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Research Article

Variation in approach for midsize (4-6cm) ventral hernias across a statewide quality improvement collaborative

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ABSTRACT

Introduction: Repair of midsize (4–6 cm) ventral hernias is challenging given lack of guidelines. Within this context, we sought to characterize surgical approach among patients undergoing repair of midsize ventral hernias within the only population-level, clinically-nuanced hernia registry in the US.

Methods: Retrospective cohort study of patients undergoing ventral hernia repair in the Michigan Surgical Quality Collaborative Core Optimization Hernia Registry (MSQC—COHR). MSQC—COHR is the only US population-level registry that captures clinically-nuanced data pertaining to patient hernia characteristics. We included patients who underwent repair of a 4–6 cm hernia from January 1, 2020-June 30, 2022. We stratified repair type as open or minimally invasive and used a multivariable logistic regression model to identify factors associated with MIS approach. Secondary outcomes included complications rate.

Results: Among 771 patients, mean hernia width (SD) was 4.7 cm (0.8) and 339 (44 %) underwent MIS approach. Patients with MIS approach had lower BMI (33.5 vs 34.8, $p = 0.02$) and less often were ASA class III (47.5% vs 54.6 %, $p = 0.02$) or ASA class IV (2.4% vs 4.2 %, $p = 0.02$). MIS approach was associated with smaller mean hernia width (4.71 cm vs 4.84 cm, $p = 0.02$) and was used more often in the elective setting (94.4% vs 84.0 %, $p < 0.01$). In the multivariable logistic regression model, higher BMI (aOR 0.97, 95 % CI 0.94–0.99) and urgent/emergent surgery (aOR 0.43, 95 % CI 0.24–0.79) were associated with lower odds of MIS. We found no significant association between MIS and risk of complications (aOR 0.62, 95 % CI 0.37–1.04). Among patients undergoing MIS, more than half ($n = 236$, 69.6 %) had a robotic approach but there were few patient factors associated with this.

Conclusion: Among patients with midsize hernias, few patient-level factors are associated with approach. This may indicate that surgeon preference factors largely into this decision.

Introduction

As hernia surgery continues to evolve, approaches to elective hernia repair are diverse and numerous. Given the historical lack of clinically-nuanced data (e.g., hernia size, use of mesh) to inform outcomes, guidelines are largely based on small case series or European registry studies [1]. Moreover, many such studies that use registry or claims data treat all ventral hernias as the same diagnosis, and in such cases very small, straightforward hernias are categorized in the same disease process as large, complex hernias. As a result, surgeons often use their experience or personal preferences to guide care [2,3].

One area of controversy is the repair of midsize ventral hernias (4–6 cm). While technique may be somewhat straightforward for very small hernias or much larger hernias, there seems to be equipoise between open and minimally invasive repair for midsize hernias. These defects are routinely approached through both minimally invasive and open techniques, but there are no published guidelines or standard of care to guide surgeons. While MIS repairs may result in lower rates of infection and less severe pain, open repair for larger hernias may be associated with fewer complications and better quality of life [4]. Choice of repair

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may also be associated with patients factors such as previous hernia repair and body mass index [5]. However, the operative approach for midsize ventral hernias has never been evaluated at a population-level with clinically nuanced data. Understanding variation in care, such as choice of approach, is the first step in designing quality improvement interventions to improve care.

Within this context, we sought to characterize variation in approach (MIS vs open) using the first and only population-based US hernia registry containing clinically nuanced data such as hernia size. The primary goal was to evaluate differences in approach by hernia size. We anticipated that choice of approach would be based less on patient factors, and more related to surgeon preference.

Methods

This secondary analysis of de-identified data was deemed exempt from regulation by the Institutional Review Board of the University of Michigan and the requirement for informed consent was waived. The study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement [6].

Overview

We performed a retrospective cohort review using data from the Michigan Surgical Quality Collaborative (MSQC) [7–11]. This population-based registry samples roughly 50,000 cases per year from 70 hospitals across general surgery, vascular surgery, and gynecologic surgery. Trained Surgical Clinical Quality Reviewers (SCQRs) abstract data pertaining to patient characteristics, peri-operative care, and 30-day clinical outcomes. All SCQRs are also nurses, most of whom have significant experience in the surgical field. SCQRs use structured templates to comprehensively review the medical record, and the MSQC conducts inter-rater reliability assessments on a regular basis to ensure validity and reliability of data. Cases are sampled according to a predetermined protocol to provide population-level representation and reduce selection bias. The Agency for Healthcare Research and Quality has classified MSQC as a Patient Safety Organization (PSO), which recognizes the highest level of quality and security in the methods by which data are gathered, analyzed, and shared.

On January 1, 2020, the MSQC Core Optimization Hernia Registry (MSQC—COHR) was founded to collect hernia-specific variables such as hernia width, mesh use, and outcomes. The variables that are included as part of this effort are listed in Table 1. We have previously described the methods used to construct this database, and have published extensively with this data [12–19]. A full description of the methods used to construct this database has been previously described [7].

Table 1
Hernia-specific variables collected in the database.

Data Element	Details
Hernia location	Epigastric, umbilical, infraumbilical, suprapubic, no midline component
Initial or recurrent	Did the patient have a previous hernia repair?
Hernia width	Width in cm
Hernia length	Length in cm
Mesh placement	Was mesh used?
Mesh width	Width in cm
Mesh length	Length in cm
Type of mesh	Synthetic nonabsorbable, synthetic absorbable, biosynthetic, biologic, other
Mesh brand	Brand of mesh (e.g., Bard, Medtronic, Ethicon, etc.)
Mesh location	Onlay, inlay, sublay
Sublay location	Retrorectus, preperitoneal, intraperitoneal
Mesh fixation	Suture, adhesive, absorbable tacks, non-absorbable tacks, self-fixating, other/multiple
Myofascial release	Was myofascial release performed?
Myofascial release type	Anterior versus posterior

Study population

We included adult patients who underwent ventral hernia repair for a hernia width of 4–6 cm between January 1, 2020 and June 30, 2022. Hernia size is measured by the operating surgeon at the time of hernia repair. This information is then abstracted from the operative report and entered into the MSQC—COHR registry. Operations included open, laparoscopic, and robotic ventral and incisional hernia repair (including epigastric, umbilical, and Spigelian hernia repair). MIS approach was defined as either laparoscopic or robotic approach. Procedures were identified using Current Procedural Terminology (CPT) codes (Open: 49505, 49525, 49550; MIS: 49650). Patient characteristics included age, race, insurance type, American Society of Anesthesiologist (ASA) classification, smoking status, body mass index (BMI) $\geq$ 35, diabetes, chronic obstructive pulmonary disease (COPD), obstructive sleep apnea (OSA), congestive heart failure (CHF), hypertension, and chronic steroid use at baseline. Hernia width was abstracted from the operative report by the SCQRs. Wound classification was defined according to Centers for Disease Control and Prevention (CDC) surgical wound classification system (clean, clean/contaminated, contaminated, and dirty/infected).

Outcomes and analysis

The primary outcome of this analysis was surgical approach, defined as either open or MIS. Descriptive statistics were generated using means for continuous variables and frequency distributions for categorical variables to describe patient characteristics as well as surgical approach. A multivariable logistic regression model was used to identify factors associated with undergoing a minimally invasive approach.

We performed two secondary analyses: the first was to determine if surgical approach was associated with complications or readmission while the second was to evaluate the use of robotics in this population. Given relatively low adverse postoperative event rates after ventral hernia repair, we made a composite postoperative complications variable that included post operative surgical site infection, pneumonia, unplanned intubation, venous thromboembolic event, renal injury, urinary tract infection, stroke, cardiac event, transfusion, sepsis, readmission, reoperation, or emergency room visit. We used a multivariable logistic regression model to determine the association between approach and complications.

All analyses were performed using StataMP version 17.0 (StataCorp, Inc., College Station, TX).

Results

Among 771 patients, slightly less than half (n = 339, 44 %) of patients underwent a MIS approach. Patients who underwent MIS approach had a lower BMI (33.5 vs 34.8, $p = 0.02$) and less often were ASA class III (47.5% vs 54.6 %, $p = 0.02$) or ASA class IV (2.4% vs 4.2 %, $p = 0.02$), but were otherwise similar regarding sex, age, race, insurance status, smoking status, and comorbid conditions. These findings are demonstrated in Table 2.

While hernia location was similar among patients, those who underwent MIS repair had a smaller mean hernia width (4.71 cm vs 4.84 cm, $p = 0.02$), more often had their case described as clean (95.3% vs 89.8 %, $p = 0.04$), and more often were undergoing their operation in the elective setting (94.4% vs 84.0 %, $p < 0.01$). Mesh was used more commonly among patients undergoing MIS repair (98.8% vs 89.4 %, $p < 0.01$), while myofascial release was less common (4.2% vs 15.4 %, $p < 0.01$). Mesh location (i.e., onlay, inlay, sublay) was similar between groups. Mesh length was larger for patients undergoing MIS repair (14.9 cm (0.3) vs 13.6 cm (0.4), $p = 0.02$), but no differences were found with regards to mesh width or total mesh area. There was a similar distribution of patients undergoing reoperation for recurrent hernia when comparing MIS to open (23.3% vs 29.5 %, $p = 0.05$). These findings are demonstrated in Table 3.

Table 2
Comparison of patients who underwent open compared to minimally invasive (MIS) approach.

	Open $N = 432$	MIS $N = 339$	*p*-value
Female Sex (%)	248 (57.4)	177 (52.5)	0.15
Mean Age (SD)	58.8 (14.4)	57.5 (14)	0.23
Mean BMI (SD)	34.8 (8.4)	33.5 (6.7)	0.02
Race			
White	342 (79.2)	268 (79.1)	0.46
Black	59 (13.7)	53 (15.6)	
Other	31 (7.2)	18 (5.3)	
Insurance			
Private	173 (41)	149 (46)	0.57
Medicare	165 (39.1)	111 (34.3)	
Medicaid	77 (18.3)	56 (17.3)	
Uninsured	3 (0.7)	3 (0.9)	
Other	4 (0.95)	5 (1.5)	
ASA Class			
I	6 (1.4)	12 (3.5)	0.02
II	172 (39.8)	158 (46.6)	
III	236 (54.6)	161 (47.5)	
IV	18 (4.2)	8 (2.4)	
Smoker	84 (19.4)	62 (18.3)	0.68
Comorbidities			
Diabetes	80 (18.5)	67 (19.8)	0.66
COPD	39 (9)	28 (8.3)	0.71
OSA	179 (41.4)	158 (46.6)	0.15
CHF	1 (0.23)	0 (0)	0.38
HTN	227 (52.6)	200 (59)	0.07
Chronic Steroids	17 (3.94)	17 (5.0)	0.47

Table 3
Hernia and operative characteristics of patients who underwent open compared to minimally invasive (MIS) approach.

	Open $N = 432$	MIS $N = 339$	*p*-value
Hernia Location			
Epigastric	143 (33.9)	113 (34.2)	0.42
Umbilical	168 (39.8)	136 (41.2)	
Infraumbilical	60 (14.2)	36 (10.9)	
Suprapubic	9 (1.9)	12 (3.6)	
No midline component	39 (9.2)	32 (9.7)	
Other	4 (0.95)	1 (0.3)	
Previous hernia repair	127 (29.5)	78 (23.2)	0.05
Mean hernia width, cm (SD)	4.84 (0.79)	4.71 (0.74)	0.02
Hernia width			
4cm	168 (38.9)	151 (44.5)	0.05
5cm	153 (35.4)	125 (36.9)	
6cm	111 (25.7)	63 (18.6)	
Mesh used	386 (89.4)	335 (98.8)	<0.01
Myofascial release	59 (15.4)	13 (4.2)	<0.01
Wound Classification			
Clean	388 (89.8)	323 (95.3)	0.04
Clean/contaminated	27 (6.3)	11 (3.2)	
Contaminated	13 (3)	3 (0.88)	
Dirty/infected	4 (0.9)	2 (0.59)	
Surgical Priority			
Elective	363 (84)	320 (94.4)	<0.01
Urgent/Emergent	69 (16)	19 (5.6)	

In the multivariable logistic regression model, only higher BMI (aOR 0.97, 95 % CI 0.94–0.99) and urgent/emergent surgery (aOR 0.43, 95 % CI 0.24–0.79) were associated with lower odds of undergoing MIS approach. These results are shown in Table 4.

We found no significant association between surgical approach and risk of complications (aOR MIS 0.62, 95 % CI 0.37–1.04).

Among patients who underwent an MIS approach ($n = 339$), the majority ($n = 236$, 69.6 %) underwent a robotic approach. As in the primary analysis, we found few differences between patients undergoing robotic compared to open or laparoscopic approaches. The most significant finding was that the robot was used almost exclusively in the elective setting (robot 96.6 %, laparoscopic 89.3 %, open 84 %, $p < 0.01$). Mean hernia width was similar among approaches (robot 4.7 cm, laparoscopic 4.8 cm, open 4.8 cm, $p = 0.34$).

Table 4
Multivariable logistic regression model for selection of MIS compared to open.

	Odds Ratio	95 % Confidence Interval	*p*-value
Female sex	0.89	0.63–1.25	0.50
Age	0.99	0.97–1.01	0.21
BMI	0.97	0.94–0.99	0.03
Race			
White (ref)			
Black	1.30	0.81–2.07	0.28
Other	0.67	0.35–1.29	0.23
Insurance			
Private (ref)			
Medicare	0.81	0.52–1.26	0.35
Medicaid	0.88	0.55–1.40	0.59
Uninsured	2.31	0.40–13.44	0.35
Other	1.52	0.36–6.35	0.57
ASA Class			
ASA 1 (ref)			
ASA 2	0.52	0.18–1.53	0.24
ASA 3	0.44	0.14–1.33	0.14
ASA 4	0.25	0.06–1.13	0.07
Comorbid Conditions			
Smoker	0.80	0.52–1.22	0.30
Diabetes	1.28	0.83–1.96	0.26
COPD	1.10	0.60–2.04	0.75
Sleep Apnea	1.28	0.88–1.86	0.20
CHF	1	–	–
Hypertension	1.44	1.00–2.09	0.05
Chronic Steroids	1.39	0.65–2.99	0.40
Hernia Location			
Epigastric (ref)			
Umbilical	1.07	0.75–1.54	0.70
Infraumbilical	0.85	0.51–1.43	0.54
Suprapubic	2.10	0.78–5.61	0.14
No midline component	0.98	0.55–1.74	0.95
Other	1	–	–
Recurrent Hernia	0.77	0.53–1.10	0.15
Urgent/Emergent Surgery	0.43	0.24–0.79	0.01
Hernia width			
4 cm (ref)			
4–5cm	0.96	0.67–1.36	0.80
5–6cm	0.68	0.44–1.03	0.07

Discussion

Caring for patients with midsize hernias can be complicated due to lack of clear guidelines informing care for this common condition. In this study, there were two important and significant findings. The first was that approach did not seem to be driven by patient characteristics. This may indicate that surgeon preference factors largely into choice of approach. The second important finding was that MIS repair was used more often for smaller hernias. For example, patients in the MIS category had a slightly smaller mean hernia width, and while it did not reach significance there was a trend towards less use of MIS in larger hernias when we categorized hernia by size. Importantly, approach did not appear to be associated with adverse outcomes. Interestingly, the mean BMI among persons undergoing MIS hernia repair was slightly lower than for open which is unexpected as many surgeons preferentially opt for an MIS approach in persons with higher BMI.

One of the challenges apparent in ventral hernia repair is the lack of evidence to guide surgeons when choosing surgical approach. For example, the European Hernia Society (EHS) guidelines provide size-based guidance on use of mesh (recommended for all hernias larger than 1 cm) [1]. Laparoscopic repair can be considered for hernias larger than 4 cm primarily to decrease the risk of wound infections [1]. This lack of guidelines results in surgeons selecting the approach that they are most comfortable with, or the one they like the best. For example, in our

prior qualitative work we demonstrated that surgical approach was largely determined by the surgeon's personal preference [2,3,12]. Even for very small hernias (<2 cm), we have shown that while most surgeons choose the open approach, nearly 10 % of hernias are repaired robotically, and another 10 % laparoscopically [13]. Guidelines also fail to address the fact that two patients with similarly sized hernias may need to have a different surgical approach based on BMI, abdominal wall contour and thickness, and prior surgical history. As we continue to deepen our understanding of hernia care, these questions and more will be critical to answer in evidence-based clinical practice guidelines.

Interestingly, we found that whether a patient presented urgently/emergently compared to electively factored largely in which approach was chosen. This again is an area where guidelines are sparse. The EHS guidelines state that repair in the emergent setting should be "tailored to patient and hernia characteristics."[1] Prior data indicates that approximately 10 % of hernia repairs occur emergently, which is consistent with our data [20]. In a 2013 study using the Danish hernia registry, Helgstrand et al. also found that MIS is used only 7.4 % of the time when patients present emergently, which is slightly higher than what we found [20]. While the reasons for this may vary, our prior work indicates that surgeons may change their approach based on the time of day or urgency of the case simply due to lack of resources. For example, when deciding whether to use the robot for ventral hernia repairs, surgeons report reluctance to use the technology at night or for emergencies, often due to lack of trained staff to facilitate use of the robot [12]. It may also be that emergent hernia repair is performed more often by surgeons without extensive experience or comfort with MIS techniques, resulting in the higher use of open approach. This presents a potential area for quality improvement and should be explored further in future work.

Finally, we noted that nearly 10 % of patients in this cohort underwent a myofascial release, commonly referred to as component separation. This was somewhat surprising as this technique is commonly reserved for the largest, most complex hernias and (as stated above) the mean size of hernia in this population was less than 5 cm. Prior studies have also demonstrated that myofascial release is not infrequently applied to very small hernias [13], leading some to say that this technique should be closely supervised given the potential complications that can occur (e.g., abdominal wall disfigurement) [21]. Future work should focus on the impact of surgeon experience and operative volume on outcomes of this increasingly common technique.

This study should be considered in terms of its limitations. First, we may be underpowered to detect some differences in outcomes. However, we are continuing to enroll patients in this registry in an iterative fashion and anticipate that as our sample size grows we will have increasing power to detect these differences. Second, given the nature of this registry we only accounted for 30-day outcomes. As we continued to grow MSQC—COHR we are increasingly focusing on long-term clinical and patient-reported outcomes which will facilitate the detection of other important outcomes such as long-term pain and hernia recurrence. Several other operative variables including whether the fascia was closed primarily prior to mesh coverage in minimally invasive techniques was unavailable, but may influence outcomes for this operation. Additionally, some of the more nuanced variables in the data set (e.g., mesh location described as onlay vs inlay vs sublay) have incomplete information which may indicate lack of understanding of this variable. Future efforts will work to ensure that all surgeons are fully familiar with and understand each element of the data abstracted for the registry. Finally, we were unable to correlate surgeon volume with preference as MSQC—COHR contained a representative sample of patients which may not correlate with the actual number of cases performed per surgeon per year.

In conclusion, we found that for midsize hernias slightly more than half of patients underwent an open approach. There were few patient characteristics that influenced this approach. Time of day and urgency of patient presentation strongly influenced surgical approach. Future work will focus on correlating approach with long-term outcomes to improve care for this population of patients.

CRediT authorship contribution statement

Anne P. Ehlers: . **Alex K. Hallway:** . **Sean M. O'Neill:** . **Brian T. Fry:** . **Ryan A. Howard:** . **Jenny M. Shao:** . **Michael J. Englesbe:** . **Justin B Dimick:** Writing – review & editing. **Dana A Telem:** Writing – review & editing, Supervision, Data curation. **Grace J Kim:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Conceptualization.

Declaration of competing interest

Dr. Ehlers and Dr. Howard receive unrelated funding from Blue Cross Blue Shield of Michigan. Dr. Fry is supported by NIH grant T32-AG062403 and receives unrelated funding from SAGES. Dr. Telem receives unrelated funding from the NIDDK. Dr. Shao receives honoraria for consulting with AbbVie Inc. Mr. Hallway, Dr. O'Neill, Dr. Englesbe, Dr. Dimick, and Dr. Kim declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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