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REVIEW ARTICLE

How Much Radiation Are Women in Saudi Arabia Receiving from Mammography? A Review

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Abstract

This review compiles and assesses data from recent studies on mammographic radiation doses in Saudi Arabia, aiming to evaluate mean glandular dose (MGD) exposure during mammography and its implications in breast cancer risk. The reviewed studies spanned from 2019 to 2023 and included a range of sample sizes and institutional settings, with patients' ages from 27 to 85 years. Considerations such as the number of mammographic views and compressed breast thickness were examined. The studies reported average MGDs below the National Diagnostic Reference Level set by the Saudi Food and Drug Authority. However, limitations were noted regarding sample size selection and incomplete data on all mammographic projections. Despite these limitations, the findings highlight the need for continued assessment of patient doses to optimize mammography practices and address the absence of quality standardization acts in Saudi Arabia. These insights are critical for governing authorities to ensure that effective patient dose monitoring occurs regularly and that the establishment of minimum quality standards for breast cancer screening is intact.(International Journal of Biomedicine. 2024;14(2):235-239.)

Keywords: mammography • breast cancer • patient dose • diagnostic reference level

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Abbreviations

BC, breast cancer; CR, cancer risk; CC, cranio-caudal; CBT, compressed breast thickness; DRLs, Diagnostic Reference Levels; ESAK, entrance surface air kerma; ICRP, International Commission on Radiological Protection; MGD, mean glandular dose; MLO, mediolateral oblique; MQSA, Mammography Quality Standards Act; NDRLs, National Diagnostic Reference Levels; QAP, quality assurance program.

Introduction

Breast cancer (BC) is a significant health concern and the main cause of cancer death in women globally, with an estimated 2.3 million new cancer cases and 685,000 cancer deaths in 2020, as per the Global Cancer Observatory (GLOBOCAN) database from 185 countries.⁽¹⁾ The incidence of BC among women in Saudi Arabia is higher than the global average, accounting for 28% of all cancers in the country.⁽²⁾ It is a major health concern, especially among women, and its prevalence is expected to rise in the coming years.⁽³⁾ The precise detection and prediction of

***Correspondence**: Sarah K. Albahiti, King Abdulaziz University, Jeddah, Saudi Arabia. E-mail: <u>sarahalbahiti@gmail.com</u> BC are critical for better patient outcomes. Machine learning techniques, such as Explainable Artificial Intelligence, have been used to predict benign and malignant BC based on clinical and pathological characteristics.⁽⁴⁾ Furthermore, BC survivors in Saudi Arabia have poor health-related quality of life, which is influenced by a variety of factors, such as age, type of therapy, and comorbidities.⁽⁵⁾

Different imaging modalities, including mammography, are used for accurate diagnosis and screening of breast tissue. Although it remains the gold standard for screening to date, mammography still has its limitations due to small differences in contrast between normal and malignant tissues. On the other hand, mammography has provided evidence that it is beneficial in detecting BC at an early stage, when changes in the breast are often too small to detect by self-examination.⁽⁶⁾

Efforts to improve the current situation must address several factors, including patient, public, and medical team awareness levels, to further improve outcomes.

Al-Wassia et al.⁽⁷⁾ conducted a cross-sectional study of 3,245 women aged 40 and older in five geographic regions of Saudi Arabia to assess mammography utilization, knowledge, and barriers. They discovered that mammography utilization and knowledge were poor, and they concluded that raising awareness through educational initiatives could assist in overcoming current barriers and misconceptions.

In addition, medical students in Saudi Arabia were found to have low awareness of BC, but there is a willingness to participate in BC prevention activities.⁽⁸⁾ Text mining algorithms and natural language processing models have been used to analyze clinical data and extract valuable insights from medical notes of BC patients in Saudi Arabia.⁽⁹⁾

Nevertheless, the radiation dose involved in mammography imaging is of concern because glandular tissue is sensitive to radiation, and the procedure itself could add to the risk of BC development.⁽¹⁰⁾ Mammographic procedures typically involve two views for each side, with reported average doses ranging from 1.1 to 2.2 mGy per view and 2.0 to 5.4 mGy per breast.⁽¹¹⁾ This is highly dependent on several factors like compressed breast thickness, technique used, positioning, qualifications of staff, and the frequent need for more projections or views for full assessment. Assessing patient doses during mammography is necessary to ensure compliance with guidelines for radiation protection safety and to minimize unnecessary exposure.

Despite the potential risk of radiation-induced malignancy, the benefits of mammographic imaging, such as early detection and reduced mortality risk, outweigh the associated risks. The benefit can reduce the mortality rate up to 25% of the screened female population and avoid aggressive treatment.⁽¹²⁾ This is on the condition that centers providing screening and diagnostic mammography services are aware of every patient dose and undergo a comprehensive quality assurance program (QAP). Implementation of a QAP in every mammography facility is crucial. Such programs include protocol evaluation, quality control tests, radiographer and radiologist qualifications, sample image quality assessment, and peer-reviewed reports.

The US Congress passed the Mammography Quality Standards Act (MQSA) to govern the quality of care provided by mammography service providers.⁽¹³⁾ The Act was implemented in 1994. In 1995, the US FDA began inspecting mammography facilities to ensure their compliance. This Act aimed to create basic requirements for ensuring that all women have access to quality mammography treatments.⁽¹³⁾ The MQSA requires that an FDA-approved accreditation body accredit facilities. Currently, the American College of Radiology is the only nationally approved body.⁽¹⁴⁾

In addition, the International Commission on Radiological Protection (ICRP) has emphasized the need for QAPs in mammography to ensure high-quality images and accurate BC diagnosis.⁽¹⁵⁾ QAPs are systematic actions, including quality control checks, that provide high-quality images while limiting radiation exposure.⁽¹⁶⁾ Implementation and continuous evaluation of QAPs have a direct impact on improving mammography image quality and reducing patient dose, resulting in enhanced BC diagnosis and management.⁽¹⁷⁾

Continuous attempts to improve mammography quality and safety in Saudi Arabia started in 2020.⁽¹⁸⁾ Currently, MQSA and similar local accreditation programs for mammography facilities are non-existent. In addition, there is a lack of comprehensive data on the radiation doses received by women undergoing mammograms in Saudi Arabia. Patient radiation doses from diagnostic imaging procedures in many healthcare centers are unknown and not documented in their medical records. The Saudi Food and Drug Authority published National Diagnostic Reference Levels (NDRLs) in early 2023 for mammography and issued a higher decree to force healthcare providers to compare their patient doses to the National Diagnostic Reference Levels (NDRLs) and establish their own Diagnostic Reference Levels (DRL).⁽¹⁹⁾

The International Atomic Energy Agency has set Diagnostic Reference Levels for diagnostic examinations, such as mammography, to enhance patient safeguarding by minimizing unnecessary radiation exposure. DRLs are used as reference points but are not intended to be dose restrictions but rather as benchmarks to ensure that doses are maintained at the lowest possible level while still obtaining the necessary diagnostic information.⁽²⁰⁾

In mammography, DRLs are usually established based on the average glandular dosage to the breast. They vary across countries and are often established using nationwide surveys of patient dose data, considering the specific equipment, procedures, and practices employed in each country. Healthcare providers should regularly assess their doses and compare them with NDRLs. If consistently exceeding the DRLs, providers should evaluate their practices and make necessary adjustments to reduce doses without compromising image quality. Maintaining image quality is crucial for the accurate detection of BC.⁽²¹⁾

The existing literature on radiation doses from mammograms predominantly focuses on Western populations, with limited information available specifically for practices in Saudi Arabia. Comparable studies from neighboring regions provide some insights into the radiation doses received during mammography, but we still need more national studies to document and optimize the doses the Saudi population is receiving. Therefore, this study reviews all articles that document radiation doses from mammography in Saudi Arabia.

Radiation Exposure in Mammography

The MGD, which refers to the average amount of radiation absorbed by breast glandular tissues, is the preferred dosimetry quantity for evaluating potential risks, as recommended by the ICRP.⁽²²⁾ The MGD is indirectly approximated using the entrance surface air kerma (ESAK) and half-value layer. It is determined using established breast parameters. Thus, MGD is estimated by utilizing the ESAK and conversion coefficients by Dance et al.⁽²³⁾

The number of views for a mammography imaging procedure varies depending on the specific case and the diagnostic requirements, but it typically involves four views, with two views for each breast in different projections: craniocaudal (CC) and mediolateral oblique (MLO).⁽²⁴⁾ Sometimes, a mediolateral (ML) projection is added to both CC and MLO.

However, additional views may be necessary to cover all breast tissue, with 12% of screen-film mammography cases and 21% of full-field digital mammography cases requiring more than the normal four views to achieve comprehensive coverage.⁽²⁵⁾ Additionally, spot compression, magnification, extended views, and additional views, may be necessary to characterize and localize abnormalities.⁽²⁶⁾

The NDRL for mammography, published by the SFDA in 2023, is 1.5 mGy for CC view. The SFDA has still to publish the full range of projections in 2024.⁽¹⁹⁾

Estimation of CR during mammography procedures

The ICRP has assessed and measured the probability of developing cancer, namely malignant tumors, to be 5.5%. The radiation-induced risk coefficient for BC is 116×10^4 Sv⁻¹. This coefficient was used to calculate the possibility of developing cancer per medical exposure.⁽²²⁾

Estimating CRs during mammography procedures is a critical consideration in BC screening. The cumulative risk of an invasive procedure with a benign outcome from mammographic screening has been reported to range from 1.8% to 6.3%.⁽²⁷⁾ Additionally, factors such as double mammogram reading, number of views, digital mammography, menopausal status, hormone replacement therapy, previous invasive procedures, and familial history can increase the risk or lead to false positives.⁽²⁸⁾

Methods

A literature search was conducted using Scopus, PubMed, and Google Scholar databases for studies reported on mammography patient doses conducted in Saudi Arabia between 2013 and 2023. The search terms used were "mammography in Saudi Arabia," "patient dose," "radiation dose," and "diagnostic reference levels." Abstracts of all results were reviewed to assess suitability for the review's purpose of identifying women's radiation exposure from mammography in the Saudi population. In addition, references in each paper were tracked down to find more relevant publications. Studies in languages other than English conducted on men or phantoms were excluded. Data measured in Saudi hospitals were included in this review, represented in five original articles.

Results

Since radiation dose from mammograms may increase the risk of developing cancer, this study intended to quantify radiation doses and estimate the cancer risks. Sixty patients (an average age of 44) were evaluated using a digital mammography unit at King Khaled Hospital in Alkharj (Saudi Arabia).⁽¹⁰⁾

The average ESAK was 4.4 ± 1.1 mGy, with a range of 1.7-7.9 mGy. The average MGD per procedure was 1.1 ± 0.26 mGy, with range from 0.4 to 1.9 mGy. The third quartile values for ESAK and MGD were 5 and 1.2 mGy, respectively.⁽¹⁰⁾

The total number of views for each patient was 6, 3 on each side. The average MGD per projection (view) was reported for CC, MLO, and LM as follows: 1.02 ± 0.2 mGy for CC view and 1.1 ± 0.3 mGy for MLO and LM. In addition, the study

concluded that 80% of the procedures had normal findings, but precise justification is required for young patients. Also, CR was calculated using mean organ equivalent dose and radiation risk factors product. Suleiman et al. estimated CR per projection was 177 per million procedures. The study's main limitation is the small sample size (60) and the fact that no mention was made of how the patients were chosen nor the institution's daily mammography load.

Local DRL based on patient radiation exposure during digital mammography was established at Riyadh Care Hospital (Rivadh Saudi Arabia).⁽²⁹⁾ The authors included 1055 participants with mammography procedures using a direct digital mammography system. Patient age ranged from 28 to 75 (mean of 51.65±9.3), and compressed breast thickness ranged from 19 to 125 mm (mean of 55.1±13.9). The study reports exposure parameters but does not report the total number of views patients received during a mammography exam. The average ESAK was 5.19±3.18 mGy, with a range of 0.33-29.9 mGy. The average MGD per procedure was 1.3±1.0 mGy. The third quartile values for ESAK and MGD were 6 and 1.5mGy, respectively. This study also does not report the total number of views patients received but the total procedure dose. Furthermore, the authors have not reported individual projection average doses within their center to compare them to the NDRL.

A study conducted at Najran University Hospital (Najan, Saudi Arabia) included 85 patients who underwent mammography studies.(30) Their protocol for suspicious cases exposes patients to three projections (CC, MLO and ML) for each side, like Suleiman et al.;(10) therefore, a total of 510 mammograms were assessed. Patient age ranged from 27 to 71 and most of the patients (71%) were between the ages of 30 to 50. The author stated that since they are young, "They are more vulnerable to risk than older patients."(30) Compressed breast thickness for the study population ranged from 24 to 76 mm. The average MGD and ESKD was 1.1 and 4.3 mGy respectively. The study reported the average MGD for each of the three projections and their associated exposure parameters. In addition, they correlated the patient doses with compressed breast thickness (CBT) (Table 1). Finally, the study estimated two cancer cases per 10,000 patients per breast as the CR due to mammography.(30)

Table 1.

Compressed breast thickness in millimeters and average mean glandular dose for the three projections.⁽³⁰⁾

Parameter	Projection			
	CC*	MLO*	ML*	
CBT, mm	$\begin{array}{c} 43.5\pm 5.0\\(24.0 \text{ to } 63.0)\end{array}$	53.4 ± 11.0 (29.0 to 76.0)	$\begin{array}{c} 50.2 \pm 7.4 \\ (27.0 \text{ to } 69.0) \end{array}$	
MGD, mGy	1.01 ± 0.3 (0.3 to 1.7)	$\begin{array}{c} 1.09 \pm 0.2 \\ (0.4 \text{ to } 1.8) \end{array}$	$\begin{array}{c} 1.09 \pm 0.2 \\ (0.4 \text{ to } 1.9) \end{array}$	

*Mean ± SD (range)

Alahmad et al.⁽³¹⁾ studied the radiation dose exposure of 167 patients, representing a randomly chosen small sample from King Fahad Medical City (Riyadh, Saudi Arabia), where over 3436 patients had bilateral mammograms from January 2020 to July 2023. Patient age ranged from 30 to 85 and compressed breast thickness from 20 to 86mm. The average MGD and ESAK was 1.17 and 5.87 mGy, respectively, for the single reported projection. In addition, patients were grouped according to their age: under 40, from 40 to 49, from 50 to 64, and above 64 to report the same projection data for the individual groups. The highest average MGD was 1.3 mGy in the 40-49 age group. Patients were also grouped depending on compressed breast thickness, where 29 mm and less received an average MGD of 0.71 mGy, from 30 to 49 mm received 0.8 mGy, and those 50 mm and above received 1.49 mGy. The main study limitation was that no MLO data was retrievable, and the researchers only reported CC view data, while a full mammogram procedure will always include at least 2 CC and 2 MLO for each patient. The authors have not specified how the small number of patients were selected from the larger pool of patients they scanned during the study period.

A group of researchers at King Fahd Hospital at Imam Abdulrahman Bin Faisal University (Al-Khobar City, Saudi Arabia) conducted a study between May 25 and November 4, 2021, to document patient radiation doses in diagnostic imaging.⁽³²⁾ Data management software was used to extract dose information from mammography and radiography patients. The study evaluated the impact of this software on radiation dose, developed DRLs, and documented achievable doses in mammography and radiography. Still, for the sake of the review, only their mammography data was evaluated. The study population included 2897 mammographs from 795 patients (average of 3.6 images per patient) using a combomode technique (two-dimensional and tomosynthesis) for screening and diagnostic protocols. Also, the authors have categorized the results of this paper in terms of two phases: pre and post-implementation of software.(32) There was no valid explanation why the average accumulated MGD had increased significantly in the post-implementation phase compared to the pre-implementation phase, from 5.65 to15.6 mGy. Also, the average ESAKs were 8.67 mGy and 9.20 mGy in the pre- and post-implementation phases, respectively. The limitation of this study is that it included data from seven men, but when reporting the MGD and ESAK the data was grouped together, which might have shifted the results and DRLs slightly. Similarly, the authors reported average MGD and ESKD per side (right and left breast) and not per projection; therefore, the results couldn't be compared to NDRL or the other four studies in this review (Table 2).

Table 2.

The average MGD reported in the reviewed studies in comparison				
with the NDRL published by the SFDA.				

Author	MGD (mGy)	Projection
Suleiman et al, 2019 (10)	1.1	Per view (CC)
Tamam et al, 2021 (29)	1.3	Per procedure*
Saeed et al, 2021 (30)	1.01	Per view (CC)
Alahmad et al, 2023 (31)	1.17	Per view (CC)
SFDA NDRL (19)	1.5	Per view (CC)

* No specific view projection was described, and no number of views was reported for each procedure.

Conclusion

Although there is limited data on the topic, these studies may offer valuable reference points for assessing the situation in Saudi Arabia and guiding further research endeavors. The current situation requires answers to a different question: Is it only about how much women are receiving from mammography procedures or also who is measuring? The percentage of mammography service providers who do not measure and patient doses that remain unknown is large. With the lack of licensing and monitoring of mammography facilities comes low quality images that result in unnecessary exposure. Therefore, the reviewed studies provide a comprehensive overview of the present measured patient doses and the need for continuous assessment to ensure the current practice is optimized under the prevailing lack of quality standardization acts for mammography within the country. All the research represented here demonstrates the crucial need for the governing authorities to enforce patient dose monitoring in mammography and set quality standards, especially for screening purposes.

Competing Interests

The authors declare that they have no competing interests.

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