# AVERAGE GLANDULAR DOSES AND NATIONAL DIAGNOSTIC REFERENCE LEVELS IN MAMMOGRAPHY EXAMINATIONS IN TURKEY

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**In order to establish National Diagnostic Reference Levels (DRLs) for mammography examinations, Entrance Skin Air Kerma (ESAK), Entrance Skin Dose (ESD) and Average Glandular Doses (AGDs) were calculated for a total of 25624 cranio-caudal (CC) and mediolateral oblique (MLO) projections of 6309 patients for 40-49 and 50-64 age groups. The average ESAK and ESD values for both age groups were found to be higher in MLO projections compared to CC projections. The minimum and maximum values of AGDs were determined as 0.4 mGy and 7.9 mGy for both projections. The maximum numbers of AGDs for CC and MLO projections were calculated in the range of 1.1-1.5 mGy and 1.6-2.0 mGy respectively. The third quartile values of AGDs were calculated for each compressed breast thickness (CBT) between 20 mm and 99 mm. The first National DRLs of the country were established for each 10 mm CBT in mammography examinations.**

## INTRODUCTION

Breast cancer is one of the most important reasons causing middle age women lose their lives [(1)]. As in all cancers, early diagnosis of this disease is very important for the success of treatment. It is recommended that patients should participate in screening programs at regular intervals in order to make early diagnosis of breast cancer. Among other screening programs, it can be easily said that mammography is the most reliable radiological examination to be used in the diagnosis of breast cancer in screening programs [(2)].

In screening programs for early diagnosis of breast cancer, women over the age of 40 are recommended to have mammography examination once a year. In 2015, the American Cancer Society updated its 2001 recommendations on mammography to diagnose early breast cancer. In this update, the starting to mammography examinations' age of a woman which has an average breast cancer risk has recommended as 45 years because of concerns about the potential adverse effects of radiation on healthy tissue [(3)]. It is also recommended that mammography examinations should be performed once a year for women aged between 45 to 54 and biennially for women aged older than 55 years. [(3)].

In correctly justified medical radiation applications, there is no limit for the radiation dose to which the patient may be exposed [(4)]. However, in all X-ray examinations including mammography, the patient should be given the lowest possible radiation dose at the image quality at which the suspected pathological findings can be diagnosed. Therefore, in medical imaging exams using radiation, it is significant to establish national diagnostic reference levels (DRLs) showing exposure parameters to determine the radiation doses of patients and for reducing radiation doses [(5)]. DRL is a value used to assess whether the amount of ionizing radiation is too high or too low in a routinely planned medical imaging study for a group of patients.

The breast tissue is highly sensitive to radiation, and the calculation of the average breast dose depends on all exposure parameters specific to the examination [(6)]. Thus, the average glandular dose (AGD), which is defined as the average ionizing radiation dose to (or absorbed by the) glandular tissue, is an important dosimetric quantity used for the assessment of the risk of radiation-induced carcinogenesis [(7)].

According to the radiation safety regulation published by Turkish Atomic Energy Agency (TAEA) in 2010, licensee is required to inform the patient for the organ and effective dose to which the patient will be exposed and related cancer risks in medical application [(8)]. As of 2018, there are 1664 licensed mammography devices in Turkey and this number corresponds to 10% of all radiology devices [(9)]. Although there is an increase in the number of full-field digital mammography (FFDM) devices, conventional (C) and computed mammography (CM) devices are still widely used in the country. In this study, AGDs in cranio-caudal (CC) and mediolateral oblique (MLO) projections applied to patients with different breast thicknesses in FFDM, C and CM devices of 275 hospitals were examined. Entrance Skin Air Kerma (ESAK), Entrance Skin Dose (ESD) and AGDs were calculated for 25624 projections of 6309 patients between 40-49 and 50-64 ages by using exposure parameters used in these examinations. In this study, the third quartile values of AGDs were calculated for each compressed breast thickness (CBT) between 20-99 mm and the first DRLs of the country were established for each 10 mm CBT in mammography examinations.

## MATERIALS AND METHODS

AGD is the reference dose level parameter for breast tissue and cannot be measured directly. Calculation of AGD in breast tissue depends on irradiation parameters (mAs, kV, CBT, focus-detector distance, target-filter material, conversion factors). AGD can be calculated by using ESAK values and conversion factors corresponding to the age-related compressed breast thicknesses [6][10]:

$$AGD = K \times g \times c \times s \qquad (1)$$

Where K refer to entrance skin air kerma (ESAK) value measured at a point surface of the breast without backscatter, g is the incident air kerma to average glandular dose conversion factor in 50% glandularity for half value layers (HVL) and breast thicknesses, c is the correction factor for any difference in 50% glandularity breast composition for women in the related age group and s being the correction factor for spectra in different anode/filter combination. ESAK can be calculated by the following formula [11]:

$$ESAK = R(\mu Gy/mAs) \times (\frac{1}{d})^2 \times q \times 10^{-3} \qquad (2)$$

Where R stands for x-ray tube output normalized at 1 m from the target, d is the target-breast surface distance and q is the exposure factor used (mAs). In this study, d was found by subtracting the breast thickness from the focal-image distance. Tube output can be found with the equation given below [11].

$$R(\mu Gy\ /\ mAs) = A \times (kV)^n \qquad (3)$$

Where A and n refer to constants and typically ranges a value between 1 and 3. In this study, the entrance surface doses (ESDs) were calculated by multiplying the ESAK values by appropriate backscatter factors (depending on half value layer) according to the Eur 16263 as follows [7]:

$$ESD = ESAK \times Fr \qquad (4)$$

Sobol et al. have improved the method of calculating the absorbed dose conversion factors determined by using tube voltage, half value thickness, compressed breast thickness and breast composition and developed a software of calculating average glandular doses [12]. Different software has also been developed to easily estimate exposed doses in mammography without the use of a dosimeter or measurement device [13][14].

In medical X-ray applications, determination of the patient doses requires the knowledge of actual tube output; which can either be directly measured or calculated using the exposure parameters (where empirical, semi-emprical or Monte Carlo techniques) [10][12]. In most cases, due to the large stock X-ray devices and the lack of sufficient technical personnel and labour, instead of direct measurement of tube outputs indirect calculation method is preferred [15]. If the properties of the X-ray device are known, the incident air kerma and the average glandular dose can be calculated theoretically by the polynomial interpolation method of the spectrum data in the 25-32 kV range without the need to measure mammography tube output [10].

In their study, Owalabi et al. showed that there was a good agreement between the measured and calculated tube outputs [15]. In the study conducted by Chapel Gómez et al., by using data obtained from 5717 mammography examinations performed between 1999 and 2003 years and tube output values, x-ray doses for breast tissue were calculated. The theoretical results were compared to the actual doses obtained with tube output measured during quality control procedures for each mammography device. The differences between calculated and measured values were found to be less than 3% for 77.6% and less than 5% for 96.6% of the samples. The results showed a significant correlation between the calculated doses and the experimental values measured [15].

For the early diagnosis of breast cancer, although women are recommended to undergo a mammography examination once a year after the age of 45, and every two years after the age of 55, women have the option of having mammography optionally after the age of 40. Although there is no complete consensus on the effect of mammography scans on life expectancy in older ages, there is no doubt about mammography scans increase the life expectancy of women aged 40-64 due to early diagnosis of breast cancer. In the Robson Parametric Method used in this study, the coefficients found by Monte Carlo simulations used in AGD calculations were calculated for the 40-49 and 50-64 age groups. Therefore, AGDs were calculated by using the examination information of women with 40-49 and 50-

64 age groups undergoing mammography examinations taken from institutions in this study.

Of a total of 331 devices, 96 of them are FFDM, 63 of them are C and 192 of them CM devices. 70 of 275 health institutions are official and 205 of them are private institutions. 27 of these health institutions are university hospitals. Of the 27 university hospitals, 19 are state universities, 8 of them belong to private universities. AGDs were calculated using the forms sent from health institutions in 66 of 81 provinces and this ratio corresponds approximately 82% of the provinces of the country. AGD calculations were performed using at least 10 patients' data on each device.

Forms were sent to institutions licensed by TAEA. Therefore, most of the technical parameters (brand, model etc.) related to the devices were kept in the regulatory authority records. Unregistered technical parameters (kV range, mAs range, focus skin distance etc.) were also found from the manufacturer's catalogues and researches on the internet. Technical parameters related to each device used in AGD calculations were requested from institutions and data that did not comply with the registered parameters were eliminated. Incorrect data filled in data collection forms (for instance filled outside the kV or mAs range of each device specified by the manufacturer) was eliminated and excluded from this study. To establish the National Diagnostic Reference Values correctly, the values of the breast thicknesses (values of outside the 15-104 mm range) that may extremely affect the AGD values were not included in the study. Data with incorrect focus-skin distance were not used due to unreliability. Forms containing single or double projection data (operated breast) were also not used. To prevent incorrect data entry, one person entered the data and another reviewed the data. By calculating the third quartile values of AGDs, the country's first national diagnostic reference levels for mammography projections were established. "Chi-square" and "one-way anova test" were performed for statistical analysis of groups' differences.

For the 40-49 and 50-64 age groups in this study, the relationship of number of views and CBT range is given in Figure 1 and Figure 2 respectively.

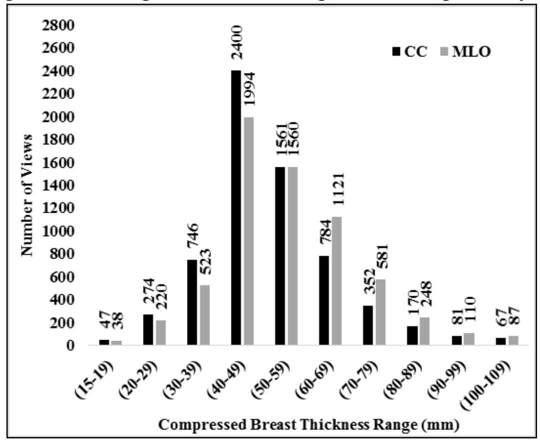


Figure 1. Number of views corresponding to the CBT for 40-49 ages

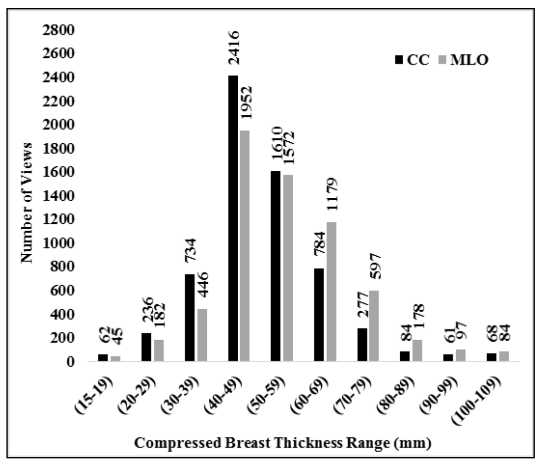


Figure 2. Number of views corresponding to the CBT for 50-64 ages

Table 1. Examinations' parameters, age ranges and standard deviations

| Projections | | Age range, mean ± SD (40-49), 44.4 ± 2.8 | | | Age range, mean ± SD (50-64), 56.1 ± 4.2 | | |
|---|---|---|---|---|---|---|---|
| | | CBT (mm) | Tube voltage (kVp) | Tube load (mAs) | CBT (mm) | Tube voltage (kVp) | Tube load (mAs) |
| CC | Mean | 50.1 | 28.7 | 88.9 | 49.3 | 28.6 | 79.9 |
| | SD | 14.5 | 2.7 | 49.5 | 13.7 | 2.7 | 44.7 |
| | Range | 15-104 | 23-45 | 13-549 | 15-104 | 23-45 | 6-392 |
| MLO | Mean | 50.1 | 28.7 | 89.3 | 49.2 | 28.5 | 79.9 |
| | SD | 14.6 | 2.8 | 51.1 | 13.7 | 2.6 | 44.8 |
| | Range | 15-104 | 23-45 | 13-549 | 15-104 | 23-45 | 6-392 |

CC: Cranio-caudal, MLO: Medio-lateral oblique, CBT: Compressed breast thickness, SD: Standard deviation

When both images are examined, it will be seen that the images corresponding to the CBT used in this study are concentrated in the range of 40-59 mm. Examination parameters, mean patient ages and their standard deviations used in this study are given in Table 1.

## RESULTS AND DISCUSSIONS

In this study, the relationship between AGD ranges and the number of imaging for the 40-49 age group for CC and MLO projections is given in Figure 3. It is observed that the AGDs calculated for this age group are concentrated between 0.6-2.5 mGy for both projections. The maximum numbers of AGDs for CC and MLO projections were calculated in the range of 1.1-1.5 mGy and 1.6-2.0 mGy respectively. Non-negligible number of AGDs which are calculated from 4 mGy up to 8 mGy were also found for 40-49 age range.

Statistically, the normal distribution (sometimes called the bell curve) was not observed in the histogram of AGD given in Figure 4 for 50-64 age ranges as in Figure 3. When the graph is examined, it is seen that the histogram is asymmetrical and concentrated in a certain region (on the left side of the graph).The largest number of AGDs were calculated between 1.1 mGy and 1.5 mGy for both projections.

If the calculated AGD value is above 3 mGy, optimisation of examination protocols is essential. In addition, it is recommended that the quality control measurements of the device are performed at regular intervals by using standard breast phantom to ensure the minimum dose to be given to the patient and that the accuracy of performance tests resulting from its use over time is checked.

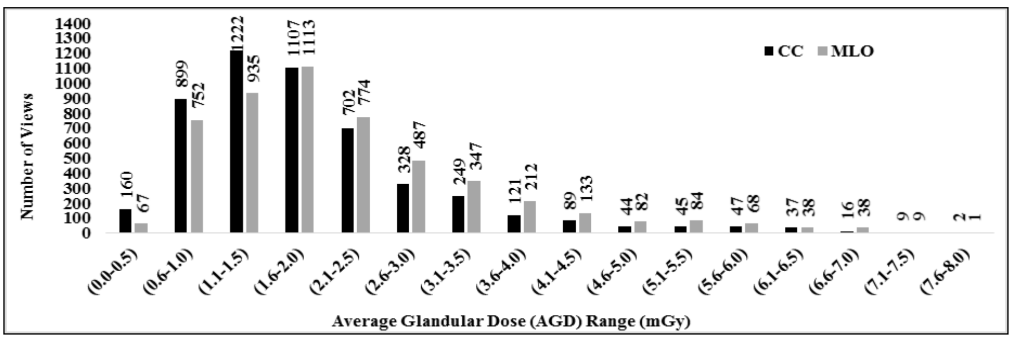


Figure 3. Relationship between AGD ranges and the number of imaging for the 40-49 ages

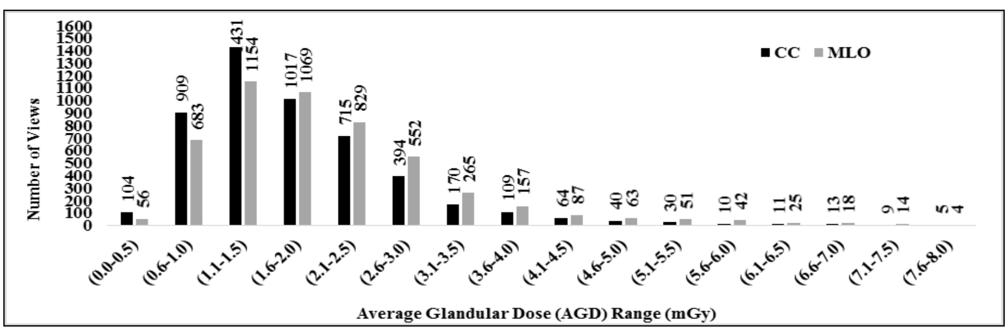


Figure 4. Relationship between AGD ranges and the number of imaging for the 50-64 ages

25th, 50th, 75th and 95th percentile values of ESAK, ESD and AGD for examinations were presented in Table 2. For 40-49 age group patients, mean AGDs for CC and MLO projections were determined as 1.7 mGy and 1.9 mGy, respectively. For aforementioned group patients, average ESDs for CC and MLO projections were calculated as 8.2 mGy and 10.0 mGy.

DRL calculations are based on the third quartile (3rd quartile) values of AGDs of patients with standard breast thickness (5 ± 0.5 cm) [(4)]. ICRP recommends the achievable level, reference dose and suspension level for AGDs in mammography as 1.5 mGy, 2 mGy and 3 mGy, respectively [(16)]. Likewise, IAEA and EC accepted the mammography DRL values proposed by ICRP and adapted them to their legislations [(4)(5)]. IAEA accepted the dose guidance level for mammography examination for a typical adult patient as 3 mGy while EC accepted the mammography reference dose as 2.3 mGy [17].

Table 2. 25th, 50th, 75th and 95th percentile values of ESAK, ESD and AGD for examinations.

| Age range | Projection | ESAK (mGy) | | | | ESD (mGy) | | | | AGD (mGy) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 25th | 50th | 75th | 95th | 25th | 50th | 75th | 95th | 25th | 50th | 75th | 95th |
| 40-49 | CC | 5.2 | 7.4 | 10.8 | 19.2 | 5.6 | 8.2 | 11.9 | 21.1 | 1.1 | 1.7 | 2.3 | 4.2 |
| | MLO | 6.1 | 9.1 | 13.2 | 24.1 | 6.7 | 10.0 | 14.5 | 26.3 | 1.3 | 1.9 | 2.7 | 4.8 |
| 50-64 | CC | 4.8 | 6.8 | 10.0 | 16.7 | 5.2 | 7.4 | 10.9 | 18.3 | 1.1 | 1.6 | 2.2 | 3.8 |
| | MLO | 5.7 | 8.3 | 11.4 | 21.0 | 6.3 | 9.1 | 12.6 | 22.8 | 1.3 | 1.9 | 2.6 | 4.4 |

In this study, the AGD values calculated for 25624 projections of 6309 patients have been examined and the first national DRL values have been established for mammography. The calculated DRL values were found to be over the reference dose level of 2 mGy recommended by ICRP for both age groups and projection types.

In similar studies conducted in Spain, Iran, Japan and South Africa, DRL values are recommended as 2.10 mGy, 1.33 mGy, 1.91 mGy and 1.90 mGy, respectively [18][19][20][21]. These DRL values are smaller than the values recommended in this study. However, it is possible to come across studies that are higher than DRL values calculated in this study [22].

In the meantime, national mammography DRL values have also been determined according to AGD values corresponding to compressed breast thicknesses for the range of 2.0-9.9 cm (for each 1 cm thickness) according to the summary recommendations of ICRP 135 revised in February 2019 [23]. The DRL results according to Compressed Breast Thickness (CBT) are given in Table 3.

Table 3. Comparison of calculated DRLs (75th percentile AGDs) of this study with European DRLs (75th percentile AGDs) according to CBT for the age ranges 40-49 and 50-64 [24][25].

| CBT (mm) | DRLs (mGy) | | | | European DRLs (mGy) | |
|---|---|---|---|---|---|---|
| | Age Range (40-49) | | Age Range (50-64) | | Acceptable level | Achievable level |
| | CC | MLO | CC | MLO | | |
| 20-29 | 2,0 | 3,0 | 2,6 | 3,1 | <1.0 | <0.6 |
| 30-39 | 2,2 | 2,4 | 2,1 | 2,4 | <1.5 | <1.0 |
| 40-49 | 2,2 | 2,5 | 2,2 | 2,5 | <2.0 | <1.6 |
| 50-59 | 2,3 | 2,6 | 2,0 | 2,3 | <2.5 | <2.0 |
| 60-69 | 2,6 | 2,8 | 2,5 | 2,5 | <3.0 | <2.4 |
| 70-79 | 2,6 | 3,2 | 2,6 | 2,9 | <4.5 | <3.6 |
| 80-89 | 2,3 | 3,3 | 3,0 | 3,3 | | |
| 90-99 | 2,5 | 3,5 | 2,2 | 4,0 | <6.5 | <5.1 |

For both age groups, it is seen that the calculated DRL values for CBTs in the range of 50-99 mm are below the acceptable level determined by EC. For CBTs of 20-49 mm, it is found that DRL values are above aforementioned levels.

It is known from the literature that there is a positive relationship between CBT and AGD. There is a minimal relationship between breast density and radiation dose [26].

All data were statistically evaluated to find any evidence which would explain the root causes of relatively increased average glandular doses. AGDs were grouped according to the recommended dose criteria of 2 mGy as lower, equal and higher. Geographical location of the health facility, technology of the mammography equipment, using manual or automatic exposure, direction of the projection, operation by the state or private sector, target and filter material, tube potential, tube current and exposure time product, compressed breast thickness and focus-detector distance were examined to find significant differences statistically. “Chi-square” analyses were performed for two groups' difference of averages and "one-way anova test" for more than two groups. The statistical difference is significant when P value is higher than 0.05 value. For this study, AGDs were significantly different according to the geographical parts of the country ($P<0.001$). Between 7 different officially distinguished geographical regions of the country, health facilities in western Anatolian regions have higher numbers of increased AGD levels than others. One of the remarkable results in this study was that the radiation doses exposed in digital mammography devices were found higher than conventional and computed mammography devices (P<0.001). More than half of exposures from DR equipment were higher than 2 mGy level. In mammography examinations used automatic exposure control (AEC), AGDs were found higher than examinations performed without AEC (P<0.001). MLO projections were delivering higher doses than CC directions (P<0.001). Approximately 45% of MLO exposures were higher than 2 mGy level. In the examinations performed with mammography devices in government facilities, AGDs were calculated lower than private and mammography screening centers (P<0.001). In this study, it is found that tubes with tungsten anode and rhenium filters (W-Rh) had given higher AGDs than five other anode filter combination couples of molybdenum, rhenium and aluminium in mammography devices (P<0.001). Between 24 different trademarks of the mammography devices, 4 of them were also delivering significantly higher doses causing statistically important difference (P<0.001).

Statistically significant differences between geographical locations, operation by the state or private sector and brands of the equipment show the importance of education and standardisation of staff and technology. The increasing dose in AEC use and W-Rh combination pair use are indicated the exposure potential of digital mammography equipment. Higher doses of MLO projections were not unexpected due to difficulties of compression of hard and thick pectoralis muscle.

## CONCLUSION

In order to increase the life expectancy of a healthy individual, women should be exposed to the as low as possible radiation dose in mammography examinations. For this reason, mammography procedures must be performed by trained and qualified personnel. In this study, AGD values obtained from a total of 25624 mammography examinations performed in 6309 patients were calculated and national DRL values were proposed. Established national diagnostic reference levels obtained in this study were found to be higher than most DRL values encountered in the literature and the European DRLs. AGD results and recommended DRL values revealed the necessity of optimisation in mammography examinations in the country.

## FUNDING

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