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Risk Factors Associated With Surgical Site Infection and Hernia Recurrence Following Ventral Hernia Mesh Repair: A Prospective Cohort Study

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ABSTRACT

Introduction: The benefits of ventral hernia mesh repair are compromised by background of surgical-site infection (SSI) and recurrence.

Methods: A prospective cohort design was set up for 240 adults who were undergoing elective ventral hernia mesh repair. Prespecified exposures were obesity, diabetes, smoking, defect width, mesh position, and operating time. The main outcome was superficial, deep, or organ-space SSI that occurred within 30 days, and clinical recurrence at 12 months was a secondary outcome.

Results: 30 SSIs were included in 240 procedures (12.5%) in the constructed analysis figures. Infection was more frequent with BMI ≥ 30 kg/m² (22/120 versus 8/120; $p=0.010$), diabetes (17/80 versus 13/160; $p=0.006$), and smoking (14/62 versus 16/178; $p=0.012$). Twenty-four patients (11.1%) had a recurrence, and 216 patients had 12-month assessment. The incidence of recurrence was 10/26 (39%) in patients with prior SSI vs 14/190 (7%) in patients without SSI ($p<0.001$). Recurrence also was associated with wider defects.

Conclusion: The drafting framework highlights the need for patient optimization, ongoing monitoring of infections and post-drafting of recurrent defects.

Keywords: Ventral Hernia, Surgical-Site Infection, Mesh Repair, Recurrence, Obesity, Diabetes, Cohort.

INTRODUCTION

Ventral abdominal-wall hernias include primary umbilical and epigastric defects, and incisional defects following previous laparotomy. The goal of durable

reconstruction is to restore fascial integrity and maintain abdominal-wall function and reduce wound morbidity. The use of mesh reinforcement decreases the tension in the repaired tissues, but also adds a foreign



body that can be problematic if it becomes infected. The European Hernia Society stresses the importance of the preoperative assessment of modifiable risk factors, the rational positioning of the mesh and the patient's risk of postoperative complications [1]. Primary ventral defects should be approached differently depending on the type of defect, umbilical versus epigastric, and there are separate guidelines for each type [2].

Ventral hernias are a spectrum of diseases, depending on the anatomical location, quality of tissue, history of recurrence, contamination of the wound, and coexisting medical disease. Practice recommendations for unusual sites and selected high-risk settings recognize that standard practice approaches might not be easily translatable to all patients [3]. This heterogeneity is a major design challenge for a prospective prognostic study: an infection after repair of a small primary defect is not directly comparable to an infection after a large recurrent incisional reconstruction.

Excess adiposity and tobacco exposure can affect local perfusion, wound edge tension, and inflammatory and healing environment. Body mass index and active smoking have been independently associated with surgical-site infection after open ventral hernia repair, according to large national datasets [4]. However, the risk of infection is not solely dependent on BMI after all techniques and in all follow-up situations. The temporal sequence could be relevant: the incidence of postoperative wounds has been correlated with subsequent failure of the fascia [5].

The location of the prosthesis may also affect the results, as onlay dissection will leave a wide subcut space, while retromuscular will leave a more protected tissue plane. A network meta-analysis supported sublay placement for multiple wound and recurrence outcomes, but noted uncertainty in the evidence base [6]. In

addition to early postoperative outcomes, the increasing popularity of registries has shown that recurrence occurs over years and is influenced by the definition and ascertainment of the event. The present manuscript describes a prospective cohort study to quantify 30 day SSI, to explore candidate risk factors, and to assess 12 month recurrence following elective mesh ventral hernia repair.

MATERIALS AND METHODS

Design and participants of the study

A prospective observational-cohort study design was created to investigate risk factors for surgical-site infection (SSI) and for SSI recurrence after elective ventral hernia mesh repair. The manuscript did not report an enrolled cohort or retrieve patient files, and constructed tabulations for 240 adults. Eligibility included age 18 years or older with elective mesh reinforcement of a primary or incisional VWH. Exclusion criteria were emergency surgery with bowel resection, active sepsis at presentation related to the mesh, abdominal-wall tumor resection, and repair without the use of mesh. The design specified separated exposures before surgery, surgical characteristics, 30-day postoperative complications and 12-month postoperative recurrence, thus maintaining the temporal order of the risk assessment.

Pre- and post-assessment

Baseline data dictionary consisted of age, sex, body mass index (BMI), diabetes mellitus, tobacco use in the last month, corticosteroid use, and prior hernia repair and medical comorbidities. BMI ≥ 30 kg/m² was considered as obesity. Operative descriptors were open or minimally invasive approach, type of mesh used, plane of mesh placement, fascial closure, drain use, intraoperative wound class, and operation duration, which was classified as ≥ 120 minutes. Hernia characteristics were



classified as primary or incisional; the maximum transverse fascial defect was categorized at a threshold of 5 cm. The placement of the onlay was compared to the other planes for the prespecified risk marker table. Perioperative antimicrobial prophylaxis, wound preparation, and glucose management were identified as important items to be documented for subsequent confounding assessment. These items were not assumed to be available in real hospital charts.

Ascertainment of outcomes and follow-up

The primary endpoint was defined as SSI within 30 days of repair and was defined as superficial incisional, deep incisional, or organ space infection by surveillance definitions. The ascertainment framework specified included wound examination, documentation by treating team, culture results (when available), antibiotic use for infection, readmission, and procedures performed for source control. An uncomplicated seroma was not considered to be an SSI. The secondary endpoint was defined as anatomical recurrence of the hernia at 12 months, defined as a clinically palpable recurrence of the hernia or supporting imaging if this was not possible. Review points were set at postoperative days 7 and 30, and at months 3, 6, and 12, but a phone call was not considered as a definite diagnosis of recurrence. Recurrence analysis was performed on the 216 records that were identified as having completed the 12-month assessment and 24 records with no assessment documentation were included as missing follow-up.

Statistical analysis

Data on baseline characteristics and outcomes were presented as mean $\pm$ standard deviation or number and percentage as appropriate. Constructed cohort consisted of 30 SSI outcomes at 30

days and 24 recurrences of SSI among 216 records that were identified as assessed at 12 months. Exposed and unexposed event fractions and 2-sided Fisher exact tests were used to express associations between binary risk factors and 30-day SSI. Recurrence comparisons were made on the subgroup of 240 records that had a 12-month follow-up, and the prior SSI was considered a time-ordered postoperative risk factor for recurrence. A p value of < 0.05 was considered statistically significant. Since only 30 SSI events were reported and no source-level observations were provided, the manuscript did not report an adjusted regression model or claim independent predictors. Selection bias, residual confounding, and losses to follow-up were preserved as limitations and final effect estimates and confidence intervals were still subject to verification against authentic patient data.

RESULTS

The constructed cohort included 240 adults with mean age 52.1 ± 12.7 years, comprising 112 women (46.7%) and 128 men (53.3%). Half had BMI ≥ 30 kg/m²; diabetes was present in 80 (33.3%), and 62 (25.8%) were current smokers. Incisional defects accounted for 144 procedures (60.0%), and 101 patients (42.1%) had a measured defect width of at least 5 cm. Onlay prosthetic placement was specified in 86 procedures (35.8%). The analytical denominator for early infection was the entire 240-participant operative cohort; one-year recurrence was assessed in 216 (90.0%) (Table 1).

Thirty-day SSI occurred in 30/240 repairs (12.5%). Infection affected 22 of 120 patients with BMI ≥ 30 kg/m², compared with 8 of 120 below this threshold. Diabetes showed a similar association (17/80 vs 13/160), as did current smoking (14/62 vs 16/178). SSI was more frequent after procedures lasting at least 120 minutes and



when mesh was in the onlay plane. Incisional defects had numerically more infections than primary defects, but this crude contrast was less precise (Table 2). Event overlap between risk-factor rows should not be misread as independent observations.

Among 216 patients assessed at 12 months, 24 had clinically established recurrence (11.1%). Of the 26 assessed patients who experienced early SSI, 10 developed recurrence, compared with 14 of 190

without SSI (38.5% vs 7.4%; Fisher $p < 0.001$). A defect width of 5 cm or greater was also associated with recurrent herniation (17/90 vs 7/126). Recurrence was numerically more common in patients with diabetes or smoking exposure, while the BMI contrast alone was smaller and statistically uncertain. These results describe simple associations from constructed counts and do not constitute an adjusted prognostic model (Table 3).

Table 1. Clinical characteristics and surgical profile of the planned cohort

Characteristic	Constructed total (n=240)	Percentage / statistic
Age (years), mean $\pm$ SD	52.1 $\pm$ 12.7	—
Women / men	112 / 128	46.7% / 53.3%
BMI ≥ 30 kg/m ²	120	50.0%
Diabetes mellitus	80	33.3%
Current smoking	62	25.8%
Primary / incisional ventral defect	96 / 144	40.0% / 60.0%
Defect width ≥ 5 cm	101	42.1%
Onlay mesh location	86	35.8%
Operative duration ≥ 120 min	90	37.5%
30-day SSI	30	12.5%
Assessed at 12 months	216	90.0%
Recurrence among assessed	24/216	11.1%

BMI = body mass index; SSI = surgical-site infection. Individual risk factors are not mutually exclusive.

Table 2. Associations of clinical and operative exposures with 30-day SSI

Risk marker	SSI / exposed	SSI / unexposed	p value
BMI ≥ 30 kg/m ²	22/120 (18.3%)	8/120 (6.7%)	0.010
Diabetes mellitus	17/80 (21.3%)	13/160 (8.1%)	0.006
Current smoking	14/62 (22.6%)	16/178 (9.0%)	0.012
Incisional (vs primary) defect	22/144 (15.3%)	8/96 (8.3%)	0.162
Onlay (vs other plane)	16/86 (18.6%)	14/154 (9.1%)	0.042
Operative duration ≥ 120 min	18/90 (20.0%)	12/150 (8.0%)	0.009

Separate two-by-two Fisher tests; associations are unadjusted and not evidence of causal effects.

Table 3. Risk markers for recurrence at 12 months (n=216 assessed)



Factor	Recurrence exposed /	Recurrence unexposed /	p value
Preceding 30-day SSI	10/26 (38.5%)	14/190 (7.4%)	<0.001
Defect width ≥ 5 cm	17/90 (18.9%)	7/126 (5.6%)	0.004
BMI ≥ 30 kg/m ²	14/110 (12.7%)	10/106 (9.4%)	0.519
Diabetes mellitus	13/75 (17.3%)	11/141 (7.8%)	0.042
Current smoking	10/58 (17.2%)	14/158 (8.9%)	0.091
All assessed patients	24/216 (11.1%)	—	—

Exposed/unexposed counts partition the 216 participants with one-year assessment for each listed risk marker; crude comparisons only.



DISCUSSION

The main clinical concept of the prospective model is that SSI is not just a "temporary wound event. Infection can interfere with the healing of the fascia, may need to be drained or mesh removed, slow down recovery and may affect the integrity of the repair. Operative strategy and patient selection influence long-term recurrence in a population level comparative context. Fry and colleagues showed the significance of long-term follow-up of recurrence in various surgical techniques [7]. Bhardwaj et al. also reported on the time-dependent changes in recurrence risk and anatomical and reconstructive features that are important for durability [8]. Therefore, the association with SSI that is demonstrated in the drafting should be interpreted as a clinically plausible sequence, but not as evidence of infection causing fascial failure.

Another consideration that is not a straightforward choice between biologic and synthetic materials is the type of prosthetic material. Rosen et al. reported lower recurrence at 2 years with synthetic mesh compared with biologic mesh in a specialized setting in a randomized trial of contaminated ventral hernias [9]. The PRICE trial also tested the hypothesis regarding the use of routine biologic mesh in more complex fields [10]. These studies highlight the importance of performing a risk stratification based on wound class, tissue plane, source control, and secure closure, as opposed to using clean elective repair results to predict contaminated reconstruction results.



In the current figures, onlay mesh placement was correlated with greater early infection as compared to other planes. A randomized comparison of retromuscular and onlay techniques revealed differences in wound complications, which offers an anatomical explanation as to why wider undermining of the subcutaneous plane may be important [11]. Selection for onlay positioning, however, will frequently be a reflection of the difficulty encountered at operation and simple comparisons without adjustment may be a case complexity effect. There are no consistent findings regarding the type of mesh, and patient selection and wound contamination will influence risk-benefit estimates, so these should be reported separately from placement plane [12]. Once established, mesh infections may need to be treated for a longer period of time, staged intervention or selected mesh salvage depending on the organism, the properties of the prosthesis and the degree of tissue involvement. A systematic review of infected mesh and negative-pressure wound therapy reinforces the concept that mesh infection is a complex and multifaceted problem, and that treatment should not be standardized without taking clinical context into consideration [13]. In isolation, minimally invasive ventral hernia meta-analyses indicate that the association of BMI with outcomes is different in minimally invasive cohorts compared to open repair cohorts [14]. Therefore, obesity must be considered a risk factor that depends on the surgical technique, the position of the mesh and the presence of concomitant metabolic disease.



Diabetes, smoking, and operative duration were indicated in Table 2, as they are a combination of potentially modifiable exposures and markers of procedure complexity. In a large safety-program analysis, Romero-Velez et al. found excess BMI, insulin-dependent diabetes and emergent operations to be risk factors for SSI, and laparoscopic access to be associated with decreased infection rates [15]. Constructed cohort does not include emergencies, but glycemic optimization, smoking cessation, careful preoperative skin assessment, and avoiding unnecessary delay in operating room are rational measures in clinical practice. They need to be evaluated in an appropriately controlled design before making an independent estimate of the benefits of any intervention. The choice of materials also has a bearing on the longer-term decisions, if an infection occurs. The selection of hernia meshes is reviewed in terms of porosity, permanence, biomechanical properties and the risks of contamination [16]. The study design should thus include precise prosthesis information, antibiotic therapy, culture findings, and superficial or deep SSI. A single undifferentiated endpoint of infection may mask important mechanisms and overemphasize similarities between superficial and deep infection with mesh sepsis.



There are significant restrictions on interpretation. All numeric results in this document were built for writing and need to be changed to patient-level results. Even after prospective collection, there would remain nonrandom differences in open versus laparoscopic selection, placement plane, contamination of the wound, and anatomy. The 30 infection events are too few to make descriptive contrasts but too few for an unrestricted multivariable model with numerous predictors. A 12-month window of recurrence will include early technical failure, but not the full impact of future recurrence. If patients with recurrent symptoms were more or less likely to return, then there is uncertainty about the follow-up attrition of 10%. Before proposing a clinical prediction rule, a completed report should demonstrate patterns of missing data, intervals of effect size, adjusted analyses and sensitivity analyses, and external validation.

CONCLUSION

Higher 30-day SSI rates are associated with obesity, diabetes, smoking, onlay mesh placement, and longer surgery, whereas early infection and larger fascial defects are associated with higher one-year recurrence rates. These findings are merely used to structure the planned analysis.

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