Global Diagnostics – Rapid method for detecting a cardiovascular disease or an increased cardiovascular risk

Carsten W.T. Nolte[1] and Martie Truschnig-Wilders[2]
[1]Epidaurus, Dresden
[2]Clinical Institute for Medical and Chemical Laboratory Diagnostics
State Hospital – University Hospital Graz

Summary

In a retrospective study, 143 patients suspected of suffering from a manifest cardiovascular disease or an increased cardiovascular risk were examined.

Each of the patients was examined using the instrument system "Global Diagnostics" (GD) by VITATEC Products AG Switzerland, and the results were compared to those obtained by conventional cardiovascular examination methods.

GD succeeded in accurately detecting both the patients already suffering from a cardiovascular disease and the patients who – still free of symptoms – showed unambiguous evidence of commencing end organ damage or exhibited more than one synergistically effective risk factor with a high efficiency (a sensitivity of 93.6 % and a specificity of 79.4 %).

The time required for an examination with GD is 8 min/patient, it may be applied by non-medical personnel, and it can be settled via private medical care.

The instrument system GD is therefore suitable both for effective screening and for progress evaluations of treatments. The method can be of the greatest utility for both medical facilities taking a multi-professional approach and businesses. These generally state-subsidised preventive examinations may support employees in implementing preventive diagnostics and therapies.

Introduction

Diseases of the cardiovascular system burden the paying entities in the health system and may affect the performance capability of large and small businesses. The tendency is increasing. A systematic and nationwide early detection so far failed because of the expenses for both individuals and businesses.

This screening method only taking eight minutes and applicable by non-medical staff could detect patients free of complaints suffering from impending cardiovascular diseases at an early stage and transfer them to a risk-adapted therapy. This is advantageous for the individual patient, for the paying entities as well as for commercial entities which may, at the same time, meet their duty of care for their employees financially supported by legislature.

Since the introduction of the bioelectric impedance analysis (BIA) it is known that, with the application of high-frequency electric signals to the body, relevant biophysical information can be gathered in a rapid and reliable way (1-10). The measurement with the aid of the GD system (VITATEC Products AG, Switzerland) is very similar to the BIA method. By applying a variety of specific frequency combinations the condition of a vast amount of specific body parameters can be analysed. The analysed frequency patterns permit a conclusion about the overall condition of the cardiovascular system.

In the retrospective pilot study involving 143 patients presented here the results of cardiovascular examinations according to conventional medicine were compared to the measurement results of GD to clarify whether a manifest heart disease and/or an increased cardiovascular risk can be reliably detected by analysing the frequency patterns.

Patients and methods

143 patients (men: n = 93, women: n = 50) aged 25 - 72 years who consulted a practice specialised in vascular medicine and concentrating on preventive medicine were consecutively examined under prevention and sports medicinal aspects as well as as a follow-up in case of a manifest cardiovascular disease.

Apart from a careful anamnesis/third-party anamnesis, the diagnosis included physical examination, transthoracic echocardiography (11,12), colour-coded duplex sonography of the extracranial arteries supplying the brain including an age-matched analysis of the intima-media thickness (13), stress echocardiography, and laboratory diagnostics. In the following text the abovementioned examinations will be referred to as examinations or examination results according to conventional medicine as compared to GD.

The parameters gathered by conventional medicine which the analysis is based on are shown in Table 1.

Risk factors:	
Hypertension at rest	>120/80 mmHg,
from 60 years of age*	Pulse pressure > 55 mmHg
Diabetes mellitus	HBA1c > 6.1 % (43.2 mmol/l Hb) (DG.diabetes)
Hypercholesterolaemia	LDL chol. > 4.1 mmol/l
Sleep apnoea*	yes/no
Exercise-induced hypertension*	> 210/90 mmHg after ACSM
Nicotine abuse/ former nicotine abuse	yes/no
chr. gingivitis*	yes/no
End organ damage:	
Left ventricular hypertrophy	IVS and LVPW > 13mm
Intima-media thickness	> value appropriate to age (mm)

Consequential damage:
C. a. heart attack,
Angiographic evidence of a coronary heart disease (heart catheter)
C. a. stroke, TIA or PRIND,
kidney insufficiency on the basis of cardiovascular risk factors
peripheral artery occlusive disease including vasoconstriction > 50%

Tab. 1

It has to be noted that some risk factors are, in the meantime, accepted as risk factors (14-25) but were not yet implemented in a score for verifying the 10 year cardiovascular risk. These variables are idendified by a *.

Measurements by „Global Diagnostics" (GD)

GD is a medically approved device and system (Fig. 1) generating weak electric signals in the form of sinus signals in the range from 70 kHz to 400 MHz by means of a frequency generator. These electric signals are applied to the patients' feet with the aid of adhesive electrodes customary in the trade.

The output amplitude is 0.225 V. eff and does not contain any direct voltage components.

The stimulating signals are changed by the patient, namely depending on his/her state of health. These altered signals are also detected by the electrodes at the feet.

One requirement for the participation in the examination was a sufficient fluid intake of the test persons in the previous days (> 1.5 liters in case of a reduced cardiac output (LVEF < 45%) $\leq$ 1.5 liters). Excessive physical activity 24 hrs. prior to the GD measurement was not permitted.

The transformation of the stimulating signals is measured with regard to phase and amplitude. Then the measuring electronics of GD analyses the signals. GD is connected to a Windows-based laptop on which the software is installed and the results of the measurements are displayed.

Fig. 1

In the cardiovascular module of GD two responses were possible: cardiovascular system healthy or not healthy - and correspondingly highlighted in the colours yellow (Fig. 2) and green (Fig. 3).

Based on these parameters patients were classified as “affected according to the diagnosis methods of conventional medicine” if

- more than one risk factor
- at least one end organ damage
- at least one consequential damage

existed.

The associated GD examination result was displayed as follows (Fig. 2):

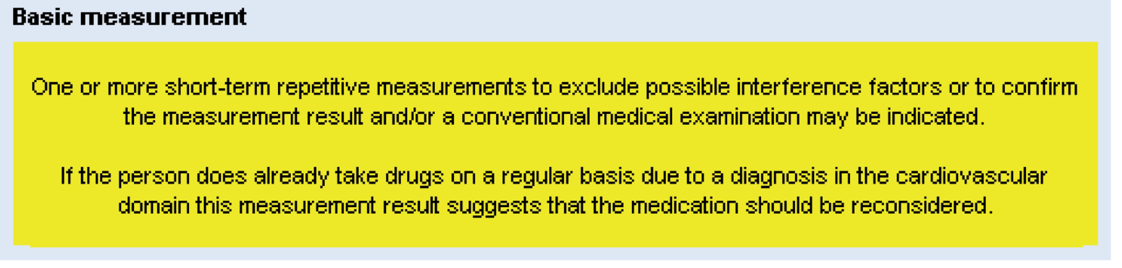

Fig. 2: Response of GD if the cardiovascular system is *not healthy*

The result was “not affected according to the diagnosis methods of conventional medicine“ if

- only one risk factor
- no end organ damage
- no consequential damage

existed.

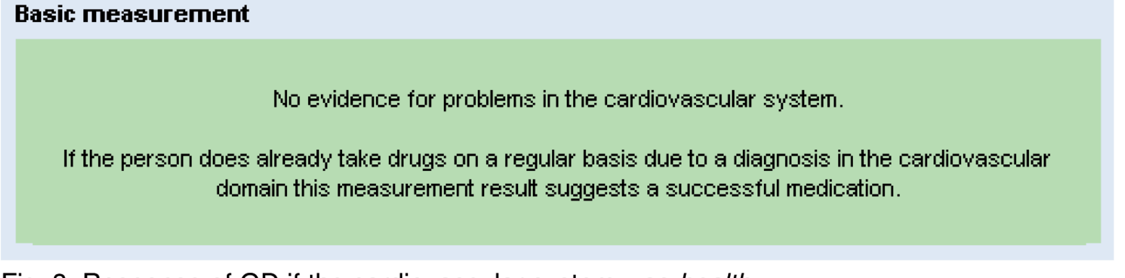

Fig. 3: Response of GD if the cardiovascular system was *healthy*

Statistics

Sensitivity and selectivity were detected:

The "sensitivity" (correctly, the positive rate of a test) defines the share of positively tested persons among all affected persons in random sampling, i.e. the probability to actually identify affected persons as affected with the aid of a diagnostic test.

Sensitivity = persons identified as affected / all affected persons

The "specificity" (correctly, the negative rate of a test) describes the share of the negatively tested persons among all non-affected persons in random sampling, i.e. the probability to correctly identify non-affected persons by means of a diagnostic test.

Specificity = persons identified as healthy / all healthy persons

Sensitivity and specificity are indicated in %. For this value, the exact confidence interval of 95% according to Pearson and Klopper is calculated.

The correlation with the diagnoses in accordance with conventional medicine were examined univariantly wherein the P values for all contingency tables refer to the bidirectional Fischer's Exact Test. Continuous variables were compared with the aid of the Wilcoxon Test.

The correlation between the results of the classical diagnosis methods and GD findings was assessed using standard chi-square tests (Pearson uncorrected including continuity correction according to Yates, analysis according to Mantel-Haenszel)

All analyses were implemented using the statistics program SAS for Windows, version 9.1.3 (SAS Institute Inc., Cary, NC, USA).

Results

143 patients were analysed for whom the defined parameters of conventional medicine had been fully established and for whom a GD measurement for the same examination period (three days) existed.

Risk factors	**n**	**%**
Hypertension/ pathologic pulse pressure /exercise-induced hypertension	70	49
Hypercholesterinaemia	60	42
Diabetes mellitus	17	12
Sleep apnoea syndrome	11	8
BMI > 25	91	64
Chronic parodontitis	4	3
End organ damage		
Pathologic intima media thickness	64	45
Left ventricular hypertrophy	27	19
Consequential damage		
Coronary disease (angiographically evidenced)	24	17
Condition after myocardial infarction	5	4
Condition after apoplexy, TIA, Prind	5	4
Peripheral artery occlusive disease	3	2
Cardiac insufficiency stadium: I-IV a. t. NYHA	8	6

Left ventricular ejection fraction ≤ 45%	26	18
10 year cardiovascular risk		
after DG for coping with hypertension		
< 15%	37	26
20-30%	91	64
> 30%	15	9

Tab. 2

Tab. 2 shows the results gathered from the anamnesis and examinations according to conventional medicine.

In Tab. 3 the GD findings for the 143 patients are compared to the results of the classical diagnosis methods.

	Affected according to GD	**Not affected** according to GD	**Total**
Affected according to conventional diagnosis methods	102	7	109
Not affected according to conventional diagnosis methods	7	27	34
Total	109	34	143

Tab. 3: Fourfold table of the results

	%	**95% confidence interval**
Sensitivity	93.6	87.2 – 97.4
Specificity	79.4	62.1 – 91.3

Tab. 4: Sensitivity and specificity as well as the exact confidence interval of 95% according to Pearson and Klopper

Conclusion and discussion

The data indicate a sensitivity of 102/109 = 93.6% and a specificity of 27/34 = 79.4% for the effectivity of GD as an early warning system for cardiovascular diseases (Tab. 4) irrespective of whether there are already symptoms of a disease, whether “only” asymptomatic, however, morphologically already detectable changes are present, or whether a plurality of synergetically interacting risk factors exist.

With this study it could, for the first time be established that the eight-minute measurements by GD are suitable as screening for manifest diseases of the cardiovascular system, for end organ damage, or for the existence of a plurality of synergistically effective risk factors.

An associated warning sign on the display of GD should, consequently, entail correspondingly comprehensive diagnostics according to conventional medicine unless cardiovascular diseases, end organ damage or a plurality of risk factors are already known.

The extensive use of the Vitalfeld-Technologie in examining persons having a per se healthy cardiovascular system in preventive medicine as well as in industrial and occupational medicine permits a focused and resource-oriented deepening of diagnostics.

However, users of GD should keep in mind that the multi-professional understanding of “cardiovascular diseases“ is not a conditio sine qua non for all general practitioners and medical specialists. This means that physicians or therapists should use the above parameters to complete their diagnostics so as not to fail to notice any risk factors or end organ damage potentially treatable at an early stage (Tab. 1).

In perspective, a multicentric, double-blind, prospective study should be planned which should, after the implementation of a neural network, indicate risk factors, end organ damage or consecutive damage even more effectively.

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