Extending the value of the National Surgical Quality Improvement Program claims dataset to study long-term outcomes: Rate of repeat ventral hernia repair

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Background. *Existing large clinical registries capture short-term follow-up. Yet, there are many important long-term outcomes in surgery, such as recurrence of a ventral hernia after ventral hernia repair. The goal of the current study was to conduct an exploratory analysis to determine whether the rates, timing, and risk factors for ventral hernia re-repair in claims data linked to registry data were consistent with the known clinical literature.*

Study Design. *The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) and Medicare inpatient claims linked data set from 2005 to 2008 was queried to identify ventral hernia re-repairs after index ventral hernia repairs. Survival analysis was used to examine the ventral hernia re-repair rate over time and to quantify the relationship with clinical variables.*

Results. *Of 3,730 index ventral hernia repairs identified in ACS-NSQIP, 247 patients (6.6%) underwent re-repair of a ventral hernia during the study period (2005–2008) in the Medicare claims data. ACS-NSQIP clinical variables that were associated with the ventral hernia re-repair rate in Medicare claims data 1 year after index ventral hernia repair were being a smoker (hazard ratio [HR] = 1.70,* P = *.02), body mass index (HR = 1.16,* P = *.04), and postoperative superficial surgical-site infection (HR = 2.88,* P < *.001).*

Conclusion. *Long-term rate and timing of ventral hernia re-repair obtained from claims data were an underestimate compared with clinical studies. Yet, several known clinical risk factors for recurrence in the clinical registry were associated with the re-repair rate in claims data at one year. It may be possible to study certain long-term outcomes using selected reoperation rates using the technique of linked clinical registry-claims data, with an understanding that event rates are conservative estimates. (Surgery 2015;157:1157-65.)*

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One of the major limitations of large clinical registries such as the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) is that they do not contain long-term follow up data. Many important long-term outcomes in surgery influence patient quality of life and may signal substandard initial operative care. An example of such a long-term outcome is the recurrence ventral hernia after operative repair. Clinical studies have shown that more than a quarter of ventral hernias recur after

repair.[1-9] Recurrent ventral hernias may become apparent up to 10 years after surgery.[10-12] Some authors have recommended that to obtain adequate estimates of recurrence rate, patients should be followed for 2–3 years,[13,14] but current large clinical surgical registries do not collect such long-term data.

Administrative data, like the Medicare inpatient claims data file, capture long-term events associated with clinical encounters, such as reoperations.[15] Linking administrative data with a clinical registry may be a means of extending the value of ACS-NSQIP to study long-term outcomes. Multiple preoperative clinical variables and postoperative complications are associated with ventral hernia recurrence in clinical studies, such as obesity, smoking,[7,16,17] and wound infection.[13,18-20] The relevance of events in claims data (such as ventral hernia re-repair) would be supported by the presence of associations with known risk factors in the clinical registry for ventral hernia recurrence.

The goal of the current study was to determine whether the rates, timing, and risk factors for long-term re-repair of ventral hernia in a linked registry-claims dataset were consistent with the known clinical literature. Specifically, the study aims were 2-fold, ie, first, to determine whether the rates and timing of re-repair of ventral hernia as captured in claims data were consistent with the clinical literature, and, second, whether known clinical risk factors for recurrence of ventral hernia in ACS-NSQIP were associated with re-repair of ventral hernia beyond 30 days by use of the Medicare inpatient claims data.

METHODS

Data source and measures. Two data sources were used in this study: the ACS-NSQIP and Medicare Provider Analysis and Review data file. ACS-NSQIP is a surgical registry containing clinical data, including preoperative comorbidities and 30-day postoperative outcomes collected by dedicated abstractors at participating hospitals.[21,22] The Medicare Provider Analysis and Review file is the Medicare inpatient administrative claims data file comprising demographic information, as well as diagnoses and procedures for inpatient encounters billed to Medicare. A strength of the Medicare claims data is its long-term capture of all procedural codes and associated dates at any hospital in the United States where the beneficiary sought inpatient care. This approach allows for the identification of whether re-repair of a ventral hernia occurred and when it occurred. The linkage of ACS-NSQIP and Medicare inpatient claims data from 2005 to 2008 was performed by the use of indirect patient identifiers and a deterministic linkage algorithm, as described previously.[23] The ACS-NSQIP contributed detailed perioperative clinical data, whereas Medicare inpatient claims data contributed long-term follow-up.

To use Medicare claims data for study of long-term outcome, 3 issues had to be addressed. First, a reliable long-term outcome had to be identified. Diagnoses of postoperative complications are captured poorly in administrative data.[24,25] In contrast, reoperations for complications seem to be more captured reliably.[15] Second, because of the different durations of patient follow-up, time to censoring had to be calculated and taken into account. This approach is done traditionally with survival analysis. Third, because of the fact that the relative importance of risk factors may vary by time period, an analysis technique that allowed for different associations between risk factors and the long-term outcome at early, medium, and late postoperative time periods was needed. Survival analysis of long-term ventral hernia re-repair rates with time-varying covariates was performed to address all these methodologic challenges.

The inclusion criteria for the study were patients 65 years and older who underwent an index ventral hernia repair as the ACS-NSQIP primary procedure between the years 2005 through 2008. Ventral hernia repairs were identified with the following Current Procedural Terminology (CPT) codes: 49560 (repair of reducible ventral hernia), 49561 (repair of non-reducible ventral hernia), 49565 (re-repair of reducible ventral hernia), and 49566 (re-repair of non-reducible ventral hernia). These CPT codes were then used to create indicator variables describing the type of hernia being repaired: nonreducible (CPT codes 49561 or 49566) or recurrent hernia (CPT codes 49565 or 49566). An interaction term was created for hernias that were both nonreducible and recurrent. In addition, the placement of mesh was created as a dichotomous variable based on the presence of the CPT code 49568 in any of ACS-NSQIP's 10 "concurrent procedure" or 10 "other procedure" data fields as previously done in the literature.[26]

Demographic and clinical characteristics were identified from ACS-NSQIP and included preoperative comorbidities, acuity of illness variables, procedure-specific variables, as well as 30-day postoperative complications and mortality. A dichotomous variable for the occurrence of any 30-day postoperative complication was created and included the following complications: surgical-site infection (superficial, deep, or organ-space),

wound disruption, sepsis, pneumonia, reintubation, prolonged ventilation, the occurrence of any intraoperative or postoperative transfusion, cardiac arrest requiring cardiopulmonary resuscitation, myocardial infarction, deep vein thrombosis, pulmonary embolism, coma, stroke, peripheral nerve injury, acute or progressive postoperative renal failure, and urinary tract infection.

The primary outcome of interest was time to ventral hernia *re-repair*, defined by the presence of an *International Classification of Diseases*, 9th edition procedure code for ventral hernia repair in any of the 6 Medicare inpatient claims *International Classification of Diseases*, 9th edition procedure data fields (Appendix 1, online version only). Ventral hernia re-repairs were counted only if they occurred at least 2 days after the index ventral hernia repair, to prevent erroneously counting the index operation in the claims data as a re-repair, because the matching algorithm allowed for up to 1 day of difference in procedure date between ACS-NSQIP and Medicare claims data. For patients who experienced a re-repair, the time to re-repair was calculated as the difference between the ACS-NSQIP index surgery date and the Medicare ventral hernia re-repair date. Patients who did not have a re-repair of a ventral hernia during the study window or who died before undergoing a re-repair were treated as censored. For these patients, the time variable was calculated by taking the difference between the last date of possible capture of a postoperative procedure event in the Medicare inpatient claims data (ie, the date of death or December 31, 2008), and the ACS-NSQIP surgery date. The resulting time variable represented the number of days patients were "followed" after their index ventral hernia repair.

Statistical analysis. A Kaplan-Meier plot was used to examine the ventral hernia re-repair rate over time. The number of person years was calculated for the medium- and late long-term time periods of interest in this study; before and after 1 year, to verify that a sufficient number of patients were available for long enough to generate reliable re-repair rates and timing estimates. Person years were calculated by multiplying the number of individuals still at risk (those who had not yet had a ventral hernia re-repair *and* not yet been censored) for ventral hernia re-repair by the number of years elapsed since index ventral hernia repair. Three separate time periods were defined based on existing follow-up practices: (1) 30 days from index ventral hernia repair; (2) 30 days to 1 year after index repair; and (3) 1 year to 4 years (the greatest time period of follow-up in the dataset) after the index repair.

The frequency of demographic and clinical characteristics, comorbidities, and 30-day postoperative complications in patients who underwent index ventral hernia repair was calculated. Univariate, mixed effects, Cox proportional hazards regression models were applied to ACS-NSQIP clinical variables from the index repair to identify individual predictors of the re-repair rate. Variables that demonstrated significant individual associations with ventral hernia re-repair ($P < .05$) were included in a mixed-effects, multivariate Cox regression to examine joint effects on the re-repair rate. Clinically important variables identified in the clinical literature, such as preoperative acute renal failure or recent chemotherapy use, which did not reach statistical significance in this analysis as defined by $P < .05$, were included in the multivariate model.

The covariates were treated as time-varying to detect the relative importance during different postoperative periods. Random intercepts were used to account for within-hospital clustering. The relationships between the re-repair and each of independent variable were hypothesized to be grossly linear on the hazard scale. Therefore, all continuous (eg, age) and ordinal variables (eg, American Society of Anesthesiologists class, body mass index [BMI] category) were treated as continuous, time-varying covariates to maximize granularity of information in the Cox proportional hazards model. BMI category was an ordinal, categorical variable treated as continuous to quantify the associated change in hazard from one clinical BMI category to another clinical BMI category rather than by incremental change in BMI.

A sensitivity analysis was performed that excluded all patients whose index operation was a repair of a recurrent ventral hernia ($n = 923$). This sensitivity analysis was performed to determine whether these patients were different fundamentally from patients undergoing primary ventral hernia repair. The RAND Corporation Institutional Review Board approved this study. All data management and analyses were done in SAS 9.3 (SAS Institute, Cary, NC).

RESULTS

The study sample included 3,730 patients who underwent an index ventral hernia repair from 212 hospitals. A total of 247 of these patients (6.6%) underwent ventral hernia re-repair within 1–4 years follow-up. Preoperative patient characteristics were as follows: 24.8% were undergoing index surgery for a recurrent hernia, 10.1% were

Table I. Demographic and clinical characteristics of patients who underwent repair of a ventral hernia

Preoperative clinical variables	N = *3,730 (%)*
Procedure-specific variables	
Mesh	1,537 (58.8)
Nonreducible hernia	1,069 (28.7)
Nonreducible & recurrent hernia	259 (6.9)
Recurrent hernia	923 (24.8)
Emergency procedure	445 (11.9)
Wound class	
Clean	2,985 (80.0)
Clean/contaminated	544 (14.6)
Contaminated	109 (2.9)
Dirty/infected	92 (2.5)
Demographic variables	
Male	1,409 (37.8)
Age, y	
65–<75	2,139 (57.4)
75–<85	1,304 (35.0)
≥85	287 (7.7)
Metabolic and immunologic conditions	
Diabetes	
No diabetes	2,959 (79.3)
Diabetes requiring medication	522 (14.0)
Diabetes requiring insulin	249 (6.7)
Body mass index	
<18.5	106 (2.8)
18.5–<25	613 (16.4)
25–<30	1,215 (32.6)
30–<35	923 (24.8)
35–<40	484 (13.0)
≥40	389 (10.4)
Steroid use	123 (3.3)
Alcohol use	67 (1.8)
10% weight loss in last 6 months	48 (1.3)
Cardiovascular conditions	
Hypertension	2,738 (73.4)
Congestive heart failure	41 (1.1)
Renal conditions	
Dialysis	20 (0.5)
Acute renal failure	16 (0.4)
Hematologic and oncologic conditions	
Bleeding disorder	291 (7.8)
Radiotherapy	8 (0.2)
Chemotherapy	30 (0.8)
Cancer	60 (1.6)
Hepatic conditions	
Ascites	43 (1.2)
Varices	6 (0.2)
Pulmonary conditions	
Smoker	375 (10.1)
Chronic obstructive pulmonary disease	378 (10.1)
Ventilator dependence	15 (0.4)
Acuity of illness	
ASA class	
ASA class I	27 (0.7)
ASA class II	1,223 (32.8)
ASA class III	2,214 (59.4)
ASA class IV	261 (7.0)
ASA class V	5 (0.1)
Preoperative transfusion	1 (0.0)
Open wound	120 (3.2)
Previous surgery within 30 days	65 (1.7)
Preoperative sepsis	
No sepsis	3,514 (94.2)
SIRS	177 (4.8)
Sepsis	24 (0.6)
Septic shock	15 (0.4)

Clinical variable identified from NSQIP. Occurrence of re-repair identified from Medicare, as described in the text.
ASA, American Society of Anesthesiologists; *NSQIP*, National Surgical Quality Improvement Program; *SIRS*, systemic inflammatory response syndrome.

smokers, and 3.2% had an open wound preoperatively (Table I). A total of 15.8% of patients had at least one 30-day postoperative complication (Table II). Specific postoperative complication rates were as follows: any type of surgical-site infection, 7.2%; return to the operating room, 3.8%; and wound disruption, 1.1%.

The minimum follow-up time was 30 days, and the maximum was 4 years. The Kaplan Meier curve leveled off at 550 days postoperatively (Fig), suggesting that the ventral hernia re-repair rate began to decrease at 1.5 years after the initial hernia repair. The study person distribution was such that 39% of person years were before 1 year, and 61% were after 1 year. Of the 247 patients who had a ventral hernia re-repair, 35 (14%) had a re-repair within 30 days. By the end of the first year postoperatively, 179 patients (72%) had re-repairs. By 2 years, 234 of the 247 patients (95%) had re-repairs.

Table III shows the results of the mixed effects, multivariate Cox regression with time-varying covariates. At 30 days, the clinical predictors of the ventral hernia re-repair rate were being a smoker (hazard ratio [HR] = 2.57, $P = .02$), presence of a nonreducible hernia (HR = 2.86, $P = .01$), presence of preoperative open wound (HR = 15.00, $P < .001$), and a postoperative surgical-site infection (HR = 33.62, $P < .001$). From 30 days to 1 year, the clinical predictors of the re-repair rate

Table II. Unadjusted 30-day postoperative complications

30-day postoperative adverse events	N = *3,730 (%)*
Any 30-day postoperative complication	589 (15.8)
Any surgical-site infection	268 (7.2)
Superficial surgical-site infection	180 (4.8)
Deep surgical-site infection	60 (1.6)
Organ space surgical-site infection	40 (1.1)
Return to the operating room	143 (3.8)
Mortality	51 (1.4)
Wound disruption/dehiscence	39 (1.1)

Clinical 30-day adverse events identified from NSQIP.
NSQIP, National Surgical Quality Improvement Program.

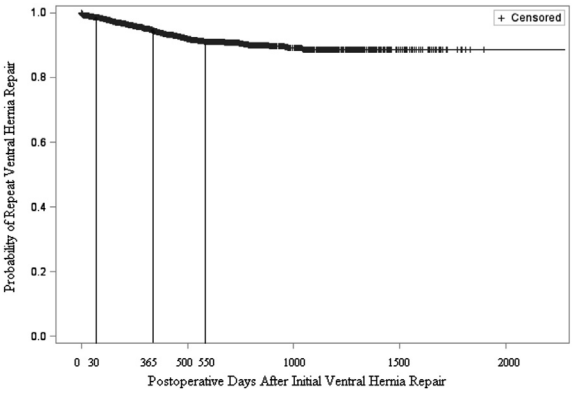

Fig. Kaplan-Meier curve displaying the probability of repeat repair of ventral hernia over time. +Censored observations included patients who died or who had not undergone repair of the ventral hernia by the end of the study period (2005–2008).

were postoperative superficial surgical-site infection (HR = 2.88, $P < .001$), being a smoker (HR = 1.70, $P = .02$), and BMI category (HR = 1.16, $P = .04$). In addition, for each 1-year increase in age, there was 3% decrease in re-repair hazard rate, HR = 0.97, $P = .03$; perhaps reflecting a selection pattern or censoring bias. There were no significant predictors of re-repair after 1 year.

Finally, a sensitivity analysis excluding all hernias labeled as recurrent at the index procedure from the multivariate Cox model was performed. The findings were unchanged with 2 exceptions. First, steroid use was associated with a 2.28 increase in re-repair hazard rate from 30 days to 1 year ($P = .04$). Second, a 1-unit increase in American Society of Anesthesiologists class was associated with a 1.75 increase in the re-repair hazard rate after 1 year ($P = .009$).

DISCUSSION

Most large, current clinical registries contain only limited short-term follow-up. There are many important long-term outcomes in general surgery, such as recurrence after ventral hernia repair. High-quality clinical studies have identified both procedure-specific and patient-specific clinical variables that are associated with recurrence.[16,17,27] Identifying an association between known ACS-NSQIP clinical variables and ventral hernia re-repair (not necessarily hernia recurrence) code captured in Medicare claims data may establish the feasibility of studying selected long-term events using the technique of linked clinical and administrative datasets.

This study demonstrated that it is possible to combine a clinical registry with claims data to study selected, long-term events. This study found that ventral hernia re-repair occurred in 6.6% of patients at up to 4 years of follow-up. In addition, it identified that the rate of re-repair ventral hernia (not necessarily recurrence of ventral hernias) leveled off by approximately 550 days (1.5 years) after the index repair. This study further confirmed that many known clinical risk factors for re-repair, including smoking, BMI, and postoperative surgical-site infection, were associated with re-repair at 1 year postoperatively in claims data.

The ventral hernia re-repair rate as captured in claims data appear to be an underestimate of the clinical literature. The observed 6.6% ventral hernia re-repair rate is less than the 9–12% reported range of ventral hernia re-repair in clinical studies.[11,28] The underestimate may be attributed the fact that the Medicare inpatient claims file does not capture outpatient procedures done on an ambulatory basis. The underestimate may be because the Medicare inpatient claims file does not capture encounters for patients enrolled in Medicare managed-care plans. Therefore, if patients were not in Medicare managed care plans initially when they underwent index surgery and then switched to Medicare managed care plans over the course of the study, these patients would not have been captured. Notably, managed care enrollment did increase over the 4 years of this study; 3% in 2005, 12% in 2006, 21% in 2007, and 32% in 2008.

Another reason the re-repair rate was an underestimate may be that there was insufficient follow-up time. Studies that have examined re-repair rates have shown that these rates may nearly double if patients are followed from 5 years (12%) to 13 years (23%).[28] Although data suggest that most ventral

Table III. Variables associated with repeat repair of ventral hernia

Clinical variables	*30-Day HR*	*30-Day 95% CI**	P *value*	*1-Year HR*	*1-Year 95% CI**	P *value*	*After 1 year HR*	*After 1 year 95% CI**	P *value*
Procedure-specific variables									
Mesh	1.74	0.36–2.01	.14	0.86	0.61–1.19	.36	0.76	0.47–1.23	.26
Nonreducible hernia	**2.86**	**1.24–6.60**	**.01**	0.71	0.44–1.15	.16	0.60	0.29–1.22	.16
Recurrent hernia	1.13	0.43–2.94	.81	1.09	0.71–1.66	.70	1.09	0.58–2.04	.80
Nonreducible*recurrent hernia	0.52	0.10–2.70	.42	1.33	0.57–3.06	.51	2.24	0.73–6.89	.16
Wound class	1.23	0.83–1.82	.32	1.23	0.99–1.54	.07	1.34	0.98–1.84	.07
Demographic variables									
Male	1.38	0.69–2.76	.36	1.31	0.94–1.85	.11	0.88	0.53–1.47	.62
Age	0.97	0.92–1.03	.33	**0.97**	**0.94–0.99**	**.03**	0.97	0.93–1.01	.18
Metabolic and immunologic conditions									
Diabetes	0.86	0.48–1.51	.59	0.96	0.72–1.27	.77	0.72	0.45–1.14	.16
Body mass index category	0.95	0.71–1.26	.71	**1.16**	**1.00–1.34**	**.04**	1.13	0.92–1.37	.25
Steroid use	0.52	0.07–3.87	.52	1.96	0.99–3.89	.05	1.18	0.37–3.79	.78
Renal conditions									
Acute renal failure	3.16	0.38–26.23	.29	2.35	0.32–17.13	.40	5.42	0.71–41.29	.10
Hematologic and oncologic conditions									
Chemotherapy	4.41	0.51–38.22	.18	1.01	0.14–7.35	.99	0.00	0.00–0.00	.97
Pulmonary conditions									
Smoker	**2.57**	**1.14–5.83**	**.02**	**1.70**	**1.08–2.70**	**.02**	0.86	0.36–2.01	.72
Acuity of illness									
ASA class	1.34	0.78–2.32	.29	1.06	0.79–1.40	.71	1.44	0.96–2.15	.08
Open wound	**15.00**	**4.56–49.31**	**<.001**	1.17	0.49–2.80	.73	1.32	0.44–3.89	.62
Postoperative events									
Surgical-site infection	**33.62**	**14.64–77.23**	**<.001**	**2.88**	**1.85–4.48**	**<.001**	1.98	0.97–4.06	.06

*A multivariate hierarchical Cox regression with time varying covariates was used to generate HRs and respective CIs at 30 days, 1 year, after 1 year. Continuous and ordinal variables treated as continuous to maximize granularity of information in the model. Clinical variable identified from NSQIP. Occurrence of re-repair identified from Medicare, as described in the text. Bold represents statistical significance $P<.05$.
ASA, American Society of Anesthesiologists; *95% CI*, 95% confidence interval; *HR*, hazard ratio.

hernia recurrences happen within 2–3 years,[2,29] having a recurrence does not necessarily mean that the patient will undergo re-repair at the time of diagnosis. Likely, the rate and timing data depict only the "tip of the iceberg" of true ventral hernia recurrence.

Nonetheless, the ventral hernia re-repair rate does seem to be a meaningful event. This contention is supported by the fact that known clinical risk factors for ventral hernia recurrence in ACS-NSQIP were associated with ventral hernia re-repair at 1 year in the Medicare inpatient claims data. The concordance in risk factors identified in large, prospective, multicenter trials with the risk factors identified in this linked registry-claims dataset study support the relevance of re-repair as a long-term outcome in claims data. The use of linked datasets is an advantageous method of studying long-term events, because these datasets are more inclusive and less expensive to obtain than clinical trial data. These data do give us an inkling of *what* lies before us, yet the *scale* of the problem is difficult to capture precisely using 4 years of inpatient, nonmanaged care data.

Several limitations must be discussed further. First, although ACS-NSQIP collects many important clinical factors, certain relevant technical factors, such as type of mesh, underlay vs onlay technique, amount of mesh overlap, and disease-specific factors, such as the hernia size, hernia sac contents, and the hernia duration are not available. For example, mesh placement is not captured routinely as a single dichotomous variable in the current ACS-NSIP, and the use of codes of concurrent procedures may be good but not 100% sensitive.[30] Likely for this reason, mesh placement was not associated with re-repair rate in this study.

ACS-NSQIP, however, is continuously changing to include disease-specific variables, and future models could control for the variation in these risk factors. Second, patients who died were treated as censored observations. Although unlikely, it is possible that a patient may die of a ventral hernia recurrence rather than undergo a ventral hernia re-repair. In this case, death could be treated as a competing risk. This approach was not performed because the authors believe that

clinically, this is an exceedingly uncommon scenario and that most deaths were probably unrelated to a ventral hernia recurrence. Finally, the findings of this patient sample of Medicare beneficiaries within ACS-NSQIP hospitals may not be generalizable to a younger population or to non-ACS-NSQIP–participating hospitals.

Long-term rate and timing of ventral hernia re-repair obtained from claims data appear to be an underestimate compared to clinical studies. Yet, known clinical risk factors for recurrence in the clinical registry were associated with the re-repair rate in claims data at 1 year lending support to the clinical relevance of re-repair in claims data as a metric. Linked datasets may offer a viable option for identifying selected postoperative events beyond 30 days postoperatively if complete, longer-term claims data (including outpatient and managed care encounters) can be obtained. Further work is needed to determine whether it is possible to study other long-term outcomes using reoperation rates in linked clinical registry-claims data.

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Appendix 1

International Classification of Disease 9	*Descriptions*
46.42	Pericolostomy Hernia Repair
53.49	Open Umbilical Hernia Repair
53.51	Incisional Hernia Repair
53.59	Abdominal Wall Hernia Repair
53.61	Open Incisional Hernia Repair with Graft
53.69	Open Hernia Anterior Abdominal Wall Graft
53.9	Other Hernia Repair
54.61	Reclose Disruption
54.62	Closure of the Abdominal Wound
54.72	Abdominal Wall Repair
83.65	Other Fascial Closure