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Rectal catheter versus diverting ileostomy after total mesorectal excision for rectal cancer: a propensity score-matched retrospective cohort study

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Abstract

Background

Diverting ileostomy is frequently used to mitigate the clinical consequences of anastomotic leakage (AL) after low rectal anastomosis, but it entails stoma-related morbidity and usually requires a second operation for closure. A modified rectal catheter may provide decompression and fecal drainage without a stoma. We compared postoperative outcomes after rectal catheter placement versus diverting ileostomy in patients undergoing total mesorectal excision (TME) for rectal cancer.

Methods

This single-center retrospective cohort study included patients with rectal adenocarcinoma who underwent TME between July 2022 and July 2024 and received either a rectal catheter or diverting ileostomy. The primary outcome was AL; secondary outcomes were AL severity and postoperative length of stay. Propensity score matching (PSM) was performed in a 1:1 ratio using nearest-neighbor matching to reduce baseline imbalance.

Results

Among 1,029 patients, 248 received a rectal catheter and 781 underwent diverting ileostomy. After PSM, 248 matched pairs were analyzed. AL occurred in 40 patients (16.1%) in the rectal catheter group and 37 (14.9%) in the ileostomy group (RR 1.097, 95% CI 0.674–1.784; P = 0.804). Grade B/C AL rates did not differ significantly (P = 0.864). Postoperative length of stay was shorter after rectal catheter placement [median 7 (IQR 6–9) vs 8 (IQR 7–11) days; P < 0.001]. In multivariable logistic regression, rectal catheter placement was not significantly associated with AL (OR 0.754, 95% CI 0.437–1.302; P = 0.311).

Conclusions

In this propensity score-matched retrospective cohort, rectal catheter placement was associated with similar observed AL rates and severity and a shorter postoperative hospital stay compared with diverting ileostomy. Because the study was not designed to establish non-inferiority, prospective multicenter trials are required before rectal catheter placement can be considered a substitute for diverting ileostomy.

Introduction

Total mesorectal excision (TME) is the standard surgical approach for mid- and low-rectal cancer [1, 2]. Anastomotic leakage (AL) remains one of its most consequential complications and is associated with greater postoperative morbidity, longer hospitalization, mortality, and adverse oncological outcomes [3–6].

Diverting ileostomy is widely used to protect a low colorectal or coloanal anastomosis and can reduce the clinical severity of leakage by diverting the fecal stream [7–10]. Its benefits, however, must be weighed against dehydration, renal dysfunction, skin and stoma complications, the possibility of a permanent stoma, additional costs, and a second operation for closure [9–12]. These disadvantages have prompted interest in less invasive strategies that decompress the rectum and reduce fecal loading around the anastomosis.

Transanal drainage tubes have been investigated as one such strategy [7, 13–17]. Proposed mechanisms include reduction of intraluminal pressure and facilitation of gas and fecal drainage. Evidence remains heterogeneous, and direct comparisons with diverting ileostomy are limited. The rectal catheter used at our center is a modified transanal drainage device incorporating a retention balloon, irrigation channel, and drainage channel, designed to maintain decompression and facilitate drainage above the anastomosis.

The aim of this study was therefore to compare rectal catheter placement with diverting ileostomy after TME for rectal cancer, focusing on the observed incidence and severity of AL and postoperative length of stay. Given the observational design, the study was intended to evaluate association rather than to demonstrate formal equivalence or non-inferiority.

Methods

Study design and patients

This retrospective cohort study identified consecutive patients who underwent TME for rectal cancer at The Sixth Affiliated Hospital of Sun Yat-sen University between July 2022 and July 2024. Eligible patients had histologically confirmed rectal adenocarcinoma with the tumor located within 12 cm of the anal verge on preoperative magnetic resonance imaging.

Exclusion criteria were age <18 or >80 years, emergency surgery, palliative surgery, distant metastasis, multiple colorectal tumors, recurrent rectal cancer, familial adenomatous polyposis, and absence of either intraoperative rectal catheter placement or diverting ileostomy. Patients were categorized according to the anastomotic protection strategy used at the index operation.

AUTHOR QUERY: The original Discussion states that patients receiving preoperative radiotherapy were excluded, but this criterion is not listed in the original Methods and 'preoperative therapy' is present in Table 1. Please verify the exact neoadjuvant-treatment eligibility criteria before submission.

Outcomes and definitions

The primary outcome was postoperative anastomotic leakage. Secondary outcomes were AL grade and postoperative length of stay.

AL was defined as a defect of the intestinal wall at the anastomotic site resulting in communication between the intra- and extraluminal compartments; a pelvic abscess adjacent to the anastomosis was also considered a leak even when direct communication with the bowel lumen was not demonstrated [4]. Leakage was graded according to the intervention required: grade A required no active therapeutic intervention; grade B required therapeutic intervention without relaparotomy; and grade C required relaparotomy.

Baseline variables included age, sex, body mass index (BMI), comorbidity, tumor distance from the anal verge, clinical tumor stage, preoperative treatment, American Society of Anesthesiologists (ASA) classification, and estimated intraoperative blood loss, as available in the study dataset. Tumor stage was classified according to the eighth edition of the American Joint Committee on Cancer staging system.

Anastomotic protection strategies

The choice between diverting ileostomy and rectal catheter placement was made by the operating surgeon. In patients assigned to rectal catheter drainage, a rectal catheter (HTKD Medical) was inserted transanally at the end of surgery, and its tip was positioned approximately 3-5 cm proximal to the anastomosis under laparoscopic visualization. The catheter incorporated a retention balloon and was connected to a drainage bag. It was secured to the inner thigh, and the balloon was checked and replenished daily by the surgical team.

The catheter was generally removed on postoperative day 4 or 5 after repeated passage of flatus or stool and when the treating surgeons found no clinical evidence of AL. Earlier removal was permitted if the patient experienced intolerable catheter-related pain. Postoperative care followed the same institutional protocol in both groups.

Statistical analysis

Statistical analyses were performed using SPSS version 21.0 (IBM/SPSS, Chicago, IL, USA). Categorical variables were compared using the chi-square test or an appropriate exact test. Continuous variables were summarized using mean and standard deviation and/or median and interquartile range, according to their distribution. All tests were two-sided, and $P<0.05$ was considered statistically significant.

Propensity scores were used to reduce measured baseline confounding. A 1:1 nearest-neighbor matching strategy was applied using age, sex, BMI, comorbidity, tumor location, and preoperative therapy as covariates in the propensity score model. Logistic regression was used to evaluate factors associated with AL. Variables assessed included surgical approach, tumor/anastomotic height, age, sex, ASA classification, BMI, preoperative therapy, comorbidity, and estimated blood loss.

AUTHOR QUERY: The original manuscript does not report the propensity-score model specification, caliper width, use/non-use of replacement, handling of missing data, or standardized mean differences after matching. Techniques in Coloproctology routinely publishes these details in propensity-adjusted studies. Please provide them if available; they should be added before submission.

Ethics

The study protocol was approved by the Ethics Committee of The Sixth Affiliated Hospital of Sun Yat-sen University (2022ZSLYEC-287) and was conducted in accordance with the Declaration of Helsinki. The requirement for informed consent was waived because anonymized retrospective data were used.

Results

Study population and matching

During the study period, 2,263 patients underwent TME for rectal cancer. After application of the eligibility criteria, 1,029 patients were included: 248 received a rectal catheter and 781 underwent diverting ileostomy (Fig. 1).

Before matching, the ileostomy group had a higher prevalence of comorbidity, a lower tumor distance from the anal verge, and greater estimated blood loss than the rectal catheter group. After 1:1 PSM, 248 matched pairs were retained. The original Table 1 reports no statistically significant between-group differences in the displayed baseline variables after matching. Postoperative hospital stay was shorter in the rectal catheter group [7 (IQR 6-9) vs 8 (IQR 7-11) days; P<0.001].

Anastomotic leakage

In the unmatched cohort, AL occurred in 40 of 248 patients (16.1%) in the rectal catheter group and 122 of 781 (15.6%) in the ileostomy group (RR 1.039; P=0.848).

After matching, AL occurred in 40 of 248 patients (16.1%) in the rectal catheter group and 37 of 248 (14.9%) in the ileostomy group (RR 1.097, 95% CI 0.674-1.784; P=0.804) (Table 2). These data show no statistically significant difference in the observed AL rate, but the confidence interval does not establish equivalence or non-inferiority.

Leakage severity

In the unmatched cohort, grade B/C leakage occurred in 19 patients (7.7%) in the rectal catheter group and 53 (6.8%) in the ileostomy group (P=0.638). After matching, 17 patients in the rectal catheter group developed grade B leakage and two developed grade C leakage; 18 patients in the ileostomy group

developed grade B leakage and none developed grade C leakage. The between-group difference in grade B/C leakage was not statistically significant (P=0.864) (Table 2).

Factors associated with anastomotic leakage

In univariable logistic regression, surgical approach and the height variable were associated with AL. Neither remained statistically significant in the multivariable model. Rectal catheter placement was not significantly associated with AL in multivariable analysis (OR 0.754, 95% CI 0.437-1.302; P=0.311) (Table 3). Estimated blood loss was not significantly associated with AL in the regression table (P=1.000).

Discussion

In this single-center propensity score-matched cohort of patients undergoing TME for rectal cancer, the observed incidence and severity of AL did not differ significantly between rectal catheter placement and diverting ileostomy. Rectal catheter placement was also associated with a one-day shorter median postoperative hospital stay. Importantly, the absence of a statistically significant difference should not be interpreted as proof of equivalence or non-inferiority; the confidence interval around the effect estimate remains compatible with clinically relevant differences between strategies.

Transanal drainage has been proposed as an alternative means of protecting a low rectal anastomosis by reducing intraluminal pressure and facilitating evacuation of gas, blood, and fecal material [7, 13–17, 24–27]. The device evaluated in the present cohort differs from a simple transanal tube in that it incorporates a retention balloon together with irrigation and drainage channels. This design may facilitate continuous decompression and drainage while the early anastomosis is healing. The present findings therefore provide contemporary comparative data for this modified device rather than establishing a class effect for all transanal drainage tubes.

Diverting ileostomy remains an established strategy for patients considered at high risk of clinically consequential leakage [18–20]. It can reduce fecal contamination and facilitate management when a leak occurs, but the trade-offs include stoma-related complications, resource use, possible failure of reversal, and a second operation for closure [9, 11, 12, 23]. In appropriately selected patients, a less invasive approach that avoids a temporary stoma could therefore be attractive. The shorter postoperative stay observed in the rectal catheter group is consistent with a lower immediate treatment burden, although residual selection bias and unmeasured differences in perioperative recovery may also contribute.

Several biological and mechanical mechanisms may explain a potential protective role of rectal decompression. Fecal stasis around a fresh anastomosis may increase local bacterial exposure, while elevated intraluminal pressure may impose mechanical stress on the staple or suture line [24–27]. By facilitating drainage and decompression during the early postoperative period, a rectal catheter may reduce these stresses. Experimental and clinical literature also indicates that anastomotic healing

evolves rapidly during the first postoperative week, with fibroblast activity and collagen deposition becoming increasingly important during the reparative phase [28–30]. These mechanisms are plausible but were not measured in this study and should therefore be considered explanatory hypotheses rather than demonstrated mediators.

Previously reported risk factors for AL include low anastomotic level, male sex, obesity, smoking, diabetes, cardiovascular disease, neoadjuvant treatment, and technically complex surgery [31–35]. In the present analysis, surgical approach and the height variable were significant only in univariable analysis and lost significance after multivariable adjustment. Contrary to an earlier statement in the original draft, the provided regression table does not show a significant association between estimated blood loss and AL; the Discussion has therefore been revised to match the reported data.

This study has several limitations. First, its retrospective single-center design is susceptible to selection bias, confounding by indication, and unmeasured confounding, particularly because the choice of rectal catheter or ileostomy was made by the surgeon. PSM can improve balance in measured variables but cannot address unmeasured factors that influence diversion decisions. Second, this was not a formal non-inferiority study and was not powered around a prespecified non-inferiority margin; consequently, similar observed event rates cannot establish that rectal catheter placement is non-inferior to diverting ileostomy. Third, the exact eligibility and representation of patients receiving preoperative radiotherapy must be clarified because the original Methods and Discussion are inconsistent on this point. Fourth, the current dataset does not provide stoma-specific complications, readmission, reversal morbidity, catheter-related adverse events, quality of life, or longer-term outcomes, all of which are important when comparing these strategies.

Taken together, the findings support further prospective evaluation of rectal catheter drainage as a stoma-sparing strategy in carefully selected patients. A multicenter randomized non-inferiority trial with explicit eligibility criteria, a prespecified margin, standardized catheter management, and patient-centered outcomes would be the appropriate next step.

Conclusions

Rectal catheter placement after TME was associated with similar observed AL rates and leakage severity and a shorter postoperative hospital stay compared with diverting ileostomy in this propensity score-matched retrospective cohort. These observational findings are hypothesis-generating and do not establish equivalence or non-inferiority. Prospective multicenter randomized evaluation is warranted before rectal catheter drainage is adopted as a substitute for diverting ileostomy.

Declarations

Conflict of interest

The authors declare that they have no relevant financial or non-financial competing interests.

Ethical approval

The study protocol was approved by the Ethics Committee of The Sixth Affiliated Hospital of Sun Yat-sen University (2022ZSLYEC-287).

Informed consent

The requirement for informed consent was waived by the institutional ethics committee because anonymized retrospective data without personal identifiers were used.

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Author Contribution

Yihang Zhou: Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Visualization, Writing – original draft, Writing – review & editing.Huanxin Hu: Conceptualization, Methodology, Investigation, Data curation, Formal analysis, Writing – original draft, Writing – review & editing.Jian Kang: Conceptualization, Methodology, Investigation, Data curation, Formal analysis, Writing – original draft, Writing – review & editing.Hao Xie: Investigation, Data curation, Resources, Writing – review & editing.Ze Li: Investigation, Data curation, Resources, Writing – review & editing.Dongxu Lei: Investigation, Data curation, Resources, Writing – review & editing.Xuanhua Yang: Investigation, Data curation, Resources, Writing – review & editing.Wei Xiao: Investigation, Data curation, Resources, Writing – review & editing.Taixuan Wan: Investigation, Data curation, Resources, Writing – review & editing.Haoqi Zheng: Investigation, Data curation, Resources, Writing – review & editing.Shimin Zhang: Investigation, Data curation, Methodology, Writing – review & editing.Haonan Zhou: Investigation, Data curation, Resources, Writing – review & editing.Minyi He: Investigation, Data curation, Resources, Writing – review & editing.Huashan Liu: Conceptualization, Methodology, Supervision, Project administration, Resources, Validation, Funding acquisition, Writing – review & editing.Ziwei Zeng: Conceptualization, Methodology, Supervision, Project administration, Resources, Validation, Funding acquisition, Writing – review & editing.Liang Kang: Conceptualization, Methodology, Supervision, Project administration, Resources, Validation, Funding acquisition, Writing – review & editing.Yihang Zhou, Huanxin Hu, and Jian Kang

contributed equally to this work and share first authorship. Huashan Liu, Ziwei Zeng, and Liang Kang jointly supervised this work and share corresponding authorship. All authors read and approved the final manuscript.

Data availability

The data underlying the findings are available from the corresponding author upon reasonable request.

Tables

Tables 1-3 are available in the Supplementary Files section.

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Figures

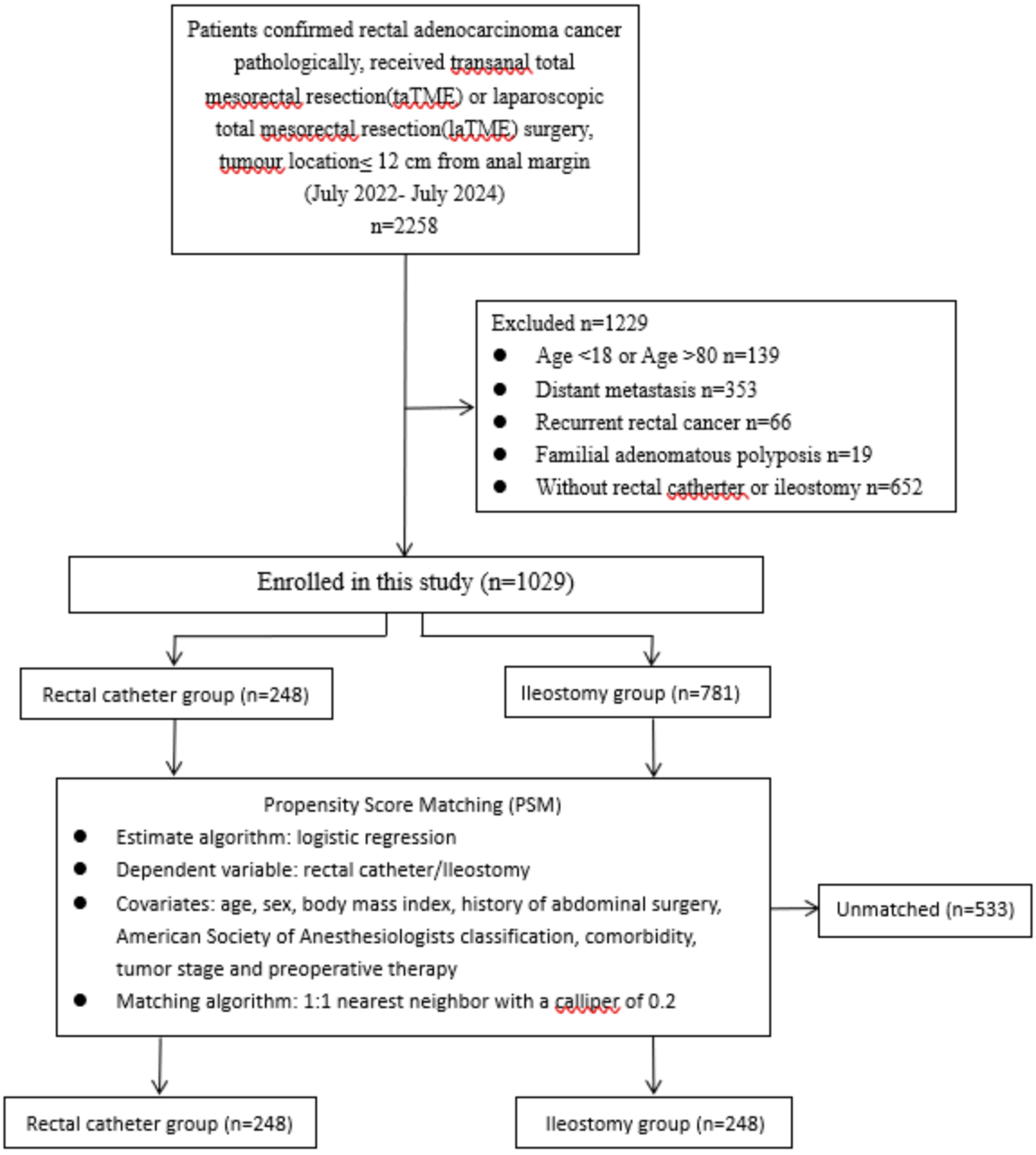


Figure 1

Study flow diagram. Flowchart of patient selection, exclusion, and propensity score matching (PSM) between the rectal catheter and diverting ileostomy groups after total mesorectal excision (TME).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- table1.docx
- table2.docx
- table3.docx