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The learning curve in pure laparoscopic donor right hepatectomy: a cumulative sum analysis

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Abstract

Background Although the use of pure laparoscopic donor hepatectomy (PLDH) is increasingly common, it remains limited to a few experienced centers and no data on the learning curve are currently available. The aim of this study is to evaluate the learning curve associated with the use of pure laparoscopic donor right hepatectomy (PLDRH).

Methods Data from donors undergoing PLDRH performed by a single surgeon between November 2015 and October 2017 were retrospectively reviewed. The learning curve was evaluated using the cumulative sum (CUSUM) method based on duration of surgery.

Results Of 100 donors evaluated, none required transfusion or conversion to open hepatectomy and no irreversible disability or mortality was reported. The mean operative time was 320.7 ± 51.8 min, and all grafts were successfully transplanted. The CUSUM analysis demonstrated a learning curve of approximately 60 cases of PLDRH. Estimated total liver volume > 1400 cm^3 and double portal vein orifices were seen to be risk factors for longer surgery time. Having adjusted for case mix with these factors, the risk-adjusted CUSUM analysis demonstrated a learning curve of 65–70 cases of PLDRH.

Conclusions In conclusion, PLDRH is a feasible and safe procedure with a learning curve of 65–70 cases.

Keywords Donor hepatectomy · Liver transplantation · Living donor · Laparoscopy · Right hepatectomy · Minimally invasive surgery

Abbreviations

ALT	Alanine aminotransferase
APD	anterior to posterior diameter
AST	Aspartate aminotransferase
CUSUM	Cumulative sum
Hb	Hemoglobin
ICG	Indocyanine green
PLDH	Pure laparoscopic donor hepatectomy
PLDRH	Pure laparoscopic donor right hepatectomy
TD	Transverse diameter

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The use of laparoscopic liver resection is increasingly common worldwide as it is associated with better cosmetic outcomes, shorter hospital stays, less bleeding, and reduced postoperative complications, while also being oncologically comparable to open liver resection [1–5]. Increased experience and knowledge of laparoscopic techniques has meant that laparoscopic donor hepatectomy is also being performed at some key centers. While some studies of pure laparoscopic donor hepatectomy (PLDH) have been reported [6–18], most involve left lateral sectionectomy and few include major hepatectomy. The Louisville consensus conference in 2008 and the Morioka consensus conference in 2014 stated that, at that point, pure laparoscopic donor major hepatectomy could not be recommended for widespread introduction due to potential and unknown risks to the donor and the high level of surgical skill required [19, 20].

Since the introduction of PLDH in our center in November 2015, more than 200 PLDHs have been performed, of which most were right hepatectomies. We recently reported our initial experience in pure laparoscopic donor right hepatectomy (PLDRH) with the largest number of cases to date, showing the feasibility and safety of this approach [9, 10]. However, greater evidence and an understanding of the learning curve is required before widespread introduction of this technique can be recommended. Here, we aimed to determine the learning curve for this procedure with a single surgeon experience of 100 consecutive cases.

Materials and methods

Patients and data

Data from donors undergoing PLDRH at our center between November 2015 and October 2017 were retrospectively reviewed. To overcome operator-dependent bias, data from procedures performed by only a single surgeon (Kyung-Suk Suh) were included.

The donor selection process has been described in detail previously [10, 21, 22]. Initially, PLDRH was performed in selected donors with no anomalies of the bile duct or portal vein. However, since March 2016, once the technique had become sufficiently established, no special selection criteria were applied.

This study was approved by the institutional review board of the Seoul National University Hospital (IRB no. 1806-033-949).

Surgical technique

Our group previously reported detailed descriptions of the technique used for PLDRH [9, 10, 22–24]. No Pringle maneuver was used.

Definitions

Warm ischemic time was the time between ligation of the right hepatic artery and removal of the liver. The Δhemoglobin (Hb)% was calculated as $\Delta Hb\% = [(\text{Preoperative Hb} - \text{postoperative Hb})/\text{Preoperative Hb}] \times 100$. Δbilirubin%, ΔAST%, and ΔALT% were calculated in the same manner. Postoperative complications were graded according to the Clavien-Dindo system [25]. Postoperative complications higher than Clavien-Dindo Grade III were regarded as major complications. Complications occurring within 30 days of transplantation were regarded as early complications. Abdominal shape was determined by the ratio of abdominal anterior to posterior diameter (APD) and transverse diameter (TD) [26–28]. APD and TD were measured at the level of the celiac artery root from the aorta [26].

Statistical analysis

All statistical analyses were performed using SPSS software (version 22.0 for Windows, SPSS Inc., Chicago, IL). Results were expressed as mean ± standard deviation for continuous data and as numbers with percentages for categorical data. Continuous variables were compared using Student's t-tests and categorical variables using the $\chi 2$ test or Fisher's exact test, as appropriate. A P value < 0.05 was considered significant for all tests.

The cumulative sum (CUSUM) method was originally developed to evaluate industrial processes, and its main advantage is the ability to provide a visual representation of the level of performance [29, 30]. A binary outcome is required for CUSUM analyses; for this study, the outcome was surgical failure. Previous studies have defined surgical failure as conversion to open surgery. However, in the present study, surgical failure was defined by the operative time as there were no conversions to open surgery. The average operative time among the 100 cases was set as the cut off value. For the CUSUM plot, the donors were ordered chronologically on the horizontal axis and data for each donor in the series were plotted on the chart from left to right. The line ascended for every donor whose surgical duration was above the average operative time and descended for every donor whose surgery time was below the average operative time. As a result, the CUSUM was displayed graphically and showed the cumulative total of a mixture of increments with each surgical failure and decrements with each surgical success. The achievement of a learning curve was seen as a continual fall in the curve after reaching a peak. Furthermore, risk-adjusted CUSUM analyses were performed to account for the expected risk of surgical failure associated with each specific case. First, univariable analysis of the factors predictive of surgical failure was performed. A subsequent multivariable logistic regression model for surgical failure was constructed using backward selection. Using this final model, a risk-adjusted CUSUM analysis was obtained and the plot provided a visual representation of surgical failure and the learning curve.

Results

During the study period, 150 donors underwent PLDH. Of these, 140 underwent right or extended right hepatectomy. Data from 40 donors who underwent PLDH performed by a surgeon other than Kyung-Suk Suh were excluded. Therefore, data from 100 donors were included in the analyses.

Among the 100 donors included, 54 were male and 46 were female with a mean age of 33.7 ± 11.8 years; 70

Table 1 Donor demographics (n = 100)

Variables	N = 100
Male:female	54:46
Mean age ± SD, years	33.7 ± 11.8
Mean BMI ± SD, kg/m^2	23.9 ± 3.4
Relationship, n (%)	
Son/daughter	70 (70)
Father/mother	2 (2)
Brother/sister	10 (10)
Husband/wife	15 (15)
Other	3 (3)
Graft including middle hepatic vein, n (%)	5 (5)
Mean estimated remnant volume ± SD	35.1 ± 4.0
Mean estimated GRWR ± SD	1.2 ± 0.3
Preoperative blood tests, mean ± SD	
Hb, g/dl	14.1 ± 1.5
Total bilirubin, mg/dl	0.7 ± 0.3
AST, IU/L	18.4 ± 5.5
ALT, IU/L	17.3 ± 9.3
Mean duration of surgery ± SD, min	320.7 ± 51.8
Mean time to remove liver ± SD, min	241.1 ± 38.3
Mean warm ischemic time[a] ± SD, min	11.3 ± 6.2
Double portal vein orifices, n (%)	11 (11)
Multiple bile duct openings, n (%)	45 (45)
Mean graft weight ± SD, g	716.1 ± 153.9
Mean GRWR ± SD	1.1 ± 0.3
Intraoperative transfusion, n (%)	0 (0)
Postoperative blood tests, mean ± SD	
Hb, g/dl	
Lowest	11.9 ± 1.3
ΔHb%[b]	15.4 ± 6.6
POD 1 week	12.8 ± 1.4
POD 1 month	13.6 ± 1.7
POD 3–4 months	14.5 ± 1.6
Total bilirubin, mg/dl	
Peak	3.9 ± 1.8
ΔBilirubin%[c]	533.7 ± 301.9
POD 1 week	1.2 ± 0.9
POD 1 month	0.8 ± 0.3
POD 3–4 months	0.9 ± 0.4
AST, IU/L	
Peak	220.6 ± 78.4
ΔAST%[d]	1164.5 ± 489.8
POD 1 week	47.9 ± 21.8
POD 1 month	26.4 ± 11.0
POD 3–4 months	21.8 ± 8.7
ALT, IU/L	
Peak	224.3 ± 81.8
ΔALT%[e]	1411.8 ± 713.6
POD 1 week	69.2 ± 33.3
POD 1 month	30.1 ± 28.0
POD 3–4 months	19.6 ± 11.0
Mean hospital stay ± SD, days	8.3 ± 3.0
Postoperative complications, n (%)	
Grade I	3 (3)
Wound problem	2 (2)
Pleural effusion	1 (1)
Grade II	4 (4)
Intra-abdominal fluid collection requiring antibiotics	2 (2)
Portal vein partial thrombus	1 (1)
Transient low grade fever requiring antibiotics	1 (1)
Grade IIIa	1 (1)
Biliary leakage requiring endoscopic stenting	1 (1)
Grade IIIb	1(1)
Bile duct disconnecting requiring operation	1 (1)
Rehospitalization, n (%)	4 (4)

[a]Warm ischemic time was considered as the time between ligation of the right hepatic artery and removal of the liver

[b]ΔHb% = [(Preoperative Hb − postoperative Hb)/Preoperative Hb] × 100

[c]ΔBilirubin% = [(Peak bilirubin − preoperative bilirubin)/Preoperative bilirubin] × 100

[d]ΔAST% = [(Peak AST − preoperative AST)/Preoperative AST] × 100

[e]ΔALT% = [(Peak ALT − preoperative ALT)/Preoperative ALT] × 100

donors were the recipients' sons or daughters (Table 1). In five cases, the right graft included the middle hepatic vein and the mean operative time was 320.7 ± 51.8 min. There were 11 cases with double portal vein orifices and 45 with multiple bile duct openings. None of the donors required intraoperative transfusion. The mean hospital stay was 8.3 ± 3.0 days. Two donors experienced complications higher than Grade III. One was readmitted due to abnormal liver function testing, leading to the discovery of a biloma near the bile duct division site. The subject was treated successfully with endoscopic stenting and percutaneous drainage. The other donor required laparoscopic duct to duct anastomosis to rectify division of the bile duct and injury to the common bile duct. The subject made a full recovery after surgery and percutaneous transhepatic biliary drainage, which was later removed.

All grafts were successfully transplanted according to a standard procedure. Among 100 recipients, 70 were men and 30 were women, with a mean age of 54.5 ± 9.8 (Table 2). The mean body mass index was 23.9 ± 3.2 kg/m^2, and the most common etiology was hepatitis B virus (68%); 67 patients had hepatocellular carcinoma, and the mean Model for End-Stage Liver Disease (MELD) score was 17.0 ± 5.0. Early major complications were seen in 27 patients.

Table 2 Recipient demographics (n = 100)

Variables	N = 100
Male:female	70:30
Mean age ± SD, years	54.5 ± 9.8
Mean BMI ± SD, kg/m^2	23.9 ± 3.2
Underlying etiology, n (%)	
HBV	68 (68)
HCV	6 (6)
Alcohol	11 (11)
Others	15 (15)
Hepatocellular carcinoma, n (%)	67 (67)
MELD score ± SD	17.0 ± 5.0
Mean hospital stay ± SD, days	19.5 ± 13.5
Early major complications, n (%)	27 (27)
Intra-abdominal bleeding	8 (8)
Intra-abdominal fluid collection	7 (7)
Wound problem	3 (3)
Hepatic artery problem	2 (2)
Portal vein or hepatic vein problem	4 (4)
Biliary problem	9 (9)
Cardiac problem	3 (3)
Pulmonary problem	4 (4)
Gastrointestinal problem	1 (1)
30 day mortality, n (%)	2 (2)

The CUSUM plot is shown in Fig. 1. The mean operative time was 320.7 min, and surgical failure was therefore defined as a procedure that required > 320.7 min to complete (41 cases). The CUSUM graph shows that the learning curve was accomplished after approximately 60 PLDRH procedures. Univariable analysis showed that donor age > 40, estimated total liver volume > 1400 cm^3, and double portal vein orifices were associated with a significantly higher risk of surgical failure (Table 3). Multivariable analysis showed that estimated total liver volume > 1400 cm^3 and double portal vein orifices were the only factors that were independently associated with surgical failure. According to these results, risk-adjusted CUSUM analysis was performed to assess the learning curve, showing a decrease in the learning curve after 65–70 PLDRH procedures (Fig. 2).

Discussion

PLDH, particularly major right hepatectomy, is still an evolving procedure that requires a high level of surgical skill [19, 20]. Currently, PLDRH is performed in only a small number of highly experienced, large volume institutions, and the feasibility of this procedure has been reported in only a few small studies [14, 18, 31]. Therefore, no formal analysis of the learning curve of PLDRH has been performed to date. To our knowledge, as of March 2017, the Seoul National University Hospital was the first to have performed 100

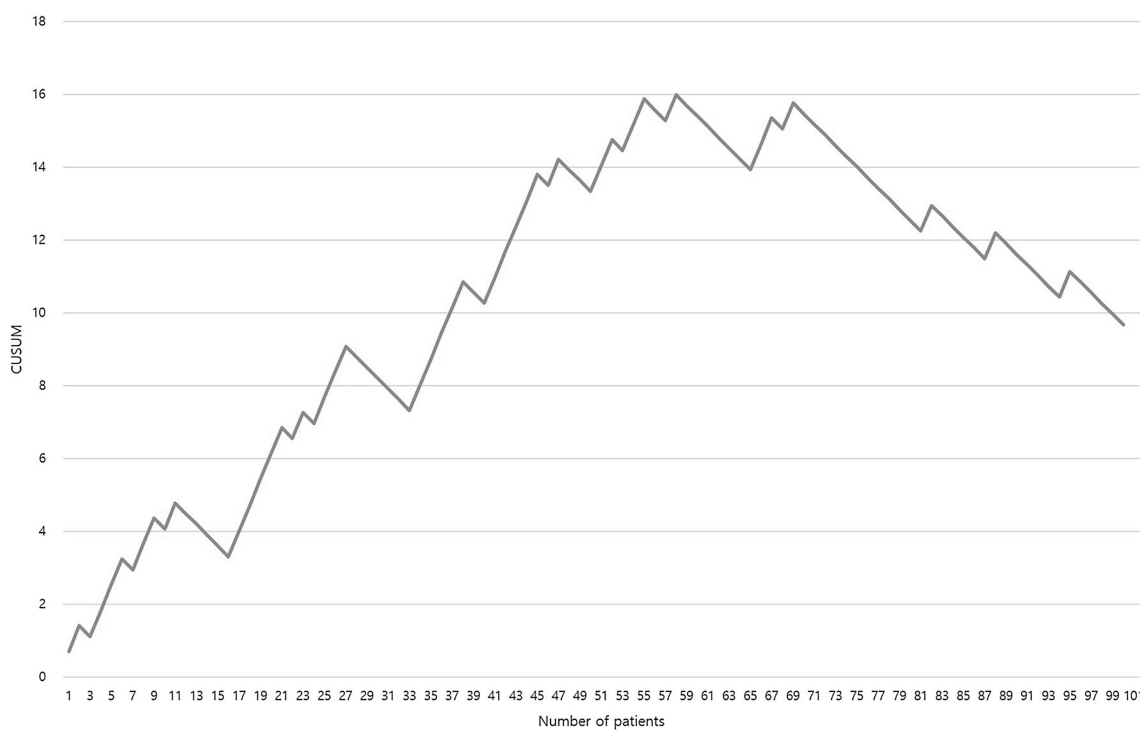

Fig. 1 Cumulative sum plot. A continual fall in the curve is shown after approximately 60 PLDRH procedures

Table 3 Univariable and multivariable analysis

Variables, n (%)	Univariable analysis			Multivariable analysis		
	Success (n = 59)	Failure (n = 41)	*P*	Odds ratio	95% CI	*P*
Male	29 (49.2)	25 (61.0)	0.24			
Age ≥ 40, years	26 (44.1)	10 (24.4)	0.04			
BMI ≥ 23, kg/m^2	33 (55.9)	26 (63.4)	0.45			
Abdominal shape, APD/TD ≥ 0.7	31 (52.5)	23 (56.1)	0.73			
Graft including middle hepatic vein	1 (1.7)	4 (9.8)	0.16			
Estimated total liver volume ≥ 1400, cm^3	9 (15.3)	17 (41.5)	0.003	4.582	1.694–12.392	0.003
Preoperative hemoglobin < 14, g/dl	30 (50.8)	14 (34.1)	0.10			
Preoperative bilirubin ≥ 0.7, mg/dl	20 (33.9)	14 (34.1)	0.98			
Preoperative AST ≥ 20, IU/L	14 (23.7)	6 (14.6)	0.26			
Preoperative ALT ≥ 20, IU/L	14 (23.7)	13 (31.7)	0.38			
Double portal vein orifices	1 (1.7)	10 (24.4)	0.001	22.396	2.646–189.564	0.004
Multiple bile duct openings	23 (39.0)	22 (53.7)	0.15			

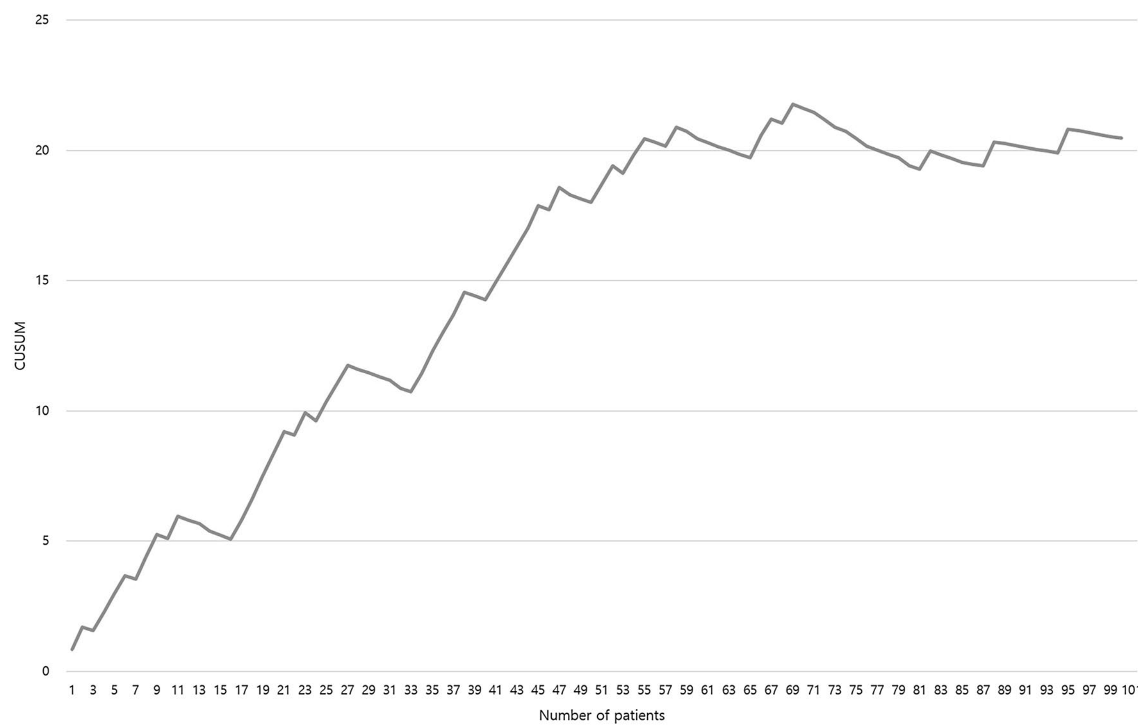

Fig. 2 Risk-adjusted cumulative sum plot. A continual fall in the curve is shown after 65–70 PLDRH procedures

PLDH procedures (which included 93 cases of PLDRH), and 200 PLDH procedures (including 187 cases of PLDRH) had been completed by April 2018. We previously reported our center-based experience of PLDRH and showed that greater experience shortened operation time, reduced blood loss, and minimized liver injury by comparing the outcomes during the initial period and the more recent period [32]. However, this was not a formal learning curve analysis. The present study is, therefore, the first analysis of a learning curve in a large series of PLDRH using the CUSUM method. To eliminate operator-dependent bias, we analyzed 100 consecutive donors who underwent PLDRH performed by a single surgeon.

To utilize the CUSUM technique for monitoring surgical performance, a binary outcome assessing surgical failure is required. Most previous studies defined surgical failure as a conversion to open surgery [33–35]. However, since there had been no conversions to open surgery during the study period, surgical failure was based on the operative time in the current study. The CUSUM plot showed a steep decrease after approximately 60 PLDRH procedures, reflecting the learning curve. This finding can be compared with that of other studies reporting the learning curve for laparoscopic major hepatectomy. Nomi et al. analyzed their experience with laparoscopic major hepatectomy using the CUSUM technique, suggesting the learning phase of laparoscopic major hepatectomy to be 45–75 cases [36]. Another center reported a learning curve of 55 laparoscopic hemihepatectomies [34]. Lee et al. analyzed 96 patients who underwent laparoscopic major hepatectomy, using CUSUM to generate a learning curve, which showed a leveling off after 50 cases [37]. However, comparison of these results (obtained in patients undergoing liver resection for the treatment of tumors) with our study population may be considered inappropriate. PLDRH differs from laparoscopic right hepatectomy in tumor patients in terms of the location and timing of hilar division [36]. In PLDRH, the location of hilar division is more to the left than laparoscopic right hepatectomy for tumors, in order to obtain a sufficient length of right hepatic artery, right portal vein, and right bile duct for the graft. In addition, a precise location of hilar division is required in order to avoid injury to the donor side. To minimize ischemic injury to the graft, the timing of hilar division should be delayed as much as possible in PLDRH. Therefore, it is more disadvantageous in terms of operative field of vision compared with laparoscopic right hepatectomy for the removal of tumors.

A particular case mix with more complexity may lengthen the operative time and introduce bias when determining the learning curve. To account for the associated risk of the case mix in this study, risk-adjusted CUSUM analysis was performed using a multivariable logistic regression model, which included estimated total liver volume > 1400 cm^3 and double portal vein orifices. The risk-adjusted CUSUM plot showed a progressive decrease in the curve after 65–70 PLDRH procedures. The decrease in the curve at this point is seen to be relatively gentle, which may reflect the fact that there are fewer cases with estimated total liver volume > 1400 cm^3 and/or double portal vein orifices in the more recent period of the study.

Previous studies showed that abdominal shape influences abdominal accessibility and therefore affects short-term surgical outcomes in both open and laparoscopic surgeries [26–28]. Safwan et al. reported that abdominal shape with larger body size increased the technical difficulty in donors who underwent mini-incision right hepatectomy [26]. However, in the present study, abdominal shape and body mass index were not seen to be significant risk factors for surgical failure. This can be explained by the use of a flexible 3-dimensional laparoscope, which allows better depth perception than conventional laparoscopes; the flexible scope also allows manipulation in a small space [9, 10, 22–24, 32, 38]. These advantages may have overcome the technical difficulty posed by abdominal shape. Multiple bile duct openings were also not seen to be a significant risk factor. Bile duct division in donor hepatectomy is still of utmost concern, and bile duct variations resulting in multiple bile duct openings can affect surgical outcome. However, the use of real-time indocyanine green (ICG) near-infrared fluorescence cholangiography may have allowed rapid and efficient bile duct division, thereby reducing surgery time.

The learning curve analyzed in the present study should be considered with caution due to the fact that the study surgeon had performed more than 1000 donor hepatectomies, including 60 cases of laparoscopy-assisted donor hepatectomies and over 200 laparoscopic hepatectomies in patients with tumors, prior to adopting the pure laparoscopic technique. The learning curve of this experienced surgeon may, therefore, differ from that of other surgeons. As a pioneer in PLDH, he has progressed surgical techniques, adopted the use of new instruments, and expanded knowledge in this area [9, 10, 22–24, 38]. Therefore, the learning curve in this study inevitably includes time required to develop and standardize innovative PLDRH procedures. Sharing technical tips and pitfalls associated with this standardized procedure may allow other surgeons to reduce their initial learning curve. We previously reported initial experiences of PLDRH undertaken by another surgeon in our center, who had performed over 700 donor hepatectomies but had almost no experience of laparoscopic procedures [9, 22]. By sharing the experience, he also successfully performs PLDRH with comparable outcomes to those of open donor right hepatectomy. Although CUSUM analysis was not performed due to inadequate case numbers, fewer intraoperative events and donor complications were seen as experience accumulated [9]. A correlation between the duration of the procedure and progressive performance of PLDRH was also reported, indirectly reflecting the learning curve.

The present study has several limitations. First, it was a retrospective study and therefore dependent on patients' medical records being complete. Secondly, this report was composed of a single surgeon's experience and it is difficult to generalize to all surgeons.

This study shows that the number of PLDRH procedures required to achieve a stable learning curve is 65–70. When performed by other surgeons who share the experience of this standardized procedure, the learning curve may be minimized. Further analyses of the learning curve of many other surgeons will be required to evaluate bias induced by personal and institutional factors.

Compliance with ethical standards

Disclosures Suk Kyun Hong, Kyung-Suk Suh, Kyung Chul Yoon, Jeong-Moo Lee, Jae-Hyung Cho, Nam-Joon Yi, and Kwang-Woong Lee have no conflicts of interest or financial ties to disclose.

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