such as deep infection and dehiscence. The only significant independent predictors of wound complications were obesity, undergoing a mastectomy, preoperative albumin, and diabetes.

Conclusions: Wound complication rate following BCS in women are low, limiting their value in assessing quality of care. Mastectomy carries higher complication rate than I-ANP with wound infection being the most common.

559 Poster

Series of modified radical mastectomies performed with ultrasonic knife

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Background: Electrocautery is the most commonly used surgical tool for mastectomy performance but ultrasonic knife should produce less tissue damage. The aim of this study was to assess the usefulness of this device for modified radical mastectomy and to evaluate postoperative complications and early functional results.

Material and Methods: Preliminary group of nineteen women who were not eligible for breast conserving surgery was studied prospectively. In each case modified radical mastectomy was performed using the ultrasonic knife with a constant frequency of 55.5 kHz and the longitudinal extension of the vibration of 75 μm. Mastectomy was done without transection of the pectoralis muscles. Perforators of the internal mammary artery were ligated, lymph nodes from all levels of the axilla were removed. Low-suction drains were placed before skin closure and were removed when their output was equal or less than 30 mL per day.

Results: Skin flaps preparation, breast dissection and axillary clearance were done easily. Neither technical difficulties nor intraoperative complications were observed. The wounds were healed by primary adhesion. Wound haematoma, flap necrosis, surgical site infection and palpable seroma formation did not occur. Operating time was (mean±SD, median, range): 107.4±19.2, 109, 61–155 min; number of removed lymph nodes: 17.2±3.5, 16, 12−24; total drainage amount: 186.6±32.3, 192, 90–330 mL; number of days with drain: 3.1±0.8, 3, 2−5; postoperative hospital stay: 4.3±1.0, 4, 3−6 days; number of office visits after discharge: 1.5±0.9, 2, 0−3, respectively.

Conclusions: Dissection using the ultrasonic knife is related to favourable early functional results after modified radical mastectomy without the increasing of the operating time: low postoperative morbidity, low total drainage amount, early drain removal, and short hospital stay. Further controlled trials are needed to assess the clinical advantages of this surgical tool and its usefulness for a routine surgical practice. Cost-effectiveness analyses should be also performed especially in low income countries.

560 Poster

Simplified axillary lymphadenectomy without suction drain and without padding in breast cancer: a prospective and comparative cohort of 100 patients with early and locally advanced breast cancer

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Hypothesis: If the sentinel lymph node (SLN) is widely used, standard axillary clearance remain the optimum technique in advanced breast cancer. In day practice, half of the patients still have a standard axillary clearance either immediately or after the discovery of a positive SLN. In most cases the standard axillary clearance is followed by a close suction drain. This extends the length of hospital stay and postoperative incomfort.

To improve these two parameters, we have simplified the technique of standard axillary clearance.

Axillary lymphadenectomy performed without the use of a drain and without padding of the axilla is feasible and safe on an outpatient basis in the setting of conservative surgery for breast cancer.

Patients: One hundred patients were included in this study between January 2006 and July 2007, an half was treated by this method of simplified axillary lymphadenectomy (without drain, without padding, surgical site infiltration with a local anesthetic long-acting), and the other half by the classical technique with close suction drain.

Main outcome measures: Prospective assessment was performed, without randomization, with regard to the length of hospital stay, number of seroma, and and the rate of surgical site infection (SSI).

Results: If there is no significant difference in the number of seroma between the two groups (30.5%). We have not seen SSI and the average length of stay is less than 24 hours in the simplified axillary clearance group, whatever the indication of axillary clearance, including advanced breast cancer.

Conclusion: Breast conservative surgery and axillary lymphadenectomy without padding of the axilla, and use of a drain, is feasible and safe on a 1-day surgery basis for non selected patients, improving quality of life on the postoperative period.

561 Poster

Oncological safety and patient satisfaction with skin-sparing mastectomy and immediate breast reconstruction

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Introduction: The management of early breast cancer with skin-sparing mastectomy (SSM) and immediate breast reconstruction (IBR) is not based on evidence from randomised controlled trials. The purpose of this study is to evaluate the oncological safety, post-operative morbidity and patients' satisfaction with SSM and IBR using the latissimus dorsi (LD) myocutaneous flap and/or breast prosthesis.

Methods: 83 consecutive women underwent 93 SSMs with IBR (10 bilateral), using the LD flap plus implant (n = 55) or implant alone (n = 38), indications included early breast cancer and prophylaxis due to BRCA-1 gene mutation. Nipple reconstruction was performed in 38 patients, using the trefoil local flap technique, nipple sharing or Monocryl mesh. 23 underwent contra-lateral surgery in order to optimise symmetry, including 15 augmentations and 8 mastopexy / reduction mammoplasties. Patient satisfaction with the outcome of surgery was assessed on a linear visual analogue scale ranging from 0 (not satisfied) to 10 (most satisfied).

Results: There was no local recurrence (LR) after a median follow-up of 34 months (range = 3−79 months). Overall survival was 98.8%, 3 patients developed distant disease and 1 patient died of metastatic breast cancer. No case of partial or total LD flap loss was observed. Morbidities included infection, requiring implant removal in 2 patients and 1 patient developed marginal ischaemia of the skin envelope. Significant capsule formation, requiring capsulotomy, was observed in 87% of patients who had either PMR or prior RT compared with 13% for those who did not have RT. Sixty-one (73.5%) of 83 patients completed the questionnaire with a median and mean satisfaction scores of 10.0 and 9.3 respectively (range = 6−10).

Conclusion: SSM with IBR is associated with low morbidity, high levels of patient satisfaction and is oncologically adequate for Tis, T1 and T2 tumours without extensive skin involvement.

Parameter	SSM & IBR	LD	IM	Median satisfaction score [range, number responding]	Implant loss due to infection	LR	SR	CA
All procedures in 83 patients	93	55	38	10 [6−10, n = 61]*	2	0	3	23
PMR	12	5	7	9 [6−10, n = 7]	2	0	0	5
Bilateral SSM and IBR	10	1	9	9.5 [8−10, n = 6]	0	0	0	-
NP-SSM and IBR	7	1	6	9 [7−10, n = 5]	0	0	0	-
Prior RT	4	4	0	9.5 [9−10, n = 2]	0	0	0	3

Key: IM, implant only; LD, LD + implant; RT, radiotherapy; PMR, postmastectomy radiation; LR, local recurrence; SR, systemic recurrence; CA, contralateral adjustment. *Overall satisfaction scores were available in 61 out of 83 patients (73.5%).

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Factors accounting for low nodal counts in axillary dissection following neoadjuvant chemotherapy

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Background: Lower node count rates in axillary dissection (ALND) are more frequent after neoadjuvant chemotherapy. The aim of this study is to investigate which factors account for this lower count.

Methods: A retrospective review from September 2004 to October 2007 included 154 patients receiving neoadjuvant chemotherapy followed by ALND. Nodal count was compared with the nodal count in 114 patients that underwent ALDN and did not receive chemotherapy during the same period. All patients received ALND at our institution by highly experienced breast surgeons. Nodes retrieved were divided in two categories (<10 for insufficient ALND and >10 for sufficient ALND). Patients age, pathologic classification, use of taxanes, pathologic complete response in tumour and Miller and Payne grading in lymph nodes were explored as potential factors for an insufficient nodal count. SPSS was used for the statistical analysis and Chi2 and Fisher's exact test applied when appropriate.

Results: Nodal count was significantly lower in patients receiving neoadjuvant chemotherapy (18% vs 6%, p = 0.05). The median nodal

count was 16.23 (SD+ 7.156). Age, pathologic classification and use of taxanes did not influence nodal count. A non-significantly higher number of insufficient ALND were observed in complete tumoral responses (37.5% vs 21%, p = 0.203). Miller and Payne grades C and D in the lymph nodes were associated with an insufficient nodal count (34.4% in Miller and Payne C−D vs 15.1% in A−B, p = 0.005).

Conclusion: as reported by other authors, in our institution, nodal counts are more frequently insufficient in ALND following neoadjuvant chemotherapy than in ALND performed in patients, not receiving chemotherapy. A non-significant trend to a lower nodal count was seen in patients with pathologic complete response in the tumour. A significant lower nodal count was seen in patients with chemotherapy changes in the pathology of lymph nodes (C and D Miller and Payne grades). This suggests that chemotherapy on lymph nodes make more difficult for surgeons to perform ALND and/or for pathologists to identify lymph nodes.

Friday, 18 April 2008 12:30–14:30

POSTER SESSION

Targeted therapies/Advanced disease

563 Poster Discussion

FDG-PET-CT in detecting locoregional disease and distant metastasis in high risk breast cancer patients

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Background and Aim: Conventional staging in breast cancer, consisting of chest-X-ray, ultrasound of the liver and bone scintigraphy, is often considered not to be sufficiently sensitive nor specific, especially with respect to detection of metastases in the internal mammary lymph nodes (IMN). The aim of this study is to evaluate the value of FDG-PET-CT in detecting locoregional disease and distant metastasis in breast cancer patients, in whom conventional screening is indicated according to the Dutch guidelines.

Material and Methods: Between June 2005 and Nov 2007 FDG-PET-CT scanning was added to conventional staging in 28 patients, prior to therapy. In nine patients (group 1) with high risk early stage primary breast cancer (grade III, tumour diameter >3 cm, clinically node positive, age <40 yrs), 4 patients with locally advanced breast cancer (group 2) and 14 patients with locoregional recurrence (group 3) FDG-PET-CT scans were made as a staging procedure. FDG-PET-CT data were analyzed by an experienced radiologist (RB) and nuclear medicine physician (MvK).

Results: A change in T or N stage was made in 10 patients (36%, 95% CI 16−56). The IMN contained a PET positive lesion in 4 patients (14%, 95% CI 0−29) (1 in group 1 and 3 in group 3). Two lesions were histologally proven, 1 was FNA negative and in 1 patient histology was not obtained because of otherwise metastatic disease. Three patients were treated with radiotherapy to the IMN. Distant metastatic disease was found in 5 patients (18%, 95% CI 2−34). One patient had multiple bony lesions; four patients had mediastinal lymph nodes (2 histologically positive, 2 not biopsied). The detection of distant metastases led to minimalisation of locoregional treatment. M1 status was converted to M0 in 4 patients (14%, 95% CI 0−29).

Conclusions: FDG-PET-CT identified metastases to the IMN in 14% of the patients, which had not been identified by conventional staging. Overall stage migration occurred in 36% of the patients, which enabled a better tailoring of the treatment.

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Disease progression as a predictor of overall survival in metastatic breast cancer: a meta-analysis

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Background: The relationship between disease progression endpoints and overall survival (OS) has been demonstrated in colorectal, colon, and non-small cell lung cancers. Patient access to novel and efficacious therapies for metastatic breast cancer (MBC) could be expedited if disease progression were documented as a valid surrogate outcome for OS in pivotal clinical trials. We assessed the association between time to tumor progression (TTP) and progression-free survival (PFS) and OS in randomized controlled trials (RCTs) for MBC.

Methods: A literature search retrieved all RCTs since 1994 in patients with MBC (first-line and refractory) in which both progression endpoints and OS were reported. Summary data on trial and patient characteristics were abstracted. Analyses across studies were performed using the hazard rate ratio where reported or the ratio of median months to event as an approximation of study effect sizes. Logarithm of the effect was regressed without an intercept and weighted by sample size for each study.

Results: A wide range of treatment types was represented in 67 studies covering 17,081 MBC patients. The exponentiated regression of study effect on survival by study effect on progression yielded the equation: $Effect_{Survival} = (Effect_{Progression})^{0.38}$ R^2(adjusted) = 0.34.

Since the confidence interval for the slope parameter does not include zero (95% CI: 0.23, 0.49), we infer that treatment effects on progression will yield treatment effects on survival, though the difference between groups is not expected to be as large. Four of the studies identified all patients as HER2+; in this subset, the association between progression and survival benefit was stronger (slope = 0.36; CI: 0.19, 0.53; R^2 = 0.92).

Conclusions: These results demonstrate that treatment differences in time to progression endpoints (TTP/PFS) observed in MBC trials are expected to coincide with differences in OS as previously established in other tumor types.

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Lapatinib plus capecitabine versus capecitabine alone for ErbB2-positive metastatic breast cancer (MBC) – Quality of Life (QOL) assessment

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Background: A Phase III randomized open-label multicenter study compared the treatment of lapatinib plus capecitabine (L+C) versus capecitabine alone (C) in adult women with ErbB2+ MBC who had received prior therapy which included an anthracycline, a taxane and trastuzumab. The study was closed early to new enrollment after 399 subjects when the primary endpoint was achieved at an interim analysis. This analysis focuses on the impact of treatments on health-related QOL.

Methods: QOL was assessed using the Functional Assessment of Cancer Therapy-Breast (FACT-B) questionnaire and the EuroQol (EQ-5D) questionnaire. Outcome measures included the FACT-B total score, FACT-general (FACT-G) score, trial outcome index (TOI) score, EQ-5D utility score, and EQ-5D visual analog scale (VAS) score. Higher scores indicate better QOL. Patients completed the questionnaires at the screening visit, every 6 weeks for the first 24 weeks, every 12 weeks thereafter and at study withdrawal. Changes from baseline scores were analyzed for the ITT population using analysis of covariance with baseline value as a covariate. Missing post-baseline data were imputed using the last observation carried forward method.

Results: The study randomized 198 subjects to the L+C arm and 201 subjects to the C arm. At the enrollment close, nearly half of the subjects had completed the Week 12 assessment and one-fifth had completed the Week 24 assessment. Point estimates for all scores were generally higher