

Evaluation of CA27.29 as prognostic marker in primary breast cancer patients - Results of the German SUCCESS trial

Background

While tumor markers are frequently used for the evaluation of treatment efficacy in metastatic breast cancer, the role of Muc-1 markers in primary disease and during recurrence-free follow-up is still under discussion. In the German multicenter SUCCESS trial we evaluated CA27.29 in 3754 patients before and after adjuvant chemotherapy and 2 and 5 years after primary diagnosis.

Methods

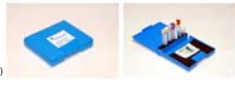
The SUCCESS Trial compares FEC-Docetaxel (Doc) vs. FEC-Doc -Gemcitabine (Doc-G) regime and two vs. five year treatment with Zoledronat in patients with primary breast cancer (N+ or high risk N-).

A competitive immunoassay is used for the detection of CA 27.29, a specific part of the MUC1 coded glycoprotein. The labeled antibody binds to an 8-amino acid sequence, which corresponds to amino acids Ser-Ala-Pro-Asp-Thr-Arg-Pro-Ala. The combination of the labeled B27.29 antibody and the solidphase antigen purified from breast cancer cells forms a competitive assay with a decreasing exponential doseresponse curve. CA27.29 has been measured with ST AIA-PACK CA27.29 reagent using MUC-1 for AIA-600II (Tosoh Bioscience, Tessenderlo, Belgium). The cutoff for positivity of CA27.29 is >31 U/ml.



Peripheral Blood Sampling

- Before start of chemotherapy
- After completion of chemotherapy (before the start of endocrine and zoledronate treatment)
- Two years after completion of chemotherapy
- Five years after completion of chemotherapy



Results

In 2807 primary breast cancer patients CA27.29 has been prospectively evaluated before and after chemotherapy. 22% of all patients had a marker >31 U/ml (n=587, mean 19.00, range 3.04-410) before and 39% (n=1058, mean 23.34, range 2.70-330) after chemotherapy. After a median follow-up period of 18 months 138 patients developed a recurrence of their disease. 12% (n=17) of patients with recurrent disease had before chemotherapy a marker >31 U/ml (mean 28.08, range 4.95-410). After completion of chemotherapy 16% of patients (n=22) had a CA27.29 marker >31 U/ml (mean 21.7, range 5.35-330). 7% (n=10) had shown positivity of CA27.29 before and after therapy. 5% (n=07) of patients changed from positive to negative (cutoff for CA27.29) afterwards. 80% (n=109) were negative before and after therapy, whereas 8% (n=12) became positive after treatment.

There is no significant difference in positivity of CA27.29 between Patients with an onset of disease recurrence in the first year (n=38), second year (n=68), the third year (n=24) after chemotherapy and all other prospectively evaluated patients with primary breast cancer (n=2784).

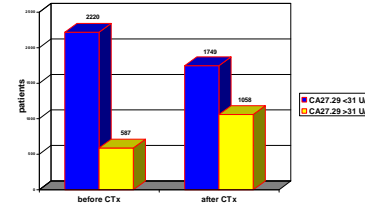
Before chemotherapy treatment the prevalence of elevated CA27.29 in all 2807 primary breast cancer patients was equally distributed between the FEC-Doc and the FEC-Doc-G arm. After chemotherapy 34% in the FEC-Doc arm showed an increased level vs. 45% in the FEC-Doc-G arm. The correlation analysis showed no significant coherence between hormonal status (ER: p<0.323; PR: p<0.078), HER2/neu status (p<0.308), Grading (p<0.565) and CA27.29 level. Tumor size (p<0.020) and the nodal status (p<0.022) were significant associated with CA27.29 levels.

Conclusions

This marker will be useful for treatment monitoring; first of all because a close relation between CA27.29 and tumor mass at primary diagnosis is evident. But only further results of the SUCCESS-trial, especially the evaluation of CA27.29 blood level at follow-up examination 2 years and 5 years after chemotherapy will improve the prognostic relevance of this marker.

SUCCESS in breast cancer treatment

CA27.29 before and after chemotherapy



Follow up 18 months after chemotherapy 138pts with recurrence of disease

	before CTx	after CTx
CA 27.29 >31U/ml	17	22

	before CTx	after CTx
07 pts CA27.29 > 31 U/ml	(+)	CA27.29 < 31 U/ml (-)
109 pts CA27.29 < 31 U/ml	(-)	CA27.29 < 31 U/ml (-)
12 pts CA27.29 < 31 U/ml	(-)	CA27.29 > 31 U/ml (+)
10 pts CA27.29 > 31 U/ml	(+)	CA27.29 > 31 U/ml (+)

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References

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