Randomised trial to assess the efficacy of pelvic drainage in preventing pelvic collection after elective rectal resection for cancer

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CERTIFICATE

This is to certify that the dissertation titled **'Randomised trial to assess the efficacy of pelvic drainage in preventing pelvic collection after elective rectal resection for cancer'** is the bonafide work of **Dr. Philip Mitta,** in fulfilment of the rules and regulations for the **M.S., Branch b-1, General Surgery** Examination of **The Tamil Nadu Dr. M.G.R. University,** to be held in 2014.

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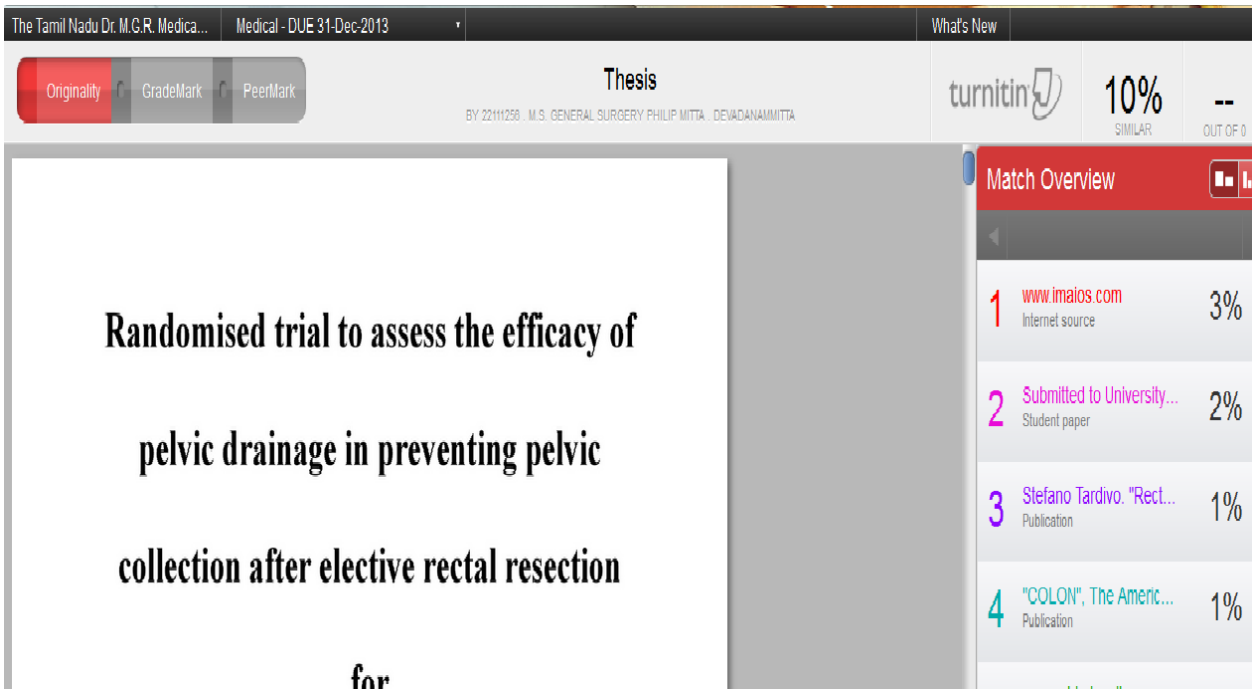
TURNITIN ORIGINALITY REPORT



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CONTENTS

INTRODUCTION

Rectal cancer is the third most commonly diagnosed cancer occurring in both males and females globally(1). In India, the incidence of rectal cancer among males is higher than females, which is different from the rest of the world. Increasing incidence among younger males in India has been seen as a trend (2). Low socioeconomic status has been seen to be associated with the incidence of rectal cancer both globally and in India (3).

Though the management of rectal cancer is multimodal, adequate surgical resection is the mainstay of treatment and is considered the primary treatment modality. Rectal resection remains a morbid operation, one of the most troublesome complications being pelvic collection.

Pelvic drainage by means of closed tubular drainage has been practised routinely with the objective of reducing the post operative morbidity (4). This study aims to observe the role of closed tube pelvic drainage in the post operative outcome following rectal resection. Although the ineffectiveness of such an intervention in reducing postoperative morbidity has been established in patients undergoing small intestinal and colonic resections, there is no conclusive data in patients undergoing rectal resection. In fact the effectiveness of such an intervention for rectal resection has been questioned(5,6).

AIM

To assess the efficacy of pelvic drainage in preventing pelvic collection after elective rectal resection for cancer.

OBJECTIVES

1. To detect the presence of pelvic collection by ultrasonographic imaging of the pelvis on the 5th post operative day and measure its volume if present.
2. To assess the morbidity in terms of deviation in the normal post operative course
3. To record the number of days of hospital stay according to 'fit for discharge' criteria *.
4. To document the occurrence of urinary tract infection (UTI) during the post operative period (30 days following surgery).

*Fit for discharge criteria are as follows:

- Have good pain control with oral analgesia;
- Are taking solid food with no IV fluids;
- Are independently mobile or at the same level as pre-operatively;
- Meet all of the above criteria and are willing to go home.

REVIEW OF LITERATURE

INTRODUCTION:

Colorectal cancer is an important public health issue. It is the third most common cancer among men (10% of all cancer cases) and second most common cancer among women (9.4% of all cancer cases) worldwide (7). Colorectal cancer is the fourth most common cause of cancer related death in the world and accounts for 8% of cancer deaths. The incidence increases with increase in age but however, some studies from India have reported higher incidence in younger males (8). The mortality rates have been shown to be lower in females than in males. The behavior of rectal cancer has been found to be similar to colon cancer. Though the pathogenesis of colon and

rectal cancer is the same, there are anatomical peculiarities specific to the rectum that require a different approach to rectal cancer (9). Unlike colon cancer which has higher incidence among higher socioeconomic groups, rectal cancer is more common among lower socioeconomic groups.

BURDEN OF DISEASE:

Colorectal cancer is the fourth most common cause of death worldwide. The incidence is found to be higher in western populations (North America, Europe, Australia and New Zealand). This trend is gradually being noticed in developing countries. Due to the presence of infectious disease and maternal mortality in the developing countries, rectal cancer burden is not perceived to be significant. However, once an individual crosses the age of 5 years, the risk attributed to cancer increases proportionately. There has been

a marked decline in incidence among females. This may be due to the stronger penetration of oral contraceptives and hormone replacement therapy. Risk on colorectal cancer in users of oral contraceptives and hormone replacement was reduced by 18% and 20% respectively (9). The incidence of colon cancer in India varies from 3.7 to 0.7/100,000 in men and 3 to 0.4/100,000 in women. The incidence of rectal cancer varies from 5.5 to 1.6/100,000 in men and 2.8 to 0/100,000 in women. The rural incidence rates are approximately half the urban incidence rates. There has been increasing incidence of rectal cancer among younger Indian males. Although there have been increase in incidence rates among males and females for colon cancer, the incidence rates for rectal cancer continue to be stable. The overall lower incidence of colorectal cancer among Indian population can be attributed to increased starch content in the diet and the presence of natural antioxidants (curcumin) (2).

NON AVOIDABLE RISK FACTORS:

There seems to be a higher incidence of right colon cancer among females, while rectal cancer is more common among males. Older age groups have higher incidence of right colon cancers while left colon and rectal cancers are higher in younger age groups. Several genetic factors seem to affect the age of onset of colorectal cancers. Earlier age of onset is seen in hereditary conditions like Familial adenomatous polyposis (FAP) and hereditary non polyposis colon cancer (HNPCC). The hypothesis that colorectal cancer, both sporadic and hereditary forms develop from premalignant lesions is accepted. A family history of colon cancer is another significant non avoidable risk factor. Other risk factors include the presence of inflammatory bowel disease, pelvic irradiation, history of non cancer surgery, history of breast, endometrial and ovarian cancer and no or low parity (9).

AVOIDABLE RISK FACTORS:

Dietary, lifestyle and environmental factors seem to contribute to difference in incidences. High red meat content in diet has been associated with greater incidence along with animal fats, proteins and sugars. High fibre diets are associated with lower incidence. Relation of energy intake, physical activity, metabolism and body mass index with incidence has been found. Other controllable lifestyle factors include alcohol consumption, use of tobacco and use of hormones in post menopausal women (9–11).

SCREENING:

Screening for early cancer can reduce the mortality associated with the disease significantly. Finding an adenoma and removing it will reduce the progression to cancer and the incidence. Survival in colorectal cancer increases from 50% to 90% when detected early, before the onset of

symptoms. Studies have shown that incidence of rectal cancer can be reduced by two yearly stool occult blood testing and yearly flexible sigmoidoscopy. Other methods of screening are CT colonography, colonoscopy and fecal immunochemical testing (12).

DIAGNOSIS OF COLORECTAL CANCER:

The two modalities used in diagnosis of colorectal cancer are endoscopy and radiology. Colonoscopy is the diagnostic test which is most accurate since it can localise the lesion and biopsy it as well. Double contrast barium enema along with flexible sigmoidoscopy can also be used but it has a lower diagnostic yield as compared to colonoscopy. CT colonography is another diagnostic investigation (13,14).

Rectal cancer is currently staged using the 7^{th} edition of the AJCC TNM classification (2010). Staging preoperatively is accomplished with CT or

MRI scan of the abdomen and pelvis and a chest X ray. Other investigations useful for locoregional evaluation of rectal cancer are rigid sigmoidoscopy, MRI and transrectal ultrasonography. An MRI scan is useful to assess the distance between the tumour and the mesorectal fascia, thereby predicting the likelihood of a positive circumferential resection margin.

7th edition AJCC TNM classification 2010:

Primary tumor (T)

TX Primary tumor cannot be assessed

T0 No evidence of primary tumor

Tis Carcinoma in situ: intraepithelial or invasion of lamina propria

T1 Tumor invades submucosa

T2 Tumor invades muscularis propria

T3 Tumor invades through the muscularis propria into the pericolorectal tissues

T4a Tumor penetrates to the surface of the visceral peritoneum

T4b Tumor directly invades or is adherent to other organs or structures

Regional lymph nodes (N)

NX Regional lymph nodes cannot be assessed

N0 No regional lymph node metastasis

N1 Metastasis in 1-3 regional lymph nodes

N1a Metastasis in 1 regional lymph node

N1b Metastasis in 2-3 regional lymph nodes

N1c Tumor deposit(s) in the subserosa, mesentery, or nonperitonealized pericolic or perirectal tissues without regional nodal metastasis

N2 Metastasis in 4 or more lymph nodes

N2a Metastasis in 4-6 regional lymph nodes

N2b Metastasis in 7 or more regional lymph nodes

Distant metastasis (M)

M0 No distant metastasis

M1 Distant metastasis

M1a Metastasis confined to 1 organ or site (eg, liver, lung, ovary, nonregional node)

M1b Metastases in more than 1 organ/site or the peritoneum

Tumour markers like carcinoembryonic antigen (CEA) and CA 19-9 have been associated with colorectal cancer. The diagnostic ability of these markers in the detection of colorectal cancer is not significant as they are non specific. However, in newly detected cancers, serum CEA levels have a prognostic ability (15,16).

LOCAL EXCISION:

Local excision allows removal of the tumour and surrounding tissue in one specimen. This permits assessment of margins, histology, vascular involvement and depth of invasion. However local excision is not an option for proximal and middle rectal tumours. The various options include

transanal excision, transanal endoscopic microsurgery, transsphincteric (York-Mason) procedure and transsacral (Kraske) procedure. There have been high rates of local recurrence after five years following these procedures and therefore are very rarely used in the treatment of rectal cancer (17,18).

SPHINCTER SPARING PROCEDURES:

Patients with invasive rectal cancers can be operated with sphincter sparing procedures provided the distal margins are histologically negative. The local recurrence rates of such procedures range from 6% to 31% (19) which are similar to abdominoperineal excision. Low anterior resection can be employed for tumours in the upper and middle third of the rectum. For distal rectal lesions a very low anterior resection is done. In very low and ultra low

anterior resections, the descending colon is anastomosed to the anal canal. In cases where there is a wide pelvis a colonic J pouch can be made (20).

ABDOMINOPERINEAL EXCISION:

This procedure involves resection of the sigmoid colon, rectum and anal canal followed by the performance of a permanent colostomy. This, for many years was the gold standard for treatment of low rectal cancers against which sphincter sparing procedures and local excision procedures were compared. Local recurrence rates and five year survival rates did not differ significantly between abdominal perineal excision and sphincter sparing procedures (21). Quality of life on a long term basis was also similar to sphincter sparing procedures with the exception of depression related to body image changes (22).

However, with emerging evidence regarding the required distal resection margin and availability of stapling devices that facilitate a low anastomosis deep in the pelvis, it is less frequently performed for low rectal cancers and only reserved for situations where the pelvic floor or sphincter complex are involved.

MULTIVISCERAL EXCISION:

This includes resection of the cancer along with adjacent organs which are involved by cancer. A total pelvic exenteration involves en bloc removal of all pelvic organs. Modified exenterations can be posterior, anterior, supralevator or composite. This procedure is associated with high morbidity rates and reoperation rates (23).

CHEMORADIOTHERAPY AND RADIOTHERAPY – ADJUVANT AND NEOADJUVANT APPROACHES:

The role of adjuvant therapy has been extensively studied in the treatment of rectal cancer, but no trial has unequivocally demonstrated improved overall survival with radiotherapy, despite a reduction in the rate of local recurrence.

The Swedish Rectal Cancer Trial was the first randomized trial conducted to study the effect of pre operative radiotherapy on rates of local recurrence and overall survival in 1997. This trial had concluded that a short-term regimen of high-dose preoperative radiotherapy reduces rates of local recurrence and improves survival among patients with resectable rectal cancer (24).

In 2001, the Dutch Colorectal Cancer Group studied the effect of pre operative radiotherapy against surgery (total mesorectal excision) alone. The

conclusions of this trial were that short-term preoperative radiotherapy reduces the risk of local recurrence in patients with rectal cancer who undergo a standardized total mesorectal excision (25).

In 2004, the German Rectal Cancer Trial group studied pre operative versus post operative chemoradiotherapy in the treatment of rectal cancer. This had shown that pre operative chemoradiotherapy decreased local toxicity and local recurrence rates but had no role in improving overall survival (26).

With improvements in surgical technique and histopathological assessment, the role of radiotherapy needed to be reassessed. This led to the MRC CR07 trial which compared pre operative radiotherapy versus selective post operative chemoradiotherapy. This trial had shown that short course pre operative radiotherapy was effective in operable rectal cancer (27).
The Polish Colorectal Study group compared pre operative short course radiotherapy against pre operative conventionally fractioned chemoradiation

in 2006. They concluded that there was no difference in survival, late toxicity or local control when compared to short course radiotherapy alone. However there was more early toxicity with short course radiotherapy (28).

.Neoadjuvant chemoradiotherapy is generally considered for T3/T4 lesions. Studies have shown that neoadjuvant approach for these lesions has a more favourable toxicity profile and lower local recurrence rates when compared to adjuvant approaches. In cases of cT3N0 disease, upfront chemoradiotherapy has been questioned due to favourable low local recurrence rates after upfront surgery (29). Studies have shown that T3 tumors with more than 5mm of extramural tumour invasion have a much higher chance of nodal involvement and therefore must be treated as high risk tumours. However data from the MERCURY trial suggest that the outcome in these patients may be good with surgery alone (30). The relative indication of chemoradiotherapy in T1/2 cancer is when MRI findings are suggestive of nodal disease. Neoadjuvant therapy may also be considered

when the tumour involves the mesorectal fascia or even is within 2mm of the fascia. This has a high predictive value of residual tumour in the circumferential resection margin (CRM) when total mesorectal excision is performed. Transrectal ultrasonography (TRUS) or high resolution MRI are the investigations of choice for locoregional staging. Prognosis of neoadjuvant chemoradiotherapy was predicted by the extent of post treatment tumour regression and the final stage based on the surgical specimen. Concurrent chemotherapy along with fractionation RT has become the standard regimen for the neoadjuvant approach (32). The optimal timing of surgery after neoadjuvant therapy is about 4-6 weeks. Patients who underwent preoperative chemotherapy did not appear to have more perioperative complications. 5 Fluorouracil forms the mainstay of chemotherapeutic regimen along with leucovorin, oxaliplatin and irinotecan used interchangeably. Bevacizumab, Cetuximab and Panitumumab ae humanized monoclonal antibodies that have been used recently (33). Radiation therapy with pelvic irradiation upto 45 Gy in 25 fractions by a

four field technique is given. For concurrent post operative chemoradiotherapy, infusional 5FU is preferred over bolus doses. Oral Capecitabine is accepted as a substitute for infusional 5FU. Options for chemotherapy are 5FU/LV and FOLFOX (5FU, Leucovorin and Oxaliplatin).

MORBIDITY FOLLOWING RECTAL RESECTION:

Although the technique in rectal resection has largely been standardized and the anatomy elucidated, there remains a risk of failure and significant morbidity to the patient. The outcome following rectal resection is the result of a complex interaction between surgeon factors, patient factors and disease factors. Some of the factors that influence the outcome following an anastomosis are given below:

Surgeon Factors	Patient Factors	Disease Factors
Intestinal blood supply	Body mass index	Inflammatory bowel disease
Tension on the anastomosis	Anesthesia severity assessment	Metastatic carcinoma
Perioperative hypoxia	Age	Radiation therapy
Perioperative resuscitation	Smoking	Damage control surgery
Intraoperative blood loss	Nutritional status	Emergent surgery/peritonitis
Operative times	Alcohol use	Steroids
		Infraperitoneal location

Complications may include those that are common to any other intra abdominal operation such bleeding, infection, deep vein thrombosis, wound problems, pneumonia, myocardial infarction and renal failure. The complications specific to rectal resection are impotence in men (50% incidence), anastomotic leak (20% incidence), intra abdominal collection, urinary dysfunction and massive venous bleeding from the presacral space. It was conventionally believed that placement of a pelvic drain following rectal resection decreased the risk of post operative pelvic collection and also anastomotic leak. Recently performed studies have raised questios on the usefulness of closed pelvic drainage. However, there is no evidence strong enough to make a recommendation either in favour of or against closed pelvic drainage following rectal resection.

This study was conducted in order to objectively establish the benefit of closed pelvic drainage in pelvic preventing pelvic complications following rectal resection for rectal cancer.

MATERIALS AND METHODS

STUDY DESIGN: Prospective randomized controlled trial.

INCLUSION CRITERIA:

All patients undergoing elective rectal resection under General Surgery unit II (Colorectal), CMCH, Vellore.

INTERVENTION AND COMPARATOR AGENT:

Intervention: No pelvic drainage.

Comparator: Closed pelvic drainage.

EXCLUSION CRITERIA:

1. Patients operated on an emergency basis.
2. Patients with disseminated disease where surgery is a palliative procedure.
3. Patients with compromised immunity (on steroids, immunosupression, post transplant patients)
4. Patients with intraoperative complications for which drainage is inevitable (spillage).

METHOD OF RANDOMISATION: Block randomisation.

METHOD OF ALLOCATION CONCEALMENT: In sealed envelopes.

PRIMARY OUTCOME:

Detection of pelvic collection by means of pelvic ultrasonography done on the 5^{th} post operative day or earlier if clinically warranted and measurement of the volume if present.

SECONDARY OUTCOMES:

1. Postoperative stay in days (measured according to ‘fit for discharge’ criteria.
2. Incidence of urinary tract infection (UTI) in the 4 weeks following surgery.

DURATION OF TRIAL:

1.10.2011 to 30.6.2013

SAMPLE SIZE CALCULATION:

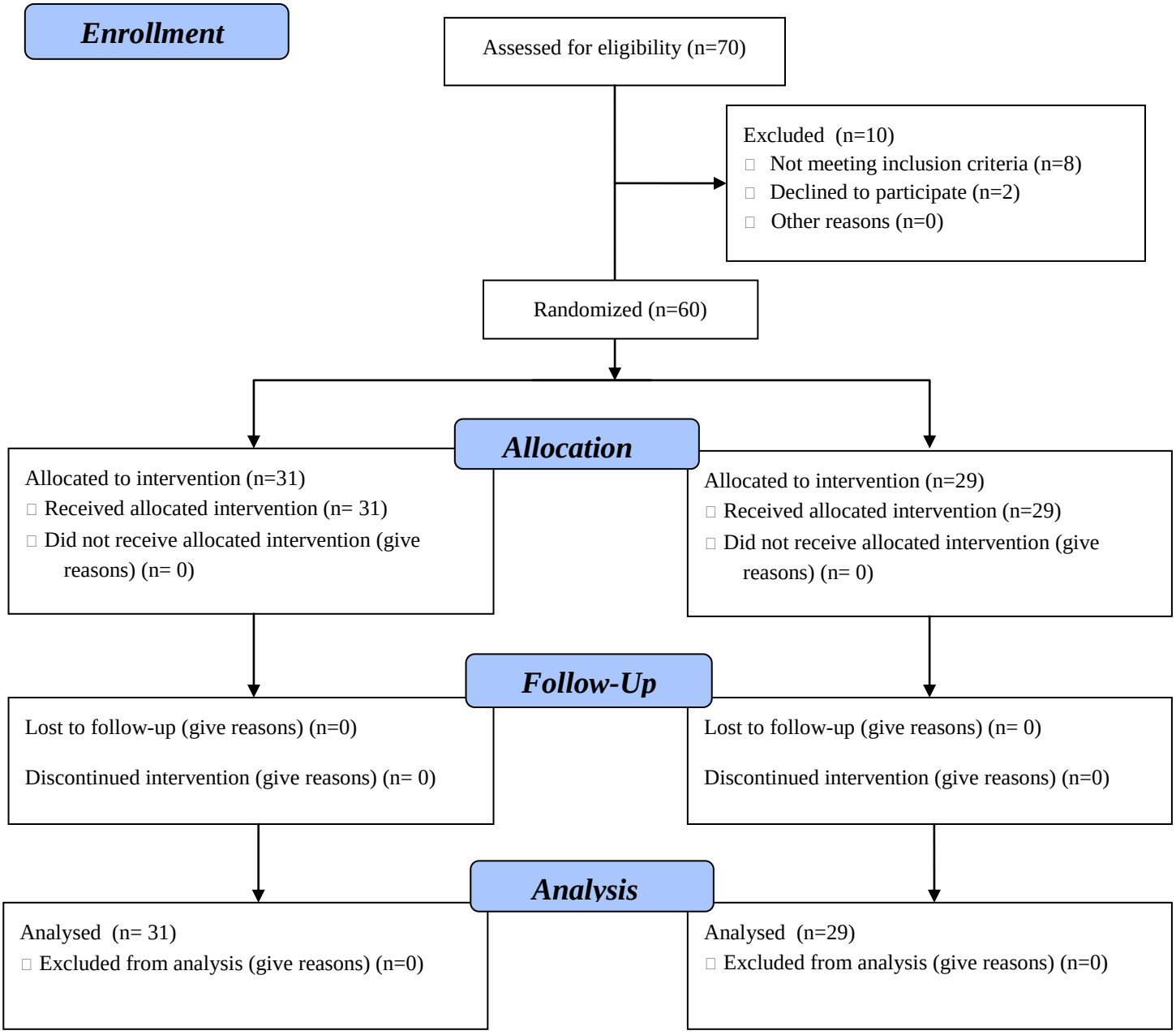
The sample size was calculated using the two proportion, equal allocation calculation with an alpha error of 5% and a power of 80%.

Proportion of collection in no drainage group	0.25
Proportion of collection in drainage group	0.10
Estimated risk difference	0.15
Power (1- beta) %	80
Alpha error (%)	5
1 or 2 sided	2
Required sample size for each arm	**100**

STATISTICAL ANALYSIS:

Statistical analysis was done using the Chi square test and independent sample T test.

CONSORT 2010 Flow Diagram



ANALYSIS

CATEGORICAL VARIABLES:

Sex distribution: Out of the total of 60 patients, 45 were male and 15 were females.

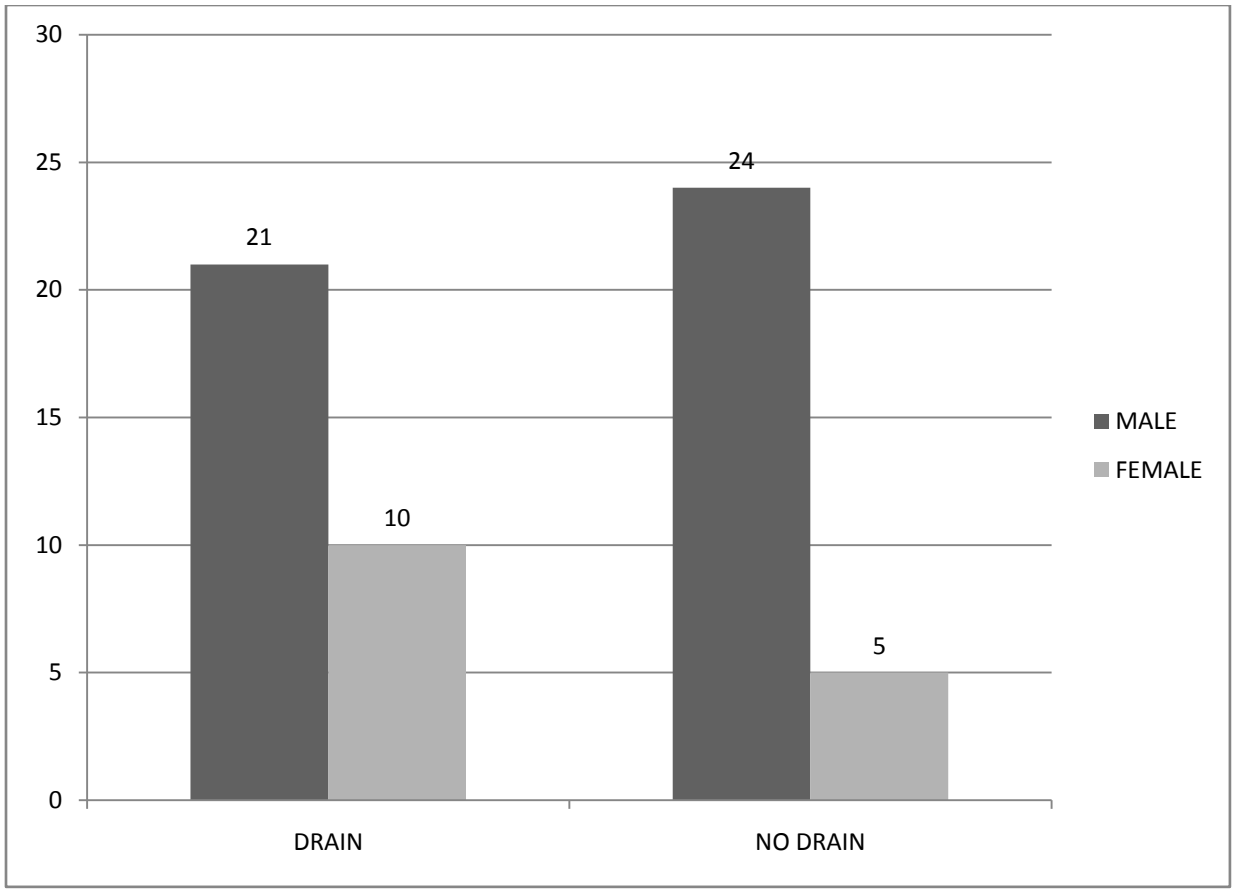


Fig. 1 showing sex distribution

SEX DISTRIBUTION AMONG THE TWO ARMS:

In the intervention (drain) group 21 patients were males and 10 patients were females.

In the no intervention (no drain) group, 24 were males and 5 were females.

		Drain		
		Drain	No Drain	Total
	Male	21	24	45
		67.7%	82.8%	75.0%
	Female	10	5	15
		32.3%	17.2%	25.0%
Total		31	29	60

Table 1 showing sex demography between the two allocation groups

AGE DISTRIBUTION:

The incidence of rectal cancer was seen mostly in the middle age group (40-60 years) and the incidence was greater among males. (Fig. 2)

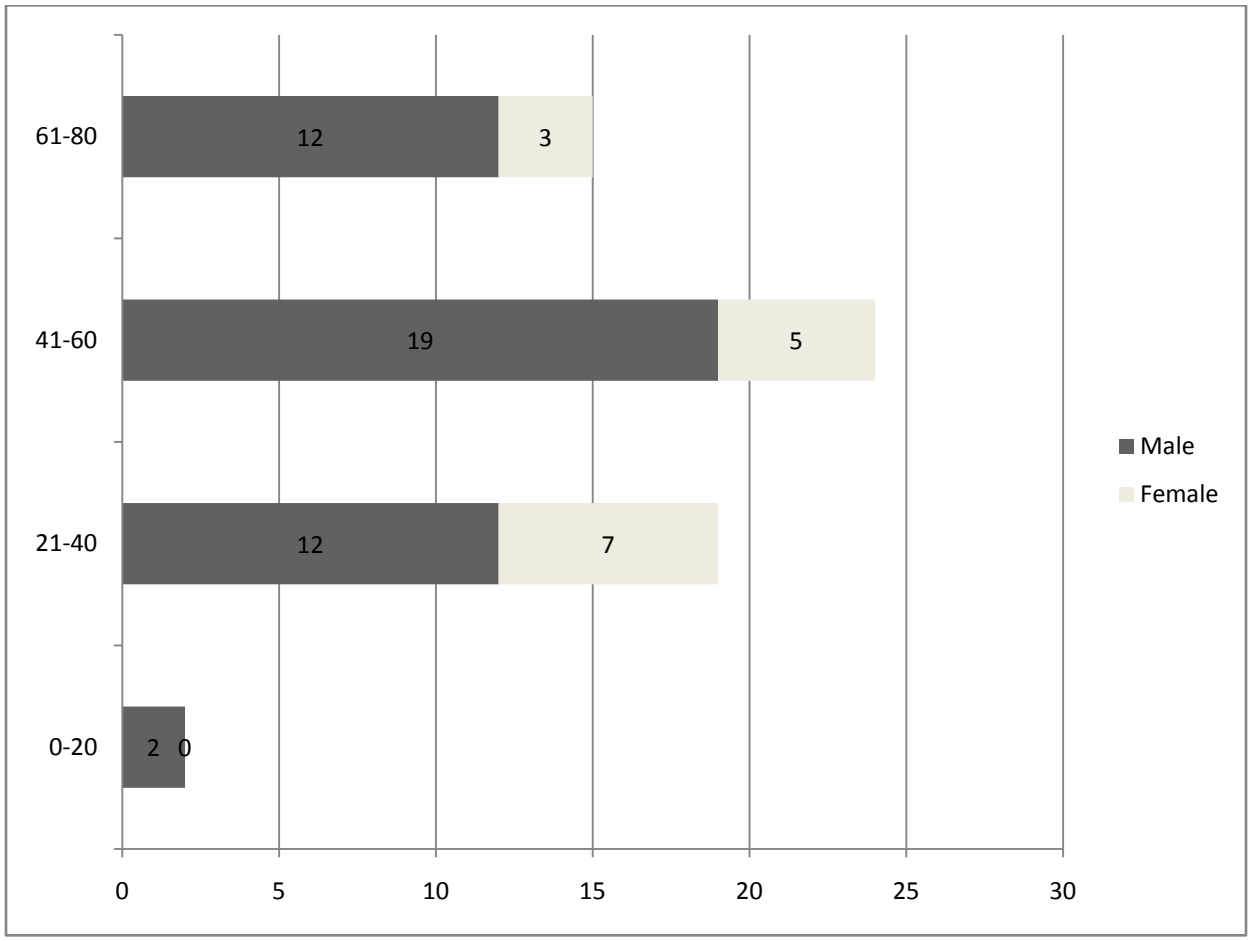


Fig. 2 showing the age distribution of rectal cancer among males and females.

AGE DISTRIBUTION:

The mean age among the two arms was comparable.

	N	Mean	Std. Deviation	Std. Error Mean
Drain	31	47.06	15.266	2.742
No Drain	29	48.59	15.587	2.894

Table 2 shows the mean ages in the two arms along with the standard deviation

DISTRIBUTION AMONG TWO ARMS ACCORDING TO DIAGNOSIS:

Most patients were diagnosed with Carcinoma Rectum or Carcinoma rectosigmoid. Other diagnoses that were included were Familial Adenomatous Polyposis (FAP), Carcinoma anal canal and Tubulovillous adenoma (TVA).

		Drain	No Drain	Total
	Carcinoma Recto Sigmoid	29	28	57
		93.5%	96.6%	95.0%
	FAP	1	0	1
		3.2%	.0%	1.7%
	Carcinoma Anal Canal	0	1	1
		.0%	3.4%	1.7%
	TVA	1	0	1
		3.2%	.0%	1.7%
Total		31	29	60

Table 3 showing distribution of patients between the two arms according to diagnosis

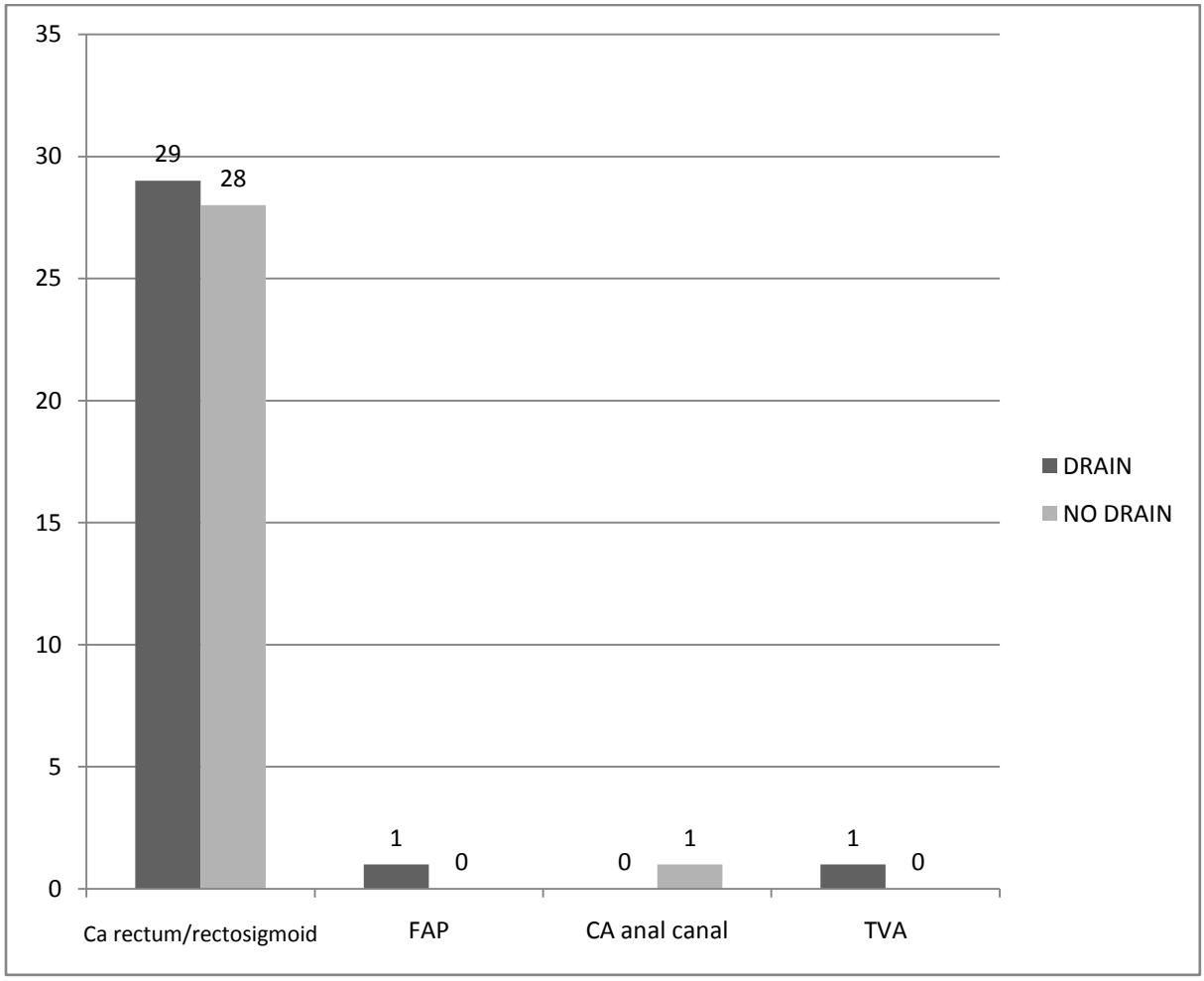


Fig. 3 showing distribution among the two arms according to diagnosis

DISTRIBUTION BETWEEN TWO ARMS ACCORDING TO TYPE OF SURGERY:

There was equal distribution between the two arms among both the surgeries performed, Abdominal perineal excision (APE) and anterior resection (AR).

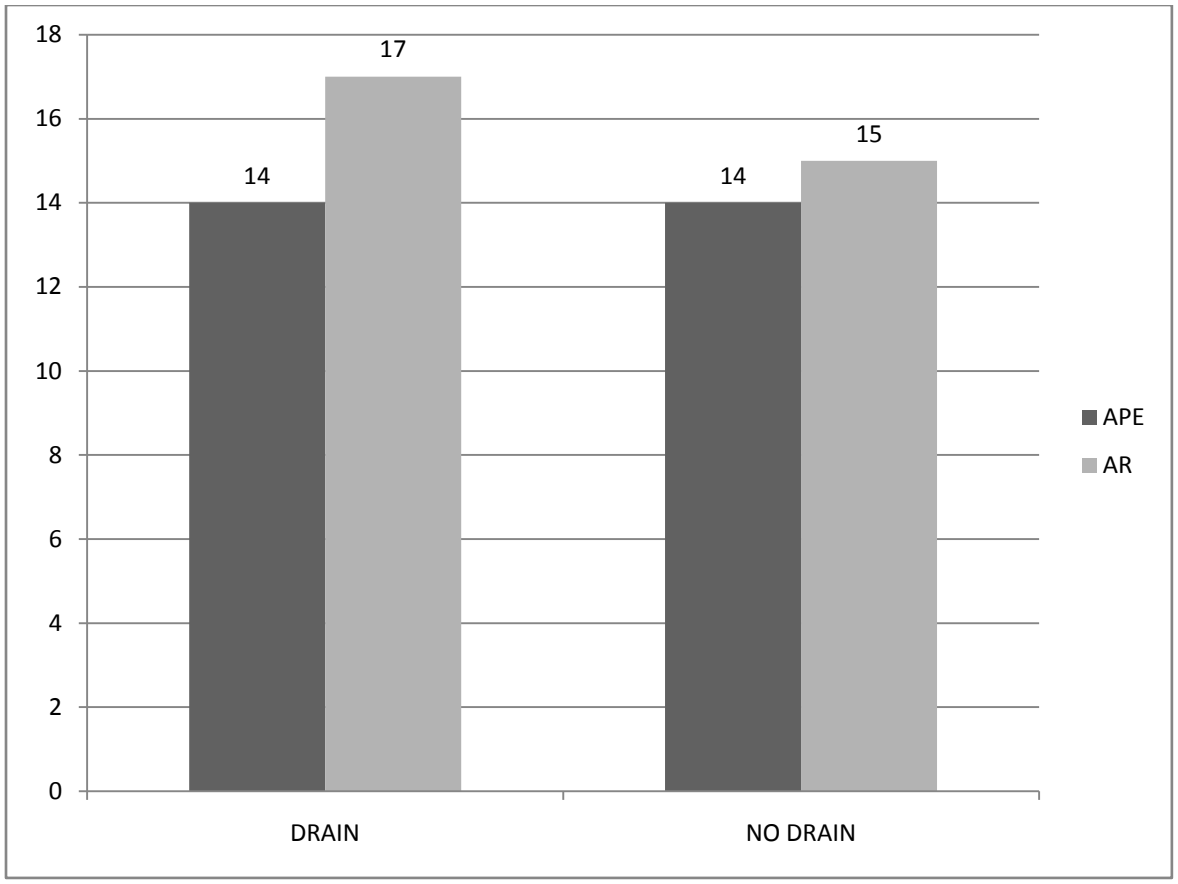


Fig. 4 showing distribution of surgeries among the two arms.

APE (Abdominal perineal excision, AR (Anterior resection)

	DRAIN	NO DRAIN
APE	14	14
AR	17	15

Table 4 showing distribution of operations between the two arms

OUTCOME ANALYSIS

PRIMARY OUTCOME (ANALYSIS OF POSTOPERATIVE PELVIC COLLECTION BETWEEN THE TWO ARMS):

There was a trend towards lesser occurrence of pelvic collection in the group with no pelvic drainage (17.2% versus 29%)

			Pelvic	
		No Collection	Collection	Total
	Drain	22	9	31
		71.0%	29.0%	100.0%
	No Drain	24	5	29
		82.8%	17.2%	100.0%
Total		46	14	60
		76.7%	23.3%	100.0%

Table 5, showing the extent of pelvic collection between the two arms.

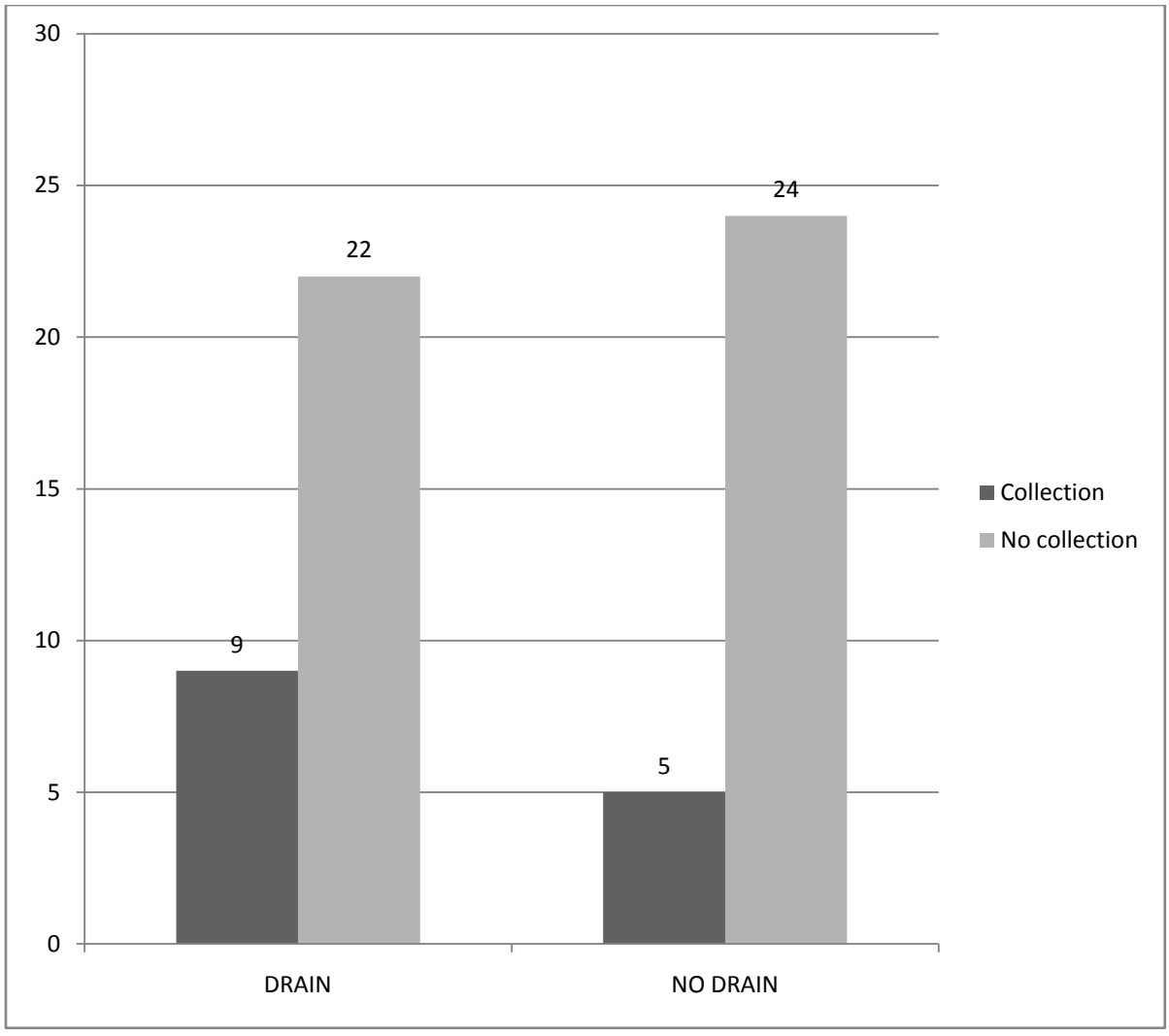


Fig.5 showing the distribution of pelvic collection between the two arms

MORBIDITY ASSESSMENT:

INCIDENCE OF PELVIC COLLECTION ACCORDING TO THE TYPE OF OPERATION:

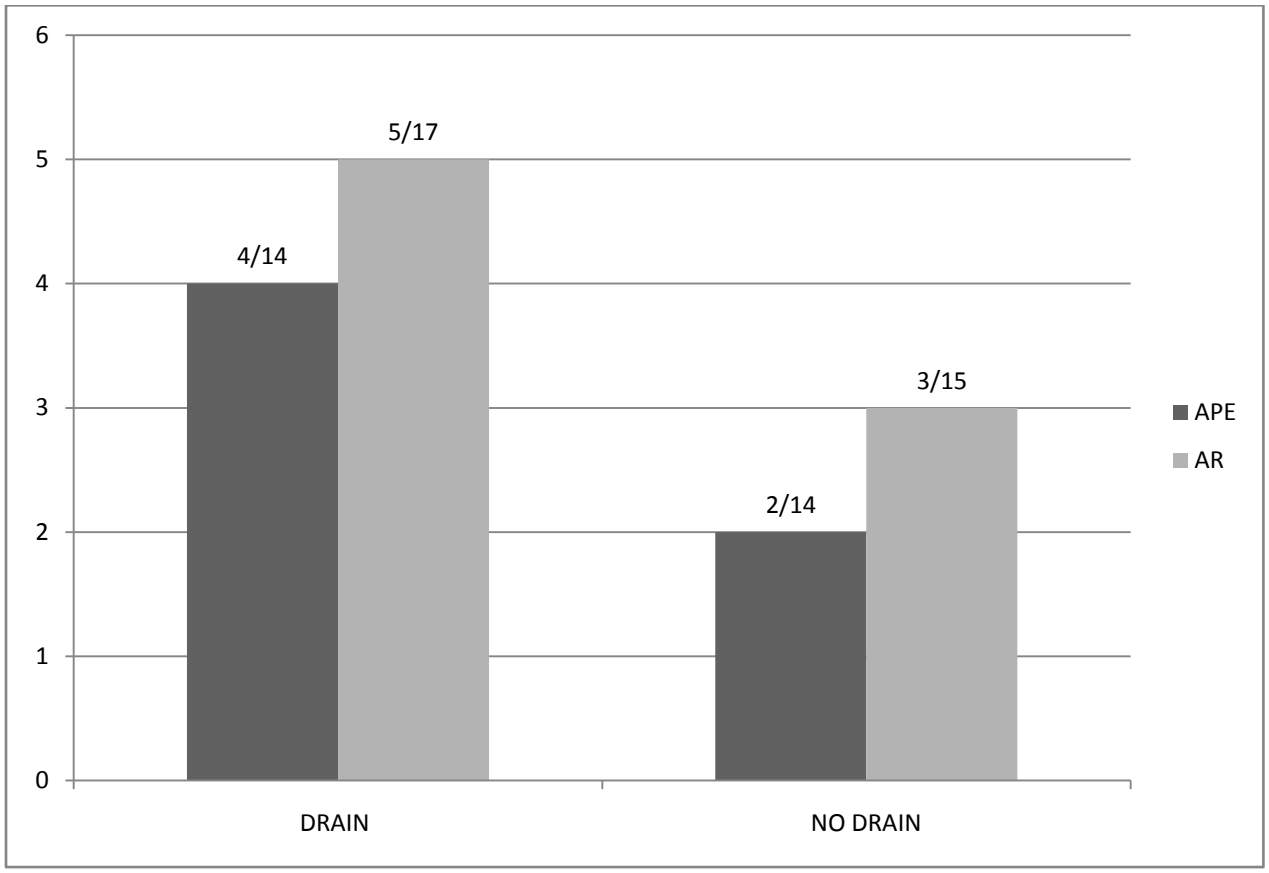


Fig. 6 showing the number of pelvic collection among the two arms according to type of surgery

EFFECT OF NEOADJUVANT CHEMOTHERAPY ON THE INCIDENCE OF PELVIC COLLECTION:

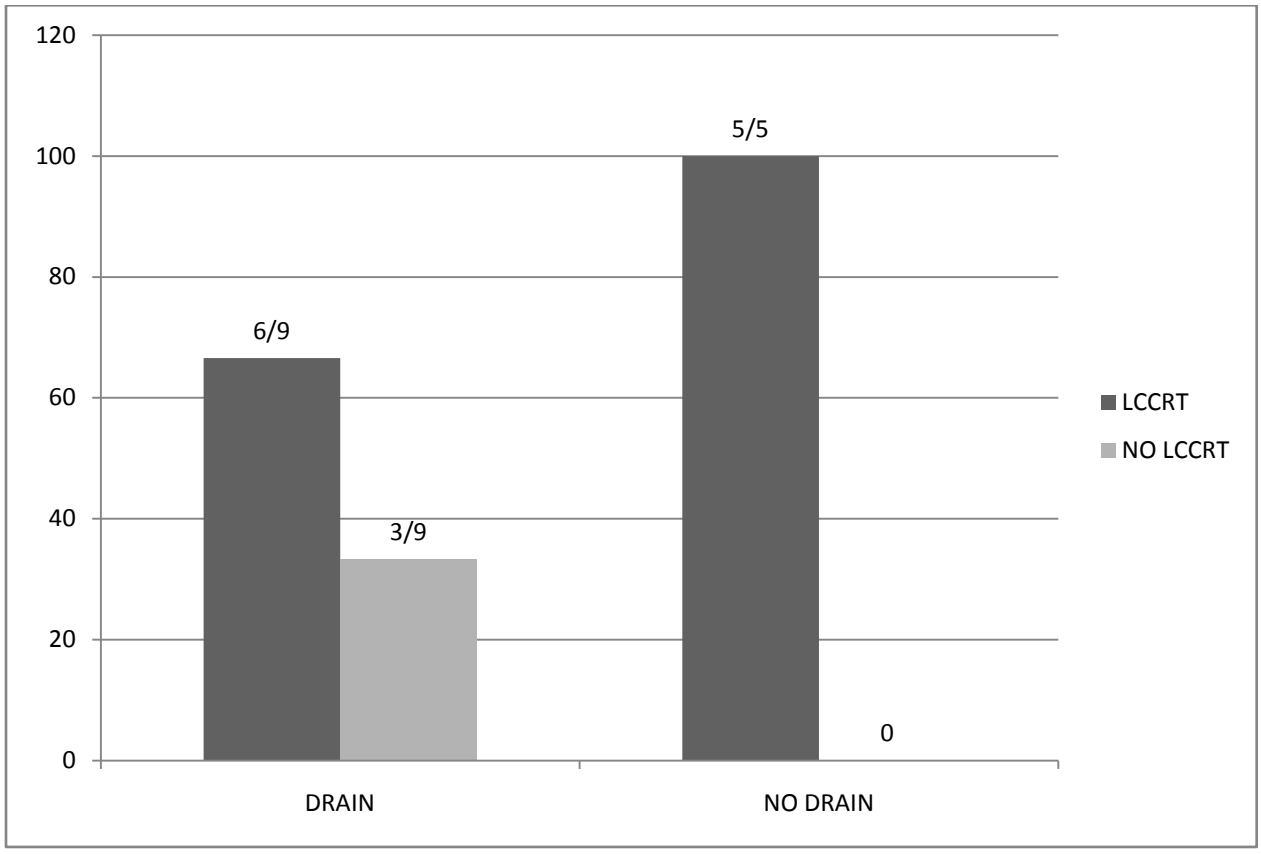


Fig. 7 showing the percentages of pelvic collection in the two arms and the reception of long course chemoradiation

TYPE OF INTERVENTION:

	DRAIN	NO DRAIN
No intervention	4	2
Surgical	2	3
Radiological	3	0

Table 6 showing the type of intervention among the two arms

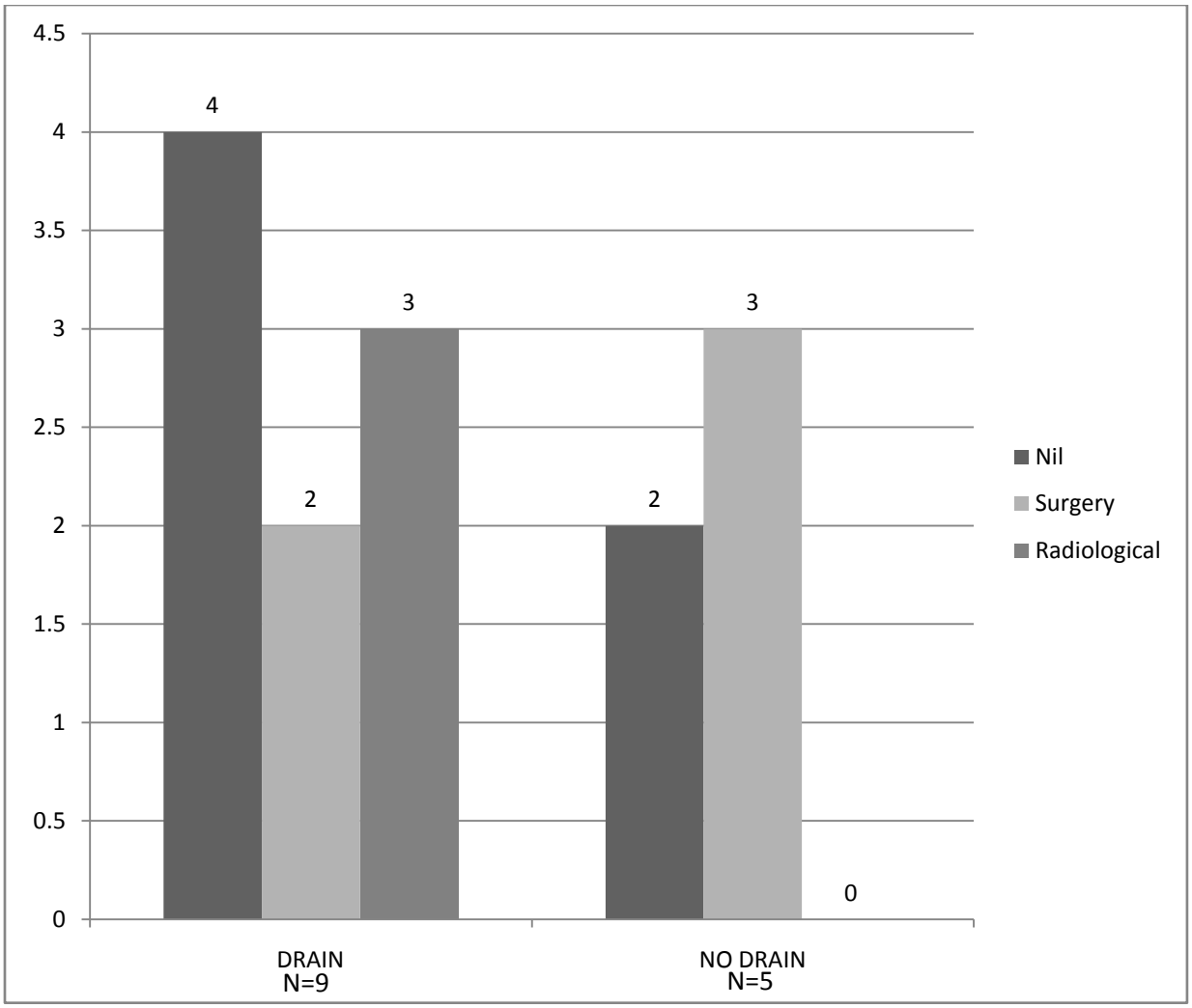


Fig. 8 showing the types of intervention in both the arms

ANASTOMOTIC LEAK RATES (Anterior resections):

The number of anastomotic leaks in the drain arm were 5 out of 17 and in the ‘no drain’ arm were 3 out of 15.

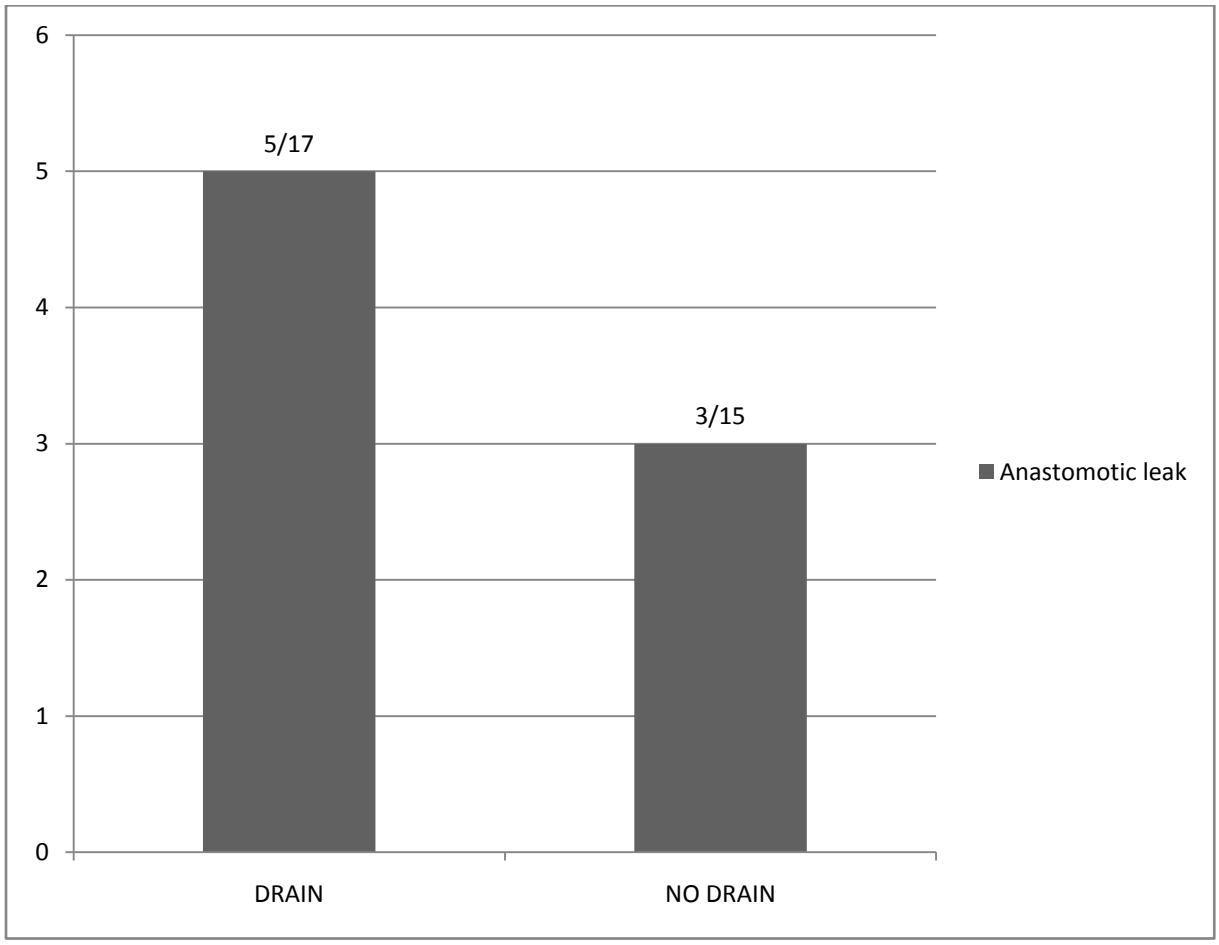


Fig.9 showing the number of anastomotic leaks among the two arms

	DRAIN	NO DRAIN
Anastomotic leak	5(29.4%)	3(20%)

Table 7 showing the percentage of anastomotic leaks among the two arms

POST OPERATIVE STAY:

Post operative stay was higher among patients in the ‘drain’ arm.

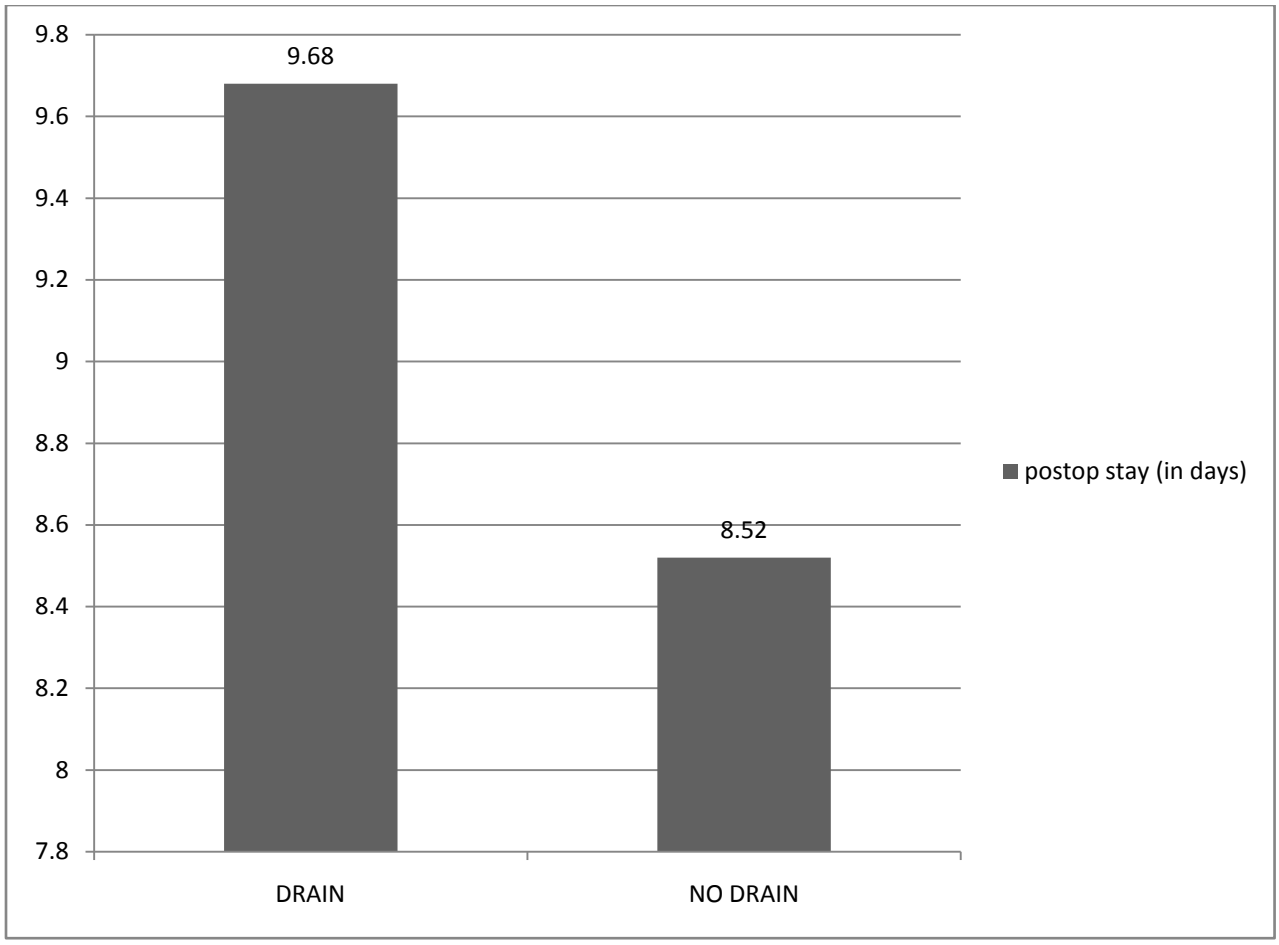


Fig.9 showing the post operative stay in days among the two arms

OUTCOME	DRAIN N = 31	NO DRAIN N = 29	P VALUE	MEAN
COLLECTION	9 (29%)	5 (17.2%)	0.281	11.8
POSTOPERATIVE STAY	9.68	8.52	0.476	1.160

Table 7 showing both measurable outcomes with P values and mean differences in the two arms

The mean post operative stay in days was higher in the ‘drain’ arm.

		N	Mean	Std. Deviation	Std. Error Mean
Postop stay	Drain	31	9.68	6.508	1.169
	No Drain	29	8.52	5.980	1.110

Table 8 showing the mean post operative stay in days between the two arms

SUMMARY OF OUTCOMES:

	DRAIN (N=31)	NO DRAIN(N=29)	P VALUE
COLLECTION	9	5	0.281
ANASTOMOTIC LEAK	5/17*	3/15*	0.588
INTERVENTION REQUIRED	5	3	0.856
RADIOLOGICAL	3	0	-
SURGICAL	2	3	0.103
DURATION OF STAY	9.68	8.52	0.456

Table 9 showing the summary of outcomes with p values

*Anterior resection only

RESULTS

A total of 70 patients were enrolled into the trial, out of which 60 patients were randomised based on the inclusion criteria. 31 patients were allocated to the intervention (drain) arm and 29 patients were allocated to the no intervention arm (no drain).

Out of the 60 patients, 45 were males which is consistent with international figures but more in favour of male sex (3:1 versus 1.06:1) The mean age overall was 47 years. Prevalence among men was highest in the 41-60 age group and among women, prevalence was highest in the 21-40 age group. In the intervention (drain) group 21 patients were males and 10 patients were females. In the no intervention (no drain) group, 24 were males and 5 were females (Table 1).

The two operations that were performed were abdominal perineal excision and anterior resection. The latter involved the performance of an anastomosis in the

pelvis. These operations were equally distributed among both the intervention arms (Fig.4)

There was a trend towards fewer pelvic collection in the group with no pelvic drainage (17.2% versus 29%) (Fig.5 and Table 5).

In the assessment of post operative morbidity (Fig.6), there was no significant difference in the incidence of pelvic collections according to the type of operation (abdominal perineal excision or anterior resection).

According to Fig.6 the percentage of pelvic collections were higher in patients who underwent anterior resection in the ‘no drain’ arm and lesser in patients who underwent anterior resection in the ‘drain’ arm.

In Fig.7, it was found that all the patients who had a pelvic collection in the ‘no drain’ arm underwent neoadjuvant therapy in the form of long course chemoradiation. One third of the patients in the ‘drain’ arm who had pelvic collection did not undergo any form of neoadjuvant therapy.

The method of intervention in the patients who had pelvic collections was mostly conservative in case of small collections and operative, if there was clinical deterioration of the patients' condition. Three patients were managed with radiological drainage of the collection (Fig.8). However, operative intervention was higher in the 'no drain' group (Fig.9) (p value 0.15, 95%CI -0.9 – 0.14).

The mean post operative stay in days was higher in the 'drain' arm. The difference between both the arms was 1.16 days (Table 9).

DISCUSSION

Rectal surgery is associated with greater morbidity and mortality as compared to surgical procedures on other parts of the gastro intestinal tract. The risk for any surgical intervention can be assessed at four levels – the patient, the procedure, the provider and the anesthetic. In colorectal surgery the procedure by definition carries a high morbidity. Therefore most of the fast track recovery protocols are centered around the patient. Assessment of the risk preoperatively and optimization certainly decreases patient morbidity and mortality for an elective operation (34).

Enhanced recovery after surgery (ERAS) or fast track pathways are multimodal approaches practiced in the perioperative period in patients undergoing colorectal surgery. They are designed to improve the overall quality of care and reduce morbidity. The typical components of the enhanced recovery pathways include

appropriate patient selection, avoidance of bowel preparation unless indicated, pain management with multimodal approach including epidural catheter, using laparoscopic approach when possible, avoidance of excess fluid infusion, early initiation of diet, ambulation and adherence to SCIP (surgical care improvement project) protocols.

However, anastomotic drainage has been a long standing controversy. Routine drainage is not a component of the ERAS pathways. Meta-analysis of trials have been unsuccessful in showing benefit of routine drainage. It has been recommended that drain placement should however not interfere with a standard fast track protocol if clinically indicated (35).

In the present trial, out of the 60 patients recruited, incidence of rectal cancer was found to be higher in males by three times which is much higher compared to the international figures.

The mean age of occurrence was found to be 47 years which is much lower than the SEER(Surveillance Epidemiology and End Results) data from the United States where the mean age was found to be 69 years. This is consistent with other Indian data which has shown increased incidence of rectal cancer among young males (2).

The two main operations that were performed for rectal cancer were abdominal perineal excision and anterior resection depending on the situation of the tumour and the possibility of obtaining free margins without sacrificing the sphincter. Greater morbidity is expected with an anterior resection as it involves the performance of an anastomosis in the pelvis. The vascularity of the anastomosis is further jeopardised due to the preoperative radiation therapy.

The incidence of pelvic collection was found to be higher in the ‘drain’ arm (20% vs 17%), although this difference was not statistically significant. This finding has also been complemented with longer hospital stays associated with the drain group.

There were no significant results obtained from the morbidity assessment but all the measurements were pointing towards greater morbidity associated with routine pelvic drainage. Moreover, the incidence of pelvic collections did not depend much upon the type of operation. This meant that performance of an anastomosis in the pelvic (anterior resection) in the absence of confounding factors, did not increase the incidence of a pelvic collection. However, it would be too early to arrive at such a conclusion without adequate sample size.

Most patients received neoadjuvant therapy in the form of long course chemoradiation. This involved radiotherapy with 50.4Gy in 28 fractions and chemotherapy with 5-Fluorouracil or Capecitabine with or without oxaliplatin and

leucovorin rescue. This certainly had an impact on the post operative outcome. All patients with a pelvic collection in the ‘no drain’ arm received some form of neoadjuvant therapy which showed that it was a significant contributing factor in determining the post operative outcome. Interestingly, in the ‘drain’ arm, three patients (33.3%) who did not have any form of neoadjuvant therapy, had a post operative pelvic collection. This suggested that in the presence of a pelvic drain there was greater chance of developing a post operative pelvic collection irrespective of undergoing chemoradiation.

Out of the 14 patients who had a pelvic collection, 5 underwent re-exploration in the form of a laparotomy and wash out of the collection. 6 patients were managed conservatively and 3 patients underwent radiological drainage of the abscess. Therefore, in hemodynamically stable patients, not showing features of systemic inflammatory response, it is prudent to proceed with a non-operative line of management.

Out of all the study patients, there was only one patient who was readmitted with urinary tract infection within 30 days of the operation. Due to the lack of substantiality, this data was not analysed.

Certain patients in both the arms required definitive drainage inspite of being randomised to the ‘no drain’ arm due to intraoperative course that warrante drainage. These patients were included in the study as they were randomised with an intention to treat.

CONCLUSIONS

The aim of conducting this study was to establish a definitive association between the routine use of closed tube drainage of the pelvis in patients undergoing resection for rectal cancer. The paucity of data in this area and the equivocal results of existing studies further warranted the need for this study.

Although the study was not carried on till the complete sample size was reached, the results were all consistent and showed trends in the same direction. However, statistically significant conclusions cannot be drawn from the analysis of the results. The duration of the study and the time constraint is one of the major

limitation of this study. Apart from this, sensitivity of a pelvic ultrasonogram, observer bias and the inability to perform blinding are the other limitations.

The increased incidence of rectal cancer among younger males has stood out in this study which is in contrast with studies from the western population.

The use of pelvic drainage has not shown to drastically contribute towards reducing post operative morbidity in terms of decreased pelvic collections or reduced hospital stays. Infact, the absence of a pelvic drain has shown a trend towards reduced incidence of pelvic collection and reduced hospital stay. However, these results are not statistically significant.

The other factor that contributed to the outcome of these patients was neoadjuvant therapy in the form of long course chemoradiation.

The lack of unequivocal evidence in the benefit of routine pelvic drainage has shown that it is a questionable intervention.

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CONSENT FORM

Informed consent form to participate in the study:

Study Title: Randomised trial of assessing morbidity in patients undergoing surgery for rectal cancer.

Subject Initials: Subject name:

Date of birth/Age:

1. I confirm that I have read and understood the patient information sheet dated _____ for the above study and have had the opportunity to ask questions [ ]

2. I understand that my participation in the study is voluntary and that I am free to withdraw at anytime , with out giving any reason, with out my medical care or legal rights being affected [ ]

3. I understand that the sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and

any further research that may conducted in relation to it, even if I withdraw from the trial, I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

5. I agree to take part in the above study. [ ]

Signature (or thumb impression) of the subject/ legally acceptable representative:

date:

Signatory's name:

Signature of the investigator:

Date:

Study investigator's name:

Signature of the witness:

Date:

Name of the witness:

PROFORMA:

S.No	Name	Age	Sex	Diagnosis	Surgery	Drain	Collection	Postop stay	Comp