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Breast Cancer Risk Assessment in Jordanian Women Using Gail Model: A Cross-Sectional Study

Hamzeh Al-Balas[a], Mahmoud Al-Balas[a], Hadeel Heilat[b], Rogayah Mustafa[c], Eyad Attoun[c], Khaled Albakri[c]

[a]*Department of General and Special Surgery, Faculty of Medicine, Hashemite University, Jordan*

[b]*Faculty of Medicine, Yarmouk University, Irbid, Jordan*

[c]*Faculty of Medicine, Hashemite University, Zarqa, Jordan*

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ABSTRACT

Background: the study aimed to apply and validate the modified Gail Model (GM) in a group of Jordanian women to identify their estimated 5-years and lifelong breast cancer risk.

Methods: This cross-sectional study was carried out in Jordan, wherein data were gathered from women who had no previous personal history of breast cancer during the period from January 2020 to June 2020. Sociodemographic characteristics and other breast cancer-related factors were gathered from the participants. Breast cancer risks were determined using the Breast Cancer Risk Assessment Tool (BCRAT) of the National Cancer Institute Online version (Gail Model version 2). Data were analyzed using the SPSS

Results: A total of 502 women were involved in our study. The mean age was 47±8.8 years (range: 35-83). The majority of the women were married (93.6%). Twenty-seven women (5.2%) were nulliparous. Regarding menarche age, 243 women (47.3%) had their first cycle at the age of 12-13 years. One hundred women (19.9%) reported at least one family member with a breast cancer diagnosis while 23 women (4.6%) had a member with an ovarian cancer diagnosis. The calculated median for the 5-year BC risk was 0.8 (0.5 to 1.2), while the median for the lifetime risk was 9.2 (7.8 to 11.1). Thirty-eight women (7.6%) and 12 (2.4%) were categorized as having a high risk of developing BC in five years and a lifetime, respectively.

Conclusion: The utilization of Gail models can help healthcare providers identify a subset of women who are at an increased risk for breast cancer and personalize their approach in selecting the timing schedule and modality for breast cancer screening.

INTRODUCTION

Breast cancer (BC) is the most common cancer affecting women in Jordan. It accounts for 19.7% of all cancer cases globally and 36.4% of cases among Jordanian women.[1] According to Jordanian cancer registry data, the incidence of BC continuously increases. In 2018, around 2143 cases were registered compared to 1187 cases in 2014.[2] On the contrary, it has been reported that the incidence of BC in some western countries is decreasing.[3] The median age of Jordanian women with BC is approximately 51 years,

***Address for correspondence:**
Mahmoud Al-Balas, MD,
Assistant Professor of Breast and General Surgery, Department of General and Special Surgery, Faculty of Medicine, Hashemite University, Zarqa 13133, Jordan
Tel: xxx
Email: drbalas1984@gmail.com

almost nine years lower than the median age in western countries.[2] The age-standardized incidence rate for BC among Jordanian women was higher than that in neighboring countries such as Iran, Saudi Arabia, Turkey, and Iraq.[4]

Therefore, the Jordanian Breast Cancer Program made considerable efforts to enhance early detection, raise public awareness about BC, and encourage women to start their mammographic screening at the age of 40. However, there are several challenges regarding the implementation of mammographic screening in this developing country, such as access to mammographic units, financial limitations, social stigma and fear of diagnosis. Accordingly, the need to use the risk identification models is highly recognized to identify women with high risk for BC in primary health care units.

There are different statistical models that predict the risk of BC such as Tyrer-Cuzick model, Claus model, BOADICEA model, and Gail model.[5] These models are used to identify high risk BC women for either utilizing risk reducing strategies or recommend special imaging techniques as breast MRI in their screening protocol. Gail model (GM) is the most widely known and commonly used statistical model for BC risk assessment. The Modified Gail model calculates the 5-year and lifetime invasive BC risk, which is based on six breast cancer risk factors (age, menarche age, age of first live birth, personal history of breast biopsies, presence of atypical hyperplasia, and a family history of first-degree relatives with breast cancer).[6] It has been well studied, validated, and applied in various studies worldwide.[7,8]

However, it has been found that the type of population changes the risk factors and incidence of BC.[9] So, GM should be validated in different populations before its application; nevertheless, there are not enough studies assessing the use of GM in identifying the high-risk BC women in the Middle East, in general, and in Jordan, in particular. Based on this, the study aimed to apply the modified GM in a group of Jordanian women to identify their estimated 5-year and lifelong breast cancer risk.

METHODS

This cross-sectional study was conducted in the northern and central Jordan on women aged 35 years or older with no previous history of breast cancer in the period between January 2020 and June 2020. After providing a short description of the study and confirming that the information would be confidential, an informed consent was obtained. All of the participants answered questions concerning their sociodemographic characteristics as well as BC risk-related questions. The ethical approval was obtained from the Hashemite University institutional review board in January 2020.

For this study, the estimated sample size was derived from the online Raosoft sample size calculator.[24] The sample size was calculated based on a response rate of 50%, a confidence interval of 95%, and a margin of error of 5%. The minimum accepted number of participants was estimated to be 385 women.

After coding the variables used in GM (i.e., Age, Age of menarches, Age of 1st life birth, Number of 1st degree relatives with Breast Cancer, Number of breast biopsies including atypical hyperplasia, and Race/Ethnicity), risk scores of BC occurrence were calculated using the Breast Cancer Risk Assessment Tool (BCRAT) of the National Cancer Institute Online version (Gail Model version 2). The five-year and lifetime risk scores represent the probability of the BC in the upcoming five years and up to the age of 90, respectively.[25] The participant had a high risk of developing BC in the next five years if the score was more than 1.7%, with a high risk in the lifetime if the value was more than 30%.[25]

The main aim of this study was to find out the percentage of Jordanian women with high five-year and lifetime risks of breast cancer using GM and to compare these scores with the scores from other countries.

Data were analyzed using the SPSS. Categorical variables were described via numbers and percentages, whereas continuous data were represented via mean and standard deviation (SD) or median and inter-quartile range (IQR) according to the normality distribution of the data. The Chi-Square and Fisher's exact tests were calculated to examine the association between the classification of the BC risks and the categorical variables of the participants, with a P-value < 0.05 considered significant. Those variables that revealed a significant association with the BC risks categories were included in logistic regression to identify the extent of their impact on BC risks. The low-risk category was chosen as a reference group in the model.

RESULTS

Overall, 502 women were involved in our study. The mean age was 47±8.8 years (range: 35-83); among them 314 (62.5%) had completed their diploma or university degree. The majority of the women were married (93.6%). Twenty-seven women (5.4%) were nulliparous while 47 women (9.4%) had their first delivery after the age of 30. Regarding the age of menarche, 236 women (47%) had their first cycle at the age of 12- 13 years and 186 women

Table 1. Socio-demographic characterstics of the participants

Variables		Mean±SD / n (%)
Age (years)		47±8.8
Age group (years)	35 to 44	223 (44.4)
	45 to 54	183 (36.5)
	< 54	96 (19.1)
Living place	North	194 (38.6)
	Middle	308 (61.4)
Menarche age (years)	From 7 to 11	58 (11.6)
	From 12 to 13	236 (47)
	More than 13	186 (37.1)
	Unknown	21 (4.2)
Marital status	Single	32 (6.4)
	Married/divorced	470 (93.6)
Age of first child (years)	Unknown	4 (0.8)
	Not married	34 (6.8)
	Nulliparous	27 (5.4)
	Less than 20	74 (14.7)
	From 20 to 24	187 (37.3)
	From 25 to 29	129 (25.7)
	More than 29	47 (9.4)
Menopausal age (years)	Non-menopause	335 (66.7)
	Unknown age	4 (0.8)
	Less than 46	43 (8.6)
	From 46 to 55	115 (22.9)
	More than 55	5 (1)
Education	Secondary school or less	188 (37.5)
	Diploma or more	314 (62.5)
Smoking status (smoker)	Less than 10	34 (6.8)
	From 10 to 20	29 (5.8)
	More than 20	19 (3.8)
	Non-Smokers	420 (83.6)
Body mass index (BMI)		28.6±5.5
Phyical activity	No activity	245 (48.8)
	≤ 3 times weekly	160 (31.9)
	> 3 times weekly	97 (19.3)
Number of breast biopsy	NA	461 (91.8)
	One biopsy	39 (7.8)
	> one biopsy	2 (0.4)
Atypical hyperplasia	Unknown	2 (0.4)
	No	17 (3.4)
	Yes	22 (4.4)
	NA	461 (91.8)
Radiotherapy	No	479 (95.4)
	Yes	23 (4.6)
Hormonal Tx	No	398 (79.3)
	Yes	104 (20.7)
Diabete (DM)	No	443 (88.2)
	Yes	59 (11.8)
Hypertension	No	397 (79.1)
	Yes	105 (20.9)
Hyprelipidemia	No	443 (88.2)
	Yes	59 (11.8)
Hypothyroidism	No	458 (91.2)
	Yes	44 (8.8)
Hyperthyroidism	No	492 (98)
	Yes	10 (2)

(37.1%) at or over the age of 14 years. Menopausal women were approximately 32.5% of the studied women (n=163), while most of them had their menopausal age between 46 and 55 years (71%).

In a review of personal history of breast biopsy, 39 women (7.8%) had performed one breast biopsy. Twenty-two women (4.4%%) had been diagnosed with atypical hyperplasia Other demographic characteristics and medical history information are presented in Table 1.

Regarding family history of breast and ovarian cancer, 100 women (19.9%) reported at least one family member with a breast cancer diagnosis while 23 women (4.6%) had a member with an ovarian cancer diagnosis. Among those with a family history of breast cancer, 51 women (13%) had a first-degree member with breast cancer, and 11 of them (22%) reported having at least two members with breast cancer diagnosis (Table 2).

According to the normality test, the five-year and lifetime risk scores were non-normally distributed (P=0.005). The calculated median for the 5-year BC risk was 0.8, while the median for the lifetime risk was 9.2. Thirty-eight women (7.6%) and 12 (2.4%) were categorized as having a high risk of developing BC in five-year and a lifetime, respectively. Only nine individuals (1.8%) showed high risks of BC incidence in both five-year and lifetime frames. Besides the factors included in GM, family history with ovarian cancer and menopausal age showed a significant association with the five-year BC risk (Table 3).

Multinomial logistic regression was conducted to examine the potential risk factors and determine the odds of developing BC in the next five years (Table 4). Table 5 compares the Gail model scores reported from women in different countries worldwide.

Table 2. Familial history of breast and ovarian cancers among the participants

Varibles		N (%)
Family history of breast cancer	No	402 (80.1)
	Yes	100 (19.9)
		1st degree (n=51)
		2nd degree (n=30)
		3rd degree (n=19)
Number of first degree women with breast cancer	One person	40 (78)
	Two persons	11 (22)
Family history with ovarian cancer	Zero	479 (95.4)
	First degree	7 (1.4)
	Second degree	8 (1.6)
	Third degree	8 (1.6)

Table 3. The association between the breast cancer risks and participants' variables

Varibles		Five-year risk			Lifetime risk		
		High risk (n= 38) N (%)	Low risk (n= 464) N (%)	P value	High risk (n= 12) N (%)	Low risk (n= 490) N (%)	P value
Place of living	Middle	28 (73.7)	280 (60.3)	0.1	10 (83.3)	298 (60.8)	0.14
	North	10 (26.3)	184 (39.7)		2 (16.7)	192 (39.2)	
Marital status	Single	0	32 (6.9)	0.16	0	32 (6.5)	1
	Married or divorsed	38 (100)	432 (93.1)		12 (100)	458 (93.5)	
Menopouse age	Active cycle	12 (31.6)	323 (69.6)	0.001*	8 (66.7)	327 (66.7)	0.85
	45≥	5 (13.2)	38 (8.2)		2 (16.7)	41 (8.4)	
	46 to 55	19 (50)	96 (20.7)		2 (16.7)	113 (23.1)	
	55<	1 (2.6)	4 (0.9)		0	5 (1)	
	Unknown	1 (2.6)	3 (0.6)		0	4 (0.8)	
Smoking status	No	30 (78.9)	390 (84.1)	0.4	10 (83.3)	410 (83.7)	1
	Yes	8 (21.1)	74 (15.9)		2 (16.7)	80 (16.3)	
Education status	Secondary school and less	14 (36.8)	174 (37.5)	1	3 (25)	185 (37.8)	0.55
	Diploma or more	24 (63.2)	290 (62.5)		9 (75)	305 (62.2)	
Family history with ovarian cancer	No cases	34 (89.5)	445 (95.9)	0.034*	11 (91.7)	468 (95.5)	0.27
	First degree	2 (5.3)	5 (1.1)		0	7 (1.4)	
	Second degree	2 (5.3)	6 (1.3)		1 (8.3)	7 (1.4)	
	Third degree	0	8 (1.7)		0	8 (1.6)	
Radiotherpay	No	37 (97.4)	442 (95.3)	1	11 (91.7)	468 (95.5)	0.43
	Yes	1 (2.6)	22 (4.7)		1 (8.3)	22 (4.5)	
Hormonal therapy	No	27 (71.1)	371 (80)	0.19	9 (75)	389 (79.4)	0.7
	Yes	11 (28.9)	93 (20)		3 (25)	101 (20.6)	
Physical activity	No	19 (50)	226 (48.7)	0.88	8 (66.7)	237 (48.4)	0.21
	Yes	19 (50)	238 (51.3)		4 (33.3)	253 (51.6)	
Diabetes mellitus	No	31 (81.6)	412 (88.8)	0.19	10 (83.3)	433 (88.4)	0.64
	Yes	(18.4)	52 (11.2)		2 (16.7)	57 (11.6)	
Hypertension	No	28 (73.7)	369 (97.5)	0.4	10 (83.3)	387 (79)	1
	Yes	10 (26.3)	95 (20.5)		2 (16.7)	103 (21)	
Hyperlipidemia	No	31 (81.6)	412 (88.8)	0.19	11 (94.7)	432 (88.2)	1
	Yes	7 (18.4)	52 (11.2)		1 (8.3)	58 (11.8)	
Hypothyroidism	No	36 (94.7)	422 (90.9)	0.56	12 (100)	446 (91)	0.61
	Yes	2 (5.3)	42 (9.1)		0	44 (9)	
Hyperthyroidism	No	37 (97.4)	455 (98.1)	0.55	12 (100)	480 (98)	1
	Yes	1 (2.6)	9 (1.9)		0	10 (2)	

*Satistically significant (P-value less than 0.05)

DISCUSSION

Breast cancer is the most prevalent form of cancer in Jordan, posing a significant threat to a considerable number of young women, as indicated by data from the Jordanian breast cancer registry.[2] Accurate assessment of the breast cancer risk is imperative for tailoring screening protocols and implementing preventive measures for high-risk groups. While several assessment models, primarily developed and applied in Western countries, address this need[5], the Gail Model (GM) stands out as one of the most widely used. However, there is a notable scarcity of studies evaluating the application of GM among women in the Middle East. In light of this, our study was undertaken to apply and validate a modified GM to assess breast cancer risks among Jordanian women.

Our findings indicate that Jordanian women exhibited lower scores than the standard scores of their counterparts worldwide. This discrepancy may be attributed to the heightened awareness of breast cancer risk factors in the Jordanian population. Surprisingly, a family history of breast cancer did not correlate with an increased risk of developing breast cancer in our study, potentially due to the limited

number of participants reporting first-degree relatives with breast cancer.

Conversely, the presence of ovarian cancers among family members was associated with an elevated risk of breast cancer. Consequently, incorporating this factor into the calculation of breast cancer risks using GM may yield more precise results.

Moreover, our study revealed a substantial proportion of women with a high risk of breast cancer falling within the menstrual age group. This observation can be explained by the youthfulness of the majority of the Jordanian population, with most participants still below menopausal age.

Analysis of global data using the Gail Model, as depicted in Table 5, has been extensive. Our study found that the median 5-year breast cancer risk was 0.8, aligning closely with the results for Saudi and Egyptian women at 0.86 and 0.87, respectively. However, the lifetime risk was lower than that observed in other countries, such as Qatar and Iraq.

Despite its widespread use, the Gail Model has noteworthy limitations. It does not account for breast cancer occurrences among second- and third-degree relatives and may overestimate the risk in studies conducted outside the United States due to variations in breast cancer incidence rates and associated risk factors.[10,11]

Table 4. Logistic regreesion of the significant regression for five-year BC risk

Varibles		Odd ratio (95% confidience interval)	P-value
Menopouse age	Active cycle	Reference group	
	45≥	3.5 (1.2-10.6)	0.024*
	46 to 55	5.3 (2.5-11.4)	0.001*
	55<	6.7 (0.7-64.9)	0.1
	Unknown	9 (0.87-92.7)	0.07
Family history with ovarian cancer	No cases	Referenc group	
	First degree	5.2 (0.98-28)	0.53
	Second degree	4.4 (0.85-22.4)	0.08
	Third degree	------- [a]	

*Satistically significant (P-value less than 0.05)
[a]There are no cases in the subpopulation

Table 5. Reported Gail's breast cancer risk: global variations and comparisons

Study	Year	Country	Sample size	Age	5-year risk	Life-time risk
Seyednoori *et al.* [23]	2012	Iran	314	>35	0.8	9
Fikree *et al.* [17]	2013	Bahrain	300	>35	0.7	9.3
Erbil *et al.* [8]	2015	Turkey	231	>35	0.88	9.37
Mirghafourvand *et al.* [19]	2016	Iran	560	>35	0.6	8.9
Ewaid *et al.* [16]	2016	Iraq	250	>35	0.95	11.13
Bener *et al.* [14]	2017	Qatar	1488	>35	1.12	10.57
Hala Al Otaibi [13]	2017	Saudi Arabia	180	>35	0.87	9.6
Challa *et al.* [15]	2013	India	200	>35	-	7.8
Nickson *et al.* [20]	2.18	Australia	883	>40	0.88	-
Eadie *et al.* [7]	2013	UK	355	>46	1.5	9
Abdel-Razeq *et al.* [12]	2020	Jordan	1213	>35	0.54	3.42
Khazaee-Pool *et al.* [18]	2016	Iran	384	>35	1.61	11.71
Novotny *et al.* [21]	2006	Czech Republic	4598	>35	1.37	8.02
Park *et al.* [22]	2013	Korea	3789	<50	0.44	2.24
Our study	2020	Jordan	515	>35	0.8	9.2

CONCLUSION

As breast cancer represents a major health challenge for women in Jordan, women should be encouraged to perform regular surveillance for early breast cancer detection. Applying Gail model by health care providers can identify women with higher risk of breast cancer, manage their referrals to screening units and offer suitable chemoprevention measures.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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ETHICAL CONSIDERATIONS

This study was approved by the institutional review board committee at the Hashemite University.

DATA AVAILABILITY

The data used in our study are available from the corresponding author upon request.

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