Original Article
Yonsei Med J 2024 Mar;65(3):148-155
https://doi.org/10.3349/ymj.2023.0140
Yonsei Medical Journal
YMJ
pISSN: 0513-5796 · eISSN: 1976-2437

The Revo-i Robotic Surgical System in Advanced Pancreatic Surgery: A Second Non-Randomized Clinical Trial and Comparative Analysis to the da Vinci™ System

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Purpose: Numerous robot-assisted pancreatic surgery are being performed worldwide. This study aimed to evaluate the feasibility and safety of the Revo-i robot system (Meerecompany, Seoul, Republic of Korea) for advanced pancreatic surgery, and also compare this new system with the existing da Vinci™ robot system (Intuitive Surgical, Sunnyvale, CA, USA) in the context of robot-assisted pancreaticoduodenectomy (RPD).

Materials and Methods: This study was a one-armed prospective clinical trial that assessed the Revo-i robot system for advanced pancreatic surgery. Ten patients aged 30 to 73 years were enrolled between December 2019 and August 2020. Postoperative outcomes were retrospectively compared with those of the da Vinci™ surgical system. From March 2017 to August 2020, a total of 47 patients who underwent RPD were analyzed retrospectively.

Results: In the prospective clinical trial, pancreaticoduodenectomy was performed in nine patients and one patient underwent central pancreatectomy. Among the 10 study participants, the incidence of major complications was 0% in hospital stay. There were eight postoperative pancreatic fistula (POPF) biochemical leaks (80%). In the retrospective analysis that compared the Revo-i and da Vinci™ robotic systems, 10 patients underwent Revo-i RPD and 37 patients underwent da Vinci™ RPD, with no significant differences in complication or POPF incidence rates between the two groups (p=0.695, p=0.317).

Conclusion: In this single-arm prospective study with short-term follow-up at a single institution, the Revo-i robotic surgical system was safe and effective for advanced pancreatic surgery. Revo-i RPD is comparable to the da Vinci™ RPD and is expected to have wide clinical application.

Key Words: Robotics, pancreatectomy, pancreaticoduodenectomy

INTRODUCTION

Since its introduction in the field of vascular surgery in the 1990s, the da Vinci™ surgical system (Intuitive Surgical, Sunnyvale, CA, USA) has been widely used in colon surgery, gastric surgery, pancreatic surgery, urology, and obstetrics and gyne-

Received: May 4, 2023 **Revised:** October 5, 2023 **Accepted:** November 13, 2023 **Published online:** February 8, 2024
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•The authors have no potential conflicts of interest to disclose.

cology.[1-4] Robotic surgery was designed to maximize joint drive by minimizing limitations to the operator's movements so that the operation can be performed with more natural finger movements. This allows the operator to perform advanced surgery freely, safely, and efficiently.

Recently, laparoscopic surgery has also shown good results in advanced pancreatic surgery, such as pancreaticoduodenectomy (PD) and central pancreatectomy (CP).[5] However, in the pancreatic anastomosis procedure, due to the nature of the laparoscopic instrument, there is a limitation in the angle and direction, so it requires a high level of skill to perform a delicate procedure. These high-level skills are only permitted by skilled surgeons, and they take a long time and effort to achieve.

Here, robotic surgery emerges as an alternative that can overcome the inherent limitations of laparoscopic surgery.[6] By using robots for processes that require significant concentration and delicate work, such as pancreatojejunostomy, the operator can more freely move and perform key steps in the procedure. In advanced pancreatic surgery, postoperative pancreatic fistula (POPF) remains the biggest challenge,[7] and it is expected that the use of a robot will enable more sophisticated anastomosis and reduce leakage.[8]

Numerous robot-assisted pancreatic surgical procedures are being performed worldwide.[9,10] Kornaropoulos, et al.[9] reported that a total of 692 robot-assisted PDs (RPD) were successfully performed worldwide over a period of nearly 13 years, and claimed that this operation is safe and feasible to perform in a high-volume institution with well-trained assistants and experienced surgeons. Nevertheless, the high cost of robotic surgery limits the use of a variety of robotic systems; the most commonly used technology in this regard by far is the da Vinci™ robotic system.[11]

The Revo-i robotic surgical system (Meerecompany, Seoul, Republic of Korea) was newly introduced as a robotic system that is expected to be comparable to the existing robotic system, given its more attractive cost and newer technology. This new system has undergone clinical trials and received approval from the Korean Ministry of Food and Drug Safety in 2017. It is also being tested in prospective research studies in various fields, such as obstetrics and gynecology, and general surgery.[12,13]

The present study aimed to evaluate the feasibility and safety of the Revo-i robotic system for advanced pancreatic surgery and to compare the capabilities of the Revo-i robotic system with those of the existing da Vinci™ robotic system in RPD.

MATERIALS AND METHODS

Robotic surgical system

Revo-i and da Vinci™ both consist of three elements; a surgeon console, a four-arm robotic operation cart, and a vision cart, with no distinct differences between the two systems. Both surgical systems have a master–slave mode, the same number of robotic arms (one camera arm and three working arms), and the same console components (e.g., hand clutch, pedal clutch, and lateral arm-switching pedal). The Revo-i system boasts a 7.4-mm instrument diameter and 10-mm three-dimensional scope diameter, while the da Vinci™ system has an 8-mm instrument diameter and 8-mm three-dimensional scope diameter. Both surgical systems have less than 80 ms of response delay. Further details have been reported in previous research.[12,14,15]

Second clinical trial[14]

Study design

This was a single-arm prospective study designed to evaluate the feasibility and safety of the Revo-i robotic system in advanced pancreatic surgery. This prospective study was approved by the Institutional Review Board of Severance Hospital, Yonsei University Health System, Seoul, Republic of Korea (approval no. 1-2019-0030), and is registered at ClinicalTrials.gov (NCT04095312). First clinical trial has been described in previous research.[14]

Study subjects

A total of 10 patients aged 30 to 73 years were enrolled from Severance Hospital between December 2019 and August 2020 (Fig. 1). Several previous studies provided evidence on how to calculate the appropriate study population size to evaluate the performance of the new technology.[16-18] This study recruited 10 subjects, which is the minimum number of clinical research subjects necessary to support statistical analysis within the limit that satisfies the purpose of our research.

Endpoints

The surgical success rate was defined by the number of cases in which the surgery was completed without conversion to another surgical technique or any major complications for 24 hours after surgery. Achievement of the primary endpoint was evaluated 24 hours after surgery, while the date of discharge after surgery was set as the secondary endpoint.

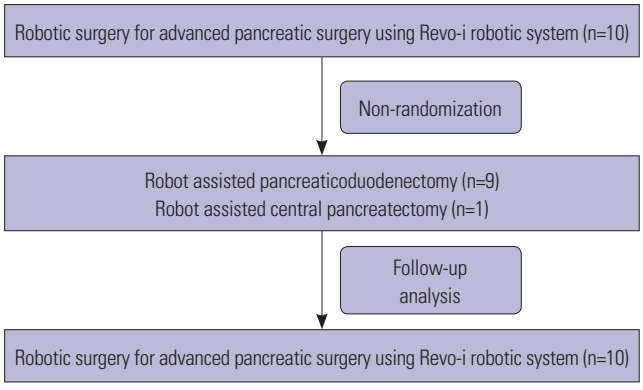

Fig. 1. The flowchart of non-randomized clinical trial.

Inclusion/exclusion criteria

All patients enrolled in this study voluntarily agreed to undergo Revo-i robotic surgery. Patients over the age of 20 years who were diagnosed with periampullary tumor and required advanced pancreatic surgery were eligible for enrollment in this study. Patients with the presence of mental illness or serious systemic disease, severe obesity [body mass index (BMI) ≥30 kg/m^2], an inability to receive general anesthesia due to uncontrolled bleeding tendency or cardiopulmonary deterioration, current pregnancy or the desire to become pregnant, conventional laparoscopic surgery, or the da Vinci™ robotic surgery were excluded from this study. In addition, those with liver cirrhosis or previous open surgery history, as well as those who were inoperable were excluded.

All robotic surgeries were performed after explaining the advantages, disadvantages, and risks of robotic surgery to each patient and receiving their consent in writing.

RPD surgical technique[19]

We adopted the approach of laparoscopic resection with robotic reconstruction.[20] We resected the pancreas, including the duodenum, common bile duct (CBD), and gallbladder (GB), using laparoscopy and reconstructed using the robotic surgical system. The whole surgical procedure was divided into the following three parts: laparoscopic pancreatic resection, where we resected the pancreas, including the duodenum, CBD, and GB, using laparoscopy; robotic reconstruction, where we reconstructed using the robotic surgical system, including pancreatojejunostomy (PJ) and hepaticojejunostomy (HJ); and extracorporeal duodenojejunostomy, where we extended the incision of the umbilicus and removed the specimen through this incision, and then performed extracorporeal duodenojejunostomy. The standard approach of PJ is an interrupted suture, two-layer, and duct-to-mucosa PJ with a short stent, and the standard approach of HJ is continuous running suture on the posterior side and simple interrupted sutures on the anterior side. Details have been described in previous research.[21] Between steps 1 and 2, the robotic surgical system was docked into the abdomen and the surgeon performed the surgery via the console. All procedures performed were the same for both robotic surgical systems and were performed by one surgeon.

Robot-assisted CP surgical technique[22]

The technique of robot-assisted CP was similar to that of RPD. We resected the pancreas body using laparoscopy and reconstructed using the robotic surgical system.

Surgical outcomes

Clinicopathological characteristics and short-term surgical outcomes, including the length of hospital stay and complications, were assessed. To assess and communicate a patient's pre-anesthesia medical comorbidities, we used the American Society of Anesthesiologists (ASA) classification.[23] Postoperative complications were graded according to the Clavien–Dindo classification system (minor complications: grades I–II; major complications: grades III–V).[24] The highest complication grade in each patient was considered the final overall complication grade for that individual. POPF was defined according to the updated International Study Group of Pancreatic Fistula criteria established in 2016.[25] Fistula Risk Score (FRS) was defined as the risk score of POPF calculated using the details of pancreas texture, pancreatic duct size, the amount of intraoperative blood loss, and diagnosis.[26] Alternative Fistula Risk Score (a-FRS) and Updated Alternative Fistula Risk Score (ua-FRS) were defined as the risk scores of POPF calculated using the details of pancreas texture, pancreatic duct size, and BMI.[27] Delayed gastric emptying was defined as an inability to tolerate oral intake, emesis, and the need for prokinetics or nasogastric tube decompression, with the grade (A, B, or C) taking into consideration the presence and duration of each of these factors.[28]

Surgical times

The total operation time was defined as that from the abdominal incision to complete closure of the port sites, while docking time was defined as the time taken to dock the robot arm to the abdomen (i.e., the time between steps 1 and 2 of the three-step surgery process described above). Finally, console time was defined as the length of time required for the surgeon to perform the surgery in the console (i.e., the length of time required for step 2).

Retrospective comparative analysis: Revo-i vs. da Vinci™ RPD

To enhance the clinical efficacy and safety profile of the Revo-i system, postoperative outcomes were retrospectively compared to those of the da Vinci™ system. From March 2017 to August 2020, a total of 49 patients who underwent RPD were analyzed retrospectively (Fig. 2). The cases with advanced malignancy, including portal vein resection and anastomosis, were

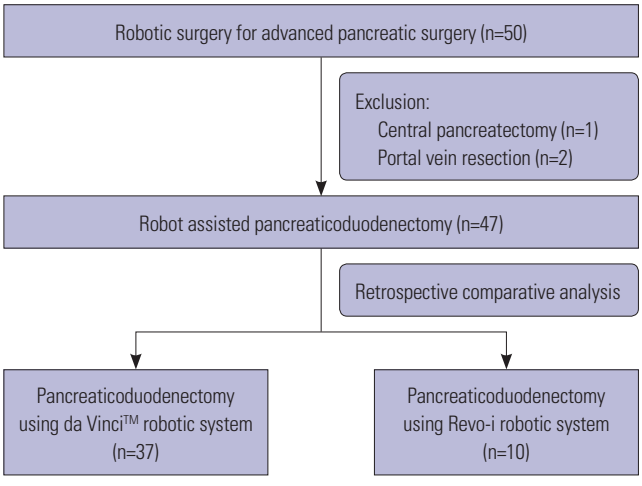

Fig. 2. The flowchart of retrospective comparative analysis.

https://doi.org/10.3349/ymj.2023.0140

excluded. Basically, the surgical technique for RPD was the same between the two groups. This retrospective analysis was also approved by the Institutional Review Board of Severance Hospital (approval no. 4-2020-1074).

Statistical analysis

Statistical analyses were performed using the R package, version 4.2.1 (http://www.R-project.org). Continuous variables were tested using the Student's t-test or Wilcoxon rank sum test. Categorical variables were tested using the chi-squared or Fisher's exact test. In this study, categorical variables are expressed as frequency (percentage), and continuous variables are expressed as mean±standard deviation or median [q1–q3], as they have a non-normal distribution. Statistical significance was defined as $p<0.05$.

RESULTS

Perioperative surgical outcomes of the second clinical trial of the Revo-i robotic surgical system in advanced pancreatic surgery

Table 1 shows the perioperative surgical outcomes of advanced pancreatic surgery realized using the Revo-i robotic surgical system. In this prospective second clinical trial, RPD was performed in nine patients, while one patient underwent RCP. Seven patients were female and three were male, with a mean±SD age of 56.60±16.68 years. The average BMI for all patients was 24.08±1.75 kg/m^2. Five patients underwent pancreatectomy for periampullary cancers and five patients underwent the same for low-grade malignant tumors of the pancreas.

The pancreas texture was noted to be soft in nine patients, while the average pancreatic duct size was 2.60±1.78 mm. The average amount of intraoperative blood loss was 159.00±56.07 mL in all patients, and no instance of transfusion occurred during surgery using the Revo-i robotic system. The total operation time was an average of 451.60±47.25 minutes, while the average docking time was 9.40±3.47 minutes and the average console time was 118.90±24.50 minutes. The average length of stay in the hospital was 14.50±3.66 days, and there were no major complications or deaths during hospital stay (Table 1).

Comparative analysis between the Revo-i and da Vinci™ systems concerning RPD preoperative characteristics

Table 2 displays the general perioperative characteristics of the study participants. A total of 47 patients underwent RPD and were divided into the following two groups: those who underwent RPD using the da Vinci™ robotic surgical system (da Vinci™ group, n=37) and those who underwent RPD using the Revo-i robotic surgical system (Revo-i group, n=10). There was no statistical difference in age, sex, BMI, and ASA score distribution between the two groups (p=0.848, p=0.168, p=0.692, and

Table 1. Perioperative Surgical Outcomes of the Revo-i Robotic Surgical System

No.	Sex/age	BMI (kg/m^2)	Diagnosis	OP name	Tumor size (cm)	Retrieved LNs	Texture	BD size (cm)	PD size (mm)	EBL (mL)	Transfusion	OP time (min)	Docking time (min)	Console time (min)	LOH (day)	Complication(s)	C–D grade
1	M/62	26.0	IPMN	PPPD	6.0	3	Soft	1.0	5	200	None	454	15	136	14	POPF BL	I
2	M/37	24.0	NET	PPPD	2.5	0	Soft	1.0	2	50	None	449	10	150	13	POPF BL	I
3	F/57	19.7	NET	CP	1.2	0	Soft	1.0	1	50	None	305	28	135	11	No POPF	I
4	F/30	25.9	SPN	PPPD	5.1	3	Soft	0.8	1	100	None	413	30	142	16	POPF BL	II
5	F/72	25.1	AoV cancer	PPPD	1.5	10	Soft	2.0	3	200	None	450	5	135	13	POPF BL	I
6	F/35	21.4	NET	PPPD	2.5	8	Soft	0.8	1	100	None	466	13	159	14	POPF BL	I
7	F/57	25.9	GIST	PPPD	5.0	12	Soft	0.8	1	210	None	480	15	133	14	POPF BL	II
8	F/73	24.4	CBD cancer	PPPD	2.5	29	Soft	0.8	2	170	None	416	7	113	24	POPF BL Chyle leak, DGE, wound seroma	II
9	F/64	21.6	AoV cancer	PPPD	1.0	31	Hard	0.8	5	200	None	419	11	125	15	No POPF	I
10	M/72	22.5	CBD cancer	PPPD	1.9	4	Soft	1.0	5	160	None	465	7	132	11	POPF BL	I

BMI, body mass index; OP, operation; LN, lymph node; BD, bile duct; PD, pancreatic duct; EBL, estimated blood loss; LOH, length of hospital stay; C-D grade was defined as the Clavien-Dindo classification system; IPMN, intraductal papillary mucinous neoplasm; NET, neuroendocrine tumor; SPN, solid pseudopapillary neoplasm; AoV cancer, ampulla of Vater cancer; GIST, gastrointestinal stromal tumor; CBD, common bile duct; PPPD, pylorus-preserving pancreaticoduodenectomy; CP, central pancreatectomy; POPF BL, postoperative pancreatic fistula biochemical leak; DGE, delayed gastric emptying.

p=0.701). Moreover, there was no statistically significant difference in preoperative Carcinoembryonic Antigen, Carbohydrate Antigen 19-9 values and diagnosis between the two groups (p=0.263, p=0.432, and p=0.473). Finally, there was no statistically significant difference in FRS, a-FRS, and ua-FRS[29] (p=0.530, p=0.335, and p=0.769).

Comparative analysis between the Revo-i and da Vinci™ systems concerning RPD intraoperative outcomes

Table 3 shows the intraoperative outcomes according to the robotic surgical system. There was no difference in tumor size, pancreas texture, or pancreatic duct size between the two groups (p=0.749, p>0.999, and p=0.310). The Revo-i group included patients with a smaller mean size of bile duct than those in the da Vinci™ group (p=0.049). There was no statistical difference in R status or the amount of intraoperative blood loss between the two groups (p>0.999 and p=0.263). There was one case of intraoperative transfusion in the da Vinci™ group.

There was no statistical difference (Revo-i vs. da Vinci™) in terms of the total operation time [8 (6–12) vs. 12 (7–18) minutes, p=0.099]. The Revo-i group had longer console time than the da Vinci™ group [107 (79–140) vs. 136 (130–152) minutes, p=0.018] (Supplementary Tables 1 and 2, only online).

Comparative analysis between the Revo-i and da Vinci™ systems concerning RPD postoperative outcomes

Table 4 shows the postoperative complications that occurred according to the robotic surgical system used, although there was no statistically significant difference in complications between the two groups (p=0.695). The da Vinci™ group had two cases of grade IIIb complications that required reoperation. One patient was readmitted due to intestinal obstruction and underwent adhesiolysis and bypass surgery, while the other patient had an accident with the remnant drainage catheter and required foreign body removal under general anesthesia. The Revo-i group had two cases of grade IIIa complications that required readmission. One patient was readmitted due to intra-abdominal abscess–related POPF and a drainage catheter was inserted, while the other patient was readmitted due to HJ stricture and percutaneous transhepatic biliary drainage was done. There was no significant difference in the POPF rate between the two groups (p=0.317) (Supplementary Table 3, only online). There was also no case of bile leakage, intra-abdominal hemorrhage, or reoperation in the Revo-i group.

Revo-i patients experienced shorter length of hospital stay [18.0 (14.0–22.0) days vs. 14.0 (12.0–15.0) days, p=0.026]. Seven patients in the da Vinci™ group were readmitted, included the one patient previously mentioned as requiring reoperation, one patient with epigastric discomfort, and five patients who required pigtail drainage catheter insertion due to intra-abdominal abscess in association with POPF. Three patients in the Revo-i group were readmitted, including the two patients previously mentioned as requiring intervention and one patient with pancreatitis.

Table 2. Comparison of Perioperative Characteristics between Patients Undergoing da Vinci™ and Revo-i Pylorus-Preserving Pancreaticoduodenectomy

	da Vinci™ (n=37)	Revo-i (n=10)	p value
Age, yr	63.0 [54.5–67.0]	62.5 [36.0–72.0]	0.848
Sex (M:F)	21 (56.8):16 (43.2)	3 (30.0):7 (70.0)	0.168
BMI, kg/m^2	23.4 [21.3–26.1]	24.2 [22.3–25.7]	0.692
ASA score			0.701
1	5 (13.5)	2 (20.0)	0.630
2	20 (54.1)	6 (60.0)	>0.999
3	12 (32.4)	2 (20.0)	0.700
CEA, ng/mL	1.9 [1.3–2.7]	1.5 [1.0–1.8]	0.263
CA 19-9, U/mL	17.8 [7.2–60.6]	8.3 [6.6–24.0]	0.432
Diagnosis			0.473
Benign	13 (35.1)	5 (50.0)	
Malignant	24 (64.9)	5 (50.0)	
FRS, %	12.3 [8.7–24.4]	17.6 [8.7–24.4]	0.530
a-FRS, %	10.9 [7.5–23.3]	20.9 [8.7–28.0]	0.335
ua-FRS, %	30.0 [20.5–54.0]	40.0 [28.0–50.0]	0.769

BMI, body mass index; ASA, American Society of Anesthesiologists; CEA, carcinoembryonic antigen; CA19-9, carbohydrate antigen 19-9; FRS, Fistula Risk Score; a-FRS, Alternative Fistula Risk Score; ua-FRS, Updated Alternative Fistula Risk Score.
Data are presented as median [q1–q3] or n (%).

DISCUSSION

In this prospective study of the Revo-i robotic surgical system,

Table 3. Comparison of Intraoperative Outcomes between Patients Undergoing da Vinci™ and Revo-i Pylorus-Preserving Pancreaticoduodenectomy

	da Vinci™ (n=37)	Revo-i (n=10)	p value
Tumor size, cm	2.2 [1.7–2.5]	2.1 [2.0–3.1]	0.749
Pancreas texture			>0.999
Soft	32 (86.5)	9 (90.0)	>0.999
Intermediate	2 (5.4)	0	>0.999
Hard	3 (8.1)	1 (10.0)	>0.999
Pancreatic duct size, mm	2.0 [2.0–5.0]	2.0 [1.0–5.0]	0.310
Bile duct size, cm	1.0 [1.0–1.2]	0.8 [0.8–1.0]	0.049
Retrieved Lymph node, n	10.0 [4.5–14.5]	7.0 [3.0–12.0]	0.600
Lymphovascular invasion	9 (24.3)	2 (20.0)	>0.999
Perineural invasion	12 (32.4)	4 (40.0)	0.716
Intraoperative blood loss, mL	200.0 [100.0–325.0]	185.0 [100.0–200.0]	0.263
Intraoperative transfusion	1 (2.7)	0	>0.999
Resection status			>0.999
R0	31 (89.2)	9 (90.0)	
R1	6 (16.2)	1 (10.0)	

Data are presented as median [q1–q3] or n (%).

https://doi.org/10.3349/ymj.2023.0140

Table 4. Comparison of Postoperative Complications between Patients Undergoing da Vinci™ and Revo-i Pylorus-Preserving Pancreaticoduodenectomy

	da Vinci™ (n=37)	Revo-i (n=10)	*p* value
Complication*			0.695
Grade I	19 (51.4)	6 (60.0)	0.730
Grade II	7 (18.9)	2 (20.0)	0.424
Grade III a	9 (24.3)	2 (20.0)	0.664
Grade III b	2 (5.4)	0	>0.999
Grade IV	0	0	
POPF			0.317
No POPF+POPF BL	31 (83.8)	9 (90.0)	
CR POPF (POPF B+C)	6 (16.2)	1 (10.0)	
Bile leak	3 (8.1)	0	>0.999
Chyle leak	2 (5.4)	1 (10.0)	0.521
Delayed gastric emptying	4 (10.8)	1 (10.0)	>0.999
Intra-abdominal hemorrhage	0	0	
Wound problem	1 (2.7)	1 (10.0)	0.384
Hospital stay, days	18.0 [14.0–22.0]	14.0 [12.0–15.0]	0.026
Readmission	7 (18.9)	3 (30.0)	0.667
Reoperation	2 (5.4)	0	>0.999
Death	0	0	

POPF, postoperative pancreatic fistula; BL, biochemical leak; CR, clinically relevant.
Data are presented as median [q1–q3] or n (%).
*Complication was defined as the Clavien-Dindo classification system.

advanced pancreatic surgery was performed with a success rate of 100%. Surgeries were spread relatively evenly in terms of age, BMI, and diagnosis. Based on the secondary endpoint of this study, the incidence of major complications during hospitalization was 0%. Among the 10 study participants, there were eight cases of POPF biochemical leak (80%), all of whom recovered after conservative management. Although these results are data from a single surgeon who passed the learning curve with the existing robotic surgical system, they support that the first clinical application of the Revo-i robotic surgical system in advanced pancreatic surgery was successful.

Until now, to our knowledge, there has been no study comparing PDs in robotic surgical systems. This is likely because the well-made da Vinci™ robotic system has been leading the robotic market to date. The most important issue in robot-assisted surgery is the cost. It is a question of whether robotic surgery has enough profits to pay a high price even though there are alternatives, such as open or laparoscopic surgery. Baker, et al.[30] reported that the cost of robotic surgery is not significantly different from open surgery considering the total hospital costs, including the costs of hospital stay and follow-up visit charges ($176931 RPD vs. $182552 open PD; p=0.69). However, it is difficult to generalize this observation since medical insurance conditions vary from country to country. If robotic surgery can be done at a laparoscopic price, then it is likely that robotic surgery will be performed. The answer to the cost problem can be achieved through the development of various robotic surgical systems and competitive markets.

Here, the Korean firm Meerecompany has developed a competitive robotic system known as Revo-i. Since its introduction in 2006, Revo-i has proven its stability step by step through preclinical experimentation in a porcine model and preclinical and clinical studies.[12-15,19] In 2017, this technology was approved for clinical use by the Korean Food and Drug Administration (no. 14, 2016-04-26). As compared with the da Vinci™ system, the Revo-i robotic surgical system exhibits no significant difference in functionality and has several advantages. Limitations placed on driving speed and movement enable safe surgery.[13] Also, Revo-i is a domestic development and can solve technical problems through a quick feedback loop. It is also expected that Revo-i will be cheaper than conventional robots, which is expected to give it a significant advantage in the global robot market. Of course, Revo-i also has some limitations, such as the angle of movement of the needle driver relative to da Vinci™. Moreover, there is an unnatural feeling in some movements as the synchronization between the robot and surgeon is not yet perfect compared to da Vinci™. These aspects are likely to be improved through continuous feedback.

The robotic surgical system has the advantage of being able to easily access and implement even when operated by beginner surgeons since there is no limit placed on the angle or movement as compared with conventional laparoscopic surgery. This technique is expected to be much easier to adopt and to decrease the learning curve relative to laparoscopic surgery.[5] Through this, a stronger and stable anastomosis process was achieved by involving robotic surgery technology.[8]

The Revo-i and da Vinci™ robotic surgical systems were effective for anastomosis, and there was no significant difference in postoperative complications or operation time between them. Revo-i patients had shorter hospital stay compared to da Vinci™ patients; notably, there was no significant difference in the length of hospital stay for patients recovering from the actual procedure, but there were statistical variations. It is thought that there were some patients with grade IIIa complications after da Vinci™ robot surgery, which influenced the overall hospital stay length of the da Vinci™ group. Especially, in terms of POPF, it was found that the robotic surgical system used was not a risk factor for clinically relevant POPF incidence (univariate analysis: p=0.667; multivariate analysis: p=0.982; data not shown), suggesting the safety and effectiveness of the Revo-i robotic surgical system in performing PD. However, the present comparative study was a retrospective investigation, and the number of cases was thought to be unbalanced between the two groups. Therefore, careful interpretation is needed and further research is mandatory, focusing on accumulating data from clinical experiences.

There are differences in the details of the console time be-

tween two robotic systems. The main cause behind such differences is the machine learning curve. In surgeries using the da Vinci™ robotic system, the surgeon has overcome the machine learning curve through several cases, and recently, both the surgeon and the assistant have been able to operate the robot efficiently in a short operation time. Moreover, since there are still relatively few cases of surgery using the Revo-i robotic system, both the surgeon and the assistant are adapting to the robotic system. In the early days of introduction of the Revo-i robotic system, the technician had to check the device during surgery due to poor contact with the docking arm. The operator needed time to adapt to the range of motion limitations of the Revo-i robotic system. The discrepancy between the movements of the operator and the robotic machine was gradually adapted. Also, since the assistant was not familiar with the Revo-i robotic system, it took some time to prepare for the operation and change instruments. These technical problems are being corrected through continuous feedback, and the Revo-i robotic system is in the process of being upgraded. Currently the Revo-i robotic system is in the stabilization stage. So efficient surgery with less operation time will be possible in the future. Judging by the experience of the recently introduced Revo-i robotic system, surgeons are adapting to the Revo-i robotic system and developing their own know-how to use the technology safely and effectively. In the future, we expect that more improved Korean-style robots will be able to address these machine learning curve issues based on various technical advice from existing users.

This study had some limitations. First, the non-randomized clinical trial was performed as a prospective single-arm study, while the comparative analysis was conducted following retrospective data collection. As a result, this study had the limitations of being a non-randomized clinical trial and retrospective study. There was one patient with RPD using Revo-i who was not enrolled in a non-randomized clinical trial, but the patient was reviewed retrospectively in the comparative analysis. Second, the number of patients was small, and only short-term follow-up results were analyzed in this study. Third, since Revo-i robotic surgery was performed by a surgeon who passed the learning curve with the da Vinci™ system, relatively good results were obtained. Likewise, by having an assistant who was trained in da Vinci™ surgery, we were able to quickly shorten the docking time in Revo-i surgery. Fourth, the Revo-i group had good discharge compliance since it was supported by research funds. This bias affected the average length of hospital stay in the two groups.

Unlike in the past, laparoscopic and robotic surgeries are now being performed as well as open surgery through improvements in surgeons' skill levels and technological advancement. Considering the concept of minimally invasive surgery, in the future, comparing robot-assisted and laparoscopic surgery would be meaningless. Once a level of cost-effectiveness with the robotic surgical system is achieved, it is expected that the day will come when this technology can be used together with conventional techniques without distinction and can be implemented freely to customize patient treatment.

In conclusion, in this single-arm prospective study with short-term follow-up at a single institution, the Revo-i robotic surgical system was safe and effective for advanced pancreatic surgery. Revo-i RPD is comparable to da Vinci™ RPD and is expected to have wide clinical application. To date, no research has compared robotic surgical systems in this context, so the present study is likely to support the continued development and refinement of robotic surgical systems.

ACKNOWLEDGEMENTS

The statistical methods and results of this study were reviewed by a member of the Biostatistics Collaboration Unit of Yonsei University College of Medicine. We would like to thank eWorldEditing (eworldediting.com) for the English language editing. We would like to thank Hyung Joo Kim and Ji Won Kim from Meerecompany. We would like to thank Seung Ho Choi from Department of Anesthesiology and Pain Medicine of Yonsei University.

The present clinical trial was supported by research funding from the Meerecompany (1-2019-0030). According to the memorandum of understanding, the company provided a fee in exchange for technical advice.

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