

“APPROVED”

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June 05, 1998

/Round stamp/:

Health Committee of Saint-Petersburg Administration

The Saint Righteous Martyr Elizabeth Hospital

“APPROVED”

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June 05, 1998

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REPORT

on clinical testing of software-hardware complex Dynamics-100
(initiative theme)

Objective: approbation of information technologies on the basis of software-hardware complex Dynamics-100 in the Gastroenterology Department of the Saint Righteous Martyr Elizabeth Hospital – the clinical basis of Gastroenterology division of the Military Medical Academy for the period from November 1996 till June 1998.

Executors: leader and responsible executor – professor of the Military Medical Academy, Doctor of Medical Science Golofeevsky V. Yu., executors: head of the Gastroenterology Department Volga N. B., lecturer of the Gastroenterology division, Candidate of Medical Science Lapaev I. V., doctors of the Gastroenterology Department.

Tasks:

1. By the blind control method to assess sensitivity of the aprobated technology in patients with previously diagnosed malignant pathologies.
2. To assess diagnostic efficiency of the software-hardware complex for detection of the oncology risk groups and early diagnostics of cancer among patients of gastroenterological and general therapeutic profiles.
3. To assess efficiency of the software-hardware complex for evaluation of quality of oncological patients treatment and in case of oncological risk – possibility of its correction as method of primary prophylaxis of cancer.
4. To give an opinion on expediency of implementation of information technology in practical health care.

Examined groups: 568 patients was examined.

The main group: 172 patients with digestive organ diseases. Among them: 38 patients with non-ulcer dyspepsia syndrome (gastroesophageal reflux disease, chronic gastritis), 27 – with peptic ulcer disease, 29 – with duodenal ulcer, 17 – with polyps in stomach or large bowel, 19 – with chronic pancreatitis, 10 – with chronic constipations, 14 – with chronic enteritis and non-specific ulcerative colitis, 18 – with disease of liver and bile passages.

Control groups: 220 patients with verified malignant tumors with localizations in esophagus, stomach, large bowel, pancreas; 54 – after radical operation due to malignant tumors of stomach or large bowel. Besides, as control groups 29 apparently healthy persons were examined, 52 women with breast fibroadenoma, 41 patients with pathologies of the cardiovascular and respiratory systems.

Essence of the method: approbated computer-aided system for health monitoring Dynamics-100, developed in Saint-Petersburg innovation and research medical and biological center “Dynamics” is a remote software-hardware complex, meant for detection in a person of informational code signs, specific for oncopathology, not only at the stages of the formed malignant process, but also at more earlier stages (preclinical, prenosological) of the disease. Informational signs of oncopathology are detected in the process of mathematical processing of amplitude-frequency characteristics of biological signals, in particular cardiosignals.

Ergonomic assessment of the diagnostic system: the system is a personal computer, original software support, minimized cardiosignal registration device, standard ECG-electrodes. During examination absolute safety of the patient is ensured. Time for examination of one patient and receipt of the expert's opinion is not more than 5 minutes. Use of the diagnostic system is extremely simple and convenient for staff, does not require conduction of complicated preparatory procedures for a patient.

Results:

The data of sensitivity assessment of software-hardware complex Dynamics-100, conducted by the “blind” method in patients with known and previously diagnosed malignant processes have determined the following:

Software-hardware complex Dynamics-100 has a high sensitivity (95,8%) for detection in a patient of a malignant process, that is achieved by a perfect software and hardware support of this diagnostic system.

It is understood from the experiment that high frequency of oncological risk detection occurs in women with breast fibroadenoma (58,3%, from them in 2 cases breast cancer was confirmed in the following), patients with hereditary oncology load (36,3%). In patients operated due to cancer, in 6-12 weeks after the operation oncological risk is continued in 50,0% of cases that is indicative of possible recurrent tumor, necessity of a more careful monitoring of the patients and in a number of cases of chemotherapeutic treatment necessity.

Follow-up (during 6-18 months) 232 patients from the oncology risk group with repeated test by the software-hardware complex showed the following. On the first hand, high stability and reproductibility of the initial results of investigation was noticed during a repeated (immediate or postponed for a short period of time) test. On the second hand, in 70 of 160 patients that were administered medicinal agents for primary prophylaxy of malignant tumors (Klamin, Pheocarpin, Lucerne, Ginseng etc.) disappearance of oncological risk was observed. In 58 patients disappearance of oncological risk was observed after the treatment of the prior disease, administered in the hospital. In 33 patients decrease of oncological risk manifestation degree was observed. 28 patients did not have any positive dynamics in terms of computerized test, but no cases of malignant tumor progress were observed during control examination (fiber gastroduodenoscopy, laboratory tests etc.). Thus, it is evident, that during dynamic control of the patients' health of the risk group by means of the same diagnostic systems it is possible to control efficiency of the administered treatment and correction means of oncological risk.

Conclusion

The tested technology does not have analogues in the world, it is noted for its high informativity, sensitivity and reproductibility. The results presented in the report, are

indicative of actuality and urgent necessity of implementation of computer-aided diagnostic system Dynamics-100 into practical health care. It can be used for screening prophylaxy examination programs for population in policlinics, clinics, health units etc. as a method of screening diagnostics of tumors and detection of risk groups, as well as method of control for health status of people working in extreme conditions or residing in unfavourable ecologic conditions. This technology is also useful in in-patient departments as differential diagnostic methods and assessment of therapy efficiency, primary and secondary prophylaxy measures. State support is expedient for this new important direction in health care.

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