The prognostic relevance of serum CA 27.29 level in primary breast cancer patients before adjuvant chemotherapy – Results of the German SUCCESS trial

Background
While tumor markers are frequently used to assess treatment efficacy in metastatic breast cancer, there is lack of evidence regarding the role of MUC-1 markers in primary disease. The value of CA27.29 in the adjuvant setting was prospectively evaluated in the German multicenter SUCCESS study.

Materials & Methods
The German SUCCESS trial is a multicenter phase III study comparing FEC-Docetaxel (Doc) vs. FEC-Docetaxel-Gemcitabine (Doc-G) and 5 versus 2 years of Zoledronate as adjuvant treatment in patients with node positive or high risk node negative primary breast cancer. In this trial serum CA27.29 level has been prospectively evaluated in 3202 patients before and immediately after adjuvant chemotherapy as well as 2 and 5 years thereafter. CA27.29 was measured with the 5T AIA-PACK CA27.29 reagent using MUC-1 for AIA-600II (Tosoh Bioscience, Tessenderlo, Belgium). The cutoff for positivity was >31 U/ml.

Results
Mean CA27.29 serum level before adjuvant chemotherapy was 19.3 U/ml (SD +/- 15.5) in both arms. 8.0% (n=127) of patients in the FEC-Doc-G arm and 7.4% (n=120) in the FEC-Doc arm had a marker of more than 31 U/ml. Mean CA27.29 serum levels were significantly higher in patients with lobular carcinoma (p=0.001), with positive lymph nodes (p=0.02) and post-menopausal patients (p<0.001). After a median follow-up period of 34 months 233 patients relapsed and 108 patients died. CA27.29 before chemotherapy was a significant prognostic marker for disease-free survival (DFS) (p<0.0001) and overall survival (OAS) (p<0.0001) in univariate and multivariate analysis.

Conclusion
These findings indicate the independent prognostic relevance of serum CA27.29 levels in primary breast cancer patients before adjuvant treatment. Further follow-up within the SUCCESS trial will show whether initial CA27.29 level could serve as a tool for adjuvant treatment monitoring.