Proffered Papers

for the utilization of FDG-PET in the follow-up of the BC patients with complete remission.

Aim: our retrospective study assessed the value of FDG-PET for the diagnosis of breast cancer recurrence in asymptomatic patients with elevated CA 15-3 and negative conventional imaging.

Material and method: Between October 2003 and February 2005, 31 women followed in our institution for BC with CA 15-3 levels above cutoff value of 30 U/ml were explored for suspected recurrence. Median age was 45 years (31-67). Histological characteristics of the initial tumor was: infiltrating ductal carcinoma in 24 cases and infiltrating lobular carcinoma in 7 cases. All the patients were in complete remission of their BC. Conventional imaging included chest radiography, liver ultrasonography, breast ultrasonography, mammography, bone scintigraphy and in some cases computer tomography and/or magnetic resonance imaging.

FDG scintigraphy was performed with a PET-CT Philips Gemini camera one hour after injection of 5 MBq/kg of [18F] FDG.

Results: Among 31 patients, the diagnosis of recurrent BC was established with conventional imaging in 21 patients: bone metastases (9 pts) detected by bone scintigraphy, liver metastases (5 pts) detected by hepatic ultrasonography, local relapse (1 pt) detected by mammography and multifocal metastases (6 pts).

FDG-scintigraphy was performed in the others 10 patients and it was positive in all cases:

In 3 patients with positive conventional imaging (bone in 2 pts and liver in 1 pt) new metastasis sites was found (lung, liver and hypodermic)

In 7 patients with negative conventional imaging, FDG found: bone metastasis (2 pts), liver metastasis and axillary nodes (1 pt), lung metastasis (1 pt), peritoneal carcinosis (1 pt), mediastinal nodes (1 pt) and multifocal metastasis (1 pt).

Conclusion: These results confirm that FDG-PET is useful for the detection of recurrent BC in patients with elevated tumor marker and negative conventional imaging.

The survival impact of early diagnostic of metastasic disease remain unclear and needs prospective randomized trials for evaluation.

Leaving from these data, a prospective study was started in our institution.

420 POSTER

Neoadjuvant chemotherapy followed by external beam radiotherapy and high dose rate brachytherapy for local disease control in locally advanced and metastatic breast cancer

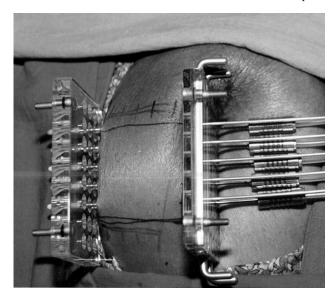
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Background: Radiation plays critical role in the multidisciplinary treatment of patients with advanced breast cancer. Radiation in locally advanced breast cancer is generally given either in breast conserving treatments for women who have achieved a favorable response to neoadjuvant chemotherapy or after mastectomy and adjuvant chemotherapy. We investigate efficacy and safety of radiation, external beam radiotherapy and high dose rate brachytherapy, without surgery following neoadjuvant chemotherapy, in local disease control, cosmesis and survival in locally advanced and metastatic breast cancer.

Material and method: The present study conducted at Acharya Tulsi Regional Cancer Treatment & Research Institute, Bikaner (Rajasthan) INDIA from October 1999 to December 2004 In this study we included 100 cases of female breast cancer who presented in advanced stage either locally or metastatic. All patients received neoadjuvant chemotherapy followed by external beam radiotherapy and then interstitial HDR application to achieve local disease control. Chemotherapy was given in the combination of 5 FU, Adriamycin and cyclophosphamide for 6 cycles at 21 day interval followed by External Beam Radiation Therapy (EBRT) 4400–4600 cGy/22–23 Fraction/5 days a week. This was followed by a gap of 20 days and then multi planner interstitial HDR was applied to give a dose of 300 cGy twice a day for 5 days. Linear Quadratic Model was used to arrive at biologically equivalent dose values (BED Value) for EBRT+HDR. The BED for EBRT after a gap of 20 days is 36 Gy while BED for HDR is 30 Gy. Thus total dose given to primary tumor is 75 Gy.

Results: The total control of primary tumor and axillary lymph nodes was observed in 12% and 17% respectively after 6 cycles of chemotherapy, 55% and 66% at end of EBRT and 72% cases after HDR application at primary site. This control was maintained in 63% at primary site and 60% in the axilla by end of 2 years.

Conclusion: Achieving local control improves the quality of life of patients, they are physically and psychologically more comfortable. No significant fibrosis was seen in breast as locally high dose given to tumor area only. This protocol is cost effective, can be given on outdoor basis, and avoids surgery therefore can easily be applied in elderly and medically unfit patients.



421 POSTER

A Phase I/II study of capecitabine (X) combined with oral vinorelbine (N) as first- or second-line chemotherapy in patients (pts)

with locally advanced or metastatic breast cancer (MBC)

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Background: The oral fluoropyrimidine X is highly effective and well tolerated in pts with MBC. Adding X to docetaxel improves survival, time to disease progression and response compared with docetaxel alone. When administered intravenously (i.v.) N is also an effective agent in MBC. The combination of X and i.v. N has been shown to be effective in Phase I/II studies with response rates of 48–61% and an good safety profile. Few overlapping toxicities between X and oral N make this an attractive new combination.

Materials and methods: To evaluate this all-oral combination, we conducted a multicentre Phase I/II study of X plus oral N in pts with MBC to determine the maximum tolerated doses (MTD), recommended doses, safety profile and efficacy. Eligibility criteria were stage III/IV BC, age >18 years, ECOG PS <2, \geqslant 12 months since the end of adjuvant or neoadjuvant chemotherapy, HER2 negative or unknown and adequate major organ function.

Results: We enrolled 61 pts: 75% received first-line XN and 25% received XN as second-line therapy. Baseline characteristics were: median age 57.2 years (range 39–81); stage III/IV disease (0/100%); sites of metastases: liver (n = 31), lung (n = 24), lymph nodes (n = 24), bone (n = 23), breast (n = 8), skin (n = 4), pleural effusion (n = 7). 15 pts had > 2 metastatic sites. DLTs determining the MTD were Febrile Neutropenia and grade 3 Mucitis. The recommended doses are: X = 1250 mg/m² twice daily and N = 60 mg/m². 33 pts received the treatment at the recommended dose. Efficacy findings were: 1 complete response (CR, 2%), 20 partial responses (PR, 43%), 16 pts with stable disease (ST, 35%), 9 pts with progressive disease (PD, 20%) and 15 not known. Most common adverse events were grade 3/4 neutropenia (11%) and grade 2/3 hand–foot syndrome (8%). Mature results will be presented during the meeting.

Conclusion: the all-oral combination of X and N is feasible and well tolerated. The recommended doses from this study are: $X = 1250 \text{ mg/m}^2$ bid d1-d14 and N = 60 mg/m² d1 and d8 q3w. This combination appears highly active and enrolment continues to confirm the response rate and to evaluate disease-free survival.