been the focus of a PSA campaign in 2008. ED has written a "Short Guide to the EU Guidelines" and translated it into 8 different languages to provide a key tool for advocates to promote these concepts on a national level. This effort has been supported by the European Commission. In addition ED continues to be active at the European Parliament to press for countries to implement these services. While there are 2 resolutions on breast cancer already in existence, it is essential to keep Guideline implementation on the public health agenda. ED provided input into the Declaration on breast cancer that was launched in December 2009. In addition the development of a certification programme for specialist breast units is proposed within the new cancer partnership and ED will work toward this in 2010. ED continues to add members from countries where services described in the EU Guidelines are not well known or available, so the challenge of educating advocates and health professionals concerning them is on-going. In September 2010 the European Commission has provided us with a grant to further educate our national leaders on these guidelines so that they can better advocate for these services in their countries. Nonetheless current surveys and research indicate there is still much to do before implementation is carried out in many countries.

Friday, 26 March 2010 18:15–19:15

POSTER SESSION

Locally advanced and metastatic disease

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Assessment of quality of life (QoL) in contemporary phase III trials in advanced breast cancer (ABC): is it worthwhile?

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Background: QoL parameters are often used as endpoints in phase III trials of systemic therapy for ABC. However, the extent to which this has been done in recent studies, as well as the frequency and correlates of significant gains in QoL, have not been assessed systematically.

Methods: We used the medical subject headings "breast neoplasms" and "drug therapy" to search PubMed for the main paper reporting phase III trials on system icantineoplastic therapies published between January 1, 1998, and July 15, 2009 in 11 leading medical journals (*Ann Oncol*, *BCRT*, *Br J Cancer*, *Cancer*, *Clin Cancer Res*, *Eur J Cancer*, *JCO*, *JNCI*, *Lancet Oncol*, *Lancet* and *NEJM*). We also searched for companion papers reporting on QOL separately. We excluded studies on high-dose chemotherapy, papers reporting combined analyses of two or more trials, and companion studies on correlative biology or prognostic factors.

Results: The search yielded 86 trials that enrolled a total of 33,669 evaluable patients in 192 trial arms, 2 of these arms with placebo/best supportive care alone (maintenance trials). QoL was mentioned/reported in the main paper in 34 trials, reported in a companion paper in 1 (a total of 35/86=41%), and mentioned in the abstract of the main paper in 19/34 cases (56%). The most common instrument used for QoL assessmentwas QLQ C-30. There was no temporal trend for reporting of QoL in the two 6-year periods ($P = 0.89$). Although formal statistical comparisons were reported in 31/35 cases (89%), a significant difference was found in only 4/31 (13%) trials, in all cases favoring the experimental arm (3 chemotherapy, 1 hormone therapy trial). Given the small number of studies with a significant QoL finding, we did not assess correlates for gain in QoL.

Conclusion: QoL has been assessed formally in nearly 40% of contemporary phase III trials in ABC. Although statistical analyses were performed in the vast majorityof those cases, a significant gain in QoL has been rare. QoL is one ofthe key indicators of treatment benefit for regulatory agencies, but contemporary systemic therapies for ABC do not appear to affect QoL differentially.

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A Belgian multicenter phase II randomized trial in HER2-negative metastatic breast cancer evaluating consolidation antiangiogenic therapy with sunitinib after objective response to taxane-based chemotherapy

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Background: We tested the hypothesis that antiangiogenic treatment with sunitinib is able to delay breast cancer progression after tumor mass reduction (objective response) induced by taxane-based chemotherapy, and describe adverse events and dose reductions.

Patients and Methods: This is a dual-arm open-label randomized multicenter phase II clinical trial with 2:1 randomization evaluating the efficacy of sunitinib (study arm A) versus no therapy (control arm B, only for descriptive purposes) in patients with metastatic breast cancer after objective response (PR or CR) to taxane-based chemotherapy. Eligible patients had metastatic HER2-negative breast cancer and objective response after 10−20 weeks of first- or second line taxane-containing chemotherapy. The primary endpoint was the proportion of patients alive and without disease progression (PFS) at 5 months after study entry in arm A. If $\leqslant$18/36 patients are progression-free and alive at 5 months, sunitinib will be declared insufficiently active (beta 0.05); if $\geqslant$22 patients are progression-free and alive at 5 months, sunitinib will be declared active (alpha 0.05) and it will be recommended to continue the trial as a phase III design.

Results: 10/36 patients (28%) reached 5 months PFS in arm A and 4/19 in arm B (21%). Median PFS was 2.8 months in Arm A and 3.1 months in Arm B. The outcome in arm A was far below the predefined threshold for moving into phase III. Because 53% (17/32) required dose reduction at a starting dose of 50 mg (4w on/2w off), the protocol was amended for a starting dose of 37.5 mg continuously, which resulted in 44% (7/16) dose reduction requirement. Most measured toxicities (all grades) were more common in arm A. Grade III-IV toxicity occurred in 69% of patients in arm A (mainly fatigue 31%, musculoskeletal pain 11%, neutropenia and thrombopenia 8%) and 11% in arm B.

Conclusion: This study does not confirm the hypothesis that sunitinib can lead to a clinically relevant and statistically significant proportion of patients with PFS of $\geqslant$5 months after objective response to taxanes. Sunitinib induces adverse events requiring dose reductions in half of the patients. This exploratory study does not support a role of consolidation therapy with sunitinib in this clinical setting.

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Locoregional treatment of inflammatory breast cancer after neoadjuvant chemotherapy

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Background: The aim of this retrospective, mono-centric, study was to assess the benefit of breast surgery for inflammatory breast cancer (IBC).

Material and Methods: From January 1st 1985 and December 31st 1999; out of 13180 patients diagnosed at the Institut Curie with non metastatic breast cancer, 280 (2%) were treated with curative intent for IBC with primary chemotherapy followed by either exclusive radiotherapy (118 patients, 51%) or surgery with or without radiotherapy (114 patients, 49%). Median follow-up of 11 years.

Results: The two groups were comparable apart from a fewer rate of tumors smaller than 70 mm (43% *vs* 33%, $p = 0.003$), a higher rate of clinical stage N2 (15% *vs* 5%, $p = 0.04$) and fewer histopathologic grade 3 tumors (46% *vs* 61%, $p < 0.05$) in the no-surgery group. The addition of surgery was associated with a significant improvement in locoregional disease control ($p = 0.04$). At 5 years locoregional free interval was 79% in the surgery group *vs* 66% in the exclusive radiotherapy group and at 10 years: 78% *vs* 59% respectively. In the univariate analysis, in addition to the absence of surgery ($p = 0.04$), other prognostic factors associated with higher locoregional recurrence rates were: high clinical nodal stage ($p = 0.009$), high histological nodal status ($p = 0.02$) and the