Routine Vascular Control Using the Nonabsorbable Polymer Ligating Clips in Open Pancreaticoduodenectomy—Early Postoperative Outcomes in Consecutive 98 Cases

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Received: 23 January 2014 / Accepted: 17 June 2014 / Published online: 27 June 2014
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Abstract The purpose of this study was to evaluate the utility of the nonabsorbable polymer ligating clips during open pancreaticoduodenectomy. Ninety-eight consecutive patients underwent open pancreaticoduodenectomy using either the polymer clip (hem-o-lock R) system for gastroduodenal artery and right gastric artery control or conventional knot tying ($n=151$) for these artery control. The two groups were similar regarding demographic data, preoperative/intraoperative characteristic, pathologic findings, anastomotic leakage, and intra-peritoneal collections or abscess. There were no intraoperative complications. Overall, postpancreatectomy hemorrhage occurred in 26 patients (10.44 %) including 16 patients (6.4 %) with severe hemorrhage, for clip system group was 1 % (1 of 98), 8.6 % (13 of 151) for the conventional technique group ($P=0.011$). Only one patient (1 %) of clip group required intervention treatment (vascular complications unassociated with ligation), with no death. For conventional ligation group, a total of 12 patients (7.9 %) underwent intervention treatment with two deaths. Eight of these patients were diagnosed with intraperitoneal hemorrhage from visceral artery pseudoaneurysms, which originated from the gastroduodenal artery in four patients, hepatic artery in one, common hepatic artery in two, and celiac trunk in one. Postoperative mortality was 1.6 % (4 of 249), all in the conventional group. The polymer clip technique is easy, safe, and effective for control of the gastroduodenal artery and right gastric artery in the open pancreaticoduodenectomy.

Keywords Pancreaticoduodenectomy · Postpancreatectomy hemorrhage · Vascular control

Abbreviations

PD	Pancreaticoduodenectomy
PPH	Postpancreatectomy hemorrhage
POPF	Postoperative pancreatic fistula
POD	Postoperative day
DPPAB	Delayed postpancreaticoduodenectomy arterial bleeding

Introduction

The vascular control is still one of the most stressful parts of pancreaticoduodenectomy (PD) for hepatopancreatobiliary surgeons. Postpancreatectomy hemorrhage (PPH) is one of the most serious and life-threatening complications of this procedure and is associated with high mortality [1]. Recent systematic review [2] reported that 66 % delayed PPH come from eroded or ruptured visceral arteries, and the gastroduodenal artery represents 50 % of all arterial hemorrhage. There is no perfect method for vascular control for reducing PPH after PD. Proper equipment maintenance in addition to experienced surgeons is critical to successful vascular control regardless of technique employed.

Currently, use of laparoscopic clips has largely replaced knot-tying, given the ease of application and general reliability. Using polymer ligating clips (hem-o-lock R) for renal vascular control has recently become popular and has been used successfully in many operations, both open and laparoscopic [3, 4]. Despite the widespread acceptance of these novel devices for vessel occlusion in laparoscopy, these techniques have received little attention in open surgery, and few data are available to support their efficacy and safety on PD.

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So, the aims of this study were to evaluate the safety and reliability of the use of polymer ligating clips for the celiac artery control during open PD.

Materials and Methods

We audited all patients undergoing PD at our unit in West China Hospital of Sichuan University between January 2010 and June 2013 to evaluate patients undergoing open PD using polymer ligating clip system for vascular control. During this interval, all PD were prospectively entered into a complication database. Patients undergoing PD by four experienced surgeons who recently preferred to use polymer ligating clip system for vascular control were identified. Patients were excluded from this study for highly cancer involvement of the base of the vascular trunk. We generally used conventional vessel ligation via 2-0 silk double ligation until the availability of the polymer ligating clip system. We started using the polymer ligating clip system for laparoscopic PD in 2010 and for open PD in December 2011. Since then, all participating surgeons had used the clip for vascular control whenever possible for open PD. All patients were provided with written, informed consent forms before exploratory laparotomy. Hospital, office, and follow-up records of patients undergoing PD were independently reviewed in detail by two authors. PPH was defined to be present when more than three units of blood were required in any 24 h after the operation [1].

Surgical Procedure

PD was performed by four experienced surgeons who shared the same expertise regarding open PD, following a standardized fashion for pancreatic head lesions. The procedure of the clip group only differed from the conventional ligation group regarding the vascular control of the celiac artery (e.g., gastroduodenal artery, right gastric artery, inferior pancreaticoduodenal artery) (Fig. 1). After complete circumferential dissection of the artery, two or three nonabsorbable polymeric clips (Hem-o-lok MLX polymeric clips, NC, USA) were applied on the proximal side (Fig. 1a). Then, the artery was transected after conventional ligation distal to the clips. The placement of the curved tip of the clip around and beyond the vessels should be confirmed. During transection of vessels, at least 1–2 mm of the artery distally to the clip should be maintained to avoid clip slippage and blood leak [5]. The largest diameter of the artery stump that can be safely closed with the clip is 10 mm. Before closure of the abdomen, a visual inspection was performed to exclude clip slippage. The anastomotic area of pancreaticojejunostomy and biliary anastomosis was drained separately with open drains.

Postoperative Management

The diagnostic procedures employed after the development of delayed PPH were endoscopy, angiography, and computed tomography (CT). The first-line treatment of delayed PPH was either interventional radiology (coil embolization or covered stenting) or endoscopic treatment. Relaparotomy was performed for postoperative hemorrhage and intra-abdominal abscess when the interventional methods were not effective or the patient showed clinical deterioration. Follow-up imaging was performed at the time of discharge or within 1 month of PD for safety evaluation and then at 3-month intervals.

Results

Between January 2010 and June 2013, 249 patients underwent PD performed by us using either conventional knot-tying ($n=151$) or the clip system ($n=98$) for vessel control. The two groups were similar regarding demographic data, pathologic findings, preoperative anemia, and preoperative jaundice (Table 1).

There were no intraoperative complications. The postoperative courses and complications are listed in Table 2. While 11 patients (11.2 %) who developed POPF was observed in the clip group, 20 patients (13.2 %) was observed in the conventional group ($P=0.637$). There was no difference between groups regarding the anastomotic leakage (biliary leakage or gastric-enteric leakage) and intraperitoneal collections or abscess. The length of the postoperative hospital stay for the clip group was 12.9 ± 6.84 days, compared with 14.7 ± 7.33 days for the conventional group ($P=0.059$).

Overall, PPH according to the ISGPS definition occurred in 26 patients (10.44 %). The characteristics and clinical course of these patients are presented in Tables 2 and 3, respectively. A half patient with PPH required interventional treatment (endoscopy, angiography, relaparotomy) with two deaths (7.7 %). The incidence of PPH for clip system group was 6.1 % (6 of 98), 13.2 % (20 of 151) for the conventional technique group ($P=0.073$), and these PPH needed transfusion of a median PRBC units 3 U (iqr, 2.8–18) after hemorrhage for the clip system group, 9.3 U (iqr, 4.3–18.4) for the conventional technique group ($P=0.767$). Statistical comparison of the subsets showed that, for the severe PPH, there was a significantly higher conventional technique group compared to the clip group (1 % vs 8.6 %, $P=0.011$) (Table 2).

As shown in Table 3, a pancreatic fistula was found in seven of ten patients with severe delayed extraluminal hemorrhage. Four patients had intra-abdominal abscess, and no patient had bile leakage. Only one patient (1 of 98, 1 %) with severe PPH of clip group required intervention treatment, with no death. This patient (patient 1) with POPF and massive PPH

Fig. 1 Ligation of celiac arteries during open PD. **a** Ligation of celiac arteries with Hem-o-lok clips in open PD. **b** Conventional knot-tying of celiac arteries. *GDA* gastroduodenal artery, *RGA* right gastric artery

on POD 18 was treated successfully for a pseudoaneurysm at splenic artery by remaining pancreatectomy and spleen pancreatectomy after failed attempts at embolization. For conventional ligation group, a total of 12 (12 of 151, 7.9 %) required intervention treatment with two deaths, needed 2 endoscopy, 11 angiography, and 3 relaparotomy. Eight patients (8 of 20) were diagnosed with intraperitoneal hemorrhage from visceral artery pseudoaneurysms. All these eight bleeding focus were verified by emergency angiography, except for one by CT with minor hemorrhage and then treated by endovascular intervention (patient 4). The pseudoaneurysms originated from the gastroduodenal artery in four patients, hepatic artery in one, common hepatic artery in two, and celiac trunk in one. In particular, one patient (patient 11) died of pseudoaneurysms originated from celiac trunk on POD 14; one patient (patient 4) with sentinel bleed died of a pseudoaneurysm at the common hepatic artery on POD33 that is 17 days after discharge,

which accompanied by severe pulmonary infection. We experienced that four postoperative mortalities (1.6 %), all in the conventional group, were a result of intraperitoneal hemorrhage ($n=2$), hepatorenal failure ($n=1$), and intraperitoneal abscess ($n=1$).

Discussion

The aim of this case control study was to compare the effectiveness and safety of a new Hem-o-lok system to conventional ligatures in open PD. To avoid bias related to surgeon's experience, four surgeons with expertise in our unit operated on all patients in this series. The procedures were performed in a standardized fashion including vessel skeletonization for lymphadenectomy. Our results demonstrate that the Hem-o-

Table 1 Patient, preoperative/intraoperative characteristic and pathologic findings

	Clip group (n=98)	Conventional group (n=151)	P value
Age (year)	59.5±9.37	58.4±12.21	0.456
Gender [male, no. (%)]	68 (69.4)	102 (67.5)	0.093
Final pathology [no. (%)]			0.936
Pancreatic carcinoma	41 (41.8)	56 (33.8)	
Duodenal carcinoma	24 (24.5)	39 (25.8)	
Carcinoma of ampulla	8 (8)	14 (8.2)	
Distal bile duct carcinoma	15 (15)	29 (19.2)	
benign or low malignant potential lesions	7(7)	10(6.6)	
Other neoplasms	3(3)	3(2)	
Preop. laboratory data (mean±SD)			
Preop. anemia [no. (%)]	11 (11.2)	12 (7.9)	0.383
Hemoglobin ^a (g/L)	73.5±13.51	70.7±10.24	0.586
Preop. jaundice [no. (%)]	61 (62.2)	99(65.6)	0.594
Total bilirubin (μmol/L)	177.8±127	201.6±114.1	0.22
Operative data			
Portal vein resection	8 (8.2)	8 (5.3)	0.368
Transfusion [no. (%)]	13 (13.3)	28 (18.5)	0.273

^a Mean value of hemoglobin of patients with preoperative anemia

lok clip is at least as safe as conventional ligatures for routine vascular control in open PD.

PPH, especially delayed post-PD arterial bleeding (DPPAB), is one of the most serious and life-threatening complications of PD and is associated with high mortality [1, 2]. Recent systematic review [2] reported that most PPH (66 %) arise from eroded or ruptured visceral arteries. The vascular control is still one of the most stressful parts of PD for hepatopancreatobiliary surgeons. Usually, the vasculature is injured by skeletonization for lymphadenectomy during radical surgery and too-tight ligation of the arterial stump. Regardless of the type of vascular control performed, a certain degree of laceration and/or damage to the vessel wall from the suture or knot formation of ligation is unavoidable. These intraoperative injuries to the arterial wall may result in acute arterial bleeding or arterial pseudoaneurysm formation, which is typical of DPPAB, and make the vessel more susceptible to erosive rupture if intra-abdominal septic complications occur around it [1, 2]. In some cases, local tissue destruction may disrupt ligatures and sutures, typically at the stump of the gastroduodenal artery which is the most frequently encountered in delayed PPH [2]. In addition, suturing the artery stump increases the complexity of operative procedures and lengthens the operating times. Proper equipment maintenance in addition to experienced surgeons is critical to successful vascular control regardless of technique employed.

Table 2 Postoperative course and complications

	Clips group (n=98)	Conventional group (n=151)	P value
Abdominal complications [no. (%)]			
POPF	11 (11.2)	20 (13.2)	0.637
Biliary leakage	2 (2)	3 (2)	1.0
Intraperitoneal collections or abscess	7(7.1)	12 (7.9)	0.815
PPH N (%)	6 (6.1)	20(13.2)	0.073
Severity			
Mild	5(5.1)	7(4.6)	1.0
Severe	1(1)	13(8.6)	0.011
PRBC units (iqr)	3 (2.8–18)	9.3 (4.3–18.4)	0.767
POPF (%)	1 (16.7)	6(30)	1.0
Interventional treatment	1(16.7)	12 (60)	0.16
Endoscopy	0	2 (10)	1.0
Angiography§	1 (16.7)	11 (55)	0.17
Relaparotomy (%)	1 (16.7)	3 (15)	1.0
Postop. hospital stay (days) (mean±SD)	12.9±6.84	14.7±7.33	0.059
Mortality [no. (%)]	0	4 (2.6)	0.352

POPF postoperative pancreatic fistula, *PPH* postpancreatectomy hemorrhage, *PRBC* packed red blood cells, *iqr* interquartile range

Currently, using knotless suturing for vascular control during laparoscopic and open surgery has recently become popular and largely replaced conventional knot-tying, given the ease of application and general reliability. The polymer clip (hem-o-lock R) is one of the most common use and has been used successfully in many operations, primarily for control of the renal vessels, both open and laparoscopic [3, 4]. With our initial experience from laparoscopic surgery, we started using the clips in 2010 for laparoscopic PD and then adapted this approach for open PD. We have so far assessed its use in nearly 100 patients undergoing open PD. For the severe PPH, there was a significantly lesser clip group compared to the conventional technique group (1 % vs 8.6 %, $P=0.011$), although the total incidence of PPH for clip system group (6.1 %) was comparable with the conventional technique group (13.2 %) ($P=0.073$). We showed that the use of the polymer clip (hem-o-lock R) for the control of peripancreatic arteries during open PD is safe.

Postoperative leak of the pancreaticojejunostomy or hepaticojejunostomy may induce digestion of vascular structures by the erosive pancreatic or biliary juice, respectively [2]. In our study, a pancreatic fistula was found in seven of ten patients with severe delayed extraluminal hemorrhage, and four patients had intra-abdominal abscess. Although the anastomotic leakage (POPF, biliary leakage, or gastric-enteric leakage) and intraperitoneal collections or abscess did not

Table 3 Clinical course of patients that underwent interventional treatment for PPH

No.	PPH grade	Underlying disease	POD	POPF ^a	Abdominal infection or abscess	Bleeding site ^b	Interventional treatment	Outcome
Clip group								
1	C	Pancreatic carcinoma	18	Yes	Yes	e/SA(pseudoaneurysm)	Angiography(Coil)/relaparotomy (TP)	Survived
Conventional group								
2	C	Pancreatic carcinoma	27	–	–	e/CHA(pseudoaneurysm)	Angiography(Coil)	Survived
3	C	Duodenal carcinoma	12	Yes	Yes	e/HA(pseudoaneurysm)	Angiography(Coil)	Survived
4	C	Distal bile duct carcinoma	31	–	–	e/CHA (pseudoaneurysm)	Angiography(Coil)	Died
5	C	Ampullary cancer	21	Yes	Yes	e/GDA (pseudoaneurysm)	Angiography(Coil)	Survived
6	C	Pancreatic carcinoma	13	Yes	Yes	e/GDA (pseudoaneurysm)	Angiography ((Coil) (Twice)	Survived
7	C	IPMN	16	Yes	–	e/GDA(pseudoaneurysm)	Angiography(Coil)	Survived
8	C	Distal bile duct carcinoma	20	Yes	–	e/GDA(pseudoaneurysm)	Angiography(Coil)	Survived
9	B	Distal bile duct carcinoma	9	Yes	–	e/diffuse ?	Angiography	Survived
10	9	Duodenal carcinoma	3	–	–	i/Gastric remnant	Angiography(POD3,LGA ,Coil)/relaparotomy (POD7)	Survived
11	C	Distal bile duct carcinoma	14	–	–	e/CT	EGJ/Angiography(Coil)	Died
12	C	Pancreatic carcinoma	13	–	–	i/Gastric remnant	EGJ(POD13)/ relaparotomy(POD13)/Angiography(Coil, POD15)	Survived
13	B	Duodenal carcinoma	1	–	–	e/PJ	relaparotomy	Survived

POD postoperative day, POPF postoperative pancreatic fistula, PJ pancreaticojejunostomy, SA splenic artery, TP total pancreatectomy, GDA gastroduodenal artery, HA hepatic artery, CHA common hepatic artery, LGA left gastric artery, CT celiac trunk, EGJ esophagogastricjejunostomy

^a POPF at time of PPH

^b Location of bleeding site (i) intraluminal or (e) extraluminal/vessel or anastomosis

show differences between the two groups, there was a significant lesser severe PPH (especially arterial bleeding) in the clip group. The total incidence PPH (10.44 %) according to the ISGPS definition, severe hemorrhage (6.4 %) and other postoperative morbidity were a highly acceptable rate of surgical complications. We did not encounter any complications related to the use of the Hem-o-lok clip. No form of ligation is fail-safe, underscoring the need for appropriate use of all devices and future development of novel tools, potentially with tissue transfixing to minimize complete failure.

Conclusion

The polymer clip (hem-o-lock R) technique is safe, effective, and reliable for use in open PD. However, because we have not yet performed this method in a large number of patients, larger prospective cohort series and prospective randomized studies are needed to further validate our preliminary outcomes.

Acknowledgments This work was supported by the research Special Fund For public welfare industry of health (201202007).

Conflict of Interest The authors have no conflict of interests to declare. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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