

A retrospective analysis of complications of laparoscopic left donor nephrectomy using the Kocak's modification of Clavien-Dindo system

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ABSTRACT

Introduction: Kocak described a modification of Clavien-Dindo classification system (CDCS) for reporting procedure-related complications in laparoscopic donor nephrectomy (LDN). We used the Kocak modification in grading and reporting the severity of complications in patients who underwent LDN and in evaluating various parameters that predict them.

Methods: In all, 1430 patients who underwent left LDN from 2000 to 2016 were included in this study. All data was retrospectively collected and analyzed for complications occurring in the postoperative period. All complications were classified according to the four grades of Kocak-modified CDCS.

Results: 124 patients (8.6%) suffered a total of 235 postoperative complications. Most of the complications were Grade I and Grade II (Grade I: 79.5% [$n = 187$] and Grade II 16.2% [$n = 38$]), 2.5% of the complications were Grade III ($n = 6$) and Kocak Grade IVa complications occurred in three patients. There was one death (Grade IVb: 0.4%, overall mortality rate: 0.06%). The incidence of complications was significantly greater for male patients, those with body mass index ≥ 25 kg/m², and if the operating surgeon had ≤ 1 year of experience in performing LDN surgery.


Conclusion: LDN is a safe procedure with low morbidity. The rate of complications is 8.6% and most of these complications are of low grade. The use of a standardized system for reporting the complications of LDN allows appropriate comparison between reported data.

INTRODUCTION

Laparoscopic donor nephrectomy (LDN) is the procedure of choice for procuring the donor kidney in living kidney donation. The evolution of LDN as a new "standard of care" procedure has been due to the continued refinement of the technique increasing number of surgeons becoming skilled in laparoscopic surgery. The reported complication rates of LDN range from 6% to 29%, with <2% incidence rate of conversion to open.^[1-10] All potential donors should

be informed about the inherent risks associated with donor nephrectomy. However, this is hindered by lack of uniformity in recognizing and reporting complications related to the procedure.

The Clavien classification system for grading complications of surgical procedures was developed in 1992, was modified in 2004 by Dindo *et al.*, and was validated as Clavien-Dindo Classification System (CDCS) of surgical complications.^[11,12] Complications of various urological procedures such as radical cystectomy,^[13] radical prostatectomy,^[14] transurethral resection of bladder tumor,^[15] laparoscopic pyeloplasty,^[16]

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transurethral resection of prostate,^[17] percutaneous nephrolithotomy,^[18] and semi-rigid ureteroscopy^[19] have all been evaluated using the CDCS. Kocak *et al.*^[20] used a similar template and proposed a modification of CDCS specifically for LDN. However, this new modification of CDCS has been less frequently used.^[21] Grade I includes those events which either resolve spontaneously or require a simple bedside procedure only and are not life threatening. Grade II complications are potentially life threatening for which some intervention is needed but there are no sequelae. Grade III complications have a residual or lasting disability while Grade IV events cause renal failure or death. The present study aimed to grade and report the severity of perioperative complications using Kocak's modification of CDCS in patients who underwent LDN. It further aimed to study the parameters which could predict these complications.

MATERIALS AND METHODS

All patients who underwent LDN from January 2000 to June 2016 at our tertiary care, high-volume renal transplant center were included in this study. All transplant-related patients (donors and recipients) were followed up in a dedicated transplant outpatient clinic held every week. The investigations were recorded in the hospital information system and were amenable to access at any time. Donor-related complications were noted at the time of their visit at the clinic. For those patients who had complications during their hospital stay, the data was retrieved from the hospital course and investigations recorded in the discharge summaries stored in the hospital information system. Those who underwent open donor nephrectomy or lacked follow-up data of at least 1-year after surgery were excluded from the study. Database review was conducted focusing on patient demographics, perioperative parameters, and complications as well as experience of the operating surgeon (>1 year or <1 year). Baseline demographic parameters were recorded which included age, gender, body mass index (BMI), the presence of comorbidities (tuberculosis/hypertension), baseline creatinine, hemoglobin level, American Association of Anesthesiology (ASA) score, and relationship with recipient. Renal characteristics and perioperative data were reviewed including glomerular filtration rate (GFR) of donated kidney, vascular anatomy, operating time, warm ischemia time, decline in hemoglobin, duration of postoperative catheterization, and duration of hospital stay. All complications, which occurred, were recorded and classified into four grades of postoperative complications as per the Kocak-modified CDCS criteria.

Patient selection and surgical technique

A team comprising a nephrologist, a psychiatrist, and a urologist at our institution first evaluated all prospective donors who were further reviewed by a multidisciplinary transplant committee. Multidetector Computed Tomography Urography and Angiography (CT) with reconstruction images

were used for evaluation of donor anatomy. Differential function of both kidneys was assessed by a split GFR assessment. In case of similar anatomy and function, the left kidney was selected for donation due to the greater length of the left renal vein and ease in transplantation. Significantly complex anatomies on the left side or any potential benefit of retaining the left kidney to the donor (e.g., GFR discrepancy) were the most common factors leading to procurement of the right kidney. At our institution, donor nephrectomy of the right side was performed by open route and left side by laparoscopy routinely. Hence, all patients recruited in this study underwent left LDN. Early arterial bifurcation was defined as branching within 2 cm from its origin from aorta. Late venous confluence was defined as the occurrence of venous branches converging within 1.5 cm from the left lateral wall of the aorta^[21]

A transperitoneal laparoscopic approach as previously described was uniformly adopted.^[22] Flank position with limited table flexion was used. Camera port was inserted by an open technique using Hasson's cannula. This was followed by insertion of visually aided 5-mm nonbladed trocar along with two 10 mm trocars. Ultrasonic shear were used for dissection. The kidney was removed after transection of the renal artery and vein and the ureter at/above the level of the common iliac artery. We used two large Hem-o-lok clips and one titanium clip for renal artery control and two extra-large Hem-o-lok clips for renal vein control. The vessels were then divided 2 mm away from the distal clip. The kidney was removed through a Pfannenstiel or flank incision. Urethral catheter was removed on postoperative day 1 and the patient was discharged on postoperative day 3 or 4.

Temperature of more than 100°F was considered as fever. Hematuria persisting for more than 6 h and resolving spontaneously by 48 h was defined as "transient hematuria." Deranged renal function was defined as serum creatinine of ≥ 1.4 mg/dl. Renal vessel anomalies included multiple veins or arteries or both, retro-aortic renal vein, and early division and late confluence of renal artery and renal vein, respectively. Patients with a BMI ≥ 25 kg/m² were considered obese as per consensus on obesity guidelines in Indian Asians.^[23] The indication of blood transfusion at our institution was hematocrit of <30%.

Statistical analysis

Univariate analysis with the Mann-Whitney and Fisher's exact tests were carried out to assess the variables which may predict complications after LDN. The significant factors were subsequently entered into multivariate analysis using a multiple logistic regression model to identify independent predictors. Intergrade comparison was done by applying "post hoc comparison test" to find the correlation between the grade of complications and parameters predicting them. All tests were two sided with significance considered at

$P < 0.05$. Statistical analyses were performed using SPSS 20.0 software (SPSS, Inc., Chicago, IL, USA).

RESULTS

A total of 2217 patients underwent voluntary kidney donation during the study period, 787 patients were excluded from the study (open donor nephrectomy in 772 patients and lack of follow-up data in 15 patients). Finally, 1430 patients were enrolled in this study. The median duration of follow-up was 28 months (range: 1–44 months). Baseline preoperative data of all patients are summarized in Table 1. Mean age of the study group was 43.8 ± 16.7 years, 83.4% of patients were female and the rest were male. The donor was the wife in 56.2% cases ($n = 804$), mother in 19% ($n = 270$), husband in 3% ($n = 43$), father in 8.9% ($n = 128$), sibling in 11% ($n = 156$), and others in 2% ($n = 29$). Baseline serum creatinine was 1.0 ± 0.3 mg/dl and BMI was 23.4 ± 7.31 kg/m². Nearly 3% patients ($n = 43$) were hypertensive preoperatively (well controlled on single medication).

Renal characteristics and perioperative parameters are summarized in Table 2. Mean GFR of donated kidney was 45.6 ± 5.8 ml/min. Vascular anomalies were present in 29.2% patients ($n = 418$). Mean operative time was 155.7 ± 25.7 min and warm ischemia time was 3.1 ± 1.3 min. Mean hemoglobin decline was 0.8 ± 0.5 g/dl. Duration of hospital stay was 3.8 ± 10.5 days. All kidneys were procured and transplanted successfully, with adequate renal artery and vein length to perform the recipient operation with standard techniques. One-year graft survival from the date of transplant was 97.1%.

A total of 235 complications were observed in 124 patients with 8.6% incidence of postoperative complications. All complications were categorized according to four grades of Kocak's modified CDCS as summarized in Table 3. Majority of the complications were Grade I and Grade II (Grade I in 79.5% [$n = 187$] and Grade II in 16.2% [$n = 38$]). Grade II was subdivided into IIa (7.2%), IIb (6.4%), and IIc (2.5%). Around 2.5% of complications were Grade III ($n = 6$; reexploration for splenectomy in two and internal hernia in four patients). Kocak's Grade IVa occurred in three patients (renal failure requiring hemodialysis [$n = 2$] and hemorrhagic shock with acute renal failure [$n = 1$]). There was one death (Grade IVb: 0.4%) due to slippage of Hem-o-lok clip from renal artery leading to severe hemorrhage (overall mortality rate: 0.06%).

Univariate analysis of various parameters and risk of complications

The correlation of risk of complications with age, smoking, hypertension, gender, BMI, vascular anatomy, operating time, and experience of the operating surgeon was evaluated by appropriate univariate analysis method [Table 4]. Statistical

Table 1: Baseline preoperative data of 1430 patients who underwent laparoscopic donor nephrectomy

Parameters	Value
Age, years (mean±SD)	43.8±16.7
Gender, n (%)	
Female	1194 (83.4)
Male	236 (16.5)
BMI, kg/m ² (mean±SD)	23.4±7.31
Smoker, n (%)	84 (5.8)
History of hypertension, n (%)	43 (3)
History of tuberculosis, n (%)	35 (2.4)
Baseline serum creatinine, mg/dl (mean±SD)	1.0±0.3
Baseline hemoglobin, g/dl (mean±SD)	12.4±3.4
ASA score, n (%)	
I	1371 (95.9)
II	59 (4.1)

ASA=American Society of Anesthesiologists, GFR=Glomerular filtration rate, SD=Standard deviation, BMI=Body mass index

Table 2: Renal characteristics and perioperative data of 1430 patients who underwent laparoscopic donor nephrectomy

Parameters	Value
GFR of donated kidney, ml/min (mean±SD)	45.6±5.8
Vascular anatomy of donated kidney, n (%)	
Single artery	1249 (87.3)
Two or more renal arteries	181 (12.6)
Early arterial bifurcation	142 (10)
Single vein	1422 (99.4)
Two or more renal veins	8 (0.5)
Late confluence of renal vein	62 (4.3)
Retro-aortic renal vein	24 (1.7)
Double ureter	6 (0.4)
Operating time, min (mean±SD)	155.7±25.7
Warm ischemia time, min (mean±SD)	3.1±1.3
Hemoglobin decline, g/dl (mean±SD)	0.8±0.5
Duration of postoperative catheterization, h (mean±SD)	18.3±3.5
Duration of hospital stay, days (mean±SD)	3.8±0.5

GFR=Glomerular filtration rate, SD=Standard deviation

significance ($P < 0.05$) was found in four parameters: male gender (t -test, $P = 0.003$), BMI >25 kg/m² ($P = 0.001$), operating time >180 min ($P = 0.044$), and experience of operating surgeon <1 year ($P = 0.002$).

Multivariate logistic regression analysis of various parameters and risk of complications

Multivariate analysis showed that independent parameters for predicting complications after LDN in descending order were BMI (odd's ratio [OR] = 2.82, 95% confidence interval [CI] = 95% = 1.23–9.79; $P = 0.027$), experience of operating surgeon (OR = 1.52, 95% CI = 1.12–5.63; $P = 0.035$), and gender (OR = 1.29, 95% CI = 1.07–3.63; $P = 0.038$). Operating time did not exhibit significant correlation with the risk of complications.

Correlation of Kocak's grades of complications with independent parameters

Statistically significant difference was observed for the distribution of the complication grades, with parameters predicting them [Table 5]. Male gender and BMI >25 kg/m²

Table 3: Complications of laparoscopic donor nephrectomy classified according to Kocak-modified Clavien-Dindo classification system grade

Grade	Complications	n (%)
I	Fever	14 (5.9)
	Acute urinary retention after catheter removal	2 (0.8)
	Transient hematuria	3 (1.3)
	Wound infection	25 (14.5)
	Diarrhea	34 (10.6)
	Transient elevation of serum creatinine	12 (5.1)
	Orchalgia	16 (6.8)
	Epididymo-orchitis	13 (5.5)
	Urinary tract infection	17 (7.3)
	Shoulder tip pain	14 (5.9)
	Scrotal swelling	7 (2.9)
	Subcutaneous hematoma	13 (5.6)
	Seroma	9 (3.8)
	Subcutaneous emphysema	8 (3.5)
	Total	187 (79.5)
	IIa	Lymphorrhoea
Drop in hemoglobin requiring blood transfusion		4 (1.7)
Paralytic ileus		4 (1.7)
Pulmonary infection		1 (0.4)
Arrhythmias		1 (0.4)
IIb	Readmission	5 (2.1)
	Wound dehiscence	3 (1.2)
	Splenic capsular tear	2 (0.8)
	Diaphragmatic tear	1 (0.4)
	Chylous ascites requiring percutaneous drainage	3 (1.2)
IIc	Reexploration for bleeding	3 (1.2)
	Reexploration of bowel injury	1 (0.4)
	Laparotomy for bladder injury	1 (0.4)
	Pleural effusion requiring chest tube drainage	1 (0.4)
	Total	38 (16.2)
III	Lumbar vein injury	2 (0.8)
	Adrenal vein injury	1 (0.4)
	Renal vein injury	1 (0.4)
IVa	Renal artery injury	2 (0.8)
	Total	6 (2.5)
	Splenectomy	2 (0.8)
IVb	Internal hernia	4 (1.7)
	Total	6 (2.5)
IVc	Acute renal failure needing hemodialysis	2 (0.8)
	Hemorrhagic shock with acute renal failure	1 (0.4)
IVd	Death	1 (0.4)
	Total	4 (1.7)
Total		235 (100)

have higher chances of Grade I complications as compared to higher grades ($P = 0.011$ and 0.023 , respectively) and operating surgeon with <1 year experience had higher chances of Grade I and Grade II complications as compared to Grade III and Grade IV ($P = 0.003$).

DISCUSSION

LDN has constantly evolved with various refinements in technique and is now a universally accepted procedure. The increase in the number of living donors and the development of less stringent inclusion criteria for donors have renewed the focus on the issue of donor safety. Various reports estimate the surgical complication rate of LDN to be between 6% and 29%.^[1-10]

Clavien *et al.*^[11] described a four-tiered classification system in 1992.^[11] It was used for the classification of peri operative and postoperative complications. In 2004, Dindo *et al.*^[12] revised this system and this revision is “highly recommended” for reporting urological complications presently.^[24-26] However, despite its universal acceptance, Kocak *et al.*^[20] recently modified this classification system, specifically to grade the complications of LDN. In the CDCS, the emphasis is on the risks and invasiveness of the intervention used to correct a complication. It does not take into account the length of hospital stay and readmission to hospital that are of utmost importance in this specific population, as they are voluntary kidney donors. Moreover, this system does not consider residual functioning disability status due to surgical complications that have a strong impact on patient’s quality of life. These factors are incorporated in Kocak’s modification which includes all complications till the last follow-up as opposed to only 30 days postoperatively in CDCS.

There is limited data in the literature regarding the complications and morbidity of LDN. Breda *et al.*^[1] reviewed their experience of 300 LDN at University of California, Los Angeles, and reported a 4% overall complication rate with 1% conversion rate to open approach. Chan *et al.*^[2] retrospectively reviewed 175 cases who underwent LDN and reported that blood transfusion was required in 3.4% cases and open conversion was required in 1.7% of cases with an overall complication rate of 14%. Jacobs *et al.*^[3] described a 6-year experience with 738 consecutive cases of LDN from the University of Maryland. Conversion to the open approach occurred in 1.6% of cases, prompted primarily by occurrence of a renovascular injury. Blood transfusion was required in 1.2% of cases. Major intraoperative complications occurred in 6.8% and major postoperative complications occurred in 17.1% of cases. In another study from the United States, a major complication rate of 5.8% after laparoscopic nephrectomies was reported by Permpongkosol *et al.*^[4] Siqueira *et al.*^[5] retrospectively reviewed seventy patients who underwent LDN and reported 15% overall complication rate (major complications in 5.7% and minor in 10%) with 2.8% conversion rate.

However, none of the above studies applied any special criteria for grading and reporting postoperative complications. In the present study, Kocak-modified CDCS was used to grade and report the severity of complications in 1430 patients who had undergone LDN. The overall complication rate was 8.6% with 0.06% mortality rate. This was comparable to a 5.46% morbidity rate (most complications were minor [Grade I in 66%], four open conversions [0.4%]) and no mortality in a study done by Harper *et al.*^[21] in an American cohort, who also graded complications of LDN in 750 patients according to Kocak-modified CDCS. Leventhal *et al.*^[6] performed a retrospective review of 1200 LDN cases and reported complications according to Kocak’s system. In their study, 46% ($n = 31$) of

Table 4: Comparison of descriptive data between those with and without complications in laparoscopic donor nephrectomy

Parameters	Complications		P
	Yes (n=124)	No (n=1306)	
Age (n)			
<50 years	86	849	0.373
>50 years	38	457	
History of smoking (n)			
Yes	8	76	0.692
No	116	1230	
History of hypertension (n)			
Yes	5	38	0.413
No	119	1268	
Gender (n)			
Male	33	203	0.003
Female	91	1103	
BMI (n)			
<25 kg/m ²	63	852	0.001
>25 kg/m ²	61	454	
Vascular anatomy (n)			
Simple	101	1052	0.905
Anomalies	23	254	
Operating time (n)			
<180 min	74	897	0.044
>180 min	50	409	
Experience of operating surgeon (n)			
<1 years	20	95	0.002
>1 years	104	1211	

Bold P values are statistically significant. n=Number of patients.
BMI=Body mass index

Table 5: Comparison of Kocak grades of complications according to various independent parameters predicting them

Parameter	Kocak-modified CCS grade				P
	I	II	III	IV	
Total number of complications (n=235)	187	38	6	4	
Parameters of patients with complications					
Gender					
Male (236 patients, n=73)	49	20	2	2	0.011
Female (1194 patients, n=162)	138	18	4	2	
BMI (kg/m ²)					
<25 (915 patients, n=120)	86	27	4	3	0.023
>25 (515 patients, n=115)	101	11	2	1	
Experience of operating surgeon					
<1 years (123 patients, n=39)	23	14	1	1	0.003
>1 years (1307 patients, n=196)	164	24	5	3	

n=Number of complications. CCS=Clavien classification system,
BMI=Body mass index

complications were categorized as Grade I, 50.7% (n = 67) as Grade II (Grade IIa – 22.3%, Grade IIb – 17.9%, and Grade IIc – 10.4%), 2.9% (n = 2) as Grade III, and no Grade IV complications occurred. The conversion rate was 0.92%, readmission for complication management was required in 1.2% and a reoperation was required in 0.25% of cases (overall complication rate was 5.6%). Ramasamy *et al.*^[7] analyzed postoperative complications of LDN using CDCS and reported that gastrointestinal complications were the most common complication (38%), followed by infectious complications (16%), with overall complication rate of 7.1%. Mjøen *et al.*^[8] assessed postoperative morbidity in

244 LDN cases and found that major complications occurred in 4.1% patients (Clavien-Dindo Grade ≥ III) and minor complications (Grade ≤ II) in 12.3% with conversion to open approach required in three patients.

The most common complication in this study was disturbance in bowel function (16.2%, n = 38). The most important and feared complication in LDN is renovascular injury, often requiring conversion to open procedure. There was one death due to slippage of Hem-o-lok clip from renal artery leading to severe hemorrhage which occurred during our initial experience. At the time, we used to place only one Hem-o-lok clip on the renal artery and divide the vessel flush with the clip.

Besides applying a standardized classification system to grade the complications of LDN, this study adds to our current knowledge of perioperative complications by evaluating parameters which predict them. Once risk factors are identified, prevention should be the focus of postoperative care in the subset of patients with these risk factors. We found that BMI, experience of the operating surgeon, and gender of donor are independent predictors of complications after LDN in descending order.

In this study, operating surgeon with <1 year experience had 1.52 times higher complication rate as compared to those with more than 1 year of experience. On intergrade comparison, operating surgeon with <1 year experience had higher chances of Grade I and Grade II complications as compared to Grade III and Grade IV (P = 0.003). However, Treat *et al.*^[9] reported no significant difference for Clavien complication rates between the early learning period (first 150 cases) and the rest of the series (n = 1275).

Heimbach *et al.*^[10] published the Mayo clinic experience with 553 consecutive LDN cases, focusing on the impact of obesity upon donor outcomes. Compared to BMI <25, high BMI donors (>35) had slightly longer operative times and more low-grade complications (wound related). Mjøen *et al.*^[8] found that BMI >25 kg/m² showed a significant increase in the risk of complications after LDN. Patel *et al.*^[27] found obesity to be significantly associated with overall morbidity in LDN (OR = 1.92, 95% CI = 1.06–3.46, P = 0.037). Our results are consistent with these studies and we found that risk of Grade I complications is 2.82 times higher in patients with BMI >30 kg/m² as compared to patients with BMI <30 kg/m². Chin *et al.*^[28] reported that obese donors (BMI ≥ 30 kg/m²) had significantly higher rates of intraoperative complications and significant bleeding. However, no significant correlation was found between BMI and complication after LDN by Ramasamy *et al.*^[7] and Treat *et al.*^[9] who evaluated complications in 663 and 1325 patients of LDN, respectively.

In this study, male gender was also found to be an independent parameter for predicting complications in

LDN (OR = 1.29, 95% CI = 1.07–3.63; $P = 0.038$). On intergrade comparison, male patients had higher chances of Grade I complications as compared to Grades II–IV ($P = 0.011$). One possible explanation is the transection of left gonadal vein during the procedure. This may result in left testicular vascular congestion that could lead to epididymo-orchitis and orchalgia postoperatively. In our experience, more lymphatic reactions at the renal hilum were identified in male donors. Similarly, Chin *et al.*^[28] reviewed 512 patients and identified that female donors had a shorter operative time by 21.1 min ($P = 0.001$) and a 60% lower risk of a postoperative complication. However, Ramasamy *et al.*^[7] and Mjøen *et al.*^[8] did not find correlation of male gender with increased risk of complications after LDN.

The limitation of the present study is its retrospective nature, and therefore it carries all inherent potential issues associated with such studies. The second limitation is that this study includes only left-sided procedure. The main strength of the present study is that it was performed on relatively large number of patients and it may be sufficient to detect all the factors significant for predicting the complications of LDN. To the best of our knowledge, this is the first study that applied Kocak's modification for grading complications of LDN in an Indian cohort and identified the parameters, which predict these complications. However, prospective studies are necessary to confirm these findings.

CONCLUSION

The complication rate associated with LDN is low. As it has an acceptable safety profile, LDN remains a standard approach for retrieval of renal allograft. A greater rate of complications of LDN is associated with male gender, higher BMI, and inexperience of the operating surgeon. The use of a standardized classification for reporting of complications during LDN should be encouraged as it serves as a platform for better communication and comparison among surgeons and institutions. It leads to an accurate estimation of risks associated with LDN that would help in counseling potential donors.

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