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Research Article

Diagnostic Reference Levels in Mammography in the Asian Context

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Abstract

Background: Breast cancer is the most frequent cancer among the female population globally. Therefore, early detection is helpful for effective treatments and to reduce the mortality rate. Mammography is a radiological examination done with low-energy X-rays to detect abnormalities in breast tissue. This study aims to review the literature to evaluate the techniques, protocols, and conversion factors used to determine the diagnostic reference levels (DRLs); within the Asian continent using both phantom- and patient-based data.

Methods: Related articles were systematically reviewed via Pub Med, Google scholar, and freehand search with the aid of relevant terms. Related abstracts in English were screened, and suitable articles were selected after reviewing the full-text. Four hundred and thirty abstracts were screened for relevance, and 12 articles were selected.

Results: The study comprises four phantom-based and eight patient-based studies. The studies varied between the types of test subjects, conversion factors, breast compression thickness, and dose calculation protocols. This obstructs continuing the DRLs with the updates and comparisons among countries. Establishments of DRLs in Asian countries are less than the rest of the world. DRLs should be measured continuously, and should be updated based on other clinical parameters of the patients.

Conclusion: DRLs in mammography were measured from time to time in different geographical locations in Asia by following various techniques. But when compared with the other regions of the world, there is less consideration for establishing DRLs in Asia. There should be standard protocols and updated conversion factors according to the advancements of the technology to ensure radiation protection with optimal absorbed dose with appropriate image quality.

Keywords: mammography, diagnostic reference level, mean glandular dose

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1. Introduction

Breast cancer is the most frequent cancer among the female population globally. This impacts 2.1 million women each year [1]. In 2018, it was estimated that 627,000 women died due to breast cancer; this was 15% of total cancer deaths among women worldwide [1]. At present, breast cancer cases among Asian women are still lower than in their Western counterparts [2]. However, there will be a gradual growth of reported cases among Asian women in the near future due to the changes in lifestyle and the technical advancements in the diagnostic field [3]. Currently, closer to one-quarter (24%) of breast cancer incidences were reported in the Asia-Pacific region (a total of 404,000 cases at a ratio of 3:100,00 women), and of them, higher percentages were reported among Chinese (46%), Japanese (14%), and Indonesian (12%) females [4]. Early detection of breast cancers is helpful for effective treatments and to reduce the mortality rate. Mammography is a radiological examination done with low-energy X-rays to detect abnormalities in breast tissue. Mammograms are performed on both symptomatic and asymptomatic women. According to the current guidelines of the American College of Radiology (ACR) and the National Comprehensive Cancer Network (NCCN), women in their 40s should begin annual mammogram screening. But those who have had breast cancer previously and who have a family history of breast or ovarian cancer should get medical advice, and must undergo mammography examinations before their 40s [5]. In the Asian region, there are fewer national population-based screening programs. Also, the mortality rate increases due to cultural and economic obstacles and misunderstandings about the disease [4].

Breast tissue is radiosensitive; therefore, mammography examination may induce a cancer risk in healthy women. Therefore, the amount of radiation to the patients during the examination should be kept as low as reasonably achievable (ALARA). According to the International Commission of Radiation Protection (ICRP) recommendations, there are two principles of radiation protection. They are the justification for the protection and optimization of radiation protection while considering diagnostic reference levels (DRLs) [6]. In mammography, mean glandular dose (MGD) is the dose quality management factor [7], and this MGD depends on surface air kerma and conversion factors [6].

According to the Annals of ICRP 2016, there are two methods for dose assessment in mammography. DRL is a parameter used in quality control processes and radiation dose level comparison among different manufacturers. DRL is a selected quantity of radiation dose defined as: an investigation level, applied as a quantitative measurement, on absorbed doses in the air, a simple phantom made up of tissue-equivalent material or directly on the representative patient [8].

In the early stages of medical imaging, mammography was film-screen based and with the advancement of technology the era of computed mammography (CR) and digital mammography (DM) emerged introducing the tomosynthesis techniques, which produces 3D images. This advancement had a significant influence on image quality and dose reduction. However still, most Asian countries do not have any national breast screening programs. In early studies, radiation dose on the breast tissue was measured using various perspectives. Different researchers define the dose as air kerma [9], entrance surface air dose [10], mid breast dose [11], total energy transmission to the breast [12], and average glandular tissue [13]. However, it was later decided that the dose to the breast could be measured as the mean glandular dose (MGD), which is the most effective method of measuring the dose because the mammary glands are highly sensitive to ionizing radiation. At present, authorities responsible for radiation protection such as the International Commission of Radiation Protection (ICRP) [14], the United States National Council on Radiation Protection and Measurements [15], the British Institute of Physics and Engineering in Medicine (IPEM) [44], European Protocol [17], and the International Atomic Energy Authority (IAEA) [18] recommend this standard measurement.

MGD is not a direct measurement, it is calculated by considering certain assumptions and the nature of the breast tissue. Moreover, it is required to consider technical factors of the machine such as kVp, HVLs, tube output, and automatic exposure control (AEC) mode [19]. Conversion factors are established by the Monte-Carlo method [8]. There are both phantom-based established DRLs as well as patient-based DRLs. Phantom-based DRLs do not reflect the clinical environment well due to the variation in the composition of the patients' breast tissue. Therefore, phantom-based DRLs are the best measurements for quality assurance of the machine, while patient-based DRLs give more information for the application in a clinical setting. DRLs are not statistic values; therefore, it should be continuously updated according to the advancement of hardware and software. In 2014, a review was done by a group of Australian researchers regarding the state of the established mammography DRLs in the world [20]. According to their findings, there is less contribution for DRLs in Asian countries. Most Asian countries are yet to develop the DRLs in mammography. This study was done to review the literature to evaluate the current state of mammography DRLs in Asian countries.

2. Materials and Methods

2.1. Search strategy and study selection

This study was done as a systematic review using preferred reporting items for systematic reviews and meta-analyses (PRISMA) [21]. Literature was searched on databases like PubMed and Google Scholar. In addition, articles and other references not available in the databases were cross-searched using Google search. Following search terms were applied *"Mammography," "Mammography Examination," "Screening,"* "*DRLs,*" *"Diagnostic Reference Levels," "MGD," "Average Glandular Dose," "Phantom-based DRLs," "Patient-based DRLs," "Asia," and "Asian countries."* The search was carried out with and without filters, such as the type of article (original research articles), geographical location (Asian continent), and the language (English). As the first step, the articles were selected by screening the title, abstract, and keywords. The abstracts of studies discussing MGD in mammography were taken into a full-text review. After referring to the mammography quality control manual 2018 [22], selected articles were separated as phantom-based and patient-based DRLs. Best matching articles were considered first, followed by the publication date. Studies in the English language were included.

2.1.1. Data extraction

General details such as author names, country, and sample size were extracted in each study. MGD at 75^{th} percentile and 95^{th} percentile was extracted. Two reviewers independently did the data extraction.

3. Results

Twelve articles published between 2000 and 2020 were deemed eligible for inclusion. Figure **1** presents the articles' search strategy. New data synthesis was done by considering the variation of MGD with breast compression thickness at the 75^{th} and 95^{th} percentile values at the distribution.

The selected 12 studies covered the different geographical locations of the Asian continent. Among them, three studies were only on phantom-based data, eight were based only on patient-based data, and one was based on both phantom- and patient-based data. There are four major quality control protocols published by the American

College of Radiology (ACR) [22], the European Protocol (EP) [23], the IAEA, IPSM [16] protocol, and two methods for conversion factors were followed to calculate MGD and determine DRLs.

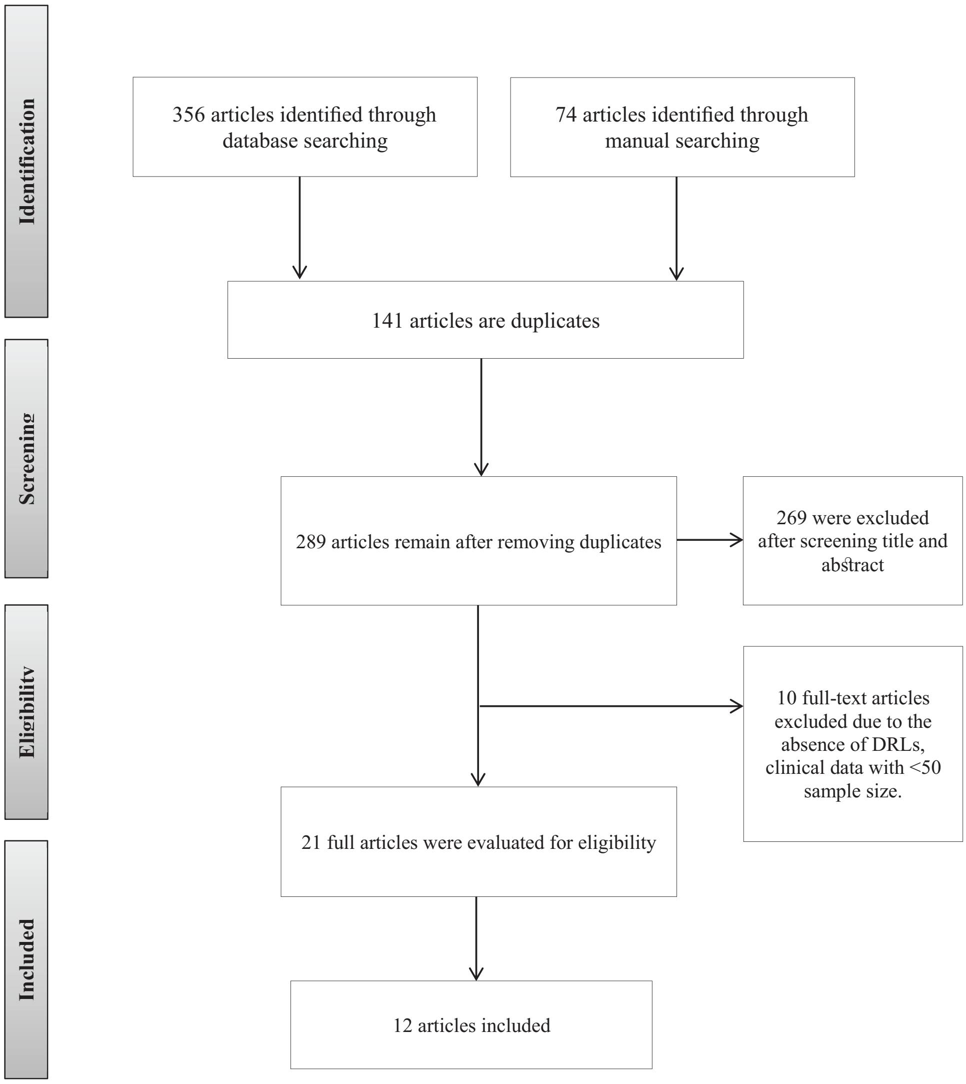

Figure 1: Flow chart of Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA).

3.1. Techniques of DRL measurements using phantom-based data

Phantom is a highly specialized object made up of tissue-equivalent material used in medical imaging for dosimetry, quality control, and equipment calibration. Phantom-based DRLs are essential in assessing the performance of the machine at the installation and ongoing quality control programs. Further, this technique is also crucial in evaluating the DRLs during the comparisons between the previous studies and at the stage of technological advancement. Poly methyl methacrylate (PMMA) is a commonly used phantom material as its radiation transmission property is similar to breast tissues. In this review, phantom-based studies done in Asian countries are selected according to the type of phantom and the protocol used. In most studies, exposures were made under specified technical factors recommended by the manufacturers. Selected machines were DR, CR, or screen film (SFM). Phantoms used in these studies were not identical, and they were different in size and composition. The selected protocols and conversion factors also varied between the studies (Table 1). Three studies measured the entrance surface air kerma (ESAK) value, and the remaining study measured the breast entrance exposure (BEE). When considering protocols and conversion factors, one study has followed the ACR measurement protocol [22] with Wu *et al.* [24] conversion factors. While the other three studies [18, 25, 29, 32]followed the ACR measurement protocol [22]with Dance *et al.* [26] conversion factors. An Indian study [25]used an inexpensive in-house built phantom which consists of PMMA, similar to the ACR PMMA phantom. It also followed ACR protocol [22]with Dance *et al.* [26] MGD conversion factors. However, in these selected studies, DRL values cannot be compared directly without having a unique conversion calculation with a standard phantom.

3.2. DRL measurements using phantom-based data

There is a difference between the DRLs of the same type of phantom, which uses the same protocol and conversion factors. This may be due to the variation of technical parameters of different manufacturers. In a Taiwanese study using the ACR phantom, the 75^{th}percentile was obtained as 1.87mGy [27], but a Turkish study [28]with the same phantom followed the IAEA protocol with Dance *et al.* [26] conversion factors produced the 75^{th} percentile as 2.0 mGy. In the Indian study [25]conducted with an in-house built phantom similar to ACR PMMA, breast entrance exposure (BEE) was measured by placing a thermoluminescence dosimeter (TLD) within the engraved slot of the phantom. Then the MGD was derived from BEE using two different methods. The measured depth ranges in the phantom are 0.32 and 0.40 cm at 75% depth dose, 0.73 and 0.92 cm at 50% depth dose, and 1.54 and 1.78 cm at 25% depth dose. The difference in MGD values determined using two different methods was in the range of 17.5–32.6%. Malaysian study [29] done with RMI156 phantom with ACR protocol [22] and Wu *et al.* [24] conversion factors produced 75^{th} percentile as 1.44 mGy.

3.3. Techniques of DRL measurements in patient-based data

There is a large diversification in breast thickness and granularity within the female population around the world. This leads to a difference between the compressed breast thickness (CBT) and the amount of radiation dose received by the breast during mammography examination. Therefore, establishing patient-based DRLs is significant for optimizing patient-specific radiation protection. A summary of the reviewed nine studies investigating patient-based DRLs is displayed in Table 2. In almost all studies, necessary data for the calculations were obtained from the DICOM images. In addition, all studies except one were conducted according to the European protocol **[23]**. The needed conversion factors were taken from Wu *et al.* **[24, 32]** and Dance *et al.* **[26]**. Most studies considered the absorbed dose for craniocaudal (CC) mediolateral oblique (MLO) views in mammography examinations. All the analyses were done after performing QC procedures in the selected machines. However, it is worth highlighting that according to the results, a wide range of CBT among the female population was observed, and also mammography examinations were done with different imaging modalities of SFM, CR, and DR. Therefore, the variation of the obtained MGD is unable to compare with other studies.

Table 1: Summary of the studies related to Phantom-based DRLs.

Country	Authors/Year	Protocol/Conversion factors	Method of data collection	Phantom type (Thickness/E-CBT/ G %)	Average MGD mGy	DRL mGy 75% 95%
Turkey	Bor *et al.* (2008) [30]	IPSM/Dance *et al.* [26]	Measured ESAK	BR12 (40 mm/45 mm/50%)	1.46	2.0
Taiwan	Hwang *et al.* (2019) [29]	ACR [22]/Dance *et al.* [26]	Measured ESAK (Using TLDs)	ACR PMMA ACR SFM Phantom ACR DM Phantom 42 mm/50%	SFM 1.57 DR 1.55	1.87
India	Sharma *et al.* (2011) [25]	ACR [22]/Dance *et al.* [26] NCRP-149 [31]/Wu *et al.* [24]	BEE	ACR PMMA 50 mm/50%	32–40mm – 75% depth dose 73–92 mm – 50% depth dose 154–178 mm – 25% depth dose	
Malaysia	Jamal *et al.* (2003) [18]	ACR [22]/Wu *et al.* [24]	Measured ESAK	RMI156 42 mm/50%	DR0 50–2.39	1.44

IPSM, Institute of Physical Science in Medicine; ACR American College of Radiology; EP, European Protocol; IAEA; International Atomic Energy Agency; ESAK, Entrance Surface Air Kerma; IAK, Incident Air Kerma; BEE, Breast Entrance Exposure; PMMA, Poly Methyl Methacrylate; SFM, Screen Film Mammography; DR, Digital Radiography; CR, Computed Tomography; EBCT, Equivalent Breast Compression Thickness; G%, Granularity; MGD, Mean Glandular Dose; DRLs, Diagnostic Reference Levels; TLD, Thermo Luminescence Dosimeters.

3.4. DRL measurements using patient-based data

The measured patient-based DRLs show a wide range at both the 75^{th} and 95^{th} percentiles, as shown in Table 2. According to the findings, there is a higher MGD for the MLO view than the CC view and also DRL is higher in SFM than that in CR and DR mammography machines. Digital breast tomosynthesis (DBT) shows a higher value than that of 2D CR and DR systems. The range of mean DRLs of the reviewed studies at the 75^{th} percentile was 1.27–2.64 mGy and at the 95^{th} percentile was 1.2–2.4 mGy.

Two Japanese studies in the CBT range of <45 mm show a 75^{th} percentile value of 1.91 [33] and 2.0 mGy [34]. Although these studies were conducted in the same geographical location, the authors used two different dose calculation methods and protocols. A study conducted at Qatar MGD for CC and MLO was 2.2 mGy and 2.5 mGy, respectively [35]. In this study, MGD was calculated according to the European protocol [23],and the Dance *et al.* [26] conversion factors were used and the obtained values were higher than the MGDs of other studies. This may be due to many factors such as the inclusion of symptomatic patients under the age of 40, the broad spectrum of CBT, the variation in the selection of the conversion factors, and the wide age range of the patients selected. A study done in Iran [36] shows the 75^{th} percentile as 0.88 and 1.11 mGy for CC and MLO views, respectively. A study done in Turkey [28]reported 1.3 and 1.8 mGy for CC and MLO views, respectively. A study done in China [37] reported that the mean MGD was about 1.6 mGy and the range of the MGD was from 0.39–5.01 mGy. Furthermore, they concluded that MGD did not differ significantly between MLO and CC views and the MGD level was higher in CR than in DR and SFM. A study done in Korea [38] found that the MGD per view of 2120 images was 1.81± 0.7 mGy, and they also concluded that kVp, mAs, breast size, and CBT were positively associated with MGD.

A worldwide survey [39] reported specific percentiles for different regions of the world. According to that, the MGD at the 75^{th} and 95^{th} percentiles was reported as 1.7 and 2.3 mGy for the Asia-Pacific region, respectively. For all geographic regions, the MGD per image for CC and MLO ranged from 1.4 to 1.5 mGy. A Malaysian study [18] has shown that MGD differs between different ethnic groups within the Asian continent; Malay (3.36 mGy), Chinese (3.31 mGy), and Indian (3.44 mGy), and their CBT varied from 38 to 46, 33 to 39, and 40 to 48 mm, respectively.

4. Discussion

Based on this review, two methods by Dance *et al.* [26]and Wu *et al.* [32] were used to calculate MGD. Both methods are related to the characteristics of the X-ray spectrum and the granularity of the breast tissue. However, the selection of conversion factors depended on the manufacturer. Dance *et al.* [26] conversion factors are the most suitable conversion factors with the technological advancement of the machine. Wu

Table 2

Country	Author	Number of Images	Dose measuring method	Protocol and conversion factors	BCT mm		Mean Glandular Dose	DRLs		
								75%	95%	RE
Iran	Bahreyni *et al.* [36]. (2013)	100	Measured ESAK (TLDs)	EP [23] Wu *et al.* [32]	CC: 47 MLO: 53 SMLO: 50–60		CC: 0.88 MLO: 1.11	CC: 0.88 MLO: 1.11		
World wide	Geeraert *et al.* [39] (2012)	14,7497	Estimated ESAK from DICOM images	N/A Dance *et al.* [26]			Europe: 1.48 North America: 1.42 Asia-Pacific: 1.42	Europe: 1.6 North America: 1.6 Asia-Pacific: 1.2	Europe: 2.4 North America: 2.1 Asia- Pacific: 23	
Qatar	Naemi *et al.* [35] (2020)	150	Measured ESAK (DICOM images)	EP [23] Dance *et al.* [26]			CC-60.3 ± 13.9 MLO-67.9 ± 12.9	CC–2.2 MLO45^0 2.5		
Japan	Kawaguchi *et al.*[a] [34] (2014)	300	Measured ESAK	EP [23] Dance *et al.* [26]	SMLO:30-40 MLO:37.6		SMLO:1.88 MLO:1.84	SMLO:2		
Turkey	Aydın *et al.* [28] (2020)	6309	Measured ESAK MGD ESD	EP [23] Dance *et al.* [26]	40–49	50.1	CC–1.3 MLO–1.8	CC–2.3 MLO–2.7	CC–4.2 MLO–4.8	CC < 2
					50–64	49.3		CC–2.2 MLO–2.6	CC–3.8 MLO–4.4	MLO < 2.5
Japan	Asada *et al.* [33] (2014)	NA	Estimated ESAK	EP [23] Dance *et al.* [26]	42	1.58	1.91			
China	Xiang *et al.* [37] (2014)	420	Measured ESAK	EP [23] Dance *et al.* [26]	13–75		1.6	2.0		
Korea	Baek *et al.* [38] (2017)	560	Estimated ESAK		47.9		1.81			
Malaysia	Jamal *et al.* [18] (2003)		Measured ESAK	ACR[22] Wu *et al.* [24]	Malay: 38–46 Chinese: 33–38 Indian: 40–48		3.36 3.31 3.44			

ACR, American College of Radiology; EP, European Protocol; ESAK, Entrance surface Air Kerma; IAK, Incident Air Kerma; SFM, Screen Film Mammography; DR, Digital Radiography; CR, Computed Radiography; BCT, Breast Compression Thickness; G, Glandularity; MGD, Mean Glandular Dose; DRLs, Diagnostic Reference Levels; TLD, Thermoluminescence Dosimeter; CC, Cranio-Caudal; MLO, Medio-Lateral Oblique; SMLO, Standard Medio-Lateral Oblique.

et al.[32]conversion factors are limited to a few X-ray spectra, namely Mo/Mo, Mo/Rh, and Rh/Rh.

The phantom studies used different types of phantoms according to the selected protocol. ACR and the European guidelines introduced two standard phantoms, and both consist of PMMA. The composition of the phantoms and their standards vary with the advancement of technology. In-house-built phantoms, at low cost, with a similar composition to standard phantoms also had an equivalent performance on MGD measurement.

DRLs are calculated at the 75th and 95th percentile of the dose distribution. Calculations of the percentiles depend on various parameters such as age, weight, height, and BMI of the selected sample. When there is a large range of data, the 75th percentile is commonly used. The application of the 75thpercentile mentioned the importance of dose reduction by 25%. The 95th percentile is suitable for a small range of data distribution and needed only 5% of dose reduction interventions. The 75thand 95thpercentiles are essential due to the difference in dose distribution in screening mammography and diagnostic mammography. Especially in the case of pathological conditions which affect breast composition. Determination of the DRL should satisfy with optimum image quality for better image interpretation accuracy.

Depending on the protocol followed, there was a wide range of CBT. Phantoms that followed EP used thicker equivalent CBT (53 mm) while ACR phantoms followed thinner equivalent CBT (42 mm). In patient-based studies, the mean CBT varied for the same protocol; therefore, a range of CBT was given for patient-based studies. This is due to the variation of breast composition with patient-related factors such as age, BMI, and hereditary of the females in different geographical locations of Asia. No patient-based study was able to provide a standard breast compression thickness. A plot of CBT versus DRLs used as a good quality control measure for nonstandard breast thicknesses.

Table 3: Summary of the protocols related to reviewed articles.

Protocol	Test subjects		Digital/SFM	Conversion factors	Reference levels for standard breast
	Standard patient number	Nature of the phantom			
ACR 2018	N/A	PMMA (4.2 cm/50%)	2D digital SFM DBT	Dance (2000) [26]	<2.0
ACR1999	N/A	PMMA (4.0/4.2 cm/50%)	SFM	Wu (1991) Dance (1990) [26] Sobol (1990)	<=3.0
EU protocol 2006	Minimum 10 patients	PMMA (4.5/5.3 cm/50%)	Digital SFM	Dance (2000) [26]	<2.5
IAEA protocol 2007	10–50 patients	PMMA (4.0/5.0 cm/50%)	Digital SFM	Dance (2000) [26]	N/A
IPEM 2005	Minimum 10 patients	PMMA (4.5/5.3 cm/50%)	Digital SFM	Dance (2000) [26]	<3.5

ACR, American College of Radiology; EU, European Protocol; SFM, Screen Film Mammography; DR, Digital Radiography; CR, Computed Radiography; BCT, Breast Compression Thickness; IPSM, Institute of Physical Sciences in Medicine; IAE, International Atomic Energy Agency.

DRLs in mammography were measured from time to time in different geographical locations in Asia by following various techniques. However, when compared with other regions of the world, there is less consideration for establishing DRLs in Asia. Most of the studies followed EU protocol and ACR protocol with Dance *et al.* [26] conversion factors. Most countries have never continued the records on DRLs within the last 20 years. Due to the variation in the BCT, age, BMI, G%, and technological advancement, there is a range of DRLs. Therefore, establishing internationally recognized protocols and updated conversion factors is essential for inter-study comparison and to ensure radiation protection with optimal absorbed dose with appropriate image quality. Measurement of MGD of various patients regularly and calculation of DRLs according to the standard protocols and conversion factors will be helpful in ensuring radiation protection in mammography.

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Competing Interests

None declared.

Availability of Data and Material

All information pertaining to the review is available upon reasonable request to the corresponding author.

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