

## Breast cancers missed during screening in a tertiary-care hospital mammography facility

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**BACKGROUND:** Breast cancer is the most common cancer in females worldwide. Screening with mammography for early breast cancer detection is standard community practice in many countries.

**OBJECTIVE:** Identify causes of missed breast cancers during screening

**DESIGN:** Retrospective, observational.

**SETTING:** Department of radiology at a tertiary-care hospital mammographic screening facility.

**PATIENTS AND METHODS:** All women who came with initial negative screens from July 2015 to July 2018 were retrospectively reviewed and followed-up for their second or subsequent mammographic screening. Missed breast cancer was defined as a cancer that was detected on a subsequent mammogram with an initial negative screen. Mammograms were interpreted by two radiologists as per BIRADS (Breast Imaging Reporting and Data System) lexicon. Causes of missed breast cancers were categorized as imaging acquisition (IA), imaging feature (IF) and imaging interpretation (II). True (occult) incident breast cancers were also documented. Percentage estimations for these causes were calculated.

**MAIN OUTCOME MEASURES:** Breast cancer detection on follow-up screening.

**SAMPLE SIZE:** 943 women.

**RESULTS:** Of 15 (1.6%) screening-detected breast cancers, 7 cases (46.6%) were missed on the initial screen; 3 (43%) of these were II related, 2 (28.5%) of each were IA and IF. The remaining true (occult) cases were detected on either the second (5 cases) or third screens (3 cases).

**CONCLUSION:** Improved screening facilities, quality mammographic acquisition and interpretation, double reading, and implementation of an organized screening program may help to avoid missed breast cancers.

**LIMITATIONS:** Retrospective, small sample, single center, and short duration study.

**CONFLICT OF INTEREST:** None.

**B**reast cancer is the most common cancer in females worldwide, accounting for nearly one-fourth of newly diagnosed cancers in Saudi Arabia.<sup>1</sup> Nearly half of women in Arab countries develop breast cancer at the age of 50 years versus the age of 65 years in the United States.<sup>2</sup> In developing countries, a large number of women are still diagnosed at a later stage in comparison to developed countries where early detection is made through organized screening programs.<sup>3</sup> The number of breast cancer cases in Saudi Arabia has increased with higher rates in the Eastern region (26.6 out of 100 000 women) compared with other regions. Nearly one-third of women develop breast cancer younger than the age of 50 years.<sup>4</sup> Various studies have highlighted risk factors that could be related to the increase in breast cancer incidence in Saudi Arabia.<sup>5</sup> Screening with mammography for breast cancer detection has already become the standard community practice in many countries. Other imaging modalities that can be helpful diagnostic tools (like ultrasound or magnetic resonance imaging) are not feasible for general screening purposes due to inherent limitations (operator dependency and lack of recognizing microcalcifications with ultrasound, claustrophobia and contrast-related concerns with MRI) and cost (especially with MRI).

Careful retrospective reviews have revealed that some of breast cancers detected on a subsequent screen after an initial negative screening were missed (i.e., false negatives). Too small a lesion, having benign imaging features, not clearly seen or even reported on initial mammographic screen have been described as causes of such false negative cases.<sup>3</sup> The four key components of any breast cancer screening program are the patient, clinician, technician, and radiologist.<sup>6</sup> Factors related to any of them may contribute towards an interval or initially missed breast cancer. For example, patient's inertia to seek timely medical advice or non-compliance to a regular or recommended imaging follow up (due to personal, social or economic reasons), a suboptimal imaging acquisition by an inexperienced technician (not covering hidden areas of the breast), misinterpretation or reporting error by a radiologist, and improper advice by a clinician (for an additional investigation or an imaging follow up may lead to delays in patient's access to medical care), are a few of the contributory events related to this chain.

Implementation of any screening program is always challenging whether the facility is costly or free.<sup>7</sup> Scrutiny from the regulatory body and participation from the target population are needed.<sup>8,9</sup> Breast cancer screening is not an exception, and can only be effective if deficiencies can be fulfilled,<sup>10</sup> and any mistakes

avoided. Screening can be successful with an early cancer detection (i.e., at an earlier stage) and better management. However, some cancers can be missed even on screening, or appear later during the interval between two screens (i.e., interval breast cancers). Missed breast cancers may be related to technical factors (inadequately imaged), and morphological characteristics (small sized or with minimal features of malignancy) that can be misinterpreted as benign on initial screen (i.e., reporting error).<sup>11</sup>

We aim to highlight various causes of missed screening-detected incident breast cancers (i.e., cancers diagnosed on a second or subsequent screen in women after initial or baseline negative studies), and to emphasize measures that could overcome weaknesses in the chain of events.

## PATIENTS AND METHODS

We retrospectively reviewed data of Saudi women who came to our radiology department in Dhahran for screening mammograms in a period of three years, from July 2015 to July 2018. The screening population included asymptomatic women who either voluntarily requested screening (i.e., self-referrals), or were referred by clinicians for screening through outpatient clinics in the specified period. Symptomatic women (with palpable nodule or mass) requiring diagnostic mammograms or BI-RADS categories >2 at screening, women with a prior breast biopsy or intervention (excision, lumpectomy, mastoplasty) cases, interval breast cancers (cancers detected during inter-screening period or before the next scheduled screen), lapsed attenders (women who did not appear on any subsequent screening) were excluded. All clinical and radiologic information were kept strictly confidential. Clinical information and radiographic/imaging findings were acquired through patient clinical notes, hospital information systems, radiology information systems, or picture archiving and communication systems. As the study was retrospective and did not involve disclosure of any patient information and privacy, the ethics committee of our hospital waived the need for patient consent. A literature review was performed through electronic search (Google Scholar, PubMed).

A screening mammogram was defined as a mammogram that was acquired in an asymptomatic woman (i.e., with no palpable nodule, lump, swelling or nipple discharge) aged 40 years or older. Regular or routine subsequent screening after an initial negative (BI-RADS 1 and 2, Breast Imaging Reporting and Data System) study was performed in our department on yearly (annual) basis. Screening in women younger than 40 years

was also offered in cases of strong family history of breast cancer (i.e., mother or first-degree relative with breast cancer).

A 'missed' breast cancer was defined as a cancer that was detected on a regular or subsequent screen with an initial or baseline negative screening exam, where the index screen was abnormal (false negative) as reviewed by two radiologists. These were categorized in to: (a) technical or imaging acquisition (IA) related (lesions not covered), (b) morphologic or imaging feature (IF) related (too small a lesion, benign features, obscured by dense breast), and (c) reporting or imaging interpretation (II) related (single reader, reporting error). True ('occult') incident breast cancers were labelled when newly detected cancerous lesions were detected on a second screen, where the cancers were not visible on an index screen.

Digital screening mammograms were performed on Hologic Selenia Dimensions (Toshiba) 2010, obtaining standard CC (craniocaudal) and MLO (mediolateral oblique) views. Mammograms were interpreted by two experienced general radiologists (with special interest in breast imaging) as per BIRADS 12 lexicon. The presence of a mass or nodule with spiculations, microcalcifications and associated architectural asymmetry or distortion were observed and scaled accordingly. Moderate to substantial inter-observer agreement was seen between the two readers for initial screening interpretation (Kappa=0.61) and for subsequent screening

(Kappa=0.69). No major discrepancies were observed, and imaging results were finalized by consensus reporting. Only biopsy-proven cases were considered positive for breast cancers. Reasons for non-compliance to regular imaging/ 'no-shows' were recorded through a departmental approved attached mammography questionnaire form that was completed by the patient in the presence of a technician or a doctor at the time of patient's (late) visit. Reasons for noncompliance were personal (e.g., not feeling so because of no symptoms, forgetfulness, fear of disease, illness or sickness, accident, event, travel etc.), social (e.g., family function or event, marital issues or constraints etc.), and others (e.g., no referral from the primary physician, economic or financial issues etc.) Percentage estimations for causes linked to detected breast cancers were made and presented.

## RESULTS

Mean (SD) age of screening women was 50.1 (6.9) years with an age range of 35-71 years. No significant association of any age group with detection of breast cancer noted ( $P=.10$ ).

Of 15 (1.6%) screening-detected breast cancers, 7 cases (46.6%) were missed; 3 (43%) of these were II related, 2 (28.5%) each of IA and IF (**Tables 1 and 2**). The true (occult) cases were detected on either a second (5 cases) or third screen (3 cases). Four cases of missed breast cancers are shown in **Figures 1-4**. Most of the breast cancers were intraductal carcinomas (6 of 7 missed cases and both of true incident cases) on biopsy. One patient with a missed cancer (IF) in young female with a positive family history had lobular carcinoma. True cases had tumor sizes between 10-15 mm, while the missed cases had sizes between 10-25 mm.

## DISCUSSION

If screening reduces breast cancer mortality by 15%, 1 out of 2000 women would be saved over 10 years.

**Table 1.** Screening outcome by age group.

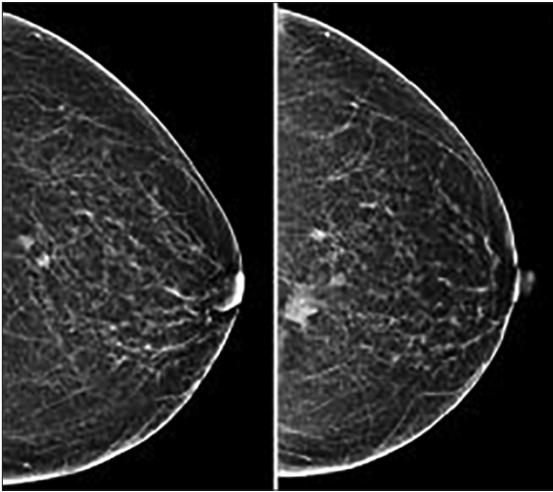
Age group	Cancer detected	Cancer not detected	Total
<40	3 (4.8)	59 (95.2)	62 (6.6)
40 to 50	6 (1.3)	469 (98.7)	475 (50.4)
>50	6 (1.5)	400 (98.5)	406 (43.1)
<b>Total</b>	<b>15 (1.6)</b>	<b>928 (98.4)</b>	<b>943 (100.0)</b>

Data are number (percentage).

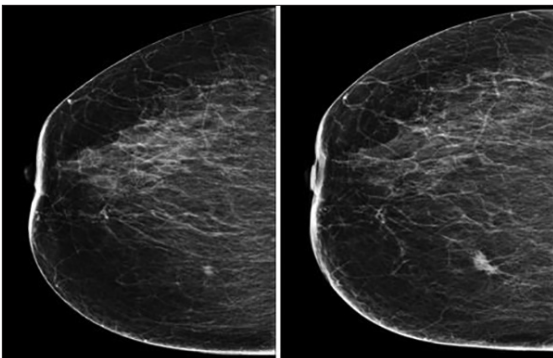
**Table 2.** Distribution of missed and true screening detected breast cancers by age groups (IA: imaging acquisition, IF: imaging feature, II: imaging interpretation).

Age group	IA-related Missed	IF-related Missed	II-related Missed	True Incident (Occult)	Total
<40	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3
40 to 50	2 (33.3)	0 (0.0)	1 (16.7)	3 (50)	6
>50	0 (0.0)	0 (0.0)	1 (16.7)	5 (83.3)	6
<b>Total</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>8</b>	<b>15</b>

Data are number (percentage).

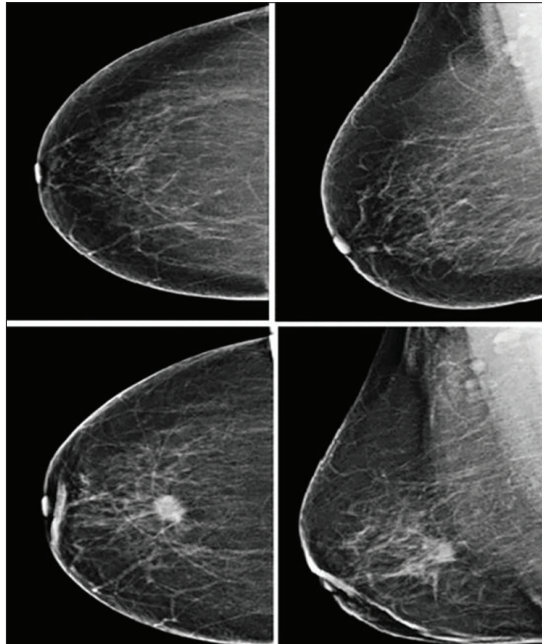


**Figure 1.** An example of IA (imaging acquisition) related cause of an interval breast cancer. A screening (on the left) and a one-year follow-up (on the right) mammogram are shown. Note that on the follow-up study, breast tissue was adequately pulled out and the nipple was seen in-profile to depict a deep-seated tumor.

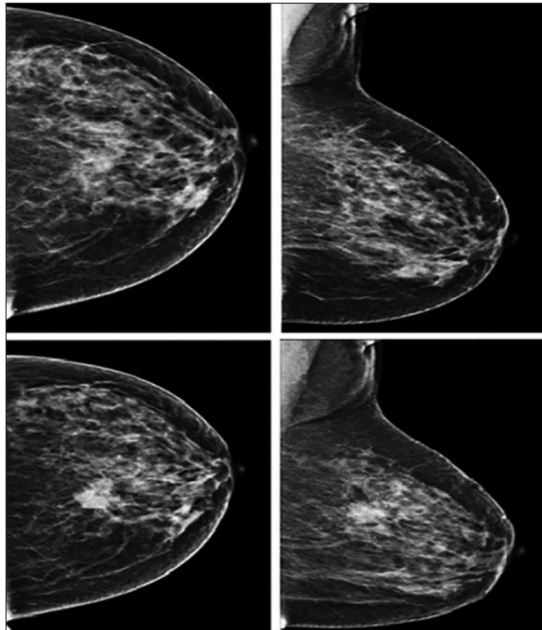


**Figure 2.** An example of II (imaging interpretation) related cause of an interval breast cancer. A screening (on the left) and a one-year follow-up (on the right) mammogram are shown. Retrospective review showed a very small nodule with subtle minimal spiculation.

Effective breast cancer screening can detect non-advanced or early stage cancer.<sup>14</sup> An increase in the incidence of true (occult) breast cancer has been observed in the transition from film screen to digital mammography.<sup>15</sup> Although our study was of a small scale and short duration, we discovered some important findings. We observed relatively higher percentages of both incident (15 cases, 1.6%) and missed (7 out of 15, 46%) breast cancers in our study. Hoff et al found a 0.24% cancer detection rate on screening with digital mammography and a 20% missed rate.<sup>11</sup> We feel that this variability in percentage outcomes might be related to various factors, like (i) screening was not organized, and did not



**Figure 3.** An example of IC (imaging compliance) related cause of an interval breast cancer. A screening two-view (CC and MLO) right breast mammogram (upper row images) and a more than two-year follow-up mammogram (lower row images) are shown. There was no evidence of a lesion on initial screen while the follow up mammogram showed an obvious irregular lesion.



**Figure 4.** An example of IF (imaging feature) related cause of interval breast cancer. A screening two-view right breast mammogram (upper row images) and a year after follow-up mammogram (bottom row images) are shown. On the initial screen (upper row images), a partly obscured and over-looked lesion was seen on a background glandular parenchyma.

involve general registered population, (ii) screening was single-center hospital-based, perhaps catering to a certain population (iii) lack of administrative structure for implementation, quality assurance, and monitoring purposes, (iv) cancer detection rates were not point-incident, but rather a cumulative percentage of detected cases in the second and third screen, (v) lack of familiarity with patient's level of awareness and perception, especially in cases of voluntary participation. These, along with regional variations and differences in the screened population (rural or urban, ethnicity), limit comparisons of our study with larger scale population-based organized screening programs. However, our screening-detected cancer rate was lower than in local data presented by Al Mulhim et al who observed a cancer detection rate of 5.3% (47 cancer patients out of 8061 women in 5 years) during screening in the Eastern province of Saudi Arabia.<sup>16</sup> Despite the fact that Abulkhair et al found an encouraging public response for breast cancer screening,<sup>17</sup> El Bcheraoui et al noticed that more than 90% of women in Saudi Arabia between the ages of 50-74 years reported never having a mammogram.<sup>18</sup> Therefore, country-wise or region-based enrollment of women needs to be implemented, besides a central cancer registry and facilitation to ensure participation of candidates for any screening program. Coldman et al reported that screening participants (of Canadian population) had 40% less breast cancer mortality than non-participants.<sup>19</sup> Also, relatively smaller-sized tumors, less aggressive and node-negative disease were observed by Braun et al in a German screening program accounting for more breast conservation surgeries among the participants.<sup>20</sup> We therefore suggest that implementation of an organized screening program greatly affects timely diagnosis of breast cancer and its treatment at an early stage with better prognosis. Good communication between a radiologist, patient and her referring physician at the time of examination or after mammogram reporting can result in better compliance towards scheduled bookings. 'No-shows' can also be avoided by frequent reminder alerts (in the form of direct phone calls or mobile messages) by the appointment/ booking officer one day prior to the scheduled dates.

'Imaging interpretation' (II) was an important cause of missed breast cancer in our study. We observed that these cases (3 in number) were retrospectively appreciable but of smaller sizes on initial screens (false negatives). In one case, we found a small lesion with a quite subtle marginal speculation that was misinterpreted as a benign lesion (with no further imaging or follow up workup suggested), while in another case the lesion was not properly described in the report (because of

its indistinct appearance on dense background parenchyma). One case was not picked up on initial screen due to its smaller size and deeper location. We observed that two cases were overlooked by obscuration because of dense breast parenchyma in a young woman- an 'imaging feature' (IF) related cause, that was statistically significant (**Table 2**). Such dense fibroglandular and increased parenchymal density in younger or post-menopausal women (taking oral contraceptives) limits mammographic sensitivity. These misinterpretations or reporting errors (II and IF) were seen on a single reading by different radiologists during their respective batch reporting. It has been emphasized by researchers that 'double reading' (by two radiologists) and use of computer aided detection (CAD) help in avoiding such mistakes.<sup>21</sup> Even so, a single reading with CAD was equivalent to double reading results. Moreover, mammographic interpretation by a dedicated breast radiologist also can add to better interpretation and mammogram reporting.<sup>22</sup> We were lacking these in our study, and strongly feel that adopting these options could have helped in avoiding such false negative cases.

Imaging acquisition'(IA)-related causes of missed breast cancers were seen in two cases, both of these were seen at deep locations close to the chest wall and were found on the next screening studies with adequate views. We found that simply observing the standard practice of having nipple in-profile configuration (by pulling the breast tissue outward during acquisition) and attempting to include the pectoral muscle on CC view may help to see deeper or hidden breast tissue in a better way. A trained mammo-technician and prior quality check by the radiologist are therefore suggested to avoid this issue. Two cases of imaging feature (IF)-related causes were related to dense fibroglandular breast tissue against which subtle small lesion or developing architectural asymmetric density may be masked. Dense breast tissue is not only a known risk factor for breast cancer, but also sometimes hinders identification of underlying small cancerous lesion. Care and observation by the radiologist, and the need for an additional (magnified) view or imaging (like breast tomosynthesis or ultrasound) may be helpful to better assess a suspected or camouflaged lesion. Though it took a longer time to read, Aase et al reported a lower recall rate by employing digital breast tomosynthesis (DBT) when compared to digital mammography.<sup>23</sup> MRI may also be considered in younger patients (aged less than 40 years) to avoid x-ray exposure with mammographic views and tomosynthesis.

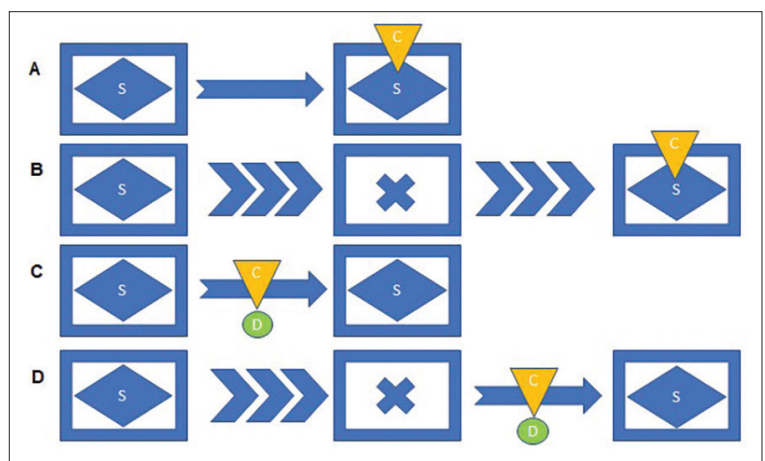
Eight cases of true (occult) incident breast cancers were observed in our study. Of these, we found

5 patients who either skipped or missed their second screen (due to personal/social reasons or general practitioner's advice), remained asymptomatic, appeared on their third screen and were detected as breast cancers (**Figure 4**). We did not include similar but symptomatic cases who presented during the inter-screening period and had cancers detected on diagnostic mammograms i.e., interval breast cancers (**Figure 5**). Detection of occult cancers in women 50 years and above in our study was statistically significant (**Table 2**), highlighting the fact that cancers in this age group are more common to be detected on regular screens, and may be treated earlier. Therefore, 'imaging compliance' (IC) and 'imaging referrals' (IR) are also important considerations for a successful screening, to identify and minimize potential delays or limitations in seeking medical advice. Educating patients and general practitioners are therefore suggested to improve awareness among women, thereby improving the effectiveness of the screening program. A nationwide screening program may also help to ensure mass education (through seminars and campaigns) and participation of women in screening, and to improve efficiency.

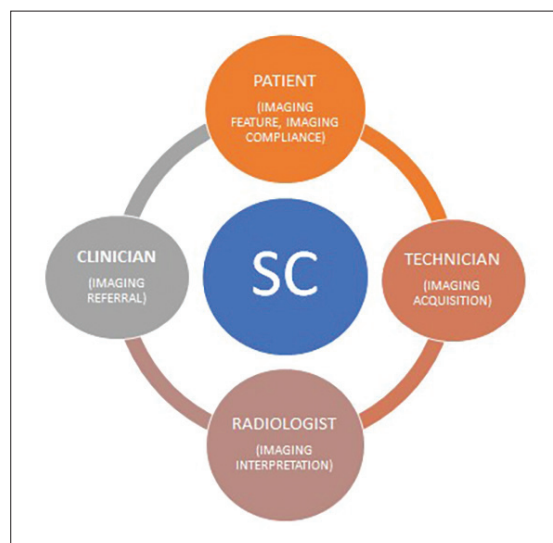
We tried to highlight three important 'components or links' in the chain of any breast cancer screening program (**Figure 6**), namely the technician, patient and doctor (physician, radiologist). A detailed clinical examination, identification of high-risk patients (i.e., those with a family history of breast cancer) and timely referral for an imaging (either for an ultrasound or mammography based on age and condition of patient) by the physician, adequately acquired and quality mammograms by a trained technician, quality assessment and proper standardized reporting by a radiologist, and clear understanding, compliance to regular imaging follow-up and recommendation by the patient, all contribute towards an effective screening program. Onega et al highlighted a similar concept and labelled them as key domains influencing process and outcome measures.<sup>24</sup> Unfortunately to date, there is neither a nation-wide breast cancer screening program nor a breast cancer registry (database for all the regions) available in Saudi Arabia, though breast cancer awareness campaigns and local hospital-based or personalized screening programs are in progress. We strongly suggest that at places where mammography services are available and screening is offered, at least a hospital-based cancer registry and data services should be maintained even if the hospital is not an oncologic center.

Use of breast tomosynthesis (3D Mammography) has been increasing for both screening and diagnostic purposes. It should be noted that an increased radia-

tion dose by breast tomosynthesis has been highlighted by researchers like Gennaro et al that compared the radiation dose delivered by digital mammography and breast tomosynthesis in more than 1000 women, and found an average increased dose of 38% with breast tomosynthesis.<sup>25</sup> However, evidence of its clinical benefits as presented by Hass (reduced recall rate and increased cancer detection by tomosynthesis group),<sup>26</sup> and later on by Hofvind et al (significantly higher rates of cancer detection by tomosynthesis with synthetic mammography screening compared to digital mammography screening)<sup>27</sup> outweighed its risks. Houssami et al also reported slightly lower interval breast cancer rates and



**Figure 5.** Diagram showing screening-detected (A and B) and interval breast cancers (C and D). S: screening mammography, C: cancer detected, D: diagnostic mammography, Interrupted arrow: asymptomatic, cross (sign): screening skipped or missed.



**Figure 6.** Components of screening programs and causes of missed breast cancers.

increased screening sensitivity with tomosynthesis as compared to standard 2D-mammography (an 85% compared to 77%) as presented in the STORM trial.<sup>22</sup> Newer imaging options like infrared digital imaging (detecting increased thermal activity in pre-cancerous tissues) as explored by Mambou et al may prove promising in upcoming years for early detection of breast cancer.<sup>28</sup> Larger scale multicenter studies are needed to establish the potential benefits of such techniques and their implementation as a standard screening approach in Saudi Arabia.

The limitations in our study included a retrospective, small sample-sized, single center, and short duration study. We also considered the limited availability of dedicated mammo-technicians and breast radiologists (in whole year), a deficient double reporting of the mammograms, unavailability of computer-aided detection and even the absence of an oncologic department as factors contributing towards such missed breast cancers. Also, we noticed lapses in communication and deficiencies in patient data and reminder alerts/recall system for the women also partly contributed towards delays in patient compliance towards imaging and recommendations. Therefore, it will be wise to consider radiologic surveillance of as a benchmark for assessing the effectiveness of any breast cancer screening program, by which limitations or deficiencies can be identified and fixed. Improved screening facilities, quality mammographic acquisition and in-

terpretation, double reading, and implementation of an organized screening program may help to avoid missed breast cancers.

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#### **Author contributions**

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*Conception and design, actual write-up of manuscript*

*Dr. Muhammad Zia Ul Hassan*

*Conception and design, patient selection*

*Dr. Donya Al Hassan*

*Data interpretation and critical appraisal of findings*

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*Zechariah Jebakumar*

*Statistical analysis*

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