

Comparison of clinical efficacy of different colon anastomosis methods in laparoscopic radical resection of colorectal cancer

Comparación de la eficacia clínica de diferentes métodos de anastomosis de colon en la resección radical laparoscópica del cáncer colorrectal

Weimin Sun¹ and Jie Zhang^{2*}

¹Department of General Surgery, Xuyi People's Hospital, Huai'an 211700, Jiangsu; ²Department of Gastrointestinal Surgery The Affiliated Huai'an Hospital of Xuzhou Medical University and The Second People's Hospital of Huai'an, Huai'an 223002, China

Abstract

Objective: The objective of this study was to investigate the clinical effect of overlap anastomosis and functional end-to-end anastomosis (FEEA) in laparoscopic radical resection of colorectal cancer (CRC). **Methods:** The clinical data of 180 patients who underwent laparoscopic radical resection of CRC and side-to-side anastomosis were retrospectively collected; the patients were divided into the Overlap group and FEEA group, according to the anastomosis method that was used to treat them. **Results:** The Overlap group had a shorter operation time, anastomosis time, post-operative hospital stay, post-operative feeding time, and post-operative exhaust time than the FEEA group ($p < 0.05$). The total incidence of post-operative complications was 14.4% (13/90) in the FEEA group and 0.7% (6/90) in the Overlap group, and there was no significant difference between the two groups ($p > 0.05$). **Conclusions:** Overlapping anastomosis can shorten the operation time and accelerate the recovery of intestinal function without increasing the incidence of post-operative complications, and it will not affect the quality of life and survival of patients in the short term after surgery.

Keywords: Colon/colorectal cancer. Laparoscopy. Overlap anastomosis. Functional end-to-end anastomosis.

Resumen

Objetivo: Investigar el efecto clínico de la anastomosis superpuesta y de la anastomosis funcional de extremo a extremo (AFEE) en la resección radical laparoscópica del cáncer colorrectal (CCR). **Método:** Se recolectaron retrospectivamente los datos clínicos de 180 pacientes sometidos a resección radical laparoscópica de CCR y anastomosis de lado a lado. Los pacientes se dividieron en grupo de anastomosis superpuesta y grupo AFEE, según el método de anastomosis que se utilizó para tratarlos. **Resultados:** El grupo de anastomosis superpuesta tuvo un tiempo de operación, un tiempo de anastomosis, una estancia hospitalaria posoperatoria, un tiempo de alimentación posoperatorio y un tiempo de escape posoperatorio más cortos que el grupo AFEE ($p < 0.05$). La incidencia total de complicaciones posoperatorias fue del 14.4% (13/90) en el grupo AFEE y del 0.7% (6/90) en el grupo de anastomosis superpuesta, y no hubo diferencias significativas entre los dos grupos ($p > 0.05$). **Conclusiones:** La anastomosis superpuesta puede acortar el tiempo operatorio y acelerar la recuperación de la función intestinal sin aumentar la incidencia de complicaciones posoperatorias, y sin afectar la calidad de vida y la supervivencia de los pacientes a corto plazo después de la cirugía.

Palabras clave: Cáncer de colon/colorrectal. Laparoscopia. Anastomosis superpuesta. Anastomosis funcional de extremo a extremo.

*Correspondence:

Jie Zhang

E-mail: zhangjie_zj23@163.com

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Introduction

Colorectal cancer (CRC) is a common malignant tumor of the digestive tract. According to global cancer statistics, there were more than 1.9 million new CRC cases and more than 935,000 deaths in 2020, accounting for around 1/10 of cancer cases and deaths¹. The incidence and mortality rates of CRC in China are among the highest in the world². The disease is caused by the abnormal proliferation of colorectal glandular epithelial cells. In addition to the aging population and the dietary habits in high-income countries, adverse factors such as obesity, lack of physical exercise, and smoking increase the likelihood of CRC³.

At present, the treatment of CRC is still based on surgery, supplemented with radiotherapy, chemotherapy, or targeted therapy⁴⁻⁶. Radical resection of the tumor and digestive tract reconstruction are two key steps for successful laparoscopic CRC surgery⁷. In terms of radical resection, it is necessary to determine the extent of resection according to the clinical stage of the tumor; however, due to the development of complete mesocolic resection (CME) and lymph node dissection specifications⁸⁻¹⁰, radical resection of cT1-4N0-2M0 CRC has been achieved in clinical practice¹¹. Digestive tract reconstruction determines the success rate of surgery, operation time, post-operative recovery, incidence of anastomotic complications, and other issues^{12,13}. Traditional digestive tract reconstruction of the colon has three anastomosis methods: end-to-end, end-to-side, and side-to-side anastomosis^{14,15}. Side-to-side anastomosis is the predominant method, and functional end-to-end anastomosis (FEEA) and overlap anastomosis are the two most important anastomosis methods for side-to-side anastomosis^{16,17}.

FEEA can reduce the incidence of anastomotic stricture, post-operative pain and intraoperative blood loss, and its short-term efficacy is better. However, it is a difficult and time-consuming endoscopic operation, requiring the free length of the intestinal canal and an experienced medical team. This anastomosis method of reconstruction is also performed against the physiological peristaltic direction of the intestinal tract^{18,19}. In 2010, Inaba et al.¹⁷ proposed an overlap anastomosis method that has the advantages of FEEA in digestive tract reconstruction during laparoscopic total gastrectomy but low requirements for free bowel length. The operation is also simple and follows the direction of physiological peristalsis of the intestine,

meaning it has been widely used in clinical surgery. Previous studies have found that overlap anastomosis takes less time and patients recover faster after surgery and have a shorter post-operative hospital stay. Moreover, it does not increase the incidence of anastomosis-related complications compared with FEEA surgery and anastomosis^{20,21}. However, there are still few studies on laparoscopic overlap anastomosis and FEEA in terms of surgical conditions, incidence of complications, and post-operative quality of life (QOL) for patients, and no unified criteria for digestive tract reconstruction have been developed. This study explores the intraoperative conditions, post-operative recovery, post-operative complications, and post-operative QOL of patients undergoing laparoscopic CRC overlapping anastomosis and FEEA to identify an anastomosis method that improves patient QOL and reduces their pain and to provide new reference suggestions for laparoscopic anastomosis of CRC.

Study participants and methods

Study participants

The convenience sampling method was used to select 180 patients who underwent laparoscopic radical resection of CRC and lateral anastomosis in the gastrointestinal surgery department of the authors' hospital between March 2020 and May 2023 as the study participants. The patients were divided into the Overlap group ($n = 90$) and the FEEA group ($n = 90$), according to the anastomosis method that was used. The study inclusion criteria were as follows: patients (1) aged 18-75 years; (2) with CRC confirmed by pre-operative colonoscopy and pathological examination; (3) with CRC without intestinal obstruction and with pre-operative bowel preparation; (4) who underwent total laparoscopic radical resection of CRC, intraoperative standard lymph node dissection and CME; and (5) with complete medical records. The exclusion criteria were as follows: patients (1) with a history of other malignant tumors or CRC combined with other malignant tumors within the previous 5 years; (2) with any distant metastasis; (3) with a history of previous abdominal surgery or inflammatory bowel disease; (4) whose surgery involved a forced conversion to laparotomy; (5) with uncontrolled nutritional disorders and mental illness; and (6) who were unable to complete the follow-up for 12 months after the surgery. The screening process of the research participants is shown in figure 1.

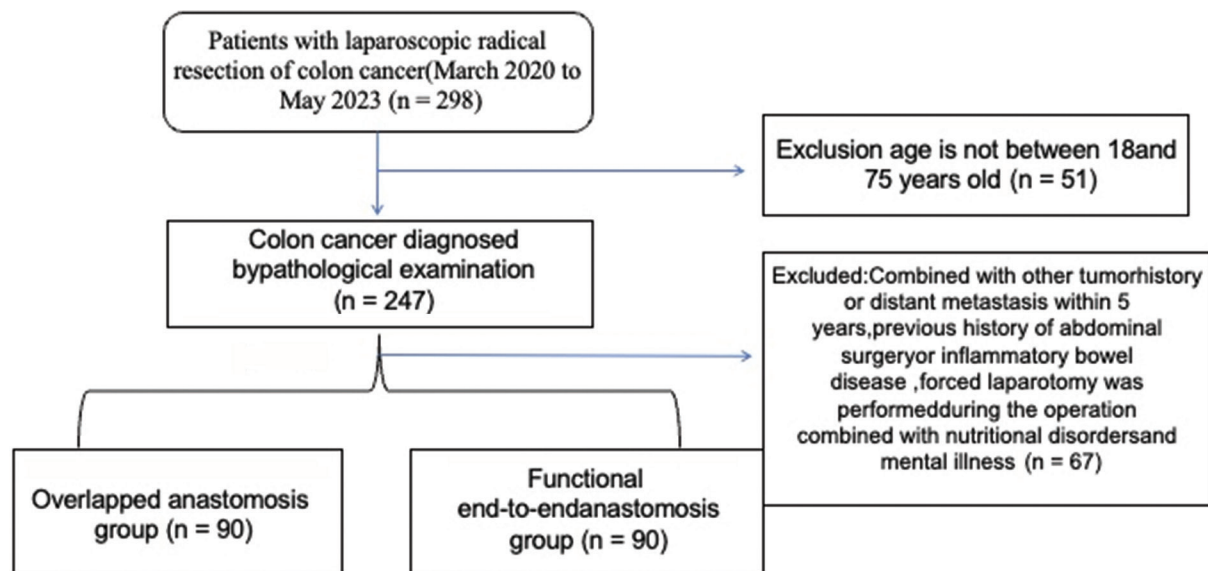


Figure 1. Research subject screening flow chart.

Study methods

The pre-operative preparation was as follows. (1) For patients with underlying diseases, such as hypertension, diabetes, and coronary heart disease, multidisciplinary consultation was conducted to assess the risk of surgery; for patients with low protein, anemia, electrolyte imbalance, and malnutrition, levels had to be adjusted to a reasonable range; for patients with small non-invasive serous tumors, pre-operative colonoscopic carbon nanoparticle localization was routinely performed. (2) A liquid diet was started 1 day before surgery, and polyethylene glycol electrolyte powder solution was taken orally to clean the intestine one night beforehand. Fasting and drinking were prohibited for 12 h and 4 h, respectively. (3) Prophylactic antibiotics were administered 30 min before the operation.

In terms of surgical methods, during the operation, CME and standardized lymph node dissection were performed under laparoscopy, and intestinal anastomosis was fully mobilized. For overlapping anastomosis, the small intestine and colon were cut off at their pre-resection sites. The ileum was placed in parallel with the transverse colon, and a small hole was made in the intestinal wall. Ileal-transverse side-to-side closure anastomosis was performed with an endoscopic cutting closure device. A barbed wire interrupted suture was used to strengthen the stump and anastomosis, and when the anastomosis was unobstructed and tension-free and the blood supply was good, the mesangial hole was closed (Fig. 2). In terms of FEEA, the right colon was pulled out

through the incision, the ileum mesentery was separated from it, and the mesentery was also detached from the middle of the transverse colon. The mesentery was clamped with a purse-string forceps 15 cm from the ileocecal junction, and a purse-string needle was inserted. A 25# tubular stapler was placed at the ileum stump, and the purse-string line was tightened. After the intended resection of the transverse colon was removed, a 25# tubular stapler was placed through the stump, and the ileum-transverse colon end-to-side anastomosis was performed. To close the transverse colon residue, the transverse colon stump was reinforced with barbed wire, and the transverse-colon ileal anastomosis was strengthened with 4-0-line interrupted sutures (Fig. 3).

The post-operative treatment was as follows: (1) bed rest with close monitoring of the patient's vital signs; (2) regular re-examination of blood, liver and kidney function and electrolytes, and the wearing of elastic stockings to prevent lower extremity deep venous thrombosis; (3) post-operative fasting and parenteral nutrition to control blood pressure and blood glucose and maintain water and electrolyte balance; (4) patient-controlled analgesia within 48 h of surgery, and non-steroidal anti-inflammatory drug administration for rescue analgesia; (5) daily assessment of pain levels using Visual Analog Scale (VAS) criteria for pain (no pain = 0 points, mild pain = 1-3 points, moderate pain = 4-6 points, severe pain = 7-9 points, and intolerable pain = 10 points); (6) monitoring and evaluation of the patient's defecation and feces to assess his/her intestinal recovery status (the patient received a liquid

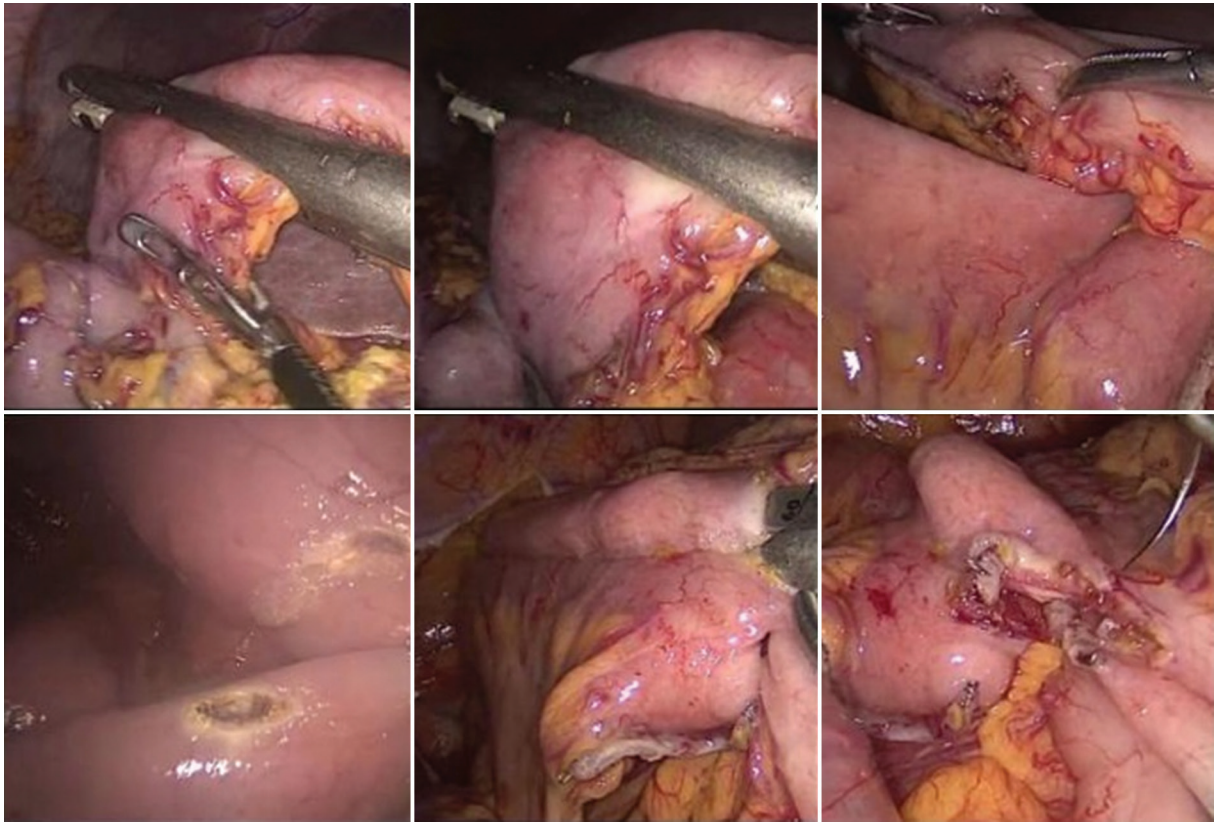


Figure 2. *Overlapping anastomosis method.*

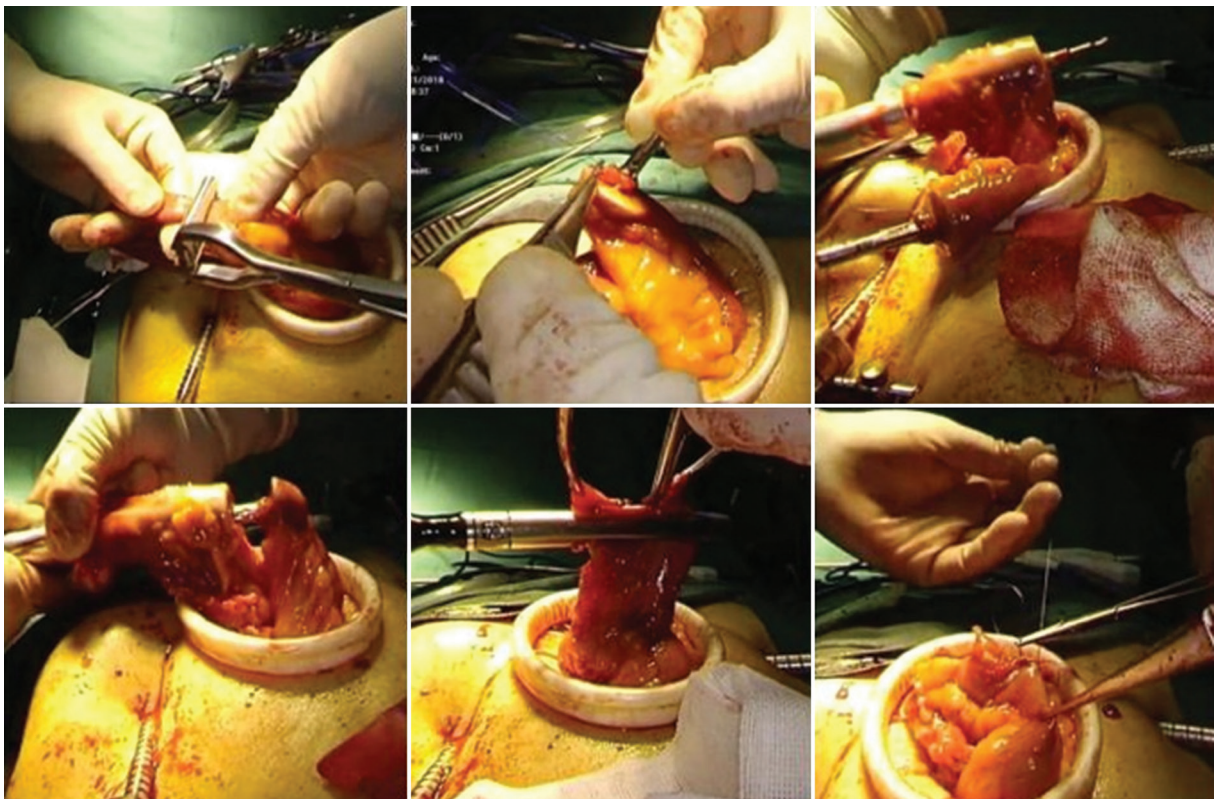


Figure 3. *Functional end-to-end anastomosis method.*

diet once defecation commenced and gradually transitioned to a regular diet); (7) the monitoring of abdominal drainage fluid and drainage volume, where once the drainage fluid was non-bloody, non-purulent, and non-chylous and < 30 mL/d, the drainage tube was removed; and (8) the discharge of patients who were asymptomatic and eating well with unobstructed defecation.

Data collection

General patient data consisting of age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, tumor location, size and stage, history of hypertension, diabetes and abdominal surgery, intraoperative conditions, post-operative recovery, post-operative perioperative complications, post-operative follow-up, and post-operative pathological results were gathered.

The intraoperative conditions included data on operation and anastomosis duration, intraoperative blood loss and abdominal incision length, and post-operative recovery included data on post-operative hospital stay, feeding and defecation times, and the post-operative 24 h pain score. Pain scores 24 h after surgery were measured using the VAS, with 0 indicating no pain, 1-3 mild pain, 4-6 moderate pain, 7-9 severe pain, and 10 intolerable pain.

Post-operative perioperative complications pertained to whether there was an incision, abdominal or lung infection, abdominal bleeding, incisional hernia, anastomotic leakage, bleeding or stenosis, and intestinal obstruction. The post-operative pathological results concerned the number of dissected and positive lymph nodes, nerve, and vascular invasion, specimen length, and tumor differentiation and growth patterns.

Regarding the 12-month post-operative follow-up, the QOL score table was used to evaluate the QOL of the two groups at 3, 6, 9, and 12 months after the operation. Every 3 months after surgery, carcinoembryonic antigen levels were assessed and enhanced computed tomography scans of the chest and abdomen were taken. Enteroscopy was performed every 6 months to ascertain whether the patients had tumor recurrence and metastasis, and the follow-up also recorded whether the patient died within 12 months of the surgery.

Statistical analysis

Data analysis was performed using SPSS 26.00, and measurement data conforming to the normal distribution were expressed in the form of mean $\pm$ standard

deviation ($\pm$ s) and compared using the independent samples t-test. Enumeration data were presented as absolute numbers or percentages (n [%]) and compared using χ^2 or Fisher's exact tests, with $p \leq 0.05$ was considered statistically significant.

Results

Comparison of general data

The FEEA group included 90 patients, 52 men and 38 women, with a mean age of 58.34 ± 7.51 years, and the Overlap group included 90 patients, 49 men and 41 women, with a mean age of 57.32 ± 6.35 years. There was no significant difference between the two groups in terms of age, gender, BMI, ASA grade, tumor location, size and stage, and history of hypertension, diabetes, and abdominal surgery ($p > 0.05$), as shown in table 1, meaning that the two groups were comparable.

Comparison of intraoperative and post-operative recovery

The results showed that there were significant differences between the FEEA group and the Overlap group in operation time (197.36 ± 31.91 vs. 182.14 ± 23.32 min), anastomosis time (24.23 ± 5.34 vs. 16.32 ± 6.77 min), post-operative hospital stay (10.21 ± 2.31 vs. 8.31 ± 2.41 days), post-operative feeding time (4.93 ± 1.12 vs. 4.51 ± 1.03 days), and post-operative defecation time (4.12 ± 1.31 vs. 3.81 ± 1.03 h) ($p < 0.05$). There was no significant difference between the two groups in intraoperative blood loss, abdominal incision length, and post-operative 24 h pain score ($p > 0.05$), as shown in table 2.

Comparison of post-operative perioperative complications

The results showed that there was one case of incision infection, one case of abdominal infection, one case of abdominal hemorrhage, one case of incisional hernia, one case of anastomotic leakage, two cases of anastomotic bleeding, one case of anastomotic stricture, and five cases of intestinal obstruction in the FEEA group, making 13 cases in total. There was one case of incision infection, one case of abdominal hemorrhage, one case of pulmonary infection, one case of incisional hernia, one case of anastomotic leakage, and one case of intestinal obstruction in the Overlap group, with six cases

Table 1. Comparison of general data between the two groups

Item	FEEA group (n = 90)	Overlap group (n = 90)	χ^2/t value	p-value
Gender (male/female)	52/38	49/41	0.203	0.652
Age (years, $\bar{X} \pm s$)	58.34 $\pm$ 7.51	57.32 $\pm$ 6.35	0.832	0.751
Body mass index (kg/m ² , $\bar{x} \pm s$)	21.19 $\pm$ 2.61	21.73 $\pm$ 3.14	0.713	0.988
ASA grade (n)			0.425	0.808
Grade II	41	43		
Grade III	32	28		
Grade IV	17	19		
Tumor site (n)			0.114	0.736
Right colon	65	67		
Left colon	25	23		
Tumor size (cm, $\bar{X} \pm s$)	5.14 $\pm$ 1.60	4.96 $\pm$ 1.57	0.925	0.138
TNM stage (n)			0.696	0.706
Phase I	11	13		
Phase II	48	51		
Phase III	31	26		
Hypertension history	10	15	1.161	0.281
Diabetes history	7	9	0.274	0.788
Abdominal surgery history	6	8	0.310	0.579

ASA: American Society of Anesthesiologists; FEEA: functional end-to-end anastomosis; TNM: tumor-node-metastasis.

Table 2. Comparison of intraoperative and post-operative recovery between the two groups

Item	FEEA group (n = 90)	Overlap group (n = 90)	t-value	p-value
Operative time (min)	197.36 $\pm$ 31.91	182.14 $\pm$ 23.32	3.431	0.024
Anastomosis time (min)	24.23 $\pm$ 5.34	16.32 $\pm$ 6.77	14.321	< 0.001
Intraoperative blood loss (mL)	52.95 $\pm$ 14.42	54.41 $\pm$ 10.53	0.841	0.753
Abdominal wall incision length (cm)	6.53 $\pm$ 1.31	6.82 $\pm$ 1.23	0.823	0.814
Post-operative hospital stay (day)	10.21 $\pm$ 2.31	8.31 $\pm$ 2.41	3.451	0.022
Post-operative feeding time (day)	4.93 $\pm$ 1.12	4.51 $\pm$ 1.03	3.211	0.017
Post-operative exhaust time (h)	4.12 $\pm$ 1.31	3.81 $\pm$ 1.03	3.321	0.009
Pain score 24 h after surgery	3.92 $\pm$ 1.24	3.89 $\pm$ 1.20	0.987	0.475

FEEA: functional end-to-end anastomosis.

in total. Overall, there was no significant difference in post-operative perioperative complications between the two groups ($\chi^2 = 2.883$, $p = 0.091$), as shown in table 3.

Comparison of post-operative pathological results

The number of dissected normal lymph nodes was comparable between the two groups (31.00 $\pm$ 17.92 vs. 27.04 $\pm$ 14.00, $p > 0.05$). The results showed that there

was no significant difference between the two groups in the number of positive lymph nodes, nerve and vascular invasion, specimen length, tumor differentiation, and tumor growth patterns ($p > 0.05$), as shown in table 4.

Comparison of post-operative follow-up

The results of the post-operative follow-up showed that there were no significant differences between the Overlap and the FEEA groups in QOL scores at 3, 6,

Table 3. Comparison of post-operative perioperative complications between the two groups

Item	FEEA group (n = 90)	Overlap group (n = 90)	χ^2 value	p-value
Post-operative complications (n)	13	6	2.883	0.091
Incision infection	1	1		
Abdominal infection	1	0		
Abdominal bleeding	1	1		
Lung infection	0	1		
Incisional hernia	1	1		
Anastomotic leakage	1	1		
Anastomotic bleeding	2	0		
Anastomotic stricture	1	0		
Ileus	5	1		

FEEA: functional end-to-end anastomosis.

Table 4. Comparison of post-operative pathological results between the two groups

Item	FEEA group (n = 90)	Overlap group (n = 90)	t/ χ^2 -value	p-value
Dissected lymph nodes (number, $x \pm s$)	31.00 $\pm$ 17.92	27.04 $\pm$ 14.00	1.213	0.084
Positive lymph nodes (number, $x \pm s$)	2.13 $\pm$ 1.24	2.34 $\pm$ 1.46	0.931	0.089
Nerve invasion (n)	22	25	0.259	0.611
Vascular invasion (n)	30	40	2.338	0.126
Specimen length (cm, $x \pm s$)	23.98 $\pm$ 3.01	25.22 $\pm$ 3.19	0.932	0.176
Tumor differentiation (n)			0.111	0.946
High	11	10		
Mid	63	65		
Low	16	15		
Tumor growth pattern (n)			0.375	0.829
Ulcerated type	51	55		
Elevated type	32	29		
Infiltrative	7	6		

FEEA: functional end-to-end anastomosis.

9, and 12 months after surgery ($p > 0.05$). The FEEA group had one case of recurrence and two cases of metastasis, while the Overlap group had one case of recurrence and three cases of metastasis, meaning there was no significant difference in recurrence and metastasis between the two groups ($p > 0.05$). There was no recurrence followed by death within 12 months of follow-up in either group, as shown in Table 5.

Discussion

This study retrospectively analyzed the intraoperative and post-operative conditions of patients undergoing laparoscopic CRC anastomosis in the gastrointestinal department of the authors' hospital. It was found that there were significant differences between the FEEA group and the Overlap group in terms of operation, anastomosis post-operative defecation times, and

Table 5. Comparison of post-operative follow-up between the two groups

Item	FEEA group (n = 90)	Overlap group (n = 90)	t-value	p-value
QOL of 3 months after operation (score, $x \pm s$)	48.92 $\pm$ 5.34	48.34 $\pm$ 4.48	0.423	0.545
QOL of 6 months after operation (score, $x \pm s$)	50.37 $\pm$ 5.65	50.83 $\pm$ 5.55	0.531	0.453
QOL of 9 months after operation (score, $x \pm s$)	51.84 $\pm$ 4.87	51.32 $\pm$ 4.64	0.511	0.624
QOL of 12 months after operation (score, $x \pm s$)	52.74 $\pm$ 4.31	52.52 $\pm$ 4.55	0.948	0.122
Recurrence (n)	1	1	-	1.000
Metastases (n)	2	3		
Death (n)	0	0		

FEEA: functional end-to-end anastomosis.

post-operative hospital stay. However, there was no significant difference between the two groups in intra-operative blood loss, abdominal incision length, post-operative 24 h pain scores, QOL score at 3, 6, 9, and 12 months after surgery, the recurrence and metastasis rate, and the recurrence and death rate during the 12 months of follow-up.

The results of this study showed that the operation and anastomosis times of the Overlap anastomosis group were shorter than those of the FEEA group. The main reason for this was that FEEA involved closing and aligning the distal bowel before lifting it and performing the anastomosis, meaning more bowel needed to be freed and more mesentery cut to avoid excessive anastomotic tension. In contrast, the overlap anastomosis only required lifting the distal bowel and overlapping the proximal bowel, and, thus, without the need to free more bowel and mesentery, the operation time was shorter. Post-operative defecation and feeding times and post-operative hospital stays were shorter for the Overlap group than the FEEA group. There was no significant difference between the two groups in the VAS pain score at 24 h after surgery, which may be because there was little difference in the length of the abdominal incision of the two groups.

In this study, intestinal obstruction and pulmonary infection occurred in the Overlap group, and intestinal obstruction occurred in the FEEA group. All the patients who developed intestinal obstruction had an incomplete intestinal obstruction caused by post-operative adhesions, and they recovered after fasting, the inhibition of digestive juice secretion, and intravenous nutritional support. There were some cases of anastomotic leakage, abdominal infection, and anastomotic bleeding in the FEEA group, which may have been caused by an insufficiently free proximal and distal intestinal canal or

an excessive opening in the left colon during the FEEA and poor strengthening sutures. These circumstances would have resulted in high anastomotic tension and greater distal transverse stress, which would have led to anastomotic leakage and abdominal infection. A total laparoscopic FEEA has previously been reported to increase the risk of uncontrollable intestinal fluid spillage, post-operative intestinal leakage, and abdominal infection due to the large opening it requires²².

Although total laparoscopic surgery is increasingly used in CRC surgery, its oncologic effect is unclear. Because intra-abdominal manipulation is difficult, many surgeons feel uncomfortable performing laparoscopic intra-abdominal anastomosis. For patients with CRC, oncologic outcomes may be compromised if the use of intra-abdominal anastomosis results in shorter specimen lengths or fewer lymph node dissections²³. In this study, the principle of radical resection of the tumor, precisely completed CME and D3 lymph node dissection using three-dimensional laparoscopy and the clear identification of subtle structures, was strictly adhered to in both groups of patients, which not only ensured the safety of the surgery but also improved its quality. In addition, the preferred caudomedial approach combined with the intermediate approach can accurately enter the anatomical level for para lymph node dissection and standardized ligation of mesangial root vessels²⁴. In terms of the number of dissected lymph nodes, there was no significant difference in the results between the two groups in this study, and the average number of dissected lymph nodes was > 12 in both groups, meeting the radical cure requirements for CRC in US National Comprehensive Cancer Network guidelines. There was also no significant difference in the number of positive lymph nodes or nerve and vascular invasion. Finally, a patient who underwent another

operation for a bypass in the terminal ileum recovered after a temporary emptying of the bowel during the anastomosis. We followed up the QOL of 180 patients at 1, 3, and 6 months after surgery and found that there were no significant differences between the two groups in QOL.

This study does have some limitations. First, this is a single-center study, and it is difficult to ensure consistent baseline assurance when cohorts are compared, and patients are likely to have other comorbidities that could affect prognosis. Second, this study is retrospective, making it difficult to determine the sequence of influencing factors and the occurrence of outcomes and, in turn, to determine the causal association. Finally, due to the limitation of time and manpower, the sample size is small; meaning the representativeness of the sample may be poor. Further exploration is needed through a large-sample, multicenter prospective study.

Conclusion

Overlap anastomosis can shorten the operation time and accelerate the recovery of post-operative intestinal function without increasing the incidence rate of post-operative complications compared with FEEA, and it will not affect the QoL and survival status of patients after surgery in the short term. Therefore, overlap anastomosis is safe and effective and has certain advantages for colorectal reconstruction, making it worthy of clinical use.

Authors' contributions

Conception and design of the work: Sun WM; Data collection: Sun WM, Zhang J; Supervision: Sun WM; Analysis and interpretation of the data: Sun WM, Zhang J; Statistical analysis: Sun WM; Drafting the manuscript: Sun WM; Critical revision of the manuscript: Sun WM, Zhang J; Approval of the final manuscript: Sun WM, Zhang J.

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the Ethical Committee of Xuyi People's Hospital.

Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Funding

The authors declare that they have not received funding.

Conflicts of interest

They declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the approval of the Ethics Committee for the analysis and publication of clinical data obtained routinely. The informed consent of the patients was not required because it was a retrospective observational study.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript nor for the creation of images, graphics, tables, or their corresponding captions.

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