

EVALUATION OF GAIL MODEL FOR BREAST CANCER RISK AND ITS ASSOCIATION WITH BI-RADS CLASSIFICATION

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ABSTRACT

Introduction: Most cases of breast cancer occur in women. It has a 1.4 million yearly worldwide incidence rate, making it the second most prevalent malignancy in women behind lung cancer. The study's objective is to determine if utilising GM5 to predict breast cancer risk in Iraqi women and its relationship to Birad category is practical. **Method:** The September–November 2022 cross-sectional research recruited 100 breast clinic women at AL-Yarmouk Teaching Hospital. convenience sampling. The ladies verbally agreed. A questionnaire based on the National Cancer Institute's online Breast Cancer Risk Assessment Tool (BCRAT), also known as Gail Model, and women's sociodemographic characteristics collected the data. All patients provide marital status, female education level, employment, residence, past breast disease, chest radiation, first-degree relative, biopsy, clinical breast examination, and hormone replacement treatment times. **Results:** A majority of them have never had breast disease, 100% have never been exposed to breast radiation, 23% have one first-degree relative, 2% and 3%, respectively, have positive clinical breast examination and biopsy results, and 85% have never received hormone therapy. The average age is 51 years and 8 months, and 93% of women are married, 49% are in primary school, and 79% are housewives. 81% of women are at low risk for breast cancer, compared to 19 women (19%) who have a high risk. Risks of GS5 breast cancer are significantly correlated with MAMMO (Birad category). **Conclusion:** Five-year breast cancer risk for women is moderate. High-risk five-year breast cancer chances are (2.5 0.76) and low-risk five-year risks are (1.046 0.36). All B4 (Birad category) women have good GS5 scores.

KEYWORDS: Evaluation, Gail Model, Breast Cancer, Risk, BI-RADS classification.

INTRODUCTION

Breast cancer (BC) is the female malignancy with the greatest incidence rate. With a worldwide incidence rate of roughly 1.4 million cases per year, it is the second most common cancer in women after lung cancer and accounts for about 25% of all instances of female cancer. This is something that individuals might perhaps go through, although it's not particularly common. Industrialized countries experience this sickness more often than less developed ones do (IARC, 2010). In many post-industrial countries, the incidence rate is rapidly increasing as a consequence of changes in Western society.^[1] Out of 721 women who underwent breast cancer screening at Iraq's early detection facility in 2010, 143 breast cancer occurrences were discovered. About half of participants in a 2012 survey that examined breast cancer knowledge, attitudes, and

behaviours among educated women had poor knowledge scores for this disease (less than 50%), despite the fact that 90.6% of women first discover these bumps on their own. Just 43% of individuals actually completed a breast self-examination (BSE), despite the fact that 90% of participants had access to information about it.^[2,3] In BC, risk factors including the Gail model (GM) and the modified Gail model (GM5) are used to estimate lifetime^[4] risk as well as 5-year BCR, with GM being the most often used approach.^[5-7] Age, age at menarche, age at first live birth, number of breast biopsies, history of atypical hyperplasia, and number of relatives with breast cancer in the first degree are the six breast cancer risk variables included in the Gail model.^[8] The model calculates and publishes predicted lifetime and 5-year probabilities of developing invasive breast cancer, and it may be used to determine who is at higher risk.^[9] A category 4 BI-RADS nodule, for example, has a 2% to

95% probability of being malignant yet is worrisome enough to need biopsy due to the wide overlap in the sonographic appearance of benign and malignant nodules. Age of the patient should be taken into consideration when deciding whether or not to do a biopsy, according to prior studies. Several clinical conditions may also have an impact on the BI-RADS score.^[10] A accurate clinical evaluation of a person's risk is essential for successfully preventing BC. The Gail model is often used to evaluate BC risk.^[11] The chance of developing breast cancer may be influenced by things including reproductive history, socioeconomic status, lifestyle, and behaviour. Medical experts can calculate a person's chance of getting breast cancer using risk assessment tools. According to the most current recommendations, they will likely encourage patients to begin annual mammograms and clinical breast examinations after women turn 40.^[12] Mammograms are accurately and efficiently categorised by BI-RADS. diagnosing or screening a patient. For a patient with no symptoms and a typical primary care physician examination, a screening mammogram is recommended. If the patient has pain, a palpable lump, or discharge, they need to undergo a diagnostic mammogram. Radiologists are not necessary for screening mammograms.^[13,14] A BI-RADS 1 means there are no masses, alarming calcifications, or abnormal architectural features. BI-RADS 2 is risk-free. Benign conditions include straightforward cysts, fat-containing tumours, calcified fibroadenomas, implants, and intramammary lymph nodes. Shorter follow-up intervals are needed to evaluate stability in BI-RADS 3 since it is most likely benign. A non-palpable, constrained mass on a baseline mammogram, a localised asymmetry that lessens in density on spot compression images, or a single group of punctate calcifications are all required BI-RADS 3 findings. BI-RADS 4 could harbour cancer. A, B, and C are present in BI-RADS category 4. Malignancy rates range from 2% to 10% for subcategory (a). The malignancy rate in subcategory (b) ranges from 10% to 50%. Subcategory (c) has a malignancy rate of 50% to 95%.^[15] The purpose of the research is to determine if utilising GM5 to forecast breast cancer risk in Iraqi women who fall within the Birad group is practical.

METHOD

The data were gathered from 100 women who attended the breast clinic at AL-Yarmouk Teaching Hospital between September and November 2022. It is a cross-sectional design. The convenience sampling technique was used to choose the participants. The study's details were explained to the ladies, and they verbally agreed to participate. In addition to information about the women's sociodemographic factors, the data were gathered using a questionnaire form based on the online version of the Breast Cancer Risk Assessment Tool (BCRAT), commonly known as the Gail Model, from the National Cancer Institute. The following information is gathered from all patients: marital status, female educational level, occupation, residency, any prior chest radiation, first-degree relatives, any biopsies performed, prior clinical breast examinations, and periods of hormone replacement treatment. Participants had to be at least 40 years old, have no history of breast cancer, and not have seen any breast masses or other abnormalities. Age requirements of under 40 years old, Breastfed women protest and refuse to participate. A rate of 1.7% or less was considered to be low risk, whereas a rate of 1.7% or more was considered to be high risk. This scoring technique was used to determine the risk score.^[16-18] For categorical data, frequency and percentage are employed; for continuous data, mean, median, and SD are utilised. Chi-square is used to analyse the relationship between independent and dependent variables (risk) (demographic variables). P-values of 0.05 or less are regarded as significant.

RESULTS

Cross sectional study of 100 females with breast cancer, mean age 51 ± 8 years old, 93% of females are married, 49% of females in primary school and 79% are house wife, most of them 83% live in urban place, most of females have no previous breast disease, 100% of them also no previously exposure to breast radiation, 23% of females have one person's first degree relative, just (2%, 3%) of female's have positive clinical breast examination and positive biopsy respectively, most of females (85%) have no previously treated by hormonal replacement therapy. As show in table 1.

Table 1: distribution of patients according to study variables.

Variables		Frequency	Percentage
Marital state	Married	93	93.0
	Single	7	7.0
	illiterate	12	12.0
Education level	Primary school	49	49.0
	Secondary school	21	21.0
	University	18	18.0
	employer	20	20.0
Occupation	House wife	79	79.0
	Retired	1	1.0
Resident	City	83	83.0

	District	17	17.0
Breast disease	Fibro adenoma	1	1.0
	No	99	99.0
Chest radiation	No	100	100.0
First degree relative	-ve	71	71.0
	1	23	23.0
	>1	6	6.0
Biopsy	No	97	97.0
	Yes	3	3.0
CBE	-Ve	98	98.0
	+Ve	2	2.0
Times of hormonal R T (years)	0	85	85.0
	1-4	9	9.0
	≥ 5	6	6.0

According to fig 1, only 19 females (19%) have high five-year breast cancer risks, and 81% of females in low risk.

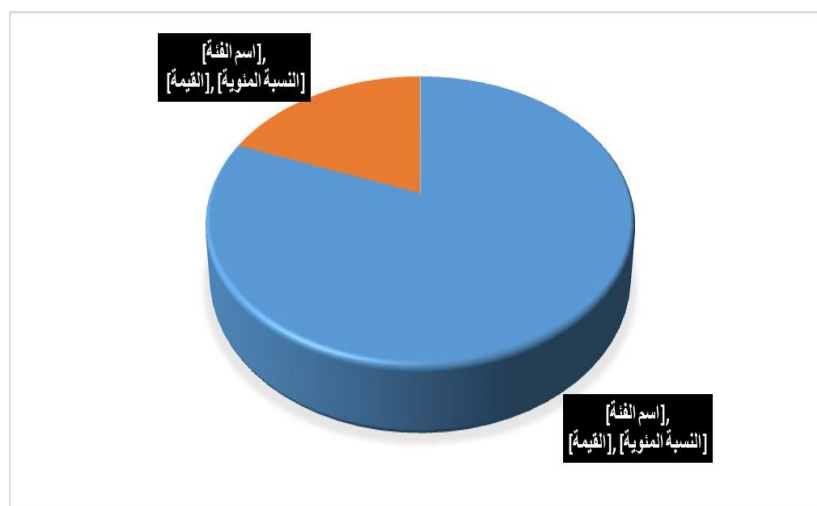


Fig. 1: Distribution of Patients According to Five-Year Breast Cancer Risks.

According to table 2, the mean of low risk of five-year breast cancer risks (1.046 ± 0.36) while high risk mean (2.5 ± 0.76).

Table 2: Mean, Sd, Min, Max And Percentage of Patients According to Five-Year Breast Cancer Risks.

GS5	N	Mean ± Std. D
low risk	81	1.046 ± 0.36
high risk	19	2.5 ± 0.76
Total	100	1.33 ± 0.75

There is significant association between GS5 breast cancer risks and MAMO (Birad category), 100% of females in B4 (Birad category) have high GS5, 75% of females in category B2 have low risk GS5, 84.1% of females classified as B1 (Birad category) have low risk GS5 and 100% of females in B0 category have low risk GS5 also. As show in table 3.

Table 3: association between GS5 breast cancer risks and MAMO (Birad category).

Mammogram (Birad category)	GS5		Total
	Low risk	High risk	
B0	5	0	5
	100.0%	0.0%	100.0%
B1	69	13	82
	84.1%	15.9%	100.0%
B2	6	2	8
	75.0%	25.0%	100.0%
B3	1	1	2
	50.0%	50.0%	100.0%
B4	0	3	3
	0.0%	100.0%	100.0%

P-value = 0.003 (significant).

DISCUSSION

Conducting prophylactic screenings among women at higher risk is essential given the growing prevalence of breast cancer in Iraq. Using information from a sizable screening survey of 284,780 women who had annual mammography screening, biostatistician Mitchell Gill developed a mathematical model to calculate the risk of

BCR. This model was employed in the present study because to its validity and reliability.^[19] Using the Gail model, we found that the average five-year risk of breast cancer for women was 1.33 0.75, whereas the average risk for those at low and high risk was 1.046 0.36 and 2.5 0.76, respectively. According to Nulufer et al., the five-year breast cancer risk for all women was 0.880.91% on average (0.28% range), and 7.4% of women had a risk of >1.66%.^[6] According to studies by Ceber et al.^[20] and Mermmer and Meseri^[21], women over the age of 40 have an 18% probability of acquiring breast cancer over the following five years, while women over the age of 50 have a 17% chance. Pan et al study's^[12, 22] showed that the risk of breast cancer increases with age. Women at greater risk should look into other screening methods, such as magnetic resonance imaging, and consider beginning their screening earlier and more regularly.^[23] Our study found that the average age of women was 51 8 years, that 93% of them were married, that 49% of them were enrolled in elementary school, and that 79% of them were stay-at-home moms. The majority of women, or 83%, also resided in urban areas, had no history of breast disease, had one first-degree relative, and only 2% to 3% of women had positive results from clinical breast exams and biopsies. The majority of women (85%) had not previously (range 35-77 years). 34.6% of the women had finished elementary education, 62.7% were stay-at-home moms, 97.4% received social security, 51.9% came from families with "middle-class" incomes, 96.1% were married, and 65.8% were city dwellers. 6.1% of participants said they had first-degree relatives who had breast cancer. 5.6% of participants had previously received a breast biopsy, and only four women (1.7%) reported having more than one first-degree relative with breast cancer.^[6] The women in this research had a mean five-year risk of (1.33 0.75), according to the modified Gail model. Over the five years, the lowest and highest numbers were 0.3% and 7.1%, respectively. Although 6.1% of women in the other study reported having a first-degree family member with breast cancer, only 4% of women reported having more than one such relative, 19 (7.6%) had a greater five-year risk compared to women of the same age and average risk variables. 7.4% of women, or 73% of first-degree relatives and 27% of second-degree relatives, had a family history of breast cancer, according to studies by Ceber et al.^[20,24] Despite the fact that the number, kind, and age of onset of affected relatives are crucial in determining the real risk, it has been shown that a family history of breast and/or ovarian cancer is associated with the biggest risk increase after correcting for age.^[25] Nevertheless, risk assessment models may help medical professionals identify a patient's prospective breast cancer risk. All women are advised to undergo a mammography every year after the age of 40.^[26] Women who have a greater chance of developing breast cancer should have extra screening done, such as beginning earlier in life or having more regular checkups. This idea is supported by data from several research by Bener et al.^[27] MAMO (Birad category) and GS5 breast cancer risk are

significantly correlated in the present research, with 100% of females in B4 (Birad category) having high GS5. This is comparable to another research that found that utilising the BI-RADS category alone had a considerably lower sensitivity than integrating the Gail model with it. The Gail model and the BI-RADS category together had a higher diagnosis accuracy than the Gail model alone.^[28]

CONCLUSION

The majority of women have modest five-year risks for breast cancer. Five-year breast cancer risk averages for low risk were 1.046 0.36 and 2.5 0.76, respectively. 100% of females in the Birad category B4 had high GS5 levels, and there is a strong correlation between GS5 breast cancer risks and MAMO (Birad category) risk.

REFERENCES

1. Veronesi, U.; Goldhirsch, A.; Orecchia, R.; Viale, G. and Boyle, P. Breast cancer. *Lancet*, 2005; 365: 1727–1741.
2. Alwan, N.A). Breast cancer: demographic characteristics and clinic-pathological presentation of patients in Iraq. *East Mediterr Health J.*, Nov., 2010b; 16(11): 1159-64.
3. 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.
4. 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.
5. 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.
6. Erbil, N., Dundar, N., Inan, C. & Bolukbas, N. Breast cancer risk assessment using the gail model: A turkish study. *Asian Pacific Journal of Cancer Prevention*, 2015; 16: 303–306.
7. 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.
8. Gail MH, Costantino JP, Pee D, et al. Projecting individualized absolute invasive breast cancer risk in African American women. *J Natl Cancer Inst.*, 2007; 99: 1782–92.
9. Bener A, Çatan F, El Ayoubi HR, Acar A, Ibrahim WH. Assessing breast cancer risk estimates based on the Gail Model and its predictors in Qatari women. *J Prim Care Community Health*, 2017; 8: 180–7.
10. Fan, L. et al. Breast cancer in China. *The Lancet Oncology*, 2014; 15.
11. Rajaram N, Mariapun S, Eriksson M, Tapia J, Kwan PY, Ho WK, Harun F, Rahmat K, Czene K, Taib NA, Hall P, Teo SH. Differences in mammographic density between Asian and Caucasian populations: a

- comparative analysis. *Breast Cancer Res Treat*, Jan, 2017; 161(2): 353-362.
12. Yilmaz M, Guler G, Bekar M, Guler N. Risk of breast cancer, health beliefs and screening behaviour among Turkish Academic women and housewives. *Asian Pac J Cancer Prev.*, 2011; 12: 817-22.
 13. Erbil, N., Dundar, N., Inan, C. & Bolukbas, N. Breast cancer risk assessment using the gail model: A turkish study. *Asian Pacific Journal of Cancer Prevention*, 2015; 16: 303-306.
 14. 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.
 15. Magny SJ, Shikhman R, Keppke AL. Breast Imaging Reporting and Data System. [Updated 2022 Aug 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK459169/>
 16. Sara OmranIssa1,2, Zainab H. Farhood1 , Zaman Subhi Madlool1. Assessment of Breast Cancer Risk by Gail Model in Women of Thi-Qar. *Medico Legal Update*, 2021; 21(1): 1273-1276. <https://doi.org/10.37506/mlu.v21i1.2494>
 17. 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.
 18. Ulusoy C, Kepenekci I, Koş se 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.
 19. Tierney LM, McPhee SJ, Papadakis MA. Current medical diagnosis and treatment. 44th ed. New York: McGraw-Hill., 2005; 682-4.
 20. Ceber E, Mermer G, OkCin F, et al. Breast cancer risk and early diagnosis applications in Turkish women aged 50 and over. *Asian Pac J Cancer Prev.*, 2013; 14: 5877-82.
 21. Mermer G, Meseri R. Evaluation of breast cancer risk status of women aged 40 and above, living in Kemalpaşa District, Izmir. *STED J.*, 2011; 20: 51-6.
 22. Pan Lei, Han Li-Li, Tao Li-Xin, et al. Clinical risk factor analysis for breast cancer: 568,000 subjects undergoing breast cancer screening in Beijing 2009. *Asian Pacific J Cancer Prev.*, 2013; 14: 5325-9.
 23. Açucena Vieira Alves S, Weller M. Breast Cancer Risk Perception and Mammography Screening Behavior of Women in Northeast Brazil. *Womens Health Rep (New Rochelle)*, Jun. 2, 2020; 1(1): 150-158.
 24. Hashim HT, Ramadhan MA, Theban KM, Bchara J, El-Abed-El-Rassoul A, Shah J. Assessment of breast cancer risk among Iraqi women in 2019. *BMC Womens Health*, Dec. 15, 2021; 21(1): 412.
 25. Koehly LM, Morris BA, Skapinsky K, Goergen A, Ludden A. Evaluation of the Families SHARE workbook: an educational tool outlining disease risk and healthy guidelines to reduce risk of heart disease, diabetes, breast cancer and colorectal cancer. *BMC Public Health*, Nov. 13, 2015; 15: 1120.
 26. Min JW, Chang MC, Lee HK, et al Korean breast cancer society. Validation of risk assessment models for predicting the incidence of breast cancer in Korean women. *J Breast Cancer*, 2014; 17: 226-35.
 27. Bener A, Çatan F, El Ayoubi HR, Acar A, Ibrahim WH. Assessing breast cancer risk estimates based on the Gail Model and its predictors in Qatari women. *J Prim Care Community Health*, 2017; 8: 180-7.
 28. Gao, L-Y, Ran, H-T, Deng, Y-B, et al. Gail model and Fifth Edition of Ultrasound BI-RADS help predict axillary lymph node metastasis in breast cancer—A multicenter prospective study. *Asia-Pac J Clin Oncol*, 2022; 00: 1- 9.