

## CLINICAL STUDY

# Effectiveness of breast electrical impedance imaging for clinically suspicious breast lesions

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**ABSTRACT**

**OBJECTIVES AND BACKGROUND:** This study was designed to compare the usefulness of the breast electrical conductivity measures performed in a surgical examination room against conventional breast screening modalities for identifying the symptomatic lesions of the breast tissue.

**METHODS:** A group of 181 patients were examined with Ultrasonography (USG), Mammography (MG), Electrical Impedance Scanning (EIS) modalities and were followed-up 24 months to clarify in terms of the lesion tumour progression relationship. Tumour biopsy was determined as an endpoint of the study.

**RESULTS:** According to USG, 13 (7.2 %) lesion were suspicious, where as EIS was reported 22 (12.2 %). 2 of these 9 patients were presented as BI-RADS 4 and histopathologic result was proven as malignant disease during 6 months short-interval follow-up. EIS exhibited compatible sensitivity (81.2 %), accuracy (84.6 %) and PPV (81.8 %) rates with USG in BI-RADS 4 subgroup, combination of these modalities raised sensitivity rates to 92.31 %, accuracy and PPV to 100 %. EIS results in BI-RADS 3 subgroup were pointed out 77.8 % specificity and 87.5 % NPV rates.

**CONCLUSION:** Breast electrical impedance measures should be useful to reduce the number of the unnecessary follow-up and biopsy rates in the clinical setting (Tab. 2, Fig. 2, Ref. 39). Text in PDF [www.elis.sk](http://www.elis.sk).

**KEY WORDS:** breast, lesion, electrical impedance measures.

**Introduction**

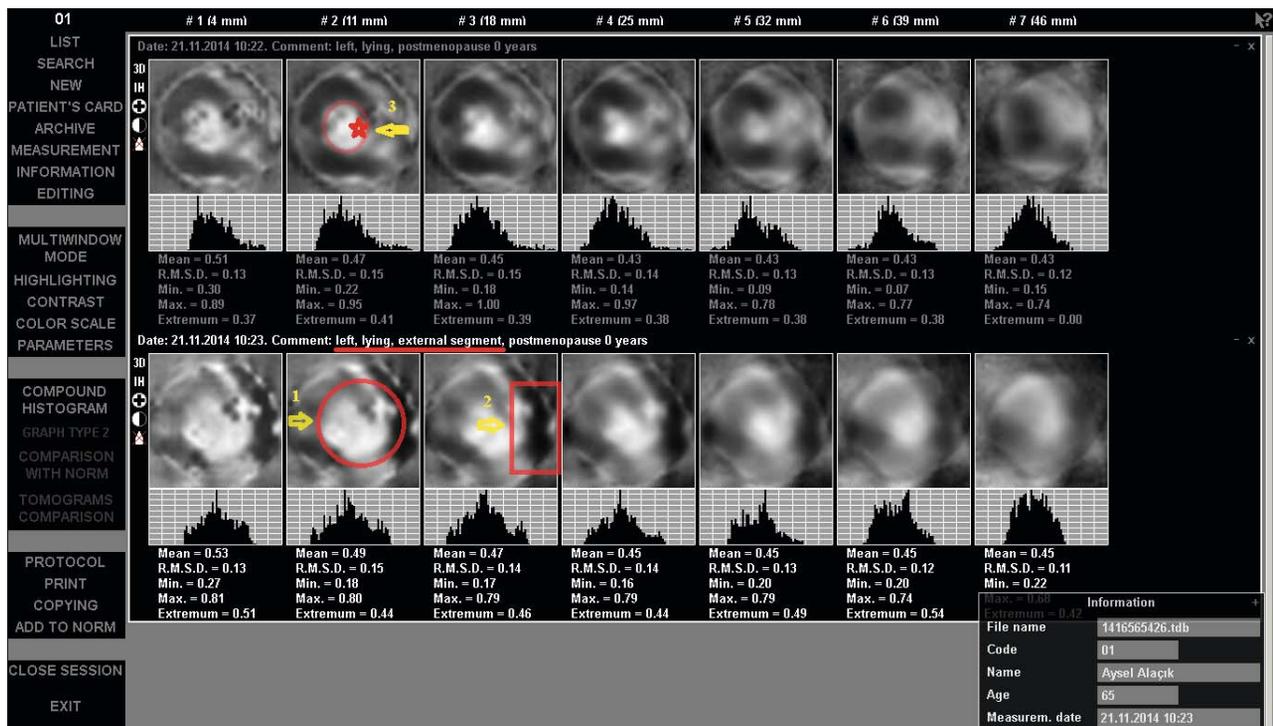
Symptomatic and suspicious breast lesions are the most common complaints of the women of all ages. Surgeons' breast examination experience and clinical skills are usually efficient to detect the palpable mass. In the multidisciplinary approach, surgeons definitely refer palpable and suspicious breast lesions to a radiologist for advanced screening. Although, Mammography (MG) is surely more decisive radiological procedure, additional Ultrasonography (US) and Magnetic Resonance (MR) imaging modalities also remains the mainstay of the imaging surveillance.

Thus, The American College of Radiology developed a reporting system to stratify the findings diagnosed on the MG, US and also MR imaging modalities (1). The Breast Imaging and Reporting Data System (BI-RADS) consist of five subgroups, where a suspicious category IV or V lesions should be considered for a biopsy. BI-RADS III category, 'probably benign lesions' of the breast, have usually been undertaken for short-term screening surveillance by

six month intervals within two years (2). Although, approximately 70 % of patients participated the short-term screening surveillance, planning an immediate work-up schedule or screening surveillance is still a matter of debate in the clinical setting (2–6). Some authors strongly recommend that BI-RADS III lesions should be considered with USG and MG modalities together for definitive categorization, to reduce the number of short-term follow-up examinations (7, 8). Even though, BI-RADS III category has been associated with lower risk of malignancy, histo-pathologic sampling of these lesions presented malignant pattern ranging from 0 % to 3.2 % in literature (9–11). In regard with the lack of MG evaluation under 40 years old, small and non-palpable probably benign lesions should be unnoticed with either clinical and/or self breast examination and screening surveillance, until they have grown sufficiently large enough that the woman herself detects a palpable mass (12, 13). In addition, there are some drawbacks to perform MG for patients under 40, due to lower incidence of breast cancer and lower sensitivity as a result of an increased breast density (14). Therefore, some lesions evaluated as benign in the screening modalities, but presented with suspicious findings in the clinical examination, are elected for an immediate work-up by surgeons, who carry the same concerns with their patients (15, 16). Though, surgeons seek for additional accurate and feasible imaging modalities to perform during the initial contact with the patient at the examination room, which helps to raise the diagnostic sensitivity and specificity of the MG/USG and also to reduce the rates of unnecessary biopsies. There have been several imaging modalities

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**Fig. 1. Electrical impedance scanning of a suspicious BI-EIM V/ BI-RADS IV lesion.** On left breast, for the breast glands that were excluded from frontal shooting, external quadrant shooting was performed. In external quadrant shooting, at the point shown by arrow sign on row 1, column 2, sign 1, so on outer quadrant of left breast at the level of 4 o'clock, a suspected lesion of disturbed shaped, and circulated with hyperimpedance due to the compression of tissues on right part (row 2, column 2, sign 2) was observed. Its disturbed shape, being circulated with a clear hyper-impedance and on frontal shooting (row 2, column 2, sign 3), dislocation of the nipple to the left due to the lesion show that this lesion is a malign formation that is progressed; compressed and dislocated the surrounding tissues.

described for adjunctive diagnosis of the breast lesions to assist the MG and USG (17–19). Among other screening modalities routinely performed, electrical impedance scanning (EIS) is a new, non-invasive, radiation-free imaging modality (20).

The purpose of this study was to determinate the prognostic value of the breast EIS over symptomatic breast lesions classified as BI-RADS category III and IV in mammography compared to USG.

**Materials and methods**

*Diagnostic evaluation*

Mammography and ultrasonography were evaluated by experienced radiologist who was unaware of clinical findings and EIS results. EIS was performed with a 3D EIS imaging system MEIC, by a trained surgeon, who attended a training session including device technical aspects of utilization and appropriate study application. MEIC device applies an alternative current (0.5 mA) with a frequency of 50 kHz to the breast tissue by scanning every 8 mm with the depth of 8 cm, via annular arrayed 256 electrodes. The distributions of the electric potentials representing the breast tissue heterogeneity and conductivity rates were processed with a software program into histograms. Each histogram represents a map of hypo- and/or hyper-impedance characteristics of the breast

tissue. The histograms help the clinicians to compare the scanning results of the patients for each suspicious lesion with the reference measures. The conductivity measures depending on the lesion shape, hyper-impedance margin, breast heterogeneity, local/relative electrical conductivity rates and surrounding tissue specifications were scored with between 0 to 2 values for each alteration or pathologic finding. The sum of the scores were stratified into a 5-grade scale impedance score (BI-EIM), in great concordance with BI-RADS classification system. BI-EIM score II and III were accepted as negative, where score IV and V were considered as positive and referred for a biopsy (Fig. 1).

*Patients*

A group of 181 patients with several breast complaints were included into a prospective cohort observational study design between January 2011 and June 2013 under an institutional review board-approved protocol. Each patient provided a written informed consent. The patient demographic characteristics, family history, clinical parameters, outcomes, imaging results and pathology results were recorded. All of the patients were evaluated with a MEIC (electrical impedance computer mammograph) device by an experienced and trained surgeon after an initial clinical breast examination. The patients provided such circumstances that have BI-EIM III and BI-RADS III lesions, were administrated for a

short term 6-month interval imaging surveillance program. Expert radiologist evaluated the patients with the complementary use of USG, MG and MR screening modalities during 24-month period to clarify the process of the suspicious lesion progression into invasive disease. The USG was performed in all 181 patients and MG in 154 patients. Only three patients were evaluated with MR. The suspicious lesions in either clinical examination or screening modalities evaluated as BI-RADS III–V category, were sampled by true-cut or open biopsy. The EIS examinations were then compared with other imaging modalities through imaging-based and/or pathology-based outcomes. The exclusion criteria were stated as suspicion of malignancy, pregnancy, lactation, electric-powered implants, chemotherapy, and a biopsy within 3 months of the EIS examination.

#### Statistical analysis

Performance characteristics of each imaging modality, including sensitivity, specificity, PPV, NPV, and accuracy, were calculated based on the histo-pathological diagnosis. We compared categorical results using a Fisher exact test and continuous variables using a 2-tailed Student t test or the Wilcoxon signed rank test, as appropriate. The Chi-squared test and/or Fisher exact test was performed for a comparison of BI-RADS lexicon and the EIS results. P values were determined with the chi-squared test and were considered to indicate a statistically significant difference if p value was lower than 0.05. Furthermore, a receiver operating curve (ROC) analysis was performed for BI-RADS and BI-EIM lexicon and a combination of both scoring systems. Data were administered and analyzed using the Statistical Package for Social Sciencers (SPSS, Release 11.5, Chicago, IL).

#### Results

The mean age of the patients was  $43.9 \pm 10.1$  (18–85) years. The most of the breast complaints were stated as localized pain in 92 (50.82 %) and palpable mass in 56 (30.93 %) on admission. BI-

RADS III-probably benign changes and BI-RADS IV-suspicious abnormalities were identified in 166 (92.26 %) and in 15 (8.28 %) patients, respectively. BI-EIM represented benign findings in 159 (87.80 %) and suspicious findings in 22 (12.2 %) patients. The ACR classification of the breast tissue was type 1 in 64 (35.4 %), type 2 in 20 (11 %), type 3 in 6 (3.3 %) and type 4 in 79 (43.6 %) patients. 12 (6.62 %) BI-RADS III lesions, and 13 (7.18 %) BI-RADS IV lesions were sampled. The mean lesion size was  $12.6 \pm 8.9$  mm (benign,  $19.5 \pm 13.9$  mm; malignant,  $11.8 \pm 8.8$  mm). Benign diseases were fibroadenoma in 83 (45.8 %), hyperplasia/metaplasia in 5 (2.8 %), cystic lesions in 60 (33.1 %), adenosis in 20 (11 %), lactation in 1 (0.6 %) patients. Subsequently, 14 (56 %) invasive ductal carcinoma results were distributed as 11 (44 %) in BI-RADS IV, and 3 (12 %) in BI-RADS III group, where 12 (48 %) benign results were distributed as 3 (12 %) in BIRADS IV and 9 (36 %) in BIRADS III group. During 6-month short interval follow-up period, BI-EIM positive-BI-RADS negative two (1.81 %) of nine patients were presented as BI-RADS IV and immediate work-up of these patients proved invasive malignant disease.

EIS was true positive in 12 of 14 malignancies and true negative in 7 of 11 benign lesions. Sensitivity, specificity, positive predictive value, negative predictive value and disease prevalence rates for EIS were 75 %, 77.78 %, 85.71 %, 63.64 % and 64 %, respectively. Although, pathology-based outcomes of each screening modality presented similar rates, adjunctive use of EIS with these modalities showed the highest sensitivity and PPV rates reaching 93.75 %, 88.2 %, respectively ( $p = 0.0005$ ) (Tab. 1).

In the BI-RADS III subgroup, the EIS was true positive in 3 of 4 malignancies and true negative in 7 of 8 benign lesions. Another noteworthy finding of EIS in BI-RADS III group is that with results of one false positive and one false negative, the specificity and NPV of the screening modality reaches the rates of 87.5 % (Tab. 2). The cystic lesions were better diagnosed with the USG and MG. Of 94 cystic and solid lesions, EIS were reported 1 (1.7 %) lesion as normal, 61 (64.9 %) lesions as cystic and solid, 32 (34 %) le-

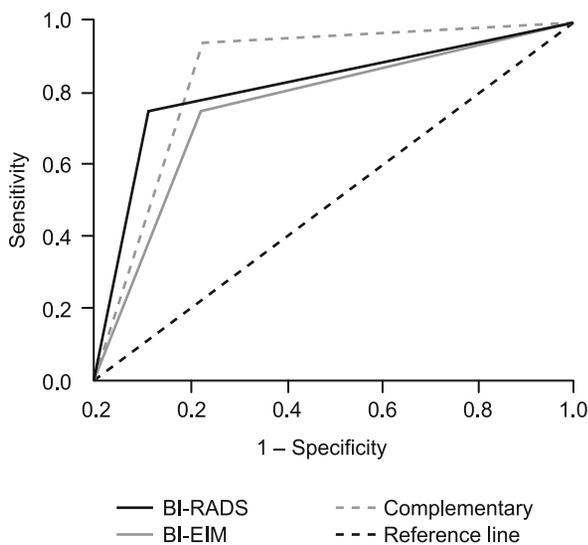
**Tab. 1. Overall 25 pathology-based outcomes of each screening modality either alone or complementary use.**

	True positive	True negative	False positive	False negative	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Disease prevalence (%)	p
MG	12	7	1	4	75.00	87.50	92.31	63.64	66.67	0.0037
USG	12	8	1	4	75.00	88.89	92.31	66.67	64.00	0.0036
EIS	12	7	2	4	75.00	77.78	85.71	63.64	64.00	0.0168
Complementary Use of EIS-USG	15	7	2	1	93.75	77.78	88.24	87.50	64.00	0.0005

**Tab. 2. Pathology based outcomes of each screening modality, either alone or complementary use in BI-RADS III and IV group.**

	True positive	True negative	False positive	False negative	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Disease prevalence (%)	p
EIS in BI-RADS 3 category	3	7	1	1	75.00	87.50	75.00	87.50	33.33	0.066
BI-RADS 4 category	12	0	1	0	100	na	92.31	na	92.31	na*
BI-EIM 4 category	9	0	1	3	75.00	na	90.00	na	92.31	na
Complementary Use in BI-RADS 4 category	12	0	1	0	100	na	92.31	na	92.31	na

\*na – not applicable



**Fig. 2. Receiver operating characteristic curves of BI-RADS and BI-EIM lexicon with single and complementary diagnostic performances for pathology-based outcomes.**

sions as solid masses. The sensitivity, specificity, disease prevalence, positive predictive value and negative predictive value of EIS for cystic lesions were, 85.92 %, 37.25 %, 58.20 %, 65.59 % and 65.52 %, respectively. Receiver Operating Curve (ROC) analyses for diagnostic performance of MG, USG and EIM screening tests presented Area Under Curve (AUC) results of 0.819, 0.764, respectively. When the tests were administered in complementary use, the AUC reached 0.858, with a significant  $p$  value ( $< 0.004$ ) (Fig. 2).

## Discussion

EIS has been recently described in many articles as an invaluable and efficient screening modality for benign and malignant diseases of the breast (21–27). EIS evaluates the electrical activity of the breast and surrounding tissue so that lower electrical impedance-conductivity rates of the lesion compared to the surrounding tissue represent a malignant disease (28). Besides the structural findings of the lesions described through the assistance of USG and MG, evaluating the characteristics of breast tissue electrical conductivity rates have been considered as a useful data for the clinicians to guide diagnosis and treatment decisions, as well. Thus, it has been argued in literature that the EIS technique should be utilized for assessing the breast tissue as a reliable tool both in single and complementary use (22, 29, 30).

Although EIS is emerging as a clinically useful diagnostic tool, there are brief reports evaluating the effectiveness of this screening modality (20). Among other supplementary diagnostic imaging modalities, EIS has the remarkable over-all sensitivity exceeding to 90 %. Malich et al. have suggested EIS with notable sensitivity rates for verification of suspicious mammographic and/or sonographic lesions (31). However, Diebold et al have dem-

onstrated overall lower sensitivity and specificity rates except for tumours smaller than 10 mm (32). Fuchsjaeager et al have also showed a better sensitivity and specificity rates in lesions sized  $\leq 10$  mm and invasive cancers (30, 33). In regard with supplementary electrical impedance of the breast, Raneta et al have reported similar outcomes with an emphasis over effectiveness of the techniques' capacity about the metabolic process, not the structural changes of the breast (34, 35). Therefore, breast tissue electrical conductivity rates have been favoured in suspicious lesions and EIS had been implemented into the clinical practice as an adjunctive imaging modality. In our study, adjunctive use of EIS in suspicious breast lesions had increased the sensitivity rates from 75 % to 93.75 % and NPV rates from 67 % to 88 %, but presented similar results in specificity and PPV. During follow-up, EIS demonstrated an abnormal electrical conductivity rates in three sonographically normal cases and biopsy proved invasive cancer in two of them. Our findings indicated that EIS was a safe and accurate diagnostic tool even in unnoticed lesions by conventional imaging modalities.

There is an ongoing debate between clinicians about referring BI-RADS III category lesions to immediate work-up and/or short term imaging follow-up (7, 36). Lee et al demonstrated in the study that screening surveillance of BI-RADS III category lesions was more cost-effective than the immediate surgical intervention and also spared the women from unnecessary biopsies (37). However, despite all efforts for close follow-up, the studies mentioned that approximately 30 % of participants did not obey to screening surveillance (2). Helvie et al reported that 12 % patients with probably benign mammographic findings had no follow-up, and only 47 % completed 3 years of surveillance (5). Similar follow-up participation rates were also reported after percutaneous biopsy of the suspicious lesions (38, 39). Although a large majority of BI-RADS III lesions referred for biopsy have a benign disease, some clinicians still prefer to sample the suspicious lesions. Lack of mammographic evaluation especially in younger patients states as a valid reason for biopsy requirement to detect an early breast cancer. Stojadinovic et al suggested that EIS has presented promising results for early detection of non-palpable breast cancer in younger patient groups and described EIS as a safe diagnostic tool in this group of patients (13). The authors have also suggested the presence of the positive EIS results in biopsy proved benign lesions were significantly higher than in normal, asymptomatic women, indicating that abnormal breast impedance rates should be targeting the women at risk of a possible malignancy and should be determined as a precursor of a possible malignancy. Nonetheless, according to guidelines, the additional value of breast electrical impedance in BIRADS III lesion is not yet clear. Malich et al have demonstrated the specificity rates of EIS in sonographically visible and not visible benign lesions as 63 % and 67 %, respectively (25). Wersbe et al have also demonstrated comparable specificity rates in proliferative and non-proliferative benign breast lesions as 67 % and 71 %, respectively (26). These reports have demonstrated similar, but insufficient outcomes to evaluate true negative results in mammographic BIRADS III lesions 13. In contrast, recent studies have

reported a negative breast EIS with high NPV of 83.8–97 % as an invaluable tool to safely exclude malignancy (30, 33). As a result, Fuchsjaeger et al also reported that EIS should be considered as an adjunctive imaging modality in combination with USG for suspicious lesions to minimize the costs and patient morbidity. In our study, complementary use of USG and EIS reduced the false negative results of USG from 16 % to 1 %. Our EIS results provided sufficient NPV (87.50 %) in BI-RADS III lesions to reduce the short term imaging follow-up rates by ruling out the potential malignancy risk with category minimization. Additionally high specificity and NPV rates of EIS also demonstrated that adjunctive use of these modalities should prevent unnecessary biopsy requirement for all equivocal findings.

Limitations of our study were the restriction of the analysis to BI-RADS III and IV cases and ethical problems in regard to sample all cases in BI-RADS III group. Therefore, no definitive statement about the sensitivity and specificity of breast USG could be made in BI-RADS III category lesions. Immediate work-up could not be performed with EIS results. Further analysis should evaluate suspicious lesions detected or missed by breast EIS as a first-line tool.

## Conclusion

Clinicians demand additional and innovative imaging modalities through the complimentary use with the MG and USG, to reach more accurate and faster diagnostic results for the suspicious breast lesions. In regards to the new advances with more comprehensive works, the EIS modality would be a standard tool (first step tool) for the management of the breast lesions in the near future.

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