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Quality of life in patients with advanced ovarian cancer under personalised treatment: the impact of HIPEC

V. E. Maksymovskyi, A. I. Rybin, V. I. Zamyshlyak

Odessa National Medical University, Odessa, Ukraine

V.E. Maksymovskyi ORCID: 0000-0001-5084-3290, e-mail: maxidoc@gmail.com
A.I. Rybin, ORCID: 0000-0002-1145-6690, e-mail: Andriy.Rybin@gmail.com
V.I. Zamyshlyak, ORCID: 0009-0001-1588-182X e-mail: vikazamishlyak@gmail.com

Abstract

Ovarian cancer ranks first among gynaecological cancers in terms of mortality, mainly due to late detection and high recurrence rates. The standard treatment for late stages remains cytoreductive surgery combined with systemic chemotherapy. However, survival and quality of life for patients receiving traditional treatment remain unsatisfactory. *The aim* of the study was to analyse the quality of life of patients with primary advanced ovarian cancer depending on the type of personalised management before the start of specialised treatment, after cytoreductive surgery in the early and late postoperative periods, during chemotherapy and after the end of specialised treatment.

Materials and methods. A comparative analysis of the results of clinical examination and treatment of 74 patients with primary serous adenocarcinoma of the ovary, stages III–IV (FIGO 2015), was performed: Group IA – patients with primary ovarian cancer who underwent

primary cytoreductive surgery (PDS) + adjuvant chemotherapy (ACT) – 43 patients; Group IB – patients with primary ovarian cancer who underwent neoadjuvant chemotherapy (NACT) + interval cytoreductive surgery (IDS) + adjuvant chemotherapy – 16 patients; IC group – patients with primary ovarian cancer who underwent primary cytoreductive surgery (PDS) + hyperthermic intraperitoneal chemotherapy (HIPEC) + adjuvant chemotherapy (ACT) – 15 patients. The quality of life of patients with advanced ovarian cancer was also assessed using special questionnaires EORTC QLQ-C30 and QLQ-OV28. *Results and discussion.* In the early postoperative period, when comparing patients in groups IA (PDS + ACT) and IC (PDS + HIPEC + ACT) using the Mann-Whitney test, a significant difference was obtained on the pain scales (Ukr. = 229, Uemp. = 208 Ukr.> Uemp. at a significance level of p = 0.05), nausea and vomiting (Ukr. = 229, Uemp. = 137 Ukr. > Uemp. at a significance level of p = 0.05), stool retention (Ukr. = 229, Uemp. = 189 Ukr. > Uemp. at a significance level of p = 0.05) and gastrointestinal symptoms (Ukr. = 229, Uemp. = 191 Ukr. > Uemp. at a significance level of p = 0.05). A significant deterioration in the quality of life of patients who underwent hyperthermic intraperitoneal chemoperfusion due to an increase in pain, nausea and vomiting scores, stool retention and gastrointestinal symptoms among patients with primary ovarian cancer was observed only in the early postoperative period. In the subsequent stages of special treatment and after its completion, no significant deterioration in the quality of life among patients who underwent hyperthermic intraperitoneal chemoperfusion was observed compared with other groups.

Conclusions. According to the authors, patients with primary ovarian cancer in the early postoperative period showed a marked decrease in physical functioning, pain intensity, general well-being and role functioning scales due to their physical condition. Subsequently, there was a tendency towards a gradual increase in physical health indicators in all groups of patients with primary ovarian cancer in the late postoperative period and after adjuvant chemotherapy. At the same time, there was a moderate decrease in the scores of the scales of life activity, role functioning due to emotional state, social functioning and mental health during special treatment and partial recovery of these scores after the end of special treatment. Hyperthermic intraperitoneal chemoperfusion was accompanied by a decrease in physical health scales in patients, most significantly in the early postoperative period. When assessing the quality of life of patients with primary ovarian cancer using the EORTC QLQ-C30 and QLQ-OV28 questionnaires, the results indicate no statistically significant negative effect of hyperthermic intraperitoneal chemoperfusion at all stages of treatment.

Keywords: ovarian cancer; carcinomatosis; surgical treatment; quality of life; chemotherapy; HIPEC.

Резюме. Рак яєчників посідає провідне місце серед онкогінекологічних захворювань за рівнем смертності, що обумовлено, передусім, пізнім виявленням та високою частотою рецидивів. Стандартним методом лікування на пізніх стадіях залишається циторедуктивна операція у поєднанні з системною хіміотерапією. Проте виживаність та якість життя пацієнток при традиційному підході все ще залишаються незадовільними. *Метою* дослідження був аналіз якості життя хворих на первинний розповсюджений рак яєчників в залежності від варіанту персоніфікованого менеджменту до початку спеціального лікування, після виконання циторедуктивної операції у ранньому та пізньому післяопераційному періодах, на етапі хіміотерапевтичного лікування та після закінчення спеціального лікування.

Матеріал і методи дослідження. Проведений порівняльний аналіз результатів клінічного обстеження та лікування 74 хворих на первинну серозну аденокарциному яєчника III–IV стадій (FIGO 2015): IA група - хворі на первинний рак яєчників, яким було проведено лікування в обсязі первинного циторедуктивного оперативного втручання (PDS) + ад'ювантна хіміотерапія (ACT) – 43 хворих; IB група – хворі на первинний рак яєчників, яким було проведено лікування в обсязі неоад'ювантноїхіміотерапії (NACT) + інтервальне циторедуктивне оперативне втручання (IDS) + ад'ювантна хіміотерапія – 16 хворих; IC група - хворі на первинний рак яєчників, яким було проведено лікування в обсязі первинного циторедуктивного оперативного втручання (PDS) + гіпертермічна інтраперітонеальна хіміоперфузія (HIPEC) + ад'ювантна хіміотерапія (ACT) – 15 пацієнток. Якість життя хворих на розповсюджений рак яєчників була оцінена також за допомогою спеціальних опитувальників EORTC QLQ-C30 і QLQ-OV28. *Результати та їх обговорення.* У ранньому післяопераційному періоді при порівнянні хворих груп IA (PDS + ACT) та IC (PDS + HIPEC + ACT) за допомогою тесту Mann-Whitney отримано достовірну різницю за шкалами болю (Uкр. = 229, Uемп. = 208 Uкр. > Uемп. при рівні значущості p = 0,05), нудоти та блювання (Uкр. = 229, Uемп. = 137 Uкр. > Uемп. при рівні значущості p = 0,05), затримки стулу (Uкр. = 229, Uемп. = 189 Uкр. > Uемп. при рівні значущості p = 0,05) та гастроінтестинальних симптомів (Uкр. = 229, Uемп. = 191 Uкр. > Uемп. при рівні значущості p = 0,05). Достовірне погіршення якості життя хворих, які перенесли гіпертермічну внутрішньочеревну хіміоперфузію за рахунок підвищення показників шкал болю, нудоти та блювання, затримки стулу та гастроінтестинальних

симптомів серед пацієнток з первинним раком яєчників спостерігалось лише у ранньому післяопераційному періоді. На подальших етапах спеціального лікування та після його завершення достовірного погіршення якості життя серед хворих, які перенесли гіпертермічну внутрішньочеревну хіміоперфузію, у порівнянні з іншими групами не спостерігалось. *Висновки.* У хворих на первинний рак яєчників у ранньому післяопераційному періоді спостерігалось виражене зниження показників шкал фізичного функціонування, інтенсивності болю, загального самопочуття та рольового функціонування, обумовленого фізичним станом. У подальшому наявна тенденція до поступового збільшення показників фізичного компонента здоров'я в усіх групах хворих на первинний рак яєчників у пізньому післяопераційному періоді та після проведення ад'ювантної хіміотерапії. Одночасно спостерігалось помірне зниження показників шкал життєвої активності, рольового функціонування, обумовленого емоційним станом, соціального функціонування та психічного здоров'я протягом спеціального лікування та часткове відновлення цих показників після закінчення спеціального лікування. Виконання гіпертермічної внутрішньочеревної хіміоперфузії супроводжувалось зниженням показників шкал фізичного компонента здоров'я у хворих, найбільше – у ранньому післяопераційному періоді. При оцінці якості життя хворих на первинний рак яєчників за допомогою анкет EORTC QLQ-C30 і QLQ-OV28, отримані результати свідчать про відсутність статистично значущого негативного ефекту гіпертермічної внутрішньочеревної хіміоперфузії на всіх етапах лікування.

Ключові слова: рак яєчників; канцероматоз; хірургічне лікування; якість життя; хіміотерапія; HIPEC.

Introduction. Ovarian cancer ranks first among gynaecological cancers in terms of mortality, mainly due to late detection and high recurrence rates. The standard treatment for advanced stages remains cytoreductive surgery combined with systemic chemotherapy. However, survival and quality of life (QOL) of patients treated with the traditional approach remain unsatisfactory [1, 2, 4, 6, 7, 12].

In recent years, increasing attention has been paid to the use of hyperthermic intraperitoneal chemotherapy (HIPEC) as an adjunct to cytoreductive surgery. The HIPEC method involves the intraperitoneal administration of chemotherapeutic agents in a heated state (42–43 °C), which provides both a direct cytotoxic effect and increased permeability of tumour cells to chemotherapeutic agents [3, 5, 9, 14, 16].

Studies conducted over the last decade, in particular the results of Van Driel et al. (2018), have demonstrated a significant improvement in recurrence-free survival with HIPEC in patients with primary peritoneal ovarian carcinoma. In addition, increasing attention has been paid to quality of life parameters as an important criterion for evaluating treatment efficacy. Studies conducted in Europe and North America have shown that although HIPEC is associated with an increased rate of postoperative complications, in the long term, the QoL of patients does not deteriorate and in some cases even improves [8, 10, 11, 17].

The study found that after an initial decline in physical functioning and overall well-being in the first months after HIPEC, most patients showed a return to baseline or better QoL levels within 6–12 months. Other authors point to improved social functioning and reduced anxiety levels in patients who underwent HIPEC compared to the control group [4-7, 16].

Despite the positive results, some publications highlight conflicting data on the long-term impact of HIPEC on quality of life, which necessitates further prospective studies, especially using standardised questionnaires such as EORTC QLQ-C30 and QLQ-OV28 [5, 6, 11, 15].

Thus, the literature indicates that the inclusion of HIPEC in the standard treatment of ovarian cancer is promising, with potential benefits in terms of both survival and quality of life, requiring further study to clarify the indications, timing of the procedure, and assessment of its impact on QoL in the short and long term.

The aim of the study was to analyse the quality of life of patients with primary advanced ovarian cancer depending on the type of personalised management before the start of specialised treatment, after cytoreductive surgery in the early and late postoperative periods, during chemotherapy and after the end of specialised treatment.

Object and methods of the study. A comparative analysis of the results of clinical examination and treatment of 74 patients with primary serous adenocarcinoma of the ovary, stages III–IV (FIGO 2015), who were treated at the University Clinic of Odessa National Medical University, was performed:

– Group IA – patients with primary ovarian cancer who underwent primary cytoreductive surgery (PDS) + adjuvant chemotherapy (ACT) – 43 patients;

– Group II – patients with primary ovarian cancer who underwent neoadjuvant chemotherapy (NACT) + interval cytoreductive surgery (IDS) + adjuvant chemotherapy – 16 patients;

– IC group – patients with primary ovarian cancer who underwent primary cytoreductive surgery (PDS) + hyperthermic intraperitoneal chemotherapy (HIPEC) + adjuvant chemotherapy (ACT) – 15 patients.

The average age of patients with newly diagnosed ovarian cancer was (58± 11.8) years (IA (PDS + ACT) group – (57.7± 12.0) years, IB (NACT + IDS + ACT) group – (60.3± 10.7) years, and in the IC (PDS + HIPEC + ACT) group – 59.4±9.1 years. Clinical, anamnestic, laboratory and instrumental examination of patients was carried out in accordance with the order of the Ministry of Health of Ukraine No. 554 of 17.09.2007 and the recommendations of the National Comprehensive Cancer Network, the European Society for Medical Oncology, European Society of Surgical Oncology and European Society of Gynaecological Oncology in accordance with the order of the Ministry of Health No. 1422 dated 29 December 2016.

During preoperative and intraoperative staging, the presence of ascites, peritoneal and omentum involvement, lymph node involvement, distant metastases and invasion of major vessels, and involvement of the digestive and urinary systems were determined to characterise the extent of the tumour process. The statistical homogeneity of the groups was determined for each indicator ($p > 0.05$).

The quality of life of patients with advanced ovarian cancer was also assessed using special questionnaires EORTC QLQ-C30 and QLQ-OV28. Statistical data processing was performed using methods of variational statistics with the use of the STATISTICA 13.0 programme and Microsoft® Excel® 2010.

Results and discussion. The presence of a malignant process, the location of the lesions and the special treatment performed have a significant impact on the quality of life of patients with ovarian cancer. In particular, abdominal (gastrointestinal) symptoms are specific to patients with ovarian cancer and can significantly reduce their quality of life. These symptoms include bloating, pain or cramps, dyspeptic symptoms and other digestive disorders. All of the above may also occur as a result of special treatment for ovarian cancer. Urological and gynaecological symptoms are less common in ovarian cancer, but they can often be caused by treatment. The most common of these are frequent urination and vaginal dryness. The most common side effects of chemotherapy for ovarian cancer are nausea and vomiting, poor appetite, alopecia, peripheral neuropathy, including numbness and weakness in the limbs, other sensory changes, skin symptoms, and muscle pain, which can also be assessed using the QLQ-C30 questionnaire.

In women of reproductive age, both surgical treatment and chemotherapy can cause early menopause. These patients experience symptoms of menopause caused by hormonal

depletion. A negative body image is also characteristic of ovarian cancer patients. Patients may feel less attractive and dissatisfied with their body or appearance. The quality of life of ovarian cancer patients may also be affected by negative changes in sexuality, which are defined by a decrease in interest in sex, actual sexual activity, and feelings of pleasure. Therefore, the assessment of the quality of life of ovarian cancer patients includes an analysis of the presence, severity, and frequency of all these symptoms. All data obtained from the EORTC QLQ-C30 and QLQ-OV28 questionnaires were analysed in accordance with the EORTC Group's data processing recommendations.

Each patient with peritoneal carcinomatosis who underwent HIPEC was assessed preoperatively using the Eastern Cooperative Oncology Group (ECOG) scale, the Karnofsky scale and the American Society of Anaesthesiologists (ASA) scale. The determination of the peritoneal carcinomatosis index (PCI) in the preoperative period using intrascopic examination methods played an important role. When comparing the incidence of postoperative complications of II–IV severity according to Clavien-Dindo among patients with ECOG 0, ECOG 1 and ECOG 2 statuses, $\chi 2 = 6.295$, $p = 0.043$. When comparing the incidence of postoperative complications among patients with a Karnofsky score of 100–90%, 80–70% and 60–50%, $\chi 2 = 6.988$; $p = 0.031$. When comparing the incidence of postoperative complications among patients with ASA I–IV, $\chi 2 = 8.126$; $p = 0.044$. Therefore, assessment using the ECOG scale, the Karnofsky scale and the ASA scale can be recommended as one of the preoperative criteria for selecting patients for CRS + HIPEC. Patients with an ECOG score of 0–1, 100–70% on the Karnofsky scale and ASA I–III are better candidates for CRS + HIPEC, as their initial somatic status allows them to undergo such surgical interventions with a lower probability of postoperative complications. Patient age < 65 years can also be included in the preoperative selection criteria for CRS + HIPEC ($p = 0.031$). However, this criterion cannot be considered absolute, and the somatic status of each elderly patient must be assessed individually.

Taking into account the possible depth of penetration of cytostatic drugs according to other studies, the use of HIPEC is pathogenetically justified when achieving CC 0 and CC 1 cytoreduction. Therefore, in the final assessment of the completeness of cytoreduction after removal of all resectable tumour mass, the advisability of performing HIPEC becomes clear. Thus, the absolute criterion for selecting patients for HIPEC is the achievement of CR 0–1. An important criterion for deciding on the advisability of performing NIR is the patient's RSI, since a high RSI is associated with a lower percentage of CR 0–CR 1 cytoreductions. When comparing the frequency of achieving CC 0–1 in patients with PCI < 10, 10 < PCI <20 and PCI >20, $\chi 2 = 7.359$; $p = 0.026$.

The average results of the EORTC QLQ-C30 and QLQ-OV28 questionnaires for all groups of patients with primary ovarian cancer, which were conducted before special treatment, 3 days after surgery, 20 days after surgery, before the fourth cycle of chemotherapy and 1 month after completion of chemotherapy (for group IB (NACTxml-ph-0000@deepl.internal IDS xml-ph-0001@deepl.internal ACT) after completion of chemotherapy (for group IB (NACT + IDS + ACT), an additional questionnaire was conducted after neoadjuvant chemotherapy), are presented in Figures 1–5.

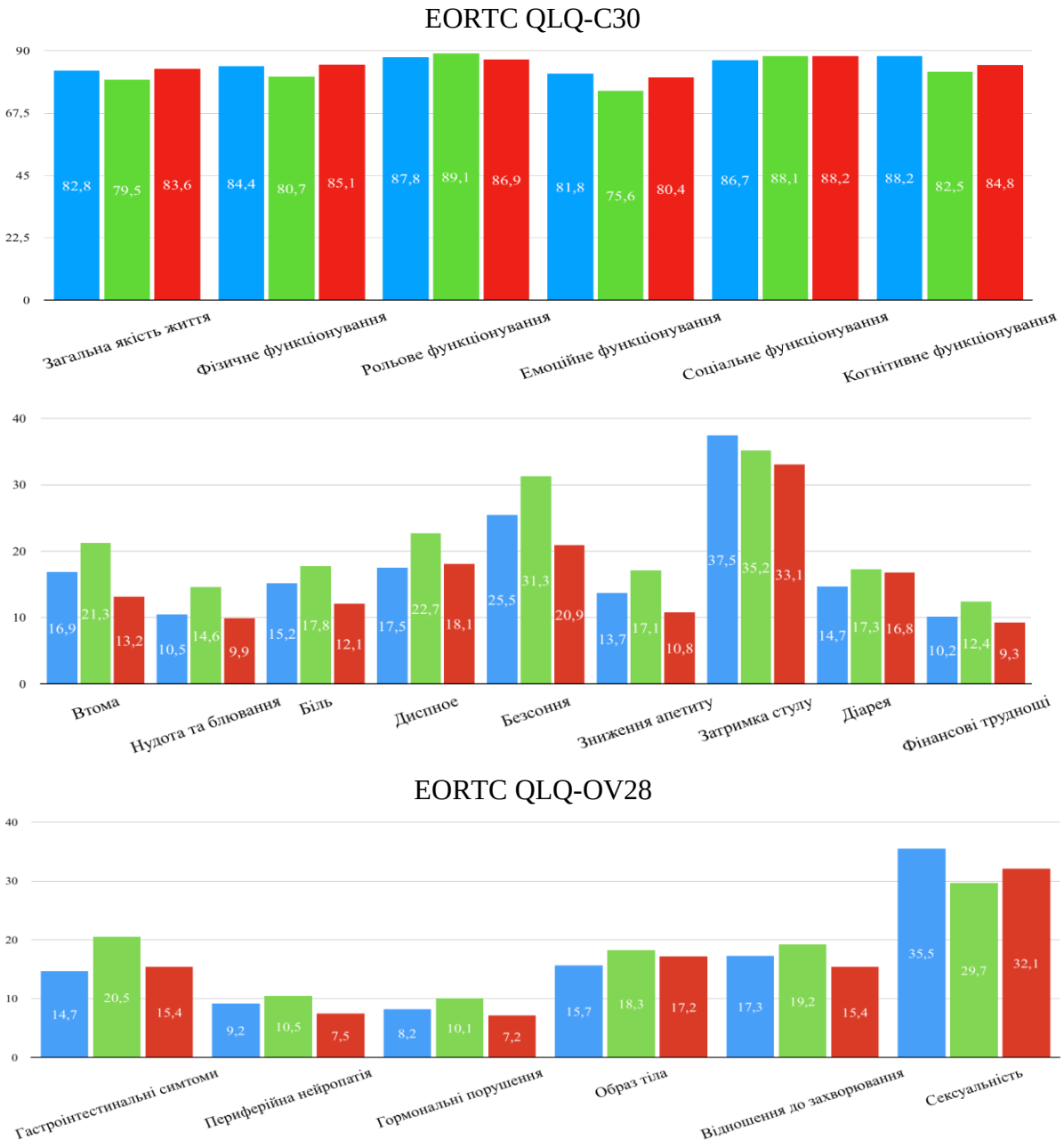
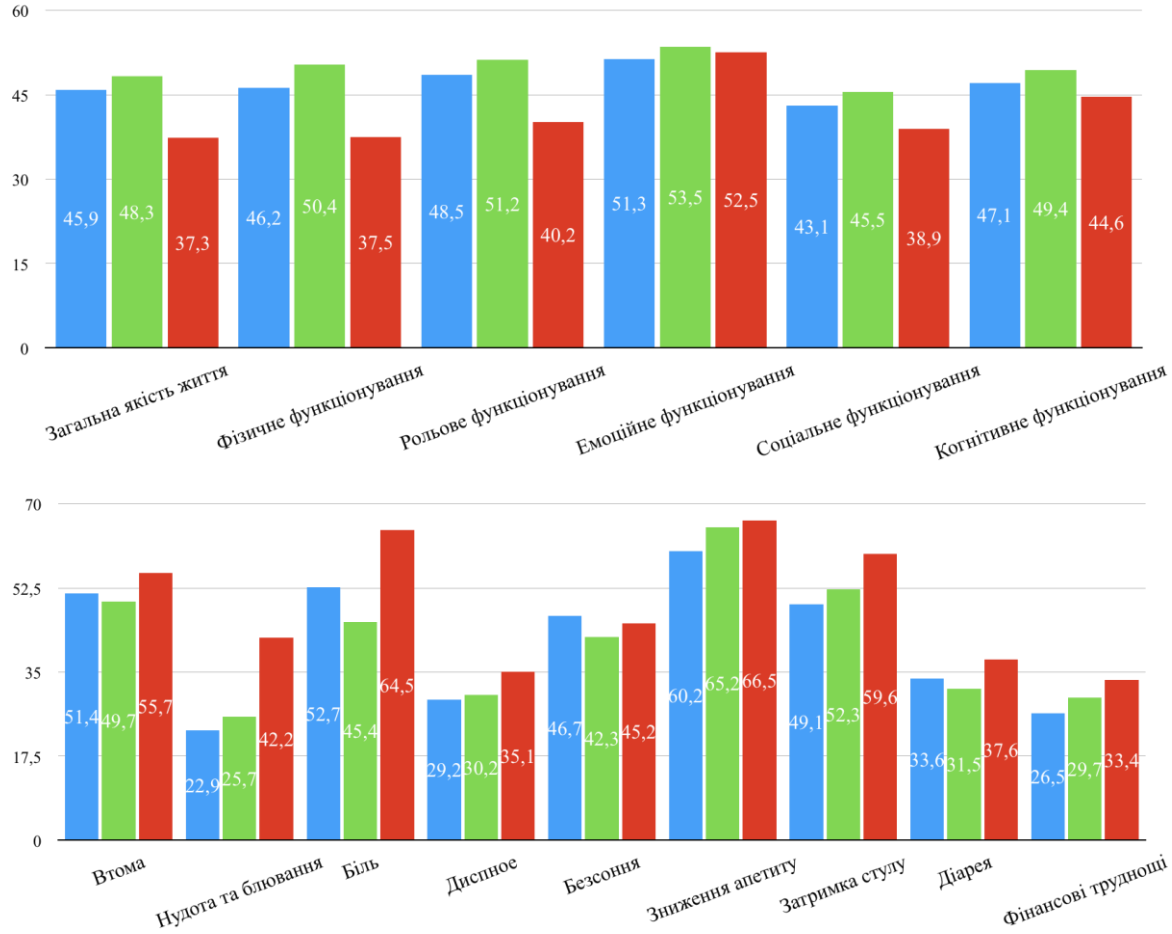


Fig. 1. EORTC QLQ-C30 and QLQ-OV28 scores in patients in groups IA (PDS + ACT) – blue, IB (NACT + IDS + ACT) – green, and IC (PDS + HIPEC + ACT) – red, before special treatment

EORTC QLQ-C30



EORTC QLQ-OV28

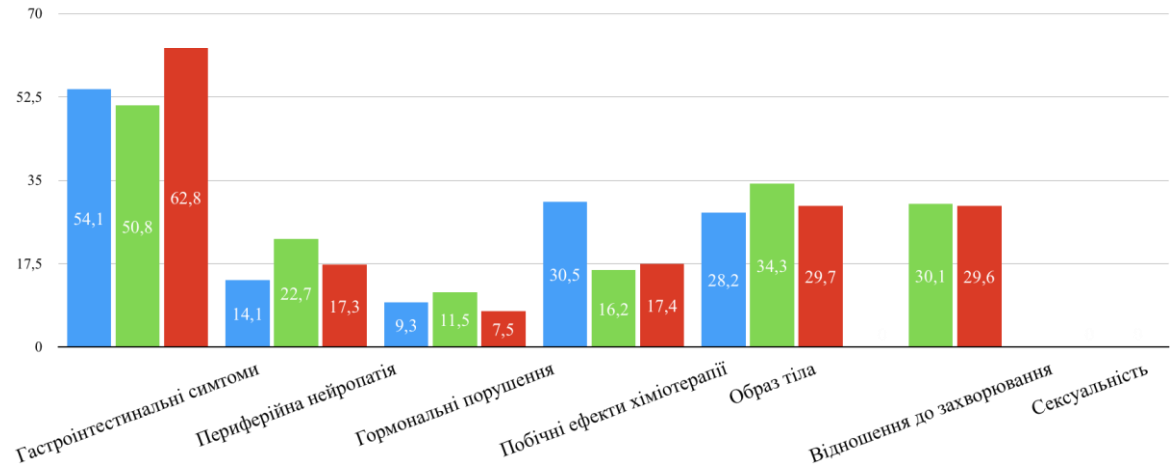
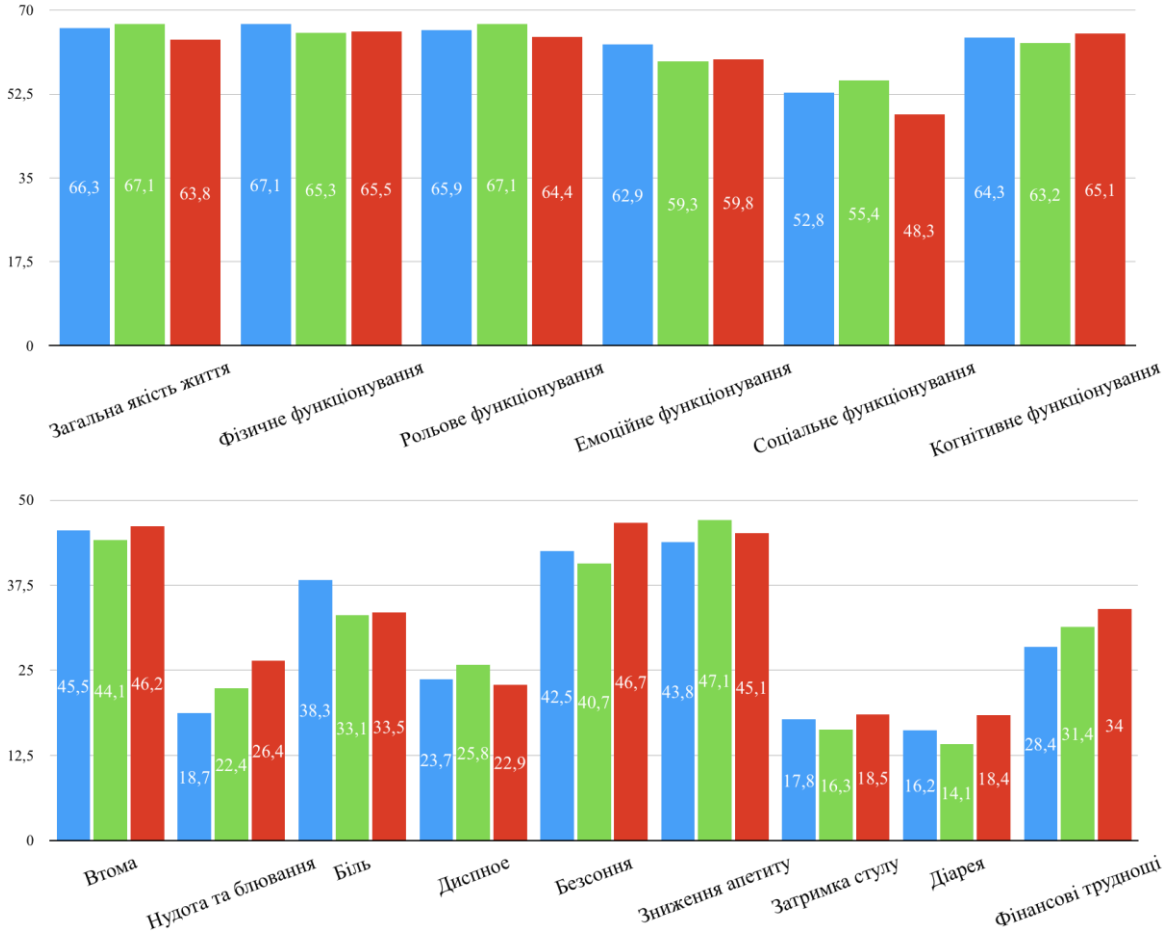


Fig. 2. EORTC QLQ-C30 and QLQ-OV28 scores in patients in groups IA (PDS + ACT) – blue, IB (NACT + IDS + ACT) – green, and IC (PDS + HIPEC + ACT) – red, 3 days after surgical treatment

EORTC QLQ-C30



EORTC QLQ-OV28

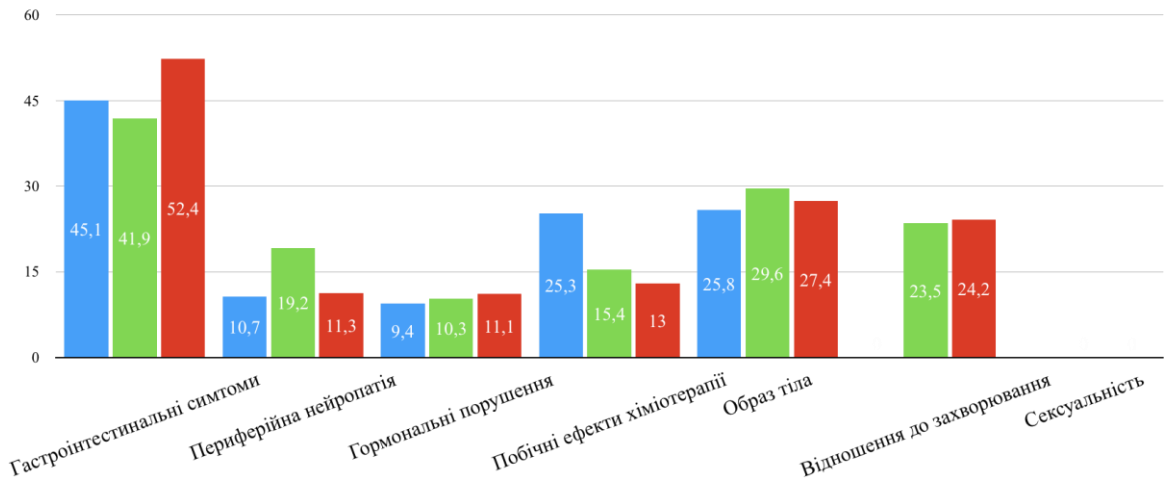
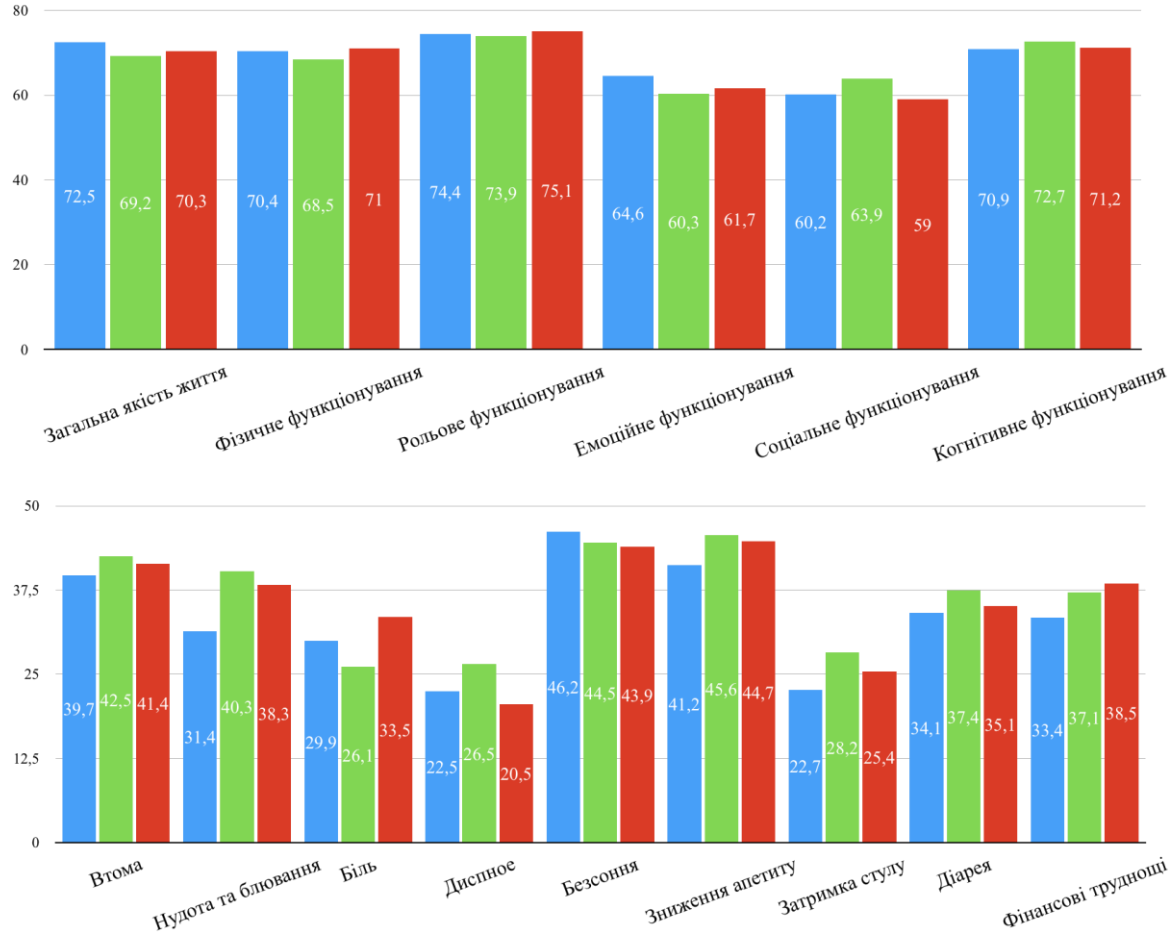


Fig. 3. EORTC QLQ-C30 and QLQ-OV28 scores in patients in groups IA (PDS + ACT) – blue, IB (NACT + IDS + ACT) – green, and IC (PDS + HIPEC + ACT) – red, 20 days after surgical treatment

EORTC QLQ-C30



EORTC QLQ-OV28

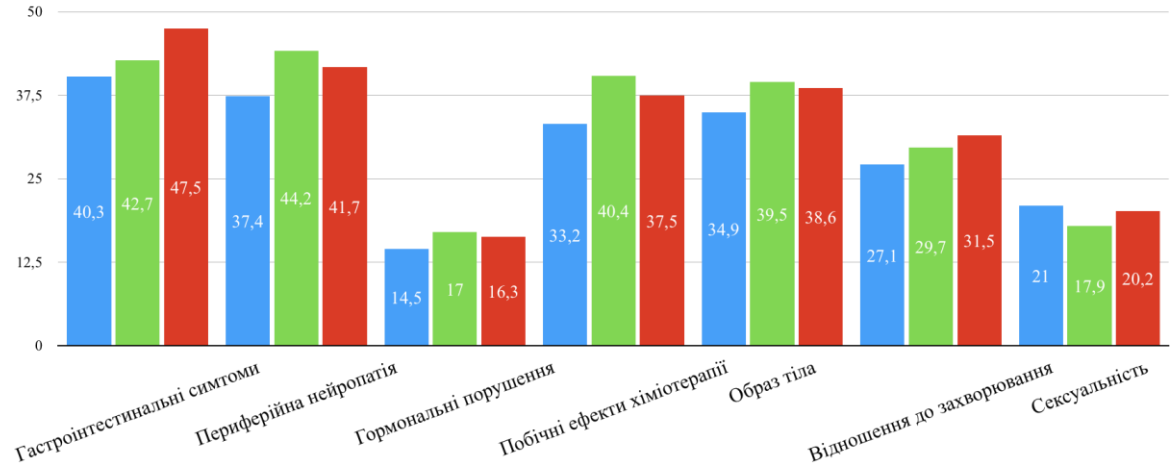
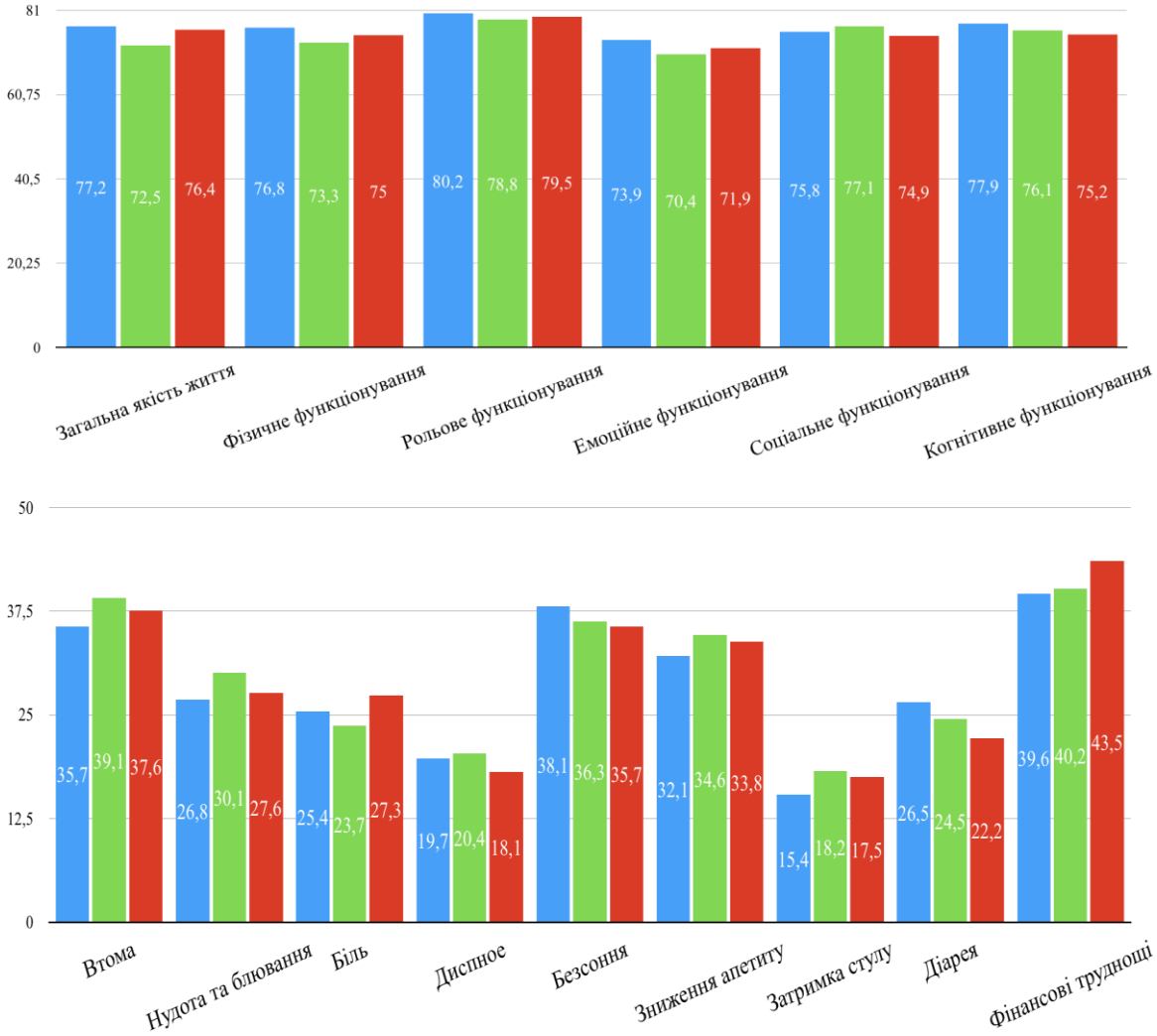


Fig. 4. EORTC QLQ-C30 and QLQ-OV28 scores in patients in groups IA (PDS + ACT) – blue, IB (NACT + IDS + ACT) – green, and IC (PDS + HIPEC + ACT) – red, after 3 courses of ACT

EORTC QLQ-C30



EORTC QLQ-OV28

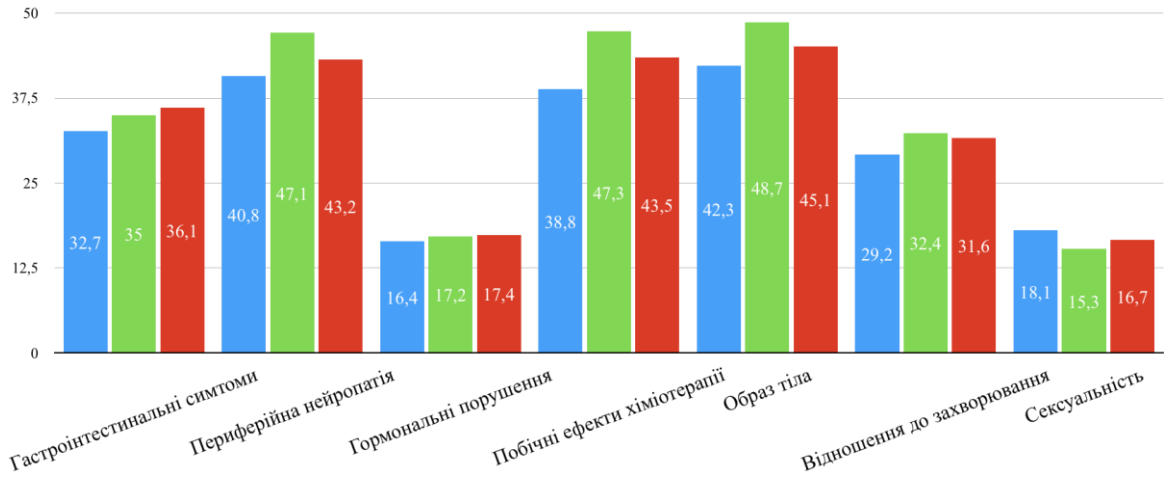


Fig. 5. EORTC QLQ-C30 and QLQ-OV28 scores in patients in groups IA (PDS + ACT) – blue, IB (NACT + IDS + ACT) – green, and IC (PDS + HIPEC + ACT) – red, one month after completion of ACT

For primary ovarian cancer, functional and symptomatic scales were compared, as well as the overall quality of life index using the Mann-Whitney test. There were no statistically significant differences in the functional and symptomatic scales and overall quality of life scores among all groups in primary ovarian cancer before the start of specialised treatment ($p > 0.05$).

In the early postoperative period, when comparing patients in groups IA (PDS + ACT) and IC (PDS + NIPES + ACT) using the Mann-Whitney test, a significant difference was obtained on the pain scales (Ukr. = 229, Uemp. = 208 Ukr. > Uemp. at a significance level of $p = 0.05$), nausea and vomiting (Ukr. = 229, Uemp. = 137 Ukr. > Uemp. at a significance level of $p = 0.05$), stool retention (Ukr. = 229, Uemp. = 189 Ukr. > Uemp. at a significance level of $p = 0.05$) and gastrointestinal symptoms (Ukr. = 229, Uemp. = 191 Ukr. > Uemp. at a significance level of $p = 0.05$).

When comparing the indicators of functional scales, other symptom scales and quality of life indicators, the difference between the groups is statistically insignificant (Ukr.< Uemp. at a significance level of $p = 0.05$). Further comparison of all groups of patients with primary ovarian cancer using the Mann-Whitney test showed no significant difference in the indicators of functional and symptomatic scales and the indicator of overall quality of life in the late postoperative period, after the fourth course of adjuvant chemotherapy and 1 month after completion of adjuvant chemotherapy. after completion of adjuvant chemotherapy (Ukr.< Uemp. at a significance level of $p= 0.05$).

Thus, a significant deterioration in the quality of life of patients who underwent hyperthermic intraperitoneal chemoperfusion due to an increase in pain, nausea and vomiting, constipation and gastrointestinal symptoms among patients with primary ovarian cancer was observed only in the early postoperative period. In the subsequent stages of special treatment and after its completion, no significant deterioration in the quality of life among patients who underwent hyperthermic intraperitoneal chemoperfusion was observed compared to other groups.

Conclusions

1. A significant deterioration in the quality of life of patients who underwent hyperthermic intraperitoneal chemoperfusion due to increased pain, nausea and vomiting, constipation and gastrointestinal symptoms among patients with primary ovarian cancer was observed only in the early postoperative period.

2. In the subsequent stages of special treatment and after its completion, no significant deterioration in the quality of life among patients who underwent hyperthermic intraperitoneal chemoperfusion was observed compared to other groups.

3. Hyperthermic intraperitoneal chemoperfusion was accompanied by a decrease in physical health scores in patients, most significantly in the early postoperative period.

4. When assessing the quality of life of patients with primary ovarian cancer using the EORTC QLQ-C30 and QLQ-OV28 questionnaires, the results indicate no statistically significant negative effect of hyperthermic intraperitoneal chemoperfusion at all stages of treatment.

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