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THE MODERN LOOK ON THE PLATINUM-BASED CHEMOTHERAPY EFFECTIVENESS

A. I. Rybin

Odessa National Medical University, Odessa, Ukraine

Rybin A. I., ORCID: 0000-0002-1145-6690, e-mail: Andriy.Rybin@gmail.com

Abstract

The aim of the work is to assess the quality of life in platinum-resistant patients with ovarian cancer, depending on the degree of pharmacoresistance and differentiated use of chemotherapy.

Materials and methods. The study was conducted on the basis of the University Clinic of the Odessa National Medical University during 2014 - 2020 years. 350 patients with adenocarcinoma of the ovaries of III-IV stage were examined, who performed cytoreductive operations.

Results and discussion. It is shown that the initial values on the subscales of the questionnaires EORTC QLQ-C30 and FACT-G in patients classified as different clinical groups were compared. When using a differentiated approach in the treatment of patients with OC, the indicators on the scales of physical (PF), role (RF) and emotional functioning (EF) were significantly improved. In addition, the intensity of nausea (NV) and general weakness

(FA) decreased in patients of groups III and IV. In the case of differentiated use of chemotherapeutic agents with metabolic support, the total score according to the FACT-G questionnaire was 77.8±0.9 points in group III, and 77.9±0.8 points in group IV, which significantly exceeds the received in I and II groups - 72.2±1,2 and 71,6±0,9 points. The described differences were kept throughout the period of catamnestic observation.

Conclusions: The use of a differentiated approach in the treatment of patients with RI significantly improved indicators on the scales of physical (PF), role (RF) and emotional functioning (EF). After treatment, the intensity of nausea (NV) and general weakness (FA) decreased in patients of groups III and IV. The described differences were retained for 12 months after the completion of the course of treatment. Prospects for further research are related to the study of the dynamics of life quality of patients with OC at the subsequent stages of catamnestic observation.

Key words: ovarian cancer; treatment; chemotherapy; platinoresistance; platinorefraction; quality of life

Introduction. Malignant ovarian tumors remain one of the main causes of death in oncogynecological practice. In the world, more than 200000 women are diagnosed with ovarian cancer (OC) every year and 100000 women die of this disease every year. The intravital risk of ovarian cancer is assessed by experts as 1/70 [1- 4].

Most often, ovarian cancer is diagnosed in women aged 55-64 years. OC incidence ranges from 3.1 cases per 100000 women in Japan to 21 cases per 100000 women in Sweden. In general, the highest incidence rates are inherent in the countries of Scandinavia, Germany, Benelux, Great Britain, Canada and the United States. Instead, in Asian countries, OC is much less common, as well as among immigrants from Asian countries in the economically developed countries of Europe and North America. The Hippisley-Cox-Coupland model describes the risk of RI occurrence, according to which two-thirds of cases occur within 2 years in 10% of women with the highest risk of developing RI [5-9]. At the same time, infertility and childlessness, early menarche and late menopause, the use of oral contraceptives, a burdened hereditary history of ovarian and breast tumors, long-term hormone therapy, lactose consumption and occupational hazards are the risk factors associated with the influence of carcinogens and mutagens.

In general, the problem of OC has considerable medical and social significance. Only in recent years, some progress has been made in increasing the five-year survival rate of patients with RI, mainly due to the introduction of effective chemotherapy regimens [10].

However, about 40% of patients are primary-resistant to platinum preparations, which are considered as first-line drugs. Depending on the timing of disease progression distinguish platinosensitive tumors (progress more than 6 months after first-line therapy), platino-resistant (progress within 6 months after first-line therapy) and platinorefractory (progress during first-line chemotherapy with inclusion of platinum preparation) [11-14]. At the same time, the functional assessment of the effect of antitumor therapy in patients with RI on the quality of life until recently was given insufficient attention.

The quality of life (QL) today is considered as one of the most informative indicators characterizing the degree of adaptation of a person to living conditions and the general state of his health and allow to determine the need for medical and psychosocial adaptation. In recent years, the study of health related quality of life, HRQL, has developed as a separate medical science, which has its own research methods, evaluation criteria, scope, etc. It is based on the definition of the World Health Organization (WHO) as an individual correlation of its position in community life in the context of culture and system of values of society with the goals of this individual, its plans, opportunities and degree of general disarrangement [15-19]. That is, a person's perception of his position in life, including physical, mental and social well-being, regardless of the quality of the environment in which he lives, the degree of satisfaction with a specific standard of living and other components of psychological comfort [20-23].

One of the most popular instruments for determining YES in oncological practice is a questionnaire of the European Organization for Research and Cancer Treatment - EORTC QLQ-C30 - developed by the Quality of Life Assessment Group of the European Organization for Research and Treatment of Cancer (EORTC Quality of Life Study Group) [24, 25]. The modern version of the 3rd revision consists of 30 issues and includes 5 functional scales (physical functioning (PF), role functioning (RF), cognitive functioning (CF), emotional functioning (EF) and social functioning (SF); 3 symptomatology scales - weakness (FA), nausea (NV) and pain (PA); as well as 6 additional criteria: sleep disturbance (SL), anorexia (AR), constipation (CO), diarrhea (DI), dyspnea (DY), financial difficulties (FI). Another popular diagnostic tool is a questionnaire for evaluating the functions of an oncological patient, Functional Assessment of Cancer Therapy-General (FACT-G) - developed by D. Gellaetal. [26]. The modern version of FACT-G includes 27 questions and assesses the quality of life on 4 scales: physical, social, emotional functioning and well-being in everyday life.Both questionnaires (EORTC QLQ-C30 and FACT-G) are modular, i.e. include a basic questionnaire to which specific question taking into account this or that type

of tumor or treatment program. However, there is still no study in which to analyze the characteristics of QL in patients with OC with varying degrees of sensitivity to platinum preparations.

The aim of the work is to assess the quality of life in platinum-resistant patients with ovarian cancer, depending on the degree of pharmacoresistance and differentiated use of chemotherapy.

Material and methods of research

The study was conducted on the basis of the University Clinic of the Odessa National Medical University during 2014 - 2022 years. 350 patients with adenocarcinoma of the ovaries of III-IV stage were examined, who performed cytoreductive operations, and of which the following clinical groups were formed: group I (control, n=50) — patients with RI who received standard first-line adjuvant chemotherapy (cisplatin — 75-100 mg/m ^{2} intravenously with hydration and diuresis formed every 3 weeks); Group II (n=100) - patients with probable platinorefraction who received second-line therapy (doxorubicin — 75-100 mg/m^2 intravenously droplets once every three weeks); Group III (n=100) — patients with probable platinoresistance who received drug correction of disregulatory disorders against the background of standard first-line therapy (donators of nitric oxide, detoxicants, antiuricemic agents); Group IV (n=100) — patients with predicted platinosensitivity (standard therapy of the first lines after the previous preventive course: 20 mg dexomethasone for 12 and 6 hours before the administration of platinum preparations, 300 mg cimetidine or 50 mg ranitidine and 50 mg of dimedrol for 30-60 minutes. Examination of patients was carried out in accordance with the requirements of the clinical protocol approved by the order of the Ministry of Health of Ukraine № 554 from 17.09.2007 “On approval of protocols of medical care in the specialty “oncology" ” [1]. Additionally, QL was determined using standard questionnaires EORTC QLQ-C30 and FACT-G [12]. QL was examined 6 and 12 months after the completion of treatment.Determination of the probability of differences between the compared groups was carried out using criterion χ^2, taking into account the Yets amendment for paired comparisons and Bonferoni corrections for multiple comparisons. Statistical processing was carried out using software STATISTICA 13.0 (Dell Stat Soft Inc., USA) [4].

Results and their discussions

It was established that patients of different age groups did not differ, the average age in groups was 55.3±3.9 years. The structure of the groups by stage of OC also did not differ, patients with stage IIIS prevailed - on average there were 64.9% in the total sample (Fig. 1). The clinical picture of the disease was stereotypical. Most patients complained of bloating and

discomfort in the lower abdomen, a feeling of pressure in the bladder and rectum, constipation. Every tenth of the examined woman had vaginal bleeding. Dyspeptic manifestations, shortness of breath, general weakness, fatigue, weight loss of thawed and a feeling of rapid saturation when consuming a small amount of food were frequent. 12.6% of patients had swelling of the lower extremities, 5.4% had signs of ascites. At the same time, 17.4% of patients were not accompanied by subjective manifestations and was diagnosed during ultrasonographic screening.

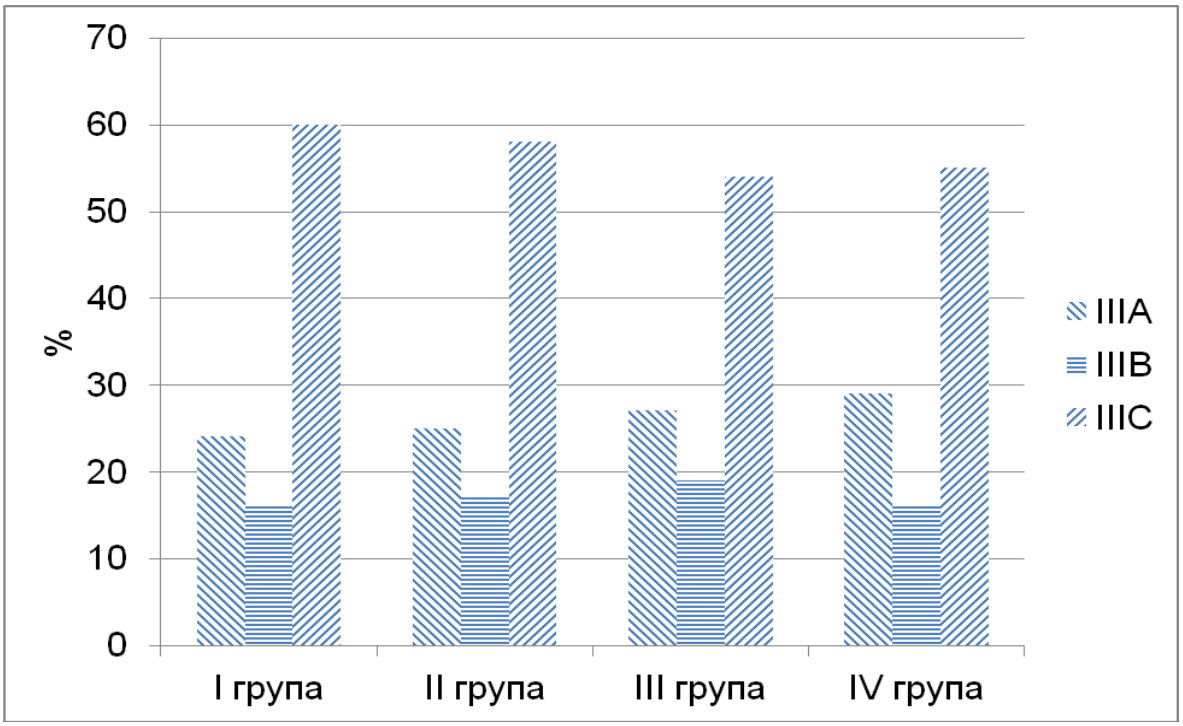

Figure 1 Structure of the studied clinical groups according to the stage of OC

During ultrasound, multilocular dense hyperechoic formations larger than 10 cm and increased intra-ovarian blood flow were determined. In biochemical screening, high figures of CA-125 content were determined in 44.6% of the surveyed, which does not allow to consider this method as quite specific for the needs of early diagnosis of OC.

During the period of treatment in different clinical groups, patients made complaints of nausea, taste disorders, immediately before eating, dizziness, general weakness. 6.0% of patients referred to the control group and 2.0% of patients group IV had visual impairment. In one case, the patient had signs of peripheral polyneuropathy and Lermitt symptom. For the general analysis of blood on the background of therapy with platinum preparations, there were signs of moderate leukopenia, and at least anemia. A frequent occurrence was arterial

hypotension. During treatment, patients of group I and IV also complained of cough, erythematous rash, and extravasates at the injection site.

As for patients of group II, against the background of therapy with doxorubicin, they determined signs of subfebrile, palpitation, thrombocytopenia and leukopenia, nausea, vomiting, signs of stomatitis, diarrhea. At the beginning of treatment, patients of group II noted a change in the color of urine with the appearance of a reddish hue. Common phenomenon was alopecia, darkening of soles and palms, sometimes - palmar erythema, changes in the shape of nails, skin itching and rash. Individual patients determined the phenomena of photophobia and enlarged lacrimation by the type of epiphorus. The least number of subjective complaints during treatment was observed in patients of groups III and IV who received pathogenetically conditioned metabolic support complex.

Further analysis showed that the initial values of the subscales of the questionnaires EORTC QLQ-C30 and FACT-G in patients assigned to different clinical groups were compared (Table 1 and 2). However, during repeated visits at the catamnestic stage, certain differences were determined at the level of QL. When using a differentiated approach in the treatment of patients with OC, the indicators on the scales of physical (PF), role (RF) and emotional functioning (EF) were significantly improved. In addition, the intensity of nausea (NV) and general weakness (FA) decreased in patients of groups III and IV. The described differences were kept throughout the period of catamnestic observation.

Changes in other indicators according to the scale of the questionnaire EORTC QLQ-C30 were fluctuating in nature and, obviously, reflect the heterogeneous structure of the investigated contingent on the adaptation potential and the transfer of chemotherapy. Similar dynamics was observed on the scales of the FACT-G questionnaire (Table 1, 2).

Table 1 - Results of the evaluation of QL by the questionnaire EORTC QLQ-C30 (±M m)

Subscales	Group I (n=50)			Group II (n=100)			Group III (n=100)			Group IV (n=100)		
	Before treatment	6 months after treatment	12 months after treatment	Before treatment	6 months after treatment	12 months after treatment	Before treatment	6 months after treatment	12 months after treatment	Before treatment	6 months after treatment	12 months after treatment
PF	72,2±3,2	77,1±4,3	84,8±3,6	71,9±2,5	79,3±2,4	85,5±2,8	71,4±2,9	85,8±2,3	85,4±1,7	72,5±2,8	87,9±3,1	86,7±1,4
RF	67,4±3,4	75,2±3,8	76,3±3,5	68,3±2,2	80,1±2,9	81,5±2,6	66,7±3,3	85,4±2,2	85,8±2,9	65,9±2,9	86,3±3,2	85,9±3,3
CF	80,1±3,2	87,0±3,2	87,2±3,2	82,2±2,4	85,5±2,5	85,3±3,3	79,8±2,8	86,3±2,5	85,9±1,9	80,6±3,7	85,8±2,9	84,6±2,4
EF	32,7±3,2	63,9±2,9	62,6±3,2	33,9±2,6	66,3±2,3	70,4±2,4	34,1±2,7	70,8±2,2	78,5±1,4	31,5±1,8	71,8±2,4	78,8±2,2
SF	77,7±3,2	81,7±2,5	82,2±3,2	76,2±2,4	81,4±2,4	80,8±2,6	78,2±2,4	82,5±2,4	82,8±1,6	75,3±2,2	81,7±3,2	82,2±3,2
FA	29,3±3,2	33,3±3,2	40,2±3,2	28,7±2,2	34,1±3,4	39,9±1,2	30,1±2,5	41,4±2,4	42,8±2,2	29,9±2,3	42,2±2,2	43,3±1,2
NV	2,1±0,3	4,3±0,4	5,1±0,4	2,1±0,2	6,4±0,3	7,0±0,2	2,4±0,2	6,3±0,2	7,5±0,2	1,9±0,2	6,6±0,2	7,0±0,1
PA	27,3±2,4	34,2±3,2	38,8±3,2	27,5±2,2	33,3±2,3	37,7±2,1	25,6±1,5	36,3±1,2	39,6±1,8	25,9±1,2	35,5±1,4	38,1±1,4
SL	18,9±2,8	22,2±3,2	23,2±3,2	18,5±2,4	21,7±2,6	21,5±2,2	16,7±1,7	21,1±1,1	22,7±1,2	17,1±2,4	20,6±1,3	21,9±1,1
AR	14,0±2,2	19,3±2,8	20,8±3,2	14,4±2,4	18,8±2,4	19,9±2,4	14,6±2,3	18,5±1,6	18,9±1,2	13,8±2,6	19,7±2,4	21,2±1,6
CO	18,1±1,2	9,3±3,2	7,1±1,2	17,7±1,6	10,5±1,4	9,9±1,6	16,9±1,4	10,4±1,2	6,1±1,2	17,9±1,6	10,2±1,2	9,8±1,4
DI	4,2±0,3	2,1±0,3	1,9±0,3	4,3±0,3	1,9±0,2	1,8±0,2	4,0±0,2	2,0±0,2	1,9±0,2	3,9±0,3	1,9±0,1	1,9±0,2
FI	39,0±3,4	40,8±2,9	39,5±2,6	38,3±2,8	40,2±2,2	39,5±1,8	39,0±2,2	40,8±1,7	39,9±1,9	37,7±2,1	40,9±1,7	36,8±3,3

Table 2 - Results of the evaluation of QL on the FACT-G questionnaire

Subscales	Group I (n=50)			Group II (n=100)			Group III (n=100)			Group IV (n=100)		
	Before treatment	6 months after treatment	12 months after treatment	Before treatment	6 months after treatment	12 months after treatment	Before treatment	6 months after treatment	12 months after treatment	Before treatment	6 months after treatment	12 months after treatment
PWB	17,8±1,1	18,6±1,2	17,9±1,2	17,5±0,9	18,3±0,8	17,5±0,9	16,9±0,8	18,8±0,9	19,2±0,8	17,3±0,9	19,3±0,9	19,5±0,9
EWB	19,6±1,3	19,8±1,4	19,9±1,2	18,6±0,9	20,3±0,9	18,6±0,9	19,3±0,9	20,9±0,9	20,7±0,8	18,9±0,8	21,1±0,9	20,9±0,8
FWB	19,4±1,4	20,3±1,6	19,3±1,6	18,8±0,8	20,5±0,9	18,8±0,8	19,0±1,1	20,5±0,8	21,1±0,9	19,5±0,9	20,7±0,9	20,5±0,9
SWB	14,8±1,2	14,9±1,2	15,0±1,2	15,3±1,1	16,6±0,9	16,7±1,1	15,1±0,9	16,9±0,9	16,8±0,9	15,0±0,8	17,2±0,9	17,0±0,8
Total	71,5±1,4	73,6±1,3	72,2±1,2	70,2±0,9	75,7±0,8	71,6±0,9	70,3±0,9	77,1±0,9	77,8±0,9	70,8±0,8	78,3±0,8	77,9±0,8

Note: * - the differences with the baseline are reliable ($p<0.05$)

With undifferentiated use of chemotherapeutic agents without metabolic support, the growth of EWB subscale was from 19.6±1.3 to 19.9±1.4 points in the first group and from 18.6±0.9 to 19.3 ±0.9 points - in the second group, whereas in the III group the same indicator one year after treatment was 20.7±0.8 points, and in the IV group - 20.9±0.8 points. In the case of differentiated use of chemotherapeutic agents with metabolic support, the total score according to the FACT-G questionnaire was 77.8± 0.9 points in group III, and 77.9± 0.8 points in group IV, which significantly exceeds the received in groups I and II - 72.2± 1,2 and 71,6± 0,9 points. In general, the analysis of the dynamics of indicators of LI on different scales indicates that the differentiated approach to the appointment of chemotherapy of patients with RI III-IV stage allows to improve physical and emotional functioning, reduces the severity of side effects, while the period of preservation of positive clinical effect on QL is kept for at least 12 months.

Conclusions

1. Application of the differentiated approach in the treatment of patients with OC significantly improved the indicators on the scales of physical (PF), role (RF) and emotional functioning (EF).

2. After treatment, the intensity of nausea (NV) and general weakness (FA) decreased in patients of groups III and IV.

3. The described differences were retained for 12 months after the completion of the course of treatment.

4. Prospects for further research are related to the study of the dynamics of life quality of patients with OC at the subsequent stages of catamnestic observation.

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