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
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 model12 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 model12 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 assistants 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 α = .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 + τ.

\[
p\{a, \tau, r(t)\} = \int_{a}^{a+\tau} h(t) r(t) e^{-\int_{a}^{t} \frac{1}{2} h(u)du} \{S_{2}(t)/S_{2}(a)\} dt
\]

where \( S_{2}(t) = e^{-\int_{0}^{t} \frac{1}{2} h(u)du} \). It is the probability of surviving competing risk up to age. In this equation, \( h(t) \) denotes the age-related risk of a subject from unknown risk factors and \( h_{t}(t) \) 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...
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 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 |
| Widows/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 |

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).

| Age group, years | 5-Year Risk | | | Lifetime Risk | | |
|------------------|-------------|---|---|----------------|---|---|
| | Low Risk, n (%) | High Risk, n (%) | P | Low Risk, n (%) | High Risk, n (%) | P |
| 35-45 | 445 (60.0) | 22 (3.7) | .001 | 160 (21.8) | 307 (50.9) | <.001 |
| 46-55 | 257 (34.6) | 278 (46.6) | <.001 | 310 (42.2) | 225 (37.3) | <.001 |
| 56-65 | 40 (5.4) | 296 (49.7) | .263 | 265 (36) | 71 (11.8) | .723 |
| 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) | .082 | 105 (14.3) | 122 (20.2) | <.001 |
| 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) | .082 | 258 (35.1) | 161 (26.7) | |
| ≥30 | 169 (22.8) | 304 (64.3) | <.001 | 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 (45.4) | <.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/m² | | | | | | |
| 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) | .964 | 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) | |
BRAC2 genes were excluded and there were 1338 women remaining. The mean 5-year and lifetime risks for breast cancer were $1.12 \pm 0.52$ and $10.57 \pm 3.1$, respectively. The mean 5-year and lifetime risks for women of the same age were $1.15 \pm 0.46$ and $11.04 \pm 1.21$, 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 as significant contributors to risk factors. 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. 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|

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
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, 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 breastfeed 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.

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

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 Qatar’s female population. The breast cancer risk assessment can be helpful in the clinical management of screening and prevention.

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