surrounding fat and the homogenisation and conditioning of the sample can lengthen the timing of the whole procedure.

Our objective is to describe our experience in order to optimize the timing of the intraoperative study.

Material and Methods: A registry of the times of every step from the extraction in the operating room of 84 consecutives sentinel nodes to the emission of the diagnosis was done. We divided the time in three stages. First, time from the operating room to the Pathology Dept. Second from reception, macroscopic study and processing until amplification begins. Third, time from this moment to the diagnostic report.

Results: A learning curve was appreciated during the present study. In the first stage, the mean of time spent was of the 48.5 min, 37.9 min in the second stage and 31 min. in the third stage.

The previous knowledge of the surgical program allows the possibility to calibrate and prepare the reactive having every thing ready for the reception of the sentinel node. Besides, a call from the operating room to Pathology Dept. allows thawing all the reactives in order to begin the pathologic work up immediately after sentinel node arrival.

Conclusions: A learning period and designing a precise circuit for the new sentinel node procedure certainly improves the total time of intraoperative diagnosis.

351 Poster

Predictive factors for non-sentinel lymph node metastasis in breast cancer patients with sentinel lymph node metastasis

N. Kobayashi¹, H. Hanada¹, T. Utsumi¹. ¹Fujita Health University, Breast surgery, Toyoake, Japan

Background: Axillary lymph node dissection (ALND) remains the standard of care for breast cancer patients with a positive sentinel lymph node (SLN). However, in more than half of patients with positive SLNs lymph node metastases are only located in SLN. The aim of this study was to identify factors predictive of non-SLN involvement after a positive SLN.

Materials and Methods: The medical records of 70 breast cancer patients who underwent SLN biopsy and ALND were selected from a prospectively collected database and were reviewed for multiple clinicopathologic factors. The statistical significance for comparing two groups was determined by Fisher's exact test.

Results: The mean number of SLNs was 3.3 ± 2.3 . Of the 70 patients with a positive SLN, 14 (20%) had metastases in non-SLNs. Approximately 96% of patients (21 of 22 patients) with SLN micrometastasis had no non-SLN metastasis. Of the 48 patients with SLN macrometastasis, 35 (72.9%) had no metastasis in non-SLNs. Univariate analysis showed a significant association between non-SLN involvement and size of SLN metastasis (p = 0.024), and the number of positive SLNs (p = 0.047).

Conclusion: Detailed pathologic examination of the SLN metastasis may increase precision in the selection of patients for further ALND. However, more additional factors need to be identified before in selected cases ALND as a surgical staging procedure can be omitted.

Univariate analysis of clinicopathologic factors for patients with Non-SLN metastasis

	р	
Tumour size	0.182	
SLN metastasis size	0.024	
No. of positive SLNs	0.047	
No. of negative SLNs	0.076	
Histological grade	0.058	
ER	0.345	
PgR	0.333	

352 Poster

Sentinel lymph node detection using intradermal microbubbles and contrast-enhanced ultrasound in a swine model and patients with breast cancer

K. Cox¹, A. Sever¹, S. Jones¹, J. Weeks¹, P. Mills¹, D. Fish¹, A. Broillet², M. Schneider², P. Jones¹. ¹Maidstone Hospital, Breast Clinic, Maidstone Kent, United Kingdom; ²Bracco Research SA, Research, Geneva, Switzerland

Background: Sentinel lymph node (SLN) identification using intradermal microbbubles and contrast enhanced ultrasound (CEUS) has been recently reported in swine models and patients with breast cancer. The objective of the present study was to investigate the dynamics of intradermally administered microbubbles as they gain access to afferent

tissue lymphatics in pigs and traverse through breast lymphatics in patients with breast cancer.

Materials and Methods: Nine anesthetized healthy pigs were used for the study and 5 female patients with primary breast cancer were recruited. Pigs recieved intradermal injections of microbubble contrast agent in several territories to access lymphatic drainage to regional lymph nodes (LN). Patients had periareolar intradermal injection of microbubble contrast agent. Ultrasound examination was performed in real time Cadence Pulse Sequencing (CPS) mode with a Sequoia scanner.

Results: SLN were identified rapidly (less than 1 minute) and consistently in pigs. In all 5 patients with breast cancer, microbubble contrast agent entered breast lymphatic channels and travelled to draining pisilateral axillary SLN within a time period of 3 minutes. Intradermal microbubble injection and CEUS were found to have perfect concordance with the Evans blue dye method in locating swine SLN.

Conclusions: In patients with breast cancer, the ability to map lymphatic drainage and identify SLN in the diagnostic period would enable targeted biopsy and may facilitate pre-operative axillary staging in patients with early breast cancer.

Thursday, 25 March 2010

18:15-19:15

POSTER SESSION

Side effects and sequelae of breast cancer

353 Poster discussion

Safety of letrozole and tamoxifen monotherapy: updated BIG 1-98

M. Colleoni¹, A. Giobbie-Hurder¹, I. Smith¹, H. Mouridsen¹, G. Romieu¹, P. Neven¹, M. Rabaglio¹, K.N. Price¹, M.M. Regan¹, A.S. Coates¹. ¹BIG 1-98 Collaborative Group, International Breast Cancer Study Group, Bern, Switzerland

Background: BIG 1-98 is a double-blind randomized trial comparing 5yrs of treatment with either letrozole (Let), tamoxifen (Tam) or sequences of Let and Tam as adjuvant therapy for postmenopausal women with endocrine-responsive breast cancer. Initial results demonstrated superiority of Let over Tam in significantly prolonging disease-free survival (DFS). After release of these results 25% of patients (pts) assigned to Tam selectively crossed over to Let. As presented elsewhere, updated results (median follow up 76 mos.) after adjusting for selective crossover showed Let was significantly superior to Tam for DFS, overall survival, and time to recurrence. This report describes safety results for the pts randomized to receive Let or Tam monotherapy (4,922 of 8,010 pts enrolled).

Methods: The analysis population for safety included 4,895 pts, excluding 27 who received no trial treatment. Adverse events (AEs) were recorded during trial treatment or within 30 days of trial treatment completion. AEs, second (non-breast) malignancies, and deaths without prior cancer event occurring more than 30 days after selective crossover from Tam to Let were ignored. Prespecified AEs were collected and graded via check boxes every 6 months during treatment. Other AEs were coded according to MedDRA without knowledge of treatment assignment.

Results: In a competing risk analysis, the cumulative incidence of stopping treatment early due to an AE was 11.9% for Tam and 13.6% for Let (Gray's test p = 0.08). Pts on Tam experienced significantly more thromboembolic events, endometrial pathology*, hot flushes*, night sweats*, and vaginal bleeding. Pts on Let experienced significantly more bone fractures*, vaginal dryness, osteoporosis, carpal tunnel syndrome and arthralgia*. (*occurred in ≥10% of patients). Although the overall incidence of cardiac AEs did not differ significantly, higher grade cardiac events were more frequent on Let compared with Tam. The incidences of second (non-breast) malignancies (4.1% pts Let, 4.3% Tam) and deaths without prior cancer event (3.6% Let, 3.5% Tam) were similar.

Conclusions: As the AE profiles for Let and Tam differ, pts should be evaluated for baseline co-morbidities and monitored during treatment. Although a slightly higher percentage of pts stopped Let early due to AEs, Let continues to demonstrate superior disease control. Guidelines to monitor and manage bone health recently adopted may reduce the risk of bone fractures on Let.