



Learning curve of robot-assisted choledochal cyst excision in pediatrics: report of 60 cases

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Abstract

Background Little data are available to assess the learning curve for robot-assisted surgery on choledochal cysts. The aim of this current study is to investigate the characteristics of the learning curve for robot-assisted choledochal cyst excisions using the da Vinci (SI) surgical system in pediatrics.

Methods A retrospectively collected database comprising all medical records of the first 60 consecutive patients undergoing a robot-assisted choledochal cyst excision and Roux-en-Y hepaticojejunostomy using the da Vinci (SI) surgical system performed by one individual surgeon was studied. Baseline information and postoperative outcomes were collected and then learning curves were analyzed using the cumulative sum (CUSUM) method. Patients were divided into two groups including group A and group B according to the cutoff points of the learning curve. Intraoperative characteristics and short-term outcomes were compared between the two groups.

Results CUSUM plots revealed that the cutoff point of the learning curve was 14 cases. Comparison of the operative time between the two groups revealed that the total operative time (203.71 ± 15.27 , 171.28 ± 3.62 min, $P < 0.001$), docking time (23.79 ± 5.81 , 14.50 ± 0.98 min, $P < 0.001$), and console time (151.86 ± 9.77 , 129.15 ± 2.96 min, $P < 0.001$) were decreased significantly. The intraoperative bleeding (20.36 ± 7.46 vs. 20.43 ± 9.18 , $P = 0.977$), time to taking water (2.89 ± 0.22 vs. 3.04 ± 0.34 , $P = 0.115$), time to starting solids diet (3.73 ± 0.17 vs. 3.79 ± 0.26 , $P = 0.387$), hospital stay (7.51 ± 1.12 vs. 7.54 ± 0.95 , $P = 0.910$), and the postoperative complications did not differ significantly between the two groups.

Conclusions The learning curve for the robot-assisted choledochal cyst excision and Roux-en-Y hepaticojejunostomy in children is 14 cases. This learning curve can be used as the basis for performance guidance during training in future.

Keywords The learning curve · Robot-assisted choledochal cyst excision · Pediatrics

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Choledochal cysts (CCs) are rare entities characterized by congenital biliary tract dilatation and has symptoms of abdominal pain, jaundice, and tumors. Its incidence in European countries and in the United States is 5–15 cases per million people [1–3], being more common in Asian countries, such as China, Korea, and Japan, with an incidence up to 1000 cases per million people [4–6].

Choledochal cysts can be discovered early during the antenatal period using prenatal sonography or late during childhood or early adulthood. About 80% of choledochal cysts are diagnosed in childhood within the first decade of life [7, 8]. Imaging tests including B-mode ultrasounds, computed tomography and magnetic resonance cholangiography can all assist in the diagnosis. Choledochal cysts have a high likelihood of progressing to severe hepatobiliary complications such as cholangitis, pancreatitis, perforation

of the cyst, and can even become cancerous [9]. Due these dangers, prompt treatment is essential.

The main treatment of choledochal cysts is the complete resection of the cyst with a Roux-en-Y hepaticojejunostomy, which traditionally has been performed as an open procedure [10]. However, minimally invasive treatment of choledochal cysts in children is currently the mainstream method, including laparoscope-assisted and robot-assisted procedures. In 1995, Farello et al. performed the first laparoscopic choledochal cyst resection with a Roux-en-Y hepaticoenterostomy in a 6-year-old girl [11]. Over the last decade, with the advent of laparoscopy, several authors have reported the feasibility and advantages of laparoscopic choledochal cyst excisions [12–15]. As of yet though, laparoscopic approaches have not gained widespread popularity because they are technically demanding procedures. The learning curve for the laparoscopic excision of choledochal cysts and Roux-en-Y hepaticojejunostomy in children is 37 cases [16]. Meanwhile, robotic surgery has been proposed as another adjunct for pediatric minimal surgery for choledochal cyst excisions which can facilitate complex minimal access procedures [17]. Woo et al. reported the first robotic laparoscope-assisted type I choledochocystectomy for a 5-year-old child patient in 2006 [18]. Subsequently, there were further related reports [6, 17, 19].

Although the prevalence and characteristics of robot-assisted choledochal cyst excisions using the da Vinci (SI) surgical system are well established, little is known about the learning curve of robot-assisted choledochal cyst excisions using the da Vinci (SI) surgical system. The aim of this current study is to investigate the characteristics of the learning curve of robot-assisted choledochal cyst excisions with the da Vinci (SI) surgical system in pediatrics.

Methods

Study population

This retrospective cohort study was approved by the ethics committee of Sichuan University's West China Hospital. Owing to the retrospective nature of this study, our committee waived the need for patient consent. Between January 2018 and August 2019, sixty consecutive patients with choledochal cysts and who were treated with robot-assisted procedures using the da Vinci (SI) surgical system were retrospectively analyzed. During the study period, all children with clinical symptoms or abdominal ultrasonography showing signs of choledochal cysts were diagnosed by computed tomography or magnetic resonance cholangiography. The operations were performed by a single surgeon who was trained in robot-assisted choledochal cyst excision with the da Vinci (SI) surgical system in pediatrics. The rest of the

robotic surgical team consisted of a fixed first assistant surgeon, nurses and an anesthetic team who were familiar with the robot setup.

Robotic procedures

After endotracheal intubation under general anesthesia, an arterial catheter and a peripheral intravenous catheter are then used. The patient should be put close to the bedside with their head elevated 15° with a slight tilt to the left 15°. A 1.5 cm incision below the umbilicus, in which an index finger could fit, is made. Following this, a Roux-en-Y jejunojunal anastomosis is performed extracorporeally by prolapsing the jejunum through this incision. Exploration through this incision is made to identify the ligament of Treitz. For subsequent anastomosis, an anti-reflux valve is used and finally sealing of blind end of loop is performed. A 12 mm trocar is placed in the incision and then insufflation to 8–10 mm Hg. The 8 mm operating port I is placed at left upper quadrant with a 5–8 cm length of the umbilicus. For infants the location is close to left anterior axillary line. The 8 mm operating port II was placed 5–8 cm right of the umbilicus and the 5 mm port for assistance is between Port I and umbilical port (Fig. 1). Traction sutures are performed at the base of ligament teres and in the middle portion of the gallbladder for better exposure of the cyst and hilum. An electric hook is used to free the cyst and transect the cyst



Fig. 1 Port placement in robot-assisted surgery for choledochal cysts: 1. Camera port. 2. Port I. 3. Port II. 4. Assistant port

after double ligation. After the openings of the hepatic duct and cystic duct are identified, the cyst is completely removed (Fig. 2A). The opening site of the hepatic duct is tailored as oval shaped with a higher left side and lower right side. A biliary loop is lifted up through the right mesentery in the avascular region of the transverse colon. An end-to-side choledochojejunostomy is made 0.5 cm away from the blind end using 4–0 Stratafix. Single-layer continuous sutures are made from left to right and from back to front (Fig. 2B). The mesentery defect and biliary loop are then promptly repaired. Finally, the Gallbladder is removed and spilled bile is cleaned. A drainage catheter is then placed around the liver portal.

Postoperative progress

Oral diet was started on the third day after surgery under evidence of return of bowel motility. Water is given first, followed by a liquid and then a soft diet. Patient discharge is considered after all diets are able to be consumed without any discomfort, abdominal pain, or other complications.

Data collection

Data were entered into the database by one author and checked by one of the other authors. This data included

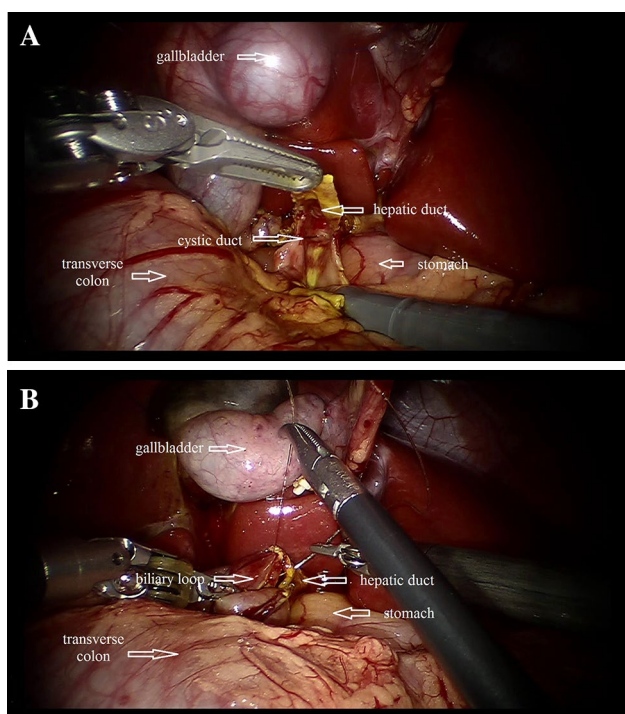


Fig. 2 Intraoperative photographs: **A** Choledochal cyst dissected and resected at the level of common hepatic duct. **B** hepaticojejunostomy with robotic instruments

demographic information of all patients, type and size of cyst, operative details and outcomes such as operative time, volume of blood loss, intraoperative blood transfusion, postoperative feeding of solids, postoperative hospital stay, and postoperative complications. The total operative time was defined as the time interval from skin incision to skin closure. The docking time was defined as the time from creation of the portal incisions to the end of the docking. The console time was the actual time the surgeon spent at the robotic console during the procedure, which directly corresponded to the robotic portion of the procedure.

Statistical analyses

The cumulative sum (CUSUM) technique for assessment of the learning curve was applied to explore the relationship between operative time and the case number of the robot-assisted procedures. The CUSUM series was defined as $S_n = P(X_1 - X_0)$, where X_1 was an individual measurement and X_0 was a predetermined reference level and this was set as the mean operative time for all the cases here. S_n was plotted against the sequence of operations. Cutoff values were chosen according to the points of downward inflection revealed by the plots. The CUSUM was used to analyze the total operative time, docking time and console time, respectively. The patients were divided into two groups according to the cutoff point of the CUSUM score: group A (\leq cutoff value) representing the early-experience group and group B ($>$ cutoff value) the late-experience group. Variables included the proportion, mean, or median with variability estimates in the form of standard deviations (SD) and interquartile ranges (IQR), as seen as appropriate. A Chi-square test or Fisher's exact test was used to compare the distribution of categorical variables between the groups. Continuous variables were analyzed using Student's t test or ANOVA. Statistical analysis was performed using SPSS version 23.0 and a P value < 0.05 was considered statistically significant.

Results

A total of 60 patients who underwent robot-assisted choledochal cyst excision were included in this study. The characteristics and outcomes of the study population are described in Table 1. The male to female ratio was 3:1. The median age of the patient was 46 months with a mean weight of 18.20 kg. The most common symptoms were abdominal pain, vomiting, and jaundice (73.33%, 56.67%, and 26.67%, respectively). A palpable abdominal mass and abdominal distension was observed in 8.33% and 6.67% of the patients, respectively. The cyst size in the series was 2.90 ± 1.56 cm. No significant differences were found among gender, age,

Table 1 Baseline characteristics of patients

Variables	Total (n = 60)	CLC cutoff	P value	
			Group A (n = 14)	Group B (n = 46)
Sex, no. (%)				
Male	15 (25.00%)	4 (28.57%)	11 (23.91%)	0.521
Female	45 (75.00%)	10 (71.43%)	35 (76.09%)	
Age (month) ^a	46.00 (31.25–73.00)	43.00 (21.25–92.00)	46.00 (33.50–72.25)	0.626
Weight (kg) ^b	18.20 (10.74)	19.51 (15.11)	17.80 (9.20)	0.606
Abdominal pain, no. (%)	44 (73.33%)	12 (85.71%)	32 (69.57%)	0.239
Vomiting, no. (%)	34 (56.67%)	8 (57.14%)	26 (56.52%)	0.807
Distension, no. (%)	4 (6.67%)	1 (7.14%)	3 (6.52%)	0.936
Jaundice, no. (%)	16 (26.67%)	5 (35.71%)	11 (23.91%)	0.444
Palpable mass, no. (%)	5 (8.33%)	1 (7.14%)	4 (8.70%)	0.857
WBC count (/mm ³) ^b	9.74 (4.02)	11.17 (3.80)	9.30 (4.01)	0.128
Neutrophils (%) ^b	45.10 (20.22)	46.91 (19.85)	44.55 (20.52)	0.706
ALT (IU/l) ^b	45.62 (44.57)	56.14 (55.43)	42.41 (40.88)	0.317
AST (IU/l) ^b	46.28 (41.08)	49.93 (45.73)	45.17 (40.03)	0.708
TBIL (μmol/l) ^b	35.46 (47.35)	44.63 (44.06)	32.66 (48.42)	0.412
DBIL (μmol/l) ^b	26.19 (40.10)	32.31 (34.41)	24.32 (41.84)	0.519
IBIL (μmol/l) ^b	9.08 (10.74)	12.31 (11.65)	8.09 (10.39)	0.201
Cyst type, no. (%)				
I	52 (86.67%)	12 (85.71%)	40 (86.96%)	0.907
II	0 (0.00%)	0 (0.00%)	0 (0.00%)	
IV	8 (13.33%)	2 (14.29%)	6 (13.04%)	
Diameter of cyst (cm) ^b	2.90 (1.56)	2.99 (1.35)	2.87 (1.63)	0.813

CLC completion of the learning curve, WBC white blood cell count, ALT alanine transferase, AST aspartic aminotransferase, TBIL total bilirubin, DBIL direct bilirubin, IBIL indirect bilirubin

^aMedian, interquartile range

^bMean, standard deviation

clinical manifestations, biochemical examination, cyst type and size categories between the two groups.

A graph of raw operative times plotted in each of the cases arranged in chronological order is shown in Fig. 3A. Once operative times were arranged, we calculated CUSUM values for each of the cases to obtain a graph for the learning curve (Fig. 3B). The length of the operation and case number of procedures led to a statistically significant cubic equation correlation ($R^2 = 0.960$, $P < 0.001$). We analyzed the learning curve and found that a decreasing point for total operative time began at the fourteenth operation. Meanwhile, a similar trend at the thirteenth operation was observed for docking time by inspecting the CUSUM plots (Fig. 3C). Console time decreased from the sixteenth operation (Fig. 3D).

Between the two groups, the total operative time (203.71 ± 15.27 , 171.28 ± 3.62 min, $P < 0.001$), docking time (23.79 ± 5.81 , 14.50 ± 0.98 min, $P < 0.001$) and console time (151.86 ± 9.77 , 129.15 ± 2.96 min, $P < 0.001$) all revealed a decreasing trend. Additionally, multiple intraoperative variables and short-term postoperative outcomes were compared

as shown in Table 2. There were no cases of conversion to open procedures among the 60 consecutive cases. The intraoperative bleeding (20.36 ± 7.46 vs. 20.43 ± 9.18 , $P = 0.977$), time to taking water (2.89 ± 0.22 vs. 3.04 ± 0.34 , $P = 0.115$), time to starting a solids diet (3.73 ± 0.17 vs. 3.79 ± 0.26 , $P = 0.387$) and hospital stay (7.51 ± 1.12 vs. 7.54 ± 0.95 , $P = 0.910$) were not significantly different between the two groups. The postoperative complications and the incidence rate for each cohort were also assessed, and from this it was found that there was no significant difference and no 30-day mortality in any cohort. The two complications in group A consist of one bleeding during the hepaticojejunostomy and one bile leakage. The patient with bleeding during the hepaticojejunostomy received a reoperation. The patient with minor bile leakage was treated with a short conservative medical treatment without any issue. The one complication in group B consisted of an intestinal obstruction. This patient with intestinal obstruction was also treated with a short conservative medical treatment without any issue. All patients were eventually discharged and made uneventful recoveries after the operation.

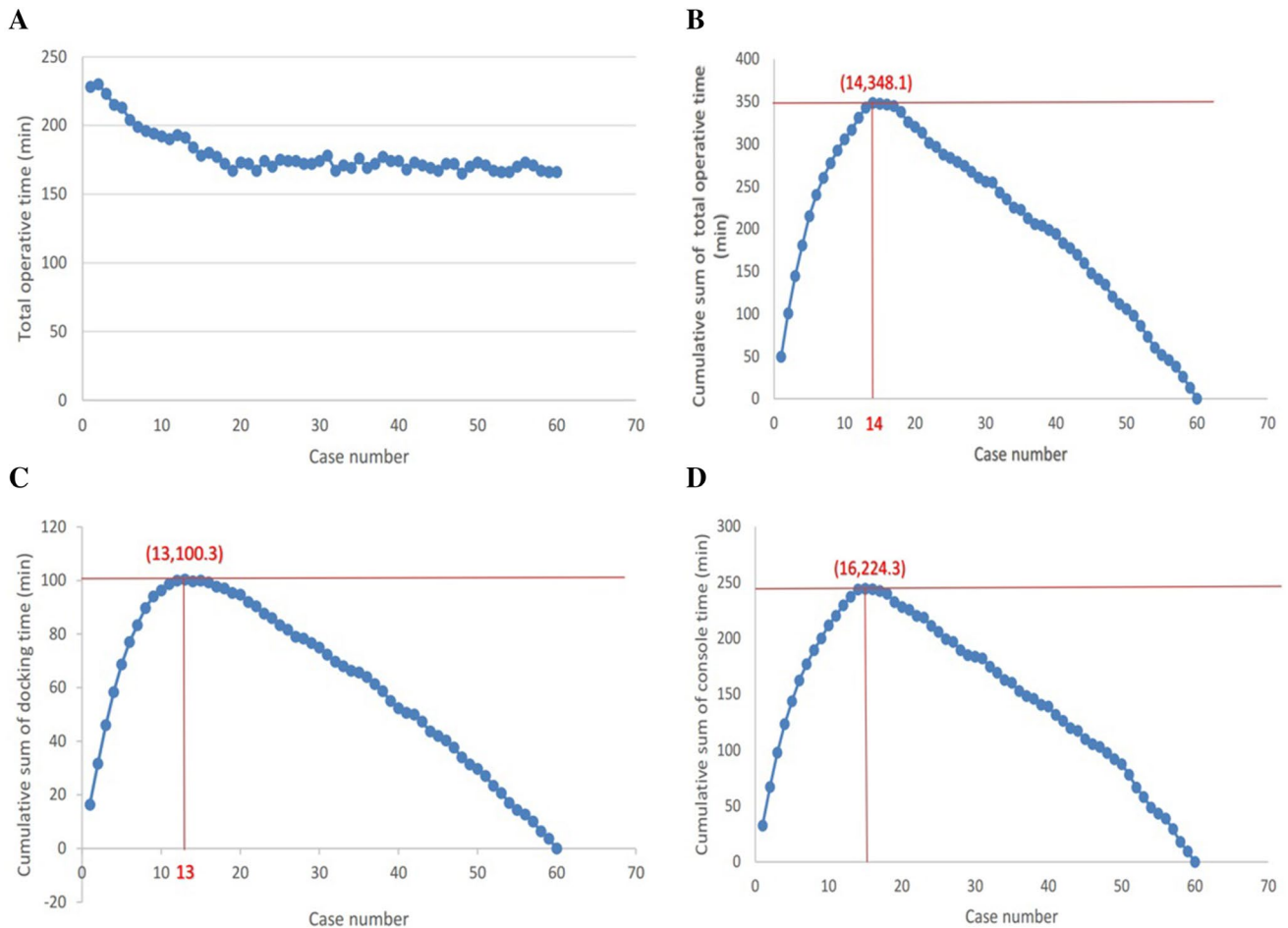


Fig. 3 Learning curve of the first 60 consecutive robot-assisted cholecystectomy and Roux-en-Y hepaticojejunostomy pediatric cases. **A** Graph of raw operative times plotted for each of the 60

consecutive patients, **B** cumulative sum (CUSUM) plot for the total operative time, **C** docking time, and **D** console time

Discussion

The ‘learning curve’ concept was first introduced in the aircraft manufacturing industry, where it was recognized that performance improves with both time and experience and subsequently leads to increased productivity [20, 21]. Learning curve principles apply equally to surgical disciplines and are becoming more relevant as new technology-based developments that influence surgeons at all levels rapidly continue to emerge. Proficiency and competence must be achieved when adopting a new device like the da Vinci surgical system. McCulloch et al. suggested that to improve the standards of clinical research in surgery, learning curves and variations in the techniques and quality of surgery must be measured and controlled continuously [22]. The CUSUM technique is one of a series of sequential analysis tests, arising from the need for quality control in industrial processes, which was first described in detail in 1954 by Page [23]. The CUSUM technique

was subsequently adopted by the medical profession in the 1970s to analyze the learning curve for surgical procedures [24, 25]. The main advantages of this approach are its independence from the sample size, effectiveness in detecting small shifts in the system, and ability to allow continuous analysis in time and rapid evaluation of data. The CUSUM method’s limitation is that a small early learning curve series will have higher mean values compared to those values that would be obtained if the series were extended and outcomes improved or stabilized for a longer period along the tail of the curve. For this reason, small sample size studies may distort the estimated inflection point by using an overly conservative central tendency value to weigh samples in the CUSUM analysis. This emphasizes the need for learning curve studies to ensure an adequate sample size. The CUSUM method has thus been used as an indicator of satisfactory outcomes in relation to the acquisition of clinical skills within an adequate sample size [26]. As far as robot-assisted surgery is

Table 2 Intraoperative and postoperative variables

Variables	Total(n = 60)	CLC cutoff	P value	
			Group A (n = 14)	Group B (n = 46)
Operative time (min) ^a				
Total time	178.85 (15.90)	203.71 (15.27)	171.28 (3.62)	<0.001
Docking time	16.67 (4.88)	23.79 (5.81)	14.50 (0.98)	<0.001
Console time	134.45 (11.02)	151.86 (9.77)	129.15 (2.96)	<0.001
Intraoperative bleeding (mL) ^a	20.42 (8.75)	20.36 (7.46)	20.43 (9.18)	0.977
Transfusion rate, n (%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Conversion to open surgery, n (%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Time to taking water (days) ^a	3.01 (0.32)	2.89 (0.22)	3.04 (0.34)	0.115
Time to starting solids diet (days) ^a	3.78 (0.24)	3.73 (0.17)	3.79 (0.26)	0.387
Total complication	3 (5.00%)	2 (14.28%)	1 (2.50%)	0.071
Bleeding at hepaticojejunostomy	1 (1.67%)	1 (7.14%)	0 (0.00%)	
Bile leakage, n (%)	1 (1.67%)	1 (7.14%)	0 (0.00%)	
Wound infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Residual cyst	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Biliary stones	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Pancreatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Intestinal obstruction, n (%)	1 (1.67%)	0 (0.00%)	1 (2.50%)	
Stricture of hepaticojejunostomy, n (%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Reoperation, n (%)	1 (1.67%)	1 (7.14%)	0 (0.00%)	0.373
Hospital stay (days) ^a	7.53 (0.98)	7.51 (1.12)	7.54 (0.95)	0.910

^aMean, standard deviation

CLC completion of the learning curve

concerned, there are reports analyzing the learning curves corresponding to colorectal procedures [27, 28]. However, in the field of surgery, there have been few studies specifically analyzing the learning curve of robot-assisted choledochal cyst excisions with the da Vinci (SI) surgical system in pediatrics using the CUSUM method.

In our study, we conclude that the learning curve for robot-assisted choledochal cyst excisions is 14 cases. Wen et al. reported that the learning curve for laparoscopic choledochal cyst excisions and Roux-en-Y hepaticojejunostomy in children is 37 cases [16]. This is because laparoscopic surgery for choledochal cysts might be technically difficult when performing surgery in the narrow abdominal cavity. Limitations include the use of straight rigid instruments within a narrow working space, limited freedom of movement by a matter of degrees, an unstable two-dimensional imaging camera platform, and poor instrument ergonomics. On the other hand, robot-assisted surgery offers technical advantages such as high-quality three-dimensional imaging, free-moving multi-joint forceps, and image stabilization over laparoscopic surgery and thus may shorten the learning curve compared with laparoscopic surgery. In our study, the long operative time in the early group A cases is shown to be mainly due to cautiousness and logistical problems, but as

we accumulate operative experience and improve our robotic techniques, the operative time is shortened.

Kim et al. reported that one case was converted to open conversion in their early cases and Alizai et al. reported five cases of open conversion due to technical problems during robot-assisted procedures [19, 29]. In our study, no case required conversion to laparotomy in robot-assisted procedures, despite other authors reporting a higher conversion rate due to technical problems.

Postoperative complications were encountered in three children. The total complications rate of our patients was 5.56%, which is comparable to that in the reported literature [30, 31]. Notably, a skilled robot-assisted surgery assistant played an important role in monitoring instrument interactions, allowing us to avoid complications secondary to the robotic arm itself in all cases. We believe that developing a skilled robotic surgical team is important for the prevention of complications due to robotic instruments.

However, there are several clear limitations in our study. Firstly the learning curve varies with the frequency in which patients are operated on, the type and volume of the practice, and there are also many parameters peculiar to the individual surgeon as well. The present study only represents the experience of a single surgeon. Of course, this study

is a retrospective study in a single center and we feel these findings warrant a large, prospective, multi-center clinical trial to validate our findings and to investigate further the true benefits of robot-assisted surgery for treatment of choledochal cysts compared with open and laparoscopic surgeries. However, our study improves the medical community's understanding of the learning curve-related robot-assisted choledochal cyst excisions using da Vinci (SI) surgical system in pediatrics and this study provides a reasonable reference about the learning curve for other surgeons.

Conclusion

The learning curve of the robot-assisted choledochal cyst excision and Roux-en-Y hepaticojejunostomy with da Vinci (SI) surgical system in children is 14 cases. This learning curve can be used as the basis for performance guiding during training.

Compliance with ethical standards

Disclosures This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. Xiaolong Xie, Liwei Feng, Kewei Li, Chuan Wang, and Bo Xiang have no conflicts of interest or financial ties to disclose.

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