MICA AI MEDICAL

A PoC Reading Study to Assess the Acceptance of MICA AI M2C processed mammography images in place of Contrast Enhanced Mammography (CEM)

Objectives

Contrast Enhanced Mammography (CEM) is a state-of-the-art technique very useful for the detection of breast cancer. CEM relies on dual-energy acquisition of images following a contrast material (iodine) injection and has been shown to improve mammography sensitivity especially in dense breast tissue. CEM has been shown to be comparable in sensitivity to breast MRI. However, although very sensitive, breast MRI is a very expensive, time consuming and much less accessible and user friendly to patients.

Additionally dense breast tissue leads to a more difficult interpretation of the mammogram. If an abnormality is detected, this almost invariably leads to biopsy for a definitive diagnosis. This PoC internal study as part of the MICA Medical's R and D, which aims to provide the acceptance of MICA's M2C processed images in place of CEM mammography images.

MICA M2C solution - MICA AI Medical is developing a dedicated and unique artificial intelligence filter called **M2C**, which provides an algorithm to identify lesions in dense breast tissue without the need for the injection of contrast material. The filter is embedded either within the radiologists' workstation as an integral part of the PACs system, or within the mammography unit itself. If the radiologist determines that the tissue of the 2D FFDM mammogram is dense, at the press of M2C button on the workstation, an image will appear which is almost identical to that of a contrast enhanced mammogram. This enables the detection of abnormalities without the injection of contrast material, which is required for CEM and without CEM screening.
As mentioned previously, the M2C processed images lead to a level of resolution equal to CEM images.

Methods

In this PoC study, five independent reviewers were required to assess and compare the resolution of standard mammography images, CEM images, and. MICA's M2C processed images. In cases where an image was determined to be uninterpretable for a variety of reasons, including the need for further imaging, the image was defined and marked as "NR (Non-Readable)" reviewers were instructed to exclude these images from the study.

MICA used a dataset of 120 anonymized images (40 Low Energy images, 40 MICA's M2C processed images and 40 CEM mammography images). Each mammogram was identified by using a code of three digits, and all randomly assigned to the PoC readers.

Results

We explored the PoC assigned images interpretation as provided by the readers. 177 (59 sets x 3 images as above-mentioned) were analyzed. We have found 86.4% (51/59 images) were interpreted identically to the of readers assessment of MICA's M2C processed images as compared to CEM mammography images. The non-interpretable images (requiring further imaging evaluation) percentage ratio was similar for both above-mentioned comparable groups (6/74 = 8.1% MICA M2C processed images vs 7/84 = 8.3% CEM images).

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Conclusions

The presented imaging processing modality, MICA's M2C platform, enables detection of abnormalities in dense breast tissue at a level equal to that of contrast enhanced mammography.

The presented image processing modality, MICA's M2C, is highly effective in Interpretation of mammographic images, especially in dense breast tissue, and is results in images extremely similar to CEM images.

It represents a significant step forward in our commitment to enhancing breast cancer detection while improving patient comfort and healthcare efficiency, Furthermore, we expect that the usage of CEM, requiring contrast material injection and increased time of exam, will likely be significantly reduced.

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