

NEW METHOD OF MODIFIED CHEMORADIO THERAPY FOR CANCER OF THE UPPER AND MIDDLE AMPULLARY RECTUM

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ABSTRACT

The last decade is characterized by significant progress in the treatment of rectal cancer (reduction in the number of relapses to 5–6 % with the use of prolonged radiation therapy) before surgery. The greatest success has been achieved in the treatment of cancer of the lower ampulla of the rectum, when it is possible to develop a complete clinical response of the rectal tumor to chemoradiotherapy. Nevertheless, the requirement issues to improve the results of treatment of cancer of the upper and middle ampullary rectum with an increase in the survival of patients remain. Which makes it relevant to develop new methods, that increase the effectiveness of the treatment of rectal cancer.

The method of modified chemoradiotherapy for cancer of the upper ampulla of the rectum was developed in our study. The method is as follows: at the first stage, one day before the start of radiation therapy, the patient undergoes superselective catheterization of the superior rectal artery through the radial or femoral artery, followed by regional administration of radio-modifying chemotherapy drugs: cisplatin 50 mg and fluorouracil 500 mg. In one day, patients begin to undergo a course of conformal remote large-fraction radiation therapy to the primary focus and metastasis pathways for 5 sessions with a single focal dose of 5 Gy to a total focal dose of 25 Gy using a low-energy linear accelerator. During the entire course of radiation therapy, fluorouracil 500 mg is administered daily intravenously for 30 minutes in 30 minutes before the session. Surgical intervention with the sampling of material for research is carried out 6–8 weeks after the radiation therapy is completed. To assess the effectiveness of the modified chemoradiotherapy, the stage of tumor regression was determined according to the RECIST scale, and the level of therapeutic pathomorphology of the tumor according to Dworak was determined during a morphological study of the rectal tumor removed during the operation.

The developed method of modified chemoradiotherapy makes it possible to achieve regression of the rectal tumor in a short time, reduce the time and increase the effectiveness of treatment. The method of modified chemoradiotherapy is intended for patients with cancer of the upper and middle ampullary rectum T3-4N0-2M0, for whom radiation therapy is indicated as the first stage of treatment, after which resection of the rectum is performed in a standard volume.

Keywords: cancer of the upper and middle ampullary rectum, radiation therapy, radiomodification, chemotherapy, surgical treatment

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НОВЫЙ МЕТОД МОДИФИЦИРОВАННОГО ХИМИОЛУЧЕВОГО ЛЕЧЕНИЯ РАКА ВЕРХНЕ- И СРЕДНЕАМПУЛЯРНОГО ОТДЕЛА ПРЯМОЙ КИШКИ

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РЕЗЮМЕ

Последнее десятилетие характеризуется значительными успехами в лечении рака прямой кишки (снижение числа рецидивов до 5–6 % при применении пролонгированной лучевой терапии) перед оперативным вмешательством. Наибольший успех достигнут при лечении рака нижеампулярного отдела прямой кишки, когда возможно развитие полного клинического ответа опухоли прямой кишки на химиолучевое лечение. При этом остаются проблемы необходимости улучшения результатов лечения рака верхне- и среднеампулярного отдела прямой кишки с увеличением выживаемости больных. Это делает актуальным разработку новых методов, повышающих эффективность лечения рака прямой кишки. В нашем исследовании был разработан метод модифицированной химиолучевой терапии рака верхнеампулярного отдела прямой кишки. Метод заключается в следующем. Первым этапом за сутки до начала лучевой терапии пациенту выполняется суперселективная катетеризация верхней прямокишечной артерии через лучевую или бедренную артерию с последующим регионарным введением радиомодифицирующих химиопрепаратов: цисплатин 50 мг и фторурацил 500 мг. Через сутки больным начинается курс конформной дистанционной крупнофракционной лучевой терапии на первичный очаг и пути метастазирования в течение 5 сеансов с разовой очаговой дозой 5 Гр до суммарной очаговой дозы 25 Гр на низкоэнергетическом линейном ускорителе. На протяжении всего курса лучевой терапии больным за 30 мин до сеанса ежедневно внутривенно вводится фторурацил 500 мг в течение 30 мин. Хирургическое вмешательство с забором материала на исследование проводится через 6–8 недель после окончания лучевой терапии. Для оценки эффективности модифицированного химиолучевого лечения определяли степень регрессии опухоли по шкале RECIST, при морфологическом исследовании удаленной во время операции опухоли прямой кишки определяли степень лечебного патоморфоза опухоли по Dworak. Разработанный метод модифицированной химиолучевой терапии позволяет добиться регрессии опухоли прямой кишки за короткий срок, сократить сроки и увеличить эффективность лечения. Метод модифицированной химиолучевой терапии предназначен для больных раком верхне- и среднеампулярного отдела прямой кишки T3-4N0-2M0, которым первым этапом лечения показана лучевая терапия, после чего выполняется резекция прямой кишки в стандартном объеме.

Ключевые слова: рак верхне- и среднеампулярного отдела прямой кишки, лучевая терапия, радиомодификация, химиотерапия, оперативное лечение

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Соблюдение этических стандартов: в работе соблюдались этические принципы, предъявляемые Хельсинкской декларацией Всемирной медицинской ассоциации (World Medical Association Declaration of Helsinki, 1964, ред. 2013). Информированное согласие получено от всех участников исследования.

Финансирование: финансирование данной работы не проводилось.

Конфликт интересов: все авторы заявляют об отсутствии явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

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Substantiation

Treatment of rectal cancer depends on the stage of cancer, the localization of the tumor [1]. There are various treatment options for rectal cancer, which include surgery, radiation therapy, chemotherapy or a combination of these approaches [2–4]. The successful use of radiation therapy for malignant tumors of the rectum has led to the fact that it is included in the standards for the treatment of malignant tumors of this localization [5]. Methods of both preoperative and postoperative radiation therapy have been developed for the treatment of rectal cancer. However, preoperative radiation therapy proved to be the most effective. In many countries, including Russia, there is an increase in the frequency of use of preoperative radiation therapy and a decrease in the frequency of use of postoperative radiation therapy for rectal cancer. Thus, according to the study, in the USA from 2004 to 2011, in the structure of patients who received radiation therapy, the frequency of preoperative radiation therapy increased from 57 to 75 %, and the frequency of postoperative radiation therapy decreased from 39 to 18 % [6].

Radiation therapy for rectal cancer is possible in the form of a prolonged and short large-fraction course of radiation therapy. Numerous studies have been conducted to clarify the advantages and disadvantages of both methods of radiation therapy. The results of the studies have shown that patients with locally advanced malignant tumors of the rectum benefit from a prolonged course of radiation therapy, especially with lesions extending beyond the rectal wall and threatening to involve mesorectal fascia in the tumor process, as well as in cases of metastatic lesions of regional lymph nodes; with cancer of the lower ampullary rectum in order to increase the chances of performing sphincter-preserving operations and reducing the frequency of local relapses. A short course of radiation therapy with large dose fractionation is carried out with localized tumors of the upper and middle ampullary rectum, when preoperative therapy cannot change the volume of surgery on the rectum; if it is impossible to carry out a prolonged course of radiation therapy [7–9].

Conducting a preoperative course of prolonged radiation therapy reduces the 5-year recurrence rate in malignant tumors of the rectum by 2 times from 10.9 to 5.6 % [8; 10]. In the conducted randomized trials (SRCSG and SRCT), in addition to reducing the

frequency of local relapses, an increase of 10 % in the overall and relapse-free survival of patients was also proven [11; 12].

A prolonged course of preoperative radiation therapy for distal rectal cancer may be so effective that it leads to a complete regression of the rectal tumor with the development of a complete clinical and pathomorphological response of the tumor to preoperative therapy [13–15]. As for cancer of the upper ampullary rectum, with this localization of the tumor, such a pronounced effect on neoadjuvant radiation therapy was not observed. All this indicates the need to develop and apply more intensive therapy regimens for the treatment of cancer of the upper ampullary rectum.

Purpose of the study is to develop a method of effective treatment of cancer of the upper ampullary rectum.

Research design

To increase the effectiveness of radiation therapy, we have developed a method of modified chemoradiotherapy, which allows us to achieve proper pathomorphological and therapeutic effects on the tumor, as well as to shorten the treatment time of patients. The method of modified chemoradiotherapy is intended for patients with cancer of the upper and middle ampullary rectum T3-4N0-2M0, who are shown radiation therapy as the first stage of treatment, after which rectal resection is performed in a standard volume.

Indications for the modified chemoradiotherapy were: unresectable locally advanced cancer of the upper and middle ampullary rectum T3-4N0-2M0; possibility of chemoradiotherapy; informed consent of the patient. Contraindications for the modified chemoradiotherapy were: unresectable rectal cancer, the presence of distant metastases, the impossibility of chemoradiotherapy.

Description of medical intervention

The method of modified chemoradiotherapy is as follows. The first stage, a day before the start of radiation therapy, the patient undergoes superselective catheterization of the upper rectal artery through the radial or femoral artery, followed by regional administration of radiomodifying chemotherapy drugs: cisplatin 50 mg and fluorouracil 500 mg. A day later, patients begin to receive a course of conformal remote radiation therapy for the primary tumor area and the area of regional metastasis, 5

sessions with a single dose of 5 Gy to a total focal dose of 25 Gy. During the entire course of radiation therapy, patients are injected daily intravenously with fluorouracil 500 mg for 30 minutes 30 minutes before the session. Surgical intervention on the rectum in the standard volume is performed 6–8 weeks after the completion of the course of radiation therapy. To assess the effectiveness of the treatment performed during the morphological examination of the surgical material, the stage of therapeutic pathomorphosis of the tumor is determined by Dworak.

Patient B., born on 09/20/1956, was admitted to the clinic of the National Medical Research Centre for Oncology on 02/03/2017 with complaints of blood and mucus in the feces, tenesmus, weakness.

It is known from the anamnesis that he considers himself ill since December 2016, when the above complaints appeared. I went to the doctor at my place of residence, a colonoscopy revealed a rectal tumor. Morphological analysis No. 449-58: G2 adenocarcinoma. The patient was sent to the National Medical Research Centre for Oncology, where a follow-up examination was conducted.

MRI of ACO and PO on 01/25/2017 revealed a tumor of the middle ampullary rectum with a spread to the upper ampullary $7.5 \times 2.4 \times 4.3$ cm, at a distance of 8.1 cm from the anus, with lesion of mesorectal lymph nodes (Fig. 1a, b).

At the FCS on 12/28/2016, a rectal tumor was detected at a distance of 10 cm from the anus, examination to the caecum.

With a clinical diagnosis of cancer of the middle ampullary rectum cT3N1M0, ct 3B, cl.gr. 2, the patient was hospitalized for treatment.

On 02/07/2017, the patient underwent catheterization of the upper rectal artery through the femoral artery (Fig. 2), into which cisplatin 50 mg at 5 % glucose 50 ml and fluorouracil 500 mg were injected. On 02/08/2017, the patient began a short course of large-fraction radiation therapy (5 sessions of 5 Gy per primary tumor and regional lymph nodes), before the start of each session for radiation therapy, fluorouracil 500 mg was administered intravenously on a 0.9 % 200 ml sodium chloride solution for 30 minutes. After a 30-minute exposure, a radiation therapy session was performed. She underwent the course of modified chemoradiotherapy satisfactorily, there were no reactions and complications.

6 weeks after the end of the modified chemoradiotherapy, the patient underwent a control examination. An MRI of the abdominal cavity and pelvic organs on 03/20/2017 revealed a residual tumor of the middle ampullary rectum with signs of pathomorphosis, as well as a decrease in mesorectal lymph nodes in dynamics (fig. 3).

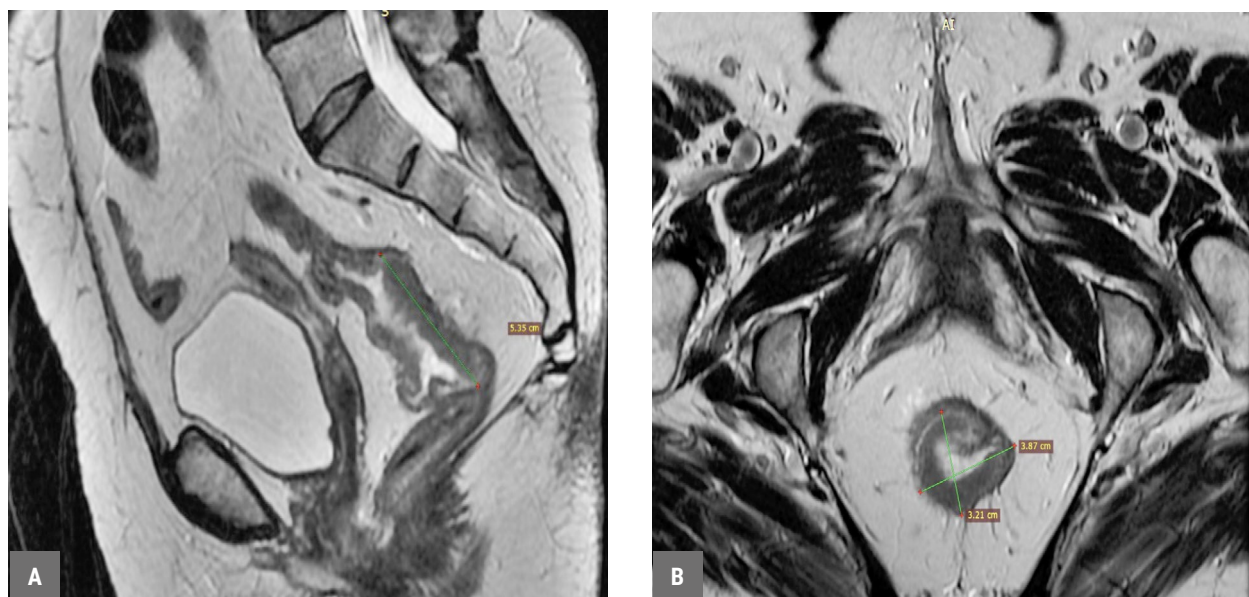


Fig. 1. MRI of the pelvic organs: a tumor of the middle ampullary rectum with a spread to the upper ampullary $7.5 \times 2.4 \times 4.3$ cm, at a distance of 8.1 cm from the anus, with lesion of mesorectal lymph nodes (a) sagittal section, (b) frontal section.

Rectoromanoscopy on 03/20/2017 revealed ulceration of the rectal mucosa up to 3 cm in diameter at 9 cm from the anus.

On 03/26/2017, the patient underwent surgery: anterior rectal resection with preventive ileostomy. Macropreparation: at the site of the tumor – ulceration of the mucous membrane of the rectum up to 3 cm in diameter (Fig. 4). Regional lymph nodes are not changed.

Histological examination of surgical material No. 24441-44/17: G2 adenocarcinoma with invasion of all layers of the wall, ulceration, inflammation. Signs of therapeutic pathomorphosis of the III grade – in the fibrous stroma of petrification; 24446-47/17 resection lines have the usual structure; 24445; 24448-49/17: in the lymph nodes sinus histiocytosis, focal lipomatosis.

Postoperative diagnosis: cancer of the middle ampullary rectum t3n1m0, st 3B, t.gr. 2, condition after chemoradiotherapy, T3N0M0. After surgery, she received courses of adjuvant chemotherapy with capecitabine. After 2 months, the patient completed the closure of the ileostomy without complications. The patient is observed without signs of progression to the present (more than 5 years).

Main study results

Thus, the given clinical example demonstrates a pronounced regression of the rectal tumor in a short period under the influence of modified radiation therapy: the tumor from 7.5 cm decreased to ulceration of the mucosa with a diameter of 3 cm (partial regression of the tumor on the RECIST scale) with the development of therapeutic pathomorphosis of the III grade.

Adverse effects

No adverse events were observed during the study.

DISCUSSION

Summary of the main research results

As a result of the study, a new method of modified chemoradiotherapy for cancer of the upper and middle ampullary rectum has been developed, which allows effective treatment in a short time with the development of therapeutic pathomorphosis of 3–4 stage.

Discussion of the main research results

The results of the application of the developed method of modified chemoradiotherapy have shown its effectiveness, which may be due to several mechanisms. Firstly, it is undoubtedly the modifying ef-



Fig. 2. Angiography: the upper rectal artery and its branches are contrasted.



Fig. 3. MRI of the pelvic organs after modified chemoradiotherapy: residual tumor of the middle ampullary rectum with signs of pathomorphosis, as well as a decrease in mesorectal lymph nodes in dynamics.

fect of radiation therapy through the introduction of chemotherapy drugs. Secondly, this is the effect of regional chemotherapy, carried out superselectively through the upper rectal artery directly to the rectal tumor. The interaction of radiation and chemotherapy methods is also important. All these factors are involved in the development of therapeutic pathomorphosis of a rectal tumor of 3–4 stages in a short time, which reduces the duration of treatment of patients. Perhaps further movement in this direction will allow us to improve the method and achieve a complete clinical response of the tumor of the upper and middle ampullary rectum, as can be observed in cancer of the lower ampullary rectum.

CONCLUSION

So, a method of modified chemoradiotherapy for cancer of the upper and middle ampullary rectum was developed and put into practice, including preoperative radiation therapy with a short course of large dose fractionation and standard surgical treatment, characterized in that patients undergo superselective catheterization of the upper rectal artery before starting radiation therapy, followed by regional administration of radiomodifying chemotherapy drugs: cisplatin and fluorouracil. A day later, patients undergo a course of remote conformal large-fraction radiation therapy for the rectal tumor area and the area of regional metastasis, a total of 5 sessions with a single dose of 5 Gy to



Fig. 4. Macropreparation: at the site of the tumor – ulceration of the mucous membrane of the rectum up to 3 cm in diameter.

a total dose of 25 Gy. During the entire course of radiation therapy, patients are injected daily intravenously with fluorouracil 500 mg for 30 minutes 30 minutes before the session. Surgical intervention on the rectum in the standard volume is performed 6–8 weeks after the completion of the course of radiation therapy. The use of the modified chemoradiotherapy method allows for highly effective treatment for cancer of the upper and middle ampullary rectum, confirmed by the development of therapeutic tumor pathomorphosis. These data indicate the effectiveness of the developed method of modified chemoradiotherapy for rectal cancer, which makes it possible to recommend it for use in clinical practice.

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