Hartmann's Procedure vs Primary Anastomosis with Diverting Loop Ileostomy for Acute Diverticulitis: Nationwide Analysis of 2,729 Emergency Surgery Patients

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BACKGROUND: Recent small randomized trials suggest that primary anastomosis with a diverting loop ileostomy (PADLI) is a safe alternative to Hartmann's procedure (HP) for patients with acute diverticulitis necessitating emergent operation. We sought to examine the 30-day outcomes of patients undergoing emergent HP vs PADLI.

METHOD: Using the American College of Surgeons NSQIP Colectomy Procedure Targeted Database from 2012 to 2016, all patients with acute diverticulitis who underwent emergent HP or PADLI were identified. Multivariable logistic models were constructed to compare the 30-day mortality, overall morbidity, and individual postoperative complications (eg surgical site infection, bleeding, sepsis) of the 2 procedures, controlling for all preoperative variables (eg demographics, comorbidities, laboratory values, illness severity), as well as intraoperative and procedure-specific variables (eg wound classification).

RESULTS: Of 130,963 patients, 2,729 patients were included. Median age was 64 years, 48.5% were male; the majority of patients underwent HP and only 208 (7.6%) underwent PADLI. Hartmann's procedure patients had more comorbidities (eg COPD: 9.8% vs 4.8%; $p = 0.017$), were more functionally dependent (6.3% vs 2.4%; $p = 0.025$), and were sicker (eg septic shock: 11.1% vs 5.3%; $p = 0.015$) compared with PADLI patients. The mortality rates for HP vs PADLI were 7.6% and 2.9%, respectively ($p = 0.011$). The morbidity rates were 55.4% and 48.6%, respectively ($p = 0.056$). In multivariable analyses, compared with HP, PADLI did not result in increased rates of mortality (odds ratio 0.21; 95% CI 0.03 to 1.58; $p = 0.129$) or morbidity (odds ratio 0.96; 95% CI 0.63 to 1.45; $p = 0.834$). The odds of most major postoperative complications were also similar for HP and PADLI overall.

CONCLUSIONS: Currently, surgeons perform HP more frequently than PADLI. When controlling for patient population differences, PADLI appears to be at least a safe alternative to HP for select patient populations needing emergent surgical management of acute diverticulitis. (J Am Coll Surg 2019;229: 48–55. © 2019 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

The burden of acute diverticulitis is increasing in the US. For example, the number of diverticulitis-related admissions increased by 26% between 1998 and 2005, with the highest increase being in patients aged younger than 45 years and for those from the Northeastern part of the country.[1,2] Although the vast majority of patients with

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acute diverticulitis can be successfully managed nonoperatively, surgical intervention is still indicated for the most complicated and/or life-threatening acute diverticulitis.[3,4] In the 1980s, the 3-stage surgical procedure was replaced by the 2-stage procedure known as Hartmann's procedure (HP).[4,5] This procedure involved sigmoid colectomy with end descending colostomy and subsequent colostomy reversal with colorectal anastomosis weeks to months after patient recovery. At present, HP arguably remains the standard of care and the most popular surgical procedure for the emergent management of acute diverticulitis.[5,6]

In recent years, a few scientific reports have suggested that primary anastomosis with a diverting loop ileostomy (PADLI) is a safe alternative to HP for selected complicated acute diverticulitis necessitating emergent or urgent operation.[7-10] Specifically, 2 randomized trials, 1 from Switzerland and 1 from France suggested the safety of PADLI, but suffered from a small number of patients enrolled and, as such, the optimal surgical approach to these complicated patients remains controversial.[7,8] In this study, we sought to use the recently created American College of Surgeon (ACS) NSQIP Colectomy Procedure Targeted Database to compare the 30-day mortality and morbidity outcomes of patients undergoing emergent HP vs PADLI for acute diverticulitis.

METHODS

Patient population

All patients 18 years or older who underwent emergency colectomy for acute diverticulitis from the ACS NSQIP Colectomy Procedure Targeted Database from 2012 to 2016 were initially included. Elective and non-urgent colectomies were excluded. All colectomies with indication or primary diagnosis other than acute diverticulitis were excluded. Patients with inflammatory bowel disease, those who underwent preoperative mechanical or antibiotic bowel preparation were excluded from the analysis.

Defining Hartmann's procedure and primary anastomosis with a diverting loop ileostomy colectomy procedures

Using a comprehensive algorithm combining the "Principal Operative Procedure CPT code" (principal CPT code) and the "Other Operative Procedure CPT code" (other CPT code) for ACS NSQIP, patients who underwent HP or PADLI were systematically identified. Principal CPT code was defined by ACS NSQIP as "the most complex of all the procedures performed by the primary operating team during the trip to the operating room."[11] "Other CPT code" was defined as "an additional surgical procedure performed by the same surgical team, under the same anesthetic which has a CPT code different from that of the Principal Operative Procedure."[11]

The HP cohort was identified using 2 different methods. First, we included all patients with principal CPT codes of 44141, 44143, and 44206, except when they also had an "other CPT code," such as 44140, 44144, 44160, 44204, 44300, 44310, 44316, and 44345. The second method included all patients with principal CPT codes 44140, 44145, 44204, and 44207 with "other CPT codes" 44141, 44143, and 44206.

The PADLI cohort was similarly identified in 2 methods. First, we included all patients with principal CPT codes 44140, 44145, 44204, and 44027 in combination with "other CPT codes" 44187 and 44310. We then included patients with principal CPT codes 44146 and 44208 except when they also had "other CPT codes" 44141 and 44320.

Hartmann's procedure vs primary anastomosis with a diverting loop ileostomy

To study the 30-day outcomes of HP vs PADLI patients, we first performed univariate analyses comparing the baseline demographics, comorbidities, severity of illness, intraoperative variables, and postoperative outcomes between the 2 cohorts. Backwards stepwise multivariable adjusted logistic regression models were then constructed to control for confounders and study the impact of PADLI in reference to HP on 30-day mortality, overall 30-day morbidity, and individual postoperative complications (eg surgical site infection, bleeding, sepsis). The confounders controlled for these models included all preoperative variables (eg demographics, comorbidities, preoperative laboratory values, illness severity), as well as intraoperative and procedure-specific variables (eg wound classification) that are uniquely found in ACS NSQIP Colectomy Procedure Targeted Database. The international normalized ratio was not included due to the variable missing for >30% of the subjects.

Statistical analysis

STATA, version 14.0 (StataCorp) statistical software package was used for statistical analyses in this study. Categorical variables were presented as absolute values and percentages. Continuous variables were presented as either mean and SD for normal distribution or median and interquartile range for non-normal distribution. The normality of continuous variables was identified by Shapiro-Wilk test. For univariate analyses, chi-square tests or Fisher's exact tests were performed for categorical variables and either Wilcoxon rank-sum tests or *t* tests were performed for continuous variables, based on the distribution. Statistical significance was set as $p < 0.05$.

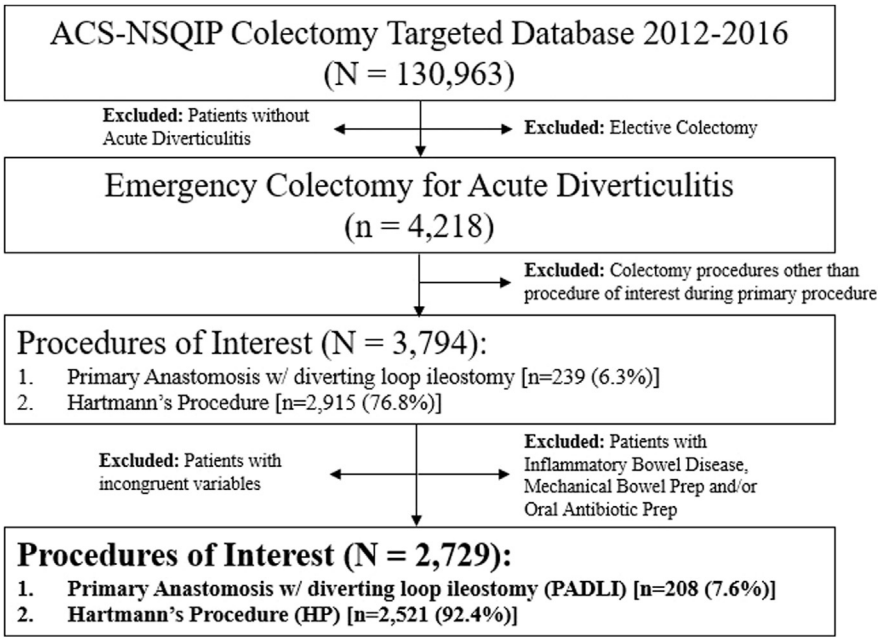

Figure 1. Inclusion and exclusion of study population.

Ethical oversight

This study was reviewed and approved by the IRB.

RESULTS

Study population

Of a total of 130,963 patients, 2,729 patients were included (Fig. 1). Median age of the patients was 64 years, 48.5% were male, 92.4% underwent HP, and 7.6% underwent PADLI.

Univariate analyses: Hartmann's procedure vs primary anastomosis with a diverting loop ileostomy

Table 1 summarizes the demographics, comorbidities, and intraoperative variables comparisons in the HP and PADLI cohorts. In summary, HP patients were overall more comorbid (American Society of Anesthesiologists class $\geq$3) than PADLI patient (72.4% vs 65.9%; $p = 0.045$). Specifically, HP patients more often had congestive heart failure (3.0% vs 0.0%; $p = 0.012$), functional dependence (6.3% vs 2.4%; $p = 0.025$), COPD (9.8% vs 4.8%; $p = 0.017$), chronic steroid use (15.2 vs 8.2%; $p = 0.006$), and bleeding disorders (12.5% vs 7.7%; $p = 0.043$).

From an illness severity perspective, HP patients were sicker than PADLI patients, with more preoperative septic shock (11.1% vs 5.3%; $p = 0.015$). However, PADLI patients had more preoperative RBC transfusion (4.3% vs 2.1%; $p = 0.034$).

Most procedures were wound classified as dirty-infected (84.8% for HP and 84.6% for PADLI; $p = 0.966$). The indication for emergency operation was mostly perforation (92.2% for HP and 87.0% for PADLI; $p = 0.040$) and, as expected, the majority of the procedures were performed open, especially for HP (90.0% for HP and 82.7% for PADLI; $p = 0.007$).

Table 2 summarizes outcomes comparisons between HP and PADLI. Hartmann's procedure patients had higher 30-day mortality (7.6% vs 2.9%; $p = 0.011$). Overall 30-day morbidity was similar between HP and PADLI (55.4% and 48.6%; $p = 0.056$). When one examines individual complications, HP patients more often had postoperative pneumonia (7.1% vs 2.4%; $p = 0.032$), unplanned intubation (6.4% vs 2.4%; $p = 0.022$), and failure to wean off ventilator more than 48 hours (12.8% vs 4.8%; $p < 0.001$). The PADLI patients had worse outcomes in superficial surgical site infection (11.1% vs 6.2%; $p = 0.007$) and were discharged more frequently to home (77.9% vs 70.0%; $p = 0.001$). The length of hospital stay was similar between the 2 cohorts.

Multivariable logistic analyses: primary anastomosis with a diverting loop ileostomy in reference to Hartmann's procedure

Figure 2 is a Forest plot that illustrates the multiple backward stepwise multivariable logistic regression analyses performed. In summary, after adjusting for all

Table 1. Univariate Comparison of Demographics, Comorbidity, Preoperative Laboratory Values, and Intraoperative Variables Between Hartmann's Procedure and Primary Anastomosis with a Diverting Loop Ileostomy

Patient characteristic	Hartmann's procedure (n = 2,521)	PADLI (n = 208)	p Value
Demographic			
Female, n (%)	1,301 (51.6)	105 (50.5)	0.755
White,* n (%)	2,024 (91.1)	167 (96.0)	0.027†
Transferred,‡ n (%)			0.495
Admitted directly from home	2,002 (82.1)	161 (78.9)	
From outside emergency department	254 (10.4)	24 (11.8)	
From acute care hospital	182 (7.5)	19 (9.3)	
American Society of Anesthesiologists class ≥3, n (%)	1,824 (72.4)	137 (65.9)	0.045†
1 normal health	41 (1.6)	6 (2.9)	0.004†
2 mild comorbidity	655 (26.0)	65 (31.3)	
3 severe comorbidity	1,104 (43.8)	101 (48.6)	
4 life-threatening comorbidity	677 (26.9)	33 (15.9)	
5 moribund	43 (1.7)	3 (1.4)	
Age, y, median (IQR)	64 (54–74)	59 (49–70)	<0.001†
Age older than 60 y, n (%)	1,574 (62.4)	95 (45.7)	<0.001†
BMI, kg/m^2, median (IQR)§	29.1 (25.4–33.9)	30.1 (27.0–35.6)	0.006†
Obesity,§ n (%)	1,027 (43.9)	94 (50.0)	0.106
BMI <18.5 kg/m^2§	493 (21.1)	30 (16.0)	0.062
BMI ≥18.5 and <25 kg/m^2	41 (1.8)	0 (0.0)	
BMI ≥25 and <30 kg/m^2	778 (33.3)	64 (34.0)	
BMI ≥30 kg/m^2	1,027 (43.9)	94 (50.0)	
Comorbidity, n (%)			
Ascites	42 (1.7)	5 (2.4)	0.432
Congestive heart failure within 30 d before operation	75 (3.0)	0 (0.0)	0.012†
Diabetes mellitus with oral agents or insulin	311 (12.3)	23 (11.1)	0.589
Current smoker within 1 y	549 (21.8)	56 (26.9)	0.086
Dyspnea	224 (8.9)	11 (5.3)	0.076
Functional dependent‡	157 (6.3)	5 (2.4)	0.025†
Ventilator dependent	65 (2.6)	1 (0.5)	0.058
History of severe COPD	248 (9.8)	10 (4.8)	0.017†
Hypertension requiring medication	1,372 (54.4)	104 (50.0)	0.219
Acute renal failure	53 (2.1)	4 (1.9)	1.000
Currently on dialysis	51 (2.0)	2 (1.0)	0.431
Disseminated cancer	111 (4.4)	5 (2.4)	0.170
Open wound/wound infection	58 (2.3)	6 (2.9)	0.593
>10% loss body weight in last 6 mo	70 (2.8)	3 (1.4)	0.252
Steroid use for chronic condition	384 (15.2)	17 (8.2)	0.006†
Bleeding disorder	314 (12.5)	16 (7.7)	0.043†
Preoperative transfusion of ≥1 U of whole/packed RBCs within 72 h	52 (2.1)	9 (4.3)	0.034†
Systematic sepsis			0.015†
None	743 (29.5)	78 (37.5)	
Systemic inflammatory response syndrome	162 (6.4)	12 (5.8)	
Sepsis	1,336 (53.0)	107 (51.4)	
Septic shock	280 (11.1)	11 (5.3)	
Laboratory value			
Albumin <3 g/dL*	664 (30.8)	36 (21.2)	0.008†
Alkaline phosphatase >125 U/L§	291 (12.8)	15 (8.1)	0.064

(Continued)

Table 1. Continued

Patient characteristic	Hartmann's procedure (n = 2,521)	PADLI (n = 208)	p Value
Bilirubin >1.0 mg/dL[§]	662 (29.0)	52 (28.3)	0.841
Blood urea nitrogen >40 mg/dL[‡]	269 (10.9)	7 (3.4)	0.001[†]
Creatinine >1.2 mg/dL[‡]	692 (27.7)	39 (19.1)	0.008[†]
International normalized ratio >1.5[*,¶]	211 (13.1)	15 (12.0)	0.737
Platelets <150/μL[‡]	259 (10.4)	21 (10.1)	0.922
SGOT >40 U/L[*]	279 (12.8)	16 (8.8)	0.124
Sodium[‡]			0.412
<135 mmol/L	626 (25.0)	43 (21.0)	
≥135 and ≤145 mmol/L	1,836 (73.4)	159 (77.6)	
>145 mmol/L	39 (1.6)	3 (1.5)	
WBC[‡]			0.011[†]
$<4.5 \times 10^9$ per L	141 (5.6)	2 (1.0)	
>4.5 and $\leq 11 \times 10^9$ per L	740 (29.6)	72 (34.6)	
>11 and $\leq 15 \times 10^9$ per L	646 (25.8)	50 (24.0)	
>15 and $\leq 25 \times 10^9$ per L	823 (32.9)	65 (31.3)	
$>25 \times 10^9$ per L	150 (6.0)	19 (9.1)	
Intraoperative variable, n (%)			
Wound class			0.966
Clean	11 (0.4)	0 (0.0)	
Clean-contaminated	154 (6.1)	14 (6.7)	
Contaminated	218 (8.7)	18 (8.7)	
Dirty-infected	2,138 (84.8)	173 (84.6)	
Operation duration, min, median (IQR)	120 (91–156)	163 (114–212)	<0.001[†]
Operation complexity, min, median (IQR)	29.9 (27.8–40.3)	46.2 (40.0–54.4)	<0.001[†]
Colectomy-specific, n (%)			
Indication for operation			0.040[†]
Perforation	2,324 (92.2)	181 (87.0)	
Obstruction	97 (3.9)	16 (7.7)	
Bleeding	12 (0.5)	1 (0.5)	
Other	88 (3.5)	10 (4.8)	
Operative approach			0.007[†]
MIS	86 (3.4)	12 (5.8)	
MIS with assist	64 (2.5)	13 (6.3)	
MIS with conversion to open	102 (4.1)	11 (5.4)	
Open	2,268 (90.0)	172 (82.7)	
Other	1 (0.0)	0 (0.0)	
Chemotherapy within 90 d	109 (4.3)	3 (1.4)	0.043[†]

*Missing <20%.
†Statistically significant.
‡Missing <5%.
§Missing <10%.
¶Excluded from backward stepwise multivariable logistic regression model.
IQR, interquartile range; MIS, minimally invasive surgery; PADLI, primary anastomosis with a diverting loop ileostomy; SGOT, serum glutamic oxaloacetic transaminase.

preoperative variables (eg demographics, comorbidities, preoperative laboratory values, illness severity), as well as intraoperative and procedure-specific variables (eg wound classification), PADLI was not associated with any independent increase in 30-day mortality (odds ratio 0.21; 95% CI 0.03 to 1.58; p = 0.129) or overall 30-day morbidity (odds ratio 0.96; 95% CI 0.63 to 1.45; p = 0.834). Similarly, additional multivariable models

Table 2. Univariate Comparison of Postoperative Outcomes Between Hartmann's Procedure and Primary Anastomosis with a Diverting Loop Ileostomy

Postoperative outcome	Hartmann's procedure (n = 2,521)	PADLI (n = 208)	p Value
SSI, n (%)	416 (16.5)	40 (19.2)	0.311
Superficial SSI	157 (6.2)	23 (11.1)	0.007*
Deep SSI	51 (2.0)	6 (2.9)	0.404
Organ-space SSI	234 (9.3)	19 (9.1)	0.944
Wound disruption, n (%)	81 (3.2)	7 (3.4)	0.905
Pneumonia, n (%)	178 (7.1)	5 (2.4)	0.010*
Unplanned intubation, n (%)	160 (6.4)	5 (2.4)	0.022*
Pulmonary embolism, n (%)	37 (1.5)	5 (2.4)	0.292
Progressive renal insufficiency, n (%)	26 (1.0)	1 (0.5)	0.718
Acute renal failure, n (%)	65 (2.6)	1 (0.5)	0.058
Urinary tract infection, n (%)	50 (2.0)	3 (1.4)	0.795
Stroke/CVA, n (%)	17 (0.7)	0 (0.0)	0.635
Cardiac arrest requiring CPR, n (%)	48 (1.9)	1 (0.5)	0.176
MI, n (%)	46 (1.8)	1 (0.5)	0.259
Blood transfusion, <1 U packed/whole RBC intra- and postoperatively, n (%)	408 (16.2)	28 (13.5)	0.303
Systemic sepsis, n (%)	846 (33.6)	61 (29.3)	0.213
Sepsis	452 (17.9)	43 (20.7)	0.324
Septic shock	401 (15.9)	19 (9.1)	0.009
Failure to wean off ventilator for >48 h, n (%)	322 (12.8)	10 (4.8)	0.001*
Deep venous thrombosis, n (%)	91 (3.6)	3 (1.4)	0.099
Ileus, n (%)	830 (33.1)	54 (26.0)	0.035*
Infectious complication, n (%)	1,159 (46.0)	86 (41.4)	0.198
30-d overall morbidity, n (%)	1,397 (55.4)	101 (48.6)	0.056
30-d mortality, n (%)	192 (7.6)	6 (2.9)	0.011*
Hospital length of stay, d, median (IQR)	10 (7–15)	9 (7–14)	0.055
Readmission with 30 d, n (%)	224 (8.9)	23 (11.1)	0.294
Discharge disposition, n (%)			0.001*
Home	1,654 (70.0)	159 (77.9)	
Skilled nursing facility	489 (20.7)	20 (9.8)	
Rehabilitation facility	199 (8.4)	21 (10.3)	
Other	21 (0.9)	4 (2.0)	

*Statistically significant.
IQR, interquartile range; PADLI, primary anastomosis with a diverting loop ileostomy; SSI, surgical site infection.

demonstrated that PADLI was not independently associated with any increase (or decrease) in all postoperative complications, such as systemic sepsis, surgical site infection, and postoperative blood transfusion or hospital length of stay, except failure to wean off mechanical ventilation for more than 48 hours (odds ratio 0.35; 95% CI 0.12 to 0.99; p = 0.048).

DISCUSSION

In our study using the well-validated ACS NSQIP database, and its recently created colectomy-specific adjunct, we found that most surgeons in the US still perform HP for complicated acute diverticulitis requiring urgent or emergent operations, and that PADLI and HP have an overall similar profile of mortality, morbidity, and length of hospital stay, after adjusting for the differences in baseline demographics, comorbidities, severity of illness, and preoperative laboratory variables. To the best of our knowledge, this is the largest clinical (non-administrative database) study comparing the 2 procedures.

In recent years, several small prospective observation and randomized controlled trials compared PADLI and HP for emergent or urgent colectomy in acute diverticulitis and found, in general, similar results.[6-8] Specifically,

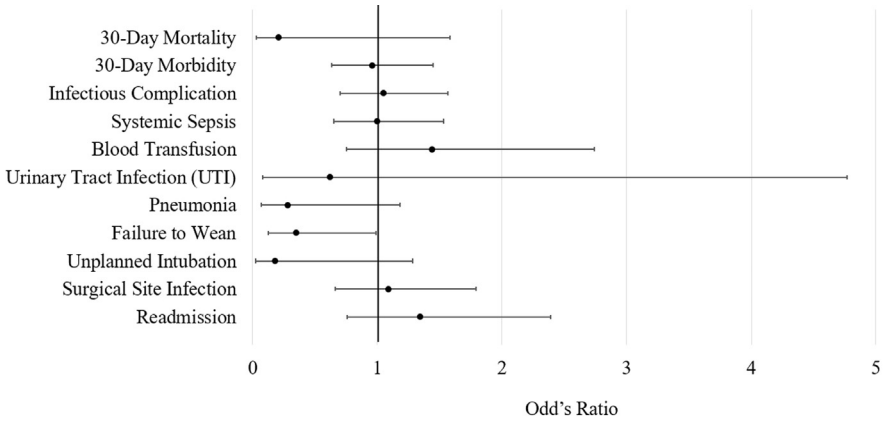

Figure 2. Forest plot of odds ratio of 30-day mortality, 30-day morbidity, and all major complications (reference is Hartmann's procedure).

both the study by Bridoux and colleagues[7] (DIVERTI randomized controlled trial) and the study by Oberkofler and colleagues[8] identified that PADLI and HP had similar mortality and morbidity rates, but noted that PADLI patients had higher stoma reversal rates than their HP counterparts. In addition, the latter study suggested that patients in the PADLI group had decreased operative time, length of hospital stay, and hospital cost compared with HP. These studies do support the findings of our study, that there are no significant differences in outcomes for PADLI and HP. Unfortunately, these studies have a very low number of randomized patients—62 total patients for the study by Oberkofler and colleagues and 102 total patients for the study by Bridoux and colleagues—to provide any solid conclusions.

There were other national comparisons between PADLI and HP using administrative database or ACS NSQIP database, but without colectomy specific variables.[10,12-14] These studies also suggest the absence of any significant mortality and morbidity differences between the 2 procedures. On close examination, many of these studies are excellent but are limited by a lack of clinical granularity and misidentification of HP vs PADLI patients. These are evident when the 2 existent ACS NSQIP studies are compared with ours, mainly due to the unavailability of, and therefore inability to use, the colectomy-specific ACS NSQIP database, as well as the less-than-strict use of CPT codes to identify HP and PADLI patients.

At present, the American Society of Colon and Rectal Surgeons states that PADLI can be considered in the emergency setting, depending on the patient's clinical status as well as the Hinchey classification. Our study supports that recommendation.[15] Whether HP or PADLI is more cost-effective in the long-term, considering rates and risks of either colostomy or ileostomy takedown, remains to be determined.

Our study has few limitations. First, despite our comprehensive algorithms to identify PADLI and HP, there is still potential inaccuracy inherent to the use of CPT codes; as such, we might have excluded a number of patients who did undergo HP or PADLI, but we opted for accuracy in identifying these patients and erred on the safe side in our inclusion/exclusion criteria. Second, as with all cohort studies, there are potentially some confounders (eg Hinchey class) that were not included in the database or analyses. Finally, the ACS NSQIP Colectomy Procedure Targeted Database does not collect information on eventual stoma reversal, so we were not able to compare it between HP and PADLI patients.

CONCLUSIONS

At present, surgeons are performing HP more widely than PADLI. When controlling for the patient population differences, PADLI appears to be at least a safe alternative to HP for certain patient populations. A large well-powered multicenter trial of HP vs PADLI might still be needed to study the outcomes differences between the 2 procedures and perhaps convince more surgeons of adopting PADLI as a first-line surgical procedure for the emergent management of acute diverticulitis.

Author Contributions

Study conception and design: Lee, Chang, El Hechi, Kongkaewpaisan, Bonde, Mendoza, Saillant, Fagenholz, Velmahos, Kaafarani

Acquisition of data: Lee, Kaafarani

Analysis and interpretation of data: Lee, Chang, El Hechi, Kaafarani

Drafting of manuscript: Lee, Kaafarani
Critical revision: Lee, Chang, El Hechi, Kongkaewpaisan, Bonde, Mendoza, Saillant, Fagenholz, Velmahos, Kaafarani

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Discussion

DR JOSEPH MULDOON (Evanston, IL): There remains a question of the best approach to perforated diverticulitis requiring urgent or emergent surgery. As identified in this study, patients with significant morbidity or comorbidities are often best treated by Hartmann's procedure (HP), but patients with Hinchey class III and IV with reasonable operative risk may be better treated with reanastomosis and proximal diversion. Several studies have shown a higher likelihood of stoma reversal and restoration of intestinal continuity in patients undergoing anastomosis with proximal diversion when compared with HP: significantly higher, at 90% vs about 50%. Though this approach has been championed in several studies because of the reported equivalence in mortality and significantly higher restoration of intestinal continuity, most are retrospective, and, as you mentioned, the prospective studies are fairly small.

Dr Kaafarani and colleagues used the American College of Surgeons-NSQIP database to evaluate 30-day outcomes for 3,100 patients with acute diverticulitis treated with HP vs primary anastomosis with proximal diversion. This study again suggests this approach is an option in appropriately selected patients. Unfortunately, we were unable to see the long-term outcomes, including stoma reversal rates, because of limitations of this database.

First, with regard to your patient selection in Table 1, why did you include patients who received preoperative bowel preparation and patients with toxic colitis? It would seem that patients who received a preoperative bowel preparation would fall almost more into an elective situation, and patients with toxic colitis can be a very broad category, including inflammatory bowel disease and infectious colitis. Second, are you comfortable assessing the safety and comparison of these procedures given the inherent bias of selection that occurs in these and you cannot control for? You are not necessarily measuring apples to apples. Finally, why do you think this is being used so infrequently in our population of surgeons given the fact that it has been studied reasonably well and shown to be fairly safe, especially in good-risk patients?

DR HAYTHAM KAAFARANI (Evanston, IL): Regarding your first question, with a few cases (less than 5% of patients still showed up with some bowel preparation or some colitis as part of the indication), we relied on using 2 ways to identify these patients. First, the emergence. I am not sure why there are a few cases. I would say about 20 patients showed up with some preparation. Probably the indication was not perforation to start with, and perhaps based on your question, the safe thing to do—I mean, it is such a small number of patients—is simply exclude them, and I do not think the analysis would change at all, but that will keep it clear.