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ORIGINAL ARTICLE

Assessing the safety of outpatient ventral hernia repair: a NSQIP analysis of 7666 patients

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Abstract

Purpose Given the paucity of literature on outpatient ventral hernia repair (VHR), and that assessment of the safety of outpatient surgical procedures is becoming an active area of investigation, we have performed a multi-institutional retrospective analysis benchmarking rates of 30-day complications and readmissions and identifying predictive factors for these outcomes.

Methods National surgical quality improvement project data files from 2011 to 2012 were reviewed to collect data on all patients undergoing outpatient VHR during that period. The incidence of 30-day peri-operative complication and unplanned readmission was surveyed. We created a multivariate regression model to identify predictive factors for overall, surgical, and medical complications and unplanned readmissions with proper risk adjustment.

Results 30-day complication and readmission rates in outpatient VHR were acceptably low. 3 % of the queried outpatients experienced an overall complication, 2.1 % a surgical complication, and 1.1 % a medical complication. 3.3 % of all patients were readmitted within 30 days. Upon multivariate analysis, predictors of overall complications included age, BMI, history of Chronic Obstructive Pulmonary Disease (COPD), and total operation time,

predictors of surgical complications included age, BMI, total operation time, predictors of medical complications included total operation time, and predictors of unplanned readmissions included history of COPD, bleeding disorder, American Society of Anesthesiologists Class 3, 4, or 5, total operation time, and use of the laparoscopic technique.

Conclusion We have demonstrated that the risk of peri-operative morbidity in VHR as granularly defined in our study is low in the outpatient setting. Identification of predictive factors will be important to patient risk stratification.

Keywords Ventral hernia repair · Outpatient · Inpatient · Unplanned readmissions · 30-day complications

Introduction

Outpatient surgery is becoming an attractive alternative for select patients undergoing ventral hernia repair (VHR). The total cost of VHR for 2006 was reported to be 3.2 billion dollars while both the number of patients electing and dollars spent on inpatient status have risen [1]. Not surprisingly, most inpatient VHR procedures result in a net financial loss to the provider [2]. The cost disparity between inpatient and outpatient procedures has affected other surgical fields, to which they have responded by closely evaluating the viability of outpatient surgeries [3–8]. However, the economic promise of outpatient procedures must be carefully balanced against its peri-operative complication profile as patient safety is a higher priority than financial concerns. To date, there is a paucity of peer-reviewed literature directly benchmarking or evaluating rates of 30-day procedural

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complications or adverse events following outpatient VHR procedures [9].

The American college of surgeons national surgical quality improvement project (NSQIP) is a nationally validated clinical registry that captures over 2 million patients in 400 institutions that has been previously used to evaluate safety in many surgical settings [3, 10–13]. Via the NSQIP database, we performed the first powerful multi-institutional retrospective analysis to accomplish two goals: (1) to benchmark the outcomes of outpatient VHR and (2) assess the safety of outpatient VHR procedures by identifying predictive factors for 30-day complications and unplanned readmission, after adjusting for other potentially confounding risk factors. We hope that our study will improve risk stratification and proper consent of patients undergoing outpatient VHR.

Methods

Population

The details of the ACS-NSQIP data collection methods have previously been described in detail and validated [14, 15]. Data files from 2011 to 2012 were reviewed to collect data on all patients undergoing VHR during that period. All patients who underwent ventral or incisional hernia repair were selected from the database based on primary current procedural terminology (CPT) codes and post-operative international classification of diseases (ICD)-9 diagnoses. The following primary CPT codes were included: 49560, 49561, 49565, 49566, 49568, 49570, 49572, 49580, 49582, 49585, 49587, 49590, 49652, 49653, 49654, 49655, 49656, 49657, and 49659. Any patient who underwent multiple procedures, identified by the presence concurrent CPT codes 15,734 (component separation) or 49,568 (use of mesh), were included in the sample. Last, the following ICD-9 codes were used to select only those patients whose post-operative diagnosis was a ventral or incisional hernia: 551.2, 551.21, 551.29, 552.2, 552.21, 552.29, 553.2, 553.21, and 553.29. Any patient with an ICD-9 other than those listed was excluded. Patients with a primary CPT code of 49652, 49653, 49654, 49655, 49656, 49657, or 49659 were considered to have undergone a laparoscopic procedure. All patients recorded to have received inpatient VHR were excluded, leaving only outpatients for analysis. NSQIP is only designed to detect if a given patient stayed in the hospital less than 23 h; NSQIP does not capture the initial inpatient/outpatient determination, nor conversions from inpatient to outpatient. Finally, outpatients were stratified by whether they experienced 30-day morbidity, as described in the next section, or not.

Variables

NSQIP-defined pre-operative variables were compared between cohorts. They included demographic variables (e.g., sex, age, BMI); lifestyle variables (e.g., smoking) and medical comorbidities (e.g., diabetes, dyspnea, wound class, previous sepsis, ventilator dependence, Chronic Obstructive Pulmonary Disease (COPD), ascites, CHF, acute renal failure, dialysis, disseminated cancer, wound infection, steroid use, weight loss, bleeding disorders). Other operative characteristics captured included total operative time, total RVU for both primary and concurrent procedures, pre-operative transfusions, and emergency case. Total operative time and total RVU were treated as surrogates for case complexity [16].

Primary outcomes were categorized as surgical complications, medical complications, and overall complications. Surgical complications included superficial, deep, or organ–space surgical site infection [SSI] and wound disruption. Medical complications included deep venous thrombosis (DVT), pulmonary embolism (PE), unplanned reintubation, ventilator dependence >48 h, progressive renal insufficiency, acute renal failure, coma, stroke, cardiac arrest, myocardial infarction (MI), peripheral nerve injury, pneumonia, urinary tract infection (UTI), blood transfusions, graft/prosthesis/flap failure and sepsis/septic shock. All morbidities were used as defined in the NSQIP user guide. Overall complications included all surgical and medical complications. A tracked outcome that was not included in overall complications was unplanned readmissions, which was defined as an unplanned readmission to the same or another hospital for a post-operative occurrence likely related to the principal surgical procedure within 30 days of the procedure.

Statistical analysis

Chi-square tests, for categorical variables, and Student t test, for continuous variables, were employed to determine if differences in pre-operative clinical characteristics and demographics between cohorts were statistically significant. Significance was defined as $P < 0.05$. 30-day perioperative complication and readmission rates were surveyed. A bivariate screen was then to employed to identify, via the inclusion criteria ($n > 10$, $P < 0.2$), peri-operative variables that were included in a multivariate regression model. The model identified predictive factors for overall, surgical, and medical complications and unplanned readmissions with proper risk adjustment. Again, $P < 0.05$ was considered significant. Hosmer–Lemeshow (H–L) and c-statistics were calculated to assess model calibration and discriminatory capability, respectively [17, 18]. All analysis was performed using SPSS version 22 (IBM Corp Armonk, NY, USA).

Results

Demographics and comorbidities

7666 patients were identified to have undergone outpatient VHR between 2011 and 2012; 15,873 total patients received VHR in this period. Table 1 compares pre-operative characteristics and demographics between patients who experienced any 30-day complication, as defined by overall complications, and patients who did not. Patients who sustained an overall complication were more likely to be American Society of Anesthesiologists (ASA) Class 3, 4, or 5 (36.5 vs 45.8 %, $P = 0.004$), have an open wound infection (0.4 vs 2.2 %, $P < 0.001$), and have COPD (3.8 vs 7.00 %, $P = 0.015$), a higher BMI and longer operation time. The same comparison was made between patients who were and were not readmitted within 30 days (Table 2). Patients who had an unplanned readmission were more likely to have a higher BMI, undergone VHR with laparoscopic technique (3.00 vs 7.9 %, $P < 0.001$), be

Table 1 Demographics and comorbidities of patients with and without any 30-day complications

	Outpatients who did not have any 30-day complications ($n = 7439$)	Outpatients with any 30-day complications ($n = 227$)	P
Male	46.40 %	44.10 %	0.479
Race			
White	79.60 %	79.70 %	0.639
Black	10.40 %	9.70 %	
Asian	0.80 %	0.00 %	
Other	0.90 %	1.30 %	
Not available	8.30 %	9.30 %	
Diabetes	14.10 %	17.60 %	0.135
Wound class*			
Clean	96.30 %	89.40 %	<0.001
Clean/contaminated	3.30 %	8.40 %	
Contaminated	0.30 %	0.90 %	
Dirty/infected	0.10 %	1.30 %	
Dyspnea	6.10 %	8.40 %	0.165
Previous sepsis	0.30 %	0.00 %	0.423
ASA Class 3, 4, or 5*	36.50 %	45.80 %	0.004
Laparoscopic	3.10 %	3.10 %	0.967
COPD*	3.80 %	7.00 %	0.015
Ascites	0.10 %	0.00 %	0.562
CHF	0.20 %	0.00 %	0.545
Acute renal failure	0.10 %	0.00 %	0.696
Dialysis	14.10 %	17.60 %	0.703
Wound infection*	0.40 %	2.20 %	<0.001
Steroid use	2.80 %	3.10 %	0.786
Weight loss	0.30 %	0.90 %	0.076
Bleeding disorders	2.00 %	3.10 %	0.256
Pre-operative transfusion	0.10 %	0.00 %	0.696
Emergency case	0.70 %	0.90 %	0.807
Component separation*	1.2 %	3.1 %	0.014
Use of mesh	99.70 %	99.10 %	0.089
Age	55.46 (14.2)	53.1 (13.9)	0.94
BMI*	31.8 (7.6)	35.2 (8.7)	<0.001
Total operation time*	60.9 (40.6)	79.6 (57.4)	<0.001

Continuous variables expressed as mean (SD)

Defined as 'Overall complications' in the manuscript

* Denotes significance, $P < 0.05$

ASA Class 3, 4, or 5 (36.3 vs 49.8 %, $P < 0.001$), have dyspnea (6.1 vs 9.5 %, $P = 0.027$), COPD (3.8 vs 8.7 %, $P < 0.001$), acute renal failure (0.00 vs 0.8 %, $P < 0.001$), bleeding disorder (1.9 vs 4.7 %, $P < 0.002$), and experience weight loss (0.2 vs 2 %, $P < 0.001$).

Post-operative outcomes

30-day complication and readmission rates in outpatient VHR were low. 3 % of the queried outpatients experienced an overall complication, 2.1 % a surgical complication,

and 1.1 % a medical complication. 3.3 % of all patients were readmitted within 30 days. Our study has established the following benchmarks for peri-operative events following outpatient VHR in a sample size of 7666 patients (Table 3).

Multivariate analysis

A regression model was employed to determine predictive factors of peri-operative morbidity following outpatient VHR, the results of which are displayed in Tables 3, 4, 5, 6, 7.

Table 2 Demographics and comorbidities of readmitted and non-readmitted patients

	Readmitted outpatients ($n = 7413$)	Non-readmitted outpatients ($n = 253$)	P
Male	46.30 %	48.60 %	0.464
Race			
White	79.70 %	77.50 %	0.074
Black	10.20 %	15.00 %	
Asian	0.80 %	0.00 %	
Other	0.90 %	0.80 %	
Not available	8.40 %	6.70 %	
Diabetes	14.10 %	16.60 %	0.267
Wound class*			
Clean	96.20 %	94.10 %	0.243
Clean/contaminated	3.40 %	5.10 %	
Contaminated	0.30 %	0.80 %	
Dirty/infected	0.10 %	0.00 %	
Dyspnea*	6.10 %	9.50 %	0.027
Previous sepsis	0.30 %	0.00 %	0.397
ASA Class 3, 4, or 5*	36.30 %	49.80 %	<0.001
Laparoscopic*	3.00 %	7.90 %	<0.001
COPD*	3.80 %	8.70 %	<0.001
Ascites	0.10 %	0.40 %	0.282
CHF	0.10 %	0.40 %	0.329
Acute renal failure*	0.00 %	0.80 %	<0.001
Dialysis*	0.60 %	2.00 %	0.007
Disseminated cancer	0.40 %	0.40 %	0.992
Wound infection	0.40 %	1.20 %	0.071
Steroid use	2.80 %	2.80 %	0.981
Weight loss*	0.20 %	2.00 %	<0.001
Bleeding disorders*	1.90 %	4.70 %	0.002
Pre-operative transfusion	0.10 %	0.00 %	0.679
Emergency case	0.80 %	0.40 %	0.512
Component separation	1.20 %	2.40 %	0.115
Use of mesh	99.70 %	100.0 %	0.386
Age	55.34 (14.1)	56.9 (14.3)	0.682
BMI*	31.8 (7.6)	32.9 (8.8)	<0.001
Total operation time	61.11 (41.4)	72.5 (37.8)	0.639

Continuous variables expressed as mean (SD)

* Denotes significance, $P < 0.05$

Table 3 Unadjusted post-operative outcomes

	%	N
Overall complications	3.00	227
Surgical complications	2.10	161
SSI	1.30	102
DSSI	0.60	44
Organ/space SSI	0.10	10
Wound disruption	0.10	10
Medical complications	1.10	81
Pneumonia	0.20	15
Reintubation	0.10	9
Pulmonary embolism	0.10	6
Failure to wean	0.10	4
Renal insufficiency	0.00	1
Renal failure	0.10	6
UTI	0.30	26
Stroke	0.00	1
Cardiac arrest	0.10	5
MI	0.00	2
Transfusion	0.10	4
DVT	0.10	11
Sepsis	0.20	15
Septic shock	0.10	5
Unplanned readmission	3.30	253
Return to OR	1.00	75

Variables that were included in the model were determined by a bivariate screen. Predictors of overall complications included age, BMI, history of COPD, and total operation time; predictors of surgical complications included age, BMI, total operation time; predictors of medical complications included total operation time; predictors of unplanned readmissions included history of COPD, bleeding disorder, ASA Class 3, 4, or 5, total operation time, and use of the laparoscopic technique.

Discussion

In light of the adoption of outpatient surgeries in many different surgical fields, and in the absence of retrospective data evaluating safety of outpatient VHR, we performed the first multi-institutional analysis of 7666 outpatients to establish benchmarks of 30-day complication and readmission rates, and identify predictive factors of these outcomes. Our studies suggest that rates of peri-operative morbidity following outpatient VHR are acceptably low, as none were higher than 3.3 %.

There is a paucity of literature regarding the safety of outpatient VHR. Outpatient surgeries have been reported to

Table 4 Predictors of overall complications

	P	Odds ratio	95 % CI for odds ratio	
			Lower	Upper
Age*	0.015	0.987	0.977	0.997
BMI*	0	1.032	1.018	1.046
Diabetes	0.726	1.068	0.738	1.547
Dyspnea	0.914	1.03	0.607	1.747
COPD*	0.033	1.868	1.053	3.313
ASA Class 3,4,5	0.105	1.285	0.949	1.739
Total operation time*	0	1.005	1.003	1.007

HL stat, 0.147

C stat, 0.662

* Denotes significance $P < 0.05$

Table 5 Predictors of medical complications

	P	Odds ratio	95 % CI for odds ratio	
			Lower	Upper
Age	0.087	1.015	0.998	1.032
Total operation time*	0	1.006	1.004	1.009
ASA Class 3,4,5	0.214	1.34	0.845	2.127

HL stat, 0.743

C stat, 0.642

* Denotes significance $P < 0.05$

Table 6 Predictors of surgical complications

	P	Odds ratio	95 % CI for odds ratio	
			Lower	Upper
Age*	0	0.969	0.957	0.982
Total operation time*	0	1.004	1.002	1.007
ASA Class 3,4,5	0.054	1.412	0.994	2.004
BMI*	0	1.039	1.024	1.054
Dyspnea	0.696	0.873	0.442	1.725
COPD	0.089	1.864	0.91	3.819

HL stat, 0.707

C stat, 0.705

* Denotes Significance $P < 0.05$

be associated with lower rates of serious morbidity and mean length of stay when compared to inpatient procedures [19, 20]. Abdel et al. reported success in laparoscopic repair performed in a single outpatient center with acceptably low risk and a recurrence rate of 5.04 % [9]. Fischer et al., via NSQIP data, reported a 3.9 % rate of major operative complications in outpatient abdominal wall repairs [21]. Many of these studies are limited by the single-institution sample size from which they were derived.

Table 7 Predictors of unplanned readmission

	P	Odds ratio	95 % CI for odds ratio	
			Lower	Upper
Age	0.628	1.002	0.993	1.012
Total operation time*	0.001	1.004	1.002	1.006
ASA Class 3,4,5*	0.008	1.46	1.102	1.936
BMI	0.259	1.009	0.993	1.025
Dyspnea	0.651	1.114	0.697	1.78
COPD*	0.007	1.974	1.207	3.226
Bleeding disorder*	0.018	2.092	1.132	3.864
Laparoscopic technique*	0	2.701	1.668	4.373

HL stat, 0.035

C stat, 0.636

* Denotes significance $P < 0.05$

We found in our study that 2.1 % of patients experienced a surgical complication. Surgical site infections, in particular, have been a focal point in the movement for outcome-driven quality improvement in VHR [22–24]. Rates of 12 and 22 % have been previously reported for surgical site infections [22, 23]. However, these studies were performed in single-institution inpatient settings, and their findings may reflect greater inpatient case complexity. Rates of unplanned readmission were also very low in the outpatient setting. Readmission in VHR, well-known to be secondary to procedural complications, contributes to rising costs and patient morbidity [25, 26]. Our studies suggest that outpatient utilization is not a major part of the readmission problem.

Our findings must be interpreted in their proper context. We have demonstrated that the rates of 30-day overall, surgical, and medical complications and readmission are low in the outpatient setting. None of the queried patients experienced renal insufficiency, stroke, or an MI within 30 days of their VHR, suggesting that the clinical relevance of benchmarking these complications may be tenuous. Other outcomes (i.e., VTE, unplanned intubation) may not be clinically relevant to outpatient procedures [10]. Effort should be directed towards reducing surgical complications as it represents the majority of the post-operative morbidity burden in outpatient VHR. Our study suggests that referral to an outpatient setting is safe and appropriate. Our study also encourages uniformly accepted qualifications for outpatient repair, such as hernia size, patient comorbidity burden, and surgeon experience.

The second aim of our study was to identify predictive factors of adverse outcomes following outpatient VHR for risk stratification efforts. Total operation time was a common predictor of all tracked outcomes [21, 27–29]. BMI was significantly associated with overall and surgical complications, as has been previously described in studies

evaluating surgical site infections [30, 31]. The laparoscopic approach, which has generated recent interest in outcomes studies, increased the risk of unplanned readmission [19, 24, 32–43].

While the ACS-NSQIP database provides a powerful platform and large sample size for our retrospective analysis, it is not without limitations [44, 45]. NSQIP is only designed to detect if a given patient stayed in the hospital less than 23 h, not the initial inpatient/outpatient determination [46]. For this reason, our results are not generalizable to a potential subset of patients who were initially designated as outpatient but experienced longer hospitalizations due to significant post-operative complications. This limitation may underestimate the complication rates for all outpatient cases. Hernia size, recurrence occurrences and rates, the reason for choosing the outpatient setting and other relevant endpoints such as post-operative pain, recovery time, and bugling are not captured by the database. The authors would like to highlight that a handful of outpatients were classified as ASA Class 4 and even fewer were recorded to undergo component separation with mesh. We attribute these findings to recording error, which is a limitation that plagues many multi-institutional registries, or exceptional cases. Still, recent evaluation of the NSQIP database suggests that the rate of inter-rater disagreement is only 1.56 %, making it highly reliable.

Conclusions

We have demonstrated that the risk of peri-operative morbidity in VHR as granularly defined in our study is acceptably low in the outpatient setting. We have also identified independent predictors of peri-operative morbidity in outpatient VHR. Our findings should be interpreted in the context of the study's limitations and as the

NSQIP database grows, future studies will either confirm or refute our conclusion on the low risk of outpatient VHR.

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