TOTALLY LAPAROSCOPIC, MULTI-STAGE, RESTORATIVE PROCTOCOLECTOMY FOR INFLAMMATORY BOWEL DISEASES.
A PROSPECTIVE STUDY ON SAFETY, EFFICACY AND LONG-TERM RESULTS.

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Abstract

Background: Laparoscopic ileo-pouch-anal anastomosis (IPAA) has been reported as having low morbidity and several advantages.

Aims: To evaluate safety, efficacy and long-term results of laparoscopic IPAA, performed in elective or emergency settings, in consecutive unselected IBD patients.

Methods: All the patients received totally laparoscopic 2-stage (proctocolectomy and IPAA – stoma closure) or 3-stage (colectomy – proctectomy and IPAA – stoma closure) procedure according to their presentation.

Results: From July 2007 to July 2016, 160 patients entered the study. 50.6% underwent a 3-stage procedure and 49.4% a 2-stage procedure. Mortality and morbidity were 0.6% and 24.6%. Conversion rate was 3.75%. 8.7% septic complications were associated with steroids and Infliximab treatment (p=0.0001). 3-stage patients were younger (p=0.0001), with shorter disease duration (p=0.0001), minor ASA scores of 2 and 3 (p=0.0007), lower inflammatory index and better nutritional status (p=0.003 and 0.0001), fewer Clavien-Dindo's grade II complications (p=0.0001), reduced rates of readmission and reoperation at 90 days (p=0.03), and shorter hospitalization (p=0.0001), but with similar pouch and IPAA leakage, compared to 2-stage patients. 8 years pouch failure and definitive ileostomy were 5.1% and 3.7%.

Conclusion: A totally laparoscopic approach is safe and feasible, with very low mortality and morbidity rates and very low conversion rate, even in multi-stage procedures and high-risk patients.

1. Introduction

Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) was first described by Parks and Nicholls in 1978, and it has since become the treatment of choice for familial adenomatous polyposis (FAP), ulcerative colitis (UC), indeterminate colitis (IC) and selected cases of Crohn's Disease (CD)[1-3]. In inflammatory bowel disease (IBD), restorative proctocolectomy with IPAA is usually performed electively in one or two stages, depending on whether a temporary ileostomy is created. Abdominal colectomy is advocated prior to IPAA procedure in high-risk patients and in emergency settings[2].

Restorative proctocolectomy remains a highly technically demanding operation with reported peri-operative morbidity and mortality rates of 15%-50% and 1%-13%, respectively[4-10]. Laparoscopy has been proposed as an appealing alternative to open surgery for IPAA, and it has been found to be associated with a reduction in post-operative complications, less intraoperative blood loss, earlier recovery, shorter length of hospitalization, reduction in visceral adhesions and incisional hernias, improved cosmesis, and better preservation of female fecundity, in comparison with open surgery[11-15]. However, totally laparoscopic restorative proctocolectomy with IPAA, especially if performed in multiple stages, is a quite complex procedure, and few studies in tertiary centers have prospectively evaluated a totally laparoscopic approach, in elective or emergency settings, and in a consistent number of consecutive and unselected IBD patients[16-20].

The aim of the present study was to evaluate safety, efficacy and long-term results of totally laparoscopic, multi-stage IPAA, in a consecutive, unselected series of IBD patients referred to a tertiary Italian center.

2. Patients and Methods

A defined diagnostic, therapeutic and clinical care protocol (in Italian: Percorso Diagnostico Terapeutico Assistenziale – PDTA) was established in January 2008, to offer a high-quality standard of surgical care, in line with international guidelines, and to provide a management and accounting tool for auditing. A Multi-Disciplinary Team (MDT) for IBD was already present, involving gastroenterologists, surgeons, paediatricians, pathologists and radiologists. Oncologists, ophthalmologists and infectious disease specialists were also involved for selected cases. A dedicated service was also guaranteed by stoma-therapists, nutritionists, and psychologists. A 24-hour joint surgery and gastroenterology IBD on-call service was already available. In all patient candidates for emergency or elective surgery, a multi-disciplinary meeting (MDM) evaluation was performed, involving the surgical team that had an experience of performing more than 250 IPAA by open approach, as well as advanced training in laparoscopic colorectal surgery. A dedicated, prospective database was set up and approved by the ethics committee of our institution, including 75 variables concerning demographic, pre-operative, peri-operative, and long-term data. Follow-up was maintained with clinical examinations at 3, 6 and 12 months after surgery, and then yearly or in case of necessity. Functional results were evaluated at 12 months. All patients received an endoscopic control of the pouch at 12 months and then every 2 years or in case of necessity. Informed consent for the surgical procedures and data auditing was obtained from all patients after specific multidisciplinary counselling.

2.1. Emergency settings

Emergency surgery was indicated in all patients with severe acute colitis refractory to salvage therapy or with surgical complications (fulminant colitis, perforation, massive haemorrhage, toxic megacolon). Severe acute colitis was defined using the Truelove and Witts criteria, as reported in the European Crohn's and Colitis Organization (ECCO) and American Society of Colon and Rectal Surgeons (ASCRS) Guidelines[2,21-26]. To exclude the risk for toxic dilation or to monitor response to therapy, a computed tomography (CT) scan and/or bowel ultrasound, instead of plain abdominal x-

ray, was performed in most cases[27,28]. At hospital admission, all patients were evaluated jointly by a dedicated gastroenterologist and surgeon at most within 24 hours, based on clinical, biochemical and radiological examinations. Patients were considered as candidates for immediate surgical procedure or re-evaluation after rescue therapy with intravenous steroids at 72 hours, based on clinical history. Patients with an indication for second line medical treatment with cyclosporine or Infliximab were re-evaluated at the 5th, and no later than the 7th day. In the case of no improvement or worsening, surgery was performed in urgent or emergency settings by means of total abdominal colectomy, rectal closure, and Brooke's ileostomy[2,29,30].

2.2. Elective settings

Indications for elective surgery were chronic refractory colitis, complicated or refractory CD of the colon, chronic obstruction, and malignant transformation[2,31]. For patients referred from other hospitals, a specific discussion with the proposing gastroenterologist or paediatrician was performed and the complete case reviewed, including reviewing previous biopsies from the referral pathologist (PF) when necessary. According to patient characteristics, restorative proctocolectomy was performed in 1, 2 or 3 stages. The 3-stage procedure consisted of abdominal colectomy and rectal closure with Brooke's ileostomy[30], followed by completion proctectomy, formation of IPAA and loop ileostomy, and ileostomy closure. The 3-stage procedure included also the elective completion proctectomy of those patients treated in the emergency setting by abdominal colectomy. The 2-stage procedure refers to a proctocolectomy with IPAA and loop ileostomy followed by closure of ileostomy. In the modified 2-stage and in the single-stage procedures ileostomy was omitted at time of restorative completion proctectomy and proctocolectomy respectively[2,29,32-35].

2.3. Study population

All consecutive patients referred to the IBD Surgical Unit for restorative proctocolectomy were considered eligible for the study. Candidate patients for open surgery due to previous major abdominal procedures or with contraindications to laparoscopy, and those treated by ileo-rectal anastomosis or proctocolectomy with definitive ileostomy, were not included. Previous open

appendectomy, cholecystectomy, gynaecological and urological procedures were not considered as contraindications to the laparoscopic approach. Patients who required conversion during the first laparoscopic procedure were considered for an "intention to treat" analysis in terms of morbidity and mortality, but then excluded from analysis of the following step according to "per protocol" analysis. In the emergency setting, hemodynamically unstable or perforated patients were candidates for open colectomy and thus were excluded from the study[2]. Toxic megacolon was not considered an absolute contraindication to laparoscopic colectomy. As previously reported and in accordance with European and North American Guidelines, aging was not considered itself a contraindication to laparoscopic restorative proctocolectomy[2,24,36]. A complete record of each patient with pre-operative, intra-operative, post-operative and long-term results was entered in the data base. Readmission and reoperation were considered within 90 days. Conversion into laparotomy was defined as an unplanned abdominal incision longer than 6cm in any abdominal quadrant. Long-term results were recorded in terms of functional results at 12 months, and diagnosis of pouchitis, IPAA stenosis or fistulisation, and pouch failure during follow-up.

2.4. Surgical procedures

All patients were treated by a totally laparoscopic approach using a five-trocars technique (Figure 1). Vascular ligations were always performed at major trunks (inferior mesenteric artery and vein, middle-, right-, and ileo-colic vessels), from left side to right side, avoiding peri-visceral dissection, in order to minimize intestinal mucosal ischemia, with loss of barrier function, and consequent intraoperative systemic toxicity[37]. The rectal stump was always managed with intra-corporeal stapling and overlock running suture. Total mesorectal excision (TME) and carcinogenic mesocolic excision were performed in the cases of dysplasia or colorectal cancer (CRC). Incomplete TME (I-TME), where the dissection was carried out in the pre-sacral plane posteriorly and close to the rectum in the anterior and lateral planes, was used in all other patients. All pouches were 15-18cm long, stapled J-pouch as designed by Utsunomiya in 1980[38]. The ileo-pouch-anal anastomosis was performed by a Knight-Griffen[39], transanal anastomosis, using a circular end-to-end stapling device (CEEA), with

intraoperative measurement of the distance from the dentate line between 1cm and 2cm. A hand-sewn anastomosis, with transanal mucosectomy, was performed when necessary (low rectal dysplasia or CRC, failure of the CEEA stapler device)[2,40]. Extraction of the specimen and pouch creation were performed through the site of the temporary ileostomy in the right iliac fossa, or through a peri-umbilical or a suprapubic incision, depending on the dimension of the specimen or the need for mesenteric lengthening of the pouch. In the patients undergoing the 3-stage procedure, the same ports and extraction site were used for abdominal colectomy (stage 1) and completion proctectomy with IPAA (stage 2) (Figure 1). The completion proctectomy with IPAA and loop ileostomy were performed between 3 and 6 months after abdominal colectomy, rectal closure and ileostomy. This time interval is based on the need to obtain adequate steroid tapering, desaturation from any pharmacological compounds, and normalization of nutritional status. Temporary ileostomy was closed at 6-8 weeks with a wide lumen, functional end-to-end, stapled anastomosis, after clinical examination. Control of the pouch and IPAA was performed by pelvic magnetic resonance imaging (MRI) prior to ileostomy closure only in selected cases with a clinical or biochemical suspicion of dehiscence.

2.5. Outcome measures

Perioperative mortality and morbidity were considered during hospital stay and within 90 days after each step of 1, 2 or 3-stage surgical procedures. Postoperative complications were classified using the Clavien-Dindo's classification[41-43]. Major surgical complications were defined as Clavien-Dindo's grade III or IV, while grade V corresponds to mortality. Intra-abdominal septic complications (IASC), including pelvic sepsis, were particularly evaluated. Functional results were considered in terms of frequency of bowel movements over 24 hours, and diurnal and/or nocturnal soiling and/or incontinence, at 12 months after ileostomy closure. Long-term complications were defined as any adverse event related to the surgical procedure occurring during the follow-up. The minimum follow-up was 12 months. Pouchitis was defined as an inflammation of the pouch in the presence of symptoms associated with endoscopic and histopathologic findings[2]. Pouch failure was defined as

excision or indefinite defunctioning of the pouch[2]. A comparison was performed between 2- and 3-stage procedures in terms of cumulative early and late postoperative results referred to IPAA creation.

2.6. Statistical analysis

Comparison of proportions was performed using chi-square or Fisher's exact test where appropriate. Continuous variables were analysed using Student's t test. Long term pouch survival was calculated with the time-to-event Kaplan and Meier estimates. This study was approved and conducted according to the ethical standards of the ethics committee of our institution, and reported according to the Strengthening the Reporting of Observational Studies in Epidemiology [STROBE] guidelines[44].

Results

From January 2008 to December 2016, 204 patients entered the diagnostic, therapeutic and clinical care protocol (PDTA) at "Luigi Sacco" University Hospital. According to patient selection criteria, 44 patients were excluded from this survey: 20 patients (9.8%) were candidates for open surgery due to previous major laparotomy or clinical contraindications to pneumoperitoneum, 14 patients (8.7%) received an IRA or permanent ileostomy (78.5% of these patients were also treated by laparoscopy), and 10 patients (4.9%) were perforated or hemodynamically unstable and thus operated on using an open approach. The total percentage of patients considered unsuitable for the laparoscopic approach was 16.1% (of all 204 patients). In the remaining 160 patients, 231 major abdominal procedures and 136 ileostomy closures were performed. There were 100 males (62.5%), 13 patients (8.1%) presented extra-intestinal manifestations of IBD, 11 (6.8%) had a family history of IBD, 12 (7.5%) were active smokers, and 21 (13.1%) received a previous abdominal surgery. Preoperative diagnosis of UC was present in 153 patients (95.6%), CD in 4 (2.5%), and IC in 3 (1.9%), while 31 (19.3%) patients were operated on for dysplasia or CRC. The mean age at diagnosis was 38.1 ±16.3 years (min 5, max 80 years), the mean age at first-stage surgical procedure was 48 ±16.1 years (min 15, max 82 years), and the mean disease duration was 10.1 ±8.9 years. Disease extension was a pancolitis in 92.5% and a left-sided colitis or proctitis in 7.5%. 81 patients (50.6%) underwent a sub-total colectomy, 47 of them (58%) in the emergency setting due to severe acute colitis, 8 for toxic megacolon (9.9%), and the remaining 26 for poor clinical conditions (32.1%). One female patient died on post-operative day 2, after emergency colectomy, for *ictus cerebri* at the age of 80 years (mortality rate 1.2%). Three patients were converted to open surgery (conversion rate 3.7%), and 6 patients have not yet completed the following stages. Characteristics of the patients submitted to abdominal colectomy, rectal closure and ileostomy are reported in Table 1. Seventy-one patients received completion proctectomy and IPAA with a conversion rate of 2.8% (2 patients), and 5 of them (7.1%) without diversion by temporary ileostomy (modified 2-stage procedure). Seventy-nine patients (49.4%) were operated on by a 2-stage (72 patients – 91.1%) or a single-stage procedure (7 patients – 8.9%). The overall rate

of patients without diversion at the time of pouch and IPAA formation was 8% (7 single-stage + 5 modified 2-stage). Comparisons of patient characteristics at time of completion proctectomy or restorative proctocolectomy are reported in Table 2. Intra-abdominal septic complications (IASC), including pelvic sepsis, occurred in 14 patients (8.7%), 5 (6.2%) at the time of colectomy, 2 (2.8%) at the time of completion proctectomy, and 7 (8.8%) after proctocolectomy. Comparing patients with IASC with patients with other or no complications, 57.1% vs. 16.2% were treated with a combination of systemic steroids and Infliximab, 28.6% vs. 24.3% with systemic steroids alone, and 14.3% vs. 59.5% were being treated with another or no therapeutic regimen (p=0.0001).

The conversion rate in the 3-stage procedure (stage 1 + stage 2) was 3.3%, and in all single and multi-stage procedures was 3.75%. Complications at ileostomy closure are listed in Table 3. Mortality rate at 90 days in 1, 2, or 3-stage procedures was 0.6%. Long-term results and the cumulative probability of the first episode of pouchitis, pouch failure, and definite ileostomy are reported in Figure 2.

Discussion

A multidisciplinary approach, which includes formal multidisciplinary meetings and allows for integration of the contributions of all specialists necessary for adequate treatment of IBD patients, is of paramount importance for tertiary standard of care. Performing such a complex surgical PDTA requires significant design and organization, medical and nursing staff upgrading, and, above all, a change in mentality. A very aggressive policy in terms of early multidisciplinary discussions, re-evaluation and surgery is necessary to achieve low morbidity and mortality rates[45-47]. Success also depends upon prospective auditing of patients concerning timing and indication for surgery, intraoperative critical issues, perioperative complications, and long-term results, in order to verify results and update strategies[48]. Selection criteria for patients who are candidates for laparoscopy for elective or emergency procedures are rarely reported in the literature. In this series, the patients were consecutive and unselected, and the only reason for an open procedure, apart from clinical contraindications, was previous major open abdominal surgery. Applying these criteria,

contraindication to laparoscopy was 16.1%, but conversion rate was very low (3.75%), considering that reported conversion rate in trials and observational studies ranges from 1 to 23%[49-56], and that conversion rate after laparoscopic cholecystectomy, the most popular laparoscopic procedure, is reported to be 5-10%[57]. Emergency sub-total colectomy for acute colitis in IBD is a potentially life-threatening procedure, with a reported mortality rate that ranges, in Europe and North America, from 1% to 13%[4-6,46]. In 2006, the United Kingdom national audit of IBD identified a mortality rate of 2.1-4.7% after emergency colectomy[46]. In 2012, Tottrup et al., in the Danish population-based nationwide cohort study of 2889 cases, showed a 30-day mortality of 5.2% after emergency colectomy and 0.9% after elective proctocolectomy for UC, and 8.1% and 1.5% for CD[5]. In 2015, an audit of 1166 patient from 237 French centers found a mortality rate of 1.5% (0-2.7%)[6,58] after elective restorative proctocolectomy. However, the vast majority of patients in all these series were operated on in the 1990's, and in the early 2000's by open procedures. Only 8 studies reported on mortality after laparoscopic colectomy, with a rate of 0.25% in a total of 402 patients[47]. The most important prognostic factors for mortality are the volume of the center, the surgeon's experience and the timing of surgery, given that high-volume centers (>10 cases per year), with dedicated surgeons and with aggressive surgical policies, have reported mortality rates around 2% for emergency surgery and 1% for elective surgery[36,45-47,52,54,59-64]. Morbidity is subject to the same prognostic factors of mortality and remains quite high in almost all the series. Expected morbidity ranges from 25% to 65%, but major complications have shown a tendency to decrease over years, in particular after laparoscopic procedures performed in referral centers[6,11,47,59,65]. In most studies, complications are reported as a description, limiting the possibility of adequate comparisons. Unfortunately, even if the Clavien-Dindo classification should be used, some specific limitations in the field of IBD are present[41-43]. In fact, the Clavien-Dindo classification has been designed to provide grading of complications after elective abdominal surgery. Accordingly, any deviation from the normal postoperative course, such as prolonged ileus or simple wound infections, are classified as Grade 1 complications, while blood transfusion and total parenteral nutrition (TPN) are classified as Grade 2. However, these therapeutic

regimens are the daily clinical practice for IBD patients, both in emergency and some elective settings. As shown in Table 1, Grade I and II complications after colectomy are 58%, but if blood transfusions and TPN are excluded, these complications only make up 8.6%. Similarly, as shown in Table 2, they change from 32.9% to 6.3% after restorative proctocolectomy. Another limitation of the Clavien-Dindo classification is that it accounts only for complication during hospitalization. Readmission and reoperation after discharge, another common aspect of IBD patients, is rarely reported in surgical series and generally within 30 days[7,66,67]. Extension of the observation period to 90 days is more indicative of the course of IBD patients[48]. The vast majority of readmission and reoperation after colectomy and proctocolectomy are related to ileostomy complications (ileus, obstruction, dehydration and electrolyte imbalance). Some authors have proposed to omit diversion after ileal pouch surgery to avoid stoma-related complications, but at the cost of a 3-fold greater (5% to 15%) incidence of IPAA leakage and pouch-related sepsis[68-72]. In the present series, the 5.3% cumulative incidence of leakage is quite low, with 8% of the patients without diversion. The 6% incidence of IASC was strongly related to treatment with steroids in association with Infliximab, as previously reported[73-77]. However, both leakage and IASC were independent of the number of surgical stages. Determining the right timing for restorative proctocolectomy and deciding on a single or a staged procedure remains the crucial issue of this surgery, since the majority of complications, including mortality, could be a consequence of this initial decision. To date, only 5 studies have focused on the comparison between the 2 and 3-stage approach: one from the same inventor of the pouch (RJ Nicholls)[18], 3 with the series dating back to the 1980's[18-20], one with a laparoscopic approach in 17.4% of the cases (25 patients)[78], and only a recent one using the total laparoscopic approach in a consistent number of patients[65]. Hicks et al. concluded in favour of the predominant use of 2-staged surgery, but the patients who underwent the 3-stage procedure in the study only totalled 28, and only 7 were treated by laparoscopy[78]. Galandiuk et al. also favored 2 stages in their series of 871 patients, while Nicholls and Penna suggested the 3-stage procedure was safer, but all the patients were operated on by open surgery in the pre-anti-TNF era[18-20]. The results from the group

of Clichy, who used laparoscopy in 100% of 185 patients, are very similar to the results in this study, in particular in terms of patient characteristics, operative findings, perioperative complications and postoperative results (Table 1 and 2). However, some interesting differences should be highlighted[65]. A direct comparison of the 2- and 3-stage procedures is quite difficult as it involves different patients with different indications. However, focusing on the construction and anastomosis of the pouch, there are major differences between patients who have previously had a colectomy (who have passed the risks of surgery in emergency or in poor clinical conditions) and those who are candidates for proctocolectomy. In fact, the latter have a higher ASA score, an altered inflammatory and nutritional status, and most of them are receiving maximal medical treatment, as well as have a higher 90-day readmission and reoperation rate (Table 2). These results suggest that perhaps a subset of the patients who were candidates for proctocolectomy would have benefited from a staged procedure. Furthermore, a higher ASA score and longer hospitalization are still factors at the time of recanalization. However, no differences are present in terms of IPAA and pouch leakage. In the past, an attempt to reduce the number of procedures appeared to be indicated by the morbidity associated with multiple laparotomies, but in different surgical fields, such as cholecystectomy, bariatric surgery and gastroesophageal reflux disease, laparoscopy has changed the indications by reducing the morbidity in comparison with previous treatments.

In this context the proposal by some Authors to carry out a modified two-stage procedure, without diverting the patient at the time of completion proctectomy, appears very intriguing. In our experience only 7% of the patients underwent this procedure, but in the future the combination of a laparoscopic approach with a modified two-stage procedure should be studied in more depth[32-35].

The possibility to perform a restorative proctocolectomy by a laparoscopic approach, with very low morbidity, morality, conversion rate and long-term results, regardless of the number of the stages, should allow for debate in the future about the possibility of having an evidence-based driven staging for IPAA surgery.

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Table 1. Patients submitted to abdominal colectomy, rectal closure and ileostomy [¶ Clavien-Dindo's complications of grade I and II excluding perioperative blood transfusion and total parenteral nutrition (TPN)].

Number of patients		81
Age		44 ± 17 years
Gender	Males	50 (61,7%)
	Females	31 (39,3%)
Extra-intestinal Manifestations of IBD		8 (9,8%)
Familiarity for IBD		4 (4,9%)
Smoking Habit		6 (7,4%)
Diagnosis	Ulcerative Colitis	76 (93,8%)
	Crohn's Disease	2 (2,4%)
	Indeterminate Colitis	3 (3,8%)
Age		44 ± 17 years
Age at Diagnosis (years)		37,8 ± 16,5 years
Disease Duration (years)		6 ± 6,47 years
ASA Score	ASA1	10 (12,3%)
	ASA2	61 (75,3%)
	ASA3	10 (12,4%)
Previous Abdominal Surgery		8 (9,8%)
Preoperative Therapy	5-ASA	5 (6,2%)
	Steroids	26 (32%)
	Combined Therapy	17 (21%)
	Biologics	26 (32%)
	Cyclosporine	7 (8,8%)
Preoperative Blood Exams	Haemoglobin (g/dL)	10,3 ± 1,99
	White Cell Count (u/L)	9411 ± 3670
	C Reactive Protein (mg/dL)	41,2 ± 45,7
	Total Proteins (g/L)	5,56 ± 0,85
	Albumin (g/L)	28 ± 6,7
	Transthyretine (g/L)	0,14 ± 0,05
Indication for Surgery	Refractory to Medical Therapy	26 (32,1%)
	Severe Acute Colitis	47 (58%)
	Toxic Megacolon	8 (9,9%)
Operative Time (minutes)		211 ± 60,6
Conversion Rate		3 (3,7%)
Specimen Delivery	Suprapubic Incision	37 (45,6%)
	Stoma Site	42 (51,8%)
	Peri-umbilical	2 (2,6%)
Complications (Clavien-Dindo)	Grade I+II	47 (58%) – 7 (8,6%)¶
	IIIA	3 (3,8%)
	IIIB	2 (2,4%)
	IV	/
	V	1 (1,2%)
Readmission (90 days)		11 (13,5%)
Reoperation (90 days)		6 (7,4%)
Hospitalisation (days)		15,2 ± 7,8

Table 2. Patients submitted to completion proctectomy or proctocolectomy with pouch construction and IPAA (the following parameters relate to the 1st stage: ASA Score¶, medical therapy†, readmission and reoperation*; summation of 1st and 2nd stage operative times §; Clavien-Dindo's stages I and II excluding perioperative blood transfusion and TPN#; considering only Clavien-Dindo's stages III-V‡; and hospitalisation^).

	Completion Proctectomy n 71		Proctocolectomy n 79		p value
Age	42,6 ± 15,5		51,3 ± 14		0,0001
Gender					
Males	42 (59,1%)		50 (63,3%)		
Females	29 (40,9%)		29 (36,7%)		0,72
Extra-intestinal Manifestations of IBD	8 (11,2%)		5 (6,9%)		0,43
Familiarity for IBD	4 (5,6%)		7 (8,8%)		0,65
Smoking Habit	6 (8,4%)		6 (7,5%)		0,92
Diagnosis					
Ulcerative Colitis	66 (92,9%)		77 (97,4%)		
Crohn's Disease	2 (2,8%)		2 (2,6%)		
Indeterminate Colitis	3 (4,3%)		0		0,28
Age at Diagnosis (years)	36,5 ± 15		37,8 ± 16,3		0,6
Disease Duration (years)	6 ± 6,4		13,6 ± 9,1		0,0001
ASA Score					
ASA1	30 (42,2%)	10 (12,3%)¶	11 (13,9%)¶		
ASA2	40 (56,4%)	61 (75,3%)¶	58 (73,4%)¶		
ASA3	1 (1,4%)	10 (12,4%)¶	10 (12,7%)¶		0,0007 - 0,9¶
Previous Abdominal Surgery	6 (8,4%)		13 (16,4%)		0,22
Preoperative Therapy					
5-ASA	/	5 (6,2%)†	13 (16,4%)		
Steroids	/	26 (32%)†	15 (18,9%)		
Combined Therapy	/	17 (21%)†	16 (20,2%)		
Biologics	/	26 (32%)†	21 (26,5%)		
Cyclosporin	/	7 (8,8%)†	1 (1,6%)		0,03
Preoperative Blood Exams					
Haemoglobin (g/dL)	12,9 ± 1,2		12,23 ± 2,07		0,7
C Reactive Protein (mg/dL)	2 ± 1,3		13,7 ± 25,8		0,0002
Total Proteins (g/L)	6,8 ± 0,96		6,35 ± 0,89		0,003
Albumin (g/L)	4 ± 0,78		3,5 ± 0,7		0,0001
Transthyretine (g/L)	0,22 ± 0,03		0,20 ± 0,05		0,003
Operative Time (minutes)	186,6 ± 56,7	352 ± 91,5§	325,75 ± 86,25§		0,07§
IPAA					
Hand sewn	2 (2,9%)		5 (6,4%)		
Stapled	69 (97,1%)		74 (93,6%)		0,44
Conversion Rate	2 (2,8%)		1 (1,6%)		0,6
Specimen Delivery					
Suprapubic Incision	30 (42,2%)		41 (51,9%)		
Stoma Site	40 (56,4%)		36 (45,5%)		
Peri-umbilical	1 (1,4%)		2 (2,6%)		0,43
Complications (Clavien-Dindo)					
Grade I+II	3 (4,3%)		26 (32,9%) – 5 (6,3%)#		
IIIA	2 (1,4%)		2 (2,6%)		
IIIB	2 (1,4%)		5 (6,3%)		
IV	/	4 (5,6%)‡	1 (1,2%)	8 (10,1%)‡	0,0001 - 0,89‡
Defunctioning Ileostomy	66 (92,9%)		72 (91,1%)		0,92
IPAA leakage	2 (2,9%)		4 (5%)		0,68
Pouch Leakege	1 (1,4%)		1 (1,6%)		1
Readmission (90 days)	2 (2,9%)	11 (13,5%)*	10 (12,7%)*		0,03 - 1*
Reoperation (90 days)	1 (1,4%)	6 (7,4%)*	8 (10,1%)*		0,03 - 0,58*
Hospitalisation (days)	9,1 ± 3,2	15,2 ± 7,8^	13,9 ± 7,2^		0,0001 – 0,2^

Table 3. Patients submitted to ileostomy closure after 2 or 3 stages procedure.

	3-stages n 66	2-stages n 70	p value
Gender			
Males	42 (63.6%)	46 (65.7%)	
Females	24 (36.4%)	24 (34.3%)	0,9
ASA Score			
ASA1	30 (45.5%)	10 (14.2%)	
ASA2	36 (54.5%)	52 (74.2%)	
ASA3	0	8 (11.6%)	0,0001
Previous Abdominal Surgery	6 (9%)	11 (15.7%)	0,03
Complications (Clavien-Dindo)			
Grade I+II	1 (1.5%)	3 (4.3%)	
IIIA	0	0	
IIIB	0	3 (4.3%)	0,1
Readmission (90 days)	1 (1.5%)	1 (1.4%)	1
Reoperation (90 days)	1 (1.5%)	1 (1.4%)	1
Hospitalisation (days)	6,6 ± 4,4	9.2 ± 4.6	0,0001

	3-stages n 66	2-stages n 70	p value
Gender			
Males	42 (63.6%)	46 (65.7%)	
Females	24 (36.4%)	24 (34.3%)	

Figure 1. Trocar positioning and ports utilisation during 1st and 2nd stage.
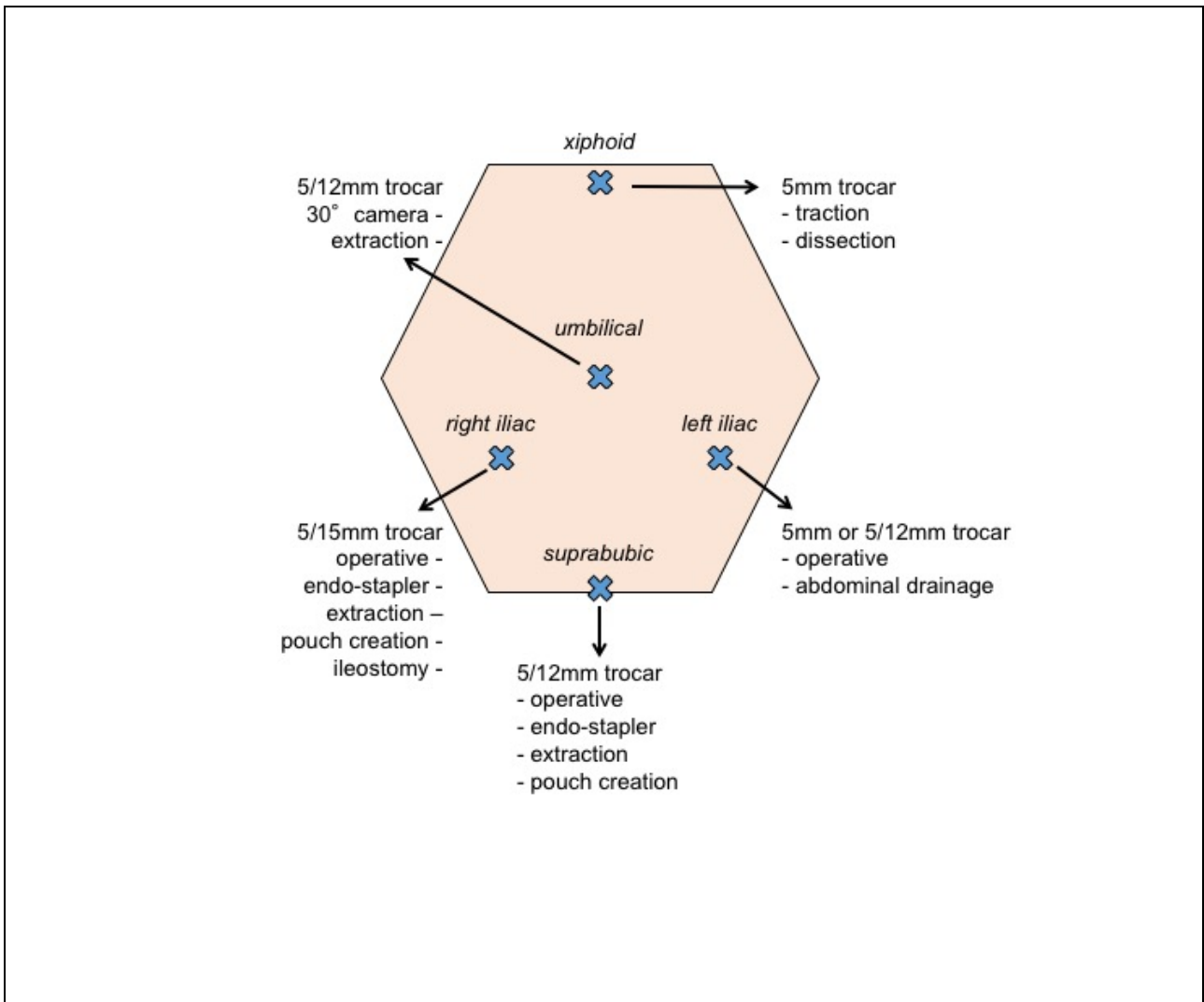
Figure 2. Upper panel: Kaplan-Meier time-to-event estimates of Pouch Failure (left) and Permanent Ileostomy (right).
Lower panel: Kaplan-Meier time-to-event estimates of first episode of Pouchitis (left) and functional results (right)

Stool Frequency		
	Day	5 (2-10)
	Night	1 (0-2)
Soiling		
	Day	5%
	Night	16%
Incontinence		
	Day	/
	Night	/
Pouch Failure		
	n (%)	7 (5,1%)
	Cumulative probability	7% at 8 years
Redo Pouch		
	n (%)	2 (28,5%)
Definitive Ileostomy		
	n (%)	5 (3,7%)
	Cumulative probability	4% at 8 years
Length of Follow-up (years ±SD)		5,1 ±2,5