



Routine placement of abdominal drainage in pouch surgery does not impact on surgical outcomes

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Abstract

The evidence does not support the routine use of abdominal drainage (AD) in colorectal surgery. However, there is no data on the usefulness of AD, specifically, after ileal pouch-anal anastomosis (IPAA). The aim of this study is to assess post-operative outcomes of patients undergoing IPAA with or without AD at a high volume referral center. A retrospective analysis of prospectively collected data of consecutive patients undergoing IPAA with AD (AD group) or without AD (NAD group) was performed. Baseline characteristics, operative, and postoperative data were analyzed and compared between the two groups. A total of 97 patients were included in the analysis, 46 were in AD group and 51 in NAD group. AD group had a higher BMI (23.9 ± 3.9 kg/m² vs 21.9 ± 3.0 kg/m²; $p = 0.007$) and more commonly underwent two-stage proctocolectomy with IPAA compared to the NAD group (50.0% vs 3.9%; $p < 0.001$). There was no difference in anastomotic leak rate (6.5% AD vs 5.9% NAD group; $p = 1.000$), major post-operative complication (8.6% vs 7.9%; $p = 0.893$); median length of stay [IQR] (5 [5–7] days vs 5 [4–7] days; $p = 0.305$) and readmission < 90 days (8.7% vs 3.9%; $p = 0.418$). The use of AD does not impact on surgical outcome after IPAA and question the actual benefit of its routine placement.

Keywords Colorectal surgery · IBD · Laparoscopic surgery · Drain · Pouch surgery

Introduction

Restorative proctocolectomy (RP) with ileal pouch–anal anastomosis (IPAA) is the gold standard for refractory ulcerative colitis (UC) or dysplasia and cancer in medically refractory UC, familial adenomatous polyposis (FAP), multiple synchronous colorectal cancer, and selected Crohn's disease (CD) patients [1–3]. RP and IPAA provide reasonable long-term functional results, as reflected in health-related quality of life studies [4–6]. However, postoperative pelvic sepsis, which is primarily responsible for significant long-term functional impairment and, eventually, for pouch failure, is the most feared complication [4].

Abdominal drainage (AD) in colorectal has been traditionally used to early detect intra-abdominal complications such as anastomotic leakage (AL), bleeding and collections [7, 8]. However, the evidence does not support its routine use in elective colorectal surgery [9]. Indeed, potential AD pitfalls such as increased post-operative pain at the drain site, surgical site infection, and abdominal obstruction have been reported [9, 10]. According to the most recent evidence, enhanced recovery program guidelines do not advise AD placement after colorectal surgery [11]. Their recommendation was corroborated by the results of a Cochrane systematic review [12] and a systematic review and meta-analysis [13] both concluding that pelvic and peritoneal AD did not decrease AL, mortality, wound infection and reoperation rates. There is no specific data on the usefulness and role of AD in pouch surgery. The aim of this study is to investigate post-operative outcomes of patients undergoing IPAA with or without AD placement.

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Methods

Patients

A prospectively maintained database was screened to collect all consecutive patients undergoing IPAA from January 2016 to June 2021 at a tertiary referral center. While before 2016, patients were routinely given AD after IPAA, over the study time-window, this practice gradually changed to a no drain policy. Data were collected according to the following variables: age at surgery, previous abdominal surgery, pathological diagnosis, pre-operative lab test (hemoglobin, creatinine and albumin), body mass index (BMI), American society of anesthesiologists (ASA) score, details on surgical procedure, length of stay (LOS), post-operative complication rate and Clavien–Dindo classification, post-operative unplanned readmission. Post-operative complications included AL, sepsis, ileus and complications other than leak. AL was registered according to the Italian multi-society consensus on the definition and management of anastomotic leak [2]. A defect of the intestinal wall at the anastomotic site leading to a communication between the intra- and extraluminal compartments diagnosed by surgical procedure, endoscopy, contrast enema was considered as AL. A pelvic abscess close to the anastomosis diagnosed by CT scan, even without any evident communication with the colonic lumen, was also considered as AL. Sepsis was defined as systemic inflammatory response syndrome (SIRS) signs with at least two of the following: fever $> 38^{\circ}\text{C}$, leukocytosis, heart rate > 90 bpm, respiratory rate $> 20/\text{min}$ and confirmed or suspected infection. Pouch patients were included in the study if they met the following criteria: diagnosis of UC, multiple synchronous colorectal cancer or FAP. Patients were divided in two groups: patients who were placed an AD (AD group), and patients not receiving AD (NAD group). During the progressive transition to a no drain policy, AD was placed according to patients' characteristics and assessment of intra-operative hazards. One experienced colorectal surgeons performed the surgical operations during the study period.

The primary end-point was the rate post-operative complications (overall rate and rated according to the Clavien–Dindo score) [14]. The secondary end-points were AL, LOS, readmission, and stoma closure rate. Patients were followed-up until ileostomy closure or at least 90 days after index procedure. The study was conducted according to the ethical standards and the principles of the Declaration of Helsinki.

This study complies with the 'strengthening the reporting of observational studies in epidemiology' (STROBE) statement for observational studies [15].

Surgical technique and post-operative care

Patients underwent either a 2-, modified 2- or 3-stage RP. Minimally invasive approach (including trans-stomal single port access after subtotal colectomy with end-ileostomy) was the preferred approach whenever feasible. A 15 cm ileal J-pouch was created using two fires of 100-mm linear stapler. Proctectomy was carried out by up-to-down approach for conventional double-stapled IPAA or transanal transection and single stapling anastomosis technique and by bottom-up approach for transanal IPAA as previously described [6, 16].

A stapled IPAA was fashioned using a 31 mm circular stapler either through double-stapled or double purse-string single-stapled technique. A Foley catheter was left transanally into the pouch for decompression. When an AD was used, a capillary drain was placed posteriorly to the pouch into the pelvic cavity. In patients with AD, the drained fluid was evaluate daily for quantity and quality.

Statistical analysis

All the statistical calculations were performed using JMP Pro 15.0 (SAS Institute Inc., Cary, NC, USA). Continuous data were described as the means $\pm$ standard deviation (SD) and analyzed through a t-test when they were normally distributed. Continuous data that were not normally distributed were expressed as medians and interquartile range (IQR) and analyzed using Mann–Whitney U tests. Both the categorical data and ordinal data were presented as the number of cases and percentages. Categorical data were analyzed using a χ^2 test or Fisher's exact tests, while the ordinal data were subsequently analyzed using Mann–Whitney U tests. All analyses were two-sided, and $p < 0.05$ was considered as statistically significant.

Results

A total of 97 consecutive patients underwent IPAA surgery during the study time-window, 51 belong to NAD group and 46 to AD group. Clinical and pathological characteristics of the study population are described in Table 1. Patients in the AD group had a higher BMI (23.9 ± 3.9 kg/m² vs 21.9 ± 3.0 kg/m²; $p = 0.007$). When compared to the NAD group, the AD group had a higher rate of 2-stage RP (50% vs 3.9%; $p < 0.001$) likely justified by the higher rate of FAP (19.6% vs 2.0%; $p < 0.001$), colorectal cancer on UC (23.9% vs 2.0%; $p < 0.001$). Table 2 describes intra e post-operative characteristics. Patients in the AD group had a longer mean operative time (344.1 ± 78.1 min vs 252.8 ± 51.2 min; $p < 0.001$) as a consequence of the higher rate of 2-stage

Table 1 Pre-operative characteristics

	Drain <i>n</i> = 46	No drain <i>n</i> = 51	<i>P</i>
Age	45.1 (12.8)	45.2 (14.2)	0.951
Female	23 (50%)	25 (49%)	0.923
BMI kg/m ²	23.9 (3.9)	21.9 (3.0)	0.007*
ASA			
1	16 (34.8%)	23 (45.1%)	0.641
2	28 (60.9%)	26 (51%)	
3	2 (4.3%)	2 (3.9%)	
S-Albumin g/dl	42.1 (3.1)	42.4 (2.5)	0.201
Hemoglobin g/dl	13.1 (2.0)	13.2 (1.7)	0.911
Creatinine mg/dl	0.8 (0.3)	0.8 (0.2)	0.486
Procedure			
3-stage	23 (50.0%)	49 (96.1%)	< 0.001*
2-stage	23 (50.0%)	2 (3.9%)	
Diagnosis			
UC	26 (56.5%)	49 (96.1%)	< 0.001*
UC with cancer	11 (23.9%)	1 (2.0%)	
FAP	9 (19.6%)	1 (2.0%)	

Values are expressed in mean $\pm$ SD or *n*° of patients and percentage

ASA American society of anesthesiologist score, BMI body mass index, SD standard deviation

*Statistically significant

procedures. AL rate was comparable between AD and NAD groups (6.5% [*n* = 3] vs 5.9% [*n* = 3]; *p* = 1.000, respectively). Using the Clavien–Dindo classification system, score's grades were homogeneous (*p* = 0.835) between the two groups. A total of eight patients developed a severe complication (Clavien–Dindo $\geq$ III). Of 4 (8.6%) patients in the AD group, 1 had hemoperitoneum occurred at the first post-operative day, 1 patient underwent laparoscopic exploration for bowel obstruction, in 1 patient was placed a percutaneous drainage for a pelvic collection and 1 patient underwent surgery to treat a pouch-vaginal fistula. In the NAD group, 4 (7.9%) patients developed severe complications, of which 2 underwent peritoneal lavage and IPAA revision for AL, 1 had a stoma reversal for intestinal obstruction at ileostomy site and 1 patient had an endoscopic hemostasis to treat acute pouch bleeding after stoma closure. The median LOS [IQR] was similar between groups (5 [5–7] days in AD group vs 5 [4–7] days in NAD group; *p* = 0.305). Readmission within 90 days was 8.7% for the AD group and 3.9% for the NAD group and (*p* = 0.418). A total of 6 patients were readmitted. Reasons for readmission were post-operative fever due to pouch-vaginal fistula in 1 case, splenic vein thrombosis in 1 case and post-operative ileus in 2 patients in AD group; 1 case of anastomotic bleeding and 1 case of IPAA stricture in NAD group. A total of 45 (97.8%) patients in AD group and 48 (94.1%) patients in NAD group received

an ileostomy after IPAA procedure. Stoma reversal rate was similar between groups (88.9% vs 93.8%; *p* = 0.752). The majority of patients who did not undergo stoma reversal declined surgery as a personal decision despite the absence of contraindications. Table 3 shows intra- e post-operative characteristics of 72 patients undergoing 3-stage procedures. Among these, 23 (31.9%) were in AD group and 49 (68.1%) were in NAD group. The 2 groups were different in the conversion rate with a higher rate in AD group (21.7% vs 2.0%; *p* = 0.011) and mean operative time [IQR] with longer time procedure in the same group (299 [269–338] min vs 236 [215–274] min; *p* < 0.001). Figure 1 shows the proportion of patients receiving AD according to study year. AD was utilized in 90.9% of patients treated in 2016. Thereafter, the highest proportion of no drain policy was in 2019 when only 30% of patients belonged to the AD group.

Discussion

In our study, the use of prophylactic AD for pouch surgery did not affect surgical outcome. Furthermore, AL rate and grade was similar between those who received an AD and those who did not. The evidence on the value of drainage placement in rectal surgery for cancer does not support its routine use [10, 13, 17, 18]. In fact, a randomized trial [10] assessing the role of pelvic drain in rectal surgery for cancer showed no benefits in terms of reoperation rate, LOS, pelvic sepsis incidence and overall surgical morbidity. Furthermore, a recent multicenter prospective study evaluated the efficacy of the routinary use of intra-abdominal drainage in elective colorectal surgery, showing that its use is not associated with the early detection of collections, while it prolongs hospital stay and surgical site infections [9]. However, specific data on the role of AD after IPAA are not available. Our colorectal surgery division, has progressively transitioned to a no drain policy in the last years as testified by the steady decreasing in the use of AD during the study time-window (Fig. 1). Even though gradually abandoned, the choice to use the AD was undertaken according to patients' characteristics and assessment of intra-operative hazards. The main reasons for AD placement were represented by the expected amount of post-operative serum secretion due to greater presence of adipose tissue, the necessity of performing an extensive adhesiolysis, and intra-operative complications that may pose the IPAA at higher risk, such as postoperative bleeding or anastomotic leak. This is reflected by the unequal BMI and operative time in the two groups (higher for the AD group), even though this difference is likely explained also by the different rate of 3- and 2-stage procedures. The choice of placing a drain in overweighted or obese patients is supported by previous studies reporting an increased risk for patients with a high BMI to develop postoperative

Table 2 Intra and post-operative characteristics

	Drain <i>n</i> = 46	No drain <i>n</i> = 51	<i>P</i>
Post-operative complications (overall)	15 (32.6%)	18 (35.3%)	0.780
Anastomotic leak [^]	3 (6.5%)	3 (5.9%)	1.000
Conversion to open [^]	5 (10.9%)	1 (2.0%)	0.098
Operative time (min)	344.1 (78.1)	252.8 (51.2)	< 0.001*
Temporary diversion	45 (97.8%)	48 (94.1%)	0.129
Clavien-Dindo [^]			
0	31 (67.4%)	33 (64.7%)	0.835
I	5 (10.9%)	4 (7.8%)	
II	6 (13.0%)	10 (19.6%)	
IIIa	2 (4.3%)	1 (2.0%)	
IIIb	2 (4.3%)	3 (5.9%)	
IV	0 (0.0%)	0 (0.0%)	
Sepsis [^]	6 (13.0%)	5 (9.8%)	0.752
Complications other than leak	12 (26.1%)	17 (33.3%)	0.435
Ileus	6 (13.0%)	6 (11.8%)	1.000
Length of stay (days) [°] (IQR)	5 (5–7)	5 (4–7)	0.305
Readmission < 90 days [^]	4 (8.7%)	2 (3.9%)	0.418
	<i>n</i> = 45	<i>n</i> = 48	<i>P</i>
Stoma closure	40 (88.9%)	45 (93.8%)	0.752

Values are expressed in mean $\pm$ SD or *n*[°] of patients and percentage, median (IQR) for length of stay

SD standard deviation, IQR interquartile range

*Statistically significant

[°]Wilcoxon's signed rank test

[^]Fisher's exact test

complications after colorectal cancer surgery [19, 20]. Akiyoshi et al. analyzed 1194 consecutive patients who underwent laparoscopic resection in a single center and they classified patients according to BMI [19]. The study showed that BMI > 35 kg/m² is an independent predictive factor of developing AL. The BMI may also have an impact on IPAA procedure [21]. In fact, an inadequate mesenteric length, which is often the case in obese patients, could determine high tension on the anastomosis and a consequent higher risk of developing an AL [22]. Our study showed that operative time was significantly longer in the AD group than the NAD group. The difference, despite the clear relation with higher number of two stage procedure for AD group, may be also related to surgeon's decision to place an AD after a more demanding surgery. Indeed, a case–control study demonstrated a stronger association between prolonged operative time and the development of post-operative AL after colorectal surgery [23]. However, a large multicenter evaluation did not consider a long operative time as a risk of AL after IPAA surgery and only an high BMI, ASA score > 2 and a long disease course were independent risk factor for AL [24]. The rate of AL after IPAA reported in the literature ranges between 8 and 15% [6, 25]. In our series of 90-day

short-term outcomes, we reported an overall leak rate of 6.2%. For instance, we mainly performed a 3-stage procedure, while in the above-mentioned studies more modified 2 stage procedures (with no protective stoma at the point of IPAA construction) were performed. The almost constant presence of ileostomy in our series may have influenced the AL rate towards a greater number of undetected leaks compared to other series. However, in our series, the use of AD did not increase the number of leak detection nor decreased its severity. This finding is supported by a systematic review and meta-analysis of Urbach et al. which questioned the use of drainage to detect AL in colon and rectal anastomosis [26]. They described only 1 out of 20 diagnosis of AL observing pus or enteric content in drainage fluid while the drain was in place. Hence, they concluded that a drain is rarely useful in expelling enteric material once a leak occurs. It is therefore unlikely that a drain may be useful even for the purpose of controlling a leak if one occurs. Interestingly, LOS was similar in both groups in our study, with a median value of 5 days. This may be explained by the early drain removal policy in our department. In fact, drains were generally withdrawn between the third and the fifth post-operative day if the postoperative course was uneventful. Despite no

Table 3 Intra and post-operative characteristics for 3-stage procedures

	Drain <i>n</i> = 23	No drain <i>n</i> = 49	<i>P</i>
Post-operative complications (overall) [^]	4 (17.4%)	18 (36.7%)	0.110
Anastomotic leak [^]	0 (0.0%)	3 (6.1%)	0.546
Conversion to open [^]	5 (21.7%)	1 (2.0%)	0.011*
Operative time (min) [°] (IQR)	299 (269–338)	236 (215–274)	<0.001*
Temporary diversion [^]	22 (95.7%)	46 (93.9%)	1.000
Clavien–Dindo [^]			
0	19 (82.6%)	31 (63.3%)	0.499
I	2 (8.7%)	4 (8.2%)	
II	2 (8.7%)	10 (20.4%)	
IIIa	0 (0.0%)	1 (2.0%)	
IIIb	0 (0.0%)	3 (6.1%)	
IV	0 (0.0%)	0 (0.0%)	
Sepsis [^]	1 (4.3%)	5 (10.2%)	0.657
Complications other than leak [^]	3 (13.0%)	17 (34.7%)	0.089
Ileus [^]	2 (8.7%)	6 (12.2%)	1.000
Length of stay (days) [°] (IQR)	5 (5–6)	5 (4–7)	0.578
Readmission < 90 days [^]	0 (0.0%)	2 (4.1%)	0.199
	<i>n</i> = 22	<i>n</i> = 46	<i>P</i>
Stoma closure	21 (95.5%)	44 (95.7%)	0.752

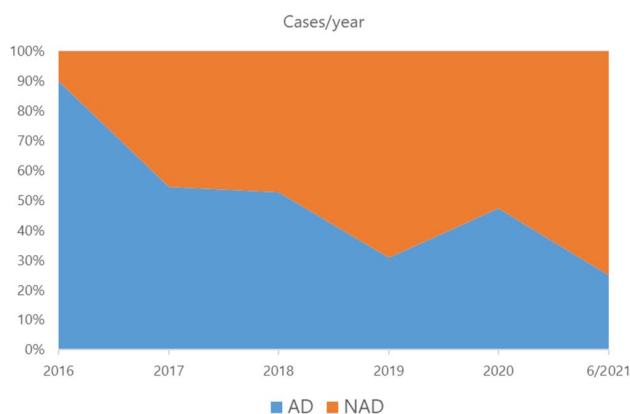
Values are expressed in median (IQR) or *n*[°] of patients and percentage

SD standard deviation, *IQR* interquartile range

*Statistically significant

[°]Wilcoxon's signed rank test

[^]Fisher's exact test

**Fig. 1** Cases/drain positioning according to year

difference in LOS, Moloo et al. advised against the use of abdominal drains underlying potential pitfalls associated with drain placement [27]. The presence of an abdominal drain may allow for bacterial infections, increase risk of incisional hernia or could cause mechanical bowel obstruction. An interesting animal study by Nora et al. shows that 34% of abdominal drains revealed bacterial growths from cultures of

their interior portion [28]. This finding suggest that bacteria could migrate into the abdomen via the drain, and may represent a reason to avoid the routine use of an AD.

The rate of post-operative ileus (POI) was 11.8% in the NAD group vs 13.0% in the AD group ($p = 1.000$). Our results are similar to those reported beforehand [29, 30]. Indeed, previous articles did not report the presence of drainage as a cause of POI. They describe open surgery, male gender, conversion to open, ileostomy diversion and AL as possible risk factor for developing POI [29, 30]. Instead, abdominal drainage was reported as a cause of bowel mechanical obstruction only in case report [31].

Our series include all consecutive laparoscopic assisted procedures. Indeed, our unit offers a minimal invasive option as a gold standard to all our patients undergoing IPAA surgery. Minimal invasive surgery provides multiple advantages in IPAA surgery. Indar et al. [32] evaluated the amount of post-operative adhesions during loop ileostomy closure in patients who underwent IPAA and they reported fewer pelvic adhesions to the abdominal wall and gynecologic organs in the laparoscopic group than in the open group. This results could explain the lower rate of female infertility after IPAA when a minimally-invasive approach is utilized [33].

Additional benefits of minimal invasive surgery compared with open surgery comprise shorter LOS, reduced post-operative pain with improvement of short-term outcomes along with better cosmetic results. Moreover, the quality of life is similar regardless of the surgical technique [34–36].

In the last few years, Enhanced Recovery Protocols (ERP) were shown to be effective in reducing post-operative complications in patients undergoing colorectal surgery through a standardization of perioperative procedures, including a routine no drain policy [37]. Most of the literature on this topic is based on colorectal cancer patients, whereas knowledge about ERP implementation in inflammatory bowel disease (IBD) has been barely investigated [38]. Vigorita et al. [39] showed in a recent systematic review that studies on the subject tend to include only patients with Crohn's disease or to include patients with Crohn's disease and ulcerative colitis despite the different disease settings. Based on our experience, we have included the no drain policy as part of our IBD-ERP.

In our sub-analysis of patients who underwent a 3-stage procedure, a higher conversion rate in the AD group was observed (5/23 [21.7%] vs 1/49 [2.0%]; $p=0.011$). The reason for conversion to open was in all patients the presence of diffuse abdominal adhesions. This is also reflected by the longer median operative time [IQR] in the AD group compared to the NAD group (299 [269–338] min vs 236 [215–274] min; $p<0.001$).

Even though a decreasing trend in the use of drain was registered in our study, in 2020 a higher rate of AD was registered in IPAA surgery (Fig. 1). One of the main reasons may be the impact of the COVID-19 pandemic [40], which severely affected our surgical practice, switching mainly to oncological or emergency procedures. As a result, a higher number of two-stage procedures, which is the gold standard in case of total proctocolectomy for polyposis or multiple concomitant colorectal cancer, was performed, while surgery for benign disease such as medically refractory UC, a three-stage procedure in our practice, was mostly deferred. Given the higher complexity of a 2-stage procedure, these patients were more likely to receive an intra-operative drain, according to the reasons expressed above. On the other hand, when a subanalysis of patients undergoing a 2- or 3-stage procedure, no differences were registered in post-operative complications, as reported by others [41].

Our study is limited by its retrospective single center design. Further, the lack of homogeneous pre-agreed policy for drain placement might be considered a selection bias.

Of note, the present study reports the real life data of a high volume dedicated colorectal surgery division and highlights the possible lack of benefits in terms of postoperative outcome behind the use of surgical drain during elective IPAA surgery posing a point of discussion, worth of further investigations. Learning curve and surgical experience may

definitively have played a role in affecting post-operative outcomes, considering that in our study the accrual date started prior to the introduction of a 'no drain' policy. Nevertheless, we present a cohort of consecutive patients treated in the same setting in a span of only 5 years. Further, even in the latest years the rate of patients who received an intra-operative drain was approximately 35%. These factors may mitigate experience as a confounder.

In conclusion, our experience has shown similar short-term outcomes in patients undergoing IPAA surgery with or without AD placement and questions the usefulness of AD in pouch surgery.

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Data availability The authors declare that no patient data appear in this article.

Declarations

Conflict of interest AS acted as speaker for Johnson and Johnson and Takeda; MC acted as speaker for Takeda and Pfizer, the other authors have no conflicts of interest to declare.

Protection of human and animal subjects The authors declare that no experiments were performed on humans or animals for this study.

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