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Added value of blue dye injection in sentinel node biopsy of breast cancer patients: Do all patients need blue dye?

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ABSTRACT

Background: In the current study, we evaluated the incremental value of blue dye injection in sentinel node mapping of early breast cancer patients. We specially considered the experience of the surgeons and lymphoscintigraphy results in this regard.
Methods: 605 patients with early stage breast cancer were retrospectively evaluated in the study. Patients underwent sentinel node mapping using combined radiotracer and blue dye techniques. Lymphoscintiraphy was also performed for 590 patients. Blue dye, radioisotope, and overall success rates in identifying the sentinel lymph node were evaluated in different patient groups. The benefit of blue dye and radioisotope in identifying the sentinel lymph nodes was also evaluated.
Results: Marginal benefits of both blue dye and isotope for overall sentinel node detection as well as pathologically involved sentinel nodes were statistically higher in inexperienced surgeons and in patients with sentinel node visualization failure. In the patients with sentinel node visualization on lymphoscintigraphy, 6 sentinel nodes were detected by blue dye only. All these six nodes were harvested by inexperienced surgeons. On the other hand 8 sentinel nodes were detected by dye only in the patients with sentinel node non-visualization. All these nodes were harvested by experienced surgeons.
Conclusions: The use of blue dye should be reserved for inexperienced surgeons during their learning phase and for those patients in whom lymphoscintigraphy failed to show any uptake in the axilla.

1. Introduction

Sentinel node biopsy is the standard of care for axillary staging in patients with early stage breast cancer. It avoids the morbidity associated with axillary lymph node dissection in patients with pathologically negative sentinel nodes [1,2].

Two commonly performed methods for sentinel node mapping during surgery include use of the radiotracer alone or in combination with blue dye. Although each of these methods has been used with acceptable results [3,4] several groups have recommended that the combined approach can increase detection rate and decrease false negative rate [5,6]. However the added value of blue dyes over radiotracer alone technique is considered minimal or "marginal" by few authors [7,8]. Although adverse reaction to blue dyes are considerably less significant than previously thought [9,10] blue dye injection carries a risk of adverse reactions including blue discoloration and tattooing of skin, and allergic reactions [11,12].

In the current study, we evaluated the incremental value of blue dye injection in sentinel node mapping of early breast cancer patients. We specially considered the experience of the surgeons and lymphoscintigraphy results in this regard.

2. Material and methods

605 patients (from March 2005 to March 2013) with early stage breast cancer (diagnosed either by excisional biopsy or core needle biopsy) were retrospectively evaluated. Patients underwent sentinel node mapping using combined radiotracer and blue dye techniques. Patients received intradermal injection of the ^{99m}Tc-Antimony sulfide colloid (in 391 patients) or ^{99m}Tc-Phytate (in 214 patients) [13] (0.5 mCi for 1-day and 1 mCi for 2-day protocols).

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Table 1
Characteristics of the patients.

Number of patients	605
Age of the patients	47 ± 18
Histology	
Ductal	405
Lobular	185
Other	25
Type of biopsy	
Core needle	482
Excisional	123
Tumor size	2.3 ± 1.6
Patients with axillary involvement	119
Median number of harvested sentinel node in the patients (range)	1(1–4)

After injection of the radiotracer, gentle massage was applied for 1 min. Lymphoscintiraphy was also performed as described elsewhere for 590 patients (using a dual head E.CAM Siemens or single head SOPHA gamma camera) [14,15].

The sentinel nodes were harvested during surgery using a hand-held gamma probe (RMD navigator or Europrobe) as well as blue dye technique. For the blue dye technique, patients were injected with Patent blue V (395 patients) or Methylene blue (210 patients) after induction of anesthesia in a sub-dermal fashion. Harvested sentinel nodes were sent to the pathologist for frozen section and/or touch imprint cytology. Axillary lymph node dissection was performed in patients with positive sentinel nodes.

Blue dye, radioisotope, and overall success rates in identifying the sentinel lymph node were evaluated in different patient groups. The benefit of blue dye and radioisotope in identifying the sentinel lymph nodes (overall as well as positive sentinel nodes) was also evaluated.

The study was approved by the local ethical committee of the Mashhad University of Medical Sciences.

2.1. Statistical analysis

Continuous variables were expressed as mean ± SD. Chi-square test (or exact test) was used for comparison between groups. All statistical analyses were performed by SPSS version 11.5 and *p*-values less than 0.05 were considered statistically significant.

3. Results

Table 1 shows the characteristics of included patients. Table 2 shows Dye, isotope, and overall success rates in identifying the sentinel nodes. Overall detection rate was 86.4%, 91%, and 93.7% for blue dye, radiotracer, and combined method respectively. Detection rates for methylene blue and patent blue V were 86.2%, and 86.6% respectively (statistically non-significant difference) and for ^{99m}Tc-antimony sulfide colloid, and ^{99m}Tc-phytate were 91.3%, and 90.6% respectively (statistically non-significant difference). Detection rate was statistically different between experienced and inexperienced surgeons (experienced surgeons had passed the learning curve period which encompassed axillary dissection in addition to sentinel node biopsy in 30 patients). Experienced surgeons had higher detection rate. Four experienced and three inexperienced surgeons were involved in the study period. Detection rate was also statistically higher in patients with visualized sentinel node on lymphoscintigraphy images.

Table 3 shows the marginal benefit of dye and isotope for identifying sentinel nodes. Marginal benefits of both blue dye and isotope were statistically higher in inexperienced surgeons and in patients with sentinel node visualization failure on lymphoscintigraphy images. In the patients with sentinel node visualization on lymphoscintigraphy, 6 sentinel nodes were detected by blue dye only (1% of the harvested nodes). All these six nodes were harvested by inexperienced surgeons. On the other hand 8 sentinel nodes (16.3% of the harvested nodes) were detected by dye only in the patients with sentinel node non-visualization. All these nodes were harvested by experienced surgeons.

Marginal benefits of blue dye and isotope were also statistically higher for identifying involved sentinel nodes by inexperienced surgeons and in patients with sentinel node visualization failure on lymphoscintigraphy images (Table 4). In one patient with visualized sentinel node on lymphoscintigraphy, the involved sentinel node was identified by blue dye alone. This patient was also operated on by an inexperienced surgeon.

Addition of blue dye, and radioisotope decreased the false negative rate 4/114 (3.5%) and 7/114 (6.1%) respectively as shown in Table 4.

4. Discussion

The rationale behind using two agents (radiotracer and blue dye) for sentinel node mapping is to increase detection rate of sentinel nodes and more importantly to decrease the false negative rate of the procedure [5,16–19]. This approach is also valid for sentinel node biopsy of other tumors besides breast cancer [20–22]. Our study confirmed this point as overall detection rate was higher using the combined blue dye/radiotracer method. Blue dye also contributed to detection of sentinel nodes which were

Table 2
Dye, isotope, and overall success rates in identifying the sentinel nodes (the numbers are patients).

	Dye success		Isotope success		Combined success	
	N/total	%	*N*/total	%	*N*/total	%
Experienced surgeons ($n = 545$)	MB 165/191	MB 89.1%	P 179/185	P 93.7%	–	–
	PB 320/354	PB 88.9%	AC 333/360	AC 94%		
	Total 485/545	Total 89%	Total 512/545	Total 94	519/545	95.2
Inexperienced surgeons ($n = 60$)	MB 16/23	MB 64%	P 15/25	P 65.2%	–	–
	PB 22/37	PB 62.8%	AC 24/35	AC 64.9%		
	Total 38/60	Total 63.3%	Total 39/60	Total 65%	48/60	80%
p-Value	<0.0001		<0.0001		<0.0001	
Sentinel node visualized on lymphoscintigraphy imaging ($n = 550$)	MB 174/190	MB 92.5%	P 184/188	P 96.8%	–	–
	PB 334/360	PB 92.5%	AC 348/362	AC 96.6%		
	Total 508/550	Total 92.4%	Total 532/550	Total 96.7%	538/550	97.8%
Sentinel node not visualized on lymphoscintigraphy imaging ($n = 40$)	MB 5/14	MB 38.5%	P 5/13	P 35.7%	–	–
	PB 10/26	PB 37%	AC 8/27	AC 30.8%		
	Total 15/40	Total 37.5%	Total 13/40	Total 32.5%	22/40	55%
p-Value	<0.0001		<0.0001		<0.0001	

MB: Methylene blue, PB: Patent blue V, P: ^{99m}Tc-phytate, AC: ^{99m}Tc-antimony sulfide colloid.

Table 3
Marginal benefit of dye and isotope for identifying sentinel nodes (the numbers are detected sentinel nodes).

	Dye alone		Isotope alone	
	N	%	*N*	%
Experienced surgeons ($n = 580$)	7	1.2	33	5.7
Inexperienced surgeons ($n = 70$)	8	11.4	10	14
p-Value	0.00004		0.018	
Sentinel node visualized on lymphoscintigraphy imaging ($n = 583$)	6	1	30	5.1
Sentinel node not visualized on lymphoscintigraphy imaging ($n = 49$)	8	16.3	10	20
p-Value	<0.00001		<0.000001	

Table 4
Marginal benefit of dye and isotope for identifying involved sentinel nodes (the numbers are involved sentinel nodes).

	Number of involved sentinel nodes	Dye alone		Isotope alone	
		N	%	N	%
Experienced surgeons	110	1	0.9	6	5.4
Inexperienced surgeons	14	3	21.4	1	7.1
p-Value		0.004		0.57	
Sentinel node visualized on lymphoscintigraphy imaging	107	1	0.9	5	4.6
Sentinel node not visualized on lymphoscintigraphy imaging	14	3	21.4	1	7.1
p-Value		0.005		0.53	

histologically positive and therefore contributed to reducing the false negative rate in 4 patients (Table 4).

Some groups have evaluated the sentinel node biopsy procedure in breast cancer patients in order to identify sub-group of patients who gain the most benefit from addition of blue dye to the radiotracer technique [7,16,23,24].

Our results showed that addition of the blue dye to the radiotracer technique was much more beneficial if the surgeon was inexperienced (marginal benefit of blue dye alone for detection rate: 11.4% vs. 1.2% and for detection of positive sentinel nodes: 21.4% vs. 0.9% for in-experienced and experienced surgeons respectively). We considered passing a learning curve of 30 breast cancer patients using sentinel node biopsy alongside axillary lymph node dissection as a criterion of surgeon experience [25]. It has been shown that false negative rate and detection failure of sentinel node mapping would decrease after a learning phase of about 30–40 breast cancer patients [26,27]. Our result showed that using blue dye would not contribute much to the sentinel node mapping in the hand of experienced surgeons. Derossis et al. in a trend analysis also showed the same finding [16]. They compared the marginal benefit of blue dye alone for overall detection rate as well as detection of positive axillary sentinel nodes in the their first 2000 breast cancer patients. In their study marginal benefit of blue dye alone for overall sentinel node detection as well as detection of positive sentinel nodes decreased steadily as the experience of the surgeons increased.

In another study by Teal et al. also demonstrated decreased benefit of blue dye as the experience of the surgeons grew. They reported the results of combined blue dye/radiotracer sentinel node mapping of 99 breast cancer patients and the added value of blue dye over radioisotope alone (blue only sentinel nodes) was only seen in their first 57 patients [28]. Another study by Kang et al., on 3402 breast cancer patients showed that the surgeons are less likely to use blue dye alongside radiotracer with increasing experience. In their study only 0.8% of patients with positive sentinel nodes had blue only nodes [7].

In accordance to our finding, New Start program showed that standard injection protocol (combined blue dye and radioisotope technique) and multidisciplinary training can eliminate the learning curve effect [29]. In our study, the inexperienced surgeons didn't have the multidisciplinary training as the New Start program recommended and actually benefited most from addition of blue dye to the sentinel node mapping technique.

Another variable that we evaluated in our study was the effect of pre-surgical lymphoscintigraphy on the added value of blue dye injection for sentinel node mapping. Overall detection rate was considerably higher in patients with visualized sentinel node on the lymphoscintigraphy images compared to those with non-visualized sentinel node. This is in accordance to other studies which demonstrated the strong predictive value of pre-operative lymphoscintigraphy for sentinel node surgical detection success [30,31]. The marginal benefit of blue dye for detection of non-involved as well as pathologically involved sentinel nodes was higher in patients with sentinel node non-visualization (16.3% vs. 1% and 21.4% vs. 0.9% respectively).

In a study by Goyal et al. 823 sentinel node procedures were reported and blue only nodes were detected in 4% and 23% of patients with sentinel node visualization and non-visualization on lymphoscintigraphy images respectively [30]. Their study supports our results and they recommended adding blue dye injection to sentinel node mapping in case of sentinel node non-visualization on lymphoscintigraphy images.

Another study by Degnim et al. showed benefit of blue dye (blue/cold nodes) of 0.6% for sentinel node detection and 2.5% for detection of pathologically involved sentinel nodes in patients with sentinel node visualization on pre-surgical lymphoscinitgram [32]. Degnim et al. argued in their study that although the marginal benefit of blue dye injection in sentinel node mapping of breast cancer is narrow, the benefits outweigh the risks and they recommended using blue dye even in case of sentinel node visualization on lymphoscintigraphy.

In another study, Wu et al. reported their experience on 170 patients with visualized sentinel node on lymphoscintigraphy. In 6 patients, sentinel node could not be harvested during surgery. They attributed these failures to "shine through effect". More importantly, the harvesting failure of their group had a decreasing trend (11.1%, 9.1%, and 1.4% for the first, second, and third years, respectively) [33]. Wu et al. results are in accordance to our findings and show the importance of surgeon experience to find visualized sentinel nodes on lymphoscintigram during surgery.

In our opinion and based on the current evidence, decision to use blue dye in addition to radiotracers in sentinel node mapping of breast cancer patients should be based on both surgeon experience and findings on pre-operative lymphoscintigraphy images. In our study, 8 sentinel nodes were only detected by blue dye alone in patients whose sentinel node was visualized on lymphoscintigraphy and 2 of these nodes was pathologically involved. Interestingly, all these 8 nodes were harvested by inexperienced surgeons. This number was 6 nodes in case of sentinel node non-visualization on pre-operative lymphoscintigraphy. Of these 6 nodes, 5 were harvested by experienced surgeons. These results confirm that in the hands of competent and experienced surgeons, lymphoscintigraphy can predict the success of sentinel node mapping using radiotracer alone and blue dye can be reserved for cases of sentinel node non-visualization. On the other hand, inexperienced surgeons would benefit from addition of the blue dye during the learning phase regardless of lymphoscintigraphy results.

In conclusion, addition of blue dye to radiotracer mapping can increase the overall detection rate of sentinel nodes as well as detection of pathologically involved nodes in breast cancer patients. However, the benefit of blue dye use is limited in the hands of experienced surgeons and in case of sentinel node visualization on lymphoscintigram. We would therefore recommend that the use

of blue dye should be reserved for inexperienced surgeons during their learning phase and for those patients in whom lymphoscintigraphy failed to show any uptake in the axilla.

Ethical approval

The study was approved by the local ethical committee of the Mashhad University of Medical Sciences under the approval number of 88773.

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Author contribution

Ramin Sadeghi: Study design, data collection; data analysis, manuscript preparation, final approval of the manuscript.

Ghazaleh Alesheikh: data collection; data analysis, final approval of the manuscript.

Seyed Rasoul Zakavi: Study design, manuscript preparation, final approval of the manuscript.

Asiehsadat Fattahi: data collection; data analysis, final approval of the manuscript.

Abbas Abdollahi: data collection; data analysis, final approval of the manuscript.

Mehdi Assadi: data collection; data analysis, final approval of the manuscript.

Ali Jangjoo: data collection; data analysis, final approval of the manuscript.

Mohammed Keshtgar: Study design, data analysis, manuscript preparation, final approval of the manuscript.

Conflicts of interest

None.

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