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Added Value of Supplemental Screening Breast MRI in Women at Average or Intermediate Breast Cancer Risk Using Abbreviated Protocols

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ARTICLE INFO ABSTRACT

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Keywords: Screening, magnetic resonance imaging, Breast cancer, Average or intermediate risk **Background**: The importance of magnetic resonance imaging (MRI) screening in high-risk women is well-known; however, its utility in women at average or intermediate risk is not well-established. The main purpose of the study was to investigate the added value and cancer detection rate (CDR) of using abbreviated MRI protocols in average or intermediate-risk women.

Methods: A total of 431 asymptomatic women with average or intermediate risk of breast cancer who underwent screening abbreviated MRI from May 2019 to May 2022 were recruited. CDR in screening MRI among average or intermediate-risk women and in low or high-breast composition was calculated.

Results: In 173 patients with intermediate risk, 5(1.16%) malignant lesions were detected and in 258 average-risk patients, 10(2.32%) added cancers were found in screening abbreviated MRI compared to mammography. Among the 15 malignant lesions, more cancers in high breast composition were detected (11 vs. 4 cases); however, there was no statistically significant difference between the cancer detection rate and breast composition. In intermediate-risk women with high breast composition, 3 (0.69%) malignant lesions, and in average-risk women with high breast composition, 8 (1.85%) added cancers were found.

Conclusion: We provided 3.48% added cancer detection in screening abbreviated MRI compared to mammography. Therefore, screening abbreviated MRI with less image acquisition and interpretation time may be useful as a supplemental screening tool for cancer detection especially in high breast composition.

Copyright © 2024. This is an open-access article distributed under the terms of the <u>Creative Commons Attribution-Non-Commercial 4.0</u> International License, which permits copy and redistribution of the material in any medium or format or adapt, remix, transform, and build upon the material for any purpose, except for commercial purposes.

INTRODUCTION

Breast cancer is a major cause of cancer death in women.¹ Early breast cancer diagnosis improves the

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Fahimeh Azizinik, Assistant Professor of Radiology, Advanced Diagnostic and Interventional Radiology Research Center (ADIR), Imam Khomeini, Amir Alam and Yas Hospitals, Tehran University of Medical Sciences, Tehran, Iran. Tel: +989128408791 Email: Azizinikfahimeh@gmail.com survival rate.² Screening mammography is currently the primary procedure for early detection of breast cancer in average or intermediate-risk women.^{3,4} Previous evidence has shown that regular screening mammography can reduce breast cancer mortality.⁵ However, the lower sensitivity of mammography in women having heterogeneously or extremely dense breasts is well-established due to the obscuring effect of dense breast parenchyma.⁶ This could justify why screening mammograms are associated with about



50% interval cancer rate.⁷ The detrimental impact of breast density on the diagnostic ability of screening mammography is well-known. Therefore, despite decades of screening mammograms, breast cancer is still among the most important causes of cancer death in women.⁸ Increased breast density decreases the sensitivity of mammogram due to obscuring effects, which potentially leads to the high rate of interval cancer on the one hand and increases the intrinsic risk of breast cancer on the other.^{6,9-12}

Therefore, the Dense Tissue and Early Breast Neoplasm Screening (DENSE) trial has investigated the effectiveness of supplemental screening MRI in women with dense breasts who had negative screening mammography. According to the results of the trial, the use of supplemental screening MRI has been supported in women with dense breasts.¹³

Limited data are available concerning nonmammographic screening methods in women at average or intermediate risk for breast cancer. Screening ultrasound has been proposed as a primary supplemental imaging modality of screening in women with dense breasts and average or intermediate risk of breast cancer. In these women, ultrasound has been found to enhance cancer detection and diminish the interval cancer rate. However, it leads to a low positive predictive value (PPV) that may result in more costs and morbidity.¹⁴⁻ ¹⁶ A low PPV for biopsy not only contributes to a considerable number of unnecessary biopsies but also a much higher rate of short-term follow-up.^{17,18} In this setting, screening MRI has superior sensitivity when compared to screening mammograms or ultrasounds and is not affected by breast density.¹⁹⁻²³

A standard breast MRI examination is timeconsuming, taking around 30 minutes requiring multiple images, while an abbreviated protocol significantly reduces the acquisition time to less than 10 minutes, decreasing the interpretation times.²⁴⁻²⁶

To make breast MRI more feasible for routine screening purposes, some authors have evaluated the usefulness of an abbreviated breast MRI protocol, showing that abbreviated MRI can significantly reduce the acquisition time and related costs while maintaining diagnostic accuracy and cancer detection rate.^{27,28}

The importance of MR screening in high-risk women (e.g., carriers of BRACA gene mutations, estimated lifetime risks at least 20%) is wellestablished, yet, its utility in women at average or intermediate risk is not well-known. Thus, the aim of this study was to assess the added value of abbreviated MRI as a supplementary screening tool in women at average or intermediate-risk compared to screening mammography.

METHODS

Study Design and Participants

This retrospective study was conducted in a thirdlevel referral academic breast center. All asymptomatic patients with average or intermediate risk of breast cancer who underwent screening MRI from May 2019 to May 2022 were recruited.

The term asymptomatic means the absence of any clinical or conventional imaging findings and the term intermediate or average risk refers to 15-20% or less than 15% lifetime breast cancer risk, retrospectively. For breast cancer risk assessment, online calculator (Gail Model) was used. (https://bcrisktool.cancer.gov/calculator.html)

Four-view mammograms were performed with the Fuji's full digital machine. The images were interpreted by a breast radiologist with 15 years of experience using monitors and a computer-assisted detection system.

The screening MRI was performed at the clinician's request mainly in women who were candidates for assisted reproductive technology (ART), cosmetic surgery, and positive personal history of breast or ovarian cancer or those with a personal history of a high-risk lesion on previous breast biopsy including atypia, lobular neoplasia, or radial scar.

In this retrospective study, we included all patients who underwent abbreviated MRI according to the clinician's request considering the following inclusion and exclusion criteria.

Inclusion and Exclusion Criteria

The inclusion criteria were as follows:

- 1. No clinical signs or symptoms of breast cancer
- 2. Negative screening mammography
- 3. Patients with average or intermediate risk of breast cancer

The exclusion criteria were as follows:

- 1. Clinical signs or symptoms of breast cancer
- 2. Positive screening mammography
- 3. High-risk patients for breast cancer such as women carrying a breast-cancer-producing mutation in BRCA1 or BRCA2

MRI Acquisition Protocol and Interpretation

MRI was performed using a GE Discovery MR750 3T MRI scanner (GE Healthcare, Waukesha, WI, USA) with a breast coil (multichannel coil 16row) and breast immobilizer device in the craniocaudal direction.

The designed abbreviated protocol included nonfat saturated T2 (4 min), fat-saturated T1-weighted [T1W] pre-contrast (80 seconds), and the first two fatsaturated T1W post-contrast series (160 seconds)

Parameter	T2 non-fat saturated	Pre-contrast T1 LAVA	2 first Post-contrast T1	
			LAVA	
TR/TE (ms)	5600/104	5/2	5/2	
Flip angle	160	10	10	
Slice thickness (mm)	5	2	2	
FOV (mm)	350	340	340	
Matrix size (mm)	320*256	384*320	384*320	
Acquisition time	4 min	80 s	160 s	

 Table 1. Pulse sequence parameters for abbreviated MRI protocols.

MRI, magnetic resonance imaging, FOV: field of view; TE: time of echo; TR: repetition time.

within the coronal and sagittal reconstruction of subtracted series including maximum intensity projection (MIP) with a total acquisition time of around 8 minutes.

Details of sequences in the abbreviated protocol MRI are summarized in Table 1.

All images were described according to the known BI-RADS lexicon and mammographic breast density was classified into four categories according to the American College of Radiology (ACR) as follows: A) almost entirely fatty, B) scattered areas of fibroglandular density, C) heterogeneously dense, and D) extremely dense.²⁹

We also classified the patients into two groups according to the amount of fibroglandular tissue: lowdensity breast composition with ACR breast composition A or B (almost entirely fatty or scattered fibroglandular tissue) and High-density breast composition with breast composition C or D (heterogeneous or extreme fibro glandular tissue).²⁹

Patients with BI-RADS 3 in screening MRI underwent short-term follow-up with MRI in 6 to12 months to determine their final BI-RADS assessment, while patients with suspicious findings (BI-RADS category 4 or 5) underwent core needle or vacuumassisted biopsy, and pathology results were gathered.

BI-RADS categories 1, 2, or 3 (which were stable on follow-up) were considered negative test results, and categories 4 or 5 were categorized as positive test results.

The association between the risk categories and the final MRI BI-RADS classification and pathology results was analyzed and, finally, the cancer detection rate in screening MRI among average or intermediate-risk women and in dense and not-dense breasts was calculated.

Statistical Analysis

Comparison between categorical variables was performed using the Chi-squared test or Fisher's exact test, when appropriate. Data are presented as mean \pm standard deviation for continuous variables and number (percentage) for categorical variables. The statistical analyses were performed using SPSS version 26 (IBM Corp., Armonk, NY, USA).

RESULTS

A total of 431 women who underwent screening MRI with abbreviated protocols were included in our study with a mean age of 44.3 years, ranging from 30 to 74 years.

Among the participants, 19.7% (85/431) had a positive family history (≥ 1 affected first-degree relative or ≥ 2 affected second-degree relatives on the paternal or maternal side), 19.7% (85/431) had a positive personal history of breast or ovarian cancer and 0.7% (3/431) had a personal history of a high-risk lesion on previous breast biopsy including atypia, lobular neoplasia, or radial scar.

Among the 431 women in our study, 173 patients had intermediate risk and 258 patients were at average risk. The frequency of patients based on the lifetime breast cancer risk, MRI breast composition and MRI BI-RADS classification are shown in Table 2.

Table 2. The frequency of patients based on lifetime breast
cancer risk, MRI Breast Composition and MRI BI-RADS
classification.

Category	Frequency (%):			
Patient risk				
Average risk	258 (59.9%)			
intermediate risk	173(40.1%)			
MRI Breast Composition				
Almost entirely fat: ACR a	32 (7.4%)			
Scattered fibroglandular	118 (27.4%)			
tissue: ACR b	214 (49.7%)			
Heterogeneous fibro glandular	67 (15.5%)			
tissue: ACR c				
Extreme amount of				
fibroglandular tissue: ACR d				
MRI BI-RADS				
1	40 (9.3%)			
2	234 (54.3%)			
3	107 (24.8%)			
4	46 (10.7%)			
5	4 (0.9%)			
Total	431			

Among 173 patients with intermediate risk, 17(9.8%) cases were classified as BIRADS1, 101(58.4%) in BI-RADS2, 37(21.4%) BI-RADS3, and 18(10.4%) labeled as BI-RADS4 in the abbreviated MRI.



In 258 patients with average risk, 23(8.9%) cases were categorized as BI-RADS1, 133(51.6%) BI-RADS2, 70(27.1%) BI-RADS3, 28(10.9%) as BI-RADS4 and 4(1.6%) as BI-RADS5.

Among the 50 patients with BI-RADS 4 or 5 who underwent biopsy, 18 patients were at intermediate risk and 32 patients were at average risk.

Finally, 5(1.16%) and 10(2.32%) malignant lesions were detected in patients with intermediate and average-risk, respectively.

Of 431 patients, 46(10.7%) women were classified as BI-RADS4 and 4(0.9%) patients were labeled as BI-RADS5. All 50 patients with BI-RADS4 or 5 categories underwent core needle biopsy or vacuumassisted biopsy, of which 35 cases (8.12%) were benign and 15 cases (3.48%) were malignant in the pathologic exam.

Of all BI-RADS 4 lesions, 12/46 cases were malignant, and of BI-RADS 5 lesions, 3/4 were found

to be malignant in pathology results (P-value=0.04), which indicates that positive predictive value of malignancy in BI-RADS 5 is statically significant in comparison with BI-RADS 4.

Finally, fifteen added cancers were detected in 431 screening MRI examinations compared to mammography, yielding an additional cancer detection rate [CDR] of 34.8 cancers per 1000 examinations (95% confidence interval [CI], 20 to 60).

The most common MRI finding in pathologyproven malignant lesions was an irregular mass with a mean size of 16.75 mm.

Malignant lesions in pathologic examination included DCIS, IDC, and ILC, and the majority of cancers were of invasive types (11 invasive carcinomas and 4 ductal carcinomas in situ [DCIS]). One of the malignant cases is shown in Figure 1.



Figure 1. A 40 y/o woman with dense breasts in mammography (A) who underwent screening abbreviated MRI before assisted reproductive technology (ART). In T1 MRI with contrast images (axial and coronal in B and C), an irregular speculated mass was seen in the right central upper part with pathology-proven invasive ductal carcinoma.

Benign lesions consisted of fibroadenoma, fibrocystic changes (apocrine metaplasia, intraductal hyperplasia, sclerosing adenosis), papilloma, and usual ductal hyperplasia in pathologic results.

The mean age of 15 women with breast cancer was 45 years (from 32 to 69 years old). No significant association between age and final pathologic result was detected (P-value= 0.22)

In a group with High-density breast composition (281 cases), 35 patients with BIRADS 4 and 3 cases were classified as BIRADS 5 and 11 (3.91%) cancer were detected.

In a group of low-density breast composition (150 cases), 11 BI-RADS4 and one case were labelled as BI-RADS 5 and after biopsy, 4 (2.66%) malignant lesions were identified.

We detected more suspicious lesions (BI-RADS4 or BI-RADS5) in the high breast density group (38/50 cases) than the low breast density (12/50 cases). Also, among all malignant lesions, more cancers were detected in high breast composition (11 vs. 4 cases); however, there was not a statistically significant difference between cancer detection and breast composition. In intermediate-risk patients with high breast composition, 3(0.69%) malignant lesions, and in average-risk patients with high breast composition, 8(1.85%) added cancers were found. Table 3 shows the characteristics of benign and malignant lesions according to patient risk, suspicious MRI BI-RADS and MRI breast composition in all patients who underwent abbreviated breast MRI.

Table 3. Characteristics of benign and malignant lesions according to patient risk, suspicious MRI BI-RADS and MRI Breast composition in patient undergoing Abbreviated MRI.

		Benign	Malignant	Total	P-
		N (%)	N (%)	Ν	value
Patient Risk:	Average Risk	248 (96.13%)	10 (3.87%)	258	
	Intermediate Risk	168 (97.11%)	5 (2.89%)	173	0.30*
Suspicious MRI BI-	4	34 (73.9%)	12 (26.1%)	46	
RADS:	5	1 (25%)	3 (75%)	4	0.07**
MRI Breast	Almost entirely fat: ACR a	31 (96.88%)	1 (3.12%)	32	
composition:	Scattered fibroglandular tissue: ACR b	115 (97.45%)	3 (2.55%)	118	0.29*
	Heterogeneous fibroglandular tissue: ACR c	208 (97.19%)	6 (3.81%)	214	
	Extreme amount of tissue: ACR d	62 (92.5%)	5 (7.5%)	67	
Combined MRI composition:	Low density breast composition(ACR a & b)	146 (97.34%)	4 (2.66%)	150	0.50*
	High density breast composition (ACR c & d)	270 (96.09%)	11 (3.91%)	281	
Total		416	15	431	

*Refers to the Chi-squared test and ** refers to the Fisher's Exact test.

P-value less than 0.05 considered statically significant.

N= number (%=percentage)

DISCUSSION

Increased breast density leads to limited sensitivity of mammography with a masking effect and high interval cancer rate. Additionally, increased breast density contributes to an elevated intrinsic risk of breast cancer not limited to a special patient's age range.^{6,9-12}

Therefore, the implementation of a more sensitive screening tool, especially for women with dense breasts is crucial.^{13,30}

Some studies have shown that breast ultrasound as a screening tool has many limitations, including time consumption, cost, and a low positive predictive value (PPV), leading to a significant number of unnecessary biopsies and a much higher rate of shortterm follow-up.^{17,18}

A study of the ACRIN 6666 trial in 2012 investigated the detection rate of breast cancer through annual screening ultrasound (US) and screening MRI to mammography in women with dense breasts who had at least one risk factor. Supplemental screening in the US identified 3.7 cancers per 1000 women screens (95% CI 2.1 to 5.8, while the supplemental cancer yield of MRI was 14.7 per 1000 (95% CI 3.5 to 25.9) which was higher in comparison with screening ultrasound. The study reported a sensitivity of 31.3% for mammography alone, which increased to 100% by adding MR imaging.³¹

MRI is considered the most sensitive screening modality not affected by breast density.¹⁹⁻²³ In a study by Kuhl *et al.* on 2120 women between 2005 and 2013, the additional cancer detection rate with supplemental MRI screening in average-risk females was substantially high, i.e., 15.5 per 1000.³²

A DENSE trial on women who underwent supplemental screening with MRI between 2011 and 2016 reported an additional cancer detection rate (CDR) of 16.5 per 1000 screening examinations at the expense of a false-positive rate (FPR) of 79.8 per 1000 screening examinations.^{4,33}

In 2014, Kuhl *et al.* included 443 women with mildly to moderately increased risk who underwent 606 screening MRIs and suggested a fast abbreviated protocol for MRI, as a screening modality in a more general population. They found that cancer detection rates using abbreviated protocols were equivalent to full protocol breast MRI. Additionally, it was associated with reduced image acquisition and interpretation time. The sensitivity, specificity, PPV, and NPV in a fast abbreviated MRI were reported at 100%, 94%, 31%, and 100%, respectively which were identical to those of the full protocol MRI (100%, 94%, 33%, 100%). ³⁴

Recent studies have also shown that abbreviated MRI can improve the early diagnosis of breast cancer in women with dense breasts, who are at a relatively higher risk of breast cancer.³⁵ The importance of MRI



screening in high-risk women is well established; however, its utility in women at average or intermediate risk is not well known. Thus, our goal was to investigate the added value of abbreviated protocol MRI as a supplemental screening tool in average or intermediate-risk women.

In the current study, of 431 patients who underwent screening abbreviated MRI with negative or benign mammography, 50 cases (11.6%) were categorized as BI-RADS4 (46/50) and BI-RADS5 (4/50) and all of them underwent biopsy. Of all BI-RADS4 lesions, 26.1% were malignant, and also 75% of BI-RADS5 lesions were found to be malignant in pathology results (P-value=0.04).

In a studt by Weinstein *et al.* between 2016 and 2019, an abbreviated MRI examination was done on 475 asymptomatic women with dense breasts who had negative mammography or breast tomosynthesis results. In the study, 39 biopsies from suspicious lesions were completed, resulting in 12/39 (30.8%) positive results (36), similar to our study, in which 15 cases of 50 biopsies (30%) were positive.

In the current study, of 15 malignant lesions that were detected in screening abbreviated breast MRI, most of them (73.3%) were in women at average risk and fewer patients (26.7%) were at the intermediate risk. Therefore, the lifetime breast cancer risk will not predict an additional need for screening MRI or a need for biopsy.

In our study, of 431 screening abbreviated MR imaging, 15 additional breast cancers were detected in average (10 cases) or intermediate (5 cases) risk women which were not detected in digital mammography accounting for the total added cancer detection rate of 34.8 per 1000 cases (95% CI, 20 to 60), which was higher in comparison with similar previous studies.

In the study by Weinstein *et al.*, of 475 asymptomatic women with dense breasts, the CDR in screening MRI was 27.4 per 1,000 (13 of 475; 95% CI, 16.1 to 46.3). There were no interval cancers at 1-year follow-up.³⁶

In general, abbreviated MRI provides a higher supplemental cancer yield than that reported for supplemental digital breast tomosynthesis screening (1.2 per 1000 cases) in a study by Friedewald SM *et al.* or that of supplemental US screening of women with an elevated risk of breast cancer (3.5–4.4 per 1000 cases) in a study by Scheel JR *et al.*^{16,37}

Kuhl *et al.* introduced the EA1141 trial in 2018 to use abbreviated breast MRI for screening women

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 Alkabban FM, Ferguson T. Breast Cancer. StatPearls. Treasure Island (FL): StatPearls Publishing Copyright © 2023, StatPearls Publishing LLC.; 2023. with dense breasts, reporting the interval cancer rate of females undergoing MRI screening at zero, and concluding that interval cancers mostly do not develop between screening rounds and, in fact, are missed by screening mammography. In other words, if a screening MRI had not been performed, occult cancer would have progressed to a more advanced interval cancer in women undergoing only routine screening mammography.³⁸

In a study by Christopher E Comstock *et al.*, evaluating the performance of screening abbreviated breast magnetic resonance imaging (MRI) and digital breast tomosynthesis (DBT) (1444 women) with dense breasts, abbreviated breast MRI detected a significantly higher rate of invasive breast cancer (exact McNemar P = .002).²⁴

In our study, we detected more suspicious lesions (BIRADS 4 or BIRADS 5) and more cancer detection rate in high-density breast composition (3.91%) than in low-density breast composition (2.66%), but it was not statistically significant.

One of the limitations of our study was the low sample volume, so large scale studies with more reliable results are recommended. Another limitation was that we did not compare the agreement of standard and abbreviated MRI in this study.

CONCLUSION

In conclusion, in this study, of 431 cases of screening abbreviated MR imaging, 15 additional breast cancers were detected in average or intermediate-risk women, which were missed in digital mammography with a total added cancer detection rate of 34.8 per 1000 cases.

In fact, screening abbreviated MRI with reduced time for image acquisition and interpretation may be useful as a supplemental screening tool for cancer detection in average or intermediate-risk women, especially in dense breast composition.

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CONFLICT OF INTEREST

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