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**Does 'intra-operative assessment' of sentinel lymph node biopsy increase patient's anxiety?**

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**Background:** Intra-operative assessment (IOA) of sentinel lymph nodes (SLN) with touch imprint cytology is a recognized technique to stage the axilla in patients with breast cancer. If IOA is positive for metastasis, axillary clearance is performed during the primary procedure thus avoiding a second operation. However this approach can leave some apprehension in the patient's mind pre-operatively regarding the extent of surgery that will be undertaken. Waking up after operation to find an axillary drain implies more extensive surgery and worse prognosis disease. Besides, patients can be disappointed where IOA is negative but final histology of SLNs are positive. Patient counseling is therefore absolutely crucial.

The aim of this study was to assess if our patient counseling on IOA was adequate and if IOA increased the patient's anxiety pre-operatively.

**Method:** This was a prospective questionnaire survey. 61 consecutive patients were included who underwent operation for primary breast cancer along with SLNB and IOA. Pre-operatively they were counselled by the Consultant Surgeon and the specialist breast care nurses. These 61 patients were given a questionnaire before discharge. Completed questionnaires were sent by patients to the audit department. Their response data was analyzed.

**Results:** 98% of patients felt that the procedure of IOA was explained to them in a way that they could comprehend. 98% of patients understood that axillary clearance would be performed if IOA was positive. However 7/61 (11%) patients expressed that they were not aware that if IOA was negative, there was a chance that final histology could be positive. Seven patients (11%) required axillary clearance due to positive IOA. Only 8/61 (13%) patients felt that IOA increased their anxiety prior to operation while 52/61 patients (85%, 95% CI: 0.74 to 0.92) felt it did not. All 61 patients felt that IOA was a good option and would choose IOA again if necessary.

**Conclusion:** Intra-operative assessment of sentinel lymph nodes did not increase the anxiety in the majority of patients. Though nearly all patients felt that they were given an adequate explanation of IOA 11% patients expressed that they were not aware of the possibility of false negative IOA. Clearly more effort and time should be spent explaining the procedure, making it clear that a false negative result can occur. Combining written information on IOA along with counseling will probably be helpful.

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**Sentinel node biopsy in "high risk" DCIS patients**

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**Background:** Ductal carcinoma in situ (DCIS) becomes a more common finding recently among women with screen detected breast cancer. DCIS should not metastasise to the axillary lymph nodes. However, postoperative examination of breast specimens may reveal invasion in some cases, raising the question about the necessity and indications for sentinel node biopsy. Almost all surgeons find the necessity of sentinel node biopsy in simple mastectomy cases, but it is also important to select a group of patients with DCIS which should have sentinel node biopsy during the first operation.

**Material and Methods:** In years 2004–09, we performed sentinel node biopsy in 2468 women patients treated for breast cancer. 285 of them had initial diagnosis of DCIS and were included into this study. The preoperative diagnosis of DCIS was based on mammography result and core, vacuum assisted (VAB) biopsy or surgical excision biopsy. Mammography showed microcalcifications (6–160 mm in diameter, BIRAD 4a-c) in 72% cases, well defined tumor in 26% and spicular structure in the remaining 2%. The visualization of sentinel node was performed using both technetium (Tc99) and methylen blue. Simple mastectomy was performed in 36% and breast conserving therapy in the remaining 64% cases.

**Results:** Sentinel node metastases were found in 20/285 patients. All of them had subsequent axillary dissection, and further lymph node metastases were found in 6/20 cases. Postoperative pathological examination of breast specimens revealed macro- or microinvasion in 19/20 cases, no invasion was found in the remaining 1 case. 18 patients had similar preoperative mammography findings: large areas (40–160 mm) of microcalcifications, two of them had tumor well defined shown by preoperative mammography. Preoperative biopsy revealed high grade (nG3) malignancy in 14/20 cases, medium (nG2) in 4/20 and low (nG1) in the remaining 2/20.

**Conclusions:** Our results suggest that sentinel node biopsy in patients with preoperatively diagnosed DCIS is justified and can save the patient an additional surgery in case of invasion findings in pathology report. One should localize a subgroup of DCIS patients, which may be called "high risk" in which the probability of underdiagnosing of the invasion component is so high that the sentinel biopsy is necessary. We suggest that sentinel node biopsy should be strongly recommended in DCIS patients with: large (>40 mm) areas of suspected microcalcifications, high or medium grade of malignancy showed in core biopsy and naturally in all cases when the patient chooses simple mastectomy.

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**A novel approach in sentinel node localisation in breast cancer: the UK experience in the use of Sentinella® the portable gamma camera in operating theatre**

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**Background:** Sentinel lymph node (SLN) biopsy is the standard practice for axillary staging in early breast cancer. Combining radio-isotope injection with patent blue dye is the most reliable detection technique. Sentinella® is a new portable imaging camera used intraoperatively to produce real time visual image of SLN, it also has an inbuilt gamma detection probe (GDP). Sentinella® was first tested in a controlled laboratory environment and followed by using in Breast cancer patients. We report the first use of this novel technique in Breast cancer patients from the UK.

**Methods:** Sensitivity and spatial resolution of Sentinella® was compared with a conventional single headed gamma camera (CGC), normally used for SLN imaging. Spatial resolution was measured by calculating the full width half maximum (FWHM) of a line profile measured perpendicular to the image of a capillary tube filled with high activity concentration of technetium-99m pertechnetate. In the second experiment a special simulator mimicking the axilla was planted with seeds containing radiocolloid Tc, mimicking lymph nodes. Seeds were placed at varying depths in the axilla. For each combination of depths and radioactivity images with Sentinella® and CGC were obtained. Sentinella® was also used in 10 patients who underwent Sentinel Node Biopsies.

**Results:** Sentinella® resolution is comparable with the CGC for objects close to the camera i.e. ~5 cm, but reduces rapidly as it's moved away from the camera. For distances up to about 7 cm the Sentinella® with the blue collimator is more sensitive than the CGC.

68 Sentinella® images and 34 CGC images were obtained from the simulated axilla. Sentinella® detects high radioactivity (500 kBq) faster than CGC (1 vs 2.5min). In cases of low radioactivity (10kBq) Sentinella® was equally accurate and faster than cGC, when placed close to the skin. Identification of different number of beads with varying radioactivity was similar in Sentinella and CGC.

Sentinella® images used in ten patients undergoing Sentinel node biopsy corresponded accurately to the scintigram images.

**Conclusion:** Sentinella® is accurate and fast in detecting radioactivity in the axilla. The anatomical shape of its collimator allows the operator to place it adjacent to the axilla, thus increasing its sensitivity in cases of low radioactivity. Its major advantage is that it can be used by surgeons in the operating theatre. Our independent tests and preliminary patient data confirms the high sensitivity and spatial resolution of the machine in localisation of radioactive nodes. This potentially increases the identification of the SLN and can resolve the problem of centres that do not have on site nuclear medicine department.

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**Feasibility and accuracy of sentinel lymph node biopsy after preoperative chemotherapy in breast cancer patients**

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**Background:** Despite the increasing use of both sentinel lymph node biopsy (SLNB) and preoperative chemotherapy (PST) in patients with operable breast cancer, there is still limited information on the feasibility and accuracy of SLNB following PST. In this study, the feasibility and accuracy of SLNB for breast cancer patients with clinically negative lymph nodes after PST were investigated. In addition, conditions that may affect SLN biopsy detection and false-negative rates with respect to clinical tumor response and clinical tumor/nodal status before PST were analyzed.

**Materials and Methods:** Between 2003 and 2008, 200 patients with Stage II and III breast cancer previously treated with PST were enrolled in this study. The eligible criteria for PST were (a) primary tumor >3 cm or (b) positive axillary lymph node status on initial examination. FNA biopsy was performed for clinically or ultrasonographically suspicious axillary lymph nodes. The patients then underwent SLNB, which involved a combination of intradermal injection over the tumor of radiocolloid and subareolar injection of blue dye. This was followed by Level I/II axillary lymph node dissection (ALND).

**Results:** The median patient age was 49 years, and the median primary tumor size was 4.9 cm. The overall SLN identification rate was 94.5% (189 of 200). In 178/189 patients (94%) the SLN accurately predicted the axillary status. Eleven patients had a false-negative SLN biopsies, yielding a false-negative rate of 12.9%. There were no significant differences in the SLN identification rate according to tumor classifications before PST, the clinical nodal status before PST, the clinical tumor response after PST, or pathological response of the tumor after PST, although the SLN identification rate tended to be lower in patients with a T4 primary tumor.

**Conclusions:** Our data suggested that SLNB was feasible method for axillary staging in breast cancer patients who received PST even in patients who initially with lymph node positive disease. However, false-negative rate of SLNB in patients with clinical and pathological complete tumor response tended to be higher than other group.

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### The impact of the Sentinel Node concept on overall survival, disease-free survival and axillary recurrence of breast cancer patients

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**Introduction and Aims:** The Sentinel Node (SN) concept emerged as a way to improve Breast Cancer (BC) staging and to reduce the morbidity of the Axillary Dissection (AD). But the influence of the SN concept on long term BC outcomes is not well defined. The aim of this work is to assess the impact of the SN concept on the overall and disease-free survival and on the axillary recurrence, in a prospectively controlled series of BC patients.

**Methods:** This revision includes 394 consecutive BC patients, from two successive randomized clinical protocols. The first (n = 166) elapsed from April 2001 to June 2003 and the second (n = 228) accrued from September 2003 to January 2005. The first study included patients with tumours less than 30 mm and the pN0sn patients were randomized between AD and SN only. The second study was divided into two groups. Group A received uT1 patients; pN0sn patients were spared from the AD and pN+sn patients were submitted to AD. Group B received uT2 patients; those with pN0sn were randomized between AD and SN only. Patients were followed-up at the out-patient breast clinic, every 3 months during the first 3 years, every 6 months until 5 five years and then yearly. Events were prospectively registered in an Institutional database.

**Results:** Median patient's age was 55 years (range: 20–78). Median follow-up time was 66 months (range: 4–100). Two men were included. Mean overall survival time for SN only patients was 98 months and for the AD patients was 93 months (p = 0.003). Mean relapse-free survival time for the SN only patients was 97 months and for the AD patients was 99 months (p = 0.43). At five years of follow-up, overall survival was 98% for the SN only group and 92% for the AD group and disease-free survival was 99% for the SN only group and 100% for the AD group. There were not detected axillary nodal recurrences among SN only patients or between AD patients.

**Conclusions:** Long-term follow-up of BC patients submitted to SN biopsy-only showed similar results to AD submitted patients, in terms of overall survival, disease-free survival and axillary node recurrence, therefore ensuring clinical perdurable adequacy of the SN concept.

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### Micrometastasis and isolated tumour cells in the sentinel lymph node after neoadjuvant treatment in breast cancer patients may reflect residual disease in non sentinel nodes

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**Background:** Recommendations about performing a complete axillary node dissection in sentinel node (SLN) with micrometastasis and isolated tumor cells in early stage breast cancer have been controversial. While SLN biopsy is considered an accurate method for staging the axilla in patients with breast cancer before systemic treatment, the use of SLN after neoadjuvant treatment (NAT) is less well established. The aim of this prospective study is to determine the accuracy of SLN technique after NAT and the significance of micrometastasis and isolated tumor cells in the SLN in this group of patients.

**Material and Methods:** From June 2005 to June 2009, a total of 71 patients with T1–3 N0–1 breast cancer who underwent NAT (chemotherapy or hormone therapy) were included in the study. After NAT, patients with a clinically negative axilla underwent sentinel node biopsy and full axillary dissection. All patients were injected subareolar with Tc-99 the day before of surgery. The SLN was identified by the gamma probe, and sent to Pathology for frozen (FS) and H&E paraffin-sections. If the SLN was negative by H&E paraffin-sections, then immunohistochemistry was performed.

**Results:** The SLN identification rate was 95.8%. Mean number of sentinel nodes removed were 2.2 (range, 1–7). Twenty three (32.3%) patients had a positive axilla. The sentinel node was positive in 22 patients, with a false negative rate of 4.3%. Three patients had isolated tumor cells in the sentinel node, 2 of this (66%) had additional positive non sentinel nodes. Four patients had micrometastasis to the sentinel node, 3 of this (75%) had additional positive non sentinel nodes. The sentinel node was the only positive node in 7 patients (32%). Pathologic complete response was achieved in 30% of patients.

**Conclusion:** Patients with NAT can benefit from sentinel node biopsy as an accurate technique and may be spared axillary node dissection and its associated morbidity. The significance of micrometastasis or isolated tumor cells to the sentinel node in NAT patients may reflect residual tumor in the axilla and these patients should have a completion axillary node dissection as 70% of patients will have additional positive non sentinel nodes.

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### Value of sentinel lymph node identification in high risk ductal carcinoma in situ

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**Background:** Although sentinel lymph node (SLN) identification have a definite role in breast cancer staging it has not yet been totally accepted for patients with ductal carcinoma in situ (DCIS) of the breast.

**Aim:** To evaluate the applicability and results of SLN technique in high risk DCIS patients.

**Method:** We studied 200 patients with preoperative diagnosis of high risk DCIS from two tertiary hospitals. The day before surgery a lymphoscintigraphy was performed by using 111 MBq of 99mTc-nanocolloid in 1 intratumoral, peritumoral or subdermal injection way based on every case. Intraoperative detection of the SLN was performed by using a hand-held gammaprobe. In 100 cases vital blue dye was used.

**Results:** One hundred and thirty six patients showed a pure DCIS, 45 an invasive carcinoma and the remaining 19 had microinvasion in definitive histology. Lymphoscintigraphy and radioguided surgery identified SLNs in 98% (197/200) of patients. The vital dye injection identified SLNs in 77% of patients.

Thirteen patients showed metastatic SLN (10 micrometastases and 3 macrometastases). Eight of them in the group with invasive carcinoma (i.e. metastatic rate 19%). The remaining five presented two micrometastases