

Current Risk Stratification Systems Are Not Generalizable across Surgical Technique in Midline Ventral Hernia Repair

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Background: Current ventral hernia repair risk estimation tools focus on patient comorbidities with the goal of improving clinical outcomes through improved patient selection. However, their predictive value remains unproven.

Methods: Outcomes of patients who underwent midline ventral hernia repair with retrorectus placement of mid-weight soft polypropylene mesh between 2010 and 2015 were retrospectively reviewed and compared with predicted wound-related complication risk from 3 tools in the literature: Carolinas Equation for Determining Associated Risk, the Ventral Hernia Working Group (VHWG) grade, and a modified VHWG grade.

Results: A total of 101 patients underwent hernia repair. Mean age was 56 years and mean body mass index was 29 m/kg² (range, 18–51 m/kg²). We found no significant relationship between the risk estimated by Carolinas Equation for Determining Associated Risk ($B = 1.45$, $P = 0.61$) and actual wound-related complications. VHWG grades >1 were not statistically different with regard to rate of wound complication compared with VHWG grade 1 (grade 2: $B = 0.05$, $P = 0.95$; grade 3: $B = -0.21$, $P = 0.86$; grade 4: $B = 2.57$, $P = 0.10$). Modified VHWG grades >1 were not statistically different with regard to rate of wound complication compared with modified VHWG grade 1 (grade 2: $B = 0.20$, $P = 0.80$; grade 3: $B = 1.03$, $P = 0.41$).

Conclusions: Current risk stratification tools overemphasize patient factors, ignoring the importance of technique in minimizing complications and recurrence. We attribute our low complication rate to retrorectus placement of a narrow, macroporous polypropylene mesh with up to 45 suture fixation points for force distribution in contrast to current strategies that employ wide meshes with minimal fixation. (*Plast Reconstr Surg Glob Open* 2017;5:e1206; doi: 10.1097/GOX.0000000000001206; Published online 9 March 2017.)

INTRODUCTION

Ventral hernia repair (VHR) is a frequently performed procedure with reported high rates of local wound complications. Each year, as many as 4 million laparotomies are performed in the United States, with an estimated 10.3% hernia rate at 2 years^{1,2} and up to 18.7% at 10 years.³ These numbers translate to a conservative estimate of between

200,000 and 400,000 new patients who will develop a ventral hernia each year in the United States alone, with \$3.2 billion in direct costs for care.⁴

Despite frequency of execution,⁴ complication rates after VHR remain unacceptably high: Ghali et al.⁵ reported a 32% rate of wound-healing complications for open component separation VHR in 2012, and Cobb et al.⁶ reported a wound event rate of 37.3% in 2015. Wound complications plague VHR for general^{7–10} and plastic surgeons⁵ alike. Hernia repairs with surgical site occurrences (SSOs) are, at a minimum, 3 times more likely to recur than those without.¹¹

Patient risk stratification scales have been created aiming to improve outcomes through patient selection and optimization. These include the Carolinas Equation

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for Determining Associated Risk (*CeDAR*),¹² the Ventral Hernia Working Group (VHWG) grade,¹³ and a modified VHWG grading scale described by Kanters et al.¹⁴ The predictive value of these risk stratification tools remains untested, particularly in the practical application of a single-surgeon cohort.

In the present study, we compare outcomes with the predicted risk of wound-related complications for our cohort made by each of these risk estimation tools. We utilize a surgical hernia repair distinguished by up to 45 point retrorectus mesh fixation.

MATERIALS AND METHODS

Data Collection

Institutional review board's approval was obtained for this study (project number: STU00099714-MOD0001). The cohort was selected using the Northwestern Medicine Enterprise Data Warehouse and included all patients of Dr. Dumanian at Northwestern Memorial Hospital, who underwent midline hernia repair with retrorectus placement of mid-weight uncoated polypropylene mesh (Soft Prolene, Ethicon, N.J.) between 2010 and 2015. Patients were excluded if additional nonmidline hernias were treated to evaluate a uniform patient cohort. Data were collected retrospectively from patient charts: prior surgical history, hernia size, and occurrence of medical and surgical complications. Complications reviewed included surgical site infection (SSI), seroma, dehiscence, development of enterocutaneous fistula, delayed wound healing requiring dressing changes, reoperation, readmission within 30 days, or hernia recurrence. SSI was defined as a clinical diagnosis of wound infection by the senior surgeon (Dr. Dumanian) based on the appearance of wound erythema, drainage, or need to open an incision due to concern for infection. Seroma was defined as any appreciable subcutaneous fluid collection in the postoperative period. Complications not related to the surgical site were excluded from analysis. Both the in-hospital chart and office notes were retrospectively reviewed for complications for the first 30 days after the procedure. Though not a focus of this article, long-term hernia outcomes were obtained through electronic medical record review and mailed patient surveys.

Risk Stratification Systems Evaluated

We compared our outcomes with predicted risk of wound-related complications of *CeDAR*, the VHWG grading scale, and a modified VHWG grading scale described by Kanters et al.¹⁴

CeDAR

*CeDAR*¹² is a smartphone app that evaluates a patient's risk of wound complication and estimates associated costs. The equation is based on International Hernia Mesh Registry data. *CeDAR* evaluates the following comorbidities: uncontrolled diabetes (defined as one of the following: blood glucose not checked daily, blood glucose averaging above 180 mg/dL in preceding month, or hemoglobin A1c exceeding 7.3% in preceding 3 months), tobacco use,

prior hernia repair, existing stoma, and body mass index (BMI). Operative characteristics evaluated by *CeDAR* include concurrent gastrointestinal tract entry, abdominal infection, advancement skin flap, and component separation. The output produced by the *CeDAR* app includes a percent "risk of complications" and estimates of "in-hospital charges" and "follow-up charges," associated with the wound complications.

VHWG Grade

The VHWG grade¹³ evaluates risk of SSO in patients undergoing repair of ventral incisional hernias. The grade is intended to direct a practitioner in selecting an appropriate surgical technique and repair material. Hernias are categorized as grade 4 if there is septic dehiscence or infected mesh. Grade 3 hernias are those in patients who have a stoma, have experienced a wound infection in the past, or in whom the gastrointestinal tract is disrupted. Grade 2 describes hernias in patients with at least one of the following comorbidities: chronic obstructive pulmonary disease, diabetes, smoking, immunosuppression (defined as recent chemotherapy use or use of immunosuppressant medications), or obese BMI. Other patients have grade 1 hernias and are considered to have a low complication risk.

Modified VHWG Grade

This modified grading scale¹⁴ places hernias into 3 categories. Grade 3 hernias are infected or are in patients with a stoma or gastrointestinal tract disruption. Grade 2 hernias are in patients with at least one of the following comorbidities: COPD, diabetes, smoking, obesity, or prior wound infection. Other patients have grade 1 hernias and are considered to have a low complication risk.

Statistics

Data were analyzed using the binary logistic regression function within SPSS (IBM Corp., Armonk, N.Y.). For *CeDAR* risk score, a continuous variable, the regression yielded a B coefficient predicting the linear relationship between the logit ratio of actual wound complication and the *CeDAR* percent "risk of complications." For VHWG and modified VHWG grades, which are categorical, the regression yielded B coefficients describing the logit difference between the mean of the reference category, or lowest hernia grade on that scale, and that of each other grade (2, 3, or 4).

Surgical Procedure

After a single preoperative dose of either cefazolin or clindamycin, the abdomen is accessed through the prior vertical midline incision or a new vertical midline incision, often extending xiphoid to the pubic symphysis. Lysis of adhesions is performed as indicated, and hernia sac is dissected from surrounding tissue and removed. Anterior rectus sheath is then cleared of overlying soft tissue for 4 cm on either side and the plane between the rectus abdominis and posterior sheath is developed, taking care to preserve the inferior epigastric artery and any segmental nerves. Anterior component separation was performed with a perforator sparing technique as needed to bring

the medial edges of the rectus abdominis to the midline. Posterior sheath is closed with a running 2-0 polydioxanone suture, and a 7.5-cm-wide, uncoated, mid-weight polypropylene mesh spanning from xiphoid to pubic symphysis is then inset in the retrorectus space. We utilize 40–45 interrupted 0-polypropylene sutures placed full thickness through the anterior rectus sheath and rectus muscle, 4cm from the medial edge of the rectus, ensuring the mesh is taught and without wrinkles. An additional row of figure of 8 sutures approximates the medial aspect of the rectus muscles in the midline. Excess skin is cut out in the midline as a vertical panniculectomy, and 2–3 surgical drains are placed between the abdominal wall and the skin. The skin is closed in layers in standard fashion.

RESULTS

Patient demographics appear in Table 1.

Overall Rate of Wound Complications

Eight patients (7.9%) experienced wound-related complications. Wound-related complications included delayed wound healing (4), seroma (2), SSI (3), and hematoma (2). Table 2 profiles the wound complications associated with each patient with a wound-related complication, and their risk score or grade from each grading system assessed.

CeDAR

No significant relationship was found between the percent risk calculated by CeDAR and occurrence of wound-related complications in this cohort ($B = 1.45, P = 0.61$). Additionally, patients were divided into deciles according to complication risk as predicted by CeDAR, and the actual rate of wound complications was calculated for each decile. This analysis appears in Table 3.

VHWG Grade

VHWG grades greater than 1 were not found to be statistically different with regard to actual rate of wound complication compared with VHWG grade 1 (grade 2: $B = 0.05, P = 0.95$; grade 3: $B = -0.21, P = 0.86$; grade 4: $B = 2.57, P = 0.10$).

The counts of patients with and without wound-related complications in each VHWG grade appear in Table 4.

Modified VHWG Grade

Modified VHWG grades greater than 1 were not found to be statistically different with regard to actual rate of wound complication compared with modified VHWG

grade 1 (grade 2: $B = 0.20, P = 0.80$; grade 3: $B = 1.03, P = 0.41$).

The counts of patients with and without wound-related complications in each VHWG grade appear in Table 5.

DISCUSSION

Wound complications in VHR occur far too frequently. Krpata et al.¹⁵ reported SSOs in 16% of patients with VHR grade 2 hernias repaired with a retrorectus technique, with 13% SSI and 5% recurrence rates at 15 months. Cobb et al.⁶ reported a 37.3% rate of wound events in a retrospective study of retrorectus mesh hernia repairs. Cobb et al.¹⁰ reported a 10.2% incidence of mesh infection in open intraperitoneal VHR. White et al.⁹ reported wound complications in 34% of VHR patients. When component separation is required, reported complication rates can increase further. Ghali et al.⁵ reported a 32% rate of wound-healing complications with open component separation and 14% with minimally invasive component separation. As a result, much effort has been devoted to understanding factors that result in recurrence and complication, with a recent focus on patient comorbidities and a relative shift away from the role of surgical technique. Emphasis on the patient as the cause of operative failure has been taken so far as to suggest highly restrictive criteria: “With a BMI > 35 (or even 30), the primary discussion with the patient should not be directed at the hernia but rather at their obesity; strong consideration should be given to obligating substantive weight loss or a bariatric operation *before* any definitive repair of the abdominal wall hernia” (italics from original manuscript).¹⁶ The introduction of preoperative risk assessment tools like those evaluated in this study follows this trend.

The use of “big data” analysis has become a popular approach to improving clinical outcomes. Perhaps a valuable method in the treatment of medical conditions such as hypertension, our data indicate that the approach may be misguided in this context, where big data may not adequately account for the profound effect that surgical technique may have on patient outcomes. We do not attempt to refute literature that supports a role of patient factors such as BMI,^{11,17,18} smoking,¹¹ diet,¹¹ COPD,¹⁷ kidney disease necessitating dialysis,¹⁷ American Society of Anesthesiologists score,^{17,18} incision class,¹⁸ and blood glucose/diabetes,^{11,17} which impact outcomes in hernia repair. Rather, we posit that the generalizations made by risk scores such as those evaluated here cannot be accurately made until surgical technique has been optimized. We achieved a low complication profile across a spectrum of patients, and we found

Table 1. Patient Characteristics

Patient	Complication Profile	CeDAR Predicted Risk (%)	VHWG Grade	Modified VHWG Grade
1	Seroma, delayed wound healing, umbilical necrosis	6	1	1
2	Delayed wound healing	8	1	1
3	Seroma	9	1	1
4	Hematoma, reoperation	20	2	2
5	SSI, delayed wound healing, readmission	20	2	2
6	Hematoma	24	3	2
7	SSI	36	2	2
8	SSI, delayed wound healing	37	4	3

Table 2. Wound Complication Profile, CeDAR Predicted Risk, VHWG Grade, and Modified VHWG Grade for the 8 Patients Experiencing Wound Complication in This Cohort

CeDAR Predicted Risk	0–10%	11–20%	21–30%	31–40%	41–50%	51–60%	Total
Wound complications	3	2	1	2	0	0	8
Total patients	37	31	19	7	5	2	101
Wound complication rate (%)	8.1	6.5	5.3	28.6	0	0	7.9

Table 3. Actual Wound-related Complication Rate Compared With Percent Risk as Predicted by CeDAR

	VHWG Grade				Total
	1	2	3	4	
Wound complication*	3 (7.3%)	3 (7.5%)	1 (5.9%)	1 (50%)	8 (7.0%)
No wound complication	39	37	16	1	93
Total	42	40	17	2	101

*Reported as number of patients (%).

Table 4. Counts of Patients With and Without Wound-related Complications by VHWG Grade

	Kanters Modified VHWG Grade			Total
	1	2	3	
Wound complication*	3 (6.7%)	4 (8.0%)	1 (16.7%)	8 (7.9%)
No wound complication	42	46	5	93
Total	45	50	6	101

*Reported as number of patients (%).

Table 5. Counts of Patients With and Without Wound-related Complications by VHWG Grade

VHWG Grade	VHWG Description of Patient/Operative Characteristics	VHWG Recommendations
1	No prior wound infection, low complication risk	“Surgeon preference and patient factors” should determine decision between prosthetic and biologic
2	COPD, diabetes, smoking, immunosuppression, or obese BMI	“Potential advantage” for the use of biologic material over prosthetic mesh
3	Patient with stoma, prior wound infection, or gastrointestinal tract disrupted	Biologic material may be superior to synthetic
4	Septic dehiscence or infected mesh	Do not use prosthetic material

no significant relationship between the CeDAR predicted risk of complications and wound-related complications or any significant difference in association with wound-related complications when comparing higher VHWG or modified VHWG grades with the lowest grade.

The VHWG grading scale is the most widely discussed and cited among those we evaluated. In 2010, a multi-institutional collaboration of surgeons under the name VHWG published a consensus statement on risk stratification of ventral hernia patients for development of an SSO, particularly SSI, with consequent recommendations for choice of surgical technique and repair material.¹³ They grouped risk-stratified patients into 4 grades based on their interpretation of the existing literature and followed a systematic approach to grading the strength of management recommendations that was set forth by the American College of Chest Physicians in 2006¹⁹ (Table 6). It should be noted that this grading system was constructed post hoc, without evidence-based attempts to determine its predictive value. Our results challenge the validity of the VHWG grading system. Greater than 50% of our patient cohort consisted of VHWG grades 2–4 patients: 40 grade 2, 17 grade 3, and 2 grade 4 patients. We only observed 3 SSIs in our series, 2 in

grade 2 patients and 1 in a grade 4 patient, and all of these subcutaneous infections were managed with intravenous antibiotics alone or in conjunction with local wound care. No patients developed a mesh infection or required mesh revision or removal. The VHWG emphasized that their recommendation to use biologic material for repair in grade 2 patients is “based on the assumption that certain patients with comorbidities (i.e. grade 2) will, in fact, develop SSOs such as wound infection and that biologic repair materials may facilitate management of infection without necessitating removal.”¹³ Our data suggest that grade 2 patients are not at a particularly high risk of infection compared with grade 1 patients and that infections can be handled with conservative measures in even VHWG grade 3 and 4 patients.

Our results indicate that patient comorbidities are less important when surgical technique is optimized, and our outcomes (wound complication rate of 7.9%) surpassed retrorectus VHR outcomes data reported in the literature to date. We attribute these results primarily to superior force distribution, maintenance of tissue perfusion with perforator preservation, and the orthopedics concept that well-fixed implants do not become infected. We postulate that improved soft-tissue stability (including overlying

Table 6. VHWG Hernia Grade and Recommendations¹³

Demographics	
Age at time of surgery (mean ± SD)	55.6 (12.0)
Males (No. patients)	34
Females (No. patients)	67
BMI (mean ± SD)	29.1 (6.2)
Smoking status	
Smoker at time of operation	6 (5.9%)
Smoker within 3 months of operation	7 (6.9%)
Comorbid conditions	
Diabetes	10 (9.9%)
Uncontrolled diabetes	3 (3.0%)
COPD	1 (1.0%)
Recent chemotherapy	6 (5.9%)
Immunosuppressant medications	8 (7.9%)
ASA score (mean ± SD)	2.2 (0.56)
Surgical history	
No. prior abdominal operations (mean ± SD, range)	2.9 (1.9, 0–9)
No. patients with previous VHR	44 (43.6%)
No. patients with previous wound or mesh infection	15 (14.9%)
Procedure time	
Total procedure time in minutes (mean ± SD)	157.2 (47.5)
Plastic surgery operative time in minutes (mean ± SD)	153.2 (44.2)

ASA, American Society of Anesthesiologists

skin) leads to better wound healing, a concept taken from the use of splints and casts for after extremity injury.

The most distinctive aspect of the technique used in this study is the use of up to 45 suture fixation points to more securely fix a narrow piece of mesh to the rectus muscles within the retrorectus space. The current consensus in hernia repair is to utilize giant prosthetic meshes held in place by friction between layers of the abdominal wall, often in combination with a transversus abdominus release to open the retrorectus space further to accommodate the large mesh. The posterior rectus fascia has all of its blood supply from the inferior epigastric artery and segmental intercostals divided to achieve this mobilization, and we question its vascularity. We believe that a more limited soft-tissue dissection, together with strong fixation of the mesh to avoid movement, leads to a lower rate of seromas that predispose to infection. Arguably, fixation is associated with pain, increased time of surgery, and possibly even increased infection risk.²⁰ To rebut each of these potential criticisms, we have both conceptual and data-driven arguments. The sutures placed in our procedure are 4 cm from the midline, where the nerves are small. Over a 3-year time frame, 59 patients treated with transrectus sutures were assessed for pain, and at 1 year, they were measured using Patient-Reported Outcome Measurement Information System^{21,22} and found to have less pain than the average American their age and sex.²³ Fixation is facilitated by the limited dissection required for placement of a narrow mesh, and our average surgery time of 157.2 minutes is faster than the average published times of Cobb et al.,⁶ Rosen et al.,²⁴ and Petro et al.²⁵ Multiple suture fixation of a narrow mesh only required 4 cm of skin elevation off the anterior rectus sheath—skin necrosis has not been a problem when perforator preservation is performed.

These findings agree with recent work by Petro et al.,²⁵ who reported no association between a number of patient

factors and comorbidities and SSO occurrence in univariate analysis with a large cohort of retrorectus hernia repairs. We differ from Petro et al.²⁵ in finding no correlation with VHWG grade, whereas they found increased complications in the more contaminated grade 3 cases, and this could relate to differences in mesh choice (biologic versus prosthetic), mesh size, and particularly mesh fixation. Another article by Petro et al.²⁶ proposes a classification system based on wound class and hernia width, rather than patient comorbidities. Other authors have also noted the importance of the inclusion of “size and location” factors associated with the abdominal wall itself in classifying complex abdominal wall hernias.²⁷ We agree that the anatomic and physiologic status of the abdominal wall is an important factor in determining outcome and requires matching surgical technique to the problem at hand. All patients in our series underwent a retrorectus placement of soft polypropylene mesh, which requires the ability to close the posterior sheath and medialize the rectus complex with or without a component separation. For patients with atypical hernias and poor fascial integrity, we have proposed using other methods of repair.^{28–30}

Our cohort represents a tertiary referral practice at a major university with all of the expected patient comorbidities. As one marker of hernia difficulty, 27.7% of the patients required anterior components releases. However, it remains possible that our patient cohort differs from those of authors experiencing higher rates of complications. Nonetheless, this would enhance, rather than detract from, our contention that current stratification tools are nonpredictive; their binary evaluation of risk factors may obscure richness of detail about the patient. Of note, a mesh suture technique^{28–30} was utilized in lieu of retrorectus mesh placement in select contaminated cases, and these cases were excluded from this cohort. We also acknowledge the inherent sample size limitations of a single-surgeon patient cohort. However, the risk scores are presented in precisely this context: as tools that surgeons can apply to their practice to impact decision making and patient optimization. Our data demonstrate that the assumptions the risk scores make about patient factors may not be applicable to all surgeons.

Our study addresses short-term wound-related complications, as they are the focus of current patient risk stratification tools. The most important of all outcomes is hernia recurrences; these data were recently published, demonstrating universally intact repairs at a mean follow-up of 2.1 years after surgery.³¹

CONCLUSIONS

High complication rates in VHR represent a significant problem. Current literature suggests that a patient’s characteristics drive their risk in undergoing this procedure. Our findings suggest that outputs of 3 risk estimation tools dependent on patient factors were not significantly associated with the outcomes seen in our cohort. The data challenge the validity of the use of current risk scores for all surgical techniques and support modifications to optimize techniques that could allow patients with various comorbidity profiles to undergo safe VHR.

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