Background: In early stage breast cancer patients, with axillary lymph node metastasis, the 70-gene signature, MammaPrint® (MP) identifies patients with a High or Low Risk of distant breast cancer (BC) recurrence. For MP Low Risk (G=enomic)-low) in patients with up to 3 positive lymph nodes (N1—3), the MINDACT trial (Cardoso, NEJM 2016) showed that it might be safe to forgo adjuvant chemotherapy. Here we evaluated the prognostic value of MP at 10 years follow-up in patients with lymph node positive early stage BC.

Methods: Between 2004 and 2006 812 women with early stage BC participated in the observational RASTER trial (Bueno de Mesquita, Lancet Oncol, 2007). 181 patients were node positive and not included in the primary analysis, 176 of them gave consent for future research. On 164 tumor samples (FFPE) MP was performed retrospectively. Survival data was collected and samples were allocated to clinical high (C-high) or C-low risk as used in MINDACT. Patients with over 3 axillary lymph node metastases (N4+) were all considered C-high. 10-year distant-recurrence-free-interval (DRFI) was compared between subgroups based on the MP and clinical assessment.

Results: In 3 patients the clinical assessment could not be determined. Over 95% of patients received chemotherapy. 82.9% (136/164) of tumors were ER-positive and 18.3% (30/164) of patients had N4+. MP identified 47% (n = 77/164) as Low Risk, including 16.9% (13/77) with N4+. 10-year DRFI in patients N1-3 and G-Low or G-High was 94.9% and 80.7% respectively (HR 4.7; 95%CI 1.3—16.2). With the clinical assessment 13.7% (n = 22/161) were low risk, only one was diagnosed with distant BC recurrence. 10-years DRFI was 94.4% in C-low and 85.8% in C-high (HR 3.7 95%CI 0.5—28.5). In N4+ 10-years DRFI was 69.7%. Combining the clinical assessment with MP risk assessment in patients N1-3 the 10-years DRFI in clinical high risk patients was 95.2% for G-Low (n = 44) and 79.6% for G-High (n = 65) (HR 4.83 95%CI 1.1—21.4).

Conclusions: We again confirm the prognostic value of Mammprint® BC patients with axillary lymph node involvement after 10 years follow up. In N1-3 patients with clinical high risk, MP can identify a subgroup with excellent prognosis after standard adjuvant systemic therapy.

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