UDC 616.34-006: 617-089.87
DOI https://doi.org/10.32782/2226-2008-2025-3-11

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POTENTIAL OF TRANSANAL ENDOSCOPIC SURGERY IN THE MANAGEMENT OF EARLY RECTAL CANCER

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Relevance. Transanal surgery for rectal pathology remains relatively rare. Transanal endoscopic surgery (TES) is performed at the early stages of rectal cancer. However, the issue of lymphogenic metastasis is still unresolved, as it is the most significant cause of local recurrence of rectal cancer and an unfavorable prognostic factor for this pathology.

Aim of study – to increase the effectiveness of treatment of patients with early rectal cancer during transanal endoscopic operations using fluorescent methods for identifying sentinel lymph nodes.

Materials and methods. Between 2009 and 2024, 175 patients underwent transanal endoscopic surgery at the Odesa Regional Clinical Hospital. Among them, 51 patients were diagnosed with rectal cancer preoperatively. In 15 patients with enlarged lymph nodes detected by MRI, an advanced TES procedure was performed using the ICG fluorescent dye.

Results. The average tumor size was (3.8±1.2) cm (ranging from 1.8 to 4.7 cm). The follow-up period after transanal endoscopic resections for rectal cancer ranged from 12 to 60 months. Recurrence of rectal cancer was identified in 3 patients (10.7%) with T1-2N0M0 cancer and in 5 patients (21.7%) with T3N0M0 cancer. We developed the advanced method of comprehensive treatment for early rectal cancer, namely the combination of transanal endoscopic surgeries with the use of the ICG fluorescent dye. It enables the identification and targeted study of sentinel lymph nodes in rectal cancer patients. Results of our research confirm the effectiveness and safety of TES procedures in patients with early-stage rectal cancer and substantiate the feasibility of expanding indications for this technique to include patients with more advanced stages (T1-T2), subject to careful patient selection.

Conclusions. TES procedures for rectal cancer significantly reduce the incidence of intraoperative and postoperative complications. The use of ICG dye for fluorescent staining of sentinel lymph nodes allows for a more accurate determination of metastases, which has high diagnostic value.

Keywords: transanal endoscopic surgery, rectal cancer, minimally invasive surgery, indocyanine green, colorectal surgery.

УДК 616.34-006:617-089.87

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МОЖЛИВОСТІ ТРАНСАНАЛЬНОЇ ЕНДОСКОПІЧНОЇ ХІРУРГІЇ РАННЬОГО РАКУ ПРЯМОЇ КИШКИ
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Трансанальні ендоскопічні операції (ТЕО) проводяться на ранніх стадіях раку прямої кишки, проте питання лімфогенного метастазування залишається актуальним.

Метою дослідження було підвищення ефективності лікування пацієнтів із раннім раком прямої кишки під час виконання ТЕО з використанням флуоресцентних методів виявлення «сторожових лімфовузлів».

У період з 2009 до 2024 року виконано 175 ТЕО, з них у 51 пацієнта діагностовано рак прямої кишки. У 15 пацієнтів зі збільшеними лімфовузлами за даними МРТ використано барвник ICG для флуоресцентного дослідження з виконанням удосконаленої ТЕО. Середній розмір пухлин становив (3,8±1,2) см. У період спостереження (12–60 місяців) рецидив виявлено у 3 пацієнтів (10,7%) з T1-2N0M0 та у 5 пацієнтів (21,7%) з T3N0M0. Розроблена методика ТЕО з використанням ICG дозволяє точно визначати сторожові лімфовузли, оптимізувати тактику лікування та знизити кількість ускладнень.

Ключові слова: трансанальна ендоскопічна мікрохірургія, рак прямої кишки, мініінвазивна хірургія, індоцианін зелений, колоректальна хірургія.

Introduction

Colorectal cancer is one of the most serious oncological problems both worldwide and in Ukraine [1; 4]. It accounts for about 15% of all malignant neoplasms, making it one of the most common types of cancer. Rectal cancer accounts for approximately 10% of all cancer cases [3; 4; 8].

A comprehensive approach is used in the treatment of rectal cancer [4; 10; 14; 19]. The main stage of treatment is surgery, which involves complete removal of the rectum with total mesorectal excision in one block with the surrounding lymph nodes, which minimises the risk of local recurrence [4; 8; 16]. Usually, in cases of low rectal cancer, quite traumatic Miles' operations are performed [3; 8]. The high incidence of intestinal anastomotic leakage, serious postoperative complications in elderly people with multiple comorbidities, high mortality rates in radical rectal cancer surgery, and deterioration in patients' quality of life

due to the need for intestinal stomas have forced to change treatment management [2; 5; 17].

To date, transanal surgery in rectal pathology is rarely used [1; 7; 8]. Transanal operations are performed in the early stages of rectal cancer [3; 8; 14]. However, the issue of lymphogenic metastasis remains open, which is the most important cause of local recurrence of rectal cancer (RC) and an adverse factor in the prognosis of this pathology [9; 11; 13; 17]. According to literature, in patients with RC who have metastasis of cancer cells in mesorectum lymph nodes, 5 years of survival does not exceed 50%, while in patients with RC without metastatic lymph node damage, 5 years of survival increases to 7 [17; 19].

The literature describes cases where lymph nodes less than 5 mm in diameter are affected with metastasis, which is observed in 15% of patients [9; 16; 18]. One of the main methods of detecting metastasis in the lymph nodes of mesorectum is magnetic resonance imaging with intravenous contrast, but MRI has no specific sensitivity for the assessment of regional metastasis and lesions of lateral groups of mesorectum lymph nodes [3; 4; 14; 15; 19].

The search for new methods of diagnosis and detection of metastasis in the lymph nodes of mesorectum in rectal cancer is very relevant, which will allow us to individually choose the method of surgery [2; 4; 10; 17; 19]. As a result of the study of lymph nodes in the cancer process, it was found that in the early stages of cancer (T1/T2), lymph nodes damage is observed in only 15–20% of patients [5; 7; 10; 18]. This means that in most patients (80–85%), radical removal of lymph nodes may be unreasonable [5; 6; 10; 18]. Studies of metastasis mechanisms have shown that in melanoma and breast cancer, specific lymph nodes and order are first affected, after which tumor cells extend to other lymph nodes I and II order. These lymph nodes playing a key role in interference with cancer cell spread were called sentinel lymph nodes (SLNs) [4; 9; 11; 12]. In the 1990s, the concept of SLNs was developed in the treatment of melanoma and breast cancer, according to which the absence of metastases in these lymph nodes indicates a low probability of lesions of higher order lymph nodes [4; 18].

Recently, a new method of determining the SLNs has been developed, based on the effect of the luminescence of the dye with the light of a certain wave [4; 7; 13; 15; 19]. For these purposes use the indocyanine green dye (ICG), which allows 95–100% to detect the affected SLNs [2; 4; 8; 15]. Diagnosis of SLNs in the treatment of RC is important, since it can be the first node from which metastases spread, starting with mesorectum [4; 7; 15; 17]. However, the concept of SLNs in RC has not yet been proven and remains the subject of scientific research [1; 3; 4; 12].

The **aim** of the study – to increase efficiency of treatment of patients with early rectal cancer when performing transanal endoscopic surgery using fluorescent methods of detection of SLNs.

Materials and methods

From 2009 to 2024, 175 patients were operated at the Odesa Regional Clinical Hospital using TES. The age of patients was from 47 to 84 years (average age (67.4±7.2) years). The average body mass index was (32.8±4.5) kg/m².

124 patients had tubulovillous rectum adenoma, of which 31 patients with a final histological examination of distant tumors were detected tumor malignancy (RC TISN0M0 cancer). Rectal cancer was diagnosed in 51 patients before surgery. Early RC T1-2N0M0 I stage, was found in 28 patients. In 23 patients, RC T3N0M0 II stage was detected, these patients were performed neoadjuvant chemoradiotherapy, which was able to reduce the size of the tumor and its into the rectal wall, as well as change the stage IIa to I. When performing 51 patients with rectal cancer preoperative computer and magnetic resonance imaging of pelvic organs with intravenous contrast, enlarged lymph nodes were detected in 15 patients (29.4%).

The study of the GSP (1996), the Council of Europe Convention on Human Rights and Biomedicine (dated 04.04.1997), the Helsinki Declaration of the World Medical Association on Ethical Principles of Scientific Medical Research with the human participation (2013–2014), Ethical) were observed during the implementation of the study. The research protocol was approved at the meeting of the Bioethical Committee of ONMedU (Minutes 1A/N 12.02.2000). The work is an integral part of the scientific topic of the Department of Surgery, Radiation Diagnosis, Radiation Medicine, Therapy and Oncology of Odesa National Medical University "Development and implementation of new methods of mini-invasive and endovascular surgical interventions for metabolic syndrome, endocrine pathology, diseases of the lungs, esophagus, liver and extrahepatic bile ducts, stomach, pancreas, colon and rectum, vessels", registration number N 0119 U 003573. All participants in the study were informed about the objectives, organisation and methods of the study and signed an informed consent form to participate in the study; all measures were taken to ensure the anonymity of patients during the study.

Before surgery, all patients were informed of possible complications, as well as the need to perform advanced radical operations in the detection of local recurrence. Preoperative examination included the implementation of general clinical studies, as well as rectomanoscopy, fibrocolonoscopy, irrigoscopy, endorectal examination and computed tomography of the chest, abdominal cavity, pelvic organs with intravenous contrast. Preoperative preparation was implemented in accordance with generally accepted standards.

All operations were performed under endotracheal anesthesia. The patient's position was on the back. A special Karl Storz Teo port with three trocars, one 10 mm trocar for the endoscope and two by 5 mm – for tools (Fig. 1) was installed in the rectum (Fig. 1).

Special curved tools were used during the operation. After carbon dioxide insufflation, the tumor resection zone was marked, with at least 10–15 mm away from the edge of the tumor (Fig. 2).

The tumor resection zone was marked using an electrocoagulation hook around the perimeter. Then a radical excision of the rectal wall with a tumor was performed with one block with the help of Coagulation apparatus of the Covidien ValleyLab Ligasure (Fig. 3).

After a radical excision of the rectal wall with a tumor closure of the rectal wall defect was performed using a V-Loc™ 2-0 self-locking barbed suture (Fig. 4 A, B).

Fig. 1. Port Karl Storz Teo with three trocars

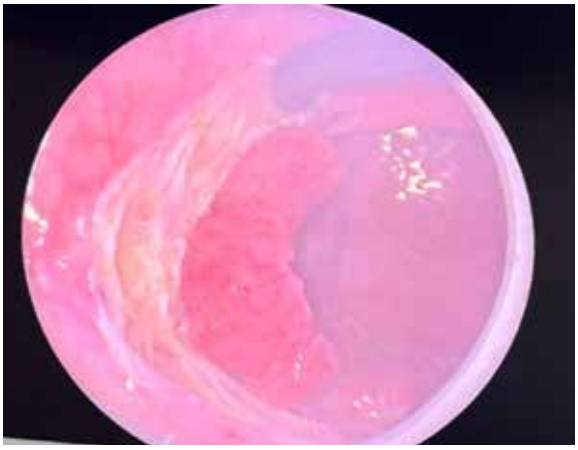

Fig. 2. Marking the tumor resection zone

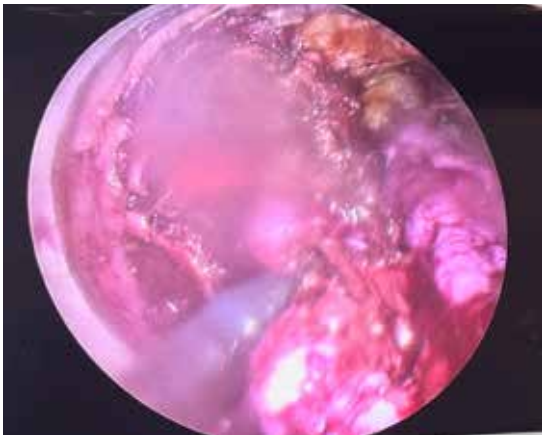

Fig. 3. Radical excision of the rectal wall with a tumor by one block by means of a coagulation apparatus Covidien ValleyLab Ligasure

In 15 patients with enlarged lymph nodes according to MRI, an improved TES was performed using fluorescent ICG dye. The technique of staining with the use of fluorescent dye contains several key stages. Initially, ICG solution was prepared: Indocyanin green 5 mg was dissolved in 2 ml of saline solution for optimal fluorescence and visualization of lymph nodes. The prepared solution was used for 20–30 minutes, because ICG may lose its properties during prolonged storage.

During surgery, 2 ml of ICG fluorescent dye solution of 2–4 aliquots were introduced into the submucosal layer around the rectum tumor to ensure a uniform distribution of dye. Immediately after ICG administration was performed diagnostic laparoscopy using a fluorescent light source that activates the fluorescence of the dye. During laparoscopy, the lymphatic vessels and the first stained lymph node were clearly visualized to which ICG dye got. In this way, the stained SLNs were identified in real time. The found lymph node were laparoscopically removed and histologically examined. In cases with no metastatic cancer cells in the lymph nodes, only transanal endoscopic resection of the rectal tumor was performed.

The statistical importance of categorical variables was evaluated using the χ^2 criterion, and continuous variables were analyzed using the Student's t-criterion. All statistical analyses were conducted in the Statistica Program 14.1.25 (Tibco, USA).

Results

When performing transanal endoscopic surgery in tumors of the rectum no serious intraoperative complications were detected, no patient died. The average tumor size was (3.8±1.2) cm (from 1.8 to 4.7 cm). In the early postoperative period, 4 patients (7.8%) after TES had postoperative bleeding, which required TES, during which the bleeding was stopped using an LIGASURE Eletrocoagulator.

The results of histological examination have shown that in all cases the rectal tumor was removed within healthy tis-

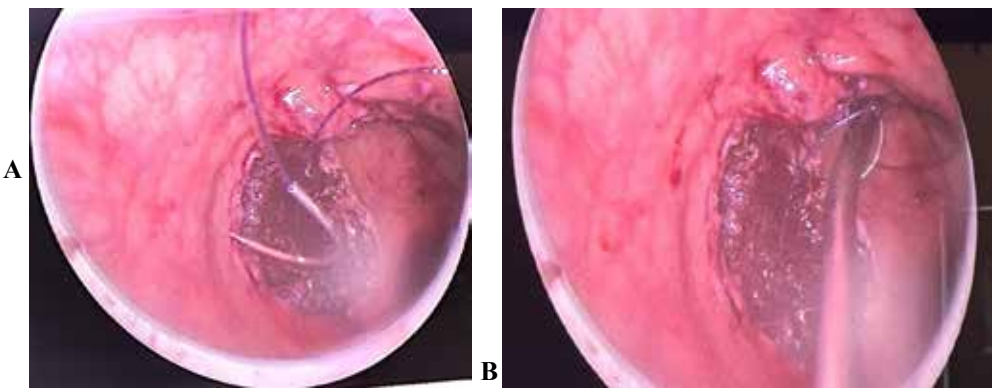

Fig. 4, A, B. Closure of the rectal wall defect was performed using a V-Loc™ 2-0 self-locking barbed suture

sues with the absence of a tumor at the edges of resection. In 3 (5.8%) patients, when the tumor was located 13, 14, 18 cm from the anus, during TES there was intraoperative penetration into the abdominal cavity, which required laparoscopy and laparoscopic suture of the defect of the rectum, without removal of a preventive stoma. Laparoscopic closure of the rectal wall defect was performed using a V-Loc™ 2-0 self-locking barbed suture. After laparoscopic suturing the defect to these patients was performed on the tightness of the seams. Wound dehiscence was absent in all the cases. Defects in the rectum in all patients heal initially, which was confirmed on control examinations with the performance of rectomanoscopy in the distant period. There were no purulent-septic, thromboembolic and serious urological complications in operated patients.

Given the possibility of lesions of mesorectum lymph nodes and the development of RC local recurrence, the transanal surgery in these patients is a contraindication. That is why we have improved this technique.

The transanal endoscopic surgery for rectal cancer with SLNs staining was performed in 15 patients. In 9 patients (60%), according to histological examination, the SLNs did not detect metastatic cells, these patients had transanal endoscopic tumor resection. Histological examination revealed metastatic cells in the SLNs in 6 patients (40%). These patients were operated by a low laparoscopic anterior resection of the rectum with total mesorectal excision (TME). A low descendorectoanastomosis was performed using 29–32 mm Ethicon circular staplers, followed by the creation of a protective diverting ileostomy, which later impacted the patients' quality of life. In the postoperative period, ileostromy closed in 2–3 months. In 1 patient (16.6%) after performing a radical surgery with TME, 2 months after the closure of the ileostoma, anastomotic stenosis developed, which required endoscopic bonding. When monitoring these patients up to 36 months, the recurrence of RC and distant metastases were not detected.

The quality of life in patients after TES was significantly better compared to radical operations with TME, the term of stay of patients in the hospital was (4±2) days and (9±4) days, respectively. The patients returned to the usual lifestyle after (14±3) days, and in case of radical operations with TME after (24±6) days without ileostomy formation, and after (109±17) days in case of radical operations with TME and ileostomy formation (Table 1).

After TES, patients did not feel pain and did not need the appointment of NSAIDs and narcotic analgesics, unlike patients who performed radical surgery with TME.

The time of observation of patients after TES in RC ranged from 12 to 60 months. During control examinations, patients were performed rectomanoscopy every 3 months, and every 6 months patients had a computer tomography of the chest, abdominal cavity and pelvic organs with i/v contrasting. Recurrence of RC was detected in 3 patients (10.7%) with cancer T1-2N0M0, in 5 patients (21.7%) with cancer T3N0M0.

Recurrence of rectal cancer was found in those patients who refused chemotherapy in the postoperative period. Patients with recurrence of rectal cancer were reoperated, these patients were performed laparoscopic anterior resection of the rectum with the imposition of primary anastomosis, as well as unloading ileostomy. The closure of ileostomy was carried out 2–3 months after the main operation. One patient (12.5%) after performing a radical anterior rectal resection revealed the anastomotic leakage, which required long-term treatment. In 1 patient (12.5%) in the early postoperative period, pulmonary embolism developed against the background of thromboembolic therapy.

Thus, the technique of complex treatment of early rectal cancer, namely the combination of transanal endoscopic operations with the use of fluorescent dye ICG, makes it possible to identify and examine the SLNs in patients with RC, as well as choose optimal treatment tactics.

Discussion

Currently, the treatment of RC using TES is a debatable theme, because the operations of the tumor without lymphadenectomy are performed [3; 8; 16; 19]. Recently, literature data indicate that in stage II cancer patients, TES may be performed after a comprehensive neoadjuvant chemoradiotherapy [4; 9; 14; 17]. A key aspect in the diagnosis of lymph node metastases is endorectal ultrasound and pelvic MRI with intravenous contrast in the preoperative period [2; 10; 11; 18]. When observing patients up to 10 years, the results in patients with TIS-0N0M0 cancer were the same. In patients with RC T2N0M0, the results of surgery during local removal of the tumor were much worse [5; 10; 14].

TES with RC is devoid of a number of serious complications that are more characteristic of performing low laparoscopic anterior resection of the rectum with total TME [8; 13; 14; 18]. TES is a mini-invasive intervention that reduces the risk of intraoperative and postoperative complications [14; 15; 17]. With TES the blood loss is less than 50 ml, with radical operations it can reach 200–500 ml, which in 30–50% of cases requires blood transfusions [15; 17]. The anastomotic leakage in transanal operations for PC is absent, and in radical operations it is 5–15% [3; 4; 8; 15]. When performing TES, there is no need for stoma formation, whereas in radical rectal cancer surgery, it reaches 30–40% [15]. The average length of hospitalisation

Table 1

Recovery time after surgery

Postoperative indicators	TES (n=175)	Radical surgery with TME (n=6)	p, value
Length of stay of patients in hospital (days)	4±2	8±4	p<0.05
Time required for patients to return to their normal lifestyle	14±3	24±6	p<0.05
Need for prescription of narcotic analgesics and NSAIDs	no	yes	p<0.05

is 1–3 days for TES and 7–14 days for radical surgery, respectively [1; 2; 10; 15].

When performing TES the damage to the surrounding organs, such as bladder, ureter and genitals is less than 1% compared to radical resections with total mesorectomy – 10% [1; 2; 4; 14; 15].

Comparative analysis of the frequency of complications and mortality of the local excision of the tumor with TES is much lower than in laparoscopic resection of the rectum with TME: 8.2% versus 47.2% (p=0.001) and 0% against 3.68% (p=0.01), respectively. Particularly important is the reduction of frequency of complications in elderly patients with severe concomitant pathologies [3; 6; 7; 8; 14]. In addition, the time of staying patients in the hospital and the term of rehabilitation after surgery is significantly reduced [10; 11; 19].

Many studies show that it is necessary to expand the indications for performing a TES method in patients with RC 1–2 stage [5; 15; 16]. To clarify the indications for the possible use of TES, many authors propose to examine SLNs in order to identify the foci of metastasis [16; 19]. The results of meta-analyses and systematic examinations show some TES benefits in the treatment of early stages of RC, as well as enlargement of indications, provided that patients are carefully selected [6; 16; 17; 19]. The authors of the research note that transanal endoscopic operations lead to a low level of complications and excellent indicators of local tumor control [6; 17].

Meta-analyses that are devoted to the comparison of long-term TES results and radical operations with TME in patients with early T1N0M0 rectal cancer show that transanal endoscopic resection provides comparators of survival and recurrence rate as compared to radical surgery, but at the same time is accompanied by fewer intra- and postoperative complications, as well as improving quality of life [13; 17; 19].

The results of our research confirm the effectiveness and safety of TES in patients with early stage of rectal cancer, as well as justify expanding the indications for the use of this technique in patients with higher stages (T1-T2) with careful selection of patients.

In our study, we used fluorescent ICG dye, which allowed to clearly identify SLNs affected by metastatic cells. It is the absence of metastatic cells in SLNs that is the basis for performing TES in patients with early rectal cancer.

Conclusions

Neoadjuvant treatment can reduce the size of the tumor, which makes it possible to use TES. This helps to preserve the rectum and improve the quality of life of the patient due to the organ-saving approach and minimal trauma of the method. Compared to radical operations of TME, TES provides faster recovery: patients stay in the hospital (4±2) days vs. (9±4) days, and return to normal life after TES occurs much earlier – (14±3) days against (24±6) days without ileostomy and (109±17) days when it is applied. Using ICG dye for fluorescent staining of SLNs in patients with rectal cancer allows to accurately determine the presence of metastases, and also allows us to decide which patients can perform TES, and who need to perform an extended anterior resection of the rectum with TME. Transanal surgery in patients with early RC is a safe, effective treatment and can be seen as an alternative method.

However, research findings are preliminary and require further studies for their verification and clarification, which will allow in the future obtaining more reliable data, developing algorithms for the treatment of patients with early RC, and making final conclusions.

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Надійшла до редакції 26.12.2024 р.
Прийнята до друку 26.06.2025 р.
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