

Efficacy and safety between sublay and onlay mesh repair for para-umbilical hernia in Mardan Medical Complex, Mardan

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Abstract

Objective: To compare the efficacy and safety between sublay and onlay mesh repair for para-umbilical hernia.

Setting: Surgical Department, Mardan Medical Complex, Mardan from June 2017 to May 2019

Study design: Randomized controlled trial

Material and Methods: In this study a total of 126 (63 in each group) patients were observed. The patients were randomly allocated in two groups by lottery method. Patients in group-A was subjected to Sublay mesh repair procedure and patients in group-B was subjected to Onlay mesh repair procedure for para-umbilical hernia repair. Post-operatively all patients were kept under observations for 2-4 days in ward and observed for complications by an expert general surgeon. Post-operatively all patients were followed at 10 days, 3 months and 6th month to confirm efficacy and safety of the procedure.

Results: The mean age of patients in Group-A was 30 years \pm 2.16 and 32 years \pm 3.71 in Group-B. In group-A 48% patients were male and 52% patients were female where as in group-B 45% patients were male and 55% patients were female. More over Sublay mesh repair was effective in 82% patients on the bases of recurrence while this procedure was safe in 90% cases on the bases of complications where as onlay mesh repair was effective in 90% patients cases on the bases of recurrence while this procedure was safe in 93% cases on the bases of complications.

Conclusion: Onlay mesh repair technique is more effective, quick and safe as compared to sublay mesh repair technique for the treatment of para-umbilical hernia.

Keywords: Efficacy, safety, sublay, onlay mesh repair, para-umbilical hernia

Introduction:

Para-umbilical hernia is a protrusion of the intestines or gut through a weak point of the muscles or ligaments in the linea alba near the navel, either superiorly or inferiorly.¹ This form of hernia along with incisional hernias constitutes about 85% of the overall ventral abdominal hernias.² These hernia sacs contain gut loops, omentum or pre-peritoneal fats. If the neck of the sac is narrow there are chances of complications like obstruction strangulation or gangrene.²⁻⁴

Mainstay of hernia treatment is surgical repair. There are different techniques of paraumbilical

hernia repair. Most popular are Mayo's, onlay, sublay and inlay mesh repair. Repair of para-umbilical hernia was previously performed by the suture technique (Keel or Mayo's). Nowadays suture repair is carried out when the defect in abdominal is less than 2 cm. But it has a high recurrence rate almost 19% - 54%.³⁻⁵

Defects in para-umbilical hernias up to 2 cm in diameter could be sutured primarily. For defects larger than 2 cm in diameters, mesh repair is recommended.⁶ There are different methods of mesh repair all of them use same principal of tension free mesh repair. The main difference is

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on the basis of anatomical site of mesh placement.⁷ In all these techniques onlay, sublay and inlay are more commonly used due to the ease of procedures. Inlay mesh repair is less frequently used because of mesh – bowel contact associated with serious complications such as chronic pain obstruction and enterocutaneous fistula formation. The choice these days largely rests between onlay and sublay procedures. Mesh repair has lower rates of recurrence as compared to suture repair 2.7% and 8.2%.⁶

In the past, these hernias were treated by tension free suture which resulted in a high rate of recurrence and this led to the reduction in its popularity.⁸ The use of mesh to repair the hernia defect either open or laparoscopic is widely used now a day. A tension free mesh technique has drastically reduced the recurrence rates for all kinds of hernia compared to tissue repair.⁹ Several factors have been implicated for recurrence after PUH repair; large seroma and surgical site infection are classical complications that may result in recurrence. Obesity and excessive weight gain following repair are other factors.^{10,11}

Sublay mesh repair technique is recently practiced in our department though there is enough study on comparison of these two procedures but no such local data is available the aim of this study is to see the efficacy and effectiveness of onlay and sublay mesh repair for para-umbilical hernia at tertiary care hospital Mardan. The results of this study will be shared with other general surgeons.

Material and methods:

An RCT was conducted at surgical department of Mardan Medical College Teaching Hospital (MMCTH) Mardan over a period of 2 years from June 2016 to May 2018. After approval from hospital ethical committee, a total of 126 consecutive patients with paraumbilical hernia admitted in surgical unit, of age between 15-65 years and either gender were included in the study. Patients of age group above 65 years, hernial defect size less than 4 cm, recurrent hernia, obstructed/strangulated hernias on clinical examination, with debilitating diseases like COPD

and chronic liver, renal or cardiac impairment (diagnosed on the basis of medical records and history) were excluded from the study.

All the patients were selected through non-probability consecutive technique. Patients were included in the study after taking informed and written consent. Detailed history and thorough examination and relevant investigations of the patients were done. Exclusion criteria were strictly followed to reduce bias in the study. The patients were randomly allocated in two groups by lottery method. Patients in group-A was subjected to Sublay mesh repair procedure and patients in group-B was subjected to onlay mesh repair procedure for para-umbilical hernia repair without being informed about the type of procedure. The respective mesh repair procedure (onlay mesh repair for group-B and sublay mesh repair for group-A) was applied to patients of relevant group under the supervision of single expert consultant surgeon. Post-operatively all patients were kept under observations for 2-4 days in ward and observed for complications (seroma, hematoma, surgical site infection) by an expert general surgeon, who were unaware about the type of procedure performed on the patient. Post-operatively all patients were followed at 10 days, 3rd month and 6 months to confirm efficacy and safety of the procedure.

All the data was recorded on a standardized proforma. Bias and confounders in the study were controlled by strictly following the exclusion criteria. The data was analyzed with the help of computer software SPSS for windows version 16.0. Frequencies and percentages were calculated for categorical variables like gender, efficacy and safety. Mean± SD was calculated for numerical variables like age. Chi-Square test was used to compare the efficacy and safety in both the groups. P value of < 0.05 was considered significant. Efficacy and safety in both groups was stratified among the age and gender to see the effect modifiers. All the results were presented as tables and charts.

Results:

In this study age distribution among two groups

Table 1: Age distribution (n=126)

Age	Sublay group (n=63)	Onlay group (n=63)
21-30 years	14(22%)	13(20%)
31-40 years	22(35%)	22(35%)
41-50 years	19(30%)	19(30%)
51-65 years	8(13%)	9(15%)
Total	63(100%)	63(100%)
Mean and SD	30 years \pm 2.16	32 years \pm 3.71

Student T test was applied to compare mean in which P was 0.0003

Table 2: Gender distribution (n=126)

Age	Sublay group (n=63)	Onlay group (n=63)
Male	30(48%)	28(45%)
Female	33(52%)	35(55%)
Total	63(100%)	63(100%)

Chi Square test was applied in which P value was 0.7207

Table 3: Complications of Sublay and Onlay mesh repair for para umbilical hernia (n=126)

Complications		Sublay group (n=63)	Onlay group (n=63)	P value
Seroma	Yes	3(5%)	2(3%)	0.6481
	No	60(95%)	61(97%)	
Total		63	63	
Hematoma	Yes	4(6%)	1(2%)	0.1710
	No	59(94%)	62(98%)	
Total		63	63	
Wound infection	Yes	6(10%)	4(7%)	0.5098
	No	57(90%)	59(93%)	
Total		63	63	
Recurrence	Yes	11(18%)	6(10%)	0.1923
	No	52(82%)	57(90%)	
Total		63	63	

Table 4: Efficacy of sublay and onlay mesh repair for para-umbilical hernia (n=126)

Efficacy	Sublay group (n=63)	Onlay group (n=63)	P value
Effective	52(82%)	57(90%)	0.1923
Not Effective	11(18%)	6(10%)	

Table 5: Safety of sublay and onlay mesh repair for para umbilical hernia (n=126)

Safety	Sublay group (n=63)	Onlay group (n=63)	P value
Yes	57(90%)	59(93%)	0.5098
No	6(10%)	4(7%)	

was analyzed as in group-A 14(22%) patients were in age range 21-30 years, 22(35%) were in age range 31-40 years and 19(30%) were

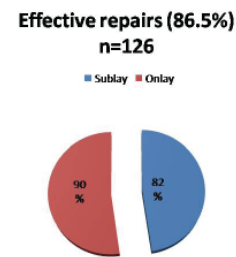


Figure 1: Graphical representation of effective repairs in sublay versus onlay repair groups

in age range 41-50 years, 8(13%) were in age range 51-65 years. Mean age was 30 years with standard deviation \pm 2.16 in group-B. In group-A 13(20%) patients were in age range 21-30 years, 22(35%) were in age range 31-40 years and 19(30%) were in age range 41-50 years, 9(15%) were in age range 51-65 years. Mean age was 32-years with standard deviation \pm 3.71 as shown in table-1.

Gender distribution among two groups was analyzed as in group-A 30(48%) patients were male and 33(52%) patients were female where as in group-B 28(45%) patients were male and 35(55%) patients were female as shown in table- 2.

Complication between two groups was analyzed as in group-A 3(5%) patients had seroma, 4(6%) patients had hematoma and 6(10%) patients had wound infection while the recurrence rate was 11(18%) where as in group-B 2(3%) patients had seroma, 1(2%) patients had hematoma and 4(7%) patients had wound infection while the recurrence rate was 6(10%) as shown in table-3.

Efficacy and safety of two groups was analyzed as group-A (Sublay mesh repair) was effective in 52(82%) patients on the bases of recurrence while this procedure was safe in 57(90%) cases on the bases of complications where as group-B (onlay mesh repair) was effective in 57(90%) patients cases on the bases of recurrence while this procedure was safe in 59(93%) cases on the bases of complications as shown in table-4 and 5.

Table 6: Stratification of efficacy w.r.t age

Age	Efficacy	Sublay group (n=63)	Onlay group (n=63)	P value
21-30 years	Effective	12	12	0.5860
	Not effective	2	1	
Total		14	13	
31-40 years	Effective	18	20	0.3796
	Not effective	4	2	
Total		22	22	
41-50 years	Effective	15	17	0.3736
	Not effective	4	2	
Total		19	19	
51-65 years	Effective	7	8	0.9293
	Not effective	1	1	
Total		8	9	

Table 7: Stratification of efficacy w.r.t gender

Gender	Efficacy	Sublay group (n=63)	Onlay group (n=63)	P value
Male	Effective	25	25	0.5112
	Not effective	5	3	
Total		30	28	
Female	Effective	27	32	0.2425
	Not effective	6	3	
Total		33	35	

Table 8: Stratification of safety w.r.t age

Age	Safety	Sublay group (n=63)	Onlay group (n=63)	P value
21-30 years	Yes	13	12	0.9566
	No	1	1	
Total		14	13	
31-40 years	Yes	20	21	0.5498
	No	2	1	
Total		22	22	
41-50 years	Yes	17	18	0.5475
	No	2	1	
Total		19	19	
51-65 years	Yes	7	8	0.9293
	No	1	1	
Total		8	9	

Table 9: Stratification of safety w.r.t gender

Gender	Safety	Sublay group (n=63)	Onlay group (n=63)	P value
Male	Yes	27	26	0.6985
	No	3	2	
Total		30	28	
Female	Yes	30	33	0.5939
	No	3	2	
Total		33	35	

Stratification of efficacy and safety with respect to age and gender is given in table no 6,7,8,9.

Discussion:

Ventral hernia in the anterior abdominal wall includes both spontaneous and, most commonly, incisional hernias after an abdominal operation. It is estimated that 2 to 10% of all abdominal operations result in an incisional hernia. Small hernias less than 2 ½ cm in diameter are often successfully closed with primary tissue repairs. However, larger ones have a recurrence rate of upto 30-40% when a tissue repair alone is performed.^{7,8} Hernia recurrence is distressing to patient and embarrassing to surgeons. Now-a-days tension free repair using prosthetic mesh has decreased recurrence to negligible. Despite excellent results increased risk of infection with placement of a foreign body and cost factor still exist; however, operating time and hospital length of stay are shortened. Primary tissue repair is associated with higher unacceptable recurrence rate, now-a-days; tension free mesh repair is ideal hernia repair technique.⁹

Our study shows that in onlay mesh repair 3% patients had seroma, 2% patients had hematoma and 7% patients had wound infection while the recurrence rate was 10%. Where as in sublay group 5% patients had seroma, 6% patients had hematoma and 10% patients had wound infection while the recurrence rate was 18%. Similar results were coted by Winker MS et al in which complication in onlay mesh repair 5% patients had seroma, 3% patients had hematoma and 12% patients had wound infection while the recurrence rate was 13%. Where as in sublay group 7% patients had seroma, 8% patients had hematoma and 20% patients had wound infection while the recurrence rate was 20%.¹⁰

Our results shows that onlay mesh repair was effective in 90% patients and was not effective in 10% cases on the bases of recurrence while this procedure was safe in 93% cases on the bases of complications. On the other hand sublay mesh repair was effective in 82% patients and was not effective in 18% cases on the bases of recurrence while this procedure was safe in 90% cases on

the bases of complications. Similar results were observed in study done by Weber G et al and Godara R et al as onlay mesh repair was effective in 88% patients and was not effective in 12% cases on the bases of recurrence while this procedure was safe in 87% cases on the bases of complications. On the other hand sublay mesh repair was effective in 80% patients and was not effective in 20% cases on the bases of recurrence while this procedure was safe in 81% cases on the bases of complications.^{10,11}

The mean total time taken for the operation in “sublay” groups was 63.15 ± 15.0 mins compared with 49.35 ± 8.29 mins in ‘Onlay’ group and was found to be statistically significant ($P < 0.001$). The difference of time can be accounted due to more dissection time needed for creating preperitoneal space. Securing reasonable hemostasis is another burden on time. Ease of operation is largely subjective (surgeon factor being constant) and depends on individual surgeon’s experience, exposure and planning, quality of assistance, conductive facilities like light, cautery, instruments quality and sutures etc. Keeping all these factors constant, a subjective gradation on a scale of 1 – 10 would give fair degree of idea of difficulty in a particular operation with regard to onlay and sublay placement of mesh. In our study ease of operation of either group was found statistically insignificant ($p > 0.05$) suggesting that fair degree of experience, meticulousness and gentleness of sublay or onlay placement should be equal in terms of skill.

Apart from recurrence other post-operative complications like seroma formation, hematoma, cellulitis, wound infection attributed largely to extensive dissection and tissue handling during hernia repair. In our study no significant difference in these complications in either group was found except that there was slightly more chances of seroma formation in sublay groups which may be due to extensive tissue dissection and increased blood loss. Duration of hospital stay give us an indirect indication of degree of morbidity in terms of post-operative complication. The mean duration in sublay groups was 6.8 days compared to 4.6 days in onlay group

and were found to be statistically significant ($p < 0.001$). The information was obtained during follow up as how long it took each one of them to return to their routine activities. It was observed that time off work in sublay group was 4.48 wks compared to 2.87 wks in onlay group, the difference was found to be statistically significant ($p < 0.05$). On two year follow up no recurrence was found in either group, similar results were also observed by others. In fact as per literature, the best position for inserting the material has not been conclusively established; but limited studies have shown that meshes implanted on the abdominal aponeurotic layer showed better and early incorporation (higher collagen deposition, capillary density and cell accumulation) and increased tensile strength reflecting tighter anchorage to the abdominal wall.^{12,13} One European study has shown that onlay technique had significantly more complications as compared to other technique but we have not found such results in our study.¹⁴⁻¹⁶ Thus it can be safely said that based on above parameters onlay is a better technique than sublay in terms of placement & overall convenience. There is paucity of literature but an experimental study has also shown superiority of onlay technique based on different parameters. However in few studies it was found that ideal position for mesh repair appears to be retromuscular, where the force of abdominal pressure holds the prosthesis against deep surfaces of muscles.¹⁶ Even after long term follow up, recurrence rates around 10% are possible.^{7,17,18} This is all the more necessary as the world literature is scanty and there is great interest in hernia surgery using mesh these days.

Conclusion:

Our study concludes that onlay mesh repair technique was more effective, quick and safe as compared to sublay mesh repair technique for the treatment of para-umbilical hernia

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Role and contribution of authors:

Dr. Muhammad Ismail, collected the data, r efer-

ences and did the initial writeup.

Dr. Shahid Khan, collected the data and helped in interpretation of the data.

Dr. Mukhtiar Ali, critically review the article and made useful changes.

Dr. Bayazeed, collected the data and helped in discussion writing

Dr. Asif Imran, collected the data, references and critically rreview the article

Dr. Abbas Ali, collected the references and helped in result writing.

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