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Usefulness of Organ Electrodermal Diagnostics in Detection of Breast Pathology: A Multicenter, Randomized, Double-Blinded Clinical Study

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ABSTRACT

Objective: Pathology of an internal organ/body part causes corresponding skin areas—organ projection areas/acupuncture points—to rectify applied electrical currents (a diode phenomenon) once the resistance ''breakthrough effect'' has been induced in these specific, and sometimes remote, skin zones. The aim of this study was to estimate the diagnostic accuracy—as well as the scope of utilization—for detection of breast pathology of organ electrodermal diagnostics (OED), which utilizes this electrophysiologic phenomenon.

Materials and Methods: A multicenter randomized, double-blinded comparative study of OED results and clinical diagnoses, as the criteria standards, was done on 400 female volunteers, with a mean age of 39 (standard deviation: 9 years), at three academic breast clinics. Participants were divided into 7 groups: (1) a control group; (2) a cancer-survivor group; (3) a breast-fibroadenoma group; (4) a mastitis group; (5) a breast-abscess group; (6) a preinvasive breast-cancer group; and (7) an invasive breast-cancer group.

Results: The OED overall detection rate was 88.8%, the sensitivity rate was 92.7%, and the specificity rate was 76.5%. The predictive value for positive OED results equaled 92.4% and, for negative OED results, equaled 77.3%. However, both sensitivity and specificity rates varied among specific groups. The highest sensitivity rates were shown by OED in groups with serious pathologies, such as invasive cancer (94.2%), preinvasive cancer (90.0%), breast abscess (94.4%), and mastitis (95.9%). The OED results correlated with the intensity of the pathologic process within breasts but were not affected by either the type or the etiology of the disease.

Conclusions: OED appears to be a reliable method for detecting breast pathology; this method might also estimate the intensity of a breast pathologic process but cannot explain the cause of the disease directly.

Keywords: breast screening examinations, organ projection area, acupuncture point, electrical breakthrough effect, rectification of electrical current

INTRODUCTION

BREAST CANCER affects ~1 in 11 women worldwide and still shows high a mortality rate. There is a general consensus that early detection is the key to successful management of breast cancer. Various diagnostic methods are currently in use, which include regular self-examination, mammography, ultrasound (US) examination, breast scintigraphy, thermography, magnetic resonance imaging (MRI), as well as histologic/cytologic investigations, and genetic testing. However, physical examination is not very accurate when it comes to early cancer and other investigations can be costly. Therefore, there

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is a great need for an accurate, yet affordable, diagnostic method suitable for mass screening/monitoring examinations on a regular basis. Common benign breast lumps include fibroadenomas and cysts as well as fibroadenosis. Rare benign breast lumps include periductal mastitis, galactoceles, abscesses, lipomas, fat necrosis, and seborrheic cysts.

Organ electrodermal diagnostics (OED) is a new, noninvasive bioelectronic method of medical regional diagnostics, which enables rapid detection of organ/body part pathology and precise estimation of the pathologic process intensity within affected internal organs/body parts.[1–6] Pathology of an internal organ/body part changes electrical features of the corresponding skin areas—organ projection areas (OPAs)—that are often identified with traditional acupuncture points/zones.

Once the resistance ''breakthrough effect'' has been induced in these specific skin areas (i.e., a rapid reversible significant resistance decrease due to sufficient measuring voltage and pressure of the negatively polarized point electrode),[1,5–9] the rectification of applied electrical currents (a diode phenomenon) occurs.[1,4–6,8,10] Pathology of an internal organ also increases the impedance of corresponding OPAs.[5–8] The location of the skin zone, where a high degree of rectification and increased impedance are observed, is indicative of which particular internal organ/body part is affected.[1–8,10–13] The degree of rectification and the difference in impedance indicate the intensity of the pathologic process within the related organ/body part.[1–8,10–13] The OED utilizes these electrophysiologic phenomena of the skin, proving that the ancient therapeutic system of acupuncture can also be a basis for a groundbreaking, advanced, bioelectronic diagnostic development.

The aim of the study was estimation of the diagnostic accuracy and the scope of utilization of OED for the detection of breast pathology.

MATERIALS AND METHODS

Study Design/Sampling

This multicenter, randomized, double-blinded comparative study of OED results and clinical diagnoses, as criteria standards, was done on 400 female patients in total, with a mean age of 39 (standard deviation: 9 years), at the Batho Pele Breast Unit, Chris Hani Baragwanath Academic Hospital, Breast Unit, Charlotte Maxeke Academic Hospital, and Breast Care Clinic, Helen Joseph Academic Hospital, all in Johannesburg, Republic of South Africa. Such a general preselection of patients with suspected pathology of the breast prevented a disproportionate number of ''healthy'' results versus ''diseased'' results.

Every week, on the same day and at the same time, OED examination of newly admitted patients was performed, before the final clinical diagnoses were established. Each patient was always brought to the OED examination room by a witness. The witness was appointed by an independent arbiter and was either a medical doctor, student, or nurse. The OED investigators (2 medical doctors and an electronic engineer, all working on a randomized basis) had no access to the patient's documentation whatsoever and the witness was present during the entire OED examination procedure to ensure that there was no communication between investigators and patients. Then, the OED results, signed by the witness, were handed over to the independent arbiter, who kept them in a sealed container until the final clinical diagnosis was made by a separate clinical team.

For statistical purposes participants were divided into 7 groups, depending on the clinical diagnosis: (1) a control group (breasts proven healthy with no history of cancer); (2) cancer survivors (at least 6 months after completion of treatment); (3) a breast-fibroadenoma group; (4) a breast-inflammation group; (5) a breast-abscess group; (6) a preinvasive breast-cancer group; and (7) an invasive breast-cancer group. *Preinvasive* (*in situ*) cancers are defined as tumors that remain in confined areas within the lining of either the ducts or lobules of the breast; once the cancer cells have spread beyond these linings, the tumor is described as *invasive*.

The study was approved by the Human Research Ethics Committee of the University of the Witwatersrand as well as the Medical Advisory Committees of the Chris Hani Baragwanath Academic Hospital and Helen Joseph Academic Hospital. Written informed consent was obtained from all participants.

Clinical Investigation Procedure

Diagnostics of various breast pathologies comprised history and clinical examination, mammogram, US examination, chest radiograph, histologic/cytologic investigations, and MRI (when indicated). Operative findings were included if the patient underwent surgery. All investigations were performed in the course of normal patient care by the medical staffs of the breast clinics. Details of all investigations and the final clinical diagnoses are available in the hospital records.

OED Examination Procedure

Only auricular OPAs were used for this study, because each auricular OPA corresponds to only one internal organ/body part[1–8,10–13] in contrast to the corporal acupuncture points (classical acupuncture points), which might be related simultaneously to quite a few internal organs or other body parts.

Electrical evaluation of respective OPAs was performed with the OED Diagnotronics device (CE Certificate C52113; South African Department of Health License No. 476/8677; Fig. 1), which was developed by the TTS Electronics (Pty) Ltd. Johannesburg-based company that was appointed specifically for this purpose in terms of the South African

FIG. 1. Organ Electrodermal Diagnostics examination by means of the Diagnotronics device (CE Certificate C52113; South African Department of Health License No. 476/8677). The location of skin area corresponding to examined organ and diagnostic result after the examination is completed are displayed on the screen. This photograph appeared in Szopinski JZ, et al. Influence of Internal Organ Pathology on Vascular Permeability of Related Skin Zones: An Attempt to Visualize Organ Projection Areas. *Med Acupunct* 2017;29(5), Fig. 1, p. 302. Patient shown with permission.

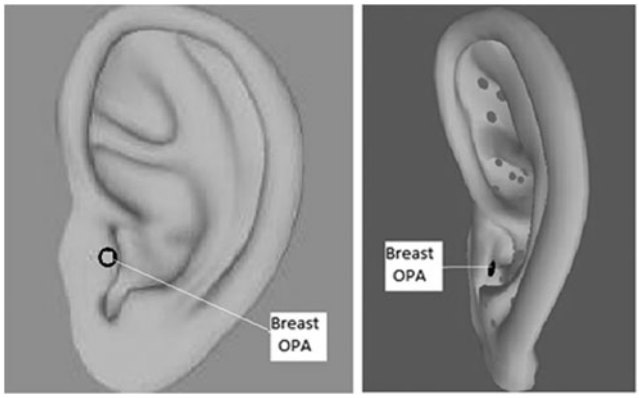

FIG. 2. The breast-related auricular organ projection area (OPA) is located on the internal aspect of the tragus.

government's program SPII No 200011051. Only the direct current (DC) measuring modality was used:[6] this modality automatically estimates the degree of rectification of the measuring electric current once the resistance breakthrough effect has been induced in the skin. This rapid, reversible significant resistance decrease achieved under the measuring conditions described below is the key to obtaining skin resistance measurements that correlate with the conditions of related internal organs/body parts. The device uses optimal measuring parameters selected on the basis of the statistical characterization of the electric resistance and impedance of the OPAs/acupuncture points.[5,6,8]

Skin areas selected for the electrical evaluation were cleansed with alcohol and dried prior to the examination. The examination entailed placement of the brass reference electrode (2 cm in diameter and covered with a conductive gel) on any area of the patient's skin (e.g., on a hand) and placement of the dry brass point measurement electrode (2 mm in diameter) on the auricular OPA corresponding to the breasts (Fig. 2.). This specific skin zone, located on the internal aspect of the auricular tragus, was chosen on the basis of the current first author's experience.[6] Depending on the size of each patient's particular ear auricle, the OPA can measure from 3 to 10 square mm. Therefore, in each case, all the areas had been checked, mm by mm, on both ear auricles, by means of a point measurement electrode, applying a constant pressure of $\sim 200g/cm^2$. Then the highest degree of the measured rectification was presumed as final.

The measuring procedure always started with gradually increasing potential of the negatively polarized point electrode until the breakthrough effect was obtained (usually between 7 V and 15 V). The current was then adjusted to 25 μA, and the skin resistance was measured. The polarity of the point electrode was subsequently inverted (set to the same voltage at which the skin resistance measurement was taken, but positively polarized), and a second resistance measurement was taken. These two measurement values, taken from the same skin point, were used to calculate the rectification ratio, which was not affected by all the factors that influence the actual (absolute) skin-resistance values:

$$\text{Rectification ratio} = [1 - \frac{\text{(First Measurement)}}{\text{(Second Measurement)}}] * 100\%$$

Every time, all the above described measurements and calculations were automatically performed, within seconds, with the Diagnotronics device. Then, the actual condition of the investigated breasts was estimated as ''healthy'' (0%–40% rectification), ''within normal limits'' (41%–60% rectification), ''subacute'' (61%–80% rectification), or ''acute'' (81%–99% rectification). A special percentage display made it possible to specify more accurately the degree of rectification of the measuring current (normal range: 0%–60%). The average time of completion of the OED examination was ~ 2 minutes.

Statistical Procedures

Comparison of clinical diagnoses and OED results was undertaken by independent arbiters, who were not involved in the diagnostic procedures. Only patients with proven clinical status of their breasts and in the statistical groups of breast pathology were considered for final statistical comparison. A χ^2 test was used to calculate statistical significance. $P < 0.05$ was accepted as the statistically significant difference. The detection rate, sensitivity, specificity, positive predictive value, and negative predictive value were determined according to standard formulas.[14,15]

RESULTS

As shown in Table 1. there was a total of 355 true OED results obtained, including 280 true–positive (regarded as diseased by both the clinical team and the OED) and 75 true–negative (regarded as healthy by both the clinical team and the OED).The 45 false OED results included 23 false–positives (regarded as healthy by the clinical team but falsely as diseased by the OED) and 22 false–negatives (regarded as diseased by the clinical team but falsely as healthy by the OED). Thus, the overall OED detection rate was 88.8%. Established OED overall sensitivity (probability that a test result will be positive when the disease is present) was 92.7% and OED overall specificity (probability that a test result will be negative when the disease is not present) was 76.5%. The predictive value for positive OED results (probability that the disease is present when the test is positive) was 92.4% and the predictive value for negative OED results (probability that the disease is not present when the test is negative) was 77.3%.

However, both sensitivity and specificity rates varied among specific groups. The highest OED sensitivity rates occurred in groups with serious breast pathologies: invasive-cancer group, 94.2%; preinvasive-cancer group, 90.0%; breast-abscess group, 94.4%; and mastitis group, 95.9%. The OED readings in these groups were mainly acute. In the case of fibroadenoma, which is a much less serious condition, the sensitivity rate was 64.9%. OED readings in this specific group were mainly subacute. The specificity rate in the control group was 83.3%, while in the cancer-survivor group, the rate was 65.8%. Healthy participants usually had within normal limits or healthy OED results.

There was no difference between the measurement results obtained on the left and on the right ear auricle—the OED does not indicate in which breast the pathology is located. The OED results were not affected by either the type or the etiology of disease (i.e., OED estimates the intensity of the pathologic process within breasts but does not explain the cause of the disease directly).

It was noted that the OED results were not influenced by a patient's muscular tension, emotional state, skin humidity, environmental temperature, or by procedure duration. The pressure of the measuring electrode had a limited influence (up to 5%) on the OED results and did not affect final estimations. OED measurements did not cause any unpleasant sensations. No side-effects of the OED examinations were noted.

DISCUSSION

Currently, the most popular method used routinely for detection of breast pathology is screening mammography, which can be used to detect a number of abnormalities, including cysts, masses, and calcifications. However, the detection rate of breast cancer varies widely from ~45% in the case of extremely dense breasts and small preinvasive tumors up to ~97% in the case of fatty breasts and bigger invasive tumors.[16–18] The examination, as such, can be uncomfortable or even painful, and the images obtained still require specialist interpretation and confirmation with biopsy in the case of suspected malignancy.

Table 1. Comparison of Clinical Diagnoses and OED Results

			True OED results						*False OED results*					
			Negative			*Positive*			*Negative*			*Positive*		
Breast clinical diagnosis	*Group assignment*	*# of patients*	*0°*	*I°*	*Together*	*II°*	*III°*	*Together*	*0°*	*I°*	*Together*	*II°*	*III°*	*Together*
Healthy (no history of cancer)	A	60	23	27	50							10		10
Cancer survivor	B	38	3	22	25							10	3	13
Fibroadenoma	C	58				31	19	50		8	8			
Inflammation	D	74				26	45	71		3	3			
Abscess	E	36				2	32	34		2	2			
Preinvasive cancer	F	30				4	23	27		3	3			
Invasive cancer	G	104				6	92	98		6	6			
Total		400			75			280			22			23

0° = healthy; I° = within normal limits; II° = subacute; III° = acute.

Statistically significant difference between the total sums of true and false results: $P < 1.268E-51$.

Statistically significant differences between the true and false results for particular groups: A, $P = 2.418E-07$; B, $P = 0.052$; C, $P = 3.490E-08$; D, $P = 2.683E-15$; E, $P = 9.643E-08$; F, $P = 1.177E-05$; G, $P = 1.858E-19$.

OED overall detection rate = 88.8%; overall sensitivity rate = 92.7%; overall specificity rate = 76.5%; overall predictive value rate (positive) = 92.4%; overall predictive value rate (negative) = 77.3%.

OED sensitivity rates for particular pathology groups: C - 64.9%, D - 95.9%, E - 94.4%, F - 90.0%, G - 94.2%.

OED specificity rates respectively for control group and cancer survivor group: A – 83.3%, B – 65.8%.

US imaging is used usually as an additional diagnostic tool to examine abnormalities found in the breast during either a physical examination or mammogram. Unlike mammography, US can create an image from many different angles and can be used to distinguish between cysts and malignant masses. The US detection rate of breast cancer also varies from ~43% in the case of nonpalpable tumors up to ~94% in the case of larger invasive changes.[16–18] However, a US examination cannot detect calcifications and still requires specialist interpretation of the images as well as confirmation with biopsy in the case of suspected malignancy. Combined use of both mammography and US imaging increases the breast pathology detection rate but can be costly and time-consuming.

MRI detection rate of breast cancer is estimated at 89%–96% depending on the size of a tumor,[17] but the examination is costly and not always easily available. Other relevant diagnostic methods are usually not routinely used for screening purposes.

OED showed high rates of sensitivity, specificity, and predictive values for detection of various breast pathologies. The sensitivity rate was relatively lower in the case of fibroadenoma, which is rather a mild benign condition, but was very high in the case of serious pathologies, such as cancers, abscesses, and mastitis. The fact that the overall sensitivity rate (92.7%) is higher than the specificity rate (76.5%) suggests that OED may be relatively oversensitive. However, no clinical follow-up was performed for this study; OED could have detected pathology earlier than the comparative clinical methods. This presumption is supported by the much lower OED specificity rate in the cancer-survivor group compared to the control group. It is well-known that cancer survivors may have complications after mastectomy/radiotherapy or even a relapse of the malignant process.

From a practical point of view, what is especially important is OED's ability to detect early preinvasive breast cancer. This method alone cannot explain directly the type or etiology of breast pathology but, in the absence of any clinical symptoms/signs, an OED acute or even subacute result can be highly indicative of early cancer. All persons with acute/subacute OED results should be then referred for further investigations in order to specify the kind of pathology these patients could have. Because of its operational simplicity, full noninvasiveness, immediate unequivocal results, and extreme cost-effectiveness, the OED is well-suited for regular screening/monitoring mass examinations. In this way, the OED might become a lifesaving test for millions of women, especially in Africa and various Asian and South American countries. In general, the OED accuracy for breast diagnostics is compatible with the one obtained for other internal organs.[1,3–6]

A risk associated with the OED is the possibility of misdiagnosis due to incorrect placement of the measuring electrode; this is similar to the risk of misplaced electrocardiograph or electroencephalograph electrodes. Therefore, various means have been implemented in the Diagnotronics device to minimize this risk. A high-resolution graphics display indicates clearly the precise location of the breast-related auricular OPAs. These specific skin zones should be checked, mm by mm, on both ears with a point-measurement electrode; the ''worst'' result obtained should be then presumed as a valid result. Yet, the software requires that the result be verified with a second, or even third and fourth measurement, before the final diagnosis is specified. In addition, it is recommended that prospective operators should undergo a training course.

A false–negative OED result in the case of a symptomatic patient would be corrected by other examinations. Because, in general, there are no 100% accurate medical diagnostic methods, in the case of an asymptomatic person, a false–negative OED result should not prevent such a person from undergoing other screening tests on a regular basis (if these tests are available/affordable).

From a scientific point of view, it is important that this study confirmed strict functional connections directly between internal organs/body parts and related OPAs on the skin surface, even far away from the affected internal organs/body parts. These specific areas are widely used in reflexive physical medicine for therapeutic purposes (e.g., acupuncture, acupressure, analgesic electrostimulation [transcutaneous electrical nerve stimulation], laser therapy, magnet therapy, reflexive thermotherapy [moxibustion or cryotherapy], and so-called reflexology [reflexive massage of the feet]).[6]

However, when it comes to the utilization of the OPAs/acupuncture points' electrical features for diagnostic purposes, there is a long history of various failed attempts.[1,2,5,6] Among the best-known methods of this kind are ''Electroacupuncture according to Voll'' with modifications ''Vegatest'' and ''Listen''/''B.E.S.T'', ''*Ryodoraku*'' after Nakatani with modification ''CITO'', and auricular electropuncture diagnostics by Nogier. The results of these usually simple measurement methods mainly depend on the pressure of the measuring electrode, the patient's individual basic skin resistance, and perspiration, which is influenced by muscular tension, emotional condition, skin hydration, procedure duration, environmental temperature, and humidity. Therefore, the diagnostic accuracy of these methods has never been confirmed clinically and, eventually, these attempts only created a negative perception surrounding this kind of research.

In contrast, the clinically proven OED uses the OPAs/acupuncture points' resistance breakthrough effect as a key to obtaining skin electrical measurements that correlate with the condition of related organs/body parts, and calculation of the rectification ratio ensures that the OED results are not affected by all the abovementioned factors that influence the other methods.[1–8,10–13]

The well-defined dependence of the OPAs/acupuncture points' electrical features on the condition of the related organs/body parts[5,6,8] is not only of great practical importance

but also sheds new light on the neurophysiologic mechanisms that are the basis for both the OED and the reflexive physical therapies. The convergence modulation theory[6,19] provides a comprehensive explanation of these mechanisms. The theory presumes on the diagnostic side that, due to the specific structure of the sensory nervous system, nervous afferent signals sent from damaged internal organs/body parts to the central nervous system could also reach, in an antidromic way, certain skin areas (making these OPAs/acupuncture points more sensitive to physical pressure). Nervous signals reaching local free nerve endings would cause them to release neuropeptides to the intercellular fluid of the innervated epidermal areas. Higher concentrations of neuropeptides would, in turn, cause vasodilatation and increased capillary permeability in the vicinity of free nerve endings, leading to extravasation of blood plasma protein molecules (mainly albumins).

In this way, contrast-enhanced MRI of the microvasculature, using labeled albumins, can be used to visualize OPAs/acupuncture points related to diseased organs/body parts.[10] Intercellular fluid has a similar composition to blood plasma, except that the concentration of proteins in blood plasma is much higher than in intercellular fluid. Higher local concentrations of negatively charged albumin molecules, which can block the ionic current epidermal passageways, would be responsible for these electrical phenomena observed at the skin surface. Thus, in the abovementioned way, the OED may access the precise diagnostic information circulating in the body's own primary information system—the sensory nervous system—which is theoretically the most accurate first-line diagnostic system known. Therefore, serving as ''the other side of the acupuncture coin,'' OED might become even more attractive to contemporary medical practitioners than traditional therapeutic acupuncture as such might be.

CONCLUSIONS

First, the present study confirmed that breast-related OPAs do exist on the internal aspects of the auricular tragi. Breast pathology causes these specific skin areas to rectify electrical currents (a diode phenomenon) once the resistance breakthrough effect has been induced in the skin. The degree of rectification is proportional to the intensity of the pathologic process within the breasts.

Second, the study results indicate that OED, which utilizes the abovementioned electrical phenomenon of the skin, is a reliable noninvasive method for detecting breast pathology, with high rates of sensitivity, specificity, and predictive values. OED may also estimate the intensity of the breast pathologic process but cannot explain the type or etiology of pathology directly.

Third, because of its high diagnostic accuracy, operational simplicity, full noninvasiveness, immediate unequivocal results, and extreme cost-effectiveness, OED is well-suited to regular screening/monitoring mass examinations, especially for early detection of breast cancer.

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AUTHOR DISCLOSURE STATEMENT

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