all dimensions. QOL declined in both TAC and FAC treated patients during the treatment phase. While the decline in TAC subjects was statistically larger in 11/23 dimensions (including Global Health Status and Physical Functioning), it was of uncertain clinical significance and both groups returned to or exceeded their baseline scores by the 6 month follow-up visit.

Table 1. Intent-to-Treat Efficacy Analyses Prospectively Powered (n=1491)

DFS	Hazard Ratio TAC/FAC (95% CI)	P-value
Adjusted for N status (Primary endpoint)	0.72 (0.59–0.88)	0.0010
1–3 nodes (n=923)	0.61 (0.46–0.82)*	0.0009
4+ nodes (n=568)	0.82 (0.63–1.08)*	0.1629
Hormone Receptor Positive†	0.73 (0.57–0.94)	0.0132
Hormone Receptor Negative†	0.66 (0.47–0.93)	0.0163
Overall Survival		
Adjusted for N status	0.70 (0.53–0.91)	0.0080

*Ratio of Hazard Ratios: 1.34 (0.90–2.00), p= 0.1476. †Centrally reviewed.

Conclusion: Docetaxel-based therapy (TAC) significantly improves both disease free survival and overall survival compared with FAC. The higher rate of neutropenic complications is manageable, and the on-therapy differences in some QoL parameters between study arms normalized on completion of therapy. TAC represents a major therapeutic advance in the adjuvant chemotherapy for patients with early breast cancer.

51 POSTER HIGHLIGHT

Preoperative hormonal therapy vs chemotherapy in postmenopausal ER-positive breast cancer patients

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Preoperative (neoadjuvant) chemotherapy or hormonal therapy is being used increasingly to downstage locally advanced and large operable breast cancer.

Following this treatment, inoperable breast cancer often becomes fully resectable, and tumors requiring mastectomy may be successfully removed by breast-conserving surgery (BCS).

Patient selection is important to optimize neoadjuvant therapy, especially in elderly postmenopausal women with co-morbid conditions.

Patients and methods: Between March 1998 and March 2003, 117 postmenopausal (PM) women with ER(+) and/or PgR(+) breast cancer (BC) T2N1-2, T3N0-1, T4N0M0 assigned neoadjuvant treatment with either chemotherapy doxorubicin 60 mg/m2 + paclitaxel 200 mg/m2, every 3 weeks, 4 cycles, n=58 patients (pts), or hormonal therapy with aromatase inhibitors, n=59 (once daily exemestane 25 mg, n=29, or anastrazole 1 mg, n=30, 3 months).

The primary endpoint was to compare overall objective response (OR) determined by clinical (palpation) and mammography. Secondary endpoint was the number of pts who qualified for BCS + radiotherapy (50 Gy for 25 fractions).

Results:

Table 1

Neoadjuvant therapy	OR %		BCS %
	Clinical	Mammography	
Chemotherapy (doxorubicin + paclitaxel)	75.8*	62	20.6*
Anastrazole	80.0	70	33
Exemestane	90.5*	72.4	37.9*
p-value	0.096*	> 0.5	0.054*

OR rate (clinical and mammography) was statistically similar ($p > 0.05$) in the chemotherapy and ≪hormonal≫ groups. Tendency to more BCS took place in the ≪hormonal≫ arm that in the chemotherapy arm (37.9% vs 20.6% p=0.054). Local recurrence rate were similar for pts receiving chemotherapy or hormonal therapy (1.7% and 1.7%, at 34 months median follow up).

In chemotherapy arm the most frequent grade III/IV toxicity was alopecia (79.3%), neutropenia (43.1%), cardiotoxicity (6.8%), diarrhea (1.7%). Hormonal treatment was well tolerated. The most commonly adverse events were hot flushes (23.3%), vaginal discharge (6.6%), musculoskeletal disorders (1.7%).

Conclusion: Preoperative hormonal treatment (anastrazole, exemestane) is a reasonable alternative to chemotherapy for PM women with ER and/or PgR-positive cancer in clinical situation where the low toxicity of the regimen is considered an advantage, for example, for women over 70.

52 POSTER HIGHLIGHT

Participation in phase III ADEBAR: Evaluating the role of adjuvant docetaxel in high-risk breast cancer patients improves treatment strategies and individual patient care in recruiting centers

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Background: The ADEBAR study is a prospective multicenter phase III trial to evaluate whether high-risk breast cancer patients with more than 3 involved lymph nodes benefit from a sequential anthracycline-docetaxel regimen ($E_{90}C$–D: 4 cycles epirubicin [E] 90 mg/m^2 plus cyclophosphamide [C] 600 mg/m^2 q21 days followed by 4 cycles docetaxel [D] 100 mg/m^2 q21 days) compared to standard anthracycline-containing polychemotherapy ($FE_{120}C$: 6 cycles E 60 mg/m^2 d 1+8, 5-fluorouracil 500 mg/m^2 d 1+8 and C 75 mg/m^2 d 1–14, q4 weeks). With 137 actively participating centers and a median recruitment of 24.5 patients/month, ADEBAR is currently the best recruiting adjuvant chemotherapy trial in this specific risk group in Germany.

Patients and Methods: We surveyed recruiting centers by questionnaire (comprising large hospital departments and community oncology practices) to assess how participation in ADEBAR had changed their treatment strategies and patient care.

Results: The return rate of the questionnaire was 67.4% (n=93). In the year preceding ADEBAR, 54.8% of study centers had not entered high-risk breast cancer patients into a clinical trial. Outside of the ADEBAR protocol, at least 51.7% of these high-risk patients would have routinely received less effective chemotherapy regimens such as CMF, EC/CMF, or 4× EC. Forty-three percent of centers reported that participation in the trial had increased the intensitiy of their patient care (apart from study specific issues) and 53.7 % noted an improvement in their professional knowledge from being part of an investigators' network with newsletters, regular meetings, etc. Although 55.9 % reported that being part of the ADEBAR study had not changed the overall quality of their patient care, 35.5 % detected improvements.

Conclusion: Our results demonstrate that participation in clinical trial protocols benefits physicians and patients by improving treatment strategies and individual patient care in recruiting centers. Moreover, our excellent recruitment rate demonstrates that modern trials, which are easy to carry out under routine care conditions, realistically have the potential of getting centers interested in conducting clinical trials.

53 POSTER HIGHLIGHT

Neutropenic events in six European audits of breast cancer chemotherapy

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Background: European data on chemotherapy (CT) related neutropenic events (NE) and their consequences is sparse. Six retrospective audits of breast cancer CT from Austria, Belgium, Germany, Spain and the UK have been collected by the INC-EU. Results of a combined analysis are reported.

Materials and methods: Variables available in all six datasets were merged into a single dataset of individual observations and their definitions were harmonised. NE were defined as neutropenia-related hospitalisation, reduction ⩾15%, and/or dose delay ⩾7 days. Analysis addressed the incidence of NE and of low average relative CT dose intensity (ARDI). Multivariate adjusted odds ratios (ORs) were calculated by robust multiple logistic regression.

Results: A total of 2860 patients were diagnosed between 1979 and 2001 and had a mean age at diagnosis ± SD of 51.1±11.3 years