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Safely extending the indications of laparoscopic liver resection: When should we start laparoscopic major hepatectomy?

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Abstract

Background Laparoscopic major hepatectomy (LMH) is an innovative procedure that is still in the exploration phase. Although new surgical techniques have learning curves, safety should be maintained from the onset. This retrospective study was conducted to evaluate the safe introduction of LMH.

Methods We retrospectively reviewed data from 245 consecutive patients who underwent pure laparoscopic liver resection. Patients were divided into three groups: Phase I, the first 64 cases, all minor hepatectomies; Phase II, cases from the first LMH case to the midmost of the LMH cases ($n = 69$, including 22 LMHs); Phase III, the most recent 112 cases, including 22 LMHs. Patient characteristics and surgical results were evaluated, and the learning curve was analysed with the cumulative sum (CUSUM) method.

Results The first LMH was adopted after sufficient preparatory experience was gained from performing 64 minor hepatectomies. In cases of LMH, there were no significant differences in the surgical time between Phases II and III (356 vs. 309 min; $P = 0.318$), morbidity rate (22.7 vs. 31.8 %; $P = 0.736$), or major morbidity rate (18.2 vs. 9.1 %; $P = 0.664$); however, estimated blood loss was significantly reduced from Phase II to Phase III (236 vs. 68 mL; $P = 0.018$). The CUSUM for morbidity also showed similar outcomes through Phases II and III.

Conclusion There is a learning curve associated with laparoscopic liver resection. To maintain a low morbidity rate, 60 laparoscopic minor hepatectomies could provide adequate experience before the adoption of LMH.

Keywords Laparoscopic · Hepatectomy · Liver resection · Major hepatectomy · Learning curve

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Historically, liver resection has been associated with high morbidity and mortality rates; it is only in recent decades that its surgical result has improved. Laparoscopic liver resection (LLR) is a relatively new surgical technique, the use of which is rapidly increasing with more than 9500 cases being performed worldwide [1–6]. Compared to the open laparotomy procedure, LLR has various advantages (e.g. fewer complications, transfusions, and analgesic requirements; less blood loss and pains; shorter hospital stays; and improved cosmetic results) [4, 7–10]. Moreover, recent studies have shown that LLR is associated with comparable long-term outcomes to open liver resection [11–18].

The Second International Consensus Conference on LLR was held in Morioka, Japan, in October 2015, to evaluate the current status of laparoscopic liver surgery and to provide recommendations to aid in its future development [2]. During the conference, minor LLR was confirmed as a standard surgical practice. However, it remains in the assessment phase despite being used by an increasing proportion of surgeons. In addition, laparoscopic major hepatectomy (LMH) is an innovative procedure that remains in the exploration phase with incompletely defined risks; therefore, extending the clinical indications for LLR should be considered carefully [19–24].

A learning curve certainly exists for such a new surgical technique, but a low rate of morbidity should be maintained from the beginning. Some studies have reported the learning curve, difficulties, and risk factors for LLR [25–31], but reports concerning when LMH should be adopted are scarce. Here, we aimed to present how LMHs were safely introduced in our institution.

Patients and methods

A prospective database of patients treated at our hospital was retrospectively reviewed for the purpose of this study. LLR has been performed at our institution since May 1997. From then until December 2015, 245 consecutive patients underwent pure LLR without the resection of other organs. Those who underwent laparoscopic donor hepatectomy were excluded from this study because of the specific surgical procedures required. All patients were informed about the procedure, and informed consent was obtained before surgery.

At our institution, the laparoscopic peripheral wedge resection procedure was introduced in May 1997, and the extent of resection was extended in a step-by-step manner. Pure laparoscopic left lateral sectionectomy (LLS) was adopted in April 2003. In November 2008, laparoscopic anatomical segmentectomy was adopted, and LMH was introduced in September 2009. The operators consisted of two experts (G. W. and H. N.) and certain junior surgeons who were learning LLR. To assess the learning curve, the patients were divided into three groups according to phases of the learning curve, and the results were compared among the three groups. Phase I comprised the first 64 cases, which involved only minor hepatectomy; Phase II comprised the cases from the first LMH case to the mid-most of the LMH cases ($n = 69$, including 22 of LMHs); and Phase III comprised the most recent 112 cases, including 22 of LMHs. The patient characteristics, tumour characteristics, liver conditions, surgical methods, and the surgical results were analysed. The primary endpoint was postoperative morbidity, and the cumulative sum (CUSUM) method was used to assess the morbidity of cases performed with LMH.

The extent of liver resection was classified according to the Brisbane 2000 terminology [32]. The definition of major hepatectomy includes the following: (1) resection of 3 or more contiguous liver segments or (2) resection of the right posterior, right anterior, or the left medial section because of the unique techniques required. Postoperative mortality was defined as any death within 90 days after liver resection. Postoperative morbidity was defined as any complication, including readmission, and was graded according to the Clavien–Dindo classification [33]. The surgical margin and liver cirrhosis were confirmed via histopathological findings.

Surgical technique

The patient was placed in the left lateral decubitus position or the supine position (when the tumour was located in the left lateral section) with the reverse Trendelenburg position. The anaesthesiologist maintained a low central vein pressure (e.g. 1–3 cm H_2O). The operator stood to the right of the patient, with the assistant and the scopist on the patient's left. Four or five ports were placed, and the carbon dioxide pneumoperitoneum was maintained at 8–12 mmHg. The liver parenchyma was transected with an ultrasonic surgical aspirator or with the clamp–crush method, and the saline dripping monopolar and soft coagulation system were used for haemostasis. The major Glissonian pedicle or the hepatic vein was divided by using a laparoscopic linear stapler. The intermittent Pringle manoeuvre was first adopted in 2012, since then it was used in most cases regardless of bleeding. Intraoperative ultrasonography was routinely performed to confirm the tumour location and intrahepatic vessels.

The exclusion criteria for pure LLR were as follows: tumour size $\geq$10 cm, number of lesions to be resected $\geq$4, lesions spreading to other organs, and the need for bile ducts and/or vessel resection with reconstruction.

Statistical analysis

Continuous data were expressed as median values, with the interquartile ranges in parentheses. Categorical data were expressed as numbers, with the percentages in parentheses. The Wilcoxon rank sum test was used to compare continuous data, whereas Fisher's exact test or the Chi-square test was employed for categorical data. Variables with a P value of <0.2 in univariate analyses were subsequently entered into multivariate analyses with backward elimination.

The CUSUM (S_t) was defined via the following formula: $S_t = \sum_{i=0}^{t} (X_i - \mu)$. X_i indicates the outcome of the surgery: $X_i = 1$ if complications occurred and $X_i = 0$ if did not. μ is set as the morbidity rate in this series.

All statistical analyses were performed with commercially available software (JMP version 9.0.0; SAS Institute, Cary, NC, USA).

Results

The cumulative number of overall LLRs and LMHs is shown in Fig. 1. Phase I lasted from January 1998 to June 2009, and the number of overall LLRs was 64. There were no major hepatectomies, and all surgeries were performed

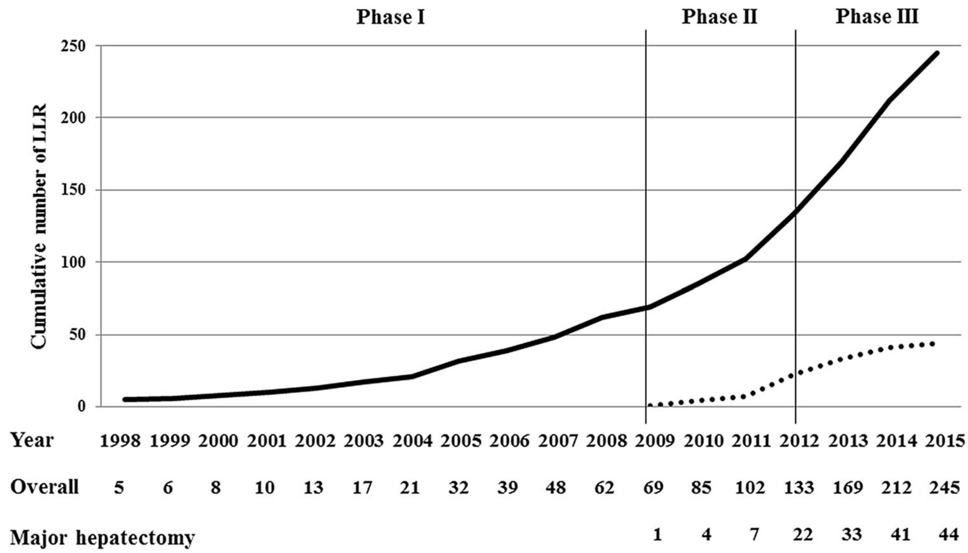

Fig. 1 Cumulative number of overall laparoscopic liver resections (*solid line*) and major hepatectomies (*dotted line*) is shown. In Phases I, II, and III, the number of overall laparoscopic liver resections and major hepatectomies was 64 and 0, 69 and 22, and 112 and 22, respectively

Table 1 Patient characteristics and operative results according to the extent of hepatectomy

	Minor hepatectomy ($n = 201$)	Major hepatectomy ($n = 44$)	P value
Patients characteristics			
Age (years)	66 (57–72)	65 (54–73)	0.638
Male sex	126 (62.7)	28 (63.4)	1.000
BMI (kg/m^2)	23.3 (21.0–25.3)	23.8 (20.1–26.6)	0.733
Diagnosis			0.010
HCC	98 (48.8)	24 (54.5)	
Metastasis from CRC	80 (39.8)	8 (18.2)	
Other malignancy	12 (6.0)	6 (13.6)	
Benign	11 (5.5)	6 (13.6)	
Largest tumour diameter (mm)	25 (19–35)	51 (35–65)	<0.0001
Multiple tumours	34 (16.9)	8 (18.2)	0.827
Child–Pugh grade B	7 (3.5)	0 (0.0)	0.357
ICG-R15 (%)	13 (9–20)	10 (7–14)	0.0004
Liver cirrhosis	52 (26.0)	6 (13.6)	0.116
Multiple hepatectomies during a surgery	22 (10.9)	3 (6.8)	0.585
Operator (junior surgeon)	47 (23.4)	1 (2.3)	0.0006
Operative results			
Surgical time (min)	169 (130–240)	322 (272–425)	<0.0001
Estimated blood loss (mL)	35 (14–106)	147 (42–308)	<0.0001
Conversion	2 (1.0)	3 (6.8)	0.042
Hand assisted	1 (0.5)	1 (2.3)	
Hybrid technique	0	2 (4.5)	
Open laparotomy	1 (0.5)	0	
Morbidity (Clavien–Dindo ≥II)	18 (9.0)	12 (27.3)	0.002
Morbidity (Clavien–Dindo ≥III)	7 (3.5)	6 (13.6)	0.015
Mortality	0 (0.0)	1 (2.3)	0.180
Length of stay (days)	8 (7–11)	12 (9–20)	<0.0001
Positive surgical margin	9 (4.5)	1 (2.3)	0.696

BMI body mass index, *HCC* hepatocellular carcinoma, *CRC* colorectal cancer, *ICG-R15* indocyanine green retention 15 min

Table 2 Interphase comparison of the patients undergoing laparoscopic minor hepatectomy

	Phase I ($n = 64$)	Phase II ($n = 47$)	Phase III ($n = 90$)	*P* value
Patient characteristics				
Age (years)	63 (56–71)	63 (56–75)	67 (61–72)	0.179
Male sex	45 (70.3)	27 (57.4)	54 (60.0)	0.298
BMI (kg/m^2)	23.6 (22.1–24.8)	21.7 (20.0–24.2)	23.4 (21.3–25.8)	0.062
Diagnosis				0.075
HCC	35 (54.7)	17 (36.2)	46 (51.1)	
Metastasis from CRC	22 (34.4)	20 (42.6)	38 (42.2)	
Other malignancy	2 (3.1)	5 (10.6)	5 (5.6)	
Benign	5 (7.8)	5 (10.6)	1 (1.1)	
Largest tumour diameter (mm)	23 (20–35)	23 (19–29)	27 (19–35)	0.226
Multiple tumours	8 (12.5)	4 (8.5)	22 (24.4)	0.032
Child–Pugh grade B	1 (1.6)	1 (2.1)	5 (5.6)	0.348
ICG-R15 (%)	14 (10–23)	12 (8–20)	14 (9–18)	0.214
Liver cirrhosis	21 (32.8)	9 (19.1)	27 (24.7)	0.251
Tumour location S7/8	9 (14.1)	5 (10.6)	27 (30.0)	0.009
Extent of hepatectomy				0.052
Non-anatomical resection	50 (78.3)	32 (68.1)	54 (60.0)	
Left lateral sectionectomy	12 (18.8)	9 (19.1)	19 (21.1)	
Segmentectomy	2 (3.1)	6 (12.8)	17 (18.9)	
Multiple hepatectomies during a surgery	5 (7.8)	3 (6.4)	14 (15.6)	0.164
Operator (junior surgeon)	0 (0.0)	12 (25.5)	35 (38.9)	<0.0001
Operative results				
Surgical time (min)	179 (130–239)	162 (127–240)	165 (133–241)	0.846
Estimated blood loss (mL)	60 (16–218)	53 (20–161)	30 (11–54)	0.002
Conversion	1 (1.6)	0 (0.0)	1 (1.1)	0.707
Hand assisted	0		1	
Open laparotomy	1		0	
Morbidity (Clavien–Dindo $\geq$II)	5 (7.8)	6 (12.8)	7 (7.8)	0.579
Morbidity (Clavien–Dindo $\geq$III)	2 (3.1)	3 (6.4)	2 (2.2)	0.444
Mortality	0 (0.0)	0 (0.0)	0 (0.0)	
Length of stay (days)	9 (7–10)	8 (6–11)	8 (7–11)	0.427
Positive surgical margin	3 (4.7)	1 (2.1)	5 (5.6)	0.651

BMI body mass index, *HCC* hepatocellular carcinoma, *CRC* colorectal cancer, *ICG-R15* indocyanine green retention 15 min

by two experts. Phase II lasted from June 2009 to December 2012; the number of overall LLRs was 69, including 22 LMHs, with 13 LLRs (18.8 %) were performed by junior surgeons. Phase III lasted from January 2013 to the end of the study period; the number of overall LLRs was 112, which included 22 LMHs, and 35 LLRs (31.3 %) that were performed by junior surgeons.

The patient characteristics and the surgical results according to the extent of hepatectomy are shown in Table 1. The surgical time, estimated blood loss, conversion rate, morbidity rate, and the length of stay showed significant differences according to the extent of hepatectomy.

The patient characteristics and surgical results in cases of laparoscopic minor hepatectomies compared among the three groups are shown in Table 2. The rate of tumours located in segment 7/8 and a junior surgeon performing the surgery significantly increased, and the rate of patients undergoing segmentectomy and multiple hepatectomies during a surgery tended to increase with the successive phases. However, there were no differences in the operative results among the three groups.

The patient characteristics and surgical results in cases of LMH compared between phases II and III are shown in Table 3. The surgical time was slightly shortened, and the estimated blood loss was significantly decreased in the latter phase. There were no differences in the morbidity rate and the length of hospital stay between the two groups. The CUSUM chart for morbidity in cases performed with

Table 3 Interphase comparison of the patients undergoing laparoscopic major hepatectomy

	Phase II ($n = 22$)	Phase III ($n = 22$)	P value
Patient characteristics			
Age (years)	69 (57–76)	64 (54–71)	0.341
Male sex	16 (72.7)	12 (54.5)	0.348
BMI (kg/m^2)	24.3 (21.6–27.7)	22.1 (19.7–26.3)	0.362
Diagnosis			0.761
HCC	12 (54.5)	12 (54.5)	
Metastasis from CRC	5 (22.7)	3 (13.6)	
Other malignancy	2 (9.1)	4 (18.2)	
Benign	3 (13.6)	3 (13.6)	
Largest tumour diameter (mm)	52 (42–81)	36 (29–62)	0.053
Multiple tumours	3 (13.6)	5 (22.7)	0.698
Child–Pugh grade B	0 (0.0)	0 (0.0)	
ICG-R15 (%)	12 (8–15)	8 (5–13)	0.086
Liver cirrhosis	2 (9.1)	4 (18.2)	0.664
Extent of hepatectomy			0.060
Left medial sectionectomy	1 (4.5)	3 (13.6)	
Right anterior sectionectomy	1 (4.5)	6 (27.3)	
Right posterior sectionectomy	5 (22.7)	3 (13.6)	
Left hepatectomy	6 (27.3)	7 (31.8)	
Right hepatectomy	9 (40.9)	2 (9.1)	
Central bisectionectomy	0 (0.0)	1 (4.5)	
Multiple hepatectomies during a surgery	2 (9.1)	1 (4.5)	1.000
Operator (junior surgeon)	1 (4.5)	0 (0.0)	1.000
Operative results			
Surgical time (min)	356 (293–421)	309 (234–437)	0.318
Estimated blood loss (mL)	236 (88–368)	68 (22–209)	0.018
Conversion	1 (4.5)	2 (9.1)	1.000
Hand assisted	0	1	
Hybrid technique	1	1	
Morbidity (Clavien–Dindo ≥II)	5 (22.7)	7 (31.8)	0.736
Morbidity (Clavien–Dindo ≥III)	4 (18.2)	2 (9.1)	0.664
Mortality	0 (0.0)	1 (4.5)	1.000
Length of stay (days)	11 (8–19)	12 (9–20)	0.451
Positive surgical margin	0 (0.0)	1 (4.5)	1.000

BMI body mass index, *HCC* hepatocellular carcinoma, *CRC* colorectal cancer, *ICG-R15* indocyanine green retention 15 min

major hepatectomy is shown in Fig. 2A, B. Figure 2A shows the chart for Clavien–Dindo ≥II morbidity, and Fig. 2B shows the chart for Clavien–Dindo ≥III morbidity. These curves showed similar outcomes through Phases II and III.

The risk factors for Clavien–Dindo ≥II morbidity are summarized in Table 4. In multivariate analyses, major hepatectomy [odds ratio (OR) 4.08, 95 % confidence interval (CI) 1.45–11.63, $P = 0.008$], multiple hepatectomies during a surgery (OR 4.25, 95 % CI 1.32–12.73, $P = 0.017$), and platelet count $\leq 100 \times 10^9$/L (OR 3.89, 95 % CI 1.20–11.84, $P = 0.024$) were factors associated with significantly high risk of surgical morbidity of Clavien–Dindo ≥II.

Discussion

The incidence of LLR has increased dramatically in the past decade, and its many advantages have been reported. During the Second International Consensus Conference on LLR, the use of minor LLR as a standard surgical practice was investigated; however, the procedure is still in the assessment phase. LMH remains in the exploration phase

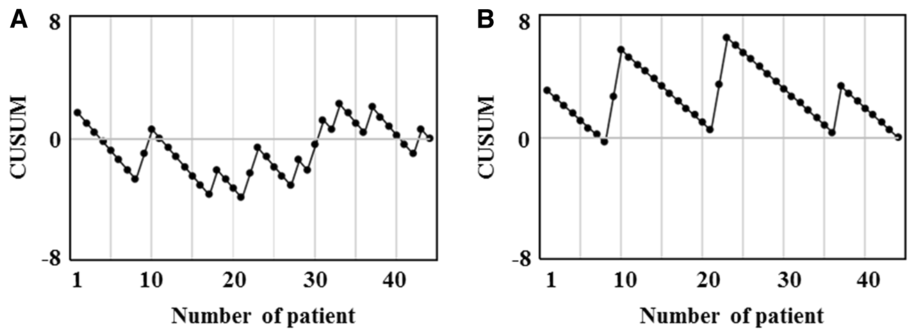

Fig. 2 Cumulative sum (CUSUM) chart for morbidity in cases performed with laparoscopic major hepatectomy is shown (**A** the CUSUM for Clavien–Dindo ≥II morbidity; **B** the CUSUM for Clavien–Dindo ≥III morbidity). These curves showed similar outcomes through Phases II and III

Table 4 Univariate and multivariate analyses of pre-operative risk factors for morbidity

	n (%)	Univariate analyses		Multivariate analyses	
		OR (95 % CI)	*P* value	OR (95 % CI)	*P* value
Phase I	64 (26.1)	1 (reference value)		1 (reference value)	
II	69 (28.2)	2.24 (0.76–7.47)	0.145	1.35 (0.38–5.18)	0.649
III	112 (45.7)	1.69 (0.61–5.43)	0.324	1.17 (0.38–4.06)	0.784
Age >70 years	79 (32.2)	2.02 (0.92–4.39)	0.075	2.22 (0.97–5.09)	0.060
Male sex	154 (62.9)	1.02 (0.47–2.33)	0.954		
BMI ≥28 kg/m^2	25 (10.2)	1.42 (0.39–4.10)	0.559		
Diagnosis HCC	122 (49.8)	1.01 (0.47–2.18)	0.981		
Tumour ≥50 mm	43 (17.6)	1.82 (0.73–4.40)	0.182	1.25 (0.41–3.50)	0.686
Multiple tumours	42 (17.2)	1.56 (0.58–3.77)	0.354		
Child–Pugh grade B	7 (2.9)	1.20 (0.06–7.38)	0.870		
ICG-R15 ≥15 %	81 (33.1)	1.01 (0.43–2.24)	0.973		
Albumin ≤3.5 g/dL	29 (11.8)	1.59 (0.50–4.27)	0.403		
Platelet ≤100 10^9/L	29 (11.8)	2.09 (0.71–5.38)	0.168	3.89 (1.20–11.84)	0.024
Major hepatectomy	44 (18.0)	3.81 (1.65–8.63)	0.002	4.08 (1.45–11.63)	0.008
Multiple hepatectomies during a surgery	25 (10.2)	2.58 (0.87–6.80)	0.084	4.25 (1.32–12.73)	0.017
Operator (junior surgeon)	48 (19.6)	0.60 (0.17–1.63)	0.337		

OR odds ratio, *CI* confidence interval, *BMI* body mass index, *HCC* hepatocellular carcinoma, *ICG-R15* indocyanine green retention 15 min

because its risks are incompletely understood. Therefore, extending the indications for LLR should be carefully considered.

Although new surgical techniques have a learning curve, the rate of postoperative morbidity should be minimized from the first introduction of LMH as an innovative procedure. Therefore, the morbidity was evaluated as the primary endpoint in this study. LMH is more complex and difficult than minor LLR, but these procedures have commonalities in terms of the parenchymal transection and the liver mobilization. Therefore, an adequate number of experiences with minor LLR will be needed before undertaking the first LMH. None of the previous studies showed when LMH should be adopted, so we evaluated the learning curve in this study in order to demonstrate the appropriate adoption time of LMH.

Several studies have reported the learning curve of LLR using CUSUM method. Nomi et al. [25] reported that 45 LMH procedures were required in order to reduce operating time. Lin et al. [26] evaluated the learning curve with respect to operating time, perioperative blood loss, and complication rate, and showed that 22 cases were needed to overcome the learning curve for minor LLR. In addition, they introduced “advanced LLR” (LLR for tumours in difficult locations and major hepatectomy) after their 60th case. In a study published by Vigano et al. [27], conversion rate was used as an indicator to analyse the learning curve; they stated that a learning period of 60 cases was required for LLR.

In our institution, only minor LLR was performed in the early phase. The 65th case of LLR was the first LMH, and it was performed because the earlier cases were considered to have provided sufficient experiences with LLR.

Subsequently, a total of 44 LMHs were performed. The surgical results were compared between the first and second halves. First, the CUSUM for morbidity showed similar outcomes, and the morbidity rate was equivalent between the two groups; we believe that this is the most important point to be considered with respect to a relatively new surgical procedure. The surgical time was slightly shorter, and the estimated blood loss was significantly less in the second half. Therefore, based on the results of past articles and of the present study, 60 minor LLR experiences in a team environment provide adequate experience before adoption of LMH as a standard procedure. There are several factors critical to the successful adoption of LMH: not only minor LLR experiences, but also basic skills of laparoscopic surgery; a correct comprehension of the liver anatomy; and experiences of major hepatectomy by open laparotomy or by the hybrid technique. The application of all of these factors is challenging; thus, the suggestion to experience 60 minor LLR before adopting LMH as a standard procedure is intended as a rough guideline.

In multivariate analyses, major hepatectomy, multiple hepatectomies during a surgery, and platelet count $\leq 100 \times 10^9$/L were significantly high-risk factors for postoperative morbidity, but the period was not. These data supported the idea that extending the indications for LMH should be performed with great care; sufficient experiences with minor LLR are needed before this step can be taken.

The main question posed by this study was thus: Is a number of 60 minor LLRs a necessary and sufficient learning curve for advancing to LMH? We demonstrated that LMH was able to be safely introduced after the experience of 60 minor LLRs. However, the answer may change according to the characteristics of each operative team, so the number of 60 should be considered as a guideline only. Further larger-scale studies will be required in order to confirm our findings.

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Compliance with ethical standards

Disclosures Dr. Yasushi Hasegawa, Dr. Hiroyuki Nitta, Dr. Takeshi Takahara, Dr. Hirokatsu Katagiri, Dr. Shigeaki Baba, Dr. Daiki Takeda, Dr. Kenji Makabe, Dr. Go Wakabayahi, and Dr. Akira Sasaki have no conflicts of interest or financial ties to disclose.

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