J Gastrointest Surg (2018) 22:503–507
https://doi.org/10.1007/s11605-017-3612-x

ORIGINAL ARTICLE

Is Diversion with Ileostomy Non-inferior to Hartmann Resection for Left-sided Colorectal Anastomotic Leak?

Caitlin Stafford[1] · Todd D. Francone[1] · Peter W. Marcello[2] · Patricia L. Roberts[2] · Rocco Ricciardi[1]

Received: 23 August 2017 / Accepted: 17 October 2017 / Published online: 8 November 2017

Abstract
Background Treatment of left-sided colorectal anastomotic leaks often requires fecal stream diversion for prevention of further septic complications. To manage anastomotic leak, it is unclear if diverting ileostomy provides similar outcomes to Hartmann resection with colostomy.
Methods We identified all patients who developed anastomotic leak following left-sided colorectal resections from 1/2012 through 12/2014 using the American College of Surgeons National Surgical Quality Improvement Program. Then, we examined the risk of mortality and abdominal reoperation in patients treated with diverting ileostomy as compared to Hartmann resection.
Results There were 1745 patients who experienced an anastomotic leak in a cohort of 63,748 patients (3.7%). Two hundred thirty-five patients had a reoperation for anastomotic leak involving the formation of a diverting ileostomy ($n = 77$) or Hartmann resection ($n = 158$). There was no difference in mortality or abdominal reoperation in patients treated with diverting ileostomy (3.9, 7.8%) versus Hartmann resection (3.8, 6.3%) ($p = 0.8$).
Conclusion There was no difference in the outcomes of mortality or need for second abdominal reoperation in patients treated with diverting ileostomy as compared to Hartmann resection for left-sided colorectal anastomotic leak. Thus, select patients with left-sided colorectal anastomotic leaks may be safely managed with diverting ileostomy.

Keywords Anastomotic leak · NSQIP · Colostomy · Ileostomy · Treatment

Introduction

In colorectal surgery, the complication of anastomotic leak can potentially expose a patient to sepsis, reoperation, and permanent stoma, increasing hospital length of stay with considerably higher risk of death. In fact, mortality following anastomotic leak has been reported to be as high as 22%.[1–3] Once a leak is suspected, the surgeon is faced with choosing the most suitable countermeasure to manage the complication, taking into account the severity of the patient's clinical status, degree of anastomotic disruption, as well as other intraoperative technical concerns. There are numerous effective treatments for anastomotic complications that range from non-operative approaches to interventional measures to more invasive surgical options. Those options involve diversion of the fecal stream with anastomosis preservation or complete removal of the failed anastomosis and creation of an end colostomy as with Hartmann's resection.[4]

Classic teaching in the containment of anastomotic leak is to reduce contamination and divert the fecal stream with Hartmann resection. This is largely due to the assumption that removing the affected anastomosis offers the smallest rate of reoperation for sepsis, highest rate of sepsis control, and lowest mortality. Though de-functioning the effected colorectal anastomoses without removing it may provide similar fecal stream management, many surgeons will chose to resect the anastomosis rather than preserve it.[5] There are clearly

✉ Rocco Ricciardi
rricciardi1@mgh.harvard.edu

1 Section of Colon & Rectal Surgery, Division of General and Gastrointestinal Surgery, Massachusetts General Hospital, 15 Parkman Street, WACC 460, Boston, MA 02114, USA

2 Department of Colon & Rectal Surgery, Lahey Hospital & Medical Center, Burlington, MA, USA

indications where the anastomosis cannot be preserved including those times where the anastomosis cannot be salvaged or in the setting of ischemia of the anastomosis. However, in the situation where either therapy is effective, data to support the non-inferiority of anastomotic maintenance with simple diversion of the fecal stream are lacking.

At this time, no data directly compare the outcomes of diversion with maintenance of the anastomosis to Hartmann resection of the anastomosis and end stoma. A properly powered prospective analysis to compare outcomes is unlikely given the fairly emergent and infrequent nature of anastomotic leak. Thus, we powered a non-inferiority trial to compare outcomes of simple diversion with anastomotic maintenance to Hartmann resection with end colostomy of left-sided colorectal anastomoses using prospectively collected quality improvement data. Our analysis seeks to develop high-quality evidence to guide the management of undiverted left-sided colorectal anastomotic leak.

Methods

Data

After approval from our institutional board review, we obtained data from the colectomy-targeted participant user file of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) from January 1, 2012 through December 31, 2014. The ACS NSQIP reports 30-day surgical adverse events based on prospectively collected clinical data which are not used for billing.[6] In addition to guiding quality improvement initiatives, NSQIP offers validated outcomes data across multiple surgical specialties and around the world using current procedural terminology (CPT) codes. The available data files contain de-identified records as defined by the Health Insurance Portability and Accountability Act Privacy Rule (Health Information Privacy, 2011).[7] A complete summary of the NSQIP sampling methods, data collection, and outcomes is available through the program.[8]

Patient and Procedure Selection

Using the NSQIP colectomy-targeted participant user data file, we selected all patients with left-sided colorectal procedures using CPT codes of partial colectomy (codes 44140 and 44204). To assure that these cases were left-sided resections and not right colectomy, we searched for a primary diagnosis of neoplasm at the splenic flexure or further distal, and/or diverticulitis. We also included patients with any diagnosis who underwent coloproctostomy (codes 44145 and 44207). We excluded patients who had concomitant formation of diverting or end stoma during one of the above procedures. In addition, we did not include subtotal or total colectomy because of the potential inability to discriminate ileostomy creation after anastomotic leak representing a Hartmann resection or simple diverting stoma. Our aim was to develop a homogenous population of left-sided colorectal resections without including more complex procedures.

Next, from this cohort, we identified a group of patients who experienced an anastomotic leak as defined by NSQIP. An anastomotic leak is defined as, "Leak of endoluminal contents through an anastomosis. This could include air, fluid, GI contents, or contrast material. The presence of an infection/abscess thought to be related to an anastomosis, even if the leak cannot be definitively identified as visualized during an operation, or by contrast extravasation, would still be considered an anastomotic leak if this is indicated by the surgeon."[6] We selected patients with evidence of "leak, no treatment intervention documented," "leak, treated with interventional means," "leak, treated with reoperation," "yes, reoperation," and "unknown." We then identified patients who had a reoperation CPT code of 44187 and 44310 for laparoscopic or open ileostomy and recoded them as having had a diversion without removal of the anastomosis. We used reoperation CPT codes of 44143, 44144, 44141, and 44320 as colostomy codes with removal of anastomosis or Hartmann procedures.

Outcome

Our primary outcome was second abdominal/pelvic reoperation. We used the variable codes "reoperation2" to identify a second unplanned reoperation. We then reviewed all listed CPT codes for second reoperation and all subsequent reoperations.

Secondary outcomes included mortality, length of stay, and septic complications. Mortality was defined within 30 days of index surgery. Length of stay was also determined from the index procedure. Septic complications reviewed include a "spectrum of disorders that span from relatively mild physiologic abnormalities to septic shock." The most significant level is reported using the following criteria: SIRS (systemic inflammatory response syndrome): SIRS is a widespread inflammatory response to a variety of severe clinical insults. Sepsis is defined as the systemic response to infection.[6]

Statistical Analysis and Power Analysis

Data were analyzed with SAS version 9.4 (SAS Institute, Cary, NC). Our analysis included two groups, the group with simple ileostomy diversion and a group with Hartmann resection. Missing variables were included as "missing" in our categorical analyses. Comparison of continuous variables was performed with Student's *t* test, and the chi-square test or Fisher's exact test was used for categorical variables. Using an estimated mortality of 4% or a 96% rate of 30-day survival with a 10% non-inferiority margin, an alpha of 0.05, and power of 90%, it was determined that a total of 132 patients, 66 in each arm, would be required to determine non-inferiority.

Results

Cohort

From January 1, 2012 to December 31, 2014, a total of 63,748 patients met inclusion criteria for the analysis. From this total, we excluded 13,045 (20%) patients who had concomitant stoma formation. A total of 2122 (4.2 ± 0.2%) patients experienced an anastomotic leak from the undiverted total sample. Out of this group, 1745 patients had an intervention for leak and 432 patients had a return to the operating room for treatment of anastomotic leak with diverting ileostomy or Hartmann resection. We then selected only patients that we could confirm a left-sided anastomosis leaving us with 235 cases, 77 treated with diverting ileostomy, and 158 with Hartmann resection (Fig. 1). Demographics of the treatment groups are detailed in Table 1. Overall, there were more male then female patients. We noted proportionately more elective cases and fewer smokers in the group that was managed with ileostomy. In addition, we noted a greater proportion of higher ASA scores in the group treated with Hartmann resection. There was a higher mean work rvu assigned to cases that eventually underwent reoperation with ileostomy. However, there were no differences in age, BMI, smoking habits, and sex. There was also no difference in the proportion of

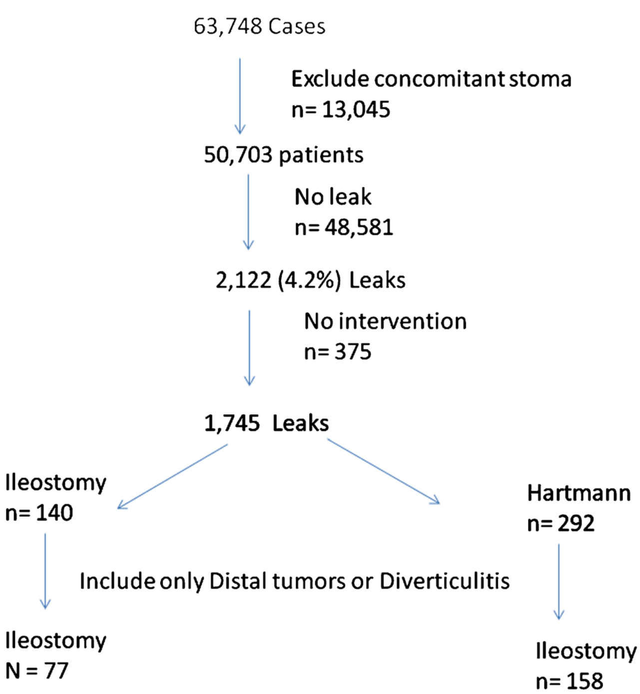

Fig. 1 Treatment paradigm with inclusions and exclusions

Table 1 Patient factors in patients with ileostomy as compared to Hartmann procedure

	Ileostomy (n = 77)	Hartmann (n = 158)	p value
Female	45 ± 11%	34 ± 8%	0.08
Mean age	57 ± 13	60 ± 14	0.1
BMI (kg/m^2)	29 ± 7	29 ± 7	0.7
Emergency	6 ± 3%	6 ± 3%	0.8
Admit from home	100 ± 5%	91 ± 6%	0.08
Smoke	13 ± 5%	27 ± 7%	0.02
Hypertension	52 ± 12%	49 ± 7%	0.7
Diabetes	9 ± 5%	15 ± 5%	0.4
Sepsis	38 ± 10%	43 ± 8%	0.4
Septic shock	21 ± 8%	24 ± 6%	0.6
ASA 1	6 (8%)	2 (1%)	0.007
ASA 2	40 (52%)	68 (43%)	
ASA 3	30 (39%)	76 (48%)	
ASA 4	1 (1%)	12 (8%)	
wRVU	29.0 ± 3.5	27.3 ± 3.6	0.0009
Clean contaminated case	62 ± 11%	73 ± 7%	0.4

emergency cases across the groups. The length of stay for the entire cohort was 16 ± 13 days and there was no difference in length of stay between treatment groups. Sepsis was documented in 41 ± 6% of all cases without substantial differences across treatment groups. Patients returned to surgery 8.9 ± 5.8 days after index surgery in the ileostomy treated group as compared to 8.5 ± 5.6 days for the Hartmann treated group (p = 0.6).

Outcomes

Our primary outcome was mortality and secondary outcome was second abdominal/pelvic reoperation. Mortality for the entire cohort of patients was 3.8 ± 2.0%. There was no difference in mortality for patients treated with diverting ileostomy alone (3.9 ± 3.0%) as compared to Hartmann resection (3.8 ± 2.0%). The overall difference in successful reoperation was thus − 0.1% with a 95% CI of − 5.4 to 5.2%. Given that the a priori inferiority margin of − 10% falls outside the 95% confidence interval of − 5.4 to 5.2%, the hypothesis that diverting ileostomy is non-inferior to Hartmann resection is accepted.

A reoperation after anastomotic leak management surgery (second reoperation) was performed in 8.9 ± 3.0% of all patients who had evidence of anastomotic leak. There was no difference in second reoperation between the group treated with ileostomy as compared to the group treated with Hartmann resection (Table 2). A small group of patients underwent reoperations for non-abdominal/pelvic procedures. Thus, we identified 7.2 ± 4% of all patients with need for a

Table 2 Outcomes for patients who underwent ileostomy procedure as compared to Hartmann procedure

	Ileostomy (n = 77)	Hartmann (n = 158)	p value
Death	3 (3.9 ± 3%)	6 (3.8 ± 3%)	1.0
Second reoperation (all)	8 (10.4 ± 5%)	13 (8.3 ± 3%)	0.6
Abd/pelvic reoperation	6 (7.8 ± 4%)	10 (6.3 ± 4%)	0.4
Surgical LOS (days)	14 ± 11	10 ± 13	0.2

second abdominal/pelvic reoperation. For the secondary outcome of second abdominal/pelvic reoperation, we noted that 7.8 ± 4.0% of patients treated with ileostomy and 6.3 ± 4.0% of patients treated with Hartmann resection were re-explored (Table 2). We determined that 76 ± 6% of patients were discharged home, 82 ± 10.0% of patients treated with ileostomy and 72 ± 7.0% of patients treated with Hartmann resection (p = 0.1).

Discussion

In this analysis of patients who underwent left-sided colorectal resections without concomitant formation of stoma abstracted from the colectomy-targeted participant user file of NSQIP, we noted an anastomotic leak rate of 4.2%. From this total, we demonstrate that a large number of patients with anastomotic leak are managed without re-operative surgery. However, approximately 11% of patients with anastomotic leak had either diverting ileostomy or Hartmann resection with colostomy. Our data reveal that length of stay, reoperation, and mortality were no different regardless of which management strategy was chosen. Ultimately, based on our a priori non-inferiority margin of 10%, we found that treatment with ileostomy was non-inferior to Hartmann resection indicating the relative safety of diverting ileostomy in managing septic complications after anastomotic leak.

Sepsis caused by anastomotic complications is one of the most common causes of mortality in patients who have colon and rectal surgery.[9] To prevent overwhelming sepsis in a patient with anastomotic leak, good clinical practice includes the provision of supportive measures, sepsis control, and management of the fecal stream when needed. As we demonstrated in this review, when patients do go to the operating room, a majority of patients are indeed treated with Hartmann resection with removal of the anastomosis and colostomy formation. However, excision of the anastomosis with colostomy formation has considerable concerns. For example, resection of the anastomosis and exteriorization of the proximal end as a stoma results in a permanent stoma in up to 56–68% of patients.[2] Patients treated with a permanent stoma have marked decrease in their overall quality of life including difficulty with intimacy, increased social restriction, and overall negative changes in lifestyle.[10] In addition, the colostomy takedown is a challenging abdominal/pelvic procedure that is associated with prolonged hospital stay and substantial morbidity.[11] Further fecal diversion such as a loop ileostomy occurs in 7% of patients during attempted Hartmann resection leading to even more operations.[12]

At this time, little evidence would suggest that fecal diversion alternatives are acceptable to Hartmann resection of the leaking anastomosis. Yet, our data indicate that treatment of a left-sided colorectal anastomotic failure with ileostomy is not inferior to Hartmann resection and does not carry an increased risk of sepsis, abdominal/pelvic reoperation, or mortality. Hedrick et al. demonstrated similar findings in their retrospective chart review of patients whose anastomotic complication required operative intervention. Mortality rates in both groups, those treated with Hartmann resection versus loop ileostomy were similar.[13,14] It was also noted that those treated with proximal diversion had a higher rate of intestinal restoration compared to those who had resections.[13] Their study however was limited in part due to a sample size of only 27 patients total.

In the clinical situation where patients are stable enough to undergo a loop ileostomy for control of anastomotic leakage, the comparative advantage is that they are more likely to be spared a permanent stoma.[3] Salvage as an alternative to anastomotic takedown in the appropriately selected patient (i.e., those who are stable enough to undergo a diverting loop ileostomy and with minor anastomotic defect) can be effective without increasing the risk of mortality or other consequences.[15] Later, at time of diversion reversal, others have noted no increased risk of mortality or releak of the prior anastomosis.[15] Of the cohort of patients who had re-leakage, 11 (78.6%) were those who had colostomy takedown, versus 3 (21.4%) who had anastomotic salvage.[15] Thus, it would seem that long-term issues related to maintenance of the prior faulty anastomosis (when sepsis has been controlled) are nominal.

Ultimately, our data reveal that patients who are hemodynamically stable can be safely treated with diverting ileostomy, which may offer stable patients better long- and short-term outcome.[14] Hanna et al. found similar lack of statistical significance in reoperation rates between patients who underwent an ileostomy versus a colostomy when comparing patients who had a diversion as a way to protect the high-risk colorectal anastomosis.[16] Chun et al. similarly found that after diverting loop ileostomy, approximately 10% of patients required another operation, which is once again in line with our findings.[10] Given the low rate of reoperation and similar mortality as those treated with Hartmann resection, ileostomy creation can be considered an alternative management strategy in the right clinical situation.

In our study, it was unclear how the fecal load was managed in cases where an ileostomy was performed. Ultimately, performance of an ileostomy without colonic washout or lavage may not reduce fecal contamination. Thus, it would be our recommendation that when ileostomy is performed, the colon is irrigated or cleansed to reduce further stool spillage. In addition, the data presented in this study do not demonstrate the functional results after ileostomy creation and in the situation where the anastomosis was maintained. It is unclear what kind of functional and long-term results these patients experience. Thus, there are likely to be times where Hartmann resection is the most optimal method of fecal stream management.

This is a secondary review of data from the NSQIP program, considered the best in the land by the Institute of Medicine for quality improvement. However, the study has several limitations because of the unrandomized nature of the assigned treatment, heterogeneous patient populations, and variable surgical and medical expertise. Surgeon preference and experience may lead to the tendency to perform one procedure over another and bias our results. Most importantly, the operative findings at the time of surgery might have persuaded surgeons to perform one technique over the other and these data points would not be available in the participant user file. Ultimately, there may have been bias toward treatment allocation. We have attempted to reduce bias by first developing a homogeneous cohort of pure left-sided colorectal resections with anastomosis and without diverting stoma. In addition, during analysis, we have attempted to account for all potential preoperative-intraoperative variables/covariates. Despite these limitations, the data do provide a mechanism to review a large number of patients who experienced anastomotic leak and identify validated outcomes.

Conclusion

In conclusion, no one anastomotic leakage treatment is best for all clinical situations, and thus, optimal treatment of anastomotic leak should be left to the surgeon based on clinical scenario, surgeon expertise, operative findings, and other technical details. However, our study demonstrates that there is no difference in the outcomes of mortality or need for second abdominal/pelvic reoperation in patients treated with diverting ileostomy as compared to Hartmann resection. We can demonstrate non-inferiority of ileostomy in relation to Hartmann resection in the treatment of anastomotic leak. Long-term results comparing quality of life, costs, and patient satisfaction would further add to these findings.

Author Contributions All authors have made (a) substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; (b) drafting the article or revising it critically for important intellectual content; (c) final approval of the version to be published. (d) Agreement to be accountable for all aspects of the work.

Compliance with Ethical Standards

Disclosures The American College of Surgeons National Surgical Quality Improvement Program and the hospitals participating in the American College of Surgeons National Surgical Quality Improvement Program are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

References

1. Trencheva K, Morrissey K, Wells M et al. Identifying Important Predictors for Anastomotic Leak After Colon and Rectal Resection. *Annals of Surgery*, 2013: 257:108–113.
2. Blumetti J, Chaudhey V, Cintron J et al. Management of Anastomotic Leak Lessons Learned from a Large Colon and Rectal Surgery Training Program. *World J Surg*, 2014: 38:985–991.
3. Francone T, Saleem A, Read T, Roberts PL, Marcello PW, Schoetz DJ, Ricciardi R. Ultimate fate of the leaking intestinal anastomosis; does leak mean perminant stoma? *J Gastrointest Surg* , 2010: 14: 987–92.
4. Murrell Z, Stamos M. Reoperation for Anastomotic Failure. *Clinics in Colon and Rectal Surgery*, 2006: 19:213–216.
5. Ricket A, Willeke F, Kienle P, Post S. Management and outcome of anastomotic leakage after colonic surgery. *Colorectal Disease*, 2010: 12:e216-e223.
6. NSQIP. National Surgical Improvement Program [Home page on the internet]. (American College of Surgeons) 2005.
7. Health Information Privacy. 2011. http://hhs.gov/ocr/privacy-Washington DC, (accessed July 27, 2011).
8. Khuri SF, Daley J, Henderston W et al. The Department of Veterans Affairs' NSQIP; the first national, validated, outcome-based, risk adjusted, and peer controlled program for the measurements and enhancement of the quality of surgical care. National VA surgical Quality Improvement Program. *Ann Surg*, 1998: 288:491–507.
9. Parc Y, Frileux P, Schmitt G, Dehni N, Ollivier J, Parc R. Management of Post-Operative Peritonitis After Anterior Resection. Experience from a Referral Intensive Care Unit. *Disease of the Colon and Rectum*, 2000: 43:579–589.
10. Chun L, Haigh P, Tam M, et al. Defunctioning Loop Ileostomy for Pelvic Anastomoses: Predictors of Morbidity and Nonclosure. *Disease of the Colon and Rectum*, 2012: 55:2;167–174.
11. Abbas, S. Resection and primary anastomosis in acute complicated diverticulitis, a systematic review of the literature. *International Journal of Colorectal Disease*, 2007: 22:4;351–357.
12. Garber A, Hyman N, Turner O. Complications of Hartmann takedown in a decade of preferred primary anastomosis. *The American Journal of Surgery*, 2014: 207, 60–64.
13. Hedrick T, Sawyer R, Foley E, Freil C. Anastomotic Leak and the Loop Ileostomy: Friend or Foe? *Disease of the Colon & Rectum* , 2006: 49: 1167–1176.
14. Fraccalvieri D, Biondo S, Saez J et al. Management of colorectal anastomotic leakage: difference between salvage and anastomotic takedown. *The Americal Journal of Surgery* , 2012: 206:671–676.
15. Krarup P, Jorhensen L, Darling H. Management of Anastomotic Leakage in a Nationwide Cohort of Colonic Cancer Patients. *J Am Coll Surg*, 2014: 218:940–949.
16. Hanna M, Vinci A, Pigazzi A. Diverting ileostomy in colorectal surgery; when is it necessary. *Langenbecks Arch Surgery*, 2015: 400:145–152.