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ORIGINAL ARTICLE

Prophylactic Sub Lay Non-Absorbable Mesh Positioning Following Midline Laparotomy in a Clean & Clean-Contaminated Operations

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Abstract

Background: ***Incisional hernia frequently occurs following midline laparotomy. Within some risk profiles, the occurrence rate can be as high as 70%.***

Aim and objectives: ***To investigate the incidence of incisional hernia following centerline clean, clean-contaminated laparotomy, we will compare the use of running sutures alone vs the use of a running suture combined with a Non-absorbable Poly Propylene mesh positioned in a sublay (retro rectus) site.***

Subjects and methods: ***This study was carried out between August 2022 and August 2023 on a total of 60 patients who underwent midsection laparotomy in clean and clean-contaminated fields. The patients were evenly divided into two groups: the Mesh Group, consisting of 30 patients who received closure with polypropylene mesh in a sub-lay fashion, and the Control Group, consisting of 30 patients who underwent closure using the Mass Closure technique with large bite fashion.***

Result: ***After 12 months of postoperative follow-up, there is a difference between the two studied groups regarding incisional hernia occurrence, with a significant decrease in the mesh group. Furthermore, there is a substantial rise in the duration of surgery in the mesh group.***

Conclusion: ***The occurrence of incisional hernia in a sterile surgical environment and clean-contaminated midline laparotomies can be effectively decreased by using non-absorbable sub-lay mesh in the abdominal wall closure procedure as a preventive measure.***

Keywords: Incisional hernia; Eventration; Prevention; Prophylaxis; Prosthesis; Prophylactic mesh

1. Introduction

The midline technique has the advantages of quick access to the abdominal viscera and avoiding potentially dangerous anatomic features that do not cross the midline. However, the linea alba is fragile because it has inadequate vascularization and heals slowly.[1]

The stomach, the duodenum, the gallbladder, the liver, and transversal colon operations are best performed via the midline incision. Using a lengthy midline incision that skirts the umbilicus, an exploratory laparotomy for the unidentified condition can be conducted. An upward or downward incision may be made in accordance with the diagnosis after the peritoneum is opened.[2]

The decision to close the abdominal wall may result in incisional hernias, which cause large financial losses and continue to be a serious public health concern.[3]

One frequent side effect of surgery on the abdomen that has been linked to morbidity and death is an incisional hernia. After undergoing a main elective midline laparotomy, there is a potential chance of developing an incisional hernia, which may be as high as 70%.[4]

Incisional herniation is associated with both technical and patient-related risk factors, such as inclement or filthy wounds and the need for immediate treatment.[5]

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Incisional hernias have been treated prophylactically, and abdominal wall integrity has been restored through a variety of mesh reinforcing techniques (position and form) and suture closure techniques (material and technique). Recurrence rates, even with improvements in early repair, are still too high (12–54%), and patients who have a recurrence are more vulnerable to a cycle of morbidity since early subsequent repair entails more technical difficulties and a higher risk of both morbidity and recurrence.[6]

As per the guidelines released by the European Hernia Society (EHS), it is recommended to use a suture to wound length ratio of at least 4:1 and a small-bites technique using absorbable suture material for closure. The available evidence supporting the use of mesh reinforcement for preventive purposes is scarce, and its efficacy is particularly limited in emergency situations, namely in the context of elective midline laparotomies performed on high-risk patients.[7]

In this study, the incidence of incisional hernias following midline clean and clean-contaminated laparotomies will be compares the efficacy of using a running suture alone with using a running suture enhanced with non-absorbable polypropylene meshes in the sublay (retrorectus) position.

2. Patients and methods

The General Surgery department at Al-Azhar University Hospitals carried out this prospective randomized control trial. Thirty people who are having a surgical incision made in the middle of their abdomen in a sterile environment were recruited for this study using a suitable sampling approach between August 2022 and August 2023. Group 1 (Mesh group) underwent non-absorbable PolyProplene mesh assisted closure in a sub-lay method, while group 2 (Control group) received primary closure (Mass closure approach). All patients were separated into two equal groups.

Patients are having midline laparotomies in fields that are both clean and cleanly polluted. An uncontaminated surgical wound that does not enter the vaginal, pulmonary, alimentary, or urinary system is referred to as a "clean field." An operating wound where the alimentary, vaginal, pulmonary, A clean-contaminated field refers to a situation where the urinary or digestive tracts are intentionally probed in a controlled manner, with minimal risk of contamination.

Inclusion Criteria: Patients who came to the general surgery department for a midline laparotomy in clean and clean-contaminated areas; age: over eighteen; sex: both male and female.

Exclusion Criteria: Individuals below the age of 18, with a projected life expectancy of less than 24 months as determined by the surgeon, who have had immunosuppressive medicine within two weeks before the surgery and have contaminated and filthy wounds (such as those caused by feces spillage or suppurative peritonitis), patients with hernias already present or who have had prior abdominal surgeries, and patients who require a second look operation.

Each and every sufferer endured the following:-

Surgical technique: Third-generation cephalosporin antibiotics used as preoperative prophylactics.

Primary closure of midline laparotomy (control group):

PDS 1 suture using the large biting method (1 cm from the cut edge, 1 cm apart) and a 4:1 suture lengths to wound length ratio will be utilized to close the midline fascia in a mass closure manner. To strengthen the mass closure with Vicryl suture, several sets of interrupted absorbable stitching were used. The surgeon will decide whether or not to close the subcutaneous tissue. All patients' skin closure will be accomplished with metal clips so that, when closed, their wounds will all look the same.

Sublay mesh-supported closure (mesh group):

Dissecting 2 cm on each side of the midline, a 4 cm gap will be made between the rectus muscle and posterior rectus sheath. The posterior rectus sheath margins will be stitched together using a running suture that absorbs slowly (PDS 0, USP 1, Needle HRT 30, 150 cm). Closing the posterior rectus sheath will accomplish posterior layer closure above the arcuate line while suturing the transversalis fascia will accomplish posterior layer closure below the arcuate line.

The posterior transverse sheath and the rectus muscle will be separated by a 4-cm Polypropylene mesh strip, with at least 2 cm of overlap on either side. The mesh's gripping face will be positioned on the posterior layer of the rectus sheath in order to shield the muscle from the grips.

Two strips of 15 cm mesh were cut to size for laparotomies longer than 20 cm.

A progressively absorbable running suture (PDS 0, USP 1, Needle HRT30, 150 cm) was used to seal the anterior rectus sheath midline. The ratio of the wound length to the suture length was 4:1. The surgeon decided whether or not to close the subcutaneous tissue.

Skin closure using metal clips was used on all patients, ensuring that wounds looked the same once they were closed.

Cointerventions

Each participant received empirical antibiotics based on their allergy status and the suspected infections. The type and course of antibiotics were modified in accordance with the availability of

culture and susceptibility results. After the patient was afebrile for 24 to 48 hours, intravenous medication was started and then moved to an oral version.

Every four hours, participants received an IV dose of either 0.05 mg/kg of morphine or 0.5 mg/kg of pethidine as a routine pain management, with extra opioid doses for discomfort that persisted. Depending on the participant's level of discomfort, the initial 24-hour dose of pain management was modified in the days that followed. Epidural anesthesia and patient-controlled analgesia are more choices for pain management. Oral acetaminophen or non-steroidal anti-inflammatory medicines were provided after oral intake was restarted.

Upon detection of GI function, an oral diet was prescribed. As usual, breathing practices and rehabilitation were recommended. There was no use of abdominal binders.

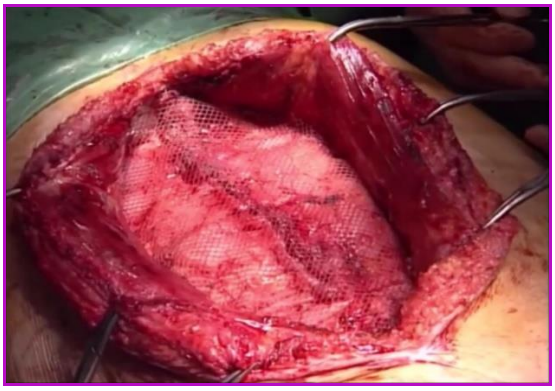

Figure 1. post laparotomy splenectomy (sublay mesh).

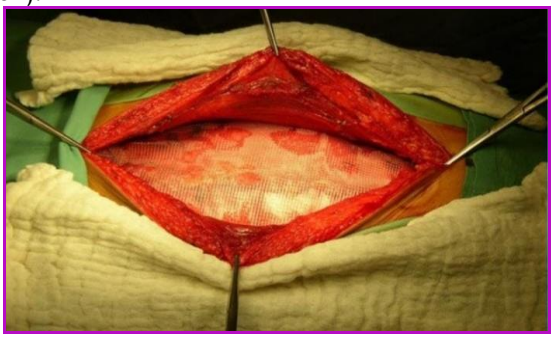

Figure 2. Post-laparotomy stab wound negative laparotomy (sublay mesh position).

Figure 3. The picture shows the posterior rectus sheet, rectus muscle, and anterior rectus sheet.

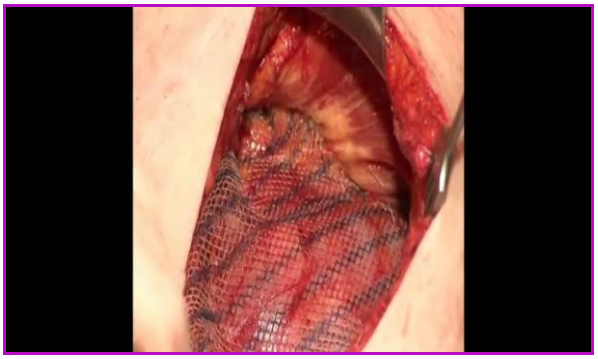

Figure 4. Post laparotomy retromusclar (sublay mesh position).

Primary outcome: The rate of incisional hernias is. Postoperative examinations will take place on patients at 3, 6, and 12 months. At the follow-up, all patients will undergo both a clinical examination and ultrasound imaging. If an ultrasound indicates a possible hernial defect and the results are ambiguous, or the hernia is not clinically proven, a plain CT scan will be ordered for additional confirmation.

Secondary outcome: The incidence of wound occurrences was the secondary result. Surgical site infections were the category for wound occurrences based on the Clavien-Dindo criteria (superficial, deep, or organ space). Among them is seroma, which developed three months following the index procedure and was described as fluid accumulation in the incisional area or serous leaking through the wound. The term "hematoma" refers to a collection of blood that appears in the incision within seven days of the initial procedure and necessitates evacuation. Other uncommon complications that were identified for six months included enterocutaneous fistula and chronic wound sinus. After surgery, on days 1 and 3, there were reports of acute postoperative pain. The range of the pain score was 0 (no pain) to 10 (highest agony). Any level of discomfort that persisted at the incisional scar was considered chronic pain. After surgery, this result was assessed three and six months later. Lastly, the total number of days spent in the hospital following the index operation was used to record the length of stay. Lastly, there was the abdominal wall closure time, which measured the amount of time needed to finish skin approximation after abdominal wall closure. Minutes were used to measure time.

Superficial surgical site infection (SSI:

Only the skin or subcutaneous tissue around the incision was infected within 30 days of the procedure, and a minimum of one of the following was involved: At least one of the following signs or symptoms of infection is present: pain or soreness, localized swelling, redness or heat. The surgeon intentionally opens the superficial incision unless the wound is culture-negative. Presence of pus discharge from the surface wound, with or without

confirmation by laboratory testing. Organisms derived from aseptically collected culture of tissue or fluid from the superficial incision.

Deep surgical site infection (SSI):

The infection seemed to be associated with the surgical procedure and affected the underlying layers of tissue, including the fascial and muscle layers of the incision, along with at least one other area. The occurrence took place within a period of 30 days after the surgery if no implant was retained or within a span of one year if an implant was present. The patient displays symptoms of a purulent discharge originating from a deep incision, excluding any discharge from the surgical site's organ or space. The deep wound may have either naturally developed or been intentionally opened by a surgeon. The patient is seen to have at least one of the aforementioned symptoms. Elevated body temperature (>38°C), specific discomfort or sensitivity in a particular area, unless the site shows no signs of infection; Upon direct examination, reoperation, and histological or radiographic review, an abscess or other indications of infection, including the deep incision, were identified.

Ethical Consideration:

The Department of Ethics Committee of Al-Azhar University in Cairo has given its approval. Patients' signed consent. The participants in the study are free to leave at any moment.

Statistical Analysis

Proper statistical SPSS analysis that was deemed to be necessary was carried out. The collected data were analyzed and tabulated using suitable statistical tests. The statistical correlation and significant relations were highlighted and demonstrated in diagrammatic forms.

Independent sample t-test: will be utilized to evaluate the parametric variable difference between the two independent means of the two research groups in terms of statistical significance.

Person correlation coefficient(r): The strength of a linear link among two quantitative variables will be gauged using correlation.

Validity: evaluated using positive and negative prediction values for sensitivity and specificity, where sensitivity is defined as TP\All diseased and specificity as TN\ALL disease-free; By screening test, NPV = TN\ALL-ve, whereas PPV = TP\ALL+ve.

Chi-square test: utilized to investigate the link between two qualitative variables; however, Fisher's Exact Test will be applied if the anticipated score is fewer than five in more than 20% of the cells

P-value: There are three levels of significance: P<0.05, highly significant (HS), P>0.05, and significant (S).

3. Results

Table 1. displays demographic information between the research groups.

	STUDIED GROUP NO (30)	CONTROL GROUP NO (30)	P VALUE
AGE MEAN±SD	55.27±9.1	53.5±10.5	0.488
SEX			
MALE	19(63.3%)	19(63.3%)	1
FEMALE	11(36.7%)	11(36.7%)	
BMI MEAN ±SD	36.26±4.75	38.1±4.38	0.124

P value < 0.05 statistically significant

Between the studied groups, there was a non-statistically significant difference.

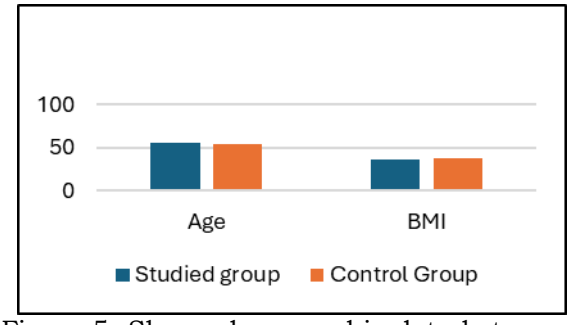

Figure 5. Shows demographic data between the studied groups.

Table 2. Show distribution of co morbidities among studied groups.

	STUDIED GROUP NO (30)	CONTROL GROUP NO (30)	P VALUE
DM	15 (50%)	13(43.3%)	0.6
HTN	14 (46.6%)	13 (43.3%)	0.5
IHD	6 (20%)	4 (13.3%)	0.4
HCV	2 (6.6%)	1 (3.3%)	0.5
NEGATIVE	12 (40%)	9 (30%)	0.41
OTHERS	2 (6.6%)	5 (16.6%)	0.22

Regarding DM, HTN, HCV, IHD, and other comorbidities, there was no statistically significant difference between the groups under study.

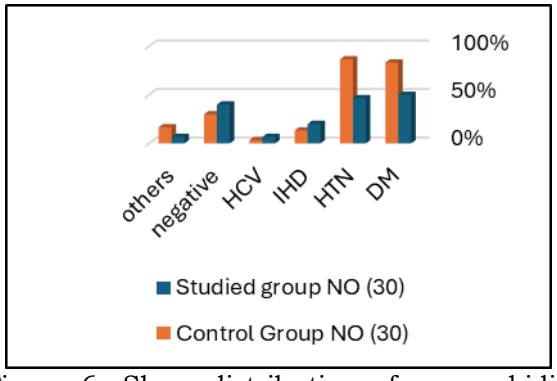

Figure 6. Show distribution of co morbidities among studied groups.

Table 3. Show distribution of type of surgery among studied groups.

	STUDIED GROUP NO (30)	CONTROL GROUP NO (30)	P VALUE
EM, SPLENECTOMY	3 (10%)	2 (6.7%)	0.9
EL. RIGHT HEMICOLECTOMY	5 (16.6%)	6 (20%)	
LAPAROTOMY FOR STAB	4 (13.3%)	3 (10%)	
EL. DISTAL GASTERECTOMY	4 (13.3%)	3 (10%)	
EL. LOW ANTERIOR RESECTION	4 (13.3%)	2 (6.7%)	
EM. PERFORATED PEPTIC	3 (10%)	5 (16.6%)	
LAR	1 (3.3%)	3 (10%)	
SIGMOIDECTOMY	3 (10%)	3 (10%)	
OTHERS	3 (10%)	3 (10%)	

Regarding the type of operation, there was no statistically significant difference between the groups under investigation.

Table 4. displays clinical and operational statistics between the groups under study.

	STUDIED GROUP NO (30)	CONTROL GROUP NO (30)	P VALUE
TIME FOR CLOSURE (MIN) MEAN±SD	40.7±4.96	41.56±4.30	0.475
POST-OP COMPLICATION			
SEROMA	6(20%)	6(20%)	0.836
HEMATOMA	1(3.3%)	2(6.7%)	
NO	23(76.7%)	22(73.3%)	

P value < 0.05 statistically significant

Between the studied groups, there was a non-statistically significant difference.

Table 5. displays the incidence of hernias in the groups under study.

	STUDIED GROUP NO (30)	CONTROL GROUP NO (30)	P VALUE
INCISIONAL HERNIA AFTER			
3 MONTHS	1(3.33%)	4(13.33%)	0.16
6 MONTHS	1(3.33%)	4(13.33%)	0.16
12 MONTHS	1(3.33%)	4(13.33%)	0.16

P value < 0.05 statistically significant

Between the groups under study, there was no statistically significant difference.

Table 6. Postoperative VAS among the groups under investigation.

VAS	STUDIED GROUP NO (30)	CONTROL GROUP NO (30)	P VALUE
3-MONTHS POSTOPERATIVE MEAN ± SD	1.26±0.381	1.03±0.365	0.077
6-MONTHS POSTOPERATIVE MEAN±SD	0.654±0.217	0.801±0.328	0.647

Based on the VAS score, there was no statistically significant difference between the groups under investigation.

4. Discussion

The findings of the randomized controlled trial provided support for the current investigation. Pizza et al.,8 100 patients were enrolled in the mesh group and 100 patients in the control group of the trial, which sought to assess the likelihood of incisional hernia in patients receiving urgent midline laparoscopic surgery for clean-contaminated surgery. In terms of age, sex, BMI, and comorbidities, the two groups were well-matched. Smoking and diabetes mellitus were the most common comorbidities in both groups. The study indicated that the mesh group was linked to a considerably longer operative time, which is consistent with our data.

Moreover, in line with the findings of the current study by Muysoms et al.,[9] 56 patients were included in the mesh group and 58 in the one with a suture (control) group in a randomized trial. The baseline data for both groups, which included age, sex, BMI, and comorbidities, were well-matched. Smoking was the most common comorbid in both groups, subsequent to coronary heart disease. According to the study, the mesh group had considerably longer operating times and abdominal closure times.

Also, Timmermans et al.[10] 107 patients were enrolled in the primary suture group, 185 in the sublay mesh group, and 188 in the only mesh group in a multicenter, double-blind, randomized controlled trial. All groups were well-matched in terms of age, sex, BMI, and comorbidities; smoking and diabetes mellitus were the most prevalent comorbidities. In comparison to the other groups, the sublay mesh group was linked to a non-significantly longer operative time, according to the study. It's possible that the discrepancy with our findings is because the study circumstances and sample size were different.

Also, in concordance with the current study Muysoms et al.,[9] revealed that the mesh group has non-significantly shorter hospital stay.

In agreement with the current study, Pizza et al.[8] demonstrated that there was no discernible variation in stoma between the groups under study.

Also, in concordance with the current study Muysoms et al.,[9] revealed that there was no significant difference between the studied groups as regard stoma.

In disagreement with the current study, Dewulf et al.,[11] In an open-label, prospective, multicenter, randomized design trial, 33 patients were enrolled in the mesh group (34/56-60.7%) and 33 patients in the no-mesh group (33/58-56.9%). Ten patients in each therapy arm passed away between the 24- and 60-month follow-up periods. After 24 months, the cumulative incidence of incisional hernias (IHs) in the no-mesh group was

32.9%, and after 60 months, it was 49.2%. In the mesh group, no IHs were found to exist. Of the 23 participants in the no-mesh group, 21.7% had an IH and required reoperation within five years. The discrepancy could result from variations in the sample size, inclusion criteria, and operational specifics.

In contrast to our results, Pizza et al.,[8] revealed that, by the time the surgery was over, six patients in the mesh group and 21 patients in the control group had incisional hernias (P=0.002). The different inclusion criteria and sample size could be the cause of this. Furthermore, the research verified that mesh plays a protective role against incisional herniation in multivariable analysis (OR 0.11, 0.03 to 0.37; P<0.001). On the other hand, risk factors for the development of incisional herniation included smoking (OR 33.97, 8.12 to 142.12; P<0.001), diabetes mellitus (OR 13.04, 3.53 to 48.18; P<0.001), and male sex (OR 8.52, 0.03 to 0.48; P=0.003), and diabetes mellitus (OR 13.04, 3.53 to 48.18; P<0.001).

As well, the current study was supported by Jairam et al.,[12] in a multicenter, double-blind, randomized controlled experiment, assessed the efficacy of mesh reinforcement in preventing incisional hernias in high-risk patients. Four hundred eighty individuals participated in the trial for the primary analysis, of whom 107 received primary suture only, 188 onlay mesh reinforcement, and 185 sublay mesh reinforcement instructions. When it came to baseline data, all groups matched well. Ninety-two patients (33 (30%), 25 (13%), and 34 (18%) in the sublay mesh group, onlay mesh vs primary suture (OR 0·37, 95% CI 0·20–0·69; p=0·0016; sublay mesh vs primary suture, 0·55, 0·30-1·00; p=0·05) were found to have an incisional hernia, according to the study.

In contrast to our results systematic review and meta-analysis by Albendary et al.,[13] demonstrated that, when comparing the mesh group to the non-mesh group, acute wound failure was significantly lower (odd ratio (OR) 0.23, p=0.002). As per our findings, there was no noteworthy distinction between the two groups for SSI (OR 1.47, p=0.06), seroma/hematoma formation (OR 2.74, p=0.07), grade ≥ 3 Clavien-Dindo sequelae (OR 2.39, p=0.28), and LOS (MD 0.26, p=0.84).

4. Conclusion

The incidence of incisional hernia can be safely and effectively reduced by the preventive sublay mesh-augmented abdominal wall closure following laparotomy in clean wounds; however, the fact that this was not statistically significant may have been caused by the small sample size. The fact that every patient was treated by the same surgeon in the same location may be the study's strongest point.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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