma related complications, anxiety and improved quality of life. This is best performed by the leading surgeon and marking done when the patient is in different positions I.E sitting, standing and lying. Ideal stoma site should be easily accessible to the patient, away from bony prominences and creases, away from surgical incisions and placed at a site the patient should be comfortable with [3].

Properly created stoma minimizes the morbidity of having to endure a stoma. The following steps are standard in ensuring creation of a proper stoma and minimize complications:

- Excise skin disk approximately 3 cm in diameter at a previously marked site

- Divide subcutaneous tissue with retractors. It's advisable not to core out or excise the subcutaneous tissue
- Vertical incision about 3 cm is made on the anterior rectus. At midpoint of this incision a perpendicular 1 cm incision is made laterally to keep the stoma away from midline.
- Rectus sheath is split along its fibers
- Vertical incision is made on the posterior rectus about 3cm
- Deliver the bowel through the incision while avoiding twisting of the bowel along its mesentery. In the obese patient, skin and subcutaneous tissue may be protected by Alexis wound protector [6]. Pushing from within is preferred to pulling the bowel.
- Confirm bowel viability and adequate length then close the midline incision in case of laparotomy before maturing the stoma to avoid contamination
- In colostomy, extend the bowel by 2 cm above the skin so that after maturation there is spouting of about 0.5-1 cm of bowel above the skin. In ileostomy, extend the bowel by 5 cm above the skin so that the matured stoma is spouted 2-2.5cm above the skin. This enables ease of application of stoma bag and reduces the chances of contact of excrement with the skin causing irritation.
- Perform enterocutaneous anastomosis. Full thickness bites of the bowel with corresponding dermal bites are taken. Avoid epidermal layers of the skin as this may lead to mucosal islands or small growths of mucosa in the skin surrounding the stoma
- In ileostomies, everting sutures should be placed away from the mesentery to avoid strangulating the blood supply to the bowel that passes via the mesentery.
- For loop ileostomies, the bowel brought out should be at least 20 cm from the ileocecal junction. This allows for ease of reversal. Marking the distal bowel with suture before delivery may help in orientation of bowel. Transect 80% of the circumference of the antimesenteric portion of the bowel just above where the distal loop meets the skin. Use of skin bridge is not necessary but if used should be removed within 5 days [7][8].

Diverting stoma can be approached through a midline incision or a stoma trephine incision. This depends on the anticipated ease of access of the bowel loop to be brought out. Stoma can also

be created laparoscopically with the advantages of less pain, shorter postoperative hospital stay, decreased postoperative ileus, reduced risk of adhesions and attendant ASBO complications [9].

Indications and complications.

Stoma fashioning can be done as an elective or as an emergency procedure due to various indications. The common indications include [1]:

- Decompression of obstructed colon
- Evacuation of stool when distal colon/bowel is removed
- Divert fecal stream/ de-functioning of bowel
- Protect distal anastomosis
- Management of congenital anomalies (Hirschsprung's/ anorectal malformations)

These stomata have been used to manage disease conditions including:

- Colorectal cancer
- Diverticular disease
- Inflammatory bowel disease (Crohn's disease and Ulcerative colitis)
- Traumatic injury to bowel
- Functional disorders such as incontinence
- Protection of distal anastomosis and perianal wounds

There are no absolute contraindications for stoma formation. However relative contraindication includes carcinomatosis, short mesentery and relatively thick abdominal wall as seen in obesity [2].

In recent times, stoma creation has been electively used in management of colorectal malignancy in which diverting stoma has been used to protect distal anastomosis. It has been shown that diverting stoma improves recovery of anastomosis leakage [10]. Mathiessen P. et al did a random multicenter trial in Sweden assessing reduction of anastomotic leak by

defunctioning stoma in low anterior resection of cancer of the rectum. A total of 234 patients were enrolled between 1999 and 2005. They were randomized for a defunctioning stoma or not. Symptomatic anastomotic leakage was 19.2% overall. Patients with defunctioning stoma showed leakage of

16.3% while those without stoma had a leakage rate of 28% (OR 3.4, 95% CI,1.6, P<0.001). Urgent abdominal reoperation was required in 8.6% of patients with stoma and 25.4% in non-stoma [11]. This study emphasized the role of stoma fashioning in protection of distal anastomosis.

Indications for stoma creation varies from region to region and from center to center. Over the years it's also been shown that some common indications in the past for stoma creation are no longer valid as there is tendency for preference for definitive treatment from the onset. In the developing world trauma and intestinal obstruction seem to be a leading indication while in the developed world, colorectal cancers and inflammatory bowel diseases are leading indications. Several studies done locally and internationally give different frequencies of various indications.

Mungai et al in MTRH studied 81 patients with stoma evaluating their quality of life. In her study the common indications for stoma were colorectal CA, intestinal obstruction and traumatic injury [12].

Massenga et al described the common indications, complications and management of stoma at Bugando medical center in Tanzania. She did a cross sectional study between 2016-2017 including 167 patients. Majority of the patients were pediatric patients (n=131). In the adult population, bowel perforation was the most common indication for stoma with 31.8% of stoma created. However, the study was limited by a small number if the adult population (n=36) [13].

In India, 2 studies done at different times yielded different indications for stoma. Ahmed Z. et al did a prospective study between 2012 January and December involving 100 patients. The main indication was enteric perforation (38%) followed by Koch's abdomen (18%). The most common type of stoma was loop ileostomy at 64% followed by sigmoid colostomy [14]. Pandiaraja J et al did a similar study assessing common indications and outcomes of intestinal

stoma in a different hospital in India between 2012 and 2015 involving 100 patients. The most common indication was GI malignancy at 25% followed by abdominal trauma at 22%. Ileostomy was the most common type of stoma constituting 80% [15].

Bekele et al studied the outcomes of colostomy reversal in two leading hospitals in Addis Ababa. Among the 155 patients studied in the period preceding 2009, sigmoid volvulus was the leading indication for stoma with 36.1% followed by colon cancer (29%) and colonic trauma (18.1%). The classical Hartman's and loop colostomy were the most common types of colostomy performed with 60.6% and 25.2% respectively. However, the study did not include ileostomies [16]. Similar findings were obtained by Abebe et al in a two-year retrospective study in the same locality involving 219 patients between 2011-2013. The predominant indications were gangrenous sigmoid volvulus (46.6%), obstructing colorectal cancer (21.0%) and bowel injuries (12.8%). The predominant stoma was Hartman's (81.7%) [17].

Karki OB et al studied indications, types and outcomes of colostomy at a teaching hospital in Nepal. In the retrospective cross-sectional study of 105 patients between 2017-2020, the most common indication was found to be trauma (33.3%) and intestinal obstruction (22.8%) [18].

Locally, Mohammed AS did a retrospective between 1999-2003 involving 115 patients done for colostomy closure at KNH. The most common indications were colonic injury (47.1%), sigmoid volvulus (38.8%) and neoplasm (5.9%). Hartman's colostomy was the predominant type (44.7%) followed by loop colostomy (28.2%) [19]. This study done 20 years ago however did not include ileostomies. Moreover, there is preference of definitive treatment and one stage procedure in the management of acute sigmoid volvulus [20].

Stoma creation comes with various complications. Rates of complications range from 10-70% and vary from center to center. Complications can be divided into early events that tend to occur within 30 days of creation and late complications that occur after 30 days [1].

Early complications include:

- Bleeding and hematoma formation

- Edema
- Cutaneous irritation
- Ischemia and necrosis

Late complications include:

- Prolapse
- Retraction
- Stenosis
- Parastomal hernia

Several risk factors have been associated with increased risk of complications of stoma creation. These include patient related factors such as presence of comorbidities, advancing age, smoking obesity (BMI>30) and poor nutritional status. Medical and surgical factors such as timing of surgery (emergency vs elective), oncological surgery, surgical technique, surgeon's qualification and experience, preoperative marking and teaching, pre-operative radiotherapy and chemotherapy as well as steroid therapy influences the risk of complications [21]. Demographic factors have also been shown to influence the risk of complications. These factors include income/employment, having a supportive partner as well as level of education [22].

Poor surgical techniques such as creation of large openings, too much bowel mobilization, suboptimal positioning and inadequate spouting coupled by suboptimal stoma care leads to increased complication and lowered quality of life in the ostomates [1].

Obese patients pose a special challenge in ostomy creation. Siting of stoma becomes a challenge in the obese patients as the usual site in the lower quadrants are inaccessible to the patient and contains a lot of subcutaneous fat. For these reasons the siting of stoma in obese patients tends to be in the upper quadrants of the abdomen. These patients also have increased risk of stoma prolapse, necrosis, and migration when they lose weight. The increased risk is due to the fact that the thick abdominal wall and thick mesentery makes it difficult to obtain adequate stoma length

[6].

Ischemia and necrosis are one of the early complications of stoma that may necessitate revision of stoma. It has an incidence of 1.6-11% [23] [24] [25] [26]. Initial edema in the first 48 hours is normal. Usually ischemia manifests in the first 24 hours as bluish discoloration of mucocutaneous junction. It is usually as a result of poor surgical technique such as mesenteric tension, blood vessel ligation and overzealous dissection. Delayed ischemia may be due to underlying medical conditions such as hypotension that compromises blood supply. Generally, when the level of ischemia extends beyond the fascia (as seen by endoscopy through the stoma) or stoma necrosis of length more than 1-2 cm, surgical revision is required to avoid stenosis and spillage. Superficial necrosis extending a few millimeters does not require revision [23].

Initial fluid loss through the stoma is usually about 1200mls post stoma creation. This decreases to 300-700mls due to ileostomy adaptation. This adaptation is due to higher average plasma aldosterone concentration brought about by prolonged water and sodium depletion. The incidence of extensive fluid depletion is higher in the initial postoperative period due to insufficient fluid intake. Fluid loss is more marked with proximal stoma as compared to distal stoma. Hyperaldosteronism also leads to loss of potassium and magnesium. High output stoma is defined as a stoma output of about 1500 mls in 24 hours (1000-2000 mls). Incidence of high output stoma is approximately 16% [23] [24].

Extensive fluid and electrolyte loss are a leading cause of readmission following stoma fashioning. Factors that have been associated with dehydration include bowel obstruction, abdominal sepsis, drugs such as prokinetic erythromycin, sudden withdrawal opioid withdrawal, enteritis due to infection by *Clostridium difficile*, use of diuretics and total proctocolectomy [23].

Paquette et al in Ohio studied retrospectively between 2007-2011 readmission rates for dehydration and renal failure. Out of the 201 patients included in the study, 17% were readmitted within 30 days due to dehydration or renal failure. Age above 50 years was a risk

factor for readmission [27]. Another study by Messaris et al revealed a readmission rate of 16.9% and the use of post-operative diuretics was a risk factor [28]. Hayden et al found a 20/1% readmission rate and the risk factor for dehydration was use of anti-diarrheal and neoadjuvant therapy [29]. Jejunostomy (less than 200 cm proximal bowel), intra-abdominal sepsis and obstructions were risk factors revealed by Baker Ml et al [30].

Surveillance is key to prevent readmission and complication of renal failure. Monitoring weight, fluid input and output as well as electrolytes in the post-operative period might help predict the chances of developing HOS. Arena J and Nightingale et al devised a treatment protocol for management of HOS. It involved the following steps [31] [32]:

- Prevent and treat underlying causes such as GI infections, bowel obstruction, intra-abdominal sepsis, IBS and short bowel syndrome.
- Avoidance of medications such as prokinetics, laxatives as well as sudden withdrawal of corticosteroids.
- Stage 1: Reduction of fluid and electrolyte loss by restricting intake to 500-1000mls/ day, use of isotonic drinks, avoidance of hypertonic drinks such as coffee, intravenous hydration, low dose loperamide and close monitoring of output.
- Stage 2: involves increasing doses of loperamide, addition of omeprazole, addition of codeine (15-60 mg/day) and Ocreotide at 200 mcg/day for 3 days
- Early reversal to avoid further decompensation

Mucocutaneous separation refers to mucosal detachment from peristomal skin either partially or circumferentially. incidence rate ranges from 3.7-9.7% [23] [25]. It can be caused by infection, DM, use of steroids, malnutrition, excessive tension and stoma necrosis. It is managed conservatively with wound care. It may lead to retraction and necrosis.

Stoma retraction refers to inversion of mucocutaneous junction. Its incidence is estimated to be between 2.9-5.4% [23] [24] [25]. It leads to poor fitting of appliances hence leakages and skin irritation. Risk factors include bowel ischemia, obesity, and difficulty in mobilizing bowel.

Management includes local repair with partial mobilization as well as revision of stoma in case blood supply and length is precarious.

The use of rods in loop stomas has been shown not to have any benefit in reducing the risk of retraction. Du R et al did a systematic review and Meta-analysis of RCTs to evaluate the value of support rods in loop enterostomy. A total of 1131 patients with loop enterostomy in six studies were included. Of these 569 cases were in the experimental group while 562 were in the control group. The incidence of stoma retraction in the rod group was not significantly lower than that in the non-rod group (OR=0.65, 95% CI 0.32-1.32, p=0.23). The incidence of stoma necrosis, peristomal dermatitis and mucocutaneous separation were significantly increased in the rod group [8]. Similar Meta-analysis by Mohan HM et al revealed similar findings [7].

Incisional hernia at the stoma site is referred to as parastomal hernia. There is a wide variation in incidence from 3-50% due to heterogeneity in definition, different diagnostic modalities, clinical and radiological factors, different patient population, different types of stoma and different follow up duration [6]. Risk factors for hernia include both patient factors and surgical technique. Obesity, advanced age, nutritional deficiency, smoking, collagen disorders, SSI, ascites, increased intra-abdominal pressure as seen in prolonged constipation, urinary outflow obstruction, chronic cough are patient based risk factors. Technical factors include improper siting of stoma away from rectus muscle, large fascial opening, extensive subcutaneous tissue dissection and stretching of the rectus muscle, injury to local nerves as well as emergent creation of stoma. Management can be non-operative or operative. Non-operative management involves the use of a belt to support the abdominal wall and modification of the risk factors outlined above. Operative management involves mesh repair. Direct suture repair is not recommended due to high recurrences of more than 60% [26]. Surgical intervention is only recommended for symptomatic patients.

Strategies to minimize parastomal hernia include the use of prophylactic mesh and extra peritoneal route of stoma creation. Jones HG et al did a systematic review of RCTs and showed that prophylactic mesh reduces incidences of parastomal hernia with no difference in need for re-operation or stoma related infection [33]. Ramirez et al recommends use of synthetic

prophylactic mesh to prevent incisional hernia in stoma closure when there is history of parastomal hernia [34]. Kroese et al did a systematic review of Meta-analysis comparing extra peritoneal vs trans peritoneal approach to reduce parastomal hernia. Extra peritoneal colostomy led to significantly lower parastomal hernia rates of 6.3% vs 17.8% for trans peritoneal as well as significantly lower rates of prolapse. There was no difference in stoma necrosis [35].

Stoma prolapse refers to prolapse of intestine through the stoma site. Incidence rates range from 2-3% in ileostomies and 2-10% in colostomies. Transverse loop colostomy is the most susceptible with over 30% incidence. Risk factors for prolapse include advancing age, obesity, increased intraabdominal pressure, bowel redundancy, and weak fascia. Surgical techniques that can predispose to prolapse include inappropriate sitting away from the rectus muscle, oversized aperture, long length redundant intestine and wide space between the abdominal wall and stoma. It leads to skin irritation, pain, difficulty of care, mucosal ulceration and bleeding. Two types of prolapse have been described: thus, fixed prolapse and sliding prolapse. Acute prolapse can be treated by reduction aided by topical granulated sugar to cause osmotic reduction of bowel edema enabling reduction and application of proper pouch size after reduction. Surgical correction remains the definitive treatment. Options include intraluminal bowel fixation, resection and relocation of stoma [25] [26].

Skin irritation, as well as hernia are still the most common complications of stoma creation. Skin irritation is particularly seen in ileostomies where effluent causes chemical burns when it comes in contact with the skin. Several studies have listed skin irritation as a common complication [36] [37]. The use of pouching systems with skin barriers and water-resistant tapes as well as proper patient education and nursing care reduces the complications of skin irritation. The spectrum of skin manifestation includes mucocutaneous separation, suture sinuses, chemical dermatitis, allergic contact dermatitis among others. Risk factors include poor sitting, type of stoma, inadequate spouting, and improper sized pouch [5]. Sier MF et al did an RCT to compare intracutaneously vs transcutaneous sutured ileostomy to prevent stoma related complications. 399 patients were randomized for intracutaneous (170) or transcutaneous (169). Leakage rates

were higher in the intracutaneous group (52.4% vs 41.4%). Skin irritation was also higher in the intracutaneous with incidence of 78.2% vs 72.2% [38].

Other than the physical complications of stoma, presence of stoma is a major life changing event associated with alternation in patient's quality of life and induces a range of psychological problems to the patient. Bwelle et al studied the outcome and QOL of patients with digestive stoma in Cameroon. 83.5% of 34 patients studies reposted stoma affected their quality of life with 73.5% having moderate dissatisfaction with life [39]. Anaraki et al in Iran demonstrated that 70% of patients were dissatisfied with sexual activity and more than half had a feeling of depression. This was influenced by type of stoma, underlying disease, location of stoma and change in clothing style [40]. SSewanyana et al in Uganda studied QOL in 51 patients with ostomy. Most exhibited psychological effects including anxiety (100%), concerns about change of body image (96.5%) and depression (88.4%) [41]. Poor body image, self-respect, sexual problems and lower psychological adaptation were some of the psychological problems identified by Ayaz et al [42] while Zewude et al reported 70% of patients adjusted their diet due to stoma [43].

Rare complication of carcinomas has also been reported occurring at the colonic site either as a primary or secondary disease [44].

Timing, non-reversal and complications of reversal

Living with stoma exposes the patient to the risk of comorbidities outlined above. The risk of these complications increases with the duration the patient has the stoma. There are no set protocols for timing of stoma closure. Scheduling for closure is extremely variable between hospitals. Timing ranges from 10 days to 27 weeks and this is affected by various factors such as [45], [59] – [62]:

- Prolonged recovery following the initial surgery
- Development of stoma complications
- Adjuvant treatment: chemotherapy and radiotherapy

- Administrative reasons: long waiting list of emergency procedures vs low priority of stoma closure
- Patients' social and economic status [61].

Limited evidence exists to show ideal timing of stoma closure. This is because there are different indications for stoma creation, different types of stoma as well as heterogeneity in complication rates. It is considered that 60-90 days is a safe window for stoma closure because [46]:

- Patients have considerably recovered from the previous surgery and are no longer in the catabolic phase.
- Intra-abdominal adhesions have matured considerably and therefore are easily managed
- Stoma inflammation and edema has resolved
- Patients nutritional status is favorable for the anastomosis to hold
- Associated injuries and wounds should have healed

Sherman et al discussed the considerations in stoma reversal. Contrast enema, DRE and endoscopic evaluation should be considered to evaluate the anastomosis before reversal of stoma in cases of temporary stoma that was created to protect distal anastomosis. Delayed reversal exposes the patient to complications of stoma. However, reversal of stoma is also associated with complications such as [46]:

- Anastomotic leak
- Ileus/ bowel obstruction
- Enterocutaneous fistula
- Surgical site infection
- Stoma site hernia

The risk of these complications is worsened by type of the stoma (Hartman's having the highest risk of about 50%), timing of reversal, underlying diseases, age and smoking history as well as

the specialty and expertise of the surgeon performing the reversal. Laparoscopic reversal has been shown to reduce the morbidity, shorten the length of hospital stay and enhance rapid recovery of bowel function [46] [76] [77].

Some stomata that were created as temporary stoma end up not being reversed. The risk of non-reversal has been evaluated in several studies and include [46]- [52]:

- Post-operative complications
- Adjuvant therapy
- Prohibitive comorbidities
- Advanced cancer/ local recurrence of cancer
- Anastomotic leak
- Advancing age of the patient
- Unsatisfactory anorectal function

Early closure of temporary ileostomy has been shown to be feasible. Bakx et al in the Netherlands studied 27 patients with loop ileostomy constructed to protect distal anastomosis. 18 patients had closure within an average of 11 days. It was associated with less morbidity without increased risk of complications [53]. Nelson et al did an RCT in India between February 2014 and November 2015 with 50 patients in each group to assess the feasibility of early closure of stoma. There was no increased risk of complications assessed (wound infection, intra-abdominal collection, anastomotic leak) whereas there was reduced cost of stoma care and improved QOL [54]. Similar studies have shown similar results with only increased risk of SSI in patients with stoma closed within 12 days of creation being the negative effect [55] – [57].

Average timing of closure varies in different studies. Herle et all found median time to closure was 5 months (17 days -18 months) with adjuvant therapy delaying closure [58]. Sier et al in his study had a mean time of 5.6 months. Intra-abdominal abscess and end ileostomy

independently delayed reversal [45]. Locally, Sheikh et al found mean time to closure to be 7.6 months (0.8991months) [19]. However, this study was only for colostomy.

Post reversal complication rates also vary from hospital to hospital due to heterogeneity of factors that influence these complications. Wang et al studied retrospectively 1504 ileostomy closure after restorative proctocolectomy between 1983 and 2002. Complication rate was 11.4% with small bowel obstruction (6.4%), wound infection (1.5%), abdominal septic complications (1%), ECF (0.6%) [63]. Sheikh et al found early complication rate 15.3% with SSI being 11.8% and ECF 3.5% [19].

Post reversal complications might necessitate stoma recreation. Sung et al retrospectively reviewed 520 patients between 2005-2014 in Korea. Stoma recreation rate after closure of diverting ileostomy in patients with rectal cancer who underwent low anterior resection was 9.8%. This was due to anastomosis related complications (57.8%), local recurrence of tumor (33.3%) and anal sphincter dysfunction (6.7%). Risk for recreation were anastomotic leakage, post-operative radiotherapy and intersphincteric resection [64].

Liang et al studied predictors of SSI after stoma reversal. He found an incidence rate of 36% among 128 patients who underwent stoma reversal between 2005-2011. Factors that influenced this incidence included seroma, fascial dehiscence, ICU admission, increased length of stay and thicker subcutaneous fat.

Certain interventions have been employed to help reduce the incidence of surgical site infection after stoma reversal. Subcutaneous drain placement reduced the risk of SSI while smoking increased the risk of SSI [66]. Type of wound closure also affects the risk of SSI. Circumferential subcuticular wound approximation has been associated with less SSI, good cosmetic results and improved patient satisfaction [67]- [70].

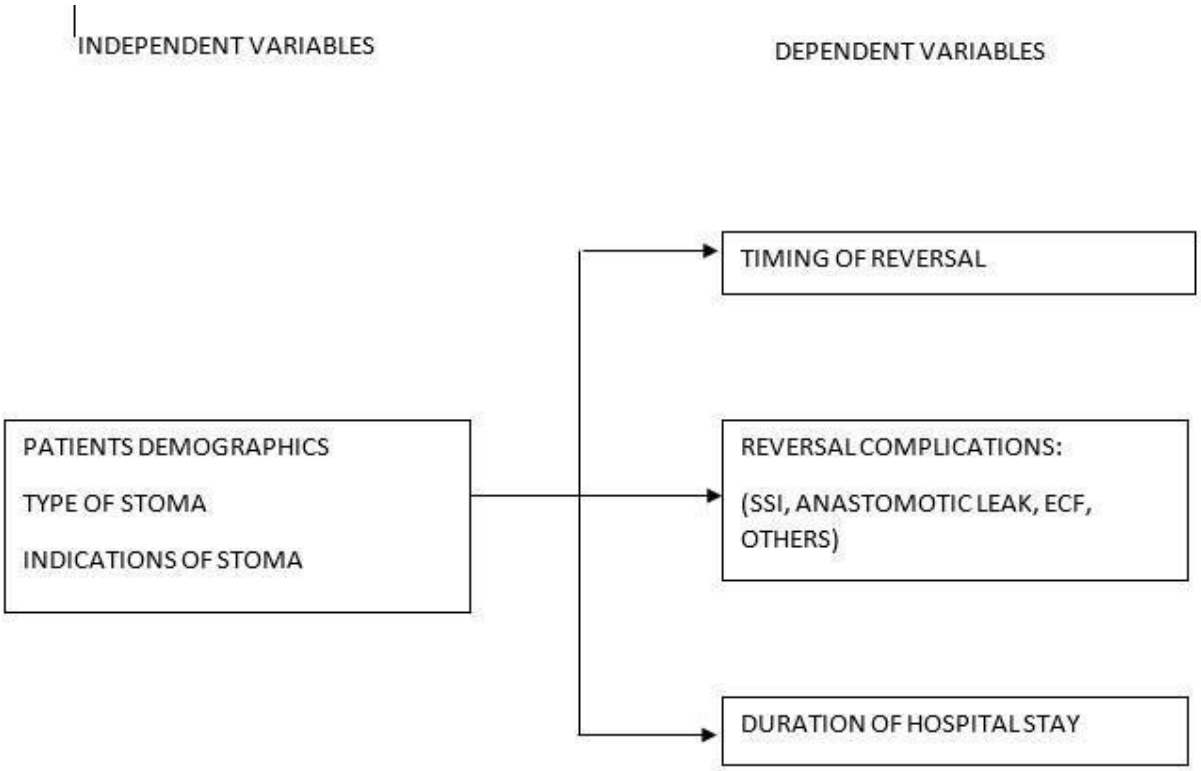
Stoma reversal is also associated with both midline and stoma site hernia. Incidence ranges from 8.7%-58%. Risk factors for hernia formation include obesity, stoma prolapse, malignancy, parastomal hernia and increased intra-abdominal pressures [71] [72]. Prophylactic synthetic

mesh placement is recommended especially in patients with a history of parastomal hernia [34].

The choice of colostomy or ileostomy for temporary fecal diversion has been a subject of debate. In an attempt to reduce complications of stoma and its reversal, different studies have attempted to compare colostomy vs ileostomy for temporary diversion. Ileostomy is preferred to colostomy due to reduced complications rates of reversal [73], colostomy has more incidence of prolapse [74], ileostomy reversal has reduced rate of wound infection and reduced rate of incisional hernia following reversal [75]. However, in instances of non-reversal, care of an ileostomy with high output and increased skin related complications becomes a burden to the patient.

Creation of stoma can be a lifesaving procedure. However due to morbidity and cost of maintaining a stoma reversal should be done as soon as possible. Guidelines are not available locally and factors that influence the timing of these reversals have not been studied locally. Moreover, no literature is available on ileostomy done in adult patients at KNH.

2.2 CONCEPTUAL FRAMEWORK



2.3 STATEMENT OF PROBLEM

Stoma creation is a common procedure done for fecal diversion. It is associated with considerable morbidity and there are no guidelines on timing of reversal of stoma. Timing of reversal affects the outcome of the reversal procedure. Factors that are associated with the timing of reversal of stoma in KNH and their influences on complications in KNH is not known.

2.4 STUDY JUSTIFICATIONS AND UTILITY

There is paucity of data regarding factors associated with timing of reversal of stoma in KNH. Available studies on stoma were done more than 20 years ago. Since then there has been increasing diagnosis of colonic malignancy, change in management strategies for colonic injury and volvulus. This has led to change in indications for stoma creation. It has been established from literature that timing of stoma reversal influences complication rates of reversal and morbidity of having a stoma.

This study will bridge the gap in knowledge of current indications, complications and timing of stoma reversal. It will also provide data on ileostomy that has never been studied locally. This data will be useful in providing a basis for formulation of local guidelines on timing of stoma reversal.

2.5 STUDY QUESTIONS

1. What are the factors that are associated with the timing of reversal of stoma in KNH?
2. What is the average timing of stoma reversal at KNH?
3. What is the rate of immediate complications of stoma reversal at KNH and its relationship to timing of reversal?

2.6 STUDY OBJECTIVES

BROAD OBJECTIVE

To determine the factors associated with the timing of stoma reversal and outcomes in adult patients with intestinal stoma at KNH.

SPECIFIC OBJECTIVES

1. To determine the demographic and clinical factors associated with the timing of stoma reversal in KNH
2. To determine the average timing of stoma reversal at KNH
3. To establish the rate of immediate complications of stoma reversal and its correlation with timing of reversal at KNH.

SECONDARY OBJECTIVES

1. To determine the common indications and type of stoma fashioned at KNH
2. To establish the common complications of stoma and their rates at KNH

CHAPTER 3: METHODOLOGY

3.1 STUDY DESIGN

This study utilized retrospective cohort design spanning through a period of 7 years (Feb 2016-Feb 2023. The study cohort were all patients who had stoma created and reversed at Kenyatta national hospital. This design enabled data regarding stoma characteristics to be collected and analyzed for outcomes.

3.2 STUDY SITE

This study was conducted at KNH medical records department. KNH records department harbors both electronic and physical data for both in-patient and out-patient records.

Kenyatta National Hospital is a national referral facility located in the Upper Hill area of Nairobi, Kenya, approximately 3.5km west of the central business district. It is a tertiary facility with 2000 bed capacity and runs a busy General surgery and oncology clinic with a special clinic dedicated for stoma care. Preliminary search showed approximately 30 stomas were created and reversed every year.

KNH also serves as the primary teaching hospital for the School of Medicine of the University of Nairobi.

3.3 STUDY POPULATION

All patients who had intestinal stoma fashioned and reversed in the preceding 7 years (February 2016- February 2023) who met the inclusion criteria.

.3.4 INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA

- All patients with intestinal stoma created and reversed between February 2016 and February 2023

EXCLUSION CRITERIA

- Patients with stoma created in other facilities and referred to KNH for definitive care or management of complications. This is because surgical details of stomas created outside KNH may not be obtainable from referral documents**.**
- Patients below 12 years of age since the study focuses on adult patients (considered above 12 years in KNH).
- Patients with permanent stoma that were planned preoperatively. These patients will not require reversal hence data in timing of reversal and reversal complications will be missing.

POTENTIAL CONFOUNDERS:

- Patients reversed in other facilities
- Patients due for reversal but experience delays due to a long elective booking list.

3.5 SAMPLE SIZE DETERMINATION

This was a census study therefore all patients with stoma created and reversed in the 7-year period were considered.

3.6 SAMPLING PROCEDURE

Records of patients with stoma fashioned and reversed were obtained from the records department and theater records**.** All included patient records were sampled.

3.7 RECRUITMENT OF STUDY PARTICIPANTS

Patient number and details were obtained from records department and theater records. Electronic data retrieval system was used to retrieve individual files. Manual data retrieval from patient files was done to complete the data collection tool.

3.8. DATA VARIABLES

Independent variables: Age, sex, indications of stoma, type of stoma

Dependent variables: stoma complications, timing of reversal, reversal complications, duration of hospital stay

3.9 DATA COLLECTION

Relevant data was collected using a pre-tested and printed data collection sheet annexed.

Patients demographic data collected included age, gender, BMI, residence, HIIF status, occupation and highest education level

Details of stoma creation collected included date of stoma creation and date of discharge from hospital, indications of the stoma creation, type of stoma creation and site of creation, complications of stoma, need for re-operation of any comorbidities and whether there was neoadjuvant treatment in case of malignancy.

Stoma reversal details collected included date of reversal and date of discharge, type of reversal, type of suturing technique, type of skin closure, immediate complications of reversal as well as length of hospital stay post reversal.

Principal investigator and two trained research assistants recruited from final year undergraduate medical students aided in collecting these data from patient files. Training of the assistants was done by the principal investigator.

3.10 DATA ANALYSIS

Data obtained and recorded in the data collection tool was entered in Microsoft Spreadsheet with the aid of google forms. Key outcomes were timing of stoma reversal and factors associated with the timing of reversal. Demographic factors of interest were age, gender, BMI, financial status, and education level. Factors relating to stoma included timing of creation as

either emergency or elective, indication and type of stoma, complications, comorbidities, neoadjuvant treatment, type of reversal, suture technique, type of skin closure and immediate complications of reversal.

Data analysis was done using both descriptive and inferential analysis. Demographic and clinical characteristics were summarized descriptively. Categorical data was summarized using frequencies and percentages. Continuous data was summarized using Median and Interquartile range (IQR). Indications for stoma creation were analyzed descriptively using frequencies and percentages.

Binary logistic regression was conducted to investigate indications associated with timing of stoma (emergency vs elective). Odds ratios were computed to explain the extent of the existing association. The timing of stoma reversal was analyzed descriptively using median (Interquartile range). A histogram was also utilized to illustrate the distribution of timing of stoma reversal.

Factors associated with stoma reversal were investigated using binary logistic regression. In investigating demographic and clinical characteristics associated with time to reversal, independent samples t -test and one-way analysis of variance were used. Binary logistic regression was also used to investigate the association between time to reversal and presence of stoma reversal complication. The significance was assessed at 95% confidence level where variables with a $p<0.05$ were considered to be statistically significant. Stata version 17 was used for analysis.

3.11 DATA MANAGEMENT

Physical data was stored in a secured place from unauthorized access under lock and key. Electronic data was stored in password protected hard drives only accessible to the principal investigator.

3.12 ETHICAL CONSIDERATION

Ethical approval from KNH/UON Ethics and Research committee was sought before onset of data collection in this study. This being a retrospective study based on patient records hence being low risk study, waiver of consent was granted by ERC.

Institutional approval was obtained from KNH administration to allow access to patients' records.

Serial numbers were assigned to patients' medical records and no identifying information was captured in the data collection form. Confidentiality was maintained strictly by the principal investigator and the research assistants.

3.13 STUDY LIMITATIONS

- Data omission in patient files
- One hospital study

MITIGATION OF LIMITATIONS

- Collection of data from complete records
- KNH is the largest referral hospital so data can be generalized

3.14. STUDY RESULTS DISSEMINATION PLAN

Study will be conducted in three phases: phase one will entail recruitment and data collection, phase two will involve data analysis and presentation to KNH and UON. Third phase will entail feedback to KNH surgical department and UON department of surgery. The recommendations from this feedback will be incorporated in the final report which will be presented in both electronic and bound booklets to be submitted to UON postgraduate studies, UON library, KNH department of research and publication in peer reviewed journals.

3.15. STUDY TIMELINE

	DURATION					
ACTIVITY	APRIL SEPT	OCT-FEB	MAR-APRIL	MAY	JUNE	JULY
Proposal development						
Ethics review						
Data collection						
Data analysis						
Dissertation submission						
Publication						

3.16 STUDY BUDGET

ITEM DESCRIPTION	AMOUNT
Ethics review and approval	5,000/=
Training of research assistants	6,000/=
Data collection	20,000/=
Stationary	30,000/=
Statistician	40,000/=
Publication	10,000
Administration cost (15%)	8,550/=
Total	**127,650/=**

CHAPTER 4: RESULTS

Patient characteristics

The median age of patients with intestinal stoma was 41 (IQR:30 – 54) years and the mean age was 42.5years, 64% (n =183) were male. The findings also showed that almost half, 49.3% (n =141) resided within Nairobi. Further, 50.7% (n =145) had active NHIF as shown in **Table 1**:

The median BMI was 19.1kg/m^2(IQR: 17.8 – 22.2), 29.7% (n =85) of the patients had a comorbidity with hypertension being the most common 29.4% (n =25). 56.6% (n =162) had stoma created as an emergency surgery. Among those who had malignancy 40% (n =22) were in stage IV as shown in **Table 2.**

Table 1: Demographic factors in adult patients with intestinal stoma at KNH.

Demographic factors	Frequency	Percent
Age (Median, IQR)	41(30 - 54)	
Gender		
Female	103	36.0
Male	183	64.0
Residence (n =265)		
Within Nairobi	141	53.2
Outside Nairobi	124	46.8
NHIF status (n =258)		
Active	145	56.2
Do not have	12	4.7
Inactive	101	39.1
Occupation (n = 211)		
Salaried employee	29	13.7
Self employed	119	56.4
Unemployed	63	29.9
Formal education (n =222)		
None	36	16.3
Primary	66	29.7
Secondary	80	36.0
Tertiary	40	18.0

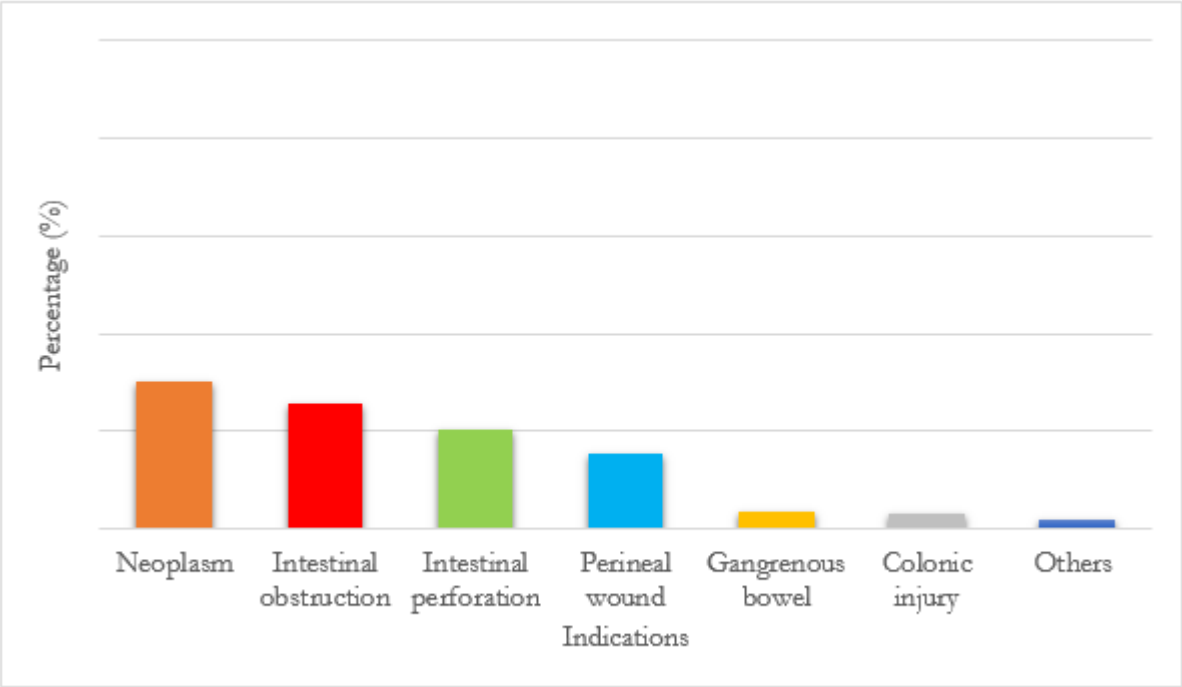
Table 2: Clinical factors in adult patients with intestinal stoma at KNH.

Clinical factors	Frequency	Percent
BMI (Median, IQR)	19.1(17.8 - 22.2)	
Presence of comorbidity		
Yes	85	29.7
No	201	70.3
Comorbidities present		
Hypertension	25	29.4
RVD	16	18.8
Malnutrition	14	16.5
Diabetes	5	5.9
Hypertension and diabetes	12	14.1
Others	13	15.3
Stoma timing (n =262)		
Elective	100	35.0
Emergency	162	65.0
Tumor staging (n = 50)		
II	11	26.0
III	17	34.0
IV	22	40.0
Neoadjuvant treatment		
Yes	44	88.0
No	6	12.0
Type of neoadjuvant treatment		
Chemotherapy	25	56.8
Radiotherapy	6	13.6
Radiotherapy and Chemotherapy	13	29.6

Indications for stoma creation

The common indications for stoma included neoplasm 30.1% (n =86), intestinal obstruction 25.5% (n =73) and intestinal perforation 20.3% (n =58) as shown in **Figure 1:**

Figure 1: Indications for stoma fashioned at KNH



Intestinal obstruction and intestinal perforation were the most common indications in emergency surgery (85.3%, n=58 and 77.2%, n=44 respectively) while neoplasm was the main indication of stoma fashioned in elective surgery. However, 44.7%(n=34) of stoma created due to malignancy were done in an emergency setting. Perineal wound was an indication in both elective and emergency surgery (54.1%, n= 20 and 45.9%, n= 17 respectively) as shown in **Table 3**:

Table 3: Stoma indications for emergency vs for elective cases

Indication	Timing Emergency n (%)	Elective n (%)
Intestinal obstruction	58(85.3)	10(14.7)
Intestinal perforation	44(77.2)	13(22.8)
Neoplasm	34(44.7)	42(55.3)
Perineal wound	20(54.1)	17(45.9)
Gangrenous bowel	5(55.6)	4(44.4)

Colonic injury	6(85.7)	1(14.3)

Type and site of stoma fashioned

Double barrel 31.1% (n =89) and Loop 30.8% (n =88) were the common types of stoma. More than half of the patients had stoma in sigmoid region 52.1% (n =149) as shown in **Table 4:**

Table 4: Type and site of stoma fashioned at KNH

Type of stoma	Frequency	Percent %
Double barrel	89	31.1
Loop	88	30.8
Hartman's	46	16.1
Divided	41	14.3
Brook's ileostomy	15	5.2
Others	7	2.4
Site		
Sigmoid	149	52.1
Ileostomy	57	19.9
Transverse	35	12.2
Descending	14	4.9
Others	31	10.8

Double barrel (31.5%) and Hartman's (27.4%) were the most common type of stoma created for intestinal obstruction whereas in neoplasm, loop (30.9%) and double barrel (25.9%) were the most common as shown in **Table 5**:

Table 5: Stoma indications and type of stoma

	Stoma type n (%)				
Indications	Double Barrell	Loop	Hartman's	Divided	Brook's ileostomy
Intestinal obstruction	23(31.5)	15(20.5)	20(27.4)	9(12.3)	6(8.2)
Intestinal perforation	23(40.4)	20(35.1)	6(10.5)	4(7.0)	4(7.0)
Neoplasm	21(25.9)	25(30.9)	17(21.0)	16(19.8)	2(2.5)

Perineal wound	11(25.6)	22(51.2)	3(7.0)	5(11.6)	2(4.7)
Gangrenous bowel	6(60.0)	2(20.0)	0	2(20.0)	0
Colonic injury	0	4(57.1)	2(28.6)	1(14.3)	0

Stoma complications

SSI was the common complication 16.8% (n =48) with a median of 18 (IQR: 18 – 19) days to occurrence, 2.8% (n =8) had prolapse as a complication of stoma with 60(IQR: 40.5 – 255) days to occurrence as shown in **Table 6**. The findings also showed that 6% (n =16) of the patients needed re-operation due to complications of stoma.

Table 6: The common complications of stoma and their rates at KNH

Complications	n (%)	Time to occurrence Median (IQR) in days
SSI	48(16.8)	18(18 - 19)
Skin irritation	18(6.3)	25(19.5 - 42.5)
Retraction	12(4.2)	55(41 - 95)
Dehydration/ Acute kidney Injury	9(3.1)	4(4 - 10)
Ischemia/necrosis	9(3.1)	4(3.5 - 4)
Prolapse	8(2.8)	60(40.5 - 255)
Hematoma	4(1.4)	3(2 - 3.5)
Parastomal hernia	3(1.0)	60(45 - 150)

It was also shown that SSI was the most common complication in all types of stoma while prolapse was mostly seen in loop and divided stoma as shown in **Table 7**.

Table 7: Stoma complications and the type of stoma

	Complications						
Type of stoma	**Skin irritation, n (%)**	**Ischemia, n (%)**	**Hematoma, n (%)**	**SSI, n (%)**	**Retraction, n (%)**	**Prolapse, n (%)**	**Hernia, n (%)**
Double barrel	6(6.7)	4(4.5)	1(1.1)	25(28.1)	4(4.5)	0	1(1.1)
Loop	4(4.5)	2(2.3)	2(2.3)	8(9.1)	2(2.3)	4(4.5)	1(1.1)
Hartman's	2(4.3)	3(6.5)	0	8(17.4)	4(8.7)	1(2.2)	0
Divided	5(12.2)	0	1(2.4)	5(12.2)	1(2.4)	3(7.3)	1(2.4)

Timing of stoma reversal

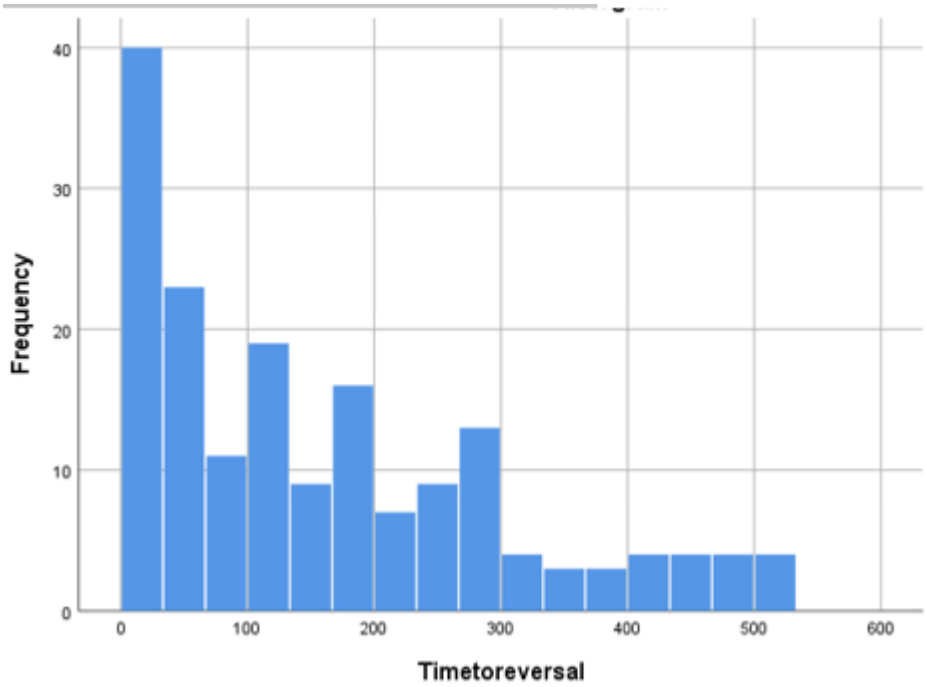
The average time of stoma reversal was 157.3(Mean±140.3) days while the median was 117(Interquartile Range (IQR) =34.5 – 243.5) as shown in **Table 8.**

Table 8: The average timing of stoma reversal at KNH

Time to stoma reversal		
Mean		157.25
Median		117.00
Std. Deviation		140.302
Skewness		0.944
Std. Error of Skewness		0.185
Quartiles	1st Quarter	34.50
	Median	117.00
	3rd Quartile	243.50

The histogram in **Figure 2** shows a skewed distribution of time to reversal with most stoma reversal occurring within 200 days after stoma creation.

Figure 2: Distribution stoma time to reversal



Stoma reversal characteristics

The findings showed that 60.5% (n =173) of the patients had stoma reversal during the study period. Further, 93% (n=161) of them had hand sewn anastomotic technique. Only 8.2% (n=16) had purse string sutures as a method of skin closure as shown in **Table 9.**

Table 9: Stoma reversal in adult patients with intestinal stoma at KNH

Characteristics	Frequency	Percent
Presence of stoma reversal		
Yes	173	60.5
No	113	39.5
Type of anastomotic technique		
Hand sewn	161	93.0
Staple	12	7.0
Type of skin closure		
Conventional	157	90.8
Purse string	16	8.2
Type of reversal		
Laparotomy/Intraperitoneal	120	69.4
Stromal/Extraperitoneal	53	30.6

Complications of stoma reversal

The findings established that 17.3% (n =30) of the patients with stoma reversal had complications within an average of 10.3(SD±6.5) days after reversal. SSI was the most common complication occurring within a median of 8(IQR:6 – 12) days after reversal as shown in **table 10**.

Table 10: The rate of complications of stoma reversal

Complications	n (%)	Time to occurrence Mean, SD or (Median (IQR) days
Presence of immediate stoma reversal complication		
Yes	30 (17.3)	
No	143(82.7)	
Anastomotic leak	5(2.9)	2.5(1 -7)
SSI	23(13.2)	8(6 – 12)
ECF	1(0.6)	11

Need for re-creation of stoma	1(0.6)	8

Demographic and clinical factors associated with stoma reversal stoma reversal

The study also investigated the factors associated with stoma reversal in KNH. The findings from binary logistic regression established that those who had primary or lower level of education (Odds Ratio (OR) =1.03(95%CI:1.01 – 1.04, p=0.001), those who were unemployed (OR =2.24, 95%CI:1.13 – 4.44, p =0.021) and having emergency timing of stoma (OR =2.09, 95%CI:1.25 – 3.49, p =0.005) were more likely to have their stoma reversed at KNH. Those who had neoplasm as stoma indication were 87% less likely to have stoma reversal, OR 0.13, 95%CI:0.07 – 0.23, p<0.001. In investigating type of stoma, those with loop (OR =5.57, 95%CI:1.19 – 25.99, p =0.029), Hartman's (OR = 5.39, 95%CI:1.10 – 26.46, p =0.038) and divided (OR =6.05, 95%CI: 1.22 – 30.06, p =0.028) were more likely to have stoma reversal as shown in **Table 11**.

Table 11: The demographic and clinical factors associated with stoma reversal in KNH

Factors	Stoma reversal			
	Yes, n (%)	No, n (%)	OR (95%)	P-value
Gender				
Female	61(35.3)	42(37.2)	0.92(0.56 - 1.51)	0.807
Male	112(64.7)	71(62.8)	Ref	
Education	39.89(14.83)	46.52(18.03	1.03(1.01 - 1.04)	**0.001**
Primary or lower	64(41.8)	38(55.1)	1.78(0.78 - 4.05)	0.168
Secondary	59(38.6)	21(30.4)	1.07(0.45 - 2.55)	0.883
Tertiary	30(19.6)	10(14.5)	Ref	
Occupation				
Salaried employee	24(16.9)	5(7.2)	Ref	
Self employed	70(49.3)	49(71.0)	0.67(0.22 - 2.05)	0.48
Unemployed	48(33.8)	15(21.7)	2.24(1.13 - 4.44)	**0.021**
Stoma timing				
Elective	51(31.5)	49(49.0)	Ref	
Emergency	111(68.5)	51(51.0)	2.09(1.25 - 3.49)	**0.005**
Presence of comorbidity				
Yes	57(32.9)	28(24.8)	1.49(0.88 - 2.54)	0.148
No	116(67.1)	85(75.2)	Ref	
Neoplasm				

Yes	23(27.4)	61(72.6)	0.13(0.07 - 0.23)	<**0.001**
No	150(74.3)	52(25.7)	Ref	
Type of stoma				
Double Barrell	58(65.2)	31(34.8)	3.74(0.80 - 17.53)	0.090
Loop	49(55.7)	39(44.3)	5.57(1.19 - 25.99)	0.029
Hartman's	26(56.5)	20(43.5)	5.39(1.10 - 26.46)	0.038
Divided	22(53.7)	19(46.3)	6.05(1.22 - 30.06)	0.028

Demographic and clinical factors associated with timing of stoma reversal

The findings showed that there was significant association between stoma timing (p =0.013), indication of stoma (p<0.001), presence of comorbidities (p<0.001) and adjuvant treatment (p=0.014) with the time to stoma reversal. Stoma created as an emergency were reversed earlier compared to those created in elective procedures (119.95±109.16 vs 177.09±151.63 days, p= 0.013). Presence of comorbidities, neoplasm and adjuvant treatment prolonged the time to reverse the stoma as shown in **Table 12.**

Table 12: Demographic and clinical factors associated with time to reversal

	Average time to stoma (Mean± SD)	P-value
Age		
≤40 years	171.69±45.54	0.105
>40 years	136.52±111.64	
Education level		
Primary or lower	138.78±124.92	0.099
Secondary or higher	180.51±152.80	
Employment status		
Employed	164.47±144.50	0.373
Unemployed	144.65±132.84	
NHIF		
NHIF	164.48±148.64	0.323
No NHIF	140.66±119.09	
Stoma timing		
Elective	119.95±109.16	**0.013**
Emergency	177.09±151.63	
Indications of stoma		
Neoplasm	341.22±153.44	<**0.001**
Non-Neoplasm	129.05±114.99	

Type of stoma		
Ileostomy	120.19±113.91	
Double barrel	140.02±131.91	
Loop	163.08±137.91	0.511
Hartman's	173.35±150.91	
Presence of comorbidities		
Present	232.96±144.37	**<0.001**
Absent	73.59±72.71	
Stoma complication		
Present	158.9±142.75	0.908
Absent	156.33±139.56	
Adjuvant treatment		
Present	233.78±171.14	**0.014**
Absent	148.37±134.12	

Timing of stoma reversal and post reversal complications

The results showed that the likelihood of stoma reversal complications was six times higher among those with late time to reversal compared to those with early time to reversal, Odds Ratio (OR) = 5.89, 95%CI: 1.96 – 17.75, p<0.001 as shown in **Table 13.**

Table 13: The rate of immediate complications of stoma reversal and its correlation with timing of reversal

	Stoma reversal complication			
Time factor	**Present n (%)**	**Absent n (%)**	**OR (95%CI)**	**P-value**
Time to reversal				
Early reversal (≤90 days)	4(13.3)	68(47.6)	Ref	
Late reversal (>90 days)	26(86.7)	75(52.4)	5.89(1.96 - 17.75)	0.002

CHAPTER 5: DISCUSSION

The average age of patients with stoma was 42.5 years with a male predominance of 64% (n =183). This represents a slightly older population compared to an earlier study in KNH by Sheikh et al that found the average age to be 35 years [19]. This can be attributed to increased diagnosis and management of colorectal malignancies with stoma fashioning especially in the elderly population. This age is however comparable to studies in the region that ranges between 40-55 years [13] [15] [16]. The male to female ratio was 1.7:1. This is also comparable to other studies in the region [16] [17]. The male predominance may be attributed to the fact that sigmoid volvulus and trauma, which are common indications for stoma creation, occur more frequently in this gender [12]. Majority of the patients resided within Nairobi owing to its proximity to the study site. Being a public institution, it attracted patients of low socio-economic status with no formal employment, medical insurance and higher level of education. Comorbidities were demonstrated in only 29.7% of the study population. This could be accounted for by the fact that the most common comorbidities, Hypertension and diabetes, affect older generations than the average age of the study participants.

Neoplasm (30.1%), Intestinal obstruction (25.5%) and intestinal perforation (20.3%) were the most common indications for stoma creation. This contrasted with earlier studies in KNH that showed colonic injury and obstruction due to sigmoid volvulus being an indication in 85% [19]. Older studies in the region also contrasted with gangrenous sigmoid volvulus, left sided colorectal cancers and trauma respectively being the common indication for stoma creation. There were no recent local or regional studies to compare with. However, the findings were comparable to studies in India in which GIT malignancy, abdominal trauma and viscus perforation were the predominant indication for stoma creation [15]. There is increasing diagnosis and management of colorectal neoplasms hence the finding of neoplasm as a common indication for stoma creation is not surprising [80]. The numbers might even be higher considering distinction was not clearly defined for the causes of intestinal obstruction and perforation in this study.

In contrast with earlier studies in which Hartman's colostomy was the most common type of stoma [19], double barrel (31.1%) and loop ileostomy (30.8%) were the most common type of stoma in this study. The Sigmoid region remains the most common site of stoma. This finding could be explained by the fact that sigmoid volvulus, which was the main indication for Hartman's stoma in the past, has been surpassed by neoplasm and trauma. Loop ileostomies are also technically easier to fashion and reverse hence are a preferred stoma choice in cases of trauma and temporary diversion.

Surgical site infection (16.8%) and skin irritation (6.3%) were the most common complications. This is comparable to both regional and international studies [13] [16] [17]. The rate of complication is also comparable to an earlier study by Sheikh et al at 16.7% [19]. However, this rate is still much lower than studies in India that report rates of 82% [15]. This might be due to inadequate identification and documentation of stoma complications in our setup. Double barrel and loop stomas were shown to be associated with more surgical site infection. This is attributable to the fact that they are the most preferred types of stoma fashioned in trauma and emergency setups associated with contamination.

The average time of stoma reversal was 5.2 months. This was a 2.4 months' decrease compared to earlier findings in KNH by Sheikh et al that found an average of 7.6 months [19]. The reason for the decrease could not be established but can be attributed to improved patient care and infrastructure over the years. This time is still longer compared to studies in India which average 1-4 months [16]. It is comparable to studies in Uganda which show an average of 6.6 months [16] [18] [45]. Hand sewn anastomosis is still the most common technique of anastomosis in KNH accounting for 93% of the reversals. This is attributed to the high cost and unavailability of stapling devices. Extra peritoneal stoma closure, despite being favored in other studies due to reduced contamination, was not common in this setup with 63% of reversals being done intraperitoneal. This could be due to the ability to achieve proper dissection and anastomosis under good vision of bowel loops in intraperitoneal anastomosis. Purse string closure of skin was only seen in 8.2% of cases despite being recommended to reduce the risk of SSI [67-70]. Lack of knowledge of this practice might be the reason for reduced utility.

Post reversal complication of 17.3% with SSI as the most common complication is comparable to other studies locally and internationally. Sheikh et al found a rate of 16.7% while Bekele et al found a rate of 19.5% [16] [19].

Stoma created during emergency setting and in patients with low socioeconomic status were more likely to be reversed. Those with neoplasm were less likely to be reversed. This was comparable to a study by Resio et al that showed similar findings [78]. Presence of comorbidities did not seem to significantly influence the timing of stoma reversal as in other studies [16]. Stoma created in emergency setup tend to be temporary hence more likely to be reversed. KNH being a public facility, those of low socio-economic status are more likely to be reversed in the facility. It is possible that those of higher socio-economic status had stoma reversal in other facilities explaining the findings. Moreover, those with neoplasm were most likely in an advanced stage and might have been deceased or deemed irreversible hence low reversal rates.

Post reversal complications were more likely in patients with late reversal. Abebe et al found similar results with optimal timing of reversal in his study being 3-6 months, during which there were low post reversal complications [16]. Karen et al found anastomotic leak rate significantly higher in stoma reversed after 90 days [79]. However, Benjamin et al found no difference in complication rates based on timings of stoma reversal. His study was however limited to Hartman's procedure for complicated diverticulitis [78].

CONCLUSION

Stoma creation is an important surgical procedure that can be lifesaving. It is associated with various complications and significant morbidity. Appropriate timing of reversal is key in preventing both morbidities of stoma and post reversal complications.

RECOMMENDATION

From the findings of this study I recommend early reversal of stoma (within 90 days of creation) in order to reduce the morbidity of stoma and post reversal complications.

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APPENDICES

DATA COLLECTION TOOL

SERIAL NO: …….

DATE: …….

STUDY*: FACTORS ASSOCIATED WITH THE TIMING OF INTESTINAL STOMA REVERSAL AND OUTCOMES IN ADULT PATIENTS AT KNH.*

1. DEMOGRAPHIC DETAIL:

1.1 AGE 1.6 RESIDENCE

1.2 SEX 1.7 NHIF STATUS

1.3 BMI 1.9 OCCUPATION

1.4 DATE OF CREATION 1.9 EDUCATION LEVEL

1.5 DATE OF REVERSAL

2. STOMA CREATION

Active	Inactive

2.1 ***DATE OF STOMA CREATION***……..……

2.2 ***DATE OF DISCHARGE***…….

EMERGENCY

2.3 TIMING:

ELECTIVE

2.4 INDICATION:

COLONIC INJURY NEOPLASM	
NEOPLASM	
PERINEAL WOUND	
INTESTINAL OBSTRUCTION	
GANGRENOUS BOWEL	
INFLAMMATORY BOWEL DISEASE	
COMPLICATED DIVERTICULOSIS	
INTESTINAL PERFORATION	
OTHER	
_____	

DIAGNOSIS

STAGE

2.5 TYPE OF STOMA

	ILEOSTOMY		COLOSTOMY/ SITE
	CM FROM ICJ	CM FROM DJ	
LOOP			
HARTMAN'S			
DOUBLE BARREL			
DIVIDED			
OTHER			

NB: ICJ: ileocecal junction, DJ: duodenojejunal junction, Colostomy site recorded as either ascending, descending, transverse or sigmoid

3.1 STOMA COMPLICATIONS

COMPLICATION	*DAYS AFTER CREATION*
Dehydration/ Acute kidney Injury	
Skin irritation	
Ischemia/necrosis	
Hematoma/bleeding	
Retraction	
Prolapse	
Parastomal hernia	
Others _____	

3.2 NEED FOR RE-OPERATION

YES	
NO	

3.3 LENGTH OF HOSPITAL STAYAFTER CREATION_____DAYS

3.4 COMORBIDITIES:

	YES	NO
DIABETES MELLITUS		
HYPERTENSION		
SMOKING		
OBESITY		
MALNUTRITION		
STEROID USE		
OTHERS		

3.5 NEOADJUVANT TREATMENT (In case of malignancy)

YES	NO

Radiotherapy		
Chemotherapy		

4 STOMA REVERSAL

4.1 DATE OF ADMISSION	
4.2 DATE OF DISCHARGE	

4.3 TYPE OF REVERSAL

LAPAROTOMY/ INTRAPERITONEAL	
STROMAL/ EXTRAPERITONEAL	

4.4 TYPE OF ANASTOMOTIC TECHNIQUE

HAND SEWN	
STAPLE	

4.5 TYPE OF SKIN CLOSURE

PURSE STRING	
CONVENTIONAL	

4.6 COMPLICATIONS OF REVERSAL

	DAYS POST REVERSAL
Anastomotic leak	
Surgical site infection	
Enterocutaneous Fistula	
Need for re-creation of stoma	
Others _____	

4.7 LENGTH OF HOSPITAL STAY AFTER REVERSAL_____DAYS