

Original Research Article

Does pre-emptive onlay mesh reinforcement of midline laparotomies reduce incidence of incisional hernia in high-risk patients?

Hosam F. Abdelhameed, Samir A. Abdelmageed*

Department of General Surgery, Faculty of Medicine, Sohag University, Sohag, Egypt

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***Correspondence:**

Dr. Samir A. Abdelmageed,

E-mail: samersamar2000@yahoo.com

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ABSTRACT

Background: One of the major morbidity after abdominal surgery is incisional hernia. In high risk patients its incidence reaches 11-20% despite various optimal closure techniques for midline laparotomy. Our aim is to evaluate the efficacy of onlay mesh placement in reducing the incidence of incisional hernia in those high risk patients.

Methods: A total of 65 high risk patients suspected to develop post-operative incisional hernia underwent midline abdominal laparotomies. Patients were divided into two groups; group1 (30 patients) for whom the incision was closed by conventional method and group2 (35 patients) for whom the incision was closed with reinforcement by onlay polypropylene mesh. The primary end point was the occurrence of incisional hernia while the secondary end point was post-operative complications including subcutaneous seroma, chronic wound pain, and surgical site infection (SSI). Patients were followed up for two years.

Results: The base line characteristics of the two groups were similar. The incidence of incisional hernia is significantly reduced 1/35 (2.8%) in group 2 while it was 6/30 (20%) in group 1. As regard seroma and chronic wound pain they increased in (group2) 6/35 (17.14%) and 5/35(14.28%) respectively compared to (group 1) which was 4/30 (13.33%) and 2/30 (6.66%). SSI occurred in 1/35 (2.85%) in group 2 and in 1/30 (3.33%) in group 1.

Conclusions: Prophylactic onlay mesh reinforcement of the midline laparotomy for high risk patients can be used safely and markedly reduces the incidence of incisional hernia with little morbidity.

Keywords: Incisional hernia, Prophylactic mesh, Midline laparotomy, Risky patients, Onlay mesh

INTRODUCTION

Incisional hernia is a common complication of abdominal wall incisions especially the midline one. Its incidence range from 5-20% in normal population and may reach up to 60% in high risk patients.^{1,2} In emergency situations the incidence of (IH) is greater than 50%.³ The advantage of the midline incision is wide and rapid access to the abdomen however; the incidence of incisional hernia is higher compared to other abdominal incisions.⁴ The risk factors for incisional hernia can be patient related or surgery related factors or both.⁵ The patient related factors include obesity, diabetes mellitus, malnutrition,

smoking, chronic obstructive pulmonary disease, immunosuppression, steroid therapy cardiac disease, malignancy, renal impairment, liver cirrhosis and jaundice.^{6,7} Surgery related factors include Emergency operations, bowel surgery, abdominal aortic aneurism, stoma closure, operations for peritonitis, re-laparotomy Technique and suture material used for closure of the abdominal incisions, Wound infection, long operating time, increased blood loss and surgeon experience.⁸⁻¹¹ This is in addition to a biological factor as defective collagen metabolism and synthesis.¹² The occurrence of IH after open laparotomies causes pain, disability and a lot of dissatisfaction.¹³ Some studies stressed on

prophylactic prevention of this iatrogenic complication after abdominal operation by using prophylactic mesh placement (PMP) whether onlay or sublay.¹⁴ However there is some controversy about the optimal mesh position, shape and fixation.¹⁵ The aim of our study is to evaluate the efficacy of onlay mesh placement in reducing the incidence of incisional hernia in high risk patients undergoing elective and non-elective midline laparotomy.

METHODS

Study design

This study is a prospective randomized study. Ethical committee approval for the study was obtained. Informed consent was signed by all patients after full explanation of the surgical procedure and possible benefits and side effects.

Settings and participants

The study was conducted at general surgery department, Sohag University, Egypt. The study included patients with risk factor(s) of incisional hernia after midline laparotomy for elective and non-elective operations that match the assigned eligibility criteria between December 2014 and November 2017. The aim of the study was to evaluate the efficacy of onlay mesh placement in reduction of the incidence of incisional hernia in high risk patients undergoing elective and non-elective midline laparotomy.

Eligibility criteria

All patients having one or more of the following inclusion criteria: old age, body mass index more than 30, malnutrition (anemia, hyop-proteinaemia and vitamin deficiency), smoking, diabetes mellitus, jaundice, liver cirrhosis, renal impairment, malignancy, chronic obstructive pulmonary disease, steroid therapy and previous abdominal incisions, who underwent midline laparotomy for elective and non-elective operations were included in this study. Patients who have peritonitis, pregnancy, immunosuppressive therapy, life expectancy less than 24 months, history of metastatic cancer and age less than 18 years were excluded from this study.

Data collection

During the period of recruitment, out of 90 patients who underwent midline laparotomy, only 65 patients were included in the study. All patients were subjected to complete preoperative assessment including proper history-taking, clinical examination, laboratory investigations (CBC, LFTs, Blood glucose, and serum creatinine) and imaging studies (U/S and /or CT abdomen in selected cases). Antibiotic prophylaxis was given at time of induction of general anesthesia. Randomization was done using computer generated random number

sequences in concealed envelopes with block randomization design. Patients were classified into 2 groups, group 1 for whom the midline incision was closed by conventional continuous suture technique with a suture/wound length ratio of 4:1 using a monofilament, non-absorbable suture (polypropylene) number 1, spaced 1 cm apart and 1 cm from the cut edge, while in group 2 the linea alba was closed with running sutures of polypropylene suture number 1, spaced 1 cm apart and 1 cm from the cut edge and reinforced by a large-pore polypropylene mesh placed in the facial onlay position. The mesh was 5 cm wide and the length of the mesh was adapted to the incision with an overlap of 2 cm at both ends. The meshes were fixed to the anterior rectus sheath with interrupted resorbable sutures 3 cm apart. The subcutaneous tissue was closed by interrupted polyglactin 2/0 stitches fixed to the mesh and a suction drain was left over the mesh. The skin was closed by interrupted 2/0 silk. The primary end point of the study was the occurrence of incisional hernia while the secondary end point was post-operative complications including subcutaneous seroma, chronic wound pain, surgical site infection and mesh removal. Incisional hernia means any abdominal wall gap with or without a bulge in the area of postoperative scar perceptible or palpable by clinical examination or imaging.¹⁶ Seroma means localized accumulation of clear serum liquid in the wound without infection. Chronic wound pain means any pain in the wound lasting more than 12 weeks.¹⁷ All patients were followed up in the outpatient clinic by clinical examination ultrasonography and/or CT when there was any clinical uncertainty, weekly during the first month then every 2 weeks for 3 months then every 6 month till the end of the follow up period which is 2 years postoperatively.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) program (version 19.0 for Windows). Quantitative variables were expressed as mean and standard deviation, and categorical variables as absolute numbers and percentages. The appearance of IH during follow-up was analyzed with the Kaplan–Meier estimation method and comparative analysis of time-to-event data was performed using the log rank test. Comparisons of data within the group were performed using paired *t*-test. $P \leq 0.05$ was considered statistically significant.

RESULTS

From December 2014 to November 2017, sixty five patients (38) females (58.46%) and (27) males (41.54%) matching the eligibility criteria were subjected to midline abdominal laparotomy. Thirty patients (group 1) were closed using the conventional method, in this group there were 19 (63.33%) females and 11(36.67%) males, their mean age was (52.3±15.6) and the mean BMI was (27.3±3.8) years while in (group 2) the midline

abdominal incision was closed with PMP, it include 19 (54.29%) females and 16 (45.71%) males and their mean age was (54.5±15.1) years and mean BMI was (25.2±4.7). There was no significant statistical difference between the two groups as regard these parameters. The base line characteristics of all participants were summarized in Table 1.

Table 1: Base line characteristics.

Parameter	Group 1 (n=30)	Group 2 (n=35)	P value
	N (%)	N (%)	
Age (mean± SD years)	52.3±15.6	54.5±15.1	0.051
Sex			
Male	11 (36.67)	16 (45.71)	0.624
Female	19 (63.33)	19 (54.29)	0.964
BMI (mean±SD)	27.3±3.8	25.2±4.7	0.246
Family history of hernia	3 (10)	4 (11.42)	0.47

P≤0.05= significant.

As regard the risk factors, obesity, malnutrition and old age were the commonest risk factors in our study and the average number of risk factors per patient was (2.35±0.51) in group 1 while it was (2.11±1.21) in group 2 but there was no statistical difference between both groups (Table 2).

Table 2: Risk factors.

Risk factor	Group 1 (n=30)	Group 2 (n=35)	P value
	N (%)	N (%)	
Obesity	11(36.66)	15 (42.85)	0.24
Malnutrition	9 (30)	12 (34.28)	0.46
Old age (>60 years)	15 (50)	20 (57.14)	0.35
Diabetes	7 (23.33)	6 (17.14)	0.43
COPD	5 (16.66)	5 (14.28)	0.38
Renal impairment	2 (6.66)	4 (11.42)	0.42
Liver cirrhosis	3 (10)	2 (5.71)	0.17
Smoking	8 (26.66)	10 (28.57)	0.42
Malignancy	6 (20)	7 (20)	0.963
Steroid therapy	2 (6.66)	3 (8.57)	
Previous abdominal incision	5 (16.66)	4 (11.42)	0.215
Average no. of risk factors (mean±SD)	2.35±0.51	2.11±1.21	0.623

P≤0.05 =significant.

As regard the operative data, we founded that the clean operations were (99.33%) and the clean contaminated operations were (6.67%) in group (1) while in group (2) it

was (91.43%) and (8.57%) respectively, and this was statistically insignificant. In this study the percentage of elective and non-elective operations in group (1) were (33.33%) and (66.67%) while it was (37.14%) and (22.86%) in group (2) respectively, and it was insignificant statistically. Concerning the type of incision, large number of patients was subjected to upper midline incision (31 patients 47.69%), while the lower midline incision and the extended midline was (19 patients 29.23%) and (15 patients 23.07%) respectively.

Table 3: Operative data.

Operative data	Group 1 (n=30)	Group 2 (n=35)	P value
	N (%)	N (%)	
Type of operation			
Clean	28 (93.33)	32 (91.43)	0.613
Clean contaminated	2 (6.67)	3 (8.57)	0.45
Elective	10 (33.33)	13 (37.14)	0.38
Non-elective	20 (66.67)	22 (62.86)	0.36
Type of incision			
Upper midline	16 (53.33)	15 (42.85)	0.17
Lower midline	8 (26.67)	11 (31.43)	0.28
Extended midline	6 (20)	9 (25.72)	0.153

p≤ 0.05= significant.

Table 4: Post-operative outcome.

	Group 1 (n=30)	Group 2 (n=35)	P value
Occurrence of incisional hernia	12 (40)	2 (5.71)	0.001
Seroma	4 (13.33)	6 (17.14)	0.241
Chronic wound pain	1 (3.33)	5 (14.28)	0.007
S.S.I	2 (6.66)	2(5.71)	0.879

P≤0.05 = significant.

The occurrence of incisional hernia was markedly reduced in group 2 (5.71%) compared to group 1 (40%) and this was statistically significant. As regard seroma and S.S.I, it occurred in (13.33%) and (6.66%) in group 1 compared to (17.14%) and (5.71%) in group 2 respectively and this was statistically not significant. The incidence of chronic wound pain was high in group 2 (14, 28%) compared to (3-33%) in group 1 and this was statistically not significant (Table 4).

DISCUSSION

Incisional hernia (IH) is a frequent long term complication in surgery. It causes much morbidity and even mortality in patients.¹⁸ Many studies describe the optimal closing techniques for abdominal incisions but still there is increased risk for incisional hernia after

midline incision.¹⁹ Despite the knowledge about the risk factors for incisional hernia, there is no sufficient method for prevention of incisional hernia yet.²⁰⁻²³

Till now the most widely accepted surgical technique to reduce the incidence of (IH) are the use of small bite technique to close the linea Alba and mesh reinforcement procedure.²⁴⁻²⁶ In spite of this the latest European hernia society guideline gives both techniques a weak recommendation.²⁷

The risk factors for IH occurrence are patient related and technical considerations in addition to other biological factors.⁵ For reduction of the incidence of the IH some of the patient-related risk factors can be modified including, smoking stoppage, diabetic control, weight loss and measures to decrease SSI. The technical considerations that can be employed to reduce the incidence of IH include the type of suture material and the use of either small bites technique to close the linea alba and prophylactic mesh placement.²⁷ In our study the commonest risk factor for development of IH are obesity, malnutrition and old age, it represent (40%), (32.30%) and (53.84%) respectively, other risk factors include smoking (27.69%), diabetes (20%) and malignancy (20%). The average number of risk factors per patient was (2.35±0.51) in group 1 while it was (2.11±1.21) in group 2 but there was no statistical difference between both groups. In a comprehensive review, Poole stated that local mechanical factors were more important than systemic diseases in prevention of wound dehiscence.²⁸ Conventional continuous suture technique with a suture/wound length ratio of 4:1 using a monofilament, non-absorbable suture (polypropylene) number 1, spaced 1 cm apart and 1 cm from the cut edge was the technique adopted for midline closure in all cases of this study, but in group 2 PMP was placed in the facial onlay position. The PRIMA study, a multicentre, double-blinded randomized trial, concluded that there was no difference in incisional hernia rate whether the mesh was placed in the only or sublay position.²⁹ Borab et al, recommend the onlay mesh placement as it is less technically complex and requires less operative time than the sublay or preperitoneal approach. Sublay mesh placement has a significant technical challenge and add operative time.³⁰ Prophylactic onlay mesh placement offers a relatively easy, generalizable technique for all patients undergoing midline laparotomy, for surgeons of all specialties.²⁹ Seilr et al stated that patients with BMI equal to or higher than 27 kg/m² have a more than 30% chance of developing IH after ML.³¹ San Miguel et al also observed that a higher level of BMI is a risk factor for the development of IH, even when a prophylactic mesh is used. Nonetheless, this fact was not confirmed on log-rank testing.³² In our study the mean BMI was (27.3±3.8) in group 1 while it was (25.2±4.7) in group 2.

Jairam et al and Timmermans et al, in their systematic reviews and meta-analysis have shown that PMP is safe and effective at reducing IH.^{29,33} However, there is

minimal data on which is the optimal mesh composition, the best anatomical position to place the mesh within the abdominal wall or the best method of mesh fixation.³⁰ There is also fear regarding the potential long-term sequelae of PMP, such as chronic seroma, chronic pain, infection or mesh removal. Again, there are no data on how to manage those patients that develop an IH after PMP.

Prophylactic mesh placement PMP is associated with 85% reduction of post-operative IH risk when compared to conventional primary suture closure PSC of the midline laparotomy incision in at risk patients with a safe and average complication profile as increased risk of seroma and chronic wound pain.^{13,33} In this study the incisional hernia IH was occurred in 2 patients (5.71%) in group 2 where an onlay PMP was placed while it occurred in 12 patients (40%) in group 1 where conventional PSC was done. Holihan et al and burgeret al, concluded that the incidence of IH after abdominal laparotomy range widely between 10% to 23% in general patient population and up to 69% in long term follow up of high risk patients.³⁴⁻³⁶ Another studies stated that the incidence of IH is 5-20% of the general population and can increased to more than 60% in high risk patients.^{3,29,37} In the emergency setting the reported incidence is greater than 50%.^{3,38} Compared to previous studies we found that the incidence of IH markedly reduced in group 2 where PMP was used to close the midline incision in those high risk patients as it occurred in 2/35 patients (5.71%) while it occurred in 12/30 patients (40%) in group 1 and this come in accordance to the results of Timmermans et al and Fischer et al in their studies.^{13,33}

In our study chronic wound pain, as a late complication was more in group 2 as it occurred in 5/35 patients (14.28%) (PMP) while it occurred in 1/30 patients (3.33%) in group 1 (PSC), and this agree with the report of El-khadrawy et al who stated that chronic pain occurred in 15% of PMP group.⁴ Another systematic review and meta-analysis done by Zachary et al concluded that 4 out of 14 studies (28.6%) have a significant increased risk of chronic wound pain in PMP group compared to PSC group. Borab et al in his systematic review and met analysis concluded that the use of PMP significantly increased the rate of post-operative seroma, 12% of PMP had post-operative seroma compared to 5% of PSC, while it was 11% of PMP compared to 5% of PSC patients in another study.^{39,30} Another study stated that the incidence of seroma in PMP reach up to 18%.³³ In our study the incidence of seroma increased in PMP group 6/35 (17.14%) compared to 4/30 (13.33%) and this was comparable to the above results. In our study SSI occurred in 2 patients (6.66%) in non-mesh group while it occurred in 2 patients (5.71%) in the mesh group, this came in comparable to several studies that describe the range of SSI was from 0-10% in the mesh group compared to 0-6% in non-mesh group.^{21-23,40} The follow up period in our study was two years.

CONCLUSION

Reinforcement of the midline closure by onlay mesh has been proved to be effective and safe method of avoidance of incisional hernia in high risk patients in both elective and emergency operations during the follow up period.

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