

positive or high-risk ($T \geq 2$ cm). Following the completion of 6 cycles Doc chemotherapy, all patients received 4 cycles Epirubicin 80 mg/m^2 and Cyclophosphamide 600 mg/m^2 every 3 weeks. The starting dose of Doc was 45 mg/m^2 , and dose was escalated in increments of 5 mg/m^2 until MTD was reached. Patients were treated in cohorts of three to six per group by using a standard phase I study design. If none of three patients had dose limiting toxicity (DLT) during cycle 1 to 3, Doc dose was escalated to next level. If one or two of three patients had DLT during cycle 1 to 3, then three additional patients were treated at the same dose level. The MTD was considered dose level of three of three patients or more than three of six patients had DLT during cycle 1 to 3. Toxicity was evaluated by NCI-CTC ver2. DLT was defined as febrile neutropenia (fever $\geq 38^\circ\text{C}$ and grade 3 to 4 neutropenia), grade 4 neutropenia, grade 3 to 4 thrombocytopenia, grade 3 to 4 nonhematologic toxicity (except nausea, vomiting, fatigue, and anorexia), or administration interval more than 3 weeks.

Results: DLT was not reached until Doc 65 mg/m^2 level. However, three DLTs were observed to five patients on 70 mg/m^2 level, and MTD of biweekly Doc was 65 mg/m^2 .

Conclusions: Doc 65 mg/m^2 was selected as the phase II recommended dose. We plan a phase II clinical study of sequential administration of biweekly Doc followed by EC chemotherapy as preoperative chemotherapy in high-risk breast cancer patients.

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PUBLICATION

Sentinel node biopsy and axillary node sampling in women with breast cancer undergoing breast conserving surgery. Preliminary results of a prospective study

F. Lumachi¹, P. Burelli², F. Marino³, U. Basso⁴, A. Roma⁴, A.A. Brandes⁴.

¹University of Padua, School of Medicine, Endocrine Surgery Unit, Department of Surgical & G, Padua, Italy; ²Azienda Ospedaliera, Unità Operativa di Chirurgia, Conegliano (TV), Italy; ³University of Padua, School of Medicine, Department of Pathology, Padua, Italy; ⁴Azienda Ospedaliera, Division of Medical Oncology, Padua, Italy

Background: Axillary dissection still represents the most accurate means of determining axillary lymph node status in patients with breast cancer (BC), but at the expense of significant morbidity. However, sentinel node biopsy (SNB) technique does not reach 100% sensitivity in detecting (or excluding) axillary node metastases, especially in the presence of unsuspected micrometastases. The aim of this study was to assess the accuracy of axillary node sampling (ALNS) in addition to SNB in patients with BC undergoing curative surgery.

Patients and methods: Sixty-seven consecutive women (median age 54 years, range 28–68 years) with pT1 primary BC undergoing breast conserving surgery were enrolled in the study. Patients were prospectively randomized to undergo SNB alone (Group A, 35 patients) or ALNS in addition to SNB (Group B, 32 patients), followed by level I-II axillary dissection. In all cases, a combined method using radioisotope and blue dye was used for SNB. Patients with positive SNB were excluded.

Results: The age of the patients (54.8 ± 8.2 vs. 54.1 ± 9.2 , $p = 0.74$) and the number of the removed nodes (median 19, range 16–25 in each Group) did not differ significantly ($p = \text{NS}$) between Groups. A median of 7 lymph nodes (range 6–9) was removed in Group B patients. In all patients intraoperative frozen section examination did not show positive nodes, whilst final histopathology showed micrometastases in six (8.9%) patients. The sensitivity of SNB technique alone (false-negative rate: 14.3%) and SNB in addition to ALNS (false-negative rate: 3.1%) was 85.7% and 96.9%, respectively.

Conclusions: SNB alone is inaccurate in detecting axillary node micrometastases, and ALNS should be performed in all patients with macroscopically suspicious nodes and negative SNB.

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PUBLICATION

Concomitant weekly tumour bed boost with whole breast irradiation in patients with locally advanced breast cancer undergoing breast conservation therapy: a prospective study

R. Jalali¹, R. Malde¹, R. Sarin¹, A. Budrukkar¹, R. Badwe². ¹Tata Memorial Hospital, Radiation Oncology, Mumbai, India; ²Tata Memorial Hospital, Surgical Oncology, Mumbai, India

Aim: To evaluate prospectively the feasibility of concomitant weekly tumour bed electron boost along with whole breast radiotherapy following breast-conserving therapy (BCT) in patients with locally advanced breast cancer (LABC) with the aim of reducing treatment duration by 1 week.

Methods: Thirty patients with LABC suitable for BCT following neoadjuvant chemotherapy were eligible for the study. Conventional bilateral tangential photon fields to the whole breast and a direct supraclavicular field was delivered every day from Monday to Friday for 25 fractions to a dose of

50 Gy. In addition, an electron boost to the tumour bed was delivered every Saturday, delivering 5 such weekly fractions to a boost dose of 12.5 Gy. During radiotherapy (RT), patients were evaluated every week and skin reactions recorded as per CTC criteria. Cosmesis was recorded as per 4 point EORTC breast cosmetic score by two clinicians independently blinded to each other before RT and at 6 month follow up. This prospective cohort of 30 patients (Concomitant Boost [CB group]) was compared to a similar cohort of 32 patients treated conventionally with tumour bed boost of 15 Gy/6# given after the completion of whole breast irradiation (Conventional Radiotherapy [CRT group]).

Results: Chemotherapy achieved a complete clinical response in 25 (40%) patients, partial response in 33 (53%) patients and pathological complete response in 12 (19%) patients. Median interval between lumpectomy and the start of RT was 87 days (range, 31 to 163 days). All patients completed RT as planned. No patient in either group developed Grade IV skin toxicity. At conclusion of RT, in the CB group, one patient (3.3%) developed confluent moist desquamation (Grade III) in the tumour bed region and 3 (10%) developed this outside the tumour bed region. In the CRT group, 2 and 4 patients (6.3%) developed moist desquamation in and outside the tumour bed region respectively. The median duration of radiation was 35 days (range, 32–40 days) in CB group patients and 45 days (range, 41–55 days) in CRT group patients. Although the cosmetic outcome was significantly worse at 6 month post RT as compared to baseline pre RT evaluation in some domains (skin colour, $p = 0.001$, location and shape of nipple, $p = 0.004$), it was not significantly different in the two groups.

Conclusion: Concomitant tumour bed boost along with whole breast RT appears to be safe and feasible in a select group of patients. Moreover it can be completed earlier by a median of 10 days than conventional practice, which can have favourable human and machine resource implications.

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PUBLICATION

Toremifen is a more desirable component of standard treatment of breast cancer than Tamoxifen

V. Tarutinov. Institute for Experimental Pathology, Oncology and Radiobiology named after R.E. Kavetsky, Kyiv, Ukraine

Background: Estrogens are acknowledged as an important pathogenetic element of the development of breast cancer. Blocking of estrogen receptors results in an improvement of the prognosis and reduction of breast cancer mortality. Toremifen and Tamoxifen are the common agents blocking estrogen receptors. However, Tamoxifen, unlike Toremifene, has genotoxic and oncogenic effects, which are due not merely to hydrooxidation of Tamoxifen.

Material and methods: We have studied the effects of Toremifen and Tamoxifen on the hormonal homeostasis of 52 patients with stage 2 breast cancer by using RIA with 'Immunotech' kits in order to determine the serum levels of follicle-stimulating hormone (FSH), luteinising hormone (LH), estrogen and progesterone in 3 and 6 months following the beginning of administration of Toremifen or Tamoxifen. Estrogen and progesterone receptors were determined by using standard enzyme-linked immune assays.

Results: Toremifen effects have been shown to be more favourable on the pathogenetic level: estrogen levels have tripled by month 6 of treatment with Tamoxifen, whereas estrogen levels have only doubled by month 6 of treatment with Toremifen. FSH levels were lowering upon administration of either of the studied drugs, however, upon administration of Tamoxifen, FSH levels were reduced by 1/3, whereas upon administration of Toremifene – by 4 times, which testified to Toremifen superiority on the pathogenetic level. Five-year follow-up of 21 patients taken the mentioned drugs have shown positive results of administration of Toremifene in both receptor-negative and receptor-positive patients.

Conclusions: Accounting for the aforementioned facts and the general oncogenicity of Tamoxifen, we suggest Toremifen to be a more suitable component of the standard treatment of breast cancer.

Poster presentations (Mon, 31 Oct)

Breast cancer – advanced disease

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POSTER

The amino-terminal propeptide (PINP) of type I collagen is a clinically valid indicator of bone turnover in osseous metastatic breast cancer while osteocalcin and CTX show inferior monitoring performance

D. Pollmann, S. Schildhauer, R. Geppert, K. Wernecke, K. Possinger, D. Lueftner. Charité, Oncology, Berlin, Germany

Background: Efficacy control of any treatment of metastatic spread to the bone in breast cancer is difficult and usually initiated later than restaging of visceral – or soft tissue metastases. The amino-terminal propeptide (PINP)