CLINICAL SCIENCE

# Comparison of standard 4-row *versus* 6-row 3-D linear cutter stapler in creation of gastrointestinal system anastomoses: a prospective randomized trial

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**OBJECTIVE:** This prospective study was conducted to compare the clinical outcomes of a 6-row 3-D linear cutter with the standard 4-row linear cutter in patients who underwent elective gastrointestinal surgery anastomosis.

**METHOD:** Patients who underwent elective open gastrointestinal surgery that included stapled anastomosis using a linear cutter (Proximate®, Ethicon Endo-Surgery, Cincinnati, OH) between January 2011 and May 2011 were included in the study. The patients were randomly assigned to two groups according to the linear cutter that was used in the surgery: the standard 4-row cutter (the S group) or the new 6-row cutter (the N group). The groups were compared based on the patient demographic data, the laboratory parameters, the preoperative diagnosis, the surgery performed, the operation time, intra- or postoperative complications, the time to oral tolerance and the length of the hospital stay.

**RESULTS:** The S group included 11 male and nine female patients with a mean age of $65 \pm 12$ (35-84) years, while the N group included 13 male and eight female patients with a mean age of $62 \pm 11$ (46-79) years ($p = 0.448$, $p = 0.443$, respectively). Anastomotic line bleeding was observed in eight (40%) patients in the S group and in one (4.7%) patient in the N group ($p = 0.006$). Dehiscence of the anastomosis line was observed in two (10%) patients in the S group and none in the N group ($p = 0.131$). Anastomotic leakage developed in three (15%) patients in the S group and in one (4.7%) patient in the N group ($p = 0.269$). The mean hospital stay was $12.65 \pm 6.1$ days in the S group and $9.52 \pm 2.9$ days in the N group ($p = 0.043$).

**CONCLUSION:** The 6-row 3-D linear cutter is a safe and easily applied instrument that can be used to create anastomoses in gastrointestinal surgery. The new stapler provides some usage benefits and is also superior to the standard linear cutter with regard to anastomotic line bleeding.

**KEYWORDS:** Anastomosis; Linear Stapler; 4-Row Staple Line; Gastrointestinal Surgery.

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## INTRODUCTION

Gastrointestinal system (GIS) anastomosis is one of the most commonly performed abdominal surgery procedures. Since Ravitch and associates (1,2) introduced a group of instruments capable of performing GIS anastomosis in the late 1960s, stapling devices have gained popularity and undergone technical improvements. Staplers make it possible to create a GIS anastomosis quickly and easily with the advantages of enhancing the blood flow across the anastomosis line, causing less tissue trauma, reducing edema and reducing surgery time (3-5). Therefore, the use of staplers in GIS surgery is now widely accepted.



No potential conflict of interest was reported.

In parallel with the technological developments in surgery, many advanced models of stapling devices have been produced to create safer GIS anastomosis. A standard 4-row linear cutter is one of the most commonly used stapling instruments for this purpose. Recently, a new 6-row 3-D linear cutter stapler has been introduced as an alternative to the standard stapler. It is claimed that the new instrument provides optimal tissue compression and better hemostasis and to facilitate the anastomosis creation (6). However, there are limited data on the clinical outcomes of the new linear cutter in the literature. Hence, we conducted this prospective study to evaluate the effect of the new linear cutter compared with the standard cutter in patients undergoing elective GIS anastomosis.

## MATERIALS AND METHODS

This prospective randomized study was performed between January 2011 and May 2011 in the Department of General Surgery, Mersin University Medical Faculty

Hospital. Fifty consecutive patients undergoing elective GIS stapled anastomosis using a linear cutter (Proximate®, Ethicon Endo-Surgery, Cincinnati, OH) for benign or malign diseases were included in the study. This study was approved by the ethics committee at Mersin University Medical Faculty Hospital, and written informed consent was obtained from all of the patients. Patients with coagulopathy, sepsis, multiple organ failure, stapled anastomosis using a different brand and those patients who refused randomization were excluded from the study. Nine patients (two with sepsis, two with coagulopathy, three using a different brand stapler, one with multiple organ failure and one who refused randomization) were excluded. Finally, 41 patients were randomized into two groups according to the type of linear cutter used: a standard 4-row (S, n = 20) group and a new 6-row (N, n = 21) group. Randomization was performed using a computer-generated program run by an independent computer consultant.

## Surgical Technique

The patients were routinely prepared for surgery. The laboratory parameters, including the plasma leukocyte, hematocrit and albumin levels, were recorded preoperatively. Nutritional support was supplied when necessary. According to our department policy, no bowel preparation was performed before the surgery. Each patient received a single dose of cephalosporin for prophylaxis; metronidazole was also used if a colectomy was performed.

The operations were performed open by the same two expert surgeons (AS, TC). The standard linear cutter had two types of cartridges: blue (3.5 mm staple) and green (4.8 mm staple). The cartridge was selected according to the tissue thickness. The blue cartridge was preferred for bowel resections, while green was preferred for gastric resections. The new cutter had a selectable staple height feature that accommodated various tissue thicknesses using one cartridge with staple heights of 1.5, 1.8, and 2.0 mm. Following the appropriate surgery, both sides of the anastomosis were prepared. The stapler was closed after checking for any tissue slippage out of the distal end of the instrument. Following the decompression of the tissue for 20 seconds, the stapler was fired with a single move. The anastomotic integrity was tested with air and evaluated with regard to bleeding and dehiscence. Bleeding that needed cauterization after firing the stapler was accepted as anastomotic line bleeding and was controlled by stitching with 3-0 polyglactin suture. If dehiscence was observed, the line was buttressed with 3-0 polyglactin separated suture. An abdominal drain was introduced for all the patients. The total amount of perioperative blood transfusions was recorded. The operating time was defined as the time from the first incision to the placement of the last suture.

A fast-track protocol (early oral feeding, early mobilization) was performed for each patient after surgery. Postoperative anastomotic leakage was determined by observing the intestinal content from the abdominal drain. The patients who did not exhibit any surgical problems were discharged from the hospital.

The patients were evaluated with regard to their demographic data, the laboratory parameters, the preoperative diagnosis, the surgery performed, the operation time, the perioperative complications, the time to oral tolerance and the length of the hospital stay.

## Statistical analysis

A power analysis was calculated using a test for the non-inferiority hypothesis. We considered a difference of less than 10% in the anastomotic line bleeding rate to be of non-clinical importance; therefore, the non-inferiority margin was chosen to be 10%. According to the non-inferiority test, approximately 20 patients should be present in each group to detect a clinically important difference in the anastomotic line bleeding with an $\alpha$ error of 5% and a $\beta$ error of 20%. The sample size was established at 20 patients in each group to provide appropriate statistical power analyses. The data obtained were summarized in a computerized spreadsheet, and statistical analyses were performed using SPSS 11.5 for Windows. The differences between the treatment groups were analyzed using $\chi^2$ tests and Student's *t*-test. The results were expressed as the mean $\pm$ standard deviation (SD) and as number and percent. The $\chi^2$ tests were performed to compare the categorical variables, and Student's *t* test was used to compare the parametric values.

# RESULTS

There were 24 (58.5%) male (M) and 17 (41.5%) female (F) patients with a mean age of $64 \pm 11.8$ years in the study group. The S group included 11 M and 9 F patients with a mean age of $65 \pm 12$ years, while the N group included 13 M and 8 F patients with a mean age of $62 \pm 11$ years ($p = 0.448$, $p = 0.443$, respectively). The demographic data, the preoperative laboratory parameters needed for nutritional support and the need for patient blood transfusion are summarized in Table 1.

The preoperative diagnoses of the patients and the operations performed are summarized in Table 2. The mean operation time was $190.5 \pm 34.1$ min in the S group and $192.3 \pm 50.6$ min in the N group ($p = 0.89$). The mean amount of preoperative blood transfusions was $0.85 \pm 0.8$ IU in the S group and $0.95 \pm 1.0$ IU in the N group ($p = 0.914$). Anastomotic line bleeding was observed in eight (40%) patients in the S group and in one patient (4.7%) in the N group ($p = 0.006$). Dehiscence of the anastomosis line was noted in two (10%) patients in the S group and none in the N group ($p = 0.131$).

Concerning the postoperative complications, anastomosis leakage developed in three (15%) patients in the S group and in one (4.7%) patient in the N group ($p = 0.269$). One patient with leakage in each group was treated conservatively, whereas two patients who underwent colonic resection in the S group were re-operated because of high-output intestinal fistula. The two re-operated patients expired from multiple organ failure, one on the 5$^{th}$ postoperative day and the other on the 10$^{th}$. Wound infection developed in six (30%) patients in the S group and three (14.2%) patients in the N group

**Table 1 -** Patient characteristics.

| | S (n = 20) | N (n = 21) | *p*-value |
|---|---|---|---|
| Age (years) | $65 \pm 12$ | $62 \pm 11$ | 0.448 |
| Gender (M/F) | 11/9 | 13/8 | 0.443 |
| Leukocyte (x$10^3$ μl) | $10.78 \pm 5.8$ | $10.77 \pm 8.2$ | 0.999 |
| Hematocrit (%) | $32.47 \pm 4.6$ | $36.65 \pm 8.7$ | 0.066 |
| Albumin (g/dl) | $2.81 \pm 0.4$ | $2.81 \pm 0.6$ | 0.982 |
| Nutritional support (n) | 11 | 10 | 0.937 |

**Table 2 -** Preoperative diagnosis and operations.

| Diagnosis | Operation | Standard | New |
|---|---|---|---|
| Gastric cancer | Gastric resection | 2 | 3 |
| Colon cancer | Colectomy | 12 | 11 |
| Small bowel cancer | Small bowel resection | 4 | 4 |
| Ulcerative colitis | Ileal J-pouch | 1 | 2 |
| Pancreas cancer | Whipple-gastroenterostomy | 1 | 1 |
| Total | | 20 | 21 |

($p = 0.228$). All the infections were superficial and were treated conservatively. An oral diet was first tolerated on a mean of $4.2 \pm 0.9$ and $4.4 \pm 1.0$ days in the S and N groups, respectively ($p = 0.465$). The mean hospital stay was $12.65 \pm 6.1$ days in the S group and $9.52 \pm 2.9$ days in the N group ($p = 0.043$). The intraoperative and postoperative patient courses are summarized in Table 3.

## DISCUSSION

Staplers are widely used instruments in GIS surgery because they allow the quick and easy creation of uniformly sutured, less traumatic anastomosis with a better blood supply. In many studies, no significant differences in elective surgery complications have been revealed between stapled and hand-sewn anastomosis (7-9). In recent studies, however, the incidence of complications with stapled anastomosis has reportedly declined in parallel with increasing experience and improved instrumentation (10,11).

Linear cutters are commonly used to create a GIS anastomosis because of their ability to cut and staple simultaneously. In particular, they are almost indispensable in bariatric, gastric and pouch surgery, surgeries in which complications lead to a high rate of morbidity and mortality. To minimize the incidence of anastomotic leakage and bleeding related to the standard 4-row linear cutter, recently a new 6-row linear cutter that provides optimal tissue compression to create safer anastomosis was introduced by the manufacturer (6). However, the superiority of the new stapler to the standard one (in terms of the clinical outcomes of the patients) was unclear. Hence, this study was planned.

The new linear cutter provides some advantages to the surgeon. Its selectable staple height feature (with a single cartridge) accommodates various tissue thicknesses. This accommodation may be helpful in case of the absence of a suitable cartridge for the standard instrument for an operation. In addition, the new instrument, which has a two-sided firing feature, can be easily manipulated even by left-handed surgeons. One of the surgeons in this study was left-handed and was satisfied with this feature.

**Table 3 -** Intraoperative and postoperative patient courses.

| | S (n = 20) | N (n = 21) | *p*-value |
|---|---|---|---|
| **Intraoperative** | | | |
| Bleeding | 8 (40%) | 1 (4.7%) | **0.006** |
| Dehiscence | 2 (10%) | 0 | 0.131 |
| Mean operation time (min) | $190.5 \pm 34.1$ | $192.3 \pm 50.6$ | 0.890 |
| **Postoperative** | | | |
| Anastomotic leakage | 3 (15%) | 1 (4.7%) | 0.262 |
| Wound infection | 6 (30%) | 3 (14.2%) | 0.228 |
| Re-operation | 2 (10%) | 0 | 0.131 |
| Mortality | 2 (10%) | 0 | 0.131 |
| Mean hospital stay (days) | $12.65 \pm 6.1$ | $9.52 \pm 2.9$ | **0.043** |

The staple line should be checked for hemostasis, pneumostasis, and proper closure after firing the stapler. In particular, intraoperative dehiscence of the anastomosis line after firing the stapler should be noted to avoid further complications. Insufficient tissue compression, inappropriate cartridge selection and tissue slippage from the tip of the stapler are among the possible causes of this complication (12,13). Dehiscence was observed in 5% of our patients in the S group due to our possible technical errors. Although there was no significant difference in anastomotic dehiscence between the two groups, the selectable staple heights (with respect to the tissue thicknesses), the optimal compression and the tissue slippage prevention mechanism are useful features of the new stapler that may help prevent this intraoperative complication.

Bleeding is another common complication that can be attributed to the stapling device. The incidence of bleeding reported in the literature ranges from 2% to 20% of patients (14-16), while our overall rate was 19.7%. Although intraoperative bleeding of the anastomosis line was encountered significantly more often in the S group, it was easily managed by appropriately suturing the anastomosis line during the open surgery. Although the incidence of intraoperative bleeding was approximately zero with the new stapler because of its optimal tissue compression feature, this effect may be an advantage in laparoscopic surgery but negligible in open surgery. This opinion has been supported by our results. Postoperative bleeding occurred in none of our patients, although a 2.5% rate has been reported in the literature (14).

Anastomotic leakage still remains a major surgical problem in GIS surgery regardless of whether the anastomosis was hand-sewn or stapled. Despite the identification of several factors that may contribute to anastomotic leakage, the actual cause and contributory factors remain unclear (12,13,17). Note that regardless of the specific technique, the basic surgical principles such as a satisfactory blood supply without tension of the suture line are essential. In addition, correct usage of the proper stapling instruments is important for preventing leakage (12,18). Note that the surgical technique used and concurrent patient health issues that disrupt wound healing, such as nutrition and systemic diseases, may also contribute to anastomotic leakage. The incidence of anastomotic leakage related to stapled anastomosis in various operations has been reported at a mean rate of 2.5% (14), 3.2% (11), 16.7% (15), and 5.2% (19) of the patients for bariatric, gastric, intestinal/colorectal, and pouch surgery, respectively. Our overall incidence of leakage was 9.7%, and all of the cases occurred after colonic resection. However, in all cases the patients were in advanced stages of cancer, malnourished and diabetic. Although the incidence of leakage was slightly lower in group N, no significant difference was found between the two groups.

Another interesting outcome of our study was the shorter hospital stay of the patients who underwent surgery with the new stapler. Despite some specific advantages of the new stapler, it is difficult to ascertain whether this result was related to the type of stapler used or if it was a result of the operation performed.

In conclusion, the results of this study reveal that the new 6-row 3-D linear cutter is as safe as the standard linear cutter and is easily used to create GIS anastomosis. In addition, the new 6-row 3-D linear cutter causes less anastomotic line bleeding than the standard cutter.

## AUTHOR CONTRIBUTIONS

Sozutek A and Colak T organized and conducted the statistical analyses, interpreted the results, wrote the majority of the manuscript and provided substantial scientific contributions. Dag A contributed to the data collection and analyses. Olmez T participated in the data collection and analyses.

## REFERENCES

1. Ravitch MM, Rivarola A. Enteroanastomosis with an automatic stapling instrument. Surgery. 1966;59(2):270-7.
2. Ravitch MM, Steichen FM. Techniques of Staple Suturing in Gastrointestinal Tract. Ann Surg. 1972;175(6):815-37, http://dx.doi.org/10.1097/00000658-197206010-00002.
3. Didolkar MS, Reed WP, Elias EG, Schnaper LA, Brown SD, Chaudhary SM. A prospective randomized study of sutured versus stapled bowel anastomoses in patients with cancer. Cancer. 1986;57(3):456-60, http://dx.doi.org/10.1002/1097-0142(19860201)57:3<456::AID-CNCR2820570309>3.0.CO;2-3.
4. El-Bakry AA. Bowel anastomosis. A comparative study of various surgical techniques. Saudi Med J. 2002;23(10):1232-36.
5. De Nardi P, Panzeri F, Staudacher C. Prospective trial evaluating new circular and linear stapler devices for gastrointestinal anastomosis: preliminary data. Tech Coloproctol. 2008;12(1):69-72, http://dx.doi.org/10.1007/s10151-008-0401-2.
6. Manufacturer's instruction for use by Ethicon Endo-Surgery Inc, Cincinnati OH, USA.
7. Reiling RB, Reiling WA, Bernie WA, Huffer AB, Perkins NC, Elliott DW. Prospective controlled study of gastrointestinal stapled anastomoses. Am J Surg. 1980;139(1):147-52, http://dx.doi.org/10.1016/0002-9610(80)90244-5.
8. George WD. Suturing or stapling in gastrointestinal surgery: a prospective randomized study. Br J Surg. 1991;78(3):337-41, http://dx.doi.org/10.1002/bjs.1800780322.
9. Brundage SI, Jurkovich GJ, Hoyt DB, Patel NY, Ross SE, Marburger R, et al. Stapled versus sutured gastrointestinal anastomoses in the trauma patient: a multicenter trial. J Trauma. 2001;51(6):1054-61, http://dx.doi.org/10.1097/00005373-200112000-00005.
10. Nomura S, Sasako M, Katai H, Sano T, Maruyama K. Decreasing complication rates with stapled esophagojejunostomy following a learning curve. Gastric Cancer. 2000;29(3):97-101, http://dx.doi.org/10.1007/PL00011703.
11. Hori S, Ochiai T, Gunji Y, Hayashi H, Suzuki T. A prospective randomized trial of hand-sutured versus mechanically stapled anastomoses for gastroduodenostomy after distal gastrectomy. Gastric Cancer. 2004;7(1):24-30, http://dx.doi.org/10.1007/s10120-003-0263-2.
12. Wind J, Safiruddin F, van Berge Henegouwen MI, Slors JF, Bemelman WA. Staple line failure using the Proximate 100 mm linear cutter. Dis Colon Rectum. 2008;51(8):1275-8, http://dx.doi.org/10.1007/s10350-008-9305-5.
13. Chassin JL, Rifkind KM, Turner JW. Errors and pitfalls in stapling gastrointestinal tract anastomoses. Surg Clin North Am. 1984;64(3):441-59.
14. Szomstein S, Whipple OC, Zundel N, Cal P, Rosenthal R. Laparoscopic Roux-en-Y gastric bypass with linear cutter technique: comparison of four-row versus six-row cartridge in creation of anastomosis. Surg Obes Relat Dis. 2006;2(5):431-34, http://dx.doi.org/10.1016/j.soard.2006.03.019.
15. Lee WS, Lee WY, Chun HK, Yun SH, Cho YB, Yun HR. Curved cutter stapler vs. linear stapler in rectal cancer surgery: a pilot prospective randomized study. Int J Colorectal Dis. 2009; 24(11):1327-32.
16. Shikora SA, Kim JJ, Tarnoff ME. Comparison of permanent and nonpermanent staple line buttressing materials for linear gastric staple lines during laparoscopic Roux-en-Y gastric bypass. Surg Obes Relat Dis. 2008;4(6):729-34, http://dx.doi.org/10.1016/j.soard.2008.02.001.
17. Morita K, Maeda N, Kawaoka T, Hiraki S, Kudo A, Fukuda S, et al. Effects of the time interval between clamping and linear stapling for resection of porcine small intestine. Surg Endosc. 2008;22(3):750-6, http://dx.doi.org/10.1007/s00464-007-9481-8.
18. Nakayama S, Hasegawa S, Nagayama S, Kato S, Hida K, Tanaka E, et al. The importance of precompression time for secure stapling with a linear stapler. Surg Endosc. 2011;25(7):2382-6, http://dx.doi.org/10.1007/s00464-010-1527-7.
19. Lovegrove RE, Constantinides VA, Heriot AG, Athanasiou T, Darzi A, Remzi FH, et al. A comparison of hand-sewn versus stapled ileal pouch anal anastomosis (IPAA) following proctocolectomy: a meta-analysis of 4183 patients. Ann Surg. 2006;244(1):18-26, http://dx.doi.org/10.1097/01.sla.0000225031.15405.a3.