Analysis of risk factors of stoma related complications- An observational study.

Dissertation submitted in partial fulfilment of the requirement of the Tamil Nadu Dr. M. G. R. Medical University for the M.S General Surgery Examination to be held in May 2020.

University Registration number: 221611452

CERTIFICATE

This is to certify that the dissertation titled, “Analysis of risk factors of stoma related complications- An observational study.” is the bonafide work of

Dr. Dany Sunny , in partial fulfilment of the requirements for the M.S General Surgery (final) examinations of The Tamil Nadu Dr. M.G.R medical university to be conducted in May 2020.

Signature:

Dr. Suchitha Chase. (Guide)
Associate Professor
Department of General Surgery,
Surgery Unit VI
Christian Medical College,
Vellore

CERTIFICATE

This is to certify that the dissertation titled, “Analysis of risk factors of stoma related complications- An observational study.” is the bonafide work of

Dr. Dany Sunny , in partial fulfilment of the requirements for the M.S General Surgery (final) examinations of The Tamil Nadu Dr. M.G.R medical university to be conducted in May 2020.

Signature:

Dr. Sukriya Nayak,
Professor and Head,
Department of General Surgery,
Christian Medical College,
Vellore

CERTIFICATE

This is to certify that the dissertation titled, “Analysis of risk factors of stoma related complications- An observational study.” is the bonafide work of

Dr. Dany Sunny , in partial fulfilment of the requirements for the M.S General Surgery (final) examinations of The Tamil Nadu Dr. M.G.R medical university to be conducted in May 2020.

Signature:

Dr. Anna B. Pulimood,
Principal,
Christian Medical College,
Vellore

DECLARATION

I hereby declare that this dissertation titled, "Analysis of risk factors of stoma related complications- An observational study" was prepared by me in partial fulfilment of the regulations for the award of the degree of M. S. General Surgery of The Tamil Nadu Dr. M.G.R medical university, Chennai. This has not formed the basis for the award of any degree to me before and I have not submitted this to any other university previously.

Candidate Signature:

Dr. Dany Sunny

P.G. Registrar

Department of General Surgery

C.M.C. Vellore Hospital

University Registration Number: 221611452

ACKNOWLEDGEMENTS

I acknowledge God, for all guidance, mercies and support.

Dr. Suchitha Chase, for all that she has taught me and for mentoring me.

Mr Bijesh Yadav, for helping me with the data analysis.

Dr. Abhinaya Nadarajan and Dr. Titus D.K for helping me with the formation of the topic and methodology of this study.

Dr. Sukriya Nayak and the entire Department of General Surgery for being supportive throughout the course.

I acknowledge all my teachers, for making this study and this course a reality.

I also thank my family for being a constant source of support and encouragement.

Finally, and most importantly, I would like to express my gratitude to all the patients for their selfless participation in this research for the evolution of medical care.

Urkund Analysis Result

Analysed Document: Dragon thesis for print - Copy.docx (D57294094)
Submitted: 10/20/2019 3:57:00 AM
Submitted By: danysunnydragon@gmail.com
Significance: 18 %

Sources included in the report:

Seminareversion.Hallgren.Astrid.doc (D34133221)
Slutversion.Hallgren.Astrid.docx (D34664973)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3709920/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5498161/
https://www.researchgate.net/publication/327943345_Preoperative_stoma_site_marking_a_simple_practice_to_reduce_stoma- related_complications
https://www.ncbi.nlm.nih.gov/pubmed/29493785
https://www.researchgate.net/publication/26672731_Stoma_Complications_a_literature_overview
https://www.researchgate.net/publication/26285787_Stoma-related_complications_and_stoma_size_-_a_2-year_follow_up
https://www.researchgate.net/publication/323503624_Randomized_clinical_trial_of_intracutaneously_versus_transcutaneously_sutured_ileostomy_to_prevent_stoma-related_complications_ISI_trial_Intracutaneously_versus_transcutaneously_sutured_ileostomy
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3133986/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5947256/
https://www.ijsurgery.com/index.php/isj/article/view/4598
https://link.springer.com/article/10.1007/BF02237308
https://www.thieme-connect.com/products/ejournals/pdf/10.1055/s-0037-1598160.pdf
https://lupinepublishers.com/surgery-case-studies-journal/fulltext/complications-of-stoma-and- the-management.ID.000132.php
https://lupinepublishers.com/surgery-case-studies-journal/pdf/SCSOAJ.MS.ID.000132.pdf
https://link.springer.com/article/10.1007/s10151-018-1924-9
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6441068/

https://www.wocnext.org/WOCN2019/Custom/Handout/Speaker0_Session737_1.pdf
https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0038-1676995 https://link.springer.com/chapter/10.1007/978-3-030-24812-3_36
https://www.semanticscholar.org/paper/Complications-and-mortality-following-stoma-Harris- Egbeare/20a77635924d537a6ff0ed66ef8d0e05e5282fd3
https://www.researchgate.net/publication/7504188_Complications_and_mortality_following_stoma_formation
https://www.ncbi.nlm.nih.gov/nlmcatalog/101736436
https://www.ncbi.nlm.nih.gov/nlmcatalog/101667903
https://www.ncbi.nlm.nih.gov/nlmcatalog/101628558
https://jamanetwork.com/journals/jamasurgery/article-abstract/591307 a2d939f0-fbd7-4754-b403-516d7e427be2
https://www.elsevier.es/en-revista-cirugia-espanola-english-edition--436-articulo-current- status-prevention-treatment-stoma-S2173507714001355
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5498169/
https://www.o-wm.com/article/role-obesity-patient-undergoing-colorectal-surgery-and-fecal- diversion-review-literature

Instances where selected sources appear:

96

CONTENTS

ABSTRACT…….. 10

REVIEW OF LITERATURE……. 13

METHODOOGY…… 53

RESULTS…… 58

DISCUSSION…… 74

CONCLUSIONS…….. 81

LIMITATIONS.…….83

BIBLIOGRAPHY……..85

ANNEXURES…… 91

Abstract

Background

Stoma is a Greek word meaning ‘mouth’ or ‘opening’. Stoma surgery results in a small opening on the surface of the abdomen being surgically created in order to divert the flow of faeces and/or urine. Stoma creation can be mentally and physically affecting the patient. The related complications due to the procedure can also have a bearing on the outcome of the stoma after the surgery and also on the financial status of the patient. There is also a social change these patients have to accept as a part of the stoma in view of need for constant change of bag, the smell that comes from it and also the difficulty in hiding the bag. There is also the additional burden of re-operation for stoma closure or for stoma complications which also puts a financial, physical and psychological strain on the patients.

Aim

To study the stoma related complications, risk factors assessment which will include patient related factors and intraoperative factors and to see if any

modifiable factors are seen with regards to these that could help change the patient outcomes.

Methodology

All the relevant data regarding the patients who have undergone surgery in the department of surgery unit IV from the year December 2011 to December 2018 was collected retrospectively and prospectively in the given period. The data was collected from hospitals electronic database and patient outpatient document. In relevant cases, telephonic communication was made with the patients to collect relevant data and for follow up. The period of study will be till the last recorded visit of the patient following the surgery to look for any complications of the procedure. The various data collected will include age, gender, initial diagnosis, comorbidities, if the surgery was elective or emergency, the person operating, if it is colostomy or ileostomy, if it is end or loop soma, albumin level, haemoglobin level and BMI of the patient. The data is then grouped for ease of study using relevant cut-off's. Once the data has been collected the same will be evaluated by means of statistical multivariant and univariant analysis to look for the relevant modifiable changes.

Results

In the study conducted the various parameters which could potentially be a cause of stoma complications were assessed as described above. The analysis of the same did not reveal any relevant finding. None of the parameters in the study showed any association with the formations of stoma complications following stoma surgery.

There was no significant association of these parameters with regards to the early and late stoma complications either.

Review of literature

Introduction

It has been estimated that around 100,000 people in the United States alone undergo surgeries that result in a stoma each year (1)

The most common underlying conditions resulting in stoma formation as per literature are colorectal cancer, bladder cancer, ulcerative colitis, Crohn's disease and Trauma surgeries (2–7). An array of stoma related complications can occur following the formation of stoma and hence the procedure of stoma creation is highly morbid (8). These could be early complications like stomal congestion, gangrene, retraction, parastomal abscess, peristomal irritation seen in the immediate postoperative period or late complications like stomal prolapse, stomal stenosis and parastomal hernia (4,5,9,10). The reported incidence of these conditions varies widely in the literature (2–7,9,11–13). Most of the data and study done on stomas put the overall rate of complications as high as 21%-70% (14). The individual rates of the complications also vary with different studies. The different complications may occur as early or as late complications (9). Many factors can predispose to these complications which include patient factors like obesity, underlying disease (indication), age and intraoperative factors like surgeons expertise, type of approach (laparoscopic or

open), placement of bridge. Other factors such as pre-operative stoma site marking can be used for improving patients' postoperative quality of life, promoting patient independence, and decreasing the rates of post-operative complications(15)

This paradox highlights the importance and tremendous impact of the surgeon's role in dealing with ostomies(6,9). The surgeon must be proficient at not only creating the stoma but also handling postoperative complications(6,13,16,17).

The study is being designed to look at the types of stoma, the related complications, the setting of the surgery and the clinical outcomes of the patients in terms of the varying complications among those who have undergone the surgery in our unit and to look at modifiable risk and outcomes from the data that has been collected.

History of stoma

The term “ostomy” is derived from the Greek word “stoma” (st0μa) which means “mouth”(18). Stoma is a surgically created opening made over the ventral abdominal wall created to divert the flow of faeces and/or urine(19,20). An entero-cutaneous stoma is therefore a controlled iatrogenic fistula. 4 A stoma may be fashioned as an alternative outlet to the gastrointestinal tract after the excision and removal of all distal bowel, or when restoration of continuity after a resection is contraindicated due to various reasons. Stomas are also used to provide a temporary or permanent diversion of the faecal stream to a distal pathology or a healing anastomosis

The evolution of the procedures leading to the formation of surgical abdominal stoma are outlined as ; intestinal exteriorization for or as a result of trauma, then stoma formation alone and lastly stoma formation associated with bowel resection done for various reasons.

The earliest depictions of stoma was seen documented by Greek literature dating back to the year 350 B.C. In this they described a person who as a result of sustaining an intestinal injury developed a stoma spontaneously. Later accounts and recommendations for the same occurred during the 16th and 17th centuries as described by Pillore and Duret, but were few in number.

Development of the stoma on a sound basis of physiology and anatomy did not occur until the late 19th century.(21)

It was Baum who performed the first ever ileostomy recorded in 1879 on a patient with an obstructing carcinoma of the ascending colon. The patient survived the procedure but died soon after from complications of a second operation that involved resecting the primary carcinoma and creating an ileocolic anastomosis(22).

Kraussold, Billroth, Bergman, and Maydl were among the other recorded 19th century surgeons who later on performed the ileostomy surgery. Maydl's patient is generally considered as the first to survive and fully recover from an ileostomy performed in combination with resection for colonic malignancy(23)

In 1776 Pillore, a French surgeon, created a cutaneous cecostomy for a wine merchant suffering from obstructing rectal carcinoma. Although the patient died a couple of weeks later due to a small bowel perforation as a result of forced catharsis, the cecostomy was the first ever recorded incidence of a successful colonic stoma being performed (22,23)

STOMAL PHYSIOLOGY

Physiologically a left-sided colostomy output is very similar to that of normal formed stool. Thus there is essentially no noticeable physiologic abnormalities associated with left-sided colostomy. Ileostomy output on the other hand clearly changes as the patient recovers from their surgery and appears to have three very distinct phases of adaptation.

In the initial three days, the output formed is bilious and mostly fluid in nature and the output of the same increases gradually with the maximum output occurring usually around the third or fourth day after the surgery.

During the second phase, starting from the fourth to the sixth day following the surgery, the output gradually stabilizes, thickens in consistency, and even decreases slightly in amount.

The third phase of adaptation is from the first week to the eighth week of surgery and is associated with a steady decrease of the volume and thickening of the stoma output (23,24).

After complete adaptation, the output from an ileostomy created without significant ileal resection stabilizes to about 200 to 700cc/day. Tang et al. (25)studied the ileostomy output of about 60 patients who underwent restorative proctectomy with a defunctioning ileostomy.

By the fourth postoperative day, about 65% of the patients had a normally functioning ileostomy. Ileostomy output was also seen to have peaked at the fourth day with a calculated median of 700mL (with a range between 10–3250mL) over a 24-hour period.

The output further decreased after the 5th day, and by the 10th postoperative day, a median output of about 300mL (range between 100–750mL) per 24-hour period was reached in spite of normal food intake. Small bowel adaptation following ileostomy creation usually results in an increased reabsorption of water and electrolytes.

In an average human being, between 1500–2000mL per day of ileal content exit the terminal ileum into the colon. In patients with ileostomy, as a result of ileostomy adaptation, about 70% to 80% of this output can be reabsorbed(23)

Types of stoma

Stoma may be categorised in multiple ways. One of this being temporary or permanent based on if the distal bowel from the stoma is functional normally or not and if the stoma will be reversed or not. The other categorisation of the stoma are named by the part of the intestine brought outside the body in order to form a stoma. A **colostomy** is a stoma created from the colon and an **ileostomy** is created from a segment of small intestine called the ileum being brought out.(20)

Both ileostomy and colostomy can be divided into two types based on if there is a continuity between the afferent and efferent limb of the stoma (23,26,27). It is hence classified into loop stoma and end stoma.

In a loop stoma the proximal and distal loops of the bowel are brought out of the same opening in the abdominal wall and there is a continuity of the two segments with each other.

An end conversely has only a proximal limb of bowel being brought out of the abdominal wall opening while the distal loop is sealed off and left behind in the abdominal cavity or the distal end may be brought out of another opening as a mucous fistula.

Apart from the above mentioned four anatomical categories, there is yet another distinct third category of stoma. This type of stoma has been called the "Prasad" style stoma or the end-loop stoma. These stomas can be made with the help of using two remote intestinal segments following bowel resection. They may be of the following types, end-loop ileo-ileostomy, ileo-colostomy, or colo-colostomy (28).

Preparation for stoma

Pre-operative

Whatever the indication for a stoma surgery may be, placement and construction are crucial for function.

Preoperative preparation of the patient expected to require a stoma should include a consultation with an enterostomal therapy (ET) nurse. ET nurses are specially trained as well as credentialed by the Wound, Ostomy and Continence Nurses Society in providing care for stoma patients and in the management of the day to day aspects of stoma care (29).

Preoperative preparation includes counselling and education of the patient and care giver, and stoma siting. Postoperatively, the ET nurse assists and teaches the patient and caregiver in local skin care and pouching of stoma. Other

considerations with regard to stoma planning include evaluation of any other medical conditions that may adversely have an impact on the patient's ability to manage a stoma (e.g., eyesight, manual dexterity).

Preoperative stoma siting is important for a patient's postoperative smooth functioning and better quality of life. A badly placed stoma can result in recurring problems such as leakage and skin breakdown (19). A stoma should ideally be created in such a way so that the patient can easily visualize and manipulate the stoma, should be within the rectus muscle fibres, and be below the belt line. As the abdominal landmarks in a supine, anesthetized patient can be varying significantly from that in an awake, vertical, or sitting patient, the stoma site should always be marked using a tattoo, skin scratch, or permanent marker preoperatively, whenever possible.

In the case of an emergency operation where the stoma site may not have been marked, attempt should be made to place the stoma within the rectus muscle and away from both the costal margin and the iliac crest. As such in emergencies, placement high on the abdominal wall is more preferred than a low-lying site (27,30).

Stoma surgery

The surgical approach for the surgery may be done as an open or as a laparoscopic surgery. The basic principles of the surgery in both the surgical methods are identical. The difference between the two being the utilization of laparoscopic techniques with smaller surgical wound in laparoscopy and in the open surgery there is a large midline incision made (31).

For any stomas to be made, a circular skin incision needs to be created and the subcutaneous tissue which is dissected up to the level of the anterior rectus sheath removing all the subcutaneous fat and then exposing the rectus sheath (23). The anterior rectus sheath is then incised in a cruciate fashion and the muscle fibres of the anterior rectus separated bluntly, and the posterior sheath identified and incised. Great care should be taken in avoid injury to and causing bleeding from the inferior epigastric artery and vein.

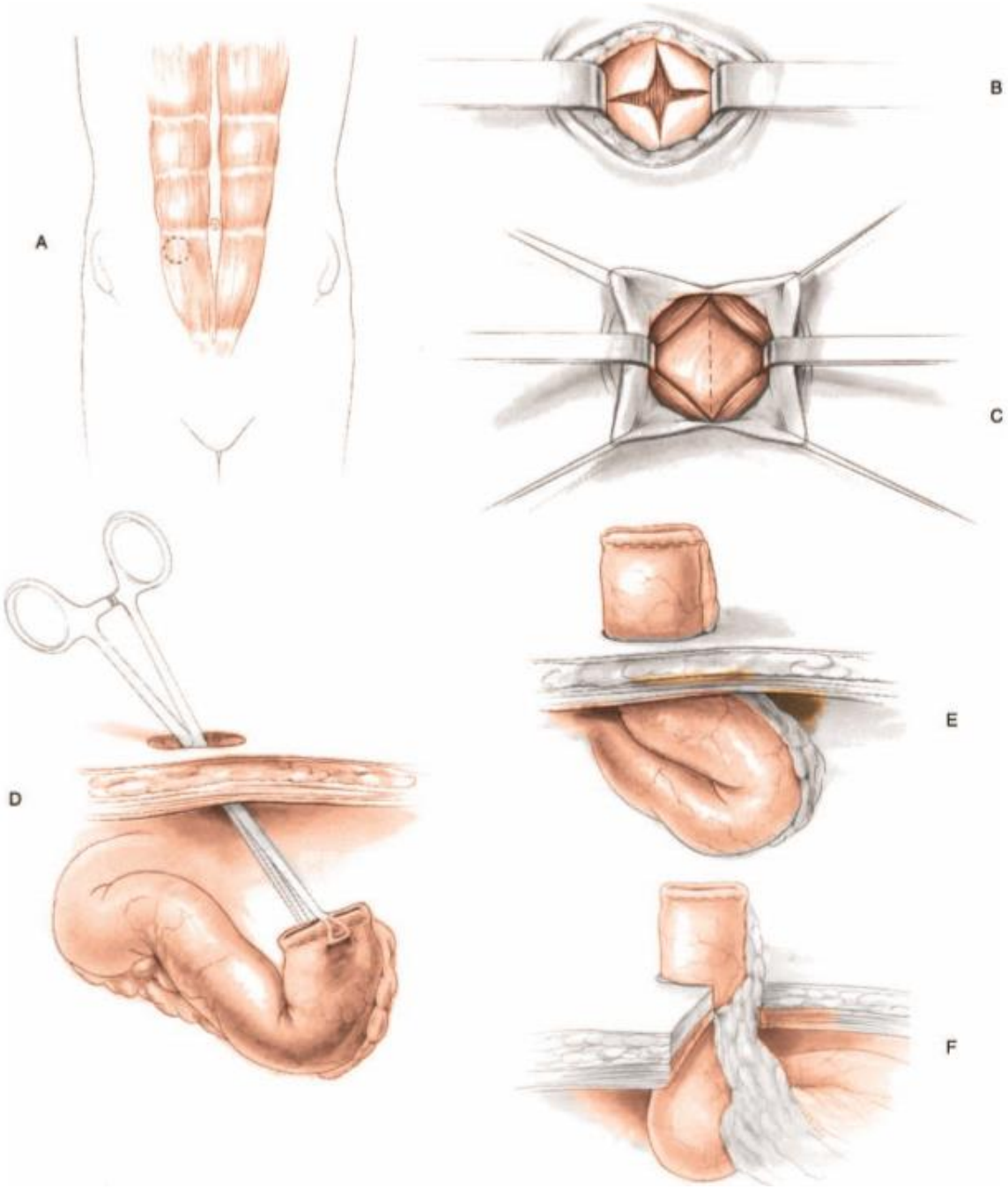
The general size of the defect depends upon the size of the bowel used so as to create the stoma, but it is to be noted that the defect should be made as small as possible without causing any compromise to the blood supply to the bowel loop (usually a width of two to three finger breadth is used) (31).

The bowel loop is then delivered through the defect made and secured all around with suture ties. The main abdominal incision made to enter the abdominal cavity so as to enable for the resection of the affected bowel and the

manipulation of the remaining bowel loops is usually closed and dressed prior to the maturing of the stoma so as to avoid any contamination of the surgical wound.

In order to facilitate the use of appliance use over the stoma easier, a protruding lip of mucosa is fashioned by everting the bowel in the case of an ileostomy. Three to four interrupted delayed absorbable sutures are taken through the edge of the bowel, then through the serosa, approximately about 2 cm proximal to the edge that is to be anastomosed to the skin, and then through the dermis (Brooke technique) (32).

Once the stoma is everted, the mucocutaneous junction is sutured circumferentially using interrupted absorbable sutures.


A
B
C
D
E
F

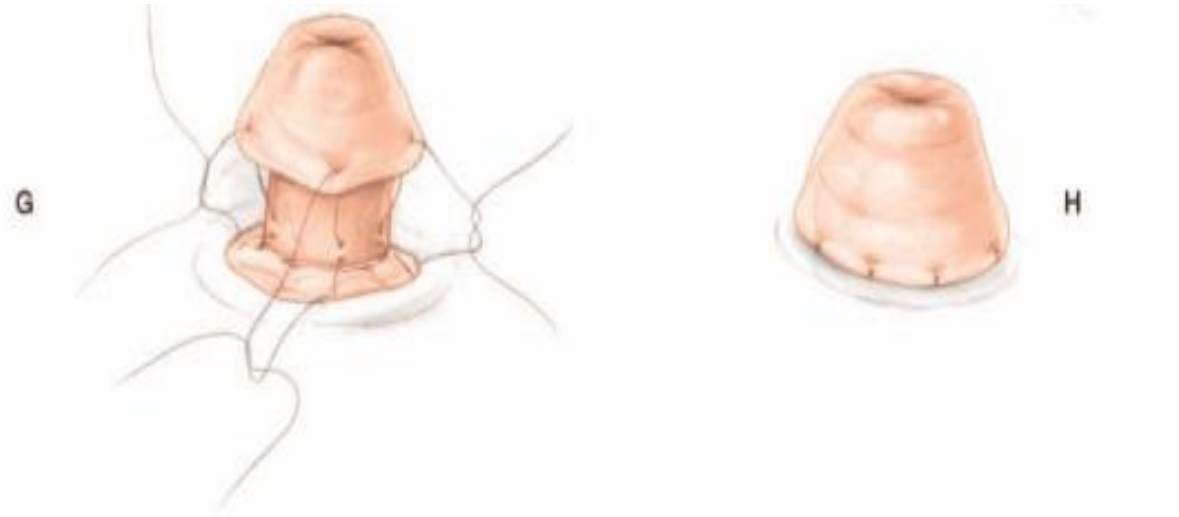


Fig 1. Technique of Brooke end ileostomy construction (intraperitoneal method). (A) Skin and subcutaneous fat are resected over rectus muscle in preselected right lower qudrant site. (B) Cruciate incision is made in fascia. (C) Rectus muscle is retracted and peritoneal cavity is entered. (D and E) Ileum is delivered through ileostomy site. (F) Ileal mesentery is fixed to peritoneum from the ileostomy to the ligamentum teres.(G and H) Brooke maturation is done (23)

In the case of a colostomy, all the above steps are again followed with the exception of having to evert the stoma. The colostomy is thus made as a stoma which is flush with the skin.

In the case of a colostomy there are different colostomies formed (33) . Based on the way it is created, colostomies are classified into four main types; Hartman's, loop, double barrel and spectacle. The choice of the type of colostomy depends on the indication, the experience of the surgeon and the

patient's general condition during surgery (34). Hartman's end colostomy and loop colostomy are the most frequently made stomas (33).

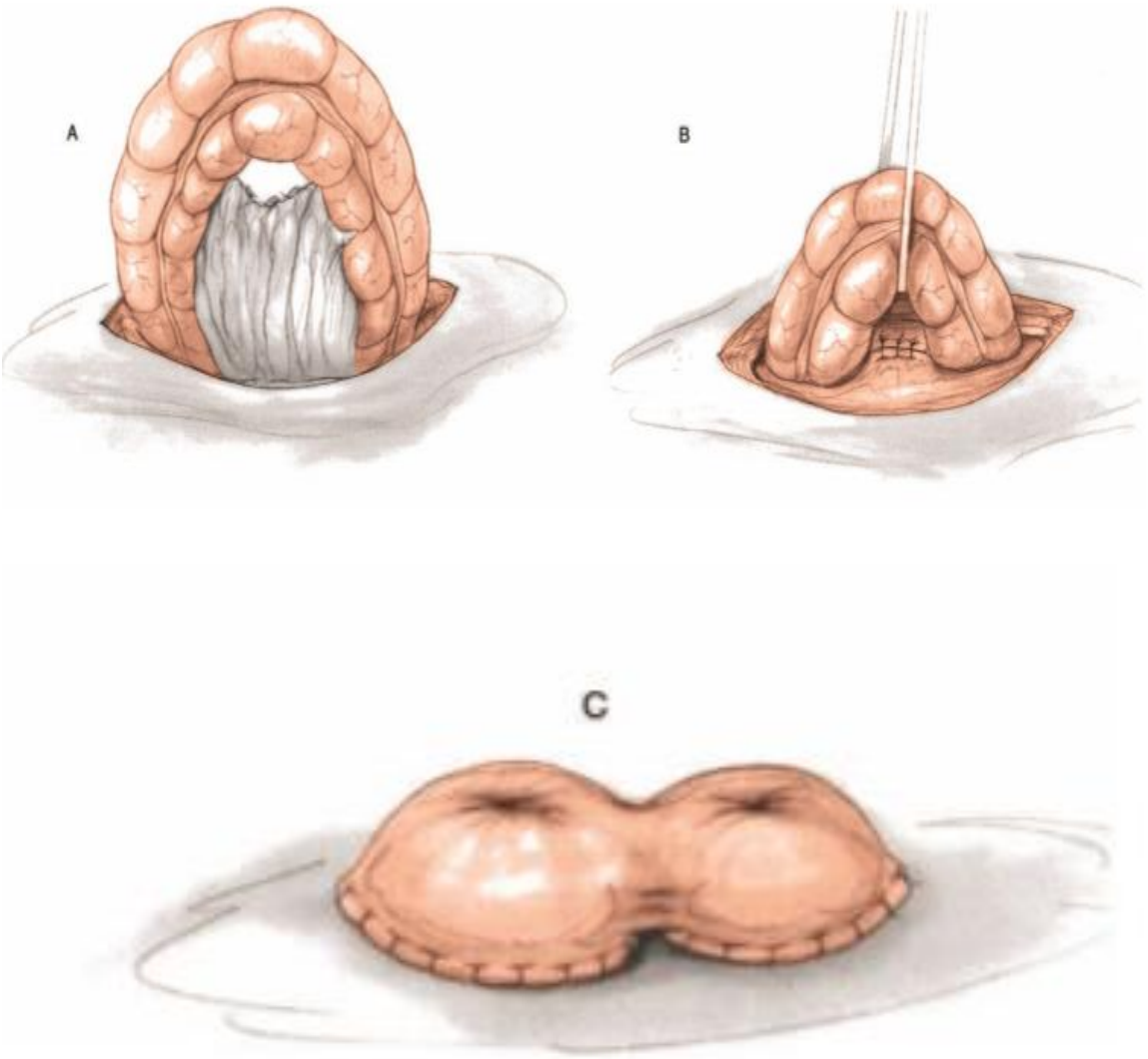


Fig 2. Loop colostomy constructed over fascial bridge. (A) Window in mesocolon is formed and colon is elevated. (B) Fascial Bridge is created

through mesocolic window with interrupted sutures. (C) Colon is opened and sutured to skin. (23)

Stoma complications

The different types of stoma related complications may be classified into early and late complications. The various complications vary from skin infections to parastomal hernia and obstruction. Many studies have been done to look into the stoma and stoma related complications as the morbidity and mortality associated with it bears a huge burden both physically, emotionally and financially on the patients. There is also the added stigma of having to walk around with a bag that continually discharges stool and the need to empty the bag continually which prevents many patients from attending any social functions.

The different complications commonly seen have been discussed in detail below.

Skin complaints

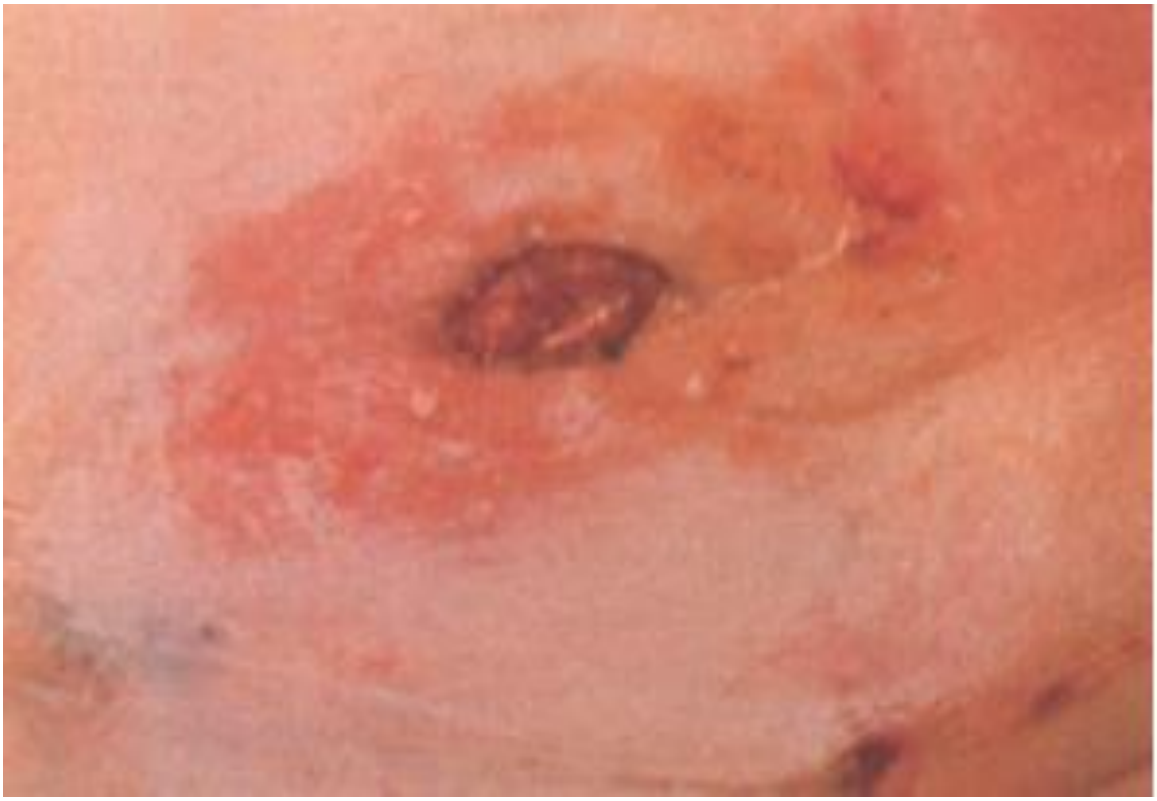


Fig 3. Skin excoriation (dermatitis) (23)

Skin irritation- The incidence of peristomal skin irritation reported in studies ranges between 3 to 42% (3,5,35,36) The degree of irritation can vary from that of mild peristomal dermatitis to full-thickness skin necrosis and ulceration. In the majority of these instances, they appear as a result of stoma neglect and improper placement or fitting of the appliance, resulting in effluent leakage.

In most cases, peristomal skin irritation occurs as a direct result of- (1) chemical dermatitis due to exposure to the stoma effluent, and (2) desquamation of peristomal skin as a result of frequent appliance changes (37). Patient education centring on stomal care and its maintenance the key to prevention.

Peristomal Infection, Abscess and Fistula- During the early postoperative period, parastomal infections and abscesses are usually uncommon, with a reported incidence of about 2 to 14.8% (3,5,37).

Though peristomal skin and soft tissue infections are relatively rare, they can become problematic in the instances where they do appear. Peristomal abscesses during the immediate postoperative period are most commonly present in the setting of stoma revision or reconstruction of stoma at the same site, and occurs mainly due to preoperative colonization of peristomal skin and perioperative seeding of the surgical site. They may also appear as a result of an infected hematoma or an infected suture granuloma.

Abscess formed at a mature stoma site is often the result of local folliculitis or recurrent inflammatory bowel disease in the appropriate clinical setting. Iatrogenic perforation of a colostomy at the time of irrigation is another less commonly seen cause of paracolostomy abscesses. Peristomal abscesses usually does not resolve unless the abscess cavity is drained surgically. Incision and drainage must be performed either at the mucocutaneous junction of the stoma or outside the border of the appliance wafer, wherever possible. Placement of a small penrose drain or mushroom-tipped catheter to facilitate drainage into the appliance itself or to the skin outside the appliance wafer is often seen to be beneficial (37).

Once the abscess has been drained, a subsequent development of a fistula is not very uncommon. Peristomal fistulae usually become evident once the enteric contents from the exposed abscess cavity occurs with subsequent skin excoriation. Fistulae can also be seen as a result of seromuscular sutures that have been placed too deep and penetrating into the bowel lumen.

In patients with Crohn's disease, a peristomal fistula seen in conjunction with an ileostomy is almost invariably seen as a result of recurrent Crohn's disease. Peristomal fistulae may occur in about 7 to 10% of patients with an ileostomy in the setting of Crohn's disease (16,38,39). In patients with presumed ulcerative colitis who have undergone resection and ileostomy, development of peristomal fistula should raise the suspicion of misdiagnosed Crohn's disease (39). Treatment of persistent peristomal fistula usually requires the resection of peristomal disease and construction of a new stoma, preferably at a new site to avoid any infection present at the former site (37,39).

Other parastomal skin conditions include pyoderma gangrenosum, peristomal dermatitis, allergic dermatitis, candidal infection.

Mucocutaneous separation

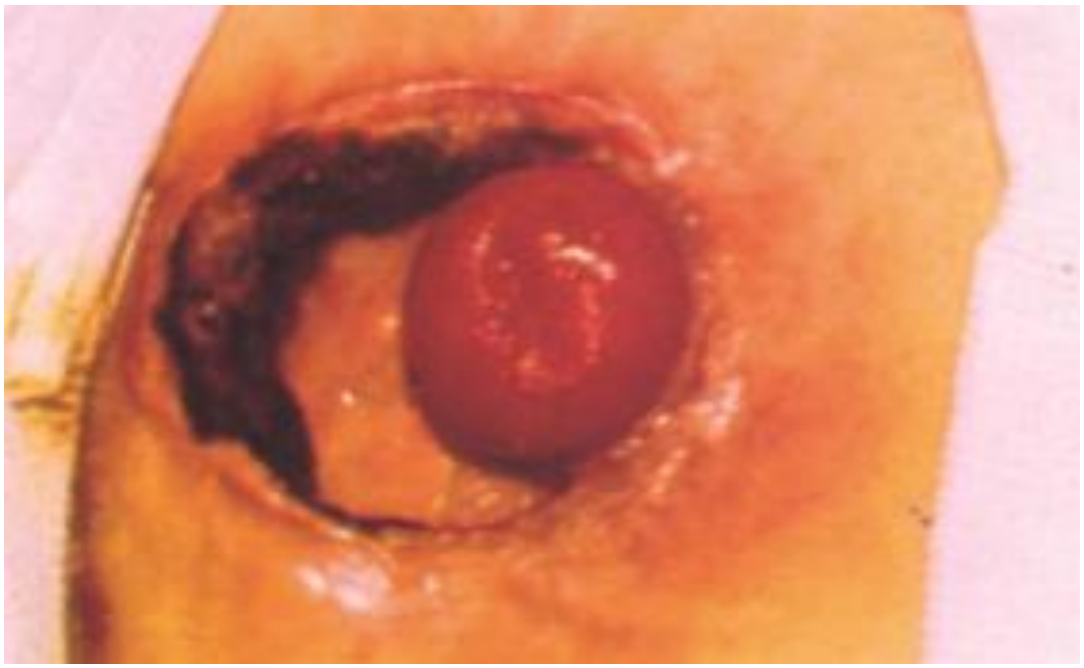


Fig 4. Mucocutaneous separation of stoma (23)

Mucocutaneous separation (or MCS for short) is a frequently seen early complication following a stoma formation, and the incidence is likely under reported (40). Mucocutaneous suture disruption usually trigger a breakdown of the wound and leads to appliance leakage in the early postoperative period.

MCS may arise from a combination of factors such as excessive stoma tension, infection, or impaired wound healing. MCS may intimidate patients and non-stoma care providers and may delay the patients pouching proficiency. Local wound care measures may be coupled with fastidious pouching so as to lead to complete healing in most cases of MCS. The mucocutaneous cleft formed may

be irrigated of any fibrinous slough with the use of warm saline (4). A skin barrier powder may then be used to fill in the MCS defect prior to the application of the pouching system. The afore said steps will prevent any faecal contamination of the wound base prior to applying the pouching system adhesive (41).

With the help of early detection and adequate wound care, most of the cases of MCS will heal well. Circumferentially occurring MCS is also treated in the same fashion, but usually present with special challenges and may predispose the stoma to eventually have retraction and stenosis.

Suture Sinus and Granulation Tissue

Granulomas are red, moist, outgrowths or lesions seen at the mucocutaneous junction representing an immunological response to the retained suture material (42). Granulomas are usually very tender, friable, and discharge serous fluid, which usually causes an impairment of complete pouch sealing as a result of constant moisture at the pouch–skin interface.

Granulomas may also lead to continuous moisture changes of the epidermis. Pseudoverrucous epitheliomatous hyperplasia (PEH) is an uncommon sequela

from chronic irritant contact dermatitis hypothesized to arise from prolonged moisture exposure (43). The granulomas, if present, is probed and all the residual suture material left behind is removed.

Reactive hypertrophic granulation tissue characteristically responds well to application of topical silver nitrate. Surgical suture removal is considered necessary only when office-based or out-patient based treatment is not tolerated or responding to the therapy.

Retraction of stoma

Retraction of a stoma if occurring in the immediate postsurgical period is usually a result of tension on the bowel or its mesentery which is a result of inadequate mobilization of the bowel prior to bringing the loop out to form the stoma (23). Also the patients are malnourished, obese, or on corticosteroid therapy, the stoma may retract as a result of the decreased wound healing and gravity (44).

Minimal distal stomal ischemia or stomal necrosis that has been managed expectantly may also eventually result in the retraction of stoma with or without

stenosis. Complete acute retraction of the stoma with mucocutaneous separation (MCS) can result in subcutaneous or subfascial contamination, peritonitis, as well as abdominal sepsis. In this case, an immediate laparotomy and revision of the stoma is advised.

In most cases, retraction is seen without complete mucocutaneous separation. A common problem in these cases is ensuring a secure seal between the stoma appliance and the abdominal wall, which can lead to faecal leakage and significant peristomal skin irritation.

The majority of these stomas which develop significant retraction eventually require surgical revision (26). The approach to a retracted stoma is similar to that of repair for distal ischemia.

If the mucosa is viable and there is no undue tension, a local revision may be performed by detaching the mucocutaneous junction, advancing the bowel loop and excising the devitalized tissue, and re-securing the viable mucosa to the skin using Brooke-type sutures (28,45). If this is not technically feasible due to any reason, a laparotomy and complete revision of the stoma may be required.

Stomal Stenosis and Stricture

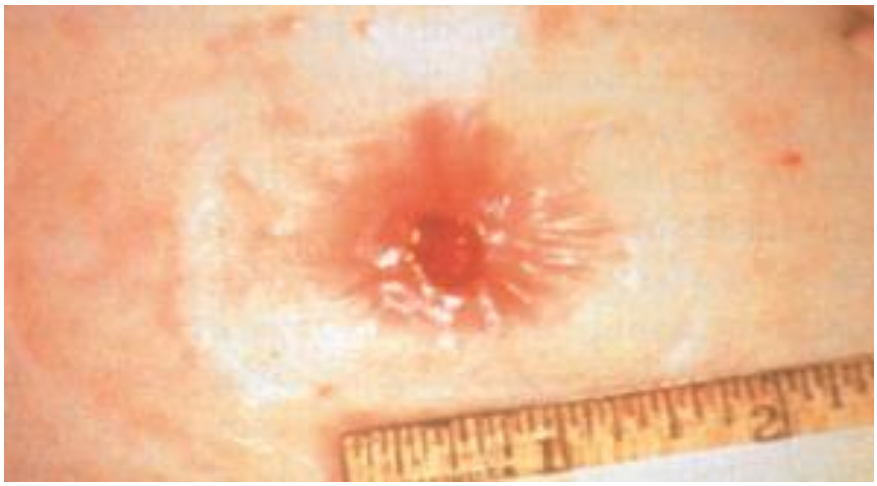


Fig 5. Stenosis of stoma (23)

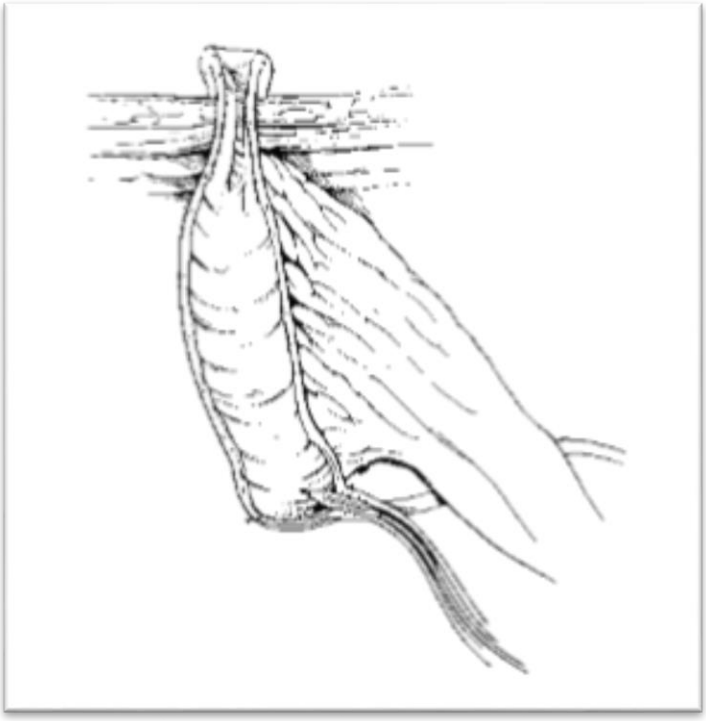


Fig 6. Stoma stricture (16)

Post-operative ischemia to the stoma is the usual underlying factor in stomal stenosis (26,27,46,47). This may present acutely immediately after the stomal creation, or may manifest after prolonged period if necrosis is not present. Local infection and retraction of stoma can also lead to stenosis (48).

The reported incidence is 2 to 14% (49–51). As part of the routine evaluation, recurrent malignancy or Crohn's disease must be ruled out. Stenosis of the subcutaneous aspect of stoma is usually treated with dilation initially; however, multiple sessions are required and tissue trauma during mechanical dilation can cause fibrosis which results in further stenosis.

Definitive treatment requires stoma revision in most cases. Damage to the ileum with the everting stitches may create a “Bishop's collar” deformity (23,51). Skin-level stricture may be fixed with the help of local procedure(52) A double “Z-plasty” is to be used to enlarge the skin opening. Adequate bowel length is required to recreate the stoma. This technique is more complex and can create a convex deformity.

Colostomy stricture can differs in some ways from an ileostomy stricture. Even though the causes are the same, local infections and inadequate skin opening may also create the complication.

If significant skin complications do not occur, a strictured colostomy can be followed expectantly and treated with dietary modification. Patients are

instructed to irrigate with a cone catheter. In Severe cases stoma revision or laparotomy and translocation of stoma may be required.

Stomal gangrene or necrosis

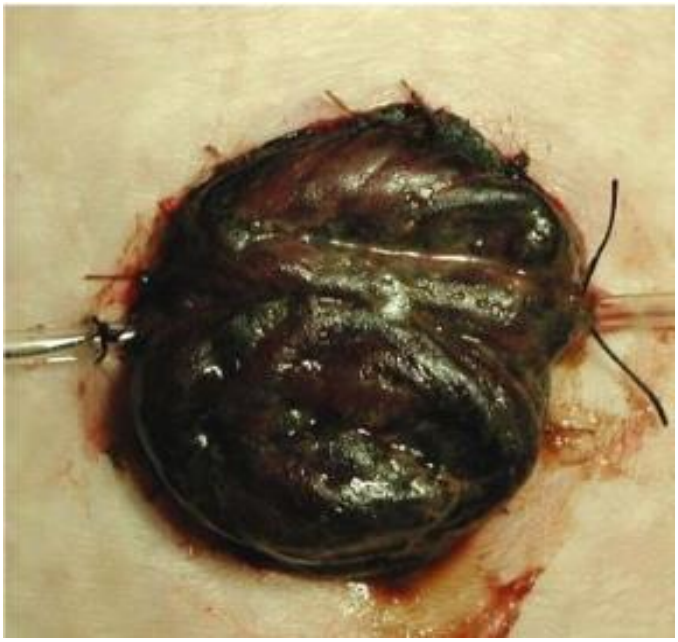


Fig 7. Stoma Necrosis (23)

Stoma necrosis is an early postoperative complication which occurs from inadequate stomal blood supply that can occur in about 13% of ostomates (4,35,48). It is most commonly seen associated with colostomies, emergency operations, and obesity (3,26,35).

A stoma will appear mildly dusky in the immediate postoperative period, and therefore it is important to distinguish between early venous congestion and arterial insufficiency.

Venous congestion occuring due to swelling or constriction of the stoma allows adequate arterial inflow but occludes venous outflow thereby causing the stoma to swell and turn cyanotic or purple-colored. As postoperative edema decreases, venous outflow improves and the stoma will attain its normal postoperative hyperemic hue.

Rarely, the edema and venous outflow obstruction can lead to transient mucosal sloughing, which may be tolerated, provided the underlying bowel wall is viable and healthy. However, and inadequate arterial inflow will cause the full-thickness of bowel wall to necrose and generally cannot be tolerated.

The main cause of stoma necrosis is the devascularization of bowel conduit used in stoma creation. This devascularization may occur due to ligation of the primary blood vessel to that segment of bowel, inadequate collateral blood flow, or as a result of excessive removal and dissection of peristomal mesentery (i.e., “cleaning off” the mesentery) (35,48,53).

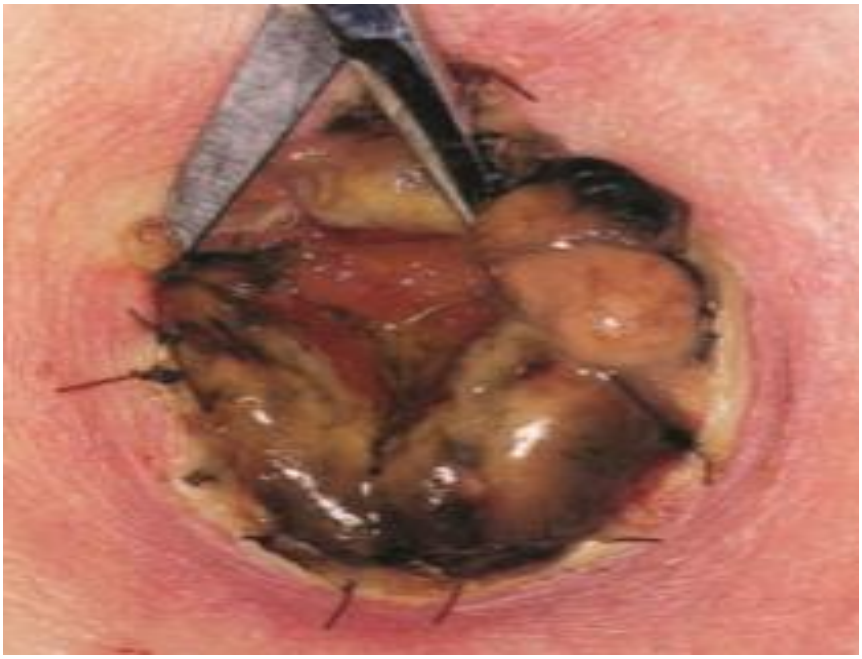


Fig 8. Ischemia of Stoma (23)

Ischemia that is noted in the operating room should be immediately revised (14,26,27). The method of management of this condition is dependent on the length of bowel necrosis. Short segments (i.e., <5 cm) of bowel ischemia which is limited to the distal stoma aspects can be ameliorated using simple mobilization to bring viable bowel to the skin surface. Longer ischemic segments of bowel may require proper mobilisation of bowel and resection and revision or repositioning of stoma (23,26,31).

Stomal Prolapse

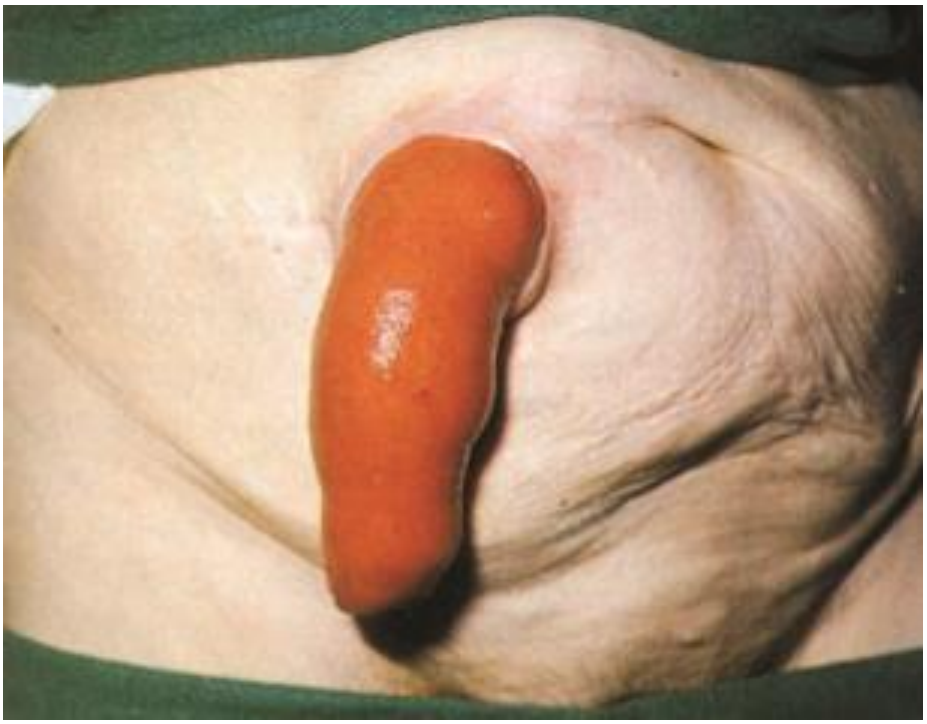


Fig 9. End-colostomy prolapse (23)

Stoma prolapse is a full-thickness protrusion of bowel through a stomal opening that occurs in about 3% of ileostomies, 2% of colostomies, and 1% of urostomies (14,42,51).

Stoma prolapse can be classified into 2 types- sliding (if it occurs intermittently as a result increased intra-abdominal pressure) or fixed (if it is present

constantly and does not retract or lengthen with any variations in the abdominal pressure).

Prolapse occurs most commonly in association with loop colostomies than with end colostomies and most often involves the efferent (distal) limb. The various risk factors for stoma prolapse include patient factors such as advanced age, obesity, bowel obstruction at the time of stoma creation, and the lack of preoperative site marking by enterostomal nurse (5).

The various techniques proposed to limit stoma prolapse include extraperitoneal tunneling, mesentery-abdominal wall fixation, and limiting the size of the aperture (23,31,51).

The various symptoms associated with stoma prolapse can include pain, skin irritation, difficulty with maintaining an appliance, and can rarely lead to obstruction, incarceration, and strangulation of the prolapsed stoma. Acute stoma prolapse can be reduced at the bedside with the use of sugar and ice to reduce bowel wall edema, allowing for an elective repair if prolapse was to recur (4,40,51,54).

The surgical options available for stoma prolapse repair include reversal (in the case of temporary stoma, when possible and feasible), resection, revision, or relocation (4).

Resection of prolapsed segment is done by incising the mucocutaneous junction, mobilizing and amputating the prolapsed segment, and rematuring a new, more proximal stoma.

Prolapsing loop stoma can be corrected by converting it into an end stoma or an end-loop configuration.

Loop stoma to end-loop stoma conversion is performed by incising the mucocutaneous junction and transecting the bowel used to create the loop stoma into a distal and proximal limb. The prolapsed bowel segment, which mostly tends to be the distal (efferent) limb, is returned to the abdominal cavity or can be matured into a mucus fistula (55,56).

Stoma relocation is to be considered if the prolapsed stoma is located at a suboptimal site that may lead to pouching issues or associated skin complications.

Parastomal Hernia

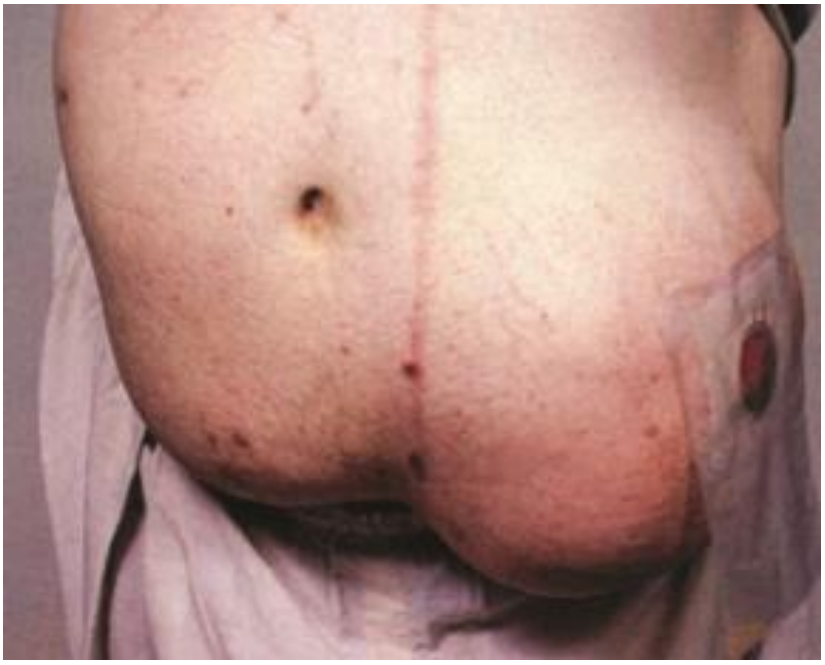


Fig 10. Huge paracolostomy hernia with laterally displaced stoma (23)

These are essentially incisional hernias that occur at ostomy sites and are believed to be an inevitable consequence of undergoing an ostomy. Parastomal hernia has an incidence which varies with stoma type and configuration (approximately 1.8–28.3% for end ileostomies and 0–6.2% for loop ileostomies, and 4–48% for end colostomies and 0–30.8% for loop colostomy) (57–59).

Studies designed with very careful follow-up suggest that a paracolostomy hernia develops in more than 50% of patients followed for longer than 5 years (59). Most parastomal hernias occur in the first 2 years but can occur up to 10 years after stoma creation (17).

Symptoms seen as a result of parastomal hernias include mild peristomal discomfort, difficulty maintaining adequate appliance skin seal, obstruction, and strangulation. Even though the majority (~75%) of patients have some symptoms attributable to the presence of parastomal hernia, these hernias are generally well tolerated (60). Life-threatening complications, such as bowel obstruction or strangulation are rare.

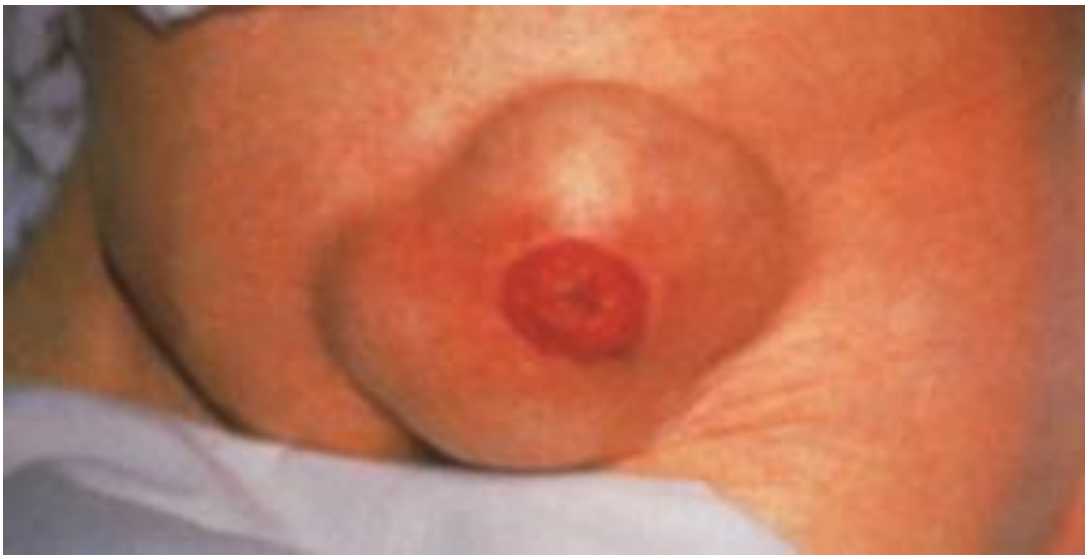


Fig 11. Large parastomal hernia around end sigmoid colostomy (23)

Parastomal hernias are diagnosed by thorough clinical examination after removing the stoma appliance and with the patient in a standing position. If clinical examination is equivocal, a computed tomography scan may be performed so as to confirm the diagnosis.

The various risk factors for the development of parastomal hernias include- obesity, malnutrition, advanced age, collagen abnormalities, corticosteroid use,

postoperative sepsis, abdominal distention, constipation, obstructive uropathy, and chronic lung disease. Technical factors also play a role in its formation such as poor site selection, oversized fascial trephine (>3 cm), excessive splitting and stretching of muscle fibres, epigastric nerve denervation, placing a stoma in an incision, and emergency stoma creation also contribute to the development of parastomal hernias (59,61).

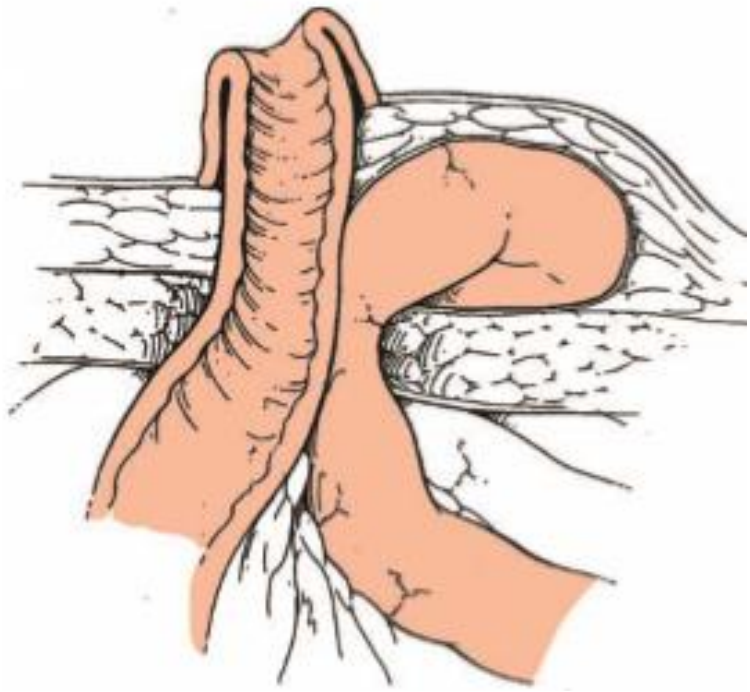


Fig 12. True parastomal hernia (23)

Parastomal hernias have been divided into four types (23). Type I is a ‘‘true’’ parastomal hernia, where small bowel protrudes within a peritoneal sac through a fascial defect (Fig.). In Type II peritoneal contents protrude between the two layers of everted bowel in association with a prolapsed stoma. Type III

describes subcutaneous protrusion of the stoma between the fascia and the peristomal skin with no real fascial defect. Type IV is a ‘‘pseudohernia’’ or a diffuse bulge due to weakness in the abdominal wall musculature and requires no treatment

Although techniques for stomal construction, such as extraperitoneal tunnelling (62,63), stapled ostomy creation (64,65) stoma–fascia fixation, and prophylactic mesh reinforcement for permanent colostomies, have been suggested; however, their role in parastomal hernia prevention is uncertain (59).

Less than 20% patients with parastomal hernias have indication that mandates its repair (59). Ideally the treatment of parastomal hernia is to eliminate the stoma and to restore intestinal continuity. The repair of parastomal hernias is considered only in patients with symptomatic parastomal hernias where elimination of the stoma is not feasible or advisable due to any reason. The three most frequently employed types of parastomal hernia repair are (1) local repair, (2) stomal relocation, and (3) prosthetic repair.

Local repair is the local exploration around the stoma site, and primary closure of the hernial defect with either absorbable or non-absorbable sutures. The potential advantages are avoidance of formal laparotomy and the ability to maintain stoma at the same location. However local repair should generally be avoided due to high recurrence rates (~75%) (66,67) and is typically reserved

for use when major abdominal surgery or use of prosthetic materials is contraindicated (59).

Stoma relocation is done in cases where parastomal hernia patients experience concomitant stoma complications such as pouching difficulty, retraction, and peristomal pyoderma gangrenosum. Laparotomy is required in a majority of these cases. Stoma relocation also exposes the patient to the risk of three new incisional hernias at (1) the old stoma site, (2) the laparotomy incision site, and (3) the new stoma site with recurrence rates reported to be ranging from 24 to 86% (66,68).

An ideal prosthetic material for parastomal hernia repair does not exist. The currently available prosthetic materials are classified into 2 groups- synthetic or biological depending on their composition. Synthetic prostheses are made up of polypropylene, polyester, or expanded-polytetrafluoroethylene (ePTFE) and are further classified into heavyweight or lightweight, micro or macro porous, and composite and coated prosthesis based on composition of materials used in the mesh (69).

Biological prosthetic meshes are made up of acellular collagen matrix derived from biological sources (such as human, porcine, or foetal dermis; porcine small intestine submucosa; and bovine pericardium) and are then processed to remove cells, antigens, and increase collagen cross-linking. The matrix obtained acts as

a scaffold which allow native tissue and neovascularization to infiltrate the healing wound and promote strong tissue in-growth which then limits contraction. The major drawback of these meshes are its high cost (69).

Hybrid meshes are made combining the desirable qualities of both biological and synthetic mesh materials (e.g., Phasix mesh, Davol, Warwick, RI). Such materials are designed to slowly dissolve in a controlled fashion while still possessing the mechanical strength as well as the physical properties of synthetic mesh.

The mesh repair technique used may be open or by laparoscopic method. The repair of parastomal hernias with mesh follows the same process as that of any of ventral hernia repair (i.e., fascial defect closure with a 3–5 cm mesh overlap). Mesh can be placed in an onlay, inlay, sublay, and intraperitoneal onlay mesh (IPOM) location depending on the location of placement of the mesh.

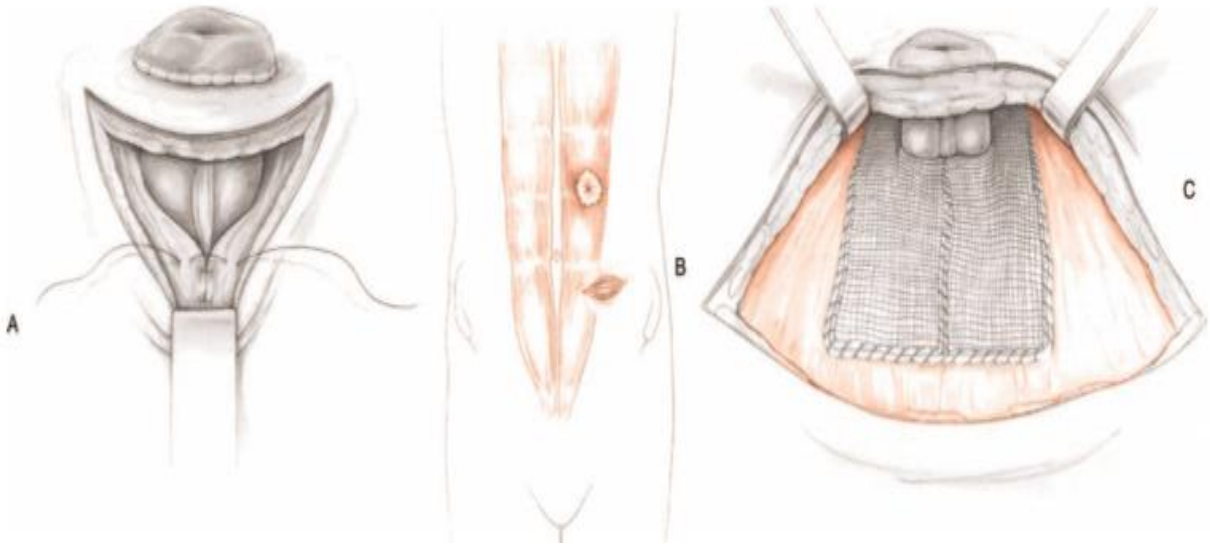


Fig 13. Types of repair: (A) Direct resuture of fascia after resecting hernia sac. (B) Repair of hernia after relocating stoma. (C) Repair with synthetic mesh (23)

Parastomal Varices

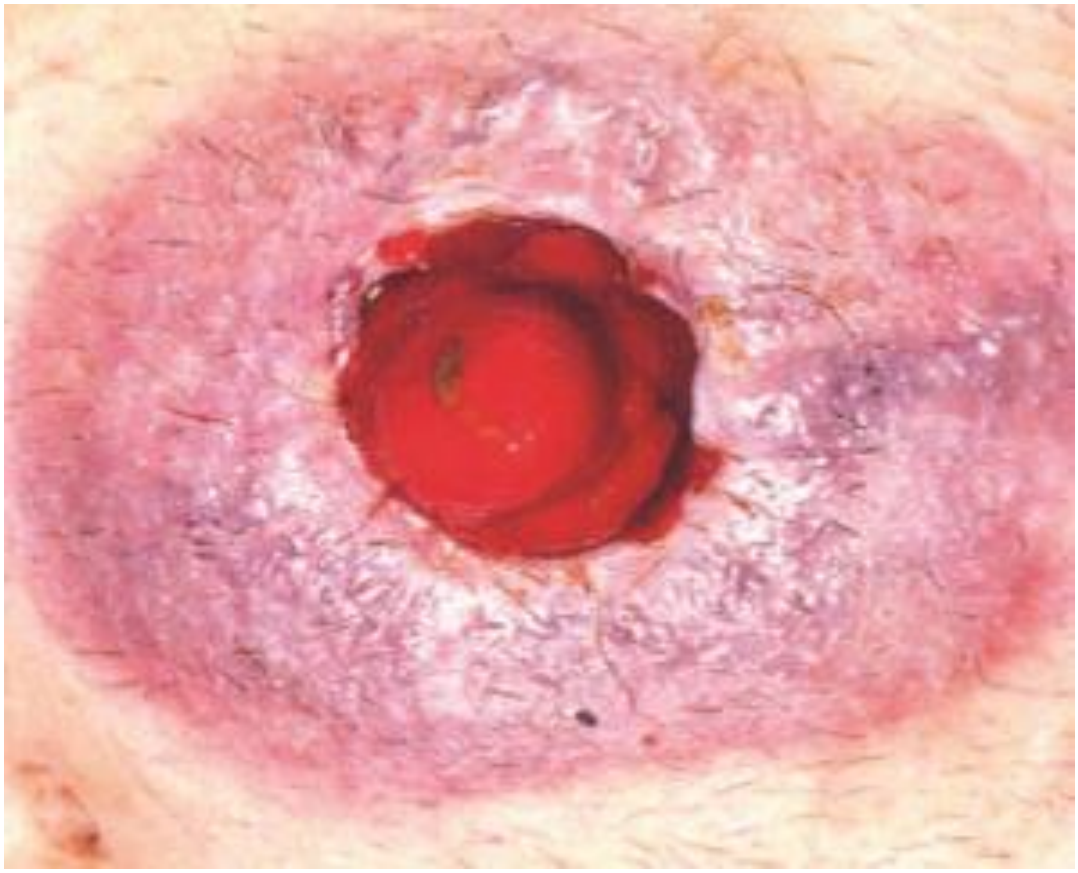


Fig 14. Ileostomy with typical circumferential caput medusa (23)

Parastomal varices is seen in patients with portal hypertension and in a stoma where there is portosystemic collateralization formed between the portal system of the stoma and the systemic venous system of the peristomal skin. These shunts between the 2 systems result in engorgement of vessels and pressurized

subcutaneous vasculature which leads to the formation of a peristomal caput medusa. Stomal varices are howevere very uncommon, but bleeding can be quite profuse and life threatening if it occurs.

As a rule, the best way to prevent any peristomal varices from occurring is to prevent stoma creation in patients with portal hypertension. Inflammatory bowel disease (IBD) with concomitant primary sclerosing cholangitis is usually the most common setting in where the stoma varices occur (59, 71).

Stomal variceal bleeding may arise at focal points seen at the mucocutaneous junction or the skin, which can be treated with the help of suture ligature, compression of bleeders, or by coagulation of the vessels. Unfortunately, recurrent bleeding is very commonly seen and therefore local methods are considered only as temporary, at best.

Brisk or diffuse life-threatening hemorrhage can occur from circumferentially congested and oozing variceal vessels and may typically requires systemic methods of reducing portal pressures in order to stop or to decrease the bleeding.

The most effective method of reducing portal pressures in such cases is transjugular intrahepatic portosystemic shunt (TIPS) or to perform a liver transplantation (59). The success rate of TIPS in preventing peristomal variceal rebleeding has been reported to be as high as 60 to 90% when used alone.

When TIPS procedure is performed in combinations with percutaneous embolization, the risk of re-bleeding has been seen to be reduced to 5 to 25%.

For the purpose of percutaneous embolization or occlusion of, the mesenteric venous system is accessed in a retrograde fashion through the portal system. The mesenteric veins can then be sclerosed with a sclerosing agent such as 1% sodium tetradecyl sulfate or may be balloon occluded.(59, 71)

Methodology

Study Setting:

This study was conducted in the Department of General Surgery, Unit IV of the Christian Medical College and Hospital, Vellore

Study Design:

The study was conducted as a retrospective analysis of all the patients undergoing stoma surgeries (colostomy and ileostomy) in the Department of General Surgery Unit IV during the period ranging from December 2011 to December 2018. This included the retrospective analysis of all the discharge summaries, operation notes, and outpatient charts of all the patients included in this study.

All patients who underwent stoma surgery in this unit during the above mentioned period for any reason, emergency or elective were included in the study.

Participant Selection:

All inpatients admitted and has undergone stoma (either colostomy or ileostomy) surgery from the year 2011 to 2018 December in the department of General Surgery unit IV in Christian Medical College, Vellore.

Sample size:

All inpatients admitted who has undergone stoma surgery from the December 2011 to December 2018 in the department of General Surgery unit IV in Christian Medical College, Vellore were considered.

A Total of 214 patients were identified during this period as having being in the required study group. Out of this population 43 patients were found to have complications related to stoma surgery which were within the parameters of the study.

Variables considered in the study:

- Patient factors – age, gender, comorbidities, indication for surgery, obesity, albumin and haemoglobin
- Operative factors- elective/emergency setting, loop vs end stoma, type of stoma, laparoscopic / open approach
- Postoperative complications – stomal gangrene, stoma retraction, mucocutaneous separation, parastomal abscess, stomal prolapse, parastomal hernia and stomal stenosis. These complications being classified into early and late complications.

Methods Used:

Initially the patients were identified using the electronic database of the hospital. The operation list of all patients who had undergone any stoma surgery in the unit was made from the electronic database. All the relevant data regarding these patients who have undergone surgery in the Department of Surgery Unit IV from the December 2011 to December 2018 was collected retrospectively and prospectively in the given period. The data was collected from the hospitals electronic database and patient outpatient document. In

relevant cases, telephonic communication was attempted with the patients to collect relevant data and for follow up. The minimum period of patient follow-up was for a minimum of 3 months from the time of surgery to look for any complications that may arise due to the procedure.

The factors such as obesity, haemoglobin and albumin were collected from the patient's investigations report and from the anaesthesia records which were recorded prior to surgery. In emergency cases, these were taken as the first post op recorded values. The operative factors were collected from the discharge summary and operation notes. The post-operative complications were collected from the patient records, discharge summary and post-operative OPD follow up records.

Statistical Analysis:

The data collected was entered into Microsoft excel spread sheet and was analysed with the following methods

The data was summarized using descriptive statistics including frequencies, means +/- standard deviations and median. ANOVA and Fisher extraction test were used to analyse the means of continuous variables. P-value of <0.05 was

considered as statistically relevant, while P-value of <0.001 were considered statistically highly significant. The co-relation between risk factors and outcomes were computed using logistical regression. Post HOC analysis for significance was also done to analyse the data.

IRB Clearance:

This study was approved by the Institutional Review Board of the Christian Medical College and Hospital, Vellore. The study was presented on 7th January 2019 and following the corrections made to the study as per the minutes of the IRB, the study was approved on the 6th of June 2019. As it was a retrospective observational study, there was no contact with the patients during any part of the study. Waiver of consent was obtained from the said IRB for the study.

Results

During the period starting from December 2011 to December 2018, a total of 214 patient were admitted under the Department of General Surgery Unit IV of CMC Vellore with stoma. This included both elective and emergency cases operated in the Unit and 52 patients had undergone stoma surgery in other centres and had subsequently come to CMC for further management of complications. The variables to be analysed for these patients after being collected showed 43 individuals who had developed complications following the surgery. Thus the total number of patients calculated to having any complication following stoma surgery in the study population was found to be 20.1%

All the surgeries done under the unit were done as open surgery and hence no comparison between open and laparoscopic approach to the surgery can be made in the study

The break-down of number of different complications seen in the patients analysed are given in the table below

Complication	Number of cases
Abscess	1
Gangrene	2
Mucocutaneous separation	6
Retraction/Stricture	7
Stomal prolapse	6
Parastomal hernia	21
Total	**43**

Table 1. Break-down of complications seen in the study population

The different variables compared in the study and the results obtained after analysing the data are given below

Age Distribution

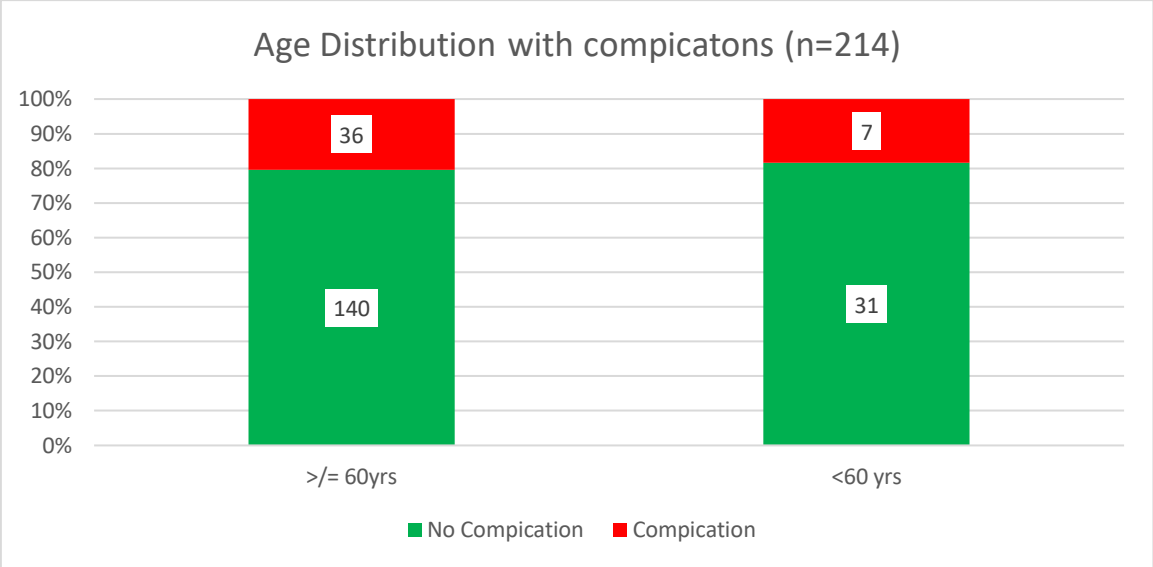


Fig 15. Age Distribution compared to complications

Parameter		Complications		p-value
		Yes	No	
Age In Yrs.	>/=60	36 (20.5%)	140 (79.5%)	0.777
	< 60	7 (18.4%)	31 (81.6%)	

Table 2. Age distribution of entire study population Vs complication

Age did not show any statistically significant association to stoma complications (p-value= 0.777)

Gender Distribution

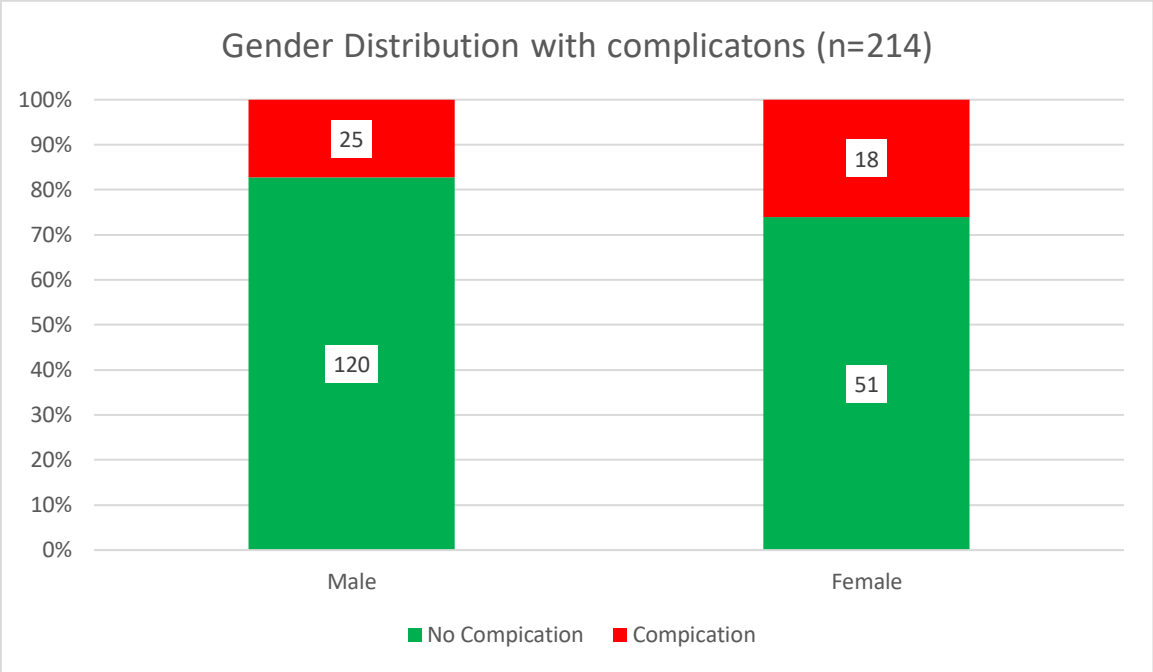


Fig 16. Gender Distribution compared to complications

Parameter		Complications		p-value
		Yes	No	
Gender	Male	25 (17.2%)	120 (82.2%)	0.131
	Female	18 (26.1%)	51 (73.9%)	

Table 3. Gender distribution of population vs complication

Gender did not show any statistically significant association to stoma complications (p-value=0.131)

Initial diagnosis

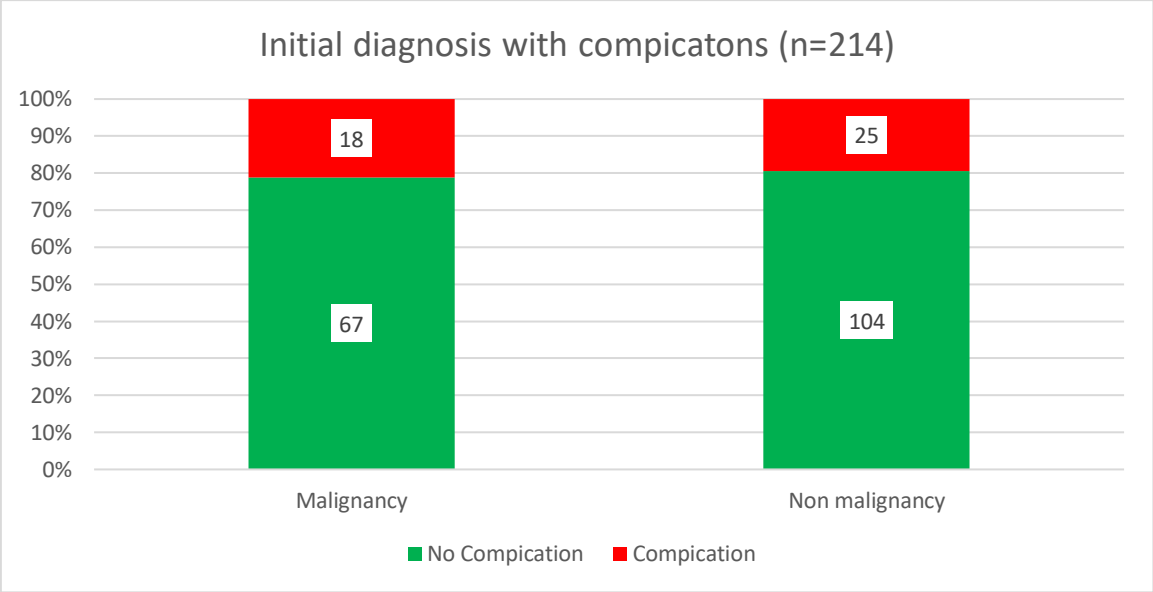


Fig 17. Initial diagnosis compared with complications

Parameter		Complications		p-value
		Yes	No	
Initial Diagnosis	Malignancy	18 (21.2%)	67 (78.8%)	0.748
	Non Malignancy	25 (19.4%)	104 (80.6%)	

Table 4.Initial diagnosis Vs complication

Initial diagnosis of malignancy did not show any statistically significant association to stoma complications (p-value= 0.748)

Emergency Vs Elective

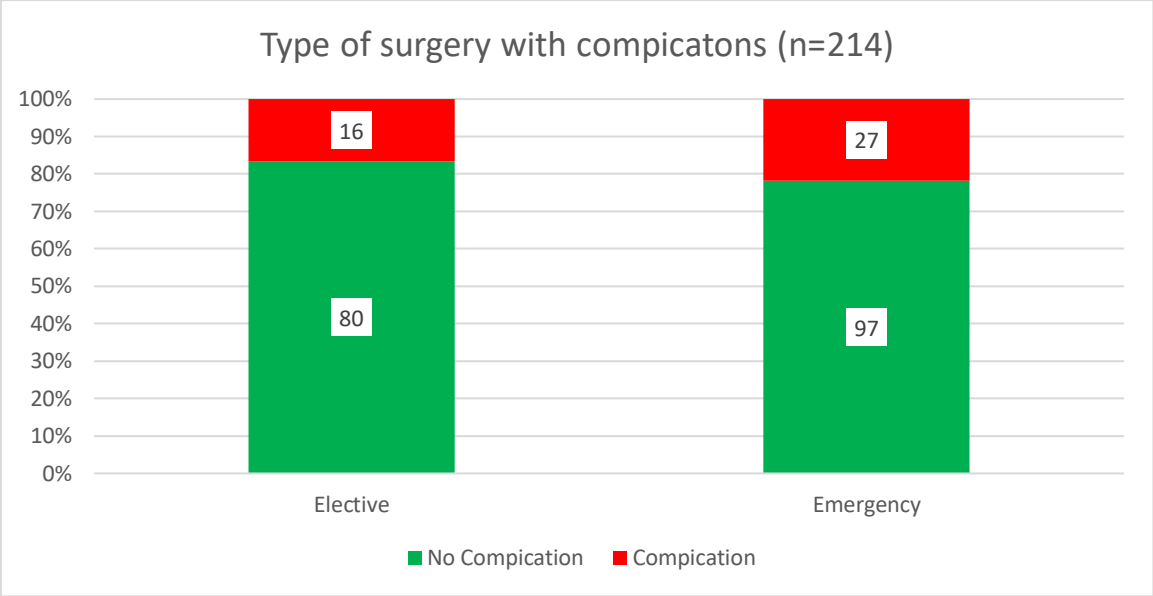


Fig 18. Type of surgery compared with complication

Parameter		Complications		p-value
		Yes	No	
Type of surgery	Elective	16 (16.7%)	80 (83.3%)	0.259
	Emergency	27 (22.9%)	91 (77.1%)	

Table 5. Type of surgery in total population

Setting of surgery (elective/emergency) did not show any statistically significant association to stoma complications (p-value= 0.259)

Person operating

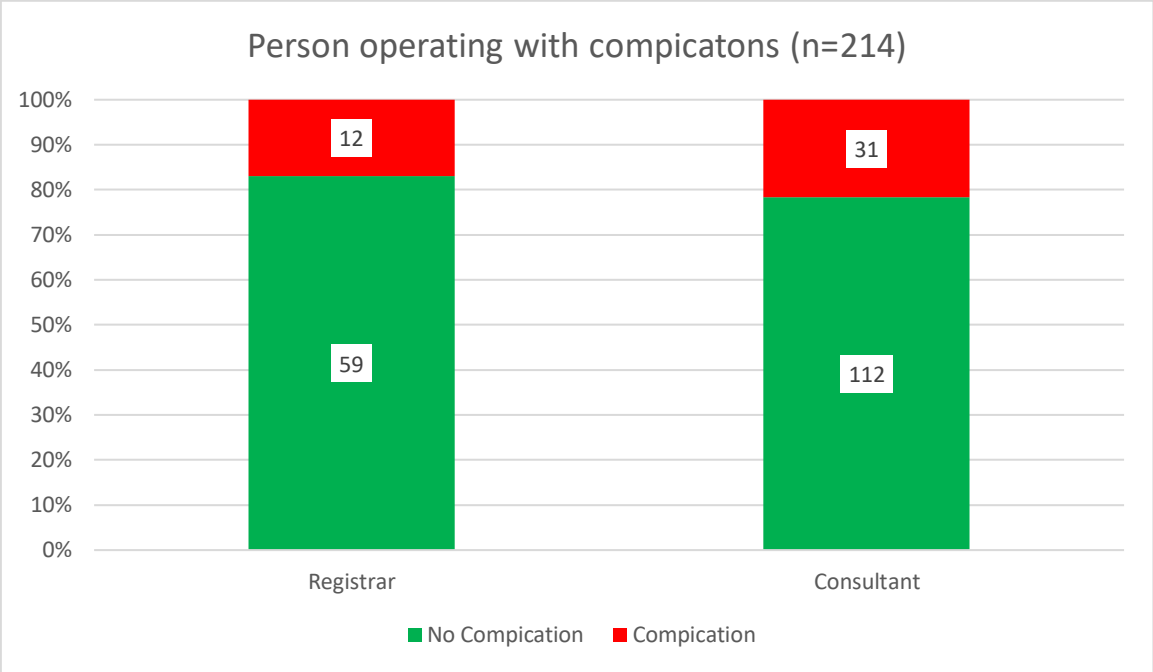


Fig 19. Comparison of person operating Compared with complications

Parameter		Complications		p-value
		Yes	No	
Person Operating	Registrar	12 (16.9%)	59 (83.1%)	0.412
	Consultant	31 (21.7%)	112 (78.3%)	

Table 6. Person operating compared with the total population

Person operating on the patient did not show any statistically significant association to stoma complications (p-value= 0.412)

Comorbidities

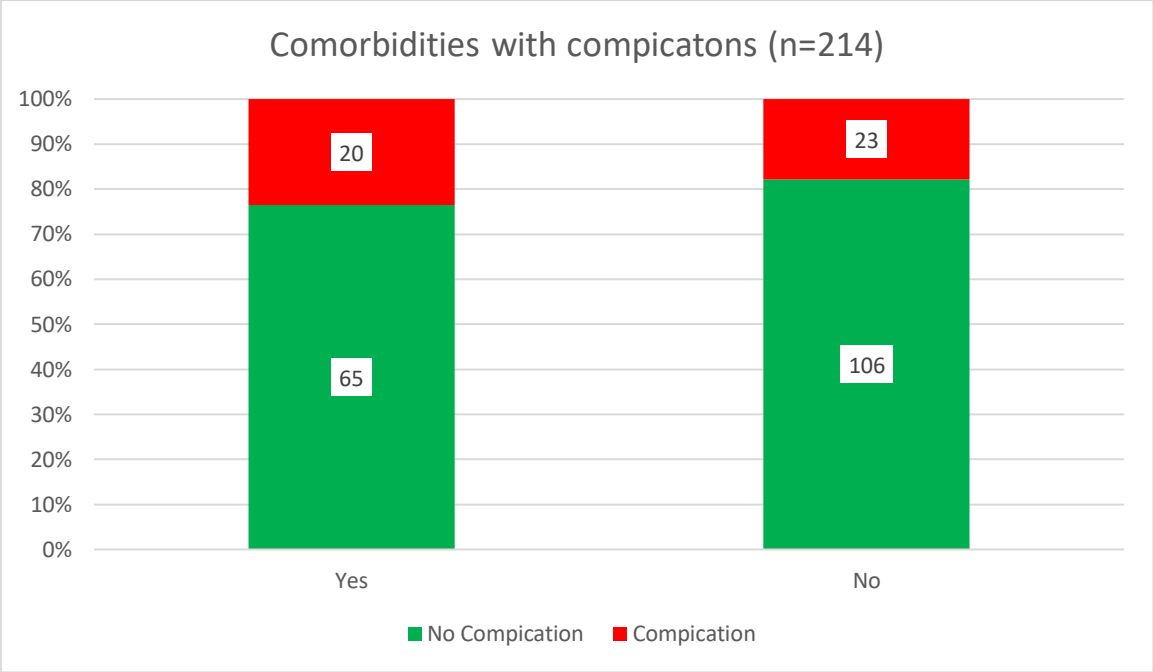


Fig 20. Presence of comorbidity compared with complication

Parameter		Complications		p-value
		Yes	No	
Presence of comorbidities	Yes	20 (23.5%)	65 (76.5%)	0.309
	No	23 (17.8%)	106 (82.2%)	

Table 7. Comorbidities compared to total population

Presence of comorbidity did not show any statistically significant association to stoma complications (p-value= 0.309)

Albumin

The normal value of albumin is taken as 3.5-5.4g/dL

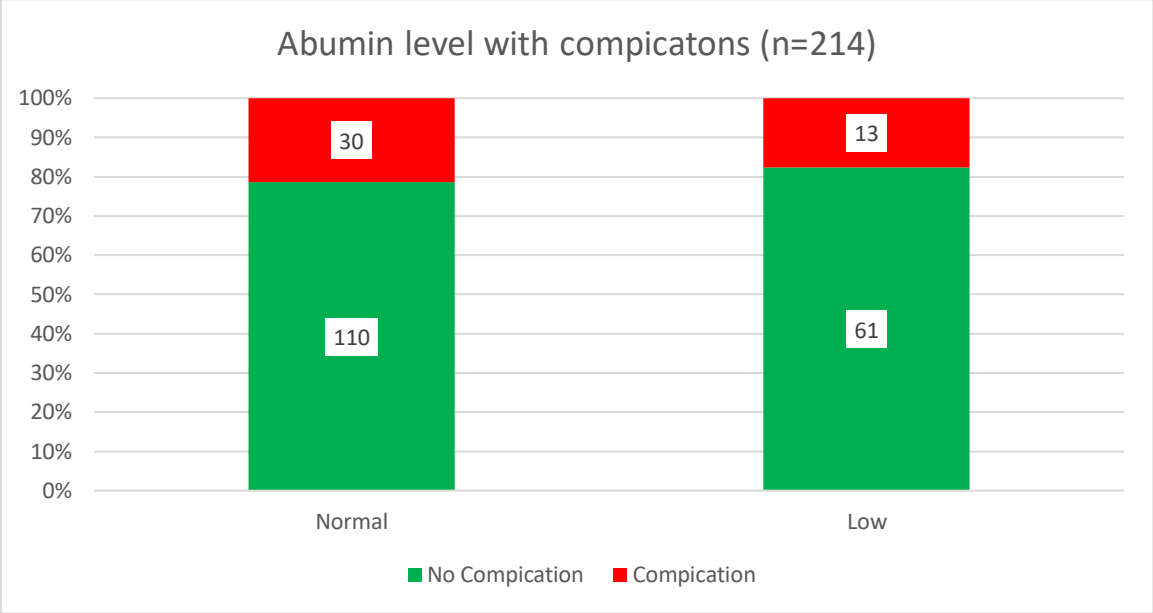


Fig 21. Albumin level in patient compared to complications

Parameter		Complications		p-value
		Yes	No	
Albumin Levels	Normal	30 (21.4%)	110 (78.6%)	0.503
	Low	13 (17.6%)	61 (82.4%)	

Table 8. Albumin values compared to the total population

Albumin level did not show any statistically significant association to stoma complications (p-value= 0.503)

Haemoglobin

The normal value of haemoglobin is taken as 12-15g/dL in females and 13-16g/dL in males

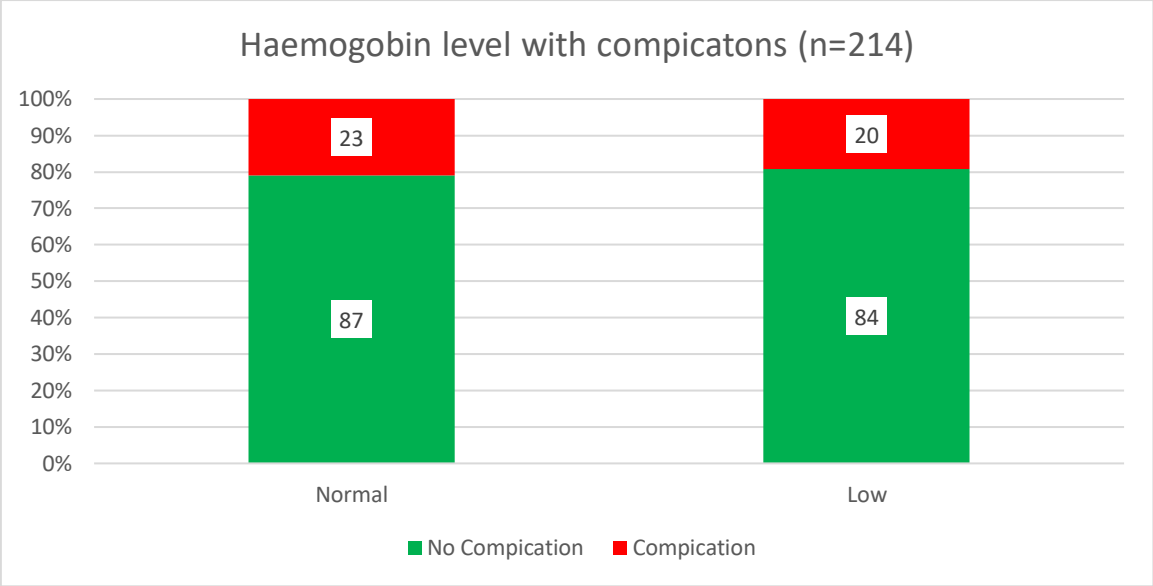


Fig 22. Haemoglobin Level in patients compared to complications

Parameter		Complications		p-value
		Yes	No	
Haemoglobin Levels	Normal	23 (20.9%)	87 (79.1%)	0.759
	Low	20 (19.2%)	84 (80.8%)	

Table 9. Haemoglobin level compared to the total population

Haemoglobin level did not show any statistically significant association to stoma complications (p-value= 0.759)

Colostomy/Ileostomy

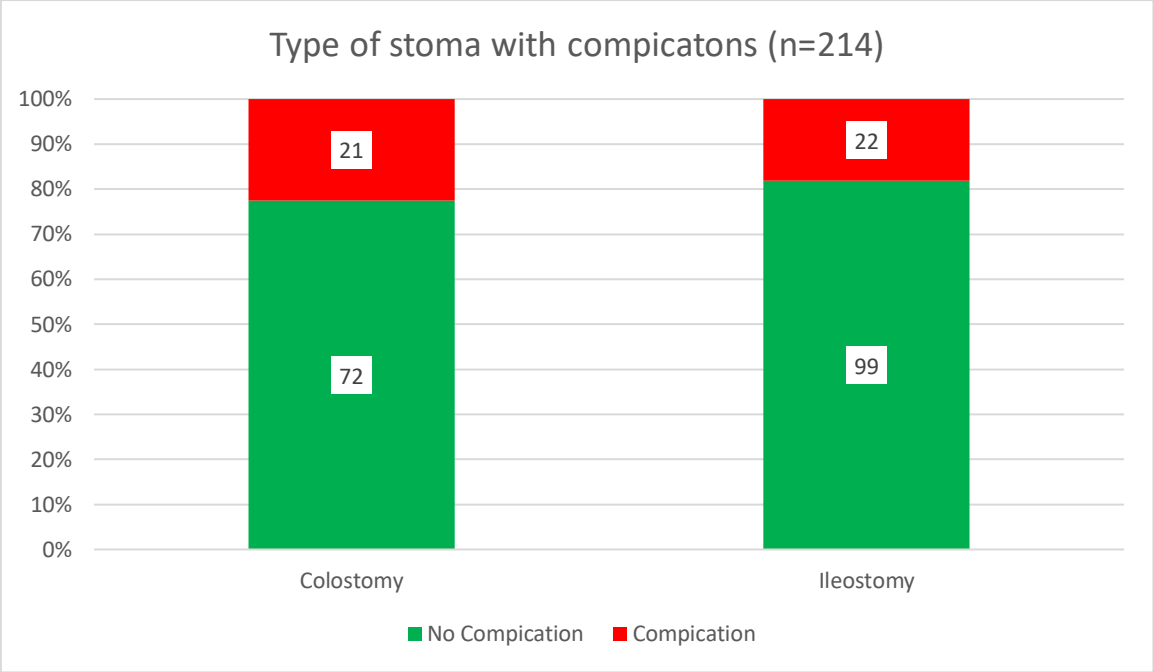


Fig 23.Comparing colostomy/ileostomy compared with complication

Parameter		Complications		p-value
		Yes	No	
Type of Stoma	Colostomy	21 (22.6%)	72 (77.4%)	0.106
	Ileostomy	22 (18.2%)	99 (81.8%)	

Table 10. Colostomy/ ileostomy compared with complication

Type of stoma (colostomy/ileostomy)did not show any statistically significant association to stoma complications (p-value= 0.106)

End and Loop Stoma

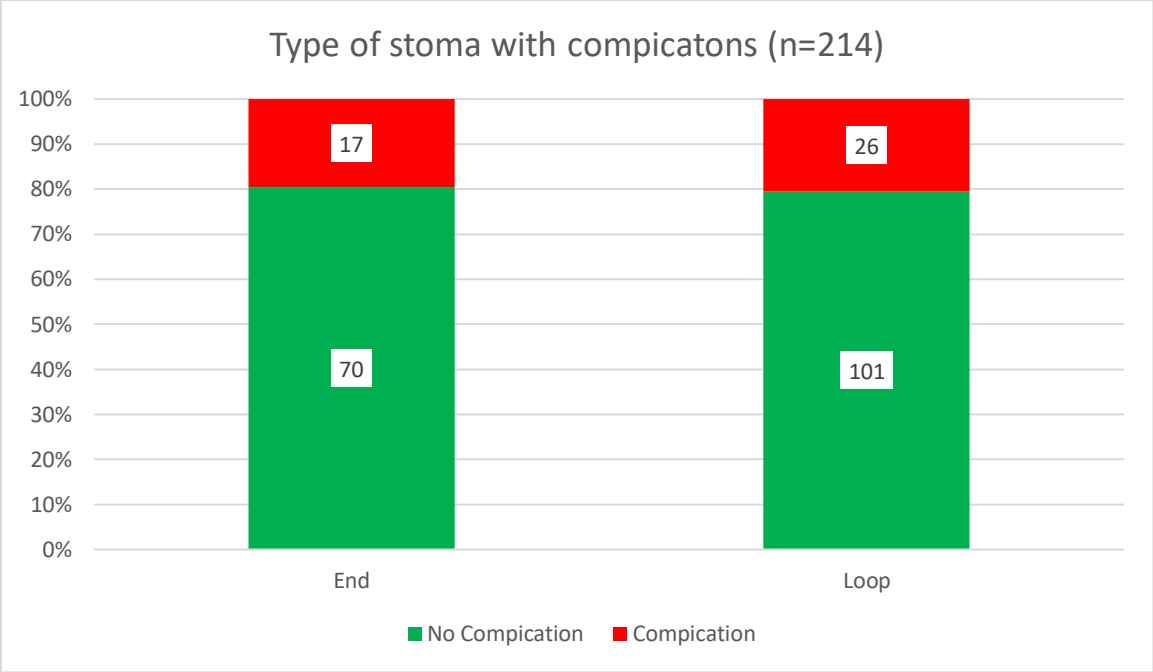


Fig 20. Comparison of End and loop stoma with complications

Parameter		Complications		p-value
		Yes	No	
Type of Stoma	End	17 (19.5%)	70 (80.5%)	0.867
	Loop	26 (20.5%)	101 (79.5%)	

Table 11. End/ loop stoma with complication in total population

Type of stoma (end/loop) did not show any statistically significant association to stoma complications (p-value= 0.867)

BMI

The normal value of BMI is in the range 18.5-24.9kg/m^2. Below 18.5 is low and above 24.9 is high.

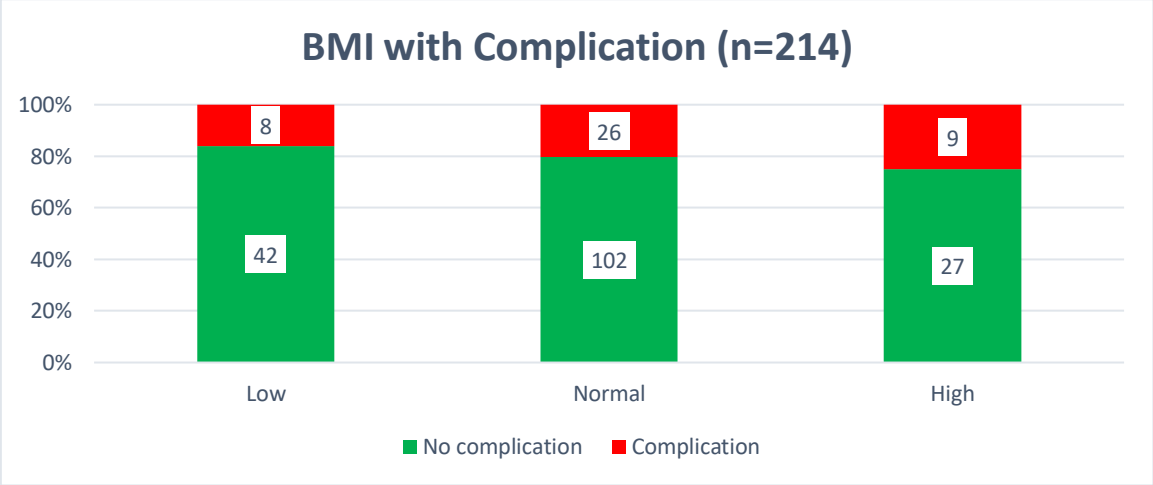


Fig 21. BMI compared with complication

Parameter		Complications		P Value
		Yes	No	
BMI	Low	8 16.0%	42 84.0%	0.587
	Normal	26 20.3%	102 79.7%	
	High	9 25.0%	27 75.0%	

Table 12. BMI distribution with complication in total population

BMI did not show any statistically significant association to stoma complications (p-value= 0.587)

As seen from the values given above, none of the factors analysed in this study showed any significant bearing with regard to causing complications in patients undergoing stoma surgeries.

Another comparison done was comparing the various variables considered with early and late complications among the patients who had developed complications (n=43). The comparison was done to see if there was any impact of these variables with respect to the early and late complications in stoma surgery.

Given below is a comparison of the different parameters with regard to early and late complications.

Parameters		Complications (n=43)		p-value
		Early Complications	Late Complications	
Age (In Yrs.)	>/=60	4 (57.1%)	3 (42.9%)	.177
	<60	11 (30.6%)	25 (69.4%)	
Gender	Male	8 (30.8%)	18 (69.2%)	.484
	Female	7 (41.2%)	10 (58.8%)	
Initial diagnosis	Malignancy	5 (33.3%)	10 (66.7%)	.876
	Non malignancy	10 (35.7%)	18 (64.3%)	
Setting of surgery	Elective	4 (25%)	12 (75%)	.141
	Emergency	10 (37%)	17 (63%)	
Person operating	Registrar	5 (36.4%)	7 (63.6%)	.905
	Consultant	10 (34.4%)	21 (65.6%)	
Comorbidities	Yes	4 (20.0%)	16 (80.0%)	.056
	No	11 (47.8%)	12 (52.2%)	
Albumin	Low	5 (38.5%)	8 (61.5%)	.189
	Normal	14 (46.7%)	16 (53.3%)	

Haemoglobin	Low	12 (60%)	8 (40%)	.052
	Normal	11 (47.8%)	12 (52.2%)	
Type of Stoma(anatomy)	Colostomy	6 (28.6%)	15 (71.4%)	.396
	Ileostomy	9 (40.9%)	13 (59.1%)	
Type of stoma (surgical)	End	5 (26.7%)	12 (73.3%)	.408
	Loop	10 (39.3%)	16 (60.7%)	
BMI	Low	5 (62.5%)	3 (37.5.0%)	.054
	Normal	6 (23.1%)	20 (76.9%)	
	High	6 (66.7%)	3 (33.3%)	

Table 13. Comparing the various factors with early and late complications (n=43)

When the data of the factors were analysed with early and late complications, there was no significant correlations.

Discussion

In the study conducted, the overall percentage of complications was noted to be 20.1%. Most of the data and study done on stomas put the overall rate of complications as high as 21%-70% (14, 26). This is probably due to the fact that most studies done also took skin complications and high stoma output also into consideration as a complication, which was not done in this particular study.

On the analysis of the individual variables with the complications the results seen were as follows.

Age

As done in most studies quoted here, the cut off age was taken as 60yrs for the purpose of analysis (14, 20, 26). In our study 176 patients were in the age group of >/= 60yrs, comprising 82.2% of the study population. The though in the previous studies it was seen that an age of >60 years was a risk factor for the development of complications, in our study conducted, age did not appear to be an factor associated with causing any complications.

Gender

There was 145 male patients 69 female patients in the sample collected for this study. There was no significant references with regard to the Gender being a factor leading to stoma complications. Our study also did not show age as a factor in causing stoma complications.

Initial Diagnosis

Initial diagnosis prior to the surgery was not a conclusive factor causing complications. Among the study sample 85 patients had malignancy as the initial diagnosis comprising 39.7% of the sample population (n=214). According to some studies (33,70) malignancy had a higher chance of causing stoma complications while in others non- malignant causes such as Crohn's disease was found to have a greater risk of developing complications . The study conducted by us did not show any bearing of malignancy being a factor.

Emergency/ Elective surgery

The setting of surgery, i.e. elective or emergency was found to have a bearing in stoma complications. In some studies conducted showed a better outcome of surgery as well as lesser complications in patients operated in an elective setting as opposed to emergency setting (5, 13 19). There was 96 elective surgeries and 118 emergency surgeries done in the sample, constituting 44.9% and 55.1% respectively. Our study did not show any statistical difference in outcome.

Person Operating

In 2 publications referenced for this study, it was noted that patients operated by colorectal surgeons had better outcomes as compared to those done by general surgeons (19, 30). In our study, we considered the possibility of the same but comparison was done between registrars and consultants. During the study period, 71 surgeries were performed by registrars and 143 surgeries by consultants. The final analysis did not show any significance.

Comorbidities

The presence of certain comorbidities such as diabetes, immunocompromised states have been seen as a factor responsible in causing complications following stoma surgery. In this study, the presence of any comorbidity was considered and not individual comorbidities. 85 patients (39.7%) of the sample population had 1 or more comorbidities which also included TB. The study did not see any significant difference in complications comparing patients with comorbidities and patients without comorbidities.

Albumin

There was no study seen studying albumin as a factor. This was hence selected as a probable factor that could alter the outcome of stoma surgery. The cut off taken for normal range of albumin was 3.5- 5.4g/dL. 74 patients (35.6%) of the study population was seen to have low albumin level. The analysis of the data however did not show low albumin as a cause for stoma complications.

Haemoglobin

Low haemoglobin was also taken as a factor that could potentially be a cause for complication in stoma. No data was seen available on this factor either. The cut off considered for the same was 12g/dL for females and 13g/dL in males as per internationally recognised cut offs. 104 patients (48.6%) of the study population was found to have a low haemoglobin. The study done by us however did not show low haemoglobin to be a factor causing stoma complications.

Colostomy Vs Ileostomy

Though there are inherent differences in the surgical techniques and the fact that the 2 surgeries are done for different reasons, a comparison was done to see if there was any difference in the rate of complications following the surgery. Most studies done does not show any difference in the outcomes of the 2 surgery (5, 6, 7, 18, 20).

There was 93 colostomy and 121 ileostomy done in the study population contributing 43.5% and 56.5% of the population respectively. Though there was a slight percentage increase in complications shown among patients with colostomy, this was not statistically significant as the p-value was 0.106

End Vs Loop Stoma

As with the previous factor considered, the techniques and reasons for doing the 2 surgeries are different. There was no particular studies seen comparing loop stoma with end stoma (as most studies mentioned in the bibliography look at colostomy as end and ileostomy as loop). In our study population we had 87 end stoma and 127 loop stomas. This also includes a few loop colostomies.

The analysis of the data however does not show any statistically significant differences in complication comparing these 2 types of stomas. The p-value calculated was 0.867

BMI

BMI (especially high BMI) is considered a predisposing factor leading to stoma complications (3, 7, 11, 13, 14, 26, 27, 35). The normal value for BMI is in the range of 18.5 to 24.9 kg/m^2 (both values inclusive) as per internationally accepted norms. Any value below this range is low and above the range is considered high respectively. In the study population here the distribution of

BMI was - 50 (23.4%) low, 128 (59.8%) normal and 36 (16.8%) high respectively.

In our study even though there was an increase in the percentage of patient with high BMI with complication, as the P value calculated for the same was 0.587, it was found to be insignificant.

Comparing the various factors with early and late complications

The data of the 43 patients with complications were further analysed. Their factors were checked against early and late complications. The values are as given in (Table 13).

The data analysed did not show any significant findings relating the factors with early and late complications when the P values were assessed.

Conclusion

1. The total percentage of patients with complications seen in this study was 20.1%, which is slightly lower than the ones mentioned in other studies probably due to the fact that skin complaints and high stoma output were not considered as part of this study.
2. In our retrospective study we analysed the above mentioned factors and their association with stoma related complications. Even though certain factors like malignancy, emergency operations, obesity and low albumin level were appeared to be more associated with complications, they were not statistically significant
3. Almost one fourth of our patients who had surgery elsewhere and came to our centre for the management of stoma related complications or reversal. Their complication profile may have skewed our results. Analysing the factors and complications of patients who had surgery only in our centre may show some correlation.
4. Dividing the complications into early and late also did not show any statistically significant association to the factors. We conclude that in our retrospective study we did not find any statistically significant correlation between studied factors and stoma related complications. We suggest that

a prospective study including skin complications and above mentioned factors with a larger sample size may show some significant association.

Limitations

1. The sample size of the study was small and limited.
2. As there was no direct contact with the patients, any new or unrecorded data could have been missed
3. Skin related complications were not considered as part of the study as it was seen that in majority of the cases, the details pertaining to these were not recorded or poorly recorded. Hence the data could not be collected and analysed
4. There were 52 individuals who were operated outside were also added to the study. This could have skewed the findings.
5. The comparison between laparoscopic and open surgery could not be made as there was no laparoscopic patients meeting the study criteria during the period of the study
6. Another comparative factor could be usage of bridges in stoma creation. This was not included in the study as the records for the same were not available for all the patients.
7. Many of the patients were found to not have any long term follow up after the surgery. Most patients were seen to be following up if they developed any complications, but in patients who did not return to the

OPD/ may have chosen to follow up in their own hometown, the data collection was not possible.

Bibliography

1. Sheetz KH, Waits SA, Krell RW, Morris AM, Englesbe MJ, Mullard A, et al. Complication Rates of Ostomy Surgery Are High and Vary Significantly Between Hospitals. Dis Colon Rectum. 2014 May;57(5):632–7.

2. Harris DA, Egbeare D, Jones S, Benjamin H, Woodward A, Foster ME. Complications and mortality following stoma formation. Ann R Coll Surg Engl. 2005 Nov;87(6):427–31.

3. Kann BR. Early Stomal Complications. Clin Colon Rectal Surg. 2008 Feb;21(1):23–30.

4. Bafford AC, Irani JL. Management and complications of stomas. Surg Clin North Am. 2013 Feb;93(1):145–66.

5. Park JJ, Del Pino A, Orsay CP, Nelson RL, Pearl RK, Cintron JR, et al. Stoma complications: the Cook County Hospital experience. Dis Colon Rectum. 1999 Dec;42(12):1575–80.

6. Malik T, Lee MJ, Harikrishnan AB. The incidence of stoma related morbidity - a systematic review of randomised controlled trials. Ann R Coll Surg Engl. 2018 Sep;100(7):501–8.

7. Arumugam PJ, Bevan L, Macdonald L, Watkins AJ, Morgan AR, Beynon J, et al. A prospective audit of stomas--analysis of risk factors and complications and their management. Colorectal Dis Off J Assoc Coloproctology G B Irel. 2003 Jan;5(1):49–52.

8. Sier MF, Wisselink DD, Ubbink DT, Oostenbroek RJ, Veldink GJ, Lamme B, et al. Randomized clinical trial of intracutaneously versus transcutaneously sutured ileostomy to prevent stoma-related complications (ISI trial). Br J Surg. 2018 May;105(6):637–44.

9. Robertson I, Leung E, Hughes D, Spiers M, Donnelly L, Mackenzie I, et al. Prospective analysis of stoma-related complications. Colorectal Dis Off J Assoc Coloproctology G B Irel. 2005 May;7(3):279–85.

10. Carne PWG, Frye JNR, Robertson GM, Frizelle FA. Parastomal hernia following minimally invasive stoma formation. ANZ J Surg. 2003;73(10) : 843–5.

11. Mäkelä JT, Turku PH, Laitinen ST. Analysis of late stomal complications following ostomy surgery. Ann Chir Gynaecol. 1997;86(4):305–10.

12. Colwell JC, Pittman J, Raizman R, Salvadalena G. A Randomized Controlled Trial Determining Variances in Ostomy Skin Conditions and the

Economic Impact (ADVOCATE Trial). J Wound Ostomy Cont Nurs Off Publ Wound Ostomy Cont Nurses Soc. 2018 Feb;45(1):37–42.

13. Lambrichts DPV, de Smet GHJ, van der Bogt RD, Kroese LF, Menon AG, Jeekel J, et al. Incidence, risk factors and prevention of stoma site incisional hernias: a systematic review and meta-analysis. Colorectal Dis Off J Assoc Coloproctology G B Irel. 2018 Oct;20(10):O288–303.

14. Shabbir J, Britton DC. Stoma complications: a literature overview. Colorectal Dis Off J Assoc Coloproctology G B Irel. 2010 Oct;12(10):958–64.

15. Person B, Ifargan R, Lachter J, Duek SD, Kluger Y, Assalia A. The impact of preoperative stoma site marking on the incidence of complications, quality of life, and patient's independence. Dis Colon Rectum. 2012 Jul;55(7):783–7.

16. Leong AP, Londono-Schimmer EE, Phillips RK. Life-table analysis of stomal complications following ileostomy. Br J Surg. 1994 May;81(5):727–9.

17. Londono-Schimmer EE, Leong AP, Phillips RK. Life table analysis of stomal complications following colostomy. Dis Colon Rectum. 1994 Sep;37(9):916–20.

18. C. Ambe* P, Rebecca Kurz* N, Nitschke C, F. Odeh S, Möslein G, Zirngibl H. Intestinal Ostomy. Dtsch Ärztebl Int. 2018 Mar;115(11):182–7.

19. Whitehead A, Cataldo PA. Technical Considerations in Stoma Creation. Clin Colon Rectal Surg. 2017 Jul;30(3):162–71.

20. McGee MF. Stomas. JAMA. 2016 May 10;315(18):2032–2032.

21. Meirelles CA, Ferraz CA. [Theoretical study of the demarcation of the intestinal stoma]. Rev Bras Enferm. 2001 Sep;54(3):500–10.

22. Alexander-Williams J. Abdominal stomas - indications, operative technique and patients care. Gut. 1985 Jul;26(7):759.

23. Gordon and Nivatvongs' principles and practice of surgery for the colon, rectum, and anus - NLM Catalog - NCBI [Internet]. [cited 2019 Apr 27]. Available from: https://www.ncbi.nlm.nih.gov/nlmcatalog/101736436

24. Soybel DI. Adaptation to ileal diversion. Surgery. 2001 Feb 1;129(2):123–7.

25. Tang CL, Yunos A, Leong APK, Seow-Choen F, Goh HS. Ileostomy output in the early postoperative period. BJS. 1995;82(5):607–607.

26. Sabiston textbook of surgery : the biological basis of modern surgical practice - NLM Catalog - NCBI [Internet]. [cited 2019 May 13]. Available from: https://www.ncbi.nlm.nih.gov/nlmcatalog/101667903

27. Schwartz's principles of surgery - NLM Catalog - NCBI [Internet]. [cited 2019 May 13]. Available from: https://www.ncbi.nlm.nih.gov/nlmcatalog/101721353

28. Whitehead A, Cataldo PA. Technical Considerations in Stoma Creation. Clin Colon Rectal Surg. 2017 Jul;30(3):162–71.

29. Bird A, Wilson K, Bertinara A, Amos L. Educating patients in stoma care. Br J Nurs Mark Allen Publ. 2019 Mar 14;28(5):S4–5.

30. Qureshi A, Cunningham J, Hemandas A. Emergency stomas; should non-colorectal surgeons be doing it? Gastroenterol Hepatol Bed Bench. 2018;11(4):306–12.

31. Farquharson's textbook of operative general surgery - NLM Catalog - NCBI [Internet]. [cited 2019 May 13]. Available from: https://www.ncbi.nlm.nih.gov/nlmcatalog/101628558

32. Dozois EJ. Proctocolectomy and Brooke Ileostomy for Chronic Ulcerative Colitis. Clin Colon Rectal Surg. 2004 Feb;17(1):65–70.

33. Engida A, Ayelign T, Mahteme B, Aida T, Abreham B. Types and Indications of Colostomy and Determinants of Outcomes of Patients After Surgery. Ethiop J Health Sci. 2016 Mar;26(2):117–20.

34. Marin AW, Di Giorgio A, Destito C, Mercuri M, Massari M, Ricciardi V, et al. [Typology of defunctioning colostomy and state of art in the treatment of bowel emergencies]. Ann Ital Chir. 2005 Apr;76(2):157–60.

35. Early Local Complications From Intestinal Stomas | JAMA Surgery | JAMA Network [Internet]. [cited 2019 May 17]. Available from: https://jamanetwork.com/journals/jamasurgery/article-abstract/591307

36. Grobler SP, Hosie KB, Keighley MR. Randomized trial of loop ileostomy in restorative proctocolectomy. Br J Surg. 1992 Sep;79(9):903–6.

37. Pearl RK, Prasad ML, Orsay CP, Abcarian H, Tan AB, Melzl MT. Early local complications from intestinal stomas. Arch Surg Chic Ill 1960. 1985 Oct;120(10):1145–7.

38. Carlsen E, Bergan AB. Loop ileostomy: technical aspects and complications. Eur J Surg Acta Chir. 1999 Feb;165(2):140–143; discussion 144.

39. Greenstein AJ, Dicker A, Meyers S, Aufses AH. Periileostomy fistulae in Crohn's disease. Ann Surg. 1983 Feb;197(2):179–82.

40. Steinhagen E, Colwell J, Cannon LM. Intestinal Stomas—Postoperative Stoma Care and Peristomal Skin Complications. Clin Colon Rectal Surg. 2017 Jul;30(3):184–92.

41. Boyd-Carson W, Thompson MJ, Trainor B, Boyd K. Mucocutaneous separation. Nurs Stand R Coll Nurs G B 1987. 2004 Jan 7;18(17):41–3.

42. Salvadalena G. Incidence of Complications of the Stoma and Peristomal Skin Among Individuals with Colostomy, Ileostomy, and Urostomy. J Wound Ostomy Continence Nurs. 2008 Nov 1;35(6):596–607.

43. Douri T, Shawaf AZ. Pseudoverrucous papules and nodules: A case report. Dermatol Online J [Internet]. 2012 Apr 1 [cited 2019 May 13];18(4). Available from: https://escholarship.org/uc/item/2p59p1xx

44. Stoffels B, Sommer N, Berteld C, Vilz T, Websky M von, Kalff JC, et al. Spätkomplikationen permanenter intestinaler Stomata. Zentralblatt Für Chir - Z Für Allg Visz Thorax- Gefäßchirurgie. 2018 Dec;143(6):603–8.

45. Marsh P, Clark J. The Spouted Colostomy. Ann R Coll Surg Engl. 2007 Jan;89(1):78.

46. Duchesne JC, Wang Y-Z, Weintraub SL, Boyle M, Hunt JP. Stoma complications: a multivariate analysis. Am Surg. 2002 Nov;68(11):961–966; discussion 966.

47. Edwards DP, Leppington-Clarke A, Sexton R, Heald RJ, Moran BJ. Stoma-related complications are more frequent after transverse colostomy than loop ileostomy: a prospective randomized clinical trial. BJS. 2001;88(3):360–3.

48. Harris DA, Egbeare D, Jones S, Benjamin H, Woodward A, Foster ME. Complications and mortality following stoma formation. Ann R Coll Surg Engl. 2005 Nov;87(6):427–31.

49. Caricato M, Ausania F, Ripetti V, Bartolozzi F, Campoli G, Coppola R. Retrospective analysis of long-term defunctioning stoma complications after colorectal surgery. Colorectal Dis Off J Assoc Coloproctology G B Irel. 2007 Jul;9(6):559–61.

50. Turnbull GB. Ostomy statistics: the $64,000 question. Ostomy Wound Manage. 2003 Jun;49(6):22–3.

51. Husain SG, Cataldo TE. Late Stomal Complications. Clin Colon Rectal Surg. 2008 Feb;21(1):31–40.

52. Shellito PC. Complications of abdominal stoma surgery. Dis Colon Rectum. 1998 Dec;41(12):1562–72.

53. Güenaga KF, Lustosa SAS, Saad SS, Saconato H, Matos D. Ileostomy or colostomy for temporary decompression of colorectal anastomosis: systematic review and meta-analysis. Acta Cir Bras. 2008 Jun;23(3):294–303.

54. Johnson P. Intestinal Stoma Prolapse and Surgical Treatments of This Condition in Children: A Systematic Review and a Retrospective Study. Surg Sci. 2016 Sep 1;7(9):400–26.

55. Maeda K, Maruta M, Utsumi T, Sato H, Aoyama H, Katsuno H, et al. Local correction of a transverse loop colostomy prolapse by means of a stapler device. Tech Coloproctology. 2004 Mar;8(1):45–6.

56. Masumori K, Maeda K, Koide Y, Hanai T, Sato H, Matsuoka H, et al. Simple excision and closure of a distal limb of loop colostomy prolapse by stapler device. Tech Coloproctology. 2012 Apr;16(2):143–5.

57. Carne PWG, Robertson GM, Frizelle FA. Parastomal hernia. Br J Surg. 2003 Jul;90(7):784–93.

58. Hansson BME, Slater NJ, van der Velden AS, Groenewoud HMM, Buyne OR, de Hingh IHJT, et al. Surgical techniques for parastomal hernia repair: a systematic review of the literature. Ann Surg. 2012 Apr;255(4):685–95.

59. Krishnamurty DM, Blatnik J, Mutch M. Stoma Complications. Clin Colon Rectal Surg. 2017 Jul;30(3):193–200.

60. Ripoche J, Basurko C, Fabbro-Perray P, Prudhomme M. Parastomal hernia. A study of the French federation of ostomy patients. J Visc Surg. 2011 Dec;148(6):e435-441.

61. Etherington RJ, Williams JG, Hayward MW, Hughes LE. Demonstration of para-ileostomy herniation using computed tomography. Clin Radiol. 1990 May;41(5):333–6.

62. Lian L, Wu X-R, He X-S, Zou Y-F, Wu X-J, Lan P, et al. Extraperitoneal vs. intraperitoneal route for permanent colostomy: a meta-analysis of 1,071 patients. Int J Colorectal Dis. 2012 Jan;27(1):59–64.

63. Whittaker M, Goligher JC. A comparison of the results of extraperitoneal and intraperitoneal techniques for construction of terminal iliac colostomies. Dis Colon Rectum. 1976 Jun;19(4):342–4.

64. Koltun L, Benyamin N, Sayfan J. Abdominal stoma fashioned by a used circular stapler. Dig Surg. 2000;17(2):118–9.

65. Christakis C, Chatzidimitrou C, Kontos N, Papadopoulou S, Karanikas M. Use of intraluminal stapler device for creation of a permanent colostomy. Tech Coloproctology. 2004 Nov;8 Suppl 1:s93-96.

66. Rubin MS, Schoetz DJ, Matthews JB. Parastomal hernia. Is stoma relocation superior to fascial repair? Arch Surg Chic Ill 1960. 1994 Apr;129(4):413-418; discussion 418-419.

67. Allen-Mersh TG, Thomson JP. Surgical treatment of colostomy complications. Br J Surg. 1988 May;75(5):416–8.

68. Cheung MT, Chia NH, Chiu WY. Surgical treatment of parastomal hernia complicating sigmoid colostomies. Dis Colon Rectum. 2001 Feb;44(2):266–70.

69. Rastegarpour A, Cheung M, Vardhan M, Ibrahim MM, Butler CE, Levinson H. Surgical mesh for ventral incisional hernia repairs: Understanding mesh design. Plast Surg Oakv Ont. 2016;24(1):41–50.

70. Koc U, Kumaran K, Gomcei I, Dalgic T, Oser I, Ulas M, Ercan M, Bostanci E, Akoglu M. A. Retrospective Analysis of Factor Affecting Early Stoma Compications. Ostomy Wound Manage 2017 Jan;63(1):28-32

71. Pennick M O, Artioukh D Y. Management of parastomal varices: who re-bleeds and who does not? A systematic review of the literature. Tech Coloproctol. 2013;17(02):163–170.

Annexure-I

IRB Clearance letter

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. **B.J. Prashantham,** M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

June 06, 2019

Dr. Dany Sunny,
PG Registrar,
Department of General surgery,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
Analysis of risk factors of stoma related complications – an observational study.
Dr. Dany Sunny (Emp. No. 29420), PG Registrar, General surgery, Dr. Suchita Chase (Emp. No. 13572), Surgery, Dr. Abinaya RN (Emp. No. 20784), General Surgery.

Ref: IRB Min. No. 11771 [OBSERVE] dated 07.01.2019

Dear Dr. Dany Sunny,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Analysis of risk factors of stoma related complications – an observational study" on January 07th 2019.

The Committee reviewed the following documents:

1. IRB application format
2. Information Sheet and Consent Form (English, Tamil, hindi)
3. Cvs of Drs. Abinaya, Bijesh, Dany Sunny, Suchita Chase.
4. Proforma
5. No. of documents 1- 4

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on January 07th 2019 in the New IRB Room, Bagayam, Christian Medical College, Vellore 632 004.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Dr. **B.J. Prashantham,** M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Dr. John Jude Prakash	MBBS, MD,	Professor, Clinical Virology, CMC, Vellore	Internal, Clinician
Dr. Rekha Pai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Ekta Rai	MBBS, MD MRCA	Professor, Department of Anaesthesia, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. Inian Samarasam	MS, FRCS, FRACS	Professor, Surgery, CMC, Vellore	Internal, Clinician
Dr. Jayaprakash Muliyil	BSC, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist & Epidemiologist
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Asha Solomon	MSc Nursing	Associate Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Dr. **B.J. Prashantham,** M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Santhanam Sridhar	MBBS, DCH, DNB	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Dr. Ajith Sivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Dr. Premila Abraham	M.Sc. Ph.D	Professor, Department of Biochemistry, CMC, Vellore	Internal Clinician
Dr. Winsely Rose	MBBS, MD (Paed)	Professor, Paediatrics, CMC Vellore	Internal, Clinician
Dr. Sathish Kumar	MBBS, MD, DCH	Professor, Child Health, CMC, Vellore	Internal, Clinician
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor, Endocrinology, CMC, Vellore	Internal, Clinician
Ms. Grace Rebekah	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Barney Isaac	MBBS, DNB (Respiratory Diseases)	Associate Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Analysis of risk factors of stoma related complications – an observational study." on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min. No. 11771 [OBSERVE] dated 07.01.2019 3 of 3

Annexure-II
Master copy of data

Pt Id/ serial no	Age(in ye <60=1 >/=60=2	Gender male=1 female=2	initian diagnosis malignancy=1 non malignancy=2	elective or eme elective=1 emergency=2	reg/consultan reg=1 consultant=2	comorbidi yes=1 no=2	albumin normal=1 less=2	hemoglot normal=1 less=2	ileostomy/colo ileostomy=1 colostomy=2	end/loop end=1 loop=2	reversed/n reversed=1 not=2	complicat yes=1	bmi low=1, normal=2	high=3
1	1	1	2	2	2	2	1	1	2	2	1	2	1	
2	1	1	2	2	1	2	2	1	1	1	1	2	3	
3	1	2	1	1	1	2	2	2	1	1	1	2	1	
4	1	1	1	1	2	1	1	1	2	1	1	1	3	
5	1	1	2	1	2	2	1	2	1	2	1	2	1	
6	1	2	2	2	1	2	2	2	1	1	1	1	1	
7	1	1	2	2	2	2	1	1	1	2	1	2	2	
8	1	1	1	1	2	2	1	2	1	1	1	2	2	
9	1	1	2	2	2	1	1	1	1	2	1	2	1	
10	1	1	2	2	1	1	2	1	2	2	1	2	3	
11	1	1	2	2	2	2	1	2	2	2	1	2	2	
12	1	2	2	2	2	1	2	2	2	1	1	2	3	
13	1	1	2	1	2	2	2	1	1	1	1	2	3	
14	1	1	2	1	2	2	2	1	2	1	1	2	3	
15	1	2	2	2	2	2	2	2	2	2	1	2	1	
16	1	1	1	2	2	1	1	2	1	2	1	2	2	
17	2	2	1	1	2	2	2	2	1	2	2	2	1	
18	1	2	2	2	2	1	1	1	1	1	2	2	2	
19	1	1	2	1	2	1	2	2	1	1	2	2	1	
20	2	2	1	1	2	1	2	2	1	1	1	2	2	
21	2	2	1	2	2	1	2	2	1	1	2	2	1	
22	1	1	2	1	2	2	1	1	2	2	1	2	2	
23	1	1	2	1	1	2	1	1	2	2	2	2	2	
24	2	1	1	1	2	2	1	1	1	1	1	2	2	
25	1	2	2	1	2	2	1	1	2	2	1	2	1	
26	1	1	2	2	2	1	1	1	1	1	1	2	2	
27	1	1	2	1	2	1	1	1	1	1	1	2	1	
28	2	2	1	1	2	1	2	2	1	1	2	1	1	
29	1	2	1	1	1	2	1	1	2	1	1	2	2	
30	2	2	1	1	2	2	2	2	1	1	1	2	1	
31	1	1	1	1	2	1	1	1	1	2	1	2	2	
32	1	2	2	1	2	2	1	1	2	1	2	1	2	
33	1	1	2	1	2	1	2	2	1	2	1	2	2	
34	1	1	1	2	2	2	1	1	1	1	1	2	1	
35	1	1	2	1	2	2	2	2	1	2	1	2	3	
36	1	1	2	2	1	2	2	1	1	1	1	2	1	
37	1	1	1	1	2	2	1	1	2	2	1	2	2	
38	1	1	2	2	1	1	2	2	2	2	1	2	1	
39	1	1	1	1	2	2	1	2	1	1	2	2	2	
40	1	2	1	2	2	2	1	1	2	2	1	2	2	
41	2	1	1	2	2	1	1	2	2	2	2	1	2	
42	1	2	1	2	2	2	1	1	1	2	2	2	2	
43	2	2	2	1	2	2	1	2	2	2	2	2	2	
44	2	1	2	2	1	1	2	1	1	1	1	2	2	
45	1	1	1	2	2	1	1	2	2	2	2	1	2	
46	1	1	1	1	2	2	1	1	2	2	2	2	2	
47	1	1	1	1	2	1	1	1	1	1	1	2	2	
48	1	2	2	2	1	1	1	1	2	2	1	2	2	
49	1	1	2	1	2	1	2	2	1	1	2	2	3	
50	1	2	1	1	2	1	1	1	2	2	1	1	1	

51	1	2	1	1	2	2	1	1	2	2	1	2	1	
52	1	1	1	1	2	2	2	1	2	2	2	2	2	
53	1	1	2	2	2	2	1	1	2	2	2	2	2	
54	1	1	2	1	2	1	1	1	1	1	1	2	2	
55	2	1	1	1	2	1	2	2	2	1	1	1	2	
56	1	1	1	1	2	2	1	2	1	2	1	2	2	
57	1	2	2	2	2	1	2	2	1	1	1	2	1	
58	2	2	2	2	2	1	1	2	1	1	1	2	3	
59	1	2	2	1	2	2	1	1	1	1	1	2	1	
60	1	1	2	2	1	2	1	1	1	1	1	2	2	
61	1	1	2	2	2	2	1	2	1	2	1	1	2	
62	1	2	2	2	2	2	1	1	2	2	1	2	2	
63	2	1	1	1	1	2	2	1	1	1	1	2	2	
64	1	1	2	2	2	2	1	1	1	1	1	2	1	
65	1	1	1	1	1	2	2	2	1	1	2	2	2	
66	1	1	1	1	2	2	1	1	1	2	1	1	2	
67	1	1	1	1	1	2	2	1	2	2	2	2	2	
68	1	1	2	2	2	1	1	2	1	1	1	2	1	
69	1	2	2	1	1	2	2	2	1	1	1	2	2	
70	1	1	1	1	2	1	2	2	1	1	2	1	3	
71	1	2	2	2	2	1	2	2	1	1	1	2	1	
72	1	1	1	2	1	2	1	1	1	2	1	2	1	
73	1	1	2	1	1	2	2	2	1	2	1	2	2	
74	2	2	2	2	2	2	1	2	2	2	1	2	2	
75	1	1	2	2	2	1	1	2	1	1	1	2	2	
76	1	1	2	1	2	2	2	2	1	1	1	2	1	
77	1	1	2	2	1	1	2	2	2	2	1	1	3	
78	1	2	1	1	2	2	2	2	1	2	1	2	2	
79	1	2	2	2	1	2	1	2	1	1	1	2	3	
80	1	1	2	2	1	2	1	2	2	2	1	2	2	
81	1	2	2	1	2	1	1	2	2	2	1	2	2	
82	1	2	1	1	2	2	1	1	2	1	2	2	2	
83	2	1	2	2	1	1	2	2	1	1	1	2	1	
84	1	1	2	1	2	2	1	1	2	1	1	2	3	
85	1	2	1	2	2	2	2	2	1	2	1	2	1	
86	1	1	1	2	1	1	2	1	1	1	1	1	2	
87	2	1	2	2	1	1	1	1	1	2	1	1	2	
88	1	1	2	2	1	1	1	1	1	1	1	1	2	
89	1	1	2	2	1	2	1	1	1	1	1	2	3	
90	1	2	2	1	2	1	1	2	1	2	1	2	1	
91	2	2	1	1	2	1	2	2	2	1	1	2	2	
92	1	1	2	2	2	2	1	1	1	2	1	2	2	
93	1	1	2	1	2	2	1	2	2	1	1	2	2	
94	1	2	1	1	2	1	2	2	2	1	1	2	2	
95	1	1	2	2	1	2	1	1	2	2	1	2	2	
96	1	1	1	2	2	2	1	2	2	1	2	2	1	
97	1	2	2	2	2	1	2	2	2	1	1	2	2	
98	1	1	2	2	1	2	1	1	1	1	1	2	2	
99	1	1	1	2	1	2	2	1	2	2	1	2	2	
100	2	2	1	1	2	2	1	2	1	1	1	1	2	
101	2	1	1	1	1	1	2	2	1	1	1	2	2	
102	1	2	2	1	2	2	2	2	2	2	1	2	1	
103	2	2	1	2	1	1	2	2	1	2	1	2	1	
104	1	1	2	2	2	1	1	2	1	1	1	2	2	
105	1	1	1	1	2	1	2	1	1	1	1	2	2	
106	2	2	1	2	2	2	1	2	1	1	1	1	1	
107	1	1	2	2	2	2	1	1	1	1	1	2	2	
108	1	1	1	1	2	1	2	1	2	1	1	1	2	
109	1	2	2	2	1	1	2	2	1	1	1	1	1	
110	2	1	1	1	2	1	1	1	1	2	1	2	3	

111	1	2	2	1	2	2	2	2	2	1	2	2	1
112	1	2	2	1	2	2	1	2	2	1	1	1	3
113	1	1	2	1	2	2	1	1	2	1	1	2	3
114	1	1	2	2	1	1	1	1	1	1	1	2	3
115	1	1	1	1	2	2	1	1	1	2	2	2	1
116	1	1	1	2	2	1	2	2	2	2	1	2	2
117	1	1	1	2	1	1	2	1	1	2	2	2	1
118	1	1	2	2	2	2	1	1	1	1	1	1	2
119	1	2	2	1	2	2	1	2	2	1	1	1	3
120	1	1	2	2	2	2	1	1	2	2	1	1	1
121	1	1	2	2	1	2	1	1	2	1	1	2	2
122	2	2	1	1	2	1	2	2	1	1	1	2	2
123	1	1	2	2	2	2	1	1	1	1	1	2	1
124	1	1	2	2	1	2	1	1	1	2	1	2	2
125	1	1	1	1	1	2	1	1	1	2	1	2	2
126	2	2	2	2	2	2	2	2	1	1	1	1	1
127	1	2	1	2	2	2	2	2	2	2	1	1	1
128	1	2	2	1	2	2	1	2	1	1	1	2	2
129	1	2	1	1	2	1	1	2	2	2	1	2	2
130	1	1	2	2	2	2	1	1	2	2	1	2	2
131	1	1	2	2	2	2	1	1	1	1	1	1	3
132	1	1	2	1	2	1	2	1	2	2	1	1	2
133	1	1	2	2	1	2	1	1	1	1	1	1	2
134	1	2	2	2	1	2	1	2	2	2	1	1	2
135	1	1	2	2	1	2	1	1	1	1	1	2	2
136	1	1	1	2	2	2	1	2	2	2	1	2	2
137	2	1	1	1	2	1	1	2	1	2	1	2	2
138	1	2	2	2	2	2	1	2	2	1	1	1	3
139	1	1	1	2	1	2	1	1	1	2	1	2	1
140	2	1	2	1	2	1	2	2	2	2	1	2	3
141	1	1	2	2	1	2	1	1	1	1	1	2	3
142	1	1	1	1	2	1	2	2	1	1	1	2	3
143	2	1	2	2	1	2	1	2	2	1	1	2	3
144	1	1	2	2	2	2	1	1	1	2	1	1	3
145	1	1	2	2	2	2	1	1	1	1	1	2	2
146	1	1	1	1	2	1	1	1	2	2	1	1	2
147	1	2	1	2	2	2	1	1	1	1	1	2	3
148	1	2	1	1	2	1	1	2	2	1	2	2	2
149	1	1	2	1	2	1	1	1	2	1	1	2	3
150	2	2	2	2	2	2	1	2	1	1	1	2	2
151	1	2	1	1	2	1	2	2	2	1	1	1	2
152	1	1	1	1	2	2	2	1	2	2	1	2	2
153	1	1	2	2	1	2	1	1	1	1	1	2	2
154	2	1	1	2	1	1	1	1	1	1	2	2	1
155	1	2	2	2	2	1	1	1	2	1	1	1	3
156	1	1	2	2	2	2	1	1	1	1	1	2	3
157	1	1	2	2	1	2	1	1	2	2	1	2	2
158	1	1	2	1	2	2	1	1	1	2	1	2	3
159	1	1	2	2	1	1	1	1	2	2	1	2	2
160	1	1	2	1	2	2	1	1	2	2	1	1	2
161	1	1	2	2	1	2	1	1	1	1	1	2	3
162	2	1	2	2	2	1	2	2	1	1	1	2	2
163	1	2	2	1	1	2	1	2	2	1	1	2	2
164	1	2	2	2	2	1	2	2	1	1	1	2	1
165	1	1	2	1	1	2	1	1	2	2	1	2	2
166	1	1	1	2	2	2	2	2	1	1	1	1	2
167	1	1	2	2	1	2	1	2	1	1	1	2	2
168	1	1	1	2	2	1	2	2	2	2	1	2	2
169	1	2	2	2	2	1	2	2	1	1	1	2	2
170	1	1	1	1	2	2	1	1	2	1	1	2	3

171	1	1	1	2	1	1	2	2	1	1	1	2	2
172	2	1	2	1	1	2	1	2	2	1	2	2	2
173	1	1	2	2	1	2	1	1	2	2	1	1	2
174	1	1	2	2	1	1	2	2	1	1	1	2	1
175	1	1	1	2	2	2	1	1	1	1	1	2	2
176	1	1	2	2	1	1	2	1	2	1	1	2	2
177	2	1	1	1	2	1	1	2	2	1	2	2	2
178	2	1	2	2	1	2	1	2	2	2	1	2	2
179	1	1	2	1	2	2	2	2	1	1	1	2	1
180	1	1	1	2	1	1	1	1	1	1	2	2	2
181	2	1	1	1	1	1	2	2	1	1	1	2	1
182	1	1	1	1	2	2	1	1	2	1	2	2	2
183	1	1	2	1	2	1	2	2	1	1	1	2	1
184	1	1	1	1	2	2	1	1	2	1	1	2	2
185	1	2	1	1	2	2	1	1	2	1	2	1	2
186	1	1	1	2	1	1	1	1	1	1	2	1	2
187	1	1	2	1	1	2	1	1	2	1	1	2	3
188	1	2	2	2	1	2	1	2	2	2	1	1	2
189	1	1	2	2	1	2	1	1	1	2	1	2	2
190	1	2	2	2	2	1	1	1	2	1	1	1	2
191	2	1	1	2	1	1	1	2	1	1	1	2	2
192	1	2	2	1	1	1	2	2	1	1	1	2	1
193	1	1	2	2	2	1	1	1	2	2	1	1	2
194	1	1	2	2	2	2	1	1	2	2	1	2	2
195	1	1	2	2	2	2	1	1	1	1	1	2	2
196	1	1	2	1	2	1	2	1	2	2	1	2	2
197	1	1	2	2	1	2	1	1	1	1	1	2	2
198	1	2	2	2	1	2	1	2	2	2	1	2	2
199	1	1	2	2	1	2	1	1	1	1	1	2	2
200	1	1	1	2	2	2	1	2	2	2	1	2	2
201	2	1	1	1	2	1	1	2	1	2	1	2	2
202	1	2	2	2	2	2	1	2	2	1	1	2	2
203	1	2	2	1	2	1	1	2	1	2	1	2	1
204	2	2	1	1	2	1	2	2	2	1	1	2	2
205	1	1	2	2	2	2	1	1	1	2	1	2	2
206	1	1	2	1	2	2	1	2	2	1	1	2	2
207	1	2	1	1	2	1	2	2	2	1	1	2	2
208	1	1	2	2	1	2	1	1	2	2	1	2	3
209	1	1	1	2	2	2	1	2	2	1	2	2	2
210	1	2	2	2	2	1	2	2	2	1	1	2	1
211	1	1	2	2	1	2	1	1	1	1	1	1	2
212	1	1	1	2	1	2	2	1	2	2	1	2	3
213	2	2	1	1	2	2	1	2	1	1	1	2	2
214	2	1	1	2	1	2	1	1	2	1	2	2	2