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HER2 amplification measurement in breast cancer tissues by droplet digital PCR and fluorescence *in situ* hybridization

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Human epithelial growth factor receptor 2 (HER2) status in breast cancer is an important biomarker with diagnostic, prognostic, and therapeutic impacts. Immunohistochemical analysis (IHC) and fluorescence *in situ* hybridization (FISH) are the two standard methods recommended by ASCO/CAP to assess HER2 overexpression/amplification. In FISH assay, chromosome 17 centromere (CEP17) has been used as the reference control to determine HER2/CEP17 ratio. However, misclassification can occur when HER2 is co-amplified with CEP17. Droplet digital PCR (ddPCR) is potentially an alternative technique to achieve a higher throughput capability and may yield a more accurate diagnosis of HER2 amplification. Therefore, in this study, we sought to quantify HER2 amplification in 31 frozen breast cancer tissues by employing ddPCR assays using the human eukaryotic translation initiation factor 2C1 (EIF2C1) gene as the reference control. HER2 status of these 31 samples had been determined by FISH. The results showed that HER2 status determined by ddPCR using HER2/EIF2C1 ratio was in good concordance with HER2 status determined by FISH using HER2/CEP17 ratio, the concordance rate 87.1% (27/31), kappa=0.719. The sensitivity and specificity of ddPCR assays were 90% (9/10) and 85.7% (18/21), respectively. The median HER2/EIF2C1 copy number ratio in HER2 amplified cancers (6.55, range 1.3-17.3) was significantly higher than in HER2 non-amplified cancers (1.05, range 0.6-3.6, $p=0.000$). This study demonstrated that ddPCR using EIF2C1 as the alternative reference control has the potential to accurately assess HER2 amplification in frozen breast cancer tissues.

Biography

Anchalee Tantiwettrueangdet has completed her Master's degree from Mahidol University. She is the research scientist of the research center of Ramathibodi Hospital. Her research interest includes: molecular biomarker in breast cancer and HCC.

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