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Using Prophylactic Prolene Mesh to Reduce the Incidence of Incisional Hernia at the Site of Stoma Closure

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Abstract: Background: Incisional hernias at stoma sites are not an infrequent problem, occurring in up to 30% of cases and it also varied in a range of studies from 0-48%. **Objectives:** This is a prospective study to detect the feasibility of application of prolene mesh at the site of stoma closure in reducing the rate of post stomal incisional.
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1. Introduction

Abdominal wall hernias are common and are a significant cause of morbidity.

Stomas are commonly constructed following colorectal surgery to protect distal anastomosis or when sepsis prevents primary anastomosis. There is a risk of a wide range of morbidity following both stoma formation and stoma reversal ***(Chow et al., 2009).***

Incisional hernias at stoma sites are not an infrequent problem, occurring in up to 30% of cases and it also varied in a range of studies from 0-48% ***(Tilney et al., 2008).***

They occur over time and are generally under-reported, which may be due to the elderly nature of the population, the significant co-morbidities or early discharge from follow-up ***(Cingi et al., 2006).***

One in three patients may develop a hernia after stoma closure, and around half of hernias that are detected require repair. Risk of hernia is greater after colostomy closure than after ileostomy closure ***(Bhangu et al., 2012)***.

A meta-analysis published in 2012 investigated the incidence of incisional hernia following closure of stoma, The overall mean incisional hernia rate following stoma closures was 7.4%. The authors reported a lower risk of hernia following reversal of ileostomy when compared to respectively ***(Bhangu et al., 2012)***.

A further systematic review found a similar incidence for stoma site incisional hernias to be 8.3% (0–33.9%) ***(Nguyen et al., 2014).***

Two factors should be noted with regard to the incidence of stoma site hernia. Firstly, that the long-term risk is not known and secondly, that clinical examination alone is shown to have a lower detection rate of incisional hernia post stoma closure when compared to clinical imaging ***(Bhangu et al., 2012; Cingi et al., 2006).***

Therefore, studies focusing on only clinical examination may be underestimating the prevalence, as radiological detected herniae may become symptomatic over time and may be missed in studies with a short follow-up period.

Aim of The Work

This is a prospective study to detect the feasibility of application of prolene mesh at the site of stoma closure in reducing the rate of post stomal incisional.

2. Patients and Methods

- **Type of Study:** Prospective study.
- **Study Setting:** Patients undergoing closure of stoma will be closed with prolene mesh insertion at the site of closure and will be followed up for 6 months.
- **Study Period:** Jan 2019 to Aug 2019.
- **Study Population:** Patients undergoing closure of stoma who presented at Ain Shams University hospitals.

Inclusion Criteria:

- Patients with temporary stoma.
- Sex: both male and females are included.

Exclusion Criteria:

- Patients who had complications that were not related to the procedure of the mesh application e.g. anastomotic leaks or abdominal dehiscence, and also patients with pre-existing parastomal hernia.

- **Sampling Method:** The patients undergoing closure of stoma.
- **Sample Size:** 50 patients.

Ethical Considerations

- **Good clinical practice:**

The procedures set out in the study protocol, pertaining to the conduct, evaluation and documentation of this study, are designed to ensure that the investigators abide by the principles of good clinical practice.

- **Delegation of researcher responsibility:**

The researcher will ensure that all persons assisting with the trial are adequately informed about the protocol, any amendments to the protocol, the study treatments, and their trial-related duties and functions. The researcher will maintain a list of sub-investigators and other appropriately qualified person to whom he or she has delegated significant trial-related duties.

- **Patient information and informed consent:**

All patients will be consented by both oral and written consents and they will be informed about the procedure and the study.

- **Confidentiality:**

Only the participant number and participant initials will be recorded in the case record form and if the participant's name appears on any other document, it will be kept in privacy by the investigator. The investigator will maintain a personal participant identification list (patient numbers with the corresponding participant names) to enable records to be identified.

- **Protocol Approval**

Before the beginning of the study and in accordance with the local regulation followed, the protocol and all corresponding documents will be declared for Ethical and Research approval by the Council of surgery Department, Ain Shams University. Furthermore, the approval of the study protocol will be granted by Research Committee (REC), Faculty of Medicine, Ain Shams University (ASU), with presentation of patient's information leaflet, consent form, and case-record data form (CRF).

Study Procedures: All patients will be subjected to:

- Preoperative:

Preoperative preparation of the patients

The focus of preoperative optimization aims at eliminating factors that inhibit wound healing. Well documented factors of adverse effects on wound healing include smoking, obesity, hyperglycemia, nutritional deficiencies, and infection.

Clinical history:

- **Personal History:** including age, sex, weight, occupation, special habits of medical importance particularly smoking.
- **History of Present illness**: symptoms, onset, course, duration, the cause of diversion, patient received chemotherapy or not, number of previous laparotomies and previous hernia repair and a review of other body systems specially chest complaints, bowel problems like constipation and urinary problems specially prostatism.
- **Past history of medical diseases** such as diabetes, infections, malignancy, liver or renal dysfunction, and drug history.
- **Clinical Examination**
  - **General:** pulse, blood pressure temperature and respiratory rate.
  - **Local abdominal examination:** for assessment of the stoma if there is stomal prolapse.

Surgical technique:

Closure of the defect by interrupted Prolene 1 sutures is done, ample wash with betadine and hydrogen peroxide. Then Prolene mesh is applied over the closed fascio-muscular defect to cover 2 cm all around the defect.

Fixation of the mesh to the underlying tissue with prolene 2/0 interrupted sutures. Ample wash of the defect with normal saline is then done. Application of a 16F suction drain, then closure of subcutaneous tissue. Closure of the skin with interrupted prolene 2/0 or 3/0 sutures.

Patients will be assessed as regards:

1) Operative time
2) Hospital stay

- All the patients are kept in the hospital under iv antibiotic coverage for 2 days and oral antibiotics for 3 other days.
- **Clinical assessment:** Patients will be monitored to detect early any postoperative complications such as wound infection and leakage.
- **Chemical assessment:** Complete Blood Count, kidney functions, liver function and serum albumin.

3) Postoperative complications.

- Recurrence detected either clinically or by abdominal pelvic computed tomography.
- Wound infection.
- Wound dehiscence.
- Postoperative pain.
- Postoperative clinically relevant seroma or Hematoma.
- Postoperative ileus.
- Need for reoperation.

Statistical Analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM

SPSS) version 23. The qualitative variables were presented as number and percentages. So, the *P-value* was considered significant as the following: *P-value*> 0.05: Non significant (NS), *P-value*< 0.05: Significant (S), *P-value*< 0.01: Highly significant (HS).

3. Results

Table (1): Descriptive Data regarding Demographic data

		No. = 50
Age	Mean±SD	50.98 ± 12.40
	Range	19 – 71
Gender	Female	15 (30.0%)
	Male	35 (70.0%)

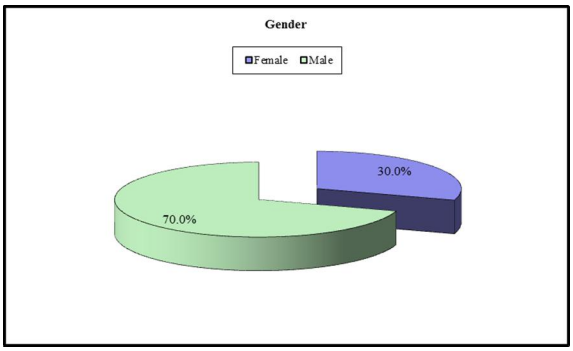

Figure (1): Shows Percent of Gender

Table (2): Descriptive Data regarding Type of Stoma

Type of stoma	No.	%
Loop ileostomy	25	50.0%
End ileostomy	5	10.0%
Loop colostomy	5	10.0%
End colostomy	15	30.0%
Total	***50***	***100.0%***

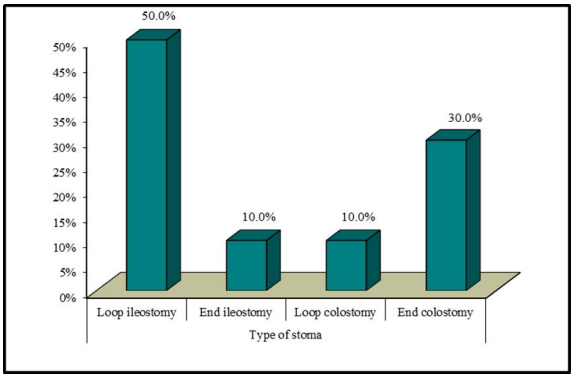

Figure (2): Shows Percent of Type of Stoma.

In this prospective study, 50 patients who required stoma reversal were operated upon by the same surgical team in Ain shams university hospitals.

Patient demographics: in this study there were 35 males 70% and 15 females 30%. Patients' ages ranged from 19 to 71 years with a mean age of 50.98 ± 12.40 (SD) years. Types of stomas were Loop ileostomies 25 cases 50%, end ileostomies 5 cases 10%, loop colostomies 5 cases 10%, end colostomies 15 cases 30%.

Indications for stoma formation were bowel carcinomas 14 cases (28%), diverticular disease 10 cases (20%), mesenteric ischemia 7 cases (14%), sigmoid volvulous 6 cases (12%), trauma 7 cases (14%), inflammatory bowel disease 3 cases (6%), intestinal pseudo-obstruction 3 cases (6%).

Elective cases were 31 cases (62%), urgent cases were 19 cases (38%).

Stomas were closed in a time period ranging from 3 months to 8 months in some patients on chemo and radiotherapy, with a mean time 6.125 ± 0.995 months.

Incisional hernia over the repaired stoma occurred only in 2 cases (4%); the first case had resistant wound infection after closure of end colostomy in a sigmoid volvulous patient with BMI of 44 kg/m^2, that necessitated mesh removal after failure of all conservative maneuvers, the hernia appeared after one and half months from the closure, the other case the hernia appeared despite mesh application, in a case of covering loop ileostomy for colo-rectal anastomosis done after resection of recto-sigmoid carcinoma, the patient received post-op. irradiation after the reversal operation for a suspicious local recurrence.

We had 4 cases of wound infection 8 % one mentioned above, that required mesh removal, the other 3 cases; 2 appeared at the end of the first post-operative week and were managed conservatively by opening the wound with continuous was twice daily till the wounds became clean and granulating where they were closed by secondary sutures, the other case got purulent discharge on the third post-operative day with the drain inside before discharge, where wash through the drain was done twice daily with betadine and hydrogen peroxide then normal saline till the infection subsided, all the above patients were subjected to culture and sensitivity from the wounds and were put on broad spectrum antibiotics till the culture results were obtained.

Seroma occurred in another 7 patients (14%) where they only required frequent aspirations on multiple sessions.

Table (3): Descriptive Data regarding Recurrence, Infection, and Seroma

		No.	%
Recurrence	No	48	96.0%
	Yes	2	4.0%
Infection	No	46	92.0%
	Yes	4	8.0%
Seroma	No	43	86.0%
	Yes	7	14.0%

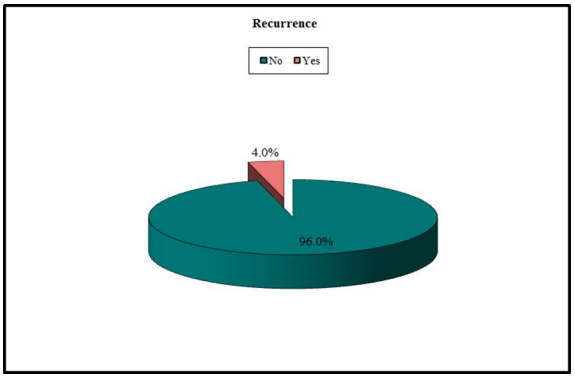

Figure (3): Shows Percent of Recurrence.

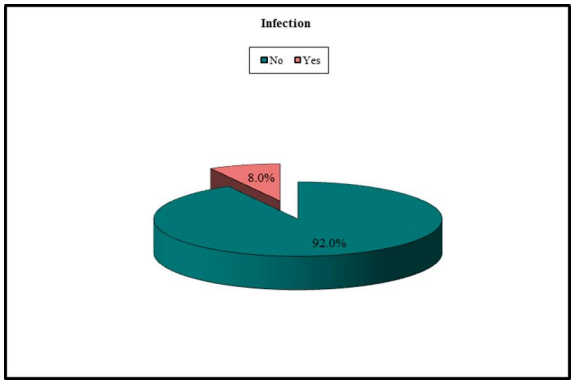

Figure (1): Shows Percent of Infection.

Table (4): Relation between recurrence and Infection and Seroma

		No Recurrence		Recurrence		Test value*	*P*-value	Sig.
		No.	%	No.	%			
Infection	No	45	93.8%	1	50.0%	4.993	0.025	S
	Yes	3	6.3%	1	50.0%			
Seroma	No	42	87.5%	1	50.0%	2.243	0.134	NS
	Yes	6	12.5%	1	50.0%			

P-value>0.05: Non significant (NS); *P-value*<0.05: Significant (S); *P*-value< 0.01: highly significant (HS)
*: Chi-square test

The Previous table shows that there was statistically significant difference found between recurrence groups regarding infection with **(p-value= 0.025).**

While there was no statistically significant difference found between recurrence groups regarding Seroma.

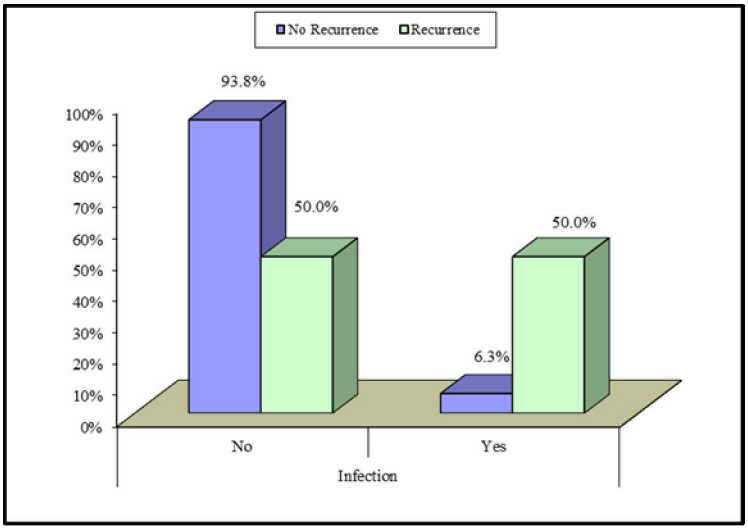

Figure (6): Shows percent of infection between recurrence.

Table (5): Relation between recurrence and Operative time (minutes)

Operative time in minutes	No Recurrence No. = 48	Recurrence No. = 2	Test value•	*P*-value	Sig.
Mean±SD	72.71 ± 18.51	85.00 ± 7.07	-0.929	0.358	NS
Range	40 – 120	80 – 90			

P-value>0.05: Non significant (NS); *P-value*<0.05: Significant (S); P-value< 0.01: highly significant (HS)
•: Independent t-test

4. Discussion

Complications following reversal of stomas include obstruction, wound infection, wound dehiscence, anastomotic leak and the development of incisional hernias ***(Tilney et al., 2007).*** Hernias are a well-recognised complication with known morbidity. They will complicate some wound infections and any wound dehiscence, which in turn can result in secondary small bowel infection. Preventing hernia will also reduce patients morbidity from these secondary events ***(Carne et al., 2003; Martin and Foster, 1996).***

A systematic review for this trial exploring hernias at the closure of stoma sites revealed that hernias occur in up to 30% of patients undergoing stoma reversal and that when present, nearly half require subsequent surgical repair ***(Cingi et al., 2006; Cingi et al., 2008; Guzman-Valdivia, 2008).***

In a retrospective review of consecutive ileostomy closures undertaken at a tertiary referral center between January 2007 and December 2011, Liu et al underwent 83 cases of ileostomy closure, 47 patients received mesh reinforcement, and 36 underwent non-mesh closure (controls). In total, 16 (19.3 %) patients developed incisional hernia, 13 (36.1 %) of which occurred in the control group; 3 (6.4 %) in the mesh group. Incisional hernia repair was performed in 3 (23 %) patients in the control group; no hernias in the mesh group required surgery. There was no significant difference in wound infection rates between mesh (2 patients, 4.3 %) and control (1 patient, 2.8 %) groups. No mesh infection was found. Thus they concluded that mesh placement significantly reduced the incidence of incisional hernia following ileostomy closure, but without increasing complication rates ***(Liu et al., 2013).*** Bhangu et al described a technique for the placement of intraperitoneal biological mesh to prophylactically reinforce stoma closure sites. Seven consecutive patients underwent mesh placement as part of a pilot study. The fascia above the mesh and soft tissues was then closed. Follow-up at 30 days showed one superficial wound infection. An ultrasound scan of this patient revealed that the mesh was still in place and that the infection did not breach the fascia. No other early adverse events occurred ***(Bhangu et al., 2014).***

In an analysis done by Mylan et al at January 2014 that included 16 studies, 1613 patients had 1613 stomas formed. The median (range) incidence of stoma site incisional hernias was 8.3% (range 0%–33.9%) When evaluating only studies with a low risk of bias, the incidence for stoma site incisional hernias is closer to one in three ***(Mylan et al., 2014).***

In a retrospective analysis done by Stephen et al. from 2001 to 2011 on 401 patients to evaluate the incidence of ostomy site incisional hernias after stoma reversal and to determine any significant risk factors that might lead to such hernias, they concluded that Sixty four percent of these patients required definitive hernia repair. Diabetes, smoking within 6 months of surgery, end colostomies, and undergoing an urgent operation were significant risk factors for the development of stoma site incisional hernias ***(Stephen et al., 2015).***

In a prospective study was done by Mohamed M. Mohamed et al. from August 2011 to March 2014 (53) patients who required stoma reversal were operated using prophylactic prolene mesh at stoma closure site. Incisional hernia over the repaired stoma occurred only in 2 cases (3.77%). They had 4 cases of wound infection 7.54%. Seroma occurred in another 7 patients (13.2%). ***(Mahfouz et al.2014)***

In our study the prophylactic use of prolene mesh during stoma closure showed incisional hernia rate of 4% (2/50) in comparison to 6.4% (3/83) in the study of ***Liu et al. (2013)***, while the infection rate in our study was about 8% (4/50), in comparison to the same study of ***Liu et al. (2013)*** that demonstrated no significant difference in wound infection rates between mesh 4.3 % (2/83) and control 2.8 % (1/83) groups.

The final observation we denoted was the presence of an easily controllable seroma in 7 patients (14%).

5. Conclusion

From our study we concluded that the prophylactic use of prolene mesh in closure of stomas during stoma reversal procedure is a relatively safe

and highly efficient procedure in prevention of future ostomy incisional hernias in such patients.

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