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A Modern Treatment in Breast Cancer: The Role of ICG

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ABSTRACT

Breast cancer (BC) is the most commonly diagnosed cancer in the world. Sentinel lymph nodes (SLN)s are the regional nodes that drain lymph from the primary tumor, as SLN biopsy is a method for screening and identifying metastases in regional lymph nodes. The objectives were to determine the sensitivity and safety of Indocyanine green (ICG) for SLN identification and lymphatic mapping in malignancies in early BC. Combining 26 articles, this study was conducted October 2023 – December 2024, on more than 100 women with early BC that underwent this intervention. By using ICG, the subcutaneous lymphatic drainage pathway and the deeper lymphatic vessels (LV)s were able to get observed. Benefits included no risk of injuring LVs, axillary lymphadenectomy was not needed, complications were rare; becoming advantageous for patients and surgeons. SLNs identification was successfully carried out with a sensitivity of 100%. Allergic reactions and local infections were less reported. SLNs were removed in all cases. ICG allowed real-time transcutaneous lymphography, visualization of the lymphatic pathway(s) to the axilla. Results confirmed the high sensitivity of ICG fluorescence for SLN detection in early BC, proving this method is safe, less allergic reactions following subareolar injection.

Keywords: Breast Cancer; Sentinel Lymph Node Biopsy; Breast Cancer; Indocyanine Green; Fluorescence Imaging

Abbreviations: ICG: Indocyanine Green; SLNB: Sentinel Lymph Node Biopsy; BC: Breast Cancer; SLN: Sentinel Lymph Nodes; LV: Lymphatic Vessels; ALND: Axillary Lymph Node Dissection; MB: Methylene Blue; FI: Luorescence Imaging; RI: Radioisotope

Introduction

The most common malignancy among women worldwide is BC. In patients with this malignacy, accurate lymph node staging is extremely important for both prognosis (of early-stage illness) and treatment (for regional disease control). The local nodes that directly receive lymph from the source tumor are known as SLN. When a primary BC is in an early stage (I or II), no imaging modality is accurate enough to find lymph node metastases, but sentinel lymph node biopsy (SLNB) is a very reliable way to screen axillary nodes and find metastatic (including micro-metastatic) disease in local lymph nodes [1]. The areola serves as the primary growth site for the lymphatic channel network in the breast, while the axilla serves as the primary export route. The initial collection point of this lymphatic flow, the SLNs, are at the fore of the immune tracking system in the breast. In terms of surgical interventions for BC, it has been discovered that skipping axillary dissection has no effect on prognosis in the absence of SLN metastases [2].

Surgery for BC has been less invasive ever since William Halsted conducted the first radical mastectomy in 1882, which involved the removal of all breast tissue, all axillary lymph nodes, and both pectoralis muscles [1]. Studies conducted over the past four decades have revealed that early-stage breast BC treated with lumpectomy

and radiation have similar survival rates to those treated with mastectomy [3]. Numerous devices have been developed to help prevent postoperative problems following reconstructive breast surgery since they frequently result in significant increases in patient suffering and treatment expenses. By identifying ischemic skin intraoperatively, intraoperative fluorescence angiography with indocyanine green (ICG) offers promising outcomes in this regard. This study wants to show the importance of the ICG method, and its benefits associated with direct visualization [4], high sensitivity and safety, in SLNs identification and lymphatic mapping in malignant tumors in early BC.

Breast cancer is now being ranked as number 1 among women everywhere, with an incidence as high as 162,468 and a fatality rate of 87,090 [5]. SLNB has advanced with our understanding of BC spread. Axillary lymph node status has been the key prognostic factor for survival and recurrence in early BC, traditionally determined by axillary lymph node dissection (ALND). While ALND provides accurate staging and control, it carries high risks, including reduced shoulder mobility, lymphedema, and nerve damage. Over time, SLNB has gradually replaced ALND [6]. ICG, a common fluorophore, is used in fluorescence imaging (FI), a potential non-invasive method for detecting primary malignancies. ICG-FI has been explored for identifying metastatic deposits, including lymph nodes, though its tumor-specific uptake isn't fully understood. The likely explanation is the enhanced permeability and retention effect due to tumor neo angiogenesis. After intravenous injection, ICG binds to serum proteins and accumulates in tumor tissue, emitting fluorescence (peak at 840 nm) when exposed to near-infrared light.

The fluorescence can penetrate tissue up to 5–10 mm thick, with tumor tissue appearing hyperfluorescent due to ICG's short half-life and extravascular accumulation. ICG is rapidly flushed out of the intravascular space due to its short half-life of 3-5 minutes in blood circulation, and the extravascular accumulation of ICG is what causes the hyper fluorescence of tumoral tissue in contrast to surrounding normal tissue [7]. Recent findings show that SLNB with NIR-FI using ICG is highly sensitive for SLN detection. ICG is injected, and its movement through lymphatic ducts to SLNs is tracked with an illumination system and a high-sensitivity camera. Combining ICG with methylene blue (MB) offers a promising alternative to traditional dual mapping, as NIR can be detected transcutaneously like radioactive agents [8]. The dual dye approach (technetium-99m and blue dye) is the gold standard for SLN identification, with high detection rates but notable side effects like allergic reactions and skin pigmentation.

Technetium-99m also presents challenges such as handling radioactive material and potential pollution. ICG fluorescence has emerged as a promising alternative due to its safety, accuracy, and ease of use. Studies show ICG offers high detection rates (90%-100%) and low false-negative rates (3%-12%) in early breast cancer [5]. It is believed that ICG's preferential use over lymphoscintigraphy may have a significant impact on preoperative times because it can be used to identify the SLN in the operating room immediately following the induction of general anesthesia and does not require patient pre-hospitalization. Furthermore, by avoiding lymphoscintigraphy, it is hoped to provide benefits to both patients (by saving them from having to visit the hospital again) and healthcare workers (by reducing patient-patient and patient-physician interaction). The study's objective is to show that the SLNB approach has a serious number of benefits, including more safety and feasibility when using ICG as the only tracer [9] and to determine the clinical significance of SLN detection using FI following ICG injection. Preoperatively, informed consent about the intervention was obtained from each patient [10].

Materials and Methods

Our study combined 28 scientific articles from medical online libraries, that were published from early 2000 that include the history of BC and its complications, focusing on the ones conducted since 2020. In Table 1., we have put 20 key studies we researched and the authors who successfully proved in their work, the importance of SLNB and the benefits of ICG in BC [11-13]. The research we have done, showed us that the important and relevant studies were conducted for over the past decade, but in the past 2 years the physicians have been impressively focused on proving the obvious safety and successful interventions on mapping the SLN by using ICG as an only tracer. Women included were all aged from 18 to 90 years old, who underwent this technique, as they gave their informed consent for their inclusion in the study. Studies including BC patients who needed SLNB treatment, research formats such as published randomized controlled trials, retrospective cohort studies, or comparative studies comparing ICG-FI and MB for SLNB in the treatment of BC and studies about intervention methods on using ICG were considered for the inclusion criteria.

Table 1: Key studies that have been researched for this article.

Article	Author	Year
"ICG fluorescence-guided sentinel lymph node biopsy in early breast cancer – a single-center initial experience"	Karamanliev, et al [23]	2023
"Meta-analysis of the application value of indocyanine green fluorescence imaging in guiding sentinel lymph node biopsy for breast cancer"	Wang, et al [22]	
"Understanding breast cancer as a global health concern"	Wilkinson, et al [20]	2022
"Indocyanine green [ICG] fluorescence guide for the use and indications in general surgery: recommendations based on the descriptive review of the literature and the analysis of experience"	Morales-Conde, et al [14]	
"The use of indocyanine green as the only tracer for the identification of the sentinel lymph node in breast cancer: safety and feasibility"	Pellini, et al [9]	
"Sentinel Lymph Node Methods in Breast Cancer"	Giammarile, et al [1]	
"Techniques for sentinel node biopsy in breast cancer"	Bove, et al [27]	2021
"Indocyanine green for sentinel lymph node detection in early breast cancer: Prospective evaluation of detection rate and toxicity-The FLUO-BREAST trial"	Ngô, et al [26]	2020
"Conserving the lymphatics from the arm using fluorescence imaging in patients with breast cancer at high risk of postoperative lymphedema: a pilot study"	Yoon, et al [19]	
"Comparison of indocyanine green fluorescence and methylene blue dye in the detection of sentinel lymph nodes in breast cancer"	Wang, et al [18]	
"Can Low-cost Indo Cyanine Green Florescence Technique for Sentinel Lymph Node Biopsy Replace Dual Dye [Radio-colloid and Blue Dye] Technique in Early Breast Cancer: A Prospective Two-arm Comparative Study"	Somashekhar, et al [5]	
"Indocyanine green fluorescence method for sentinel lymph node biopsy in breast cancer"	Lin, et al [6]	
"Intraoperative indocyanine green fluorescence imaging in breast surgery"	Kühn, et al [4]	
"Comparison of the indocyanine green dye method versus the combined method of indigo carmine blue dye with indocyanine green fluorescence imaging for sentinel lymph node biopsy in breast conservative therapy for stage ≤IIA breast cancer"	Takemoto, et al [2]	2018
"ICG fluorescence imaging as a new tool for optimization of pathological evaluation in breast cancer tumors after neoadjuvant chemotherapy"	Veys, et al [7]	
"Sentinel lymph node biopsy using indocyanine green fluorescence in early-stage breast cancer: a meta-analysis"	Sugie, et al [21]	2017
"Comparison of sentinel lymph node biopsy guided by indocyanine green, blue dye, and their combination in breast cancer patients: a prospective cohort study"	Guo, et al [8]	
"Indocyanine Green: Historical Context, Current Applications, and Future Considerations"	Reinhart, et al [25]	2016
"Evaluation of the Clinical Utility of the ICG Fluorescence Method Compared with the Radioisotope Method for Sentinel Lymph Node Biopsy in Breast Cancer"	Sugie, et al [24]	
"Transcutaneous detection and direct approach to the sentinel node using axillary compression technique in ICG fluorescence-navigated sentinel node biopsy for breast cancer"	Kitai, et al [16]	2012

The primary exclusion criteria included researches that poorly utilized ICG, studies whose complete texts are not accessible, and studies whose summaries offer few or no useful information. Also, general patient clinical aspects like age, BMI, nicotine exposure, comorbidities and medical history regarding prior breast surgery, breast radiation and chemotherapy, clinical features like the type of surgery (nipple sparing mastectomy, skin sparing mastectomy, other – including follow-up resection, scar correction, implant exchange, secondary implant insertion, reduction mammoplasty) and the type of reconstruction (implant based, use of mesh, acellular dermal matrix or tissue expander, autologous tissue transfer) were noted. In case of implant based reconstruction, the implant position, shape and size were recorded [6].

SLN Detection with ICG-FI

A fluorescence imaging system was used to see ICG fluorescence. It consists of a digital video camera and an integrated NIR light source (energy 0.16 W, wavelength 780 nm). A filter (835 nm) was placed over the camera's objective to gather NIR light and block visible light. The subareolar area of the breast received an average of 1-5 mg/ml of ICG solution intraoperatively. Fluorescence imaging was used to track the lymphatic transit of ICG at the anterior chest wall, covering the supraclavicular, parasternal, and axillary regions, for 5 to 15 minutes after injection. The skin was marked where the lymphatic vessel ended and the SLNs were removed directly on the spot. Only qualified surgeons could perform fluorescence lymphography, which included using ICG for SLN detection and SLN biopsy [10].

Briefly, specific cameras are used to detect the fluorescence, and these cameras send this information to a monitor, helping to identify the structures that the dye is present in, as seen in Figure 1. ICG binds to plasma proteins quickly and it is removed unaltered by bile without enterohepatic recirculation. ICG is injected directly into tissue, binds to proteins, travels to the closest lymph node in a matter of minutes, and then binds to nearby lymph nodes. ICG is also often given while being diluted with distilled water. When used to locate the SLN that drains the tumor, ICG is diluted with albumin. It is being used with albumin because it has the ability to stop in that first draining lymph node and be successfully identified. This drug shouldn't be diluted with saline solutions (Ringer's solution, saline), as this might lead to precipitation of the dye. The goal of conservative surgery and preventing excessive unneeded lymphadenectomies is the development of ICG to identify the SLN in oncological surgeries [14].

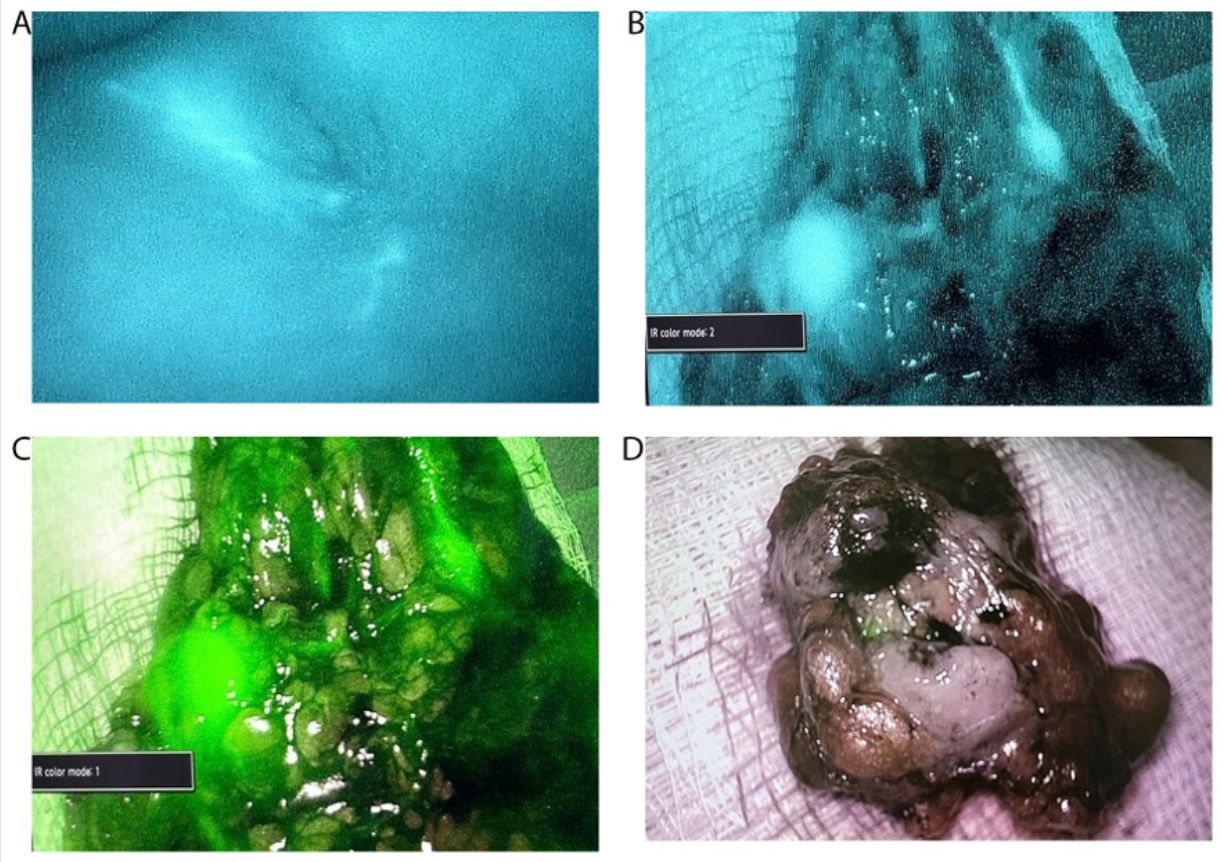


Figure 1:
(A) The drainage passage that helped us localize the lymphatic vessels after ICG injection.
(B) Infrared-color mode 2: the identified specimen shown on screen.
(C) Infrared-color mode 1: ICG uptake seen as a green signal inside the specimen.
(D) The specimen excised after dissection of the lymphatic passage to the lymph node.

The initial steps of the ICG fluorescence technique have been previously explained elsewhere [15]. In simple terms, the periareolar skin receives an intradermal injection of ICG, as shown in Figure 2, except that we also used a harpoon to help us identify the lymph nodes. Fluorescence images highlight subcutaneous lymphatic drainage moving toward the axilla after just a short amount of time. In some cases, no signal was recorded beyond the lateral margin of the pectoralis major muscle, where the subcutaneous lymphatic vessel extends deep into the axillary space, as the lymphatic vessels (LV)s and the lymphatic nerves came close to the surface when the axillary skin was compressed against the chest wall with a transparent plastic device, like the ones used in Japan; two types of compression devices: an hemispheric bowl with a diameter of 4 cm and a cone-shaped device [16]. This kind of compression on the axillary skin, caused a fluorescence signal to appear at the bottom of the device.

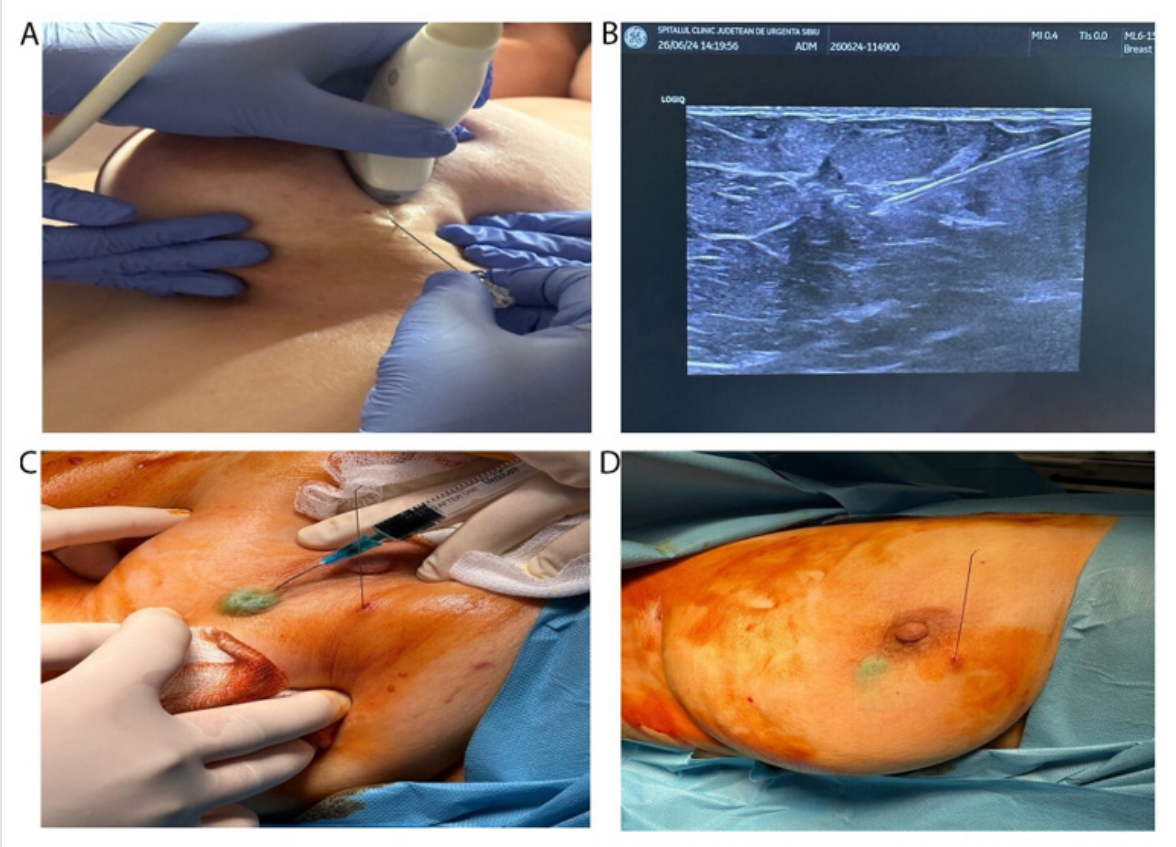


Figure 2:
A. (A, B). Tumor marked with an echo-guided harpoon.
B. (C). ICG injection in the periareolar area for lymphatic mapping.
C. (D). Tumor identified and ready for excision.

The compression-inducible fluorescence signal can be followed to the axilla to carry out the transcutaneous lymphatic mapping. It is thought that the initial SLN will be the first pressure-induced, round, and strong fluorescence signal. Before enough ICG is deposited in the SLNs, it often takes several minutes following ICG injection. A skin incision is made at the anticipated site, and the SLN is then directly approached. The dissecting process only requires cutting the axillary fascia and subcutaneous tissue in the direction of the fluorescent signal, much less invasive than biopsy by identifying and removing an entire sector of the breast, that has been preoperatively marked with a harpoon using ultrasound guidance, shown in Figure 3. Because the upper pole of the breast has a deep anatomical integration and overlap of fascial components, surgical dissection in this area poses significant technical obstacles [17]. The strength of the SLN's fluorescence signal grows as the dissection plane deepens. A subcutaneous LV draining to the fluorescent nodes can be seen on a fluorescence image after the fluorescent nodes have been removed from the incision, helping to confirm that the SLNs have been properly removed. Most of the

time, a few more luminous nodes were seen in the fat when the first SLN was removed from the incision with the surrounding fatty tissue. These nodes were removed along with adipose tissue that served as a lymphatic basin. It is crucial to widely open the axillary fascias and properly pull them out of the incision by releasing the nearby arteries and nerves in order to clearly examine these SNs and drain LV without harm. Using electrical dissection turned out helpful to reduce ICG contamination in the operating room. When only one node could be removed, the axillary region was examined once more, using fluorescence to see if any fluorescent nodes remained after the first node was removed. The next steps are the same as the first approach [16].

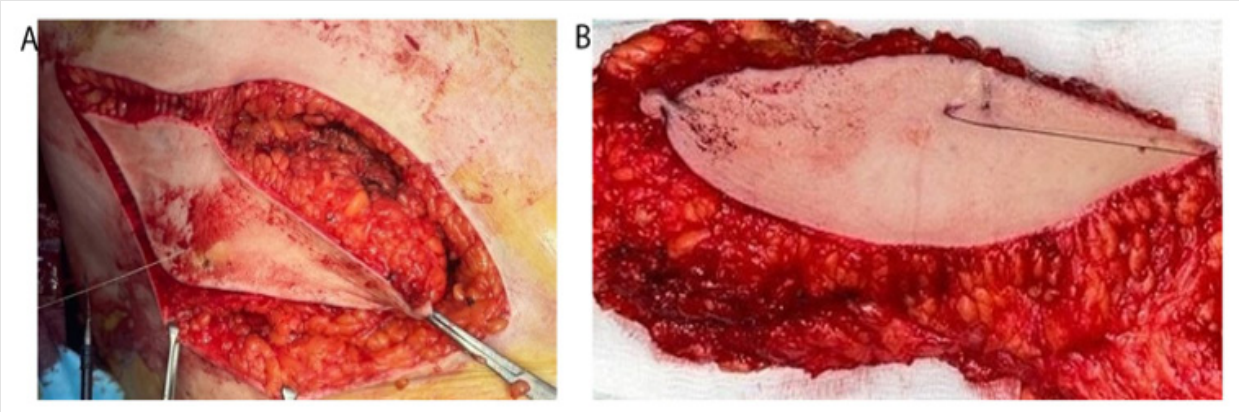


Figure 3:
A. Marked breast sector with a harpoon before dissection.
B. The specimen removed after successful identification.

Results

A systematic literature search identified 20 studies in the PubMed database and an additional 3 studies in the Cochrane Library. Of the 34 studies initially deemed relevant to the research topic, 11 were excluded from the final analysis due to the following reasons: improper use of the radioisotope (RI), commentary-type publications, non-English language, and inclusion of malignancies other than breast cancer. The remaining 23 studies comprised a total of 1,569 patients. The number of breast cancer (BC) patients enrolled per study ranged from 6 to approximately 100, with recruitment occurring over a period of up to ten years prior to surgical intervention. In all eligible patients, sentinel lymph node biopsy (SLNB) was performed as the initial surgical procedure, followed by axillary lymph node dissection (ALND) when indicated, according to the intraoperative assessment of the sentinel lymph nodes (SLNs). In the majority of the included studies, SLNB was performed using indocyanine green (ICG) fluorescence as the sole tracer [18].

It was discovered that the exceptionally high sensitivity of ICG enabled the identification of extra SLNs that MB was unable to identify. SLNs were likely discovered by ICG in greater numbers than SLNs detected by MB. ICG's increased sensitivity may be due to the fact that it is more visible to high-resolution NIR equipment. The greater identification rate of positive nodes (ICG =25.7% > MB =21.5%) that resulted from better level of visibility may also have helped to reduce false-negative evaluations of axillary nodes and produce advantageous treatment options. However, the detection of additional positive SLNs by ICG helps them to avoid being missed by ALND, which minimizes the potential of recurrence and metastasis and improves patient prognosis. For example, some patients with no SLNs found by blue staining do not require ALND. While its effects on prognosis are unknown, a number of studies have revealed that high ALND increases the probability of postoperative complications in the upper limb. In that case, more surgeons hope ICG fluorescence to replace one day the conventional uses of blue staining and radioactive agents as the preferred method due to its high recognition rate and accurate diagnostic performance [19,20].

In order to detect SLNs in BC patients, this study wanted to demonstrate the high detection rate and superiority of ICG. In hospitals, ICG fluorescence should be used and, in the absence of radioactive agents, it can also be used as a replacement for MB or radioisotope. The SLN detection rate varied depending on the tracer utilized, from 77.8% for blue dye alone to 100% for ICG [21,22]. Both allergic reactions and surgical site infections were not reported. ICG fluorescence indicated a tendency toward better axilla staging than radioisotope (RI), despite the fact that there was no statistically significant difference between the two methods for SLN detection. These findings demonstrate the value of the ICG fluorescence technique as an SLNB substitute for the traditional RI technique. As

mentioned, ICG is a fast-binding amphiphilic chemical that serves as a fluorescent tracer agent on NIR imaging systems by binding to albumin. According to recent studies, the third method of NIR fluorescence imaging that is used in clinical practice is ICG. Recent meta-analyses showed that ICG-guided SLN biopsy was effective for detecting SLN metastases and had a high detection rate for SLN.

In a side-by-side comparison, ICG fluorescence was significantly more accurate than blue dye for SLN detection [23]. According to another study [24], the average number of SLN removed using ICG fluorescence was 2.3, which was much higher than the 1.7 for radioisotope, indicating that the detection rate for tumor-positive SLN using ICG fluorescence is significantly comparable to RI, including that the hypersensitivity to ICG was not associated with any severe adverse effects. As many studies proved this theory, the treatment and detection of cancer, particularly BC has been done using ICG for over the past years. Surgeons who carried out SLNB, report a 94% detection rate in successfully recognizing sentinel lymph nodes, compared to the 93% detection rate and 5% false negative rate when using a combination of technetium 99 and blue dye. Using the ICG technique, in most cases, the lymph node of interest can be identified via fluorescence that appears after ICG has been injected into the lymphatic channels [25,26].

Discussion

The concept of SLN biopsy is widely accepted for the treatment of early BC. Rapid evolution of this disease has led to a wide range of modifications in this technique. Blue dye, radioactive colloid, vital dye, or a combination of both have been used as tracers since the first reports utilizing radio localization. Apart from these methods, ICG is a highly used diagnostic tool that is authorized for practice in medical situations for the assessment of cardiac output, hepatic function, and retinal angiography, as it is now being studied and used to help identify SLN in early BC, showing more promising and improved results, better than the standard method. Among the many advantages of the dye-guided approach are its affordability and ease of use [15]. The fluorescence method using ICG is known to be an excellent SLNB method with no radiation exposure and high detection and low false-negative rates [2].

To determine whether there is a concordance or discordance between the techniques, ICG should be directly compared with radiocolloid and other more well-established dyes in further research [10]. 2 of the studies [2,6] had shown that ICG method to identify SLNs is effective, safe and efficient and has the ability to achieve a high SLN identification rate, as one of them found ICG as superior to blue dye in SLN localization with a much more accuracy, where their patients did not experience any local toxicity or systematic adverse events after periareolar injection of indocyanine green. In a study conducted by Hirche C [10], the results also verify that there is no risk of local toxicity or allergic reactions when using subareolar injections of ICG for lymphatic mapping and SLNB. The study's findings validate the initial findings from feasibility studies on lymphatic mapping and SLNB using ICG, indicating the method's clinical viability and supporting the need for larger-scale research. Somashekhar SP [5] wrote in his study that after SLNB, a high detection rate and low false-negative rates can result from proficiency with the ICG technique. 40 years of clinical use of ICG has led to reports of its safety and complications have been rarely reported.

According to Kühn F [4], overall complication rates decreased from 15.1% to 4% and described a specificity of 91% and sensitivity of 100% in ICG imaging used in breast surgery. In comparison to the MB dye alone, the fluorescence and dye combination had a substantially greater detection rate (99.5 vs. 89%), according to Guo J.'s findings [8] and to Wang P [22], where his analysis's findings demonstrated that the ICG-FI group outperformed the MB group in terms of detection rate. An alternate, non-radioactive technique for dual tracing of SLNs may be possible thanks to the ICG+ MB modality's excellent identification rate and precise diagnosis performance. Considering that ICG detected a greater number of SLNs than dye uptake, they assumed ICG's greater sensitivity resulted from its greater visibility as measured by the high-resolution NIR equipment.

Pellini F [9] showed that the findings of his study support the viability, effectiveness, and safety of the ICG approach, which can be recommended as a single tracer for SLNB when paired with the most current experiences detailed in the literature. In his study, Kitai T [15] presented that this method's primary benefits are as follows:

1. It allows for precise identification of the skin incision site because it allows for mapping of subcutaneous lymphatic drainage from the skin.
2. Fluorescence navigation also makes it easier to trace the lymphatic channels into the axillary lymph nodes.

Even if it does have a lot of benefits, it has been proven some problems still stand:

1. The current technique cannot detect a lymph node located deep into the axilla. Therefore, in order to ascertain their presence, skin incision and dissection are required.
2. Due to the requirement to switch off the NIR light in the operation room during fluorescence observation, it is challenging to conduct both lymphatic dissection and fluorescence navigation simultaneously.
3. The dissection process is to be finished in half an hour. However, administered ICG diffuses into subcutaneous adipose tissue, making it challenging to investigate subcutaneous tissues further. On the other hand, in clinical situations, the green color quickly identifies lymphatic channels or nodes with an ICG concentration over the optimal level.

As many others [2,6,10] demonstrated in their studies this as well, Ngô C [26] presented that in addition to low toxicity, his study demonstrated a "fair", as he said, concordance rate, excellent sensitivity for macro metastatic nodes, and a high SLN detection rate using the ICG approach. It was demonstrated that among the techniques compared (radioisotope), the ICG fluorescence technique had the lowest false-negative rate (0.6%) and the highest detection rate (97.9%). In addition to that, the ICG method is proven to be easily taught. To better define its indications, applications, and toxicity, additional research is needed to be conducted [25,27] as SLN biopsy guided by ICG fluorescence imaging is a promising technique for further clinical exploration. Also, probiotic supplements have demonstrated promise in reducing adverse effects by boosting the immunological responses [28].

Conclusion

With a focus on recent advancements in SLNB approaches for BC, this study particularly highlights the safety and efficacy of ICG method compared to traditional techniques. Before turning attention to more complex choices like early diagnosis of asymptomatic populations and more sophisticated therapies like breast conserving surgery and radiotherapy, it is important for BC to develop the fundamental diagnostic and treatment techniques. The SLNB in early BC patients using ICG-FI is a quick and easy procedure that is suitable for clinical use. For additional method validation, a multicenter randomized controlled experiments with a significant number of participants should be conducted in the future. With a short operating time and a great number of SLN removed, ICG offers a high detection rate (97.9%) and sensitivity for SLNB in early BC. There is no toxicity, and allergies are incredibly uncommon.

The ICG approach is simple to be taught. Authors mention how simple the technique is to learn. It takes up to 10 cases to master the isotope technique. It is feasible, safe, and accurate to use ICG with NIR-FI for real-time guided SLNB, as it does not increase the operative time or number of lymph nodes removed. Compared to 99m Technetium, it is less expensive, easier to use, easier to set up and it is also more comfortable for the patient. In urbanized and developing nations, the ICG fluorescence method may be used instead of radioisotopes since it can address logistical and financial challenges.

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Availability of Data and Materials

All data generated or analyzed during this study are available in the Dryad repository.

Patient Consent for Publications

Not applicable.

Competing Interests

The authors declare that they have no competing interests.

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