

**ORIGINAL ARTICLE** 

### Alexandria University Faculty of Medicine

## Alexandria Journal of Medicine





# Breast cancer risk assessment by Gail Model in women of Baghdad



## Salam Hussein Ewaid<sup>a,\*</sup>, Luma Hussein Ali Al-Azzawi<sup>b</sup>

<sup>a</sup> Technical Institute of Shatra, Southern Technical University, Iraq <sup>b</sup> College of Health and Medical Technology, Middle Technical University, Iraq

Received 27 May 2016; accepted 5 September 2016 Available online 22 September 2016

<ul> <li>assessment can help healthcare providers in Iraq to estimate an individual's probability of developing BC for screening and prevention.</li> <li>© 2016 Alexandria University Faculty of Medicine. Production and hosting by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).</li> </ul>	KEYWO Breast c Gail Mo Iraq	ancer risk;	© 2016 Alexandria University Faculty of Medicine. Production and hosting by Elsevier B.V. This is an
--	--------------------------------------	-------------	--

#### 1. Introduction

Breast cancer (BC) is the most common cancer and the main cause of cancer mortality among women in the world and there was a sharp rise in BC worldwide, and in 2012, 1.7 million women were diagnosed with BC and 6.3 million women alive

E-mail addresses: salamalhelali@yahoo.com (S.H. Ewaid), luma.

who had been diagnosed in the previous five years in 140 of 184 countries.<sup>1,2</sup>.

Since 2008, the disease incidence has increased by more than 20%, while mortality has increased by 14% (522,000 deaths in 2012).<sup>3</sup>

Like many other developing countries, Iraq struggles with the growing burden of BC, the incidence in Iraqi women increased in the last two decades and the frequency rate shifted toward younger age, while lacking the healthcare infrastructure required to identify, diagnose, and treat the disease.<sup>4</sup> The cases in Iraqi women increased from 26.6/100,000 in 2000 to 31.5/100,000 in 2009.<sup>5</sup>

Peer review under responsibility of Alexandria University Faculty of Medicine.

\* Corresponding author.

http://dx.doi.org/10.1016/j.ajme.2016.09.001

hussein@yahoo.com (L.H.A. Al-Azzawi).

This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

<sup>2090-5068 © 2016</sup> Alexandria University Faculty of Medicine. Production and hosting by Elsevier B.V.

The age standardized incidence rate in Iraq is more than that in Iran, Saudi Arabia and Turkey and less than that in Jordan and Kuwait.<sup>3</sup>

Age, level of education, smoking, body mass index, low physical activity, type of food and family history of BC are important risk factors among Iraqi women.<sup>6,7</sup>

The increase of disease incidence in Iraq has multifactorial reasons, such as the lack of awareness to early detection, the rapid socioeconomic changes to westernized lifestyle including delayed childbirth, low birth numbers, null parity, reduced breastfeeding, weight gain, and increased consumption of animal fat.<sup>8,4,9–11</sup>

Latif et al. in their study<sup>12</sup> found that there was a significant increasing risk of BC with reducing periods of lactation, decreasing age at menarche, early age of marriage, early age of having first full term baby and family history.

As proposed by the World Health Organization, early detection and screening such as breast self-examination and mammography, especially when combined with adequate therapy, offer the most immediate hope for a reduction in mortality.<sup>2</sup>

Over the past two decades, a number of statistical models that predict the risk of BC have been designed to select high risk women for risk reduction strategies based on some risk factors that are associated with increased risk. There are two main types of models. The first type assesses the probability of BRCA mutations such as Claus model in which all predictions are only based on family history.<sup>13</sup>

The second type used risk factors of BC includes Gail model (GM) and its modified one (GM2) which calculates 5-year and lifetime invasive BCR.<sup>14</sup>

The GM is the most commonly used risk prediction model and has been well studied, validated and applied in various studies worldwide.<sup>15–17</sup>

Therefore the aim of the current study was to apply the GM2 to the Iraqi population and assess whether it can be used to assess the prediction of BC for the Iraqi women.

#### 2. Materials and methods

This is a cross-sectional descriptive field design study conducted at the College of Health and Medical Technology and the nearby Medical Technical Institute in the middle of Baghdad, where academic women and women living in the near districts were included. Necessary permissions were obtained from the deans of both the college and the institute and Baghdad Health Directorate. The purpose of the study was explained to each woman and those who refused to participate were excluded.

A total of 250 women in the ages of  $\ge$  35 years were included and data were collected between January and March 2016.

The questionnaire was used in this study based on the National Cancer Institute's online version of the Breast Cancer Risk Assessment Tool (BCRAT) also known as Gail Model available at (http://www.cancer.gov/bcrisktool/) which has questions about the five-year and lifetime BC risk based on age, age at menarche, age at first live birth, first degree relative numbers with BC, previous breast biopsies with or without atypical hyperplasia, BRCA mutations and woman race.<sup>18</sup> The questionnaire also had additional questions about socio-

demographic features such as education, occupation, family income, marital status, and husband education level.

Unknown BRCA mutations and the white race/ethnicity (Caucasian) variables were used for all the women in this study in estimating their risks.<sup>19</sup>

For five-year risk assessment, a rate of 1.7% or less was defined as low risk while a rate of 1.7% or more was defined as high risk.<sup>14,19</sup> Lifetime risks were classified as usual (<15%), moderate (15–30%), or strong (>30%).<sup>20,21</sup>

Descriptive statistics including the mean, standard deviation and percentage was used to analyze data.

#### 3. Results

The socio-demographic features studied showed that 74 (29.6%) of the women had completed primary, secondary or high schools and 176 (70.4%) had completed diploma, college or postgraduate studies, and of their husbands there were eighty (32%) completed diploma, college or postgraduate studies and 103 (41.1%) completed primary, secondary or high schools.

Eighty-seven (34.8%) were teaching staff and 52 (20.8%) housewives. There are 163 (65.2%) married, 58 (23.2%) unmarried, 7 (2.8%) divorced and 22 (8.8%) widow. About 112 (44.8%) of them had high level family income, 47 (18.8%) had middle level and 91 (36.4%) had low level income (Table 1).

The five-year and lifetime BCR variables studied showed that the mean age of women was  $45.46 \pm 9.2$  years (range 35–70 years) and that 136 (54.4%) of the participants had their menarche at the age of 12–13 years, 31 (12.4%) of women had their first live birth between the ages of 20–24 years and 51 (20.4%) between 25–29 years.

There were 23 (9.2%) of the participants reported having first degree relatives who had diagnosed with breast cancer. Only 4 (1.6%) women reported two first-degree relative with breast cancer, six (2.4%) had undergone one breast biopsy and 3 (1.2%) had more than one. Six of the participants reported having atypical hyperplasia (Table 2).

Based on the modified Gail model, the women in this study had a mean five years risk of  $0.952 \pm 0.84$  and a mean of lifetime risk of  $11.134 \pm 5.25$ . The minimum and maximum values were 0.3%, 7.1% and 3.7%, 39.6% for the five years and lifetime risks, respectively. In comparison with women of the same age and average risk factors, 19 (7.6%) had a higher five years risk and 6 (2.4%) had higher lifetime risk (Table 3).

#### 4. Discussion

As the incidence of BC is rising in Iraq, it is important to detect women with a high risk for early detection and prevention.

Mitchell Gail, a biostatistician, developed a mathematical model in 1989 to assess the risk of BCR based on the results from a large screening study that included 284,780 women who had been undergoing annual mammographic examination, and due to the proven reliability and validity of the Gail model, it was used in the present study.<sup>18</sup>

As shown in Table 4, there are many countries validated and used Gail model, and the five year BCR rate was determined as 18.1% among the USA women over the age of 40 in Mermer and Meseri study whereas it was 2.5% among the

Table 1 Socio-demographic information about the women included in the study, 35 years and over (N = 250).

Occupation	Marital status	Family income	Education level	Husband's edu. level
Teaching staff 87 (34.8%) Employees 72 (28.8%) Workers 4 (1.6%) Students 35 (14%) Housewives 52 (20.8%)	Married 163 (65.2%) Unmarried 58 (23.2%) Divorced 7 (2.8%) Widow 22 (8.8%)	Low 91 (36.4%) Middle 47 (18.8%) High 112 (44.8%)	Prim. school 34 (13.6%) Med. school 24 (9.6%) High School 16 (6.4%) Diploma 25 (10%) College 59 (23.6%) Higher study 92 (36.8%)	Prim. school 68 (27.2%) Med. school 21 (8.4%) High school 14 (5.6%) Diploma 33 (13.2%) College 23 (9.2%) Higher study 24 (9.6%)

**Table 2** Women risk factor values used in the BCRAT Tool in women, 35 years and over (N = 250).

Age	Age at menarche	Age at first live birth	No of first degree relatives with BC	Having a biopsy
35–44 years 144 (57.6%)	Unknown 16 (6.4%)	Not married 61 (24.4%)	One relative 23 (9.2%)	One biopsy 6 (2.4%)
45–54 years 58 (23.2%) 55–64 years 27 (10.8%)	7–11 years 62 (24.8%) 12–13 years 136 (54.4%)	Unknown 22 (8.8%) No birth 19 (7.6%)	>One relative 4 (1.6%)	<ul><li>&gt; One biopsy 3 (1.2%)</li><li>6 had atypical</li><li>hyperplasia</li></ul>
≥65 years 21 (8.4%)	>14 years 36 (14.4%)	<20 years 44 (17.6%) 20-24 years 31 (12.4%) 25-29 years 51 (20.4%) ≥30 years 22 (8.8%)		

Table 3	Calculated	BCR	in	women,	35 years	and	over
(N = 250)							

Five years risk Number and percentage	Lifetime risk
Standard of Gail Model 1.02%	Standard of Gail Model 11.21%
Mean of five-year risk of all women $0.952 \pm 0.84$ Low risk (<1.7%) 231 (92.4%) High risk ( $\ge 1.7\%$ ) 19 (7.6%)	Mean risk of all women up to age 90 years 11.134 $\pm$ 5.25 Usual risk (<15%) 226 (90.4%) Moderate risk (15–30%) 18 (7.2%) High risk (>30%) 6 (2.4%)

women aged 35–60 in Abu-Rustum et al. study.<sup>22,23</sup> Panahi et al. in their study<sup>24</sup> found that the five year risk rate in Iranian women was 0.92% and the lifetime risk was 19.4%. Fikree and Hamadeh,<sup>25</sup> reported that the five year risk in Bahraini women was 0.7% and the lifetime risk was 9.3%. Erbil et al.<sup>16</sup> determined that the five year risk rate in Turkish women was 0.88% and the lifetime risk was 9.3%.

The mean estimated five years risk of 0.952% and lifetime BCR of 11.134% reported in this study are within the range in some other countries, comparable to other studies and provide information for future assessment of risks (Table 4).

The Gail model qualifies women of 35 years and older for BC prevention trial if they had five years risk of 1.7% or more. In this study, there were 19 women who had five years higher

Table 4	Comparison	the	BCR	values	with	some	world
studies.							

5 year BC risk	Lifetime BC risk	Country	Reference
0.9%	5.4-8.5%	USA	23
0.68%	-	USA	26
1.5%	8.4%	USA	27
0.92%	19.4%	Iran	24
0.7%	9.3%	Bahrain	25
0.9%	1.5%	England	15
0.76%	1.135%	Iran	28
0.37%	4.48%	Iran	29
1.51%	-	Bulgaria	17
0.88%	9.3%	Turkey	16
0.952%	11.134%	Iraq, Baghdad	This study
1.02%	11.21%	Gail M. Standard	18

risk; therefore, these women are eligible for BC prevention strategies.

The Iraqi Cancer Board statistics showed an increasing incidence of BC in the younger Iraqi women [ICB, 2010]. In this study, although the risk within five years and within the ninety years lifetime was lower than the standard of Gail model, those who had a Gail score of equal or more than 1.7% were regarded as high risk and recommended to have regular breast examinations, mammography,<sup>30,31</sup> chemoprevention<sup>32</sup> and even prophylactic mastectomy.<sup>31,30</sup>

#### 5. Conclusion and recommendation

Iraqi women should be given the chance to survey their risk of BC and give them direct screening strategies.

There are no studies in Iraq to date for assessing predictive breast cancer risk models, so efforts should be made to verify the usefulness of Gail model taking into consideration the early age appearance of the disease in Iraq and other local factors such as environmental pollution.

#### Limitation of the study

In Iraqi women, breast cancer is diagnosed in a relatively younger age and higher stage compared to their Western counterparts. The relationship between the environmental pollution and the possibility of ethnic differences might affect the applicability of the Gail model, so these factors must be studied well.

#### References

- Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M, et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. *Int J Cancer* 2014;2014. <u>http://dx.doi.org/10.1002/ijc.29210</u>, PMID: 25220842 published online 9 October.
- WHO. Media Centre: Cancer-Fact Sheet No. 297; 2015. < http:// www.who.int/mediacentre/factsheets/fs297/en/>.
- Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, et al. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC Cancer Base No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from <<u>http://globocan.iarc.fr</u>>.
- Alsamarai AM, Abdula SS. Breast cancer frequency rate shift toward younger age in Iraq. *IJSRSET* 2015;1(5).
- Iraqi Cancer Board (ICB). Results of the Iraqi Cancer Registry 2010. Baghdad: Iraqi Cancer Registry Center, Ministry of Health; 2010.
- Zangana AM, Garota SA. Risk factors of breast cancer in a sample of Kurdish women of Kurdistan Region-Iraq: a comparative study between pre-menopausal and post-menopausal women. *Zanco J Med Sci* 2012;16(3).
- Lafta RK, Saeed EQ, Isa SA. Risk factors of breast cancer among women (A Sample from Baghdad). *Iraqi J Commun Med* 2013(1), Jan. 2013.
- Salim E, Moore MA, Bener A, Habib OS, Seif-Eldin IA, Sobue T. Cancer epidemiology in South-West Asia – Past, Present and Future. *Asian Pacific J Cancer Prevent* 2009(10), 2009.
- Alwan N. Breast cancer: demographic characteristics and clinicopathological presentation of patients in Iraq. *EMHJ* 2010;16 (11.16):1159–64.
- Al-Hashimy M, Wang X. Breast cancer in Iraq, incidence trends from 2000–2009 Asian Pac. J Cancer Prev 2014;15(1):281–6.
- 11.. Hussain RA, Habib OS. Incidence of cancer in Basrah: results of a household survey. *APJCP* 2015, 2015.16.1.163.
- Latif SM, Baqer HH, Habib KD. Study of risk factors for breast cancer in a hundred breast cancer patients. *Iraqi Postg Med J* 2009;8(4):200.
- Amir E, Freedman OC, Seruga B, Evans DG. Assessing women at high risk of breast cancer: review of risk assessment models. J Natl Cancer Inst 2010;102:1–12.

- Bevers TB, Anderson BO, Bonaccio E, et al. NCCN clinical practice guidelines in oncology: breast cancer screening and diagnosis. J Natl Compr Canc Netw 2009;7:1060–96.
- Eadie L, Enfield L, Taylor P, Michell M, Gibson A. Breast cancer risk scores in a standard screening population. *Breast Cancer Manage* 2013;2(6):1–17.
- Erbil N, Dundar N, Inan C, Bolukbas N. Breast cancer risk assessment using the Gail model: a Turkish study. *APJCP* 2015, 2015.16.1.303.
- 17. Baytchev G, Inkov I, Kyuchukov N, Zlateva E. Breast cancer risk evaluation a correlation between mammographic density and the Gail model. *I J Surgery Med* 2015;1(1):18–21.
- Gail M, Brinton L, Byar D, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. J Natl Cancer Inst 1989;81:1879–86.
- 19. De La Cruz P, Brittingham A. *The Arab population: 2000.* Washington, DC: US Census Bureau; 2003.
- 20. Ulusoy C, Kepenekci I, Köse K, et al. Applicability of the Gail model for breast cancer risk assessment in Turkish female population and evaluation of breastfeeding as a risk factor. *Breast Cancer Res Treat* 2010;**120**:419–24.
- 21. Quillin JM, Fries E, McClish D, et al. Gail Model risk assessment and risk perceptions. *J Behav Med* 2004;27:205–14.
- Mermer G, Meseri R. Evaluation of breast cancer risk status of women aged 40 and above, living in Kemalpasa District, Izmir. *STED J* 2011;20:51–6.
- 23. Abu-Rustum NR, Herbolsheimer H. Breast cancer risk assessment in indigent women at a public hospita. *Gynecol Oncol* 2001;**81**:287–90.
- 24. Panahi G, Shabahang H, Sahebghalam H. Breast cancer risk assessment in Iranian women by Gail model. *MJIRI* 2008;22 (1):37–9.
- 25. Fikree M, Hamadeh R. Breast cancer risk assessment among Bahraini Women. *Bahrain Med Bull* 2013;35(1).
- Miller BE. Breast cancer risk assessment in patients seen in a gynecologic oncology clinic. Int J Gynecol Cancer 2002;12 (4):389–93.
- Davids SS, Schapira MM, McAuliffe TL, et al. Predictors of pessimistic breast cancer risk perception in a primary care population. J Gen Intern Med 2004;19(4):310–5.
- 28. Omranipoura R, Karbakhsh M, Behforouz A, Neishabouryc M, Mahmoodzade H, Koma K Bagher, et al. Performance of the Gail model for breast cancer risk assessment in Iranian Women. *Arch Breast Cancer* 2015;2(1):27–31.
- 29. Mohammadbeigi A, Mohammadsalehi N, Valizadeh R, Momtaheni Z, Mokhtari M, Ansari H. Lifetime and 5 years risk of breast cancer and attributable risk factor according to Gail model in Iranian women. *J Pharm Bioall Sci* 2015;7:207–11.
- Olopade OI, Artioli G. Efficey of risk-reducing salpingooophorectomy in women with BRCA-1 and BRCA-2 mutations. *Breast J* 2004;10(1):S5–9.
- Tierney LM, McPhee SJ, Papadakis MA. Current medical diagnosis and treatment. 44th ed. New York: McGraw-Hill; 2005. p. 682–4.
- **32.** Rockhill B, Spiegelman D, Byrne C, et al. Validation of the Gail et al. Model of breast cancer risk prediction and implications for chemoprevention. *J Natl Cancer Inst* 2001;**93**(5):358–66.