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REVIEW OF DECOMPRESSION ILEOSTOMY DURING LAPAROSCOPIC RECTAL CANCER SURGERY

Gastroenterology

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ABSTRACT

Introduction: Decompression ileostomy is always applied to avoid clinically significant anastomotic leakage and other postoperative complications for patients receiving laparoscopic rectal cancer surgery. However, whether it is necessary to perform the ileostomy is still controversial. This analysis aims to analyse the efficacy of ileostomy on laparoscopic rectal cancer surgery. **Methods:** Cochrane Library, EMBASE, Web of Science, and PubMed were applied for systematic search of all relevant literature, updated to March 31, 2022. Studies compared patients with and without ileostomy for laparoscopic rectal cancer surgery. The analysis was performed using Review Manager software. The quality of the non-randomized controlled trials was assessed using the Newcastle-Ottawa scale (NOS), and the randomized studies were assessed using the Jadad scale. **Results:** A total of 1203 references were obtained, and 7 studies were included using the research methods. The clinically significant anastomotic leakage rate was significantly lower in ileostomy group (27/567, 4.76%) than that in non-ileostomy group (54/525, 10.29%) (RR = 0.47, 95% CI 0.30–0.73, P for overall effect = 0.0009, P for heterogeneity = 0.18, I2 = 32%). However, the postoperative hospital stay, reoperation, wound infection, and operation time showed no significant difference between the ileostomy and non-ileostomy groups. **Conclusion:** The results demonstrated that protective ileostomy can decrease the clinically significant anastomotic leakage rate for patients undergoing laparoscopic rectal cancer surgery. However, ileostomy has no effect on postoperative hospital stay, reoperation, wound infection, and operation time.

KEYWORDS

Clinically significant anastomotic leakage, Ileostomy, Laparoscopy, Rectal cancer

INTRODUCTION

Colorectal cancer (CRC) ranks third in the global incidence of malignant tumors, affecting human health seriously (1). According to the American Cancer Society statistics, the incidence of CRC in males is lower than that in prostate and lung cancer. In females, CRC incidence is lower than that in breast and lung cancer (2). In terms of mortality, CRC ranks second in males and the third in females worldwide (2). Since the 1990s, laparoscopic surgery has attracted more and more attention as a new minimally invasive surgical method to treat many diseases (3, 4). Many multi-centre researchers and a large number of randomized controlled trials have confirmed the safety and reliability of laparoscopic rectal cancer surgery (5-7). The laparoscopic operation can follow the total mesorectal excision (TME) principle with many advantages, including less surgical trauma and bleeding, lower surgical complications and postoperative pain, and faster postoperative recovery to achieve R0 resection of the tumour (8, 9). As a result, laparoscopic low anterior resection (LAR) has become a basic operation for rectal cancer.

Many patients receiving rectal cancer surgery routinely undergo protective ileostomy to avoid clinically significant anastomotic leakage and other complications. However, whether it is necessary to perform the ileostomy is still controversial. At present, there are only a small number of randomized controlled trials and comparative studies assessing the effect of ileostomy during laparoscopic rectal cancer surgery. Therefore, the efficacy of ileostomy on laparoscopic rectal cancer surgery was analysed using the analysis.

MATERIALS AND METHODS

Search Strategies

This study was performed according to the stated guidelines of Preferred Reporting Items for Systematic Reviews and Analysis (PRISMA) (10). Cochrane Library, EMBASE, Web of Science, and PubMed were applied for systematic search of all relevant literature, updated to March 31, 2022. The following terms of ("rectal neoplasms") OR ("neoplasm, rectal") OR ("rectum neoplasms") OR ("neoplasm, rectum") OR ("rectal tumors") OR ("tumour, rectal") OR "neoplasms, rectal") OR ("cancer of rectum") OR ("rectum cancers") OR ("rectal cancer") OR ("cancer, rectal") OR ("rectal cancers") OR ("rectum cancer") OR ("cancer, rectum") OR ("cancer of the rectum") AND ("ileostomy") OR ("ileostomies") OR ("tube ileostomy") OR ("ileostomies, tube") OR ("ileostomy, tube") OR ("tube ileostomies") OR ("incontinent ileostomy") OR ("ileostomies, incontinent") OR ("ileostomy, incontinent") OR ("incontinent ileostomies") OR ("loop ileostomy") OR ("ileostomies, loop") OR ("ileostomy, loop") OR ("loop ileostomies") OR ("continent ileostomy") OR ("continent ileostomies") OR ("ileostomies, continent") OR ("ileostomy, continent") AND ("laparoscopy") OR "laparoscopies) OR ("celioscopy") OR ("celioscopies") OR ("peritoneoscopy") OR ("peritoneoscopies") OR ("surgical procedures, laparoscopic") OR "laparoscopic surgical procedure") OR "procedure, laparoscopic surgical") OR ("procedures, laparoscopic surgical") OR ("surgery, laparoscopic") OR ("laparoscopic surgical procedures") OR ("laparoscopic surgery") OR ("laparoscopic surgeries") OR ("surgeries, laparoscopic") OR "laparoscopic assisted surgery") OR ("laparoscopic assisted surgeries") OR ("surgeries, laparoscopic assisted") OR ("surgery, laparoscopic assisted") OR ("surgical procedure, laparoscopic") were used.

Inclusion And Exclusion Criteria

A. The inclusion criteria were listed as follows: (1) patients who were diagnosed with rectal cancer by histopathology and were treated with laparoscopic rectal cancer surgery; (2) clinical trials compared patients with and without protective ileostomy; (3) patients were grouped by whether they received protective ileostomy (4) at least one of the following outcomes were reported (incidence of postoperative anastomotic fistula, reoperation rate, length of hospital stay, incidence of postoperative peritonitis, and postoperative incision infection rate); (5) studies reported in English.

B. The exclusion criteria were listed as follows: (1) studies included benign colorectal diseases; (2) review, letter, case report, or analysis; (3) other surgical methods were used, such as open abdominal Dixon surgery, Miles, robot-assisted resection of the rectum, and natural orifice transluminal endoscopic surgery (NOTES); (4) single group studies; (5) full extraction could not be obtained. In the case of studies comprising the same patient cohort, only the most recent or complete study was included.

Data Extraction And Methodology

All authors extracted and assessed the data independently. At least two

researchers assessed each citation. The extracted data mainly included the first author, publication year, number of patients, age and sex of patients, clinical characteristics, and outcomes. The primary outcome mainly included clinically significant anastomotic leakage rate, and the secondary outcomes include operation time, length of hospital stay, complication rate, reoperation rate, etc. Any uncertainties about the extracted data were carefully discussed until the consensus was reached. For the assessment of non-randomized controlled trials in this study, the NOS was applied, including selecting patients, comparability and controls on the study design, and outcome assessment. The study was considered moderate to high quality if the score was more than 6. Randomized studies were assessed with the Jadad scale. Two researchers scored each study independently, and a discussion was made if there was a disagreement.

Statistical Analysis

Review Manager 5.3 provided by the Cochrane Collaboration Network was used for statistical analysis. Weighted Mean differences (MDs) and risk ratios (RRs) with 95% confidence intervals (CI) were calculated for analysing continuous and dichotomous data, respectively. $P < 0.05$ was considered as statistical significance. I2 test was applied to assess the heterogeneity of the studies. There was significant heterogeneity when I2 >50% or $P < 0.05$ and the random-effects model should be used. Otherwise, the fixed effects model should be applied. Sensitivity analysis was employed when there was significant heterogeneity of studies. By omitting each study at a time, the effect of an individual study on the overall heterogeneity could be analysed. Publication bias was assessed by funnel plots.

RESULTS

1. Study Characteristics.

According to the research methods, a total of 1203 references were obtained, including 15 references in Cochrane Library, 650 references in EMBASE, 403 references in Web of Science, 132 references in PubMed, and other 3 additional references identified through other sources. The 238 duplicated citations were deleted and 952 studies were excluded after scanning the title and abstract of the remaining citations according to the inclusion and exclusion criteria. Finally, 7 cohort studies were chosen in this analysis (11-17), and only 1 was a randomized controlled trial (RCT), and others were comparative.

There were 1092 patients in this analysis, with 567 patients in the ileostomy group and 525 patients in the non-ileostomy group, with an average patient age of 61.5 years in the ileostomy group and 62.6 in the no ileostomy group. All patients had been confirmed as rectal cancer by postoperative pathologic diagnosis and met the standard of laparoscopic rectal cancer surgery. The characteristics of all the 7 included cohort studies are shown in Table 1, where 6 comparative studies scored 6 or more assessed by NOS, and 1 RCTs scored 3 assessed with the Jadad scale.

2. Clinically Significant Anastomotic Leak.

All 7 studies involved the clinically significant anastomotic leakage data. Study, shows significant difference in the clinically significant anastomotic leakage rate between the ileostomy group (27/567, 4.76%) and non-ileostomy group (54/525, 10.29%) (RR = 0.47, 95% CI 0.30-0.73, P for overall effect = 0.0009, P for heterogeneity = 0.18, I2 = 32%). The funnel plot on clinically significant anastomotic leakage shows that all the studies lie inside the limit of 95% CI, indicating no obvious publication bias.

3. Postoperative Hospital Stay.

There were 4 studies that reported the postoperative hospital stay with 419 patients in the ileostomy group and 376 patients in the non-ileostomy group. There is no statistical difference between the two groups. (MD = -0.18, 95% CI -4.18– effect = 0.93, P for heterogeneity 1 < 0.00001, I2 = 98%).

4. Re-operation.

The reoperation outcome in all included studies was specifically caused by anastomotic leakage. Three studies reported the reoperation outcome with 331 patients in ileostomy group and 278 patients in non-ileostomy group. There is no statistical difference between the two groups (Study shows, RR = 0.69, 95% CI 0.14–3.40, P for overall effect = 0.65, P for heterogeneity = 0.26, I2 = 22%).

5. Surgical Site Infection.

Data on wound infection were provided in 3 studies. The analysis shows no difference in wound infection rate between ileostomy group (5/138, 3.62%) and non-ileostomy group (6/166, 3.61%) (Study shows, RR = 1.01, 95% CI 0.34–3.01, P for overall effect = 0.98, P for heterogeneity < 0.32, I2 = 11%).

6. Operation Time.

Three studies reported the operation time of 341 patients in the ileostomy group and 338 patients in the non-ileostomy group. There was significant heterogeneity among the studies, and a random effects model was used for analysis. Data analysis shows no statistical difference between the two groups (Study shows, MD = 14.17, 95% CI -12.95–41.29, P for overall effect = 0.31, P for heterogeneity < 0.00001, I2 = 96%).

Sensitivity Analysis

There was no significant heterogeneity in the clinically significant anastomotic leakage, reoperation after laparoscopic rectal cancer surgery, and wound infection after surgery. As a result, the fixed-effects model was applied for the three models. Significant heterogeneity was observed in the postoperative hospital stay and operation time. Therefore, the random-effects model was performed for the two models. Unfortunately, the sensitivity analysis did not reduce heterogeneity in the postoperative hospital stay and operation time. After removing the study of Shimizu et al., no significant heterogeneity was observed in the operation time. However, during the sensitivity analysis, both the pooled results of postoperative hospital stay and operation time remained unchanged. We analyse that the heterogeneity may be due to the regional differences and medical level. For example, the laparoscopic rectal cancer surgery regimens have changed significantly and postoperative treatment regimens have varied a lot over the past 10 years.

DISCUSSION

Colorectal malignancies are common digestive system tumors with increased morbidity and mortality every year (1). Surgical resection is still the main method to treat CRC. TME is the key to radical resection for rectal cancer (4, 8, 18), and rectal washout has been integrated in the TME technique in recent years (19). According to the principles of TME, laparoscopic LAR for rectal cancer has become the mainstream treatment method for patients (20, 21). Especially, laparoscopic tumour-specific mesorectal excision (TSME) have been utilized for upper rectal cancer (22). Many problems that cannot be solved by conventional laparotomy, such as anus-preserving surgery for rectal cancer with anal distance less than 5cm, can be solved by laparoscopic technique, which greatly improves the life quality of patients (23, 24). Laparoscopic surgery has many advantages, such as a clear vision of operation, small incision, mild postoperative pain, and short hospital stay (25-27). Especially, in order to pursue better treatment benefits, many laparoscopic surgery regimens have been improved, such as 3D laparoscopy, robotic surgery, single-incision laparoscopic surgery, two-port laparoscopic anterior resection, LAR with natural orifice specimen extraction (NOSE LAR) and so on (28-32). Moreover, some researchers proposed that sphincter-saving rectal resections can be seen as a feasible alternative to extralevator abdominoperineal resection or transanal total mesorectal excision (33).

Clinically significant anastomotic leakage is the main postoperative complication that threatens the life of patients with rectal cancer. The CT scan was the most common diagnostic method, and contrast enema, endoscopic examination, reoperation and other postoperative complications also can assist in the diagnosis (34). Clinically significant anastomotic leakage for laparoscopic rectal cancer surgery usually occurs on the 7th day post-surgery (35). Generally, the small anastomotic leakage can be treated through conservative treatment (fasting water, nutritional support, anti-inflammation, fluid replacement, etc.), while the severe clinically significant anastomotic leakage requires surgical intervention (36). We mainly focused 1 whether protective ileostomy can decrease the rate clinically significant anastomotic leak, and microscopic leaks are not evaluated in any studies. Protective colostomy or ileostomy has been performed to reduce the incidence of clinically significant anastomotic leakage. However, it is still controversial that whether it is beneficial to perform the protective stoma. Some surgeons believe that preventive

intestinal stoma is unnecessary because most clinically significant anastomotic leakage can be cured conservatively, and intestinal stoma increases the cost of hospitalization and requires secondary surgery (37-39). The second surgery will undoubtedly delay the subsequent treatment of patients with rectal cancer surgery, especially those who

are old and have many underlying diseases (such as postoperative chemoradiotherapy), and even accelerate the deterioration and increase mortality (40-43). On the other hand, frail patients often require ileostomy closure surgery before adjuvant therapy (due to frequent nutritional deficiencies) and this delays adjuvant therapy as well. Moreover, researchers haven't reached an agreement about the concrete interval time from ileostomy closure surgery to adjuvant therapy. Some other researchers believe that protective intestinal stoma can reduce intestinal oedema, promote local intestinal function recovery, facilitate anastomotic healing, and reduce clinically significant anastomotic leakage and other complications (11). This analysis was based on 7 comparative studies with more than 1000 patients. The results showed that protective ileostomy could reduce clinically significant anastomotic leakage in patients who underwent laparoscopic rectal cancer surgery. However, ileostomy has no influence on postoperative hospital stay, reoperation, wound infection, and operation time.

According to the principles of enhanced recovery after surgery (ERAS), postoperative recovery has been significantly increased (44). The postoperative hospital stay showed no difference in the analysed groups. According to the combination of included studies and clinical experience, although preventive stoma could reduce clinically significant anastomotic leakage, most clinically significant anastomotic leakage could be cured through conservative treatment. There was no significant difference in the perioperative reoperation rate between the two groups of patients. Besides, no statistical difference 1 in wound infection rate and operation time was found in ileostomy and non-ileostomy groups. There are some limitations to this analysis. First of all, the funnel plot suggests that publication bias has existed in this study because the included studies are all retrospective studies without a random controlled trial. Second, the surgeons have a clinical bias in performing protective ileostomy for patients receiving laparoscopic rectal cancer surgery possibly. Many different factors can influence the clinically significant anastomotic leakage rate, such as anastomotic position, sex, tumour diameter, operation time, location of ligation IMA, postoperative management, and so forth (36, 45, 46). Therefore, there is bias in choosing ileostomy for patients receiving laparoscopic rectal cancer surgery. Third, the bias is caused by the length between the anastomosis and anal verge, which is not reported in all studies. It seems that clinically significant anastomotic leakage is tentative to occur when the anastomosis is in a lower position (47, 48). Fourth, the types of performed rectal resection are not fully evaluated. In 4 studies, the authors have reported them as LAR, while in other 4 studies, it has been TME. The other 2 studies have not clearly reported rectal resection type. However, concerning the relative publication date of all 7 studies, LAR is performed according to the principles of TME in all the cases. In addition, because it is unclear whether these included patients have received neoadjuvant therapy or not, the influence of neoadjuvant therapy on leakage rate was not evaluated in this article. Interestingly, an analysis has reported that neoadjuvant therapy did not increase the rate of postoperative anastomotic leakage after middle and low rectal anterior resection (49), which provides guidance for future research. Finally, this study did not analyse whether ileostomy can affect the long-term survival rate of patients, bowel function, and postoperative quality of life.

CONCLUSION

The study indicates that protective ileostomy can decrease the clinically significant anastomotic leakage rate in patients receiving laparoscopic rectal cancer surgery. However, ileostomy has no effects on postoperative hospital stay, reoperation, wound infection, and operation time.

Abbreviations

NOS: Newcastle-Ottawa scale; CRC: colorectal cancer; TME: total mesorectal excision; LAR: low anterior resection; NOTES: natural orifice transluminal endoscopic surgery; MDs: Mean differences; RRs: risk ratios; CI: confidence intervals; RCTs: randomized controlled trials; TSME: tumour-specific mesorectal excision; NOSE-LAR: LAR with natural orifice specimen extraction; ERAS: enhanced recovery after surgery; IMA: inferior mesenteric artery.

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