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TECHNICAL NOTE

Use of the new ultrasonically curved shear in pancreaticoduodenectomy for periampullary cancer

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Abstract
Objectives To examine whether the use of the new ultrasonically curved shear (UCS) can reduce the number of surgical stitches, extent of blood loss, and operation time in (pylorus-preserving) pancreaticoduodenectomy (PD) for periampullary cancer.
Methods The study population comprised 26 consecutive patients who underwent PD for periampullary cancer. Intraoperative data, including number of stitches used, was prospectively collected. Results from 13 patients who underwent conventional PD (Group A) were compared with those from 13 patients who underwent PD using UCS (Group B).
Results There were no significant differences in baseline characteristics between the two patient groups. The extent of blood loss in Group B was significantly less than in Group A ($p < 0.0001$). Although there was no difference in total operation time, the time spent on hilar lymph node dissection was significantly shorter in Group B patients than in Group A patients ($p = 0.0189$). The number of surgical stitches used was significantly less in Group B patients than in Group A patients ($p < 0.0001$). There were no incidences of post-pancreatectomy hemorrhage.
Conclusion The use of the new UCS was safe and associated with the economical benefit of fewer surgical stitches as well as reduced blood loss.

Keywords Number of surgical sutures · Extent of blood loss · Operative time · Surgical cost · Harmonic focus curved shear

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Introduction

In recent years, mortality and morbidity in pancreaticoduodenectomy (PD) including pylorus-preserving PD (PpPD) have decreased due to advances in surgical techniques and appropriate perioperative management. In most high-volume centers, mortality has decreased to less than 5%, although post-operative morbidity remains at approximately 40% [1–5]. Intraoperative bleeding and blood transfusion have been reported to be two main risk factors for post-operative complications after PD [3, 6, 7]. It is important to obtain effective hemostasis and to minimize the extent of devitalised tissue as well as the presence of foreign bodies, such as surgical sutures and charred tissue, during the surgery to prevent post-operative complications.

Several types of energy-based surgical devices that dissect, seal, cauterize, and transect vessels and viscera are commercially available. Ultrasonic energy devices employ mechanical vibration for simultaneous coagulation and cutting. This device mechanically denatures protein by disrupting the hydrogen bonds within the protein structure and causes significantly less damage to the adjacent tissue [8]. The ultrasonically curved shear (UCS; FOCUS, Ethicon Endo-Surgery, Cincinnati, OH) is the newest device to be developed for fine and delicate dissections. The advantages of this device are its curved tip and its lightness and small size, making it a valuable tool for lymph node (LN) dissection. We hypothesized that the use of UCS would reduce the number of surgical sutures and the extent of blood loss during surgery as well as shorten the operation time for patients undergoing PD for periampullary cancer. In this study, we compared the intraoperative parameters of cancer patients who underwent PD using UCS ($n = 13$) with those of patients who underwent conventional PD ($n = 13$).

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Patients and methods

From September 2009 to April 2010, 26 consecutive patients with periampullary cancer underwent PD, including PpPD, at Kansai Medical University Hospital. Perioperative management was standardized according to departmental guidelines [9–11]. General and surgery-related complications were recorded prospectively throughout the study. In-hospital death, re-operation, or re-admission of a patient for any reason was also recorded.

We prospectively divided the 26 consecutive cancer patients who underwent PD into two study groups: Group A consisted of 13 consecutive cancer patients who underwent conventional PD between September 2009 and January 2010. Within this group, six patients (46%) had pancreatic cancer, including intraductal papillary mucinous cancer (IPMC). During PD, visible blood and lymphatic vessels, including anonymous vessels, were ligated or sutured with surgical stitches. Invisible vessels were coagulated and cut using monopolar electrocautery. Group B consisted of 13 consecutive cancer patients who underwent PD between February 2010 and April 2010. During PD, the UCS was used in all the dissection steps, while ligation and sutures were applied to the vessels mentioned above or to vessels >3 mm in diameter. The specimen-sided vessel was sealed with UCS. During the PD procedure, the number of stitches that were used specifically for tying or suturing vascular and lymphatic vessels was counted. The number of surgical stitches used for reconstruction was excluded because they were similar between the two groups. Intraoperative parameters of the extent of blood loss, operation time, and the number of surgical stitches were compared between the two groups.

The harmonic system (Ethicon Endo-Surgery) consists of a generator, a hand-piece, and an instrument. Electromagnetic energy is transmitted from the generator to a piezoelectric transducer in the hand-piece, which produces high-frequency ultrasonic mechanical energy that is delivered to the end effector of the instrument through a titanium shaft. The blade vibrates longitudinally at 55,500 times/s with a displacement of up to 80 μm. These vibrations generate heat energy, which can be utilized to cut and coagulate tissue simultaneously [12]. The power level of the generator was set at the third level (I–V). In this study, we used this system for sealing vascular and lymphatic vessels <3.0 mm in diameter.

Operative techniques

All patients underwent either subtotal stomach-preserving PD or PpPD. We divided the PD operation into four sections: (1) kocherization; (2) exposure of the portal vein (PV) and dissection of the LN around the superior mesenteric artery (SMA) and vein (SMV) (LN nos. 14 and 15, as defined by the Japan Pancreas Society [13]); (3) skeletonization of the hilar vessels and LN dissection; (4) removal of surgical specimen. The total operation time and the time spent completing each section were recorded and compared between the two groups.

Section 1 comprised kocherization, LN dissection around the celiac axis (CA) and the SMA in all patients; para-aortic LN dissection and right-sided dissection of the nerve plexus around the CA and the SMA were only carried out in patients with pancreatic ductal cancer. Section 2 comprised the exposure of the PV and LN dissection around the SMA and SMV. The middle or right colic artery or inferior mesenteric vein were divided when necessary. Section 3 comprised skeletonization of the hilar vessels and LN dissection of the hepatoduodenal ligament, transection of the common bile duct, division of the gastroduodenal and the right gastric artery, and LN dissection around the common hepatic artery and the CA. Section 4 comprised transection of the duodenum or the stomach and of the pancreatic neck, LN dissection of the left-sided SMA and SMV, a sacrifice of the jejunum by dividing the first (and the second) jejunal arteries, and division of the connective tissue and nerve plexus at the 12 o'clock position of the SMA, resulting in removal of the specimen. When limited macroscopic invasions of the PV or SMV were encountered, partial or segmental resection of these veins was performed. Subsequently, reconstruction was undertaken with an isoperistaltic limb of the jejunum in retrocolic fashion and anastomosed with pancreaticojejunostomy, followed by end-to-side choledochojejunostomy and an antecolic gastrojejunostomy or duodenojejunostomy with Braun anastomosis. The pancreaticojejunostomy was performed using duct-to-mucosa anastomosis without duct stenting as previously reported [10]. The closed-suction drain was placed near the pancreatojejunostomy. Four surgeons were involved in this study, and all procedures were carried out by three surgeons under the supervision of S.S.

Statistical analyses

The intraoperative parameters, including the number of surgical stitches, extent of blood loss, and operation time (overall and divided into the four sections), were compared between Groups A and B. Post-operative mortality, morbidity, the rate of re-operation and re-admission, and the length of in-hospital stay were also compared. Patient variables included age, sex, clinical diagnosis, co-morbid disease, obstructive jaundice, operative variables, and pre-operative blood tests (see Table 1). All data were entered into an electronic database on a personal computer. Continuous variables are expressed the as median and range. Statistical analyses, including the Mann–Whitney *U* test

Table 1 Patient demographics and baseline characteristics

Parameters	Group A ($n = 13$)	Group B ($n = 13$)	p value
Age (years)	64 (50–81)	72 (38–86)	0.166
Male:female	10:3	8:5	0.673
Disease			
Pancreatic ductal cancer	5	8	0.476
IPMC	1	1	
Bile duct cancer	4	2	
Ampullary cancer	2	1	
Duodenal cancer	1	1	
Neoadjuvant chemoradiation (−:+)	9:4	9:4	1.000
Total bilirubin (mg/dl)	0.9 (0.3–6.2)	0.6 (0.4–19.3)	0.817
Albumin (g/dl)	3.7 (2.9–4.6)	3.8 (2.8–4.7)	0.797
White blood cell count ($\times 10^2$/ml)	47 (37–84)	54 (32–97)	0.521
Hemoglobin (g/dl)	12 (9–15)	12 (11–15)	0.441
Diabetes mellitus (−:+)	11:2	8:5	0.378
Jaundice (−:+)	4:9	3:10	1.000
Type of operation (PD:PpPD)	7:6	9:4	0.688
Portal vein resection (−:+)	9:4	9:4	1.000
Operation time (min)	462 (354–633)	485 (307–577)	0.505
Blood loss (ml)	1231 (269–3853)	790 (239–1664)	0.043
Transfusion (allo:auto:none)	5:5:3	3:4:6	0.447
Resection of other organs (+:−)	5:8	6:7	1.000
Pancreatic duct diameter (>3:≤3 mm)	7:6	6:7	1.000

Data are given as the median value with the range given in parenthesis, or as the number of patients

IPMC Intraductal papillary mucinous cancer, *PD* pancreaticoduodenectomy, *PpPD* pylorus preserving pancreaticoduodenectomy, *allo* allogenic blood transfusion, *auto* autologous blood transfusion, *none* no transfusion

and Fisher's exact test, were performed using SPSS ver. 18.0 for Windows (SPSS, Chicago, IL). p values <0.05 were considered to be significant.

Results

Patient demographic and baseline characteristics, including surgical details The baseline characteristics of the 26 patients enrolled in the study are shown in Table 1. None of the variables differed significantly between the two groups. Among the operative characteristics, the extent of blood loss in Group B patients was significantly lower than that in Group A ($p = 0.043$). There were no differences in total operation time, rate of PV resection, and blood transfusion between the groups. There were four patients with ductal cancer of the pancreas in each group who underwent neo-adjuvant chemoradiation. Although there was no statistical difference in the rate of patients with invasive ductal cancer between two groups, 62% of Group B patients showed a higher tendency for this cancer, relative to 38% of Group A patients. The operation was divided into four sections and the time spent in each section was recorded, as shown in Table 2. The time spent in Section 3 (the hilar part) during surgery on Group B patients was significantly shorter than that spent on Group A patients ($p = 0.0189$), but no differences were found between the two groups for the time spent during surgery performing the other three sections of the procedure.

Table 2 Comparisons of operative time spent in the four sections of pancreaticoduodenectomy

Section of surgery[a]	Group A ($n = 13$)	Group B ($n = 13$)	p value
Section 1	63 (31–131)	57 (21–101)	0.284
Section 2	30 (22–59)	29 (16–100)	0.816
Section 3	90 (49–219)	68 (16–88)	0.0189
Section 4	76 (39–135)	61 (35–150)	0.643
Total time of PD	462 (354–633)	485 (307–577)	0.505

The data are expressed as the median, with the range in parenthesis, of the number of minutes recorded for each section of the surgery

[a] The operation into four sections: Section 1, kocherization; Section 2, exposure of the portal vein and dissection of the lymph node (LN) around the superior mesenteric artery and vein [SMV; LN nos. 14 and LN as defined by the Japan Pancreas Society [13]; Section 3, skeletonization of the hilar vessels and LN dissection; Section 4, removal of surgical specimen

Table 3 Comparisons of number of surgical stitches between two groups

Stitch type	Group A ($n = 13$)	Group B ($n = 13$)	p value
For suturing	48 (34–81)	49 (29–86)	0.682
For tying	200 (140–240)	36 (24–60)	<0.0001
Total of stitches	253 (180–314)	77 (58–130)	<0.0001

Data are expressed as the median, with the range in parenthesis, of the number of surgical sutures

Table 4 Comparison of post-operative complications

Parameters	Group A ($n = 13$)	Group B ($n = 13$)	p value
Overall complications	8	6	0.695
Septic complications	4	2	0.645
Re-operation	0	0	–
In-hospital death	1	0	1.000
Pancreatic fistula	4	5	1.000
Grade B/C	1	2	1.000
Delayed gastric emptying	3	0	0.220
Abdominal abscess	1	0	1.000
Hemorrhage	0	0	–
Wound dehiscence	2	2	1.000
Pneumonia	2	0	0.480
Peritoneal/pleural effusion	1	0	1.000
In hospital stay (POD)	14 (9–61)	12 (8–25)	0.164

Data are given as the percentage (%) of patients or as the median, with the range in parenthesis

POD Post-operative day

Comparisons of number of surgical stitches between the two groups As shown in Table 3, the number of surgical stitches for tying or suturing vascular and lymphatic vessels was compared between two groups. The number of absorbable and non-absorbable surgical sutures used for suturing bleeding points was not significantly different between the two groups. Significantly fewer surgical stitches were used for tying vascular and lymphatic vessels in Group B patients than in Group A patients ($p < 0.0001$). An 80% decrease in the number of surgical stitches used for tying was found in Group B, relative to Group A. Consequently, the total number of surgical stitches used in Group B patients was also significantly lower than that in Group A patients ($p < 0.0001$).

Post-operative complications

The post-operative course was complicated in 62% of Group A and 46% of Group B patients, respectively. As shown in Table 4 there were no differences in the frequencies of overall complications, septic complications, post-operative pancreatic fistula, post-pancreatectomy hemorrhage, re-operation, and in-hospital death between the two groups.

Discussion

Pancreaticoduodenectomy is the main abdominal surgical procedure associated with high morbidity and mortality. Intraoperative bleeding and blood transfusion have been reported to be two major risk factors for post-operative complications after PD [3, 6, 7]. Ultrasonic energy devices employ mechanical vibration for simultaneous coagulation and cutting. Such devices mechanically denature protein by disrupting the hydrogen bonds within the protein structure. Moreover, they are associated with a considerably lower production of thermal energy (up to 80°C), thus causing significantly less damage to adjacent tissue [8] The UCS (FOCUS; Ethicon Endo-Surgery) is the newest of such devices and is specifically designed for fine and delicate dissections. The advantages of this device are its curved tip and its light weight and small size, which make it an ideal tool for LN dissection during open abdominal surgery.

Our results demonstrate, as expected, that the use of UCS significantly decreased the number of surgical stitches and was associated with decreased blood loss and reduced surgical time (specifically during the hilar part of the PD). Notably, the UCS was useful for dissecting the hepatoduodenal ligament as well as the fat tissue, including the numerous small vessels between the pancreas parenchyma and the common hepatic artery, resulting in less blood loss and reduced operating time. The main limitation to our study was the small sample size and the non-randomized control trial which could have biased the outcome, although the study was conducted throughout by the same staff, all of whom followed standard perioperative management procedures during the short study period. The diseases in this study are various, although there was no difference between two groups. Since the surgical time spent in each section and the extent of blood loss can vary according to the severity of metastasis to the LN or type of cancer, a large-scale study is needed to verify the results of this study.

The UCS has been widely used in abdominal and laparoscopic surgeries and is a commonplace instrument even in hepatobiliary and pancreatic surgery. It has been used in thyroidectomy [14], tonsillectomy [15], mastectomy [16], gastrectomy [17], and hepatecomy [18]. The use of ultrasonic energy devices in body surface surgery is associated with decreased blood loss and a reduced operation time or a smaller skin incision [14–16]. Tsimoyiannis et al. [17] reported that the use of an ultrasonic energy device in gastric surgery is a safe method of lymphatic dissection,

reducing operative blood loss, post-operative lymphorrhea, and blood transfusions and shortening hospital stay. Clinical application to liver surgery is associated with decreased blood loss and a reduction in the time required for the liver transection [18]. Thus, the use of an ultrasonic energy device in all types of general surgery is characterized by decreased blood loss and reduced operative time. PD for periampullary cancer can induce a very high level of surgical stress in the abdominal surgery. In particular, the majority of patients with pancreatic cancer also have LN metastases, and the tumor frequently extends beyond the pancreas. Therefore, PD for pancreatic cancer needs to take into account probable widespread LN involvement and the clearance necessary. This can occasionally require resection of the PV, the adjacent organ, and the plexus around the celiac axis or the SMA in order to achieve pathologically curative resection [5]. Consequently, all of the cases in this study involved pathologically curative resection. However, PD with extended LN dissection can lead to the use of many surgical stitches, increased blood loss, and an extension of the operative time, resulting in an excess of surgical stress to the patients. For this reason, we performed this prospective study to compare the number of surgical stitches, extent of blood loss, and operative time between conventional PD and PD using UCS. Our results demonstrated that the use of UCS significantly reduced the number of surgical stitches, extent of blood loss, and the time spent on the hilar lymph node clearance without vascular injury in PD; as such, they are similar to results reported for other types of surgery [14–18]. It may be possible that the use of UCS can reduce the number of surgical sutures used in PD, resulting in a reduction in the rate of surgical site infection.

Using a porcine model, Hruby et al. [8] reported vessel sealing capabilities and peripheral energy spread associated with energy-based surgical instruments, such as the ultrasonic and electric energy devices. These authors found the LigaSure device to have the best vessel sealing capability, with consistent control of arteries and veins up to 7 mm in diameter; the ultrasonic energy device was able to reliably seal arteries up to 3.0–5.0 mm in diameter and veins up to 5.0–7.0 mm in diameter. The ultrasonic energy device had a better efficient vessel transection time than the LigaSure. Importantly, the ultrasonic energy device produced a peripheral energy spread of 1.0 mm, and the LigaSure caused 5.5 mm of thermal damage. This difference means that the use of the ultrasonic energy device allow a more precise dissection since a 2-mm margin should be maintained to ensure peripheral tissue viability. This in vivo study indicated that the use of the ultrasonic energy device could be efficacious for LN clearance along the artery because of less peripheral energy spread. There were no cases of post-operative bleeding and iatrogenic tissue or organ injury in our study. However, Chamberlain et al. [19] emphasized that caution should be used to avoid collateral thermal injury when using the ultrasonic devices because they are activated when the finger trigger is in contact with the body wall while being advanced into the abdomen, and this may cause burns on the small intestine, leading to ileus.

In conclusion, we found the use of the new UCS in PD to be a safe procedure and associated with the economical benefit of fewer surgical stitches as well as with reduced blood loss and reduced operative time spent during the hilar part of PD.

Conflict of interest We have no commercial associations that might pose conflicts of interest in connection with this study.

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