Original Article

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The Value of Tyrer-Cuzick Versus Gail Risk Modeling in Predicting Benefit from Screening MRI in Breast Cancer

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ABSTRACT

Objective: Breast cancer is the most commonly diagnosed malignancy in US women. Risk assessment tools such as the Gail and Tyrer-Cuzick (TC) models calculate risk for breast cancer based on modifiable and non-modifiable factors in order to guide screening and prevention for high-risk patients. Screening with magnetic resonance imaging (MRI) in addition to mammography is recommended in high-risk patients (>20% lifetime risk on TC or other familial based models). Currently, no published data indicate these recommendations improve cancer detection.

Materials and Methods: With the aim to determine what percentage lifetime risk (LR%) is associated with a statistically significant increase in cancer detection, the Virginia Commonwealth University (VCU) breast imaging database was reviewed to identify patients who received screening MRI.

Results: The receiver operating characteristics (ROC) curves for the Gail and TC models and the rate of cancer detection correlated to 20% LR% were calculated. The Gail model was considered the control model as it is NOT considered a validated screening tool for MRI. TC is not more accurate than Gail when predicting benefit of breast MRI screening. (area under the curve (AUC): 0.6841, 0.6543 respectively, p = 0.828). Univariate analysis failed to demonstrate a statistically significant relationship between the Gail or TC LR % and diagnosis of breast cancer when using 20% as the cutoff for high-risk classification (p = 1.0, 0.369 respectively). Neither the TC nor the Gail risk calculators demonstrated a significant correlation between risk and the likelihood of diagnosis of breast cancer when screened with MRI.

Conclusion: Larger cohort studies are necessary to determine the risk percentage most predictive of a breast cancer diagnosis using MRI as screening.

Keywords: Breast cancer, breast cancer screening, MRI, risk factors

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Key Points

- Currently the Tyrer-Cuzick model is used for determination of MRI eligibility for high-risk patients whereas the Gail model guides eligibility for chemoprevention.
- Our study demonstrated that there might not be any additional predictive value using the Tyrer-Cuzick versus Gail model when determining screening MRI breast eligibility.
- The 20% lifetime risk, as calculated by Tyrer-Cuzick, did not appear to lead to a greater detection of breast cancers over our control, the Gail model. This calls into question the 20% cutoff but would require larger studies to determine a more appropriate cutoff value.

Introduction

Breast cancer is the most commonly diagnosed malignancy in women in the United States and the second most common cause of cancer death among women worldwide (1). On average, a woman's risk for developing invasive breast cancer in the United States (US) is approximately 1 in 8 or about 12.5%. This risk increases with age, with a woman aged 70 being almost 10 times more likely to develop breast cancer in the next five years as compared to a woman in her 30s (2). There are several other factors, both modifiable and non-modifiable, that can increase a woman's risk for developing breast cancer. Such modifiable factors include obesity, alcohol consumption, activity level, parity, breastfeeding, radiation therapy and use of hormone replacement therapy (HRT) (3). Non-modifiable factors include genetic mutations, family history of breast cancer, prior history of atypical lesions, as well as race and age (4, 5).

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Studies have demonstrated that early detection of breast cancer decreases the morbidity and mortality of the disease (6). Routine screening with mammography has decreased mortality, especially in women aged 50 to 69 years (7, 8). In fact, most women with clinically occult disease are diagnosed with breast cancer by mammographic screening alone. While breast cancer screening primarily relies on mammography, there are proven benefits in screening for breast cancer with contrast-enhanced breast magnetic resonance imaging (MRI). Contrast-enhanced breast MRI has superior sensitivity to mammography (9-11). Even when adding ultrasound to mammography, the two have relatively lower specificity and sensitivity to mammogram and MRI (12, 13). Some factors that have hindered the wider use of MRI for screening for breast cancer are its high cost, need for heavy metal (Gadolinium) contrast, the limited availability of MRI scanners and its low specificity for breast cancer detection. The specificity of MRI in multiple studies remains around 70%. Increased sensitivity and decreased specificity, as compared to mammography, results in MRI generating fewer false negative studies but a greater number of false positive studies, which can result in unnecessary biopsy (14, 15). Additionally, studies have shown that screening with MRI is not cost-effective in women with lower to average risk for breast cancer, which is reflected in its omission for these groups in the current American Cancer Society (ACS) recommendations (16, 17).

Women with genetic mutations associated with an increased risk for breast cancer, history of previous mantle radiation or those with an estimated lifetime risk greater than 20%, based on risk stratification tools, are classified as high risk for breast cancer (18). For these individuals, several organizations have recommended breast MRI for screening as an adjunct to mammography (19-22). The Claus model is the only validated model which predicts benefit from screening MRI, which mostly takes into account a woman's age and family history (23). Alternative models such as the Tyrer-Cuzick (TC), the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA) and Gail attempt to be more comprehensive and include both family history, as well as non-familial risk factors (24, 25). Due to inherent differences in the data included in these models, there can be great variability in mathematical risk calculation, which can impact screening recommendations. In a previous study, 33 women were evaluated for MRI-based breast screening. Using 20%–25% lifetime risk as a minimum cutoff for MRI, the Claus model identified one eligible patient, while alternative models such as Gail model and the TC model identified nine and 12 eligible patients, respectively (26). The authors did not determine the benefit patients received from enhanced screening, such as an increase in cancer detection.

The Gail and TC models are readily available online risk calculators that account for family history, personal history and modifiable factors in some variation to determine risk. Currently the TC model is used to guide MRI screening eligibility for high-risk patients, whereas the Gail model has been designed to guide use of chemoprevention as determined by the NSABP STAR trial (27). In our study, we compared the TC and Gail Lifetime Risk (LR%) and their correlation with biopsy proven breast cancer diagnosis subsequent to MRI screening. We also aimed to determine if the largely accepted 20% lifetime risk is associated with a statistical increase in cancer detection in a cohort of eligible patients undergoing MRI breast cancer screening.

Materials and Methods

After receiving IRB approval, we performed a retrospective review of the Virginia Commonwealth University (VCU) Imaging Database from January 2005 to December 2015. We evaluated patients who received screening breast MRI as an adjunct to mammography, based on a variety of reasons including: presence of genetic mutations such as *BRCA1/BRCA2*; presence of atypia or other high-risk lesions on previous biopsy; LR% greater than 20% on TC or other risk models; presence of extensive breast or ovarian family history; or presence of extremely dense breasts on mammography.

The cohort included females, aged 18 to 75, who underwent screening breast MRI between January 2005 to December 2015 within a VCU Health affiliated hospital. In addition to screening MRI, patients received screening mammography, alternating mammogram and MRI every six months. Subjects who received a diagnostic breast MRI due to a diagnosis of breast cancer were excluded from the study. Additionally, subjects with a prior history of breast cancer, or those with breast cancer diagnosis with a screening method other than MRI, that is ultrasound, were also excluded.

We collected clinical and pathological data for all subjects. Variables associated with an increased risk of breast cancer including race, body mass index (BMI), parity, age at first birth, genetic testing, age of menarche, menopausal status, HRT and family history for breast cancer including first- and second-degree relatives were collected. Using those variables, we calculated the lifetime risk percentage for future development of breast cancer for every subject in our cohort using both the Gail and TC risk calculators. Of note, we did not calculate Gail risk on subjects aged less than 35 years at first presentation, as the model is not validated in women less than age 35. We chose not to include a Claus model risk score as it is no longer used in clinical practice. We recorded the results of the MRI report as well as patient age at the time of the first MRI used for screening and the age for patients diagnosed with biopsy proven breast cancer using MRI as a method for screening.

Ethics committee approval was obtained from Virginia Commonwealth University Institutional Review Board and the approval was given on May 31, 2018.

Statistical Analysis

We compared the accuracy of the Gail and TC models as lifetime risk calculators for breast cancer detection by calculating the receiver operating characteristic (ROC) curves for each test separately. The Gail model was considered our control model as it is a well validated standardized risk model used for other purposes but is not considered validated for determining utility of MRI. ROC curves are popular tools summarizing the trade-off between true positive and false positive rates for a predictive model (corresponding to the competing tests in this study) under various probability thresholds. Comparison of the ROC curves via the calculated area under the curve (AUC) corresponding to the Gail and TC models was performed using DeLong's test. Additionally, Fisher's Exact Test was utilized to determine the significance of cancer detection with screening MRI when the TC or Gail LR percentages are greater than 20%. A p-value of <0.05 was considered statistically significant for our analyses. All statistics were performed using SAS Software, version 9.4 (Cary, NC., USA).

Results

We identified 163 subjects in the VCU breast imaging database eligible for the study based on inclusion criteria. A total of five subjects were diagnosed with biopsy proven breast cancer after undergoing screening with MRI, representing 3.1% of our patient cohort. The mean age at first screening MRI was 48.2 years and the mean age at cancer diagnosis was 41.4 years (Table 1). The mean lifetime risk of developing breast cancer according to TC version 7 and Gail model was 25.5% and 16.9%, respectively. Furthermore, 20.2% of our cohort had undergone a prior breast biopsy with 24.2% having findings such as atypia, or lobular carcinoma in situ (LCIS). The majority (90.8%) of subjects had a first degree relative with known breast cancer and 71.8% were parous with a mean age of parity at 26.6 years. Lastly, 49 patients had undergone prior genetic testing with 19 testing positive for *BRCA1/BRCA2* or other hereditary unspecified genetic mutations (Table 1).

Logistic ROC analysis results showed that the AUC scores for TC and Gail were 0.6841 and 0.6543, respectively. There was no significant difference in predictive ability between the two calculators (p = 0.828) (Figure 1).

In order to determine whether utilizing a 20% lifetime breast cancer risk as an MRI screening cutoff clinically improves cancer detection, the relationship between biopsy proven breast cancer diagnosis with the Gail and TC calculators was explored when the cutoff value was set at 20%. Based on available information from electronic medical records, the Gail model was utilized in 134 of the subjects. (remaining subjects were age <35 years and did not qualify for Gail LR calculation). One hundred subjects were determined to have a LR ≤ 20%, with four subjects in this cohort later developing biopsy proven breast cancer (Table 2). Thirty-four subjects were determined to have LR% greater than 20%, with one subject later being diagnosed with breast cancer. There was no statistically significant difference in the diagnosis of breast cancer between the two Gail groups (p = 1.0) (Table 2). There were a total of 163 calculated TC lifetime risk percentages, with 78 corresponding subjects receiving ≤20% and 85 subjects receiving greater than 20% (Table 3). One subject with LR% less than or equal to 20% later developed biopsy proven breast cancer, while four subjects belonging in the high-risk group were diagnosed with malignancy during the study period. There was no statistically significant difference in the diagnosis of breast cancer between the two groups (p = 0.369) (Table 3).

Table 1. Population demographics

Number of subjects in the study	163
Mean age first screening MRI	48.2
Mean age of menarche	12.5
Mean BMI	28.9
Percentage of parity	71.8
Mean age of parity	26.6
Percentage with a breast biopsy	20.2
Percentage with atypia/LCIS in biopsy result	24.2
Percentage of first-degree relatives with breast cancer	90.8
Average Percentage of TC score	25.5
Average Percentage of Gail Score	16.9
Mean age of biopsy confirmed breast CA	41.4
Number of patients with genetic testing	49
Number of patients with genetic mutations known to predispose to breast cancer (eg. BRCA1, BRCA2)	19

MRI: Magnetic resonance imaging, BMI: Body mass index, LCIS: Lobular carcinoma in situ, TC: Tyrer-Cuzick, CA: Cancer

Discussion and Conclusion

Breast cancer risk calculators can provide valuable information that can be used to guide prevention, screening and chemoprophylaxis strategies in women. The Gail model, while not intended to determine MRI eligibility, has been utilized to guide chemoprophylaxis eligibility in women with a 5-year breast cancer risk of 1.67% or higher (28, 29). In contrast, the TC, in addition to the Claus and BOADICEA models, has been used to determine MRI eligibility for screening

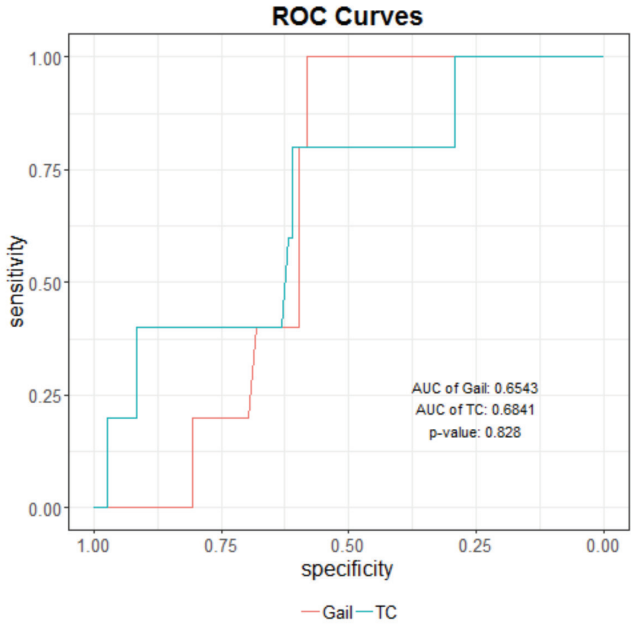

Figure 1. ROC curves of the Gail (red line) and TC (blue line) models when predicting MRI detection of breast cancer

ROC: Receiver operating characteristics curve, TC: Tyrer-Cuzick, MRI: Magnetic resonance imaging, AUC: Area under the curve

Table 2. Subject frequency and percentage of the diagnosis of breast cancer in Gail Risk Score Group [low risk (≤20%) vs. high risk (>20%)]

	Breast cancer diagnosis		
Gail group (%)	**No n (%)**	**Yes n (%)**	**Total n (%)**
≤20	96 (96.0)	4 (4.0)	100
>20	33 (97.1)	1 (2.9)	34
Total	129	5	134

The Fisher's exact test p-value 1.00 indicated that there was no statistically significant difference in diagnose breast cancer between the two Gail groups.

purposes (30). These risk assessment models, while commonly used in clinical practice, have been shown to have significant variability when identifying different populations of women eligible for screening MRI (31).

While all models have their strengths and weaknesses, the Gail and TC model are the only two that are readily available and free to all users. The Gail model contains fewer factors and can be easily run by patients themselves. However, it is not validated in women less than age 35 years, which limits its usefulness as a risk model for younger patients. TC is a more complex and robust risk model. However, it can be difficult to use and requires a provider to enter data, thus limiting its use outside of the clinic (24, 25). Conflicting data exist in the literature regarding the level of accuracy between these two models, with some studies indicating that the TC model is superior in terms of specificity, sensitivity, and positive and negative predictive value (32, 33), while others reporting greater AUC and specificity for the Gail model (34, 35). Guidelines warn against the use of the Gail model when assessing MRI eligibility for screening purposes due to accounting for limited family history (31). The TC model collects additional data, such as menopausal status, BMI, more extensive family history and the presence of LCIS, which theoretically can increase breast cancer risk prediction (Table 4). Additionally, variables such as mammographic density and genetic and non-genetic factors have been supported to aid in improved cancer risk prediction (36). When accounting for all the additional risk factors that the TC model takes into account, our data suggest that the TC lifetime risk percentage offers no additional accuracy in predicting breast cancer detection by MRI than the Gail model. These findings are supported by a recent study which found that the TC lifetime risk percentage failed to identify approximately 40% of women who were eligible for changes in their medical management, such as undergoing screening MRI (37) and another large cohort study that reported significant overestimation of breast cancer with the TC model when high risk lesions are found (38).

Breast MRI has been recommended as an adjunct to mammography in women classified as high-risk for development of breast cancer. The recommendations stem from a consensus panel which determined that a Claus LR% equal or greater than 20% is associated with increased cancer detection. The Claus model takes into account hereditary risk factors but fails to include non-hereditary risk factors that have been found to impact the lifetime risk of breast cancer in a woman. Since the TC and Gail models additionally account for non-hereditary risk factors and are widely available online, they are routinely used for risk stratification of MRI eligibility and chemoprophylaxis management, respectively. The 20% cutoff associated with increased cancer detection remains a criterion for classifying a woman as high-risk for breast cancer development, irrespective of the limitations of the Claus model. The TC and Gail models vary from the Claus model, as demonstrated in previous studies, with the TC and Gail models estimating a far higher lifetime risk than Claus (26). In fact, a more recent study found significant differences in the number of women that were eligible for MRI screening identified by the risk assessment models utilized in the study (TC, Claus, BRCAPRO) (31). In our study, we demonstrated no statistically significant correlation between the Gail or TC models when utilizing MRI as a screening modality with 20% lifetime risk cutoff to classify patients as high-risk. While the TC model is a rich source of information and risk stratification, this information calls into question the common practice of using 20% lifetime risk as cutoff for yearly MRI screening when the TC model is used to determine risk. Our data, along with others, suggest the 20% LR, as determined by testing the Claus model, may be too low when using a more sensitive model such as TC.

The results of our study should be interpreted in the context of its limitations. A major limitation of our study was the limited number of subjects who underwent screening MRI at our center and the low number of patients that were diagnosed with biopsy proven breast cancer after undergoing screening with breast MRI. With only five subjects, or 3.1% of our high-risk patient population, diagnosed with

Table 3. Subject frequency and percentage of the diagnosis of breast cancer in TC risk score [low risk (≤20%) vs. high risk (>20%)]

	Breast cancer diagnosis		
TC group (%)	**No n (%)**	**Yes n (%)**	**Total n (%)**
≤20	77 (98.7)	1 (1.3)	78
>20	80 (95.2)	4 (4.8)	85
Total	158	5	163

The Fisher's exact test p-value 0.3689 indicated that there was no statistically significant difference in diagnose breast cancer between the two TC groups
TC: Tyrer-Cuzick

Table 4. Variable used in the Claus, Gail and Tyrer-Cuzick models

Variables	Gail	Claus	Tyrer-Cuzick
Personal information			
Age	Yes	Yes	Yes
Body mass index	No	No	Yes
Hormonal factors			
Menarche	Yes	No	Yes
First live birth	Yes	No	Yes
Menopause	No	No	Yes
Personal breast disease			
Breast biopsies	Yes	No	Yes
Atypical hyperplasia	Yes	No	Yes
LCIS	No	No	Yes
Family history			
First degree relatives	Yes	Yes	Yes
Second degree relatives	No	Yes	Yes
Age of onset of cancer	No	Yes	Yes
Bilateral breast cancer	No	No	Yes
Ovarian cancer	No	No	Yes
Male breast cancer	No	No	No

LCIS: Lobular carcinoma in situ, TC: Tyrer-Cuzick

breast cancer during the study period, it is possible that our lack of predictive value is due to a low event rate rather than lack of predictive value of either calculator. This study serves only as a pilot study to guide larger trials. A larger prospective clinical trial would be necessary to determine at what percentage lifetime risk we should recommend patients undergo MRI screening when using a more sensitive model such as TC.

In conclusion, the TC model is a risk stratification tool that is currently used to guide breast cancer screening recommendations, while the Gail model has mainly been utilized to guide chemoprophylaxis management in women with increased risk for development of breast cancer. Neither have been validated as a predictive model for utility of MRI screening in a large study. In our study, the TC model did not appear superior to the Gail model when predicting the benefit of breast MRI screening. Additionally, the current 20% cutoff that classifies a woman as high-risk for future development of breast cancer, which was originally determined based on calculations derived from the Claus model, was not found to be statistically significant between the Gail or TC LR calculators and a diagnosis of breast cancer. These findings suggest that we should use the 20% LR cutoff using the TC model with caution when making MRI recommendations. A larger, multicenter trial, with a higher event rate of cancer diagnoses would be necessary to determine a more appropriate cutoff value for initiating MRI screening using this widely available risk calculator.

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Authorship Contributions

Conception: A.S., X.D., D.B., K.P.M.; Design: A.S., X.D., D.B., K.P.M.; Supervision: A.S., X.D., D.B., K.P.M.; Materials: A.S., X.D., D.B., K.P.M.; Analysis and/or Interpretation: A.S., X.D., D.B., K.P.M.; Writing: A.S., X.D., D.B., K.P.M.

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