Calcifications Clusters – Impact of Contrast-enhanced Mammography Guided Biopsy Preliminary results

Dr. Valentina Iotti, MD

Suspicious calcifications are about 30-40% of recalls in mammographic screening. Despite the low positive predictive value (~15%) for ductal carcinoma in situ (DCIS) or invasive cancer, calcifications are more frequently sent to biopsy than other uncertain findings, due the difficulty in resolving the suspect lesions with ultrasounds or other imaging techniques. In this horizon, calcifications spread in an extended area or in multiple clusters could likely hide an invasive component, revealed as an upgrade from DCIS on biopsy to invasive carcinoma on surgical specimen (10-30%). To avoid undertreatment or the repetition of surgery (for sentinel lymph node biopsy), contrast-enhanced mammography (CEM) has been increasingly used for a precise pre-surgical planning of newly diagnosed DCIS.

The recent introduction of CEM-guided biopsy allows a rethinking of this workflow. Performing a CEM before the biopsy of suspicious calcifications would directly allow the target of the area of major malignancy (i.e. enhancement concomitant to calcifications), just being an anticipation of the pre-surgical CEM.

This is the rationale of BoCCE Trial (Biopsy of Calcifications under Contrast Enhancement guide, NCT04862429), a prospective randomized trial designed to compare the accuracy of CEM-guided biopsy (study arm) with the traditional stereotactic biopsy (control arm) in targeting the area of greatest malignancy/grade of the lesion, using the pathology of the surgical specimen as gold-standard. Secondarily, it compares the waiting time between enrolment and surgery, the proportion of patients undergoing preoperative CEM in the control arm, and the proportion of upgrading from biopsy to the results of the surgical specimen.

In the first year of the trial, a total of 54 patients have been enrolled among women with indication to perform a stereotactic biopsy for suspicious calcifications not mass-associated, 27 in the control arm (1 intention to treat) and 27 in the study arm. No adverse reaction, nor severe complications occurred. The biopsy revealed B5 in 41% of patients in the study arm and 42% in the control arm. In this small sample, only in the study arm invasive components have been diagnosed on biopsy. Except one, all patients diagnosed with B5 (DCIS) on biopsy in the control arm underwent a pre-surgical CEM. The waiting time in the two arms was comparable, showing that the planning of a pre-biopsy CEM does not slow down the workflow. Ten patients per arm underwent surgery due to malignancy, with no upgrade from DCIS G1/G2 (in pre-operative biopsy) to DCIS G3 in surgical specimen.

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