





# Perioperative Complications During Living Donor Nephrectomy: Results From a Multicenter Cohort Study

Canadian Journal of Kidney Health and Disease  
Volume 6: 1–14  
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DOI: 10.1177/2054358119857718  
journals.sagepub.com/home/cjk



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## Abstract

**Background:** While living kidney donation is considered safe in healthy individuals, perioperative complications can occur due to several factors.

**Objective:** We explored associations between the incidence of perioperative complications and donor characteristics, surgical technique, and surgeon's experience in a large contemporary cohort of living kidney donors.

**Design:** Living kidney donors enrolled prospectively in a multicenter cohort study with some data collected retrospectively after enrollment was complete (eg, surgeon characteristics).

**Setting:** Living kidney donor centers in Canada (n = 12) and Australia (n = 5).

**Patients:** Living kidney donors who donated between 2004 and 2014 and the surgeons who performed the living kidney donor nephrectomies.

**Measurements:** Operative and hospital discharge medical notes were collected prospectively, with data on perioperative (intraoperative and postoperative) information abstracted from notes after enrollment was complete. Complications were graded using the Clavien-Dindo system and further classified into minor and major. In 2016, surgeons who performed the nephrectomies were invited to fill an online survey on their training and experience.

**Methods:** Multivariable logistic regression models with generalized estimating equations were used to compare perioperative complication rates between different groups of donors. The effect of surgeon characteristics on the complication rate was explored using a similar approach. Poisson regression was used to test rates of overall perioperative complications between high- and low-volume centers.

**Results:** Of the 1421 living kidney donor candidates, 1042 individuals proceeded with donation, where 134 (13% [95% confidence interval (CI): 11%-15%]) experienced 142 perioperative complications (55 intraoperative; 87 postoperative). The most common intraoperative complication was organ injury and the most common postoperative complication was ileus. No donors died in the perioperative period. Most complications were minor (90% of 142 complications [95% CI: 86%-96%]); however, 12 donors (1% of 1042 [95% CI: 1%-2%]) experienced a major complication. No statistically significant differences were observed between donor groups and the rate of complications. A total of 43 of 48 eligible surgeons (90%) completed the online survey. Perioperative complication rates did not vary significantly by surgeon characteristics or by high-versus low-volume centers.

**Limitations:** Operative and discharge reporting is not standardized and varies among surgeons. It is possible that some complications were missed. The online survey for surgeons was completed retrospectively, was based on self-report, and has not been validated. We had adequate statistical power only to detect large effects for factors associated with a higher risk of perioperative complications.



**Conclusions:** This study confirms the safety of living kidney donation as evidenced by the low rate of major perioperative complications. We did not identify any donor or surgeon characteristics associated with a higher risk of perioperative complications.

**Trial registration(s): NCT00319579:** A Prospective Study of Living Kidney Donation (<https://clinicaltrials.gov/ct2/show/NCT00319579>)

**NCT00936078:** Living Kidney Donor Study (<https://clinicaltrials.gov/ct2/show/NCT00936078>)

## Abrégé

**Contexte:** Bien que le don vivant d'un rein soit sécuritaire chez un individu en santé, plusieurs facteurs sont susceptibles d'engendrer des complications périopératoires.

**Objectif:** Nous avons exploré l'association entre l'incidence des complications périopératoires et les caractéristiques du donneur, la technique chirurgicale employée et l'expérience du chirurgien au sein d'une vaste cohorte contemporaine de donneurs vivants d'un rein.

**Type d'étude:** Une étude de cohorte multicentrique où certaines données (notamment les renseignements concernant le chirurgien) ont été recueillies rétrospectivement, après l'inclusion complète des sujets (donneurs vivants d'un rein).

**Cadre:** Des centres de transplantation au Canada (n=12) et en Australie (n=5).

**Sujets:** Des individus ayant fait don d'un rein entre 2004 et 2014, et les chirurgiens qui ont procédé à la néphrectomie.

**Mesures:** Les notes médicales au dossier, opératoires et à la sortie de l'hôpital, ont été recueillies de façon prospective; les données concernant les renseignements périopératoires (peropératoires et postopératoires) ayant été extraites des notes une fois l'inclusion du sujet complétée. Les complications ont été catégorisées selon la classification de Clavien-Dindo, puis caractérisées comme étant mineures ou majeures. En 2016, les chirurgiens ayant pratiqué les néphrectomies ont été invités à répondre à un sondage en ligne au sujet de leur formation et de leur expérience.

**Méthodologie:** Des modèles de régression logistique multivariée utilisant des équations d'estimation généralisées ont été employés pour comparer les taux de complications périopératoires entre les différents groupes de donneurs. L'effet exercé sur le taux de complications par les caractéristiques du chirurgien a été exploré selon une approche similaire. Une régression de Poisson a été utilisée pour évaluer et comparer les taux globaux de complications entre les centres à volume élevé et les centres à faible volume.

**Résultats:** Des 1 421 candidats répertoriés, 1 042 individus ont subi une néphrectomie, desquels 134 (13 % [IC 95 %: 11–15 %]) ont vécu un total de 142 complications périopératoires (55 peropératoires; 87 postopératoires). La complication peropératoire la plus fréquente était une lésion à l'organe, alors qu'un iléus s'est avéré la principale complication postopératoire. Aucun donneur n'est décédé en période périopératoire. La plupart des complications rencontrées étaient mineures (90 % des 142 complications répertoriées [IC 95 %: 86–96 %]). Toutefois, 12 donneurs (1 % des 1 042 donneurs [IC 95 %: 1–2 %]) ont souffert de complications majeures. Aucune différence significative du point de vue statistique n'a été observée entre

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les groupes de donneurs et le taux de complications. Des 48 chirurgiens admissibles, 43 (90 %) ont répondu au sondage en ligne. Les taux de complications périopératoires n'ont pas varié de façon significative en fonction des caractéristiques des chirurgiens, ou selon le volume de patients de l'hôpital.

**Limites:** La façon d'inscrire les renseignements médicaux (opératoires ou à la sortie de l'hôpital) dans les dossiers des patients n'est pas normalisée et varie d'un chirurgien à l'autre. Certaines complications pourraient ne pas avoir été notées. Le sondage en ligne destiné aux chirurgiens a été rempli rétrospectivement, il reposait sur des déclarations volontaires et n'avait pas fait l'objet d'une validation. Nous ne disposions d'une puissance statistique que pour détecter les effets importants des facteurs associés à un risque accru de complications périopératoires.

**Conclusion:** Cette étude confirme le caractère sécuritaire d'un don vivant de rein, comme en témoigne le très faible taux de complications périopératoires majeures. Nous n'avons pu établir de caractéristiques, du donneur ou du chirurgien, qui soit associées à un risque accru de complications périopératoires.

## Keywords

living kidney donor, perioperative complications, nephrectomy, surgeons' experience

Received March 5, 2019. Accepted for publication April 30, 2019.

## What was known before

The perioperative mortality rate of living donor nephrectomy ranges between 0.02% and 0.04% and morbidity rate goes from 8% to 18%.<sup>1-6</sup>

Living kidney donation is considered safe in healthy individuals; however, perioperative complications can occur, ranging from minor events that resolve before discharge to major events such as life-threatening bleeding, pulmonary embolism, and in extremely rare cases (<0.04%) death. Ongoing assessment of perioperative complications in living kidney donors is needed given the evolving characteristics of donors and the introduction of new surgical techniques.

## What this adds

This study confirms the perioperative safety of living kidney donation in modern practice. Consistent with previous reports, approximately 13% of donors experienced a perioperative complication, but only 1% experienced a major complication. The risk of perioperative complications did not vary with donor or surgical characteristics.

## Introduction

Living kidney donation exposes a healthy individual to the risk of surgery to help a patient with kidney failure, often a relative, friend or spouse of the donor. While living kidney donation is considered safe in healthy individuals, perioperative complications can occur, ranging from minor events that resolve before discharge to major events such as life-threatening bleeding, pulmonary embolism, and in extremely rare cases death.<sup>2,3,7,8</sup>

Several factors may contribute to perioperative complications. Individuals who come forward for living kidney donation undergo a rigorous evaluation to ensure they are of sufficiently good health to become a donor. However, the

persistent shortage of organs combined with evidence of minimal risk to donors means that many transplant programs are allowing a broader spectrum of individuals to donate; nearly 25% of living donor transplants in the United States and Canada now include donors with at least one potential risk factor for perioperative complications such as smoking, older age, obesity, or predonation hypertension.<sup>4,9,10</sup> Ongoing assessment of perioperative complications in living kidney donors is warranted given the evolving characteristics of donors and the introduction of new surgical techniques.<sup>2,3,11</sup>

During their predonation health evaluation, donor candidates undergo a presurgical assessment, including computed tomography angiogram or magnetic resonance angiogram.<sup>12</sup> These assessments may reveal anatomical variations and abnormalities including accessory arteries, early arterial branching or cysts, which may be associated with longer operative and ischemia times. While such abnormalities do not necessarily preclude donation, they may increase the difficulty of surgery and increase the risk of perioperative complications; however, few reports are available to estimate this risk.<sup>13</sup>

Surgical factors, including a surgeon's training, experience, and operative practice, may also influence the risk of perioperative complications.<sup>5</sup> While center volume may serve as a proxy for the surgeon experience, no studies have directly examined whether a surgeon's training or experience associates with the risk of perioperative complications in living kidney donors.<sup>14-16</sup>

To confirm the safety of living kidney donation in contemporary practice, a better understanding of the frequency of perioperative complications is needed.<sup>5,8,17-19</sup> Here, we report the incidence and severity of perioperative complications in a contemporary cohort of living kidney donors, including paired exchange and nondirected donors, who underwent nephrectomy between 2004 and 2014. We investigated whether the risk of perioperative complications varied with donor characteristics (including predonation risk

factors), surgical technique (including type of nephrectomy and technique for vascular control of the renal artery), or surgeon characteristics (including surgeon training, experience, and practices).

## Materials and Methods

### Design, Setting, and Participants

Data for this study were obtained from an ongoing multicenter prospective cohort study examining the medical, financial, and psychological implications of living kidney donation (clinicaltrials.gov: NCT00319579 and NCT00936078). The participants in this study, 1042 living kidney donors, were enrolled before surgery from 12 centers in Canada and 5 centers in Australia between 2004 and 2014 (the pilot phase occurred from 2004 to 2009 and phase II from 2009 to 2014). All donors who participated had been approved by their local nephrology team for living kidney donation, were 18 years of age or older, and were able to communicate in English or French. In 2016, all surgeons who performed living donor nephrectomies in this study were invited to complete an online survey on their surgical training and their experience at the time of the study nephrectomies. All participants provided written, informed consent. Ethics approval was obtained from Western University's Research Ethics Board (REB approval # 6056) and all enrolling centers. The results are reported following Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies (see Table S1 in Supplemental Digital Content 1).<sup>20</sup>

### Data Collection and Measures

Data collection occurred at 3 time points: preoperatively (baseline), intraoperatively, and postoperatively (until discharge). At baseline, all participants completed a standardized health questionnaire and underwent a physical exam (see Image S1 and Table S2, in Supplemental Digital Content 1, which provides definitions). Surgical characteristics (eg, left vs right nephrectomy, planned laparoscopic vs open nephrectomy, and technique for vascular control of the renal artery [transfixion vs nontransfixion]) were abstracted from the donors' operative and discharge notes by an author with a medical degree (C.G.-O.). In transfixion techniques, the suture or staple material penetrates the vessel, while in nontransfixion techniques, a tie or clip is placed around the vessel.<sup>21</sup>

Data abstraction sheets were created by C.G.-O. and reviewed independently by 2 authors (L.S.F. and A.X.G.). Data on perioperative complications were systematically abstracted, retrospectively, from the donors' operative notes (immediate chart, dictated operative, or both) and discharge summaries. Two reviewers (C.G.-O. and L.S.F.) independently assessed the presence and severity of intraoperative complications using a modified version of the Clavien-Dindo

classification system (see Table S3, in Supplemental Digital Content 1).<sup>22</sup> Agreement between the 2 reviewers was excellent (kappa 0.84 [95% confidence interval (CI): 0.80-0.89]); differences were resolved by consensus. Postoperative complications were independently assessed by the same 2 reviewers using the Clavien-Dindo classification system (see Table S4, in Supplemental Digital Content 1)<sup>23-25</sup> with complete agreement (kappa 1.0). All events classified as complications were deviations from the normal expected course.<sup>22,26</sup> Perioperative complications (including intraoperative and postoperative complications) were categorized as minor or major as follows: minor complications included Clavien-Dindo grade I and II complications, and major complications included Clavien-Dindo grade III and IV complications. Major complications required an intervention and were life-threatening or resulted in permanent disability. There were no intraoperative or postoperative deaths, nor were there any deaths related to perioperative complications, so there were no Clavien-Dindo grade V events. Examples of minor complications include splenic laceration without the need of another surgical intervention or surgical site infection. Examples of major complications include pulmonary embolism, sepsis and intraoperative bleeding requiring conversion from a laparoscopic to an open procedure.

Survey development was informed by a literature review<sup>27-29</sup> and consultation with experts in the field, including 5 transplant surgeons, a nephrologist and an epidemiologist, although formal Delphi methods were not used. The survey was sent to 6 transplant surgeons for pilot testing.

The survey included questions on surgical training and experience with different nephrectomy techniques, year of specialty completion, and preference for intraoperative use of antibiotics and heparin (see Supplemental Digital Content 2 for a copy of the survey). To facilitate recall, some of the survey's questions were specifically targeted to the period 2009-2014; this was due to the fact that all the surgeons who performed a living kidney nephrectomy from 2004 to 2009 also did from 2009 to 2014. We made 5 contact attempts: 3 e-mails were sent at 2-week intervals and 2 other contact attempts with nonresponders were made by fax and/or phone. Surveys were de-identified before being entered into the database. Each center was contacted to assess the overall number of living kidney donor nephrectomies performed per year.

### Statistical Analysis

Donor and surgeon characteristics are summarized using the median (25th and 75th percentiles) or as numbers and percentages. To compare the perioperative complication rate between different groups of donors (eg, age groups), we computed predictive margins using a multivariable logistic regression model with generalized estimating equations using the `xtgee` command with margins statement in Stata/SE, version 15.1 (StataCorp). Predictive margins are a form

of direct standardization that average predicted values from the regression models across the covariate distribution in the population; they can be used to provide an estimate of the rate by group, and the absolute difference between groups, with 95% CI. In all multivariable analyses, the unit of analysis was the donor (multiple complications within one donor were only counted once [the most severe complication]), and the clustering of donors within surgeons was accounted for using generalized estimating equations with an exchangeable correlation structure. We tested whether the following donor characteristics were associated with complication rates: age at donation (<40, 40-60, >60 years), sex, white race (vs other), predonation estimated glomerular filtration rate (eGFR) <80 mL/min per 1.73 m<sup>2</sup>, predonation hypertension or obesity (body mass index [BMI] ≥30 kg/m<sup>2</sup>) within the 30-day period before donation, smoking, year of surgery, laparoscopic versus open surgery and left versus right nephrectomy. In each model, we adjusted for the following donor characteristics (where appropriate): age, sex, year of surgery, scheduled surgical technique, and nephrectomy side (left vs right); we also adjusted for the following surgeon characteristic: year since completion of surgical specialty training.

We used a similar approach to examine the effect of surgeon characteristics (eg, surgical specialty, number of nephrectomies per year) on the complication rate. We also performed a logistic regression to compare differences in intraoperative bleeding between vascular control techniques (transfixion vs nontransfixion). These models were adjusted for the number of nephrectomies performed per year, and the following donor characteristics: age, sex, year of surgery, scheduled surgical technique, and nephrectomy side. For this analysis, we excluded donors whose surgeon did not respond to the survey.

Using a Poisson regression, we tested whether the rate of overall perioperative complications differed between centers with high volumes (≥20 living donor nephrectomies per year on average between 2004 and 2014) and low volumes (<20 living donor nephrectomies per year on average). The threshold to define high-volume centers was based on previous literature.<sup>30</sup>

## Results

### Donors

We enrolled 1421 living kidney donor candidates from 17 centers (12 centers in Canada and 5 in Australia) from 2004 to 2014. Reasons for exclusion included participant decision, nephrology/transplant team decision, recipient death, loss to follow-up, and donation after the study closed. In total, 1042 individuals proceeded with donation and were eligible to participate in the present study (Figure 1). Predonation characteristics of the 1042 donors are shown in Table 1. The median donor age was 49 (39, 56) years and 12% were older

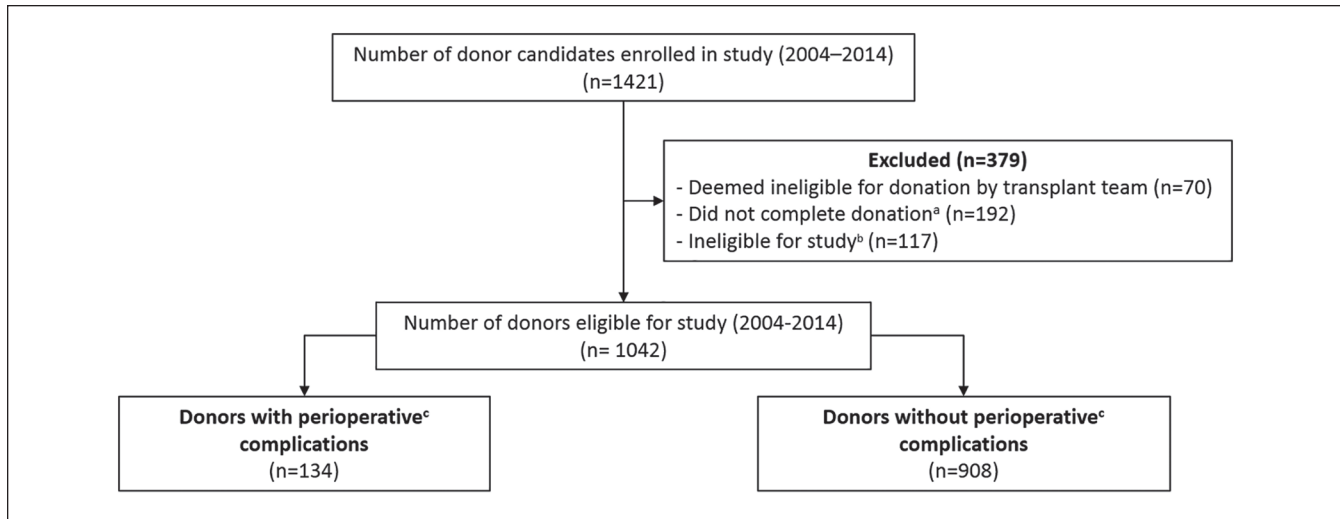
than 60 years; 66% were women and 87% were white. Fifty-six donors (5%) had a predonation diagnosis of hypertension, 138 (13%) were current smokers, and 174 (17%) were obese, BMI >30 kg/m<sup>2</sup> (measurement done within 30 days before surgery); 25 (2%) had a BMI ≥35 kg/m<sup>2</sup> and the highest BMI was 39 kg/m<sup>2</sup>. Donors had a median predonation eGFR of 96 mL/min/1.73 m<sup>2</sup> (86, 106), and the eGFR was <80 mL/min/1.73 m<sup>2</sup> in 148 (14%) donors. Most donors were genetically (49%) or emotionally (35%) related to their recipients, and the remaining were paired (12%) and nondirected donors (4%). Most nephrectomies (86%) were left-sided; 87% were scheduled as laparoscopic and 13% as open; 9 laparoscopic surgeries (1%) were converted to open.

### Surgeons

Of 48 surgeons invited to participate in this study, 43 (90%) completed the online survey between April and November 2016 (responses reflected their experience during the study period); all surgeons who performed a living donor nephrectomy during the pilot phase (2004-2009) also performed a living donor nephrectomy during phase II (2009-2014). Characteristics of these 43 surgeons are shown in Table 2. Nearly half of the surgeons (47%) self-identified as urologists and 40% as transplant surgeons. Most surgeons (86%) reported having basic laparoscopic training during their residency or fellowship, and 70% reported having advanced laparoscopic training. Surgeons had been practicing for a median of 13 years (8, 19) after training, and the median time since performing their first living donor nephrectomy was 11 years (6, 16). Surgeons reported performing a median of 15 (8, 24) living donor nephrectomies per year during the study period. Most surgeons (95%) reported a preference for prescribing antibiotics to donors before the nephrectomy, and 88% used subcutaneous heparin to prevent venous thromboembolism (preoperatively and/or postoperatively).

### Perioperative Complications

Of 1042 donors, 134 (13%) experienced a total of 142 perioperative complications (55 intraoperative; 87 postoperative); 8 donors experienced both an intraoperative and a postoperative complication. No donors died in the perioperative period. The type and severity of intraoperative and postoperative complications are summarized according to the Clavien-Dindo grade classification (Table 3). The most common type of intraoperative complication was organ injury (50% of 55 complications; 45% were classified as minor and 5% as major). In 55 donors who experienced an intraoperative complication during laparoscopic surgery, 6 procedures were converted to open (an additional 3 of 709 laparoscopic surgeries in donors who did not experience complications were converted to open as a preventive measure). The most common type of postoperative complication was ileus (34% of 87 complications; all classified as minor).



**Figure 1.** Participant selection.

<sup>a</sup>Reasons include participant decision, recipient illness or death, and other (eg, recipient received a kidney from another donor).

<sup>b</sup>Reasons include participant or study team decision, loss to follow-up, and donation after study closed.

<sup>c</sup>Includes both intraoperative and postoperative complications.

**Table 1.** Predonation Characteristics of 1042<sup>a</sup> Living Kidney Donors (2004-2014).

Demographic characteristics	
Age at donation, years	49 (39, 56)
Age category, n (%)	
<40 years	270 (26%)
40-60 years	646 (62%)
>60 years	126 (12%)
Women, n (%)	691 (66%)
White, n (%) <sup>a</sup>	907 (87%)
Predonation health characteristics	
eGFR, mL/min/1.73 m <sup>2b</sup>	96 (86, 106)
eGFR <80 mL/min/1.73 m <sup>2</sup> , n (%)	148 (14%)
Nuclear GFR, mL/min/1.73 m <sup>2c</sup>	103 (92, 118)
Serum creatinine, mg/dL	0.78 (0.70-0.89)
Systolic blood pressure, mmHg <sup>d</sup>	120 (113, 127)
Diastolic blood pressure, mmHg <sup>d</sup>	74 (68, 78)
Diagnosed with hypertension, n (%) <sup>e</sup>	56 (5%)
Current smoker, n (%)	138 (13%)
Body mass index, kg/m <sup>2f</sup>	26 (23, 29)
Obese, body mass index ≥30 kg/m <sup>2</sup> , n (%) <sup>f</sup>	174 of 1041 (17%)
Relationship to recipient, n (%)	
Genetically related <sup>g</sup>	509 (49%)
Emotionally related <sup>h</sup>	362 (35%)
Paired	128 (12%)
Nondirect	43 (4%)

Note. Data presented as number (percent) or median (25th, 75th percentile). eGFR = estimated glomerular filtration rate; CKD-EPI = chronic kidney disease epidemiology collaboration; GFR = radionuclide glomerular filtration rate.

<sup>a</sup>Ethnicity (see Table S5, in Supplemental Digital Content 1).

<sup>b</sup>Obtained using the formula CKD-EPI eGFR.

<sup>c</sup>774 (74%) living kidney donors underwent a radionuclide glomerular filtration rate measurement.

<sup>d</sup>Participants completed home blood-pressure measurements following a standardized protocol.

<sup>e</sup>Hypertension<sup>31,32</sup> (see Table S2, in Supplemental Digital Content 1).

<sup>f</sup>Body mass index measured within 30 days before donor surgery (see Table S6, in Supplemental Digital Content 1). Body mass index was missing in 1 (<0.1%) donor.

<sup>g</sup>Defined as parent, sibling, offspring, grandparent, grandchild, aunt, uncle, niece, nephew, or cousin.

<sup>h</sup>Emotionally related includes spousal donors.

**Table 2.** Self-Reported Training and Experience of 43 of 48 Surgeons Who Together Performed a Total of 925 of 1042 Nephrectomies in This Study.

	n = 43
Surgical specialty, n (%)	
Urology	20 (47%)
Transplant	17 (40%)
Other <sup>a</sup>	6 (14%)
Training during residency or fellowship, n (%)	
Basic laparoscopic training <sup>b</sup>	37 (86%)
Advanced laparoscopic training <sup>c</sup>	30 (70%)
Laparoscopic donor nephrectomy	25 (58%)
Open donor nephrectomy	35 (81%)
Years of practice <sup>d</sup>	
Years of practice since end of fellowship	13 (8, 19)
Years of practice since first donor nephrectomy performed	11 (6, 16)
Nephrectomies performed per year, 2009-2014 <sup>e</sup>	
Number of complete living donor nephrectomies per year	15 (8, 24)
Number of complete tumor nephrectomies per year	4 (0, 20)
Most common technique used, 2009-2014, n (%)	
Pure laparoscopic	27 (63%)
Hand-assisted laparoscopic	9 (21%)
Open	7 (16%)
Proportion who indicated they were “experienced with performing the following type of living donor nephrectomies, 2009-2014,” <sup>f</sup> n (%)	
Left-sided laparoscopic	38 (88%)
Right-sided laparoscopic	33 (77%)
Pure laparoscopic	31 (72%)
Open living donor nephrectomy	25 (58%)
Hand-assisted laparoscopic	18 (42%)
Retroperitoneoscopic	3 (7%)
Medication preferences, 2009-2014, n (%)	
Preoperative antibiotics	41 (95%)
Intravenous heparin prior to cross-clamping	13 (30%)
Subcutaneous heparin to prevent venous thromboembolism	38 (88%)

Note. Data presented as number (percent) or median (25th, 75th percentile).

<sup>a</sup>General surgery, vascular surgery, and endocrine surgery.

<sup>b</sup>Diagnostic, cholecystectomy, and appendectomy.

<sup>c</sup>All other laparoscopic operations.

<sup>d</sup>Number of years since end of fellowship or first nephrectomy to the year 2014.

<sup>e</sup>Number of complete nephrectomies per year include nephrectomies performed outside this study.

<sup>f</sup>Level of agreement regarding personal experience while performing different types of living donor nephrectomies; 1 = strongly disagree, 5 = strongly agree; categories 1, 2, and 3 were grouped as “No” and categories 4 and 5 were grouped as “Yes.”

Overall, most complications were minor (90% of 142 complications); however, 12 donors (1% of 1042) experienced a major complication: 6 required conversion from a

laparoscopic to open procedure, and the remaining experienced a pulmonary embolism, splenectomy, myocardial infarction, surgical reintervention for wound dehiscence, or sepsis. Two of the 12 donors that experienced a major complication had both an intraoperative and a postoperative complication. The median length of hospital stay among donors who experienced a major complication was 5 days (4-6); donors with minor complications stayed 4 days (3-5), and donors with no complications stayed 3 days (4-6). Types of perioperative complications (intraoperative and postoperative combined) across clinical categories are presented in Table 4.

### Perioperative Complications In Relation to Donor Characteristics, Surgical Technique, Surgeon Characteristics, and Center Volume

The overall rate of perioperative complications (minor and major combined) was 13% (95% CI: 11%-15%) and the rate of major perioperative complications was 1% (95% CI: 1%-2%). The rate of perioperative complications (overall and major) are shown by donor characteristics, by surgical technique (Table 5), or by surgeon characteristics (Table 6). No statistically significant differences were observed between groups; however, given the low event rates, a larger sample size would be needed to detect minimally clinically important between-group differences. Of 689 (66%) nephrectomies that reported both intraoperative bleeding and vascular control technique, 337 (49%) used a transfixion technique and 352 (51%) used a nontransfixion technique. The proportion of donors in these groups with intraoperative bleeding exceeding 200 mL was 7% (22 of 337) and 6% (20 of 352), respectively. The rate of perioperative complications in donors whose nephrectomies were performed by surgeons who performed >10 vs ≤10 living kidney donor nephrectomies per year was 13% (95% CI: 9%-16%) and 13% (95% CI: 4%-23%), respectively (Table 6). The rate of perioperative complications in donors whose nephrectomies were performed in high-volume centers (≥20 living kidney donor nephrectomies per year) vs low-volume centers was 12% (102 of 824) and 15% (31 of 205), respectively; relative rate: 0.82 (95% CI: 0.55-1.22).

### Discussion

In our cohort of living kidney donors, 134 donors (13%) experienced a total of 142 perioperative complications (5% intraoperative and 8% postoperative). While 90% of complications were minor, 12 donors (1%) experienced a major complication. No donors died during the first 90 days after surgery, and no donors died as a result of a perioperative complication. We did not observe a significant difference in the overall rate of complications by the donors' demographic

**Table 3.** Perioperative<sup>a</sup> Complications in 1042 Living Kidney Donors (2004-2014).

Severity and type of complication <sup>b</sup>	n = 55
Intraoperative complications	
<b>Minor (Clavien-Dindo Grades I-II)</b>	<b>46 (84%)</b>
Organ injury	25 (45%)
Spleen laceration	10 (18%)
Pleural rent	10 (18%)
Bowel laceration <sup>c</sup>	5 (9%)
Bleeding with estimated blood loss >500 mL <sup>d</sup>	19 (35%)
Corneal abrasion	2 (4%)
<b>Major (Clavien-Dindo Grades III-IV)<sup>e</sup></b>	<b>9 (16%)</b>
Bleeding <sup>f</sup>	5 (9%)
Organ laceration	3 (5%)
Bowel laceration <sup>f</sup>	1 (2%)
Nerve	1 (2%)
Spleen <sup>f</sup>	1 (2%)
Myocardial infarction	1 (2%)
Severity and type of complication <sup>g</sup>	
n = 87	
Postoperative complications	
<b>Minor (Clavien-Dindo Grades I-II)</b>	<b>82 (94%)</b>
Gastrointestinal	31 (36%)
Ileus	30 (34%)
Partial obstruction	1 (1%)
Other <sup>h</sup>	14 (16%)
Renal/ureteral	14 (16%)
Unexpected elevated creatinine/dehydration	9 (10%)
Urinary retention	3 (3%)
Acute tubular necrosis	1 (1%)
Pitting edema	1 (1%)
Infectious	10 (11%)
Surgical site infection	6 (7%)
Urinary tract infection	3 (3%)
Hospital acquired pneumonia	1 (1%)
Respiratory	9 (10%)
Atelectasis	8 (9%)
Pulmonary edema	1 (1%)
Wound-related	2 (2%)
Allergic reaction	2 (2%)
Cardiovascular	2 (2%)
Hypertensive emergency	2 (2%)
<b>Major (Clavien-Dindo Grades III-IV)<sup>e</sup></b>	<b>5 (6%)</b>
Cardiovascular	3 (3%)
Pulmonary embolism	2 (2%)
Myocardial infarction	1 (1%)
Wound-related	1 (1%)
Wound dehiscence	1 (1%)
Infectious	1 (1%)
Sepsis	1 (1%)

Note. There were 142 perioperative complications in 134 donors, 55 donors had intraoperative complications, 87 had postoperative complications, and 8 had both.

<sup>a</sup>Includes both intraoperative and postoperative complications.

<sup>b</sup>Severity of intraoperative using a modified version of the Clavien-Dindo classification.<sup>22,25</sup>

<sup>c</sup>Laceration only penetrated the bowel's serosa.

<sup>d</sup>All intraoperative bleeding required the use of transfusion techniques, nontransfusion techniques, or both.

<sup>e</sup>Two of the 12 donors that experienced a major complication had both intraoperative and postoperative complications. Major complications required an unplanned surgical intervention, were life-threatening, or resulted in permanent disability.

<sup>f</sup>Required conversion to open or had hemodynamic instability.

<sup>g</sup>Severity of postoperative complications graded according to the Clavien-Dindo classification.<sup>25</sup>

<sup>h</sup>Excessive pain, hematoma nephrectomy bed, lower extremity edema, lower limb paresthesia, rectus sheath hematoma, rhabdomyolysis, vertigo, anemia, and nonspecified fever.



**Table 4.** Perioperative<sup>a</sup> complications in 1042 living kidney donors (2004-2014).

Type of complication	n = 142 <sup>b</sup>
Gastrointestinal	31 (22%)
Ileus	30 (21%)
Partial obstruction	1 (1%)
Organ injury	28 (20%)
Spleen laceration	11 (8%)
Bowel laceration	6 (4%)
Transection of the femoral nerve	1 (1%)
Pleural rent	10 (7%)
Bleeding <sup>c</sup>	24 (17%)
Estimated blood loss $\geq$ 500 mL	19 (13%)
With hemodynamic instability	5 (4%)
Other <sup>d</sup>	16 (11%)
Renal/Ureteral	14 (10%)
Unexpected elevated creatinine/dehydration	9 (6%)
Urinary retention	3 (2%)
Acute kidney injury/acute tubular necrosis	1 (1%)
Fluid overload	1 (1%)
Infectious	11 (8%)
Surgical site infection	6 (4%)
Urinary tract infection	3 (2%)
Hospital acquired pneumonia	1 (1%)
Sepsis	1 (1%)
Respiratory	9 (6%)
Atelectasis	8 (6%)
Pulmonary edema	1 (1%)
Cardiovascular	6 (4%)
Pulmonary embolism	2 (1%)
Myocardial Infarction	2 (1%)
Hypertensive emergency	2 (1%)
Dermatological	3 (2%)
Allergic reaction	2 (1%)
Wound dehiscence	1 (1%)

<sup>a</sup>Includes both intraoperative and postoperative complications.

<sup>b</sup>There were 142 perioperative complications in 134 donors; 55 donors had intraoperative complications, 87 had postoperative complications, and 8 had both.

<sup>c</sup>All intraoperative bleeding required the use of transfusion techniques, nontransfusion techniques, or both.

<sup>d</sup>Excessive pain, hematoma nephrectomy bed, lower extremity edema, lower limb paresthesia, rectus sheath hematoma, rhabdomyolysis, or vertigo.

or predonation health characteristics or by their surgeon's training or experience.

In previous studies, the incidence of perioperative complications in living kidney donors has ranged from 8% to 18%.<sup>2-6</sup> Reasons for this variation may be explained by differences in ascertainment methodology and in the way perioperative complications were defined (eg, some studies used more liberal or restrictive definitions). As well, studies with higher complication rates tended to have a higher proportion of donors with risk factors such as non-white race, obesity,

and hypertension.<sup>5</sup> The overall perioperative complication rate in our study (13%) is similar to the rate reported in a prospective cohort study of 1649 donors in Switzerland (1998-2015), which reported an overall rate of 13.5%.<sup>18</sup> A study of 69 117 living kidney donors in the National Inpatient Sample in the United States reported a perioperative complication rate of 7.9% (1998-2010); however, only procedure-related complications were included in the outcome.<sup>2</sup> In a study of 14 964 donors from the United States, transplant registry (2008-2012), the overall perioperative complication was 16.8%.<sup>5</sup> This higher rate might be explained by the comprehensive analysis of all diagnostic and procedural codes in the donors' medical charts, which may have resulted in a more sensitive capture of perioperative complications. In our study, 12 donors (1% of 1042) had a major perioperative complication, which is lower than that reported by Patel et al (4.2%)<sup>3</sup>; however, our study used a more stringent definition of major complications (ie, complications that required an intervention and were life-threatening or resulted in permanent disability). In contrast, in the study by Patel et al, a complication was classified as major only if an intervention was required (without specifying whether the complication was life-threatening).<sup>26</sup>

In our study, the most common type of intraoperative complication was organ injury (50% of 55 intraoperative complications [45% minor and 5% major] and 20% of all 142 perioperative complications). The most common postoperative complication was ileus (34% of 87 postoperative complications [all minor] and 21% of all 142 perioperative complications).

In contrast to this study, previous studies have reported that predonation hypertension and obesity were significantly associated with increased rates of perioperative complications in living kidney donors.<sup>2,5,6,33</sup> Whereas we defined obesity as a BMI  $\geq$ 30 kg/m<sup>2</sup>, some previous studies defined obesity as a BMI  $\geq$ 35 kg/m<sup>2</sup>, and it is possible that other studies had a higher percentage of donors with a BMI  $\geq$ 35 kg/m<sup>2</sup> (only 2% of donors in our study had a BMI  $>$ 35 kg/m<sup>2</sup>).<sup>33</sup> It is also possible that the risk from obesity and hypertension is augmented by other factors, such as older age, non-white ethnicity, or other predonation risk factors that were not as common in our cohort.<sup>12</sup> In our study, the complication rate in hypertensive donors was 3% higher than in nonhypertensive donors; however, the CI for the difference was wide, indicating a lack of precision.

The two most common techniques for vascular control of the renal artery are staplers (transfusion) and surgical clips (nontransfusion).<sup>34</sup> Whereas our study showed similar rates of bleeding for these 2 techniques (7% vs 6%, respectively, when defined by  $>$ 200 mL of blood loss), other studies have shown a higher bleeding risk when clips are used.<sup>21,34</sup> Furthermore, due to documented fatal outcomes with the use of the Hem-o-lok<sup>®</sup> ligating clip in laparoscopic donor nephrectomies, the U.S. Food and Drug Administration (FDA) issued a Black Box warning on the use of this clip in

**Table 5.** Perioperative<sup>a</sup> Complications in Relation to Donor Characteristics.

	No. surgeries	Donors with minor or major complications	Donors with major complications
		No. (%; 95% CI) <sup>b</sup>	No. (%; 95% CI) <sup>b</sup>
Overall	1042	134 (13, 11-15)	12 (1%, 1%-2%)
Demographic characteristics			
Age at donation, years			
<40	270	31 (12, 8-15)	2 (1, 0-3)
40-60	646	87 (13, 11-16)	8 (1, 1-2)
>60	126	16 (13, 8-18)	2 (2, 0-6)
Sex			
Female	691	85 (12, 10-15)	6 (1, 0-2)
Male	351	49 (14, 11-17)	6 (2, 0-3)
Ethnicity			
White	907	122 (13, 11-16)	11 (1, 1-2)
Non-white	135	12 (9, 3-14)	1 (1, 0-4)
Relationship to recipient			
Genetically related <sup>c</sup>	509	61 (12, 9-15)	8 (2, 1-3)
Emotionally related <sup>d</sup>	362	55 (15, 12-19)	3 (1, 0-2)
Paired/nondirected	171	18 (11, 7-16)	1 (1, 0-4)
Predonation health characteristics			
eGFR, mL/min/1.73 m <sup>2</sup>			
>80	894	113 (13, 10-15)	10 (1, 1-2)
<80	148	21 (14, 6-22)	2 (1, 0-5)
Hypertension <sup>e</sup>			
No	986	124 (13, 11-15)	11 (1, 1-2)
Yes	56	10 (18, 7-29)	1 (2, 0-10)
Obese <sup>f</sup> , BMI ≥30 kg/m <sup>2</sup>			
No	868	113 (13, 11-15)	12 (1, 1-2)
Yes	174	21 (12, 8-16)	0 (0, 0-2)
Current smoker			
No	904	122 (14, 11-16)	10 (1, 1-2)
Yes	138	12 (9, 4-12)	2 (1, 0-5)
Scheduled surgical technique <sup>g</sup>			
Pure laparoscopic	806	97 (12, 9-15)	10 (1, 1-2)
Open	139	26 (19, 6-32)	2 (2, 0-5)
Hand-assisted laparoscopic	97	11 (11, 5-18)	0 (0, 0-4)

Note. CI = confidence interval; eGFR = estimated glomerular filtration rate; BMI = body mass index.

<sup>a</sup>Includes both intraoperative and postoperative complications.<sup>25,26</sup>

<sup>b</sup>Rates were computed using predictive margins from a multivariable logistic regression model and compared between groups; the percentage of complications for smokers and nonsmokers was significantly different ( $P = .0305$ ). For donor characteristics, where the number of events in one or more of the groups is <5, exact confidence intervals were computed.

<sup>c</sup>Donor is a biologic parent, sibling, offspring, grandparent, grandchild, aunt, uncle, niece, nephew, or cousin of the recipient.

<sup>d</sup>Emotionally related includes spousal donors.

<sup>e</sup>Hypertension<sup>31,32</sup> (see Table S2, in Supplemental Digital Content 1).

<sup>f</sup>Weight was measured within 30 days before the donor's nephrectomy. One donor missing weight and was assumed to be nonobese.

<sup>g</sup>Nine (<1%) of the planned laparoscopic surgeries were converted to open, 3 performed as a preventive measure. Pure laparoscopic includes 6 cases of robotic-assisted nephrectomies.

2006.<sup>35</sup> One explanation for the lack of difference in bleeding risk between these 2 techniques in our study is that 94% of surgeries that used surgical clips used multiple clips, and only 35 surgeries (3% of 1042) used Hem-o-lok<sup>®</sup> clips alone for securing the renal artery, limiting the statistical power to detect differences. We agree with the FDA ruling and believe

that it is vital for all transplant programs to update their existing practices to minimize the risk of donor harm.

While previous studies (in general—not specific to living donor nephrectomies) have shown an inverse association between surgeon/center volume and perioperative complications,<sup>15,36,37</sup> in this study, donors whose surgeons

**Table 6.** Perioperative<sup>a</sup> Complications in Relation to Surgeon Characteristics.

	No. surgeons	No. surgeries	Donors with minor or major complications	Donors with major complications
			No. (%; 95% CI) <sup>b</sup>	No. (%; 95% CI) <sup>b</sup>
Overall	43	925	118 (13, 10-15)	12 (1, 1-2)
Surgical specialty				
Urology	20	528	71 (13, 11-16)	6 (1, 0-2)
Transplant	17	287	31 (11, 6-16)	4 (1, 0-4)
Other <sup>c</sup>	6	110	16 (14, 10-19)	2 (2, 0-6)
Training during residency or fellowship				
Basic laparoscopic training <sup>d</sup>				
Yes	37	844	108 (13, 11-16)	10 (1, 1-2)
No	6	81	10 (9, 2-15)	2 (2, 0-9)
Advanced laparoscopic training <sup>e</sup>				
Yes	30	707	86 (12, 10-15)	8 (1, 0-2)
No	13	218	32 (14, 9-18)	4 (2, 1-5)
Laparoscopic donor nephrectomy				
Yes	25	658	79 (12, 9-15)	7 (1, 0-2)
No	18	267	39 (14, 10-18)	5 (2, 1-3)
Open donor nephrectomy				
Yes	35	771	100 (13, 11-15)	8 (1, 0-2)
No	8	154	18 (12, 6-17)	4 (3, 1-7)
Years of practice <sup>f</sup>				
Years of practice since end of fellowship				
>10 years	27	587	84 (14, 11-17)	5 (1, 0-3)
≤10 years	16	338	34 (10, 7-14)	7 (1, 0-4)
Years of practice since first nephrectomy performed				
>10 years	22	529	68 (12, 10-15)	4 (1, 0-2)
≤10 years	21	396	50 (14, 9-18)	8 (1, 0-3)
Number of nephrectomies performed per year (2009-2014) <sup>g</sup>				
Living donor nephrectomies				
>10	26	720	85 (13, 9-16)	9 (1, 0-2)
<10	17	205	33 (13, 4-23)	3 (2, 0-3)
Tumor nephrectomies				
>10	17	434	49 (11, 9-14)	5 (1, 0-2)
<10	26	491	69 (14, 11-18)	7 (1, 0-2)
Most common technique used (2009-2014)				
Pure laparoscopic	27	718	85 (13, 8-19)	11 (2, 1-3)
Hand-assisted laparoscopic	9	66	9 (16, 6-27)	0 (0, 0-5)
Open	7	141	24 (10, 0-21)	1 (1, 0-4)
Experience performing living donor nephrectomies (2009-2014) <sup>h</sup>				
Left-sided laparoscopic				
Yes	38	825	101 (13, 10-15)	11 (1, 1-2)
No	5	100	17 (14, 4-24)	1 (1, 0-5)
Right-sided laparoscopic				
Yes	33	791	97 (12, 10-15)	11 (1, 1-2)
No	10	134	21 (14, 6-22)	1 (1, 0-4)
Pure laparoscopic				
Yes	31	811	104 (13, 11-16)	11 (1, 1-2)
No	12	114	14 (9, 4-14)	1 (1, 0-5)
Open living donor nephrectomy				
Yes	25	548	71 (12, 9-15)	8 (1, 1-3)
No	18	377	47 (14, 10-17)	4 (1, 0-3)

(continued)

**Table 6. (continued)**

	No. surgeons	No. surgeries	Donors with minor or major complications	Donors with major complications
			No. (%; 95% CI) <sup>b</sup>	No. (%; 95% CI) <sup>b</sup>
Hand-assisted laparoscopic				
Yes	18	355	36 (11, 7-14)	2 (1, 0-2)
No	25	570	82 (14, 11-17)	10 (2, 1-3)
Retroperitoneoscopic				
Yes	3	70	12 (19, 9-29)	1 (1, 0-8)
No	40	855	106 (12, 10-14)	11 (1, 1-2)
Medication preferences(2009-2014)				
Preoperative antibiotics				
Yes	41	889	114 (13, 11-15)	12 (1, 1-2)
No	2	36	4 (11, 3-26)	0 (0, 0-10)
Intravenous heparin prior to cross-clamping				
Yes	13	177	19 (11, 5-18)	2 (1, 0-4)
No	30	748	99 (13, 11-15)	10 (1, 1-2)
Subcutaneous heparin for venous thromboembolic prophylaxis				
Yes	38	875	111 (13, 10-15)	12 (1, 1-2)
No	5	50	7 (17, 5-30)	0 (0, 0-7)

Note. Clustering of donors within surgeons was accounted for using generalized estimating equations with an exchangeable correlation structure. For 5 (10%) surgeons who did not respond to the survey, we searched university and hospital databases to obtain year of graduation from subspecialty. This was not available for 2 (4%) of the surgeons, and we obtained data on date of completion of surgical subspecialty through personal websites that are accessible to the public. CI = confidence interval.

<sup>a</sup>Includes both intraoperative and postoperative complications.

<sup>b</sup>Rates were computed using predictive margins from a multivariable logistic regression model and compared between groups; there were no statistically significant differences between groups. For surgeon characteristics where the number of events in one or more of the groups is <5, exact confidence intervals were computed.

<sup>c</sup>General surgery, vascular surgery, and endocrine surgery.

<sup>d</sup>Defined as training in diagnostic laparoscopy, cholecystectomy, and appendectomy.

<sup>e</sup>All other laparoscopic operations.

<sup>f</sup>Number of years since end of fellowship or first nephrectomy to the year 2014.

<sup>g</sup>Number of complete nephrectomies per year includes nephrectomies performed outside this study.

<sup>h</sup>Level of agreement regarding personal experience while performing different types of living donor nephrectomies; 1 = strongly disagree, 5 = strongly agree; categories 1, 2, and 3 were grouped as "No" and categories 4 and 5 were grouped as "Yes."

performed >10 vs ≤10 living donor nephrectomies per year had the same rate of perioperative complications (13%). In a similar way, the relative risk of perioperative complications between high- and low-volume centers was not statistically significant (0.82 [95% CI: 0.55-1.22]). The low rate of complications despite low surgeon or center volume might be related to an overall increasing attention devoted to donors' safety and to the fact that donors' surgeons are also performing comparable or more difficult surgeries.

In this study, 14% and 30% of surgeons reported a lack of basic or advanced laparoscopic training during residency/fellowship, respectively, and 12% of surgeons reported a lack of experience performing laparoscopic donor nephrectomies. However, the rate of perioperative complications did not vary significantly with the surgeons' self-reported training and experience. This suggests that a variety of training pathways can produce surgeons who safely perform donor nephrectomies.

Our study has several strengths. This multicenter cohort study of 1042 living donor nephrectomies from 2004 to 2014

in 17 centers in Canada and Australia is one of the largest of its kind to date (an earlier cohort study conducted in Switzerland between 1998 and 2015, followed a registry-based cohort of 1649 donors).<sup>18</sup> In contrast to major previous studies, which typically relied on the use of administrative data, our manual abstraction of operative and discharge notes allowed for a more specific capture of perioperative complications, particularly minor complications that might otherwise be missed. We included both intraoperative and postoperative complications. We also surveyed 90% of the surgeons who performed the nephrectomies for donors in this study; few prior studies have examined the characteristics of surgeons performing living donor nephrectomies and whether these characteristics associate with perioperative complications.<sup>31,32,38,39</sup>

Our study has several limitations. First, although medical charts and surgical notes contain detailed information on perioperative complications, operative and discharge reporting is not standardized and varies among surgeons. For example, while some surgeons provide detailed notes (eg, type of clips used: metallic, plastic, etc), others report only

the use of a clip (but not the material). Future intrahospital and interhospital comparisons would be enabled by standardizing the operative and discharge notes in routine living kidney donor care. Second, it is possible we missed some complications if they were recorded elsewhere in the donors' medical charts; however, we would expect these complications to be minor. Third, the online survey completed retrospectively by the surgeons was not validated, and therefore, its content and construct validity are unknown. Measurement error resulting from faulty recall or inaccurate responses to survey items may have made it difficult to detect associations between surgeon training and experience and perioperative complications in donors; however, we tried to decrease this by limiting recall to a more contemporary era (2009-2014). Fourth, our convenience sample of donors lacked the statistical power to detect small differences between subgroups.

In conclusion, this study confirms the perioperative safety of living kidney donation in modern practice. Approximately 13% of donors experienced a perioperative complication, but only 1% experienced a major complication. This information may inform quality improvement initiatives and informed consent.

### List of Abbreviations

AKI, acute kidney injury; ATN, acute tubular necrosis; BMI, body mass index; CKD-EPI, chronic kidney disease epidemiology collaboration; eGFR, estimated glomerular filtration rate; GFR, glomerular filtration rate (radionuclide); EBL, estimated blood loss; No., number.

### Ethics Approval and Consent to Participate

All participants provided written, informed consent. Ethics approval was obtained from Western University's Research Ethics Board (REB approval # 6056) and all enrolling centers.

### Consent for Publication

Consent for publication was obtained from all authors.

### Availability of Data and Materials

Not available.

### Author Contributions

C.G.-O. participated in data abstraction, research design, performance and writing; L.F. participated in research design and performance; C.N. participated in research design and performance; M.M.-C. participated in research design and performance; J.A. participated in data abstraction and research performance; N.B. participated in research design; C.D. participated in research design; M.E. participated in research design; J.G. participated in research design; W.G. participated in research design; M.K. participated in research design; S.K. participated in research design; M.C. participated in data analysis; G.K. participated in research design; K.L. participated in research design; C.L. participated in research design; P.L. participated in research design; R.P. participated in research design;

A.S. participated in research design; J.S. participated in research design and writing of the paper; L.S. participated in research design; D.T. participated in research design; A.G. participated in obtaining research funding, research design, and performance.



### Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr Amit Garg was supported by the Dr Adam Linton Chair in Kidney Health Analytics and a Canadian Investigator Award from the Canadian Institutes of Health Research (CIHR) and received operating grant support from the CIHR, which included partnership funding from Astellas for data collection. Dr Liane S. Feldman received investigator-initiated research grants from Merck and Johnson & Johnson and an educational grant from Medtronic.

### Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the Canadian Institutes of Health Research (CIHR; grant number MOP 130308) and Astellas Canada (grant number SG-156).

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### Supplemental Material

Supplemental material for this article is available online.

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