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The Gail Model and Its Use in Preventive Screening

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Abstract

Background

The purpose of this study is to determine the usage of the Gail model in screening for breast cancer during physical examinations of women by sampling primary care physicians in two regions of Texas. The null hypothesis for this study is that primary care physicians do not use the Gail model in screening for breast cancer during physical examinations of women.

Methods

A survey was distributed to 100 physicians in the specialties of Internal medicine (IM), Family medicine (FM), and Gynecology (GYN) from May 2022 to July 2022. The survey assessed the physician's frequency of use of the Gail model and chemoprevention. Data was collected by distributing survey questionnaires to physicians in person. Descriptive statistics were used for response distributions. The Fisher Exact Probability test was used for comparisons across specialties.

Results

Response rate was 34% (34/100). Thirty-eight percent of the physicians surveyed reported using the Gail model in their practice (IM 46%, FM 23%, GYN 31%). All thirteen of the physicians using the Gail model were open to using chemoprevention.

Conclusions

Only 38% of the physicians surveyed responded that they use the Gail Model in their practice. Within the three groups surveyed 62% responded that they do not use the Gail Model. The null hypothesis regarding the use of the Gail Model is not rejected.

Categories: Family/General Practice, Preventive Medicine, Epidemiology/Public Health
Keywords: gail score, bcrat, risk assessment tool, preventive screening, risk calculator, chemoprevention, gail model, breast cancer

Introduction

The incidence of breast cancer is predicted to continue rising over the next 20 years [1]. Early age of menarche, late age of first pregnancy, fewer pregnancies, decreased breastfeeding, and a later onset of menopause are all cited as major breast cancer risk factors. Other risk factors include obesity, alcohol consumption, lack of exercise, and hormone replacement therapy (HRT) [1]. Non-modifiable risk factors include female gender, older age, family history, genetic mutations, race/ethnicity, and estrogen exposure. Modifiable risk factors include hormonal replacement therapy, diethylstilbestrol, physical activity, overweight/obesity, alcohol intake, smoking, vitamin deficiency, excessive exposure to artificial light, intake of processed food, exposure to chemicals, and other drugs [2]. In the United States the American Cancer Society (ACS) estimates new cases in 2023 to be 297,790 and 2800 for women and men respectively [3]. Estimated deaths from breast cancer in 2023 are 43,170 and 530 for women and men, respectively. According to the ACS in 2022 there were 51,400 ductal carcinoma-in-situ (DCIS) cases, 287,850 cases of invasive breast cancer, and 43,250 deaths [4]. In 2020 the Centers for Disease Control and Prevention listed the mortality from breast cancer as second only to lung and bronchus cancer in the United States [5]. According to Corbelli (2014) there has been less focus on breast cancer risk reduction and risk reduction medications [6].

The Gail model (also known as the Breast Cancer Risk Assessment Tool or BCRAT) was developed by Mitchell H. Gail in 1989 [7]. It predicts both a 5-year and lifetime risk of invasive breast cancer. Women with a score of 1.66% or higher are considered to be at increased risk for breast cancer (http://www.cancer.gov/bcrisktool/) [8].

The Gail model (or BCRAT) asks a series of questions which include: medical history of breast cancer, mutation in BRCA1 or BRCA2 gene, age, aged at first menstrual period, age at first live birth, first degree relatives with breast cancer, breast biopsy, and race/ethnicity.

The Gail risk score calculator is not recommended for women with a BRCA1 or BRCA1 mutation, previous history of lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS), women with Li-Fraumeni mutation or those who have had radiation therapy to the chest [8,9]. Referral to a medical geneticist is recommended for Li-Fraumeni Syndrome and other inherited causes [8].

The International Breast Cancer Intervention Study (IBIS) Breast Cancer Risk Evaluation Tool is used with women who have had a previous LCIS. This tool determines the risk of DCIS or invasive breast cancer (http://www.ems-trials.org/riskevaluator/) [8,10].

The Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA) (http://ccge.medschl.cam.ac.uk/boadicea/) is used for calculating risks for women with a history of breast and ovarian cancer. It is also used for determining the risk of being a carrier of the BRCA1 and BRCA2 gene mutations [8,11].

Corbelli (2014) published a study on the use of the Gail model and breast preventive therapy [6]. This study consisted of a web-based survey of resident and attending physicians at the University of Pittsburgh Medical Center. Three specialties were included in the survey: Internal medicine (IM), Family medicine (FM), and Gynecology (GYN). These physicians were required to be university or community-based doctors who practiced at least one half-day per week in an outpatient setting. The Corbelli survey occurred in April 2012. Corbelli (2014) concluded that a minority of primary care physicians used the Gail model (BCRAT) to prevent or to decrease breast cancer risk [6].

The U.S. Food and Drug Administration has approved tamoxifen and raloxifene for use in breast cancer prevention. These medications are also known as selective estrogen receptor modulators (SERMs) [12].

Tamoxifen (Nolvadex) binds to estrogen receptors and competitively blocks binding of endogenous estrogens. In breast tissue tamoxifen acts as an estrogen receptor antagonist. It inhibits breast cancer cell proliferation in patients who are estrogen receptor positive. Side effects of tamoxifen include nausea, vomiting, hot flashes, vaginal bleeding, and menstrual irregularities. It increases the risk of endometrial cancer due to the proliferation of endometrial cells. Raloxifene (Evista) is also a SERM that is an antagonist in the breast and uterus and a partial agonist in bone. It helps reduce the risk of breast cancer in postmenopausal women. Raloxifene is not associated with increased risk of endometrial cancer [13].

Both tamoxifen and raloxifene have been shown to significantly reduce breast cancer risk. The use of SERMs is recommended by the United States Preventive Services Task Force (USPSTF) for women who have an increased risk for breast cancer and a low side-effect profile. However, the USPSTF has recommended against routine use of tamoxifen and raloxifene at low or average risk for breast cancer [14]. The American Society of Clinical Oncology recommends the use of tamoxifen or raloxifene as an option for treating ER-positive breast cancer and in premenopausal women who are 35 years and older with a five-year Gail score of greater than or equal to 1.66%. Tamoxifen or raloxifene is recommended for women with lobular carcinoma in situ (LCIS). Contraindications for these medications include deep vein thrombosis (DVT), pulmonary embolus (PE), stroke, transient ischemic attack (TIA) or patient immobilization. Pregnant women, those who may become pregnant, and nursing mothers should avoid tamoxifen. Also, tamoxifen is not recommended while using hormone medications [15].

The Breast Cancer Prevention Trial (BCPT) showed that women with a history of atypical hyperplasia (AH) benefited more from preventive therapy. This trial showed an 86% risk reduction in women with AH. BCPT data also showed that women under 50 years were less likely to be harmed by the preventive therapy [16].

The study by Tchou (2004) found that only atypical hyperplasia and hysterectomy were significant risk factors. This study concluded that the risk due to AH or lobular carcinoma in situ (LCIS) were the primary risk factors that influenced the offering and acceptance of tamoxifen treatment [17].

The aim of the present study is to determine if there are any significant differences from the Corbelli (2014) [6] study in the use of the Gail model and breast cancer preventive therapy with a sample of non-university based primary care physicians in Hidalgo County and Johnson County, Texas. The survey and data gathering occurred during the Spring 2022 and Summer 2022.

The null hypothesis is that primary care physicians in Hidalgo and Johnson counties do not use the Gail model in screening for breast cancer during physical examinations of women. The alternative hypothesis is that primary care physicians in Hidalgo and Johnson counties do use the Gail model in screening for breast cancer during physical examinations of women.

Materials And Methods

Data source and study survey

The Institutional Review Board (IRB) committee at Oceania University of Medicine approved this study (IRB number: 21-0914WP). Physicians in three primary care specialties- Internal medicine (IM), Family medicine (FM), and Gynecology (GYN) were surveyed by using a written questionnaire (refer to Appendix).

The sample population consisted of private practice physicians in Johnson County, Texas and Hidalgo County, Texas. Physicians in the sample were located using the Google search engine. Search terms consisted of Internal medicine, Family medicine, Gynecology, physicians, Hidalgo County, Texas and Johnson County, Texas. The sample size of 100 was selected from physicians located in proximity to the primary author residence. There were more physicians in Hidalgo County than Johnson County. This led to taking the sample of 85 in Hidalgo County and 15 in Johnson County. The sample was selected based on proximity to the primary authors residence and physician identification in one of the three specialties of Internal medicine, Family medicine, and Gynecology. The sample was taken from private practice physicians only.

The survey was performed during the Spring / Summer of 2022. The two Texas locales were selected for convenience. The primary author resides in both locations. The questionnaires were distributed by the primary and secondary authors visiting the physician clinics and offices. A self-addressed stamped envelope and cover letter was attached to each questionnaire. The questionnaire was anonymous with no identifying information. Completion of the questionnaire required about five minutes. Survey questions were based on the Corbelli (2014) study [6]. Refer to the Appendix.

The survey questionnaire consisted of ten questions. The first three survey questions were demographic: medical specialty, experience, and gender. The fourth question asked if the physician used the Gail model (yes or no). If no, the respondent skipped to question 10. If yes, the survey continued with questions 5 through 9. Question 5 asked about application of the Gail score. Question 6 through 10 concerned the use of chemoprevention.

Corbelli (2014) sampled resident and attending physicians at the University of Pittsburgh Medical Center who were university or community based. The category of resident (first year through fourth year) or attending physician was identified. These physicians were practicing at least one half-day per week in an outpatient office or clinic. The Corbelli study participants accessed a public survey URL that was sent as an email. Consent was obtained through e-mail. A random drawing was offered to win one of two iPad computers. The Corbelli study included 575 physicians of which 316 participated. The survey occurred from February to April 2012 [6].

Inclusion criteria

Inclusion criteria consisted of private practice physicians in three medical specialties (Internal medicine, Family medicine, and Gynecology) located in the Texas counties of Johnson and Hidalgo. Other Texas counties and medical specialties were not surveyed. The Google search engine was used to identify the medical specialty credentials and private practice location for each physician.

Statistical analysis

Due to the small sample size the Fisher Exact Probability was calculated using the VassarStats: Statistical Computation Web Site [18]. The Freeman-Halton extension of the Fisher exact probability test for two-rows and three-columns was utilized. Data from the completed and returned questionnaires was input into the VassarStats online calculator 2 x 3 table to compute the Fisher Exact Probability. The study dependent variables were the use of the Gail model (Table *2*) and use of chemoprevention (Table *3*). Independent variables were the three physician categories (Internal medicine, Family medicine, and Gynecology) for Table *2* and Table *3*.

Results

Of the 100 questionnaires distributed there were 34 responses. The physicians responding consisted of three specialties: 38% Internal medicine, 47% Family medicine, and 15% Gynecology. Twenty-three percent had 5 years or less experience as a physician. Thirty-two percent of the physicians responding had greater than 20 years of experience as a physician. Sixty-two percent of the respondents were male physicians and 38% were female physicians (refer to Table *1*).

Thirty-eight percent of the responding physicians reported use of the Gail Score in their practice (46% IM, 23% FM, GYN 31%) (refer to Table *2*). Fifty-four percent stated they would use the Gail score in women who may be at a higher-than-average risk for breast cancer. Among the reasons for not using the Gail score 34% responded that they did not see patients in who

Characteristic			Responses	%
Specialty:				
Internal Medicine			13	38%
Family Medicine			16	47%
Gynecology			5	15%
	Total (n)		34	100%
Years of Experience as a Physician:				
< 5 years			8	23%
6-10 years			4	12%
11-15 years			5	15%
16-20 years			6	18%
> 20 years			11	32%
	Total (n)		34	100%
Gender:				
Male			21	62%
Female			13	38%
	Total (n)		34	100%

TABLE 1: Characteristics of Survey Participants

Variable		Responses	%	Fisher Exact Probability
Use of the Gail model:				
Yes		13	38%	
No		21	62%	
	Total (n)	34	100%	
Proportion using Gail by specialty:				P(a)=0.032
Internal medicine		6	46%	
Family medicine		3	23%	
Gynecology		4	31%	
	Total (n)	13	100%	
Usage of the Gail was applied in the following situations:				
Women over 35 years of age		2	15%	
Women over 60 years of age		0	0%	
Women with a history of breast cancer		4	31%	
Women who may be at a higher than average risk for breast cancer		7	54%	
	Total (n)	13	100%	
Reasons for not using the Gail model:				
"I do not see patients in whom calculation of the Gail score is indicated"		7	34%	
"I do not have enough time with my patients to use the Gail score"		1	4%	
"I do not think that the results of the Gail score would change my management"		4	19%	
"I am not sufficiently familiar with the Gail score"		9	43%	
	Total (n)	21	100%	

TABLE 2: The Gail Model and Barriers to Use

Variable		Responses	%	Fisher Exact Probability
Use of chemoprevention:				
Yes		13	100%	
No		0	0%	
	Total (n)	13	100%	
Proportion using chemoprevention by specialty:				P(a)=1.0
Internal medicine		6	46%	
Family medicine		3	23%	
Gynecology		4	31%	
	Total (n)	13	100%	
Among providers using chemoprevention,				
minimum Gail score required to recommend:				
1-2 %		2	15%	
3-5 %		9	70%	
6-10 %		2	15%	
11-15 %		0	0%	
> 15 %		0	0%	
	Total (n)	13	100%	
Among providers using chemoprevention, number of times prescribed:				
none		2	15%	
1 to 5		4	31%	
6 to 10		2	15%	
11 to 20		2	15%	
> 20		3	24%	
	Total (n)	13	100%	
Reasons for not using chemoprevention: (only 10 of the 21 physicians not using the Gail Model responded)				
"I have not identified a patient in whom chemoprevention was indicated"		8	80%	
"I do not believe that chemoprevention benefits most women				
who are eligible to receive it."		0	0%	
"I am not comfortable prescribing chemoprevention."		2	20%	
"I do not have time to discuss chemoprevention with my patients."		0	0%	
	Total (n)	10	100%	

TABLE 3: Chemoprevention and Barriers to Use

Discussion

The study by Corbelli, (2014) found similar results in the utilization of the Gail model. The Corbelli study found that only 41% of the physicians reported use of the Gail model. This result is very similar to the present study with 38% reporting use of the Gail model. In the Corbelli research 54% of the responding physicians were IM physicians, 24% FM, and 21% GYN versus 38% IM, 47% FM, 15% GYN in the current study. Physicians responding were 47% male and 53% female versus 62% male and 38% female in the current

study (refer to Table *1*). Corbelli showed that 59% of the physicians stated they did not use the Gail model versus 62% in the current study {refer to Table *2*) [6]. Providing more information to physicians about the Gail model (or BCRAT} would likely help increase its use. The National Institutes of Health: National Cancer Institute website provides a Gail score calculator (https://bcrisktool.cancer.gov/calculator.html) [8].

Both the Corbelli (2014) study and the present study showed that there was low use of the Gail model. One barrier to use described by Brewster (2005) found that a physician would need to screen 5 or 6 women aged 40 to 70 years to find one woman eligible to be counseled for breast cancer chemoprevention. The study participants were members of the CLUE cohort, which is based in Washington County, Maryland. The study found that an estimated 18% of white women aged 40-70 would meet the criteria for chemoprevention counseling. Brewster found that 26 women ages 40-49 years and 142 women from age 60-70 years with a uterus would need to be screened with the Gail model or other model to find one woman eligible to receive counseling on chemoprevention and to have a benefit-risk index for use the of tamoxifen. Brewster suggested considering the differences between clinical trial populations and community populations under study. Brewster found that women in clinical trials are generally healthier than women in other patient populations [19]. Salent (2006) found that many women did not consider themselves high-risk for breast cancer because they did not have any signs or symptoms. A 5-year Gail score of 1.67 or higher was used to meet the clinical threshold for the use of SERMs. Salent (2006) notes that breast cancer is not often put at the top of the list for health concerns. Many women consider breast cancer risk to fluctuate. The high-risk is considered depending on physical signs and symptoms. Most of the women in the Salent study thought cancer was started by stress or worry. Women were not interested in taking medications for breast cancer [20]. In the current study there were only 38% of the physicians using the Gail score (refer to Table *2*). A possible explanation for the low use of the Gail score might be that women did not relate to a numerical score [20]. The low survey response rate might have been due to a lack of interest or knowledge of the Gail score model, breast cancer screening, and risk reduction medications. It is important to improve the use of the Gail model to help prevent and lower the risk of women developing breast cancer which is currently the number one cancer in women in terms of estimated new cases in the United States [3].

Improving the use of the Gail model may help to improve the use of chemoprevention. The USPSTF recommends that women at increased risk for breast cancer who have a low risk for side-effects should be offered risk-reducing medications such as tamoxifen or raloxifene. The USPSTF found that treatment with tamoxifen or raloxifene can significantly reduce the relative risk for ER-positive breast cancer in post-menopausal women [21]. In the present study, 34% of the physicians who did not use the Gail model stated that they did not see patients in whom the Gail score calculation is indicated versus 17% in the Corbelli (2014) study. Nineteen percent of the physicians responded that the Gail score would not change their management versus 26% in Corbelli (2014). Forty-three percent of the physicians not using the Gail model responded that they were not familiar with the Gail score (refer to Table *2*). Corbelli (2014) found that 82% were not sufficiently familiar with the Gail score vs. 43% in the current study [6]. The small sample size of the current study may account for some of the differences.

The main strength of the Gail model is that it can inform women of their breast cancer risk. Other studies of different populations have associated age, age of first birth, age at menarche, family history, menopausal status, and parity with breast cancer risk [22]. The weaknesses of the Gail model are that it leaves out some risk factors when applied in different ethnicities and populations. Different populations have shown different results in its use. Iranian women had a lower discriminatory power in determining breast cancer risk [23]. The breast cancer risk in women with atypical hyperplasia of the breast may be underestimated with the Gail model. Risk assessment could be improved by using tissue-based risk factors with a biopsy [24].

Limitations of the current study include the small sample size. One-hundred questionnaires were distributed to physicians, but only 34 participated. The Corbelli (2014) study survey participants were categorized as first through fourth year resident or attending physician at an academic medical center [6]. The participants in the current study were selected from private practice physicians. The sample geographic area consisted of only two counties in Texas - Hidalgo County and Johnson County. Khaliq (2016) suggested that the chemoprevention use threshold be based on a woman's age and any comorbidity [25]. Developed countries often have more obesity and sedentary lifestyles. This would help in identifying women at high-risk [26-27].

Conclusions

The data collected in this study shows that primary care physicians in the specialties of Internal medicine, Family medicine, and Gynecology do not frequently utilize the Gail model to identify and decrease the risk of breast cancer in women. Further research would help to better define the Gail model and its use in preventing breast cancer in women. The Gail model appears to be beneficial to breast cancer risk reduction; however, risk reduction medication side-effects need to be minimized.

Appendices

Survey Questionnaire modified from the Corbelli study (2014).

1. What is your specialty?

Internal medicine

Family medicine

Gynecology

2. Years of experience as a physician?

Less than 5 years

6-10 years

11-15 years

16-20 years

Greater than 20 years

3. Gender?

Male

Female

4. Do you use the Gail Model in your practice?

Yes

No

If no, please skip to question 10.

5. If yes, which of the following situations would apply to a Gail score use:

Women over 35 years of age

Women over 60 years of age

Women with a history of breast cancer

Women who may be at higher-than-average risk for breast cancer.

6. Do you prescribe medications for breast cancer prevention?

Yes

No

7. What is the minimum Gail score required to recommend chemoprevention?

1-2 %

3-5 %

6-10 %

11-15 %

Greater than 15 %

8. How many times have you prescribed chemoprevention?

0

1-5

6-10

11-20

Greater than 20

9. If not using chemoprevention, which choice below would you most agree with?

I have not identified a patient in whom chemoprevention was indicated.

I do not believe that chemoprevention benefits most women who are eligible to receive it.

I am not comfortable prescribing chemoprevention.

I do not have time to discuss chemoprevention with my patients.

10. If not using the Gail model, which choice below would you most agree with?

I do not see patients in whom calculation of the Gail score is indicated.

I do not have enough time with my patients to use the Gail score.

I do not think the results of the Gail score would change my management.

I am not sufficiently familiar with the Gail score.

Please write your address if you would like a copy of the study results.

e-mail address: _____

Additional Information

Disclosures

Human subjects: Consent was obtained or waived by all participants in this study. Institutional Review Board (IRB) at Oceania University of Medicine issued approval 21-0914WP. The Institutional Review Board (IRB) at Oceania University of Medicine approved this study (IRB number: 21-0914WP). **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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