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Pure laparoscopic donor nephrectomy without routine drainage does not increase postoperative morbidity

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Purpose: We aimed to define the feasibility of the omission of routine insertion of a drain after pure laparoscopic donor nephrectomy (PLDN). We compared the outcomes between those with and without routine drain insertion.

Materials and Methods: From July 2014 to October 2018, 178 PLDN were consecutively performed by a single surgeon. Since October 2016, we stopped routine insertion of a drain after PLDN. Thus, the former 80 drained routinely were defined as the Drainage group and the latter 98 were defined as the Non-drainage group. One patient drained non-routinely in the Non-drainage group was excluded from the final analysis. Operative and convalescence parameters and intra- and postoperative complications were compared between the groups. Intra- and postoperative complications within 90 days of surgery were graded using the Satava and Clavien–Dindo classifications, respectively.

Results: Baseline characteristics were similar between the groups, except for concomitant surgery, American Society of Anesthesiologists score, and preoperative glomerular filtration rate. All operative and convalescence parameters were similar between the groups, except for postoperative glomerular filtration rate. The rates of overall intra- (22.5% versus 28.9%, p=0.337) and postoperative (62.5% versus 59.8%, p=0.713) complications were similar between the groups. The rates of potentially drain-related postoperative complications were also similar between the groups (36.3% versus 33.0%, p=0.650). Two patients per group suffered from major drain-related complications (2.5% versus 2.1%).

Conclusions: PLDN without routine drainage can be performed safely without an increase in postoperative morbidity.

Keywords: Drainage; Intraoperative complications; Laparoscopy; Living donors; Postoperative complications

INTRODUCTION

Since the late 19th century, routine insertion of a drain into an operative site has been considered to be a standard procedure in spite of the scarcity of evidence for its value [1]. They may be placed to prevent expected fluid build-up (e.g., after extended lymph node dissection or a contaminated surgical site) or to detect early complications (e.g., postoperative bleeding, urine leakage). However, since the late 20th century, several trials have identified possible drawbacks

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of routine insertion of a drain [2]. Possible problems related to drains include infection around the insertion site, pain, a prolonged hospital stay, and even severe incidents, such as a retained drain fragment and visceral perforation [3]. With the development of laparoscopic/robotic surgery and advances in surgical techniques, routine insertion of a drain after surgery has become increasingly questioned [4-7].

Pure laparoscopic living donor nephrectomy (PLDN) was first reported in 1995 at Johns Hopkins Hospital by Ratner et al. [8]. There is a consensus that routine insertion of a drain is not usually needed after PLDN [9,10]. In practice, even experienced surgeons may still insert routine drains after PLDN [11,12]. Because donor nephrectomy requires longer and delicate detachment of renal vessels and the ureter compared with radical or simple nephrectomy, the incidence of chylous leakage after PLDN has been reported to be up to 3.8% [13].

In addition, the Swiss Registry shows more major complications after PLDN compared with open donor nephrectomy [14]. The Norway Registry also shows an increased risk for a combined endpoint of intraoperative incidents, major complications and significant bleeding after PLDN with an odds ratio of 2.63 [15]. Therefore, routine insertion of a drain may be justified to detect early complications after PLDN such as chylous leakage or bleeding. To our knowledge, however, only limited information is available on routine insertion of drains after PLDN.

In the present study, we sought to determine the feasibility to the omission of routine insertion of a drain after PLDN, comparing the outcomes between those with and without the insertion of a routine drain.

MATERIALS AND METHODS

1. Baseline characteristics

The study protocol was approved by the Institutional Review Board of the Asan Medical Center (approval number: 2020-1187), and it conformed to the tenets of the Declaration of Helsinki. The Institutional Review Board of the Asan Medical Center waived the requirement for informed consent due to the retrospective design of the study. A prospectively maintained database of 178 donor nephrectomies consecutively performed by a single surgeon (DY) from July 2014 to October 2018, was reviewed. The surgeon had performed 30 hand-assisted and 30 PLDN during the approximately 2 years before the study period [16]. Since October 2016, we decided to omit routine drainage after surgery. The former 80 donor nephrectomies drained routinely were defined as the Drainage group and the latter 98 were defined as the Non-drainage group. One patient in the Non-drainage group suffered from massive bleeding due to an endoscopic stapler malfunction and had a drain placed as a consequence. This patient was excluded from the final analysis.

Before surgery, the renal vascular anatomy and relative renal function of both kidneys were examined by computed tomography angiography and diethylene triamine penta-acetic acid or dimercaptosuccinic acid scintigraphy. The kidney to be extracted was determined on the basis of its relative renal function and the number of arteries. If the difference in relative renal function was ≤5%, and both kidneys had a single artery, the left kidney was preferred. Baseline data included the patient's age, sex, relationship to the recipient, body mass index, medical and surgical history, American Society of Anesthesiologists (ASA) score, laterality, relative function, number of arteries and veins, hemoglobin concentration, and glomerular filtration rate (GFR). GFR was estimated from the serum creatinine concentration with a variation of the original Modification of Diet in Renal Disease [17].

2. Surgical techniques

PLDN was performed as described previously with some technical modifications over time [16]. For right (left)-sided allografts, the patients were placed in a 45° oblique position with their left (right) side down while under general anesthesia. A 6 cm omega-shaped incision was made around the umbilicus for insertion of a SurgiTractor (SurgiCore Co., Ltd., Ansan, Korea). A SurgiTractor was used to establish pneumoperitoneum and for camera placement. A second 12 mm trocar was placed below the right (left) costal margin in the right (left) midclavicular line and a third 12 mm trocar was placed below the level of the umbilicus in the right (left) anterior axillary line. Finally, a 5 mm trocar was placed approximately 2 cm from the tip of the right (left) 12th rib for retraction. Since January 2015, the 5 mm trocar was omitted in left-sided allografts. It was moved from the tip of the right 12th rib to the xiphoid process in right-sided allografts.

After the white line of Toldt was incised and the colon was reflected medially, Gerota's fascia was entered near the renal hilum. The renal artery and vein were completely freed of lymphatic and other perivascular tissue, avoiding any injuries to the vessels. The gonadal, lumbar, and adrenal branches were tied and divided from the renal vein. The ureter was dissected caudally to the level of the internal iliac vessels, leaving sufficient margins to ensure an adequate blood supply around it. Forty milligrams mannitol and 5,000 IU heparin were administered intravenously. An extra-large Hem-o-Lok clip (Teleflex Medical, Research Triangle Park,

NC, USA) was applied at the caudal end of the dissected ureter, and the ureter was divided cephalad to the clip without electrocautery. The renal artery was clamped with 1 (for left-sided) or 2 (for right-sided) extra-large Hem-o-Lok clips and 2 titanium clips (AutoSuture Endo Clip L; Covidien Surgical, Norwalk, CT, USA). An Endopath ETSFlex articulating endoscopic linear stapler (Ethicon EndoSurgery, Inc., Cincinnati, OH, USA) was applied to transect the renal vein. The kidney was removed through the umbilical incision in a Lap bag (Sejong Medical, Seoul, Korea), placed immediately in sterile ice slush, and delivered to the recipient team for grafting.

Fifty milligrams protamine sulfate was administered intravenously. After the abdomen was carefully inspected at a reduced intraperitoneal pressure, any bleeding was controlled, and a Jackson-Pratt drain was inserted. As mentioned above, routine drainage after surgery was omitted since October 2016. The SurgiTractor and trocars were removed and the pneumoperitoneum was evacuated with manual compression of the abdominal wall. In the Non-drainage group, active aspiration using a laparoscopic suction irrigation device was combined with the manual compression. The wounds were closed in the usual method.

3. Outcome measurements

The operative parameters (total operation time, warm ischemia time, estimated blood loss) and the convalescence parameters (postoperative pain, interval to return to a regular diet, hospital stay, postoperative hemoglobin, postoperative GFR) were assessed in the study group. Total operation time was defined as the time between skin incision for placement of the first trocar and skin closure of the trocar wounds. Warm ischemia time was defined as the time from renal artery occlusion to immersion of the kidney in the ice slush. Blood loss was estimated by the hemoglobin dilution method [18]. Postoperative pain was assessed with a patient-reported visual analog scale (VAS) three times a day from immediately after surgery to discharge.

Intraoperative complications were analyzed according to the Satava classification [19]. Grade I indicates an error without consequence, which may not be significant enough to result in a complication. Grade II is defined as an error that has the possibility of being resolved with minimal or no consequence via immediate identification and correction. Grade III indicates an error with a consequence for which there is a clear culpability of the surgeon. Not only is an error committed, but it is also unrecognized and, therefore, recovery is impossible.

All complications within 90 days of surgery were graded according to the Clavien–Dindo classification [20]. Grade I indicates any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic or radiological intervention. Grade II is defined as a complication requiring pharmacological treatment with drugs other than those allowed for grade I complications. Grade III indicates a complication requiring surgical, endoscopic or radiological intervention. Grade IV indicates a life-threatening complication requiring intermediate care or intensive care unit management. Grade V indicates the death of a patient.

4. Statistical analysis

Continuous variables were analyzed with Student's t-test, and categorical variables were analyzed with Pearson's chi-square test or Fisher's exact test. Quantitative data are expressed as the mean±standard deviation. All statistical tests were 2-tailed, with significance set at $p<0.05$. All statistical analyses were performed with SPSS Statistics, version 25 (IBM Corporation, Armonk, NY, USA).

RESULTS

Table 1 shows the baseline characteristics of the 177 donors included in the final analysis. There were no significant differences between the Drainage and Non-drainage groups, except for concomitant surgery, ASA score, and preoperative GFR. Concomitant surgery and ASA score II were more frequently assigned in the Non-drainage group, and their preoperative GFR was significantly lower. The operative and convalescence parameters of the donors are outlined in Table 2. All procedures were completed as planned without conversion to another technique. There were no significant between-group differences in total operation time, warm ischemia time, estimated blood loss, VAS pain scores, interval to return to a regular diet, hospital stay, or postoperative hemoglobin. Mean time to removal of the drain was 3.4 days in the Drainage group. Mean total amount of drainage was 437.1 mL in the Drainage group. Mean postoperative GFR was significantly lower in the Non-drainage group (65.8±14.5 mL/min/1.73 m^2 vs. 60.7±13.1 mL/min/1.73 m^2, $p=0.015$).

Intra- and postoperative complications are outlined in Tables 3 and 4, respectively. The rates of overall intraoperative complications were similar in both groups ($p=0.337$). Eighteen patients (22.5%) in the Drainage group experienced a total of 19 intraoperative errors, and 28 (28.9%) in the Non-drainage group experienced a total of 32 intraoperative errors. The most common intraoperative complication was related to the adrenal gland (two intra-adrenal hematomas

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Table 1. Baseline characteristics of donors

Characteristic	Drainage (n=80)	Non-drainage (n=97)	p-value
Age (y)	44.2±11.3	47.0±11.9	0.113
Sex, male/female	33/47	40/57	0.999
Relationship to recipient			0.202
Related	44 (55.0)	53 (54.6)	
Spouse/partner	26 (32.5)	39 (40.2)	
Distantly related	5 (6.3)	1 (1.0)	
Unrelated	5 (6.3)	4 (4.1)	
Body mass index (kg/m^2)	24.2±3.2	24.3±3.2	0.746
Diabetes mellitus	0 (0.0)	5 (5.2)	0.065
Hypertension	3 (3.8)	11 (11.3)	0.092
History of abdominal surgery	18 (22.5)	25 (25.8)	0.613
Concomitant surgery	0 (0.0)	8 (8.2)	0.009
ASA score			0.002
I	68 (85.0)	62 (63.9)	
II	12 (15.0)	35 (36.1)	
Laterality, right/left	34/46	50/47	0.230
Number of artery			0.768
1	64 (80.0)	77 (79.4)	
2	13 (16.3)	19 (19.6)	
3	3 (3.8)	1 (1.0)	
Number of vein			0.823
1	65 (81.3)	73 (75.3)	
2	11 (13.8)	22 (22.7)	
3	3 (3.8)	2 (2.0)	
4	1 (1.3)	0 (0.0)	
Preoperative hemoglobin (g/dL)	13.8±1.6	13.5±1.5	0.239
Preoperative GFR (mL/min/1.73 m^2)	106.6±12.8	101.4±14.1	0.012

Values are presented as mean±standard deviation, number only, or number (%).
ASA, American Society of Anesthesiologists; GFR, glomerular filtration rate.

Table 2. Operative and convalescence parameters of donors

Parameter	Drainage (n=80)	Non-drainge (n=97)	p-value
Total operation time (min)	173.8±25.7	165.9±32.6	0.078
Warm ischemia time (s)	284.9±108.7	285.6±88.8	0.960
Estimated blood loss (mL)	478.6±273.5	546.1±255.8	0.092
Maximum VAS at postoperative day 0	6.0±1.6	5.5±1.9	0.097
Maximum VAS at postoperative day 1	4.2±1.8	4.2±1.8	0.810
Maximum VAS at discharge	1.5±0.8	1.5±1.2	0.685
Interval to removal of drain (d)	3.4±0.9	NA	NA
Total amount of drainage (mL)	437.1±318.6	NA	NA
Interval to return of a regular diet (d)	2.8±1.3	3.0±1.3	0.222
Hospital stay (d)	5.4±1.2	5.2±1.3	0.454
Postoperative hemoglobin (g/dL)	11.4±1.6	11.1±1.5	0.302
Postoperative GFR (mL/min/1.73 m^2)	65.8±14.5	60.7±13.1	0.015

Values are presented as mean±standard deviation.
VAS, visual analogue scale; GFR, glomerular filtration rate; NA, not applicable.

and 11 adrenal gland injuries, including eight that required repair). A total of 18 patients experienced 20 major intraoperative complications, defined as grade II or higher.

The rates of overall postoperative complications were similar in both groups (p=0.713). Fifty patients (62.5%) in the Drainage group experienced a total of 64 postoperative complications, and 58 (59.8%) in the Non-drainage group experienced a total of 70 postoperative complications. Nausea/

Table 3. Intraoperative complications

Complication		Drainage (n=80)	Non-drainge (n=97)	p-value
Number of intraoperative complication		18 (22.5)	28 (28.9)	0.337
Grade I	Liver (capsular or parenchymal) injury	2	8	
	Spleen (capsular or parenchymal) injury	2	2	
	Adrenal gland injury	1	2	
	Bowel injury	1	2	
	Arterial injury	1	1	
	Intra-adrenal hematoma	0	2	
	(Port site) muscle bleeding	1	1	
	Subcutaneous emphysema	1	0	
	Venous or its branch injury	1	0	
	Dislocation of clip from vessels	0	1	
	Gallbladder injury	0	1	
	Mesentery injury	0	1	
Grade II	Adrenal gland injury needing repair	4	4	
	Venous or its branch injury needing repair	1	5	
	Bowel injury needing repair	1	1	
	Bleeding from remnant ureter needing cystoscopy	1	0	
	Mesentery injury needing repair	1	0	
	Omentum bleeding needing suture	1	0	
	(Port site) muscle bleeding needing suture	0	1	

Values are presented as number (%) or number only.

Table 4. Postoperative complications

Complication		Drainage (n=80)	Non-drainge (n=97)	p-value
Number of postoperative complication		50 (62.5)	58 (59.8)	0.713
Grade I	Nausea/vomiting[a]	12	13	
	Ileus needing enema or diet delaying[a]	11	14	
	Aspartate aminotransferase/alanine aminotransferase elevation	11	9	
	Bilirubinemia	6	8	
	Dizziness or vertigo	6	3	
	Urinary retention	6	2	
	Atelectasis[a]	2	5	
	Neck/shoulder/back pain[a]	2	3	
	Headache	0	3	
	Rhino-pharyngo-laryngitis	1	2	
	Extremity musculoskeletal pain or numbness	0	2	
	Urticaria or contact dermatitis	1	1	
	Atypical chest pain (negative cardiac workup)	1	0	
	Diarrhea	1	0	
	Vaginal bleeding	1	0	
	Arrhythmia	0	1	
	Ecchymosis	0	1	
	Epigastric discomfort	0	1	
Grade II	Chylous ascites[a]	1	0	
	Jackson-Pratt drain site oozing needing skin stapling[a]	1	0	
	Pseudomembranous colitis	1	0	
	Aspiration pneumonia[a]	0	1	
Grade IIIa	Chylothorax needing thoracentesis[a]	0	1	

Values are presented as number (%) or number only.
[a]:Potentially drain related-complications.

vomiting and ileus were commonly reported in both groups. A total of five patients experienced five major postoperative complications, defined as grade II or higher.

The rates of potentially drain-related postoperative complications were also similar between the groups (p=0.650). Twenty-nine patients (36.3%) in the Drainage group experi-

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enced a total of 29 postoperative complications, including two major complications related to the drain. Thirty-two patients (33.0%) in the Non-drainage group experienced a total of 37 postoperative complications that were potentially related to the lack of a drain, including two major complications.

DISCUSSION

Routine insertion of a drain into the operative site has always been a controversial issue in surgery, along with the use of prophylactic antibiotics. Surgeons may be divided into those who always drain after surgery, fence-sitters who use drainage in selected patients, and skeptics who never use it [1]. The results of several randomized controlled trials have led to recommendations that routine insertion of a drain should be omitted after many types of gastrointestinal surgeries, such as hepatic, colonic, or rectal resection with primary anastomosis and appendectomy [2]. Some studies have evaluated the feasibility of not inserting a drain or to inserting one only selectively after various urologic surgeries for decades [21,22]. The development of laparoscopic/robotic surgery and the advancement of surgical techniques have raised increasing questions about the routine insertion of drains after surgery [4-7].

The first successful kidney transplantation between living patients was performed in 1954 in the United States [23]. Thereafter, living kidney donation has successfully improved the lives of many patients worldwide for over half a century. In 2018, 36% of 95,479 kidney transplants worldwide were from live donors, according to the Global Observatory on Donation and Transplantation [24]. The first PLDN was reported by Ratner et al. [8] in 1995, resulting in a small incision and easier recovery for the donor. Approximately 35% of kidneys from living donors in the United States in 2017 were harvested by a pure laparoscopic technique [25]. Despite some statements about the needless routine insertions of drain after PLDN [9,10], even experienced surgeons habitually put in a routine drain after PLDN due to a lack of verified evidence [11,12]. Because PLDN has been reported to be prone to chylous leakage and major complications including significant bleeding compared with open surgery [13-15], the benefits and risks of drain insertion after PLDN have been questioned. Therefore, we examined a prospectively maintained database of PLDN consecutively performed by a single surgeon to determine the feasibility of omitting the insertion of a drain.

Both groups had similar operative and convalescence outcomes, except for postoperative GFR. The lower postoperative GFR in the Non-drainage group may be simply due to chance rather than any effect of the drain. It might, at least in part, be attributable to the lower preoperative GFR in the Non-drainage group.

The rates of overall intra- and postoperative complications were similar in the groups. The intraoperative complication rate in the present study was higher than that previously reported in patients undergoing PLDN (26.0% in the present study versus 2.8%–25% in previous reports) [26]. The postoperative complication rate was also higher than reported previously (61.0% in the present study versus 0%–43% in previous reports) [6]. The higher complication rates may be due to prospective recording by systematic classification methods, including minor complications that may have been underreported in previous reports [16]. Indeed, the rates of grade II or higher intra- and postoperative complications were only 10.2% and 2.8%, respectively.

The most important findings of the present study include a lack of significant differences in potentially drain-related postoperative complications between the groups. Because most complications are likely unrelated to the drain itself, analyzing overall complications could obscure the true impact of drain insertion or omission. To solve this problem, we performed sub-analysis examining complications that could potentially be drain-related.

Postoperative pain and abdominal distension might, at least in part, be attributable to the amount of residual pneumoperitoneum after laparoscopic surgery [27,28]. The carbon dioxide used to maintain pneumoperitoneum during laparoscopic surgery can induce irritation of the phrenic nerve, which is felt as neck, shoulder, or back pain. The carbon dioxide trapped inside the peritoneal cavity can induce intraperitoneal gas pain, which interferes with deep breathing and aggravates atelectasis. This can induce some degree of abdominal distension, which aggravates nausea/vomiting and ileus. Thus, the evacuation of any residual carbon dioxide through drain insertion is expected to reduce these particular complications [29]. In the present study, similar drain-related complications might be attributable to the application of an active aspiration technique combined with manual compression of the abdominal wall at the end of the surgery in the Non-drainage group.

Two patients in each group suffered from major potentially drain-related complications. One patient in the Drainage group had prolonged chylous leakage from a drain, requiring long-term drainage (7 days) and a low-fat diet. Another patient required skin stapling for Jackson-Pratt drain site oozing. One patient in the Non-drainage group suffered from aspiration pneumonia due to vomiting in the recovery room, requiring long-term intravenous antibiotics (7 days)

and nil per os (2 days). Another patient required thoracentesis for chylothorax diagnosed belatedly after discharge. These major complications were considered to be caused by drain insertion or omission.

Based on the results of the present study, we failed to demonstrate a clear and significant advantage to either drain insertion or omission after PLDN. However, we found that most of the drain-related complications could be reduced through the application of an active aspiration technique at the end of the surgery, and the major complications were too rare to justify routine insertion of a drain.

The main limitation of the present study is its retrospective nonrandomized design, resulting in unavoidable bias. Surgeries in the Non-drainage group were also performed in a more experienced condition, which could have induced learning curve biases. Therefore, the 30 PLDN performed before the study period by this surgeon were excluded from the analysis [16]. Other limitations include the small sample size and uniformly negative results. An absence of a significant difference does not prove equivalence, but it might be caused by an underpowered study. Nevertheless, the present study has the advantage of including a prospectively maintained homogeneous cohort in which all surgeries were consecutively performed by a single surgeon.

CONCLUSIONS

The present study failed to demonstrate a clear advantage to either drain insertion or omission in terms of operative/convalescence parameters and intra-/postoperative complications after PLDN. Based on the results of the present study not showing any clear disadvantage of drain omission, we have eliminated routine drainage in patients undergoing PLDN.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Dong Hyeon An and Dalsan You. Data acquisition: Joomin Aum and Yu Seon Kim. Statistical analysis: Myoung Jin Jang. Data analysis and interpretation: Dalsan You. Drafting of the manuscript: Dong Hyeon An. Critical revision of the manuscript: Dalsan You. Obtaining funding: Dalsan You. Administrative, technical, or material support: Jae Hyeon Han. Supervision: Jae Hyeon Han. Approval of the final manuscript: Dalsan You.

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