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Topics: Toward zero pancreatic fistula after distal pancreatectomy

A simple and safe pancreas transection using a stapling device for a distal pancreatectomy

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Abstract Pancreatic fistula is the most common major complication to occur after distal pancreatectomy, ranging in frequency from 5% to 40%. The appropriate technique for treating the pancreatic stump still remains controversial. Thirty-six patients underwent distal pancreatectomy in Kagawa University Hospital between January 2000 and February 2007. Their hospital records were reviewed to evaluate the usefulness of a stapling closure using several types of staplers in comparison to a suture closure. They were subdivided according to the method used to close the pancreas stump: the suture group comprised 11 patients, the staple group comprised 24 patients, including 7 patients for whom was used the new endopath stapler Echelon 60 (Ethicon Endo-surgery; Johnson & Johnson, Cincinnati, OH, USA). Overall pancreatic fistula rate was 17% (6/36) in this series. In the staple group, 3 of the 24 patients (12%) developed a pancreatic fistula, whereas in the suture group, 3 of 11 patients (27%) developed a pancreatic fistula. Of the 7 patients for whom the Echelon 60 was used, none developed a pancreatic fistula. The length of postoperative hospital stay was also significantly shorter for the patients with the Echelon 60 than in the patients either with sutures or another stapling device. These findings support the advantages of using a stapler closure in distal pancreatectomy. This method, using a new stapler device, is considered to be a simple and safe alternative to the standard suture closure technique.

Key words Distal pancreatectomy · Staple closure · Pancreatic fistula

Introduction

Although mortality after distal pancreatectomy has significantly decreased during the past decade, the morbidity rates have remained unchanged, ranging from 10% to 47%.[1–3] In general, such problems prolong the hospital stay for specialized treatment, including reoperation and drainage.[4] As pancreatic fistula is the most common postoperative complication and occasionally leads to intraabdominal abscess, sepsis, and serious hemorrhage, the appropriate closure of the pancreatic stump is the most important subject in this surgical procedure. Several surgical techniques and instruments for treating the surgical stump after distal pancreatectomy have been proposed, including hand-sewn sutures, staplers, the use of pledgetted sutures, fibrin-glue sealing, and prolamine injection.[2,5–15] The most commonly used techniques for pancreas remnant management are the suture and staple closure. The aim of this study was to determine the usefulness of performing a staple closure after distal pancreatectomy and herein report the standard procedures and new treatment techniques using a stapling device.

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Patients and methods

Patients

A retrospective review of the 36 patients who underwent distal pancreatectomy between January 2000 and February 2007 at Kagawa University Hospital was conducted. The indications for distal pancreatectomy are summarized in Table 1, including 27 malignant diseases and 9 benign diseases. In 10 patients with gastric cancer, total gastrectomy was performed with distal pancreatectomy to resect the lymph nodes or tumor invasion to the pancreas. In 1 patient with transverse colon cancer, a left hemicolectomy was performed with distal pancreatectomy to resect tumor invasion to the pancreas.

Surgical procedure

The changing trends regarding the closure method are described in detail in Table 2. Before January 2003, we

Table 1. Indications for distal pancreatectomy

	No. of patients (36)
Malignant	27
Invasive ductal adenocarcinoma	11
Gastric cancer	10
Endocrine tumor	3
Colon cancer	1
Liposarcoma	1
Metastatic tumor	1
Benign	9
IPMN, MCN, LEC	6
Chronic pancreatitis	2
Trauma	1

IPMN, intraductal papillary mucinous neoplasms; MCN, mucinous cystic neoplasms; LEC, lymphoepithelial cyst

Table 2. Changing trends in the surgical procedures for distal pancreatectomy (2000–2007)

No. of patients	Suture method (11)	Staple method (24)	Other (1)
2000–2002	10	0	0
2003–2005	1	15	0
2006–2007	0	9	1

Table 3. Selection of the stapling device

Stapling device	No. of patients (24)
EndoGIA 45-60	10
Echelon 60 EC/SC60	7
Endocutter ETS-45	2
Proximate linear stapler TL-60	2
GIA 60	2
Linear cutter 75	1

mainly performed a suture method to close the pancreatic stump. In the suture method, the pancreas was transected with a knife, followed by the identification of the main pancreatic duct and then the closure of the duct using double stitches with either 3-0 or 4-0 polydioxanone (PDS) suture (Ethicon Endo-surgery; Johnson & Johnson, Cincinnati, OH, USA). The parenchyma was then closed using single stitches with either 4-0 or 5-0 PDS.

Standard procedure using the stapling device

After February 2003, our closure method was changed to a staple method from the suture method. In the staple method, several types of stapling devices were used for closure, depending on the discretion of the surgeon between February 2003 and January 2006 (Table 3). We began using the Echelon 60 stapler mainly for distal pancreatectomy from February 2006, as the Eschelon 60 provides precise and uniform wide compression throughout the entire 60-mm length and works with a wide range of cartridges, which can thus attach two triple-staggered rows of titanium staples (Fig. 1).

The operating procedure is as follows. The spleen and the distal pancreas were mobilized after division of the gastrocolic ligament with the visualization of the pancreas. The splenic artery and vein were then individually ligated using double stitches of 3-0 vicryl close to the planned dissection line of the pancreas. The pancreas was then transected with the stapling device, using the Echelon 60 with a gold cartridge (compressible thickness to 1.8 mm) (Fig. 2A). The device produces a staple line consisting of a triple row of closely placed staples (see Fig. 1). With the Echelon 60 stapler, an excellent articulation is achieved because the pressure is even throughout the entire length of the closure jaw; the pressure on the tissue is more uniform than with other devices. The closure jaw was clamped carefully and slowly taking more than 5 min at a fixed speed. To ensure hemostasis of the pancreatic stump, the stapler was not released immediately after firing, and the jaws of the stapler were held shut for 2 min. Occasionally, depending on the texture of the pancreas and on the discretion of the surgeon, either blue or green cartridges were used. In some cases, the pancreas was gently compressed with an atraumatic intestinal clamp at the transection line for a few minutes before performing the stapling transection (Fig. 2B). This procedure reduced the thickness of the pancreatic parenchyma at the site of planned resection and facilitated the subsequent application of the linear stapler across the pancreas. A ligation of the main pancreatic duct was not necessary, and minor bleeding from the stump could be easily controlled by either compression or coagulation using electrocautery. In a few cases, single Z stitches using 5-0 PDS were applied to control bleeding. This staple procedure with the above-described techniques provides a secure staple line without any tissue tearing (Fig. 2C).

Diagnostic criteria for a clinical pancreatic fistula and management

Local findings were used to diagnose a postoperative pancreatic fistula: saponification of the drainage fluid, skin excoriation around the drain site, or a high concentration of amylase, and more than 10000 IU/l in the drainage fluid after postoperative day 3. There was no standard treatment protocol for pancreatic fistula. The basic principle of the management was appropriate drainage. In general, oral food intake was stopped, and either the drains were left in place or interventional drains were put into place. In some cases, protease inhibitor or octeotide was given for several weeks.

Fig. 1. The endopath stapler (Echelon 60) delivers a true 60-mm staple line and works with a wide range of cartridges including white, blue, green, and gold cartridges. The cartridges have an internal cutting knife, and they can place two triple-staggered rows of titanium staples

Statistics

The background characteristics and surgical outcome measures were compared using Fisher's exact test for categorical data and the Mann–Whitney *U* test for continuous data. The results are presented as the mean ± SD. A *P* value of less than 0.05 was considered to be statistically significant.

Results

There were no statistical differences between the two groups regarding the clinical background. On review, there was no in-hospital mortality, and 6 pancreatic fistulas (17%) occurred in this series. In the staple group, 3 of 24 patients (12%) developed a pancreatic fistula, whereas in the suture group, 3 of 11 patients (27%) developed a pancreatic fistula (see Table 5). The selection of the stapler device is summarized in Table 3. Three patients who developed pancreatic fistula were treated by Endo GIA45, proximate linear stapler TL-60 or GIA60, depending on the individual case. In the case of Endo GIA45, additional second stapling was required to perform an entire transection of the pancreatic parenchyma. All the surgical devices with a 60-mm staple line could provide an entire transection by single stapling. None of the 7 patients for whom the Echelon 60 was used developed a pancreatic fistula.

The selection of the cartridge is summarized in Table 4. The cartridge type was chosen according to the texture and thickness of the pancreas, according to the discretion of the surgeon; blue cartridges were mainly used before January 2006. The gap setting for TL-60 was a 2-mm thickness. The Echelon 60 uses the newly developed gold cartridge (1.8 mm). The gold cartridges were mainly used for the standard dissection line (usually to the left of the superior mesenteric vein) of the pancreas with a normal texture after January 2006.

The length of the postoperative hospital stay was significantly shorter in the patients with the Echelon 60 than in the patients with either sutures or other stapling devices. The postoperative outcome of these patients is summarized in Table 5. All six patients with pancreatic fistulas were successfully managed conservatively with drainage and medications.

Discussion

The management of the pancreatic remnant following distal pancreatectomy remains a clinically relevant problem. Duct ligation, ultrasonic dissection, fibrin glue, patches and meshes, pancreaticoenteric anastomosis, and hand-sewn and stapler closures are all examples of the various efforts made to reduce the occurrence of postoperative pancreatic fistula.[2,5–15] Pancreatic fistula formation is a main source of postoperative morbidity and it is associated with numerous further complications, such as sepsis, an electrolyte imbalance, and hemorrhaging.

There have been many reports describing the usefulness of a stapler transection for the pancreas as a simple, quick, and secure method of closure of the proximal pancreas.[7,14] Conversely, a meta-analysis indicated neither a suture closure nor a stapler closure was found to be a significantly influencing factor with respect to pancreatic fistula formation, although pancreatic leakage did tend to occur more often after hand suturing.[16]

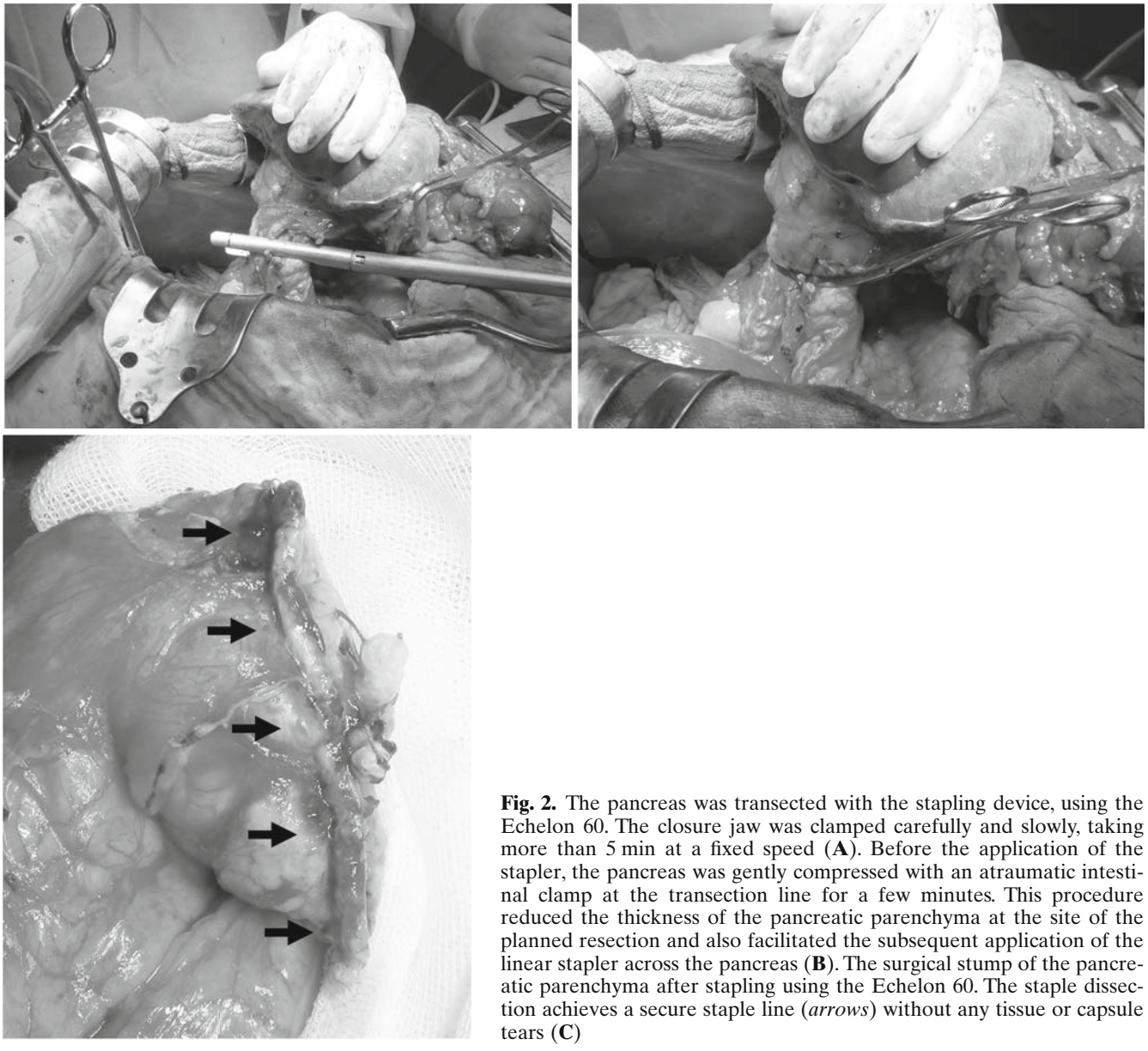

Fig. 2. The pancreas was transected with the stapling device, using the Echelon 60. The closure jaw was clamped carefully and slowly, taking more than 5 min at a fixed speed (**A**). Before the application of the stapler, the pancreas was gently compressed with an atraumatic intestinal clamp at the transection line for a few minutes. This procedure reduced the thickness of the pancreatic parenchyma at the site of the planned resection and also facilitated the subsequent application of the linear stapler across the pancreas (**B**). The surgical stump of the pancreatic parenchyma after stapling using the Echelon 60. The staple dissection achieves a secure staple line (*arrows*) without any tissue or capsule tears (**C**)

Table 4. Selection of the cartridges for the stapler

Cartridge (compressible thickness, mm)	No. of patients (24)
Green (2.0 mm)	3
Gold (1.8 mm)	7
Blue (1.5 mm)	10
White (1.0 mm)	2
TL-60 (flexible)	2

Takeuchi et al.[14] described a statistically significant reduction in the fistula rate after a stapler closure using the Powered Multifire Endo GIA 60 in comparison to a suture closure (pancreatic fistula: stapler, 0% versus suture, 35%). Fahy et al.[2] described suture closure to be a risk factor for fistula. On the other hand, the opposite result was reported by Sheehan et al.,[13] who found the hand-sewn closure of the pancreatic stump to be superior to the stapling method (pancreatic fistula: stapler, 25% versus suture, 14%). In addition, two observational studies showed no difference at all. In a series of 35 patients undergoing distal pancreatectomy with the GIA-80 stapler (US Surgical, Norwalk, CT, USA), Kajiyama et al.[7] observed fistulas in 40%, in comparison to 46% in a historical control group who received a suture closure.

A recently published large consecutive series of distal pancreatectomy cases indicated a stapler closure to be

Table 5. Postoperative outcome for distal pancreatectomy

Method	No. of patients	Pancreatic fistula (%)	Length of postoperative stay (days), mean ± SD
Suture	11	3 (27%)	50 ± 22
Staple	24	3 (12%)	35 ± 21
EndoGIA 45-60	10	1 (10%)	30 ± 13
Echelon 60	7	0	15 ± 4*#
Other staple device	7	2 (28%)	56 ± 19

* $P = 0.004$ compared to the suture method
# $P = 0.025$ compared to other staple devices

associated with a significantly higher fistula rate.[17] There was a difference in the pancreas fistula rate between the three different methods, with 15.9% in the stapler group, 9.3% in the suture group, and 8.3% in the seromuscular patch group. In their series, the pancreas was transected with an ETS flex 45 cutter with a white vascular cartridge. This incidence might reflect either torn tissue or tissue tears in the pancreatic parenchyma. The most important and technically difficult step of stapler dissection is to prevent pancreatic tissue tearing during compression. In our series, the stapler jaw was clamped carefully and slowly during more than 5 min at a fixed speed. Furthermore, the pancreas was gently compressed with an atraumatic intestinal clamp at the transection line for a few minutes before performing the stapling dissection to reduce the thickness of the pancreatic parenchyma at the site of the planned resection. Appropriate cartridge selection might be another important factor for reducing the damage to the pancreatic parenchyma. Gold or blue cartridges (1.8- or 1.5-mm compressible thickness) are thought to be appropriate for the pancreas with a normal texture in our experience. A case using double stapling with cartridges measuring 45 mm in length for the entire dissection of the pancreas body developed pancreatic fistula in our series. Single stapling with a 60-mm length cartridge is therefore recommended for distal pancreatectomy, as a staple-on-staple line is thought to be a risk factor for leakage in the gastrointestinal anastomosis.[18]

Since modern surgical stapling instruments have found a wide range of uses in gastrointestinal surgery, many studies have attempted to establish safe and alternative stapler techniques for distal pancreatectomy. Pachter et al.[19] described the efficacy of the TA-55 stapler (Tyco Healthcare), which has two triggered stainless steel staple lines for performing distal pancreatectomy. Kajiyama et al.[7] later reported the GIA-80 stapler (Tyco Healthcare), which similarly places two lines of titanium staples, to result in a lower incidence of pancreatic fistula in comparison to the TA-55 stapler. In addition, Takeuchi et al.[14] more recently reported the Endo GIA stapler, which places three rows of titanium staples, to be useful for preventing pancreatic fistula after distal pancreatectomy. However, the frequency of pancreatic fistula after distal pancreatectomy using these two- to three-row staplers has been reported to vary, and the clinical benefits using these staplers remain controversial.[13,16] If the closure of both the main pancreatic duct and the small pancreatic branches is critical for the prevention of pancreatic fistula after distal pancreatectomy, then the safest device would be a stapler that places many rows of closely aligned staples. However, the broad width of the staple zone might cause ischemic changes in the pancreatic parenchyma followed by necrosis. Three rows of titanium staples in the closure line is considered to be sufficient to prevent pancreatic fistula after distal pancreatectomy, based on our experience. Takeuchi et al.[14] recommended using the GIA stapler without a ligation of the main pancreatic duct or any additional suturing of the pancreatic parenchyma when performing distal pancreatectomy. We also did not use any additional suturing along the staple line in our patients and have not experienced any obvious clinical inconvenience.

The Endopath stapler Echelon 60, which has an ergonomic handle that permits surgeons to close the jaws gently, provides a precise and uniform wide compression throughout the entire length of the closure jaw, while also providing a six-row capability. The Echelon 60 seems to be a one of the best stapling devices available for performing distal pancreatectomy, as it has a design with an enhanced compression that features the combination of a rigid anvil and a new three-point gap control for consistent staple formation.

A systematic review of mostly observational data revealed insufficient sample size, selection bias, nonhomogeneous or even missing definitions of pancreatic fistula, and other possible confounding factors.[16] A meta-analysis indicated a statistically nonsignificant, but possibly clinically relevant, trend toward the superiority of a stapler closure. Based on these findings, both the stapler transection and stapler closure of the pancreatic remnant should probably be regarded as the current state-of-the-art technique for distal pancreatectomy, to minimize the occurrence of pancreatic fistula. However,

even this preferred technique resulted in a fistula rate of 22.9%, according to a meta-analysis.

The present study suggested the advantages of stapler closure in distal pancreatectomy. The use of this new device is considered to be a simple and safe alternative to the standard suture closure technique, by using this new stapler device with several associated new techniques. A RCT must also be conducted in the future to confirm and validate the results of the above findings. Such further studies should verify whether a stapler closure of the pancreatic remnant is truly superior to other closure methods.

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