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INTRA-ARTERIAL CHEMOTHERAPY AS A CLINICAL OPTION FOR METASTATIC COLORECTAL CANCER: CONVERSION OF INOPERABLE LIVER METASTASES TO OPERABLE ILLUSTRATED WITH A CLINICAL CASE

Colorectal cancer exerts a very high level of liver metastases, even on primary diagnosis, with 80%—90% unresectable nodules. At the same time, the possibility of resection has a significant impact on survival: 5-year survival is 6%—10% without liver surgery and up to 30% upon resection of liver metastases. Finding ways to improve resectability is a topical search for doctors all over the world. One of the promising methods to convert unresectable liver metastases of colorectal cancer into resectable ones is a hepatic artery infusion, or intra-arterial chemotherapy allowing for the delivery of cytotoxic drugs directly to the common hepatic artery via catheter or pump with decreased systemic toxicity and increased local drug concentration. In this article, we discuss the literature data on the impact of intra-arterial chemotherapy on the resectability of colorectal metastases in the liver and present the results of the successful clinical case. The literature shows a positive impact of the hepatic artery infusion on the resectability of hepatic metastases of colorectal cancer. The National Cancer Institute (Ukraine) has its own experience in hepatic artery infusion with further resection of primary-unresectable colorectal metastases in the liver. In our clinical case, a patient with liver-limited metastasis of colorectal cancer was initially inoperable due to the size of tumor lesions and an insufficient residual volume of the liver. Hepatic artery infusion tactics was chosen for this patient. The patient received six cycles of intra-arterial chemotherapy, namely five FOLFOX cycles and one 5-FU cycle, and then met the resectability criteria. Also, it is important to notice that the case demonstrates chemoresistance overcoming, since the patient had disease progression before, following systemically administered XELOX,

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and the period until readmission of the drugs was less than 6 months. So, hepatic artery infusion can be considered a promising method to convert unresectable liver metastases of colorectal cancer into resectable ones for highly selected patients.

Keywords: metastatic colorectal cancer, liver metastasis, hepatic artery infusion, intra-arterial chemotherapy, conversion to respectability.

Colorectal cancer (CRC) is the third most common type of cancer in the world. Among other malignancies, it takes third place in men and second place in women for the frequency of diagnosis. In 2020, more than 1.9 million new cases of CRC were diagnosed [1]. As for cancer incidence in Ukraine, the CRC statistics is separate for colon and rectal cancer. In 2020—2021, the incidence of malignant neoplasms of the colon in men and women was in fourth place (7.1% and 6.8%, respectively), malignancies of the rectum in sixth place (6.7%) in men and in seventh place (5.0%) in women (among all cancer types). Mortality from colon and rectal cancer ranked third (7.7%) and fifth (7.3%) in men and third (7.5%) and sixth (5.5%) in women, respectively [2].

60% of CRC patients have liver metastases, about 80%—90% of which are unresectable [3]. The failure to perform metastasectomy is associated with a worse prognosis: the 5-year survival in this case is only 6%—10% [4, 5]. If surgery is performed successfully, the survival increases up to 30% [6]. The median overall survival for unresectable but systematically treated primary liver metastases ranges from 9 to 19.5 months and depends on the number of lines of therapy and drugs used. Therefore, the possibility of conversion of metastatic lesions in the liver is highly important for long-term survival prognosis. Hence, approaches that potentially can increase the chance of conversion deserve special attention.

One of such approaches is intrahepatic arterial chemotherapy (or hepatic arterial infusion, HAI). The anatomical features of the blood supply of the liver and its metastatic lesions (healthy tissue is perfused via the portal vein, and metastases are perfused via the hepatic artery) allow the direct delivery of cytotoxic agents and provide a higher local concentration with lower systemic toxicity [7, 8].

The aim of this paper is to demonstrate the successful conversion of liver metastases in a clinical case from the National Cancer Institute (Kyiv, Ukraine), in which a patient was previously treated with HAI. We propose to consider this technique an additional therapeutic option for patients who have exhausted the generally recommended algorithms.

Clinical case

Patient V., female, 56 y.o. at the time of diagnosis with colon cancer in December 2021. The clinical diagnosis was based on CT of the chest, abdomen, and pelvis with IV contrast, colonoscopy, and biopsy and was formulated as follows: adenocarcinoma of the transverse colon G2 cT3N1M1 (liver), stage IV. She received 9 courses of XELOX polychemotherapy from December 2021 to July 2022, after which, due to the disease progression (appearance of a new lesion in the liver), the systemic therapy was changed to the second line. She received 3 courses of FOLFIRI polychemotherapy from September to November 2022, but on follow-up CT the disease progression appeared again (enlargement of the existing foci and appearance of new foci in the liver). The symptoms of intestinal obstruction began developing, and the patient was referred to the National Cancer Institute in November 2022 for surgical treatment. It was decided to perform a colon surgery for life-saving reasons, and also, taking into account the patient's chemoresistance and the area of metastasis limited to the liver, to install a port in the hepatic artery for further intra-arterial chemotherapy. The liver

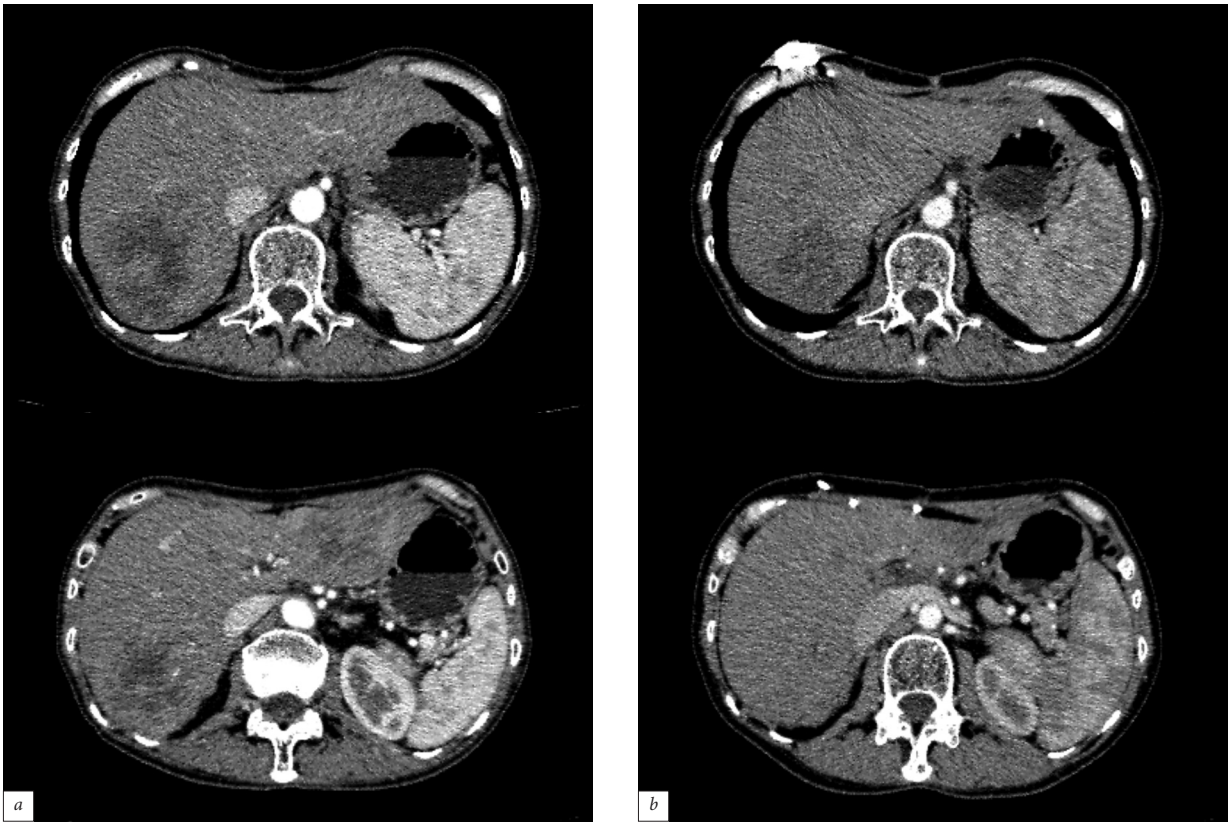

Fig. 1. Size dynamics of metastatic lesions in the liver before (*a*) and after (*b*) HAI

lesions were considered unresectable because the residual liver volume would be < 30%. At the time of examination, the following metastatic lesions were present: S2, S3, S6/borderline S7, S7, and S7/borderline S8.

In December 2022, the patient underwent palliative resection of the transverse colon, cholecystectomy, and implantation of an intra-arterial hepatic port. The postoperative histology reported: intestinal adenocarcinoma after polychemotherapy, with widespread necrosis, hemorrhages, and the presence of lymphovascular invasion. The tumor infiltrates all layers and grows into adipose tissue. The resection margin is without tumor elements. Carcinoma metastases in 2 adjacent lymph nodes. Carcinomatosis of the mesentery. pT3N1b LVI1 PNI0 R0.

From December 2022 to April 2023, the patient received 5 cycles of HAI FOLFOX (HAI oxaliplatin 85 mg/m^2 on an infusion pump, IV calcium folinate 400 mg/m^2, HAI 5-fluorouracil 2400 mg/m^2 on an infusion pump for 46 h) and 1 cycle of HAI 5-FU (IV calcium folinate 400 mg/m^2, HAI 5-fluorouracil 2400 mg/m^2 on an infusion pump for 46 h) due to the peripheral sensory neuropathy.

In June 2023, the patient underwent imaging: CT of the chest, abdominal cavity, and pelvis with IV contrast, and MRI of the abdominal cavity with IV contrast. Per RECIST 1.1, the effect of the treatment was assessed as a stable disease with positive dynamics. The multidisciplinary tumor board revised the possibility of liver surgery and assessed the disease as operable.

The patient underwent the surgery: left lateral resection of the liver and anatomical resection of Sg 6—7. The postoperative period had no Grade 3—4 adverse events.

The postoperative histology showed metastases of poorly differentiated intestinal- type adenocarcinoma with necrosis.

This case demonstrates the possibility of not only converting inoperable cases of metastatic colorectal cancer into operable ones but also overcoming chemoresistance with HAI as the tumor responded to treatment with a regimen using oxaliplatin and fluoropyrimidines, taking into account that the disease progressed before on the systemically administered XELOX, and the period before readmission of the drugs was less than 6 months.

The comparative CT images are shown in the Figure.

This case is not a single one demonstrating successful management of the primary unresectable liver lesions. Another one, published by the authors in a previous paper [9], also reflects a conversion of liver-limited metastatic colorectal cancer of the patient who received two lines of systemic therapy before HAI (monocapecitabine and IROX). The regimen used for intra-arterial administration also was FOLFOX, the patient received four full cycles and one unfinished, then the liver surgery was performed, and a complete pathological response was obtained.

This case clearly illustrates that after two lines of systemic therapy and several progressions, the use of an intra-arterial approach helps not only to reduce the volume of metastatic liver damage and to stabilize the disease but also to perform surgical resection, which was not possible in the beginning.

Review of Literature

The technique of the intra-arterial administration of chemotherapy drugs has been used in the world for more than 40 years, in Ukraine — since the 1960s. But even today, it is an alternative approach rather than an approved algorithm due to a significant list of clinical and technical requirements for potential candidates, the requirement for multidisciplinary discussion with surgeons, clinical oncologists, radiologists, anesthesiologists, and also the necessity of using angiography in the clinic during surgical interventions. Because of all that, the available publications covering this therapeutic approach present mostly separate clinical cases or 0reports of phase I—II clinical trials.

At the beginning of the patient's preparation for the surgical stage, namely the installation of a port or a pump into the hepatic artery, a general assessment of contraindications is required. This includes but is not limited to the general condition of the patient according to the classification of the Eastern Cooperative Oncology Group (should be ECOG 2 and higher), the presence of concomitant liver pathology or insufficiency of its function, portal hypertension, portal vein occlusion, or a significant tumor burden in the liver [10]. The presence of extrahepatic metastases is a relative contraindication and can be considered by a multidisciplinary consensus: if these lesions are single and clinically stable, the patient has exhausted therapeutic options and is a candidate for only supportive or symptomatic treatment otherwise, performing HAI is more beneficial than all the risks, and intra-arterial chemotherapy may be performed even with extrahepatic metastases.

The administration of the drugs into the artery is preceded by the surgical implantation of a port or pump. The distal gastroduodenal artery, the right gastric artery, and small collateral branches supplying the stomach, small intestine, and pancreas are all ligated. At the same time, a cholecystectomy is performed to prevent further chemo-induced cholecystitis. The port or pump is located subcutaneously on the anterior abdominal wall. The assessment of the functioning and bilobular liver perfusion is made under angiography control with an X-ray contrast agent or methylene blue dye [11—13].

The complications of HAI can be divided into three groups: surgical, port- or catheter-related,

and general side effects from cytotoxic agents. The most common surgical complications include bleeding from large vessel injury, infection, and abscessation. The port- or catheter-related complications include port migration, drug extravasation, catheter thrombosis, and hepatic artery occlusion. The complications associated with the cytotoxic agents include all common side effects of the systemic administration of the corresponding drugs, with additional local manifestations (pain) and those associated with the hepatobiliary system such as the increased levels of transferases and bilirubin, biliary sclerosis, and toxic hepatitis [10]. The most dangerous side effect of HAI is a dilation of the hepatic sinusoidal capillaries and hepatocyte atrophy, a progressive degenerative process that can lead to liver cirrhosis and necrosis [14]. The vigilance about specific adverse events requires adjustments to the routine examination before each new course of chemotherapy, namely mandatory angiographic control of the port and more frequent sonographic control.

The drugs used in HAI must meet certain requirements: elimination mostly by the liver, short half-life, and high total clearance of the body. These conditions lead to a lower systemic accumulation of the drug and, accordingly, to a decrease in overall toxicity, simultaneously with a greater local concentration of the drug. In the world practice, the "ideal agent" for intra-arterial administration is floxuridine (FUDR), which turns into 5-FU in the process of metabolism. The regimens using this drug range from monotherapy to the variations of the more common FOLFOX with intra-arterial modification and replacement of 5-FU with FUDR.

The literature provides examples of the study of intra-arterial chemotherapy with FUDR in the context of the conversion of unresectable liver metastases of CRC into resectable ones. Kemeny et al. [15] have described a single-arm study in which patients with mCRC received HAI FUDR/Dex followed by intravenous oxaliplatin and irinotecan. Both naïve and previously treated patients were included. Among the latter, the percentage of successful conversion was 47% whereas in the subgroup of naïve patients — 57%. Compared to the previously reported conversion percentage after systemic chemotherapy of 15%, the results look quite encouraging. The phase II study by D'Angelica et al. [16] highlights the conversion after HAI FUDR/Dex combined with two IV regimens: oxaliplatin, irinotecan, and bevacizumab; and irinotecan, 5-FU, leucovorin, and bevacizumab. The results demonstrate 47% of conversions of primary unresectable liver metastases, as well as good survival rates after surgery: ORR 76%, median PFS, and median OS – 13 and 38 months, respectively, for the all-patients group (vs. the historical data on the primary-metastatic CRC and systemic PCT: 30%—45% survival rate depending on the number of the lines; the median survival of 17.4—19.5 months for the first line depending on the drugs and of 9—12 months for the subsequent lines [17]).

FUDR is not registered in Ukraine, but the worldwide experience gained from its intra-arterial administration is valuable and indicative anyway: Lorenz and Müller [18] demonstrated the comparability of the survival results and safety for FUDR and 5-FU administered intra-arterially.

Oxaliplatin is the second most frequently used intra-arterial drug in mCRC. The schedules with this agent also have a positive effect on the conversion.

Ducreux et al. [19] published results of a phase II trial of the HAI oxaliplatin efficacy in combination with the IV “de Gramont” regimen in patients with unresectable liver metastases of CRC. The ORR was 64%, with 18% of patients successfully transitioning to the possibility of radical surgical resection of metastases. At the same time, the median indicators of OS and PFS were 27 months. In another study by Boige et al. [20], HAI oxaliplatin was administered in combina-

tion with intravenous leucovorin (200 mg/m^2) and bolus administration of 5-FU (400 mg/m^2) on day 1 followed by a 48-h intravenous infusion of 5-FU (2400 mg/m^2, modified "de Gramont" regimen) to the cohort of previously treated patients, mostly chemoresistant (from 1 to 5 lines of systemic chemotherapy based on irinotecan and/or oxaliplatin plus 5-FU and leucovorin). The PFS was 55%, and 18% of the initially inoperable patients became eligible for R0 surgical resection or radiofrequency ablation as a result of the treatment. The median PFS and OS were 7 months and 16 months, respectively.

The accessible studies demonstrate the possibility to administer intra-arterially not only one drug with the following IV components of the schedule but also HAI doublets or triplets. As an example, the goal of the European multicenter phase II OPTILIV study was to determine the potential for the conversion of unresectable CRC liver metastases into resectable ones after intravenous administration of cetuximab followed by HAI triplet (irinotecan, oxaliplatin, and 5-FU). The intra-arterial infusion was performed in chronomodulated and sequential modes. 64 patients with unresectable primary-metastatic wt-KRAS (wild-type KRAS (Kirsten RAt Sarcoma) CRC participated in the study. The possibility of resection of liver metastases was reassessed by a multidisciplinary team after every third 14-day cycle. Achieving a conversion rate of 30% was taken as the primary endpoint. The researchers report the achievement of the primary endpoint, that is, the rate of R0—R1 hepatectomy after the treatment was 29.7% (95% CI 18.5—40.9). The median OS after surgery was 35.2 months (32.6—37.8 mo.), and 4-year survival was 37.4% (23.6%—51.2%). Thus, the investigated schedule confirmed the perspective of HAI triplet for the conversion of unresectable liver metastases of CRC [21].

To date, intra-arterial chemotherapy of liver metastases of CRC is not a standard of care, but it is already indicated in the NCCN guidelines as a possible option [22]. Such an approach may become an additional variant for the treatment of chemoresistant metastatic CRC, as well as give hope for the conversion of previously unresectable metastases to resectable ones, thus improving long-term survival prognoses.

The promising conversion results are reported in the literature on the Ukrainian experience as well. The two cases, one presented in this manuscript and another published earlier by Cherchenko et al. [9], have much in common. Both patients had CRC with liver lesions, too big to perform R0 surgery: the residual volume of the liver was expected to be insufficient. Both patients already received 2 systemic lines of treatment each: XELOX, FOLFIRI for the patient described here, and mono-capecitabine, IROX for the case published earlier. There are also differences between them. In the present study, the patient had a primary-metastatic disease and liver metastases only during the course of the disease; she had colon surgery for life-saving reasons because of intestinal obstruction after 2 lines of chemotherapy. The patient from the previous case started with a surgically treated localized disease, but later cancer spread to the lungs, was resected, and only after that liver lesions appeared. The cases show the variety of clinical representations, for which HAI was considered later, and it gives hope for patients even after several lines and approaches of therapy. The successful Ukrainian cases correlate with the literature data from American and European colleagues.

Therefore, the hepatic artery infusion can be considered a promising method to convert unresectable liver metastases of colorectal cancer into resectable ones for highly selected patients.

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ВНУТРІШНЬОАРТЕРІАЛЬНА ХІМІОТЕРАПІЯ ЯК КЛІНІЧНА ОПЦІЯ ДЛЯ МЕТАСТАТИЧНОГО КОЛОРЕКТАЛЬНОГО РАКУ: КОНВЕРСІЯ НЕОПЕРАБЕЛЬНИХ ПЕЧІНКОВИХ МЕТАСТАЗІВ В ОПЕРАБЕЛЬНІ, ПРОІЛЮСТРОВАНА КЛІНІЧНИМ ПРИКЛАДОМ

Колоректальний рак має дуже високий рівень метастазуваня у печінку навіть на етапі первинної діагностики, при цьому 80—90% випадків є нерезектабельними. У той же час, можливість резекції значною мірою впливає на результати виживаності: 6—10% 5-річної виживаності, якщо операції на печінці не було, та зростання показника до 30% за її успішності. Пошук способів збільшити резектабельність є пріоритетним для ікарів в усьому світі. Одним із перспективних методів конвертувати нерезектабельні печінкові метастази в резектабельні є печінкова артеріальна інфузія, або внутрішньоартеріальна хіміотерапія. Цей етод дозволяє подавати цитотоксичні препарати напряму в загальну печінкову артерію через катетер або помпу, знижуючи системну токсичність та збільшуючи місцеву концентрацію. У цій статті ми аналізуємо публікації щодо впливу внутрішньо артеріальної хіміотерапії на резектабельність печінкових метастазів колоректального раку, а також наводимо результати успішного клінічного випадку. Літературні дані описують позитивний вплив печінкової артеріальної інфузії на резектабельність печінкових метастазів колоректального раку. Також Національний інститут раку має власний успішний випадок застосування внутрішньоартеріальної хіміотерапії з подальшою резекцією первиннонерезектабельних печінкових метастазів колоректального раку. Пацієнтка з колоректальним раком та метастатичним ураженням лише печінки була первиннонеоперабельною через значний розмір пухлинних вогнищ та недостатній розрахунковий залишковий об'єм печінки. Для пацієнтки було обрано тактику печінкової артеріальної інфузії. Вона отримала шість курсів внутрішньо артеріальної хіміотерапії: п'ять курсів FOLFOX та один курс 5-фторурацилу, після чого досягла відповідності критеріям резектабельності. Важливо зазначити, що цей випадок демонструє також подолання хіміорезистентності, оскільки пацієнтка вже мала прогресію після застосування схеми XELOX, а до моменту повернення до цих препаратів пройшло менше 6 місяців. Внутрішньоартеріальна хіміотерапія може бути розглянута як перспективний метод для конверсії нерезектабельних печінкових метастазів колоректального раку у резектабельні за умови ретельної селекції пацієнтів.

Ключові слова: метастатичний колоректальний рак, печінкові метастази, печінкова артеріальна інфузія, внутрішньоартеріальна хіміотерапія, конверсія до резектабельності.