Title: Triple-Stapled Technique Effectively Reduces the Operating Time for Rectal Anastomosis

Running Title: Double versus Triple-stapled anastomoses

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Abstract

**Purpose** Stapled anastomotic techniques to the distal rectum have gained widespread acceptance due to their procedural advantages. Various modifications in the stapling techniques have evolved since their inception. The triple-staple technique utilizing stapled closure of both the proximal colon and distal rectal stump provides a rapid and secure colorectal anastomosis. The aims of this study are to determine the safety and efficacy of the triple-staple technique, and to compare the clinical outcomes with a historical control group for which the conventional double-staple technique had been performed.

**Methods** One hundred consecutive patients operated on by a single surgeon were included, 50 patients who underwent double-staple (DSA), then 50 triple-staple anastomoses (TSA).

**Results** The most common indication for surgery in both groups was rectal cancer followed by diverticular disease and distal sigmoid cancer. There was no significant difference in the number of covering loop ileostomy formation in both groups (TSA 56% vs DSA 68%; p=0.621). The mean operating time for the TSA group was significantly shorter compared to the DSA group (243 vs 306 minutes; p=0.001). There was no significant difference in complication rates (TSA 40% vs DSA 50%; p=0.315) and length of hospital stay between the two groups (TSA 11.3 vs DSA 13.0 days, p=0.246). Post-operative complications included anastomotic leak, prolonged ileus, bleeding, wound infection and pelvic collection.

**Conclusion** The triple-staple technique is a safe alternative to the double-staple anastomosis after anterior resection. It also effectively shortens the operating time.

**Keywords:** triple-stapled anastomosis, colorectal anastomosis, leak rate, anterior resection
Introduction

A sound surgical technique is integral to optimizing post-operative outcomes and minimizing morbidity in colorectal surgery, especially anastomotic leakage. The reported clinical leakage rate after anterior resection varies from 3% to 20% [1-3]. Reports of the resulting morbidity and mortality vary considerably [1-3]. Many risk factors are associated with anastomotic leakage and are categorized as patient-specific, intra-operative and specific for low rectal anastomosis. The latter is attributed to the theory that low rectal resection with primary anastomosis poses more risks, due to the poor colonic vascularity and reduced remaining tissue available to support the anastomotic site. Patient-specific risk factors include malnutrition, steroids, tobacco use, leukocytosis, cardiovascular disease, alcohol use and American Society of Anesthesiologists (ASA) score [4]. Other suggested factors that influence leakage rate are related to the technique used and the surgical expertise of the operator [1-4].

Surgeons have long sought to refine the technical aspects of constructing anastomoses with the goal of lowering the incidence of anastomotic leak. The introduction of surgical staplers has simplified constructing anastomoses, and this has contributed to their widespread clinical use, especially in the lower one-third of the rectum. Creation of anastomoses can still be difficult, especially in cases with poor exposure, such as in obese patients, or male patients with a narrow pelvis, or with distal rectal tumors.

Various modifications in the application of the stapling techniques have evolved since its inception. The double-staple technique is now the most widely performed procedure, which facilitates colorectal anastomoses at a lower level, minimizing the potential risk of fecal contamination [5-6]. The triple-staple technique utilizing stapled closure of both the proximal colon and distal rectal stump, holds the potential for a more rapid and secure colorectal anastomosis.
The aims of this study are to determine the safety and efficacy of the triple-staple technique, and to compare the clinical outcomes with a historical control group for which the conventional double-staple technique had been performed.
Methods

During a twenty-six month period from December 2015 to February 2018, 50 consecutive patients underwent rectal resection with triple-staple anastomosis (TSA) by a single surgeon. This cohort was compared to a consecutive group of 50 patients who underwent rectal resection with double-staple anastomosis (DSA) from June 2011 to November 2015, immediately prior to the TSA group, by the same surgeon. Patients with locoregionally advanced rectal cancer or those with distant metastases who were not down-staged after neoadjuvant therapy precluding curative resection and subsequent anastomosis were not included in the study. Similarly, patients with low rectal tumours less than 5 cm from the anal verge, involving anal sphincter or requiring emergency operation were also excluded.

The impetus to commence TSA was one case involving a 56 year-old female with cirrhosis, portal hypertension and excessive bleeding, where the 2/0 prolene proximal purse-string for DSA could not be inserted due to the associated hemorrhage. The anastomosis was successfully completed with a TSA technique as described below, and the single surgeon permanently changed his technique from DSA to TSA.

Data was collected for age, sex, American Society of Anesthesiologists (ASA) score, and indication for surgery, mean operating time, mean length of post-operative hospital stay, 30-day morbidity and mortality rates.

Ethical approval of this study (X18-0344) was obtained from Sydney South West Area Health Service Ethics Review Committee (RPAH Zone). Waiver of consent was granted by the Human Research Ethics Committee (HREC). The research involves no more than minimal risk to subjects and the waiver or alteration will not adversely affect the rights and welfare of the subjects.
Common to commencement of both techniques

Following adequate mobilization of the rectum and left colon, the mesorectum where appropriate was divided below the anticipated lower margin of resection. A linear stapler is placed across the rectum at the distal margin of resection. A long right-angle clamp is placed proximal to the staple line (unless a stapling device was used that applies two separate linear staple lines and divides between) to prevent fecal soiling and the rectum is divided along the edge of the staple line.

Double-Staple Anastomosis Technique

A 2/0 prolene hand-sewn ‘whip-stitch’ purse-string suture is placed at the proximal colon resection margin. The anvil shaft assembly is placed in the proximal bowel through the purse-string and it is tied into the groove on the shaft.

Triple-Staple Anastomosis Technique

The proximal colon resection margin is chosen and divided proximal to one hard, straight bowel clamp. The anvil of the circular stapler with the extension spike is then placed into the proximal colon bowel lumen (Figure 1). Care by control of the position of the spike inside the proximal bowel, usually with the left-hand, ensures that no early or too proximal a penetration of the colon bowel wall occurs with the spike. A linear stapler is used to close the end of the proximal segment of the colon (Figure 2), and the spike attached to the shaft of the anvil is then used to pierce through the colon wall, just to either side of the linear staple line, and the anvil head is then brought down flush with the linear staple line (Figures 3-4). The spike of the anvil shaft is then removed (Figure 5).

Common to completion of both techniques

The circular stapler is introduced into the rectal segment with the anvil shaft assembly removed and the center rod retracted within the cartridge and advanced through to either the anorectal junction or the rectal wall adjacent to the distal linear staple line. The anvil shaft is then inserted into the rod and a circular end-to-end inverting anastomosis is completed.
All stapled anastomoses are tested for complete anastomotic doughnuts. Additionally, all anastomoses are both endoscopically inspected and tested for integrity by insufflation of air. This is done by occluding the proximal colon with a soft clamp across above the anastomosis while insufflating air to distend the colon. Leakage was detected by arising air bubbles.

Statistical analysis was completed using SPSS version 23.0 software (IBM, Armonk, New York, USA). Categorical variables were compared using Chi-square test and continuous variables were compared using an independent-samples t-test. P<0.050 was considered statistically significant.
Results

The demographic details of the patients are shown in Table 1. The mean age of the TSA group was 62.2 years (31-82), compared with 65.8 years (38-87) for the DSA group (p=0.098). The majority of the patients in the TSA group were female (58%), compared with the DSA group who were 68% male (p=0.015).

The majority of patients in both groups were ASA 2 with mild systemic disease (p=0.546). The most common indication for surgery in both groups was rectal cancer followed by diverticular disease and distal sigmoid cancer (p=0.621). Three patients in the TSA group also had ischemic bowel, sigmoid volvulus and appendiceal cancer with peritoneal metastases. There was no significant difference in the number of covering loop ileostomy formation in both groups (TSA 56% vs DSA 68%; p=0.621).

The mean operating time for the TSA group was significantly shorter than the mean operating time for the DSA group (TSA 242.8 vs 306.1 minutes; p=0.001). There was no significant difference in complication rates (TSA 40% vs DSA 50%; p=0.315) or length of hospital stay between the two groups (TSA 11.3 vs DSA 13.0 days, p=0.246).

Post-operative complications are outlined in Table 2. There were no deaths or major cardiopulmonary complications in either group. One clinical anastomotic leak (2%) was recorded in the TSA group and three (6%) from the DSA group (p=0.307). All three patients in the DSA group had a covering ileostomy at initial resection; two were managed with percutaneous drainage and antibiotics and one with antibiotics alone. The patient in the TSA group with a clinical leak was a 65 year-old male with a body mass index (BMI) of 52, and did not have a covering ileostomy. He required a laparotomy, washout and proximal diversion. There were no radiologic leaks in either group. Other post-operative complications including hemorrhage from the anastomotic staple line, prolonged ileus, obstruction, wound infection and respiratory complications were also similar in both groups.
Discussion

Anastomotic leak is the most feared colorectal resection complication, and is the primary outcome by which success of rectal anastomosis is measured. There is concern that the use of more intersecting staple lines that result from performing staple line on staple line anastomoses may increase the risk of anastomotic leak. Although this concern might seem justified, Jualian and Ravitch addressed this issue by conducting experimental studies with dogs, which showed that the linear staples are usually removed with doughnuts and are deformed, cut or squeezed out [7]. Another experimental study further demonstrates that intersecting staple lines in small bowel and colonic anastomoses do not reduce anastomotic blood flow to a dangerous level that may potentially increase the risk for anastomotic leakage. [8]. Reports of increasing clinical experience also attest to the safety of stapling across a staple line.[2-3]

The double-staple technique is currently the most widely performed technique in colorectal anastomoses [3, 5, 9]. It has been associated with a shorter operation time, minimal contamination, a lower rate of covering colostomy and the ability to create a very low anastomosis compared to a hand-sewn technique. This translates to sphincter-saving surgery and permanent stoma avoidance. Double-staple anastomoses have, however, also been associated with anastomotic stenosis varying between 3-21% and the risk of pelvic sepsis due to fecal contamination [3, 5, 9]. The use of a purse-string suture on the proximal colon poses a contamination risk upon opening of the bowel lumen. Moreover, the difficulty associated with purse-string placement in patients with dilated bowel due to obstruction is a commonly encountered concern. The problem of size disparity between the two ends of the bowel in such obstructed patients make the purse-string placement technically difficult, and may fail to include the entire circumference of the bowel wall regardless of whether manual or automatic purse-string devices are used.

Illuminati reported his results using DSA in 108 patients with carcinoma of the rectum and found a leak rate of 6% [5]. Meanwhile, Redmond reported a leak rate of 9% and
perioperative mortality of 2% in 111 patients who had rectal resection with DSA [10]. Both studies concluded that DSA has made low anterior resection for rectal resections a safe procedure with low mortality and low anastomotic leakage rates. Similarly, Mahid reported the results of his review of 291 consecutive patients who underwent rectal resection with TSA and noted a low anastomotic leak rate of 1% [11]. The anastomotic leak rate in this review of 50 patients in the DSA group was 6%, which is comparable to reported rates in literature. While the anastomotic leak rate in the TSA group is lower (2%), this result was not significantly different with that of the DSA group.

In patients with low rectal anastomosis, TSA may be appropriate and result in better postoperative outcomes compared to the existing stapling methods such as the DSA. Elimination of the purse-string placement in both the proximal and distal bowel stumps using the triple-staple technique addresses size disparity concerns between the two ends of the bowel seen in obstructed patients. It does not eliminate the need to open the proximal bowel, but can help minimize fecal spillage. The additional cost for a reload cartridge of the linear stapler may be justified by the operating room time saved and the low rate of anastomotic leak using this technique [11].

There are limitations to the conclusions that can be drawn from this study because of the number of patients and the historical control design. This study demonstrated that TSA is associated with a shorter mean operating time compared to the DSA group. The additional operating time in the DSA group may be attributed to the required time to construct a purse-string or correct a leak. But this may also be explained by the fact that the majority of the patients in the DSA group were males with narrower pelvis that can make dissection more difficult and time-consuming.
Conclusion

The triple-staple technique is a safe alternative to the double-staple anastomosis after anterior resection. It effectively shortens the operating time.
References


Table 1. Demographics and details of the operation

<table>
<thead>
<tr>
<th></th>
<th>DSA, n=50</th>
<th>TSA, n=50</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td><strong>Age (years); mean (range)</strong></td>
<td>65.8 (38-87)</td>
<td>62.2 (31-82)</td>
<td>0.098</td>
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<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>34 (68%)</td>
<td>21 (42%)</td>
<td>0.009</td>
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<tr>
<td>Female</td>
<td>16 (32%)</td>
<td>29 (58%)</td>
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<tr>
<td><strong>ASA Score</strong></td>
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<tr>
<td>1</td>
<td>16 (32%)</td>
<td>16 (32%)</td>
<td>0.546</td>
</tr>
<tr>
<td>2</td>
<td>27 (54%)</td>
<td>23 (46%)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>7 (14%)</td>
<td>11 (22%)</td>
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<tr>
<td><strong>Indication for Surgery</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectal cancer</td>
<td>29 (58%)</td>
<td>25 (50%)</td>
<td>0.621</td>
</tr>
<tr>
<td>Diverticular Disease</td>
<td>11 (22%)</td>
<td>13 (26%)</td>
<td></td>
</tr>
<tr>
<td>Distal sigmoid cancer</td>
<td>10 (20%)</td>
<td>9 (2%)</td>
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</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>3 (6%)</td>
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<tr>
<td><strong>Covering ileostomy</strong></td>
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<td></td>
<td>0.621</td>
</tr>
<tr>
<td></td>
<td>34 (68%)</td>
<td>28 (56%)</td>
<td></td>
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<tr>
<td><strong>Complication Rate</strong></td>
<td>25 (50%)</td>
<td>20 (40%)</td>
<td>0.315</td>
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<tr>
<td></td>
<td>306.1</td>
<td>242.5</td>
<td></td>
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<tr>
<td><strong>Mean length of hospital stay (days)</strong></td>
<td>13.0</td>
<td>11.3</td>
<td>0.246</td>
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</table>

Table 2. Comparison of post-operative complications between DSA and TSA groups

<table>
<thead>
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<th>Complication</th>
<th>DSA</th>
<th>TSA</th>
<th>p</th>
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<tr>
<td>Anastomotic leak</td>
<td>3 (6%)</td>
<td>1 (2%)</td>
<td>0.307</td>
</tr>
<tr>
<td>Ileus/Obstruction</td>
<td>11 (22%)</td>
<td>5 (10%)</td>
<td>0.086</td>
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<td>High stoma output</td>
<td>3 (6%)</td>
<td>3 (6%)</td>
<td>1.000</td>
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<tr>
<td>Urinary tract infection</td>
<td>4 (8%)</td>
<td>1 (2%)</td>
<td>0.169</td>
</tr>
<tr>
<td>Pelvic collection</td>
<td>3 (6%)</td>
<td>1 (2%)</td>
<td>0.307</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Wound infection</td>
<td>4 (8%)</td>
<td>3 (6%)</td>
<td>0.654</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>2 (4%)</td>
<td>3 (6%)</td>
<td>0.646</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>0</td>
<td>3 (6%)</td>
<td>0.079</td>
</tr>
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</table>
FIGURE LEGENDS

Figure 1. Anvil of the circular stapler with extension spike attached is inserted into the bowel lumen.

Figure 2. A linear stapler is used to close the end of the proximal segment of colon.

Figure 3. The spike of the anvil is used to pierce through the colon wall to just either side of the linear stapler line.

Figure 4. The shaft of the anvil is fully brought down to be flush with the proximal end of colon.

Figure 5. The spike of the anvil shaft is removed, prior to stapled anastomosis.