



Robot-assisted pancreatoduodenectomy with the da Vinci Xi: can the costs of advanced technology be offset by clinical advantages? A case-matched cost analysis versus open approach

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Abstract

Background Robot-assisted pancreatoduodenectomy (RPD) has shown some advantages over open pancreatoduodenectomy (OPD) but few studies have reported a cost analysis between the two techniques. We conducted a structured cost-analysis comparing pancreatoduodenectomy performed with the use of the da Vinci Xi, and the traditional open approach, and considering healthcare direct costs associated with the intervention and the short-term post-operative course.

Materials and methods Twenty RPD and 194 OPD performed between January 2011 and December 2020 by the same operator at our high-volume multidisciplinary center for robot-assisted surgery and for pancreatic surgery, were retrospectively analyzed. Two comparable groups of 20 patients (Xi-RPD-group) and 40 patients (OPD-group) were obtained matching 1:2 the RPD-group with the OPD-group. Perioperative data and overall costs, including overall variable costs (OVCs) and fixed costs, were compared.

Results No difference was reported in mean operative time: 428 min for Xi-RPD-group versus 404 min for OPD, $p=0.212$. The median overall length of hospital stay was significantly lower in the Xi-RPD-group: 10 days versus 16 days, $p=0.001$. In the Xi-RPD-group, consumable costs were significantly higher (€6149.2 versus €1267.4, $p<0.001$), while hospital stay costs were significantly lower: €5231.6 versus €8180 ($p=0.001$). No significant differences were found in terms of OVCs: €13,483.4 in Xi-RPD-group versus €11,879.8 in OPD-group ($p=0.076$).

Conclusions Robot-assisted surgery is more expensive because of higher acquisition and maintenance costs. However, although RPD is associated to higher material costs, the advantages of the robotic system associated to lower hospital stay costs and the absence of difference in terms of personnel costs thanks to the similar operative time with respect to OPD, make the OVCs of the two techniques no longer different. Hence, the higher costs of advanced technology can be partially compensated by clinical advantages, particularly within a high-volume multidisciplinary center for both robot-assisted and pancreatic surgery. These preliminary data need confirmation by further studies.

Keywords Robotic pancreatoduodenectomy · Open pancreatoduodenectomy · Costs' analysis

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Pancreatoduodenectomy (PD) is such a complex operation that the diffusion of the minimally invasive approach has lagged behind other abdominal surgical oncology procedures, including other minimally invasive pancreatic interventions such as distal pancreatectomy. In fact, since the description of the first minimally invasive pancreatoduodenectomy (MIPD) in 1994 [1], in contrast to laparoscopic distal pancreatectomy which is widely performed, laparoscopic PD is still uncommon due to the difficulty in performing this operation completely laparoscopically [2].

Robotic assisted surgery (RAS) emerged as a potential alternative to laparoscopy, overcoming some of its intrinsic limitations. Since Giulianotti et al. [3] reported the first case of robot-assisted PD in 2003, several studies have compared robotic and open pancreatoduodenectomy (OPD), showing that robotic pancreatoduodenectomy (RPD) is a feasible and safe procedure for both benign and malignant pathologies [4]. Some studies have demonstrated that RPD reduces estimated blood loss and length of post-operative stay in comparison to OPD [5–7] and that RPD is associated with better oncological outcomes respect to OPD, showing superiority in terms of disease-free survival, time to starting adjuvant chemotherapy, and rate of negative margins [8]. Nevertheless, the diffusion of RPD is still very limited, mainly because of the technical challenges of the MIPD, as well as for the economic impact of the use of da Vinci Surgical System. Indeed, it is well known that robotic assisted surgery is generally associated with higher costs in comparison to laparoscopy and traditional open approach [9].

However, despite the cost analyzes carried out in the initial experience with the robotic platform use were strongly against the use of the da Vinci Surgical System, more recent studies have reported different results in contrast with the initial ones, also in the field of pancreatic surgery [10–12]. Moreover, very few studies have focused on the cost analysis of RPD [13–16]. Therefore, the aim of our study is to perform a structured cost-analysis comparing RPD carried out with the use of the da Vinci Xi and traditional OPD performed in a multidisciplinary robotic surgery center, considering healthcare direct costs associated to the interventions and those associated to the short-term post-operative course.

Materials and methods

A total of 20 RPD performed at the Multidisciplinary Center for Robotic Surgery of Pisa, from January 2018 to December 2020, and 194 OPD still performed at our tertiary care center for pancreatic surgery from January 2011 to December 2020, were included in the present study. All patients were operated by the same surgeon (LM) with high experience of pancreatic surgery (> 400 procedures) and minimally invasive surgery (both laparoscopic and robotic surgery, > 800

procedures), and had undergone PD, with several indications for surgery (either benign or malignant).

Since we started performing RPD in 2018, the choice of the operative technique (open or robot-assisted) was at the discretion of the operating surgeon and based also on the robotic platform availability. The only surgical exclusion criteria for minimally invasive approach were the presence of vascular involvement (borderline resectable or locally advanced tumors), or previous major open surgery on supramesocolic area. Moreover, also some patients with malignant tumors diagnosed in a moment of low availability of the robot, although without clinical contraindication for RAS, were operated with an open approach to avoid stretching excessively the time interval between diagnosis and surgery. In case of availability of the robot and absence of clinical contraindications, the operating surgeon always proposed the robotic approach to the patient, and no patient refused a priori the choice of the robot. All the RPDs were performed with the da Vinci Xi platform.

To compare outcomes and costs between the two groups minimizing possible biases deriving from treatment allocation, two comparable groups were obtained by matching 1:2 RPD with OPD patients. To further minimize biases, patients who had undergone OPD with vascular resection were excluded before matching, as in RPD group no cases of PD with vascular resection were performed. The following parameters were considered for the matching: age, gender, Body Mass Index (BMI), American Society of Anesthesiology (ASA) score, type of procedure excluding from the OPD-group the cases in which a vascular resection was performed, histological diagnosis, T stage for malignant neoplasms, and tumor dimension. After matching, the final population included 60 patients divided in two groups: 20 cases in the XI-RPD-group and 40 cases in the OPD-group.

Data on patients' preoperative characteristics, surgical procedures, post-operative course, follow-up and resources used (i.e., associated to operative time (OT), length of stay, re-intervention, major post-operative complications, etc.) were retrospectively reviewed and analyzed, from a prospectively collected database.

The preoperative workup included abdominal ultrasonography, abdomen CT and/or MRI.

The decision about hospital dismissal of the patients was always made by the same surgeon who performed the operation, on the basis of clinical criteria, such as the patient's complete autonomy (ability to feed himself and manage his daily routine) and absence of signs of sepsis. The presence of an abdominal drainage for biochemical leak or pancreatic fistula was not a criterion for not discharging patients.

Surgical procedures

Robotic PD

For RPD we adopted the technique already described in our previous manuscript [17]. The patient is placed supine with the legs parted. A total of five trocars are placed at least 8 cm aside from each other to minimize the risk of collision of manipulator arms. Four robotic trocars are placed about 1–2 cm above the transverse umbilical line, two along the mid-clavicular line and two on the anterior axillary line, on either side. The 12-mm assistant port is placed immediately below or above the umbilicus, depending on the distance between the xiphoid process and the umbilicus. The right mid-clavicular line trocar is used for the camera. The robot is docked from the patient's right side. Monopolar scissors, bipolar Maryland forceps, and a grasper are used for the right hand, the left hand, and the fourth arm, respectively. In addition, the EndoWrist Vessel Sealer Extend is used for the dissection. One needle driver only is used in the right hand for the anastomoses. The dissection phase of the procedure follows the steps of open surgery, with some refinements needed for RAS approach. As first step, the stomach is grasped along the greater curve and elevated to open a window in the gastro-colic ligament, below the gastroepiploic arch and section of the right gastroepiploic vessels. Then the lymphadenectomy along the hepatic pedicle is performed with the identification of the elements of the hepatic pedicle. The common bile duct is isolated and dissected after placing Hem-o'-lock clips, also on the proximal portion, to avoid a bile leakage staining the operative field. After the section of the right gastric artery, the gastric section is performed with a stapler. Afterwards, the gastroduodenal artery is sectioned between clips immediately after its origin from the common hepatic artery. The transection of the pancreas is performed with the monopolar curved scissors and the pancreatic stump is then freed by only about 1–2 cm from the splenic artery and vein. The next step is Kocher's maneuver with the progressive mobilization of duodenal C-loop and pancreatic head. The Treitz liberation is performed by the right side, continuing the Kocher maneuver, to minimize the risk of malrotation of the intestinal loop during its retro-mesenteric transposition in the reconstructive phase. After the preparation and transection of the first jejunal loop with a stapler, the dissection phase is completed with the dissection of the pancreatic head from the portal vein and the retro portal lamina using the Vessel Sealer Extend. The first reconstructive step is the pancreatojejunostomy performed using a technique similar in many respects to our previously described modified PJ technique [18] in open surgery, with some modifications and technical refinements needed for the RAS technique and recently described (RmPJ) [17]. The RmPJ technique consists of a double layer of 3–0 absorbable

monofilament running barbed suture (V-Loc, Medtronic, MN). The outer layer is used to invaginate the pancreatic stump. Thereafter, a small enterotomy is made in the jejunum exactly opposite to the location of the pancreatic duct and a ureteral (usually 5 Fr) stent is inserted inside the duct, with the straight end placed in the Wirsung duct and the pigtail end in the jejunal lumen. The internal layer consists in a second barbed running suture placed between the pancreatic capsule/parenchyma and the jejunal seromuscular layer. The second anastomosis is the hepaticojejunostomy. The clip on the main bile duct is removed, an enterotomy of the equivalent size of the hepatic duct is created and a 5–0 polyester (PDS, Ethicon, Inc., NJ) single layer suture is carried out. Finally, the gastro-enteroanastomosis is carried out with 3/0 V-Loc double layer running suture.

Open PD

To perform the open pancreaticoduodenectomy the same principles and steps described before are followed. To perform the pancreatojejunostomy we used our own technique described in details in our previous article [18]. It consists in an interrupted atraumatic transverse 5–0 polypropylene (Prolene; Ethicon, Inc., NJ) sutures for the outer layers and in a single continuous running 5–0 polypropylene non-absorbable suture for the inner layers. In addition, in this technique, after the posterior layers, a small enterotomy is made in the jejunum exactly opposite to the location of the pancreatic duct and an ureteral (usually 5 Fr) stent is inserted inside the duct, with the straight end placed in the Wirsung duct and the pigtail end in the jejunal lumen. The second anastomosis is the hepaticojejunostomy performed with a 5–0 PDS single-layer suture. Finally, the gastro-enteroanastomosis is carried out with 3/0 Polisorb (Medtronic, MN) double-layer running suture.

Data collection

Preoperative data included age, gender, BMI, ASA score, and preoperative diagnosis. Operative data included the type of surgical procedure, OT, conversion rate, any additional organ or vascular resection, and intraoperative complications. Postoperative data included length of hospital stay (LoS), both considering intensive care unit (ICU) and general ward, complications (according to the Clavien-Dindo Classification [19]), post-operative procedures (abdominal drain placement, biliary drain placement, endoscopic procedures), re-operation rate, and mortality. The postoperative medical complications included pulmonary or urinary tract infections, cardiac complications, and neurologic complications. The surgical complications comprised surgical site infections, post-pancreatectomy hemorrhage [20], delayed gastric emptying [21], biliary leakage [22], post-operative

pancreatic fistula (POPF) [23], and abdominal collection. Pathological data included the final histology, tumor size, and the number of harvested lymph nodes.

Cost analysis

Direct healthcare costs associated with each intervention were valued using a micro-costing approach based on resources used and unit costs collected from the accounting department of the hospital. Overall direct costs (OCs) were divided in fixed costs and variable costs, including among the first, the purchase and maintenance costs of the technology and the proportion of fixed costs attributable to a single intervention. This latter was estimated firstly deriving a cost per year based on acquisition costs, the amortization period and annual maintenance costs, then dividing these costs for the overall number of interventions for which each technology was used. On the other hand, overall variable costs (OVC) comprised items related to disposable instruments used within each intervention (consumable costs, CCs), operating room personnel (personnel costs, PCs), and hospital stay costs (HCs) which included LoS, in both ICU and general ward, costs of reoperation, and post-operative procedures. For each intervention variable costs associated with the specific intervention were estimated valuing resources used according to unit costs collected. Details about resources used and related costs are reported in Tables 1, 2, 3 and 4. All costs were expressed in Euro and referred to 2020.

The study was approved by the Institutional review board.

Statistical analysis

Categorical variables were depicted as number of cases and percentages, while continuous variables were expressed as mean \pm (standard deviation) or median and [25–75 percentile] or [minimum; maximum value] as appropriate, depending on their distribution. Chi-square test and Fisher test were used to compare the distribution of categorical variables between groups. For continuous variables, comparisons

Table 1 Details of fixed costs

	OPD-group	Xi-RPD-group
Fixed costs attributable to the single intervention ^a (€)	34.4	1827.25

OPD open pancreatoduodenectomy, Xi-RPD robotic pancreatoduodenectomy with da Vinci Xi

^aThe costs are estimated dividing the acquisition costs for the amortization period, then considering annual maintenance costs and finally dividing annual costs by the overall number of interventions performed with the specific technology

Table 2 Personnel and hospital stay cost

Personnel group	Unit cost (€/h)	Number of figures
Surgeon	62.69	2
Anesthetist	65.63	1
Anesthesiology technologist	27.96	1
Surgical nurse	30.50	1
Surgical technologist	31.34	1
Nurse assistant	21.36	1
Hospital stay costs in a surgical ward	420.00	–
Hospital stay costs in an ICU	1150.00	–

OPD: open pancreatoduodenectomy, Xi-RPD robotic pancreatoduodenectomy with da Vinci Xi, ICU intensive care unit

were made using independent *T*-test or Mann–Whitney test depending on variables' distribution.

Generalized linear models were used to evaluate the impact of the different surgical techniques on costs. In details, in addition to simple models, multiple models were developed including those variables with *p*-value < 0.10 in simple models. A *p*-value < 0.05 was considered statistically significant. All analyses were performed using Stata version 14.

Results

Preoperative data of the two matched groups are summarized in Table 5. After the matching, OPD and Xi-RPD groups resulted well matched with respect to demographics and ASA score as no differences were found between the two groups with respect to those variables.

Operative data are summarized in Table 6. The mean OT was similar between the two groups: 404 min for the OPD-group versus 428 min for the Xi-RPD-group (*p* = 0.212). No conversion to open or laparoscopic approach was reported in the Xi-RPD-group. No differences were reported in terms of overall post-operative

Table 3 Consumable cost of OPD-group

	Unit costs (€)	Quantity	Overall CC (€)
Prolene 5/0	10	€ 7.00	€ 70.00
PDS 5/0	2	€ 17.10	€ 34.20
Polisorb suture	4	€ 1.30	€ 5.20
Stapler	1	€ 207.40	€ 207.40
Stapler charge	2	€ 109.80	€ 219.60
Ligasure	609.00	1	€ 609.00
Stent 5Fr	1	€ 122.00	€ 122.00

OPD open pancreatoduodenectomy, CC consumable cost

Table 4 Consumable cost of Xi-RPD-group

	Unit costs (€)	Quantity	Overall CC (€)
Instrument arm drape	128.93	1	128.93
Column drape	61.53	1	61.53
Cadiere forceps	568.57	1	568.57
Maryland bipolar forceps	769.00	1	769.00
Monopolar curved scissors	909.73	1	909.73
Robotic large needle driver	623.91	1	623.91
Vessel sealer	1805.96	1	1805.96
Tip cover accessory	57.52	1	57.52
Cannula seal 5–8 mm	44.63	4	178.52
8 mm bladeless obturator	72.39	1	72.39
12 mm laparoscopic trocar	48.00	1	48.00
Laparoscopic stapler	219.00	1	219.00
Laparoscopic stapler charge	189.00	2	378.00
Verees needle	6.13	1	6.13
V-Loc suture	10.23	8	81.82
PDS 5-0	2	€ 17.10	€ 34.20
Hem-O-Lock	2	€ 42.00	€ 84.00
Stent 5Fr	1	€ 122.00	€ 122.00

Xi-RPD robotic pancreatoduodenectomy with da Vinci Xi, *CC* consumable cost

complications rate between the two groups: 37.5% in the Xi-RPD-group and 50% in the Xi-RPD-group ($p=0.355$). The incidence of complications with Clavien-Dindo \geq III was similar between the two groups, being 10% in both groups ($p=1.000$). The incidence of POPF was similar between the two groups: it occurs in 11/40 patients (27.5%) in the OPD-group and in 4/20 patients (20%) in the Xi-RPD-group ($p=0.527$). No difference was reported also in terms of POPF grading: in OPD group a biochemical leak was registered in 7/40 patients (17.5%), a grade B POPF in 3/40 patients (7.5%) and a grade C POPF in 1/40 patient (2.5%), while in Xi-RPD-group a biochemical

leak occurred in 3/20 patients (15%) and a grade B POPF in 1/20 patient (5%) ($p=0.881$). The incidence of clinically significant POPF was 10% (4/40 patients) in the OPD-group and 5% (1/20 patient) in the Xi-RPD-group, $p=0.501$. Grade B POPF required a percutaneous abdominal drainage placement in 1/3 patient of the OPD-group and in 1/1 patient of the Xi-RPD-group. The grade C POPF of the OPD-group required re-operation and the patient eventually died following this and multiple other complications. Only in the Xi-RPD-group it was reported a bile leak in 1/20 patient (5%) who was treated with the positioning of an ultrasound-guided biliary drainage ($p=0.154$). Only in the OPD-group, 2/40 patients (5%) underwent reoperation in the post-operative course: in one case, due to e grade C POPF with hemorrhage, a completion of pancreatectomy with splenectomy was performed, while the second patient was re-operated for hemoperitoneum. A post-operative abdominal collection was detected in 7/40 patients (17.5%) of the OPD-group and in 3/20 patients (15%) of the Xi-RPD-group. The median LoS was significantly shorter in the Xi-RPD-group than the OPD-group: 10 days versus 16 days, respectively ($p=0.001$). No difference instead was reported in terms of median length of ICU recovery between the two groups ($p=0.285$).

Pathological data are shown in Table 7, with no differences between the two groups, being the criteria of matching. The T and N status, the mean tumor dimension and the mean number of harvested lymph nodes were also similar between the two groups.

The results of the cost analysis are summarized in Table 8. The median PCs were similar between the two groups: €2115 both for Xi-RPD-group and for OPD-group, $p=0.230$. The comparison of the CCs showed significantly higher costs of Xi-RPD-group with respect to the OPD-group, median values being €6149 and €1267, respectively, $p<0.001$. HCs were significantly lower in the Xi-RPD-group with respect to the OPD-group, median values being €5232 and €8180, respectively, $p<0.001$. OVCs were not statistically different being €13,483 for the Xi-RPD-group and €11,880 for the OPD-group, $p=0.076$;

Table 5 Preoperative data

	OPD-group ($n=40$)	Xi-RPD-group ($n=20$)	<i>p</i> value
Age (years), mean \pm SD	71.6 \pm 9.2	68.4 \pm 7.7	0.191
Male: female (%)	23:17 (57.5:42.5)	8:12 (40.0:60.0)	0.201
BMI (Kg/m ²), mean \pm SD	24.7 \pm 3.7	23.8 \pm 3.8	0.353
ASA score, <i>n</i> (%)			0.392
ASA I	0	1 (5.0)	
ASA II	8 (20.0)	4 (20.0)	
ASA III	30 (75.0)	15 (75.0)	
ASA IV	2 (5.0)	0	

BMI Body Mass Index, *ASA score* American Society of Anesthesiologists score

Table 6 Perioperative data

	OPD-group (n=40)	Xi-RPD-group (n=20)	p value
Operative time (min), mean ± SD	404 ± 68	428 ± 67	0.212
Conversion to OPD	–	0	
Overall complications, n (%)	25 (62.5)	10 (50.0)	0.355
POPF, n (%)	11 (27.5)	4 (20.0)	0.527
Grade of POPF, n (%)			0.855
BL	7 (17.5)	3 (15.0)	
Grade B	3 (7.5)	1 (5.0)	
Grade C	1 (2.5)	0	
Bile leak, n (%)	0	1 (5.0)	0.154
Post-operative digestive hemorrhage, n (%)	3 (7.5)	0	0.209
Abdominal collection, n (%)	7 (17.5)	3 (15.0)	0.806
Clavien–Dindo score ≥ III, n (%)	4 (10.0)	2 (10.0)	1.000
Reoperation, n (%)	2 (5%)	0 (0%)	0.309
Length of hospital stay, median [Q1–Q3] (days)	16 [13–24.5]	10 [7.5–18]	0.001
ICU recovery, n (%)	1 [0;12]	1[0;3]	0.285
In hospital mortality, n (%)	1 (2.5%)	0 (0%)	0.476

POPF post-operative pancreatic fistula, BL biochemical leak, ICU intensive care unit

Table 7 Pathological data

	OPD-group (n=40)	Xi-RPD-group (n=20)	p value
Pathological diagnosis, n (%)			0.999
PDAC	18 (45.0)	9 (45.0)	
Ampullary adenocarcinoma	5 (12.5)	3 (15.0)	
Cholangiocarcinoma	3 (7.5)	1 (5.0)	
Duodenal adenocarcinoma	4 (10.0)	2 (10.0)	
IPMN	2 (5.0)	1 (5.0)	
Pancreatitis	4 (10.0)	2 (10.0)	
Ampullary adenoma	3 (7.5)	1 (5.0)	
Duodenal adenoma	1 (2.5)	1 (5.0)	
T status, n (%)			1.000
T1	6 (20.0)	3 (20.0)	
T2	16 (53.3)	8 (53.3)	
T3	4 (13.3)	2 (13.3)	
T4	4 (13.3)	2 (13.3)	
N status, n (%)			0.164
N0	8 (26.7)	8 (53.3)	
N1	10 (33.3)	2 (13.3)	
N2	12 (40.0)	5 (33.3)	
Tumor size (mm), mean ± SD	27.1 ± 13.4	26.5 ± 15.0	0.896
Harvest lymph nodes, mean ± SD	30.4 ± 6.8	27.0 ± 8.9	0.107

PDAC pancreatic ductal adenocarcinoma, IPMN intraductal papillary mucinous neoplasm

while OCs including fixed costs were significantly higher for Xi-RPD-group with respect to the OPD-group: €15,311 versus €11,914, respectively, $p=0.003$.

Table 9 showed results from the simple regression models for both OVCs and overall costs including fixed costs. Results from the generalized regression models

confirmed that, also when adjusting for BMI and complications, there were no differences in OVCs between the OPD-group and Xi-RPD-group ($p=0.115$); while fixed costs remained significantly higher in the Xi-RPD-group vs the OPD-group, $p=0.001$ (Table 10).

Table 8 Costs' analysis

	OPD-group	Xi-RPD-group	<i>p</i> value
Personnel's costs (€), median [Q1–Q3]	2115.2 [1825.6–2215.9]	2115.2 [1989.3–2,329.2]	0.230
Hospital stay costs (€), median [Q1–Q3]	8180 [6455–12,745]	5231.6 [3880–8290]	0.001
Consumables costs (€), median [Min;Max]	1267.4 [1267.4;1267.4]	6149.2 [6149.2;6149.2]	<0.001
Overall variable costs (€), median [Q1–Q3]	11,879.8 [10,145.4–16,572.8]	13,483.4 [12,194.8–16,466.3]	0.076
Overall costs (€), median [Q1–Q3]	11,914.2 [10,179.8–16,6624.4]	15,310.6 [14,022–18,295.5]	0.003

Table 9 Simple regression models

	Coef (std.Err)	<i>p</i> value
Overall variable costs		
Age	0.006 (0.005)	0.236
Male Gender	0.088 (0.086)	0.311
T1	0.106 (0.140)	0.447
T2	0.065 (0.109)	0.555
T3	– 0.204 (0.160)	0.204
T4	0.006 (0.160)	0.972
ASA 2 vs 1	– 0.015 (0.346)	0.966
ASA 3 vs 2	0.149 (0.337)	0.657
ASA 4 vs 3	0.344 (0.408)	0.399
BMI	0.027 (0.011)	0.015
Duodenum vs biliary duct	– 0.100 (0.211)	0.637
Pancreas vs biliary duct	– 0.135 (0.182)	0.458
Papilla vs biliary duct	– 0.010 (0.199)	0.960
Regular post-operative course	– 0.357 (0.070)	< 0.001
Surgical complications	0.332 (0.083)	< 0.001
Medical complications	0.337 (0.074)	< 0.001
Re-intervention	0.213 (0.245)	0.385
RPD vs OPD	0.057 (0.094)	0.549
Overall costs		
Age	0.005 (0.005)	0.363
Male Gender	0.065 (0.086)	0.449
T1	0.102 (0.139)	0.464
T2	0.062 (0.109)	0.568
T3	– 0.194 (0.159)	0.224
T4	0.005 (0.159)	0.973
ASA 2 vs 1	– 0.101 (0.344)	0.769
ASA 3 vs 2	0.055 (0.334)	0.869
ASA 4 vs 3	0.209 (0.405)	0.606
BMI	0.024 (0.011)	0.033
Duodenum vs biliary duct	– 0.081 (0.208)	0.696
Pancreas vs biliary duct	– 0.120 (0.179)	0.505
Papilla vs biliary duct	0.000 (0.196)	0.999
Regular post-operative course	– 0.325 (0.073)	< 0.001
Surgical complications	0.326 (0.082)	< 0.001
Medical complications	0.312 (0.075)	< 0.001
Re-intervention	0.171 (0.242)	0.479
RPD vs OPD	0.172 (0.093)	0.050

Parameters with a statistically significant *p* values are given in bold

Table 10 Multiple regression models

	Coef (std.Err)	<i>p</i> value
Overall variable costs		
RPD vs OPD	0.115 (0.073)	0.115
BMI	0.016 (0.009)	0.091
Regular post-operative course	– 0.131 (0.110)	0.234
Surgical complications	0.123 (0.096)	0.198
Medical complications	0.195 (0.089)	0.028
Overall costs		
RPD vs OPD	0.232 (0.073)	0.001
BMI	0.015 (0.009)	0.108
Regular post-operative course	– 0.127 (0.110)	0.246
Surgical complications	0.118 (0.095)	0.217
Medical complications	0.191 (0.089)	0.031

Discussion

The use of robotic technology to perform a minimally invasive PD was firstly reported by Giulianotti in 2003 [3]. However, so far, the use of minimally invasive techniques is limited to highly specialized centers, while the open approach is still chosen in most surgical centers. Indeed, it has been reported that only 4–14% of the PDs performed in the United States over the last two decades, were carried out with a minimally invasive approach. This could be due to the high complexity of minimally invasive PDs, especially if performed with traditional laparoscopy [24]. Nevertheless, in the last years, RAS has been increasingly diffused for different surgical procedures, including pancreatic surgery, mostly for distal pancreatectomy but also for PD. Considering the clinical outcomes, RPD represents a remarkable application of minimally invasive surgical technology, and some studies have shown favorable results if compared to the open approach [25–27]. Hence, the technical advantages of robotic systems should theoretically allow the expansion of the adoption of minimally invasive approach in the field of pancreatic surgery [28]. However, the costs associated with the robotic systems, thought to be high, are one of the major deterrents for the diffusion of RAS. Indeed, although RPD seems to be

associated with some positive impact on the outcomes with respect to the traditional open approach, it is still a matter of debate whether the use of the da Vinci is sustainable, and whether the technological advantages offered by the da Vinci Surgical System can justify its use [29].

In this setting, some recent studies on costs of RAS, have reported intriguing results, revealing possible biases of the cost-analysis published so far, and reporting on data in favor of the robotic approach, for pancreatic surgery and not only [11, 12, 14, 15, 30–32]. Indeed, previous studies concluding that procedure-related costs associated with RAS are too higher to be justified, did not consider important aspects for the cost analysis, such as the differences between the da Vinci Si and Xi platforms, several clinical aspects such as LoS or postoperative care costs, and the different outcomes related to the learning curve of the surgeon, as most of the published studies reported on their early experiences with RAS. [15]. Therefore, it becomes clear that, to be more comprehensively evaluated the costs-effectiveness of RAS for PD, that different factors should be evaluated comprising both those strictly related to the operating room costs including the instrumentations and personnel costs associated to the OT, but also those referring to the clinical outcomes, particularly the post-operative course, within a high-volume center both for RAS and for pancreatic surgery.

For all these reasons, and as very few structured cost analyzes have been performed on RPD so far [14, 15], we decided to evaluate the impact of the use of da Vinci Xi in this field, comparing the clinical outcomes of RPD and OPD performed by the same surgeon highly experienced in both RAS and pancreatic surgery, but also evaluating how these outcomes could influence the costs of the two techniques. Hence, to conduct our cost analysis, we divided them in fixed and variable costs, including in the first the purchase and maintenance of the technology, and in the latter the CCs, the HCs, and the PCs.

Not surprisingly, confirming previous reports, OCs including fixed and OVCs, resulted more expensive for RPD than for OPD, due to the high costs of purchase and maintenance of the da Vinci Xi. However, on the contrary, considering only the OVCs, we no longer observed any statistically significant difference between RPD and OPD, particularly thanks to the post-operative course which has clearly benefited from the minimally-invasive approach of RPD, as well as to the absence of differences in OT. Indeed, as different aspects contribute to the determination of the OVCs, the post-operative course resulted to be the parameter that seems to have influenced the results the most, being better in the Xi-RPD-group, and therefore compensating the higher instruments' purchase cost of RPD, while OTs and PCs resulted comparable.

Hence, in accordance with other data already reported in literature, the most relevant consequence of the better

post-operative course after RPD positively impacting on costs was the significantly shorter LoS [4, 26, 27, 33, 34]. Indeed, despite the minimal differences in clinical outcomes between the two groups, the stay of the open group was meaningful 6 days longer, likewise or even better to data reported by some authors in series showing no differences in term of overall post-operative complications between OPD and RPD [35, 36]. This is probably due to the well-known advantages of the minimally invasive approach, which is associated to a reduced tissue trauma, postoperative pain, pulmonary impairment, and systemic stress response [2, 27, 37]. In this regard, the main specific advantage of the robotic system is probably to allow to perform complex procedures such as PD without conversion to open surgery, and therefore to gain the benefits of the minimally invasive approach in all cases of the Xi-RPD-group [26]. Moreover, also the lower incidence of overall complication of the Xi-RPD-group, although not significantly different, may have partially contributed to the shorter LoS, in accordance with data reported in literature [27, 34]. In addition, the higher incidence of clinically significant POPF of the OPD-group, whose percentage was double that of the Xi-RPD-group, even if without statistically significant difference, may have played a role in the longer LoS of the OPD group. On the other hand, the lower rate of clinically significant POPF in RPD group could be due to the intrinsic advantages of the robotic technique, as reported in a recent meta-analysis [34], but possibly also to our recently described personal RmPJ technique [17]. Moreover, it has also to be noticed that we reported a mean LoS longer as compared with other robotic and open case series of international literature, however, in accordance with data of Italian series [38, 39]. This could probably be due to cultural factors characterized by a more cautious policy in discharging patients from hospital, as in Italy patients expect to leave hospital only when fully recovered and, therefore, needing little outpatient [3]. However, although in theory this particular aspect should have influenced both groups equally, it is possible instead that surgeon and patient's perception influenced by the new technology, could have contributed to increase the difference in the days of hospitalization between the Xi-RPD-group and the OPD-group.

With regards to the use of high-tech disposables of RAS, the higher CCs of RPD in our analysis were strictly conditioned by the high robotic instruments' purchase costs. However, with respect to other published experiences, and in line with our previous publications [10, 11], we confirmed that the standardization of the technique can contribute to reduce the number of instrument used in each operation and therefore to partially reduce the gap with the other techniques.

Another key point of our analysis is the reported OT. Indeed, while robotic procedures have been traditionally associated to longer OT respect to open ones, also for PD [4,

33, 34], in our series no differences were reported in terms of OT between RPD and OPD, therefore overcoming also this second criticism of RAS. Many factors could explain this data. First of all we used the last version of the da Vinci Surgical System, the da Vinci Xi, and it is well known that its technical advantages contribute to decrease the OT thanks to the enhancement of the surgical workflow, the lower risk of robotic arms' conflicts and the shorter docking time [40]. Moreover, also the standardization of the technique itself, with the improvement in robotic expertise, allowed to optimize the use of instruments, by performing all phases of the surgical operation with a basic set including the essential instruments to perform the operation, and using all other instruments on request and only if strictly necessary, therefore, contributing to decrease the OT due to the shorter traffic instruments times. The absence of differences in OTs made possible also to eliminate the gap in PCs between the two groups. Moreover, with RAS the console surgeon can control the camera directly by itself and can count on the availability of the fourth robotic arm as well as on gravity for retractions for the dynamic exposure of the surgical field. This could result in a possible further reduction of PCs of RPD, as it becomes easier to perform the RPD with only one assistant at the bedside also in difficult cases that would have required a further assistant in case of OPD.

All this considered, once these factors are incorporated into the OVCs calculation, particularly by including HCs, there was no longer statistical difference between costs associated with RPD and OPD, therefore giving a different perspective to the common view that robotic assisted pancreaticoduodenectomy is necessarily more expensive than other techniques.

A final important aspect which partially contributed to reduce the gap of CCs between the RPD and OPD in our series, is the use of the robotic platform in a multidisciplinary high-volume center. Indeed, in accordance with our experience, thanks to the high number of robotic operations performed each year at the Multidisciplinary Center of Robotic Surgery at Cisanello Hospital in Pisa, we obtained a 2% discount of robotic instruments' purchase costs, partially contributing to reduce the gap of CCs between the OPD and RPD. Moreover, performing at our Centre even more than a thousand robotic interventions per year, thanks to the purchase of a large number of robotic instruments, it is possible to obtain a further bulk discount, thus reducing the average cost of robotic instruments for each robotic intervention, with the possibility to obtain a further reduction of CCs of RPD. Furthermore, it has always been said that an important factor in CCs reduction would be the depreciation of robotic instruments. This recently occurred thanks to an evolution of robotic instruments that allowed to extend the number of uses while keeping the price of each instrument unchanged. In fact, until now each robotic instrument could

be used in ten different surgical procedures, spreading the purchase costs in ten uses. However, since the beginning of 2021, the new version of the Maryland bipolar forceps, robotic large needle drivers and Cadiere forceps can be used respectively for fourteen, fifteen and eighteen different surgical procedures respectively, thus contributing to reduce the CCs of €680.4. A further evolution of robotic instruments, also involving other instruments such as monopolar scissors, with a further extension of the number of uses and/or a reduction in purchase costs, would lead to a further reduction in CCs therefore increasing the sustainability of RAS.

As already mentioned, considering the OCs including fixed and overall variable ones, RPD confirmed to be more expensive than OPD, due to the high costs of purchase and maintenance of the da Vinci Xi. However, one final consideration may suggest that the fixed costs calculated for RPD in our analysis could be higher than the real value. In fact, in accordance to the accounting standards, fixed costs of each RPD were estimated considering the 5-year amortization period of the instruments. This period is obviously limited when compared to the actual period of use of the technologies, since the da Vinci Xi was purchased in our Multidisciplinary Center of Robotic Surgery in 2014 and it is still in full use. Hence, spreading costs over the entire product life cycle can give a more realistic view of the economic impact and the gap in fixed costs between RPD and OPD would be reduced.

Our study has some limitations, first its retrospective nature, and the not standardized choice of open versus robotic approach. However, in order to minimize and prevent possible biases deriving from treatment allocation, and to homogenize the surgical complexity of the cases, we used a case-control matching analysis including type of procedure, excluding from the OPD-group cases in which a vascular resection was performed, and histological criteria such as histological diagnosis, T stage for malignant neoplasms, and tumor dimension. In this way we eliminated the risks to compare patients who underwent RPD to those who underwent OPD for tumors which were perceived to be more difficult to remove secondary to location encroaching upon or involving the portal or mesenteric veins or hepatic artery. Moreover, to create two comparable groups also in terms of factors possibly influencing the post-operative course, the clinical criteria age, BMI and ASA score were used for the matching. Therefore, we also excluded the risk to have, in one of the two groups, patients with higher comorbidities which can negatively influence the post-operative course.

The matching performed provided quite good results as, despite slight differences, the matched groups showed no significant differences with respect to the parameters used. Moreover, we adopted a multiple regression model to assess every potential difference between groups, adjusting for possible confounders. Due to the limited

number of cases, we included in the multiple model just variable being significant in simple models to avoid overfitting. Moreover, although there is a tendential difference between the two groups for some parameters such as age, BMI and percentage of N2 cases which resulted slightly higher in OPD group, the difference for all these parameters was not statistically significant (neither in the descriptive nor in the regressions), and therefore, it is unlikely to attribute to these aspects the longer LoS. Furthermore, with regard to the higher percentage of N2 status and the higher number of harvested lymph nodes in OPD-group, these parameters are expected to affect above all the long-term prognosis of patients rather than the immediate post-operative course, while the T parameter, the tumor dimension and the histological diagnosis, should better represent the possible technical complexity of the intervention, and therefore to the post-operative complications and LoS.

In addition, the sample size, although in line with previous researches [12, 15], could represent a criticism. Indeed, as for the retrospective nature of the study, and for the still not widespread surgical technique (RPD), no sample size calculation has been performed a priori, so that we cannot exclude—also based on the actual differences found between costs of the OPD- and Xi-RDP groups and associated variability—that the statistical power reached could not be considered optimal. However, we believe that the present study, still represents one of the few studies focused on a structured cost-analysis in this scenario and, considering healthcare direct costs associated to the interventions and those associated to the short-term post-operative course, it provides valuable and up to date information for future research, aiming at comparing costs of the two approaches on similar patients.

Finally, another limitation to be mentioned is that, since this study comes from a high-volume center for both RAS and pancreatic surgery, the results of the analysis may not be applicable to all centers.

In conclusion, RAS is more expensive than open surgery, because of higher acquisition and maintenance costs. However, though RPD is associated to higher material costs, the advantages of the robotic system associated to lower hospital stay costs, and the no different personnel costs thanks to the similar OT with respect to the OPD, can make the OVCs of the two techniques no longer different.

Therefore, the higher costs of advanced technology can be partially compensated by clinical advantages, particularly within a high-volume multidisciplinary center for both robot-assisted and pancreatic surgery, but overall high costs of RAS remain an issue to be faced for the sustainability of RPD. Further studies considering a wider population and prospective in nature are needed to draw mode definitive conclusions.

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Declarations

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