The Impact of Surgical Approach on Late Recurrence in Incisional Hernia Repair

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ABSTRACT

Background and Objectives: We conducted a retrospective, observational study to compare real-world recurrence rates for different surgical approaches after incisional hernia mesh repair.

Methods: Two large US insurance claims databases, Truven Commercial Claims (CCAE) and Medicare Supplemental (MDCR), were evaluated for the period from 2009 to 2015. The first incisional hernia repair with mesh for patients 21 years or older was identified (INDEX). One-year continuous enrollment before INDEX was required. Mesh and approach (OPEN, laparoscopic [LAP], and conversion [CONV]) were identified with the use of CPT-4/ICD-9 codes. Recurrence was defined as a second incisional hernia repair 31 days or longer after INDEX. Kaplan-Meier (KM) estimates and Cox models were used to analyze the effect of approach on recurrence.

Results: A total of 68,560 patients were identified for CCAE (78.7%) and MDCR (21.3%) with a mean (SD) age of 55.3 (12.8) years. The majority of procedures were OPEN (80.1%) followed by LAP (16.3%) and CONV (3.6%). OPEN had fewer female patients 53.7% compared with LAP (62.1%) and CONV (62.2%). CONV represented more inpatient (51.9%) procedures compared with LAP (41.0%) and OPEN (27.3%). Starting at 2 years post-INDEX, LAP (5.1%, 95% confidence interval [CI] 4.5%–5.6%) had lower KM estimates compared with OPEN (5.9%, 95% CI 5.7%–6.2%]); after 3 years, LAP (6.8%, 95% CI 6.2%–7.5%]) had lower estimates than both OPEN (7.9%, 95% CI 7.6%–8.3%) and CONV (9.3%, 95% CI 7.6%–11.0%). After controlling for confounders, the risk was lower for LAP compared with OPEN (hazard ratio 0.839, 95% CI 0.752–0.936) and CONV (hazard ratio 0.808, 95% CI 0.746–0.875), while OPEN and CONV were not significantly different from each other.

Conclusion: Successful laparoscopic surgery incisional hernia mesh repair was associated with decreased risk of recurrence compared with OPEN and CONV.

Key Words: Incisional hernia, Mesh, Recurrence, Laparoscopic, Conversion.

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Disclosure: This study was funded by Johnson & Johnson, Inc. All authors are full-time employees of Johnson & Johnson or Ethicon, Inc. There is no off-label use of products in the manuscript.

Ethical Approval: The use of Truven CCAE and MDCR was reviewed by the New England Institutional Review Board (IRB) and was determined to be exempt from broad IRB approval, as this research project did not involve human subject research.

Conflicts of Interest: All authors declare no conflict of interest regarding the publication of this article.

Informed consent: Dr. Yoo declares that written informed consent was obtained from the patient/s for publication of this study/report and any accompanying images.

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DOI: 10.4293/JSLS.2018.00053

INTRODUCTION

In the United States, surgical repair of abdominal wall hernias is one of the most common procedures, with approximately 350,000 procedures performed in 2006.[1] The use of mesh is a standard treatment for ventral and incisional hernias affirmed by multiple consensus articles and society guidelines.[2–5] Laparoscopic ventral hernia repair (LVHR) continues to increase due to decreased postoperative pain and reduction of wound complications combined with similar reported rates of recurrence as open ventral hernia repair (OVHR).[2,4] General considerations for performing LVHR include hernia defect size, factors that may contribute to increasing technical complexity, along with surgeon training and experience.[5] The risk of hernia recurrence increases over time, but because the majority of clinical studies and registries report either intent-to-treat analyses or short-term outcomes of 1 to 2 years, there remains uncertainty as to the long-term recurrence rates. Risk factors for recurrence identified by the International Endohernia Society in 2014 include size of the hernia (10 cm), body mass index (BMI) 30 kg/m^2, history of previous repair, chronic obstructive pulmonary disease, chronic cough, diabetes, smokers with earlier failed prior hernia repairs, and surgical site infection (SSI).[6,7]

In a 2011 Cochrane meta-analysis of 10 randomized controlled trials with a total of 880 patients undergoing LVHR and OVHR, the recurrence rates were not different, but LVHR reduced the risk of wound infection and shortened hospital stay significantly. Because patients were followed for less than 2 years in half of the trials, it was concluded that LVHR had promising short-term results.[8] Due to lack of data on long-term effectiveness, further studies with follow-up beyond 3 years are required.

Our study evaluates and explores longer-term recurrence (> 3 years) estimates and recurrence risk factors for patients undergoing incisional hernia repair among different surgical approaches: successful laparoscopic (LAP), planned open (OPEN), and laparoscopic conversion to open (CONV) in a real-world setting. Because this was an exploratory analysis, there was no formal hypothesis.

MATERIALS AND METHODS

Databases

We performed a retrospective observational study using the Truven Health MarketScan® Research Databases: Commercial Claims and Encounters (CCAE) and Medicare Supplemental and Coordination of Benefits (MDCR). The CCAE and MDCR contain individual-level, deidentified healthcare claims information including medical and drug insurance claims for inpatient admission records, outpatient services, and prescription drugs. CCAE includes data for approximately 30 million patients per year collected from more than 300 large self-insured US employers and more than 25 health plans, while the MDCR includes data for approximately 2 million patients per year with Medicare Supplemental. Longitudinal analyses can be performed in this database when analyzing individuals who are continuously enrolled in an insurance plan. Institutional review board approval was not necessary to conduct this study, as data within these databases are deidentified and comply with Health Insurance Portability and Accountability Act regulation.

Patient Selection

All patients undergoing primary incisional or ventral hernia repairs with mesh from January 1, 2009, through December 31, 2014, were identified. The first incisional or ventral hernia repair with mesh (INDEX) was identified with the use of *Current Procedural Technology Fourth Edition* (CPT-4) and *International Classification of Diseases, Ninth Revision* (ICD-9-CM) procedure codes: incisional hernias (49654, 49655; 53.61, 53.62), ventral hernias (53.63, 53.69), or nonspecific incisional or ventral hernias (49560, 49561). Other nonincisional ventral hernia repairs such as unspecified anatomy, Spigelian, parastomal, umbilical, or epigastric were excluded. Mesh was identified by CPT-4 (49568) or if the index surgery description included mesh. Patients were required to have 1 year of continuous enrollment in the Marketscan database before INDEX (PRE-PERIOD). Patients were excluded if they had any evidence of a prior abdominal hernia repair during the PRE-PERIOD. This included primary or recurrent incisional repairs, abdominal wall mesh removal or infection, and other nonincisional ventral hernia repairs (i.e., unspecified anatomy, Spigelian, parastomal, umbilical, or epigastric). Patients with any missing demographic information were excluded from the study (**Fig. 1**). See Appendix 1 for all exposure, outcome, covariate, and censoring codes.

Hernia Recurrence Outcome and Censoring Events

Incisional hernia recurrence outcome events were defined as either a second primary incisional hernia repair or a CPT-4 code indicating a repair of a recurrent incisional or ventral hernia (49656, 49657, 49565, 49566) occurring at 31 days or later after INDEX. Patients were excluded from the study if they had a recurrence before 31 days. Censoring events included: mesh removal procedure (CPT-4 code 11008), other nonincisional ventral wall hernia repairs different from index anatomy (i.e., unspecified anatomy, Spigelian, parastomal, umbilical, or epigastric), end of study period, or loss of Marketscan database continuous insurance enrollment.

Covariates

Patient demographics included age, sex, geographic location, and type of insurance. Comorbidities were identified by using ICD-9-CM diagnosis codes during the PRE-PERIOD and included the complete Elixhauser Comorbidity Index (ELIX) and individual categories along with myocardial infarction and cerebrovascular disease from the Charlson Comorbidity Index categories.[9,10] Additionally, smoking, steroid use, abdominal open wound, and femoral or inguinal hernia risk factors were also evaluated. Procedural covariates included year of surgery, inpatient versus outpatient setting,

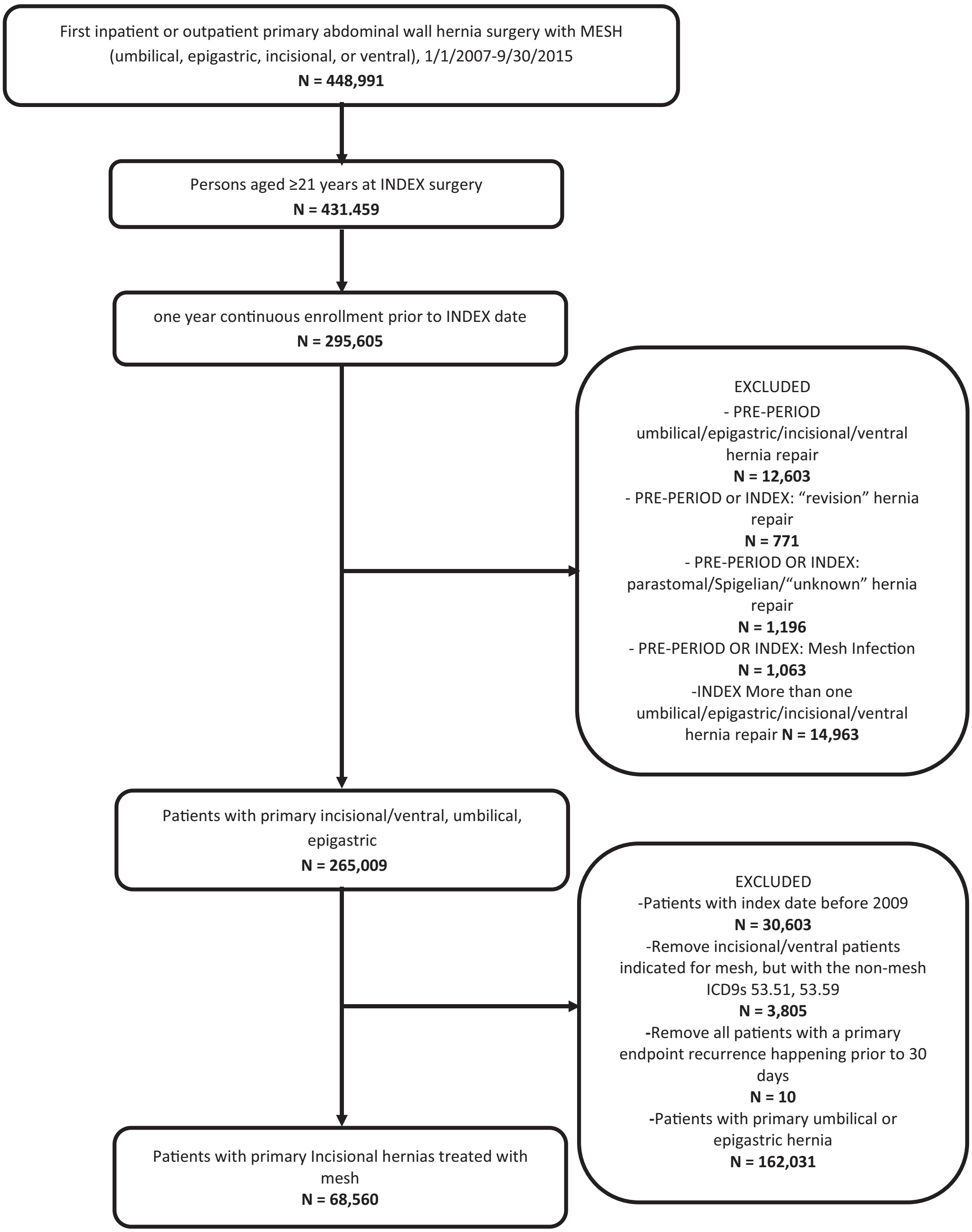

Fig. 1. Identification of the study cohort.

emergency room (ER) visits occurring on INDEX or 1 day earlier, and length of stay (LOS). Outpatient procedures were assigned an LOS of 0. Surgical approach was defined as open planned (OPEN), successful laparoscopic (LAP), or laparoscopic conversion (CONV). CONV was identified with either ICD-9-CM (V46.41) or having both an OPEN and LAP code. Additional variables included robotic assistance (17.4*) and concomitant procedures and hospital census region (see **Table 1** and **Table 2** for complete listings).

Statistical Analysis

A descriptive analysis was performed for all study variables. Incidence of hernia recurrence was reported as a risk rate via 2 methods: the Kaplan-Meier (KM) estimator[11] and a simple proportion (SP) with 95% confidence intervals (CIs). For the SP, patients were included only if they had continuous enrollment in the database at the yearly intervals. KM curves were compared by using log rank tests between each pairwise combination for surgical approach. Hernia recurrence risk factors were evaluated with Cox proportional hazards (CPH) models. The CPH assumption was tested for each variable individually. Additionally, logistic regression (LR) models at 1- and 2-year follow-up were used to assess the potential effect of censoring on risk factors. Only patients with continuous enrollment at these time points were included in these models. The following covariates were a priori present in all models: age, sex, ER procedure, ELIX, smoking, steroid use, diabetes, peripheral vascular disease, obesity, chronic obstructive pulmonary disease, and renal failure. Additional variables were evaluated by stepwise variable by using goodness-of-fit optimization (Akaike information criterion [AIC]). Hospital LOS and ELIX were treated as ordinal variables and grouped based on distributions. Age was modeled as a continuous variable. Only main effects were evaluated. Predictive performance of each final model was evaluated based on area under the curve (AUC) at an 80:20 training/test split.[12] All study variables were included as candidate variables. Statistical significance was ≤0.05 (2-sided), and adjustments for multiple testing (due to 3 pairwise comparisons of approach) were deemed not necessary due to the exploratory nature of this observational study. All analyses were performed with R version 3.3.1.

Sensitivity Analyses

The sensitivity of the 3 censoring events (unknown hernia anatomy repair, mesh removal, and epigastric or umbilical hernia repairs) representing hernia recurrence was evaluated by considering each of these censoring events as hernia recurrence events. The incremental effect on the hernia recurrence rates (KM) and risk factors (CPH) were evaluated for each type of censoring event separately.

RESULTS

Patient and Procedure Demographics

A total of 68,560 patients were included in the study based on the procedural code description: "incisional or ventral" (76.5%), "incisional" (20.5%), and "ventral" (3.0%). **Fig. 1** presents the cohort attrition. The overall cohort had more women (55.4%), more patients with commercial insurance (78.7%), and a mean (SD) age of 55.3 (12.8) years. The mean (SD) Elixhauser score was 2.5 (2.3), and the most prevalent comorbidities were hypertension (52.4%), diabetes (22.2%), chronic pulmonary disease (17.6%), and obesity (16.8%). In addition, approximately 9.0% of patients had a groin hernia diagnosis. The majority of procedures performed were OPEN (80.1%), followed by LAP (16.3%) and CONV (3.6%). The conversion rate was 18.0% of all laparoscopic attempted procedures. More female patients underwent LAP (62.1%) compared with OPEN (53.7%). A bivariate analysis by surgical approach shows that the laparoscopic surgical cohort had more women (62.1%) and occurred more often in the South (42.3%), and procedure counts increased from 2009 (7.7%) to peak in 2012 (22.4%) and then decline to 17.4% in 2014. Table 1 provides the cohorts demographics.

The mean (SD) length of stay (LOS) for inpatient procedures was 5.4 (6.5) days. A small percent of patients had an ER visit (3.4%). The most common concomitant procedures were component separation (5.9%), adhesiolysis (5.4%), and groin hernia repair (3.4%). Procedural differences related to surgical approach included more OPEN procedures performed in the outpatient setting (72.7%) compared with LAP (59.0%) and CONV (48.1%). For inpatient procedures, OPEN had a longer mean LOS of 6.0 days (7.2) compared with LAP at 4.1 days (3.8) and CONV at 3.9 days (2.9). OPEN surgery had more component separation (7.1%) compared with CONV (2.8%) and LAP (0.7%), although adhesiolysis was slightly less frequent in OPEN (5.0%) compared with LAP (7.1%) and CONV (8.4%). Table 2 provides the procedural characteristics.

Table 1.
Patient Demographics

	Overall	OPEN	LAP	CONV
	N = 68,560	n = 54,942	n = 11,167	n = 2451
Database, %				
CCAE	78.7	78.3	79.4	83.4
MDCR	21.3	21.7	20.6	16.6
Female	55.4	53.7	62.1	62.2
Age, years				
Mean	55.3	55.3	55.6	54.2
Median	56.0	56.0	56.0	55.0
SD	12.8	12.9	12.3	12.2
Geographic region, %				
South	38.7	37.6	42.3	47.0
North Central	26.7	27.1%	25.5	23.9
West	17.4	18.2	13.8	15.1
Northeast	15.3	15.2	16.3	12.8
Unknown	1.9	1.9	2.1	1.2
Year of index, %				
2009	14.1	14.3	7.7	41.1
2010	14.2	14.4	13.8	11.7
2011	19.1	19.0	20.8	12.4
2012	20.8	20.8	22.4	14.6
2013	15.9	15.7	17.9	10.5
2014	15.9	15.8	17.4	9.7
Elixhauser score				
Mean	2.5	2.5	2.7	2.7
Median	2.0	2.0	2.0	2.0
SD	2.3	2.3	2.2	2.2
Comorbidities, %				
Hypertension	52.4	51.6	55.9	55.2
Diabetes	22.2	21.6	24.9	24.7
COPD	17.6	17.3	18.9	18.4
Obesity	16.8	15.4	22.3	23.3
Smoking	9.9	9.8	10.5	11.0
Groin hernia	9.2	9.5	8.1	8.4

OPEN, planned open; LAP, successful laparoscopic; CONV, laparoscopic conversion to open; CCAE, Truven Health MarketScan® Research Database Commercial Claims and Encounters; MDCR, Truven Health MarketScan® Research Database Medicare Supplemental and Coordination of Benefits; COPD, chronic obstructive pulmonary disease.

Table 2.
Procedural Characteristics

	Overall N = 68,560	OPEN n = 54,942	LAP n = 11,167	CONV n = 2451
Procedure location, %				
Outpatient	69.6	72.7	59.0	48.1
Inpatient	30.4	27.3	41.0	51.9
Inpatient LOS, days				
Mean	5.4	6.0	4.1	3.9
Median	4.0	5.0	3.0	3.0
SD	6.5	7.2	3.8	2.9
ER visit, %[a]	3.4	3.3	3.2	3.6
Robotic assistance, %	0.1	0.0	0.5	0.6
Concomitant procedure, %				
Component separation	5.9	7.1	0.7	2.8
Adhesiolysis	5.4	5.0	7.1	8.4
Groin hernia repair	3.4	3.7	2.1	2.0
Bowel resection	0.7	0.9	0.2	0.2
Enterotomy	0.1	0.1	0.1	0.1

OPEN, planned open; LAP, successful laparoscopic; CONV, laparoscopic conversion to open; LOS, length of stay.
[a]Emergency room (ER) visit INDEX and 1 day earlier.

Hernia Recurrence Estimates

KM Estimate

Overall, for the entire cohort, the KM estimate for early hernia recurrence was low at 0.4% and 1.1%, respectively, at 3 and 6 months with the yearly estimate starting at 3.1% (95% CI 2.9%–3.2%) at 1 year and steadily increasing. The largest increase in absolute recurrence rates was from year 1 to 2 increasing 2.7%, from 3.1% to 5.8% (95%CI [5.6%–6.0%]). The yearly absolute difference slowed over the 3- to 6-year POST-INDEX interval: 2.0%, 1.6%, 1.2%, and 0.8%. **Table 3** gives the KM estimate and 95% CI for the overall cohort and by surgical approach at 3 and 6 months, and then yearly until 6 years POST-INDEX. Table 3 gives the KM estimate and 95% CI for the overall cohort and by surgical approach at 3 and 6 months, and then yearly until 6 years POST-INDEX. **Fig. 2** shows the cumulative recurrence incidence for the overall cohort and by surgical approach. Within 1 year, there was little difference in KM estimates between approaches as demonstrated by overlapping CIs. For year 2, LAP showed a decreased recurrence rate 5.1% (95% CI 4.5%–5.6%) compared with OPEN 5.9% (95% CI 5.7%–6.2%) but still had substantial confidence interval overlap with CONV 6.3% (95% CI 5.1%–7.6%). After 3 years post INDEX, both OPEN 7.9% (95% CI 7.6%–8.3%) and CONV 9.3% (95% CI 7.6%–11.0%) had higher recurrence rates compared with LAP 6.8% (95% CI 6.2%–7.5%). Log-rank tests were statistically significant for LAP-CONV ($p = .001$) and LAP-OPEN ($p = .002$), while OPEN-CONV was $p = .085$. The SP estimate mirrored the KM estimate with an expected widening of CIs due to sample loss compared with the KM technique (**Table 4**).

Recurrence Sensitivity Analysis

An evaluation was performed of the effect on the KM estimate of 3 censoring events (mesh removal, unknown abdominal wall anatomy, and umbilical/epigastric procedures) potentially representing failures of the INDEX mesh hernia repair. For the entire cohort, the effect in general increased the KM estimate by a small amount, which varied by time from INDEX. This effect on the absolute recurrence rate was smallest in the early part of POST-INDEX ranging from approximately 0.5% and 0.4% at 1 year for mesh removal and unknown abdominal wall anatomy to ~0.9% and ~1.3% at 6 years. The umbilical/

Table 3.
Kaplan-Meier Cumulative Hernia Recurrence Incidence Estimates

	All			OPEN			LAP			CONV		
Time, Months	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL
3	0.4	0.3	0.4	0.3	0.3	0.4	0.4	0.3	0.5	0.4	0.1	0.7
6	1.1	1.0	1.2	1.1	1.0	1.2	1.1	0.9	1.3	1.2	0.7	1.6
12	3.1	2.9	3.2	3.1	3.0	3.3	2.7	2.3	3.0	3.1	2.3	3.9
24	5.8	5.6	6.0	5.9	5.7	6.2	5.1	4.5	5.6	6.3	5.1	7.6
36	7.8	7.5	8.1	7.9	7.6	8.3	6.8	6.2	7.5	9.3	7.6	11.0
48	9.4	9.0	9.7	9.5	9.1	9.9	8.2	7.3	9.1	11.8	9.7	13.9
60	10.6	10.1	11.0	10.7	10.2	11.2	8.9	7.8	9.9	13.7	11.2	16.1
72	11.4	10.8	11.9	11.6	11.0	12.2	9.4	8.1	10.6	13.7	11.2	16.1

OPEN, planned open; LAP, successful laparoscopic; CONV, laparoscopic conversion to open; KM, Kaplan-Meier; UCL, upper confidence limit; LCL, lower confidence limit.

epigastric censoring event had a smaller effect on the absolute failure rate with 0.1% at year 1 increasing to 0.6% at 6 years. Appendix 2 (Table 1) presents the sensitivity analysis for all patients. Appendix 2 (Table 2) illustrates that the trends were generally consistent when evaluated by surgical approach.

Risk Factors for Hernia Recurrence

The CPH models were generally consistent with the LR models. LAP and CONV were both associated with decreased risk for reherniation surgery (hazard ratio [HR] 0.839, 95% CI 0.752–0.936 and HR 0.808, 95% CI 0.746–0.875) compared with OPEN. OPEN and CONV were not statistically different. Important control variables included region with the Northeast having decreased risk for recurrence compared with the South (HR 0.782, 95% CI 0.690–0.887) and year of surgery with years from 2009 to 2013 having significantly increased hazard ratios compared with 2014. Increasing LOS from 0 days (outpatient) was associated with increased risk (HR) of recurrence of 17.8% (95% CI 12.5–23.3%) for LOS of 1–3 days and 36.0% for LOS of 4+ days. Increasing Elixhauser score (ordinal variable: 0–1, 2, 3–4, +5) was associated with increased risk of recurrence (HR 1.083, 95% CI 1.015–1.156]) for each strata compared with 0–1. Other risk factors that were significant and had HR 1.2 included abdominal wound at index (HR 1.584, 95% CI 1.232–1.956), peptic ulcer disease (HR 1.426, 95% CI 1.112–1.828), smoking (HR 1.329, 95% CI 1.117–1.501), and fluid and electrolyte disorders (HR 1.278, 95% CI 1.126–1.450]). Interestingly, patients with a concomitant groin hernia repair (HR 0.611, 95% CI 0.461–0.810) and congestive heart failure (HR 0.797, 95% CI 0.662–0.959) were associated with decreased risk of recurrence. In general, the LR models at 1 and 2 years mirrored the CPH identified risk factors. Differences included decreased odds of recurrence in the 1-year LR model for patients undergoing concomitant component separation (OR 0.737, 95% CI 0.574–0.945) and increased odds for patients with depression (OR 1.279, 95% CI 1.097–1.493).

The proportional hazards assumption was evaluated for each predictor variable, and several variables included via stepwise selection failed this assumption. These included age, component separation, Elixhauser score, fluid and electrolyte disorder, and abdominal wound. All included variables for all models are listed in **Table 5**.

Model Predictive Performance

Predictive performance contextualizes the aggregate ability of the selected risk factors in predicting hernia recurrence. AUC was generally poor. CPH (AUC 0.634, 95% CI 0.602–0.660) was nonsignificantly higher than LR (AUC 0.623, 95% CI 0.592–0.653) in predicting recurrences up to 1 year but was similar at predicting recurrences up to 2 years (CPH 0.613, 95% CI 0.589–0.636, LR 0.614, 95% CI 0.588–0.639). CPH AUCs from 3 to 6 years were 0.618, 0.618, 0.617, and 0.616, respectively.

Fig. 2. (*A*) Cumulative hernia recurrence incidence estimates for all incisional patients. (*B*) Cumulative hernia recurrence incidence estimates for all incisional patients by surgical approach.

Table 4.
SP Hernia Recurrence Incidence Estimates

	ALL			OPEN			LAP			CONV		
Time, Months	SP Estimate	95% LCL	95% UCL	SP Estimate	95% LCL	95% UCL	SP Estimate	95% LCL	95% UCL	SP Estimate	95% LCL	95% UCL
3	0.4	0.3	0.4	0.4	0.3	0.4	0.4	0.3	0.5	0.4	0.2	0.8
6	1.1	1.0	1.2	1.1	1.0	1.2	1.1	0.9	1.3	1.2	0.8	1.8
12	3.1	2.9	3.2	3.1	3.0	3.3	2.7	2.3	3.1	3.4	2.6	4.5
24	5.9	5.6	6.2	6.0	5.7	6.4	5.0	4.3	5.7	6.8	5.4	8.6
36	7.9	7.5	8.3	8.1	7.6	8.6	6.7	5.7	7.7	8.9	7.0	11.3
48	9.9	9.3	10.6	10.2	9.5	10.9	8.0	6.6	9.7	10.3	7.8	13.6
60	11.4	10.5	12.4	11.7	10.7	12.8	8.8	6.5	11.7	11.8	8.5	16.0
72	12.2	10.6	14.0	12.7	10.9	14.7	9.4	5.2	16.1	10.8	6.5	17.2

SP, simple proportion; OPEN, planned open; LAP, successful laparoscopic; CONV, laparoscopic conversion to open; KM, Kaplan-Meier; UCL, upper confidence limit; LCL, lower confidence limit.

DISCUSSION

Hernia Recurrence Estimates

The method of estimating recurrence reported in the literature varies significantly despite the recommendation for using the KM method by the European Registry of Abdominal Wall Hernias.[13] The reported literature has used a variety of methods for reporting recurrence outcomes, including KM estimate, simple proportions for all patients with reported outcomes at the time interval of interest, and intent to treat.[13–17]

Our study analyzed recurrence with both the preferred KM estimate and a simple proportion approach to allow for contextualization of prior studies. Two analyses of the Danish Ventral Hernia Database evaluated long-term recurrence estimates for incisional hernia repair focusing on surgical approach. The first study included both mesh (n = 1,129) and nonmesh (n = 366) OVHR and mesh-only LVHR (n = 1763). The 4-year cumulative recurrence rate was significantly higher for OVHR (21.1%) compared with LVHR (15.5%).[18] The subsequent study evaluated mesh-only repairs and used a competing risk analysis (hernia recurrence reoperations and mesh complications). The 5-year cumulative recurrence estimates were 12.3% (95% CI 10.4%–14.3%) for OVHR and 10.6% (95% CI 9.2%–12.1%) for LVHR. The 5-year competing risk estimates are close to our study results: OVHR 10.7% (95% CI 10.2%–11.2%) and successful laparoscopic repair 8.9% (95% CI 7.8%–9.9%).[19] The small differences between studies could be due to endpoint definition or baseline risk differences in populations studied. Our sensitivity analysis, which evaluated the scenario where mesh removal procedures or ventral hernia repairs of unknown anatomy were considered recurrence events rather than censoring events, brings the recurrence estimates even closer: OVHR 12.0% (95% CI 11.2%–12.3%) and LVHR 9.6% (95% CI 8.5%–10.7%). Other studies have estimated 1-year recurrence rates as a simple proportion. An analysis of the Herniamed Registry estimated a recurrence rate of at 6.3% (95% CI 5.8%–6.8%) for all patients with a mesh incisional hernia repair at 1-year follow-up.[15] The individual open and laparoscopic recurrence rates were not given. These estimates were higher than this study's findings for simple proportions (3.1%). This is likely due to the difference in endpoint definitions, as our study's was a second hernia repair and the Herniamed endpoint is surgical repair and hernia diagnosis.

In addition to the variability in including hernia anatomy, there is a significant amount of heterogeneity in anatomic classification of abdominal wall hernias and research varies widely in the literature. The grouping of abdominal wall hernias can vary and may include all types of anatomies (such as umbilical or epigastric). Prior studies have found recurrence differences based on hernia anatomy and have recommended not pooling these different anatomies.[15,16] A recent study from the Herniamed Registry found significantly decreased recurrence risks for umbilical (2.0%) and epigastric (4.1%) hernia anatomies compared with incisional hernias (6.3%) within 1 year and

Table 5.
Hernia Recurrence Risk Factors

	Cox PH			Logistic (1 yr)			Logistic (2 yr)		
	N = 68,560			N = 44,848			N = 28,730		
	HR	95% LCL	95% UCL	OR	95% LCL	95% UCL	OR	95% LCL	95% UCL
Abdominal wound[b]	1.584	1.282	1.956	2.108	1.604	2.770	2.020	1.578	2.584
Female[c]	1.122	1.037	1.214	1.138	1.014	1.278	1.108	1.009	1.218
Length of stay (Days)[b,c]	1.178	1.125	1.234	1.147	1.066	1.233	1.153	1.087	1.222
Age (years)	0.996	0.993	1.000	1.000	0.995	1.005	0.996	0.992	1.000
ER visit prior to index	1.081	0.874	1.336	1.036	0.765	1.404	1.250	0.977	1.600
Hernia repair approach[b]									
Converted vs. open	1.038	0.860	1.254	0.847	0.619	1.158	0.895	0.705	1.137
Laparoscopic vs. open	0.839	0.752	0.936	0.836	0.715	0.979	0.815	0.716	0.929
Converted vs. laparoscopic	1.238	1.143	1.340	1.012	0.866	1.183	1.098	0.985	1.224
Concomitant procedures									
Groin hernia repair[b]	0.611	0.461	0.810	0.488	0.312	0.764	0.513	0.360	0.732
Adhesiolysis	–	–	–	1.154	0.964	1.382	1.139	0.981	1.322
Component separation	–	–	–	0.737	0.574	0.945	–	–	–
Comorbidities									
Elixhauser score[b,d]	1.083	1.015	1.156	1.140	1.055	1.233	1.132	1.052	1.218
Peptic ulcer disease[b]	1.426	1.112	1.828	–	–	–	1.390	1.004	1.925
Smoking[c]	1.330	1.177	1.501	1.482	1.255	1.750	1.538	1.330	1.779
Fluid/electrolyte disorders[b]	1.278	1.126	1.286	1.487	1.252	1.766	1.426	1.227	1.657
Blood loss anemia	1.307	0.977	1.748	–	–	–	–	–	–
Solid tumor without metastasis[b]	1.193	1.071	1.329	1.180	1.014	1.373	1.259	1.109	1.429
Chronic pulmonary disease	1.141	1.029	1.264	1.066	0.920	1.234	1.066	0.941	1.209
Liver disease[c]	1.136	1.004	1.286	–	–	–	1.220	1.052	1.414
Depression	1.103	0.985	1.234	1.279	1.097	1.493	–	–	–
Diabetes	0.923	0.833	1.020	0.880	0.760	1.018	0.884	0.784	0.997
Congestive heart failure	0.797	0.662	0.959	–	–	–	0.844	0.68	1.047
Drug abuse	0.703	0.472	1.049	–	–	–	–	–	–
Steroids	1.251	0.763	2.052	1.596	0.849	3.000	1.448	0.817	2.575
MI	–	–	–	–	–	–	–	–	–
Obesity	1.042	0.933	1.164	0.947	0.807	1.111	1.151	1.007	1.314
Cerebrovascular disease	–	–	–	–	–	–	0.800	0.648	1.000
Hypertension	1.074	0.977	1.180	–	–	–	1.085	0.971	1.212
Peripheral vascular disease	1.089	0.943	1.258	0.968	0.787	1.190	1.093	0.918	1.301
Renal failure	1.023	0.864	1.212	1.120	0.892	1.407	1.027	0.837	1.26

Continued

Table 5.
Continued

	Cox PH			Logistic (1 yr)			Logistic (2 yr)		
	N = 68,560			N = 44,848			N = 28,730		
	HR	95% LCL	95% UCL	OR	95% LCL	95% UCL	OR	95% LCL	95% UCL
Region[b]									
Unknown vs. South	0.982	0.728	1.326	0.912	0.594	1.401	1.177	0.844	1.642
North Central vs. South	0.961	0.877	1.054	0.920	0.803	1.053	0.891	0.797	0.996
West vs. South	0.857	0.766	0.959	0.783	0.663	0.925	0.862	0.755	0.985
Northeast vs. South	0.782	0.690	0.887	0.808	0.678	0.963	0.801	0.689	0.930
Year of index surgery[b]									
2009 vs 2014	1.427	1.194	1.705	–	–	–	–	–	–
2010 vs 2014	1.364	1.144	1.627	–	–	–	–	–	–
2011 vs 2014	1.452	1.225	1.722	–	–	–	–	–	–
2012 vs 2014	1.261	1.059	1.503	–	–	–	–	–	–
2013 vs 2014	1.265	1.054	1.518	–	–	–	–	–	–

HR, hazard ratio; OR, odds ratio; MI, myocardial infarction; KM, Kaplan-Meier; UCL, upper confidence limit; LCL, lower confidence limit.
[b]Clinical variables a priori identified and always included in the models.
[c]Length of stay modeled as ordinal = 0; 1–4; 4+.
[d]Elixhauser score modeled as ordinal = 0–1, 2, 3–4, 5+.

recommended studying these hernia anatomies separately.[15] Given this potential for recurrence risk differences based upon hernia anatomy, this study focused on incisional hernias.

Hernia Recurrence Risk Factors

The CPH and LR model results were consistent with successful laparoscopic surgery being associated with a 15.9% reduction in recurrence risk compared with planned OPEN and CONV. Planned OPEN and CONV were not associated with statistically different hazards. Other identified risk factors for recurrence included increasing LOS, increasing Elixhauser score, abdominal wound, peptic ulcer disease, solid tumor without metastases, chronic pulmonary disease, smoking, and electrolyte disorders. These all point to increasing patient or procedural complexity. The 1- and 2-year LR models were generally consistent with the CPH analysis. Depression was an additional risk factor not identified in the CPH model. An interesting finding is that congestive heart failure, diabetes, drug abuse, and concomitant groin hernia repair were associated with decreased recurrence. Potential reasons for these associations may be that patients with these characteristics are deemed as poor surgical candidates if a recurrent hernia was diagnosed and treated nonsurgically.

Risk factors observed in this study have been identified in prior database or registry studies. An analysis of any incisional or ventral hernia repairs in the American College of Surgeons National Surgical Quality Improvement Program identified risk factors for recurrence within 1 year (age, postoperative superficial surgical site infection, steroid use, smoking, increasing American Society of Anesthesiology score, and BMI).[14] Similar to our study, increasing age was associated with decreasing risk for recurrence and being a smoker increased recurrence risk. In comparison, a Danish study identified defect size, prior hernia repair, and nontacking fixation (for laparoscopic surgery) as risk factors for hernia repair reoperation.[19] Similar to our study, 2 studies found that increasing age was associated with decreased risk of hernia rerepair,[18,19] and open repair or a hernia size of 7 cm had increased risk of recurrent hernias treated with surgery.[18] Surgical approach is likely prone to confounding by indication where higher-risk patients more often undergo open surgical repair compared with the laparoscopic approach. Future mesh surveillance likely should be performed stratified by surgical approach similar to other authors' recommendations to evaluate recurrence stratified by hernia anatomy.[15,16]

Strengths

The strengths of this analysis are the large number of incisional hernia mesh procedures allowed for the estimation of 6-year recurrence rates with relatively good precision (95% CI of ±0.6% for OPEN and ±1.3% for successful LAP). This large sample size and follow-up allowed for individual evaluation of successful LAP, planned OPEN, and laparoscopic CONV. Additionally, this analysis included both KM and simple proportion for calculating yearly recurrence rates to help provide context for past and future recurrence evaluations. Risk factors were evaluated with both CPH models and LR models for years 1 and 2 post INDEX surgery. These models were relatively consistent in the risk factors identified. Finally, potential recurrence endpoint misclassification was assessed with 3 different sensitivity analyses: mesh removal, subsequent abdominal wall hernias of unknown anatomy, and umbilical and epigastric hernias where these procedures were evaluated as recurrence events rather than censoring events.

Limitations

The current limitations in performing surgical outcomes research in an insurance claims database can be classified into 3 categories: exposure identification, confounding adjustment, and recurrence outcome measurement. The most obvious limitation is that identification of specific mesh brands was not available. The study focused on incisional hernias by excluding specific nonincisional ventral hernias codes (i.e., unspecified anatomy, Spigelian, parastomal, umbilical, or epigastric). There may be misclassification error (bilical anatomies), thereby affecting the internal validity of this study. Several clinical risk factors that have been described in clinical studies were not available in the claims database, such as hernia width. The European Hernia Society has standardized the classification of width and the hernia size location.[20] Additional procedural parameters not captured include hernia defect closure, the fixation method, or mesh placement location. Other covariates are known to be undercoded (e.g., obesity) or have unknown positive predictive value or sensitivity. These clinical variables may represent unmeasured confounding, which could manifest as channeling bias, where less-complex patients and hernias are shunted to laparoscopic repairs. While a 1-year continuous enrollment washout period was enforced, where patients with prior abdominal wall hernias were excluded, these patients may have had hernia repairs before this 1-year period. The recurrence endpoint is defined as a subsequent coded incisional or ventral hernia repair, which may represent a different hernia than the one repaired at initial repair. This also does not capture recurrent hernias that are diagnosed but not operatively repaired; thus, our study underestimates the true recurrence rate, which has been previously studied.[21] This may have contributed to the decreased risk for reoperation for well-known clinical risk factors for hernia recurrence such as congestive heart failure because the patients may be poor candidates for a second hernia repair.

The cohort studied in this assessment represents only patients with employee-sponsored commercial or Medicare supplemental insurance; thus, the results here are only reflective of those patients who receive this type of health insurance. The relatively low AUC scores across all models demonstrate the gap between identifying relevant clinical risk factors versus model predictive performance.

Discussion on Postmarket Surveillance and Unique Device Identifiers

Hernia mesh postmarket surveillance is challenging due to multiple factors. These factors include a relatively low early recurrence rate that increases gradually over time, a wide variety of patient and procedural risk factors, and large variation in the technique and utilization of other devices that may contribute to overall procedural performance (e.g., tacker or mesh fixation technique). Registries play a critical role in mesh surveillance, as realized by the recent Herniamed Registry analysis, which estimated 1-year recurrence rates for Physiomesh (Ethicon, Inc) after laparoscopic incisional hernia repair.[17] These registries may still lack the requisite size and variety to adjust for confounding, especially when evaluating long-term outcomes. Additionally, registries can require significant cost to create, enroll, and follow patients. One potential supplement to registries is the use of real-world data such as insurance claims for postmarket surveillance. Pharmacoepidemiology has used National Drug Codes to develop a large body of scientific methods for specific drug surveillance. The major limitation for medical devices to similarly harness real-world data for surveillance is the lack of unique device identifiers. The US Food and Drug Administration has mandated that manufacturers create UDIs, but the uptake and timing for incorporation of unique device identifiers into insurance billing are uncertain. Additional areas of methodological development include appropriate adjustment for confounding. This includes improved capture of surgeon volume/training, clinical parameters important to surgery (disease pathology and anatomic complexity), device channeling, and postoperative care. The last factor required for postmarket surveillance is reliably captured.

Conclusion

The potential for using insurance claims databases for hernia mesh surveillance is emerging and methodological development is required to address potential confounding and bias. Multiple patient and procedural risk factors for hernia recurrence were identified and will require adequate adjustment in future research. Surgical approach was identified to be an important factor to consider for surveillance of hernia mesh devices. These results help contextualize the real-world utilization of devices and surgical technique along with the patients receiving these interventions. This analysis provides a basis for understanding how mesh device surveillance may be supplemented by insurance claims databases once unique device identifiers are implemented.

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Appendix 1

Table A1.
Primary Hernia Procedure Codes, Surgical Approach, and Mesh Flags

Data Type	Code	Definition	Anatomy	Approach	Mesh
CPT4	49560	Repair initial incisional or ventral hernia; reducible	Incisional OR ventral	Open	UNK
CPT4	49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	Incisional OR ventral	Open	Unknown
CPT4	49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible	Incisional	Laparoscopic	Unknown
CPT4	49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	Incisional	Laparoscopic	Mesh
ICD9	53.61	Other open incisional hernia repair with graft or prosthesis	Incisional	Open	Mesh
ICD9	53.62	Laparoscopic incisional hernia repair with graft or prosthesis	Incisional	Laparoscopic	Mesh
ICD9	53.63	Other laparoscopic repair of other hernia of anterior abdominal wall with graft or prosthesis	Ventral	Laparoscopic	Mesh
ICD9	53.69	Other and open repair of other hernia of anterior abdominal wall with graft or prosthesis	Ventral	Open	Mesh
CPT4	49568	Implantation of mesh or other prosthesis for incisional or ventral hernia repair (List separately in addition to code for the incisional or ventral hernia repair)	Must be used in conjunction with above hernia repair code	N/A	Mesh

Table A2.
Conversion Procedure Definition

Data Type	Code	Definition
ICD9	V64.41*	Laparoscopic surgical procedure converted to open procedure

*Conversion was identified via either the V64.41 ICD-9 code or if both an 'Open' and 'Laparoscopic' procedure codes (Table 1) occurred at INDEX.

Table A3.
Censoring Codes

Data Type	Code	Definition	Censoring Type
ICD9	46.42	Repair of pericolostomy hernia	Parastomal Hernia Repair
CPT4	49590	Repair Spigelian hernia	Spigelian Hernia Repair
CPT4	11008	Removal of prosthetic material or mesh, abdominal wall for necrotizing soft tissue infection (List separately in addition to code for primary procedure) [mesh infection]	Mesh infection
ICD9	54.61	Reclose Disruption	Unknown hernia repair
ICD9	54.62	Closure of the Abdominal Wound	Unknown hernia repair
ICD9	54.72	Abdominal Wall Repair	Unknown hernia repair
ICD9	83.65	Other Fascial Closure	Unknown hernia repair
ICD9	53.9	Other hernia repair	Unknown hernia repair
CPT4	49652	Laparoscopy, surgical, repair, ventral, umbilical, Spigelian or epigastric hernia (includes mesh insertion, when performed); reducible	Unknown hernia repair
CPT4	49653	Laparoscopy, surgical, repair, ventral, umbilical, Spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated	Unknown hernia repair
CPT4	49570	Repair epigastric hernia (e.g., preperitoneal fat); reducible (separate procedure)	Epigastric hernia
CPT4	49572	Repair epigastric hernia (e.g., preperitoneal fat); incarcerated or strangulated	Epigastric hernia
CPT4	49585	Repair umbilical hernia, age 5 years or over; reducible	Umbilical hernia
CPT4	49587	Repair umbilical hernia, age 5 years or over; incarcerated or strangulated	Umbilical hernia
ICD9	53.41	Other and open repair of umbilical hernia with graft or prosthesis	Umbilical hernia
ICD9	53.42	Laparoscopic repair of umbilical hernia with graft or prosthesis	Umbilical hernia
ICD9	53.43	Other laparoscopic umbilical herniorrhaphy	Umbilical hernia
ICD9	53.49	Other open umbilical herniorrhaphy	Umbilical hernia

Table A4.
Hernia Recurrence Codes

Data Type	Code	Definition	Anatomy
CPT4	49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	Incisional OR ventral
CPT4	49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible	Incisional
CPT4	49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	Incisional
CPT4	49560	Repair initial incisional or ventral hernia; reducible	Incisional OR ventral
ICD9	53.51	Incisional hernia repair	Incisional
ICD9	53.59	Repair of other hernia of anterior abdominal wall	Ventral
ICD9	53.61	Other open incisional hernia repair with graft or prosthesis	Incisional
ICD9	53.62	Laparoscopic incisional hernia repair with graft or prosthesis	Incisional
ICD9	53.63	Other laparoscopic repair of other hernia of anterior abdominal wall with graft or prosthesis	Ventral
ICD9	53.69	Other and open repair of other hernia of anterior abdominal wall with graft or prosthesis	Ventral
CPT4	49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated	Incisional OR ventral
CPT4	49656	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible	Incisional
CPT4	49657	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	Incisional
CPT4	49565	Repair recurrent incisional or ventral hernia; reducible	Incisional OR ventral

Table A5.
Concomitant Procedure Codes

Data Type	Code	Definition	Concomitant Procedure
CPT4	15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk [component separation]	Component Separation
ICD9	86.70	Pedicle or flap graft, not otherwise specified [component separation]	Component Separation
ICD9	86.72	Advancement of pedicle graft [component separation]	Component Separation
ICD9	86.74	Attachment of pedicle or flap graft to other sites [component separation]	Component Separation
ICD9	45.61	Multiple segmental resection of small intestine [bowel resection]	Bowel resection/repair
ICD9	45.62	Other partial resection of small intestine [bowel resection]	Bowel resection/repair
ICD9	45.74	Open and other resection of transverse colon [bowel resection]	Bowel resection/repair
ICD9	46.02	Resection of exteriorized segment of small intestine [bowel resection]	Bowel resection/repair
ICD9	46.04	Resection of exteriorized segment of large intestine [bowel resection]	Bowel resection/repair
CPT4	44020	Enterotomy, small intestine, other than duodenum; for exploration, biopsy(s), or foreign body removal	Enterotomy
CPT4	44021	Enterotomy, small intestine, other than duodenum; for decompression (e.g., Baker tube)	Enterotomy
CPT4	44110	Excision of one or more lesions of small or large intestine not requiring anastomosis, exteriorization, or fistulization; single enterotomy	Enterotomy
CPT4	44615	Intestinal stricturoplasty (enterotomy and enterorrhaphy) with or without dilation, for intestinal obstruction	Enterotomy
ICD-9	54.51	Laparoscopic lysis of peritoneal adhesions	Adhesiolysis
ICD-9	54.59	Other lysis of peritoneal adhesions	Adhesiolysis
CPT4	44005	Enterolysis (freeing of intestinal adhesion) (separate procedure)	Adhesiolysis
CPT4	44200	Laparoscopy, surgical; enterolysis (freeing of intestinal adhesion) (separate procedure)	Adhesiolysis
CPT4	49505	Repair initial inguinal hernia, age 5 years or over; reducible	Inguinal hernia repair
CPT4	49507	Repair initial inguinal hernia, age 5 years or over; incarcerated or strangulated	Inguinal hernia repair
CPT4	49520	Repair recurrent inguinal hernia, any age; reducible	Inguinal hernia repair
CPT4	49521	Repair recurrent inguinal hernia, any age; incarcerated or strangulated	Inguinal hernia repair
CPT4	49525	Repair inguinal hernia, sliding, any age	Inguinal hernia repair
CPT4	49550	Repair initial femoral hernia, any age; reducible	Inguinal hernia repair
CPT4	49650	Laparoscopy, surgical; repair initial inguinal hernia	Inguinal hernia repair
CPT4	49651	Laparoscopy, surgical; repair recurrent inguinal hernia	Inguinal hernia repair
ICD9	17.11	Laparoscopic repair of direct inguinal hernia with graft or prosthesis	Inguinal hernia repair
ICD9	17.12	Laparoscopic repair of indirect inguinal hernia with graft or prosthesis	Inguinal hernia repair
ICD9	17.13	Laparoscopic repair of inguinal hernia with graft or prosthesis, not otherwise specified	Inguinal hernia repair
ICD9	17.21	Laparoscopic bilateral repair of direct inguinal hernia with graft or prosthesis	Inguinal hernia repair
ICD9	17.22	Laparoscopic bilateral repair of indirect inguinal hernia with graft or prosthesis	Inguinal hernia repair
ICD9	17.23	Laparoscopic bilateral repair of inguinal hernia, one direct and one indirect, with graft or prosthesis	Inguinal hernia repair
ICD9	17.24	Laparoscopic bilateral repair of inguinal hernia with graft or prosthesis, not otherwise specified	Inguinal hernia repair

Continued

Table A5.
Continued

Data Type	Code	Definition	Concomitant Procedure
ICD9	53.00	Unilateral repair of inguinal hernia, not otherwise specified	Inguinal hernia repair
ICD9	53.01	Other and open repair of direct inguinal hernia	Inguinal hernia repair
ICD9	53.02	Other and open repair of indirect inguinal hernia	Inguinal hernia repair
ICD9	53.03	Other and open repair of direct inguinal hernia with graft or prosthesis	Inguinal hernia repair
ICD9	53.04	Other and open repair of indirect inguinal hernia with graft or prosthesis	Inguinal hernia repair
ICD9	53.05	Repair of inguinal hernia with graft or prosthesis, not otherwise specified	Inguinal hernia repair
ICD9	53.10	Bilateral repair of inguinal hernia, not otherwise specified	Inguinal hernia repair
ICD9	53.11	Other and open bilateral repair of direct inguinal hernia	Inguinal hernia repair
ICD9	53.12	Other and open bilateral repair of indirect inguinal hernia	Inguinal hernia repair
ICD9	53.13	Other and open bilateral repair of inguinal hernia, one direct and one indirect	Inguinal hernia repair
ICD9	53.14	Other and open bilateral repair of direct inguinal hernia with graft or prosthesis	Inguinal hernia repair
ICD9	53.15	Other and open bilateral repair of indirect inguinal hernia with graft or prosthesis	Inguinal hernia repair
ICD9	53.16	Other and open bilateral repair of inguinal hernia, one direct and one indirect, with graft or prosthesis	Inguinal hernia repair
ICD9	53.17	Bilateral inguinal hernia repair with graft or prosthesis, not otherwise specified	Inguinal hernia repair
ICD9	53.21	Unilateral repair of femoral hernia with graft or prosthesis	Femoral hernia repair
ICD9	53.29	Other unilateral femoral herniorrhaphy	Femoral hernia repair
ICD9	53.31	Bilateral repair of femoral hernia with graft or prosthesis	Femoral hernia repair
ICD9	53.39	Other bilateral femoral herniorrhaphy	Femoral hernia repair
CPT4	49553	Repair initial femoral hernia, any age; incarcerated or strangulated	Femoral hernia repair
CPT4	49555	Repair recurrent femoral hernia; reducible	Femoral hernia repair
CPT4	49557	Repair recurrent femoral hernia; incarcerated or strangulated	Femoral hernia repair
CPT4	49540	Repair lumbar hernia	Lumbar hernia repair

Appendix 2

Table A6.
Sensitivity Analysis of Recurrence Endpoint (all patients)

	Primary Endpoint			Mesh Removal			Unknown Anatomy			UMBI/EPI Anatomy		
Time (Months)	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL
3	0.4%	0.3%	0.4%	0.5%	0.4%	0.6%	0.4%	0.4%	0.5%	0.4%	0.3%	0.4%
6	1.1%	1.0%	1.2%	1.4%	1.3%	1.5%	1.3%	1.2%	1.4%	1.2%	1.1%	1.3%
12	3.1%	2.9%	3.2%	3.6%	3.4%	3.7%	3.4%	3.3%	3.6%	3.2%	3.1%	3.4%
24	5.8%	5.6%	6.0%	6.5%	6.3%	6.8%	6.4%	6.2%	6.6%	6.1%	5.9%	6.3%
36	7.8%	7.5%	8.1%	8.6%	8.3%	8.9%	8.6%	8.3%	8.9%	8.2%	7.9%	8.5%
48	9.4%	9.0%	9.7%	10.2%	9.9%	10.6%	10.4%	10.0%	10.8%	9.9%	9.5%	10.2%
60	10.6%	10.1%	11.0%	11.5%	11.1%	12.0%	11.8%	11.3%	12.2%	11.2%	10.7%	11.6%
72	11.4%	10.8%	11.9%	12.3%	11.8%	12.9%	12.7%	12.1%	13.3%	12.0%	11.4%	12.6%

OPEN, planned open; LAP, successful laparoscopic; CONV, laparoscopic conversion to open; KM, Kaplan-Meier; UCL, upper confidence limit; LCL, lower confidence limit.

Table A7.
Sensitivity Analyses of Recurrence Endpoint by Approach

	OPEN			Mesh Removal			Unknown Anatomy			UMBI/EPI Anatomy		
Time (Months)	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL
3	0.3%	0.3%	0.4%	0.5%	0.5%	0.6%	0.4%	0.4%	0.5%	0.4%	0.3%	0.4%
6	1.1%	1.0%	1.2%	1.5%	1.4%	1.6%	1.3%	1.2%	1.4%	1.2%	1.1%	1.3%
12	3.1%	3.0%	3.3%	3.7%	3.5%	3.9%	3.5%	3.3%	3.7%	3.3%	3.1%	3.5%
24	5.9%	5.7%	6.2%	6.7%	6.5%	7.0%	6.5%	6.3%	6.8%	6.2%	6.0%	6.5%
36	7.9%	7.6%	8.3%	8.8%	8.5%	9.1%	8.8%	8.5%	9.1%	8.3%	8.0%	8.7%
48	9.5%	9.1%	9.9%	10.4%	10.0%	10.8%	10.5%	10.1%	11.0%	10.0%	9.6%	10.4%
60	10.7%	10.2%	11.2%	11.8%	11.2%	12.3%	12.0%	11.5%	12.5%	11.3%	10.8%	11.9%
72	11.6%	11.0%	12.2%	12.6%	12.0%	13.2%	13.0%	12.4%	13.7%	12.3%	11.6%	12.9%
	Laparoscopic			**Mesh Removal**			**Unknown Anatomy**			**UMBI/EPI Anatomy**		
Time (Months)	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL
3	0.4%	0.3%	0.5%	0.4%	0.3%	0.5%	0.4%	0.3%	0.5%	0.4%	0.3%	0.5%
6	1.1%	0.9%	1.3%	1.2%	1.0%	1.4%	1.1%	0.9%	1.3%	1.1%	0.9%	1.3%
12	2.7%	2.3%	3.0%	2.9%	2.5%	3.2%	3.0%	2.6%	3.3%	2.7%	2.4%	3.1%
24	5.1%	4.5%	5.6%	5.4%	4.9%	5.9%	5.6%	5.1%	6.2%	5.3%	4.8%	5.8%
36	6.8%	6.2%	7.5%	7.3%	6.6%	8.0%	7.5%	6.8%	8.2%	7.2%	6.5%	7.8%
48	8.2%	7.3%	9.1%	8.7%	7.8%	9.6%	8.9%	8.0%	9.8%	8.6%	7.7%	9.4%
60	8.9%	7.8%	9.9%	9.4%	8.3%	10.5%	9.6%	8.5%	10.7%	9.3%	8.2%	10.4%
72	9.4%	8.1%	10.6%	9.9%	8.6%	11.2%	10.6%	9.1%	12.0%	9.8%	8.5%	11.1%
	Conversion			**Mesh Removal**			**Unknown Anatomy**			**UMBI/EPI Anatomy**		
Time (Months)	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL	KM Estimate	95% LCL	95% UCL
3	0.4%	0.1%	0.7%	0.5%	0.2%	0.8%	0.5%	0.2%	0.8%	0.4%	0.1%	0.7%
6	1.2%	0.7%	1.6%	1.5%	1.0%	2.1%	1.4%	0.9%	1.9%	1.2%	0.7%	1.6%
12	3.1%	2.3%	3.9%	3.7%	2.9%	4.6%	3.8%	2.9%	4.7%	3.3%	2.5%	4.1%
24	6.3%	5.1%	7.6%	7.0%	5.7%	8.3%	7.2%	5.8%	8.5%	6.8%	5.5%	8.1%
36	9.3%	7.6%	11.0%	10.4%	8.6%	12.1%	10.3%	8.5%	12.0%	9.8%	8.1%	11.5%
48	11.8%	9.7%	13.9%	12.8%	10.7%	14.9%	12.9%	10.7%	15.0%	12.4%	10.3%	14.5%
60	13.7%	11.2%	16.1%	14.7%	12.1%	17.1%	14.7%	12.2%	17.2%	14.3%	11.8%	16.7%
72	13.7%	11.2%	16.1%	15.0%	12.4%	17.6%	14.7%	12.2%	17.2%	14.3%	11.8%	16.7%