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Transanal endomicrosurgery in the treatment of large and giant rectal adenomas.

Results of a prospective study

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ABSTRACT *AIM: the aim of this article was to demonstrate the possibilities of using TEM for large (more than 5.0 cm) and giant (more than 8.0 cm) rectal adenomas.*

PATIENTS AND METHODS: more than 1000 transanal endoscopic microsurgery procedures were performed in 2011–2023. Three groups were distinguished according to the tumor size: Group I — tumors less than 5.0 cm; Group II — tumors 5.0–8.0 cm (large); Group III — tumors more than 8.0 cm (giant).

RESULTS: the final analysis included 600 patients. Group I with sizes less than 5.0 cm included 465 (77.5%) patients. Group II — large adenomas 5.0–8.0 cm included 120 (20%) patients. The group of giant tumors, larger than 8.0 cm, included 15 (2.5%) patients. In group I (less than 5.0 cm), the R0 rate was 92%, then in group II of large adenomas (5.0–8.0 cm) it was only 75%, and in the case of removal of giant adenomas (more than 8.0 cm) — 46% ($p < 0.001$). In multivariate analysis, independent risk factors for R1 resection were giant tumor size over 8.0 cm (OR 5.5; 95% CI: 1.4–20.3; $p = 0.006$) and tumor site close to the dentate line (OR 2.6; CI: 1.17–5.89; $p = 0.0005$).

CONCLUSION: giant size (over 8.0 cm) and adenoma site in the low rectum close to the dentate line are independent risk factors for non-radical resection during transanal endomicrosurgery.

KEYWORDS: transanal endomicrosurgery, rectal adenomas, TEM, rectal neoplasms

CONFLICT OF INTEREST: the authors declare no conflict of interest

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BACKGROUND

Transanal endomicrosurgery (TEM) is the method of choice for patients with adenomas and early rectal cancer. The main advantages of TEM over other methods are adequate access to all parts of the rectum, high-quality imaging and precision removal of tumors, which is accompanied by a low incidence of fragmentation and, mainly, R0 resection [1–4], including with adenomas over 5.0 cm in size, with the risk of local recurrences in less than 2.5% [5,7,8,9].

However, the issue of local excision of large and giant rectal adenomas, over 5.0 cm, is a subject for

discussion in the literature. When removing such tumors, which can involve almost the entire low and mid rectum, technical difficulties arise due to problems with adequate visualization of the resection edge, with the extraction of the specimen, while the surgery usually ends in fragmentation. A direct correlation has been established between the size of the rectal adenoma (over 5.0 cm) and the postoperative complications rate, as well as local recurrences [10].

Some authors indicate that the size of an adenoma exceeding 8.0 cm or more is a risk factor for intraoperative bleeding and tumor fragmentation [4,11].

AIM

To demonstrate the possibilities of TEM for large (over 5.0 cm) and giant (over 8.0 cm) rectal adenomas.

PATIENTS AND METHODS

Between 2011 and 2023, more than 1,000 surgical procedures in the scope of transanal endomicrosurgery were performed in one center. All procedures were performed under combined (spinal + intravenous sedation) anesthesia, with prolonged operation under total intravenous anesthesia with muscle relaxation and artificial lung ventilation. Antibacterial prophylaxis was performed 30 minutes before surgery with intravenous fluoroquinolones or third-generation cephalosporins. The procedures were performed on Karl Storz's equipment (Germany). All removed surgical specimens were studied *en bloc* in the Pathomorphology and Immunohistochemical Unit. According to the size of the adenomas, the classification proposed by Serra-Aracil X. et al. [4] was used. According to the tumor size, three groups were identified: Group I — tumors less than 5.0 cm in size; Group II — tumors 5.0–8.0 cm in size (large); Group III — tumors larger than 8.0 cm (giant).

The severity of postoperative complications was assessed by Clavien-Dindo's classification [12].

Statistical Analysis

Patient data and treatment outcomes were prospectively entered into an Excel spreadsheet MS Office Microsoft. Statistical analysis was performed using the Statistica 13.3 program (Tibco, USA). The normal distribution was checked using Shapiro-Wilk's criterion in small groups (< 50 observations) and Kolmogorov-Smirnov's criterion in the remaining cases. In the normal distribution, continuous indicators were described by the mean and standard deviation ($M \pm SD$), in the non-Gaussian distribution — by the median and quartiles (Me (Q1; Q3)). The comparison of the three groups by quantitative criteria, regardless of the nature of the distribution, was carried out

using Kraskel-Wallis's H-test; pairwise comparisons were carried out using the unpaired t-test or Mann-Whitney's U-test, depending on the nature of the distribution. The comparison of multifield tables by qualitative characteristics was carried out using Pearson's χ^2 -test; pairwise comparisons using Fisher's two-sided exact test. Binary logistic regression analysis was used to assess risk factors, and odds ratios (OR) with a 95% coincidence interval (CI) were calculated. The selection of factors in the multivariate model was based on the results of a univariate analysis. During the factor analysis, such indicators as the surgeon's experience and the patient's age were reduced to binary indicators using cut-off points based on data from the world literature [10]. The values at $p < 0.05$ were considered significant. In the case of pairwise comparisons, the correction of the significance level was carried out using Bonferroni's method.

RESULTS

In the period from 2001 to 2023, more than 1,000 TEM patients were operated on for various rectal tumors (adenoma, adenocarcinoma, neuroendocrine tumor, GIST, melanoma, etc.). For subsequent analysis, patients who, according to the pathomorphology of removed specimens, revealed adenoma were selected.

The final analysis included 600 patients. The average age ($M \pm SD$) of the patients was 57.5 ± 5 years, and there were more women (61%). The mean diameter ($M \pm SD$) of the adenomas was 4.2 ± 1.2 cm. The minimal size of the adenoma was 2.0 cm, and the neoplasms with a maximal size of 11.0 cm were regarded as gigantic. The most common 411/600 (68.5%) tumors were located in the middle rectum: at a height of 3.8 (2.5;5.4) cm proximal to the dentate line and at a height of 6.2 ± 1.5 cm from the outer edge of the anal canal. 465/600 (77.5%) patients with a tumor size of less than 5.0 cm were included in Group I. Group II — large adenomas of 5.0–8.0 cm — comprised 120/600 (20%) patients. The group of giant

Table 1. Characteristics of clinical observations depending on the size

Parameter	All tumors N = 600	Group I (less than 5.0 cm) N = 465	Group II (5.0–8.0) cm N = 120	Group III (over 8.0 cm) N = 15	p
Age, M ± SD (min–max), years	57.5 ± 5 (19–92)	62 ± 11 (21–92)	63.5 ± 10 (19–88)	62.5 ± 9 (43–78)	0.3
Gender	229 (39%)	164 (35%)	59 (49%)	5 (33%)	0.6
Male	271 (61%)	301 (65%)	61 (51%)	10 (66%)	
Female					
Average size M ± SD (min–max), cm	4.2 ± 1.2 (0.4–11.0)	2.8 ± 0.9 (0.4–4.0)	5.4 ± 0.6 (5.0–7.5)	8.6 ± 1.0 (8.0–11.0)	
Distance from dentate line Me (quartiles), cm	3.8 (2.5;5.4)	4.0 (3.3;6.3)	3.3 (2.2;6.1)	2.5 (1.8;4.4)	0.1
Distance from the anal verge M ± SD (min–max), cm	6.2 ± 1.5 (1.0–17.0)	6.8 ± 2.7 (1.0–17.0)	6.2 ± 2.5 (2.0–14.0)	5.2 ± 2.0 (0–10.0)	0.2
Operation time Me (quartiles), min.	49 (30;58)	36 (30;55)	55 (50;74)	84 (61;105)	0.03

Table 2. The results of the pathomorphological examination of surgical specimens depending on the tumor size

Parameter	All tumors N = 600	Group I (less than 5.0 cm) N = 465	Group II (5.0–8.0) cm N = 120	Group III (over 8.0 cm) N = 15	p
R0-resection	527 (88%)	429 (92%)	91 (76%)	7 (47%)	< 0.0001 p _{I-II} < 0.0001 p _{I-III} < 0.0001
Resection margins < 1 mm (R1)	67 (11%)	34 (7%)	26 (22%)	7 (47%)	< 0.0001 p _{I-II} < 0.0001 p _{I-III} < 0.0001
Intraoperative tumor fragmentation	6 (1%)	2 (0.4%)	3 (3%)	1 (7%)	0.01
Mean lateral margin of resection, Me (quartiles), mm	3.8 (2.1;4.5)	3.7 (1.8;3.5)	4.7 (2.4;5.5)	2.7 (1.5;3.3)	0.2
Mean deep resection margin, Me (quartiles), mm	3.9 (2.5;5.2)	4.1 (3.3;5.6)	2.4 (1.5;3.6)	4.1 (3.4;5.6)	0.1
Full-thickness resection of the rectal wall	523 (87%)	404 (87%)	105 (88%)	14 (93%)	0.8

tumors larger than 8.0 cm included 15/600 (2.5%) patients. There were no significant differences in the gender, age, and location of the tumor relative to the dentate line between the groups, depending on the size (Table 1). The mean operation time was significantly different depending on the tumor size and was higher in patients in groups II and III, $p = 0.03$.

A pathomorphological study of removed specimens revealed that among all 600 patients, the R0 resection rate was 88%, while full-thickness resection of the rectal wall was performed in 87%, the mean horizontal lateral margin was 3.8 mm, and the vertical was 3.9 (2.5; 5.2) mm (Table 2). The incidence of R0 resection decreased significantly depending on the size of the neoplasms.

So, if in Group I (less than 5.0 cm) the rate of R0 resections reached 92%, then in Group II of large adenomas (5.0–8.0 cm) it was only 76%, and with removal of giant adenomas (over 8.0 cm) — 47% ($p < 0.001$). It should be noted that there were no significant differences between the groups in the incidence of full-thickness resection, but there were significant differences in the incidence and intraoperative fragmentation of the tumor, if in Group I it was only 0.4%, then in Group III it was already 7% (Table 2).

Taking into account the significant trend towards an increase in the rate of R1 resection depending on the tumor size, we analyzed the risk factors for non-radical removal of neoplasms. So, in univariate analysis (Table 3) among the

Table 3. Results of a univariate analysis of risk factors for performing R1 resection for rectal adenomas

Factor	OR	95% CI		p
Male	4.1	1.26	13.8	0.05
Age over 70 years	1.44	0.7	2.9	0.6
Site relative to the dentate line is 5.0 cm higher)	2.8	1.3	5.9	0.005
Tumor size is 5–8 cm	1.47	0.61	3.5	0.39
Tumor size is over 8 cm	5.5	1.4	20.5	0.006
Operation time is more or less than 50 minutes	3.9	1.01	16.3	0.02
Surgical experience (more or less than 50 TEM)	0.6	0.25	1.4	0.4

Table 4. Results of multivariate analysis of R1 resection for rectal adenomas

Factor	OR	95% CI		p
Site relative to the dentate line (at or above 5.0 cm)	2.6	1.17	5.89	0.0005
Tumor size is over 8 cm	5.5	1.4	20.3	0.006
Operation time is more or less than 50 minutes	1.7	0.4	6.7	0.4

Table 5. Distribution of postoperative complications after TEM depending on the type and severity

The nature of the complications	Severity of the complication	All tumors n = 600	Group I (less than 5.0 cm) n = 465	Group II (5.0–8.0) cm n = 120	Group III (over 8.0 cm) n = 15	p
Bleeding	II	1 (0.1%)	1			
Bleeding	III/IIIa	4 (0.6%)	2	1	1	
Leakage	I	8 (0.9%)	6	1		
Leakage	III/IIIa	1 (0.1%)		1		
Cryptogenic perianal abscess	III	1 (0.1%)	1			
Pelvic abscess	III/IIIa	5 (0.7%)	3	2		
Rectovaginal fistula	IIIa	1 (0.1%)			1	
Urinary retention	II	1 (0.1%)		1		
Total:		22 (3.6%)	13/465 (2.7%)	6/120 (5.0%)	2/15 (13.3%)	0.2

factors: gender (men/women), age (more or less than 70 years old), group distribution depending on the tumor size, site of neoplasms depending on the closeness to the dentate line (at the level or 5.0 cm above the dentate line — lower/middle ampullary rectum), the operation time, the surgeon's experience (more or less than 50 TEM procedures performed), the mean operation time of less or more than 50 minutes, it was found that the risk factors for non-radical procedure are a giant adenoma size exceeding 8.0 cm (OR 5.5; 95% CI:1.4–20.5, $p = 0.006$), the operation time of over 50 minutes (OR 3.9; 95% CI:1.01–16.3, $p = 0.02$), the neoplasm site too close the dentate line (OR 2.8; 95% CI: 1.3–5.5, $p = 0.005$).

Multivariate analysis showed independent risk factors for performing R1 resection: the giant tumor size of over 8.0 cm (OR 5.5; 95% CI:1.4–20.3; $p = 0.006$) and the tumor site in the immediate

contact with the dentate line (OR 2.6; 95% CI:1.17–5.89; $p = 0.0005$) (Table 4).

No post-op mortality occurred. The postoperative morbidity rate was 22/600 (3.7%). One (0.2%) patient developed bleeding, which was controlled conservatively. In 4 (0.7%) cases, bleeding required re-operation. Suture leakage occurred in 9 (1.5%) cases, in 8 (1.3%) patients this complication did not require additional treatment, while in 1 (0.2%) patient, the pelvic collection was detected which required the loop sigmoidostomy. In 5 (0.8%) patients, a pelvic abscess was detected, which required active surgical approach, drainage and diversion sigmoidostomy. One (0.2%) patient developed a rectovaginal fistula, which also required the loop sigmoidostomy. In one case, urinary retention occurred, which was stopped by conservative therapy. One patient developed cryptogenic perianal abscess, which required the antibiotics, opening and drainage of the abscess.

In accordance with the size of the adenomas, the complications rate in Group I was 2.8% (13/465), in Group II — 5.0% (6/120), and in Group III with giant tumors — 13.3% (2/15) (Table 5).

It is important to emphasize that there is a definite trend in higher rate of postoperative complications depending on the size of the neoplasms, the revealed results did not reach statistical significance.

DISCUSSION

Transanal endomicrosurgery is a safe and precise method of local removal of rectal tumors.

According to the results of the studies, the rate of postoperative complications does not exceed 2–3.0% [1–4], while the most significant complications, as a rule, correspond to no more than grade IIIa by Clavien-Dindo's. In this study, we also obtained a 3.6% rate of postoperative complications, which correlates with the results of previously published data. At the same time, the rate of postoperative complications was higher with giant tumors, although it did not reach significant differences, due to the small sample size. Scala et al. presented their classification of adenomas depending on size and showed that a diameter of over 5.0 cm is a risk factor for postoperative complications [10]. Levic et al. also showed that with a neoplasm size of over 4.0 cm, there is also a trend to worse early results [13]. As part of the study, it was found that the size of an adenoma of 5.0 cm is not a deterrent to performing TEM, which correlates with the results obtained by Serra-Aracil et al., according to which technical difficulties appear only in the presence of a giant adenoma larger than 8 cm in diameter during TEM, which are realized in a higher rate of fragmentation and R1-resections [14].

Taking into account the fact that the rate of R1 resection is higher with giant adenomas, we performed a univariate and multivariate analyses, and it turned out that the size of the neoplasms exceeding 8.0 cm, as well as the site of the tumor in immediate contact with the dentate line, i.e. in

the low rectum are independent factors of non-radical procedure. Apparently, these two factors are inextricably linked, since with a giant tumor with a low site, extremely difficult conditions are created for searching and isolating the negative resection margins; the surgeon often has to start the tumor excision transanally and then proceed to the endovideoscopic surgery. At the same time, the number of specimen tractions increases, which is described in the study by Serra-Aracil et al. [14]. Also, according to Skala et al., the main cause of R1 resection is the tumor site in the immediate contact with the dentate line which is a risk factor for relapse [10].

The method of choice for large adenomas with location in the rectum may be endoscopic submucosal dissection (ESD). This method has shown good results when used in the colon with an R0 resection rate exceeding 80% [15]. However, a systematic review of the literature and meta-analyses aimed at comparing the results of TEM and submucosal dissection in patients with large (over 40 mm) rectal adenomas done by Arezzo A. et al. has shown the advantages of TEM in the quality of are moved specimen [16]. Thus, the rate of *en bloc* resection after TEM was 98.7%, while this indicator after submucosal dissection was 87.8%, the differences were significant, $p = 0.001$. The rate of negative margin after TEM for large adenomas was significantly higher — 88.5% than after dissection — 74.6%, $p = 0.001$, with equivalent early and late outcomes. In our opinion, the size of the neoplasm is a determining factor and it is logical to assume that with giant rectal tumors, exceeding 8.0 cm, the difference in the rate of fragmentation and R0 resection between TEM and ESD will persist or increase.

An alternative method for removing large and giant rectal adenomas may be a combination of TEM and submucosal dissection (TEM-ESD), which was described by Kouladouros K. et al. in patients with tumors of a median size of 7.5 cm. The authors combined the TEM method with the advantages of flexible endoscopy and showed no fragmentation in all 43 (100%) patients included in the cohort.

However, only 29/43 (67%) patients had microscopically detected R0 resection [17]. Thus, local excision of large and giant rectal adenomas is a rather meticulous and complex process. Transanal endomicrosurgery is the method of choice that allows achieving acceptable quality of removed specimens in almost all patients. However, the selection of patients should be carried out taking into account the risk factors for specimen fragmentation.

CONCLUSION

The giant size (over 8.0 cm) and adenoma site in low rectum in the immediate contact with the dentate line are independent risk factors for non-radical removal during transanal endomicrosurgery.

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