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Commentary

Indocyanine Green (ICG) fluorescence-Guided Surgery (FGS) in pediatric Wilms tumor: Opportunities and Challenges

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1. Invited commentary

Indocyanine green (ICG) fluorescence-guided surgery (FGS) has increasingly been adopted as an intraoperative adjunct across multiple domains of surgical oncology [1–3]. Its appeal resides in its favorable safety profile, ease of administration, and capacity to provide real-time visual information without significantly altering operative workflow [1–3].

In pediatric surgical oncology, and particularly in the management of Wilms tumor, ICG has been proposed as a tool to improve lymph node staging, facilitate tumor margin identification, and assist in the detection of metastatic disease. While early studies have demonstrated the feasibility of these applications, a critical appraisal of the current evidence suggests that the clinical value of ICG remains fundamentally constrained by its lack of tumor specificity.

1.1. Lymph node mapping

Accurate lymph node staging is a cornerstone of Wilms tumor management, as it directly influences postoperative treatment stratification. Both the International Society of Paediatric Oncology (SIOP) and the Children's Oncology Group (COG) protocols mandate systematic lymph node sampling (Table I) [4,5]. However, this requirement is not consistently fulfilled in clinical practice [6–9]. The identification of lymph nodes intraoperatively remains challenging due to their small size, anatomical variability, and the difficulty of distinguishing nodal tissue from surrounding fat [6–9]. In this context, ICG lymphography has emerged as a potential solution to improve the identification of lymphatic drainage pathways (Fig. 1) [6–9]. The technique typically involves intra-parenchymal injection into grossly normal renal cortex or peri-hilar injection into the connective tissue adjacent to the renal hilum, followed by near-infrared (NIR) imaging to visualize lymphatic channels and nodal basins [6–9].

The feasibility of this approach has been demonstrated in several studies (Table II) [6–9]. Abdelhafeez and colleagues [6] reported successful lymphatic mapping in most patients using both intra-parenchymal and peri-hilar techniques, with fluorescence appearing in draining lymph nodes within minutes. Similarly, Roberts et al. [8]. observed a significant increase in the number of harvested lymph nodes following intraparenchymal ICG injection, without any measurable impact on operative time or postoperative recovery. Early case-based evidence further supports the ability of ICG to reveal lymph nodes that might otherwise be overlooked [7]. These findings suggest that ICG may enhance the surgeon's ability to identify the relevant nodal basin and improve compliance with established staging guidelines [6–9].

However, the interpretation of fluorescence in this setting remains problematic. The available literature consistently demonstrates that fluorescence does not correlate reliably with lymph node metastatic involvement [6–9]. Fluorescent lymph nodes are not necessarily pathological, and non-fluorescent nodes may still harbor disease [6–9]. As a result, ICG cannot currently be considered a diagnostic tool for nodal staging but rather an anatomical adjunct that may facilitate lymph node identification. Therefore, ICG-guided lymphatic mapping should not be interpreted as a method for identifying metastatic lymph nodes. Fluorescence reflects anatomical tracer drainage rather than tumor

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Table 1
International Society of Pediatric Oncology (SIOP) and Children's Oncology Group (COG) staging criteria.

Stage	SIOP staging system - Description
I	Tumor limited to the kidney or present in the perirenal fat but surrounded by a fibrous (pseudo)capsule, which may be infiltrated by viable tumor not reaching the outer surface. Tumor may show protruding (botryoid) growth into the renal pelvis or ureter but does not infiltrate their walls. Vessels or soft tissues of the renal sinus are not involved; intrarenal vessel involvement may be present.
II	Viable tumor present in the perirenal fat without a (pseudo)capsule but completely resected (clear margins). Viable tumor infiltrates the soft tissues or vessels of the renal sinus. Viable tumor infiltrates blood and/or lymphatic vessels of the renal sinus or perirenal tissue, but completely resected. Viable tumor infiltrates the wall of the renal pelvis or ureter. Viable tumor infiltrates the vena cava or adjacent organs (except the adrenal gland) but completely resected.
III	Viable tumor present at a resection margin. Nonviable tumor or chemotherapy-induced changes at a margin are not considered stage III. Abdominal lymph node involvement with viable or nonviable tumor. Preoperative or intraoperative tumor rupture confirmed microscopically (viable tumor at the surface at rupture site). Viable or nonviable tumor thrombus present at resection margins of ureter, renal vein, or vena cava (to be discussed with the surgeon). Viable or nonviable tumor thrombus attached to the inferior vena cava wall and removed piecemeal. Wedge or open tumor biopsy before preoperative chemotherapy or surgery. Presence of viable or nonviable tumor implants anywhere in the abdomen. Tumor (viable or nonviable) has penetrated through the peritoneal surface.
IV	Hematogenous metastases (e.g. lung, liver, bone, brain) or lymph node metastases outside the abdominopelvic region.
V	Bilateral renal tumors at diagnosis. Each side should be substaged according to the above criteria.
Stage	**COG staging system - Description**
I	Tumor is limited to the kidney and completely resected. The renal capsule is intact, with no invasion beyond the kidney, renal sinus vessels, or through the capsule. Margins are tumor-free, and no rupture occurred before or during surgery.
II	Tumor extends beyond the kidney but is completely resected. May invade perirenal fat, renal sinus, or blood vessels outside the kidney, but no residual tumor remains. Lymph nodes are negative.
III	Residual tumor confined to the abdomen due to one or more of the following: regional lymph node involvement, tumor rupture or spill before or during surgery, invasion of peritoneal surfaces, positive margins, or non-hematogenous residual tumor in the abdomen. No distant metastasis.
IV	Hematogenous metastases (for example, to lungs, liver, bones, or brain) or distant lymph node involvement.
V	Bilateral renal involvement at diagnosis. Each kidney is assigned its own stage after preoperative therapy.

involvement, and both tumor-positive and tumor-negative nodes may fluoresce. In this context, a fluorescence-defined "sentinel" node would represent the first-echelon anatomical drainage node rather than a node identified as malignant. Its clinical value therefore depends on the still unproven assumption that the pathological status of this node accurately represents the wider regional nodal basin.

The technique of ICG administration introduces additional considerations. Intrarenal injection, although effective in delineating lymphatic pathways, carries an inherent oncological risk. Tumor spills cause local restaging and subsequent treatment intensification, particularly within COG treatment paradigms [5]. Conversely, avoiding tumor injection raises an unresolved question regarding the reliability of lymphatic mapping. If the dye is not introduced into or immediately adjacent to tumor tissue, it remains uncertain whether the visualized lymphatic pathways accurately represent tumor-specific drainage. This paradox highlights a fundamental limitation of the technique that has yet to be addressed. At present, the optimal injection site remains unresolved. Intraparenchymal injection into grossly normal renal tissue has generated the most consistent fluorescence mapping in the

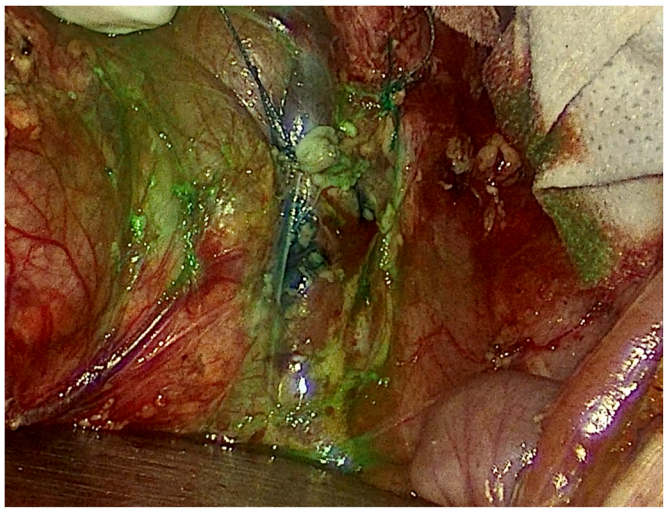


Fig. 1. Intraoperative near-infrared ICG fluorescence demonstrating lymphatic channels converging to a fluorescent retroperitoneal lymph node, highlighting anatomical drainage pathways without specificity for metastatic involvement.

published series, but it may not reproduce drainage from the tumor-bearing region and carries a risk of inadvertent tumor puncture when residual normal parenchyma is limited. Perihilar injection avoids direct puncture of the tumor and renal parenchyma and may therefore represent the more oncologically acceptable approach, particularly in COG-treated patients, in whom tumor violation may have staging and therapeutic consequences. However, perihilar tracer distribution cannot yet be assumed to reproduce tumor-specific lymphatic drainage. Consequently, neither technique can presently be recommended for routine use, and comparative prospective studies incorporating pathological correlation are required before a standardized injection strategy can be defined.

A further layer of complexity arises from the anatomical organization of renal lymphatics (Fig. 2).

Renal lymphatic anatomy is complex and incompletely characterized, and lymphatic vessels are generally considered more abundant within the cortex and hilar interstitium than in the medulla [13–15]. Because renal lymphatic drainage may vary according to the site of injection, tracer administration into a limited area of normal renal cortex may not reproduce drainage from the tumor-bearing pole or from the entire kidney.

In this context, multicenter collaborative studies will be essential to further clarify the accuracy, reproducibility, and clinical significance of fluorescence-guided sentinel lymph node mapping in Wilms tumor. Until an acceptable false-negative rate and negative predictive value have been demonstrated in adequately powered prospective studies, ICG-guided mapping should be considered an adjunct to, rather than a replacement for, protocol-mandated regional lymph node sampling.

2. Primary tumor identification

The use of ICG for primary tumor identification addresses a different surgical challenge, particularly in the context of nephron-sparing surgery (NSS). The ability to distinguish tumor from normal renal parenchyma would represent a significant advancement, especially in bilateral and multifocal diseases. However, the behavior of ICG in Wilms tumor differs from that observed in many adult malignancies. Rather than preferentially accumulating within tumor tissue, ICG highlights normal renal parenchyma, resulting in an inverse fluorescence pattern in which the kidney appears hyperfluorescent and the tumor relatively hypofluorescent. This phenomenon has been consistently observed in both clinical and experimental studies [9–11]. The inverse fluorescence pattern appears to arise primarily from preferential uptake or retention

Table 2
Summary of published studies investigating the use of indocyanine green (ICG) fluorescence-guided surgery in Wilms tumor, including lymph node mapping, primary tumor identification (in vivo and ex vivo), and detection of lung metastases. *Abbreviations.* ICG, indocyanine green; IP, intraparenchymal; PH, perihilar; IV, intravenous; IA, intra-arterial; MIS, minimally invasive surgery; nd, not described; F, female; M, male; L, left; R, right.

	N. patients	Age	Sex	Side	Tumor Stage	Neoadjuvant chemotherapy	Injection technique	Approach	ICG dose and time of administration	ICG brand	Timing	Camera	N. resected lymph nodes	Fluorescence signal	Lymph nodes metastasis
Lymph node mapping															
Pachl et al., 2021 [7]	1	2 years	F	L	Intermediate risk (n = 1)	Yes (nd)	IP	MIS	2 ml of a 2.5 mg/ml solution (4 aliquots 0.5 ml)	Verdye, (Diagnostic Green, Renew Health, Republic of Ireland)	nd	Rubina OPAL 1 (Karl Storz Endoskope, Tuttlingen, Germany)	8 lymph nodes	7 out of the 8 harvested lymph nodes	0 lymph nodes out of the 8 harvested lymph nodes
Abdelhafeez et al., 2022 [6]	7	2-6 years	F (n = 3), M (n = 4)	L (n = 3), R (n = 4)	Low risk (n = 2), intermediate risk (n = 4), high risk (n = 1)	Vincristine/ Dactinomycin (n = 3), Vincristine/ dactinomycin/ doxorubicin (n = 2), none (n = 2)	IP (n = 4), PH (n = 3)	MIS (n = 4), Open (n = 3)	IP: 5-10 mg of a 5 mg/ml solution PH: 2.5-5 mg of a 5 mg/ml solution	IC-Green (Diagnostic Green, Renew Health, Republic of Ireland) Verdye, (Diagnostic Green, Renew Health, Republic of Ireland)	5-20 minutes	OPAL1 RUBINA (Karl Storz Endoskope, Tuttlingen, Germany) Iridium (Visionsense Corp, Philadelphia, Pennsylvania, USA)	From 3 to 15 lymph nodes/ patient	7 out of 8 patients (not detailed how many lymph nodes/patient)	From 0/15 harvested lymph nodes/ patient to 3/ 8 harvested lymph nodes/ patient
Feng et al. [9], 2023	3	15-64 months	F (n = 2), M (n = 1)	R (n = 3)	Low risk (n = 1), intermediate risk (n = 1), high risk (n = 1)	Vincristine/ Dactinomycin (n = 1), Vincristine/ Dactinomycin/ Doxorubicin (n = 1), na (n = 1)	IP	Open	5 mg of a 2.5 mg/ml solution	ICG (Dandong Yichuang Pharmaceutical Co., Ltd, Dandong, China).	5 minutes	FLI-10B (Nanjing Nuoyuan Medical Devices CO., Ltd, Nanjing, China) OPTO-CAM2100 (Guangdong Optomedic Technologies, Inc., Guangdong, China)	From 3 to 23 lymph nodes/ patient	From 3 to 23 lymph nodes/patient	From 0/3 harvested lymph nodes/ patient to 0/ 23 lymph node/ patient
Roberts et al. [8], 2024	7	20 months (median)	F (n = 3), M (n = 4)	nd	nd	Yes (n = 7, nd)	IP	MIS	5 mg of a 5 mg/ mL solution	Verdye (Diagnostic Green, Renew Health, Republic of Ireland)	nd	nd	A median of 7 lymph nodes/ patient	33 out of 46 harvested lymph nodes were fluorescent, 10 out of 46 harvested lymph nodes were non-fluorescent, 3 out of 46 harvested lymph node were identified histologically taken en bloc with the main specimen	1 out of 46 harvested lymph node contained active disease
Primary tumor															
Abdelhafeez et al. [10], 2022	7	nd	nd	nd	Favorable histology (n = 5), high-risk (n = 2)	Vincristine/ Dactinomycin/ Doxorubicin (n = 7)	IV (in vivo)	nd	1.5 mg/kg (not detailed the concentration of the solution)	IC-GREEN (Akorn Inc., Lake Forest, Illinois, USA)	The day before surgery	Iridium system (Visionsense Corp, Philadelphia,	na	7 out of 7 tumors were hypofluorescent	na

(*continued on next page*)

Table 2 (*continued*)

	N. patients	Age	Sex	Side	Tumor Stage	Neoadjuvant chemotherapy	Injection technique	Approach	ICG dose and time of administration	ICG brand	Timing	Camera	N. resected lymph nodes	Fluorescence signal	Lymph nodes metastasis
Feng et al. [9], 2023	4	15-64 months	F (n = 3); M (n = 1)	R (n = 4)	Low risk (n = 1), intermediate risk (n = 1), high risk (n = 2)	Vincristine/ Dactinomycin (n = 1), Vincristine/ Dactinomycin/ Doxorubicin (n = 2)	IV (in vivo)	Open	2.5 mg of a 2.5 mg/ml solution (0.16-0.21 mg/ kg)	ICG (Dandong Yichuang Pharmaceutical Co., Ltd, Dandong, China)	1-7 min	Pennsylvania, USA) FLI-10B (Nanjing Nuoyuan Medical Devices CO., Ltd, Nanjing, China) OPTO-CAM2100 (Guangdong Optomedic Technologies, Inc., Guangdong, China)	na	4 out of 4 tumors were hypofluorescent	na
Pachl et al. [11], 2026	9	nd	F (n = 4), M (n = 5)	nd	Low risk (n = 1), intermediate risk (n = 6), high risk (n = 2)	Yes (nd)	IA (ex vivo)	Open (n = 7), MIS (n = 2)	20 mg of a 0.4 mg/ml solution	Verdye (Diagnostic Green, Westmeath, Republic of Ireland)	nd	Opal 1 Rubina (Karl Storz Endoskope, Tuttlingen, Germany)	na	7 out of 7 low and intermediate risk tumors were non-fluorescent, 2 out of high risk tumors were isofluorescent	na
Lung metastasis															
Harris et al. [12], 2023	1	22 months	F (n = 1)	nd	nd	Yes (nd)	IV	MIS	0.5 mg/kg (not reported the ICG concentration)	Verdye (Diagnostic Green, Renew Health, Republic of Ireland)	54 min	Rubina OR1 endoscope (Karl Storz Endoskope, Slough, United Kingdom)	na	1 out 1 lung metastases was weakly hyperfluorescent	na

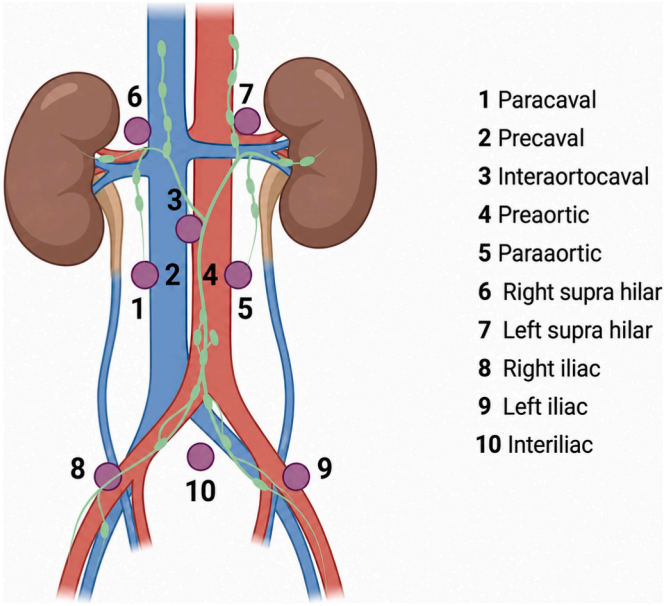


Fig. 2. Anatomical classification of retroperitoneal lymph node stations. The illustration was created by the authors; nodal station classification is based on Roberts and Pachl [8].

of ICG by functioning renal parenchyma, particularly tubular structures, rather than from active or tumor-specific targeting of Wilms tumor. Expression of the putative ICG transporter bilitranslocase in proximal and distal tubular cells has been proposed as one possible mechanism, although this association remains to be confirmed [10]. Accordingly, the fluorescent contrast depends not only on tumor biology but also on the presence and functional integrity of adjacent renal tissue.

This inverse contrast fundamentally limits the interpretative value of ICG. The surgeon is not visualizing tumor tissue directly but rather inferring its location based on the absence of fluorescence. Such an approach is inherently indirect and highly dependent on operative conditions. Factors such as renal perfusion, removal of perirenal fat, and the presence of adhesions can significantly influence the quality of fluorescence imaging. Consequently, while ICG may assist in identifying the tumor–parenchyma interface in selected cases, it cannot be considered a definitive method for intraoperative margin assessment.

The most significant limitation of ICG in Wilms tumor surgery, however, emerges from its interaction with tumor histology. Recent ex vivo investigations have demonstrated that fluorescence patterns are not uniform across histological subtypes [11]. In low- and intermediate-risk tumors, a degree of contrast between tumor and normal parenchyma may be observed, allowing some degree of margin identification [11]. In contrast, high-risk blastemal-predominant tumors exhibit fluorescence patterns that are indistinguishable from normal kidney tissue [11]. Pachl and colleagues [11] demonstrated that in blastemal disease there was no significant difference in fluorescence between tumor and parenchyma, resulting in the absence of a discernible margin. This finding has profound clinical implications. Blastemal tissue represents the most aggressive and treatment-resistant component of Wilms tumor, and its complete resection is critical to achieving optimal oncological outcomes. If ICG fails to identify this component intraoperatively, its utility as a tool for guiding surgical margins becomes fundamentally limited. Moreover, histological subtype is only determined following post-operative pathological analysis, meaning that the surgeon cannot anticipate this limitation during the procedure. As a result, ICG may fail precisely in the clinical scenario in which accurate intraoperative guidance is most needed. In this context, its role in margin assessment must be considered limited, if not negligible, in high-risk disease.

2.1. Lung metastatic disease

The application of ICG to the detection of Wilms tumor metastatic disease, particularly in the lung, represents a further area of investigation. Minimally invasive approaches to pulmonary metastasectomy are limited by the absence of tactile feedback, and fluorescence imaging offers a potential means of identifying lesions intraoperatively. Early clinical experience suggests that ICG can facilitate the identification of metastatic deposits, with confirmation of viable disease on histopathology [12]. However, the signal in Wilms tumor metastases appears weaker and less consistent than in other tumor types, and the available data are limited by small sample sizes and incomplete reporting of histological characteristics [12]. As with primary tumors, the lack of specificity limits the reliability of fluorescence as a guide for surgical decision-making. The apparently divergent fluorescence patterns of primary and metastatic Wilms tumor should not necessarily be interpreted as biologically contradictory, because the optical background and likely mechanisms of contrast differ between the two settings. In the kidney, the “inverse” pattern is predominantly created by intense fluorescence of functioning renal parenchyma relative to the tumor. A pulmonary metastasis, by contrast, is surrounded by non-renal tissue and may demonstrate relative hyperfluorescence through different and currently undefined mechanisms, including vascular delivery, heterogeneous permeability, stromal retention, or treatment-related alterations in tumor architecture. These observations therefore further illustrate the context-dependent and non-specific behavior of ICG rather than demonstrating reliable Wilms tumor targeting. Moreover, because pulmonary fluorescence in Wilms tumor has so far been described in only a single patient, its reproducibility, sensitivity, and biological basis remain unknown.

2.2. Need for structured evidence and ongoing clinical trials

Due to the rarity of the disease, the currently available literature remains limited and heterogeneous in terms of study design, patient selection, tumor histology, injection technique, and reporting standards. Nevertheless, these early experiences provide an important foundation for the progressive refinement of fluorescence-guided approaches in Wilms tumor surgery. Greater standardization of methodologies and reporting criteria, ideally through multicenter collaborative efforts, will be crucial to enable more robust comparisons across studies and to better define the clinical utility of ICG in this setting. Recent clinical trials, including the Phase I study (NCT04084067) [16] and the open-label, single-center, single-arm prospective feasibility study (NCT04854018) [17], are expected to provide further insight into the safety and feasibility of ICG-guided techniques in this setting. The GLO-Surgery trial (ISRCTN26150156) [18] has been initiated as a Phase II randomized controlled trial comparing ICG/NIR fluorescence-guided pediatric oncological surgery with conventional white-light surgery. Notably, in patients undergoing nephroureterectomy for renal tumors, the trial directly compares lymph-node yield between ICG/NIRF-guided and standard surgery, with secondary assessment of the location and histopathological status of the retrieved nodes. This trial is therefore expected to provide prospective comparative and pathology-correlated evidence regarding the clinical value of ICG-guided lymph-node identification in pediatric renal tumor surgery.

In summary, [6–9], [9–11], [12], [11]. ICG fluorescence-guided surgery in Wilms tumor is feasible and appears safe, but its interpretation is strongly dependent on the method of administration and the anatomical context. Systemic administration may provide inverse contrast between functioning renal parenchyma and selected tumor components [9–11], whereas local injection may delineate lymphatic drainage without identifying metastatic involvement [6–9]. Current evidence is predominantly Level IV and does not establish diagnostic accuracy or oncological benefit. ICG should therefore be considered an anatomical and optical adjunct rather than a tumor-specific diagnostic

agent. Future studies should standardize injection techniques, correlate fluorescence with detailed pathology, validate the sentinel-node concept, and determine whether fluorescence guidance improves nodal staging, margin status, or patient outcomes. Future progress in FGS for Wilms tumor will likely depend on the development of tumor-specific imaging agents capable of providing biologically relevant information in addition to the anatomical guidance currently offered by ICG [19].

CRediT authorship contribution statement

Irene Paraboschi: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Gloria Pelizzo:** Visualization, Validation, Supervision, Project administration, Data curation.

Conflict of interest statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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