

for IBC. The last patient also developed distant metastases concurrently. One patient developed distant metastasis without locoregional recurrence. Of the patients with LR, one patient was treated with excision of DCIS, one patient was treated with excision combined with chemo-, hormonal, and radiation therapy. The two patients with distant metastases were treated only with hormonal therapy.

**Conclusions:** SSM with IBR carries no increased risk for loco regional or distant recurrence compared to a non-skin sparing mastectomy in our single institute.

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POSTER

#### Ultrasonography by Breast Surgeons in the Operating Theatre – Evaluation of the Initial Learning Phase

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**Background:** Many studies have proven that intra-operative use of ultrasonography (US) during breast-conserving surgery is the most accurate method to achieve high rates of tumour-free margins, with small volumes excised. US, therefore, has become an increasingly popular modality to guide the excision of malignant breast tumours. This study was performed to assess the accuracy of a surgeon's learning in US-guided excision of palpable breast cancer. Difficulties and potential pitfalls were analysed.

**Methods:** A total of 30 female patients undergoing breast-conserving surgery for palpable T1-T2 invasive breast cancer were recruited. The US assisted three individual breast surgeons to target and excise the tumour with continuous intra-operative imaging. The main objective was to obtain adequate resection margins with optimal resection volumes. The specimen volume was measured, and the tumour diameter and histological margin status were registered from the pathology reports. An optimal resection volume was defined as the spherical tumour volume with an added 1.0-cm margin. The specimen volume was compared to the optimal resection volume. The resulting calculated resection ratio (CRR) indicated the excess tissue resection.

**Results:** All tumours were correctly identified during the surgery, and 29 of 30 tumours (96.7%) were removed with adequately negative resection margins; focally positive margins were found in one tumour (3.3%). Median CRR was 1.0 (range, 0.4–4.4); for all breast surgeons, CRR improved during the learning period. By the 8<sup>th</sup> procedure, all surgeons showed proficiency in performing intra-operative breast-US. The main difficulties were recognising ill-defined tumour margins, and relating the US-image to the tumour position in the breast.

**Conclusions:** Surgeons can easily learn the skills to perform intra-operative US for the excision of palpable breast cancer. Intra-operative surgeon-performed US is non-invasive, simple, safe and effective in obtaining adequate resection margins, as it permits a real-time localisation of the breast carcinoma and the subsequent planning of surgical margins. The resection volumes markedly improved during the learning period into optimal volume resection, thereby presumably resulting in improved cosmetic outcome. In a prospective randomised controlled clinical trial the surgical accuracy of intra-operative US guidance is compared with the traditional palpation-guided surgery for palpable breast cancer.

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POSTER

#### Comparison of Level 3 Nodal Yield in Carcinoma Breast Patients Using the Subpectoral and Interpectoral Approach of Axillary Dissection

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**Background:** Level 3 Axillary nodal clearance during modified Radical Mastectomy in Carcinoma Breast is done conventionally by retracting the pectoralis minor muscle medially and exposing the Axillary vein. However, we have been performing the level 3 clearance by retracting the Pectoralis minor muscle laterally and entering the interpectoral groove.

The aim of the study was to compare the nodal yield of level 3 axillary nodes using the conventional Subpectoral route and the Interpectoral route.

**Materials and Methods:** A total of 50 females with Carcinoma Breast were enrolled in the study and were randomly allocated to the Subpectoral and

Interpectoral Axillary clearance group with 25 patients in each. Statistical analysis was done.

**Results:** The nodal yield was 20% higher in the interpectoral group as compared to the Subpectoral group which was statistically significant. The number of complications was lower in the subpectoral group. However, three patients required prolonged Axillary drainage for more than 3 days.

**Conclusion:** Level 3 Axillary Clearance using Interpectoral approach gives a better nodal yield and less complications as compared to the Subpectoral approach in Carcinoma breast patients.

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POSTER

#### Evaluation of Clinical Utility of Sentinel Lymph Node (SLN) Examination by One-step Nucleic Acid Amplification (OSNA) Assay in Breast Cancer

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**Background:** Sentinel lymph node biopsy (SLNB) in Breast cancer has been commonly used in place of axillary lymph node dissection (ALND) for local control and nodal staging. Recently completed large scale clinical studies have suggested that ALND doesn't improve the prognosis of breast cancer patients for SLN positives cases significantly and can even increase patient morbidity. Therefore the significance of ALND in SLN positive patients will be called into question in the future and the value for nodal staging of SLNB will increase. The OSNA assay is utilized for lymph node examination by measuring the amount of CK19mRNA in lymph nodes using molecular techniques. The assay is expected to improve the accuracy and standardization of LN examination with the advantage of being able to assess a large portion of a lymph node. The OSNA assay has been in clinical use in Japan and EU. We conducted a multi central clinical study with 11 institutes in Japan to investigate the relationship between the results in SLN and non-SLN status as well as to identify the clinical and pathologic factors that show a correlation with non-SLN status.

**Material and Methods:** 417 clinically node negative breast cancer patients scheduled for SLNB were enrolled. After cutting off a central 1 mm thickness slice for pathological examinations from each SLN, the residual portion was applied to the OSNA assay. For patients who received ALND, non-SLN status was examined by routine pathological method at each site.

**Results:** Ninety-four of 417 (22.5%) patients were judged as SLN positive by the OSNA assay. 86 of these patients received ALND and 29 (33.7%) of these had metastases in the non-SLN. Among those who received ALND, 50 patients had an OSNA ++ result and 34 patients had an OSNA + result, with metastases in non-SLN in 22 and 6 patients respectively. Positive predictive value of OSNA ++ for non-SLN metastasis (22/50 = 44.0%) was significantly higher than that of OSNA + (6/34 = 17.6%) ( $p=0.01$ ). A strong association with non-SLN involvement was found in cT (cT1 vs cT2  $p=0.0104$ ), pT (pT1 vs pT2/T3  $p=0.0389$ ) and Grade (Grade 1 vs Grade 2/3  $p=0.0066$ ).

**Conclusions:** SLN evaluation by OSNA can reflect non-SLN status appropriately. The semi-quantitative result of OSNA(++/+) has potential to indicate non-SLN status by combination with tumour size and tumour grade.

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POSTER

#### OSNA is Suitable for Intraoperative Analysis of Sentinel Lymph Node Metastasis in Breast Cancer

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**Background:** Sentinel node (SN) biopsy is the standard procedure in breast cancer patients who are clinically node-negative. However, our hospital has no pathologist, so we have not been able to perform intraoperative analysis of SNs. The one-step nucleic acid amplification (OSNA) technique is simple to perform and allows straightforward diagnosis of SN metastasis by quantitative evaluation of cytokeratin 19 m-RNA. The analysis results are available in as little as 30 minutes. This technique enables us to now perform SN analysis during the operation. In this study,

we compared OSNA to histological investigation to determine the suitability of OSNA.

**Methods:** Surgically obtained SNs were sectioned into three pieces along the major axis. The central piece was sliced into 1 mm wide and sent to a pathologist in an external laboratory for histological investigation with H&E and immunohistochemical staining. The other two pieces were examined with the OSNA method. Both methods were compared in the evaluation of 81 SNs from 52 breast cancer patients.

**Result:** Both methods yielded the same results in 77 SNs; 63 were metastasis-negative and 14 were metastasis-positive. Two SNs were positive for metastasis on OSNA but negative on histology. Other two SNs were metastasis-negative on OSNA but positive on histology, and these nodes contained only micrometastasis lesion. The concordance rate was 95.1% and specificity was 96.9%. The false positive rate and false negative rate were very low.

**Conclusion:** OSNA is a very useful technique for the intraoperative analysis of SN metastasis in breast cancer patients. The OSNA analysis results appear to be very reliable. This method is useful not only in major hospitals but also in smaller hospitals where pathologists are not available during an operation.

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POSTER

# Biological Features of Primary Tumour as Predictors of Ipsilateral Axillary Node Relapse in Elderly Breast Cancer Patients

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**Background:** The lymphnode status of the axilla is considered the most important predictive factor of mortality in breast cancer patients and the question on which subgroups could be safely spared from axillary lymphnode dissection is not yet defined. The present study was performed to investigate on the predictive relevance of primary tumour biological markers on the risk of ipsilateral axillary node relapse.

**Patients and Methods:** The study included 351 elderly breast cancer patients ( $\geq 70$  years) with no-palpable axillary nodes and ER positive tumours, submitted to quadrantectomy (70.1%) or quadrantectomy plus radiotherapy (29.9%), without axillary dissection and followed by adjuvant Tamoxifen for at least 2 years.

ER and PgR were assayed by Dextrane-coated charcoal method and cell proliferation was expressed as 3H Thymidine labelled cells (TLI).

Patient follow-up involved clinical, biochemical and radiological assessments at 6 month intervals, for the first 5 years, and once year thereafter.

**Results:** At a median follow-up of 16 years, in the overall series ipsilateral axillary relapse was directly and significantly associated with proliferation index: 2.1% (95% CI: 0.8–5.6%) in patients with slowly proliferating tumours vs 11.8% (95% CI: 7.7–18.0%) in patients with rapidly ( $p=0.0002$ ). The difference was consistently observed in patients with pT1 lesions 0.9% (95% CI: 0.1–6.4%) vs 9.3% (95% CI: 4.8–18.1%) ( $p=0.003$ ) and in patients with pT2–4b lesions 3.9% (95% CI: 1.3–11.8%) vs 14.7% (95% CI: 8.5–25.4%) ( $p=0.019$ ). In the present series of elderly patients with a ER+ tumours, PgR status by itself showed no predictive relevance but in association with proliferation index was able to identify two subgroups with statistically significant difference in axillary relapse: 2% (95% CI: 0.6–6.2%) in patients with PgR+ and a low proliferation index vs 13.7% (95% CI: 6.8–27.5%) ( $p=0.002$ ) in patients with opposite biological features.

**Conclusion:** Cell proliferation of primary breast cancer is an independent predictive factor of ipsilateral axillary relapse risk and could represent a valid, efficacious and low expensive tool to identify patients candidate to axillary surgery.

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POSTER

# Ex-vivo MRI of Breast Specimen: an Innovative Procedure to Verify the Surgical Removal of Only MRI Detected Lesions

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**Purpose:** Besides the increasing development of MRI as a diagnostic problem solving tool, the need to achieve the histologic diagnosis of the only MRI detected lesions rose progressively up. When Open Surgical Breast Biopsy is request as the last opportunity to get a diagnosis of MRI findings, the challenge remains to demonstrate their effective removal. We designed an innovative procedure to demonstrate MRI highlighted nodules within Breast Surgical Specimen (BSS).

**Materials and Methods:** Before surgery, MRI diagnostic images were reconstructed in orthogonal views to allow the surgeon to evaluate the true extension of the disease.

Ex-vivo MRI was performed within 15' after the surgical resection. Technical procedure provided the study of the BSS by means of a surface coil. Two orthogonal Spair sequences allowing fat signal suppression were applied.

To visualize pre-operative MRI lesions, we injected contrast medium (Gd-DTPA) 1' before surgical incision. Following this procedure, we obtained a BSS where enhancing lesions of former diagnostic examination were newly highlighted and could be visualized on ex-vivoMRI. 27 patients were enrolled in the present study.

Informed consent was requested both before diagnostic pre-operative MRI and before surgery for ex-vivo evaluation.

**Results:** All MRI detected lesions were retrieved in ex-vivoMRI, including additional foci and dendritic branches not associated with microcalcifications. In 3 cases the further lesions were in another quadrant of the same breast: these patients were submitted to double resection and both BSS were analysed during the same MRI session.

**Discussion:** Careful assessment of the true extent of the disease in surgical planning for Breast Cancer is mandatory. Several studies report how MRI can improve local staging and depict even conventionally invisible additional foci. Only MRI detected nodules require however pre-operative localization and peri-operatively confirmation of their removal.

Until now, breast lesions were considered to be non-highlightable ex vivo. We succeeded instead in demonstrating the enhanceability of breast cancer by means of the same procedure that previously provided the most accurate staging of the disease.

To our knowledge, our method is the first that visualizes neoplastic lesions inside BSS by means of MRI.

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POSTER

# Breast Cancer After Mastectomy – Long Term Results and Prognostic Factors

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**Background:** The aim of this study was to determine the clinical characteristics, the therapeutic results and factors affecting disease free survival of breast cancer in women who underwent mastectomy followed by radiotherapy from a series of 231 cases treated in our department over one one year period.

**Patients and Methods:** A retrospective study of 231 patients with invasive BC who received radiotherapy after mastectomy, between January and December 1998, in our department. Survival curves were estimated by Kaplan–Meier methods. Univariate and multivariate analyses were performed using the Cox proportional hazards regression models.

**Results:** The median age was of  $46.8 \pm 1.9$  years (25–77 years). Nineteen tumours were of stage I (8%), 118 of stage II (51%), 70 of stage III (30%) and 24 of unspecified stage (11%). They were CCI in 88% of cases and CLI in 10% of cases. 59% of cases were SBR I or II grade and 41% GIII. The average of histological tumoral size was of  $36.1 \pm 2.6$  mm (10–95 mm). Seventy patients (30%) have a pT  $\geq 35$  mm, 176 (76%) of pN+, with an extra capsular extension in 36% of cases and lymphatic vascular embolus in 32% of cases. 87 patients were presented with RH+. 221 patients (96%) received chemotherapy and/or hormonotherapy. With a median follow-up of 77 months (9 to 127 months), we found 95 recurrences (41%) (locoregional relapses, distant and secondary cancer). The 10-year locoregional control (LRC), disease free survival (DFS) and overall survival (OS) rates were 88.7% ( $\pm 2.2\%$ ), 56.6% ( $\pm 3.6\%$ ) and 76.2% ( $\pm 3.3\%$ ), respectively. In univariate analysis, age  $\leq 40$  years ( $p < 10^{-3}$ ; HR:2,349), T3-T4 ( $p=0.001$ ; HR:2,095), stage III ( $p=0.04$ ; HR:1,554), pT $\leq 35$  mm ( $p=0.01$ ; HR:1,872), pN = 1–3 ( $p=0.04$ ; H R:1,911), pN  $> 3$  ( $p=0.003$ ; H R:2,598) and RH- ( $p < 10^{-3}$ ; HR:2,929) had an influence on DFS. In multivariate analysis, DFS was influenced by: tumours classified T3-T4 ( $p=0.05$ ; HR: 2,388), pN = 1–3 ( $p=0.02$ ; HR:5,605), pN  $> 3$  ( $p=0.004$ ; HR:8.9) and RH- ( $p=0.02$ ; HR:2,432).

**Conclusion:** Our therapeutic results were satisfactory. The study found that T (T3 or T4), N status (PN+) and RH status (negative) are the most reliable predictors of unfavorable events (a poor DFS), from where interest of a therapeutic intensification in order to improve the results.

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POSTER

# Intra-operative Specimen Microradiography in Wide Local Excision of Breast Cancer

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**Introduction:** Methods have been sought to reduce the need for re-excision following wide local excision of breast cancer. Methods include departmental specimen x-ray [1], intraoperative ultrasound [2] and fresh frozen section [3]. Our tertiary referral unit uses a cabinet microradiography system (Faxitron) for intra-operative assessment of tumour margins. This pilot study aims to assess the impact of this method on re-excision rates.