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INFLUENCE OF UKRAIN ON PATIENTS WITH SURGICALLY TREATED BREAST CANCER (INTRODUCTORY REMARKS)

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Summary: *Studies were undertaken to evaluate the influence of Ukrain on the postoperative period in patients with breast cancer. The group under Ukrain medication was comprised of 10 patients in stage T1-3NO-1MO. The control group was comprised of 22 patients in the same clinical and laboratory staging as those treated with Ukrain. In the first year of postoperative follow-up, metastatic lymph nodes were observed in one patient from the control group. It is planned to enlarge the groups and to continue the observation up to the third year to obtain reliable and more statistically significant data.*

Introduction

The drug Ukrain is a derivative of alkaloids from the plant *Chelidonium majus L.* (1). It is applied in the therapy of many neoplastic diseases. It depresses DNA, RNA and protein synthesis, reduces oxidative processes in cancerous cells, restores the cytotoxic function of macrophages and shapes the immunological status of patients with cancer (2-4). The wide application of Ukrain in oncological practice requires, however, further clinical and experimental work.

Clinical application of Ukrain in the Oncological Clinic of the Medical Institute in Grodno, Belarus, began in 1993. In the period 1993-1994 a random group of ten patients was selected from breast cancer patients and subjected to therapy by injection of Ukrain intravenously ten times, every second day for 20 days (50 mg cycle). The investigations allowed the conclusion that inclusion of Ukrain into the surgical scheme of breast cancer therapy may be helpful (5).

The aim of the present studies was to confirm and extend the previous investigations on the influence of Ukrain on breast cancer disease.

Patients and methods

The studies with Ukrain done in patients with breast cancer were performed in accordance with the Declaration of Helsinki revised in Tokyo

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with subsequent amendments added in Venice and Hong Kong.

For randomization of the studies concerning comparative therapy of breast cancer with application of the commonly accepted methods and utilisation of Ukrain, two group of patients were selected (Table I).

Table I *Classification of patients according to age and disease stage*

Groups of patients	Mean age, years	Stage of cancerous process			
		T1N0M0 or T2N0M0	T1N1M0 or T2N1M0	T3N0M0 or T3N1M0	Total
Control	52	4	12	6	22
UKRAIN	54	2	6	2	10

The experimental group consisted of ten patients in which, as a first step of treatment, a series of intravenous injections of Ukrain was applied in a dose of 5 mg every second day (total dose 50 mg). Seven to ten days after the end of this therapy the patients were subjected to radical mastectomy.

The control group consisted of 22 patients with primary breast cancer, hospitalised in the clinic with the experimental group and receiving general routine therapy without Ukrain.

Diagnosis was established in both groups on the basis of physical data, results of mammography (MA), ultrasonography (USG) and needle biopsy of the tumour. The degree of differentiation of the tumour and its metastases was precisely established histologically after the operation. The experimental and control groups were comparable as regards age, histological structure of the tumours and local spread of the cancerous process (Table I).

In the control group therapy was applied according to the stage of the disease and included preoperative radiotherapy and surgery, or surgical intervention alone. The type of treatment is shown in Table II.

In view of the fact that recurrences and metastases of breast cancer appear most frequently in the first three years after operation, with 83% of them occurring in the first two years, an adequate programme of control examinations was planned. In the first year the patients were recommended to return for control examination every three months; in the second year every four months and in the third year once every six months. In further years reexamination was suggested once a year. During the control examination a complete evaluation of the state of health of the patient is carried out, comprising physical examination, clinical-laboratory and X-ray evaluation (as indicated) ultrasonic tests and registration of recurrences or metastases.

Table II *Surgical procedure*

Groups of patients	Kind of operation		
	Mastectomy (Patey)	Mastectomy (Halsted)	Total
Control	18	4	22
UKRAIN	8	2	10

Results

In the postoperative period part of the patients of the control and experimental groups, depending on the stage of the disease, were additionally subjected to chemotherapy or radiotherapy (Table III). In four patients in the experimental group, instead of chemo- or radiotherapy, two cycles of treatment with Ukrain were applied (50 mg per cycle) intravenously, 5 mg every second day, with an interval of one month between the

Table III *Special therapy applied postoperatively to patients with breast cancer*

Type of treatment	Control group	Experimental group
Ukrain	—	4
Radiotherapy	2	—
Chemotherapy	10	3
Chemo-radiotherapy	4	2
No special treatment	6	1
TOTAL	22	10

therapeutic cycles. At present we are able to analyse the state of health of the patients for a maximal period of one year (Table IV). We found no significant differences in the subjective state of the patients, laboratory data or further examinations in the compared groups of patients in the given period.

Table IV *Classification of patients according to the period of observation after surgical treatment*

Time after operation	Control group	Ukrain group
1 - 3 months	6	2
4 - 6 months	8	3
7 - 9 months	4	2
10 - 12 months	4	3
TOTAL	22	10

In the group receiving Ukrain in the pre- and postoperative periods and subsequent periods of observation, no recurrences or metastases were noted. In one patient of the control group, after two months a cytologically confirmed metastasis to the lymph nodes was found on the operated side above the clavicle. No recurrences were noted in the Ukrain group.

At present clinical monitoring is continued in patients of the two groups in order to evaluate long-term results of treatment of breast cancer with Ukrain.

References

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