

ORIGINAL ARTICLE

# PRESEPSIN AS A MARKER OF SEPSIS IN ONCOLOGICAL PATIENTS AFTER SURGICAL INTERVENTIONS

N. K. Guskova<sup>1✉</sup>, A. A. Morozova<sup>1</sup>, D. A. Rozenko<sup>1</sup>, A. V. Alyoshkina<sup>1</sup>, A. M. Skopintsev<sup>1</sup>,  
O. N. Selyutina<sup>1</sup>, N. V. Golomeeva<sup>1</sup>, E. A. Guskova<sup>2</sup>, A. K. Donskaya<sup>1</sup>, I. V. Tselishcheva<sup>1</sup>,  
A. S. Nozdricheva<sup>1</sup>

1. National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation

2. Da Vinci Clinical and Diagnostic Center, Rostov-on-Don, Russian Federation

✉ guskova.nailya@mail.ru

## ABSTRACT

**Purpose of the study.** Analysis of the possibility of using presepsin in the early diagnosis of sepsis in cancer patients after extensive surgical interventions for tumors of the thoraco-abdominal localization.

**Materials and methods.** The study included 27 people: 10 healthy individuals (control) and 17 patients who received surgical treatment at the National Medical Research Center of Oncology for malignant neoplasms of thoraco-abdominal localization. In the blood of all patients, studies of sepsis markers were performed: presepsin (P-SEP), highly sensitive CRP (hsCRP) (PATHFAST, Japan), procalcitonin (PCT), interleukin-6 (IL6) (Cobas e 411, Germany), as well as lactate, total leukocyte count (WBC) with a leukocyte formula, a blood culture test for suspected septic complications included in a routine examination. The studies were carried out before and on the 2nd day after the operation. Data were assessed by comparing P-SEP levels with hsCRP, PCT, IL6, lactate, WBC, blood culture test results, and the clinical status of patients. Depending on the data obtained, 2 groups were distinguished: I – patients with confirmed sepsis (3 people), II – without sepsis (14 people). Statistical processing was performed using STATISTICA 13.0.

**Results.** In the control group, the level of P-SEP was  $182.7 \pm 11.9$  pg/ml. In patients before surgery, the marker values were  $213.7 \pm 47.7$  pg/ml, which did not differ statistically from the control data and did not go beyond the reference values, as did the content of PCT, hsCRP, IL6. On the 2nd day after surgery, all patients showed unidirectional changes, characterized by an increase in the levels of the studied parameters, but with varying degrees of intensity. The most significant was the increase in the concentration of presepsin. At the same time, it was noted that the level of presepsin on the 2nd day after surgery in patients of group I patients with confirmed sepsis averaged  $2577.5 \pm 1762.5$  pg/ml with a maximum level 4340.0 pg/ml, and in group II with in the absence of confirmed bacteremia, there was an increase in the level of presepsin 1205.0 pg/ml. The data obtained correlated with the dynamics of changes in the concentration of other sepsis markers – hsCRP, PCT, IL6. Thus, the study of the level of presepsin, along with widely used markers – hsCRP, PCT, IL6, allows diagnosing sepsis in the early postoperative period in cancer patients.

**Conclusion.** In patients with malignant neoplasms of thoracoabdominal localization, changes in the levels of sepsis markers in the early postoperative period can be used as a basis for prescribing antibiotic therapy. Presepsin may be recommended for use as an early marker of sepsis in patients with oncological pathology.

## Keywords:

sepsis, sepsis markers, presepsin, surgical interventions, malignant neoplasms of thoraco-abdominal localization

## For correspondence:

Nailya K. Guskova – Cand. Sci. (Biol.), head of clinical diagnostic laboratory, National Medical Research Centre for Oncology of the Ministry of Health of Russia, Rostov-on-Don, Russian Federation.

Address: 63 14 line, Rostov-on-Don 344037, Russian Federation

E-mail: guskova.nailya@mail.ru

ORCID: <https://orcid.org/0000-0002-4222-1579>

SPIN: 5407-6285, AuthorID: 306979

Scopus Author ID: 6506703993

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## ПРЕСЕПСИН КАК МАРКЕР СЕПСИСА У ОНКОЛОГИЧЕСКИХ БОЛЬНЫХ ПОСЛЕ ХИРУРГИЧЕСКИХ ВМЕШАТЕЛЬСТВ

Н. К. Гуськова<sup>1✉</sup>, А. А. Морозова<sup>1</sup>, Д. А. Розенко<sup>1</sup>, А. В. Алешкина<sup>1</sup>, А. М. Скопинцев<sup>1</sup>, О. Н. Селютина<sup>1</sup>, Н. В. Голомеева<sup>1</sup>,  
Е. А. Гуськова<sup>2</sup>, А. К. Донская<sup>1</sup>, И. В. Целищева<sup>1</sup>, А. С. Ноздричева<sup>1</sup>

1. НМИЦ онкологии, г. Ростов-на-Дону, Российская Федерация

2. Клинико-диагностический центр «ДА ВИНЧИ», г. Ростов-на-Дону, Российская Федерация

✉ [guskova.nailya@mail.ru](mailto:guskova.nailya@mail.ru)

### РЕЗЮМЕ

**Цель исследования.** Анализ возможности применения пресепсина в ранней диагностике сепсиса у онкологических пациентов после проведения обширных оперативных вмешательств по поводу опухолей торако-абдоминальной локализации.

**Материалы и методы.** В исследование включены 27 человек: 10 здоровых лиц (контроль) и 17 пациентов, пролеченных хирургическим методом по поводу злокачественных новообразований торако-абдоминальной локализации в ФГБУ «НМИЦ онкологии» Минздрава России. Всем пациентам в крови выполнены исследования маркеров сепсиса: пресепсина (P-SEP), высокочувствительного СРБ (hsCRP) (PATHFAST, Япония), прокальцитонина (PCT), интерлейкина-6 (IL6) (Cobas e 411, Германия), а также лактата, суммарного показателя лейкоцитов (WBC) с лейкоцитарной формулой, исследование крови на гемокультуру при подозрении на септические осложнения, входящие в плановое обследование. Исследования проводились до- и на 2-е сутки после операции. Данные оценивались путем сопоставления уровня P-SEP со значениями hsCRP, PCT, IL6, лактата, WBC, результатами теста на гемокультуру и клиническим состоянием больных. В зависимости от полученных данных выделено 2 группы: I – больные с подтвержденным сепсисом (3 человека), II – без сепсиса (14 человек). Статистическая обработка выполнялась с использованием STATISTICA 13.0.

**Результаты.** В контрольной группе уровень P-SEP составил  $182,7 \pm 11,9$  pg/ml. У больных до операции значения маркера составили  $213,7 \pm 47,7$  pg/ml, что статистически не отличалось от данных контроля и не выходило за пределы референтных значений, как и содержание PCT, hsCRP, IL6. На 2-е сутки после операции у всех больных отмечены однонаправленные изменения, характеризующиеся повышением уровней исследуемых показателей, но с разной степенью интенсивности. Наиболее значимым было увеличение концентрации пресепсина. При этом обращало на себя внимание, что на 2-е сутки после операции у больных I группы с подтвержденным сепсисом уровень пресепсина составил в среднем  $2577,5 \pm 1762,5$  pg/ml с максимальным значением 4340,0 pg/ml, а во II группе, при отсутствии подтвержденной бактериемии, отмечалось повышение уровня пресепсина до 1205,0 pg/ml. Полученные данные соотносились с динамикой изменения концентрации других маркеров сепсиса – hsCRP, PCT, IL6. Таким образом, исследование уровня пресепсина, наряду с широко используемыми маркерами – hsCRP, PCT, IL6 позволяет диагностировать сепсис в раннем послеоперационном периоде у онкологических пациентов.

**Заключение.** У больных со злокачественными новообразованиями торако-абдоминальной локализации изменение уровней маркеров сепсиса в раннем послеоперационном периоде можно использовать как основание для назначения антибиотикотерапии. Пресепсин может быть рекомендован к применению в качестве раннего маркера сепсиса у больных с онкологической патологией.

### Ключевые слова:

сепсис, маркеры сепсиса, пресепсин, хирургические вмешательства, злокачественные новообразования торако-абдоминальной локализации

### Для корреспонденции:

Гуськова Наиля Катионовна – к.б.н., заведующая клинико-диагностической лабораторией ФГБУ «НМИЦ онкологии» Минздрава России, г. Ростов-на-Дону, Российская Федерация.

Адрес: 344037, Российская Федерация, г. Ростов-на-Дону, ул. 14-я линия, д. 63

E-mail: [guskova.nailya@mail.ru](mailto:guskova.nailya@mail.ru)

ORCID: <https://orcid.org/0000-0002-4222-1579>

SPIN: 5407–6285, AuthorID: 306979

Scopus Author ID: 6506703993

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## RELEVANCE

Sepsis is a life threatening organ dysfunction caused by the body's dysregulatory response to infection. According to WHO, mortality from sepsis is caused by the development of septic shock and multiple organ failure and amounts to 11 million people annually. Of the surviving patients, only half recover completely, and the rest either die within 1 year or live with acquired chronic pathology. The most susceptible to septic complications are newborns, pregnant women, the elderly, people with weakened immunity, as well as cancer patients [1]. In the presence of oncological pathology, aggravating factors are both the tumor itself and the implementation of a complex of specific treatment methods i.e. chemo and radiation therapy, surgical interventions [2]. When conducting extensive surgical interventions, the urgent task of surgery is to reduce the frequency of purulent-septic complications [3]. The development of septic complications and high mortality are usually caused by untimely diagnosis and late onset of pathogenetic treatment. The concept of sepsis itself has been repeatedly revised and changed in recent years, which has given the medical community a clearer prediction of the course and outcomes of this pathology. Nevertheless, the problems of early diagnosis have not been solved definitively [1; 4]. Hemoculture, a very specific and accessible method in routine practice, is recognized as the "gold standard" for the diagnosis of infection. However, the duration of the study (more than 48 hours), the low sensitivity of the method (25–42 %) and the negative result of blood culture do not guarantee the absence of bacteremia. At the same time, the inability to assess the effect of uncultivated forms of microorganisms on the infectious and inflammatory process limits the diagnostic capabilities of the method [4] and, as a consequence, prevents the timely initiation of pathogenetic treatment.

Currently, various biochemical markers are used to diagnose sepsis: procalcitonin, C-reactive protein, cytokines. Procalcitonin – glycoprotein, which is a precursor of calcitonin, is synthesized by pancreatic C-cells. In the inflammatory process of bacterial or fungal nature, when stimulated by endotoxins or proinflammatory cytokines, the level of procalcitonin increases within 6–12 hours. However, there are limitations in the use of procalcitonin as a marker of sepsis, since an increase in the level of the indicator

is known due to injuries, extensive damage to organs and tissues of a non-infectious nature [4; 5]. Much earlier than the increase in procalcitonin, there is an increase in the level of interleukin-6 with a peak after 2–4 hours, which is associated with a severe course of the disease or the volume of surgical intervention, which also makes it difficult to establish the nature of the inflammatory process [4]. C-reactive protein (CRP) belongs to the group of proteins of the acute phase of inflammation and is synthesized mainly in hepatocytes. The synthesis of CRP is initiated by antigens, immune complexes, infectious agents and particles of necrotic tissue. The concentration of CRP increases after 4–6 hours from the beginning of the pathological process and continues to increase for 24–48 hours, increasing hundreds of times. The marker is most often used to diagnose acute inflammatory conditions and necrotic processes, as well as to evaluate the effectiveness of therapeutic measures. In some cases, an increase in the level of CRP may be due to non-specific causes, such as necrotic tissues formed during burns, necrosis, which reduces its diagnostic significance and does not allow it to be used to confirm the infectious etiology of inflammatory processes [5; 6].

There are data on the use of presepsin in the diagnosis of acute inflammatory reactions. Presepsin is a circulating protein whose concentration in the blood increases rapidly with the development of systemic infections, sepsis, severe sepsis and septic shock. It was first described in 2005 by a group of researchers from Iwate Medical University, Japan [7]. The mechanism of increasing presepsin levels is fundamentally different from the mechanism of increasing other pro-inflammatory markers – interleukin-6, interleukin-10, procalcitonin, CRP, since immune mechanisms aimed at activating phagocytosis participate in its production. The increase in presepsin level is registered earlier due to a short half-life (0.5–1.0 hours) [8; 9]. The reference values of presepsin in healthy people do not exceed 320 pg/ml, however, the manufacturer of test systems LSI Medience Corporation, Japan [10], shows the threshold values of the marker recommended for use in the early diagnosis of septic reactions (Table 1).

However, according to the literature, the level of presepsin increases with varying degrees of intensity during surgical interventions, injuries and burns both in the absence of an infectious component, and

with the development of septic reactions in patients without oncological pathology [11–15]. In this regard, the study of presepsin levels in oncological practice in patients after extensive surgical interventions is very relevant.

**The purpose of the study:** to analyze the possibility of using presepsin in the early diagnosis of sepsis in cancer patients after extensive surgical interventions for tumors of the thoraco-abdominal localization.

## MATERIALS AND METHODS

The study included 27 people: 10 healthy individuals (control) and 17 patients who received surgical treatment at the National Medical Research Center of Oncology for malignant neoplasms of thoraco-abdominal localization. There is informed consent of patients for the study. Sepsis markers were studied in the blood of all patients: presepsin (P-SEP), highly sensitive CRP (hsCRP) (PATHFAST, Japan), procalcitonin (PCT), interleukin-6 (IL6) (Cobas e 411, Germany), as well as lactate, total leukocyte count (WBC) with leukocyte formula, blood testing for hemoculture in case of suspected septic complications included in the routine examination. The studies were conducted before and on the 2nd day after the operation. The data were evaluated by comparing the P-SEP level with the values of hsCRP, PCT, IL6, lactate, WBC, the results of the hemoculture test and the clinical condition of patients. Depending on the data obtained, 2 groups were identified: I – patients with confirmed sepsis (3 people), II – without sepsis (14 people). Statistical processing was performed using STATISTICA 13.0.

## RESEARCH RESULTS AND DISCUSSION

In the control group of individuals, the P-SUP level averaged  $182.7 \pm 11.9$  pg/ml. In the examined group of patients before surgery, the marker values were in the range of 166.0–261.5 pg/ml and averaged  $213.7 \pm 47.7$  pg/ml, which did not statistically differ from the data of the control group ( $p > 0.001$ ) and did not exceed the reference values ( $< 320$  pg/ml) recommended by the manufacturer of the test systems (Table 1). The content in the blood of patients before surgery of other markers of inflammation – PCT, hsCRP, IL6 was also within the reference boundaries (Table 2).

On the 2nd day after surgery, unidirectional changes were noted in all patients included in the study, characterized by an increase in the levels of the studied indicators, but with varying degrees of intensity. At the same time, the most significant was the increase in presepsin concentration. Thus, in group I (with sepsis), the P-SEP level averaged  $2577.5 \pm 1762.5$  pg/ml, 8.1 times higher than the reference values proposed by the manufacturer, 14.1 times higher than the data of the control group and 12.1 times higher than the values before surgery ( $p < 0.001$ ). The content of other markers in this group of patients also increased and averaged: PCT –  $328.3 \pm 284.0$  ng/ml ( $p < 0.001$ ), hsCRP –  $211.68 \pm 153.52$  mg/l ( $p < 0.001$ ), IL6 –  $982.4 \pm 128.3$  pg/ml ( $p < 0.001$ ), which is in accordance with the literature data indicated the development of sepsis [11]. At the same time, the lactate level in this group of patients (I) increased and amounted to  $6.31 \pm 0.4$  mmol/l ( $p < 0.05$ ), which, in turn, reflected the fact of bacteremia with the development of metabolic

Table 1. Interpretation of presepsin level results

Presepsin Level* (pg/ml)	Diagnosis
< 200	Sepsis excluded
200–299	Low chance of systemic infection
300–499	Possible systemic infection
500–999	Moderate risk of sepsis, increased risk of adverse outcome
$\geq 1000$	High risk of systemic infection (severe sepsis/septic shock). High risk of 30-day mortality, comparable to the risk on the APACHE scale $\geq 25$

Note: presepsin values are recommended by the manufacturer of test systems LSI Medience Corporation, Japan, 2013.

acidosis characteristic of the septic process. The WBC level also increased to  $13.15 \pm 2.55 \times 10^9/L$  ( $p < 0.05$ ). This, along with lymphopenia observed in almost all patients, the appearance of immature granulocytes in the blood and a significant number of rod-shaped forms of neutrophils (more than 25.0 %), reflected the presence of an inflammatory process caused by both the body's reaction to surgery and bacteremia. The development of sepsis in this group of patients was confirmed by positive results of blood culture for hemoculture.

In the II group of patients (without sepsis) after surgery, the degree of increase in the concentration of the studied parameters was less pronounced and had a short-term character. Thus, the P-SEP level averaged  $657.5 \pm 547.5$  pg/ml in the group, 2.1 times higher than the reference data ( $p < 0.001$ ), 3.6 times higher than the control values ( $p < 0.001$ ), 3.2 times higher than the results obtained before surgery ( $p < 0.001$ ) and 3.9 times It was lower than the values in group I patients (with sepsis) ( $p < 0.001$ ), which is extremely important in assessing the role

Table 2. Dynamics of changes in the level of sepsis markers in cancer patients

Indicators, reference values, units of measurement	Groups				
	Control	Group I (n = 3)		Group II (n = 14)	
		Before surgery	After surgery	Before surgery	After surgery
P-SEP, < 320 pg/ml	$182.7 \pm 11.9$ (170.8–194.6)	$213.7 \pm 47.7$ (166.0–261.5)	$2577.5 \pm 1762.5$ (815.0–4340.0) $p_1 < 0.001$ $p_2 < 0.001$	$206.4 \pm 39.6$ (166.8–246)	$657.5 \pm 547.5$ (110.0–1205.0) $p_1 < 0.001$ $p_2 < 0.001$ $p_3 < 0.001$
hsCRP, < 5.0 mg/l	$1.24 \pm 0.77$ (0.47–2.01)	$2.4 \pm 0.3$ (2.0–3.1) $p_1 < 0.05$	$211.68 \pm 153.52$ (58.16–365.2) $p_1 < 0.001$ $p_2 < 0.001$	$2.1 \pm 0.2$ (1.9–3.3) $p_1 < 0.05$	$32.2 \pm 21.4$ (10.8–53.6) $p_1 < 0.001$ $p_2 < 0.001$ $p_3 < 0.001$
PCT, < 0.05 ng/ml	$0.015 \pm 0.015$ (0.00–0.03)	$0.025 \pm 0.015$ (0.01–0.04)	$328.3 \pm 284.0$ (44.24–612.33) $p_1 < 0.001$ $p_2 < 0.001$	$0.01 \pm 0.01$ (0.00–0.02)	$2.6 \pm 0.5$ (2.10–3.05) $p_1 < 0.05$ $p_2 < 0.05$ $p_3 < 0.001$
IL6, < 7.0 pg/ml	$2.85 \pm 1.75$ (1.1–4.6)	$4.0 \pm 0.2$ (3.3–4.7)	$982.4 \pm 128.3$ (45.46–1127.7) $p_1 < 0.001$ $p_2 < 0.001$	$3.6 \pm 0.3$ (3.3–3.9)	$10.1 \pm 1.5$ (8.6–11.6) $p_1 < 0.05$ $p_2 < 0.05$ $p_3 < 0.001$
Lactate, 0.5–2.2 mmol/l	$1.56 \pm 0.48$ (1.08–2.04)	$1.66 \pm 0.22$ (1.44–1.88)	$6.31 \pm 0.4$ (5.91–6.71) $p_1 < 0.05$ $p_2 < 0.001$	$1.59 \pm 0.27$ (1.32–1.86)	$2.06 \pm 0.68$ (1.38–2.74) $p_3 < 0.001$
WBC, $4.0–10.0 \times 10^9/L$	$7.4 \pm 2.1$ (5.3–9.5)	$10.95 \pm 2.55$ (8.4–13.5)	$13.15 \pm 2.55$ (10.60–15.7) $p_1 < 0.05$	$10.15 \pm 2.25$ (7.9–12.4)	$15.2 \pm 5.6$ (9.6–20.8) $p_1 < 0.05$

Note: values are statistically significant if  $p < 0.05$  –  $p < 0.001$

$p_1$  – in comparison with control group;

$p_2$  – in comparison with indicators before the surgery;

$p_3$  – in comparison with indicators in the group I.



of presepsin as an early marker of sepsis. The PCT content increased on average to  $2.6 \pm 0.5$  ng/ml ( $p < 0.05$ ), hsCRP –  $32.2 \pm 21.4$  mg/l ( $p < 0.05$ ), IL6 –  $10.1 \pm 1.5$  pg/ml ( $p < 0.05$ ) (Table 2). The lactate level remained within the reference values. The totality of laboratory data, the clinical condition of patients, and the negative results of hemoculture made it possible to exclude the development of the septic process in this group of patients. We believe that the marked increase in the level of acute phase proteins and WBC ( $14.2 \times 10^9/L$ ) in group II patients is due to the peculiarities of the immune response of cancer patients to extensive surgery. The level of the studied markers began to decrease already on 3–4 days, which was expected and typical for this group of patients (without sepsis).

Thus, changes in the presepsin level seemed to be the most significant. The results obtained confirm the data of other studies, which note that P-SEP is an effective biomarker of sepsis, which complements the clinical assessment, and is also significant in diagnosing the severity of sepsis and the effectiveness of therapy [11–13]. It has been shown that with the development of systemic infections, presepsin increases earlier than other markers of sepsis, and regardless of their increase or decrease, with 100 % reliability, subsequently confirmed by a positive test for hemocultures, diagnoses sepsis before the manifestation of clinical symptoms, which allows timely initiation of therapy, predicts favorable and unfavorable outcomes [14]. In a study by M. Behnes et al. (2014), the diagnostic level of P-SEP  $\geq 530$  pg/ml was established in sepsis, and in severe sepsis –  $\geq 600$  pg/ml [12]. In a study by T. Shozushima et al. (2011) the following levels of P-SEP were estab-

lished: local infection –  $721.0 \pm 611.3$  pg/ml; sepsis –  $817.9 \pm 572.7$  pg/ml; severe sepsis –  $1992.9 \pm 1509.2$  pg/ml [15]. In other studies in patients with sepsis and severe sepsis, the optimal borderline level of P-SEP for detecting the development of sepsis with artificial lung ventilation was 1,965 pg/ml, in the absence of sepsis –  $< 1600$  pg/ml [13].

According to our data, in patients with malignant tumors of thoraco-abdominal localization in the absence of confirmed bacteremia, there is an increase in presepsin levels on the 2nd day after surgery with a maximum level 1205.0 pg/ml, and in a similar group of patients with confirmed sepsis, presepsin values averaged  $2577.5 \pm 1762.5$  pg/ml with a maximum level 4340.0 pg/ml, which correlated with the dynamics of changes in the concentration of other markers of sepsis – hsCRP, PCT, IL6. According to the results of the study, this category of cancer patients after undergoing surgery has a moderate risk of sepsis and an increased risk of its adverse outcome, which serves as the basis for starting antibiotic therapy in accordance with the protocols for the treatment of septic conditions. In this regard, the study of presepsin levels, along with widely used markers – hsCRP, PCT, IL6, will make it possible to diagnose sepsis in the early postoperative period in cancer patients.

## CONCLUSION

Changes in the levels of sepsis markers in early postoperative period can be used as a basis for prescribing antibiotic therapy in patients with malignant neoplasms of thoracoabdominal localization. Presepsin may be recommended as an early marker of sepsis in patients with oncological pathology.

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#### Information about authors:

Nailya K. Guskova  – Cand. Sci. (Biol.), head of clinical diagnostic laboratory, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0002-4222-1579>, SPIN: 5407-6285 AuthorID: 306979, Scopus Author ID: 6506703993

Antonina A. Morozova – biologist, clinical and diagnostic laboratory, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0003-3443-4694>

Dmitriy A. Rozenko – Cand. Sci. (Med.), head of department of anesthesiology and intensive care, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0002-5563-484X>, SPIN: 4658-5058, AuthorID: 917988

Alexandra V. Alyoshkina – MD, anesthesiologist-resuscitator, department of anesthesiology and intensive care, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0002-1532-2761>

Aleksandr M. Skopintsev – MD, anesthesiologist-resuscitator, department of anesthesiology and intensive care, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0001-8834-4817>, SPIN: 3635-3780, AuthorID: 1096021

Olesya N. Selyutina – biologist, clinical and diagnostic laboratory, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0001-6762-0835>, SPIN: 4347-0302, AuthorID: 759134, Scopus Author ID: 57194276434

Nadezhda V. Golomeeva – biologist, clinical and diagnostic laboratory, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0001-5009-5560>

Ekaterina A. Guskova – Cand. Sci. (Med.), obstetrician-gynecologist Clinical and Diagnostic Center «DA VINCI», Rostov-on-Don, Russian Federation. SPIN: 6776-4011, AuthorID: 812913

Aliya K. Donskaya – MD, radiotherapist, radiotherapy department, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. SPIN: 9764-9563, AuthorID: 734505

Irina V. Tselishcheva – biologist, clinical and diagnostic laboratory, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0002-9096-0173>

Anastasiya S. Nozdricheva – biologist, clinical and diagnostic laboratory, National Medical Research Centre for Oncology, Rostov-on-Don, Russian Federation. ORCID: <https://orcid.org/0000-0003-3336-9202>

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#### Contribution of the authors:

Guskova N. K. – development of research design, systematization and analysis of the data obtained, writing the text of the manuscript, consultation;  
Morozova A. A. – performing laboratory research, collecting, systematization and analysis of the data obtained, writing the text of the manuscript;  
Rozenko D. A. – analysis of the received data, consultation;  
Alyoshkina A. V. – analysis of the received data, consultation;  
Skopintsev A. M. – analysis of the received data, consultation;  
Selyutina O. N. – systematization and analysis of the data obtained, review of publications on the topic of the article, writing the text of the manuscript;  
Golomeeva N. V. – performing laboratory tests, analyzing the data obtained;  
Guskova E. A. – analysis of the received data, consultation;  
Donskaya A. K. – analysis of the received data, consultation;  
Tselishcheva I. V. – collection of clinical material;  
Nozdricheva A. S. – collection of clinical material.