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ORIGINAL ARTICLE

Single-stage restorative proctocolectomy for ulcerative colitis in pediatric patients: a safe alternative

Nathan S. Rubalcava[1] · Samir K. Gadepalli[1,2] · Cory N. Criss[1] · Natalie A. Moreno[1] · Jeremy Adler[2,3] · James D. Geiger[1]

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Abstract

Background Surgical management for refractory ulcerative colitis (UC) has been restorative proctocolectomy (RP) with ileal-pouch-anal-anastomosis (IPAA) done as one to three stages, with safety and effectiveness of a single-stage operation unclear.
Methods Pediatric UC patients from 2004 to 2019 who underwent RP/IPAA in the initial operation were retrospectively reviewed. 1-stage operations were matched 1:2 to 2-stage operations using age, duration of disease, and disease severity.
Results Ninety-nine patients (33 1-stage, 66 2-stage) were identified. The median total operative time was shorter in the 1-stage group (6 h:00 min vs. 7 h:47 min, $p=0.004$). Total length of stay was shorter in the 1-stage group (9 vs. 17 days, $p=0.001$). Rates of readmission were higher in 2-stage group (30 vs. 9%, $p=0.02$). There was no difference in pouch leak rates ($p=1.00$). Stricture rates were higher in the 2-stage group (50 vs. 16%, $p=0.005$). Functional outcomes including pouchitis ($p=0.13$), daily bowel movements ($p=0.37$), and incontinence ($p=0.77$) were all similar.
Conclusions Restorative proctocolectomy with IPAA in children with UC can be performed as a 1- or 2-stage operation with equivalent short-term, long-term, and functional outcomes in similar risk population. Our findings suggest 1-stage RP/IPAA operations without ileostomy are a safe alternative for patients considered for a 2-stage operation.

Keywords Pediatric · Ulcerative colitis · Restorative proctocolectomy · IPAA · J-pouch

Introduction

Surgical management for the treatment of refractory ulcerative colitis (UC) has continued to evolve from the traditional three-stage operation to the multiple approaches of the restorative proctocolectomy (RP) with ileal pouch-anal anastomosis (IPAA) [1–3]. The RP/IPAA without ileostomy was first described by Metcalf et al. [4] in 1986 and subsequently described in children in 1991 by Sugerman et al. [5] Increased experience with RP/IPAA and understanding of expected outcomes has allowed for widespread utility of the operation in children [6]. Recently, controversy has developed around the safety and efficacy of a 1-stage operation without creation of a diverting ileostomy.

A known complication of RP/IPAA is anastomotic leak with pelvic sepsis, which remains an important cause of morbidity and a known risk factors associated with pouch failure [7]. Given the concern for postoperative leak and other complications, the RP/IPAA continues to be performed routinely with a diverting ileostomy in pediatric patients [8]. A meta-analysis by Petrides found while there was increased rate of leak seen in the group without a diverting ileostomy, the rate of anastomotic stricture was higher in the group with diversion [9]. Other studies have shown diverting ileostomy with associated dehydration requiring hospitalization, leak at the time of ileostomy takedown, and increased rates of small bowel obstruction [10–12]. The issue related to routine creation of a diverting ileostomy remains controversial in the literature.

Over the last 2 decades, a growing body of literature has provided conflicting advice regarding performing versus avoiding a single-stage operation without a diverting

✉ Samir K. Gadepalli
samirg@med.umich.edu

1 Section of Pediatric Surgery, Department of Surgery, C.S. Mott Children's Hospital, Michigan Medicine, 1500 E. Hospital Dr, Ann Arbor, MI 48109, USA

2 Susan B. Meister Child Health Evaluation and Research Center, Michigan Medicine, Ann Arbor, MI 48109, USA

3 Department of Pediatric Gastroenterology, Michigan Medicine, Ann Arbor, MI 48109, USA

ileostomy without increasing morbidity [13–17]. Therefore, we reviewed our experience and compared 1-stage RP/IPAA to 2-stage RP/IPAA to determine short- and long-term outcomes in matched groups of children with UC. Our hypothesis was that postoperative and long-term functional outcomes following a 1-stage operation in children would be similar when compared to those who underwent a 2-stage operation.

Materials and methods

Study group

After IRB approval (HUM00179798), we performed a single-institution retrospective review of all patients under the age of 18 years old with biopsy-proven UC who underwent a single-stage ileal anal-pouch anastomosis (IPAA) without an ileostomy (1-stage) from Jan 2004 to July 2019. Exclusion criteria included patients with major congenital anomalies that resulted in abdominal operations unrelated to UC, those that underwent a 3-stage operation and patients that underwent a 2-stage operation with the IPAA created at the time of their second operation.

A priori, patients who underwent a 1-stage operation were matched 1:2 to a group of patients with UC under 18 years of age who underwent an IPAA with ileostomy (2-stage) during the same study period. Matching was based on the Pediatric Ulcerative Colitis (PUCAI) score ± 10 points at the time of surgical admission, age ± 3 years, and duration of disease prior to surgery ± 2 years [18].

We analyzed demographics, operative variables, postoperative complications (anastomotic leak, pelvic abscess, bleeding, wound infection, small bowel obstruction, deep-vein thrombosis) within 90 days. We also looked at surgery- and disease-related morbidity (pouchitis, need for reoperation, stricturing of the pouch requiring dilation in the operating room, small bowel obstruction, and fistula) and functional outcomes (number of bowel movements per days and continence at 1 year, amount of loperamide per day). Pouchitis was defined by clinical symptoms (increased bowel movements, abdominal pain, tenesmus, and/or blood in stool) with subsequent antibiotic administration or endoscopically with tissue diagnosis. Pouch failure was defined as need for pouch revision or creation of ileostomy.

All operations in both groups were performed by pediatric surgeons at the same tertiary referral university hospital. With the exception of seven patients who underwent a hand-sewn J-pouch, the IPAA in all patients was performed in the manner of an endorectal mucosectomy with a double-stapled IPAA in a J-pouch configuration, as previously described by our group [13, 14]. The decision to undergo 1-stage or 2-stage operation was based on preoperative patient health factors, patient/family preference, surgeon preferences, and intraoperative findings (leak following pouch construction). In preparation for surgery, particularly in the 1-stage group, a deliberate effort was made to reduce the dosage of steroids and accept some worsening of clinical symptoms.

Statistical analysis

Data were collected and stored in Microsoft Excel (Microsoft, Redmond, WA). Sample characteristics are reported as number of observations and percentages for categorical variables, and median and interquartile range for continuous variables. Comparisons between categorical variables utilized Fisher's exact test. Continuous variables were treated as non-parametric, and were compared using the Mann–Whitney *U* test/Wilcoxon rank sum test. All data were converted to and analyzed in STATA v16.1 (STATACorp, College Station, TX) with a two-tailed *p* value less than 0.05 considered significant.

Results

Demographic and preoperative data

A total of 138 patients underwent RP/IPAA during the study period. Eleven patients who underwent a 3-stage operation were excluded. Another 16 patients who underwent the IPAA at the second operation were also excluded. After 1:2 matching, we included 33 1-stage patients and 66 2-stage RP/IPAA (Fig. 1). The 12 patients who were not matched included a single 1-stage patient with a PUCAI score of 5 and 11 2-stage patients with high PUCAI scores (> 65).

Demographic and preoperative data are included in Table 1. Just under half were female ($n = 49$, 49%). Median age at diagnosis was 12 years (interquartile range [IQR] 9–15) and median age at RP/IPAA creation was 14 years (interquartile range [IQR] 12–16). Sixty-five percent (22/33) of the 1-stage group took anti-TNF biologic agents compared to 44% (27/66) of the 2-stage group ($p = 0.04$). The majority of the study cohort had pan colitis. No difference was seen for those on the α4β7 integrin antagonist Vedolizumab ($p = 0.06$). There was no difference in overall steroid use ($p = 0.19$). BMI was comparable between the two groups (19 [17–25] vs. 20 [17–24], $p = 0.79$) as was weight *z*-scores −0.16 [−1.1 to 1.2] vs. 0.44 [−0.7 to 1.1], $p = 0.38$). PUCAI score was similar between the two group ($p = 93$). Laboratory investigations were similar between the two groups including CRP ($p = 0.12$) and albumin ($p = 0.15$).

Operative data

Most patients ($n = 96$, 97%) had a tissue diagnosis of UC with the other ($n = 3$, 3%) patients diagnosed with indeterminate colitis (Table 2). Of the 3 patients with pathologic

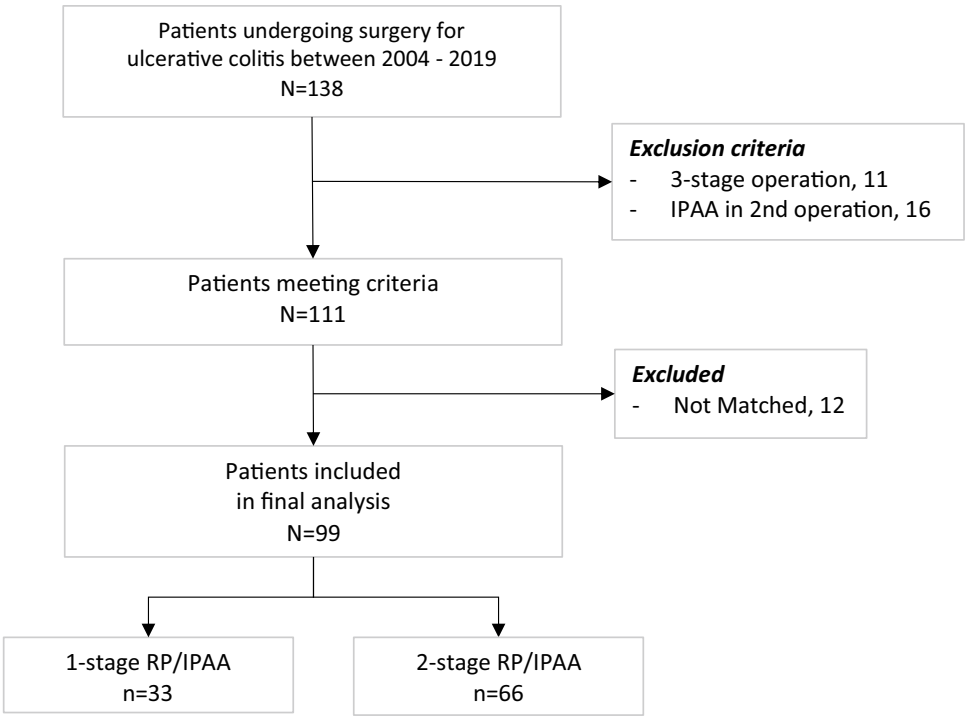

Fig. 1 Study flow diagram of the enrollment process. We identified 138 patients with RP/IPAA. After 1:2 severity matching, our study group was 99 patients

features of indeterminate colitis, one patient had preoperative diagnosis of indeterminate colitis with UC features. Total operative duration in the 1-stage group was statistically shorter compared to the two operations required in the 2-stage group (6 h:00 min [5:31–7:45] vs. 7 h:47 min [6:32–8:57], $p=0.004$). This includes operative duration for three ileostomy takedowns in the 1-stage group that required ileostomy creation for complications. Most cases in both groups were performed laparoscopically and with a double-stapled pouch creation. Rates of laparoscopic approach and use of stapled IPAA were similar. Total hospital length of stay for operative admissions was shorter in the 1-stage group compared to the 2-stage group (9 [7–15] vs. 17 days [9–23], $p=0.001$).

Postoperative complications

Ninety-day postoperative complications after RP/IPAA were similar among the groups (Table 2). Overall, the rate of complications was not different between the two groups. There were 9% (9/99) of each group that experienced an anastomotic leak. Eight of the nine patients that developed leaks required abdominal exploration and washout. Two patients in the 2-stage group had a suspected anastomotic leak at the time of ileostomy takedown but no perforation was identified. The two patients were put a 14-day course of antibiotics. One patient in the 1-stage group experienced an intraoperative leak when air bubbles were noted during the leak test of the pouch. As a result, the patient was diverted. One patient required a transfusion following ileostomy takedown in the 2-stage group. Rates of readmission were significantly higher in the 2-stage group (30 vs. 9%, $p=0.02$). There was no perioperative or long-term mortality in either group.

Long-term results and functional outcomes

Overall, long-term and functional outcomes at 1 year were not different between the two groups (Table 3). One patient in the 2-stage group developed severe prolapse of their J-pouch necessitating takedown of the J-pouch and creation of permanent ileostomy. Rates of anastomotic stricture requiring dilation in the operating room were higher in the 2-stage group than the 1-stage (50 vs 16%, $p=0.001$). At 1 year, there were similar rates of bowel movement per 24-h period ($p=0.37$), stool incontinence ($p=0.77$), and daily loperamide dose ($p=0.97$). There was no difference in rates of patients with symptoms of pouchitis (50% in 1-stage group vs .69% in 2-stage group, $p=0.10$) or rates of pouch failure (6% in 1-stage vs. 12% in 2-stage group, $p=0.24$).

In a subgroup analysis, functional outcomes between those who experienced a leak in each group were compared. There were no differences in the other functional outcomes at 1 year between the 1-stage and 2-stage groups, including rates of bowel movement per 24-h period (5.5 [5, 16] vs. 4.75 [4, 7], $p=0.31$), stool incontinence (0 vs. 33%, $p=0.26$), daily loperamide dose (6 [0, 10] vs. 11 mg [6, 12], $p=0.33$), and pouch resection (0 vs. 0%, $p>0.99$).

Table 1 Demographics and preoperative data

Variable frequency (%) or median [Interquartile range]	1-stage ($n=33$)	2-stage ($n=66$)	p value
Female	16 (45)	33 (50)	0.89
Age at diagnosis (years)	12 [8–15]	12 [9–14]	0.93
Duration of disease (years)	1.5 [1.3–4.3]	1.7 [1.1–3.1]	0.56
Indication for surgery			0.12
Elective patient decision	8 (24)	10 (15)	
Failure of medical management	24 (73)	56 (85)	
Colitis of the entire colon	28 (85)	58 (92)	0.27
Extraintestinal manifestations			
Anemia	4 (12)	9 (14)	0.87
Primary sclerosing cholangitis	2 (6)	5 (8)	0.81
Thromboembolic	2 (6)	5 (8)	0.81
Medical management			
5-ASA/mesalamine	19 (58)	39 (60)	0.95
Methotrexate	3 (9)	6 (9)	1
Immunomodulators	17 (51)	39 (60)	0.52
Anti-TNF	22 (65)	27 (44)	**0.04**
α4β7 integrin antagonist (Vedolizumab)	3 (9)	1 (2)	0.06
Oral steroid use	22 (67)	52 (78)	0.19
Dosage (mg/kg)	0.28 [0–0.58]	0.54 [0.1–0.81]	0.08
Nutritional data			
BMI	19 [17–25]	20 [17–24]	0.79
Weight-to-age percentile	16 [0.55–44]	26 [0.15–66]	0.4
Weight-to-age z score	− 0.16 [− 1.1–1.2]	0.44 [− 0.7–1.1]	0.38
PUCAI score	50 [35–65]	50 [40–65]	0.93
Laboratory investigations			
WBC[a]	8 [7–12]	11 [17–14]	0.11
CRP (mg/dL)[b]	0.45 [0.1–1.6]	1.3 [0.4–2.8]	0.12
Albumin (g/dL)[c]	4 [3.8–4.3]	3.8 [3.2–4.2]	0.15

p value < 0.05 was considered statistically significant

TNF tumor necrosis factor, *WBC* white blood cell, *CRP* C-reactive protein, *CBC* complete blood count, *CMP* complete metabolic panel

[a]32 in the 1-stage group; 65 in the 2-stage group

[b]27 in the 1-stage group; 58 in the 2-stage group

[c]30 in the 1-stage group; 63 in the 2-stage group

Discussion

In a retrospective analysis of severity-matched pediatric patients with UC, we present the largest series to date of children with UC undergoing a 1-stage RP/IPAA ($n=33$). Here, we sought to investigate the impact of a 1-stage RP/IPAA on postoperative complications and long-term functional outcomes compared to those undergoing a 2-stage operation. Our data suggests comparable rates of operative duration, total hospital length of stay, readmission rates, and rates of pouch stricture when comparing the 1-stage and 2-stage operations. These findings support the notion that a 1-stage operation is a safe alternative.

Traditionally, pediatric surgeons have performed 2-stage and 3-stage operations for children with fulminant or medically refractory UC to reduce the risk of postoperative complications, particularly risk of anastomotic leak [19]. However, the potential benefits of a 1-stage operation include: (1) single hospital admission, (2) preventing diversion ileitis and disuse atrophy of the anal sphincter, and (3) reducing potential pouch ischemia when creating the ileostomy [9]. Further, proponents of single-stage operations argue undergoing a second and third operation are associated with their individual risk both intra- and postoperative complications [9, 20]. In a systematic review by Chow et al. [21], closure of a defunctioning ileostomy was associated with a morbidity rate of 17.3%. Widmar et al. [22] recently reported on 987 UC patients undergoing an RP/IPAA of which 378 were 1-stage operations. They found similar rates

Table 2 Perioperative variables

Variables frequency (%) or median [IQR]	1-stage ($n=33$)	2-stage ($n=66$)	p value
Operative data			
Total operative duration (h:min)[a]	6:00 [5:31–7:45]	7:47 [6:32–8:57]	**0.004**
Laparoscopic	30 (91)	55 (83)	0.06
Stapled pouch creation	32 (97)	60 (91)	0.07
Total hospital length of stay (days)	9 [7–15]	17 [10–23]	**0.001**
Time to ileostomy takedown (months)	3 [2.5–3]	2.5 [2–3.3]	0.98
Postoperative complications			
Pouch leak	3 (9)	6 (9)	1
Bowel obstruction	2 (6)	9 (14)	0.26
Transfusion	0 (0)	4 (6)	0.15
Superficial site infection	0 (0)	3 (5)	0.21
Dehiscence	0 (0)	2 (3)	0.31
DVT/PE	0 (0)	4 (6)	0.15
Other (ileus, UTI, urinary retention)	1 (3)	8 (12)	0.14
Readmission within 90 days	3 (9)	20 (30)	**0.02**

p value < 0.05 was considered statistically significant

DVT deep-vein thrombosis, *PE* pulmonary embolism

[a]31 in 1-stage; 57 in 2-stage

Table 3 Long-term results and functional outcomes

Variables frequency (%) or median [IQR]	1-stage ($n=33$)	2-stage ($n=66$)	p value
Stricture[a]	5 (16)	33 (50)	**0.001**
Number of anastomotic dilations	1 [1, 2]	2 [1, 3]	0.43
Prolapsing J-pouch	0 (0)	1 (2)	0.48
Symptoms of pouchitis	18 (55)	46 (70)	0.13
No. of BM per day at 1 year[b]	5 [4–7]	6 [5–8]	0.37
Daily loperamide dose at 1 year (mg/day)[b]	6 [4–8]	8 [5–11]	0.97
Stool incontinence at 1 year[b]	3 (11)	8 (13)	0.77
Pouch failure	2 (6)	9 (14)	0.26
Follow-up time (months)	55 [17–96]	66 [41–114]	0.39

p value < 0.05 was considered statistically significant

BM bowel movement

[a]33 in 1-stage; 66 in 2-stage

[b]32 1-stage; 65 in 2-stage

of leak between those who had a diverting ileostomy and those without and thus concluding diversion by a proximal ileostomy at the time of pouch creation does not preclude the long-term risks of pouch excision or need for a long-term diversion following a pouch leak. Others have suggested multi-stage operations are significant risk factors for associated with SBO after IPAA creation in UC [23].

The use of RP/IPAA without diversion has been increasing recently in the pediatric literature [14, 20, 24, 25]. Gray et al. [14] found their series of 22 children undergoing 1-stage RP/IPAA without diverting ostomy had similar postoperative outcomes compared to children with a diverting ostomy. Although the groups were matched on age, other preoperative variables may impact postoperative morbidity and outcomes including degree of disease severity and control, use of steroid at the time of surgery, and overall nutritional status. Theoretically, in children whose disease is well controlled, not on steroids, and have good nutrition, their operative course may mirror children undergoing a 1-stage RP/IPAA for familial adenomatous polyposis [24, 26]. As part of our practice, once a patient is identified as a candidate to undergo an RP/IPAA, regardless of 1-stage or 2-stage, we optimize nutrition with nutritionist consultation and directed dietary modifications. In addition, our gastroenterology colleagues monitor patients for failure of medical management and will refer them sooner for surgical evaluation to avoid having a sicker patient with fulminant UC from undergoing pouch reconstruction, which may explain the median

moderate PUCAI score of 50 seen in both groups. Part of this practice includes reducing the steroid dose as much as possible in preparation for surgery as previous studies have shown preoperative poor nutritional status and steroid use are associated with need for reoperation [27, 28].

In our study, children undergoing 1-stage RP/IPAA had similar rates of complications and long-term pouch outcomes. The overall anastomotic leak rate in our cohort was 9%, which is consistent with the pediatric UC literature [29, 30]. The major concern with performing a RP/IPAA without a diverting stoma is pouch complications and risk of pouch failure. Chen et al. [20] note that despite having a 30% leak rate in the undiverted group compared to 5% in the diverted group, there was no difference in pouch failure at a mean follow-up of 25 months. Despite no impact on pouch failure in their study, this point speaks to the importance of patient selection when deciding to perform a 1-stage RP/IPAA. A clinical algorithm that incorporates duration of disease control, steroid usage, and nutritional status is needed to help guide pediatric surgeons on what entails a 'carefully selected' patient.

The results of this study are not without limitations. This single institutional study is subject to limitations inherent to retrospective studies and thus, may not be as generalizable to the entire ulcerative colitis population. The sample size may limit the power to detect differences in safety events, long-term results and functional outcomes between the two groups; however, this is one of the largest cohorts of pediatric patients with UC who underwent 1-stage RP/IPAA since biologics came to market 20 years ago. Finally, there is important potential for selection bias in patients undergoing 1-stage operations, despite matching for severity. These patients were selected based on preoperative state of health, severity of disease, desire of the patients, and ultimately the decision was dictated by intraoperative findings, which are all consistent with the recommendations by the American College of Gastroenterologists and ESPGHAN [16, 28]. Further multi-institutional studies are needed to increase the power to better characterize the impact of a 1-stage RP/IPAA in children with UC.

Conclusion

Our study compared 1-stage RP/IPAA to the 2-stage RP/IPAA for children with ulcerative colitis. The 1-stage RP/IPAA operations allow patients to forgo an ileostomy without an increased rate of leak. Our findings suggest the 1-stage RP/IPAA operation without ileostomy in select patients is an effective and safe alternative in the short- and long-term for patients who may otherwise be considered for a 2-stage operation.

Author contributions Guarantor of the article: SKG. NSR collected the data, analyzed the data and wrote the paper; NAM helped collect data and write the paper; CNC helped write the paper; JA helped write the paper; SKG collected, helped to collect the data, designed the research study and wrote the paper. JDG helped with study conception and design and wrote the paper. All the authors helped with editing the drafts of the manuscript. All the authors read and approved the final version of the manuscript.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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