

Usefulness of a powered circular stapler compared with a manual circular stapler in patients undergoing colorectal cancer surgery: A retrospective cohort study and systematic review

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Abstract. Postoperative complications related to anastomosis, including postoperative anastomotic bleeding and anastomotic leakage, remain a serious issue. The effect of anastomotic devices on suture complications during intestinal anastomosis remains unclear. The present study examined the utility of automated anastomotic devices for reducing anastomotic complication risks. A retrospective cohort study of colorectal cancer surgeries in which an anastomosis device was used at Osaka University Hospital (Suita, Japan) between January 2018 and December 2022 was conducted. Cases of emergency surgery, inflammatory bowel disease and simultaneous surgery for other cancers were excluded. Experienced gastrointestinal surgeons performed manual anastomosis using the ETHICON Circular Stapler CDH or EEA Circular Stapler, and automatic anastomosis using the ECHELON CIRCULAR Powered Stapler, with no observed operator bias. Additionally, a meta-analysis that included other study results was performed. The outcomes included postoperative complications, mainly anastomotic leakage. The study included 414 patients: 183 in the manual circular stapler group and 231 in the powered circular stapler (PCS) group. Although this retrospective study found no statistically significant association between the anastomotic device

used and anastomotic complications, an increased risk ratio was observed in the manual group compared with the automatic group when restricted to elderly patients. Similarly, a meta-analysis found a significantly higher anastomotic complication risk in the manual group compared with the automatic group (random-effects model; odds ratio, 0.376; 95% confidence interval, 0.232-0.610; $P < 0.0001$). The findings of the present study suggested that a PCS is useful for reducing the anastomotic complication risk in patients undergoing colorectal cancer surgery.

Introduction

Colorectal cancer (CRC) is highly prevalent in many countries, and surgery is an important curative treatment. Postoperative complications related to anastomosis, including postoperative anastomotic bleeding and leakage, remain serious, and surgeons are always concerned about them. Anastomotic complications are related to short-term outcomes, including the length of hospital stay and reoperation rate, and to long-term outcomes, such as disease-free survival and overall survival, because they are related to postoperative chemotherapy administration (1,2). The reported anastomotic leakage incidence in left-sided colorectal surgery is approximately 10%, and various risk factors have been identified, including male sex and low rectal anastomosis (3,4). The significance of instrumented anastomosis compared to manual suturing in anastomotic leakage is still under debate (5). However, the use of instrumented anastomosis is globally widespread because of its advantage of being a simplified and stable anastomotic technique, and secure stapler manipulation is becoming increasingly important (6). Manual circular staplers (MCSs) have long been used for anastomosis. Applying considerable force is necessary to run the MCS stably. Stabilizing the anastomosis device and performing an anastomosis without applying stress to the site is difficult for some surgeons, depending on their body shape and arm strength. Automated anastomosis devices have

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Abbreviations: CRC, colorectal cancer; MCS, manual circular stapler; PCS, powered circular stapler

Key words: automated anastomosis device, CRC, anastomosis, risk reduction, systematic review

been commercially available in Japan since 2019. Automatic anastomosis machines significantly reduce the force required by the operator for anastomosis. Therefore, it is expected that surgeons with small hands, including female surgeons, can stably use them. However, analyses of the association between manual/automatic anastomosis devices and postoperative anastomosis-related complications are limited. We aimed to clarify the usefulness of the automatic anastomosis device in sigmoid colon and rectal cancer surgeries, using cases from our institution and a meta-analysis based on a literature review.

Materials and methods

Patients and study design of the retrospective study. This retrospective observational cohort study was approved by the Ethical Review Board of the Osaka University Hospital (No. 15144-7). Written informed consent was obtained from the patients for data publication.

This was a single-center retrospective study. Patients undergoing radical resection and anastomosis for sigmoid colon or rectal cancer using a circular stapler between 2018 and 2022 were enrolled in this cohort study. Cases of emergency surgery, inflammatory bowel disease, and simultaneous surgery for other cancers were excluded, and 415 were included in this study (Table I). The median age was 66 years (age range: 27-98 years). Skilled gastrointestinal surgeons performed the surgeries. Bowel dissection was performed using a stapler, and an air leak test was intraoperatively performed after anastomosis in all cases. No air leak was confirmed in all cases. Preoperative chemotherapy, super-low anterior resection, and high-risk cases were treated by covering the stoma and/or performing transanal drainage at the discretion of the surgeon. Postoperative management followed a uniform flow according to the clinical pathway. The primary endpoint was the anastomotic complication rate. All data were collected from medical records up to 30 days after surgery.

Anastomosis. Manual anastomosis was performed using the ETHICON Circular Stapler CDH or the EEA Circular Stapler, and automatic anastomosis was performed using the ECHELON CIRCULAR Powered Stapler. Gastrointestinal surgeons with at least five years of experience operated the anastomotic devices.

Definition of anastomotic complications. Anastomotic leakage and bleeding were included as anastomotic complications. Postoperative fever, abdominal pain, elevated inflammatory levels, other clinical findings, peri-anastomotic fluid retention and free air observed on computed tomography, and digestive fluid drainage from the drain were considered to indicate anastomotic leakage. Additionally, postoperative hemorrhage with delayed initiation of postoperative feeding was considered an anastomotic hemorrhage.

Statistical analysis of the retrospective study. Statistical analyses were performed using JMP 17.0 statistical software (SAS Institute) and R. Enumeration data were compared using Mann-Whitney's U test, Pearson's Chi-square tests, Fisher's

Table I. Patient characteristics (n=414).

Characteristics	Value
Mean age, years (range)	66.0 (27-98)
Sex, n (male/female)	229/185
BMI, n (<25/≥25 kg/m ²)	329/85
Smoking history, n (yes/no)	79/335
History of DM, n (yes/no)	56/358
Preoperative Alb, n (<3.8/≥3.8 g/dl)	78/336
Tumor lesion, n (Ra, Rb/S, RS)	197/217
Surgical method, n (LAR, sLAR/SR, AR)	189/225
Surgical approach, n (Op/Lp/Rbs)	7/212/195
Mean operation time, min (range)	289 (69-836)
Mean blood loss, ml (range)	61 (0-4900)
CS, n (manual/automatic)	231/183
Transanal drain, n (yes/no)	106/308
Diverting stoma, n (yes/no)	81/333
Anastomosis complication, n (yes/no)	11/403

DM, diabetes mellitus; Alb, albumin; S, sigmoid colon; RS, rectosigmoid colon; Ra, upper rectum; Rb, lower rectum; SR, sigmoidectomy; AR, anterior resection; LAR, low anterior resection; sLAR, super-low anterior resection; Op, open surgery; Lp, laparoscopic surgery; Rbs, robotic surgery; CS, circular stapler.

exact test and propensity score matching. Statistical significance was defined as a P-value <0.05.

Meta-analysis. We performed a meta-analysis, including the present outcomes to evaluate the advantages of the powered circular stapler (PCS) over the manual circular stapler for anastomoses in left-sided colorectal surgery. The included studies assessed anastomotic complications and validated circular staplers following CRC surgery. This review was performed in accordance with the PRISMA Reporting Items for Systematic Reviews and Meta-Analyses guidelines. To collect the trial data, we searched the Cochrane Central Register of Controlled Trials (Central) and PubMed, using the following search terms: 'powered circular' AND 'anastomotic' on October 20, 2023. The following studies were excluded: emergency surgery and non-colorectal surgery. Two independent reviewers at Osaka University assessed the titles and abstracts. We performed the meta-analysis with the Mantel-Haenszel random-effects model, using R software (CRAN, R3-6-2; <https://cran.r-project.org/>). Statistical significance was set at a P-value <0.05. This systematic assessment has not been registered in a public database. The statistical methods used in this study were reviewed by Miyoshi N. Because all included studies were observational, the Risk of Bias Assessment tool for Nonrandomized Studies was used to assess the risk of bias in the included studies. Funnel plots assessed publication bias.

Results

Retrospective study. Table II presents the background characteristics of the 414 patients in the two groups, 183 and 231

Table II. Characteristics of patients in the two groups.

Characteristics	Circular stapler (n=414)		P-value
	Manual (n=231)	Automatic (n=183)	
Mean age, years (range)	64.6 (27.0-93.0)	67.9 (35.0-98.0)	0.001 ^a
Sex, n (male/female)	129/102	100/83	0.807 ^b
BMI, n (<25/≥25 kg/m ²)	175/56	154/29	0.035 ^b
Smoking history, n (yes/no)	54/177	25/158	0.012 ^b
History of DM, n (yes/no)	29/202	27/156	0.515 ^b
Preoperative Alb, n (<3.8/≥3.8 g/dl)	43/188	35/148	0.895 ^b
Tumor lesion, n (Ra, Rb/S, RS)	116/115	81/102	0.228 ^b
Surgical method, n (LAR, sLAR/SR, AR)	105/126	84/99	0.927 ^b
Surgical approach, n (Op/Lp/Rbs)	5/135/91	2/77/104	0.001 ^c
Mean operation time, min (range)	293.6 (69.0-836.0)	284.3 (86.0-793.0)	0.527 ^a
Mean blood loss, ml (range)	55.6 (0.0-3400.0)	68.5 (0.0-4900.0)	0.692 ^a
Transanal drain, n (yes/no)	67/164	39/144	0.074 ^b
Diverting stoma, n (yes/no)	38/193	43/140	0.072 ^b
Anastomosis complication, n (yes/no)	8/223	3/180	0.359 ^c

Univariate analysis was performed used ^aMann-Whitney's U test, ^bchi-square test or ^cFisher's exact test. DM, diabetes mellitus; Alb, albumin; S, sigmoid colon; RS, rectosigmoid colon; Ra, upper rectum; Rb, lower rectum; SR, sigmoidectomy; AR, anterior resection; LAR, low anterior resection; sLAR, super-low anterior resection; Op, open surgery; Lp, laparoscopic surgery; Rbs, robotic surgery.

Table III. Results of univariate analysis of clinical factors for anastomotic complications.

Characteristics	Anastomotic complication		Univariate analysis		P-value
	Yes, n	No, n	OR	95% CI	
Age (<70/≥70 years)	8/3	214/189	2.355	0.615-0.999	0.234
Sex (male/female)	7/4	222/181	1.426	0.411-4.950	0.761
BMI (<25/≥25 kg/m ²)	9/2	320/83	1.167	0.247-5.505	1.000
Smoking history (yes/no)	2/9	77/326	0.940	0.199-4.442	1.000
History of DM (yes/no)	1/10	55/348	0.632	0.079-5.040	1.000
Preoperative Alb level (<3.8/≥3.8 g/dl)	3/8	75/328	1.640	0.424-6.328	0.441
Tumor lesion (Ra, Rb/S, RS)	9/2	188/215	5.146	1.098-24.116	0.027
Surgical method (LAR, sLAR/SR, AR)	9/2	180/223	5.575	1.189-26.127	0.029
CS (manual /automatic)	8/3	223/180	2.152	0.562-8.231	0.359
Surgical approach (Op/Lp, Rbs)	1/10	6/397	6.616	0.727-60.198	0.173
Operation time (>274/≤274 min)	9/2	160/243	6.834	1.457-32.042	0.009
Blood loss (>15/≤15 ml)	9/2	204/199	4.389	0.936-20.569	0.038
Transanal drain (yes/no)	5/6	101/302	2.491	0.744-8.339	0.158
Diverting stoma (yes/no)	3/8	78/325	1.562	0.405-6.025	0.456

Univariate analysis was performed used Fisher's exact test. DM, diabetes mellitus; Alb, albumin; S, sigmoid colon; RS, rectosigmoid colon; Ra, upper rectum; Rb, lower rectum; SR, sigmoidectomy; AR, anterior resection; LAR, low anterior resection; sLAR, super-low anterior resection; CS, circular stapler; Op, open surgery; Lp, laparoscopic surgery; Rbs, robotic surgery; OR, odds ratio.

in the MCS and PCS groups. On the basis of ROC curves, the age and albumin level cutoff values were 70 years and 3.8 g/dl. There were 11 anastomotic complication cases, including postoperative anastomotic leakage and bleeding: eight (3.5%) and three (1.6%) in the MCS and PCS groups. There was only one reoperation case which occurred in the

PCS group. The PCS group was older than the MCS group, had a body mass index ≥25 kg/m², and smokers were more common in the MCS group. The risk analysis of each factor for anastomotic complications was performed. Univariate analysis revealed significant surgical site and methodological differences (Table III).

Table IV. Results of univariate analysis of clinical factors for anastomotic complications among patients older than 55 years.

Characteristics	Anastomotic complication		Univariate analysis		P-value
	Yes, n	No, n	OR	95% CI	
Sex (male/female)	6/1	181/139	4.607	0.548-38.715	0.245
BMI (<25/≥25 kg/m ²)	7/0	254/66			0.352
Smoking history (yes/no)	2/5	62/258	1.666	0.315-8.781	0.626
History of DM (yes/no)	1/6	53/267	0.839	0.099-7.117	1.000
Preoperative Alb level (<3.8/≥3.8 g/dl)	3/4	64/256	3.000	0.654-13.741	0.154
Tumor lesion (Ra, Rb/S, RS)	5/2	145/175	3.017	0.576-15.780	0.253
Surgical method (LAR, sLAR/SR, AR)	5/2	138/182	3.297	0.630-17.248	0.246
CS (manual/automatic)	6/1	172/148	5.162	0.614-43.373	0.131
Surgical approach (Op/Lp, Rbs)	1/6	5/315	10.500	1.059-104.096	0.122
Operation time (>274/≤274 min)	5/2	125/195	3.900	0.745-20.411	0.119
Blood loss (>15/≤15 ml)	6/1	162/158	5.851	0.696-49.159	0.122
Transanal drain (yes/no)	2/5	75/245	1.306	0.248-6.872	0.669
Diverting stoma (yes/no)	3/4	62/258	3.120	0.680-14.304	0.148

Univariate analysis was performed using Fisher's exact test. DM, diabetes mellitus; Alb, albumin; S, sigmoid colon; RS, rectosigmoid colon; Ra, upper rectum; Rb, lower rectum; SR, sigmoidectomy; AR, anterior resection; LAR, low anterior resection; sLAR, super-low anterior resection; CS, circular stapler; Op, open surgery; Lp, laparoscopic surgery; Rbs, robotic surgery; OR, odds ratio.

Subsequently, we limited the analysis to patients older than 55 years of age and found an increased risk of anastomotic complications with MCS compared with PCS. However, this difference was not statistically significant in patients older than 55 years of age (Table IV). In the population older than 65 years of age, there were 0 and 4 anastomotic complications in the PCS and MCS groups, respectively. This finding indicates an increased risk of anastomotic complications with manual anastomotic devices in this cohort (Table V).

To balance the baseline characteristics between the MCS and PCS groups, we implemented 1:3 propensity score matching. After this matching, 285 patients were ultimately included in this study (Table SI). Although the risk associated with age did not increase as significantly as in the pre-matching analysis, the risk of anastomotic complications remained higher in the PCS group (Tables SII-SIV). The systematic review did not reveal a clear significance; recognizing the limitation posed by the small sample size, we subsequently conducted a meta-analysis.

Meta-analysis. The search strategy retrieved 29 articles. Four articles were excluded on the basis of the article type. Of the remaining articles, 11 focused on vascular or upper gastrointestinal surgery, one was a duplication, and the other was a single-arm trial. Five articles and the present study were ultimately included in the meta-analysis (Fig. 1). Table VI summarizes the clinical characteristics of the five included studies (7-11), and Table SV summarizes the risk of bias for all the studies. The number of events reported by Nanishi *et al* (9) and Vignali *et al* (11) included anastomotic bleeding. Fig. 2 presents the funnel plot. Three studies demonstrated significant differences in the anastomotic complications between the powered and manual circular staplers. All articles were respective cohort studies, comprising 2793 patients: 763

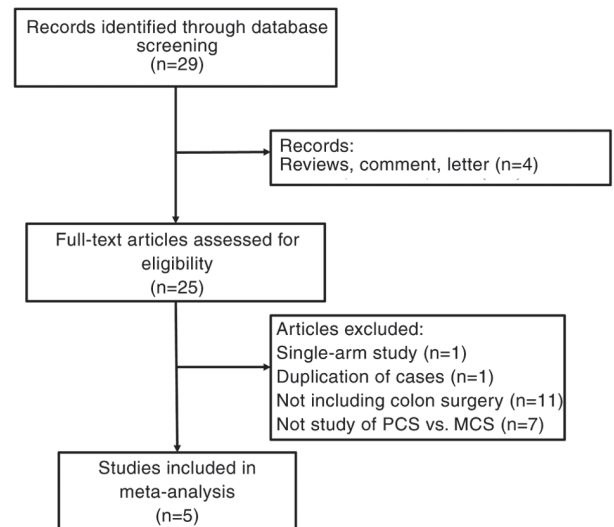


Figure 1. Study flow diagram. MCS, manual circular stapler; PCS, powered circular stapler.

and 2030 using PCS and MCS, respectively. Anastomotic leakage was observed in 27 and 156 patients in the PCS and MCS groups, retrospectively. One study focused on robot-assisted low anterior resection, whereas another focused exclusively on rectal surgery. Three studies focused on left-sided colorectal surgery, one of which focused on cancer surgery. The meta-analysis results are presented as a forest plot (Fig. 3). No heterogeneity was observed in these data. In the meta-analysis, the common-effect and random-effects models demonstrated similar results between PCS and MCS, with both methods demonstrating significant differences (common-effects model: odds ratio [OR]=0.346, 95% confidence interval [95% CI]: 0.219-0.547 P<0.0001;

Table V. Results of univariate analysis of clinical factors for anastomotic complications among patients older than 65 years.

Characteristics	Anastomotic complication		Univariate analysis		P-value
	Yes, n	No, n	OR	95% CI	
Sex (male/female)	3/1	135/110	2.444	0.250-23.830	0.630
BMI (<25/≥25 kg/m ²)	4/0	194/51			0.584
Smoking history (yes/no)	1/3	49/196	1.333	0.135-13.097	1.000
History of DM (yes/no)	1/3	45/200	1.481	0.150-14.573	0.560
Preoperative Alb level (<3.8/≥3.8 g/dl)	2/2	55/190	3.454	0.475-25.090	3.454
Tumor lesion (Ra, Rb/S, RS)	2/2	109/136	1.247	0.172-9.000	1.000
Surgical method (LAR, sLAR/SR, AR)	2/2	104/141	1.355	0.187-9.782	1.000
CS (manual/automatic)	4/0	122/123			0.122
Surgical approach (Op/Lp, Rbs)	1/3	3/242	26.888	1.153-302.993	0.063
Operation time (>274/≤274/min)	2/2	94/151	1.606	0.222-11.597	0.640
Blood loss (>15/≤15 ml)	3/1	119/126	3.176	0.325-30.962	0.362
Transanal drain (yes/no)	2/2	64/181	2.828	0.390-20.495	0.286
Diverting stoma (no/yes)	3/1	201/44	1.522	0.154-14.985	0.551

Univariate analysis was performed using Fisher's exact test. DM, diabetes mellitus; Alb, albumin; S, sigmoid colon; RS, rectosigmoid colon; Ra, upper rectum; Rb, lower rectum; SR, sigmoidectomy; AR, anterior resection; LAR, low anterior resection; sLAR, super-low anterior resection; CS, circular stapler; Op, open surgery; Lp, laparoscopic surgery; Rbs, robotic surgery; OR, odds ratio.

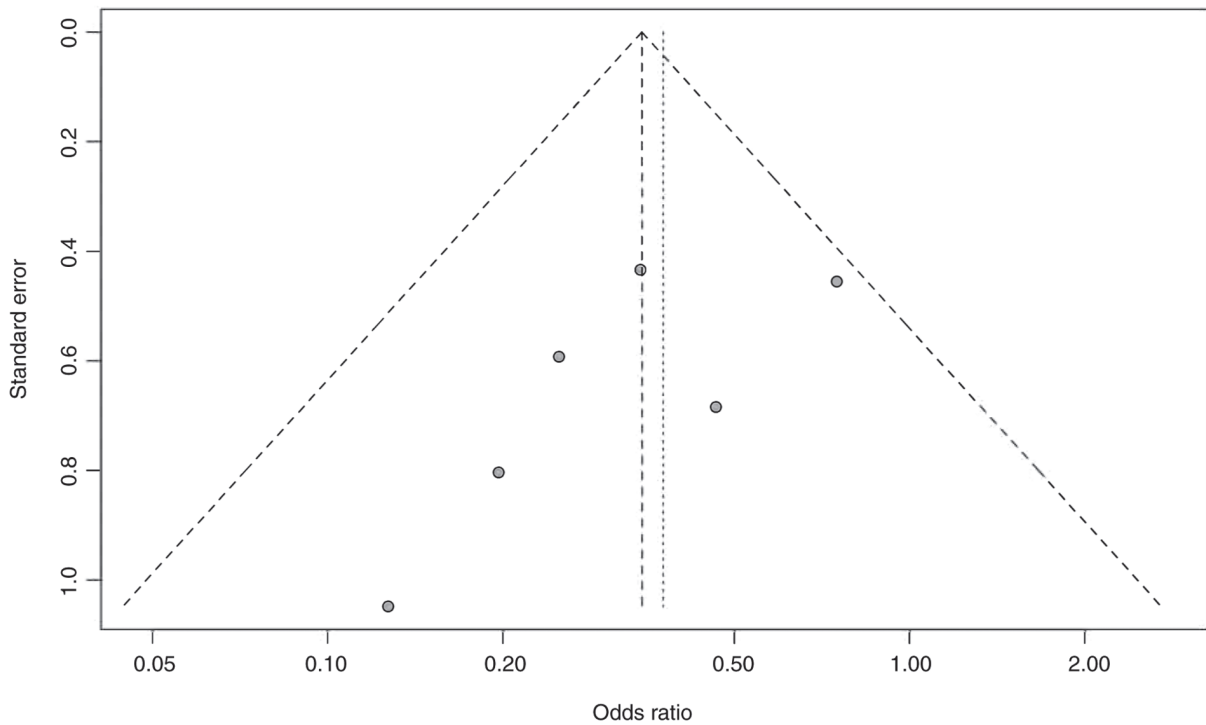


Figure 2. Funnel plot of publication bias.

random-effects model: OR=0.376, 95% CI: 0.232-0.610 P<0.0001).

Discussion

In this cohort study conducted at our institution, patients in the PCS group were significantly older than those in the

MCS group. Automatic anastomosis machines have become popular only in recent years, possibly reflecting the older patients associated with the aging society of Japan. Attention has recently been focused on safe surgery in elderly patients at high surgical risk; however, age was not an independent risk factor in this cohort study. Conversely, the analysis limited to elderly patients demonstrated no significant difference;

Table VI. Characteristics of the included studies.

First author/s, year	Study design	Setting (center)/ country	Study period	No. of patients		Anastomosis type	Included benign tumor	Diverting stoma present/ absent, n		AL rate, %				
				MCS	PCS			MCS	PCS	MCS	PCS	PCS	(Refs.)	
Shibutani <i>et al</i> , 2023	Retrospective cohort study	Single/Japan	2016-2022	63	63	Left-sided colorectal cancer with DST	No	5/58	7/56	NR	NR	14.30	3.20	(7)
Sylla <i>et al</i> , 2022	Retrospective cohort study	Multi/USA	2016-2020 (single arm and historical cohort)	1,348	165	anastomosis Left-sided colorectal resection with anastomoses	Yes	NR	NR	NR	28±14 days after discharge	6.90	1.80	(8)
Nanishi <i>et al</i> , 2023	Retrospective cohort study	Single/Japan	2019-2022	124	147	Ro-LAR for primary rectal cancer	No	4/120	2/145	30 days	30 days	8.90	6.80	(9)
Pla-Martí <i>et al</i> , 2021	Retrospective cohort study	Single/Spain	2017-2020	119	60	Left-sided circular stapled colorectal	Yes	0/119	0/60	30 days	30 days	11.80	1.70	(10)
Vignali <i>et al</i> , 2023	Retrospective cohort study	Single/Italy	2017-2022	145	145	anastomosis 5 cm above the anal verge Laparoscopic colon resection and anastomosis to the rectum; age >18 years	Yes	33/112	37/108	30 days	30 days	14.50	5.50	(11)

MCS, manual circular stapler; PCS, powered circular stapler; DST, double stapling technique; Ro-LAR, robotic low anterior resection; NR, no record; AL, anastomotic leakage.

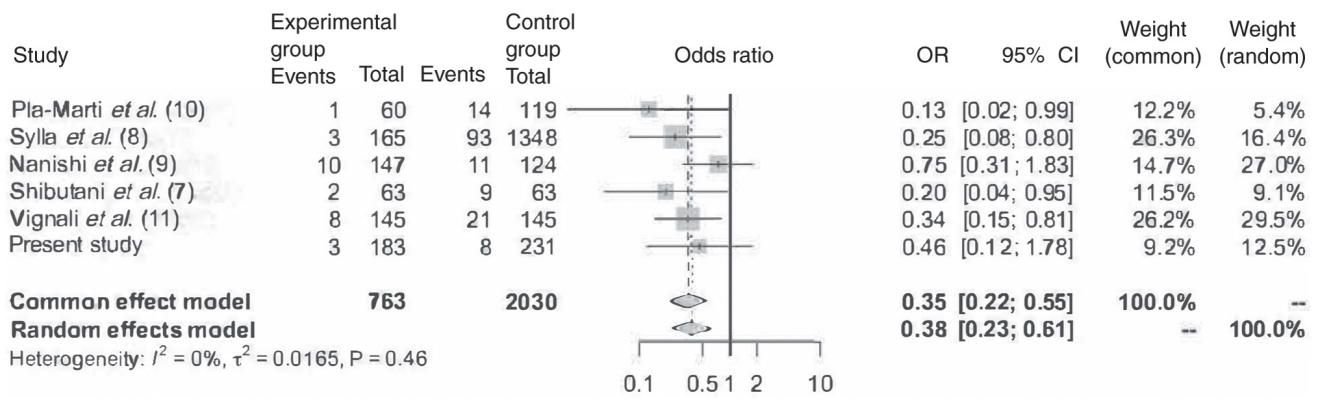


Figure 3. Forest plot of the six studies. OR, odds ratio.

however, the risk ratio increased in the MCS group compared with the PCS group, suggesting that anastomotic device developments positively affected older patients. Older patients have more vulnerable tissues and less tissue regenerative capacity compared to younger patients, and the difference in stress on the anastomotic tissues was considered to have a major influence. Although the association between postoperative transanal drain placement, anastomotic leakage prevention, and increased anastomotic bleeding has been discussed, no association was found in the present cohort study (6,12). As is accepted, the complication risk increased as the anastomosis was lowered, and an increased risk was observed in patients with a covering stoma. However, this observation was made because the stoma was originally placed in patients with a high anastomotic leakage risk, including those with a low anastomosis.

Circular staplers and double-stapled techniques have been common anastomosis methods used for over 40 years (13). Circular staplers have improved over the years, with the automatic version becoming available in 2019 and introduced to our hospital in 2020 for colorectal surgery. The anastomosis has been modified regarding staple alignment and tissue compressibility, and automation is considered an alteration that can reduce inter-operator differences. Conventional manual anastomosis requires approximately 30 kg of force to fire, but the average grip force of women in Japan is approximately 30 kg, proving that it is not easy to fire (14-16). Inadequate manipulation causes complications by anastomotic tip instability, intestinal mucosa damage, and anastomotic site stress.

The meta-analysis revealed a significant difference between PCS and MCS. Furthermore, this analysis concluded that automatic anastomosis devices may be more useful than manual devices in reducing anastomotic complications.

This meta-analysis has several limitations. First, patients and their backgrounds differed slightly between studies. Notably, one study excluded all cases with diverting stomas, and another excluded cases in which a stoma was planned before surgery, possibly influencing the results. Second, publication bias could not be ruled out because of the few included studies. Third, all included studies were retrospective cohorts and may have had reporting bias.

In conclusion, a PCS may be useful for reducing the risk of anastomotic complications in patients undergoing CRC surgery.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

RM, NM, YD and HE designed the study. RM, NM, RH, SK, SM, MTa, YS, TH, AH, TO, MTe, YK and MU performed the research and were responsible for collecting and analyzing clinical data. RM and NM confirm the authenticity of all the raw data. RM and NM analyzed the data. RM and NM wrote the manuscript. All authors commented on previous versions of the manuscript. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

The present retrospective, observational cohort study was approved by the Ethical Review Board of the Osaka University Hospital (approval no. 15144-7; Suita, Japan). Written informed consent was obtained from the patients for participation.

Patient consent for publication

Written informed consent was obtained from the patients for data publication.

Competing interests

The authors declare that they have no competing interests.

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