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### Title

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**Permalink** https://escholarship.org/uc/item/302570qs

**Journal** Surgical endoscopy, 27(11)

**ISSN** 0930-2794

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**Publication Date** 

2013-11-01

### DOI

10.1007/s00464-013-3062-9

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## Laparoscopic versus open repair of parastomal hernias: an ACS-NSQIP analysis of short-term outcomes

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Received: 19 April 2013/Accepted: 10 June 2013/Published online: 9 July 2013 © Springer Science+Business Media New York 2013

#### Abstract

*Background* Parastomal hernia (PSH) is a frequent complication following the creation of a stoma. While a significant number of cases require operative management, data comparing short-term outcomes of laparoscopic versus open repair of parastomal hernias are limited.

*Methods* The ACS-NSQIP was retrospectively reviewed from 2005 to 2011 for all PSH cases that underwent open or laparoscopic repair. Patients characteristics, operative details, and outcomes were listed for both procedure types. Selected end points were compared on multivariate regression analysis.

*Results* Among the 2,167 identified parastomal hernia cases, only 222 (10.24 %) were treated laparoscopically. The open and laparoscopic groups were similar with respect to mean patient age (63 vs. 63 years; p = 1) and gender distribution as the majority of patients were females (56.8 %). However, open repair was more likely to be performed in patients with a higher ASA class (III and IV) (p < 0.001). Also, the open approach was more likely to be used emergently (8.64 vs. 3.60 %; p = 0.01) and for recurrent hernias

Presented at the SAGES 2013 Annual Meeting, April 17–20, 2013, Baltimore, MD,USA.

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V. Q. Nguyen · M. Phelan Department of Statistics, University of California Irvine, Irvine, CA, USA (6.99 vs. 3.15 %; p < 0.05). After adjusting for all potential confounders including age, gender, ASA, emergency designation of the operation, hernia type, and wound class, laparoscopy was associated with shorter operative time (137.5 vs. 153.4 min; p < 0.05), shorter length of hospital stay by 3.32 days (p < 0.001), lower risk of overall morbidity (OR = 0.42; p < 0.001), and a lower risk of surgical site infections (OR = 0.35; p < 0.01) compared to open repair. Mortality rates were similar in the laparoscopic and open groups (0.45 vs. 1.59 %, respectively; p = 0.29).

*Conclusions* Laparoscopic parastomal hernia repair is safe and appears to be associated with better short-term outcomes compared to open repair in selected cases. Large prospective randomized trials are needed to confirm those results and to assess long-term recurrence rates.

**Keywords** Laparoscopy · Parastomal · Peristomal · Hernia · Colorectal · Stoma · Ostomy · Short-term outcomes · NSQIP

Stoma creation is a frequently performed procedure in various surgical specialties. In the US, an estimated 450,000 people are living with a stoma and 120,000 new stomas are created each year, a number predicted to increase by 3 % per year [1]. In the UK, 102,000 people are living with a stoma and around 20,000 new stomas are fashioned annually, 50 % of which are permanent [2].

While a stoma is clearly indicated in certain situations, its presence is associated with early and late complications [3, 4], which significantly impact a patient's quality of life [4, 5]. Among these complications, parastomal hernias (PSH) account for a large percentage, with a reported incidence ranging from 11 to 66 % [3, 4, 6, 7], depending on the follow-up period and stoma type. The presence of a

PSH may further reduce quality of life [6], as patients complain of pain and difficulty fitting the appliance, leading to leakage and skin necrosis [7]. Parastomal hernias may also cause bowel obstruction, incarceration, and strangulation [8], in which case surgical management becomes necessary.

It is estimated that 30-56 % of patients with a clinically apparent PSH require surgical intervention [7, 9]. Operative options include relocation of the stoma or repair with or without the use of prosthetic material, using either a laparoscopic or an open approach [8, 10]. Most of the literature on PSH repair consists of case series and retrospective reviews representing single-center experiences or comparative studies evaluating different types of mesh repair [11–25]. It is interesting to note that only one small study compared the outcomes of the laparoscopic approach to those of open surgery in the management of parastomal hernias [26].

The aim of our study was to compare the short-term outcomes of laparoscopic and open surgery in the management of PSH. To this end we performed a retrospective review of a large validated database over a 7-year period.

#### Methods

The American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) was retrospectively reviewed for all cases of parastomal hernias that underwent operative repair between January 1, 2005 and December 31, 2011. ACS-NSQIP is the first nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care. The program provides approximately 500 participating hospitals with data on preoperative risk factors, intraoperative variables, and 30-day postoperative mortality and morbidity for patients undergoing major surgical procedures in both the inpatient and outpatient setting. Each participating hospital has a dedicated surgical clinical nurse reviewer (SCNR) who captures these data using a variety of methods, including medical chart abstraction. Full description of the ACS-NSQIP is available on the NSQIP website [27]. Approval for the use of the ACS-NSQIP database for this study was obtained from the institutional review board of the University of California Irvine and the ACS-NSQIP.

### Case selection

In order to identify true PSH cases, we used a combination of ICD-9 diagnoses codes and Current Procedural Terminology (CPT) codes and made sure that no coding mismatch occurred. Since the available CPT codes do not differentiate between parastomal, ventral, and incisional hernias, the addition of ICD-9 codes specific for "stomal hernia or prolapse" enabled us to select cases that truly represent parastomal hernias. The following ICD-9 diagnoses codes were used in our analysis: 569.60, 569.62, 569.69, and 569.89. Cases were divided into two groups based on whether the repair was open or laparoscopic. Open cases were identified by the CPT codes 44346, 49560, 49561, 49565, and 49566, and laparoscopic cases were identified by the CPT codes 44238, 49652- 49657, and 49659.

### Study variables

The variables used in our study were provided by the NSQIP database and include patient demographics (age, gender), comorbid conditions, and American Society of Anesthesiologists (ASA) class. The operative variables used were emergency designation of the procedure, intraoperative transfusion, hernia type (initial reducible, initial incarcerated, recurrent reducible, recurrent incarcerated, or unspecified), wound classification, and operative time. Variables with a high percentage of missing data, such as "intraoperative blood transfusions," were excluded from the analysis.

### Study end points

The primary aim of our study was to analyze and compare the short-term outcomes of laparoscopic and open repair of parastomal hernias. To this end, the following end points chosen a priori were examined on multivariate regression analysis: 30-day mortality, 30-day morbidity, length of hospital stay, any surgical site infections (SSI), and operative time. We also listed the unadjusted incidences of the following outcomes: 30-day mortality, 30-day morbidity, length of hospital stay, and postoperative complications, including cerebrovascular accidents (CVA), myocardial infarction (MI), pneumonia, superficial SSI, deep SSI, organ/space SSI, wound disruption, urinary tract infections (UTI), renal insufficiency, acute renal failure (requiring dialysis), deep venous thrombosis (DVT), sepsis, septic shock, and return to the operating room (OR) within 30 days of the index operation.

#### Statistical analysis

Data extraction and statistical analyses were performed using SAS ver. 9.3 and the R Statistical Environment.  $\chi^2$  test with Yate's correction and the *t* test with unequal variance were used where appropriate. Multivariate logistic (categorical variables) and linear (continuous variables) regression analyses were performed to compare the outcomes of laparoscopic vs. open PSH repair using the open group as reference.

For analyses of 30-day morbidity and length of hospital stay, we controlled for age, gender, ASA class, admission type (elective vs. emergent), and hernia type. For analysis of SSI, in addition to these variables, we also adjusted for diabetes, smoking, use of steroids, and BMI >30. For analysis of the operative time, we adjusted for hernia type and admission types. The results of our multivariate analysis were adjusted for the effect of multiple comparisons using Holm's method. Estimates of adjusted mean differences and adjusted odds ratios were obtained with 95 % confidence intervals. Statistical significance was declared if p < 0.05.

### Results

Based on our sampling criteria, a total of 2,167 PSH cases were identified over the study period, of which 222 (10.24 %) were performed laparoscopically.

Table 1 gives the characteristics of the patients in the open and laparoscopic groups. Mean patient age was 63 years in the open and laparoscopic groups. Female gender was predominant in both groups with no observed differences. Patients who underwent PSH repair had high incidence of the following comorbidities: BMI >30 (43.52 %), diabetes (19.01 %), smoking (19.29 %), and COPD (chronic obstructive pulmonary disease) (8.86 %). Also, the majority of patients who underwent PSH repair (58.24 %) had an ASA of III. While the incidences of most comorbidities were similar between the groups, we observed major differences in the distribution of ASA class. Patients with an ASA of I or II were more likely to have undergone laparoscopic PSH repair (15.32 vs. 7.37 %, p < 0.001), whereas patients with an ASA of III were more likely to have undergone open repair.

Table 2 gives the operative details for the open and laparoscopic groups. Most cases were elective; however, when we examined emergent cases, we noticed that they were less likely to be performed laparoscopically (3.60 vs. 8.64 %; p < 0.05). Laparoscopic repair was also less likely to be used for recurrent hernias (3.15 vs. 6.99 %; p < 0.05). With regard to wound classification, laparoscopic cases were more likely to be classified as "clean" (44.14 vs. 10.39 %; p < 0.001) and less likely to be classified as "clean-contaminated" or "contaminated" [45.98 vs. 61.32 % (p < 0.001) and 10.34 vs. 27.04 % (p < 0.001), respectively]. Mean operative time was shorter for laparoscopic cases (137.5 vs. 153.4 min; p < 0.05).

Table 3 gives the unadjusted outcomes for both groups. The mean length of hospital stay was 4 days in the laparoscopic group and 8.32 days in the open group (p < 0.001). The overall morbidity in the laparoscopic group was 11.71 % compared with 27.04 % in the open group (p < 0.001). Thirty-day mortality was 0.45 % in the laparoscopic group and 1.59 % in the open group (p = 0.29). When examining individual postoperative complications, the laparoscopic group had a lower incidence of pneumonia (0.90 vs. 3.75 %; p < 0.05), superficial SSI (2.70 vs. 9.97 %; p < 0.01), deep SSI (0 vs. 3.39 %; p < 0.01), and sepsis (1.80 vs. 5.04 %; p < 0.05).

Table 4 gives the results of a multivariate regression analysis of the association of laparoscopic PSH with selected end points. Compared to open repair, the operative time for laparoscopic PSH repair was shorter by 13 min (p < 0.05) and the length of hospital stay was 3.32 days shorter (p < 0.001). Moreover, laparoscopy was associated with a 58 % reduction in 30-day morbidity (p < 0.001) and a 65 % reduction in all SSI (p < 0.001). Mortality was excluded from the multivariate analysis as only one case was reported in the laparoscopic group.

#### Discussion

The past two decades have witnessed an increased use of laparoscopy in the management of several colorectal pathologies. By 2009, 43 % of colectomies performed for cancer and diverticular disease in the US were laparoscopic [28, 29]. The increasing popularity of laparoscopy does not appear to extend to the management of parastomal hernias as only 10.24 % of the cases in our study were performed laparoscopically. This rate is similar to that of a large retrospective study of the French federation of ostomy patients which found only 9 % of 782 operative parastomal hernias were managed laparoscopically [7]. The reasons for this limited use are multiple. While the laparoscopic approach may offer benefits such as minimal injury to the abdominal wall and a potentially superior view of the defect allowing more precise repair and mesh reinforcement [13, 14], PSH cases are often complicated by dense adhesions making laparoscopy more challenging [15, 30]. Moreover, there is a lack of strong clinical evidence favoring the use of laparoscopy in PSH repair. In contrast to incisional and ventral hernias for which a large Cochrane review demonstrated the favorable short-term outcomes of laparoscopy in reducing SSI and length of hospital stay [31], such a level of evidence does not exist for parastomal hernias for which most of the literature consists of small case series [12-20, 26, 30, 32] or retrospective studies that evaluated different types of mesh repair such as "keyhole" or "Sugarbaker." Parastomal hernias are less common than incisional or ventral hernias and represent a significantly heterogeneous group of cases; thus, any comparative studies should be large enough to address this heterogeneity. Moreover, the recurrence rate following laparoscopic

Table 1 Patients' characteristics in the open and laparoscopic groups

	Open	Laparoscopic	p value
N	1,945	222	
Age (years)	63 (54–73)	63 (54–75)	1
Gender			
Female	1,074 (55.22)	134 (60.36)	
Male	868 (44.63)	88 (39.64)	0.17
Missing	3 (0.15)	0	
Comorbidities			
BMI >30	850 (43.70)	93 (41.89)	0.66
Hypertension	1,071 (55.06)	111 (50.00)	0.17
Diabetes	377 (19.38)	35 (15.76)	0.22
Smoking	384 (19.74)	34 (15.32)	0.14
Alcohol use	32 (1.65)	3 (1.35)	0.96
Dyspnea	231 (11.88)	14 (6.31)	0.02
COPD	180 (9.25)	12 (5.41)	0.07
Cardiac history	111 (5.71)	10 (4.50)	0.56
Vascular disease	32 (1.65)	4 (1.80)	0.92
Chronic kidney disease	29 (1.49)	1 (0.45)	0.34
Steroid use	114 (5.86)	7 (3.15)	0.13
Weight loss	23 (1.49)	3 (1.72)	0.93
ASA class			
1 = No disturbance	10 (0.51)	10 (4.50)	< 0.001
2 = Mild disturbance	653 (33.57)	110 (49.55)	< 0.001
3 = Severe disturbance	1,172 (60.26)	90 (40.54)	< 0.001
4 = Life threatening	110 (5.66)	12 (5.41)	1

Continuous variables are reported as mean and interquartile range, and categorical variables are reported as counts and percentages in parentheses

BMI body mass index, COPD chronic obstructive pulmonary disease

repair is similar to that of open surgery [8] and as such laparoscopy may not seem to offer obvious advantages.

We found that laparoscopy was safe, as it was associated with low mortality, low morbidity, low SSI, and a mean length of stay of 4 days. These findings agree well with those of previously published reports [12-20, 26, 30, 32] and with a meta-analysis of 338 laparoscopic PSH cases by Hansson et al. [8]. In that meta-analysis, the wound infection rate following laparoscopic PSH was found to be 3.3 %, whereas mesh infection rates occurred in 2.7 % of cases. In our data, superficial SSI and organ/space SSI each occurred in 2.7 % of the cases. In the laparoscopic approach, because the mesh is placed intraperitoneally, organ/space SSI may represent mesh infection or an inadvertent enterotomy. However, the meta-analysis by Hansson et al. [8] reported a morbidity rate of 17 %, whereas the morbidity rate in our study was just under 12 %. This discrepancy may be explained by the fact that several studies in the meta-analysis reported "ileus" as a postoperative complication, whereas this complication is not available in the NSQIP database.

In addition to its safety, the laparoscopic approach appears to be associated with significantly better short-term outcomes compared to open surgery. The large numbers in the NSOIP database enabled us to perform a risk-adjusted analysis which demonstrated that laparoscopy was associated with a 3-day reduction in length of hospital stay, a shorter operative time, a 58 % reduction in morbidity, and a 65 % reduction in the odds of SSI compared to open surgery. These findings echo the findings of Pastor et al. [26], who, in their retrospective review of 11 laparoscopic and 14 open PSH cases, found that the laparoscopic approach is associated with a shorter length of stay. However, due to the small numbers in their study, no differences were observed in overall mortality, morbidity, or operative time. The unique characteristic of our findings is that they held true after controlling for all confounding variables. Some of these findings, such as length of hospital stay and SSI, are in line with those of a large meta-analysis that compared laparoscopic to open surgery in the management of incisional hernias [31].

The low morbidity rate of laparoscopic PSH repair appears to be primarily the result of a lower incidence of postoperative infectious complications such as pneumonia, SSI, and sepsis. In the case of SSI, our findings persisted after adjusting for potential confounders such as the use of steroids, obesity, smoking, and wound class. Taken together, these findings may be explained by the significantly lower surgical stress response and the better preservation of the postoperative immune function offered by laparoscopy [33].

It is interesting to note that while laparoscopy is associated with improved short-term outcomes, it was used mostly in relatively healthy patients with a low ASA class, whereas the majority of patients with higher ASA class underwent open repair. Many surgeons are still reluctant to use laparoscopy in high-risk patients despite the increasing evidence of the safety and feasibility of laparoscopy in high-risk patients [34, 35]. Of note, patients with PSH had a higher ASA class because most were older and had a high incidence of obesity, diabetes, smoking, and COPD. Older age and the presence of these comorbidities have all been linked to the development of parastomal herniation [4, 7, 36].

While our study is the largest comparing laparoscopic to open PSH repair, it certainly has its limitations. Its retrospective design may be prone to significant selection bias. To overcome this limitation, we accounted for a large number of confounding variables. The effect of intraoperative adhesions on selection bias was accounted for by adjusting for the type of hernia (initial vs. recurrent, and reducible vs. incarcerated). For the remaining hernia types that were unspecified, we further adjusted for the emergency designation of the operation in an attempt to reduce

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	Open	Laparoscopic	p value
N	1,945	222	
Emergency case	168 (8.64)	8 (3.60)	0.01
Intraoperative transfusion	27 (1.39)	2 (0.90)	0.77
Hernia type			
Initial reducible	493 (25.35)	56 (25.22)	0.96
Initial incarcerated	135 (6.94)	15 (6.76)	0.97
Recurrent reducible	97 (4.99)	5 (2.25)	0.10
Recurrent incarcerated	39 (2.00)	2 (0.90)	0.38
Unspecified	1,181 (60.72)	144 (64.87)	0.26
Wound classificatio	n		
Clean	202 (10.39)	98 (44.14)	< 0.001
Clean- contaminated	1,226 (63.03)	99 (44.59)	<0.001
Contaminated	454 (23.34)	21 (9.46)	< 0.001
Dirty/Infected	63 (3.24)	4 (1.80)	0.33
Operation time (min)	153.40 (88.00–196.00)	137.49 (83.00–170.00)	< 0.05

Continuous variables are reported as mean and interquartile range, and categorical variables are reported as counts and percentages in parentheses

the effect of selection bias and to make sure that we were comparing similar cases. The adjustment for the emergency designation of the operation would account for the fact that some of these cases may represent incarcerated or strangulated hernias. The NSQIP database does not provide information about the defect size, case complexity, or the surgeon's experience, which may favor one approach over the other. Converted cases were counted in the open group and, as such, the conversion rate was unknown. However, the conversion rate for laparoscopic PSH repair ranges from 0 to 15 % [1, 13, 14, 16-18, 20], with an average of 3.6 % [8]. Conversion to open surgery may be due to inadvertent enterotomy [13, 20, 26], which has a reported incidence of 4.1 % among laparoscopic PSH [8]. Inadvertent enterotomy may change the wound classification from clean to clean-contaminated or contaminated and may explain why a higher percentage of these cases were seen in the open group. We accounted for this limitation by adjusting for the different wound classifications. While it is not possible to determine the exact technique of mesh placement (onlay vs. sublay vs. underlay, and keyhole vs. Sugarbaker), this limitation is unlikely to affect short-term outcomes as postoperative complications rates are similar following different techniques [8, 11]. The number of PSH cases is relatively low, especially when considering that up to 500 hospitals (depending on the data-year) participate in

Table 3 Unadjusted outcomes in the open and laparoscopic groups

	Open	Laparoscopic	p value
N	1,945	222	
Length of stay (days)	8.32 (4.00–9.00)	4.12 (1.00–5.00)	<0.001
Morbidity	526 (27.04)	26 (11.71)	< 0.001
Mortality	31 (1.59)	1 (0.45)	0.29
Postoperative complication	ons		
CVA	5 (0.26)	0	1
Myocardial infarction	8 (0.41)	0	0.71
Pneumonia	73 (3.75)	2 (0.90)	< 0.05
Renal insufficiency	12 (0.62)	0	0.49
Acute renal failure	11 (0.57)	0	0.53
UTI	100 (5.14)	7 (3.15)	0.25
Superficial incisional SSI	194 (9.97)	6 (2.70)	<0.001
Deep incisional SSI	66 (3.39)	0	< 0.01
Organ/space SSI	53 (2.72)	6 (2.70)	0.88
Wound disruption	30 (1.54)	1 (0.45)	0.31
Sepsis	98 (5.04)	4 (1.80)	< 0.05
Septic shock	54 (2.78)	1 (0.45)	0.06
Bleeding	32 (1.65)	2 (0.90)	0.58
Return to OR	152 (7.81)	10 (4.50)	0.10
DVT	21 (1.08)	1 (0.45)	0.59

Continuous variables are reported as mean and interquartile range, and categorical variables are reported as counts and percentages in parentheses

CVA cerebrovascular accident, UTI urinary tract infection, SSI surgical site infection, OR operating room, DVT deep venous thrombosis

 Table 4
 Multivariate regression analysis evaluating the association of laparoscopic repair with selected end points

	Adjusted OR/MD (95 % CI)	p value
Operative time (min)	-13.24 (-23.62, -2.86)	< 0.05
Total length of stay (day)	-3.32 (-4.12, -2.52)	< 0.001
Morbidity	0.42 (0.27, 0.64)	< 0.001
SSI	0.35 (0.19, 0.65)	< 0.01
Operative time (min) Total length of stay (day) Morbidity SSI	$\begin{array}{c} -13.24 \ (-23.62, \ -2.86) \\ -3.32 \ (-4.12, \ -2.52) \\ 0.42 \ (0.27, \ 0.64) \\ 0.35 \ (0.19, \ 0.65) \end{array}$	<0.05 <0.00 <0.00 <0.01

Open group used as reference

*OR* odds ratio, *MD* mean difference, *CI* confidence interval, *SSI* any surgical site infection (superficial, deep, or organ space)

NSQIP. Our strict selection criteria led to the exclusion of several cases because we wanted to ensure that no incisional or ventral hernias fell into any of the study groups.

### Conclusions

Laparoscopic PSH repair appears to be safe in selected patients as it is associated with significantly lower morbidity, lower SSI, and shorter length of hospital stay compared to the open approach on risk-adjusted analysis. Further studies in the form of large randomized trials are still needed to validate these findings.

**Disclosures** The Department of Statistics at UC Irvine, with which V. Nguyen and M. Phelan are affiliated, was paid a statistical consulting fee by the Department of Surgery at UC Irvine. The Department of Surgery at UC Irvine, with which S. Mills is affiliated, was paid an educational grant from Ethicon. Ethicon, Covidien, Olympus, Adolor, and NiTi gave educational grants and speaker fees to the Department of Surgery at UC Irvine, with which M. Stamos is affiliated. Intuitive Surgical paid consultancy and educational grants to the Department of Surgery at UC Irvine, with which A. Pigazzi is affiliated.

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