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THE RESULTS OF 600 TRANSANAL ENDOSCOPIC SURGERIES OF RECTAL ADENOMAS AND ADENOCARCINOMAS

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AIM: transanal endomicrosurgery (TEM) is the method of choice for local excision of rectal cancer. The presented series of patients is collected prospectively and is the largest of the published in the Russian medical periodicals.
PATIENTS AND METHODS: six-hundred patients [average age ±σ 59.8±9 (31-90) years old; 375/600 (62.5%) – women with rectal adenomas and adenocarcinomas, who underwent TEM in 2011-2019.
RESULTS: the mean size of the removed tumors was 3.4±1.5 cm (0.5-10.0). R0 resection was performed in 571/600 (95.2%) of the cases. The complication rate was 3.6% (22/600). Pathomorphological study of the removed specimens revealed adenoma in 450/600 (75.0%) patients, adenocarcinoma in 150/600 (25.0%) cases. The mean time of observation of patients with adenomas was 38.4±25.1 months, with adenocarcinomas – 33.4±23.8 months. The rate of local recurrence in adenomas was 4.5%. Loco-regional recurrence of adenocarcinoma pT1 after TEM was revealed in 6.8% of patients and 30% of pT2 patients without adjuvant treatment.
CONCLUSION: TEM is an effective and safe method of treatment of rectal adenomas. With rectal cancer, a thorough selection of patients is required.

[Key words: transanal endomicrosurgery, adenoma, adenocarcinoma, rectum]

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Transanal endomicrosurgery (TEM) is an effective and standardized method of local excision of benign rectal tumors due to the almost complete absence of mortality and low, not exceeding 3-4% [1-3] rate of postoperative complications. In turn, the precision nature of tumor removal *en bloc*, even with large (>3 cm) rectal adenomas provides local recurrences rate not exceeding 6% [1,4]. Thorough selection of patients with early rectal cancer before surgery allows to apply this method successfully in malignant tumors [5-8]. On the other hand, total pathomorphological study of surgical specimens can reveal the factors of unfavorable prognosis of locoregional metastasis and enable perform in time a «rescue operation» comparable in efficiency with primary radical treatment [9], and in patients with severe comorbidities and high operational risk to conduct adjuvant chemoradiotherapy (CRT).

It should be noted that TEM, despite the more than thirty years of history [10], has become widely used only since the late 1990s, as evidenced by the exponentially increasing number of publications. This was due to the cost-effectiveness of the equipment, as well as the long learning curve of a surgeon. The development of laparoscopic technologies and the emergence of new platforms for endorectal surgery have changed the situation [11].

This paper reflects the TEM single-center experience, which amounted to 600 procedures for the epithelial rectal tumors in 2011-2019. Search for publications on this method on the database of RSCI and PubMed showed that the presented series of prospectively followed-up patients is the largest of those published in the domestic medical periodicals. At the same time, only a few centers abroad [12,13] appeal in their publications to the results of treatment of a comparable number of patients.

PATIENTS AND METHODS

The program of preoperative examination included: digital rectal examination, proctoscopy and biopsy, colonoscopy, endorectal ultrasound (ERUS) and/or magnetic resonance imaging (MRI) of the pelvis. Computer tomography of chest and abdominal organs,

as well as determination of cancer-embryonic (CEA) and carbohydrate (CA 19-9) serum antigens were performed in patients with histologically confirmed invasive rectal cancer before surgery.

All procedures were elective and performed by two surgeons. Bowel cleansing was carried out the night before and in the morning with enema (commercially available product of Enema Clean, Nabiqasim Industries (Pvt.) Ltd. Pakistan) containing the solution of mixture of dihydrogen phosphate and hydrogen phosphate of sodium, or by using a polyethyleneglycol – containing drugs.

Antibacterial prophylaxis was carried out 30 minutes before the surgery intravenously with antibiotics of the fluoroquinolone group or cephalosporins III. Combined spinal anesthesia with intravenous sedation was used, total intravenous anesthesia with muscle relaxation and artificial ventilation was used for prolonged surgical interventions.

Karl Storz (Germany) TEO equipment was used as a platform for operations:

Operative proctoscope 40 mm in diameter, 15 cm long, standard video endoscopic tools. With the help of an ultrasonic scalpel (Ultra Cision Harmonic Scalpel, Ethicon Endosurgery, USA) the tumor was removed with full-thickness excision of the rectal wall. The anal retractor «Lone Star Retractor System» (Cooper Surgical, Inc.) was used for tumor site close to dental line, when a transanal approach was required and after mobilization of the rectal wall with the lower part of the neoplasm continued videoendoscopically. The wound defect was closed with a continuous stitch Vicry l 3/0 (Ethicon) with fixation of the beginning and end of the suture using an endoscopic clipper Lapro TYX C200 (Ethicon Endo-Surgery), or with a node-free V-Loc Medtronic wound closure.

After removal, the specimens were straightened on a foam plate and fixed in a 10% solution of neutral buffered formalin for 24 hours. Then the specimen was cut into slices 3 mm thick with marking the resection edges. The obtained sections were prepared according to the standard procedure and stained with hematoxilin and eosin.

When adenocarcinoma was detected, the TNM classification (7th edition) was used for staging, to determine the degree of invasion of the submucosa, the Kikuchi subclassification [8] was used, in which three degrees of infiltration of the submucosa were distinguished: sm1 – invasion by the tumor of the upper third, sm2 – invasion of the middle third and sm3 – invasion of the entire thickness of the submucosa.

The severity of postoperative complications was assessed according to the Clavien-Dindo classification [14]. After discharge from the hospital, all patients were followed-up dynamically in the Outpatient Clinic of the Center. The patients with adenomas and non-invasive forms of intraepithelial and intracellular carcinoma (pTis) were observed every 6 months, and the ones with invasive cancer (pT1sm1-2) were recommended to be examined every 3 months during the first two years after surgery. When a tumor with a deep invasion of the submucosal layer of the corresponding pT1sm3 and deeper (pT2, pT3) was detected in the specimen, the patients were recommended to perform radical surgery in the volume of total or partial mesorectumectomy (TME) or as an alternative – radiation therapy (RT) according to the «radical program».

STATISTICS

Information about the patients and the treatment results were collected prospectively and entered into an electronic database Excel MS Office Microsoft. Statistical analysis was performed using GraphPad 7 GraphPad Software, La Jolla California USA. In Gaussian distribution, continuous values were described by standard deviation and amplitude, in non-Gaussian distribution by median and quartiles. Accordingly, the comparison of the mean and median – using unpaired t-test and Mann-Whitney test. Discrete values were compared using Fisher's exact test. The odds ratio (OR) was calculated to assess risk factors. Survival curves were constructed using Kaplan-Mayer method, comparison was performed bylog-rank method, calculated risk ratio (hazard ratio, HR).

RESULTS

Demographic data of the patients and preoperative characteristics of tumors are presented in Table 1. Histological examination of preoperative biopsy specimens of adenoma was diagnosed in 482/600 (80.3%) patients, adenocarcinoma from 118/600 (19.7 percent). The average operation time was 49.5±28.8 (15-300) minutes and depended on the size of the tumor. In tumors <3 cm the operation time ±σ was 33.0±11.3 (15-54) min., and in tumors >3 cm – 60.0±34.7 (49-300) min., (p=0.0001). Intraoperative bloodloss in all cases was minimal and not subject to accounting.

In 7/600 (1.2%) cases, the tumors were circular with a length of at least 5.0 cm along the length of the intestine. In these cases, tumor excision was performed with circular resection of the intestinal wall *en bloc*. The defect was restored with a continuous stitch, and the diverting sigmostomy was created routinely. Currently, all seven patients underwent stoma takedown.

In 45/600 (7.5%) cases, tumors were located in the upper rectum. At the same time, in 19 of 45 patients

Table 1. *Characteristics of clinical cases*

Parameter	
N of patients	600
Age, M±SD (min – max), years old	59.8±9.0 (31-90)
Sex, Males Females	 225 (37.5%) 375 (62.5%)
Tumor diameter, M±SD (min – max), cm	3.4±1.5 (0.5-10.0)
Height from dentateline, M±SD (min – max), cm	4.4±2.5 (0-12.0)
Height from the external edge of the anal canal M±SD (min – max), cm	6.9±2.7 (2.0-14.0)
Histological structure of the tumor* Adenoma Adenocarcinoma	 482 (80.3%) 118 (19.7%)

* *Histological structure of the tumor according to preoperative biopsy*

with this tumor site there was an entry to the peritoneal cavity during TEM. Contact with the peritoneal cavity was an expected event and did not affect the method of tumor removal, except for 2/19 patients in whom the possibility of suturing the defect of the extraperitoneal and peritoneal part of the rectum was technically impossible. Endorectal removal of neoplasms and suturing of the bowel wall defect in all other cases were carried out, after which all the patients underwent laparoscopy and bubble test, the diverting sigmostomy was created. The postoperative period was uneventful. At present the diverting sigmostomy at 15/19 patients was closed within the period of up to 6 weeks after the control proctography, which confirmed extravasation. Three patients are waiting for stoma takedown. And in 1/19 patient, according to the histological study of the specimen, adenocarcinoma with tumor invasion into the muscular wall of the intestine (PT2) was revealed, in connection with which, transabdominal surgery in the volume of anterior rectal resection was performed. In a removed specimen adenocarcinoma pT2N2aM0 was revealed, so the adjuvant chemotherapy was recommended. Currently, the patient's disease has been locally controlled for the follow-up period of 36 months.

Conversion to abdominal surgery was required in 3/600 (0.5%) patients. 2/600 patients underwent laparotomy because of impossibility of transrectal suturing the wound defect of the peritoneal part of the upper rectum. The reason for conversion to abdominal surgery in the third observation was the under diagnosis of tumor in the preoperative period and the revealed hidden malignancy with the tumor invasion in the perianal tissue during TEM.

Postoperative morbidity

No mortality occurred. Postoperative complications developed in 22/600 patients, thus their overall incidence was 3.6% (Table 2). The most frequent complication was bleeding – 7/600 patients, while in six of them, hemostasis required reoperation: rectal revision and hemostasis by coagulation or stitching. In one case, there was bleeding that did not require surgery. The second most frequent complication after TEM was the wound dehiscence, which did not require any active treatment (Grade I by Clavien-Dindo). In two cases, on the background of postoperative wound dehiscence, there was the pathological pelvic cavity formation, the treatment of which demanded a diverting sigmostomy. In one case (0.16%) on the third day, cryptogenic acute anorectal abscess developed, requiring cutting, drainage and antibiotics.

Rectovaginal fistula developed in one patient (0.16%) on the third day after TEM. As the first stage of her treatment the diverting sigmostomy was performed laparoscopically. Subsequently, the patient underwent fistulectomy by perineal approach and after 3 months the stoma was closed.

In 4/600 cases in the postoperative period abscesses in the perianal tissue developed, in this connection, in the operating room, their opening and drainage were performed and laparoscopic loop sigmostomy was performed.

Thus, we can say that TEM is a safe method for local excision of rectal cancer: incidence of complications requiring re-operation does not exceed 2.3% (14/600), with this the diverting sigmostoma was required for only 3/600 (0.5%) patients.

The results of pathomorphological studies

In microscopic study of removed specimens in 20/600 (3.3%) cases, the lateral resection margin was less than 1.0 mm – R1. In addition, 9 specimens were of poor quality R2: in four cases (0.7%) there was the tumor fragmentation (all the adenoma tumors of the size >6.0 cm with large intraluminal component). Five (0.8%) cases showed intraoperative specimen damage due to excessive traction (Table 3). After studying the remote TEM micro-specimens in 591/600 (98.5%) cases, the surgery was recognized as R0.

Table 2. *Characteristics of TEM complications (Clavien-Dindo Classification [14])*

Complication	Grade by Clavien-Dindo	The severity of complications	TEM (n=600)
Bleeding	II		1 (0.16%)
Bleeding	III/IIIa		6 (1%)
Suture insufficiency	I		7 (1.20%)
Suture insufficiency	III/IIIa		2 (0.32%)
Cryptogenic paraproctitis	III		1 (0.16%)
Pelvic abscess	III/IIIa		4 (0.64%)
Rectovaginal fistula	IIIa		1 (0.16%)
Total:			22 (3.64%)

Table 3. *The results of pathomorphological study of removed specimens*

Parameter	
Resection R0	571/600 (95.2%)
Resection boundaries <1 mm (R1)	20/600 (3.3%)
Intraoperative tumor fragmentation (R2 resection)	9/600 (1.5%)
Meanlateral resection margin M±SD (min – max), mm	3.2±2.2 (0-17)
Mean deep resection margin, M±SD min – max), mm *	3.3±2.4 (0-11)
Full-thickness rectal wall resection	527/600 (87.8%)
Incomplete rectal wall resection (at the musclelayerlevel)	73/600 (12.2%)

* *for adenocarcinomas*

Table 4. *Comparison of data of pathomorphological study of preoperative biopsies and removed specimens*

The tumor structure	Preoperative biopsy	Pathomorphological study of removed specimens
	n=600	n=600
Adenomas	411/600 (68.5%)	352/600 (58.7%)
Adenocarcinomas	189/600 (31.5%)	248/600 (41.3%)
Tis	–	98/248 (39.5%)
T1	–	105/248 (42.4%)
sm1	–	42/105 (40%)*
sm2	–	21/105 (20%)*
sm3	–	42/105 (40%)*
T2	–	36/248 (14.5%)
T3	–	9/248 (3.6%)

* *% is calculated from 105 specimens with PT1 invasion*

Pathomorphological study of specimens after TEM fully confirmed the benign nature of the tumor in 352/600 (58.7%) cases (adenoma). The other 98 (16.3%) specimens revealed adenoma with sites of intracellular cancer (Tis), and the remaining 150 (25%) specimens revealed invasive cancer with varying in vasion to the rectal wall (Table 4).

It should be noted that for most patients with adenocarcinomas (pTis, pT1sm1-2) – 161/248 (65%) local excision is recognized as an adequate method of treatment.

Also, the other factors have been investigated (Table 5). They indirectly characterize tumor aggressiveness: invasion of venous vessels (VI), invasion of lymphatic vessels (LVI). It has been noted that early cancer with a full invasion of the submucosal layer (sm3) statistically significantly more often (p=0.0003) has a structure of moderately differentiated adenocarcinoma than cancer with superficial invasion (sm1-sm2), in which tumors are often represented by well differentiated adenocarcinoma.

Also, in surgical specimens with sm3 tumors, lymphovascular invasion 21/42 (50%) was detected more often, but not statistically significant (p=0.15), compared with sm1-2 – 22/62 tumors (35%).

Long-term results of TEM in rectal adenomas, including Tis

329/450 (73%) patients with adenomas, including pTis, were followed-up. The mean follow-up time (M±SD) was 38.4±25.1 months.

Local recurrence in the scar after TEM in patients with adenomas and adenocarcinomas pTis was detected in 15/329 (4.5%) cases, including 10 patients with

Table 5. *Characteristics of PT1 tumors depending on the depth of invasion of submucosal layer*

Tumor structure	pT1, n=105		p
	sm1-sm2 n=63	sm3 n=42	
	14/63 (22.2%)	–	–
	41/63 (65%)	40/42 (95.2%)	0.0003
(G3)/mucosa	7/63 (11.1%)	2/42 (4.8%)	0.3
Venous invasion	2/63 (3.2%)	1/42 (2.4%)	1.0
Lymphovascular invasion	22/63 (35%)	21/42 (50%)	0.15

Table 6. *Risk factors for local recurrence of adenomas and pTis after TEM*

Factor	HR	95%CI	$P_{univariant}$	$P_{multivariant}$
Experience: <50 TEM annually vs >50 TEM per annum	1.01	0.2-5.13	0.12	–
Dissemination: >1/2 circumferencevs<1/2 circumference	3.51	0.66-18.6	0.11	–
Fragmentation: yes vs no	22.1	3.04-148.1	0.01	0.2
Operative time: <40 min vs <40 min	4.46	0.89-22.18	0.13	–
Degree of dysplasia: Severe vs Moderate	6.67	0.99-44.59	0.01	0.01
Lateral margin: ⩽1 mm vs >1 mm	2.05	0.27-15.47	0.4	–
Tumor site: <6 cm vs ⩾6 cm	1.0	0.25-3.99	1.0	–
Tumor type: recurrent vs primary	16.83	1.75-161.9	0.01	0.04
Tumor size: >3 cm vs ⩽3 cm	12.75	2.0-75.0	0.008	0.3

adenomas and 5 patients with pTis, for the period of 7-48 months. All the patients with recurrent adenoma were re-operated: 13 patients underwent TEM again, in two cases of recurrent adenoma and pTis due to the presence of invasive cancer in the recurrent tumor rectal resection was performed in the volume of low anterior resection and pull-through procedure and preventive ileostomy. Recently, all re-operated patients are alive without recurrence. Thus, 5-year local control of patients with adenomas and pTis after TEM was 90.1% (Fig. 1).

Univariant and multivariant analysis was performed while analyzing risk factors for local recurrence of adenomas and pTis after TEM (Table 6). The presence of severe dysplasia of the adenoma epithelium (p=0.01) and the recurrent nature of the tumor (p=0.04) are independent risk factors for local recurrence.

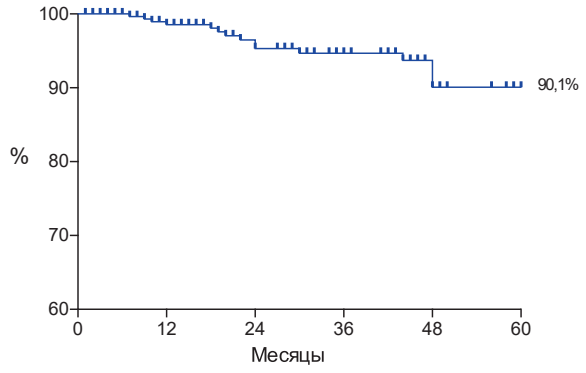

Figure 1. *5-year local control of the disease after TEM with rectal adenomas and pTis*
Months

Long-term results of TEM in invasive adenocarcinomas

106/150 (70.6%) patients with invasive adenocarcinomas (RT1-3) were followed up the mean follow-up time (M±SD) was 33.4±23.8 months.

Long-term results of TEM in the cases of rectal adenocarcinomas T1 sm1-2

74/105 (70.4%) patients with pT1, including 29/42 ones with pT1sm1 and 12/21 patients with pT1sm2, were followed up (Fig. 2).

Locoregional recurrence after TEM was detected in two patients with pT1sm1 (3 months and 9 months). In the patients with recurrences after pT1sm1, in one case low anterior rectal resection and loop ileostomy in R0

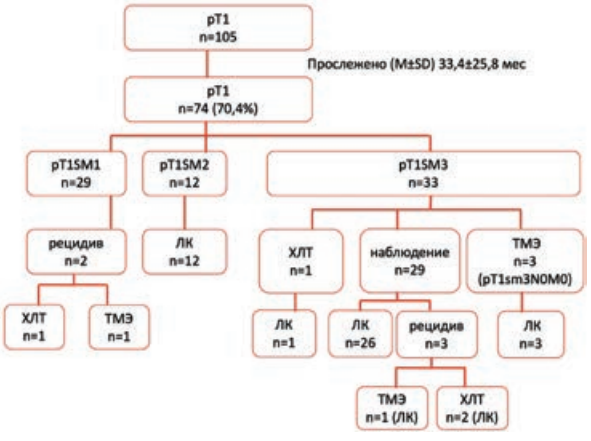

Figure 2. *Long-term results of treatment of patients with rectal cancer pT1*
LC – local control
Followed up / recurrence /observation

volume were performed, in the other case preoperative chemoradiotherapy was assigned to the patient with recurrence after TEM. Radical surgery is planned in the future.

Long-term results of «rescue» surgery and RT in the cases of rectal adenocarcinomas T1sm3

All 42 patients with pT1sm3 were offered surgery in the volume of rectal resection with mesorectumectomy. However, only three patients agreed to the surgery, and the final pathomorphological study revealed the absence of affectedlymph nodes: pT1sm3N0M0.

The remaining 39 patients refused radical surgery. Later, two of them underwent CRT TFD (total focal dose) 50 Gr. One patient did not attend follow-up appointments, the second one underwent thelocal control of the disease in terms of30 months after CRT. Of the patients with pT1sm3, who refused «rescue» surgery, 29 ones were followed up (Fig. 2). Locoregional recurrence after TEM was detected in three patients with pT1sm3 (6, 10 and 26 months). Among the patients with recurrences after pT1sm3 in the first observationlocoregional recurrence was revealed in 6 months, the patient underwent the proctectomy with coloanal anastomosis. In the other two cases of recurrences, CRT of 50 Gr. was performed. Recently, there is local control of the disease in terms of 7 and 12 months. In the analysis of the long-term results in the patients with pT1sm3 who underwent «rescue» surgery, the secondary 5-yearlocal control was 100%, and in those who remained under observation – 84.7%, p=0.4 (Fig. 3).

Thus, the frequency of locoregional recurrence after TEM in the patients with pT1 (sm1-2 and the monitoring group sm3) amounted to 5/74 (6.75%). In the analysis of the long-term results of TEM 5-year local control of the disease (Fig. 4) in the patients with pT1sm1-2 was 95%, and in the patients with pT1sm3 – 84.7%. However, no significant differences were found (p=0.3). In the analysis of risk factors for the development of locoregional recurrence pT1 after TEM univariant and multivariant analysis was carried out (Table 7). The presence of poorly differentiated and/or mucosal adenocarcinoma is an independent risk factor for the development of locoregional recurrence (p=0.04).

Long-term results of TEM operations and «rescue» RT in cases of rectal adenocarcinoma T2-3

Among 36 patients with pT2, 14/36 (38.9%) underwent «rescue» operations – rectal resection with total mesorectumectomy. No signs of residual tumor in the area of previously performed TEM were found in any removed specimens, the average number of examined lymph nodes (M±SD) was 21±11 (8-44). After examination of the specimens in 7/14 (50%) cases cancer metastases in mesorectal lymph nodes were detected, including five patients with pT2N1aM0, one patient with pT2N2aM0 and one – pT2N1bM0). All these patients underwent adjuvant polychemotherapy XELOX of 8-12 courses.

Two patients with pT2 in connection with comorbidities were subjected to CRT. In the remaining 20/36 observations with pT2, TEM remained the only method of treatment, which was associated with the presence of severe comorbidities, as well as a categorical patients' rejection of resection with the stoma creation.

26/36 (72.2%) patients with pT2 were followed up (Fig. 5). In 14 patients, as described above, resections were performed and currently all the patients are alive without signs of recurrence.

Among the remaining 12 patients with pT2, for whom the primary treatment was TEM, two patients underwent CRT under the radical program. Recently the patients are alive without recurrence in terms of 9 and 12 months. Locoregional recurrence developed in 3/10 (30%) cases within 9, 12 and 30 months. One patient died from the disease progression (M1Hep), and two ones were subjected to CRT, after which one patient underwent proctectomy R0.

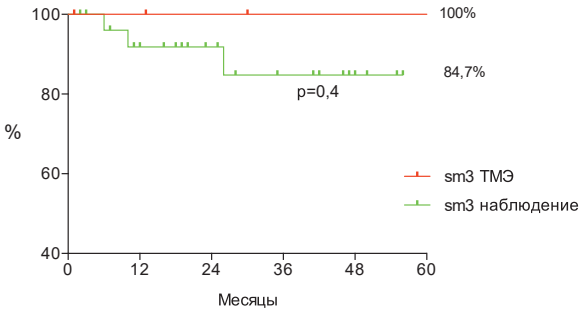

Figure 3. *5-year local control of the disease in the patients with pT1sm3 who underwent «rescue» surgery and the patients who remained under observation*
observation / months

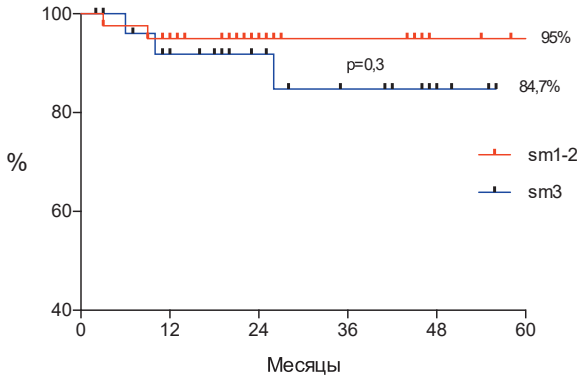

Figure 4. *5-year local control of the disease after TEM in rectal cancer pT1 depending on the depth of invasion of the submucosal layer*
Months

Table 7. *Risk factors for local recurrence of pT1 after TEM*

Factor	HR	95%CI	$P_{univariant}$
Experience: <50 TEM annually vs >50 TEM annually	3.41	3.2-40.5	0.55
Surgeon 1 vs Surgeon 2	2.50	0.28-22.38	0.08
Deep margin: ⩽1 mm vs >1 mm	0.30	0.005-15.66	0.5
Operation time: <40 min. vs <40 min.	2.05	0.20-20.84	0.9
Lymphovascular invasion: no vs yes	1.37	0.13-11.37	0.9
Lateral margin: ⩽1 mm vs >1 mm	0.34	0.0012-97.00	0.7
Tumor site: <6 cm vs ⩾6 cm	1.67	0.22-12.46	0.8
Differentiation: poorly differentiated, mucus vs moderately differentiated adenocarcinoma	27.80	1.47-523.9	0.04
Tumor size: >3 cm vs ⩽3 cm	6.71	0.8-54.0	0.07

In all the patients with pT3 in the removed specimens after TEM, rectal resections with total mesorectumectomy were performed, with the exception of two patients aged 79 and 82 years old, for whom TEM was the only method of treatment due to general contraindications for radical surgery. Among the seven operated patients, the final stage II of the disease (pT3N0M0) was detected in 6 cases and the third stage of rectal cancer (pT3N2bM0) was identified in only one case. This patient underwent 12 courses of systemic polychemotherapy in XELOX mode. It is important to emphasize that in all cases there were no signs of residual tumor in the TEM zone, the mean number of examined regional lymph nodes (M±SD) was 28±8 (13-34). Subsequently, one patient, for whom TEM became the main treatment method, fell out of the observation, and the other one is undergoing local control of the disease in the follow-up period of 24 months (Fig. 6).

In the analysis of long-term results among the patients with pT2-3 who underwent «rescue» surgery, 5-year local control was 100%, and in the patients who remained under observation due to refusal of rectal resection or the presence of contraindications to it, 5-year local control was 76.2% (Fig. 7).

At the same time, there is a trend to statistically significant difference between long-term results in pT2-3 depending on the method of surgical treatment, p=0.08.

DISCUSSION

Transanal endoscopic microsurgery (TEM) is a safe method of removing rectal adenomas and early adenocarcinomas. The morbidity rate in the analyzed group of the patients in our study was 3.64%. Reproducibility of the results is confirmed by the experience of Serra-Aracil X. et al., summarizing the results of treatment of 639 patients. In the referred study, the incidence of clinically significant complications (>II by Clavien-Dindo) was 5.6%. According to the obtained Serra-Aracil X. results, significant risk factors for postoperative complications were tumor size >6 cm (OR=3.2, 95% CI 1.3-7.8), anticoagulant therapy

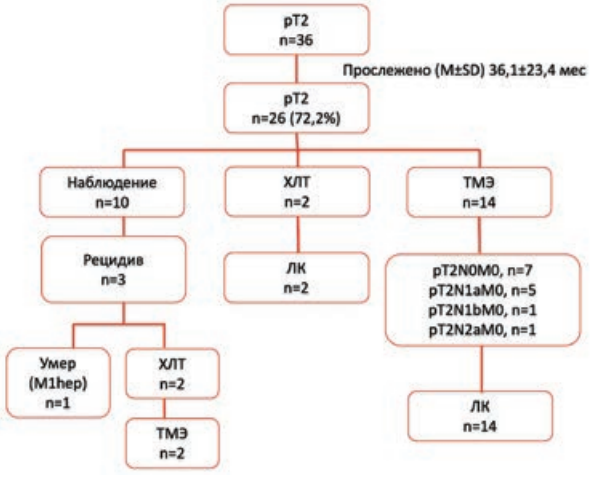

Figure 5. *Long-term results of treatment of patients with rectal cancer pT2*
LC – local control
Followed up / Observation / Recurrence / Died

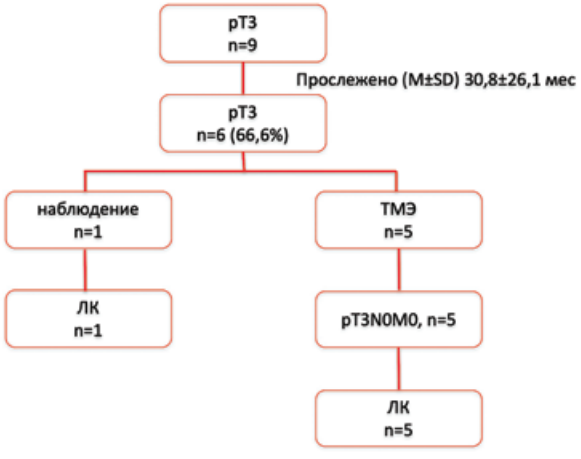

Figure 6. *Long-term results of treatment of patients with rectal cancer pT3*
LC – local control
Followed up / Case, observation

(OR=2.3, 95% CI 1.1-5.1) and surgical experience (OR=2.0, 95% CI 1.0-4.1). It is important to note that the authors indicate the possibility to carry out TEM even in the one day hospital [13].

In addition to encouraging immediate results, transanal endoscopic microsurgery allows to achieve comparable oncological results in comparison with TME in large adenomas and early rectal cancer [16]. In accordance with the recommendations of NCCN (National Comprehensive Cancer Network, NCCN Guidelines Version 1.2019, Rectal Cancer) [17], the recommendations of the European Association of clinical oncologists (ESMO Clinical Practice Guidelines) [18] –local removal of rectal cancer as an independent radical treatment method – is possible in patients with benign tumors and with tumor invasion of the corresponding sT1Nx. However, the frequency of diagnosis of tumors of this site at an early stage does not exceed 6-7% [19]. Thus, the most difficult issue is the presence of «hidden» malignancy in adenomas [15]. According to our own data and the results of the analysis of the world literature, the frequency of mismatch between preoperative and pathomorphological diagnoses varies from 6% to 43%, depending on the analyzed sample [1,20]. The complexity of the diagnosis of latent malignancy leads to the fact that the only method can be excision of all layers of the rectum wall together with the tumor and compliance with adequate lateral margins of resection, regardless of the results of preoperative staging and histological examination of the biopsy material [4].

The presence of latent malignancy, intraoperative fragmentation of the specimen and R1 resection boundaries are directly related to the incidence of local recurrences after local tumor excision [21,22]. So, in the study of Vukanic D et al. the results of 328 TEM operations of rectal tumors removal were analyzed. During the removal of tumors, fragmentation of the specimen occurred in 54 patients. The average tumor size was 41.9 mm (10-150 mm), while the tumor size was the only prognostically unfavorable

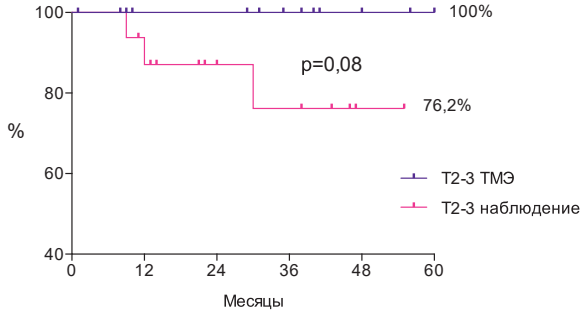

Figure 7. *5-year local control in patients with pT2-3 Case, observation / Months*

factor of latent malignancy and positive resection margins [22].

The frequency of latent malignancy directly depends on the tumor size. A retrospective study conducted by Scala A. et al. included the results of treatment of 320 patients. The total frequency of *en bloc* and full-thickness resections was 99% and 80.7%, respectively. In the group of benign tumors (N=279) R0 resections, according to the final pathomorphological study of removed specimens, were performed in 90.3% of cases. The frequency of latent malignancy in adenomas progressively increased with the tumor size: 9.3% in adenomas <3 cm, 12.8% in adenomas 3-5 cm and 14.4% in adenomas more than 5 cm. Similarly, in these groups, the frequency of R0 resections decreased respectively: 95.9% in adenomas <3 cm, 92.2% in adenomas 3-5 cm and 85.1% in adenomas more than 5 cm. Of the 31 follow-up patients who underwent only TEM without adjuvant treatment for malignant tumors, recurrences occurred in 7 patients: three patients with superficial invasion into the submucosal layer, three patients with deep invasion into the submucosal layer and two patients with T2 tumors [21].

Due to the high incidence of local recurrences in deep invasion into the submucosal layer, a number of researchers consider this factor to be one of the main limitations for the use of TEM in rectal cancer [9,20]. According to the literature, the frequency of local recurrences after local excision (TEM) at T2 exceeds 26%. [1,20]. According to our study, the frequency of locoregional recurrences after TEM in patients with pT1 was 4.1%, and in patients with pT2 – 16.7%.

TEM is also an attractive palliative option in patients with high surgical risk. In our study, two patients, aged 79 and 82, with the decompensated comorbidities TEM was the only possible treatment option for T3 rectal tumors, and, despite the known excess of cancer indications forlocal excision, with dynamic observation for 2 and 3 years, there is alocal control of the disease. Undoubtedly, TEM as a palliative intervention should be applied individually under a decision of the MDT, since the published data, in particular, a retrospective study by Leijtens J. et al., combining the TEM results on T2-T3 rectal cancer in 41 patients revealed a high recurrence rate of 35% and alow overall 3-year survival rate of 63% [23].

The need for additional treatment after TEM with high-risk tumors is dictated by the high frequency of their locoregional recurrence after local excision. Timely «rescue» surgery does not compromise the long-term oncological results in comparison with the primary TME [24].

However, a systematic review of the literature [9] showed significant differences in the worst quality of mesorectumectomy after TEM (p=0.0003), although