

A Comparison between Sub-lay and On-lay Mesh Repair in Incisional Hernia: A Randomized Controlled Trial

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ABSTRACT

Objective: To compare frequency of post incisional hernia repair complications in view of on-lay and sub-lay mesh repair.

Study Design: Randomized Controlled Trial

Place and Duration: Surgery Department Jinnah Postgraduate Medical Centre, Karachi from 10th October 2018 to 10th April 2019.

Methodology: Patients from both genders with incisional hernia for more than 6 months, ASA grade I and II were included. Patients were randomly assigned by non-probability consecutive sampling into one of two groups of 30 patients each. Group A, patients had on-lay mesh repair and group B patient received sub-lay mesh repair. Patients were called for follow up on 15th day to assess the post-operative complications i.e.; wound infection, hematoma and seroma.

Results: Among total of 60 patients, each group (Group A and B) comprises of 30 patients each and female gender was dominant in both group (53.3% and 76.7%). In both groups 26.7% patients were diabetics. In Group- A, wound infection was observed in 6.7% patients as compare to 13.3% patients in sub-lay mesh repair Group- B (P=0.389). In on-lay mesh repair group hematoma was noticed in 6.7% patients as compare to 16.7% patients in sub-lay mesh repair group (P=0.227). In Group- A seroma was seen in 13.3% patients whereas, in 3.3% patient in Group- B (P=0.161).

Conclusion: There was no significant difference regarding post-operative complications with on-lay and sub-lay mesh method in repair of incisional hernia with acceptable complication rates.

Keywords: Incisional hernia, On-lay mesh repair, Sub-lay mesh repair, Post-operative complications, Wound infection, Hematoma, Seroma,

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INTRODUCTION

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Incisional hernias repair with mesh in comparison to anatomical repair has noticeably improved continuing consequences and is acknowledged as a standard hernia repair all over the world¹. In literature, it is reported that mesh placement has significantly enhanced risk for wound complications like seroma formation, hematoma, wound or mesh infection and mesh erosions². The risks of these complications have a strong correlation with the mesh placement site. It has been reported that if mesh is exposed to peritoneal organs, there is potentially increase risks of complications like adhesions formation, gut erosion, gut fistula formation or bowel obstruction³. Some surgeons place on-lay whereas other prefer in-lay mesh placement during incisional hernia repair and literature review shows lack of consensus on the best location for mesh placement in terms of complications and outcome^{3,4}.

In open incisional hernia repair, different options i.e. inlay, on-lay or sub-lay placement of mesh are used. Whereas during laparoscopic repair, the mesh is routinely placed in the intra-peritoneal position⁴. In On-lay repair, mesh is placed anteriorly over the anterior fascia, in which typically after flap the fascia is closed primary below the mesh. Whereas, in large complex hernias, the space for on-lay mesh is usually dissected with hernia sac excision or with mayo-fascial release (i.e., anterior

component separation)⁵. In in-lay mesh repair, mesh is placed inside the hernia defect and then mesh is secured circumferentially over the edges of the fascia or defect⁵. The Sub-lay mesh repair refers to the placement of mesh pre-peritoneally or at retro-rectus position. This repair is also commonly referred to as a retro muscular or Rives-Stoppa repair. Finally, in under-lay mesh repair, the mesh is secured to the anterior abdominal wall after placing intra-peritoneally^{5,6}.

Each mesh repair location, has its own benefits and risks as reported in literature. The on-lay mesh is technically easy to place. But at the other end, with on-lay mesh repair, skin flaps dissection most likely leads to enhanced prevalence of mesh infection and wound complications⁶.

In-lay mesh repair is technically easy to perform, but other than that the mesh is often exposed to the intra-peritoneal organs, it is also vulnerable to superficial wound complications. In this repair, the lack of tissue overlap, precludes the integration of mesh and tissue and theoretically enhances the risk of recurrence⁷. In a study by Saeed and colleagues has reported almost 5% frequency of wound infection, Hematoma formation and 7.5% of seroma formation in on-lay repair as compare to 10% of wound infection, 12.5% of Hematoma formation and no seroma in sub-lay method⁸. In another study by Leithy et al, the frequency of wound infection and seroma formation observed is much higher (40% each) in on-lay technique as compare to only 6% of wound infection and seroma was 6 % in sub-lay repair⁹. Similarly, the Aoda et al has reported 4% incidence of wound infection and 24% in seroma formation in on-lay repair technique as compare to only 4% rate of wound infection and 2% of seroma formation after sub-lay repair¹⁰.

Keeping in view the practice variation in hernia repair and scarce literature availability in our set up on, this aspect of hernia repair and additional data comparing sub-lay versus on-lay mesh repair in incisional hernia is needed and it will help us to take a right decision for our general population. Moreover, different studies showed variable results regarding post-operative wound infection after these two repair methods, few studies^{8,9} had shown less wound infection after on-lay method while another showed more wound infection after on-lay method⁹.

Therefore, this study is planned to compare post-operative complications after Sub-lay and on-lay mesh repair for incisional hernia which will pave the way to get more evidence and further research in our general population. A large size, multicenter and well-designed randomized control trial is needed in future in order to draw a better conclusion. So this study was conducted with an objective to compare frequency of post incisional hernia repair complications in view of on-lay and sub-lay mesh repair.

METHODOLOGY

This Randomized Controlled Trial was conducted at Department Of General Surgery, Jinnah Postgraduate Medical Centre Karachi from 10th October 2018 to 10th April 2019. A sample size of 60 patients was calculated among which 30 patients for On-lay mesh repair (Group-A) and 30 patients for Sub-lay mesh repair (Group-B) were planned. Patients of both genders, between age

of 12 to 50 years, with Incisional hernias as per operational definition for more than six months duration and ASA Grade I and II were included in study. Whereas, patients with BMI >40 kg/m² (BMI= weight (in kilogram) divided by height (in meters) squared), Pregnancy, H/o Intra-abdominal malignancies and those who lost follow up excluded. The purpose, procedure, risk and benefit of the study was described to the participants and written informed consent was taken from the patients/guardian.

Patients were evaluated meticulously before surgery and were randomly allocated to both groups through non probability sampling technique. All the patients were operated under general anesthesia by a consultant surgeon having minimum of three years of experience and well versed with both on-lay mesh and in-lay mesh hernia repair technique.

Patients in Group-A, polypropylene mesh (Prolene Ethicon, Germany) was placed on to the anterior rectus fascia (on-lay technique) with continuous or interrupted 2/0 and 3/0 polypropylene sutures. In group-B Sub-lay method used involving the placement of a permanent prosthetic mesh (polypropylene) in a pre-peritoneal plane. The mesh will then opposed to the adhering layers with continuous 1/ 0 polypropylene sutures. The mesh was secured with a few interrupted 3/0 polypropylene suture. The anterior rectus sheath was closed with continuous 1/0 poly propylene suture in both groups. Two redivac drains were placed above the mesh in all the patients. Drains were taken off when drainage is below 20 cc. Post-operatively, prophylactic antibiotics and oral analgesics were given to all patients.

Patients were called for follow up on 15th post-operative day, then monthly over telephone or face to face which one is possible for one year for the assessment of post-operative complications like wound infection, hematoma, seroma formation and recurrence as per operational definition. Correlation of outcome is assessed with co-morbidities, duration of surgery, post-operative duration etc.

Data Analysis: Data was collected on specially designed proforma and analyzed with statistical analysis program (IBM-SPSS V22). Analysis was done to compare proportion of group A and group B. Mean $\pm$ SD was presented for quantitative variables like age, duration of complain, duration of procedure, weight, height and BMI. Frequency and percentage was computed for qualitative variables like gender, Diabetic/Non diabetics, ASA grade and post-operative complications (wound infection, hematoma and seroma). Chi-square test was applied to compare post-operative complications of both groups, taken $p \leq 0.05$ as significant.

Post stratification chi-square test for both groups was applied, $p \leq 0.05$ was considered statistically significant.

RESULTS

Among total of 30 patients included, the age range is from 12 to 50 years with mean age of 33.300 ± 6.28 years in Group-A while 37.133 ± 6.95 years in Group-B.

Mean duration of complain was 9.533 ± 2.40 months in Group-A

and 11.766 ± 2.82 months in Group-B. Mean duration of procedure was 98.533 ± 14.46 minutes in Group-A and 78.766 ± 11.91 minutes in Group-B. Mean weight was 67.433 ± 11.71 Kg in Group-A and 73.000 ± 13.19 Kg in Group B, mean height was 1.513 ± 0.07 meters in Group-A and 1.563 ± 0.11 meters in Group-B and mean BMI was 29.534 ± 5.13 Kg/m² in Group-A and 30.088 ± 5.63 Kg/m² in Group-B. Female gender was dominant in both groups (53.3% and 76.7%).

In on-lay mesh repair group wound infection was seen in 2(6.7%) patients as compare to 4(13.3%) patients in Sub-lay mesh repair group, ($P=0.389$). In on-lay mesh repair group hematoma was seen in 2(6.7%) patients as compare to 5(16.7%) patients in Sub-lay mesh repair group, ($P=0.227$). In on-lay mesh repair group seroma was seen in 4(13.3%) patients as compare to 1(3.3%) patient in Sub-lay mesh repair group, ($P=0.161$). (Table-I) Further evaluation of wound infection with regard to age showed 20% infection seen in Group-A under 30 years of age in comparison in Group-B 16.7% of wound infection was noted above 30 years of age which is not that significant

whereas, hematoma was significantly seen more under 30 years of age (10% in group-A and 50% in group-B). Seroma formation was significantly seen in Group-A regardless of age.

In both group 26.7% patients were diabetics, and amongst them 25% in Group-A diabetic patients had wound infection and hematoma whereas, 50% of diabetic patients in Group-B showed wound infection and hematoma. In comparison seroma formation was significantly seen in 50% diabetic patients of Group-A but 0% in Group-B, which signifies that this comorbidity has no significant impact on Group-B.

Table – I: Comparison of Complication in both groups (N=60)

	Group A (n=30)	Group B (n=30)	P-Value
Wound infection	2(6.7%)	4(13.3%)	0.389
Hematoma	2(6.7%)	5(16.7%)	0.227
Seroma	4(13.3%)	1(3.3%)	0.161

Table – II: Stratification of complication with respect to following variables in Group A and Group B

Complication	Variables	Group	Yes	No	p- value
Wound Infection	Age 12 - 30	A	2(20%)	8(80%)	0.241
		B	0(0%)	6(100%)	
	Age 31- 50	A	0(0%)	20(100%)	0.055
		B	4(16.7%)	20(83.3%)	
	Diabetes	A	2(25%)	6(75%)	0.301
		B	4(50%)	4(50%)	
	ASA I	A	0(0%)	21(100%)	0.166
		B	2(8.7%)	21(91.3%)	
Hematoma	Age 12 -30	A	1(10%)	9(90%)	0.073
		B	3(50%)	3(50%)	
	Age 31- 50	A	1(5%)	19(95%)	0.662
		B	2(8.3%)	22(91.7%)	
	Diabetes	A	2(25%)	6(75%)	0.301
		B	4(50%)	4(50%)	
	ASA I	A	0(0%)	21(100%)	0.166
		B	2(8.7%)	21(91.3%)	
Seroma	Age 12 -30	A	2(20%)	8(80%)	0.241
		B	0(0%)	6(100%)	
	Age 31 - 50	A	2(10%)	18(90%)	0.444
		B	1(4.2%)	23(95.8%)	
	Diabetes	A	4(50%)	4(50%)	0.000
		B	0(0%)	22(100%)	
	ASA I	A	4(19%)	17(81%)	0.124
		B	1(4.3%)	22(95.7%)	
	ASA II	A	0(0%)	9(100%)	1.000
		B	0(0%)	7(100%)	

Table – III: Stratification of Complication with respect to duration of complain and duration of procedure in Group A and Group B

Variables	Duration	Group	Yes	No	p-Value
Duration of wound infection symptoms	For 7-12 months	A	2(7.7%)	24(92.3%)	0.246
		B	3(20%)	12(80%)	
	For > 12 months	A	0(0%)	4(100%)	0.595
		B	1(6.7%)	14(93.3%)	
Wound infection in relation to procedure duration	For ≤ 90 minutes	A	0(0%)	9(100%)	0.286
		B	3(11.5%)	23(88.5%)	
	For > 90 minutes	A	2(9.5%)	19(90.5%)	0.382
		B	1(25%)	3(75%)	
Hematoma with respect to duration of complain	For 7-12 months	A	2(7.7%)	24(92.3%)	0.557
		B	2(13.3%)	13(86.7%)	
	For > 12 months	A	0(0%)	4(100%)	0.329
		B	3(20%)	12(80%)	
Hematoma with respect to duration of procedure	For ≤ 90 minutes	A	0(0%)	9(100%)	0.155
		B	5(19.2%)	21(80.8%)	
	For > 90 minutes	A	2(9.5%)	19(90.5%)	0.519
		B	0(0%)	4(100%)	
Seroma with respect to duration of complain	For 7-12 months	A	3(11.5%)	23(88.5%)	0.612
		B	1(6.7%)	14(93.3%)	
	For > 12 months	A	1(25%)	3(75%)	0.046
		B	0(0%)	15(100%)	
Seroma with respect to duration of procedure	For ≤ 90 minutes	A	1(11.1%)	8(88.9%)	0.084
		B	0(0%)	26(100%)	
	For > 90 minutes	A	3(14.3%)	18(85.7%)	0.592
		B	1(25%)	3(75%)	

ASA-I Grade was 70% in Group-A and 76.7% in Group-B while ASA II was 30% in Group-A and 23.3% in Group-B. On estimating wound infection and hematoma with respect to ASA grade, it showed that patients in Group-A 0% wound infection and hematoma but 19% seroma formation in ASA Grade-I and 22.2% of wound infection and hematoma in ASA Grade-II comparing with Group-B, ASA Grade-I had 8.7% wound infection and hematoma respectively but seroma formation was much less only one patient had it (4.3%) and in ASA Grade -II 28.6% patients had wound infection and 42.9% had hematoma formation.

All three complications were evaluated in relation to duration of primary complain for which surgical intervention took place and the impact of duration of surgical intervention was also reviewed as shown in Table- II.

DISCUSSION

Literature review shows that numerous studies have been conducted to understand the hernia mechanism and the methods of repair. All these studies have stressed on managing hernia defects as a part of generalized abdominal wall disorders. After repair, the patient's assessment, reveals that different predisposing factors are responsible for herniation either primary or secondary ventral hernia. These factors most commonly include obesity, anaemia, wound infection, inadequate local fascial and muscular layers due to prior tissue loss, muscle denervation or vascular insufficiency due to prior irradiation, sepsis, chronic pulmonary disease, malnutrition,

corticosteroid dependency, and/or current malignant process^{6,10}.

Intra-abdominal surgeries are increasing continuously during last decades. Incisional hernia has become a frequently encountered surgical complication all over the world, leading to a high morbidity and mortality in affected individuals¹⁰. In USA alone, almost two million abdominal surgeries were performed each year and among them almost 100 000 incisional hernias were reported annually¹¹.

Clinically, incisional hernia usually asymptomatic, and presents with a painless swelling or bulge in operation scar or occasionally as a discomfort or painful swelling over incision scar. The pain is the most commonly reported in small hernia defects. The defect increases gradually in size with time and sometime presented with serious complications like gut obstruction, strangulation or perforation. Usually, almost 50% of the incisional hernias are detected in first two years after first surgery. Some time they may also be detected many years after surgery¹²⁻¹⁴.

As prosthetic mesh placement in subcutaneous plane (on-lay technique) is the most frequently practiced method of hernia repair. It is also associated with many complications and disadvantages, like wound infection, seroma formation, and prolonged drainage of pus or seroma which leads to prolonged hospital stay of the patients¹⁵. Among these complications, the wound Infection is one of the most common complications of this technique. Stoppa reported an infection rate of 12%¹⁶ while White et al has reported 6% of wound infection after this technique¹⁷. In our study in on-lay mesh repair group wound

infection was seen in 6.7% patients as compare to 13.3% patients in sub-lay mesh repair group, ($P=0.389$). In on-lay mesh repair group hematoma was observed in 6.7% patients as compare to 16.7% patients in sub-lay mesh repair group, ($P=0.227$). similarly, in on-lay mesh repair group seroma was seen in 13.3% patients as compare to 3.3% patients in sub-lay mesh repair group, ($P=0.161$). But all these cases were having mild superficial infection, which was treated conservatively without any surgical intervention. There is no strong clarification to this relatively high incidence of wound infection in a procedure characterized as clean surgery.

In a study by Saeed et al, has observed that the frequency of wound infection almost 5%, Hematoma formation up to 5% and seroma formation among 7.5% of patients in on-lay method as compare to wound infection by 10% Hematoma 12.5% and seroma was none in sub-lay repair technique⁸. In another study by Leithy and his associate, has reported that the frequency of wound infection up to 40% and seroma formation among 40% of patients in on-lay repair as compare to 6 % wound infection and seroma formation in sub-lay method⁹. In another study Aoda and colleagues, the wound infection is reported by 4% and seroma formation by 24% in on-lay repair group as compare to 4% wound infection and 2% seroma formation in sub-lay repair group¹⁰. Nevertheless, the placement of the mesh in the subcutaneous plane, the fact that the patients who are commonly obese, the extended subcutaneous drainage and the buildup of seroma may exemplify reasonable explanations¹⁸ while in sub-lay repair technique this complication is relatively less common.

The second frequently reported complication in mesh hernia repair is seroma formation. The frequency of seroma formation in on-lay mesh repair technique is inconstant as reported in literature. In our study, the post-operative seroma collection is almost inconsistent with the frequency as reported by White et al in his patients¹⁷.

In view of the detriments of the on-lay repair, the placement of the mesh in the retro-muscular plain seems to be more rational and insolent substitute. Firstly, this plane is highly vascular, therefore there are less chance of infection, and if any infection took place in the subcutaneous plane, it will less likely to disturb the mesh, as the mesh is placed in the retro-muscular plan which is located deeply¹⁹. Secondly, the mesh in this plane is least likely to be ruptured or displaced by intra-abdominal pressure, but rather it is held in situ by the same or similar force which was responsible for hernia formation and, the leads to adherence of mesh timely to the rectus sheath posteriorly and reduces it in-extensible, permitting no further herniation. Finally, the retro muscular space is anatomical plane which is existed already, it demands no tissue dissection, so there is no bare posterior rectus muscle surface but it is rich in lymphatics which is capable to absorb any collecting seroma. In addition, the mean operative time is much shorter in the sub-lay mesh placement technique (78.766 ± 11.91 min) as compared to the on-lay mesh placement technique (98.533 ± 14.46 min), by avoiding the three important steps which are essentially important during on-lay mesh repair technique ie dissection of large subcutaneous flaps, hemostasis after dissection and mesh fixation.

CONCLUSION

There was no significant difference regarding post-operative complications with on-lay mesh method and Sub-lay mesh method in repair of incisional hernia with acceptable complication rates and both the methods are compatible.

AUTHOR'S CONTRIBUTION

Magsi AM: Conceived idea, Designed methodology, Literature review, Manuscript writing

Malik M: Manuscript writing, Data analysis, Statistical Analysis Final review of manuscript.

Anwar K: Data collection and analysis

Rafi AU: Literature review, Manuscript writing, Final proof reading

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