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Usefulness of automated breast volume scanner (ABVS) for monitoring tumor response to neoadjuvant treatment in breast cancer patients: preliminary results

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Abstract. – OBJECTIVE: We investigated the accuracy of Automated Breast Volume Scanner (ABVS) compared to handheld ultrasound (HHUS) for monitoring tumor response to neoadjuvant treatment (NAT) in breast cancer (BC).

PATIENTS AND METHODS: All the patients submitted to biopsy in our Institution, from January 2017 to May 2017, proven invasive BC and eligible for NAT, were enrolled in this prospective study. The participants underwent ABVS, HHUS, dynamic contrast-enhanced Magnetic Resonance Imaging (DCE-MRI) and mammography at the beginning of NAT and ABVS, HHUS and DCE-MRI at the halfway point of therapy and before the surgery. DCE-MRI was considered the standard of reference. Two breast radiologists (R1, R2), with fifteen and five years of experience in breast imaging, independently assigned a visibility score (ordinal 5-point scale) to ABVS, HHUS, and DCE-MRI. Diagnostic performance of ABVS and HHUS as measured by sensitivity, specificity, positive and negative predictive values (PPV and NPV) was calculated. Correlations between ABVS and MRI, and between HHUS and MRI were analyzed using Pearson's correlation test.

RESULTS: A total of 21 patients were enrolled. 189 examinations were performed. The comparison between ABVS and DCE-MRI was similar for the both readers: ABVS had a sensitivity of 63,16%, specificity of 83,58%, PPV of 76,60%, NPV of 72,73%, accuracy of 74,19% (R1) and a sensitivity of 54.54%, specificity of 85.51%, PPV of 75%, NPV of 70,24%, accuracy of 71.77% (R2). The comparison between HHUS and DCE-MRI showed that HHUS had a sensitivity of 63,16 %, specificity of 83,58%, PPV of 76,60%, NPV of 72,73%, accuracy of 74,19% (R1) and a sensitivity of 36.84%, specificity of 85.07%, PPV of 67.74%, NPV of 61.29%, accuracy of 62.90% (R2). The calculated Pearson's correlation coefficient r values were 7.8 for HHUS *vs.* DCE-MRI and 28.5 for ABVS *vs.* DCE-MRI (R1) and 7.8 for HHUS *vs.* DCE-MRI and 22.4 for ABVS vs. DCE-MRI (R2). Statistical significance of ABVS and HHUS was $p < 0.0001$ and $0.005 < p < 0.01$, respectively (R1, R2).

CONCLUSIONS: DCE-MRI is recommended for the tumor response assessment. ABVS, a product of the biotechnology development, providing reproducible images, in addition to DCE-MRI, can be a potentially useful tool for the monitoring of response to NAT.

Key Words
Automated breast volume scanner, Magnetic resonance imaging, Breast cancer, Neoadjuvant treatment.

Introduction

Neoadjuvant treatment (NAT), chemotherapy, and endocrine therapy, is often the first treatment of locally advanced breast cancer. It is used to improve tumor resection, increase the rates of breast conservative surgery, and identify patients with better prognoses, who exhibit a pathologic complete response (pCR). Monitoring treatment response during NAT is performed using dynamic contrast-enhanced Magnetic Resonance Imaging (DCE-MRI), ultrasound, and clinical examination[1,2].

Because of its high sensitivity to tumor presence and angiogenic changes, DCE-MRI is the preferred imaging modality in the NAT setting[3,4].

DCE-MRI has been demonstrated to be more accurate than physical examination, ultrasound, and mammography, in assessing initial disease extent and response to NAT, although a tendency for DCE-MRI to slightly overestimate or underestimate residual disease[5].

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The conventional handheld US (HHUS) alone is unsuitable for assessing response to NAT therapy owing to high operator dependence and low reproducibility[3].

Automated Breast Volume Scanner (ABVS), a product of the biotechnology development, aims to overcome these limitations of HHUS of operator dependence, image variability, and physician time for acquisition, as all images are acquired by using standardized views and by non-physician personnel[6,7].

We investigated the accuracy of ABVS compared to HHUS in the evaluation of tumor response to NAT, in addition to DCE-MRI.

Patients and Methods

Study Population

This prospective single-center study was conducted with the approval of the institutional Review Board.

All patients with breast lesions submitted to histologic biopsy in our Institution, from January 2017 to May 2017, were considered for inclusion in the study. Among these, we selected lesions of interest according to the following criteria.

Inclusion criteria were:

1) Percutaneous biopsy-proven primary invasive BC (cT1-3, cN0-1, M0)
2) Patients eligible for NAT

Exclusion criteria was:

Women with previous breast surgery or had a history of breast cancer and/or breast cancer treatment during the previous 12 months

Pathological Assessment Criteria

The expression status of the estrogen receptor (ER), progesterone receptor (PR), Ki67 and human epidermal growth factor receptor 2 (HER2) was determined from histopathologic reports of core biopsies performed before chemotherapy. Hormone receptor positivity was defined as > 1% of cells staining for ER or PR. Tumors with HER2 scores of 3+ (strong homogeneous staining) were considered positive. In tumors with 2+ scores (moderate complete membrane staining in ≥ 10% of tumor cells), *in-situ* hybridization was used to determine HER2 amplification.

Therapy Regimens

Participants were treated with different antineoplastic treatment according to the expression of ER and PR, HER2 and Ki67. Indeed, patients were classified in LUMINAL A (ER and PR positive, HER2 negative, Ki67 < 30%), LUMINAL B HER2 negative (ER and PR positive, HER2 negative, Ki67 ≥ 30%), LUMINAL B HER2 positive (ER and PR positive, HER2 positive and any Ki67), HER2 enriched (ER and PR negative, HER2 positive, any Ki67), Triple negative (ER, PR and HER2 negative with any Ki67). Patients with LUMINAL A or LUMINAL B HER2 negative have been treated with neoadjuvant therapy with or anti-hormonal therapy with anastrozole (1 mg/die) or chemotherapy with adriamycin (60 mg/m^2 every 21 days) cyclophosphamide (600 mg/m^2 every) and docetaxel (80 mg/m^2 every 21 days). Patients with HER2 enriched or LUMINAL B HER2 positive patients were treated with carboplatin (AUC 6 every 21 days), docetaxel (75 mg/m^2 every 21 days) and trastuzumab (8 and then 6 mg/kg every 21 days). Patients with triple negative disease were treated with adriamycin (60 mg/m^2 every 21 days), cyclophosphamide (600 mg/m^2 every) and docetaxel (80 mg/m^2 every 21 days)[8-10].

The outcome of NAC is the pCR, the absence of residual invasive tumor cells (ypT0/isN0) or presence of only a small number of scattered invasive cells in the breast and nodes resection specimen (ypTmic/N0) following antineoplastic therapy[11,12].

Imaging

Each patient underwent breast examinations, including DCE-MRI, ABVS, HHUS and digital mammography (DM). Imaging examinations were performed according to this scheme:

— Time 0 (*T0*, baseline/ before the start of therapy) DCE-MRI, ABVS, HHUS, DM
— Time 1 (*T1*, middle/at the halfway point of therapy) DCE-MRI, ABVS, and HHUS
— Time 2 (*T2*, preoperatively/fifteen days after the final course of therapy) DCE-MRI, ABVS, HHUS, DM

ABVS

It was performed using ACUSON S2000™ ABVS (Siemens Medical Solutions, Inc, Mountain View, CA), a computer-based system for evaluating the whole breast, with the patient in a supine position[13]. The system was used in combination with 6–14 MHz broadband mechanical transducers attached to a rigid compression plate and arm. A technician maintained appropriate contact pressure and vertical orientation to the breast surface[14]. Three image acquisitions (lateral, anteroposterior and medial) of each breast were usually sufficient to image virtually all of the breast tissue[15]. In women with larger breasts, four or five acquisitions of each breast might be needed. The total time to complete the examination was on average 15 minutes[16]. Once

the imaging data were obtained, the data were processed using computer algorithms and stored on a hard drive. The axial image series are sent to a dedicated workstation and combined to form a 3D ultrasound image that can be examined in multiplanar reconstructions, including sagittal and 2-mm-thick coronal images. The radiologist could then review the images on a standard workstation[17-19].

HHUS

The ultrasound examinations were performed with ACUSON S2000™ (Siemens Medical Solutions, Inc, Mountain View, CA) equipped with a 12-18 MHz linear transducers, with freehand positioning technique.

MRI

All patients were scanned in the prone position using a 1.5 T MRI scanner (Optima MR450w GEM; GE Medical System, Milwaukee, WI, USA) with an 8-channel bilateral breast coil. For contrast administration, an intravenous cannula was placed in the cubital vein just before the investigation. During the examination, Gadoteridol (ProHance) was injected at a dose of 0.2 mmol/kg using a power injector at a flow rate of 2 mL/s, followed by a 20 mL saline flush. The following sequences were acquired: propeller axial sequence, DWI axial sequence, three-dimensional (3D) VIBRANT axial sequence, 3D VIBRANT sagittal sequence.

Image Analysis and Assessment of NAT Response

Qualitative Image Analysis

Two breast radiologists, with fifteen (reader 1, R1) and five (reader 2, R2) years of experience in breast imaging, read ABVS (on the transverse plane), HHUS (on the transverse plane) and DCE-MRI (on the 3D VIBRANT axial plane) examinations and they independently assigned a visibility score (ordinal 5-point scales) to the lesions. The visibility was rated on a 5-point confidence scales (1 = minimal, 2 = sufficient, 3= good, 4 = very good, 5 = excellent). The readers assessed the visibility score to all the examinations regardless of the time (*T0, T1, T2*). No CAD software was used for MRI analysis. In the case of uncertain visibility attribution, a real-time consensus was achieved with a consultant colleague from a pool of radiologists of our Institution.

Examples of imaging processing in a patient are shown in Figures 1, 2, and 3.

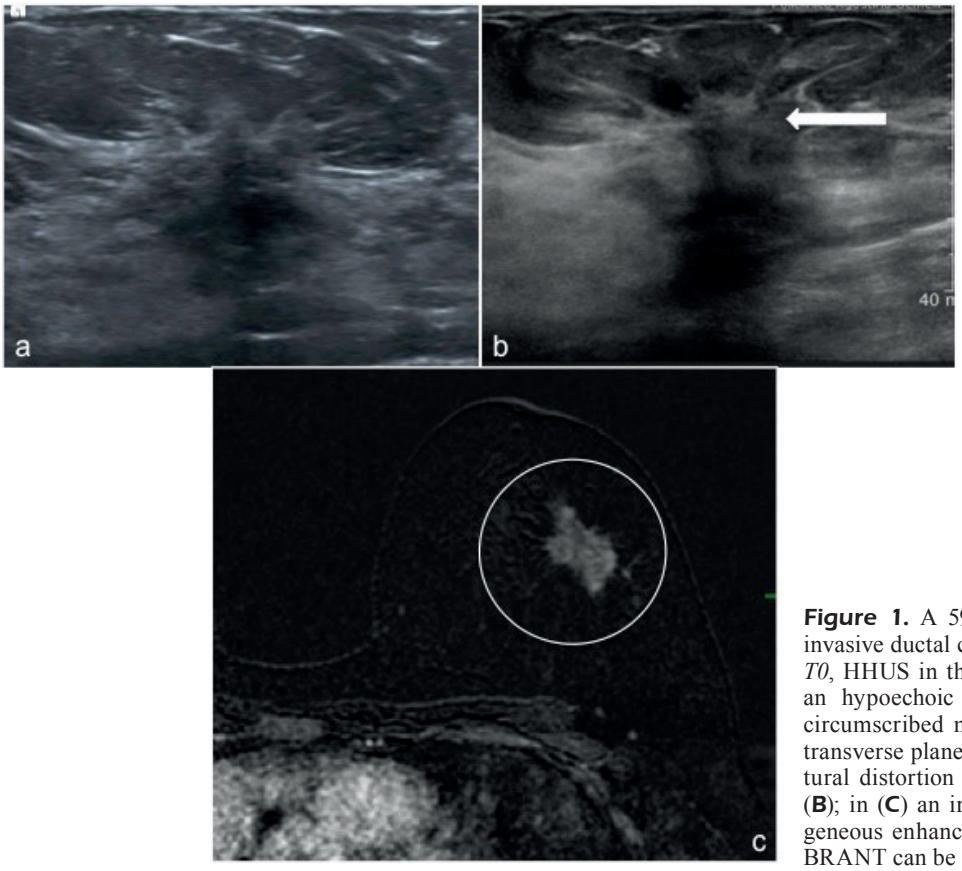

Figure 1. A 59-year-old patient with an invasive ductal cancer in the left breast. At *T0*, HHUS in the transverse plane reveals an hypoechoic irregular mass with not circumscribed margins (**A**). ABVS in the transverse plane shows better the architectural distortion associated with the lesion (**B**); in (**C**) an irregular mass with heterogeneous enhancement in the axial 3D-VIBRANT can be appreciated.

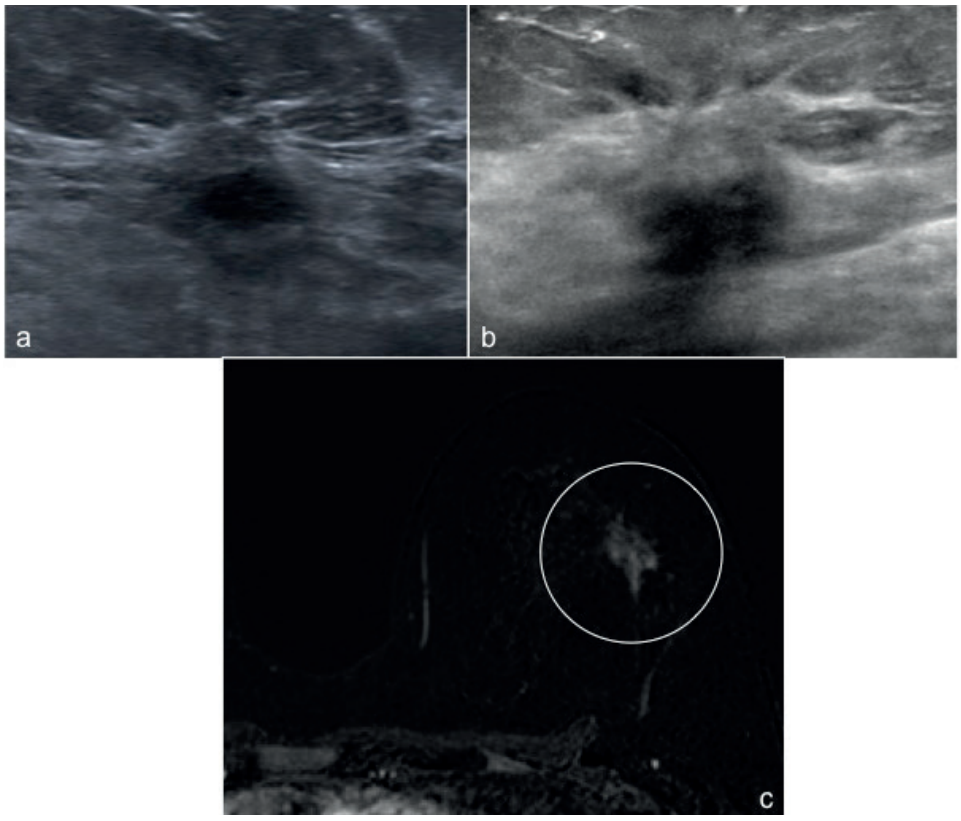

Figure 2. The same patient at *T1*. The tumor is slightly reduced in size; HHUS (**A**), ABVS (**B**) and 3D-VIBRANT (**C**) in the axial plane.

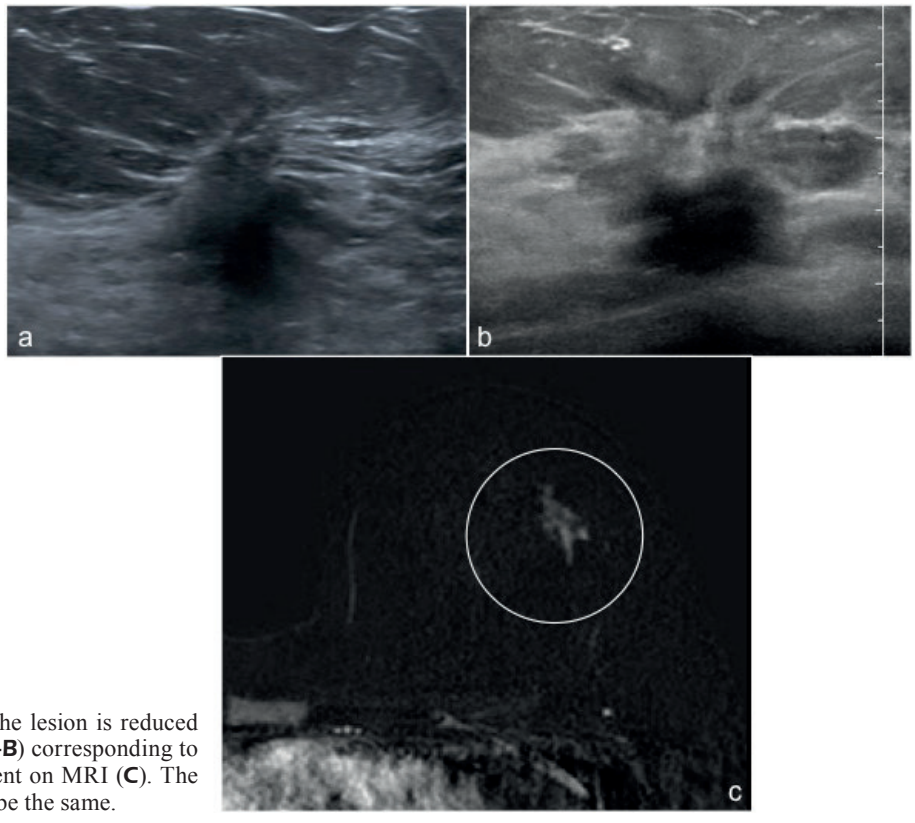

Figure 3. At *T2*, after NAT. The lesion is reduced to a small hypoechoic lesion (**A-B**) corresponding to a small area of faint enhancement on MRI (**C**). The visibility of the tumor seems to be the same.

Quantitative Image Analysis

Moreover, the tumor response to treatment was evaluated measuring tumor size. Tumor measurements were performed on the transverse plane of ABVS, HHUS and on the 3D VIBRANT axial plane of MRI. In the case of lesion fragmentation after treatment, the diameter of the lesions is summed. RECIST 1.1[20] classification was used to assess the tumor response based on the longest diameter measure of the target lesion.

Statistical Analysis

DCE-MRI was regarded as reference standard, in the absence of pathology at *T0* and *T1*. The agreement between ABVS and MRI, and between HHUS and MRI was assessed in assigning the visibility score. For the purpose of analysis, the visibility assignments were dichotomized as follows: "0" including 1, 2, 3 values and "1" including 4, 5 values. After completing the reading session, diagnostic accuracy, sensitivity, specificity, positive (PPV) and negative (NPV) predictive values of ABVS and HHUS were calculated. Correlations between ABVS and MRI, and between HHUS and MRI were analyzed using Pearson's correlation test. All statistical analyses were performed using SPSS (SPSS v22.0, IBM, Chicago, IL, USA). Between-reader agreement was analyzed using Cohen *k* statistic.

Results

A total of 21 consecutive patients (range, 25 to 65 years; mean age 45 years) with primary invasive breast cancer appropriated for NAT, were included in the study. 189 examinations were performed. Resulting visibility values dichotomized "0", "1" for both methods (ABVS, HHUS) are given in Tables I, II. III, IV.

The diagnostic accuracy of ABVS was 74.19% and of HHUS was 62.90% for R1 and 71.77% and 62.90% for R2; the sensitivity of ABVS and HHUS was 63.16% and 36.84% for R1 and 54.54% and 36.84% for R2; the specificity of ABVS and HHUS was 83.58% and 85.08% respectively for R1 and 85.51% and 85.07% respectively for R2. The PPVs of ABVS and HHUS were 76.60% and 67.74% for R1 and 75% and 67.74% for R2; the NPVs of ABVS and HHUS were 72.73% and 61.29%, respectively for R1 and 70.24% and 61.29% respectively for R2. The main results are reported in Table V. The calculated Pearson's correlation coefficient *r*-values were 7.8 for HHUS *vs.* MRI and 28.5 for ABVS *vs.* MRI respectively (R1); *r*-values were 7.8 for HHUS *vs.* DCE-MRI and 22.4 for ABVS *vs.* DCE-MRI respectively (R2). Statistical significance of ABVS and HHUS was $p < 0.0001$ and $0.005 < p < 0.01$, respectively (R1, R2). Inter-reader κ agreement was 0.74.

Table I. Visibility assignments to ABVS and DCE-MRI, R1.

		DCE-MRI		
		0	1	Total
ABVS	0	56	21	77
	1	11	36	47
Total		67	57	124

Table II. Visibility assignments to ABVS and DCE-MRI, R2.

		DCE-MRI		
		0	1	Total
ABVS	0	59	25	84
	1	10	30	40
Total		69	55	124

Discussion

Currently, there are no univocally recognized guidelines for determining tumor response to therapy except for volumetric measurements. MRI is recommended for the tumor response assessment, and it has a main role in guiding breast cancer surgical extent by measuring the size of the residual tumor after NAT[3,21]. MRI is limited by high cost, relative lack of availability, variable patient tolerance and the injection of contrast medium.

The HHUS is frequently used to monitor tumor response in routine clinical practice because it is an easily available and non-invasive modality. In this study, we investigated the ability of ABVS, compared to HHUS, in monitoring the response to NAT for breast cancer. ABVS, a product of the biotechnology development, is a standardized examination, reproducible, not operator-dependent,

Table III. Visibility assignments to HHUS and DCE-MRI, R1.

		DCE-MRI		
		0	1	Total
HHUS	0	57	36	93
	1	10	21	31
Total		67	57	124

Table IV. Visibility assignments to HHUS and DCE-MRI, R2.

		DCE-MRI		
		0	1	Total
HHUS	0	60	40	100
	1	8	16	24
Total		65	55	124

and it allows a virtual review of the data sets without the patients presence[22,23]. Furthermore, it does not require the use of ionizing radiation and the injection of contrast agents. ABVS can be more complete than HHUS for evaluating breast lesions because it could improve breast lesion analysis by an additional coronal-plane image which shows better observation of lesion margin and each sectional plane of the saved volume can be visualized avoiding non-standardized documentation[22].

Our preliminary results showed that ABVS for the lesions examined in the study was not inferior to HHUS. The diagnostic performance as assessed by measuring sensitivity, specificity, accuracy, PPV, and NPV was high in ABVS. Specifically, the accuracy, sensitivity, and specificity of ABVS were found to be 74.19%, 63.16%, and 83.58% respectively (R1) and 71.77%, 54.54%, and 85.51% respectively (R2). Whereas the specificity of ABVS was slightly lower than that of HHUS, the sensitivity of ABVS was significantly higher than HHUS (63.16% *vs.* 36.84%, R1 and 54.54% *vs.* 36.84%, R2), probably due to the lower visibility values assigned to HHUS examinations at *T2* (after NAT). It suggests, the potential of ABVS to effectively compensate for the drawbacks of HHUS. Cancers visible only through ABVS were predominantly invasive and small sized. Moreover, the superior diagnostic performance of ABVS than HHUS in multifocal disease, also depicting satellite lesions smaller than 1 cm. Our data showed that low visibility values were assigned to ABVS in the evaluation of lesions under the nipple. In the cases in which the mammary gland under the nipple is not sufficiently visualized, comprehensive evaluation of all four quadrant scans may enable an adequate assessment of the mammary gland under the nipple.

The results suggested that there is a much stronger correlation between ABVS and MRI than HHUS (*r* 28.5 *vs. r* 7.8, R1; *r* 22.4 *vs.* 7.8, R2) concerning lesion visibility, probably because ABVS image interpretation is performed at a reading station rather than in real time, evaluation of lesions is less affected by HHUS-related subjectivity. Moreover, our study demonstrated a lower ability of both ABVS and HHUS to detect a non-mass lesion than a mass-type lesion, which confirms the known limits of ultrasound examinations.

Furthermore, inter-reader agreement was excellent ($k = 0.74$) and underscores the clinical applicability of ABVS. ABVS may reduce inter-operator variability, provide greater consistency, and ensure reproducibility of high-quality images.

There are some limitations of our study. First, the study is limited by the relatively small sample size; however, it could be representative for preliminary results. Second, we analyzed all the examinations without considering the different acquisition time (T0, T1, T2). Finally, participants were treated with different antineoplastic treatments (chemotherapy and endocrine therapy) and it could influence the response obtained after therapy. Further study is needed to assess this aspect.

Conclusions

We found that ABVS could be a potential useful tool, in addition to DCE-MRI, for the assessment of response to NAT. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of Interests

The Authors declare that they have no conflict of interests.

Table V. Factors affecting OS.

	R1		R2	
	ABVS	HHUS	ABVS	HHUS
Diagnostic accuracy	74.19%	62.90%	71.77%	62.90%
Sensitivity	63.16%	36.84%	54.54%	36.84%
Specificity	83.58%	85.08%	85.51%	85.07%
Positive predictive value	76.60%	67.74%	75%	67.74%
Negative predictive value	72.73%	61.29%	70.24%	61.29%

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