Estimation of the diagnostic accuracy of organ electrodermal diagnostics

J Z Szopinski, D Pantanowitz, G P Lochner

Objective. To estimate the diagnostic accuracy and the scope of utilisation of a new bio-electronic method of organ diagnostics.

Design. Double-blind comparative study of the diagnostic results obtained using organ electrodermal diagnostics (OED), with clinical diagnosis as the criterion standard.

Setting. Department of Surgery, Helen Joseph Hospital, Johannesburg.

Patients. Two hundred pre-selected inpatients of mean age 38 years (standard deviation 9 years) with suspected pathology of one (or more) of the following organs: oesophagus, stomach, gallbladder, pancreas, colon, kidneys, urinary bladder and prostate. In total, 714 of the abovementioned internal organs were selected for statistical consideration.

Main outcome measures. The degree of rectification of the measuring current once the resistance 'breakthrough effect' has been induced in the skin, as well as the difference in impedance measured at organ projection areas (OPAs) (skin zones corresponding to particular internal organs).

Results. In total, 630 true OED results were obtained from the 714 subjects considered, with a detection rate of 88.2% (95% confidence interval (CI): 85.6 - 90.5%). Established OED sensitivity was 89.5% (CI: 85.2 - 92.8%) and OED specificity equalled 87.5% (CI: 84.0 - 90.4%). The predictive value for positive OED results was 81.7% (CI: 76.9 - 85.9%) and for negative OED results 93.0% (CI 90.1 - 95.2%). Healthy organs usually produced the OED result 'healthy' or 'within normal limits', while subacute pathology displayed 'subcute' and acute pathology 'acute'. The OED results were not affected by either the type or the aetiology of disease, i.e. OED estimated the actual extent of pathological process activity within particular organs but did not directly explain the cause of pathology.

Conclusions. So-called OPAs do exist on the skin surface. Pathology of a particular organ causes a related OPA to rectify electrical currents once the resistance 'breakthrough effect' has been induced in the skin. Pathology of an internal organ also increases the impedance of the corresponding OPA. The degree of rectification or difference in impedance is proportional to the extent of the pathological process within this organ. OED which utilises the abovementioned electrical phenomena of the skin, is a reliable bio-electronic method of non-invasive medical diagnostics, with high rates of sensitivity, specificity and predictive values. OED may be used to detect diseased organs and estimate the extent of pathological process activity.

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A connection exists between the state of health of specific internal organs and the electrical characteristics of related, although sometimes remote, skin areas. These skin areas are referred to as organ projection areas (OPAs) and include so-called acupuncture points (APs). Pathology of a particular organ causes related OPAs to rectify electrical currents once the resistance 'breakthrough effect' has been induced in the skin.[1-14] The 'breakthrough effect' is a rapid reversible decrease in skin resistance which takes place under certain electrical stimulatory conditions.[1-15] Once it has occurred, the skin resistance measured by means of a positively polarised point electrode is significantly higher for a diseased organ's projection areas than the resistance estimated for the same areas with the same but negatively polarised measuring electrode (rectification/diode phenomenon). This phenomenon is not observed for a healthy organ's projection areas. The ratio of these two measurements (positive/negative polarisation of measuring electrode) is not affected by the patient's muscular tension, emotional condition, skin hydration, procedure duration, environmental temperature and humidity or the pressure of the measuring electrode.[1-14] The pathology of an internal organ also increases the impedance of the corresponding OPA.[1,2,4,7,9,13] The location of the skin zone, where a high degree of rectification and increased impedance is observed, indicates which particular organ is diseased. The degree of rectification or difference in impedance indicates the extent of the pathological process within the organ. These findings created the basis for a new non-invasive diagnostic method — organ electrodermal diagnostics (OED).[4,5,8-14,16]

The aim of the study was estimation of the diagnostic accuracy and the scope of utilisation of OED, using the CE-

Pain Clinic, Mayo Medical Centre and University of the Witwatersrand, Johannesburg

J Z Szopinski, DM, DIntMed, MMed (Phys), PhD

Department of Surgery, Helen Joseph Hospital and University of the Witwatersrand, Johannesburg

D Pantanowitz, BSc, MB BCh, FRCS, FCS

Department of Electronic Engineering, University of Pretoria

G P Lochner, MSc (Eng)

certified automatised OED device Diagnotronics South African Department of Health Licence No 476/8677). This study is an extension of, and completes, the pilot study[10] done earlier on the prototype OED device.

Patients and methods

Study design/sampling

A double-blind comparative study of OED results, with clinical diagnosis as a criterion standard, was performed on a group of 200 inpatients at Helen Joseph Hospital's surgical department. The group consisted of 107 men and 93 women, with a mean age of 38 years (standard deviation) (SD) 9 years). During the post-intake ward rounds the surgical consultants pre-selected newly admitted patients with suspected pathology of one (or more) of the following organs: oesophagus, stomach, gallbladder, pancreas, colon, kidneys, urinary bladder and prostate. These organs are relatively easy to access clinically, i.e. sufficient clinical data can be easily and cost-effectively obtained to prove both diseased and healthy conditions. Pathologies of these eight organs also represent a variety of aetiological and pathogenetic factors, e.g. infections, inflammation, neoplasms, and immunological and metabolic disorders.

In each case the OED examination of all the abovementioned organs was undertaken before the final clinical diagnosis was established. The patients, selected by the independent arbiter, were always brought to the OED examination room by the witness. The witness was also appointed by the independent arbiter and was either a medical doctor, student or nurse. The OED investigator had no access to the patient's documentation whatsoever and the witness was present during the whole OED examination procedure to ensure that there was no communication between investigator and patient. The documented OED results, signed by the witness, were then 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.

Clinical investigation procedure

Clinical investigations of the chosen internal organs comprised:

1. Oesophagus — history and physical examination, chest radiograph, barium swallow, oesophagoscopy with biopsy for confirmation/exclusion of oesophagitis or a neoplastic process. Operative findings were included if the patient had undergone surgery.

2. Stomach — history and physical examination, barium meal, gastroscopy with biopsy for confirmation/exclusion of mucosal inflammation or a neoplastic process. Operative findings were included if the patient had undergone surgery.

3. Gallbladder — history and physical examination, acute phase indicators, liver function tests, hepatitis markers, urine for bilirubin and urobilinogen assessment, ultrasound examination, cholecystogram/cholangiogram (if indicated), and hepatic immuno-diacetic acid (HIDA) cholescintigraphy (if indicated). Operative findings were included if the patient had undergone surgery.

4. Pancreas — history and physical examination, serum and urine amylase, blood glucose, faecal fats, ultrasound examination, abdominal radiograph, computed tomography (CT) scan, and endoscopic retrograde cholangiopancreatography (ERCP). Operative findings were included if the patient had undergone surgery.

5. Colon — history and physical examination, full blood count, barium enema, sigmoidoscopy and/or colonoscopy. Liver function test, liver ultrasound examination, and CT scan were performed if indicated. Operative findings were included if the patient had undergone surgery.

6. Kidneys — history and physical examination, urine for microscopy, culture and susceptibility, urea and electrolytes, creatinine clearance, acute phase indicators, ultrasound examination, and intravenous pyelogram. CT scan, cystoscopy and renal biopsy were performed if indicated. Operative findings were included if the patient had undergone surgery.

7. Urinary bladder — history and physical examination, urine for microscopy, culture and susceptibility, urea and electrolytes, creatinine clearance, acute phase indicators, and ultrasound examination. CT scan, cystoscopy and biopsy were performed if indicated. Operative findings were included if the patient had undergone surgery.

8. Prostate — history and physical examination, urine for microscopy, culture and susceptibility, urea and electrolytes, creatinine clearance, acute phase indicators, ultrasound examination and biopsy, if indicated. Operative findings were included if the patient had undergone surgery.

All clinical investigations were done in the course of normal patient care by the medical staff of the Department of Surgery, Helen Joseph Hospital. For example, a patient admitted for a stomach problem may not have undergone extensive clinical investigations of the prostate or colon. For statistical purposes the patient's statement that he did not experience any problems with these organs, supported only by physical examination, did not constitute sufficient clinical evidence to accept the condition of these organs as healthy. Details of all investigations and the final clinical diagnoses are available in the hospital records.

OED examination procedure

OED examinations were performed using the Diagnotronics device, supplied by Breakthrough Neurotechnologies (Pty) Ltd, Johannesburg. The examination entails placement of the reference electrode on any area of the patient's skin, e.g. on a hand, and the placement of the measurement electrode on the skin area corresponding to the particular organ (Fig. 1). The

Diagnotronics device performs all required measurements and calculations automatically and specifies the actual condition of the organ related to the investigated skin area as being 'healthy', 'within normal limits', 'subacute' or 'acute'. A special display graded according to percentage of the disease intensity makes it possible to specify precisely the activity of organ pathology. The location of skin areas corresponding to the examined organs (Fig. 2) and final results are displayed on a screen.

A special OED information sheet was given to each patient before examination. Ethical approval was obtained from the Ethics Committee of the University of the Witwatersrand.

Fig. 1. OED examination using the Diagnotronics device. The location of skin areas corresponding to examined organs and diagnostic results after the examination is completed are displayed on the screen.

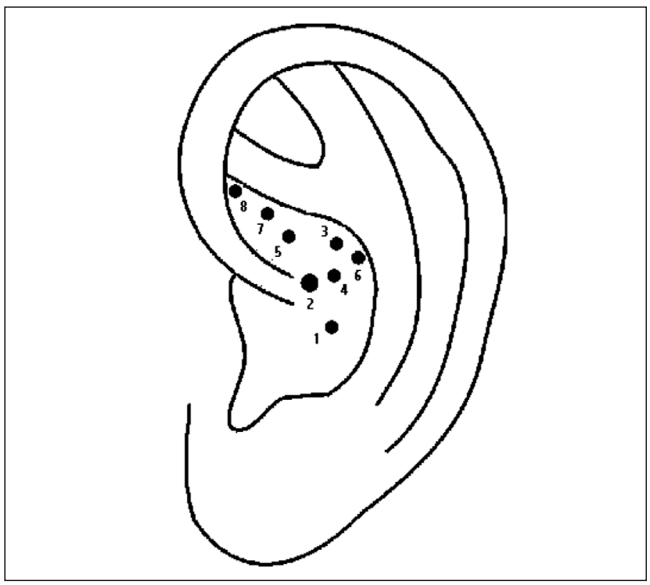

Fig. 2. Location of auricular organ projection areas of the oesophagus (1), stomach (2), gallbladder (3), pancreas (4), colon (5), kidneys (6), urinary bladder (7) and prostate (8).

Statistical procedures

Comparison of the clinical diagnoses and OED results was undertaken by an independent arbiter who was not involved in the diagnostic procedures. The chi-square 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.[17,18] Only organs with proven clinical conditions (healthy/diseased) were considered for final statistical comparison.

Results

OED results were obtained for 1 600 subjects. However, for statistical purposes the independent arbiter selected only those subjects (a total of 714) for which sufficient clinical evidence was available. In total, 630 true OED results were obtained from the 714 subjects considered, with a detection rate of 88.2% (95% confidence interval (CI): 85.6 - 90.5%) (Table I). Established OED sensitivity was 89.5% (CI: 85.2 - 92.8%) and OED specificity equalled 87.5% (CI: 84.0 - 90.4%). The predictive value for positive OED results was 81.7% (CI: 76.9 - 85.9%) and for negative OED results 93.0% (CI: 90.1 - 95.2%).

There were no significant differences in the results obtained for various internal organs. Healthy organs usually display the OED result 'healthy' or 'within normal limits', while subacute pathology displays 'subacute' and acute pathology 'acute'. The OED results were not affected by either the type or the aetiology of disease, i.e. OED estimated the actual extent of pathological process activity within particular organs but did not directly explain the cause of pathology.

It was observed 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 diagnoses. No side-effects of the OED examinations were observed.

Discussion

There is a lot of controversy surrounding the existence of OPAs/APs on the skin in general and their bio-electrical features in particular. Nevertheless, these specific areas have been used in physical medicine, especially for reflexive therapy purposes, e.g. acupuncture, acupressure, analgesic electrostimulation (TENS), laser therapy, magnet therapy, reflexive thermotherapy ('moxa', cryotherapy), and so-called reflexology (reflexive massage of feet). This already suggests a specific role for OPAs/APs in human physiology. However, there has been no direct evidence of a real functional connection between the skin surface and related internal organs.

Table I. Comparison of clinical diagnoses and OED results obtained using the Diagnotronics device (0° = healthy, I° = within normal limits, II° subacute, III° = acute)

Organ and clinical diagnosis	No. of subjects	True OED results						False OED results					
		Negative			Positive			Negative			Positive		
		0°	I°	Together	II°	III°	Together	0°	I°	Together	II°	III°	Together
Oesophagus													
Healthy	50		21	25	46						4		4
Oesophagitis	18					10	6	16			2	2	
Cancer	16					1	14	15			1	1	
Stomach													
Healthy	39		9	25	34						4	1	5
Gastritis	29					19	5	24		2	3	5	
Ulcers	11					1	9	10			1	1	
Cancer	6					1	5	6				0	
Gallbladder													
Healthy	66		17	42	59						6	1	7
Gallstone	30					9	17	26			4	4	
Cholecystitis													
Acute	5						5	5					
Chronic	4					2	1	3			1	1	
Pancreas													
Healthy	51		8	33	41						8	2	10
Pancreatitis													
Acute	9					1	8	9				0	
Chronic	12					7	3	10			2	2	
Cancer	3					1	2	3				0	
Colon													
Healthy	21		10	7	17						4		4
Colitis	12					8	2	10			2	2	
Cancer	11					2	7	9			2	2	
Kidneys													
Healthy	108		33	63	96						10	2	12
Pyelonephritis	14					11	2	13			1	1	
Hydronephrosis	26					5	19	24			2	2	
Urinary bladder													
Healthy	72		30	33	63						8	1	9
Cystitis	23					17	4	21			2	2	
Cancer	21					4	15	19			2	2	
Prostate													
Healthy	32		17	11	28						3	1	4
BPH	11					10	0	10			1	1	
Cancer	14					2	11	13			1	1	
Total	714				384			246				29	55

Statistically significant difference between the total sum of true and false results: $p < 0.0001$. Detection rate = 88.2% (CI: 85.6 - 90.5%), sensitivity rate = 89.5% (CI: 85.2 - 92.8%), specificity rate = 87.5% (CI: 84.0 - 90.4%), predictive value rate (positive) = 81.7% (CI: 76.9 - 85.9%), predictive value rate (negative) = 93.0% (CI: 90.1 - 95.2%).
BPH = benign prostate hypertrophy.

The OED results directly confirmed a functional connection between internal organs and related OPAs/APs on the skin surface, and created the basis for an evidence-based map of auricular OPAs. The key to obtaining these values of the electrical resistance of OPAs/APs, which demonstrate a correlation with the condition of a related organ, is the 'breakthrough effect'. This electrodermal phenomenon is probably due to the creation of so-called electropores in the lipid layers of the stratum corneum,[15] under sufficient electrical stimulation. Once the 'breakthrough effect' has been achieved, the skin resistance measured with a positively polarised electrode is significantly higher for the diseased organ's projection areas than the resistance estimated for the same areas with the same but negatively polarised measuring electrode. For healthy organs' projection areas this phenomenon is not observed to a significant extent. The ratio of the 'positive' and 'negative' measurements is not affected by all the factors that influence the actual skin resistance values, and therefore a universal point of reference is established.[16]

The impedance of skin areas corresponding to diseased organs is higher than that of healthy organ related skin zones. However, the use of impedance measurements for organ diagnostic purposes requires separate calibration for different kinds of skin, e.g. on the ear auricle, face, abdomen, back, internal and external aspects of extremities, to determine a

point of reference.[16] This must be compared with the impedance value obtained with a measurement electrode in order to obtain a diagnostic result.

This study confirmed that OED is a reliable bio-electronic method of non-invasive medical diagnostics, with high rates of sensitivity, specificity and predictive values. The fact that the negative predictive value (93%) is higher than the positive predictive value (81.7%) suggests that OED may be relatively oversensitive. However no clinical follow-up was done — OED could have detected pathology earlier than the comparative clinical methods. OED produces unequivocal diagnostic results immediately, with no need for any additional calculations. Special attention should be paid to the ability of OED to investigate organs that are not easily accessible using standard diagnostic methods. Furthermore, it makes a rapid assessment of all internal organs possible. The OED procedure is painless, easy to perform, quick and very cost effective, therefore the technology would be well suited to regular screening examinations. This method not only detects diseased organs, but it also estimates the extent of the pathological process. The possibility of utilising OED in monitoring the course of chronic diseases as well as for the early estimation of the efficacy of treatment has therefore become evident.

A risk associated with this method is the possibility of misdiagnosis due to incorrect placement of the measuring electrode, similar to the risk of misplaced ECG or EEG electrodes. If, for example, the operator is intending to assess the condition of the lungs and the measuring electrode is placed at the OPA corresponding to the heart, the result would be misinterpreted. Therefore various means have been implemented in the Diagnotronics device to minimise this risk. A high-resolution graphics display clearly indicates where the electrodes should be placed during each measurement. The software requires that each result be verified with a second measurement before the final diagnosis is specified. In addition it is recommended that prospective operators should undergo training courses. The interpretation of OED results and further diagnostic/therapeutic procedures, should be done by the doctor in charge. A false-negative OED result in the case of a symptomatic patient would be corrected by other examinations. In the case of an asymptomatic person a false-negative OED result should not prevent such person from attending comprehensive regular medical examinations.

OED will not replace existing diagnostic methods, but provides additional information. An important benefit of OED technology is that it can evaluate internal organs, which could not otherwise be examined on a regular basis because of cost and/or risk posed by existing techniques. Therefore the relatively small risk (less than 10% according to clinical trials) posed by a false-negative OED result must be weighed against the probability that no examination would have taken place at all.

Neurophysiological mechanisms underlying the described electrical phenomena of the skin can be explained by convergence modulation theory.[19]

Conclusions

1. So-called OPAs do exist on the skin surface. Pathology of a particular organ causes a related OPA to rectify electrical currents, once the resistance 'breakthrough effect' has been induced in the skin. Pathology of an internal organ also increases the impedance of the corresponding OPA. The degree of rectification or difference in impedance is proportional to the extent of the pathological process within this organ.

2. OED which utilises the abovementioned electrical phenomena of the skin, is a reliable bio-electronic method of non-invasive medical diagnostics, with high rates of sensitivity, specificity and predictive values. OED may detect diseased organs and estimate the extent of pathological process activity.

3. OED results are not affected by either the type or aetiology of disease, i.e. OED cannot directly explain the cause of pathology.

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