

Intra-individual comparison between Contrast-Enhanced Spiral Photon-Counting Dedicated Breast CT and MRI for Breast Cancer Detection

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Abstract

Objectives To prospectively compare the diagnostic performance of contrast-enhanced spiral photon-counting dedicated breast CT (CE-SBCT) with breast MRI for breast cancer detection.

Materials and Methods In this single-centre substudy as part of the prospective multicentre trial "IdBCT-MRI-C" (Trial registration ClinicalTrials.gov: NCT05989022, registered 08/14/2023), 136 women (mean age 53 ± 13 years) underwent CE-SBCT and MRI within one week (December 2023–December 2025). Three blinded readers independently assigned BI-RADS categories per breast (265 total). Diagnostic performance was evaluated using ROC analysis, multireader–multicase (MRMC) mixed-effects modelling, conditional logistic regression (CLR), and case-resampling bootstrap analysis (1,000 iterations). Histopathology and clinical imaging served as the reference standard.

Results Among 265 breasts, 67 malignancies were confirmed. CE-SBCT and MRI demonstrated equivalent diagnostic performance (pooled AUC 0.92 for both; MRMC $\beta = 0.001$, $p = 0.94$; CLR Odds Ratio = 1.02, $p = 0.91$). Pooled bootstrap-derived sensitivity, specificity, PPV, and NPV were 93%, 93%, 74%, and 99% for CE-SBCT, and 91%, 92%, 71%, and 97% for MRI, respectively. In dense breasts (ACR C/D; $n = 168$, 35 malignancies), sensitivity and specificity were 92% for both modalities. Inter-reader agreement was substantial (CE-SBCT $\kappa = 0.76$; MRI $\kappa = 0.81$). Background parenchymal enhancement was lower on CE-SBCT than on MRI, despite strong inter-modality correlation (Spearman $\rho = 0.66$, $p < 0.0001$).

Conclusion CE-SBCT demonstrated diagnostic performance equivalent to MRI for breast cancer detection, including in dense breasts, with substantial inter-reader agreement.

Introduction

Mammography and digital breast tomosynthesis (DBT) are the cornerstones of breast cancer screening and diagnostic evaluation. However, these techniques are inherently limited by their two-dimensional or pseudo-3D nature, which often results in the masking of malignant lesions by overlapping fibroglandular tissue. This limitation is most pronounced in women with dense breast tissue (BI-RADS categories C and D), where sensitivity is significantly reduced [1], a concern that is amplified in individuals with additional breast cancer risk factors [2]. Furthermore, the requirement for breast compression during mammography can cause substantial patient discomfort, potentially leading to reduced screening compliance [3, 4, 5].

Contrast-enhanced imaging techniques, which leverage tumor neoangiogenesis rather than morphological changes alone, have significantly improved detection rates. Contrast-enhanced MRI is currently the most sensitive modality for breast cancer detection and is the preferred supplemental imaging tool for high-risk women and those with dense breasts [6].

Contrast-enhanced mammography (CEM) and CE-DBT offer improved detection over standard mammography but still rely on breast compression and do not provide true 3D volumetric data [7]. Recently, contrast-enhanced spiral photon-counting dedicated breast CT (CE-SBCT) has emerged as a potential alternative, providing 3D reconstructions that facilitate lesion characterization [8, 9, 10, 11, 12]. This technology utilizes a direct-converting photon-counting detector to provide high spatial resolution images (0.15 mm isotropic voxels) at radiation doses comparable to mammography [10,11,12] without the need for breast compression [8]. Calcifications suggestive of DCIS can be visualized [13,14], and iodinated contrast agents enhance malignant lesions [8,15]. CE-SBCT has been shown to detect malignant breast lesions at a higher rate than mammography, regardless of breast density [15].

The objective of this study was to assess the diagnostic performance of CE-SBCT in comparison with MRI in a prospective, intra-individual cohort. We hypothesized that CE-SBCT would achieve diagnostic performance comparable to MRI for breast cancer detection, particularly in the challenging context of dense breast tissue.

Materials and Methods

Study Design and Participants

This single-center prospective substudy was performed in women who participated in the IRB-approved, prospective, non-randomized, intra-individual multicenter trial "IdBCT-MRI-C" (ClinicalTrials.gov ID: NCT05989022). All participants gave written informed consent.

AB-CT– Advanced Breast-CT GmbH (Erlangen, Germany) funded the multicenter trial. While two authors were employees of the sponsor, the non-employee authors maintained full control of the data and analysis.

Between December 2023 and December 2025, 136 women (mean age 53 ± 13 years) were enrolled for the local study. Inclusion criteria were an indication for supplemental breast MRI following mammography or ultrasound (e.g., for clinical problem solving, staging, or high-risk surveillance). Exclusion criteria included age under 18 years, BRCA1/2 mutation carriers (to avoid additional radiation exposure), and contraindications to contrast agents or MRI. To ensure comparability, MRI and CE-SBCT were required to be performed within one week of each other.

CE-SBCT Image Acquisition

Dedicated breast CT was performed using a spiral photon-counting scanner (nu:view, AB-CT– Advanced Breast-CT GmbH, Erlangen, Germany). SBCT has received European conformity certification and is approved for clinical use in the European Union and other regions worldwide. Scans were acquired at a fixed tube voltage of 60 kVp and a tube current of 32 mA [9]. A non-ionic iodinated contrast agent

(iohexol, 350 mg I/mL) was administered at a dose of 1.1 mL/kg body weight, and a rate of 3 mL/s. Imaging commenced 70 seconds after the start of injection.

SBCT acquisition involves the patient lying in a prone position with the breast pendant freely through an aperture in the examination table into the scanner bore. Each breast is scanned separately in a spiral acquisition without compression. The spiral trajectory (2 seconds and 1000 projections per rotation) results in an acquisition time of 7–12 seconds per breast. The total procedure time for both breasts is max. 3 minutes, including 70 seconds waiting time after contrast injection and time for change of breast side. Standard reconstructions are performed in the coronal plane with isotropic voxels of 0.15 mm³ using a filtered back-projection reconstruction algorithm.

Reported mean absorbed glandular radiation dose of SBCT is in the range of 5 to 7 mGy [10,11,12].

Post-processing of CE-SBCT images was done using Vitrea medical imaging software version 7.16.0.703 (Canon Medical Systems). Axial and sagittal 1 mm thick multiplanar reconstruction (MPR) slices were reconstructed from the isotropic voxels and a 3D Maximum-Intensity-Projection (MIP) reconstruction, encompassing the entire imaging volume. All reconstructions and the native coronal images were sent to the PACS-system.

MRI Image Acquisition

Breast-MRI was performed on a 3T Philips Ingenia Elition scanner using a 16-channel sense breast-coil. The full diagnostic multiparametric protocol included T2-weighted Dixon sequences (with and without fat suppression), diffusion-weighted imaging (b-values: 0, 500, 1000), and dynamic contrast-enhanced 3D gradient-echo Dixon sequences (6 phases, 65 sec/phase). Gadolinium-based contrast agent (gadoterate meglumine 0.1 mmol/kg) was administered intravenously at 3 mL/sec, followed by a saline flush.

Reader Study

CE-SBCT

Images were independently evaluated in PACS according to BI-RADS (1–5) per breast by three blinded readers (TK, JS, and MW) with 1 to 4 years of experience in CE-SBCT. Readers were blinded to clinical history and prior imaging. Since lesion characterization in CE-SBCT has not yet been defined in the BI-RADS Atlas, raters used the MRI BI-RADS score. The raters could use the reconstructed images in PACS including axial and sagittal MPR and 3D MIP images.

MRI

After a washout period of at least 8 weeks in between, the MRI images were independently evaluated in PACS according to BI-RADS (1–5) per breast by the same readers (again blinded to clinical history and

prior imaging) with 2 to 25 years' experience in breast MRI.

For both modalities, the BI-RADS-scores were dichotomized in test-positive (malignant, BI-RADS ≥ 4) and test-negative (benign, BI-RADS 1–3).

Reference standard The reference standard for diagnosis was a combination of the results of clinical imaging and histologic diagnosis of a specimen from surgery, core biopsy, or vacuum-assisted biopsy under US, stereotactic or MRI guidance. Results of the clinical MRI-report with BI-RADS 1 or 2 were considered benign and lesions classified as BI-RADS 3 on clinical MRI that did not undergo biopsy were confirmed as benign via 6–12 month follow-up.

Breast density and background parenchymal enhancement (BPE) Breast density was classified according to BI-RADS (A–D) based on prior mammography reports and dichotomized in non-dense (fat or scattered fibroglandular densities) and dense (heterogeneously dense or dense). BPE was graded on a 4-point scale (1: minimal to 4: marked) for both MRI (based on the clinical report of the MRI-study) and CE-SBCT (assigned by a single observer, MW, using similar criteria as for MRI according to BI-RADS).

Statistical analysis

The primary outcome was diagnostic performance of MRI and CE-SBCT for breast cancer detection, based on dichotomized BI-RADS ratings from three readers (BI-RADS 1–3 = benign; BI-RADS 4–5 = malignant). ROC analysis was first performed to obtain AUC values. Because each breast was interpreted by three readers under both modalities, observations were correlated. Therefore, two complementary multireader approaches were used: **Multireader-multicase (MRMC) analysis**. A linear mixed-effects ANOVA model was fitted to the binary correctness outcome (1 = correct, 0 = incorrect), with modality as a fixed effect and reader and case as random intercepts to account for between-reader and between-case variability. **Conditional logistic regression (CLR)**. CLR was then used for a paired, within-case comparison [16]. By conditioning on case, CLR evaluates whether MRI provides a higher probability of correct classification than CE-SBCT for the same case. All reader interpretations were included, and results were expressed as odds ratios (OR). Inter-reader-variability was assessed using Fleiss' kappa statistics and MRMC-variance analysis. Performance metrics (sensitivity, specificity, PPV, NPV) were estimated using case-resampling bootstrap analysis (1,000 iterations). For each bootstrap sample, paired MRI and CE-SBCT metrics and their differences (MRI – CE-SBCT) were calculated. Nonparametric 95% confidence intervals were derived from the 2.5th and 97.5th percentiles.

Subgroup analyses were performed by breast density (ACR A/B vs C/D) and BPE level (minimal/mild vs moderate/marked). Correlation between BPE on CE-SBCT and MRI was assessed using Spearman's rank correlation.

Sample size was estimated using McNemar's test for paired proportions. Assuming a conservative 30% discordance fraction [17] and aiming to detect a 10% difference in positive rates ($\alpha = 0.05$, power = 0.80), 260 breasts were required, corresponding to 130 participants.

All analyses were performed in R, using RStudio (Posit.co), with aid of AI-powered tool RTutor (2024 Orditus LLC). Two-sided $p < 0.05$ was considered statistically significant.

Results

Participant characteristics

The study flowchart is presented in Fig. 1. Out of the 144 women who initially provided informed consent, eight participants discontinued involvement for the following reasons: Two withdrew consent, one experienced unexpected claustrophobia during MRI (the CE-SBCT examination had not yet been performed), five were unable to complete both CE-SBCT and MRI within the required one-week interval due to logistical scheduling constraints.

This resulted in a final study cohort of 136 women (mean age 53 ± 13 years, range 23–79 years) who underwent both CE-SBCT and MRI within one week (median interval 3 days, range 0–7 days). Participant demographics and lesion characteristics are detailed in Table 1. All women had an indication for supplemental MRI after mammography or breast ultrasound: 114 for clinical problem solving, tumor staging, or surgical planning, and 22 for surveillance due to high risk and a dense mammogram. Malignant breast lesions were diagnosed in 64 participants, corresponding to 67 malignancies in 265 breasts, three women had bilateral disease. Cancer types included invasive ductal carcinoma (41), invasive lobular carcinoma (12), ductal carcinoma in situ (10), mucinous carcinoma (2), liposarcoma (1) and apocrine carcinoma (1). The majority of participants (63%) had dense breasts (39% ACR C, 24% ACR D), corresponding to 168 dense breasts and 97 non-dense breasts. Background parenchymal enhancement on CE-SBCT and MRI was strongly associated (Spearman's coefficient $\rho = 0.66$, 95% CI 0.59–0.72, $p < 0.0001$), but less prominent on CE-SBCT than on MRI. BPE was minimal on CE-SBCT in 65% of breasts (53% on MRI), mild in 20% (23% on MRI) moderate in 10% (15% on MRI), and marked in 5% (9% on MRI). On MRI, 19 of the 25 (76%) breasts with marked BPE were dense, while on CE-SBCT 13 breasts had marked BPE, of which 6 were dense (46%).

None of the participants had significant contrast-media adverse events.

Inter-Reader Agreement Complete agreement (all three readers assigning the same BI-RADS category) for CE-SBCT was observed in 168 of 265 breasts (63%). In 82 breasts (31%), two of three readers agreed, and in only 15 breasts (6%) all three readers assigned different categories. For comparison tests, the BI-RADS scores were dichotomized in test-positive (BI-RADS 4 and 5) and test-negative (BI-RADS 1–3). Inter-reader agreement among the three blinded readers for BI-RADS assessment was substantial, with a Fleiss' kappa of 0.76 (95% CI: 0.71–0.81) for CE-SBCT and 0.81 (95% CI: 0.733–0.869) for MRI. Variance analysis in the MRMC-analysis confirmed that most variability stemmed from case complexity, not reader inconsistency (case variance $\sigma^2 = 0.153$ vs reader variance $\sigma^2 = 0.039$).

Diagnostic Performance *Overall Performance*

Differences in BPE between sequentially scanned breasts did not affect results: reader accuracy was 0.93 for right breasts and 0.92 for left breasts (difference $\approx$ 1%).

ROC analysis showed substantial overlap between modalities, with pooled AUCs of 0.92 for both CE-SBCT (95% CI 0.90–0.94) and MRI (95% CI 0.90–0.95). Individual reader AUCs are shown in Fig. 2a and Supplement Table S1.

In the MRMC mixed-effects model, MRI and CE-SBCT demonstrated no significant difference in overall performance ($\beta = 0.001$, $SE = 0.029$; $t \approx 0.08$; $p = 0.94$), indicating equivalent diagnostic accuracy. Conditional logistic regression likewise showed no modality effect. The coefficient for MRI vs CE-SBCT was 0.024 (OR = 1.02; 95% CI 0.67–1.58; $p = 0.91$), demonstrating no detectable difference in correctness after conditioning on case difficulty.

Bootstrap case-resampling (1,000 iterations) confirmed high and nearly identical diagnostic accuracy for both modalities (Fig. 2b; Table 2). Sensitivity MRI vs CE-SBCT was 91% vs 93% (difference – 2%; 95% CI – 8 to + 5%), and specificity 92% vs 93% (difference – 1%; 95% CI – 8 to + 5%). PPV MRI vs CE-SBCT was 71% vs 74% (difference – 2%; 95% CI – 7 to + 3%) and NPV 97% vs 99% (difference – 2%; 95% CI – 2 to + 1%). All differences were small, with confidence intervals crossing zero, indicating equivalent diagnostic performance across modalities. *Performance Stratified by Breast Density* Also in dense breasts (ACR C/D; $n = 168$, 35 malignancies), MRI and CE-SBCT showed high and nearly identical performance (Table 3). Sensitivity was 92% for both modalities (difference – 1%; 95% CI – 16% to + 3%), and specificity was 92% for both (difference – 1%; 95% CI – 5% to + 3%). PPV was 76% for both (difference – 3%; 95% CI – 5% to + 3%), and NPV remained high (97% vs 98%, difference – 1%; 95% CI – 3% to 0%).

Sensitivity differences (MRI – CE-SBCT) had wide uncertainty (– 16% to + 3%), indicating that moderate differences cannot be excluded. Specificity was estimated more precisely (– 5% to + 3%), suggesting only minor differences are plausible. PPV was moderate but its interval crossed zero. NPV was consistently high for both modalities, showing that MRI and CE-SBCT effectively rule out malignancy even in dense tissue.

Error Analysis: False negatives were rare across density categories and readers: 18 for MRI and 15 for CE-SBCT out of 402 possible positive ratings (4% for both modalities). False positives were more frequent, especially in dense breasts, with 49 on MRI (39 dense) and 45 on CE-SBCT (36 dense). The overall error rate was 4.2% for MRI and 3.7% for CE-SBCT.

There were 79 discordant modality pairs (MRI+/CE-SBCT – or MRI–/CE-SBCT+), a 34% discordance ratio (79/265). In one case, all readers rated CE-SBCT true negative and MRI false positive. In two cases, all readers rated CE-SBCT true positive and MRI false negative (MRI BI-RADS 3 lesions). No case showed CE-SBCT positive with MRI BI-RADS 1–2, indicating no verification bias.

In two cases, all readers rated MRI true positive and CE-SBCT false negative. These were due to a lesion in the axillary tail (outside CE-SBCT field-of-view) and a minimally enhancing lobular carcinoma.

Illustrative Cases Figures 3 to 6 illustrate representative cases, in three of them the masses were not or incompletely visible on mammography. Sagittal and axial 3D-MIP reconstructions of CE-SBCT mimic mammographic projections, facilitating image-interpretation. Additional volume renderings in Fig. 4 illustrate the high resolution of the CE-SBCT images.

Discussion

This prospective intra-individual study shows that contrast-enhanced spiral photon-counting breast CT (CE-SBCT) provides diagnostic performance equivalent to MRI for breast cancer detection. Across all statistical analyses—multireader-multicase modelling, conditional logistic regression, ROC, and bootstrap—no significant modality differences were observed. Inter-reader variability was low, indicating consistent interpretability.

These findings suggest that CE-SBCT may represent a clinically relevant alternative to breast MRI for contrast-enhanced breast imaging.

Diagnostic performance was maintained in dense breasts, with sensitivity, specificity, and NPV all > 90%. Given the reduced mammographic sensitivity and increased cancer risk associated with dense breasts, the high NPV of CE-SBCT is clinically relevant for ruling out malignancy.

The comparable performance of CE-SBCT and MRI is biologically plausible because both techniques exploit tumor-associated angiogenesis through the administration of intravenous contrast agents. Although image contrast is generated through different physical mechanisms—iodine-related X-ray attenuation in CE-SBCT and gadolinium-induced T1 shortening in MRI—both primarily visualize tumor vascularity rather than morphological distortion alone. The close agreement between modalities supports the concept that CE-SBCT can provide functional information comparable to breast MRI, while simultaneously offering very high isotropic spatial resolution.

Notably, background parenchymal enhancement (BPE) was less pronounced on CE-SBCT than on MRI, despite a strong correlation between the two modalities. Although the reasons for this finding remain speculative, differences in contrast pharmacokinetics, acquisition timing, and image formation likely contribute. In all participants MRI and CE-SBCT were performed within one week, in 50% on the same day. Menstrual cycle timing is therefore unlikely to have contributed to variations in BPE between CE-SBCT and MRI. Reduced BPE may represent a practical advantage because marked BPE is a recognized source of false-positive findings and decreased interpretive confidence on breast MRI. Future studies should investigate whether lower BPE on CE-SBCT translates into improved lesion conspicuity or reduced recall rates.

Clinical Implications

Dedicated breast CT is an emerging modality available in two technical implementations. The earlier clinically approved system uses cone-beam CT with a flat-panel detector [18] and has been validated for

breast cancer staging, showing strong agreement with mammography and MRI in assessing tumor size and extent [19]. The new SBCT-system used in this study employs spiral acquisition with a direct-converting photon-counting detector, offering high spatial resolution (0.15 mm isotropic voxels), low image noise, and absorbed radiation doses comparable to mammography.

Several features distinguish CE-SBCT from existing supplemental breast imaging modalities. Unlike contrast-enhanced mammography, CE-SBCT provides true three-dimensional isotropic imaging without tissue superposition and without breast compression. Compared with MRI, CE-SBCT offers shorter examination times, simpler workflow, and fewer contraindications related to metallic implants or claustrophobia. In the present study, CE-SBCT provided breast cancer detection performance comparable to MRI while maintaining a mean glandular radiation dose within the range reported for modern mammographic examinations. Together, these characteristics position CE-SBCT as a promising supplemental imaging modality, particularly for women with dense breasts and for patients who cannot tolerate or access MRI.

The findings should not be interpreted as evidence that CE-SBCT should replace MRI. Rather, CE-SBCT has the potential to expand the spectrum of contrast-enhanced breast imaging options. Future studies should determine its comparative effectiveness relative to abbreviated MRI, contrast-enhanced mammography, and digital breast tomosynthesis in screening and diagnostic populations. In addition, the development of CT-guided biopsy techniques [20,21,22] may further strengthen the clinical utility of dedicated breast CT by enabling a complete diagnostic pathway within a single imaging platform.

Limitations

Several limitations warrant consideration. First, diagnostic performance was analyzed on a per-breast basis, with bilateral observations included and within-patient correlation not explicitly modeled. We did not find any clinically significant difference in CE-SBCT performance between left and right breasts (despite the sequential imaging of both breasts). Second, this was an enriched diagnostic cohort with a high prevalence of malignancy, which limits direct extrapolation to screening settings. Third, although overall study power was adequate for the primary comparison, only 35 cancers were present in dense breasts, resulting in relatively wide confidence intervals for sensitivity estimates in this subgroup. Finally, dedicated breast CT remains subject to technical limitations in breast coverage; one false-negative examination resulted from incomplete inclusion of tissue in the axillary tail, highlighting a known challenge of prone breast CT systems.

Conclusion

CE-SBCT achieves MRI-level diagnostic performance with short (~ 3 min) exams and high-resolution isotropic 3D imaging. These advantages may broaden access to high-quality breast imaging, especially for women with dense breasts or MRI contraindications.

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Tables

Table 1 to 3 are available in the Supplementary Files section.

Figures

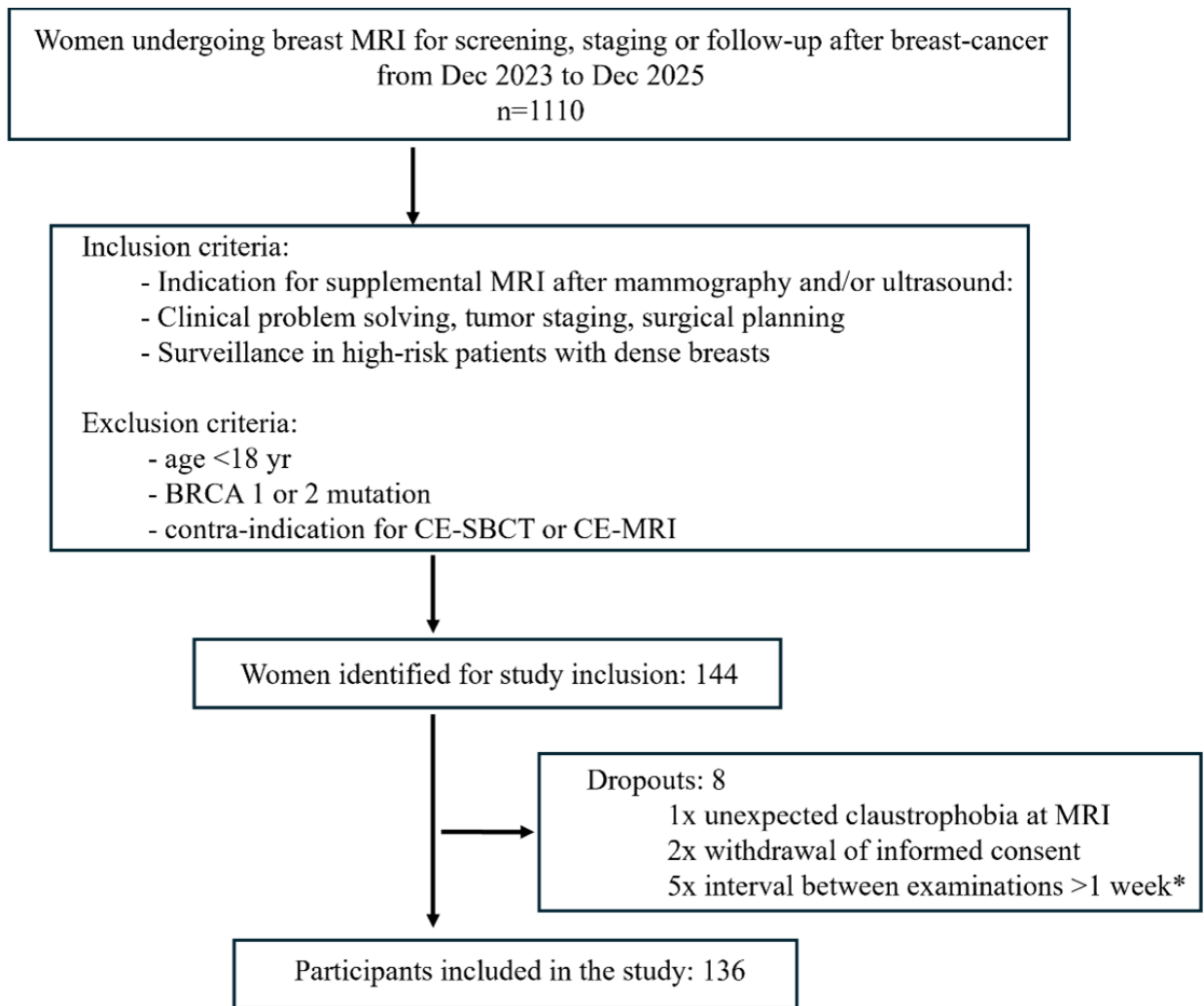


Figure 1

Study flowchart illustrating inclusion and exclusion criteria and imaging timeline. CE-SBCT and MRI were performed within 1 week for all participants.

* In five participants that gave informed consent, MRI and CE-SBCT could not be scheduled within 1 week due to logistic reasons

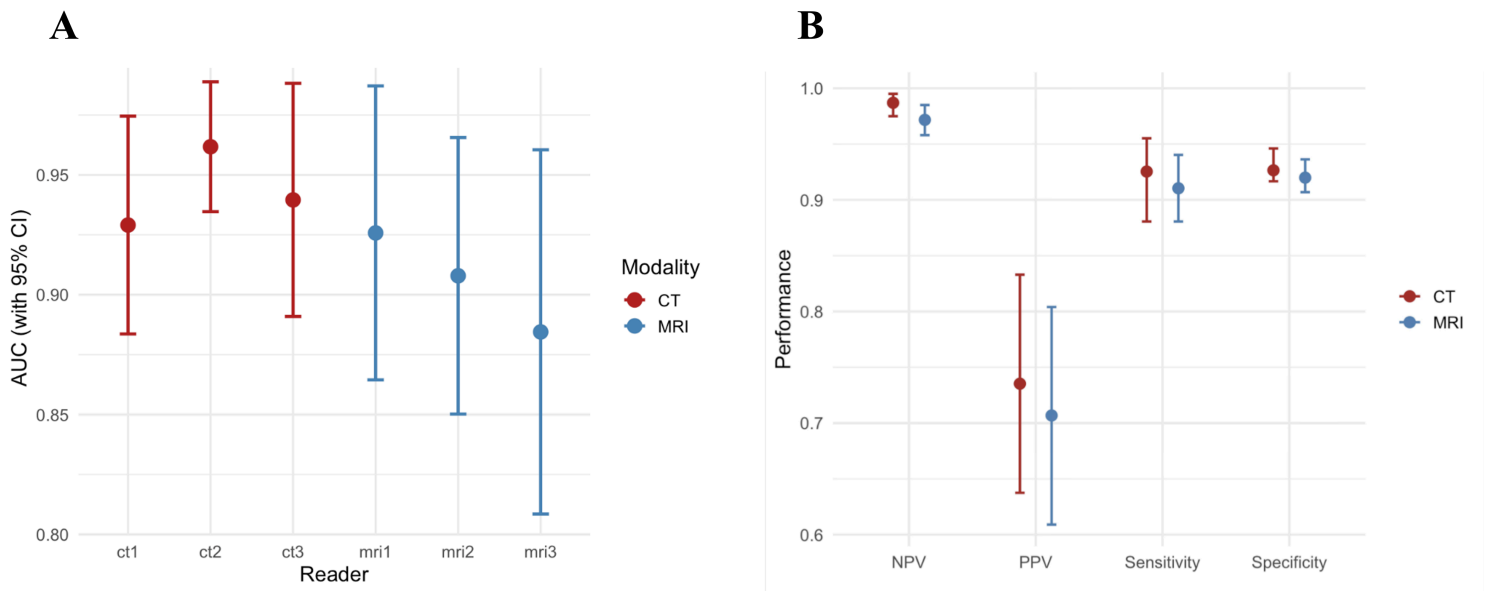


Figure 2

Performance plots of CE-SBCT and MRI in all breasts (n= 265)

A: areas-under-the curve (AUC) plots from ROC analysis for the three readers of the MRI and CE-SBCT images. Bars represent 95%CI-intervals

B: Performance metrics plot for MRI vs CE-SBCT from case-resampling bootstrap analysis, pooled data for the three readers. Bars represent 95%CI-intervals

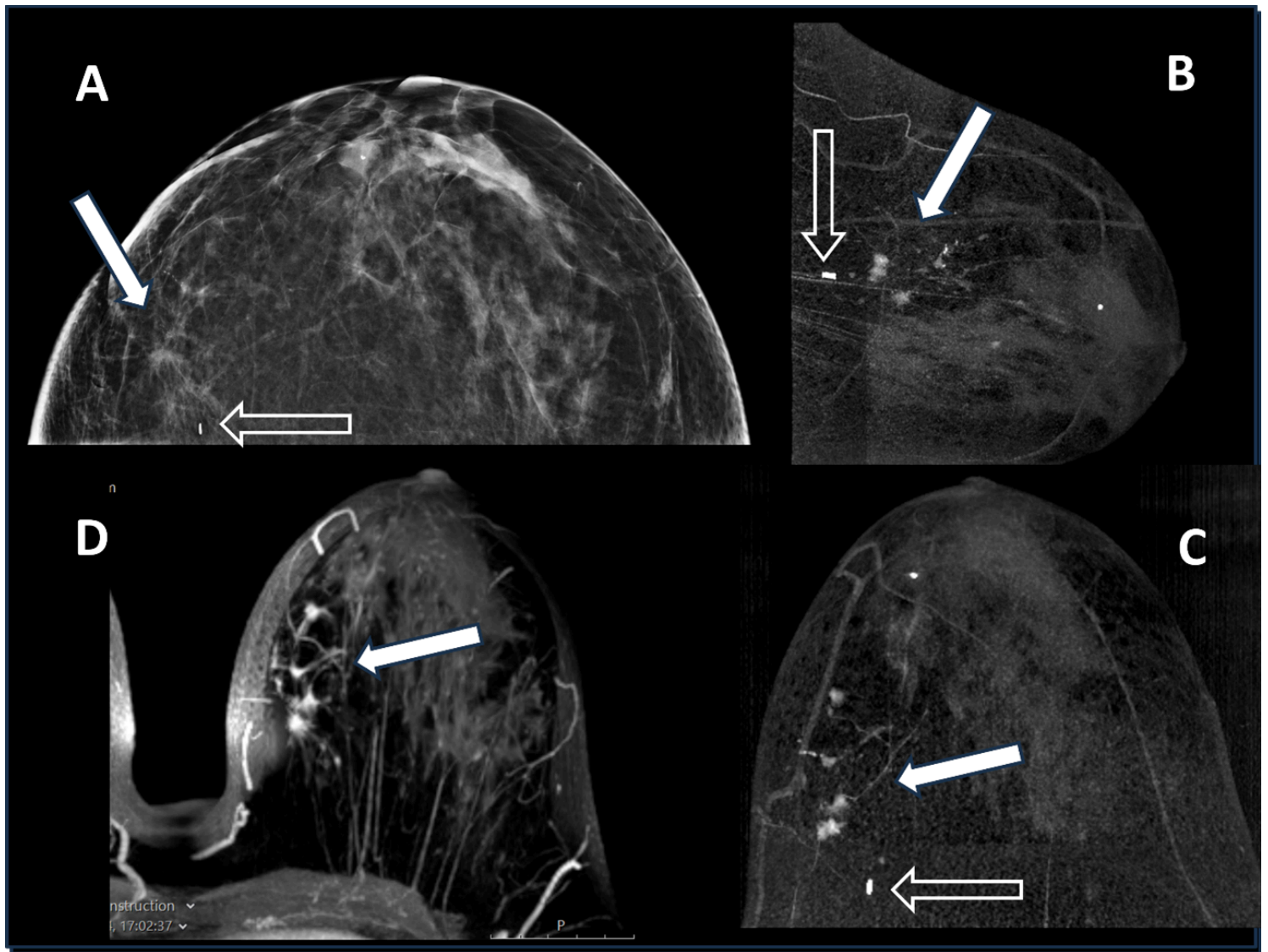


Figure 3

52-year old woman after US-guided biopsy of a small lesion medially in the left breast. Histology revealed NST gr 2. (A) CC-image of mammogram: suggestion of multiple small lesions (arrow), clearly visible on (B) axial and (C) sagittal 3D-MIP images of CE-SBCT and confirmed on axial MIP of dynamic contrast-enhanced MRI (D). A post-biopsy marker (open arrow) is visible on mammography and CE-SBCT, but not on MRI.

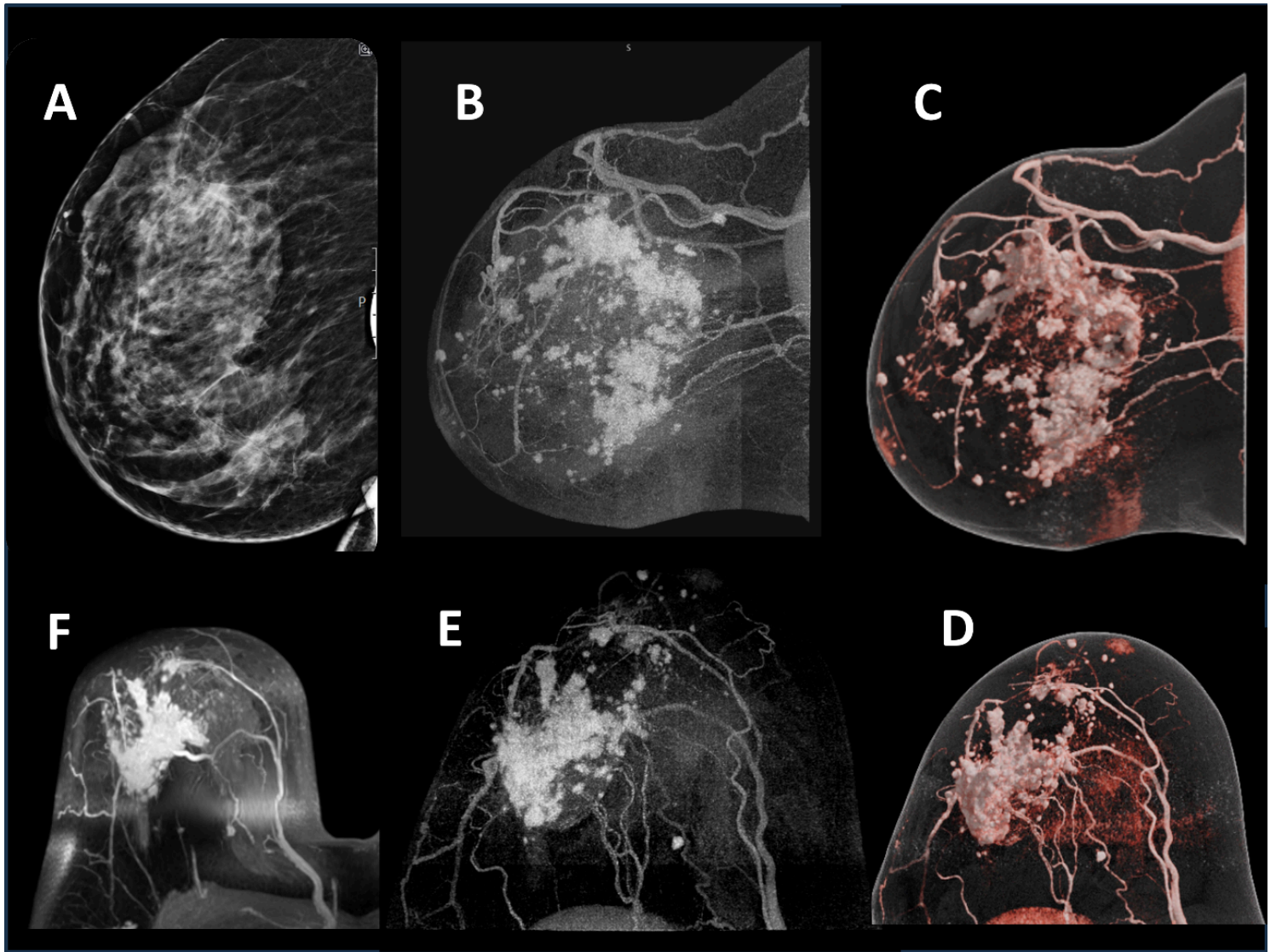


Figure 4

45-year-old woman with a palpable lesion in the right breast. (A) MLO mammogram of the right breast shows dense tissue but no mass. (B) Sagittal and (E) axial projections of the 3D-MIP of CE- SBCT and (F) axial MIP of dynamic contrast-enhanced MRI show a large area with multiple masses and satellite lesions in the right breast. C and D show sagittal and axial volume renderings of the CE-SBCT images.

Histology revealed invasive ductal carcinoma no special type, grade 1.

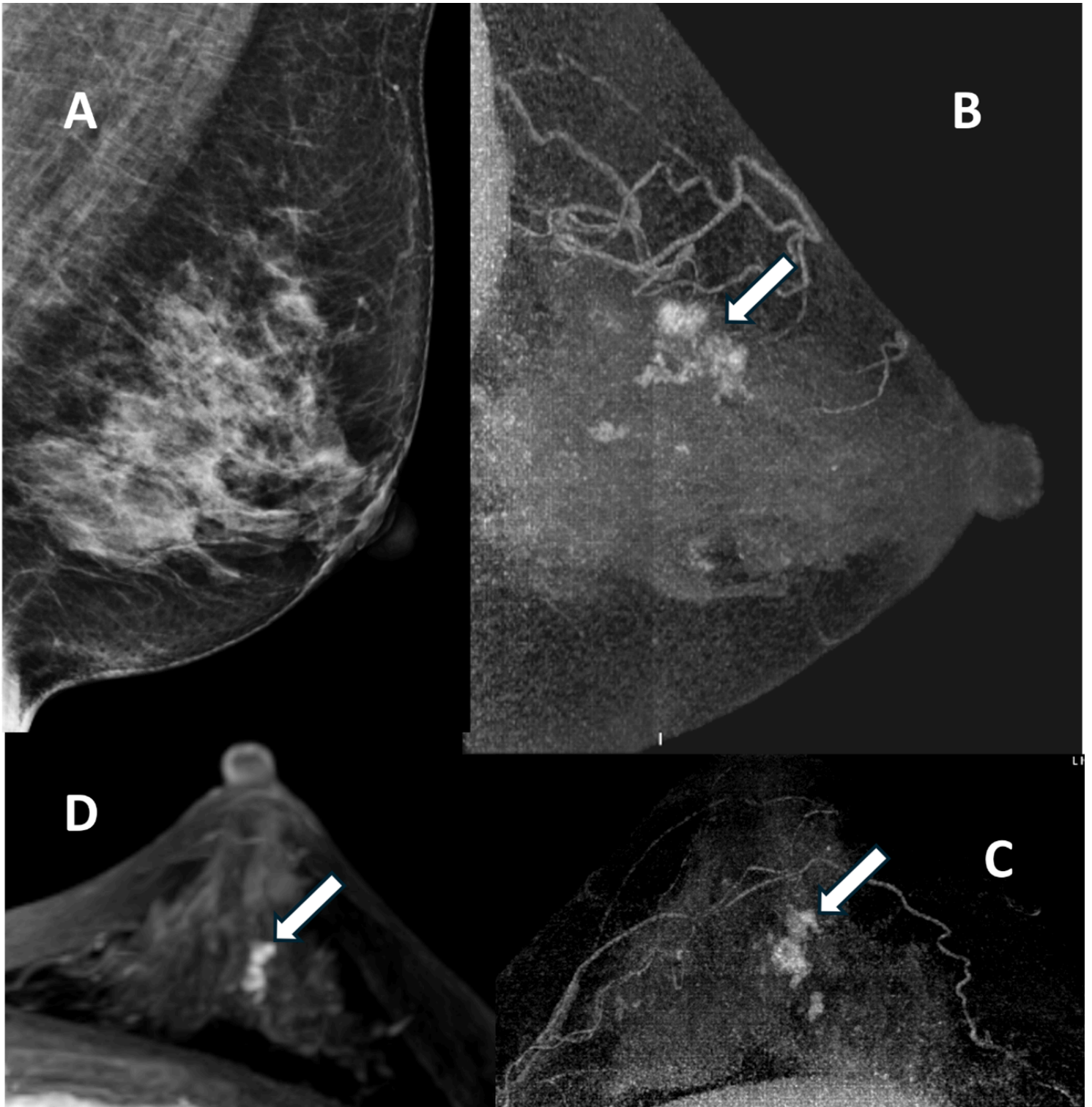


Figure 5

51-year-old woman with high familial breast cancer risk. (A) Mammogram shows heterogeneously dense tissue without abnormality. (B) Sagittal and (C) axial 3D-MIP projections from CE-SBCT reveal a 2 cm enhancing non-mass lesion (arrow) in the left breast. (D) Axial MIP from contrast-enhanced MRI confirms the lesion. Ultrasound-guided biopsy: ductal carcinoma in situ (DCIS) grade 2.

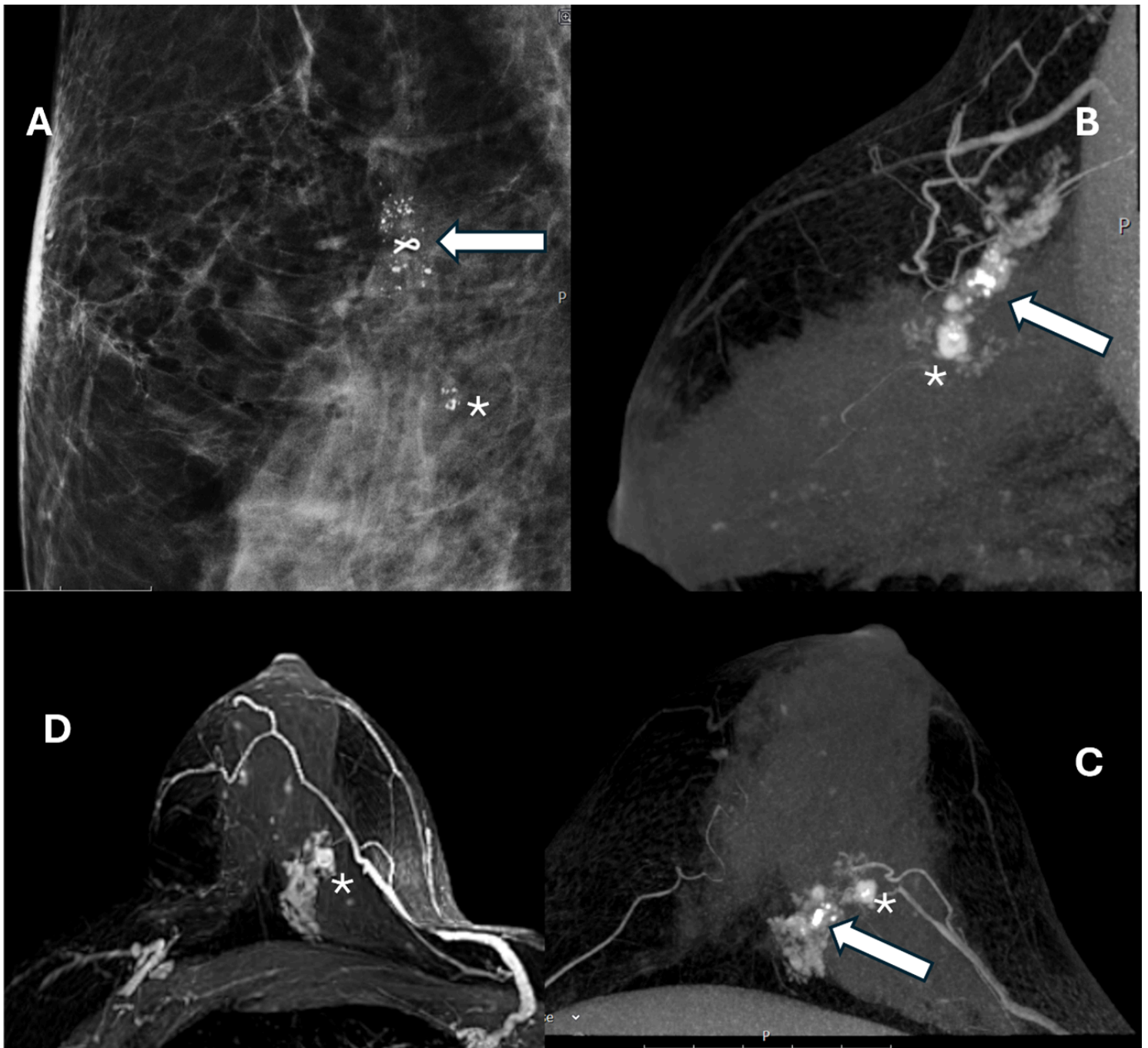


Figure 6

61-year-old woman with calcifications detected on screening mammogram. (A) Magnification view after stereotactic biopsy shows post-biopsy marker (arrow) and initial calcifications; an additional small group of calcifications is visible at 1 cm distance (asterisk). (B) Sagittal and (C) axial projections of the 3D-MIP images from CE-SBCT demonstrate a 3 cm enhancing non-mass lesion encompassing the marker and calcifications, as well as enhancement of the additional calcifications (arrow). (D) Axial MIP of contrast-enhanced MRI confirms similar lesion extent. Histology: invasive lobular carcinoma.

Supplementary Files

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- [Table3.docx](#)
- [SupplementTableS1.docx](#)
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