Applied Radiation and Isotopes 141 (2018) 266–269

Contents lists available at ScienceDirect

Applied Radiation and Isotopes

journal homepage: www.elsevier.com/locate/apradiso

Exploratory survey of initial image quality in new digital mammography units prior to use in patients in Mexico

E. Gaona[a,*], T. Rivera[b], N. Molina-Frechero[a], J.G. Franco[a]

[a] Biological and Health Sciences Division, Metropolitan Autonomous University Xochimilco, Calz. del Hueso 1100, 04960 Mexico City, Mexico
[b] CICATA, National Polytechnic Institute, Calz. Legaria 694, 11500 Mexico City, Mexico

HIGHLIGHTS

- Image Quality in New Digital Mammography Units Prior to Use in Patients were analyzed.
- Factors causing the loss of image quality in the mammography facilities were analyzed.
- Average glandular dose in FFDM units using different anode/filter combinations were analyzed.
- Absence of audits in mammography facilities was observed.
- Recommendations to improve the performance of mammography facilities was observed.

ARTICLE INFO

Keywords:
Initial Image Quality
Quality control
Mammography
FFDM units

ABSTRACT

In Mexico, previous studies performed to evaluate the image quality in 2D digital mammography facilities show a poor image quality that is not compatible with mammography screening that may modify breast cancer mortality rate. Image quality is lost due to the quality assurance programs are not implemented. We carried out an exploratory survey of thirty-six new (FFDM) units from a single manufacturer installed in several cities of the Mexican Republic with two types of target/filter combination (Mo/Mo and W/Rh). Tests were performed according to NOM-041-SSA1–2011 (Mexico), the regulation indicates that all facilities using digital mammography systems must maintain a QC program equal to the QC program recommended by the manufacturer. However, QC program recommended by the manufacturer meets with FDA and ACR Regulations. Digital mammography units evaluated exceeds quality image standards established by the ACR and FDA, even though, the W/Rh combination achieved a higher performance and reduces the average glandular dose. All mammography units met the quality control standards established by ACR, FDA and Mexican regulations. Then, the objective of this study was to evaluate the initial image quality and compliances with the manufacturer's quality control specifications before use it in patients in new full-field 2D digital mammography (FFDM) units and compares average glandular dose (AGD) with FFDM units using different anode/filter combinations (Mo/Mo and W/Rh).

1. Introduction

The aim of mammography screening is to detect malignant breast cancer when there are no clinical signs or symptoms of breast disease, at a certain stage when the effective treatment can be provided and the risk of breast cancer death is reduced. However, in Mexico, breast cancer has been a national public health problem since 2006 and it has been the leading cause of death due to cancer in the female population of 25 years and over (SSA, 2014). In our country, we have a history of poor image quality at mammography facilities as it is shown in the following studies. In the radiology facility evaluation from five Latin American countries, experts have found that 33.3% of mammograms in Mexico were clinical images of the worst quality (Fleitas et al., 2006). In a comparative study of full-field digital mammography (FFDM) and film-screen mammography (FSCM) systems, the results showed that in the evaluation of image quality with American College of Radiology (ACR) phantom, FFDM systems obtained lower scores than the film-screen mammography (FSCM) and 40% of those FFDM units presented artifacts and lack of uniformity in ACR phantom images (Gaona et al., 2012).

As important data from a survey conducted in 65 mammography facilities, which used computed radiographic digital mammography

* Corresponding author.
E-mail addresses: gaen1310@correo.xoc.uam.mx (E. Gaona), riveramt@hotmail.com (T. Rivera).

https://doi.org/10.1016/j.apradiso.2018.07.013
Received 10 December 2017; Received in revised form 7 July 2018; Accepted 10 July 2018
Available online 23 July 2018
0969-8043/

(CRDM) systems in Mexico City and surrounding States (either private clinics or public as part of the health care system). No distinctions were made regarding manufacture and model of the systems, only four CRDM mammography facilities barely reached the minimum image quality standards in the ACR protocol, and guidelines image quality (Gaona et al., 2014). A survey was done on 979 patients having an advanced breast cancer, so they were treated at several cancer centers from the public health system on Mexico City. The percentage of 35% of the patients with breast cancer in an advanced stage who they had an annual and biennial screening examination before to the diagnosis of breast cancer. This fact may be an indicator of the lack of efficiency of mammography facilities detecting any kind of breast cancer. When quality assurance programs are not implemented a number of consequence will show as a difficult detection of breast cancer (Gaona et al., 2017). The lack of quality control programs in mammography is a characteristic of some Latin American countries, for instances, in the Republic of Colombia, in general, they do not have quality assurance programs in mammography with the supervision of qualified personnel (Alejo-Martínez et al., 2014). Then, the objective of this study was to evaluate the initial image quality and compliances with the manufacturer's quality control specifications before use it in patients in new full-field 2D digital mammography (FFDM) units and compares average glandular dose (AGD) with FFDM units using different anode/filter combinations (Mo/Mo and W/Rh). Medical physicist under NOM-041-SSA1–2011 Mexican regulations must perform these quality control activities according to the manufacturer's quality control specifications (SSA, 2011). Mexico has less than 350 radiologists who are experts and certified in mammography for women population in their 40 s and over that were approximately 19 million in 2016 (CMRI, 2017) and, there are less than 15 qualified medical physicists with mammography training.

2. Material and methods

We surveyed of thirty-six new (FFDM) units from a single manufacturer (Selenia and Selenia Dimensions models are included, both are Hologic) installed in several cities of the Mexican Republic with two types of target/filter combination (Mo/Mo and W/Rh). Manufacturer's quality control manual specifies the Quality Control (QC) procedures, testing frequency, regulatory action levels and time limits for corrective action for each required quality control activity that falls under the responsibility of the medical physicist (Hologic, 2011). NOM-041-SSA1–2011 regulations require that all facilities using digital mammography systems must maintain a QC equal program to the QC program provided by the manufacturer of FFDM system. However, QC program recommended by the manufacturer meet with U.S. Food and Drug Administration (FDA) and ACR Regulations (SSA, 2011). FDA regulations require that medical physicists and technologists adhere to the procedures, testing frequencies, and performance criteria outlined in the quality control (QC) manuals provided by the manufacturers of full-field digital mammography (FFDM) systems (Williams et al., 2004). After installation at the static site, the FFDM systems at facilities were tested in compliance with the Manufacturer and FDA to assure that the units are properly working. All new full-field digital mammography units were evaluated according to the manufacturer's quality control manual, phantoms, accessories and a PTW nomex dosimeter calibrated at PTW-Freiburg calibration laboratory. The tests performed were: 1. Mammographic Unit Assembly Evaluation Collimation Assessment, 2. Artifact Evaluation, 3. kVp Accuracy and Reproducibility, 4. Beam Quality Assessment–Half-Value Layer (HVL) Measurement, 5. Evaluation of System Resolution, 6. Automatic Exposure Control (AEC) function performance, 7. Exposure compensation AEC performance, 8. AEC Reproducibility, 9. Breast Entrance Exposure, 10. Average Glandular Dose (AGD), 11. Radiation Output Rate, 12. Phantom Image Quality Evaluation phantom (Gammex 156), 13. Signal-To-Noise Ratio (SNR), 14. Contrast-To-Noise Ratio (CNR) Measurement and 15. Diagnostic Review Workstation QC.

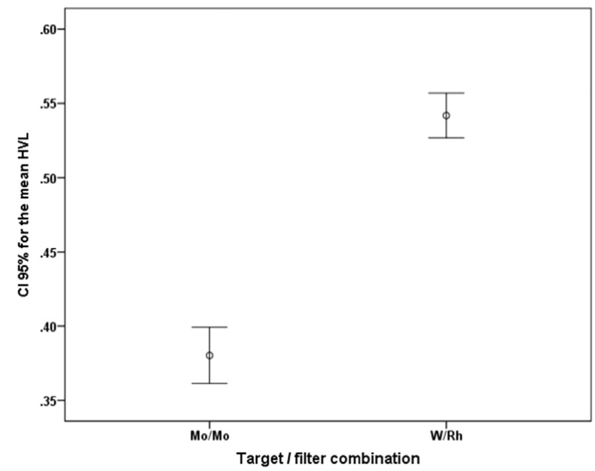

Fig. 1. Shows the distribution of the HVL depending on the type of target /filter combination, CI 95%.

3. Results and discussion

The study results found that the accuracy of the kVp is 2.93% ± 0.48 and coefficient of variation < 0.02 for Mo/Mo combination and for W/Rh 2.66% ± 0.51 (coefficient of variation < 0.02). W/Rh combination has higher HVL (Fig. 1) and it has a higher X-ray beam quality with greater penetration of x-ray beam into tissue and greater efficiency of the digital image detector and reduction of Average Glandular Dose (Fig. 2). Measurements of the half-value layer (HVL) was = 0.38 mm Al ± 0.02 at 30 kVp for Mo/Mo combination and HVL = 0.54 mm Al ± 0.01 at 30 kVp for W/Rh. Other authors found HVL values with a mean of 0.33 mm Al ± 0.04 for the Mo /Mo combination at 28 kVp (Sharma et al., 2012).

Tungsten X-ray tube with rhodium filter for 2D imaging reduces radiation dose to the while maintaining superb image quality and contrast (Figs. 3–5). W/Rh combination is the ideal selection for all other breast sizes. The calculated AGD craniocaudal view for a breast with 50% glandularity to a 4.2-cm-thick was of 1.60 ± 0.16 for Mo/Mo and 1.16 ± 0.04 for W/Rh, AGD values were calculated at 28 kVp and CAE in position 2 (Fig. 2). Using FFDM systems with W/Rh combination, the AGD is reduced by 27% using amorphous selenium detector. However, other authors applying a W/Rh beam quality permits the reduction of the patient dose by approximately 50% when using an

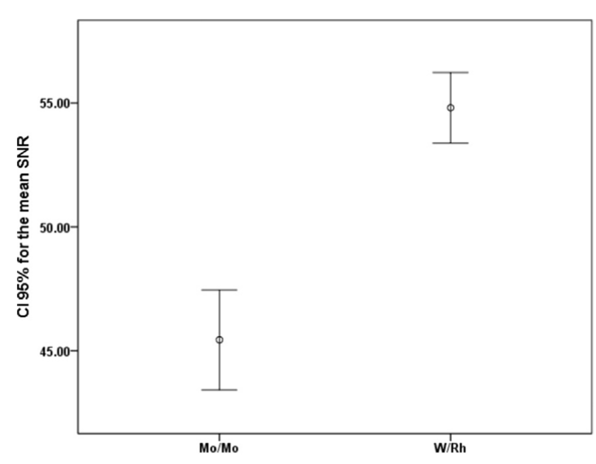

Fig. 2. Shows the distribution of the AGD per view depending on the type target/filter combination, CI 95%.

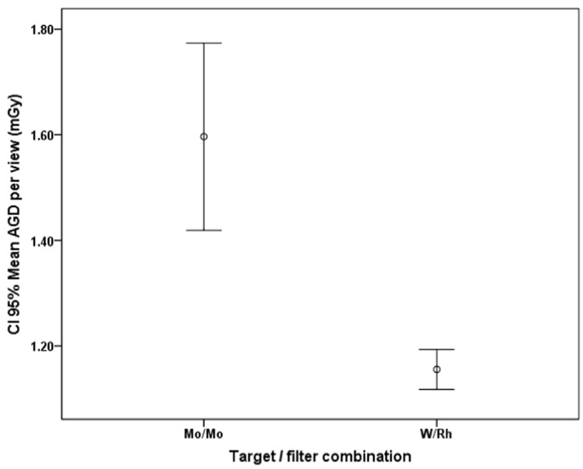

Fig. 3. Shows the distribution of the SNR depending on the type of target/filter combination, CI 95%.

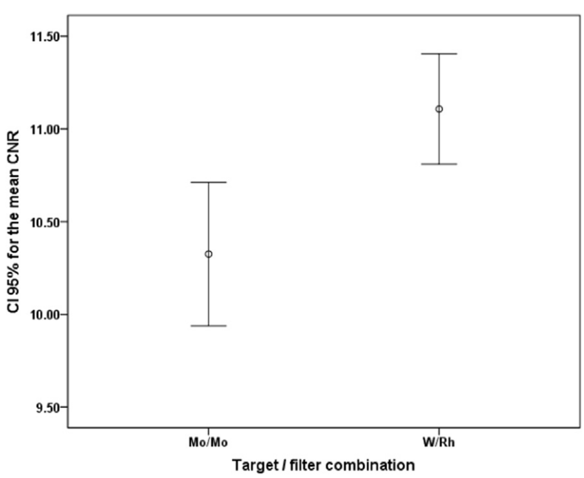

Fig. 4. Shows the distribution of the CNR depending on the type of target/filter combination, CI 95%.

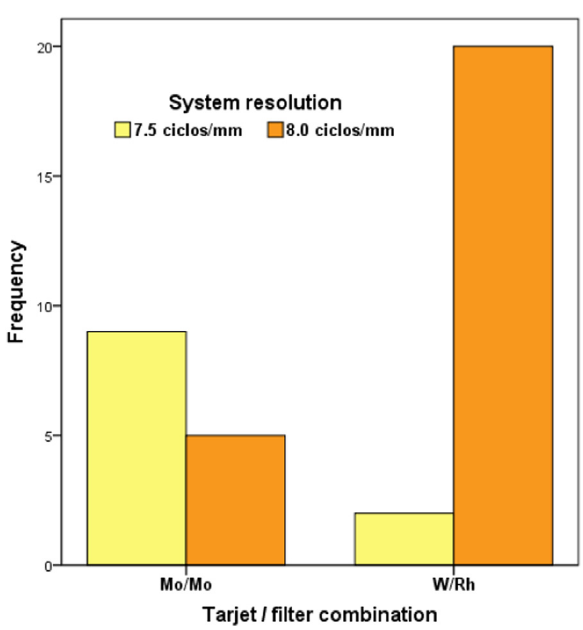

Fig. 5. System resolution distribution in target/filter combination.

FFDM system based on amorphous selenium (Uhlenbrock and Mertelmeier, 2009). All mammography units had a dose under the 3.0 mGy limit.

W/Rh combination has a higher signal-to-noise ratio (SNR) and DQE also concerns to SNR. Thus, DQE measures the SNR and MTF at various spatial frequencies. High DQE values indicate that less radiation is needed to achieve identical image quality; increasing the DQE and leaving radiation exposure constant will improve image quality. Thus, DQE is the efficiency of a detector in converting incident X-ray energy into an image signal. The SNR should be equal to at least 40 (Hologic, 2011). We found that Signal-to-Noise Ratio (SNR) was 45.45 ± 1.83 for Mo/Mo and 54.81 ± 1.34 for W/Rh (Fig. 3).

SNR values were calculated using the mean and standard deviation values obtained from the ROI next to the acrylic discussing the images obtained from ACR mammography accreditation phantom.

$$SNR = \frac{mean_{background} - DC_{offset}}{std_{background}}$$

Where $mean_{background}$ and $std_{background}$ are the mean and standard deviation obtained from the ROI Statistics dialog for the ROI next to the acrylic disk and DC offset added to the detector signal (DC_{offset}) and is equal to 50 (Hologic, 2011). SNR definition by Rose's model corresponds to what we now call contrast-to-noise ratio (CNR) or signal-difference-to-noise ratio (SDNR). In other words, the Rose's model is applied with a significant number of approximations when contrast-detail phantoms are used to assess image quality (Burgess, 1998; EFOMP, 2015). Signal-difference-to-noise ratio (SDNR) is obtained from the difference between the mean pixel values of background ($mean_{background}$) and acrylic disk detail ($mean_{disk}$), divided by the standard deviation of the background ($std_{background}$), according to the following equation.

$$CNR = \frac{mean_{background} - mean_{disk}}{std_{background}}$$

Where $mean_{disk}$ is the mean value obtained from the ROI Statistics dialog for the ROI on the acrylic disk. CNR values were calculated using the images obtained from ACR mammography accreditation phantom (Gammex 156), 18–220, using the Rose's model. W/Rh combination has a higher Contrast-To-Noise Ratio (CNR) than Mo/Mo combination (Fig. 4). Contrast-to-noise ratio (CNR) was 10.33 ± 0.35 for Mo/Mo and 11.11 ± 0.28 for W/Rh.

Tungsten X-ray tube with rhodium filter for 2D imaging has a higher spatial resolution than Mo/Mo combination with excellent sharp digital images and enabling low-dose. Spatial resolution was measured with a bar pattern (type 21) at 45° relative to the anode-cathode axis and was 7.54 cycles/mm ± 0.13 for Mo/Mo and 7.95 cycles/mm ± 0.06 for W/Rh (Fig. 5).

Image quality was assessed in a workstation with the images obtained from ACR phantom (Gammex 156) according to the American College of Radiology (ACR) Mammography Quality Control Manual (Hendrick et al., 1999) by determining the total score of resolved phantom structures in the accreditation phantom. The scoring ACR phantom images with more frequency were five and six fibers, four specks groups and four masses. All mammography units had a higher score than the minimum image quality standards established in the ACR protocol and guidelines image quality. Entrance exposures were measured using a PTW nomex dosimeter calibrated at PTW-Freiburg calibration laboratory using standard technique factors as those for a right craniocaudal (CC) mammographic view. These exposure values, along with the corresponding kV, half-value layers (HVL) and target/filter combination values were used to determine the Average Glandular Dose (AGD) using the appropriate ACR tables (Hologic, 2011).

Artifacts were not apparently found or not significant in images in all units, all mammographic unit assembly passed all the tests, radiation output rate was higher than 800 mR/s for Mo/Mo and more significant than 230 mR/s for W/Rh, room illuminance does not exceed 20 lx and Softcopy Workstation QC passed all the tests. In Automatic Exposure Control (AEC) function performance tests corrected pixel value of each image corresponding to a breast thickness between 2 and 8 cm at any operating mode were less than 10% of the mean pixel value computed for all tested breast thicknesses and operating modes. In exposure compensation AEC performance, a pixel value at each exposure compensation step results within allowed ratio range by the manufacturer and in the measurements of AEC reproducibility the coefficient of variation was within 5% for all units. Collimation assessment includes the following quality control tests: 1. Sum of left plus right edge deviation or anterior plus chest edge deviation does not exceed 2% of source-image distance (SID), 2. X-ray field does not exceed image receptor at any side by more than 2% of SID and 3. Chest-wall edge of compression paddle does not project beyond the chest-wall edge of the image receptor by more than 1% of SID. All mammography units met the quality control standards established by ACR, FDA and Mexican regulations.

In general, the factors that cause loss of image quality in mammography facilities is the lack of a comprehensive quality assurance program in digital mammography systems and the small number of certified radiologists specialize in mammography and a minimal number of medical physicists with mammography training (Gaona et al., 2017). Although, an important source of the loss of image quality in mammography is the lack of radiologist technicians with training in mammography according to Mexican regulations.

4. Conclusions

Digital mammography units evaluated exceeds quality image standards established by the ACR and FDA even though, the W/Rh combination, achieved a higher performance and reduced the average glandular dose. To improve the performance of mammography facilities in Mexico, a national quality control audit program should be implemented at mammography facilities equivalent to the FDA's auditing program in the United States to verify that mammography facilities comply with current national standards. Although, it is also necessary to implement a national training and certified program to increase the number of radiologists, radiologist technicians and medical physicists with mammography training. The fact about breast cancer is a major national health issue and the mortality rate in Mexico annually increases.

References

Alejo-Martínez, H., Salazar-Hurtado, E.J., Poveda-Suárez, C.A., Puerto-Jiménez, D.N., Ramírez-Campos, F., Roldán-Sánchez, O.I., 2014. Impacto del programa de aseguramiento de la calidad de las mamografías en Colombia. Anal. Radiol. 13 (4), 369–383.

Burgess, A.E., 1998. The rose model revisited. J. Opt. Soc. Am. 16, 633–646.

CMRI, 2017. Base de datos de Radiólogos Certificados, 〈http://www.cmri.org.mx/mostrarconsulta.php〉/, (accessed 4 September 2017).

EFOMP, 2015. Protocol for Quality Controls in Digital Mammography. 〈https://www.google.com.mx/url?Sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwi83aj5rvnXAhUTyYMKHTm6DRQQFggoMAA&url=http%3A%2F%2Fcdn.drg.de%2Fmedia%2Fdocument%2F8158%2FEFOMP-MAMMO-PROTOCOL-Mar15.pdf&usg=AOvVaw3DXQz9paMli11czncFhkTz〉. (accessed 4 September 2017).

Fleitas, I., Caspani, C.C., Borrás, C., Plazas, M.C., Miranda, A.A., Brandan, M.E., et al., 2006. La calidad de los servicios de radiología en cinco países latinoamericanos. Rev. Panam. Salud Publ. 20, 113–124.

Gaona, E., Perales Wendy, P., Franco, J., Franco, J., Molina, N., Gaona, G., 2012. Optimización de la calidad de Imagen en la Mamografía Analógica y su Comparación con la Mamografía digital. Anal. Radiol. 12 (1), 3–10.

Gaona, E., Rivera, T., Arreola, M., Franco, J., Molina, F.N., Alvarez, B., Azorín, C.G., Casian, C., 2014. Exploratory survey of image quality on CR digital mammography imaging systems in Mexico. Appl. Radiat. Isot. 83, 245–248.

Gaona, E., Izel, O.S., Arenas, V., Bernal, M.S., Tzitzitlini, L.S., Alvarez, B., Molina-Frechero, N., Rivera, T., Franco, J.G., 2017. Efficiency indicators of mammography in the detection of breast cancer early stages: exploratory study in Mexico. Int. J. Appl. Sci. Technol. 7 (4).

Hendrick, R.E., Bassett, L., Botsco, M.A., et al., 1999. ACR mammography quality control manual, 149–63. Am. Coll. Radiol., Rest. 117–121 (VA).

Hologic, 2011. Quality control manual, selenia dimensions 2D FFDM.

Sharma, R., Sharma, S.D., Mayya, Y.S., 2012. A survey on performance status of mammography machines: image quality and dosimetry studies using a standard mammography imaging phantom. Radiat. Prot. Dosim. 150 (3), 325–333. https://doi.org/10.1093/rpd/ncr420.

SSA, 2011. Norma Oficial Mexicana NOM- 041-SSA2-2011, Para la prevención, diagnóstico, tratamiento, control y vigilancia epidemiológica del cáncer de mama. In: Diario Oficial de la Federación de México de 9 de junio de 2011.

SSA, 2014. Prevención y Control del Cáncer de la Mujer 2013–2018. 〈https://www.gob.mx/cms/uploads/attachment/file/242390/PrevencionyControldelCancerdelaMujer_2013_2018.pdf〉. (accessed 28 June 2018).

Uhlenbrock, D.F., Mertelmeier, T., 2009. Comparison of anode/filter combinations in digital mammography with respect to the average glandular dose. Rofo: Fortschr. Auf Dem Geb. Rontgenstrahlen Nukl. 181 (3), 249–254. https://doi.org/10.1055/s-2008-1027942.

Williams, M.B., Goodale, P.J., Butler, P.F., 2004. The current status of full-field digital mammography quality control. J. Am. Coll. Radiol. 1 (12), 936–951.