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Research article

Does higher field strength translate into better diagnostic accuracy? A prospective comparison of breast MRI at 3 and 1.5 Tesla

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ABSTRACT

Objective: We performed a prospective monocentric study to inter-individually compare the diagnostic accuracy of breast MRI at 1.5 T and 3 T.

Methods: During a consecutive period of 12 months all 982 patients receiving breast MRI according to standard indications (problem solving, preoperative staging) were randomized to one 3 T or 1.5 T scanner both equipped with dedicated 16-channel breast coils. Protocols at 1.5 T and 3 T were optimized and in line with international recommendations. Due to restricted time slot availabilities, the randomization-key was defined as 1/10 (3 T/1.5 T).

All examinations were read by two experts in breast MRI (> 25 and 8 years of experience) who assigned a BI-RADS category per breast. Histopathological verification or long-term MRI follow-up (> 24 months) served as standard of reference.

Results were analyzed using cross tabulations, standard estimates of diagnostic accuracy, Chi-square test and Mann-Whitney U test (alpha = 5%).

Results: 1961 breasts were included. 1746 (89%) were imaged at 1.5 T and 215 at 3 T (11%). The 1.5 T and 3 T study cohort did not show significant differences regarding patient age (P = 0.71), results of the reference standard (P = 0.09) and indication for MRI (P = 0.53).

Overall Sensitivity (94.7%), Specificity (91.4%), Accuracy (91.9%) and Negative Predictive Value (99.0%) were within the range of the literature. Pairwise comparison of Sensitivity (1,5 T/3 T: 94.1/97.9%), Specificity (91.6/%89.3%), Accuracy (92.0%/91.2%) and Negative Predictive Value (98.9%/99.3%) were without significant differences (P = 0.29-0.74).

Conclusion: In this prospective monocentric study, we identified comparably high diagnostic accuracy for both 1.5 T and 3 T breast MRI. Both 1.5 T and 3 T are equally suited for breast imaging.

1. Introduction

The main advantages of magnetic resonance imaging of the breast (bMRI) are excellent soft tissue contrast, functional multiparametric assessment of tumor vascularization and simultaneous bilateral visualization of both breasts [1,2]. Clinically these technical properties enable a supreme sensitivity and negative predictive value [3]. In recent years, bMRI benefited from numerous technical developments including the introduction of multi-channel coils and high-field scanners. To date routine clinical breast examinations can be performed using multi-channel coils either at 1.5 T or 3 T (1.5 T or 3 T) [4–9]. The main advantage of 3 T bMRI is an increased signal to noise ratio (SNR) [10].

Abbreviations: BI-RADS, breast imaging reporting and data system; bMRI, magnetic resonance imaging of the breast; CI, 95% confidence interval; FLASH, fast low angle shot; Gd, Gadolinium; Gd-DTPA, gadolinium-diethylenetriamine pentaacetic acid; GRAPPA, GeneRalized autocalibrating partial parallel acquisition; SOR, standard of reference; SPAIR, spectrally adiabatic inversion recovery; STIR, Short Tau Inversion Recovery; T, Tesla; TE, echo time; TI, inversion time; TIM, total imaging matrix; TR, repetition time; TSE, turbo spin echo; VIBE, volumetric interpolated breath-hold examination

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Table 1
Scan protocol at 1.5 T and 3 T.

Details	Dynamic T1		T2-TSE		STIR	
	1.5 T	3 T	1.5 T	3 T	1.5 T	3 T
Sequence	FLASH 2D	VIBE 3D	T2w-TSE		STIR	
Temporal resolution [minute]	1*		2:15	3:10	2:33	3:36
In plane resolution [mm^3]	1.1 × 0.9 × 3	0.8 × 0.8 × 2	0.8 × 0.7 × 3	0.8 × 0.7 × 2	1.7 × 1.4 × 3	1.4 × 1.1 × 2
TR/TE$_{eff}$ [milliseconds]	113/ 5	4.09 / 1.54	8900 / 207	15740 / 196	8420 / 70	4460 / 81
TI [milliseconds]					150 ms	230 m
GRAPPA factor	2	2	2	3	2	2
flip angle	80°	6°	90°	90°	180°	180°
Fat suppression	None	SPAIR	none		IR	
number of slices	33	88	33	88	33	88

Note: **T** (tesla), **FLASH** (fast low angle shot), **VIBE** (volumetric interpolated breath-hold examination), **TSE** (turbo spin echo), **STIR** (Short Tau Inversion Recovery), **TR/TE** (repetition/echo time), **TI** (inversion time), **GRAPPA** (GeneRalized Autocalibrating Partial Parallel Acquisition), **SPAIR** (spectrally adiabatic inversion recovery). * Refers to one scan of the dynamic series. The dynamic series consisted of one baseline scans followed by 5 post contrast scans.

This can be invested in many ways, including a higher spatial and/or temporal resolution as well a reduced dose of contrast agent [10–12].

Early investigations reported increased imaging quality of 3 T bMRI compared to standard 1.5 T scanners [13]. Meanwhile some authors have verified some diagnostic benefits of 3 T [13–19]. Yet, these papers investigated small patient groups [13–16], specific clinical questions [14,15] or selected diagnostic criteria [16,19]. Therefore, the evidence, whether increasing the field strength from 1.5 T to 3 T alters the diagnostic accuracy of bMRI is still limited.

In context of these considerations we report our prospective monocentric diagnostic performance data of breast MRI at 1.5 T compared with 3 T. Hereby, we aimed to investigate whether increasing the field strength from 1.5 T to 3 T has an impact on the diagnostic accuracy of bMRI.

2. Methods

2.1. Patients

Informed consent for this randomized prospective non-interventional monocentric study was waived by the institutional ethical committee. Data were collected at the university hospital of Jena, Germany, an academic tertiary care institution and stored in a central database. This breast center consists of the Departments of Gynecology, Oncology, Radiology, Pathology, and Radiation Oncology. Diagnostic workup, treatment, and follow up of patients with suspected or proven breast cancer are done in accordance to evidence based multidisciplinary guidelines.

Consecutive patients receiving breast MRI over a period over 12 consecutive months were eligible. MRI indications were:

1 *problem solving* (Breast Imaging Reporting and Data System/BI-RADS: 0, 3, 4a, 4b) of equivocal ipsilateral findings
2 *preoperative staging* of suspicious findings (BI-RADS 4c and 5).

All patients provided written informed consent prior to the examination. Patients were randomly assigned to 1.5 T and 3 T examination. Due to the limited availability of time slots at the 3 T scanner, the randomization key was defined as 10/1 (1.5 T/3 T).

2.2. Standard of reference (SOR)

In case of suspicious bMRI findings, histopathology workup was defined as the SOR. Biopsy specimens were analyzed by board-certified breast pathologists. Tissue samples were taken from image-guided biopsy (core biopsy, vacuum-assisted biopsy) or surgical excision as follows: 14-Gauge core biopsy under sonographical guidance was done, if the lesion could be visualized by ultrasound. Otherwise, 12-Gauge vacuum-assisted biopsy using stereotactical guidance was performed. MRI-guided biopsy was restricted to bMRI-only lesions. Surgery was standard of care in all malignant lesions. Furthermore, surgery was performed in case of discrepant findings between imaging and histology as well as in lesions with uncertain malignant potential upon pathological examination.

In case of benign bMRI findings, patients received clinical and imaging follow up. All patients with bMRI follow-up > 24 months after the baseline bMRI were eligible. If this follow-up scan showed stable results, the initial rating was rated as true negative. In any other case, histological work-up was defined as the next diagnostic step. As all follow-up scans showed stable results, this step however was not necessary within our study collective.

2.3. Index test: MRI protocols at 1.5 and 3 T

Two MRI scanners were used (3 T/1.5: Siemens Magnetom TIM Trio/TIM Avanto; Siemens Healthineers). One standardized protocol was used per scanner. Both protocols were optimized to achieve optimal image quality at each field strength. Due to long-term positive clinical experience, 2D sequences were standard of care for dynamic contrast enhanced imaging at our institution at 1.5 T. Unfortunately, 2D imaging is associated with specific drawbacks due to B1 inhomogeneities at 3 T [20]. Therefore, a 3D protocol for 3 T was implemented as recommended [20]. 3D sequences can be blurry due to phase encoding artifacts. This is one reason why a 2D protocol was used at 1.5 T. To compensate these phase encoding artifacts at 3 T we applied spectral fat suppression [21,22].

Standard scan orientation was axial with the patient lying in prone position. 16 channel surface coils were used for 1.5 T and 3 T (RAPID MR international). Both protocols consisted of dynamic T1-weighted contrast enhanced sequences before and after (n = 5) contrast injections. In addition, Short Tau Inversion Recovery (STIR) and T2-weighted Turbo Spin Echo (TSE) sequences were acquired. Technical details on the protocol are given in Table 1.

A body weight adapted dosage of 0.1 mmol Gadolinium/kg was applied. Contrast agent was injected as a rapid bolus followed by a 20 ml saline flush. We used contrast media at 0.5 M formulations for 1.5 T (gadolinium-diethylenetriamine pentaacetate: Gd-DTPA; Bayer Healthcare) and 3 T imaging (Gd-DTPA-butyl-methacrylate; Nycomed). Different contrast agents where used as both scanners were run by different subdivisions of our department with different vendor contracts. It should be noted that the differences between both agents are chemically marginal as shown in [23].

Scaled subtractions were generated automatically by the scanner for all dynamic contrast-enhanced scans irrespective of fat suppression. Particularly in scans with fat suppression this approach is important, as it allows to distinguish T1 weighted hyperintense findings (for instance

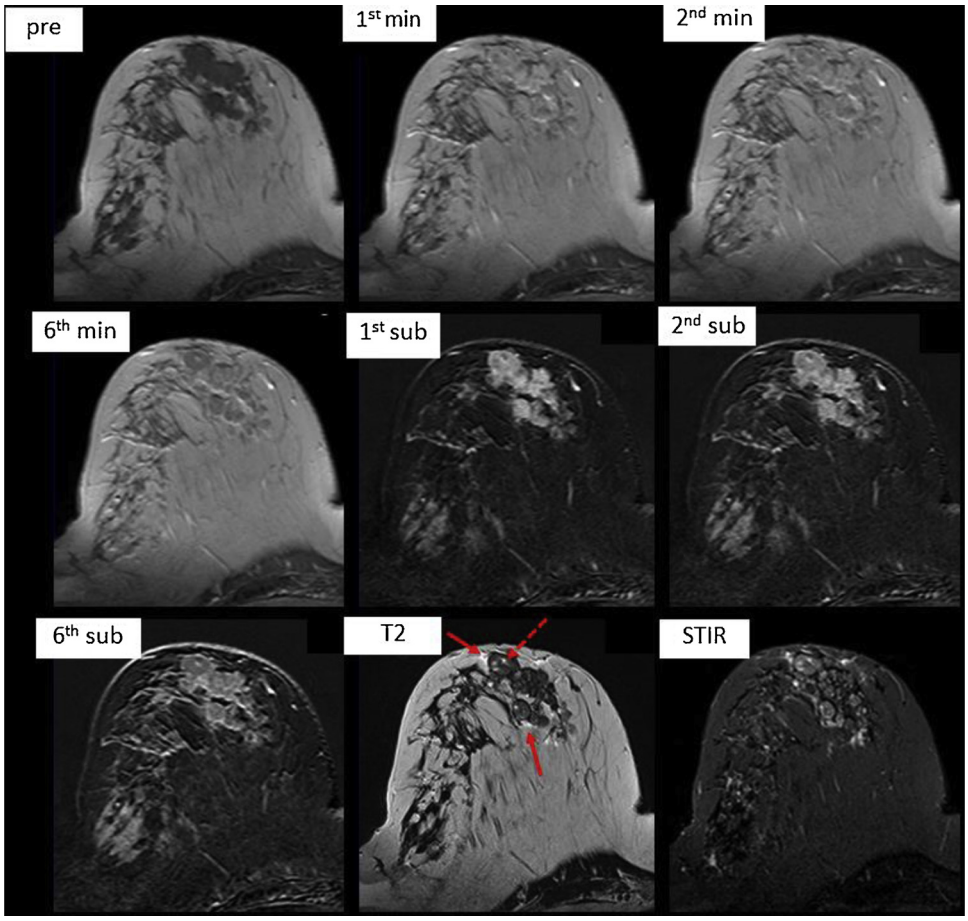

Fig. 1. Case example of a breast MRI at 1.5 T. Sequences shown from upper left to lower right: Precontrast T1w FLASH 2D, followed by 1st, 2nd and 6th minute post contrast. Then 1st, 2nd and 6th subtractions (sub), T2w-TSE and STIR. An early enhancing mass lesion with fast wash-out is depicted. Note small internal hyperintensities corresponding to necrosis on the T2-weighted scans (dashed arrows) and perifocal edema, corresponding to lymphangiosis (red arrows). Histology revealed an invasive ductal cancer G3, both necrosis and lymphangiosis were corroborated histologically.

proteinaceous fluid) from subtle enhancements (for instance in situ cancer or periductal mastitis) [21].

2.4. Interpretation of the index test

Examinations were prospectively evaluated by two breast MRI experts blinded to the SOR (both reporting > 1000 breast MRI annually, experience of reader 1/2: 8/ > 25 years). A double reading approach similar to that used for routine clinical practice was applied. While this approach does not allow to investigate inter-reader differences, it best reflects clinical practice and minimized the possibility of observer related bias in our setting. Readers had access to all relevant clinical data and previous imaging of the patient. Readers performed a structured read according to BI-RADS MRI using criteria described in [2,24]. In addition, reading conditions were standardized regarding software (Syngo viewer application, Siemens Healthineers, Erlangen, Germany) hanging protocol and window/center levels [2]. The reading layout is illustrated in Figs. 1 and 2.

2.5. Statistical analysis

bMRI ratings were analyzed on a per breast basis. BI-RADS 4 & 5 ratings were defined as “positive”, BI-RADS 1–3 as “negative” bMRI results. In case of multiple lesions per breast, only the most suspicious finding defined the diagnosis.

bMRI ratings (“positive” or “negative”) were stratified by the field strength (1.5 T or 3 T) and were compared with the SOR (benign or malignant). Contingency tables were created and descriptive statistics were applied (absolute/relative frequencies, mean, median, range). In addition, group comparisons were performed (nominal/quantitative parameters: Chi-square/Mann-Whitney U test).

Finally, the diagnostic performance estimates sensitivity, specificity, diagnostic accuracy, positive predictive value and negative predictive value were calculated including corresponding 95% confidence intervals (CI) [25]. Corresponding values for 1.5 T and 3 T were compared by 'N-1′ chi-squared test [26]. Alpha was defined as 5%.

3. Results

1961 breasts (further referred to as “cases”) in 982 patients were included into the final analysis. 1746 (89%) were imaged with 1.5 T and 215 with 3 T (11%).

Both study cohorts showed similar clinical background data: *Mean age* was 57 and 55 years for 1.5 T and 3 T (P = 0.71). *Indication for bMRI* were alike and consisted of problem solving (1.5 T, 3 T: 51.7%, 48.4%), preoperative staging (18.0%, 17.7%). In the remaining cases, the breast was examined to rule out ipsilateral disease in the presence of suspicious contralateral findings (30.3%, 34.0%: P = 0.53). Median lesions size was 18.5 mm (range: 3–105 mm) with a similar distribution between the 1.5 T (median 19 mm: range 3–105 mm) and 3 T cases (median: 18 mm, range 7–98 mm; P = 0.63). Results of the SOR are listed in Table 2: In both cohorts, invasive ductal and lobular cancers were the most frequent type of malignant lesions (11.9%, 16.3%). Although minor differences in the results of the SOR were noted, these did not translate into a significant different composition between the study cohorts (P = 0.09).

Cross tabulations of diagnostic performance stratified by field strengths are given in Table 3. Overall diagnostic accuracy was 91.9% (CI: 90.6–93.0). This parameter reached 92.0% (CI: 90.6–93.2) for 1.5 T and 91.2% for 3 T examinations (CI: 86.6–94.3). With a difference of 0.8% there was no statistical significance between 1.5 T and 3 T bMRI (P = 0.68). Based on sample size calculation, this difference would

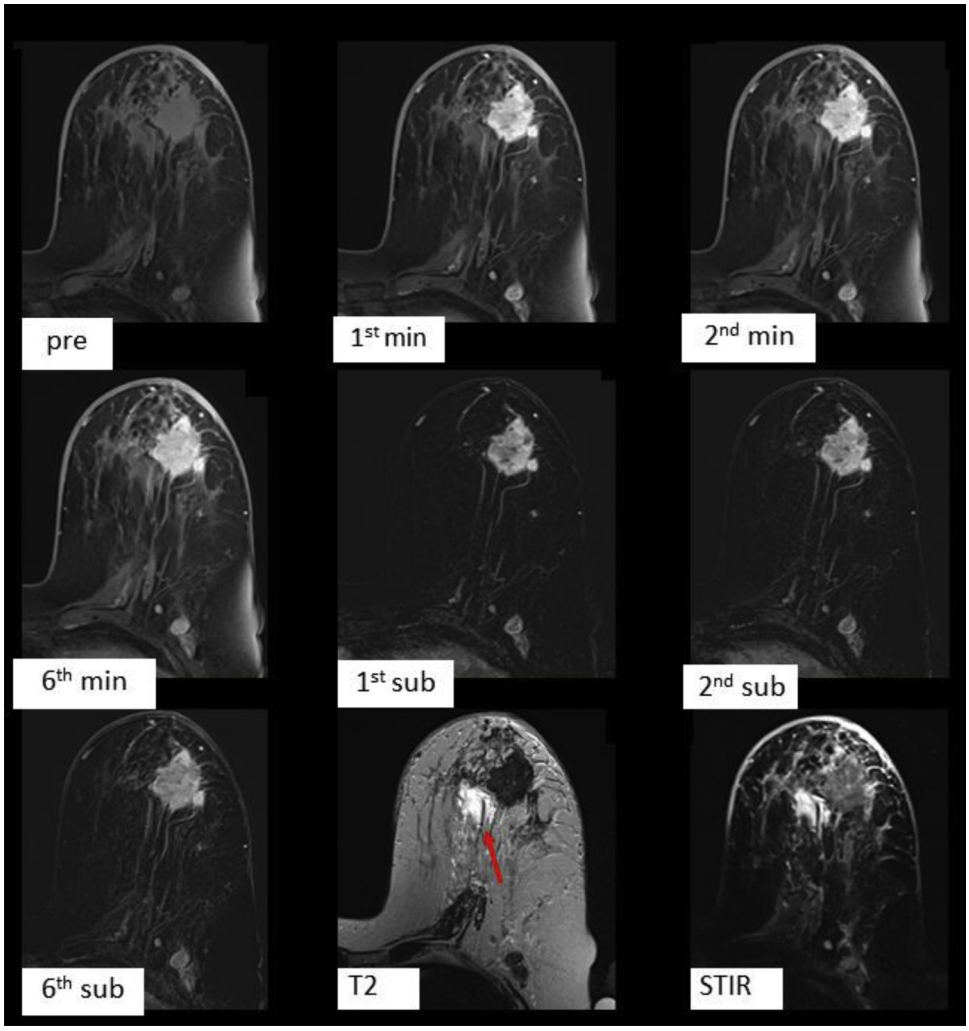

Fig. 2. Case example of a breast MRI at 3 T. Sequences shown from upper left to lower right: Precontrast T1w 3D VIBE with spectral fat suppression, followed by 1st, 2nd and 6th minute post contrast. Then 1st, 2nd and 6th subtractions (sub), T2w-TSE and STIR. The exam shows an early enhancing mass lesion with wash-out. Note distinct perifocal edema, corresponding to lymphangiosis (red arrows). Histology revealed an invasive ductal cancer G3, lymphangiosis was also reported histologically.

become statistically significant at a 24-fold increase of the study population (> 47.000 patients). Further key parameters of diagnostic accuracy are summarized in Table 4. All were without statistical significance between the 1.5 T and 3 T bMRI group (P = 0.29-0.65).

4. Discussion

This randomized prospective monocentric study identified high diagnostic performance both for 1.5 T and 3 T bMRI. All key parameters of diagnostic accuracy were similar and did not show significant differences between 1.5 T and 3 T (Table 4). As a secondary result, our data provide evidence that, if a protocol is optimized for the specific scanner hardware (magnet, coil, etc.), high image quality is achievable on either MRI unit.

Our results are representative, as the diagnostic accuracy determined in our study corresponds to the values known from the literature: A recent meta-analysis reported a true positive (276/283) and true negative rate (1813/2033) for breast MRI in the assessment of non-calcified lesions [3]. This equals a diagnostic accuracy of 90.2% and corresponds to the value observed in our analysis (92.0%; Table 4).

All key parameters of diagnostic accuracy were similar and did not show significant difference between 1.5 T and 3 T breast MRI. To the best of our knowledge this has not been demonstrated in the literature previously. The few studies published to date on 3 T MRI were generally in favor of the higher field strength. However, these papers focused either on small patient groups [13–16], specific clinical questions, selected diagnostic criteria [16,19] or the cancer detection rate only [14,18]. Perceived advantages of 3 T bMRI might thus be due to study design and a classical publication bias in favor of newer techniques.

As a secondary result our data provide evidence that high image quality can be achieved by any MRI unit. To achieve a high image quality, a standard clinical scanner equipped with a breast surface coil is sufficient. The only prerequisite is the optimization of the protocol for the specific scanner hardware (magnet, coil, etc.). This secondary result is important, as there has been much discussion in the past decades which protocol is necessary for accurate diagnosis. This included the choice of sequence type (2D or 3D imaging) or the question whether fat suppression is needed. A recent survey highlighted the heterogeneity of bMRI protocols used throughout Europe [9]. Our data suggest, that diagnostic performance differences between institutions might less depend on technical issues but inter-reader difference and experience as also suggested in [27].

Although 1.5 T and 3 T performed similar, we currently witness a general trend to 3 T *imaging.* To date 3 T imaging has achieved a market penetration of about 16% [28]. This development is certainly driven by the major MRI applications such as neuro and musculoskeletal imaging.

Table 2
Reference standard stratified by magnetic field strength.

Standard of reference	Results	Field strength		Total
		1.5 T	3 T	
Histology	Invasive ductal cancer	155	27	182
		8.9%	12.6%	9.3%
	Invasive lobular cancer	53	8	61
		3.0%	3.7%	3.1%
	Ductal carcinoma in situ	21	6	27
		1.2%	2.8%	1.4%
	Other cancer	25	6	31
		1.4%	2.8%	1.6%
	Fibroadenoma	15	4	19
		0.9%	1.9%	1.0%
	Papilloma	7	1	8
		0.4%	0.5%	0.4%
	Fibrocystic changes	71	6	77
		4.1%	2.8%	3.9%
	Inflammation	8	2	10
		0.5%	0.9%	0.5%
Follow up	Benign*	1391	155	1546
		79.7%	72.1%	78.8%
Total		1746	215	1961
		100%	100%	100%

Note: According to the design of an intra-individual comparison study minor differences in the standard of reference were noted. Yet, these did not translate into a significant different composition of both study cohorts (P = 0.09). If the MRI showed benign findings, no biopsy was done and the patient received **Follow up** clinically and by MRI for a minimum of 24 months. If this follow-scan showed stable results, the initial rating was rated as **Benign** (details see main text). * No false negative cases were identified during follow up. **Percentages** are given per column.

Table 3
Cross tabulation of MRI Diagnosis, standard of references and field strength.

Field strength	MRI Diagnosis				
	TP	FP	FN	TN	Total
1.5 T	239	125	15	1367	1746
	13.7%	7.2%	0.9%	78.3%	100%
3 T	46	18	1	150	215
	21.4%	8.4%	0.5%	69.8%	100%
Total	285	143	16	1517	1961
	14.5%	7.3%	0.8%	77.4%	100%

Note: **MRI Diagnosis** is stratified by the results of the standard of reference (see Table 2) as: true or false positive (**TP or TP**) and false or true negative (**FN or TN**). **Percentages** are given per row.

Yet, bRMI is still a niche market accounting for 3% of the examinations [28]. In the context of these data it is interesting to analyze a recent survey on the utilization of breast MRI in clinical practice [9]. Results show that the dissemination of 3 T breast MRI is much higher than expected [28]: Actually 22.6% of the radiologists perform bMRI only at 3 T, whereas an additional 19.5% perform bMRI both at 1.5 T and 3 T [9]. Considering equivalent time slots, the costs of a 3 T examination are at least 30% higher concerning both purchasing and maintenance [29]. Interestingly, the SNR benefit of 3 T systems has not been used to shorten bMRI protocols, a current trend that gains considerable attention in the community.

Yet, there are arguments to perform 3 T bMRI as well: 3 T breast MRI examinations can help to reduce the dosage of contrast agents [10–12]. Though physically evident, this potential advantage of high field MRI is currently not exploited [10–12,30]. However it could become more important, due to the ongoing discussion regarding the safety of gadolinium containing contrast agents [31]. This effect is even more accentuated in the context of repeated follow-up scans, a typical situation in patients at high risk of developing breast cancer [1,32].

Higher field strength such as broadly available now by clinical 3 T (and 7 T) units has further advantages regarding the application of newer functional and quantitative MRI techniques that are usually limited by low SNR and/or low spatial resolution and long acquisition times. An example is multinuclear MRI: classically, bMRI is proton imaging based due to the abundance of hydrogen within the body. Yet, with higher field strength, sodium could also be investigated that plays an important role in physiological and pathophysiological processes throughout body including but not limited to neoplastic conditions [33]. For instance, sodium increase has been associated with malignant tumors and could thus be used as an imaging biomarker [33]. Chemical exchange saturation transfer imaging (CEST) is another emerging MRI technique benefitting from high field strength. CEST is able to measure compounds whose concentration is too low to be measured by standard MR imaging or spectroscopy [34]. Both for CEST and for sodium imaging the higher SNR of magnets with a minimum of 3 T field strength is a prerequisite.

4.1. Limitations of our study should be addressed

We did not perform an intra-individual comparison of 3 T and 1.5 T protocols. In the context of the ongoing critical discussion of gadolinium containing contrast agents such a study would only be justified, if significant benefits could be expected from 3 T bMRI [31]. According to our observation this is unlikely.

As we had to opt for an inter-individual comparison study some inhomogeneities between both study cohorts had to be accepted. As reported above, no major differences between both cohorts have been observed and our results are within the range of recently published metadata [3]. Therefore, we do not expect a relevant bias.

Another potential limitation of our study is the consensus reading design. This should however not be considered a weakness, but rather a strength of this study: Although inter-reader differences cannot be evaluated, the double-reading approach largely eliminates observer related bias and resembles clinical practice in our and many other institutions that employ a double-reading approach for bMRI. Therefore, results of our study are directly applicable to the investigated setting. Though possibly not necessary considering the findings reported within this paper, a more complex laboratory reading session including multiple readers might investigate the potential effect of single factors such as field strength, sequence protocol and reader experience on inter-reader variability or diagnostic confidence.

Table 4
Diagnostic accuracy stratified by the magnetic field strength.

Parameter*	All cases	1.5 T	3 T	*P*
Sensitivity	94.7 (91.5-96.9)	94.1 (90.4-96.7)	97.9 (88.7-99.9)	0.29
Specificity	91.4 (89.9-92.7)	91.6 (90.1-93.0)	89.3 (83.6-93.5)	0.31
Accuracy	91.9 (90.6-93.0)	92.0 (90.6-93.2)	91.2 (86.6-94.3)	0.68
Positive Predictive Value	66.6 (63.0-70.0)	65.7 (61.7-69.4)	71.9 (62.2-79.8)	0.33
Negative Predictive Value	99.0 (98.3-99.4)	98.9 (98.2-99.3)	99.3 (95.6-99.9)	0.65

Note: There was no significant difference of the diagnostic accuracy between 1.5 and 3 T breast MRI (P = 0.68). * Values are given as %. Numbers in brackets are 95% confidence interval.

5. Conclusion

In conclusion, this randomized prospective monocentric study identified high diagnostic performance both for 1.5 T and 3 T breast MRI. All key parameters of diagnostic accuracy were comparable and did not show significant differences between 1.5 T and 3 T breast MRI. Our data provide evidence for a secondary result: If a protocol is optimized for the specific scanner hardware (magnet, coil, etc.), high image quality and thus high diagnostic accuracy is achievable on either MRI unit.

Our findings have several implications: bMRI is robust and can be performed with various protocols and scanner types. The impact of sequences parameters and the scanner hardware is probably much lower than expected previously. While examinations at 1.5 T are cheaper, 3 T bMRI has certain inherent advantages: most of all, the potential to reduce the dosage of contrast agents.

Conflicts of interest

None.

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The authors dedicate this work to the memory of Dr. Werner A. Kaiserour mentor and friend and one of the readers of this study.

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