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Study Protocol

Diffusion-Weighted Magnetic Resonance Imaging for Preoperative Evaluation of Patients With Breast Cancer: Protocol of a Prospective, Multicenter, Observational Cohort Study

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ABSTRACT

Purpose: Detection of multifocal, multicentric, and contralateral breast cancers in patients affects surgical management. Dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) can identify additional foci that were initially undetected by conventional imaging. However, its use is limited owing to low specificity and high false-positive rate. Multiparametric MRI (DCE-MRI + diffusion-weighted [DW] MRI) can increase the specificity. We aimed to describe the protocols of our prospective, multicenter, observational cohort studies designed to compare the diagnostic performance of DCE-MRI and multiparametric MRI for the diagnosis of multifocal, multicentric cancer and contralateral breast cancer in patients with newly diagnosed breast cancer.

Methods: Two studies comparing the performance of DCE-MRI and multiparametric MRI for the diagnosis of multifocal, multicentric cancer (NCT04656639) and contralateral breast cancer (NCT05307757) will be conducted. For trial NCT04656639, 580 females with invasive breast cancer candidates for breast conservation surgery whose DCE-MRI showed additional suspicious lesions (breast imaging reporting and data system [BI-RADS] category ≥ 4) on DCE-MRI in the ipsilateral breast will be enrolled. For trial NCT05307757, 1098 females with invasive breast cancer whose DCE-MRI showed contralateral lesions (BI-RADS category ≥ 3 or higher on DCE-MRI) will be enrolled. Participants will undergo 3.0-T DCE-MRI and DW-MRI. The diagnostic performance of DCE-MRI and multiparametric MRI will be compared. The receiver operating characteristic curve, sensitivity, specificity, positive predictive value, and characteristics of the detected cancers will be analyzed. The primary outcome is the difference in the receiver operating characteristic curve between DCE-MRI and multiparametric MRI interpretation. Enrollment completion is expected in 2024, and study results are expected to be presented in 2026.

Discussion: This prospective, multicenter study will compare the performance of DCE-MRI

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Conflict of Interest
The authors declare that they have no competing interests.

Author Contributions
Conceptualization: Ha SM, Moon WK; Data curation: Park VY, Ha SM, Song SE; Formal analysis: Park VY, Ha SM, Song SE, Moon WK; Funding acquisition: Song SE; Investigation: Park VY, Shin HJ, Kang BJ, Kim MJ, Song SE, Ha SM, Moon WK; Methodology: Ha SM, Park VY, Song SE, Moon WK; Project administration: Ha SM, Song SE; Resources: Park VY, Ha SM, Song SE; Writing-original draft: Ha SM, Park VY; Writing-review&editing: Park VY, Shin HJ, Kang BJ, Kim MJ, Song SE, Ha SM, Moon WK.

Correction
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versus multiparametric MRI for the preoperative evaluation of multifocal, multicentric, and contralateral breast cancer and is currently in the patient enrollment phase.

Trial Registration: ClinicalTrials.gov Identifier: NCT04656639, NCT05307757. Registered on April 1 2022

Keywords: Breast Neoplasms; Clinical Trial; Multicenter Studies as Topic; Multiparametric Magnetic Resonance Imaging

INTRODUCTION

Mammography and breast ultrasonography (US) are conventional imaging modalities for breast cancer diagnosis and are performed for preoperative evaluation of patients with newly diagnosed breast cancer. However, the extent of breast cancer is often underestimated by conventional imaging [1]. On the contrary, dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) can be used to detect additional cancer lesions that are initially occult on conventional imaging, with a reported incremental cancer detection rate of approximately 10% for the ipsilateral breast and 4% for the contralateral breast [2,3]. Owing to such high sensitivity, DCE-MRI has recently been widely applied in the preoperative evaluation of patients with breast cancer [2-5]. However, DCE-MRI also results in unnecessary biopsies, increased mastectomy rates, and treatment delay [6]. Several studies have shown that only 19%–36% of MRI recommendations for biopsy yield cancer diagnosis when performed for preoperative evaluation [4,7].

To enhance the low specificity of DCE-MRI, the combined use of diffusion-weighted (DW) MRI, which is defined as multiparametric MRI, has been suggested. DW-MRI is a fast and unenhanced technique that measures the movement of water molecules to create tissue contrast without the need for injection of contrast agents [8-10]. Owing to restricted or hindered diffusion of water molecules within the tissue, breast cancers appear hyperintense on high b-value DW-MRI and have low apparent diffusion coefficient (ADC) values [9]. Several studies have reported that multiparametric MRI improved the diagnostic accuracy of breast lesions detected by preoperative DCE-MRI in patients with breast cancer [11,12]. A previous study that enrolled 77 patients (107 lesions) revealed that the implementation of DW-MRI increased the specificity of DCE-MRI from 18.9% to 67.6% for DCE-MRI-detected additional breast lesions without a significant loss of sensitivity [13].

Therefore, prospective, multicenter studies in a large population are needed to validate the benefit of DW-MRI for the diagnosis of additional lesions detected by preoperative DCE-MRI. This report describes the protocols of two prospective, multicenter study designs that evaluate the potential role of DW-MRI in addition to DCE-MRI for the diagnosis of multifocal, multicentric cancer in the ipsilateral breast and contralateral cancer in patients with newly diagnosed breast cancer.

METHODS

The study was funded by the Korean Society of Breast Imaging and Korean Society for Breast Screening (KSBI&KSFBS-2021-1) and a grant of the Korea Health Technology R&D Project

through the Korea Health Industry Development Institute (KHIDI) funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HR22C1302), the protocol was approved by the Institutional Review Boards (NCT04656639: 2202-105-1302, S2022-1954, 4-2021-1814, 2022AN0175, 2022-0407-0002; NCT05307757: 2202-104-1302, S2022-1957, 4-2021-1815, 2022AN0096, 2022-0408-0002) of the participating centers, and written informed consent will be obtained from all enrolled patients to allow the use of their data.

Study design

These are prospective, multicenter, intraindividual, comparative cohort studies. Participants will be recruited from five tertiary academic centers, i.e., Seoul National University Hospital, Asan Medical Center, Severance Hospital, Korea University Anam Hospital, and Catholic University of Korea Seoul, providing multiparametric breast MRI and high-quality standards. The participating institutions are equipped with the latest 3.0-T MRI scanners. Radiologists are required to complete a training clinical case series of 100 MRI studies before interpretation of the study. Each eligible participant newly diagnosed with invasive breast cancer that provides informed consent for this study will undergo DCE-MRI and DW-MRI. The investigator will obtain written informed consent from all participants. Each patient will be assigned a unique identification number at the time of enrollment, according to the institution and registration order. The flowchart of the study design is shown in **Figure 1**. The schedule of measures and time of assessment are shown in **Figure 2** according to the format recommended by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. The SPIRIT checklist is presented in **Supplementary Table 1**. Data will be collected using an electronic case report form (**Supplementary Data 1** and **2**).

Ethical consideration

This study was funded by the Korean Society of Breast Imaging and Korean Society for Breast Screening (KSBI & KSFBS-2021-1) and a grant from the Korea Health Technology R&D Project through the Korea Health Industry Development Institute funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HR22C1302). The study protocols were first approved by the Institutional Review Board of Seoul National University Hospital in March 2022. Clinical trials were registered in an international trial registry (ClinicalTrials.gov: NCT04656639, NCT05307757) on April 1, 2022. The first participant was enrolled on April 4, 2022. At the time of manuscript submission (October 2022), the active inclusion of patients is ongoing in five centers. Enrollment completion is expected in 2024, and the study results will be presented in 2026.

Study population

Study on the diagnosis of multifocal, multicentric breast cancer (NCT04656639)

Females aged ≥ 25 years with newly diagnosed invasive breast cancer who are candidates for breast conservation surgery after clinical examination and conventional imaging are eligible for inclusion. Patients who underwent breast MRI for preoperative staging with at least one additional MRI-detected lesion classified as breast imaging reporting and data system (BI-RADS) category 4 or higher in the ipsilateral breast will be considered for enrollment. Only mammographically occult lesions will be enrolled for the ipsilateral breast, regardless of ultrasound findings.

The exclusion criteria are as follows: age < 25 years at the time of enrollment, biopsy results of ductal carcinoma in situ, personal history of breast cancer, excisional biopsy within 6 months, neoadjuvant chemotherapy before surgery, pregnancy or lactation, and contraindications to MRI. The enrolled patients must undergo any recommended biopsy or surgery.

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Figure 1. Flow chart showing an overview of the study design.
DCE = dynamic contrast-enhanced; MRI = magnetic resonance imaging; DW = diffusion-weighted; BI-RADS = breast imaging reporting and data system.

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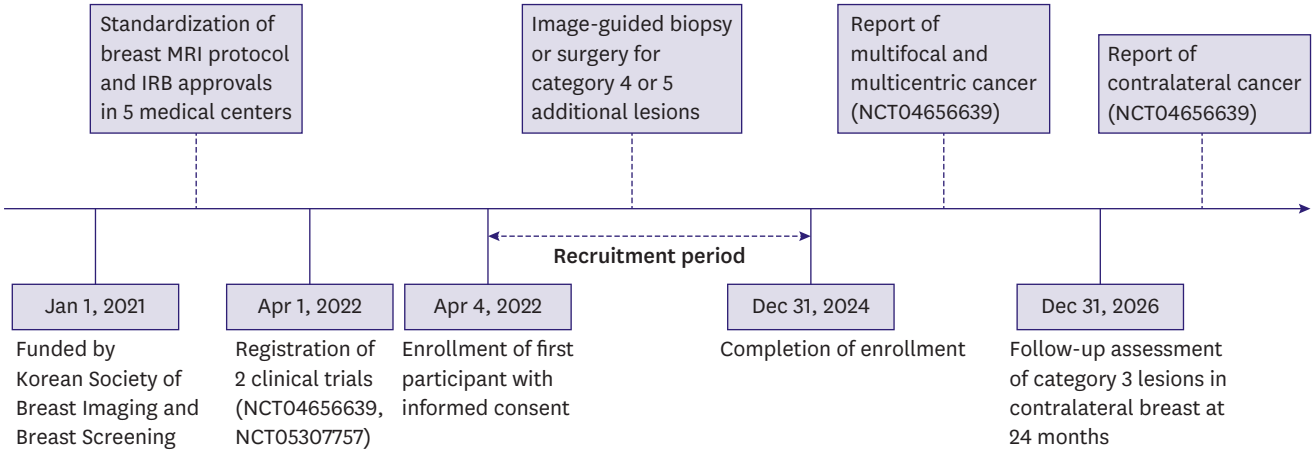

Figure 2. Overview of the study timeline.
MRI = magnetic resonance imaging; IRB = Institutional Review Board.

Study on the diagnosis of contralateral breast cancer (NCT05307757)

Females aged ≥ 25 years with newly diagnosed invasive breast cancer who underwent breast MRI for screening of the contralateral breast and had at least one MRI-detected lesion classified as BI-RADS category 3 or higher in the contralateral breast (considered positive for "screening" according to the BI-RADS guidelines) are eligible for inclusion [14]. For the contralateral breast, lesions will be enrolled regardless of visibility on conventional imaging. The exclusion criteria are identical to those of the trial NCT04656639.

Imaging acquisition

Breast MRI will be performed in the prone position using 3.0-T MRI scanners with a dedicated 16- or 18-channel breast coil (**Table 1**). MRI sequences included an axial T2-weighted imaging (T2WI) sequence, axial non-fat-suppressed T1-weighted-imaging (T1WI) sequence, and axial fat-suppressed dynamic three-dimensional T1-weighted spoiled gradient-echo sequence of one unenhanced and 2–5 dynamic contrast-enhanced acquisitions, with a temporal resolution of 60 seconds. The detailed protocol for the DW-MRI is described in **Supplementary Table 2**.

Table 1. Magnetic resonance imaging sequences for preoperative evaluation of breast cancer

Parameters	DCE MRI	DW MRI
Equipment		
Magnetic field strength	3.0T	
Type of coil	Double-breast, 16- or 18-channels	
Acquisition parameter		
Orientation	Axial	Axial
In-plane resolution	≤ 1 × 1 mm^2	≤ 1.3 × 1.3 mm^2
Slice Thickness	≤ 1 mm*	≤ 3 mm
Imaging sequences	T2, preT1, T1 DCE, delayed T1	EPI with b values of 0, 800, 1,200 sec/mm^2
Post-processing		
Subtraction	Post-contrast minus pre-contrast	NA
ADC map	NA	0 and 800 sec/mm^2
MIP	Axial and sagittal	Axial and sagittal
Acquisition time	15–20 min	6–7 min

DCE = dynamic contrast-enhanced; MRI = magnetic resonance imaging; DW = diffusion-weighted; EPI = echo-planar imaging; NA = not applicable; ADC = apparent diffusion coefficient; MIP = maximum intensity projection.
*Slice thickness = 3 mm in one institution.

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Imaging interpretation

Radiologists at each site will prospectively interpret each additional lesion using the standard BI-RADS final assessment category [14] and the likelihood of malignancy (score range, 0%–100%). The findings of conventional imaging performed before enrollment in the study (up to 2 months before breast MRI) will be reviewed. A targeted US will be performed for the area of concern on MRI, and a US- or MR-guided biopsy will be performed accordingly. A more detailed description of the lesion interpretation is provided in the **Supplementary Data 3**.

Main outcomes and measures

The primary outcome is the difference in the receiver operating characteristic (ROC) curve (AUC) between DCE-MRI and multiparametric MRI interpretation. The ROC curves will be estimated based on the readers' likelihood of malignancy. The secondary outcome consists of a comparison of the sensitivity, positive predictive value (PPV), and characteristics of the detected cancers. Sensitivity is estimated as the fraction of participants with cancer for whom the results of the imaging modality are positive and confirmed by the final pathological diagnosis. Positive imaging findings are defined as those given BI-RADS categories 4 or 5 for the staging of the ipsilateral breast (NCT04656639) and those given BI-RADS categories 3, 4, or 5 for the screening of the contralateral breast (NCT05307757) as contralateral breast in patients with unilateral breast cancer are considered for "screening" rather than as "diagnostic." According to the BI-RADS guideline [14], the assessment of BI-RADS category 3 is considered negative during the diagnostic examination because tissue diagnosis is not recommended, while it is considered positive during the screening examination because it is associated with the recommendation of additional imaging before the next routine screening examination.

The extent of the disease on MRI will be classified as follows: multifocal breast cancer is defined as the presence of more than two separate cancers in the same quadrant with at least 1.0 cm of normal-appearing tissue from the index cancer and multicentric breast cancer is defined as the presence of two or more synchronous ipsilateral cancers located in different quadrants [15].

Sample size or power calculation

Study on the diagnosis of multifocal, multicentric breast cancer (NCT04656639)

The sample size was calculated according to the hypothesis that the AUC of DCE-MRI would increase by 20% with multiparametric MRI (0.59–0.71) [13]. Approximately 580 patients would be needed to show this difference with 5% significance (two-sided) and 80% power, while allowing 10% missing data based on a disease prevalence of 15%, with at least one additional lesion other than known index cancer [3].

Study on the diagnosis of contralateral breast cancer (NCT05307757)

The sample size was calculated according to the hypothesis that the AUC of DCE-MRI would increase by 10% with multiparametric MRI with DW-MRI (0.85–0.94) [16]. To show this difference with 5% significance (two-sided) and 80% power, while allowing for 10% missing data based on a disease prevalence of 15%, approximately 1,098 patients would be needed with at least one additional lesion other than the known index cancer.

Dropout criteria

Patients who have withdrawn their informed consent, those who have undergone surgery without prior biopsy or localization of MRI-detected additional lesions, and those who have not undergone the necessary follow-up will be labeled dropouts.

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Reference standard

The reference standard for each lesion is determined from the results of an image-guided biopsy or surgery for BI-RADS category 4 or 5 lesions and an image-guided biopsy or 2-year follow-up for BI-RADS category 3 lesions. Lesions with indeterminate reference standards will be excluded from the study. During the study period, we will communicate with pathologists and surgeons to correlate the image findings with the histopathological findings, with additional sectioning performed as needed after image-guided needle localization. Tumor size, tumor focality, histological type, margin status, tumor grade, molecular subtype, and lymph node status will be recorded after all surgeries.

Statistical methods

The analysis will be performed at the lesion and breast levels. The ROC curve will be plotted and the AUC will be compared using the Delong's method for the breast level and Obuchowski's method for the lesion level, confirming the correlation between multiple lesions per patient [17,18]. Sensitivity and PPV with a 95% confidence interval will be estimated using the exact Clopper–Pearson method for the breast level or logistic regression with a generalized estimating equation for the lesion level. Continuous variables will be summarized with descriptive statistics, including mean, standard deviation, median, and interquartile range, and compared using Student's *t*-test or Mann–Whitney U test. Categorical variables will be analyzed using the χ^2 test or Fisher's exact test. Our study will be exploratory for a single group of patients diagnosed with breast cancer. A two-sided *p*-value < 0.05 indicates statistical significance. The analysis will be conducted using R software (R Foundation for Statistical Computing, Vienna, Austria).

DISCUSSION

These clinical trials aim to determine whether the combined use of DCE-MRI with DW-MRI can improve the performance of DCE-MRI alone in the preoperative evaluation of patients with newly diagnosed breast cancer.

DCE-MRI is an important imaging tool for the preoperative evaluation of breast cancer and is highly sensitive in detecting additional suspicious lesions [2,3]. However, the specificity ranges from 37% to 97%, and false-positive biopsies prompted by DCE-MRI findings cause additional examination, patient stress, costs, and delayed treatment [4,19]. DW-MRI has allowed differentiation between benign and malignant lesions with a pooled sensitivity ranging from 84% to 91% and specificity ranging from 75% to 84% [16,20]. Therefore, several researchers have advocated the use of multiparametric MRI that integrates DW-MRI with DCE-MRI to increase specificity [11,21]. A recent study that focused on additional multifocal, multicentric lesions in patients with breast cancer [13] reported that the application of an ADC threshold of 1.11×10^{-3} mm^2/s improved diagnostic accuracy with a reduced number of false positives without significantly decreasing sensitivity. Another prospective study using an ADC threshold of $1.53 - 1.68 \times 10^{-3}$ mm^2/s showed an 11% increase in PPV_2 and a corresponding 21% reduction in the biopsy recommendation rate without missing any cancer [10]. Therefore, the optimal ADC threshold to reduce false positives varies greatly ($0.9 - 1.76 \times 10^{-3}$ mm^2/s) among many studies [16,20]. In our study, we will also investigate optimal ADC thresholds, specifically in patients with newly diagnosed invasive breast cancer.

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Early DW-MRI studies have been conducted mainly at 1.5 T and used basic EPI techniques with differences in sensitivity and specificity exceeding 50% and 30%, respectively [22,23]. In our study, the conditions of participating institutions are strict with 3.0-T MRI scanners because high-spatial-resolution DW-MRI with less noise and artifacts are essential [24]. Therefore, we attempted to improve the spatial resolution of DW-MRI, and three b-values are selected to optimize the specificity and sensitivity of DW-MRI [8,25].

In summary, the clinical trials are prospective, multicenter studies designed to compare the performance of DCE-MRI and multiparametric MRI for the diagnosis of multifocal, multicentric cancers and contralateral breast cancer. We expect that patients diagnosed with breast cancer with additional identified foci on MRI will benefit better from targeted locoregional treatment and prevent unnecessary biopsy or surgery with improved interpretative accuracy. Owing to the large number of patients and data, we will be able to answer several other questions regarding the management of patients with breast cancer who have MRI-detected additional lesions. Patient enrollment is currently in progress.

SUPPLEMENTARY MATERIALS

Supplementary Table 1
Standard Protocol Items: Recommendations for Interventional Trials checklist

Click here to view

Supplementary Table 2
Diffusion-weighted magnetic resonance imaging sequences of 3 vendors

Click here to view

Supplementary Data 1
Case report forms for study (NCT04656639)

Click here to view

Supplementary Data 2
Case report forms for study (NCT05307757)

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Supplementary Data 3
Supplementary materials

Click here to view

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