Effects of a Diverting Stoma on Symptomatic Anastomotic Leakage after Low Anterior Resection for Rectal Cancer: A Propensity Score Matching Analysis of 1,014 Consecutive Patients

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BACKGROUND: Routine creation of a diverting stoma (DS) in every patient who undergoes low anterior resection (LAR) remains controversial. We aimed to investigate the effect of DS on symptomatic anastomotic leakage (AL) after LAR.

STUDY DESIGN: Patients with rectal cancer within 10 cm from the anal verge were eligible for this prospective, multicenter, cohort study (UMIN-CTR, number 000004017). Propensity score matching (PSM) was used to compare groups of patients with and without DS.

RESULTS: One thousand fourteen consecutive patients were registered, of whom 936 patients who underwent LAR were analyzed. Before PSM, the overall rate of symptomatic AL was 13.2% (52 of 394) in patients with DS vs 12.7% (69 of 542) in cases without DS ($p = 0.84$). Symptomatic AL requiring re-laparotomy occurred in 4.7% (44 of 936) of all patients, occurring in 1.0% (4 of 394) of patients with DS vs 7.4% (40 of 542) of patients without DS ($p < 0.001$). After PSM, the 2 groups were nearly balanced, and the incidence rates of symptomatic AL in patients with and without DS were 10.9% and 15.8% ($p = 0.26$). The incidences of AL requiring re-laparotomy in patients with and without DS were 0.6% and 9.1% ($p < 0.001$). Multivariate analysis identified male sex ($p < 0.001$; odds ratio [OR] 3.2; 95% confidence interval [CI] 1.8 to 5.7) and tumor size ($p < 0.001$; OR 1.2; 95% CI 1.1 to 1.4) as independent risk factors of symptomatic AL.

CONCLUSIONS: Diverting stoma did not have a significant relationship with symptomatic AL before and after PSM. However, DS does seem to mitigate the consequences of leakage, reducing the need for urgent abdominal reoperation. (J Am Coll Surg 2015;220:186−194. © 2015 by the American College of Surgeons)

Anastomotic leakage (AL) is a serious potential complication after low anterior resection (LAR) for rectal cancer, and has been reported to occur in 5% to 20% of cases.[1-8] When it occurs, the associated risk of postoperative mortality is increased to between 6% and 22%.[8] Furthermore, some reports suggest that AL resulted in increased local

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Abbreviations and Acronyms
AL = anastomotic leakage
DS = diverting stoma
IQR = interquartile range
LAR = low abdominal resection
OR = odds ratio
PSM = propensity score matching
RCT = randomized controlled trial

recurrence, decreased cancer-specific survival,[9,10] and poor functional outcomes.[11]

Several series have suggested various risk factors for AL, including male sex, obesity, smoking, steroid use, poor bowel preparation, blood transfusion, preoperative radiochemotherapy, location of the tumor, level of anastomosis, and absence of diverting stoma (DS).[1,2,4,6-8,12,13]

The results of nonrandomized studies that examined the impact of DS on AL, however, should be interpreted cautiously, because patient characteristics have been extremely biased to 1 treatment arm in most studies. Recent randomized controlled trials (RCT)[14,15] and meta-analyses[16,17] have shown that DS does reduce the incidence of symptomatic AL after LAR for cancer, but they are still limited series, and the evidence shown from these RCTs still has some problems. Therefore, whether DS should be constructed routinely for every patient who undergoes LAR remains controversial.

The purpose of this study was to assess the effect of DS on symptomatic AL after LAR for rectal cancer in a large consecutive cohort of patients before and after propensity score matching (PSM). Propensity score matching was used to eliminate the potential bias due to a lack of equal distribution between the 2 groups in this nonrandomized study. Applying newer statistical methods could help close the gap between limited RCTs and the confused results from non-RCT studies.

METHODS

Patients

This study was designed as a prospective, multicenter, cohort study. Data were collected from 40 specialized institutions linked to the Japanese Society for Cancer of the Colon and Rectum (JSCCR). The study was approved by the Ethics Committee of JSCCR and by the institutional review board of each participating hospital, and informed consent was obtained from all patients. This study is registered with UMIN-CTR, number 000004017. The primary endpoint of this study was to investigate the effect of DS on symptomatic AL after LAR. The secondary endpoint was to analyze the risk factors for symptomatic AL.

Patients were eligible for this study if they had primary rectal cancer in which the lower edge of the tumor was within 10 cm from the anal verge. For inclusion in this study, patients had to fulfill the following requirements preoperatively: age greater than 20 years; rectal adenocarcinoma proven on preoperative pathologic examination; no multiple rectal lesions other than carcinoma in situ; and receipt of LAR with anastomosis using a circular stapler. Exclusion criteria were a history of major colorectal surgery and emergency operation for bowel obstruction. Preoperative tumor staging was done by digital examination, anoscopy, CT, MRI, barium enema, and colonoscopy examination.

Of the total cohort, patients who underwent LAR with anastomoses using circular staplers were analyzed. Patients converted to a sutured colo-anal anastomosis were excluded. Cases converted to subtotal colectomy, total proctocolectomy, abdominoperineal resection, Hartmann's procedure, or pull-through procedures were also excluded. The decision to construct DS and the choice of ileostomy vs colostomy were made by the individual surgeon in each case. Other clinical factors, such as use or nonuse of bowel preparation, types of surgical procedure (open vs laparoscopic), types of reconstruction, and performance of an intraoperative leakage test were also decided by the individual surgeon in each case.

Registration

Eligible patients were registered preoperatively by sending a registration form to the Data Center in Shizuoka Cancer Center Hospital after confirmation of the inclusion and exclusion criteria.

Definition of anastomotic leakage

Anastomotic leakage was defined as a defect of the intestinal wall at the anastomotic site (including suture and staple lines of neorectal reservoirs) leading to a communication between the intra- and extraluminal components, owing to a defect in the integrity of the intestinal wall at the anastomosis between the colon and rectum or colon and anus. Clinical symptoms caused by AL were defined as the emission of gas, pus, or feces from the drain or wound or the vagina. All clinically suspicious symptoms, such as fever, peritonitis, or turbid drain discharge were confirmed to be related to the anastomotic site by contrast enema radiography and CT. If imaging studies revealed the absence of anastomotic insufficiency, they were defined as pelvic abscess and not as AL. It was decided that for patients with DS, even those with no symptoms, contrast enema radiography would be performed during the period up to discharge, in order to radiologically confirm the presence or absence of integrity of the anastomotic site.