

of most breast tumors. Among them, benign breast disease (BBD) has a high prevalence and a noticeable impact on women's quality of life and for certain histological types, increases breast cancer (BC) risk. Epidemiological studies of BBD faced major difficulties since they included a wide range of pathological conditions that are associated with varying risks of BC. In recent years, attempts have been made to improve the standardization of histological classification for CNB including high risk lesions.

**Aim:** Hence, the objective of this study was to examine the pattern of breast diseases diagnosed by CNB using the B-classification for histopathological categorization.

**Methods and Results:** The studied population included asymptomatic and symptomatic women with breast imaging abnormalities who were referred to the Saint Pierre University Hospital for CNB after clinical and radiological examination between 2002 and 2010 (n total:2214). CNB was performed by stereotactic- or ultrasound guided automated gun method. Years 2002 and 2010 were compared.

Results of CNB (according to the B classification system)

Year	CNB/total radiological examination (%)	B1 (normal/No diagnosis)	B2 (benign)	B3* (uncertain malignant potential)	B4 (suspicious of malignancy)	B5 (malignant)
2002	45/512 (11.38%)	17/45 (37.8%)	14/45 (31.1%)	0	0	14/45 (31.1%)
2010	449/6070 (13.49%)	75/449 (16.7%)	200/449 (44.5%)	18/449 (4%)	0	156/449 (34.7%)

\*B3 lesions included atypical intraductal epithelial proliferations, lobular neoplasia, papillary lesions, radial scars, and potential phyllodes tumors.

In women aged 50 or less, B2 lesions were diagnosed in 11 cases (45.8%) and 132 (55.9%) during the years 2002 and 2010 respectively; B3 in 13 (5.5%) for year 2010; B5 in 5 (20.8%) and in 49 (20.8%) for years 2002 and 2010 respectively.

**Conclusion:** Our results show a gradual increase in the number of CNB performed in our breast unit in parallel with the radiological examinations carried out. Observed increase in CNB rates reinforces the need to carefully select patients amenable for biopsy to achieve efficient, efficacious, and cost-effective programs for early detection of BC. The increase in CNB results of 'uncertain malignant potential' (B3) stresses the importance of applying a decision-making algorithm for diagnosis and treatment in order to decrease BC risks in this increasing population.

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#### Health-related Quality of Life After Stereotactic Vacuum Assisted Breast Biopsy System Utilizing Radio Frequency – Breast Lesion Excision System (BLES)

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**Background:** Breast Lesion Excision System by Intact® (BLES) is a novel stereotactic, vacuum-assisted breast biopsy device that utilizes radiofrequency in order to excise suspicious non palpable mammographic lesions according to the BI-RADS system, for histologic diagnosis. The impact of BLES assisted breast biopsy upon Health-related Quality of Life (HRQoL) remains an open field for investigation and this study aims to evaluate short-term responses in terms of HRQoL after BLES.

**Material and Methods:** This study included 107 consecutive women with suspicious non palpable mammographic lesions in a 8-month time frame. Inclusion criteria were microcalcifications, solid lesions and asymmetric densities, all classified as BI-RADS ≥4. All patients were informed about the method by reading the same leaflet that has an informed consent purpose. HRQoL was measured using the EQ-5D questionnaire and all patients were asked to complete the questionnaire just before the BLES procedure and four days after, prior to obtaining the pathologic diagnosis. The EQ-5D questionnaire encompasses five parameters: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each one of these factors has three levels: no problems, some problems and extreme problems/unable. Furthermore, EQ-5D contains a visual analogue scale for patients to rate their own health from zero to 100 (EQ-5D VAS 'thermometer').

**Results:** Evaluation of patients' responses the morning before the BLES assisted biopsy and four days after the procedure showed that there was no alteration in mobility and self-care. One patient (0.9%) switched from 'some problems' to 'no problems' concerning usual activities and ten patients (9.3%) reported that pain/discomfort increased whereas six (5.6%) that pain/discomfort decreased. None of these differences was statistically significant. Comparison of the values concerning anxiety/depression and own health showed that there was statistically significant difference between the responses before and after the procedure. Anxiety/depression was significantly (p < 0.0001) reduced while eight (7.5%) patients reported

that their anxiety/depression increased and 31 (29%) that anxiety/depression decreased. Self-assessed health was significantly improved (p < 0.0001) while using the visual analogue scale, 57 patients (53.3%) rated their own health as better than before the procedure of B.L.E.S. assisted biopsy and only 14 (13.1%) as worse.

**Conclusions:** Vacuum assisted breast lesion excision system (BLES) for biopsy of suspicious non palpable mammographic lesions is a safe and effective diagnostic method which seems not to influence in a negative way the HRQoL of patients, in a short-term period after the procedure. Moreover, the use of BLES seems to positively affect self-assessed health and reduce the patients anxiety/depression. These statements indicate that, in the future, BLES assisted biopsy could become a first-line biopsy method.

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#### Correlation Between FDG-PET/CT and Pathological Features in Primary Breast Cancer

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**Goal:** We evaluated the usefulness of preoperative FDG-PET/CT (positron emission tomography/computed tomography) examination to predict the pathological features and select the treatment strategy in primary breast cancer. Especially we evaluate correlation between SUVmax (max standard uptake value) of FDG-PET/CT and Ki67 expression in invasive carcinoma, and Van Nuys Prognostic Index (VNPI) in DCIS.

**Methods:** Primary breast cancer patients operated between March 2009 and November 2010 in Okayama University Hospital were enrolled. We evaluated correlation the SUV max with postoperative pathology (diameter of invasive lesion (pT), histological grade, vessel invasion), status of ER, PgR, HER2 and Ki67 and node status. Status of Ki67 expression was classified 0–5%, 5–15%, 15–50% and >50%. DCIS and predominantly DCIS which have micro invasive component (<5 mm) were evaluated total tumor size and VNPI (low, intermediate, high).

**Results:** 86 patients with primary breast cancer were enrolled. Invasive cancers and DCIS were 78 (8 patients with predominantly DCIS) and 8. The median SUVmax in invasive ductal carcinomas was 3.35 (range: 0–52.57). In univariate analysis, SUV max related significantly with pT (p = .0001), Grade (3 > 1.2; p = .001), ly (0.1 > 2.3; p = .024), ER (negative > positive; p < 0.0001), PgR (negative > positive; p = .0007) and Ki67 (high > low; p = .0051). pT (p = .0024) was significant relative factor of SUVmax in multivariate analysis. The DCIS patients with high VNPI had comparatively higher level of SUVmax than those with low VNPI. In the evaluation of node status, sensitivity and specificity of preoperative PET/CT were 43% and 100%.

**Conclusion:** The preoperative FDG-PET/CT of the primary breast cancer had significantly relation with pathological status. pT was the strongest relative factor of FDG-PET/CT.

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#### 18F-FDG PET-CT Compared to Conventional Staging Procedures in Patients with Advanced Breast Carcinoma

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**Purpose:** To compare the diagnostic yield of standard dissemination investigations according the Dutch Guidelines (chest X-ray, ultrasound of the liver and bone scintigraphy) in patients with advanced breast cancer with total-body 18F-FDG PET-CT.

**Methods and Materials:** In all patients with advanced breast cancer between march 2009 and june 2011 18F-FDG PET-CT and conventional imaging procedures were performed. All investigations were done within a 14 daystime frame. Suspected lesions, found in either modality, were confirmed by additional imaging techniques and/or pathology.

**Results:** 51 patients, all women, mean age 59.9 year (min-max 31–85 y) were included in the analysis. Dissemination investigations were indicated preoperatively in 34 patients (13 patients with primary tumors (>cT4, N2) and 21 with suspicion of recurrent disease), and postoperatively in 17 (>pN2). In the 34 patient's no metastasis were found in both modalities in 21 cases. Conventional imaging showed metastasis in 4, and PET-CT showed metastasis in 9 additional patients. These were metastasis in bone (n = 2), pulmonary (n = 1) and supraclavicular (n = 6). In the 17 patients that were investigated direct postoperatively because of >pN2 status, 10 patients had no metastasis in both modalities, conventional imaging showed metastasis in 2, PET CT scan showed metastasis in 5 additional patients. These were metastases of bone (n = 3), pulmonary (n = 1), axillary (n = 3) and supraclavicular (n = 1). All suspected lesions on

the conventional imaging modalities were also detected by FDG-PET-CT scan. In a total of 14 patients additional lesions were found. In half of these patients the treatment plan was changed (2x no operation, 2x no adjuvant chemotherapy, 4x adaption of radiotherapy).

**Conclusion:** A 18F-FDG PET-CT is more accurate than the usual conventional imaging techniques in staging patients with advanced breast cancer. In our experience therapy can be more accurately planned.

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#### Combination of Breast Scintigraphy and Ultrasound is Promising Tool for Diagnosis and Staging of Breast Cancer

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**Purpose:** To evaluate diagnostic accuracy of breast scintigraphy (BrSc), ultrasound (US) and their combination in diagnosis and staging of primary breast cancer (BC).

**Material and Methods:** We studied 132 consecutive patients (pts) with clinical and/or radiological suspicion for BC. BrSc was performed 15 min after i/v injection of 740–860 MBq of 99mTc-sestaMIBI. Images with focal and scattered patchy uptake were scored as abnormal. Focal areas of tracer accumulation in axial region were considered as signs of lymph node metastases (LNM). High frequency digital wide field of view US was performed by experienced radiologist. Following signs were considered abnormal: irregular morphology, poorly defined edges, inhomogeneous echo structure, posterior acoustic attenuation, hyperechogenicity. Nodes with diameter more than 1 cm were considered abnormal. All breast lesions and LNs were verified by biopsy and follow-up or by operation.

**Results:** BrSc demonstrated high diagnostic value in 132 evaluated pts with following sensitivity (Sen), specificity (Sp) and accuracy (Ac): 94% (105/112), 68% (7/21), 90%. In 35 pts with lesions below 11 mm Sen of BrSc dropped to 86% (12/14), Sp reached 76% (16/21) and Ac 80%. In this group diagnostic value of US was as follows: Sen 57% (8/14), Sp 100%, Ac 82%. Combination of BrSc and US resulted in excellent Sen (100%) with moderate Sp (76%) and Ac (82%).

BrSc had moderate efficacy in diagnosis of axillary LNM with Sen – 74%, Sp – 75% and Ac – 74%. US demonstrated comparable figures: Sen – 79%, Sp – 77%, Ac – 77%.

When LNM were diagnosed as the combination of concordantly abnormal US and scintigraphy examinations Sp reached 96%, Sen dropped to 52% and Ac remained at 79%. If LNM were diagnosed in all patients with abnormal US or axillary LN scintigraphy Sen raised to 87% with Sp – 68% and Ac – 78%.

#### Conclusions:

1. Combination of BrSc and US can significantly improve Sen (100%) in patients with small (below 11 mm) breast lesions.
2. In diagnosis of axillary LNM BrSc with US help to increase Sen (87%) or Sp (96%). Final result is determined by chosen diagnostic strategy.

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#### Retrospective Comparison of the Accuracy of two Different Computer Aided Detection Systems for Detecting Malignant Lesions on Mammography

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**Background:** To retrospectively compare the accuracy of two computer aided detection (CAD) systems (SecondLook versus AccuDetect Galileo) for the detection of malignant breast lesions on full-field digital mammograms.

**Material and Methods:** Digital mammograms of 326 patients were analysed (117 patients with biopsy proven breast cancer, 209 negative cases). Positive cases consisted of 85 masses, 6 calcifications, and 26 masses plus calcifications. Twelve month follow-up was available for all negative cases. Each set of cases was read by both CAD systems and true positive fraction (TPF) for both systems and per image, case, and total cancers was assessed. Operating points for both systems was set at approximately the same false positive rates per image and case. One-sided, exact McNemar's tests were used to assess statistical significance of the results.

**Results:** When compared to SecondLook, AccuDetect Galileo significantly increased TPF per image for masses (increase of 10.6% to 72.2%,  $p = 0.0001$ ) and calcifications (increase of 12.8% to 61.5%,  $p = 0.03$ ). Per case, AccuDetect Galileo did not significantly increase TPF for masses and

calcifications. More importantly, AccuDetect Galileo achieved higher TPF for all cancers (per image increase to 6.9% to 72.2%; per case increase to 4.3% to 84.6%). Interestingly, AccuDetect Galileo had a significant performance improvement in detecting masses on extremely dense breasts (qualitative BI-RADS breast density class 4) over SecondLook, increasing TPF with 15.4% to 69.2% ( $p = 0.0156$ ).

**Conclusions:** AccuDetect Galileo showed better overall performance than SecondLook in detecting masses, microcalcifications and all cancer types, especially in extremely dense breasts.

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#### Comparison of Different Vacuum Assisted Breast Biopsy Methods – A Time-based Analysis

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**Background:** Minimally invasive biopsy is the standard of care for the diagnosis of suspicious non palpable breast lesions. Stereotactic vacuum assisted breast biopsy (VABB) with the use of devices such as Mammotome<sup>®</sup> is considered as an established method for the evaluation of suspicious non palpable mammographic lesions. Breast Lesion Excision System (BLES) is a new method that has been introduced for these kinds of procedures. The BLES utilizes radiofrequency in order to perform a one-pass intact specimen excision of the suspicious lesion. It has been proven that the duration of the procedure has an influence on many parameters for the patient such as pain, compliance, quality of life etc. The aim of the study was to record and compare the amount of time needed in order to complete a stereotactic VABB, with the use of Mammotome and BLES techniques respectively.

**Material and Methods:** From April 2010 to March 2011, 50 consecutive patients (mean age=49.8, range 35–76) underwent VABB with the use of Mammotome<sup>®</sup>, while another 50 consecutive patients (mean age=53.3, range 33–82) underwent a biopsy with the use of BLES. Inclusion criteria consisted of suspicious non palpable mammographic lesions such as microcalcifications, asymmetric density and solid lesions, categorized as BI-RADS 4 or 5. Biopsies were performed under stereotactic image guidance by the same surgeon–radiologist team and were successful and uncomplicated in all cases. Time intervals at the beginning of the procedure, i.e. positioning the patient and performing the stereotaxis, the anesthesia injection, the needle/basket withdrawal and at the end of the procedure were recorded and analysed.

**Results:** Breast biopsies conducted with the use of Mammotome<sup>®</sup> resulted in anesthesia injection at 15.5±9.6 min and needle withdrawal at 30.7±11 min later, while the total procedure lasted 46.2±13.4 min. On the other hand, biopsies conducted with the use of BLES resulted in anesthesia injection at 13.5±5.3 min, the basket was withdrawn after 9.8±3.8 and the total procedure lasted 28.2±6.6 min. Overall, there was no statistically significant difference between the two procedures in the amount of time required to appropriately position the patient and perform the stereotaxis. Nevertheless, the duration of the invasive part of the biopsy as well as the overall procedure time were significantly shorter ( $p < 0.0001$ ) in biopsies that were performed using the BLES.

**Conclusion:** According to our initial experience, the BLES device is a simple and time-saving diagnostic breast biopsy system. Patients undergoing a breast biopsy with the BLES might find it less inconvenient compared to Mammotome, due to shorter duration of the procedure. However, the choice of Mammotome<sup>®</sup> over the BLES or vice versa as a diagnostic procedure for non palpable mammographic lesions should be made based on objective criteria such as the morphology, size and location of the lesion rather than the estimated duration of the procedure itself.

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#### Identification of Sentinel Lymph Node Metastasis and Axillary Status in Early Breast Cancer by Indocyanine Green Fluorescence Method

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**Background:** Indocyanine green (ICG) fluorescence detection has been shown to be superior to blue dye in terms of the number of sentinel