Chapter 28 Surgery for Acute Complicated Diverticulitis: Hartmann vs. Primary Anastomosis

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Introduction

Acute diverticulitis is a significant and growing problem within the United States, accounting for over 160,000 hospitalizations per year and 875,000 days of inpatient care [1]. Rates of admission for acute diverticulitis are increasing, especially in the younger population [1, 2]. While the vast majority of cases can be managed without surgery, approximately 14% require surgical intervention [1].

Historically, the most commonly performed operation performed for sigmoid diverticulitis is a Hartmann's procedure, in which the diseased segment of bowel is resected and an end colostomy formed [3]. As a surgical option, the Hartmann's procedure eliminates the risk of anastomotic complications at the time of initial surgery. By delaying anastomosis until there is complete resolution of pelvic inflammation, the risk of anastomotic leak is theoretically minimized. The risk of subsequent operation for restoration of bowel continuity is not without its own morbidity, however, with reported anastomotic leak rates of up to 30 %, and a reported mortality of up to 14.3 % [3–9]. As a result of the burden associated with colostomy reversal, a significant number of patients will never have the colostomy reversed, resulting in a permanent stoma [10, 11].

The natural alternative to a Hartmann's procedure is resection with primary anastomosis. The goal of this approach is to reduce the morbidity and mortality associated with the reversal of Hartmann's procedure, while maintaining an acceptable level of risk associated with anastomosis at the time of an urgent operation [6, 12]. With the intent of minimizing this risk, surgeons may choose to employ a defunctioning ostomy. Defunctioning ostomies (either loop ileostomy or loop colostomy)

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may serve to reduce rates of anastomotic leak while lowering the burden of the subsequent reoperation and restoration of gastrointestinal continuity.

The choice of which of these operations is controversial, and depends upon patient and surgeon factors. Current guidelines published by the American Society of Colon and Rectal Surgeons recommend immediate resection in the setting of purulent or fecal peritonitis (Hinchey III and IV), but do not offer any distinct guidance regarding the decision between Hartmann's procedure or primary anastomosis [13]. In this chapter, studies published over the last 20 years are evaluated to decide which operation (Hartmann's vs. primary anastomosis) should be preferred in treating acute diverticulitis. Options such as laparoscopic lavage have been intentionally excluded as the purpose of the chapter is to compare Hartmann's procedure to a primary anastomosis.

Methods/Search Strategy

To identify articles for inclusion in this review, we searched the MEDLINE database. The primary goal was to identify studies reporting outcomes of patients with acute diverticulitis who underwent surgical treatment with either Hartmann's procedure or primary anastomosis. Case reports, case series with 20 or fewer patients, case series with less than 10 patients in either of the intervention groups, and studies where no novel patient outcomes were reported (e.g. review articles) were excluded. Systematic reviews and meta-analyses were included, but considered separately.

We started our search by querying for diverticulitis, Hartmann and anastomosis as keywords, in the following orientation: ("diverticulitis" AND ["Hartmann" OR "anastomosis"]). The following limits were placed on the search: articles written in English, involving humans and published from January 1, 1995 to 2016. This initial search strategy yielded 295 articles. Abstracts of all articles were reviewed, as well as full text when a study potentially met the inclusion criteria. References from articles retrieved through this query were also examined for inclusion. A total of 24 articles were eligible for the final review.

Pt population	Intervention	Comparator	Outcome studies
Pts with complicated	Primary anastomosis (with	Hartmann's	Morbidity,
diverticulitis	or without diversion)	procedure	mortality

Results

The articles included in this review were individually analyzed for quality of evidence as per the GRADE criteria [14]. The results of the search are listed in Table 28.1.

A total of 24 articles (2 RCTs, 2 meta-analyses, 3 large database studies, 2 systematic reviews, 2 prospective cohort studies and 13 retrospective cohort studies) were reviewed. Analysis of the results based on study types and outcomes are summarized below:

Table 28.1 Summary	of all stu	Table 28.1 Summary of all studies included in this review					
			Patients	Patients	Patients		Evidence
Author	Year	Study design/data source	(HP)	(PA)	(PAD)	Author's conclusion	quality
Oberkofter [15]	2012	RCT	30	I	32	No difference in primary outcomes between HP and PA ^a	Low
Binda [16]	2012	RCT	34	56	1	No difference in primary outcomes between HP and PA ^a	NA
Jafferji [17]	2014	Retrospective Cohort Study	74	20	32	PA is underutilized	Very low
Hergoz [18]	2011	Retrospective Cohort Study	19	21	1	PA superior to HP with lower morbidity and mortality	Very low
Miccini [19]	2011	Retrospective Cohort Study	85	28	I	No difference in morbidity between PA and HP	Very low
Trenti [20]	2011	Retrospective Cohort Study	60	22	5	PA is safe with no difference in morbidity or mortality between PA and HP	Very low
Thornell [21]	2011	Retrospective Cohort Study	82	24	1	Randomized trial needed to accurately answer this question	Very low
Mueller [22]	2011	Retrospective Cohort Study	26	36	11	Decision to make anastomosis should be made on patients general condition, not local factors	Very low
Zingg [23]	2010	Retrospective Cohort Study	65	35	11	PA is not superior to HP. Diversion should be considered if PA is performed	Very low
Vermeulen [24]	2007	Retrospective Cohort Study	139	45	16	PA is not inferior to HP in carefully selected patients	Very low
Stumpf [25]	2007	Retrospective Cohort Study	30	36	I	PA is safe in selected patients	Very low
Zorcolo [26]	2003	Retrospective Cohort Study	86	29	I	PA is safe and comparable to HP	Very low
Blair [27]	2002	Retrospective Cohort Study	64	28	5	PA is safe	Very low
Gooszen [28]	2001	Retrospective Cohort Study	28	I	32	Both PA and HP equivalent	Very low
Wedell [29]	1997	Retrospective Cohort Study	15	10	4	PA superior to HP	Very low

(continued)

 	;	-	Patients	Patients	Patients		Evidence
Author	Year	Study design/data source	(HH)	(FA)	(DAD)	Author's conclusion	quality
Regenet [30]	2003	Prospective Cohort Study	33	27	I	PA has less morbidity than HP	Very low
Schilling [31]	2001	Prospective Cohort Study	42	13	Ι	PA has lower cost than HP	Very low
Tadlock [32]	2013	Retrospective Cohort Study NSQIP	991	285	38	PA and PAD are safe compared to HP	Low
Masoomi [33]	2012	Retrospective Cohort Study NIS	56,875	39,023	3361	PA with diversion is superior to HP	Low
Gawlick [34]	2012	Retrospective Cohort Study NSQIP	1678	340	I	No difference in morbidity and mortality between PA and HP	Low
Cirocchi [35]	2013	Systematic review plus meta-analysis	246	174	I	No conclusion could be drawn as evidence Low quality low	Low
Constantinides [36] 2006	2006	Meta-analysis	416	547	I	Overall reduced mortality in PA group compared to HP	Low
Abbas [37]	2006	Systematic review	526	358	Ι	PA compares favorably to HP	Very low
Salem [38]	2004	Systematic review	1051	431	93	PA is a safe alternative to HP	Very low
HP Hartmann's proced	lure, NIS	Nationwide Inpatient Sample, NS	QIP Nation	al Surgical (Quality Impr	HP Hartmann's procedure, NIS Nationwide Inpatient Sample, NSQIP National Surgical Quality Improvement Program, PA primary anastomosis, PAD primary	PAD primary

anastomosis with diversion, RCT randomized controlled trial ^aTrial prematurely terminated due to poor patient accrual

Table 28.1 (continued)

Randomized Control Trials (RCTs)

Two RCTs have been completed comparing outcomes between Hartmann's procedure and primary anastomosis in patients undergoing surgery for acute diverticulitis [15, 16]. These studies, however, fare poorly on the Cochrane Collaboration's tool for assessing risk of bias [39]. Additionally, both studies were terminated prematurely due to lack of accrual of patients.

Oberkofler et al. conducted a multicenter RCT in Switzerland to compare Hartmann's and primary anastomosis with loop ileostomy in patients with left-sided diverticulitis [15]. Their analytic approach considered the initial operation together with the subsequent ostomy reversal. Their power analysis included a very liberal estimate of expected differences in complication rates (40% for primary anastomosis, 80% for Hartmann's), and estimated that 68 patients should be enrolled. During the 3 years that the study was conducted, the researchers were only able to recruit a total of 62 patients (30 in Hartmann's and 32 in primary anastomosis+ileostomy group). In addition, 52 potential study patients were not assessed for eligibility because of the surgeons' choice not to enroll patients resulting in the potential for significant selection bias [15]. Their analysis revealed differences in several endpoints in favor of primary anastomosis with loop ileostomy. Only 15 of 26 (58%) end colostomies (after Hartmann's procedure) were eventually reversed, whereas the stoma reversal rate after ileostomy was significantly higher at 90 % (26/29, P < 0.012). Diverting ileostomies were reversed much earlier than the end colostomies after Hartmann's procedure (median 3 months vs. 6 months, respectively). The rate of severe complications (20% vs. 0%, P=0.046), as well as the total number of complications per patient (median 1 vs. median 0, P < 0.001), was significantly higher after reversal of Hartmann's procedure (colostomy) compared to ileostomy reversal. Anastomotic dehiscence, sepsis, and bleeding occurred only after reversal of the end colostomy. Furthermore, the duration of the operation (183 min vs. 73 min, P < 0.001) as well as the hospital stay (9 days vs. 6 days, P=0.016) was significantly longer after reversal of Hartmann's procedure. Of note, all the advantages of primary anastomosis with diverting ileostomy relate to the reversal operation.

Binda et al. from Norway conducted a multicenter RCT, but terminated it prematurely as they could recruit only 15% of the target sample size (300 patients in each group) in 9 years [16]. No conclusions could be drawn from this study.

Meta-analyses

Two meta-analyses have been performed that examined evidence regarding outcomes in patients undergoing Hartmann's procedure vs. primary anastomosis. The first of these, conducted by Constantinides et al. in 2006 included a total of 15 studies; 10 of these studies were published between 1984 and 1995 and 5 after 1995 – these 5 studies are a part of our review [36]. Results from this meta-analysis show lower mortality with primary anastomosis than with Hartmann's operation, (4.9% vs. 15.1%). Another meta-analysis of 14 studies was performed by Cirocchi et al. in 2013, and also found lower mortality rates with primary anastomosis than Hartmann's procedure (9.8% vs. 22.0%) in the treatment of acute diverticulitis. The authors, however, found that the heterogeneity of the included studies was very high and recommended that their findings be interpreted with caution [35].

Despite the intuitive appeal of relying on meta-analyses as a quantitative synthesis of existing evidence, there is good reason to discount the findings from these two studies. First, the technique of meta-analysis does not apply well to small, non-randomized studies with heterogenous populations/interventions. This limitation was articulated nicely in the study performed by Cirocchi [35]. Second, these studies are ambiguous as to whether they are estimating the clinical burden of the initial operation or the initial operation plus any subsequent operations (to restore intestinal continuity).

Database Studies

Three studies have been conducted using secondary databases in order to compare outcomes of primary anastomosis vs. Hartmann's procedure for acute diverticulitis [32–34].

In 2012, Gawlick et al. published a study using patient data from the NSQIP database in 2005–2009 to analyze 2018 patients undergoing surgery for acute diverticulitis [34]. This study used wound classification (contaminated and dirty) as a surrogate marker for severity in patients who underwent emergent surgery with a diagnosis code of diverticulosis or diverticulitis. The study found no significant difference in the risk of infectious complications, return to the operating room, prolonged ventilator use, death, or hospital length of stay between Hartmann's procedure and primary anastomosis with diversion. In examining the subgroup of patients where the operation was classified as dirty/infected, however, the adjusted mortality rate was twice as high when primary anastomosis with diversion was performed compared to the Hartmann's procedure.

Also in 2012, Masoomi et al. published a study using discharge data from the NIS between 2002 and 2007 to analyze 99,259 patients undergoing primary anastomosis with diversion vs. Hartmann's procedure for acute diverticulitis [33]. This study found a lower complication rate in the primary anastomosis (plus diversion) group compared with the Hartmann's group (primary anastomosis: 39.06 % vs. Hartmann's: 40.84 %; p=0.04). Mortality was lower in the primary anastomosis group (3.99 % vs. 4.82 %, p=0.03). However, patients in the Hartmann's group had a shorter mean length of stay (12.5 vs. 14.4 days, p<0.001) and lower mean hospital costs (USD 65,037 vs. USD 73,440, p<0.01) compared with the primary anastomosis group. This study, while based on a very large cohort of patients, may suffer from issues regarding the granularity and accuracy of administrative coding. The International Classification of Disease (ICD) coding scheme is not a perfect system in terms of describing the type of operation performed, and there is the potential that

many of the patients in this study were mischaracterized in terms of the type of surgical care they received.

In 2013, Tadlock et al. published a study using patient data from the NSQIP database in 2005–2008 to analyze 1313 patients undergoing surgery for acute diverticulitis [32]. Three operative approaches were analyzed: Hartmann's procedure, primary anastomosis without diversion, and primary anastomosis with diversion. In this study, the 30-day mortality was 7.3%, 4.6%, and 1.6%, respectively (P=0.163), while surgical site infections occurred in 19.7\%, 17.9%, and 13.2% of patients (p=0.59). In addition, the three groups did not have significant differences in surgical infectious complications, acute kidney injury, cardiovascular incidents, or venous thromboembolism after surgery. The authors of this study concluded that primary anastomosis in the acute setting is a safe alternative to a Hartmann's procedure, with no significant difference in mortality or postoperative surgical site infections.

As with meta-analyses, the results from large database studies should be interpreted with caution. Statistical differences in outcomes may not always be clinically significant due to the large sample sizes. This is illustrated by the small difference in complication rate between the primary anastomosis group (39.06%) compared with the Hartmann's procedure group (40.84%) in the NIS study above which was statistically significant (p=0.04). More importantly, the translation of clinical phenomena into accurate representation in codes (ICD or otherwise) may lead to inaccuracy, bias, and confounding.

Retrospective/Prospective Cohort Studies

We reviewed 13 retrospective cohort studies and 2 prospective observational studies examining patient outcomes with Hartmann's vs. primary anastomosis [17–31, 40]. The quality and sample size vary widely, and taken together do not provide significant guidance regarding the central topic of this chapter.

Focus on Mortality

All studies, except two [19, 21] reported procedure-specific mortality. The mortality data from the studies included in this review are compiled in Table 28.2.

Most studies did not find a statistically significant difference in mortality between Hartmann's procedure and primary anastomosis. The three studies which showed a statistically significant difference in mortality were by Masoomi et al., Trenti et al. and Mueller et al. [20, 22, 33]. Masoomi's study analyzed a discharge database (NIS) and is not the best method for clinical assessment of cause specific mortality [33]. The study by Trenti et al. is a retrospective chart review with small patient numbers and an unusually high mortality rate (45% mortality overall). Authors of

Author	Year	HP (n/N) (%)	PA (n/N) (%)	Ρ	HP (n/N) (%)	PAD (n/N) (%)	Ρ
Jafferji [17]	2014	1/74 (1.4%)	0/20 (0 %)	NS	1/74(1.4%)	0/32 (0%)	NS
Tadlock [32]	2013	72/991 (7.3%)	13/285 (4.6%)	0.465	72/991 (7.3%)	1/38 (2.6%)	0.479
Cirocchi [35]	2013	54/246 (22%)	17/174 (9.8%)	0.02	I	I	NA
Oberkofter [15]	2012	4/30 (13.3%)	1	NA	4/30 (13.3 %)	3/32 (9.4%)	NS
Binda [16]	2012	1/34 (2.9%)	6/56 (10.7%)	0.24	1	1	NA
Toro [41]	2012	139/800 (17.4%)	38/1010 (3.8%)	NA	139/800 (17.4%)	11/153 (7.2%)	NA
Masoomi [33]	2012	2741/56,875 (4.8%)	NR	NA	2741/56,875 (4.8 %)	134/3361 (4%)	0.03
Gawlick [34]	2012	89/1674 (5.2%)	25/340 (7.4%)	NS	1	1	NA
Hergoz [18]	2011	6/19 (31.6%)	1/21 (4.8%)	0.15	1	1	NA
Miccini *[19]	2011	-/85	-/28	NA	1	1	NA
Trenti [20]	2011	27/60 (45%)	2/22 (9.1%)	0.001	27/60 (45%)	NR	NA
Mueller [22]	2011	7/26 (26.9%)	2/36 (5.6%)	0.008	7/26 (26.9%)	0/11 (0%)	NR
Zingg [23]	2010	19/65 (29.2%)	8/35 (22.9%)	0.156	19/65 (29.2%)	0/11 (0%)	NR
Vermeulen [24]	2007	47/139 (33.8%)	6/45 (13.3%)	<0.01	47/139 (33.8%)	1/16 (6.3%)	<0.01
Stumpf [25]	2007	5/30 (16.7%)	0/36 (0%)	0.025	I	I	NA
Constantinides [36]	2006	63/416 (15.1%)	27/547 (4.9%)	0.13	1	1	NA
Abbas [37]	2006	102/526 (19.4%)	32/358 (8.9%)	NA	1	1	NA
Salem [38]	2004	198/1051 (18.8%)	56/569 (9.8%)	NA	198/1051 (18.8%)	9/93 (9.7%)	NA
Regenet [30]	2003	4/33 (12.1 %)	3/27 (11.1%)	0.9	I	I	NA
Zorcolo [26]	2003	19/86 (22.1%)	3/29 (10.3%)	0.3	1	1	NA
Blair [27]	2002	13/64 (20.31%)	3/33 (9.1%)	0.2	13/64 (20.31%)	NR	NA
Gooszen [28]	2001	6/32 (18.8 %)	1	NS	6/32 (18.8%)	5/28 (17.9%)	NS
Schilling [31]	2001	4/42 (9.5%)	1/13 (7.7%)	0.9	1	1	NA
Wedell [29]	1997	4/15 (26.7 %)	0/10 (0%)	NR	4/15 (26.7%)	1/4 (25%)	NR

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this study attributed the high mortality to the fact that surgical quality was heterogeneous in their institution, with a disproportionate number of deaths being in the patients operated upon by general surgeons. This study is limited by selection bias and lack of generalizability. In addition, the groups were not matched and confounding factors were not accounted for. Thus, the results of this study are not reliable [20]. Mueller et al. found a statistically significant lower mortality with primary anastomosis compared with Hartmann's procedure. However, this was a retrospective chart review with a very small sample size. The number of deaths in the Hartmann's procedure group was 7/26 (27 %) and in the primary anastomosis group was 2/36 (6%). However, it must be recalled that larger database studies show surgical mortality rates (both types of procedures combined) less than 5% [1].

Focus on Anastomotic Leak

In the studies reviewed here, ten reported clinical anastomotic leak rate after primary anastomosis, with rates ranging from 3 to 28% [18–20, 22–27, 30]. In one of the larger retrospective studies, the clinical anastomotic leak rate was 13/46 (28%) in the primary anastomosis group [23]. During the same time period, the authors reported a 3% anastomotic leak rate for their elective colon resections. This study highlights the increased risk for anastomotic leak in patients undergoing an urgent/ emergent operation for acute diverticulitis compared with elective anastomoses.

Recommendations Based on Data

The procedures most reasonably performed in an urgent/emergent setting for acute diverticulitis are Hartmann's procedure, primary anastomosis without diversion, and primary anastomosis with diversion. Recent randomized trials have found increased rates of severe complications in patients undergoing laparoscopic lavage, and this *avant garde* approach is no longer widely considered appropriate [42, 43]. In analyzing the existing body of experiences for properly selected patients, each of these three procedures are equivalent in terms of morbidity and mortality from the index procedure. Some lessons can be taken however, to guide decision-making. Morbidity from anastomotic leak in patients with primary anastomosis is substantial, and higher than for elective resections. The likelihood of restoration of intestinal continuity is higher in patients who undergo primary anastomosis with loop ileostomy compared to those who undergo a Hartmann's resection. Finally, the morbidity and mortality from a Hartmann's reversal procedure is substantially higher than that of ileostomy reversal.

Thus, primary anastomosis with diverting loop ileostomy is recommended in stable patients undergoing surgery for acute diverticulitis. (Evidence quality: Low, Weak recommendation)

Personal View of Data

Each patient has a unique set of risk factors, and general/colorectal surgeons are well-acquainted with these. For the sake of discussion, these factors include sepsis/ hemodynamic instability, age, functional status, immunosuppression, extent/duration of inflammation, and degree of involvement of regional tissues with the acute inflammatory process. For a patient who manifests with the most severe profile of disease (e.g. septic, feculent peritonitis), it would be foolhardy to challenge conventional surgical wisdom by constructing an anastomosis. The reverse may be true as well. A patient with refractory diverticulitis and localized disease may be best served with an anastomosis (with or without diversion), thereby minimizing the burden of subsequent reoperation.

The choice of surgery for acute diverticulitis, therefore, clearly depends on an individual surgeon's estimation of a patient's degree of risk, and a mechanism for translating this estimation into the selection of one of three competing options. In the authors' practice, primary anastomosis with diverting loop ileostomy (with or without colonic lavage) is preferred in patients who are stable and are not at an unduly high risk for anastomotic failure. The authors rarely perform primary anastomosis without diversion in patients undergoing urgent/emergent surgery for acute diverticulitis. For patients who are clinically unstable, the priority is to minimize the risk of mortality, and in these situations an anastomosis is an avoidable source of risk.

It is tempting to look to ongoing randomized studies, such as the Dutch LADIES trial [44] to give better guidance regarding the preferability of one approach over another. It is unlikely, however, that any trial will quantify the risk factors described above adequately, or allow for a translation of this quantification into standardized surgical decision-making. Given this, surgeons treating patients for acute diverticulitis will need to continue to exercise their best judgment, encompassing a broad spectrum of potential risks and challenges that face each patient.

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