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MELODY: A prospective non-interventional multicenter cohort study to evaluate different imaging-guided methods for localization of malignant breast lesions (EUBREAST-4/iBRA-NET, NCT 0555941 1)

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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%. Other techniques (radioactive seed or radio-occult lesion localization, intraoperative ultrasound, magnetic, radio-frequency 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 the majority of studies, the patient's perspective with regard to discomfort and pain level 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, and surgeon and radiologist satisfaction.

Prospective Clinical Trial Design: 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).

Specific Aims: 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, comparison of patient-reported outcomes, rates of "lost markers" and diagnostician/radiologist's and surgeon's satisfaction as well as the health economic evaluation of the different techniques.

Statistical Methods: The study is defined as a non-inferiority study with two primary endpoints and six comparisons for each endpoint. Each localization device/method will be compared to the wire-guided localization considered standard. Each commercially available device will be analyzed in a separate cohort.

Target accrual: 7,416 patients. Enrollment started in January 2023. The study will be conducted in 30 countries and is supported by the Oncoplastic Breast Consortium, AWOgyn, AGO-B, SENATURK and Korean Breast Cancer Study Group. Financial support will be provided by Endomag, Merit Medical, Sirius Medical and Hologic.

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Conflict of interest:

Corporate-sponsored Research: EndoMag, Mammotome, Sirius Medical, Gilead, ExactSciences, Endomag, Merit Medical, Holigic.

Other Substantive Relationships: Roche, Novartis, Pfizer, pfm, Eli Lilly, Onkowissen, Seagen, AstraZeneca, Eisai, Amgen, Samsung, Canon, MSD, GSK, Daiichi Sankyo, Gilead, Sirius Medical, Syantra, resitu, Pierre Fabre, ExactSciences.

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