Robotic transduodenal ampullectomy: A novel minimally invasive approach for ampullary neoplasms

Short running head: Robotic transduodenal ampullectomy

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Disclosure: Dr. Jin Woo Lee, Sung Hoon Choi, Hong Jae Chon, Dae Jung Kim, Gwangil Kim, Chang Il Kwon, and Kwang Hyun Ko have no conflicts of interest or financial ties to disclose.

Presentation: This paper was presented as an oral presentation at A-PHPBA 2017 (The 6th Biennial Congress of the Asian-Pacific Hepato-Pancreat-Biliary Association) Yokohama,

Japan

ABSTRACT

Background. The adoption of minimally invasive surgery for transduodenal ampullectomy has been slow because of special characteristics and complexity of this procedure.

Methods. Six patients underwent robotic transduodenal ampullectomy. We employed novel methods to facilitate exposure of the ampulla.

Results. All patients completed robotic transduodenal ampullectomy, but 1 patient was immediately converted to robotic pancreaticoduodenectomy because of presence of invasive carcinoma on frozen biopsy. The final pathologic report revealed high-grade dysplasia in four patients, low-grade dyplasia in one, and T2N0 in one patient who converted to pancreaticoduodenectomy. There was no immediate postoperative complication or mortality. One patient was readmitted after 3 months because of stricture of the bile duct outlet. There was no recurrence over a median follow-up period of 20 months.

Conclusion. An appropriate combination of patient positioning and retraction method helps the robot surgical system to provide competent performance for sophisticated and precise manipulation of ampullary lesions.

Keywords: robotics; minimally invasive surgery; ampulla of Vater; duodenal neoplasm

INTRODUCTION

Ampullary adenoma is a rare neoplasm comprising less than 1% of all gastrointestinal neoplasms.[1] The detection rate of this tumor has recently increased due to increased use of screening tools.[2] Although its malignant potential has been suggested, the clinicopathological characteristics of these neoplasms have not been fully elucidated. Further, the exact diagnosis of invasive carcinoma and extent of tumor extension are still challenging prior to resection despite diagnostic improvement in technologies including endoscopy with biopsy, endoscopic ultrasonography (EUS), endoscopic retrograde cholangiopancreatography (ERCP), computed tomography (CT), magnetic resonance image (MRI), intraductal ultrasonography, and so on. Such diagnostic uncertainty has complicated decisions about treatment modality.

Currently, endoscopic papillectomy has largely replaced surgical resection of ampullary tumor as a less invasive procedure with less morbidity.[3,4] However, indications of endoscopic papillectomy are different according to the experience of the endoscopists and are still not fully established. Unsuitable lesions for endoscopic treatment or incomplete endoscopic resection require a surgical approach, such as transduodenal ampullectomy (TDA) or pancreaticoduodenectomy (PD).

In the past, pancreaticoduodenectomy (PD) was not preferred due to its high postoperative morbidity and mortality rate. However, with the advances in pancreatic surgery, operative techniques, and perioperative management, the morbidity and mortality rate after PD has been dramatically reduced in the recent decade.[5,6] Therefore, PD has been shown to be a treatment option for malignant periampullary lesions.

Nevertheless, due to the broad spectrum of disease entities of ampullary neoplasm, various treatment options are available. The lesions in the middle zone of the disease spectrum would be indications for TDA. These lesions might be undertreated by the endoscopic approach and over-treated by PD. Although minimally invasive surgeries have largely replaced conventional laparotomy in the gastrointestinal field, only a few cases of laparoscopic and robotic TDA have been reported.[7-9] This implies special characteristics and difficulties in the minimally invasive approach for TDA.

We introduce a novel technique of robotic TDA for ampullary neoplasms and report preliminary perioperative outcomes to show the feasibility and safety of our technique.

METHODS

A series of eight consecutive patients underwent robotic local resection of duodenal pathologies using the da Vinci Si system (Intuitive Surgical, Sunnyvale, CA, USA) between January 2016 and December 2017 at Bundang CHA Medical Center, CHA University, Seongnam, Korea. Prospectively collected data on patient demographics and perioperative outcomes were retrospectively analyzed. Two patients who underwent duodenal partial resection with the same setting of the robotic system were excluded in this report and six patients underwent robotic TDA were included. Approval to conduct this study was obtained from the Institutional Review Board and ethics committees of CHA University (IRB No.: 2018-08-036). Demographic data and clinical characteristics included age, sex, body mass index (BMI), clinical presentation, and findings of preoperative studies. Extracted pathologic data included preoperative endoscopic biopsy, result of endoscopic papillectomy if it was performed, safety of margin and presence of invasive carcinoma on frozen section, and final pathologic report. Operative details and postoperative outcomes included operative time, whether to convert to other procedure, estimated blood loss, postoperative hospital stay, and complications according to the Dindo-Clavien scoring system.[10]

"Endoscopic papillectomy" was defined as resection of the peri-Vaterian duodenum including the mucosa and submucosal layer. The term "ampullectomy" refers to resection of the full thickness of the duodenal wall around the sphincter of Oddi including the distal bile duct and pancreatic duct, which reach the pancreatic parenchyma (Figure 1).

Positive margins were defined as the presence of any benign or malignant neoplastic tumor at the resection margin.

Localization of the ampulla of Vater was made on the duodenal mucosa of the antimesenteric side using preoperative endoscopic clipping and intraoperative ultrasonography.

Indications

The surgical indications of robotic TDA included patients with an American Society of Anesthesiologists performance score less than class 2, lesions of high grade dysplasia and carcinoma in situ on endoscopic biopsy without invasive carcinoma and ~~unsuitable for endoscopic papillectomy~~ neoplasms impossible to remove by endoscopy (intraductal extension or intraductal growing of the tumor), tumors less than 4cm, and lesions of incomplete resection of endoscopic papillectomy. Finally, surgical treatment decisions were made by the pancreatobiliary multidisciplinary team.

Operative techniques

Patient positioning and docking procedure (Figure 2)

The patient was placed in the left semi-lateral decubitus position on the operating table after general anesthesia (Figure 2-A). The available operative field was relatively limited in the lateral position compared to that in the supine position. Therefore, we applied two working ports, a camera port, and an assistant port (Figure 2-B). First, a transumbilical 2.5 cm-long skin incision was made vertically, and the single port system (Glove port®, Nellis, Bucheon, Korea) for robotic camera was applied. This single-port system facilitated easy specimen retrieval for frozen biopsy without re-docking process, application of laparoscopic ultrasonography, and access of assistant. The installation details of the Glove port were previously reported.[11] The robotic camera and a single-site instrument were introduced through the Glove port placed at the umbilicus. Two 8 mm trocars were added bilaterally at about 15 cm apart from the umbilicus (one at the subxyphoid and another at the right lower abdomen). The da Vinci Si robot system was advanced from the back of the patient, while the center column, camera arm, target organ (duodenum), and umbilical port are in a straight line. Additional 5mm trocar was inserted at the upper abdomen between the umbilicus and subxyphoid trocar. The assistant surgeon worked through the umbilical single-port and the 5mm trocar.

Exposure methods (Figure 3)

After cholecystectomy, the procedure was started with Kocherization and dissection of the gastrocolic ligament at the pancreatic head, which facilitated complete exposure of the second and third portions of the duodenum. Kocherization allowed the antimesenteric side of the duodenum to be rotated toward the camera view by gravity in the semi-lateral decubitus position. The location of the ampulla of Vater was confirmed by detection of the preoperative clipping by laparoscopic ultrasonography, which could be performed through the Glove port. Patients with preoperative ERBD (endoscopic retrograde bile duct drainage) were not localized prior to surgery because ERBD itself was easily identified through the duodenal wall. A small longitudinal duodenotomy was made, and the ampulla of Vater was identified. Then, the duodenal incision was extended. The proximal and distal duodenal lumens were packed with gauze to avoid disturbance by the digestive juice (Figure 3-A).

The superior wall of the opened duodenum was fixed to the inferior border of the liver by suturing, and the inferior wall of the opened duodenum was retracted downward using the laparoscopic suction catheter or grasper by the assistant surgeon (Figure 3-B). These procedures were very helpful for proper exposure of the ampulla of Vater.

Resection step

The firmness of the ampullary tumor was checked to assess invasiveness of the tumor. If the tumor was previously resected by an endoscopic papillectomy, a fire-fly fluorescent image using indocyanine green (ICG) was useful to find the orifice of the bile duct. A short silicone catheter was inserted to the pancreatic duct before the ampullectomy, because the thin pancreatic duct was very difficult to find after resection. Resection preparation began with serial circumferential stay sutures facilitated upward traction of the lesion. With upward traction holding the stay sutures using the Maryland dissector® (Intuitive Surgical, Sunnyvale, CA, USA), duodenal wall dissection was performed using the permanent cautery hook® (Intuitive Surgical, Sunnyvale, CA, USA). The assistant surgeon allowed for precise dissection by keeping the operative field clean by suction. The dissection proceeded to the pancreas to ensure a sufficient proximal resection margin. The sphincter of Oddi was completely removed and the openings of biliary and pancreatic ducts were exposed. During this procedure, the pancreatic catheter was kept. The resected specimen was retrieved using a plastic bag through the channel of single port. The specimen was sent for frozen biopsy and assessed for tumor involvement on resection margin and presence of invasive component of carcinoma. After confirmation on frozen biopsy, reconstruction was then performed.

Reconstruction step (Figure 4)

A short silicone catheter was properly positioned into the pancreatic duct and fixed with 4-0 Vicryl™ sutures (Polyglactin; Ethicon, Sommerville, NJ, USA). Because the diameter of the bile duct was large enough, insertion of a biliary stent was not necessary. The septum between the ducts was plastered, and the biliary and pancreatic ducts were reconstructed on the duodenal wall with 3-0 Vicryl interrupted sutures (Figure 4). We believe that thinner absorbable sutures would be better for the reconstruction of the biliary and pancreatic duct. However, we inevitably use 3-0 Vicryl suture to manage the wide gab between the duodenal mucosa and biliary and pancreatic duct, which is quite wide after ampullectomy. In this step, the magnified three-dimensional vision and articulating motion of the two 8 mm working arms resulted in performance comparable to that of the open technique in order to manage 360-degree circumferential sutures. Finally, the opened duodenum was close obliquely with 3-0 V-Loc^{TM} barbed suture (Covidien, New Haven, CT, USA).

RESULTS

Patient demographics and preoperative data (Table 1)

The median age of the six patients was 55.5 years (range, 40 to 78 years), and there were five males and one female. Incidental detection of the ampullary tumors occurred on routine check-up in 4 patients, but two patients presented with cholangitis. The median tumor size was 1.9 cm (range, 1.5 to 3.0 cm). A preoperative endoscopic retrograde bile duct drainage (ERBD) was inserted in two patient. All patients underwent endoscopic forceps biopsy, which revealed tubular adenoma in one patient, low-grade dysplasia in one, high-grade dysplasia in four. The second patient diagnosed with tubular adenoma (Figures 5-A and a) underwent endoscopic papillectomy, but the pathology was reported as high-grade dysplasia with marginal involvement (Figures 5-B and b). Therefore, robotic TDA was performed for the patient (Figure 5-C and c), while the other patients underwent robotic TDA as the primary treatment. In the third patient, endoscopic findings of central ulceration and mild firmness were highly suggestive of the presence of invasive carcinoma despite the results of endoscopic biopsy of low-grade dysplasia with focal high-grade dysplasia. We recommended PD because of the risk of incomplete resection and presence of invasive carcinoma. The patient strongly wanted to avoid PD if possible, but she agreed to convert to PD when the presence of invasive carcinoma was confirmed. Therefore, the patient also underwent robotic TDA as an initial approach. The sixth patient who suffered from recurrent cholangitis was diagnosed with an intraductal growing low-grade dysplasia of 1.8 cm in size. This intraductal growing tumor was endoscopically unresectable and this patient underwent robotic TDA.

Operative outcome and follow-up data (Table 2)

Frozen biopsy was evaluated during the operation in all patients. Three patients had high-grade dysplasia with free resection margin, one patient had low-grade dysplasia with free resection margin. There were no remnant tumors in one patient (the second case, Figures 5-C and c) who had undergone previous endoscopic papillectomy. These patients proceeded to reconstruction and successfully completed robotic TDA. In the third patient, however, frozen biopsy after ampullectomy showed multi-focal invasive carcinoma with lateral margin involvement despite a clear proximal margin. Therefore, this patient was decided to immediately convert to robotic PD.

The median total operation time was 200 min (range, 180-350 min) in the pure robotic TDA cases and 450 min in the conversion case. The estimated median blood loss was 160 ml (range, 30-350 ml). The final pathologic report revealed high-grade dysplasia in four patients, low grade dysplasia in one, and T2N0 in one patient who converted to PD. There was no postoperative complication or mortality. The median postoperative hospital stay was 6 days (range, 5-8 days). One patient (first case) was readmitted after 3 months because of stricture of the bile duct outlet. The stricture was resolved by percutaneous bile duct drainage after failure of ERCP cannulation. All patients were on routine endoscopic surveillance, whereas the PD conversion patient was treated with adjuvant gemcitabine chemotherapy. There was no recurrence over a median follow-up period of 20 months (range, 8-28 months).

DISCUSSION

Although TDA is a much less invasive and simpler procedure for managing ampullary neoplasms compared to PD, minimally invasive surgery for TDA has rarely been tried.[7-9] This is probably due to the difficulty with proper exposure of the surgical field in the narrow luminal space of the duodenum and the complicated procedures for delicate resection and reconstruction of fine biliary and pancreatic structures. Therefore, TDA has been mostly performed by open laparotomy to date. There have been only a few case series of minimally invasive TDA. Here, we report six consecutive cases of robotic TDA, which were successfully performed using our novel technique.

Ampullary neoplasms are well-known premalignant lesions to be extirpated since Cattell and Pyrtek suggested the adenoma → carcinoma sequence.[12] However, sequential changes with this disease makes accurate diagnosis difficult, and the uncertainty of the initial diagnosis makes it difficult to select the proper treatment modality. High-grade dysplasia is considered suitable indications for TDA because endoscopic papillectomy for these tumors has a risk of local recurrence, and PD is thought to be an over treatment. The problem is that the preoperative endoscopic biopsy cannot represent the entire lesion. Endoscopic biopsies have shown a high false-negative rate of 45 to 60 percent in identification of presence of carcinoma.[13,14] Therefore, the Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) guidelines emphasize the importance of gross endoscopic findings of firmness, ulceration, friability, and non-lifting with attempted submucosal injection.[15] Ridtitid et al.[16] also suggested that jaundice at presentation was a risk factor of presence of invasive carcinoma. As with our third case that converted to PD because of presence of invasive carcinoma, endoscopic findings of firmness and ulceration accompanied by cholangitis strongly imply invasiveness of the tumor. Therefore, under the uncertainty of endoscopic biopsy, the indications of TDA should be carefully selected by combining the clinical features of the biliary obstructive sign and endoscopic findings.[17]

With the advance of interventional endoscopy, endoscopic papillectomy has been a first-line treatment of ampullary neoplasms.[18,19] Even though endoscopic treatment is the least invasive approach for ampullary lesions, with a low complication rate of 8 to 27 %[20-22] and high complete resection rate of 71 to 90 %,[16,23,24] its use is limited to benign pathologies and protruding lesions. Some reports have shown a high recurrence rate in patients with high-grade dysplasia.[25,26] Ridtitid et al.[16] mentioned that intraductal extension of the tumor was risk factor of incomplete resection by endoscopic papillectomy. Therefore, high-grade dysplasia, and intraductal extension are indications for surgical ampullectomy due to the high risk of local recurrence. The second case in our study underwent endoscopic papillectomy as initial treatment for biopsy-proven tubular adenoma, which revealed intraductal extension with proximal marginal involvement. Therefore, the patient underwent robotic TDA, and complete removal was achieved. It is very difficult to preoperatively determine the exact pathologic diagnosis and intraductal extension. Recent advances in endoscopic ultrasonography could help to determine the intraductal involvement.[27,28] However, even if such intraductal extension of the tumor is identified after endoscopic papillectomy, robotic TDA could help to achieve further complete resection, minimizing deterioration in patient quality of life. In addition, as in our sixth case, intraductal benign lesions that are difficult to remove by endoscopy are also considered good indications of TDA.

On the other hand, it is still debatable whether early ampullary carcinoma is an indication of TDA. A recent study by Lee at al.[29] demonstrated that Tis (carcinoma in situ) could be an indication of TDA with low risk of local recurrence and lymph node metastasis, but not of T1 ampullary carcinoma.

Preoperative differential diagnosis of Tis and T1 ampullary cancer is extremely difficult. Therefore, we routinely perform intraoperative frozen-section biopsy. Lai et al.[30] showed an accuracy rate of 83.9 % on frozen biopsy in their recent study. In such a situation, detailed communication between the surgeon and pathologist is very important for detection of occult focal invasive carcinoma and involvement of the surgical margin.

The size of the tumor is also an important consideration. Tumors larger than 4 cm have a greater chance of malignant transformation compared to smaller tumors. Thereby, tumors larger than 4 cm, even which was benign on endoscopic biopsy, might not be candidates for TDA. To sum it up, our indications for robotic TDA include remnant lesions after endoscopic papillectomy, intraductal involvement of the tumor, lesions of high grade dysplasia, and tumors less than 4 cm. In addition to the indications mentioned above, patients with a high ASA score are expected to be indications if the safety and learning curve of robotic TDA are demonstrated.

In terms of the technical aspects, the key procedures for TDA include 1) localization of ampulla of Vater, 2) proper exposure of the ampulla located within the hollow viscus, 3) gentle traction of the fragile tumor for delicate dissection of the duodenal wall including the sphincter of Oddi, and 4) 360-degree circumferential reconstruction of the fine biliary and pancreatic ducts. 1) Localization - Initial experience with direct incision and extension of the duodenal wall has sometimes resulted in unnecessary long incision of the duodenum. Starting with the third case in our series, we applied preoperative endoscopic clipping on the duodenal mucosa of the antimesenteric side, and intraoperative ultrasonography was performed to detect the clips. 2) Exposure - We employed 3 methods to facilitate exposure of the ampulla located within the deep and narrow space in the duodenum. First, the combination of a left lateral semi-decubitus position and Kocherization caused the duodenum to rotate forward, allowing the ampulla to be headed toward the robotic camera view. Second, the superior wall of the opened duodenum was sutured to the inferior edge of the liver, and the inferior wall was retracted downward by the assistant surgeon to maintain a wide incision of the duodenum for sufficient exposure of the operative field. Third, the proximal duodenal lumen was packed with gauze to avoid disturbance by the digestive juice. 3) Resection - Upward traction of the tumor was essential to ensure an adequate resection margin and to maintain tension on the loose duodenal wall. For this, serial circumferential stay sutures around the tumor were easily facilitated by the wrist motion of the robot system. Prior to resection of the tumor, we inserted a short silicone catheter into the pancreatic duct. Unlike the bile duct, the pancreatic duct was very difficult to identify after resection without guidance of the catheter. 4) Reconstruction - The reconstruction stage was the reason for using the robotic system for minimally invasive TDA. In order to re-implant the biliary and pancreatic ducts into the duodenal wall, a very sophisticated suture should be performed 360 degrees around the two openings, which was very difficult with the laparoscopic approach. In the robot surgical system, however, the three-dimensional stable magnified operative view and free articulating motion of the instruments enabled a delicate and precise procedure.

Difficulties in exposure, and reconstruction were the main reasons for limited use of laparoscopic TDA.[7,8] There has been a lack of follow-up series since a case report of laparoscopic TDA, which might imply the inherent technical limitation of the conventional laparoscopic surgery with non-articulating motion, amplified tip vibration due to a fulcrum effect, two-dimensional operative view, and lack of ergonomics for the surgeons. Zeh et al.[9] reported the first robotic TDA of multicenter experience and they show the feasibility and safety of the robotic TDA. Our report is the largest single center experience and our novel techniques facilitated effective exposure of the target operative field, allowing easy manipulation of the ampullary structures.

Ampullary neoplasms unsuitable for endoscopic papillectomy and incomplete endoscopic resection are good candidates for TDA. An appropriate combination of patient positioning and retraction method provides excellent exposure of the operative field, and the robot surgical system equipped with three-dimensional vision and "endo-wrist" movement of effector instruments provides competent performance for sophisticated and precise manipulation of ampullary lesions associated with the fine biliary and pancreatic duct system.

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Table 1. Demographics and clinicopathological, and preoperative treatment data of the patients

Case	Sex/ Age	BMI (kg/m^2)	Symptom	Initial total bilirubin (mg/dL)	Tumor size (cm)	Endoscopic biopsy	Endoscopic papillectomy
1	M/78	25.10	None	0.39	3.0	HGD	No
2	M/42	22.89	None	0.34	1.5	Tubular adenoma	Yes/ Margin (HGD)
3	F/64	30.00	Cholangitis	1.48	2.5	LGD with focal HGD	No
4	M/40	26.03	None	0.30	2.0	HGD	No
5	M/76	23.05	None	0.74	1.5	HGD	No
6	M/47	21.63	Cholangitis	4.18	1.8	LGD	No

BMI = body mass index; LGD = low-grade dysplasia; HGD = high-grade dysplasia

Table 2. Operative outcomes and follow-up data

Case	Frozen biopsy (Center/ Margin)	Conv.	Final path.	OP time (min)	EBL (ml)	Postop. Cx.	LOH (days)	Late Cx.	F/U (mon)
1	HGD/free	None	HGD	350	350	None	5	Biliary stricture	28
2	- /free	None	HGD	210	150	None	6	None	25
3	Focal IC/ lateral margin +	Robot PPPD	T2N0	450	210	None	8	None	21
4	HGD/free	None	HGD	190	170	None	5	None	19
5	HGD/free	None	HGD	200	30	None	7	None	18
6	LGD/free	None	LGD	180	50	None	6	None	8

Tis = carcinoma in situ; IC = invasive carcinoma; HGD = high-grade dysplasia; Conv. = conversion; path.=pathology; OP = operative; EBL = estimated blood loss; Cx. = complication; LOH = length of hospital stay; PPPD = pylorus-preserving pancreaticoduodenectomy

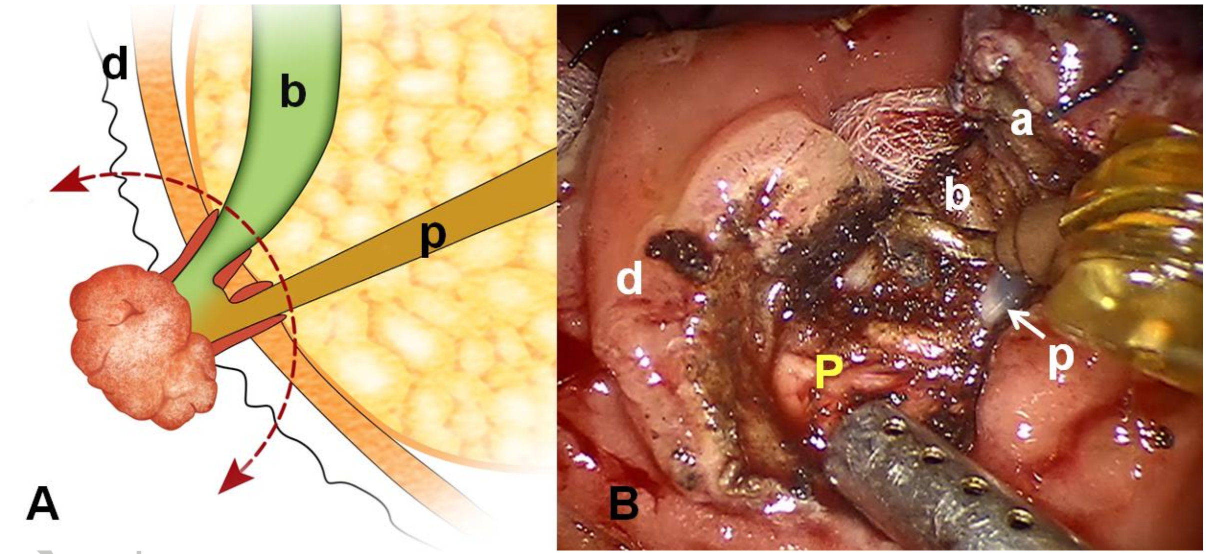

Figure 1. Surgical plane of ampullectomy (A) and exposed bile duct (b), pancreatic duct (p), and pancreatic parenchyme (P) during ampullectomy (B). a = ampulla; b = bile duct; d = duodenal mucosa; p = pancreatic duct and silicon catheter in pancreatic duct; P = pancreatic parenchyme

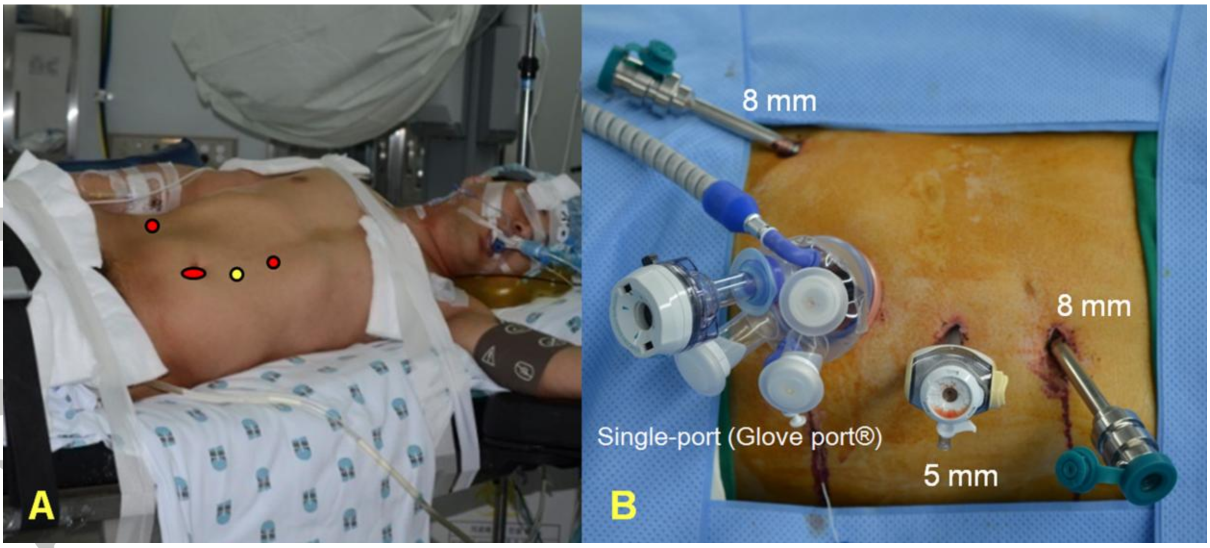

Figure 2. Patient position and the docking method. The patient was positioned in a left semi-lateral decubitus position (A). Because of the relatively limited operative field in the semi-lateral position, we designed a novel ports placement. A single port system for the robotic camera was placed at the umbilicus, and it allowed easy specimen retrieval for frozen biopsy without re-docking process, application of laparoscopic ultrasonography, and access of assistant. Two 8-mm robotic trocars and an additional assistant trocar were inserted (B).

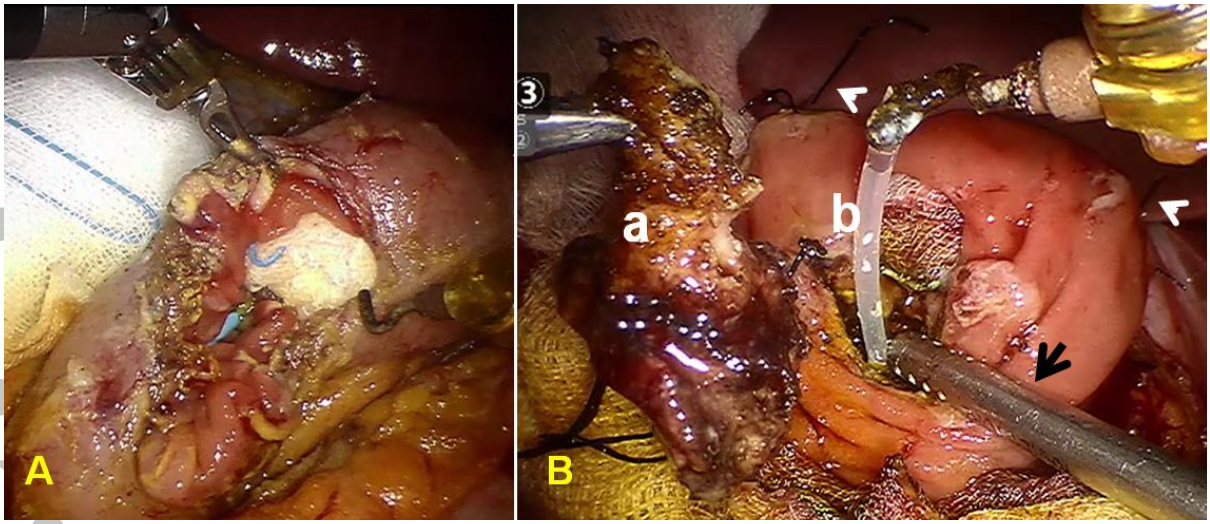

Figure 3. Exposure method. The proximal and distal duodenal lumens were packed with gauze to avoid disturbance by the digestive juice (A). The superior wall of the opened duodenum was fixed to the inferior border of the liver by suturing (arrow heads), and the inferior wall of the opened duodenum was retracted downward using the laparoscopic suction catheter or grasper by the assistant surgeon (arrow) (B). a = resected ampulla of Vater, b = short silicone catheter in pancreatic duct

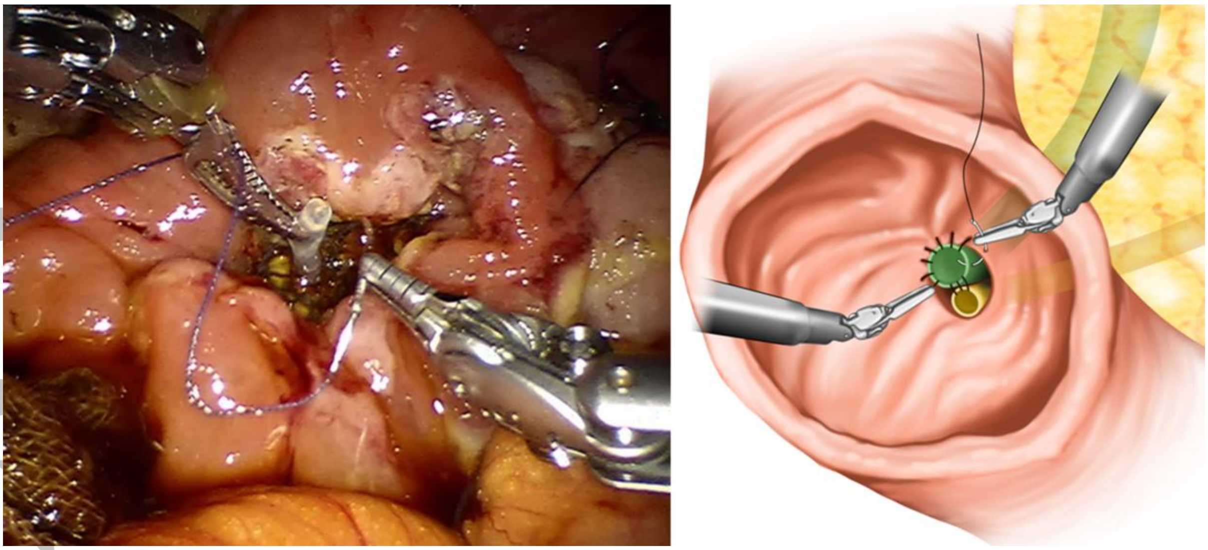

Figure 4. Reconstruction of the biliary and pancreatic ducts. A short silicone catheter was properly positioned in the pancreatic duct. The septum between the ducts was plastered, and the biliary and pancreatic ducts were reconstructed on the duodenal wall.

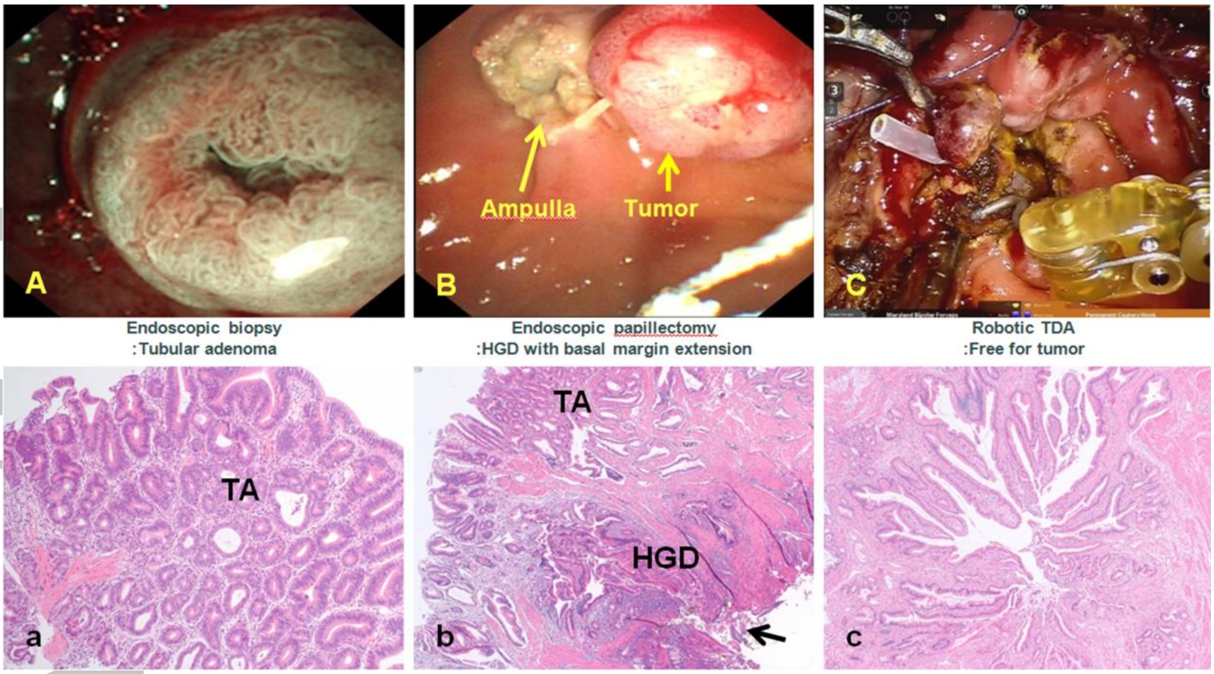

Figure 5. Treatment process in the second patient. Using an endoscope, we identified a 1.5 cm ampullary tumor (A), and endoscopic biopsy identified it as tubular adenoma (a). The patient underwent endoscopic snare papillectomy (B), but the pathology revealed high-grade dysplasia with basal margin involvement (arrow) (b). The patient underwent robotic TDA (C), and final pathology confirmed no remnant tumor at the resection margin (c).