RESEARCH PAPER

"Indocyanine Green Fluorescence Imaging in Sentinel Lymph Node Mapping for Breast Cancer: A Narrative Review of Current Evidence and Future Directions"

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ABSTRACT

Indocyanine green (ICG) fluorescence imaging has emerged as a promising modality for sentinel lymph node biopsy (SLNB) in breast cancer, offering real-time visualization of lymphatic pathways without radiation exposure. This narrative review synthesizes evidence from meta-analyses, randomized controlled trials, and prospective studies to evaluate the diagnostic performance, clinical applicability, and limitations of ICG in axillary staging. Meta-analytical data demonstrate consistently high sentinel lymph node detection rates ranging from 95% to 100%, with pooled estimates of approximately 98%. Comparative studies indicate that ICG achieves detection rates comparable to radioisotope techniques (approximately 96–98%) and superior to blue dye alone (85–95%). Dual tracer approaches combining ICG with radioisotope yield the highest detection rates, often exceeding 98–100%, suggesting a synergistic effect. Prospective studies further confirm real-world feasibility, with detection rates of 96–99% and favorable safety profiles. ICG offers several advantages, including real-time intraoperative guidance, absence of radiation, and applicability in resource-limited settings. However, limitations such as reduced tissue penetration in obese patients, variability in injection protocols, and occasional discordance with radioisotope detection persist. Current evidence supports the use of ICG as part of a dual tracer strategy, although its role as a standalone modality continues to evolve. Further research focusing on protocol standardization, long-term oncological outcomes, and cost-effectiveness is required to establish ICG as a universal standard in sentinel lymph node mapping for breast cancer.

Keywords: Indocyanine green, sentinel lymph node biopsy, breast cancer, fluorescence imaging, axillary staging, dual tracer

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Introduction

Breast cancer remains the most frequently diagnosed malignancy among women globally and continues to contribute substantially to cancer-related morbidity and mortality. Accurate assessment of axillary lymph node status is a cornerstone in staging, prognostication, and treatment planning. Historically, axillary lymph node dissection (ALND) was considered the standard approach; however, it is associated with significant complications including lymphedema, seroma formation, and restricted shoulder mobility. The introduction of sentinel lymph node biopsy (SLNB) has revolutionized axillary management by providing equivalent staging accuracy with significantly reduced morbidity.

Despite its advantages, conventional SLNB techniques rely on radioisotope tracers and blue dye, both of which have inherent limitations. Radioisotopes require specialized nuclear medicine facilities and involve radiation exposure, while blue dye is associated with hypersensitivity reactions and lower detection rates when used alone. These challenges have prompted the

exploration of alternative tracers that are safe, effective, and logistically feasible.

Indocyanine green (ICG) fluorescence imaging has emerged as a promising modality that enables real-time visualization of lymphatic drainage pathways using near-infrared (NIR) technology. This technique allows surgeons to directly visualize lymphatic channels intraoperatively, potentially improving accuracy and reducing operative time. As highlighted by Sukhera J Narrative Reviews Flexible Rigorous and Practical, narrative reviews are particularly suited for synthesizing such evolving evidence, integrating findings from diverse study designs while maintaining analytical rigor [1]. The present review aims to evaluate early and high-level evidence regarding the diagnostic performance and clinical utility of ICG in SLNB for breast cancer.

Methodological Approach to Narrative Review

This narrative review follows the methodological framework described by Sukhera [1], emphasizing flexibility, critical synthesis, and transparency. Unlike systematic reviews, narrative reviews allow integration of heterogeneous evidence, including meta-analyses, randomized controlled trials, and observational studies, which is particularly relevant for emerging technologies such as ICG fluorescence imaging.

The present synthesis focuses on key domains including detection rates, comparative effectiveness, and clinical applicability. Studies were selected based on their relevance to ICG-guided SLNB in breast cancer, with particular emphasis on meta-analyses and randomized trials to ensure high-quality evidence. The analytical approach prioritizes comparison of numerical outcomes across studies and identification of consistent patterns, rather than mere descriptive summarization.

Principles of Indocyanine Green Fluorescence Imaging

ICG is a water-soluble tricarbocyanine dye that binds rapidly to plasma proteins following injection. When exposed to near-infrared light (approximately 800 nm), it emits fluorescence that can be detected using specialized imaging systems. After periareolar or peritumoral injection, ICG travels through lymphatic channels, allowing real-time visualization of lymphatic drainage pathways and sentinel lymph nodes.

The ability to directly visualize lymphatic flow represents a significant advantage over conventional techniques, which rely on indirect detection methods such as gamma probes. This real-time guidance may enhance surgical precision and reduce the likelihood of missed nodes. However, the technique is limited by shallow tissue penetration (approximately 5–10 mm), which may affect detection in patients with higher body mass index or deeper lymph nodes.

Diagnostic Performance of ICG: Evidence from Meta-Analyses

Overall Detection Rates

Meta-analyses consistently demonstrate high detection rates with ICG-guided SLNB. Xiong et al. reported a **pooled detection rate of 98%**, with high sensitivity and acceptable false-negative rates, indicating strong diagnostic performance [2]. Similarly, Sugie et al. reported a **detection rate of 97.2%**, confirming the reliability of ICG in early-stage breast cancer [3]. These findings suggest that ICG provides consistent and reproducible results across different clinical settings.

ICG versus Radioisotope

Comparative studies indicate that ICG performs equivalently to radioisotope-based techniques. Goonawardena et al. demonstrated **detection rates of approximately 96–98% for both ICG and radioisotope**, with no statistically significant difference in diagnostic accuracy [4]. This equivalence is clinically significant, as radioisotope-based SLNB is considered the gold standard. The ability of ICG to achieve comparable results without radiation exposure positions it as a viable alternative.

ICG versus Blue Dye

The superiority of ICG over blue dye is consistently reported. Thongvitokomarn et al. found that **ICG achieved detection rates of 97–100%, compared to 85–95% for blue dye alone** [5]. This difference highlights the limitations of blue dye as a standalone tracer and underscores the advantage of fluorescence-guided imaging in improving detection accuracy.

ICG versus Dual Tracer Techniques

When compared to dual tracer techniques (radioisotope + blue dye), ICG demonstrates comparable performance. Kedrzycki et al. reported that fluorescence imaging achieved detection rates similar to dual tracer methods while significantly outperforming blue dye alone (risk ratio >1.1) [6]. Yin et al. further observed that ICG-guided SLNB resulted in **higher nodal yield, with an average of more than**

two sentinel nodes retrieved per patient, compared to conventional tracers [7]. This increased nodal yield may contribute to reduced false-negative rates and improved staging accuracy.

Recent Meta-Analytical Trends

Recent meta-analyses reinforce the robustness of ICG. Wang et al. reported **pooled detection rates exceeding 98.5%**, with improved intraoperative visualization [8]. Rocco et al. concluded that ICG represents an "emerging superior modality," particularly in terms of consistency and reproducibility [9]. Akrida et al. summarized that detection rates with ICG consistently range between **95% and 100%**, demonstrating minimal variability across studies [10].

Evidence from Randomized Controlled Trials

ICG versus Technetium

Vermersch et al. demonstrated that the addition of ICG to technetium resulted in **detection rates approaching 100%**, compared to slightly lower rates with technetium alone [12]. This finding suggests that ICG enhances the performance of conventional tracers when used in combination.

ICG in Post-Neoadjuvant Setting

Jung et al. evaluated SLNB in patients who had received neoadjuvant chemotherapy and reported **detection rates exceeding 98% with ICG combined with radioisotope**, compared to lower rates with radioisotope alone [13]. This is particularly relevant, as SLNB accuracy is often compromised after neoadjuvant therapy.

Dual Tracer Validation

The GREENORBLUE trial demonstrated that **dual tracer techniques incorporating ICG achieved detection rates greater than 97%**, confirming non-inferiority to standard methods [14]. The study also highlighted improved intraoperative visualization with fluorescence imaging.

Large Prospective Trials

The INFLUENCE trial reported **detection rates of 98–99% using ICG fluorescence imaging**, with high concordance with conventional techniques and minimal complications [15]. These findings support the clinical feasibility and safety of ICG-guided SLNB.

Synthesis of Early Evidence (Critical Interpretation)

The cumulative evidence from meta-analyses and randomized trials demonstrates that ICG fluorescence imaging is a highly effective modality for sentinel lymph node mapping in breast cancer.

Detection rates consistently range from **95% to 100%**, with pooled estimates of approximately **98%**, indicating high reliability. Comparative analyses show that ICG is **equivalent to radioisotope techniques (~96–98%)** and **superior to blue dye alone (97–100% vs 85–95%)**. Dual tracer approaches combining ICG with radioisotope achieve the highest detection rates, often exceeding **98–100%**, suggesting a synergistic effect.

Importantly, ICG offers unique advantages beyond detection rates. The ability to provide real-time visualization of lymphatic pathways enhances surgical precision and may reduce operative time. Furthermore, the absence of radiation exposure makes it particularly attractive in settings where nuclear medicine facilities are limited.

However, despite these advantages, the evidence also suggests that ICG performs optimally when used as part of a dual tracer strategy. While standalone ICG demonstrates high detection rates, combination techniques consistently achieve superior outcomes, particularly in complex clinical scenarios.

Overall, the early evidence positions ICG not merely as an alternative tracer but as a **technological advancement that enhances the accuracy and feasibility of SLNB**, with the potential to reshape current clinical practice.

Prospective and Observational Clinical Studies

Prospective and observational studies play a crucial role in validating the real-world applicability of indocyanine green (ICG) fluorescence imaging beyond controlled environments. These studies consistently demonstrate high detection rates, strong feasibility, and favorable safety profiles across diverse patient populations.

Valente et al. [16] conducted a prospective clinical study and reported a **sentinel lymph node (SLN) detection rate of 99% using ICG**, with clear visualization of lymphatic pathways. This study emphasized that fluorescence guidance enabled direct tracing of lymphatic channels, improving intraoperative decision-making. Similarly, Dumitru et al. [18] compared ICG with radioisotope and demonstrated **comparable detection rates (ICG: 96–**

98% vs radioisotope: 95–97%), confirming non-inferiority of ICG as a standalone tracer.

Jin et al. [19] evaluated multiple tracer combinations and found that **ICG combined with radioisotope achieved detection rates exceeding 98%**, outperforming single-tracer techniques. This finding highlights the additive value of fluorescence imaging in improving detection accuracy. The FLUOBREAST trial further reinforced these observations, reporting **detection rates ranging from 97% to 100% with minimal adverse events**, confirming both safety and clinical feasibility of ICG-guided SLNB [20].

However, variability in outcomes has been noted. Mazouni et al. [17] reported that **patients with higher body mass index exhibited reduced detection rates**, attributed to the limited penetration depth of near-infrared fluorescence. This suggests that patient-specific factors may influence performance and should be considered during clinical application.

Collectively, prospective evidence indicates that ICG achieves **real-world detection rates of approximately 96–99%**, with consistent reproducibility and excellent safety profiles.

Technique-Based Comparative Studies

Technique-based studies provide insight into the relative performance of ICG compared to other tracers and highlight the influence of procedural variations on outcomes.

Papathemelis et al. [21] demonstrated that ICG fluorescence imaging achieved **detection rates exceeding 95%**, with improved visualization of lymphatic drainage compared to conventional approaches. Agrawal et al. [22] compared **ICG combined with methylene blue versus radioisotope combined with methylene blue**, reporting **comparable detection rates (~97–98%)**, indicating that ICG-based protocols can effectively substitute radioisotope-based methods.

Technological advancements further enhance the utility of ICG. Wang et al. [23] introduced a real-time navigation system and demonstrated improved intraoperative localization of sentinel nodes, emphasizing the importance of imaging systems in optimizing outcomes.

Comparative studies consistently show the superiority of ICG-based combinations over dye-only techniques. Shen et al. [24] reported that **ICG combined with blue dye significantly improved detection rates compared to blue dye alone**, while Yuan et al. [25] demonstrated similar findings, with higher detection rates observed when fluorescence imaging was incorporated.

Takemoto et al. [26] reported **higher concordance rates with ICG compared to dual dye techniques**, suggesting improved reliability in identifying sentinel nodes. Qin et al. [27] further demonstrated that **ICG combined with blue dye outperformed methylene blue alone**, reinforcing the advantage of fluorescence-guided mapping.

These findings collectively indicate that:

- ICG enhances detection when combined with other tracers
- Fluorescence imaging provides superior visualization compared to dye-based techniques
- Imaging technology plays a critical role in determining outcomes

Role of ICG in Axillary Surgical Management

The role of ICG extends beyond sentinel node detection and has significant implications for overall axillary management.

Yuan et al. [28] emphasized that accurate SLNB is essential for avoiding unnecessary axillary dissection, and high detection rates with ICG contribute to safer surgical de-escalation. Lin et al. [29] reported that ICG-guided SLNB achieved **high identification rates (>95%) with reduced operative time**, suggesting improved efficiency.

Somashekhar et al. [30], in a study conducted in an Indian setting, demonstrated that **low-cost ICG techniques achieved detection rates of approximately 97–98%, comparable to dual tracer methods**, highlighting its feasibility in low- and middle-income countries. This is particularly important in settings where access to nuclear medicine facilities is limited.

Long-term outcomes are equally important. Wang et al. [31] reported that **ICG-guided SLNB demonstrated comparable oncological outcomes to conventional methods**, indicating that high detection rates translate into effective long-term management. Xu et al. [32] further demonstrated that **dual tracer techniques achieved higher detection rates than single tracers**, reinforcing the importance of combined approaches.

Hua et al. [33] confirmed that **ICG-guided SLNB is associated with favorable short- and long-term outcomes**, supporting its integration into routine clinical practice.

Table 1: Detection Rates and Outcomes in Prospective and Comparative Studies

Study	Design	Technique	Detection Rate	Key Outcome
Valente et al. [16]	Prospective	ICG	99%	High feasibility
Dumitru et al. [18]	Prospective	ICG vs RI	96–98%	Equivalent
Jin et al. [19]	Comparative	ICG + RI	>98%	Highest accuracy
Ngô et al. [20]	Trial	ICG	97–100%	Safe, effective
Agrawal et al. [22]	Comparative	ICG + MB	~97–98%	Comparable to RI
Shen et al. [24]	Comparative	ICG + BD	Higher than BD	Improved detection
Somashekhar et al. [30]	Indian study	ICG	~97–98%	Cost-effective
Hua et al. [33]	Outcomes	ICG	>95%	Favorable outcomes

Limitations and Sources of Heterogeneity

Despite strong evidence supporting ICG, several limitations must be critically examined.

Mazouni et al. [17] identified **reduced detection rates in obese patients**, highlighting a key limitation related to tissue penetration. Kang et al. [34] reported variability in fluorescence intensity, suggesting that **signal strength may influence detection accuracy**, particularly in deeper nodes.

Jimbo et al. [37] reported **discordance between ICG and radioisotope detection**, indicating that certain sentinel nodes may be detected by one modality but not the other. This raises concerns about relying solely on ICG.

Additional sources of heterogeneity include:

- Variability in injection protocols (dose, timing, site)
- Differences in imaging equipment
- Lack of standardized guidelines

These factors contribute to inconsistencies across studies and limit generalizability.

Special Clinical Scenarios

Post-Neoadjuvant Chemotherapy

Jung et al. [13] demonstrated that **ICG combined with radioisotope achieved detection rates exceeding 98%**, improving accuracy in patients after neoadjuvant therapy. Chirappapha et al. [39] reported similar findings, confirming the reliability of ICG in this challenging setting.

Obesity

Ng et al. [38] reported that ICG remains effective regardless of BMI, although other studies suggest reduced visualization in obese patients. This discrepancy indicates the need for further research.

Targeted Axillary Dissection

Pinto et al. [40] demonstrated that ICG improves localization of sentinel nodes in targeted axillary dissection, enhancing surgical precision and accuracy.

Technological Advances and Future Innovations

Technological advancements aim to address current limitations and enhance the performance of ICG.

Hsieh et al. [41] introduced a modified injection protocol that resulted in **improved fluorescence intensity and enhanced lymphatic visualization**, potentially overcoming limitations related to signal penetration.

Emerging innovations include:

- High-resolution near-infrared imaging systems
- Real-time navigation platforms
- Hybrid tracers combining fluorescence and radioactivity

These developments are expected to improve detection accuracy and expand clinical applications.

Research Gaps and Future Directions

Despite promising evidence, several gaps remain.

Sukhera [1] emphasizes the importance of identifying research gaps in narrative synthesis, while Kurdi et al. [11] highlight the need for comprehensive evaluation of ICG applications.

Key gaps include:

- Lack of large multicentric randomized trials
- Absence of standardized protocols
- Limited long-term survival data
- Insufficient cost-effectiveness analyses

Addressing these gaps will be essential for establishing ICG as a universal standard.

Table 2: Advantages and Limitations of ICG Fluorescence Imaging

Domain	Advantages	Limitations

Detection	95–100% accuracy	Variable in obesity
Safety	No radiation	Equipment dependent
Visualization	Real-time mapping	Limited depth (5–10 mm)
Cost	Feasible in LMICs	Initial setup cost
Accuracy	Comparable to RI	Possible discordance

Conclusion

Indocyanine green fluorescence imaging represents a major advancement in sentinel lymph node mapping for breast cancer. Evidence from prospective studies and comparative analyses demonstrates detection rates consistently ranging from **95% to 100%**, with diagnostic accuracy comparable to radioisotope techniques and superior to blue dye.

ICG offers unique advantages, including real-time visualization, absence of radiation exposure, and applicability in resource-limited settings. However, limitations such as reduced penetration in obese patients, variability in technique, and lack of standardization must be addressed.

Current evidence supports the use of ICG as part of a **dual tracer strategy**, where it enhances detection accuracy beyond conventional methods. With continued technological advancements and further research, ICG has the potential to evolve into a standalone modality and redefine the standard of care in axillary staging.

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