(inter-audit range: 48.5±10.9 to 53.1±11.8 years). Patients were post-menopausal in 51% of cases and 64% were hormone receptor positive. The diagnostic spread was stage I 18%, II 63%, III 15% and IV 4%. Concomitant radiotherapy was reported in 35%. Fifty-seven percent received CMF-based regimens, 39% anthracycline-containing, and 4% other regimens. Use of colony-stimulating factors (CSF) was reported in 13% (inter-audit range: 1–18%). NE were observed in 20% of patients (inter-audit range: 15–27%). Repeated NE were seen in 8% (inter-audit range 6–11%). Neutropenia-related hospitalisations, dose reductions, and dose delays were seen in 4%, 6% and 13%. Mean ARDI ± SD was 96±8% vs 87±11% in patients without and with NE ($p<0.005$). ARDI * 85% was observed in 10% vs 35% of patients without and with NE ($p<0.005$; OR 5.0, 95% CI 4.0–6.4; multivariate adjusted OR 4.8, CI 3.8–6.0). NE were independently associated with postmenopausal status (OR 1.2. CI 1.0–1.5); use of a non-anthracycline-containing regimen (OR 1.3, CI 1.1–1.6; unadjusted association not uniform across studies); number of CT cycles planned (OR 1.2 per additional cycle, CI 1.2–1.3); and concomitant radiotherapy (OR 1.5, CI 1.2–1.9). NE from cycle 2 onwards were additionally associated with cycle 1 NE (OR 10.4, CI 5.0–21.6); negative hormone receptor status (OR 1.4, CI 1.0–2.0); and higher disease stage (OR 1.2 per stage, CI 1.0–1.3); but not with menopausal status. A risk score based on menopausal status, number of CT cycles planned, and concomitant radiotherapy administration appears to differentiate patient groups with increasing NE risk (10–27%) as shown in Figure 1.

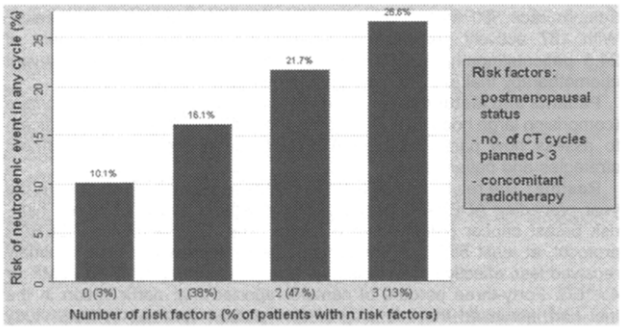

Fig. 1. Risk of neutropenic event by risk score. The more risk factors that are present the higher the incidence of observed neutropenic events in breast cancer patients receiving chemotherapy.

Conclusions: NE occur in a relevant proportion of patients receiving breast cancer CT and are associated with low ARDI which may affect treatment outcomes. This data adds to the growing evidence supporting the development of risk models to enable better targeting of preventative measures. Prospective data from ongoing EU and US studies should enable the relationship between risk factors for NE to be more clearly defined.

54 POSTER HIGHLIGHT

Efficacy of adjuvant chemotherapy according to hormone receptor status in young breast cancer patients

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Purpose: breast cancer at a young age is associated with an unfavorable prognosis. Very young breast cancer patients receive chemotherapy irrespective of tumor stage or grade. However, chemotherapy alone may not be adequate adjuvant systemic therapy in hormone receptor positive young breast cancer patients. Therefore we studied the effect of adjuvant chemotherapy in young breast cancer patients in relation to hormone receptor status.

Patients and Methods: paraffin embedded tumor material was collected from 480 early stage breast cancer patients who participated in one of four EORTC trials; 10801, 10854, 10901, 22881. All patients were younger than 41 years at time of diagnosis. Estrogen receptor- and progesterone receptor status were scored by immunohistochemistry using a tissue micro array. Patients were followed up for overall survival and distant disease-free survival; the median follow up period was 7.3 years.

Results: overall, patients with ER-positive tumors had better overall survival rates compared to ER-negative patients (HR 0.63, 95%CI 0.43–0.93, P=0.02). However no significant difference in overall survival (HR 0.87, 95%CI 0.50–1.52, P=0.63) and distant disease-free survival was found between patients with ER positive tumors or ER negative patients in the subgroup that did receive chemotherapy. Patients with ER positive tumors who did not receive adjuvant chemotherapy had better overall survival (HR 0.63, 95%CI 0.43–0.93, P=0.02) rates than ER negative patients. Outcome results were similar for PgR status.

Discussion: Patients with ER positive tumors benefit less than those with ER negative tumors from adjuvant systemic chemotherapy. Therefore, chemotherapy alone in breast cancer patients aged 40 years or less with hormone receptor positive tumors is sub optimal adjuvant systemic treatment. The addition of adjuvant hormonal treatment with or without endocrine ovarian suppression may result in improved survival.

55 POSTER HIGHLIGHT

Hormone adjuvant strategies in breast cancer (BC) patients (pts): results from the National Oncological Research observatory on Adjuvant therapy (NORA)

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NORA is a national observatory aimed at investigating adjuvant therapeutic modalities and relapse pattern in patients (pts) with breast cancer (BC), radically treated with surgery in 77 Italian Oncological Centres (OCs). About 3500 BC pts will be enrolled consecutively, according to the following criteria: 10 pts each year starting from 2000 (retrospective cohort) and 20 pts starting from the beginning of 2003 or the date of ethical approval, if subsequent (prospective cohort). Until now, data about 1662 pts are available. Median age was 58.6 years (28–92). Most of the pts were menopausal (73.7%). More than half of the pts underwent breast conservative surgery (63.1%), were T1 (60.1%) or T2 (34%) and node +ve (44.7%). Estrogen receptor (ER) status was positive in 1284 pts (79.6%). The majority of the pts received a medical therapy (97.5%), with (59.3%) or without radiotherapy (RXT). Data about hormone therapy (HT) choice and the principal reasons leading to it are presented. Irrespective to RXT, HT was administered alone (540/1621, 33.5%), or as a part of a combination program: chemotherapy (CHT) followed by HT: 671, 41.4%; concomitant CHT and HT: 73, 4.5%. Tamoxifen was administered in 1004 out of 1662 pts (62.8%), as HT alone (475, 45.5%) or sequential to CHT (569, 54.4%). Aromatase inhibitors (AI) represented the treatment of choice in 112 pts (6.9%), alone (52/112, 46.4%) or after CHT (53.6%). HT was chosen in 821 ER+ pts (63.9%) as single modality, or together with CHT (714, 55.6%). We asked investigators to indicate the three main reasons for choosing hormone therapy, both as the only therapy or combined with CHT: biological tumour data (80.5%), standard guide lines (70.2%) and tumour stage (52.9%) were referred as the principal criteria. In conclusion, tamoxifen is still the wide used HT, mainly as a part of combination program togheter with CHT. AI have been used in a small percentage of pts. NORA results provide useful information about adjuvant strategies in BC pts, allowing us to better understand factors involved in our choice.

56 POSTER HIGHLIGHT

Cost-effectiveness of anastrozole vs tamoxifen as adjuvant therapy in postmenopausal women with early breast cancer: a UK National Health Service perspective

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Background: Results from the ATAC trial (Lancet 2002; 359:2131–9), at a median follow-up of 33 months, indicated that anastrozole (n=3125) was superior to tamoxifen (n=3116) in terms of disease-free survival in the adjuvant treatment of postmenopausal women with hormone receptor-positive (HR+) early breast cancer. Updated data (median follow-up 47.2 months for efficacy and 37 months for safety) confirmed these findings (Cancer 2003; 98:1802–10). Using the updated data, the direct medical costs and incremental cost-effectiveness ratio (ICER) per life year gained (LYG) for managing this group were calculated for anastrozole compared to tamoxifen within the UK National Health Service (NHS) setting.

Methods: A probabilistic Markov model was developed using the updated ATAC data. The model projected outcomes for both anastrozole and tamoxifen to 25 years (lifetime horizon) by extrapolating pooled Kaplan-Meier curves using parametric statistical methods. General mortality data were obtained from UK national statistics. It was assumed that anastrozole and tamoxifen would be given for a maximum of 5 years and that recurrence rates after this treatment period would be equivalent in the two groups –a conservative approach. Resource utilisation data associated with treating adverse events pre-specified in the ATAC study were obtained from published literature. Other resource utilisation data were estimated from structured telephone interviews with 6 UK physicians. Unit costs in GBP were obtained from 2002 NHS reference costs and 2003 drug costs (BNF). Costs and benefits were discounted at 6% and 1.5%, respectively. Sensitivity analyses were conducted. The perspective was that of the UK NHS.