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SEGMENTAL ISCHEMIA AND INDOCYANINE GREEN NAVIGATION: IMPACT ON PERIOPERATIVE PARAMETERS IN LAPAROSCOPIC VS. OPEN PARTIAL NEPHRECTOMY

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Ключові слова: *ниркова пухлина, резекція нирки, сегментарна ішемія, лапароскопія, відкрита хірургія, періопераційні показники, швидкість клубочкової фільтрації, індоціанін зелений*

Abstract. Segmental ischemia and indocyanine green navigation: impact on perioperative parameters in laparoscopic vs. open partial nephrectomy. Molchanov R.M., Honcharuk O.O., Khareba G.G., Blyuss O.B., Duka R.V. *The aim of this study is to compare perioperative parameters of laparoscopic partial nephrectomy and open partial nephrectomy in renal tumor management, and to evaluate the effect of using novel method of indocyanine green navigation in segmental ischemia on these parameters. The prospective study included 455 patients (89 laparoscopic partial nephrectomies, 366 open partial nephrectomies). Sub-groups (n=39, 32, 18) in Laparoscopic partial nephrectomy employed diverse ischemia techniques, including full warm ischemia, segmental ischemia with indocyanine green navigation and segmental ischemia without navigation. Parameters assessed encompassed estimated blood loss, operative time, warm ischemia time, and changes in estimated glomerular filtration rate. Covariate-balancing propensity scores ensured homogeneity. Statistical analysis included the Wilcoxon signed-rank test, for two matched groups. Two-sided p-values were reported for all statistical tests, a p-value <0.05 was considered to be statistically significant. The findings of the conducted research indicate that open partial nephrectomy has revealed significant differences in estimated blood loss, operative time, and warm ischemia time, in favor of open partial nephrectomy. Laparoscopic partial nephrectomy offers advantages in preserving renal function and minimizing estimated Glomerular Filtration Rate decline compared to open partial nephrectomy. The utilization indocyanine green navigation, facilitates precise and limited ischemia, contributing to enhanced preservation of renal function. Surgeons must weigh these considerations for optimal renal tumor management.*

Реферат. Сегментарна ішемія та навігація з індоціаніном зеленим: вплив на періопераційні параметри при порівнянні лапароскопічної та відкритої часткової нефректомії. Молчанов Р.М., Гончарук О.О., Хареба Г.Г., Блюсс О.Б., Дука Р.В. *Метою цього дослідження є порівняння періопераційних параметрів лапароскопічної часткової нефректомії та відкритої часткової нефректомії при лікуванні пухлин нирки, а також оцінити вплив використання нового методу навігації з використанням індоціаніну зеленого при сегментарній ішемії на ці параметри. Проспективно-ретроспективне дослідження включало 455 пацієнтів (89 лапароскопічних резекцій нирки, 366 відкритих резекцій нирки). У підгрупах (n=39, 32, та 18) при лапароскопічній резекції нирки використовували різні методи ішемії, включаючи тотальну теплову ішемію,* *сегментарну ішемію з навігацією індоціаніном зеленим та сегментарну ішемію без флуорисцентної навігації. Оцінювалися параметри, такі як об'єм крововтрати, тривалість операції, час теплової ішемії і зміни швидкості клубочкової фільтрації. Рівномірність забезпечували оцінкою схильності коваріант-балансування. Для статистичного аналізу використовували непараметричний критерій Вілкоксона для відповідних вибірок з двосторонніми p-значеннями. Значення p<0,05 вважалося статистично значущим. У результаті проведеного дослідження було визначено, що відкрита резекція нирки має значущу різницю в обсягу втрати крові, тривалості операції та часі теплової ішемії на користь відкритої резекції нирки. Лапароскопічна резекція нирки має переваги в збереженні функції нирок та в мінімізації зниження швидкості клубочкової фільтрації порівняно з відкритою резекцією нирки. Використання навігації індоціаніном зеленим сприяє точній та обмеженій ішемії, що покращує збереження функції нирок. Хірурги повинні ретельно оцінювати ці умови для оптимального лікування пухлин нирок.*

In recent decades, there has been a a significant increase in the global incidence of kidney cancer [1]. In response to this prevailing trend, the medical field has intensified its efforts to develop effective therapeutic strategies. Among the array of available options, surgery has emerged as a primary foundation for addressing localized kidney cancers. Specifically, partial nephrectomy (PN) and radical nephrectomy (RN) have ascended as pivotal surgical modalities, each possessing distinct roles in the management of renal tumors [2, 3].

At the present stage, PN remains the gold standard for treating localized renal tumors (cT1-2) [2, 8]. Although minimally invasive techniques offer several advantages, open radical nephrectomy (ORN) still holds an advantage, especially for complex tumors located in challenging areas such as the renal hilum [6, 7]. Due to the development of minimally invasive techniques, laparoscopic partial nephrectomy (LPN) has emerged as an alternative to traditional open procedures, offering reduced postoperative morbidity and comparable oncological results while preserving kidney parenchyma [4, 5, 9].

To evaluate the effectiveness of PN, three key aspects are considered: complete tumor removal, minimal warm ischemia time (less than 20 minutes), and absence of perioperative complications [11]. Warm ischemia, induced by clamping the renal artery, is an integral part of PN [10]. Therefore, to minimize ischemic kidney damage and preserve its function, a "zero-ischemia" technique has been developed [12]. One of the techniques under this category is segmental ischemia, which has become a promising direction, thanks to the use of intraoperative navigation with indocyanine green (ICG) [17, 21, 24]. This dynamic approach aims to limit ischemic impact and enhance surgical precision.

The aim of this study is to compare perioperative parameters of laparoscopic partial nephrectomy and open partial nephrectomy in renal tumor management, and to evaluate the effect of using novel method of indocyanine green navigation in segmental ischemia on these parameters.

MATERIALS AND METHODS OF RESEARCH

The study encompassed 455 patients diagnosed with renal tumors, confirmed by contrast-enhanced CT scans. Between 2018 and 2022, a prospective study included 89 patients who underwent laparoscopic partial nephrectomy (LPN), categorized into three sub-groups based on the warm ischemia technique: IA (n=39) with full ischemia via main renal artery clamping; IB (n=32) underwent segmental ischemia through segmental renal artery clamping using ICG navigation and IC (n=18) without it. Classification was based on renal blood circulation anatomy, such as the presence of segmental arteries identified by computer tomography data, enabling the application of segmental ischemia. The selection of participants for subgroups of segmental ischemia was carried out through random sampling.

All patients underwent transperitoneal (laparoscopic) partial nephrectomy under general anesthesia. After exposing the kidney and its vessels in the hilum, an incision of the renal capsule at the tumor border was made, followed by common or segmental renal artery clamping with a "Bulldog" clamp using standard techniques. For ICG-guided navigation in the IB subgroup, 25 mg of Indocyanine green (ICG) dye (Verdye) was utilized alongside IMAGE1 S™ 4K Rubina™ KARL STORZ equipment. Intravenous injection of 12.5 mg of ICG facilitated identification of the ischemic zone with the tumor in 2-3 minutes [24].

Enucleoresection occurred within the tumor capsule zone, preserving a 1-2 mm margin of normal parenchymal tissue. "Cold" scissors were used for precise visualization of surgical margins. Control of intraparenchymal vessels was performed using clips (Absolock, Ethicon, or Hem-o-lok®). A 3-0 polyglycolic acid running suture secured with Hem-o-lok® clips was placed in the tumor bed area. A second suture line, using a 0 polyglycolic acid suture, closed the parenchymal defect. After applying the suture to the parenchyma in the tumor bed area, arterial clamps were released. In group IIA blood flow was monitored in the resection zone through a repeated 12.5 mg ICG intravenous injection. All LPN procedures were performed by the same expert senior surgeon.

To select comparative Group II patients, data from 366 patients with renal tumors subjected to open partial nephrectomy between 2013-2019 were used. These procedures were performed by three senior surgeons in a high-volume urological center where laparoscopy was unavailable. For all 366 patients, open partial nephrectomy as enucleoresection within healthy margins was conducted through a transabdominal approach with warm ischemia provided via clamping of the renal artery. Intraoperative management of intraparenchymal vessels utilized a 3-0 polyglycolic acid running suture in the tumor bed area, followed by the removal of arterial clamps. A second suture line, using a 0 or 1 polyglycolic acid suture, closed the parenchymal defect.

Demographic data, Charlson comorbidity scale score, and ASA scores were collected [25]. Preoperative contrast-enhanced CT scans determined tumor size and localization. The estimated glomerular filtration rate (eGFR) was calculated using the MDRD formula based on blood creatinine levels at baseline and on postoperative (PO) day 4-5. Percentage eGFR change was [(PO eGFR-baseline eGFR)/baseline eGFR] [14]. Tumor characteristics were assessed through routine postoperative histopathological examination. Operative time (OT) and estimated blood loss (EBL) were documented. Complications were categorized using the Clavien–Dindo classification system [15].

To establish uniform groups for covariate comparison, an analysis using propensity score matching (PSM) was conducted. PSM serves as an alternative approach to estimate treatment effects in observational studies, considering the conditional likelihood of choosing a particular treatment. This technique entails creating matched sets of patients undergoing various treatments with similar propensity scores. A propensity score is essentially the likelihood of being assigned a specific treatment, given the observed baseline characteristics. Matching based on propensity scores ensures that the distribution of these baseline characteristics is comparable across the studied groups, thus minimizing bias in comparative analysis. The propensity score for each patient was calculated by integrating continuous and categorical variables, using a multivariate logistic regression model. This model incorporated variables such as patient age, gender, body mass index, baseline estimated glomerular filtration rate (eGFR), and the largest tumor size. Patients in Group I (undergoing laparoscopic partial nephrectomy, LPN) were paired in a 1:1 ratio with those in Group II (undergoing open partial nephrectomy, OPN) based on the logit transformation of their propensity scores. This matching used a greedy, nearest-neighbor algorithm with a caliper width set at 0.285, equivalent to 20% of the standard deviations of the logit-transformed scores, and was executed without replacement.

The effectiveness of the PSM process was evaluated by calculating the standardized mean difference (SMD) in propensity scores between matched pairs, along with comparing baseline covariates and cumulative distribution functions of the scores for each matched set. Both p-values and SMD were employed for intergroup comparisons, with an SMD greater than 0.1 (10%) signifying a significant imbalance.

Clinical data were presented as medians within interquartile ranges. Following the matching, surgical methods were compared using the Wilcoxon signed-rank test, a statistical method used for comparing two related or matched samples, or for analyzing repeated measurements on a single sample to determine if their average ranks are significantly different [26, 27].

A two-sided $p<0.05$ was deemed to indicate statistical significance. PS-matching and statistical analysis were performed using R version 3.5.1., GNU GENERAL PUBLIC LICENSE, Version 3, 29 June 2007.

Written informed consent for the study was obtained from all patients, in accordance with the Helsinki Declaration of the World Medical Association on ethical principles for conducting medical research involving human subjects (1964–2008), the directive of the European Community 86/609 regarding the participation of humans in biomedical research, as well as the order of the Ministry of Health of Ukraine with amendments No. 690 dated September 23, 2009.

The conduct of the study was approved by the Ethics and Bioethics Committee of Dnipro State Medical University (research protocol No. 6 dated October 4, 2019).

RESULTS AND DISCUSSION

The comparative analysis of perioperative indicators between laparoscopic partial nephrectomy (LPN) and open partial nephrectomy (OPN) provides insights into the complex landscape of renal tumor treatment. Our study assessed such parameters as estimated blood loss, operative time, warm ischemia time, and post-operative changes in estimated glomerular filtration rate (eGFR).

Group 2 patients underwent partial nephrectomy using full warm ischemia achieved through clamping the main renal artery. On the contrary, Group 1 was divided into three sub-groups: Group 1A experienced complete ischemia with main renal artery clamping; Group 1B underwent segmental ischemia with clamping of segmental renal arteries using ICG navigation; and Group 1C experienced segmental ischemia without ICG navigation. Subsequently, Group 1A was matched with Group 2, 39 patients being in each group. Similarly, Group 1B was matched with Group 2, as were Group 1C and Group 2. For each matched comparison, the types of surgeries were evaluated using the Wilcoxon signed-rank test, and two-sided p-values were recorded. The comparison results are detailed in Tables 1-4.

The evaluation of changes in estimated glomerular filtration rate (eGFR) provides valuable insights into post-surgery renal function. Notably, Group 1 (LPN) consistently exhibited smaller changes with a median value of 66 [56–80] in eGFR compared to Group 2 (OPN) with a median value of 57.2 [46.9-66.6]. Both the absolute change in eGFR and its percentage change revealed significant differences between the groups. Group 1 (LPN) displayed a smaller change in eGFR with a median value of -10 [-21-1.2], in comparison to Group 2 (OPN) with a median value of -20.1 [-26.7-8.3] (Table 1). The statistically significantly higher values of post-surgery eGFR were also found in all laparoscopic sub-groups. This observation suggests that laparoscopic approaches might be associated with relatively better preservation of renal function compared to open surgery. This finding aligns with studies emphasizing the renoprotective benefits of minimally invasive approaches [21]. LPN's precision and reduced renal parenchymal trauma contribute to the preservation of renal function. This supports the findings of research that segmental renal artery clamping under ICG guidance enables precise and limited ischemia, contributing to enhanced preservation of renal function [21, 24]. This underlines the evolving role of intraoperative navigation in refining surgical techniques and optimizing outcomes.

Table 1

Results of comparative analysis of perioperative indicators between laparoscopic partial nephrectomy and open partial nephrectomy

Variables	Group 1 LPN (n=89)	Group 2 OPN (n=366)	p-value
Estimated blood loss, ml, median (IQR)	200 [100; 500]	100 [100; 120]	*<0.001
Operative time, min, median (IQR)	160 [135; 190]	100 [90; 120]	*<0.001
Warm ischemia time, min, median (IQR)	20 [14; 23]	10 [6; 15]	*<0.001
eGFR at follow-up, mL/min/1.73m^2 , median (IQR)	66 [56; 80]	57.2 [46.9; 66.6]	*<0.001
Change in eGFR, mL/min/1.73m^2 , median (IQR)	-10 [-21; 1.2]	-20.1 [-26.7; -8.3]	*<0.001
Change in eGFR (%), median (IQR)	-0.13 [-0.26; 0.01]	-0.26 [-0.35; -0.11]	*<0.001

Note: * – significant differences (p<0.05).

The comparison of estimated blood loss (EBL) between the groups reveals significant differences. Group 1 (LPN) exhibited notably higher EBL with a median value of 200 [100-500] mL compared to Group 2 (OPN) with a median value of 100 [100-120] mL. The same pattern is observed for sub-groups 1A and 1C with a p-value less than 0.001, while in sub-group 1B, no statistically significant differences in EBL were found as compared to Group 2 (p=0.065) (Tables 2-4). None of the patients from either group required blood transfusion. This variance can be attributed to the minimally invasive nature of laparoscopic techniques, which generally lead to reduced surgical trauma and associated blood loss. However, it is essential to note that EBL is a multifaceted parameter influenced by various factors, including surgical technique, tumor size, and patient characteristics.

The significantly higher estimated blood loss in the LPN group contradicts the common perception of laparoscopy as a minimally invasive technique with reduced blood loss. Although some studies associate laparoscopic techniques with lower blood loss [7], our findings align with those of Kartal et al., who reported increased blood loss in LPN [16]. On one hand, potential explanations for sub-group 1A could involve the technical intricacies of laparoscopic dissection, especially in case of intraparenchymal tumors, leading to inadvertent vascular injury [19]. On the other hand, segmental ischemia, while preserving partial blood circulation in the kidney, often fails to entirely exclude the tumor-bearing part of the kidney from the blood supply, ultimately resulting in increased blood loss (sub-group 1C). The introduction of ICG/NIR navigation facilitates visualization of ischemic margins, aiding in initiating tumor excision within the ischemic zone, minimizing the time of excision within the area of preserved blood circulation, and performing intraparenchymal clipping of vessels feeding the tumor. This approach contributes to a reduction in blood loss.

Table 2

Results of comparative analysis of perioperative indicators between laparoscopic partial nephrectomy with full ischemia and open partial nephrectomy

Variables	Group 1A LPN (full ischemia) (n=39)	Group 2 OPN (n=39)	p-value
Estimated blood loss, median (IQR)	250 [150; 500]	100 [100; 110]	*0.003
Operative time, median (IQR)	155 [140; 180]	100 [90; 117.5]	*<0.001
Warm ischemia time, median (IQR)	20 [16; 23.5]	11 [7; 14.5]	*<0.001
eFGR at follow-up, mL/min/1.73m^2 , median (IQR)	61 [52.6; 71.5]	49.4 [42.4; 58.1]	*<0.001
Change in eGFR, mL/min/1.73m^2 , median (IQR)	-11.9 [-22.8; -4.1]	-19.8 [-25.7; -11.2]	0.062
Change in eGFR (%), median (IQR)	-0.16 [-0.27; -0.05]	-0.28 [-0.34; -0.17]	*0.007

Note: * – significant differences (p<0.05).

The significantly higher estimated blood loss in the LPN group contradicts the common perception of laparoscopy as a minimally invasive technique with reduced blood loss. Although some studies associate laparoscopic techniques with lower blood loss [7], our findings align with those of Kartal et al., who reported increased blood loss in LPN [16]. On one hand, potential explanations for sub-group 1A could involve the technical intricacies of laparoscopic dissection, especially in case of intraparenchymal tumors, leading to inadvertent vascular injury [19]. On the other hand, segmental ischemia, while preserving partial blood circulation in the kidney, often fails to entirely exclude the tumor-bearing part of the kidney from the blood supply, ultimately resulting in increased blood loss (sub-group 1C). The introduction of ICG/NIR navigation facilitates visualization of ischemic margins, aiding in initiating tumor excision within the ischemic zone, minimizing the time of excision within the area of preserved blood circulation, and performing intraparenchymal clipping of vessels feeding the tumor. This approach contributes to a reduction in blood loss.

Table 3

Results of comparative analysis of perioperative indicators between laparoscopic partial nephrectomy with segmental ischemia and ICG navigation and open partial nephrectomy

Variables	Group 1B LPN (segm. ischemia+ ICG) (n=32)	Group 2 Open nephrectomy (n=32)	p-value
Estimated blood loss, median (IQR)	180 [50; 500]	100 [100; 110]	0.065
Operative time, median (IQR)	181.5 [143.8; 200.5]	100 [90;120]	*<0.001
Warm ischemia time, median (IQR)	20 [18.8; 24.3]	10 [6; 15]	*<0.001
eGFR at follow-up, mL/min/1.73m^2 , median (IQR)	69.5 [61; 91]	61.9 [50.2; 77.6]	*0.005
Change in eGFR, mL/min/1.73m^2 , median (IQR)	-3 [-11.6; 4]	-16.7 [-32; -3.2]	*0.002
Change in eGFR (%), median (IQR)	-0.03 [-0.16; 0.07]	-0.21 [-0.4; -0.47]	*<0.001

Note: * – significant differences (p<0.05).

Operative time (OT) represents another crucial factor under scrutiny. In all sub-groups, Group 1 (LPN) exhibited significantly longer operative time with a median value of 160 [135-190] as compared to

Group 2 (OPN) with a median value of 100 [100-120] minutes, displaying a p-value of less than 0.001. This finding aligns with the prevailing understanding that laparoscopic procedures often involve more intricate and time-consuming maneuvers due to the limitations of the minimally invasive approach. The utilization of segmental ischemia adds further complexity, considering the necessity of dissecting segmental vessels within the renal parenchyma. Conversely, open surgery provides a clearer line of sight and manipulation, potentially leading to shorter operative times. This observation is consistent with studies by Yu et al. and Hinata et al., where LPN was associated with longer operative time [7]. While LPN is generally viewed as time-efficient, the complexities associated with this technique may contribute to its prolonged duration. Implementation of refined laparoscopic techniques and incorporation of innovative technology could potentially streamline the procedure and reduce operative time [7].

Warm ischemia time (WIT), a critical consideration in kidney surgeries, it demonstrates significant variations between the groups. Notably, Group 1 (LPN) consistently exhibited longer WIT compared to Group 2 (OPN) in all sub-groups except 1C. A p-value of less than 0.001 underlines the statistical significance of this difference (Tables 2-4). The identification of prolonged WIT in LPN corresponds to data obtained by other researchers and represents a feature of this treatment method, which requires further refinement [18, 22]. Literature supports the potential of laparoscopy to minimize ischemic damage through magnified visualization and meticulous dissection [20]. However, our results highlight the need for a more thorough exploration of ischemia management during laparoscopic procedures. The adoption of segmental ischemia techniques, as investigated in this study, presents a promising avenue for addressing this concern [21]. As mentioned earlier, segmental ischemia preserves blood circulation in a larger portion of the kidney, potentially minimizing harm to the kidney and permitting longer segmental WIT, thereby reducing blood loss, as demonstrated in sub-group 1B.

Table 4

Results of comparative analysis of perioperative indicators between laparoscopic partial nephrectomy with segmental ischemia and open partial nephrectomy

Variables	Group 1C LPN (segm. ischemia) (n=18)	Open nephrectomy (n=18)	p-value
Estimated blood loss, median (IQR)	180 [108.8; 395]	100 [100; 110]	*0.035
Operative time, median (IQR)	137.5 [117.5; 176.2]	112.5 [91.3;130]	*0.006
Warm ischemia time, median (IQR)	3 [1,2; 17.5]	7 [1.3; 13]	0.446
eFGR at follow-up, mL/min/1.73m^2 , median (IQR)	67.5 [58.5; 70.1]	58.8 [52.5; 73.4]	0.389
Change in eGFR, mL/min/1.73m^2 , median (IQR)	-12.7 [-19.5; -3.7]	-21.2 [-25.8; -7.1]	0.161
Change in eGFR (%), median (IQR)	-0.16 [-0.27; -0.05]	-0.21 [-0.33; -0.09]	0.252

Note: * – significant differences (p<0.05).

These findings collectively underline the intricate considerations that surgeons must weigh when choosing between LPN and OPN. While LPN offers advantages in terms of preserving renal function and minimizing eGFR decline, along with reduced abdominal trauma, it also presents potential drawbacks such as increased blood loss and extended operative time. The adoption of refined techniques, intraoperative navigation, and further exploration of ischemia management could potentially mitigate these challenges.

It's essential to acknowledge certain limitations of our study. The retrospective nature of the data for OPN patients, along with the absence of information regarding the localization of kidney tumors, and the potential for selection bias, could influence the generalizability of our findings. Additionally, the long-term outcomes, which fall beyond the scope of this study, warrant further investigation to determine the enduring impact of these surgical approaches on renal function.

CONCLUSIONS

1. The comparative analysis between laparoscopic partial nephrectomy and open partial nephrectomy has revealed significant differences in perioperative indicators, including estimated blood loss, operative time, and warm ischemia time, in favor of open partial nephrectomy.

2. Laparoscopic partial nephrectomy offers advantages in preserving renal function and minimizing estimated Glomerular Filtration Rate decline compared to open partial nephrectomy, reflecting its potential to uphold long-term renal health. The utilization of innovative techniques, such as intraoperative indocyanine green navigation, facilitates precise and limited ischemia, contributing to enhanced preservation of renal function.

3. The observed benefits of laparoscopic partial nephrectomy, including reduced surgical trauma and enhanced preservation of renal function, need to be weighed against challenges like increased blood loss and extended operative time. The incorporation of refined techniques, intraoperative navigation, and further exploration of ischemia management could potentially address and mitigate these challenges.

Contributors:

Molchanov R.M. – conceptualization, methodology, writing – review & editing;

Goncharuk O.O. – investigation, writing – original draft preparation;

Khareba G.G. – provision of resources, conducting investigations;

Blyuss O.B. – formal analysis, data curation;

Duka R.V. – validation, project administration.

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