Variant Two-Stage Ileal Pouch-Anal Anastomosis: An Innovative and Effective Alternative to Standard Resection in Ulcerative Colitis

Jennifer Samples, MD, Krista Evans, MD, Nicole Chaumont, MD, Paula Strassle, MSPH, Timothy Sadiq, MD, FACS, Mark Koruda, MD, FACS

BACKGROUND: Ulcerative colitis patients have been historically treated with standard single, 2-, and 3-stage operative approaches. We perform a variant 2-stage procedure beginning with total abdominal colectomy and end ileostomy followed by completion proctectomy and ileal pouch-anal anastomosis (IPAA) without a diverting loop ileostomy. This study evaluates the effectiveness of this innovative alternative.

STUDY DESIGN: Patients with ulcerative colitis, admitted to the University of North Carolina Hospital between 2003 and 2010 for IPAA, were eligible for inclusion. The 3-year cumulative incidence of pouch leaks among patients undergoing variant 2-stage were compared with those undergoing classic 2-stage, using inverse probability-of-treatment weighted Kaplan- Meier survival curves, and 95% CIs were estimated using nonparametric bootstrapping.

RESULTS: There were 248 patients who underwent IPAA; 139 (56.1%) underwent classic 2-stage and 109 (43.9%) underwent variant 2-stage. After standardization, there was no significant difference in the 3-year cumulative incidence of pouch leaks between patients undergoing variant 2-stage, compared with the standard single- or 2-stage procedure (risk difference 0.01; 95% CI −0.08, 0.15). At the time of the first surgical procedure, patients undergoing a variant 2-stage were more likely to have lower BMIs (median 22.5 kg/m^2 vs 26.7 kg/m^2; $p < 0.0001$), an urgent/emergent procedure (56.9% vs 0.0%; $p < 0.0001$), biologic use within 2 weeks of surgery (32.1% vs 17.5%; $p = 0.003$), and high dose steroid use (60.4% vs 16.7%; $p \leq 0.0001$).

CONCLUSIONS: Variant 2-stage IPAA is a safe and effective operative approach with comparable outcomes in a more acute population based on BMI, steroid use, and urgency of operation. (J Am Coll Surg 2017;224:557−563. © 2017 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Ulcerative colitis and Crohn's disease currently affect millions of people worldwide. The prevalence of inflammatory bowel disease in the US alone is estimated to be more than 1 million and rising.[1-3] As this population continues to grow, the onus to offer quality surgical options with individualized care becomes all the more crucial. Additionally, it becomes more important to look critically at standard practice and learn to innovate.

The pouch procedure was first described in 1978, and little has changed since.[4] The classic 1-, 2-, and 3-stage approaches, while tried and true, do not exclude the possibility that a modified approach cannot only be safe, but possibly better. Our practice has evolved to include a modified 2-stage variant. We complete a total abdominal colectomy with end ileostomy at the first operation. After a recovery interval, we return to the operating room for completion proctectomy and J-pouch creation. We have found this approach to be equal, if not superior, to the classic 1- and 2-stage procedures in a much sicker cohort of IBD patients.

Disclosure Information: Nothing to disclose.

Presented at the Southern Surgical Association 128th Annual Meeting, Palm Beach, FL, December 2016.

Received December 19, 2016; Accepted December 20, 2016.

From the Department of General Surgery (Samples, Evans, Chaumont, Sadiq, Koruda) and the Division of Gastrointestinal Surgery (Samples, Evans, Chaumont, Sadiq, Koruda), University of North Carolina Healthcare, and the Department of Epidemiology (Strassle), University of North Carolina, Chapel Hill, NC.

Correspondence address: Jennifer Samples, MD, Department of General Surgery, University of North Carolina, 4035 Burnett-Womack Building, Chapel Hill, NC 27599-7081. email: Jsamples@unch.unc.edu

http://dx.doi.org/10.1016/j.jamcollsurg.2016.12.049
ISSN 1072-7515/17

Abbreviations and Acronyms

ASA = aminosalicylic acid
AZA = azathioprine
IPAA = ileal pouch-anal anastomosis
IQR = interquartile range
6-MP = 6-mercaptopurine
RD = risk difference
RR = risk ratio

METHODS

Patients with ulcerative colitis, undergoing an ileal pouch-anal anastomosis (IPAA) between academic years 2003 and 2010 at the University of North Carolina (UNC) Hospital, were eligible for inclusion. Procedures were stratified into either a classic 2-stage (total proctocolectomy IPAA and loop ileostomy followed by an ostomy takedown) or a variant 2-stage (total abdominal colectomy and end ileostomy followed by completion proctectomy and IPAA). Patients who underwent a 1-stage or 3-stage procedure, had plans for abdominal or pelvic radiation therapy, or did not undergo the entire procedure at UNC, and within the study period were excluded. Patients were followed from the date of their first operation until the date of their last follow-up visit, or were administratively censored on September 30, 2012.

Patient demographics, surgical status (elective vs urgent/emergent), and pre-surgical drug usage before the first and second procedures were compared using Fisher's exact and Wilcoxon-Mann-Whitney tests, where appropriate. A value of $p < 0.05$ was considered significant. Preoperative factors included low BMI (defined as <18 kg/m^2) or high BMI (defined as ≥ 30 kg/m^2) at the time of their preoperative clinic visit (within 30 days of their first operation); corticosteroid use; high-dose corticosteroid use (defined as a total of 40 mg of prednisone equivalent daily); or long-term corticosteroid use (defined as 3 months of use) within 30 days of the first stage of their surgery; aminosalicylic acid (ASA) derivative use at the time of the first stage of their surgery; 6-mercaptopurine (6-MP) or azathioprine (AZA) use at the time of the first stage of their surgery; biologic use (infliximab, certolizumab pegol, or adalimumab) within 2 weeks of the first stage of their surgery; and urgent or emergent indication for surgery (defined as those hospitalized for their symptoms without pre-admission plans for surgery and had surgery before discharge).

The primary outcome of interest was pouch leak after the final procedure (total proctocolectomy IPAA and loop ileostomy followed by an ostomy takedown). Pouch leaks were defined as abscess or fluid collection within the pelvis in communication with the pouch. Kaplan-Meier survival curves were used to estimate the cumulative 3-year risk of pouch leaks among patients undergoing the variant 2-stage and standard (either single stage or classic 2-stage) IPAA. Both risk differences (RDs) and risk ratios (RRs) were calculated for each analysis. Weighted Kaplan-Meier curves were used to estimate the standardized, cumulative 3-year risk for each outcome of interest.[5] Standardized estimates were adjusted using inverse probability of treatment weights to account for potential confounding.

Briefly, the inverse probability of treatment weights for each patient was estimated using logistic regression, which modeled the probability of undergoing variant 2-stage IPAA using admission year, patient age (modeled as a linear variable as per functional form assessment), sex, race, smoking status, diabetes, dysplasia, or cancer diagnosis, BMI at the pre-surgical visit (modeled as a linear variable as per functional form assessment), 6-MP/AZA, aminosalicylic acid derivative (ASA), biologics (infliximab, certolizumab pegol, or adalimumab), and steroid drug use before their first surgical procedure. Weights were stabilized using the marginal (ie overall) probability of receiving a variant 2-stage IPAA in the cohort.

Confidence intervals for both the crude and standardized cumulative incidence measures were calculated using a nonparametric bootstrap. Specifically, 500 resamples with replacement were conducted and the RDs and RRs were calculated using the above procedures. The 95% CIs were determined using the 2.5 and 97.5 percentile cutpoints for each effect estimate.

Secondary outcomes were stricture at the site of former stoma, pouch/rectal anastomosis, pouchitis, diarrhea, and 30-day risk of wound infections after each procedure. Diarrhea was diagnosed through patient reporting of 8 or more bowel movements within a 24-hour period. Follow-up time after the first procedure was censored the day the second procedure was performed if it occurred before the full follow-up time was completed. For all secondary outcomes, each outcome event was assumed to be independent, and patients undergoing 2-stage operations were able to contribute up to 2 of each outcome (1 after each surgery).

All analyses were performed using SAS 9.4 (SAS Institute). Institutional Review Board approval was obtained from the University of North Carolina at Chapel Hill.

RESULTS

Between 2003 and 2010, 248 patients with ulcerative colitis underwent a 2-stage IPAA and met inclusion criteria. Just over half of the procedures were classic