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Patent Blue V dye: Time to say goodbye?

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Background: Patent Blue V is used in conjunction with Technetium-99 in the detection of sentinel lymph nodes. It is a food-dye that has provoked a variety of hypersensitivity reactions, including anaphylaxis, when used intravenously. The aim of our study was to assess if the improvements in the techniques of sentinel lymph node imaging have made the continued routine use of Patent Blue V unnecessary in the 21st century.

Materials and Methods: A cohort of 349 consecutive patients for this retrospective audit was derived from a combination of hospital admission data and operative theatre lists over a 12-month period from a University Hospital and a District General Hospital. All patients underwent intradermal injection of Technetium-99 either the day before or on the morning of surgery, while Patent Blue V was injected in the peri-areolar region of the index quadrant at the time of surgery. All patients had a gamma-camera image taken prior to surgery to visualise the sentinel node.

Results: 98.2% of our harvested sentinel lymph nodes were detected using a gamma-probe, while only 79% were stained blue. Our lymph node positivity rate is 21.5%. Less than 1% of sentinel lymph nodes were stained blue but undetectable using a gamma-probe and in only 1 patient, from 349 consecutive patients, was there a positive node that was stained blue but 'cold' radioactively.

Conclusions: Our results show that as refinements in techniques of both nuclear imaging and radiological localisation of sentinel lymph nodes occurs, the use of Patent Blue V should not be as prescriptive as previously reported. We suggest the judicious use of Patent Blue V be limited to those rare situations where there are no detectable sentinel nodes pre-operatively using a gamma-camera.

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A new scoring system for predicting non-sentinel lymph node status using only clinicopathological variables proved at pre- or intra-operation

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Background: Axillary lymph node dissection (ALND) is the standard treatment for patients with positive sentinel lymph node (SLN), but only about a half of these patients have positive non-SLN. Several models have been developed to predict non-SLN status. However, almost all models include some permanent pathological variables revealed after the operation. The purpose of our investigation was to develop a new scoring system for predicting non-SLN status using only clinicopathological variables proved at pre- or intra-operation.

Patients and Methods: This study was based on a prospective database of 1320 patients who underwent SLN biopsy for cT1−2N0M0 invasive breast cancer, of whom 247 (19%) patients had positive SLN(s) proved by intra-operative frozen section analysis and subsequently underwent ALND. All clinical and pathological variables were collected and analyzed according to non-SLN status (negative non-SLN; n = 141 vs. positive non-SLN; n = 106). Univariate analysis showed that clinical T stage ($p = 0.033$), size of metastasis in the SLN (>2 mm) ($p < 0.001$), the proportion of positive SLN among harvested SLNs ($p = 0.002$), presence of lymphatic invasion ($p = 0.003$) and presence of vascular invasion ($p = 0.029$) were significant predictive variables of positive non-SLN. The first three variables of those could be proved at pre- or intra-operation. We developed a scoring system (range 0−7) to predict the likelihood of positive non-SLN. Each patients were assigned a score based on the sum of three variables: clinical T stage (T1a, b = 0, T1c = 1, and T2 = 2), size of metastasis ($\leqslant$2 mm = 0, >2 mm = 3), the proportion of positive SLN (<50% = 0, 51−99% = 1, and 100% = 2).

Results: Twenty-nine (12%) of the 247 patients had a score of 3 or less. Among these 29 patients, 3 had at least one positive non-SLN. With a score cut-off of 3, the negative predictive value was 90% (26/29) and the false-negative rate was 3% (3/106). By comparison, the number of patients with a score of 4 or less was fifty-nine (24%). Among these patients, 13 had at least one positive non-SLN. In this instance, the negative predictive value and the false-negative rate were 78% (46/59) and 12% (13/106), respectively.

Conclusions: This scoring system incorporating these valuables may help determine which patients would benefit from additional axillary surgery, intraoperatively. If we accept the false negative rate of 12% in a score cut-off of 4, one quarter the patients with positive SLN could omit routine ALND.

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Real-time polymerase chain reaction to detect micrometastases in sentinel nodes

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Background: Sentinel node biopsy permits detection of micrometastases, but they are often diagnosed postoperatively, so a second operation must be performed.

Materials and Methods: 390 consecutive cases of negative sentinel node biopsy (no malignancy shown in routine intraoperative frozen section) were studied by: 1. paraffin embeded tissue:hematoxilin-eosin staining (HE), 2. real-time polymerase chain reaction (intraoperative) (RTPCR), 3. inmunohistochemical study (IHQ) and 4. postoperative polymerase chain reaction (PCR). These four groups were compared in terms of diagnostic cabability to detect malignancy using mammaglobin and other gene expression markers to obtain quantitative information on gene expression.

Results: This trial has been designed to detect metastases of a clinically relevant size (0.2 mm or greater), nodes may be found that are histologically positive (isolated tumor cells or clusters <0.2 mm) and assay negative.

	Percentage of diagnosis of malignancy	p
HE	2%	0.001
RTPCR	12%	
IHQ	8.5%	
PCR	12.6%	

A second comparison was made between RTPCR and PCR groups, and no statistic difference was encountered.

Conclusions: RTPCR has shown to be a rapid, reliable, method that accurately reflects the presence or absence of clinically actionable metastases in SLNs, and can be used intra-operatively during a SLND.

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Radioisotope count in preoperative lymphoscintigraphy predicts sentinel lymph node metastasis in patients with early breast cancer

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Background: Preoperative lymphoscintigraphy (LPG) is used in sentinel lymph node biopsy (SNB) for patients with early breast cancer. But in LPG, the clinical significance of radioisotope (RI) count is unknown.

Material and Methods: 129 patients with clinically node-negative breast cancer were performed LPG before SNB. ^{99m}Tc-colloid (0.3 ml, 74MBq) was injected into the periareolar site and into subcutaneous tissue around the primary tumor. LPG was underwent immediately after injection (early phase) and after 3 hours (delay phase). Before SNB, hot spots were counted and measured RI count in each phase of scintigraphic image (*in vivo)*. After SNB, the removed SNs were measured RI count (*ex vivo*) and evaluated histological state. The relation between RI counts (*in vivo* and *ex vivo*) and histological state was analyzed.

Results: In all the patients, SNs were identified by combining methods of radio-colloid and dye. There were 29 cases with SN metastasis (pN+) and 100 cases with no metastasis (pN−). Between pN+ and pN− group, there was no significant difference about age, body mass index (BMI), tumor size and mean number of SNs. The frequency of lymphovascular invasion was significantly higher in pN+ group. In 129 cases, the number of SNs that was visualized in both phases of LPG was 168 (45 in pN+ and 123 in pN−). From evaluation of location and histological state about all the 168 SNs, there were 37 SNs with positive for metastasis (n+) and 131 SNs with negative (n−). In 37 SNs, there were 17 SNs with macrometastasis (n+macro) and 20 with micrometastasis (n+micro). RI count (*ex vivo*) was not significant about histological state. From RI count of LPG (*in vivo*), retention index [(delay-early)/early] was calculated about each SN and analyzed relationships to histological state, age and BMI. Mean retention index was lower in n+ ($p < 0.01$), age $\geqslant$65 ($p = 0.08$) and BMI $\geqslant$25 ($p < 0.01$) group. There was no significant difference between n+macro and n+micro groups.