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Brief communication (Original)

Rate of sentinel lymph node identification using isosulfan blue dye in breast cancer patients at Charoenkrung Pracharak Hospital, Thailand

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Background: The sentinel lymph node (SLN) is the first lymph node to receive lymphatic drainage from a primary breast tumor. If the SLN contains no metastatic tumor, then it is unlikely other lymph nodes will contain breast cancer metastasis. When the SLN does contains metastasis, an axillary lymph node dissection (ALND) is recommended to further stage the axilla and to maintain locoregional control. SLNs can be identified by using a dye, radioisotope, or combined techniques.
Objective: To determine the rate of SLN identification using isosulfan blue dye in breast cancer patients at Charoenkrung Pracharak Hospital, Thailand, and factors that affect it.
Methods: This prospective study of 106 consecutive cases breast cancer enrolled 105 women (1 bilateral breast cancer case) between October 2011 and October 2013 at Charoenkrung Pracharak Hospital. Clinical and pathological features were analyzed for the effectiveness of SLN identification using isosulfan blue dye.
Results: The rate of SLN identification using isosulfan blue dye in breast cancer patients at Charoenkrung Pracharak Hospital was 92%. The method was safe and well tolerated in early-stage breast cancer patients.
Conclusion: The effectiveness of sentinel node identification using isosulfan blue dye in breast cancer patients at Charoenkrung Pracharak Hospital is consistent with that shown in studies from other countries.

Keywords: Blue dye, breast cancer, isosulfan, sentinel lymph node

Breast cancer is currently the most common malignancy in women worldwide. In 2007, the Thai National Cancer Institute reported 12,000 new breast cancer patients. The incidence was higher than that of cervical cancer patients, the most commonly reported malignancy in Thai women during the previous 3 years [1, 2]. Breast cancer treatment is multidisciplinary including chemotherapy, radiation, and surgery.

Radical axillary surgery has long been an integral part of breast cancer treatment to stage the axilla and provide locoregional control [3]. During the past decade, a paradigm shift has occurred in axillary staging, from a standard complete axillary lymph node dissection (ALND) for every breast cancer patient to a sentinel lymph node biopsy (SLNB) in the group of patients with a clinically nonpalpable axillary lymph node [3-5]. The axillary lymph node has proven to have adequate prognostic value in breast cancer treatment because patients with stage I and II breast cancer have an axillary lymph node metastases incidence of only 20%–30% [6-9]. Moreover, ALND may result in serious complications such as lymphedema, nerve injury, and shoulder dysfunction. All complications compromise the quality of life of the patient [3, 9-11].

The sentinel lymph node (SLN) is defined as "the first lymph node to receive lymphatic drainage from a primary breast tumor". If this SLN, sometimes consisting of more than one lymph node, contains no metastatic tumor, then it is unlikely other lymph nodes will contain metastasis of breast cancer. In breast cancer, this means that when a SLNB contains no metastasis, it is unnecessary to perform ALND [3, 4, 12, 13].

When the SLNB does contain metastasis, ALND is recommended to further stage the axilla and to maintain locoregional control [14, 15]. SLNs can be

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identified by using isosulfan blue dye, a radioisotope, or combined techniques [15-18]. In this paper, we report the identification of SLNB using isosulfan blue dye in breast cancer patients at Charoenkrung Pracharak Hospital, Thailand. SLNB in breast cancer patients at Charoenkrung Pracharak Hospital was first started in 2011. To our knowledge, this is the first report of SLN identification using the isosulfan blue dye technique to show: the (1) rate of sentinel node identification using isosulfan blue dye in breast cancer patients at Charoenkrung Pracharak Hospital, (2) factors that may affect the rate of SLN identification such as age, menstrual status, BMI, breast cancer histology, diagnostic method, tumor size, tumor location, hormonal status, and proliferative index (Ki-67), and (3) side effects of isosulfan blue dye in Thai patients.

Methods

Between October 2011 and October 2013, we enrolled 105 women with 106 consecutive breast cancer cases (1 bilateral breast cancer case) in this prospective study. Patients with all stages of breast cancer including T category Tis (ductal carcinoma in situ on core needle biopsy), T4 with clinically negative or positive nodes, and patients with prior neoadjuvant chemotherapy who underwent SLNB at Charoenkrung Pracharak hospital were included in this study.

The study was approved by the Ethics Committee for Research Involving Human Subjects of the Bangkok Metropolitan Administration and all participants provided their written informed consent to participate in the study.

After induction of general anesthesia, 1 mL of isosulfan blue dye was injected into the subareolar area of the breast parenchyma. During the surgery, the surgeon dissected and identified the SLN for frozen section. If the results of the SLNB showed no metastasis, the surgeon omitted ALND. If the result of the SLNB indicated metastasis, ALND was performed. In patients with cases of inflammatory or locally advanced breast cancer, the surgeon performed the SLNB first as usual, but also performed ALND for all these patients. In breast cancer patients whose SLN could not be identified, the surgeon performed ALND as part of the standard treatment of breast cancer.

Clinical and pathological features analyzed in this study were age, menstrual status, BMI, preoperative pathology, previous diagnostic method, tumor size, tumor location, clinical nodal status, operation, stage, final pathology, pathological nodal metastasis, nuclear grade, margin, lymphovascular invasion (LVI), neural invasion, estrogen receptor (ER), progesterone receptor (PR), HER2/neu, FISH, Ki-67, detection rate of SLN, number of SLNs, and side effects of the isosulfan blue dye.

Statistical analysis

Demographic data were evaluated and reported using descriptive statistics (mean and percentage). Patient characteristics were compared using *t* tests for continuous variables and a χ^2 test for categorical variables. $P < 0.05$ was considered statistically significant.

Results

A total of 105 female breast cancer patients representing 106 cases (1 bilateral breast cancer case) underwent SLNB using isosulfan blue dye alone. No patient had any side effects from isosulfan blue dye injection. There were 16 cases where SLN could not be identified. The identification rate was therefore 90/106 (85%). There were 15 cases of locally advanced or inflammatory breast cancer patients in this study. The rate of SLN identification increased to 84/91 (92%), when locally advanced or inflammatory breast cancer patients were excluded.

In locally advanced or inflammatory breast cancer patients whose SLN could not be identified (15 cases), 9 cases were in breast cancer patients with locally advanced or inflammatory who had prior neoadjuvant chemotherapy (**Table 1**).

The 106 cases were divided into 2 groups based upon whether or not SLN could be identified. The result was 16 cases in the group with absent SLN. Mean patient age at the time of diagnosis was 48.9 ± 11.1 years (range 30–68 years), mean weight was 54.3 ± 9.7 kg, mean height was 156.4 ± 7.2 cm, and mean BMI was 22.3 ± 4.2 (kg/m^2).

The remaining 90 cases fell in the group with SLN present. Mean patient age at the time of diagnosis was 52.6 ± 11.5 years (range 30–81 years), mean weight was 59.5 ± 11.3 kg, mean height was 155.5 ± 5.3 cm, and mean BMI was 24.6 ± 4.4 (kg/m^2). In this study, characteristics of breast cancer patients including age, weight, height, and BMI did not affect the rate of SLN identification (**Table 2**).

Table 1. The results of sentinel lymph nodes (n = 106)

Sentinel lymph node result	N (%)
Number of sentinel lymph nodes	
0 (absence SLN)	16 (15.09)
1 node	40 (37.74)
2 nodes	28 (26.42)
3 nodes	13 (12.26)
4 nodes	5 (4.72)
5 nodes	3 (2.83)
7 node	1 (0.94)
Frozen section of SLN	
SLN positive	35 (33.02)
SLN negative	55 (51.89)
Side effect of Isosulfan blue dye	
No	105 (0)
Locally advanced or inflammatory breast cancer	
absence of SLN	9 (8.48)
Presence of SLN	6 (5.67)

Table 2. Characteristics of breast cancer patients

Characteristics (n = 106)	Absencs SLNB (n = 16)		Presence SLNB (n = 90)		*P*
	Median	SD	Median	SD	
Age (years)	48.94	11.05	52.60	11.49	0.317
Weight (kg)	54.25	9.68	59.54	11.31	0.081
Height (cm)	156.44	7.16	155.49	5.29	0.534
BMI (kg/m^2)	22.25	4.23	24.61	4.44	0.051

About half the patients (48 patients, 45%) were premenopausal, and the remaining 57 patients were either perimenopausal or postmenopausal (55%). The majority of patients (96 patients, 91%), had a preoperative diagnosis of invasive ductal carcinoma, and the SLN was clinically negative in 91 patients (86%). Core needle biopsy was used to diagnose breast cancer in 90 patients (85%). In about half the patients (56%) tumor location was in the upper outer quadrant. When classified using the absence or presence of SLN, the results showed that the presence of clinical axillary lymph node, tumor location, staging, and tumor size have an effect on the rate of SLN identification (P = 0.004, 0.008, <0.001, and 0.013 respectively) as presented in **Tables 3 and 4.**

Type of operation, histopathology, grading, lymphovascular invasion, perineural invasion, margin, ER, PR, HER2/neu, and percentage of Ki-67 did not affect the rate of SLN identification (**Tables 5 and 6**).

Factors that were found to affect the rate of SLN identification in univariate analysis were subjected to further multivariate analyses. Only a higher stage of cancer had an effect on the rate of SLN identification (Stage 3b; P = 0.025) (**Table 7**).

Discussion

Findings from many clinical trials and meta-analyses demonstrated no statistical difference in the survival or nodal recurrence between SLNB and ALND groups. This proved that SLNB is a standard of care for clinically node-negative breast cancer patients [5, 9, 16, 19-24].

The rate of SLN identification in breast cancer patients is affected by many factors such as skill or experience of the surgeon, stage of cancer, and diagnostic methods. There is evidence that different diagnostic methods affect the rate of SLN identification. Patients, who underwent fine-needle aspiration cytology or core needle biopsy have a better

Table 3. Characteristics of breast cancer

Characteristics (n = 106)	Absence SLN (n = 16)	Presence SLN (n = 90)	*P*
Menstrual status			
Pre-menopause	8	40	0.830
Peri-menopause	2	9	
Post-menopause	6	41	
Pre-operative diagnosis			
DCIS	1	7	0.936
Invasive ductal carcinoma	15	81	
LCIS	0	0	
Invasive lobular	0	1	
Others	0	1	
Clinical axillary lymph node			
Not palpable	10	81	0.004
Palpable	6	9	
Diagnosis methods			
FNA	0	5	0.504
Core needle biopsy	15	75	
Excision	1	10	
Incision	0	0	
Tumor location			
UIQ	1	6	0.008
LIQ	0	2	
UOQ	5	54	
LOQ	1	9	
Central	6	18	
Whole breast	3	1	
Pathological tumor size (excluded neoadjuvant chemotherapy case)			
Mean±SD	5.72 ± 4.03	2.86 ± 1.72	0.013

Table 4. Staging of breast cancer patients

Stage	Abscence SLN (n = 16)	Presence SLN (n = 90)	*P*
1a	2	22	<0.001
2a	1	34	
2b	1	13	
3a	3	15	
3b	9	6	

Table 5. Characteristics of operation and pathological report of breast cancer patients

Characteristics (n = 106)	Absence SLN (n = 16)	Pesence SLN (n = 90)	*P*
Operation perform			
BCT	1	7	0.968
Mastectomy	13	73	
Mastectomy with reconstruction	2	10	
Final pathology			
DCIS	1	4	0.873
DCIS with microinvasive	0	1	
Invasive ductal carcinoma	14	85	
LCIS	0	1	
Invasive lobular	0	0	
Other (unknown)	0	0	
Pathologic grade			
Grade 1	2	2	0.10
Grade 2	9	66	
Grade 3	5	22	
Lymphovascular invasion			
No	4	43	0.091
Yes	12	47	
Neural invasion			
No	15	87	0.573
Yes	1	3	
Margin			
Negative	14	75	0.473
Close	1	13	
Positive	1	2	

Table 6. Immunohistochemistry of breast cancer patients

Immunohistochemistry	Absence SLN (n = 16)	Presence SLN (n = 90)	*P*
ER			
Negative	7	27	0.278
Positive	9	63	
PR			
Negative	6	35	0.916
Positive	10	55	
HER 2/neu			
1+	8	60	0.296
2+	2	12	
3+	6	18	
FISH			
Negative	0	0	0.511
Positive	2	0	
ki-67 (≥20)			
Negative	4	30	
Positive	12	60	

Only 2 cases have FISH examination for confirm HER/2 neu positive.

Table 7. Multivariate analysis of factors which showed effect on SLN identification

	B	S.E.	Wald	df	*P*	Odd ratios	95% C.I. for Odd ratios	
							Lower	Upper
BMI	0.144	0.084	2.948	1	0.086	1.154	0.980	1.360
Clinical node palpable	-0.793	0.821	0.933	1	0.334	0.452	0.091	2.262
Tumor size	-0.055	0.205	0.072	1	0.788	0.946	0.633	1.414
Staging			12.758	4	0.013			
Staging 2a	1.324	1.296	1.044	1	0.307	3.758	0.297	47.630
Staging 2b	0.308	1.346	0.053	1	0.819	1.361	0.097	19.034
Staging 3a	-0.338	1.130	0.089	1	0.765	0.713	0.078	6.534
Staging 3b	-2.349	1.049	5.014	1	0.025	0.095	0.012	0.746

rate of SLN identification than patients who had a previous breast biopsy. The proposed reason for this difference is the possibility of an interruption of the lymphatic drainage of the breast [25-27]. However, in this study the diagnostic methods did not affect the identification rate of SLN.

Preoperative lymphatic mapping of SLNB with combined techniques (blue dye and radioisotope) may be used to increase the rate of SLN identification in breast cancer as described by Zengel et al. [17] and O'Hea et al. [28]. A combination of isosulfan blue and the radioisotope allowed SLN identification in 93% of cases [17, 28]. Cox et al. using a combination of techniques successfully identified SLN in 94% [29]. Canavese et al. identified SLN in 97.1% [30].

However, for isosulfan blue dye alone to become widely accepted in the management of breast cancer; it needs to identify SLNs reliably by reaching a rate of identification better than 80% and by having a lower cost than the combined techniques [18, 31-35]. Giuliano et al. reported a study of a series of 100 patients in which they found the rate of detection of the SLN using the isosulfan blue dye technique was 93% [31]. Some studies have used methylene blue dye to identify the SLN and found the same rate of identification as for isosulfan blue dye [32, 33]. In most studies, the rate of SLN identification was the same for subareolar, intradermal, or peritumoral blue dye injection sites [34, 35]. Patent (isosulfan) blue dye injections may have side effects. Allergic reactions have been reported, but their incidence is very low, estimated between 0.1% and 1%, and more than two thirds of them are grade 1, while grade 3 reactions are very rare [36, 37].

In the current study, we used isosulfan blue dye alone; the subareolar injection identification rate was 90/106 (85%). No patient had any side effect from isosulfan blue dye injection. To date, despite the increasing use of both SLNB and neoadjuvant chemotherapy (NAC) in the management of breast cancer, there is still limited information on the feasibility and accuracy of SLNB after NAC. It has been suggested that when NAC is used, there is an increase in the rate of false-negative SLN, inaccurate staging, and subsequent undertreatment, e.g. omission of ALND [18, 38, 39]. A meta-analysis of the published data suggested that SLNB is an accurate staging investigation of the axilla after NAC [40]. However, all of those studies were performed in patients who had clinically negative lymph node status and excluded patients with suspected or proven axillary metastases prior to NAC and found SLNB in neoadjuvant chemotherapy patients had axillary metastases in up to 40% of patients [41, 42].

At present, the use of SLNB after NAC remains highly controversial. For patients who undergo NAC and American Society of Clinical Oncology (ASCO) guidelines recommend a complete ALND, which remains the standard treatment for all patients, regardless of the clinical status of the axilla [27].

In this study, there were 15 patients with locally advanced or inflammatory breast cancer. When patients in this group were excluded, the rate of SLN identification increased to 84/91 (92%). In univariate analysis, clinicopathologic features, which were clinical axillary lymph node, tumor location, staging, and tumor size had no effect on the identification rate of SLN. This finding consistent with those of Goyal [43]. In multivariate analyses, only the stage of breast cancer had an effect on the rate of SLN identification. The finding is consistent with ASCO guidelines, which recommend a SLNB in early-stage breast cancer patients because in advanced-stage breast cancer patients, it had a low identification rate and possibly a high false-negative rate [27].

Conclusions

The effectiveness of sentinel node identification using isosulfan blue dye in breast cancer patients at Charoenkrung Pracharak Hospital, Thailand, is consistent with that found in studies from other countries. This method is safe, well tolerated, and effective in early-stage breast cancer patients.

The authors have no conflict of interest to report.

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