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Are the criteria of the international consensus relevant for laparoscopic left hemicolectomy with transanal specimen extraction?

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ABSTRACT *AIM: to optimize patient selection criteria for the laparoscopic left hemicolectomy with transanal specimen extraction (TES).*

PATIENTS AND METHODS: the treatment outcomes of 68 patients who underwent surgery for left-sided colon tumours between October 2022 and August 2024 were analyzed. Transanal extraction of the specimen (TES) was successfully performed in 42 (62%) cases (TES group), while 26 (38%) patients required a minilaparotomy (minilaparotomy group — ML). In addition to assessing early postoperative outcomes, intraoperative specimen circumference was measured in all patients, and the sensitivity and specificity of the patient selection criteria according to the Consensus were analyzed.

RESULTS: in the successful TES group, in addition to the excellent cosmetic effect due to the absence of an incision in the anterior abdominal wall, several advantages were also identified, such as a pain reduction already within the first day of the postoperative period — 3 (2; 4.3) points in the TES group compared to 5 (4; 6) points in the ML group ($p < 0.001$) with a significant decrease in the complication rate: 3/42 (7%) cases in the TES group versus 8/26 (31%) in the ML group ($p = 0.0003$). The circumference of the specimen in the TES group was 11.7 (2.6) cm, while in the ML group it was 16.2 (2.1) cm ($p < 0.0001$). The threshold value of this parameter for successful TES, based on ROC-analysis, was 16 cm. The diagnostic value of the Consensus criteria in predicting the successful performance of TES showed that their relative risk (RR) was 2.3 (95% CI: 1.2–5.1); $p = 0.004$; sensitivity — 88.1% (95% CI: 75–94.8); specificity — 42.3% (95% CI: 25.5–61.1). Adding another parameter (intraoperative circumference of the specimen) to the Consensus criteria significantly increased the diagnostic value: RR = 3.1 (95% CI: 1.8–6.2); $p < 0.0001$; sensitivity = 83.3% (95% CI: 69.4–91.7); specificity = 73.1% (95% CI: 53.9–86.3).

CONCLUSION: laparoscopic left hemicolectomy with transanal specimen extraction demonstrates superior early postoperative outcomes compared to laparoscopy-assisted procedures with minilaparotomy. Adding intraoperative specimen circumference to the Consensus criteria for TES patient selection significantly improves their accuracy.

KEYWORDS: transanal extraction, NOSES, colon cancer, colorectal surgery, laparoscopic surgery

CONFLICT OF INTEREST: the authors declare no conflict of interest

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INTRODUCTION

More than 30 years ago in 1993, Franklin et al. published one of the first articles on laparoscopic surgery for colorectal cancer with the natural body orifice specimen extraction [1]. Since then, more than one study has been conducted that has demonstrated the advantages

of this technique over classical laparoscopic-assisted bowel resection in terms of achieving the best early results. Thus, the absence of an incision in the anterior abdominal wall provides an excellent cosmetic effect, resulting in a lower level of postoperative pain [2,3,4]. However, there are still limitations when using this method, due to the problem

of selecting patients to successfully perform this type of surgery. First of all, the extraction of the specimen being removed is limited by its size and the size corresponding to the chosen extraction method of the natural orifice of the body, be it the vagina or rectum. In an attempt to combine and systematize the accumulated international experience, the consensus on the use of NOSES (natural orifice specific extraction surgery) in coloproctology was first published in 2019, and in 2023 the consensus on the use of NOSES in coloproctology was finalized, which most researchers of this problem began to use in their practice. Among other things, it reflects the criteria for selecting patients for transanal and transvaginal removal of the specimen. According to this document, when selecting patients for transanal specimen extraction, the depth of tumor invasion according to the TNM system should correspond to the T1-T3 level, the maximum tumor size is < 5 cm, and the body mass index is < 30 kg/m². It is worth noting that, according to the Consensus, the NOSES technique can also be used for benign neoplasms and Tis cancer, when endoscopic removal is not indicated for some reason [6,11]. It should be noted that these criteria, including the size of the tumor measured by computed tomography, are determined at the preoperative stage, which is not always identical to the size of the surgical specimen itself [6,11]. Since it is impossible to reliably estimate the volume of the mesentery of the removed segment of the large intestine and its configuration change after mobilization, and often it is the mesentery, not the tumor, that makes up the bulk of the specimen being removed, this leads to the fact that even a combination of the three criteria does not always guarantee the possibility of NOSES. Considering the above, it seems necessary to optimize the criteria for selecting patients, which was the purpose of this study.

PATIENTS AND METHODS

In October 2022, a prospective single-center observational study included adult patients with left colon tumors who were scheduled for laparoscopic resection of the left colon with transanal specimen extraction (TES). In the framework of this study, in order to obtain more objective data, the Consensus criteria have been somewhat expanded. So, the maximum size of the tumor should have been less than 5 cm. As for the body mass index criterion, it was increased to 35 kg/m², taking into account our previous experience of successfully performing TES in patients with a BMI above 30 kg/m². As for the depth of tumor invasion, we adhered to the Consensus here, since the use of the TES technique with a locally widespread nature of tumor growth can discredit the oncological results of such surgeries. The depth of invasion according to preoperative computed tomography should not exceed T₃ (TNM classification, 8th revision).

Patients with polypous syndromes, inflammatory bowel diseases, intestinal stoma, stricture of the anal canal or rectum, carcinomatosis or locally advanced tumor, as well as with an ASA score of class III were not included. Patients whose carcinomatosis or locally advanced tumor was detected by intraoperative revision were excluded from the study.

All patients included in the study underwent laparoscopic resection of the left colon with an attempt at transanal specimen extraction.

In all cases, standard antibacterial prophylaxis with drugs from the penicillin group with a beta-lactamase inhibitor in a dosage of 1000 + 500 mg was performed before the surgery. Depending on whether the TES was successful, the patients were further analyzed in groups of laparoscopic resections with successful TES and traditional laparoscopic-assisted resections in cases where a minilaparotomy (ML) was required to extract the specimen.

Statistical Analysis

The patient data was entered into a spreadsheet Microsoft Excel 2019 for Windows. The data was analyzed using the GraphPadPrism statistical software package, version 9.3.1 (GraphPad Software, USA). Descriptive characteristics of variables are presented as absolute values for categorical data. For quantitative data, a preliminary assessment of the normality of the distribution was carried out using D'Agostin-Pearson's test. With a normal distribution, the variables are represented as an arithmetic mean with an indication of the standard deviation (M (SD)), and with a distribution other than normal, as medians with an indication of the inter quartile range ($Me(Q1;Q3)$). A comparative analysis of numerical variables was performed using Mann-Whitney's U-test for median values and Student's t-test for averages. Categorical data were compared using Fischer's two-way precise test with expected values less than 10 or Pearson's χ^2 in the other cases. The differences between the groups were considered statistically significant at $p < 0.05$.

In order to determine the threshold diagnostic value of the circumference of the surgical specimen, a ROC analysis was performed with the calculation of sensitivity, specificity, and likelihood ratio indicators. To determine the appropriateness of applying Consensus criteria, a comparison of compliance cases using Pearson's χ^2 was performed. For this purpose, four-field tables were constructed for the Consensus criteria and its modified version (a combination of criteria with the intraoperative circumference of the specimen). Statistical significance was assumed at $p < 0.05$. Indicators of relative risk, sensitivity, and specificity were calculated, indicating 95% CI according to Klopfer-Pearson's test, and the likelihood ratio.

RESULTS

In the period from October 2022 to August 2024, 70 patients were included in the study. Two

patients were excluded from the analysis due to the detection of the locally widespread nature of the tumor according to the intraoperative revision. In 42/68 (61.8%) patients, laparoscopic resection of the left colon with transanal extraction of the specimen (TES group) was successfully performed, and in 26/68 (38.2%) cases, conversion of the specimen extraction method with its transabdominal extraction (ML group) was required. Patients in both groups were comparable in most of the assessed parameters: age, gender, ASA grade, history of abdominal surgery, as well as the main characteristics of the tumor according to preoperative computed tomography (CT). At the same time, in patients who successfully underwent TES, such a parameter as body mass index was statistically significantly lower — 25.3 (3.3) versus 29.2 (4.1) kg/m² in the ML group ($p < 0.0001$). An analysis of the main tumor characteristics using the TNM system showed that at the preoperative stage, tumors with a depth of invasion of cT2 — 18/32 (56.3%) cases were more often registered in patients in the TES group compared to 4/21 (19%) cases ($p = 0.01$), and in the group of laparoscopic-assisted procedures with minilaparotomy (ML), cT3 tumors in 17/21 (81%) cases were more often detected versus 11/32 (34.4%) cases ($p = 0.002$) (Table 1).

The use of the method of transanal specimen extraction and the formation of an intracorporeal anastomosis during laparoscopic resections of the left colon did not lead to a significant increase in the operation time, which was 200 (179.5; 220) minutes in the TES group and 178 (160; 205) minutes in the ML group ($p = 0.2$). The volume of blood loss was also assessed intraoperatively, amounting to 30 (28.8; 53) ml in the TES group and 85 (50; 108) ml in the ML group, while the differences were statistically significant ($p < 0.0001$) (Table 2).

After completing the stage of mobilization of the removed segment of the intestine, all patients underwent intraoperative measurement of the circumference of the specimen in the

Table 1. Characteristics of patient groups

Parameters	TES (N = 42)	ML (N = 26)	p
Age, years, M (SD)	61.0 (11.3)	63.5 (10.3)	0.4***
Male, n (%)	16 (38.1)	13 (50.0)	0.3*
BMI, kg/m ² M(SD)	25.3 (3.3)	29.2 (4.1)	< 0.0001***
Index on the scale of anaesthetic risk ASA, n (%)			
I	4 (9.5)	2 (7.7)	0.9**
II	25 (59.5)	13 (50.0)	0.5*
III	13 (31.0)	11 (42.3)	0.4*
The presence of previous abdominal surgery, n (%)	17 (40.5)	12 (46.2)	0.8*
Characteristics of the tumor (as per computed tomography)			
The transverse tumor size, cm, Me (Q1;Q3)	2.1 (1;3.8)	2.8 (1.8;3.5)	0.2****
Benign (c), n (%)	10 (23.8)	5 (19.2)	0.8**
Malignant (c), n (%)	32 (76.2)	21 (80.8)	0.8*
The depth of tumor invasion, n (%)			
cT1	3/32 (9.4)	0/21	0.3**
cT2	18/32 (56.2)	4/21 (19.0)	0.01**
cT3	11/32 (34.4)	17/21 (81.0)	0.002*
Lymphnodelesion, n (%)			
cN0	30/32 (93.8)	19/21 (90.5)	0.9*
cN+	2/32 (6.2)	2/21 (9.5)	0.8**
Localization of the tumor (colon), n (%)			
Descending	1 (2.4)	0	0.9**
Proximal third of the sigmoid	3 (7.1)	2 (7.7)	0.9**
Middle third of the sigmoid	11 (26.2)	8 (30.8)	0.8**
Distal third of the sigmoid	27 (64.3)	16 (61.5)	0.9*

Note: * Pearson's χ^2 , ** Fisher's two-way exact test, *** t-test, **** U-test

Table 2. Intraoperative parameters

Parameters	TES (N = 42)	ML (N = 26)	p
Volume of intraoperative bloodloss, ml, Me (Q1;Q3)	30 (28.8; 53)	85 (50; 108)	< 0.0001**
Operation time, min. Me (Q1;Q3)	200 (179.5; 220)	178 (160; 205)	0.2**
Intraoperative specimen circumference, cm, M (SD)	11.7 (2.6)	16.2 (2.1)	< 0.0001*

Note: * t-test, ** U-test

most voluminous place. To do this, a sterile medical centimetre tape was inserted into the abdominal cavity. The latter was inserted using laparoscopic instruments under the mobilized mesentery of the left colon. The two ends of the tape were connected to each other, skirting the removed specimen around the circumference in the most voluminous place. The result obtained in centimetres was taken as the circumference of the specimen being removed. The latter was significantly smaller in the TES group and

averaged 11.7 (2.58) cm, while in the ML group it was 16.2 (2.12) cm ($p < 0.0001$) (Table 2). Additionally, a ROC analysis was performed to determine the threshold diagnostic value of the circumference of the specimen with the highest predictive value for determining the success of TES. As a result, it was found that the threshold value was 16 cm. AUC = 0.92 (95% CI: 0.85–0.98); $p < 0.0001$; likelihood ratio = 14.54; sensitivity = 69% (95% CI: 50–83.5); specificity = 97% (95% CI: 87–99) (Fig. 1).

Table 3. Immediate results of treatment in groups

Parameters	TES (N = 42)	ML (N = 26)	p
Pain severity as per 10-point VAS scale, points			
P/O Day 1 Me (Q1;Q3)	3 (2; 4.3)	5 (4; 6)	< 0.0001**
P/O Day 2 M (SD)	2.6 (1.4)	3.6 (1)	0.002*
P/O Day 3 M (SD)	2 (1.2)	3.1 (1.1)	0.0003*
P/O Day 4 M (SD)	1.2 (0.77)	2.4 (0.81)	< 0.0001*
P/O Day 5 Me (Q1;Q3)	1 (0;1)	1 (1;2)	0.002**
P/O Day 6 Me (Q1;Q3)	1 (0;1)	1 (1;2)	0.0002**
Postoperative hospital stay, Me (Q1;Q3)	7 (6; 8)	8 (7; 9)	0.06**
Discharge of first gas, days, Me(Q1;Q3)	1 (1; 1.6)	1 (1; 1)	0.7**
Discharge of first stool, days, Me (Q1;Q3)	2 (1; 3)	2 (1; 3)	0.3**

Note: * t-test, ** U-test

Table 4. The incidence and structure of postoperative complications

Parameters	TES (N = 42)	ML (N = 26)	p*
Postoperative complications, n (%)	3 (7)	8 (31)	0.0003
The structure of postoperative complications, n (%)			
Seroma of the anterior abdominal wall	0	3 (11)	0.05
Hematoma of the anterior abdominal wall	0	1 (4)	0.4
Gastrointestinal ileus	0	1 (4)	0.4
Antibiotic-associated diarrhea	3 (7)	1 (4)	0.9
Bleeding from the anastomosis	0	1 (4)	0.4
Anastomosis leakage	0	1 (4)	0.4

Note: * Two-way precise Fischer's criterion

RESULTS

The use of the technique of transanal specimen extraction (TES) and the formation of an intracorporeal anastomosis during laparoscopic resections of the left colon demonstrated such statistically significant advantages of TES as a reduction in the severity of pain syndrome for 6 days in the postoperative period. Significant differences between the groups in this parameter appeared already on the first day of the postoperative period — 3 (2; 4.3) points in the TES group versus 5 (4; 6) points in the ML group ($p < 0.001$) and persisted for the next 5 days. The postoperative hospital stay was 1 day shorter in the TES group -7 days (6; 8), in contrast to the ML group -8 days (7; 9) ($p = 0.06$). As for the bowel movements, there was no difference between the groups in the timing of gas discharge ($p = 0.7$) and the first act of defecation ($p = 0.3$) (Table 3).

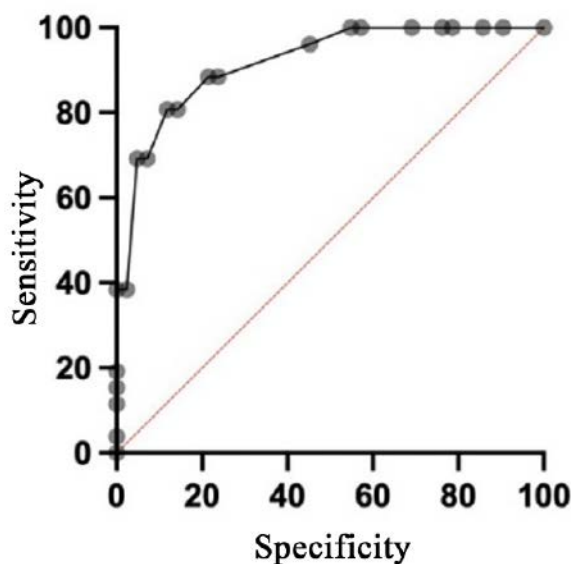
**Figure 1.** ROC-curve — determination of the threshold value for the circumference of the preparation for performing TES

Table 5. Compliance with Consensus criteria in the groups

Criteria	TES (N = 42)	ML (N = 26)	p*
The depth of tumor invasion as per CT \leq cT ₃ , n (%)	42 (100)	26 (100)	–
Tumor size as per CT < 5 cm, n (%)	40 (95.2)	24 (92.3)	–
BMI less than 30 kg/m ² , n (%)	37 (88)	15 (57.7)	–
Patient's compliance with 3 criteria, n (%)	37 (88)	15 (57.7)	0.004

Note: * Pearson's χ^2

Analyzing the rate of postoperative complications in the groups, it was found that this indicator was significantly higher in the ML group — 8/26 (31%) cases compared with the TES group — 3/42 (7%) cases ($p = 0.0003$). It is noteworthy that most of the complications in the ML group were associated with the presence of a mini-laparotomy wound in patients — 4/26 (15%) cases. While in the TES group, antibiotic-associated diarrhea occurred in 3/42 (7%) cases versus 1/26 (4%) case in the ML group. However, this was not significant in the presented sample ($p = 0.9$) (Table 4).

Considering that transanal specimen extraction (TES) can be successfully performed only in a selected category of patients, in order to determine the predictive value of the patient selection criteria, according to the Consensus on the use of the NOSES technique, the patients of our sample were analyzed for compliance with these criteria. The results show that only 37/42 (88%) of the patients in the successful TES group met 3 criteria, while the remaining 5/42 (12%) of the patients had transanal extraction performed just as successfully. On the contrary, in the ML group of 15/26 (57.7%) patients who fully met the criteria developed in the Consensus, it was not possible to extract the specimen through the rectum, which required conversion and minilaparotomy, $p = 0.004$ (Table 5).

Additionally, the diagnostic value of the Consensus criteria for predicting successful TES performance was calculated. The risk of performing transanal specimen extraction increased if the patient met the criteria of the international

Consensus of 2023. The relative risk = 2.3 (95% CI: 1.2–5.1); $p = 0.004$; sensitivity = 88.1% (95% CI: 75–94.8); specificity = 42.3% (95% CI: 25.5–61.1); likelihood ratio = 1.5.

In search of additional predictors that could allow us to predict the successful outcome of surgery with TES, intraoperative measurement of the specimen circumference was performed in all patients after completion of the stage of mobilization of the removed segment of the intestine, and the threshold value of this parameter was 16 cm (Fig. 1).

Taking this into account, we used 4 criteria for selecting patients: 3 criteria of the Consensus in combination with the circumference of the specimen. The analysis performed for the diagnostic value of combining the Consensus criteria with the parameter of the intraoperative circumference of the specimen demonstrated a higher prognostic value: relative risk RR = 3.1 (95% CI: 1.8–6.2); $p < 0.0001$; sensitivity = 3.3% (95% CI: 69.4 — 91.7); specificity = 73.1% (95% CI: 53.9 — 86.3); likelihood ratio = 3.1.

DISCUSSION

The feasibility and safety of the NOSES technique has been repeatedly confirmed by research results [5,7,10,13]. In particular, the advantages of applying intracorporeal intestinal anastomosis have been previously demonstrated [12]. Nevertheless, a number of unresolved issues remain, including the criteria for selecting patients to perform large intestine resections with the specimen extraction through

the natural orifice of the body, despite the previously developed international Consensus [6,11]. The study included 68 patients who were scheduled for laparoscopic resection of the left colon with an attempt at transanal specimen extraction.

This category of patients was identified because when the tumor is localized in the left part, the specimen can be extracted through the intestinal lumen at the level of the distal resection boundary, thereby avoiding additional incisions not only of the anterior abdominal wall, as in traditional laparoscopic-assisted surgeries, but also recto- or colpotomy in cases of using NOSES for tumor site in other parts of the colon. This approach provides an excellent cosmetic effect, since the fully laparoscopic nature of the surgery implies the absence of even a minilaparotomic incision.

The analysis of the early results of the presented sample showed such advantages of using the method as a statistically significant reduction in pain levels during the 6 days of the postoperative period — 3 (2; 4.3) points in the TES group versus 5 (4; 6) points in the ML group ($p < 0.001$) on the first day of the postoperative period; 1 (0; 1) point in the TES group versus 1 (1; 2) point in the ML group ($p = 0.0002$) on day 6 of the postoperative period. Patients in the group of successful transanal specimen extraction were discharged from the hospital 1 day earlier ($p = 0.06$) [14]. In addition to the described advantages, there was a decrease in the incidence of postoperative complications in the TES group — 3/42 (7%) cases in the TES group versus 8/26 (31%) cases in the ML group ($p = 0.0003$), which was primarily due to the absence of complications associated with an anterior abdominal wall wound.

As for the mentioned criteria for selecting patients, when analyzing the data, it was noted that 88% of patients in the successful TES group met the Consensus criteria. However, in the remaining 12% of cases, we were also able to extract the specimen through the intestinal

lumen. At the same time, in the ML group, in 57.7% of patients who met the Consensus criteria, transanal specimen extraction was unsuccessful, and there were other reasons for this, in particular, the size of the surgical specimen. This fact indicates that the criteria for preoperative selection for surgery with TES have a relatively low predictive value, which is confirmed by our analysis, as well as the results of studies by other authors [8,9]. The results of the study demonstrated that the combination of the Consensus criteria with a parameter such as a specimen circumference of less than 16 cm increases the prognostic value for successful transanal specimen extraction compared with using the Consensus criteria alone: HR = 3.1 (95% CI: 1.8–6.2); $p < 0.0001$; sensitivity = 83.3% (95% CI: 69.4–91.7); specificity = 73.1% (95% CI: 53.9–86.3); likelihood ratio = 3.1. It should be noted that there are no reports in the literature on the use of the criterion of the intraoperative circumference of the specimen in order to predict the feasibility of TES. Considering the above, it seems to us quite justified to use 4 criteria for selecting patients for TES surgeries with a mandatory assessment of the circumference of the specimen as the most significant factor.

The limitations of the presented study include a single-center, non-randomized nature, as well as an insufficiently large sample size, which dictates the need to continue recruiting patients. Evaluation of the long-term results of the study will also be of interest, since most of the patients underwent surgery for colon cancer.

CONCLUSION

The analysis showed that the Consensus criteria for selecting patients for surgery with TES have low sensitivity and specificity. However, supplementing them with criteria such as the intraoperative circumference of the specimen significantly increases the prognostic value of the model. In addition, the study demonstrated the advantages

of using the TES technique during laparoscopic resections of the left colon compared with laparoscopic-assisted surgeries with minilaparotomy, such as reducing the severity of postoperative pain, reducing the frequency of postoperative complications and earlier discharge from the hospital.

AUTHORS CONTRIBUTION

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