



How many cases are required to learn how to perform minimally invasive pancreaticoduodenectomy?

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In this manuscript by Nagakawa and colleagues (1), the authors reported on their experience with 150 consecutive cases of laparoscopic pancreaticoduodenectomy. Specifically, the outcomes of three separate surgeons performing their first 50 cases were described. Their main finding was that there was a significant learning curve for minimally invasive pancreaticoduodenectomy (MIPD). They describe an introductory period, consisting of an initial learning phase for the first 20 cases and a plateau phase for cases 20–30. During the initial 20 cases, the surgeons familiarized themselves with the procedure and overcame their initial difficulties in its execution and outcomes. Between cases 20 and 30 variables such as blood loss and operative time began to stabilize. After case 30, the surgeons entered a stable phase where they report overall improvement in their outcomes compared to their earlier cases. Operative time and blood loss were significantly higher in the introductory period compared to the stable period, but there was no difference in postoperative complications between the two time periods. The authors should be commended on their careful analysis of a substantial MIPD case volume for a single institution. There are some important points that bear consideration.

Advanced laparoscopic surgery and pancreatic surgery both require experience and specialized skills, and relatively few surgeons have sufficient experience with both to master MIPD quickly. Previous laparoscopic experience varied greatly between the three surgeons evaluated in this series. While all performed many open pancreatic resections, one of the three (Surgeon C) had performed many

more complex laparoscopic hepatobiliary and pancreas procedures than the others. While the authors did not describe the individual learning curves for the 3 surgeons who participated in their series, from their data it is likely that surgeon C became adept at MIPD at a faster pace than the other two. The less experienced surgeons (Surgeons A and B) did nearly all their MIPDs using a hybrid approach in which the pancreaticojejunostomy reconstruction was performed through an open “mini-laparotomy”. In contrast, Surgeon C did nearly all his pancreaticojejunostomies (47/50) using a fully laparoscopic approach. The pancreaticojejunostomy is the “Achilles heel” of the Whipple procedure. Pancreatic leaks are one of the major causes of post-operative complications (2). As the authors themselves note, that fact that 2/3 of the patients in their series had an open pancreaticojejunostomy reconstruction may account for the why they did not observe a higher incidence of complications in the introductory phase of the learning process.

Given the wide variation in experience and skills between surgeons in practice, there are limited data regarding the best strategy to train surgeons how to safely learn to perform MIPD. Existing reports are difficult to interpret because the methodology varies widely. Furthermore, some of the larger studies assessing improvement in outcomes of surgeons who undergo formal training in minimally invasive pancreas resections do not compare their results prospectively with those of surgeons performing these procedures without training. Examples include two large multicenter studies from the Netherlands. Training for

minimally invasive distal pancreatectomy was evaluated for 32 surgeons at 17 national hospitals with a high volume of pancreatic surgery, while training for MIPD was evaluated for a smaller group of 8 surgeons at 4 high volume centers (3,4). Training was done using didactic teaching, review of operative videos, and through on-site proctoring in the operating room. Prospective data collected after the training period were compared to data gathered retrospectively for pancreatic resection cases done prior to training. The key findings were that formalized training increased the use of the minimally invasive approach for distal pancreas resections from 9% before training to 44% after completion of the curriculum. In addition, blood loss and the incidence of conversion to open procedure was significantly reduced. Indeed, for patients undergoing distal pancreatectomy, the only independent predictor for reduced open conversion rate was surgeon training (3).

In contrast to their observations with distal pancreatectomy, the Dutch investigators did not find that training reduced blood loss or conversion rates for MIPD. The conversion rate was 11% and average blood loss was 350 mL, regardless of whether they compared the first and last half of all MIPDs performed or the first 5 cases with cases through 25 (4). One explanation may be that in the MIPD study, two experienced surgeons who completed the formal training curriculum performed every study procedure together. Certainly, with two trained surgeons participating there may be less hesitation, errors in judgement, and technical mistakes, and the learning curve may be mitigated to some extent.

It is widely thought to be true that individual surgeons attempting to master MIPD will require some threshold of experience before being able to perform these operations facily with a low complication rate. Estimates for this threshold vary widely, ranging from 40 to 80 cases (5-7). Given that MIPD is still very new, some insights may be gained by reviewing data on the learning curve for minimally invasive distal pancreatectomy. Goh and colleagues evaluated outcomes for after forty consecutive minimally invasive distal pancreatectomies performed at their institution from 2006 to 2015. Nearly half the cases (n=19) were performed by two surgeons who met the arbitrary designation of being deemed “high volume” because they had each performed more than 5 cases. The remaining 21 cases were performed by 10 surgeons, each of whom performed less than 5 cases, who were deemed to be “low volume”. On univariate analysis, the high-volume surgeons had nearly a four-fold lower incidence of open

conversion (38.1% *vs.* 10.5%) (8). A separate report from the Johns Hopkins Hospital evaluated 211 patients who received a laparoscopic distal pancreatectomy from 2007 to 2015. On multivariate analysis, they found that conversion rates did not begin to decrease until after a surgeon had performed 15 cases. Given that minimally invasive distal pancreatectomy is technically much less complicated than MIPD, it is reasonable to postulate that it will take a significantly greater case volume than 10–15 cases to become proficient at MIPD (9).

Recent data do suggest more case volume is required to gain proficiency in MIPD. Boone and colleagues reported a decrease in blood loss and open conversion after 20 cases (6). Similarly, Speicher and colleagues described a multiphasic learning curve in which the first 10 cases were the most challenging and time consuming. After 10 cases the learning process became smoother, and proficiency and mastery begin to be achieved after 50 cases (5,7). It is reasonable to assume it will require 10–20 procedures for the surgeon and staff to become familiar with the basic steps and setup of the operation, after which time to process of refining and mastering the procedure can begin. How many more procedures it will actually take to become adept will primarily depend on an individual surgeon’s prior experience and comfort with pancreaticoduodenectomy and minimally invasive surgery. Certainly, the results of Nagakawa *et al.* describing that it requires approximately 30 cases to reach stability in their outcomes are consistent with what others have published.

Besides surgeon experience, hospital experience with MIPD may also play an important role in outcomes. One registry study of the National Cancer Center Database compared outcomes between two different cohorts of patients undergoing either MIPD (n=430) or open pancreaticoduodenectomy (n=4,309) between January 2010 and December 2011. Hospitals performing the procedures were stratified into four quartiles based on the total number of pancreaticoduodenectomies performed annually (Quartile 1: ≤ 5 cases per year, Quartile 2: 6–13 cases per year, Quartile 3: 13–25 cases per year, Quartile 4: 26 or more cases per year). The data suggest that hospitals performing ≤ 25 total pancreaticoduodenectomies per year had higher 30- and 90-day mortality rates. These negative outcomes were more pronounced in the MIPD cohort. Patients who underwent MIPD at a first quartile hospital had a 3.7-time higher 30-day mortality compared to those undergoing MIPD at a fourth quartile hospital, and patients undergoing MIPD at a second quartile hospital had a 1.7-time higher

30-day mortality. There were no statistically significant differences in death rates between those undergoing MIPD at third and fourth quartile hospitals (10). During the same time interval (January 2010 to December 2011), Sharpe and colleagues performed a separate study in which they specifically evaluated whether institutional MIPD volume, rather than total pancreaticoduodenectomy volume, was associated with outcomes after surgery. Only 5 of the 133 institutions evaluated (3.8%) did more than 10 MIPD cases in the 2-year study period. This was the threshold the authors designated as “high volume”. High volume centers, had a significantly lower 30-day mortality than those performing less than 10 MIPDs in the 2-year time frame (0 vs. 7.5%) (11). Very similar results were reported in a more recent analysis of the National Cancer Database evaluating 22,013 patients who underwent pancreaticoduodenectomy in over 700 US institutions from 2010 to 2015. Of these, 3,754 (17.1%) were done using a minimally invasive approach. The authors found that centers performing 6 or more MIPDs per year had lower 90-day mortality than those performing 1–5 cases per year (overall risk ratio =0.7, comparing high volume to low volume centers) (12). Adams and colleagues analyzed a different database [the Health Care Utilization Project National Inpatient Sample Data Sets (HCUP-NIS)], and they concluded that the number of MIPDs performed annually must be even higher. Complications were minimized at a threshold of 22 MIPDs per year (13).

Given that there is a convincing body of data that higher hospital volume is associated with better outcomes for open pancreatectomy, this is also likely to be true with MIPD. In a seminal study published in 2002, a very high-volume center pancreas center was defined as one that does over 16 resections per year (14). Since not every patient requiring a pancreaticoduodenectomy will be a candidate for a minimally invasive procedure, it is likely that only the highest volume centers (performing over 20–25 pancreaticoduodenectomies per year) will be able to perform MIPD frequently enough for surgeons to learn and master the procedure.

As more interest grows in MIPD, the skills necessary to perform it will increasingly be incorporated into surgical training programs. There are a few hepatobiliary programs that are already introducing formal training in minimally invasive pancreas surgery into their curricula. The University of Pittsburgh incorporates elements of virtual reality simulation, suturing on biotissue specimens, video training, intraoperative assessment, and skills maintenance

protocols to enable their fellows to become familiar with robotic pancreaticoduodenectomy. Under the formalized curriculum, trainees were increasingly able to perform more steps of the operation using the robot. In addition, it was observed that the number of pancreaticoduodenectomies for which trainees were able to complete the entire resection increased (15). As such training programs become more common, surgeons will be able to gain proficiency and better outcomes more quickly. Until then, it is advisable that MIPD only be performed at high volume centers that enable MIPD to be performed at least 5–10 times per year. In addition, the learning curve may be improved by having two experienced surgeons work together through their initial cases.

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