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Original Article

Outcomes of Sentinel Lymph Node Biopsy by Using Isosulfan Blue Dye Alone Technique in Early Breast Cancer Patients

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Abstract

Background: Sentinel lymph node biopsy (SLNB) in patients with early-stage breast cancer with undetected axillary lymph node abnormalities is the current standard surgery. It is generally recommended that isosulfan blue and radiocolloid be injected together for a higher identification rate of the sentinel lymph nodes. But radiocolloids are expensive, specialized detection equipment and specialized staff are required. Therefore, it is the origin of this study to determine whether the injection of isosulfan blue injection alone, because it is cheap, safe and easy to access, will be able to provide standard sentinel lymph node identification result.

Methods: This is a retrospective study of breast cancer patients underwent SLNB by using isosulfan blue dye injection alone technique of Maharat Nakhon Ratchasima Hospital by Dr. Noppadol Trikunagonvong. From August 1st, 2016 to May 31st, 2022, there are 81 people.

Results: The mean age of the patients was 52.4 years (range, 31 to 71 years). Fifty-nine patients (72.84%) underwent mastectomy and 22 patients (27.16%) underwent breast conserving surgery. Mean (standard deviation) number of SLN were 3.73 (1.6) nodes. The identification rate of sentinel lymph nodes was 95.06%. The accuracy of frozen section report of our hospital was 97.4%. Fifty-one patients (66.23%) had negative SLNB and 26 patients (33.77%) had positive SLNB. ALND was reduced by 66.23%. There were 35 of 51 patients whose SLNB were negative and were followed for more than 2 years, 1 recurrence (2.85%) was found.

Conclusion: SLNB, using isosulfan blue dye alone technique, is a reliable, inexpensive, safe and simple surgery alternative.

Keywords: Sentinel lymph node biopsy, Isosulfan blue dye, Identification rate

Introduction

There are an estimated 19.3 million new cancer cases worldwide in 2020. Female breast cancer was the most commonly diagnosed cancer, with an estimated 2.3 million new cases (11.7%).[1] Surgical procedure is the one of main treatment in breast cancer that can divide in breast and axillary surgery. Breast surgery can be performed wide excision or mastectomy with or without reconstruction. Axillary surgery, in the past we performed radical axillary lymph node dissection (ALND) in all patients as standard treatment[2] and it caused many serious complications such as arm lymphedema and paresthesia.[3] Majority cases of early breast cancer did not have axillary lymph node metastasis so there were many patients underwent the unnecessary radical axillary lymph node dissection and had many complications. Sentinel lymph node biopsy (SLNB) was developed for solving this problem.

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Sentinel lymph nodes are defined as the first lymph node group which cancer cells are most likely to spread from a primary tumor. In 1994, Guiliano AE and his colleagues reported the feasibility and accuracy of intraoperative lymphatic mapping via Isosulfan blue dye with sentinel lymphadenectomy in patients with breast cancer. Sentinel lymph nodes were identified in 114 of 174 (65.5%) procedures and accurately predicted axillary nodal status in 109 of 114 (95.6%) cases.[4] From this research, SLNB was interested by many surgeons. There were many researches reported about lymphatic mapping via radioisotope agent, blue dye agent, indocyanine green alone and combine with two agents. Identification rates were more than 85% in all agents alone but more accurate in combine agents and false negative rate was less than 5%.[5–11]

ALND had more paresthesia (risk ratio [RR] 0.26, 95% confidence interval [CI] 0.20-0.33; $p < 0.01$) and lymphedema (RR 0.28, 95% CI 0.20-0.41; $p < 0.01$) than those had SLNB alone. There were no significant differences in overall survival (hazard ratio [HR] 0.95, 95% CI 0.85-1.06; $p = 0.35$), disease-free survival (HR 1.00, 95% CI 0.98-1.02, $p = 0.96$), and locoregional recurrence (RR 0.92, 95% CI 0.59-1.44; $p = 0.73$).[3] In 2010 and 2013, Krag and his colleague reported at 10 years no significant differences were observed in overall survival (OS), Disease free survival (DFS), or regional control between the SLNB and ALND in clinically node-negative breast cancer patients groups (At 10 years, no significant difference in OS between the two groups (HR: 1.11, $p = 0.27$). 10 yr Kaplan-Meier (K-M) estimates for OS are 87.8% and 88.9%. No significant difference in DFS between the two groups (HR: 1.01, $p = 0.92$). 10-yr K-M estimates for DFS were 76.9% for both groups).[12–14] Accordingly SLNB became the standard procedure of axillary treatment in early-stage breast cancer with negative lymph node patients

In 1999, Ratanawichitrasin A. and his colleagues had the first reported in Thailand about outcomes of sentinel lymph node mapping with Isosulfan blue dye in breast cancer patients. Their research was able to identify sentinel lymph node 87% and can accurately diagnose axillary metastasis when compared to the axillary dissection 92% of all patients.[10]

Patients and Methods

All breast cancer patients who underwent surgical treatments by Dr.Noppadol Trikunagonvong at Maharat Nakhon Ratchasima Hospital from August 1st, 2016 to May 31st, 2022 were included. All patients underwent standard preoperative evaluations, including clinical examination, digital mammography, and breast and axillary ultrasonography. Magnetic resonance imaging is not routinely performed.

Inclusion criteria

1. Invasive breast cancer patients who underwent breast surgery and SLNB
2. Tumor size less than or equal 5 cm.
3. Clinically node-negative (both of clinical examination and imaging)

Exclusion Criteria

1. Patient who already had distant metastasis.
2. Clinically node-positive and FNA demonstrated cancer metastasis
3. Pregnancy
4. Patient who was received neo-adjuvant chemotherapy
5. Recurrent breast cancer
6. DCIS

The study was approved by the Research Ethics Committee of our institute.

SLNB technique: After induction of general anesthesia and sterile fashion, we used isosulfan blue dye 3-4 cc. injected into subdermal layer of periareolar area and peritumoral area then massage around injection site for 5 minutes. In patient who planned to underwent breast conservative surgery, skin incision was made at 1 cm. below the lowest hair line of axilla perpendicular with Pectolaris major muscle edge but in patient who planned to mastectomy, we used the same incision with mastectomy. Axilla was explored under direct vision. Sentinel lymph nodes identified as blue staining nodes, we dissected and removed all blue nodes and its nearby lymph nodes. We usually removed at least 3-4 nodes and sent for frozen section (FS). If FS positive, we performed an immediate ALND and if FS negative, we did not perform further axillary surgery. To verify frozen section report, the pathologist will report the result again as permanent pathological result in 2 weeks.

All demographic data, tumor characteristics and oncological outcomes were presented using descriptive statistics. Means, standard deviations (SD), medians,

and ranges were used for continuous variables, while frequencies and percentages were used for the categorical variables. The primary outcome was the identification rate of sentinel lymph node biopsy in clinically negative axillary lymph node breast cancer. All statistical analyses were performed using STATA version 11.1.

Results

Eighty-one early breast cancer patients underwent SLNB by using blue dye alone technique between August 1st, 2016 to May 31st, 2022. The mean age of the patients was 52.4 years (range, 31 to 71 years). Thirty-seven patients (45.68%) had mass in upper outer quadrant, 17 patients (20.99%) in upper inner quadrant and central quadrant, 6 patients (7.41%) in lower inner quadrant and 4 patients (4.94%) in lower outer quadrant. Seventy-nine patients (97.53%) presented with clinically negative axillary lymph node status and 2 patients (2.47%) presented with enlarged axillary lymph node but FNA reported negative for malignancy cells. Fifty-nine patients (72.84%) underwent mastectomy and 22 patients (27.16%) underwent breast conserving surgery. Patient characteristics are shown in Table 1.

Table 1 Baseline characteristics of 81 SLNB patients

Characteristics	Summary
Sex: n (%)	
Female	81 (100)
Male	0 (0)
Age (years): median (range)	52.44 (31 - 71)
Tumor location: n (%)	
Upper outer quadrant	37 (45.68)
Upper inner quadrant	17 (20.98)
Lower outer quadrant	4 (4.94)
Lower inner quadrant	6 (7.41)
Central quadrant	17 (20.99)
Clinical lymph node status: n (%)	
Negative	79 (97.53)
Positive but FNA demonstrated negative for cancer	2 (2.47)
Breast operation: n (%)	
Breast conservative surgery	22 (27.16)
Mastectomy	59 (72.84)

In all patients, grade 2 was the most pathologic tumor grading had 47 patients (58.03%), grade 3 had 28 patients (34.57%) and grade 1 had 6 patients (7.40%). Thirty-seven patients (45.68%) had tumor size not more than 2 cm. Twenty-three patients (28.40%) had 2.1 to 3 cm. Twenty-one patients (25.92%) had 3.1 to 5 cm. The most breast cancer subtype were Luminal A and Triple negative breast cancer, each having the same number of 23 patients (28.4%), Luminal B HER-2 negative had 19 patients (23.46%), Luminal B HER-2 positive had 10 patients (12.34%), and Non-luminal HER-2 positive had 6 patients (7.40%). The number of patients with LN staging in N0, N1, N2, N3 were 53 patients (65.43%), 23 patients (28.40%), 4 patients (4.94%) and 1 patient (1.23%) respectively. Tumor characteristics are shown in Table 2.

Table 2 Tumor's characters

Characteristics	Summary
Pathologic tumor grading: n (%)	
Grade 1	6 (7.40)
Grade 2	47 (58.03)
Grade 3	28 (34.57)
Pathologic tumor size: n (%)	
Tumor ≤ 2 cm.	37 (45.68)
Tumor > 2-3 cm.	23 (28.40)
Tumor > 3-5 cm.	21 (25.92)
St Gallen breast cancer subtype: n (%)	
Luminal A	23 (28.40)
Luminal B, HER-2 negative	19 (23.46)
Luminal B, HER-2 positive	10 (12.34)
Non-luminal HER-2 positve	6 (7.40)
Triple negative	23 (28.40)
Pathologic LN staging: n (%)	
N0	53 (65.43)
N1 (1-3)	23 (28.40)
N2 (4-9)	4 (4.94)
N3 (> 9)	1 (1.23)

The sentinel lymph nodes can identify in 77 of 81 patients (95.06%). Mean (standard deviation) number of SLN were 3.73 (1.6) nodes. Fifty-one patients (66.23%) had negative SLNB and 26 patients (33.77%) had positive SLNB which had macrometastasis 23 patients (88.46%) and micrometastasis 3 patients (11.54%).

In positive SLNB group, we underwent immediately axillary lymph node dissection (ALND) and found only 9 patients (42.31%) had non-sentinel LN metastasis and 15 patients (57.69%) had no further LN metastasis. When compared frozen section and permanent reports, there were only 2 of 77 results (2.6%) out of SLNB reports were reported mismatch. And all of 2 mismatch reports were negative SLNB results. Thus, accuracy of frozen section report of our hospital was 97.4%. And no patient who underwent SLNB, had allergic reaction. Four patients who failed for SLNB we underwent ALND instead. Two patients (50%) had LN metastasis but others had not. There were 35 of 51 patients whose SLNB were negative and were followed for more than 2 years, 1 recurrence (2.85%) was found. Data are shown in Table 3.

Table 3 Result of sentinel lymph nodes biopsy

Characteristics	n (%)
Number of sentinel node (mean ± SD)	3.73 ± 1.60
Sentinel identified	77 (95.06)
SLN not identified and underwent ALND (n = 4)	
Negative metastatic LN	2 (50.00)
Positive metastatic LN	2 (50.00)
SLNBx negative	51/77 (66.23)
SLNBx positive (n = 26)	26/77 (33.77)
Micrometastasis	3 (11.54)
Macrometastasis	23 (88.46)
SLNBx positive and underwent ALND (n = 26)	
Negative non-sentinel metastatic LN	15 (57.69)
Positive non-sentinel metastatic LN	9 (42.31)
Accuracy of frozen section report (compared to permanent report) (n = 77)	75 (97.40)
Allergic reaction	0 (0)

Discussion

Lymph node (LN) metastasis is the one of most predictive factors that affect to prognosis, and recurrence. Identification of LN status is therefore very important. In the past, ALND was the mainstay surgical treatment of axilla and caused many serious complications such as lymph edema and paresthesia[3] until SLNB was introduced. From several studies that examined the comparisons between SLNB and ALND in early breast cancer patients with negative axillary LN metastasis reported that no significant difference in the survival and axillary LN recurrence but SLNB causes significantly less complications than ALND.[3,11–16] However, identification rate of SLN is very important. Guidelines from the American society of clinical oncology (ASCO) recommended a rate of SLN identification should more than 85% and false negative rate should less than 5%. Surgeons should maintains that performance of a minimum of 20 SLNB procedures in combination with axillary dissection or with mentoring is necessary to minimize the risk of false-negative results.[11] Data from several trials recommended addition of radiocolloid agents with blue dye can increase identification rate up to 97%.[6,17–19] Indocyanine green was also used as an injection which can identified SLN 97 to 100%.[20,21] But radiocolloid agents and indocyanine green are expensive and require specialized equipment to detect them. Therefore, we used only isosulfan blue dye alone in SLNB due to low cost, safe and can underwent by direct vision.

In Thailand, there are several researches which study about identification rate of SLNB in early breast cancer patients by using blue dye alone technique. Identification rate ranges from 87 to 98%.[10,22–25] In this study, the identification rate of SLNB by using isosulfan blue dye alone technique was 95.06% which was better than the ASCO instructions given and the accuracy of frozen section report of our hospital was 97.4%. Fifty-one patients (66.23%) had negative SLNB status, therefore we can reduce unnecessary ALND by 66.23%. Data from the ACOSOG Z0011 (Alliance) trial which Eligible patients were women who underwent breast conserving surgery with clinical T1 or T2 invasive breast cancer, non-palpable axillary adenopathy, and 1 or 2 sentinel lymph nodes containing metastases and planned further systemic treatment and radiation can omit ALND without affecting recurrence and survival rates.[26,27] Currently, ASCO and NCCN guidelines recommended that patients with indications meet ACOSOG Z0011 trial can safely omit ALND.[11,16] If we follow these guidelines, we can reduce unnecessary ALND by 70.37%. However, most of the patients in this study chose Mastectomy because they did not want to receive radiation because they wanted to return to work as soon as possible. Therefore, if most of patients choose breast conservative surgery, not only will we able to greatly reduce unnecessary ALND but we will also be able to reduce unwanted complications.

Conclusion

SLNB in patients with early-stage breast cancer with clinically negative axillary LN can reduce unnecessary ALND and unwanted complications. SLNB, using the injection technique isosulfan blue dye alone, is a reliable, inexpensive, safe and simple surgery alternative.

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Conflict of Interest

No authors have any potential conflict of interest to disclose.

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บทคัดย่อ **รายงานผลการผ่าตัดตรวจต่อมน้ำเหลืองเซนทิเนลโดยใช้การฉีดสาร Isosulfan blue ในผู้ป่วยมะเร็งเต้านมระยะเริ่มต้น**

นพดล ไตรคุณากรวงศ์, พบ.

กลุ่มงานศัลยกรรม โรงพยาบาลมหาราชนครราชสีมา

ความเป็นมา: การผ่าตัดตรวจต่อมน้ำเหลืองเซนทิเนลในผู้ป่วยมะเร็งเต้านมระยะเริ่มต้นที่ตรวจไม่พบความผิดปกติของต่อมน้ำเหลืองที่รักแร้ เป็นการผ่าตัดที่เป็นมาตรฐานในปัจจุบัน โดยมีคำแนะนำให้ฉีดสาร Isosulfan blue และสาร Radiocolloid ร่วมกันเพื่อให้อัตราการตรวจพบต่อมน้ำเหลืองเซนทิเนลสูงขึ้น แต่สาร Radiocolloid มีราคาแพง ต้องมีเครื่องมือตรวจจับเฉพาะ มีแพทย์และเจ้าหน้าที่เฉพาะทาง จึงเป็นที่มาของงานวิจัยนี้ว่าการฉีดสาร Isosulfan blue เพียงแค่ตัวเดียวเนื่องจากราคาไม่แพง ปลอดภัย และสามารถเข้าถึงได้ง่าย จะสามารถให้ผลลัพธ์ที่ผ่านเกณฑ์มาตรฐานได้หรือไม่

วิธีการศึกษา: เป็นการศึกษาข้อมูลย้อนหลังของผู้ป่วยมะเร็งเต้านมที่ได้รับการผ่าตัดต่อมน้ำเหลืองเซนทิเนล โดยใช้เทคนิคการฉีดสาร Isosulfan blue dye ของโรงพยาบาลมหาราชนครราชสีมา โดย นพ.นพดล ไตรคุณากรวงศ์ ตั้งแต่วันที่ 1 สิงหาคม พ.ศ. 2559 - 31 พฤษภาคม พ.ศ. 2565 มีจำนวน 81 ราย

ผลการศึกษา: อายุเฉลี่ยของผู้ป่วยคือ 52.4 ปี (น้อยสุด 31 ปี มากสุด 71 ปี) มีผู้ป่วยที่ได้รับการผ่าตัดเต้านมออกทั้งหมด 59 ราย (72.84%) อีก 22 ราย (27.16%) ผ่าตัดแบบสงวนเต้านม มีจำนวนต่อมน้ำเหลืองเซนทิเนลที่นำไปตรวจเฉลี่ย 3.73 ต่อม อัตราการตรวจพบต่อมน้ำเหลืองเซนทิเนลเท่ากับ 95.06% ความถูกต้องของการรายงานผล Frozen section เมื่อเทียบกับการรายงานผลชิ้นเนื้อแบบถาวรคือ 97.4% มีผู้ป่วยที่มีผลการตรวจต่อมน้ำเหลืองเซนทิเนลเป็นลบ 51 ราย (66.23%) อีก 26 ราย (33.77%) มีผลการตรวจเป็นบวก การผ่าตัดตรวจต่อมน้ำเหลืองเซนทิเนลสามารถลดการผ่าตัดเลาะต่อมน้ำเหลืองที่รักแร้ออกทั้งหมดได้ 66.23% มีผู้ป่วย 35 ราย จาก 51 รายในกลุ่มที่ผลการตรวจต่อมน้ำเหลืองเซนทิเนลเป็นลบ มีระยะเวลาในการตรวจติดตามเกิน 2 ปี ในจำนวนนี้พบผู้ป่วยมีการกลับเป็นซ้ำ 1 ราย และไม่มีผู้ป่วยมีอาการแพ้เลย

สรุปผลการศึกษา: การผ่าตัดต่อมน้ำเหลืองเซนทิเนลด้วยวิธีการฉีดสาร Isosulfan blue เพียงตัวเดียว ให้ผลการผ่าตัดที่น่าเชื่อถือ ราคาถูก เข้าถึงได้ง่าย ไม่ซับซ้อน ปลอดภัย สามารถใช้เป็นอีกทางเลือกหนึ่งในการผ่าตัดได้