Awareness of digital tomosynthesis and attitudes towards breast cancer early diagnosis in women at first screening: findings from the IMPETO trial survey

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Abstract

Background. The European guidelines on breast cancer and diagnosis recommend digital mammography (DM) or digital breast tomosynthesis (DBT) for screening asymptomatic women with an average risk of breast cancer. The research project innovation in mammography: tomosynthesis pathways (IMPETO) includes an interventional randomised trial conducted in Tuscany, Italy, aiming to assess the feasibility and impact of DBT in screening. Limited evidence exists on women's preferences and acceptability of this new technology. To address this gap, as part of the IMPETO trial, a questionnaire was administered to 441 women aged 45 at their first inclusion in the screening programme, to investigate women's awareness of tomosynthesis and their attitudes toward early diagnosis.

Methods. This cross-sectional study was nested within the IMPETO trial, whose participants were randomly sampled. From October 2021 to February 2022 all women who participated in the face-to-face enrolment for the IMPETO trial were asked to fill out a structured questionnaire collecting socio-demographic information and assessing awareness of tomosynthesis, breast density, attitudes toward breast cancer early diagnosis, and sources of information on breast health. Multiple logistic regression was performed to identify predictors of tomosynthesis awareness and attitudes toward early diagnosis.

Results. Out of the 441 women surveyed, only 12% knew what tomosynthesis was and this awareness was positively associated with prior mammography experience (OR=2.092; 95% CI: 1.036-4.11). More than half of the participants (56.7%) had undergone mammography before joining the screening programme. Education attainment emerged as a significant predictor, with women holding a secondary degree being more likely to undergo mammography before age 45 (OR=2.18; 95% CI: 1.04-4.56). Among those who had undergone mammography before 45, 38.8% were advised by their gynaecologist, 27.6% made the decision independently, and 13.6% followed the advice of their general practitioner.

Conclusion. This study highlights the need for improved education on screening appropriateness and associated risks and the importance of tailored communication to reduce knowledge differences across educational levels without increasing inappropriate use.

INTRODUCTION

Breast cancer is the most common cancer affecting women in the European Union, with 374,800 women estimated to be diagnosed with breast cancer and 95,800 women estimated to die of breast cancer in 2023, according to the European Cancer Information

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System [1]. Advancements in organised population-based screening programmes have contributed to reduced mortality rates in most European countries [2-4]. Early detection through breast cancer screening is pivotal in identifying treatable cases, significantly reducing mortality [5, 6].

The European guidelines on breast cancer screening and diagnosis, established under the European Commission Initiative on Breast Cancer (ECIBC) 2021 (https://healthcare-quality.jrc.ec.europa.eu/en/ecibc/european-breast-cancer-guidelines?topic=65&usertype=60&updatef2=0), provide guidance on the implementation of breast cancer screening. These guidelines suggest using either digital mammography (DM) or digital breast tomosynthesis (DBT) for asymptomatic women with an average risk of breast cancer. Women with high mammographic breast density are likely to benefit most from the increased detection capability of DBT. However, the guidelines underline the limited certainty of evidence and the absence of data on the downstream impact of DBT, such as its effect on reducing advanced cancer and mortality. Moreover, the guidelines reveal a lack of data regarding women's preferences, acceptability, and the value they attribute to the routine use of DBT.

In the Florence local health unit, the breast cancer screening programme was fully implemented in the first 1990s for women aged 50-69, with biennial invitations to mammography. In 2016 the programme was expanded to include women aged 45-49, receiving annual invitations.

In 2018, the Institute for Cancer Research, Prevention and Clinical Network (Istituto per lo Studio, la Prevenzione e la Rete Oncologica, ISPRO) initiated an interventional randomised trial to assess the impact of the introduction of tomosynthesis in mammography screening, analysing the benefits, disadvantages, and feasibility in current practice.

As part of this study, a questionnaire was developed to investigate women's awareness of tomosynthesis and their attitudes toward early diagnosis upon their initial inclusion in the screening programme. The questionnaire was administered to participants from October 2021 until the study concluded in February 2022. As new evidence emerged in the Italian context, we recognised the importance of conducting this questionnaire to analyse our specific circumstances [7].

METHODS
Participant selection and recruitment

The research project *Innovation in mammography: tomosynthesis pathway (IMPETO - Innovazione in Mammografia: PErcorsi di TOmosintesi)* involved in a randomise controlled trial women aged 45 who were participating in the Florence screening programme for the first time. Women in this age group were randomly assigned to either the control arm (2D DM) or the intervention arm (DBT plus 2D synthetic reconstruction). This study joined the Mammography screening ITAlian (MAITA) Consortium (a consortium of four Italian trials, REtomo, Proteus, Impeto, and MAITA trial). [8].

The cross-sectional study reported here was nested in the IMPETO trial. Women were invited to join the IMPETO study through a randomised selection process. The randomization of invitees (rather than enrolees) followed a simple random sampling method at a 1:1 ratio. All women who accepted to participate in the face-to-face enrolment were asked to fill out a self-administered questionnaire on their awareness of tomosynthesis and their attitudes toward early diagnosis. Neither the study recruiter nor the woman knew the study arm assignment before signing the consent form.

Data collection

The questionnaire is reported in *Appendix 1 available online as Supplementary Material*. It was structured into three sections aimed at assessing: (i) general attitudes toward breast cancer early diagnosis; (ii) awareness of breast density, tomosynthesis, and sources where women seek information related to breast cancer prevention (iii) socio-demographic information. The questions were designed drawing on insights from previous research [9, 10] and the Centers for Disease Control and Prevention (CDC) Q-Bank (https://wwwn.cdc.gov/qbank/).

A panel of experts in cancer screening reviewed the questionnaire incorporating all relevant observations. Administered on a self-reported and anonymous basis, the questionnaire aimed to mitigate response order bias by randomising the sequence of answers (questions 3, 4, 8, 10) after the first 200 responses using the Excel function Random.

Analysis

Data was processed using Stata/SE version 16.1 (StataCorp LP, College Station, TX). Descriptive statistics, including frequency distribution, were used to summarise participants' demographics and questionnaire responses. Multiple logistic regression analysis was performed to identify significant predictors of tomosynthesis awareness and attitudes toward early diagnosis. All statistical tests were two-sided and statistical significance was set at 0.05 ($p<0.05$). In the multiple logistic regression analysis to investigate the association between socio-demographic factors and the likelihood of having undergone mammography as a preventive measure before turning 45, women who had mammography due to symptoms (such as pain, skin changes, palpable nodules, nipple discharge) or benign lesions (fibroadenomas or cysts) control were excluded, as they were not undergoing the mammography for preventive reasons.

RESULTS
Socio-demographic characteristics

The study sample (*Table 1*) included women aged 45 years, following the IMPETO cohort inclusion criteria. Of the 441 women who completed the questionnaire, not all participants responded to every item. The number of non-responders is reported as missing values in the tables. The majority of participants (77.1%, n. 340) were either Italian or from highly developed countries (HDC), while 19.1% (84) were from high migratory pressure countries (HMPC) [11]. Educational backgrounds varied, with 44.7% (197) holding a high school

Table 1
Socio-demographic characteristics

	N.	%
Country of birth		
HDC[1]	340	77.1
HMPC[2]	84	19.1
Missing	17	3.9
Level of education		
None	2	0.5
Primary school	43	9.8
Secondary school	197	44.7
University graduate	189	42.9
Other	5	1.1
Missing	5	1.1
Residence[3]		
Florence	169	38.3
Piana municipalities	92	20.9
Rural areas	118	26.8
Missing	62	14.1
Occupational status		
Full-time employed	274	62.1
Part-time employed	93	21.1
Unemployed	28	6.4
Housewife	20	4.5
Private job	20	4.5
Missing	6	1.4
Had mammography before		
No	191	43.3
Yes	250	56.7
N. of mammography in lifetime		
1	144	32.7
2	40	9.1
3	34	7.7
4+	26	5.9
Missing	6	1.4

[1]Highly developed countries; [2]high migratory pressure countries; [3]piana municipalities: Calenzano, Sesto F.no, Campi, Prato; rural areas: Vicchio, Reggello, Incisa, Greve, Figline, Bagno a Ripoli.

diploma, 42.9% (189) being graduates, 9.8% (43) having completed the primary education cycle, and only 0.5% (2) lacking an education certificate. 38.3% (169) of participants resided in the city of Florence, 26.8% (118) in rural areas, and 20.9% (92) in the industrial area around Florence. The majority of participants were full-time employed (62.1%, n. 274), followed by 21.1% (93) part-time employed individuals. The remaining participants were either unemployed (6.4%, n. 28), housewives (4.5%, n. 20), or engaged in private jobs (4.5%, n. 20). In terms of mammography history, 43.3% (191) had never undergone mammography, while 56.7% (250) had at least one mammography session in

their lifetime. Among these women 32.7% (144) had one, 9.1% (40) had two, 7.7% (34) had three, and 5.9% (26) had more than four.

Breast density and DBT awareness and source of information

While 51.0% (225) women have heard about breast density, only 12.0% (53) were aware of DBT. However, 91.2% (402) women had never undergone DBT, 1.6% (7) did not know and only 3.9% (17) experienced this test (15 missing). Among those who already had a mammography, 7.6% experienced this test. The 53 women aware of DBT were asked about the source of their knowledge through a multiple-select item: none cited a general practitioner (GP) or media channels, 43.4% (23) learned about DBT at the facilities where they underwent mammography, 16.9% (9) through specialist doctors, and 15.1% (8) via friends and family. Additionally, 15.1% (8) were informed through the Internet and Social Networks, and 13.2% (7) through specialised and non-specialised magazines/newspapers.

Attitudes towards early diagnosis

The 441 participants were asked where they would seek information about mammography in case of doubts or questions. Responders indicated as main points of reference general practitioners (41.5%, n. 183) and specialist doctors (43.8%, n. 193), followed by screening facilities (20.2%, n. 89) and the Internet (6.1%, n. 27). Family and friends (3.4%, n. 15) and specialised information sources (2.5%, n. 11) were cited less frequently.

Among the responders, 43.3% (191) had never undergone mammography, while 56.7% (250) had at least one mammography session (*Table 2*). Among those who had mammography, 51.2% (128) opted for private facilities, and 37.6% (94) chose public facilities. The primary motivation for mammography was secondary prevention in the absence of family history 52.8% (132), followed by prevention due to the presence of a family history 18.8% (47), and symptoms 18.4% (46). Among women who had undergone at least one mammogram, 38.8% (97) were advised by their gynaecologist, 27.6% (69) made the decision independently, and 13.6% (34) followed the advice of their GP.

Among women who underwent mammography for secondary prevention without a family history or symptoms (132), 50.0% (66) followed their gynaecologist's recommendation, 25.8% (34) made the decision independently, 7.6% (10) were influenced by family or friends, and 7.6% (10) followed a breast specialist's advice, and 5.3% (7) followed the GP advice (missing 5). For those with a family history (47), 31.9% (15) decided independently, 29.8% (14) were advised by their gynaecologists, 17.0% (8) by their GPs, 8.5% (4) by a breast specialist, and 8.5% (4) by their family or friends (missing n. 2). Among those who had mammography due to symptoms or for benign lesions control (64), 31.2% (20) made the decision independently, 29.7% (19) were advised by GPs, 25.0% (16) followed their gynaecologist's suggestion, 6.6% (4) followed a breast specialist recommendation, only one person was influenced by family or friends (missing n. 4).

Table 2
Attitudes towards early diagnosis

	N.	%
Where did you have mammography?		
Don't remember	1	0.4
Public health facility	94	37.6
Private facility	128	51.2
Abroad	5	2.0
Both in a private and public facility	15	6.0
Missing	7	2.8
Reason to undergo a mammography		
Symptoms[1]	46	18.4
Benign lesions[2] control	18	7.2
Family history	47	18.8
Prevention (no family history)	132	52.8
Missing	7	2.8
Who suggested undergoing mammography?		
Breast specialist	18	7.2
Gynaecologist	97	38.8
General practitioner	34	13.6
Family/friends	15	6.0
None, I decided on my own	69	27.6
Other	12	4.8
Missing	5	2.0

[1]Pain, skin changes, palpable nodules, nipple discharge; [2]fibroadenomas or cysts.

Predictors of DBT awareness

Table 3 column a shows the association between socio-demographic factors and DBT awareness. Participants who had previously undergone mammography showed a significant association with DBT awareness (OR=2.09; 95% CI: 1.04-4.11). Similarly, there was a correlation between knowledge about breast density and DBT awareness (OR=2.44; 95% CI: 1.20-4.93). Association with education and place of birth was weak, if any. Occupational status showed a non-significant association with being unemployed and an inverse association with being a housewife.

Predictors of attitudes towards early diagnosis by logistic regression

Table 3b presents the association between socio-demographic characteristics and having had screening mammography before the age of 45. As mentioned, symptomatic women and those who had benign lesions controls were excluded (N=64). Educational level emerged as a significant predictor, with women holding a secondary degree showing an increased likelihood of undergoing mammography before 45 (OR=4.00; 95% CI: 1.30-23.27). Moreover, university-educated women exhibited a stronger association, with a higher odds ratio for undergoing mammography before the age of 45 (OR=7.49; 95% CI: 2.43-23.07).

In addition, the knowledge of breast density showed a positive association (OR=1.60; 95% CI: 1.02-2.54). Place of birth and occupational status showed small, if any association.

DISCUSSION

This study examined women's awareness of tomosynthesis and their attitudes towards early diagnosis within the context of the IMPETO study nested in the breast cancer screening programme of the Florence local health unit.

The findings of this study lie in two main themes. Firstly, there is a notable lack of awareness regarding tomosynthesis, despite the relatively high educational levels of the participants. To our knowledge, no prior studies have explored perceptions of tomosynthesis among women undergoing breast cancer screening. Awareness of breast density is higher but still around 50%, consistent with findings from similar studies [12, 13]. In this study, knowledge of tomosynthesis correlated more strongly with having undergone a mammogram than with educational attainment. Indeed, the primary source of information was the facility where participants had prior mammograms, with minimal influence by general practitioners or media channels.

Secondly, a significant number of women had a mammography before 45, aligning with previous studies [14], despite European guidelines on breast cancer screening and diagnosis (European Commission Initiative on Breast Cancer, ECIBC, 2021) not recommending routine mammography before the age of 45. Women with higher educational levels were more likely to undergo mammograms, often in private clinics and without a family history of breast cancer, consistent with other studies [15, 12]. Gynaecologists played a significant role in directing women to mammography, but a substantial percentage make the decision independently.

The phenomenon of mammography overuse, previously observed in Italy [16], persists regardless of education level. Thus, there is a need to improve knowledge about appropriateness and associated risks, especially concerning unnecessary screenings, consistent with previous findings [7]. It is crucial to re-imagine a communication strategy to enhance women's awareness of screening and tomosynthesis, to avoid an uneven introduction of DBT in breast cancer secondary prevention. Without such measures inappropriate use of DBT may rise, undermining women's trust in public screening programs.

As DBT becomes more common in private clinics, public screening programmes must address the increased demand for radiologists dedicated to screening reading or adopt new technologies to reduce DBT reading time [17]. Failure to balance access risks creating inequities: private clinics offering paid DBT while public programs rely on free DM.

The strength of our study lies in its unique focus on women invited to the first round of organised screening, providing insights into initial awareness and information-seeking behaviours regarding breast cancer prevention. In addition, this study contributes

Table 3
Association between socio-demographic factors and DBT[1] awareness investigated through multiple logistic regression analysis (a) and between socio-demographics factors and the likelihood of having undergone mammography before turning 45 years old as preventive measure (symptomatic women and those who had benign lesions controls were excluded) (b)

	a		b	
	N=53	OR (95% CI)	N=186	OR (95% CI)
Had mammography before				
None	14	1*	-	-
Yes	39	**2.09[2]** **(1.04-4.11)**	-	-
Country of birth				
HDC[2]	41	1*	158	1*
HMPC[3]	9	1.31 (0.57-2.99)	16	0.41 (0.21-0.83)
Level of education				
Primary education	2	1*	6	1*
Secondary education	22	1.28 (0.34-4.74)	75	**4.00** **(1.30-23.27)**
University graduated	28	1.38 (0.37-5.22)	98	**7.49** **(2.43-23.07)**
Occupational status				
Full/Part-time/Private job	46	1*	162	1*
Unemployed	5	2.34 (0.79-6.95)	7	0.71 (0.25-2.07)
Housewife	1	0.52 (0.06-4.21)	9	1.05 (0.36-3.04)
Knowledge of breast density				
No	14	1*	66	1*
Yes	37	2.44 (1.20-4.93)	109	1.60 (1.01-2.54)

*Reference status; [1]DBT= digital breast tomosynthesis; [2]HDC = people from highly developed countries (or Italians); [3]HMPC = people from high migratory pressure countries; values in bold indicate statistical significance.

to exploring the scarcely investigated perceptions and knowledge of tomosynthesis. However, this study has some limitations such as a relatively small sample size, and the questionnaire was exploratory. Additionally, it is important to acknowledge that the demographic characteristics of our participants may be influenced by self-selection bias, as individuals with certain traits may be more likely to accept to participate in the face-to-face enrolment and screening programmes, potentially impacting the generalizability of our findings to the whole population. However, the questionnaire was completed before the experimenter introduced the IMPETO study to the participants, allowing for a reduced influence of self-selection bias and ensuring a more representative sample. As a result, the responders to the questionnaire had a higher educational level and employment rate compared to data from the local female population aged 25-49. Indeed, only 9.8% of the questionnaire participants had a primary education level, while 42.9% were university graduates, compared to 19.3% and 37.1% respectively, among Florence's female population aged 25-49, according to National Institute of Statistics (Istituto Nazionale

di Statistica, ISTAT) [18]. Regarding respondents' employment rate, 87.7% were employed, 6.4% were unemployed and 4.5% were housewives, compared to Florence's female population aged 25-49, where 74.3% were employed, 6.8% unemployed, and 11.2% housewives [18].

Nonetheless, the proportion of eligible citizens from HMPC countries aligns with the percentage of participants in the questionnaire, adding validity to our study sample composition. Specifically, 19.8% of participants were from HMPC countries, compared to 19.4% of the eligible population in the Florence province in 2022 [19].

CONCLUSIONS

Our study provides valuable insights into breast cancer screening, highlighting the importance of raising awareness about screening appropriateness and potential risks, particularly concerning unnecessary screenings. In addition, a communication strategy should involve not only screening centres but also general practitioners and gynaecologists. Moreover, the influence of educational levels on screening attitudes un-

derscores the need for tailored interventions to address existing disparities.

Further investigations and interventions should focus on improving women's awareness and decision-making regarding breast cancer screening. Addressing these issues will contribute not only to individual healthcare decisions but also to the overall success and effectiveness of breast cancer screening programmes. Specifically, there is a need to enhance the training of general practitioners and gynaecologists, enabling them to enrich women's understanding and facilitate their well-informed decision-making processes.

Conflict of interest statement

All Authors have no relevant financial or non-financial interests to disclose.

Ethics approval

Before data collection, formal approval was obtained from the local Ethics Committee (Approval n. CEAVC Em. 2021-460 Studio 11784_spe 27/09/2021) to ensure compliance with ethical guidelines. Participants were provided with clear and comprehensive information about the study's purpose, and their voluntary participation was contingent upon obtaining informed consent. Confidentiality was strictly maintained, with all collected data anonymised and stored securely. Participants were assured that their responses would be used solely for research purposes, and personal identifiers were carefully protected to uphold privacy. The study design and execution adhered to the principles outlined in the Declaration of Helsinki, prioritising the welfare and rights of the participants.

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