Outcome of robot-assisted pancreaticoduodenectomy during initial learning curve versus laparotomy

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Research article

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Abstract

Background : To analyze the initial learning curve (LC) for robot-assisted pancreaticoduodenectomy (RAPD) and compare RAPD during the initial LC with open pancreaticoduodenectomy (OPD) in terms of outcome.

Methods : This study is a retrospective review of patients who consecutively underwent RAPD between October 2015 and May 2019 in our hospital. Experiences from 30 initial consecutive RAPD cases, considered the initial LC of a single surgeon team, were compared with those from laparotomy cases during the same period in terms of outcome. Preoperative demographic and comorbidity data were obtained. Perioperative data on operation time, blood transfusion, numbers of harvested lymph nodes, 90-day mortality and readmission, surgery-related complications, postoperative hospital stay, and total costs were acquired for analysis. The operation time for RAPD was evaluated using the cumulative sum(CUSUM) method.

Results : Seventy-eight patients, including 30 consecutive RAPD cases and 48 consecutive open cases, were enrolled for review. The demographic and comorbidity characteristics of the two groups were similar. Compared with OPD, RAPD required a significantly longer operative time (423.67 ± 137.627 min vs. 228.75 ± 44.988 min, $P < 0.001$) and higher cost (185700 ± 54500 RMB vs. 120600 ± 41700 RMB, $P < 0.001$). Moreover, compared with the OPD group, the RAPD group revealed a significantly smaller mean number of lymph nodes harvested in malignant cases (8.72 ± 4.9 vs 14.26 ± 7.633, $P = 0.007$). No statistically significant differences were observed between the two groups in terms of incidence of Clavien–Dindo grade III–V morbidities and 90-day mortality and readmission. In the CUSUM graph, one peak point was observed at the 8th case, after which the operation time began to decrease.

Conclusions : RAPD is safe when performed in well-selected patients by well-trained teams with extensive experience in open pancreaticoduodenectomy during the initial LC,and the LC of RAPD may be shorten less than 30 cases.

Background

Although pancreatectomy was first performed 80 years ago, it remains a challenging abdominal surgery with relatively high morbidity and mortality(1). Laparoscopic pancreaticoduodenectomy (LPD) was first reported in 1994 by Gagner(2); today, this procedure could be performed as safely as open pancreaticoduodenectomy (OPD) by skilled surgeons(3, 4). However, the long learning curve (LC) for LPD continues to challenge many surgeons. In general, LPD presents intrinsic disadvantages compared with conventional laparoscopy, including instrument motion, two-dimensional imaging, poor surgeon ergonomics, and a long LC. In 2000, the Da Vinci system was approved by the Food and Drug Administration. In 2003, Giulianotti et al. published a case series verifying the feasibility of robotic pancreatectomy; the series included eight robot-assisted pancreaticoduodenectomy (RAPD) and five robot-assisted distal pancreatectomy (RADP) cases(5). Robotic surgery is an advanced minimally invasive surgical technique that has several benefits in pancreaticoduodenectomy, such as enhanced three-dimensional vision, application of EndoWrist instruments (which have a great range of motion), and a short LC. However, the safety of RAPD during the initial LC and the possible shortening of the LC remain unclear. Therefore, this article addresses the LC of a single surgical team in our hospital.

Methods

Patient Selection: This study is a retrospective research on pancreaticoduodenectomy conducted by a single surgical team that had performed over 300 OPD and more than 20 robotic operations at the Department of Pancreatic Surgery (The Second Xiangya Hospital, Central South University, Changsha, China) between October 2015 and May 2019. A total of 30 RAPD and 48 OPD cases were included in this study. All cases were confirmed resectability on the basis of preoperative radiology. The exclusion criteria for RAPD were as follows: (1) tumor diameter greater than 5 cm, (2) any suspicious invasion of the superior mesenteric artery/vein, (3) body mass index ≥28 kg/m^2, and (4) patients with severe cardiorespiratory comorbidities that cannot tolerate RAPD. The study was approved by the Ethics Committee of The Second Xiangya Hospital.

Perioperative cure: All patients underwent preoperative routine examination (routine blood tests, chest X-ray, electrocardiogram), tumor markers (cancer antigen 19–9, carcinoembryonic antigen, and α-fetoprotein), abdominal computed tomography, or magnetic resonance imaging. Percutaneous transhepatic cholangio drainage was performed when total bilirubin exceeded 250 umol/L. On the second postoperative day, the nasogastric tube was removed if drainage was less than 200 ml/d. Prophylactic antibiotic treatment was used for 3 days, and prophylactic somatostatin was given for at least 7 days. Self-administered analgesia, including 100 μg of sufentanil, 10 mg of butorphanol tartrate, and 16 mg of ondansetron hydrochloride, was given to 3 days after surgery. The amylase level of the peripancreatic drainage fluid was measured for the first time on the third day after surgery and then recorded every 2 days thereafter.

Surgical technique: All RAPD and OPD cases were performed by the same surgical team. The operator was Dr. Yu Wen, and the first assistant was Dr. Jiangjiao Zhou or Dr. Heng Zou. For RAPD, the patients were placed on their back with the head and right side raised by 30°. The location of the trocar is shown in Fig. 1.

Extensive exploration of the abdominal cavity and pelvis was performed before the start of the operation, and any nodule considering metastasis was biopsied. The gastrocolic omentum was opened with an ultrasonic scalpel (Ethicon), and the hepatic flexure and transverse colon were pushed downward to reveal the pancreatic head and the duodenum. The duodenum was then mobilized using the Kocher maneuver until the aorta was exposed, and the stomach was transected 6–10 cm along the left side of the pylorus with an endo linear stapler. The gastric duodenal artery and the right gastric artery were clipped at the root, and the lymph nodes around the hepatic artery and hepatic hilum were removed. Next, cholecystectomy was performed, and the common hepatic duct was exposed and incised. The lower edge of the pancreas was separated, the superior mesenteric and portal veins were identified, and the posterior pancreatic tunnel was established. The pancreas was disconnected by the ultrasonic scalpel, and the main pancreatic duct was cut using scissors. Afterward, the jejunum was pulled to the right side of the superior mesenteric vein. The distal jejunum was divided at a distance of 10–15 cm to the duodenojejunal flexure using an endo linear cutting stapler (Ethicon). The head of the pancreas and duodenum were removed by the ultrasonic scalpel (Ethicon). The pancreatic uncinate process was dissociated along the right aspect of the superior mesenteric vein until the specimen was completely removed.

Digestive tract reconstruction was performed using Child's method. The order of anastomosis was as follows: pancreaticojejunostomy → hepaticojejunostomy → gastrojejunostomy. Gastrointestinal anastomosis reconstruction was performed behind the transverse colon. Pancreaticojejunostomy was performed from the pancreatic duct to the jejunal mucosa. A pancreatic duct catheter was placed in the pancreatic duct to drain the pancreatic juice to the distal jejunum of the pancreatic intestine. The biliary anastomosis was continuously sutured by an absorbable barb wire without T tube placement. Gastrointestinal anastomosis was performed by a linear cutting occluder to achieve side-to-side anastomosis between the posterior wall of the stomach and jejunum. After the operation, drainage tubes were placed under the Winslow hole and the pancreatic intestine anastomosis, which were individually taken out from both sides of the abdominal wall. Specimens were obtained through a 3 cm incision in the upper abdomen midline incision.

Date collection: All perioperative information was collected retrospectively for analysis, including the following variables:

1. Baseline characteristics: age, gender, initial symptoms, comorbidities, and American Society of Anesthesiology (ASA) score;
2. Surgical information: operative time, transfusion rate, and conversion rate; and
3. Postoperative data: total medical expenses, postoperative hospital stay, final pathologic results, short-term complications, and 90-day mortality and readmission.

For tumor cases, pathological dates were recorded by tumor-node-metastasis staging, as recommended by the AJCC Cancer Staging Manual (8th Edition). Postoperative complications were classified by the Clavien–Dindo classification of surgical complications(6). Furthermore, morbidities were defined and graded following the criteria drafted by the International Study Group of Pancreatic Surgery, including delayed gastric emptying, pancreatic fistula, and hemorrhage(7, 8).

Statistical analysis: The statistics software SPSS (version 25.0, SPSS Inc., Chicago, IL, USA) was used for data analyses. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were presented as numbers and percentages. The mean values of continuous variables were compared by either the two-tailed Student's *t*-test or the nonparametric Wilcoxon rank-sum test. Categorical variables were compared by using Pearson's χ^2 test or Fisher's exact test contingency tables, and Student's *t* test was used to compare data between the groups. Statistical significance was defined as $P < 0.05$.

Cumulative sum (CUSUM) method

The LC of RAPD was calculated using CUSUM. $CUSUM_{OT}$, which refers to the difference between the operation time of the first patient and the mean OT of all patients, is calculated as $CUSUM_{OT} = \Sigma ni = 1 (xi - \mu)$, where μ is the median overall operation time and xi is an individual operation's time. Notable change points were identified at the point showing the largest peak in the CUSUM curve.

Results

Details of patients and pathology: In total, 30 cases and 48 cases were scheduled for RAPD and OPD, respectively, between October 2015 and May 2019. These procedures were performed by one experienced pancreatobiliary surgical team. All 30 successful RAPD cases were considered the initial LC.

The baseline characteristics of the patients are summarized in Table 1. The mean age of the RAPD group (12 men and 18 women) was 56.23 ± 10.820 years. In addition, 14 (46.7%) and 16 (53.3%) patients were classified as ASA II and III, respectively. In the OPD group (38 men and 10 women), the mean age was 57.96 ± 10.233 years. In total, 1 (2.1%), 22 (45.3%), and 25 (52.1%) patients were classified as ASA I, II, and III, respectively. Pathologic diagnoses included malignant lesions in 53.3% (16/30) of the RAPD cases, including pancreatic cancer (n = 7), periampullary adenocarcinoma (n = 2), and duodenum adenocarcinoma (n = 7), and in 79.2% (38/48) of the OPD cases, including pancreatic cancer (n = 21), periampullary adenocarcinoma (n = 3), cholangiocarcinoma (n = 5), duodenum adenocarcinoma (n = 8), and malignant branch-duct intraductal papillary mucinous neoplasm (n = 1). Jaundice, followed by epigastric pain, was the most common chief complaint of the RAPD and OPD groups. No statistically significant differences between the two groups were observed in terms of age, gender, comorbidity, and ASA score.

Intraoperative and postoperative outcomes: The mean operative time in the RAPD group was much longer than that in the OPD group ($P < 0.001$) (Table 2). No statistical difference between the two groups was identified in terms of perioperative transfusion. The mean number of lymph nodes harvested in the RAPD group was fewer than that in the OPD group ($P = 0.007$). All patients underwent R0 resection. The incidence of pancreatic fistula between the two groups was not statistically different. According to the Clavien–Dindo classification, the rates of grades I–V in the RAPD group were lower (16/30, 53.3%) than those in the OPD group (26/48, 54.2%) ($P = 0.077$), and no statistically significant difference between the two groups was found in terms of rates of grades III–V incidence (RAPD: 9/30, 30%; OPD: 15/48, 31.3%; $P = 0.907$). Moreover, no difference between the two groups was observed in terms of 90-day mortality and readmission. Patients in the RAPD group (22.97 ± 16.481) had longer postoperative hospital stays compared with those in the OPD group (20.29 ± 14.068), but the difference was not statistically significant ($P = 0.447$). As expected, the total cost of pancreaticoduodenectomy in the RAPD group was much higher than that in the OPD group (185700 ± 54500 RMB versus 120600 ± 41700 RMB, $P < 0.001$) (Table 2).

LC analysis: The operation time was calculated for each case (Fig. 2). A significantly negative correlation was identified between the number of RAPD cases experienced and operation time. The operation time was rapidly reduced from the 1st to the 10th RAPD cases, fluctuated slightly between the 10th and 14th cases, and became relatively stable from the 15th to the 30th cases. The LC was assessed by the CUSUM method. In the $CUSUM_{OT}$ graph (Fig. 3), one peak point was observed at the 8th case, after which the operation time began to decrease.

Discussion

Minimally invasive pancreaticoduodenectomy (MPD) includes LPD and RAPD. LPD was first described by Gagner and Pomp in 1994(2), while RAPD was first performed by Giulianotti et al. in 2001(5). LPD is a safe and effective procedure in specialized high-volume medical centers(4, 9, 10). However, traditional laparoscopy systems are associated with intrinsic disadvantages, including two-dimensional visualization, poor surgeon ergonomics, and a restricted range of movement (up to only four degrees of freedom) inside the abdominal cavity due to the straight bodies of laparoscopic instruments. Some components of the procedure, such as pancreatic enteric reconstruction, are technically demanding because of these limitations. Robotic systems provide surgeons with superior three-dimensional visualization and instrumentation that mimics the latter's hands; these instruments have an articulating wrist, can achieve seven degrees of freedom, and provide tremor filtration and stable retraction. Given the above advantages of robotic systems, surgeons can control surgical instruments flexibly, accurately, and with a wide range of motion, which is critical for operations requiring complex resection and reconstruction. Such operations include pancreaticoduodenectomy, which entails considerable suturing and knotting due to the need for pancreaticojejunostomy, hepaticojejunostomy, and gastrojejunostomy. Therefore, RAPD surgery is more advantageous than LPD surgery. Recent reports have shown that RAPD is safer and more efficient than LPD among properly selected patients(11, 12). Therefore, RAPD is technically a feasible alternative to the laparoscopic procedure. Further studies may be needed to evaluate the cost-effectiveness of RAPD(13).

To the best of our knowledge, only four reports have been published on the LC for RAPD. Napoli et al. reported decreased operation times and postoperative gastric emptying delay rates after an 33 initial RAPD procedures(14). Liu et al. divided the LC of RAPD into two parts; the operation time first decreased after 20 cases of RAPD and then decreased again after 20 additional cases ($P < 0.01$)(15). Therefore, the authors believe that the LC is completed after 40 RAPD procedures(15). Boone et al.(16) and Chen et al.(17) described their LC in RAPD(16, 17). Boone et al. completed 200 cases of RAPD and found that the operation time was significantly reduced after the 80th operation(16). Chen et al. designed a non-randomized prospective case-control study comparing 120 OPD with 60 RAPD cases and found that the average postoperative time of the last 20 RAPD patients was significantly shorter than that of the first 40 cases(17). As shown by the results of these four studies, the LC is completed within at least 33 RAPD cases. The present research included 30 RAPD procedures. Thus, the team's completion of the LC cannot be conclusively determined. However, peak points in the $CUSUM_{OT}$ graph (Fig. 3) were observed at the 8th case. In our opinion, if we can learn from the experiences of other surgical teams well, we can shorten the LC to even less than 33 cases.

According to previous reports, the LC of OPD corresponds to 50–60 operations(18–20). Speicher et al. reported that OT and blood loss could be reduced after an initial 50 cases of LPD(21). However, RAPD should theoretically have a shorter LC than LPD due to the advantages of the robotic system(22). As shown by the results of the present and the four previous studies, RAPD can be safely performed at a specialized pancreatic surgery center, and each surgeon will require approximately 30–40 cases to complete the LC. The LC for RAPD is shorter than that of either OPD(18–20) or LPD(21).

We compared the outcomes of RAPD during our initial LC with OPD groups. No statistical differences between the two groups were found in terms of the need for perioperative transfusion, PF rate, length of stay, rate of Clavien–Dindo grade ≥ III morbidity, and rate of mortality. All of the patients underwent R0 resection, and no case conversion to open surgery occurred in the RAPD group. The mean operative time was longer, the mean number of lymph nodes harvested was fewer, and total cost was much higher in the RAPD group than in the OPD group. Therefore, while RAPD is safe during the initial LC, additional patients and resources may be necessary due to its long operation time and high cost.

We also compared the outcome of RAPD during the initial LC with the results from the four previous reports(14–17) (Table 3). The mean operation time ranged from 418 min to 581 min. Boone et al(16) reported 9 days as an unusually short length of hospital stay. However, this finding may be due to differences in medical systems across countries. Unlike in the United States(16), patients in China who do not recover completely cannot easily be arranged for discharge. In two cited reports from China(15, 17), the mean length of hospital stay exceeded 20 days. Our number of harvested lymph nodes was relatively small. Interestingly, the numbers of harvested lymph nodes reported by the cited studies from China(15, 17) were 6.42 and 13.6, respectively, similar to our results and significantly fewer than the 36.8 and 22 reported by Italian(14) and American(16) scholars, respectively. We believe that, on the one hand, surgeons give insufficient attention to lymph node dissection. On the other hand, they may be related to pathological reporting habits.

Our analysis has several limitations. First, experiences were from only 30 initial consecutive RAPD cases. Therefore, additional RAPD cases are necessary to confirm completion of the LC. Second, surgeons with experience in LPD may have a short LC for RAPD. By contrast, our team has no experience in LPD. Third, this research is a retrospective study. Thus, the integrity and homogeneity of research data cannot be guaranteed.

Conclusions

In conclusion, RAPD can be safely performed in well-selected patients during the initial LC by pancreatobiliary surgeon teams with extensive experience in OPD surgery. The LC may be completed after less than 30 operations.

Declarations

Abbreviations

LC:Lnitial learning curve; RAPD:Robot-assisted pancreaticoduodenectomy; OPD:Open pancreaticoduodenectomy; CUSUM:Cumulative sum; LPD:Laparoscopic pancreaticoduodenectomy; ASA:American Society of Anesthesiology; SD:standard deviation; MPD:Minimally invasive pancreaticoduodenectomy;

Ethics approval and consent to participate

The study was approved by the Ethics Committee of The Second Xiangya Hospital.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Conceived and designed the article: Jiangjiao Zhou. Performed the operation: Heng Zou,Jiangjiao Zhou and Yu Wen. Analyzed the data: Xiong Li,Juan Liu and Zhongtao Liu.Wrote the paper: Jiangjiao Zhou. Proofread and revised the manuscript: Yu Wen, Heng Zou and Xiongying Miao.

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Tables

Table.1 Demographic and comorbidity characteristics of all patients

Characteristic	RAPD	OPD	P value
Age, yr (range)	56.23 ±10.820 (34-76)	57.96 ± 10.233 (25-77)	0.481
Male/female	12/18	27/21	0.163
Malignant/benign	16/14	38/10	0.016
Comorbidities			
Diabetes	2	4	1
Hypertension	5	7	1
Cardiovascular diseases	1	1	1
Cerebrovascular disease	1	1	1
Pulmonary disease	0	1	1
Chronic pancreatitis	1	1	1
Cirrhosis	1	2	1
ASA score			0.59
ASA 1	0	1	
ASA 2	14	22	
ASA 3	16	25	

OPD: Open pancreaticoduodenectomy; RAPD: Robot-assisted pancreaticoduodenectomy;

ASA: American Society of Anesthesiologists

Table.2 Intraoperative and postoperative information among the learning curve phases

Characteristic	RAPD	OPD	P value
Operative time (min)	423.67±137.627	228.75±44.988	□0.001
Perioperative transfusion needed, n	5(16.7%)	6(12.5%)	0.607
No. of lymph nodes harvested	8.72±4.9	13.39±7.487	0.007
PHS (d)	22.97±16.481	20.29±14.068	0.447
Clavin-Dindo, n	16(53.3%)	26(54.2%)	0.077
I	0	7(14.6%)	
II	7(23.3%)	4(8.3%)	
IIIA	4(13.3%)	8(16.7%)	
IIIB	4(13.3%)	5(10.4%)	
IV	0	0	
V	1(3.3%)	2(4.2%)	
Clavin-Dindo ≥III, n	9(30%)	15(31.3%)	0.907
Pancreatic fistula	19(63.3%)	20(41.7%)	0.318
A	8(26.7%)	8(16.7%)	0.287
B	10(33.3%)	11(22.9%)	0.313
C	1(3.3%)	1(2.1%)	1
Mortality (90-day)	1(3.3%)	2(4.2%)	1
Readmission (90-day)	1(3.3%)	3(6.4%)	0.968
Fee(RMB,yuan)	185700±54500	120600±41700	□0.001

PHS: Postoperative hospital stay; OPD: Open pancreaticoduodenectomy; RAPD: Robot-assisted pancreaticoduodenectomy;

Table.3 Comparison of RAPD learning curve with previous studies

Research	Zhou	Zhang	Napoli	Boone	Chen
Cases before complete LC	30	40	33	80	40
Operative time, min	423.67	418	564.7	581	445
Conversion to open	0.00%	10%	0.00%	11.20%	1.70%
Length of hospital stay	22.97	22	22.6	9	20
Post-operative complications	53.30%	65%	78.80%	67.50%	35%
Clavien–Dindo≥III	30.00%	30%	12.10%	26.00%	11.70%
Postoperative mortality	3.33%	7.50%	3.00%	3.30%	1.70%
Margin negative resection	100%	100%	100%	92.00%	97.80%
Lymph nodes harvested	8.72	6.42	36.8	22	13.6

Figures

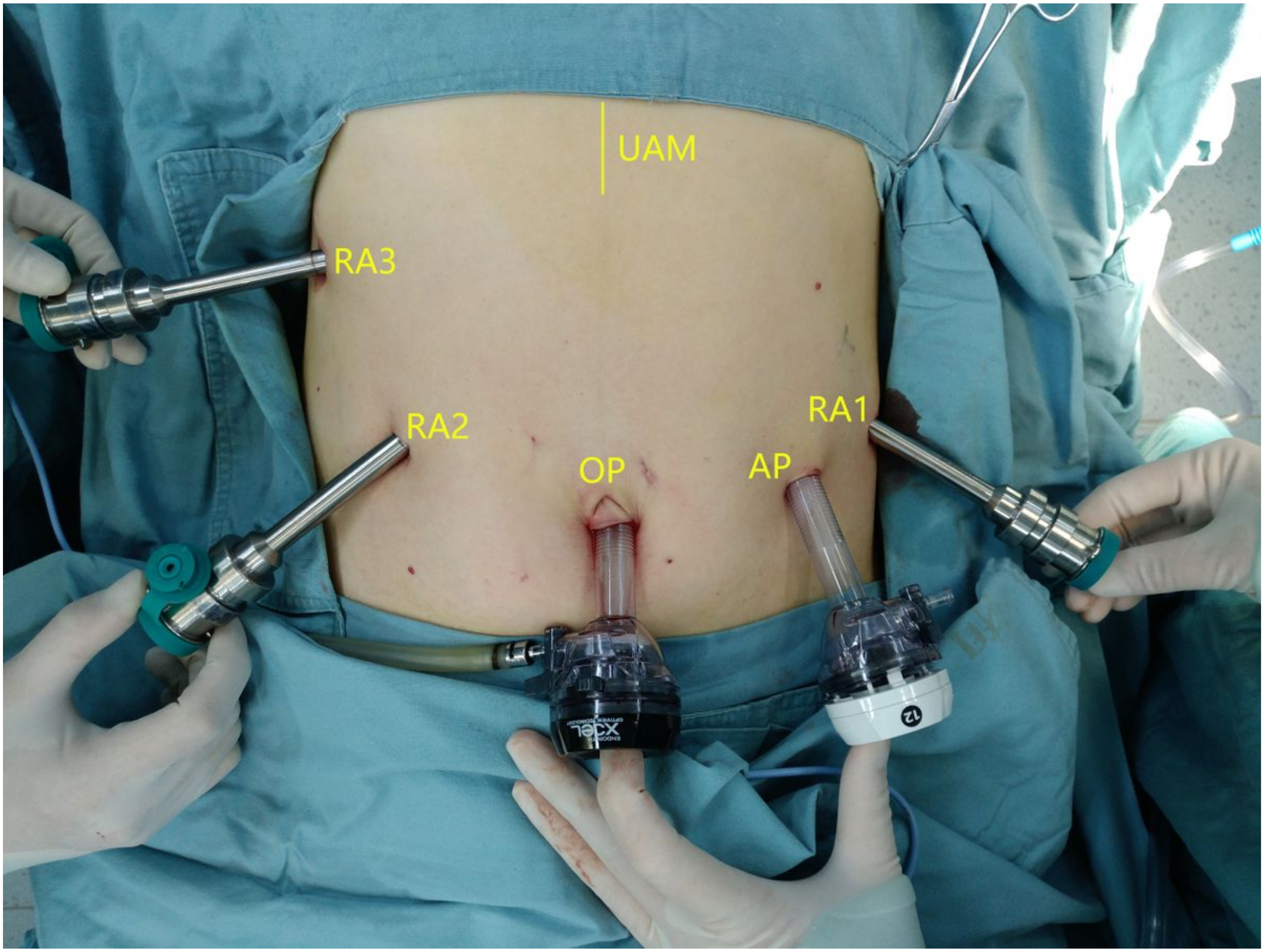

Figure 1

Placement of the 5 ports. RA1: 8-mm trocar along the left anterior axillary line; RA2: 8-mm trocar along the right midclavear line; RA3: 8-mm trocar along the right anterior axillary line; The optic port (OP):12-mm trocar under umbilicus; The assistant port (AP):12-mm trocar along the left midclavear line. UAM：Upper abdomen midline incision

Fig.2

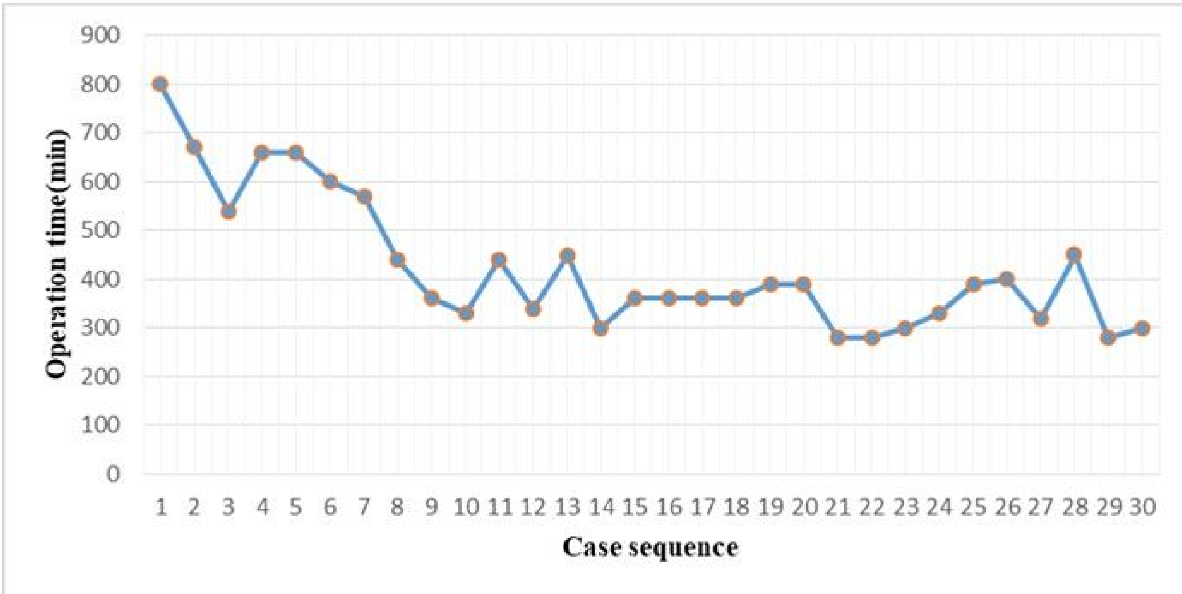

Figure 2

Graph of operative times plotted for each of the 30 consecutive patients

Fig.3

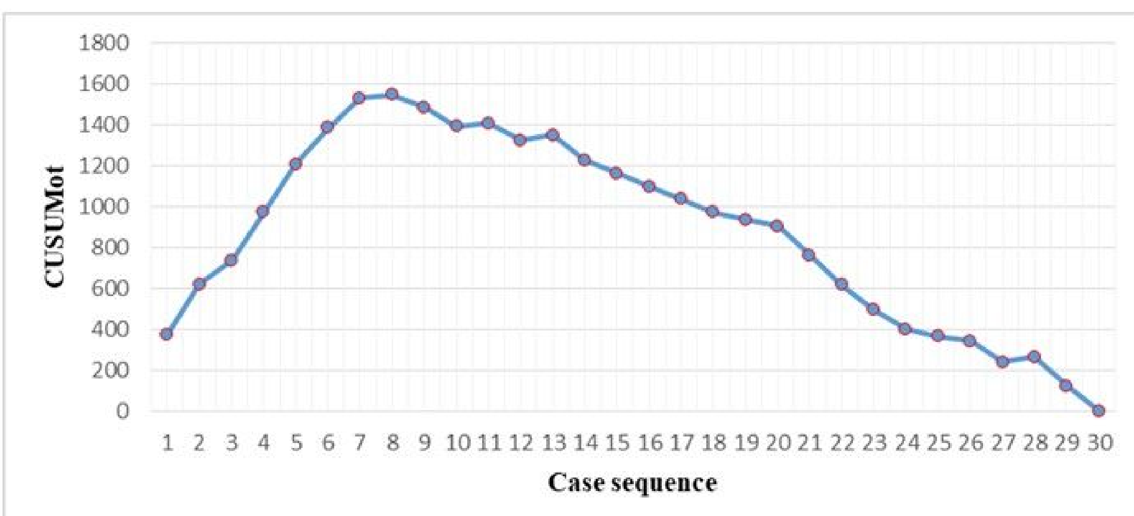

Figure 3

Cumulative sum graph for operative time