Diverting ileostomy versus no diversion after low anterior resection for rectal cancer: A prospective, randomized, multicenter trial

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Background. *This study sought to determine whether a protective diverting ileostomy improves short-term outcomes in patients with rectal resection and colonic J-pouch reconstruction for low anastomoses. Criteria for the use of a proximal stoma in rectal resections with colonic J-pouch reconstruction have not been defined sufficiently.*

Methods. *In a multicenter prospective study, rectal cancer patients with anastomoses below 8 cm treated with low anterior resection and colonic J-pouch were randomized to a defunctioning loop ileostomy or no ileostomy. The primary study endpoint was the rate of anastomotic leakage, and the secondary endpoints were surgical complications related to primary surgery, stoma, or stoma closure.*

Results. *From 2004 to 2014, a total of 166 patients were randomized to 1 of the 2 study groups. In the intention-to-treat analysis, the overall leakage rate was 5.8% in the stoma group and 16.3% in the no stoma group (*P = *.0441). However, some patients were not treated according to randomization and only 70% of our patients with low anastomoses received a pouch. Therefore, we performed a second analysis as to actual treatment. In this analysis, as well, leakage rates (*P = *.044) and reoperation rates for leakage (*P = *.021) were significantly higher in patients without a stoma. In multivariate analysis, male gender (*P = *.0267) and the absence of a stoma (*P = *.0092) were significantly associated with anastomotic leakage.*

Conclusion. *Defunctioning loop ileostomy should be fashioned in rectal cancer patients with anastomoses below 6 cm, particularly in male patients, even if reconstruction was done with a J-pouch. (Surgery 2016;159:1129-39.)*

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Low anterior rectal resection and abdominoperineal excision are the most effective treatments for localized rectal cancer. The introduction of total mesorectal excision (TME) was a major advance in the surgical strategy for rectal cancer, resulting in a reduction of local recurrence without adjuvant therapy. In radically operated patients, the local recurrence rates with TME after 5 and 10 years have been reported to be <10%, with a 5-year survival rate of 80%.[1-4]

Recent years have seen a decrease in the frequency of abdominoperineal resection in favor of sphincter-sparing procedures.[5] Although patient satisfaction and quality of life may be superior after sphincter-preserving surgery,[6] significant morbidity and mortality may occur, with anastomotic dehiscence being the primary concern.[7,8] The incidence of anastomotic leakage after anterior resection varies from 2 to 25%, depending on the level of anastomosis,[9] tumor diameter, tumor location, and absence of a protective stoma[10] or the method of reconstruction.[11-13] In patients with leaks and generalized abdominal sepsis,

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mortality rates of ≤50% have been reported,[2,14] whereas patients surviving the immediate consequences of anastomotic failure may expect a poor functional outcome owing to stenosis and reduced compliance of the neorectum.[15]

Therefore, it is the major goal of dedicated colorectal surgeons to prevent complications caused by anastomotic leaks subsequent to rectal surgery. For this purpose, several studies have suggested to fashion a protective stoma in patients undergoing TME with neoadjuvant treatment, in obese patients and those with low anastomoses and after technically demanding procedures.[16-18] However, the literature yields inadequate definitions as to the precise criteria for the use of a proximal stoma after elective rectal resections.

The role of a temporary diverting stoma in patients undergoing low anterior resection remains controversial. Some authors have considered the risk of leakage to be sufficiently low such that patients do not require diversion routinely.[19] Selective or nonroutine use of a fecal diversion is supported by the knowledge that both the application of a stoma and stoma reversal may cause significant morbidity and even mortality. Moreover, stoma reversal also implies a secondary hospital stay and several temporary stomas become permanent.[20,21]

Another technique reported to reduce possibly leakage rates is to perform a colonic J-pouch for reconstruction in low anastomoses.[12,13] A pouch may improve leakage rates most likely owing to an improved blood supply to the apex of the pouch[22] and may help to avoid a protective stoma.

The objective of this study was to determine whether a protective diverting ileostomy reduces the anastomotic leakage rate in patients with operable rectal cancer treated by mesorectal excision and colonic J-pouch for low anastomoses.

METHODS

Study design. The study was designed as a 2-arm, randomized, open-label, multicenter study in patients with operable rectal cancer. Preoperative screening and patient recruitment were performed in 3 participating colorectal centers in Austria. Patients were stratified by gender, anastomotic height, and preoperative radiochemotherapy to be operated either by rectal resection and coloanal/rectal anastomosis with a diverting ileostomy (group A) or rectal resection and coloanal/rectal anastomosis without protective ileostomy (group B). Patients in both groups with low anastomoses (<8 cm) were planned to receive a colonic J-pouch reconstruction. In accordance with the study protocol, all randomized patients were assessed preoperatively and during their hospital stay for primary surgery. Patients randomized for a diverting ileostomy were assessed additionally at the time of stoma reversal 8–10 weeks after the primary operation. Patients without protective stoma underwent a follow-up visit 10 weeks after the initial rectal resection. The study protocol was approved by the local ethics committees and institutional review boards of each participating center. Additionally, the study was registered in the International Standard Registered Clinical/Social Study Number registry under ISRCTN15655996.

Patient population and randomization. Patients aged 19–85 years with biopsy-proven and operable rectal cancer, with or without preoperative radiochemotherapy, a distal border of the tumor <16 cm from the anal verge as demonstrated by rigid rectoscopy, and a World Health Organization performance status of ≤2 were eligible for study inclusion. Patients with previous rectal surgery, emergency cases, planned laparoscopic resections, and those suffering from metastatic disease or synchronous colon cancer were excluded.

After completing preoperative rectal cancer staging and obtaining written informed consent, patients were randomized before surgery to either of the 2 groups using an Internet-based electronic randomization and documentation system. Randomization was performed using a dynamic 1:1 balanced allocation procedure with a block size of 4 (2 per group) and stratified by study site, gender, preoperative radiotherapy/chemotherapy, and anastomotic height (≤ 60 vs > 60 mm). The corresponding treatment group was obtainable after baseline assessments were performed and registered in the system. The data collected from each patient were documented using this online system and supported by automatic plausibility and completeness checks. The following data were gathered and collected prospectively: preoperative data (gender, age, body height and weight, body mass index, smoking habits, preoperative radiochemotherapy, tumor location, cTNM, blood chemistry including serum albumin, World Health Organization performance status), intraoperative data (anastomotic height, performance of a pouch, intraoperative blood loss, duration of surgery), postoperative data during primary hospitalization (anastomotic leakage, treatment of leakage, postoperative complications and morbidity, pTNM stage, duration of hospital stay) and data from hospital stay for ileostomy closure (days until closure, duration of stay, complications).