Impact of a Nationwide Training Program in Minimally Invasive Distal Pancreatectomy (LAELAPS)

Thijs de Rooij, BSc, Jony van Hilst, MD,* Djamila Boerma, MD, PhD,† Bert A. Bonsing, MD, PhD,‡ Freek Daams, MD, PhD,§ Ronald M. van Dam, MD, PhD,|| Marcel G. Dijkgraaf, PhD,¶ Casper H. van Eijck, MD, PhD,# Sebastiaan Festen, MD, PhD,** Michael F. Gerhards, MD, PhD,** Bas Groot Koerkamp, MD, PhD,# Erwin van der Harst, MD, PhD,†† Ignace H. de Hingh, MD, PhD,‡‡ Geert Kazemier, MD, PhD,§ Joost Klaase, MD, PhD,§§ Ruben H. de Kleine, MD,|||| Cornelis J. van Laarhoven, MD, PhD,¶¶ Daan J. Lips, MD, PhD,## Misha D. Luyer, MD, PhD,‡‡ I. Quintus Molenaar, MD, PhD,*** Gijs A. Patijn, MD, PhD,††† Daphne Roos, MD, PhD,‡‡‡ Joris J. Scheepers, MD, PhD,‡‡‡ George P. van der Schelling, MD, PhD,§§§ Pascal Steenvoorde, MD,§§ Menno R. Vriens, MD, PhD,*** Jan H. Wijsman, MD, PhD,§§§ Dirk J. Gouma, MD, PhD,* Olivier R. Busch, MD, PhD,* Mohammed Abu Hilal, MD, PhD,|||||| and Marc G. Besselink, MD, PhD*, for the Dutch Pancreatic Cancer Group*

Objective: To study the feasibility and impact of a nationwide training program in minimally invasive distal pancreatectomy (MIDP).
Summary of Background Data: Superior outcomes of MIDP compared with open distal pancreatectomy have been reported. In the Netherlands (2005 to 2013) only 10% of distal pancreatectomies were in a minimally invasive fashion and 85% of surgeons welcomed MIDP training. The feasibility and impact of a nationwide training program is unknown.
Methods: From 2014 to 2015, 32 pancreatic surgeons from 17 centers participated in a nationwide training program in MIDP, including detailed technique description, video training, and proctoring on-site. Outcomes of MIDP before training (2005–2013) were compared with outcomes after training (2014–2015).
Results: In total, 201 patients were included; 71 underwent MIDP in 9 years before training versus 130 in 22 months after training (7-fold increase, $P < 0.001$). The conversion rate (38% [n = 27] vs 8% [n = 11], $P < 0.001$) and blood loss were lower after training and more pancreatic adenocarcinomas were resected (7 [10%] vs 28 [22%], $P = 0.03$), with comparable R0-resection rates (4/7 [57%] vs 19/28 [68%], $P = 0.67$). Clavien-Dindo score ≥III complications (15 [21%] vs 19 [15%], $P = 0.24$) and pancreatic fistulas (20 [28%] vs 41 [32%], $P = 0.62$) were not significantly different. Length of hospital stay was shorter after training (9 [7–12] vs 7 [5–8] days, $P < 0.001$). Thirty-day mortality was 3% vs 0% ($P = 0.12$).
Conclusion: A nationwide MIDP training program was feasible and followed by a steep increase in the use of MIDP, also in patients with pancreatic cancer, and decreased conversion rates. Future studies should determine whether such a training program is applicable in other settings.

Keywords: distal pancreatectomy, laparoscopic surgery, pancreatectomy, pancreatic cancer, pancreatic disease, pancreatic surgery, robot-assisted surgery, training

(*Ann Surg* 2016;264:754–762)

Distal pancreatectomy (DP) is the standard treatment for left-sided symptomatic benign, premalignant or malignant pancreatic disease, but DP is still associated with morbidity rates >50% and

From the *Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands; †Department of Surgery, St Antonius Hospital, Nieuwegein, The Netherlands; ‡Department of Surgery, Leiden University Medical Center, Leiden, The Netherlands; §Department of Surgery, VU University Medical Center, Amsterdam, The Netherlands; ||Department of Surgery, Maastricht University Medical Center, Maastricht, The Netherlands; ¶Clinical Research Unit, Academic Medical Center, Amsterdam, The Netherlands; #Department of Surgery, Erasmus Medical Center, Rotterdam, The Netherlands; **Department of Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands; ††Department of Surgery, Maasstad Hospital, Rotterdam, The Netherlands; ‡‡Department of Surgery, Catharina Hospital, Eindhoven, The Netherlands; §§Department of Surgery, Medisch Spectrum Twente, Enschede, The Netherlands; ||||Department of Surgery, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands; ¶¶Department of Surgery, Radboud University Medical Center, Nijmegen, The Netherlands; ##Department of Surgery, Jeroen Bosch Hospital, Den Bosch, The Netherlands; ***Department of Surgery, University Medical Center Utrecht, Utrecht, The Netherlands; †††Department of Surgery, Isala Clincs, Zwolle, The Netherlands; ‡‡‡Department of Surgery, Reinier de Graaf Gasthuis, Delft, The Netherlands; §§§Department of Surgery, Amphia Hospital, Breda, The Netherlands; and ||||||Department of Surgery, Southampton University Hospital NHS Foundation Trust, Southampton, United Kingdom.
Reprints: Dr Marc G. Besselink, MD, MSc, PhD, Hepato-Pancreato-Biliary surgeon, Academic Medical Center, Meibergdreef 9, PO Box 22660, 1100 DD Amsterdam, The Netherlands. E-mail: m.g.besselink@amc.nl.
The authors report no conflicts of interest.
Disclosures: The Dutch Pancreatic Cancer Group received 3 unrestricted grants (NLEG00569, BNLEA00021, and BNLEA00065) from Johnson & Johnson Medical B.V. to organize nationwide training in minimally invasive distal pancreatectomy within the LAELAPS project.
MAH and MGB share senior authorship.
Dutch Pancreatic Cancer Group Collaborators: Marieke T. de Boer, MD, PhD (Department of Surgery, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands); Peter B. van den Boezem, MD, PhD (Department of Surgery, Radboud University Medical Center, Nijmegen, The Netherlands); Koop Bosscha, MD, PhD (Department of Surgery, Jeroen Bosch Hospital, Den Bosch, The Netherlands); Peter-Paul L Coene, MD, PhD (Department of Surgery, Maasstad Hospital, Rotterdam, The Netherlands); Cees H, Dejong, MD, PhD (Department of Surgery, Maastricht University Medical Center, Maastricht, The Netherlands); Peter van Duijvendijk, MD, PhD (Department of Surgery, Gelre Hospital, Apeldoorn, The Netherlands); Tom M. Karsten, MD, PhD (Department of Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands); Joris I. Erdmann (Department of Surgery, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands), MD, PhD; Vincent B. Nieuwenhuijs, MD, PhD (Department of Surgery, Isala Clincs, Zwolle, The Netherlands); Hjalmar C. van Santvoort, MD, PhD (Department of Surgery, St Antonius Hospital, Nieuwegein, The Netherlands); Rutger-Jan Swijnenburg, MD, PhD (Department of Surgery, Leiden University Medical Center, Leiden, The Netherlands).

ISSN: 0003-4932/16/26405-0754
DOI: 10.1097/SLA.0000000000001888

mortality rates of 2% to 6%, even in high-volume expert centers.[1,2] A complicated postoperative course results in slow postoperative recovery and a decreased quality of life during the first months after surgery.[3–5] Minimally invasive approaches to gastrointestinal surgery have the possibility to improve postoperative recovery compared with open surgery, which has already been shown for several abdominal procedures.[6–8]

Since the first report on minimally invasive DP (MIDP) in 1994,[9] the implementation has been rather slow, presumably because of the lack of training in MIDP and the absence of randomized controlled trials confirming superior outcomes of minimally invasive versus open DP.[1,10] Yet, in recent years, several systematic reviews of cohort studies have reported lower operative blood loss, lower postoperative morbidity, and a shorter hospital stay after MIDP compared with open DP.[1,11–14] Recently, a nationwide retrospective study performed in centers of the Dutch Pancreatic Cancer Group (DPCG), each performing at least 20 pancreatoduodenectomies annually, showed that in the period 2005 to 2013, only 10% of all DPs in the Netherlands had been performed in a minimally invasive fashion.[15] Furthermore, around one-third of MIDPs were converted to open surgery because of bleeding, inappropriate overview or the inability to identify the tumor.[15] Notably, over the 9-year study period, no increase in the use of MIDP or decrease in the conversion rate was seen.[15] These outcomes were by far not comparable to those of expert centers from the United States or United Kingdom, and 85% of Dutch pancreatic surgeons stated to welcome training in MIDP in a national survey, which was conducted at the end of 2013.[15]

Several studies have demonstrated that the introduction of minimally invasive pancreatic surgery is prone to increased postoperative morbidity and mortality during the surgical learning curve.[16,17] For example, a recent registry study reported an increased mortality for minimally invasive compared with open pancreatoduodenectomy.[16,17] This difference might be because of significantly higher mortality after minimally invasive pancreatoduodenectomy in low-volume centers and because of technical aspects and difficulties of the procedure. This was potentially related to the absence of adequate surgical training within a structured training program.[16,17] Increased morbidity and mortality have also been reported during the introduction of other minimally invasive gastrointestinal procedures.[18] Structured implementation programs might therefore be helpful to increase surgical proficiency before starting with minimally invasive pancreatic surgery on a national scale. Surgical training itself is obviously very likely to improve surgeon's proficiency, but the question is whether such a nationwide training program is feasible.

The feasibility and impact on outcomes of a nationwide training program in minimally invasive pancreatic surgery are unknown. The DPCG developed the Longitudinal Assessment and rEalization of minimaLly invAsive Pancreatic Surgery (LAELAPS) national program, which aimed to safely implement MIDP into Dutch surgery. Aim of this study was to assess the feasibility of the LAELAPS training program and its impact on the use and outcomes of MIDP.

METHODS

This study was performed in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[19] The medical ethics review committee of the Academic Medical Center (Amsterdam, The Netherlands) waived the need for informed consent because of the observational and anonymous nature of this study.

Design and Patients

This is a multicenter before–after study to investigate the impact of the LAELAPS training program in all Dutch pancreatic centers (n = 17), who are all high-volume pancreatic centers participating in the DPCG. Each of these centers performs at least 20 pancreatoduodenectomies annually, which is the criterion for maintaining the license to perform pancreatic surgery in The Netherlands. All patients who underwent MIDP during the study period in one of the 17 DPCG centers were included. Patients were excluded when essential data on the surgical procedure or postoperative course were lacking and when MIDP was performed because of nonpancreatic disease, such as gastric or renal tumors involving the pancreatic tail. Data of MIDPs performed before training (January 2005–December 2013) were retrospectively collected. Data of patients (n = 64) operated up to September 2013 were published previously.[15] Data of MIDPs performed during and after training (January 2014–October 2015) were prospectively collected in every center until the start of a nationwide randomized controlled trial on MIDP versus open DP in that center.[20] Both laparoscopic and robot-assisted procedures were included in the minimally invasive group, as they were performed using the same surgical technique. Analyses were performed according to intention-to-treat principles, meaning that converted MIDPs remained in the MIDP group. Additionally, average number of DPs per year and the crude proportions of DPs performed through minimally invasive surgery before and after training were calculated using the previously published retrospective study and the Dutch Pancreatic Cancer Audit (a nationwide prospective registry), respectively. The decision whether a patient underwent MIDP or open DP was up to the local surgeon. It was advised to consider the Yonsei criteria for patient selection (ie, tumor had to be confined to the pancreas, with an intact posterior fascial layer, and >1 cm distance from the celiac trunk).[21]

Training

From January 2014 to July 2015, 32 pancreatic surgeons from 17 centers of the DPCG participated in the LAELAPS nationwide MIDP training program. At the start of the program, all participating surgeons had multiple years of experience with minimally invasive gastrointestinal surgery and open pancreatic surgery, but 50% of participants had no experience with MIDP. Only 3 centers had completed >5 MIDPs without conversion before training. The LAELAPS training program was initiated on January 1, 2014, but it was started and completed for every surgeon at different points in time because of their personal planning. The program consisted of detailed technique description, video training, and on-site proctoring. All surgeons received the detailed technique description before video training and on-site proctoring. This description contained a list of required surgical equipment and a detailed procedure explanation, as well as tips and tricks to prevent and solve potential intraoperative problems. Video training was performed before actual surgical on-site proctoring. Four surgeons only participated in video training because they considered themselves experienced in MIDP. During video training, which was performed by one of the proctors, the entire procedure was reviewed (duration: 15 min.) and surgical tips and tricks were discussed. Additionally, short videos (duration: 3 min.) of intraoperative complications were displayed to discuss and train how to prevent and solve them. Discussion during video training was always performed in a "live" setting. Detailed technique description and video training took on average 2 hours per surgeon. For proctoring, 2 options were available. The first option was on-site proctoring, where 18 surgeons were proctored in MIDP by a single international MIDP expert (MAH) in their own operating room. The second option was proctoring at the Academic Medical Center by a single national MIDP expert (MGB), which was completed by 16 surgeons. The national expert was initially trained by MAH during an 8-month fellowship. Six surgeons participated in both on-site proctoring and proctoring at the Academic Medical

Center. Surgeons were suggested to start performing MIDP independently when the proctors confirmed they were ready for it. In 1 center, multiple proctoring sessions were desired and subsequently organized. The opinion of participating surgeons on proctoring was assessed directly after the procedure using a 1-page survey. Completing all training phases by a single surgeon took on average around 8 hours. A full-time equivalent PhD candidate spent 1 year on coordinating the program. The proctors spent 25 days on training surgeons in total, as 25 MIDPs were performed during proctoring sessions. These procedures were included in the analysis, as 15 of them were performed at the Academic Medical Center. The effect of including these cases was assessed in a sensitivity analysis (please see Statistical Analysis).

Surgical Technique

Herein we describe the technique of laparoscopic DP as performed during LAELAPS training. Patients were placed in a supine position with the left side 20 to 60 degrees elevated depending on the location of the tumor (the more distal the tumor the higher the elevation to facilitate inspection of the splenic hilum). In total, 4 to 5 trocars were placed in a semicircular fashion, centered around an umbilical camera. In case of potential malignant disease, the presence of metastases was excluded first. Surgical dissection was performed using an energy device (eg, HARMONIC ACE+7, Ethicon Endo-Surgery, Inc., Cincinnati, OH). The lesser sac was opened by dividing the gastrocolic ligament. The posterior fundus of the stomach was retracted using a retraction suture, exiting next to a subxyphoidal trocar. The pancreatic lesion was identified, either visually or by using laparoscopic ultrasound. For dissection, a medial to lateral approach was used, including mobilizing the splenic flexure of the colon from medial to lateral. The caudal pancreatic margin was mobilized, and the inferior and superior mesenteric veins were identified. An umbilical tape was placed under the pancreas and secured with Hem-o-lok clips (Teleflex Medical, Weck Drive, Research Triangle Park, NC). The splenic vein and splenic artery were identified. In case of benign or premalignant disease, attempts were made to preserve the spleen. This was preferably performed while preserving the splenic vessels (Kimura technique), but otherwise while transecting the splenic vessels (Warshaw technique). In case of malignant disease, resection of Gerota's fascia, subsequent splenectomy and extended lymphadenectomy were performed, as described previously.[22] The pancreas was divided using an endostapler (eg, ECHELON FLEX™ ENDOPATH, Ethicon Endo-Surgery, Inc, Cincinnati, OH or Endo GIA™ with Tri-Staple™ Technology, Covidien, Mansfield, MA) with stapler size and the site of pancreatic transection adapted according to the surgeon's preference. The specimen was extracted through a Pfannenstiel incision. A surgical (nonsuction) drain was placed near the pancreatic remnant and left subphrenic space.

Definitions

Conversion was defined as any laparotomy during MIDP for other reasons than trocar placement or specimen extraction. Major complications were defined as a Clavien-Dindo score of III or higher.[23] Postoperative pancreatic fistula (grade B or C according to the International Study Group on Pancreatic Fistula (ISGPF) definition),[24] delayed gastric emptying (grade B or C according to the International Study Group on Pancreatic Surgery (ISGPS) definition),[25] and postpancreatectomy hemorrhage (grade B or C according to the ISGPS definition)[26] were assessed. Surgical site infection was defined using the Centers for Disease Control and Prevention (CDC) definition.[27] Resection margins, including transection and circumferential margins, were classified into R0 (distance margin to tumor $\geq$1 mm), R1 (distance margin to tumor $<$1 mm), and R2 (macroscopically positive margin).[28]

Data Collection

Data before training were retrospectively collected, whereas data during and after training were prospectively collected. All postoperative complications during hospital stay and at least up to 30 days postoperatively were collected. Collected baseline characteristics were age (years), sex, body mass index (kg/m^2), previous abdominal surgery, American Society of Anesthesiologists (ASA) physical status, indication for surgery, histopathological diagnosis, and tumor size (mm) upon histopathology. Collected outcomes were operative time (min.), intraoperative blood loss (mL), additional resection (besides DP and splenectomy), splenectomy, conversion, procedure type (laparoscopic vs robot-assisted DP), resection margin status and lymph node retrieval (both in case of pancreatic ductal adenocarcinoma), overall complications (Clavien-Dindo score), postoperative pancreatic fistula (POPF), delayed gastric emptying, postpancreatectomy hemorrhage, surgical site infection, pulmonary complication, intensive care unit admission, length of hospital stay (days), readmission, and mortality.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows version 22.0 (IBM Corp., Armonk, NY). Normally distributed continuous data were presented as means with standard deviations. Non-normally distributed continuous data were presented as medians with interquartile ranges. Categorical (binary, nominal, and ordinal) data were presented as frequencies with percentages. For comparison of continuous variables, the 2 independent samples t test or the Mann–Whitney U test were used, depending on the data distribution as appropriate. Categorical variables were compared using the χ^2 or Fisher exact test, depending on the sample size. Predictors of a minimally invasive completed procedure (ie, no conversion) were assessed in a multivariable logistic regression with backward selection, including the MIDP number per center to correct for surgical learning curve and other potential confounders. Outcomes of the multivariable analysis were reported as odds ratios (ORs) with corresponding 95% confidence intervals (CIs). Sensitivity analyses were accomplished by excluding MIDPs performed during training, by excluding robot-assisted DPs, and by excluding MIDPs from centers performing $>$10 MIDPs after training (to assess the influence of case volume on outcomes). A subgroup analysis was performed to compare intraoperative blood loss, operative time, and the conversion rate of patients who underwent MIDP with splenectomy before versus after training. A 2-tailed P value $<$0.05 was considered statistically significant.

RESULTS

Patients

In total, 201 patients were included, of whom 71 patients underwent MIDP in the 9 years before training (2005–2013) versus 130 patients in the 22 months after training ($>$7-fold increase, $P <$ 0.001). Baseline characteristics did not differ significantly between the groups, besides a higher rate of ASA physical status III patients (8 [11%] vs 34 [26%] patients, $P = 0.01$) and more pancreatic adenocarcinomas (7 [10%] vs 28 [22%] patients, $P = 0.03$) in the period after training (Table 1). Furthermore, in the period after training, tumors were larger (23 [18] vs 34 [20] mm, $P < 0.001$).

In 2014 and 2015, centers performed a mean of 8 DPs annually. The numbers of DPs out of the previously published retrospective study and Dutch Pancreatic Cancer Audit were assessed. On average, 84 DPs were performed before training versus

TABLE 1. Baseline Characteristics

Characteristic	MIDP Before Training (n = 71)	MIDP After Training (n = 130)	*P*
Male, n (%)	38 (54)	55 (42)	0.13
Age, y, mean (SD)	56 (14)	60 (15)	0.07
BMI, kg/m^2, mean (SD)	26 (5)	26 (6)	0.72
Previous abdominal surgery, n (%)	21 (30)	50 (38)	0.21
ASA physical status*, n (%)	—	—	0.002
1	19 (27)	14 (11)	—
2	44 (62)	82 (63)	—
3	8 (11)	34 (26)	—
Indication for surgery†, n (%)	—	—	0.27
Solid neoplasm	45 (63)	67 (52)	—
Pancreatic ductal adenocarcinoma	7 (10)	28 (22)	0.03
Neuroendocrine tumor	30 (42)	31 (24)	—
Other	8 (11)	8 (6)	—
Cystic neoplasm	19 (27)	50 (38)	—
Mucinous cystic neoplasm	7 (10)	13 (10)	—
Serous cystic neoplasm	2 (3)	9 (7)	—
Intraductal papillary mucinous neoplasm	7 (10)	17 (13)	—
Other	3 (4)	11 (8)	—
Chronic pancreatitis	4 (6)	10 (8)	—
Other	3 (4)	3 (2)	—
Tumor size†, mm, mean (SD)	23 (18)	34 (20)	< 0.001

ASA indicates American Society of Anesthesiologists; BMI, body mass index; MIDP, minimally invasive distal pancreatectomy; SD, standard deviation.
*One patient operated before training was previously classified as American Society of Anesthesiologists physical status 4[15], but retrospective reassessment showed American Society of Anesthesiologists physical status 3.
†Upon histopathological diagnosis.

138 DPs on average per year after training. The proportion of MIDPs (number of MIDPs divided by the total number of DPs) was therefore 9% before training versus 47% after training. Before training, a mean of 16 DPs were performed for pancreatic ductal adenocarcinoma annually versus 30 after training. The proportion of MIDPs for pancreatic ductal adenocarcinoma was 5% before training versus 51% after training.

Operative Outcomes and Pathology

Operative time was similar before and after training, whereas blood loss was decreased (Table 2). The conversion rate was lower in the period after training (38% [n = 27] vs 8% [n = 11], $P < 0.001$). In patients with pancreatic ductal adenocarcinoma, the R0 (microscopically radical) resection rate (57% [4/7] vs 68% [19/28], $P = 0.67$) and median numbers of resected lymph nodes (13 [3–17] nodes vs 15 [7–21] nodes, $P = 0.54$) did not differ between the groups. Robot-assisted DP was performed in 4 (6%) patients before training compared with 20 (15%) patients after training ($P = 0.04$). More patients with nonmalignant disease underwent splenectomy in the period after training (8 [11%] vs 33 [25%] patients, $P = 0.004$). Fifteen of these patients (12%) underwent MIDP with splenectomy because of technical difficulty during an initially intended spleen preserving procedure, the others because they were expected to have malignant disease. The only independent predictor of a minimally invasive completed (ie. no conversion) DP was MIDP performed after training (OR = 10 [95% CI = 4–24], $P < 0.001$) in a multivariable analysis also including age, sex, body mass index, a history of abdominal surgery, MIDP number per center (for learning curve correction), a robot-assisted procedure, a multivisceral resection, a spleen preserving procedure, and a pancreatic ductal adenocarcinoma diagnosis. In the subgroup analysis in patients who underwent MIDP with splenectomy, the operative time (267 [102] vs 220 [91] min., $P = 0.07$) and intraoperative blood loss (525 [135–1300] vs 200 [100–438] mL, $P = 0.16$) were not significantly different. The conversion rate (50% [9/18] vs 10% [7/68], $P < 0.001$) was significantly lower after training, also for patients who underwent spleen-preserving MIDP (34% [18/53] vs 6% [4/62], $P < 0.001$).

Postoperative Outcomes

Postoperative outcomes are summarized in Table 3. ISGPF grade B/C pancreatic fistulas (20 [28%] vs 41 [32%] patients, $P = 0.62$) and major complications (15 [21%] vs 19 [15%] patients, $P = 0.24$) did not differ significantly before and after training. Length of hospital stay was shorter in the period after training (9 [7–12] vs 7 [5–8] days, $P < 0.001$). Thirty-day or in-hospital mortality was 3% vs 0% ($P = 0.12$), respectively. The 90-day mortality rate was known for all patients before training, but because of the length of follow-up, it was only known for 107 of 130 patients (82%) after training. For those patients, 90-day mortality was 3% vs 0%, respectively. In a subgroup analysis of patients without a major complication, length of hospital stay was 8 (6–10) days before versus 6 (5–8) days after training ($P < 0.001$).

Sensitivity Analyses

Sensitivity analysis by excluding the 25 MIDPs performed during training (conversion rate 38% vs 8% [$P < 0.001$], major complication rate 21% vs 15% [$P = 0.25$], median length of hospital stay 9 [7–12] vs 7 [5–8] days [$P < 0.001$], and 30-day or in-hospital mortality 3% vs 0% [$P = 0.13$]) and by excluding robot-assisted DPs (conversion rate 39% vs 7% [$P < 0.001$], major complication rate 21% vs 15% [$P = 0.28$], median length of hospital stay 9 [7–12] vs 7 [5–9] days [$P < 0.001$], and 30-day or in-hospital mortality 3% vs 0% [$P = 0.14$]) did not change outcomes of MIDP performed before versus after training, respectively. Excluding MIDPs after training from hospitals that performed >10 MIDPs after training showed a similar conversion rate (11%), major complication rate (17%), length of hospital stay (median 7 [6–10] days), and 30-day mortality (0%).

TABLE 2. Operative Outcomes and Pathology

Outcome	MIDP Before Training (n = 71)	MIDP After Training (n = 130)	*P*
Operative time, min, mean (SD)	223 (112)	223 (85)	0.98
Intraoperative blood loss, mL, median (IQR)	350 (105–1000)	200 (50–400)	0.03
Additional resection*, n (%)	4 (6)	16 (12)	0.13
Partial gastrectomy	3 (4)	4 (3)	—
Cholecystectomy	1 (1)	4 (3)	—
Partial colectomy	0 (0)	4 (3)	—
Adrenalectomy	0 (0)	3 (2)	—
Nephrectomy	0 (0)	1 (1)	—
Spleen-preserving MIDP, n (%)	53 (75)	62 (48)	<0.001
Resection of splenic vessels (Warshaw technique)†	—	39 (30)	—
Preservation of splenic vessels (Kimura technique)†	—	23 (18)	—
Nonmalignant disease, n (%)‡	53 (75)	88 (68)	0.30
Splenectomy	8 (11)	33 (25)	0.004
Due to technical reasons†	—	15 (12)	—
Conversion, n (%)	27 (38)	11 (8)	<0.001
Because of bleeding	15 (21)	3 (2)	—
Adhesions	4 (6)	5 (4)	—
Insufficient overview	6 (8)	1 (1)	—
Tumor advancement	1 (1)	1 (1)	—
Guaranteeing spleen preservation	1 (1)	1 (1)	—
Robot-assisted DP, n (%)	4 (6)	20 (15)	0.04
R0 resection (PDAC only), n (%)	4 (57)	19 (68)	0.67
Lymph nodes retrieved (PDAC only), median (IQR)	13 (3–17)	15 (7–21)	0.54
Tumor positive lymph nodes retrieved (PDAC only), median (IQR)	1 (1–2)	0 (0–3)	0.61

DP indicates distal pancreatectomy; IQR, interquartile range; MIDP, minimally invasive distal pancreatectomy; PDAC, pancreatic ductal adenocarcinoma; R0, microscopically radical resection; SD, standard deviation.
*Procedure with additional resection besides DP and splenectomy.
†Before training data unavailable.
‡Upon histopathological diagnosis.

Survey After Proctoring

In this survey (100% response rate), all of the 32 trained surgeons reported to be satisfied with the training program and declared that training sessions were of considerable added value. In total, 72% (n = 23) of surgeons had the intention to perform more MIDPs after training and 78% (n = 25) of surgeons stated that MIDP was as of that moment considered the preferred technique.

Impact of Training

In 10 of the 17 participating centers, MIDP had already been performed 1 to 20 times during the 9-year period before LAELAPS training, with a range of 2 to 11 through minimally invasive surgery completed (ie, no conversion) DPs. In these, 10 centers, 76 MIDPs were performed after training, with a range of 4 to 21 MIDPs completed without conversion and an overall conversion rate of 11%. So, a 4-fold increase in the number of MIDPs performed per year was seen. In 7 of 17 participating centers, MIDP had not been performed before training. These centers performed 54 MIDPs after training, with a range of 2 to 16 MIDPs completed without conversion and an overall conversion rate of 4%. The 4 surgeons who did not participate in proctoring performed 29 MIDPs after training altogether, with nonsignificantly differing outcomes compared with those who completed proctoring (conversion 14% vs 7% [$P = 0.24$], major complication 21% vs 13% [$P = 0.29$], and median length of hospital stay 7 [6–11] vs 7 [5–8] days [$P = 0.06$]).

TABLE 3. Postoperative Outcomes

Outcome	MIDP Before Training (n = 71)	MIDP After Training (n = 130)	*P*
Clavien-Dindo score ≥III complications	15 (21)	19 (15)	0.24
POPF grade B/C*, n (%)	20 (28)	41 (32)	0.62
Radiological catheter drainage for POPF	9 (13)	11 (8)	0.34
Delayed gastric emptying grade B/C†, n (%)	3 (4)	4 (3)	0.48
Postpancreatectomy hemorrhage grade B/C†, n (%)	2 (3)	4 (3)	0.64
Surgical site infection, n (%)	5 (7)	2 (2)	0.06
Pulmonary complication, n (%)	7 (10)	5 (4)	0.16
ICU admission, n (%)	9 (13)	9 (7)	0.18
Length of hospital stay, d, median (IQR)	9 (7–12)	7 (5–8)	<0.001
Readmission, n (%)	9 (13)	14 (11)	0.77
30-day mortality, n (%)	2 (3)	0 (0)	0.12

ICU indicates intensive care unit; IQR, interquartile range; MIDP, minimally invasive distal pancreatectomy; POPF, postoperative pancreatic fistula.
*According to the International Study Group on Pancreatic Fistula definition.
†According to the International Study Group on Pancreatic Surgery definition.

DISCUSSION

This is the first report on a nationwide training program for minimally invasive pancreatic surgery. Training was followed by a 7-fold increase in the use of MIDP with decreased conversion rates, blood loss and length of hospital stay, even while more ASA physical status III patients, more patients with pancreatic ductal adenocarcinoma, and larger tumors were operated through minimally invasive surgery.

The increased use of MIDP after training was very obvious. Even though the average number of DPs performed per year increased from 84 before training to 138 after training, the proportion of MIDPs increased from 9% to 47%, including for DPs performed for pancreatic ductal adenocarcinoma (average number of DPs for pancreatic ductal adenocarcinoma per year increased from 16 to 30, but the proportion of MIDPs increased from 5% to 51% as well). The outcomes of MIDP performed in the Netherlands before training were clearly inferior to those of expert centers from the United States and the United Kingdom.[15,29–32] Especially the conversion rate (38%) was one of the highest reported in the literature. This conversion rate steeply dropped after training, possibly because of the adoption of a structured surgical technique as proctored within the LAELAPS program. In previous series, robot-assisted DP was shown to be associated with lower conversion rates compared with laparoscopic DP,[33] which was not the case in this series. Besides increased surgical proficiency, more ASA physical status III patients, higher amounts of pancreatic ductal adenocarcinomas, and larger tumors were operated through minimally invasive surgery after training, indicating that surgeons dared to take on more challenging cases. This may also explain the higher splenectomy rate seen in patients with non-malignant disease after training, as many of these patients (18/33 [55%] patients) were expected to have a malignant pancreatic tumor requiring splenectomy. After training, only 12% of patients underwent splenectomy because of technical difficulties. Despite operating on larger tumors, the amount of tumor-negative (R0) resection margins in patients with pancreatic ductal adenocarcinoma did not worsen after training.

Nationwide outcomes after training, including the conversion rate, operative blood loss, operative time, and postoperative morbidity, were comparable to expert series.[29–31,34,35] The overall postoperative ISGPF grade B/C pancreatic fistula rate (30%) was relatively high, potentially because many patients with high drain amylase levels on postoperative day 3 were discharged with a surgical drain in situ, defined as an ISGPF grade B pancreatic fistula.[24] A low percentage of patients underwent postoperative radiological percutaneous catheter drainage because of a pancreatic fistula (10%) or were readmitted (11%). Data on the stapler size was not collected, but evidence that stapler size influences the rate of POPF is lacking. The location of pancreatic transection (pancreatic isthmus, body, or tail) could also be associated with POPF development, although a recent study showed that the clinically relevant pancreatic fistula rate is not influenced by the site of pancreatic transection.[36] The Clavien-Dindo $\geq$III complication rate seemed similar to expert series,[1,11–13] although after training none of the individual postoperative complication rates significantly improved. Postoperative length of hospital stay was decreased after training, but this may also be related to the increased use of enhanced recovery after surgery programs over time.[37] Length of hospital stay was also significantly shorter in uncomplicated patients, so it is expected that a secular trend of earlier discharge influenced this outcome. It is obviously interesting to evaluate the influence of the implementation of MIDP and enhanced recovery after surgery programs separately, but due to the multicenter design of this study such analyses were not possible.

Surgical training will naturally improve perioperative outcomes. The influence of training programs on surgical outcomes has already been investigated for minimally invasive colon and bariatric surgery, but none of these studies have directly compared surgical outcomes before and after training.[38,39] The question remains how a training program should be organized. In the literature, training programs using human cadaver models, porcine models, or procedure simulation have been described.[40–42] These methods were however used in training programs for surgical residents or surgeons without experience in minimally invasive surgery. Training pancreatic surgery in a porcine model is furthermore difficult because of the deviating anatomy of the pig. All surgeons participating in LAELAPS training had sufficient experience with both open pancreatic surgery and advanced minimally invasive gastrointestinal surgery. In this group of surgeons using a standardized and reproducible surgical technique, detailed technique description, video training combined with proctoring was expected to be a more appropriate training method. The LAELAPS training program was feasible and effective on a national scale, but such an approach is only achievable when centers and surgeons are dedicated. They must be willing to collaborate closely and share knowledge and skills with the mutual aim to improve both operative and postoperative results. In the Netherlands, the collaborative structure of the DPCG facilitates such a program. During the entire training program, on-site proctoring was warmly welcomed by Dutch surgeons. The combination of the availability of multiple proctoring sessions and a proctor advising surgeons whether to start performing MIDP on their own after training turned out to be a success. Obviously, the keys of success were the willingness of these surgeons to put themselves under training, even while half of participating surgeons had their own experiences already, the transparency of outcome assessment, and a core research group coordinating the entire process carefully. Importantly, this is the first study on feasibility and impact of a nationwide training program in pancreatic surgery, so it remains unknown to what extent such an approach can be translated to other surgical procedures and other health care settings.

This study has some limitations. First, outcomes of MIDPs performed before training were collected retrospectively, what could have led to underreporting of surgical complications compared with the prospective study. However, this could potentially only enlarge the impact of training on outcomes. The 30-day follow-up used in this study would preferably have been extended to 90 days. Unfortunately, this was not possible because of the inclusion of very recently operated cases. Owing to this restricted patient follow-up, the proportion of patients receiving adjuvant chemotherapy was unknown. However, adjuvant chemotherapy is the standard treatment for patients diagnosed with pancreatic ductal adenocarcinoma, so we expect that the majority of those patients have been treated accordingly. Despite inclusion of more complex cases after training, patient selection could have influenced results. Future studies will have to determine whether these training programs are of significant value in other health care settings as well as for other surgical procedures, such as the more demanding minimally invasive pancreatoduodenectomy.[43] Ultimately, the actual clinical benefit of MIDP over open DP will have to be assessed in a large multicenter randomized controlled trial.[1,44] Such a study, the LEOPARD trial, is currently ongoing in the Netherlands.[20]

CONCLUSION

A nationwide training program was shown to be feasible and was followed by a steep increase in the use of MIDP. After training, more patients with pancreatic cancer were operated through minimally invasive surgery. Furthermore, decreased conversion rates and intraoperative blood loss were observed. Future studies will have to determine whether such a multicenter training program is also applicable for other surgical procedures and in other health care settings.

ACKNOWLEDGMENTS

We acknowledge the work of the Dutch Pancreatic Cancer Group.

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DISCUSSANTS

J.R. Delpero (Marseille, France):

First, I would like to thank the authors for sharing their manuscript before and after a substantial revision, and congratulate them for the organization and the success of a training program in MIDP.

The debate about laparoscopic or robotic approach versus open surgery focuses on 3 major points: what is the impact on postoperative outcomes, what are the oncologic results in case of cancer, and finally is it really more cost-effective than the open approach? MIDP is feasible, safe, and reported to have potential advantages compared with open DP for benign conditions (particularly in terms of duration of in-hospital stay and postoperative recovery), but its use for pancreatic duct adenocarcinoma (PDAC) remains controversial and today, there is no evidence despite some case–control studies and 2 meta-analyses published in 2015 (Mehrabi A. et al and Ricci C. et al.).

The major contributions of the «training program» reported in this study are: such a program is feasible and successful; the rate of MIDP was growing after training as half of the DP (130/275: 47%) were performed in the Netherlands by minimally invasive approach, which is far beyond the percentages reported in French (13%) or American registries (<20%); for pancreatic cancer, the rate of R0 resections, the number of lymph nodes retrieved, and the surprising low rate of positive lymph nodes clearly reflect the selection of the indications.

The substantial revision of the initial manuscript provided many answers to the questions raised by the study. Thus, my last questions are: as the Dutch group has a registry of pancreatic resections, can you assess how many patients had sparing parenchyma resections during the same period (enucleations or central resections, particularly for NET which account for nearly one-quarter of the indications [31/130]); have you dropped out central pancreatectomies for DP; finally, it is obvious today that the next step should be a randomized controlled trial (RCT), which would offer convincing evidence in favor of MIDP. Congratulations for having planned such an RCT: your primary endpoint is «time to recovery» (Ref. 20). You publish (*Nature Reviews Gastroenterology & Hepatology, April 2016*) a decision-aid algorithm with «small tumor, pT1/pT2 tumor, and non-PDAC» as criteria for a first choice of MIDP: how many patients have you planned to include for an adequately powered trial? Despite the increased number of DP since 2014, do you think that by including benign, premalignant, or malignant disease (Ref. 20), we will have an answer on one of the secondary outcomes which seems to me very important: the oncologic effectiveness of the procedure?

Once again, thank you for the opportunity to review the manuscript and the privilege of the floor.

Response From T. de Rooij (Amsterdam, The Netherlands):

Thank you kindly for reviewing our work and improving our manuscript. The parenchyma-sparing resections were not included in the present study, as they are technically differing from DP and importantly the operative and postoperative outcomes not comparable. I looked into our registry data and saw that in the last 10 years, 8 to 10 enucleations were performed for neuroendocrine tumors in the Netherlands per year. Of the registry data, I know that in 2014 and 2015, 10 enucleations were performed for those tumors and only 4 of them were performed through minimally invasive surgery. Central pancreatectomy was performed 8 times in 2014 and 2015 together and none of them was performed through minimally invasive surgery.

We think that the superiority of MIDP versus open DP has to be assessed and it is most likely that the difference will be faster postoperative recovery. The LEOPARD trial, which is currently ongoing and has included 50% of patients, focuses on time to functional recovery. In this trial, both benign and malignant diseases are included. Of course, oncological safety is the key and therefore we added the Yonsei criteria to the inclusion criteria for the trial, meaning that tumors have to be confined to the pancreas with an intact posterior facial layer and at least 1 cm free from the celiac axis.

In the LEOPARD trial, only a small subset of patients will be diagnosed with malignant disease. This will not enable to investigate the oncological results. However, we recently started the pan-European DIPLOMA initiative. Together with Southampton University Hospital, we have joined forces and are collecting data from over 25 different European centers on minimally invasive and open distal pancreatectomies for pancreatic ductal adenocarcinoma.

First, we performed a pan-European cohort study and we already have received data from >1000 patients. We will do a propensity score-matched analysis and that data will be used to prepare adequately for the DIPLOMA randomized controlled trial on cancer specifically. We think that trial will start this year and it will involve over 25 European centers.

C. Bruns (Cologne, Germany):

Could you comment on qualification of the surgeons that participate at the training program with respect to their experience in laparoscopic surgery in general but also pancreatic surgery?

Do you have any kind of concrete inclusion criteria with respect to their experience? Do you have an amount of pancreatic resections that have to be done to come and join the program?

Response From T. de Rooij (Amsterdam, The Netherlands):

In the Netherlands, pancreatic surgery has been centralized, so all participating centers are performing at least 20 pancreatoduodenectomies a year. The surgeons who participated in our program have all a high amount of experience in open pancreatic surgery and advanced laparoscopic gastrointestinal surgery. That was the criteria to be eligible for the nationwide training program. To be allowed to participate in the LEOPARD trial, surgeons need to have performed at least 50 advanced laparoscopic gastrointestinal procedures, 20 DPs, and 5 MIDPs.

P.J. Friend (Oxford, UK):

How do you know the effect your describing weren't simply due to the natural adoption of a new technique and that your training had actually very little to do with increasing activity and improving outcome?

Were there any centers that were not subject to the same training, but perhaps still developed laparoscopic DP as a procedure? Was there a difference in the trained versus the untrained groups?

Response From T. de Rooij (Amsterdam, The Netherlands):

It is obviously difficult to analyze the specific effect of the training itself. The nationwide program at least increased the awareness of the minimally invasive procedure. It may be the awareness or the training itself, but in the period after the training, we saw a steep increase in the use of the minimal invasive technique and improved outcomes. In both cases, it was a positive effect.

In the Netherlands, all centers performing minimally invasive procedures participated in the training program. We did several sensitivity analyses, for example, comparing centers that already performed minimally invasive procedures before training to centers that did not. However, those outcomes were comparable, so we think that centers that started to perform the procedure after training did as good as the centers that had experience before the training.