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ORIGINAL ARTICLE

Surgical and oncological outcomes of our first 59 cases of robotic pancreaticoduodenectomy

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Summary

Purpose: Robotics has shown encouraging results for a number of technically demanding abdominal surgeries including pancreaticoduodenectomy, which has originally represented a relative contraindication to the application of the minimally-invasive technique. We aimed to investigate the perioperative, clinicopathologic, and oncological outcomes of robot-assisted pancreaticoduodenectomy by assessing a consecutive series of totally robotic procedures.

Methods: All consecutive patients who underwent robotic pancreaticoduodenectomy were included in the present analysis. Perioperative, clinicopathologic and oncological outcomes were examined. In order to investigate the role of the learning curve, surgical outcomes were also used to compare the early and the late phase of our experience.

Results: A total of 59 patients underwent surgery. Median hospital stay was 9 days (5 - 110), with an overall morbidity and mortality of 37% and 3%, respectively. Of note, the rate of clinically relevant pancreatic fistula was 11.8%. R0 resections were achieved in 96% of patients and the 3-year disease-free and overall survivals were 37.2 and 61.9%, respectively. Overall, surgical outcomes did not vary significantly between the first and the late phase of the series.

Conclusions: Robotic pancreaticoduodenectomy can be performed competently. It satisfies all features of oncological adequacy and may offer a number of advantages over standard procedures in terms of surgical results.

Introduction

Nearly two decades after its introduction in clinical practice, the minimally-invasive method is becoming more popular also in pancreatic surgery, essentially due to increased experience in this field and the availability of new technologies [1—5]. Despite this, if on one side minimally-invasive surgery (MIS) has been associated with considerable advantages over traditional open surgery in case of left-sided pancreatectomies [2,6,7], pancreaticoduodenectomy (PD) has been originally regarded as a relative contraindication to the application of laparoscopic techniques [2,4,8—10]. Indeed,

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until recently the acceptance of minimally-invasive PD has been relatively low and limited evidence is currently available, especially in terms of oncological data [2,4,8,11]. The last years have seen a growing enthusiasm for minimally-invasive PD, at least partially driven by the idea that the use of robotic platforms can be of help in expanding the application of MIS for pancreatic resection [1,2,4,8–16].

We aimed to evaluate a consecutive series of totally robotic PD with respect to surgical and oncological results. The influence of the learning curve on a single surgical team experience has been also examined.

Methods

All data were retrieved from a prospectively maintained database including all robotic pancreatic surgeries.

Preoperative evaluation featured esophagogastroduodenoscopy, contrast-enhanced CT, endoscopic ultrasound with fine-needle biopsy and FDG-PET scan, as needed. A multidisciplinary panel including our surgical team together with oncologists, radiologists and radiotherapists gave all indications for surgery according to a multimodal strategy.

All patients who were scheduled to receive a fully robotic PD were included in the study, according to an intention to treat principle. There were no exclusion criteria apart from contraindication to the minimally-invasive approach or preoperative evidence of locally advanced lesions with vascular involvement. A procedure-specific informed consent was obtained from each patient.

Operative technique

The same surgical team, supervised by the same experienced surgeon (AC) performed all interventions at two different Institutions: Misericordia Hospital, Grosseto (until March 2014) and Careggi University Hospital, Florence (since April 2014). For all interventions, a four-arm Da Vinci Surgical Robot (Intuitive Surgical, Sunnyvale, CA) was employed: a third-generation system (Da Vinci *Si*) was used earlier in the series and a fourth-generation system (Da Vinci *Xi*) later in the series depending on availability. The patient is placed supine, in a reverse-Trendelenburg position and the robot is placed on his right side. Fig. 1 describes our trocar strategy.

Each intervention commences with standard laparoscopic visual assessment of the peritoneal cavity in order to exclude advanced disease in the case of malignancy. Laparoscopic adhesiolysis is thus performed where needed to allow adequate ports placement. The robot is docked, and robotic instruments are placed next. After sectioning the gastrocolic ligament and mobilizing the hepatic flexure inferiorly up to the origin of the right gastroepiploic vessels, the duodenum is exposed and the superior mesenteric vein (SMV) is identified. A Kocher maneuver is performed up to the left lateral border of the aorta and the pancreas is fully exposed. An ultrasound inspection of the pancreas follows, to evaluate diagnoses made preoperatively and confirm resectability. In the early phase of our experience, these first steps were performed via conventional laparoscopy. After the first 10 cases, we converted our surgical technique to a fully robotic PD.

The pylorus with the first duodenum is dissected away from the pancreatic head. The right gastroepiploic and right gastric pedicles are isolated and divided between ties. The duodenum is then divided using an endoscopic stapler. Cholecystectomy, and isolation of the common hepatic

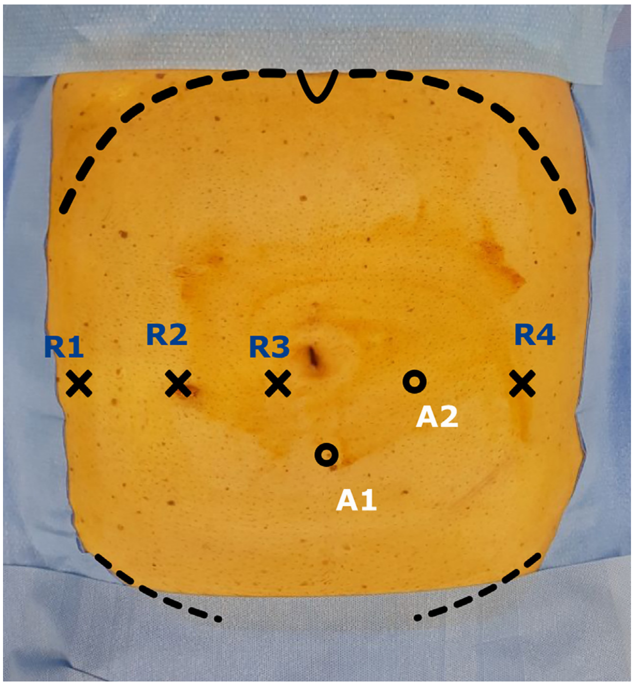

Figure 1. Trocar placement for robotic pancreaticoduodenectomy. The robot is docked on the right side of the patient. R1-4: robotic ports (R3 is used for the endoscope); A1-2 standard laparoscopic assistant ports.

artery (CHA) are then performed. The gastroduodenal artery (GDA) is prepared and transected between polypropylene ties. The isolation and transection of the common bile duct (CBD) is next performed. In the case of malignancy, a formal hilar lymphadenectomy including nodal stations 8a and 8p is routinely performed and the CBD proximal margin is sent for frozen-section evaluation. The lesser omentum is dissected including nodal station 12. Dissection proceeds towards the celiac axis and nodal station 9 lymphadenectomy is carried out.

The anterior surface of the SMV is exposed, the pancreas is gently retracted upward at the inferior edge of its neck and the *retropancreatic tunnel* is created between the pancreas and the SMV-portal vein (PV) confluence. An ultrasound inspection of the pancreatic parenchyma is generally repeated at this point and the main pancreatic duct (MPD) is identified and measured. The pancreas is thus divided with ultrasound dissector and monopolar scissors and its proximal margin sent for frozen-section evaluation.

The pancreaticoduodenal bloc is thus retracted medially, the retropancreatic lamina is excised and the anterior surface of the vena cava and the aorta are exposed. The greater omentum and the transverse colon are retracted cephalad. The jejunum is then stapled and isolated 10 to 15 cm distal to the ligament of Treitz. The proximal jejunum is then reflected posterior to the superior mesenteric pedicle into the right hypochondrium with the help of a rubber drain. The head of the pancreas is retracted rightward and the SMV-PV axis is gently retracted medially to expose the superior mesenteric artery (SMA). The uncinate process is exposed and dissected from caudal to cephalad (Video 1). Lymphadenectomy of stations 14 is then completed. During this phase, minor venous or arterial vessels from the superior mesenteric pedicle are generally clipped and divided, whereas major vasculatures such as pancreaticoduodenal branches are sectioned after selective manual placement of monofilament sutures. A final ultrasound inspection is usually performed to examine both the specimen and the residual pancreas, to confirm that radical resection has been effective.

The reconstructive phase is performed using a single bowel loop with robotically hand-sewn anastomoses. First, the transected jejunum is brought into the upper right quadrant and an end-to-side duct-to-mucosa pancreaticojejunostomy is created with two layers of interrupted sutures. In selected cases, such as when soft pancreases with small pancreatic ducts are encountered, a pancreaticogastrostomy is preferred. The CBD is trimmed freshly and a hepaticojejunostomy is performed approximately 10 cm distal to the pancreatic anastomosis. This anastomosis is performed with interrupted or running (depending on size of CBD) sutures in a single layer fashion.

The jejunum is traced distally to the biliary anastomosis and brought to lye antecolically. Finally, a single-layered running end-to-side duodenojejunostomy is fashioned. In the case of Whipple procedure, a posterior, stapled gastrojejunostomy is fashioned. At the end of the procedure, a drainage tube is usually placed.

Operative time was calculated as the time between skin incision and port-site closure. The same surgical group evaluated the postoperative course of all patients in the hospital service and in the outpatient setting thereafter. The severity of postoperative pancreatic fistula (POPF) was assessed according to the definition and grading given by the recent update of the International Study Group on pancreatic surgery. [17]. Postoperative complications were categorized according to the Clavien—Dindo classification system for surgical complications [18]. Recurrence was defined on the basis of any histologically or radiologically proven local or distant evidence. Survivals were calculated from the time of surgery to the last follow-up or the time of death. Postoperative mortality was defined as death while in the hospital service or within the first 90 days following surgery.

To assess possible differences due to the impact of the procedure-specific learning curve, we divided the entire series into an early phase (EP) and a late phase (LP) according to the principles suggested by Boone et al. [19].

Table 1 Baseline demographic and clinical characteristics of the population.

Patients	59
Age	69 (38—85)
BMI	24 (19—32)
Sex	
Male	34 (57.6%)
Female	25 (42.4%)
Diagnosis	
Pancreatic ductal adenocarcinoma	33 (55.9%)
Ampullary carcinoma	9 (15.3%)
Cholangiocarcinoma	3
Pancreatic cystoadenocarcinoma	2
Pancreatic carcinoma on IPMN	1
Pancreatic endocrine carcinoma	1
Pancreatic acinar carcinoma	1
Duodenal GIST	1
Chronic pancreatitis	3
Pancreatic cystoadenoma	4
Dysplasia on IPMN	1
ASA score	
ASA I	8 (13.7%)
ASA II	43 (72.9%)
ASA III	7 (11.9%)
ASA IV	1 (1.7%)

Values are presented as median (with range) or events (with percentages). ASA: American Society of Anesthesiologists.

Statistical analysis

Statistical analysis was carried out using the Statistical Package for the Social Sciences, SPSS v20.0 (SPSS Inc., Chicago, IL, US). Results were reported in descriptive statistic. To determine possible differences between homogeneous samples, univariable analysis was performed running a Student *t*-test or a Fisher's exact test for continuous or categorical variables, respectively. Kaplan-Meier estimates of disease-free survival (DFS) and overall survival (OS) were calculated. A two-tailed *P* value of 0.05 or less was deemed statistically significant.

Results

Fifty-nine consecutive patients underwent RPD during the observation period (March 2010—April 2017) and were eventually included in the analysis. The median age and BMI were 69 (range 38—85) and 24 (range 19—32), respectively. Thirty-four patients were males (58%). Table 1 provides general clinical characteristics. Overall, median operative time was 515 (390—720). The median estimated blood loss was 150 ml (range 30—900). Overall, 11 cases of conversion to an open procedure occurred (18.6%), whereby one case due to uncontrolled bleeding and the remaining cases because of technical impossibility to proceed robotically, mainly in relation with the presence of adhesions. Of note, 6 cases of conversion were observed in the EP (20 patients) in comparison to 5 cases in the LP group (39 patients). This difference did not elicit statistical significance ($P = 0.16$). Postoperatively, all patients were provided with first-line non-opioid analgesia (i.e. acetaminophen 1000 mg every 6—8 hours for 48—72 hours). Overall, the percentage of patients requiring opioid adjuncts for pain control was 10% on postoperative day one, 22% on postoperative day three and 3% on postoperative day 5.

Following surgery, the need for a radiological interventional procedure, including that of percutaneous drainage, transhepatic cholangiogram and angiography was 10%. The procedures were required due to abdominal abscess (4 patients), bile leak (1 patient), or pseudoaneurysm of superior mesenteric artery (1 patient). In total, 22 patients experienced some postoperative complications, defining an overall morbidity of 37.3%. Seven patients (11.9%) had Grade I—II complications, whereas 15 patients had Grade III—V complications (25.4%). Overall, 10 patients developed some grade of postoperative pancreatic leaks (16.9%) whereas clinically relevant POPF (B/C) were experienced by 7 patients (11.8%). Biochemical fistulas (Grade A) and B leaks occurred in 3 and 5 patients, respectively. Two of these needed percutaneous drainage. Two patients underwent reintervention due to severe sepsis and delayed abdominal hemorrhage (grade C leaks). Both patients were discharged after a long period of ICU stay and hospital stay (81 and 68 days, respectively). Interestingly, on the relative percentages of POPF, the influence of the learning curve did not elicit any statistical difference between the EP and the LP of the series ($P = 0.82$). Median hospital stay was 9 days (range 5—110). Two patients succumbed during the

Table 2 Details of perioperative outcomes and results.

Procedures	59
Type of surgery	
Pylorus preserving	32 (54.2%)
Whipple	27 (45.8%)
Pancreatic anastomosis	
Robotic	48 (81.4%)
Duct-to-mucosa	37/48 (77.1%)
Pancreatogastrostomy	11/48 (22.9%)
Open	11 (18.6%)
Duct-to-mucosa	7/11 (63.6%)
Pancreatogastrostomy	4/11 (36.4%)
Pancreatic fistula	7 (11.9%)
Postoperative complications	30 events/22 patients
Clavien I	7/30 (23.3%)
Biochemical POPF	3
Delayed gastric emptying	1
Biliary anastomosis leak	1
Melena	1
Subphrenic fluid collection	1
Clavien II	4/30 (13.3%)
POPF grade B	3
Gastrojejunal anastomosis leak	1
Clavien III	12/30 (40%)
POPF grade B	2
Pseudoaneurism of SMA	1
Abdominal fluid collection	2
Biliary obstruction	1
Biliary anastomosis leak	2
Jejunal occlusion	1
Bleeding from pancreatogastrostomy	1
Abdominal hematoma	1
Pulmonary embolism	1
Clavien IV	5/30 (16.7%)
PF grade C	2
Abdominal hemorrhage	2
Digestive hemorrhage	1
Clavien V	2/30 (0.7%)
Myocardial infarction	1
Cardiorespiratory failure	1
Duration of hospital stay	9 (5—110)
Overall postoperative morbidity	22 (37.3%)
REDO surgery	10 (16.9%)

Values are presented as median (with range) or events (with percentages). POPF: postoperative pancreatic fistula.

postoperative period (90 days mortality 3.3%). Surgical data and postoperative complications are described in Table 2.

The pathology confirmed 51 malignant tumors. Pancreatic ductal adenocarcinoma was diagnosed in 33 patients and other tumors in 18 patients. The median number of lymph nodes harvested was 26 (range 10—56). Specimen examinations confirmed R0 resection in 96.1% of patients, with 2 patients having had microscopic involvement of the posterior pancreatic margin. With a median follow-up of 14.1 months (range 1.3—87), the global estimated 3-year DFS and OS were 37,2 and 61,9%. Notably, the estimated 3-year DFS and OS rates were 26 and 51.8%, and 54.7 and 77.7% for ductal and non-ductal malignancies, respectively. Pathological and oncological findings are summarized in Table 3.

Table 3 Pathological and oncological findings.

Procedures	51
Margins	
R0	49 (96.1%)
R1	2
Lymphadenectomy	25 (10—68)
Hystopathological grade	
Ia	3
Ib	9 (17.6%)
IIa	10 (19.6%)
IIb	23 (45.1%)
III	2
IV	3
GIST	1
Estimated 3y-DFS	37.2%
Estimated 3y-OS	61.9%

Values are presented as events (with percentages).

Discussion

Pancreatic surgery has been historically considered a challenge for the surgeon, essentially due to significant perioperative risks and the associated dismal oncological outcomes [2,8,20,21]. Indeed, although the overall mortality and morbidity sustained following PD has substantively fallen along the last decades, the risks associated with the procedure are still relatively high [2,4,8,10,14,20,22,23], mostly in terms of pancreatic fistula [8,10,17,24].

More than twenty years have now elapsed since Gagner and Pomp from the University of Montreal reported the first laparoscopic PD [25]. However, despite the last decades have seen a drastic propagation of the minimally-invasive method in surgical practice for a number of abdominal procedures, PD has been originally considered a relative contraindication to the application of laparoscopy. This is basically due to the deep localization of the pancreas, its intrinsic relationship with major vascular structures and the technically demanding reconstruction phase of the procedure, which involves at least three anastomoses [2,4,10,21]. Nevertheless, during the recent years minimally-invasive surgery is gaining popularity and diffusion worldwide, essentially due to enhanced experience in dedicated centers and the availability of innovative technologies. As a consequence, in a few number of experienced centers, standard and robotic laparoscopy is increasingly employed to perform PD competently [2,4,10—14,21—23,25].

In particular, as supported by growing evidence, minimally-invasive PD is possibly associated with advantages over traditional surgery on intraoperative blood loss, length of intensive care unit and hospital stay, wound complications and time to return to daily life [2,4,10,13]. Such postoperative benefits have been also suggested as having the potential to provide a higher percentage of patients with the possibility of having adjuvant treatments at appropriate timing following surgery [13,21,26]. At this regard, also some initial concerns about oncological outcomes, with particular regard to the extent of lymphadenectomy and negativity of resection margins have been recently overcome by a number of reports [4,8,12—14,21,26].

In a comprehensive and timely review of the inherent scientific evidence including twenty-two studies and more than six thousands patients, the comparison between traditional open and minimally-invasive PD did not show any significant difference on mortality, morbidity, pancreatic fistula or bile leakage [26]. Conversely, MIS was favorably associated with intraoperative blood loss, wound complication rates, length of postoperative hospitalization and oncological results. Apart of a possible confounding factor in connection with surgical complexity (as considering the relative rates of vascular encasement and tumor size), nearly all studies in the analysis included patients that were matched for demographics characteristics between open and minimally-invasive surgery.

Correa-Gallego et al. had suggested possible clinicopathologic advantages of minimally-invasive over traditional surgery already in 2014 [24]. In their systematic review with meta-analysis, the authors included more than five hundred patients from 6 studies. The analysis of pooled data elicited significantly higher rates of negative resection margins and number of lymph nodes retrieval. Nevertheless, tumor size was significantly higher in the open compared to the MIS group, and this may have influenced overall results, at least in part.

Analogous data have been also confirmed with specific regard to robotic PD. Peng et al. [8] recently published a focused meta-analysis looking at possible differences between open and robotic PD. The authors included nine comparative, nonrandomized trials involving nearly 700 patients. Besides a significantly shorter length of hospital stay, at the meta-analysis of pooled data the overall incidence of postoperative complications significantly favored RPD over OPD (odds ratio [OR] 0.65). This difference was realistically in connection with significantly decreased rate of wound infection following RPD (OR 0.18), given that the rates of bile leakage, delayed gastric emptying and reoperation did not differ between the two groups. Similarly, the relative rates of POPF did not differ between the two groups, as considering only clinically relevant fistulas, or when including biochemical fistulas. Interestingly, the pooled data from eight studies revealed a statistically significant difference in terms of resection margin positivity between the two methods, favoring robotics with an OR of 0.4. As far as lymphadenectomy is concerned, a tendency toward higher numbers of harvested lymph nodes was present in favor of robotics, although this difference did not reach statistical significance. More recently, Kornaropoulos et al. [4] have noticed similar clinicopathologic data within a comprehensive meta-analysis including 13 comparative studies. The results of the pooled data showed that globally robotic PD tended to achieve a higher percentage of R0 resection.

What seems to be a crucial point is whether robotics may prove superior to standard laparoscopy in performing PD. Possible advantages of robotics over laparoscopy are still a matter of debate with no high-level scientific evidence available upon the matter to date. This issue presents a number of indirect aspects that should be thoroughly evaluated over time. Currently, most surgical teams are still at their early stage of minimally-invasive PD program [19,26—28]. Moreover, most centers have considerable experience either in laparoscopic *or* in robotic PD. As a consequence, comparative reliable comparisons are still difficult to be performed.

Despite the impossibility to draw definitive conclusions, previous reports have suggested that robotics may facilitate the application of minimally-invasive surgery for PD [8—10,14,21,22,29]. Several crucial maneuvers, such as hand-sewn anastomoses and lymphadenectomy, require angulated or curved lines of dissection and rigid laparoscopic instruments, with restricted freedom of movement, may cause some technical difficulties [9,10,14,16,29]. Actually, a number of technical issues associated with conventional laparoscopy have been overcome by robotic platforms. The magnified 3D intraoperative view and the well-known augmented dexterity due to the endowristed maneuverability enable not only easier resections and sutures, but also facilitate the management of possible intraoperative complications such as major bleedings, which are reported as main factors affecting the rate of conversion to open surgery [2,4,9]. Interestingly, in our series 11 conversions (18%) to open surgery occurred, 30 and 12% being the relative percentages of the EP and the LP groups. This data compares favorably to that reported in the inherent literature, with generally ranges between 3 and 35% [19,24] for laparoscopic procedure and between 0 and 35% for robotic PD [4,8,9,19,24].

With oncological outcomes in particular, a radical extirpation was achieved in 96% of cases. This finding, which is probably attributable, at least partially to a routinely use of an ultrasound-guided resection, [16] compares favorably with the majority of reports analyzing both conventional open and minimally-invasive PD, in which R1 or R2 resections are noticed in up to 25% of patients [19,28—30]. Similarly, the overall estimate 3-year DFS and OS of our series seem to be encouraging in comparison with those associated with both open and standard laparoscopic surgery in well trained centers [13,27].

The present study has several limitations. First, it lacks a comparator group and general outcomes have been compared to those present within the inherent available literature [30,31]. Furthermore, the whole series has a relatively small sample size and, importantly, it includes the initial experience with robotic PD of a surgical team, rather that of a single surgeon [23]. Actually, the increasing role played by trainees along the entire experience may have influenced our results. On the other hand, enhancing a dedicated program of pancreatic surgery is of paramount importance to improve surgical outcomes [9,19,30]. In this regard, the availability of a second console is crucial in promoting surgical education in robotic surgery. The possibility of a simultaneous proctoring on the same surgical field provides fellows and young surgeons with the possibility to proceed toward progressively more challenging steps of the whole procedure under the continuous guidance of an experienced operator [9,19,30]. Finally and importantly, although it comes for the analysis of a prospectively maintained database, this is a retrospective analysis of a single institution series and, as such, is potentially hindered by some selection and reporting biases.

Conclusion

Based on the available evidence on robotic PD, definitive conclusions cannot be made, essentially due to the absence of well-designed, randomized analyses upon the matter. Nevertheless, our data, in consistency with that from the literature, suggests that robotic PD can be performed competently according to current oncological standards of conventional surgery, thus respecting adequate resection margins and appropriate lymphadenectomy.

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Compliance with ethical standards

All procedures performed in the present study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

The present paper has been registered with the Research Registration Unique Identifying Number (UIN): 2802.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.jviscsurg.2018.07.011.

Disclosure of interest

The authors declare that they have no competing interest.

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