# EXPERIENCE WITH DEVICE CARDIOVISOR IN CARDIOLOGICAL CARE

G.V. Ryabykina, A.S. Sula, E.V. Shchedrina
Moscov Cardiology Center, Moscov - Russia

Çalışmanın amacı, normal ve patolojinin ayırt edilmesinde CardioVisor cihazının duyarlılığını ve spesifitesini belirlemektir.

Kardiyovasküler çeşitli hastalıklara sahip 172 hasta (87'si koroner arter hastalığı, 85'i koroner arter hastalığı bulunmayan arteriyel hipertansiyon kazanılmış yada doğuştan kalp hastalığı, dilate veya hipertrofik kardiyomiyopati, endokrin ve metabolik hastalıklı) mueyene edildi. Kontrol grubunu 21 sağlıklı birey oluşturdu. Çalışmaya alınan tüm bireyler EKG dispersiyon analizini oluşturmak üzere CardioVisor cihazı ile incelendi. Normal ve patolojik grupları ayırt etmede cihazın duyarlılığını ve spesifitesini tayin etmek için intermediate patoloji rating scala kullanıldı.

Bu cihaz koroner arter hastalığını belirlemede oldukça yüksek duyarlılık ve spesifite (%90 ve %60) gösterdi. CardioVisor cihazı preklinik dönemde kalp hastalıklarını erkenden saptamaya yardımcı olabilir.

CardioVisor cihazı emniyet ve etkinliğini saptamada tarama çalışmaları uygun olur. Bu cihaz, cerrahi operasyonlar sırasında miyokardiyal metabolik durumdaki değişikliklerin dinamiklerinin çok hassas bir şekilde monitorizasyonuna ve endakrin hastalıklarda uygulanan tedavinin değerlendirilmesine yarar.

Anahtar kelimeler: Kalp hastalıkları, Visualizasyon, Normal, Patoloji

(Türk Girişimsel Kard. Der. 2006; 10: 138-145)

## GİRİŞ

The recently designed device CardioVisor is being successfully tested in clinics and diagnostic centers in Russia and abroad. The device has not only shown high screening sensitivity but has also demonstrated promising results as a handy and operative instrument to monitor the dynamics of treatment in clinical conditions along with thorough comparison of the data of dispersion charting and the results of clinical instrumental examinations of patients with cardiovascular pathologies [1].

The doctors testing and practicing this method are faced with many questions, including the physical nature of the method and its diagnostic abilities. Despite the fact that the principle warranty limitation of the device is its using only for screening, there are clear prospects of using it for new additional information when making clinical diagnosis. At the same time, however, there arise many difficulties with interpretation of the new information and its comparison with cardiologic nosology. For instance, the high sensitivity of the method which is undoubtedly a strong point in screening, in clinical conditions, in a number of cases, leads to pseudo-positive results. Nevertheless, this is rather a question of correct comparison of the nosological classification and supernosological data supplied by the device, as some of these data contain absolutely new information which is not supplied by other instrumental means of cardiac diagnosis. However, it is a methodological question for further development of ECG dispersion charting technology.

**The aim of the study** was to define the abilities of the new screening device in cardiovascular pathology diagnoses. This article cites the results of joint investigations of the authors of the ECG dispersion charting method and the department of new diagnostic methods of the A.L. Myasnikov Clinical Cardiology Institute.

## MATERIAL AND METHOD

172 patients with various cardiovascular diseases – 87 patients with coronary heart disease (CHD) and 85 patients without CHD (patients with arterial hypertension, acquired or congenital, with dilated cardiomyopathy (DCMP) and hypertrophic cardiomyopathy (HCMP) as well as patients with endocrine metabolic diseases were examined to evaluate the sensitivity and specificity of the CardioVisor device. The patients were 27-72 years old, the mean age being 53 ± 5.2. The control group consisted of 21 healthy individuals. All clinical

Corresponding address: Dr G.V. Ryabykina
Moscov Cardiology Center
Moscov- Russia

diagnoses were verified by complex clinical and instrumental examination data with the use of coronary angiography, myocardial magnetic resonance tomography and scintigraphy. Clinical instrumental syndrome diagnoses (norm, myocardial ischemia, focal-cicatricial changes – CHD, left ventricle hypertrophy – LVH, combined ventricle hypertrophy – CVH, interventricular septum hypertrophy – IVSH, endocrine metabolic diseases, intraventricular blocks,  and auricular fibrillation) were compared with the conclusion and the heart portraits  which were plotted by CardioVisor.

The CardioVisor device is based on the technology of ECG low amplitude fluctuation  computer analysis [2] which  resembles the method of coherent accumulation of weak signals in Giss-electrography [3]. The essence of the new technology is as follows : a 30 sec. ECG input signal registered in the limb leads is digitalized and  approximately 15 QRSR complexes are singled out. Further, the singled out complexes in each of the 6 limb leads (L, …, aVF) are synchronized by the initiation moment and low amplitude fluctuation signals of the QRST complex are obtained at each moment of registration. The obtained digital fluctuation data arrays  are passed through a special weak signal coherent amplifying module. It is this module that is the now-how main element.  On the module outlet a surface electric fluctuation chart is formed which by a certain algorithm is projected against the epicardium surface of a computer three-dimensional anatomic model of the heart. As a result, a digital electric fluctuation model appears on the display  screen which the designers of the device called the heart portrait. The portrait of a healthy heart has  an  even  green  coloring. With changing fluctuations, the corresponding part of the heart portrait changes in color from green to red, depending on the expressiveness of these changes. The color of the heart portrait reacts to the slightest changes in the electric stability of the myocardium.

The ECG dispersion charting method takes into account some factors affecting   ECG formation on the surface of a body :

- non-linear effects appearing on activating and deactivating  the ion canals of membrane of contractile cardiac myocytes giving rise to acting potential (AP) and fluctuations of myocardial electromagnetic  radiation  in successive cardiac cycles;
- radiation fluctuations causing corresponding fluctuations of surface potentials [4];
- electrodynamic reflection    and    over-radiation effects appearing in avalanche ion current processes at the time of passing through  the contractile cardiac myocytes  membrane.

As a result, the heart portrait is an indirect integral indicator of changes in electric characteristics of cardiac myocyte ion canals. Changes in a heart portrait reflect electrolytic, metabolic or anatomic myocardial changes, i.e. give information about the current state of the myocardium and its dynamics. This conclusion is the conceptual base of clinical interpretation of a dispersion chart (a heart portrait).

Evaluation of the sensitivity and specificity of the method in differentiation of norm and pathology. CardioVisor-06c reacts not only to clear pathological changes, but to hardly distinct deviations from the norm. For this reason when calculating statistic sensitivity and specificity indicators it was necessary to correctly take into account hardly   distinct deviations. This account was performed on the basis of introducing intermediate degrees of pathology expressiveness into the estimating scale [5]. A 5 degree scale of positive conclusion was used: D1 - very distinct  pathology, D2 – distinct pathology, D3 – medium degree of expressiveness of pathology, D4 – slightly expressed pathological changes, and absence of changes (norm). The classifier of the device has probability values of clinically significant pathology for each of these gradations: D1 $\rightarrow$ probability of clinically significant pathology is equal to 1.0; D2 $\rightarrow$ probability of clinically significant pathology is equal to 0.8; D3 $\rightarrow$ probability of clinically significant pathology is equal to 0.5; D4 $\rightarrow$  probability of clinically significant pathology is equal to 0.3; D5 $\rightarrow$ probability of clinically significant pathology is equal to 0. These 5 gradations of a positive result are opposed by 5 gradations of negative result: U1 …U5: U1 –clear norm (no deviations), U2 – slightly distinct deviations from the norm, U3 – medium degree of deviations from the norm, U4 – high degree of deviations from the norm, and U5 – clear  abnormality (distinct pathology) As  the events U1…U5 are events opposite to positive events D1…D5, the probability values of  the absence of  pathological changes are given as : U1$\rightarrow$1.0; U2 1.0-0.3 = 0.7; U3 $\rightarrow$1.0-0.5 =0.5; U4 $\rightarrow$1.0-0.8 =0.2 ; U5 $\rightarrow$0.

Sensitivity is calculated by the formula:

$$Sens = \frac{PD1 \times 1.0 + PD2 \times 0.8 + PD3 \times 0.5 + PD4 \times 0.3}{PD1 + PD2 + PD3 + PD4 + FU} \times 100\%,$$

where

   PD1 - the number of positive **D1** type  conclusions in patients (with pathology),
   PD2 - the number of positive **D2** type  conclusions in patients (with pathology),
   PD3 - the number of positive **D3** type  conclusions in patients (with pathology),
   PD4 - the number of positive **D4** type  conclusions in patients (with pathology),
   FU - the number of negative **D5** type conclusions in patients (with pathology).

This formula differs from the standard one:

$$Sens = \frac{PD}{PD + FU} \times 100\%$$

as the number of positive conclusions PD are substituted by the sum of all the distinctive states D1...D4 with weight coefficients determined by the classifier of the device.

Respectively, specificity is calculated by the formula:

$$Spec = \frac{PU1 \times 1.0 + PU2 \times 0.7 + PU3 \times 0.5 + PU4 \times 0.2}{PU1 + PU2 + PU3 + PU4 + FD} \times 100\%,$$

where
PU1 -the number of negative **U1** type conclusions in healthy patients (with clinical diagnosis "norm",
PU2 - the number of negative **U2** type conclusions in healthy patients,
PU3 -the number of negative **U3** type conclusions in healthy patients,
PU4 -the number of negative **U4** type conclusions in healthy patients,
FD -the number of positive **U5** type conclusions in healthy patients.

### RESULTS AND DISCUSSION

Sensitivity and specificity when differentiating norm and pathology were 96 % and 90% respectively. Two cases corresponded to pseudo-

**Table 1.** Calculation of sensitivity for detecting CHD in individuals examined

| Pathology subgroup | PD1 | PD2 | PD3 | PD4 | FU | Sens % |
|---|---|---|---|---|---|---|
| CHD without myocardial scars | 1 | 2 | 3 | 2 | 1 | 52 |
| CHD with myocardial cicatricial changes | 13 | 3 | 0 | 0 | 0 | 96 |
| CHD against LV hypertrophy | 1 | 8 | 2 | 1 | 0 | 73 |
| CHD after ACS and heart transplantation | 22 | 5 | 8 | 1 | 0 | 80 |

negative conclusions (FU = 2) in the group of sick individuals - the first case after successful coronary angioplasty, the other a year after successful aortic coronary shunting (ACS). Similarly, in the group of healthy individuals the 2 cases of pseudo-positive conclusions (PU3 = 2) were most probably due to lack of data of more profound clinic instrumental examination which could have confirmed the detected dispersion deviations.

To evaluate the sensitivity and specificity of the device to ischemic changes only, 87 patients with CHD and 50 patients without CHD were selected. The control group without CHD included 10 healthy people and 20 patients with heart diseases, LVH and arterial hypertension (AH), and 20 patients with CVH. The results of evaluation of sensitivity and specificity of detecting myocardial ischemia by the subgroups of patients are given in Tables 1 and 2.

The average sensitivity and specificity indicators for detecting myocardial ischemia were 79 and 76 respectively. For the sake of comparison, it is a well-known fact that the sensitivity of a resting electrocardiogram in the 12 generally accepted leads in detecting CHD is low and, according to various reference data, is 25-50 % [6].

Heart portraits maintain high reproducibility and individuality in different patients (Fig.1) This confirms the objective nature of information obtained from low amplitude ECG fluctuations. As a whole, individual color patterns of deviations in the portraits vary to a rather high degree. Therefore, it is impossible to single out a dominating color pattern of CHD. The most highly specific changes for CHD embrace the left

ventricle and the projection of the interventricular septum on the left aspect of the heart portrait (shown by arrows in Fig. 2) The more intensive reddening in these zones of the portrait, the higher probability of ischemic changes.

The higher sensitivity of a " fluctuation" heart portrait to CHD is adequately demonstrated by cases where the usual ECG has no generally accepted signs of CHD while specific changes appear in the portrait (Fig. 3).

High recurrence of a portrait ensures highly sensitive and accurate subliminal control of electric dynamics of myocardial stability. The more severe is coronary atherosclerosis, the more variable are the portrait foci of changes in their dynamic registration. Though, in this case to single out such insignificant changes in the initial ECG by other methods is practically impossible.

No sensitivity blunders were observed in the course of the study, i.e. the device always indicated significant deviations if they were present in verifying diagnosis. Somewhat low sensitivity indicators are due to the fact that the heart portraits of patients with some heart diseases and patients with myocardial ischemic lesions turned out to be alike by the color pattern of fluctuations. Experimental studies show that in a similar portrait plotted by signals from 12 generally accepted leads, specificity of detecting CHD in these cases increases to 85%. There are no registered cases of false detection of CHD in healthy people. Adequately high sensibility was observed in diagnosing intraverticular blocks (98%) and auricular fibrillations (77%), the latter being detected by brown

**Table 2.** Calculation of specificity for detecting CHD in individuals examined

| Subgroup of individuals examined | PU1 | PU2 | PU3 | PU4 | FD | Sens % |
|---|---|---|---|---|---|---|
| Norm | 10 | 0 | 0 | 0 | 0 | 100 |
| LV hypertrophy (aortomitral valvular disease and AH ) | 8 | 2 | 3 | 0 | 0 | 76 |
| LV hypertrophy against background of endocrinal metabolic changes | 1 | 0 | 3 | 1 | 2 | 39 |
| Hypertrophic cardiac myopathy | 0 | 1 | 1 | 0 | 0 | 60 |
| Combined ventricular hypertrophy (congenital and acquired heart diseases) | 4 | 2 | 4 | 3 | 5 | 39 |

coloring of the auricular zone. Table 1 shows sensitivity indicators in detecting myocardial ischemia.

Mean sensitivity Sens to ischemia in a selection of 87 cases of verified CHD was 95% :

$$\text{Sens} = \frac{52 + 96 + 73 + 98 + 77 + 80}{6} = 79\%.$$

The results of evaluation of specificity to myocardial ischemia by subgroups of patients are shown in Table 2.

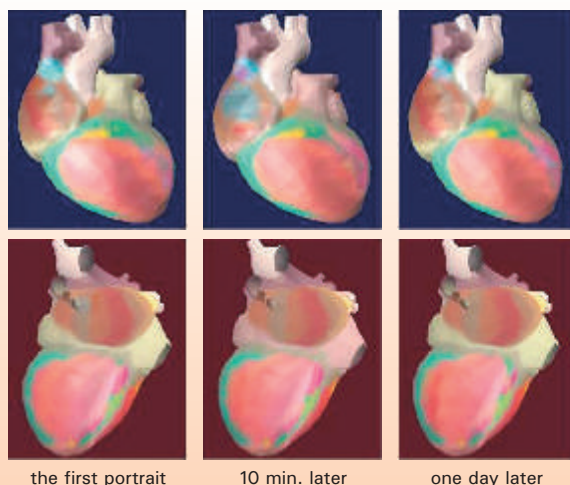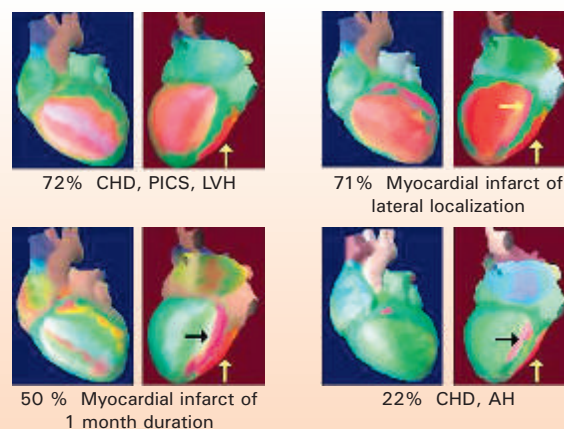Mean specificity Spec to ischemia in a selection of 50 cases of verified absence of CHD was 63% :

$$\text{Spec} = \frac{100 + 76 + 39 + 60 + 39}{5} = 63\%.$$

### DISCUSSION

Pseudo-positive diagnosis of pathology in the group "norm" is the most frequent observation of the users of the device. Let us try to analyze the causes of such diagnoses. Clinical interpretation of the results of charting is performed by comparing the dispersion chart under study with similar charts of different groups of pathology. Therefore, for instance, the conclusion about possible myocardial ischemia is evidence only of resemblance of the dispersion chart under analysis with the chart of confirmed myocardial hypoxia. To receive an answer to the question whether this state is stable or transient with the help of a dispersion chart is impossible. To do that it is necessary to control the dynamics of the process. At the same time the high sensitivity of the method most urgently raises the question of the limits of physiological norm. For instance in a number of cases the heart portrait indicates significant myocardial changes caused by neurogenetic factors in absence of organic changes. Thus, the same metabolic changes which are apparent in fluctuations, can be both of organic and functional origin. As fluctuation indicatory space at the present time is not studied in detail, the clinical value of a number of fluctuation variations is determined only step by step with growing experience of lengthy clinical use of this method. However, present experience of tests for a few years is evidence of the indisputable fact that among non-invasive methods, simple and accessible for wide clinical practice, the ECG dispersion charting method has the best indicators of sensitivity to myocardial metabolic changes of any genesis. Moreover, as to transient functional lesions which are forerunners of pathology, the given technique in many cases gives unique information which cannot be obtained in real time by other methods.

The diagnostic efficiency of dispersion charting can be raised at the expense of performing small load tests (medicamentous, physical, etc.). Dynamics of dispersion indicators in a healthy myocardium and in a myocardium with lesions (even at the preclinical stage) is considerably different. Therefore, the most insignificant load tests are highly effective means of early detection of developing pathology.

**Fig. 1.** Reproducibility of the heart portrait of a patient



the first portrait          10 min. later          one day later

**Fig. 2.** Heart portraits from verified CHD group



72% CHD, PICS, LVH

71% Myocardial infarct of lateral localization

50 % Myocardial infarct of 1 month duration

22% CHD, AH

**Note:** % - Integral indicator of deviation from norm
The arrows indicate CHD specific signs.
PICS - Post-infarct cardiac sclerosis.

**Fig.3.** Heart portrait with verified CHD, not appearing in ECG from 12 generally accepted leads
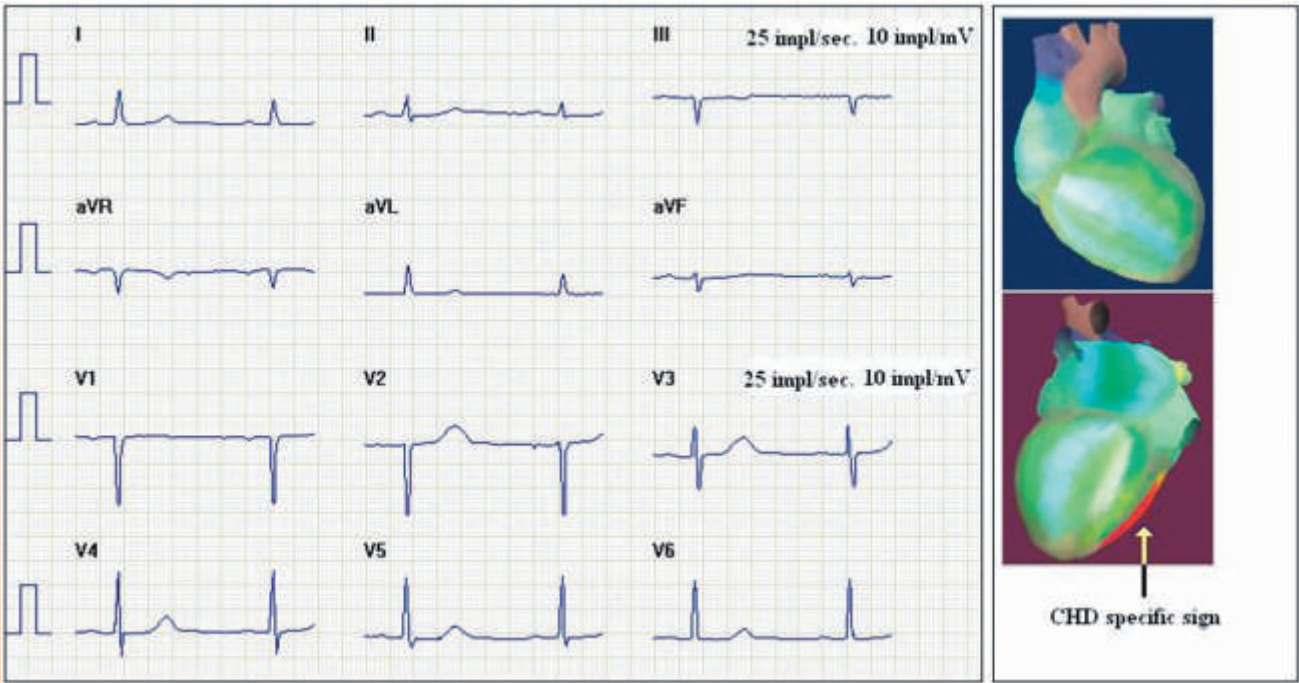


The sensitivity and specificity of diagnoses of myocardial pathology are proportional to the area of the surface on which one can make accurate calculation of fluctuations by ECG registered signals.  In its turn, the location and the area of zones of accurate calculation of fluctuations is determined by the number of ECG leads. The average indicators of sensitivity and specificity of ECG dispersion charting concerning the mostly observed myocardial pathologies increase with the increasing number of applied leads. Following from the data given in Fig. 4 one can come to the conclusion that for screening diagnoses the standard number of ECG leads is quite sufficient. Sensitivity and specificity increase with the use of 12-axis system of leads. Further increase in the number of leads is senseless as it does not change the informative value of the method.

Thus, despite the fact that  CardioVisor, designed for screening, processes an ECG plotted in limb leads only, sensitivity to detecting myocardial ischemia is about 80%. Therefore the given device is very promising as a new means of accurately and operatively obtaining early diagnostic information both in clinical conditions and during the preclinical period of disease in  prophylactic screening examinations, sanitary-and-resort  therapy and in emergency  medical service. ECG dispersion charting can also be used to non-invasively control myocardial metabolism practically in real time.

### CONCLUSIONS

1. Evaluation of the sensitivity of CardioVisor -06c has shown that by authenticity and efficiency of obtaining

**Fig. 4.** Mean sensitivity and specificity indicators of dispersion charting depending on the number of leads

| The number of leads (name of device) | Zone of accurate calculation of  fluctuations | Mean sensitivity and specificity indicators |
|---|---|---|
| 6 limb leads (DP-6) | | For mostly observed pathologies 80% / 70% For all pathologies (screening) 95% / 90% |
| 12 generally accepted leads (DP-12) | | For mostly observed pathologies 95% / 85% |
| >60 leads (DP-F) | | For mostly observed pathologies 97% / 90% |

information it is suitable for screening examinations to detect cardiac pathologies.

2. The device has adequate sensitivity and specificity indicators (79% and 63%) when used to detect CHD.
3. The device has resources for further highly sensitive control of dynamics of myocardial metabolic state to evaluate the results of applied therapy.

### REFERENCES

1. A.S. Sula, G.V. Ryabykina, V.G. Grishin  ECG analyzer CardioVisor-06-c: new prospectsof detecting myocardial ischemia in screening examinations and perspective use in functional diagnoses. Functional diagnoses 2003;2: 66-77.
2. G.M.T. Tompson. Instability and catastrophes   in science and technology (translated from the  English) M: Mir, 1985; 254.
3. Human physiology. P.Schmidt and G. Tevs (translated from the English) M; Mir, 2004; v. 1; 323.
4. A. M. Khazen   On the possible and the impossible in science; M; Nauka, 1988; 181.
5. V.P. Bulygin, S.S Koltsun, S.I. Feodorova, et al .Improving methods of testing medical interpreting devices. Functional diagnoses. 2003; 1; 93-100.
6. Cardiology in tables and charts. M. Frid, S.M. Grains; Praktica, 1996; 254.