

Comparison of Outcome between Ostomy Closure with Permanent Synthetic Mesh and Conventional Technique without Mesh to Prevent Incisional Hernia

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Abstract

Background: Stomal site incisional hernia is a common complication following ostomy closure. Prophylactic mesh reinforcement of the fascial defect is typically not considered due to the contaminated nature of the case. The effectiveness of prophylactic mesh placement at the time of stoma closure is unknown because of fear of mesh infection and subsequent wound complications. **Purpose:** To compare the results obtained by placing synthetic mesh in the stoma site during closure with conventional technique without mesh to prevent incisional. **Patients and Methods:** Prospective interventional study had been designed to compare the outcome of permanent synthetic mesh placement at the time of ostomy closure. Total 45 patients were selected purposively who were candidates for ostomy closure and presented at the Department of Colorectal Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU) from April 2019 to September 2020 and divided into two groups (no mesh and mesh). In the mesh group, permanent synthetic mesh (Prolene™ – Polypropylene) was placed. Primary outcome, incisional stomal hernia was assessed at regular follow-up for one year along with associated morbidities. **Results:** The primary outcome of this study i.e. incisional hernia (stomal site) was observed among 1 (4.8%) patients at 4th week, 3 (14.3%) at 3rd month, 7 (33.3%) at 6th month and 8 (38.1%) at 12th month follow-up in no mesh group. And, only 1 patient at 6th month and 12th month follow-up had hernia in the mesh group (Figure 3). There was no difference statistically between no mesh and mesh groups at 4th week and 3rd month but significant difference found at 6th and 12th month follow-up ($p=0.280$, $p=0.344$, $p=0.033$ and $p=0.017$, respectively). **Conclusion:** Prophylactic placement of permanent polypropylene mesh during ostomy closure placement significantly reduced the rate of incisional hernia without any additional morbidity. Placement of mesh was found to be both safe and effective.

Keywords: Outcome, Ostomy Closure, Permanent Synthetic Mesh.

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INTRODUCTION

The term “stoma” is derived from the Greek word meaning “mouth” or “opening” and is used to describe the creation of an artificial opening made into a hollow organ brought on the surface of the body. A stoma is also sometimes known as an ostomy [1]. Within colorectal surgery, stomas are most commonly formed as either an ileostomy or colostomy. They may

be permanent or temporary and may be formed from either the end of the bowel or the side of the bowel still in continuity (known as a loop stoma). Stomas are routinely created by surgeons to divert stool from distal pathology. Once the distal process has resolved, the intention is to reverse the stoma [2]. The most frequent temporary stoma is defunctioning ileostomy and its closure involves the complete freeing of the bowel from

all layers of the surrounding abdominal wall, followed by anastomosis of both proximal limb and distal limb of bowel to restore bowel continuity. Stoma closure can be associated with significant morbidity, including anastomotic leak, obstruction, wound dehiscence, wound infection and the development of an incisional hernia [3-5]. Incisional hernias are defined as “abdominal wall defects, with or without a bulge, around post-operative scars, perceptible or palpable by clinical examination or imaging” according to the European Society [6]. Combining clinical and imaging (CT or MRI) assessment to identify incisional hernias provided a higher rate than clinical or radiological detection alone [7].

Development of a hernia at the site of previous colostomy or ileostomy is an underappreciated, delayed morbidity associated with enterostomy reversal [8]. The incidence of ostomy site incisional hernias after stoma closure has been studied, yet the rates are wide ranging 0 to 50 percent due to small sample size and inconsistent follow-up [9]. Up to 50% of patients who develop a hernia are subsequently submitted to complex re-operation with significant morbidity [10]. Preventing hernia formation should benefit long term patient outcomes and reduce the cost from the need for further follow up and possible re-operation. This long-term benefit will only be realized if the mesh can be safely implanted, without a significant increase in short term procedure complications and wound healing [11].

Synthetic mesh reinforcement is an established treatment for primary and recurrent hernias, and has been advocated for selected use in clean wounds to prevent herniation. However superficial healing problems at stoma sites include a high risk of infection and wound breakdown, due to contamination from the previously open bowel lumen. Concern therefore exists about infection risk and consequent mesh related complications in the early postoperative period have precluded their widespread use in contaminated wounds such as closure of a stoma site [12]. In this situation, a biologic mesh may carry a less risk of infection [13]. Biologic mesh is fully incorporated into host tissue, reducing the subsequent infection risk, [14] whilst still providing structural reinforcement during high-risk abdominal wall closure, particularly during the healing phase [15].

There are several risk factors for postoperative hernia, such as obesity, diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD) and surgical site

infection (van Ramshorst *et al.*, 2010), correction of the comorbid condition along with, proper operative technique might be the cornerstone of preventing hernia formation after stoma reversal [16]. On the other hand, because of lack of sufficient treatment options, surgeons started focusing prevention of the hernia with local reinforcement of the abdominal wall using a prosthetic mesh [17]. Although safety concerns persist regarding the use of prosthetics in a contaminated surgical field [18]. In addition, the presence of a midline hernia might have necessitated the use of mesh reinforcement in the midline as well [18]. The aim of the study was to evaluate the outcome between ostomy closure with permanent synthetic mesh on stoma site during closure and conventional technique without mesh to prevent incisional hernia

METHODOLOGY

The study was a Prospective interventional study which was conducted in Department of Colorectal Surgery Bangabandhu Sheikh Mujib Medical University from April, 2019- September, 2020. Patients aged 18 or over undergoing elective surgery to close a stoma (ileostomy or colostomy; loop or end) were eligible. The stoma may have been constructed by open or laparoscopic technique. Trepine, midline or laparoscopic approaches to the planned stoma closure were all eligible. The exclusion criteris includes large parastomal hernias definitely need mesh repair, Patients took part in another clinical study related to the surgical procedure, Allergic to prolene mesh , history of familial adenomatous polyposis (due to increased risk of cutaneous desmoid tumors) and unable or unwilling to provide written informed consent. Maintaining all formalities face to face interview was taken by using pre-tested questionnaire with Purposive sampling type of sampling technique. Total 25 patients were enrolled in this study. The detail of the study was explained to each eligible respondent and consent was taken. After collection, the data were checked and cleaned, followed by editing, compiling, coding and categorizing according to the objectives and variable to detect errors and to maintain consistency, relevancy and quality control. Collected data were edited and analyzed according to the objectives and variables by IBM software- Statistical package for Social Science (SPSS 24) version. Ethical clearance was taken from the IRB of the institution. The aim of the study was to assess outcomes of incisional surgical site infection without mesh to prevent incisional hernia. The mean duration of surgery was 78.88±15.

RESULTS

Table I: Distribution of patients by their baseline characteristics (N=45)

	No Mesh (n=24)		Mesh (n=21)		p*-value
	n	%	n	%	
Age (years)					
< 40	0	0	3	14.3	
40 - 60	15	62.5	12	57.1	
> 60	9	37.5	6	28.6	
Mean±SD	55.83±8.42		53.29±9.81		0.354 ^{ns}
Gender					
Male	17	70.8	14	66.7	0.763 ^{ns}
Female	7	29.2	7	33.3	
Occupation					
Service Holder	3	12.5	2	9.5	0.976 ^{ns}
Businessman	3	12.5	4	19.0	
Students	2	8.3	2	9.5	
Housewives	7	29.2	6	28.6	
Others	9	37.5	7	33.3	
Body Mass Index (BMI)					
Underweight (< 18.5)	4	16.7	2	9.5	
Normal Weight (18.5-25)	6	25.0	4	19.0	
Overweight (25-30)	6	25.0	7	33.3	
Obese (> 30)	8	33.3	8	38.1	
Mean±SD	25.13±5.49		26.98±4.46		0.227 ^{ns}
Smoking Habit					
Current Smoker	3	12.5	4	19.0	0.384 ^{ns}
Former Smoker	9	37.5	4	19.0	
Non-Smoker	12	50.0	13	61.9	
Comorbidities					
Diabetes Mellitus	2/24	8.3	1/21	4.8	0.472 ^{ns}
COPD	1/24	4.1	1/21	4.8	0.923 ^{ns}
Hypertension	3/24	12.5	2/21	9.5	0.526 ^{ns}

ns= non-significant. *p-value reached by Student *t*-test and was considered significant when $p < 0.05$.

Table I shows the mean age of no mesh group was 55.83±8.42 years while the mesh group was 53.29±9.81 years and the difference between both groups was statistically not significant ($p=0.354$). Majority of the patients from both groups were aged between 40 – 60 years (62.5% and 57.1%). The data were a majority of male patients in both, no mesh (70.8%) and mesh (66.7%), groups. Distribution of patients by their gender among both groups were statistically not significant ($p=0.763$). Distribution of patients by their occupation among no mesh and mesh group was statistically insignificant ($p=0.976$). The distribution of patients among assigned groups (no mesh and mesh) by their BMI is shown in the Table I. The mean BMI of no mesh group was 25.13±5.49 while the mesh group was 26.98±4.46 and the difference between them was not statistically significant ($p=0.227$). Smoking habits of the patients from both

groups are outlined in Table I. Majority of the patients from both groups were non-smoker (50.0% vs 61.9%). Three (12.5%) in no mesh group and 4 (19.0%) in mesh group were current smokers while 9 (37.5%) and 4 (19.0%) were former smokers in mesh and no mesh group, respectively. The distribution of patients among these groups by their smoking habit was statistically not significant ($p=0.384$). Two (8.3%) patients from no mesh group and 1 (4.8%) patients from mesh group were diabetic and no statistically difference noted ($p=0.472$). One (4.1%) in no mesh and also 1 (4.8%) in mesh group patients had COPD and the difference was statistically insignificant ($p=0.923$). Similarly, hypertension was observed among 3 (12.5%) and 2 (9.5%) patients in no mesh and mesh groups, respectively, which was statistically insignificant ($p=0.526$).

Table II: Distribution of Clinical Characteristics

	No Mesh (n=24)		Mesh (n=21)		p*-value
	n	%	n	%	
Ostomy					
Ileostomy	19	79.2	15	71.4	0.547 ^{ns}
Colostomy	5	20.8	6	28.6	
Hernias					
Parastomal Hernia	4/24	16.7	3/21	14.3	0.807 ^{ns}
Midline Incisional Hernia	2/24	8.3	1/21	4.8	0.632 ^{ns}
Duration of Surgery					
Mean±SD	79.88±15.03		106.05±17.40		<0.001 ^s
Duration of Hospital Stay					
3 Days	5	20.8	2	9.5	
4 Days	4	16.7	7	33.3	
5 Days	3	12.5	5	23.8	
6 Days	9	37.5	5	23.8	
7 Days	3	12.5	2	9.5	
Mean±SD	5.04±1.39		4.90±1.17		0.726^{ns}

ns= non-significant. *p-value reached by Pearson Chi-Square test and was considered significant when $p < 0.05$.

The distribution of patients by their type of ostomy. Nineteen (79.2%) and 15 (71.4%) patients in no mesh and mesh group, respectively had ileostomy while 5 (20.8%) and 6 (28.6%) patients, respectively had colostomy. Statistically there was no difference among group distribution by ostomy type ($p=0.547$). Presence of hernias – parastomal and midline incisional hernia before ostomy closure are reflected in the Table II. Both patients with parastomal and midline incisional hernias were distributed among both groups without statistically significant difference ($p=0.807$ and

$p=0.632$, respectively). The comparison of duration of surgery among no mesh and mesh groups. The mean duration of surgery of no mesh group (79.88±15.03min) was much less than mesh group (106.05±17.40min) which was statistically highly significant ($p < 0.001$). The mean length of hospital stay of no mesh group was 5.04±1.39 and mesh group was 4.90±1.17. No significant difference was found statistically ($p=0.726$) (Table II). Distribution of patients among both groups according to their number of post-operative days stay at hospital highlighted in above table.

Table III: Comparison of pain among both groups (N=45)

Post-operative pain (VAS)	No Mesh (n=24)		Mesh (n=21)		p-value
	n	%	n	%	
7th POD					
Mild	20	83.3	14	66.7	0.194 ^{*ns}
Moderate	4	16.7	7	33.3	
Severe	0	0	0	0	
VAS, Mean±SD	2.75±1.59		3.29±2.05		0.331 ^{#ns}
3rd month					
No	24	100	21	100	
Yes	0	0	0	0	

Table III shows pain was present at 7th POD (Post-operative days) but not during 3rd months of follow-up. Mild pain was present in 20 (83.3%) and 14 (66.7%) patients in no mesh and mesh group respectively while moderate pain was present in the rest

of the patients. Difference in the distribution by pain among both groups was statistically insignificant ($p=0.194$). The mean of VAS score of no mesh group was 2.75±1.59 and 3.29±2.05 of mesh group, which was statistically not significant ($p=0.331$).

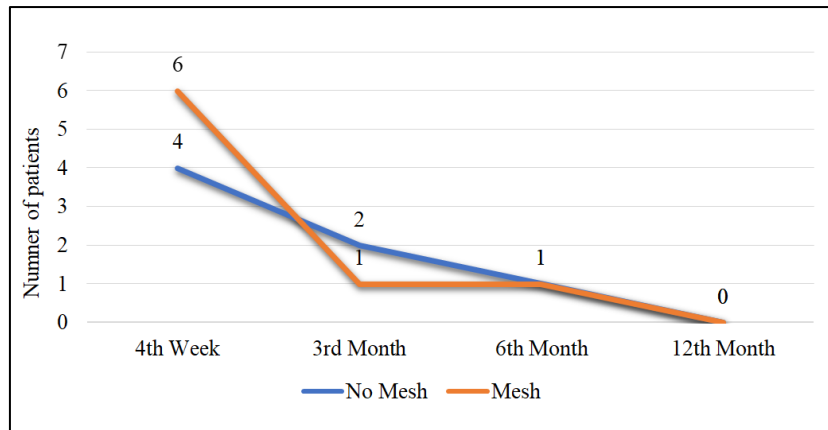


Figure 1: Comparison of SSO after ostomy closure at follow up among both groups (N=45)

Figure above shows 4 (16.7%) patients at 4th week, 2 (8.3%) at 3rd month, 1 (4.2%) at 6th month and none at 12th month follow-up had SSO in no mesh group. And, 6 (28.6%) patients at 4th week, 1 (4.8%) at 3rd month, 1 (4.8%) at 6th month and none at 12th month

of follow-up had SSO in the mesh group. There was no difference statistically between no mesh and mesh groups at any point of follow-up ($p=0.338$, $p=0.632$, $p=0.923$, respectively).

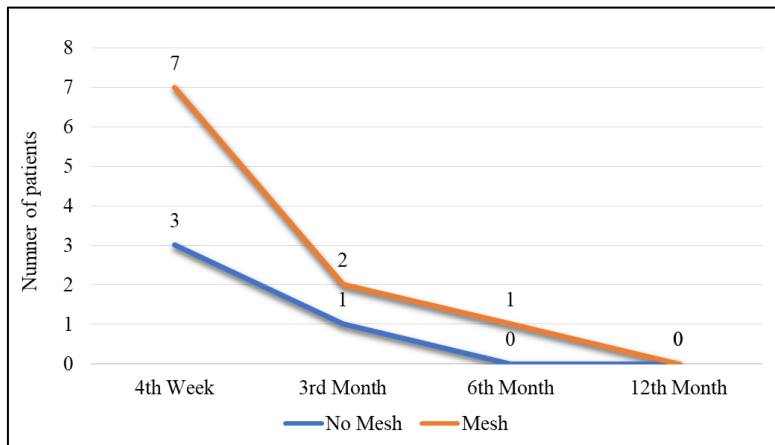


Figure 2: Comparison of infection after ostomy closure at follow up among both groups (N=45)

Figure above shows 3 patients at 4th week and 1 patient at 3rd month had infection in no mesh group. And, 7 patients at 4th week, 2 at 3rd month and 1 patient at 6th month had infection in the mesh group. There was

no difference statistically between no mesh and mesh groups ($p=0.094$, $p=0.472$ and $p=0.280$ at 4th week, 3rd month and 6th month, respectively).

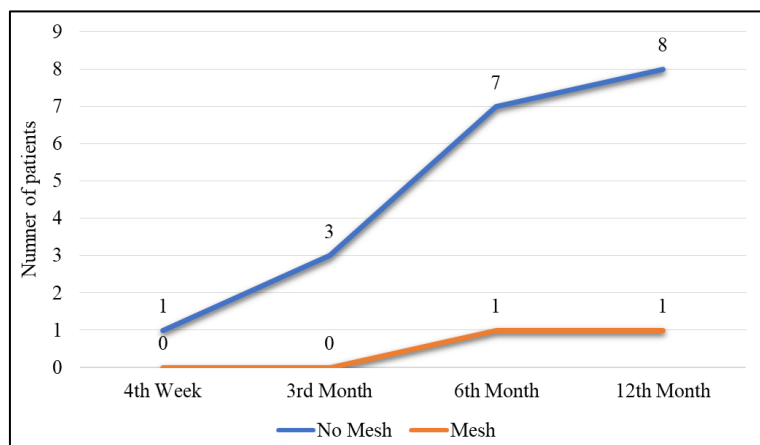


Figure 3: Comparison of hernia after stoma closure at follow up among both groups (N=45)

Figure above shows 1 (4.2%) patients at 4th week, 3 (12.5%) at 3rd month, 7 (29.1%) at 6th month and 8 (33.3%) at 12th month follow-up had stoma site incisional hernia in no mesh group. And, only 1(4.8%) patient at 6th and 12th month follow-up had hernia in the mesh group. There was no difference statistically between no mesh and mesh groups at 4th week and 3rd month but significant difference at 6th and 9th month follow-up ($p=0.344$, $p=0.094$, $p=0.033$ and $p=0.017$, respectively).

DISCUSSION

This prospective interventional study had been designed to compare the outcome of permanent synthetic mesh placement on the stoma site during closure with that of the cases which were closed without mesh. Total 45 patients were selected who were candidates for ostomy closure and presented at the Department of Colorectal Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU) from April 2019 to September 2020. Patients were divided into two groups (No mesh – control group, 24 patients and mesh – experimental group, 21 patients). Permission for the study was granted by the Institutional Review Board of BSMMU, prior to the commencement of study. In the experimental group (mesh group), permanent synthetic mesh (Prolene™ – Polypropylene) was placed.

Patients fulfilling the selection criteria of ages between 18 – 70 years and of both genders were included in this study. Sampling for study population was made by purposive sampling technique. Informed written consent was obtained from each patient prior to enrollment in this study. Data were collected from each patient (for one year after ostomy closure viz. at 4th week, 3rd month, 6th month and 12th month) in pre-designed data collection sheet. Data were compiled and presented in the form of table, graphs and charts.

In this study, the mean age of no mesh group was 55.83 ± 8.42 years while that of the mesh group was 53.29 ± 9.81 years and the difference between both groups was statistically not significant ($p=0.354$). A study found the mean age of no mesh group was 54.8 ± 15.7 years and of mesh group was 57.3 ± 11.3 years. In ROCSS (2020) study, the mean age of no mesh group was 59 ± 16 years and 58.4 ± 16 years [19].

In the following study, the mean BMI of no mesh group was 25.13 ± 5.49 while the mesh group was 26.98 ± 4.46 and the difference between them was not statistically significant ($p=0.227$) (Table I). BMI was classified as per WHO BMI index (<18.5 as under weight, 18.5 – 25 as normal, 25 – 30 as overweight and >30 as obese). In a study no mesh group BMI was 25 ± 4 while mesh group BMI was 26 ± 4 . Likewise, the study of Liu, Banham and Yellapu (2013) found BMI – 27.8 ± 5.3 and 25.6 ± 4.6 of no mesh and mesh group, respectively [20].

In this study, comorbidities, principally – diabetic mellitus (DM), chronic obstructive pulmonary disease (COPD) and Hypertension were evaluated. 2 (8.3%) patients from no mesh group and 1 (4.8%) patients from mesh group were diabetic and no statistically difference noted ($p=0.472$). 1 (4.1%) in no mesh and 1 (4.8%) in mesh group patients had COPD and the difference was statistically insignificant ($p=0.923$). Similarly, hypertension was observed among 3 (12.5%) and 2 (9.5%) patients in no mesh and mesh groups, respectively, which was statistically insignificant ($p=0.526$). Warren *et al.*, (2017), in their study 11.9% from no mesh group and 19% from mesh group ($p>0.05$) had DM. 46.7% and 52% were hypertensive from no mesh and mesh group, respectively ($p>0.05$). Maggiori *et al.*, (2015) found 13% and 20% from no mesh and mesh group, respectively, had DM ($p>0.05$). COPD was observed among 13% and 10% in no mesh and mesh group, respectively ($p>0.05$). These observations are consistent with the observation of this study.

In current study, smoking habits of the patients from both groups are outlined (Table I). Majority of the patients from both groups were non-smoker (50% vs 61.9%). Three (12.5%) in no mesh group and 4 (19.0%) in mesh group were current smokers while 9 (37.5%) and 4 (19.0%) were former smokers in mesh and no mesh group, respectively. The distribution of patients among these groups by their smoking habit was statistically not significant ($p=0.384$). Smoking status was evaluated only by Warren *et al.*, (2017) which was similar to this study. In their study, 27.2% and 25.27% from no mesh and mesh group were current smokers ($p>0.05$) while 16.8% and 13.19% were former smokers ($p>0.05$), respectively.

In this series, 19 (79.2%) and 15 (71.4%) patients in no mesh and mesh groups, respectively had ileostomy while 5 (20.8%) and 6 (28.6%) patients, respectively had colostomy. Statistically there was no difference among group distribution by ostomy type ($p=0.547$). In our study, patients with parastomal and midline incisional hernias were distributed among both groups without statistically significant difference ($p=0.807$ and $p=0.632$, respectively). ROCSS (2020) study stated 24% in no mesh and 28% in mesh group had parastomal hernia and 4% in no mesh and 6% in mesh group had midline incisional hernia. A study found similar results, consistent with our study [21].

In our series, surgeries were performed by three experienced surgeons in the field (colorectal surgeons). The mean duration of surgery of no mesh group (79.88 ± 15.03 min) was much less than mesh group (106.05 ± 17.40 min) which was statistically highly significant ($p<0.001$) (Table II). Warren *et al.*, (2017) found mean duration of surgery was 133.5 ± 87.5 min versus 255 ± 106 min in no mesh and mesh group,

respectively. ROCSS (2020) found the median duration of surgery was 70 min and 90 min in no mesh group and mesh group, respectively. Significant difference in duration of surgery was observed in both studies. The obvious reason for the significant difference was due to additional time required for the placement of mesh. In current study, the mean length of hospital stay of no mesh group was 5.04 ± 1.39 and mesh group was 4.90 ± 1.17 . No significant difference was found statistically ($p=0.726$). Similar results to current study were observed in some studies [20-22].

In this study, surgical site pain was present at 7th POD (Post-operative days) but not during 3rd months of follow-up. Mild pain was present in 20 (83.3%) and 14 (66.7%) patients in no mesh and mesh group respectively while moderate pain was present in the rest of the patients. Difference in the distribution by pain among both groups was statistically insignificant ($p=0.194$). The mean of VAS score of no mesh group was 2.75 ± 1.59 and 3.29 ± 2.05 of mesh group, which was statistically not significant ($p=0.331$).

In our series we found 4 (16.7%) patients at 4th week, 2 (8.3%) at 3rd month, 1 (4.2%) at 6th month and none at 12th month follow-up had SSO in no mesh group. And, 6 (28.6%) patients at 4th week, 1 (4.8%) at 3rd month, 1 (4.8%) at 6th month and none at 12th month of follow-up had SSO in the mesh group (Figure 1). There was no difference statistically between no mesh and mesh groups at any point of follow-up ($p=0.545$, $p=0.632$, $p=0.923$, respectively).

Again, in this series, 3 patients at 4th week and 1 patient at 3rd month had infection in no mesh group. And, 7 patients at 4th week, 2 at 3rd month and 1 patient at 6th month had infection in the mesh group. There was no difference statistically between no mesh and mesh groups ($p=0.094$, $p=0.472$ and $p=0.280$ at 4th week, 3rd month and 6th month, respectively). These results are consistent with the results of some studies [21, 23].

Finally, the primary outcome of this study i.e. stoma site incisional hernia was observed among 1 (4.2%) patients at 4th week, 3 (12.5%) at 3rd month, 7 (29.1%) at 6th month and 8 (33.3%) at 12th month follow-up had hernia in no mesh group. And, only 1 patient at 6th and 12th month follow-up had hernia in the mesh group. There was no difference statistically between no mesh and mesh groups at 4th week and 3rd month but significant difference at 6th and 12th month follow-up ($p=0.280$, $p=0.344$, $p=0.033$ and $p=0.017$, respectively). The result was similar with the primary outcome (stomal site incisional hernia) in some studies [21, 22].

Limitations of the Study

The limitations of the present study were i). This is not a randomized controlled trial (RCT). ii) Randomization was not performed during selection of

patients. iii) The study period was short and the sample size was also small. iv) Blinding of the study was not done, therefore, selection bias was present in the study. It was a single centered study.

CONCLUSION

This study was conducted in the Department of Colorectal Surgery, BSMMU for a period of one year. During this period, I observed and assessed the results in terms of operative efficacy and safety as well as functional outcome. From my experience, it can be concluded that Prophylactic placement of permanent polypropylene mesh on the stoma site during closure significantly reduced the rate of incisional hernia without any additional morbidity. Although operating time was significantly increased in case of mesh placement, the use of prophylactic mesh was found to be both safe and effective.

RECOMMENDATIONS

Based on the findings of the present study and their analysis, we strongly recommend for the placement of permanent polypropylene mesh on the stoma site during ostomy closure. Placement of polypropylene mesh can be safely implemented and prevent a substantial proportion of incisional hernias. Further studies as multicentric, population based for longer follow up period is recommended.

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