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Active surveillance program of patients with rectal cancer with a complete clinical response after prolonged chemoradiotherapy with consolidating chemotherapy

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ABSTRACT *AIM: to determine the algorithm for selecting patients included in the ASP program after prolonged chemoradiotherapy (CRT) with consolidation chemotherapy (CCT).*
PATIENTS AND METHODS: the retrospective study included patients with adenocarcinoma of the low and middle rectum (2017 to 2024), who achieved cCR after CRT with CCT, which led to the decision to implement ASP. Radiotherapy was administered in a prolonged mode at a dose of 50–55 Gy with oral capecitabine intake. Between the completion of CRT and the first follow-up examination, 4 cycles of CCT were done in the FOLFOX6 regimen. Clinical tumor regression was assessed 4 weeks after the completion of CCT, based on the data from endoscopy, digital examination, and MRI. cCR was understood to refer to cases where, during endoscopic treatment performed after CRT and CCT at the site of the previously determined tumor, there were signs of a flat white/red scar.
RESULTS: the study included 27 patients (15 (55.6%) men, 12 (44.4%) women). The patients' age ranged from 38 to 80 years (median 63 years). The median distance from the anal verge to the lower edge of the tumor was 4.5 (2.0–9.5) cm. Most patients had clinical stage III disease — 18/27 (66.7%), while the tumor size in the largest dimension ranged from 2.4 to 6.5 cm (median 4.0 cm). The median interval between the completion of CRT and the follow-up examination was 16 (9–25) weeks. MRI of the pelvic organs revealed TRG1 in 13/27 (48.1%) patients, TRG2 also in 13/27 (48.1%) and in one patient (3.7%) has a mucinous tumor that is not subject to standard TRG assessment. The MRI findings of all patients selected for ASP was characterized by fibrosis of the tumor bed without signs of residual tumor tissue/affected lymph nodes in the mesorectal tissue and deep layers of the wall, while both thin and full-thickness and split fibrous scars present, extending up to half the circumference. All patients who achieved cCR had a primary tumor of category up to T3b inclusive. With a median follow-up of 14.7 (3.8–80.2) months, tumor regrowth was observed in 2/27 patients (7.4%), both of whom underwent radical surgeries. Three-year relapse-free survival rate was 81.1 ± 10.1%, while overall survival 95.2 ± 4.6%.
CONCLUSIONS: the implementation of an ASP program after CRT should be based on careful selection of patients who have achieved cCR according to comprehensive check-up. It is advisable to begin the examination with MRI followed by endoscopy, as this approach provides all necessary information and avoids artifacts in MRI that may arise after endoscopy. Endoscopy plays a leading role in assessing the intraluminal tumor component, with the only manifestation of cCR being a flat white or red scar.

KEYWORDS: *rectal cancer, complete clinical response, watch and wait*

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INTRODUCTION

Modern treatment of RC in most cases involves neoadjuvant therapy (chemotherapy, chemoradiotherapy, immunotherapy) aimed not only at reducing the size, but also at achieving the disappearance of the tumor. It has been shown that overall and disease-free survival in patients with a complete response to CRT is significantly higher than in other patients [1]. In addition, numerous studies have shown the possibility of using active surveillance program (ASP) for cCR. The rate of tumor re-growth in such cases, according to the Watch and Wait registry and large population studies, can reach 20–25%. However, in most cases, tumor re-growth occurs from the rectal lumen during the first two to three years after treatment, and with regular checkup, most of them undergo radical surgery [2–4].

Despite the apparent simplicity and attractiveness of ASP, its use cannot be called standard. It is still not included in the clinical guidelines in many countries, and therefore it can only be used in clinical trials. An indication of the possibility of monitoring patients with cCR with low rectal tumors has appeared in the Russian clinical guidelines since 2020, but only in federal centers with the necessary experience [5]. On the one hand, this is due to the fact that the detection of tumor re-growth is associated with a high risk of late metastasis, therefore, monitoring should be active in order to perform radical surgery timely [6,7]. On the other hand, despite the fact that the first description of the possibility of using ASP was given in 2004 [8], there are still no effective criteria for the diagnosis of cCR. The standard diagnosis is based on the use of the endoscopy, magnetic resonance imaging (MRI) and rectal digital examination. Other methods, such as positron emission tomography, endosonography, and biopsy, have low diagnostic effectiveness and are not recommended for routine use by most expert communities [4,9,10].

The endoscopic method and MRI complement each other and, when used together, increase the accuracy of cCR diagnosis by up to 98% [11]. The endoscopic method is of leading importance, while cCR is usually understood as the complete disappearance of a tumor with the presence of a flat scar/telangiectasia at the site of a pre-existing tumor [10]. In this case, the magnetic resonance pattern may be variable and not so unambiguous, and the possibilities of the method require further study and improvement.

The A.F. Tsyba MRRC of Radiology has been using ASP for cCR after CRT since 2018.

AIM

To work out selection criteria for ASP after prolonged CRT with CCT.

PATIENTS AND METHODS

The study included patients with malignant neoplasms of the low and middle rectum, who underwent prolonged CRT with consolidating chemotherapy (CCT) in 2017–2024, and who had cCR during a follow-up; and therefore, it was decided to conduct ASP in relation to them.

Before starting the treatment, all patients underwent magnetic resonance imaging (MRI) of the pelvic organs with 1.5 Tl Magnetom Symphony (Siemens) and Philips Ingenia magnetic resonance imaging without prior preparation, intestinal lumen contrast and intravenous contrast. The staging protocol included high-resolution T2 weighted images (T2WI) (field of view 16–12 cm, slice thickness 2–3 mm, submillimeter resolution in the slice plane, without intersections) in an obliquely axial plane oriented perpendicular to the intestinal wall at the level of the tumor center. During the initial staging, the depth of tumor invasion, the status of regional lymph nodes, the distance from the anal margin to the lower pole of the tumor, the presence of extramural vascular invasion (EVI), as well as the distance from the tumor to the potential circular border of resection (CBR) were evaluated. Computed tomography (CT) of the abdominal and thoracic organs was also performed in all

patients to exclude distant metastasis as well. Conventional radiation therapy in the period from 2017 to 2021 was performed with a linear accelerator using the four-field isocentric irradiation method in a single focal dose (SFD) of 2 Gy to a total focal dose (TFD) of 50 Gy (Fig. 1). The volume of the irradiation fields included the primary tumor, lymph nodes of the pararectal tissue, as well as presacral, lymph nodes along the distal part of the common iliac artery and along the internal iliac artery, and lymph nodes in the middle part of the obturator fossa. Patients included in the study since June 2021 underwent conformal radiation therapy in the range of SFD of 2 Gy to TFDof 50 Gy using technologies of rotational radiation therapy with volumetric modulation of radiation intensity (VMAT — RapidArc), volumetric imaging of the IGRT target (CBCT).

In some patients, the technology of simultaneous integrated boost was used with dose escalation — up to SFD 2.2 Gy to TFD 55 Gy for 25 fractions in the area of the primary tumor and affected lymph nodes. SFD on the pelvic lymph node area is 1.8 Gy to TFD 46 Gy for 25 fractions. In all patients, RT was accompanied by oral administration of capecitabine at a daily dose of 825 mg/m^2 orally twice a day with an interval of 12 hours on the days of radiation therapy for 5 weeks. In the interval between radiation therapy and the decision to include in the ASP, all patients were supposed to undergo CCT in FOLFOX6 mode in the amount of 4 cycles.

Four weeks after the completion of CCT, all patients were expected to undergo the first control checkup, which was the main one in determining further treatment. The clinical regression of the tumor was assessed using a combination of MRI, digital examination, and endoscopic imaging data. cCR in endoscopy included cases in which there were no signs of a tumor, superficial or deep ulceration, and the only manifestation was the presence of a white or red scar or telangiectasia at the site of a pre-existing tumor. Taking into account the fact that the introduction of gas into the intestinal lumen during endoscopy makes it difficult to perform subsequent MRI, creating artifacts, we started the examination by performing an MRI scan, and then performed an endoscopy. The MRI assessment of the degree of tumor regression was performed visually in comparison with the initial MR picture of the tumor according to the ratio of fibrosis and residual tumor on T2WI using the generally accepted tumor regression grade (TRG) scale: the first degree of regression (mrTRG1) corresponded to the complete absence of visual manifestations of the tumor or minimal fibrosis (thin fibrous scar) with low MR intensity signal; the second degree (mrTRG2) — dense fibrosis and absence of tumor signs; the third degree (mrTRG3) — predominance of fibrosis over residual tumor/mucin; the fourth degree (mrTRG4) refers to small areas of fibrosis with a predominance of a residual tumor; the fifth degree (mrTRG5) refers to the preservation of the picture of the primary tumor. Diffusion-weighted images (DWI), oriented similarly to T2WI in the oblique axial plane, were used for additional assessment of the residual tumor, due to the preservation of diffusion restriction sites. Lymph nodes in the mesorectal tissue with a diameter of less than 5 mm, internal iliac

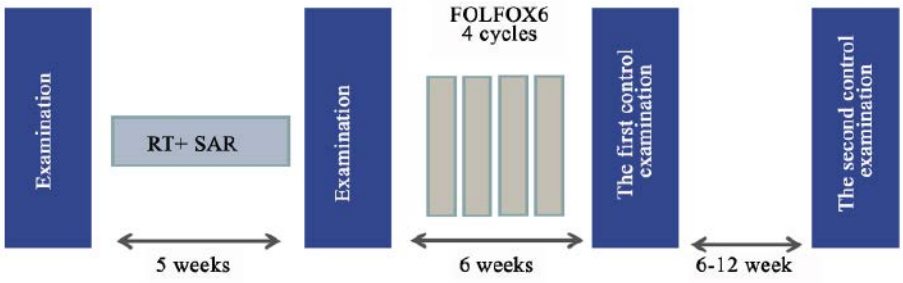

Figure 1. *Treatment regimen*

lymph nodes of less than 4 mm and occlusal lymph nodes were considered intact.

Due to the fact that in 2023 the Society of Abdominal Radiology updated the system of clinical assessment of treatment response, all MRI data of non — mucinous tumors were reviewed retrospectively with a detailed description of the fibrous scar in the tumor bed in accordance with the latest guidelines [12]. The clinical response was divided into complete (cCR), almost complete (nCR) and incomplete (iCR), while the complete response according to MRI data suggested a significant decrease in the size and fibrosis of the tumor bed without a visible residual tumor signal on T2WI and DWI, wall thickening due to edema was allowed in the absence of suspicious lymph nodes in the mesorectum and in pelvic walls.

According to the results of the first control examination, only those patients were selected who had cCR established during endoscopy. In cases where the MR picture corresponded to cCR, but signs of a residual tumor were observed during endoscopy, the patient was not included in the ASP. The MR criterion for not including the patient in the ASP during endoscopic CR was the presence of a residual tumor/affected lymph nodes in the mesorectum or deep layers of the intestinal wall on T2WI and DWI.

The follow-up of patients with cCR involved regular clinical and instrumental examinations, including rectal digital, colonoscopy and MRI, every 2–3 months for the first three years, then every 6 months for the 4th and 5th years, and once a year thereafter.

Statistical Analysis

Commercial biomedical packages Prism 3.1 and InStat (GraphPad Software, Inc., San Diego, USA) were used for statistical processing.

The quantitative values were described by the median, minimum and maximum values in the Me (Min-Max) format. The survival rate of patients was analyzed using Kaplan-Meier's test. Overall and disease-free survival was calculated from the time of completion of CRT. When calculating the overall survival rate, the death of the patient was considered an 'event'. When calculating disease-free survival, a local recurrence, distant metastasis, or death of a patient from any of the causes was considered an 'event'.

RESULTS

Based on a comprehensive checkup, 27 patients with low and middle RC were selected for the ASP, who underwent CRT with CCT in FOLFOX6 mode in the period between 2017 and 2023 (Table 1).

The number of men and women selected for ASP was 15 (55.6%) and 12 (44.4%), respectively. The age of the patients ranged from 38 to 80 years (median — 63 years). The median distance from the anal margin to the lower pole of the tumor was 4.5 (2.0–9.5) cm. The majority of 18 (66.7%) patients had stage III of the disease, while the tumor size in the largest dimension had values in a wide range (2.4–6.5 cm) with a median of 4.0 cm. Conventional radiation therapy was performed in 9 (33.3%) patients, conformal radiation therapy in 18 (66.7%) patients, while simultaneous integrated boost technology was used in 6 (22.2%) patients in the conformal radiation therapy group. In all cases, the CRT was completed in full. CCT was fully completed in 23 (85.2%) patients. The median interval between the completion of CRT and the first control examination was 16 (9–25) weeks, the median interval between the completion of CCT and the first control examination was 5 (1–12) weeks. The MRI data performed at the first control examination was available for retrospective analysis in 26 (96%) patients. In one case, cCR was achieved in a patient with a mucinous tumor of the rectum, who at the time of the first control MRI retained mucinous inclusions in the structure of the fibrous scar, but there were no signs of a residual tumor according to endoscopy (Fig. 2). Given the young age of the patient, the oncological council decided to include the patient in the ASP. Upon follow-up for 21 months, there were no signs of tumor re-growth and distant metastasis, and follow-up continues with an interval of

Table 1. *Clinical characteristics of the group*

Parameters	All patients N = 27
Gender Female Male	12 (44.4%) 15 (55.6%)
Age, years	63 (38-80)
Clinical stage of the disease I II III	5 (18.5%) 4 (14.8%) 18 (66.7%)
Clinical T T1-2 T3	13 (48.1%) 14 (51.9%)
Clinical N N0 N1 N2	9 (33.3%) 13 (48.1%) 5 (18.5%)
Histological type of tumor G1 G2 G3	8 (29.6%) 18 (66.7%) 1 (3.7%)
Distance from the anal margin to the lower pole of the tumor, cm	4.5 (2.0–9.5)
Tumorsize (median), cm	4.0 (2.4–6.5)
mrEVI «+»	5 (18.5%)
mrCRM «+»	7 (25.9%)

3 months. At the time of the first control MRI, cCR was established in all patients included in the ASP during endoscopy. In the prospective MR assessment, changes in the tumor bed corresponded to TRG1 in 12 (44.4%) patients, TRG2 in 14 (51.9%) patients. A thin fibrous scar extending up to half the circumference in the tumor bed was detected in 16 (59.3%) cases (Fig. 3), in 3 (11.1%) cases– a split fibrous scar with a smooth outer contour (Fig. 4). In the remaining 7 patients, the MR pattern corresponded to a full-thickness semicircular fibrous scar, while the scar structure was homogeneous in 4 cases (Fig. 5), and weakly heterogeneous in 3 more. In 3 cases, in the presence of a full-thickness fibrous scar, the outer contour was smooth, and in 4 cases it was uneven with the presence of spicules, while there was no restriction of diffusion in the scar area in all patients.

The results of the retrospective analysis of MR images are presented in Table 2. When comparing prospective and retrospective assessments, we found a coincidence in the number of cases of TRG1 and fine linear scar in 75% of cases. It should be emphasized that there was no restriction of

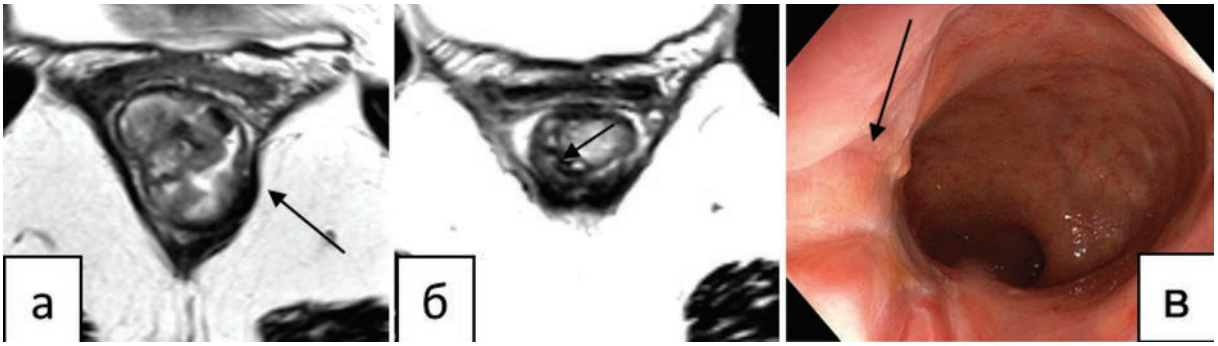

Figure 2. *MRI of a cCR in a 38-year-old patient with an initial mucinous tumor of the lower rectum T2 to T2VI (а); 25 weeks after the end of the CT scan, a full-layered fibrous scar with small inclusions of mucin (б) and a flat white scar (в). The arrows indicate the tumor and the scar*

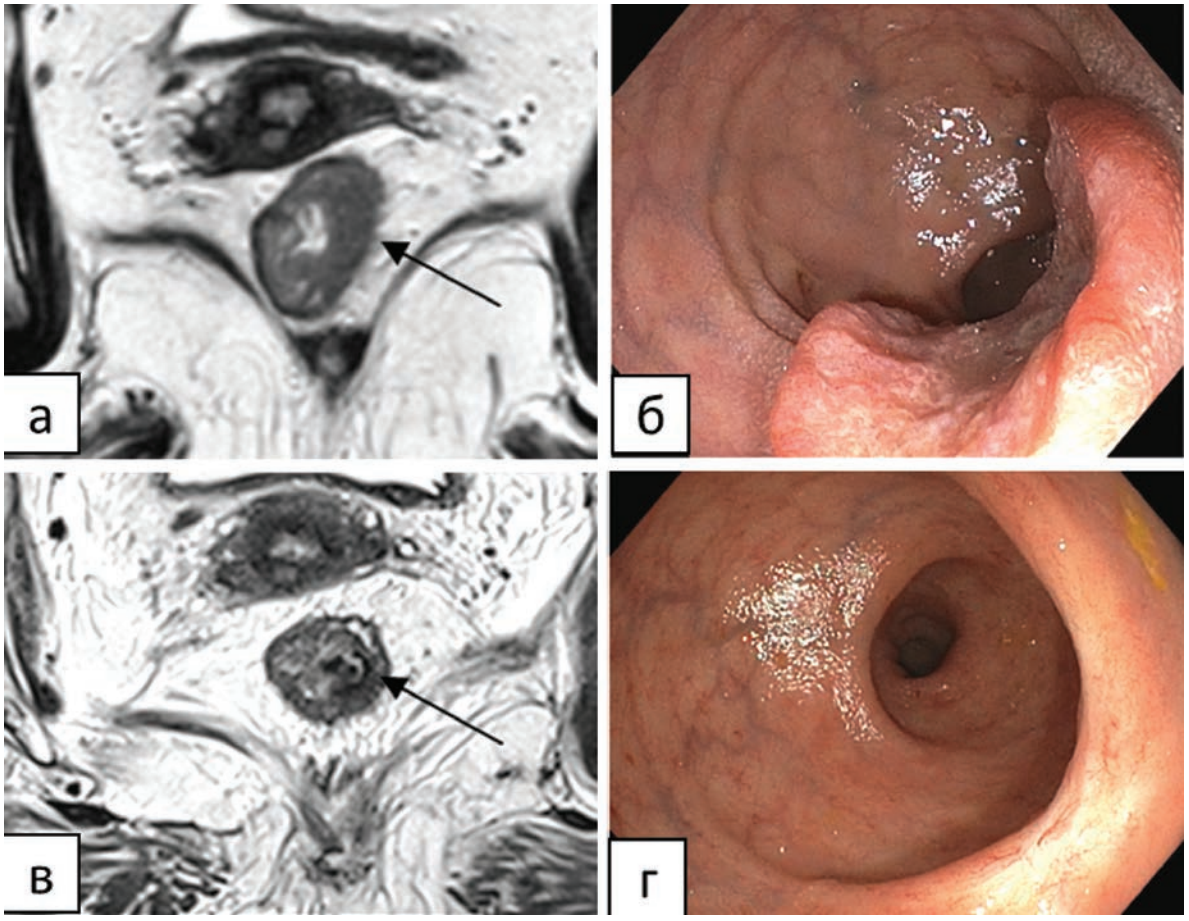

Figure 3. *MRI of the cCR in a patient with an initial semicircular tumor of the lower rectum T2-3a to T2VI (а), endoscopic picture (б); 17 weeks after the end of the CT scan, a thin fibrous scar on T2VI (в) and a flat white scar on endoscopy (г). The arrows indicate a tumor and a fibrous scar*

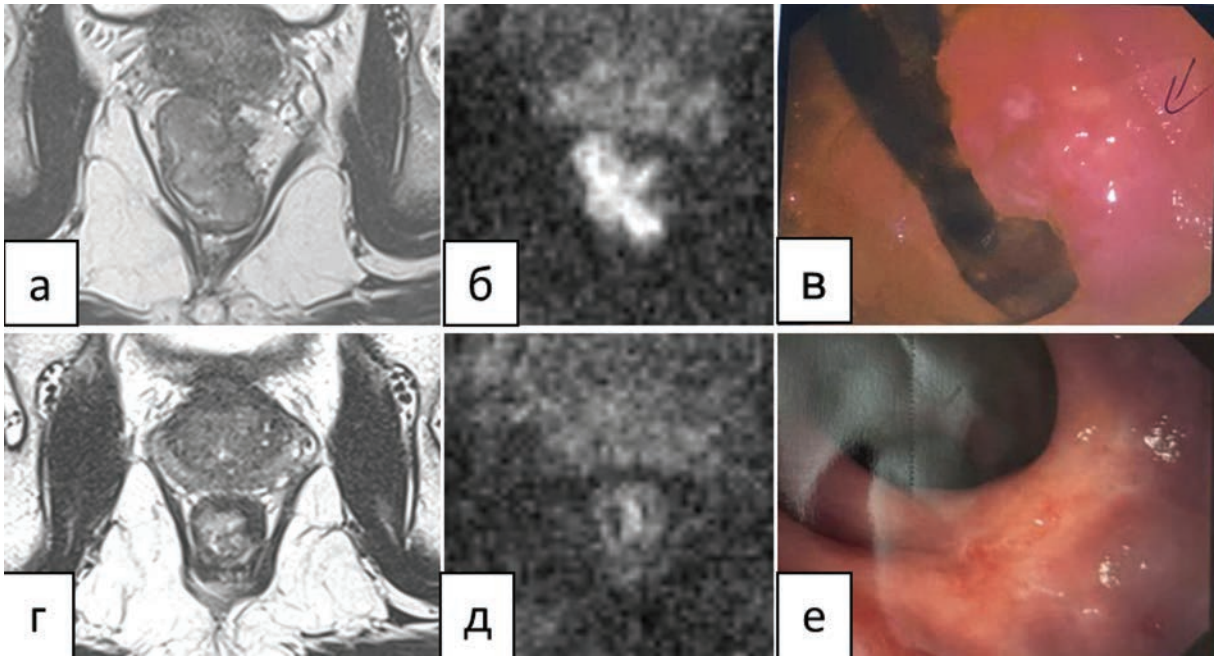

Figure 4. *MRI of the cCR in a 59-year-old patient with an initial exophytic tumor of the lower ampullary rectum T3b to T2vi (а) and DVI (б), endoscopic picture (в); 16 weeks after the end of the CT scan, a full-layered fibrous scar (г), without signs of limited diffusion (е) and a flat whitish scar with telangiectasia during endoscopy (д). The arrows indicate a tumor and a fibrous scar*

Table 2. *MR-image of the tumor bed in patients with cCR according to endoscopy*

MR pattern of fibrosis	TRG	The number of patients
Thin fibrous scar(*n* = 16)	1	12 (46.2%)
	2	4 (15.4%)
Split fibrous scar(*n* = 3)	2	3 (11.5%)
Full-thickness ibrous scar (*n* = 7)	2	7 (26.9%)
Total		26

diffusion in the tumor bed, and there were no suspicious lymph nodes in the mesorectal tissue and pelvic walls.

When comparing the primary MRI staging with the post-therapeutic MRI picture, it was found that cT1-2 tumors transformed into a thin superficial scar in 10/13 (76.9%) patients as a result of NACRT. In the cT3a-b category, a thin superficial scar as a result of CRT was observed in 6/13 (46.2%) patients, while 7/13 (53.8%) patients had a split or full-thicknes scar. Repeated control checkup 14 (8–27) weeks after the 1st control checkup and 30 (22–47) weeks after the completion of CRT was performed in 24/27 (88.9%) patients, in 3/27 (11.1%) cases, the deadline for the next control checkup did not come. As a result, cCR was confirmed in all 24 patients during endoscopy. The MRI data obtained during the second control examination was available for a retrospective analysis in 21 (77.8%) patients. It should be noted that in no case was there a negative trend in the structure of fibrous changes. In 18 (85.7%) patients, a thin fibrous scar was detected up to half the circumference; in 2 patients a split fibrous scar with an even outer contour was detected. 1 patient retained a thick fibrous scar with an uneven outer contour, without restriction of diffusion. Subsequently, 16 months after the completion of CRT, the patient had a recurrent tumor growth, and therefore underwent surgery in the volume of anterior rectal resection.

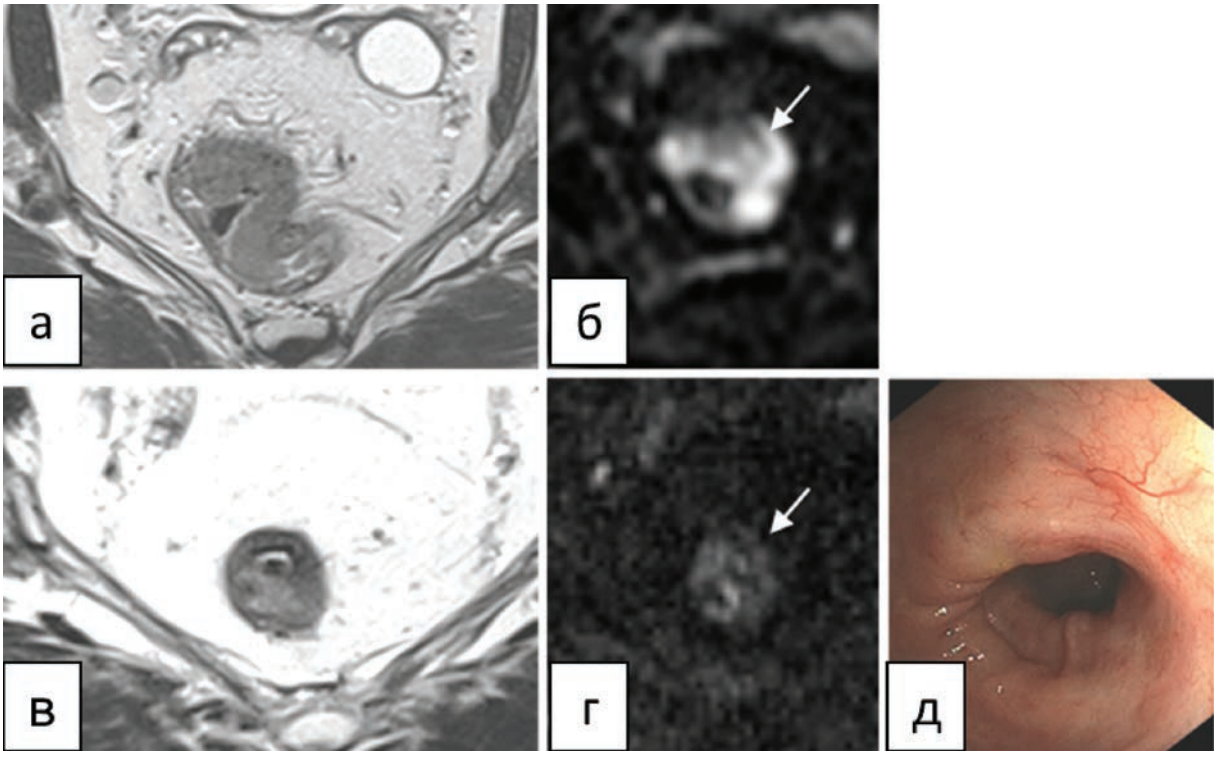

Figure 5. *MRI of the cCR in a 66-year-old patient: initial semicircular tumor of the middle ampullary rectum T3b to T2VI (а) and DVI (б); 15 weeks after the end of the CT scan, a split fibrous scar (в) is detected, there is no restriction of diffusion to DVI (г), with endoscopy — flat whitish scar (д). The arrows indicate a tumor and a fibrous scar*

With a median follow-up of 15 (4–80) months, repeated tumor growth in 15 and 16 months was detected in 2 (7.4%) patients. In both cases, radical rectal operations were performed.
Cumulative three-year disease-free survival was 81.1 ± 10.1%, total 95.2 ± 4.6%.

DISCUSSION

The history of the use of the ASP in RC began with the publication of Habr-Gama, A. and co-authors' studyin 2004. [8]. From a controversial technique at that time, it turned into a whole field, the relevance and expediency of which in a certain category of patients is beyond doubt. While in most patients with medium and upper cancer, the main goal of radiation/chemoradiotherapy is to prevent local recurrence, and a complete response is a random event that does not affect treatment, with low rectal tumors (⩽ 7 cm), achieving cCR is a treatment goal that allows 20–30% of patients to avoid crippling surgery [13,14]. The main problem hindering the widespread use of the ASP is the high rate of tumor re-growth, which increases the risk of long-term metastasis. At the same time, the stricter the selection criteria applied, the lower the risks. The inclusion of patients with a good but incomplete clinical response (nCR) leads to an increase in the number of cases of tumor regrowth. This group of patients requires a special approach, in which dynamic monitoring within six months after completion of the treatment is very important [10]. Unfortunately, many authors do not describe the criteria they apply, simply referring to the absence of a tumor during digital examination, endoscopy, and MRI [15,16]. However, the versatility of the clinical and radiological patterns of the tumor response and their changes in dynamics require the use of reliable selection criteria. Rectal digital examination and endoscopy are used to assess the degree of response in the rectal lumen, while MRI allows to identify a substantial tumor in the deeper layers of the rectal wall and mesorectum, to determine the condition of the lymph nodes [17]. At the same time, improving the accuracy of MRI in the diagnosis of cCR currently remains a problem, primarily for mucin-producing tumors [18]. This study presents 27 cases of cCR, detected on endoscopic picture: the presence of a flat scar or/and telangiectasia at the site of a previously detected tumor. We did not include patients with any ulceration or other residual changes at the site of a pre-existing tumor.
The MRI assessment of the rectal tumor response to radiation/chemoradiotherapy is based on high-resolution T2WI. Diffusion-weighted imaging (DWI) is recommended as an adjunct to T2WI, which helps to increase the effectiveness of detecting patients with cCR by increasing the sensitivity of diagnosis. The use of intravenous gadolinium contrast agents is not mandatory [19].
The RECIST criteria, which are widely used for radiological assessment of the response of solid tumors, are usually not used in RC due to the difficulty of measuring tumors localized in the hollow organ and having a complex configuration. The assessment of fibrotic transformation of the tumor became the basic approach for MRI. A significant decrease in the intensity of the tumor signal, resulting from its replacement with a fibrous scar in T2WI, was the basis for the five-level MRI tumor regression scale (mrTRG), according to which the complete response according to MRI corresponds to TRG1 with a thin scar of up to 3 mm along the inner contour of the intestine. The accuracy of this criterion for pCR detection is estimated to be moderate with a sensitivity of 74% and a specificity of 63% [20]. In our study, patients with cCR selected for ASP had TRG1 at the first control examination in 48% of cases, while suspicious lymph nodes in the mesorectum and pelvic walls were not detected, in the other cases TRG2 was detected. At the same time, there was a limited overlap (75%) in the number of cases assessed as a thin linear scar in prospective (TRG1) and retrospective assessments, which may be due to a subjective approach to image assessment and indicates limited reproducibility of the MR assessment. However, in all cases, there were no areas of diffusion restriction in the structure of the fibrous scar. The

limitations of MR evaluation also apply to mucinous tumors, in which mucin inclusions remain in the tumor bed after CRT even in the case of a complete endoscopic response.

A new terminology developed in recent years divides the clinical response to neoadjuvant treatment into complete (cCR), almost complete (nCR) and incomplete (iCR), based on rectal digital examination, endoscopy and MRI [10]. An international consensus has recently been published proposing standardized criteria for assessing response in patients who are planning organ-preserving treatment in the future [12]. According to these recommendations, the c CR MRI criteria should be based on the principles proposed by Martens, M.H. et al. in 2016 [21], which include a significant decrease in the size and fibrosis of the tumor bed without a visible residual tumor signal T2WI and DWI; wall thickening due to edema is allowed in the absence of suspicious lymph nodes in the mesorectum and pelvic walls. In this study, all patients, with the exception of one patient with a mucinous tumor, met these criteria not only in terms of MRI assessment, but also in terms of endoscopic and rectal digital examinations.

The variability of MR fibrosis patterns in the tumor bed can be very significant, from a thin fibrous scar along the inner contour of the wall to a thick circular scar. As the fibrous scar matures, the signal from it decreases and becomes significantly lower than the signal from the tumor tissue. It has been shown that semicircular and polypoid primary tumors are replaced by small, well-defined fibrous scars limited by the intestinal wall, whereas circular tumors with extramural spread usually form thick fibrous scars with uneven contours, which are likely to contain residual tumor cells that are not visualized by MRI [22]. Therefore, the shape of the primary tumor is recommended to be taken into account when assessing the fibrous scar in order to increase the reliability of the interpretation of the post-therapeutic image. In this study, the T category of the primary tumor correlated with the post-therapeutic MRI picture, with cT2 tumors characterized by a thin superficial scar in most patients. In the cT3a-b category, a thin superficial scar as a result of CRT was observed in 46% of cases, while in 54% of cases there was a split or full-thickness scar.

Split scar is a special fibrosis pattern associated with resistant cCR and having high specificity (97%), high positive prognostic value (93–94%) and high negative prognostic value (73–78%), but only average sensitivity (52–64%) [23].

The MR pattern of a split scar after neoadjuvated CRT is usually formed in the bed of locally advanced tumors in the form of thin internal hypointensive fibrosis corresponding to the submucosal layer and peripheral hypointensive fibrosis in the perirectal tissue with variable contours and thickness, between which there is a layer of uniform intermediate signal intensity corresponding to the muscle layer.

In this study, the symptom of a 'split scar' was detected in 3 patients, in all cases, patients had cT3 tumor category before the treatment. Thus, when evaluating the MRI result of neoadjuvant CRT in comparison with the initial MRI image of the tumor, we consider it advisable to focus on the fibrosis of the tumor bed within the intestinal wall or the presence of a 'split scar' symptom in locally advanced tumors, assessing the status of regional lymph nodes. Patients with a complete endoscopic response in the form of a flat scar or/and telangiectasia at the site of a previously identified tumor and an MR image of a thin, full-thickness or split scar without signs of a residual tumor and limited diffusion should be offered inclusion in the ASP with careful control every 2–3 months for the first two to three years. In this paper, we did not address those clinical situations where, according to the control study, there is a good but incomplete clinical response (nCR). This is a fairly large and diverse clinical group that requires separate discussion, but, as shown by the data of large foreign studies, some of these patients can also be effectively monitored using ASP [4,10,24].

The disadvantages of this study include a small number of cases and a short follow-up period. At the same time, we tried to emphasize the

importance of using clearer criteria for selecting patients for inclusion in the ASP, which will make this technique safer and allow specialists working in different medical institutions to speak the same language, knowing full well that the future lies in creating joint registries and conducting cooperative research.

CONCLUSION

The use of the ASP in patients after NACRT is based on a careful selection of patients who have achieved cCR according to a comprehensive checkup. The leading role in the assessment of the intraluminal component of the tumor is played by endoscopy, in which a flat white or red scar is detected in the tumor bed. In the absence of such an endoscopic picture, even in the case of a complete response according to the MRI data, we did not include the patient in the ASP. MRI evaluation of the tumor response to CRT is performed in comparison with the initial MR picture. In our study, all patients who achieved cCR had a primary tumor with a category up to and including T3b. The MR pattern in all patients included in the ASP was characterized by fibrosis of the tumor bed without signs of residual tumor tissue/affected lymph nodes in the mesorectal tissue and deep layers of the wall, with both thin and full-thickness and split fibrous scars extending up to half the circumference. It is advisable to start the examination by performing an MRI followed by an endoscopy, which allows to obtain all the necessary information within one day and avoid MRI artifacts that occur after an endoscopy.

COMPLIANCE WITH PATIENT RIGHTS AND PRINCIPLES OF BIOETHICS

This trial was conducted in accordance with the World Medical Association (WMA) Declaration of Helsinki, as amended in 2013. All participants provided informed consent before participating in the study.

AUTHORS CONTRIBUTION

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