

## breast cancer, early stage

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### WEEKLY DOCETAXEL (WD) VS CMF AS ADJUVANT CHEMOTHERAPY FOR ELDERLY EARLY BREAST CANCER (EBC) PATIENTS (PTS): FINAL RESULTS FROM THE RANDOMISED PHASE 3 ELDA TRIAL

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**Aim:** Evidence on adjuvant chemotherapy in elderly EBC pts is poor. The ELDA trial tested whether wD is more effective than CMF (NCT00331097).

**Methods:** EBC pts, 65 to 79 years old, were eligible if they had metastatic nodes or average to high risk of recurrence according to 2001 St.Gallen criteria. Pts were randomly assigned to wD (35 mg/m<sup>2</sup> dd 1, 8, 15) or CMF (cyclophosphamide 600 mg/m<sup>2</sup>, methotrexate 40 mg/m<sup>2</sup>, fluorouracil 600 mg/m<sup>2</sup>, dd 1, 8), both every 4 wks and given for 4 cycles in ER+ pts and 6 cycles in ER- ones. With 178 events, the study would have 80% power to detect a 0.65 hazard ratio (HR) of disease-free survival (DFS) with bilateral alpha = 0.05. Quality of life (QoL) was assessed with EORTC C30 and BR23 tools; activity of daily living (ADL), instrumental ADL (IADL) and Charlson score for comorbidities were assessed. ER+ and HER2+ pts received endocrine treatment and trastuzumab after chemotherapy, respectively.

**Results:** From July 2003 to April 2011, 302 pts were randomized and 299 (152 CMF, 147 wD) were evaluable. Median age was 71. Hypertension (62%), arthropathy (34%) osteoporosis (17%) and controlled diabetes (16%) were the most frequent comorbidities. At baseline: pT1 44%, pN0 37%, G3 64%, ER+ 75%, HER2+ 19%. After 5.5 years median follow-up, with a plateau of DFS after 108 events (50 with CMF and 58 with wD), the Independent Data Monitoring Committee recommended to anticipate final analysis. HR of DFS for wD vs CMF was 1.20 (95% CI: 0.82-1.75, p = 0.35); HR of death was 1.23 (95% CI: 0.73-2.07, p = 0.42); outcome is similar at multivariable analysis, also including ADL, IADL and Charlson scores. QoL was significantly worse with wD for emesis, appetite loss, diarrhoea, body image, future perspective, side effects and hair loss items. Hematologic toxicity, mucositis and nausea were significantly worse with CMF, while allergy, fatigue, hair loss, onicopathy, dysgeusia, diarrhoea, abdominal pain, neuropathy, cardiac and skin toxicity were significantly worse with wD. There were 1 toxic death with CMF and 2 with wD.

**Conclusions:** The ELDA trial shows that wD is not more effective than CMF, and produces worse QoL and toxicity. CMF remains a standard for elderly EBC pts. (Partially supported by Sanofi-Aventis).

**Disclosure:** All authors have declared no conflicts of interest.