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

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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.

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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

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(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.

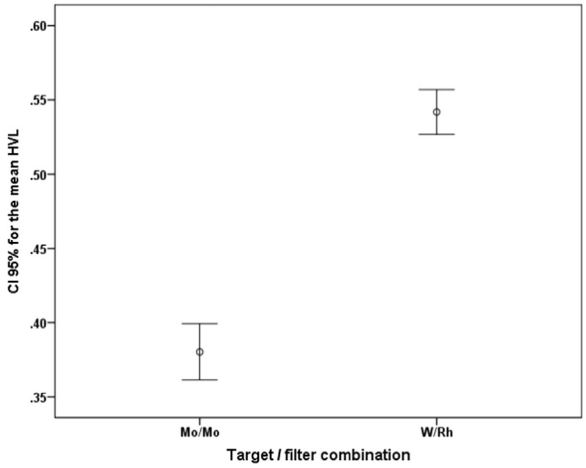

Fig. 1. Shows the distribution of the HVL depending on the type of target /filter combination, CI 95%.

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

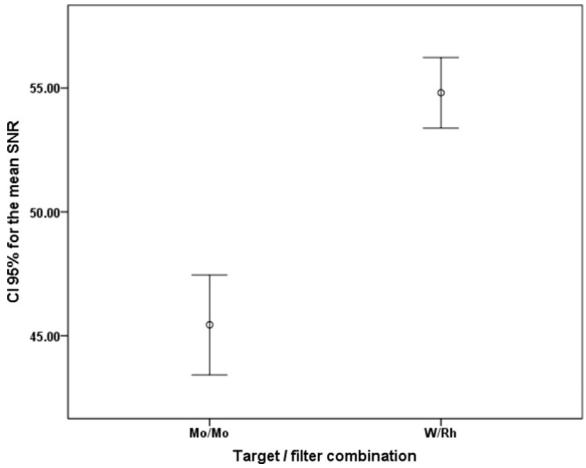

Fig. 2. Shows the distribution of the AGD per view depending on the type target/filter combination, CI 95%.