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Prevalence of high-risk individuals for breast/ovarian cancer in a general Iranian female population using the International Breast Cancer Intervention Study (IBIS) risk calculation tool

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Abstract

Objectives: Various risk assessment tools have been developed to evaluate the risk of hereditary breast/ovarian cancer. This study aims to estimate the risk of breast/ovarian cancer in a sample of the general population in Iran using the IBIS software.

Methods: A total of 2020 women aged 18-79 years were consecutively selected from the gynecology clinic of Imam Hossein Medical Center between April 2019 and 2021. The Tyrer-Cusick (IBIS) questionnaire was used to collect data on variables such as age, BMI, age at menarche, age at first pregnancy, menopausal status, history of hormone replacement therapy (HRT), and family history of breast/ovarian cancer. The risks of developing breast/ovarian cancer were calculated, with patients having a calculated risk of more than 20% considered high-risk and those below 20% considered low-risk.

Results: Out of the 2020 cases studied, 69 (3.4%) were classified as high-risk for developing breast/ovarian cancer. The moderate risk of breast/ovarian cancer in patients with a positive family history was 18.47%, compared to 10.15% in those without a family history. All high-risk individuals had a positive family history, while only 9.4% of the low-risk population had a family history; this difference was statistically significant ($p<0.001$).

Conclusion: Routine assessment of family history of cancer in all patients is recommended, with positive cases being further evaluated using a cancer risk assessment tool and referred for genetic counseling as appropriate.

Keywords: Breast cancer, Ovarian cancer, Risk assessment tool, IBIS.

Introduction

Breast cancer accounted for 7.2% of all cancer deaths in the USA in 2021. Globally, approximately 3.4% of all female cancer cases and 4.7% of female cancer mortalities in 2020 were attributed to ovarian cancer. Late diagnosis is the primary reason behind the low survival rates of this malignancy.[1,2] The overall lifetime risk of ovarian cancer is approximately 1.3%, meaning 1 in 73 women are affected. Early-stage ovarian cancer boasts a five-year survival rate of about 93%.[3] A key risk factor for developing breast and ovarian cancer is a positive family history of these conditions.[4] The relationship between gene mutations and these malignancies can be elucidated by the observation of unconventional occurrences of mutations, such as BRCA1 and BRCA2, among females in regions with high prevalence rates of breast and ovarian cancer. These mutations are reported to be present in 0.2 to 0.3% of the general female population, while they are found in nearly 5 to 10% of breast cancer cases and 15% of ovarian cancer cases. Among patients with a positive family history of breast and ovarian cancer, 13.6% have the BRCA1 mutation, 7.9% have the BRCA2 mutation, and the

prevalence of having either mutation is 19.8%.[5-7] Having a family history of ovarian cancer in one first-degree relative increases the risk of developing ovarian cancer by 50%, while the risk is 10% in the case of breast cancer. Implementing an actual screening program based on ovarian/breast cancer development risk stratification can help identify at-risk patients, leading to early diagnosis, the implementation of prophylactic measures, and more cost-effective strategies.[8,9]

Various risk assessment tools have been developed to evaluate the risk of hereditary breast and ovarian cancer. Most of these tools incorporate genetic risk factors, such as family history and BRCA1/BRCA2 carrier status, as well as non-genetic risk factors like age, age at menarche, age at first birth, ethnicity, BMI, hormone replacement therapy, previous breast biopsies, and history of atypical hyperplasia.[10,11] Family history of breast and ovarian cancer is a crucial variable in all these tools, with a focus on gathering detailed information about the specific family history, the number and ages of family members affected, and instances of male breast cancer.[12,13]

One notable tool is BOADICEA (Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm), an online tool developed by Cambridge University for estimating the risk of breast and ovarian cancers. The Breast Cancer Risk Assessment Tool (BCRAT), based on the Gail Model and provided by the National Cancer Institute, calculates both 5-year and lifetime risks of cancer development by analyzing patients' medical and fertility records along with the family history of cancer in their first-degree relatives. The University of Rochester Ovarian Cancer Risk Assessment tool also determines the lifetime risk of cancer by considering factors such as age, height, gender, childbearing history, hormone therapy, menopausal status, and family history.[14,15]

Several other assessment tools, including the Ontario Family History Assessment Tool, Manchester Scoring System, Referral Screening Tool, Pedigree Assessment Tool, 7-Question Family History Screening Tool, International Breast Cancer Intervention Study instrument (Tyrer-Cusick or IBIS), and abbreviated versions of BRCAPRO have been evaluated by the US Preventive Services Task Force (USPSTF). While each tool has its own strengths and limitations, none were deemed to have sufficient evidence-based priority to warrant a specific recommendation according to the study's findings.[6,9,16]

Developed from the International Breast Cancer Intervention Study (IBIS) (http://www.ems-trials.org/riskevaluator/), the Tyrer–Cusick or IBIS risk calculator is one of the most comprehensive tools for assessing breast and ovarian cancer risk. This model takes all risk factors into account and balances them appropriately during risk evaluation.[17] It is one of the most commonly used cancer risk assessment tools and has been developed by the Wolfson Institute for predicting ovarian and breast cancer risk. Many researchers utilize this tool for cancer risk stratification and educating women at risk. The tool calculates both the 5-year risk of developing these cancers and the lifetime risk. It is easily accessible online, free of charge, and user-friendly for healthcare workers.[18] After comparing various tools for investigating the risk of these cancers in the general population, the Tyrer–Cuzick Model (IBIS) was chosen for the present study.

Objectives

The aim of this study is to estimate the risk of breast and ovarian cancer in the Iranian general population using the IBIS software. The goal is to facilitate timely and careful, user-friendly screening, early diagnosis, and more cost-effective treatment by focusing on high-risk individuals.

Methods

A total of 2,020 women who presented to the gynecology clinic of Imam Hossein Medical Center were consecutively enrolled in the study from April 2019 to 2021. This is a public hospital that primarily serves low to middle-income individuals. Women aged between 18 and 79 years were included in the study, while those with a personal history of cancer were excluded. Data on age, height, weight, age at menarche, age at first pregnancy, menopausal status, history of hormone replacement therapy (HRT), and family history of breast/ovarian cancer were collected and entered into the IBIS software for the assessment of breast/ovarian cancer risk.

The software is user-friendly and can be easily downloaded without the need for online completion. Data collection was performed by an individual who had undergone a 2-hour training session conducted by the researcher. The researcher directly supervised the completion of questionnaires for the initial 50 study participants. Following risk calculation, individuals with a calculated risk exceeding 20% were classified as high-risk and advised to seek genetic counseling. Those with a risk below 20% were considered low-risk.

During genetic counseling sessions, high-risk individuals were encouraged to undergo genetic testing for common

mutations associated with breast/ovarian cancers after a comprehensive history was obtained. Women who declined testing due to various reasons, including financial constraints, were provided with recommendations for non-invasive or invasive risk reduction procedures following consultation and approval from a geneticist.

Continuous variables were presented as mean±SD, while categorical variables were expressed as percentages. Data between the two groups were compared using the Chi-square and independent t-test. Statistical analyses were conducted using SPSS (version 16.0, SPSS Inc, Chicago, IL, USA). A significance level of $p < 0.05$ was considered statistically significant. In this study, grade 1 family members were defined as parents, siblings, and children, while grade 2 family members included aunts, uncles, cousins, paternal and maternal grandparents, nephews, nieces, and half-siblings.

The study adhered to the principles of the Helsinki Declaration and was approved by the Medical Ethics Review Board of Shahid Beheshti University of Medical Sciences (Code: IR.SBMU.MSP.REC.1398.457). Women's information was kept strictly confidential and reported in aggregate without disclosing individual names. Participants did not incur any costs, and the study protocol did not cause harm. Written informed consent was obtained from all participants, and they were fully informed about the study's details and purpose.

Results

The mean age of the study subjects was 39±12.9 years. Based on a calculated risk cut-off point of 20%, 69 cases (3.4%) were classified as high risk with a risk exceeding 20%, while the remaining 1951 cases (96.6%) were considered low risk for breast/ovarian cancer. Demographics and reproductive characteristics of low-risk and high-risk patients are summarized in Table 1.

A comparison of family history of breast/ovarian cancer between the two groups is presented in Table 2. The moderate risk of breast/ovarian cancer in patients with a positive family member involvement was 18.47%, compared to 10.15% in those without such involvement.

Among the 69 high-risk cases, only 4 (5.8%) had the financial means for BRCA genetic testing, both of which yielded positive results, leading to recommendations for prophylactic mastectomy/ oophorectomy. The remaining 65 high-risk patients declined genetic testing due to economic constraints. Among them, 14 opted for surgical risk reduction methods, while 22 chose a follow-up strategy involving transvaginal sonography and periodic examinations, with no malignancies detected during the follow-up period. Twenty-nine high-risk cases did not pursue genetic counseling and dropped out of the study.

All individuals with a cancer risk exceeding 20% had a positive family history, compared to only 9.4% in the low-risk population, a statistically significant difference ($p <0.001$) [Table 2]. Additionally, considering a cut-off point of 15%, 91% of the high-risk group had a positive family history, significantly higher than the low-risk group with only 3% positive family history ($p<0.001$). The average cancer risk was 18.47% in individuals with a positive family history and 10.15% in those without, with a statistically significant difference ($p<0.001$) [Table 2].

Table 1. Demographic and reproductive data in high-risk and low-risk groups (cut off=20%)

			Overall (n=2020)	
	High risk (n=69)	**Low risk** (n=1951)	Mean±SD	Range
Age, mean±SD	38.22±9.77	39.41±12.12	39.37±12.95	14-79
Menarche age, mean±SD	12.13±1.24	13.28±1.47	13.24±1.48	9-19
BMI, mean±SD	26.41±4.35	26.87±4.95	26.85±4.93	14.69-52.33
Age at first live birth, mean±SD	23.27±5.30	21.43±4.70	21.49±4.73	12-45
Menopause age, mean±SD	45.80±4.66	47.76±4.90	47.73±4.90	30-60
Parity	1	2	Parity	Frequency (%)
Menopausal status			Nulliparous	469 (23.2)
Pre-menopause, n,(%)	59 (85.5)	1380 (70.7)	Parous*	1551 (76.8)
Peri menopause, n,(%)	5 (7.2)	212 (10.9)	Premenopausal	1655 (81.9)
Menopause, n,(%)	5 (7.2)	359 (18.4)	Menopause	365 (18.1)
HRT				
Yes, n,(%)	69 (100)	1942 (99.5)		
No, n,(%)	0 (0)	9 (0.5)		

*Parous: parity of 1 or more

Table 2. Comparison of family history in high risk and low risk population (cut off=20%)

	All (n=2020) N (%)	**Low risk** (n=1951) N (%)	**High risk** (n=69) N (%)	**P value**
Positive FH	253 (12.4)	184 (9.4)	69 (100)	<0.001
First degree family	147 (7.2)	80 (4.1)	67 (97.1)	<0.001
Second degree family	160 (7.8)	137 (7.00)	23 (33.3)	<0.001
Number of first-degree family				<0.001
1	120 (5.9)	72 (3.7)	48 (69.6)	
2	22 (1.1)	7 (0.4)	15 (21.7)	
3	4 (0.2)	0	4 (5.8)	
Number of second-degree family				<0.001
1	96 (4.7)	84 (4.3)	12 (17.4)	
2	45 (2.2)	39 (2)	6 (8.7)	
3 ≥	19 (0.9)	14 (0.7)	5 (7.2)	
1st degree FH <50 y (%)	38 (15.02)	18 (22.8)	20 (29.9)	0.332
2nd degree FH <50 y (%)	16 (6.3)	12 (9.00)	4 (18.2)	0.186

Discussion

In this study, the IBIS software was utilized for risk stratification of breast/ovarian cancer in a group of Iranian women. Using a risk cut-off point of 20%, 69 individuals (3.4%) were identified as high-risk, while the remaining 1951 (96.6%) were classified as having a low risk of breast/ovarian cancer. Various cut-off values have been employed in previous studies on breast/ovarian cancer risk assessment.[19,20] Himes et al., recommended genetic counseling for women identified with a >20% risk of cancer in their study.[20] In a study by Gagnon et al., patients with a risk between 17 to 30% were categorized as moderate-risk, while those with a risk above 30% were classified as high-risk and advised to undergo hereditary analysis and testing.[21] Another study highlighted the importance of identifying women with over 10% risk of breast cancer for further investigation and genetic counseling.[22]

Numerous assessment tools are available for estimating the risk of developing breast/ovarian cancer, each considering various personal risk factors (e.g., age, body mass index, estrogen consumption) and hereditary genetic risk factors (e.g., family history, bilateral breast cancer, male breast cancer, ovarian cancer, and the age of onset of cancer in family members).[5-7, 22] None of these calculation tools are designed to account for all relevant variables such as ethnicity and age.[22] For instance, the Gail model is more applicable in American and European populations.[23] Family history is a significant risk factor for the development of breast/ovarian cancer, often associated with a higher prevalence of BRCA1 and BRCA2 genetic mutations. According to NCCN guidelines, genetic testing should be considered for individuals with a family history of breast cancer under 50 years of age, male breast cancer, and breast cancer in two or more family members.[24]

Various software tools are employed by different healthcare systems for calculating the risk of genetic cancers. The Tyrer–Cuzick (IBIS) model is considered to be the most reliable and precise risk assessment tool; its comprehensive data collection allows for a more accurate assessment of an individual's long-term risk of breast/ovarian cancer.[22]

The risk of developing breast cancer in females with BRCA1 and BRCA2 mutations is approximately 55-65% and 45%, respectively.[25] BRCA1 and BRCA2 mutations are present in about 40% of patients with ovarian cancer.[26] The risk of ovarian cancer in females with BRCA1 and BRCA2 mutations is 44% and 17%, respectively.[10] A study indicated that the prevalence of BRCA gene mutations in the African-American population is 29.4% in the high-risk population.[27] In our current study, 69 individuals (3.4%) were classified as high risk. Assuming that nearly 20 cases (29.4%) would have tested positive for BRCA gene mutations, the estimated mutation rate in our study population is approximately 0.9% (1 in 110 individuals). Identifying this high-risk population is crucial as nearly half of these patients are likely to develop breast or ovarian cancer, making early detection and genetic testing cost-effective.

The accessibility of genetic analysis and testing plays a vital role in populations at high risk for BRCA-related cancers. In developing regions such as Latin America and African countries, access to genetic screening, counseling, and testing methods is limited, despite the increasing mortality rates from breast and ovarian cancers in these areas. The average age at ovarian cancer diagnosis is lower

in developing countries, possibly due to a higher prevalence of hereditary cancers and inadequate screening methods. Conversely, developed countries like the United States, France, and Iceland have widespread availability of genetic screening, counseling, and testing at affordable costs.[9,18]

Studies have highlighted the poorer prognosis and reduced life expectancy of cancers, including breast and ovarian cancer, in developing countries due to late-stage diagnosis resulting from limited access to screening, patient identification, genetic counseling, and testing, as well as inadequate preventive measures.[28] In our study population, only 4 out of 69 high-risk patients underwent genetic testing, primarily due to financial constraints. Limited insurance coverage and the high costs of genetic testing pose significant barriers to access in developing countries. Identifying high-risk individuals and implementing risk reduction strategies may ultimately reduce the overall economic burden associated with disease progression. In contrast, developed countries with comprehensive insurance coverage make genetic testing more accessible and affordable.[22]

The results of the current study, as well as previous research examining various factors utilized in cancer risk assessment tools, have consistently identified a positive family history as a significant risk factor for predicting the likelihood of developing breast and ovarian cancers. Research indicates that the risk of breast cancer escalates to 25% and 36% in patients with one and two first-degree relatives with breast cancer, respectively, compared to the 13% risk for the average woman.[2,29] Family history emerges as a common factor across all the aforementioned risk assessment tools, with some institutions deeming the presence of a positive family history sufficient to classify an individual as high-risk.[22]

In our study, it was observed that 97.1% of the high-risk population and 4% of the low-risk population had at least one first-degree relative with breast or ovarian cancer. Furthermore, 9.4% of individuals classified as low-risk for breast or ovarian cancer exhibited a positive family history, whereas this figure stood at 100% for those with a cancer risk exceeding 20%, and this disparity was statistically significant ($p<0.001$). Notably, 91% of high-risk individuals (using a cut-off point of 15%) reported a positive family history, in stark contrast to the mere 3% in the low-risk group, underscoring a significant difference ($p<0.001$). A statistically significant contrast was also evident in the average cancer risk between the 253 individuals out of 2020 with a positive family history and the 1767 individuals without such a history, standing at 18.47% and 10.15%, respectively ($p<0.001$).

These findings underscore the substantial impact of a positive family history on the lifetime risk of developing breast or ovarian cancer. Consequently, inquiring about an individual's family history of cancer assumes paramount importance when assessing the general population for cancer risk, aiding in the identification of candidates suitable for genetic testing.

The current tool is straightforward and history-based. It is feasible to educate first-level healthcare providers, such as staff at health centers, general clinics, general practitioners, and midwives, on cancer risk screening through training courses and workshops. Additionally, ensuring the availability of screening forms that include details about clients' family history could be beneficial. By incorporating this data collection into primary screening protocols, it could greatly assist in the second level of screening through genetic tests, if affordable within specific contexts. High-risk individuals identified should be directed towards genetic counseling and further investigations. Even in cases where high-risk individuals lack access to genetic tests due to financial constraints, such as in low-income regions, interventions based solely on history can be recommended following genetic guidelines to prevent cancer.

A limitation of the study is its hospital-based nature. To enhance the generalizability of this population, patients with common reasons for outpatient visits across various settings were included in the study.

It is feasible to train first-level healthcare providers, including staff at health centers, general clinics, general practitioners, and midwives, in cancer risk screening through educational programs and workshops. Additionally, ensuring that screening forms containing information about clients' family history are readily available can aid in identifying high-risk individuals who may benefit from genetic counseling and further assessments.

Conclusions

Based on the findings of the current study, where 3.4% of the population were identified as high-risk (with a risk above 20%) and an estimated 29.4% probability of a positive BRCA test in this group, it is advisable to collect a concise family history of cancer from all clients. This information should be gathered across various settings, and if a person's family history indicates a positive correlation with cancer, they should undergo further assessment using one of the available cancer risk calculation tools. Subsequently, individuals identified as

high-risk should be referred for genetic counseling as deemed appropriate.

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Competing interests

The authors declare that they have no competing interests.

Abbreviations

International Breast Cancer Intervention Study: IBIS;
hormone replacement therapy: HRT;
Breast Cancer Risk Assessment Tool: BCRAT;
US Preventive Services Task Force: USPSTF.

Authors' contributions

All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

The study adhered to the principles of the Helsinki Declaration and was approved by the Medical Ethics Review Board of Shahid Beheshti University of Medical Sciences (Code: IR.SBMU.MSP.REC.1398.457). Women's information was kept strictly confidential and reported in aggregate without disclosing individual names. Participants did not incur any costs, and the study protocol did not cause harm. Written informed consent was obtained from all participants, and they were fully informed about the study's details and purpose.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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