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Non-enhancing asymmetries on screening contrast-enhanced mammography: Is further diagnostic workup required?☆

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ABSTRACT

Objectives: Asymmetries on screening contrast-enhanced mammography (CEM) often lead to patient recall. However, in diagnostic settings, negative CEM has effectively classified these as normal or benign, questioning the need for further workup of non-enhancing asymmetries (NEAs).

Material and methods: A computational search of all screening CEM examinations performed between December-2012 and June-2021 was conducted to identify cases reporting NEAs. Their diagnostic workup was reviewed, and the positive predictive value for cancer was statistically compared to that of enhancing asymmetries on screening CEMs.

Results: During the study period, 97 cases of 106 NEAs were identified among 3,482 screening CEM exams (2.8 %). NEAs were classified as asymmetry (n = 83), focal asymmetry (n = 22), and global asymmetry (n = 1), with no cases of developing asymmetry. The mean size of NEAs was 1.0 ± 0.7 cm (range: 0.3–4.9 cm). Diagnostic workup for NEAs included additional mammographic views (AMV) (n = 63), AMV plus ultrasound (n = 30), AMV plus MRI (n = 1), and all three modalities (n = 3), leading to four biopsies. None of the NEAs were malignant on follow-up, as opposed to enhancing asymmetries ($P < 0.05$).

Conclusion: NEAs detected on CEM were relatively uncommon and were usually investigated with additional mammographic views and US, yielding no cancer. Ruling out malignancy based on lack of enhancement without further workup may reduce patient recall rates and improve CEMs specificity.

1. Introduction

Asymmetries refer to areas of fibroglandular tissue that are more prominent or denser in one breast or in one part of the breast, compared to the other [1]. They can be classified into four types: asymmetry, focal asymmetry, global asymmetry, and developing asymmetry [2]. Unlike a mass, which typically has a denser center, asymmetries have a concave-outward appearance and are interspersed with fat [3]. Overall, asymmetries are estimated to appear in 3 % of screening mammograms [4]. They are often an isolated finding, and can represent cancer in 4.4–19.7 %, depending on the type and setting [5].

Contrast-enhanced mammography (CEM) is an emerging breast imaging tool which utilizes two energy acquisitions to generate low-energy images, equivalent of digital mammography (DM) [6], and recombined

Abbreviations: CEM, Contrast-enhanced mammography; DM, digital mammography; US, ultrasound; NEA, non-enhancing asymmetry; AMV, additional mammographic views; PPV, positive predictive value; BPE, background parenchymal enhancement; MLO, mediolateral oblique; CC, craniocaudal; BI-RADS, Breast Imaging-Reporting and Data System; ILC, Invasive lobular carcinoma; AMV, Additional mammographic views.

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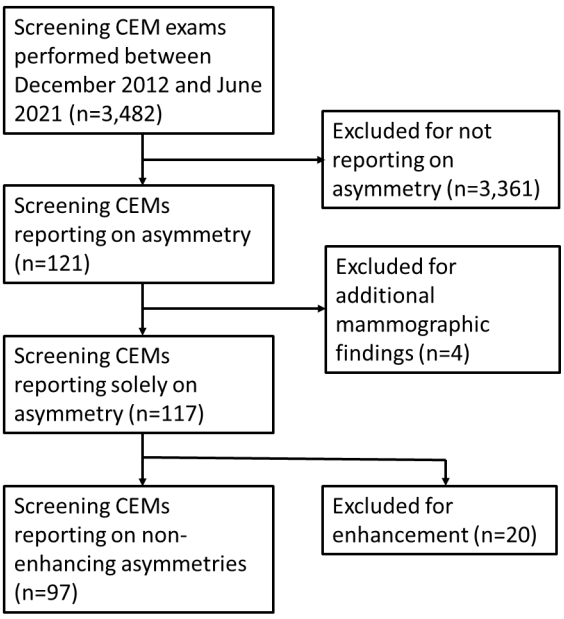

Fig. 1. Non-enhancing asymmetries on contrast-enhanced mammography inclusion and exclusion flowchart. Flow chart of patient inclusion and exclusion criteria.

images, which display contrast-enhanced abnormalities thus enabling a joint anatomical and vascular evaluation [7]. In recent years, CEM has gained increasing recognition as an effective screening modality [8], especially for women with dense [9–13]and extremely dense breasts [14,15], where DM demonstrates reduced sensitivity [13].

Asymmetries detected on screening CEMs have been a frequent cause for patient recall [9,15]. However, in diagnostic settings, a negative CEM has been was proven effective in defining these asymmetries as normal or benign [16]. This raises the question of whether further diagnostic workup, such as additional mammographic views or targeted ultrasound (US) of non-enhancing asymmetry (NEA) is necessary. The aim of this study was to review our experience with NEAs detected on screening CEMs, focusing on their prevalence, types, diagnostic workup, and positive predictive value (PPV) for cancer.

2. Materials and methods

This retrospective Health Insurance Portability and Accountability Act-compliant review was approved by our institutional review board. The necessity for informed consent was waived.

2.1. Study population

A computational search was conducted within a prospectively maintained database of screening CEM exams performed between December 2012 and June 2021, using the filter word “asymmetry”. Then, a case-by-case review was undertaken to exclude any potentially misclassified cases, particularly those erroneously collected as representing an “asymmetric” (background parenchymal enhancement) [17]. NEAs were defined as asymmetries detected on low-energy images without a correlate on the recombined images, whereas enhancing asymmetries were defined as asymmetries noted on the low-energy images that did enhance on the recombined images. The study population flow chart is presented in Fig. 1.

2.2. Imaging technique

All CEM studies were performed using a dual-energy mammography system (Senographe Essential; GE Medical Systems). Iohexol

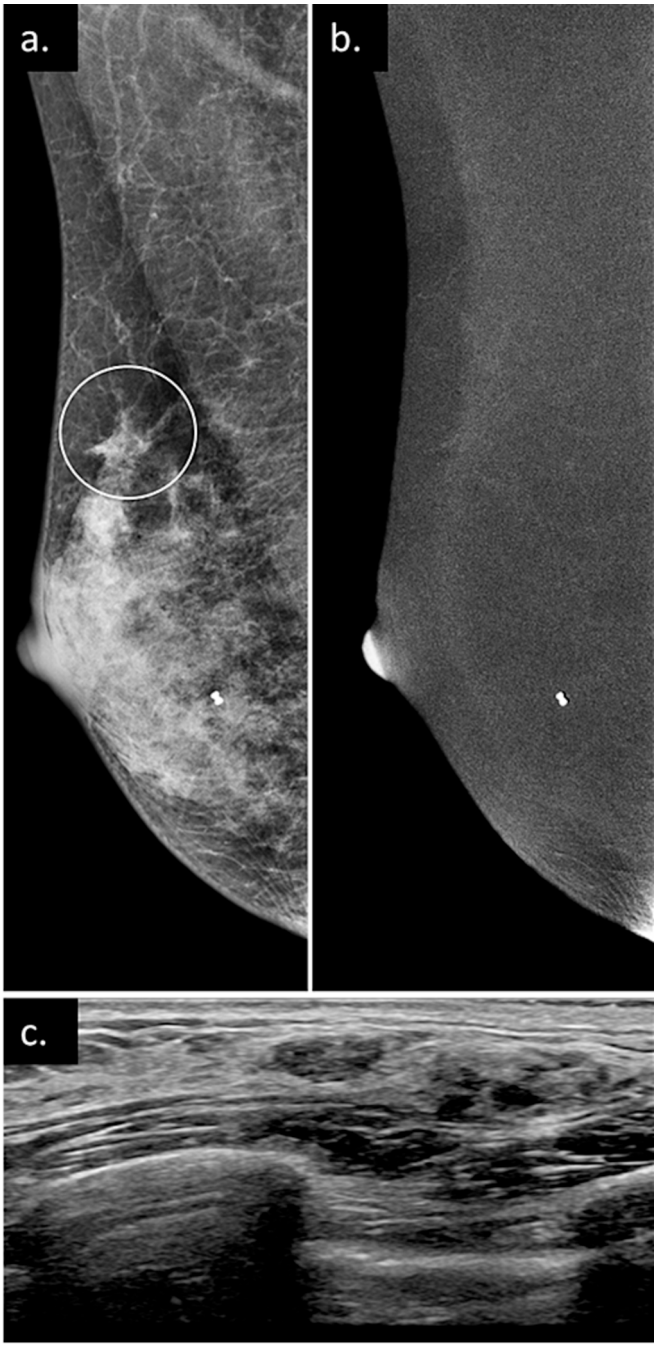

Fig. 2. Non-enhancing asymmetry on contrast-enhanced mammography representing a benign lesion. Right medio-lateral oblique low-energy (a) and recombined (b) images of a 52-year-old patient demonstrate a 1.0 cm asymmetry in the upper breast without associated enhancement. Additional mammographic views and ultrasound (c) were performed, revealing a hypoechoic mass on ultrasound, which was diagnosed as a fibroadenoma on biopsy.

(Omnipaque 350; GE Healthcare) was administered intravenously at a dose of 1.5 mL/kg, up to a maximum of 150 mL, at a rate of 3 mL/s, followed by a saline flush. Imaging of the breasts began approximately two minutes after contrast injection, using standard mediolateral oblique (MLO) and craniocaudal (CC) views. Both low-energy (26–30 kVp) and high-energy (45–49 kVp) exposures were captured almost simultaneously.

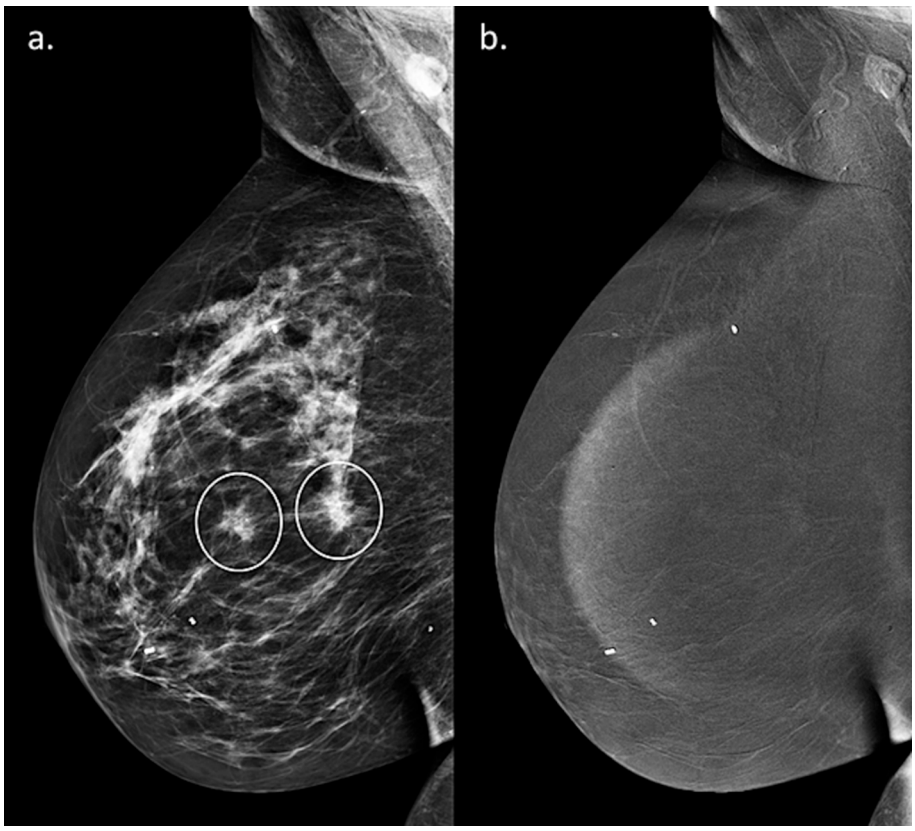

Fig. 3. Non-enhancing asymmetries on contrast-enhanced mammography resulting in negative result. Right medio-lateral oblique low-energy (a) and recombined (b) images of a 48-year-old patient show two non-enhancing asymmetries in the central breast. Additional mammographic views and ultrasound were performed, with no malignancy detected on follow-up.

2.3. Mammographic assessment

The official CEM reports, each of which was originally dictated by one of the dedicated breast radiologists at our breast imaging service, were used for data collection, including indication for imaging, type of asymmetry (i.e. asymmetry, focal asymmetry, global asymmetry and developing asymmetry) adhering closely to the Breast Imaging-Reporting and Data System (BI-RADS) lexicon descriptors, mammographic density BI-RADS category, any additional imaging performed (i.e., additional mammographic views (AMV) and/or targeted US, etc.), and final BI-RADS score, assigned for both modalities (low energy and recombined) together. The diagnostic workup and follow-up results of cases reporting asymmetry were reviewed and summarized. Medical records were reviewed to obtain information on age, risk factors, biopsy results and tumor pathology.

2.4. Statistical analysis

Descriptive statistics were summarized by using frequencies and percentages. Difference in size between NEAs and enhancing asymmetries was tested using unpaired two-way Student's *t*-test. The prevalence rate of positive BI-RADS scores (i.e. BI-RADS3-5) was compared between NEAs vs. enhancing asymmetries using the Chi-Square test (MedCalc Software Ltd). Among all CEMs that had an adequate reference standard (biopsy) or at least one year of radiological follow-up, the PPV for cancer detection between the two groups of asymmetries was compared using Chi-Square test. Statistical significance was defined as $p < 0.05$.

3. Results

3.1. Patient characteristics

Overall, 97 cases of NEAs were reported among 3,482 screening CEM exams during the study period (2.8 %). The mean age of the patients was 52.5 ± 7.9 years (range: 33 to 72). All patients were female, and the majority of patients, (90/97, 92.8 %) were at elevated risk for developing breast cancer, for personal history of breast cancer (n = 32), family history of breast cancer (n = 34) or a high-risk lesion (n = 32), including 8 patients with more than one risk factor. In terms of mammographic density, breasts were most commonly heterogeneously dense (n = 64, 66.0 %), followed by a scattered fibroglandular pattern (n = 18, 18.6 %) and extremely dense (n = 15, 15.4 %).

In addition, 20 enhancing asymmetries were reported accounting for 0.6 % of exams. Their mean age was 50.9 ± 9.9 years (range: 27 to 68). All patients were females at elevated risk for developing breast cancer, for either personal history of breast cancer (n = 9), family history of breast cancer (n = 12), high risk lesion (n = 2) and/or a BRCA mutation (n = 2), including 5 patients with more than one risk factor. In terms of mammographic density, breasts were most commonly heterogeneously dense (n = 15, 75.0 %), followed by a scattered fibroglandular pattern (n = 3, 15.0 %) and extremely dense (n = 2, 10.0 %). All patients from both groups had a prior mammogram available for comparison.

3.2. Asymmetries characteristics

Nine cases had two asymmetries each, comprising three unilateral and six bilateral asymmetries, resulting in a total of 106 NEAs. The NEAs were categorized as follows: asymmetry (n = 83), focal asymmetry (n = 22), and global asymmetry (n = 1), with no cases of developing

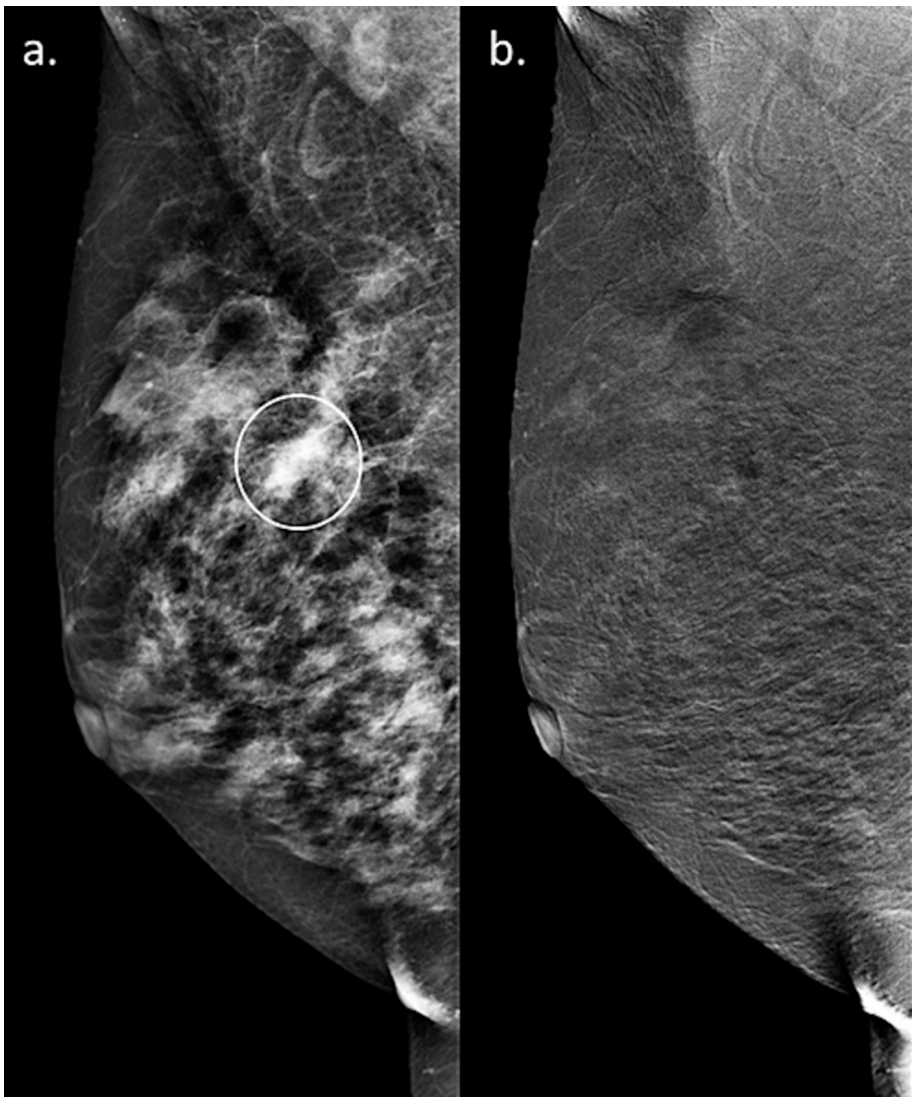

Fig. 4. Non-enhancing asymmetry on contrast-enhanced mammography resulting in negative result. Right medio-lateral oblique low-energy (a) and recombined (b) images of a 43-year-old patient exhibiting a questionable non-enhancing asymmetry in the upper breast, posterior depth. Additional mammographic views and ultrasound were performed, with no malignancy detected on follow-up.

asymmetry. The mean size of NEAs was 1.0 ± 0.7 cm (range: 0.3–4.9 cm), which did not differ significantly from the size of enhancing asymmetries (0.8 ± 0.6 cm, range: 0.3–2.9 cm) (P = 0.20). Enhancing asymmetries included asymmetries (n = 15) and focal asymmetries (n = 5).

3.3. Assessment and BI-RADS score

NEA cases underwent diagnostic workup including acquiring AMV (n = 63), AMV and US (n = 30), AMV plus MRI (n = 1), and AMV plus US and MRI (n = 3). Additional imaging alleviated the concerns regarding the NEAs and a negative BI-RADS score was assigned in most cases (n = 85), whereas BI-RADS 3 (n = 7) and BI-RADS 4 (n = 5) were assigned for the remaining cases.

Enhancing asymmetries underwent diagnostic workup that included AMV plus targeted US (n = 4), AMV plus MRI (n = 1), targeted US plus MRI (n = 2) and AMV plus targeted US and MRI (n = 7). The remaining were either followed up with CEM (n = 3) or did not necessitate further imaging (n = 3). Overall, most enhancing asymmetries (n = 17/20, 85 %) received positive BI-RADS score, including BI-RADS 3 (n = 10) and BI-RADS 4 (n = 7), which was significantly higher than NEAs ($p < 0.001$).

3.4. Diagnostic yield

Adequate reference in follow-up or biopsy was available for 90 of the 97 NEA patients, and for 19 out of the 20 patients with enhancing asymmetries. Four patients with NEAs underwent either MRI-guided guidance (n = 2) or US-guided (n = 2) biopsies, while seven patients with enhancing asymmetries underwent biopsy, including MRI-guided (n = 6) or US-guided (n = 1). None of the patients developed cancer at the area of NEA, whereas one patient with enhancing asymmetry. Thus, the PPV of NEA was 0 %, as compared with 5 % for enhancing asymmetry ($p < 0.05$). Representative cases of NEA yielding a benign result are demonstrated in Figs. 2–4 and enhancing asymmetry yielding cancer in Fig. 5.

4. Discussion

In this study, we investigated the diagnostic value of non-enhancing asymmetries (NEAs) detected during screening contrast-enhanced mammography (CEM) examinations. Existing data suggest that asymmetries without correlates on the recombined images are a frequent cause of patient recalls during screening [9,15]. While enhancement or the lack of enhancement using CEM has been reported as useful in

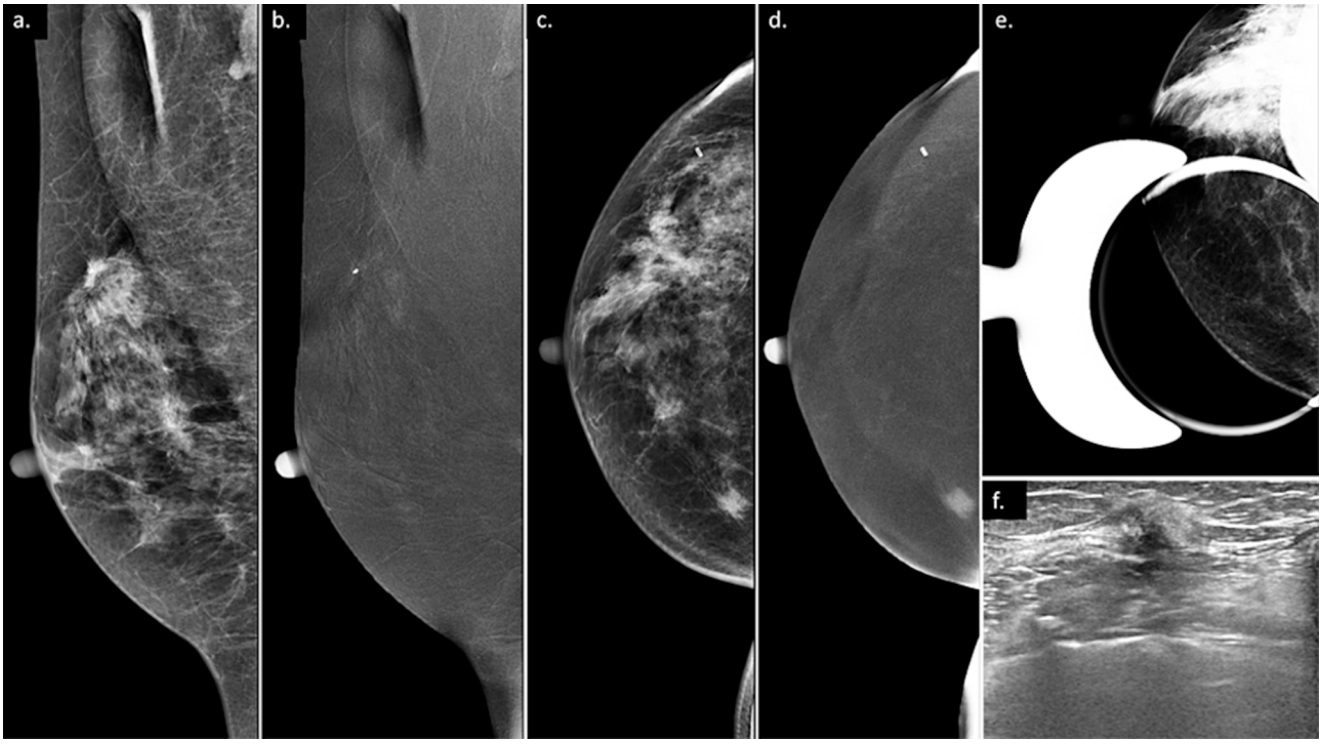

Fig. 5. Enhancing asymmetry on contrast-enhanced mammography yielding a cancer. Contrast-enhanced mammography (a-d), including right mediolateral oblique low-energy (a) and recombined (b) images, as well as craniocaudal low-energy (c) and recombined (d) images, reveals an enhancing asymmetry in the medial breast. Spot-compression view (e) and ultrasound (f) were subsequently performed, followed by an ultrasound-guided biopsy, which confirmed invasive carcinoma.

assessing asymmetries in diagnostic settings [16,18]. Based on this, we demonstrated that additional workup for NEAs may not be required.

Asymmetries represent a common cause of abnormal finding on mammograms, representing 12 % of cases, following masses (56 %) and calcifications (29 %) but preceding architectural distortion (4 %). Among these screening findings, asymmetries have the lowest likelihood of being malignant, at 3.6 % [5]. Of the four types of asymmetries, developing asymmetry is the least common (0.16 %) [19] but carries the highest likelihood of malignancy (12.8 %) [2,19–21]. More often, asymmetries represent a normal variation in fibroglandular tissue, which can resolve with spot compression views or tomosynthesis. Simple cysts may also present as asymmetries, warranting targeted ultrasound to confirm their presence [22].

Our findings indicate a relatively low prevalence of NEAs in screening CEMs. This may be attributed to the fact that all patients in our cohort had prior mammograms for comparison. Asymmetry that represents a normal variant in the mammographic appearance of healthy breasts is probably more concerning on baseline mammograms, where no prior exams are available for comparison, and may be overlooked if stable [23]. In a study that evaluated baseline mammograms performed in women in patients age 60 and older, asymmetries were noted in 10.4 % of exams, and were the most common cause for recall (38 %) [24]. In our institution, CEMs were almost always performed after a baseline DM. Thus, the prevalence of NEAs might have been higher had CEM been performed without available prior mammograms.

Our results showed that, regardless of the size of asymmetry, no cancer was detected during the diagnostic workup of NEAs, in contrast to enhancing asymmetries. The ability of recombined CEM images to provide vascular assessment of the breast mirrors the function of contrast-enhanced breast MRI [25], with both demonstrating comparable screening [26,27], preoperative [28] and post-treatment [29] performances. Contrast-enhanced breast MRI was previously found useful in evaluating inconclusive mammographic findings [30], and in the evaluation of asymmetries in particular [31]. In this context, using CEM's recombined images to evaluate asymmetries detected on low-energy images could similarly help rule out underlying malignancy, potentially eliminating the need for further diagnostic workup.

However, our findings should be interpreted with caution, as both CEM [32] and contrast-enhanced breast MRI can yield false negatives and may miss cancer detection [33–35]. Potential pitfalls in ruling out malignancy based solely on negative recombined images include breast cancers with faint enhancement or, in rare instances, non-enhancing malignancies. Invasive lobular carcinoma (ILC), especially, poses a detection challenge [36]. A comparative study found significantly weaker and sometimes faint enhancement in ILCs [37]. Additionally, rare non-enhancing breast malignancies, involving various pathologies, may also be difficult to detect [38]. In particular, mucinous carcinoma [39] and papillary carcinoma [40] have been noted to lack enhancement on CEM, though they typically appears as round masses, rather than an asymmetry, on low-energy images. Finally, none of the NEAs in our study were classified as developing asymmetries, the most suspicious type of asymmetry. Therefore, our findings cannot be extended to this category.

Another potential limitation in evaluating asymmetries on recombined images could arise from normal tissue enhancement, known as background parenchymal enhancement (BPE) [41]. Higher levels of BPE have been reported to hinder accurate assessment of disease extent on CEM [42], though its impact in the screening setting remains to be studied. In MRI, pronounced BPE reduces lesion conspicuity, but additional sequences can aid in detection [43,44], a feature not available in CEM.

Several limitations of our study should be noted. First, this is a single-center retrospective study with a relatively small population of patients. Large-scale studies are needed to validate our preliminary findings and reinforce the conclusion that NEAs do not warrant further diagnostic workup. Additionally, in our study the original readers were not blinded to the recombined images while interpreting the low-energy images, which may have influenced their assessments. Lastly, the prevalence of

NEAs would have probably been higher if the patients had undergone CEM without prior DM.

In conclusion, NEAs were a relatively uncommon finding on screening CEMs. Their diagnostic workup typically included additional mammographic views and ultrasound, with no cancers found. Therefore, our preliminary results support relying on the absence of enhancement on the recombined images to rule out malignancy in non developing asymmetries detected on the low-energy images, without further diagnostic workup. If validated by additional studies this practice could lower patient recall rates and improve the specificity of CEM.

CRediT authorship contribution statement

Noam Nissan: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Jeffrey S. Reiner:** Data curation. **Victoria L. Mango:** Data curation. **Hila Fruchtman-Brot:** Data curation. **Rosa Elena Ochoa Albiztegui:** Data curation. **Yuki Arita:** Formal analysis. **Jill Gluskin:** Writing – review & editing. **Tali Amir:** Writing – review & editing. **Kimberly Feigin:** Writing – review & editing, Supervision. **Maxine S. Jochelson:** Writing – review & editing, Supervision, Resources. **Janice S. Sung:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Data curation.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr. Maxine Jochelson's disclosure includes a previous paid lecture for GE, whose mammograms were utilized as part of the routine clinical work in our institute, regardless of this current study. The rest of the authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

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