e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2026; 17(5); 74-80

Original Research Article

Assessing The Utility of Indocyanine Green Fluorescence in Real-Time Intraoperative Imaging for Sentinel Lymph Node Biopsy in Breast Cancer

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Received: 18-03-2026 / Revised: 16-04-2026 / Accepted: 17-05-2026
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Conflict of interest: Nil

Abstract:

Aim: Sentinel lymph node biopsy (SLNB) is the standard operative method for axillary staging in clinically node-negative early breast cancer, because it reduces morbidity compared with axillary lymph node dissection while preserving staging accuracy. Indocyanine green (ICG) fluorescence imaging has emerged as a near-infrared, real-time intraoperative mapping method that may simplify sentinel node localization while maintaining oncologic reliability. The aim of this paper is to assess the utility of ICG fluorescence in real-time intraoperative imaging for SLNB in breast cancer, with emphasis on feasibility, detection performance, safety, comparative effectiveness against conventional tracers, practical limitations, and its current role in evidence-based surgical practice.

Materials and Methods: This paper is a narrative evidence synthesis based on peer-reviewed reviews, meta-analyses, prospective studies, and guideline-oriented literature addressing ICG-guided SLNB in breast cancer. Core evidence was drawn from an updated review published in 2023, a systematic review and meta-analysis published in 2020, an earlier diagnostic meta-analysis published in 2016, a prospective open-label clinical trial published in 2015, and a prospective observational noninferiority study published in 2022.

Result: ICG fluorescence demonstrates consistently high sentinel node detection rates in breast cancer surgery and is repeatedly reported as superior to blue dye alone and broadly comparable to radioisotope-based mapping. In the 2016 meta-analysis of 19 studies and 2,594 patients, the pooled detection rate for ICG-guided SLNB was 0.98, with pooled sensitivity of 0.92, specificity of 1.00. Review-level evidence further suggests that ICG may increase intraoperative visualization, support real-time lymphatic mapping, and help identify a slightly greater number of sentinel nodes per patient than conventional techniques, although standardization of dose, concentration, injection site, timing, and imaging platform remains incomplete.

Conclusion: Current evidence supports ICG fluorescence as a safe, feasible, and highly effective technique for real-time intraoperative sentinel lymph node mapping in breast cancer surgery. The most defensible present conclusion is that ICG is an important contemporary tracer for SLNB in breast cancer, either as an alternative to conventional agents in selected settings or as part of a combined strategy, pending further multicenter randomized evidence and broader guideline harmonization.

Keywords: Breast Cancer; Indocyanine Green; Fluorescence Imaging; Sentinel Lymph Node Biopsy; Near-Infrared Imaging.

DOI: 10.25258/ijpqa.17.5.11

Introduction

Breast cancer remains one of the most common malignancies in women worldwide, and accurate axillary staging continues to influence prognosis estimation, adjuvant treatment planning, and local-regional management. For patients with clinically node-negative disease, sentinel lymph node biopsy has replaced routine axillary lymph node dissection in most settings because it achieves pathologic staging with substantially less arm morbidity, pain, seroma formation, sensory disturbance, and lymphedema.

Radioisotope-based mapping offers reliable detection but requires nuclear medicine support, strict handling regulations, coordination around isotope availability, preoperative injection workflows, and specialized facilities that may not be available in every hospital. These limitations have encouraged the search for alternative tracers that can preserve diagnostic accuracy while improving feasibility and operative convenience. In breast SLNB, ICG is injected peri-tumorally, periareolarly, sub dermally, or by combined approaches depending on institutional protocol, and the lymphatic channels can then be visualized in real time with near-infrared cameras as the dye travels toward sentinel nodes. Surgeons can therefore follow fluorescent pathways toward nodal

basins, confirm node fluorescence before excision, and inspect the wound cavity for residual signal after removal.

Over the past decade, a substantial body of literature has evaluated ICG in breast SLNB, including prospective cohorts, single-center comparative studies, systematic reviews, and meta-analyses. Protocol heterogeneity remains a major issue. Studies differ in ICG concentration, injected volume, injection site, time interval before incision, camera platform, patient population, and whether ICG is used alone or in combination with other tracers. The available meta-analytic evidence suggests favorable sensitivity and specificity, yet robust false-negative rate data are still less abundant than simple detection data, especially in subgroups such as patients undergoing neoadjuvant chemotherapy. Recent multicenter prospective work has expanded the evidence base in more complex settings, indicating that dual ICG plus blue dye tracing can achieve high detection rates and very low false-negative rates after neoadjuvant chemotherapy in initially node-positive disease.

The current guideline environment also reflects this transitional phase. Contemporary guidance strongly endorses SLNB for appropriate early-stage breast cancer populations, but global consensus has not yet fully converged on ICG as the single universal replacement for traditional tracers. The purpose of this paper is therefore to examine the utility of indocyanine green fluorescence in real-time intraoperative imaging for sentinel lymph node biopsy in breast cancer from a practical, diagnostic, and clinical perspective.

Materials & Method

This paper uses a narrative review design intended for academic synthesis of published evidence on ICG fluorescence in breast cancer SLNB. Because the requested assignment emphasizes appraisal of clinical utility rather than original patient recruitment, the materials consist of published studies, systematic reviews, meta-analyses, and guideline updates relevant to tracer performance, intraoperative visualization, and surgical outcomes.

Study Design: The work was structured as a focused secondary analysis of the literature. Priority was given to sources that offered quantitative results on identification rate, diagnostic accuracy, noninferiority, or comparative detection odds. Five core evidence categories were considered: narrative review evidence, systematic reviews, diagnostic meta-analyses, prospective clinical studies in early breast cancer, and guideline statements that contextualize the role of SLNB in current practice.

Data Sources: Data were drawn from peer-reviewed articles indexed in PubMed and related academic repositories. The principal documents included an updated 2023 review on the emerging role of ICG in breast cancer SLNB, a 2020 systematic review and meta-analysis comparing ICG with blue dye and radioisotope, a 2016 diagnostic meta-analysis, a 2015 prospective open-label trial, and a 2022 prospective observational study evaluating noninferiority to radioisotope. A 2025 ASCO guideline update on sentinel lymph node biopsy in early-stage breast cancer was used to frame the broader standard-of-care environment in which these tracer techniques operate. A 2025 multicenter prospective cohort study on ICG plus methylene blue after neoadjuvant chemotherapy was also incorporated to provide perspective on evolving indications beyond straightforward upfront surgery.

Eligibility Approach: Included reports had to address breast cancer SLNB and evaluate ICG fluorescence either alone or in combination with other tracers. Preference was given to studies that reported explicit numerical outcomes such as detection rate, sensitivity, specificity, node yield, tumor-positive node detection, or safety endpoints. Reviews that only discussed fluorescence conceptually without outcome data were not used for quantitative tables. Since this was not a formal systematic review conducted de novo, no PRISMA flow diagram or independent duplicate screening process was generated; instead, the paper used a descriptive selection of high-yield studies from the available evidence base.

Technique Overview: In the underlying studies, ICG was generally administered as a periareolar, subareolar, peri-tumoral, intradermal, or combined injection, followed by massage and intraoperative visualization with near-infrared fluorescence imaging systems In comparative studies, the same patient often underwent dual mapping using ICG and a standard tracer, allowing head-to-head analysis of nodal localization performance.

Data Presentation: The findings were organized into four observation tables to improve clarity. Table 1 summarizes key quantitative findings from major studies. Table 2 compares practical characteristics of ICG, blue dye, and radioisotope. Table 3 lists advantages and limitations of ICG in operative use. Table 4 provides a simplified evidence synthesis relevant to clinical adoption.

Observation Tables

Table 1: Selected Studies on ICG-Guided SLNB in Breast Cancer

Study	Design	Sample	Key finding
Sugie et al., 2016 meta-analysis	Meta-analysis	19 studies; 2,594 patients	Pooled detection rate 0.98; sensitivity 0.92; specificity 1.00; AUC 0.9758.
Thongvitokomarn and Polchai, 2020	Systematic review and meta-analysis	30 studies; 4,216 SLN procedures	ICG better than blue dye for SLN detection, OR 6.73; no significant difference versus RI, OR 0.90.
Samorani et al., 2015	Prospective open-label trial	Clinical prospective cohort	ICG judged valid and feasible compared with blue dye method and scintigraphy
Jones et al., 2022	Prospective observational study	79 patients; 162 nodes	Overall identification rate 98.7%; ICG noninferior to radioisotope; no serious adverse reactions.

Table 2: Practical Comparison of Tracer Methods In Breast SLNB

Parameter	ICG fluorescence	Blue dye	Radioisotope
Intraoperative visualization	Real-time near-infrared lymphatic mapping.	Visual staining only, limited tissue penetration	Audible probe localization rather than direct optical lymphatic mapping.
Logistics	No radioactive handling; requires fluorescence camera.	Simple and inexpensive; minimal equipment.	Requires nuclear medicine support and regulatory handling.
Detection performance	Superior to BD; comparable to RI in many studies.	Inferior to ICG in pooled analyses.	Historical standard with high reliability.
Safety considerations	Generally safe; serious adverse reactions uncommon in cited prospective data.	Allergic and anaphylactic reactions reported.	Radiation-related logistics rather than dye allergy is the main issue.

Table 3: Advantages and Limitations of ICG Fluorescence

Advantages	Limitations
Real-time mapping of lymphatic channels and sentinel nodes improves surgical orientation	Lack of universal standardization for dose, concentration, injection site, and timing.
Nonradioactive technique reduces dependence on nuclear medicine infrastructure.	Requires dedicated near-infrared imaging equipment and training.
Higher pooled detection than blue dye in meta-analysis.	Tissue penetration may be limited, especially for transcutaneous visualization in deeper tissue.
Comparable performance to radioisotope in several studies, including prospective noninferiority data.	Long-term guideline harmonization and universal replacement strategy remain unsettled.

Table 4: Evidence Synthesis Relevant to Clinical Adoption

Clinical question	Evidence summary
Can ICG identify sentinel nodes reliably?	Yes. Meta-analytic pooled detection is very high, reaching 0.98 in one major analysis.
Is ICG better than blue dye?	Yes in detection performance, with a significant pooled advantage over blue dye.
Is ICG comparable with radioisotope?	Broadly yes in detection, with no significant difference in one major meta-analysis and noninferiority in prospective data.
Should ICG completely replace conventional tracers everywhere?	Evidence is promising, but standardization and guideline consensus remain incomplete, so adoption is best considered context-specific.

Result

The evidence reviewed in this paper shows that ICG fluorescence is a highly capable tracer for sentinel lymph node mapping in breast cancer surgery. The 2016 diagnostic meta-analysis provides the clearest quantitative summary, reporting a pooled detection rate of 0.98, sensitivity of 0.92, specificity of 1.00, and a summary receiver operating characteristic area of 0.9758, all of which support strong diagnostic performance. The superior detection profile of ICG suggests that fluorescence can improve mapping reliability where surgeons might otherwise depend on dye-only visualization.

A prospective observational study published in 2022 further showed an overall identification rate of 98.7%, and ICG met the study's predefined criterion for noninferiority compared with radioisotope. The reviewed studies also support a favorable safety profile ICG therefore appears to offer both technical efficacy and acceptable intraoperative safety when

used appropriately. A further result of practical significance is the qualitative benefit of real-time visualization. This can improve operative orientation, help confirm the lymphatic pathway before nodal excision, and make the technique particularly intuitive for surgeons experienced in image-guided procedures.

In addition, the evidence for ICG as a sole replacement in every patient population remains less mature than the evidence showing it is a strong alternative or adjunct. Even so, the balance of published results supports routine consideration of ICG for SLNB in breast cancer, especially where nonradioactive real-time imaging would solve logistical or workflow problems.

Statistical Analysis: The statistical interpretation of the available evidence rests mainly on pooled detection metrics, comparative odds ratios, and diagnostic accuracy parameters reported in meta-analyses and prospective comparative studies.

The odds ratio comparing ICG with radioisotope was 0.90 with a 95% confidence interval of 0.40 to 2.03, which crosses 1.0 and therefore indicates no statistically significant difference in detection performance between the two methods. Clinically, this means ICG cannot be declared clearly superior to radioisotope on the basis of that pooled analysis, but it can reasonably be considered comparable in detection effectiveness.

Discussion

Sentinel lymph node biopsy has become the standard method for axillary staging in clinically node-negative early breast cancer because it reduces the morbidity associated with full axillary dissection while maintaining oncologic accuracy.The contemporary ASCO guideline further narrows the indications for routine sentinel node surgery in selected low-risk patients, but it still supports SLNB in most patients who require pathologic axillary staging, making optimization of tracer technique clinically relevant. In this context, indocyanine green (ICG) fluorescence has emerged as a practical alternative to conventional blue dye and radioisotope methods because it offers real-time lymphatic visualization without radioactive handling requirements.

The present study can be interpreted against a body of evidence that consistently shows high detection rates with ICG-guided mapping. A recent review by Akrida and colleagues concluded that ICG is safe and effective, is superior to blue dye, and is at least comparable to radioisotope alone or radioisotope combined with blue dye in many clinical settings. If the present study demonstrated a high sentinel node identification rate with acceptable nodal yield, those findings would align closely with that synthesis and support the view that ICG is no longer an experimental adjunct but a mature tracer platform for breast surgery.

Comparison with meta-analytic evidence is especially important because pooled studies reduce the uncertainty inherent in single-center series. Thongvitokomarn and Polchai analyzed 30 studies comprising 4,216 sentinel lymph node procedures and found a statistically significant advantage of ICG over blue dye for detection rate, whereas no significant difference was observed between ICG and radioisotope. Therefore, if the present study found performance superior to blue dye or broadly equivalent to radioisotope, it would be strongly concordant with this meta-analysis rather than an isolated favorable result.

Earlier pooled evidence also supports the same direction of effect. The 2021 evidence synthesis comparing ICG with conventional tracers reported that ICG was better than blue dye in patient identification rate, SLN identification rate, and false-negative rate, and it was not inferior to the combined standard technique of blue dye plus radioisotope. This means that any present-study observation showing greater technical ease, higher node retrieval, or better localization than dye-only methods should be discussed as part of a stable pattern already seen across multiple comparative datasets.

The historical trajectory of the literature further strengthens the interpretation of a positive present-study result. One of the earliest clinical reports, by Kitai and colleagues, demonstrated visible lymphatic channels in all patients and successful sentinel node identification in 17 of 18 cases, corresponding to a 94 percent detection rate.That early experience showed proof of concept rather than definitive equivalence, so if the present study achieved a higher detection rate than this pioneering series, the difference would likely reflect advances in imaging systems, operator familiarity, and refined injection techniques rather than contradiction of the original work.

Subsequent feasibility and validation studies moved the field from concept to reproducibility. Verbeek and colleagues reported successful SLN identification in 94 of 95 patients, or 99 percent, using near-infrared fluorescence imaging or a combination of fluorescence and radioactive guidance, and all 177 resected sentinel nodes were fluorescent. Notably, a small number of metastatic sentinel nodes were detected only by near-infrared fluorescence in that study, so if the present study also found that fluorescence identified clinically meaningful nodes not easily recognized by standard methods, it would be consistent with the incremental diagnostic value described in this multicenter experience.

Direct prospective comparison with radioisotope is particularly relevant when discussing whether ICG can replace established tracers. Jones and colleagues

prospectively studied 79 patients and found an overall identification rate of 98.7 percent, with ICG proving noninferior to radioisotope for nodal detection; all 13 metastatic nodes were both fluorescent and radioactive, and no serious adverse reactions occurred. Accordingly, if the present study found equivalent accuracy between ICG and radioisotope, those findings would support the growing argument that ICG can function as a sole tracer in appropriately selected early breast cancer patients.

The number of nodes removed is another useful comparison point because excessive retrieval may negate some of the minimally invasive intent of sentinel surgery, whereas inadequate retrieval may worsen false-negative risk. Thongvitokomarn and Polchai reported average numbers of removed sentinel nodes of 2.35 for ICG, 1.92 for blue dye, and 1.72 for radioisotope. If the present study retrieved approximately two to three nodes per patient, it would sit squarely within the expected range from pooled evidence and would suggest that ICG provides robust mapping without clearly excessive nodal excision.

Our study should also be compared with reports evaluating combination tracer strategies rather than ICG alone. Evidence summarized in comparative analyses shows that dual mapping with ICG plus radioisotope can outperform single-tracer approaches in sensitivity, and combination approaches with methylene blue may increase nodal yield and identify additional positive axillae. Therefore, if the present study used ICG as a sole tracer and still achieved high detection and low false-negative performance, that would be an important practical finding, because it would suggest that some of the benefits of dual mapping may be attainable with fluorescence alone in experienced hands.

The neoadjuvant setting deserves separate discussion because sentinel node biopsy after systemic therapy is technically more challenging and clinically more controversial. In a 2025 multicenter prospective cohort of initially cN1 patients treated with neoadjuvant chemotherapy, Shimazu and colleagues found a detection rate of 97.4 percent and a false-negative rate of 6.7 percent for ICG plus methylene blue, with a median retrieval of three nodes and no allergic reactions. If the present study involved upfront surgery rather than post-neoadjuvant staging, its results should not be equated directly with this cohort; however, favorable present-study findings would still reinforce the broader conclusion that ICG-based mapping remains reliable even in more demanding clinical scenarios.

Safety is another domain in which the literature provides consistent support for ICG. Both the updated review and major prospective studies describe ICG as safe, with no serious adverse reactions in the Jones study and no allergic reactions in the Shimazu cohort. Thus, if the present study observed no tracer-related complications, that result would not merely be reassuring locally but would fit the prevailing international evidence that ICG has an acceptable perioperative safety profile when used for SLNB.

The practical advantages of ICG over radioisotope should be explicitly weighed in the discussion because technical performance is only one part of clinical adoption. The literature repeatedly notes that ICG avoids the logistical burdens associated with nuclear medicine infrastructure, radioactive licensing, tracer scheduling, and disposal requirements, while still producing detection rates that are broadly comparable to radioisotope. Therefore, if the present study was conducted in a center where radioisotope access is limited or costly, favorable findings with ICG would have particular relevance for workflow simplification and wider dissemination of sentinel node biopsy.

At the same time, the discussion should acknowledge that superiority is not universal across every comparator and endpoint. While meta-analyses strongly support superiority over blue dye, they usually show equivalence rather than clear superiority when ICG is compared with radioisotope for overall detection rate, although some analyses suggest improved positive node identification or false-negative performance relative to radioisotope alone. If the present study showed only comparable, not superior, performance against radioisotope, that would still represent a clinically meaningful result and would be fully consistent with the most credible pooled evidence.

Another important comparison concerns the evolution of guideline relevance. The 2025 ASCO guideline emphasizes careful patient selection for SLNB and recommends omission of routine SLNB in some postmenopausal patients aged 50 years or older with small, hormone receptor-positive, HER2-negative tumors and negative axillary ultrasound undergoing breast-conserving therapy. In patients who still meet indications for SLNB, however, the choice of tracer remains crucial; therefore, if the present study focuses on technically eligible patients requiring axillary staging, its contribution lies not in expanding indications for SLNB but in refining how the procedure is performed.

The limitations of the reference literature should also be used to frame the present study appropriately. Many earlier studies were single-center, involved modest sample sizes, used heterogeneous comparator tracers, or combined ICG with other mapping agents, all of which complicate cross-study comparison. If the present study includes a clearly defined protocol, consistent injection technique, and transparent endpoint reporting, it may offer a more practice-oriented contribution even if its sample size is smaller than that of the large meta-analyses.

Overall, the available references support a balanced conclusion: ICG fluorescence-guided sentinel lymph node biopsy in breast cancer is clearly superior to blue dye, broadly noninferior to radioisotope, and particularly attractive where nuclear medicine resources are limited. If the present study found high identification rates, adequate sentinel node yield, low false-negative performance, and good safety, then its results are best interpreted as confirmatory of the strongest contemporary evidence rather than exceptional outliers. Such concordance would strengthen the case for integrating ICG more widely into routine breast cancer surgery, while still recognizing that tracer choice should remain tailored to institutional expertise, equipment availability, and clinical setting.

Conclusion

Indocyanine green fluorescence has become one of the most important innovations in sentinel lymph node mapping for breast cancer because it aligns modern surgical oncology with real-time image guidance. Real-time near-infrared visualization of lymphatic channels transforms node mapping from a largely indirect process into a directly observed one

The clinical utility of ICG is therefore best defined in balanced terms. The most accurate present position is that ICG is a mature, evidence-supported tracer that can serve as an excellent alternative to conventional mapping in many patients and an excellent complement to other tracers in others. In conclusion, indocyanine green fluorescence in real-time intraoperative imaging offers substantial utility for sentinel lymph node biopsy in breast cancer. It combines high detection rates, strong safety, operative visibility, and freedom from radioactive logistics, making it one of the most promising advances in contemporary breast surgery. Future multicenter randomized trials with standardized protocols will clarify the settings in which ICG should be used alone, but existing evidence already justifies its serious adoption in modern surgical practice.

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