

RESEARCH ARTICLE

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Age-Specific Predictive Value of Ultrasound, Mammography, and Magnetic Resonance Imaging for Breast Malignancy in Baghdad, Iraq

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Abstract

Background: Breast cancer is the most prevalent malignancy among women worldwide and in Iraq. The rising incidence and mortality are mostly attributed by late diagnosis and inadequate screening. Although mammography, ultrasound, and magnetic resonance imaging are essential for early detection, their diagnostic performance varies by age, breast density, and population characteristics. Most available guidelines are based on Western populations and may not be fully applicable to younger Iraqi women with dense breasts, particularly in resource-limited settings. **Methods:** This prospective comparative study was carried out from January 2023 to December 2024 at two teaching hospitals in Baghdad. A total of 485 symptomatic women (25–80 years) underwent the three imaging modalities, with histopathological confirmation. Breast density was classified using the Breast Imaging Reporting and Data System, and patients were stratified into four age categories (<40, 40–49, 50–59, and ≥60 years). Findings categorized as 4 or 5 were considered positive. Diagnostic accuracy (sensitivity, specificity, positive predictive value, and negative predictive value) was evaluated overall and by age groups. **Results:** Dense breasts were observed in 65.6% of participants, especially in women under 40 years (87.3%). Ultrasound showed higher sensitivity in women <40 years (92.3% vs. 78.5% for mammography), while mammography performed best in women aged 50–59 years (94.2%). Magnetic resonance imaging had the highest sensitivity (91.4%) but the lowest specificity (78.5%), particularly in younger women (73.0%). Mammography had the highest false-negative rate in women <40 years (21.5%), whereas magnetic resonance imaging showed higher false-positive rates (26.8%). Dense breasts reduced mammographic sensitivity but had limited impact on ultrasound and magnetic resonance imaging. **Conclusions:** Imaging performance in Iraqi women is age- and density-dependent. Ultrasound is most suitable for women under 40 years, mammography for those aged 50–59 years, and magnetic resonance imaging for high-risk cases. These findings support age-adapted imaging strategies in Iraq.

Keywords: Breast cancer- Age-specific imaging- Ultrasound- Mammography- Magnetic resonance imaging

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Introduction

Breast cancer is the most common malignancy diagnosed in women worldwide. It accounts for approximately one quarter of all cancers in women, is a leading cause of cancer-related deaths, and results in over 2.3 million new cases each year [1, 2]. Incidence rates have also increased significantly in the Middle East, and specifically in Iraq, the concomitant increase in the incidence and mortality rates is linked to the late diagnosis and inadequate screening programs [3]. The early disease diagnosis that highly relies on the proper interpretation of the imaging studies is yet another pillar in the effective management of the patients [4]. There are three main imaging modalities which are in regular use; they are mammography, ultrasonography and magnetic resonance imaging (MRI). All modalities have their own strengths

and weaknesses which are adjusted depending on the age of patients and their breast density [5].

The traditional standard of screening is mammography, which is particularly effective in postmenopausal women who have fatty breasts [6]. However, its sensitivity is quite reduced in younger women who have dense breast parenchyma- a trend that has been recorded clearly in Western cohorts but not sufficiently proved in the Middle East [7]. Adjunctive imaging is necessary due to the increased incidence of aggressive tumour subtypes in the younger patients [8].

Ultrasonography is a helpful complementary method, particularly in dense breasts, as it has a better ability to distinguish cystic and solid lesions, cost-effective and does not produce ionising radiation, which is a positive feature in resource-limited regions like Iraq [9, 10]. Nonetheless, the method is operator-dependent and has a low ability

to identify micro calcifications thus limiting its use as a diagnostic modality [11]

MRI is the most sensitive modality for identifying multifocal disease, assessing tumour extent, and detecting contralateral malignancy [12]. However, its reduced specificity, high cost, and limited supply hinder its use in developing health systems in routine [13]. The age-related differences in hormone effects on MRI patterns of enhancement also require population-specific analysis [14].

Most available evidence is based on Western populations, although ethnic and racial differences in the manifestation of breast cancer, its biology, and imaging have been reported [15, 16]. It has been reported that earlier age of diagnosis, more severe stages of the disease, and different molecular subtypes are observed in studies in Iraq and neighbouring areas [3, 17], which highlights the need to use locally validated imaging methods. Age contingencies in breast density, tumour biology and availability of healthcare further complicate the methods of diagnostic procedures [18].

The current Iraqi guidelines do not provide age-stratified imaging protocols, but they make use of the international protocols, which might not be congruent with local demographic and resource distributions. To fill this gap, this study aimed to evaluate the performance of ultrasound, mammography, and MRI across age groups in Baghdad, assess breast density prevalence, and formulate evidence-based, age-specific imaging recommendations tailored to Iraq's healthcare context.

Materials and Methods

This is a prospective comparative clinical study, which was conducted in Baghdad Teaching Hospital and Al-Yarmouk Teaching Hospital between January 2023 and December 2024; the study was aimed at evaluating the diagnostic accuracy of three of these breast imaging modalities, mammography, ultrasound, and MRI, in a cohort of symptomatic females. Both institutions are tertiary referral centers that together cater to a population size of about 2.5 million people with dedicated breast imaging units that have board-certified radiologists. The study was designed to ensure methodological rigor; all imaging studies followed internationally accepted guidelines and were interpreted according to the Breast Imaging Reporting and Data System (BI-RADS).

Participant enrollment was guided by well-defined inclusion and exclusion criteria, carefully applied to enhance clinical homogeneity and ensure data reliability. The women in question, aged 25 to 80 years, were of a clinical or radiologic suspicion of breast malignancy, and had to pass through all three imaging modalities within a 30-day period. As well, they were to undergo histopathological confirmation through core needle biopsy or surgical excision. The exclusion criteria included previous breast cancer, pregnancy, contraindications of MRI (e.g., a pacemaker or severe renal failure), recent breast surgery, or unavailable pathological information. A sample size of 485 patients was calculated based on OpenEpi software, with the assumption that the sensitivity

difference of modalities was 15 %, power was 80%, the significant level was 5%, cancer prevalence was expected (40%), and the attrition rate was 10 %.

The imaging protocols were standardized in all modalities. A digital mammography was done using a system of Hologic Selenia 5 Dimensions with bilateral craniocaudal and mediolateral oblique images, and interpretation was performed according to the BI-RADS 5th edition [19]. Breast ultrasound (GE LOGIQ E10) employed 5–12 MHz linear transducers with Doppler assessment of solid lesions, also classified using BI-RADS ultrasound criteria [19]. MRI scans were performed using 1.5T Siemens systems with dedicated breast coils, including T1- and T2-weighted sequences and dynamic contrast-enhanced imaging; premenopausal women were scheduled between days 7–14 of their menstrual cycle [20]. Mammograms and MRI studies were interpreted by two fellowship-trained breast radiologists with more than 10 years of experience each, while ultrasound examinations were performed by two certified radiologists with over 8 years of dedicated breast imaging experience. Annual quality audits were conducted at both institutions according to national radiology standards. Breast density was independently assessed using the BI-RADS density classification (A–D) by two senior radiologists and dichotomized into non-dense (A/B) and dense (C/D), with inter-observer reliability measured using Cohen's kappa. Participants were further stratified into four age groups (<40, 40–49, 50–59, ≥60 years) [21].

The histopathological diagnosis was the reference standard and tissue sampling was performed within 30 days of the imaging. A multidisciplinary team chose biopsy methods (core needle, vacuum-assisted, or surgical) concerning the characteristics of the lesions and image evidences. Of the 198 malignant cases, 142 (71.7%) were diagnosed by core needle biopsy, 28 (14.1%) by vacuum-assisted biopsy, and 28 (14.1%) by surgical excision. Each of the specimens was handled by specialized breast pathologists in accordance with standardized procedures with immunohistochemical staining where necessary. In order to reduce the bias in interpretation, two fellowship trained radiologists independently reviewed all the imaging studies without clinical information, other imaging findings, or pathology findings. All three modalities had BI-RADS categories assigned by each reviewer. The inter-observer agreement was measured by the use of Cohen kappa coefficient of categorical data and intraclass correlation coefficient (ICC) of continuous variables with discordant cases being resolved by a third senior radiologist consensus. For diagnostic accuracy assessment, findings were dichotomized as negative (BI-RADS 1–3) and positive (categories 4–5) across all modalities; category 3 was classified as negative given its <2% malignancy risk, consistent with standard methodology.

Data were collected using standardized case report forms covering demographics, clinical observation, imaging findings, and histopathology, then entered into a secure, quality-audited electronic database. Statistical analysis was performed using SPSS version 26.0. The diagnostic measures such as sensitivity, specificity, positive

and negative predictive value and the 95% confidence interval were calculated by each modality in general and age subgroups. The overall diagnostic accuracy was evaluated by receiver operating characteristic (ROC) curves, and area under the curve (AUC) values. Chi-square tests, ANOVA tested the relationships between categorical and continuous variables in different age groups, respectively. Multivariate logistic regression was used to determine independent predictors of malignancy and the statistical significance was determined as $p < 0.05$.

Results

This study enrolled 527 patients initially, of whom 485 completed all study procedures and constituted the final analysis cohort. Exclusions ($n=42$) were due to incomplete imaging ($n=18$), loss to follow-up ($n=15$), or inadequate tissue samples ($n=9$). The study flow is shown in Figure 1. The mean age of participants was 47.3 ± 12.8 years, with the 40-49 age group being the largest ($n=158$, 32.6%). Dense breasts (BI-RADS categories C and D) were observed in 318 patients (65.6%), with a marked age-related decline: 87.3% in those under 40 years versus 42.9% in those aged ≥ 60 years ($p < 0.001$). Body mass index (BMI) also varied significantly by age ($p=0.032$), though family history of breast cancer and presence of a palpable mass showed no significant age-related differences ($p=0.541$ and $p=0.782$, respectively).

These baseline characteristics are detailed in Table 1.

Inter-observer agreement was assessed using Cohen's kappa (κ). Breast density classification showed excellent agreement ($\kappa = 0.84$, 95% CI: 0.80–0.88). BI-RADS assessments demonstrated substantial agreement across modalities: mammography ($\kappa = 0.79$, 95% CI: 0.74–0.84), ultrasound ($\kappa = 0.81$, 95% CI: 0.76–0.86), and MRI ($\kappa = 0.77$, 95% CI: 0.72–0.82). These values align with Landis and Koch criteria, confirming high reliability of imaging interpretations. Histopathological analysis confirmed malignancy in 198 patients (40.8%). Invasive ductal carcinoma (IDC) was the most common type ($n=156$, 78.8%), peaking in the 50–59 age group (81.0%) and lowest in those <40 years (71.8%). Invasive lobular carcinoma (ILC) accounted for 18 cases (9.1%) and increased with age, reaching 13.9% in patients ≥ 60 . Ductal carcinoma in situ (DCIS) was more prevalent in younger women (15.4% in <40 years vs. 2.8% in ≥ 60 years). Mixed and other malignant types comprised 5.0% of cases. Full distribution is shown in Table 2.

Overall diagnostic performance varied by modality. MRI showed the highest sensitivity (91.4%, 95% CI: 86.7–94.8%) but lowest specificity (78.5%, 95% CI: 73.2–83.1%). Mammography offered balanced performance: sensitivity 86.9% (81.4–91.3%) and specificity 89.2% (85.1–92.4%). Ultrasound was intermediate: sensitivity 89.4% (84.3–93.2%), specificity 85.7% (81.2–89.4%). Positive predictive values (PPV) were highest for

Table 1. Demographic and Clinical Characteristics of Study Sample

Characteristic	Overall (n=485)	<40 years (n=102)	40-49 years (n=158)	50-59 years (n=134)	≥ 60 years (n=91)	p-value
Age, mean $\pm$ SD	47.3 $\pm$ 12.8	34.2 $\pm$ 4.6	44.8 $\pm$ 2.9	54.2 $\pm$ 2.8	66.1 $\pm$ 5.2	-
BMI, kg/m ²	28.4 $\pm$ 4.2	27.1 $\pm$ 3.8	28.9 $\pm$ 4.1	29.2 $\pm$ 4.5	28.0 $\pm$ 4.3	0.032
Family history, n (%)	89 (18.4)	22 (21.6)	31 (19.6)	23 (17.2)	13 (14.3)	0.541
Dense breasts (BI-RADS C/D)	318 (65.6)	89 (87.3)	112 (70.9)	78 (58.2)	39 (42.9)	<0.001
Palpable mass	376 (77.5)	81 (79.4)	125 (79.1)	102 (76.1)	68 (74.7)	0.782

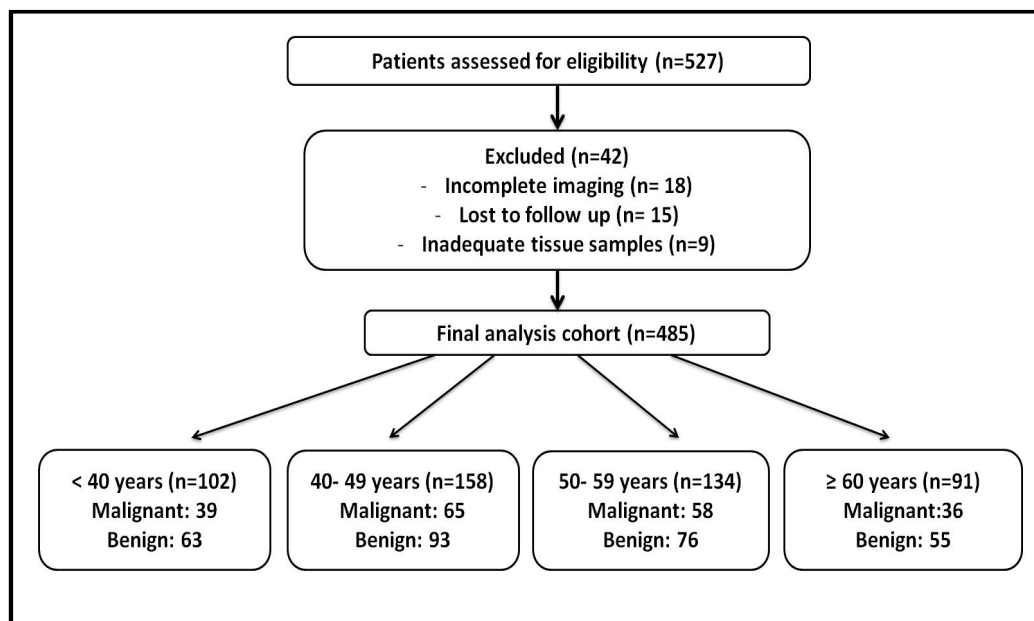


Figure 1. Study Flow Diagram

Table 2. Detailed Histopathological Distribution

Histotype	Overall N (%)	<40 years	40-49 years	50-59 years	≥60 years
Invasive ductal carcinoma	156 (78.8)	28 (71.8)	52 (80.0)	47 (81.0)	29 (80.6)
Invasive lobular carcinoma	18 (9.1)	2 (5.1)	5 (7.7)	6 (10.3)	5 (13.9)
Ductal carcinoma in situ	14 (7.1)	6 (15.4)	4 (6.2)	3 (5.2)	1 (2.8)
Mixed invasive carcinoma	6 (3.0)	2 (5.1)	2 (3.1)	1 (1.7)	1 (2.8)
Other malignant	4 (2.0)	1 (2.6)	2 (3.1)	1 (1.7)	0 (0.0)

mammography (82.1%) and lowest for MRI (69.8%), while negative predictive values (NPV) were high across all modalities (>92%). Accuracy and AUC values are reported in Table 3.

Age-specific performance demonstrated significant variation, with ultrasound showing higher sensitivity than mammography in women <40 years (92.3% vs. 78.5%), while MRI also maintained high sensitivity (89.2%); mammographic sensitivity improved with age, reaching 94.2% in the 50–59 group. Specificity was consistently lower for MRI, particularly among younger patients. The low Positive Predictive Values (PPVs) in younger patients likely reflect lower cancer prevalence, whereas the high Negative Predictive Values (NPVs) (>88%) should be interpreted within the context of the study's relatively high malignancy prevalence (40.8%), as screening settings with lower prevalence would yield higher NPVs and lower PPVs; detailed results are presented in Table 4.

Breast density had a significantly influenced on diagnostic performance; in dense breasts (65.6% overall, 87.3% in <40 years), ultrasound consistently outperformed mammography in sensitivity across all age groups, while MRI performance remained consistently strong, as summarized in Table 5.

ROC analysis confirmed age-specific accuracy patterns: ultrasound had the highest AUC (0.908) in <40 years, while mammography peaked in the 50–59 group (AUC 0.932). MRI AUC ranged from 0.831 to 0.876 across ages. Multivariable logistic regression identified age (OR 1.02, 95% CI 1.00–1.04), dense breasts (OR 2.18, 95% CI 1.34–3.54), and family history (OR 1.87, 95% CI 1.12–3.12) as independent predictors of malignancy. The significant interaction between age and modality performance ($p=0.018$) supports age-stratified imaging strategies (Figure 2).

False-positive (FP) and false-negative (FN) rates

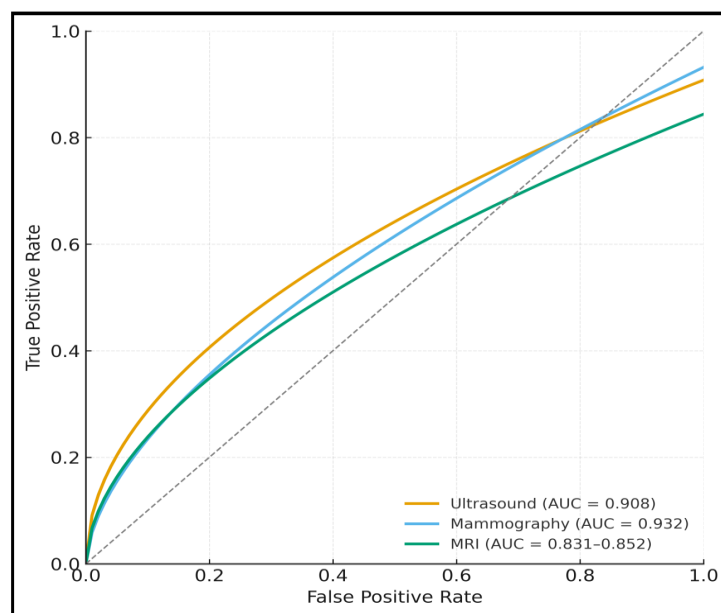


Figure 2. ROC Curves Demonstrating the Diagnostic Performance of Mammography, Ultrasound, and MRI across Four Age Groups

Table 3. Overall Diagnostic Performance by Modality

Metric	Mammography	Ultrasound	MRI
Sensitivity (95% CI)	86.9% (81.4-91.3)	89.4% (84.3-93.2)	91.4% (86.7-94.8)
Specificity (95% CI)	89.2% (85.1-92.4)	85.7% (81.2-89.4)	78.5% (73.2-83.1)
PPV (95% CI)	82.1% (76.2-87.0)	78.9% (73.1-84.0)	69.8% (63.8-75.3)
NPV (95% CI)	92.3% (88.7-95.0)	93.2% (89.8-95.7)	94.5% (90.8-97.0)
Accuracy	88.20%	87.20%	83.70%
AUC (95% CI)	0.881 (0.847-0.910)	0.876 (0.841-0.906)	0.849 (0.812-0.882)

Table 4. Complete Age-Stratified Diagnostic Performance by Modality

Age Group	n	Malignancy Rate	Modality	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
<40 years	102	38.20% (39/102)	Mammography	78.50% (62.7-89.4)	87.30% (76.5-94.0)	76.9% (60.7-88.9)	88.7% (78.1-95.3)
			Ultrasound	92.30% (79.7-97.3)	82.50% (70.9-90.9)	75.0% (60.4-86.4)	94.5% (84.9-98.9)
			MRI	89.20% (75.3-96.0)	73.00% (60.3-83.4)	64.8% (50.6-77.3)	92.0% (80.8-97.8)
40-49 years	158	41.10% (65/158)	Mammography	84.60% (73.3-91.8)	90.30% (82.4-95.3)	84.6% (73.3-91.8)	90.3% (82.4-95.3)
			Ultrasound	87.70% (77.2-94.0)	86.00% (77.6-92.0)	80.3% (69.5-88.5)	91.4% (83.8-96.2)
			MRI	90.80% (80.8-96.2)	79.60% (70.5-86.7)	72.8% (62.3-81.8)	93.6% (86.6-97.6)
50-59 years	134	43.30% (58/134)	Mammography	94.20% (84.9-98.1)	92.10% (83.6-96.8)	89.3% (79.1-95.6)	95.9% (88.5-99.1)
			Ultrasound	89.70% (78.6-95.4)	88.20% (79.4-94.0)	83.9% (72.3-91.8)	93.0% (85.4-97.4)
			MRI	93.10% (83.0-97.5)	81.60% (71.5-89.1)	77.1% (66.0-85.9)	94.8% (87.2-98.6)
≥60 years	91	39.60% (36/91)	Mammography	91.70% (77.5-97.9)	90.90% (79.7-96.9)	86.8% (71.9-95.6)	94.3% (84.3-98.8)
			Ultrasound	86.10% (70.5-94.3)	87.30% (76.5-94.4)	81.6% (65.7-92.3)	90.6% (80.7-96.5)
			MRI	94.40% (81.0-99.0)	83.60% (72.5-91.5)	77.3% (62.2-88.5)	95.8% (87.8-99.1)

Table 5. Diagnostic Performance in Dense Breasts by Age Group

Age Group	Dense Breasts (n)	Mammography Sensitivity (95% CI)	Ultrasound Sensitivity (95% CI)	MRI Sensitivity (95% CI)
<40 years	89/102 (87.3%)	76.90% (58.0-89.9)	94.10% (80.9-98.4)	88.20% (72.6-95.7)
40-49 years	112/158 (70.9%)	80.40% (66.1-90.0)	89.10% (76.4-95.4)	89.10% (76.4-95.4)
50-59 years	78/134 (58.2%)	89.50% (75.9-96.0)	86.80% (70.3-94.7)	92.10% (78.6-97.7)
≥60 years	39/91 (42.9%)	85.70% (60.1-96.0)	78.60% (52.4-92.4)	92.90% (68.5-98.7)

Note: Malignant cases within dense breasts: 142 of 318 (44.7%).

varied by age and modality. In <40-year-olds, MRI had the highest FP rate (26.8%), while mammography had the highest FN rate (21.5%); ultrasound showed the lowest FN (7.7%). In older groups, FP rates declined (e.g., mammography: 5.8–7.3%), and FN rates were generally lower. However, ultrasound FN rates remained elevated in dense tissue among older patients. These findings, shown in Table 6, highlight trade-offs in test selection, especially in resource-limited settings.

Discussion

This prospective study represents one of the largest

Table 6. False-Positive and False-Negative Rates by Modality and Age

Age Group	Modality	False-Positive Rate (%)	False-Negative Rate (%)
<40 years	Mammography	12.4	21.5
	Ultrasound	16.8	7.7
	MRI	26.8	10.8
40-49 years	Mammography	8.6	15.4
	Ultrasound	14.2	12.3
	MRI	22.4	9.2
50-59 years	Mammography	5.8	5.8
	Ultrasound	11.6	10.3
	MRI	18.2	6.9
≥60 years	Mammography	7.3	8.3
	Ultrasound	13.9	13.9
	MRI	16.4	5.6

systematic evaluations of age-specific performance of breast imaging in a Middle Eastern cohort. It is important to emphasize that the study was conducted in a symptomatic referral population with a malignancy prevalence of 40.8% and therefore the findings should not be directly extrapolated to population-based screening settings. Imaging performance varied according to age and breast density. Ultrasound demonstrated higher sensitivity in women under 40 years, mammography performed more favorably in the 50–59 age group, and MRI maintained high sensitivity across age groups, although with comparatively lower specificity in younger patients. A high prevalence of dense breast tissue was observed (65.6% overall and 87.3% in women under 40 years), which may influence imaging selection in regional clinical practice. The excellent inter-observer agreement ($k = 0.77$ – 0.84) further supports the reliability and reproducibility of these findings.

Our findings are in agreement with the recent Asian research which reports the superiority of ultrasound in younger women with dense breasts. Similar ultrasound sensitivity (91.7%) was reported between Korean and Japanese studies that used ultrasound in women aged 30-39 years, and added incremental detection of cancer when ultrasound is used to complement mammography in dense breasts. The decreased mammographic sensitivity in younger patients (78.5%) is due to the well-recorded masking effect of dense tissue; meta-analyses have revealed a loss of sensitivity (89.1%) in fatty breasts to a lower sensitivity of 62.9% in extremely dense breasts [22, 23].

The critical finding of this study is that the prevalence

of dense breast tissue in our population (65.6% in the overall and 87.3% in <40) is comparable to that reported in Western populations (43 - 50%) [24]. The observation is in line with other Middle East studies and has important implications on the screening algorithm design. International studies indicate that Middle Eastern women have much higher breast density than their European populations of the same age [25].

The best mammographic performance in the age group of 50-59 years, this is consistent with international guidelines that prioritize the role of mammography during postmenopausal women. Similar sensitivity was found with European studies (93.8%) in women aged 50-59 years with non-dense breasts [26]. The high MRI sensitivity at all ages is consistent with the established literature [12, 21], also the lower specificity of younger patients (73%) is reported in the American literature on false-positive rates ranging between 12.5 - 27.3% for premenopausal women due to hormonal enhancement patterns [27].

This younger age at presentation of our cohort is consistent with the epidemiological trends in the Middle East in which 40-50% of the cases are observed before age 50 years as compared to 25 - 30% years in the Western populations. The research in Iran, Lebanon, and Jordan reports similar demographic changes, which suggest that the screening should start earlier than the Western guidelines recommend [28].

The implications of the high false-positive rates are enormous in terms of patient counselling, costs of health care and the burden of the psychological impact especially on the MRI in younger women. The best approach in the resource-limited setting would be integration of clinical risk factors, breast density examination and age-appropriate imaging combinations.

Strengths

The main strengths of this study are its prospective character, systematic three-modality imaging assessment of each patient, a large sample size with histopathologically verified diagnoses and strong measures of inter-observer reliability. The findings demonstrate good generalizability and fill a critical gap by validating imaging principles in an understudied population. The study was conducted over two years on two major hospitals, with a high prevalence of dense breast tissue being reported.

Limitations and future directions

The major weaknesses include a symptomatic referral cohort (40.8% malignancy rate), which introduces spectrum bias and limits applicability to low-prevalence screening contexts, preventing direct extrapolation of positive and negative predictive values. Other limitations have to do with the single-region focus, lack of interval cancer tracking and deficit of molecular subtyping or cost-effectiveness data. Future studies must focus on age-specific screening trials to be performed in asymptomatic Iraqi women, explore causes of elevated breast density, evaluate advanced imaging technologies, and integrate artificial intelligence to reduce interpretation variability. Policy development requires multicenter regional

collaborations and health-economic analyses tailored to middle-income settings.

In conclusion, this study demonstrates that the diagnostic performance of breast imaging modalities in symptomatic Iraqi women varies according to age and breast density. Higher breast density in younger women was associated with reduced mammographic sensitivity, while ultrasound showed stronger performance in this group. Mammography demonstrated more favorable performance in older women, and MRI maintained high sensitivity across age groups, although with comparatively lower specificity in younger patients. The findings support consideration of age- and density-adapted imaging approaches within resource-constrained clinical settings. Ultrasound may be considered an appropriate first-line modality in younger symptomatic women with dense breasts, whereas mammography remains suitable for middle-aged patients; MRI may be reserved for high-risk assessment or problem-solving indications. These conclusions arise from a symptomatic referral cohort and should be interpreted cautiously when applied to screening populations. Overall, the findings offer context-specific evidence to support more tailored and efficient diagnostic strategies in comparable healthcare settings.

Author Contribution Statement

All authors contributed equally in this study.

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Ethical Approval

The study protocol was approved by the Institutional Review Boards of Baghdad Teaching Hospital (BTH-IRB-2023-015) and Al-Yarmouk Teaching Hospital (ATH-IRB-2023-008). Written informed consent was obtained from all participants in accordance with the Declaration of Helsinki and Good Clinical Practice requirements.

Data availability

Datasets are available upon reasonable request, subject to IRB approval.

Conflict of Interest

No conflicts declared.

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