local failure after breast conserving primary treatment. The purpose of this work is to report about the treatment results of 13 patients treated with local excision of the tumor recurrence followed by PDR-Brachytherapy.

Methods: From 1994 to 1996 thirteen patients with recurrent breast carcinoma after initial breast conserving therapy were treated with local tumor excision in association with postoperative PDR-Brachytherapy. Primary treatment consisted of lumpectomy or quadrantectomy followed by 50 Gy adjuvant external beam irradiation on the whole breast in eleven cases. A boost of 10 Gy was additionally given in seven of these patients. Another two received an HDR-Brachytherapy boost of 7 Gy and 8 Gy respectively. One female received 60 Gy on the whole breast and one was treated with 42 Gy orthovoltage therapy. Recurrences occurred mean 59 months (from 11–208 months) after primary treatment. In all cases PDR-Brachytherapy was given in a curative intention after a second try of breast conserving surgery. Treatment was performed under general anaesthesia using the classical plastic tube technique. For treatment planning orthogonal images in two planes were used. Dose calculation and prescription was performed according to the recommandations of the Paris system. Clinical target volume (CTV) was defined as the former tumorbed with a 2 cm safety margin. The peripheral dose entirely encompassed the CTV. Prescribed dose was 0.8 Gy per puls, total dose ranged from 16 to 50 Gy. In eight cases radiotherapy was performed by PDR-Brachytherapy alone. Five patients with got an additional EBT from 12 to 30 Gy.

Results: Eleven out of thirteen patients are locally free of disease with a median follow up of 19 month (range 5–38 month). In two cases another local recurrence after treatment occurred 4 and 8 month later and consequently those women were salvaged with mastectomy. Another two patients without evidence of local relapse failed distantly with bone metastases. Despite of the previously performed radiotherapy no severe side-effects are observed at present. Side effects are a moderate fibrosis grade 1–2.

Conclusion: Local tumor excision combined with PDR-Brachytherapy in case of small local failure after primary breast conserving therapy is a feasible and well tolerated method, which can prevent breast cancer patients from mastectomy. Although follow up time is short preliminary experience is encouraging.

712 PUBLICATION

A new active combination of tamoxifen (T)-vinorelbine (V)-anthraciclines in metastatic breast cancer (MBC)

L. Nardone, G. Salvi, L. Marmiroli, M.E. Rosetto, L. Marucci, G. Ausili-Cèfaro. *Div. Radiotherapy II, Catholic Univ. Sacro Cuore, Rome, Italy*

Purpose: Experimental data show that T acts through several cellular pathways which are not always Estrogen Receptor-dependent (Gelmann EP, 1996). Chadjaa (ASCO, 1993) and Spielmann (JCO, 1994) obtained significant results with a combination of anthaciclines (Adriamicin A – Epirubicin E) and Vinorelbine (V). We started the present study to assess the clinical benefit of the new following schedules: TAV: T 60 mg/die, d 1-2-3; A 25 mg/m^2 d 2; V 25 mg/m^2, d 2 every 2 weeks or TEV· the same doses of T and V plus E 50 mg/m^2, d 2, every 3 weeks.

Methods: From 2/93 to 10/96, 35 patients (21 TAV and 14 TEV), average age 58.8 (38–79), 10 pt over 65 years old, PS 0–2, are evaluable for response and toxicity assessment. Previous treatments included chemotherapy (65.7%), 13 pt as 2nd line, 6 pt as 3rd line and 4 pt as 4th line, hormones (28.5%) and radiotherapy (45.7%). Sites of metastatic disease were bone (63%), lung (46%), liver (40%), lymph nodes (28.5%), skin (20%), retina (5.7%). A total of 203 cycles was administered, average 5.8 cycles/pt, range 2–17. The patients were treated since achievement of CR, or since progression disease or since unacceptable toxicity.

Results: Because we included in this study also patients heavy pretreated, we considered in our results the overall objective tumor response inclusive of stable disease (total tumor growth control). Response rate was 85.7% (CR 8.5%, PR 45.7%, SD 31.4%). The median duration of CR was 12 months, of PR and SD was at least 3 months. 5 pts (14.3%) showed progressive disease during chemotherapy. WHO grade II and III leukopenia occurred in 10 pts (28.5%) and it was observed in 5 pts after 2° cycle and in 5 pts after 4° cycle; in 5 pts G-CSF was given. Cardiac impairment grade 2 was observed in 2 pts.

Conclusions: these results confirm the high activity of TAV-TEV combinations, the excellent tolerance profile, low morbidity. This interaction between T and V+anthraciclines should be particularly studied for first-line treatment in metastatic breast cancer to provide more impressive results.

713 PUBLICATION

Induction preoperative chemotherapy with high-dose epirubicin in locally advanced breast cancer (LABC)

P. Silvestro, G. D'Aiuto, G Caparrotti, C. Menditto, R. Tambaro, L. Rinaldi, M. Pergola. *Division of Medical Oncology B, National Cancer Institute, Napoli, Italy*

From January 1994 to June 1996, 47 patients (pts.) with LABC were treated with Epirubicin 150 mg/m2 i.v. every 15 days for 3 courses + G-CSF. Characteristics of the pts.· median age 47 years, performance status (ECOG) 0–1, T > 3 (median tumor size 7 cm), N1, M0.

Results in 47 evaluable pts.: 2 (4.2%) complete pathologic responses, 21 (44.7%) partial responses >50%, 4 (8.5%) partial responses <50%, 20 (42.6%) stable diseases; 6 (12.7%) pts. showed pathologic negative axillary nodes. After median follow-up of 10 months (range 6–30), 3 pts. had disease relapse and 6 pts died.

A longer follow-up to define the disease free survival and overall survival is needed.

714 PUBLICATION

Phase II trial of paclitaxel (P) and cisplatin (CDDP) in patients with advanced breast cancer refractory to anthracycline (A) therapy

F. Riccardi, G. Rosati, M. Biglietto, G. Carteni, P. De Rosa, A. Tucci, G. Pacilio. *Medical Oncology Division, "A Cardarelli" Hospital, Naples, Italy*

Introduction: The observation of clinical response induced by P among pts with A-resistant breast cancer were of particular interest after the demonstration of in vitro cross-resistance between P and other agents to which resistance is due to P-glycoprotein-mediated pleiotropic drug resistance.

Methods: From March until December 1996, 22 consecutive pts entered this phase II trial; all pts had received previous chemotherapy containing doxorubicin or Epirubicin, and all pts showed disease progression while receiving the A-containing regimen or after a response lasting less then six months. 12/22 pts had received two or more chemotherapic regimens for advanced disease. Metastatic sites included liver (10), lung (9), bone (13), lymphnodes and skin (4), liver was predominant site in 8/22 pts; multiple metastatic sites in 18/22 pts. P 135 mg/sqm was administered IV by a 3-hour infusion, followed by intravenous CDDP 75 mg/sqm, on day 1, every 3 weeks.

Results: At the present analysis 112 cycles of treatment have been given (range: 2–8; median: 5), and two pts are not yet evaluable for response. Among 20 pts evaluable (4 of whom are still receiving therapy), 7 (35%) have had a partial response, 11 (55%) achieved a stabilisation of metastases, and 2 progressive disease. Neuropathy and arthralgia/myalgia syndrome were the most frequently occurring toxicities. Treatment was delayed because of slow haematological recovery in 13/112 courses. Nausea-vomiting G2-G3 WHO in 25/112 courses, mucositis G3 in 11/112.

Conclusion: P-CDDP is a safe regimen in the treatment of pts with advanced breast cancer refractory to A therapy. In a patient population with a very poor prognosis it has showed moderate clinical activity and the rule of higher dosages of P should be investigated.

Colorectal cancer I

715 ORAL

Are disseminated tumor cells detected by RT-PCR in patients with colorectal cancer of prognostic value?

I. Vogel, E. Soeth, H. Juhl, C. Röder, H. Kalthoff, D. Henne-Bruns, B. Kremer. *Department of Surgery, University of Kiel, Germany*

Purpose: In a prospective study we evaluated the consequences of the detection of disseminated tumor cells on survival in patients with colorectal cancer.

Methods: We developed a cytokeratin 20 specific nested RT-PCR for the detection of disseminated tumor cells in bone marrow and venous blood. Samples of both compartments were aspirated prior to operation.

Results: Bone marrow from 79 patients and blood specimens from 53 patients were analysed. For the statistical analysis only patients with R0