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Estimating the Risk for Development of Breast Cancer using Gail Model

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Abstract: ***Background: Breast Cancer (BC) is the most recurrent malignancy in women worldwide and is curable in 70 - 80% of patients with early - stage and it is non - metastatic disease. The study's goal is to examine and forecast the Gail Model effectiveness for the data sets. We applied the Gail Model retroactively using the records of individuals with breast cancer and benign breast illness. Gail et. al model is considered as one of the finest tool to estimate women's risk of developing breast cancer and are useful in directing, screening and prevention efforts. Materials and Methods: Data were acquired from 115 women using a descriptive and Cross - Sectional technique. The National Cancer Institute's online version of the Breast Cancer Risk Assessment Tool (BCRAT) or the Gail Risk Assessment Tool was used to calculate the risk of breast cancer. BC predictors were identified using general linear modelling. Statistical Analysis: The data set was analysed using SPSS 23. Result: The average age of woman affected by breast cancer is 1.37 ± 1.09 years with the mean of the 5 - year risk for BC is1.3%±0.85. Meanwhile, the mean of the lifetime risks for BC is 9.9%±5.5, respectively. The majority of women being between the ages at menarche is 12 - 13 years (33%).40.9% of women experienced their first live birth between the ages of 20 - 24 years.54.8% of women had reported that zero first degree relatives are affected with BC.26 women reported more than one first - degree relative with BC (22.6%). Conclusion: The current study added to our understanding of the risk variables for five - year and lifetime invasive breast cancer in women.***

Keywords: Gail Model (GM), Breast Cancer (BC), Risk assessment, Risk factors.

1. Introduction

Cancer is an abnormal growth of body cells and each one of us in this world is born with potential for cancer. Cancer is not an overnight disease and one cannot catch it as the form of infection or cold. The development of abnormal cells or unpatterns cells known as cancer cells occur when a collection of cells is harmed, disrupted, or grows to a billionth of its original size. The cells start to grow out of control and continue to grow and new abnormal cells like a chain reaction. In cancer cells the damaged DNA, is not repaired and goes on making new cells that the body does not need. The terms such as "neoplasm" and "malignant tumour" are also used to describe cancer. In a multistage process that often moves from a precancerous lesion to a malignant tumour, normal cells are changed into human cells. These modifications bring about interplay between a person's genetic factors and three categories of outside stimuli, such as physical carcinogens, chemical carcinogens, and biological carcinogens.

Alarming new estimates show that there will be approximately 10 million cancer deaths in 2022, compared to 609, 360 in 2020, and that there will also likely be 1.9 million newly diagnosed cases. There are numerous varieties of cancer. There are 7 malignancies in total that might be generally linked to lifestyle choice. The main types of cancer are

- Breast cancer (2.26 million cases and 685, 000 deaths in 2020)
- Lung cancer (2.21 million cases and 1.8 million deaths)
- Colon and rectum cancer, including bowel cancer (1.93 million cases and 935, 000 deaths)
- Stomach cancer (1.09 million cases and 769, 000 deaths)
- Liver cancer (906, 000 cases and 830, 000 deaths)
- Prostate cancer (1.41 million cases and 375, 000 deaths)
- Skin cancer (non - melanoma) (1.20 million cases and 57, 000 deaths)

In India, among the many frequent malignancies, BC is by far the most common malignancy, as shown by the aforementioned.

Breast Cancer

Breast cancer is the most often diagnosed cancer among all other forms, and it affects women globally in both developed and developing nations. According to latest data (2019), this disease claims 1 woman's life every 2 minutes. Among women certain breast cells start to develop erratically, which leads to breast cancer. These cells continue to grow and divide more quickly than healthy cells, generating a bulk or lump. The cells have the potential to expand (metastasize) to the lymph nodes or other bodily regions. Breast cancer typically starts in cells found in the milk - producing ducts (invasive ductal carcinoma), the glandular tissue known as lobules (invasive lobular carcinoma), or other cells or tissues within the breast. The risk of breast cancer has been linked to hormonal, behavioural, and environmental factors, according to research. Yet, it is unclear why some women with no risk factors for the disease experience cancer while others with risk factors do not. It is believed that a complicated interplay between a person's genetic make - up and environmental circumstances leads to breast cancer.

According to studies, India is seen more than 170, 000 additional instances of BC by 2020. Research indicates that the condition will likely impact 1 in every 28 womenis getting affectedby the disease. While men are prone to develop breast cancer at a rate of 1 - 2%, women account for the majority of cases. The most frequent cancer in women, with high rates of morbidity and mortality is breast cancer. Recognizing high - risk women for breast cancer and

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calculating an individual's absolute risk of developing it, various mathematical and statistical models are developed in order to assess the risk among the affected.

Stages of Breast Cancer

Breast cancer is classified into five stages: stage 0 (zero), which refers to non - invasive ductal carcinoma in situ (DCIS), and stages I through IV (1–4), which refer to invasive breast cancer. The stage provides a standard manner for clinicians to describe the cancer so that they can collaborate to determine the best treatments.

Stage 0 this is the very beginning of the scale. It refers to non-invasive breast cancers or precancers. This includes the most prevalent type of non-invasive cancer, ductal carcinoma in situ (DCIS). There is no evidence that cancer cells or other abnormal cells have invaded neighbouring normal tissue within stage 0.

Stage I Breast cancer is classified as invasive when it has spread to attack healthy tissue. This is divided into two sections.
IA the cancer has progressed into the fatty breast tissue. The tumour itself is scarcely larger than a shelled peanut, and there may be no tumour at all.
IB indicates that some cancer cells, albeit in trace numbers, have been identified in a few lymph nodes.

Stage II Cancer has either grown or spread.
IIA indicates that the breast tumour is still tiny, if present at all. There may or may not be cancer in the lymph nodes.
IIB breast tumours are larger and can be the size of a walnut or a lime. It could be in a lymph node or not.

Stage III Although the cancer has not progressed to the bones or organs, it is considered advanced and more difficult to treat.
IIIA cancer has been discovered in up to nine lymph nodes that go from your underarm to your collarbone.
IIIB Even if the cancer has not migrated to the lymph nodes, it has grown into the chest wall or the skin around your breast.
IIIC cancer has been detected in ten or more lymph nodes, or it has migrated above or below your collarbone. Outside the breast, fewer lymph nodes are damaged, but those within it are swollen or malignant.

Stage IV Breast cancer cells have migrated far beyond the breast and the lymph nodes that surround it. The bones, lungs, liver, and brain are the most commonly affected organs. This stage is known as "metastatic," who means that the cancer has moved beyond the region of the body where it was first discovered.

High risk levels are essential when deciding on prevention and screening measures. To estimate a woman's risk of developing breast cancer, a wide range of empirical and mathematical risk assessment models based on personal and familial risk factors have been developed. The Breast Cancer Risk Assessment Tool (BCRAT), Tyrer - Cuzick, Claus and Ford models, BOACICEA, and BRCAPRO are all well - established risk assessment models for quantifying breast cancer risk. However, because these models are based on different aspects of a woman's personal and familial history, they are not equally well calibrated for all populations. The most popular assessment technique for determining the absolute risk of getting breast cancer was the Breast Cancer Risk Assessment Tool (BCRAT), often known as the Gail model. High risk individuals were those whose 5 - year risk was more than 1.67%. Only first - degree relatives are included in the GM, which has the primary drawback of underestimating risk in 50% of families.

Several models, such the Claus model, which was created to evaluate familial risk of breast cancer from a case - control study conducted by the Centre’s for Disease Control, were employed in other investigations. The BRCAPRO model was created by Parmigiani and colleagues, which focused primarily on genetic factors when determining the likelihood that a family will carry a BRCA 1 or BRCA 2 mutation. The Tyrer - Cuzick model, which was utilised as an alternative to the GM for eligibility for the International Breast Intervention Study (IBIS - 1), is the only model that takes into account numerous epigenetic elements and a thorough family history for assessing risk.

The Gail Model has undergone extensive research and has been utilised in several studies, making it the most widely used risk prediction model. In this instance, we'd like to apply the Gail Modelfor the available data sets and can be used to forecast BC. From the age of screening to the conclusion of the follow - up at 5 years and 10 years, respectively, the absolute risks for each individual woman over the next five and ten years were estimated.

2. Review of Literature

Some studies have evaluated the applicability of the Gail model in specific populations. In Brazil, the study by Lopes et al. (2014) underestimated the risk of breast cancer, as only 51 (48.57%) of the women who already had breast cancer were identified as high - risk. The same result was found in another Brazilian study conducted by Crusoé et al., (2015), in which a case–control design was used and the mean five - year Gail risk score was higher in the control group than the case group. In India, the studies conducted by Challa et al., (2013), and Thomas et al., (2016), both case–control, underestimated the risk within five years of developing

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breast cancer. The same occurred in Iran in the studies by Omranipour et al., (2015) and Farahmand et al., (2017), which underestimated the risk in women with the disease and found no significant between - group difference in the risk factors evaluated by the model. In contrast, in Mexico, a cohort study conducted by Garza - Gangemi et al., (2014) validated the tool, demonstrating that the percentage of women assessed as high risk within up to five years was in agreement with the total number of women diagnosed with breast cancer in the period. A similar result was found in a study conducted by Clavelle et al., (2015) in the United States on a population of homosexual and heterosexual women, as a high risk was found for this population, making the model viable to be routinely used in the clinical setting.

The study conducted by Ansari et al., (2018) in 260 Iranian women evaluated socioeconomic and reproductive factors, correlating them with the estimated risk of breast cancer using the Gail model. The same was observed in Korea in the study conducted by Park et al., (2013) in a set of 3, 789 cases and controls, where they evaluated the performance of the Gail model in the population and developed a breast cancer risk assessment tool (KoBCRAT) based on equations developed for the Gail model for predicting the risk of breast cancer from the identification of risk factors among Korean women. Thus, the study concluded that KoBCRAT is a better tool to predict the risk of breast cancer in Korean women compared to the Gail model.
A similar study was conducted in Spanish women by Pastor - Barriso et al., (2013), which recalibrated the Gail model for the lower incidences of breast cancer and risk factors in the studied cohort. The Gail model was also evaluated in China in a study by Zhao et al., (2017), who compared it with the health risk assessment (HRA) model. A total of 3, 030 Chinese women were followed up, and the Gail model had a lower specificity than the HRA model, and the sensitivity of the Gail model was greater than that of the HRA model. The AUC and Youden index of the HRA model were more reliable than those of the Gail model. Based on this information, the study concluded that the HRA model is more appropriate for Chinese women than the classic risk assessment tool, the Gail model.

Another comparative study of the Gail model was performed by Shieh et al., (2018), who compared the risk estimates generated by the Breast Cancer Risk Assessment Tool (BCRAT) based on the Gail model, the Breast Cancer Surveillance Consortium model, and the Breast Cancer Surveillance Consortium model modified by the Polygenic Risk Score (BCSC - PRS) in a sample of 2, 060 participants. Although it was comparative, the study did not report the use of the Gail model as a validated tool in this, population but suggested that changes in variable inclusion could improve its applicability.

In a study conducted in Brazil, Clementino et al., (2013) compared the Gail model with the Claus, BRCAPRO, and BOADICEA models in estimating the risk of breast cancer and the probability of risk conferred by the BRCA 1/2 mutation, correlating the values found in the different models. The study concluded that the risk assessment models for breast cancer and for mutations showed good agreement in their predicted values, but it was recommended to include other risk factors in order to increase the accuracy of these models, given that in Brazil, the adaptation and validation of risk models for breast cancer are necessary.

The Gail model has been used to determine the clinical indication of chemoprevention based on the eligibility of women according to their breast cancer risk (Pruthy et al., 2015; Reimers et al., 2015; Vanegas et al., 2018; Green et al., 2014; Oseni et al., 2016). In turn, Pederson et al. (2018) compared the use of the Gail model and the Tyrer - Cuzick model to determine the risk of breast cancer and the implications for chemoprevention. The analysis showed that the Gail model is limited and should be applied cautiouslyto risk assessment or to counseling on the benefit of chemoprevention because it underestimated the risk in minority populations. The study concluded that dual modelling may be clinically useful in the formulation of chemopreventive recommendations. In some countries, the Gail model was not considered a good predictor for the calculation of breast cancer risk. Thus, some studies have suggested modifying the model for the specific population to improve its effectiveness.

GailModel

The Gail model is the most regularly used and well - known model for predicting the risk of breast cancer. It was designed in 1989 and updated in 1999. This model was created using data from the Breast Cancer Detection Demonstration Project (BCDDP), a screening trial that included over 300, 000 women aged 35 to 74 between 1973 and 1980. The improved version is known as the National Cancer Institute - Gail Model or the Breast Cancer Risk Assessment Tool (BCRAT). The modified model varies from the original model in that it only comprises invasive breast cancers, whereas the original version included both DCIS and invasive tumours. The amended version's age - specific incidence was calculated using data from the National Cancer Institute's surveillance, Epidemiology and End Results Program rather than the BCDDP, as in the original model.

This model focuses on non - genetic risk variables and incorporates limited information on breast cancer family history. The original and modified Gail models both use six input variables: age, hormonal or reproductive factors (age at menarche and first live birth), family history (number of first - degree female relatives with breast cancer), and previous history of breast disease (number and results of breast biopsy). It is widely and easily accessible online at http: //www.cancer. gov/bcrisktool/, and it assesses the risk of invasive breast cancer over the next five years as well as the lifetime risk of breast cancer through age 90. If the five - year risk is 1.66% or above, the NCCN recommendations recommend utilising the Gail Model to identify candidates for risk management, such as chemoprevention.

The Gail model has some drawbacks. It does not provide a precise risk estimate for women who already have specific illnesses, such as breast cancer. It is also not appropriate for women who have had previous chest wall irradiation treatment or who have known genetic abnormalities associated with breast cancer. The model cannot be applied to women under the age of 35. Another drawback is that the

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model only inquires about the number of first - degree relatives who have had breast cancer, rather than the age at which the illness was diagnosed. It also does not take into account a family history of breast cancer or the age at which breast cancer was diagnosed. It also does not take into account a paternal breast cancer history or a male breast cancer history. As a result, it may understate the risk in women with 2nd degree relatives who have breast cancer while overstating the risk in women who had a benign breast biopsy.

3. Material and Methods

3.1 Study Population

In the study, a descriptive methodology was applied to the selected population, which included women with diagnosed and treated breast cancer (n=115) and their respective first - degree female family members.

3.2 Data Analysis

After filling out online forms through site http: //www.cancer. gor/bcrisktool/, the 5 - year and lifetime risk of developing breast cancer were determined. The Statistical Package for Social Science (SPSS) programme for statistical analysis version 23 was used to analyse data. The mean, standard deviation, frequency, and percentages were used as descriptive statistics. The predictors of Breast Cancer risk were evaluated using analytical statistics like the general linear model. A p - value less than 0.05 were considered statistically significant. To control for confounders, variables with $p<0.05$ in bivariate tests were entered into a general linear model to determine breast cancer risk predictors.

Table 1: Applicability and ease of use of Risk Assessment Gail Model

Model	PersonalRisk Factors	Family History	Cancers Gender Included	Inclusiveness	Calculation Method	Data Entry
Risk of Breast Cancer						
Gail	Age, Age at menarche, Age at First Birth, Prior Breast Biopsy	1st degree relatives	Female Breast Cancer	Unaffected women	Webpage or CaGene5 Software	One - page Questionnaire

4. Results

According to the findings of the socio - demographic information, the age of the women ranged from 35 to 84 years, with the majority of women affected (34.8%) falling between the ages of 45 - 54 years. The average age of woman was 1.37 ± 1.09 years. The average age of participants at menarche age was 1.68 ± 0.969 years old, with the majority of women being between the ages of 12 - 13 years (33%).40.9% of women experienced their first live birth between the ages of 20 - 24years.54.8% of women had reported that zero first degree relatives are affected with breast cancer.26 women reported more than one first - degree relative with breast cancer (22.6%).72.2% of women had undergone previous breast biopsy. Participants did not report having atypical hyperplasia (Table 2). Our study also determined that the mean 5 - year breast cancer risk for all women was1.32 ± 3.91% (range 0.30 ± 4.20%) and the mean lifetime breast cancer risk up to age 90 years was 9.92 ± 5.56% (1.20 ± 12.60%) (Table 3)

Table 2: Frequency Distribution of Risk Assessment Characteristics (n=115)

Socio - demographic Characteristics of Women Risk Factors the BRCA Tool of women	n (%)
Age, mean ± SD (1.37 ± 1.09)	
Age (years)	
35 - 44	28 (24.3)
45 - 54	40 (34.8)
55 - 64	28 (24.3)
65 - 74	15 (13.0)
75 - 84	4 (3.5)
Age at menarche, mean ± SD (1.68 ± 0.969)	
Age at menarche (years)	
Unknown	14 (12.2)
7 - 11	36 (31.3)
12-13	38 (33.0)
>13	27 (23.5)
Age at first live birth, mean ± SD (2.60 ± 1.146)	
Age at first live birth (years)	
Unknown	8 (7.0)
No births	8 (7.0)
<20	31 (27.0)
20 - 24	47 (40.9)
25 - 29	17 (14.8)
>30	4 (3.5)
First degree relatives, mean ± SD (1.03 ± 0.694)	
First degree relatives with Breast Cancer	
Unknown	25 (21.7)
Zero relatives	63 (54.8)
One relative	26 (22.6)
More than one	1 (0.9)
Previous Breast Biopsy, mean ± SD (1.05 ± 0.527)	
Previous Breast Biopsy	
Unknown	13 (11.3)
Yes	83 (72.2)
No	19 (16.5)
>1 Breast Biopsy with a typical Hyperplasia, mean ± SD (0.21 ± 0.487)	
>1 Breast Biopsy with a typical Hyperplasia	
Unknown	95 (82.6)
No	16 (13.9)
Yes	4 (3.5)

Table 3: Mean Risk values Five - year Risk and Mean Risk values Life Time Breast Cancer Risk (n=115)

Risk	Mean	Standard Deviation	Minimum risk	Maximum risk
Five - year risk of participants	1.32	3.9	0.3	4.2
Average Five - year risk of participants	1.34	0.55	0.3	2.2
Life Time Breast Cancer Risk	9.92	5.56	1.2	33.5
Average Life Time Risk of participants	10.11	2.37	2.1	12.6

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Table 4: Regression Results for 5 - year and Lifetime Gail Risk

Independent Variables	CI 95%	Standard Error	t	p
5 - year risks				
Constant	- 0.416 (- 0.769 to 0.063)	0.178	-2.335	0.021
Age	0.376 (0.281 to 0.472)	0.048	7.829	0
First Menstrual Period	0.063 (- 0.058 to 0.185)	0.061	1.029	0.306
First Live Birth	0.023 (- 0.086 to 0.133)	0.055	0.422	0.674
First Degree Relatives	0.606 (0.445 to 0.767)	0.081	7.449	0
Previous Breast Biopsy	0.415 (0.206 to 0.624)	0.105	3.94	0
Lifetime risks				
Constant	5.385 (3.138 to 7.632)	1.134	4.75	0
Age	- 2.104 (- 2.710 to - 1.497)	0.306	-6.877	0
First Menstrual Period	0.666 (- 0.108 to 1.440)	0.39	1.705	0.091
First Live Birth	- 0.122 (- 0.821 to 0.576)	0.353	-0.347	0.729
First Degree Relatives	4.326 (3.300 to 5.351)	0.517	8.36	0
Previous Breast Biopsy	2.065 (0.737 to 3.393)	0.67	3.083	0.003

5 - Year Risk and Lifetime Risk of Developing Breast Cancer

The results reveal that the general linear regression model analysis predicts the 5 - year and lifetime risks of getting breast cancer in women aged 35 and older. The results suggest that the average probability of developing breast cancer in the next five years is 1.3% (standard deviation: 0.85%). Age, first menstrual period, first live birth, first degree relatives, and previous breast biopsy were all indicated as predictors of breast cancer in women for 5 - year risks. These variables predict 76.9% of the variance in the five - year risk. The overall risk of breast cancer was 9.9% (SD: 5.5%). According to multivariate linear regression analysis, the first menstrual period, first degree relatives, and previous breast biopsy were favourably correlated with lifetime breast cancer risk, but age and first live birth were negatively associated with lifetime risks. These variables predicted 78.3% of the variance in lifetime risk.

5. Discussion

In this study, we employed the BCRA technique to quantify risk for women. Using the Gail model, we discovered that the mean five - year breast cancer risk for all women was 1.33.90% (range 0.34.2%), with 5.5% of women having a risk more than 1.66%. Ceber et al. (2013) discovered a 5 - year breast cancer risk rate of 17.6% among women over the age of 50, whereas Mermer and Meseri (2011) discovered a risk rate of 18.1% among women over the age of 40. According to Pan et al. (2013), the risk of breast cancer rose with age, with OR1=2.759 (95%CI: 1.837 - 4.144, 56 - 60 vs 40 - 45), OR2=2.047 (95%CI: 1.394 - 3.077, 51 - 55 vs 40 - 45), and OR3=1.668 (95%CI: 1.145 - 2.431). Yilmaz et al. (2011) found that academic women had a greater risk of breast cancer than housewives, with both lifetime and five - year risks computed using the Gail model. Furthermore, for both academic women and housewives, the average lifetime and five - year risk was less than 15% for lifetime risk and 1.7% for five - year risk. (Yilmaz et al., 2011). In Seyednoori et al. 's study, this rate was 5.1% among women aged 35 - 81, and 2.5% among women aged 35 - 60 in Abu - Rustum and Herbolsheimer's study. (Abu – Rustum & Herbolsheimer, 2001; Mermer and Meseri, 2011; Seyednoori et al., 2012; Ceber et al., 2013). Women who experienced early menarche, had previously undergone a breast biopsy, and had their first live delivery after the age of 30 had a much greater risk of developing breast cancer. (2012) Chay et al. According to the findings of the current study, 52.4% of women gave birth to their first child between the ages of 20 and 24; 55.8% of women experienced menarche between the ages of 12 and 13; and 6.1% of study participants reported having first - degree relatives who had breast cancer. Four women alone (1.7%) reported having more than one first - degree relative who had breast cancer. There were no cases of atypical hyperplasia recorded.

We also discuss the limits of utilising the Gail model to assess breast cancer risk. There are certainly additional risk assessment models in use in clinical settings (reviewed in Domcheck et al., 2003 and Sakorafas et al., 2002). The Gail model is unique in that it uses multiple types of risk factors to assess risk (previous breast disease, family history of breast cancer, some hormonal risk factors, and race). Its primary limitations are that it only includes first - degree relatives with breast cancer and does not take their ages of diagnosis into account. As a result, it has been proposed that the Gail model is best suited for calculating breast cancer risk in the absence of a significant family history. Other risk models, such as the Claus model (Claus et al., 1994), or genetic risk estimating tools, such as BRCAPRO (Parmigiani et al., 1998), may be more suited in these cases. In our study sample, 28% had breast cancer in distant relatives (i. e., not first degree relatives). (data not shown).

To summarize, breast cancer remains a major health issue for women. We discovered that 7.4% of women had a five - year breast cancer risk of more than 1.66%. Breast cancer risk assessment can aid in the clinical treatment of patients seeking screening and preventative guidance. As a result, it is critical to emphasise the importance of healthcare practitioners' understanding of breast cancer risk factors, as well as the use of risk assessment methods to evaluate an individual's likelihood of acquiring this disease. There were some limitations to this investigation. The researchers only collected risk information from women at one institution, and the sample for this study was drawn at random. These are the limits of this study, and the findings can only be generalised to this sample.

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