

cycle. Mastectomy was done in responders. The sonographic changes were recorded and correlated with histological changes.

**Results:** Fourteen cases were evaluated. Nine patients showed response in form of reduction in tumour size, improved tumour margin definition, decreased echogenicity of tumour, more homogenous internal echos and reduction of skin oedema.

**Conclusions:** Sonomammography can be used as a readily available cost effective tool for assessment of tumour response following primary chemotherapy in patients with LABC.

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POSTER

### Activity of chemotherapy based on Navelbine in pre-treated metastatic breast cancer patients

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**Purpose:** To evaluate the activity and hematologic toxicity of Navelbine-based combinations in metastatic breast cancer patients previously treated with one or more line of chemotherapy.

**Materials:** From March 1996 through January 1997, 34 metastatic breast cancer patients were included in the study. The age ranged from 31 to 73 (mean 47). According to ECOG scale, their performance status was 0-2. All the patients had two-dimension measurable or assessable tumor lesions. The sites of metastases: were lymph nodes (16 patients), bones (15), lungs (12), skin (8), breast (7), liver (4), kidney (1). The number of metastatic sites was 1 in 9 (26.5%) patients, 2 in 14 (41.2%) and 3 in 11 (32.3%). Metastases in the internals occurring in 50% of the cases (in 17 of 34 patients). Twenty-two of the 34 patients had previously received one line of chemotherapy, 12 patients – two lines. The mean number of previous courses of multidrug chemotherapy for one patient was 5 (range 1 to 8). Get the start of Navelbine treatment all patients had a disease progression.

**Methods:** Twenty-three patients were administered combination chemotherapy: Navelbine 25 mg/m<sup>2</sup> day 1 and 8 plus Doxorubicin 50 mg/m<sup>2</sup> day 1, every 21 days. Eleven patients were given Navelbine 39 mg/m<sup>2</sup> day 1 and 5 plus 5-Fluorouracil 750 mg/m<sup>2</sup> days 1 through 5, every 21 days.

**Results:** We evaluated 122 courses with Navelbine. Leucopenia occurred in 88 (72.1%) courses, but only in 24 (19.6%) courses it was grade III-IV toxicity. Grade III anemia developed only after 1 (0.8%) course. Grade III thrombocytopenia was observed in none of the patients. Navelbine dose had to be decreased due to hematologic toxicity in 13 (10.7%). No treatment-related fatal outcomes were registered. Partial response occurred in 11 (32.4%) patients. 17 (50.0%) stabilizations of disease and 6 (17.6%) progressions were observed. 9 patients (26.5%) are still alive in follow-up time of 9 to 17 months. The median survival was 9.8 months. The one-year survival rate is 36.9%.

**Conclusion:** Navelbine-based chemotherapy combinations are satisfactorily tolerated and are moderately active in the 2nd or 3rd lines of metastatic breast cancer therapy.

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### Vinorelbine (VNR) + 5-fluorouracil continuous infusion (5-FU c.i.) in pretreated advanced breast cancer – Adria Medica Group

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The results in terms of objective response in pretreated advanced breast cancer are generally not over 30-40%, and the median duration of the response is about 5 months. From March 1997 we investigated the therapeutic effect and the tolerability of a combination of VNR + 5-FU c.i. as second line in patients with metastatic breast cancer.

The schedule is the following:

|      |                                 |             |               |
|------|---------------------------------|-------------|---------------|
| 5-FU | 700 mg/m <sup>2</sup> i.v./day  | for 5 days  | every 3 weeks |
| VNR  | 25 mg/m <sup>2</sup> i.v. bolus | day 1 and 6 | every 3 weeks |

In December 1997 n.27 patients were enrolled and 19 were valuable. Median age 55 years, 4 pts were premenopausal and 23 postmenopausal. Recetorial state: positive 15 patients, negative 5 and 7 unknown. 14 patients had received prior chemotherapy in adjuvant setting, 23 for advanced disease, 13 for both. The site of metastatic disease were visceral + bone

13, bone 6, visceral and soft tissue 21 pts, WHO PS was 0 in 6 pts, 1 in 18 and 2 in 3 pts. There were 8 PR and 6 SD. The median duration of the response was 5 months. 5 pts progressed on treatment.

**Toxicity:** Grade 1: leukopenia in 7 pts and grade 3 in 1 pt. Grade 2: mucositis in 4 pts and grade 3 in 1 pt. Grade 3: diarrhea in 1 pt. Grade 4: vomiting in 1 pt. The study is ongoing.

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### Treatment of liver-metastases in patients with breast cancer

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**Purpose:** Treatment of liver metastases with anthracyclines or antimetabolites leads to few responses and does probably not prolong survival significantly. Therefore the effectiveness of taxanes was tested in these patients.

**Methods:** Breast cancer patients with only liver metastases as first side of relapse were treated with 200 mg/m<sup>2</sup> taxol as monotherapy or in combination with epirubicin (60 mg/m<sup>2</sup>) (in the latter combination the dose of taxol was reduced to 175 mg/m<sup>2</sup>). Response was categorized according to the WHO-criteria.

**Results:** 18 patients were treated between 1994 and 1996 with 200 mg/m<sup>2</sup> taxol. One patient achieved a complete remission (CR), 4 patients a partial remission (PR), giving an overall response rate of 30%. Mean duration of response was 5 months and mean survival was 20 months.

10 patients received the combination chemotherapy since 1996. While only one patient achieved a complete remission, 5 patients had a PR, giving a response rate of 60%. Mean duration of response was 8 months. Mean survival could not be calculated since 6 patients are still alive.

**Conclusion:** In previous studies mean survival of patients with liver metastases was reported to be in the range of 12 months. Using taxol, 6 of the 14 patients survived more than 24 months and the remaining 14 patients are still living. That could be considered as an improvement. According to the still preliminary data the combination with epirubicin could be even more effective.

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POSTER

### Primary medical treatment of locally advanced disease reveals causes of failure of adjuvant chemotherapy

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**Hypothesis:** The sequestered cell – a cell remote from the circulation at the time of treatment – is a major cause of failure of chemotherapy. The effectiveness of systemic therapy may be improved in tumours that shrink slowly (grades I and II) by protracting the treatment to allow time for revascularization of poorly nourished areas.

**Methods:** New primary breast cancers were treated by sequential single agent therapy (chemotherapy and hormones). Timing was regulated by the rate of shrinkage of individual tumours. The existence of poorly nourished tissue around the margins of ulcerated tumours was demonstrated by thermographic scanning. Sites of recurrent nodules after early healing of these tumours were compared photographically to the original areas of poor circulation.

**Results:** Despite improved early local control, nearly all tumours eventually regrew. In ulcerated tumours close correspondence was seen between areas of poor circulation and sites of local recurrence.

**Conclusions:** The demonstrable failure in ulcerated tumours will be repeated on a microscopic scale in smaller, non-ulcerated tumours. If shrinkage, with accompanying improvement of the local circulation, does not occur during treatment, then systemic therapy is unlikely to succeed. Tumours that shrink slowly will do better if treatment time is extended. However, total extinction is rare and therefore surgery should follow when possible.

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POSTER

### Comparative study of taxol (T) and Cisplatin® versus Taxotere (Tx) and vinorelbine (V) in metastatic breast cancer (MBC). Preliminary results

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**Introduction:** Taxanes have shown important activity as rescue treatment in metastatic breast cancer refractory to anthracycline therapy. In this trial