

ORIGINAL RESEARCH

Breast cancer: is the current screening appropriate? The RISCAM study

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Abstract

Background: Early diagnosis is key to improving outcomes of breast cancer cases. However, controversy remains regarding the lower age limits and the non-personalized nature of screening programs. The main objectives of this study are to investigate the relevance of defining a new lower age limit for breast cancer screening, characterize risk factors not included in the Tyrer-Cuzick™ risk assessment calculator, and explore the feasibility of personalizing screening. **Methods:** This is an observational case-control study. The case group included 64 women with a breast cancer diagnosis. Breast cancer incidence was calculated by age group. Participants were characterized with respect to three cancer risk factors, namely smoking habits, alcohol consumption, and breastfeeding. A risk score was assigned to each woman through the Tyrer-Cuzick™ risk model, and patients were subsequently stratified into several risk groups. Finally, the relationships between intermediate to high-risk groups and breast cancer development were studied. **Results:** We found no statistically significant differences between breast cancer incidence in women aged 40 to 49 vs. 50 to 69, in the health units studied. There was no statistically significant link between the 3 studied risk factors and breast cancer development. We observed a statistically significant relationship between intermediate to high-risk scores and the development of breast cancer (odds ratio (OR) 10.0 with $p = 0.0009$). **Conclusions:** These results support initiating screening from the age of 40 and adopting a patient-centered model, provided that a screening tool with high sensitivity becomes available.

Keywords

Breast cancer; Screening; Early diagnosis; Risk assessment; Medical oncology

1. Introduction

Breast cancer is the most frequently diagnosed cancer worldwide, with 2.3 million new cases in women detected in 2022 accounting for 11.6% of total new cancer cases [1]. It is the fourth leading cause of death worldwide, having been responsible for 665,684 deaths in 2022 [1]. In women, breast cancer is the most common type of cancer and the leading cause of cancer death worldwide [1]. In Portugal, breast cancer is the most commonly diagnosed type of cancer in women, with an incidence of around 118 per 100,000 inhabitants and a mortality rate of 18.2 per 100,000 inhabitants [2].

There has been an increasing trend in breast cancer incidence in both the US and Europe. This trend reflects, on the one hand, an increase in case detection due to organized screening programs. On the other hand, recent lifestyle changes (including smoking, alcohol intake, obesity, and sedentary behavior) and in reproductive patterns (such as early menarche, late menopause, advanced age at first birth, lower breastfeeding rate, use of hormone replacement therapy during menopause, and use of oral contraceptives) constitute known risk factors

for the development of breast cancer [1].

Organized screening for breast cancer has been implemented in a large number of countries worldwide since 1990, with mammography being the most widely used diagnostic method and the only one has shown efficacy in reducing mortality [3]. However, these programs have been the subject of much debate. One of the points of debate is the definition of the target age group for screening, namely its lower age limit [4–6].

In 2014, the Canadian National Breast Screening Study found no evidence that screening women aged 40 to 49 had an impact on breast cancer mortality after 25 years of follow-up. This Canadian study was the first to estimate a breast cancer overdiagnosis rate associated with organized annual screening programs: one in every 424 women who received mammography screening. This overdiagnosis results in overtreatment, consequent toxicity, and treatment sequelae, compromising the patient's quality of life and mental health [7]. In parallel, in 2015, the American Cancer Society modified its recommendations, advising women to have a mammogram annually from the age of 45, replacing a previous lower limit of 40 years old [8]. Nevertheless, in 2020, the UK Age Trial reported that an-

nual mammography screening starting at age 40 was associated with a significant reduction in mortality from breast cancer in the first 10 years of follow-up [9]. Other studies conducted in Canada and Sweden also demonstrated that screening women between the ages of 40 and 49 reduced mortality from breast cancer by 30% [10]. In 2024, the United States Preventive Services Task Force updated recommendations to include biennial screening mammography for females at average risk aged 40 to 74 years, based upon a commissioned systematic review. The American College of Radiology also encourages patients to undergo breast cancer risk assessment by 25 years of age, so elevated-risk patients have the opportunity to benefit from earlier and more aggressive breast cancer screening regimens, when appropriate [11].

Currently, the Council of the European Union recommends breast cancer screening from the age of 50 to the age of 69, every two years, and suggests it for women aged 45 to 74 [12]. Portugal updated its national guidelines according to the suggested wider range in March 2025 [13].

In fact, according to the US Surveillance and Epidemiology data, about 18% of breast cancers occur in women aged 40 to 49, with 23% occurring in women aged 50 to 59, 26% in women aged 60 to 69, and 28% in women aged 70 and older [14]. In Europe, it is estimated that 21% of breast cancer cases occur in women under 50 years of age and 35% occur in women aged 50–64 years [15]. These data demonstrate that there is currently no abrupt increase in the incidence of breast cancer at age 50. Furthermore, it is important to highlight that tumors diagnosed before the age of 50 generally progress faster, are more likely to be estrogen receptor-negative, and present with less favorable histological grades, resulting in a worse prognosis [16, 17].

Considering the controversy surrounding the current screening methodologies and the growing knowledge of the risk factors associated with breast cancer, researchers have been seeking to personalize screening, namely with the implementation of a user-centered model [18]. Tools that integrate clinical information relating to individual risk predictors and epidemiological characteristics of breast cancer have therefore been developed. The Tyrer-Cuzick™ risk assessment is one of the most sensitive models for estimating 10-year and lifetime risk of developing breast cancer. The Tyrer-Cuzick™ score considers several risk factors, namely age, biometric data, personal and family history of breast or ovarian cancer, previous breast biopsy results, age at menarche, age at first pregnancy, age at menopause, and history of hormone therapy use [19]. A Tyrer-Cuzick™ calculated lifetime risk below 15% indicates an average risk of developing breast cancer [8], while a score above 20% is considered high risk [20].

This personalized approach involves assessing the individual risk of each woman, stratifying the population into several risk groups, and adapting prevention and early detection interventions to each of these risk groups [17]. Thus, evolving towards a user-centered model could address the limitations of current screening, increase the sensitivity and specificity of breast cancer screenings, and improve the risk-benefit balance associated with screening [17, 19].

Here, we aimed to investigate the relevance of defining a new lower age limit for breast cancer screening, characterize

risk factors not included in the Tyrer-Cuzick™ risk assessment calculator, and explore the feasibility of personalizing screening.

2. Materials and methods

2.1 Study design

This is an observational case-control study, focusing on the 8560 female patients registered at Carvalhido and Prelada Family Health Units. The case group includes female patients from these Units who were diagnosed with breast cancer, according to the following criteria.

2.2 Inclusion criteria

- Code “Malignant Neoplasm of Breast” in the records;
- Diagnosis of breast cancer between the ages of 40–49;
- Diagnosis carried out in the last 10 years.

2.3 Exclusion criteria

- Diagnosis of breast cancer before the age of 40 years or after the age of 50 years;
- Malignant Neoplasm of Breast codification, without confirmed breast neoplasm;
- Known genetic mutations, namely in breast cancer genes 1 (*BRCA1*) and 2 (*BRCA2*), at diagnosis;
- Death declared prior to the time of data collection;
- Lack of response to the questionnaire.

2.4 Sample size

The control group consists of a sample of female patients from the Units without a diagnosis of breast cancer. The sample size was calculated using the Epi info® platform, considering the total number of female users without breast cancer registered in the participating Units. The sample selection and recruitment were randomized, with all elements of the population having a uniform probability of belonging to the sample. Only patients aged 40 to 49 years were considered for randomization. Thus, the samples were matched by age and registration unit.

2.5 Sources of information

We used a public business intelligence program to collect lists of users diagnosed with breast cancer and a digital clinical process platform to collect clinical data. As both tools rely on routinely recorded clinical information, data quality was influenced by the completeness, accuracy, and consistency of coding and clinical records. Verification procedures were performed through cross-validation between both platforms, with manual review of clinical entries to confirm diagnoses and to detect inconsistencies, missing data, or potential miscoding. Despite verification procedures, residual inaccuracies related to incomplete coding or delayed data entry cannot be entirely ruled out.

A structured questionnaire based on the Tyrer-Cuzick™ risk assessment model (**Supplementary Fig. 1**) was applied to the study participants. The only modifications to the original Tyrer-Cuzick™ model were that our questionnaire did not include mammographic density and Ashkenazi inheritance, due

to the low reliability of self-reported mammographic density and because Ashkenazi Jews represent a very small proportion of the Jewish population in Portugal. Data from the questionnaires were used in the Tyrer-Cuzick™ calculator to obtain 10-year and lifetime risks of developing breast cancer for each participant. Every patient who took part in the questionnaire answered every question; therefore, there was no missing data.

2.6 Data collection

The recruitment process was conducted over a period of 3 months, from August to October 2023, after approval from the Ethics Committee of the Northern Regional Health Administration. A list of all female users diagnosed with Malignant Breast Neoplasia was acquired, yielding a universe of 228 women. After calculating the sample size and randomly selecting the two samples, the inclusion and exclusion criteria were verified for each participant by consulting digital medical records.

The variables under study were collected by consulting the patients' medical records and applying the questionnaire (Supplementary Fig. 1).

Finally, using the data above, the individual risk score of each woman was calculated by applying the Tyrer-Cuzick™ risk assessment model, and the sample was stratified into several risk groups according to the risk score.

2.7 Statistical analysis

Data processing was performed using Microsoft Excel® 2020 (Microsoft Corporation, Redmond, WA, USA) and Statistical Package for Social Science®, version 23.0 (IBM Corp, Armonk, NY, USA) for Windows®. In the descriptive statistical analysis, absolute and relative frequencies were calculated for qualitative variables, and measures of central tendency

and dispersion (mean and standard deviation) were calculated for quantitative variables. Normality was assessed through visual inspection of histograms. In the inferential analysis, the relations between the variables were studied using Student's *t*-test for continuous variables with normal distribution, the Mann-Whitney test for continuous variables with non-normal distribution, and the Odds Ratio for discrete variables. The results were considered statistically significant for *p*-values < 0.05, and 95% confidence intervals are reported.

3. Results

3.1 Group characterization

Regarding the characterization of the two groups under study (Table 1), there was no statistically significant difference in age ($p = 0.058$).

TABLE 1. Mean age of case and control groups.

	Controls	Cases
N	60	64
Mean Age (in yr)	50.5 (40–59)	53.0 (40–83)

3.2 Breast cancer incidence by age group

In the overall Portuguese population, breast cancer incidence increases with age and reaches a plateau from age 45 onward, according to data from the National Oncology registry [21], as illustrated in Fig. 1. The difference between new cases of breast cancer at the ages of 40 to 49 and at the ages of 50 to 69 (the latter being included in the national screening) was statistically significant ($p < 0.0001$). However, there was no statistically significant difference between the age groups of 45 to 49 and 55 to 60 ($p = 0.071$).

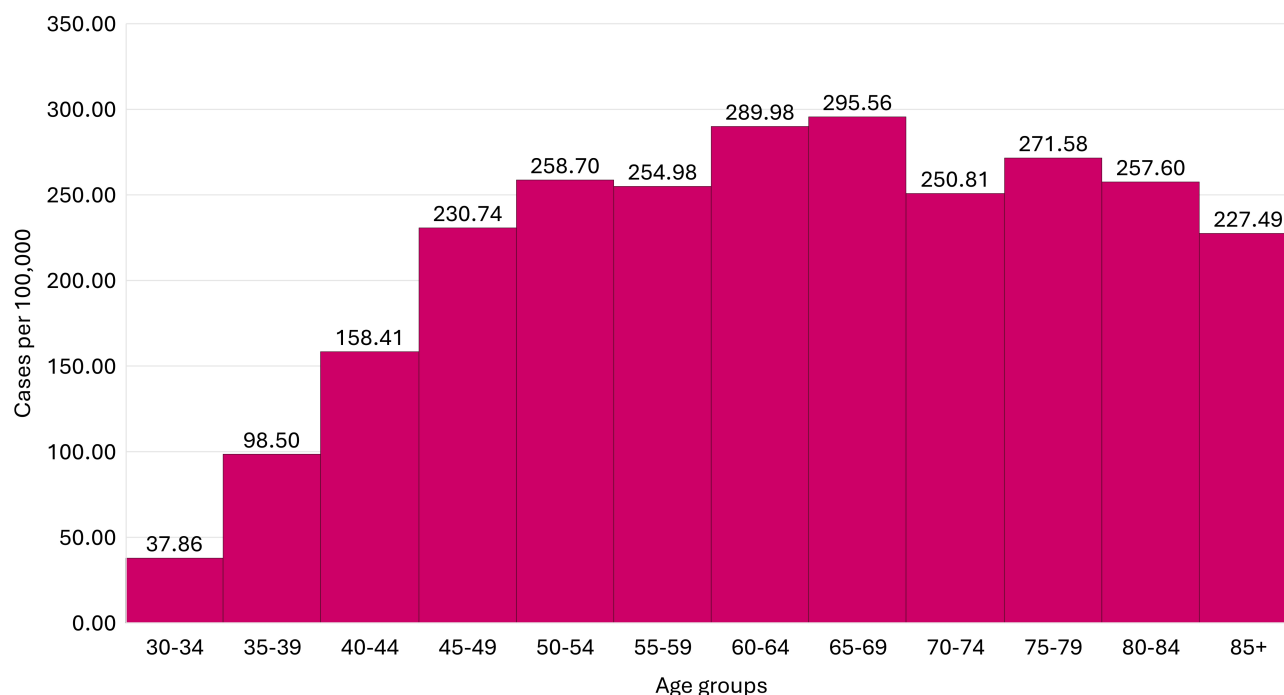


FIGURE 1. Breast cancer incidence by age group in Portugal in 2019.

In the women from the Carvalhido Health Unit (Fig. 2), we observed a higher breast cancer incidence in the age groups 40 to 44 and 45 to 49 than in the 50 to 54, 55 to 59, and 65 to 69 groups. The difference between new cases at the ages of 40 to 49 compared to 50 to 69, the latter being the age range for screening, was not statistically significant ($p = 0.22$).

In women from the Prelada Health Unit (Fig. 3), breast cancer incidence in the age group 45 to 59 was higher than in the 65 to 69 age group. The difference between new cases at the ages of 40 to 49 compared to 50 to 69, the latter being the age range for screening, was not statistically significant ($p = 0.1220$).

3.3 Risk factors

Most of our participants were non-smokers, but the proportion of smokers was higher in the case group (Fig. 4). Regarding alcohol consumption, most women did not drink regularly, however all those who do belong to the case group (Fig. 5). There was no statistically significant difference in either the smoking or alcohol status ($p = 0.87$ and $p = 0.47$, respectively) between the case and control groups.

There was a higher percentage of women who breastfed in the control group and a higher percentage of women who did not breastfeed in the case group (Fig. 6), although this difference was also not statistically significant ($p = 0.1183$).

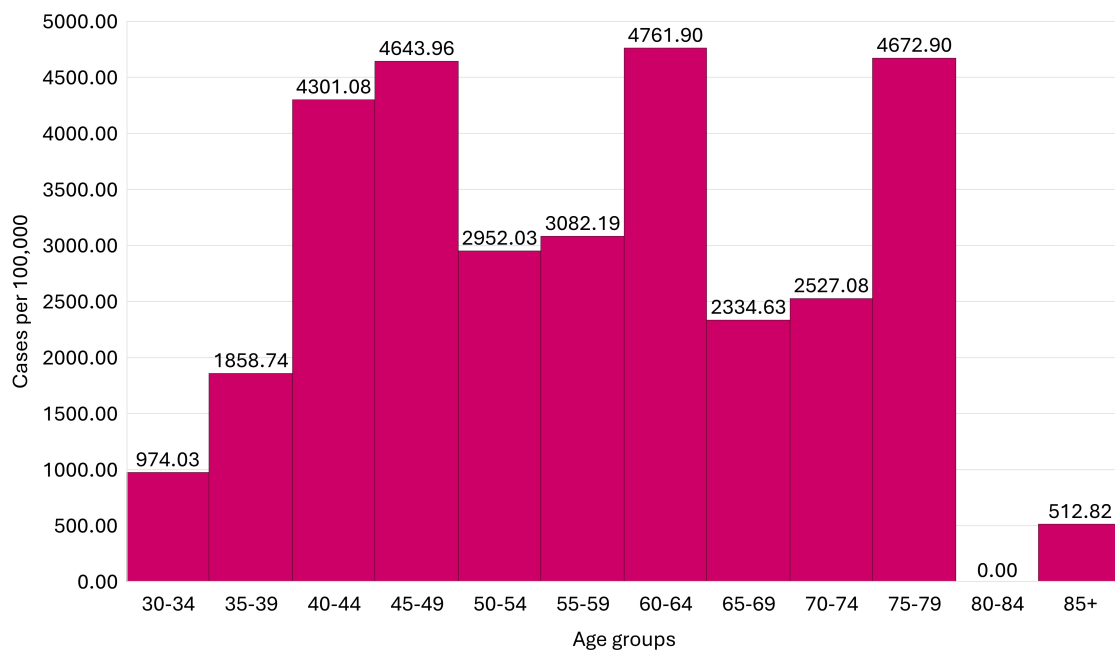


FIGURE 2. Breast cancer incidence by age group in the Carvalhido unit.

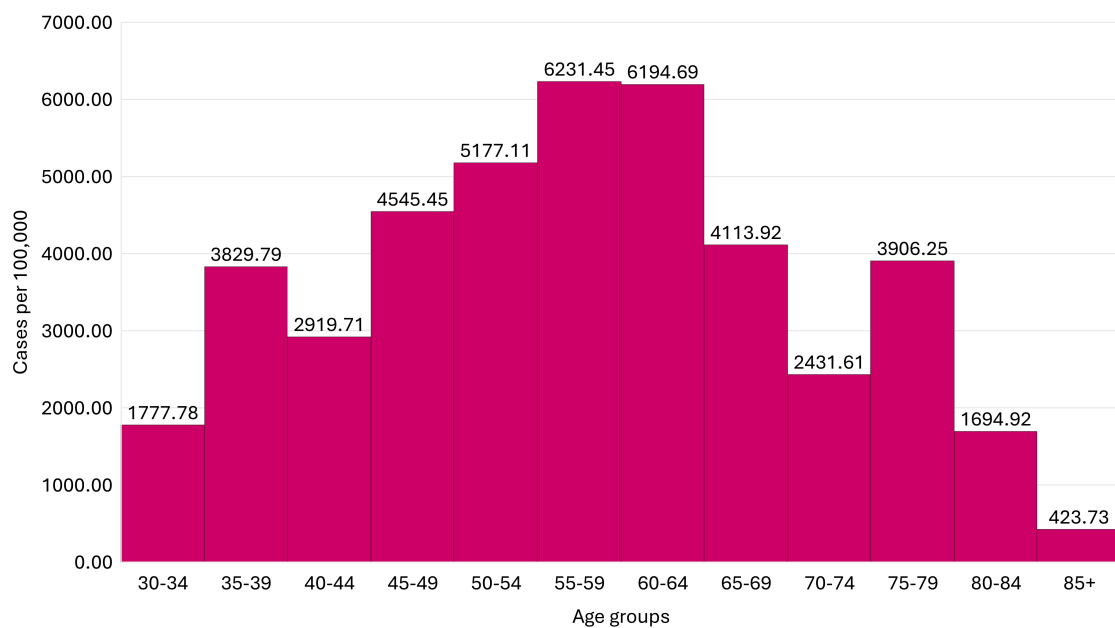


FIGURE 3. Breast cancer incidence by age group in the Prelada unit.

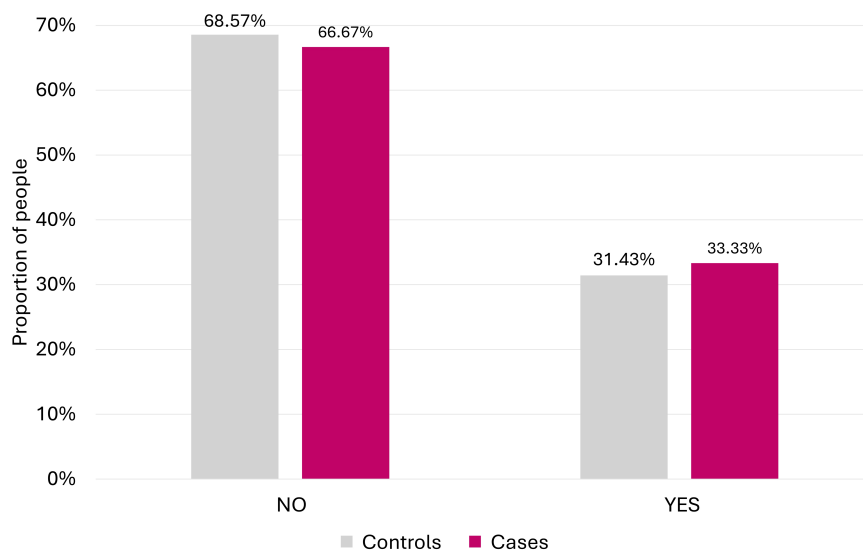


FIGURE 4. Active smoking.

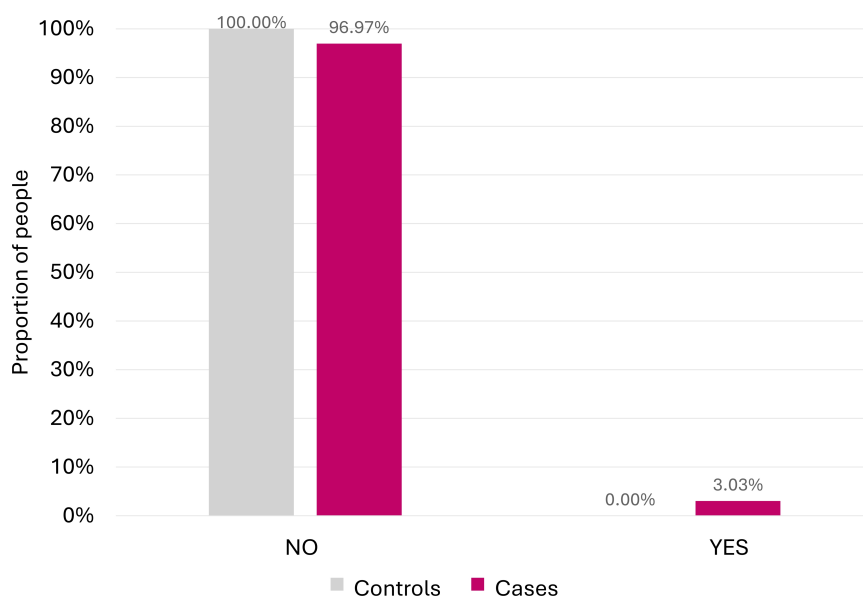


FIGURE 5. Alcohol consumption.

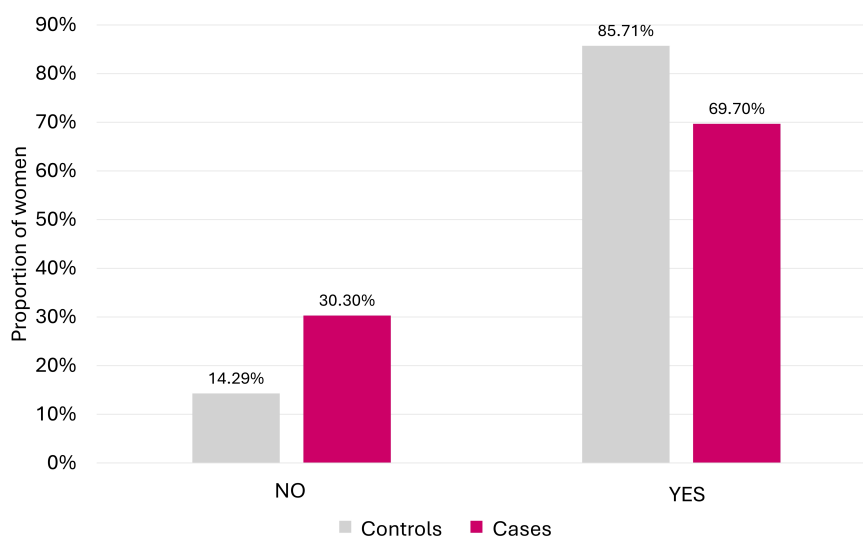


FIGURE 6. Proportion of women who breastfed.

3.4 Risk score

Regarding the risk score data (Table 2), the average 10-year risk was 3.47% in the case group and 2.55% in the control group, while the average lifetime risk was 15.68% in the case group and 11.14% in the control group. Considering these risk scores, 32 of the individuals in the control group were classified as baseline risk and 3 as intermediate or high risk. On the other hand, in the case group, 17 individuals were classified as baseline risk, and 16 presented an intermediate or high risk (Table 3). Thus, a statistically significant positive odds ratio (OR = 10.04, $p = 0.0009$) was observed between intermediate-to-high risk scores and the development of breast cancer.

TABLE 2. 10-year and lifetime risk scores.

	10-year risk	Lifetime risk
Mean		
Cases	3.47	15.68
Control	2.55	11.14
Maximum		
Cases	8.30	28.80
Control	6.30	24.90
Minimum		
Cases	1.60	7.00
Control	1.30	6.30

4. Discussion

4.1 Breast cancer incidence by age group

In the Family Health Units we studied, breast cancer incidence in women aged 40 to 49 was equal to or higher than the incidence in women within the screening age range. In contrast, in the overall Portuguese population, breast cancer incidence increases with age before plateauing from age 45, and we found a statistically significant difference between breast cancer incidence in the 40–49 and 50–69 groups. This discrepancy can possibly be explained by reduced medical monitoring in the general population compared to patients of the Family Health Units. Nonetheless, we found age groups contained within the screening age range that showed incidences similar to the 45 to 49 group. Altogether, this evidence supports the relevance of lowering the minimum screening age to 45, in accordance with the new Portuguese screening program, or to 40 years, in accordance with the American College of Radiology, the Society of Breast Imaging, and the UK Age

Trial recommendations [8, 11].

4.2 Risk factors and the Tyrer-Cuzick™ calculator

Regarding breast cancer risk factors, although the Tyrer-Cuzick™ model is currently the tool that includes the largest number of established breast cancer risk factors [22], its score does not consider smoking habits, regular alcohol consumption, and breastfeeding (the latter being a known protective factor against breast cancer [23]). We studied these three factors and did not find a statistically significant relationship between them and the diagnosis of breast cancer in women aged 40 to 49 years.

We also observed that the calculator presents 91% specificity and 49% sensitivity, corresponding to relatively few false positives, thereby mitigating overdiagnosis, but frequent false negatives.

Nonetheless, as the Tyrer-Cuzick™ risk assessment calculator does not consider all breast cancer-linked variables (e.g., the risk factors previously discussed), we hypothesize that adding more risk and protective factors could improve sensitivity. This hypothesis supports the need for further investigation in this area.

4.3 Tyrer-Cuzick™ risk assessment score and breast cancer development

As previously mentioned, the Tyrer-Cuzick™ risk assessment is one of the most comprehensive models for estimating 10-year and lifetime risk of developing breast cancer. In contrast to other existing models, it considers genetic inheritance, accommodating detailed family history, and therefore can be applied not only to the general population, but also to women with a strong breast cancer family history. The risk score combines this data with several other risk factors, namely age, biometric data, previous breast biopsy results, age at menarche, age at first pregnancy, age at menopause, and history of hormone therapy use [19].

A Tyrer-Cuzick™ calculated lifetime risk of 20% or more is considered high. This threshold is commonly used to determine eligibility for supplemental screening, such as breast magnetic resonance imaging (MRI) [20]. On the other hand, a risk score below 15% is considered average [8].

The relationship between a high-risk score in the Tyrer-Cuzick™ model and the development of breast cancer has been described in previous studies, in which the age range of the studied population was either broad [24] or restricted to postmenopausal women [25]. Our work focuses on women aged 40–49, where we found a statistically significant rela-

TABLE 3. Test performance measures.

	Base population risk	Intermediate-high risk	
Control	32 TN	3 FP	E = 0.91
Cases	17 FN	16 TP	S = 0.49
	NPV = 0.65	PPV = 0.84	

E: Specificity; S: Sensitivity; NPV: Negative predictive value; PPV: Positive predictive value; TN: True negative; FP: False positive; FN: False negative; TP: True positive.

tion between intermediate-to-high individualized risk scores ($\geq 15\%$) and the development of breast cancer. This result specifically supports the applicability of an individualized, patient-centered model in screening women from the age of 40. This finding is in agreement with the US National Comprehensive Cancer Network guidelines, which advise that women with a high risk undergo breast magnetic resonance imaging and genetic counselling [20], emphasizing the importance of calculating risk scores in clinical practice to adapt the course of action and improve prognosis.

4.4 Study strengths

This study addresses a present-day topic under discussion, in light of the new recommendations included in the European plan to combat cancer presented by the European Commission. To our knowledge, it is the first application of the Tyrer-Cuzick™ risk assessment calculator for individual assessment of breast cancer in Portugal. The results of the study may serve as a basis for the implementation of strategies aimed at improving breast cancer screening programs and for conducting other larger studies. Additionally, our findings may lead to potential health gains through increased early detection of breast cancer.

4.5 Study limitations

Inherent to the retrospective design of our study, there is potential for recall bias and classification bias (*e.g.*, some participants in the control group may develop breast cancer in the future, before age 50). Additionally, we did not include 2 of the 25 variables that are part of the original Tyrer-Cuzick™ risk model (Ashkenazi ancestry and mammography density), though we believe this limitation is sufficiently mitigated by the comprehensive information on risk factors and family history contained in the questionnaire. More broadly, the results of this study support the implementation of strategies that could potentially contribute to overdiagnosis of breast cancer; however, this is mitigated by the high (91%) specificity of the Tyrer-Cuzick™ risk model. Overall, we consider that these limitations do not compromise the conclusions of the study.

4.6 Future perspectives

Considering the high breast cancer incidence before the age of 50, our results suggest a possible benefit from extending screening programs to women starting at the age of 40, with an individualized approach. Further research is needed to validate our findings in larger-scale studies, and to develop a predictive risk model that integrates more known risk factors for breast cancer, as higher sensitivity is beneficial for screening programs.

5. Conclusions

In this study, we observed a high breast cancer incidence in women aged 40–49 years and a statistically significant relation between intermediate to high Tyrer-Cuzick™ individualized risk scores and the development of breast cancer. Our findings support the discussion on lowering the starting age for breast cancer screening, as they suggest a relevant incidence among

younger women, especially considering that tumors diagnosed before the age of 50 generally have a worse prognosis. This change already occurred in the new Portuguese screening program. Our results also support the applicability of an individualized, patient-centered model for screening women from the age of 40, provided that a high-sensitivity screening tool becomes available. A more individualized approach to screening could improve the risk-benefit balance of breast cancer screening, although currently available risk assessment tools still need improvement to increase sensitivity. Given the risk of increased overdiagnosis, our results should be interpreted with caution and considered as a prompt for large-scale studies and cost-effectiveness analyses, which are necessary before a change in screening policy can be justified. Altogether, our results may serve as a basis for larger studies, specifically testing the link between breast cancer risk scores and breast cancer diagnosis in women under 50. Until such investigations are carried out and a more sensitive individualized screening tool is available, our incidence findings support discussing the extension of the initial screening age range to at least 45, and possibly to 40 years of age.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on request from the corresponding author due to privacy and ethical concerns, as the data involves human subjects.

AUTHOR CONTRIBUTIONS

MIL, DCB and ALP—designed the research study. MIL, ST and DB—performed the research. ABS and ALP—analyzed the data. MIL, ABS, ST and DB—wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The present study was conducted in accordance with the Declaration of Helsinki. Data confidentiality was guaranteed by researchers at all stages of the process.

Before completing the questionnaire, all users were informed about the objectives of the study and how anonymity and confidentiality were guaranteed. Informed written consent was obtained in duplicate, one copy for the researcher and another copy for the participant, including for those who did not complete the questionnaire.

The data collected is confidential and for exclusive use in this study. To ensure data protection, a list of users was created including the National Health Service number and a sequential identification number. This identification number is subsequently used as the sole identifier within the database. Access to the database was restricted to researchers, password-protected, and will be kept for a maximum period of four years.

The researchers ensured that the data collected in the questionnaire were used exclusively for this research and will not be made available to third parties, thus ensuring both the

confidentiality and anonymity of the participants.

This protocol was submitted and approved by the Coordinators of the Units where the study was carried out, and by the Ethics Committee of the Northern Regional Health Administration (protocol code CE/2023/84 and date of approval of 09 November 2023).

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CONFLICT OF INTEREST

The authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at <https://oss.ejgo.net/files/article/2110263986312101888/attachment/Supplementary%20material.docx>.

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