Thirty-Day Outcomes of Paraesophageal Hernia Repair Using the NSQIP Database: Should Laparoscopy Be the Standard of Care?

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BACKGROUND: Although surgical repair is universally recognized as the gold standard for treatment of paraesophageal hernia (PEH), the optimal surgical approach is still the subject of debate. To determine which surgical technique is safest, we compared the outcomes of laparoscopic (lap), open transabdominal (TA), and open transthoracic (TT) PEH repair using the NSQIP database.

STUDY DESIGN: From 2005 to 2011, we identified 8,186 patients who underwent a PEH repair (78.4% lap, 19.2% TA, 2.4% TT). Primary outcome measured was 30-day mortality. Secondary outcomes included hospital length of stay, and NSQIP-measured postoperative complications. Multivariable analyses were performed to compare the odds of each outcome across procedure type (lap, TA, and TT) while adjusting for other factors.

RESULTS: Transabdominal patients had the highest 30-day mortality rate (2.6%), compared with 0.5% in the lap patients (p < 0.001) and 1.5% in TT patients. Mean length of stay was statistically significantly longer for TA and TT patients (7.8 days and 6.5 days, respectively) compared with lap patients (3.3 days). After adjusting for age, American Society of Anesthesiologists score, emergency cases, functional status, and steroid use, TA patients were nearly 3 times as likely as lap patients to experience 30-day mortality (odds ratio [OR], 2.97; 95% CI, 1.69 to 5.20; p < 0.001). Moreover, TA and TT patients had significantly increased odds of overall morbidity (OR 2.12; 95% CI 1.79 to 2.51; p < 0.001; OR 2.73; 95% CI 1.88 to 3.96; p < 0.001; respectively) and serious morbidity (OR 1.90; 95% CI 1.53 to 2.37, p < 0.001; OR 2.49; 95% CI 1.54 to 4.00; p < 0.001; respectively).

CONCLUSIONS: In the absence of published data indicating improved long-term outcomes after open TA or TT approach, our findings support the use of laparoscopy, whenever technically feasible, because it yields improved short-term outcomes. (J Am Coll Surg 2014;219:229e236. © 2014 by the American College of Surgeons)
benign, it is worth noting that PEH can occasionally result in potentially life-threatening complications such as acute gastric obstruction and ischemia/necrosis.7

Although the role of medical therapy is well established for managing symptoms, surgical repair continues to be the only definitive treatment for PEH. In the past, the presence of a large hernia defect was considered, in and of itself, to be an indication for surgical repair; however, a recent analytic decision model demonstrated that the risk of developing acute symptoms requiring emergency surgery decreases significantly with patient age.8 This evidence has led to adoption of a more conservative strategy in elderly and asymptomatic patients, reserving surgical treatment mainly for symptomatic hernias.7

Accepted surgical approaches to PEH repair include thoracotomy, laparotomy, and more recently, laparoscopy. Although each approach has its particular advantages, there have, as yet, been no randomized controlled trials to demonstrate superiority of one technique over the others. Consequently, the choice of the approach still depends largely on individual surgeon’s preference and skills. Introduced in 1992, laparoscopic PEH repair has gained increasing popularity, in large measure due to such benefits as quick recovery, short length of stay, and low mortality, morbidity, and postoperative pain.10,11

In this study, we performed a retrospective analysis using the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database to compare short-term outcomes after PEH repair by the different surgical approaches. In the absence of randomized controlled trials, the use of a large surgery-oriented dataset provides a valuable overview of the outcomes of different surgical approaches; this study attempts to assess if surgical technique affects the short-term outcomes of PEH repair.

METHODS

Data

This retrospective study was performed using the ACS NSQIP database from 2005 to 2011. The NSQIP is a nationally validated, risk adjusted, outcomes-based program, and it is used to measure and improve the quality of surgical care. This program uses a prospective systematic data collection on 135 preoperative and intraoperative variables, as well as 30-day postoperative morbidity and mortality. Details of ACS NSQIP are described elsewhere.12,13 This study protocol was granted exempt status by the institutional review board of the Johns Hopkins University School of Medicine.

Study population

The study population was limited to adults 18 years of age or older who underwent a surgical procedure for PEH repair between January 2005 and December 2011. In order to minimize inclusion of patients with simple sliding hiatal hernias, when we generated our initial cohort, we included only patients with a primary diagnosis of PEH (ICD-9 code of 553.3 or 552.3) in addition to having a primary Current Procedural Terminology (CPT) code indicating PEH repair. Three treatment groups were identified based on surgical approach. The first group included patients who underwent a laparoscopic PEH repair. The specific codes for laparoscopic PEH repair with and without mesh (43281 and 43282) were introduced in 2010; before this, patients were identified using CPT codes of 43280, 43281, or 43282. The second group underwent an open transabdominal (TA) PEH repair, identified by CPT codes 39502, 39599, 43324, 43332, or 43333. The third group consisted of patients who underwent a transthoracic (TT) PEH repair, identified by CPT codes 39520, 43334, 43335, 43336, or 43337. We reviewed our initial TA group (n = 1,923) by manually performing a detailed examination of individual patient records. Patients were then reassigned to the laparoscopic (lap) group based on the presence of accessory CPT codes indicating a concurrent laparoscopic procedure (43280, 43289, 43653, 43659, 44180, 47562, 47563, 49329, 49320, or 49659) (Table 1).14 As a result, 352 patients were reassigned to the lap group. Patients were then further stratified into 2 groups: laparoscopic vs open TA and laparoscopic vs open TT treatments for comparison.

Patient baseline demographics and clinical characteristics were compared. Patient demographics included age, sex, and race (white, black, or other). Clinical characteristics consisted of body mass index (BMI) (underweight/normal, overweight, and obese), American Society of Anesthesiologists (ASA) classification of patient physical condition, functional health status before surgery (independent, or partially/totaly dependent), and preoperative comorbidities such as diabetes mellitus (with oral agents or insulin), smoking status (within 1 year before the operation), alcohol consumption (of more than 2 drinks per day), dyspnea, hypertension requiring medication, steroid

Abbreviations and Acronyms

ACS = American College of Surgeons
ASA = American Society of Anesthesiologists
Lap = laparoscopic
NIS = Nationwide Inpatient Sample
OR = odds ratio
PEH = paraesophageal hernia
TA = (open) transabdominal
TT = (open) transthoracic

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use, previous cardiac surgery, renal disease (including patients with preoperative acute renal failure and those on dialysis), and history of COPD, congestive heart failure (CHF), or myocardial infarction (MI). After reviewing the frequency distribution of patients by ASA class, we combined ASA classes I and II (no or mild disturbance) and ASA classes IV and V (life threatening and moribund), while leaving ASA class III (serious disturbance) as a stand-alone variable.

Outcomes
The primary outcome was 30-day mortality. Secondary outcomes included overall and serious morbidity as well as length of hospital stay. Overall morbidity was defined as having at least one of the following postoperative complications: wound infection, pneumonia, urinary tract infection (UTI), return to operating room, venous thromboembolic events (VTE), cardiac complication, shock/sepsis, unplanned intubation, bleeding requiring transfusion, ventilator dependence for >48 hours, and renal complication. Serious morbidity was defined as having at least one of the following postoperative complications: return to operating room, cardiac complication, shock/sepsis, intubation, and ventilator dependence for >48 hours. We combined similar NSQIP-measured postoperative complications into groups as follows: the wound infection variable was classified as the combination of superficial wound infection, deep incisional superficial surgical site infection, and wound disruption; the cardiac complication variable included cardiac arrest requiring CPR and myocardial infarction; the renal complication variable was defined as a postoperative acute failure or progressive renal insufficiency; and the venous thromboembolic event variable consisted of deep vein thrombosis/thrombophlebitis and pulmonary embolism.

Statistical analysis
Baseline demographics, clinical characteristics, and postoperative outcomes after PEH repair were compared using the chi-square test or Fisher's exact test for categorical variables and Student's t-test for continuous variables. Multiple logistic regression models were used to compare the use, previous cardiac surgery, renal disease (including patients with preoperative acute renal failure and those on dialysis), and history of COPD, congestive heart failure (CHF), or myocardial infarction (MI). After reviewing the frequency distribution of patients by ASA class, we combined ASA classes I and II (no or mild disturbance) and ASA classes IV and V (life threatening and moribund), while leaving ASA class III (serious disturbance) as a stand-alone variable.

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odds of 30-day mortality and overall and serious morbidity across procedure type (Lap, TA, and TT) while adjusting for other factors. First, exploratory data analysis was performed using univariate logistic regression. Initially, the 3 models included all covariates with associations in exploratory analysis at the p < 0.25 level, as recommended by Hosmer and Lemeshow. Additionally, all covariates of clinical importance were included, regardless of statistical significance. Models were then refined based on clinical importance of covariates and their impact on overall fit as assessed by likelihood ratio tests. As a result, the final logistic regression model for 30-day mortality was adjusted for procedure type, age, ASA, emergency cases, functional status, and steroid use; the final logistic regression models for overall and serious morbidity were adjusted for procedure type, age, sex, ASA, functional status, emergency cases, steroid use, and dyspnea. Due to low 30-day mortality rates in the TT group, the multivariable logistic model for 30-day mortality excluded patients who underwent a TT treatment. Lastly, the 3 final models were evaluated using the Hosmer-Lemeshow goodness of fit test (to assess overall model fit). Statistical significance was defined at p < 0.05. All statistical analysis was conducted using Stata/MP version 12 (StataCorp LP).

RESULTS
Study population
A total of 8,186 patients who underwent elective or emergent PEH repairs were identified. Of those patients, 6,415 (78.4%) underwent repair via laparoscopic approach, 1,571 (19.2%) via open TA approach, and 183 (2.4%) via TT approach. There were 307 (3.8%) patients who underwent emergency PEH repair. Overall, baseline demographic and clinical characteristics were significantly different for the laparoscopic vs TA and laparoscopic vs TT groups (Table 2). Patients undergoing open TA PEH hernia repair were older, thinner, and had more comorbidities compared with those having the laparoscopic approach. Patients undergoing TT treatment in comparison with those with the laparoscopic approach were more often male, sicker, and more likely to have a history of COPD and congestive heart failure.

Unadjusted outcomes
The overall 30-day mortality rate was 0.92%, with the highest unadjusted mortality seen in patients who underwent a TA procedure (2.6%), which was significantly higher than the mortality rate of 0.5% in lap patients (Table 3). However, 30-day mortality rates between the lap and TT patients were comparable. The TA and TT approach patients experienced significantly higher rates of overall and serious morbidity compared with the lap patients. The mean length of hospital stay was statistically significantly greater for TA and TT patients (7.8 days and 6.5 days, respectively) compared with lap patients (3.3 days).

Adjusted outcomes
Multiple logistic regression models were used to compare the odds of 30-day mortality and overall and serious morbidity across procedure type (Lap, TA, and TT) while adjusting for other factors. The TA patients were nearly 3 times as likely as lap patients to experience 30-day mortality (odds ratio [OR] 2.97; 95% CI 1.69 to 5.20; p < 0.001) after adjusting for age, ASA, emergency cases, functional status, and steroid use (Table 4). Moreover, patients undergoing TA and TT procedures had significantly increased odds of overall (OR 2.12, 95% CI 1.79 to 2.51, p < 0.001; OR 2.49, 95% CI 1.54 to 4.00, respectively; p < 0.001) and serious morbidity (OR 1.90, 95% CI 1.53 to 2.37, p < 0.001; OR 2.73; 95% CI 1.88 to 3.96, respectively; p < 0.001) when compared with patients undergoing a lap procedure.

DISCUSSION
In this retrospective analysis using the NSQIP database, we identified 8,186 patients who underwent PEH repair between 2005 and 2011, via laparoscopic (n = 6,415; 78.4%), transabdominal (n = 1,571; 19.2%), or transthoracic (n = 200; 2.4%) techniques. After comparing postoperative outcomes of these 3 surgical approaches, we found, on multivariable analysis, that patients undergoing transthoracic or transabdominal open repair had significantly greater odds of experiencing overall morbidity and serious morbidity compared with those treated with laparoscopic repair, even when adjusting for emergent cases. Moreover, patients undergoing TA repair were nearly 3 times as likely as patients treated with laparoscopic repair to experience 30-day mortality.

The benefits of laparoscopic PEH repair include decreased postoperative pain, shorter length of stay, faster recovery, and improvement in quality of life; these have been amply documented in the literature. Such benefits make laparoscopic PEH repair an especially attractive therapeutic option for fragile and elderly patients. However, laparoscopic PEH repair can be highly technically challenging, especially when repair of large or complicated hernias is considered, and the incidence of visceral injuries has been reported to be higher than that observed with traditional open surgical repair. Additionally, some series have reported a high hernia recurrence rate after laparoscopic PEH repair. In general, however, it appears...
that a substantial percentage of such recurrences consist solely of small anatomic defects seen on follow-up radiographic imaging, which are asymptomatic and quite probably clinically unimportant\(^\text{26}\)—an observation we have made previously.\(^\text{27}\)

Transthoracic repair inarguably provides a better view of the herniated structures, allowing for easier sac dissection and resection, and better mobilization of the esophagus. However, this advantage may, in fact, be offset by the considerable postoperative pain and greater difficulty in constructing an adequate fundoplication through the thorax, as well as increased use of esophageal lengthening procedures in these patients.\(^\text{9}\) In regard to an open transabdominal approach, it has been posited that the more conspicuous formation of adhesions associated with laparotomy may paradoxically constitute an advantage in reducing recurrent herniation by helping to retain the reduced structures within the abdomen. However, laparotomy, in contrast to laparoscopy, is characterized by a slower recovery, a higher incidence of wound infections, poorer mediastinal visualization and, therefore, more challenging transhiatal dissection.\(^\text{1}\)

Finally, although it is commonly held that open PEH repair should be the technique of choice in the emergency setting, it has been shown that laparoscopic repair of acute PEH is safe,

<table>
<thead>
<tr>
<th>Table 2. Baseline Demographic and Clinical Characteristics</th>
</tr>
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<tbody>
<tr>
<td><strong>Variable</strong></td>
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<tr>
<td>--------------</td>
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<tr>
<td>Age, y, mean (median)</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Race</td>
</tr>
<tr>
<td>White</td>
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<tr>
<td>Black</td>
</tr>
<tr>
<td>Other</td>
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<tr>
<td>Body mass index</td>
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<tr>
<td>&lt;25 kg/m(^2)</td>
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<tr>
<td>25–29.9 kg/m(^2)</td>
</tr>
<tr>
<td>≥30 kg/m(^2)</td>
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<tr>
<td>ASA classification</td>
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<tr>
<td>No/mild disturbance</td>
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<tr>
<td>Serious disturbance</td>
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<tr>
<td>Life-threatening/moribund</td>
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<tr>
<td>Functional status</td>
</tr>
<tr>
<td>Independent</td>
</tr>
<tr>
<td>Dependent</td>
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<tr>
<td>Diabetes</td>
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<tr>
<td>Current smoker</td>
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<td>Alcohol consumption</td>
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<tr>
<td>Dyspnea</td>
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<tr>
<td>History of COPD</td>
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<td>History of CHF</td>
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<td>History of MI</td>
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<tr>
<td>Hypertension</td>
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<td>Previous cardiac surgery</td>
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<td>Steroid use</td>
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<td>Renal disease</td>
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<tr>
<td>Emergency cases</td>
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</table>

Unless otherwise stated, data are reported as n (%). Different denominators due to missing observations: female (laparoscopic [Lap], n = 6,391; transabdominal [TA], n = 1,569; transthoracic [TT], n = 199); race (Lap 6,346, TA 1,529, TT 198); body mass index (Lap 6,376, TA 1,529, TT 196); functional status (Lap 6,409, TA 1,571, TT 200); alcohol consumption (Lap 5,695, TA 1,507, TT 192); history of MI (Lap 5,695, TA 1,507, TT 192); previous cardiac surgery (Lap 5,695, TA 1,507, TT 192).

\(^\ast\)p Value for laparoscopic vs transabdominal approach.

\(^\dagger\)p Value for laparoscopic vs transthoracic approach.

ASA, American Society of Anesthesiologists; CHF, congestive heart failure; lap, laparoscopic; MI, myocardial infarction; TA, transabdominal; TT, transthoracic.
feasible, and provides good results, especially in the absence of obvious perforation.

Despite a large number of series reporting on the results of PEH repair, both open and laparoscopic, there are, to date, no randomized controlled trials comparing approaches. To address this paucity of data, Fullum and colleagues\(^7\) queried the Nationwide Inpatient Sample (NIS) database, and concluded, similar to our results, that laparoscopic repair is associated with a lower mortality in noncomplicated PEH. However, the NIS is an administrative database, which makes it inherently susceptible to errors due to missing or inaccurately coded entries.\(^7\) Moreover, the NIS data available for analysis are limited to events occurring during the hospitalization in which surgery took place, and offer no means of tracking clinical developments occurring subsequent to a patient’s discharge. Necessarily, Fullum and associates’ analysis focused primarily on mortality because the data provided in the NIS are not conducive to a detailed comparison between the specific technique-related morbidities. Our study included patients undergoing PEH repair between 2005 and 2011, in contrast to Fullum and coworkers,\(^28\) whose analysis covered the period from 1998 to 2005. During the period of time represented in our analysis, fully 76% of patients undergoing PEH repair did so via a laparoscopic approach; the corresponding percentage of patients undergoing laparoscopic PEH repair in Fullum’s study was a mere 35%. The marked increase in the rate of performance of laparoscopic PEH repair over this relatively short time interval is noteworthy and may reflect either a growing acceptance by surgeons of the advantages of laparoscopic repair, or it may simply reflect the acquisition of advanced laparoscopic skills by an increasing number of practitioners, or perhaps some combination of these 2 factors.

In contrast, the NSQIP database provides a richer and more detailed body of data with which to analyze specific outcomes, having been precisely developed to study and improve quality of care. Complications occurring up to 30 days postoperatively are tracked by NSQIP, making it a more useful tool than the NIS for analyzing early surgical outcomes.\(^26\) Our analysis confirms, on a larger scale, the results of other large laparoscopic series and datasets in the literature.\(^17,19,31\) The 30-day mortality yield by our study is comparable to that achieved with large laparoscopic series, yet lower than that reported by other authors.\(^17,32,33\) However, case series from single centers have remarkably variable inclusion criteria (ie, emergency cases, hernia size, use of esophageal lengthening procedures, surgeon experience, etc), which likely account for the observed difference in mortality. In this regard, NSQIP proves to be advantageous because it allows us to analyze a large number of patients from multiple institutions, therefore minimizing the effect of any bias. Our data demonstrate that laparoscopy does indeed hold key advantages compared with open surgery, both transabdominal and transthoracic,
with respect to its significantly reduced incidence of most of the established morbidities of PEH repair.

The principal limitations of our study are related to the chosen database. In particular, functional outcomes and the risk of recurrence are extremely important variables to be considered when comparing surgical techniques for PEH repair. In this regard, a recurring criticism of laparoscopic PEH repair has centered on the high recurrence rate reported by some authors. Conversely, others posit that ongoing advances and refinements in the minimally invasive technique (eg, use of mesh, appropriate use of Collis gastroplasty, etc) have led to a recurrence rate as low as that achieved with open surgery. In the same vein, another limitation of our study—again reflecting the very nature of the queried database—is the lack of data beyond 30 days postprocedure, significantly limiting any ability to draw conclusions regarding PEH recurrence and functional outcomes. In addition, patients experiencing serious complications ultimately resulting in death, who were however kept alive for more than 30 days (eg, in the ICU setting), cannot be detected with NSQIP.

Many operative variables likely to affect the outcomes of PEH repair are simply not available within this dataset. As such, this method of analysis does not allow us to take into consideration specific technical aspects of PEH repair (eg, type of fundoplication, addition of an esophageal lengthening procedure, type of mesh used, type of hiatal closure, and use of gastropexy), which are likely pivotal in determining both short- and long-term results. The NSQIP does not allow us to identify whether the open transabdominal and transthoracic group included more patients with complex anatomy (ie, previous antireflux surgery or multiple previous abdominal operations), which could lead to selection bias, nor does it give information on intraoperative need for conversion to an open procedure. Unfortunately, there is no separate code to identify re-do operations, so it is not possible to determine how our results might have been affected if we had been able to analyze this subset of patients separately. Moreover, the ICD 9 codes for diaphragmatic hernia (553.3 and 552.3) do not specifically discriminate between sliding hiatal hernias (type I) and true PEH (type II, III, IV); as a result, some of the included patients may have been misclassified. However, in order to minimize inclusion of patients with simple sliding hiatal hernias, when we generated our initial cohort, we included only patients with a primary diagnosis of paraesophageal hernia (ICD-9 code of 553.3 or 552.3) in addition to having a primary CPT code indicating paraesophageal hernia repair. Finally, hospital participation in NSQIP is voluntary and self-funded, so it is not known whether the data reported by this small subset of hospitals, usually high volume centers, can properly be extrapolated to all hospitals and the general population. Despite the above-mentioned limitations, we believe that the use of a surgically oriented database, as well as the large number of patients analyzed in this study, represent a valuable tool for evaluating the comparative safety of the different surgical techniques under consideration.

CONCLUSIONS

In conclusion, the results of our analysis demonstrate that laparoscopic PEH repair is safer in terms of overall and adjusted morbidity and significantly decreases hospital length of stay when compared with the transthoracic and open transabdominal approaches. In view of the lack of level I evidence indicating improved long-term outcomes after open transabdominal or transthoracic PEH repair, we believe the laparoscopic approach should be considered, whenever technically feasible, based on our data demonstrating superior short-term outcomes.

Author Contributions

Study conception and design: Mungo, Molena, Stem, Feinberg, Lidor

Acquisition of data: Mungo, Molena, Stem, Feinberg, Lidor

Analysis and interpretation of data: Mungo, Molena, Stem, Feinberg, Lidor

Drafting of manuscript: Mungo, Molena, Stem, Feinberg, Lidor

Critical revision: Mungo, Molena, Stem, Feinberg, Lidor

Table 4. Multivariable Logistic Regression for Mortality And Morbidity

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Group</th>
<th>Odds ratio (95% CI)</th>
<th>p Value</th>
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<tbody>
<tr>
<td>30-day mortality</td>
<td>TA</td>
<td>2.97 (1.69—5.20)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Overall morbidity*</td>
<td>TA</td>
<td>2.12 (1.79—2.51)</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
<td>TT</td>
<td>2.73 (1.88—3.96)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Serious morbidity†</td>
<td>TA</td>
<td>1.90 (1.53—2.37)</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
<td>TT</td>
<td>2.49 (1.54—4.00)</td>
<td>&lt;0.001</td>
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</table>

Laparoscopic group is the reference. Thirty-day mortality was adjusted for procedure type, age, ASA, emergency cases, functional status, and steroid use. Overall and serious morbidity were adjusted for procedure type, age, sex, ASA, functional status, emergency cases, steroid use, and dyspnea.

*Overall morbidity: wound infection, pneumonia, urinary tract infection, return to operating room, VTE, cardiac complication, shock/sepsis, unplanned intubation, bleeding transfusion, on ventilator >48 hours, and renal complication.

†Serious morbidity: return to operating room, cardiac complication, shock/sepsis, unplanned intubation, and on ventilator >48 hours.

ASA, American Society of Anesthesiologists; TA, transabdominal; TT, transthoracic; VTE, venous thromboembolic event.
REFERENCES