REVIEW PAPER

UROLOGICAL ONCOLOGY

The use of indocyanine green in partial nephrectomy: a systematic review

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Introduction The aim of this review was to assess the outcomes of partial nephrectomy using indocyanine green (ICG) regarding ischemia time, positive surgical margins (PSM), estimated blood loss (EBL) and estimated GFR reduction while also suggesting the optimal dosage scheme.

Material and methods A systematic review was performed using Medline (PubMed), ClinicalTrials.gov, and Cochrane Library (CENTRAL) databases, in concordance with the PRISMA statement. Studies in English regarding the use of indocyanine green in partial nephrectomy were reviewed. Reviews and meta-analyses, editorials, perspectives, and letters to the editors were excluded.

Results Individual ICG dose was 5 mg in most of the studies. The mean warm ischemia time (WIT) on each study ranged from 11.6 minutes to 27.2 minutes. The reported eGFR reduction ranged from 0% to 15.47%. Lowest mean EBL rate was 48.2 ml and the highest was 347 ml. Positive surgical margin rates were between 0.3% to 11%.

Conclusions Indocyanine green seems to be a useful tool in partial nephrectomy as it can assist surgeons in identifying tumor and its related vasculature. Thereby, warm ischemia time can be reduced and, in some cases, selective ischemia can be implemented leading to better renal functional preservation.

Key Words: partial nephrectomy ‹› indocyanine green ‹› ICG ‹› Near-infrared fluorescence ‹› NIRF ‹› renal cancer

INTRODUCTION

Identification of the tumor and its related vasculature while being in the operating room and renal functional preservation are paramount elements in kidney surgery, affecting the surgeon's results and patients' quality of life. Partial nephrectomy (PN) has been established as the preferred treatment for small renal masses, as it offers greater renal functional preservation and oncological equivalence with radical nephrectomy [1–4]. Preoperative imaging and intraoperative ultrasonography are used by most surgeons for tumor localization and identification of anatomical structures on patients undergoing PN. However, despite these advancements there is still room for improvement in accurately identifying tumors and vasculature. Near-infrared fluorescence (NIRF) using indocyanine green (ICG) has been adopted to enhance the surgeon's ability to reduce ischemia time or even obtain selective ischemia limited only to the tumor and immediate adjacent normal parenchyma, leaving blood flow to the remainder tissue uninterrupted during surgery. ICG received approval from the Food and Drug Administration (FDA) in 1959 for clinical use and has since been commonly utilized in a broad range of medical procedures such as

cholangiography, gastrointestinal surgeries and lymph node dissections due to its impressive pharmacokinetic properties [5]. This systematic review aims to assess the outcomes of PN using ICG regarding ischemia time, positive surgical margins (PSM), estimated blood loss (EBL) and estimated GFR reduction while also suggesting the optimal dosage scheme.

MATERIAL AND METHODS

This systematic review was conducted in accordance with the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) [6]. Bibliographic search was performed in Medline (PubMed), ClinicalTrials.gov, and Cochrane Library (CENTRAL) from database inception until March 1, 2023. The following medical subject heading terms were used in combination with Boolean operators: indocyanine green, fluorescence, nephrectomy. Two independent reviewers (S.K., T.B.) screened all articles retrieved by the initial search. All disagreements were resolved with discussion, and final decision was reached by consensus with a third reviewer (L.T.). Reference lists were systematically searched for potentially eligible, missed studies. The protocol was registered to PROSPERO (CRD42023424430).

Study criteria

Clinical trials, cohort studies, and case-control studies were considered for inclusion. Only well-described studies were included in analysis. In order to be characterized as well-described, a study had to include a documented outcome concerning the intraoperative use of ICG and fulfill at least 5 of the following 6 criteria:

1. research question regarding intraoperative use of ICG on partial nephrectomy
2. individual dosage or dosage range,
3. results regarding surgical margins
4. ischemia time
5. estimated GFR change (eGFR)
6. estimated blood loss (EBL)

Case reports, systematic reviews and metanalyses were excluded. Excluded studies met ≥1 of the following criteria:(1) irrelevant to the subject studies, (2) studies published in a non-English language, (3) reviews and meta-analyses, editorials, perspectives, and letters to the editors, (4) studies fulfilling less than five from the aforementioned inclusion criteria.

Evidence synthesis

Literature search revealed 522 studies from which 437 were excluded after abstract screening and/or duplicate removal. After reviewing full-text, 70 records did not meet our criteria and were therefore excluded. Finally, 14 studies were deemed eligible for qualitative analysis [7–20]. The flow diagram is shown in Figure 1. Table 1 shows general characteristics of all articles included in our review. We saw greater utility in organizing our discussion in a systematic review form without meta-analysis, to avoid biased numerical conclusions due to the small sample sizes and to present the variety of surgical experiences obtained through synthetic logical interrelations. Hozo et al. [21] and Wan et al. [22] formulas were used to transform median and interquartile ranges to mean and standard deviation, wherever necessary in order to interpret better each study.

Risk of bias assessment

Risk of bias assessment was performed by two authors (S.K and L.T) using the Cochrane Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool for nonrandomized studies [23] (see Table 2). Most common reasons for the studies to be classified as having moderate or serious risk of bias was the selection bias during participant

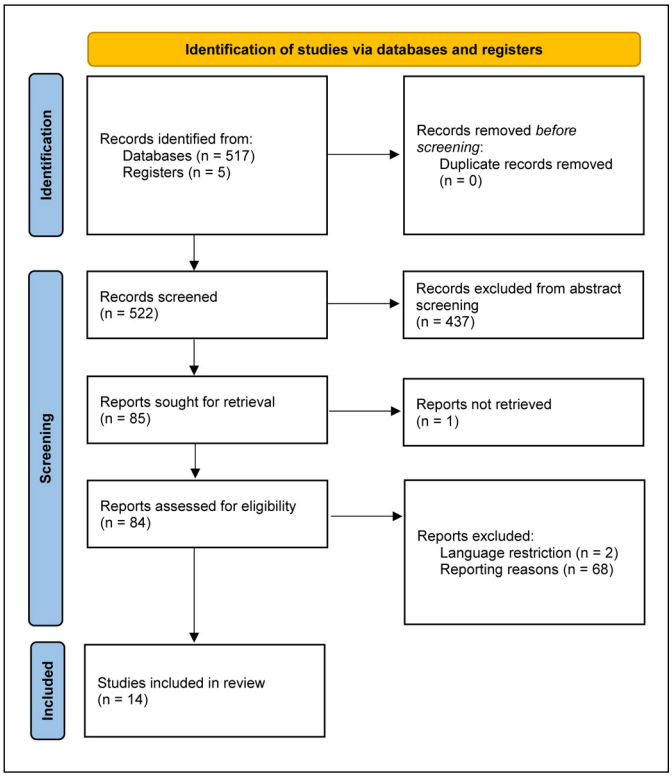

Figure 1. *Review flow diagram based on PRISMA 2020 for new systematic reviews which included searches of databases and registers only.*

Table 1. *Baseline characteristic*

Study	Sample size	Age mean (years)	Type of ischemia	Type of appoach	Tumor complexity	Tumor size	Control group	Follow-up (days)
Tobis et al. (2011) [7] Prospective, USA	11	61	Global ischemia	Robot assisted: 11/11	Median RENAL score: 7.5	Median radiographic lesion: 3.6 cm	NA	NA
Borofsky et al. (2012) [8] Prospective, USA	34	60.1	Selective ischemia	Robot assisted: 34/34	Median RENAL score: 8	Mean tumor size: 2.79 cm	Retrospective Matched-pair analysis: 27 patients	13.5
Krane et al. (2012) [9] Prospective, USA	47	59.6	Global ischemia	Robot assisted: 47/47	Median RENAL score: 6	Median tumour size: 2.7 cm	Retrospective group:47 patients	150
Angell et al. (2013) [10] Retrospective, USA	79	55	Global ischemia	Robot assisted: 79/79	Mean RENAL score: 8	Mean tumor size: 3.5 cm	NA	NA
Harke et al. (2013) [11] Retrospective, Germany	22	62.8	Selective ischemia	Robot assisted: 22/22	Mean RENAL score: 8.1	Mean tumor size: 3.77 cm	Retrospective Matched-pair analysis: 15 patients	NA
Bjurlin et al. (2014) [12] Retrospective, USA	70	56.3	Selective ischemia	Robot assisted: 70/70	Median RENAL score: 6	Median tumor size: 2.6 cm	NA	14
Lanchon et al. (2018) [13] Prospective, France	30	65.3	Selective ischemia	Robot assisted: 30/30	NA	Median tumor size: 3 cm	Retrospective Matched-pair analysis: 25 patients	180
Simone et al. (2018) [14] Prospective, Italy	10	61.3	Selective ischemia	Robot assisted: 10/10	Median RENAL score: 9	Median tumor size: 3 cm	NA	360
Mattevi et al. (2018) [15] Prospective, Italy	20	65.3	Selective ischemia	Robot assisted: 20/20	NA	Median tumor size: 4 cm	42 patients who underwent selective clamping RAPN	30
Diana et al. (2020) [16] Retrospective, Italy	318	61.1	Mixed approach	Robot assisted: 318/318	RENAL score categories: Low: 36.5% Intermediate: 51.9% High: 11.6%	Median tumor size: 3 cm	NA	NA
Gadus et al. (2020) [17] Retrospective, Czech Republic	37	57	Mixed approach	Robot assisted: 37/37	RENAL score categories: Low: 21% Intermediate: 76% High: 3%	Mean tumor size: 3.1 cm	NA	NA
Sentell et al. (2020) [18] Retrospective, USA	288	57.9	Selective ischemia	Robot assisted: 288/288	Mean RENAL score: 7.3	Mean tumor size: 3.3 cm	NA	NA
Wang et al. (2021) [19] Retrospective, China	21	61.1	Global ischemia	Laparoscopic: 21/21	Mean RENAL score: 7.9	Mean tumor size: 4.4 cm	39 patients laparoscopy without ICG	NA
Yang et al. (2022) [20] Retrospective, China	21	55.6	Global ischemia	Robot assisted: 21/21	Median RENAL score: 8	Median tumor size: 3.5 cm	106 patients RAPN without ICG	180

NA – not available

selection and the inadequate adjustment for confounding factors.

ICG dosage

There is no general consensus for the optimal total dose for ICG administration. Due to the lack of standardization of ICG dosing, the dose and frequency of injections are decided by the surgeon's judgement. However, it is generally accepted that the daily maximum dose should not surpass 2 mg/kg as this is considered a toxic level [7, 9, 11]. Thirteen studies in our review provided information for the dosage scheme followed by the surgeons.

Table 2. *Risk of bias assessment for non-randomized studies*

First author et al. (year)	Confounding	Participant Selection	Intervention classi-fication	Deviation from intended treatment	Missing data	Outcome measure-ment	Selected reporting	Overall bias
Tobis et al. (2011)	Moderate	Serious	Low	Low	Low	Moderate	Low	Serious
Borofsky et al. (2012)	Moderate	Serious	Low	Low	Moderate	Moderate	Low	Serious
Krane et al. (2012)	Moderate	Serious	Low	Low	Moderate	Low	Low	Serious
Angell et al. (2013)	Moderate	Serious	Low	Low	Low	Low	Low	Serious
Harke et al. (2013)	Moderate	Serious	Low	Low	Low	Low	Low	Serious
Bjurlin et al. (2014)	Moderate	Serious	Low	Low	Low	Moderate	Low	Serious
Lanchon et al. (2018)	Moderate	Moderate	Low	Low	Moderate	Low	Low	Moderate
Simone et al. (2018)	Low	Low	Low	Low	Low	Low	Low	Low
Mattevi et al. (2018)	Moderate	Serious	Low	Low	Low	Low	Low	Serious
Diana et al. (2020)	Moderate	Serious	Low	Low	Low	Low	Low	Serious
Gadus et al. (2020)	Moderate	Serious	Low	Low	Low	Low	Low	Serious
Sentell et al. (2020)	Moderate	Serious	Low	Low	Low	Moderate	Low	Serious
Wang et al. (2021)	Moderate	Serious	Low	Low	Low	Low	Low	Serious
Yang et al. (2022)	Moderate	Serious	Low	Low	Moderate	Low	Low	Serious

Six of them were prospective studies [7, 8, 9, 13, 14, 15] and seven were retrospective cohort studies [10, 11, 12, 16, 17, 18, 20]. An initial bolus dose of 5 mg was administered in 7 studies [7, 9, 11, 12, 13, 15, 17] while in one study the starting dose was 7.5 mg [8]. In order to improve the visualization of the structures that is often distorted from ICG overdose some surgeons adapted their dosing protocols lowering their initial dose. Angell et al. [10] reported using a test dose of 1.25 mg followed by an additional same dose, provided that differential fluorescence is achieved, right before clamping. They claim to have highly reliable results regarding tumor identification. Similarly, Sentell et al. [18], suggested a dosing scheme with a starting dose of 0.625 mg ICG when using Da Vinci Xi robot and 1.25 mg when using Da Vinci Si, followed by a re-dose of 0.825 mg and 1.875 mg respectively. They successfully achieved differential fluorescence in a large majority of tumors during robotic assisted PN with an exceedingly low positive margin rate (0.3%) which they attribute to their dosing scheme.

The reported time interval between injection and fluorescence of the vasculature or the renal parenchyma ranges from five seconds to two minutes [7, 11, 13, 15–20] with one minute considered adequate time in most of the studies. An extra ICG dose after tumor excision and the performance of the renorrhaphy was given by some authors in order to confirm that kidney is fully perfused [7, 8, 14, 15, 16]. The dosage schemes used in each study are summarized in Table 3.

Table 3. *The dosage schemes used in each study*

Study	Individual dose	Number of doses/ Patient
Tobis et al. (2011) [7]	5 mg	3
Borofsky et al. (2012) [8]	7.5 mg	2
Krane et al. (2012) [9]	5 mg	1
Angell et al. (2013) [10]	1.25 mg	2
Harke et al. (2013) [11]	5 mg	1
Bjurlin et al. (2014) [12]	5 mg	1
Lanchon et al. (2018) [13]	5 mg	1
Simone et al. (2018) [14]	1.5 ml ICG + 0.75 ml lipiodol	2
Mattevi et al. (2018) [15]	5 mg	2
Diana et al. (2020) [16]	5–10 mg	2
Gadus et al. (2020) [17]	5 mg	1
Sentell et al. (2020) [18]	0.625–1.25 mg	2
Wang et al. (2021) [19]	2.5 mg	1
Yang et al. (2022) [20]	7.5–12.5 mg	1

Ischemia time

In our review global ischemia time, defined as the clamping of the main renal artery was applied in four studies [7, 10, 19, 20], selective ischemia time was applied in six studies [8, 11–15,] and a mixed approach in 3 studies [9, 10, 11]. The mean warm ischemia time (WIT) on each study ranges from 11.6 minutes to 27.2 minutes [7–18, 20]. Someone

Table 4. *Estimated blood loss and positive surgical margins rates*

Study	Estimated blood loss (ml), mean	Positive surgical margins, n (%)
Tobis et al. (2011) [7]	181	0 (0)
Borofsky et al. (2012) [8]	206.5	0 (0)
Krane et al. (2012) [9]	165	3 (6.4%)
Angell et al. (2013) [10]	103	0 (0)
Harke et al. (2013) [11]	347	0 (0)
Bjurlin et al. (2014) [12]	200	2 (3.8%)
Lanchon et al. (2018) [13]	131	1 (3.3%)
Simone et al. (2018) [14]	266.6	0 (0)
Mattevi et al. (2018) [15]	206	0 (0)
Diana et al. (2020) [16]	123.3	11 (3.5%)
Gadus et al. (2020) [17]	190	3 (8%)
Sentell et al. (2020) [18]	112.2	1 (0.3%)
Wang et al. (2021) [19]	48.2	0 (0)
Yang et al. (2022) [20]	93.3	2 (11%)

would expect a lower ischemia time to the studies were the main renal artery was clamped due to the bloodless field, however, that was not proved from the available studies probably because it is affected by other factors that were not examined, such as the surgeon's competence and the tumor characteristics. While there is lack of prospective comparative studies in the current literature comparing PN with and without the use of ICG, three studies included in our review conducted a retrospective and/or matched-pair analysis for patients undergoing PN with and without ICG [9, 19, 20]. Superiority of PN with NIRF over traditional PN without ICG, in terms of warm ischemia time was observed by Krane et al. The mean WIT in the group of ICG was 16.3 minutes compared to 19.66 minutes in the control group ($p < 0{,}001$). In a more recent study, Yang et al. presented reduced WIT by four minutes when NIRF with ICG was implemented (mean WIT 21.33 minutes vs 25.33 minutes) [20].

Estimated GFR reduction

Eleven studies were included in the analysis of eGFR reduction after PN with the use if ICG [8, 9, 11–17, 19, 20]. Assessment of renal function was available for all patients at discharge at seven studies [9, 11, 13, 14, 16–19]. The reported eGFR reduction ranged from 0% [13] to 15.47% [19] in these studies. In three studies eGFR reduction was calculated at 1 month post op with mean rates of 0.3% [15] 1% [13] and 1.8% [8]. At six months follow up, eGFR reduction was 2% [13] and 15.77% [20] in two studies.

NIRF using ICG dye has been incorporated in robotic PN not only as an auxiliary mean for tumor identification but also as a helpful tool in performing selective ischemia and by extension renal functional preservation. In our review this seems to be achieved, as studies where selective ischemia was performed had lower eGFR reduction rates compared to studies with global ischemia (e.g., 6.2% [11] vs 15.47% [19]). However, these results should be interpreted with caution as they need to be further determined by prospective randomized studies of larger scale.

Estimated blood loss and positive surgical margins

In terms of blood loss, PN with the use of NIRF with ICG dye presented EBL rates that are in line with published literature for PN [24, 25]. Lowest mean EBL rate was 48.2 ml [19] and the highest was 347 ml [11]. Furthermore, there were no clinically significant differences in EBL between studies where NIRF was used to facilitate selective ischemia [8, 11–15,] and studies where NIRF was used for tumor identification with main renal artery clamping [7, 10, 19, 20] (see Table 2).

Regarding positive surgical margin rates, 7 studies did not present positive surgical margins [7, 8, 10, 11, 14, 15, 19] while in the rest of the studies involved in our analysis PSM rates were 6.4% [9], 3.8% [12], 3.3% [13], 3.5% [16], 8% [17], 0.3% [18] and 11% [20]. EBL and PSM rates are summarized in Table 4.

DISCUSSION

Surgical treatment of renal cancer has faced many changes over the last twenty years due to the ongoing development of robotic surgery and imaging technology. While partial nephrectomy was first indicated for small renal masses has now been extended to cases with larger masses whenever feasible [26]. There is also an ongoing trend towards kidney preservation shifting the concept of trifecta during PN to pentafecta to encompass renal functional preservation [27]. The use of ICG that has been adopted to enhance these efforts for kidney preservation, has demonstrated a high safety and convenience profile in our review. The dosing schemes are more or less the same, however a standardized ICG dose has to be defined. Most import advantage of utilizing ICG in PN seems to be the selective ischemia that can be achieved. Selective clamping with NIRF using ICG seems to be technical feasible and safe without compromising surgical margins, as it guarantees a nearly blood-less tumor resection. Thus, eGRF is not dramatically reduced, demonstrating lower

reduction rates when compared with global ischemia (e.g., 6.2% [11] vs 15.47% [19]). Moreover, the 25 minutes that Hung et al. [28] suggested as the maximum WIT for optimal postoperative performance in terms of renal function were not surpassed in most cases were global ischemia with ICG was performed [7, 10, 20]. In a recent study from Yang et al., WIT was reduced by four minutes when NIRF with ICG was implemented compared to the group without ICG use (mean WIT 21.33 minutes vs 25.33 minutes) [20]. Similar results were presented by Krane et al. The mean WIT in the group of ICG was 16.3 minutes compared to 19.66 minutes in the control group ($p < 0{,}001$). Regarding positive surgical margin rates, they were consistently low (0% to 11%) and in line with published literature (PSM between 0–10%), confirming the efficacy of the technique [29–32].

Despite the aforementioned positive results PN using ICG has its limitations primarily being more suited for tumors that are superficially localized, as its tissue penetration is limited. However, research has been conducted to increase its penetration depth and make it suitable for endophytic renal masses. One study mixed ICG with lipiodol to prevent quick washout from the renal tumor [11]. The lipiodol-ICG mixture was superselectively transarterially delivered before surgery, and a postprocedural CT scan was done for localization. The outcome of this method on completely endophytic tumors was positive, with no intraoperative and postoperative complications observed, and acceptable renal functional outcomes.

Tumor complexity is a very important factor in PNs, especially in terms of tumor identification and anatomical dissection. In our review the included studies demonstrated tumors with a range in median RENAL score from 6 to 9 rated as of low and moderate complexity respectively. We have to say that no considerable discrepancies were observed between these studies regarding oncological or functional outcomes. However, we have to admit that we cannot draw safe conclusions due to the small sample size of most of the studies and the lack of randomized controlled trials. Future prospective randomized studies are indubitably essential in order to assess whether the utilization of NIRF technology can improve results in more complex tumors comprising RENAL scores of 10 and above.

Limitations of our present study include the absence of randomized controlled trials, the retrospective nature of many of the studies included, the relatively small sample sizes and the lack of long follow-up time in most of them. However, to the best of our knowledge this is the first attempt to present a thorough review of a technique which was first received with enthusiasm by urologists but has relatively been abandoned, considering the lack of attention in the current literature.

CONCLUSIONS

Indocyanine green seems to be a useful tool in partial nephrectomy as it can assist surgeons in identifying tumor and its related vasculature. Thereby, warm ischemia time can be reduced and, in some cases, selective ischemia can be implemented leading to better renal functional preservation.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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