

mandatory in MBC patients to improve their QoL, and will result in maintaining performance status and continuing chemotherapy.

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Patterns of Care and Outcome of Locally Advanced Breast Cancer

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Background: Locally advanced breast cancer (LABC) comprise 5–10% of breast cancer cases. We present a review of practice patterns and outcomes in patients with LABC treated at our institution.

Patients and Methods: We reviewed 120 consecutive patient file records treated at our institution for LABC between 1998 and 2007. Patient and disease characteristics, treatment-related data and patterns of relapse were collected.

Results: Patients' median age was 49 years (range: 28–84 years). Median tumor size at diagnosis was 7cm (range 1–11 cm). Histology showed invasive duct carcinoma in 68% and invasive lobular carcinoma in 9.3% of patients. Estrogen receptors were positive in 67% and progesterone receptors were positive in 58% of the patients. In 31% HER2/new was over-expressed and 13% of the patients were triple negative. Nineteen patients (6.3%) underwent sentinel lymph node biopsy at diagnosis. Eighty-five percent of the patients received preoperative chemotherapy (CT) and 15% received hormone therapy (11% aromatase inhibitors and 4% tamoxifen). Primary CT was anthracycline-based in 37% and anthracycline followed by taxanes in 48% of the patients. Fourteen percent of the patients received Trastuzumab before surgery.

Type of surgery: 39% of the patients underwent lumpectomy, 56% had unilateral mastectomy and 3% preferred bilateral mastectomy. Tumor size was reduced to a median of 1cm (range: 0–10 cm).

Post-treatment pathological findings: 15% of patients showed no residual tumor (pathological complete response) and 42% had negative axillary lymph nodes. All patients received adjuvant radiotherapy and patients with hormone receptors positive received adjuvant hormonal therapy. At a median follow-up of 4 years (range: 1–13), 67% of the patients had no evidence of disease, 10% developed local recurrence, 31% developed distant metastasis, 2% developed secondary breast cancer and 7% developed secondary non-breast malignancy. Median survival time was 11 years (range: 8–10 years) with 5-year survival rates of 76%.

Conclusions: Management of LABC at our institution is consistent with the current clinical guidelines. In our patients, local recurrence rate was low (10%) and 31% of patients developed distant metastasis. In order to improve the LABC patients' outcome, it is mandatory to increase population awareness to early tumor detection and to optimize systemic treatment strategies according to histological subtypes.

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Oral Vinorelbine (VNR) and Capecitabine (CAP) – an Acceptable and Effective Combination Chemotherapy for Early Metastatic Breast Cancer (MBC)

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Background: Most guidelines recommended a sequential single agent approach for MBC because of toxicity with combinations. At our centre practice is divided between doctors, providing an opportunity to compare approaches. First line taxane-capecitabine is used, but severe toxicity limits its use to fit patients. The combination of oral vinorelbine (VNR) and capecitabine (CAP) has demonstrated additive efficacy with good tolerability, providing a combination option for patients not prescribed the taxane combination due to poor performance status (PS) or patient preference. We compared toxicity and efficacy of this combination with the same agents used sequentially.

Methods: An observation study of patients with MBC treated with 1st/2nd line oral VNR and CAP combined as a doublet or given sequentially. Combination dose: VNR 60–80 mg/m² day 1, 8 q21 plus CAP 1000 mg/m² bd days 1–14, q21 for a maximum of 9 cycles; sequential dose: CAP 1250 mg/m² bd d1–14, q21, VNR 60–80 mg/m² day 1, 8 q21, both given until disease progression. Patients were reviewed every 3 weeks and outcome and toxicity recorded.

Results: Between Oct07 and Jan11 33 patients whose PS or preference precluded a taxane doublet received the doublet. Outcomes were compared with 30 patients who received the agents sequentially. Doublet/singlet mean age 59/57.5 yrs and median PS 2/1. Most treatment was 1st line metastatic (64%/83%). Two patients unfit for FEC received the doublet adjuvantly. Median cycles: doublet 4.5/CAP 6/VNR 5; dose delays doublet 23%/CAP 10%/VNR 20%. Severe (G3/4) toxicity was generally less frequent with the combination than either single agent. G3/4 toxicity, doublet/CAP/VNR: haematological 11%/4%/29% (no neutropenic

sepsis); gastrointestinal 0%/8%/4%; dermatological 0%/13%/0%; other non-haematological 0%/0%/13%. One patient stopped treatment due to erythema multi-forme (EM) and one due to palmar-plantar erythrodysesthesia (PPE). PFS (n = 16): doublet 6 m (range 0–31 m); CAP-VNR (n = 11) 7 m (range 3–29 m), VNR-CAP (n = 2) 17 m. Response rate for doublet: 50%. No response data available for single agent.

Conclusions: All-oral combination of VNR and CAP demonstrates effectiveness and good tolerability with minimal severe toxicity. G3/4 haematological toxicity and G3 PPE were less frequent with the doublet than with single agent VNR and CAP. The low incidence of PPE has been noted in previous phase II studies. Most patients find the combination acceptable, even those with poor PS. Our findings warrant further investigation in a randomised study to challenge the standard premise of sequential single agent therapy in MBC.

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Does 'PDO' Deserve T4b Status in Early Breast Cancer?

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Background: Clinically apparent skin involvement (T4b) in breast cancer is a morphological criterion for staging patients in the highest non metastatic stage (stage III B) irrespective of tumor size. This heterogeneous group shows inconsistency as a prognostic variable and hence results in a non-homogenous grouping of patients with different outcomes.

Material and Methods: A retrospective analysis of prospectively maintained computerized breast cancer database in Department of Surgical Oncology, AIIMS, New Delhi was carried out from 1995–2008. Inclusion criteria for the current study were tumor size less than 5cm (T1/T2) and pathological nodal involvement less than 4 nodes (pN1). Patients who received Neoadjuvant Chemotherapy were excluded from analysis. The study group was patients with T1/T2 tumors with clinical skin involvement (Ulcer, PDO), pN1 stage taken for upfront surgery. The control group was T1T2 patients without clinical skin involvement.

Result: Total 71 patients with PDO were compared with 695 early breast cancer patients in the control group. The distribution of age, tumor size, nodal burden and Hormone receptor positivity, and adjuvant therapy was comparable in both groups. There was no statistically significant difference in recurrence rates, disease free survival, and overall survival in patients with or without PDO in the two groups.

Conclusion: Presence of PDO does not impact survival in patients with small tumors and limited nodal disease. Patients with ulcer have significantly poor outcomes. Using PDO to classify breast cancer patients with small tumors as stage III B results in a heterogeneous grouping of patients with different survival outcomes.

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Bone Marrow Micrometastases in Breast Cancer. Changes in Hematologic Parameters

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Background: Bone marrow plays the key role in distant metastases formation and at the same time has no clinical symptoms. The purpose of the study was to define a complex of changes in hematologic parameters, associated with bone marrow micrometastases (BMMM) in breast cancer (BC) patients.

Material and Methods: Fifty patients with breast cancer treated in the Ulyanovsk regional oncology center were recruited into the trial. 37 patients (74%) had distant metastases, other 13 (26%) – locally-advanced disease. Bone marrow was obtained by biopsy from both anterior iliac crests under local anesthesia and was studied by cytological, histological and immunocytochemical (ICC) methods. The analyses was made using monoclonal antibodies against cytokeratins PAN, clone MNF 116, DAKO. Positive test was defined as detection of 1 metastatic cell per million myelokaryocytes. In ICC-positive cases we also determined tumor cell receptor status and proliferative activity with Ki-67.

Results: Nineteen (38%) of the 50 BC patients presented with BMM. The bone marrow involvement was detected more frequently (12/19) by ICC. Combinations of diagnostic techniques failed to improve detection of BMMM. Of the 12 cases with bone BMMM detected by ICC all had receptor-negative tumor cells and low Ki-67 expression. Bone metastases were discovered in half of patients free from bone marrow involvement. 26.7% of patients with non-skeletal metastases were bone marrow-positive.