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Assessing Breast Cancer Risk Estimates Based on the Gail Model and Its Predictors in Qatari Women

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Abstract

Background: The Gail model is the most widely used breast cancer risk assessment tool. An accurate assessment of individual's breast cancer risk is very important for prevention of the disease and for the health care providers to make decision on taking chemoprevention for high-risk women in clinical practice in Qatar. **Aim:** To assess the breast cancer risk among Arab women population in Qatar using the Gail model and provide a global comparison of risk assessment. **Subjects and Methods:** In this cross-sectional study of 1488 women (aged 35 years and older), we used the Gail Risk Assessment Tool to assess the risk of developing breast cancer. Sociodemographic features such as age, lifestyle habits, body mass index, breast-feeding duration, consanguinity among parents, and family history of breast cancer were considered as possible risks. **Results:** The mean age of the study population was 47.8 ± 10.8 years. Qatari women and Arab women constituted 64.7% and 35.3% of the study population, respectively. The mean 5-year and lifetime breast cancer risks were 1.12 ± 0.52 and 10.57 ± 3.1, respectively. Consanguineous marriage among parents was seen in 30.6% of participants. We found a relationship between the 5-year and lifetime risks of breast cancer and variables such as age, age at menarche, gravidity, parity, body mass index, family history of cancer, menopause age, occupation, and level of education. The linear regression analysis identified the predictors for breast cancer in women such as age, age at menarche, age of first birth, family history and age of menopausal were considered the strong predictors and significant contributing risk factors for breast cancer after adjusting for ethnicity, parity and other variables. **Conclusion:** The current study is the first to evaluate the performance of the Gail model for Arab women population in the Gulf Cooperation Council. Gail model is an appropriate breast cancer risk assessment tool for female population in Qatar.

Keywords

breast cancer, Gail model risk assessment, lifestyle, predictor, risk factors, consanguinity, Arab women

Introduction

Breast cancer is a major public health concern worldwide. It is the most prevalent cancer accounting for nearly 30% of all cancer types in women in both developed and developing countries.[1] The World Health Organization (WHO) estimated more than 536 521 deaths from breast cancer in 2012 worldwide.[2,3] Each year, nearly 1.7 million women are diagnosed with breast cancer and 522 000 die from the disease.[2] Furthermore, it has been estimated that almost 53% of the diagnosed breast cancer cases and 62% of breast cancer–related deaths occur in less developed regions.[2] This high mortality rate can be attributed to the late diagnosis of the disease.[2] Hence, early diagnosis of breast cancer is of paramount importance to reduce such mortality rates and the burden of breast cancer. Qatar is one of the Gulf Cooperation Council (GCC) countries with a total population of 2 258 283 (July 2016 estimate). In Qatar, breast cancer constitutes about 39% of all cancer types in females (Qatar Cancer

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Society website). Qatari nationals account for 32% of all breast cancer cases in Qatar (age 40-50 years).[4-6]

Breast cancer screening is an efficient approach for early diagnosis and prevention of breast cancer in "high-risk" women.[7-11] Among the widely available risk assessment models for breast cancer, Gail model remains the most frequently used tool for prediction of the 5-year and lifetime risks of developing breast cancer for women aged 35 years and older.[12-15] It uses 6 breast cancer risk factors, including age, hormonal or reproductive history (age at menarche and age at first live birth), previous history of breast disease (number of breast biopsies and history of atypical hyperplasia), and family history (number of first-degree relatives with breast cancer).

The Gail model[12] is the most widely used breast cancer risk assessment tool. An accurate assessment of individual's breast cancer risk is very important for prevention of the disease and for the health care providers to make decision on taking chemoprevention for high-risk women in clinical practice. One of the advantages of the Gail model[12] is the extensive validation it underwent in different female populations since its development over the past 2 decades. Despite being validated in different Western populations, Gail model validation in Arabian Gulf women has not been performed previously. The aim of this study was to assess the breast cancer risk among Arab women population in Qatar using the Gail model and provide a global comparison of risk assessment.

Subjects and Methods

This is a cross-sectional study conducted at tertiary and primary health care facilities in Qatar. Data collection took place from July 2012 to June 2014, inclusive. Among the 22 primary health care centers available in Qatar, 12 were randomly selected (10 located in urban and 2 in semiurban areas). A 1-in-2 systematic sample was performed. A representative sample of 1993 women aged 35 years and older was selected. Among the 1993 invited, 1488 (74.6%) subjects gave consent to take part in this study. Each participant was informed about the study and guaranteed promises of confidentiality. The trained nurses and research assistances coordinated the face-to-face interviews with women to complete questionnaires in the Arabic language. The pilot survey instruments were initially tested for validation on 100 women. Cronbach's alpha coefficients values >.70 indicates adequate scale reliability. Overall internal reliability (Cronbach's $\alpha = .85$) was high. A structured questionnaire was used to collect sociodemographic data and details of risk factors for breast cancer such as age, age at first period, age at the first live birth, the number of previous breast biopsies, the presence of atypical hyperplasia in any previous breast biopsy specimen and history of breast cancer among the participant's first-degree relatives (mother, sisters, and daughters). The study was approved by the Research Ethical Committee of Hamad Medical Corporation and conducted in accordance with the Declaration of Helsinki. All participants signed consent form prior to inclusion in the study.

Student's *t* test was used to check significant differences between mean values of 2 continuous groups. Moreover, differences in proportions of categorical variables between 2 or more groups were ascertained by chi-square and Fisher's exact tests. Multiple linear regression models with stepwise method were used to estimate the effect of each variable on the 5-year and lifetime breast cancer risk. The level $P < .05$ was considered as the cutoff value for significance. The Gail model risk for each subject was calculated by Breast Cancer Risk Assessment Tool (BCRAT) (an interactive tool designed for estimating the women's risk of developing invasive breast cancer).[12,16-18]

The Gail model calculates the probability of a woman at age a who has age-related relative risk $r(t)$. This will develop breast cancer by age $a+\tau$.

$$p\{a,\tau,r(t)\} = \int_{a}^{a+\tau} h_1(t)\, r(t)\, e^{-\int_{a}^{t} h_1(u) r(u)\, du} \{S_2(t)/S_2(a)\}\, dt$$

where $S_2(t) = e^{-\int_{0}^{t} h_2(u)\, du}$. It is the probability of surviving competing risk up to age. In this equation, $h_1(t)$ denotes the age-related risk of a subject from unknown risk factors and $h_2(t)$ refers to the age-related risk of causes of death.[12]

BCRAT calculated 4 types of risk, including 5-year risk, lifetime risk, average 5-year risk, and lifetime risk for each women of same age. To stratify women into high-risk category is one of the main purposes of using breast cancer risk tools. Accordingly, health care provider can provide better screening decision or clinical management strategies for individual patient.[17] Using the Gail model, as a golden standard, a woman with a probability of getting breast cancer of less than 1.66% in 5 years is considered being at low risk. Conversely, a woman with a probability of more than 1.66% is classified as high-risk and should undergo intensive screening by annual mammography and clinical breast examination every 6 to 12 months.[19]

Inclusion Criteria

Women of Qatar and Arab nationals aged 35 years or older were included in the current study. Subjects with prior history of breast cancer and mentally-incapacitated patients were excluded from the study.

Results

Table 1 shows the sociodemographic characteristics of all reported women (N = 1488). The mean age of the women in the study was 47.7 ± 10.2 years. Qatari nationals constituted

Table 1. Sociodemographic Characteristics of Breast Cancer Patients (N = 1488).

Characteristic	n	%
Age, years, mean ± SD (range)	47.8 ± 10.8 (35-65)	
Age group, years		
35-45	468	31.5
46-55	528	37.5
56-65	462	31.0
Ethnicity		
Qatari	963	64.7
Other Arabs	526	35.3
Age at menarche, years		
9-11	274	18.4
12-13	857	57.6
≥14	357	24.0
Menopausal		
Premenopausal (nonmenopause)	586	39.4
Postmenopausal (menopause)	902	60.6
Marital status		
Single	67	13.9
Married	1329	86.1
Widowes/divorced	92	6.1
Education level		
Illiterate	211	14.2
Primary	282	19.0
Intermediate	256	17.2
Secondary	384	25.8
University or higher	355	23.9
Occupation		
Housewife	789	53.0
Sedentary/Professional	298	20.0
Clerk/Officer/Administrator	235	15.8
Businesswoman	86	5.8
Police/Army/Security force	80	5.4
Household income		
Low	504	33.9
Medium	624	41.9
High	360	24.2
Smoking		
Yes	72	4.8
No	1416	95.2
Sheesha smoking		
Yes	144	9.7
No	1344	90.3

64.7% of participants whereas 35.3% were Arab expatriates. Around 86 % of participants were married women, 14.6% were illiterate, 23.9% were university graduates, and 53% were housewives. The age of menarche for the majority of participants (57.6%) was between 12 and 13 years. Majority of participants (60.6%) were postmenopausal women. Interestingly, *sheesha* smoking habit was more popular in Arab women (9.7%) than cigarette smoking (4.8%).

Table 2. Lifestyle and Clinical Characteristics of Study Sample (N = 1488).

Variables	Frequency and Percentage, n (%)
Physical activity, walking per day	
30 minutes	409 (27.5)
60 minutes	178(12.0)
None	901 (60.5)
Body mass index group, kg/m^2	
20-24.99 (normal)	405 (27.2)
25-30 (overweight)	637 (42.8)
>30 (obese)	446 (30.0)
Infertility	
Yes	106 (7.1)
No	1382 (92.9)
Parity	
None	121 (8.1)
1 child	422 (28.4)
2-3 children	353 (23.7)
4-5 children	311 (20.9)
>6 children	281 (18.9)
Breast-feeding	
Yes	1220 (82.0)
No	268 (18.0)
Breast-feeding duration	
≤6 months	376 (25.3)
>6 months	1006 (67.7)
None	106 (7.1)
Consanguineous parents	
Yes	456 (30.6)
No	1032 (69.4)
First-degree family cancer history	
Yes	203 (13.6)
No	1285 (86.4)
Family cancer history more than 1	
Yes	90 (6)
No	1398 (94)
Mammography screening	
Yes	107 (8)
No	1231 (92.0)

Table 2 presents the lifestyle and clinical characteristics of the study population. Daily physical activity was less practiced among participants during hot seasons, only 27.5% walked 30 minutes per day and 12% walked 60 minutes per day. Around 43% of women were overweight and 30% were obese. Majority of women had one child. Consanguineous marriage among parents was observed in 30.6% of the studied women. Most of the women in this study (67.7%) breast-fed their children more than 6 months.

Table 3 shows the sociodemographic characteristics of women with breast cancer risk using Gail model for 5-year and lifetime risk of breast cancer. The women who had a medical history of breast cancer and mutation of BRAC1 or

Table 3. Sociodemographic Characteristics of Patients With Breast Cancer Risk Using the Gail Model (N = 1338).

	5-Year Risk			Lifetime Risk		
	Low Risk, n (%)	High Risk, n (%)	*P*	Low Risk, n (%)	High Risk, n (%)	*P*
Age group, years						
35-45	445 (60.0)	22 (3.7)		160 (21.8)	307 (50.9)	
46-55	257 (34.6)	278 (46.6)	<.001	310 (42.2)	225 (37.3)	<.001
56-65	40 (5.4)	296 (49.7)		265 (36)	71 (11.8)	
Ethnicity						
Qatari	515 (69.4)	419 (70.3)	.723	519 (70.6)	415 (68.8)	.478
Other Arabs	227 (30.6)	177 (29.7)		216 (29.4)	188 (31.2)	
Age at Menarche, years						
9-11	112 (15.1)	115 (19.3)		105 (14.3)	122 (20.2)	
12-13	437 (58.9)	346 (58.1)	.082	405 (55.1)	378 (62.7)	<.001
≥14	193 (26.0)	135 (22.7)		225 (30.6)	103 (17.1)	
Age at first birth, years						
<20	94 (12.7)	5 (0.8)		94 (12.8)	5 (0.8)	
20-24	256 (34.5)	91 (15.3)	<.001	299 (40.7)	48 (8.0)	<.001
25-29	223 (30.1)	196 (32.9)		258 (35.1)	161 (26.7)	
≥30	169 (22.8)	304 (64.3)		84 (11.4)	389 (29.1)	
Family history						
Yes	35 (4.7)	115 (19.3)	<.001	8 (1.1)	142 (23.5)	<.001
No	707 (95.3)	481 (80.7)		727 (98.9)	461 (76.5)	
Menopausal						
Premenopausal	484 (65.2)	37 (6.2)	<.001	194 (26.4)	327 (54.2)	<.001
Postmenopausal	258 (34.8)	559 (93.8)		541 (73.6)	276 (45.8)	
Breast-feeding						
<6 months	150 (20.2)	110 (18.5)	.419	151 (20.5)	109 (18.1)	.256
≥6 months	592 (79.8)	486 (81.5)		584 (79.5)	494 (81.9)	
Consanguinity						
Yes	225 (30.3)	181 (30.4)	.986	214 (29.1)	192 (31.8)	.281
No	517 (69.7)	415 (69.6)		521 (70.1)	411 (68.2)	
Parity						
≤3 children	570 (76.8)	429 (72.0)	.043	540 (73.5)	459 (76.1)	.267
>3 children	172 (23.2)	167 (28.0)		195 (26.5)	144 (23.9)	
Body mass index, kg/m^2						
20-24.99	222 (29.9)	138 (23.2)		191 (26.0)	169 (28.0)	
25-30	277 (37.3)	304 (51.0)	<.001	332 (45.2)	249 (41.3)	.361
>30	243 (32.7)	154 (25.8)		212 (28.8)	185 (30.7)	
Breast biopsies						
Yes	4 (0.5)	8 (1.3)		5 (0.7)	7 (1.2)	
No	738 (99.5)	588 (98.7)	.149	730 (99.3)	596 (98.8)	.394
Sheesha smoking						
Yes	76 (10.2)	60 (10.1)	.916	66 (9.0)	70 (11.6)	.113
Occupation						
Housewife	362 (48.8)	341 (57.2)		380 (51.7)	323 (53.6)	
Sedentary/Professional	206 (27.8)	63 (10.6)	<.001	129 (17.6)	140 (23.2)	.001
Clerk/Administrator	137 (18.5)	149 (25)		182 (24.8)	104 (17.2)	
Businesswoman	37 (5.0)	43 (7.2)		44 (6.0)	36 (6.0)	
Education level						
Illiterate	71 (9.6)	118 (19.8)		117 (15.9)	72 (11.9)	
Primary	132 (17.8)	126 (21.1)		133 (18.1)	125 (20.7)	
Intermediate	105 (14.2)	127 (21.3)	<.001	135 (18.4)	97 (16.1)	.019
Secondary	202 (27.2)	140 (23.5)		196 (26.7)	146 (24.2)	
University or higher	232 (31.3)	85 (14.3)		154 (21.0)	163 (27.0)	

Table 4. Regression Results for 5-Year and Lifetime Gail Risk.

Independent Variables	Coefficient	Standard Error	*t*	*P*
5-year risks				
Constant	−0.519	0.063	−8.222	<.001
Age	0.055	0.001	50.735	<.001
Age at menarche	−0.039	0.003	−13.036	<.001
Age of first birth	0.034	0.001	37.682	<.001
Family history	−0.734	0.014	−51.293	<.001
Menopause	0.062	0.018	3.499	<.001
Lifetime risks				
Constant	25.055	0.430	58.229	<.001
Age	−0.161	0.007	−21.622	<.001
Age at menarche	−0.322	0.021	−15.692	<.001
Age of first birth	0.315	0.006	51.732	<.001
Family history	−6.087	0.097	−62.432	<.001
Menopause	−0.221	0.121	−1.831	.067

BRAC2 genes were excluded and there were 1338 women remaining. The mean 5-year and lifetime risks for breast cancer were 1.12 ± 0.52 and 10.57 ± 3.1, respectively. The mean 5-year and lifetime risks for women of the same age were 1.15 ± 0.46 and 11.04 ± 1.21, respectively. The 5-year and lifetime risks were considered as low if they were lower than their mean value. Similarly, the 5-year and lifetime risks were considered as high if they were higher than their mean value. We found a relationship between the 5-year and lifetime risks of breast cancer and variables such as age, age at menarche, gravidity, parity, body mass index (BMI), family history of cancer, menopause age, occupation, and level of education.

Table 4 shows the general linear regression model analysis as predictors for 5-year and lifetime risks of developing breast cancer in women 35 years and older in the state of Qatar. The linear regression analysis identified the predictors for breast cancer in women for 5-year and lifetime risks such as age, age at menarche, age of first birth, family history, and age of menopause were considered the strong predictors and significant contributing risk factors for breast cancer after adjusting for ethnicity, parity, and other variables ($P < .001$). Meanwhile the model and analysis did not have significant affect for breast-feeding, consanguinity, BMI, sheesha smoking, smoking, occupation, and education level; however, did not enter into the model as predictors.

Globally reported Gail's breast cancer risks are presented in Table 5. The Gail model overestimates risk in most of the studies apart from the United States, because the risk factors and incidence rates of breast cancer are varied across different ethnicities.

Discussion

Breast cancer in Qatar is the most common form of cancer in Qatari Arab women and the most frequent cause of cancer-related death.[4,5,30] Hence, an accurate assessment of individual's breast cancer risk is of paramount importance to patients as well as health care providers to make decision on taking chemoprevention for high-risk women. It is important to know that the women at high risk of developing breast cancer need valuable supports for making a decision in health care and accepting the effect of different prevention policies.

Various mathematical models are widely available to estimate individual breast cancer risk. For the past 2 decades, the Gail model has been considered to be the best available means for estimating risk of development of breast cancer.[12,17,18] It is also the most frequently used model in chemoprevention trials and counseling. The original model was derived from general American white women with annual mammography screening[12,17] and hence, it can be suitable for populations such as in the current study and other similar studies.[13-15,20] Nevertheless, one of the important limitations of Gail model is the lack of consideration of breast cancer among second degree-relatives as a risk factor. Furthermore, a number of previous studies have shown that the Gail model may overestimate the risk of development of breast cancer.[7,21,27] The Claus model (1998) on the other hand, focuses on presence of first- and second-degree relatives with breast cancer and their age at diagnosis as important risk factors. Unlike the Gail and Claus models,[32] the BRCAPRO model uses Mendelian approaches and Bayesian statistics and takes into consideration family history of bilateral breast cancer and ovarian cancer. The Tyrer-Cuzick model[33] (IBIS model) assesses 10-year risk and presents a non-BRCA1/BRCA2 breast cancer susceptibility gene mutation for individuals. However, the limitation of this model is to collect unaffected relatives and type of benign disease.

The Gail model has not been validated in female population of the Gulf Cooperation Council (GCC) countries. To

Table 5. Reported Gail's Breast Cancer Risk: Global Variations and Comparisons.

Study	Year	Country	Sample Size (n)	Study Design Type	Age (Years)	5-Year Breast Cancer Risk	Lifetime Breast Cancer Risk
Gail et al[12]	1989	USA	4496	Case-control	>50	1.02	11.21
Ulusoy et al[9]	2010	Turkey	650	Cross-sectional	>35	1.67	7.70
Khazaee-Pool et al[14]	2016	Iran	3847	Cross-sectional	>35	1.61	11.71
Erbil et al[20]	2015	Turkey	231	Cross-sectional	>35	0.88	9.37
Seyednoori et al[13]	2012	Iran	314	Cross-sectional	>35	0.80	9.0
Yilmaz et al[10]	2011	Turkey	415	Cross-sectional	>20	1.70	15.0
Khaliq et al[11]	2016	USA	124	Cross-sectional	>50	1.67	—
Eadie et al[16]	2013	UK	355	Cross-sectional	>46	1.50	9.0
Tice et al[21]	2005	USA	8,388	Cross-sectional	>18	0.80	8.0
Baitchev et al[8]	2009	Bulgaria	315	Retrospective	>35	1.51	—
Challa et al[22]	2013	India	200	Case-control	>35	—	7.80
Mirgahfourvand et al[23]	2016	Iran	560	Cross-sectional	>35	0.60	8.90
Abu Rustum et al[7]	2001	USA	319	Prospective	>35	1.67	—
Park et al[24]	2013	Korea	3789	Cohort	<50	0.44	2.24
Davids et al[25]	2004	USA	254	Cross-sectional	>40	1.50	8.40
Ewaid and Al-Azzawi[15]	2016	Iraq	250	Cross-sectional	>35	0.95	11.30
Novotny et al[26]	2006	Czech Republic	4598	Case-control	>35	1.37	8.02
Adams-Campbell et al[27]	2009	USA	883	Retrospective	>40	0.88	—
Panahi et al[28]	2008	Iran	2000	Cross-sectional	>35	0.92	9.14
Palomares et al[29]	2006	USA	99	Prospective	>35	4.13	23.50
Bener et al (present study)	2016	Qatar	1488	Cross-sectional	>35	1.12	10.57

the best of our knowledge, the current study is the first to evaluate the performance of the Gail model for Arab women population in the GCC. Furthermore, we studied the effects of factors that were not included in the Gail model such as consanguinity, BMI, menopausal and postmenopausal status, duration of breast-feeding on the risk of developing breast cancer. In agreement with other studies,[5,31,34,35] the current study revealed that the general risk of breast cancer was high in single women, women with a positive family history of breast cancer, and women who did not breast-feed their children. The risk was higher with lower menarche ages, higher level of education and higher women's age at first childbirth. We also found that certain factors could lower the risk of breast cancer such as multiparity, breast-feeding history, and absence of family history of breast cancer.

Our study has a number of limitations. The cross-sectional nature of the study does not allow future assessment and update regarding changes in the various risk factors among the participants. Moreover, bias may affect the results due to self-reported data; however, this study was based on face-to-face interviews and randomly we checked 50% of women's medical records for accuracy. Furthermore, we did not examine the genetic susceptibilities of the study population as well as the association between history of other malignancies (such as ovarian cancer) and the risk of development of breast cancer.

Conclusion

Breast cancer is an important health problem in Qatar and estimating risk of development of breast cancer in Qatari and Arab nationals is very important for screening and prevention of the disease. The current study highlights the usefulness of Gail model as important breast cancer risk prediction model for clinical decision making. The Gail model is an appropriate breast cancer risk assessment tool for Qatari's female population. The breast cancer risk assessment can be helpful in the clinical management of screening and prevention.

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