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ORIGINAL ARTICLE

Outcomes of transversus abdominis release (TAR) with permanent synthetic retromuscular reinforcement for bridged repairs in massive ventral hernias: a retrospective review

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Abstract

Purpose In a subset of patients with massive and multiply recurrent hernias, despite performing a transversus abdominis release (TAR), anterior fascial re-approximation is not feasible and a bridged repair is required. We aim to report on the outcomes of this patient population at our institution.

Methods Patients that underwent a TAR-bridged repair at the Cleveland Clinic were identified retrospectively within the Americas Hernia Society Quality Collaborative (AHSQC) database. Outcomes of interest were quality-of-life metrics measured through HerQLes and PROMIS pain intensity 3a and composite recurrence measured by patient-reported outcomes, physical examination, or CT imaging.

Results Ninety-six patients met inclusion criteria. The mean hernia width was 26 ± 8 cm. The majority (93%) were incisional hernias and 71% were recurrent with 21% having five prior hernia repairs. Of those eligible for recurrence and QoL analysis, 54 (70%) had data points available. HerQLes scores showed a steady improvement throughout postoperative recovery (26 ± 21 at baseline, 44 ± 26 at 30-day follow-up, and 60 ± 33 at 6 months–3 years; $P < 0.001$), as did the PROMIS Pain Intensity 3a scores (46 ± 11 at baseline, 45 ± 11 at 30-day follow-up, and 39 ± 11 at 6 months–3 years; $P = 0.001$). At a mean follow-up of 20 ± 10 months, a composite recurrence of 46% was reported, primarily from patients reporting a "bulge" at the site.

Conclusion Performing a bridged TAR repair with synthetic mesh in patients with complex hernias is associated with high rates of patient-reported bulge perception. Despite this, there was a significant improvement in quality-of-life metrics. When counseling these patients during preoperative evaluation, the results of our study should be shared in candor to aid in informed decision-making.

Keywords Transversus abdominis release · TAR · Anterior fascia · Bridged · Synthetic mesh · Complex hernia

Introduction

The component separation technique has been used for decades in large or multiply recurrent hernia defects to help achieve midline apposition while minimizing tension on abdominal musculature [1]. The transversus abdominis release (TAR) is a recently described abdominal-wall reconstruction technique [2, 3], which does not require creating large skin flaps and allows for further dissection of the retromuscular space into the lateral abdominal wall. This avoids the wound morbidity associated with skin flaps and creates a wide interface for mesh positioning within a well-vascularized plane, separating the mesh from intra-abdominal contents by the posterior rectus sheath [2–4]. These advantages with excellent outcomes have allowed for the acceptance and wide adoption of this approach by abdominal-wall reconstructive surgeons [5]. Midline fascial closure can be achieved with the TAR technique for most hernia defects.

Few options exist for patients with tissue loss, wide defects, loss of domain, or fibrotic/non-compliant abdominal walls who may not achieve midline fascial closure despite undergoing a TAR. While abdominal-wall transplant and pedicle flaps have been suggested by some as a solution for these patients, there is no evidence that these interventions

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restore abdominal-wall function, they require immunosuppression in the case of the transplants, and in our view contribute mostly to soft-tissue coverage of the viscera, which often is not the main concern of our patients. Therefore, in our practice, patients are offered either watchful waiting or a bridged repair. In a bridged repair, after performing the TAR and closing the posterior rectus sheath, a mesh is placed in the retromuscular space, traversing the hernia defect immediately deep to the un-approximated anterior fascia, thus creating a "bridge". The skin and subcutaneous tissue is then re-approximated to cover the mesh. The theoretical advantage of the TAR technique in this scenario is the creation of a broad pocket in the retromuscular and retroperitoneal space, allowing for extensive overlap of the mesh, offsetting the tension on the un-approximated midline.

This subset of patients with end-stage abdominal-wall failure represents one of the most complex groups of reconstructive challenges. Many of these patients are refused repair, their defects deemed impossible to reconstruct, and are relegated to a life with an abdominal binder that rarely fits. Our group has a wide range of experience with bridged repair in these challenging cases. In this study, we report on the outcomes of this subgroup of patients at our institution, with specific interest on the impact of quality of life, recurrence rates, post-operative wound morbidity, and mortality.

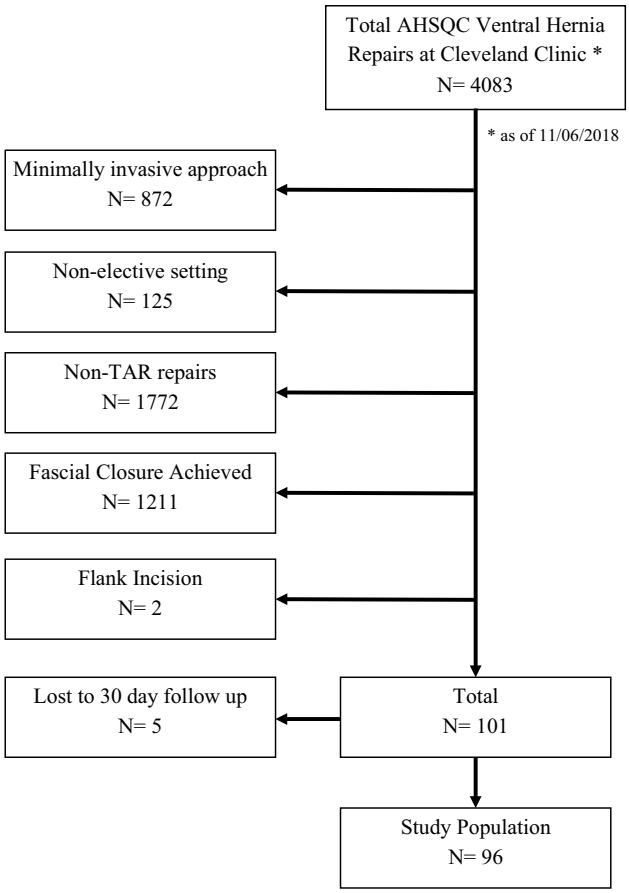

Fig. 1 Inclusion and exclusion criteria

Methods

Data source and patient selection

After receiving Institutional Review Board (IRB) approval, the Americas Hernia Society Quality Collaborative (AHSQC) was used to acquire data for bridged repairs performed at the Cleveland Clinic from 2014 to 2018. The AHSQC data registry is a prospectively maintained, surgeon-entered, point of care continuous quality-improvement registry. Details regarding the design, implementation, and data quality assurance of the registry are discussed elsewhere [6].

The study population included all Cleveland Clinic patients who had an elective open ventral hernia repair using the transversus abdominis release technique with failed midline anterior fascial approximation, requiring a bridged repair with synthetic mesh. Two patients approached through a flank incision for hernia repair were excluded. The remaining patients were approached through a midline incision. Patients that did not show up for their 30-day follow-up clinic visit were excluded from the analysis. Figure 1 describes the inclusion and exclusion criteria for identifying the study population. The STROBE Statement was followed for the presentation of this study [7].

Data collected and study eligibility

We conducted a retrospective review of the collected data. Relevant variables included patient demographics, comorbidities, operative information, and post-operative outcomes. All surgical procedures were performed between September 2014 and October 2018 by seven surgeons. Seventy-seven patients were eligible for follow-up beginning at 1 year (range 1–3 years), 54 (70%) of which had data points available for analysis. Figure 2 highlights the eligibility criteria for recurrence within this study and the patient selection process for analysis.

Patient- reported quality-of-life measures

Our main outcome of interest was patient-reported quality-of-life changes throughout the study period. Baseline PROs are collected as standard of care at our institution and include a hernia-specific quality-of-life tool, HerQLes [8], and the Patient-Reported Outcome Measurement Information System (PROMIS) Pain Intensity 3a survey [9].

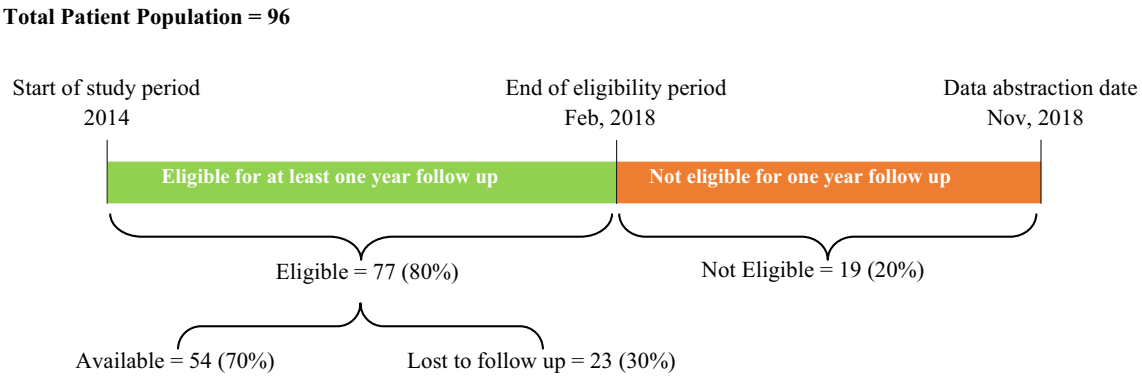

Fig. 2 Schematic illustrating eligibility period for recurrence assessment

HerQLes survey

The HerQLes survey is a 12-question, validated, hernia-specific quality-of-life instrument with a focus on abdominal-wall function and the impact of ventral hernia repair on quality of life [8]. The HerQLes score has been found to correlate with changes in core physiology and abdominal-wall functionality [10]. Patients report their answers on a Likert scale from 1 to 6 with a raw score calculated by adding each item's score. Raw scores are then converted to summary scores using the following formula:

$$\text{12 Question Average} = \frac{\text{Response to } Q1 + \text{Response to } Q2 + \ldots + \text{Response to } Q12}{12}$$

$$\text{HerQLes Summary Score} = 120 - 20 \times \left[\text{12Question Average}\right].$$

This rescales the raw score so that a 0 value is the worst possible response, and a value of 100 indicates the best possible response. Higher summary scores represent a better quality of life. This is an updated method for interpreting the HerQLes score, which has not been published yet. The updated HerQLes score is superior to its predecessor in that it provides values where the range of scores is consistently between 0 and 100 across cohorts, untethering the score from the reference population and simplifying the calculation.

PROMIS pain intensity 3a survey

The PROMIS Pain Intensity 3a Survey is a National Institute of Health-developed validated tool, which focuses on PROs of pain characteristics [9, 11]. It consists of three questions assessing the levels of pain over the prior week. Answers are ranked from 1 to 5 as follows: 1—no pain; 2—mild; 3—moderate; 4—severe; and 5—very severe. A raw score is then obtained by adding each item's value, with a minimum possible score of three (No pain on all three domains), and a maximum of 15 (very severe pain on all three domains). The raw score is then converted to standardized scores using the raw score/scale score tables provided by the PROMIS scoring manual [11]. A higher standardized score represents more pain.

Definition of recurrence

Hernia recurrence was evaluated at a minimum of 1-year follow-up. Hernia recurrence was assessed through three separate mechanisms: (1) radiologic (CT/MRI/US) examination; (2) clinical examination; and (3) the Ventral Hernia Recurrence Inventory (VHRI) [12]. The VHRI, a validated patient-reported outcomes tool, is a three-question survey that can be administered directly to patients without clinical interaction. At a minimum of 1 year, the question, "Do you feel or see a bulge?", has been found to have higher sensitivity and specificity than a physical examination in a cohort of incisional hernia patients (hernia width 6 ± 4.5) repaired mostly through open approaches [12]. The VHRI is included in the patient-reported outcomes (PROs) routinely collected by the AHSQC. If a patient answered "Yes" to "Do you feel or see a bulge?", they were counted as a recurrence by the VHRI.

Patients are considered to have a positive composite recurrence if any of the three mechanisms are considered positive for a hernia recurrence. If more than one data point was found for the same patient, the last available follow-up was considered for the analysis.

Wound morbidity and other outcomes of interest

Secondary outcomes of interest included wound morbidity on 30-day follow-up, extending up to 3 years. Post-operative

wound events collected in the AHSQC include Surgical Site Infection (SSI), Surgical Site Occurrence (SSO), and SSO requiring procedural intervention (SSOPI) [13]. SSI was defined according to the Center for Disease Control and Prevention (CDC) classifications as superficial, deep, or organ space [14]. Surgical Site Occurrence (SSO) included any SSI, in addition to wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft-tissue ischemia, skin or soft-tissue necrosis, serous or purulent wound drainage, stitch abscess, seroma, hematoma, infected or exposed mesh, or development of an enterocutaneous fistula. Procedural interventions to be considered SSOPI included wound opening, wound debridement, suture excision, percutaneous drainage, partial mesh removal, and/or complete mesh removal. Wound morbidity was also presented according to the Clavein–Dindo classification [15].

Other outcomes of interest included mortality throughout the duration of the study, and 30-day medical complications, readmissions and reoperations.

Study analysis

Descriptive statistics were used to analyze the data, using exact frequencies, percentages, means and standard deviations, as well as medians and interquartile ranges wherever appropriate. A rank-based two-sample test for partially matched two-sample data was used to measure comparisons of means [16]. Wilcoxon rank sum test was used to measure comparisons of medians. No missing data were encountered in our study. Patients that were lost to follow-up beyond 30 days were reported and excluded from the overall denominator.

Results

Patient demographics and characteristics

During the study period, 1314 patients underwent an open elective abdominal-wall reconstruction using the TAR technique; of these, 96 (7%) patients had a bridged repair and met inclusion criteria. The demographics and patient characteristics of this cohort are presented in Table 1. The mean age of the cohort was 60 ± 12 years with a mean BMI of 32 ± 6 kg/m^2. The majority (68; 71%) were recurrent hernias, of which 43 (63%) had at least two or more repairs, with 14 (21%) having five prior hernia repairs. Component separation had previously been performed for 17 (18%) patients, and 34 (35%) had a history of an open abdomen.

Table 1 Demographics and patient characteristics

N	96	
Age, years (mean ± SD)	60 ± 12	
Gender		
Male	54	56%
Female	42	44%
ASA class		
2	7	7%
3	79	82%
4	10	10%
BMI, kg/m^2 (mean ± SD)	32 ± 6	
Smoker	4	4%
Diabetes	23	24%
COPD	15	16%
Immunosuppressants	9	9%
Inflammatory Bowel Disease	4	4%
Recurrent	68	71%
Number of prior hernia repairs		
1	25	37%
2	16	24%
3	9	13%
4	4	6%
5	14	21%
History of component separation	17	18%
History of open abdomen	34	35%
History of abdominal-wall SSI	33	34%
Infection location		
Superficial	2	6%
Deep	27	82%
Organ	3	9%
Prior prosthetic mesh infected	19	58%
Infected mesh removed	17	89%
History of MRSA infection	6	6%

Hernia and operative details

Hernia characteristics and operative details are presented in Table 2. Notably, the mean hernia width was 26 ± 8 cm [range 12–50], comprised mostly of incisional hernias (89; 93%). Figure 3 illustrates a histogram of hernia width in this population. Pain and an enlarging hernia interfering with activities were the most common indications for surgery (86% and 89%, respectively). The majority of cases were classified as clean (72; 75%), and synthetic mesh was used universally and placed in a sublay (retromuscular/preperitoneal) position. The mesh materials used included heavy weight polypropylene (38; 40%), medium weight polypropylene (36; 38%), and heavy weight polyester (22; 23%). A variety of mesh sizes were used: a 50 × 50 mesh was used in 49 (50%) patients, a 30 × 30 mesh was used in 10 (15%) patients, a 36 × 26 mesh was used in 5 (8%) patients, and a 40*40 mesh was used in 1 (2%) patient. In the remaining 31 (32%) patients, two to four meshes were quilted to achieve adequate coverage. Transfascial sutures were used in all patients to secure the mesh.

Table 2 Operative details and hernia characteristics

N	96	
Hernia width, cm (mean ± SD)	26 ± 8 [range 12–50]	
Hernia area, cm^2 (Mean ± SD)	622 ± 314	
Mesh area, cm^2 (Mean ± SD)	2206 ± 806	
Hernia type		
Incisional	89	93%
Incisional and parastomal	5	5%
Umbilical	2	2%
EHS classification (ventral)		
Midline component		
M1—subxiphoildal	64	67%
M2—epigastric	88	92%
M3—umbilical	88	92%
M4—infraumbilical	75	78%
M5—suprapubic	56	58%
No midline component	2	2%
Lateral component		
L1—subcostal	8	8%
L2—flank	18	19%
L3—iliac	10	10%
L4—lumbar	2	2%
No lateral component	69	72%
Stoma present	6	6%
Wound class		
Clean	72	75%
Clean-contaminated	12	13%
Contaminated	11	11%
Dirty	1	1%
Primary indication for surgery		
Bowel obstruction	11	11%
Fistula	2	2%
Infected mesh	1	1%
Enlarging/interfering with activity	85	89%
Pain	83	86%
Mechanical bowel prep used	5	5%
Preoperative chlorhexidine used	43	45%
Prophylactic antibiotics	96	100%
Prior mesh	52	54%
Prior mesh excision		
None	17	33%
Partial	7	13%
Complete	28	53%
Mesh fixation	96	100%
Drains used	96	100%
Subcutaneous flaps raised	21	22%
OR time		
120–179	2	2%
180–239	19	20%
240+	75	78%
Enterotomy	8	8%
Management		
Primary repair	4	50%
Bowel resection	4	50%

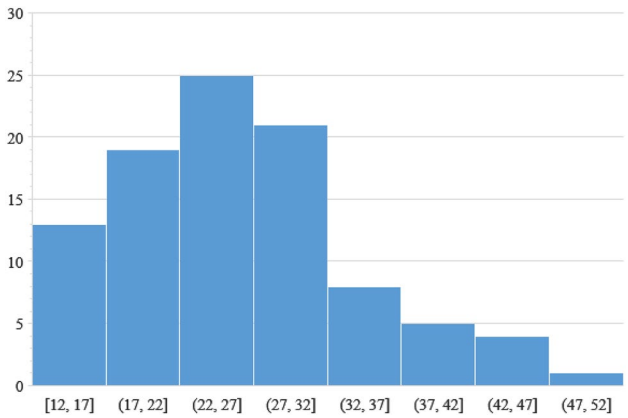

Fig. 3 Histogram of hernia width (cm)

In the five cases where the posterior rectus sheath could not be completely closed, a second rapidly absorbable synthetic mesh (polyglactin 910-Vicryl®, Ethicon, Inc, Cincinnati, Ohio) placed in inlay position was secured to the edges of the posterior sheath to avoid risk of internal hernia through the posterior rectus sheath. No preoperative pneumoperitoneum or botulin toxin injection was used in this cohort of patients.

There was an 8% rate of enterotomies; half were repaired primarily and the rest required bowel resection. Table 3 describes all concomitant procedures performed, with 33 total reported cases. Five patients required a bowel resection. Of those, one patient was readmitted for major wound complications (wound serous drainage and small ulcer formation) unrelated to the bowel resection. Twelve patients required either rotational or free flaps for adequate soft-tissue coverage on top of the mesh.

Quality-of-life metrics (HerQLes and PROMIS pain intensity 3a):

From the entire cohort ($n = 96$), 42 (44%) had baseline quality-of-life metrics available, 38 (40%) had 30-day follow-up scores available, and 54 (56%) had greater than 30-day follow-up scores available (6 months–3 years).

Figure 4a depicts the means and standard deviations of the HerQLes summary score across the recovery period for these patients. A steady increase and gain in their abdominal-wall function quality of life is observed, with

Table 3 Concomitant procedures

N	96	
Concomitant procedures	33	34%
Hernia	1	3%
Separate hernia repair (>7 cm)	1	
Endocrine/foregut	3	9%
Adrenalectomy	1	
Splenectomy	2	
Hepatobiliary/pancreatic	3	9%
Cholecystectomy	3	
Small intestine	8	24%
Small bowel resection	5	
Ileostomy takedown	1	
EC fistula takedown	2	
Gastrectomy	1	
Colorectal	2	6%
Revision and re-siting of colostomy	2	
Obstetric	1	3%
Bilateral tubal ligation	1	
Urologic	1	3%
Renal cyst drainage	1	
Plastic/soft tissue	21	64%
Panniculectomy	5	
Scar revision	1	
Free flap	11	
Rotational flap	1	
Others	7	
Removal of abdominal-wall tumors (pseudomyxoma peritonei)	1	
Soft-tissue reconstruction	2	
Skin and subcutaneous flap	1	

an 18-point increase in mean scores at 30-day follow-up. At follow-up beyond 30 days (6 months–3 years), a statistically significant ($P < 0.001$) increase of 34 points from baseline HerQLes scores was observed. Figure 4b illustrates the mean and standard deviation of the PROMIS pain intensity 3a scores. There was a steady improvement in pain scores observed across the recovery period with a statistically significant change from 46 ± 11 at baseline to 39 ± 11 at last follow-up (6 months–3 years) ($P = 0.001$)

Recurrence

Table 4 depicts the results of composite recurrence beginning at 1-year post-hernia repair. Seventy-seven (80%) patients were eligible for follow-up from the initial population. Of those, 54 (70%) were available for analysis (Fig. 2). The rate of composite recurrence reported for our patient population was 46%, with the majority reported using the VHRI. Of the 23 that answered "Yes" to "Do you feel or see a bulge?", 11 also answered "Yes" to "Do you feel your hernia has come back?". Furthermore, 11 of 23 also received a CT scan or physical examination; one confirmed the recurrence, while the rest were negative for a recurrence.

Thirty-five patients received a clinical examination or CT scan. Three recurrences were reported using this method; all were due to central mesh fracture of a monofilament polyester mesh detected on CT scan. Two of those patients had the VHRI available, and both reported a bulge.

Overall, the mean follow-up for quality of life and recurrence data in our cohort was 20 ± 10 months.

Effect of composite recurrence on patient-reported outcomes

To determine the effect of patient-reported outcomes of feeling a bulge to abdominal-wall function quality of life, a subgroup analysis was performed comparing patients who had a composite recurrence reported to those who did not (Table 5). Figure 5 shows a box plot illustrating the relationship between each group and the quality-of-life metrics across the recovery period. Although both groups started with similar median HerQLes baseline scores, and improved steadily on 30-day follow-up, the group reporting a bulge and composite recurrence reported significantly worse median HerQLes summary scores at last follow-up [44 (20–73) vs 78 (31–95), respectively; $P = 0.019$]. A similar observation is present within the PROMIS pain intensity scores, where the recurrent group reported significantly more pain at last follow-up [42 (31–55) vs 31 (31–42), respectively; $P = 0.008$]. A univariate analysis of patient and hernia characteristics (not shown) found diabetes to be the only significant difference between the two groups, with the "no recurrence" group having a higher rate of diabetes (38% vs 12%; P value $= 0.035$).

Wound morbidity

Table 6 outlines 30-day wound morbidity. On 30-day follow-up, 10 (10%) SSIs were reported, and the majority were classified as deep (8; 80%). A total of 23 (24%) SSOs were reported, with non-infectious complications consisting mainly of non-healing incisional wounds (7; 30%) and seromas (6; 26%). Procedural interventions for the management of these events included wound opening (9; 60%), wound debridement (3; 20%), and/or percutaneous drainage (5; 33%). In total, 15 (15%) SSOPIs were reported. Of note, 6 (60%) of the SSIs, 10 (43%) of the SSOs, and 6 (40%) of the SSOPIs occurred in clean-contaminated, contaminated and dirty wound classes (wound classes II, III, IV).

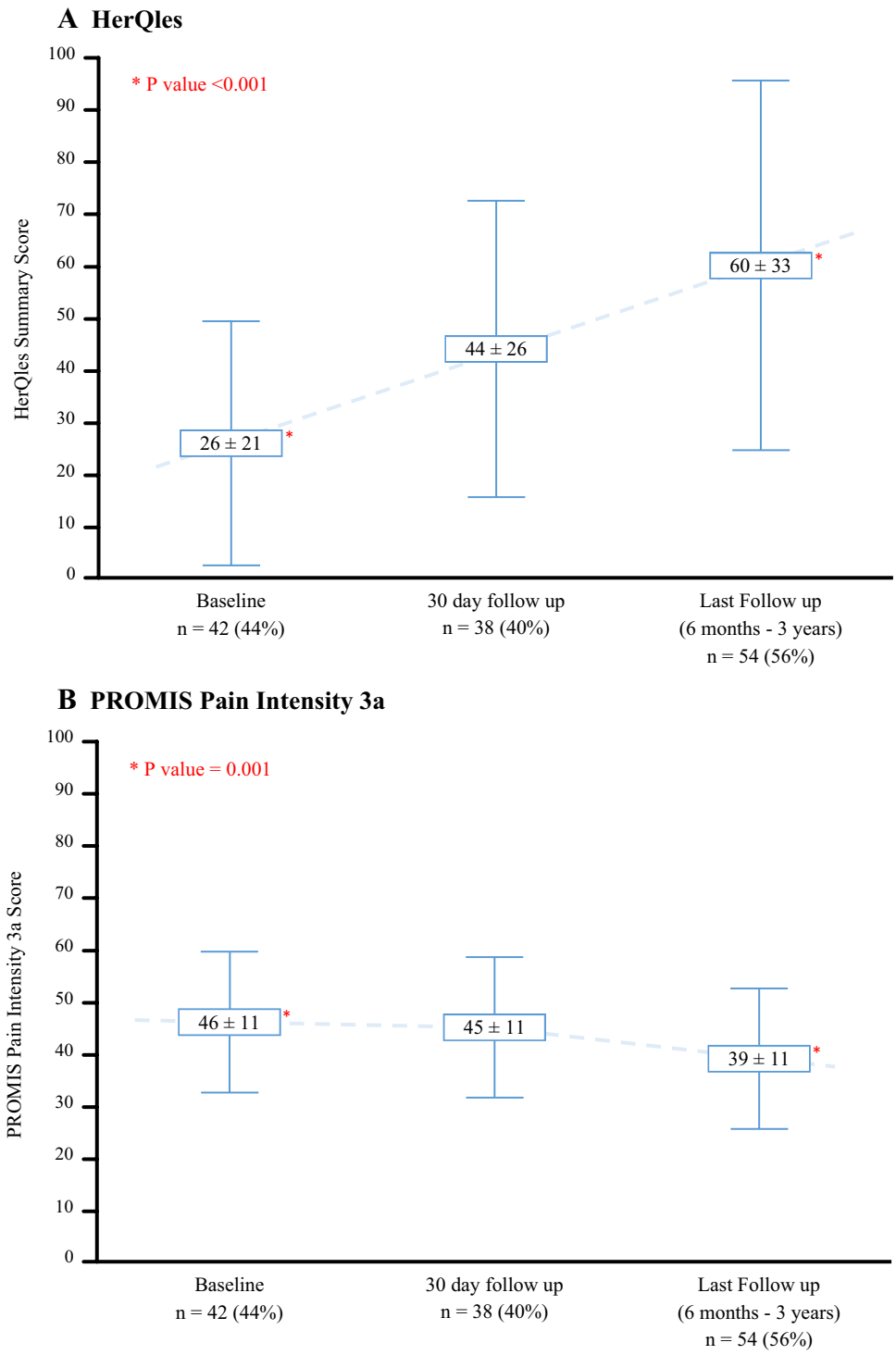

Fig. 4 Quality-of-life metrics in the overall cohort; (**a**) HerQles Summary Score; (**b**) PROMIS Pain Intensity 3a score. *Measured using rank-based two-sample test for partially matched two-sample data [11]

On follow-up beyond 30 days (3–36 months), three more SSIs, four more SSOs, and four more SSOPIs were reported. Two of the three SSIs were classified as deep, one of which was due to mesh infection. This patient required partial mesh excision for wound management. Four other partial mesh excisions were required for previously reported deep SSIs during 30-day follow-up.

Other outcomes of interest

The median length of stay for our patient population was 8 days [6, 7]. There were 8 (8%) readmissions within 30 days of surgery. Five (63%) of the readmissions were due to major wound complications. There was one reoperation reported due to major wound complications.

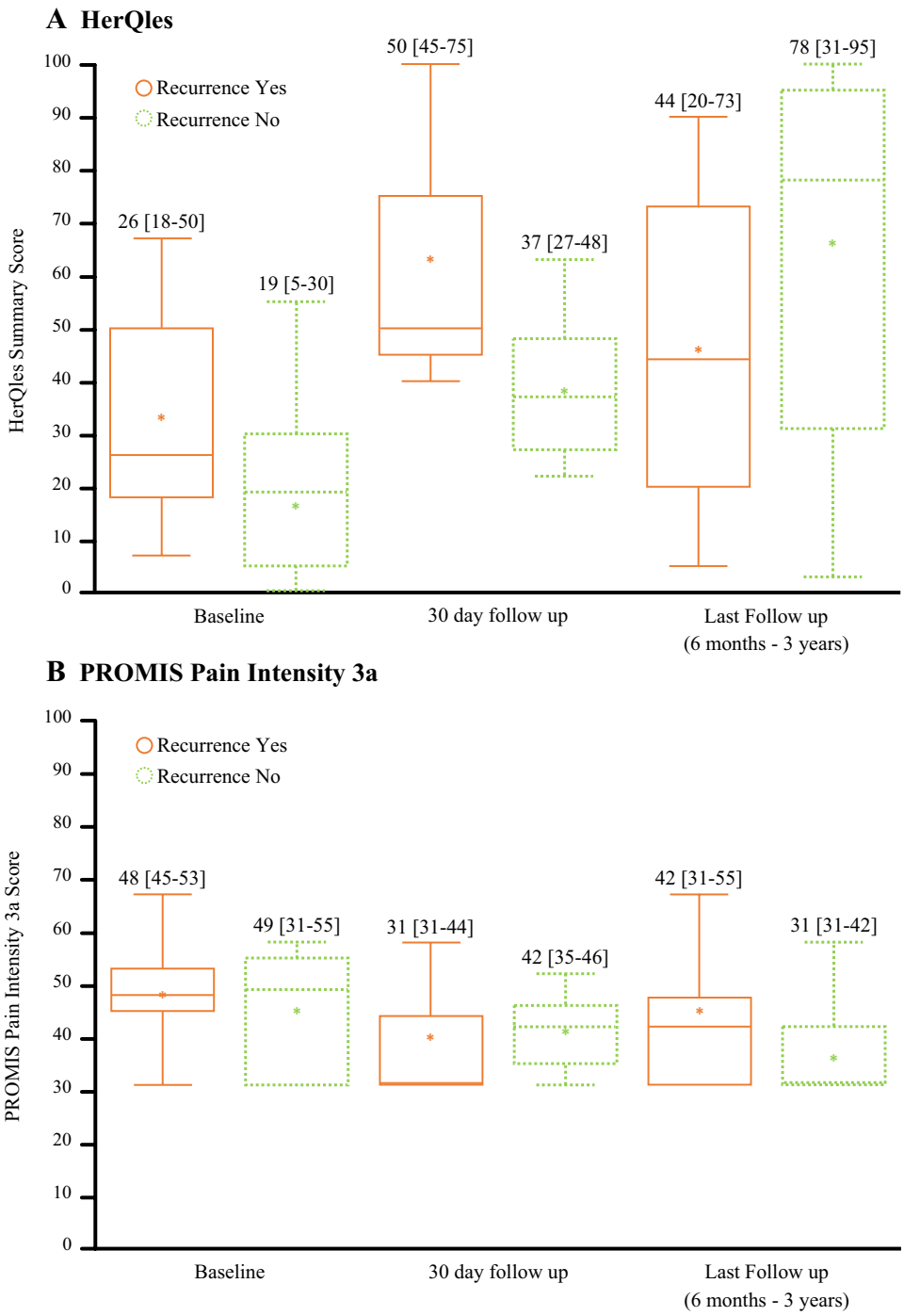

Fig. 5 box plots illustrating quality-of-life metrics comparing patients with a recurrence to those without; (**a**) HerQles Summary Score; (**b**) PROMIS Pain Intensity 3a score

Within the 30-day follow-up period, 6 (6%) patients had a venous thromboembolic (VTE) event reported. There was a 5% pulmonary embolism (PE) rate in this cohort. Other 30-day outcomes measures are presented in Table 7.

Overall, there were 6 (6%) mortalities reported in this cohort with a mean time to death of 11 ± 8 months. One mortality was related to a PE and occurred within the perioperative period. The remaining mortalities were remote from the time of surgery. Two of these were due to cardiac arrest and one due to small bowel ischemia thought to be unrelated to the hernia repair. The remaining three mortalities did not have a documented cause of death.

Table 4 Recurrence

			Available
Composite recurrence			54
Yes	25	46%	
No	29	54%	
Radiology/physical exam			35
Yes	3	9%	
No	32	91%	
VHRI[a]			
Do you feel or see a bulge? Yes	23	51%	45
Do you feel your hernia has come back?			23
Yes	11	48%	
No	12	52%	
Do you feel or see a bulge? No	22	49%	45
Do you feel your hernia has come back?			22
Yes	2	9%	
No	20	91%	

[a]Ventral hernia recurrence inventory

Table 5 Quality-of-life metrics comparing patients with a recurrence to those without

	Recurrence No		Recurrence Yes		
	score	available	score	available	*P* Value
HerQles					
Baseline	19 [5–30]	9	26 [50–67]	8	0.063
30 days	37 [27–48]	8	50 [45–75]	3	0.073
Last follow-up	78 [31–95]	23	44 [20–73]	24	**0.019**
PROMIS					
Baseline	49 [31–55]	9	48 [45–53]	8	0.884
30 days	42 [35–46]	8	31 [31–44]	3	0.675
Last follow-up	31 [31–42]	23	42 [31–55]	24	**0.008**

Table 6 30-day wound morbidity

N	96	
SSI	10	10%
Type of SSI		
Superficial	3	30%
Deep	8	80%
SSO	23	24%
Type of SSO		
Wound cellulitis	1	4%
Non-healing incisional wound	7	30%
Skin or soft-tissue ischemia	1	4%
Skin or soft-tissue necrosis	1	4%
Wound serious drainage	3	13%
Seroma	6	26%
Exposed synthetic mesh	2	9%
SSOPI	15	16%
Type of SSOPI		
Wound opening	9	60%
Wound debridement	3	20%
Percutaneous drainage	5	33%
SSO	23	24%
Clavien–Dindo classification		
Class I	7	30%
Class II	8	35%
Class III	8	35%

Discussion

Our study is the first to describe the outcomes for a large cohort of patients undergoing a TAR with a bridged retromuscular synthetic mesh for massive hernias where the anterior fascia could not be approximated. This was a challenging cohort of patients with massive hernia defects (hernia width 26 ± 8 cm), where the majority (71%) had a prior hernia repair attempted. This population of incisional hernia repairs represents a palliative group of patients that are often denied repair due to perceived prohibitive perioperative risks and presumed inevitable repair failure. In our cohort, these patients were often repaired due to non-life-threatening complaints (pain and hernia enlarging/interfering with activities), highlighting the palliative nature of this repair and the importance of studying quality of life as a primary outcome measure. Our study shows a significant improvement in quality of life and pain scores for these patients compared to their baseline, with an overall doubling of HerQLes scores, and a seven-point decrease in PROMIS pain intensity 3a score. This complicated cohort of patients still had substantial morbidity in the immediate post-operative period and overall relatively high patient-reported recurrence rates.

Achieving complete midline closure with approximation of the anterior rectus sheath is considered an important component of an abdominal-wall reconstruction. In a large series evaluating TAR in 428 patients with smaller defects than the present study (mean hernia width of 15 cm), a 97.2% rate of anterior fascial closure was reported. This correlated with low hernia recurrence rates (3.7%), and acceptable rates of wound morbidities (18.7%, consisting mainly of superficial SSIs) [5]. Our group also espouses a similar belief that fully reconstructing the midline results in improved outcomes as evidenced by full midline reconstruction in over 90% of the 1314 TARs performed during this study period. However, 7% of patients in our practice could not achieve primary midline fascial closure. This 7% represent this study's cohort, which is likely not comparable

Table 7 Other 30-day outcomes

N	96	
Length of stay, days [median (Q1–Q3)]	8	[6, 7]
Readmission	8	8%
Readmission reason		
Wound complications	5	63%
GI complications[a]	1	13%
Respiratory complications	1	13%
Urinary tract infection	1	13%
Reoperation	1	1%
Reoperation type		
Major wound complication	1	100%
Recurrence at 30 day	0	0%
30-day medical complication		
Pain	0	0%
Thromboembolic events	6	6%
Pulmonary embolism	5	5%
DVT	2	2%
Stroke	1	1%
Sepsis	1	1%
Septic shock	1	1%
MI	0	0%
Cardiac arrest	0	0%
UTI	3	3%
Renal insufficiency	1	1%
Renal failure	0	0%
Pneumonia	2	2%
Endotracheal intubation	0	0%

[a]Enteritis of unclear etiology, resolved with NPO and antibiotics

to any series of smaller hernias that were completely reconstructed. There is little literature describing the outcomes of a TAR in circumstances where the anterior fascia could not be approximated. Usually, these patients are a subgroup of the main cohort described, and the outcomes reported are not specific to this patient population [17, 18]. Apart from our study, no current literature evaluates patient-reported outcomes in this scenario.

The most similar cohort of massive hernias presented in the literature is a study by Posielski et al. evaluating the outcomes of using quilted mesh to achieve the required overlap for these wide defects [19]. They describe 32 patients with hernia widths of 24.7 ± 6.4 cm and a mean BMI of 38.3 ± 5.8 kg/m^2. Complete restoration of the linea alba was still achieved in 90.5%, suggesting that these defects were not as significant as the ones encountered in the present study. The reported wound morbidity is similar to ours; with a total wound morbidity of 25%, and 12.5% SSIs, half of which were classified as deep. They also reported a 6.3% rate of recurrence with a mean follow-up of 9 months ($\pm$ 14 months). Although this is significantly lower than our results, the follow-up is significantly shorter than our mean follow-up of 20 ± 10 months where we detect 46% composite recurrence rate. In addition, due to the significant variation in the tools used to detect recurrence and the complexity of our patients' hernia characteristics leading to failed complete fascial re-approximation, these differences are difficult to interpret. Moreover, assessing the relative success of a complex operation in this unique population by composite or clinical recurrence might not be relevant. Instead, evaluating the success of the operation from the patient's perspective and noting the improvement in quality of life might be the most appropriate measure of ultimate success of any intervention of this magnitude.

The findings of our study on the quality-of-life metrics are reassuring. Overall, our population reported significant improvement in abdominal-wall function quality of life and pain. However, we noticed a decline in the median quality of life and pain scores after an initial observed improvement at 30-day follow-up when studying changes in QoL metrics for patients perceiving a bulge. It is important to note that 11 of 23 patients perceiving a bulge received a CT scan, which showed no recurrence except in one patient. This might indicate that even when an anatomically intact repair is present, a patient's perception of a bulge may limit their abdominal-wall function due to fear of disease deterioration and recurrence, reflected by worse scores on HerQLes. It could also be that the suboptimal contour outcomes of a hernia repair, despite an intact abdominal wall, may functionally limit these patients. The factors leading to changes in HerQLes and PROMIS scores are not fully elucidated, and an anatomically intact repair may only be one of many factors that ultimately influence these changes. In the setting of these massive hernias with loss of domain and tissue loss with severe fascial retraction, it is likely that patient reports of a bulge are not synonymous with a perceived failed repair by the patient. Regardless, it is apparent that a subgroup of patients undergoing this operation are not experiencing the robust recovery observed in the overall population. Moreover, patient-reported recurrences, even in the setting of normal imaging, are valid concerns regarding the contour outcomes of a hernia operation. Given these findings, we believe that it is important to set reasonable expectations with the patients as to what the ultimate outcome of these complex procedures will be and what will be considered a success. It is important to recognize that these are the findings of our group, as described in an extremely complex group of patients with multiple prior failed hernia repairs and substantially large defects undergoing a palliative repair. These findings are not widely generalizable to all ventral hernia repairs.

Our approach to repairing these types of hernias involves the use of TAR, the use of synthetic mesh, as well as our standard of care preoperative optimization. The TAR has

become standard of care at our practice for all patients requiring myofascial advancement. This is driven by its described benefit in improving wound morbidity by avoiding the creation of large skin flaps while providing similar medialization to the anterior component separation (ACS) [1, 3, 4, 20]. A benefit essential for bridged repairs is the wide pocket for mesh positioning in the retromuscular space compared to the ACS. Because the anterior fascia is not approximated in this patient population, a wider overlap is essential to offset the tension on the weaker midline component of the hernia repair. The use of synthetic mesh for the bridged repairs is also an essential component, as the use of a biologic mesh has been found to result in higher recurrence rates when placed in bridging repairs [21, 22]. Finally, this patient population underwent our standard of care preoperative optimization of their comorbidities, with heavy emphasis on weight loss [23]. We did not use any preoperative pneumoperitoneum or botulinum toxin injection as no high-level evidence exists for their benefit adjacent to the TAR for midline approximation.

Several concerning findings are present in our study; as previously mentioned, the wound morbidity present in our population is higher and more complex than those reported for elective TARs [5]. However, when looking at the literature evaluating TARs in complex scenarios similar to ours, the wound morbidity reported approximates our rate: Petro and colleagues studied the outcomes of TAR for the management of an open abdomen where fascial closure was achieved in 88.2% of cases [24]. They found a 35% rate of total wound morbidity; most of their wound events were attributed to wound infections, with deep SSIs and organ space infections comprising more than half of total wound infections. About 83% of their wound events required procedural management. This is comparatively high relative to the number of patients that required a procedural management in our cohort, as only 65% of our total wound events required a procedural management. These differences in wound morbidities can be explained by cohort characteristics; 75% of our patient population were clean cases, whereas only 38.2% of their patient population were classified as clean. Unfortunately, this study, as many other retrospective hernia papers, does not report patient-reported outcomes to further compare our outcomes to theirs.

Another concerning finding in our analysis is the high rate of VTE, with 5% being pulmonary embolism, causing one mortality in our cohort of patients. This is a significantly higher rate than previous literature assessing thromboembolic events in ventral hernia repair. An NSQIP analysis on the association of venous thromboembolic events with component separation found a 0.04% rate of pulmonary embolism [25]. Our group has previously studied the rates of VTE at our practice and found similarly high rates, with the majority of these thromboembolic events occurring almost exclusively in patients with larger hernia widths (≥15 cm) [26]. Considering that the mean hernia width of our cohort is 26 ± 8 cm, this is not a surprising finding. In addition, 78% of our bridged repair patients had OR time of 4 h or more, which may have contributed to this population's VTE rate. Our group has recognized the gravity of this issue and a quality-improvement project is currently underway to implement changes to our protocol and assess compliance and success [26].

Our study has several limitations that deserve mention. The first lies in the method used to detect a recurrence. While the Ventral Hernia Recurrence Inventory (VHRI) has been validated with specificity and sensitivity to detect a recurrence greater than that of a physical exam [12], the hernia width in that cohort was 6 ± 4.5 cm. Patients with massive hernia widths similar to our cohort have different anatomic disruption, with different contour outcomes after abdominal-wall reconstruction and as mentioned, a bulge might be an expected outcome. The validity of the VHRI in this population has not been well established. Therefore, improvement in long-term follow-up with imaging and quality-of-life measures may provide a more accurate depiction for these patients' actual anatomic recurrence rate. However, due to the difficulty in obtaining physical follow-up on this patient population [12], the VHRI remains an efficient tool that can be administered easily over the phone to obtain long-term outcome measures on these patients.

Another limitation is the lack of a comparison arm reporting on outcomes of patients with similar hernia disease who were either not offered a repair or underwent a different intervention. Our study reflects the treatment of these complex patients, as has been the practice of our group. Due to the multiply recurrent nature and large defect size of these hernias, attaining a comparable group is challenging, and a prospective study is unlikely to be undertaken. Moreover, only 70% of our population had follow-up available greater than 30 days, and although a significant number of patients had data available for their quality of life, not many had data available for all three timepoints assessed. Therefore, we were not able to adjust for baseline evaluation when analyzing postoperative scores. The subgroup analysis of the quality-of-life scores in the groups with recurrence vs no recurrence also contained small numbers, which may have biased our results. Finally, our study is an analysis of a registry-based database, a degree of error in data collection and measurement is expected.

In conclusion, abdominal-wall reconstruction with TAR and bridged synthetic mesh for large, complex abdominal-wall defects has a difficult post-operative recovery course, and relatively high patient-reported recurrences. Despite this, there was an overall improvement in patient-reported quality of life. Therefore, performing a TAR with bridged repair for these patients remains a reasonable option, and

the evaluation of non-operative management remains viable if the perioperative risks are too great. Finally, when counseling patients during preoperative evaluation, the results of our study should be shared in candor to aid in postoperative expectations and informed decision-making.

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Compliance with ethical standards

Conflicts of interest Dr. Ajita S. Prabhu reports grants from Intuitive Surgical Inc., personal fees from Intuitive Surgical Inc., and personal fees from Medtronic, outside the submitted work. Dr. Michael J. Rosen receives salary support for his position in the leadership of the Americas Hernia Society Quality Collaborative (AHSQC), which is the data source for the present submission. Other unrelated conflicts of interest outside of the submitted work include grants from Intuitive Surgical Inc., grants from Pacira Pharmaceuticals Inc., board member support and stock options from Ariste Medical. Dr. David M. Krpata reports grants from W.L Gore, outside the submitted work. Dr. Luciano Tastaldi reports grants from Americas Hernia Society Quality Collaborative, outside the submitted work. Dr. Aldo Fafaj reports grants from Americas Hernia Society Quality Collaborative, outside the submitted work. Drs. Steven Rosenblatt, Hemasat Alkhatib, and Clayton Petro report no conflicts of interest.

Ethical approval This study did not need approval from the local ethical committee.

Human and animal rights This study does not contain any studies with participants or animals performed by any of the authors.

Informed consent For this type of study, consent was not required.

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