

# Diagnostic System in Mono Frequency Electrical Impedance Mammography (EIM) in Breast Cancer Screening.

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## Research article

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# Abstract

**Background** Some evidence has been found that malignant breast tumors have lower electrical impedance than surrounding normal tissues. Electrical impedance could be used as an indicator for breast cancer detection. **Methods** Is a prospective, cross-sectional epidemiological observational study of serial screening. The women were invited to participate and signed their consent letter. The purpose of our study was to analyze the sensitivity and specificity of electrical impedance mammography (EIM) and its implementation for the differential diagnosis of pathological lesions of the breast, either alone or in combination with mammography / ultrasound, in 1200 women between 25 to 70 years old. **Results** We found a sensitivity of 85 % and a specificity of 96 %, the positive predictive value was 12% and 99% negative predictive value. Seven biopsy confirmed cancers. Significant correlation between electrical conductivity index and Body mass index (BMI) ( $p < 0.05$ ) and patient's age was observed ( $p = 0.01$ ). We also observed that the average of the conductivity distribution is increasing according to the age group ( $p < 0.01$ ). We used chi-squared test to assess for interactions between percent density mammary and BMI (normal  $< 25 \text{ kg/m}^2$  ( $n = 310$ ), overweight  $25-29.9 \text{ kg/m}^2$  ( $n = 418$ ) and obese  $\geq 30$  ( $n = 437$ ) ( $p < 0.05$ ). The patients with a diagnosis of mammary carcinoma had a BMI of  $35.51 \text{ kg / m}^2$ . **Conclusions** Our study showed that the sensitivity and specificity of Mono Frequency Electrical Impedance Mammography (EIM) has 85% and 96% respectively. These results suggest that breast electroimpedance can be used in women with obesity and dense breasts since these factors generate an effect that leads to a high rate of cancers at intervals, especially in young women. **Keywords:** Breast cancer, Screening, Frequency Electrical Impedance.

## Introduction

Mammography of electrical impedance is a relatively new method for the diagnosis of mammary diseases (1). In a short period of time, diagnostic criteria have been developed for the early detection of breast cancer by means of electrical impedance imaging (2). It is a non-invasive diagnostic technique based on the electrical storage potential different from normal and pathologically altered tissues that allows image differences in the conductivity and permittiveness of inferred tissue from electrical measurements of the body surface. Mammography by electrical impedance belongs to the class of 3D tomography systems (3).

Raneta et.al. reported that electro-impedance mammography showed a sensitivity of 87% with specificity of 85%. The use of electro-impedance mammography in addition to Mammography and Ultrasound (MMG/USG) can improve the sensitivity of these methods and to increase the rate of early detection of breast cancer with minimal economic costs and highly qualified staff time expenditures (3).

The Electric Impedance Mammography Mono-frequency (EIM) apparatus appears in Russia, created by Modern Impedance Medical Equipment (MEIK) and has been used for breast screening without radiation, allowing screening of high-risk groups, as well as the effective monitoring of any treatment in the patient, with a high degree of precision (4). Its efficiency was estimated to be 87.39%. Of 75 patients with breast

cancer, 96% were found to have degree III of risk of disease progression; 4%, degree II of disease progression risk. Additional examination was recommended. Taking into consideration that EIM works without any type of ionizing radiation, it can be recommended to be used in pregnant patients, hospitalized patients, as well as ambulatory, Family Medicine and Obstetrics and Gynecology Units for the screening of women under 40 years of age (5).

The electrical conductivity index (IC) obtained from the electrical impedance exploration is a quantitative variable, which characterizes the structure of the mammary gland. A low index is typical of a gland that contains a large number of cellular elements and, subsequently, a high concentration of ions. A high index of electrical conductivity is typical of a gland that contains a large number of fatty lobes and a large amount of connective tissue and, therefore, a low concentration of ions (6).

Thus the mammary gland structure can be assessed from the perspective of electrical impedance mammography with a view to the electric conductivity index. As it is well known, the mammary gland structure determines its density, so that the different ranges of electrical conductivity correspond to different types of mammary density (7, 8). The assessment is done in line with the American College of Radiology (ACR) terms (9).

Wang k, et al, showed that there are significant differences in the properties of electrical impedance between cancerous tissue and healthy tissue. The impedance of the benign tumor is smaller and is at the same level as that of the mammary glandular tissue. The different growth pattern of the mammary lesions determined the different electrical impedance characteristics in the EIS results (10).

The structural types of breast have been defined according to the correlation between the ductal component and the fat lobes, the breast can have a variable appearance in the tomogram. This is why the mammographic scheme of electrical impedance depends on the type of mammary structure, so the structure of the mammary gland is studied from the perspective of mammography by electrical impedance according to the types of mammary density of the ACR classification (11).

A volumetric lesion is an affectation that is detected in several planes of exploration (12). The analysis of the image involves the evaluation of the shape of the lesion, the contour, the internal electrical structure and the changes in the surrounding tissues were scored between 0 and 2 values for each alteration or pathological finding (13,14). The sum of the scores is stratified into a scale impedance score of 5 degrees BI-EIM, in great agreement with the BI-RADS classification system (15).

The BI-EIM IV and V scores are considered positive and are referred to biopsy (16). The use of the numerical score for the evaluation of the volumetric lesions by electro breast impedance allows comparing this information with the BI-RADS categories.

The cancer cells exhibit altered local dielectric properties compared to normal cells, measurable as different electrical conductance and capacitance by electrical impedance scanning (17). The divergence

of the distribution form of the histograms should be evaluated. In the course of the development of the oncological process, the general and local electrical conductivity naturally tends to change. The distortion of the mammographic scheme can be observed from the onset of the disease. Comparative conductivity is the alteration of the electrical conductivity of one breast with respect to the other.

The EIM point scale allows standardizing the description of volumetric lesions when performing an electrical impedance mammography examination, as well as using the patient monitoring algorithm developed by the specialists of the American College of Radiology. The electrical conductivity rates have been considered as useful data for clinicians to guide the diagnosis and treatment decisions, it can be used to evaluate the breast tissue as a reliable tool both in individual and complementary use (18).

Fuchsjaeger MH, et al, 2005 demonstrated in a prospective trial to discriminate benign lesions of malignant lesions with classification of Bi-rads 4 by mammography, by means of electro impedance in comparison with ultrasound focusing on the negative predictive value (19).

## **Methods And Materials**

### **Study design and populations**

Is a prospective observational epidemiological study of cross section of screening of breast cancer in series, of the medical unit of high specialty number 1, Guanajuato Delegation of the Mexican Institute of Social Security. The women were invited to participate and signed their consent letter.

To know the sensitivity and specificity of mammography by mono frequency electroimpedance, we screened one thousand one two hundred women from 25 to 70 years of age, underwent EIM examinations as part of this study. This protocol was approved by committee bioethics (R-2017-785-108). Written informed consent was obtained from each volunteer.

Four groups were formed, Group 1 = younger 25-35 years, Group 2= 36 to 45 years, Group 3= 46-55 and Group 4= 56 to 70 years. Impedance imaging of the mammary gland was evaluated with the computerized mammography equipment of MEIK electroimpedance v.5.6. (0.5mA, 50 kHz), developed and manufactured by PKF SIM-Technika®.

All women aged  $\geq 40$  years were subjected to a screening mammography (asymptomatic) and complementary ultrasound. Doppler ultrasound was performed in those <40 years old, with BIRADS 3 to 5.

In addition to collecting data on results of the EIM examination and other breast examinations, menopausal status and exogenous hormone use were also recorded.

## **Mono Frequency Electrical Impedance Mammography (EIM).**

It was performed in the patient at rest in dorsal decubitus, the electrodes were placed. For the recording of conductivity, two electrodes were placed: on the right arm to analyze the right breast and, later, on the left arm to analyze the left breast. The interpretation of the study consists in the analysis of the image that describes the following: contour (deformation, hyperimpedance), anatomy of the mammary gland (anatomical changes, displacement of internal structures, hyperimpedance of the area around the focus), local changes of the electrical conductivity (hyperimpedance area, hypoimpedance) and area of the galactophore sinus, which can form a dilated image.

Conductivity measurement: average electrical conductivity index (histogram of distribution of electrical conductivity, divergence of electrical conductivity distribution and local changes in electrical conductivity). In order to know the sensitivity and specificity of the mammography study with electroimpedance, it was carried out at the beginning and, later, the concordance with mammography and ultrasound imaging studies was analyzed. The final diagnosis was made by biopsy and histopathological study.

## **Mammary Gland Structure and Density types.**

Percent density was measured with EIM Classification to evaluate the association between percent density, age and BMI subgroup (normal/underweight,  $< 25\text{kg/m}^2$  versus overweight/obese,  $\geq 25\text{ kg/m}^2$ ). We used wald chi-squared test to assess for interactions between percent density and BMI.

## **Statistical Analysis.**

The successful identification of breast cancer along with the sensitivity, specificity, and positive and negative predictive values of EIM were determined: % sensitivity; % specificity; % positive predictive value (PPV); % negative predictive value (NPV). True-positive examinations in all patients were based on biopsy-proven cancer (ductal carcinoma-in-situ and invasive cancer). False-negative findings on EIM were identified by other imaging modalities (US, Mammography) and confirmed histologically. Breast US, Mammography were interpreted by certified radiologists specializing in women's breast imaging. Summary statistics were obtained using established methods.

We analyzed the following clinical factors: age, divided into four categories (younger 25-35 years, 36 to 45 years, 46-55 and 56 to 70 years); menopausal status, premenopausal versus postmenopausal (a woman was considered postmenopausal if she had gone 6 months without menstruating); exogenous

hormone use (oral contraceptives, contraceptive implants, or intrauterine devices with hormones if premenopausal, hormone replacement therapy if postmenopausal); previous history of breast cancer, yes or no; family history of breast cancer (categories were no first-degree relatives with breast cancer, one first degree [sister/mother] relative with breast cancer, or two or more first-degree relatives with breast cancer); palpability of lesion (palpable mass present or not present); and breast tissue density.

The methods included the Breast Imaging Reporting and Data System (BI-RADS) numerical system. Distribution of mammary gland structure and density types from the perspective of EIM execution in accordance with to ACR classification, for the purposes of this analysis, women were classified into one of four categories: Predominantly Fat, Fat whit some fibroglandular tissue, Heterogeneously dense, Extremely dense. All data are presented as mean  $\pm$  SE, with a P value  $< 0.05$  was considered significant.

## Results

The study involved 1,200 female participants. Patient characteristics are shown in Table 1. Patients had a median age of  $47.58 \pm 11.39$  years, range (25 – 70 years). Four groups were formed, the first with 196 women between 25 and 35 years old, the second with 319 women between 36 and 45 years old, the third group with 393 women between 46 and 55 years and the fourth group with 292 women between 56 and 70 years old.

The body mass index (BMI) was  $28.63 \pm 5.94$  kg / m<sup>2</sup>. The anthropometric distribution was as follows: percentage of body fat  $37.28 \pm 7.52\%$ , muscle  $41.77 \pm 5.45\%$ , water  $44.58 \pm 16.67\%$ , visceral fat  $8.21 \pm 3.52\%$  and bone  $2.27 \pm 0.82\%$ . In 310 (26.60%) women normal weight was observed  $<25$  kg/m<sup>2</sup>, overweight 25-29.9 kg/m<sup>2</sup> in 418 (35.87%), obesity  $\geq 30$ , in 294 (25.23%) grade I, in 96 (8.24%) grade II and 47 (4.03%) grade III.

### Electrical Conductivity Index.

When analyzing the electrical conductivity in the mammary tissue of the patients, it was observed that the average of the conductivity distribution is increasing according to the age group ( $r= 0.49$ ,  $p < 0.01$ ) (Fig. 1). Group 4, which corresponds to women from 56 to 70 years, presented the highest conductivity, with a mean of  $0.53 \pm 0.11$ , and group 1, of women between 25 and 35 years, had the lowest conductivity, of  $0.36 \pm 0.11$ , with a statistically significant difference ( $p < 0.001$ ).

The difference in the distribution of conductivity between mammary glands of the total group was  $10.15 \pm 5.18$ , the conductivity in the left breast was  $0.48 \pm 0.13$  and in the right breast,  $0.49 \pm 0.13$ ,  $p = > 0.05$ .

## **Sensitivity and Specificity of Mono Frequency Electrical Impedance Mammography (EIM).**

Regarding the distribution of the BIRADS diagnosis with MEIK electroimpedance mammography, it was BIRADS 1 (n = 211, 17.58%), BIRADS 2 (n = 765, 63.75%), BIRADS 3 (n = 173, 14.41%), BIRADS 4 (n = 46, 3.83%) and BIRADS 5 (n = 4, 0.33%). The distribution of the BIRADS diagnosis by Mammography was BIRADS 0 (n = 51, 4.24%), BIRADS 1 (n = 135, 11.25%), BIRADS 2 (n = 505, 42.08%), BIRADS 3 (n = 74, 6.16%), BIRADS 4 (n = 20, 1.66%) and BIRADS 5 (n = 3, 0.25%). The distribution of the BIRADS diagnosis by Doppler Ultrasound was BIRADS 1 (n = 27, 15.16%), BIRADS 2 (n = 114, 64.0%), BIRADS 3 (n = 27, 15.16%), BIRADS 4 (n = 9, 5.05%) and BIRADS 5 (n = 1, 0.56%) Table 2.

The diagnosis of certainty of breast cancer together with the sensitivity, specificity and positive and negative predictive values of EIM were determined: 85 % sensitivity [(true positives/ (true positives false negatives)) x 100; 96 % specificity [true negatives/(true negatives false positives)] x 100; 12 % positive predictive value [true positives/(true positive false positives)] x 100; 99 % negative predictive value (NPV) [true negatives/(true negatives false negatives)] x 100 Table 3 .

In total 6 biopsy-proven benign and 7 biopsy-proven malignancies. Negative cases were followed for at least 1 year without evidence of cancer. The 7 cases suggestive of malignancy were corroborated by EIM: BI-RADS 3 (n=1), BI-RADS 4 (n=4), B-IRADS 5 (n=2), which were confirmed with a histopathological diagnosis of mammary carcinoma. 44 cases False-negative findings on EIM were identified by other imaging modalities (US, Mammography) and 6 cases confirmed histologically benign. Table (4)

## **Distribution of mammary gland structure and density types from the perspective of EIM execution in accordance with to ACR classification.**

The mammary density according to the EIM classification being consistent with the ACR classification, was the following: Amorphous n= 63 (5.25%), Mixed with the predominance of the amorphous component n=219 (18.25%), Mixed n= 775 (64.5 %), Mixed with the predominance of the ductal component, high density of the ductal component n=98 (8.16%), Ductal extremely high density of the ductal component n= 44 (3.6%). The table summarizing the results of the mammary gland density assessment from the perspective of electrical impedance mammography with a view to the electric conductivity index (Table 5).

## **Electric conductivity and Body Mass Index.**

Electric Conductivity was associated with body mass index, we observed a statistically significant correlation ( $r=0.28$ ,  $p<0.05$ ) Figure (2). We used chi-squared test to assess for interactions between percent density and BMI (normal  $<25$  kg/m<sup>2</sup> ( $n= 310$ ), overweight  $25-29.9$  kg/m<sup>2</sup> ( $n= 418$ ) and obese  $\geq 30$  ( $n=437$ ) ( $p<0.05$ ). The patients with a diagnosis of mammary carcinoma had a BMI of  $35.51$  kg / m<sup>2</sup>.

The case of a 63-year-old asymptomatic patient who underwent exploration without positive palpation is described below. On admission, a mammography study was performed by electroimpedance (Figure 3), followed by bilateral mastography and ultrasound (Figure 4). A trucut biopsy was performed with a histopathological diagnosis of ductal carcinoma.

## Discussion

This study investigated the electrical impedance properties of breast tissue and demonstrated the different characteristics of electrical impedance scanning (EIM) images in groups of women of different ages, from 25 to 70 years old. There are several authors who analyze the benefits of different techniques for the early diagnosis of breast cancer (20).

Stojadinovic A, et al reported that 50 of 189 women in the Sensitivity arm had verified cancers, 19 of whom had a positive Electrical Impedance Scanning (EIS) test that resulted in a sensitivity of 38% (19/50). Of the 1361 women in the Specificity arm, 67 had a positive EIS test that resulted in a specificity of 95% (1294/1361) (21). In the present study, we demonstrated that Mono Frequency Electrical Impedance Mammography has a sensitivity of 85% and a specificity of 96% in 1200 women between 25 to 70 years of age, confirming previous studies. Glickman et al, reported results of an independent test group with 87 carcinomas, 153 benign and 356 asymptomatic cases. Histology was only available in symptomatic cases. The sensitivity was 84% with a specificity of 52% (22). Malich et al examined 387 lesions with the initial setup and found an overall sensitivity of 79% and a specificity of 64% (23).

Fuchsjäger et al, found the same increased sensitivities for smaller cancer as we did in our study, the increased sensitivity for small malignant lesions could indicate a potential of this method, our results showed that the use of EIM in addition to Mammography/US can improve the sensitivity of these methods and to increase the rate of early detection of breast cancer with minimal economic costs and highly qualified staff time expenditures (24). We included visible lesions by ultrasound and were located posteriorly to EIM in the suspected area. The high specificity is the result of a low number of false positives.

With a NPV of 99 % of EIM in BI-RADS category 4 breast lesions, a negative result in these lesions could be firm indication to manage them as BI-RADS category 3 and refer patients for a 6 month short interval follow up rather than performing a biopsy (25). Negative cases were followed for at least 1 year without evidence of cancer.

Many investigations have been oriented to establish an association between obesity and breast cancer (26, 27). It is necessary to have methods that allow us to select, in those patients with high breast density, those with a high risk of breast cancer to undergo complementary studies and / or breast biopsies in order to diagnose cancers in the early stages. Obesity and high breast density are common risk factors for breast cancer (28). In our study, 7 patients with mammary carcinoma had a BMI of 30.64. Shien Y et al, found a significant correlation between the percentage of mammary density in the BMI (29). We analyzed the distribution of the conductivity and the mammary density we could find its relation with the BMI! We found that 40% of postmenopausal women have a high BMI. The average of the conductivity was higher  $0.62 \pm 0.04$  in the category 1 of the ACR (Predominantly fat, parenchyma below 25%) vs.  $0.17 \pm 0.03$  in the category 4 (Extremely dense, parenchyma 75-100%).

Chiu et al, reported that dense breast tissue was significantly associated with breast cancer incidence [relative risk (RR) = 1.57 (1.18-1.67)] and with breast cancer mortality [RR = 1.91 (1.26-2.91)] after adjusting for other risk factors, also found that dense tissue was significantly associated with increased mortality from breast cancer ( 30 ).

The electroimpedance contributes to an evaluation with greater sensitivity in the dense breast tissue (31) and estrogen use in postmenopausal women (32). On the other hand women < 40 years of age are not screened and in their majority have dense breasts, as observed in our study. In addition to biological causal effects, dense breasts also have a masking effect that leads to a high rate of interval cancers due to a lower sensitivity, particularly in young women (33-35). This population can be analyzed with EIM the best adjunctive diagnostic performance can be achieved by a combination of US and EIM. Costs and patient morbidity could be minimized.

## Conclusions

In conclusion, our study showed that the sensitivity and specificity of Mono Frequency Electrical Impedance Mammography (EIM) has 85% and 96% respectively. These results suggest that breast electroimpedance can be used in women with obesity and dense breasts since these factors generate an effect that leads to a high rate of cancers at intervals, especially in young women. Our results showed that the use of EIM in addition to Mammography / US can improve the sensitivity of these methods and increase the rate of early detection of breast cancer with minimal economic costs and shorter time of highly qualified personnel.

## Abbreviations

**EIM** Mono Frequency Electrical Impedance Mammography

**US** Ultrasound

**IC** Electrical Conductivity Index

**PPV** Positive Predictive Value

**NPV** Negative Predictive Value

**ACR** American College of Radiology

**BI-RADS** Breast Imaging Reporting and Data System

**IDC** Infiltrating Ductal Carcinoma

**ILC** Infiltrating Lobular Carcinoma

**DCIS** Ductal Carcinoma in situ

**CC** Canalculus Carcinoma

**BMI** Body mass index

## Declarations

Ethics approval and consent to participate include a statement on ethics approval and consent (even where the need for approval was waived) **R-2017-785-108**.

Include the name of the ethics committee that approved the study and the committee's reference number if appropriate. **National Commission for Scientific Research (R-2017-785-108)**.

**Consent for publication Availability of data and material.** None Apply.

**Competing interests All Authors.** None to declare

**Declaration of Competing Interests:** None to declare. Non-financial competing interests "The authors declare that they have no competing interests in the elaboration of this investigation".

## Funding Authors' contributions

**BM** Conceived the study, participated in its design and coordination, and edited the draft of the manuscript.

**AH** Contribute with the interpretation of the mammography, ultrasound and biopsy performance by tru cut. Mammography interpreted by certified radiologists specializing in women's breast imaging.

**TR** Contribute with the interpretation of the mammography, ultrasound and biopsy performance by tru cut. Mammography interpreted by certified radiologists specializing in women's breast imaging.

**DS** Participated with the clinical evaluation of patients with diagnosis of mammary carcinoma and following treatment.

**MM** Histopathology studies of biopsy tissue samples were carried out.

**SM** Participated in coordination and helped to draft the manuscript.

**AR** Contributing with the realization of Electroimpedance Mammography.

**RR** Participated with data collection and statistical analysis.

**XL** Participated in coordination of the study, recruiting clinical data.

All authors read and approved the final manuscript.

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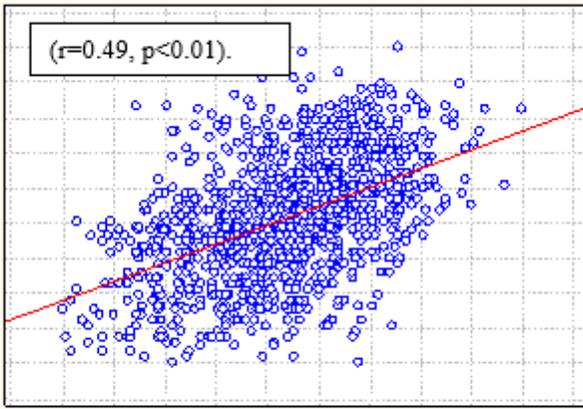
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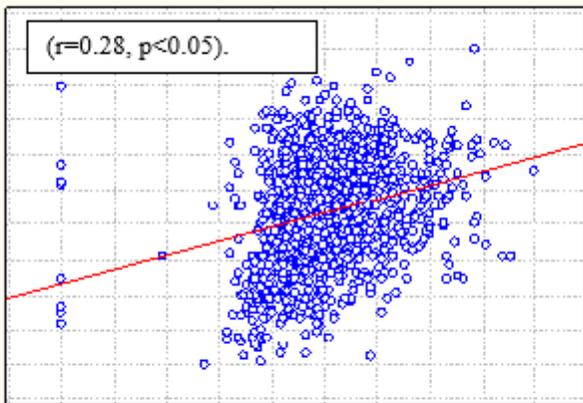
## Figures



$p < 0.05$  was considerate significant.

**Figure 1**

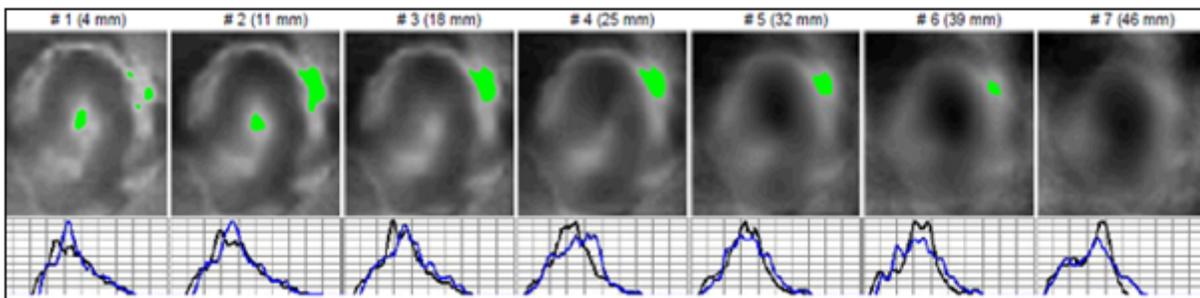
Correlation of Electrical Conductivity in the mammary tissue and age of the patients.



$p < 0.05$  was considerate significant

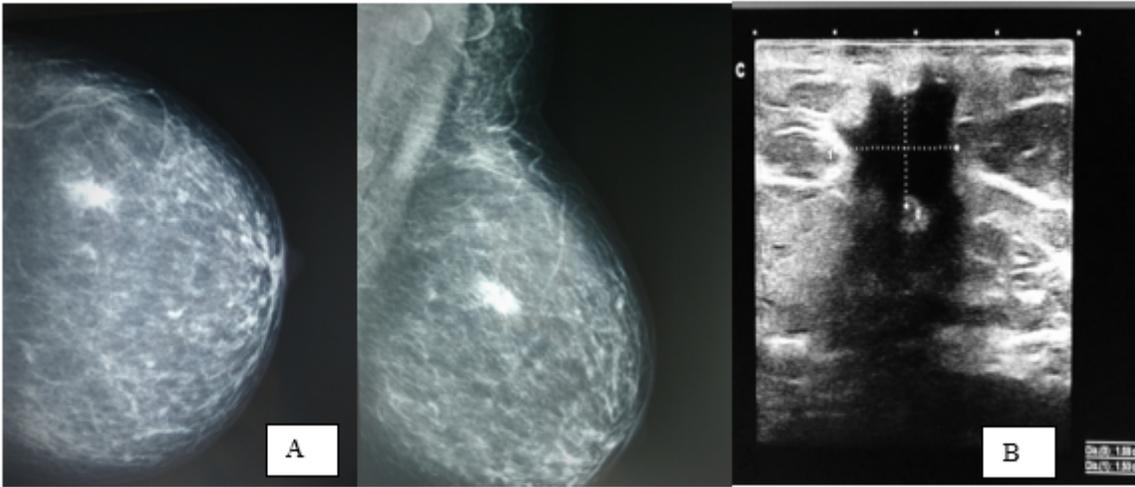
**Figure 2**

Correlation of Electric Conductivity and Body Mass Index.



**Figure 3**

Electroimpedance Mammographic. Series of 7 cuts of approximately 7 mm each. Left breast is observed: mammary contour with extrusion in the radius of the 3 that displaces the mammary structure and generates distortion of the architecture. Mammary anatomy with change marked with marker, oval type with electroconductivity of 0.39, which makes a lesion of suspicion of malignancy since it is above 0.95.



**Figure 4**

On 3 o'clock next to the areola a focus is visualized, highlighted-arrow, A: X-Ray: composition of tissue type B, a lesion of 10 mm in size with radiant contour in the upper –outer segment. B: US: A lesion of an irregular shape, partially angulated, undefined, hypoechoic margin, with a major axis not parallel to the plane of the skin, central vascularity to Doppler, and posterior acoustic shadow, in radius of 3 to 5 cm of the nipple, with dimensions of 15x9x10mm, to 6 mm of depth. Category 5 of the BI-RADS suggestive of malignancy that merits histopathological correlation.

## Supplementary Files

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- [supplement1.pdf](#)