

Short-term Outcome of Robot-assisted and Open IPAA: An Observational Single-center Study

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BACKGROUND: The potential advantages of robot-assisted laparoscopy are being increasingly investigated, although data on its efficacy in benign colorectal surgery are scarce.

OBJECTIVE: We compared the early postoperative outcome in robot-assisted IPAA with open surgery procedures.

DESIGN: This was an observational study based on prospectively collected data obtained from chart reviews.

SETTING: The single-center data set covers patients operated on from January 13, 2004, to September 16, 2014, at a specialist center.

PATIENTS: Patients with ulcerative colitis undergoing IPAA surgery were included.

MAIN OUTCOME MEASURES: Study end points included the duration of operation, admission length, complications (Clavien-Dindo), reoperations, and readmissions.

RESULTS: Eighty-one robot-assisted and 170 open IPAA procedures were performed. The duration of operation was significantly longer for robot-assisted laparoscopic procedures (mean difference, 154 minutes; CI, 140–170). During a mean follow-up of 102 days, no significant differences in the distribution of

complications were found (Spearman $p = 0.12$; $p = 0.07$), and no postoperative deaths occurred in either group. Postoperative admission length was shorter following robot-assisted procedures (mean difference, -1.9 ; CI, -3.5 to -0.3), whereas 40% of patients were readmitted, compared with 26% of patients who had open surgery (OR, 1.9; CI, 1.1–3.4). Pouch failure occurred in 3 patients (1 following robot-assisted laparoscopy; 2 following open surgery). On multivariate regression analyses, robot-assisted laparoscopy was associated with a significantly longer duration of operation (mean difference, 159 minutes; CI, 144–174), and more readmissions for any cause (OR, 2; CI, 1.1–3.7).

LIMITATIONS: This was a nonrandomized, single-center observational study.

CONCLUSION: In this implementation phase, robot-assisted IPAA surgery offers acceptable short-term outcomes. The limitations of this observational study call for randomized controlled trials with long-term follow-up and exploration of functional results.

KEY WORDS: Colorectal surgery; Ileal pouch-anal anastomosis; Laparotomy; Robot-assisted; Short-term outcome; Ulcerative colitis.

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Restorative proctocolectomy with IPAA is the surgical treatment of choice for refractory chronic ulcerative colitis and in selected cases of familial adenomatous polyposis. Traditionally, the procedure is performed in 2 or 3 stages by using either an open, a hand-assisted laparoscopic, or a total laparoscopic approach. Short-term recovery seems to be augmented by laparoscopy,^{1,2} although the only randomized controlled trials^{3,4} have failed to show better outcomes compared with open surgery. Long-term benefits of laparoscopy in terms of improved body image have been reported,⁵ and reduced

infertility rates^{6,7} represent an additional advantage, presumably facilitated by the diminution of adnexal adhesions following the minimally invasive approach.⁸

The use of robot-assisted laparoscopy (RAL) in colorectal surgery has increased dramatically during the past years in the treatment of both malignant and benign conditions.^{9,10} Although improved dexterity and optimized triangulation of instruments are the proposed advantages of RAL, the superiority of RAL over conventional laparoscopy has so far been limited to a lower conversion rate and a subclinical lower intraoperative blood loss, as reported by 2 meta-analyses primarily based on data from studies of rectal cancer.^{9,11}

It is unknown whether robot assistance improves outcome in IPAA surgery. Only 3 case series on 18 total procedures have been published,¹²⁻¹⁴ and none of these has included a reference group that was offered the standard open surgery (OS) procedure.

With this study, we describe the procedure and report short-term outcomes of the first 81 robot-assisted IPAA procedures performed at our specialist center, compared with a consecutive cohort of 170 open procedures.

MATERIALS AND METHODS

Study Cohort

Patients operated on from January 13, 2004, to September 16, 2014, at the Department of Surgery P, Aarhus University Hospital, Denmark, were included, and all were diagnosed with ulcerative colitis before surgery. Baseline variables, surgical specifications, and early postoperative outcome was extracted from hospital charts by 3 investigators (A.M.C., F.R.P., and C.B.N.) using predefined spreadsheets. The study adheres to the *Strengthening the Reporting of Observational Studies in Epidemiology* (STROBE) guidelines. Because this study was a quality assurance activity, institutional review board approval was not needed.

Surgical Technique

Experienced colorectal surgeons performed all open procedures, whereas the robot-assisted procedures were performed either by experienced colorectal surgeons or by colorectal surgical fellows supervised by senior surgeons. Because 79 of the RAL procedures were performed as completion proctectomies and only 2 as proctocolectomies, only the former will be described in the following. The RAL approach was used for patients who had undergone laparoscopic colectomy, whereas OS was performed on patients previously colectomized by an open approach.

Throughout the study period, a strict policy of not offering restorative procedures to patients receiving corticosteroids or who had been treated with biologics within the preceding 3 months was followed. In addition, a consensus

at the department of always diverting the reservoirs whenever possible was also followed.

Robot-Assisted and Open IPAA

First, the terminal ileostomy was incised in its circumference to the peritoneum by using sharp dissection and electrocautery. The peritoneal cavity was insufflated with carbon dioxide by using a balloon trocar inserted at the ostomy site. Six trocars were inserted, and the small-bowel mesentery was mobilized laparoscopically. The uterus was then retracted to the anterior abdominal wall by using transabdominal sutures and the robot device (da Vinci Surgical System, Intuitive Surgical, Inc) was subsequently docked. Next, the robot-assisted proctectomy was performed by the principles of total mesorectal excision, with the modification that close rectal dissection was performed anterolaterally to minimize the risk of damaging the parasympathetic nerves in relation to the seminal vesicles. The rectum was stapled approximately 1 to 1.5 cm above the dentate line with the use of an endoscopic surgical stapling device (iDrive Ultra, Covidien) and the specimen was extracted through a Pfannenstiel incision. If satisfactory positioning of the stapling device was unachievable, an open technique using TA30/TA45 (Covidien) or Contour (Ethicon) staplers was performed. A handsewn anastomosis was performed if adequate stapling of the rectum could not be achieved. From the distal ileum, a 15- to 20-cm J-pouch was created by extracorporeal stapling (GIA80, Covidien, Boulder, CO) with 2 to 3 magazines. Without tension or mesenteric rotation, the pouch was anastomosed to the top of the anal canal with a curved circular stapler. In some instances, it was necessary to improve reach by a number of well-described principles for mesenteric lengthening.¹⁵⁻¹⁸

Ultimately, a diverting loop ileostomy was fashioned at the old ostomy site to protect the pouch-anal anastomosis with 25 to 50 cm of interposed small bowel between the top of the J-pouch and the ostomy. The pelvic cavity and the pouch were prophylactically provided with catheters to allow for drainage in the immediate postoperative period.

The Pfannenstiel incision and port sites were closed by using running and interrupted absorbable monofilament sutures, whereas surgical staples or monofilament, absorbable intradermal sutures were used for closure of the skin wounds.

All open IPAA procedures at our center were performed via midline laparotomies. The approach followed the general principles outlined above.

Outcome Measures

We compared durations of operation, admission lengths, readmissions, complications, pouch failures, and intervals from IPAA to ileostomy reversal between RAL and OS. In agreement with international consensus, we applied the

Clavien-Dindo classification of postoperative morbidity¹⁹ for comparison of early complications between the groups. On the individual patient level, complications that were believed to be unrelated (eg, parastomal hernia and urinary tract infection) were considered separate complications, whereas complications or interventions that arose consecutively as a result of 1 initial event (eg, a suspected localized infection initially treated with antibiotics and subsequently drained under local anesthesia) were defined by the most severe complication or intervention in that chain of events. Because not all postoperative medical care contacts were linked to exact historical dates, we defined the early postoperative period as the time interval between IPAA surgery and loop ileostomy reversal. When a loop ileostomy was omitted, the first outpatient control visit after pouch surgery concluded the early postoperative period.

Statistical Analysis

Continuous variables are expressed with mean (SD) or median (range), depending on distribution, whereas dichotomous and categorical variables are described as numbers and proportions. Differences in continuous variables were tested by the Student *t* or Mann-Whitney *U* test, whereas categorical variables were compared by using the χ^2 or Fisher exact test and the Spearman rank correlation for ordered categorical variables. To test for an overall difference in the distribution of complications using Spearman rank correlation, in the event of a patient experiencing multiple complications classified by separate Clavien-Dindo strata, only the most severe was included. Multivariate analyses for all outcomes were adjusted for the predefined potential confounders ASA grade, BMI, age, sex, and primary operation. Univariate multiple imputation²⁰ was made for 44 cases of incomplete BMI data, and all analyses were performed on intention-to-treat data, ie, RAL procedures converted to OS were treated as RAL procedures.

Intercooled STATA 13 (StataCorp LP, College Station, TX) was used in all analyses, where a *p* value of <0.05 was considered statistically significant.

RESULTS

During the period from January 14, 2004, to September 24, 2014, 278 IPAA procedures were performed at our department. Of these, 27 were conventional laparoscopic procedures, some of which were performed under the supervision of a foreign expert; these operations were excluded from analyses. Of the remaining 251 procedures (170 OS and 81 RAL), 233 were restorative proctectomies, whereas 14 were proctocolectomies (Table 1). In 3 cases, additional surgery was performed (1 herniorrhaphy, 1 sterilization, 1 puncture and excision of pelvic inclusion cyst), and 1 patient had IPAA performed after a primary ileorectal anastomosis. Besides dissimilar distributions in ASA

Table 1. Baseline characteristics

Baseline	OS	RAL	<i>p</i>
Number of patients	170	81	
Females, n (%)	75 (44)	39 (48)	0.55
Age at operation, mean (SD)	36.5 (12.7)	35.4 (13.6)	0.55
BMI, mean (SD)	24.2 (3.7)	23.5 (4)	0.20
ASA grade, n (%)			<0.01
I	112 (66)	32 (40)	
II	57 (33.5)	47 (58)	
III	1 (0.5)	2 (2)	
Primary operation, n (%):			0.14
Restorative proctectomy (RP)	155 (91.2)	78 (96.3)	
Restorative proctocolectomy (RPC)	12 (7.1)	2 (2.5)	
RP + other (hernioplasty, sterilization, etc)	3 (1.7)	1 (1.2)	
Length of follow-up, days (SD)	106 (57)	95 (42)	0.11

OS = open surgery; RAL = robot-assisted laparoscopy.

P-values < 0.05 are in bold

grade (higher in the RAL group), there were no differences in baseline characteristics or length of the observation periods between the open and RAL study groups (Table 1).

Data on the duration of operation were available for 101 OS and 79 RAL procedures, where the mean procedure lengths were 130 minutes (CI, 122–137) for OS procedures and 284 minutes (CI, 269–299) for RAL procedures (mean difference (MD), 154; CI, 140–170; *p* < 0.01) (Table 2). Nine (11.1%) RAL procedures were converted to midline laparotomies (8 males; median BMI, 26.2), and diverting loop ileostomies were fashioned in 84.1% and 91.4% of OS and RAL procedures (unadjusted OR, 2; CI, 0.8–4.8; *p* = 0.1).

In 26 (32%) RAL procedures (22 males, 4 females, Fishers exact < 0.05), stapling of the rectum had to be performed by open technique, ie, by use of nonendoscopic devices, whereas a handsewn anastomosis was needed in 2 RAL procedures. Patients in the RAL group who had open stapling performed had a longer length of stay than RAL patients who had laparoscopic stapling of the rectum (10 days (CI, 8–12) versus 8.6 days (CI, 7.3–10), *p* = 0.25).

The mean postoperative admission length was shorter following RAL procedures (9.1 versus 11 days (MD, –1.9; CI, –3.5 to –0.3; *p* = 0.02)), whereas the relative number of patients readmitted for any cause during follow-up was higher (40% versus 26% (unadjusted OR, 1.9, CI, 1.1–3.3; *p* = 0.03)). Of the patients readmitted, 7 (22%) patients from the RAL group and 9 (20%) patients from the OS group were readmitted because of grade III to IV complications, whereas the other readmissions were associated with minor (grade I–II) complications, eg, simple dehydration, uncomplicated occult infection treated with antibiotics, or incomplete small-bowel obstruction/ileus alleviated by afferent limb catheterization and irrigation.

The distribution of intra- and postoperative complications is listed in Table 2 by roman numerals in ascending

Table 2. Postoperative outcome, univariate and multivariate analysis

Perioperative outcome	Differences in outcome				Differences in outcome	
	Univariate analysis				Multivariate regression analysis ^a	
	OS (n = 170)	RAL (n = 81)	OR or mean difference (95% CI)	p	OR or mean difference (95% CI)	p
Duration of operation in minutes, mean (SD)	130 (38)	284 (67)	154 (140 to 170)	<0.01	159 (144 to 174)	<0.01
Complications, number of patients (%)						
None	105 (62)	41 (51)	0.6 (0.4 to 1.1)	0.09	0.6 (0.3 to 1.1)	0.08
I	20 (12)	15 (19)	1.7 (0.8 to 3.5)	0.15	2.2 (0.99 to 4.8)	0.06
II	44 (26)	23 (28)	1.1 (0.6 to 2.1)	0.67	1.1 (0.6 to 2)	0.81
IIIa	4 (2)	4 (5)	2.2 (0.5 to 8.8)	0.28	1.5 (0.3 to 6.6)	0.59
IIIb	17 (10)	14 (17)	1.9 (0.9 to 4)	0.10	1.9 (0.85 to 4.3)	0.12
IVa	0 (0)	1 (1)	NA	0.15	NA	–
IVb	0 (0)	0 (0)	NA	–	NA	–
V	0 (0)	0 (0)	NA	–	NA	–
Reoperations, n (%)	9 (5)	8 (10)	1.96 (0.7 to 5.3)	0.18	1.7 (0.6 to 4.8)	0.32
Admission length in days, mean (SD)	11 (6.4)	9.1 (5)	–1.9 (–3.5 to –0.3)	0.02	–1.51 (–3.14 to 0.1)	0.07
Patients readmitted, n (%)	44 (26)	32 (40)	1.9 (1.1 to 3.3)	0.03	2 (1.1 to 3.7)	0.02
Time from operation to ileostomy closure in days, mean (SD)	118 (54)	100 (40)	–18 (–31.8 to –3.4)	0.02	–14.5 (–29 to –0.01)	0.05
Pouch failures, n (%)	2 (1.1)	1 (1.2)	0.95 (0.1 to 11)	0.97	NA	–

OS = open surgery; RAL = robot-assisted laparoscopy; NA = not applicable (insufficient data volume).

P-values < 0.05 are in bold.

^aAdjusted for BMI, ASA grade, sex, age, and primary operation.

order of severity. In recognition of their potential negative impact on pouch survival, complications that required intervention under local or general anesthesia (grade III–IV) are further subcategorized by their clinical manifestations in Table 3. Although the relative distribution of type I to IV complications was numerically higher in the RAL group, there were no statistically significant differences on univariate regression (Spearman $p = 12$, $p = 0.07$). Pelvic sepsis, ie, anastomotic leaks, fistulas, and parapouch abscesses occurred in 8 (3.2%) cases (4 (4.9%) RAL; 4 (2.3%) OS; OR, 2.2; CI, 0.5–8.8), whereas 10 nonpelvic or nonseptic

grade III to IV complications were observed (1 abdominal wall abscess following RAL, 2 intra-abdominal hematomas following OS, and 7 intra-abdominal abscesses).

An intraoperative duodenal perforation, which was sutured immediately, occurred in 1 RAL patient, who had an uneventful recovery. Nine (5%) and 8 (10%) reoperations were performed in the OS and RAL groups.

No postoperative deaths occurred in either group, and ileostomy reversal was performed after an average of 100 days following RAL surgery and 118 days after OS (–18 days; CI, –31.8 to –3.4; $p < 0.01$). Pouch failure necessitating pouch excision or fecal diversion with an end-ileostomy occurred after 2 OS procedures because of 1 case of postoperative development of a pouch-vaginal fistula and 1 case of necrosis of the pouch-anal anastomosis. In the latter case, reestablishment of the enteroanastomosis was accomplished 16 weeks after the initial failure. One patient from the RAL group (primarily nondiverted) developed a pouch-vaginal fistula, forcing temporary fecal diversion with a loop ileostomy. Open redo pouch surgery with handsewn anastomosis and mucosectomy was performed 5 months later.

Over the initial 4 years of the RAL-implementation phase, a trend of reduced operation times was observed (Figure 1), but no consistent patterns of either increased or reduced admission lengths, complication rates, or readmission rates were found (data not shown).

Adjusted for primary operation, BMI, ASA group, sex, and age at operation, RAL was associated with a significantly longer duration of operation (MD, 159 minutes; CI, 144–174; $p < 0.01$), an increased risk of readmission for any

Table 3. Specifications of grade III to IV complications

Complications requiring endoscopic, radiologic, or surgical intervention	OS (n = 170)	RAL (n = 81)
Bleeding	2	6
Septic complications:		
Anastomotic leak	0	2
Perianal abscess	2	0
Pouch fistulas (pouch-vaginal, pouch-enteric)	2	1
Leak from top of the pouch	0	1
Intra-abdominal abscess	3	4
Abdominal wall abscess	0	1
Intra-abdominal hematoma	2	0
Anastomotic stenosis	5	2
Fascia dehiscence	2	0
Anastomotic necrosis	1	0
Myonecrosis of lower extremity	0	1
Parastomal hernia	1	0
Pneumothorax	1	0
Mechanical bowel obstruction	0	1
Total	21	19

OS = open surgery; RAL = robot-assisted laparoscopy.

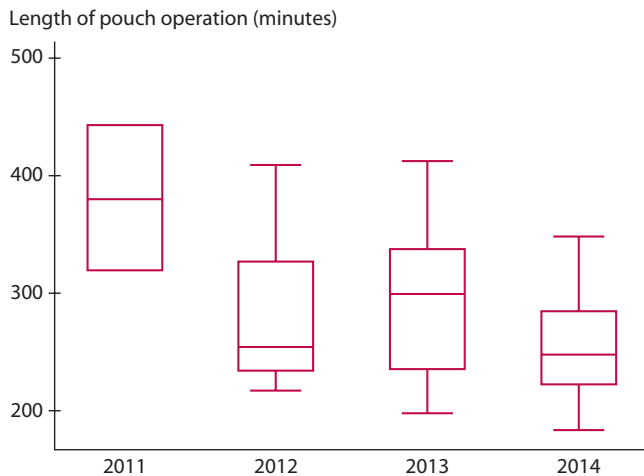


Figure 1. Box and whisker plot of temporal changes in median duration of operation for RAL procedures. RAL = robot-assisted laparoscopy.

cause (OR, 2; CI, 1.1–3.7; $p = 0.02$), and a shorter interval from the index IPAA operation to closure of the loop ileostomy (–14.5 days; CI, –29 to –0.01; $p = 0.05$). Postoperative admission length was 1.5 days shorter in the RAL group on multivariate regression (CI, –3.1 to 0.1; $p = 0.07$), although the studied explanatory variables only accounted for 8% of the total variance (R^2) of admission length. ASA grade was not a significant predictor for any of the analyzed outcomes.

DISCUSSION

Robot-assisted laparoscopic surgery has become the primary technical approach for many colorectal procedures in the hope to further optimize surgical outcome in the field of minimally invasive surgery. With this study, we report our initial experience with RAL in IPAA surgery with data from a large prospectively maintained patient database, which contains the greatest volume of RAL-IPAA procedures reported internationally. We demonstrate comparable early postoperative outcomes between robot-assisted laparoscopy and OS, consolidating the overall feasibility of the RAL approach as reported in other observational studies in rectal surgery.^{21,22}

The general paucity of evidence to suggest a positive effect of laparoscopy specifically in IPAA surgery⁵ may stem from the complexity of the procedure, where supplementary use of minilaparotomies or Pfannenstiel incisions often are necessary to aid in the extraction of the rectal specimen and for fashioning of the ileal reservoir. The observation that rectal stapling in one-third of the RAL procedures had to be performed by using nonendoscopic staplers to ensure an adequate level and completeness of the stapling emphasizes an important technical challenge of the laparoscopic approach in a very crucial part of the procedure, which is yet to be overcome.²³

Our findings of apparent equality between minimally invasive surgery and OS on short-term complications and admission lengths following IPAA underscores the complexity of the procedure and is largely in keeping with previous randomized and observational studies.^{3,4,24}

The ultimate purpose of IPAA surgery is to ensure satisfactory pouch function. Although the absence of information on this exact parameter is an obvious limitation to our results, the similar rates of early pouch complications might suggest the equivalence of the 2 approaches from a functional point of view and in terms of overall pouch survival,^{25,26} although such direct inferences to pouch function are uncertain at best. The overall occurrence of pelvic sepsis of 3.2% in this series is below the combined occurrence of 9.5% (range, 2.3%–26.7%), as reported in a meta-analysis of 43 observational studies,²⁷ and also lower than more recent reports from high-volume IPAA centers^{28,29} where pelvic sepsis rates close to or exceeding 10% are found. Differences in length of follow-up and annual hospital volume and thence experience with the procedure, however, may explain the considerable differences in sepsis rates between studies. Our conservative approach regarding medication and use of diversion may contribute to the fairly low complication rate.

The risk for unplanned readmissions after rectal resections has been shown to be independently associated with laparoscopy and operation length.³⁰ Indeed, significantly more patients in the RAL group were readmitted for any cause (40% vs 26%, $p = 0.03$), but, importantly, this was not reflected in the distribution of “major” complications on readmissions (22% vs 20%, $p = 0.9$). This finding may be indicative of a general attitude of active surveillance and a low readmission threshold in this start-up phase of RAL-IPAA.

The level of low transverse stapling of the rectum is a key factor when performing restorative proctocolectomies. This part of the procedure is especially challenging laparoscopically,²³ irrespective of the use of RAL, as illustrated by our need for open stapling in one-third of the procedures. It is not surprising that the need for open stapling was more often encountered in male patients than in female patients. The importance of achieving an adequate level of stapling is underscored by the observation that a residual rectal cuff may result in emptying problems, cuffitis, and probably an increased risk of cancer.³¹

We did not investigate long-term outcome in this cohort of patients. It is likely that the laparoscopic approach benefits patients in many important medium- and long-term aspects, eg, in terms of lower morbidity and faster recovery following the subsequent restoration of bowel continuity,³² in addition to increased fecundity^{6,7} and presumably a lower risk of incisional hernias.³³

Although the power of this study predominantly lies in the considerable volume of RAL-IPAA procedures,

there are several limitations, the most important of which is the observational single-center design, which imposes restrictions to the transferability of our results. Furthermore, the overall economic feasibility of RAL was not determined, because we did not compare the costs of the 2 procedures. Finally, the clinical elusiveness of certain type I and II complications (eg, urinary tract infections, superficial wound infections, and dehydration) requiring only treatment by primary care physicians made the actual incidences of these complications difficult to establish. However, the shorter interval from IPAA to ileostomy reversal in the RAL group (MD, 14.5 days; $p = 0.05$) might reflect a greater occurrence of postoperative ileus and dehydration, forcing a temporary ileostomy to be reversed sooner than scheduled. Changing practice patterns at our department might also offer some of the explanation to this possibly arbitrary finding.

The generally higher ASA grades in the RAL group may represent an underlying clustering of significant comorbidities (eg, smoking) and thereby introduce bias to our results. In addition, changing temporal patterns in the adherence to principles of fast-track surgery over the period 2004 to 2014 may represent a more substantial source of bias; in terms of postoperative admission lengths, the finding of a residual variance of 92% ($R^2 = 8\%$) unexplained by the included covariates on multivariate analysis underscores this potential for biased results. This observation leads us to conclude that many other perioperative factors unaccounted for (eg, specific analgesic regimens, dissimilar attitudes toward observation vs early discharge, social and cultural disparities, patient resources), affected admission length. However, the distribution and impact of the specific variables contained in fast-track protocols, eg, the *Enhanced Recovery After Surgery* recommendations,³⁴ were indeterminable owing to the retrospective data collection.

CONCLUSION

Robot-assisted laparoscopy-IPAA appears to be a safe alternative to open IPAA surgery, offering comparable short-term outcome. Although associated with a longer duration of operation and higher readmission rates, the distribution of complications is not statistically significantly different from OS. Randomized controlled trials of robot-assisted IPAA with exploration of functional outcomes and long-term morbidity seem justified and relevant at this point.

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