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Estimation of the diagnostic accuracy of organ electrodermal diagnostics

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5.0 CLINICAL ASSESSMENT OF OED ACCURACY

5.1 Patients and methods

5.1.1 Study Design/Sampling

A double-blind comparative study of OED results and clinical diagnoses, 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 of mean age 38 (SD = 9) years. During the post-intake ward rounds, the surgical consultants had pre-selected newly admitted patients with suspected pathology of one (or more) of the following organs: oesophagus, stomach, gall bladder, 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 patient, selected by the independent arbiter (Prof. Pantanowitz), was 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.

5.1.2 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. Gall bladder — history and physical examination, acute phase indicators, liver function tests, hepatitis markers, urine for bilirubin and urobilinogen assessment, ultrasound examination, cholecystogram/cholangiogram (if indicated), 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, 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, CT scan (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, 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, 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. It means, that e.g. the patient admitted for a stomach problem may not have undergone extensive clinical investigations of the prostate or colon. The patient's statement that he does not experience any problems with these organs, supported only by physical examinations, did not constitute sufficient clinical evidence to accept the conditions of these organs as healthy, for the statistics purposes. Details of all investigations and the final clinical diagnoses are available in the hospital records.

5.1.3 OED Examination Procedure

OED examinations were performed by means of the Diagnotronics device (see chapter 4). 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 5.1).

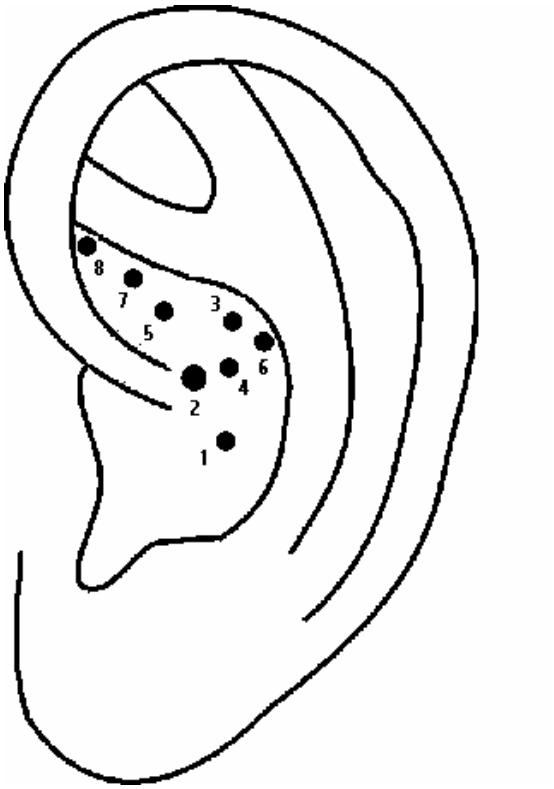


Fig. 5.1 Location of auricular organ projection areas of oesophagus (1), stomach (2), gall bladder (3), pancreas (4), colon (5), kidneys (6), urinary bladder (7) and prostate (8).

The Diagnotronics device specifies the actual condition of the organ related to the investigated skin area as 'HEALTHY', 'WITHIN NORMAL LIMITS', ‘SUBACUTE’ and ‘ACUTE’. A special display graded according to percentage of the disease intensity makes it possible to specify accurately the activity of organ pathology. The locations of skin areas corresponding to the examined organs and final results are displayed on a screen.

A special OED information sheet (Appendix A) was given to each patient prior to examination. Ethical approval was obtained from the Ethics Committee of the University of the Witwatersrand (Appendix B). OED results were noted on a Case Report Form (Appendix C).

5.1.4 Statistical Procedures

The comparison of clinical diagnoses and OED results was undertaken by an independent arbiter who was not involved in the diagnostic procedures.

OED detection rate was defined as the proportion of correctly classified subjects among all subjects (7,40). The detection rate was estimated with the formula:

$$DR = \frac{a + d}{a + b + c + d} \times 100\%$$

DR = detection rate; a = true positive; b = false positive; c = false negative; d = true negative.

OED sensitivity was defined as the proportion of correctly classified positives, i.e. 'true positives' among the total of diseased persons (7,40). The sensitivity rate was estimated with the formula:

$$S = \frac{a}{(a+c)} \times 100\%$$

S = sensitivity rate; a = true positive; c = false negative.

OED specificity was defined as the proportion of true negatives among the total of persons free of disease (7,40). The specificity rate was estimated with the formula:

$$SP = \frac{d}{(b+d)} \times 100\%$$

SP = specificity rate; d = true negative; b = false positive.

The positive predictive value (7,40) of the OED result was defined as the probability of having the disease among the group of persons classified as positive by OED:

$$PV(pos) = \frac{a}{(a+b)} \times 100\%$$

PV = predictive value rate; a = true positive; b = false positive.

The negative predictive value (7,40) of the OED result was defined as the probability of not having the disease among the group of persons classified as negative by *OED:*

$$PV(neg) = \frac{d}{(c+d)} \times 100\%$$

PV = predictive value rate; d = true negative; c = false negative.

The χ^2-test was used to calculate statistical significance. $P < 0.05$ was accepted as the statistically significant difference. Only organs with proven clinical conditions (healthy/diseased) were considered for final statistical comparison.

5.2 Results

5.2.1 COMPARISON OF CLINICAL DIAGNOSES OF PARTICULAR INTERNAL ORGANS W ITH OED RESULTS

The OED examinations included 1600 diagnostic subjects (internal organs). However, sufficient clinical data were available for only 714 of these organs, to be accepted by the independent arbiter as clinically proven.

Comparison of clinical diagnoses of oesophagus with OED results shows that oesophagitis manifested most often as “SUBACUTE” while cancer (advanced) produces the result “ACUTE” (Table 5.1).

Table 5.1 Comparison of clinical diagnoses of oesophagus and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III^0- ACUTE).

		True OED Results						False OED Results					
Clinical	No. of	Negative			Positive			Negative			Positive		
Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	Together
Healthy	50	21	25	46							4		4
Oesophagitis	18				10	6	16		2	2			
Cancer	16				1	14	15		1	1			
Total	84			46			31			3			4

Statistically significant difference between the total sum of true and false results: $P<0.0001$

Detection rate = 91.7% (76,3-98,1%); Sensitivity rate = 91.2% (75,8-97,6%); Specificity rate = 92.0% (80,8-97,8%); Predictive value rate (pos.) = 88.6% (73,3-96,8%); Predictive value rate (neg.) = 93.9% (83,1-98,7%).

Comparison of clinical diagnoses of stomach with OED results shows that gastritis manifested most often as “SUBACUTE” while ulcers and cancer (advanced) usually produce the result “ACUTE” (Table 5.2). According to investigations OED can detect even mild gastritis changes, not detectable with radiological methods.

Table 5.2 Comparison of clinical diagnoses of stomach and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III^0- ACUTE)

		True OED Results						False OED Results					
Clinical	No. of	Negative			Positive			Negative			Positive		
Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	Together
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			
Total	85			34			40			6			5

Statistically significant difference between the total sum of true and false results: P<0.0001

Detection rate = 87.1% (73,1-95,4%); Sensitivity rate = 87.0% (73,7-95,1%); Specificity rate = 87.2% (72,5-95,7%); Predictive value rate (pos.) = 88.9%; Predictive value rate (neg.) = 85.0% (70,2-94,3%).

Comparison of clinical diagnoses of gall bladder with OED results shows that acute cholecystitis manifested as “ACUTE” while chronic cholecystitis yielded more distributed results (Table 5.3). Asymptomatic gall stones produced the OED result “SUBACUTE” or “WITHIN NORMAL LIMITS” while symptomatic gall stones displayed “ACUTE”.

Table 5.3 Comparison of clinical diagnoses of gall bladder and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III^0- ACUTE).

		True OED Results						False OED Results					
Clinical	No. of	Negative			Positive			Negative			Positive		
Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	Together
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			
Total	105			59			34			5			7

Statistically significant difference between the total sum of true and false results: P<0.0001

Detection rate = 88.6% (80,9-93,5%); Sensitivity rate = 87.2% (72,6-95,7%); Specificity rate = 89.4% (79,4-95,6%); Predictive value rate (pos.) = 82.9% (67,9-92,8%); Predictive value rate (neg.) = 92.2% (82,7-97,4%).

Comparison of clinical diagnoses of pancreas with OED results shows that acute pancreatitis manifested mainly as “ACUTE” while chronic pancreatitis yielded more distributed results (Table 5.4).

Table 5.4 Comparison of clinical diagnoses of pancreas and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III^0- ACUTE).

		True OED Results						False OED Results					
Clinical	No. of	Negative			Positive			Negative			Positive		
Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	Together
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			
Total	75			41			22			2			10

Statistically significant difference between the total sum of true and false results: $P<0.0001$

Detection rate = 84.0% (63,9-95,5%); Sensitivity rate = 91.7% (73,0-98,9%); Specificity rate = 80.4% (60,2-94,0%); Predictive value rate (pos.) = 68.8% (53,0-86,6%); Predictive value rate (neg.) = 95.3% (82,8-99,5%).

Comparison of clinical diagnoses of colon with OED results shows that colitis manifested mainly as “SUBACUTE” while cancer tended to yield “ACUTE” (Table 5.5).

Table 5.5 Comparison of clinical diagnoses of colon and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III^0- ACUTE).

		True OED Results						False OED Results					
Clinical	No. of	Negative			Positive			Negative			Positive		
Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	Together
Healthy	21	10	7	17							4		4
Colitis	12				8	2	10		2	2			
Cancer	11				2	7	9		2	2			
Total	44			17			19			4			4

Statistically significant difference between the total sum of true and false results: P<0.0001

Detection rate = 81.8% (60,8-94,6%); Sensitivity rate = 82.6% (61,2-95,0); Specificity rate = 81.0% (58,1-94,5%); Predictive value rate (pos.) = 82.6% (61,2-95,0%); Predictive value rate (neg.) = 81.0% (58,1-94,5%).

Comparison of clinical diagnoses of kidneys with OED results shows that pyelonephritis manifested mainly as “SUBACUTE” while hydronephrosis (various origins) tended to yield “ACUTE” (Table 5.6).

Table 5.6 Comparison of clinical diagnoses of kidneys and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III^0- ACUTE).

		True OED Results						False OED Results					
Clinical	No. of	Negative			Positive			Negative			Positive		
Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	Together
Healthy	108	33	63	96							10	2	12
Pyelonephritis	14				11	2	13		1	1			
Hydronephrosis	26				5	19	24		2	2			
Total	148			96			37			3			12

Statistically significant difference between the total sum of true and false results: P<0.0001

Detection rate = 89.9% (83,8-94,2%); Sensitivity rate = 92.5% (81,7-98,4%); Specificity rate = 88.9% (81,4-94,1%); Predictive value rate (pos.) = 75.7% (61,1-86,6%); Predictive value rate (neg.) = 97.0% (92,8-99,7%).

Comparison of clinical diagnoses of urinary bladder with OED results shows that cystitis manifested mainly as “SUBACUTE” while cancer tended to yield “ACUTE” (Table 5.7).

Table 5.7 Comparison of clinical diagnoses of urinary bladder and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III°- ACUTE).

		True OED Results						False OED Results					
Clinical	No. of	Negative			Positive			Negative			Positive		
Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	Together
Healthy	72	30	33	63							8	1	9
Cystitis	23				17	4	21		2	2			
Cancer	21				4	15	19		2	2			
Total	116			63			40			4			9

Statistically significant difference between the total sum of true and false results: $P<0.0001$

Detection rate = 88.8% (81,6-93,9%); Sensitivity rate = 90.9% (78,3-97,5%); Specificity rate = 87.5% (77,6-94,1%); Predictive value rate (pos.) = 81.6% (68,0-91,2%); Predictive value rate (neg.) = 94.0% (85,4-98,3%).

Comparison of clinical diagnoses of prostate with OED results shows that BPH manifested mainly as “SUBACUTE” while cancer tended to yield “ACUTE” (Table 5.8).

Table 5.8 Comparison of clinical diagnoses of prostate and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III°-ACUTE).

		True OED Results						False OED Results					
Clinical	No. of	Negative			Positive			Negative			Positive		
Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	Together
Heathy	32	17	11	28							3	1	4
BPH	11				10	0	10		1	1			
Cancer	14				2	11	13		1	1			
Total	57			28			23			2			4

Statistically significant difference between the total sum of true and false results: $P<0.0001$

Detection rate = 89.5% (78,5-96,0%); Sensitivity rate = 92.0% (71,9-98,8%); Specificity rate = 87.5% (72,5-96,7%); Predictive value rate (pos.) = 85.2% (63,9-95,5%); Predictive value rate (neg.) = 93.3% (79,2-99,2%).

Healthy subjects in general produced “HEALTHY” or “WITHIN NORMAL LIMITS” OED results (Table 1-8).

5.2.2 COMPARISON OF CLINICAL DIAGNOSES AND OED RESULTS IN TOTAL

In total 630 true OED results were obtained from the 714 subjects considered: detection rate 88.2% (85,6-90,5%) (Table 5.9). Established OED sensitivity was 89.5% (85,2-92,8%) and OED specificity equaled 87.5% (84,0-90,4%). The predictive value for positive OED results was 81.7% (76,9-85,9%) and for negative OED results 93.0% (90,1-95,2%).

There were no significant differences in the results obtained from various internal organs (Table 5.1-5.8). 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 affected neither by the type nor the aetiology of disease, i.e. OED estimated the actual extent of pathological process activity within particular organs but did not explain the direct cause of pathology.

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.

Table 5.9 Comparison of clinical diagnoses and OED results obtained by means of the Diagnotronics device (0° - HEALTHY, I° - WITHIN NORMAL LIMITS, II° - SUBACUTE, III°- ACUTE).

			True OED Results						False OED Results					
	Clinical	No. of	Negative			Positive			Negative			Positive		
Organ	Diagnosis	Subjects	0	I^0	Together	II^0	III^0	Together	0	I^0	Together	II^0	III^0	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			
Gall Bladder	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	Healthy	72	30	33	63							8	1	9
Bladder	Cystitis	23				17	4	21		2	2			
	Cancer	21				4	15	19		2	2			
Prostate	Heathy	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% (85,6-90,5%); Sensitivity rate = 89.5% (85,2-92,8%); Specificity rate = 87.5% (84,0-90,4%); Predictive value rate (pos.) = 81.7% (76,9-85,9%); Predictive value rate (neg.) = 93.0% (90,1-95,2%).