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Evaluation of a Transection Method for Distal Pancreatectomy : A Comparative Study on the Use of Electrosurgical and Stapling Devices in Swine

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Abstract

Background : Despite marked improvements in pancreatic surgery, the high incidence of pancreatic fistula and high morbidity after resection persists.

Purposes : The objective of this study was to evaluate the role of electrosurgical and stapling devices as an alternative to traditional methods of stump closure in an animal model of distal pancreatectomy.

Methods : Four devices were used for transection of the pancreatic body : a bi-polar thermofusion system attached to an automatic irrigation function (BI, n = 3), a bi-polar tissue sealer (BS, n = 3), an ultrasonic scissor (US, n = 3), and an endoscopic stapling device (ES, n = 3). For each group, burst pressure was tested using an electronic manometer, with a focus on the location (s) of the first disruption (s). Histological examination was performed for the dissected surfaces. The transection line, including staples, was embedded in a polyester resin, and histological examination was performed for these polished sections of the resin.

Results : Pressure was significantly higher for BI ($P < 0.01$) than that for the other devices. In contrast, thermal denaturation of the pancreas parenchyma was observed at a depth of approximately 1 mm from the dissected portion for BS, while it extended beyond 15 mm for BI. The staple line was the first disruption point for all of ES cases.

Conclusions : The pellicle of the pancreas is likely to be deficient after a surgical operation. If the pellicle is preserved, the strength of the pellicle may be insufficient for complete closure with high stapling mechanical pressure or the protein coagulation of usually used electrosurgical devices.

Key words : Distal pancreatectomy · Pancreas fistula · Electrosurgical devices · Stapling devices · Bursting pressure

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Introduction

It is often difficult to obtain a good operative field for distal pancreatectomy (DP) for pancreatic lesions because the pancreas is located deep in the body. Consequently, laparoscopic surgery offers some advantages for such lesions because reconstruction is not needed after the procedure. Moreover, given the national health insurance coverage in Japan for laparoscopic DP since 2012, particularly for that preserving the spleen and splenic vessels, it can be suggested that this type of surgery will become the primary treatment of choice for benign and low-grade malignant tumors in the body and tail of the pancreas.

According to a recent meta-analysis, the rate of postoperative complications after DP ranged from 13.3% to 64%¹⁾. The most common complication is pancreatic fistula. Despite the existence of a large variety of techniques for the closure of the pancreatic stump after DP, pancreatic fistulas continue to be the most frequent and relevant surgical complication. The development of pancreatic fistulas increases the length of hospital stay and the cost of treatment and can cause life-threatening complications such as abdominal bleeding, abscess formation, and septicemia. Therefore, it is essential to explore a safe and effective way to prevent pancreatic fistula. However, the coexistence of multiple technologies reflects the present situation that an effective and widely accepted stump-treating method is absent for DP.

In the present study, we evaluated transection methods during the laparoscopic DP to find the preventive measures.

Methods

Animal care

Nine healthy female Japanese domestic pigs (age, 3–4 months; weight, 30–38 kg) were used in this study. This study was conducted in accordance with the principles and authorization of the Helsinki declaration for animal studies. Animals

were fasted overnight prior to the experiments but were allowed free access to water. For initial sedation, ketamine, at a dose of 10 mg/kg, was administered intramuscularly (IM), and intravenous (IV) access was obtained via marginal ear vein cannulation, performed using large-gauge venous catheters. Atropine, at a dose of 0.05 mg/kg IV, was administered 5 min before intubation to help dry secretions, and anesthesia was maintained using 1% napental at a dose of 0.5 a dose of, as needed. The pigs were intubated endotracheally, and anesthesia was maintained by administering a mixture of nitrous oxide, oxygen, and isoflurane (Forane; Dainabot Ltd., Tokyo, Japan). Perioperative fluids consisted of Plasma-Lyte (balanced salt solution) at 20 mL/kg. Oxygen saturation and heart rate were monitored using a pulse oximeter placed on the ear.

Pancreatic transection devices

Four devices were used for transection of the pancreatic body: a bi-polar thermofusion system (BiClamp[®], ERBE Elektromedizin, Tübingen, Germany) attached to an automatic irrigation function (BI, n = 3) (Fig. 1), a bi-polar tissue sealer (ENSEAL[®], Ultracision, Ethicon Endo-Surgery Inc, Cincinnati, OH, USA) (BS, n = 3), an ultrasonic scissor (Harmonic ACE[®], Ultracision, Ethicon Endo-Surgery Inc, Cincinnati, OH, USA) (US, n = 3), and an endoscopic stapling device (ECHELON ENDOPATH[®]) (ES, n = 3).

Surgical procedure

Through a midline laparotomy, the liver, pancreas, spleen, and duodenum were excised en bloc. After separating the splenic artery and vein from the pancreas, the thickest portion of the dorsal lobe of the pancreas (approximately 4–6 cm of the distal pancreas) was transected using each of the devices. During transection with BI, the pancreas body was compressed and coagulated slowly around the planned transection line in a 10-mm wide area, while irrigation with saline was maintained at a rate of 50 mL/h. Then, the

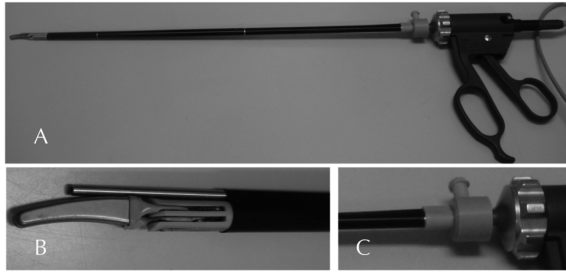


Fig. 1 The prototype forceps of bipolar high-frequency electric cautery attached an automatic irrigation function. The overall picture is shown A, the tip spout is shown B and the water supply inlet is shown C.

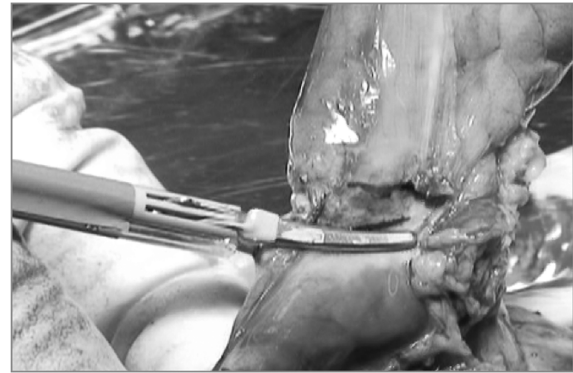


Fig. 2 The dorsal lobe of the pancreas (approximately 4–6 cm of the distal pancreas) is compressed and coagulated in a 10-mm wide area with a bi-polar thermofusion system (BiClamp®) attached to an automatic irrigation function (BI).

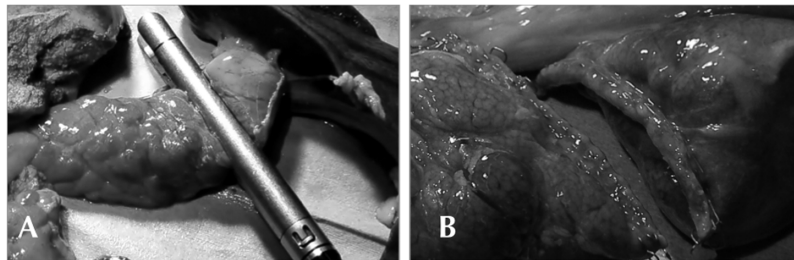


Fig. 3 A : The dorsal lobe of the pancreas (approximately 4–6 cm of the distal pancreas) is compressed with a endoscopic staler (60-mm green fork) for 5 min.
B : The pancreas immediately after transection in the body.

pancreas was transected with scissors at the distal margin of the coagulated area (Fig. 2). During transection with ES, only a 60-mm green fork was used. Both jaws were closed slowly, and the pancreas was compressed on the planned transection line for 5 min, followed by gradual stapling for 5 min and cutting (Fig. 3).

Pressure test of the anastomosis

A 4-Fr vinyl chloride tube was inserted from the pancreatic duct opening in the duodenum (located 10 cm to the anal side of the bile duct opening) to the pancreatic duct of the dorsal lobe and was placed near the tip of the tube, 3 cm ahead of the planned dissection line (Fig. 4). The pressure resistance of the resection surface of the pancreas body was tested. Air leakage was monitored by placing the specimens in a water-filled basin and observing escaping air bubbles. Burst pressure was measured using an electronic manometer (PG-100N ; Copal electronics, Tokyo,



Fig. 4 Black arrow : A 4-Fr vinyl chloride tube is inserted in the orifice of bile duct in the duodenum.
White arrow : Same tube is inserted in the orifice of pancreatic duct in the duodenum.

Japan) the moment the air leak began. Special attention was paid to the location (s) of the disruption (s). Differences between groups were analyzed using JMP 9.0 software and subjected to the Student's t-test.

Histological examination

For evaluating thermal damage, transected pancreas sections were fixed, embedded in paraffin, serially cut, and stained with hematoxylin and eosin. The mean depth of thermal damage was calculated using the depth of thermal damage recorded at 3 locations : at 1 cm each cranial, caudal, and central to the transected pancreas stump.

Specimens from stapled regions were preserved in formalin, embedded in polyester resin, and polished to 80- μ m thickness using a type HT hard tissue polishing apparatus (Maruto, Tokyo, Japan). The regions were polished as parallel as possible to the linear transection line of the staple. The polished tissue sections were stained with Cole's hematoxylin and eosin.

Results

The thickness of the parenchyma of the transected portion was 22.3 ± 2.5 mm.

The pressure resistance for each devices was as follows : BI (n = 3), 78.00 ± 17.43 mmHg ; BS (n = 3), 10.33 ± 6.5 ; US (n = 3), 7.67 ± 1.53 ; and ES, 21.33 ± 9.02 mmHg. Pressure resistance were significantly higher in BI than that for other electrosurgical devices and ES ($P < 0.01$) (Table 1).

The depth of the thermal damage from the transection surface for each device was as follows : BI (n = 3), 13.33 ± 1.53 mm ; BS (n = 3), 2.67 ± 0.58 ; and US (n = 3), 1.67 ± 0.69 mm. The depth of the thermal damage from the transection surface were significantly deeper in BI than other electrosurgical devices (BS and US) ($P < 0.01$).

The first disruptions occurred on the staple

Table 1. Results of pancreatic dissection.

Devices	Number	Pressure resistance (mmHg)	P	Thermal damage (mm)	P
Electrosurgery	BiClamp [®]	3	78.00 ± 17.43	13.33 ± 1.53	<0.01
	ENSEAL [®]	3	10.33 ± 6.5	2.67 ± 0.58	
	Harmonic ACE [®]	3	7.67 ± 1.53	1.67 ± 0.69	
Staple	ENDOPATH [®]	3	21.33 ± 9.02	—	

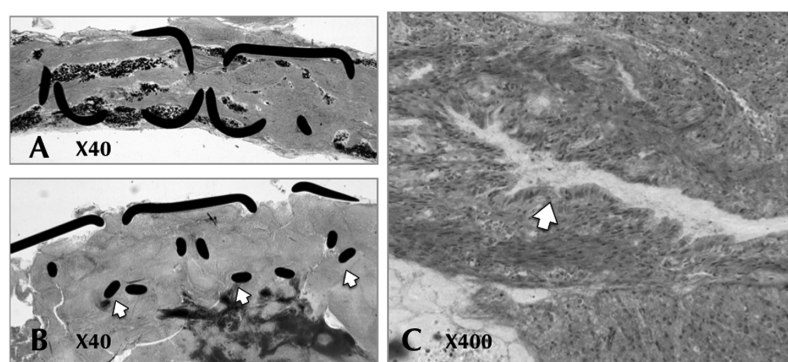


Fig. 5 A : Shows a separating line when transected the ventral lobe of the pancreas of about 10mm in thickness by the endoscopic stapler. All visible staples are transformed into a suitable form and are gripping the pancreas.
B : Shows a separating line when transected the dorsal lobe of the pancreas of about 22mm in thickness by the endoscopic stapler. Although, all visible staples are transformed into a suitable form, they are found to be embedded in the parenchyma of the pancreas (arrows).
C : Shows the patent pancreatic duct (arrow) is observed in the sections of a transected dorsal lobe was 10mm in thickness.

lines in specimens stapled using ES. And also in electrosurgical devices group (BS and US) except for BI, the first disruptions occurred at the opening of the main pancreatic duct on the transected surface.

Histological examination of stapled regions is shown in Figure 5. Although all visible staples have been transformed into a suitable form, they were found to be embedded in the parenchyma of the pancreas (Fig. 5B). The patent pancreatic duct was observed in the sections (Fig. 5C).

Discussion

In the preliminary stage while transecting the pancreas, liver dissections were performed using electrosurgical and stapling devices. For achieving sufficient hemostasis of the dissected hepatic surface, it was found that electrosurgical devices were better at withstanding intraluminal pressure than stapling devices. However, both devices exerted maximum physiological pressure on the bile duct. In contrast to open surgery, in laparoscopic dissection of the liver parenchyma, the hemostasis and closure of the small Glisson sheath by suturing or ligature is rarely achieved. However, the incidence of postoperative bile leakage was found to be only 2–3%.

The pancreas is quite different from the liver. In the conventional method of pancreatic duct ligation and suturing of pancreatic parenchyma and even in the recent transection method involving stapling, pancreatic fistulas occurred in more than 30% of patients²⁾³⁾. Despite marked improvements in pancreatic surgery, the high incidence of pancreatic fistula and high morbidity after resection persists. Therefore, we conducted this study to determine differences in such procedures for the liver and pancreas by focusing on the differences between the pellicles of both organs. The pellicle of the liver closely adheres to the liver parenchyma and surrounds the hepatic lobules in the liver parenchyma. The hepatic pellicle also surrounds from outside the Glisson sheath containing the portal vein, the hepatic

artery, and bile duct. The pellicle of liver is composed of collagen fibers. In the liver parenchyma, the bile duct is covered by the pellicle of the liver and Glisson sheath of the other bile duct. When the liver parenchyma is dissected using electrosurgical or stapling devices, the bile duct is closed by closing the triple membranes.

However, the pellicle of the pancreas covers the pancreatic parenchyma outside the splenic artery and vein. Therefore, when the splenic artery and vein are dissected from the pancreatic parenchyma, the pellicle is simultaneously peeled off from the pancreatic parenchyma. Because the pellicle of the pancreas appears to float unsteadily from the pancreas parenchyma, it can be easily peeled off during surgery. The pellicle of the pancreas also enters the parenchyma and covers the vessels and pancreatic duct. However, the pellicle of the pancreas contains a wealth of fat and the proportions of the collagen required to closer is less. In this experiment, the pancreatic duct was closed completely when enough compression at suitable temperature were applied to pancreas in more than 10 mm wide area. The thermofusion device attached an automatic saline dripping function is necessary to prevent the instrument from sticking to the tissue. However, with advances in surgical tools and apparatuses in recent years, many attempts have been made to reduce the incidence of pancreatic fistula formation; these attempts include resection using a linear stapler or an ultrasonic dissection device, the use of a radiofrequency-assisted transection device, spraying fibrin sealant, ensuring secure placement of the jejunum and the stomach onto the pancreatic stump, and anastomosis of the jejunum and pancreatic duct at the stump^{4)–11)}. The technique of wrapping the pancreatic stump with bovine pericardium combined with closure by manual sewing was reported to prevent pancreatic fistula formation¹²⁾¹³⁾. The results of a recent registered clinical trial showed that prophylactic pancreatic stent placement does not reduce pancreatic fistula formation when per-

forming a standardized resection of the body and tail of the pancreas.

Therefore, further studies are needed to develop pancreatic transection methods, taking into account the pellicle of the pancreas.

Disclosures

Drs. Tetsuo Ikeda, MD, PhD¹, Hirofumi Kawanaka, MD, PhD², Hideaki Uchiyama, MD, PhD², Yoichi Yamashita, MD, PhD², Masaru Morita, MD, PhD², Eiji Oki, MD, PhD², Hiroshi Saeki, MD, PhD², Keishi Sugimachi, MD, PhD³, Toru Ikegami, MD, PhD², Tomoharu Yoshizumi, MD, PhD², Yuji Soejima, MD, PhD², Ken Shirabe, MD, PhD², Koshi Mimori, MD, PhD³, Masayuki Watanabe, MD, PhD⁴ and Yoshihiko Maehara, MD, PhD² have no conflicts of interest or financial ties to disclose.

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(和文抄録)

膵切離方法の検討：動物実験における高周波電気器機と吻合器の比較検討

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【背景】膵臓に関する手術手技の進歩にも関わらず，膵切離後膵液瘻の発生頻度は減少しておらず，依然として最も重大な合併症である。

【目的】この研究の目的は近年従来の膵管結紮，膵実質切離に変わって，鏡視下手術の普及と共に一般に行われるようになった，膵の高周波電気器機と吻合器での切離方法を動物実験によって評価し最適な切離方法を検討する事にある。

【方法】4つの器機を用いて膵体部での切離を行った。使用した器具は① bi-polar thermofusion system (BiClamp[®]) に自動 irrigation 装置を装着した器機 (BI) (n = 3)，② bi-polar tissue sealer (ENSEAL[®]) (BS) (n = 3)，③ ultrasonic scissor (Harmonic ACE[®]) (US) (n = 3)，④ endoscopic stapling device (ECHELON ENDOPATH[®]) (ES) (n = 3) である。ブタを用いて全麻下に，肝，膵，脾そして十二指腸を一回に摘出し膵体部の切断を4種の器具を用いて行った。十二指腸乳頭の膵管開口部より背側膵管にカニューレーションを行い膵切離断端の耐圧力を測定した。また高周波電気器機での切離断端のみではなく，吻合器での切離断端も polyester resin 樹脂化標本の研磨切片から Stapler での切離線の組織学的評価を行った。

【結果】切離断端の膵管耐圧力は BI で約 10mm の膵を thermofusion 後に尾側で切断する方法のみで高い耐圧能を認め，他の方法と比較して有意な差を認めた ($P < 0.01$)。組織学的には BI では 15mm 程度の熱変性を認めたのに対して BS や US では熱変性の深さは 1mm 程度であった。Staple 切離線の組織所見では各々の staple は正常に閉鎖した形となっていたが，staple は膵実質に食い込んでおり切離面に開存した膵管を認めた。

【結語】膵臓断端の十分な閉鎖は高周波電気器機や吻合器では得られなかった。適切な膵切離には膵の被膜の形態を考慮した閉鎖方法を検討する必要があると考えられた。