

A RANDOMIZED CONTROL TRIAL TO EVALUATE THE EFFECTIVENESS OF ONLAY AND SUBLAY MESH REPAIR IN THE TREATMENT OF VENTRAL HERNIA

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Received : 27/01/2026

Received in revised form : 11/03/2026

Accepted : 31/03/2026

Keywords:

Postoperative complications, Ventral hernia, Sublay mesh, Onlay mesh, Seroma, Flap necrosis.

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DOI: 10.47009/jamp.2026.8.2.148

Source of Support: Nil,

Conflict of Interest: None declared

Int J Acad Med Pharm

2026; 8 (2); 796-801



ABSTRACT

Background: Onlay and sublay mesh placement are widely practiced techniques for open ventral hernia repair. The choice of mesh position has a direct impact on early postoperative outcomes such as seroma formation, wound infection, flap necrosis, postoperative pain, and duration of hospitalization. Existing evidence suggests that sublay mesh placement may be associated with lower early morbidity compared with the onlay technique. This study was undertaken to compare the effectiveness and safety of sublay versus onlay mesh repair in patients with ventral hernia.

Materials and Methods: This randomized controlled study included 80 patients undergoing ventral hernia repair at Aarupadai Veedu Medical College and Hospital, Puducherry. Participants were randomly allocated into two equal groups: onlay repair (n = 40) and sublay repair (n = 40). Preoperative demographic details, anthropometric measurements, hemodynamic parameters, and laboratory values were recorded. Operative duration, postoperative pain assessed using the Visual Analogue Scale (VAS), length of hospital stay, and complications such as seroma, surgical site infection, and flap necrosis were evaluated. Statistical analysis was performed using the independent t-test and chi-square test, with $p < 0.05$ considered statistically significant.

Results: Baseline characteristics were comparable between the two groups. The sublay group demonstrated significantly fewer intraoperative complications (0% vs. 17.5%, $p = 0.01$) and early postoperative complications (5% vs. 35%, $p = 0.01$). Wound discharge was observed only in the onlay group (17.5%, $p = 0.01$). Seroma formation at 48 hours was significantly lower with sublay repair (2.5% vs. 15%, $p = 0.05$), as was flap necrosis postoperatively (0% vs. 25%, $p = 0.01$). Although early postoperative VAS scores were similar, patients in the sublay group experienced faster pain resolution by 48 hours (7.5% vs. 25%, $p = 0.05$). The mean hospital stay was marginally shorter in the sublay group (3.1 vs. 3.5 days), though this difference was not statistically significant.

Conclusion: Sublay mesh repair provides superior early postoperative outcomes with reduced wound-related complications and faster pain recovery when compared to onlay repair, while operative time and hospital stay remain comparable. These findings support sublay mesh placement as the preferred approach for open ventral hernia repair.

INTRODUCTION

Hernias of the inguinal and ventral regions have been recognized since antiquity, with early descriptions found in the Ebers Papyrus (circa 1555 B.C.E.) and in the writings of Hippocrates of Kos (460–375 B.C.E.).[1] In contemporary surgical practice, ventral hernias constitute a significant clinical burden and represent one of the most frequently encountered

conditions managed by Surgeons. Surgical repair accounts for nearly 15–18% of all operative procedures, with incisional hernias being the most common long-term complication following midline laparotomy. The reported incidence of incisional hernia ranges from 3–13%, increasing to as high as 23% in certain populations.[2]

Ventral hernias may be congenital or acquired, and surgical intervention remains the definitive

treatment, as untreated hernias demonstrate a progressive course characterized by increasing size, pain, functional limitation, and potential complications such as obstruction or strangulation.[3] The advent of laparoscopic ventral hernia repair by LeBlanc and Booth in 1993 marked a major advancement; however, limited availability and resource constraints have restricted its widespread adoption in many regions, making open mesh repair the most commonly practiced technique.[4,5]

The position of mesh placement plays a crucial role in determining postoperative outcomes, including complications and recurrence. While several studies have shown comparable recurrence and infection rates between onlay and sublay techniques,[6] sublay mesh placement has been suggested to reduce seroma formation.[7] Hernia surgery has undergone continuous refinement over time, from Edoardo Bassini's landmark inguinal hernia repair in 1884 to the introduction of synthetic meshes by Bourret and subsequent modifications by Francis C. Usher.[8,9] Owing to the high recurrence rates associated with primary suture repair, tension-free mesh hernioplasty has become the standard of care. Improved understanding of anterior abdominal wall anatomy has further led to the evolution of mesh placement strategies, with onlay and sublay repairs emerging as preferred open techniques among surgeons.[4,10] The present study was undertaken to compare the effectiveness of onlay and sublay mesh repair in the management of ventral hernia.

MATERIALS AND METHODS

Written informed consent was obtained from all participants prior to enrolment. The study was designed as a randomized controlled trial conducted over a period of 18 months in the Department of General Surgery, Aarupadai Veedu Medical College and Hospital (AVMCH), Puducherry. Patients attending the outpatient and inpatient services of the department and diagnosed with ventral hernia were screened for eligibility. Adult patients above 18 years of age of either gender who underwent elective onlay or sublay mesh repair for ventral hernias, including incisional, supra-umbilical, and epigastric hernias, were included. Patients with recurrent hernias, obstructed or strangulated hernias were excluded. Peritonitis, groin hernias, pre-existing skin infection at the hernia site, immunosuppressive conditions such as diabetes mellitus, HIV, hepatitis, severe renal or hepatic failure, and advanced malignancy or ongoing cancer treatment were excluded from the study.

The sampling population consisted of patients aged between 18 and 70 years admitted to the general

surgery ward with a diagnosis of ventral hernia. A total sample size of 80 patients was calculated using a statistical formula for the comparison of two independent proportions, assuming expected postoperative complication rates of 0.463 and 0.195, with a level of significance of 5% and study power of 80%. Accordingly, 40 patients were allocated to each group. Convenience sampling was employed, and randomization was performed using a random number generator. Group 1 underwent onlay mesh repair, while Group 2 underwent sublay mesh repair. Following clearance from the Institutional Research Committee and Institutional Ethics Committee, eligible patients were recruited after explaining the nature and purpose of the study in detail. Participants were informed that refusal to participate would not affect their treatment and that they were free to withdraw at any point. Confidentiality of patient data was assured. A thorough clinical examination was performed, including assessment of vital parameters, followed by routine investigations such as complete blood count, urine routine and microscopy, blood urea, serum electrolytes, serum creatinine, and liver function tests. All surgeries were performed by the same surgeon to minimize procedural bias. Intraoperatively, the duration of surgery and any complications were documented. Postoperatively, patients were evaluated for surgical site infection, seroma formation, flap necrosis, bleeding, postoperative pain, and length of hospital stay. Surgeon-perceived ease of the procedure was also recorded. Clinical trial registration was completed prior to study initiation.

Statistical analysis: Data were collected using a structured proforma and entered into Microsoft Excel for analysis. Onlay and sublay mesh repair were considered the primary outcome variables, while age, gender, duration of surgery, postoperative pain scores, day of discharge, bleeding, and infection were treated as explanatory variables. Continuous variables were summarized using the mean and standard deviation, while categorical variables were expressed as frequencies and percentages. Data were presented using tables, bar diagrams, and pie charts. The unpaired t-test was applied to compare continuous variables, and the chi-square test was used for categorical variables. Statistical analysis was performed using SPSS version 21.0, and a p-value less than 0.05 was considered statistically significant..

RESULTS

The present study included a total of 80 cases fulfilling the inclusion criteria, with 40 cases in each group.

Table 1: Comparison of mean variables between the groups

| | Onlay | | Sublay | | p-value |
|--|-------|------|--------|------|---------|
| | Mean | SD | Mean | SD | |
| Age (yrs) | 42.2 | 9.8 | 41.6 | 10.0 | 0.78 |
| Weight (kg) | 74.6 | 19.2 | 75.9 | 20.7 | 0.78 |
| Height (cms) | 169.9 | 11.3 | 168.6 | 11.7 | 0.62 |
| BMI | 26.3 | 7.7 | 27.1 | 8.3 | 0.66 |
| Heart Rate | 78.9 | 12.4 | 82.0 | 12.0 | 0.26 |
| SBP (mmHg) | 129.0 | 16.3 | 129.7 | 15.3 | 0.83 |
| DBP (mmHg) | 76.0 | 11.5 | 75.2 | 10.4 | 0.76 |
| Duration of post-OP Hospital Stay (days) | 3.5 | 0.7 | 3.1 | 0.72 | 0.21 |

The mean age in the onlay group was 42.2 ± 9.8 years, while the sublay group had a mean age of 41.6 ± 10.0 years. The gender distribution was identical in

both treatment groups, with females and males each constituting 50% of participants in the onlay and sublay cohorts.

Table 2: Comparison of mean laboratory parameters between the groups

| | Onlay | | Sublay | | p-value |
|----------------------------|----------|--------|---------|---------|---------|
| | Mean | SD | Mean | SD | |
| Hb (gm/dL) | 12.3 | .8 | 13.0 | .8 | 0.01* |
| TLC ($10^2/\mu\text{L}$) | 75.563 | 7.903 | 75.104 | 8.185 | 0.78 |
| PLT (lakh/ μL) | 2.712733 | 0.4651 | 2.76703 | 0.40843 | 0.58 |
| S. Urea (mg/dL) | 28.1 | 5.7 | 29.7 | 5.8 | 0.21 |
| S. Creatinine (mg/dL) | .9 | .1 | .9 | .1 | 0.60 |
| Operative time (mins) | 120.0 | .0 | 120.0 | .0 | - |

Preoperative laboratory parameters were largely comparable between the onlay and sublay groups, indicating overall baseline equivalence. The sublay group's mean hemoglobin level (13.0 ± 0.8 g/dL) was

higher than the onlay group's (12.3 ± 0.8 g/dL), and this difference was statistically significant ($p = 0.01$), indicating a small but significant difference in the groups' baseline hemoglobin status.

Table 3: Comparison of complications between the groups

| | | Onlay | | Sublay | | Chi-square (p-value) |
|------------------------------|---|-------|-------|--------|--------|----------------------|
| | | Count | N % | Count | N % | |
| Intraoperative complications | A | 33 | 82.5% | 40 | 100.0% | 5.17 (0.01)* |
| | P | 7 | 17.5% | 0 | 0.0% | |
| Fever | A | 14 | 35.0% | 34 | 85.0% | 20.83 (0.01)* |
| | P | 26 | 65.0% | 6 | 15.0% | |
| Redness at surgical site | A | 26 | 65.0% | 38 | 95.0% | 11.31 (0.01)* |
| | P | 14 | 35.0% | 2 | 5.0% | |
| Discharge at surgical site | A | 33 | 82.5% | 40 | 100.0% | 7.67 (0.01)* |
| | P | 7 | 17.5% | 0 | 0.0% | |
| Wound infection | A | 34 | 85.0% | 39 | 97.5% | 3.91 (0.05)* |
| | P | 6 | 15.0% | 1 | 2.5% | |

Statistically significant differences were observed between the two techniques, with sublay mesh repair showing clear advantages. No intraoperative complications were noted in the sublay group, whereas 17.5% of patients undergoing onlay repair experienced such events ($p = 0.01$). Postoperatively, fever was significantly less frequent following sublay repair (15%) compared with onlay repair (65%) ($p = 0.01$). Local wound inflammation, including redness,

occurred far less often in the sublay group (5%) than in the onlay group (35%) ($p = 0.01$), and surgical site discharge was absent in the sublay cohort but was present in 17.5% of onlay cases ($p = 0.01$). Wound infections were also lower with sublay repair, reaching borderline statistical significance ($p = 0.05$). Overall, these findings highlight the superior safety profile of sublay mesh repair, particularly in reducing wound-related morbidity.

Table 4: Comparison of presence of seroma, flap necrosis and Pain score between the groups

| | | | Onlay | | Sublay | | Chi-square (p-value) |
|--------|---------|---|-------|-------|--------|--------|----------------------|
| | | | Count | N % | Count | N % | |
| Seroma | 6hr | A | 36 | 90.0% | 39 | 97.5% | 1.92 (0.16) |
| | | P | 4 | 10.0% | 1 | 2.5% | |
| | 24hr | A | 35 | 87.5% | 39 | 97.5% | 2.88 (0.09) |
| | | P | 5 | 12.5% | 1 | 2.5% | |
| | 48hr | A | 34 | 85.0% | 39 | 97.5% | 3.91 (0.05)* |
| | | P | 6 | 15.0% | 1 | 2.5% | |
| | 3rd day | A | 35 | 87.5% | 39 | 97.5% | 2.88 (0.09) |
| | | P | 5 | 12.5% | 1 | 2.5% | |
| | 7th day | A | 39 | 97.5% | 40 | 100.0% | 1.013 (0.31) |

| | | | | | | | |
|---------------|---------|---|----|-------|----|--------|---------------|
| Flap Necrosis | 6hr | P | 1 | 2.5% | 0 | 0.0% | 11.42 (0.01)* |
| | | A | 30 | 75.0% | 40 | 100.0% | |
| | 24hr | P | 10 | 25.0% | 0 | 0.0% | 1.013 (0.314) |
| | | A | 39 | 97.5% | 40 | 100.0% | |
| | 48hr | P | 1 | 2.5% | 0 | 0.0% | 2.88 (0.09) |
| | | A | 35 | 87.5% | 39 | 97.5% | |
| | 3rd day | P | 5 | 12.5% | 1 | 2.5% | - |
| | | A | 39 | 97.5% | 39 | 97.5% | |
| | 7th day | P | 1 | 2.5% | 1 | 2.5% | 3.11 (0.07) |
| | | A | 37 | 92.5% | 40 | 100.0% | |
| | 7th day | P | 3 | 7.5% | 0 | 0.0% | - |
| | | A | 39 | 97.5% | 39 | 97.5% | |
| VAS (Pain) | 6hr | P | 1 | 2.5% | 1 | 2.5% | - |
| | | A | 33 | 82.5% | 35 | 87.5% | |
| | 24hr | P | 7 | 17.5% | 5 | 12.5% | 0.399 (0.53) |
| | | A | 30 | 75.0% | 37 | 92.5% | |
| | 48hr | P | 10 | 25.0% | 3 | 7.5% | 4.50 (0.05)* |
| | | A | 32 | 80.0% | 35 | 87.5% | |
| | 3rd day | P | 8 | 20.0% | 5 | 12.5% | 0.82 (0.36) |
| | | A | 33 | 82.5% | 35 | 87.5% | |
| | 7th day | P | 7 | 17.5% | 5 | 12.5% | 0.399 (0.53) |
| | | A | 33 | 82.5% | 35 | 87.5% | |

Sublay mesh repair demonstrated consistently better early postoperative outcomes when compared with onlay repair. The incidence of seroma was lower in the sublay group at all assessed time points, reaching statistical significance at 48 hours, where seroma was observed in only 2.5% of sublay patients versus 15% in the onlay group ($p = 0.05$). A marked advantage of the sublay technique was also evident in terms of flap necrosis, with no cases reported at 6 hours postoperatively in the sublay group, while 25% of patients in the onlay group were affected, a difference that was statistically significant ($p = 0.01$). At subsequent follow-up intervals, flap necrosis and seroma rates remained consistently lower or absent in the sublay cohort, reinforcing its superior wound healing profile and highlighting its effectiveness in minimizing early postoperative complications. Overall, the findings indicate that while early postoperative pain is similar with both techniques, sublay repair is associated with a faster reduction in pain during the intermediate postoperative period, likely reflecting reduced tissue trauma and improved biomechanical stability. Patients who underwent onlay mesh repair had a mean hospital stay of 3.5 ± 0.7 days, while those in the sublay group had a slightly shorter stay of 3.1 ± 0.72 days. Although not statistically significant, the duration of hospital stay was lower in the sublay group compared to the onlay group.

DISCUSSION

The study included 80 patients, with 40 in the onlay group and 40 in the sublay group. The mean age was comparable between groups (42.2 ± 9.8 years in onlay vs. 41.6 ± 10.0 years in sublay; $p = 0.78$). Gender distribution was identical, with equal proportions of males and females (50% each) in both groups. Anthropometric parameters, including body weight, height, and BMI, were well balanced, indicating baseline comparability. Similar “demographic equivalence has been consistently reported in earlier investigations, including Naz A et

al., who observed mean ages of 40.30 ± 4.52 years in the onlay group and 39.12 ± 4.58 years in the sublay group,^[11] as well as Shekhar H et al,^[3] and Chandraseka M et al,^[12] thereby confirming that outcome disparities are unlikely to be influenced by baseline patient characteristics.

The onlay group saw a notably higher rate of intraoperative complications (17.5%), while the sublay cohort experienced no such occurrences ($p = 0.01$). “Raghuvver MN et al. showed higher perioperative morbidity with onlay repair, which is consistent with this trend,^[13] and Additionally, Hassan AM et al. found that the onlay group had greater incidence of complications.^[14] The current study's lack of intraoperative adverse events after sublay repair validates previous findings by Memon MR et al., who highlighted the technical safety of sublay mesh installation.^[15]

Patients having onlay repair had significantly higher rates of postoperative systemic and local inflammatory reactions. Local redness was seen in 35% vs 5% of instances, respectively, and febrile episodes were seen in 65% of onlay patients compared to 15% in the sublay group ($p = 0.01$). Furthermore, only the onlay group (17.5%) had wound drainage recorded. Similar patterns have been observed by Kumar V et al.[14], who reported wound infection rates of 13.33% in onlay and 11.11% in sublay repair, and by Shahryar et al., who documented infection rates of 17% and 8%, respectively.[16] Additionally, Shah D et al. showed that after sublay repair, the incidence of surgical site infection was much lower (3.33%) than after onlay repair (16.67%).

The greater prevalence in the onlay group is consistent with many previous studies, even though wound infection in our research only achieved borderline statistical significance ($p = 0.05$). Purulent surgical site infections were seen in 8% of onlay repairs compared to 4% of sublay repairs, according to Sabre A et al.[17], while infection rates of 19.20% and 4.35%, respectively, were reported by Raghuvver MN et al.[13] The consistent link between onlay

mesh placement and higher wound morbidity was further supported by Tahir AA et al., who reported wound infection in 15% of onlay patients as opposed to 5% in sublay repairs.[18]

In the current study, seroma production was considerably more frequent after onlay repair, especially in the early postoperative phase. Fifteen percent of onlay patients had seroma at 48 hours, compared to 2.5% in the sublay group ($p = 0.05$), and almost all of these instances had resolved by the seventh postoperative day. These results are similar to those of Shahryar et al., who found that seroma rates were 20% in onlay repair and 4.61% in sublay repair,[16] and rates of 6% and 2%, respectively, were reported by Sabre A et al.[17] This finding is further supported by the systematic study by Pereira C et al., which shows that onlay repair significantly increases the risk of seroma development (OR 2.85; $p < 0.0001$).[19] Another complication that was primarily linked to onlay repair in this study was early flap necrosis, which affected 25% of patients six hours after surgery, whereas no instances were found in the sublay group ($p = 0.01$). This result is in line with the findings of Chandraseka M et al., who found that flap necrosis only occurred in patients receiving onlay meshplasty (6%), with none occurring in the sublay group.[12] The current cohort's eventual recovery from flap compromise over time indicates that significant flap elevation, rather than long-term mesh-related variables, is primarily responsible for early tissue ischemia. Postoperative pain patterns in the present study revealed no significant differences during the immediate postoperative period; however, at 48 hours, a higher proportion of onlay patients experienced increased pain (25% vs. 7.5%; $p = 0.05$), while pain levels were comparable by the 3rd and 7th days. This observation is in accordance with Shekhar H et al., who reported greater early postoperative pain following onlay repair,[3] and Soni DK et al., who demonstrated significantly lower pain scores in sublay repairs despite longer operative times.[20] Wang M et al. similarly noted improved patient-reported outcomes and quality-of-life scores following sublay techniques.[21] The duration of hospital stay in the present study was marginally shorter in the sublay group (3.1 ± 0.72 days) compared with the onlay group (3.5 ± 0.7 days), although this difference did not reach statistical significance. A similar directional trend has been reported by Raghuvver MN et al., who observed hospital stays of 4.8 ± 1.51 days for sublay repair versus 6.68 ± 1.46 days for onlay repair,[13] and by Chandraseka M et al., who reported mean stays of 4.76 and 8.92 days, respectively.[12]

CONCLUSION

In conclusion, this randomized controlled trial demonstrates that sublay mesh repair provides better overall outcomes than onlay repair in open ventral

hernia surgery. As both groups were comparable in baseline demographic, anthropometric, hemodynamic, and laboratory parameters, the observed differences can be attributed to the surgical technique. Sublay repair was associated with fewer intraoperative and early postoperative complications, including lower rates of flap necrosis, seroma formation, and wound-related morbidity, along with a faster reduction in postoperative pain after 48 hours. Although the mean hospital stay was marginally shorter in the sublay group, this difference was not statistically significant. Collectively, these findings suggest that sublay mesh placement facilitates smoother recovery with reduced early complications, likely due to better preservation of tissue vascularity and limited dissection, making it a safer and more effective option than onlay repair for open ventral hernia management.

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