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ORIGINAL ARTICLE

Drain Placement Does Not Increase Infectious Complications After Retromuscular Ventral Hernia Repair with Synthetic Mesh: an AHSQC Analysis

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Abstract

Background The use of surgical drains after ventral hernia repair (VHR) remains controversial. Some have concerns of increased infectious complications; others advocate that drains reduce fluid accumulation and surgical site occurrences (SSO). The aim of our study was to investigate the impact of retromuscular drains on SSO following retromuscular VHR with synthetic mesh.

Methods Utilizing the Americas Hernia Society Quality Collaborative, patients between January 2013 and January 2016 undergoing retromuscular VHR with synthetic mesh were assessed for the presence of a drain. Propensity score matched patients (2 drains: 1 no drain) were evaluated for 30-day rates of SSO, surgical site infections (SSI) and SSO requiring procedural intervention (SSOPI).

Results Five hundred eighty-one patients were identified as having undergone open, retromuscular VHR with synthetic mesh. Four hundred eighty-one patients with drains and 100 without drains. After matching, 300 patients were compared, 200 with drain placement and 100 without. Retromuscular drains were less likely to develop a noninfectious SSO (OR, 0.33). Drain placement was not associated with SSI (OR, 1.30) or SSOPI (OR, 0.94).

Conclusion Drain placement after retromuscular VHR with synthetic mesh is a common practice. Based on an analysis of early outcomes, surgical drains do not increase the risk of surgical infectious complications, and may be protective against some SSOs, such as seroma formation.

Keywords Surgical drain · Closed suction drain · Ventral hernia repair · Surgical site occurrence · Surgical site infection

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Introduction

Optimization of hernia mesh integration remains one of the key principles in achieving a successful hernia repair. While there is a lack of standardization in approaches to hernias, retromuscular ventral hernia repair (VHR) theoretically provides an environment that maximizes mesh-tissue interface by placing the mesh in between two well-vascularized structures, the peritoneum and abdominal musculature. Despite the theoretical advantage of the retromuscular plane, the development of this plane requires extensive dissection and creates a potential space that may result in fluid accumulation, and seromas inhibiting mesh integration. While surgical drains are purported to reduce post-operative fluid accumulation, their usage in hernia repair remains controversial.

Opponents of surgical drains in various surgical fields cite higher rates of infectious complications,[1–7] prolonged hospital stays,[8,9] and increased post-operative pain.[10] Regarding VHR

specifically, there is concern that drains placed directly on the prosthetic may also serve as a nidus for infection by allowing bacteria to inoculate the prosthetic.[1] Thus, it remains unclear whether drains placed during retromuscular hernia repairs are helpful or harmful. Despite VHR being one of the most common operations performed by general surgeons, and since over 50% of mesh hernia repairs utilize drains,[7] the paucity of data available to guide surgeons on the potential implications of surgical drains in VHR is problematic. Prior studies that have previously investigated the relationship of drains to outcomes in hernia repairs included small sample sizes and did not control for patient demographics or surgical techniques that are known to have a negative impact on wound events after hernia repair. The aim of this study was to assess the impact of retromuscular drains on early infectious complications after open retromuscular VHR with synthetic mesh.

Methods

After obtaining institutional review board approval, the Americas Hernia Society Quality Collaborative (AHSQC) data registry was queried for all VHRs entered between January 2013 and January 2016. The AHSQC is a nationwide registry designed to improve the value of hernia care using real-time continuous quality improvement principles.[11] At the time of this study, the AHSQC had data available from over 150 surgeons who practice in a variety of clinical settings, including academic, community, and academic-affiliated hospitals. The registry component of the AHSQC is comprised of predetermined standardized definitions for data collection in the preoperative, intraoperative, and 30-day post-operative phases of hernia care. Details regarding the AHSQC and registry structure, governance, and data assurance process have been previously reported.[11] The information collected within the AHSQC is available to all participants on a real-time basis for continuous quality improvement in hernia care.

All patients in the data registry undergoing open VHR with sublay mesh placed in a retromuscular position were included in this study. Retromuscular position is defined as retro-rectus and/or preperitoneal mesh placement as mesh is placed both retro-rectus and preperitoneal for posterior component separations. Patients were excluded from analysis if they underwent laparoscopic repair and had mesh placed in the intraperitoneal, onlay, or inlay position. Additionally, patients with, biologic mesh, bio absorbable mesh, hernia defects greater than 15 cm wide, operative times less than 60 min, subcutaneous drains, or concomitant procedure were excluded from analysis. Patients were separated into two groups based on the use or avoidance of surgical drains. Group 1 includes patients with closed suction drains placed adjacent to the mesh in the retromuscular tissue plane. Group 2 includes patients with retromuscular mesh and no surgical drain placement.

The AHSQC data registry was queried for 30-day surgical wound events including surgical site infection (SSI), surgical site occurrence (SSO), and surgical site occurrence requiring procedural intervention (SSOPI). SSO includes any SSI as well as wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischemia, skin or soft tissue necrosis, wound serous or purulent drainage, stitch abscess, seroma, hematoma, infected or exposed mesh, or development of an enterocutaneous fistula. SSI is further characterized according to the Centers for Disease Control and Prevention (CDC) classification guidelines as a superficial, deep, or organ space infection. SSOPI is defined as any SSO that requires opening of the wound, wound debridement, suture excision, percutaneous drainage, or partial or complete mesh removal.

For analysis, Group 1 was compared with Group 2 using descriptive statistics and multivariable logistic regression modeling to control for multiple factors to predict odds of 30-day wound events. We then used propensity scores to match patients from Group 1 and Group 2. The propensity score was based on patient gender, elective status, CDC wound class, ASA class, Ventral Hernia Working Group Grade, presence of subcutaneous tissue flaps, and hernia width with a ratio of two patients in Group 1 to every one patient in Group 2. A second comparison again using descriptive statistics and multivariable logistic regression modeling was performed using the matched groups. A p value of < 0.05 was considered statistically significant.

Results

Within the AHSQC data registry, 581 patients were identified as having undergone open VHR with retromuscular synthetic mesh placement that met all inclusion criteria. Of those, 481 (82.8%) had a drain placed in the retromuscular position adjacent to the mesh and 100 (17.2%) patients did not have a drain placed. Patient demographics for each group are reported in Table 1. There were notable differences between the two groups with regard to baseline demographics and hernia characteristics. The patients that received drains had more complex hernias as reflected by a higher average body mass index (BMI), greater number of recurrent hernia repairs, greater number of prior wound infections, larger average hernia width, and more myofascial advancement flaps performed. Despite these differences, both groups had similar rates of SSOs, SSIs, and SSOPIs (Table 2).

In order to account for the disparities between the two groups, a 2:1 match was performed as described above. After matching, 300 patients remained for comparison, 200 (66.6%) with retromuscular drain placement and 100 (33.3%) without drain placement. Baseline demographics and hernia characteristics for matched groups are demonstrated in Table 3. After matching, the only variations in the groups

Table 1 Baseline demographics and hernia characteristics for all ventral hernia repairs with retromuscular mesh

	Drain ($N = 481$) mean (25–75%) N (%)	No drain ($N = 100$) mean (25–75%) N (%)	p value
Age (years)	59 (50–67)	57 (49–78)	0.09
Gender (female)	263 (55)	53 (53)	0.76
BMI	32.0 (28.0–35.8)	301.8 (28.2–36.2)	0.85
Diabetes	99 (21)	21 (21)	0.99
COPD	38 (8)	8 (8)	0.92
Current smoker	42 (9)	10 (10)	0.63
ASA	13 (3)	7 (7)	< 0.01
1	135 (28)	42 (42)	
2	315 (65)	50 (50)	
3	8 (2)	1 (1)	
4			
Elective surgery	467 (97)	96 (96)	0.58
Recurrent hernia	246 (51)	36 (36)	< 0.01
Hx of abdominal wall infection	120 (25)	14 (14)	0.02
CDC wound status	428 (89)	92 (92)	0.75
Clean	30 (6)	4 (4)	
Clean-contaminated	21 (4)	4 (4)	
Contaminated	2 (< 1)	0 (0)	
Dirty			
Hernia grade (VHWG)	97 (20)	24 (24)	0.27
Grade 1	241 (50)	56 (56)	
Grade 2	135 (28)	19 (19)	
Grade 3	8 (2)	1 (1)	
Grade 4			
Stoma present	28 (6)	5 (5)	0.75
Prophylactic antibiotic use	480 (100)	100 (100)	0.65
Enterotomy	7 (1)	3 (3)	0.28
Hernia width (cm)	10 (8–13)	6 (4–8)	< 0.01
Operative time (> 2 h)	402 (84)	41 (41)	< 0.01
Subcutaneous flaps raised	20 (4)	9 (9)	0.04
Myofascial release performed	459 (95)	74 (74)	< 0.01

included a longer operative time, more myofascial releases and slightly larger hernias (8 vs 6 cm) with the patients that had a drain placed representing slightly more complex hernias. After logistic regression modeling, drain placement was not associated with a higher rate of SSI (OR, 1.30; 95% CI, 0.33–5.21) or SSOPI (OR, 0.94; 95% CI, 0.29–3.01); however, there were less noninfectious SSO when retromuscular drains were employed (OR, 0.33; 95% CI, 0.14–0.78).

Table 2 A 30-day wound morbidity for all ventral hernia repairs with retromuscular mesh

	Drain ($N = 481$)	No drain ($N = 100$)	p value
SSO	12% ($N = 60$)	17% ($N = 17$)	0.23
SSI	6% ($N = 28$)	3% ($N = 3$)	0.25
SSOPI	6% ($N = 27$)	5% ($N = 5$)	0.81

Rate of SSO for the drain group was 9 vs 17% for the no drain group ($p = 0.04$). The most common SSO in the drain group was a superficial SSI (4.0%), while the most common SSO for the no drain group was seroma formation (8.0%). Seroma formation was significantly higher in patients with no drains (8.0 vs 1.0%; $p < 0.01$), while rates of superficial SSI were similar between the two groups (4.0 vs 3.0%; $p = 0.19$). All SSOs are reported in Table 4.

Discussion

Our study is the first large-scale study to evaluate retromuscular drains after VHR with retromuscular synthetic mesh. Within it we describe the potential benefit of reduced seroma formation and the lack of increased infectious complications from the utilization of surgical drains in contact with a synthetic mesh

Table 3 Baseline demographics and hernia characteristics for matched ventral hernia repairs with retromuscular mesh

	Drain ($N = 200$) *M*ean (25–75%) *N* (%)	No drain ($N = 100$) Mean (25–75%) *N* (%)	*p* value
Age (years)	60 (49–67)	57 (44–67)	0.19
Gender (female)	100 (50)	53 (53)	0.62
BMI	31.2 (27.6–35.5)	31.8 (28.2–36.2)	0.42
Diabetes	38(19)	21 (21)	0.74
COPD	11 (6)	8 (8)	0.36
Current smoker	16 (8)	10 (10)	0.51
ASA	8 (4)	7 (7)	0.42
1	72 (36)	42 (42)	
2	118 (59)	50 (50)	
3	2 (1)	1 (1)	
4			
Elective surgery	192 (96)	96 (96)	1.0
Recurrent hernia	83 (42)	36 (36)	0.37
Hx of abdominal wall infection	46 (23)	14 (14)	0.07
CDC wound status	180 (90)	92 (92)	0.69
Clean	13 (6)	4 (4)	
Clean-Contaminated	6 (3)	4 (4)	
Contaminated	1 (< 1)	0 (0)	
Dirty			
Hernia grade (VHWG)	49 (24)	24 (24)	0.38
Grade 1	94 (47)	56 (56)	
Grade 2	53 (26)	19 (19)	
Grade 3	4 (2)	1 (1)	
Grade 4			
Stoma present	9 (4)	5(5)	0.85
Prophylactic antibiotic use	200 (100)	100 (100)	1.0
Enterotomy	1 (< 1)	3 (3)	0.08
Hernia width (cm)	8 (6–10)	6 (4–8)	< 0.01
Operative time (> 2 h)	134 (67)	41 (41)	< 0.01
Subcutaneous flaps raised	13 (6)	9 (9)	0.43
Myofascial release performed	186 (93)	74 (74)	< 0.01

during open retromuscular VHR. Utilizing the AHSQC data registry, we noted that post-operative drain placement after sublay hernia repair was common, with 481 out of 581 repairs (83%) using surgical drains. After identifying comparable groups, we found that there were no increased rates of any infectious complications with the utilization of drains during retromuscular VHR with mesh. In addition, we found that drains were protective against seroma formation in this patient population. Given this analysis, it seems that routine drainage of the retromuscular space is warranted after sublay VHR.

The lack of available data to inform surgeons on surgical drains and VHR is surprising, given that over 350,000 VHRs are performed each year.[12] A 2013 Cochrane review addressing this question identified only one randomized controlled trial (RCT) evaluating the outcomes of drain utilization during VHR.[13] Furthermore, the RCT was a comparison of drain types (electrified drain vs corrugated drain),[14] and did not include a control arm that did not receive drains. As a result, the Cochrane review authors concluded, "there is insufficient evidence to determine whether wound drains after incisional hernia repair are associated with better or worse outcomes than no drains." Since 2013, there has been one additional RCT evaluating surgical drains in VHR. In that study, Westphalen et al., evaluated drain placement in 42 patients undergoing onlay mesh repair.[15] No difference in seroma formation or SSI was noted between the groups; however, the study was powered to identify a difference in seroma formation or SSI from 50 to 10%, and therefore included only 21 patients in each study group. Our study has several unique advantages over these randomized controlled trials. We were able to accrue a large number of patients undergoing open VHR, and the granularity of our database allowed us to match two fairly comparable groups to address the risk versus benefit of surgical drains in this population.

Table 4 Description of SSOs for matched ventral hernias. Patients with more than one SSO have each SSO listed separately

	Drain (N = 200) (%)	No drain (N = 100) (%)	p value
Superficial SSI	8 (4.0)	3 (3.0)	0.19
Deep SSI	1 (1.0)	0 (0.0)	NA
Organ space infection	0 (0.0)	0 (0.0)	NA
Wound cellulitis	5 (2.5)	3 (3.0)	0.06
Wound dehiscence	0 (0.0)	3 (3.0)	NA
Fascial dehiscence	0 (0.0)	0 (0.0)	NA
Skin/soft tissue necrosis	0 (0.0)	0 (0.0)	NA
Wound serous drainage	3 (1.5)	2 (2.0)	0.10
Seroma	2 (1.0)	8 (8.0)	< 0.01
Hematoma	0 (0.0)	0 (0.0)	NA
Anastomotic leak	0 (0.0)	1 (1.0)	NA
Unspecified SSO	2 (1.0)	0 (0.0)	NA
Total	21 (10.5)	20 (20.0)	0.02

The reduction in SSO rates reported in our trial is important given some of the baseline differences between the two groups. In an effort to reduce bias by confounding, we performed a 2:1 (drains:no drains) propensity matched analysis. Despite matching, patients that received drains did appear to have slightly more complex hernias. Patients receiving drains had greater hernia widths (8 vs 6 cm), underwent more myofascial advancements, and had longer operative times. These factors would predictably lead to a higher rate of surgical wound morbidity including seromas and infectious complications in the drains group. Despite these differences, the drain group still did not have a higher rate of SSIs and there was no difference in rates of deep infection involving the prosthesis. It is concerning that even in the smallest and least complex hernias, the rate of seromas without drain usage was higher than a more complex group of patients receiving drains. Given the fact that there was no increased risk of SSIs, the authors would thus suggest that drain usage should be considered in all open retromuscular repairs to at least reduce seroma rates regardless of defect characteristics. The implication that reduced fluid will improve mesh integration thus durability will require further long-term analysis to confirm.

Mesh repair of ventral hernias has become the gold standard given the significant reduction in hernia recurrence rates with mesh.[16] During open VHR, mesh can be placed in multiple positions including as an onlay, sublay, or underlay. Retromuscular mesh placement has the benefit of completely excluding the mesh from underlying viscera while maintaining sub-fascial mesh location. Alternative approaches such as onlay mesh positioning have the benefit of keeping the mesh out of the abdomen, however, are hindered by the potential increased risk of mesh infection associated with surgical wound complications as a result of the lipocutaneous flaps.[17] Alternatively, intraperitoneal or underlay mesh placement avoids the subcutaneous location for mesh placement and might reduce wound complications; however, concerns of mesh adhesions and mesh erosion with subsequent mesh infection and fistula formation are concerning. Despite these advantages, there were still higher rates of seroma formation in the no drain group in our study. While our study did not specifically examine the role of drains versus no drains in the onlay or intraperitoneal sublay group, it is concerning that if no drains resulted in higher rates of retromuscular hernia repair seromas, that rate would likely only increase in these other approaches.

Further, highlighting the importance of surgical approach is a recent study assessing surgical drains after abdominal wall reconstruction (AWR) by a single center.[1] In this study, 69 patients undergoing AWR without drains were compared to a historical control group of 33 patients with drains and demonstrated a reduction in wound complications from 48 to 19% when drains were eliminated. However, several confounding factors related to surgical technique that have been clearly linked to wound morbidity were not adequately controlled for over the study period. Most notably, the surgeons had actually modified their approach to repairing ventral hernias from an anterior component separation with lipocutaneous skin flaps to a posterior component separation that avoids subcutaneous dissection. Other groups have clearly linked surgical approach to significant reductions in wound morbidity after open VHR.[17] In the current study, we were able to control for many operative factors that are captured in the AHSQC database that can allow a fair comparison including subcutaneous flaps raised. As such, a surgeon contemplating not utilizing a drain during a retromuscular hernia repair likely should reconsider that approach particularly if they are additionally creating a subcutaneous flap.

To maximize durability of a hernia repair, the mesh-tissue interface must be optimized for mesh integration. The presence of either synthetic or biologic mesh, combined with the tissue flaps required for mesh placement, provides an environment for potential fluid accumulation. Retromuscular surgical drains adjacent to the mesh may optimize the mesh-tissue interface by eliminating fluid within this plane. In our study, the presence of surgical drains significantly reduced seroma formation from 8 to 1%, thus advocating for the use of surgical drains during these repairs. Unfortunately, within the AHSQC data registry there is no delineation between superficial, or subcutaneous, seroma and deep, or retromuscular, seromas. While the intention of the drain is to remove fluid around the mesh, the drain may have also reduced noticeable fluid in the subcutaneous space by either suctioning fluid through the fascial closure or by preventing fluid from passing up through the fascial closure. To avoid confounding, patients with subcutaneous drains were excluded from analysis and thus had no influence on the seroma formation within this study. Importantly, in opposition to what many opponents of

surgical drains would claim, the presence of a surgical drain did not increase the risk of SSI or mesh infections, only strengthening support for post-operative drains.

Our study is not without limitations. First and foremost, it should be emphasized that this study addresses retromuscular sublay VHR only and these results are not meant to inform the use of drains for onlay or intraperitoneal sublay mesh VHR. Additionally, this study addresses synthetic mesh as whole and does not predict performance of individual synthetic meshes but manufacturer nor does this study address drains and biologic mesh which typically requires more and/or longer drain usage. Almost equally as important as whether or not drains should be used is the question about when to remove them post-operatively. Because this data is not captured within the AHSQC registry, another limitation is that we are unable to comment on the timing of drain removal, duration of antibiotic use, or use of antibiotic patches around drains in the group that received drains. A recent study by Plymale et al., addressed this question.[18] In 117 patients undergoing abdominal wall reconstruction, wound complications increased linearly with amount of time a drain was left in place. Their criteria for drain removal was < 40 cm^3/24 h. Importantly, seroma and hematoma rates were not influenced by timing of drain removal. As such, drains should be removed early. Notably, however, in their study, biologic and synthetic meshes were used in multiple locations including the retromuscular, onlay, and intraperitoneal positions. Future studies should focus on determining the ideal timing of drain removal after retromuscular VHR.

Additionally, some opponents of drain placement cite increased post-operative pain from drains. Our study cannot address this concern and certainly, while there do not appear to be significant differences in early outcomes related to drains, if patients are in significant discomfort related to drains, this may be an indication to try to optimize drain placement technique to minimize discomfort. Lastly, hernia recurrence and delayed mesh infection are not addressed as we do not currently have long-term data to establish whether or not drains impact hernia recurrence rates. The AHSQC is an ongoing endeavor and long-term data on these same patients will be available in the future, allowing us to strengthen recommendations on drain usage in retromuscular VHR with more of a focus on hernia recurrence rates.

Conclusion

Drain placement after retromuscular VHR with synthetic mesh is a common practice within the AHSQC data registry. Based on an analysis of early outcomes, surgical drains do not increase the risk of SSIs and may be protective against seroma formation. Future data from this cohort will allow us to establish the impact of drain placement on hernia repair durability.

Author Contribution Statement All listed authors have contributed to the conception and designs of this study and/or acquisition, analysis, or interpretation of the data. All authors have drafted or revised the manuscript and approved the final version. All authors agree to be accountable for all aspects of this work.

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