TPS627 Poster Session

MELODY: A prospective non-interventional multicenter cohort study to evaluate different imaging-guided methods for localization of malignant breast lesions (EUBREAST-4/iBRA-NET/AGO-B-062, NCT 05559411).

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Background: In the last decades, the proportion of breast cancer patients receiving breast-conserving surgery has increased, reaching 70-80% in developed countries. In case of non-palpable lesions, surgical excision requires some form of breast localization. While wire-guided localization has long been considered gold standard, it carries several limitations, including logistical difficulties, the potential for displacement and patient discomfort, and re-excision rates reaching 21% (in DCIS up to 30%). Other techniques (radioactive seed or radio-occult lesion localization, intraoperative ultrasound, magnetic, radiofrequency, and radar localization) have been developed with the aim of overcoming these disadvantages. However, comparative data on the rates of successful lesion removal, negative margins, and re-operations are limited. In most studies, the patient perspective, addressing e.g. discomfort and pain, has not been evaluated. The aim of MELODY (MEthods for LOcalization of Different types of breast lesions) is to evaluate different imaging-guided localization methods with regard to oncological safety, patient-reported outcomes, surgeon and radiologist satisfaction and economic impact. **Methods:** The EUBREAST and the iBRA-NET have initiated the MELODY study to assess breast localization techniques and devices from several perspectives (NCT05559411, http://eubreast.org/melody). MELODY is a prospective intergroup cohort study which enrolls female and male patients. planned for breast-conserving surgery with imaging-guided localization for invasive breast cancer or DCIS. Multiple or bilateral lesions and neoadjuvant chemotherapy are allowed. Primary outcomes are: 1) Intended target lesion and/or marker removal, independent of margin status on final histopathology, and 2) Negative resection margin rates at first surgery. Secondary outcomes are, among others: rates of second surgery and secondary mastectomy, Resection Ratio (defined as actual resection volume divided by the calculated optimum specimen volume), duration of surgery, marker dislocation rates, rates of marker placement or localization failure, patient-reported outcomes, rates of "lost markers", radiologist and surgeon satisfaction, and health economic evaluation of the different techniques. Target accrual is 7,416 patients. Enrollment started in January 2023. Until 24 January 2025, 3938 patients from 20 countries were enrolled in the study. The study is expected to complete patient enrollment in year 2026. The study will be conducted in 30 countries and is supported by the Oncoplastic Breast Consortium (OPBC), AWOgyn, AGO-B, SENATURK, the American Society of Breast Surgeons (ASBS) and the Korean Breast Cancer Study Group (KBCSG). Clinical trial information: NCT05559411. Research Sponsor: None.