

COMPARISON OF ONLAY VERSUS SUBLAY MESH REPAIR FOR VENTRAL ABDOMINAL HERNIAS. A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Objective: To compare onlay versus sublay mesh repair for ventral abdominal hernias in terms of mean operative time, frequency of post-operative wound infection, seroma formation and hematoma formation.

Study Design: Randomized controlled trial.

Place and Duration of Study: Department of General Surgery, Pak Emirates Military Hospital Rawalpindi, from Apr 2017 to Dec 2017.

Material and Methods: A total of 78 patients (39 in each group) diagnosed as a case of ventral abdominal hernia meeting the inclusion and exclusion criteria were included in the study. Patients with complicated hernias, recurrent hernias and bleeding disorders were excluded. Group-A patients underwent mesh repair by the onlay method while group-B patients underwent mesh hernioplasty via the sublay technique. All patients were followed for wound infection, seroma formation and hematoma formation. Data was analyzed by SPSS ver. 23.0.

Results: The mean operation time in group A was 46.10 ± 7.25 minutes while in group B, the mean operation time was 77.82 ± 9.97 minutes ($p < 0.001$). The frequency of wound infection was 5.13% vs 0% ($p = 0.49$) and hematoma formation was 5.13% vs 7.69% ($p = 0.999$) between the two groups respectively which were statistically insignificant. However, seroma formation between the two groups was 23.08% vs 5.13%, which was statistically significant ($p = 0.023$).

Conclusion: Sublay mesh repair for ventral hernias is better than onlay mesh repair for ventral abdominal wall hernias in terms of frequency of complications. However, it requires a longer operative time.

Keywords: Mesh Repair, Onlay, Sublay, Ventral Hernia.

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INTRODUCTION

Ventral hernia is an abnormal protrusion of an intra-abdominal viscus or a part of viscus through a defect in the abdominal wall. Ventral hernia repair is one of the commonest procedures performed worldwide with an estimated 300,000 procedures performed in Europe and 400,000 procedures performed in the United States annually¹. They can be congenital or acquired. Studies have reported prevalence rates between 3.7%-28% in patients undergoing various abdominal surgeries^{2,3}. Surgery is the main stay of treatment since the natural history of hernia is progressive. i.e. Hernia can increase in size, cause pain and discomfort or they may lead to complications like obstruction, incarceration and

strangulation of bowel¹. Hernia surgery has evolved over time. Notable contributors include Bassini with first repair of inguinal hernia in 1884, Bourret designed the first nylon prosthetic mesh in 1948, replaced by prolene by Usher in 1963. Further contributions from Rives, Stoppa, and Wantz improved the technique. Lichtenstein's tension-free repair of was introduced in 1986⁴. Leblanc and Booth in 1993 described the first laparoscopic repair of ventral hernia⁵. Although laparoscopic repair has gained popularity worldwide, it is not widely available in our country. Hence open mesh repair is the most widely practiced technique for ventral hernia repair⁶. Various techniques have been introduced for placement of prolene mesh in ventral hernias. They include onlay repair in which mesh is placed in the subcutaneous plane above the anterior rectus sheath or external oblique; inlay repair in which mesh is sutured to

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the hernial neck; sublay repair in which mesh is placed in the retromuscular layer above the posterior rectus sheath, preperitoneal repair in which mesh is placed between the peritoneum and posterior rectus sheath and intraperitoneal repair in which mesh is placed from inside the peritoneal cavity and fixed to anterior abdominal wall⁷. Onlay and sublay techniques are most commonly applied techniques for ventral hernia repair in our setups. The number of local studies on this topic are limited with onlay technique being more commonly employed by most surgeons because of shorter operation time however it is associated with higher incidence of complications. Therefore we conducted this study with the objective of comparing onlay versus sublay mesh repair for ventral abdominal hernias in terms of mean operative time, frequency of post-operative wound infection, seroma formation and hematoma formation. The findings of this study will help establish local evidence based practices for our setups.

MATERIAL AND METHODS

We conducted a randomized controlled trial from Apr 2017 to Dec 2017 in the Department of Surgery, Pak Emirates Military Hospital Rawalpindi on patients diagnosed as cases of ventral abdominal hernia who fulfilled the sample selection criteria after approval from ethical review committee of Pak Emirates Military Hospital, Rawalpindi. A written informed consent was taken from every patient included in the study. The sample size was calculated by using the WHO sample size calculator with Power of test (1-β)=95%, Level of significance (α)=5%, population SD (σ)=41, population variance (σ²)=1681, test value of population mean=124.5 minutes and anticipated population mean=155.1 minutes (operation time)⁸. The sample size was calculated as 39 ± 39 = 78 patients. The sampling technique was non-probability consecutive sampling. The inclusion criteria included patients of both genders with uncomplicated ventral abdominal hernias between 20-70 years of age and ASA class I to III. The exclusion criteria included patients with complicated hernias

(irreducible, obstructed or strangulated), ASA class IV & V, recurrent hernias, renal failure and coagulopathies. Patients were randomly divided into two equal groups (group A and B) consisting of 39 patients each by lottery method. Group-A patients underwent mesh repair of ventral hernia by onlay technique while group-B patients underwent mesh repair of ventral hernia by sublay technique. In group A, the mesh was placed above the rectus sheath. The defect was closed primarily by prolene 1/0 suture followed by placement of prolene mesh. The mesh was placed such that it extended 3-4 cm beyond the edges of the defect and is not merely sewn to the hernia edges. In group B, mesh was placed broadly under the defect in the retro muscular layer of abdominal wall posterior to the rectus muscles and anterior to the posterior rectus sheath. The

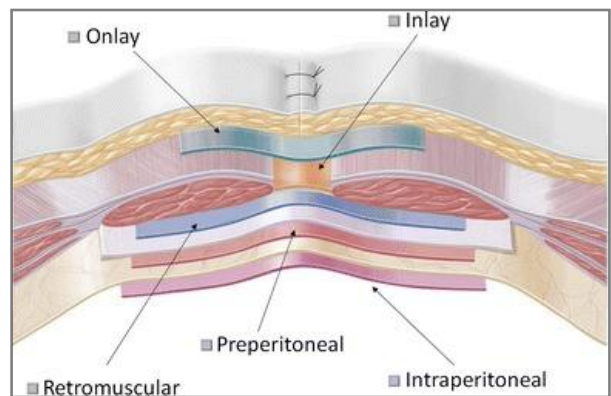


Figure-1: Different mesh repair positions for ventral hernia.© Muysoms et al¹⁸.

mesh was placed such that it extended 3-4 cm beyond the edges of the defect and is not merely sewn to the hernia edges. The contact between intestines and mesh is avoided by the posterior rectus sheath and the layer of peritoneum that lies under the mesh. All the operations were carried out under general anesthesia and prophylactic antibiotic dose of injection (Amoxi-cillin/Clavulanic Acid) 1.2 grams intravenous was given at the time of induction of anesthesia. Redi-vac™ suction drain was placed in all patients after the surgery. Post-operatively patients were discharged on 2nd post-operative day with removal of drain and they were followed in outpatient department on 14th and 28th post-

operative days. Drain was removed if the output was less than 20 ml in 24 hours. Operation time (in minutes) of every operation was recorded for comparison among the groups. It was measured in minutes from time of incision till the application of last stitch at the end of operation. All patients were followed for wound infection (Development of post-operative fever, incision site redness and tenderness, wound discharge and wound abscess was labelled as wound infection), seroma formation (Collection of pocket of clear serous fluid developing after hernia

recorded in terms of frequency percentage. Chi square test was applied for qualitative variables. Independent sample t-test was applied for quantitative variables. A *p*-value of ≤ 0.05 was considered as significant.

RESULTS

A total of 78 patients were included in the study and were divided into two groups of 39 patients each. The patients included 73 females (93.59%) and 5 males (6.41%). Female to male ratio was 14.6:1. The mean age of patients was

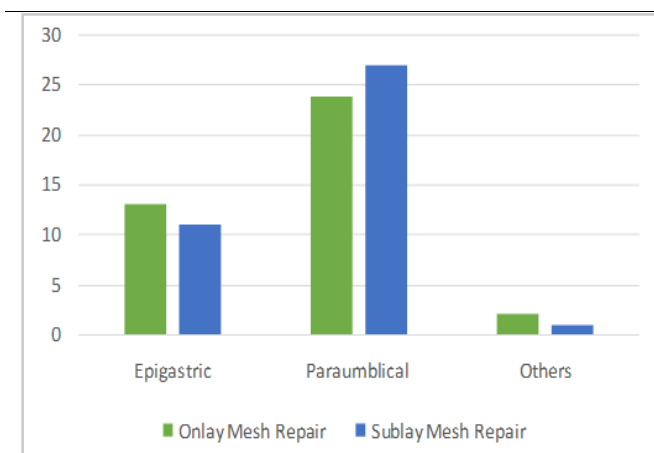


Figure-2: Hernia location.

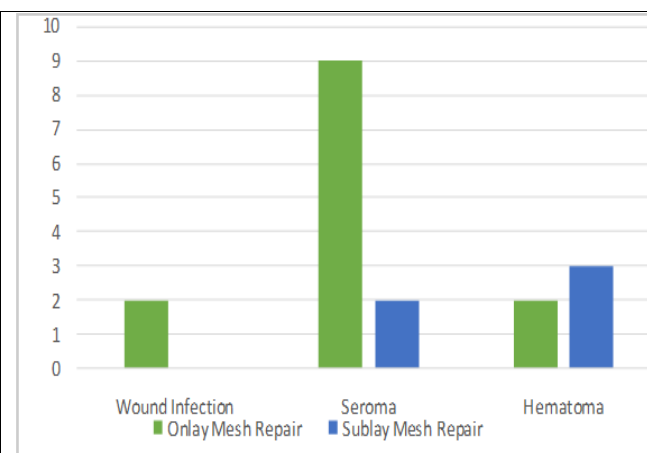


Figure-3: Complications.

Table: Summary of Results.

	Group A (n=39)	Group B (n=39)	<i>p</i> -value
Gender (M:F)	2 (5.13%): 37 (94.87%)	3 (7.69%): 36 (92.31%)	0.999
Age [years]	40.95 ± 9.6	42.95 ± 8.6	0.336
Operation time min	46.10 ± 7.25	77.82 ± 9.97	<0.001
Complications	13 (33.33%)	5 (12.82%)	0.032
Wound Infection	2 (5.13%)	0 (0%)	0.49
Seroma	9 (23.08%)	2 (5.13%)	0.023
Hematoma	2 (5.13%)	3 (7.69%)	0.999

repair) and hematoma formation (localized collection of blood outside the blood vessels, due to trauma to blood vessels during surgery). All the patients will be followed on 1st, 2nd, 14th and 28th postoperative days for wound infection. Follow up was ensured by taking contacts of patients. Data was analyzed using SPSS version 23.0. Mean and SD was calculated for quantitative variables like age and operation time. Qualitative variables like wound infection, seroma formation and hematoma formation were

41.95 ± 9.11 years (range 28-65 years). Mean age was 40.95 ± 9.6 years (range 28-65 years) for patients in onlay mesh repair group and 42.95 ± 8.6 years (range 34-64 years) for sublay mesh repair group. Out of 78 patients, 24 (30.77%) had epigastric hernia, 51 (65.38%) had paraumbilical hernia and 3 patients (3.85%) were cases of other types, i.e. 2 cases of umbilical and 1 case of incisional hernia (fig-2). In group A, the mean operation time was 46.10 ± 7.25 minutes (range 34-65 minutes) while in group B, the mean

operation time was 77.82 ± 9.97 minutes (range 56-98 minutes). The operative time between the two groups was statistically significant ($p < 0.001$). Complications were observed in 13 patients (33.33%) in onlay group versus 5 patients (12.82%) in sublay group (fig-3). The p -value with regard to complications between the two groups was statistically significant ($p = 0.032$). There were 2 cases (5.13%) of surgical site infection in group A which were managed conservatively by intravenous antibiotics. There was no wound infection in group-B. The difference between the two groups was statistically insignificant ($p = 0.49$). The most common complication observed was seroma formation in 11 patients (14.10%) included in the study. Seroma formation occurred in 9 patients in group A (23.08%) versus 2 patients (5.13%) in group B. The difference being statistically significant ($p = 0.023$). Seroma cases were managed by opening of the wound under local anesthesia, drainage of seroma, insertion of a tube drain and closure of wound. Drains were kept until the drain output became less than 20 ml in 24 hours. There were 2 cases (5.13%) of hematoma formation in onlay mesh repair group versus 3 cases (7.69%) in sublay mesh repair group. The hematoma formation between the two groups was statistically insignificant ($p = 0.644$). The results have been summarized in table below.

DISCUSSION

Most of our patients were females because of the entitlement of families of serving persons of Pakistan Army in Pak Emirates Military Hospital, Rawalpindi. In our randomized controlled trial, 73 (93.59%) out of 78 patients were female. The mean age of patients was 41.95 ± 9.11 years. A similar study by Gondal *et al* from Lahore, Pakistan in 2012 reported a mean age of 40.07 ± 10.71 years while another study by Bessa *et al* in 2013 from Egypt found the mean age to be 38.2 ± 7.8 years in patients presenting for mesh repair with ventral abdominal wall hernias^{9,10}. The presentation in the western population is late with study from United States by Shahan *et al* reporting a mean age of 57.3 years¹¹. The mean

operation time in onlay group was 46.10 ± 7.25 minutes while in sublay group, the mean operation time was 77.82 ± 9.97 minutes. The combined mean operative time was 61.96 ± 18.16 minutes in our study. The results are comparable to the study by Sevinc *et al* in 2018 who reported that the operative time was significantly shorter in the onlay group (56.7 ± 15.7 minutes) versus the sublay group (73.9 ± 14.2 minutes) with $p < 0.001$ ¹². The combined mean operation time reported was 65.3 ± 17.2 minutes¹² studies have reported mean operative times ranging from 50.96 to 124.5 minutes for onlay repair and mean operative times ranging from 70.72 to 155.1 minutes for sublay repair^{8,13}. Complications were reported in 13 patients (33.3%) in onlay group and 5 patients (12.82%) in sublay group, the difference being statistically significant with $p = 0.032$. Demetrashvili *et al* reported a complication rate of 50.0% versus 22.1% in onlay versus sublay groups respectively with $p < 0.001$ ⁸. The seroma formation in the two groups was statistically significant in our study with $p = 0.023$. The results were in agreement with studies by Demetrashvili *et al* ($p = 0.0013$), Saeed *et al* ($p = 0.076$) and Ibrahim *et al* ($p = 0.010$)^{8,14,15}. However our results were contrary to the study by Bessa *et al* who reported that the seroma formation in both groups was statistically insignificant with $p = 0.494$ ¹⁰. Hematoma formation in both groups in our study was 5.13% and 7.69% between the two groups which was statistically insignificant ($p = 0.999$). Similarly Demetrashvili *et al* and Timmermans *et al* reported no significant difference between the two groups with $p = 1.0$ and $p = 0.19$ in the two studies respectively^{8,16}. Finally the wound infection in our study was statistically insignificant between the two groups with $p = 0.49$. Similar results were reported by Afzal *et al* ($p = 0.167$), Demetrashvili *et al* ($p = 0.44$) and Dhaigude *et al* ($p = 0.307$)^{6,8,10}. Contrary to this studies by Ibrahim *et al* ($p = 0.010$), Timmermans *et al* ($p = 0.05$) and Naz *et al* ($p = 0.04$) have reported a statistically significant difference between the two groups in terms of frequency of wound infection with sublay repair reported to be superior

technique¹⁵⁻¹⁷ Saeed *et al* reported that wound infection was more frequent in the sublay group with a statistically significant difference ($p=0.019$)¹⁴. Serious complications following ventral hernia repair are rare. It is pertinent to know the detailed medical history especially about the presence of chronic cough, constipation and urinary retention. Laparoscopic hernia repair has also gained popularity over the recent times but in a developing country like ours, the equipment is not available everywhere. Although the operative time is longer in sublay repair, it has been found to be the better technique in our study and can be a reasonable alternative to the commonly performed onlay method for repair of ventral abdominal hernias. Our study mainly comprised of female patients and covered short term complications occurring within a month after ventral hernia repair. Further research is required on the topic with bigger sample and to determine recurrence rates, long term morbidity and complications associated with ventral hernia repair.

CONCLUSION

Sublay mesh repair is a safe, reliable and effective technique for ventral abdominal hernias as compared to onlay mesh repair. The benefit associated with the lesser frequency of post-operative complications in sublay repair outweighs the longer operative time needed to perform the surgery.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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