

of impalpable lesions has become a daily challenge. Various localisation techniques were developed and tested but none can be considered ideal. ROLL was pioneered in Milan at EIO, we modified the technique and implemented at our Breast Unit, we have compared our ROLL and WGL series to provide sufficient data to demonstrate the efficacy of ROLL vs. WGL.

**Methods:** We have treated 100 consecutive impalpable breast cancers between January 2002 to September 2003, and ROLL was introduced in December 2002: this series represents a comparison between the last 50 WGL patients and the first 50 ROLL (Technetium<sup>99</sup> labelled colloidal albumin). Data was collected in relation to age, radiological abnormality, pre-operative core biopsy, type of primary surgery, length of localisation/excision, hospital stay, cancer size, weight and volume of the excised specimen, clearance margins, for both groups. Tumour volume ( $V_t$ ) was calculated and compared with the volume of the excised specimen:  $V_t$  was theoretically computed with the formula  $(\pi/6)d^3$  by assuming the cancer was spherical. The theoretical volume of an ideal specimen with 1 cm safe margins ( $V_{is}$ ) was also computed; finally the volume of the excised specimen was calculated ( $V_{exs}$ ). The following equations were then computed:

$R^* = V_{exs}/V_{is}$  (ratio of the excised specimen's volume to the volume of the ideal excised specimen); and

$R^{**} = V_{exs}/V_t$  (ratio of the excised specimen's volume to the tumour volume).

**Results:** The two groups proved comparable with respect to median age, radiological findings, type of surgery, and pathological findings. Median hospital stay (2 days) and operative time (30 min) were similar in both groups. Median localisation time with US or stereotactic technique was 6 min (5–7) and 12 min (10–15) respectively in the ROLL group, as compared to 15 min (15–17) and 20 min (20–25) respectively in WGL. Median pathological tumour size was larger in the ROLL group (15 mm) than WGL (10 mm); consequently,  $V_t$  was larger in the ROLL group (1768 mm<sup>3</sup> vs. 696 mm<sup>3</sup> for WGL). Conversely, median weight of the excised specimen was smaller in ROLL (39 g; range 6–128 g vs. 45 g in the WGL; range 7–167 g), and median volume of the excised specimen was similar in both groups (107,250 mm<sup>3</sup> vs. 115,500 mm<sup>3</sup>). Although median minimal clearance was similar for the 2 groups, more ROLL patients had clear margins (78% vs. 62%). Amongst patients with clear margins,  $R^*$  and  $R^{**}$  were higher in WGL than ROLL (6.56 vs. 4.17, and 98.38 vs. 66.65) respectively: this implies that a larger amount of normal breast tissue was excised with WGL, without achieving a better cancer clearance. Average cost of <sup>99m</sup>Tc is £28/patient, compared to £35/patient for wire insertion. Cosmetic results were excellent (70%) or good (30%) in ROLL group vs. (58%) and (42%) respectively in WGL. No major complication/technical fault was recorded.

**Conclusions:** ROLL localises the lesion very precisely, surgical removal is easy and margins clearance is better than with WGL, size of the excised specimen is smaller resulting in better cosmetic results.

Radiological localisation is quick and cost-effective.

362

ORAL

### **Surgical approaches to early breast cancer in the Intergroup Exemestane Study: large differences by country and geographical region**

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**Background:** Breast conserving therapy (BCT) has been widely accepted as a valuable alternative to mastectomy in early breast cancer. Despite that, in many countries mastectomy continues to be used as a main surgical approach. Our aim was to analyse the rate of mastectomy in various geographical regions in a large group of breast cancer patients entered into a global randomised study.

**Patients and methods:** The objective of the IES (96OEXE031-C/13/96-BIG02/97) was to compare the efficacy and safety of continued adjuvant tamoxifen versus exemestane in postmenopausal women with operable breast cancer after having received adjuvant tamoxifen for 2–3 years. Major eligibility criteria included positive or unknown steroid receptor status and adequate surgical treatment (both breast conserving and mastectomy were allowed) with or without postoperative chemotherapy and/or radiotherapy. Patients were randomised to subsequent exemestane, 25 mg daily or further tamoxifen, 20 mg daily for a total of 5 years adjuvant endocrine therapy period.

**Results:** Between February 1998 and February 2003, 4743 patients from 35 countries and 5 continents were enrolled into the study. Surgery data are currently available for 4689 patients. Of those, 2411 patients (51%) underwent mastectomy, 1810 (39%) – wide local excision and 465 (10%) – other types of breast-conserving surgical procedures. Main clinical and

therapeutic characteristics were well balanced between the study arms. However, there were large differences in surgical approaches between particular countries and geographical regions. Mastectomy rate was highest in Central and Eastern Europe (77%), followed by USA (56%), Western and Northern Europe (46%), Southern Europe (42%), and Australia and New Zealand (34%). Among countries with representative number of patients (>150), mastectomy rates were as follows: Belgium: 37%, France: 28%, Germany: 43%, Italy: 41%, the Netherlands: 48%, Poland: 98%, Spain: 66%, Switzerland: 47%, UK: 31% and USA: 56%.

**Conclusions:** The results of this analysis demonstrate substantial differences in surgical approaches to early breast cancer in various geographical regions and countries. A retrospective multivariate analysis of factors predictive for the extent of surgery will be presented.

363

ORAL

### **Quadrantectomy and axillary dissection vs quadrantectomy alone as surgical treatment for T1a,b,c N0 breast cancer. Early results of Milan V: a randomised clinical trial**

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**Introduction and Study design:** Currently, tumor size and nodal status, which represent the most important prognostic factors, are combined with several independent predictive and prognostic factors to assess the risk of relapse and to plan adjuvant treatment.

Several findings underscore the fact that in clinically node-negative patients, treatment of regional lymph node metastases does not seem to be a determining factor in the outcome of breast cancer. Nevertheless axillary dissection, which is nowadays performed in case of positive sentinel node, has maintained its role in prevention of regional relapse. The integration of additional tumour features with those commonly used may allow a more reliable selection of patients for adjuvant chemotherapy without performing axillary surgery. Toward this end, a randomised clinical trial comparing surgical staging of axillary lymph nodes at primary treatment (control arm) with a surgical treatment only in case of relapse (study arm) is currently in progress at the National Cancer Institute in Milan. Adjuvant treatment of patients who received quadrantectomy alone without nodal staging was determined through a prognostic panel including only morphological and biological features of the primary tumour while traditional criteria was applied to the control arm.

The primary end point of this study was to verify if the Overall Survival (OS) of the patients enrolled in the study arm is equal or improved when compared with the control group.

**Results:** Starting from May 1998, accrual was completed on May 2003. 527 patients with T1a,b,c clinically node negative were enrolled: 262 and 265 patients were assigned to the study and control arm respectively. Median follow up was 30 months. According to the prognostic panel, in the first group 88 patients (33.6%) were eligible for adjuvant chemotherapy compared to 135 (51.0%) of the control group by means of traditional criteria. Ten patients of the study group (3.8%) developed axillary lymph node relapse and was subsequently operated. Analysis of first unfavourable event (regardless of axillary relapse) did not show any significant difference between the two groups.

**Conclusion:** We can't argue any conclusion concerning the primary end point, but our early results suggest that a prognostic panel obtained by the primary tumour characteristics without lymph node surgery may represents a reliable method affected by a low rate of nodal relapses to select patients for adjuvant therapies.

364

POSTER HIGHLIGHT

### **Breast Cancer Units can significantly improve surgical management of early invasive breast cancer**

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Breast cancer research has significantly contributed to reduce aggressiveness of surgical treatment of early invasive cancer (EIBC). Long term results have confirmed safety and acceptability of breast conserving surgery (BCS) as a standard of care for T1–T2 tumours. More recently, the introduction of sentinel node biopsy (SLNB) for nodal staging has allowed the reduction of unnecessary axillary dissection (AD) for node-negative pts. Breast Cancer Units (BCU) with dedicated teams of surgical senologist and a multidisciplinary approach to this disease have been advocated for optimal disease management, and such a Unit is active at our Centre. In the present study, we retrospectively analyse all consecutive cases of EIBC referred for post-operative evaluation and adjuvant therapy to our Oncology

Multidisciplinary Clinic (OMC). Most pts. were treated in our BCU, while a proportion of cases were referred after treatment in General Surgery Units (GSU) operating in the same area. The purpose of the present study is to compare these two groups of women in terms of optimal diagnostic and surgical treatment.

From Jan 2000 through May 2003, from the Bergamo area a total of 755 cases of EIBC were referred to our OMC. Of these, 542 (72%) were BCU pts., while 213 were GSU pts. Median age was 60 yr, 60% of the women reported self-detection of a suspicious breast lump, 16% presented non-palpable lesions and 6% were both not-palpable nor ultrasound detectable, 51% were cT1 and 22% cT2, and in 16% palpable axillary nodes were present. Age, clinical tumour size, clinical nodal status and symptomatic vs. asymptomatic pts. were not statistically different in the two groups. Of pts. with detectable lesions, 96% of BCU pts. had a pre-operative FNA or core-biopsy diagnosis, while 48% of GSU pts. underwent either surgical biopsy or frozen section analysis at the time of surgery. Overall, BCS was performed in 72% vs. 62% ( $p<0.01$ ) of BCU and GSU pts., respectively. Effective SLNB was performed in 68% of BCU pts. vs. in only 14% of outside pts. ( $p<0.0001$ ), and AD was avoided in 47% vs. 13% of BCU and outside pts., respectively.

In conclusion, pts. treated at a specialised BCU receive better standard of care, with better pre-operative diagnostic workup and less aggressive surgical treatment. We believe that our study strongly supports recent recommendations that dedicated and highly specialised BCU become state-of-the-art settings for management of EIBC outside research institutions.

365

POSTER HIGHLIGHT

**Long-term prognosis of patients with local recurrence after breast conservation therapy for early breast cancer. A report of the Dutch Study Group on Local Recurrence after Breast Conservation (BORST)**

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**Background:** Controversies exist concerning the long-term prognosis of patients with local recurrence (LR) after breast-conserving treatment (BCT) of invasive breast cancer and prognostic factors are uncertain.

**Material and Methods:** Regular follow-up of the patients of eight institutes for radiation oncology, two cancer institutes and one surgical clinic in the Netherlands who underwent breast conservation therapy between 1980 and 1992 yielded 266 patients with an isolated LR in the breast. The interval between BCT and diagnosis of LR was more than 5 years for 61 patients (23%). Of the 266 recurrences, 164 (62%) were localized at or near the site of the original tumour, 37 (14%) were in a quadrant distinct from the primary tumour, 35 (13%) were diffuse or had multiple localizations and 19 (7%) were recurrences with skin involvement. Of all patients 85% underwent salvage mastectomy, 8% local excision, 4% only received systemic treatment and 3% remained untreated. The median follow-up of the patients still alive was 11.2 years.

**Results:** Of the 266 patients with LR 166 (62%) had died. Distant metastases were observed in 159 patients (60%) and subsequent LR or local progression in 70 (26%). Of the 159 distant metastases, 98 (62%) were detected within 2.5 years of diagnosis of LR, 137 (86%) occurred within 5 years and 153 (96%) within 10 years. At 10 years from the date of salvage treatment, the actuarial overall survival rate for all 266 patients was 42% (95% CI, 36–48), the distant recurrence-free survival rate was 40% (95% CI, 34–46), and the local control rate (i.e. survival without subsequent LR or local progression) was 71% (95% CI, 65–77). Size and growth pattern of LR were significant prognostic factors for the development of distant metastases; compared to those with a recurrences  $\leq 1$  cm the relative risk was 1.8 for tumours between 1.1 and 3 cm, 2.4 (95% CI, 1.5–3.9) for tumours  $>3$  cm or multicentric or diffuse and 4.1 (95% CI, 2.2–7.6) for recurrences with skin involvement.

**Conclusions:** Of the patients with invasive LR after BCT more than 60% ultimately develops distant metastases. The better distant disease-free survival for patients with LR measuring 1 cm or less might indicate that early detection of LR can improve the treatment outcome but might as well point towards a different biologic behaviour, facilitating early detection.

366

POSTER HIGHLIGHT

**Invasive breast cancer in women aged 35 and under: surgical treatment**

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**Background:** It has been reported that the prognosis of young women ( $\leq 35$  years) with invasive breast cancer is unfavourable when compared

with older women, even if the reason for this finding remains unclear. The adequacy of breast conservation therapy (BCT) in young patients is still a matter of debate. The aim of this study was to analyze the prognostic factors in such women and to assess BCT and mastectomy outcomes.

**Material and Methods:** The records of 37 young women with invasive breast cancer treated at our institution between 1992 and 2002 have been reviewed. All patients had lymph node status assessed by either axillary dissection or sentinel node biopsy. The details of histological type, tumour grade (according to the Elston classification) and size, estrogen receptor status (ER), lymph node involvement, type of surgery performed, overall and disease-free survival rates were obtained for all patients.

**Results:** The mean age of patients was 31 years (range 26–35). Twenty-six (70.3%) were diagnosed as having infiltrating ductal carcinoma (IDC) and 11 (29.7%) infiltrating lobular carcinoma. Tumour grade evaluated in the IDC was G3 in 9 patients (34.6%) and G2 in 17 (65.4%). No G1-tumours were found. RE were positive in 17 cases (45.9%) and negative in 20 (54.1%). Mean tumour size was 2.1 cm (range 0.5–3.5). All patients were submitted to adjuvant chemotherapy, and in 6 neoadjuvant chemotherapy was also undertaken. Fifteen patients (40.5%) had lymph node involvement. Eighteen patients with tumour size  $\leq 2$  cm were submitted to BCT and subsequent radiotherapy, 19 with tumour size  $\geq 2.1$  cm to Madden radical mastectomy. Median follow-up duration was 47.8 months (range 3–114). Median overall survival was 41 months. In the group of 18 patients (48.6%) operated on before 1998, the 5-years survival rate was 68.8% and the disease-free survival was 62.4 months. Mean overall survival was similar in patients submitted to mastectomy or BCT (44.7 months vs 46.9 months); interestingly, patients treated with BCT were found to have a higher disease-free survival (40.3 months vs 28.6 months).

**Conclusions:** According to the findings of the literature, our data confirm that breast cancer occurring in young women compared to older women is associated to a higher probability of G2-G3 tumour grade, absence of ER, lymph node involvement, and thus they have a worse prognosis. As regards type of surgery performed, in our series there was no difference in terms of overall survival in patients submitted to BCT compared to those undergoing mastectomy, however we observed a longer disease-free survival in the BCT group. These data suggest that BCT may be considered an effective and safe surgical option also in young patients with invasive breast cancer up to 2 cm.

367

POSTER

**Breast conservation surgery – the surgeon's factor**

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**Aim:** This study attempts to look at factors that may influence the rate of breast conserving surgery in patients with early breast cancer.

**Material and Method:** It is a retrospective study that includes patients with T1 or T2 breast cancers operated from year 2000 to 2002. Besides looking at patient's and tumor factors, the year of operation as well as the subspecialty of the surgeon is also analyzed. There were additional 2 breast subspecialty surgeons who joined the department at the end of 2001.

**Results:** The study population consists of 389 patients. Mean age of the patient is 53.9 years (24 to 90 years). There was no difference in the patient demographics seeing breast and non-breast sub-specialists. The rate of BCS is 21%, 25% and 56% from 2000 to 2002 respectively. 26% of patients who underwent mastectomy had no documentation of reasons for not offering BCS. There was no significant difference in the BCS rate with respect to patient's age, menopausal status, ethnic group or histology of tumor. Univariate analysis showed size of tumor ( $p=0.005$ ), surgeon's subspecialty ( $p=0.02$ ) and year of operation ( $p<0.001$ ) as factors affecting BCS. To avoid possible bias, patients with absolute contraindications to BCS are excluded from the analysis and the result shows surgeon's subspecialty and year of operation remaining as independent factors ( $p=0.003$  and  $p<0.001$ ) affecting BCS rates.

**Conclusion:** Our study found that surgeon's subspecialty training plays an important role in increasing the rate of BCS in eligible patients with early breast cancer.