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ORIGINAL SCIENTIFIC REPORT

Short-Term Outcomes of Tri-Staple Versus Universal Staple in Laparoscopic Anterior Resection of Rectal and Distal Sigmoid Colonic Cancer: A Matched-Pair Analysis

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Abstract

Background Anastomotic leakage is a serious complication in laparoscopic colorectal surgeries. To resolve this problem, a new stapling technology (Tri-staple) is developed. In this study, we aim to compare the short-term outcomes of Tri-staple versus Universal staple in laparoscopic anterior resection of rectal and distal sigmoid colonic cancer.

Methods A total of 446 patients were admitted to our hospital and received laparoscopic anterior resection for rectal and distal sigmoid colonic cancer between January 2016 and December 2020. Among them, Tri-staples were used in 202 patients, and the Universal staples were used in 244 patients. Propensity score matching was performed, followed by a comparison between the two groups (Tri-staple vs. Universal staple) in the incidences of anastomotic leakage, bleeding, and reoperation.

Results In total, 270 patients were included in this retrospective cohort study by the propensity score matching, with each group having 135 patients. Tri-staple group had a significant lower incidence of anastomotic leakage compared with the Universal staple group (4.44% vs. 11.11%, $P < 0.05$). The reoperation rate was also lower in Tri-staple group than the Universal staple group (3.70% vs. 8.15%, $P < 0.05$). The anastomotic bleeding rates, average postoperative hospital stay, average drain indwelling period, and average fasting period had no statistical differences between the two groups.

Conclusion The usage of Tri-staple in laparoscopic anterior resection of rectal and distal sigmoid colonic cancer is associated with lower postoperative complications compared with Universal staple. Future high-quality randomized controlled trials are needed to confirm our findings.

Introduction

Laparoscopic anterior resection is a common procedure used for the treatment of rectal and distal sigmoid colonic cancer. However, this procedure is associated with post-operative complications, typically anastomotic leakage—a complication that may lead to severe and life-threatening conditions, require reoperation, and prolong hospital stay [1, 2]. Hültl [3] first introduced surgical staple in 1908. Since then, staples had been used for creating anastomoses. In the era of minimally invasive surgery, surgical staples become particularly relevant. Although recent years have

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witnessed a wide range of research on stapling technology, the optimal anastomotic devices and techniques remain controversial [4–7]. Since 2010, our center has been using the Universal staple (Endo GIA Universal straight reload, blue, Covidien, Mansfield, MA) for bowel closure and dissection in laparoscopic rectal and distal sigmoid colonic cancer surgery, and until 2015, the Tri-staple (Endo GIA articulating reload with Tri-staple technology, purple, Covidien, Mansfield, MA) was officially used in our clinical practice. The Tri-staple is a novel endoscopic linear staple characterized by its stepped cartridge faces and varied height staples [8] (Fig. 1a). This technology is designed to improve staple security across a broad range of tissues while preserving the blood supply of the stump [9–12]. These outstanding features might help the surgeons to reduce incidences of postoperative complications such as anastomotic leakage and improve the short-term outcomes. In this study, we aim to retrospectively compared the short-term outcomes of Tri-staple vs. Universal staple (Fig. 1b) in laparoscopic anterior resection of rectal and distal sigmoid colonic cancer.

Materials and methods

Patient selection

A total of 690 patients were admitted to Shanghai Changzheng hospital and received radical resection for rectal and distal sigmoid colonic cancer between January 2016 and December 2020. Exclusion criteria: A patient should be rendered ineligible for the study if he/she suffered from any anorectal diseases or malignant tumors related to other factors than laparoscopic anterior resection, or the patient experienced symptoms of severe organ failure, or received any treatment that might bring bias to results of the study [13]. Among the 690 patients, 114 patients received laparoscopic anterior resection without using the aforementioned two kinds of staples; 45 underwent Hartmann's procedure; 50 underwent Miles' procedure; 35 patients underwent complete or partial intersphincteric resection (ISR) procedure. The remaining 446 patients received laparoscopic anterior resection of rectal and distal sigmoid colonic cancer using either Tri-staple (purple staple, $n = 244$) or Universal staple (blue staple, $n = 202$). In light of the diagnostic criteria of rectal or distal sigmoid colonic cancer set out by the National Comprehensive Cancer Network (NCCN), all research subjects showed signs and symptoms of rectal or distal sigmoid colonic cancer, and definite diagnoses were established on the basis of preoperative colonoscopic biopsy and histology [14]. We excluded cases involving (1) other serious systemic disorders; (2) prophylactic terminal ileostomy; (3) Hartmann surgery; (4) emergency cases. In the propensity score matching, the following factors were taken into consideration: age, sex, blood serum biochemical indicators, coexisting diseases, pathological stage, number of staples for closure, number of lymph node dissection, TNM stage, distance from anal verge, neoadjuvant radiochemotherapy, and dwelling anal tubing. Intergroup comparisons were conducted before and after propensity score matching. The study was approved by the institutional review board and was reported following the STROBE guideline (Supplement Table 1).

Surgical technique

Four well-trained surgeons (surgical experience $\geq$ 10 y) performed the surgery. All procedures were carried out according to the guidelines for radical resection of colorectal cancer developed by the European Society for Medical Oncology (ESMO). In brief, a five-port

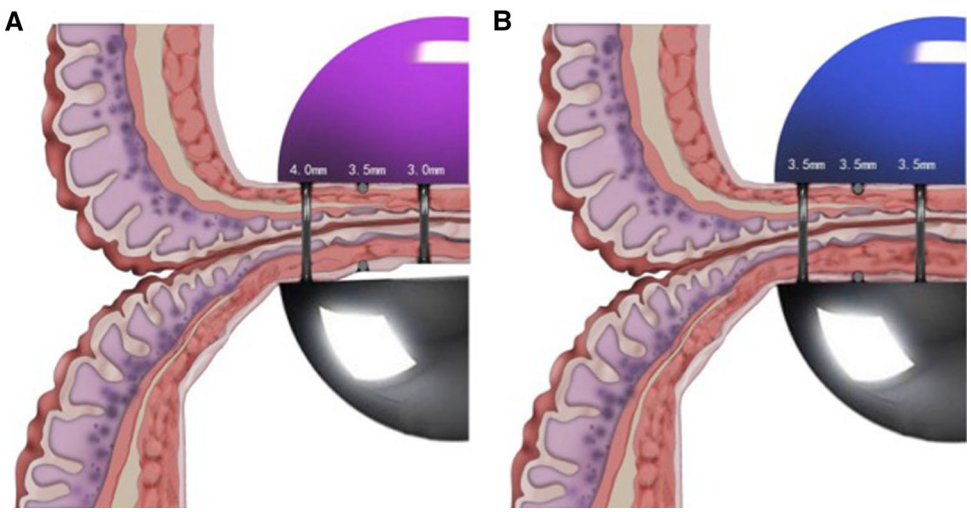

Fig. 1 Schematic diagram of tissue compression profiles of the two stapling devices. **a** Tri-staple reloads with graduated-height staples. **b** Universal reloads with single-height staples

laparoscopic approach was performed [15]. Carbon dioxide pressure for pneumoperitoneum was maintained around 12 mmHg during the procedure. The sigmoid colon was mobilized using a medial approach. The roots of the inferior mesenteric vessels were ligated and cut. The left Toldt's space was fully dissected to mobilize the sigmoid colon. The mesorectum was mobilized as needed. The distal line was determined and divided by endoscopic staples (Tri-staple or Universal staple) (Fig. 2a and b). The specimen was extracted through a 4 cm transverse mini-laparotomy incision on the left lower quadrant. An intra-abdominal end-to-end anastomosis was performed using a circular stapler (Premium Plus CEEA, Covidien, Mansfield, MA) under laparoscope (Fig. 2c). All patients were indwelling abdominal drains.

Short-term outcomes

Primary outcomes include anastomotic leakage and anastomotic bleeding. In this study, the definition of anastomotic leakage developed by the International Study Group on Rectal Cancer (ISREC) was used as reference [16]. Secondary outcomes include reoperation rate and postoperative hospital stay. Other short-term outcomes were also collected and analyzed.

Post hoc power analysis

Since some specific factors may contribute to the choice of surgical staples, we designed this post hoc power analysis. The outcomes including tumor location, body mass index (BMI), age, diabetes, surgeon's preferences, and medical insurance were collected and analyzed.

Statistical analysis

The demographic data, operative data, and postoperative outcomes of the patients were retrieved. The stapling devices used were ascertained. Operative outcomes were analyzed in accordance with the type of stapling device used, either Universal staple or Triple-staple. A propensity score was generated for each of these cases, taking into account the following: age, sex, serum biochemical indicators, number of staples for closure, number of lymph node dissection, TNM stage, pathological stage, distance from anal verge, coexisting diseases, neoadjuvant therapy, and dwelling anal tubing. Comparisons were made before and after matching of the patients according to their propensity scores.

The primary end points were anastomotic complications, namely anastomotic leakage and anastomotic bleeding. Anastomotic leakage was defined according to the well accepted guidelines of the 1991 United Kingdom Surgical Infection Study Group as "leak of luminal content from a surgical join between two hollow viscera". The secondary end points were reoperation rate, average postoperative hospital stay, average drain indwelling period and average fasting period.

SPSS 23.00 (IBM, USA) was used for statistical analysis. The Chi-squared test and the Fisher's exact test were employed in the comparison of classification variables; the Shapiro–Wilk test was applied to examine normal distributions of continuous variables; the Mann–Whitney U test was used on non-normal distributions. Only binary comparisons were involved in this study where $P < 0.05$ indicated statistical significance. Because categorical data, which included missing data, were created with "missing"

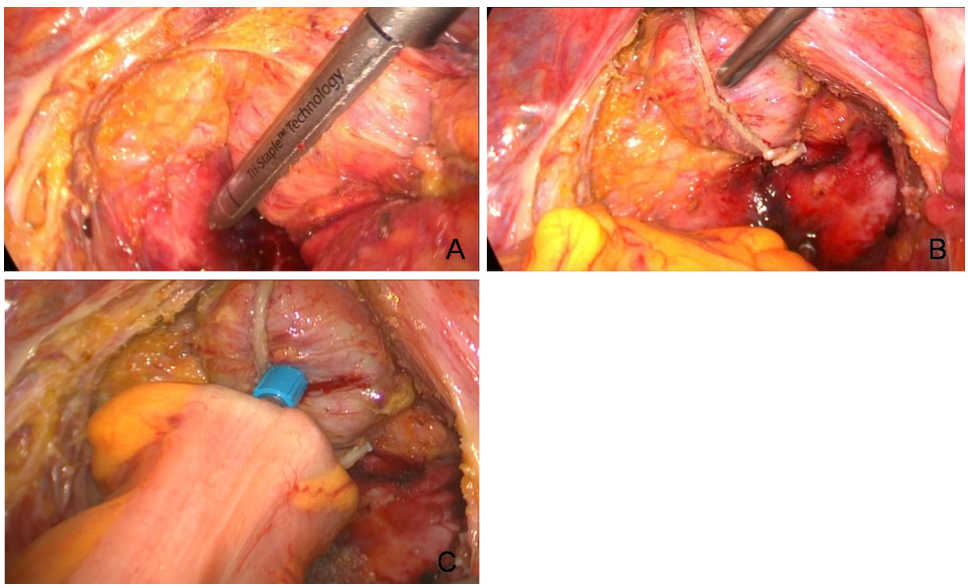

Fig. 2 An intra-abdominal end-to-end anastomosis techniqueunder laparoscope. **a** Transecting rectum with an endoscopic linear stapler. **b** Distal transection of rectum. **c** Intra-abdominal end-to-end anastomosis by a circular stapler

categories, participants with "missing" information were included in the analysis to maximize the statistical power.

We conducted a series of sensitivity analyses to evaluate the robustness of the findings of the study and how our conclusions can be affected by applying various association inference models. We added two association inference models in the original cohort and the weighted cohort in the sensitivity analysis. The calculated effect sizes and p values from all these models were reported and compared. All results are reported according to the STROBE statement.

Results

Cohorts and baseline feature comparison

Follow-up time of all patients in the study was 15–35 days. One hundred thirty-five patients of each group were selected for intergroup comparison following the propensity score matching (Fig. 3). Before propensity score matching, the two groups were not comparable in terms of diabetes, neoadjuvant therapy, dwelling anal tubing. After the propensity score matching, patients of the two groups became broadly comparable in terms of age, sex, serum biochemical indicators, number of lymph node dissection, TNM stage, pathological stage, distance from anal verge, coexisting diseases, neoadjuvant therapy, and indwelling anal tubing ($P > 0.05$) (Table 1).

Surgical outcomes

The incidence of anastomotic leakage was significantly lower in Tri-staple group compared with Universal staple group (4.44% vs. 11.11%, $P < 0.05$). The anastomotic bleeding rates were comparable between the two groups (2.22% vs. 2.96%, $P = 0.534$). Whether reoperations were performed mostly depends on the patient's general vital signs and toxemia. The reoperation rate of the Tri-staple group was significantly lower than that of the Universal staple group (3.70% vs. 8.15%, $P < 0.05$). All Grade C anastomotic leakages were treated with reoperations. The anastomotic bleeding rates, average postoperative hospital stay, drain indwelling period, and fasting period had no statistical differences between the two groups (Table 2).

Post hoc power analysis

The ratios of BMI $\geq$ 30 and diabetes in Tri-staple group were higher than those in Universal staple group. Surgeon's preferences had an impact on the choice of surgical staples. Tumor location, age, and medical insurance were comparable between the two groups (Table 3).

Discussion

Minimally invasive colorectal surgery has gained popularity worldwide due to its similar safety, resection margins, and completeness of resection, and improved recovery compared with that of open surgery [17, 18]. The reconstruction is a critical step in such a procedure and

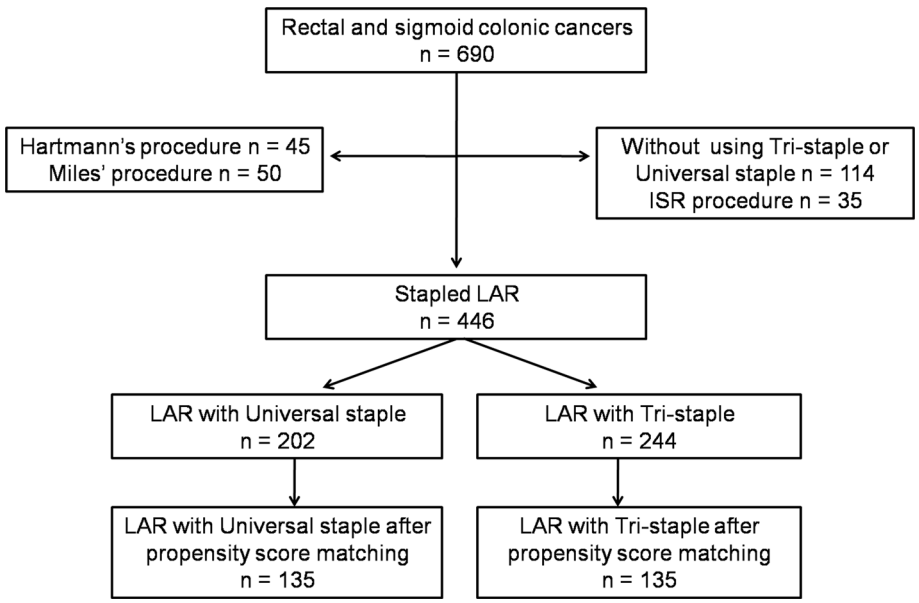

Fig. 3 Flowchart of the patients included in this study

Table 1 Intergroup comparison of baseline features

Parameter	Characteristic	Before matching			After matching		
		Universal staple group (n = 244)	Tri-staple group (n = 202)	P-value	Universal staple group (n = 135)	Tri-staple group (n = 135)	P-value
Age	< 65	97	75	0.387	52	49	0.489
	≥ 65	147	127		83	86	
Sex	Male	149	130	0.315	91	95	0.558
	Female	95	72		44	40	
Serum biochemical indicators	Albumin	35.0 ± 3.11 (29.0–50.0)	36.0 ± 3.02 (27.0–52.0)	0.462	35.0 ± 2.98 (29.0–49.0)	34.0 ± 3.17 (27.0–52.0)	0.516
	Hemoglobin(g/L)	99.5 ± 7.57 (72.0–132.0)	101.8 ± 8.01 (71.0–128.0)	0.455	99.1 ± 6.54 (75.0–119.0)	100.5 ± 6.50 (78.0–114.0)	0.509
Number of staples for closure	1	214	183	0.153	111	114	0.472
	2	30	19		24	21	
Number of lymph node dissection	< 12	5	3	0.562	0	0	–
	≥ 12	239	199		135	135	
TNM stage	T1	3	1	0.435	1	0	0.513
	T2	74	67		41	49	
	T3	101	87		63	60	
	T4a	43	36		22	19	
	T4b	23	11		8	7	
	N1	71	51	0.385	40	38	0.480
	N2	52	33		26	25	
	M1	31	20	0.497	10	7	0.419
Pathological stage	I	20	13	0.198	14	12	0.355
	II	101	85		55	60	
	III	92	64		56	56	
	IV	31	20		10	7	
Distance from anal verge	≤ 6 cm	30	31	0.087	22	20	0.253
	> 6 cm	214	171		113	115	
Coexisting disease(s)	Hypertension	79	51	0.161	51	47	0.478
	Diabetes	35	49	< 0.05	17	31	< 0.05
	Cardiac disease	23	18	0.244	15	10	0.243
Neoadjuvant therapy	*Y*	7	21	< 0.05	6	9	0.253
Dwelling anal tubing	*Y*	11	35	< 0.05	8	12	0.111

largely replies on the surgical staplers. Complications related to stapled resection and anastomoses are mainly anastomostic leakage and bleeding [19]. We hypothesized that Tri-staple technology reduced the risk of anastomostic leakage and bleeding in laparoscopic anterior resection of rectal and distal sigmoid colonic cancer. Our results showed Tri-staple group had a significant lower incidence of leakage compared with the Universal staple group (4.44% vs. 11.11%, $P < 0.05$). The reoperation rate was also lower in Tri-staple group than the Universal staple group (3.70% vs. 8.15%, $P < 0.05$). The anastomotic bleeding rates and postoperative hospital stay were comparable between the 2 groups.

The Tri-staple is a novel linear staple with outstanding performance across a broad range of tissues [9–12]. According to the information from the manufacturer, with its stepped cartridge face, the Tri-staple delivers graduated compression, can result in decreased stress in tissues compared to single height staples [20]. In animal study using micro-computed tomography methodology, graduated-height staples had significantly higher micro-perfusion volume than single height staples, which likely could translate into a downstream benefit on wound healing and

Table 2 Intergroup comparison of surgical outcomes

Parameter	Before matching			After matching		
	Universal staple group (n = 244)	Tri-staple group (n = 202)	P-value	Universal staple group (n = 135)	Tri-staple group (n = 135)	P-value
Anastomotic leakage (%)	14.815	4.950	< 0.05	11.111	4.444	< 0.05
Grade *A*	5	2		5	1	
Grade *B*	7	3		3	2	
Grade *C*	8	5		7	3	
Anastomotic bleeding (%)	2.049	1.980	0.523	2.963	2.222	0.534
Reoperation rate (%)	6.557	4.455	0.152	8.148	3.704	< 0.05
Average postoperative hospital stay (days)	10.12 ± 1.57 (7–44)	10.08 ± 1.93 (6–38)	0.469	10.53 ± 1.63 (7–42)	10.01 ± 1.55 (6–36)	0.486
Average drain indwelling period (days)	7.32 ± 0.65 (3–31)	7.98 ± 0.75 (3–31)	0.534	7.41 ± 0.63 (3–28)	7.51 ± 0.32 (3–31)	0.556
Average fasting period (days)	6.69 ± 1.32 (5–32)	6.13 ± 1.11 (5–30)	0.632	6.24 ± 0.45 (5–33)	6.00 ± 0.55 (5–28)	0.598

Table 3 Post hoc power analysis in different staples

Parameter	Characteristic	Before matching			After matching		
		Universal staple group (n = 244)	Tri-staple group (n = 202)	P-value	Universal staple group (n = 135)	Tri-staple group (n = 135)	P-value
Tumor location	Rectal	134	105	0.464	65	69	0.398
	Sigmoid colon	110	97		70	66	
BMI (kg/m^2)	≥ 30	21	33	< 0.05	11	22	< 0.05
	< 30	223	169		124	113	
Age (y)	< 65	97	75	0.387	52	49	0.489
	≥ 65	147	127		83	86	
Diabetes	Yes	35	49	< 0.05	17	31	< 0.05
	No	209	153		118	104	
Surgeon's preferences	Surgeon *A*	82	32	< 0.05	41	17	< 0.05
	Surgeon *B*	44	68		28	47	
	Surgeon *C*	47	70		25	47	
	Surgeon *D*	71	32		41	24	
Medical insurance	Yes	130	108	0.252	71	67	0.310
	No	114	94		64	68	

clinical outcomes [21]. Also, the improved design of the stronger fixed anvil and I-beam incorporated into the Tri-staple results in improved burst pressure strength, consistent hemostatic performance, and improved tissue retention during manipulation and transection [22].

The main limitation of this study was its retrospective nature. The choice of linear stapler mainly depends on surgeon preference and the supply of instruments. The chief surgeons in this study were four senior surgeons in our center who have been engaged in laparoscopic colorectal cancer surgery for more than 10 years. We increased a post hoc power analysis, and the results showed that the ratios of BMI ≥ 30 and diabetes in Tri-staple group were higher than those in Universal staple group; surgeon's preferences had an impact on the choice of surgical staples; tumor location, age, and medical insurance were comparable between the two groups. In the presence of risk factors for anastomotic leakages, such as obesity

and diabetes, we were indeed more inclined to choose Tri-staple. Although all patients used the same manufacturer's EEA and we performed propensity score matching, the exact site of anastomotic leakages cannot be confirmed to be from the linear staple line or from the EEA. Despite robust matching of potential confounding variables, bias could still exist, and the results should be interpreted cautiously. In this study, all patients with unexplainable toxemia with or without abdominal pain after operation were clinically diagnosed as anastomotic leakages, which may explain why the leak rate was higher than many studies.

No study has been published to date with regard to the effect of Tri-staple technology on the clinical outcome in laparoscopic anterior resection of rectal and distal sigmoid colonic cancer. The present study filled the gap and showed lower rates of anastomotic leakage and reoperation in Tri-staple group compared with the Universal staple group.

Based on our findings and experience, we recommend the usage of Tri-staple in laparoscopic anterior resection of rectal and distal sigmoid colonic cancer as a more effective tool with better short-term outcomes compared with Universal staple. Future high-quality randomized controlled trials are needed to confirm our findings.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00268-022-06704-9.

Author contributions QS and AW wrote the manuscript. SW, YH, HL, ZH, HZ collected and analyzed the data. ZH and HZ revised the manuscript critically. All authors read and approved the final manuscript.

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Declarations

Conflict of interest All authors have no conflicts of interest or financial ties to disclose.

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