

VALIDATION OF THE DDFAO SYSTEM/CLINICAL TESTS

DEFINITIONS OF ALGORITHMS BY INVERSE PROBLEMS

I. History of functional examinations:

➤ **Functional tests**

These tests are used to quantify respiratory, endocrine and hepatogastric function and require the insertion of an intraoesophageal balloon, injection of products or hormones or isotopic markers (radioactive substances) and are therefore invasive, costly and rarely prescribed by physicians in spite of their diagnostic utility.

➤ **Measurement of cardiac and cerebral electrical function**

The electroencephalogram is still reserved for central nervous system specialists and evoked potentials.

Only the electrocardiogram, which analyses cardiac function, is widely used.

➤ **PET scan**

Positron Emission Tomography (PET Scan) is used to display the functions of various organs perfectly, but the examination is invasive (radioactivity), costly and focuses on one organ only. This disadvantage limits its use to a hospital environment.

➤ **Laboratory examinations**

Physicians commonly prescribe laboratory examinations to establish a functional diagnosis and follow up with targeted lesional examinations according to the results.

The disadvantage is that the blood sample will indicate a global constant applied to the whole body and will therefore detect lesional problems but rarely functional problems.

The optimal use of tests is not only based on comparing a result with reference values, but also requires a definition of the physiological limits. These cover 95% of healthy subjects.

On the other hand, the physiological limits of decision making fluctuate according to objectives:

- ✓ Diagnosis made
- ✓ Patient monitoring
- ✓ Diseases concerned
- ✓ Possible therapies
- ✓ Prevalences

They are therefore based on scientific and medical knowledge at the time.

➤ **Bioelectric impedance metering**

While attempting to calculate the water content of the human body, Thomasset (Lyon France) in 1962, then Nyboer J. in the USA in 1970, showed that a low voltage direct current applied to the skin could be used to analyse extracellular liquid (interstitium and plasma), and alternating current between 50 and 200 Hz to analyse intracellular liquid. This was the origin of bioelectric impedance metering. (2) (3) (4) (5) (6)

At present, single or multifrequency alternating current is used and there are many medical applications of these algorithms, particularly the calculation of body fat and lean mass, validated scientifically and widely used throughout the world.

➤ **The DDFAO electrosonatograph: chronopotentiometry.**

The use of low voltage direct current (below any rheobase) applied to the skin has not yet been explored in the field of medical diagnostics.

This method is taken from research into analytical electrochemistry (Appendix 7) known as: **Chronoamperometry.**

By giving access to electrochemical membrane and local extracellular measurement in vivo and hence a localised acid-base balance approach, passing direct current across the skin gives a local reflection of organic function and the fundamental mechanisms which are in action.(1) (11) (12),

There are also many buffer systems, which can be used to draw up a hypothesis, which states that variations in the concentration of H⁺ ions have very long time constants.

For the same reasons as laboratory analyses, the physiological limits of decision fluctuate according to objectives and are therefore based on current scientific and medical knowledge. The system has been validated due to mathematical progress and the scientific validation of a field known as "inverse problems" (8) (12).

The mathematical algorithms of "inverse problems" are based on the following principle: **Every phenomenon is governed by equations with parameters such as initial conditions or various coefficients; when some of these parameters are unknown, we are in the field of inverse problems and finding them by using experimental measurements solves the problem.** (8)

II. Clinical trial conditions

To validate algorithms of inverse problems in the DDFAO system, clinical trials were performed in 4 hospitals under the control of scientific committees led by hospital or university professors.

Hospital complexes:

Botkin Hospital Moscow (Russia)

Scientific manager: **Prof. Aleexev**

Pathologies:

- ✓ Cardiovascular
- ✓ Respiratory
- ✓ Digestive
- ✓ Neurological

Institut Gustave Roussy Paris (France)

Scientific manager: **Prof. Alimi**

Pathologies:

- ✓ Oncology post-treatment

St Louis Hospital Urology Department Paris

Scientific manager: **Prof. Tritto**

Pathologies:

- ✓ Andrology

University hospital of Beijing (China)

Scientific manager: **Prof. Gy**

- ✓ Oncology before treatment and chemotherapy monitoring

III. Presentation of the DDFAO electrosomatograph system

Medical norms CE 0459 (European medical device norms) & CSA (American and Canadian medical device norms).

Definition

The principle of the ESG is to measure electrical potential membrane activity and the ionic concentration of intercellular liquid (interstitium) locally in the body and in vivo by applying a low voltage direct current between different points of the skin.

Measuring principle:

Measuring electrical resistance and ionic concentration

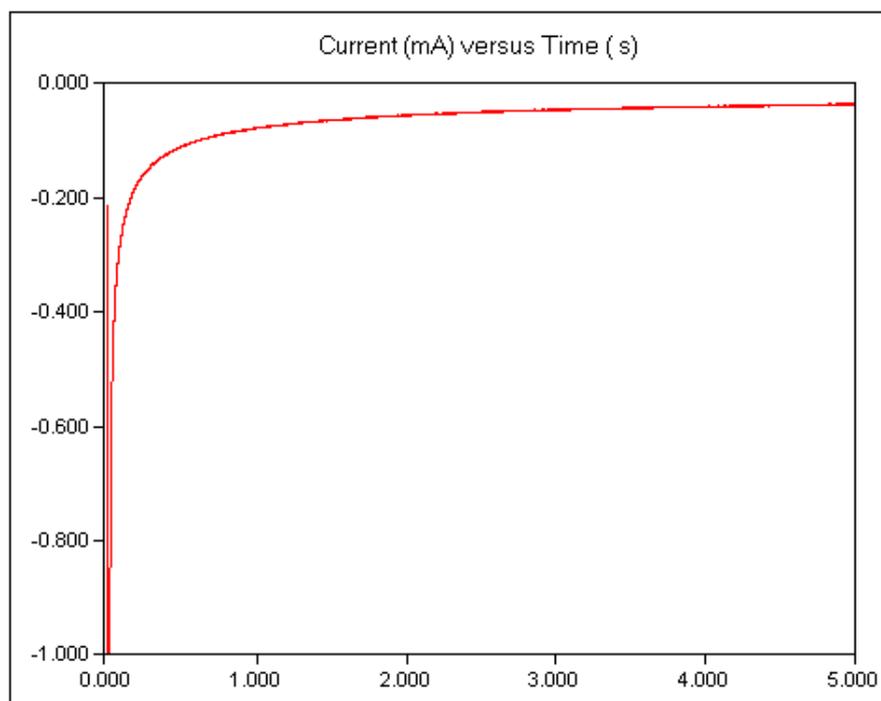
A DC current of 1.28V (below any rheobase) is applied across 6 electrodes placed symmetrically on the forehead, hands and feet. Each electrode is alternately cathode then anode so that 22 volumes of the human body can be registered (Appendix 0). These records are incorporated in a graph. The graph of 22 volumes is an electrosomatogram (ESG) (Appendix 0)

The interface box transmits the intensity* in digital form for each volume to a computer program which transforms the value according to 2 types of information:

- Measurement of membrane electric resistance or conductivity: application of Ohm's law $U = RI$ then $C = 1/R$
- Measurement of the ionic concentration of the interstitium: application of Cottrell's equation**.

The Cottrell equation

In chronoamperometry, the working electrode potential is suddenly stepped from an initial potential to a final potential, and the step usually crosses the formal potential of the analyte. The solution is not stirred. The initial potential is chosen so that no current flows (i.e., the electrode is held at a potential that neither oxidizes or reduces the predominant form of the analyte). Then, the potential is stepped to a potential that either oxidizes or reduces the analyte, and a current begins to flow at the electrode. This current is quite large at first, but it rapidly decays as the analyte near the electrode is consumed, and a transient signal is observed (see Figure 1).



Figure

1.

If the point in time when the potential is stepped is taken as time zero, then the Cottrell equation describes how the current, I , decays as a function of time, t :

$$I = n F A c_o \sqrt{\frac{D}{\pi t}}$$

The Cottrell equation

Although the current decay may appear to be exponential (in the case of adsorbed redox species), it actually decays as the reciprocal of the square root of time. This dependence on the square root of time reflects the fact that physical diffusion is responsible for transport of the analyte to the electrode surface.

Non-equilibrium conditions: The Cottrell Equation

The case that we have looked at in the previous pages has been the one where the solution is stirred. This results in stable diffusion profiles at the electrode surface (i.e. the concentration gradient does not change with time) and hence the establishment of a steady unchanging current.

Now, imagine the case where a planar electrode is placed in an unstirred solution containing excess electrolyte and a small amount of electroactive material. Until a potential is applied, the electrode and the solution can co-exist without any chemical reaction taking place. When a potential sufficient to electrolyse the electroactive component completely is applied to the electrode (at $t = 0$), the concentration at the electrode surface ($x = 0$) is reduced to zero. Thus, a concentration gradient will be established down which material will flow to the electrode surface.

Because the solution is quiet (not in motion) the diffusion layer (which we encountered in the previous page) will not remain at a constant thickness. Instead, as time progresses so the diffusion layer grows stretching further and further into the bulk solution. Consequently, the slope of the diffusion gradient will also change with time resulting in a non-steady state current.

Thus, relationships must be developed which describe how the flux of material to the electrode surface changes as a function of time. This is appropriately accomplished by starting with Fick's second law of diffusion;

$$\frac{\partial [c_o(x, t)]}{\partial t} = D_o \frac{\partial^2 [c_o(x, t)]}{\partial x^2}$$

where all the variables have their usual significance. This is a differential equation having many solutions under different conditions known as **boundary conditions** and solution of this equation requires use of the Laplace transform.

Using the Laplace Transform gives a solution for concentration in terms of the parameters x and t (where erf is the error function).

$$c_{(x,t)} = c \operatorname{erf} \left(\frac{x}{\sqrt{Dt}} \right)$$

By taking the derivative of the above equation for the proper boundary conditions (i.e. $x = 0$) the diffusion gradient at the electrode surface is expressed as;

$$\left(\frac{dc}{dx} \right)_{x=0} = \frac{c}{\sqrt{\pi Dt}}$$

As we have seen previously, we can convert such an equation to current by the expression;

$$i = nFAD \left(\frac{dc_{(0,t)}}{dx} \right)$$

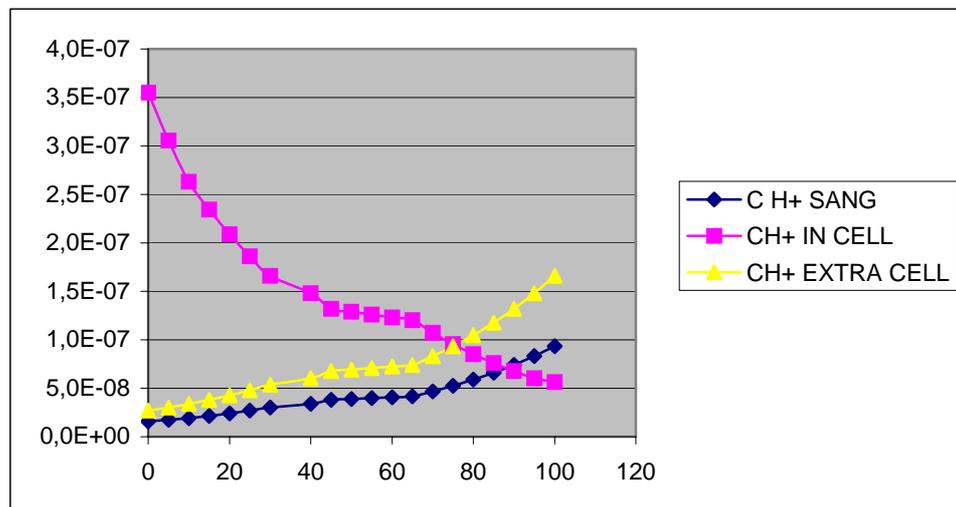
Substituting into the above equation gives;

$$i = nFAc_o \sqrt{\frac{D}{\pi t}}$$

This equation, which is known as the Cottrell equation, holds true for any process involving semi-infinite linear diffusion to a horizontal plane. According to it, the product of current and square root of time is constant if the area and diffusion coefficient are constant. Furthermore, the equation tells us that no stable time dependent current is ever achieved for diffusion to a horizontal planar electrode

pH measurement

In application of Cottrell's equation, the system determines the ionic concentration and using the molecular weight of the ions (Nerst's equation), we can determine their concentrations, applying the same principles as electrophoresis



Location of organ and system zones:

The clinical tests were used to determine the functional location of organs and systems by solving equations via "inverse problems" (see results of the combination of branches in reconstituted images in appendix 6)

Parameters

DDFAO parameters are set for 0 to 100 and depending on the value assigned to this scale, the 0 point can be used to situate increased (negative value) or reduced (positive value) concentrations.

The concentration of volumes is measured on a scale of 0 to 100 in absolute values, then it can be converted into a positive or negative value by means of a mathematical formula*

Depending on the 2 types of parameters set, the 0 point is situated differently:

1. Parameter set to norms (N):

After a statistical study of more than 20 000 measurements over 5 years, we determined a 0 point corresponding to the standard parameter setting on the CAFDD at 70 + or – 8 according to age, sex and BMI (Appendix 2): This parameter depends on the body's water content (4) and, after taking into account the above factors of variation, corresponds to functional norms of optimal concentration of the interstitium.

2. Parameter of permeability called automatic (A):

The 0 point for this parameter is calculated relative to the mean electrical resistance of cell membranes or their permeability (electrochemical gradient of diffusion and activity). This will demonstrate the relationship between electrical membrane conductivity and ionic concentration of the interstitium. This ratio will be used to target volumes showing the most dysfunction.

2 measurements are made for each parameter:

- ✓ 2 derivations to norms Nb and Na
- ✓ 2 derivations in automatic Ab and Aa

b: basic reference measurement (32 impulses)

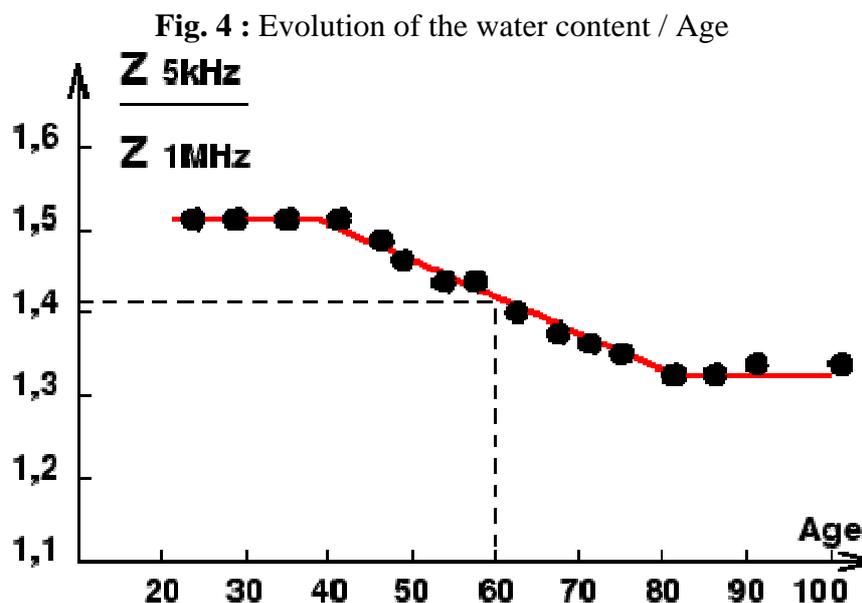
a: adaptive measurement (255 impulses therefore greater accuracy)

This is done to stabilise measurement: only Aa and Na measurements are taken into account in analysing the results.

All the measurements are made according to an optimal dispersion delta (automatic delta)**

During ageing, the body is dehydrated as one underlines it by impedancemetry while showing:

A reduction ratio Z_{5kHz}/Z_{1MHz} on 1200 subjects in good health whose ages spread out between 15 and 104 years, J. Lenoir and A.L. Thomasset showed that the ratio R depends only on the age and the sex of the measured subjects without intervening. the indices morphometric of these subjects



The curve was built by calculating the arithmetic mean of R scale 5 years for each age; each point representing the average value of R for the corresponding section. R is less low at the woman (- 0.05) , that at the man at the same age, but this constant shift due to the sex is not represented on the curve. R is of a remarkable fixity at the normal subject:

$$R_{normal} = \begin{cases} 1.57 - 0.00256 \times Age & \text{chez l'homme} \\ 1.52 - 0.00256 \times Age & \text{chez la femme} \end{cases}$$

Reproduction and stability of results

Reproduction of results must be reconciled with the results of laboratory analysis. The program compensates these physiological undulatory variations, which must be within a physiological functional delta or reference value. (Appendix 2)

Reference value and limits of decision:

Test interpretation is based, among other things, on comparing the result obtained with reference values (Appendix 3).

These variations depend on:

- ✓ Analytical variation of the method
- ✓ Biological variation: this is the summing of intra and interindividual variations.
- ✓ Its specificity and sensitivity

Analytical variation reflects the inaccuracy of the method used: this is estimated by analysing the test several times (Appendix 5).

Intraindividual variation is estimated by repeating the examination on the same person.

Interindividual variation is estimated by using the mean values for several people and is influenced by variables such as age and sex.

Like laboratory examinations, test interpretation therefore requires available adequate references and lists of variables which can modify the results: (Table 2)

The optimal use of tests is not based only on comparing a result with reference values but also requires a definition of physiological limits. These cover 95% of healthy subjects.

On the other hand, the physiological limits of decision making fluctuate with the objectives:

- ✓ Diagnosis made
- ✓ Patient monitoring
- ✓ Diseases concerned
- ✓ Possible therapies
- ✓ Prevalences

They are therefore based on current scientific and medical knowledge.

Cost of the examination:

The frontal electrodes are disposable and cost about 0.60 Euro per examination. This examination is performed in the doctor's office or the functional department of a hospital or clinic. The price will take into account the price of frontal electrodes, amortization of the purchase of equipment and the moderate fees charged by the physician producing the interpretation and report.

Variation factors: Table 2

Apart from the factors Age / sex / BMI, Acid-base balance can be altered by the elements in the following table, towards acidosis, alkalosis or according to a variable.

| ACIDOSIS | ALKALOSIS | VARIABLE FACTORS |
|------------------------------------|---|---|
| room temperature < 15° | room temperature > 25° | Contraceptive pill |
| Tranquilizer | Radiotherapy | > 20 cigarettes per day |
| Antidepressant | Surgery | Seasonal rhythms |
| Barbiturates | Chemotherapy | Weekly rhythms |
| Diuretics: Carbonic anhydrase | Post or menopausal hormone replacement treatment | Circadian rhythms |
| Hypotensives | Thyroid hormone treatment | Biological rhythms |
| Statins | Coffee and caffeine | Race |
| Anticoagulants | Puberty | Posture |
| Antibiotics | Stay at high altitude | Noise |
| Bereavement | Intense physical activity 8 hours before the examination | Pregnancy from the 5 th month |
| Exposure to light | Taking strong alcohol or drugs or stimulants (amphetamines) 12 hours before the examination | Metal in the body (pins, excluding dental prostheses) |
| Menopause | Fever and infections | Immobilisation lying down |
| Spa cure | Vomiting | Menstruation |
| Starvation | | Breast-feeding |
| Essentially vegetarian diet | | Recent emotional shock |
| Acidic food or high protein intake | | Obesity |
| Diarrhoea | | Haemorrhage of all kinds |

Contraindications for the examination:

- ✓ pacemaker
- ✓ Amputation of one or more limbs
- ✓ Pregnancy after the 5th month

Definition of the functional delta:

healthy subject with no pathology or symptomatic dysfunction (Fig.2 and 3)

The volumes must be within the DDFAO scale between -20 and + 20 with a rise in value (closest to 0) during the automatic lead measurement (Aa).

The first digit in Aa (1Aa) must be between 65 and 75 depending on age, sex and BMI.

Volumes 1 3 16 18 must be between -40 and - 50

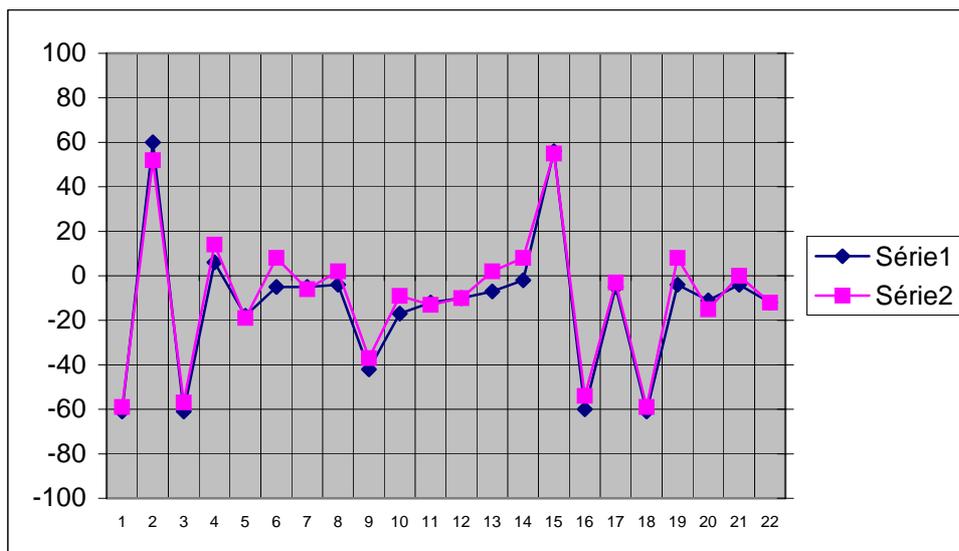
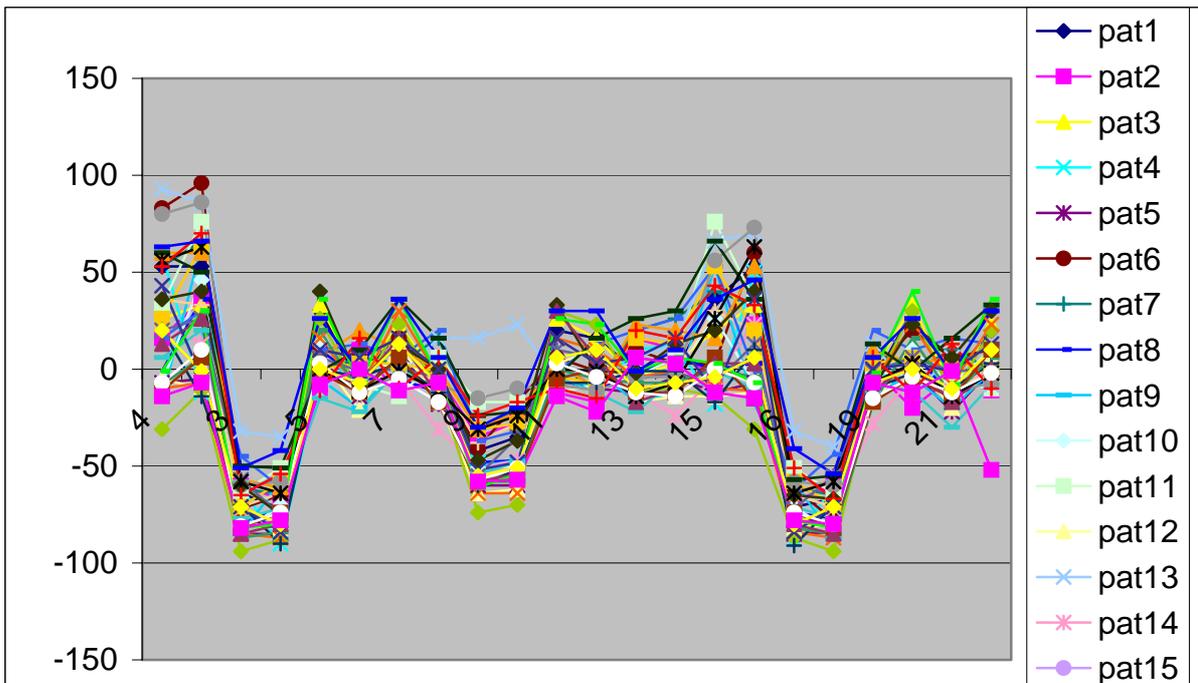
9 10 must be between -20 and - 40

Volumes 2 4 15 17 may be in excess (between +10 and +20) with a reduction between the measurement to norms (Na) and the automatic measurement (Aa).

A measurement with all values 1 3 9 10 16 18 between -20 and + 20 is pathological.

Figure 3 shows all the measurements made on a basis of healthy subjects (see appendix 3.).

Figure 4 shows the mean for the curves produced on healthy subjects.



Calculations of the mean and standard deviation for this population show a distinct improvement in the healthy patient population after the transformation to Automatic, which shows the validity of this type of transformation to make pertinent diagnoses.

Physiological significance of excessive and insufficient values

Excess or insufficiency in one zone is only determined by calculating the algorithms for 22 volumes of the Na measurement and 22 volumes for the Aa measurement.

The synthetic reconstituted image and risk analysis take into account the algorithms used to calculate these 44 volumes to determine excessive or insufficient zones.

The interpretation will take into account:

- ✓ Patient monitoring
- ✓ The diagnosis made
- ✓ Diseases concerned
- ✓ Possible therapies
- ✓ Prevalences
- ✓ Variation factors

For membrane electrical activity:

This activity is indicated by 1Aa (for sign conventions see Appendix 5)

1Aa value (+) (+)

1Aa value (+)

- Increased conductivity
- Reduced resistance
- Reduced voltage
- Increased intensity

Increase in cellular exchanges (Na⁺ and K⁺ ATPase pump). In these zones there may be extracellular hypocalcemia and hypokalemia up to +40 +or - 8*, beyond the risks of necrosis with membrane destruction.

Membrane permeability increased ((+)) to greatly increased ((+) (+)) .

1Aa value (-)

1Aa value (-) (-)

- Reduced conductivity
- Increased resistance
- Increased voltage
- Reduced intensity

Reduction in cellular exchanges (Na⁺ and K⁺ ATPase pump) which may cause intracellular damage and increased apoptosis.

Membrane permeability reduced ((-)) to greatly reduced ((-) (-))

1Aa Normal values

Membrane permeability normal

For ion concentration of the interstitium

Excessive values:

Positive values +20 to +100

- **Alkalosis: increased pH**
- **Reduced concentration of positive ions**
- **Increased volemia and / or blood pressure**

□ **Neuronal hyperexcitability:**

to be taken into account for the cortex, limbic system and dermatome

- ✓ **Cortex (volumes 9+10):** Normal cortex values are between -20 and - 40; all values > - 19 are excessive.

All values > -19 reflect neuronal hyperexcitability due to an increase in cerebral vascular pressure, which may be the source of hypertension, respiratory insufficiency, oedema, pulmonary embolism, ischemia or cardiac insufficiency.

Clinical signs are tension headaches, vertigo, loss of memory.

✓ **The limbic system (volumes 1+2+3+4):**

All values > 0 reflect increased aggressivity, loss of short-term memory or learning, dermatological problems, insomnia. The source of these disorders is psychological or behavioural.

✓ **The thalamus, hypothalamus and hypophysis:**

All values > 0 reflect subcortical deregulation, notably neurovegetative, hormonal and psychological.

✓ **Dermatomes:** Values $> +20$: increased excitability which may lead to muscle spasms and pain, or limb paralysis.

(values $> +60$) depending on nerve circuits.

□ **Vasoconstriction of blood vessels or ischemia**

In excessive zones, blood pressure is increased to $+40$ +or - 8^* (hyperoxia), beyond which there is a risk of ischemia (hypoxia) and necrosis of vascularized tissues except in the limbs (normal values for the limbs are between 0 and $+20$)

□ **Increase in organic function**

Same up to $+40$ +or - 8^* , then inversion and necrosis with reduced function. Note that the function is not necessarily linked to metabolic production (e.g. type II Diabetes).

□ **Reduced bone density and bone deformation**

□ **Inflammation, acute infections and stress** (which may be caused by: bacteria, viruses, psychological conflicts, allergies, intoxication...), which can lead to necrosis in zones beyond $+40$ +or - 8^* .

*This value can be modified according to age, sex, height and weight.

> **Depending on how long this condition has been present, if it persists, it could lead to an increase in the relative risk of developing the following pathologies:**

- Cardiovascular diseases: Metabolic syndrome, atherosclerosis of coronary and aortic vessels, infarction, arterial thrombosis, cerebrovascular accident, micro angiopathies or retinopathies
- Increase in the risk of infection or tissue necrosis
- Immune system storage
- Allergy or intoxication (forms of inflammation)
- Hepatic and digestive dysfunction (allergies or inflammation)
- Type II diabetes
- Neurovegetative dystonia
- Kidney disorders
- Endocrine dysfunction
- Hypofertility by deregulation of hypophyseal tract activity
- Manifestation of vicious post-traumatic sequelae, with or without disturbing or destabilising reactional foci (old lesions such as bone calluses, previous surgery or disturbing dental fields)
- Inflammatory crises due to osteoarthritis
- Psychological disorders (aggressivity, psychological stress, emotivity)
- Initiation of benign or malignant tumoral processes following necrosis or exhaustion of reserves or the body's resistance

➤ **Insufficient values: negative values –20 to –100**

- **reduced pH: Acidosis**
- **Increased concentration of positive ions:** In these zones there may be extracellular hypercalcemia and hyperkalemia
- **Reduction in volemia or blood pressure**

□ **Neuronal hypoexcitability:**

to be taken into account for the cortex, the limbic system and the dermatome

- ✓ **Cortex: (9 10)** The normal values of the cortex are between –20 and – 40, therefore only values < -40 need be taken into consideration.

Below -40, depression may occur, all the more in that the values are worse for volume 10 between the values for Aa and Na.

Below –80 neurological disorders are possible

- ✓ **Limbic system:(1 2 3 4)** values < -40 should be taken into consideration: Reflect a docile, fatalistic nature, exacerbated emotion and fear and anxiety or even phobias. Problems with communication and sleeping are possible as are repeated or chronic dermatological problems. Unilateral affect on a system is possible: on the right for a recent situation, on the left for an old situation.

- ✓ **In the thalamus, hypothalamus and hypophysis:**

All values < -40 reflect subcortical deregulation, particularly neurovegetative, hormonal and psychological

- ✓ **Dermatome:** reduction in excitability which can lead to somesthesia of the limbs and extremities depending on nerve circuits

□ **Vasodilatation of blood vessels (hypervascularisation)**

There is hypervascularisation promoting tissue proliferation and plasma leakage.

□ **Reduction in organic function**

□ **Dehydration** due to reduction of interstitial liquid

□ **Osteochondrosis and osteoarthritis**

- **Chronic inflammation:** Acidosis due to these effects leads to chronic or degenerative inflammatory diseases, chronic tiredness, genetic damage, particularly to mitochondrial DNA, thereby reducing the cell's energy production.

> Depending on the prior history of this condition and its persistence, it may provoke an increase in respiratory and renal compensation, and if this is inadequate, there is a greater risk of the following pathologies:

- Development of a benign or malignant tumoral process: Initiation of apoptotic acceleration and genetic damage (mutations or deletion of part of the DNA), terrain favourable to tumour development by hypervascularisation, reduced cell nutrient supply, hypoxia, information interference.
- Osteoarthritis and bone pain
- Pancreatic insufficiency or cell insulin-resistance
- Cardiovascular dysfunction (insufficiency, arrhythmia via hypercalcemia)
- Venolymphatic insufficiency
- Hepatic and digestive dysfunction (digestive intolerance, constipation, diarrhoea or degenerative disorders)
- Endocrine or metabolic dysfunctions
- Psychological disorders

IV. CLINICAL PROTOCOL

The protocol consisted of selecting pathologies which had been perfectly diagnosed by conventional means, with fully completed anamnesis. The 44 values were the unknowns (values for the 22 Aa branches and 22 Na branches), the results were the pathologies, the principle being to find the solution of the inverse problem equation to make the connection between the measurement and the pathology in an adequate number of cases.

The tests performed at the Botkin hospital were used to validate the algorithms for cardiovascular, respiratory, digestive, endocrine and neurological pathologies and the tests performed at Beijing university hospital for algorithms in oncology screening and therapeutic monitoring.

The tests at Gustave Roussy and St Louis, on the other hand, showed the advantage of the system in oncological monitoring between 16 months and 4 years, and in the field of andrology, to determine the source of the disorder. This document will not include these last 2 tests which are not involved in validating the system. (See Appendix 8)

Botkin Hospital (Moscow Russia)

Under Prof. Aleexev's management, measurements were taken by Dr Elena Markelova, in the functional medicine department, including an ECG , an electromyogram and an EEG. The patients had several pathologies so the number of pathologies is greater than the number of patients.

Different pathologies were selected: (Appendix 4)

- ✓ Cardiovascular diseases: Total 195 distributed as follows:
 - Hypertension: 54 patients
 - Angina: 31 patients
 - Recent myocardial infarction: 31 patients
 - Coronary atherosclerosis: 35 patients
 - Aortic atherosclerosis: 35 patients
 - Cerebral atherosclerosis: 39 patients
 - Arrhythmia: 35 patients
 - Cardiac stenosis: 35 patients
 - Circulatory disorders, thrombophlebitis and varicose veins on the lower limbs: 13 patients

- ✓ Respiratory diseases: Total 171 distributed as follows:
 - Chronic bronchitis: 38 patients
 - Chronic obstructive bronchitis: 33 patients
 - Asthma: 36 patients
 - Pneumonia: 38 patients
 - Pneumosclerosis: 30 patients
 - Pneumothorax: 31 patient
 - Hydrothorax : 31 patient
 - Emphysema: 39 patients
 - Pulmonary embolism: 33 patients
- ✓ Endocrine diseases: Total 135 distributed as follows:
 - Diabetes I: 33 patients
 - Diabetes II: 30 patients
 - Goitre: 32 patients
- ✓ Digestive diseases: Total 182 distributed as follows:
 - Gastritis: 35 patients

- Duodenal ulcer: 39 patients
- Spasmodic colitis: 33 patients
- Pancreatitis: 36 patients
- Hepatitis :
 - Hepatositis dietetica: 34 patients
 - Chronic hepatitis and cirrhosis: 32 patients
 - Viral hepatitis A B C: 33 patients
- ✓ Neurological diseases: Total 138 patients
 - Cerebral circulatory disorders and neurological diseases: 30 patients
 - Depression: 38 patients

Measurements were made between November 2003 and September 2004

Number of patients: 302 men and 218 women, average age 48

Each patient underwent 3 successive examinations

All confidence intervals were calculated at 95%

Beijing University hospital (China)

Measurements were made at the Beijing University hospital in the oncology department by Prof. Gy.

353 patients were used for the examination, with ages varying between 30 and 65

Measurements were made after diagnosis of lesions, before and after chemotherapy (6 days after the session), using conventional resources. The distribution of cancers was as follows:

- 64 breast cancers
- 45 digestive cancers
- 55 pulmonary cancers
- 47 prostate cancers
- 49 uterine cancers
- 52 liver cancers
- 41 bone cancers

V. RESULTS:

! The results obtained and algorithms are applicable only to the DDFAO patented system and depend on the calibration , surface and the redox of the electrodes and cannot apply to other electric measurement systems of the body

! Any use of these algorithms on other systems would be wrong.

Botkin hospital

The various pathologies were analysed as a function of the values of the electrosomatogram 22 volumes in Na and Aa, leading to the creation of new algorithms for the relationship between function and pathology.

Total false positives and false negatives: (Appendix 5 and 5 b)

- ✓ Cardiovascular diseases: Total 195 patients
23 false negatives and 8 false positives
- ✓ Respiratory diseases: Total 171 patients

- 17 false negatives and 12 false positives
- ✓ Endocrine diseases: Total 135 patients
- 15 false negatives and 7 false positives
- ✓ Digestive diseases: Total 182 patients
- 15 false negatives and 6 false positives
- ✓ Neurological diseases: Total 138 patients
- 9 false negatives and 6 false positives

Algorithms drawn up / Result sensitivity and specificity (See conventions and definitions in Appendix 5)

1. CARDIOVASCULAR DISEASES:

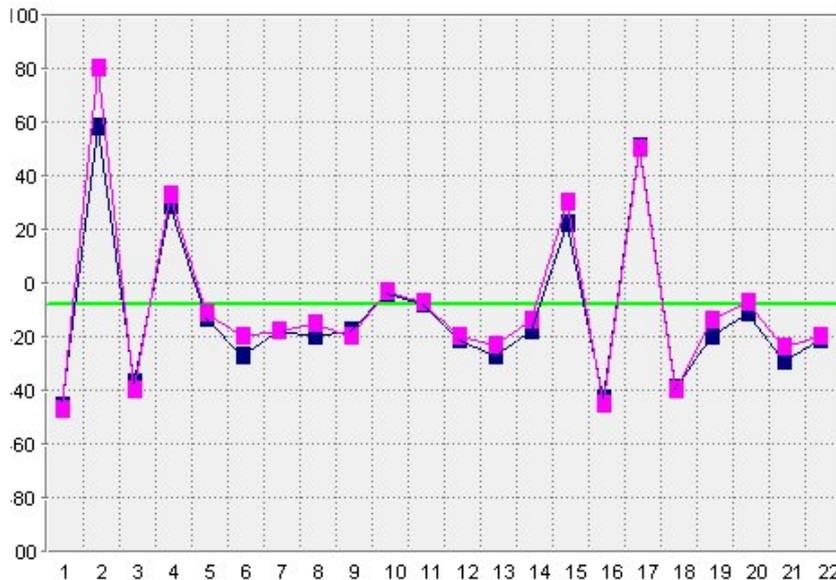
A. Hypertension

The volumes which determine hypertension are the branches corresponding to hypothalamus function, i.e. 1 2 3 4 9 10 for which the following algorithm ((10+9 + (1+2+3+4)) must be > -19, but variants and associations with other volumes are possible, depending on the origin of the disease. The patients were split into 4 groups, meeting the following algorithms:

Group 1: Hypertension of neurovegetative origin: Excess catecholamines: beta-blockers are indicated.

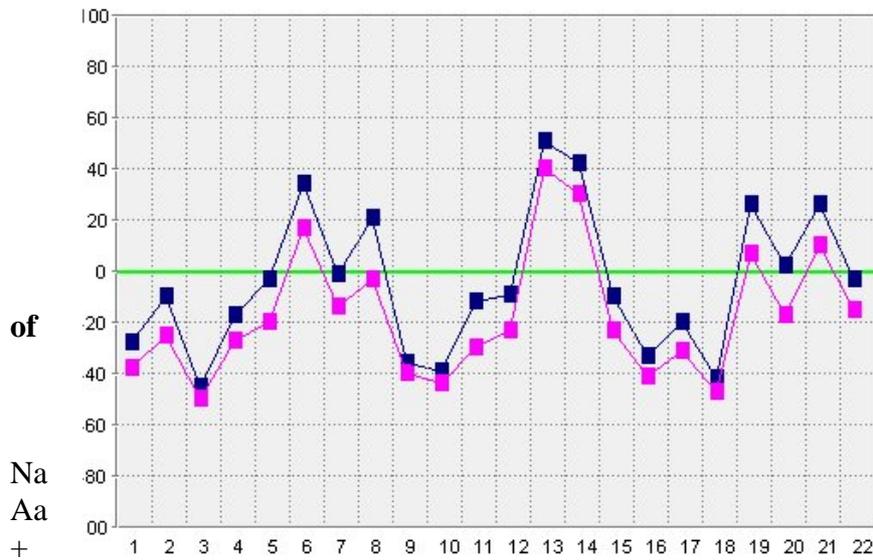
Na (2+15) >= 20

Aa (2+4+15+17) >= 20) + 9 or 10 >-20

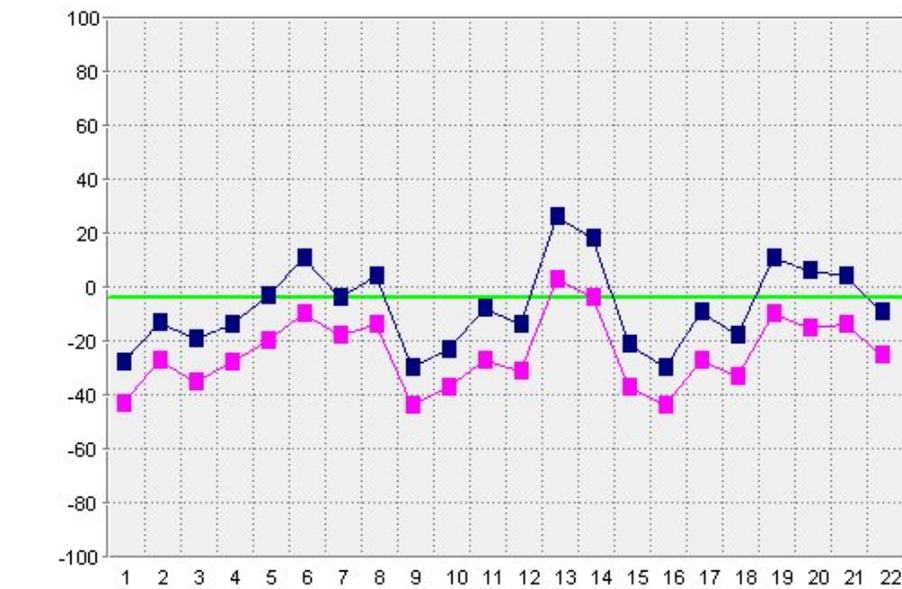


Group 2: Hypertension linked to a high cardiovascular risk (coronary atherosclerosis): an aspirin-type anticoagulant must be prescribed at the same time as the hypotensive which will be a conversing enzyme inhibitor (CEI or sartan except during pregnancy) .

Na (11+12) > 20 or Na (6+13+19) > 20) + Aa (6 > 20 +13 > 20 +19 > 20) + ((10+9 + (1+2+3+4)) > -19)



Group 3: Hypertension renal insufficiency origin, owing to a diuretic (not Carbonic anhydrase)
 $(11+12) < -20$
 $(13+14) > +20 + ((10+9$
 $(1+2+3+4)) > -19)$



In terms of positive and negative predictive value, the results are as follows:

| | VP+ | VP- | |
|---------|-----|-----|---|
| GROUP 1 | 89% | 73% | The very high values of positive prediction show that we link groups of hypertensive patients to different functional causes. |
| GROUP 2 | 80% | 66% | |
| GROUP 3 | 89% | 70% | |

2. Angina pectoris/Cardiac stenosis/Coronary atherosclerosis

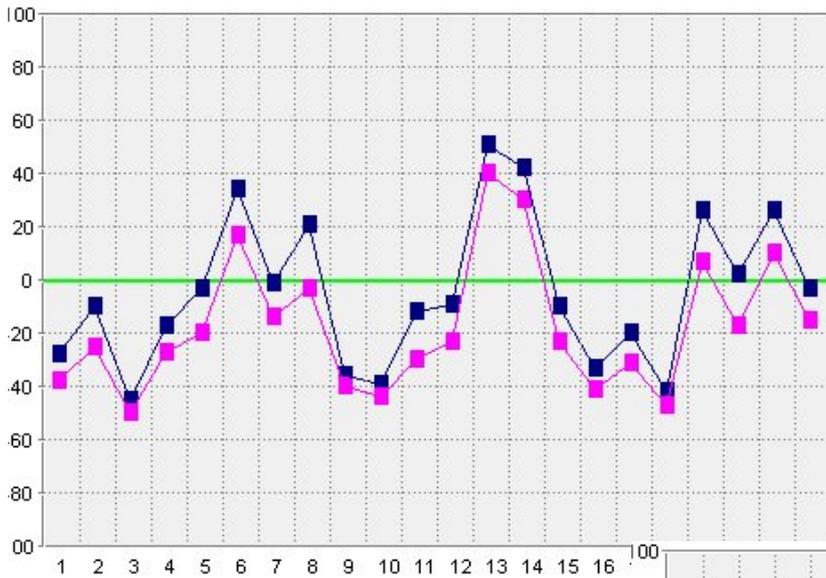
The volumes determining cardiovascular atherosclerosis are the branches corresponding to the relationship between $(6+13+19) / (2+15) / (9+10) / 1Aa$

- $(6+13+19)$ = left ventricle
- $(2+15)$ = neurovegetative system
- $(1+9+10+16)$ = cerebral vascularisation
- 1Aa = membrane permeability

depending on the risks of the disease. The patients were split into 3 groups meeting the following algorithms:

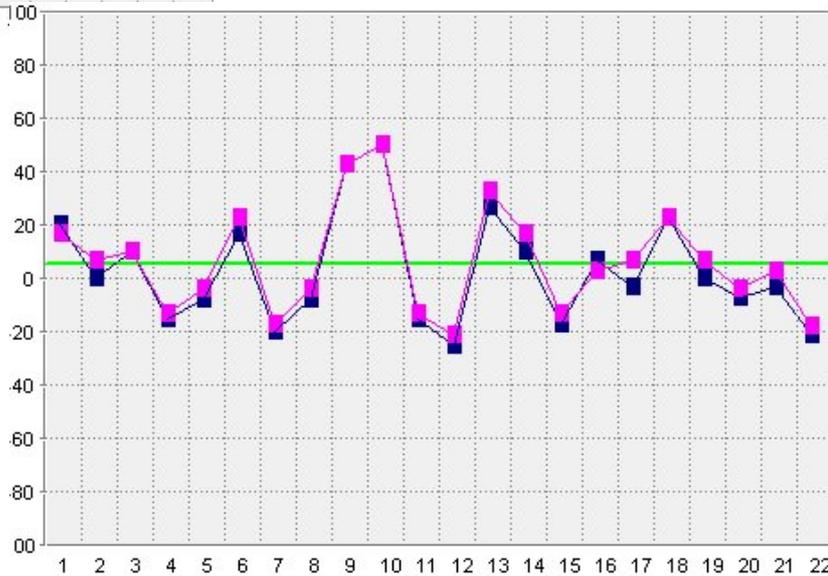
Group 1: Increased cardiovascular risk

Aa $6 > 20 + 13 > 20 + 19 > 20 +$ (Hdi) -



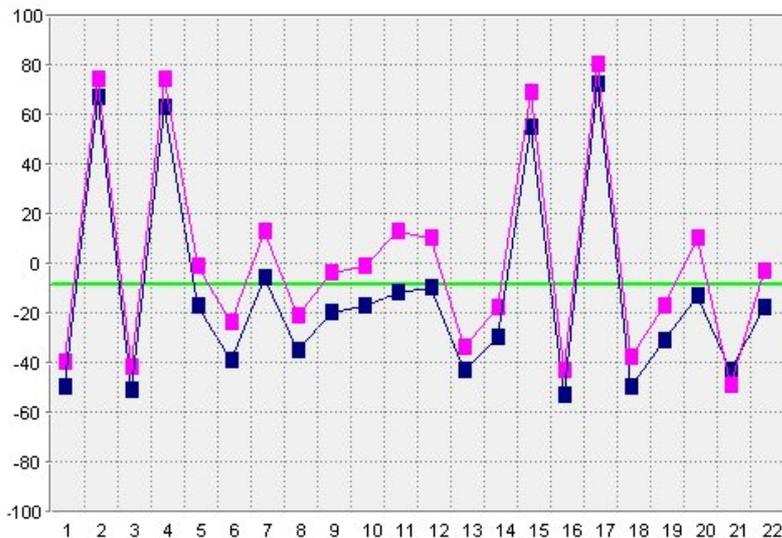
Group 2: Increased risk of thrombosis

Aa $(1+9+10+16) > -10 + 6 > 0$



Group 3: Increased risk of cardiac insufficiency

Aa (value (+) ou (+) (+) ou $(2+15) > +20$) + $(6 < -16 + 13 < -16 + 19 < -16)$



| | VP+ | VP- | In terms of positive and negative predictive value, |
|---------|-----|-----|---|
| GROUP1 | 91% | 79% | the results are as follows: |
| GROUP2 | 84% | 72% | sensibility 88% (+/-9%) |
| GROUP 3 | 87% | 74% | spécificity 76% (+/-5%). |

3. Myocardial infarction (left ventricle)

The volumes determining cardiac ischemias are the branches corresponding to excessive left ventricle function (mean ischemia + 38) i.e. 6 13 19, but associations (1Aa / (2+15) / (11+12) with other volumes are also possible.

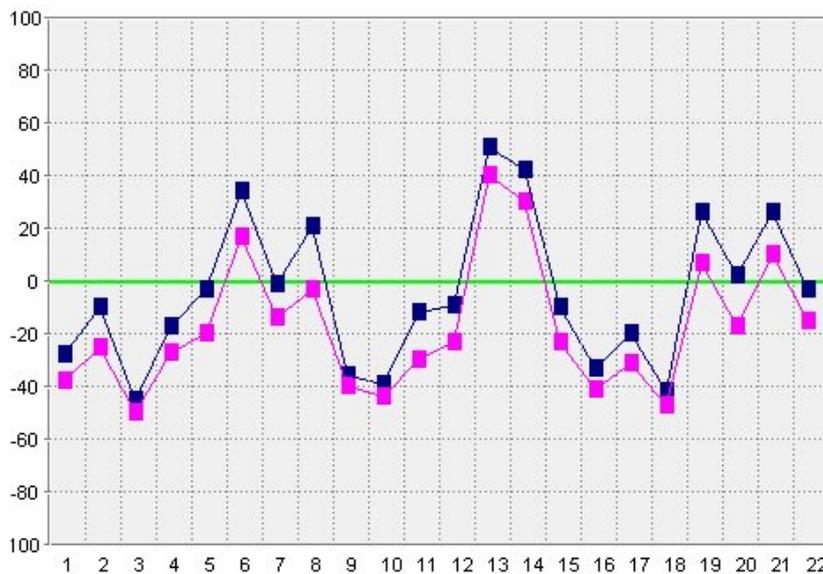
(11+12)= respiratory system

depending on the risks of the disease. The patients were split into 4 groups meeting the following algorithms:

Group 1: associated risks: aortic atherosclerosis, extrasystole, and hypertension

Na : (2+4+11+12+15+17) < -20 + (11+12) < -20 + (13+14) > 0

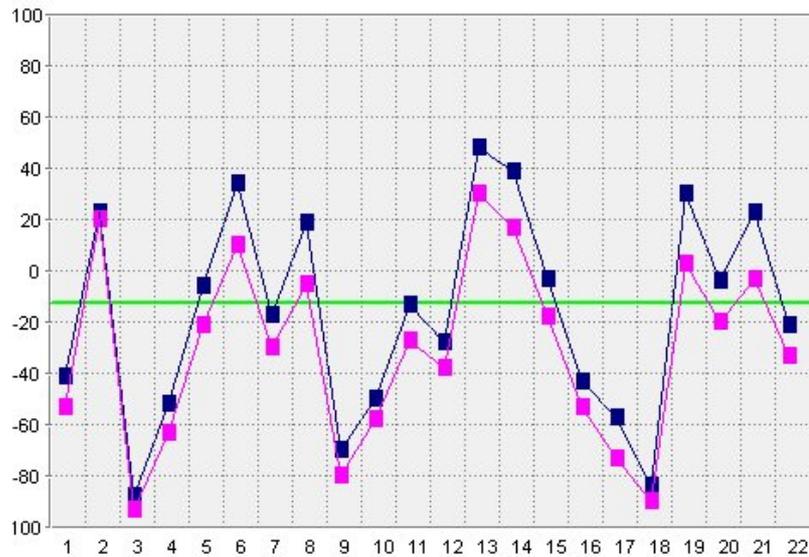
1Aa < 64 + 1Aa > 50 + Aa (6>20+13>20+19>20) + (2+4+15+17) < 0 + Abs Aa 6 >Abs Na 6 + Abs Aa 13 >Abs Na 13+ Abs Aa 19 >Abs Na 19:



Group 2: associated risks: anaemia, cardiac rhythm disorders, hypertension

Na(2+4+11+12+15+17) < -20

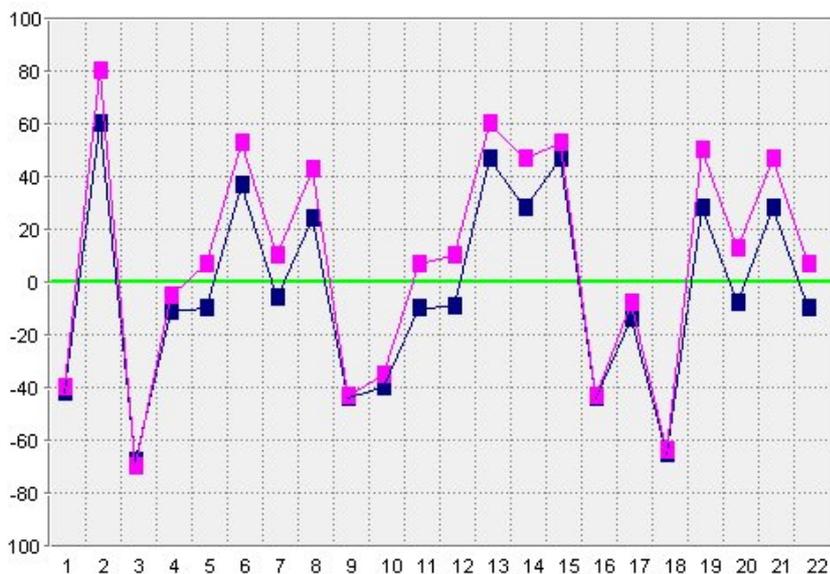
Aa: $1Aa < 60$ and $> 50 + (11) < -20$ or $Aa(12) < -20 + Na(13+14) > 20 + -(6 > 10 + 13 > 10 + 19 > 10) + (\Delta Aa 6 / Na 6 > =20 + \Delta Aa 13 / Na 13 > =20 + \Delta Aa 19 / Na 19 > =20)$



Group 3: associated risks: Cardiac stenosis, disappearance of Q waves, inflammation of the pulmonary system (possibility of pneumothorax)

Na : $(2+15) > 20 + (6+13+19) > +40$

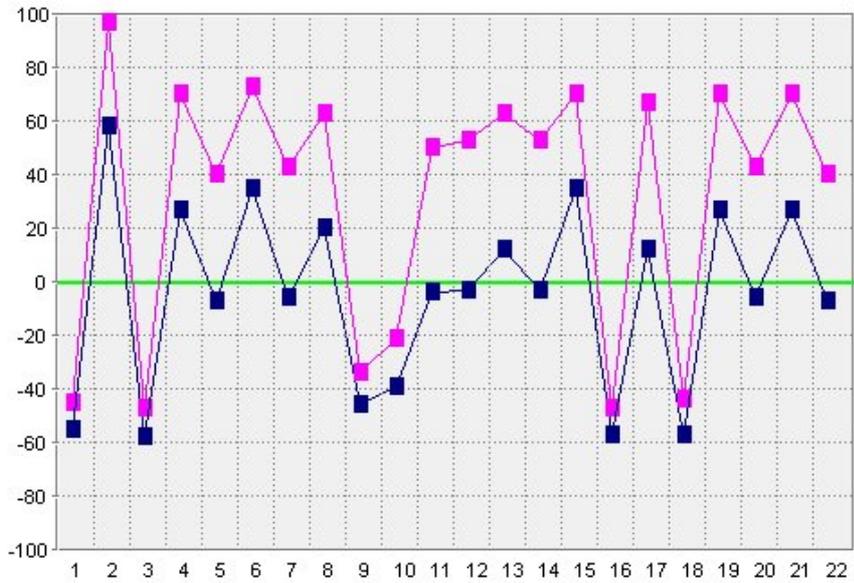
Aa $1Aa > \text{Value } (+) + (2+15) > 20 + (6 > 20 + 13 > 20 + 19 > 20) + (4+17) < 0$



Group 4: Major risk of recurrence

Na Hdi +

Aa: $1Aa > 80 + (6+13+19) > +20$

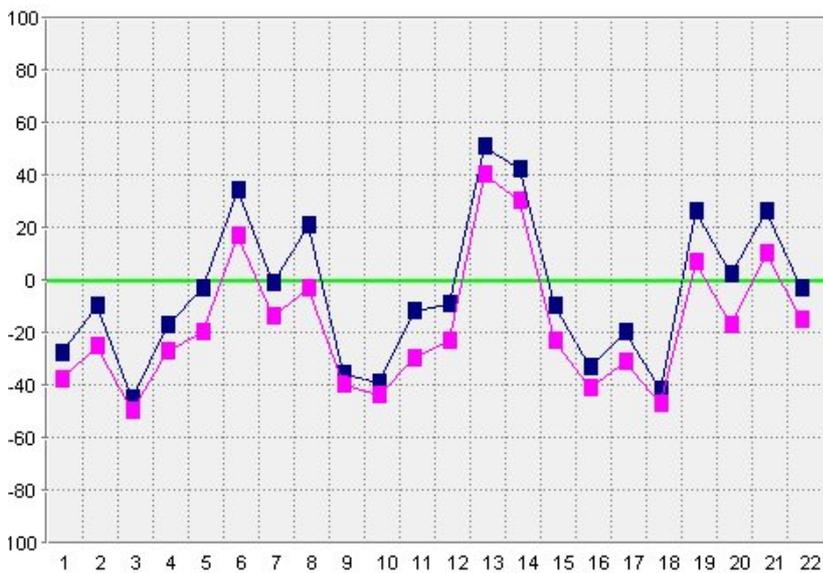


| | VP+ | VP- | In terms of positive and negative predictive value, the results are as follows: |
|---------|---------|--------|---|
| GROUP 1 | 97,50% | 84,09% | sensibility 97% (+/-5%) |
| GROUP 2 | 80,00% | 55,93% | spécificity 87% (+/-9%) |
| GROUP 3 | 90,00% | 77,27% | |
| GROUP 4 | 100,00% | 64,41% | |

4. Aortic atherosclerosis

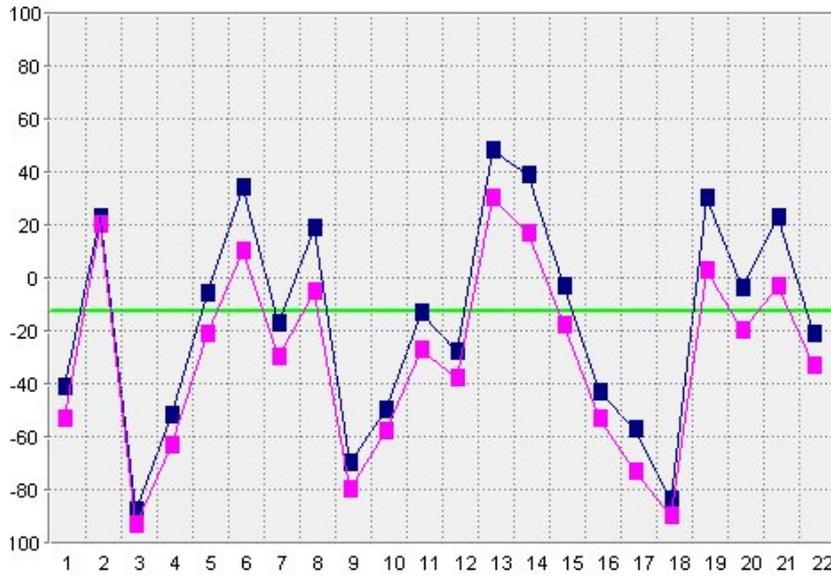
The volumes determining aortic arteriosclerosis are the branches corresponding to aortic pressure linked to left ventricle function, i.e. 6 13 19, in relation with 1Aa depending on the risks of the disease. The patients were split into 3 groups meeting the following algorithms:
Group 1: Cardiovascular risk requiring monitoring and anticoagulant and hypotensive treatment (CEI)

Value norm or (-) + Aa ((6>20 +13>20+19>20) + Aa 6 > Na 6+ Aa 13 > Na 13 + Aa 19 > Na 19)



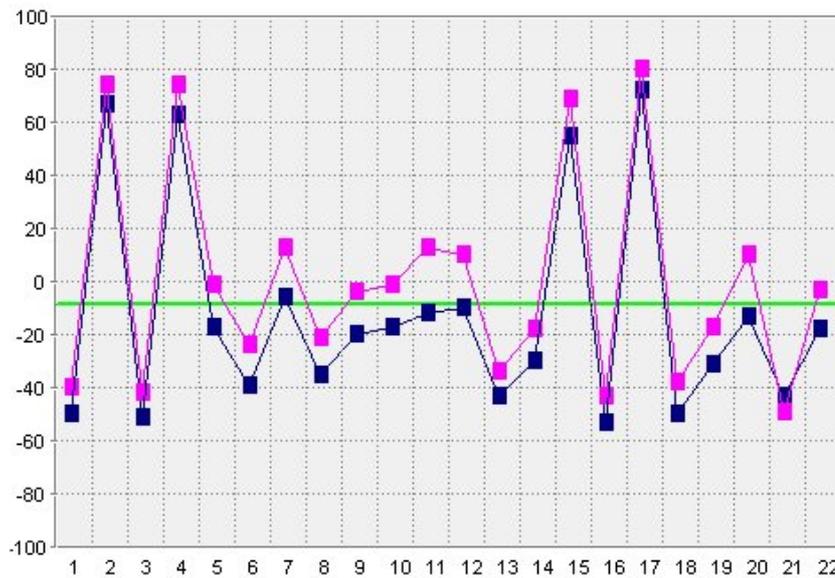
Group 2: Monitoring essential and further examination (clinical signs very mild)

Delta Aa6-Na6 > 20+ Delta Aa13-Na13 > 20+ Delta Aa19-Na19 > 20



Group 3: Risk of insufficiency

Aa Value (+) + 6<=- 16 + 13 <=- 16 + 19 <=- 16 + (2+15)> +20



| | VP+ | VP- | In terms of positive and negative predictive value, the results are as follows: |
|---------|-----|-----|--|
| GROUP 1 | 78% | 83% | sensibility 80% (+/-9%) |
| GROUP 2 | 81% | 82% | spécificity 83% (+/-5%) |
| GROUP 3 | 79% | 84% | |

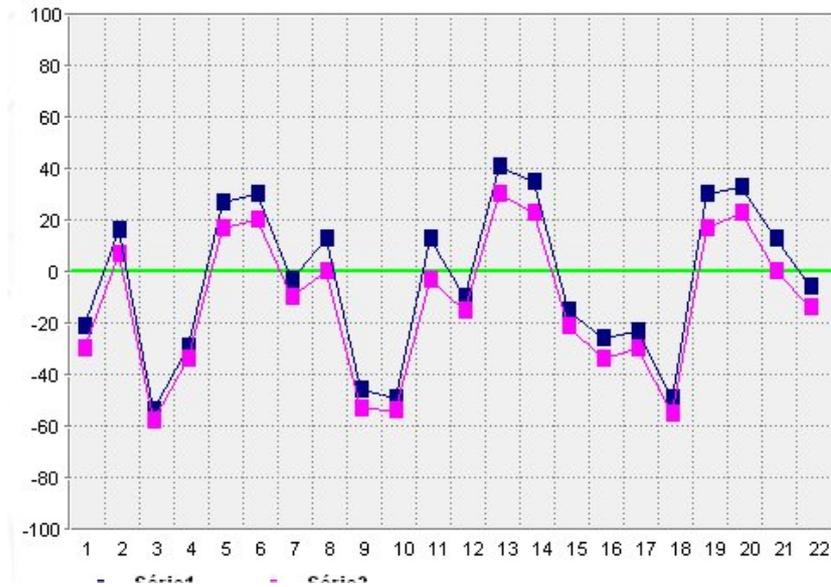
5. Cerebral atherosclerosis

The volumes determining cardiac disorders are the branches corresponding to cerebral vascularisation, i.e. 1 3 9 10 16 18, but associations with (6+ 13+ 19) (vascularisation of the left ventricle) are possible depending on the origin of the disease. The patients were split into 3 groups meeting the following algorithms:

Group 1: Cerebral atherosclerosis linked to a risk of Stoke (cerebrovascular accident)

$Na((6>20 +13>20+19>20) +$

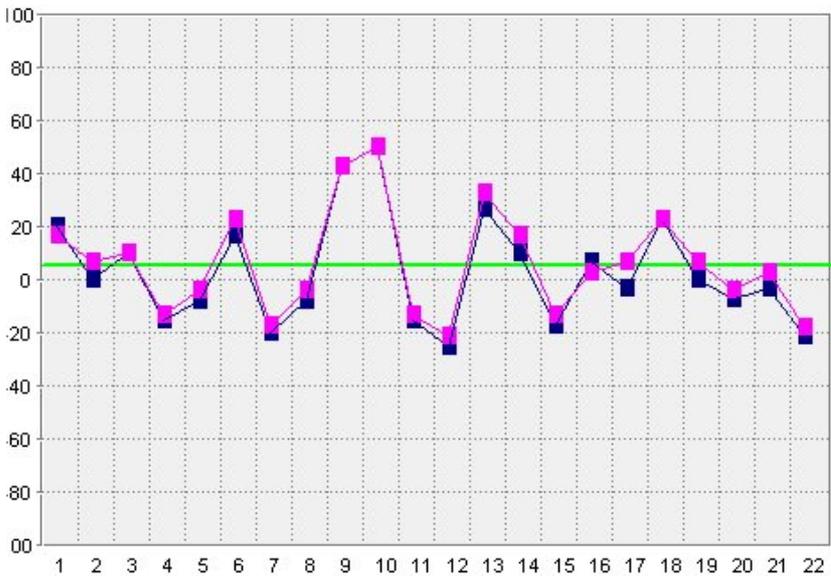
$Aa 6< Na 6+ Aa 13< Na 13+ Aa 19< Na 19) + (Aa (1 +16) or (1+18) > - 30)$



Group 2: Post-treatment cerebral

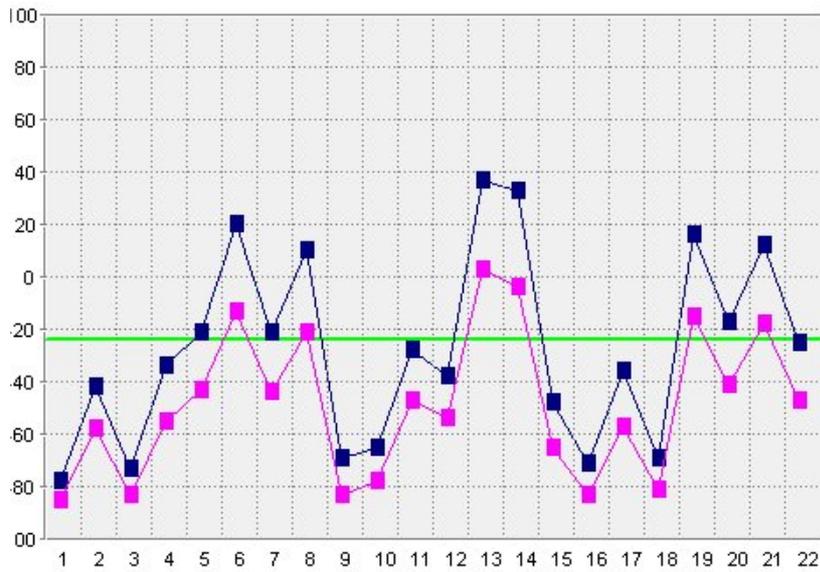
atherosclerosis with risk of pulmonary embolism

$Aa (1+16+9+10) > 0$



Group 3: Cerebral atherosclerosis with risk of neurological disease

$Aa < 55 + (9+10) < - 80+ (6+13+19) > 20$



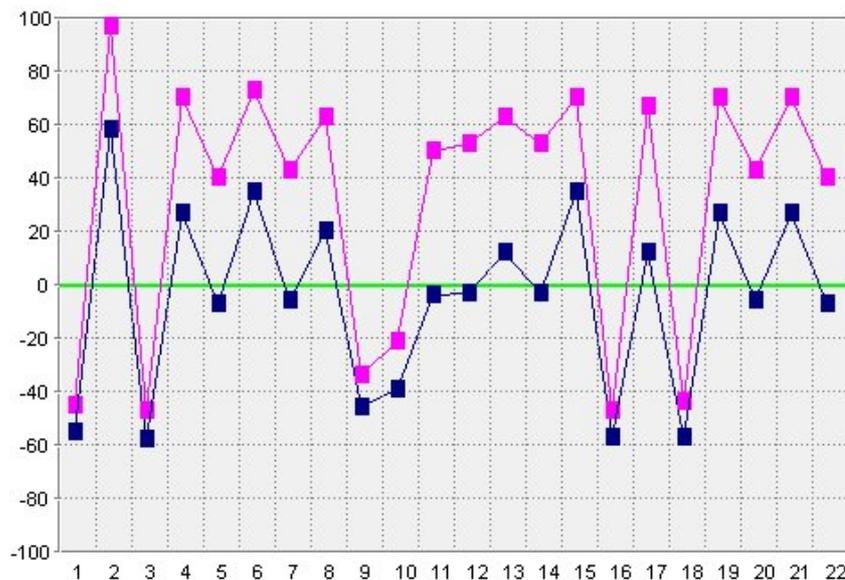
| | VP+ | VP- | |
|---------|-----|-----|--|
| GROUP 1 | 75% | 98% | In terms of positive and negative predictive value, the results are as follows: Sensibility 78% (+/-9%) Specificity 97% (+/-5%) |
| GROUP 2 | 80% | 96% | |
| GROUP 3 | 81% | 97% | |

6. Arrhythmia

The volumes determining cardiac disorders are the branches corresponding to left ventricle function, i.e. 6 13 19, and elevation in basal metabolism 1 Aa , and the patients were split into 2 groups meeting the following algorithms:

Group 1: Imminent risk of infarction: treatment to be instigated immediately

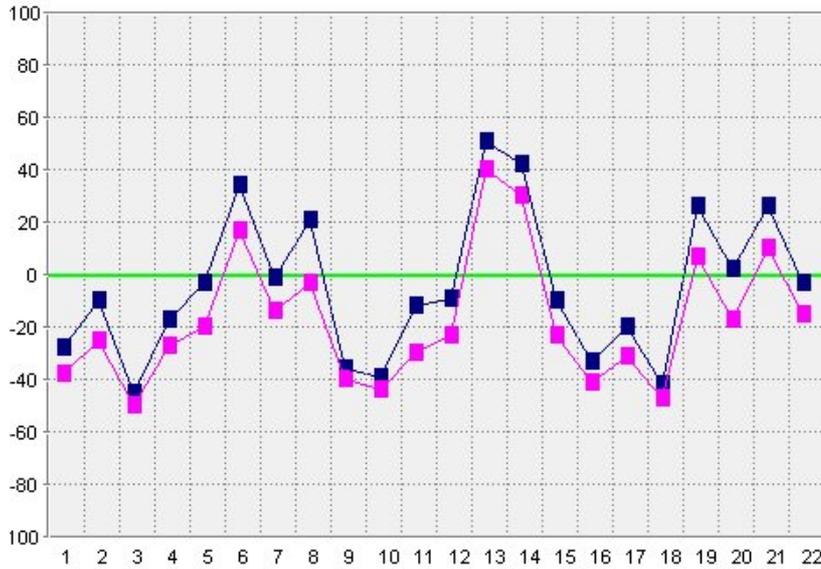
1Aa value (+) + (6+13+19) > 20 +2>20



Group 2: Risk of fibrillation

Age > 55

Aa (6+13+19) > 20 + Aa (6+13+19) > Na (6+13+19)



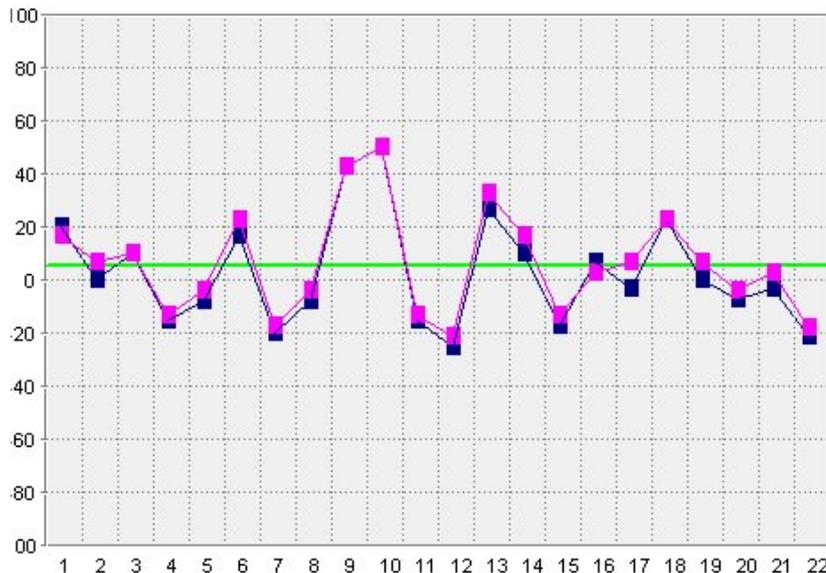
| | | | |
|---------|-----|-----|---|
| | VP+ | VP- | |
| GROUP 1 | 91% | 95% | In terms of positive and negative predictive value, |
| GROUP 2 | 87% | 90% | the results are as follows: |
| GROUP 3 | 92% | 93% | Sensibility 90% (+/-9%) |
| | | | Specificity: 92% (+/-5%) |

7. Thrombophlebitis, circulatory disorders and Varicose veins in the legs:

The volumes determining vascular disorders are the branches corresponding to cerebral vascularisation, i.e. 9 10, the respiratory system (11+12), the lower limbs, i.e. (6+8+19+21+13 14), and the portal circulation, i.e. (7+5+20+22), depending on the origin of the disease. The patients were split into 2 groups meeting the following algorithms:

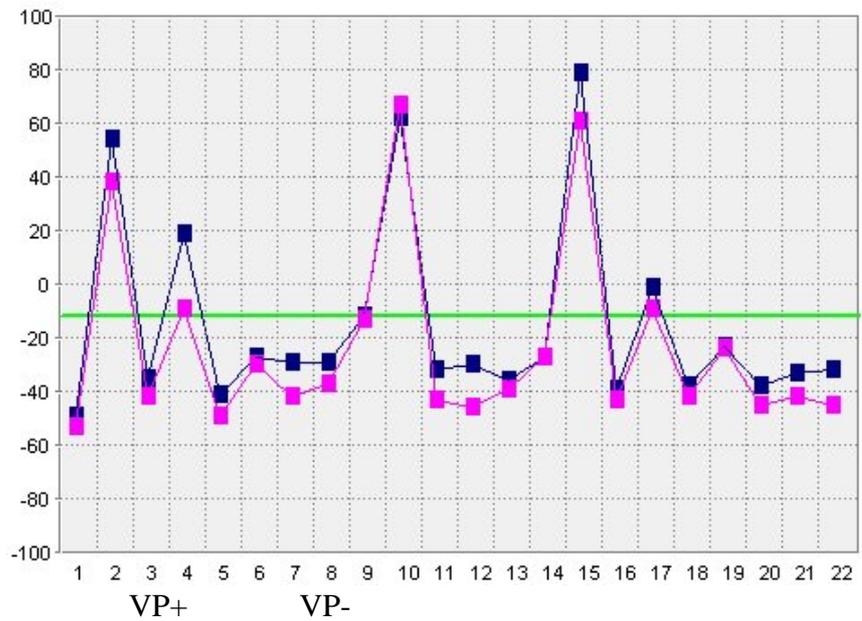
Group 1: Cerebral circulatory disorders, often linked to a risk of pulmonary embolism

Aa (+ (9) > 20 or (10) > 20) + 1Aa <= 70 + ((11) < -20 or (12) < -20)



Group 2: Circulatory problems in the portal system with repercussion in the lower limbs, heart and cerebral irrigation

Aa abs (7+5+20+22) > 20 or (Aa abs (6+13+19) > 20) or (9or 10>20)) + Aa abs(6+19+8+21+13+14) > 20

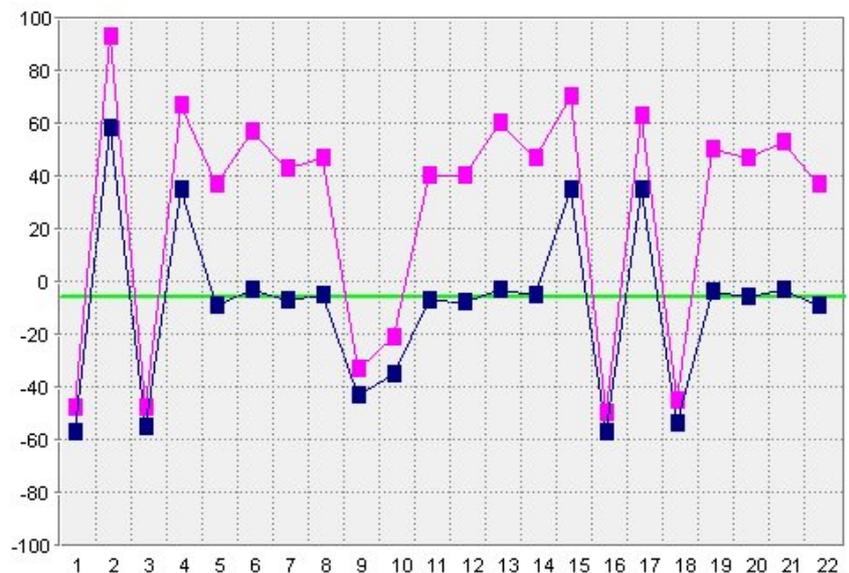


| | | | |
|---------|-----|-----|--|
| GROUP 1 | 89% | 73% | In terms of positive and negative predictive value, the results are as follows: Sensibility 90% (+/-9%) Specificity:: 74% (+/-5%) |
| GROUP 2 | 75% | 75% | |
| GROUP 3 | 84% | 74% | |

8. Lipid metabolism disorders (cholesterol, triglycerides, hyperlipemias)

Group 1: Hyperlipemia and increased triglycerides with pancreatic affection

Age > 40
 +BMI>23 ou % masse grasse >30%
 +Na (Mdi) > +20
 Aa 1Aa Value (+) + (Mdi) < +20 et > - 20

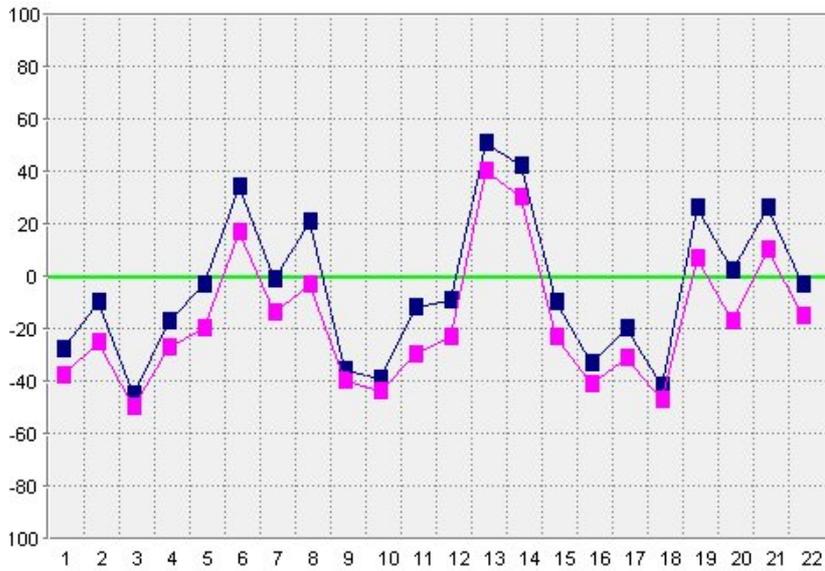


Group 2: increased LDL Cholesterol with atherosclerosis

Age > 40

+BMI>23 ou % masse grasse >30%

Aa 1Aa Value (-) + 6>0+ 13>0+19>0

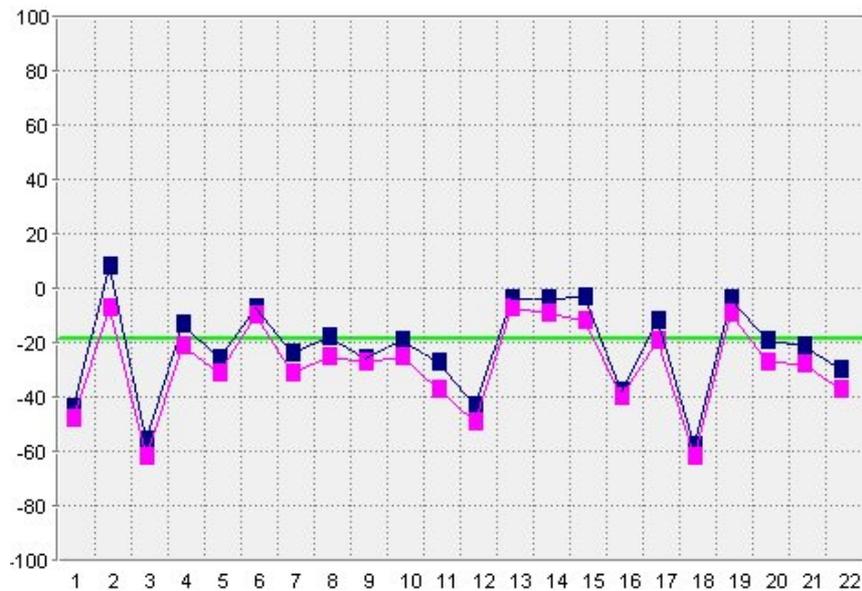


Group 3: Increased LDL Cholesterol:no immediate cardiovascular risk

Age > 40

+BMI >23 ou % masse grasse >30%

Aa (7+11+12+22) < -20 + (9+10) > -20



| | VP+ | VP- | In terms of positive and negative predictive value, the results are as follows: |
|---------|-----|-----|--|
| GROUP 1 | 89% | 73% | Sensibility 85% (+/-9%) |
| GROUP 2 | 80% | 66% | Specificity: 69% (+/-5%) |
| GROUP 3 | 89% | 70% | |

II. RESPIRATORY DISEASES

The volumes determining respiratory disorders are the branches corresponding to bulbar regulatory centre function 2 4 15 17 and respiratory function (11+12), but associations with other volumes are possible, particularly the volumes corresponding to the skeletal and digestive systems, i.e. 6 8 19 21 and cardiac function, i.e. 6 13 19 or cerebral circulation, i.e. 9 10 depending on the origin of the disease.

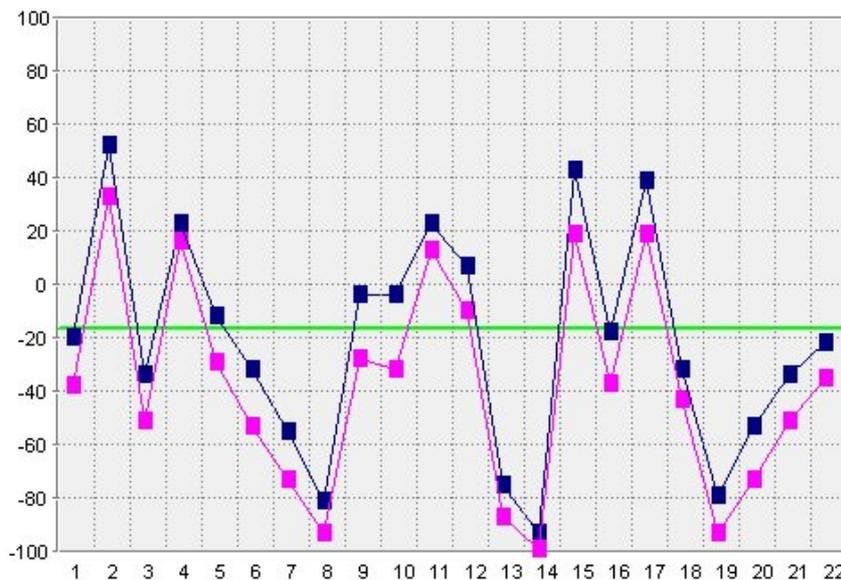
A. Chronic bronchitis

The patients were split into 4 groups meeting the following algorithms:

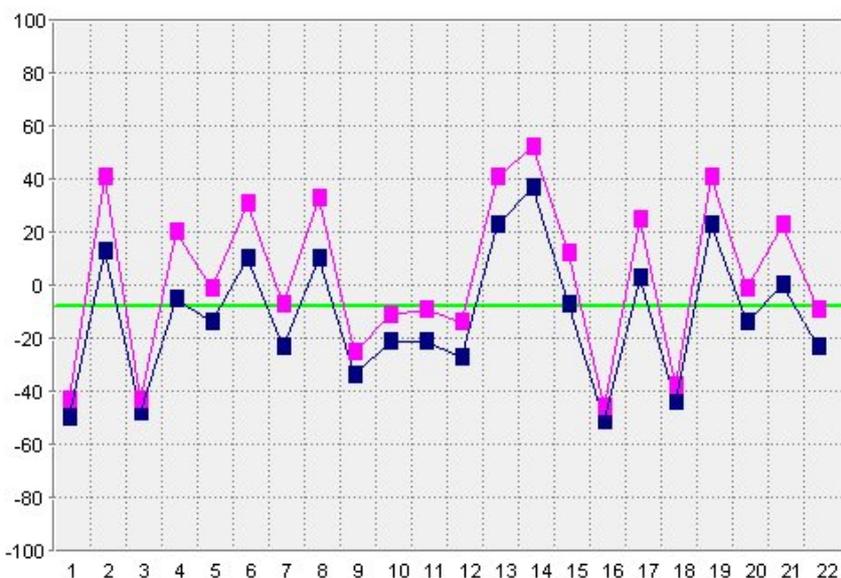
Group 1: Bronchitis or asthma aggravated by stress

Na ($2 > +20 + 4 > +20 + 15 > +20 + 17 > +20$)

Aa ($2 + 4 + 15 + 17 > Na (2 + 4 + 15 + 17)$)



Group 2: Bronchitis or pharyngitis or laryngitis or chronic tracheitis



Na ($2 + 4 + 15 + 17 > +20$)

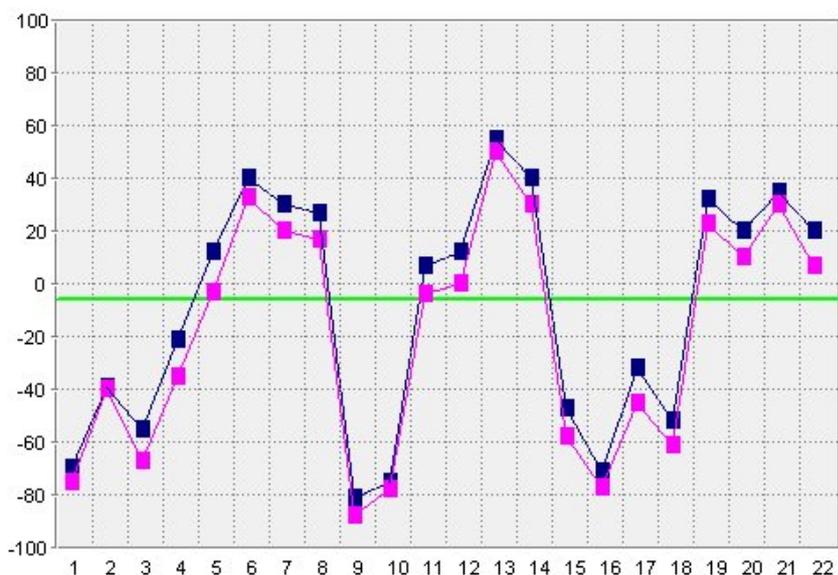
Aa ($11 + 12 < -20$ and Aa

$(11 + 12) < Na (11 + 12)$)

Group 3: chronic bronchitis in the acute development stage

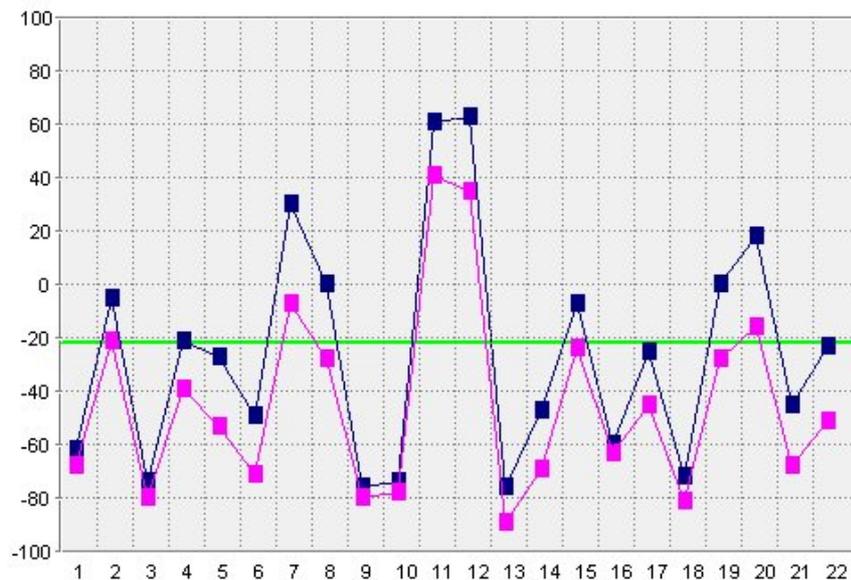
Na (2+4+15+17) < -20

Aa ((5+20) or (7+22)) > +20 + Aa ((5+20) or (7+22)) > Na ((5+20) or (7+22)) ou Aa ((5+20) or (7+22)) > 30



Group 4: Inflammation of the pharynx, trachea or larynx

Aa (11+12) > +30 + Abs Mdi < 20



| | VP+ | VP- | |
|---------|-----|--------|--|
| GROUP 1 | 80% | 84,09% | In terms of positive and negative predictive value, the results are as follows: Sensibility 79% (+/-9%) Specificity:: 78% (+/-5%) |
| GROUP 2 | 80% | 55,93% | |
| GROUP 3 | 76% | 77,27% | |
| GROUP 4 | 81% | 64,41% | |

B. Obstructive bronchitis/ Pneumosclerosis/ Emphysema/ Asthma/ Pneumonia:

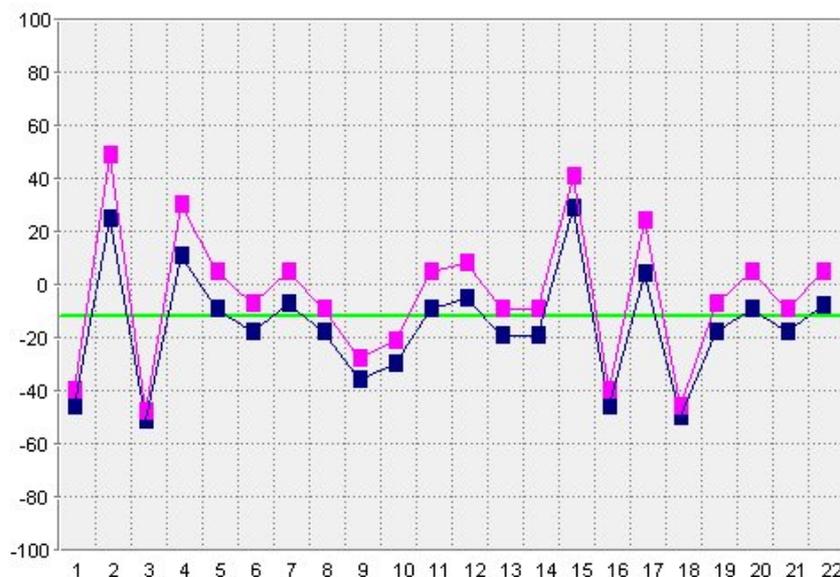
The patients were split into 3 groups meeting the following algorithms:

Group 1: Risk of infection

Age > 65

Na ((2+4+15+17) >20)

Aa Value (+) + (2+4+15+17) > 20+ ((5+20) or (7+22)) < -10 and >-16)

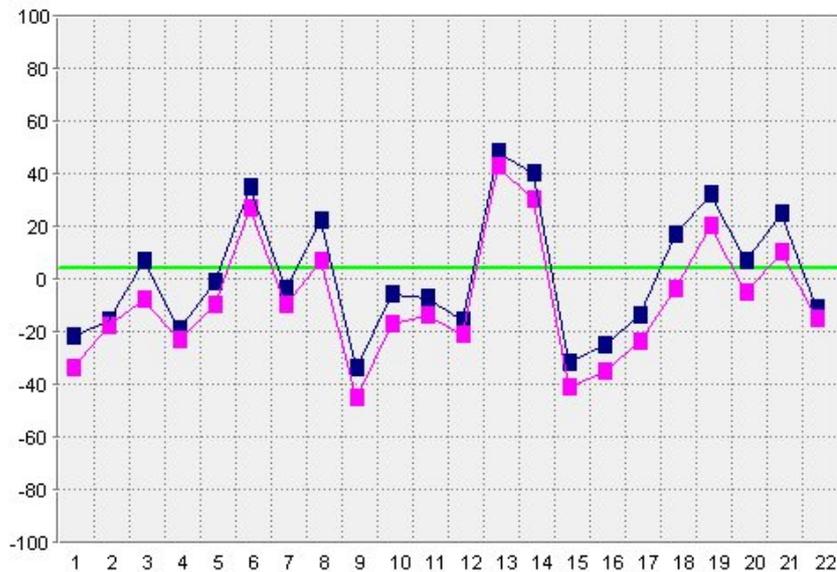


Group 2: aggravating factors due to weakened terrain

Age > 50

Na (2+4+15+17) < - 20 + Hdi -

Aa (((5+20) or (7+22)) > +20 + Aa ((5+20) or (7+22)) > Na ((5+20) or (7+22))



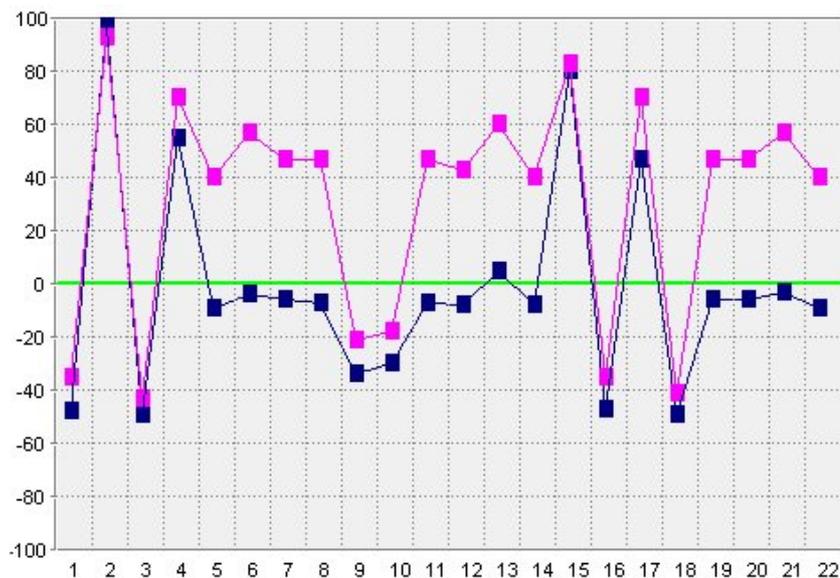
Group 3: Obstructive

bronchitis originating in cardiac dysfunction

Age > 60

Na (2+4+15+17) > 40

Aa value (+) (+) + (2+4+15+17) > 30 + ((5+20) or (7+22)) > - 10 et >-16



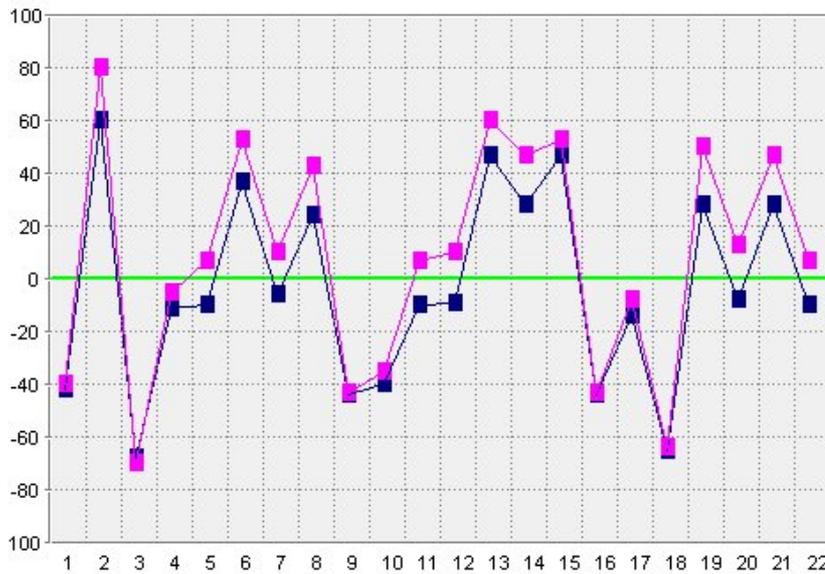
| | VP+ | VP- | In terms of positive and negative predictive value, the results are as follows: |
|---------|-----|-----|--|
| GROUP 1 | 89% | 73% | Sensibility 91% (+/-9%) |
| GROUP 2 | 92% | 80% | Specificity: 77% (+/-5%) |
| GROUP 3 | 89% | 70% | |

C. Pneumothorax / Hydrothorax

The patients were split into 2 groups meeting the following algorithms:

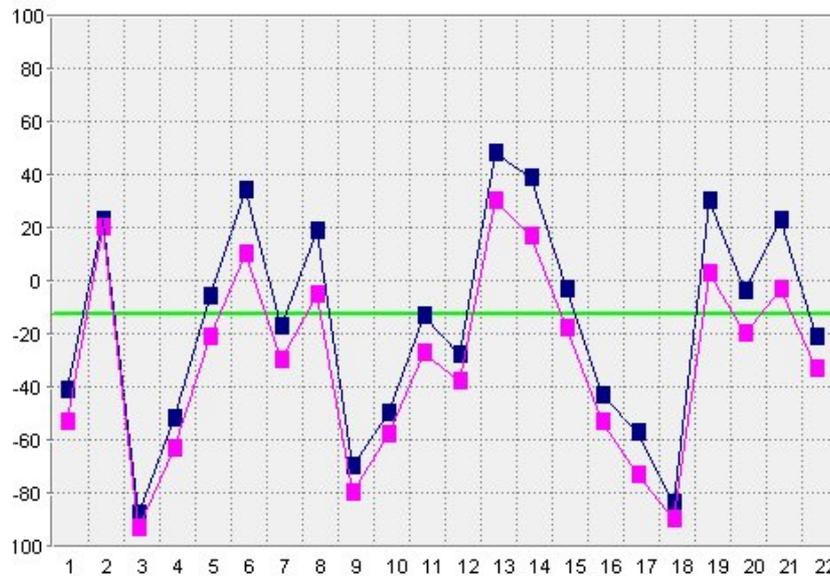
Group 1: Pneumothorax

Aa Value (+) (+) + 2> 20 +4> 20 +6> 20 +13> 20 +15> 20 +17> 20 +19> 20



**Group 2:
Hydrothorax**

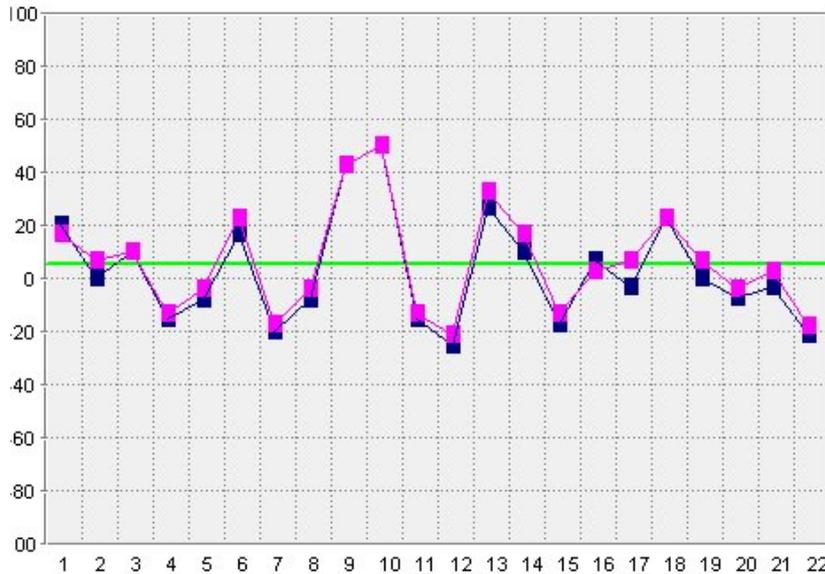
Aa Value (-) + (2+4+15+17)>20+ (Mdi) < -20



| | | | |
|---------|-----|-----|---|
| | VP+ | VP- | In terms of positive and negative predictive value, |
| GROUP 1 | 89% | 73% | the results are as follows: |
| GROUP 2 | 82% | 66% | Sensibility 86% (+/-9%) |
| | | | Specificity: 70% (+/-5%) |

D. Pulmonary embolism

Aa (+ (9) > 20 or (10) > 20) + 1Aa <= 70 + ((11) < -20 or (12) < -20)



In terms of positive and negative predictive value, the results are as follows:
 Sensibility 96% (+/-9%)
 Specificity: 69% (+/-5%)

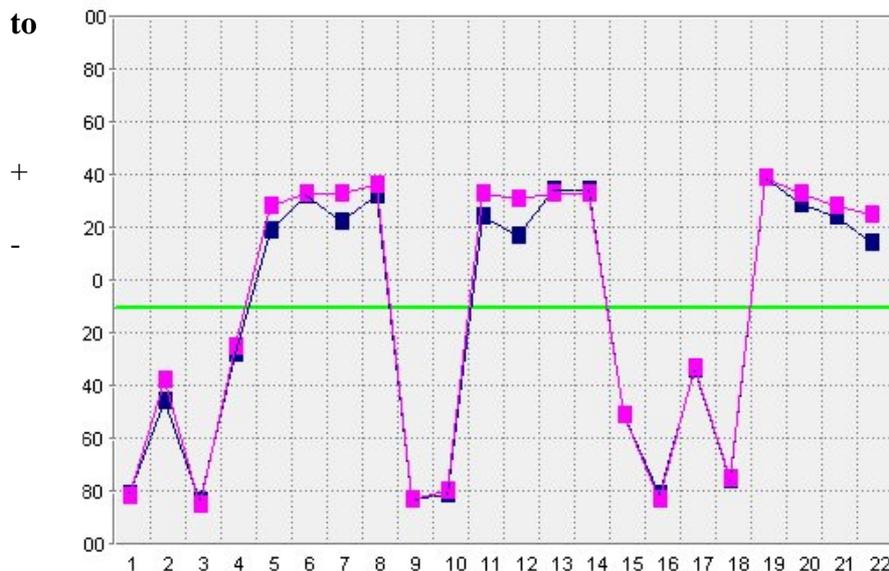
III. GASTROINTESTINAL DISEASES

The volumes determining gastrointestinal disorders are the volumes corresponding to the digestive system, i.e. 6 8 19 21, portal circulation, i.e. 7 8 21 22, stress (2+15), psychological factors (1+3+16+18) and (9+10) or the risk of infection (1Aa), depending on the origin of the infection.

A. Duodenal or stomach ulcer

The patients were split into 3 groups meeting the following algorithms:

Group 1: Tendency develop hepatic complications

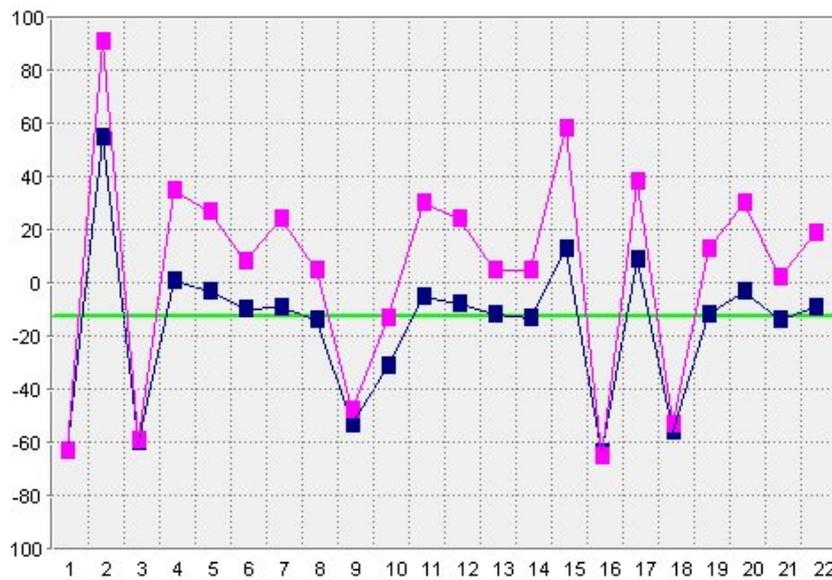


Na(Hdi)+
 Aa (7+22 +5 +21) >
 +20 + (1+3+16+18) <
 60)

Group 2 : Test for helicobacter or another germ is required

Na (7+22 +5 +21) > +20

+ Aa (2+4+15+17) > 20 + value (+) (+) + (7+22 +5 +21) < +15 et > -15

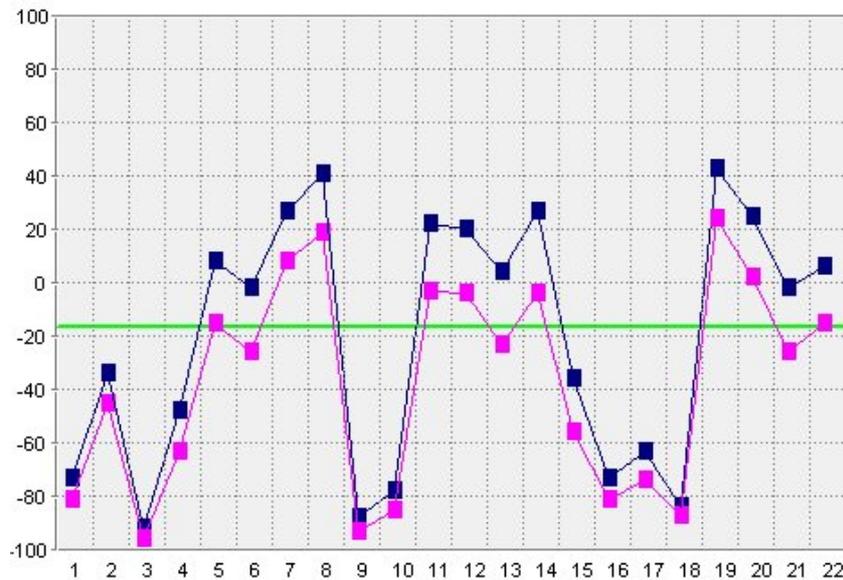


Group 3: The

psychological factor is predominant

(Na abs (5+6+11+19+20) <= 20 or Na abs (Mdi) <= 20) + Aa ((Mdi > +20 or

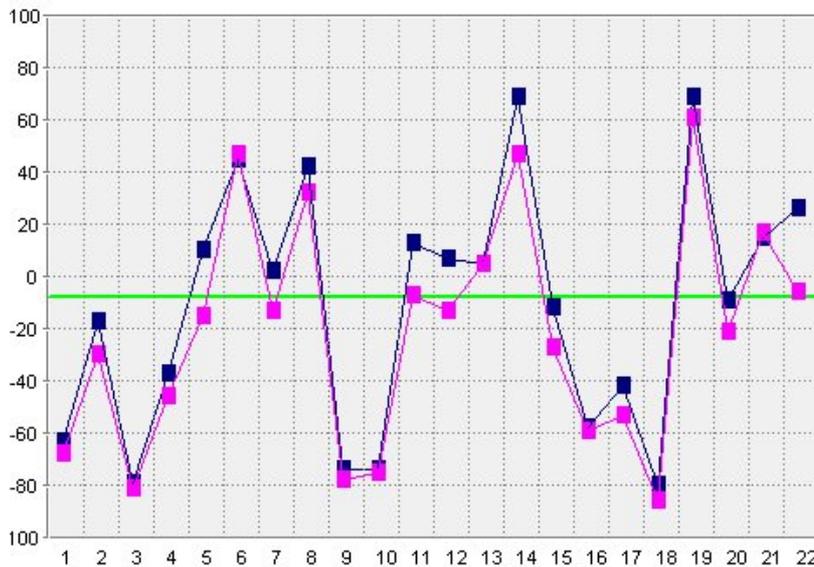
(6>+20 +19>+20)) + ((9+10) < -50)



| | VP+ | VP- | |
|---------|-----|-----|---|
| GROUP 1 | 79% | 83% | In terms of positive and negative predictive value, the results are as follows: Sensibility 79% (+/-9%) Specificity: 84% (+/-5%) |
| GROUP 2 | 80% | 86% | |
| GROUP 3 | 79% | 82% | |

B. Spasmodic colitis

Aa: ((6+8+19+22) > 20) and > Na (6+8+19+22)



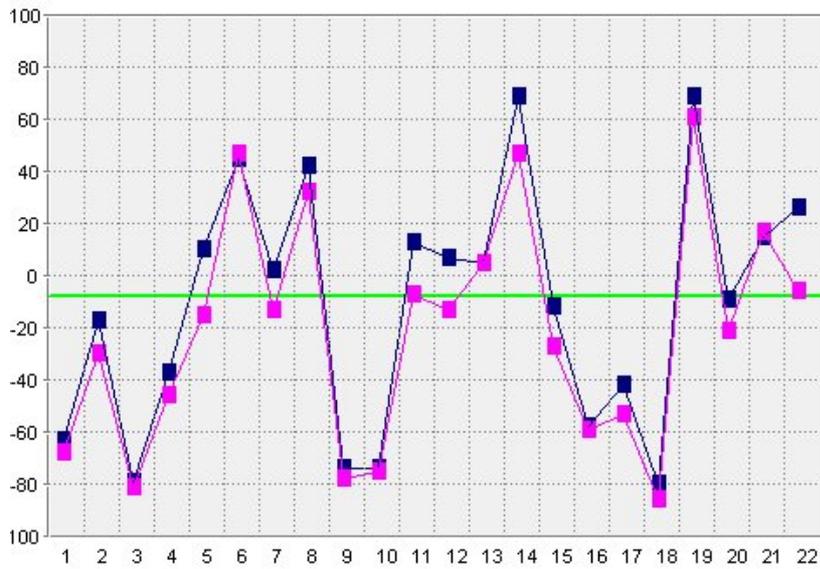
In terms of positive and negative predictive value, the results are as follows:
Sensibility 81% (+/-9%)
Specificity: 78% (+/-5%)

C. Gastritis

The patients were split into 2 groups meeting the following algorithms:

Group 1: Irritation of the intestinal mucosa and intolerance to certain foods

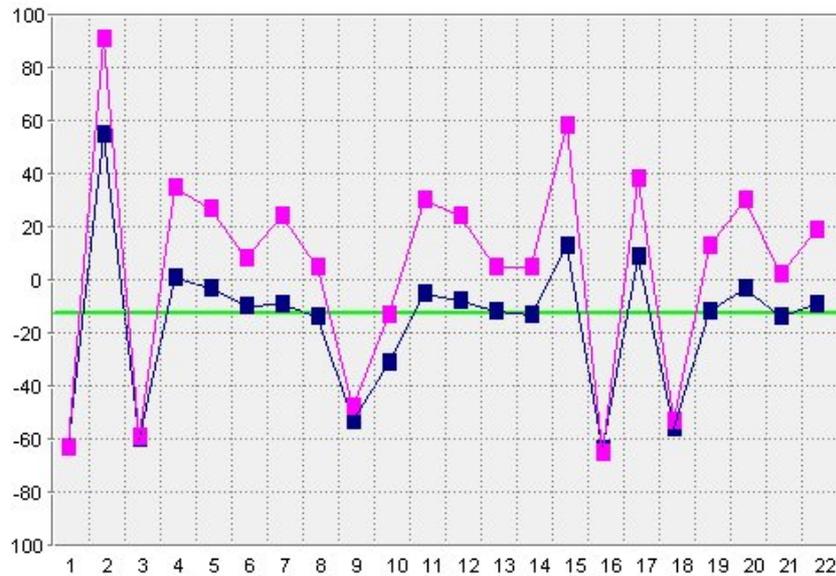
Abs Aa ((5+6+11+19+20)>20and > Na ((5+6+11+19+20)) ou
(Na (6+8+19+21) > 20 + Aa: ((6+8+19+21) > 20))



Group 2: Test for germs: infection possible

Na ((7+22 +5 +21) > +20) > +20

+ Aa (2+4+15+17) > 20 + value (+) (+) + (7+22 +5 +21) > +20 < +15 et > -15



In terms of positive and negative predictive value, the results are as follows:

Sensitivity 81% (+/-9%)

Specificity: 74% (+/-5%)

| | VP+ | VP- |
|---------|-----|-----|
| GROUP 1 | 82% | 73% |
| GROUP 2 | 80% | 75% |

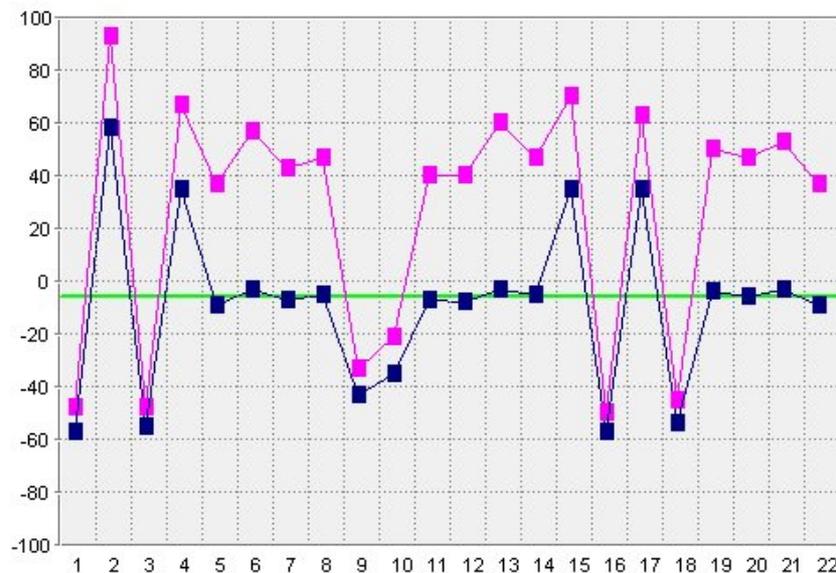
D. Hepatitis

The patients were split into 3 groups meeting the following algorithms:

Group 1: Hepatosis dietetica and drug-related hepatitis often linked to pancreatitis

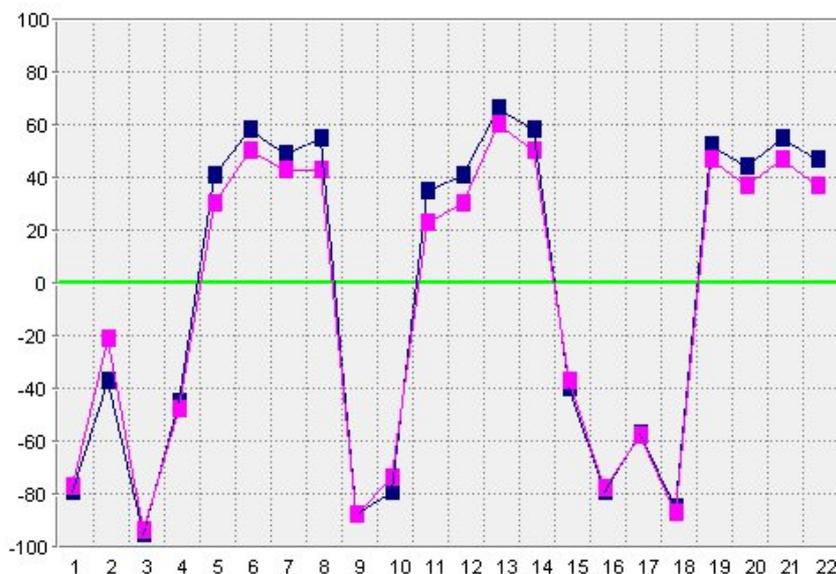
Na (Hdi) > 20

1Aa Value (+) (+) + (2+4+15+17) > 20 + (7 < 15 ou 12 < 15 ou 22 < 15)



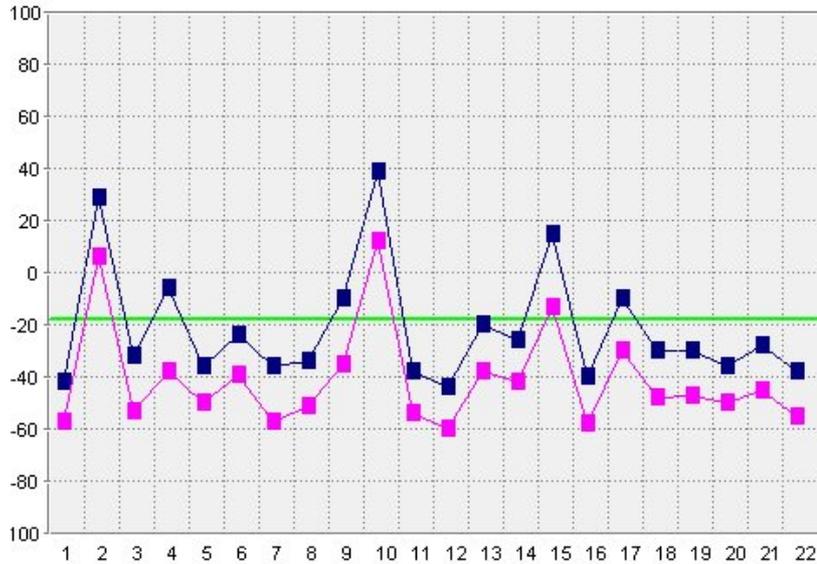
Group 2: viral hepatitis

Na (Hdi) > +20 + Aa (Hdi) > + 20 + Aa (2+4+15+17) < - 20 + (9+10) < -60



Group 3: chronic hepatitis

1Aa < 56 + ((7+12+22 < -30) or (Mdi) < -20) + Aa (2+4+15+17) > -20 or (13+14) > 0))



| | VP+ | VP- | |
|---------|-----|-----|---|
| GROUP 1 | 89% | 63% | In terms of positive and negative predictive value, |
| GROUP 2 | 91% | 66% | the results are as follows: |
| GROUP 3 | 87% | 70% | Sensibility 89% (+/-9%) |
| | | | Specificity: 67% (+/-5%) |

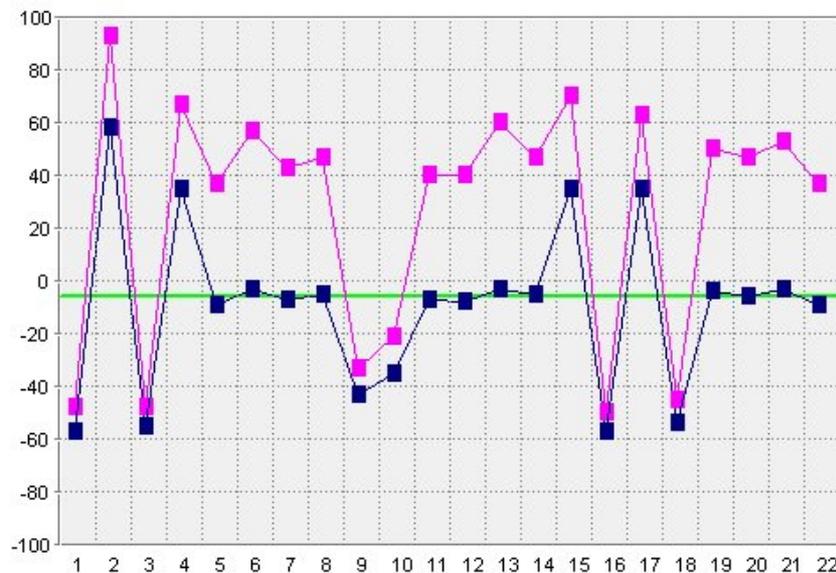
E. Pancreatitis

The patients were split into 2 groups meeting the following algorithms:

Group 1: Test for germs: infection possible

Na (Hdi) > 20

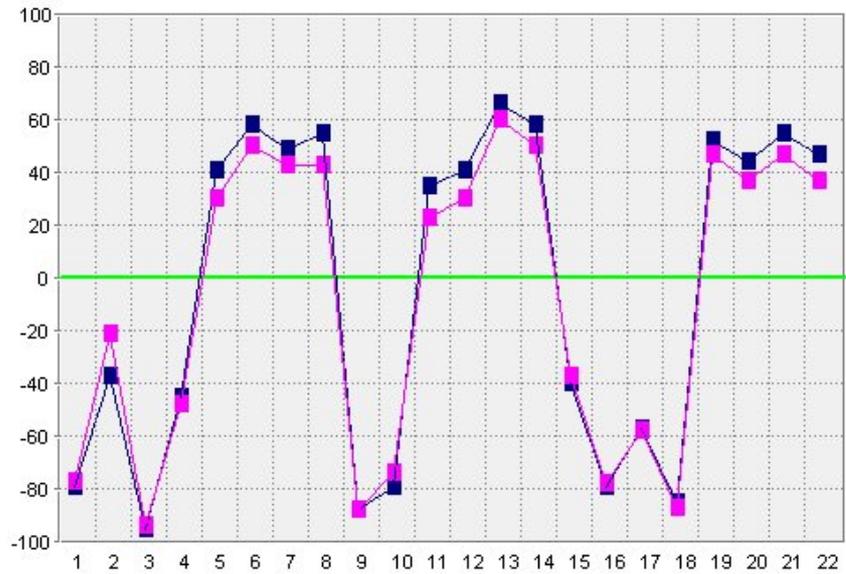
1Aa Valeur (+) (+) + (2+4+15+17) > 20 + (5 < 15 ou 11 < 15 ou 20 < 15)



**Group 2: Possibility of
Choledocholithiasis and associated hepatic disorders**

Group 2: Possibility of

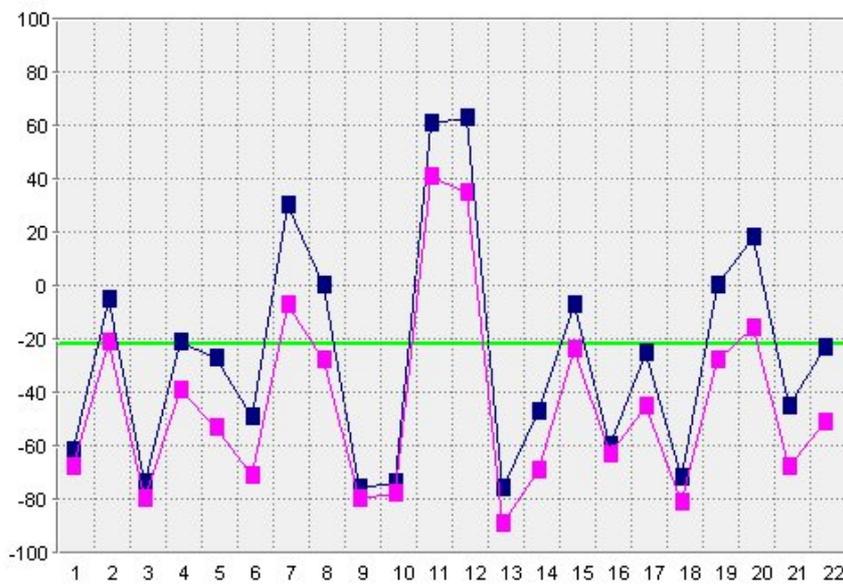
Na (Hdi) > +20 + Aa (Hdi) > + 20 + Aa (2+4+15+17) < - 20 + (9+10) < -60



| | | | |
|---------|-----|-----|---|
| | VP+ | VP- | In terms of positive and negative predictive value, |
| GROUP 1 | 89% | 83% | the results are as follows: |
| GROUP 2 | 82% | 77% | Sensibility 86% (+/-9%) |
| | | | Specificity: 80% (+/-5%) |

F. Oesophagitis

Aa (11+12) > +30 +Abs Mdi >20



In terms of positive and negative predictive value, the results are as follows:
 Sensibility 88% (+/-9%)
 Specificity: 68% (+/-5%)

IV. ENDOCRINE INFECTIONS

The volumes determining endocrine disorders are the branches corresponding to the thyroid, i.e. 4 17 and its stimulation by the hypophysis i.e. $((2+16+17+1+9)+(2+1)+9+(1+3)+(2+17+1))$, pancreatic function which controls good digestive function as a whole i.e. 5 6 8 19 21, according to the origin of the infection.

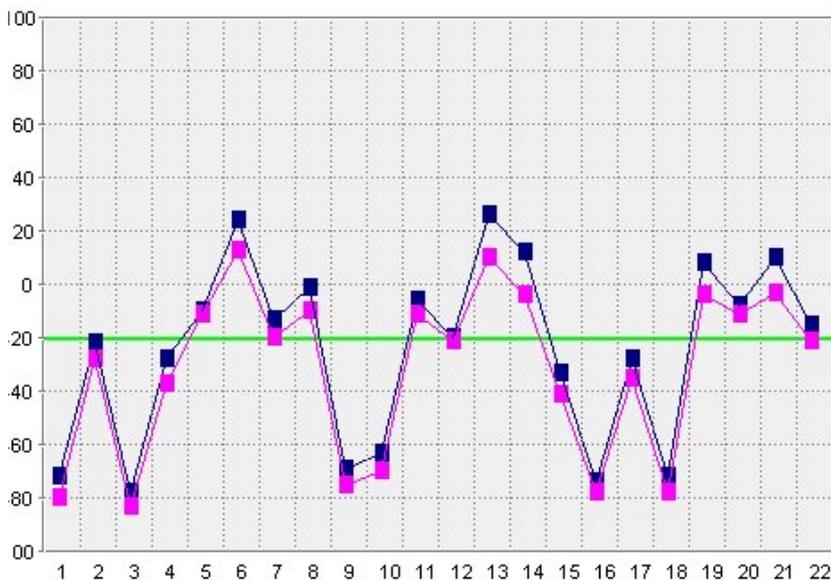
A. Thyroid infections

The patients were split into 3 groups meeting the following algorithms:

Group 1: Hypoactivity

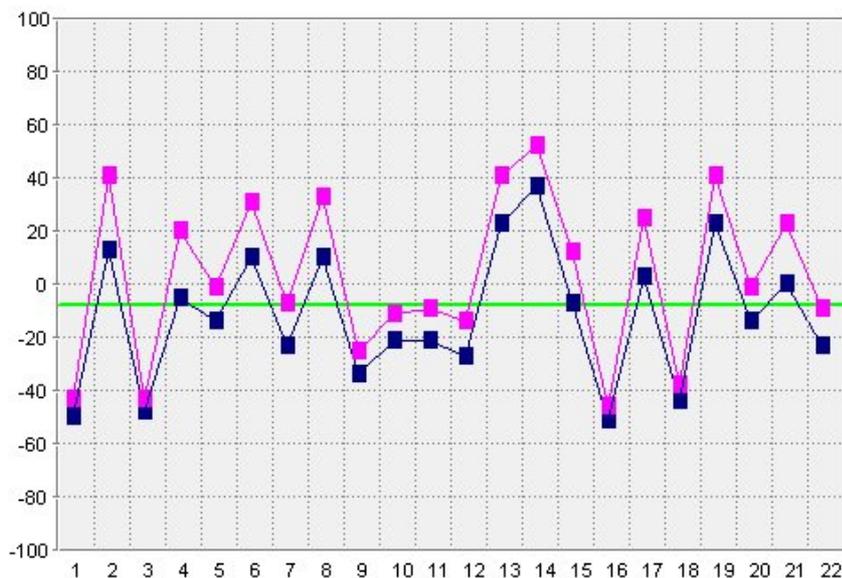
The examination determines the dose of hormone treatment required more accurately than laboratory examinations; indeed the acid-base balance in tissues is the sign of an adequate dose. An increase in thyroid production (yellow) is the sign of an overdose and a reduction in thyroid production (blue) is the sign of an under-dose.

$$\text{Abs Aa}(4+17) > 20$$



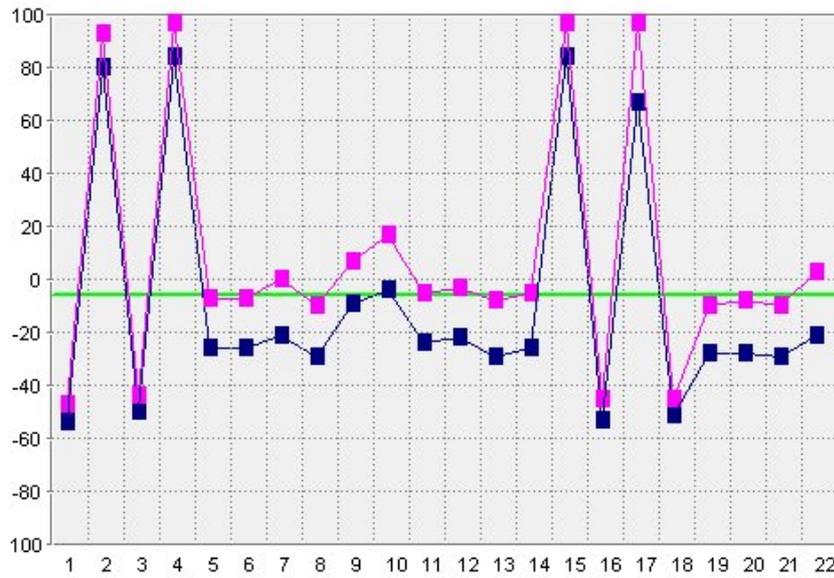
Group 2: Thyroid hypofunction

$$\text{Na}(4+11+12+17) < -20 + ((2+16+17+1+9)+(2+1)+9+(1+3)+(2+17+1)) \leq -30$$



Group 3: thyroid hyperfunction

$$Na (4+11+12+17) > 20 + ((2+16+17+1+9)+(2+1)+9 + (1+ 3)+(2+17+1)) >= 20$$



| | VP+ | VP- | In terms of positive and negative predictive value, the results are as follows: |
|---------|-----|-----|---|
| GROUP 1 | 79% | 63% | Sensibility 75% (+/-9%) |
| GROUP 2 | 70% | 66% | Specificity: 64% (+/-5%) |
| GROUP 3 | 74% | 65% | |

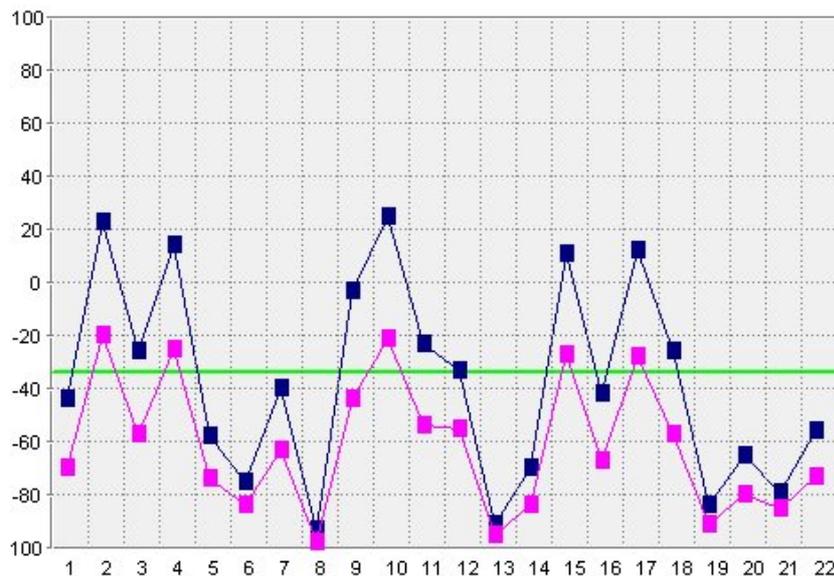
B. Diabetes

Type I diabetes: type I diabetes meets the following algorithms:

Group 1: insulin resistance ,coma risk

$$Na(Mdi) < -20$$

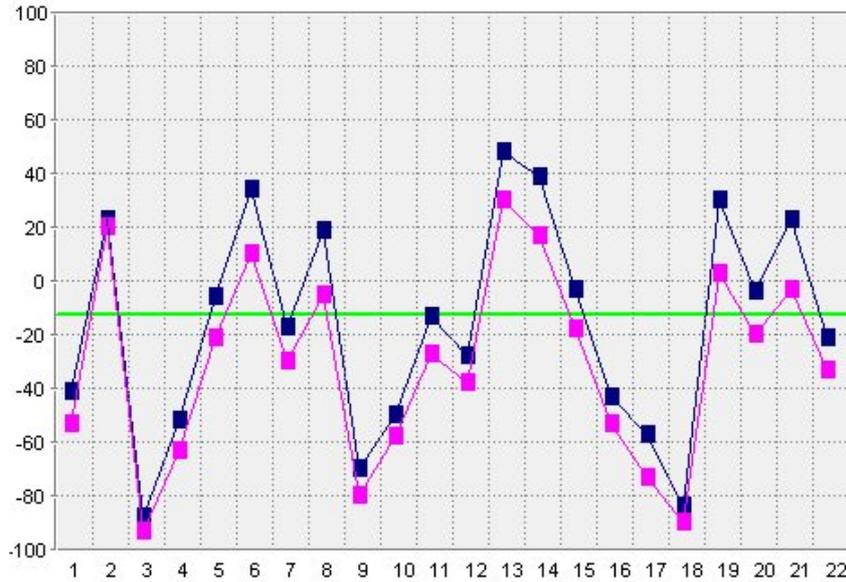
$$1Aa - 1Na < -10 + Aa (5+6+20+21) < -20 + ((5) < -20 \text{ ou } (6) < -20) + ((21) < -20 \text{ ou } (20) < -20)) + (13+14) < -20 + ((2+4+15+17) > -20) + (9 \text{ ou } 10) > 0$$



Group 2: possibility of cardiovascular and/or renal pathology

Na (Mdi) < -20

1Aa - 1Na < -10 + Aa+ (5+20) <or = 0 and >- 15 + (6+21)> +20



| | | | |
|---------|-----|-----|---|
| | VP+ | VP- | In terms of positive and negative predictive value, |
| GROUP 1 | 99% | 83% | the results are as follows: |
| GROUP 2 | 91% | 85% | Sensibility 95 % (+/-9%) |
| | | | Specificity: 84% (+/-5%) |

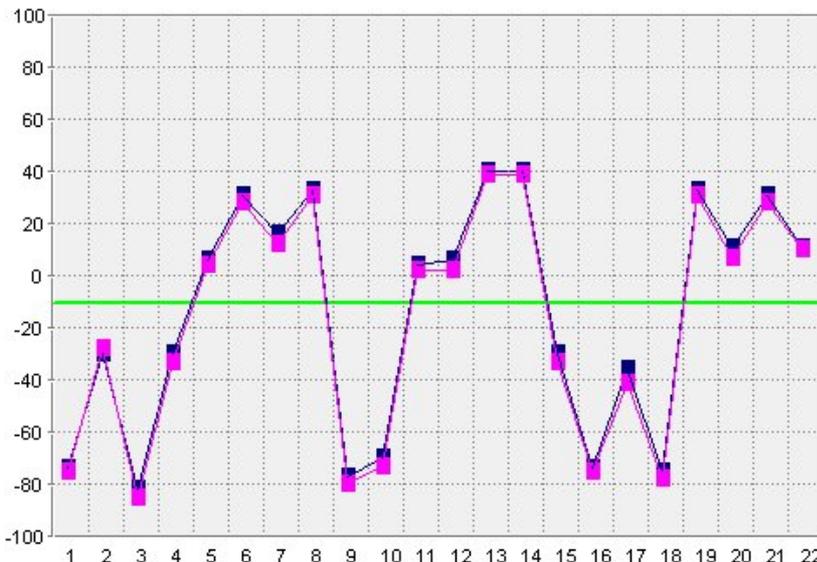
Type II diabetes: type II diabetes meets the following algorithms:

Group 1: Type II diabetes + hypertension: ICE treatment is recommended

Age > 40 + BMI > or=22

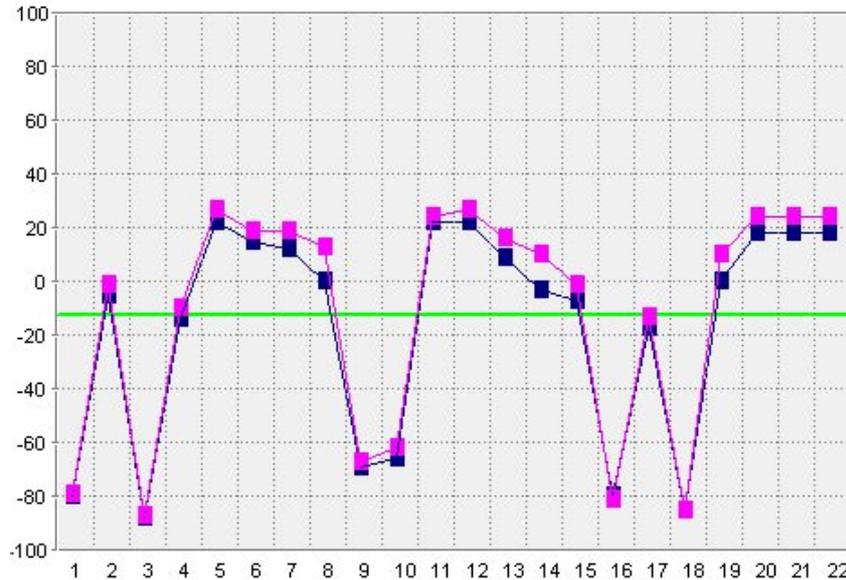
Na(6+5+20+21) > 20 +

1Aa >= 53 < 73 + Aa(6+5+20+21) > 20 + Aa (6+5+20+21) < Abs Na (6+5+20+21)



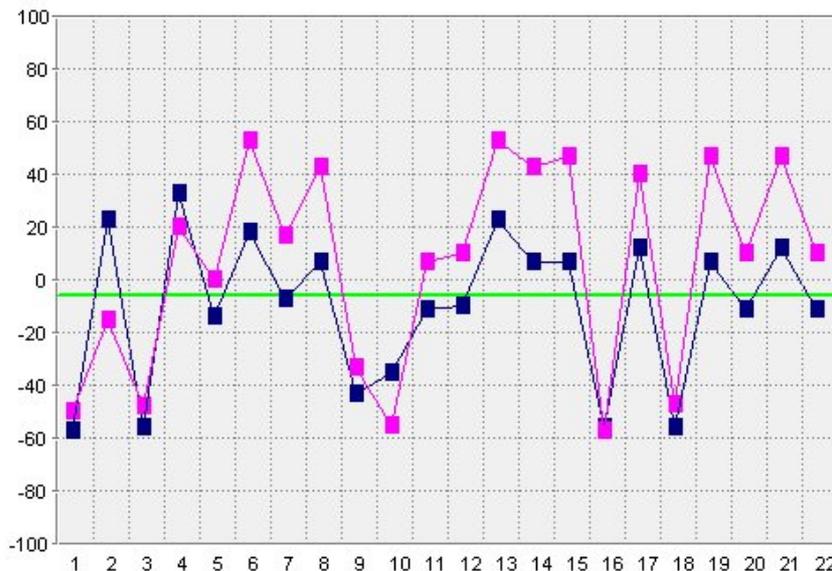
Group 2: Type II diabetes under control : diet and exercises are very important + sulfamid-metformin or glitazones are recommended

Age > 40 + BMI > or=22
 Na (Hdi) - + Na(6+ 5+20+21) > 20 +
 1Aa >= 53 < 73 + Aa(6+ 5+20+21) > 20



Group 3: Type II diabetes not under control. Possibility of microangiopathy, retinopathy, cardiovascular and/or renal pathology: ICE + statins + sulfamid-metformin or glitazones are recommended

Age > 40 + IMC > or=22
 Na (Mdi) > 20
 1Aa Value (+) (+) + (5+20) < 0 and >- 10+ (6+21)> +20



| | | | |
|---------|-----|------|---|
| | VP+ | VP- | In terms of positive and negative predictive value, the |
| GROUP 1 | 87% | 85 % | results are as follows: |
| GROUP 2 | 80% | 86% | Sensibility 86% (+/-9%) |
| GROUP 3 | 95% | 79% | Specificity: 84% (+/-5%) |

V. BONE DISEASES

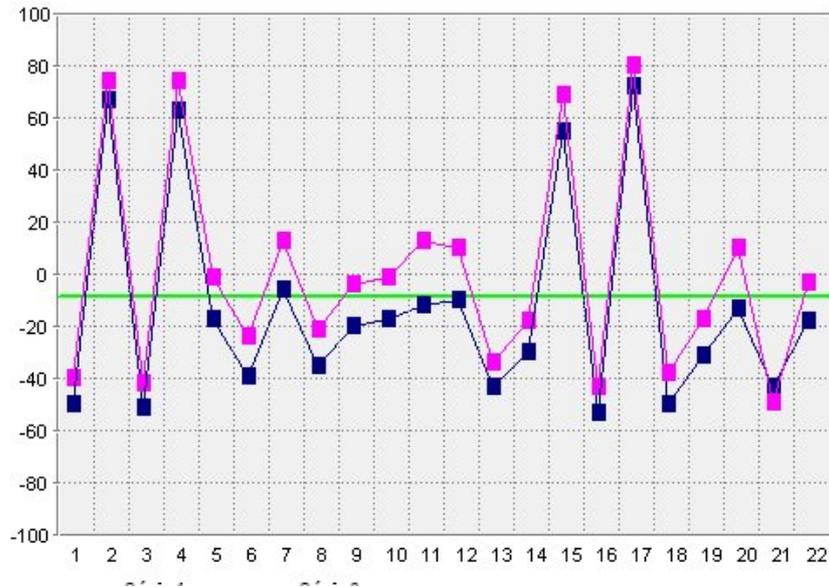
The volumes determining bone disorders are the branches corresponding to sections of the vertebral column, i.e. 6 8 20 21, depending on the origin of the disease.

The patients were split into 3 groups meeting the following algorithms:

Group 1: arthritis, reduced bone density

Age > 40

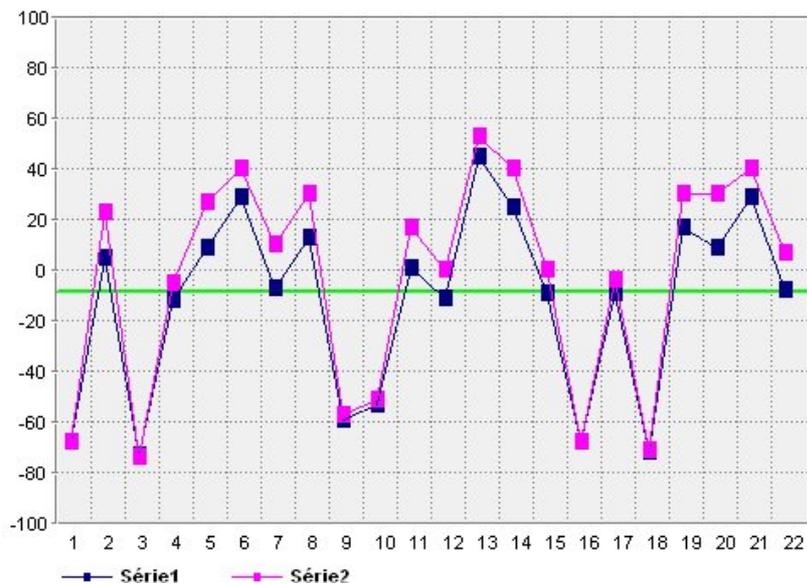
Aa 6 <-20 + 8<-20 +19<-20 +21<-20



Group 2: osteoarthritis, osteochondrosis

Age > 21

Aa 6 > + 20 + 8> + 20 +19> + 20 +21> + 20



Group 3:

1Aa > 81 or < 55

1Aa > 81: bone deformation, reduced bone density and joint problems

1Aa <55: osteoarthritis and bone pain

| | VP+ | VP- | |
|---------|-----|-----|--|
| GROUP 1 | 79% | 73% | In terms of positive and negative predictive value, the results are as follows: Sensibility 75% (+/-9%) Specificity: 71% (+/-5%) |
| GROUP 2 | 70% | 66% | |
| GROUP 3 | 75% | 70% | |

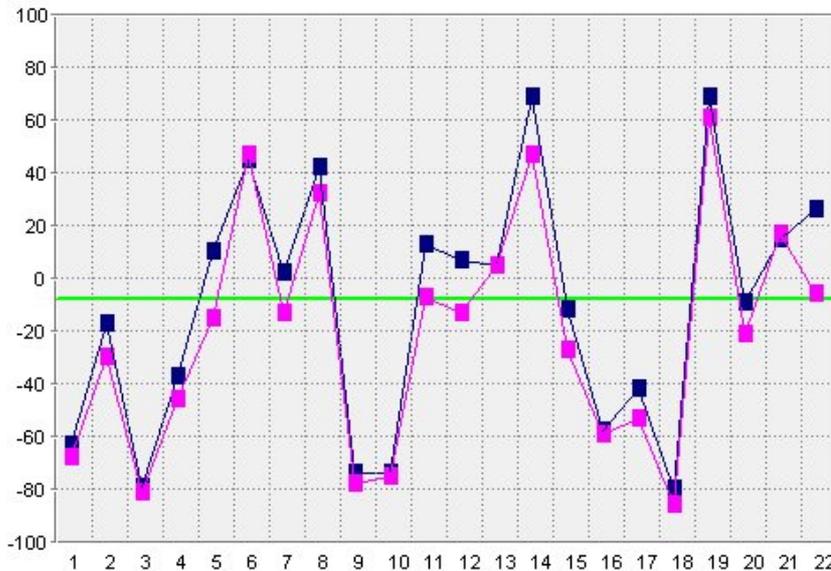
VI. NEUROLOGICAL DISEASES

The volumes determining neurological disorders are the branches corresponding to the frontal cortex, i.e. 9 and 10.

The patients were split into 3 groups meeting the following algorithms:

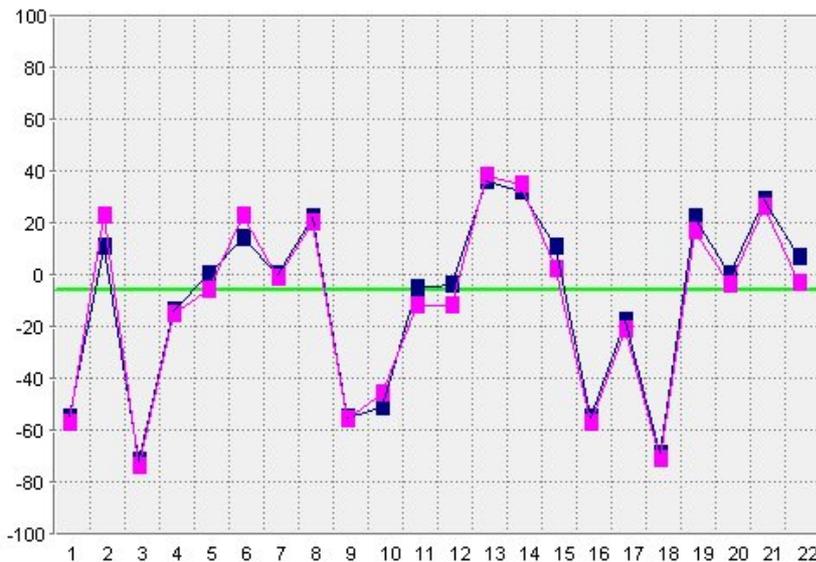
Group 1: Cortical hypoexcitability: Depression

Aa (9+10) < -60



Group 2: Predominance of the right brain in developing thought

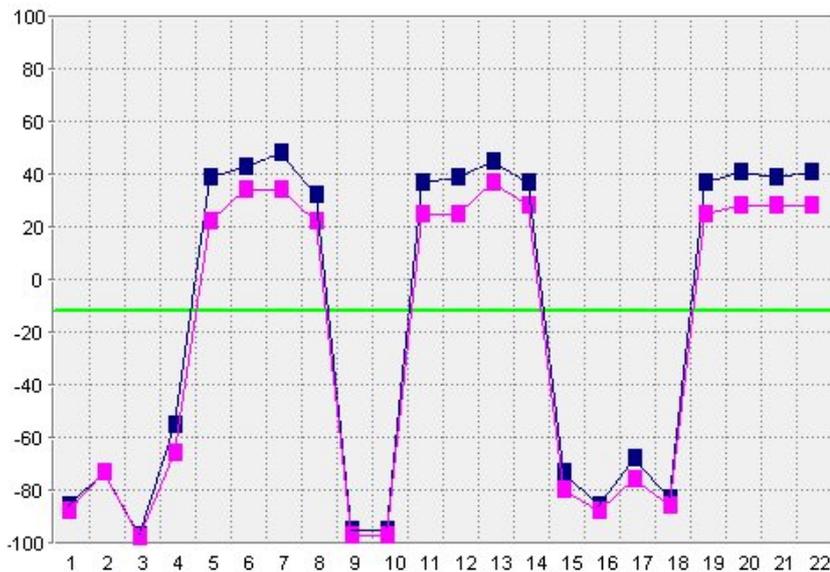
Aa (10) < -40 + Aa (10) < Na (10))



Group 3: Neurological disease

Age > 60 + BMI < 22

Na (Hdi) > +20 + Aa (Hdi) > + 20 + Aa (2+4+15+17) < - 20 + (9+10) < -60



In terms of positive and negative predictive value, the results are as follows:

Sensitivity 71% (+/-9%)

Specificity: 69% (+/-5%)

| | VP+ | VP- |
|---------|-----|-----|
| GROUP 1 | 69% | 72% |
| GROUP 2 | 73% | 66% |
| GROUP 3 | 71% | 70% |

University Hospital of Beijing

The analysis of the various pathologies was performed as a function of the values of the electrosonatogram 22 volumes in Na and Aa, which led to the creation of new algorithms for the relationship between function and pathology.

Total of false positives and false negatives: (Appendix 7 and 7 b)

- ✓ Breast cancers: Total 64 patients
4 false negatives and 5 false positives
- ✓ Digestive cancers: Total 45 patients
3 false negatives and 2 false positives
- ✓ Lung cancers: Total 55 patients
5 false negatives and 2 false positives
- ✓ Prostate cancers: Total 47 patients
5 false negatives and 3 false positives

- ✓ Uterine cancers: Total 38 patients
4 false negatives and 3 false positives
- ✓ Liver cancers: Total 52 patients
7 false negatives and 3 false positives
- ✓ Bone cancers: Total 41 patients
5 false negatives and 6 false positives

I. BREAST CANCERS

Women +age >35

Na (11+12) <- 20

Aa 7+11+ 12+ 20+22 >-22

+ Aa 5< +20+6< +20+7< +20+8< +20+19< +20< +20+20< +20+21< +20+22< +20

+ Aa 13+ 14 > -15

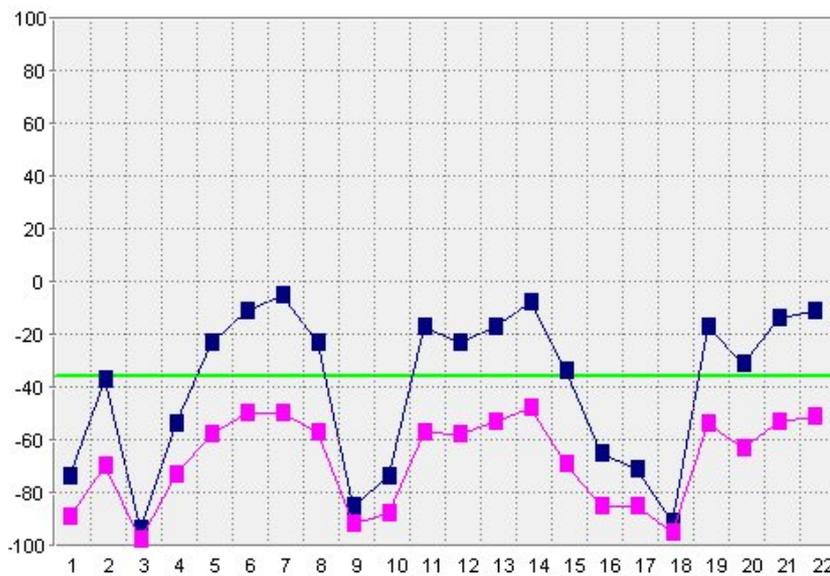
+ Aa 1+ 3+ 16+ 18 <-60

+ Aa 9+ 10 <-50

+ Aa (2+ 4+ 15+ 17) <-20

+1Aa < 48

+11 or 12 <or =-20



In terms of positive and negative predictive value, the results are as follows:

Sensibility 78% (+/-9%)

Specificity: 69% (+/-5%)

II . DIGESTIVE OR LIVER CANCERS:

Group 1: Cancer developing with possibility of metastasis

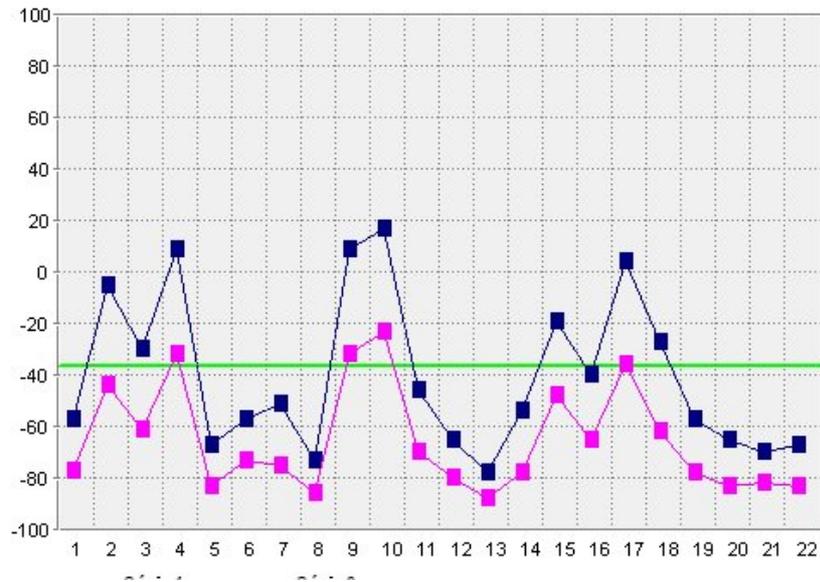
Age >45

Aa Value (-)

+Aa 5+ (7or8)+11+ 12 +20+22 < -22

+Aa 1 +3 +16+ 18 <-60 OR 10>- 5

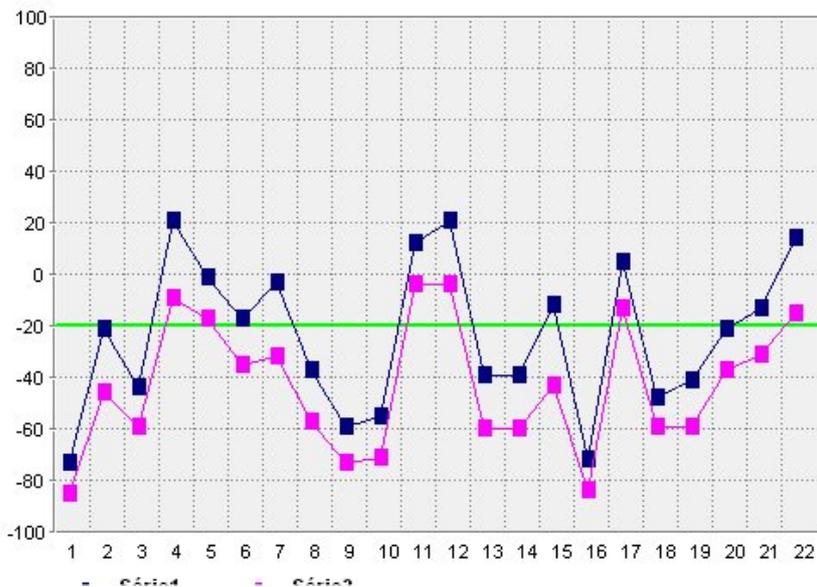
+ Aa 5<-60 + Aa 22<-60



Group 2: Stomach cancer stabilised

Na (Mdi) <-20 +(8+19) < - 40 + (13+14) < -40

1Aa < or = 55 +Aa (8+19) < - 20 + (13+14) <-20

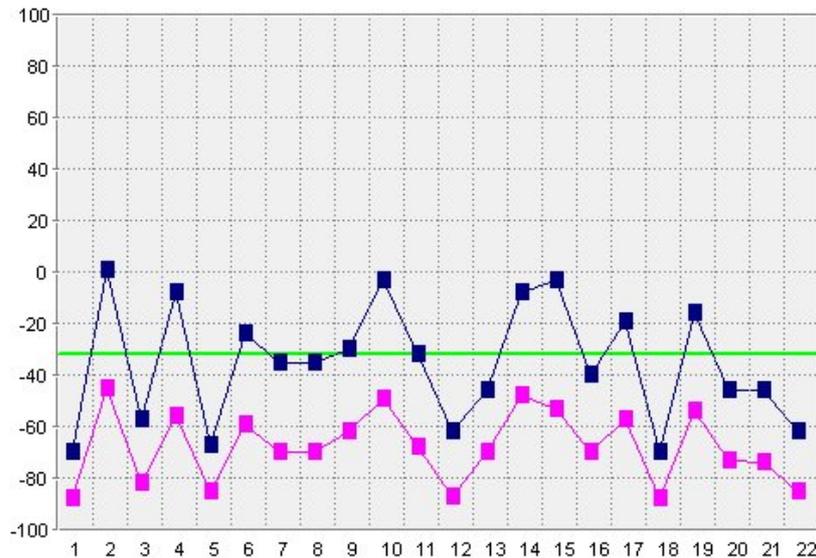


| | | | |
|---------|-----|-----|---|
| | VP+ | VP- | In terms of positive and negative predictive value, |
| GROUP 1 | 72% | 93% | the results are as follows: |
| GROUP 2 | 70% | 86% | Sensibility 71% (+/-9%) |
| | | | Specificity: 89% (+/-5%) |

III. LUNG CANCER:

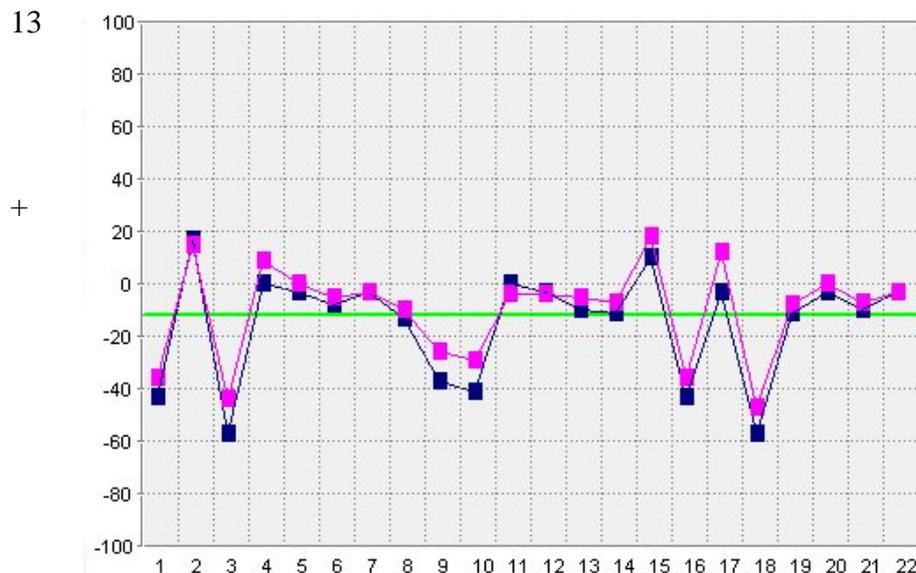
Group 1: chemotherapy must be instigated rapidly

Age > 60
+Value (-)
+Aa 5+7+ 8+ 11+ 12+ 20+ 21+ 22 < -30
+ Aa 5+7+ 8+ 11+ 12+ 20+ 21+ 22 ALL < -20
+ Aa 11+12< -30
+ Aa 5<-60 + Aa 22<-60



Group 2: prognosis very reserved

Age > 60
Abs Na + Abs Aa (5+6+7+8+11+12+13+14+15+17+19+20+21+22) < 5 + Abs (5< 13 +6< 13 +7< 13 +8< 13 +11< +12< 13 +13< 13 +14< 13 +15< 13 +17< 13 +19< 13 +20< 13 +21< 13 +22< 13)
dv < 5



In terms of positive and negative predictive value, the results are as follows:
 Sensibility : 69% (+/-9%)
 Specificity :67% (+/-5%)

| | VP+ | VP- |
|---------|-----|-----|
| GROUP 1 | 68% | 68% |
| GROUP 2 | 70% | 66% |

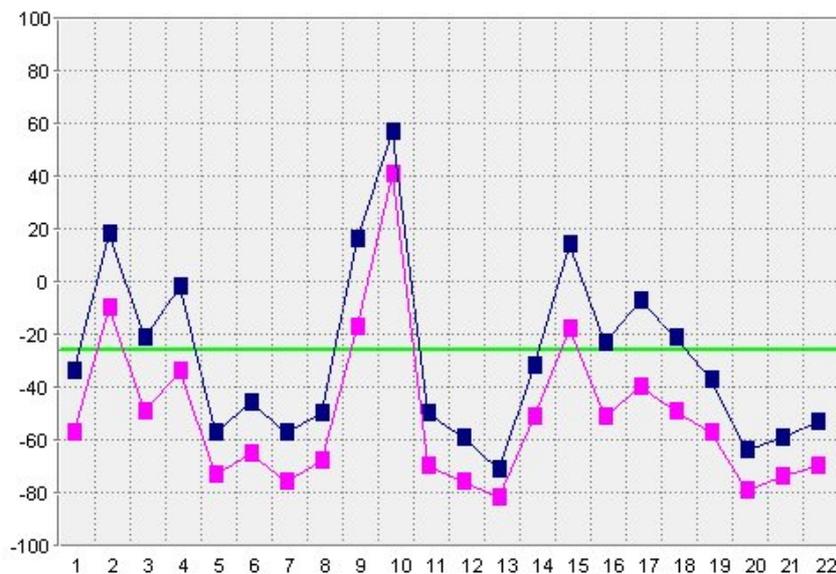
IV. PROSTATE CANCER:

Group 1: Prostate cancer evolving with metastases possible

Men + age > 50

Na (9) < -60 + (1+3+16+18) < -50

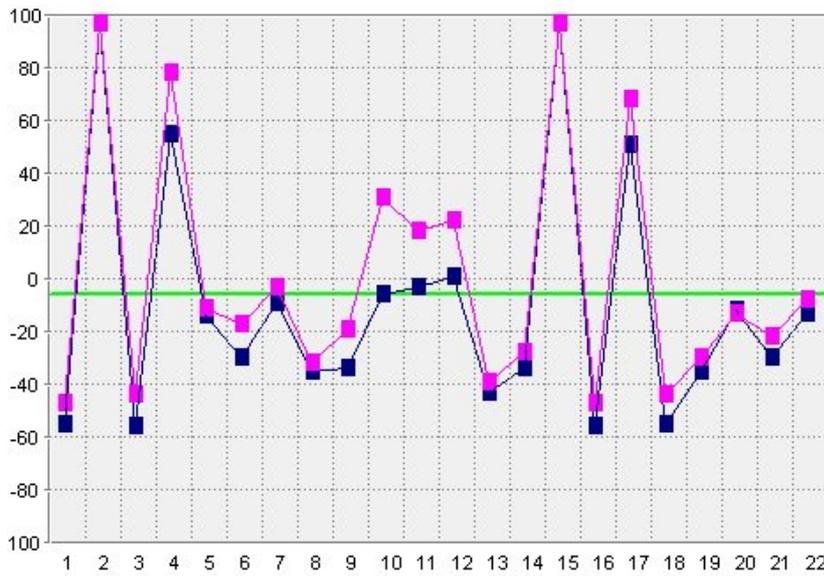
1Aa Value (-) + (1+3+16+18) < -50 + (13+14) < -40 + Aa (5+6+7+8+19+20+21+22) > -30



Group 2: Prostate cancer stabilised

Na(2+4+15+17) > +20 + Na(8+13+14+19) < -20

+ Aa: 1Aa Valeur (+) + (2+4+15+17) > 20 + Aa(8+13+14+19) < -20 + Aa (13+14) < -30 + Aa(13+14) < Na(13+14))



| | | | |
|---------|-----|-----|--|
| | VP+ | VP- | In terms of positive and negative predictive value, the results are as follows: Sensibility : 81% (+/-9%) Specificity : 73% (+/-5%) |
| GROUP 1 | 82% | 72% | |
| GROUP 2 | 80% | 74% | |

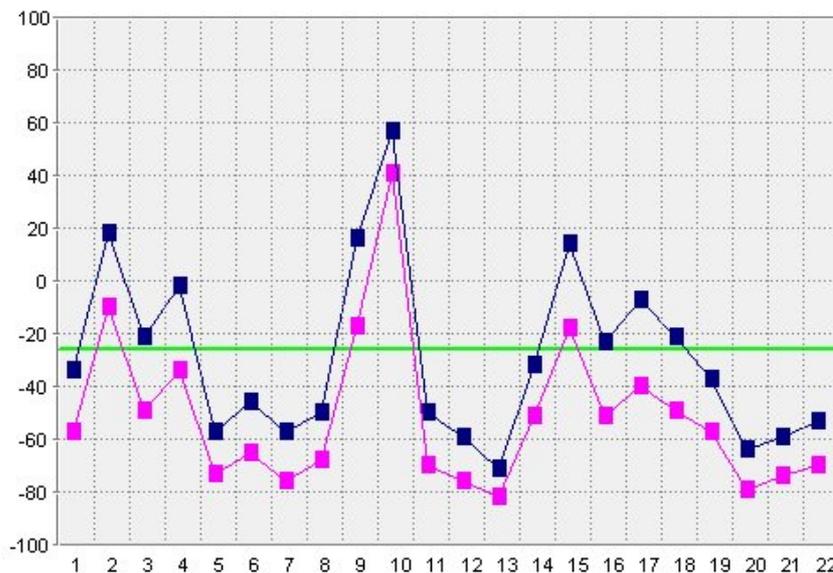
V. UTERINE CANCER

Group 1: Uterine cancer evolving with metastases possible

Women + age > 35

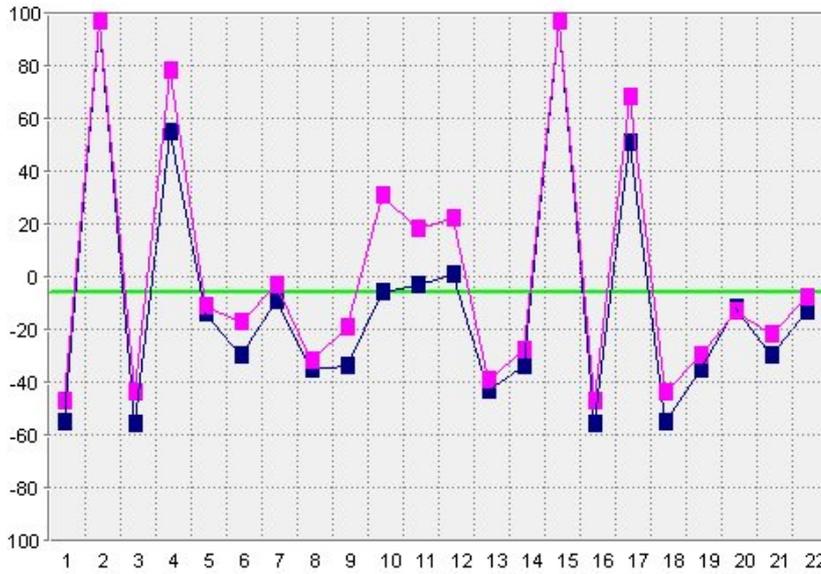
Na (9) < -60 + (1+3+16+18) < -50

1Aa Valeur (-) + (1+3+16+18) < -50 + (13+14) < -40 + Aa (5+6+7+8+19+20+21+22) > -30



Group 2: uterine cancer stabilised

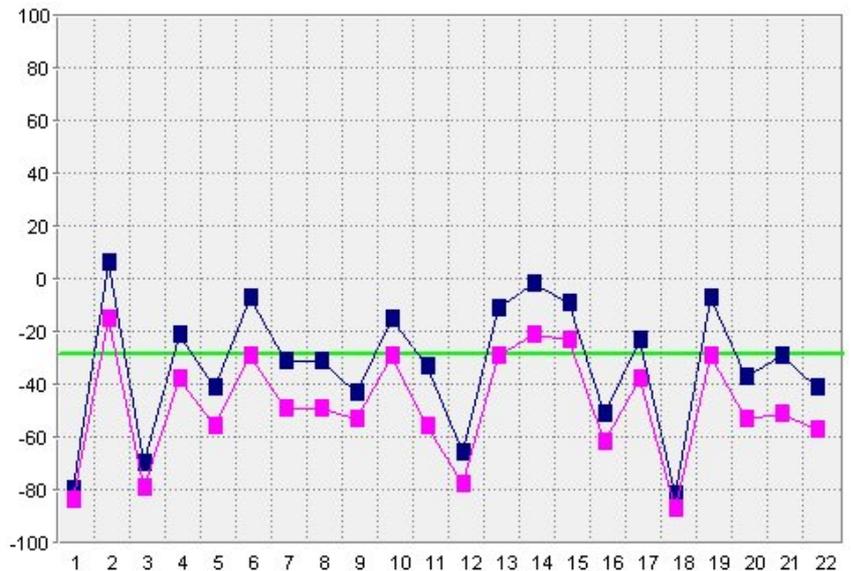
$Na(2+4+15+17) > + 20 + Na(8+13+14+19) < -20$
 $+ Aa: 1Aa \text{ Valeur } (+) + (2+4+15+17) > 20 + Aa(8+13+14+19) < -20 + Aa (13+14) < -30 + Aa(13+14) < Na(13+14)$



| | | | |
|---------|-----|-----|---|
| | VP+ | VP- | |
| GROUP1 | 84% | 73% | In terms of positive and negative predictive value, |
| GROUP 2 | 80% | 71% | the results are as follows: |
| | | | Sensibility : 82% (+/-9%) |
| | | | Specificity : 72% (+/-5%) |

VI. BONE CANCER

$Aa < \text{or} = 50$
 $+ Aa 5+7+ 8+ 20+ 21+ 22 < -30$
 $+ Aa 5+7+ 8+ 20+ 21+ 22 \text{ ALL} < -20$
 $+ Aa 11+12 < -15$
 $+ Aa 2+4+15+17 > -15$
 $+ 6 > -20 + 19 > -20$



In terms of positive and negative predictive value, the results are as follows:
 Sensibility : 67% (+/-9%)
 Specificity : 62% (+/-5%)

CONCLUSIONS

1. Validation of the system:

For all the clinical tests:

- The clinical tests were used to solve the equations, applying the mathematical law of inverse problems and hence the DDFAO system's ability to detect the pathologies recorded at the time of testing at 79.7%..
- Of the 1163 pathologies recorded, we noted:
False positives: 63
False negatives: 112
- Sensitivity was 89% with a confidence interval of 9% for a remarkable specificity of 84% with a confidence interval of 11% (calculated at 95%).

All these figures are acceptable in the field of medical diagnosis. These figures are close to those obtained by laboratory examinations and comparable to those of conventional medical devices.

These first clinical results obtained for clear pathologies show the validity of the measuring concept described.

2. Location of organs and systems on reconstituted images

The clinical tests were used to determine the significance and reading of volumes and by combining them, the location of organs on the reconstituted images (see appendix 6)

3. Advantage of the complementary DDFAO examination

The reproduction of results and reference values and limits of decision must be compared with laboratory analyses and display the same indications, and are useful in all medical specialities.

The functional examination can be used to view certain pathologies with a different approach from that of a lesional examination in so far as the disease is presented in the form of different graphs depending on its origin, prognosis or efficacy of treatment, and therefore the examination will have its role in a therapeutic approach.

In the future, the very rich data provided by the CAFDD will be the subject of systematic application of all new methods of data mining developed for sorting medical data.

Indeed, artificial intelligence techniques are likely to supply other hypotheses or identify highly characteristic sub-populations.

These techniques can be used in areas with very large dimensions so that all possible combinations of resources can be added to the 44 leads used, starting with the clinically pertinent zones in the sense of the pathologies concerned. It is the team work between physicians and mathematicians which will lead to rapid and promising developments.

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AID IN INTERPRETATION

Summary of test results

Units of volumes and correspondence with the function:

- (1 3 9 10 16 18) -20 to -40 Corresponds to the nervous system, endocrine system under hypophyseal control and immunity
- ✓ Subgroup (9 10): Frontal cortex and cerebral vascularisation
- (2 4 15 17) + 10 to + 20: Corresponds to the neurovegetative system (catecholamines), production of cortisol (inflammatory condition) and pulmonary ventilation.
 - ✓ Subgroup (4 17) thyroid activity
- (5 6 7 8 19 20 21 22): Elimination systems: kidneys and digestive system
 - ✓ Subgroup: (5+6+20+21) pancreas
 - ✓ Subgroup: (7+8+19+22) liver
 - ✓ Subgroup: (6+8+19+21) bone pathologies
- (11 12): Supradiaphragmatic organs, particularly: Bronchi, thorax or breasts (women), trachea, cesophagus, pharynx
- (13 14): lower limbs and genital organs, including urinary organs
- Combination of groups: 6+13+19: cardiac function, particularly the left ventricle

The pathology is revealed by an imbalance:

- ✓ Either 1Aa is outside the norms
- ✓ Or 1Aa is within the norms but there are modifications in the volume unit values

1Aa outside the norms

- **Upwards: (+) (+) and (+) (see conventions at the end of the document)**
 - ✓ (+)(+):

All Na volumes have increased

In this case, unit (2 4 15 17) remains > +20

the pathologies are:

Digestive inflammation or infection:

- Digestive inflammation
- hepatitis (dietary or drug-related)
- pancreatitis

If in Aa units (5 6 7 8 19 20 21 22) are between + 15 and -10

Pulmonary inflammation or infection

If in Aa units (5 6 7 8 19 20 21 22) are between -10 and -16

Acute cardiovascular (infarction)

If subgroup 6 13 19 is > + 20

Chronic cardiovascular (atherosclerosis)

If subgroup 6 13 19 is < - 17

Renal:

Si (13+14) > +20 or < -20

Fibroma / adenoma/ prostate or uterine cancer according to sex

If (13+14) < -20 + Aa (13+14) < Na (13+14)

If (13+14) > +20 + Aa (13+14) > Na (13+14)

- **Value (+):**

Na unit 2 4 15 17 is greatly increased

Aa unit (2 4 15 17) remains > +20

The pathologies are identical with, in addition:

- ✓ **Stress**
- ✓ **Neurovegetative dystonia**
- ✓ **Essential hypertension**
- ✓ **Increased catecholamines**
- ✓ **Increased cortisol production**
- ✓ If Aa (2 4 15 17) > Na (2 4 15 17) =>**Chronic bronchitis or asthma**

- ✓ **Downwards**

- **Value (-)(-)**

All the volumes in Na are reduced

1. Aa values remain negative

A **cancer** test is necessary

2. Certain Aa values become positive: notably units (2 4 15 17) and / or (9 10):

In this case there are different pathologies:

Chronic hepatitis unit (11 12) remains very low

Type I diabetes

3. **Cancers being treated** display increased volume units (5 6 7 8 19 20 21 22) or (9 10)

- **Value (-)**

Volume unit (1 3 9 10 16 18) is greatly reduced

Depending on the level of Aa units, the following pathologies are detected:

Kidney disorders: All the units are between 0 and - 20 with unit (13 14) the closest to -20

Depression, hypophyseal drop, menopause, hypothyroidism: All the units are between +10 and -10

Cardiovascular pathology: (6 13 19) > +20 or (6 8 19 21)>+20

Digestive pathology: (5 6 7 8 19 20 21 22) >+20

Encephalopathic neurological disease: (5 6 7 8 19 20 21 22) >+ 40

➤ **1Aa within the norms and modification of volume unit values**

Cardiovascular pathologies: hypertension, thrombosis, atherosclerosis

Respiratory pathology: chronic bronchitis, pulmonary embolism

Digestive pathology: Gastritis, viral hepatic ulcers, pancreatitis

Endocrine pathology: Type II diabetes

Bone pathology: reduced bone density, osteochondrosis

If a serious pathology is diagnosed (particularly lung or liver cancer) and 1Aa is within the norms with no changes to units: the prognosis is very reserved.