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ORIGINAL ARTICLE

Sentinel Lymph Node Biopsy in Early Breast Cancer Using Patent Blue Dye as a Single Identification Method: Experience of an Academic Center

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ABSTRACT:

Background: Sentinel lymph node biopsy (SLNB) has become the standard of care in the assessment of metastatic spread to axillary lymph nodes in cases with early breast cancer. The use of single or dual method for identification of the sentinel nodes was an area of much research that concluded that dual method using both dye and radiolabeled tracer has a preference given higher identification rates. **Methods:** In this study we assessed our experience with SLNB using patent blue dye in the period 2019-2023 in patients with early breast cancer eligible for SLNB treated in Suez Canal University Hospitals. The primary outcome was to estimate the identification rate and percentage of upstaging and need for axillary dissection (AD) following SLNB. **Results:** A total of 128 patients were included and successful identification of SLN was attained in 122 patients (95.3%). 95 of them showed negative nodes while metastatic deposits was identified in 27 patients (22.1%) that necessitated completion axillary clearance in 16 (13.1%). **Conclusions** SLNB is a reliable method even in the setting allowing only single method of identification giving patients with early breast cancer the chance to avoid unnecessary axillary clearance and its future morbidity.

Keywords: Sentinel lymph node biopsy, Breast cancer, Dye method, Identification rate, Axillary nodes.

INTRODUCTION:

With age-standardized incidence rates of 19.7 cases per 100,000 premenopausal women and 152.6 cases per 100,000 postmenopausal women, breast cancer is the most frequent cancer globally and among women [1]. Additionally, it is one of the main causes of female mortality and is thought to be the most prevalent type of cancer affecting Egyptian women reaching up to 38.8% of all female malignancies [2].

One of the best indicators of a woman's prognosis in the early stages of breast cancer is the condition of her axillary lymph nodes, and the sentinel lymph node biopsy (SLNB) is now the gold standard for determining whether or not metastatic dissemination to the lymph node basin has occurred [3, 4].

As the lymphatic basin's first node to receive drainage from an anatomical site and be immunologically responsible for it, the sentinel lymph node is by definition the first node that does

so[5]. This minimally invasive procedure has become a common and standard technique in the diagnosis of metastasis to axillary lymph nodes due to its high sensitivity rate that reaches 90 to 95% and reasonably low false negative rate of 5 to 10% [6, 7]. In the past, lymphatic drainage mapping was first proposed in the 1950s [8]. The term "sentinel node" was coined in the 1970s when it was discovered that certain nodes received drainage before others [9]. Donald Morton originally described the use of blue dye in lymphatic mapping to identify the sentinel node in 1992 for cutaneous melanoma [10]. Later, in 1993, Krag et al. used gamma probe-assisted injectable radiotracer for mapping of sentinel lymph node in the treatment of breast cancer [11]. Because of its accuracy, low morbidity, and minimal invasiveness, SLNB has currently replaced axillary lymph node dissection (ALND) as the gold standard procedure for axilla staging in clinically node-negative illness [12].

Regardless of breast surgery, sentinel lymph node biopsy is recommended in staging female patients who have clinically negative axilla and early T1-2 tumors [13]. Since disruption of lymphatics during a mastectomy may impede the ability to accurately identify sentinel lymph node in the event that an invasive focus is found, women with duct carcinoma in situ (DCIS) scheduled for mastectomy are candidates for SLNB [13]. Additional indications could be a patient with DCIS who needs a major resection or an oncoplastic treatment that could disturb lymphatic channels; in such case, SLNB might be taken into consideration**.**

The injection of dye or radio-labeled material is done before surgery. The sentinel lymph node may generally be identified the best when both dye and radioactive methods are used in combination [14].

When both methods were utilized, the identification rates of sentinel lymph nodes were about 96–100% [14,15], compared to less than 86–90% [15,16] when using just one agent as stated in some studies.

This study was conducted to assess the result of our work with SLNB in early breast cancer using blue dye as a single identification method regarding identification rates, rate of upstaging the disease, and the rate of positive SLNB that needed more axillary management.

METHODS

This study was approved by the Research Ethics Committee at faculty of medicine in Suez Canal University under No: 5313

All procedures and data management ran in accordance with the code of ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

The need for signed informed consent was waived due to the retrospective nature of the study with the following rules put into consideration:

Confidentiality of data was preserved by coding patients' records and keeping the keys of the codes with the primary investigator only.

All procedures are standard surgical techniques; no investigational procedures were carried out.

All patients to be included in the study must have had a preoperative informed consent signed explaining the surgical procedure and its benefit.

All procedures and data management ran in accordance with the code of ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. [17]

Study Design and Patients

Retrospective analysis of all patients who underwent SLNB during breast cancer surgery from 2019 to 2023 at Suez Canal University Hospital. All patients who showed early breast cancer, T1-2, and clinically negative nodes by examination and US were included whatever which surgical procedure was done for the primary tumor including wide local excision or mastectomy. Patients who had SLNB for clinically negative axilla after neoadjuvant chemotherapy were excluded.

Study's Procedures

Baseline data of the eligible patients, which included demographic characteristics, examination findings, the findings of breast imaging, medical comorbidities, tumor characteristics, the eligibility for SLNB, type of breast surgery and the technique performed, number of identified SLNs, the result of final pathology including, tumor size, grade, and lymph nodes status. Also, the need for axillary re-surgery (AD), complications as seroma and hematoma formation, infection, lymphedema, limitation of shoulder motion and paraesthesia, follow up and axillary failure rate were included to evaluate the results.

All our patients had SLNB (whenever eligible) using a single method by blue dye. Patent blue dye V (PB) , (Patent Blue V 2.5% Guerbet laboratories, France), was the one available at our hospital and where 2 ml was injected retroareolarly in four quadrant fashion and SLN was searched for via a separate axillary incision just below hair line in cases underwent conservative breast surgery or through the mastectomy incision in cases treated so. Going into

axilla was recorded to start 10 minutes after dye injection and mild breast massage. Blue- stained nodes were retrieved and their level was recorded. (Figures 1-3)

Breast specimens and SLNs were sent for paraffin pathology examination and final pathology results were analyzed. Patients with negative SLNB required no further management and were sent for adjuvant treatment and put under follow-up. Patients with metastatic SLN(s) were assessed and managed according to ACOSOG Z0011 trial by either no more axillary management if only 1 or 2 nodes were positive with T1-2 tumor or if not they had to go to axillary clearance. SLNs that showed micrometastasis required no further axillary management according to results of IBCSG23–01 trial.

From the retrieved data, identification and failure rate were calculated. The number of identified SLNs was recorded, upstaging rate will was pointed out and also the need for further axillary management. Complications and axillary failure on follow-up were represented.

Study's Outcomes:

The primary outcome of this study is to assess our results with SLNB in early breast cancer surgical management using blue dye as a single method estimating the success rate in identifying SLN. The secondary outcomes were to estimate the rate of upstaging following SLNB and need for more axillary management and how far it could help in omission of unnecessary axillary clearance. Also type and rate of early complications following the technique and rate of axillary failure.

Statistical analysis:

Descriptive statistics employed to describe baseline characteristics of the study population and presented as frequencies and percentages (%) in qualitative data or mean values and standard deviations (SD) in quantitative data. Collected data were coded, entered, using Microsoft Excel software. Data were processed with Statistical Package for the Social Sciences (SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.).

RESULTS:

Figure 4 shows a flowchart of all included patients.

Patients' Clinical Characteristics

Between January 2019 and December 2023, a total of 128 female patients suffering from early breast cancer with clinically negative axilla underwent breast surgery with SLNB. The mean age was 49.8 years. The majority of the patients (87.5%) underwent conservative breast surgery in the form of wide local excision, while 12.5% had mastectomy.

Final histopathology reports showed that 80% of the patients had invasive ductal carcinoma, 17% had invasive lobular carcinoma, and 2% showed other types. The tumor size was T1 in 45.3% of patients and T2 in 54.7% of patients. Regarding tumor grade, about (69.5%) of the patients had grade II tumors while 21.1% and 9.4% of patients had grades I and III tumors, respectively. (Table 1)

Operative Results

SLNs were identified successfully in 122 out of 128 patients giving identification rate of 95.3% in our series. Failed identification of SLN mandated ALND in six patients. Number of retrieved SLNs was one in 14 patients (11.5%), 2 in 19 patients (15.7%), 3 in 31 patients (25.4%), 4 in 29 patients (23.7%), 5 in 18 patients (14.7%) and more than 5 nodes in 11 patients (9%). (Table 2)

SLNB-Related Results

After histopathological examination, a total of 27 patients (22.1%) showed metastasis in their SLN(s), 16 of them (13.1%) needed completion ALND while 7 patients showed only 1 or 2 positive nodes and get benefit of ACOSOG Z0011 trial and 4 patients showed only micrometastasis where AD was omitted following IBCSG23–01 trial .

During the early post-operative follow up (4 weeks period) there were no wound infections recorded, no lymphedema, nor shoulder dysfunction. However six patients developed hematoma at axillary wound that treated conservatively, and 2 patients complaining of arm numbness. Regarding seroma formation apart from patients with mastectomy, where elective suction drainage used routinely, axillary wound seroma was recorded in 21 (21.9%) patients of 96 who had conservative surgery.

72 patients out of 104 patients who exposed to SLNB had a retrievable long term follow-up data covering a median of 25 months' follow-up (range 6 to 56). Of them, there were two patients had axillary failure detected by means of PET-CT within the first 6 months and one patient had clinical axillary recurrence after 6 months. (Table 3)

Table (1): Patients' characteristics.

	No =128	(%)
Age (Mean +/- SD)	49.8+/- 14	
Surgical Procedure		
Conservative Breast Surgery	122	87.5
Mastectomy	16	12.5
Final Histopathology Result		
Invasive duct carcinoma	102	80
Invasive lobular carcinoma	22	17
Other pathology	4	3
Tumor Size		
T1	58	45.3
T2	70	54.7
Tumor Grade		
I	27	21.1
II	89	69.5
III	12	9.4

Table (2): operative results and need for further interventions:

	No =128	(%)
SLN Identification		
Successful	122	
Failed	6	
Number of retrieved SLNs		
1	14	
2	19	
3	31	
4	29	
5	18	
> 5	11	
Further Axillary Surgery (ALND Vs. No surgery)		
ALND	22	
No Surgery	106	
<u>Detailed:</u>		
Failed Identification ALND	6	
Negative SLNB No	95	
Positive SLNB		
Macrometastasis	16	
ALND	7	
1 or 2 positive nodes (Z0011)	4	
No		
Micrometastasis (IBCSG23-01)		
No		

Table (3): Outcomes and results of patients had SLNB only

	No	(%)
Early Postoperative Complications	106*	100
hematoma (axillary, of 96 patients) **	6	6.2
wound infection	0	0
seroma (axillary, of 96 patients) **	21	21.9
arm numbness	2	2.1
shoulder movement affection	0	0
lymphedema	0	0
long term complications	72***	100
Axillary failure (nodal recurrence)	3	0.04

* Patients who had SLNB only with no need for further ALND.
** Patients had conservative breast surgery with Axillary management via separate incision.
*** Patients with retrievable long term follow-up data

Group I: without VMS **(N =37)**

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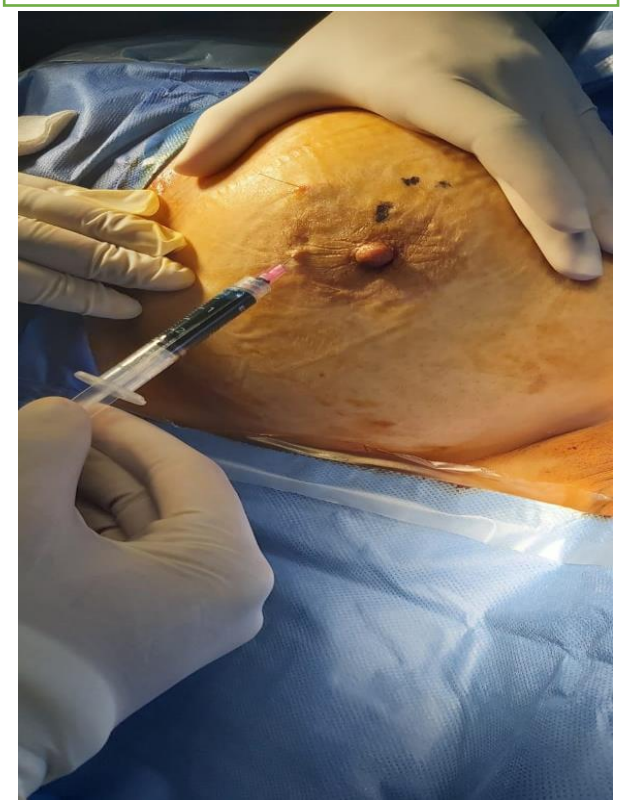

Fig. 1

Group II: with VMS (N =37)

Fig. 2

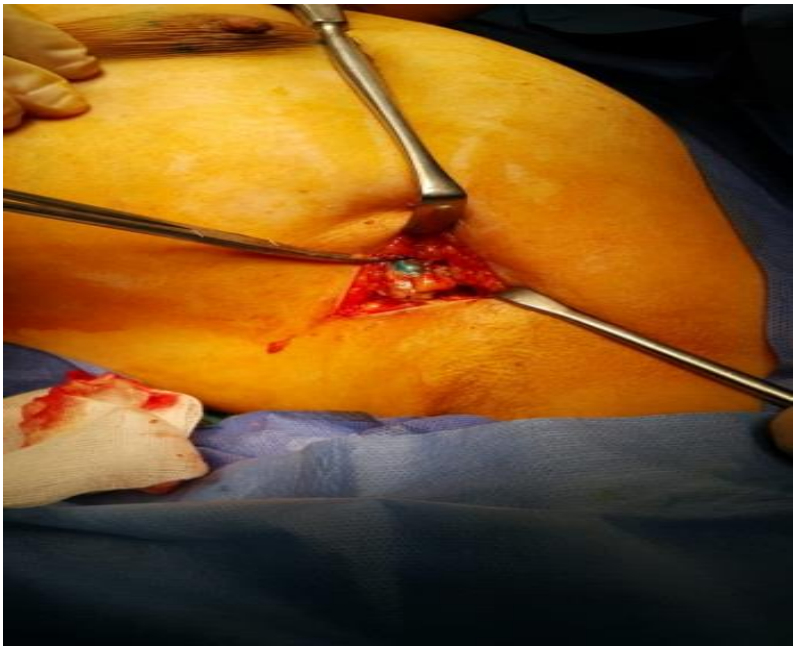

Fig: 3

Fig.1: Retroareolar blue dye injection
Fig.2: Retrieval of SLNs during mastectomy
Fig.3: Blue-stained SLN at level 1 of axilla during conservative surgery

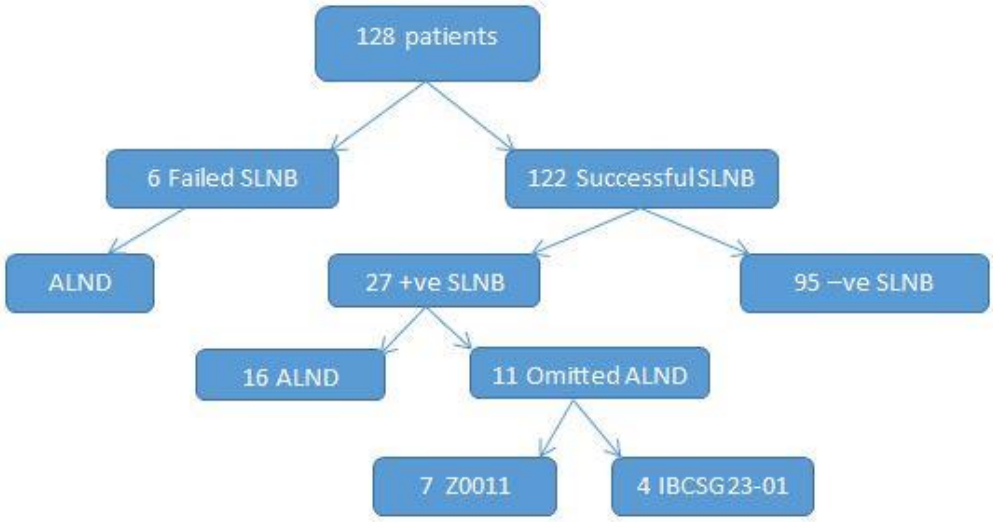

Fig. 4: Flow chart of our patients regarding SLNB results and further management

DISCUSSION:

SLNB was sparsely utilized in our institution and was not routinely in use for patients with breast cancer until 2018 when it was deployed by our surgical team with strict inclusion criteria. The indications for SLNB adopted were T1 or T2 tumors with clinically negative axilla following international guidelines. The indication of SLNB has been expanded to include patients with large or multicenteric DCIS, when total mastectomy is mandated. [18]

While early researches indicated that dual method is preferable in terms of fewer false-negative and non-identification rates, more recent studies [19,20] have revealed equivalent results using blue dye method only, indicating that results get better with familiarity

of the technique and more expertise. Blue dye method is the only utilized method in the authors' center for SLNB. This is due to a deficiency of nuclear medicine facilities and logistics necessary for radiolabeled colloid preparation and lymphoscintigraphy.

Isosulfan blue, methylene blue (MB) dye, and Patent Blue V (PB) are the most frequently utilized dyes during SLNB. In our center, PB was routinely used because of its availability and being affordable. The use of blue dye is not without risks. Although rare, risk of anaphylaxis mandate cautious usage of PB [21]. In our study, only one patient showed slight intraoperative skin reaction and the procedure completed without any hemodynamic instability and the post-operative period passed uneventful. Also temporary skin tattooing was observed in most of our patients that lasted in some patients for up to 2 weeks but none developed skin necrosis nor serious anaphylactic reaction.

The American Society of Breast Surgeons indicated that SLN should be identified in > 95% of patients undergoing sentinel lymph node biopsy with a false negative rate of 5–10% when adopting standard protocols. [22] However, using blue dye for SLNB in low resource settings remains an appropriate option. [23]

The identification rate of SLN using the blue dye method in our center is 95.3% and Our series' outcomes were on par with other published researches that exclusively used the blue dye as a single identification method. [23, 24]

Upstaging was documented in 27 patients out of the 122 patient with successful SLNB due to nodal metastatic involvement. From those patients with positive SLNs, 16 underwent completion ALND in another setting. In 7 patient's completion ALND was omitted according to the ACOSOG Z0011 trial that shown that patients with 1 to 2 positive SLNs do not get benefit from more ALND and that the 10-year overall survival (OS) is comparable to SLNB only [25]. Also, 4 patients with positive SLNs, showed only micrometastatic disease and ALND was omitted following the IBCSG23–01 trial recommendations. [26]

Another concern is that using blue dye method alone may result in fewer SLNs identification. This raises the possibility of missing positive nodes and getting a false-negative results. A meta-analysis including 1559 patients showed that using blue dye method alone for SLNB is appropriate but should be used cautiously as it can have an inadmissible false-negative rate. [27]

Given that the ratio of negative SLNs to total SLNs retrieved can indicate the possibility of more non-SLNs affection, some studies [28, 29] have provided indirect evidence that there may be an ideal number of SLNs to harvest. There is disagreement on what this ideal number ought to be. According to one study [30], removal of a positive SLN occurred by the third SLN retrieved, suggesting that eliminating more than three SLNs is not very beneficial.

It was shown that attempting to have an average of roughly three nodes removed is a common practice [31]. Bonneau et al.'s 2015 study demonstrated a correlation between better survival outcomes for breast cancer patients and the retrieval of three sentinel lymph nodes [32]. Similar findings from a 2018 study that compared patients who had two or more lymph nodes removed to those who had only one lymph node removed in terms of recurrence-free survival [33].

With three SLNs retrieved in about 24% of our patients with successful identification and attaining 3.4 as a mean number of identified SLN in our series, this finding goes in hand with several other studies [28,29] performed using dual-method SLNB, indicating that in experienced hands there is no difference in the number of retrieved SLNs using either method of identification.

In the present study, 3 or fewer SLNs were identified in 52.6% of patients with successful SLNB while 5 or more SLNs were identified in 23.7% of those patients. In earlier literature, most cases showed a median number of identified SLNs of 2 but limiting the number of SLNs retrieved to 3 may be resulting in a high false-negative rate [34]. In contrary, retrieval of up to 5 SLNs was enough to identify nodal metastasis in not less than 99% of patients. [35]

Some studies suggest using axillary nodal recurrence as a surrogate for the low likelihood of a false-negative SLN and residual nodal disease when axillary dissection is omitted, such recurrence was evident in only 0.04% of our patients who had SLNB using blue dye method only with a retrievable long term follow-up data.

Surgery for breast cancer and the technique used for axillary sampling could possibly result in some postoperative complications as seroma formation, arm paraesthesia, wound infection, and all are less common in SLNB patients compared to ALND patients. [36]

In our series, 21 (21.9%) of patients who had SLNB with conservative breast surgery developed axillary wound seroma postoperatively.

Compared to ALND, SLNB results in far less long-term morbidity. In earlier study comparing 431 patients who received SLNB alone with 210 patients who underwent ALND, the former group experienced fewer post-operative episodes of arm numbness or pain, impaired shoulder movements, and lymphedema. [37]

After SLNB, none of the participants in our research experienced lymphedema until a median of 25 months later. According to prior research, lymphedema rates with follow-up periods of six to thirty-six months varied from 0% to 7%. [38]

Following a negative SLNB, the probability of an axillary recurrence is said to be minimal. At a median follow-up of 126 months, the Swedish Multi-center Cohort Study, which included 2216 patients with negative SLNB, showed a 1.6% chance of regional recurrence. [39] Another investigation comprising 464 patients with a median follow-up of 38 months revealed a more significant lower risk of 0.6% [40]. With a median follow-up of 25 months, 3 out of 72 (0.04%) patients who had retrievable long term follow-up data in our series experienced axillary recurrence.

We consider some of the limitations of our study as being a retrospective one with small population number, and some what a short follow-up which could have some effect notably on the rate of long term oncologic incidents.

The results obtained in this research indicated that carrying out SLNB using a single method of identification namely the dye method could be reliably depending on. Given 95.3% Successful identification rate with 82.8% of sample size spared what seemed to be unnecessary ALND, we had a convenience to opt to utilize SLNB as a less invasive axillary procedure in comparison to axillary dissection that was once the standard routine technique in our center and still so in some other centers and countries with low resources or less trained to the procedure of SLNB.

CONCLUSIONS:

In conclusion, as SLNB is considered now the gold standard for axillary staging in early breast cancer. Giving that much research concluded that dual method using both dye and radiolabeled tracer has a preference given higher identification rates. yet, In regards to the logistics in nuclear medicine departments and availability of radiolabeled tracers and its detectors in low resources countries or centers, using blue dye as a single method to identify SLN could provide patients with early breast cancer the opportunity to reliably stage their axillae and sparing number of them the unnecessary nodal dissection that was routine practice earlier.

Conflicts of Interest

The authors report no conflicts of interest.

FUNDING INFORMATION

None declared

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