Breast cancer biomarkers in clinical testing: analysis of a UK NEQAS ICC & ISH database containing results from 199 300 patients.

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Abstract

We describe a collated data set of results from clinical testing of breast cancers carried out between 2009 and 2016 in the United Kingdom and Republic of Ireland. More than 199 000 patient biomarker data sets, together with clinicopathological parameters were collected. Our analyses focused on human epidermal growth factor receptor-2 (HER2), oestrogen receptor (ER) and progesterone receptor (PR), with the aim of the study being to provide robust confirmatory evidence on known associations in these biomarkers and to uncover new data on previously undescribed or unconfirmed associations, thus strengthening the evidence-base in clinical breast cancer testing. Overall, 13.1% of tumours were HER2-positive; 10.6% in ER-positive tumours, and 25.5% in ER-negative tumours. Higher rates of HER2 positivity were significantly associated with patient age <56 years versus age ≥56 years, symptomatic versus screen-detected tumours, testing of involved axillary node versus primary breast cancer, invasive ductal carcinoma (not otherwise specified) versus other histological types, higher histological grade, increasing tumour size, increasing nodal involvement, ER-negative versus ER-positive tumour status, PR-negative versus PR-positive tumour status. Where ER status was known, 82.7% of tumours were ER-positive; 80.9% in women age <56 years, and 83.6% in those age ≥56 years (ER-positive cut-off ≥1.0% positive tumour cells or equivalent). Where PR status was known, 64.9% of tumours were PR-positive; 65.8% in women age <56 years, and 64.4% in women age ≥56 years (PR-positive cut off ≥10.0% or equivalent). These analyses of clinical test results provide contemporary benchmarking data for HER2, ER and PR positive rates.

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