1267 POSTER DISCUSSION

The role of positron-emission tomography (PET) in the assessment of pathologic response to neoadjuvant chemotherapy with doxorubicin and docetaxel in patients with locally advanced breast cancer

S. Gupta-Burt, E. Marcus, J. Coon, G. Fronda, C. Holden, H. Preisler, A. Ali. *RUSH University, Radiation Oncology, 1653 W. Congress Parkway, Women's Board Cancer Treatment Center, Chicago, IL 60612, United States*

Objective: To evaluate the role of positron-emission tomography (PET) studies with 18F-fluoro-2-deoxy-D glucose (18F-FDG), in assessing the pathologic response to neoadjuvant chemotherapy in patients with locally advanced breast cancer (LABC).

Patients and Methods: Patients with stage IIB (T3N0), IIIA, and IIIB LABC have been enrolled in a prospective trial evaluating neoadjuvant chemotherapy with doxorubicin (50 mg/m^2) and docetaxel (75 mg/m^2) given every 21 days for six cycles, followed by modified radical mastectomy (MRM) and loco-regional radiation therapy. PET scans were obtained before the initiation and at the completion of chemotherapy. Pathologic response was assessed as complete response (pCR) if there was no evidence of residual tumor in the resected specimen. Microscopic residual disease (MRD) was defined as minimal areas of infiltrating carcinoma in not more than 2 high powered fields. Pathologic partial response (pPR) and stable disease (pSD) were defined as greater than 50% and less than 50% reduction, respectively, in the tumor volume as measured clinically prior to therapy.

Results: Since January, 1998, 14 patients have completed chemotherapy and proceeded to surgery. 14/14 (100%) patients had a positive PET scan at diagnosis. 10/14 (71%) patients had a negative post chemotherapy PET scan. 1 patient with a clinical CR refused MRM. This patient's post chemotherapy PET scan was negative. Thirteen patients are evaluable for pathologic response. 6/13 patients had a pCR or MRD, 7/13 patients had pPR or pSD. All patients, 6/6 (100%), with pCR or MRD had a negative post chemotherapy PET scan. 4/7 (57%) patients with pPR or pSD had a positive post chemotherapy PET scan. 6/9 (67%) patients with a negative post chemotherapy PET scan had a pCR or MRD. All patients (4/4) with a positive post chemotherapy PET scan had significant residual disease.

Conclusions: This preliminary analysis indicates that PET scans may be of clinical value in the diagnosis and assessment of chemotherapy response in patients with locally advanced breast cancer.

This study was supported by the Bears Care Fund, Brian Piccolo Cancer Research Fund and Rhone-Poulenc-Rorer.

1268 POSTER DISCUSSION

Herceptin (R) is active as a single agent in women with metastatic breast cancer overexpressing HER2

M. Cobleigh[1]. [1]*Rush-Presbyterian-St. Luke's Medical Center, Medical Oncology, Chicago, Illinois, United States*

Purpose: To determine the efficacy and safety of Herceptin (trastuzumab) as a single agent in women with relapsed metastatic breast cancer overexpressing HER2.

Methods: 222 women, mean age 50 years, were enrolled. Previous treatment included adjuvant chemotherapy (69%), one or two chemotherapy regimens for metastatic disease (32% and 68%) and high-dose chemotherapy (9%). The median disease-free interval was 17 months. Patients received a loading dose of iv Herceptin 4 mg/kg followed by a weekly dose of 2 mg/kg.

Results: Responses were confirmed by an independent Response Evaluation Committee. The overall response rate (intent to treat) was 15%: 8 CRs, 26 PRs. Most of the CRs were seen many months after the first PR. The median duration of response was 9.1 months (range 1.6–26+ months). The median time to progression was 3.1 months (0–28+ months); median survival was 13 months (range 0.5–30+ months). Two patients discontinued treatment because of adverse events. Cardiac ejection fraction was reduced in 9 patients of whom 6 were symptomatic; all had either received previous anthracycline treatment or had a significant cardiac history at entry. One woman died of a ventricular arrhythmia.

Conclusion: Herceptin is active as a single agent in women with metastatic breast cancer overexpressing HER2.

1269 POSTER

Does psychotherapeutic intervention effect survival in metastatic breast cancer? An oberservational study from the Macmillan Cancer Unit in Lancaster, United Kingdom

M.B. McIllmurray[1], S. Ruel[1], A. Al-Hamad[2]. [1]*Department of Medical Oncology, Royal Lancaster Infirmary;* [2]*University of Lancaster, United Kingdom*

Background: Patents with cancer in North Lancashire and South Cumbria, U.K. are offered psychological support (PS) and relaxation therapy (RT) alongside conventional medical treatment. Survival data for women with metastatic breast cancer (MBC) has been analysed. The survival of women who accepted PS and/or RT is compared with the survival of those who declined it.

Results: 148 women were treated for MBC between 1995 and 1998 in the Macmillan Cancer Unit in Lancaster, U.K.. 57 women had 6 or more psychotherapeutic sessions after presentation and their median survival was significantly longer than the 91 women who had no psychotherapeutic intervention (8.8 months and 22 months respectively: $p = < 0.001$). The two groups were similar in age but there were more women with visceral disease in the intervention groups (61% v 52%) and more women were treated with chemotherapy (88% v 55%). The disease-free interval from primary treatment to relapse was greater in the intervention group. These factors may not explain the observed difference in survival and a randomised controlled trial of psychotherapeutic intervention is suggested.

1270 POSTER

Hormonal therapy in breast cancer and predominant visceral disease: Effectiveness of the new oral aromatase inactivator, Aromasin® (exemestane), in advanced breast cancer patients having progressed on antiestrogens

M. Tedeschi[1], S. Kvinnsland[2], S.E. Jones[3], M. Kaufmann[4], A. Polli[1], C. Fowst[1], G. Massimini[1]. [1]*Pharmacia & Upjohn, Milan, Italy;* [2]*The Radium Hospital, Montebello, Oslo, Norway;* [3]*PRN Research, Baylor University Medical Center, Dallas, TX, United States;* [4]*Goethe University, Frankfurt, Germany*

The presence of visceral disease still represents a major challenge in the treatment of advanced breast cancer, and is usually an indication for treatment with cytotoxic chemotherapy. Exemestane (Aromasin®) is a novel oral aromatase inactivator that has been demonstrated effective and well tolerated in postmenopausal advanced breast cancer patients. We report here an explanatory analysis on the efficacy of exemestane in a subset of postmenopausal patients with predominant visceral disease having progressed on antiestrogens. One lesion in one visceral organ qualified a Patient as having predominant visceral disease. Deep nodes were considered as visceral disease. A total of 626 patients received exemestane in two open phase II studies and one randomized, peerreviewed, phase III study; 337 of them had at least one visceral site involved. The overall response rate in the 130 patients enrolled in the phase II studies was 29.2% (95% C.I. 21.3–37.1) and 13.5% (95% C.I. 8.8–18.2) in the 207 patients enrolled in the exemestane arm of the phase III study. The response rate in patients with predominant visceral disease in the phase III study control arm (megestrol acetate) was 10.5% (95% C.I. 6.6–14.1). An analysis by selected disease sites (lung and liver) indicates that a total of 27/65 measurable lung lesions (42%, 95% C.I. 29.45-4.4) responded to exemestane treatment in the phase II program, as well as 8/55 measurable liver lesions (14%, 95% C.I. 6.5–26.7). In the phase III program the corresponding figures were 25% (95% C.I. 15.8–36.3) for lung and 19% (95% C.I. 11.0–29.4) for liver lesions with exemestane, while with the control treatment (megestrol acetate) the corresponding figures were 17% (95% C.I. 11.0–29.4) and 11% (95% C.I. 5.4–18.3). Of notice, the 1-year survival difference between the two arms in the phase III study is similar in patients with predominant visceral disease and in the overall population (6% and 7%, respectively, in favour of exemestane).

In conclusion, exemestane is active in patients with predominant visceral disease. Based also on these results, combination trials with chemotherapy are under way.