Breast Cancer Risk Assessment using Gail Model in 35 to 69-year-old Women Referred to the Breast Cancer Screening Center at Omid Hospital in Isfahan, Iran, from 2008 to 2016

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Abstract

Background: Prediction of breast cancer risk and identifying women who are at high risk of breast cancer, would be a great help for planning and conducting screening programs. The aim of this study was to estimate the 5-year breast cancer risk among women in Isfahan.

Methods: This cross-sectional study was conducted on 9674 women aged 35-69 years who referred to the Breast Cancer Screening Centre at Omid Hospital in Isfahan from 2008 to 2016. Data were collected using a breast cancer risk assessment tool (Gail model). Any woman with Gail scores greater than 1.67% was considered as a high-risk woman for breast cancer. Using STATA 14, logistic regression was employed to determine the predictors of breast cancer risk at significance level of 5%.

Results: The mean 5-year breast cancer risk (BRCA) for all women was $0.62 \pm 0.39\%$, and 2.56% of women had 5 years breast cancer risk greater than or equal to 1.67%. There was a relationship between the 5-year risk of breast cancer and age, age at menarche, age at first live birth, family history of breast cancer, and history of breast biopsy.

Conclusion: According to the results, the Gail model can predict the risk of breast cancer and may be employed as a breast cancer risk assessment tool in screening and prevention of breast cancer program.

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Introduction

Breast cancer (BC) is the most common cancer among women, affecting about 2.1 million women every year. According to the estimates in 2018, BC accounts for approximately 15% of all mortalities among women (1). About 1 out of 8 women suffers from BC (2). Although the incidence of BC in developing countries is lower than Western countries, the BC death rate is more prevalent in developing countries, which may be due to the late detection and poor access to medical treatment services (3).

According to the predictions, the incidence and mortality rates of BC in developing countries may reach 55% and 58%

by 2020, respectively (4). BC is the most common and second leading cause of death in Iran (5). The 5-year survival rate for women with BC is 80-90% in the early stages of cancer, which decreases to 22-63% in the last stages of cancer (6).

BC screening is an effective approach for early detection and prevention of BC among women at high risk (7,8). BC screening using mammography was suggested as an approach to assess the risk of malignant cancer, however, it has not been welcomed. Moreover, the BC risk assessment using gene mutation is not commonly used because of the high-cost considerations and ethical issues (9-11). Accordingly, mathematical modeling for BC risk assessment is considered as an appropriate and cost-effective method. BC risk models estimate the risk of developing BC in the future, therefore, risk assessment is essential in the implementation of screening and prevention strategies (12).

The Gail model is one of the most well-known mathematical models in this regard (2,13,14). The Gail model includes risk factors, such as age, age at menarche, age at first live birth, the number of breast biopsies, the number of biopsies with abnormal hyperplasia, the number of first-degree relatives (mother, sister, and daughter) diagnosed with BC, and race (15,16).

The incidence of the local malignancy and invasive BC can be estimated using this model based on the high-risk clinical factors over the next 5 years, and ultimately, for the whole lifetime. This model has been tested in different races and the 5-year risk of developing BC was obtained at 1.67%. A study in Tehran, Iran, indicated that the mean 5-year risk of developing BC was estimated as $1.61 \pm 0.73\%$. In addition, for 9.36% of the participants, the 5-year risk of developing BC was more than 1.66%. Consequently, it should be noted that the Gail model is a useful approach for the assessment of BC risks (17). The main benefit of the Gail model evaluation is that it helps physician choose the appropriate preventive and therapeutic options (18).

The early diagnosis of BC reduces the mortality rate and increases the 5-year survival rate among women with BC. Moreover, the Gail model is one of the most common and simple BC risk assessment tools. Therefore, this approach can be applied to assess developing BC in women at high risk, thereby, mortality rate decreases and the quality of life is improved through BC prevention strategies and timely referrals. Accordingly, the aim of this present study was to assess the risk of developing invasive BC among a female cohort population in Isfahan, Iran, using the Gail model.

Materials and Methods

This cross-sectional study was conducted based on the registered data obtained from a female cohort population aged 35-69 years who referred to the BC Screening Center at Omid Hospital, Isfahan, Iran, from 2008 to 2016. The study population consisted of three groups. Group 1 included women who referred to the center from other health centers with a suspected diagnosis of breast carcinoma after the initial examinations. Group 2 included those who referred to the center with a family history of BC. Furthermore, healthy women referring to the center for regular health checkup were included in group 3. This study evaluated the baseline information obtained from the medical records of all 15,168 women who referred to the BC Screening Center from 2008 to 2016. It is worth noting that people who were diagnosed with BC were excluded.

Data Collection

The medical records of the patients were collected from BC Screening Center at Omid Hospital in Isfahan, Iran. The Gail model consists 6 variables, including current age, age at menarche, age at first live birth, the number of breast biopsies, the number of first-degree relatives (mother, sister, and daughter) with BC, and race. The data were collected using the questionnaires completed by women. To detect missing data, the questionnaires were completed through a telephone interview. Eventually, the obtained data were analyzed along with this assumption that all participants were whites with no gene mutation in the BRCA genes.

Statistical analysis

The data were initially entered into the Excel software, then, errors were checked. In the case of any errors, the corrections were made using the original medical records of the patients. The risk scores were calculated according to the Gail model guidelines (10), the results are shown in Tables 1 and 2.

Table 1. Descriptive characteristics of women based on the Gail model for assessment of breast cancer risk factors (n=9737)

Characteristics	n=9737	Mean 5-year Risk
Age [Year] (Mean ± SD)	44.29 ± 6.98	-
Age at menarche (Year) (Mean±SD)	13.54 ± 1.48	-
Menarche age (%)		
<12 year old	597(6.3)	0.037
12-13 year old	4338(44.55)	0.027
≥14 year old	4802(49.32)	0.022
***Age of first live birth (Year) (Mean ± SD)**	19.3 ± 7.6	-
Age at first live birth (%)	n=8863	
<20 year old	4861(54.85)	0.026
20-24 year old	1930(21.77)	0.017
25-29 year old	1442(16.27)	0.02
≥30 year old	630(7.1)	0.046
Live birth (%)		
Yes	8863(91.6)	0.32
No	811(8.4)	0.25
Number of family history of BC (%)		
No family history	9144(93.91)	0.004
1	579(5.95)	0.341
≥2	14(0.14)	0.642
Number of history of breast biopsies (%)		
0	9411(96.65)	0.021
1	299(3.07)	0.114
≥2	27(0.28)	0.629

*Regarding the age at first childbirth, there were 63 missing data (n=9674), and 811 women had no live birth.

Table 2. The results of the univariate logistic regression regarding the 5-year risk assessment of developing BC according to the variables used in the Gail model (n=9674)

Outcome Variable Gail Score Binary Risk	Odds Ratio	[95% Confidence Interval]	P-value
Age (Year)			
35-49	1(Reference category)		
50-54	18.9	12.8-27.7	0.0001<
55-59	22.3	14.4-34.4	0.0001<
60-64	26.01	15.7-43.2	0.0001<
65-69	82.6	47.5-143.7	0.0001<
Menarche age (Year)			
≥14	1(Reference category)		
12-13.9	1.2	0.95-1.6	0.11
<12	1.7	1.05-2.7	0.02
Age at first live birth (Year)			
<20	1(Reference category)		
20-24.9	0.65	0.4-0.95	0.02
25-29.9	0.74	0.5-1.1	0.16
30+	1.7	1.2-2.6	0.007
Live birth			
Yes	1(Reference category)		
No	1.2	0.58-1.9	0.22
Number of family history of BC			
0			
1	1(Reference category)		
2≥	111.6	78.8-158.1	0.0001<
	387.5	124.6-1204.8	0.0001<
Family history of BC			
No			
Yes	1(Reference category)		
	115.2	81.4-163	0.0001<
Number of history of breast biopsies			
0	1(Reference category)		
1	6.006	4.09-8.8	0.0001<
2≥	78.98	35.7-174.7	0.0001<
History of breast biopsies			
No	1(Reference category)		
Yes	8.6	6.2-12.08	0.0001<

A 5-year risk assessment of developing BC for a 42-year-old white woman (RR = 0.366) with the menarche age at 12 years (RR = 1.10) and one breast biopsy (RR = 1.70) without any childbirth and family history of BC in the first-degree relatives (RR = 1.55) is obtained by multiplying the relative scores of risk factors of the Gail model as follows:

Absolute 5-year risk $= 1.10 \times 1.55 \times 1.70 \times 0.366 = 1.06\%$

According to the above equation, individuals with a risk score of at least and lower than 1.67% were classified as high- and low-risk individuals, respectively. Risk scores were described as mean ± standard deviation (mean ± SD) at a 95% confidence interval. The number, percentage, and a confidence interval of 95% were used to describe the proportion of high- and low-risk individuals.

In addition, logistic regression analysis, an estimate of the odds ratio, and a 95% confidence interval were used to determine the BC risk predictors based on the Gail model. In this model, the dependent variable is binary, which is either 0 or 1. Individuals with a minimum score of 1.67% and those who obtained a risk score lower than 1.67% were given the codes 1 and 0, respectively. The data were analyzed using Stata version 14. Statistical significant level was considered at P<0.05.

Results

The mean age of the participants was 44.29 ± 6.98 years and 77.8% of them was in the age group of 35-49 years. Menarche age in 49.3% of the participants was above 14 years. Moreover, 50.3% had their first live birth before the age of 20 years, whereas 6.5% had their first live birth after the age of 30 years. 6.1% (n=593) of women reported a family history of BC in their first-degree relatives, and 14 women had more than one first-degree relatives with BC. In addition, 3.4% (n=326) had a history of breast biopsy, and 0.28% (n=27) of them had more than one breast biopsy. No atypical hyperplasia was observed in the participants (Table 3).

The mean score of 5-year risk of developing BC based on the Gail model was estimated to be 0.62 ± 0.39% (range: 0.19-5.35%) (95% CI: 0.61-0.62). Moreover, 2.56% (n=248) of the women (95% CI: 2.2-2.9) obtained a 5-year risk of developing BC higher than 1.67% (Table 3).

Table 3. Multiple logistic regression results regarding the 5-year risk assessment of developing BC according to the variables used in the Gail model

(n = 9674)

Outcome Variable Gail Score Binary Risk	Model 1 (age +) Odds ratio (95%CI) Univariate	Model 2 (model 1 + menarche age +) Odds ratio (95%CI) Tow variable	Model 3 (model 2 + age at first live birth) Odds ratio (95%CI) Three variable	Model 4 (model 3 + the number of family history of BC) Odds ratio (95%CI) Four variable	Model 5 (model 4 + the number of breast biopsies) Odds ratio (95%CI) Five variable	P-values for Model 5
Age (Year)						
35-49	1(reference category)	1(reference category)	1(reference category)	1(reference category)	1(reference category)	
50-54	18.9(12.84-27.68)	18.7(12.7-27.5)	21.4(14.5-31.6)	286.4(127.8-641.6)	1644.14(536.6-5037.8)	<0.0001
55-59	22.3(14.4-34.4)	22.05(14.3-34.06)	25.98(16.7-45.5)	764.15(278.1-2099.2)	8045.7(1776.7-36434.6)	<0.0001
60-64	26.01(15.7-43.2)	26.1(15.7-43.3)	28.8(17.2-48.2)	279.6(90.09-867.9)	1644.5(354.6-7626.3)	<0.0001
65-69	82.6(47.5-143.7)	82.6(47.5-143.7)	100.9(57.1-178.2)	10838.4(3471.5-33838.5)	459891.1(72269.4-2926548)	<0.0001
Menarche age (Year)						
14+		1(reference category)	1(reference category)	1(reference category)	1(reference category)	
12-13.9		1.1(0.8-1.46)	1.1(0.8-1.46)	1.4(0.87-2.4)	1.99(1.04-3.8)	0.3
<12		1.56(0.95-2.5)	1.55(0.9-2.5)	4.9(2.3-10.6)	12.4(4.6-33.0008)	<0.0001
Age at first live birth (Year)						
<20			1(reference category)	1(reference category)	1(reference category)	
20-24.9			1.07(0.7-1.59)	1.56(0.7-3.3)	2.6(1.01-6.9)	0.04
25-29.9			1.48(0.96-2.28)	3.8(1.87-7.8)	8.4(3.2-22.5)	<0.0001
30+			3.9(2.48-6.2)	21.3(10.3-44.005)	82.6(29.6-230.2)	<0.0001
Number of family history of BC						
No family history				1(reference category)	1(reference category)	
1				2338.97(1034.3-5289.5)	41515.4(10289.5-167502.9)	<0.0001
2≥				55863.3(10793.3-289133.9)	4099709(396850.3-4.24e+07)	<0.0001
Number of history of breast biopsies						
0					1(reference category)	
1					65.8(26.1-165.7)	<0.0001
2≥					517362.3(51355.5-5211981)	<0.0001

The odds ratio (OR) for the age groups shows an upward trend when compared to the reference group (35-49 years). In other words, the chance of being in a group with a 5-year high risk of developing BC was estimated as 18.9, 22.3, 26.01, and 82.6 times for the age group of 50-54, 55-59, 60-64, and 65-69 years, respectively. Furthermore, women who experienced menarche before the age of 12 years had a 70% more chance of being in the high-risk group for BC, compared to those who experienced menarche after the age of 14 years (OR=1.70, 95%CI: 1.05-2.7, P=0.02) (Table 3).

The chance of being at risk of BC for women with the menarche age of 12 to 13 years was estimated 1.2 times more than the reference group (OR = 1.2 95% CI=0.95-1.6, P=0.11). Moreover, women whose age at their first live birth was 30

years or older were 70% more likely to be at the high-risk group of developing BC compared with those whose age at their first live birth was less than 20 years (OR = 1.70, 95% CI: 1.20-2.60, P=0.007) (Table 4).

According to the results, the probability of being in the high-risk group of developing BC over the next 5 years was 111.6 times greater in women with a family history of BC in one of their first-degree relatives, compared to those without this condition (OR=111.6; 95% CI=78.8-158.1, P≤0.0001). In other words, an increase in the number of first-degree relatives with BC also increased the probability of being in the high-risk group of developing BC (P≤0001, Table 4).

In addition, the risk of developing BC was 8.6 times greater in women with a history of breast biopsy, compared to those without a history of breast biopsy (OR=8.6; 95%CI=6.2-12.08, P≤0.0001) (Table 4).

Table 5 presents five different models of multiple logistic regression, including a univariate model (i.e., age), a bivariate model (i.e., age and menarche age), a three-variable model (i.e., age, menarche age, and age at first live birth), a four-variable model (i.e., age, menarche age, age at first live birth, and the number of first-degree relatives with BC), and a five-variable model (i.e., all 4 models plus the number of history of breast biopsies).

It is worth noting that due to the low number of people at high risk in each group, large odds ratios were obtained in this study.

Discussion

Based on the results, the mean score of the 5-year risk assessment of developing BC for subjects was estimated as 0.62 ± 0.39%. Based on Gail score cut off of 1.67, of all studied women, 2.56% of them had 5 years' breast cancer risk. The results showed that the risk of BC increased with age. The model also indicated that women who experienced menarche before the age of 12 years were more likely to be in the high-risk groups, compared to those who experienced menarche after the age of 14 years. In addition, the probability of being at high-risk groups for women whose age at first live birth was over 30 years was greater than those whose age at first live birth was under 20 years.

Moreover, women with a family history of BC in their first-degree relatives and a history of breast biopsy had significantly more chance of being in the high-risk group of developing BC.

The findings of this study are comparable to other studies conducted in Iran. In a study by Mirghafourvand et al. (2016) on 560 healthy women with a mean age of 42.7 ± 7.7 years (aged 35 years and older) referring to Tabriz health centers, the mean score of a 5-year BC risk assessment was determined as 0.6 ± 0.2% (19), which is consistent with the findings of this study. Furthermore, in a study conducted by Panahi et al. (2008), the BC risk was assessed in 2000 Iranian women aged 35 years and older using the Gail model, and 7% of the patients showed a 5-year BC risk more than 1.67% (2), which is 2.7 times higher than that reported in the present study.

Furthermore, a study by Hosseinpour et al. (2012) on 513 women aged 35 years and older in Yasuj showed that the mean score of BC risk over the next 5 years was estimated as 0.47 ± 0.55%, and 2.7% of the women were classified as high-risk subjects of developing BC (20). Lower mean scores of the 5-year BC risk assessment in this study can be explained by the low marriage age, having a child, and breastfeeding.

Furthermore, in a study by Erbil et al. (2015), 213 women aged 35 years and older with a mean age of 45 ± 8.06 years

were subjected to BC risk assessment in Turkey. The mean score of the 5-year risk of BC was 0.88% ± 0.91%. In addition, 7.4% of women in this study had a 5-year risk of BC greater than 1.66% (21).

Ewaid and Al-Azzawi (2017) also used the Gail model to assess the BC risk in 250 women with a mean age of 45.46 ± 9.2 years in Baghdad. The mean score of 5-year risk of BC and the proportion of high-risk subjects were estimated as 0.95 ± 1.4% and 7.6%, respectively (22).

The observed discrepancies between the findings of this study and other studies, especially in the increased percentage of people at high risk of BC, can be attributed to the following factors.

1)   Sample size: It is obvious that studies with smaller sample size less accurately estimate the mean score of BC risk and percentages of people at high risk of developing BC.

2)   The differences in the characteristics of the population under study, and in particular, the studied age groups

3)   The selection bias that mainly focuses on the sampling sites, such as hospitals or clinics providing services for cancer patients

4)   Sampling errors and evaluation of women at high risk of developing BC

5)   Possible errors in recording data

In this study, the 5-year risk of BC increased with age. A study by Banks et al. (2004) reported that increasing age would be the most important risk factor for BC (23). Moreover, a study by Omranipour et al. (2015) revealed a significant association between the age of patients and BC risk (24).

In the present study, there was a significant difference between the high- and low-risk groups in terms of the menarche age, so that the risk of developing BC in women whose age at menarche was under 12 years was more than those aged 14 years at menarche. A study in Singapore (25) demonstrated that the early age of menarche increased the risk of breast cancer. Another study in Qatar (26) showed that the risk of BC was higher with lower menarche ages.

Moreover, in the present study, the risk of developing BC was greater in women whose age at their first live birth was over 30 years, compared to those whose age at their first live birth was under 20 years. Pregnancy during early adolescence, especially under 20 years, is associated with a remarkable reduction in the risk of BC (27). In contrary, having no childbirth and the first live birth at an age over 30 years are associated with an increased BC risk (28). McPherson (2000) indicated that the risk of BC in women who had their first birth after the age of 30 years was two times higher than those who had their first birth at age of 20 years (29).

In this study, the risk of developing BC was higher in women with a history of breast biopsy than those without this condition, therefore, the increase in the number of biopsies led to an increase in the chance of being at high risk for developing BC. The findings of this study are consistent with the results of studies conducted by Omranipour et al. (24) and Mohammadbeigi et al. (30).

Family history of BC in the first-degree relatives is one of the risk factors for BC based on the Gail (10) and Claus models (31). According to the results of the univariate regression analysis in this study, the family history of BC in the first-degree relatives was the strongest predictor of the increased risk of BC. In other words, BC risk was estimated to be greater in

women with a family history of BC in their first-degree relatives than those without this condition.

Mirghafourvand et al. (2016) identified family history as a strong risk factors of a 5-year BC risk assessment, which is consistent with the results of the present study (19). Similarly, a study by Marzbani et al. (2017) showed that the risk of BC was 2.41 times higher in individuals with a family history of BC in their first-degree relatives, compared to those without this condition (32), which is consistent with the findings of several studies (33,34).

The present study clearly had some limitations. The data might be exposed to recall and selection bias. In order to minimize the recall bias, the data were collected through interviews with the participants by trained people as well as the medical history of women in the screening center. In addition, the baseline information of all individuals registered in the cohort study was employed, thereby, the selection bias was avoided. Despite these limitations, a standard model (Gail model) was utilized in order to assess the 5-year risk of developing BC. Moreover, this sample size used in this study has the power to accurately assess and identify the people at high risk of developing BC. Another advantage of this study includes the utilization of various population groups. Accordingly, the sample is representative of the target population and the results are generalizable.

In conclusion, this study indicated that the Gail model can predict the risk of breast cancer and may be employed as breast cancer risk assessment tool in screening and prevention of breast cancer health program.

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