Discussion: Interpretation of these results is difficult due to the heterogeneity of this group. Yet, despite the poor prognosis in these patients, many of whom already had multiple lines of treatment for their recurrent breast cancer, the combination of removal of macroscopic tumour, re-irradiation and hyperthermia appears to achieve a good locoregionaal control, at the cost of some severe toxicity.

387 PUBLICATION

Potential health economic benefits of adjuvant (A) trastuzumab (H) therapy of node-positive (N+) her-2+breast cancer (BC)

E. Wilson¹, J. Ballot¹, J. Healy¹, J. Mackey², M. Martin², M. Lindsay², J. Crown¹. ¹St. Vincent's University Hospital, Medical Oncology Department, Dublin, Ireland; ²CIRG, Oncology, Edmonton, Canada

Background: H, an established, effective therapy for patients (pts) with HER-2+metastatic (M) BC, has been reported to reduce the rate of relapse for pts with early stage BC (ESBC) by approximately 50% when combined with adjuvant (A) chemotherapy (CT) (NSABP and INT, HERA: ASCO 2005). There is a perception that AH might have serious negative health economic consequences. We attempted to analyse the potential cost implications of AH, in the context of current use of H in MBC (MH), and of predicted reduction in the risk of relapse.

Material and methods: We conducted a retrospective analysis of the mean per pt cost of AH and MH in St. Vincent's Hospital. All AH pts were treated on BCIRG 006, and received a mean of 27 cycles of AH over one year (12–18 weeks of weekly schedule, with three-weekly to completion of year). Based on published/presented data (BCIRG 001), we assumed a 35% risk for relapse at five years for pts with HER-2+, node+ BC receiving conventional ACT, and a 50% risk reduction (RR) for AH (ASCO 2005 data), providing an absolute benefit of 17.5%. We also costed the following drugs administered in standard A regimens: docetaxel (D-BCIRG 001), paclitaxel (P-CALGB 9344) and, filgrastim (G-CALGB 9741, dose-dense), and noted the following published absolute relapse reductions for these regimens: D-7%, P-5% and G-4%.

Results: We identified 50 and 63 pts who received AH/MH respectively. The following are the mean cost/per pt. for the listed agents in standard A regimens (Euro): AH -34 k, AD-8.8 k, AP-7.4 k, G-9.3 k. The mean cost per pt. for MH was 47 k. The following costs per relapse prevented (CRP) were calculated: AH-194 k (i.e. 3.4 m/17.5); P-(148 k); G-(231 k); D-126 k. In addition, in the absence of retreatment with MH, the incremental cost of AH for 100+ pts. is 1.8 m ($100\% \times 34$ k=3.4 M for AH, minus $35\% \times 47$ k=1.6 M) or 18k/pt. Under this "no-re-treatment with MH" assumption, the cost per relapse prevented (CRP) for AH would equal 102 k.

Conclusions: 1) AH appears to be a relatively cost-efficient means of reducing relapses. 2) The optimal schedule of AH must be determined. 3) The efficacy of MH following prior AH must be determined. 4) It is possible that the impact and cost-efficiency of H will be greater in patients selected for HER-2+ by FISH.

88 PUBLICATION

Tumor characteristic and clinical outcome of elderly women with breast cancer

A. Karanikolic, N. Djordjevic, M. Pesic, D. Budjevac, D. Milic, I. Pesic. Surgical Clinic, General surgery, Nis, Yugoslavia

Background: Breast cancer is major health problem in elderly women. Although the number of elderly patients with breast cancer is increasing, knowledge about possible differences in the biology and clinical outcomes of breast cancer according to age is limited.

Methods: Retrospectively were followed: tumor characteristic and clinical outcome of breast cancer treated women at the Surgical Clinic in Nis between 1990–1995. Patients were divided in two groups: study (\geqslant 65 years) and control group (<65 years).

Results: The study involved 619 women (262 study group; 357 control group). The mean age was 74.3 years, study group, and 49.7 years control group. Ductal carcinoma was the most frequently observed histological type in (70.3% vs. 61.92%). The majority of our patients presented with early-stage disease (69.02% vs.60.20%). Estrogen receptor positive tumors occurred in 67.88% of elderly patients versus 28. 42% of young cases, and negative axillary lymph nodes were observed in 45.78% and 34.40% of patients in the elderly and young group, respectively. Modified radical mastectomy was the treatment of choice for both groups. There is no significant difference in disease-specific survival by age.

Conclusion: In our population the presentation, surgical treatment, and survival from breast cancer is similar in older and younger women.

9 PUBLICATION

Suggestions for follow-up (FU) strategies according to the risk of recurrence in patients with T1N0M0 breast cancer (BC): a single-institution experience

G. Gullo¹, I. Garassino¹, L. Tondulli¹, P. Salvini², G. Masci¹, S. Orefice³, M. Alloisio⁴, M. Eboli³, A. Santoro¹. ³ Istituto Clinico Humanitas, Medical Oncology and Hematology, Rozzano, Italy; ² Cliniche Gavazzeni, Medical Oncology and Hematology, Bergamo, Italy; ³ Istituto Clinico Humanitas, Surgery Department, Rozzano, Italy; ⁴ Istituto Clinico Humanitas, Thoracic Surgery Department, Rozzano, Italy

Background: The risk of recurrence for early stage (T1N0M0) BC after multimodal therapies is not well defined and the FU strategies are still controversial.

Materials and methods: We retrospectively evaluated 214 T1N0M0 BC patients (pts) diagnosed at Istituto Clinico Humanitas/Cliniche Gavazzeni during April 1999-June 2003. Fifty-eight pts(27%) had T1a-b and 156 pts(73%) T1c BC. Pts characteristics(T1a-b/T1c, respectively): premenopausal 26/36%; invasive ductal 71/79%, invasive lobular 4/11%, other histology 25/10%; G1-2 90/80%, G3 10/12%; ER+ 93/88%, PgR+ 86/82%. Most pts were treated with conservative surgery(91/90%) followed by radiotherapy. In T1a-b group 4 pts(7%) received adjuvant chemotherapy vs 63 pts(40%) in T1c. Pts with ER+ and/or PgR+ received adjuvant tamoxifen(TAM) \pm LHRH-analogues according to menopausal status; 8(14%) T1a-b and 43(26%) T1c pts received or switched to aromatase inhibitors due to contraindications or intolerance to TAM.

Results: At a median FU time of 34.7 mos (range 8.6–64.6) we observed 3 recurrences(5%) in T1a-b group:2 relapses in homolateral breast and 1 in chest wall with lung metastasis. In T1c group there were 7 recurrences(4%): 2 local relapses(1%) and 5 (3%) metastatic diffusions in bone (2pts), liver (1pt), supraclavicular lymphnodes (1pt) or other site (1pt). Second tumours in controlateral breast were observed in 1 (2%) T1a-b pt and 6 (4%) T1c pts. All the bone recurrences were diagnosed after bone scan for pain; lymphnode recurrence by ultrasonography(US) and fine needle agobiopsy(FNA) after clinical evidence of lymphoadenopathy; liver recurrence by routine US and confimed by FNA; lung recurrence by routine chest X-ray. All the homolateral relapse and controlateral BC were detected by routine mammography(Mx).

Conclusions: Our data show that T1N0M0 BC has a very low risk of early recurrence after multimodal therapies. At a median FU time of about 3 yrs, no differences in the recurrence rate were found between T1a-b and T1c BC, with a trend (not statistically significant) for higher incidence of distant metastases in T1c group. These observations suggest that in this group of pts early FU strategies should be targeted to detect local relapses more than distant metastases. Medical interview, physical examination, Mx and breast US are strongly recommended but there is not enough evidence to support the routine use of other diagnostic exams without specific clinical indications.

390 PUBLICATION

The implications of delaying the start of aromatase inhibitor (AI) therapy

J. Cuzick. Wolfson Institute of Preventive Medicine, Department of Epidemiology Mathematics and Statist, London, United Kingdom

Background: The introduction of Als has transformed adjuvant hormonal therapy for postmenopausal women with early breast cancer (EBC). However, debate continues as to the optimal Al administration strategy.

Methods: Initial adjuvant trials randomise patients (pts) about to begin adjuvant therapy to tamoxifen (T) or an AI for 5 years. Switching trials randomise pts partway through a 5-year course of adjuvant therapy and compare the relative efficacy of continuing with T or switching to an AI. Extended adjuvant trials enrol pts after completion of 5 years' T and evaluate the efficacy of additional therapy with an AI versus placebo or no treatment. Switching and extended adjuvant trials select pts who have already responded to 2–3 years' or 5 years' T, therefore, pts with an early recurrence will be excluded from such trials. Results from trials using an AI initially versus sequencing will not be available for several years

Results: Modelling indicates that the risk of recurrence and especially the years of life lost to recurrence are always lower over the first 10 years of follow-up when an AI is initiated first. Switching to an AI will reduce the risk of recurrence, compared with continuing on T, but even after 10 years recurrences are more likely than in those who received an AI from the outset. This is particularly apparent in the progesterone receptor (PgR)-negative subgroup, but the results are model dependent for the PgR-positive subgroup. The ATAC trial, a double-blind randomised trial, compared anastrozole with T as initial adjuvant therapy in 6241 postmenopausal women with EBC. Risk: benefit data from ATAC (68 months' median follow-up) show that, compared with T, anastrozole