

Impact of Circular Stapler Size on the Risk of Anastomotic Complications in Patients With Left-sided Colorectal Cancer: A Propensity Score-matched Study

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Abstract. *Background/Aim:* The present study examined the impact of circular stapler size on anastomotic complications, including leakage and stricture in patients undergoing double-stapling technique (DST) anastomosis for left-sided colon or rectal cancer. *Patients and Methods:* A total of 403 patients were enrolled in this study, with circular stapler sizes of 25, 28, and 29 mm. *Results:* A small circular stapler (25 mm) was used in 170 cases (42.2%), and a medium-sized circular stapler (28/29 mm) was used in 233 cases (57.8%). After propensity score matching, there was no marked difference in the incidence of anastomotic leakage/stricture between the groups (13.9% vs. 10.9%, 3.0% vs. 1.0%, respectively). *Conclusion:* The size of the circular stapler was not associated with the incidence of anastomotic leakage or stricture in this cohort.

Double-stapling technique (DST) anastomosis with a circular stapler is a common reconstruction method in left-sided colorectal cancer surgery (1). Although DST anastomosis has enabled safe, quick and reproducible reconstruction, anastomotic leakage remains an unresolved problem (1).

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Anastomotic leakage is associated with poor short-term outcomes, such as the need for emergency surgery, an increased mortality rate and extended hospital stays (2), as well as poor longer-term outcomes, such as increased rates of local recurrence (3, 4). Therefore, improvements in procedures and devices, such as adequate mobilization of the left side colon (5), the evaluation of intestinal perfusion by indocyanine green (6), the placement of a transanal drain to reduce intraluminal pressure (7, 8), the application of intracorporeal reinforcement sutures (9), development of a circular side stapling technique (10), and the improvement of circular staplers (11), have been made to prevent anastomotic leakage. However, anastomotic leakage has not yet been completely resolved.

A previous study on risk factors for anastomotic leakage reported that a circular stapler with a diameter of ≥ 31 mm may cause blood flow obstruction due to overstretching, leading to increased risk of anastomotic leakage (12). Based on such findings, in recent years, a circular stapler of ≤ 29 mm has been used in most cases in Japan. However, whether or not the use of a smaller-diameter circular stapler, specifically a 25-mm circular stapler, can reduce the rate of anastomotic leakage is unclear, as is the impact of small circular staplers on anastomotic stricture.

The present study therefore examined the impact of circular stapler size on anastomotic leakage and anastomotic stricture.

Patients and Methods

A total of 403 patients who underwent DST anastomosis during surgical resection for left-sided colon or rectal cancer at Osaka City University Hospital between January 2016 and October 2022 were enrolled in this study. The following four circular staplers were used for DST anastomosis: 25- and 29-mm ENDOPATH® ENDOSCOPIC INTRALUMINAL STAPLER (Ethicon, Somerville, NJ, USA); 25- and 29-mm ECHELON CIRCULAR™ Powered Stapler (Ethicon); 25- and 28-mm EEA™ Circular Stapler with DST Series™ Technology (Medtronic plc, Dublin, Ireland) and 28-mm

EEA™ Circular Stapler with Tri-Staple™ Technology (Medtronic plc). The circular stapler size was determined by the operator based on the diameter of the proximal colon.

Perioperative management, such as placement of transanal drains and the timing of meal initiation after operation, was standardized in all cases. For patients with intestinal obstruction, decompression was performed first by various means, such as a metallic stent, transanal tube or colostomy, and then the primary lesion was resected. Diverting ileostomy was created in cases of super-low anterior resection, neoadjuvant chemoradiotherapy or a positive leakage test despite additional suture reinforcement. Surveillance of the anastomosis was performed between three months and one year after surgery.

Definition of anastomotic leakage. Anastomotic leakage was defined as extravasation observed on radiologic examinations. In cases with clinical symptoms that suggested anastomotic leakage, such as abdominal pain, a high fever, pus or fecal discharge from the pelvic drain or leukocytosis, computed tomography (CT) was performed to confirm the presence of anastomotic leakage. The following CT findings were considered suggestive of anastomotic leakage: abscess, fluid collection or air bubbles surrounding the anastomotic site. Water-soluble contrast enema was also performed as needed to confirm the presence of communication between the intra- and extraluminal compartments.

Definition of anastomotic stricture. Anastomotic stricture was defined as narrowing of the anastomosis beyond which a normal size endoscope could not pass. The colonoscopes CF-Q260AI, PCF-Q260AI, CF-HQ290ZI and PCF-H290ZI (Olympus Medical Systems, Tokyo, Japan) used to observe the anastomosis had outer diameters of 12.2, 11.3, 13.2, and 11.7 mm, respectively.

Ethics statement. This study was strictly conducted according to the provisions of Declaration of Helsinki. Use of the clinical data was approved by the Ethics Committee of Osaka City University (approval number: 4182) and written informed consent was obtained from all patients.

Statistical analyses. All of the statistical analyses were conducted using IBM SPSS Statistics for Windows (version 26; IBM Corp., Armonk, NY, USA). The significance of differences between the circular stapler size and the clinicopathological factors/surgical factors/postoperative anastomotic complications were analyzed using a chi-squared test and Fisher's exact test. A p -value of <0.05 was considered statistically significant. To reduce the impact of selection bias and potential confounding in an observational study, we performed propensity score matching. The propensity scores were estimated using multivariate logistic regression models, with the groups as the dependent variable and the clinicopathological and operative factors as covariates. Matching was performed with a 1:1 greedy nearest neighbor algorithm with a caliper of 0.2 without replacement.

Results

Patient backgrounds and surgical factors. The patient backgrounds and surgical factors of all cases, as well as those of the cohort after matching are shown in Table I. A small circular stapler (25 mm) was used in 170 cases (42.2%), and a medium-sized circular stapler (28/29 mm) was used in 233 cases (57.8%).

Differences in background and surgical factors between the two groups before propensity score matching were observed for the sex, ileostomy, tumor location, number of stapler cartridges for rectal transection and use of a powered circular stapler. Propensity score matching was performed using these factors as covariates. After calculating the propensity scores, 101 pairs were matched. After propensity score matching, there were no marked differences between the two groups regarding patient background characteristics and surgical factors.

Surgical outcomes. The comparison of surgical treatment outcomes after propensity score matching is shown in Table II. Anastomotic leakage occurred in 14 cases (13.9%) with the small circular stapler and 11 cases (10.9%) with the medium-sized circular stapler, showing no marked difference in the incidence of anastomotic leakage between the groups. There was one case in each group that required reoperation. Anastomotic stricture occurred in three cases (3.0%) with the small circular stapler and one case (1.0%) with the medium-sized circular stapler, showing no marked difference in the incidence of anastomotic stricture between the groups. No patient required operation for anastomotic stricture. All cases were treated with endoscopic balloon dilatation.

Risk factors for anastomotic stricture. The only factor associated with anastomotic stricture was the presence of diverting ileostomy (Table III). No correlation was observed between the circular stapler size and anastomotic stricture.

Discussion

The present study found no marked difference in the incidence of anastomotic leakage between 25-mm and 28/29-mm circular staplers. This is consistent with the report published by Nagaoka *et al.* (13). There may have been cases where the intestinal tract was overstretched by using a 31/33-mm circular stapler, resulting in an inadequate blood supply. However, since a 28/29-mm circular stapler is the optimal size for Asians, overstretching of the intestinal tract is rare. This may explain why a 25-mm circular stapler did not contribute to a reduction in the anastomotic leakage rate.

In addition, no correlation was observed between the circular stapler size and anastomotic stricture. This is also consistent with the report by Nagaoka *et al.* (13). It has been thought that anastomotic stricture is less likely to occur when using a large circular stapler because the diameter of the anastomosis consequently increases. However, this was not the case in our study. Similar to previous reports, construction of the diverting ileostomy was revealed to correlate with anastomotic stricture in the present study (13). This may be because the lack of fecal passage reduces rectal peristalsis and induces muscle atrophy, leading to anastomotic stricture. Although no correlation was found in this study, anastomotic

Table I. Patient background characteristics and surgical factors before and after propensity score matching.

Factors (n=170)	Entire cohort			Matched cohort		
	Small group (n=233)	Medium group	p-Value	Small group (n=101)	Medium group (n=101)	p-Value
Age (years)						
Median (range)	70 (37-91)	70 (31-92)	0.503	69 (37-89)	68 (31-92)	0.188
Sex, n						
Male	77	81		38	40	
Female	93	152	0.039	63	61	0.885
Tumor location, n						
Above the peritoneal reflection	99	169		59	62	
Below the peritoneal reflection	71	64	0.003	42	39	0.774
Tumor diameter (cm), n						
<5	122	157		69	70	
≥5	48	76	0.383	32	31	>0.999
Neoadjuvant chemoradiotherapy, n						
Absent	165	224		97	99	
Present	5	9	0.785	4	2	0.683
Number of stapler cartridges for rectal transection, n						
1, 2	161	229		98	97	
3	9	4	0.083	3	4	>0.999
Type of circular stapler						
Manual	91	215		83	83	
Powered	79	18	<0.001	18	18	>0.999
Diverting ileostomy, n						
Absent	142	209		86	89	
Present	28	24	0.073	15	12	0.680

Table II. Correlations between the circular stapler size and postoperative anastomotic complications.

Anastomotic complications	Small group (n=101)	Medium group (n=101)	p-Value
Anastomotic leakage, n			
Absent	87	90	
Present	14	11	0.670
Anastomotic bleeding, n			
Absent	101	100	
Present	0	1	>0.999
Anastomotic stricture, n			
Absent	98	100	
Present	3	1	0.621

leakage has also been reported as a risk factor for anastomotic stricture (13, 14), as the intense inflammation caused by anastomotic leakage enhances scarring (14).

Based on the above, it seems unlikely that the use of a 25-mm circular stapler will directly lead to a reduction in the anastomotic leakage rate. However, a small circular stapler is recommended in cases with a narrow proximal colon or anus, low anastomosis with the risk of involving the vagina/levator ani muscle or a long residual rectum that makes insertion of a

circular stapler difficult. Although it is not necessary to use a small circular stapler in all cases, a small one should be used under the aforementioned conditions, as it does not increase risk of anastomotic stricture.

Study limitations. First, this was a retrospective study with a small cohort performed in a single center. Propensity score matching was used to minimize the bias, but not all confounding influences were excluded. Second, the results

Table III. Correlations between anastomotic stricture and clinico-pathological/surgical factors.

Factors	Anastomotic stricture		p-Value
	Absent (n=198)	Present (n=4)	
Sex, n			
Male	77	1	>0.999
Female	121	3	
Tumor location, n			
Above the peritoneal reflection	120	1	0.304
Below the peritoneal reflection	78	3	
Tumor diameter (cm), n			
<5	137	2	0.590
≥5	61	2	
Neoadjuvant chemoradiotherapy, n			
Absent	192	4	>0.999
Present	6	0	
Number of stapler cartridges for rectal transection, n			
1, 2	192	3	0.133
3	6	1	
Diverting ileostomy, n			
Absent	173	2	0.087
Present	25	2	
Circular stapler size, n			
25-mm	98	3	0.621
28/29-mm	100	1	
Anastomotic leakage, n			
Absent	174	3	0.413
Present	24	1	
Anastomotic bleeding, n			
Absent	197	4	>0.999
Present	1	0	

of this study are based on an analysis of Asians, who are relatively petite individuals. Therefore, it is necessary to verify whether this result applies to Westerners, who are relatively strapping individuals.

Conclusion

On comparing 25-mm and 28/29-mm circular staplers, we found that the size of the circular stapler was not associated with the incidence of anastomotic leakage or stricture. The size of the circular stapler should be selected appropriately based on the size of the oral intestinal tract and anus and the location of the anastomosis. When in doubt about which size to use, it was considered safer to choose a 25-mm circular stapler.

Conflicts of Interest

The Authors declare no conflicts of interest in association with the present study.

Authors' Contributions

MS designed the study, performed the statistical analysis and drafted the article. TF, YI, HK, YS and KM designed the study and critically reviewed the article. All Authors read and approved the final article.

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