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CORRESPONDENCE

Are you treating ypN0 patient with adjuvant abemaciclib?

The results of the monarchE trial[1] established a new standard of care for the adjuvant treatment of early high-risk hormone receptor (HR)-positive, HER2-negative breast cancer. Adding abemaciclib to adjuvant endocrine therapy reduced the risk of developing an invasive disease-free survival event by 30% and experiencing distant relapse by 31%, at 3 years. On these bases, the European Medicines Agency (EMA) approved the use of abemaciclib for the adjuvant treatment of adult patients with HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence.[2] 'High-risk' has been defined according to the inclusion criteria of cohort 1 of the monarchE trial: either four or more positive axillary lymph nodes or one or three positive lymph nodes and at least tumor size $\geq$5 cm or histological grade 3. Nevertheless, this indication could be easily misinterpreted. It is crucial to underline that the EMA indication of abemaciclib extends to patients with cytological tumor involvement at the time of initial diagnosis and that meet at least one of the following criteria: grade 3 or pathological primary invasive tumor size $\geq$5 cm. Moreover, tumor size in patients who receive neoadjuvant therapy can be evaluated on breast imaging, and importantly, patients with multifocal/multicentric tumors may be eligible based on the addition of diameters of the individual lesions.

In a recent research study, nodal pathological complete response (pCR) rate after neoadjuvant chemotherapy (NAC) in luminal breast cancer was 24.8%.[3] Therefore almost one out of four patients diagnosed with node-positive luminal breast cancer treated with NAC potentially achieve nodal pCR and could be erroneously excluded by adjuvant treatment with abemaciclib. Overall, 36% of the monarchE intent-to-treat population received NAC, but documentation of nodal pCR after NAC was not collected, and thus only pCR in the breast is reported.[4]

These considerations highlight the need for a proper clinical staging on locoregional lymph nodes at the diagnosis of disease and the importance of looking for cytological confirmation of all suspect nodes. All these additional criteria shall be stressed and spread to avoid missing any patient that could benefit from an effective adjuvant treatment and spare patients from unnecessary axillary dissections.

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