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Preoperative Axillary Ultrasound-guided Wire Localization and Lymphoscintigraphy for Sentinel Lymph Node Biopsy in Breast Cancer Patients

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ABSTRACT

Background: Breast cancer has the highest incidence and mortality among female malignant tumors. Breast cancer with negative axillary lymph nodes has been diagnosed mainly at an early stage. Sentinel lymph node biopsy (SLNB) is a standard screening technique for patients with early-stage breast cancer and clinically negative lymph nodes. Lymphoscintigraphy (sentinel lymph node mapping) has been regularly used as the standard method for SLNB. Today, ultrasound-guided wire localization (USGWL) is a well-established technique with superior outcomes. Therefore, we attempted to determine whether preoperative UGWL and lymphoscintigraphy (blue dye and isotope injection) improve SLN detection and false-negative rate in breast cancer patients undergoing SLNB and identify clinical factors that may affect the diagnostic accuracy of axillary ultrasound (AUS).

Methods: Between December 2018 and June 2019, 55 patients with clinical T1-3N0 breast cancer eligible for an SLNB at Imam Khomeini Hospital in Tehran were included in our study. Tumor characteristics and demographic data were collected by reviewing medical records and questionnaires prepared by our surgical team. The day before SLNB, all patients underwent ultrasound-guided wire localization of SLN. Lymphoscintigraphy was performed with an unfiltered 99mTc-labelled sulfur colloid peritumoral injection followed by methylene blue dye injection. The results were analyzed based on the permanent pathology report.

Results: Among the 55 patients, 71.8% of SLNs were detected by wire localization, while 57.8% were found by methylene blue mapping and 59.6% by gamma probe detection. Compared with wire localization and isotope injection, the methylene blue dye technique had a low sensitivity (72.2%), while both wire localization and isotope injection reached 77.8%. The sensitivity, specificity, and accuracy of UGWL were 77.8%, 42.1%, and 65.4%, respectively. Otherwise, methylene blue dye and isotope injection accuracy was 47.3% and 50.1%, respectively. Furthermore, there was a significant relationship between BMI, tumor size, laterality, reactive ALN, and the accuracy of preoperative AUS. But there was no significant correlation between age, weight, height, tumor biopsy, tumor location, the time interval between methylene blue dye and isotope injection to surgery, and also the type of surgery to the accuracy of preoperative AUS.

Conclusion: Preoperative UGWL can effectively identify SLNs compared to lymphoscintigraphy (blue dye and isotope injection) in early breast cancer patients undergoing SLNB.

Keywords: Breast Cancer, Sentinel Lymph Node, Sentinel Lymph Node Biopsy, Axillary Ultrasound, Lymphoscintigraphy, Wire Localization

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INTRODUCTION:

Breast cancer has the highest occurrence and mortality among female malignant tumors in the world. Most breast cancers diagnosed at an early stage are clinically axillary lymph node (ALN) negative due to increased population understanding of cancer prevention and medical diagnostic technologies (1). Sentinel lymph nodes (SLNs) are the first lymph nodes to obtain lymphatic drainage from the primary tumor (2). Awareness of the regional lymph node status is prominent for determining the staging, prognostic outcomes, and local breast cancer control (3). Sentinel lymph node biopsy (SLNB) is a common screening technique for patients with early-stage breast cancer and clinically negative lymph nodes (4). It requires an accurate estimation of the axillary lymph node status, with a false negative rate ranging from 4.6 % to 16.7 % (5). In the SLNB process, different methods have been performed regularly to evaluate SLNs, including blue dye and radioisotope injection (6). Currently, the standard procedure for SLNB is a dual technique involving the injection of technetium-labeled nano-colloid and blue dye interstitially into the breast. The detection rate for these nodes was 96% in a meta-analysis, with a false negative rate of 7.3% (7). However, this technique has some drawbacks despite its clinical efficacy, such as being time-consuming and involving complex operational steps (8). The use of ultrasound for axillary staging has been well-known for breast cancer (9). Several recent studies have used ultrasound to detect sentinel axillary lymph nodes using either fine-needle aspiration (FNA) or core needle biopsy (CNB) (10, 11). They showed a reasonably good predictive value for axillary status, and the reoperation rate was reduced (12). Ultrasound-guided wire localization (USGWL) is a well-established breast pathology management technique presented with superior results (13, 14). Therefore, in our study, we attempted to identify clinical factors that may have an impact on the diagnostic accuracy of axillary ultrasound in the preoperative breast cancer assessment and also determined whether preoperative UGWL and lymphoscintigraphy (blue dye and isotope injection) enhance SLN identification and false-negative rate in breast cancer patients undergoing SLNB.

METHODS:

Between December 2018 and June 2019, all 55 patients with clinical T1-3N0 breast cancer eligible for an SLNB at Imam Khomeini Hospital in Tehran were included. The methods were carried out following the approved guidelines, and written informed consent was obtained from all patients before SLNB. Patients who were pregnant and had palpable lymph nodes, neoadjuvant chemotherapy, ductal carcinoma in situ (DCIS) without mastectomy, history of axillary, or breast cancer surgery were excluded. Besides, during ultrasound evaluation of the axillae, any defined criteria of suspicious lymph nodes, including cortical thickness more than 3 mm, uniformity, irregular margins, encroachment, or displacement of the fatty hilum, were considered positive axilla and excluded from our study. Tumor features and demographic information were collected from medical records and prepared questionnaires by our surgical team.

This trial study aimed to determine the predictive value of the sentinel lymph node (SLN) in early breast cancer using SLNB by comparing UGWL with lymphoscintigraphy, including methylene blue dye and isotope injection. All patients scheduled for SLNB underwent ultrasound-guided wire localization of SLN the day before surgery. The radiologist selected the lowest part of the axilla as the SLN. Then, the lymph node was localized by a wire under ultrasound guidance. Before SLNB, lymphoscintigraphy was performed with an unfiltered 99mTc-labelled sulfur colloid peritumoral injection followed by methylene blue dye injection by the surgeon after induction of anesthesia. The sentinel node was identified via the visual detection of blue dye staining and a hand-held gamma detector. The SLN radioactivity was measured, counting for 10 s while using the gamma probe. All the SLNs were removed until radioactivity in the axilla reached the background level. The sentinel nodes were divided into three groups according to their mapping characteristics: (1) hot and blue; called W+, (2) hot only (T+); and (3) blue only (B+). Lymph nodes that were neither hot nor blue were removed as W- and labeled non-sentinel lymph nodes (NSLN). The frozen section procedure was performed intraoperatively. The results were analyzed by a permanent pathology report.

Data Analysis

The results were presented by descriptive statistics and frequency distribution. Patients' characteristics were compared using independent *t*-tests for continuous variables, and the associations between categorical variables were assessed using Pearson's chi-square test and logistic regression. Diagnostic performance of axillary ultrasound in SLN detection was calculated by the estimates of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy relative to the final pathology. Statistical analysis was carried out using SPSS version 20, and the differences were considered statistically significant at $P < 0.05$. Our study was approved by the Ethics Committee of Tehran University of Medical Sciences.

RESULTS:

Axillary ultrasound-wire localization was performed preoperatively on 55 breast cancer patients. The majority of participants were premenopausal women (mean age 44.7 ± 12.8 years). Almost half of the SLN (44.8%) were located in the upper outer quadrants on the left side (50.9%) with a mean size of 1.69 ± 1.7 cm. In most patients, the time interval between blue injection and surgery was 30-60 minutes and less than 12 hours between isotope injection and surgery. The frequency of breast mass in patients was 85.5% in CNB and 14.5% in an open or surgical biopsy. Besides, 43.6% of patients had undergone a mastectomy, and in 56.4% of patients, breasts were conserved. The frequency of SLN based on preoperative axillary ultrasound (AUS) was reactive in 94.5% of patients, and only 5.5% of SLNs have been reported normal. There were no significant differences between the accuracy of preoperative AUS and age, weight, height, tumor biopsy, tumor location, the time interval between methylene blue dye and isotope injection to surgery, and also the type of surgery. But, there was a significant relationship between the ALN type, tumor size, laterality, BMI, and the accuracy of preoperative AUS, as shown in **Table 1**. Intraoperatively, non-sentinel lymph nodes (NSLNs) were positive in 43.6% of patients, and frozen section analysis of the SLN was positive in 50.9% of patients. However, based on the final pathology report, the involvement of SLN and NSLN were 65.5% and 25%, respectively. Besides, there was no significant relationship between NSLN involvement and the accuracy of AUS based on frozen section analysis (P=0.86).

SLN was identified in 65.5% of patients (36/55). Among these, wires were successfully located (W+) in 77.8% (28/36), and gamma probe detection through isotope (T+) was used in 77.8% (28/36). Nevertheless, the SLN was identified by methylene blue dye (B+) in 72.2% (26/36) of patients **Table 2**. Following the final pathology report, 70.9% (39/55) of patients were W+ with a positive predictive value (PPV) of 71.8% (28/39). At the same time, 85.5% (47/55) and 81.8% (45/55) of patients were confirmed to be T+ and B+. Thus, the PPVs of T+ and B+ were 59.6% (28/47) and 57.8% (26/45), respectively (Table 3). Furthermore, the false negative rates of the isotope, methylene blue dye, and wire localization were 40.4% (19/47), 42.2% (19/45), and 28.2% (11/39), respectively. Additionally, the negative predictive value (NPV) of W+ was 50% (8/16). As mentioned in **Table 3**, AUS demonstrated

Table 1. Clinical and pathological characteristics of patients (n=55) whose axillary ultrasound detected positive sentinel lymph nodes

Variables	Number	%	AUS(SLN+) N (%)	P-value
Age (year)				
≤50	39	70.1	24(64.9)	0.8
>50	16	29.1	12(66.7)	
Weight (kg)				
<70	24	43.6	13(54.2)	0.12
>70	31	56.4	23(74.2)	
BMI (kg/m2)				
18.5-24.9	19	34.5	9(47.4)	0.02*
25-29.9	17	30.9	11(64.7)	
30-34.9	14	25.5	13(92.9)	
≥35	5	9.1	3(60.0)	
Height (cm)				
<160	14	25.5	10(71.4)	0.5
>160	41	74.5	26(63.4)	
Breast tumor size (cm)				
T1 (<2)	18	32.7	12(66.7)	0.01*
T2 (2-5)	33	60	24(72.7)	
T3 (≥5)	4	7.3	0(00.0)	
Tumor location				
UOQ	23	41.8	15(65.2)	0.8
UIQ	10	18.2	5(50.0)	
LOQ	9	16.4	7(77.8)	
LIQ	8	14.5	4(50.0)	
UOQ, UIQ	2	3.6	2(100.0)	
UOQ, LOQ	2	3.6	2(100.0)	
UIQ, LIQ	1	1.8	1(100.0)	
Laterality				
Right	27	49.1	14(51.9)	0.03*
Left	28	50.9	22(78.6)	
Type of biopsy				
CNB	47	85.5	30(63.8)	0.5
Surgical	8	14.5	6(75.0)	
Type of ALN				
Reactive	52	94.5	36(69.2)	0.03*
Normal	3	5.5	0(00.0)	
lymphoscintigraphy				
Blue dye injection	45	81.8	26(72.2)	
Isotope injection	47	85.5	28(77.8)	
Time interval of blue-dye (min)				
0-30	20	36.4	12(60.0)	0.12
30-60	29	52.7	18(62.1)	
60-90	2	3.6	2(100.0)	
90-120	4	7.3	4(100.0)	
Time interval of isotope (h)				
≤ 12	34	61.8	20(58.8)	0.18
>12	21	38.2	16(76.2)	
Breast surgery				
Mastectomy	24	43.6	14(58.3)	0.32
BCT	31	56.4	22(71.0)	

AUS: axillary ultrasound; SLN: sentinel lymph node; ALN: axillary lymph node; BCT: breast-conserving therapy; BMI: body mass index; UOQ: upper outer quadrant; UIQ: Upper inner quadrant; LOQ: Lower outer quadrant; LIQ: lower inner quadrant. *P value < .05 indicates statistical significance

Table 2. Absolute and relative distribution of SLN by the preoperative AUS and the pathological results of SLNB between m ethylene blue, isotope injection, and wire localization

AUS		SLNB Positive	Negative	Total (N)
B	Positive (+)	26(72.2)	19(100)	45(81.8)
	Negative (-)	10(27.8)	0(0.0)	10(18.2)
T	Positive (+)	28(77.8)	19(100)	47(85.5)
	Negative (-)	8(22.2)	0(0.0)	8(14.5)
W	Positive (+)	28(77.8)	11(57.9)	39(70.9)
	Negative (-)	8(22.2)	8(42.1)	16(29.1)
NSLN	Positive (+)	16(66.7)	8(33.3)	24(100)
	Negative (-)	20(64.5)	11(35.5)	31(100)

AUS: axillary ultrasound; SLNB: sentinel lymph node biopsy; NSLN: non-sentinel lymph node; B: methylene blue dye injection; T: isotope injection; W: wire localization

Table 3. Comparison of sensitivity, specificity, PPV, NPV, and accuracy of UGWL andlymphoscintigraphy

Test		B (+)	T (+)	W (+)
B	Sensitivity	72.2%	77.8%	77.8%
T	Specificity	0%	0%	42.1%
W	PPV	57.8%	59.6%	71.8%
NSLN	NPV	0%	0%	50%
	Accuracy	47.3%	50.1%	65.4%

AUS: axillary ultrasound; SLNB: sentinel lymph node biopsy; NSLN: non-sentinel lymph node; B: methylene blue dye injection; T: isotope injection; W: wire localization

better overall accuracy for wire localization (65.4%) than lymphoscintigraphy, including methylene blue dye and isotope injection. Therefore, we believe that the sensitivity, specificity, and accuracy of UGWL in detecting SLN is superior to that of lymphoscintigraphy mapping, especially in early breast cancer patients undergoing SLNB.

DISCUSSION:

Lymphoscintigraphy is an efficient SLN mapping technique. The latest analysis of 3-year clinical experience on SLNB in early breast cancer confirms the feasibility of combined lymphatic mapping (blue dye lymphatic mapping, lymphoscintigraphy, and radio-guided surgery), resulting in a 97.9% success rate (278/284 patients) in diagnosis (15). Combined lymphatic mapping and SLNB is a reliable indicator of the histopathologic status of the ALNs in early breast cancer and is rapidly gaining acceptance as the method of preference in women undergoing primary surgical therapy (16). In early breast cancer, methylene blue dye (MBD) is also a safe procedure for SLN detection. Injections of dilute MBD without massage improve technical performance and sustain low complication rates (17). Besides, research has shown that the effects of methylene blue were comparable with using isosulfan blue combined with an isotope (18). The axillary ultrasound has shown to be moderately sensitive and more specific in diagnosing lymph node involvement (19). The diagnostic specificity of lymph node sampling under ultrasound guidance for CNB or FNA can be as high as 100 %, and the sensitivity is reported from 65% to 70% (20, 21). Chen et al. have revealed that ultrasound is superior in evaluating ALNs than physical examination (PE). Then, the ultrasound should replace PE as the standard method for clinical staging of ALNs in breast cancer (22). However, ultrasound alone to guide the biopsy of ALNs resulted in highly variable false-negative rates (23). Ultrasound-guided axillary sampling has recently been explored in various studies as an alternative staging technique to boost the accuracy of SLNB (24, 25). Wang et al. showed that compared to SLNB alone (11.3%), SLNB + US-ALNB resulted in a significantly lower false-negative rate (2.8%) (26).

Stachs et al. displayed that the accuracy of preoperative AUS in patients with early breast cancer depends primarily on the size of metastases in the axillary lymph node (27). In 482 breast cancer patients, Choi et al. examined the influence of BMI on the performance of AUS and found no improvement in the false-negative rate (28). Besides, Shah et al. reported that the sensitivity of AUS did not differ across BMI groups, whereas the specificity and accuracy were higher for overweight and obese patients (29). In line with our study, there was a significant relationship between BMI, tumor size, laterality, ALN type, and the accuracy of preoperative AUS. However, other clinical and pathological factors such as age, weight, height, tumor biopsy, tumor location, the time interval between methylene blue dye and isotope injection to surgery, and the type of surgery were not correlated to the accuracy of preoperative AUS.

More recently, ultrasound-guided wire localization (UGWL), a well-recognized technique in breast pathology (30), has been used in the treatment of impalpable head and neck lesions and identified with the advantages of accurate operational position, reduced operating time, and decreased tissue damage (31). Compared to conventional surgery using wire marking for localization, ultrasound-assisted tumor surgery significantly increases the possibility of tumor-free margins in breast-conserving surgery (32). Khare et al. used the wire ultrasound-guided localization (WUGL) technique to excise non-palpable breast lesions. They showed that this technique has positive results and could be widely accepted in resource-constraint situations. Clear margins obtained with WGL were 70.8% to 87.4%, respectively (14). Indeed, UGWL can guide the decision on the precise surgical incision site, which results in a more effective SLNB. Our research included the differences between the number of SLNs detected by UGWL and the conventional method (isotope and blue dye). Surgeons could preoperatively locate SLN accurately and position wire markers via UGWL, which can further enhance the feasibility of SLNB. For SLNB guidance, blue dye mapping is more commonly used to locate SLNs of breast cancer. However, radionuclide use is limited in SLNB due to radioactive pollution and its legislative issues (33). Our results indicated that in comparison with wire localization and isotope injection, the methylene blue dye technique had low sensitivity of 72.2%, while both wire localization and isotope injection reached 77.8%. In addition, we investigated the preoperative accuracy of

UGWL in the identification of SLNs in patients with early breast cancer to guide SLNB. Compared with the methylene blue staining and isotope detection, the accuracy of UGWL localization was 65.4%. Among the 55 patients in our study, 71.8% of SLNs were detected by wire localization, while 57.8% were found using methylene blue mapping, and 59.6% were seen by gamma probe detection. The pathological results had performed as the gold standard to confirm the value of UGWL in determining SLN involvement. The results of our study demonstrated that the sensitivity and specificity of UGWL were 77.8% and 42.1%, respectively. Therefore, preoperative UGWL could effectively localize SLNs to guide SLNB in patients with early breast cancer. However, it is used to complement the isotope and blue dye method, but as an independent technique, UGWL requires further investigation.

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