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Evaluation of the Learning Curve of Hand-Assisted Laparoscopic Donor Nephrectomy

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Statistical Analysis C
Data Interpretation D
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Background: In this study, we analyzed the learning curve of hand-assisted laparoscopic donor nephrectomy (HALDN).

Material/Methods: The first 198 consecutive donors (110 cases by expert surgeon and 88 cases by newbie surgeon) operated on using HALDN were included in this study. The primary outcome measures were warm ischemic time (WIT), total operation time and estimated blood loss (EBL). The secondary outcome measures included length of hospital stay (LOS), graft outcome, and surgery-related complications. We used the cumulative sum (CUSUM) method to generate learning curves.

Results: Except for WIT, all operative and convalescence parameters of donors and graft outcomes were similar for the 2 groups, including the total operation time (174.13 minutes *vs.* 171.75 minutes, *P*=0.140), EBL (108.27 cc *vs.* 116.82 cc, *P*=0.494), LOS (4.80 days *vs.* 4.92 days, *P*=0.144), and overall rates of intraoperative and postoperative complications (*P*>0.05). A significant difference was observed in WIT between the 2 groups (140.59 sec *vs.* 106.85 sec, *P*=0.027). Upon visual assessment of the CUSUM plots, a downward inflexion point for decreasing WIT was observed in 4 cases, total operation time in 12 cases, and EBL in 15 cases.

Conclusions: HALDN has a relatively short learning curve and similar results may be expected from newbie urologists who are trained in minimally invasive surgery fellowship.

MeSH Keywords: **Hand-Assisted Laparoscopy • Kidney Transplantation • Learning Curve • Warm Ischemia**

Abbreviations: **HALDN** – hand-assisted laparoscopic donor nephrectomy; **WIT** – warm ischemic time; **EBL** – estimated blood loss; **LOS** – length of hospital stay; **CUSUM** – cumulative sum; **ODN** – open donor nephrectomy; **PLDN** – pure laparoscopic donor nephrectomy; **SD** – standard deviation; **BMI** – body mass index; **Hb** – hemoglobin; **GFR** – glomerular filtration rate

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Background

Currently, renal transplantation is the most effective treatment option for end-stage renal disease. Kidneys for use in renal transplantation procedures are available from 2 sources: cadavers and living donors. Compared to the use of kidneys sourced from deceased donors, the use of live-donor kidneys allows for better outcomes [1]. However, the optimal operative procedure for the procurement of kidneys from live donors has not yet been established. The most important aspect of donor nephrectomy is donor safety and donated kidney function. Above all, the donor safety is of greatest concern in cases of living donation; therefore, the medical reward of this noble act is to minimize the donor's sacrifice [2].

In donor nephrectomy, various surgical methods have been applied, including open donor nephrectomy, laparoscopic donor nephrectomy, robot-assisted laparoscopic donor nephrectomy, and hand-assisted laparoscopic donor nephrectomy (HALDN). Historically, donor nephrectomy was performed by open techniques, but recently, minimally invasive surgery skills have been applied in donor nephrectomy [3]. Recent meta-analysis suggests that compared with open donor nephrectomy (ODN), minimally invasive donor nephrectomy (including HALDN or pure laparoscopic donor nephrectomy [PLDN]) has some advantages, including decreased postoperative pain, decreased length of hospital stay (LOS), early return to work, early postoperative recovery, and better cosmetic results [4]. Above all, many authors have reported that HALDN provided more easily retracted tissue planes, operative time comparable with that of open approach, better tactile feedback through the operator's hands, and readily controllable bleeding by manual compression [5,6]. In addition, potential advantages of HALDN include a shorter learning curve (particularly during the transition from ODN), and shorter operative time and WITs than PLDN [7–9].

Gaston et al. reported in their prospective study that HALDN has a relatively short learning curve, reflected by the rapid decrease in difficulty scores and operative times by the surgeon's 4th case [7]. However, donor nephrectomy, which requires the last cut of renal artery and renal vein, requires more skill than simple nephrectomy. But there have been few studies that have conducted analyses of the learning curve of HALDN. Therefore, we analyzed the learning curve and safety of newbie surgeon-performed HALDN in this consecutive case series.

Material and Methods

Ethics statement

The Institutional Review Board of Seoul National University Hospital approved this study (H-1605-005-757). We retrospectively evaluated data collected from 198 patients who underwent HALDN from September 2013 to April 2016 in our Department.

Study sample and design

During the considered time, the first 198 consecutive donors (110 cases involving single expert surgeon, 88 cases involving single newbie surgeon) operated on using HALS were included in this study. We retrospectively reviewed the medical records of patients who received donor nephrectomy and kidney transplantation. The primary outcome measures were warm ischemic time (WIT), total operation time, and estimated blood loss (EBL). Secondary outcome measures included the length of hospital stay (LOS), graft outcome, and surgery-related complications. Most of the reviewed patients received left HALDN; therefore, the patients who received right HALDN (3 patients operated on by newbie surgeons) were not included in this analysis.

We retrospectively reviewed the medical records of patients who received donor nephrectomy and kidney transplantation. The primary outcome measure was WIT, which was measured from the time of cross clamping until cold perfusion. [10] Secondary outcome measures included the total operation time, EBL, LOS, and surgery-related complications.

Definition of expert surgeon and newbie surgeon

Expert surgeons were defined as those having more than 10 years of experience with complex urological laparoscopy and over 100 cases of HALDN. Newbie surgeons were those who completed a training course of minimally invasive surgery fellowship and urologic-oncology fellowship during a period of 2 years. After the training period, the newbie surgeon in this study performed a minimum of 5 prior laparoscopic nephrectomies and 20 urologic laparoscopic surgeries (8 cases of laparoscopic ureter or pelvis stone removal, 4 cases of laparoscopic ureteroureterostomy, 5 cases of laparoscopic ureteroneocystostomy, and 3 cases of laparoscopic pyeloplasty), but did not have any prior human HALDN experience. The newbie received mentoring only in the initial case and not in the subsequent cases.

Surgical procedure

The procedure is described in the enclosed video file. The standard preoperative evaluation ensures that the donor has normal renal function after unilateral nephrectomy. An upper midline incision (7.5 cm) is made and we use a pneumatic sleeve (GelPort; Applied Medical, Rancho Santa Margarita, CA, USA) to permit tactile sensation for mobilization of the kidney and for better tissue control and easier removal of the kidney. Two additional ports (12 mm) were created, including 1 in the

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mid-clavicular line for the video laparoscope and a working port in the anterior axillary line. One additional 5-mm port was created under the subcostal margin to allow for traction of the kidney or other organs using a laparoscopic stick instrument.

Both newbie and experienced surgeon followed the same surgical steps. First, the descending colon was dissected and medially reflected along the white line of Toldt. After descending colon mobilization, the ureter and gonadal vein were identified and elevated off the psoas muscle together, maintaining the periureteral tissues, and then dissected toward the hilum, at which point the renal artery and vein in the renal hilum were identified. Subsequently, the adrenal and lumbar veins were dissected, divided, and ligated using 5-mm metal clips (Ethicon Endo-Surgery, Cincinnati, OH, USA) and 4–0 silk tie. Ligation and transection of the procedure were performed using vessel sealing systems (LigaSure™ or Sonicision™, Covidien, Boulder, Colorado, USA).

After the renal artery and vein were totally skeletonized from the perivascular tissues, the renal artery was transected by a safe margin after the ligation of the renal artery using multiple Endoclips (Ethicon Endo-Surgery, Cincinnati, OH, USA). The renal vein was completely ligated using the iDrive™ endovascular stapler system or 10-mm Hem-o-Lok clips (Teleflex Medical, Research Triangle Park, NC, USA) perpendicularly across the vessels. Before dividing the vascular pedicle, the ports were switched to attain better instrument angulation. The kidney was extracted by hand through the hand port and was given to the transplant surgeon.

Statistical analysis

We compared the 2 groups for operative time, WIT, total operation time, EBL, LOS, complications of donor, and recipient graft outcomes. The differences in parameters between the 2 groups were analyzed using Fisher's exact test (2-sided). All statistical analysis was conducted using with SPSS® Statistics 21.0 (IBM, Armonk, NY, USA). The *P*-value was considered statistically significant if less than 0.05.

The cumulative sum (CUSUM) technique for the assessment of the learning curve was applied to explore the relationship between operation time and sequence number of the laparoscopic procedure.[11] The CUSUM series was defined as $Sn=\Sigma(X_i-X_0)$, where X_i was an individual measurement and X_0 was a predetermined reference level that was set as the mean WIT for all of the cases overseen by the expert surgeons. However, X_0 was a predetermined reference level that was set as the mean value for all of the cases overseen by the newbie surgeon in total operation time and EBL. Sn was plotted against the sequence of operations. Cutoff values were chosen according to the points of downward inflection revealed by the plots. Statistical analysis was conducted using SAS, version 9.2 (SAS Institute, Cary, NC, USA).

Results

Patient characteristics

Baseline characteristics in the expert group and newbie group are shown in Table 1. A total of 198 HALDNs were reviewed, including 110 cases overseen by expert surgeon and 88 cases overseen by newbie surgeon. The mean ± standard deviation (SD) age of the patients was 47.58±9.41 years in the expert group and 47.63±10.67 years in the newbie group. The gender ratio (male/female) of the patients was 51 out of 59 in the expert group and 41 out of 47 in the newbie group. There were no statistically significant differences between the 2 groups with respect to patient co-morbidity (e.g., hypertension, diabetes), body mass index (BMI), history of abdominal surgery, numbers of arteries, and veins or mean preoperative hemoglobin (Hb), or glomerular filtration rate (GFR). Only the number of renal arteries had a significant difference in both groups (*P*=0.002).

Outcomes

There were no significant differences between both groups in terms of total operation time (174.13±86.68 min *vs.* 171.75±39.24 min, *P*=0.140), EBL (108.27±86.69 cc *vs.* 116.82±87.67 cc, *P*=0.494), or LOS (4.80±2.00 days *vs.* 4.92±2.00 days, *P*=0.144), as seen in Table 2. WIT was shorter in the newbie group than in the expert group (140.59±63.04 second *vs.* 106.85±45.61 second, *P*=0.027). Postoperative parameters such as postoperative Hb and postoperative GFR showed no differences between the 2 groups. Graft outcomes had no significant difference in the 2 groups (*P*=0.226). Serum creatinine level at 7 days post operation (1.06±0.36 *vs.* 1.16±0.66, *P*=0.335) and total Lasix® (furosemide; Sanofi, Paris, France) usage (62.28±71.17 mg *vs.* 59.43±74.59 mg, *P*=0.743) showed no significant difference in either the expert or newbie groups. Intraoperative and postoperative complications are shown in Table 3. There were no significant differences in intraoperative complications (2 *vs.* 0, *P*=0.307) or postoperative complications. However, the most common complication seen was chylous leakage (6.1%). There were no complications that needed intervention under general anesthesia or admission to the intensive care unit.

Learning curve

Figure 1 shows a CUSUM chart of WIT against number of HALDN procedures performed. Commonly, CUSUM analysis is performed based on the mean value of the tester. However,

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Table 1. Baseline characteristics of donor.

	Expert (N, 110)	Newbie (N, 88)	P value
Mean age (years)	47.58±9.41	47.63±10.67	0.106
Gender (male,%)	51 (46.4%)	41 (46.6%)	0.544
BMI (kg/m^2)	23.84±2.90	24.09±2.80	0.653
HTN	6 (5.5%)	4 (4.5%)	0.519
DM	0 (0)	0 (0)	–
Hx of Abd surgery	19 (17.3%)	10 (11.4%)	0.167
Arteries, n (%)			0.002
1	90 (81.8%)	54 (61.4%)	
2	16 (14.5%)	20 (22.7%)	
3	4 (3.6%)	14 (15.9%)	
Veins, n (%)			0.086
1	110 (100%)	85 (96.6%)	
2	0 (0%)	3 (3.4%)	
Mean PreOP Hb (g/dL)	13.66±1.66	13.72±1.63	0.899
Mean PreOP GFR (mg/dL)	92.77±21.00	96.57±23.45	0.368

Table 2. Operative and convalescence parameters of donors and graft outcomes.

	Expert (N, 110)	Newbie (N, 88)	p-Value
Warm ischemia time (sec)	140.59±63.04	106.85±45.61	0.027
Total OP time (min)	174.13±86.68	171.75±39.24	0.140
EBL (cc)	108.27±86.69	116.82±87.67	0.494
Hospital day	4.80±2.00	4.92±2.00	0.144
Post OP Hb (g/dL)	12.58±1.56	12.67±1.57	0.390
Post OP GFR(mg/dL)	67.08±15.93	68.67±15.91	0.318
Recipient outcome graft function (%)			0.266
Excellent	105 (95.5%)	84 (96.6%)	
Slow	5 (4.5%)	3 (3.4%)	
Delayed	0 (0%)	0	
Recipient POD#7 Cr	1.06±0.36	1.16±0.66	0.335
Intra OP lasix dosage (mg)	45.91±27.81	40.00±22.75	0.215
Post op lasix dosage (mg)	16.82±60.84	19.43±70.71	0.527
Total lasix dosage (mg)	62.28±71.17	59.43±74.59	0.743
Recipient GFR at POD#30 (mg/dL)	65.36±33.43	76.14±30.02	0.186

because the mean value of the newbie group was too good, we adjusted the CUSUM model to until the newbies achieve similar results to those of the experts. The resulting CUSUM curve showed an increasing slope from the 1st to the 4th case in WIT. After that point, the curve flattened, which meant that an acceptable level of performance was achieved. The curve

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Table 3. Intra- and postoperative complications.

Complication	Expert (N, 110)		Newbie (N, 88)		P value
IntraOP Cx, n (%)	2	(1.8%)	0	(0%)	0.307
Accidental hemorrhage	2	(1.8%)	0	(0%)	
Adrenal gland injury	0		0		
Intra-adrenal hematoma	0		0		
Intra OP transfusion	0		0		
Postoperative complications, n (%)	13	(11.8%)	13	(14.8%)	0.430
Gr I					
UTI	1	(0.9%)	0	(0%)	
Atelectasis	1	(0.9%)	2	(2.3%)	
Others	1	(0.9%)	0	(0%)	
Post op fever	2	(1.8%)	0	(0%)	
Gr II					
Chylous leakage	5	(4.5%)	7	(8%)	
Post OP transfusion	0	(0%)	0	(0%)	
Post OP ileus	4	(3.6%)	2	(2.3%)	
Gr IIIa					
Wound dehiscence needing revision	0	(0%)	1	(0.5%)	

continuously declined after 4th case, where a plateau of performance had been reached. In addition, the resulting CUSUM curve showed an increasing slope from the 1st–6th case in total operation time. After that point, the curve continuously declined after the 13th case, which meant that an acceptable level of performance was achieved. Otherwise, the CUSUM curve showed an increasing slope from the 1st–8th case in EBL. After that point, the curve continuously declined after the 15th case, which meant that an acceptable level of performance was achieved. On the other hand, the 1st–27th CUSUM curves showed fluctuation in EBL. In particular, the 21st–27th had a strong tendency to increase, and the 8th–21st and 27th–46th had a strong tendency to decrease.

Discussion

Minimally invasive surgery for donor nephrectomy has evolved as a viable alternative to ODN. Open procedure may result in a prolonged recovery and a high rate of postoperative complications, including wound-related morbidity [12,13]. A recent meta-analysis presented that laparoscopic donor nephrectomy (LDN) has been associated with fewer complications, shorter LOS, and faster return to work than those with ODN [14,15]. Our center also reported in a previous comparison study that LDN may have the ability to provide grafts of similar quality to ODN [16]. Among these, HALDN is one of the most frequently performed procedures in living donor nephrectomy. HALDN was originally described in 2001 and has similar advantages as PLDN does over open donor nephrectomy with regards to postoperative recovery [9,17]. HALDN is a relatively new and effective technique designed to make kidney donation more attractive and minimally invasive, without affecting recipient outcomes. It allows for kidneys to be harvested with shorter operating and warm ischemic times [18]. Actually, approximately 66% of trans-peritoneal LDN procedures in the United Kingdom are currently performed with hand-assistance [8].

HALDN has many potential advantages over PLDN. First, there are many reports that HALDN is easier to perform and has a shorter operating time than PLDN. Kokkinos et al. presented in their systematic review that PLDN results in longer operative (30 minutes) and WIT (75 seconds) than HALDN does [19]. The authors also reported that HALDN offered substantial advantages in terms of decreased intraoperative bleeding in comparison with PNDN. An explanation for the advantages of HALDN could be the spatial orientation the surgeon gains with the hand-assisted method, as well as the better bleeding control that can be achieved by direct digital manipulation [9,19].

Second, HALDN is a relatively safer procedure than the other procedures. With the presence of hands in the abdominal

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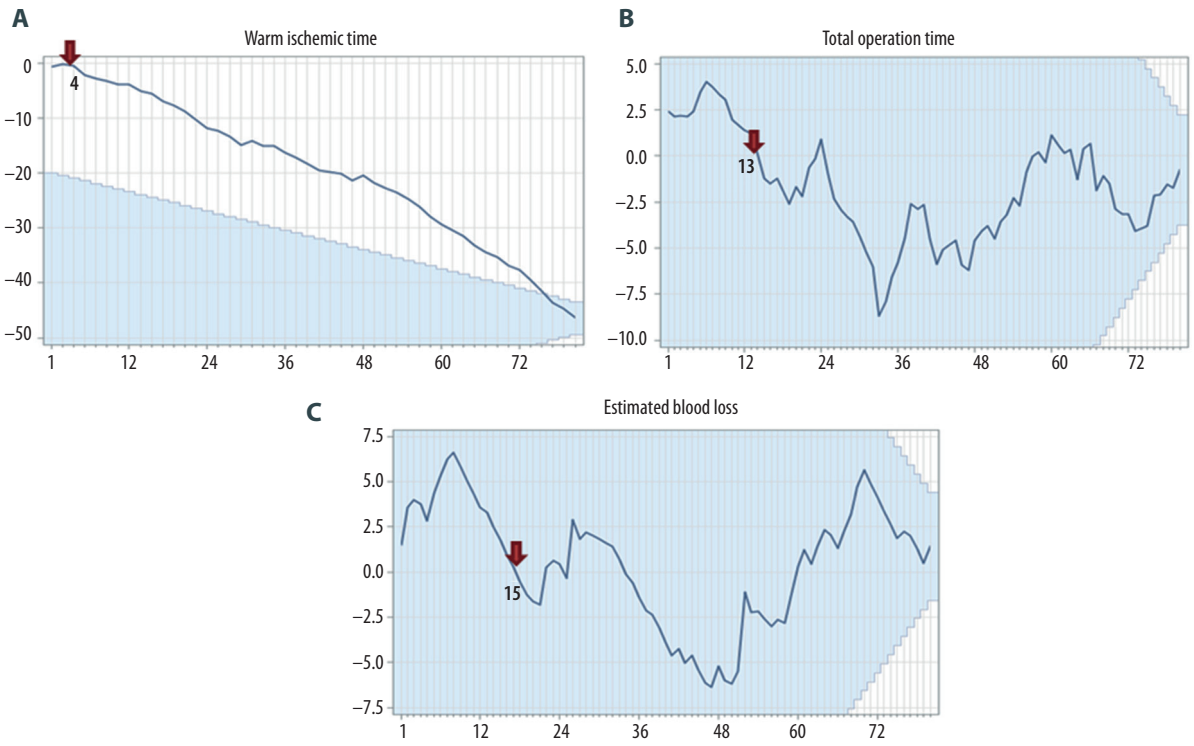

Figure 1. (**A**) Cumulative sum (CUSUM) analysis for warm ischemic time in hand-assisted laparoscopic donor nephrectomy (HALDN). (**B**) CUSUM analysis for total operation time in HALDN. (**C**) CUSUM analysis for estimated blood loss in HALDN.

cavity, tactile feedback is provided to allow manual operation of the tissue for the dissection and mobilization of the kidneys. [20]. HALDN is well-suited for controlling venous and minor arterial bleeding, which can often be controlled by digital pressure or the application of a hemostatic material. The risk of major vascular injury has also been a dire concern, with inadvertent division of the aorta or vena cava performed during presumed renal pedicle division. The use of HALDN helps to alleviate this issue.

Third, the potential advantage of HALDN is that it is easy to learn [8]. Gaston et al. demonstrated that HALDN has a relatively short learning curve, as reflected by the rapid decrease in difficulty scores and operative times by the surgeon's fourth case [7]. This previous report does not include donor nephrectomy; however, because the steps involved in HALDN are similar to those in "pure" transperitoneal LDN, HALDN is also expected to show a short learning curve.

Learning-curve issues are the most likely cause of the morbidity and mortality initially associated with the procedure. However, there are various conflicting reports on learning issues. The United Network for Organ Sharing recommends that surgeons should have operated or assisted with 15 LDNs to be considered experienced enough. However, recent meta-analysis showed that the preferred learning curve for LDN is 35 cases [21]. There is a considerable range among the studies as to how many cases are necessary to become proficient in LDN. Saad et al. considered 10 cases to provide an appropriate learning curve, whereas Horgan et al. considered the learning curve to be >100 cases [22,23].

In this study, the newbie surgeon trained under a minimally invasive surgery fellowship for 2 years. Additionally, he had no experience of HALDN from start to finish prior to this study. Nonetheless, the newbie surgeon showed a short learning curve and excellent surgical results. In this study, we tried to use CUSUM analysis to analyze the learning curve. We tried to calculate the learning curve by finding the part where the grades were getting better after the gradual plateau formation from the beginning. However, the newbie did not show a typical learning curve in this HALDN. Thus, we performed CUSUM analysis based on the mean value of the expert group. The CUSUM curve showed an increasing slope from the 1st to the 4th case in WIT. After that point, the curve flattened. In addition, in total operation time, the acceptable level of performance was met in the 13th case. On the other hand, in EBL, the acceptable level of performance was met in the 15th case. Hence, we assumed that hand-assisted laparoscopic nephrectomy has a relatively shorter learning curve, reflected by the

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rapid decrease in score difficulty and operative times, as seen in the 4th–15th cases.

Most studies have used total operating time to compare learning curves of surgery. However, in practice, total operating time is longer than the actual operation time because the operation progresses according to the preparation of the recipient. In actually, the recipient is not always ready for surgery, so we often wait for an hour *vs.* 10 minutes. Therefore, the total operating time cannot be accurately represented unless it is measured prospectively. Nevertheless, total operative time was not measured as long when compared with other studies.

It was surprising that the newbie group WIT results were better than that of the expert group in this study. However, the expert group WIT results are never worse than other studies. Recently, Choi et al. presented in their matched-cohort comparison study that mean WIT was 141 seconds [24]. Similarly, a recent meta-analysis demonstrated that mean WIT of HALDN was 150 to 170 seconds [25]. The expert group WIT in this study was not as long or was even better than these studies. Although the typical newbie surgeon would have begun the surgery for the first time, it should be considered that the learning curve was short because the newbie surgeon had already been faithfully trained in minimally invasive surgery. In addition, HALDN is relatively easier to learn because it does not require as much skill in laparoscopic surgery as other procedures. Therefore, we think that the newbie surgeon demonstrated good results for these reasons. A recent meta-analysis presented that hand-assisted procedures may improve safety for surgeons or in centers with less experience in LDN [25]. The results of our institution are also in line with this previous study. There was no severe intra-operative or postoperative bleeding in either group. In addition, the rate of serious postoperative complications requiring long-term hospitalization or reoperation was very small. Therefore, this result shows that HALDN can be safely performed by a well-trained newbie surgeon.

However, a distinctive feature of our analysis is the relatively higher rate of chylous leakage. In the current literature, chylous leakage after living LDN reportedly ranges from 0% to 1.8% [26]. In our study; however, 6.1% of donors suffered chylous leakage, which even extended the hospital stay for some patients. Most of the affected patients were treated with conservative treatment, including the use of somatostatin [27]. Postoperative chylous leakage may actually occur more frequently given that during laparoscopy, the lymphatics are not routinely ligated or clipped, despite being burned with energy-based sealing devices [28,29]. However, due to the reporting of a higher rate of chylous leakage, our institution plans to conduct a further analysis related to this.

We should point out that our study had some limitations. Our study was a retrospective analysis involving 2 small sample groups at a single center. In addition, we could not subdivide the operation time. If the operation time could be subdivided according to the steps of each procedure, it could be a more accurate and useful analysis. Second, the newbie surgeon's outcomes were so excellent that we could not set a realistic learning curve. Furthermore, we performed CUSUM analysis that was based on the average outcomes of the expert surgeon, not those of the newbie surgeon. Therefore, this study analyzed the case of experience, which is needed to reach the average level of expert group results. In addition, the short follow-up period of the donors in our study was also limitation. Most of donors visited the urology department only once or twice after their discharge. Hence, we could not conduct a long-term analysis of renal function changes. Finally, we used Endoclips for the management of renal vessels. However, the American Society of Transplantation recommended that, as the stump of the renal artery tends to be shorter with laparoscopic living donor nephrectomy, vascular transfixion is the safest method to achieve vascular control of the renal artery [30]. However, the specific procedure may be slightly different because the licenses are different for each country and the preference varies according to the vascular surgeon. We experienced 2 cases that had risk of bleeding after kidney extraction; however, there was a particular problem after oversewing. Even if using Endoclips, we can safely use and add the over-sewing suture if necessary, as a bleeding risk can occur after nephrectomy [31].

Conclusions

Our findings suggest that HALDN has a relatively short learning curve, and a well-trained newbie surgeon may have the ability to complete grafts of a quality similar to those of an expert surgeon. HALDN is a good procedure for newbie surgeon to ensure the quality of donor safety and renal function. Similar results may be expected when newbie urologists, who are trained in a minimally invasive surgery fellowship, perform HALDN.

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