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J-pouch vs. side-to-end anastomosis after hand-assisted laparoscopic low anterior resection for rectal cancer: A prospective randomized trial on short and long term outcomes including life quality and functional results

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**ABSTRACT:**

**Purpose:** To analyze the outcomes of j-pouch and side-to-end anastomosis in rectal cancer patients treated with laparoscopic hand-assisted low anterior resection.

**Methods:** Prospective trial on cases randomized to have a colonic j-pouch or a side-to-end anastomosis after low anterior resection. Demographics, characteristics of disease and treatment, perioperative results, and functional outcomes and life quality were compared between the groups.

**Results:** Seventy four patients were randomized. Reservoir creation was withdrawn in 17 (23%) patients, mostly related to reach problem (n=11, 64.7%). Anastomotic leakage rate was significantly higher in j-pouch group (8 [27.6%] vs. 0, p=0.004). Stoma closure could not be achieved in 16 (28.1%) patients. Life quality and functional outcomes, measured 4, 8 and 12 months after the stoma reversal, were similar.

**Conclusions:** Colonic j-pouch and side-to-end anastomosis are similar regarding perioperative measures **including operation time, rates of postoperative complications, reoperation and 30-day mortality, and hospitalization period except anastomotic leak rate, which is higher in j-pouch group.** Postoperative aspects **are not different in patients receiving either technique** including functional outcomes and life quality for the first year after stoma closure. **In our opinion, both techniques may be preferred during the daily practice while performing laparoscopic surgery; but surgeons may be aware of a possibly higher anastomotic leak rate in case of a j-pouch.**

**Key words:** j-pouch; rectal cancer; ileostomy; life quality; anastomosis

## 1. INTRODUCTION:

A safe and oncologically adequate resection appreciating total mesorectal excision with negative circumferential margin, has paramount importance in patients with rectal cancer. However since reconstructing bowel may not adequately reproduce natural rectal functions, these cases may suffer from a constellation of symptoms including fecal urgency, frequent bowel movement, bowel fragmentation and incontinence, when the treatment course is completed [1]. This is particularly true if a straight end-to-end anastomosis is performed, since normally compliant rectum is removed and replaced by a less compliant segment of descending or sigmoid colon, where is physiologically less suitable for storing and regulating feces [2,3]. Therefore for the last two decades, reservoir procedures including colonic J-pouch and side-to end anastomosis have been proposed and several prospective randomized trials and meta-analyses have shown that both formations improve functional results and life quality measures compared to straight anastomosis [3-7]. On the other hand there have been several concerns on reservoirs regarding perioperative technical difficulties and postoperative complications.

It may be necessary to evaluate different reservoir techniques in order to find out which one will be suitable with minimally invasive practice, since laparoscopy is another topic altering life quality and functional results [8]. The outcomes of reservoir creation have been rarely analyzed on the basis of laparoscopic rectal cancer surgery [3-5]. However, colonic j-pouch and side-to-end anastomosis have never been compared in laparoscopic era. Thus current study aims to compare the best option for improving functional outcomes between J-pouch and side-to-end anastomosis after hand-assisted laparoscopic low anterior resection for rectal cancer.

## 2. METHODS

A prospective randomized trial was initiated at June 2009 at our institute after local ethics committee had approved the study protocol. The protocol was also registered at ClinicalTrials.gov. Before initiating the study, a sample size analysis was completed. During the calculation, a difference of 15 points between the groups was predicted in life quality measure (SF-36) on 12<sup>th</sup> month postoperatively and the study was planned to have an 80% power to detect the predicted value with a standard deviation of 20 in the significance level of <0.05. The calculation required a total of 58 patients. A dropout rate of 22% was expected because of death, omission of reservoir creation after randomization, failure of stoma closure and protocol violation. Thus, this parallel arm study was planned to include a total of 74 patients. Patients were randomly assigned to study groups using a permuted block method. The randomization sequence were generated using a random number generating program, with a 1:1 allocation ratio with blocks of different sizes to ensure a balanced allocation.

The dropout cases were excluded and not replaced. There were several mid-term analyses inspected by the ethics committee after the completions of one and two thirds of planned numbers of patients and the committee was also free to ask for the study documents anytime while the study was running. These were the exclusion criteria: patient refusal, pregnancy, previous radiation therapy to pelvis, those have cancers other than adenocarcinoma, those were planned to have local excision or abdominoperineal resection before surgery. Patients were informed in details and consent was obtained.

All consecutive rectal cancer patients, who had tumors up to 12 cm from the dentate line observed with a rigid rectosigmoidoscope, were included. Patients received standard pre-operative evaluation including total colonoscopy, thorax tomography and magnetic resonance imaging of abdomen and pelvis. A preoperative chemoradiation treatment was routinely scheduled for patients with T3 or 4 or node positive cancers. It included 45 Gray radiation

fractionated in 25 days with 5-fluorouracil based induction chemotherapy. Operation was performed 6 to 8 weeks after the chemoradiation therapy had ended.

A single surgeon (MO) performed or supervised the procedures. The operations were completed considering some technical details described in our previous studies from our institution including high ligation of inferior mesenteric artery, complete splenic flexure mobilization, hand assistance through a left inferior quadrant oblique incision and total mesorectal excision [9-11]. At the time of operation, surgeon was blinded to the randomization until the resection had been completed. In j-pouch group, a 5 to 6 cm-long pouch was created with an 80 mm linear cutting-closing stapler (Figure 1). Similarly, a 5 to 6 cm-long colonic segment was left at the distal part of coloanal anastomosis in side-to-end anastomosis group. Same type of staplers was used for closing the luminal ends in both groups. The anastomoses of j-pouch were almost routinely strengthened with 3:0 polyglactin 910 (Vicryl<sup>®</sup>) sutures. **If the patient was not suitable for a reservoir creation because of a reach problem or a narrow pelvis or other reasons; a straight anastomosis was decided. In this case, the reason for the omission of reservoir creation was recorded, and then the patient was excluded from the further analyses, and not replaced.** A diverting ileostomy was routinely created, and closed 4 weeks after the operation, or completion of the chemotherapy regimen. The presence of one of the following conditions was defined as an anastomotic leakage: any suspicious drainage for colonic content from the intrapelvic drains, extravasation of water-soluble material in computed tomography examination and suspicious findings on digital or flexible sigmoidoscopy examinations. The patients, but not the surgeon, who was responsible for the follow-up period, were blinded to the type of the anastomosis.

Primary measure was the life quality by Short Form Health Survey (SF-36) questionnaire at 12 months and these were the secondary measures: functional outcome and life quality analyses 4, 8 and 12 months after the stoma closure by using 4 other

questionnaires in addition to SF-36 questionnaire (Fecal Incontinence Severity Index [FISI], Sexual Health Inventory for Men [SHIM], Female Sexual Function Index and Overactive Bladder-Validated Form), all of which had been previously validated on Turkish population [12-21]. The answers of questionnaires were obtained either with telephone calls or face-to-face interviews by one of two observers (YEA or FCG), who were blinded to the randomization. These data were prospectively collected and compared within the groups as the secondary measures: demographics, American Society of Anesthesia (ASA) scores, tumor location (distance from the dentate line), presence/ absence of neoadjuvant chemoradiation therapy, anastomotic technique, operation time, bleeding and transfusion amounts, complications, reoperation and 30-day mortality, length of hospital stay, and pathological features. Finally, the progress in life quality measures by time was monitored in both groups.

**2.1 Statistical Analysis:** Data were collected in a computer-based program, and analyzed by using SPSS 21.0 for Windows (IBM Corp, Armonk, NY). Results were given as percentages, mean and standard deviations or as median and ranges. Quantitative and qualitative variables were compared with Student's t-test or Mann-Whitney U test and Chi-square (Pearson's or Fischer's Exact) tests, respectively. The functional parameters and SF-36 scores on different evaluations were compared with the paired samples t-test. A p level less than 0.05 was considered to be significant.

### **3. RESULTS:**

A total of 74 cases (49 [66.2%] male, and an average [standard deviation] age of 59.8±12.6 years) with rectal cancers were included to the study. Protocol was not violated in any patients (Figure 2). Patients were randomized to have either a j-pouch or a side-to-end anastomosis after laparoscopic hand-assisted low anterior resection had been completed. However, reservoir could not be achieved in 17 (22.9%) cases; 8 and 9 in j-pouch and side-to-end anastomosis groups, respectively (p=0.782). These were the reasons for the failure of

reservoir creation: reach problem (n=11, 64.7%), narrow pelvis (n=4, 23.5%), edematous proximal segment (n=1, 5.9%), and not stated (n=2, 11.8%) (A patient was stated to have both reach problem and narrow pelvis). These patients received an end-to-end anastomosis, were excluded from the study and not replaced.

Thus a total of 57 patients (37 [64.9%] male, and an average [standard deviation] age of  $59 \pm 12.8$  years) were evaluated for further analyses, and there were 29 and 28 cases in j-pouch and side-to-end anastomosis groups, respectively. Groups were similar regarding gender, age, ASA scores, tumor location, necessity for neoadjuvant chemoradiation therapy, and intraoperative aspects (Table 1). There was no patients required conversion to open surgery in both groups. Complication rates were not statistically different; but anastomotic leakage was significantly higher (8 [27.6%] vs. 0,  $p=0.004$ ) in j-pouch group. Two cases required a reoperation because of intraabdominal sepsis originating from the anastomotic leakage from the j-pouch and both received Hartman procedure because of the presence of fecal peritonitis. Of those, one patient died related to septic complications 2 days after the second operation. Another patient was deceased secondary to pulmonary emboli and consequent cardiovascular complications (Figure 2 and Table 2). Pathological features regarding tumor stage were similar within the groups (Table 3).

Among the 57 patients who received a reservoir procedure, stoma closure could not be achieved in 16 (28.1%); and of those 11 (37.9%) and 5 (17.9%) were in j-pouch and side-to-end anastomosis groups, respectively ( $p=0.092$ ). Stoma reversal was achieved in a mean (SD) period of  $8.5 \pm 4.4$  months after the initial operation. These were the reasons for the failure of stoma closure: mortality prior to closure (n=8, [**6 in j-pouch and 2 in side-to-end groups**]), anastomotic stricture (n=4, [**2 in each group**]), metastatic disease (n=3, [**2 in j-pouch and 1 in side-to-end groups**]) and patient refusal (n=1, [**in j-pouch group**]).

A total number of 41 cases (25 [61.0%] male, and an average [standard deviation] age of  $58.8 \pm 12.9$  years) were evaluated for functional outcomes and life quality measures 4, 8 and 12 months after the stoma closure. There were 18 and 23 patients in j-pouch and side-to-end anastomosis groups, respectively. The age and gender were not statistically significant between the groups (Table 4). The comparisons of information regarding the life quality and other measures (SF36, FIS, SHIM, Overactive Bladder-Validated Form and Female Sexual Function Index) did not reveal any statistical significance within the groups (Tables 4 and 5). Finally, life quality measures in different postoperative periods revealed that life quality was improving by time in both groups (Figures 3 and 4).

#### 4. DISCUSSION

Functional outcomes after rectal cancer surgery may be improved with the creation of reservoirs during the completion of reconstruction [3-7]. However, it remains unclear which reservoir type produces best results while performing a laparoscopic operation. The introduction of J-pouch aimed to maximize the neo-rectal compliance and volume by increasing the caliber with a longitudinal anastomosis [3]. Since shorter pouches have been shown to be superior to longer ones, the recommended pouch size has been successively decreased to about 5 to 6 cm, and a side-to-end anastomosis has been initiated as the final step of reducing pouch size [7, 22]. Current study analyzed the outcomes of reconstructions of colonic j-pouch and side-to-end anastomosis after laparoscopic hand-assisted resection of rectal cancer.

Reservoir creation may be abandoned due to some intraoperative problems. Two different prospective randomized trials have revealed that a j-pouch may not be achieved in one fourth of cases after removal of distal rectal cancers [23, 24]. The incidence of failure in reservoir creation was 22.9% in our study, and the rates were similar between j-pouch and side-to-end anastomosis groups. Pouch constructions require a longer segment of bowel,

consequently cannot be achieved in some cases because of the difficulty of taking the reservoir down to the pelvis without tension, which is stated as ‘reach problem’. Narrow pelvis is another challenging condition that should be considered at the time of decision making for performing or omitting a reservoir creation because of the possibility that the reservoir may not fit into the pelvic cavity. Current study has shown that reach problem and narrow pelvis are the most common reasons for the failure of reservoir creation and conversion to a straight anastomosis.

A recent review has shown that the anastomotic leakage rate may reach up to 29.2% after low anterior resection [22]. **It may worsen the oncological results including local recurrence of the tumor [25].** Many have stated that an anastomotic problem may be rare in case of a side-to-end anastomosis or j-pouch formation, since these construction techniques supply better blood flow to the anastomosis than a straight anastomosis [2, 22]. In contrast, a randomized trial has revealed an anastomotic leakage of 15.9% in cases with colonic j-pouch, which is significantly more than that in coloplasty and end-to-end anastomosis group [26]. Another study evaluating the sequels of anastomotic leakage after low anterior resection has showed that a colonic J-pouch or a side-to-end anastomosis increases the risk of leakage from intrapelvic anastomosis for 2.7 fold [27]. **Two recent meta-analyses have revealed that anastomotic stricture and fistula or leak rates are similar between j-pouch and side-to-end anastomosis techniques (RR=0.85, 95% CI [0.27-2.61], p=0.78 and RR=1.25, 95% CI [0.29-5.35], p=0.76, OR=1.16, 95% CI [0.49-2.71], p was not significant, respectively) [28, 29].** However, the leakage rate in the current study was 27.6% after j-pouch formation, which was unexpectedly high. In contrast, it was 0% and significantly less after side-to-end anastomosis (p=0.004). We do not know why the leakage rate was that high after j-pouch creation in our hands, however it may be related to the definition of anastomotic leakage in our study. All ‘suspicious’ conditions were defined as an anastomotic leakage, but the

consequences of an anastomotic leakage was rarely observed in these cases and the outcomes were not worsened in most instances. Accordingly, although anastomotic leakage was reported in 8 cases, an intraabdominal sepsis was observed and related reoperation was necessitated in only two cases. Similarly, hospitalization period has not been lengthened and anastomosis related failure of ileostomy closure in j-pouch group has not been significantly more common than that in side-to-end anastomosis group. However, current study has concluded that side-to-end anastomosis seems to be a safer and better option, since no anastomotic leakage was observed in this group. We believe that this is an important finding to be considered while deciding the reservoir technique after a laparoscopic low anterior resection.

Almost half of the rectal cancer patients treated with low anterior resection suffers from functional problems if reconstruction is completed with a straight anastomosis; and studies and meta-analyses have reported that these symptoms are less common after reservoir creation [3-6, 22]. **In a study by Doeksen et al. [7], j-pouch group had better functional outcomes compared to side to end anastomosis at both postoperative 4<sup>th</sup> and 12<sup>th</sup> months (9.6 [-32-33] vs. 20 [-27-53] and -1.4 [-30-26] vs. 11 [-38-36], respectively, p=0.04 for both). However, meta-analyses have failed to reveal significance in functional outcomes after j-pouch and side-to-end anastomosis techniques [28, 29]. It has also been advocated that patients with colonic j-pouch may experience some late evacuation problems requiring the use of laxatives and enemas, but current study has not analyzed this particular problem [30]. Besides, there is limited information analyzing the functional outcomes after the creation of a reservoir in minimally invasive surgery era, although laparoscopy may alter life quality, and urinary, sexual and colonic functions [8]. So, the primary queries of the current study have been life quality and functional outcomes, which have been questioned with several questionnaires in patients who received laparoscopic**

procedures. Current study has failed to reveal a statistical difference between the side-to-end anastomosis and j-pouch groups in any of outcome measures including SF36, FISI, SHIM, Female Sexual Function Index Form and Overactive Bladder-Validated Form questionnaires. Finally, life quality was improving by time in both groups. Thus, we believe that both techniques result in similar life quality and functional outcomes and both formations are favorable after laparoscopic low anterior resections.

Finally, the stoma non-reversal rates were 17.9% and 37.9% in side-to-end anastomosis and colonic j-pouch groups, respectively, which were quite high in both groups, but rather discouraging in colonic j-pouch group. Although the difference was not significant, it seems that stoma closure may be more likely to be achieved in cases received side-to-end anastomosis group, probably related to higher anastomotic leakage rates in colonic j-pouch group that consequently prohibits stoma closure because of consequent anastomotic problems.

Current study has some important limitations. Although a power analysis was completed prior to initiation of the study, it may be underpowered to examine some aspects. The most disappointing feature of the current prospective analysis was the fact that the dropout rate was more than expected, which has led to consider limited number of cases than projected during the statistical evaluations and accordingly may restrict the confidence of some analyses, **and may limit the validity of the results**. This is particularly true for rare conditions, or problems or findings, which have close incidences in both techniques such as infrequent complications and intraoperative information including operation time or amount of bleeding. However, we still believe that this is an important report showing that both techniques produce similar functional outcomes and side-to-end anastomosis may be safer than colonic j-pouch. **In our opinion, current study underlines some precise issues, although some previous papers have evaluated the reservoirs on life quality after rectal cancer operations. Current data contribute the effects of j-pouch and side-to-end**

**anastomosis on outcomes in minimally invasive surgery era; particularly evaluating the long-term life quality and functional outcomes after reservoir procedures.**

## **5. CONCLUSION**

Either a j-pouch or a side-to-end anastomosis may not be achieved in more than 20% of rectal cancer patients undergoing a laparoscopic low anterior resection. In our hands, colonic j-pouch may be associated with a higher risk for anastomotic leakage after a hand assisted laparoscopic procedure. However, colonic j-pouch and side-to-end anastomosis produce similar perioperative measures, and postoperative aspects including functional outcomes and life quality during the first year after stoma closure. Due to its small sample size and substantial drop-out rate, the current trial is not able to end the ongoing discussions about the best reconstruction method after rectal resection but it adds valuable information to the overall basis of evidence. **In our opinion, both j-pouch and side-to-end anastomosis techniques equally generate similar functional results and life quality, and may be preferred during the daily practice while performing laparoscopic surgery; but surgeons may be aware of a possibly higher anastomotic leak rate in case of a j-pouch.**

**6. Conflicts of interests:** None

**7. Sources of funding:**

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**Fig. 1** Configuration of colonic j-pouch: an incision is created on the antimesenteric side of the colon at 6-7 cm from the distal edge (A), a 4 to 6 cm long anastomosis is constructed with a linear stapler (B), the tip of j is closed with hand-sewn sutures or stapler (C), and a leak test is performed while the pouch is pumped with the saline up (D).

**Fig. 2** CONSORT flow diagram on enrollment of patients into the study.

**Fig. 3** Changes in mean Physical Component Score (PCS) scores within groups during the study period.

**Fig. 4** Changes in mean Mental Component Score (MCS) scores within groups during the study period.

Table 1: Demographics, and Tumor and Operation Related Measures

	J-Pouch (n=29)	Side-to-End Anastomosis (n=28)	P
Gender (females) (%)	11 (37.9)	9 (32.1)	0.647
Age	58.9±13.7	59.1±11.9	0.934
ASA <sup>a</sup> Scores (1/2/3/4) (%)	1/14/14/0 (3.4/48.3/48.3/0)	0/17/11/0 (0/60.7/39.3/0)	0.507
Distance between the tumor and dentate line (in cm)	7.9±3.8	6.2±3.8	0.774
Neoadjuvant chemoradiation therapy	17 (58.6)	19 (67.9)	0.470
Anastomotic <sup>b</sup> technique (stapled/hand-sewn) (%)	22/7 (75.9/24.1)	16/12 (57.1/42.9)	0.134
Operation time (in min.)	213.1±44.5	209.5±50.1	0.089
Bleeding (mean, range) (in cc)	200, 50-1300	150, 50-400	0.320
Transfusion (%)	8 (27.6)	5 (17.9)	0.381
Transfusion (mean, range) (in cc)	0, 0-22	0, 0-4	0.333

<sup>a</sup> American Society of Anesthesiology, <sup>b</sup> Pouch-anal or coloanal anastomosis

Table 2: Postoperative Complications, Reoperation, Hospital Stay and Mortality

	J-Pouch (n=29)	Side-to-End Anastomosis (n=28)	P
Surgical site infection			
Wound infection	1 (3.4)	1 (3.6)	0.999
Intraabdominal abscess	1 (3.4)	2 (7.1)	0.611
Evisceration	0	1 (3.6)	0.491
Anastomotic leakage	8 (27.6)	0	0.004
Ileus	1 (3.4)	4 (14.3)	0.194
Prolonged hemorrhagic drainage	2 (6.9)	2 (7.1)	0.999
Medical <sup>a</sup>	1 (3.4)	2 (7.1)	0.611
Overall	10 (34.5)	10 (35.7)	0.922
Reoperation	2 (6.9)	0	0.491
Hospitalization period	5 (4-36)	5 (4-31)	0.156
30-day mortality <sup>b</sup>	2 (6.9)	0	0.491

<sup>a</sup> Medical complications include myocardial infarction on postoperative day 5 in j-pouch group and pulmonary emboli and asthma attack (n=1 for each) in side-to-end anastomosis group.

<sup>b</sup> Causes for deaths were pulmonary emboli (n=1) and anastomotic leakage and consequent intraabdominal sepsis (n=1).

Table 3: The Pathological Results

	J-Pouch (n=29)	Side-to-End Anastomosis (n=28)	P
pT <sup>a</sup> (0/1/2/3) (%)	4 / 0 / 6 / 19 13.8/0/20.7/65.5	3 / 2 / 6 / 17 10.7/7.1/21.4/60.7	0,681
pN status (0/1/2) (%)	16 / 9 / 4 (55.2/31/13.7)	17 / 8 / 3 (60.77/28.6/10.7)	0,999
Stage* (0/1/2/3/4) (%)	3 / 5 / 8 / 11 / 2 (10.3/17.2/27.6/37.9/6.9)	3 / 7 / 7 / 9 / 2 (10.7/25/25/31.2/7.1)	0,976
Radial margin positivity ( $\leq 2$ mm)	1 (3.4)	0	0.999
Length of distal margin	4.4 $\pm$ 2.4	4.2 $\pm$ 2.5	0.740

<sup>a</sup> Complete response to the chemoradiation therapy was stated as pT0 cancers.

Table 4. The Comparison of the Measures Regarding Functional Outcomes between the Groups Obtained Preoperatively and 4, 8 and 12 Months after the Stoma Closure

	J-pouch-anal anastomosis (n=18)	Side-to-End Anastomosis (n=23)	P
Gender (females) (%)	7 (38.9)	9 (39.1)	0.987
Age	59.3±13.7	58.4±12.7	0.821
Defecation Frequency			
Day-time			
Preoperative	0 (0-6)	0 (0-2)	0.820
4 <sup>th</sup> month	4.4±2.8	5±2.8	0.531
8 <sup>th</sup> month	3.9±2.8	4.1±2.6	0.780
12 <sup>th</sup> month	3.5 (0-10)	3 (1-15)	0.365
At Night			
Preoperative	0 (0-6)	0 (0-2)	0.820
4 <sup>th</sup> month	0.5 (0-4)	2 (0-4)	0.420
8 <sup>th</sup> month	0 (0-5)	2 (0-5)	0.258
12 <sup>th</sup> month	0 (0-3)	0 (0-10)	0.601
Daily			
Preoperative	1 (1-6)	2 (1-10)	0.257
4 <sup>th</sup> month	5.5±3.5	6.3±3.5	0.472
8 <sup>th</sup> month	4.7±3.9	5.5±3.8	0.535
12 <sup>th</sup> month	5.2±3.5	5.7±6.3	0.777
Urgency			
Preoperative	3 (16.7)	0	0.077
4 <sup>th</sup> month	14 (77.8)	17 (73.9)	0.999
8 <sup>th</sup> month	12 (66.7)	14 (60.9)	0.702
12 <sup>th</sup> month	14 (77.8)	15 (65.2)	0.380
Pad Use			
Preoperative	1 (5.6)	0	0.439
4 <sup>th</sup> month	13 (72.2)	15 (65.2)	0.632
8 <sup>th</sup> month	11 (61.1)	15 (65.2)	0.786
12 <sup>th</sup> month	12 (66.7)	13 (56.5)	0.509
Overactive Bladder			
Preoperative	9 (50)	6 (26.1)	0.115
4 <sup>th</sup> month	7 (38.9)	9 (39.1)	0.987
8 <sup>th</sup> month	12 (66.7)	9 (39.1)	0.080
12 <sup>th</sup> month	12 (66.7)	9 (39.1)	0.080
FISI <sup>a</sup> Scores			
Preoperative	0 (0-41)	0 (0-54)	0.192
4 <sup>th</sup> month	27.9±24.6	25.6±20.8	0.748
8 <sup>th</sup> month	19.4±21.4	18.7±18.1	0.911
12 <sup>th</sup> month	19.6±20	18.0±20.5	0.814
Sexual Functions in men	n=8	n=13	
Preoperative	20 (12-21)	20 (11-25)	0.546
4 <sup>th</sup> month	5 (3-20)	10 (5-24)	0.137
8 <sup>th</sup> month	10 (5-22)	20 (5-25)	0.273
12 <sup>th</sup> month	9.5 (5-25)	20 (5-25)	0.351
Sexual Functions in women	n=4	n=1	
Preoperative	28.9 (7-32)	8.4	0.480
4 <sup>th</sup> month	13.9 (2-26)	6.8	0.999
8 <sup>th</sup> month	12.6 (2-23)	6.8	0.999
12 <sup>th</sup> month	12.6 (2-23)	6.8	0.999

<sup>a</sup>FISI: Fecal Incontinence Severity Index

Table 5. The Comparison of the Measures Regarding Life Quality between the Groups Obtained Preoperatively and 4, 8 and 12 Months after the Stoma Closure

	J-pouch-anal anastomosis (n=18)	Side-to-End Anastomosis (n=23)	P
<b>Scales</b>			
<b>Physical functioning (PF)</b>			
Preoperative	82,5 (0-100)	85 (0-100)	0,934
4 <sup>th</sup> month	80 (10-100)	95 (0-100)	0,211
8 <sup>th</sup> month	100 (40-100)	100 (50-100)	0,356
12 <sup>th</sup> month	100 (0-100)	100 (10-100)	0,312
<b>Role-physical (RP)</b>			
Preoperative	100 (0-100)	100 (0-100)	0,415
4 <sup>th</sup> month	62,5 (0-100)	100 (0-100)	0,318
8 <sup>th</sup> month	100 (0-100)	100 (0-100)	0,561
12 <sup>th</sup> month	100 (0-100)	100 (50-100)	0,207
<b>Bodily pain (BP)</b>			
Preoperative	66,9±34,4	71,0±28,6	0,685
4 <sup>th</sup> month	100 (41-100)	100 (51-100)	0,152
8 <sup>th</sup> month	100 (74-100)	100 (62-100)	0,245
12 <sup>th</sup> month	100 (74-100)	100 (50-100)	0,168
<b>General health (GH)</b>			
Preoperative	69,3±23,8	63,6±22,2	0,437
4 <sup>th</sup> month	76,0±23,3	86,3±16,9	0,108
8 <sup>th</sup> month	93,5 (57-100)	100 (52-100)	0,478
12 <sup>th</sup> month	87,5 (57-100)	100 (52-100)	0,096
<b>Vitality (VT)</b>			
Preoperative	60,9±26,2	65,0±28,2	0,637
4 <sup>th</sup> month	70,3±28,6	80,7±20,2	0,202
8 <sup>th</sup> month	92,5 (50-100)	90 (65-100)	0,417
12 <sup>th</sup> month	85 (35-100)		
<b>Social functioning (SF)</b>			
Preoperative	76,8±23,8	67,9±29,4	0,306
4 <sup>th</sup> month	75 (25-100)	87,5 (12,5-100)	0,306
8 <sup>th</sup> month	87,5 (50-100)	100 (25-100)	0,275
12 <sup>th</sup> month	100 (38-100)	100 (63-100)	0,161
<b>Role-emotional (RE)</b>			
Preoperative	100 (0-100)	100 (0-100)	0,283
4 <sup>th</sup> month	100 (0-100)	100 (0-100)	0,228
8 <sup>th</sup> month	100 (0-100)	100 (0-100)	0,920
12 <sup>th</sup> month	100 (0-100)	100 (67-100)	0,748
<b>Mental health (MH)</b>			
Preoperative	65,3±26,6	70,1±23,5	0,545
4 <sup>th</sup> month	84 (24-100)	88 (28-100)	0,595
8 <sup>th</sup> month	84,7±18,6	89,7±11,1	0,316
12 <sup>th</sup> month	86 (52-100)	100 (56-100)	0,058
<b>Summary measures</b>			
<b>Physical health (PCS)</b>			
Preoperative	46.5 ±11.6	44.7 ±10.7	0.618
4 <sup>th</sup> month	48.0 ±9.5	51.4 ±8.8	0.245
8 <sup>th</sup> month	57.3 (39-58)	58 (41-59)	0.226
12 <sup>th</sup> month	57.7 (33-61)	58 (35-64)	0.077
<b>Mental health (MCS)</b>			
Preoperative	48.8±10.6	47.2±14.5	0.672
4 <sup>th</sup> month	49.9±13.8	53.9±9.6	0.272
8 <sup>th</sup> month	55.3±8	56.9±6.1	0.473
12 <sup>th</sup> month	55±8.6	58.4±4.4	0.142

PCS: physical component score, MCS: Mental component score

J-POUCH VS. SIDE-TO-END ANASTOMOSIS AFTER HAND-ASSISTED  
LAPAROSCOPIC LOW ANTERIOR RESECTION FOR RECTAL CANCER: A  
PROSPECTIVE RANDOMIZED TRIAL ON SHORT AND LONG TERM OUTCOMES  
INCLUDING LIFE QUALITY AND FUNCTIONAL RESULTS

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**Running Title:** Reservoir outcomes after laparoscopic low anterior resection

## **REGISTRATION**

The protocol was also registered at ClinicalTrials.gov (NCT02627729).

## **ETHICS**

The local ethics committee, Istanbul University Istanbul Medical School Ethics Committee had approved the study protocol. protocol number: 201148422.

## International Journal of Surgery Author Disclosure Form

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned. If you have nothing to declare in any of these categories then this should be stated.

### Please state any conflicts of interest

None

### Please state any sources of funding for your research

None

### Please state whether Ethical Approval was given, by whom and the relevant Judgement's reference number

Istanbul University Istanbul Medical School Ethics Committee-  
protocol number: 201148422

### Research Registration Unique Identifying Number (UIN)

Please enter the name of the registry and the unique identifying number of the study. You can register your research at <http://www.researchregistry.com> to obtain your UIN if you have not already registered your study. This is mandatory for human studies only.

ClinicalTrials.gov NCT02627729  
researchregistry2772

### Author contribution

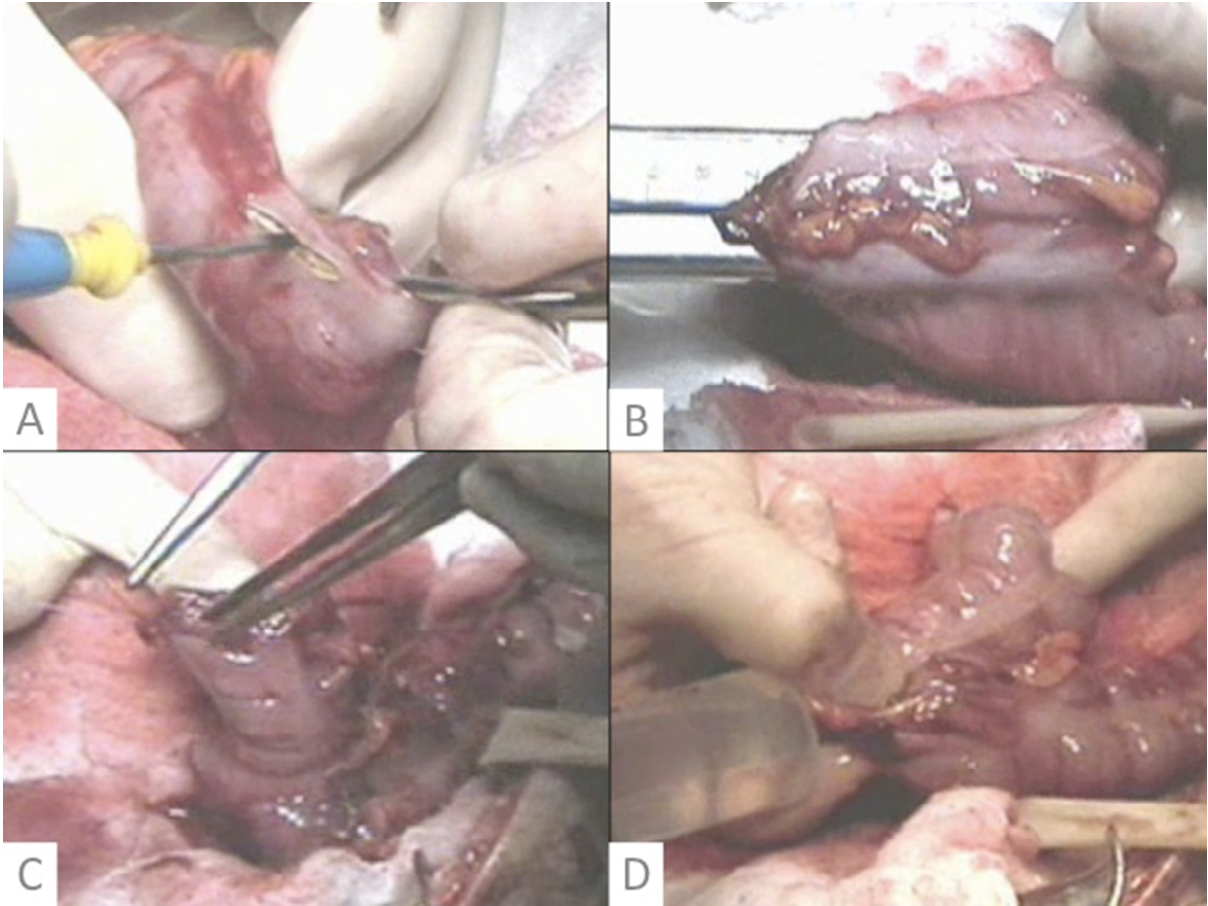
Please specify the contribution of each author to the paper, e.g. study design, data collections, data analysis, writing. Others, who have contributed in other ways should be listed as contributors.

Conception and design of the study: NO, MO, FCG; Acquisition of data: MH, YEA, FCG, EG; Interpretation of data: AEA, YEA, FCG; Drafting the article: NO, MH, MO; Critical revisions during the creation of the manuscript: AEA, YEA, EG, FCG

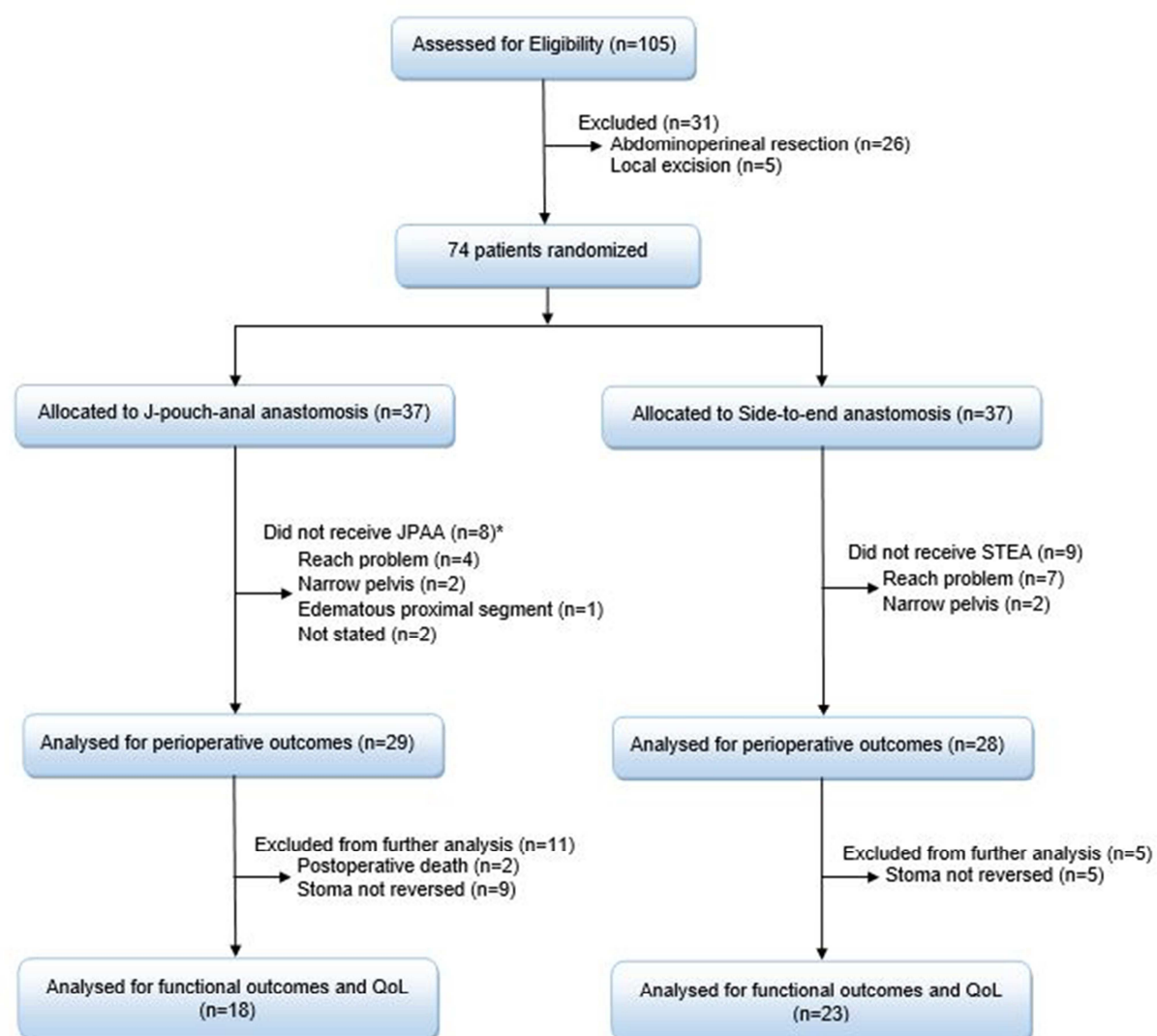
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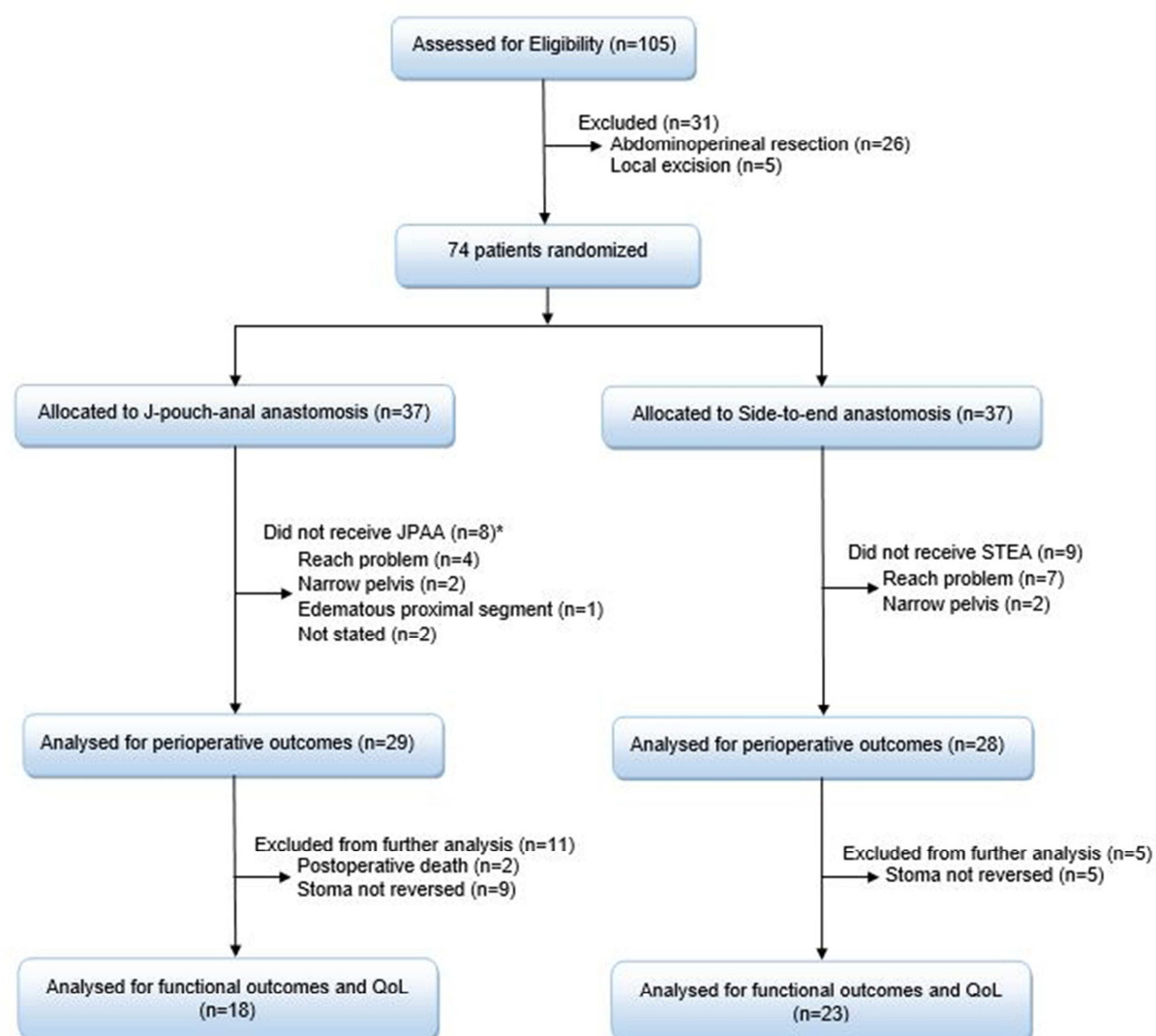
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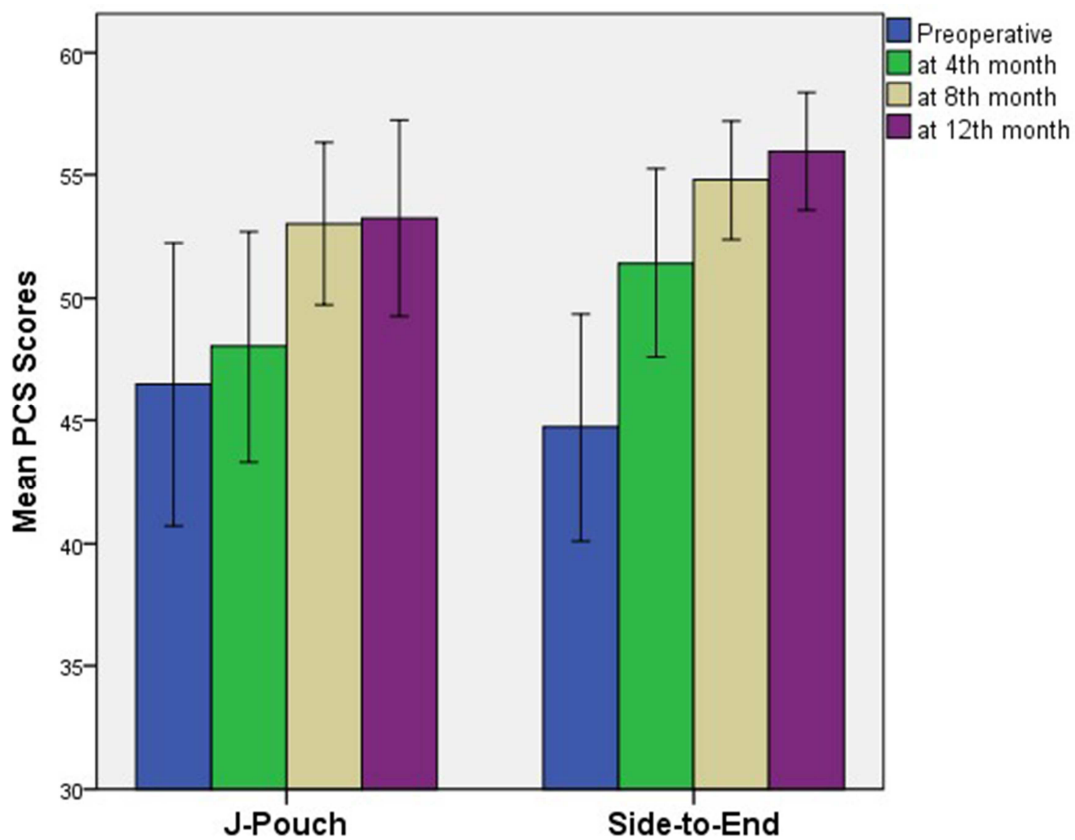
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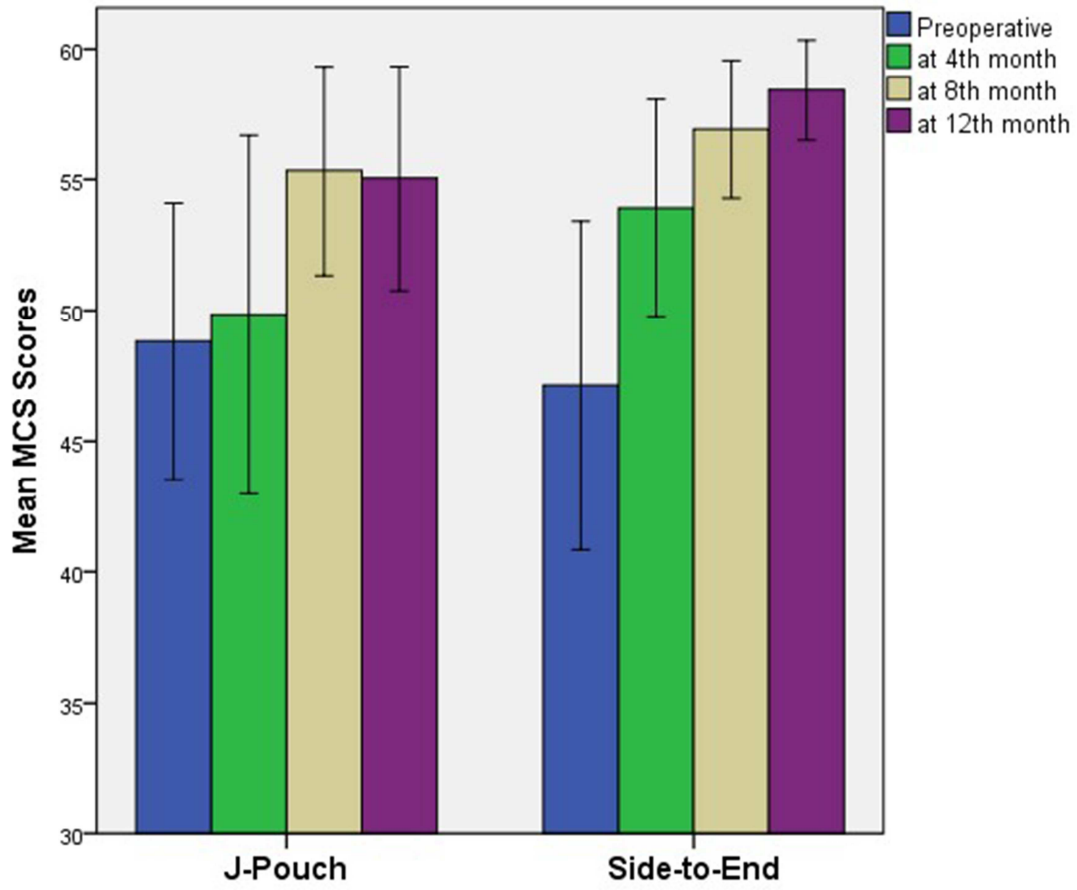


ACCEPTED MANUSCRIPT









ACCEPTED

- 1- Reservoir could not be achieved in about 1 in 4 patients after laparoscopic low anterior resection
- 2- Functional outcomes and quality of life measures were not different between J pouch and side to end groups
- 3- Quality of life has improved over time after stoma closure in both groups