S122 Tuesday 23 September 2003 Poster Session

function (-14  $\pm$  19, 95% c.i. 8 to -19) and role function (-18  $\pm$  22, 95% c.i. -11 to -24) were moderate in clinical magnitude. Emotional function was better at the completion of chemotherapy than baseline (P<0.01). At six months after completion of chemotherapy, cognitive function (83  $\pm$  24), physical function, role function and global health status did not differ from baseline values.

Conclusions. We conclude that (1) self-reported cognitive function is unimpaired or impaired to a minor extent by adjuvant chemotherapy for breast cancer, (2) whereas physical function and role function are impaired to a moderate extent by adjuvant chemotherapy, but recover subsequently. These data are longitudinal and avoid potential confounding by the effects of chemotherapy-induced menopause; however, the instrument does not address specific cognitive domains in detail and may be insufficiently sensitive to limited but clinically relevant changes in cognitive function.

399 POSTER

Cost-effectiveness of intensive adjuvant chemotherapy for high-risk breast cancer: Is dose-escalated chemotherapy with growth factor support (GFS) more costly and less effective than high dose chemotherapy (HDCT) with peripheral stem cell transplantation (PSCT)?

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**Background:** Based on randomized studies HDCT with PSCT is not superior to conventional CT as adjuvant treatment for high-risk breast cancer patients. The cost-effectiveness of these treatments has never been compared. In the present study, we examined the actual treatment costs of Finnish high-risk breast cancer patients treated with adjuvant chemotherapy in the Scandinavian Breast Cancer Group Adjuvant Trial, SBG9401 (Bergh et al. Lancet 2000;536,1384).

Patients and methods: Fifty-nine patients were randomized to nine cycles of dose escalated FEC (5-fluorouracil-epiadriamycin-cyclophosphamide) with granulocyte GFS (group A) and seventy patients to three cycles of standard FEC and HDCT with PSCT (group B). Both groups received adjuvant radiotherapy and tamoxifen for five years. All treatment costs (hospitalization, drugs, transfusions, growth factors etc) were considered. Effectiveness was measured by the number of days on sick leave and survival. Two patients did not receive the trial medication and were excluded. The mean age of the patients at the time of diagnosis was 49 years (range 41-59 yrs, N.S.)

**Results:** The mean total costs of the adjuvant treatment were significantly higher in group B (25829 \* vs. 36605 \*, p < 0.05). The main reason for the higher costs was the higher amount of hospitalization days. The lowest total cost (22047 \*) for an individual patient occurred in group A and the highest (52451 \*) was recorded in group B. Costs of filgrastim were 15335 \* in group A and 2969 \* in B. The costs of radiotherapy were almost similar in both groups: 1687 \* in A (6% of total costs) and 1573 \* in B (4% of total costs). Surprisingly there was no difference (p=0.5) in the number of sick leave days between the groups, mean 435 days. At 35 months' follow-up 88% patients in group A and 80% in group B were alive (N.S.).

Conclusions: The HDCT with PSCT (group B) was significantly more costly than dose escalated FEC with growth factor support (group A) although over half of the total costs in group A were due to growth factors. Radiotherapy was cheap compared to the overall costs (less than 10%). There was no difference between the groups in effectiveness as measured by the number of days on sick leave and survival. According to the SBG9401 and this study HDCT with PSCT as an adjuvant treatment of breast cancer is more costly, but no more effective than dose escalated FEC.

400 POSTER

Dose-dense sequential adriamycin-paclitaxel-cyclophosphamide (A-T-C) chemotherapy in high-risk early breast cancer - a phase II study

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The superiority of dose-dense sequential chemotherapy over conventionally scheduled combination chemotherapy in regard of higher efficiency and less severe toxicity was recently suggested. Fifty patients after surgery for high-risk breast cancer were recruited into a phase II study. The median

age was 50 years, the median number of positive nodes was 7, and 10 or more positive nodes were present in 36%. Forty-five percent of the tumors were ER-positive, while 40% were PR-positive. The following chemotherapy schedule was used:  $4xA \rightarrow 4xT \rightarrow 4xC$ , q2weeks (A = adriamycin 60 mg/m², T= paclitaxel 200 mg/m² over 3 hours, C= cyclophosphamide 800 mg/m²). Hemopoietic cytokin was used individually: in the event of neutropenia hampering the implementation of the dose-dense schedule, filgrastim was started and administered in all the subsequent cycles.

Toxicity in dose-dense sequential A-T-C chemotherapy

Grade	Toxicity (% of cycles					
	Adriamycin 1-4		Taxol 1-4		Cytoxan 1-4	
	1-2	3-4	1-2	3-4	1-2	3-4
Nausea	76.1	2.2	11.9		62.1	_
Vomiting	23.4	1.4	-	~	29.7	2.7
Neutropenia	25.5	68	61.9	14.3	51.3	10.8
Anemia	79.4	2.1	100	~	97.3	_
Thrombopenia	8.5	-	2.3	~	_	_
Arthralgia	4.3	_	71.5	21.4	-	_
Myalgia	2.1	_	14.2	4.7	_	_
Sensory neuropathy	2.1	_	57.1	_	-	_
Skin	2.1	_	9.5	2.3	4	_

Neutropenic fever occurred 3 times each after treatment with A or T. Grade 2-3 alopecia was usual. Almost all the premenopausal patients developed amenorrhea. A mild and transitory PFS deterioration occurred in 6 patients. Chemotherapy was terminated in 4 cases due to cardiac (A, n=1) or skin toxicity (T, n=1 and C, n=1), or because of an anaphylactic reaction to T (n=1). No cardiac dysfunction was detected. The effective dose intensity was 93.7, 98.1, and 96.6% of that planned in the A, T, and C cycles, respectively. Filgrastim was used in 59.6, 84 and 71.4% of all the A T and C cycles, respectively. Dose-dense sequential A-T-C chemotherapy is well tolerated. Individually used hemopoietic citokines help to maintain the planned dose intensity. The follow-up of the patients, and analysis of the prognostic and predictive factors are planned.

401 POSTER

Adjuvant chemotherapy in breast cancer patients older than 70: CMF or FEC, feasability, acute and late toxicities. Experience of a single Institution

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**Background:** Breast cancer (BC) in patients older than 70 will be a major health care problem in the next decades. Adjuvant treatment are still not standardized: benefit of chemotherapy seems to exist in regards of age but its toxicities have never been clearly evaluated. Since 2000 in our institution, we used standard prognosis criteria (N+ or size and grade, RH-) for surgery, chemotherapy (CT) and radiotherapy in elderlys. CT was CMF, FEC75 or FEC100. Our aim was to investigate compliance of treatment, toxicities with each regimen.

**Patients:** We recorded all patients aged 70 or older who underwent adjuvant CT from 2000 to 2002 for BC. Treatment disruption, reasons, acute and delayed toxicities, use of GCSF or erythropoietin (Epo) were reviewed.

Results: There were 95 patients. Median age 75 [70-85]. 5 had inflammatory BC and received primary CT. 57 had a conservative surgery and 36 had a mastectomy. CT was: CMF (60 pts), FEC75 (11pts), FEC100 (17pts). 6 disrupted CT (CMF: 2, FEC75 4). Reasons were fever or asthenia. Any of pts receiving FEC100 stopped CT. In 2002 only one patient disrupted treatment. All but one pt receiving FEC75 had primary preventive GCSF, 5 had curative Epo. All pts receiving FEC100 had GCSF and Epo. All but two grade III and IV toxicities were observed in pts receiving anthracycline: 18 pts had severe side effects: febrile neutropenia (n:9), pulmonary embolism (n: 2), angor (n: 1), 3 pts requiered red blood cell transfusion. Median decrease in Hb is 1.6g/dl with CMF and 2.6 with FEC. Analysis according regimen and comparison with pts youngers, prognostic factors will be analyzed in may 2003. Delayed cardiac toxicity has never been reported.

**Conclusions:** Adjuvant anthracycline based CT is feasible in elderly with reasonable safety profile but required adequate supportive care. Our data suggest that compliance is influenced by initial criteria and willingness of physician. Factors impacting on toxicity, physician's decisions and compliance of CT will be presented in may.