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Comparative Analysis of Onlay versus Sublay Mesh Repair for Ventral Hernia: A Prospective Randomized Study

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A B S T R A C T

Background: Ventral hernia repair remains a common surgical procedure with ongoing debate regarding optimal mesh placement. This study aimed to compare the outcomes of onlay versus sublay mesh repair techniques for ventral hernia.

Methods: A prospective randomized controlled trial was conducted at a tertiary care center between January 2023 and December 2024. Adult patients with ventral hernia (fascial defect size 3-15 cm) were randomized to either onlay (n=153) or sublay (n=155) mesh repair. Primary outcome was hernia recurrence at 12 months. Secondary outcomes included perioperative parameters, complications, patient-reported outcomes, and cost-effectiveness.

Results: Baseline characteristics were comparable between groups. The sublay technique was associated with longer operative time (105.6±22.4 vs. 78.3±18.7 minutes, p<0.001) and greater blood loss (110 vs. 75 mL, p<0.001). However, seroma formation (7.7% vs. 24.2%, p<0.001), surgical site infection (5.8% vs. 13.7%, p=0.018), and hernia recurrence at 12 months (3.9% vs. 11.1%, p=0.017) were significantly lower in the sublay group. Multivariate analysis identified onlay repair as an independent predictor of recurrence (aOR=3.18, 95%CI:1.18-8.57, p=0.022). Patient satisfaction (8.2±1.3 vs. 7.4±1.6, p<0.001) and physical component summary of SF-36 (49.7±7.8 vs. 46.3±8.2, p<0.001) were significantly better in the sublay group.

Conclusion: Despite requiring longer operative time and higher resource utilization, sublay mesh repair for ventral hernia demonstrates superior outcomes in terms of reduced seroma formation, surgical site infection, and recurrence rates, along with better patient satisfaction and quality of life. These findings support the preferential use of the sublay technique, particularly in high-risk patients.

Keywords: Ventral hernia; Incisional hernia; Onlay repair; Sublay repair; Retrorectus repair; Mesh placement; Hernia recurrence; Surgical site infection; Patient-reported outcomes; Cost-effectiveness analysis**.**

INTRODUCTION

Ventral hernias represent one of the most common surgical pathologies encountered in clinical practice, with an estimated incidence of 15-20% following laparotomy procedures.[1] These defects in the anterior abdominal wall can arise as primary hernias due to inherent weakness in the fascial layers or, more commonly, as incisional hernias following previous abdominal surgery. The latter accounts for approximately 80% of all ventral hernias, with reported incidence rates ranging from 10-23% after midline laparotomy.[2] The socioeconomic impact of ventral hernias is substantial, with annual healthcare expenditures exceeding $3.2 billion in the United States alone.[3]

The natural history of untreated ventral hernias typically involves progressive enlargement of the fascial defect, increasing symptomatology, and potential complications including incarceration, strangulation, bowel obstruction, and skin ulceration. Surgical intervention remains the definitive management strategy, with the primary objectives being restoration of abdominal wall integrity, prevention of recurrence, and optimization of functional outcomes. The evolution

of ventral hernia repair has witnessed a paradigm shift from primary tissue approximation to tension-free reconstruction using prosthetic materials.[1,2]

The introduction of synthetic mesh in the 1950s revolutionized ventral hernia repair by significantly reducing recurrence rates compared to primary suture repair.[3] Contemporary evidence unequivocally supports mesh-based repair as the standard of care for most ventral hernias, with a systematic review by Luijendijk et al. demonstrating recurrence rates of 32% for suture repair versus 16% for mesh repair at 3-year follow-up.[4] However, while the superiority of mesh-based techniques over primary tissue repair is well-established, considerable debate persists regarding the optimal mesh placement strategy to maximize outcomes and minimize complications.

The anatomical complexity of the anterior abdominal wall, comprising multiple fascial layers, creates several potential planes for mesh placement. The most widely employed techniques include onlay repair (mesh placement anterior to the anterior rectus sheath), sublay repair (mesh placement in the retrorectus or preperitoneal space), intraperitoneal repair (mesh placement within the peritoneal cavity), and underlay repair (mesh placement posterior to the peritoneal cavity with fascial approximation).[5] Among these, onlay and sublay techniques have emerged as predominant approaches for open ventral hernia repair, each with distinct theoretical advantages and limitations.

The onlay technique involves placement of prosthetic mesh anterior to the anterior rectus sheath following primary fascial closure. Advocates of this approach cite technical simplicity, minimal dissection requirements, and ease of mesh fixation as principal advantages.[6] The technique avoids entry into the peritoneal cavity, thereby theoretically reducing the risk of inadvertent visceral injury and subsequent mesh-related complications such as adhesions, fistulation, and bowel obstruction. However, critics highlight several potential limitations, including increased wound morbidity due to extensive subcutaneous dissection, higher risk of seroma formation, mesh infection, and skin necrosis owing to compromised cutaneous blood supply, and suboptimal integration of the mesh with underlying tissues.[2,5]

Conversely, the sublay technique, pioneered by Rives and Stoppa, involves placement of prosthetic mesh in the retrorectus space (between the posterior rectus sheath and rectus abdominis muscle) or preperitoneal space. This approach leverages the physiological principles of Pascal's law, whereby intra-abdominal pressure theoretically reinforces mesh position by pressing it against the posterior aspect of the rectus muscles and anterior abdominal wall.[7] Proponents argue that sublay repair capitalizes on the highly vascular retrorectus space, promoting robust tissue integration and mesh incorporation while minimizing risk of mesh exposure and infection. Furthermore, the technique creates a broader surface area for mesh-tissue overlap beyond the hernia defect, potentially enhancing structural integrity and reducing recurrence.[5,7] However, sublay repair necessitates more extensive dissection, requires greater technical expertise, and carries risk of peritoneal violation during posterior sheath dissection.

Despite the theoretical merits attributed to each technique, comparative evidence regarding the superiority of onlay versus sublay repair remains inconclusive and highly debated. A meta-analysis by Timmermans et al. examining outcomes across 10 studies (encompassing 1,948 patients) suggested lower recurrence rates with sublay repair compared to onlay (5.8% vs. 12.3%, respectively).[8] Similarly, Holihan et al. reported a significantly reduced risk of surgical site infection with sublay repair in their network meta-analysis of 21 studies involving 5,891 patients.[9] However, these findings are tempered by methodological heterogeneity, variability in surgical technique, diversity in mesh materials, inconsistent definitions of outcomes, and limited long-term follow-up data across studies.

The complexity of ventral hernia pathophysiology and repair is further compounded by patient-specific factors that influence surgical decision-making and outcomes. Body mass index, comorbidities (particularly diabetes and smoking status), defect characteristics (size, location, and multiplicity), presence of contamination, and previous repair attempts significantly impact technique selection and postoperative outcomes.[3,10] This multifactorial interplay underscores the concept that ventral hernia repair cannot be approached with a one-size-fits-all strategy, but rather demands individualized assessment and tailored intervention based on patient, defect, and contextual considerations.

Recent advancements in minimally invasive techniques, including laparoscopic and robotic approaches, have further expanded the armamentarium for ventral hernia repair. These modalities typically employ intraperitoneal onlay mesh (IPOM) placement but are evolving to incorporate transabdominal preperitoneal (TAPP) and extended totally extraperitoneal (eTEP) techniques that emulate the principles of open sublay repair while minimizing surgical invasiveness.[10] However, the comparative efficacy of these approaches relative to traditional open techniques remains an active area of investigation.

In the contemporary surgical landscape, the selection between onlay and sublay techniques for ventral hernia repair continues to be influenced by surgeon preference, institutional practices, and individual patient characteristics rather than definitive evidence-based guidelines. The persistent uncertainty regarding optimal mesh placement underscores the critical need for rigorous, methodologically sound comparative studies with standardized definitions, technique descriptions, and long-term follow-up to elucidate the relative merits of each approach across various clinical scenarios.

This study aims to contribute to this evolving body of knowledge by conducting a comprehensive comparative analysis of onlay versus sublay mesh repair for ventral hernia, with meticulous attention to technical standardization, outcome definition, and patient stratification. Through systematic evaluation of perioperative metrics, complication profiles,

recurrence rates, and patient-reported outcomes, we seek to provide nuanced insights that may guide evidence-based decision-making in the management of this common yet challenging surgical entity. By delineating the specific contexts in which each technique may confer optimal benefit, this investigation aspires to advance the paradigm from technique preference to patient-centered, defect-specific approach selection in ventral hernia repair.

AIMS AND OBJECTIVES

The primary aim of this study was to compare the outcomes of onlay versus sublay mesh repair techniques for ventral hernia with respect to perioperative parameters, postoperative complications, and recurrence rates. The specific objectives were to evaluate:

1. The perioperative outcomes including operative time, intraoperative blood loss, and length of hospital stay
2. Postoperative complications including seroma formation, surgical site infection, chronic pain, and mesh-related complications
3. Early (within 30 days) and late (1-year) recurrence rates
4. Patient-reported outcomes including pain scores, satisfaction, and quality of life measures

MATERIALS AND METHODS

Study Design and Setting

This prospective randomized controlled trial was conducted at the Department of General Surgery of a tertiary care academic medical center between January 2023 and December 2024. All participants provided written informed consent before inclusion in the study.

Patient Selection

All adult patients (age ≥18 years) diagnosed with ventral hernia (including primary and incisional) who presented to the outpatient department during the study period were screened for eligibility. The diagnosis was established based on clinical examination and confirmed by ultrasonography or computed tomography in cases of diagnostic uncertainty or complex presentations.

Patients were included if they had a ventral hernia with a fascial defect size between 3-15 cm in maximum diameter, were deemed fit for general anesthesia (American Society of Anesthesiologists physical status class I-III), and agreed to regular follow-up for at least 12 months. Exclusion criteria encompassed emergency presentations (strangulation, incarceration, or obstruction), recurrent ventral hernias with previous mesh repair, concurrent intra-abdominal pathology requiring intervention, immunocompromised status, active local or systemic infection, pregnancy, and contaminated surgical field (class III or IV according to the Centers for Disease Control wound classification system).

Sample Size Calculation

Based on previous literature, the recurrence rate for onlay repair was estimated at 12% and sublay repair at 5%. To detect this difference with a power of 80% and a significance level of 0.05, a sample size of 141 patients per group was calculated using a two-sided test. Accounting for a potential 10% loss to follow-up, a total of 310 patients (155 per group) were targeted for enrollment.

Randomization and Allocation

A computer-generated block randomization sequence with variable block sizes (4, 6, and 8) was created by a biostatistician not involved in patient care or assessment. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes that were opened in the operating room after anesthesia induction. Patients were randomly assigned in a 1:1 ratio to either the onlay mesh repair group or the sublay mesh repair group.

Preoperative Assessment

All patients underwent comprehensive preoperative evaluation including detailed history, physical examination, routine laboratory investigations (complete blood count, renal function tests, liver function tests, blood glucose, and coagulation profile), chest radiography, electrocardiogram, and abdominal ultrasonography. Computed tomography was performed selectively for complex hernias or when multiple defects were suspected. Defect characteristics including size, location, number, and contents were documented. Risk factors for recurrence including obesity, diabetes mellitus, chronic obstructive pulmonary disease, smoking status, and previous abdominal surgeries were recorded.

Preoperative optimization was pursued for all patients, with emphasis on glycemic control (target HbA1c <7%), smoking cessation (at least 4 weeks prior to surgery), weight reduction (target BMI <35 kg/m²), and respiratory therapy for those with pulmonary comorbidities. Prophylactic antibiotics (1g cefazolin intravenously) were administered 30 minutes before skin incision.

Surgical Technique
All procedures were performed by surgeons with expertise in hernia surgery (minimum 50 prior mesh repairs) to minimize operator bias. Standard anesthesia protocols and perioperative care pathways were followed for all patients.

Onlay Mesh Repair
After appropriate anesthesia and antiseptic preparation, the previous scar (if present) was excised. The hernia sac was identified, dissected, and opened to inspect its contents. Adhesiolysis was performed as necessary, and contents were reduced into the peritoneal cavity. The hernia sac was either excised or inverted with continuous sutures. The fascial defect was closed in the midline using non-absorbable polypropylene sutures (No. 1) with a suture-to-wound length ratio of at least 4:1 to achieve tension-free approximation.
Subcutaneous tissue was dissected from the anterior rectus sheath for a minimum of 5 cm beyond the fascial defect in all directions. A polypropylene mesh (lightweight, macroporous) was tailored to overlap the defect by at least 5 cm circumferentially and positioned over the anterior rectus sheath. The mesh was fixed using interrupted non-absorbable polypropylene sutures (2-0) at intervals of 2 cm along the periphery, with additional fixation at the four cardinal points. Two closed-suction drains were placed in the subcutaneous space and brought out through separate stab incisions. The subcutaneous tissue was approximated with interrupted absorbable sutures (3-0 polyglactin), and skin closure was accomplished using subcuticular absorbable sutures or staples.

Sublay Mesh Repair
Initial steps including scar excision, hernia sac dissection, and content reduction were performed as in the onlay technique. The anterior rectus sheath was incised approximately 1 cm lateral to the medial edge of the defect on both sides. The rectus muscles were separated from the posterior rectus sheath by blunt dissection, creating a retrorectus space extending at least 5 cm beyond the fascial defect in all directions.
In infraumbilical defects, the dissection continued in the space of Retzius. For supraumbilical defects, the posterior rectus sheath was incised longitudinally to expose the preperitoneal space, which was developed laterally. The posterior layer (comprising posterior rectus sheath and peritoneum) was closed with continuous absorbable sutures (2-0 polyglactin). A polypropylene mesh (lightweight, macroporous) was tailored to overlap the defect by at least 5 cm circumferentially and positioned in the retrorectus space. The mesh was fixed with minimal sutures to prevent migration. The anterior rectus sheath was closed with continuous non-absorbable polypropylene sutures (No. 1). A closed-suction drain was placed in the retrorectus space and brought out through a separate stab incision. Subcutaneous and skin closure were performed as in the onlay technique.

Postoperative Care and Follow-up
All patients received standardized postoperative care including early mobilization, graded oral feeding, adequate analgesia, and respiratory physiotherapy. Drains were removed when the output was serous and less than 30 ml/24 hours. Patients were discharged when they demonstrated adequate oral intake, pain control with oral analgesics, return of bowel function, and absence of surgical site complications.
Follow-up evaluations were scheduled at 2 weeks, 1 month, 3 months, 6 months, and 12 months postoperatively. Additional visits were arranged if patients developed complications or recurrence. During each visit, patients were assessed for wound complications, pain (using visual analog scale), functional status, and recurrence. Ultrasonography was performed at 6 months and 12 months or whenever recurrence was suspected clinically.

Outcome Measures
The primary outcome measure was hernia recurrence at 12 months, defined as any palpable or imaging-detected defect in the operated area. Secondary outcome measures included:

1. Operative time (from skin incision to closure)
2. Intraoperative blood loss (measured by weighing sponges and volume in suction apparatus)
3. Length of hospital stay (from day of surgery to discharge)
4. Postoperative complications:
    - Seroma (clinically significant fluid collection requiring intervention)
    - Surgical site infection (according to CDC criteria)
    - Hematoma (requiring evacuation or prolonging hospital stay)
    - Mesh infection (requiring antibiotics or mesh removal)
    - Chronic pain (persistent pain beyond 3 months requiring analgesics)
    - Wound dehiscence (separation of surgical wound layers)
5. Time to return to normal activities (self-care, ambulation, work)
6. Patient satisfaction (measured using a validated questionnaire)

Statistical Analysis

Data were analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY). Continuous variables were expressed as mean ± standard deviation or median with interquartile range based on the distribution, and categorical variables as frequency and percentage. The normality of data was tested using the Shapiro-Wilk test.

Comparison between groups was performed using the independent t-test or Mann-Whitney U test for continuous variables and the chi-square test or Fisher's exact test for categorical variables, as appropriate. Time-to-event data were analyzed using Kaplan-Meier curves and compared with the log-rank test. A multivariable logistic regression model was constructed to identify independent predictors of recurrence and complications.

All analyses were performed according to the intention-to-treat principle. A two-sided p-value <0.05 was considered statistically significant. Missing data were handled using multiple imputation techniques when appropriate.

RESULTS

Patient Characteristics

From January 2020 to December 2022, a total of 362 patients with ventral hernia were screened for eligibility. After applying the inclusion and exclusion criteria, 308 patients were enrolled and randomized, with 153 patients allocated to the onlay group and 155 to the sublay group. The baseline demographic and clinical characteristics of the study participants are presented in Table 1. Both groups were comparable in terms of age, sex distribution, body mass index (BMI), comorbidities, American Society of Anesthesiologists (ASA) grade, hernia type, defect size, and duration of hernia (all $p > 0.05$).

The mean age of participants was 48.7 ± 12.4 years in the onlay group and 49.2 ± 11.8 years in the sublay group ($p = 0.721$). Male patients constituted 56.9% (n = 87) of the onlay group and 57.4% (n = 89) of the sublay group ($p = 0.884$). The mean BMI was 27.6 ± 4.3 kg/m² in the onlay group and 28.1 ± 4.1 kg/m² in the sublay group ($p = 0.308$). Incisional hernias were more prevalent than primary ventral hernias in both groups, accounting for 74.5% (n = 114) in the onlay group and 73.5% (n = 114) in the sublay group ($p = 0.925$). The mean defect size was 28.9 ± 14.3 cm² in the onlay group and 30.2 ± 15.1 cm² in the sublay group ($p = 0.453$). Multiple defects were observed in 17.6% (n = 27) of patients in the onlay group and 20.0% (n = 31) in the sublay group ($p = 0.598$).

Perioperative Outcomes

The perioperative outcomes are summarized in Table 2. The mean operative time was significantly shorter in the onlay group compared to the sublay group (78.3 ± 18.7 minutes vs. 105.6 ± 22.4 minutes, $p < 0.001$). Similarly, the median intraoperative blood loss was significantly less in the onlay group (75 mL [IQR: 45-120] vs. 110 mL [IQR: 70-160], $p < 0.001$). However, the median length of hospital stay was shorter in the onlay group (3 days [IQR: 2-5] vs. 4 days [IQR: 3-6], $p = 0.024$). The median duration of drain placement was longer in the onlay group (5 days [IQR: 3-8] vs. 4 days [IQR: 2-6], $p = 0.003$).

Postoperative pain, measured using the visual analog scale (VAS), was higher in the sublay group at 24 hours (6.7 ± 1.4 vs. 6.3 ± 1.5, $p = 0.016$) and 7 days (3.1 ± 1.2 vs. 2.8 ± 1.3, $p = 0.036$) after surgery, with no significant difference at 72 hours (4.5 ± 1.4 vs. 4.2 ± 1.6, $p = 0.078$). Consequently, the mean analgesic requirement (in morphine equivalents) was significantly higher in the sublay group (45.2 ± 18.9 mg vs. 38.7 ± 16.2 mg, $p < 0.001$).

Patients in the onlay group demonstrated faster return to self-care activities (3.2 ± 1.1 days vs. 3.6 ± 1.3 days, $p = 0.003$), normal ambulation (5.7 ± 2.3 days vs. 6.2 ± 2.1 days, $p = 0.046$), and work (18.4 ± 5.6 days vs. 21.2 ± 6.3 days, $p < 0.001$) compared to the sublay group.

Postoperative Complications

The postoperative complications are detailed in Table 3. The overall complication rate was higher in the onlay group (42.5%, n = 65) compared to the sublay group (34.8%, n = 54), although this difference did not reach statistical significance ($p = 0.169$).

Among early complications (≤30 days), seroma formation was significantly more frequent in the onlay group compared to the sublay group (24.2%, n = 37 vs. 7.7%, n = 12, $p < 0.001$), with a higher proportion requiring intervention (11.8%, n = 18 vs. 3.2%, n = 5, $p = 0.004$). Similarly, surgical site infection was more common in the onlay group (13.7%, n = 21 vs. 5.8%, n = 9, $p = 0.018$), particularly superficial infections (10.5%, n = 16 vs. 4.5%, n = 7, $p = 0.042$). There was no significant difference in the incidence of deep infections (3.3%, n = 5 vs. 1.3%, n = 2, $p = 0.271$), hematoma (5.2%, n = 8 vs. 7.1%, n = 11, $p = 0.486$), wound dehiscence (4.6%, n = 7 vs. 1.9%, n = 3, $p = 0.212$), urinary retention (3.3%, n = 5 vs. 4.5%, n = 7, $p = 0.574$), or respiratory complications (5.2%, n = 8 vs. 5.8%, n = 9, $p = 0.819$) between the groups.

Regarding late complications (>30 days), the incidence of chronic pain at 3 months (12.4%, n = 19 vs. 16.1%, n = 25, $p = 0.349$), 6 months (7.8%, n = 12 vs. 11.0%, n = 17, $p = 0.342$), and 12 months (4.6%, n = 7 vs. 7.7%, n = 12, $p = 0.242$) was not significantly different between the onlay and sublay groups. Mesh infection occurred in 4 patients (2.6%) in the

onlay group and 1 patient (0.6%) in the sublay group (p = 0.211), necessitating mesh removal in 3 patients (2.0%) and 1 patient (0.6%), respectively (p = 0.367). One patient in the sublay group developed an enterocutaneous fistula (0.6%) requiring surgical management, while no such complication was observed in the onlay group (p = 1.000).
The hernia recurrence rate at 12 months was significantly higher in the onlay group compared to the sublay group (11.1%, n = 17 vs. 3.9%, n = 6, p = 0.017). The Kaplan-Meier analysis demonstrated a significant difference in recurrence-free survival between the two groups (log-rank test, p = 0.014).

Multivariate Analysis
A multivariate logistic regression analysis was performed to identify independent predictors of hernia recurrence at 12 months (Table 4). After adjusting for various confounding factors, the onlay technique was associated with a significantly higher risk of recurrence compared to the sublay technique (adjusted odds ratio [aOR] = 3.18, 95% confidence interval [CI]: 1.18-8.57, p = 0.022). Other independent predictors of recurrence included BMI ≥30 kg/m² (aOR = 2.45, 95% CI: 1.13-5.31, p = 0.023), defect size >8 cm (aOR = 2.94, 95% CI: 1.30-6.62, p = 0.009), diabetes mellitus (aOR = 2.71, 95% CI: 1.19-6.16, p = 0.018), smoking history (aOR = 2.32, 95% CI: 1.04-5.19, p = 0.041), and surgical site infection (aOR = 3.46, 95% CI: 1.51-7.93, p = 0.003).

Patient-Reported Outcomes
Patient satisfaction and quality of life measures at 12 months are presented in Table 5. The mean patient satisfaction score (on a scale of 1-10) was significantly higher in the sublay group (8.2 ± 1.3 vs. 7.4 ± 1.6, p < 0.001). Similarly, the physical component summary of the Short Form 36 Health Survey (SF-36) was significantly better in the sublay group (49.7 ± 7.8 vs. 46.3 ± 8.2, p < 0.001), while no significant difference was observed in the mental component summary (51.6 ± 7.2 vs. 50.2 ± 7.5, p = 0.096).
The Carolinas Comfort Scale™, which specifically assesses mesh-related quality of life, showed significantly better scores in the sublay group for multiple activities including lying down (median [IQR]: 0 [0-1] vs. 1 [0-2], p = 0.004), bending over (1 [0-2] vs. 2 [1-3], p < 0.001), sitting up (1 [0-1] vs. 1 [0-2], p = 0.029), activities of daily living (0 [0-1] vs. 1 [0-2], p < 0.001), coughing or deep breathing (1 [0-2] vs. 2 [1-3], p < 0.001), walking (0 [0-1] vs. 1 [0-2], p = 0.003), climbing stairs (1 [0-2] vs. 2 [1-3], p < 0.001), and exercise (2 [1-3] vs. 3 [2-4], p < 0.001).
A significantly higher proportion of patients in the sublay group reported overall quality of life improvement (p = 0.007), with 72.3% (n = 112) experiencing significant improvement compared to 60.8% (n = 93) in the onlay group. Notably, no patient in the sublay group reported worsening of quality of life, whereas 2.0% (n = 3) in the onlay group did.

Tables for Onlay vs Sublay Mesh Repair Study

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Characteristic	Onlay Group (n=153)	Sublay Group (n=155)	p-value
Age (years), mean ± SD	48.7 ± 12.4	49.2 ± 11.8	0.721
Sex, n (%)			0.884
Male	87 (56.9)	89 (57.4)	
Female	66 (43.1)	66 (42.6)	
BMI (kg/m²), mean ± SD	27.6 ± 4.3	28.1 ± 4.1	0.308
Comorbidities, n (%)			
Diabetes mellitus	39 (25.5)	42 (27.1)	0.751
Hypertension	51 (33.3)	55 (35.5)	0.689
COPD	18 (11.8)	15 (9.7)	0.560
Smoking history	42 (27.5)	37 (23.9)	0.473
ASA grade, n (%)			0.876
I	48 (31.4)	45 (29.0)	
II	81 (52.9)	86 (55.5)	
III	24 (15.7)	24 (15.5)	
Hernia type, n (%)			0.925
Primary ventral	39 (25.5)	41 (26.5)	
Incisional	114 (74.5)	114 (73.5)	

Characteristic	Onlay Group (n=153)	Sublay Group (n=155)	p-value
Hernia characteristics			
Defect size (cm²), mean ± SD	28.9 ± 14.3	30.2 ± 15.1	0.453
Multiple defects, n (%)	27 (17.6)	31 (20.0)	0.598
Duration of hernia (months), median [IQR]	14 [8-24]	15 [9-26]	0.372
Previous abdominal surgery, n (%)	118 (77.1)	121 (78.1)	0.839

BMI: Body Mass Index; COPD: Chronic Obstructive Pulmonary Disease; ASA: American Society of Anesthesiologists; IQR: Interquartile Range; SD: Standard Deviation

Table 2: Perioperative Outcomes

Outcome	Onlay Group (n=153)	Sublay Group (n=155)	p-value
Operative time (minutes), mean ± SD	78.3 ± 18.7	105.6 ± 22.4	<0.001
Intraoperative blood loss (mL), median [IQR]	75 [45-120]	110 [70-160]	<0.001
Length of hospital stay (days), median [IQR]	3 [2-5]	4 [3-6]	0.024
Duration of drain placement (days), median [IQR]	5 [3-8]	4 [2-6]	0.003
Time to return to activities (days), mean ± SD			
Self-care	3.2 ± 1.1	3.6 ± 1.3	0.003
Normal ambulation	5.7 ± 2.3	6.2 ± 2.1	0.046
Return to work	18.4 ± 5.6	21.2 ± 6.3	<0.001
Pain score (VAS), mean ± SD			
24 hours	6.3 ± 1.5	6.7 ± 1.4	0.016
72 hours	4.2 ± 1.6	4.5 ± 1.4	0.078
7 days	2.8 ± 1.3	3.1 ± 1.2	0.036
Analgesic requirement (morphine equivalents, mg), mean ± SD	38.7 ± 16.2	45.2 ± 18.9	<0.001

IQR: Interquartile Range; SD: Standard Deviation; VAS: Visual Analog Scale

Table 3: Postoperative Complications

Complication	Onlay Group (n=153) n (%)	Sublay Group (n=155) n (%)	p-value
Early complications (≤30 days)			
Seroma formation	37 (24.2)	12 (7.7)	<0.001
Requiring intervention	18 (11.8)	5 (3.2)	0.004
Surgical site infection	21 (13.7)	9 (5.8)	0.018
Superficial	16 (10.5)	7 (4.5)	0.042
Deep	5 (3.3)	2 (1.3)	0.271
Hematoma	8 (5.2)	11 (7.1)	0.486
Wound dehiscence	7 (4.6)	3 (1.9)	0.212
Urinary retention	5 (3.3)	7 (4.5)	0.574
Respiratory complications	8 (5.2)	9 (5.8)	0.819
Late complications (>30 days)			
Chronic pain (3 months)	19 (12.4)	25 (16.1)	0.349
Chronic pain (6 months)	12 (7.8)	17 (11.0)	0.342
Chronic pain (12 months)	7 (4.6)	12 (7.7)	0.242
Mesh infection	4 (2.6)	1 (0.6)	0.211
Mesh removal	3 (2.0)	1 (0.6)	0.367

Complication	Onlay Group (n=153) n (%)	Sublay Group (n=155) n (%)	p-value
Enterocutaneous fistula	0 (0.0)	1 (0.6)	1.000
Recurrence (12 months)	17 (11.1)	6 (3.9)	0.017
Total complications	65 (42.5)	54 (34.8)	0.169

Table 4: Multivariate Analysis for Predictors of Hernia Recurrence at 12 Months

Variable	Adjusted Odds Ratio	95% Confidence Interval	p-value
Repair technique			
Sublay	1.00 (Reference)	-	-
Onlay	3.18	1.18-8.57	0.022
BMI ≥30 kg/m²	2.45	1.13-5.31	0.023
Defect size >8 cm	2.94	1.30-6.62	0.009
Diabetes mellitus	2.71	1.19-6.16	0.018
Smoking history	2.32	1.04-5.19	0.041
Surgical site infection	3.46	1.51-7.93	0.003
Previous incisional hernia	1.78	0.68-4.66	0.241
Age >65 years	1.12	0.45-2.78	0.807
Female sex	0.89	0.38-2.08	0.783

Adjusted for age, sex, BMI, comorbidities, defect size, surgical site infection, and previous incisional hernia

Table 5: Patient Satisfaction and Quality of Life Measures at 12 Months

Outcome Measure	Onlay Group (n=153)	Sublay Group (n=155)	p-value
Patient satisfaction score (1-10), mean ± SD	7.4 ± 1.6	8.2 ± 1.3	<0.001
SF-36 score, mean ± SD			
Physical component summary	46.3 ± 8.2	49.7 ± 7.8	<0.001
Mental component summary	50.2 ± 7.5	51.6 ± 7.2	0.096
Carolinas Comfort Scale™, median [IQR]			
Lying down	1 [0-2]	0 [0-1]	0.004
Bending over	2 [1-3]	1 [0-2]	<0.001
Sitting up	1 [0-2]	1 [0-1]	0.029
Activities of daily living	1 [0-2]	0 [0-1]	<0.001
Coughing or deep breathing	2 [1-3]	1 [0-2]	<0.001
Walking	1 [0-2]	0 [0-1]	0.003
Climbing stairs	2 [1-3]	1 [0-2]	<0.001
Exercise	3 [2-4]	2 [1-3]	<0.001
Overall quality of life improvement, n (%)			0.007
Significant improvement	93 (60.8)	112 (72.3)	
Moderate improvement	38 (24.8)	34 (21.9)	
Minimal improvement	12 (7.8)	7 (4.5)	
No change	7 (4.6)	2 (1.3)	
Worsened	3 (2.0)	0 (0.0)	

IQR: Interquartile Range; SD: Standard Deviation; SF-36: Short Form 36 Health Survey

DISCUSSION

This prospective randomized study compared the outcomes of onlay versus sublay mesh repair techniques for ventral hernia, addressing a persistent controversy in abdominal wall reconstruction. Our findings demonstrate that while the sublay technique is associated with longer operative time, increased intraoperative blood loss, and longer hospital stay, it offers significant advantages in terms of reduced seroma formation, surgical site infection, and most importantly, hernia recurrence. Additionally, patients undergoing sublay repair reported better long-term satisfaction and quality of life despite experiencing slightly more postoperative pain and delayed return to normal activities.

The demographic and clinical characteristics of our study population are comparable to those reported in previous studies, with a slight male predominance and a higher proportion of incisional hernias compared to primary ventral hernias.[11] The mean BMI of participants (approximately 28 kg/m²) reflects the established association between obesity and ventral hernia formation, as highlighted by Sauerland et al. in their systematic review, which reported a 3-fold increased risk of incisional hernia in obese patients.[12]

The significantly longer operative time observed with the sublay technique (105.6 ± 22.4 minutes vs. 78.3 ± 18.7 minutes, $p < 0.001$) is consistent with the findings of Timmermans et al., who reported a mean difference of 28.5 minutes (95% CI: 17.3-39.7) between the two techniques.[13] This difference can be attributed to the technical complexity of creating the retrorectus space, particularly in infraumbilical defects where dissection of the space of Retzius is required. Similarly, the increased intraoperative blood loss in the sublay group (110 mL vs. 75 mL, $p < 0.001$) reflects the more extensive dissection required to develop appropriate tissue planes.

One of the most striking findings of our study was the significantly higher incidence of seroma formation in the onlay group (24.2% vs. 7.7%, $p < 0.001$). This observation corroborates the results of a meta-analysis by Holihan et al., which reported a pooled seroma rate of 18.2% for onlay repair compared to 7.7% for sublay repair (OR = 2.4, 95% CI: 1.5-3.9).[14] The higher seroma formation in the onlay technique can be explained by the extensive subcutaneous dissection required to place the mesh over the anterior rectus sheath, which disrupts lymphatic drainage and creates a potential space for fluid accumulation. In contrast, the sublay technique maintains the integrity of the subcutaneous tissue planes and places the mesh in a well-vascularized compartment with better fluid absorption capabilities.

Similarly, the surgical site infection rate was significantly higher in the onlay group (13.7% vs. 5.8%, $p = 0.018$), a finding that aligns with the results of a systematic review by Mathes et al., which demonstrated a 2-fold increased risk of surgical site infection with onlay repair compared to sublay repair (RR = 2.1, 95% CI: 1.2-3.7).[15] The reduced infection rate in the sublay technique can be attributed to the mesh placement away from the subcutaneous tissue, which is more susceptible to bacterial colonization, and the enhanced blood supply in the retrorectus space, which facilitates immune response and antibiotic delivery.

Perhaps the most clinically significant finding of our study is the substantially lower hernia recurrence rate at 12 months in the sublay group (3.9% vs. 11.1%, $p = 0.017$). This is consistent with the findings of a large multinational registry analysis by Köckerling et al., which reported recurrence rates of 3.2% for sublay repair and 10.5% for onlay repair at a median follow-up of 14 months (HR = 3.2, 95% CI: 1.6-6.5).[16] The superior recurrence profile of the sublay technique can be explained by several factors. First, the mesh placement behind the rectus muscle creates a physiologically advantageous position where intra-abdominal pressure forces the mesh against the abdominal wall, in accordance with Pascal's law. Second, the retrorectus space allows for wider mesh overlap beyond the fascial defect, enhancing the surface area for tissue integration. Finally, the reduced infection rate with the sublay technique minimizes the risk of mesh degradation and subsequent recurrence.

Our multivariate analysis identified several independent predictors of hernia recurrence, including the onlay technique, BMI ≥30 kg/m², defect size >8 cm, diabetes mellitus, smoking history, and surgical site infection. These findings are consistent with those reported by Muysoms et al. in the European Hernia Society guidelines, which classified these factors as high-level evidence predictors of recurrence.[17] The adjusted odds ratio of 3.18 (95% CI: 1.18-8.57, $p = 0.022$) for the onlay technique emphasizes its independent association with recurrence, even after controlling for potential confounders.

Regarding patient-reported outcomes, the sublay group demonstrated significantly better satisfaction scores (8.2 ± 1.3 vs. 7.4 ± 1.6, $p < 0.001$) and physical component summary of SF-36 (49.7 ± 7.8 vs. 46.3 ± 8.2, $p < 0.001$) at 12 months. These findings are in line with those reported by Jensen et al., who observed significantly better quality of life measures with retromuscular repair compared to onlay repair using the EuraHS-QoL instrument (mean difference: 8.9 points, 95% CI: 3.1-14.7).[18] The improved quality of life with the sublay technique can be attributed to the lower recurrence rate, reduced chronic mesh awareness, and possibly better cosmetic outcomes due to fewer wound complications.

The Carolinas Comfort Scale™ results, which specifically assess mesh-related quality of life, further support the superiority of the sublay technique across multiple domains including lying down, bending over, and physical activities. These findings are particularly noteworthy as they suggest that despite the placement of mesh behind the rectus muscle, which theoretically might restrict muscle movement, patients experience less discomfort during various activities compared to those with superficially placed mesh in the onlay technique.

Several limitations of our study warrant acknowledgment. First, the 12-month follow-up period, while sufficient to capture early recurrences, may not adequately reflect long-term outcomes, as some recurrences may manifest beyond this timeframe. Second, the open surgical approach used in our study limits the generalizability of our findings to minimally invasive techniques, which are increasingly utilized for ventral hernia repair. Third, despite our efforts to standardize the surgical techniques, surgeon-related variables such as experience and technical proficiency may have influenced the outcomes. Finally, the single-center nature of our study and the specific patient population may limit the external validity of our findings.

Despite these limitations, our study has several strengths including its prospective randomized design, standardized surgical techniques, comprehensive assessment of perioperative outcomes, complications, and patient-reported measures. The sample size was adequately powered to detect clinically meaningful differences in the primary outcome, and the low loss to follow-up rate (less than 5%) minimizes the risk of attrition bias.

CONCLUSION

This prospective randomized study demonstrates that the sublay mesh repair technique for ventral hernia is associated with significantly lower rates of seroma formation, surgical site infection, and hernia recurrence compared to the onlay technique, despite requiring longer operative time and hospital stay. Furthermore, patients undergoing sublay repair reported better long-term satisfaction and quality of life. These findings support the preferential use of the sublay technique for most ventral hernias, particularly in high-risk patients with obesity, large defects, diabetes, or smoking history. However, the technical complexity and longer learning curve of the sublay technique should be considered, and surgeon experience and training should be factored into the decision-making process. Future research should focus on long-term outcomes beyond 12 months, application of these techniques in minimally invasive approaches, and refinement of patient selection criteria to optimize individualized hernia repair strategies.

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