

Original article

A prospective randomized trial of hand-sutured versus mechanically stapled anastomoses for gastroduodenostomy after distal gastrectomy

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Abstract

Background. Although mechanical stapling is now an established alternative to conventional hand suturing for the construction of gastrointestinal anastomoses, its role in gastroduodenostomy remains to be defined. We compared the clinical outcome after mechanical stapling with that after hand suturing in patients who underwent gastroduodenostomy after distal gastrectomy.

Methods. From April 2000 through August 2001, a total of 187 patients with gastric cancer who received distal gastrectomy were randomly assigned to reconstruction by mechanically stapled or by hand-sutured gastroduodenal anastomoses.

Results. The baseline clinical characteristics were similar in the patients with mechanically stapled and those with handsutured anastomoses. There was no in-hospital mortality in either group. One patient (1.1%) in the mechanically stapled group (n = 92) and 2 (2.1%) in the hand-sutured group (n =95) had anastomotic leakage. Anastomotic stenosis developed in 4 patients (4.3%) who underwent mechanical stapling, as compared with 6 (6.3%) who underwent hand suturing. Anastomotic bleeding occurred in 1 patient (1.1%) who underwent mechanical stapling and 1 patient in the hand-sutured group (1.1%). Mechanical stapling of the anastomoses was significantly quicker than hand-suturing of the anastomoses (median time, 14 vs 25 min; p = 0.02). The two groups were comparable with respect to other outcome measures, including incidence of general complications, recovery of gastrointestinal function, duration of postoperative hospital stay, and radiological diameter of the anastomosis.

Conclusion. In patients with gastric cancer who undergo gastroduodenostomy after distal gastrectomy, mechanical stapling is quicker than hand suturing. These procedures are similar with respect to anastomotic complications and other outcome measures.

Key words Billroth I anastomosis · Stapling technique (EEA) · Gastric cancer · Prospective randomized trial

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Introduction

The use of automatic staplers for gastrointestinal anastomoses is now widely accepted. These instruments permit procedures such as total gastrectomy and low anterior colorectal resection, lengthy operations previously associated with a high incidence of complications, to be done relatively safely. Mechanical staplers have shortened the operation time, facilitated the performance of gastrointestinal anastomoses at sites with a poor field of view, and lowered the likelihood of suture failure [1–3]. Several prospective, randomized controlled studies have compared hand suturing with mechanical stapling in patients undergoing total gastrectomy and low anterior colorectal resection [1,4–10].

More than 100 years have passed since Billroth described his procedure for reconstruction after distal gastrectomy, in 1881. Because this technique provides a good field of view and permits anastomosis within a relatively short time, the basic procedure has remained largely unchanged. Distal gastrectomy with Billroth I anastomosis has a low incidence of postoperative complications, but can lead to suture failure and anastomotic stenosis. In this prospective randomized controlled study, we compared the usefulness of mechanical stapling with that of hand suturing for Billroth I anastomosis.

Patients and methods

Patients

Patients with gastric cancer who underwent surgery between April 2000 and August 2001 at the Department of Academic Surgery, Chiba University, School of Medicine, or 17 affiliated hospitals were eligible for this study. A total of 187 patients who received distal gastrectomy with gastroduodenostomy were enrolled.

The study protocol placed no restrictions on age or preoperative complications. We excluded patients found to have unresectable disease at operation, those switched to other procedures or reconstruction techniques, and those in whom other gastrointestinal anastomoses were performed. All surgeons participating in this study received their postgraduate surgical training at Chiba University, School of Medicine Hospital.

Randomization

The patients were randomly assigned to mechanical stapling or hand suturing, at a 1:1 ratio. The assignments were contained in sealed envelopes. The study protocol was approved by the ethics review board of Chiba University, School of Medicine, in February 2000. Informed consent to participate in this study was obtained from all patients before surgery.

Operative technique

Laparotomy was done via an upper midline incision. Lymph node dissection was performed as required by disease stage. Distal gastrectomy was done, and the residual stomach and duodenum were reconstructed by Billroth I anastomosis. The use of hand suturing or mechanical stapling for reconstruction was randomly assigned. Hand suturing was done by Albert-Lembert anastomoses. Albert anastomoses were performed with 3-0 Vicryl (Ethicon; Johnson & Johnson, Somerville, NJ, USA) running sutures. Lembert anastomoses were done with 3-0 silk knotted sutures.

For mechanical stapling, PCEEA staplers (United States Surgical, Norwalk, CT, USA) were used in 76 patients (model PCEEA-25 in 2 patients, model PCEEA-28 in 55, and model PCEEA-31 in 19), and CDH staplers (Ethicon Endo-surgery; Johnson & Johnson, Cincinnati, OH, USA) were used in 16 patients (model CDH-25 in 1 patient and model CDH-29 in 15). The procedure has been described previously by Nance [11]. The anvil head was inserted into the cut end of the duodenum. The head of the circular stapler was introduced into the stomach through the gastrotomy, 5cm from the gastric closure (Fig. 1). Then, the anastomosis was performed on the greater curvature of the gastric closure (Fig. 2). Gastroduodenostomy was performed in a manner similar to that used with the handsuturing technique.

Postoperative assessment

The integrity of the anastomosis was checked on postoperative day 7 by the use of water-soluble contrast medium (Gastrografin; Nihon Schering, Osaka, Japan). In addition, the diameter of the anastomosis was measured on X-ray film.

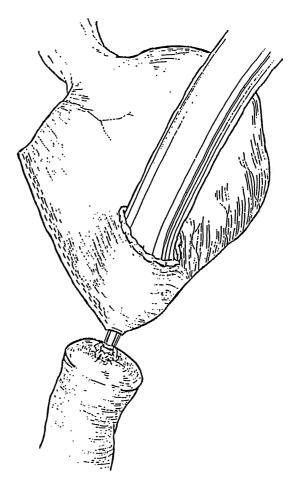


Fig. 1. The circular stapler has been inserted through the gastrotomy, 5 cm aborally from the gastric closure. The instrument will now be closed and fired

The patients' postoperative progress until discharge (day of nasogastric tube removal, day of starting liquid intake, day of starting solid food intake, C-reactive protein level on postoperative day 7, body weight loss on postoperative day 14 as compared with the preoperative value, duration of hospital stay after operation), complications related to the anastomosis (suture insufficiency, stenosis, bleeding), and other complications were analyzed. Suture failure was defined as distinct clinical evidence of suture failure or evidence of suture failure on postoperative fluoroscopy. Anastomotic stenosis was defined as distinct stenosis on postoperative fluoroscopy, causing solid food intake to be delayed until after postoperative day 14.

The stage of gastric cancer and the extent of lymph node dissection were classified according to the *Japanese classification of gastric carcinoma* [12]. Staging was based on intraoperative findings.

The values for means and SDs of the collected data were calculated. The data were statistically analyzed by the use of the Mann-Whitney *U*-test. All results were

considered statistically significant at P values of less than 0.05

Results

Clinical analyses

The median age of the 92 patients with mechanically stapled anastomoses was 65 ± 11 years, and that of the 95 with hand-sutured anastomoses was 68 ± 11 years (P = 0.5; Table 1). There were no significant differences

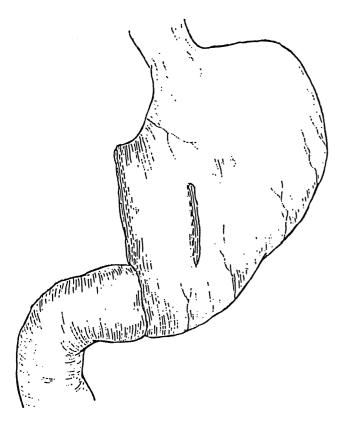


Fig. 2. Completed anastomosis. The anastomosis was performed on the greater curvature of the gastric closure. The gastrectomy was closed with a linear stapler

between the groups in sex ratios or in the presence of concomitant disease. Stage I disease was diagnosed in 74 patients (80.4%) in the stapled group and in 70 (73.7%) in the hand-sutured group.

Although the total operation time did not differ significantly between the groups, the time required for anastomosis was significantly shorter in the stapled group ($14 \pm 5.9 \,\mathrm{min}$) than in the hand-sutured group ($25 \pm 6.9 \,\mathrm{min}$; P = 0.02; Table 2). The bleeding volume was similar in both groups. Duodenal mobilization (Kocher's maneuver) was done in slightly more than half of the patients in each group. There was no significant difference between the groups in the extent of lymph node dissection. About 60% of the patients in each group received D2 lymph node dissection.

Postoperative course

The nasogastric tube was removed on postoperative day 3 in the stapled group as compared with day 4 in the hand-sutured group, but this difference was not significant (Table 3). Liquid intake was started on postoperative day 5 in both groups. Solid food intake was started on day 8.5 in the stapled group and day 9.0 in the handsutured group. The C-reactive protein level on postoperative day 7 was similar in the stapled group (2.6 mg/dl) and the hand-sutured group (2.4mg/dl). Body weight loss 2 weeks after operation as compared with the preoperative value was similar in the stapled group (3.5 \pm 2.5kg) and hand-sutured group (4.0 \pm 2.2kg). The median hospital stay after operation was 2 days shorter in the stapled group (18 \pm 11.7 days) than in the handsutured group (20 \pm 12.9 days), but the difference was not significant.

Complications

Among the 187 patients enrolled, there was no inhospital mortality in either the stapled group or the hand-sutured group (Table 4). Complications of anastomosis occurred in 6 patients (6.5%) in the stapled group

Table 1. Clinical characteristics of patients

	Stapling $(n = 92)$	Hand-suturing $(n = 95)$	P
Median age, in years (±SD)	65 (±11)	68 (±11)	NS
Male: Female	69:23	63:32	NS
Concomitant disease (%) ^a	27 (29.3)	32 (33.7)	NS
Cancer stage (%)	, ,	,	
I	74 (80.4)	70 (73.7)	
II	9 (9.8)	10 (10.5)	NS
III	8 (8.7)	9 (9.5)	
IV	1 (1.1)	6 (6.3)	

^a Arteriosclerosis, coronary heart disease, pulmonary disease, diabetes mellitus, chronic renal failure, hepatitis, liver cirrhosis, and hypertension

Table 2. Characteristics of operation

	Stapling $(n = 92)$	Hand-suturing $(n = 95)$	P
Total operating time, in min (±SD)	165 (±68.2)	185 (±58.3)	NS
Time required for anastomosis, in min $(\pm SD)$	$14(\pm 5.9)$	$25(\pm 6.9)$	0.02
Bleeding, in g (\pm SD)	$308.5 (\pm 228.5)$	$330 (\pm 229.2)$	NS
Kocher's maneuver (yes/no)	51/41	49/46	NS
Lymph node dissection (%)			
D0	1 (1.1)	0 (0)	
D1	30 (32.6)	36 (37.9)	NS
D2	59 (64.1)	58 (61.1)	
D3	2 (2.2)	1 (1.0)	

Table 3. Postoperative course

	Stapling $(n = 92)$	Hand-suturing $(n = 95)$	P
Removal of nasogastric tube (days)	$3(\pm 1.8)$	4 (±1.7)	NS
Time to liquid intake (days)	5 (±3.4)	$5(\pm 1.4)$	NS
Time to solid intake (days)	$8.5(\pm 4.4)$	$9(\pm 6.8)$	NS
CRP (mg/dl) on seventh postoperative day	$2.6 (\pm 3.3)$	$2.4 (\pm 2.3)$	NS
Body weight loss (kg) 2 weeks postoperation	$3.5 (\pm 2.5)$	$4.0~(\pm 2.2)$	NS
Median hospital stay (days)	$18.0\ (\pm 11.7)$	20.0 (±12.9)	NS

Figures in parentheses are ±SD values

CRP, C-reactive protein

Table 4. Morbidity and mortality rates in the stapling and hand-suturing groups

	Stapling $(n = 92)$	Hand-suturing $(n = 95)$	P
Complications of anastomosis	6 (6.5)	9 (9.5)	NS
Pneumonia	4 (4.3)	4 (4.2)	NS
Ileus	3 (3.3)	3 (3.2)	NS
MRSA enteritis	0 (0)	1 (1.1)	NS
Candidemia	0 (0)	1 (1.1)	NS
Endocarditis	1 (1.1)	1 (1.1)	NS
Reoperation	1 (1.1)	2 (2.1)	NS
Mortality	0 (0)	0 (0)	NS

Figures in parentheses are percentages

MRSA; methicillin-resistant Staphylococcus aureus

and in 9 patients (9.5%) in the hand-sutured group (P = N.S.). Suture failure of the anastomosis occurred in 1 patient (1.1%) in the stapled group and 2 (2.1%) in the hand-sutured group. All 3 patients had minor leaks that resolved after conservative therapy. Anastomotic stenosis developed in 4 patients (4.3%) after mechanical stapling as compared with 6 (6.3%) after hand suturing. Reoperation was required in 1 patient in each group (reconstruction by Roux-en-Y anastomosis in the stapled group and reconstruction by the double-tract technique in the hand-sutured group). In the other 8 patients, the stenosis resolved after conservative treatment. Although the incidence of suture failure and stenosis of the anastomosis was slightly higher in the hand-sutured group, the difference was not statistically

significant. Postoperative bleeding from the anastomosis occurred in 1 patient (1.1%) in the hand-sutured group and 1 (1.1%) in the stapled group. In both patients, the bleeding responded to conservative therapy, and anemia resolved after treatment with iron preparations.

Postoperative complications not directly related to the anastomosis included pneumonia in 4 patients (4.3%), ileus in 3 (3.3%), and endocarditis in 1 (1.1%) in the stapled group. In the hand-sutured group, complications included pneumonia in 4 patients (4.2%), ileus in 3 (3.2%), methicillin-resistant *Staphylococcus aureus* in enteritis in 1 (1.1%), candidemia in 1 (1.1%), and endocarditis in 1 (1.1%). Reoperation was required by 1 patient with ileus in the hand-sutured group.

So far no stump and/or locoregional recurrence has been encountered in either of the two groups, though the follow-up period is short.

Diameter of the anastomosis

The diameter of the anastomosis was measured on X-ray film obtained at fluoroscopic examination on post-operative day 7. The anastomotic diameter was slightly but not significantly smaller in the hand-sutured group $(14.0 \pm 5.6\,\mathrm{mm})$ than in the stapled group $(15.0 \pm 5.6\,\mathrm{mm}; P = \mathrm{N.S.})$. Representative X-ray films, obtained at fluoroscopic examination, showing the findings with the two different techniques, are presented in Fig. 3A,B.

Comparison of costs of anastomosis for the two techniques

The price of a PCEEA stapler, for example, which is used for mechanically stapled anastomoses, is ¥69000. However, ¥59000 can be paid back for the stapler by the social medical insurance system in Japan. On the other hand, each hand-sutured anastomosis costs doctors about ¥5900 for a vicryl traumatic needle and silk sutures, on average, and this cost cannot be paid back by the insurance system. Thus, the actual costs for the two techniques do not differ greatly.

Discussion

Mechanical staplers have been used for gastrointestinal surgery since the latter half of the 1970s. Studies

comparing mechanical stapling with hand suturing for esophagojejunostomy after total gastrectomy were reported in the 1980s [13–19]. The incidence of suture failure in these studies ranged from 5.0% to 14.3% for mechanical stapling as compared with 0% to 29% for hand-suturing. Many studies found no significant difference between mechanical stapling and hand suturing in the occurrence of suture failure. However, the incidence of suture failure with mechanical stapling after total gastrectomy has been reported to have declined from 5.9% between 1985 and 1991 to 1.0% between 1992 and 1997 [20]. Recently, improved instrumentation and increased experience in handling have apparently led to a decrease in the incidence of suture failure.

Previous studies have compared Billroth II anastomoses done by mechanical stapling with those done by hand suturing for reconstruction after distal gastrectomy [21]. Among 474 patients with hand-sutured anastomoses studied by Weil and Scherz [21], 12 had suture failure, bleeding, or stenosis. In contrast, none of 71 patients with mechanically stapled anastomoses had these complications. Their study concluded that mechanical stapling was superior to hand suturing. For reconstruction after distal gastrectomy, we usually perform Billroth I anastomosis because it is simpler and more physiological than other techniques. Exceptions to this rule include patients with a small residual stomach, in whom the anastomosis is liable to be subjected to excessive tension; those with a risk of reflux esophagitis due to an increased angle of His; and those at risk of local recurrence around the anastomosis. The mortality rate after total gastrectomy ranges from 1.3% to 9.5% [22-24], as compared with 0.8% to 5.9% after distal gastrectomy [22-27]. Distal gastrectomy is thus consid-

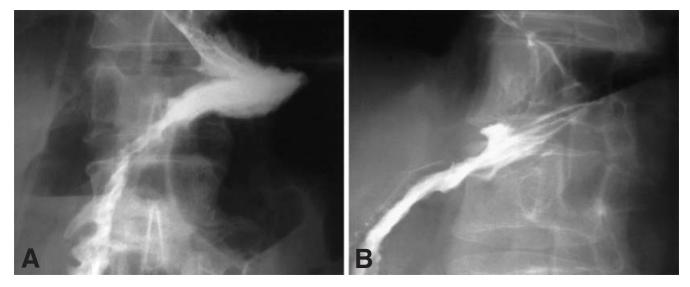


Fig. 3A,B. X-ray films obtained at fluoroscopic examinations on postoperative day 7. A Mechanically stapled anastomosis; B hand-sutured anastomosis

ered to be safer than total gastrectomy. However, suture failure of the anastomosis is an important cause of operative mortality. Safer techniques for anastomosis are therefore urgently required.

Several techniques have been described for Billroth I reconstruction with a mechanically stapled anastomosis [11,28–30]. Some authors perform anastomosis before gastrectomy, whereas others perform anastomosis to the posterior wall of the residual stomach. We incised the anterior wall of the residual stomach after gastrectomy, inserted the mechanical stapler, and performed the anastomosis, as described by Nance [11], at the same site as that used for hand suturing. This reconstruction technique has several advantages. (1) Because the anastomosis is done after gastrectomy, the resection line of the stomach can be accurately defined, similar to a hand-sutured anastomosis; in addition, the shaft of the stapler does not come in contact with cancer tissue. (2) The shaft of the stapler can be easily inserted into the residual stomach, reducing twisting of the stomach at the time of the performance of the anastomosis. (3) Because the anastomosis is performed at the same site as that used for hand suturing, a blind sac is not formed. (4) Blood flow to the anastomosis is preserved.

Regarding the cost mechanically stapled anastomoses require approximately \(\frac{4}{60000}\) for the stapler; however, this cost can be paid back by the insurance system in Japan. There is not a great difference between the costs of the two anastomosis techniques, as stated in the "Results."

In conclusion, our randomized study comparing hand-sutured with mechanically stapled anastomoses demonstrated that stapled anastomoses required a significantly shorter time to complete the procedure. The incidence of complications, such as leaks and stenosis, was higher after hand-sutured anastomoses than after mechanically stapled anastomoses, although no statistically significant differences in these parameters were observed between the two groups. The results showed that mechanically stapled anastomoses are equivalent to those with hand-sutured anastomoses. The shorter time required for mechanically stapled anastomoses is likely to place less stress on the surgeon as compared with the time required for hand-sutured anastomoses.

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