Stapled versus hand-sewn: A prospective emergency surgery study. An American Association for the Surgery of Trauma multi-institutional study

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BACKGROUND: Data from the trauma patient population suggests handsewn (HS) anastomoses are superior to stapled (ST). A recent retrospective study in emergency general surgery (EGS) patients had similar findings. The aim of the current study was to evaluate HS and ST anastomoses in EGS patients undergoing urgent/emergent operations.

METHODS: The study was sponsored by the American Association for the Surgery of Trauma Multi-Institutional Studies Committee. Patients undergoing urgent/emergent bowel resection for EGS pathology were prospectively enrolled from July 22, 2013 to December 31, 2015. Patients were grouped by HS/ST anastomoses, and variables were collected. The primary outcome was anastomotic failure. Similar to other studies, anastomotic failure was evaluated at the anastomosis level. Multivariable logistic regression was performed controlling for age and risk factors for anastomotic failure.

RESULTS: Fifteen institutions enrolled a total of 595 patients with 649 anastomoses (253 HS and 396 ST). Mean age was 61 years, 51% were men, 7% overall mortality. Age and sex were the same between groups. The overall anastomotic failure rate was 12.5%. The HS group had higher lactate, lower albumin, and were more likely to be on vasopressors. Hospital and intensive care unit days, as well as mortality, were greater in the HS group. Anastomotic failure rates and operative time were equivalent for HS and ST. On multivariate regression, the presence of contamination at initial resection (odds ratio, 1.965; 95% confidence interval, 1.183–3.264) and the patient being managed with open abdomen (odds ratio, 2.529; 95% confidence interval, 1.492–4.286) were independently associated with anastomotic failure, while the type of anastomosis was not.

CONCLUSION: EGS patients requiring bowel resection and anastomosis are at high risk for anastomotic failure. The current study illustrates an apparent bias among acute care surgeons to perform HS techniques in higher-risk patients. Despite the individualized application of technique for differing patient populations, the risk of anastomotic failure was equivalent when comparing HS and ST anastomoses. (*J Trauma Acute Care Surg.* 2017;82: 435–443. Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic study, level II.

KEY WORDS: Emergency general surgery; anastomosis; bowel resection; stapled; handsewn.

The trauma literature has extensively explored the relationship between stapled (ST) and handsewn (HS) anastomotic techniques as they relate to anastomotic failure, with varying conclusions. In a retrospective analysis, Brundage and colleagues,[1] working with the Western Trauma Association Multi-Institutional Study Group, found that ST anastomoses appeared to have a higher leak and abscess rate when compared to HS. The author's previous single-institution retrospective study showed similar results.[2] However, in a multicenter prospective analysis sponsored by the American Association for the Surgery of Trauma (AAST), Demetriades et al.[3] found no difference in leak rates or abscess formation between the two techniques after penetrating injury to the colon.

In 2004, Catena and colleagues[4] reported the results of a randomized trial in patients undergoing emergency intestinal operations. They compared ST to HS techniques and found no difference in leak rate or mortality; they did however find that HS anastomotic techniques took longer to perform. More recently, Farrah et al.[5] have reported their single-institution retrospective experience examining emergency general surgery (EGS) patients, specifically. The overall anastomotic failure rate in the series was 11.1%, with HS anastomotic techniques having a lower leak rate than ST (6.1% vs. 15%). Additionally, they found operative times were shorter for those in the ST group when compared with HS.

In a 2012 Cochrane review, Neutzling and colleagues[6] examined this question in elective colorectal surgery and identified nine trials consisting of 1233 patients (622 ST and 611 HS). They found the evidence was insufficient to demonstrate superiority of ST or HS anastomotic techniques in elective colorectal surgery. However, they did conclude the following: "in risk situations, such as emergency surgery, trauma and inflammatory bowel disease, new clinical trials are needed".

Given these data and overall clinical equipoise, the aim of the current study was to determine the overall anastomotic failure rate for EGS patients undergoing urgent/emergent bowel resection and anastomosis, and to determine whether ST or HS anastomotic techniques are associated with lower failure rates. Additionally, patients managed with an open abdomen (OA) were specifically examined with the hopes of better determining the ideal time (immediate or delayed) and technique (ST or HS) for anastomosis creation. We hypothesized that the overall anastomotic failure rate would be high in the EGS patient population and would be higher for ST when compared with HS.

PATIENTS AND METHODS

The study was sponsored by the AAST's Multi-Institutional Studies Committee. Patients undergoing urgent/emergent (<24 hours after decision to operate) bowel resection and anastomosis,

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From the Mayo Rochester (D.S.M., M.Z.); Wake Forest (N.T.M., P.R.M.); University of Texas Southwestern–Parkland Hospital (K.A., H.A.P.); East Texas Medical Center (J.M.); Loma Linda (D.T., J.F.); Walter Reed National Military Medical Center (J.S.O); Vanderbilt (O.L.G.); Utah (T.E.); University of Texas Health Science Center - Houston (J.D.L.); University of Florida–Jacksonville (D.S.); University of Louisville (M.B.); Einstein (A.F., P.S.L.); Medical Center of Plano (M.M.C.); MUSC (B.J., J.S.); R Adams Cowley Shock Trauma Center (L.O.); University of Maryland School of Medicine (A.V.H., H.C.); and R Adams Cowley Shock Trauma Center at the University of Maryland School of Medicine (T.M.S., J.J.D.), Baltimore, Maryland.
This study was presented at the 75th annual meeting of the American Association for the Surgery of Trauma, September 14–17, 2016, in Waikoloa, Hawaii.
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by acute care surgeons, were prospectively enrolled from July 22, 2013, to December 31, 2015. Exclusion criteria included proximal diverting stoma creation at the time of intestinal resection and anastomosis, duodenal resection/anastomosis, elective operations performed by acute care surgeons within 24 hours of the decision to operate, trauma patients, prisoners, pregnancy, and patients 18 years or younger. After obtaining IRB approval, each institution was granted access to the AAST data entry portal via a unique logon and password. Data were entered electronically by investigators at the coordinating institutions, the principal investigator (B.R.B.) at the University of Maryland Medical Center, procured and analyzed the data, and distributed for review by all co-authors.

Data points were prospectively collected (demographic, clinical, laboratory, operative variables, and outcomes) by each institution. The choice to perform ST or HS anastomosis was left at the discretion of the operating acute care surgeon. No guidelines or protocols were suggested by the PI or the AAST so as to avoid any influence on practitioner decision-making. Anastomoses performed were classified as either ST or HS, and the location of the anastomosis was queried (small bowel to small bowel, small bowel to large bowel, large bowel to large bowel). Similar to previous works, an anastomosis with a ST common wall and a HS open end were classified as ST.[1,3,5] For the purposes of analysis, single-layer and double-layer HS techniques were grouped together. Similarly, linear and circular ST techniques were considered equivalent.

The data collection instrument contained the following indications for operation: small-bowel obstruction, perforated viscus/free air (defined as extraluminal gas on imaging study), “other,” mesenteric ischemia, incarcerated hernia, volvulus, gastrointestinal mass/cancer, peritonitis, appendicitis, perforated diverticulitis, or “more than one indication for operation.” In an attempt to account for preoperative comorbidities and other risk factors for anastomotic failure, Charlson Comorbidity Index (CCI)[7] was calculated in the standard fashion. Body mass index (BMI), age, sex, and baseline laboratory values (defined as the most immediate preoperative laboratories available) were recorded if available. The presence of intraoperative vasopressors (defined as any vasopressor usage in the operating room), intraoperative hypothermia (a single temperature <36°C), and any perioperative corticosteroid administration were recorded as dichotomous variables.

The primary outcome was anastomotic failure, which included: dehiscence of the anastomosis, perianastomotic abscess, or fistula formation. Similar to other studies,[1,5] anastomotic failure was examined at the anastomosis level, and only one failure was allowed per anastomosis and was defined as follows: (1) dehiscence of anastomosis identified during re-operative therapy or during radiographic imaging, (2) abscess identified during reoperative therapy or on radiographic imaging, (3) fistula documented in the medical record or based on physical examination findings. Operative time for anastomotic operation (entire operation time as recorded in the medical record), hospital and intensive care unit (ICU) length of stay (LOS), and mortality were all recorded as secondary outcomes. ST versus HS anastomoses were then compared.

The mode of initial operation (laparoscopic versus open) and conversion to open was additionally recorded. If the patient was managed with an OA, an additional set of questions were prompted, including the timing of anastomosis (at the index operation leading to OA or in a delayed fashion). Additionally, the indication was requested, with the options being damage control, excessive contamination, to facilitate second-look, abdominal decompression, or “other.” More than one indication could be chosen. If damage control was chosen, the presence of coagulopathy, acidosis, or hypothermia were queried.

Previously studied risk factors for anastomotic complications in the EGS population[5] (hypothermia, vasopressor usage, corticosteroid usage, ST vs. HS, CCI, contamination at initial operation, and OA management) were used for univariate and multivariate analyses. A logistic regression model was constructed using stepwise selection of variables and generalized linear mixed modeling was done to account for intrapatient and intrahospital correlation. Normally distributed variables were analyzed using Student's t test, whereas nonparametrically distributed variables were analyzed via Wilcoxon-Mann-Whitney U test, Fischer's exact, and Pearson's χ^2 tests were used where appropriate to assess categorical variables. A p value less than 0.05 was considered statistically significant. Using data from Farrah and colleagues,[5] we assumed a 10% difference in anastomotic complications between HS and ST anastomotic techniques. With an alpha of 0.05 and a power of 90%, we projected 224 patients in both the HS and ST groups.

RESULTS

Fifteen medical centers across the country enrolled patients. Enrolling centers included (alphabetically listed): East Texas Medical Center, Einstein, Loma Linda, Mayo Rochester, Medical University of South Carolina, University of Texas Southwestern/Parkland Hospital, Medical Center of Plano, University of Florida Jacksonville, University of Louisville, University of Maryland, University of Texas Health Science Center Houston, University of Utah, Vanderbilt, Wake Forest, and Walter Reed.

A total of 595 patients underwent 649 anastomoses (396 ST vs. 253 HS). The median age was 62 years (interquartile range [IQR], 49–74) and 305 (51%) were men. The mean CCI was 1 (SD, 1.8), and the overall mortality for the entire cohort

TABLE 1. Indication for Operative Intervention (Anastomosis-Level Analysis)

Indication	n (%)
Small-bowel obstruction	151 (23.3)
Perforated viscus/free air	70 (10.8)
Other	46 (7.1)
Mesenteric ischemia	45 (6.9)
Incarcerated hernia	39 (6.0)
Volvulus	38 (5.9)
GI mass/cancer	11 (1.7)
Peritonitis	9 (1.4)
Appendicitis	7 (1.1)
Perforated diverticulitis	4 (0.6)
>1 indication for OR	229 (35.2)

TABLE 2. Anastomosis-Level Demographic, Laboratory, and Intraoperative Characteristics (HS vs. ST)

Anastomotic Technique, n (%)	HS 253 (39)	ST 396 (61)	*p* Value
Sex, n (%)			
Male	131 (51.8)	200 (50.5)	0.75
Female	122 (48.2)	196 (49.5)	
Age, y	63 (52–74)	61 (47–74)	0.48
CCI	0 (0–2)	0 (0–2)	0.02
BMI, kg/m^2	27.7 (23.1–34.1)	26.4 (22.8–31.5)	0.03
Laboratory values			
Hgb (n = 645), g/dL	11.7 (9.6–13.5)	12.8 (10.7–14.6)	<0.01
WBC (n = 645)	11.7 (8.1–17.5)	10.9 (7.8–15.8)	0.17
Platelets (n = 645)	222 (163–307)	235 (182–294)	0.32
pH (n = 425)	7.4 (7.3–7.4)	7.4 (7.3–7.4)	0.84
INR (n = 425)	1.2 (1.1–1.4)	1.1 (1.0–1.3)	<0.01
Lactate (n = 425), mg/dL	2.1 (1.3–4.6)	1.6 (1.1–2.6)	<0.01
Base deficit (n = 425), mEq/L	−4.7 (−8.1 to −2.5)	−4.0 (−7.0 to −1.8)	0.09
Albumin (n = 445), g/dL	3.3 (2.6–3.9)	3.7 (3.0–4.1)	<0.01
Total bilirubin (n = 445), mg/dL	0.7 (0.4–1.2)	0.6 (0.4–0.9)	0.04
Serum Cr (n = 642), mg/dL	1.1 (0.8–1.7)	0.9 (0.7–1.2)	<0.01
BUN (n = 643)	19 (13–35)	16 (11–24)	<0.01
Intraoperative vasopressors, n (%)			
Yes	127 (50.2)	148 (37.4)	<0.01
Intraoperative hypothermia, n (%)			
Yes	80 (32.3)	136 (34.8)	0.51
Perioperative corticosteroids, n (%)			
Yes	44 (17.5)	59 (14.9)	0.39

Data presented as median (IQR), unless otherwise indicated. (n = x), indicates number of variables available for analysis if other than 649.

BUN, blood urea nitrogen; Cr, creatinine; Hgb, hemoglobin; pH, potential hydrogen; WBC, white blood cell.

was 7.7%. The most common single indication for operative intervention was small-bowel obstruction (23%), and 229 (35%) patients had more than one indication (Table 1). Ninety-two (15%) of the patients' operations started laparoscopically, and 85 (92%) of those were converted to open. The distributions of the anastomoses were as follows: 446 (72%) small bowel to small bowel, 139 (21%) small bowel to large bowel, and 44 (7%) large bowel to large bowel. Overall, the anastomotic failure rate was 12.5% (n = 81).

Patients in the HS and ST groups were similar in regards to sex and age, with a slightly higher CCI in the ST group and a higher BMI in the HS group. The HS group had a lower baseline hemoglobin level (four missing values), higher international normalized ratio (INR) (224 missing values), higher lactate (224 missing values), lower albumin (204 missing values), and higher BUN/Cr (6/7 missing values, respectively). Intraoperative hypothermia and perioperative corticosteroid usage were equivalent between the two groups, but perioperative vasopressor usage was higher in the HS group of patients (Table 2).

Without adjustment, HS anastomoses failed 15.4% of the time versus a 10.6% failure rate in the ST group ($p = 0.07$), with no difference in the type of failure (dehiscence, abscess, fistula) between the groups. There was no difference in failure rates based on the location of anastomosis (small bowel to small bowel, small bowel to large bowel, large bowel to large bowel), though colocolonic anastomoses had higher failure rates than small bowel to small bowel. Operative time was equivalent between the HS and ST groups (165 vs. 152 minutes; $p = 0.13$). Hospital LOS, ICU LOS, and mortality were all significantly higher in the HS cohort of patients (Table 3).

Preoperative albumin was collected on only 445 (69%) of patients and was thus not used in the final multivariate model; however, on univariate analysis, albumin was lower in patients with anastomotic failure (3.1 vs. 3.5, $p < 0.01$). Complete data were submitted for anastomotic technique (ST vs. HS), intraoperative vasopressor usage, intraoperative hypothermia, perioperative corticosteroid usage, contamination at initial operation, and whether or not the patient was managed with an OA (Table 4). On multivariate logistic regression, controlling for age, CCI, perioperative vasopressor usage, perioperative corticosteroids, and intraoperative hypothermia; only initial contamination (odds ratio [OR], 1.965; 95% confidence interval [CI], 1.183–3.264) and being managed with an OA (OR, 2.529; 95% CI, 1.492–4.286) were associated with anastomotic failure. Type of anastomosis was not associated with an increased risk

TABLE 3. Outcomes of HS Versus ST Anastomotic Techniques

	HS	ST	*p* Value
Anastomotic Failures, n (%)	39 (15.4)	42 (10.6)	0.07
Dehiscence	26 (66.7)	21 (50.0)	0.29
Abscess	11 (28.2)	16 (38.1)	
Fistula	2 (5.1)	5 (11.9)	
Failures by type, n (%)			
Small bowel to small bowel	31/204 (15)	25/262 (10)	0.06
Small bowel to large bowel	4/35 (11)	11/104 (11)	0.89
Large bowel to large bowel	4/14 (29)	6/30 (20)	0.53
Operative time, min	165 (120–218)	152 (104–222)	0.13
Hospital LOS, d	14 (9–24)	10 (7–18)	<0.01
ICU LOS, d	5 (0–13)	0 (0–5)	<0.01
Mortality, n (%)	36 (14.2)	20 (5.1)	<0.01

Data presented as median (IQR), unless otherwise indicated.

TABLE 4. Univariate Analysis of Risk Factors for Anastomotic Failure

	Anastomotic Failure	No Complication	*p* Value
Anastomotic technique			
HS	39 (15.4)	214 (84.6)	0.07
ST	42 (10.6)	354 (89.4)	
Intraoperative vasopressors	42 (51.9)	233 (41.0)	0.07
Intraoperative hypothermia	28 (34.6)	188 (33.7)	0.88
Perioperative steroids	16 (20.0)	87 (15.3)	0.29
Contamination at initial operation	41 (50.6)	166 (29.2)	<0.01
Managed with an OA	42 (52)	149 (26)	<0.01

Data presented as n (%).

TABLE 5. Comparison of OAs and Non-OA (Patients)

	OAs	Closed at Index (non-OA)	
	165 Patients	430 Patients	
	191 Anastomoses	458 Anastomoses	*p* Value
Age, y	63 (51–74)	61 (41–75)	0.30
Sex, n (%)			
Male	94 (57)	211 (49)	0.08
Female	71 (43)	219 (51)	
BMI	28.17 (24.01–34.69)	26.22 (22.33–31.76)	<0.01
CCI	0 (0–2)	0 (0–2)	0.51
Laboratory data			
Lactate	2.20 (1.3–3.3)	1.60 (1.1–3.0)	<0.01
INR	1.30 (1.1–1.5)	1.10 (1.0–1.3)	<0.01
Base deficit	−3.8 (−8.0 to −0.4)	−2.1 (−4.3 to −0.4)	<0.01
Intraoperative vasopressors, n (%)			
Yes	96 (58.2)	147 (34.2)	<0.01
No	69 (41.8)	283 (65.8)	
Intraoperative hypothermia, n (%)			
Yes	55 (33.9)	148 (34.8)	0.84
No	69 (41.8)	277 (65.2)	
Hospital LOS, d	19 (12–31)	9 (7–15)	<0.01
ICU LOS, d	8 (4–18)	0 (0–3)	<0.01
Mortality, n (%)	30 (18.2%)	16 (3.7%)	<0.01

Data presented as median (IQR), unless otherwise indicated.

of anastomotic failure (OR, 0.919; 95% CI, 0.554–1.526). Performing multivariate logistic regression in the 445 anastomoses with albumin data available, again only initial contamination (OR, 2.208; 95% CI, 1.233–3.951) and being managed with an OA (OR, 2.279; 95% CI, 1.195–4.349) were associated with failure of the anastomosis.

One hundred sixty-five patients were managed with an OA and had a total of 191 anastomoses (94 men [57%]). The median age of OA patients was similar to those managed without an OA (non-OA) (63 vs. 61 years). There were equivalent numbers of men and women between the two groups, and the CCI was the same. BMI was higher in those undergoing management with an OA. Regarding laboratory values, the lactate level was higher, INR was higher, and the base deficit was more negative in the OA group. Additionally, more OA patients were on vasopressors, and hospital and ICU LOS were greater. The mortality was significantly higher in the OA group (18.2%) when compared with those patients not managed with an OA (3.7%) (Table 5).

Damage control was listed as the indication for OA management in 72 (43.6%) of the OA patients. Of those, 25 (34.7%) were reported to have coagulopathy, 46 (63.9%) were reported to have acidosis, and 32 (44.4%) were reported to be hypothermic. Excessive contamination was cited for reason for OA in 19 (11.5%), to facilitate early reexploration in 125 (75.8%), for the purposes of abdominal decompression in 12 (7.3%), and "other" in 13 (7.9%). The overall anastomotic failure rate of patients managed with an OA was 22% (n = 42) versus 8.5% (n = 39) ($p < 0.01$) in patients closed at the index operation. There was no difference in the type of failure (dehiscence, abscess, fistula) between OA and non-OA patients. The failure rate of HS technique was 25.2% (n = 28), which was not statistically different than the ST anastomotic failure rate of 17.5% (n = 14) [$p = 0.20$]. Of the 191 anastomoses created in OA patients, 140 (73%) were performed in a delayed fashion (not on the index operation leading to OA) and 51 (27%) were performed at the index operation leading to OA. Delayed and nondelayed anastomoses had statistically similar anastomotic failure rates of 27.5% and 20%, respectively. Additionally, there was no difference in the type of anastomotic failure that occurred ($p = 0.535$) (Table 6).

DISCUSSION

In this population of EGS patients undergoing bowel resection and anastomosis in an urgent/emergent fashion, the overall anastomotic failure rate was 12.5 % in patients managed with a single-stage operation and was 22% in those managed with an OA. Unlike previous studies,[4,5] the operating time in patients with a HS anastomosis was the same as those that received an ST anastomosis. For those patients who managed with an OA, 73% of anastomoses were created in a delayed fashion with equivalent failure rates to those anastomoses created at the initial operation. Additionally, failure rates were equivalent between HS and ST techniques.

The primary finding of the current work is that patients managed with an OA and those with contamination at initial operation are at increased risk of anastomotic failure after urgent/emergent bowel resection and anastomosis. In this study, acute care surgeons performed HS anastomoses 39% of the time and performed these anastomoses in patients with greater BMIs, lower hemoglobin levels, higher INRs, higher lactates, lower albumins, and worse renal function than those managed with ST anastomoses. Additionally, patients managed with HS techniques were more likely to be on intraoperative vasopressor agents, had greater hospital and ICU LOS, as well as an almost threefold increase in mortality compared with patients that had ST techniques. It appears that acute care surgeons participating in SHAPES (Stapled vs. Handsewn: A Prospective Emergency Surgery Study) preferentially chose HS anastomotic techniques in patients they perceived to have an elevated burden of disease, and despite this elevated disease burden, patients had equivalent failure rates to those managed with ST techniques. Many of these variables are not yet determined at the time of

TABLE 6. Initial Anastomosis Versus Delayed Anastomosis (Not-Index Operation) for Anastomoses in Patients Managed With an OA

	Initial	Delayed	*p* Value
Patients	51 (26.7)	140 (73.3)	
Intraoperative vasopressors	21 (41)	91 (65)	0.003
Mortality	6 (11.8)	34 (24.3)	0.060
Any anastomotic failure	28 (20)	14 (27.5)	0.535
Dehiscence	19 (67.9)	7 (50.0)	
Abscess	7 (25.0)	5 (35.7)	
Fistula	2 (7.1)	2 (14.3)	

Data presented as n (%).

anastomosis (hospital/ICU LOS and mortality), and many are likely not taken into consideration in choosing an anastomotic technique (hemoglobin, INR, renal function).

Anastomotic leaks have been extensively studied in multiple populations, likely secondary to the clinically significant postoperative mortality rate that approaches 40% in some series.[8,9] Reporting of anastomotic failure rates in the literature is challenging to interpret given the patient population heterogeneity and varying anatomic location of anastomosis (small bowel vs. large bowel), but ranges from 2% to 12%, with higher rates typically seen in anastomoses involving the large bowel and rectum.[10–13] Two fairly recent studies have specifically focused on anastomotic failure in the nontraumatic, emergency surgical population. Catena et al. performed a randomized trial in patients undergoing emergent intestinal resection and found an overall leak rate of 8%, though the study population is not clearly defined. More recently, Farrah and colleagues retrospectively illustrated on overall failure rate of 11.1%, similar to the current study's failure rate of 12.5%. Farrah's work, similar to SHAPES, clearly defines the study population as an EGS population being managed by acute care surgeons, thus likely represents a more similar population.

Catena and colleagues'[4] study was significant for a longer operative time in the HS group of patients (HS, 180 ± 27 minutes vs. ST, 122 ± 30 minutes), similar leak rates (HS, 7.5% vs. ST, 8.4%), and equivalent mortalities (HS, 5.2% vs. ST, 6.6%). The anastomosis failure rates in the current study are substantially higher than those reported by Catena and colleagues (HS, 15.4% vs. ST, 10.6%), though the current work appears to agree with the finding that HS and ST techniques are equivalent. However, unlike the work by Catena, the mortality is nearly double (14.2%) in the HS group, along with higher BMIs, higher lactates, and lower albumin levels. Similarly, HS patients in the current study had more intraoperative vasopressor utilization as well as longer hospital and ICU LOS. This suggests a surgeon-derived bias toward performing HS anastomotic techniques in patients perceived to be more ill. On the surface, the current results may seem to contradict that by Farrah and colleagues,[5] who showed HS techniques to be superior to ST. However, we do believe that the current results show surgeon preference for the HS technique for the most critically ill patients, with equivalent failure rates between the two anastomotic techniques.

Compared with Farrah and colleagues'[5] article that had an 18% rate of OA management, the current series has a 28% rate. Catena et al.'s[4] randomized trial does not specifically mention OA management, but personal communication with the author has verified no patients were managed with an OA (personal communication with Dr. Catena via e-mail). Again, the fact that almost one in four patients was managed with an OA seems to reflect an overall increased burden of illness in the current multicenter study. The anastomotic failure rate in the current study (22%) is strikingly similar to the results of Farrah et al.[5] (24%), and performing the anastomosis in a delayed fashion, other than at index operation leading to OA, does not increase the failure rate in either analysis. Confirmation of this finding is of particular importance in the EGS patient population, as bowel viability is often questionable during index operation, whether due to underlying mesenteric vascular disease or bowel dilation. These results seem to confirm the equivalent nature of delayed versus immediate anastomosis in the EGS patient population, thus providing some support for "second-look" operations and delayed anastomosis creation.

This article represents the largest prospective study of EGS patients undergoing urgent/emergent bowel resection and anastomosis. However, this study is not without limitations. Missing laboratory data, specifically albumin, limit the ability to control for baseline nutritional deficits that may have been different between the ST and HS populations. Many participating centers simply do not perform preoperative albumin in this patient population, or it may not be available at the time of anastomosis. When multivariable logistic regression with available albumin is performed, the findings remain unchanged; however, previous literature must be taken into account that clearly shows hypoalbuminemia is a risk factor for anastomotic failure.[14,15] We are not able to comment on specifics of colonic anastomoses, such as location in the ascending, transverse, or descending colon, because we were limited in the amount of data which were feasible to collect. Though prospective in nature, SHAPES was not a randomized controlled trial, thus inherent bias in choosing anastomotic techniques is present; however, given the findings of the study, this bias toward HS anastomotic technique likely positively influences patient outcomes.

It is the opinion of the author, that a randomized controlled trial of ST versus HS anastomotic techniques in the EGS patient population would be a disservice to patients undergoing urgent/emergent bowel resection. Clinical experience has shown us that the EGS patient often has bowel wall edema, size mismatch between adjacent loops, bowel wall friability, and other inherent unique attributes that influences the operating surgeon to choose a HS anastomotic technique over that of a ST technique. The prevailing dogma amongst practicing acute care surgeons seems to favor the security of visualized individual suture placement over the "one-size-fits-all" staple height and placement rigidity of a stapler. Perhaps, this is the reason for similar anastomotic failure rates between HS and ST techniques, even when patients in the HS group appear to be more physiologically compromised. Placing a surgeon in the situation of being forced to use a ST technique, dictated by randomization, when he or she believes a sutured anastomosis is indicated, does not appear to be the logical next step to follow the SHAPES initiative.

EGS bowel resection and anastomosis is a unique entity with a failure rate that exceeds those reported by other surgical subspecialties. As emergency surgery by itself is a risk factor for anastomotic failure, this is not a revelation.[16–18] In patients managed with an OA and in those with gross contamination of the peritoneal cavity at initial operation, the acute care surgeon should be aware that the patient is at increased risk for anastomotic failure and take appropriate surveillance measures in anticipation of such a potentially mortal complication. In the current study, ST versus HS anastomotic technique did not have a statistically significant association with failure of the anastomosis. However, acute care surgeons participating in the SHAPES study appear to favor the HS technique in patients with an elevated disease burden, and in doing so, have achieved equivalent anastomotic failure rates despite performing this technique in patients with a higher disease burden.

AUTHORSHIP

B.R.B. performed the literature search. B.R.B., L.O.M., A.H., H.C., T.M.S., and J.J.D. contributed to the study design. B.R.B., D.S.M., M.Z., N.T.M., P.R.M., K.A., H.P., J.M., D.T., J.F., J.S.O., O.L.G., T.E., J.D.L., D.S., M.B., A.F., P.L, M.M.C., B.J., J.S., L.O.M., A.H., H.C., and J.J.D. contributed to data acquisition. B.R.B., D.S.M., M.Z., J.S., H.P., N.T.M., O.L.G., L.O.M., A.H., H.C., and J.J.D. contributed to analysis and interpretation of data. B.R.B., D.S.M., M.Z., N.T.M., P.R.M., K.A., H.P., J.M., D.T., J.F., J.S.O., O.L.G., T.E., J.D.L., D.S., M.B., A.F., P.L, M.M.C., B.J., J.S., L.O.M., A.H., H.C., T. M.S, and J.J.D. contributed to drafting and critical revision of the manuscript.

DISCLOSURE

The authors declare no conflicts of interest.

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DISCUSSION

Dr. Gregory J. "Jerry" Jurkovich (Sacramento, California): Thank you for the privilege of and the opportunity of discussing this important paper. It is from, of course, the AAST Multi-Institutional Trials Committee and you have just heard the largest study on the outcome of bowel anastomosis in the emergency general surgery population ever presented.

I think what's notable is that it is presented on the opening day of the world's premier trauma society. I believe that's a testament to the importance of an acute care surgeon as a practice paradigm and an academic focus of this society and I applaud the organization for that.

But the paper is notable for a number of other aspects, as well: 15 centers, almost 600 patients collected over the past 2.5 years, with a very contemporary analysis and presentation to us. It's quite up-to-date. And I applaud the Program Committee for that as well.

The data presented reveal that small bowel obstructions and perforations, mesenteric ischemia, hernia, and volvulus are the dominant reasons for operations, bowel resections, and anastomoses.

An overall mortality rate of 8% and an anastomotic complication rate of 12.5% should emphasize the dire nature of these operations and the need for meticulous operative as well as surgically directed perioperative care in these patients. We, as surgeons, must pay attention to all aspects of care in these patients.

The authors conclude that today's acute care surgeons are selective in the anastomotic type, choosing handsewn anastomosis in the more critically-ill patients and that this selection bias results in an equal anastomotic complication rate.

But without adjusting for the factors known to affect anastomotic breakdown the handsewn anastomoses do, indeed, have a higher rate of complications; and this higher rate persists, although not in a statistically-significant fashion, even after the adjustment is made.

This, of course, is the bane of a non-randomized trial trying to adjust for patient differences. The data leaves me wondering if I really have a better understanding of the difference in handsewn versus stapled anastomoses in the emergency setting.

Just briefly, stapling was first introduced in anastomotic technique in the early 1900s, first in Hungary. It was not until Mark Ravitch brought the technique back from Moscow in the 1960s and that the medical device industry developed mass production of stapled devices in the United States that it really took hold.

In 1977 a couple, Jameson and Pamela Chassin from NYU, presented a very large paper, 800 operative procedures on the GI tract using the stapled device, and concluded that safety was equivalent. And from that paper onward the use of staplers has taken off.

The authors have nicely introduced the background to us and where this emanated from and why there is a question about handsewn versus stapled. So I will then ask the following questions of the authors.

First and foremost, are you confident in the statistical methodology you have used to adjust for real differences in these two patient populations? In other words, are there other statistical techniques other than a multivariate analysis that might help better compare these definitely divergent populations?

I would suggest you exclude colon-to-colon anastomosis from this study and see if it would alter the results. It's a totally different operation. It's a different outcome and data have shown that. There are too few of them to involve so I would just exclude them from the study, as has been done with separate Cochrane analyses.

If the bias is toward selecting handsewn anastomosis and that is really beneficial in this EGS population, how are we to know which patients the handsewn is preferred on? Is this simply surgical judgment? And how in the world do we teach that skill to the selection of anastomotic techniques?

I will conclude by noting that I received the paper in plenty of time to consider it for this meeting and recommend for you all the discussion to read and consider.

It is thoughtful, perhaps controversial, but I believe accurately reflects the current state of our practice in this important patient population.

Again, thank you for the privilege.

Dr. Kimberly A. Davis (New Haven, Connecticut): Brandon, very nicely presented. My question revolves around those patients with open abdomens.

Can you give us some insight as to why the study had so many patients requiring small bowel anastomosis who were managed with the open abdomen technique rather than primary closure? Was the primary pathology ischemia that required a second look, or patient with a high volume contamination, or another reason that the operating surgeon elected damage control? And is there a way, then, to avoid the open abdomen and potentially lower the anastomotic complications thereafter? Perhaps more liberal use of damage control resuscitation, a higher tolerance for postoperative abscess requiring drainage? Thank you.

Dr. David Livingston (Newark, New Jersey): Brandon, that was excellent. Again, a little bit more on the open abdomen. With respect to when you actually got these patients closed or if you got them closed and if you can't close them on the second go-around, are you recommending that all of these patients should be diverted? Obviously, if they have distal small bowel or colon.

Dr. Paula Ferrada (Richmond, Virginia): Brandon, congratulations on a great paper. My question is about inherent patient disease. Did you find any difference in fluid status, fluid overload, or sarcopenia?

Furthermore, was there a difference in the time that the patient remained with an open abdomen regarding anastomosis leak? Thanks.

Dr. H. Gill Cryer (Los Angeles, California): I applaud your study and I think that one of the things that we showed about ten years ago was handsewn anastomosis was clearly superior in a group of patients. I'm not sure we'd have that same result today and the reason is the following.

I was asked to come to the operating room a year ago or so by a new colorectal surgeon at our institution because they had had an anastomotic failure and needed a handsewn anastomosis and wanted a senior surgeon to help him do one. When I questioned him, you know, basically today's trainees probably do a handful of handsewn anastomoses whereas some of the senior surgeons in the audience have done thousands. And I think that, in today's world, what really transpires is that you do the anastomosis that you feel you are best at in a high-risk situation.

So I just wondered if you had any measure or the ability or think that in any future study you'd be able to have some measure of experience of the people doing the handsewn anastomoses? Thank you.

Dr. Ben L. Zarzaur, Jr. (Indianapolis, Indiana): My question is: did you look at the time to failure?

And then the second question, related to the first, is there was a mortality difference in the handsewn versus the stapled, what if all those patients who had handsewns died as a result of their leaking anastomoses? That might change your results a little bit, so just wondering if you could make a comment on that.

And my congratulations on the great study.

Dr. Brandon R. Bruns (Baltimore, Maryland): I'd like to thank Dr. Jurkovich for his comments and thank you all for your questions.

To address the first question regarding statistical methodology and adjustment, I think it's difficult to adjust for the clinical variability and heterogeneity that we see in emergency general surgery patients in general.

I'm not sure that statistics are going to give it a fair shake. That's why I think the most impressive thing that we found was just in the sicker patients that got the handsewn technique, their accrued difference, there was no difference.

I do think propensity scoring as a way to maybe look at this data down the road would be an interesting proposition.

Regarding colocolonic anastomoses and techniques, we had 44 colocolonic anastomoses out of 649 with a 29% failure rate for handsewn and 20% for stapled. I do agree that it's such a small number that probably taking it out, I'm not sure it would affect the results.

I would say, though, I can't remember the last time in one of these sick, urgent or emergent EGS patients who is undergoing a colonic operation where I actually put them back together, which may address a question that comes up later.

And then regarding the bias towards handsewn and how do we teach this skill, in these patients in the emergency general surgery population, I kind of let the residents choose if we do stapled or handsewn, as long as they choose handsewn, because I just feel like it is vastly superior.

And to speak to some of the other comments, like how do we teach the skill, I mean if we're not doing it, the residents are not doing it, they're not going to have any exposure to it.

To address Dr. Davis' question, why so many open abdomens, the most common indication was damage control. This is all in the manuscript. And I believe 20% were for second looks. We're actually looking at that at the institution level to figure out how many of those actually had further bowel resection and anastomoses, if there was actually any need to keep them open, because I do agree that we're keeping more and more people open and it is the bane of my existence.

I'm trying to get us to close them, but you know our preliminary data does seem to suggest that we are resecting bowel at the second look or the second look operations.

Dr. Livingston, diversion, I guess I kind of let my bias be exposed earlier when I talked about the colon in the sick emergency general surgery patient. I don't want to say never, but I don't remember putting a lot of those people back together, because I just think the risk of failure and the consequences of failure are so high.

And, Dr. Ferrada's question about fluid status and sarcopenia, unfortunately we were limited by the number of variables we could collect by the AAST, just for cost constraints, so we were not able to look at that.

Experience of surgeon, we do have that data. I do want to get into it because that was a variable we collected as far as who performed the anastomoses.

And Dr. Zarzaur's question about time to failure, unfortunately, again, not to take the easy road out, but we were not able to collect that variable because of restraints as far as the online data collection instrument.

Thank you all.

