Background

Taxane containing regimens have been established as standard of care for node-positive primary breast cancer patients and have shown superiority to mere anthracycline containing regimens. The SUCCESS-trial evaluates, whether adjuvant taxane based treatment can be further improved by the addition of Gemcitabine.

Methods

The SUCCESS-Study is an open-label randomized controlled, Phase III study comparing the disease free survival after randomisation in patients treated with 3 cycles of Epirubicin (100 mg/m²) – Fluorouracil (500) -Cyclophosphamide (500, FEC) -chemotherapy, followed by 3 cycles of Docetaxel(100mg/m², D) versus 3 cycles of FEC, followed by 3 cycles of Gemcitabine (1,000mg/m² d1,8) -Docetaxel (75 mg/m²) (DG) . Complete, monitored toxicity data of 2.691 pts were available for this analysis.

Results

Dose reduction >20% (3.97% vs 2.90%) and postponement of treatment cycles >7die (22.85% vs 14.19%) was rare, but more frequent in the FEC-DG arm (both p<.001). Cytostatic treatment was prematurely stopped in 119 pts (4.4%) receiving FEC-DG and in 103 pts (3.8%) with FEC-D (p=0.21). G-CSF support was applied in 850 (29.2%) vs. 602 pts (20.7%, p< .001). Toxicities NCI grade > 2 which occurred with incidence > 1% or significantly different in the two arms are depicted in Table 1. Afebrile and febrile neutropenia and anemia did not differ between the two arms, but thrombocytopenia was more frequent in the FEC-D arm (1.7%, p= .007). Hand-foot syndrome and neuropathy was more frequent in the FEC-D arm (p=.09 and p=.02, respectively).

Conclusions

No unexpected toxicities were observed and severe adverse effects were rare in both treatment arms. With the addition of gemcitabine to FEC-D adjuvant chemotherapy toxicity was moderately increased. Outcome data will have to be awaited to further interpret these findings.