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A REVIEW ON BREAST ELECTRICAL IMPEDANCE TOMOGRAPHY CLINICAL ACCURACY

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ABSTRACT

Electrical Impedance Tomography (EIT) is a non-invasive procedure using electrical impedance to image the human breast. Due to its mobility and using non-compression technique it is appealing to patients. This scanning device does not emit any ionizing radiation thus it can be done on pregnant women by means of no age limit. Since the EIT has play some supplementary function in the breast imaging, a lot of research on its clinical accuracy has been done. Therefore, the aim is to carry out a review of EIT clinical accuracy and assess the quality of journal by using Quality Assessment of Diagnostic Accuracy Studies (QUADAS) criteria. The journals that assess the sensitivity were search through various databases and the clinical accuracy of EIT in each journal is recorded. The review shows that the range sensitivity (S_n) of EIT system to human breast in ten journals was between 17% and 94.6%. The range of specificity (S_p) is between 49% and 97.1%. The negative (NPV) and positive predictive value (PPV) is between 74% and 98%; 4% and 73.3% respectively. The accuracy (ACC) of EIT is between 69% and 80.5%. This value is found to be supported that EIT can be used as an adjunct screening technique for human breast.

Keywords: electrical impedance tomography, diagnostic accuracy, breast cancer.

INTRODUCTION

Breast cancer is considered to be the final outcome of multiple environmental and hereditary factors and therefore the best way to prevent mortality is by early detection. Nowadays, there are various modalities for diagnostic imaging such as magnetic resonance imaging (MRI), computed tomography (CT) scan and mammography. Between all the modalities, mammography has become a gold standard for breast imaging (Tinberg *et al.* 2011). Mammography has become an effective imaging tool for detecting early stage of carcinomas in the breast (Park *et al.* 2007). However it uses ionizing radiation and causes discomfort to patients due to compression of the breast tissues (Prasad et al., 2008). Attenuation of the tissues using radiation enables the inner structure of breast tissues to be visualized on the mammogram tissues (Zou and Guo, 2003). Other modalities namely ultrasound is used as an adjunct to mammography for the differentiation of potentially suspicious breast lesions (Subbhuraam *et al.* 2011).

Breast imaging together with other more advanced complementary methods focuses on improving early detection of the cancer cells and reduces the occurrence of missed cancers (Houssami *et al.* 2009). One suggested method is electrical impedance tomography (EIT). A potentially, new noninvasive diagnostic technique based on different electrical storage potential of normal and pathologically altered tissues allowing image differences in the tissue conductivity and permittivity inferred from the body surface electrical measurements. EIT consists of a hand-held scanning probe and a computer screen that displays two-dimensional images of the breast. The EIT examination is performed with the subject recumbent, with both arms raised above the head. The purpose of this position is to flatten the breast as much as possible, allowing optimal contact of the flat surface of the scan probe with the breast tissue. The transducer is firmly pressed against the breast and the probe is moved in such a way as to remove air bubbles and to ensure good contact with the breast. Due to its mobility and utilizing a non-compression technique it is appealing to patients. This scanning device does not emit any ionizing radiation thus it can be done on pregnant women by resulting in no age limit (Abdi and Liatsis, 2011).

The aim of this review is to systematically collect journals on the clinical accuracy of breast EIT in detecting breast cancer. The journals then will be evaluated according to the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) criteria.

METHODOLOGY

The literature search for relevant references was performed by using two different databases, which included Medline and Scopus to cover publications between 2000 and 2015. Archived journal are assessed through the University Kebangsaan Malaysia library database and were extracted based on the criteria mentioned bellow. The terms used for identification of references were 'electrical impedance tomography'; 'breast cancer'; and 'sensitivity'. The search was limited to include all the studies that had been published in the English language and related to the clinical accuracy of EIT specifically on human breast tissue. Exclusion criteria included experimental studies, studies that did not highlight details on sensitivity (S_n) on overall performance of breast EIT and any review studies. Additionally those which full text could not be obtained were excluded. Comparisons of the sensitivity in each journal were performed based on overall performance.

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RESULTS

The search process and results of obtaining these references are shown in Figure-1. Sixteen citations were identified to be relevant to the S_n of EIT on the human breast. After screening all the journals in the database, ten journals were included in this study. Table-1 show the result of the S_n of EIT on the human breast from each journal. According to the data, the highest and the lowest S_n of the EIT system on the human breast that have been recorded in previous studies were 94.6% and 17% respectively. The range of specificity (S_p) is between 49% and 95.1%. The negative (NPV) and positive predictive value (PPV) is between 74% and 98%; 4% and 73.3% respectively. The accuracy (ACC) of EIT is between 69% and 80.5%.

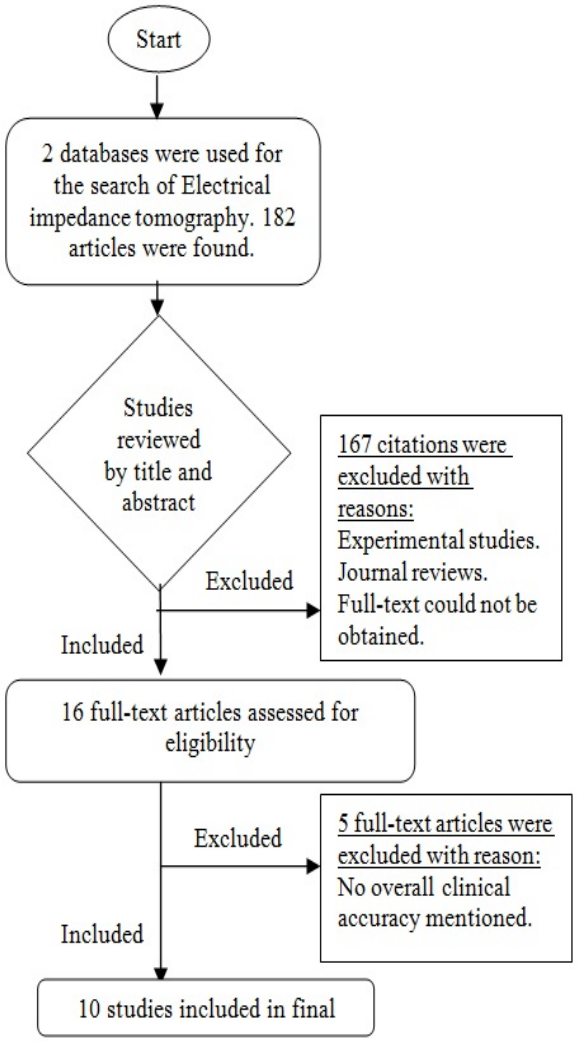

Figure-1. Flow diagram of study inclusion.

Table-1. Clinical performance of EIT to human breast.

Authors	Year	No of Subject	S_n %	S_p %	NPV %	PPV %	ACC %
Malich et al.	2000	52	75.9	72.4	75.0	73.3	-
Alexander et al.	2005	1,103 Age: <40 - ≥50	17.0	89.0	98.0	4.0	-
Fuchsjaeger et al.	2005	121 Mean age: 51.8	94.6	74.7	97.1	60.3	80.5
Szabo et al.	2005	137 Age: 33-92	86.0	49.0	74.0	67.0	69.0
Alexander et al.	2006	1,550 Age: 30-45	38.0	95.1	-	-	-
Alexander et al.	2007	2,141 Age: 30-45	26.4	94.7	-	-	-
Wang et al.	2010	583 Mean age: 36.1	86.7	72.9	94.1	51.2	76.3
Pak et al.	2012	117 Age: 22-84	87.4	-	-	-	-
Renata et al.	2012	808 Mean age: 54	87.0	85.0	96.0	63.0	-
Zain and Kanaga	2014	150 Age: 40-65	64.4	70.1	67.5	67.1	-

DISCUSSIONS

Various attempts have been made to improve the diagnostic efficiency of conventional breast imaging methods by introducing new techniques. The aim of screening is to apply early breast cancer diagnosis and to determine which female patients should be subjected to expensive examinations. The radiation-free EIT meets this requirement. This kind of imaging method detects early symptoms of the human breast pathology using the abnormality in breast impedance distribution which is based on the structural parameters of human breast tissue or metabolic processes in the tissues of interest and in the surrounding tissues. Hence this study is important to know the range of EIT S_n for breast cancer screening.

The highest S_n of breast EIT is 94.6% recorded from Fuchsjaeger *et al.* in 2005. In this journal, the author evaluates the S_n of EIT with mammography and ultrasonography. The 94.6% S_n illustrated a true positive in 35 of 37 malignancies and a true negative in 68 of 91 benign lesions. The author compared a number of previous studies (Wersabe et al.; Fuchsjaeger *et al.* 2002) which evaluate the S_n by using old software (version 2.66) and no detailed ultrasonography localization of lesions. In the previous study with old software, the S_n was between 62% and 87.8% which is lower than the study from Fuchsjaeger *et al.* 2005. The author concludes that the newest software (version 2.67) shows an increase in breast S_n for EIT and the best adjunctive diagnosis results can be achieved by a combination of EIT and ultrasonography.

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The highest S_p of breast EIT at 95.1% demonstrates by Alexander *et al.* in 2006. In this journal, the author obtained S_p estimated from a prospective consecutive series of EIT examinations in the population of asymptomatic women under age of 40. For the purpose of this study, S_p was defined as the percentage of woman in the studied population with a negative EIT examination. Hence it was assumed that all participating women were negative for breast cancer. The author concludes that EIT should be used to identify women who should be investigated further rather than to spot women who have known abnormalities from being recommended for a follow-up.

The highest NPV of breast EIT was 98% reported by Alexander *et al.* in 2005. In this journal, the author evaluates the feasibility of EIT for early detection of breast cancer in young women which involved 1,103 participants, stratified according to age (<40, 40-49, ≥50 years). The author determines that NPV was higher for younger (<40 year) than older women due to the higher incidence of cancer in older age group. Hence, this journal concludes that the high S_p of EIT reduces the need for unnecessary additional testing and potentially invasive diagnostic procedures. The study by Fuchsjaeger *et al.* in 2005 reported 97.1% NPV for EIT in BI-RADS IV breast lesions with the newest software (version 2.67) supported by previous studies by Wersabe *et al.* and Fuchsjaeger *et al.* 2002 which has shown 83.9% and 91.3% difference. However these previous studies have a limited number of cases and the older software version was used. In this study, the author reported that the ACC of EIT performance is 80.5%.

Hence, the usefulness of a negative result from an adjunctive imaging modality such as EIT with its high NPV is important to reduce the number of unnecessary biopsies. This statement is supported by Elmore *et al.* in 1998. The highest PPV of breast EIT was 73.3% recorded from the study by Malich *et al.* 2000. In this study, the author evaluates whether EIT is useful in routine screening examinations in fifty-two women with fifty-eight suspicious lesions. The study design enables the use of magnetic resonance mammogram (MRM) to exclude signals from areas not corresponding to mammography to detect focal malignancies, thereby confirming that the spots were indeed a false positive. The author determines that false-positive rate is 0.43 per patient and suggests that it could be useful for patients with denser breasts. The author concludes that EIT is a promising technique as an adjunct to mammography.

All journals have been assessed through QUADAS format questions. This assessment is to evaluate the quality of the journals used in this review. Table-2 shows the questions used in assessing the quality of journals selected.

Table-2. QUADAS questions.

S. No.	Questions
1.	Was the spectrum of patient's representative of the patients who will receive the test in practice?
2.	Were selection criteria clearly described?
3.	Is the reference standard likely to correctly classify the target condition?
4.	Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?
5.	Did the whole sample or a random selection of the sample, receive verification using a reference standard of diagnosis?
6.	Did patients receive the same reference standard regardless of the index test result?
7.	Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)?
8.	Was the execution of the index test described in sufficient detail to permit replication of the test?
9.	Was the execution of the reference standard described in sufficient detail to permit its replication?
10.	Were the index test results interpreted without knowledge of the results of the reference standard?
11.	Were the reference standard results interpreted without knowledge of the results of the index test?
12.	Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?
13.	Were uninterpretable/ intermediate test results reported?
14.	Were withdrawals from the study explained? (withdrawals)

Question 1 assesses whether the subject is selected randomly and represents the population. Question 2 assesses the inclusion and exclusion criteria for the entire study. For these two questions, almost all journals specifically stated the character of cases or patients included and excluded in the study. Two journals had unclear explanations pertaining to the criteria. The study by Malich *et al.* 2000 did not mention the mean age of the patients because in the images viewed were collected from the database. Another journal by Pak *et al.* 2012 had not described the sampling method in the study.

Question 3 evaluates determines if the condition or criterion of the image is correctly matched with reference standard. The entire journal has a standard reference mentioned in the study. Various combinations of Clinical Breast Examination (CBE); mammography; ultrasonography; biopsy or histopathology results; and MRM are used in almost all journals to obtain the clinical performance of EIT on the human breast. One journal by

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Pak *et al.* 2012 has did not mentioned the standard reference in the study. Question 4 assesses the quality of the time interval during the collection of the data in the journal. Some diseases may be aggressive in nature resulting in an alteration in the final results. Hence the duration of assessing and obtaining the data is important. All journals have a clear explanation of the collection of data. Question 5 evaluates the bias in relation to the selection of result and subject. All journals applied the standard verification technique to avoid biasness.

Question 6 assesses the quality of the journals whether all the subjects or patients verified had the same reference standard. All journals had their own reference standard in ensuring the disease experience by the patients. The biopsy or histopathology results of patients were assessed. Question 7 states that the result or test performed is not influenced by the standard reference. All journals did not have any influence by the standard reference. They interpreted the data independently. Question 8 and question 9 evaluate the execution of the test in the journal and the reference standard. All journals reported sufficient details and citations of the reference they used in the study. Question 10 and question 11 evaluate the interpretation of the result in the journal. All journals performed comparisons with the reference standard. Hence the results were interpreted blindly.

Question 12 assesses the availability of clinical data during the interpretation of test results which may affect estimates of a test performance. From our point of view, all studies had their own reference. References vary from previous journals evaluated. Question 13 assesses any bias towards unacceptable or un-interpretable results in the journal. All journals have a clear interpretation of results. Indeed some journals did not contain vital criteria necessary such as the S_p; PPV; NPV; and ACC value, however the journals still interpreted data based on the aim of their study.

Question 14 evaluate whether the withdrawal of subjects from the study were explained. All journals had a clear explanation on the subject from the beginning of the study until the results were obtained. There were no withdrawals and "no loss" follow up of such patients in all journals. Interestingly, some of these journals did not indicate the overall sensitivity value of EIT; therefore limiting the number of appropriate information orientated journals available for utilization in this study. Furthermore; the missing information on the S_p; PPV; NPV; and ACC value has limited the evaluation on that area.

CONCLUSIONS

In conclusion, this value from ten journals is found to be supported this until EIT can be used as an adjunct screening technique for the human breast. The sensitivity of EIT performance on other factors such as type; size and depth of breast malignancy; family history of breast cancer and exogenous hormone usage could be included in future systemic reviews.

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