126 Proffered Papers

regimens even beyond 2nd line. Albeit these data, it is still necessary to include patients in randomised trials, to make a final conclusion possible.

448 **PUBLICATION** 

## Radiosensitized treatment of metastatical breast cancer with hemetoporphyrin derivative

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Background: Currently the methodologies that are used in oncology are quite of limited possibilities; therefore, there is a constant search for new, perspective treatment methods. One of such methods is sensitized tumor therapy based on quite selective porphyrin accumulation in tumors. Most widespread method of such treatment is photodynamic therapy (PDT). Applying PDT, a sensitizer is activated by visible light. Unfortunately, visible light can penetrate into a tissue only for several cm. This greatly narrows the indications of PDT. In 1987 we suggested new method, which remarkably broadens the possibilities of PDT application. We proved that some haematoporphyrin derivatives (HpD) can be activated by the ionizing radiation rays of certain power. During such radiosensitized tumors treatment (RST) the patient is injected with HpD and the tumor is irradiated with small amounts of gamma rays. The purpose of this report was to review our primary results of RST of metastatical breast cancer.

Materials and methods: Since 2001 the 11 patients with advanced breast cancer underwent RST. HpD was injected i.v. with a dose of 5 mg/kg body weight. 24, 48 and 72 h after injection of the sensitizer tumors were irradiated with gamma rays - 2 Gy at a time from radioactive cobalt. The full dose of a course was 6 Gy. 3 patients underwent one course of the treatment, for the rest 8 the treatment was repeated after 1-4 mo. The bone metastases of bone were estimated in 8 patients. The metastatical lung lesions – in 3 patients. The multiplex brain metastases were diagnosed in 4 patients, lymph node metastases - in 5, hepatic metastases - in 4 patients. In one patient multiplex metastatical lesions of soft tissue were identified and in one - the conjunctival metastasis was finded. In all these cases patients underwent RST as palliation.

Results: As the immediate result of RST of advanced breast cancer approximately 15% of all metastatical lesions fully disappeared after single course of RST. The best effect was noticed in bone and brain metastases. The effectiveness of RST of lymph nodes and hepatic metastases was slight. The significant response was observed in 6 patients. Only for one patient the treatment was ineffective.

Conclusions: RST is effective method in metastatatical breast cancer. The effectiveness of RST depends on the location of metastases.

449 **PUBLICATION** 

Navelbine-Doxorubicin combination chemotherapy is an active and safe regimen for patients (pts) with Advanced Breast Cancer (ABC): Final results of a large Syrian. Phase II trial

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Background: Navelbine (N) and doxorubicin (A) are active agents in the management of breast cancer. Several international studies reported the definite efficacy of N+A in advanced or in early disease (Blagman; cancer 99, Smith; ASCO 03).here we report our experience of a large Phase II trial conducted in our cancer center with N-A combination in ABC

Patients and methods: Eligible patients had confirmed locally advanced(LABC)(tumor size > 3 cm of diameter) or chemonaive metastatic Adequate bone marrow, renal and liver functions. Patients received N:  $25\,\mathrm{mg/m^2}$  on day 1 and day 8, plus A:  $50\,\mathrm{mg/m^2}$  on day 1. Cycles were repeated every 3 weeks. Patients with LABC were restaged after 3 cycles; pts showing clinical CR or PR received 3 additional cycles of the combination. Patients with MBC were evaluated every 2 cycles for response and every cycle for toxicity.

Results: Sixty-six patients were enrolled into the study, 36 pts with LABC, and 30 with MBC at presentation. median age was 46 years (range 25-67), WHO PS 0-1, median tumor size 6 cm (2-16). 50% of pts with MBC had visceral involvement. All pts were evaluable for efficacy and safety. Thirty-one pts with LABC achieved clinical objective responses (ORR = 88%) including 55% of clinical complete response. 68% of pts received Breast conservative surgery was performed in 68% of pts and pathological complete responses observed in 35% of pts. Twenty-four pts with MBC achieved objective responses (ORR = 80%) including 30% of CR.

This combination was well tolerated, a total of 298 cycles were administered with a median number of 5 cycles by pts (1-6) WHO grade 3-4 neutropenia occurred in 25% of pts. and G3 anemia in 2 pts Non-hematological toxicity was mild and manageable, alopecia was universal, there were no severe nausea/vomiting, neuropathy or constipation.

Conclusion: Results of our study are similar to the international data and

confirm that NA is highly active and safe regimen for BC pts.

## PUBLICATION

Evaluation of fulvestrant (F) activity and toxicity in heavily pretreated patients with advanced breast cancer (ABC)

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Background: F is an estrogen receptor antagonist with no agonist effect. Although F showed a similar activity to anastrozole when given as first/second line to patients with ABC resistant to tamoxifen, its activity in heavily pretreated women is not well documented.

Methods: Forty-six postmenopausal (16/46 induced by LH-RH analogue) women received F 250 mg i.m. q 28 days (Faslodex® compassionate use program by Astra-Zenaca, Italy), after the failure of previous endocrine treatments (median: 4, range 1–7 lines). Thirty-nine patients also received previous chemotherapy (median 5, range 1-12 regimens) for advanced disease. Namely, 30 pts received F as 4th-7th endocrine treatment and 33 pts after 4 to 12 chemotherapy regimens. Patients were treated until disease progression/unacceptable toxicity/treatment refusal.

Results: Fulvestrant toxicity and activity were registered every 4 and 12 weeks, respectively; 42 pts were evaluable for response. The median length of treatment administration was 4 months (2-15+). Fulvestrant was very well tolerated, with no G2-4 NCI-CTC toxicity. Overall, no CR/PR were observed. Nineteen pts (45%) had SD and 23 pts (55%) progressed. Twenty-four out of 42 pts received F at the time of tumour progression, 20/24 being valuable for response (4 pts: too early): 8/20 obtained a SD (3 pts: >3 months <6; 5 pts: ≥6 months). All these 8 pts were pretreated with both endocrine treatment (median: 3, range: 2-5 lines) and chemotherapy (median: 5, range 1-11 regimens) for advanced disease. Conclusions: F is well tolerated and can obtain a sustained disease

stabilization in heavily pretreated ABC with tumour progression at the time of treatment starting.

PUBLICATION

## Morphological type as prognosis factor for conservative surgery of locally advanced breast cancer

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Background: To research morphological type as prognosis factor for conservative treatment in group patients with locally advanced breast cancer (T2-3N0-1M0); (T0-3N1-2M0).

Materials and methods: Four hundred and forty seven women 447 with locally advanced breast cancer were treated from 1986 to 2001 at the Russian Cancer Research Center. Two hundred and twenty seven 227 women underwent quadrantectomy with axillary dissection and radiotherapy. Two hundred and twenty 220 women underwent different variants of radical mastectomy (Patey or Madden). Women from both groups received neoadjuvant and adjuvant therapy. 320 (71.6%) was diagnosed invasive ductale cancer, invasive lobular cancer was in 72 (16.1%), combination invasive ductale and lobular cancer was in 21 (4.7%). The medicine follow-up was 54 months.

Results: 5 years overall survival in patients with invasive ductale cancer in group of mastectomy was 81.0±3.9%, in group of quadrantectomy - $85.2\pm8.3\%$  in patients with invasive lobular cancer -  $82.4\pm8.3\%$  and  $81.5\pm6.5\%$  (p > 0.05). 5 years desease-free survival was poor in group of quadrantectomy in patients with invasive lobular cancer  $-63.0\pm6.5\%$ compare with group of invasive ductale cancer  $-74.5\pm3.0\%$  (p < 0.05). In group of radical mastectomy in patients with invasive lobular cancer  $73.6 \pm 8.0\%$  and invasive ductale cancer  $-76.6 \pm 4.9\%$  (p > 0.05).

Conclusion: 5 years desease-free survival was poor in group of quadrantectomy with invasive lobular cancer compare invasive ductale cancer. Invasive lobular cancer is factor of risk locally recurrences conservative surgery in patients with breast cancer.