REPORT
concerning results of clinical tests of
hardware-software complex DYNAMICS

Ground: permit No. 161/7/21 5615 of the Main Military Medical Department dated October 29, 2004 and of the Committee for New Medical Equipment of the Ministry of Healthcare of the RF dated December 16, 2003; Science Agreement No. 4/13/21 between Military Medical Academy and OOO Dynamika dated November 29, 2004.

Research purpose: to carry out clinical tests of Computer complex for assessment of the functional state of a human organism Dynamics, manufactured by OOO "Scientific Research Laboratory Dynamika" (St. Petersburg), prior to conduct of complex clinical examination of medical patients.

Objectives:
1. To assess general health condition of patients with basic forms of internal pathologies on the basis of telemetric data complex.
2. To mark out telemetric criteria of critical conditions, including criteria of oncological risks.
3. To assess effectiveness of the administered treatment in dynamics on the basis of the telemetric data.

Design and methods of the research
General clinical laboratory and instrumental examination of patients in accordance with nosological form, telemetric examination using hardware-software complex Dynamics prior to and after course of treatment, maintenance of computer database (based on General Therapy Clinic No. 2 of the Military Medical Academy).
Computer testing is intended for integral estimation of the functional state of organisms of a healthy person and a sick person in the screening mode at different stages of observation; assess effectiveness of the treatment and prophylaxis; respond quickly to occurrence of signs of health deterioration and signs of critical conditions, including oncological risks.
Technical implementation: personal computer of Pentium-3-4 class with the software of 2004 version; set of peripheral equipment.
Principle of the method: mathematical treatment of the information born by biological signals of the organism, in particular cardiological signals with consecutive assessment of vegetative probability, energy and regulatory resources, brain rhythms, their fractal analysis, etc.

During information processing code patterns and criteria are separated in respect of which functional state of the patient (general quality of health) may be assessed. It allows, upon availability of signs of development of life-threatening conditions, precancerous and cancerous conditions, to respond promptly and correct the treatment, and then assess effectiveness of the treatment.

Technique is non-invasive. The information is taken with the help of 2 standard ECG sensors put over the patient's forearms. The patient is out of reach of power, because information is being transferred into the computer with the help of the remote device along IR channel. The time spent for one patient does not exceed 6-7 minutes, including analysis of the information and receipt of the conclusion decision.

The amount of examinations: during testing period 428 patients were examined with the following standard-practice clinical laboratory examination in accordance with detected nosological form of the disease.

1. Control group – healthy individuals (22 persons).
2. Planned autumn preventive medical examination (160 persons).
3. Patients with ulcer disease (63 persons).
4. Cancer of different localizations (22 patients) and 11 control patients.
5. Randomly formed groups of gastroenterological patients (150 persons).

RESULTS OF THE RESEARCH

1. Telemetric indicators in the group of healthy persons (control)

With the purpose of repeatability of the results and detection of the scope of normal values 24 hours were dedicated to measurement of the majority of indicators of 22 healthy volunteers in the age from 18 to 30 years, who did not have chronic diseases of internals in the past medical history or social habits and had congenial hereditary history.

24-hours dynamics of almost all telemetric indicators represented linear function with moderate steady decrease during evening and night hours with the following recovery by morning hours. Such nature of the curve confirms repeatability of the results, and moderate trend of curves towards one or another side is conditioned by individual daily fluctuations of physiological parameters. Fluctuations of indexes of the vast majority of healthy persons (18 out of 22, 87%) were within the scope of normal values set forth in comments to the research program.

Indexes of vegetative equilibrium (reflecting ratio of sympathetic and parasympathetic vegetative nervous systems), vegetative rhythm index (reflecting vegetative equilibrium) and tension index (reflecting degree of the heart rate control centralization) were notable for relatively higher instability. At the same time average values of the general health index, fractal index, porosity, "golden ratio" parameter of all patients varied within the scope of normal values and did not significantly vary with different patients.

Taking into consideration the highest *individual* stability for the following analysis in the group of examined patients the general health index, neurodynamic indicators, fractal index and vegetative equilibrium indexes were selected with the purpose to assess the influence of short-term and long-term factors on integral health indicators.

2. Preventive examination group

First of all upon carrying out of tests the possibility of selection of three

categories of patients was provided: 1) almost healthy patients; 2) patients having signs of health deterioration (subcompensation); 3) patients having apparent signs of health deterioration (decompensation) or signs of oncological risk. It is important that the second and the third categories of patients were often verified even upon subjective well-being and absence of objective (clinical) signs of a disease. Results of the general statistical analysis are provided in the Table 1 which for a total of all examined patients confirms the reliability of registration of indicators.

Data of the analysis of telemetric indicators among preventive examination groups allowed answering the question about differences of "telemetric" portraits of different categories of examined patients and the possibility of primary "before-doctor" examination with the help of the hardware-software complex (Table 2).

Table 2 shows that in the process of computer testing of persons passing preventive medical examination it is possible to detect more or less apparent functional deviations in the state of health earlier and therefore pay greater clinical attention with the following in-depth examination. So, in different age groups upon regular (common practice) preventive examination conclusions "healthy" and "functional diseases" are drawn oftener, whereas according to the results of testing with the help of HSC Dynamics such conclusions may become more objective, timely and reasonable.

For example, in the group of examined patients of 20-30 years 86.9% are recognized as "healthy", according to the physician's conclusion, whereas upon computer testing their number is only 68.9% (the others showed signs of health deterioration that evidence the need of the in-depth examination and correction of the functional condition of the organism). On the other side, in 50% of cases persons above 50 years had chronic diseases diagnosed earlier, but upon passing computer testing in 31.2% of cases signs of apparent health deterioration were detected, frequently close to the criteria typical of the oncological risk. After careful and detailed consultation with the physician such patients were recommended, besides the bulk of the preventive examination, to pass an additional examination, for example gastrofibroscopy, proctosigmoidoscopy, abdominal ultrasound, echocardiography, additional laboratory tests, etc.

Economy aspect is obvious, because, according to the results of the computer testing, time and money costs may be directed at persons who really need examination and treatment.

According to the results of the examination of control and preventive examination groups, principal criteria of the norm, subcompensation and decompensation of the functional state of the organism were detected (Table 3); and with the purpose of further implementation the procedure of use of HSC Dynamics in the outpatient setting and for clinical practice was developed (Picture 1).

3. Results of telemetric observation of patients with ulcer disease

63 patients with ulcer disease were under observation, among which 29 participated in emergency clean-up after the Chernobyl nuclear accident and 34 presented the group of patients having regular run of the ulcer disease (Table 4).

It is obvious that initial functional indicators of liquidators are significantly lower in comparison with the control group and moreover – with healthy individuals. Liquidators, as a rule, had combination of several chronic diseases (ischemic heart disease, essential hypertension, irritable bowel syndrome, diabetes mellitus, immunodeficiency disorder, etc.), which distinguished them in the general population from patients with ulcer disease. Many telemetric criteria corresponded to the criteria

characteristic for precancerous conditions, i.e. for oncological risk.

Regular antiulcer therapy included Lactulose preparations, Deep-Sea Tangle, DNA immunomodulatory preparations. Such preparations not only improved general quality of functional indicators, but significantly accelerated restoration of ulcerous defects and increased eradication rate of H. pylori as in the general, so in the control group. Irritable bowel syndrome was actively jugulated, and clinical profiles of associated diseases and metabolic disturbances were improved. These observations show the possibility of use of the computer monitoring in the process of control of effectiveness of therapeutic activities, and possibility of monitoring for objective evidence of improvement of the patients' health, i.e. elimination of signs of decompensation of the functional state of the organism in general.

4. Assessment of sensitivity of the method to oncological processes of various localizations

22 patients with oncological diseases of the stages 2-3 (5 women with breast cancer, 2 – with uterine and ovarian cancer, 5 men with stomach cancer, 6 – with colorectal cancer, 3 – with hematological malignances, 1 – with pancreatic cancer) were examined by method of blind telemetry testing. At the same time 11 patients of the similar age without oncological pathologies were examined. The examiner was not informed of the diagnoses, and the final analysis was carried out by an independent expert.

Telemetric results of 20 patients with cancer (90.9%) agreed with clinic pathologic diagnosis having shown high sensitivity of the method. Telemetric indicators conformed to the so-called level of decompensation of functional indicators presented in the Table 3. None in the control group showed such signs, though 4 patients (persons above 45 years) had signs of deterioration of the functional state of the organism caused by availability of chronic diseases.

At the same time upon assessment of the specificity of the method signs, characteristic for a certain localization of the tumor, were absent what evidences universality of the informational essence of the cancerous disease and also the fact that the right of the final diagnosing belongs not to the computer, but to the experienced medical officer.

At the same time the number of patients upon screening (groups 2, 3, 5) had many telemetric signs very similar to those of patients with cancer, though upon clinical examination the tumor was not detected or a pathology was detected which could be interpreted as a precancerous disease (for example, atrophic gastritis, gastric and colonic polyps, gastric ulcer, and other).

This circumstance allowed using the term "risk of oncological pathology" based on detection of similar mathematical features (for example, high indexes of vegetative equilibrium and tension, low index of fractal analysis) with patients having cancer of various localizations and with patients having diseases conventionally recognized as "precancerous". For example, rate of this "risk" in various nosological groups of gastroenterological patients varied from 15% to 50% (Table 5).

It was concluded that detection of the category of patients with "oncological risk" is utterly important for dedicated and timely examination of patients and further observation over them, what allows significant improvement of the probability of primary diagnosing of cancer at the early stages.

In all other cases the group of patients with significant deterioration of the health condition caused by, for example, ischemic heart disease, essential

hypertension, diabetes mellitus, liver and bowels diseases, and other, may be distinguished, even in the absence of evident clinical signs of acute attack of the disease. We suppose that such patients need medical observation, early (prophylactic, anti-relapse) treatment in accordance with the principal disease; additional correction of immune and metabolic disturbances is also rational.

5. Observation over gastroenterological patients

With the help of the random sampling technique 150 patients suffering various verified and non-verified (for the moment of examination) diseases of the digestive apparatus. According to the Table 5 it is obvious that the highest rate of indexes characteristic for oncological risk is detected under availability of gastric ulcers, polyps, chronic constipations, nonspecific ulcerative colitis, i.e. diseases which are recognized as background conditions of carcinogenesis. 6 detected cases out of 38 cases of malignant degeneration make up about 15% what may reflect rather high effectiveness of the computer screening (pursuant to the data of Moscow Scientific Research Institute of Oncology n.a. Gertsen, effectiveness of the primary screening on the outpatient level does not exceed 1%).

Closing control at the system Dynamics allowed to be convinced, in the majority of cases, in the positive effect of carried out therapeutic activities (including targeted use of prebiotics, probiotics, Deep-Sea Tangle preparations, immunocorrecting preparations, etc.).

Therefore upon assessment of the results of the telemetric screening high efficiency of the criteria, assisting in formation of risk groups of not only tumor diseases, but also of general threatening physical conditions, which are reasonably used for making of prompt clinical decisions, may be confirmed.

This is, first of all, an integral health index, indexes of vegetative equilibrium and tension, fractal index. The primary decision may be also aided by the "traffic light" principle, visual assessment of the histogram of R-R intervals, scattergram, neurodynamic matrix, structure of codes (percentage ratio of normal, altered and pathologic codes under neurodynamic analysis), and patterns of fractal analysis. If any doubts in primary results occur, examination may be carried out on repeated occasions. If indicators of the telemetric screening are low, the patient should be recommended clinical examination with application of the necessary bulk of laboratory and instrumental methods.

CONCLUSION

The field of use of the obtained results may be the system of medical observation (prophylactic health examination) on the outpatient level, and also practice of inpatient hospitals under control of effectiveness of the treatment.

Economic effectiveness may be reached at the cost of decrease of expenses due to increase of the effectiveness of the early diagnosing of diseases, including oncological ones, and increase of the quality of therapeutic activities.

The results of the performed work evidence significant diagnostic potential of HSC Dynamics which upon wide implementation into practice may be used for solving of various problems of clinical, prophylactic, emergency and sports medicine.

According to the results of Research Works No. 4.00.182.p2 and 1.00.145.p10 of the Military Medical Academy and pursuant to the results of the current research computer complex Dynamics may be implemented with the high degree of effectiveness into work of the outpatient level of medical service of the Armed Forces

of the RF, work of air medical officers and system of preventive medical examination of military personnel.

Manager of the research:

Head of the inpatient therapy department of the
Military Medical Academy n.a. S.M.Kirov
Professor, Doctor of Medical Sciences   /signature/   V.Yu.Golofeyevsky

Responsible executive:

Candidate of Medical Sciences   /signature/   A.P.Kretsu

Executive:

Candidate of Medical Sciences   /signature/   V.L.Kuzmichev

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Table 1

Average values of general telemetric indicators in the prevention examination group

	Health index	Vegetative equilibrium index	Tension index	Fractal index
Average	0.56	246.48	172.27	64.53
Constant error	0.019	21.57	15.23	1.91
Median value	0.57	198.9	131.3	65.7
Mode	0.33	267.6	142.8	66.1
Standard deviation	0.19	216.80	153.13	19.26
Sampling variance	0.039483	47005.23	23449.82	370.98
Excess	-0.22	15.94	5.52	1.62
Asymmetric property	-0.27435	3.226482	2.188225	-1.02
Interval	0.9	1576.9	854.8	92.6
Minimum	0.05	45.6	27.2	6.2
Maximum	0.95	1622.5	882	98.8
Amount	56.75	24894.6	17399.9	6518.1
Calculation	251	251	251	251
Highest (1)	0.95	1622.5	882	98.8
Lowest (1)	0.05	45.6	27.2	6.2
Reliability level (95.0%)	0.039	42.80	30.23	3.80

PATIENT

EXAMINATION
Dynamics

SIGNS OF PATHOLOGICAL CONDITION	SIGNS OF THE NORM	SIGNS OF PRE-SICK CONDITION

ADJUSTMENT OF THE DIAGNOSIS

CURRENT AND CLOSING CONTROL OF EFFECTIVENESS OF THE CARRIED OUT ACTIVITIES

UNDOUBTFUL DIAGNOSIS AVAILABLE

DOCTOR'S ADVICE (PHYSICIAN)

DIAGNOSE: EXAMINATION

NO DIAGNOSIS OR DOUBTFUL DIAGNOSIS

TREATMENT AFTERCARE PROPHYLAXIS

Picture 1. Procedure of the medical officer's actions in accordance with the results of the examination with the help of HSC Dynamics

Table 4

Dynamics of telemetric indicators prior to and after antiulcer therapy

		ndicators prior to and	after antiulce r thera	
			Ge	ner	al
up n = 29 Control group N = 34 n_1 % n_2 % **General healt** Age: under 4 0 years old (n₁ = 11, n	₂ = 16):	- Prior to t reatm	e n t I n 3 we	e k s In 3 mon ths
9 18.2* 72.7 81.8 14 13 14 87.5 81.3 87.5 **General health ind** Age: above 4 0 years old (n₁ = 18, n₂	= 18): -	P r ior to trea tment	I n 3 wee	k s - In 3 mo nths
9 13 22.2* 50.0 72.2 9 6 11 50.0 33.3 61. 1 **Tensi** **on index more**	**t han 5 00**	Prior to tre atment	In 3 wee	k s - I n 3 m onths
9 5 48.3* 31.0* 17.2* 8 16 14 23.5 41.2 **Vegetativ** **e equilibri** **um index more**	**t han 50 0**	P rior t o tre atmen	t I n 3 w	e eks - In 3 mont
15 10 4 51.7* 34.5 13.8 6 14 9 17.6 41.2 26.5 **%% o** **f pathologi** **cal codes more**	**tha n 5 0**	P rior to tr eatme	n t I n 3 w	e eks - In 3 mont
18 14 7 62.1 48.3 24.1 12 13 5 35.3 38.2 14.7 **%% of nor** **mal codes more**	**th an 50**	Prior to tr eatme	n t I n 3 we	e ks - In 3 month
6 11 6.9* 20.7* 37.9 15 1 4 14 44.1 41.2 41. 2 **Fract** **al index more t**	**h an 5 0%**	P rior t o trea tment	In 3 w eek	s - In 3 mo nths

3
9   14   10.3* 31.0* 48.3   18   17   19   52.9
5
0

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Table 5

Results of the screening examination of gastroenterological patients

Nosological forms	n	Deterioration of the health condition (oncological risk)	%%
Chronic gastritis	41	6	14.6
Gastric ulcers	14	9 (2)	54.3
Duodenal ulcers	19	3	15.8
Gastric and colonic polyps	11	5 (3)	45.5
Chronic pancreatitis	23	6 (1)	26.1
Chronic constipation	11	4	36.4
Ulcerative colitis, IBS (diarrhea form)	17	4	23.5
Hepatobiliary pathology	14	2	14.2
Total:	150	38 (6)	25.3

Note: numbers in brackets specify number of cases of verified oncological pathologies detected after targeted clinical examination.