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RESEARCH ARTICLE

ASSESSMENT OF BREAST CANCER RISK AMONG WOMEN USING THE GAIL MODEL, EGYPT.

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Abstract

The rationale of this study: breast cancer is an increasing global public health problem due to its high incidence and mortality. Lots of debates over the actual value of screening program at population level continue justifying, enthusiasm for risk-stratified screening is gaining momentum and can be useful for guiding public health strategies of breast cancer prevention. The Gail model is considered the best available means to quantify an individual woman's risk of developing BC and is crucial to provide risk-benefit analysis before deciding interventions designed to lower breast cancer risk.

Objectives: to identify the mean five years and lifetime risk development of breast cancer among Egyptian women.

Methods: cross sectional study conducted on a sample of 156 women attending family planning clinics using systematic random sampling technique. The instrument used is based on the information required for analysis by the Gail model.

Results: after analyzing the collected data according to the Gail Model, about 30% of the sampled females had high risk for developing BC >1.66% with their mean five-year breast cancer risk was 1.53 ± 1.49 , and their mean lifetime breast cancer risk up to age 90 years was 20.54 ± 11.86 .

Conclusions: our findings surges the need for BC screening services for early detection directed mainly for women with multiple risk factors making informed decisions about the screening methods best suited to their individual situations.

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Introduction:-

Although advances in early detection, diagnosis, and treatment, led to significant declines in breast cancer (BC) deaths yet it remains the most prevalent and the second leading cause of cancer deaths in females worldwide based on the findings from the WHO Global Health Estimates 2013⁽¹⁾. BC among Egyptian women, accounts for 18.9% of total cancer cases, according to findings from the Egyptian National Cancer Institute's (NCI),⁽²⁾ Incidence rates are steadily rising in the world. Between 2002 and 2020, breast cancer incidence and mortality are expected to rise 50%, with the greatest rise occurring in developing countries 19,20. With the steadily rising incidence rates, it is imperative to continue research, increase resource opportunities and raise global awareness of BC⁽³⁾.

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Egyptian BC patients showed a shift towards a younger age distribution affecting mainly 30–60 years of age. The mortality rate of BC is decreasing in developed countries, compared to the increasing mortality in the developing countries as people are diagnosed with BC in late advanced stages⁽⁴⁾. According to WHO, early detection is the cornerstone for BC control and it can improve its survival and is extremely important to reduce the burden on the health care system. There is growing interest in trying to estimate individual BC risk women and follow-up screening for “high-risk” individuals. This not only to improve early detection, but also to avoid many unnecessary inspections and reduce the burden on the economy if the women subgroup with higher risk can be adequately identified (5). Consequently, the accuracy of a woman's perception of her risk of developing BC has gained importance as a priority for primary prevention. “High-risk” individuals in BC can be identified by the risk assessment tool for women aged 35 and older⁽⁶⁾.

BC is one of the diseases predominantly influenced by risk factors, according to American cancer society, the reported risk factors of BC are being a female, ageism, race, ethnicity, younger age at menarche (before 12 years old), older age at menopause (55 years old), mutations in BC genes namely BRCA1 or BRCA2, history of BC in first degree relatives, having history of previous BC, some benign breast diseases, hyperplasia or lobular carcinoma in situ, exposure to huge dose of radiation at a young age, HRT, smoking, postmenopausal women, overweight or obesity, didn't breast feed their babies, and being physically inactivity⁽⁷⁾.

Several models were developed to assess the additive effect of multiple risk factors to estimate the overall risk. Gail model (GM) is commonly used BC risk assessment model and is used to assess the individual risk of BC. And estimating the probability of a currently healthy women having given risk factors will develop BC within 5 years and lifetime by developing a mathematical model that provides individualized risk estimates of developing BC with varying risk factors, including age, age at menarche, number of prior breast biopsies, age at first live birth, and number of first degree relatives affected with BC. Relative risk was calculated for each of these risk factors; then were used to calculate the absolute five years risk from the time of assessment and a lifetime risk up to 90 years old⁽⁸⁾.

The results of risk assessment can be used to develop an individualized plan to assist patients in decision-making regarding the implementation of frequent surveillance, chemoprevention, or prophylactic surgery⁽⁹⁾. In women aged ≥ 35 years with a 5-year risk of $\geq 1.67\%$, it is recommended to perform CBE biannually and mammography annually. It is crucial that among a population with increasing incidence and mortality, to monitor the risk of developing BC and take precautionary public health interventions. The purpose of this study is to utilize quantitative assessment to. Despite the fact that, there are a lot of up-to-date investigation equipment and screening projects directed for females, most of them are very expensive. Therefore, if the subgroup of specific high-risk females can be identified, unnecessary inspections avoided and burden on the economy reduced. It can also achieve the purpose of early detection and early treatment of BC. Those who are at high risk for BC (Gail score $\geq 1.67\%$) will benefit more from invasive approaches, while women who are categorized as low risk are followed-up through the routine screening program to avoid complications and high costs⁽¹⁰⁻¹¹⁾. When women are more knowledgeable about their personal risk, they can make informed decisions about prevention methods and screening options to detect cancer early. Women at higher risk should be educated on their need for higher screening methods such as magnetic resonance imaging, and initiating screening at an earlier age and at more frequently should be taken into consideration. Ultimately, planning and implementing early detection and screening programs of BC can be more successful⁽¹²⁾.

Hypothesis:- using the Gail model helps predict BC risk.

Objectives:-

- 1- To estimate the risk of developing breast cancer over next five years
- 2- To estimate the risk of developing breast cancer over lifetime periods

Methodology:-

Study design and setting: to fulfill the objectives of the study a cross sectional study conducted over 4-month period (from May to end of September 2016) on women attending the family planning outpatient clinic at Zagazig University Hospital.

Sampling technique and sample size:-

The participants considered eligible for the study if they met the following inclusion criteria: being able to read and write women, without a history of BC and being 35 years or older (as in the GM) as GM provides the five-year and

lifetime (up to age 90) BC potential risk for women ≥ 35 years. The exclusion criteria included women younger than 35 years, refused to participate, and those suffering of acute medical conditions. A sample size of 156 women was calculated using open epi program ⁽¹³⁾, based on the following parameters: 80% power of the test, 95% confidence interval, and 19%¹³, 450 monthly flow to the clinic, and prevalence from published literature ⁽²⁾. For data collection (three days per week) using a systematic random technique, where every third (450/156), attending the clinics included if she met the inclusion criteria. If did not meet the eligibility criteria, then the next (4th) was selected and so on till the required sample size was achieved.

The tool for data Collection:-

The assessment made using a self-administered questionnaire, the instrument used for data collection is the BC risk assessment tool using the model developed by Gail ⁽⁸⁾. The questionnaire formed of 2 parts, the first part about the socio-demographic characteristics: educational level, occupation status, place of residence and, marital status.

The second part included information about women's characteristic and risk factors related to breast cancer: age, age at first menstrual cycle whether (responses were: at least 14 years, 12 to 13 years, or fewer than 12 years), age at first childbirth (responses were: nulliparous, fewer than 20 years, 20 to 24 years, 25 to 29 years, or at least 30 years), and having a family history of BC (i.e., mother, sister) and their number. History of previous breast biopsy, those women had had any previous biopsy were asked about the number of biopsies (1, or 2), presence of atypical hyperplasia in a biopsy specimen (yes or no).

Questionnaire translation and Pilot testing:-

Using forwards- backwards translation process by two bilingual expert translators, then comparing the agreement (between the original English version and the back translation version) was done. The translated Arabic version of the questionnaire pilot tested on a sample of females before the actual commencement of the study to assess its face validity, its clarity and the time required for filling it up.

Statistical Methods:-

The collected data were analyzed by SPSS 24 ⁽¹⁴⁾ using descriptive statistics including the mean, standard deviation, frequency, and percentage. To estimate each woman's 5-year and lifetime risk for developing BC, calculated using the software program available from the NCI online ⁽⁸⁾. We used 1.66% in Gail score as a cut-off value to define low and high risk groups for developing BC according to the estimated BC five years risk assessment as women with the BC risk of $\geq 1.67\%$ were considered as high-risk ⁽¹⁵⁾.

Ethical considerations:-

Before collecting data, the entire required official permissions were obtained before carrying out the study. Participants were informed that their participation is voluntary and were informed about the objectives of the study and importance of the research and those who agree to participate signed an informed consent. The confidentiality of the collected information is assured through anonymity of the participant, the questionnaires were numerically coded and the study results would be used only for the purpose of research.

Results:-

Table 1: - Personal characteristics of the sampled females (n=156).

Variables	Categories	No.	Percent
Marital status			
	Not married	31	19.9
	Married	125	80.1
Educational level			
	Primary	12	7.7
	Secondary	56	35.9
	University	88	56.4
Employment state			
	Not Working	40	25.6
	Working	116	74.4
Family income			
	High	19	12.2
	Middle	107	68.6
	Low	30	19.2
Total		156	100.0

Our finding revealed the personal characteristics of the sample in table (1) as the majority of them were married, working, having middle income and are university graduates (80.1, 74.4, 68.6 and 56.4%) respectively.

Table 2:- Distribution of Risk Factors among Participants according to the Gail model.

Variables	Category	No	Percent
Age groups (y):			
	36- 45	92	59.0
	46-55	29	18.6
	≥55	35	22.4
Age at 1st menstrual period (y):			
	Unknown	13	8.4
	≥14	19	12.2
	12-13	84	53.8
	7- 11	40	25.6
Age at 1st child birth (y):			
	No children	8	5.1
	≤ 20	16	10.2
	20-24	93	59.7
	25-29	29	18.6
	≥30	11	6.4
Number of 1st degree relatives with breast cancer			
	Unknown	6	3.8
	Zero relative	33	21.2
	1 relative	72	46.2
	More than 1 relative	45	28.8
Biopsy			
	Unknown	0	0.0
	Yes	19	12.2
	No	137	87.8
TOTAL		156	100.0

On assessing women's risk factors among the study subjects the results showed that the majority of them (59.0%) aged from 36-45. 53.8% experienced their first menses at age 12 to 13; 59.7% of the sample women had first live birth in age group (20 - 24) years old, 46.2% of them had first degree relatives suffered from BC. Only 12.2 % of them performed breast biopsies. Table 2

Table 3:- Breast Cancer five-year Risk and life time Risk Based on the Gail Model.

Risk	X±SD	Minimum risk	Maximum risk
Mean five-year risk	1.53 ±1.49	0.3	10.80
Mean five-year risk for women of the same age without risk factors	0.91±0.44	0.3	1.80
Mean risk of participants up to age 90 years	20.54±11.86	6.8	91.6
Mean risk up to age 90 years for women of the same age without risk factors	12.65±9.14	9.10	95.0

Table 3 assessed the mean five-year BCR was 1.53 ±1.49 according to the GM, and The mean lifetime BCR up to age 90 years was 20.54±11.86. In comparison with women of the same age and average risk factors, 46 (29.6%) had a higher five years risk and 29 (18.7%) had higher lifetime risk (figure 1 and Table 3).

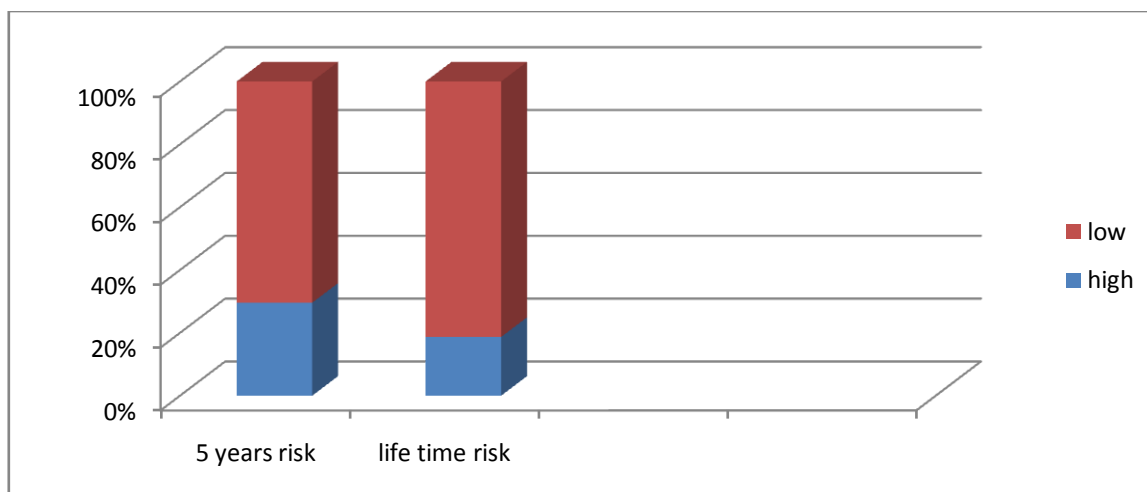


Figure 1:- comparing high and low 5 years and lifetime risk among the sampled female.

Discussion:-

Breast Cancer Risk Assessment (BCRA) is crucial when making decisions about screening for individual women with recommended intervals for screening mammography. Breast cancer risk was calculated using the National Cancer Institute's on-line BCRA Tool or the Gail Risk Assessment Tool developed by Gail, based on data from the BC Detection and Demonstration Project, a mammography screening project conducted on 280,000 women between 1973 and 1980. By applying the GM for the current study, the findings showed that about (30%) of the sample had a higher five years risk and about (19%) had a high lifetime risk. On the other hand, our findings are higher than other previously published researches⁽¹⁶⁻¹⁸⁾.

BC risk factors using the GM are as follows: current age, age of menarche, previous breast biopsies, including the number and presence of atypical hyperplasia, age of first live birth, family history of BC in first-degrees, and ethnicity⁽¹⁹⁾. The findings of the current study support the growing body of evidence from female breast cancer incidence suggesting that age is a well-known risk factor for BC susceptibility²⁴, as the findings revealed that the majority the sampled women (59%) were in age group 35-45 years old. The finding contradict with another 2 studies indicated the highest occurrence of female BC is shown in the age category of 45-50 years⁽²⁰⁾. A much higher risk for BC was found in women who had experienced early menarche, a previous breast biopsy, and a first live birth after 30 years of age⁽²¹⁾.

Regarding the age of the sample at first childbirth we found that the majority of them (59.7%) have their birth were in the age group from 20-24 years, this supported the long-standing hypothesis that the earliest age at first pregnancy and longer duration breastfeeding has a protective effect lower incidence of BC⁽²²⁾. Nulliparity and first live birth at older than 30 years of age are associated with an increased risk of subsequent breast cancer. Women who have never given birth or who have given birth to their first child after age 30 are at high risk for BC⁽²³⁾. Pregnancy at a young age is associated with a markedly reduced risk for BC⁽²⁴⁾.

In a previous study, after controlling for age, the greatest increase in risk has been associated with a family history of BC but the number, type, and age at onset in their relatives are important in estimating the magnitude of risk⁽²⁵⁾. Together with having family history in first-degree relative increasing the susceptibility to develop BC, where one first-degree relative could double the risk and having two first degree relatives increases the risk approximately 3-times. The findings in present study illustrated that 46.2% have one first degree relative this is even higher than findings of a study conducted in Alexandria, where the 20% of them had first degree cousins and nearly two thirds of the cancers which will appear in the next 25 years will occur due to unawareness of the public⁽²⁶⁾. Which surges the need for BC screening for early detection prior to the onset of symptoms through various methods as frequent monthly breast self examination, periodic clinical examination and mammogram and management of breast cancer to decrease the burden of morbidity and mortality associated with the disease⁽²⁷⁾.

Conclusion and Recommendations:-

The current study showed that about thirty percent of the sample had a higher five years risk and nineteen percent had higher lifetime risk.

1. Our findings surges the need for BC screening services for early detection directed mainly for women with multiple risk factors with health education on proper performance of monthly BSE, stress on the importance periodic clinical examination and mammography and making individualized informed decisions about the screening methods best suit them through individual counseling approach.
2. For clinicians , health providers and practitioners, incorporating risk assessment as part of routine clinical visits using the GM can supply women with accurate information about BC risk factors, consequently the appropriate prevention strategies and screening modalities can be tailored to each individual woman's risk profile to lower their risks.
3. For policy makers, they need to put an organized screening program on their agenda and develop national breast cancer screening guidelines.
4. Systematic screening and Early detection of breast cancer is improved by a follow-up screening for "high-risk" individuals. Therefore, it is important to define what is meant by "high-risk" individuals.
5. Women at higher risk should be educated on the their need for additional screening methods also consider initiating screening at an earlier age and at more frequently. When women are more knowledgeable about their personal risk, they can make informed decisions about prevention methods and screening options to detect cancer early.

Conflict of interest:- the author declared no conflict of interest.

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Ethical approval:-

"All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

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