Original study article | Оригинальное исследование
DOI: https://doi.org/10.35693/SIM629314



# Algorithm for surgical treatment of patients with metastatic colorectal cancer complicated by intestinal obstruction

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## Abstract

**Aim:** to develop an algorithm for selecting the optimal surgical intervention for patients with metastatic colorectal cancer complicated by obstructive intestinal obstruction.

**Material and methods.** The study is based on an analysis of the treatment outcomes of 202 patients with metastatic colorectal cancer complicated by obstructive intestinal obstruction. The patients were divided into two groups. Group 1 included 119 patients who underwent primary tumor removal as the first stage. Group 2 included 83 patients who underwent only symptomatic drainage surgery to relieve intestinal obstruction.

**Results.** The one-year mortality rate was 37 patients (31.1%) in Group 1 and 51 (61.4%) in Group 2. Multivariate analysis identified predictors influencing the one-year mortality rate: the number of internal organs affected by metastases, albumin/globulin ratio, Krebs index, MCV index, and the planned targeted therapy regimen.

**Conclusion.** Based on this analysis, a step-by-step decision-making algorithm was developed to determine the indications for primary tumor removal, and a computer program was created to calculate the one-year mortality risk in patients with metastatic colorectal cancer.

**Keywords:** metastatic colorectal cancer, intestinal obstruction, adverse events of chemotherapy, palliative surgery, cytoreductive surgery – R2 resection.

**Conflict of interest:** nothing to disclose.

**Citation**
Shvets DS, Kaganov OI, Orlov AE, Kozlov AM, Frolov SA, Mikolenko NI, Kaganova TO. **Algorithm for surgical treatment of patients with metastatic colorectal cancer complicated by intestinal obstruction.** *Science and Innovations in Medicine*. 2026;11(1):45-51. DOI: https://doi.org/10.35693/SIM629314

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**Received:** 21.03.2024
**Accepted:** 17.10.2025
**Published:** 04.01.2026

# Алгоритм хирургического лечения больных метастатическим колоректальным раком, осложненным кишечной непроходимостью

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## Аннотация

**Цель:** разработать алгоритм, позволяющий выбрать оптимальный объем хирургического вмешательства больным метастатическим колоректальным раком, осложненным обтурационной кишечной непроходимостью.

**Материал и методы.** Исследование основано на анализе результатов лечения 202 пациентов метастатическим колоректальным раком, осложненным обтурационной кишечной непроходимостью, которые были разделены на две группы. В первую группу вошли 119 пациентов, которым первым этапом выполнено удаление первичного опухолевого очага. Вторую группу составили 83 пациента, которым выполнена только дренирующая симптоматическая операция, направленная на ликвидацию кишечной непроходимости.

**Результаты.** Показатель одногодичной летальности в первой группе составила 37 человек (31,1%), а во второй группе – 51 (61,4%) пациент. Многофакторный анализ выявил предикторы, влияющие на показатель одногодичной летальности: количество внутренних органов, пораженных метастазами, альбумин/глобулиновый коэффициент, лейкоцитарный индекс Кребса, индекс MCV, схема предстоящей таргетной терапии.

**Заключение.** Разработан этапный алгоритм принятия решения, позволяющий определить показания к удалению первичной опухоли, и создана программа ЭВМ для расчета риска одногодичной летальности больных метастатическим колоректальным раком.

**Ключевые слова:** метастатический колоректальный рак, кишечная непроходимость, нежелательные явления химиотерапии, паллиативная операция, циторедуктивная операция – R2 резекция.

**Конфликт интересов:** не заявлен.

**Для цитирования:**
Швец Д.С., Каганов О.И., Орлов А.Е., Козлов А.М., Фролов С.А., Миколенко Н.И., Каганова Т.О. **Алгоритм хирургического лечения больных метастатическим колоректальным раком, осложненным кишечной непроходимостью.** *Наука и инновации в медицине.* 2026;11(1):45-51. DOI: https://doi.org/10.35693/SIM629314

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**Список сокращений**
КРР – колоректальный рак; мКРР – метастатический колоректальный рак; ХТ – химиотерапия; ТТ – таргетная терапия; КН – кишечная непроходимость.

**Получено:** 21.03.2024
**Одобрено:** 17.10.2025
**Опубликовано:** 04.01.2026

## INTRODUCTION

The colorectal cancer (CRC) ranks third in morbidity and mortality in the world and in the Russian Federation [1, 2]. In the Samara Region, the morbidity and mortality rates correlate with the overall indicators of the Russian Federation [3]. The high rate of mortality from this pathology stems from a large number of neglected diseases. In the international practice, the incidence of the primary metastatic CRC is within 17–32%. From the data of V.A. Aliev and A.D. Kaprin it follows, that despite the active implementation of screening programs and gradual decrease of morbidity rate in the Russia Federation, the primary metastatic CRC (mCRC) is identified in 20–30% cases, which has a statistically significant poorer outcome [4, 5].

According to the clinical recommendations of the AOR, RUSSCO, NCCN, the primary method of mCRC treatment is chemotherapy (CT) combined with targeted therapy (TT), and the surgical stage of treatment is only auxiliary and preparatory for the systemic therapy. The complications developing on various stages of treatment result in extension of the term of the start of therapy and necessitate reduction of dosages of administered drugs, increase of intervals between cycles, or require cancellation of therapy, which aggravates the remote outcomes. About 45% of patients die within the first year after being diagnosed [6].

One of the most frequent complications is the intestinal obstruction (IO) [7]. Prior to administration of CT and TT, patients with IO require surgical treatment to rectify the existing complications on the first stage. This poses the question as to the volume of surgical intervention: formation of a colostomy or performance of a debulking operation to remove the primary tumor site.

## AIM

To analyze outcomes of complex treatment of patients with metastatic colorectal cancer and develop an algorithm for selecting the optimal surgical intervention for this category of patients.

## MATERIAL AND METHODS

Based on the experience of treatment of patients with mCRC complicated by IO, a study was performed at the Samara Regional Clinical Oncology Dispensary that included 202 patients.

*Inclusion criteria:* patients with mCRC complicated by obturation intestinal obstruction in the stage of compensation or subcompensation; histological type of tumor: adenocarcinoma; debulking operation to remove the primary lesion or drainage operation; subsequent chemotherapy under the FOLFOX/XELOX schemes combined with targeted therapy; status of the peritoneal carcinomatosis: P1-P2 in the Japanese classification; performance status: ECOG 2 and lower.

*Exclusion criteria:* patients refusing from specific treatment; patients with mCRC with symptom-free primary tumor; patients diagnosed with P3 peritoneal carcinomatosis in the Japanese classification; patients with colon cancer (lower and medium ampullas), and anal form of the rectal cancer; performance status above ECOG 2.

Prior to commencement of treatment, all patients underwent examination, their clinical diagnosis established and verified, staged under the TNM system, the number of organs affected by the metastases was identified. The participants of the study were divided into two groups. Group 1 included 119 patients after a debulking operation, the first stage of which was the R2 debulking resection of the primary tumor lesion. Group 2 included 83 patients after just the drainage symptomatic operation aimed at relief of intestinal obstruction without removal of the primary lesion.

In both study groups, patients exhibited either isolated metastatic involvement of a single organ or combined involvement of two or more organs. Patients in both groups were comparable in terms of sex, age, TNM stage, and primary tumor location. The study design is presented in **Fig. 1**.

**Statistical analysis.** The study results were processed in Statistica 10.0, SPSS 13. To assess the risk of one-year mortality, univariate binary logistic regression was first performed. Subsequently, predictors with a significance level below 0.1 were included in a multivariate binary logistic regression model using stepwise backward elimination based on the Wald algorithm. The quality of prediction was evaluated based on the statistical significance of the predictors included in the model and on sensitivity and specificity metrics. The algorithm for selecting the optimal surgical treatment method was developed using the Chi-Square Automatic Interaction Detection (CHAID) decision tree method. The CHAID

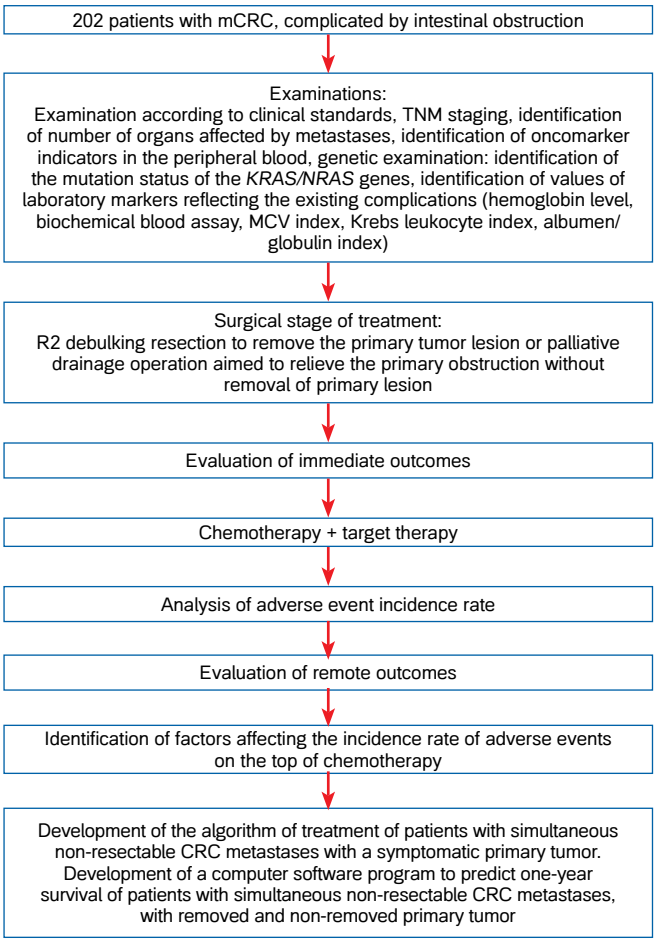


***Figure 1.*** *Study design.*
***Рисунок 1.*** *Дизайн исследования.*

method is based on testing the hypothesis of independence between two variables using the $\chi^2$ (chi-square) test. Construction was performed using the SPSS 13 software package based on data from a training dataset comprising 202 observations. The significance level $\alpha$ was set at <0.05.

## RESULTS

The following parameters were assessed: intraoperative blood loss and number of bed-days. The average intraoperative blood loss among patients in Group 1 was 150 ± 20 mL; among patients of Group 2, 80 ± 20 mL (p = 0.000). The average number of in-patient bed-days in Group 1 was 20 ± 2, in Group 2, 12 ± 2 bed-days (p = 0.000). These indicators in the group with patients after the debulking surgery were significantly higher, which is accounted for by the volume of the surgery.

In the subsequent phase, postoperative complications were analyzed in patients in both study groups. In Group 1, postoperative surgeries developed in 37 patients (31.1%), which was significantly higher than in Group 2, where postoperative complications developed in 15 patients (18.1%) (Chi = 4.336; df = 1; p = 0.037).

The postoperative complications affected the time of start of chemotherapy: in Group 1, in patients after the debulking surgery to remove the primary lesion the average value of CT start after the surgery was 44.0 ± 2.0 days; in Group 2 of patients who had a colostomy, this value was 30.0 ± 1.0 days (Z = 2.732; p = 0.006).

Later, on the chemotherapy stage, adverse events were analyzed as they developed that required suspension of systemic treatment, dosage reduction or stoppage

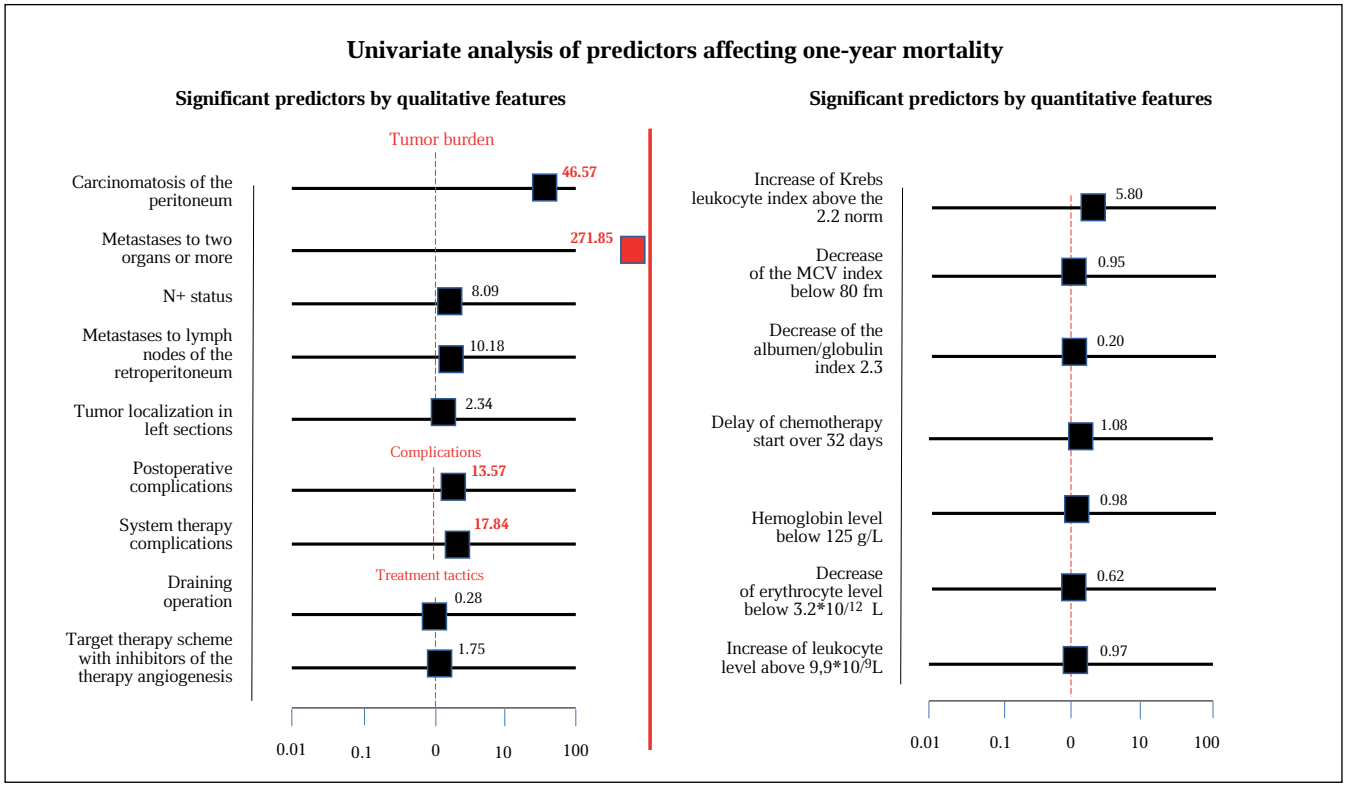


***Figure 2.*** *Univariate analysis of significant predictors influencing 1-year mortality in patients with metastatic colorectal cancer complicated by intestinal obstruction (qualitative and quantitative characteristics).*
***Рисунок 2.*** *Однофакторный анализ значимых предикторов, влияющих на годичную летальность у пациентов с метастатическим КРР, осложненным кишечной непроходимостью (качественные и количественные признаки).*

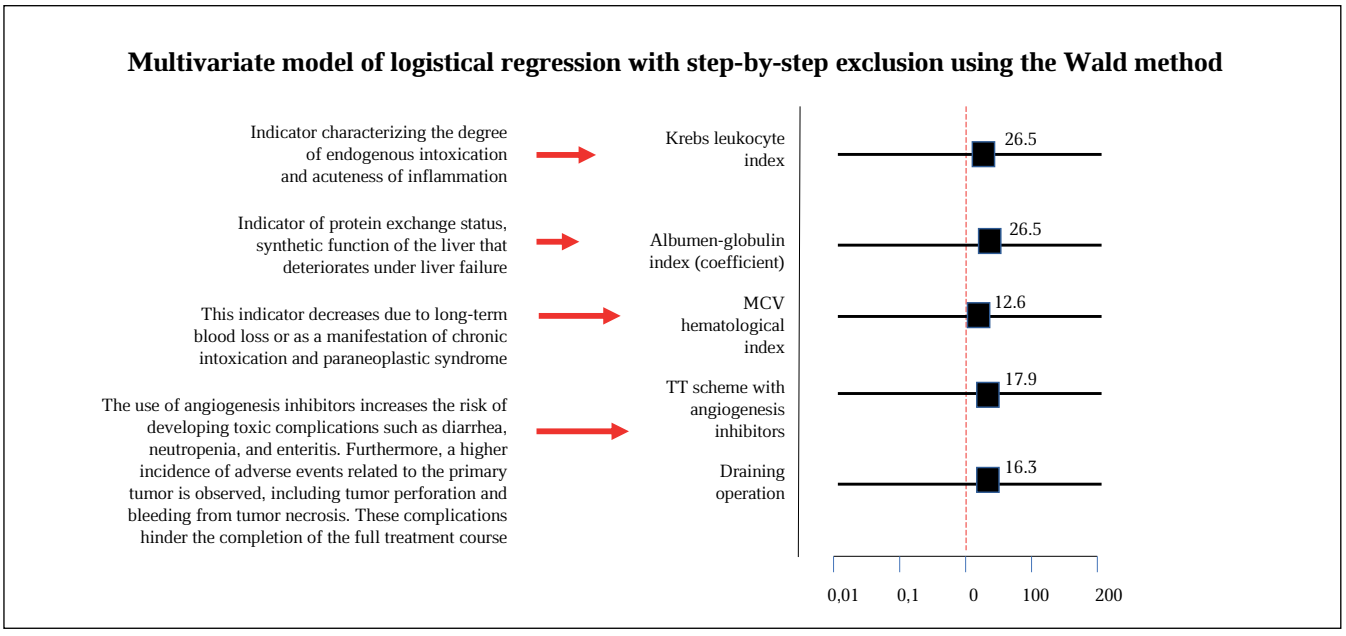


***Figure 3.*** *Multivariate analysis of variables associated with 1-year mortality in patients with metastatic colorectal cancer complicated by intestinal obstruction.*

***Рисунок 3.*** *Многофакторный анализ переменных, ассоциированных с годичной летальностью у пациентов с метастатическим КРР, осложненным кишечной непроходимостью.*

of the therapy. In Group 1 of the study, such adverse events were observed in 47 (39.6%), in Group 2, in 67 (80.9%) patients. In both groups, the following complications were observed: complications of the blood (leukopenia, thrombocytopenia), thrombotic and ulcerous complications. Such complications as tumor perforation and hemorrhage from the disintegrating tumor were not observed in the group of patients with the removed primary tumor. The developing complications in the course of the chemotherapy affected the number of cycles. The initially planned 12 CT cycles in the group with the primary tumor removed were delivered to 51.8% patients; in the group with non-removed primary tumor, only to 19.9% patients: it became necessary to stop special treatment for the majority of patients of this group due to development of adverse events on top of the systemic treatment ($p = 0.000$).

In the next stage, indicators of event-free and overall survival. One-year mortality in the Group 1 was 37 people (31.1%), in Group 2, 51 patients (61.4%) ($Chi = 18.323$, $df = 1$; $p = 0.000$). In order to evaluate the significance of the factors influencing one-year mortality, univariate equations of logistic regression were derived and predictors were identified that significantly affected one-year mortality (**Fig. 2**).

Based on the identified significant predictors, a multivariate logistical regression model was constructed with step-by-step exclusion using the Wald method (**Fig. 3**). The predictors that had significant influence on one-year survival were the increase of the Krebs leukocyte index (KLI), decrease of the albumen-globulin index (AGI) and decrease of the MCV, affection by metastases of more than one organ and increase of incidence rate of postoperative complications. As far as the surgery method is concerned, the colostomy without removal of the primary tumor also increased probability of death within one year.

For the further assessment of the factors influencing patient survival depending on the volume of surgical intervention, we constructed the CHAID decision trees (**Fig. 4**).The identified factors that had significant impact on one-year mortality reflected the status of complications related to the presence of the primary tumor and the tumor burden.

**Implementation of the algorithm**

1. If metastases are found to affect two or more internal organs, primary tumor removal surgery is not indicated due to the lack of oncological practicability of such intervention.

2. If metastases are not found to affect two or more internal organs, the second step of analysis follows: if the albumen-globulin index decreases below 1.5, primary tumor removal surgery is also not indicated, for the patient has signs of liver failure, when drug therapy efficiency is significantly compromised.

3. If the albumen-globulin index does not decrease below 1.5, the third step follows: the analysis of the Krebs leukocyte index. If KLI is above 2.2, primary tumor removal surgery is indicated, for the relief of the respective inflammatory process related to the presence of the primary tumor will relieve, in the subsequent stages, the onset of adverse septic events on top of the system treatment.

4. If the Krebs leukocyte index is below 2.2, the fourth stage of analysis will follow: the analysis of the MCV index relation to the scheme of the future target therapy. If the MCV index is below 80 with the combination of angiogenesis inhibitor TT, the removal of primary tumor is indicated. The MCV marker reflects the presence of a chronic hemorrhage, the source of which in the majority of CRC cases is the primary tumor. Once angiogenesis inhibitors are added to the therapy scheme, the probability of development of such an adverse event as bleeding from

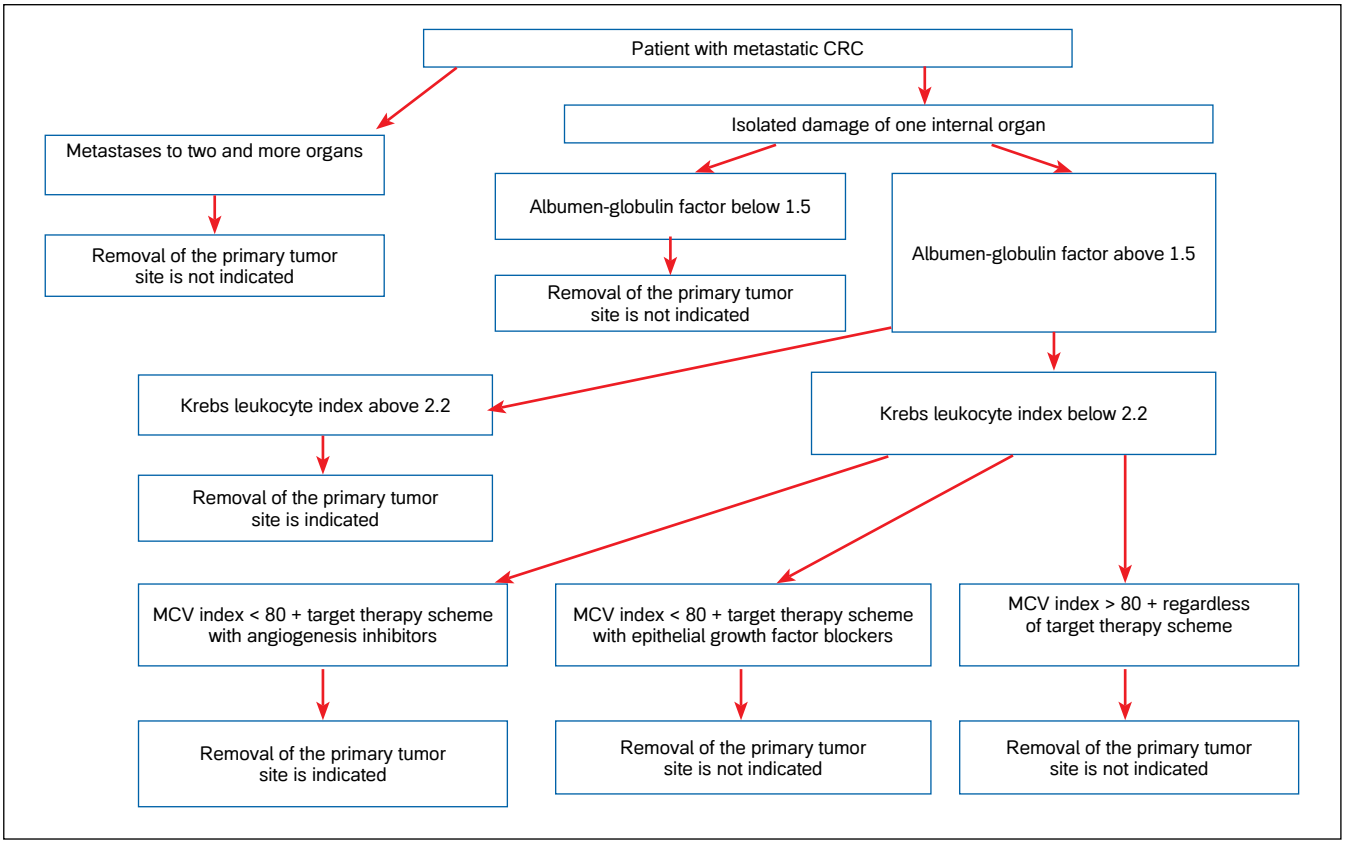


***Figure 4.*** *Decision tree.*
***Рисунок 4.*** *Дерево принятия решений.*

the disintegrating tumor increases significantly. If the MCV index is below 80 with the combination of epithelial growth factor blocker TT, regardless of the planned TT course, the removal of the primary tumor on the first stage of treatment is not indicated, and the formation of the colostomy would be sufficient. Since the risk of development of adverse events on the top of system therapy administration in this group of patients is minimal, it would be sufficient to relieve the manifestations of intestinal obstruction, start administration of chemotherapy in the shortest time possible, and later look into the possibility of R0 resection.

Based on this algorithm, a computer program was developed that calculates the risk of mortality within the first year in mCRC patients with a symptomatic primary tumor and determines the practicability of debulking surgery with respect to all of the above predictors.

In order to produce a prediction for a mCRC patient before the surgical stage of treatment, the following indicators are analyzed. Chest and abdomen CT scans are used to determine the number of internal organs affected by metastases. Biochemical blood assay is used to calculate the albumen-globulin coefficient. The values of the general blood test are used to calculate the MCV index, percentages of neutrophils and lymphocytes, and to calculate the Krebs leukocyte index.

The testing of the software performance quality involved its sensitivity and specificity. We tested the possible points of outcome discrimination, and the incidence of erroneous predictions was 1.0 ± 0.7%.

## DISCUSSION

Patients with mCRC are some of the most complicated groups to develop treatment tactics. They have an adverse long-term prognosis. According to practical recommendations of RUSSCO, in effect prior to 2018, it was recommended to perform the debulking surgery to remove the primary tumor before starting the chemotherapy. In the opinion of Yu.A. Barsukov, M.F. Cherkasov, debulking surgeries are aimed at reduction of the amount of tumor tissue and improve efficiency of the administered chemotherapy [4, 8, 9]. However, some studies report that complications after surgeries in CRC are seen in 19.3 – 26.7%, and mortality after these surgeries is 2.2 – 5.4% [10, 11]. Development of postoperative complications significantly delays the start of drug therapy and, in some cases, render further treatment impossible. According to the Clavien – Dindo classification of surgical complications, in 7.1% cases after surgery for CRC there occur fatal complications that render the patient's further drug therapy impossible [12]. This is explained by the volume of the surgery and technical difficulties in the performance of the surgery. According to our data, the group with a history of debulking surgeries to remove the primary tumor, postoperative complications occurred more often than in the group without removal of the primary tumor (29.8% vs. 9.6%), which resulted later in the delay of start of chemotherapy. In Group 1, the average number of days the chemotherapy started after the surgery was 44.0 days, whereas in Group 2, this number was 30.0 days ($Z = 2.732$; $p = 0.006$), which had a respective impact on the treatment efficiency.

The complications that develop regularly and deteriorate the patients' quality of life became the cause for a number of international randomized studies. In 2016, 2019 and 2020 the following studies were completed: China Multicenter (China), JCOG1007 (Japan) and PTR Trial (South Korea). Their findings are as follows: in the symptom-free progression of the primary tumor, debulking operations to remove the primary tumor do not improve 1-, 2-, 3- and 5-year survival of mCRC patients.

At the moment, four European studies are in the process of enrolling patients: SYNCRON0US (Germany), CAIR04 (Netherlands), CCRe-IV (Spain), CLIMAT (France). According to the published intermediate results of these studies, no connection is seen between the improved survival of patients with a history of debulking operations to remove the primary tumor [13].

This resulted in the modification of recommendations, and since 2018, recommendations have been in effect that call for a personalized approach to the removal of the primary tour with respect to the risk of development of complications.

It should be mentioned that the above studies focused on the symptom-free (uncomplicated) progress of the primary tumor. The presence of a complicated (symptomatic) primary tumor necessitates removal of existing complications by removal of the primary tumor prior to administration of system treatment.

Remote outcomes strongly depend on the development of adverse events on top of the chemotherapy in progress. According to the data of the European Society for Medical Oncology, adverse events accompany chemotherapy in more than 50% patients. E. Savu reports that the degree of their manifestation depends on the therapy scheme, dosage, tumor burden and individual factors, i.e. presence or absence of existing complications without clinical manifestation [14]. According to S.N. Fedorinov and A.Yu. Dobrodeev, the following adverse events may be seen in the course of the chemotherapy: hemorrhage from a disintegrating tumor, tumor perforation with subsequent development of septic complications [15, 16]. All of these complications are related to the presence of a non-removed primary tumor. In our observations, the number of adverse events in the group with the non-removed primary tumor was above the European level of 50% and was 68.2%, whereas in the group with the removed primary tumor this indicator was 33.3%. We believe that this is related with the presence of subclinical complications of the primary tumor that existed even before the start of the system treatment.

## CONCLUSION

The proposed algorithm and the computer program developed on its basis consider the amount of metastatic affection of the internal organs and such indicators as albumin-globulin coefficient, Krebs leukocyte index, MCV index and the scheme of the chemotherapy to be administered. The algorithm and the program allow for a justification of necessity of removal of the primary tumor or formation of a colostomy and for improvement of outcomes of system treatment and levels of overall survival of patients with metastatic colorectal cancer.

| ADDITIONAL INFORMATION | ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ |
|---|---|
| ***Ethics approval.*** Protocol No. 265 of June 21, 2023. | ***Этическая экспертиза.*** Протокол ЛЭК №265 от 21.06.2023 года. |
| ***Consent for publication.*** All patients signed a written informed consent form. | ***Согласие на публикацию.*** Все пациенты подписывали добровольное информированное согласие. |
| ***Study funding.*** The study was carried out with the support of the Samara Regional Clinical Oncology Dispensary. | ***Источник финансирования.*** Исследование выполнены при поддержке Самарского областного клинического онкологического диспансера. |
| ***Conflict of interest.*** The authors declare that there are no obvious or potential conflicts of interest associated with the content of this article. | ***Конфликт интересов.*** Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с содержанием настоящей статьи. |
| ***Contribution of individual authors.*** Shvets D.S.: planning of the scientific work, study design, writing of the text. Mikolenko N.I., Kozlov A.M., Frolov S.A.: critical revision. Kaganova T.O.: statistical processing, concept development. Kaganov O.I., Orlov A.E.: study design, editing of the manuscript.<br>All authors gave their final approval of the manuscript for submission, and agreed to be accountable for all aspects of the work, implying proper study and resolution of issues related to the accuracy or integrity of any part of the work. | ***Участие авторов.*** Швец Д.С. – планирование научной работы, дизайн исследования, написание текста. Миколенко Н.И., Козлов А.М., Фролов С.А. –критический пересмотр. Каганова Т.О.– статистическая обработка. разработка концепции. Каганов О.И., Орлов А.Е. – дизайн исследования, редактирование рукописи.<br>Все авторы одобрили финальную версию статьи перед публикацией, выразили согласие нести ответственность за все аспекты работы, подразумевающую надлежащее изучение и решение вопросов, связанных с точностью или добросовестностью любой части работы. |
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| ***Data availability statement.*** The editorial policy regarding data sharing does not apply to this work. | ***Доступ к данным.*** Редакционная политика в отношении совместного использования данных к настоящей работе не применима. |
| ***Generative AI.*** No generative artificial intelligence technologies were used to prepare this article. | ***Генеративный искусственный интеллект.*** При создании настоящей статьи технологии генеративного искусственного интеллекта не использовали. |
| ***Provenance and peer review.*** This paper was submitted unsolicited and reviewed following the standard procedure. The peer review process involved 2 external reviewers. | ***Рассмотрение и рецензирование.*** Настоящая работа подана в журнал в инициативном порядке и рассмотрена по обычной процедуре. В рецензировании участвовали 2 внешних рецензента. |

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