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Characteristics of clinically node negative breast cancer patients needing preoperative MRI

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ABSTRACT

Background: International guidelines do not recommend magnetic resonance imaging (MRI) for all breast cancer patients at primary diagnostics. This study aimed to understand which patient or tumor characteristics are associated with the use of MRI. The role of MRI among other preoperative imaging methods in clinically node negative breast cancer was studied.
Material and methods: Patient and tumor characteristics were analyzed in association with the use of MRI by multivariable logistic regression analysis in 461 patients. Primary tumor size was compared between MRI, mammography (MGR), ultrasound (US) and histopathology by Spearman correlation. The delays in surgery and diagnosis were analyzed among patients with or without MRI, and axillary reoperations were evaluated.
Results: Age ($p < 0.0001$), primary operation method ($p < 0.0001$), tumor histology ($p < 0.0001$) and HER2 status ($p = 0.0064$) were associated with the use of MRI. Spearman correlations between tumor size in histopathology and the difference in tumor size between histopathology and imaging methods were 0.52 in MGR, 0.66 in US and 0.36 in MRI ($p < 0.0001$ for all). A seven-day delay in surgical treatment was observed among patients with MRI compared to patients without MRI ($p < 0.0001$). Axillary reoperation rates were similar in patients with or without MRI ($p = 0.57$).
Conclusion: Patient selection through prearranged characterization is important in deciding on optimal candidates for preoperative MRI among breast cancer patients. MRI causes moderate delays in primary breast cancer surgery. Preoperative MRI is useful in the evaluation of tumor size but might be insufficient in detecting lymph node metastases.

1. Introduction

Preoperative imaging has a central role in the planning of primary breast cancer surgery. The imaging methods need to estimate the tumor size, the location, the presence of accompanying ductal carcinoma in situ and the regional lymph node status as accurately as possible. This way the extent of primary surgery can be optimized. Investigating the role of different imaging methods is a continuing concern within early breast cancer diagnostics.

The staging in clinically node negative breast cancer is based on physical examination, preoperative imaging and postoperative pathological methods [1]. To detect cancer at early stage, the standard breast cancer screening is performed by mammography (MGR) for women aged 50–69 years old [2]. When cancer is suspected, an ultrasound (US) examination and a core biopsy are performed prior to surgery. Preoperative axillary lymph node (ALN) assessment is mainly based on the US findings and clinical palpation. Fine needle aspiration cytology is employed on morphologically altered ALNs. In some cases, preoperative magnetic resonance imaging (MRI) is requested for additional information.

Currently, MRI is not recommended as a routine breast cancer screening method or as a part of the routine preoperative stage assessment [1,3]. Concerns in routine preoperative MRI on unselected patients include false positive findings, overtreatment and increasing costs [3,4].

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A European survey study has reported that referring patients to preoperative MRI is mainly in line with the imaging guidelines, although the indications for MRI vary between countries [5]. Yet there may be discrepancy between guidelines and clinical practice as a substantial number of patients are referred to MRI prior to primary operation in order to improve the understanding on tumor extent.

This study presents the role of MRI and other preoperative imaging investigations among clinically node negative breast cancer patients. The aim was to clarify which patient characteristics are associated with the more frequent use of MRI, how preoperative MRI portrays the tumor in comparison to MGR, US and postoperative histopathological findings, and how it may affect the treatment path.

2. Material and Methods

We identified 2574 breast cancer patients operated in 2012–2016. Patients who were both clinically node negative and underwent breast-conserving surgery or mastectomy together with sentinel lymph node biopsy and axillary lymph node dissection (ALND) formed the study cohort, n = 461. ALND was performed either during primary operation or in a delayed, separate operation according to the clinical practice of the time. Delayed ALNDs were due to the detection of sentinel lymph node positivity in paraffin section after primary surgery. All patients had preoperative imaging by MGR and US and histopathological assessment of tumor samples performed. 1.5 T and 3.0 T MRI scanners (Magnetom Avanto and Magnetom Aera, Siemens) were used for MRI on selected patients. To evaluate axillary nodal burden in preoperative imaging, a subcohort of patients (n = 96) with triple imaging (MRI in addition to MGR and US) was chosen for further analysis. Male patients and patients who received systemic neoadjuvant therapies or had bilateral breast cancer were excluded.

2.1. Statistical methods

To characterize the patient cohort, continuous variables are reported with means and standard deviations (SD) when normally distributed, and with medians and interquartile ranges (IQR) otherwise. Categorical variables are reported with counts and percentages. Patient age was categorized as $<$ 50 years old or $\geq$50 years old according to the age limit in the national breast cancer screening program.

The time from tumor detection to primary operation and final postoperative pathological anatomic diagnosis (PAD) was calculated in days from the date of first tumor detection in any imaging modality to the date of primary breast cancer surgery, and to the date of final histological report of the excised breast cancer specimens.

Chi-square test or Fisher exact test was used to compare the frequencies of categorical variables. The differences in normally distributed continuous variables were examined with two-sample *t*-test or 1-way analysis of variance using Tukey's method in pairwise comparisons. Mann-Whitney *U* test and Kruskal-Wallis tests with Dwass-Steel-Critchlow-Fligner method in pairwise comparisons were used to compare non-normally distributed continuous variables. Median differences between tumor size in final PAD and imaging methods were tested using Wilcoxon signed rank. Correlations between between tumor size in final PAD and the difference in tumor size between final PAD and imaging methods were calculated with Spearman correlation coefficients. McNemar's test was used to compare the frequencies of negative and suspicious ALNs in preoperative imaging.

Statistically significant patient and tumor characteristics in the univariate analysis were included in a multivariable logistic regression analysis to detect which characteristics were independently associated with triple imaging or operation method. Age was used in two separate analyses as a continuous and as a categorical variable ($<$50 or $\geq$ 50 years). Results of logistic regression analysis are expressed using odds ratios (OR) with 95% confidence intervals (CI).

Significance level 0.05 was used, and all tests were two-sided. Statistical analyses were performed with SAS System for Windows (version 9.4, SAS Institute Inc., Cary, NC).

2.2. Ethical consideration

Being a register study, no patient contacts were activated. The study plan was approved by the local ethics committee. The study was conducted according to the current laws of our country. Data storage, registration and analyses were conducted pseudonymized, and data management was compatible with local instructions and the EU General Data Protection Regulation.

3. Results

The mean age of patients was 63.2 years (SD 12.6, range 26–93). Of the patients, 71 (15.4%) were $<$50 years old at the time of primary operation. Triple imaging was performed for 198 (42.9%) patients. The mean age of patients with triple imaging was 58.7 years (SD 11.2) whereas the mean age of patients with standard imaging was 66.5 years (SD 12.6) ($p < 0.0001$). Among patients under 50 years old, MRI was performed in 41 (57.7%) cases, whereas among patients 50 years old or

Table 1
Univariate analysis of patients selected for preoperative MRI.

	Without MRI, n = 263	With MRI, n = 198	p
Mean age in years, (SD)	66.5 (12.6)	58.7 (11.2)	<0.0001
Number of patients			0.0062
< 50 years old	30 (11.4%)	41 (20.7%)	
≥ 50 years old	233 (88.6%)	157 (79.3%)	
Type of primary operation:			<0.0001
Breast-conserving	171 (65.0%)	91 (35.0%)	
Mastectomy	92 (46.0%)	107 (54.0%)	
Axillary dissection:			0.5739
In the primary operation	249 (94.7%)	185 (93.4%)	
In a separate operation	14 (5.3%)	13 (6.6%)	
Median tumor size, mm (IQR)	23.0 (16.5)	28.0 (25.0)	0.0016
Histological type:			<0.0001
Invasive ductal	234 (89.0%)	133 (67.2%)	
Invasive lobular	20 (7.6%)	55 (27.8%)	
Mixed invasive ductal and lobular	6 (2.3%)	6 (3.0%)	
Other	3 (1.1%)	4 (2.0%)	
Tumor grade:			0.0459
I	32 (12.2%)	12 (6.1%)	
II	149 (56.9%)	130 (65.7%)	
III	81 (30.9%)	56 (28.3%)	
Lymphovascular invasion:			0.7574
Present	32 (12.2%)	26 (13.1%)	
Not present	231 (87.8%)	172 (86.9%)	
ER, median % of positive cells (IQR)	95.0 (8.0)	95.0 (8.0)	0.4630
PR, median % of positive cells (IQR)	90.0 (35.0)	90.0 (35.0)	0.2261
HER2:			0.0058
Positive	18 (6.8%)	29 (14.7%)	
Negative	245 (93.2%)	168 (85.3%)	
Ki67	20.0 (18.0)	20.0 (18.0)	0.2530
Biological subtype:			0.6231
Luminal A-like	74 (28.1%)	57 (29.1%)	
Luminal B-like	169 (64.3%)	127 (64.8%)	
HER2	3 (1.1%)	4 (2.0%)	
Triple negative	17 (6.5%)	8 (4.1%)	
Multifocality:			0.0071
Present	76 (28.9%)	81 (40.9%)	
Not present	187 (71.1%)	117 (59.1%)	
Tumor palpability:			0.2151
Palpable	215 (81.7%)	149 (75.3%)	
Not palpable	46 (17.5%)	46 (23.2%)	
Unknown	2 (0.8%)	3 (1.5%)	

ER estrogen receptor, *PR* progesterone receptor, *HER2* human epidermal growth factor receptor 2, *MRI* magnetic resonance imaging.

older, MRI was performed in 157 (40.3%) cases (p = 0.0062). Table 1 shows patient and tumor characteristics of patients selected for preoperative MRI.

3.1. Tumor detection method

151 (32.8%) tumors were detected by screening MGR, 280 (60.7%) tumors by palpation and 30 (6.5%) tumors by other ways (for example as an incidental finding). The mean age of patients with tumor detection by screening MGR was 60.3 years (SD 5.8), whereas by palpation it was 64.0 years (SD 14.8) and by other ways it was 69.5 years (SD 11.7); the difference was statistically significant (p = 0.0010 for screening vs palpation, p = 0.0001 for screening vs other ways and p = 0.0449 for palpation vs other ways). Tumor size was larger when detected by palpation than by screening (p < 0.0001) or by other ways (p = 0.0359). Tumor detection method was not associated with the number of axillary metastases (p = 0.0764), multifocality (p = 0.8750) or tumor histology (p = 0.2298).

3.2. Time to operation and final postoperative pathological anatomic diagnosis

The time from tumor detection to primary operation differed between patients with standard preoperative imaging and patients with triple imaging: The median time from tumor detection to primary operation was 36 days for patients without additional MRI and 43 days for patients with additional MRI (p < 0.0001). Similarly, the median time from tumor detection to final PAD was 57 days for patients without MRI and 64 days for patients with MRI (p = 0.0004).

The median time from tumor detection to final PAD was 60 days for patients with ALND performed in the primary operation (n = 434), and 81 days for patients with ALND performed later in a separate operation (n = 26). Thus, the decision to re-operate the ALNs after a late positive sentinel lymph node finding delayed the final PAD with three weeks compared to the patients with ALND performed in the primary operation (p = 0.0044).

3.3. The association of preoperative imaging with primary operation method

Patients with triple imaging underwent mastectomy as the primary surgery more often than patients imaged by US and MGR only (p < 0.0001): Of the patients with MRI, 91 (46.0%) underwent tumor resection and 107 (54.0%) underwent mastectomy. Without MRI, 171 (65.0%) patients underwent tumor resection and 92 (35.0) underwent mastectomy. Information on breast reoperations were not collected. No statistically significant difference was found between patients with or without MRI and axillary reoperation rate (p = 0.5739).

3.4. Axillary lymph nodes in preoperative imaging

In final PAD, the median number of metastatic ALNs was one (IQR 2, range 0–30); 80.3% of patients had 1 or 2 ALN metastases of any size. All patients had at least one positive lymph node in the final PAD, when isolated tumor cells were included. Among selected 96 patients with triple imaging, no difference in the suspicion of axillary metastases was detected between MRI and US (p = 0.7815): In axillary MRI, 85 (89.5%) patients had negative ALNs and 10 (10.5%) had a suspicion of positive ALNs preoperatively. In axillary US, 86 (90.5%) patients had negative ALNs and 9 (9.5%) patients had a suspicion of positive ALNs preoperatively. The information of one patient was missing for analysis.

3.5. Tumor size in preoperative imaging and final postoperative pathological anatomic diagnosis

Table 2 presents the tumor size by different imaging methods and final PAD. The median tumor size in MRI was 5.5 mm (IQR 22.5) larger than in final PAD (p < 0.0001). Contrarily, the median tumor size was 4.0 mm (IQR 13.5) smaller in US (p < 0.0001) and 2.0 mm (IQR 12.0) smaller in MGR (p < 0.0001) than in final PAD. The correlation between tumor size and the difference in tumor size between histopathology and imaging was the smallest in MRI and the largest in US: the Spearman correlations between tumor size in final PAD and the difference in tumor size between final PAD and imaging methods were 0.52 in MGR, 0.66 in US and 0.36 in MRI (p < 0.0001 for all). The discrepancy between tumor image and histopathological size increased with the increase in tumor size, as shown in Fig. 1.

Table 2
Tumor size by imaging and final PAD.

	MGR (n = 401)	US (n = 404)	MRI (n = 195)	PAD (n = 461)	p
Median tumor size, mm (IQR)	20.0 (16.0)	18.0 (13.0)	40.0 (36.0)	24.0 (18.3)	
Median difference in tumor size between PAD and imaging	2.0 (0.52)	4.0 (0.66)	−5.5 (0.36)		<0.0001*

PAD pathological anatomic diagnosis, *MGR* mammography, *US* ultrasound, *MRI* magnetic resonance imaging. *p < 0.0001 for all pairwise comparisons PAD vs MGR, PAD vs US and PAD vs MRI.

3.6. Multifocal tumors

Multifocal tumors were observed in 157 (34.1%) patients. The median multifocal tumor extent was 43.0 mm (IQR 37.5) in MRI, 20.0 mm (IQR 11.5) in US, 20.0 mm (IQR 17.0) in MGR and 33.0 mm (IQR 23.5) in final PAD. The comparable tumor sizes for unifocal tumors were 35.0 mm (IQR 30.0), 17.5 mm (IQR 11.5), 20.0 mm (IQR 17.0) and 21.0 mm (IQR), respectively. The imaging findings showed that multifocal tumors were significantly larger than unifocal tumors in MRI (p = 0.0029), US (p = 0.0129) and final PAD (p < 0.0001), but not in MGR (p = 0.2022). Multifocality was most found in combination tumors (invasive ductal together with other histology found in the same breast), in which multifocality was present in 75–100% of cases. Multifocality was found in 50.7% of pure invasive lobular tumors and in 29.7% of pure invasive ductal tumors.

3.7. Multivariable analysis of patient and tumor characteristics associated with triple imaging

Age, primary operation method (breast-conserving surgery or mastectomy), tumor histology, tumor grade, HER2 status, multifocality and tumor size were included in the multivariable analysis to detect independent associations of different characteristics with triple imaging, according to the results in univariate analysis (Table 1). Age was used in two separate analyses as a continuous and as a categorical variable. Multivariable logistic regression analysis showed that age (OR 0.93, 95% CI 0.91 to 0.95, p < 0.0001), primary operation method (OR 2.57, 95%CI 1.60 to 4.13, p < 0.0001), tumor histology (invasive lobular vs invasive ductal carcinoma, OR 5.74, 95% CI 2.94 to 11.20, p < 0.0001 and other histology vs invasive ductal carcinoma, OR 13.04, 95% CI 2.09 to 81.31, p = 0.0060) and HER2 status (OR 2.82, 95% CI 1.34 to 5.93, p = 0.0064) had independent associations with the more frequent use of MRI, when age was determined as a continuous variable. When age was categorized as < 50 years old or ≥50 years old, the result was similar.

4. Discussion

This study investigates a view on preoperative imaging, patient characteristics associated with preoperative MRI, and the effects of MRI on the breast cancer treatment path. The more frequent use of

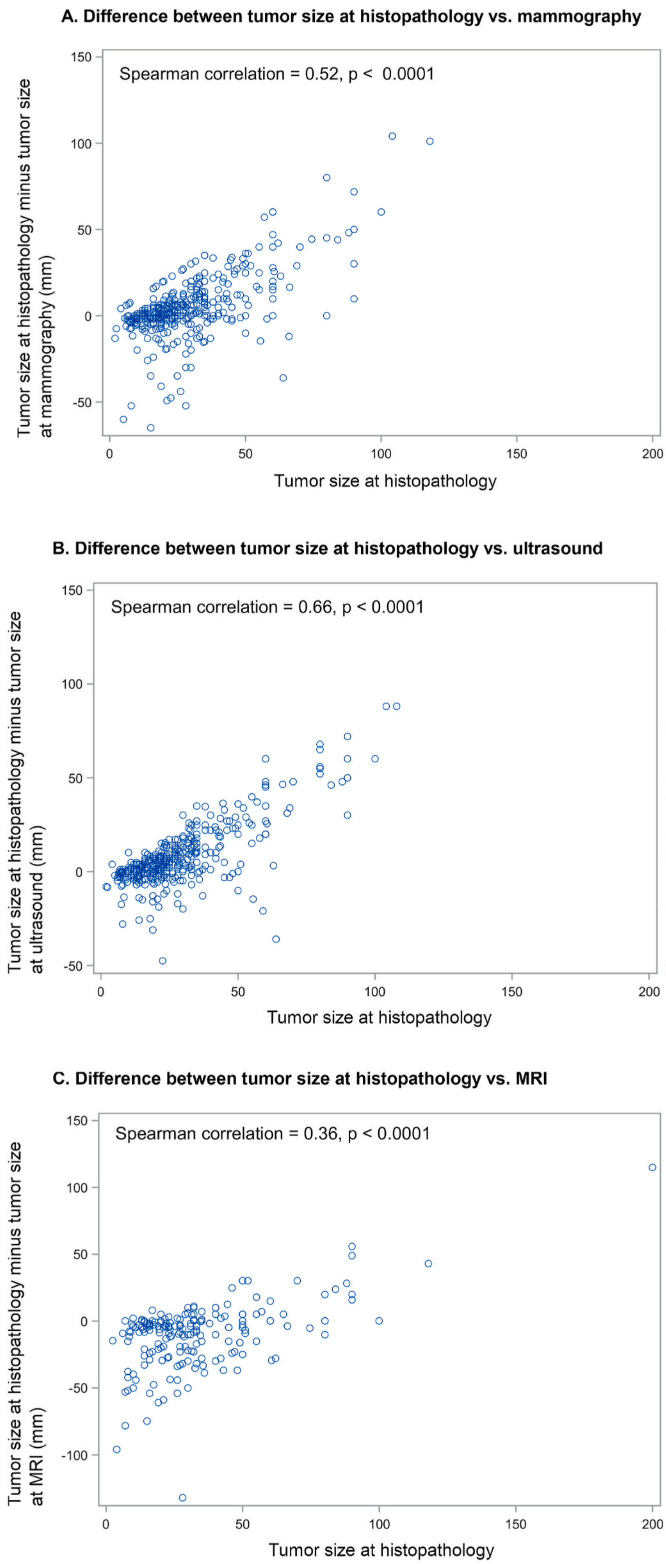

Fig. 1. Difference between tumor size at histopathology vs. A. mammography B. ultrasound and C. MRI, as a function of size at histopathology.

preoperative MRI was associated with younger patient age, primary operation method, tumor histology and HER2 positivity in a multivariable analysis.

The breast cancer diagnosis should include clinical examination, diagnostic MGR and/or US imaging and a core biopsy to maximize the diagnostic accuracy [1,6]. The sensitivity of MGR increases with age since MGR performs better on fatty than on dense breast tissue [7]. MRI can be considered complementary to MGR, especially in the evaluation of DCIS, invasive lobular cancer and tumor extent [8]. Because MRI is a very sensitive test, it can pick up precancerous changes. "Second-look" breast US is helpful in characterizing abnormal areas detected by MRI and preventing overtreatment in non-cancerous cases [9]. Multidisciplinary case management meeting should have discussions of preoperative breast cancer cases for optimal treatment planning [10].

In the current study, clinically node negative patients who were selected for preoperative MRI were younger, had invasive lobular tumors and HER2 positive tumors more often than those without preoperative MRI. These results seem to reflect the clinical guidelines: preoperative MRI is recommended in invasive lobular histology and if the patient is considered for neoadjuvant therapy due to HER2 positivity [1,3]. Younger patients may be selected due to breast density or hereditary cancer, although information on these factors were not collected in the current study. Patients with preoperative MRI were more likely to undergo mastectomy than breast-conserving surgery in the primary operation, which can be explained by larger tumor size. In the univariate analysis, multifocality and large tumor size associated with more frequent use of MRI. These results indicate that there is a good concordance between clinical practice and guideline recommendations in selecting patients with certain characteristics to preoperative MRI, although preoperative MRI may be considered unnecessary in cases with planned mastectomy [4].

Many previous studies have investigated primary tumor size in different imaging methods. As stated by the EUSOMA working group, both US and MGR have been outperformed by MRI in the accuracy of detecting tumors and estimating tumor size [3,11–13]. The current study is in line with this statement: MRI was the most accurate imaging method in estimating tumor size, although it tended to overestimation. The discrepancies between tumor size in imaging and histopathology were larger when tumor size increased. This may be partly explained by DCIS which appears abnormal in imaging but is not counted in the final invasive histopathological tumor size. Concerning the ALN status, US and MRI should be able to differentiate negative ALNs from positive ones with false negative rate of 25% [14]. Yet, in the current study, only 10% of ALN metastases were suspected by MRI or US. The cases of false negative imaging results were probably concentrated in the study population.

Some studies have indicated that preoperative MRI delays surgical treatment for as long as 11–22 days [15,16]. Our study showed a more moderate delay of seven days in surgical treatment after additional MRI. Including MRI in the routine diagnostic work-up might further shorten this delay. In the current clinical practice, patients wait for the multidisciplinary meeting's decision on referral to preoperative MRI, after which another US examination must be waited for additional needle biopsies. Then, the histopathological reports of the biopsies are waited. Postoperatively, the conclusive PAD may be delayed due to the careful work by breast pathologists to search for the abnormalities seen in MRI. Nevertheless, a moderate delay in surgical treatment can be tolerated, if reoperations can thus be avoided.

Recently, a considerable literature has grown up around preoperative imaging in breast cancer. A randomized study and a meta-analysis have presented that preoperative MRI does not decrease the need for reoperation [17,18], although contradiction exists [19]. Even though MRI resulted in larger tumor size estimates and more mastectomies in the primary operation, the relevance and the necessity of mastectomy after MRI cannot be evaluated by this study. We did not investigate the reoperation rate of the primary breast surgery, and we had no information on patient wishes for surgical method, which might have affected the decision on a more radical surgery. The current results indicate that reoperation rate for ALNs was not different between patients with or without preoperative MRI. This is notable, since sentinel lymph node biopsy is more common after preoperative MRI than after standard imaging [19]. However, the change in clinical practice has further decreased axillary dissections, as adjuvant therapies are often considered an adequate treatment for the regional lymph nodes.

Our study confirms some previous findings that have been under debate, but also has some limitations. Firstly, these results are only applicable for clinically node negative patients. Secondly, the sub-cohort for evaluating axillary metastases in different imaging methods was small and lacking sample size calculations, and thus possibly affected the statistically insignificant result.

In conclusion, the patient characterization in clinical guidelines seem to be well recognized in selecting clinically node negative patients for preoperative MRI. Patient selection through prearranged characterization is an important part of deciding on optimal candidates for MRI among breast cancer patients. MRI causes moderate delays in surgery and final postoperative pathological diagnosis. Preoperative MRI is useful in the evaluation of tumor size but may be insufficient in detecting lymph node metastases without surgical investigations.

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Declaration of competing interest

The authors declare that there is no conflict of interest.

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