TAXTOX - a retrospective study regarding the side effects of docetaxel given as part of the adjuvant treatment to patients with primary breast cancer in Denmark from 2007 to 2009.

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Abstract: Abstract Background. In 2007 docetaxel was introduced as part of the adjuvant setting offered to high risk breast cancer patients in Denmark. Meta-analyses had shown that taxane-containing chemotherapy reduced the relative risk of relapse and death by 20-30%, apparently with moderate side effects. The treatment was given as three cycles of cyclophosphamide (600 mg/m(2)) and epirubicin (90 mg/m(2)) followed by three cycles of docetaxel (100 mg/m(2)). Because of an apparent high incidence of side effects, especially febrile neutropenia (FN) and non-hematologic side effects, the DBCG (The Danish Breast Cancer Cooperative Group) initiated a retrospective study of adverse reactions to the newly introduced regime and all patients were offered primary prophylaxis with growth factors (G-CSF) pr 1/1-2008. Material and methods. Two medical doctors examined available journals and nurse charts from the 13 oncology departments in Denmark, and graded all side effects according to NCI CTC version 2.0. To be enrolled, the patients should have received three cycles of EC and at least one cycle of docetaxel. The side effects were investigated before and after routine use of G-CSF. Results. One thousand one hundred and forty-three patients entered the study. In 2007 (before G-CSF) the incidence of FN was 25% and 90.6% of the patients completed the planned treatment. In 2008 (after the introduction of G-CSF) the incidence of FN was 10% and 94.5% completed the treatment. The incidence of non-hematological adverse events, in 2007 and 2008 combined, was for neuropathy 35%, mucositis 75%, muscle and joint pain 53%, skin rash 25% and fatigue 43% (all grades). Conclusion. The introduction of G-CSF was justified because of the high incidence of FN. However, it could not have been predicted after reviewing the published literature. The incidence of non-hematological adverse events had been reported in some, but not all adjuvant taxanes studies. In the future, focus should be more on the side effects, especially when introducing new toxic systemic regimes.

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