Original Article

Preoperative MRI features predict failed breast-conserving surgery: construction of a predictive model

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Background: Breast-conserving surgery (BCS) is the preferred method for early breast cancer, and the accurate preoperative prediction of the feasibility of BCS can formulate the surgical plan and reduce the violation of the patient's will. The present study proposed to explore the preoperative magnetic resonance imaging (MRI) features associated with failed BCS and constructed an MRI-based model to predict BCS.

Methods: This retrospective study included patients between March 2015 and July 2016, who planned to undergo BCS, had preoperative MRI examination, and had at least 2 years of follow-up. A total of 30 patients with failed BCS were identified and matched with 90 patients with successful BCS (ratio 1:3) according to age, neoadjuvant therapy, and hormone receptor expression. The patients were divided into the training group for model construction and the testing group for model validation. The MRI features, including the site of the tumor, the lesion type, and the lesion and breast volume, were compared between failure and successful BCS groups. A multivariate logistic model for predicting failed BCS was constructed using independent factors associated with failed BCS from the training group and was evaluated in the testing group. The performance of the model was evaluated using the receiver operating characteristic (ROC) curve.

Results: The mean age of the cohort was 45.7±10.3 years. A significantly more non-mass lesion and multifocality, the larger volume of lesion, and the ratio of lesion and breast volume were observed in failed BCS group compared to the successful BCS group. The ratio of lesion and breast volume and multifocality were independent factors associated with failed BCS, odds ratios were 1.044 (95% CI: 1.016–1.074) and 11.161 (95% CI: 1.739–71.652), respectively. An MRI-based model for predicting failed BCS was established, the area under the ROC curves in the training and testing group were 0.902 and 0.821, respectively.

Conclusions: This model might help clinicians predict failed BCS preoperatively and make an accurate surgical strategy.

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Keywords: Breast neoplasm; magnetic resonance imaging (MRI); mastectomy; segmental; tumor burden; breast-conserving surgery (BCS)

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Introduction

Breast cancer is a malignant tumor with the highest and increasing incidence in women in China every year (1), which severely threatens women's health. Traditional surgery includes complete mastectomy and axillary lymph node dissection, resulting in the destruction of female sexual organs, paresthesia, and upper limb edema and dysfunction in some patients (2). With the improvement of the treatment technique, the need for breast cancer operation is reduced selectively. Thus, breast cancer narrowly escapes the scope of surgery, such that a large number of patients do not have to undergo mastectomy.

Breast-conserving surgery (BCS) is the preferred method for early breast cancer. Several studies have shown that women with breast cancer undergoing breast-conserving therapy (mastectomy combined with adjuvant radiotherapy) have survival rates similar to mastectomy (3-5). Compared to the 50% breast-conserving rate in European and American countries, the proportion of BCS in China for operable breast cancer still has a gap, ranging from 10% to 20% (6-10). However, with the continuous increase in the diagnosis rate of early breast cancer and the change in women's awareness in China, BCS has become the leading surgical method, and a large number of patients will be protected from unnecessary whole breast removal.

The aim of BCS is the complete removal of the tumor while maintaining a satisfactory breast shape. Presently, doctors subjectively judge whether BCS is feasible mainly according to the results of ultrasound, magnetic resonance imaging (MRI), and mammography. Previous studies have shown that within 12 months after BCS, radical mastectomy was performed in 3–17% of cases, and secondary BCS was performed in 11–18% of cases (8,11,12). In the secondary resection, tumor remnants were detected in 20% of breast-conserving cases and 59% of radical resection cases, while in secondary breast-conserving resection, the ipsilateral recurrence rate was almost three times that of breast-conserving cases, regardless of the presence of tumor residues in the second surgery (11). This phenomenon indicated that the accuracy of doctors' subjective judgment on the feasibility of BCS is not high. Also, due to the lack of objective quantitative standards and the high reliance on doctors' experience, the secondary surgery rate after BCS varied across hospitals (8). When lumpectomy is performed, if the breast-conserving operation fails, the surgical plan should be changed to complete mastectomy. This increases medical costs, delays adjuvant treatment, and has poor cosmetic results. Therefore, accurate preoperative prediction of the feasibility of BCS helps to formulate an appropriate surgical plan and reduce the will violation of the patient. To evaluate the feasibility of BCS, it is essential to establish objective and quantitative criteria for clinical practice. Currently, no relevant standards have been reported worldwide.

In previous studies, the maximum diameter of the tumor is the most commonly used indicator for tumor size (13). However, due to the irregular shape, the maximum diameter often fails to reflect is the actual size of the tumor. Some studies have shown that the measurement of breast tumor diameter alone cannot improve the success rate of BCS and reduce ipsilateral recurrence or the rate of secondary BCS (12). Interestingly, MRI is significantly more accurate than ultrasound and mammography in measuring the tumor size and range (12,14-17), and the measurement of breast tumor volume before and after neoadjuvant therapy is reliable (18,19). It has been speculated that the main factors influencing the feasibility of BCS are tumor size, location, proportion in the breast, and patient willingness. Therefore, measuring and screening effective imaging indicators to predict failed BCS preoperatively is a major concern. Previously, only MRI signs were used to predict the positive margin to judge the success of BCS surgery (20), but no studies have reported the combination of imaging modalities with multiple factors such as tumor volume and location for accurate prediction.

Therefore, the present study proposed to explore the preoperative MRI features associated with failed BCS and construct an MRI-based predictive model to help the clinicians determine the approach for BCS. We present the

following article in accordance with the STARD reporting checklist (available at https://tcr.amegroups.com/article/view/10.21037/tcr-21-1919/rc).

Methods

Patients

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). It was approved by the institutional review board of Peking University Cancer Hospital (China) (ID. 2017KY96), and patient informed consent was waived due to its retrospective nature.

We included pathologically proven breast cancer patients in our hospital who planned to retain their breasts and receive preoperative magnetic resonance (MR) examination. The follow-up was required for at least 2 years. Patients with incomplete clinical or follow-up data or with unqualified or missing MRI were excluded. Both groups of patients who underwent surgery directly and received neoadjuvant therapies were included. Subsequently, the preoperative MRI after neoadjuvant therapies were used.

A total of 295 women between March 2015 and July 2016 were included: 265 underwent successful BCS, and 30 presented failed BCS. Failure to retain breast is defined as meeting any of the following three criteria: (I) positive margins identified by intraoperative pathology of frozen sections; (II) ipsilateral breast recurrence within 2 years after BCS; (III) the appearance evaluation of the breast surgery is not ideal (poor and very poor).

Failed and successful BCS patients were at a ratio of 1:3 matched according to age, neoadjuvant therapy, and hormone receptor expression. Finally, a total of 120 preplanned BCS patients (age: 45.7±10.3 years; range, 22–75 years) were included in the analysis.

Patients were chronologically divided into training groups (including 15 patients with failed BCS and 45 patients with successful BCS) for model construction and testing group (including 15 patients with failed BCS and 45 patients with successful BCS) for model validation.

MR protocol

MR examination was carried out on a 1.5T MRI scanner within 2 weeks before surgery. Four-channel phased-array breast coil (Echospeed plus and excite II, GE Medical Systems, Milwaukee, WI, USA) was used. The examination program involved dynamic enhanced sagittal, three-dimensional vibrant SPGR sequence (TR =6.4 ms, TE =3.0 ms, TI =7.0 ms, flip angle =10°, slice thickness =4 mm, no interlayer gap, matrix size =256×256, field of vision =20–22 cm, NEX =1, ZIP2, scan time per acquisition =68 s), and an axial, fat suppression, T1 weighted pulse sequence enhancement. The vibration sequence was repeated six times successively, and the dynamic acquisition was carried out in the first phase before contrast enhancement and five phases after contrast enhancement. The contrast agent (Gd-DTPA) was injected into the anterior elbow vein by a power syringe at a speed of 2.0 mL/s [based on the patient's weight (0.2 mmol/kg)], and flushed with saline. First, the T1 weighted pre-contrast scan with fat saturation was collected initially. Then, 2 min after injection of contrast medium, the first contrast medium was collected and scanned. Subsequently, four postcontrast images were obtained every 90 s, and five post-contrast images were obtained (t=2, 3.5, 5, 6.5, and 8 min).

MRI evaluation

All MR images were examined by two independent radiologists (YH Qu with 10-year experience and RJ Sun with 5-year experience of breast MR diagnosis) using 3D slicer software (version 4.8.1).

Both radiologists were blinded to the clinical data and follow-up information of enrolled patients. The region of interest (ROI) was marked manually using 3D slicer software, delineating the tumor boundary layer by layer, and the tumor volume was calculated. The ROI is delineated along tumor edges, including surrounding burrs and bands, in the first phase of the postcontrast T1-weighted imaging contrast enhancement sequence (21). In patients after neoadjuvant therapy, if the first phase of postcontrast T1 dynamic enhancement (early dynamic enhancement) shows tumor signals, then the principles are the same as before the neoadjuvant therapy. If no clear tumor signal was found in the first phase of postcontrast T1 dynamic enhancement after neoadjuvant therapy, the disease was characterized by MR-pathological complete response (MR-pcr), and the tumor volume was 0. The 3D slicer software was used to measure the volume of the affected breast, and the threshold method was used to segment the affected breast and automatically calculate the volume of the breast. The safety of BCS in multifocal breast lesions has been demonstrated previously (21), which prompted us to assess whether the lesions are multifocal. Multifocal lesions are defined as those located within the same quadrant and multicentric

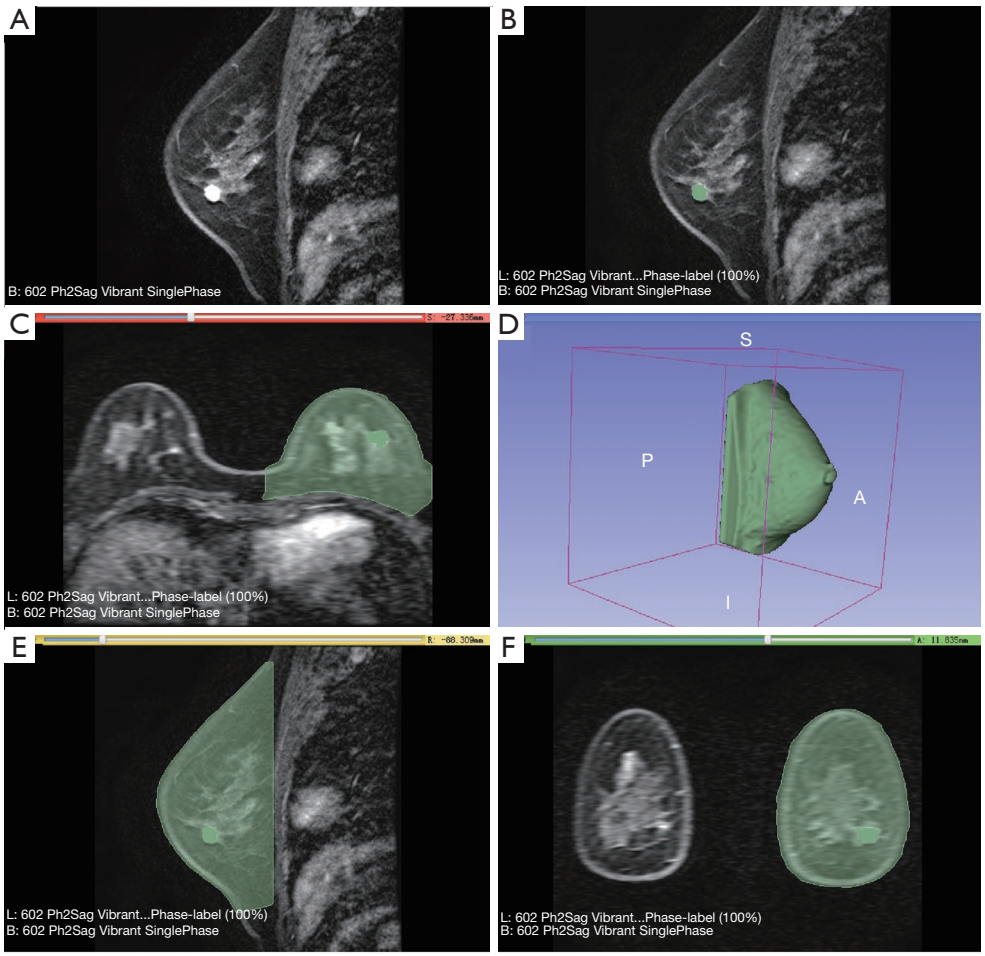

Figure 1 Illustration of tumor and affected side breast volume measurement. (A) 3D slicer software shows a mass in the lower outer quadrant of the left breast; (B) green label shows a mask with a mass outlined along the edge; (C) tumor and the affected breast were covered with a mask in the axis position as much as possible; (D) volume reconstruction of the affected breast was generated by the software; (E) tumor and the affected breast were covered as much as possible with a mask in the sagittal position; (F) tumor and the affected breast were covered as much as possible with a mask in the coronal position.

tumors residing in different quadrants. The preoperative MRI features were assessed on the site of the tumor (upper-outer quadrant, upper-inner quadrant, lower-outer quadrant, and lower-inner quadrant), the lesion type (mass and non-mass enhancement), the existence of multifocality, and the volume features (the volume of lesion, the volume of affected breast, and the ratio of the two) (*Figure 1*).

The agreement between the two radiologists was evaluated. The average of measurement was used for continuous variables for subsequent analysis. For categorical variables, a third experienced radiologist was introduced for arbitration.

Evaluation of breast appearance

The surgeons evaluated the appearance of the breast 2 years after BCS. Excellent appearance was defined when the treated breast was almost identical to the untreated; good appearance was defined when the treated breast was slightly different from the untreated breast; poor appearance was defined as the obvious difference between the two sides without major distortion; very poor appearance was defined as severely distorted treated breast. The breast appearance was evaluated by two surgeons, and a third surgeon was introduced for arbitration in the case of divergence.

Table 1 Patient demographics and tumor characteristics

Variables	Values
Age (years)	45.7±9.3
HR(+)*	96 (80.0%)
HER2(+)**	20 (16.7%)
BCS	
Successful	90 (75.0%)
Failure	30 (25%)
Neoadjuvant therapies	
No	44 (36.7%)
Yes	76 (63.3%)
Lesion type	
Mass	106 (88.3%)
Non-mass	14 (11.7%)
Tumor location	
Upper-outer quadrant	63 (52.5%)
Upper-inner quadrant	21 (17.5%)
Lower-outer quadrant	27 (22.5%)
Lower-inner quadrant	9 (7.5%)
Volume features	
Volume of lesion (mm^3)	2,081.50±3,221.16
Volume of affected breast (mm^3)	794,398.53±322,544.63
Ratio of lesion and breast volume ($\times10^{-4}$)***	29.03±50.23
Multifocality	
No	98 (81.7%)
Yes	22 (11.3%)

Data are represented as mean ± SD or n (%). *, HR: hormone receptor, including ER and PR, was determined on the biopsy specimens or surgically excised specimens. ER and PR were evaluated by the percentages of stained tumors. The positivity for ER or PR was defined as ≥10% stained tumor cells, and either ER- or PR-positive was regarded as HR-positive. **, HER2: human epidermal growth factor receptor type 2, determined with respect to biopsy specimens or surgically excised specimens. HER2 immunohistochemistry was scored using the ASCO/CAP criteria to assess the intensity and completeness of membrane staining. A score of 0/+ was considered negative, and 3+ was considered positive. A score of 2+ was further evaluated with FISH to determine the HER2 status. If the ratio of the *HER2* gene signal to the chromosome 17 probe signal was >2.2, the tumor was classified as HER2 positive. ***, ratio of lesion and breast volume: the ratio of lesion and breast volume, calculated as V_{lesion}/V_{breast}. ER, estrogen receptor; PR, progesterone receptor; ASCO/CAP, American Society of Clinical Oncology and the College of American Pathologists; FISH, fluorescence in situ hybridization; BCS, breast-conserving surgery.

Statistical analysis

The differences in MRI features between failure and successful BCS groups were compared. Continuous variables were compared using an independent *t*-test or Mann-Whitney U test. Categorical variables were compared using chi-square test or Fisher's exact test. The statistically significant factors were substituted into the multivariate logistic model to select independent factors to predict failed BCS. Univariate analysis was conducted using the whole sample to explore the potentially useful factors associated with failed BCS, followed by multivariate analysis using the training group to construct an MR-based model to predict failed BCS; this model was validated using the testing group. Receiver operating characteristic (ROC) curve was drawn, and the area under the curve (AUC) was calculated to evaluate the diagnostic capability of the MR-based model in predicting failed BCS. The cutoff was determined by the maximum Youden's method; then, the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and total accuracy were calculated for failed BCS. The intra-class correlation coefficient (ICC) was calculated to evaluate the inter-observer agreement: 0.0–0.20, 0.21–0.40, 0.41–0.60, 0.61–0.80, and 0.81–1.00 indicated no, poor, moderate, substantial, and perfect agreement, respectively. SPSS 22.0 was used for statistical analysis, and a two-sided P<0.05 indicated statistical significance.

Results

Patient characteristics

The cohort comprised 30 patients with failed BCS and 90 successful BCS. The median follow-up after surgery was 43 months. Patient demographics and tumor characteristics are listed in *Table 1*. The reasons for failed BCS in 30 patients were due to the positive margins based on the intraoperative rapid pathological diagnosis.

The distribution of age, neoadjuvant therapy, hormone receptor expression, and HER2 expression was similar between the successful and failure groups (all P>0.05; *Table 2*).

Comparison of MRI features between successful and failure BCS groups

Significantly more non-mass lesions (26.7% *vs.* 6.7%, P=0.007) and multifocality (50.0% *vs.* 7.8%, P<0.001) were observed in the failure BCS group compared to the successful group. Also, the volume of the lesion (5,060.92±4,702.65 *vs.*

Table 2 Comparison of MRI features between successful and failure BCS groups

Variable	Successful group (n=90)	Failure group (n=30)	P
Age (years)	46.2±8.8	44.3±10.6	0.684
Neoadjuvant therapies			1.000
No	33 (36.7%)	11 (36.7%)	
Yes	57 (63.3%)	19 (63.3%)	
HR*			0.572
Positive	16 (30%)	4 (13.3%)	
Negative	74 (70%)	26 (86.7%)	
HER2**			1.000
Positive	18 (20%)	6 (20%)	
Negative	72 (80%)	24 (80%)	
Lesion type			0.007
Mass	84 (93.3%)	22 (73.3%)	
Non-mass	6 (6.7%)	8 (26.7%)	
Tumor location			0.416
Upper-outer quadrant	50 (55.6%)	13 (43.3%)	
Upper-inner quadrant	13 (14.4%)	8 (26.7%)	
Lower-outer quadrant	21 (23.3%)	6 (20.0%)	
Lower-inner quadrant	6 (6.7%)	3 (10.0%)	
Volume features			
Volume of lesion (mm^3)	1,088.36±1,636.37	5,060.92±4,702.65	<0.001
Volume of affected breast (mm^3)	787,922.16±323,872.50	813,827.65±323,214.31	0.598
Ratio of lesion and breast volume ($\times10^{-4}$)***	15.66±23.48	71.05±79.82	<0.001
Multifocality			<0.001
No	83 (92.2%)	15 (50.0%)	
Yes	7 (7.8%)	15 (50.0%)	
Pathological type			0.721
Invasive ductal carcinoma	80 (89.0%)	25 (83.3%)	
Ductal carcinoma *in situ*	2 (2.2%)	1 (3.3%)	
Invasive lobular carcinoma	6 (6.7%)	2 (6.7%)	
Others	2 (2.2%)	2 (6.7%)	

Data are represented as mean ± SD or n (%). *, HR: hormone receptor, including ER and PR, was determined on the biopsy specimens or surgically excised specimens. ER and PR were evaluated by the percentages of stained tumors. The positivity for ER or PR was defined as ≥10% stained tumor cells, and either ER- or PR-positive was regarded as HR-positive. **, HER2: human epidermal growth factor receptor type 2, determined with respect to biopsy specimens or surgically excised specimens. HER2 immunohistochemistry was scored using the ASCO/CAP criteria to assess the intensity and completeness of membrane staining. A score of 0/+ was considered negative, and 3+ was considered positive. A score of 2+ was further evaluated with FISH to determine the HER2 status. If the ratio of the *HER2* gene signal to the chromosome 17 probe signal was >2.2, the tumor was classified as HER2 positive. ***, ratio of lesion and breast volume: the ratio of lesion and breast volume, calculated as V_{lesion}/V_{breast}. ER, estrogen receptor; PR, progesterone receptor; ASCO/CAP, American Society of Clinical Oncology and the College of American Pathologists; FISH, fluorescence in situ hybridization; BCS, breast-conserving surgery; MRI, magnetic resonance imaging.

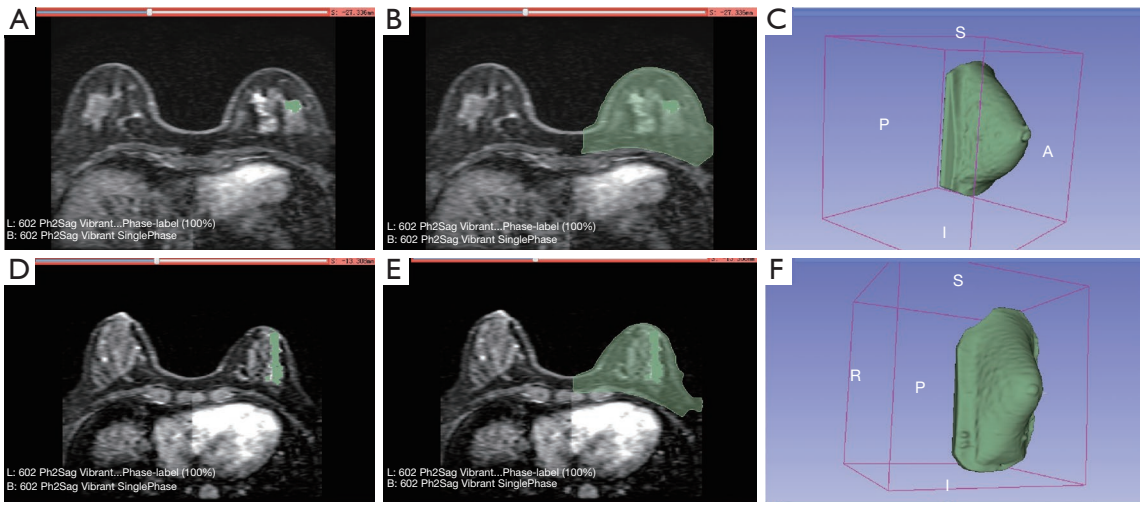

Figure 2 Schematic of the tumor and affected side breast volume measurements in patients with successful and failed BCS. (A-C) A 50-year-old patient with invasive ductal carcinoma who had a successful breast-conserving operation; (D-F) a 48-year-old patient with invasive ductal carcinoma who failed in BCS. (A) 3D slicer software shows a mass with a mask in the outer lower quadrant of the left breast; (B) tumor and the affected breast was covered as much as possible with mask in the axis position in a patient who had a successful breast-conserving operation; (C) volume reconstruction of the affected breast in the patient who had a successful breast-conserving operation was generated by the software. The patient with successful BCS had a model-yielded Y of 0.547 with indication of successful BCS. (D) 3D slicer software shows non-mass enhancement in the upper outer quadrant of the left breast; (E) tumor and the affected breast was covered as much as possible with a mask in the axial position in the patient who failed BCS; (F) volume reconstruction of the affected breast in the patient who failed BCS was generated by the software. The patient with failed BCS had a model-yielded Y of 4.50 with indication of failed BCS by model. BCS, breast-conserving surgery.

1,088.36±1,636.37 mm^3, P<0.001) and the ratio of lesion and breast volume (0.0071±0.0079 *vs.* 0.0015±0.0023, P<0.001) was significantly larger in the group than the successful group. The data are listed in *Table 2*.

Construction of MR-based model for predicting failed BCS in the training group and the validation of the model in the testing group

In the training group, the multivariate logistic model showed that the ratio of lesion and breast volume and multifocality of the tumor were independent factors associated with failed BCS [odds ratios (ORs) were 1.044, 95% confidence interval (CI): 1.016–1.074] and 11.161 (95% CI: 1.739–71.652), respectively. An MR-based model was established as Y=0.044 × the ratio of lesion and breast volume (10^4) + 2.412 × multifocality, yielding an AUC of 0.902 (95% CI: 0.801–1.000) for predicting failed BCS. A cutoff of 2.3 was selected; Y>2.3 indicated failed BCS, while Y≤2.3 indicated successful BCS. The sensitivity, specificity, PPV, NPV, and total accuracy for predicting failed BCS were 53.3%, 88.9%, 61.5%, 85.1%, and 80%, respectively.

In the testing group, the AUC was 0.821 (95% CI: 0.700–942), and the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and total accuracy for predicting failed BCS was 46.7%, 88.9%, 58.3%, 83.3%, and 78.3%, respectively. Two cases with successful and failed BCS were showed in *Figure 2*.

The diagnostic performance of the constructed model for predicting failed BCS in the training and testing groups is summarized in *Table 3* and *Figure 3*.

Inter-observer agreement

A perfect interobserver agreement was observed for the volume of the lesion (ICC =0.874), the volume of the breast (ICC =0.828), the lesion type (ICC =0.959), the multifocality (ICC =0.860), and the site of the tumor (ICC =0.824). A substantial agreement was observed for the ratio of the lesion and breast volume (ICC =0.787).

Table 3 Diagnostic performance of the model combining volume ratio and multifocality to predict failed BCS in the training and testing groups

Group	AUC (95% CI)	Cutoff	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Training	0.902 (0.801–1.000)	2.3	53.3 (8/15)	88.9 (40/45)	61.5(8/13)	85.1 (40/47)	80 (48/60)
Testing	0.821 (0.701–0.942)	–	46.7 (7/15)	88.9 (40/45)	58.3(7/12)	83.3 (40/48)	78.3 (47/60)

BCS, breast-conserving surgery; AUC, area under the receiver operating characteristic curve; PPV, positive predictive value; NPV, negative predictive value.

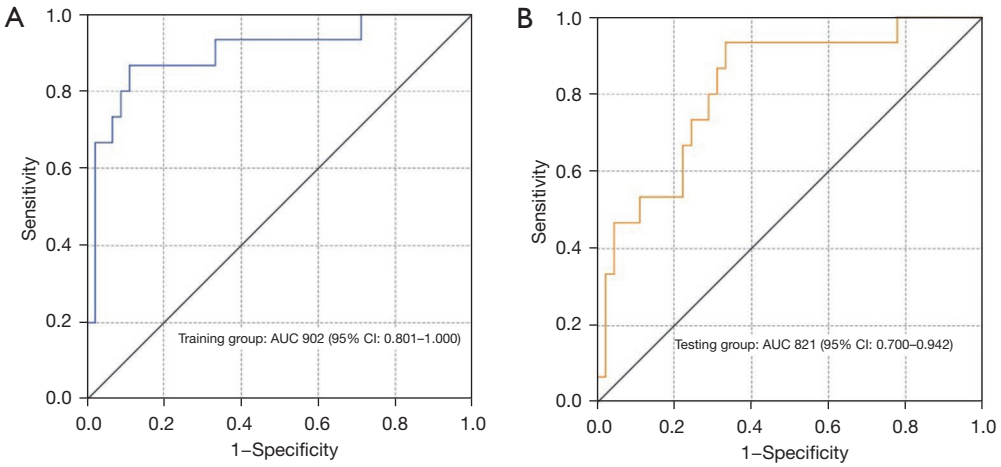

Figure 3 The receiver operating characteristic curve of the model combining volume ratio and multifocality for predicting failed BCS in (A) training group and (B) testing group. BCS, breast-conserving surgery.

Discussion

The present study demonstrated that preoperative MRI parameters of the ratio of lesion and breast volume and multifocality were associated with failed BCS. The study also constructed a multivariate MR-based model for predicting failed BCS and tested the model using samples from the same center.

Currently, when clinicians decide to conduct BCS, the size and location of the tumor, combined with the patient's will, are considered. Importantly, the doctors demonstrated high accuracy of the feasibility of breast conservation preoperatively, and their decision directly affects whether the patient can receive the most suitable treatment and the patient's subjective willingness to choose the type of operation. According to the data of this study, the failure rate of BCS is about 10%. The constructed combination model selects 73.3% of patients who received but may not be suitable for BCS, deeming it to be of clinical significance.

The objective indicators that judge the feasibility of breast conservation can overcome the influence of doctors' subjective experience. The primary method for measuring the tumor volume is to combine doctor delineation and software to calculate the volume automatically; the finding was consistent among the measurers (18,22,23). A few studies have reported the measurement of breast volume by MRI; nonetheless, these comprised a small sample. The principle is to scan the area of each layer of the breast tissue at specific intervals of height and summarize the data (24). Because MRI measurement of breast tumor and volume highly depends on the judgment of the researchers, especially the image measurement after new adjuvant therapy, few studies are based on this parameter in the evaluation of breast tumor surgery type. The measurement method of this study is simple and easy, and unaffected by the machine and scanning parameters. Perfect interobserver agreement was observed to measure tumor volume, breast volume, and the ratio of the two parameters.

Nevertheless, the present study has some limitations. First, it was a single-center, retrospective design, consisting of both patients with and without neoadjuvant therapies. Due to the relatively small samples that failed breast conservation, we used a 1:3 matched ratio to control bias

and improve the statistical power of the study. Second, the model constructed in this study needs to be validated in external independent samples. In addition, whether the clinicians can improve the accuracy of preoperative judgment for BCS using the model is a major concern.

Conclusions

This study established an MRI-based preoperative breast-conserving feasibility prediction model using simple and easy-to-measure parameters. After further verification in more samples, the predictive model with high diagnostic accuracy may provide an effective objective reference for clinicians to predict the feasibility of breast conservation.

Acknowledgments

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Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://tcr.amegroups.com/article/view/10.21037/tcr-21-1919/rc

Data Sharing Statement: Available at https://tcr.amegroups.com/article/view/10.21037/tcr-21-1919/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tcr.amegroups.com/article/view/10.21037/tcr-21-1919/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). It was approved by the institutional review board of Peking University Cancer Hospital (China) (ID. 2017KY96), and patient informed consent was waived due to its retrospective nature.

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