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Establishment of Baseline Diagnostic Reference Level for Full Digital Mammography in Gaza Strip

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إنشاء مستوى مرجعي تشخيصي أساسي لتصوير الثدي بالأشعة الرقمية في قطاع غزة

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Abstract

In Gaza-Palestine, breast cancer is one of the most frequent cancers among women. The mammography treatment is the most prevalent and effective method of early breast cancer detection. Diagnostic reference levels (DRLs) play a vital role in patient radiation safety and health care delivery. The goal is to build a DRL for mammography assessment in Gaza and compare it to existing research. The sample types were acquired from EL-Remal Martyr's clinic's database. A total of 200 cases, ranging in age from 40 to 65 years, were chosen using systematic random sampling procedures. Right and left craniocaudally (CC) and right and left Mediolateral oblique (MLO) mammography locations were recorded and categorised. The average glandular dose (AGD) and the entrance surface dose (ESD) were calculated from the unit output. All projections had a compressed breast thickness (CBT) of 60-70 mm. The average AGD for the MLO projection was 1.10 mGy, while the average for the CC projection was 1.01 mGy. The average AGD for all projections was 1.06 mGy. The mean ESD for CC and MLO predictions, on the other hand, was 4.32 mGy and 4.70 mGy, respectively. In addition, the average ESD for all estimates was 4.51 mGy. The DRLs for AGD and ESD were found to be 1.24 mGy and 5.20 mGy, respectively. DRLs were discovered to be lower than international standards. When compared to internationally accepted work, the DRL in this study was lower. These findings could serve as a benchmark for DRLs in Gaza and, of course, Palestine.

Keywords: Mammography, Diagnostic reference level.

الملخص:

يعتبر سرطان الثدي من أكثر أنواع السرطانات شيوعا بين النساء في غزة وفلسطين. التصوير الإشعاعي يعتبر الاكثر شيوعا و الاكثر فعالية للاكتشاف المبكر لسرطان الثدي. تلعب المستويات المرجعية لكميه الاشعة (DRLs) دورًا حيويًا في السلامة الإشعاعية وتقديم الرعاية الصحية للمريض. الهدف من الدراسة هو ايجاد DRL لتقييم التصوير الشعاعي للثدي في غزة ومقارنتها بالبحوث المنجزة. تم الحصول على معلومات المرضى من قاعدة بيانات عيادة الشهيد الرمال. اذ تم اختيار ما مجموعه 200 حالة ، تتراوح أعمارهم من 40 إلى 65 عامًا اخذت بشكل عشوائى منتظم. تم تسجيل وتصنيف اوضاع مختلفة للتصوير الشعاعي للثدي الأيمن والايسر (عمودى -CCو جانبى .(MLO -تم حساب متوسط الجرعة الغدية (AGD) وجرعة السطح المدخل (ESD) من مخرجات الجهاز . في كل الاوضاع تم استخدام الضاغط على الثدى (CBT) من 60-70 ملم. كان متوسط AGD للاسقاط الجانبى (MLO) 1.10 mGy، بينما كان المتوسط للاسقاط العمودى (CC 1.01 mGy)) في حين كان متوسط AGD لجميع الإسقاطات 1.06 mGy . كان متوسط ESD للاسقاط العمودى (CC) و للاسقاط الجانبىmGy 4.32 (MLO) و 4.70 mGy على التوالي. بالإضافة إلى ذلك ، كان متوسط ESD لجميع التقديرات 4.51 .mGy المرجعية للجرعة الاشعاعية لكل من AGDو ESD لهذه الدراسة كانت 1.24 mGy و 5.20 mGy على التوالي. حيث ان هذه النتائج تعتبر اقل مقارنه بالدراسات الدولية الاخرى و بالتالى فان DRL لهذه الدراسة هو اقل من الدراسات العالمية بنفس المعايير و بذلك ممكن ان تكون نتائج هذه الدراسة مرجعية للجرعة الاشعاعية في حالة تصوير الثدى في غزة و فلسطين

كلمات مفتاحية: التصوير الإشعاعي ، سرطان الثدي.

Introduction

Early detection of breast cancer has been proven to reduce mortality by 25-40% (Jayadevan et al., 2016). Mammography examination is an important procedure for early detection of breast cancer. The primary goal of a mammography examination is to provide accurate diagnostic information with a low exposure to the breast organ while avoiding the danger of cancer (Suleiman et al., 2016). As a result, the radiation dose should be kept as low as reasonably possible without sacrificing image quality (Suleiman et al., 2016). It was necessary to create Diagnostic Reference Levels in order to accomplish this (DRLs).

DRLs were introduced to give a measurement of quality monitoring in order to decrease dosage variance between imaging sites. The International Commission on Radiation Protection established the DRLs (ICRP). DRLs are "a type of investigation level, usually the absorbed dose in air, or tissue-equivalent material, at the surface of a simple phantom or a representative patient" (ICRP,1996). The methods established by DRLs become significant when trying to perform international comparisons. The dosage of radiation to the breast has been computed in a variety of ways, as it can be directly determined by screening or estimated using a standard based on breast granularity, thickness, tube voltage (kVp), and spectrum (target-filter combination, half-value layer). The effective dose absorbed is denoted by Mean Glandular Dose (MGD), which can be calculated using either a standard subject or a standard phantom. Mean Glandular Dose (MGD) denotes the effective dose absorbed and the estimation of MGD can be attained utilizing either a standard patient or a standard phantom. DRLs have been established in a number of researches (Storm et al., 2020; Liu et al., 2022).

Even though many nations have created DRLs for mammography screening, many more have yet to do so. As a result, establishing DRLs for our region is critical (Gaza Strip). In the Gaza Strip, no mammography DRLs have been constructed. To achieve dose optimization, the DRLs value for each detector technology in mammography machines should be established (Dellie & Rao, 2016). In the Gaza Strip, work is needed to establish a baseline for mammography dose levels. The goal of this study was to construct DRLs for mammography exams in Gaza and compare them to previous research.

Methodology

Study design

A cross-sectional analytical constructive design with quantitative and qualitative data was used. This study design allows the collection of data during mammographic screening and the diagnosis.

Study Setting

The study was carried out at a governmental center (El-Remal Martyrs Clinic), as it is the main center of breast screening in the Gaza Strip.

Sampling technique

Mammography was used to screen 488 women between the ages of 40 and 65. The current study evolved 200 cases (n= every 2nd: 1, 3, 5, and so on.) aged 40 to 65 years were chosen using systematic random sampling methods. Approximately 800

mammography positions (200*4 positions=800) were recorded and classified as Right CC, Left CC, Right MLO, and Left MLO.

Data Collection

The researcher collected the data by filling out a dose survey booklet for each patient. The data include mammogram parameters, taken from the operator console, for each examination, including; age, ID number, breast thickness, view position, compression forces, KVP, mAs, AGD, and ESD.

Data entry and analysis

For data entry and analysis, the Statistical Package of Social Science (SPSS version 25) program was used. The current frequency was quantitative data. The difference and range between quantitative variables were measured by the researcher. Quantitative data was also analyzed to establish the mean, standard deviation, and correlation between different variables, as well as comparisons between our data and data from other countries.

Results

Body characteristics of the study participants

Table (1) represents the mean and stander deviation of weight, age, height, and BMI. The study participants' ages ranged from 40 to 64 years old, with a mean value of 47.6 years and a standard deviation of 6 years.

Table 1: Distribution of study participants characteristic

Variables	Mean ± SD	(Min-Max)
Age (years)	47.6±6.0	40-64
Weight (Kg)	81.5±15.4	49-133
Height (cm)	158.8±5.2	147-174
BMI (Kg/m^2)	32.3±6.1	18.7-52.5

Exposure and technical factor acquisition

The exposure and technical data acquisition for the 200 examinations are presented in Table (2), the mean value of kVp for CC views is 30.21±1.91kVp, the MLO views are 32±2.05kVp, while the mean value for all projections was 31.10±1.62kVp. The range of KVp was between 25-34 KVp.

Table 2: Exposure and technical factor acquisition

	Mean kilovoltage (kVp)	Mean Tube Load (mAs)	Mean CBT (mm)	Mean Compression Force (N)
CC projections	30.21±1.91	75.34±19.63	56.92±11.33	74.5±16.5
(min-max)	(25-34)	(38.5-145.1)	(23-83)	(31-145)
MLO projections	32±2.05	89.82±22.68	66.5±13.5	86±25.41
(min-max)	(27-35)	(34.2-192)	(29-100)	(35-183)

All projections (min-max)	31.10±1.62 (25-35)	86.72±21.95 (34.2-192)	61.32±13.2 (23-100)	80.25±20.95 (31-183)

Similarly, for all projections, the tube load has a mean value of 86.72±21.95 mAs, 75.34±19.63 mAs for CC projections, and 89.82±22.68 mAs for MLO projections. The range of mAs varied from 34.2 to 192 mAs. For all projects, the CBT acquisition predicted a mean value of 61.32±12.2 mm; for CC projections, the mean value is 56.92±11.33 mm, and for MLO predictions, the mean value is 66.5±13.5 mm. All the views have a range of 23-100 mm. Similarly, for all projections, the tube load has a mean value of 86.72±21.95 mAs, 75.34±19.63 mAs for CC projections, and 89.82±22.68 mAs for MLO projections. The range of mAs varied from 34.2 to 192 mAs. For all projects, the CBT acquisition predicted a mean value of 61.32±13.2 mm; for CC projections, the mean value is 56.92±11.33 mm, and for MLO predictions, the mean value is 66.5±13.5 mm. All the views have a range of 23-100 mm.

Dose acquisition-mean doses and doses distributions

The ESD and AGD readings can be seen on the mammography system. Table (3) shows the mean ESD and AGD values, as well as the 75th and 95th percentile values for CC, MLO, and all projects. The mean AGD for CC projections was 0.980.23 mGy, while the mean AGD for MLO projections was 1.130.26 mGy. The mean AGD values for all projections are 1.060.25mGy. The mean ESD for CC and MLO projections, on the other hand, was 3.771.18mGy and 4.921.57mGy, respectively. In addition, the average ESD for all estimates was 4.341.5mGy.

Table 3 mean ESD and AGD, 75th percentile, and 95th percentile for CC, MLO, and for all projection

	Mean AGD (mGy)	Mean ESD (mGy)	AGD (mGy) percentiles		ESD (mGy) percentiles	
			75th	95th	75th	95th
CC projections (min-max)	0.98±0.23 (0.53-1.69)	3.77±1.18 (0.9-7.4)	1.12	1.46	4.5	5.7
MLO projections (min-max)	1.13±0.26 (0.57-1.98)	4.92±1.57 (1.3-11.5)	1.28	1.64	5.8	7.9
All projections (min-max)	1.06±0.25 (0.53-1.98)	4.34±1.5 (0.9-11.5)	1.21	1.56	5.2	7.1

Baseline diagnostic reference levels

The choice of CBT and the projection for estimating the DRLs are the subject of a contentious dispute. To determine DRL, many writers recommend considering the distribution's mean AGD and/or mean CBT (Suleiman et al., 2016; Lekatou et al., 2019). Both the means of AGDs and the mean of CBT are used to calculate the DRL in this study. The histogram (Figure 1) reveals strong evidence that the CBT range between 60 and

70 mm for MLO views is the most representative for estimating DRLs, with the highest frequency of roughly 123 views.

Calculated the DRLs by using the CBT

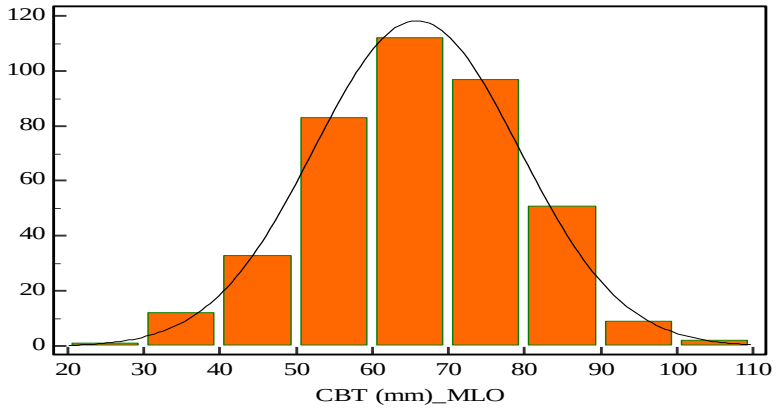

Figure 1: Histogram of the CBT (mm)

Table (4) and Figures (1,2,3) show the results of the study subjects with a CBT of 60-70 mm (2,3). The mean AGD for the MLO projection is 1.10 mGy, whereas the 75th percentile and 95th percentiles are 1.24 mGy and 1.64 mGy, respectively. The average CC projection is 1.01 mGy, with the 75th percentile at 1.15 mGy and the 95th percentile at 1.34 mGy. The mean of all projections was 1.06 mGy, with the 75th and 95th percentiles of 1.18 mGy and 1.52 mGy, respectively. The 75th and 95th percentiles of ESD for CC and MLO projections, respectively, are 4.32 mGy and 4.70 mGy, while the 75th and 95th percentiles are 4.88 mGy and 5.20 mGy. Furthermore, for all projections, the mean ESD is 4.51 mGy, the 75th percentile is 5.0 mGy, and the 95th percentile is 6.42 mGy.

Table 4: Results of all views with 60 -70 mm compressed breast thickness.

	ESD (mGy)			AGD (mGy)		
		percentile			Percentile	
	Mean ±SD	75th	95th	Mean ±SD	75th	95th
CC projections	4.32±0.84	4.88	6.10	1.01±0.19	1.15	1.34
MLO projections	4.70±1.02	5.20	6.82	1.10±0.24	1.24	1.64
All projections	4.51±0.96	5.00	6.42	1.06±0.22	1.18	1.52

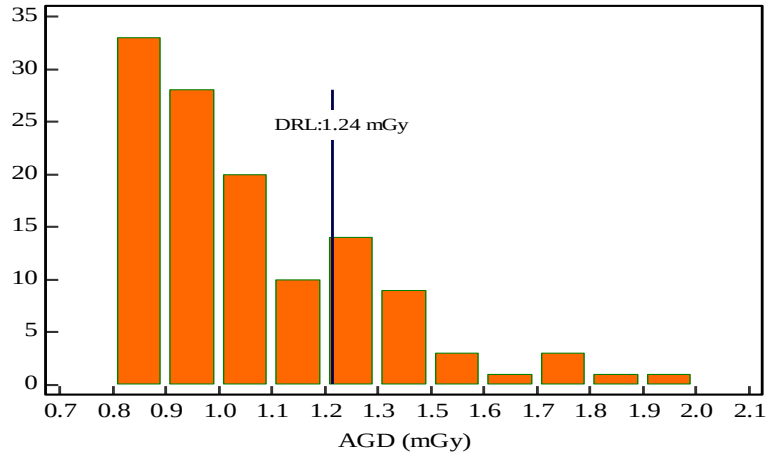

Figure 2: Histogram of AGD for MLO views between 60-70mm CBT with DRL at 75th percentile

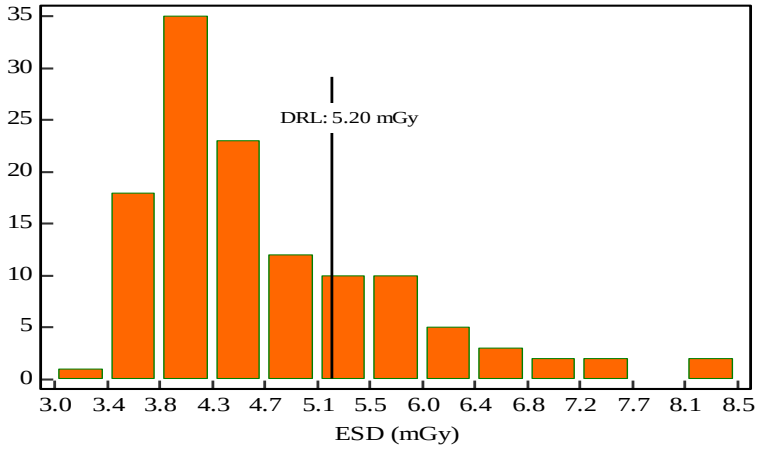

Figure 3: Histogram of ESD for MLO views between 60-70mm CBT with DRL at 75th percentile

Comparison between countries

The dividing for DRLs, as illustrated in figure (4), enables for comparisons between countries despite differences in methodology. When comparing national DRLs to international norms, this point is critical. Though it is not immediately beneficial to the patient, screening centers and regulatory agencies may benefit from the ability to distinguish dosage irregularities within a specified CBT range.

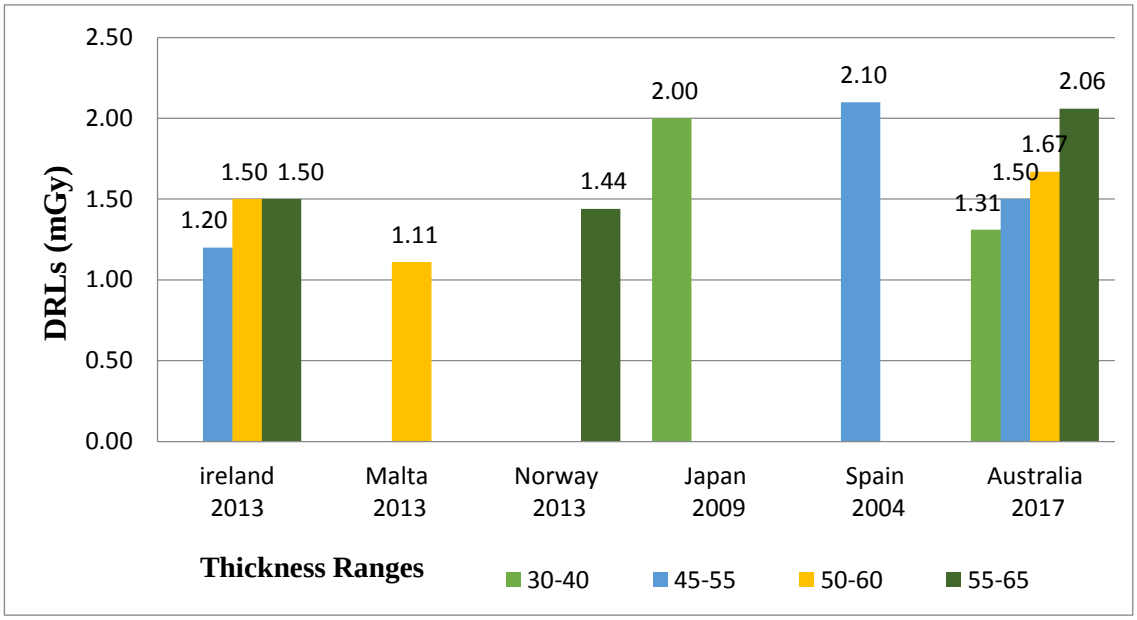

Figure 4: DRLs (75th percentile) for patient studies categorized by Compressed Breast Thickness

Comparison with international studies

The following Table (5) shows the findings of the mean CBT, mean AGD, and main percentiles 75th and 95th of many research studies conducted in different countries, and in the end, the author's data is concluded.

Table 5: Summary of data from patients studies worldwide

Country	Authors	Mean CBT	Mean AGD	75th	95th
Spain	(Chevalier et al., 2005)	All=52 CC=49 MLO=54	All=1.88 CC=1.80 MLO=1.95	All=2.1 CC=2.0 MLO=2.1	
Ireland	(Baldelli et al., 2010)	CC=60.5 MLO=63	CC=1,27 MLO=1.34	SMLO=1.33	2.5
Malta	(Borg et al., 2013)	All:57.5 CC:53.8 MLO: 63.4	All: 1.07 CC: 1.06 MLO: 1.07	All: 1.11 CC: 1.11 MLO: 1.11	All: 1.68 CC: 1.65 MLO: 1.87
Ireland	(O'Leary et al., 2012)	DR=54.7 SFM=52.3 54-55 55-65	DR=1.33 SFM=2.64 All=2.04 DR=1.4 SFM=2.88	DR=1.5 SFM=3.17 ALL=1.2 DR=1.2 SFM=2.55 ALL=2.47 DR=1.5 SFM=3.41	DR=2.26 SFM=5.59 ALL=4.33 DR=2.4 SFM=5.84
Greece	(Lekatou et al., 2019)	All: 56.3 CC: 53.9 MLO: 58.6	ALL=1.25 CC=1.18 MLO=0.58	ALL=1.44 CC=1.41 MLO=1.48	ALL=1.77 CC=1.76 MLO=1.78

Discussion

Cancer is the second leading cause of death in the oPt, accounting for 15% of all deaths, with lung cancer in men and breast cancer in women being the most common. The Palestinian government's health insurance programme covers basic cancer chemotherapy and radiotherapy for Palestinians with cancer in public hospitals in Gaza, and in those hospitals outside of Gaza to which they have been referred, while UNRWA sponsors the care of cancer patients by covering the cost of enrolling them in the government-funded health scheme. Despite being demographically a young population, 32% of avoidable deaths in Gaza are attributable to non-communicable diseases such as cancer (MoH, 2019)

According to the findings, the average BMI is 32.36.1 (kg/m^2), which falls into the obesity category. The BMI ranges from 18.7 to 52.5 (kg/m^2). It was discovered that 11% (22) of study participants are of normal weight, while 23% (46) are overweight, and 132 study participants are obese, accounting for 66% of the total (majority).

The choice of percentile for estimating the DRL is at the center of the present dispute. The majority of the authors, on the other hand, adhered to the 75^{th} percentile, while others advocated for the introduction of the 95^{th} percentile.

Since the 75^{th} percentile value for patient data yield is so low as a DRL that it is unreachable for many clinics and others. It is suggested that a standard international percentile be established so that global comparisons may be made (Suleiman et al., 2014).

Based on the evidence now available, it is reasonable to suggest institutional diagnostic reference levels for MLO projections at the 75^{th} percentile of 60-70 mm compressed thickness, which is 1.24 mGy for AGD and 5.20 mGy for ESD, respectively.

Although the use of CBT to stratify doses adds to the complexity of foundation DRLs, it has been established that a single standard CBT provided by previous studies does not take into account the wide variations in CBT among the population. A study conducted by Sulieman et al. (2019) showed that the CBT, MGD and DRLs of 60 patients (Age: 23-76 years) conducted three mammography projections (CC, MLO and LM) in Saudia Arabia were 48.1 mm, 1.1 mGy and 1.2 mGy, respectively. These values considered lower than the results obtained in the current study.

Heggie et al. (2017) recommended three different DRLs based on different mean CBTs, one of which was the mean CBT and the other two to allow for comparisons with the European (O'Leary & Rainford, 2012) and Irish (Perry et al., 2008; Baldelli et al., 2010) guidelines for CBT ranges of 45–55 mm and 55–65 mm, respectively. Despite this, in other research, the limited presentation of DRLs to a single CBT reduces the power of DRLs for calculating the dose of a population with changing CBTs.

In this investigation, the overall mean CBT values were compared to the standard breast, which is 53 mm, according to the European Protocol (Vañó et al., 2017), and it is obviouse that this value isn't correspond to the Palestinian population. To compare the CBT values of this study to those of other

studies, the median CBT in CC views in this study is 56.92 mm, which does not represent in this population study. Still, considering our population of MLO view means is 65.73 mm, if the DRLs are based on MLO views, a redefinition of the standard breast is highly recommended.

The average CBT projection in the UK breast screening program was 57 mm in MLO views and 54 mm in CC projections. However, additional studies indicated that the standard breast was insufficient and that it should be altered, therefore the UK set the standard breast CBT at 50 to 60 mm (Young, 2002). However, it is not appropriate for the research of our populations. Because a large breast necessitates a greater dose, screening women with large breasts may receive higher doses than recommended DRLs. Thus, substantially greater doses are not always attributable to faults in the screening method or equipment to use and reaffirm the requirements to consider when establishing DRLs for larger CBTs.

This study, on the other hand, was able to make a direct comparison of AGD results across countries. The diversity of CBT and the methods used made establishing DRL problematic. The author used data from the PACS repository in this investigation. The majority of studies (Dance et al., 2009; Qian, 2011) calculated the absorbed dosage using conversion factors. There was no need to calculate the dose using any of the methods listed above in this investigation. In the current study we estimated the absorbed dose by extracting the AGD and ESD directly from the digital mammography.

The 75^{th} and 95^{th} percentiles are the two percentile values used to determine DRLs. When there is a wide range of AGDs, the 75^{th} percentile is more commonly employed, and it advises 25% of patients to reduce their dose. When there is a small range of AGDs and means, on the other hand, the 95^{th} percentile is employed. Only 5% of instances require dose reduction intervention, and it is better suited to well-established screening setups where dose disparity is expected to be minor (Vañó et al., 2017). The DRL is defined in this study using the 75^{th} percentile.

The most common protocols for quality control and exposure measurements are EP (Perry et al., 2008) and the ACR (Hendrick, 2010); both were well-established protocols. EP was updated to utilize full digital mammography.

The differing standard techniques for determining DRLs, such as the sort of digital screening services utilized, make comparing doses between nations more challenging. International comparisons have shown differences that have sparked heated controversy among authors, such as the differences in digital screening services. The DRL was determined to be (1.75 mGy) in Ireland (Bahreyni Toossi et al., 2012) and (1.98 mGy) in Norway (Hauge et al., 2013). The 95^{th} percentile was used in the previous study to estimate the DRL, and the 95^{th} percentile is used in this study to compare with Ireland and other countries with the same percentile. The 95^{th} percentile was found to be 1.64mGy in the current investigation. As a result, the predicted value was 6% and 17% lower than Baldelli's (1.75 mGy) and Norway's (1.98 mGy), respectively. The results of both investigations revealed

that AGDs varied depending on the type of mammography unit utilized.

O'Leary & Rainford study (2012) in Ireland assessed DRLs for digital and screen-film mammography units for various CBT ranges, as well as the 75th and 95th percentiles in DR units. The CBT range was 55-65 mm, with the 75th percentile at 1.50 mGy and the 95th percentile at 2.40 mGy. As a result, the values in the 75th and 95th percentiles in this study were 17.3% and 31.6% lower, respectively, than the O'Leary study's computed values.

The DRL in the Maltese study (Borg et al., 2013) was estimated at 1.11 mGy at the 75th percentile, 50-70 mm breast thickness, and only for MLO views, which is 12.7% lower than the DRL in the current investigation. It's 1.87 mGy at the 95th percentile, which is 12.2% greater than the present study's findings. More than one clinic for the screening program, with individuals ranging in age from 50 to 60 years old, is blamed for the lower DRL value at the 75th percentile.

Chevalier et al. (2010) conducted a study in Spain that resulted in a DRL for MLO views with a 75th percentile of 2.1 mGy, which is 40.9% greater than the author's comparable figure. For MLO views, the mean CBT was 54 mm, which was lower than the value obtained in the current study. The difference could be explained by the fact that the Spanish investigation was conducted in 2004, and the procedures and digital systems were more optimized.

The Greece study (Lekatou et al., 2019) has estimated the DRL at 75th and 95th percentile for MLO views with a CBT between 55-65 mm. This study used the same procedure as obtained by the current research. It is calculated at the 75th percentile at 1.41 mGy, 12.05% higher than the present study result. The 95th percentile was found to be 1.76 mGy; in the same way, it is higher than the current study by 6.8%.

Comparisons have been challenging due to a variety of approaches, protocols, and systems. There is no specified thickness for compressed breasts. It would be unthinkable to believe that there is a universally accepted breast size. Thus, it is preferable to consider the variation of racial and environmental issues among countries before establishing a gold standard.

Conclusion:

Diagnostic reference levels (DRLs), which are a type of dose estimation level, play a vital role in health care delivery and patient radiation safety. The dose benefit of digital technology was further established by the use of institutional dose reference levels, which showed to be much lower than national and international dose reference levels.

For the first time in the Gaza Strip, this study is being conducted to create DRLs for radiological mammography examinations. Several international councils have proposed the DRLs, which are a type of inquiry levels, in relation to the radiation dose during mammography according to macroscopic quantities, such as the ESD or AGD. In the Gaza Strip, the present study built DRLs for mammography screenings. For MLO projections at the 75th percentile, the DRLs for AGD and ESD were 1.24 mGy and 5.20 mGy, respectively, for 60-70 mm compression thickness. When compared to internationally studies, the DRL in this study was lower.

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