DOI: http://dx.doi.org/10.18203/issn.0019-5359.IndianJMedSci20163529

International Section Original Article

SUGGESTED DIAGNOSTIC REFERENCE LEVELS FOR MAMMOGRAPHY X-RAY EXAMINATION IN ETHIOPIA

SEIFE TEFERI DELLIE, A. DURGA PRASADA RAO[1]

ABSTRACT

BACKGROUND: *A diagnostic reference levels (DRLs) form an efficient, concise, and powerful standard for optimizing the radiation protection of a patient.* ***OBJECTIVES:*** *To establish the first Ethiopian mammography diagnostic reference level (DRL) as a part of ongoing dose reduction program.* ***MATERIALS AND METHODS:*** *A cross-sectional study was conducted on breast patients having compressed breast thickness (CBT) between 3.7 cm to 5.3 cm in Addis Ababa, Ethiopia. Five mammographic units and 755 mammograms were included in the study period. The mean glandular dose (MGD) was assessed for standard size breast substituted by different polymethyl methacrylate (PMMA) phantoms and imaged under typical clinical conditions in two mammography units. Peak kilo voltage (kVp) and entrance surface air kerma (ESAK) were measured using calibrated digital dosimeter Mult-O-Meter Unfors, model 535L, Sweden. The data were analyzed statistically.* ***RESULT:*** *The 3rd quartile value of all mammography units and that of private mammography units were found to be 2.37 and 1.73 milligray (mGy), respectively. Hospitals 3rd quartile values of MGD ranges between 1.57 to 7.21 mGy. The MDG based on 4.0 cm polymethyl methacrylate (PMMA) measurements was found to be 1.5 mGy.* ***CONCLUSION:*** *Both phantom and patient dose values indicated unnecessary high doses in one government mammography unit. For this mammography unit, urgent dose-reduction measures and follow-up actions were recommended.*

Key words: *Diagnostic reference level, mammography, mean glandular dose, polymethyl methacrylate phantoms*

INTRODUCTION

Mammography is the single most important diagnostic tool in the early detection of breast cancer.[1,2] The objective of any mammography examination is to obtain accurate diagnostic information with an acceptable dose to the breast. Thus, mammography examination must be well justified in terms of radiation protection, and that requires regular dose monitoring. Diagnostic reference dose values have been introduced by the International Commission on Radiological Protection in ICRP Publications 60[3] and 73[4] and by the European Directive 97/43/EURATOM for assisting the optimization of radiological investigations.[4] A diagnostic reference level (DRL) is a dose level for a typical X-ray examination of a group of patients with standard body sizes and for broadly defined types of equipment.[5] These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. Many factors influence the level of radiation doses delivered to patients undergoing mammography examinations. These can be responsible for large dose variations within and between hospitals for standard size patients undergoing the same examination.[2,5] Diagnostic reference levels (DRLs) help to facilitate standardization and optimization within departments and encourage the reduction of dose variations between hospitals. If doses in different centers are regularly compared to the DRL, it can be guaranteed that those centers do not use excessive doses.

At present, it is assumed that the glandular tissue is vulnerable to radiation-induced cancer, whereas fatty tissue and skin tissue are less critical. Therefore, several authors[6-13] proposed that the average X-ray dose to the glandular tissue (MGD) is the most appropriate dosimetric quantity to predict the risk of carcinogenesis. It can be calculated from measurements on patients using breast thickness, breast composition, and X-ray exposure factors. Measurements on phantoms may provide a good estimate of the average patient dose. Ideally, a MGD that is representative for the patients should be used for the establishment of DRLs.

DRLs should be obtained from pooling sets of dose measurements of a large number of units.[1-4] The average doses of the different centers can be ordered from low to high. The third quartile of the distribution found in a survey is frequently suggested as the value to be used. For mammographic X-ray examination, the requirements should be higher. Because of the involvement of healthy women and the extraordinary diagnostic demands, much emphasis must be put into achieving low doses whilst maintaining excellent image quality. For developed countries, it is expected that the mean dose distribution is very narrow due to extensive quality control programs. As a result, many

Departments of Radiology, College of Health Sciences, Addis Ababa University, Addis Ababa, [1]Department of Nuclear Physics, College of Science and Technology, Andhra University, Visakhapatnam, India

Address for correspondence:
Dr. Seife Teferi Dellie, Department of Nuclear Physics, Andhra University, Vishakhapatnam - 530 003, India.
E-mail: seifeteferi@yahoo.com

units that already follow good practice would have a mean dose above the 3rd quartile. In the Belgium, it has, therefore, been proposed to use a 95 percentile.[1] But, in Ethiopia, since mammography quality control program were not yet practiced, some units may not follow good practice. As a result, the 3rd quartile of the MGD was taken as DRL.

During the past two decades, several dose surveys have been performed for the study of patient radiation doses in many countries around the world.[8-12] The lesson learned is significant variations in patient doses between different radiological departments for the same type of examination. The reason justifies dose assessment in order to optimize the diagnostic radiology practice. For these reasons, the objective of the present work is to asses MGD on standard size breast patients having compressed breast thickness (CBT) between 3.7 cm to 5.3 cm in Addis Ababa, Ethiopia, thereby to set the first DRLs for mammography examination in the country.

MATERIALS AND METHODS

This is a cross-sectional study design performed on breast patients who visited all mammography units between September 1st, 2011 and May 21st, 2012 in Addis Ababa, Ethiopia. Out of a total of seven mammography units found in the country, five of them were included in this study. Four of which were from private hospitals/clinics while the remaining one were from government hospital. The hospitals are thereafter refereed as P_A, P_B, P_C, and P_D private mammography units and G_E government mammography unit. The survey includes three types of mammography systems: 2 Villa (Italy) Melody, 2 Siemens Mammoat 300, 1 Acoma x-ray M48-6020.

Initially, a self-administered questionnaire regarding the mammography unit, patient data, and mode of exposure was prepared in English and distributed to the radiographers working in the study mammography units. The completed questionnaires were checked for completeness and consistency.

All tube output (O/P) reproducibility, half value layer (HVL) measurements, kVp accuracy and reproducibility were performed with new calibrated digital dosimeter (Mult-O-Meter Unfors, model 535L, Sweden) using exposures of 32 and 80 mill ampere-seconds (mAs) for the range of kV selections used in the clinical practice. For measuring HVL, high purity (99.9%) aluminum (Al) foils of different thickness were used. The detector was positioned on the breast support Table midways along the direction perpendicular to the anode–cathode axis at 4.8 cm from the image receptor holder, 6 cm from the chest wall edge with the compression plate positioned half way from the detector in place to account for the exposure reduction and beam hardening introduced by the compression plate. Phantom measurements were performed by the researcher. In this method, the Radiation Measurements Gammex Mammographic Accreditation Phantom, model 156 (Gammex Inc., Middleton, WI), described as equivalent to 50% glandular tissue and 50% adipose tissue with CBT of 4.2 cm, and 4.0 cm polymethylmethacrylate (PMMA) with CBT of 4.5 cm were used. Measurements of the phantoms started with exposing the phantoms in clinical conditions in P_B and P_C private units where AEC is available. The phantoms were positioned on the breast support, the compression plate on it, a film in a cassette was positioned in the cassette holder, and an exposure was made in AEC mode. Exposure parameters were recorded. In the next stage, the phantom was removed, the exposure mode from automatic to manual changed, and a vertical view in the same conditions kVp and mAs performed. Based on the applied kVp, mAs, tube output, and calculated entrance surface air kerma at the surface of the breast and or the phantom, the mean glandular dose was calculated using the following formula:

$$MGD = ESAK\ gcs \quad (1)$$

In this equation, ESAK is the entrance air kerma (in the absence of scatter) at the upper surface of the breast. It was calculated for each exposure by multiplying the tube loading and the measured tube output for the relevant tube voltage with correction for the distance to the patient's skin surface. The factor *g* corresponds to a glandularity of 50% and is derived from the values calculated by Dance *et al*. for a range of HVL.[7,8] The *c*-factor corrects for any difference in breast composition from 50% glandularity. The factor *s* corrects for any difference due to the choice of X-ray spectrum as noted earlier. The c and g factors were interpolated for age groups, according to which the breast thickness, the anode/filter combination used and in 0.01 mm HVL interval. Equation (1) was also used for the calculation of the MGD from phantom measurements. The factors *g* and *c* still have the same meaning, but the *c* and *g* factors applied are those for the corresponding thickness of compressed breast rather than the thickness of PMMA blocks.[7] The target optical density in the reference point of the exposed films was measured. The average ESAK and MGD for the patient's group of mean (range) compressed breast thicknesses 4.51 (3.7-5.3) cm was compared with the results from the measurements on the standard Gamex 156 and 4.0 cm polymethylmethacrylate (PMMA) phantoms. Before conducting the study, the research was ethically cleared by faculty of medicine Institute of Review Board (IRB). Ethical clearance and permission was obtained from the respective hospitals. All participants were informed about the purpose of the study and confidentiality of information. For all mammography units mentioned, the mean, minimum, maximum, and third quartile of MGD was calculated using SPSS 16.0. As proposed by,[2] the average mean glandular dose of a particular system was considered to be significantly greater than the diagnostic reference level if the mean

glandular dose plus twice the SEM exceeded the diagnostic reference level. Finally, the results of calculated MGDs were compared with national and international established diagnostic reference levels (DRLs).

RESULT

In this study, a total of 755 radiographs constituting of 143 (18.9%), 159 (21%), 178 (23.6%), 114 (15%), and 161 (21.3%) radiographs from P_A, P_B, P_C, P_D, and G_E mammography units were analyzed. The mean age and CBT of patients was 48.36 (40-64) years and 4.51 (3.7-5.3) cm, respectively [Table 1]. From the technical point of view, efficiency of mammography lies upon numerous physical and technical factors and operators' skill. Dose survey for 5 mammography units in the country demonstrated substantial differences in technical condition of the equipment. As shown in Table 1, the lowest kVp was observed at P_B 26 (25-27) and P_C 26.61 (26-28) mammography units having a value of 25 and 26 kVp, respectively. The highest kVp was also observed at P_A and G_E mammography units having mean values of 31.32 (29-32) and 29.57 (26-31), respectively. The mean values of kVp and the range in parenthesis of all mammography units in the study period was found to be 28.45 (25-32) kVp. Of all the surveyed units, 45.5% were operated at tube potential of 26 (24.5%) and 30 (21%) kV. The survey demonstrated considerable variations in technical parameters that affect image quality and patients' doses. The lowest average MGD were observed in P_B and P_D mammography units with values of 1.35 (0.7-2.67) mGy and 1.35 (0.95-1.80) mGy, respectively [Table 1 and Figure 1]. While the highest MGD was observed at G_E mammography units with mean value and range in parenthesis of 6.81 (3.17-7.89) mGy. Table 1 also shows the calculated third quartile MGD for all mammography units, with values of 1.57 mGy for P_B and 7.21 mGy for G_E mammography units having the lowest and highest values for mean CBT of 4.4 and 4.64 cm in that order. The calculated third quartile of MGD for all and private mammography units was also found to be 2.37 mGy [Figure 2] and 1.73 mGy, respectively [Figure 3]. Figure 1 shows the tube output of all mammography units with respect to peak kilo voltage (kVp) with highest and lowest values of P_D and P_A mammography unit, respectively. All units use manual film processor with eye inspection method. All mammography units were operated by technicians with Mo/Mo anode/filter combinations.

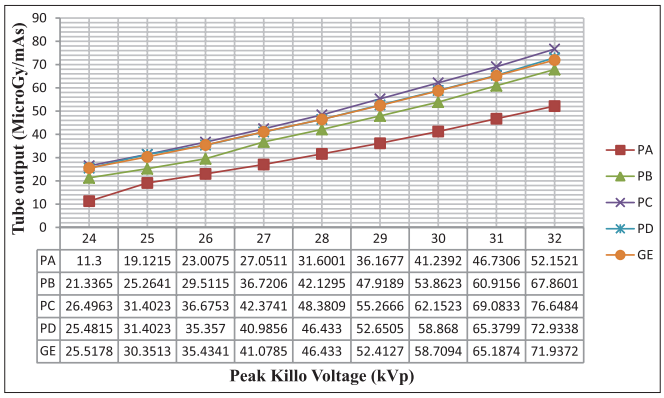

Figure 1: Tube output of all mammography units at a distance of 1 meter from X-ray tube

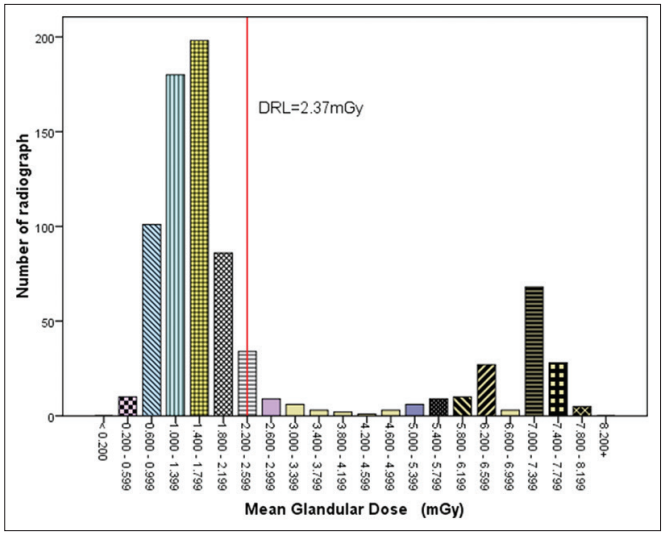

Figure 2: The distribution of Mean Glandular Doss (mGy) of all patients during the study period

Table 1: The mean and range in parentheses of patient information, exposure parameters, calculated ESAK and MGD for all mammography examinations

Mammography units	*Patient information*			*Exposure parameters*			*Calculated ESAK and MGD*				
	No mammogram	*Age (years) (range)*	*CBT (mm)*	*FFD (cm)*	*kVp*	*mAs*	*ESAK mean (range) 3rd quartile*			*MGD SEM mean (range) 3rd quartile*	
P_A	143	47.44 (40-62)	4.7 3.7-5.3)	48	31.32 (29-32)	18 (15-32)	4.67 (2.84-9.02)	5.39	0.04	1.51 (0.89-3.12)	1.69
P_B	159	48.82 (40-60)	4.40 (3.7-5.3)	65	26 (25-27)	74.1 (40-125)	6 (3.17-12.87)	7.30	0.03	1.35 (0.7-2.67)	1.57
P_C	178	46.15 (40-60)	4.51 (3.8-5.3)	65	26.61 (26-28)	68.7 (8.6-160)	7.37 (0.87-7.50)	9.66	0.06	1.71 (0.20-4.54)	2.14
P_D	114	51.85 (40-64)	4.27 (3.7-5.3)	65	30.12 (28-32)	31.89 (28-32)	5.39 (3.6-6.9)	6.68	0.03	1.35 (0.95-1.80)	1.58
G_E	161	48.43 (40-61)	4.64 (3.8-5.3)	65	29.57 (26-31)	185.7 (160-200)	28.6 (15.7-32.9)	29.55	0.06	6.81 (3.17-7.89)	7.21
All	755	48.36 (40-64)	4.51 (3.7-53)	48, 65	28.45 (25-32)	78.80 (8.6-200)	10.6 (0.88-32.9)	10.04	0.08	2.57 (0.2-7.89)	2.37
All private	594	48.27 (40-64)	4.48 (3.7-53)	65	28.26 (25-32)	50.88 (8.6-160)	5.99 (0.88-17.5)	5.5	0.02	1.5 (0.2-4.54)	1.73

ESAK=Entrance surface air kerma, MGD=Mean glandular dose, CBT=Compressed breast thickness, kVp=Peak kilo voltage, mAs=Mill ampere-seconds, FFD=Film focus distance

The results from the calculation of ESAK and MGD for the patient's group of mean compressed breast thicknesses 4.51, as well as the results from the phantom measurements of these parameters are shown in Table 2. The measured optical densities of the exposed films with range of (1.4-1.6) are also included in this table. The Mo/Mo anode/filter was the automatic choice of the systems for all PMMA thickness. As shown in Table 2, minimum percentage difference of ESAK (19.58%) and MGD (1.96%) between patient survey and phantom measurements were found for 4.0 cm PMMA phantoms in two mammography units. Comparing the patient dose with the proposed DRL shows that the government mammography unit (GE) has a MGD of 6.81 (3.17-7.89) mGy, which is above a DRL of 2.37 mGy [Figure 2] and even above the highest acceptable value of 3.0 mGy set by EU guidance (6).

DISCUSSION

DRL is a dose level for a typical X-ray examination of a group of patients with standard body sizes and for broadly defined types of equipment. This concept has been developed from earlier European dose survey studies that had shown large spreads between doses for similar examinations performed in different hospitals.[14,15] A DRL assessed in this work is a guide to investigate dose reduction potentials in mammography practice in Ethiopia. The 3rd quartile of the dose then allows finding the units that apply the highest doses. A third quartile MDG of 1.5 mGy and 2.37 mGy were found based on phantom and all mammography units, respectively. The 2.37 mGy DRL found in this study was lower than the acceptable limiting value of 2.5 mGy, but higher than the achievable dose level of 2.0 mGy, according to European Guidelines for quality assurance in breast cancer screening and diagnosis.[7] The average MGD for all private mammography units ranges from 1.35 mGy to 1.71 mGy, yielding a third quartile MGD of 1.73 mGy [Table 1]. This dose sample is most probably representative for mammography screening in our region, as they have similar technical data's. Large spread of dose values was observed within all mammography units during the study period. The smallest MGD was 0.203 mGy, the largest was 7.89 mGy. This is probably attributed to the fact that these centers are not involved in a common, centrally controlled QA program.

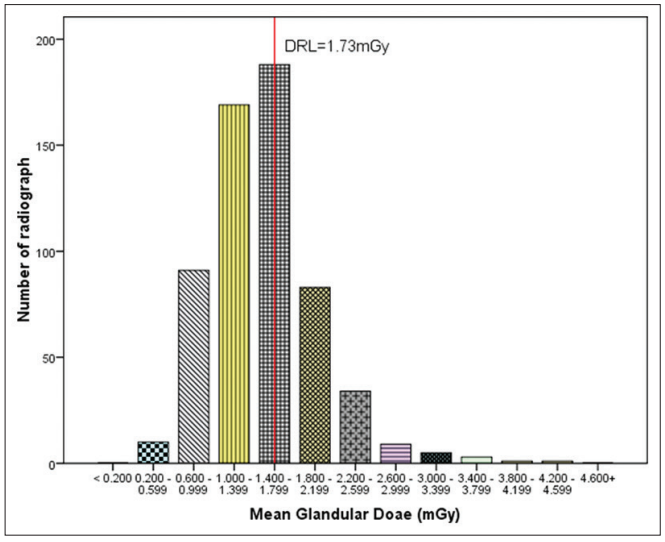

Figure 3: The distribution of Mean Glandular Doss (mGy) for all patients in private mammography units

For 1.04 ratio of mean compressed breast thickness (CBT) between private and government mammography units, a ratio of 1.05, 3.65, 4.77, and 4.54 have been found for mean kVp, mAs, ESAK, and MGD in that order. In addition to this, as shown in Figure 1, the tube output of the government mammography unit (G_E) has the second highest output next to P_C private mammography unit. These together with usage of higher mAs is the main reason for having higher ESAK and MGD in government mammography unit. Even though it is not recommended to mix screens and films, because of the potential variation in speed and contrast characteristics,[16] in government mammography unit (G_E), it was observed that blue sensitive films can be used during mammography examination. The reason could partly be inadequate supply of fast green sensitive films by administrators will force less educated mammography technicians to use slow films (blue sensitive) supplied from different manufacturers. Such finding urges the need for improving the practice in this particular hospital, primarily by introducing regular QC tests.

Breast equivalent phantoms can assist in dose reduction actions. Phantom dose values for different CBT have generally shown similar trend as dose to patients. The average MGD of a breast thickness with range of 3.7-5.3 cm for all private mammography units and that

Table 2: Comparison of the mean ESAK and MGD for different size of phantoms and two mammography units (P_B and P_C) having CBT between 3.7-5.3 cm

Mammography units	*Phantoms*	*Net OD*	*Phantom measurements*		*Patient measurements*		*% deference between phantoms and patient data*	
			ESAK (mGy)	*MGD (mGy)*	*ESAK (mGy)*	*MGD (mGy)*	*ESAK (mGy)*	*MGD (mGy)*
P_C	Gammex 156	1.4	3.6	0.85	7.37	1.71	51.15	50.29
	4 cm PMMA	1.4	7.3	1.06	7.37	1.71	0.95	38.01
P_B	Gammex 156	1.4	4.57	1.03	6	1.35	23.83	23.7
	4 cm PMMA	1.5	8.7	1.93	6	1.35	−45	−42.96
Mean values	Gammex 156	1.4	4.09	0.94	6.69	1.53	38.89	38.56
	4 cm PMMA	1.45	8	1.5	6.69	1.53	−19.58	1.96

ESAK=Entrance surface air kerma, MGD=Mean glandular dose, CBT=Compressed breast thickness, mGy=Milligray, PMMA=Polymethyl methacrylate, OD=Optical density

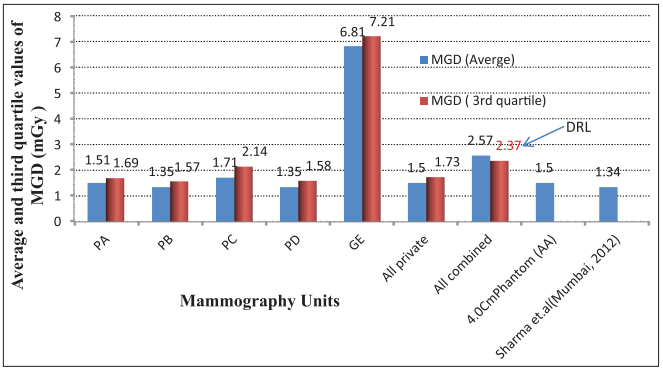

Figure 4: Average and third quartile values of MGD (mGy) for phantom and patient data

of 4.0 cm PMMA phantom has similar value of 1.5 mGy [Figure 4].

The average MGD of our phantom result is similar with the average MGD of (7) and higher than,[8,12] and[17] having a value of 1.5 mGy, 1.1 mGy, 1.42 mGy, and 1.34 mGy in that order. In Sharma *et al*.[17] work, they found the measured MGDs variation between centers by a factor of 27.14 as opposed to this work, which is 1.8. This is because of the deference in the number of mammography units included in the two studies.

As shown in Table 2, the average ESAK and MGD values for patient survey of two mammography units (P_B and P_C) exceed the mean value from Gammex 156 phantom study with values of 38.89% and 38.56%, respectively. Young *et al*.[12] and Smans *et al*.[2] reported the patient dose exceeding the phantom MGD by 30% and 15%, respectively. In this study, the average ESAK and MGD values from the patient survey of two mammography units and 4.0 cm PMMA phantoms are comparable with values of 19.58% and 1.96%, respectively, which is significantly less than the recommended follow up level of 50%, according to the European protocol for dosimetry in mammography.[1] Therefore, the percentage difference found in this research shows that the 4.0 cm phantom dose measurements, which are already a part of QC activities in deferent countries, can be used as a test to assess mammography practice in our country and compare doses from different mammography systems. As proposed by,[2,18] the average mean glandular dose of the government mammography unit (G_E) was considered to be significantly greater than the diagnostic reference level since the mean glandular dose plus twice the SEM exceeded the diagnostic reference level. The average MGD of Two mammography units were slightly above MGD of 4 cm PMMA phantom measurements. This approximation shows that the wildly accepted 4 cm PMMA phantom measurements can be used in a first approach to check whether “normal” practice is applied in these particular units.

Finally, we recommend that, the findings of both phantom and patient dose assessments made clear the need for optimization and implementation of dose-reduction measures in G_E mammography unit. For this unit, urgent dose-reduction measures and follow-up actions were recommended. Therefore, the present result indicates the need to introduce annual quality control using 4.0 cm PMMA phantoms and image quality assessment using Gammex 156 phantom in all mammography units found in the country.

ACKNOWLEDGMENT

We gratefully acknowledge the financial support of Addis Ababa University and Ethiopian Embassy in India, all hospitals that participated in this study and their staff for their co-operation. The authors also express their gratitude to Atnatiwos zeleke meshesha acting Director for Ethiopian Radiation Authority and all radiographers participated in data collection processes.

REFERENCES

1. European Commission. European protocol on dosimetry in mammography. EUR 16263 EN. Luxembourg: European Communities; 1996.
2. Smans K, Bosmans H, Xiao M, Carton AK, Marchal G. Towards a proposition of a diagnostic (dose) reference level for mammographic acquisitions in breast screening measurements in Belgium. Radiat Prot Dosimetry 2005;117:321-6.
3. International Commission on Radiological Protection (ICRP) 1990 recommendations of the International Commission on Radiological Protection. UK: ICRP publication no. 60. 21; 1991. p. 1-201.
4. International Commission on Radiological Protection (ICRP) Radiological protection and safety in medicine. UK: ICRP Publication no. 73. 26. 1996. p. 1-47.
5. European Commission. Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the danger of ionizing radiation in relation to medical exposure. Official Journal of the European Communities, L 180:22-27; 9.7.97. Available on (http://europa.eu.int/comm/environment/radprot. [Last accessed 2012 May 08].
6. Urban Zdes˘ar. Reference levels for image quality in mammography. Radiat Prot Dosimetry 2008;129:170-2
7. Perry N, Broeders M, de Wolf C, Tornberg S, Holland R, von Karsa L, editors. European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. Luxemburg; European Communities. Chapter 2, European protocol for the quality control of the physical and technical aspects of mammography screening; 2006. p. 57-104.
8. Dance D, Skinner C, Young K, Beckett J, Kotre C. Additional factors for estimation of mean glandular breast dose using the UK mammography dosimetry protocol. Phys Med Biol 2000;45:3225-40.
9. Faj D, Posedel D, Stimac D, Ivezic Z, Kasabasic M, Ivkovic A, *et al*. Survey of mammography practice in croatia: Equipment performance, image quality and dose. Radiat Prot Dosimetry 2008;131:535-40.
10. Paknyat A, Samarin ER, Jeshvaghane NA, Paydar R, Fasaei B, Karamloo A, *et al*. Evaluation of patient dose in

some mammography centres in Iran. Radiat Prot Dosimetry 2011;147:192-5.
11. Ciraj-Bjelac O, Beciric S, Arandjic D, Kosutic D, Kovacevic M. Mammography radiation dose: Initial results from serbia based on mean glandular dose assessment for phantoms and patients. Radiat Prot Dosimetry 2010;140:75-80.
12. Young KC, Burch A, Oduko JM. Radiation doses received in the UK Breast Screening Programme in 2001 and 2002. Br J Radiol 2005;78:207-18.
13. Broisman A, Schlesinger T, Alfassi ZB. Measurement of the radiation dose and assessment of the risk in mammography screening for early detection of cancer of the breast, in Israel. Radiat Protect Dosimetry 2011;143:113-6.
14. National Radiological Protection Board (NRPB), Royal College of Radiologists (RCR) Patient Dose Reduction in Diagnostic Radiology. Report of the RCR and NRPB Documents of the NRPB. 1990; 1 (3).
15. European Guidelines on Quality Criteria for Diagnostic Radiographic Images. Available on ftp://ftp.cordis.lu/pub/fp5-euratom/docs/eur16260.pdf. [Last accessed 2012 May 08].
16. Bushberg JT, Seibert JA, Leidholdt Jr EM, Boone JM. The Essential Physics of Medical Imaging. 2nd ed. USA: Lippcott Williams and WilkinS; 2002.
17. Sharma R, Sharma SD, Mayya YS. A survey on performance status of mammography machines: Image quality and dosimetry studies using a standard mammography imaging phantom. Radiat Prot Dosimetry 2012;150:325-33.
18. Baldelli P, McCullagh J, Phelan N, Flanagan F. Comprehensive dose survey of breast screening in ireland. Radiation Protection Dosimetry 2011;145:52-60.

How to cite this article: Dellie ST, Rao ADP. Suggested diagnostic reference levels for mammography X-Ray examination in Ethiopia. Indian J Med Sci 2016;68:36-41.

Source of Support: Nil. **Conflict of Interest:** None declared.