Laparoscopy-Assisted Transanal Total Mesorectal Excision

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Background: Rectal cancer located in distal third still remains a technical challenge for surgeons. Transanal total mesorectal excision with laparoscopic assistance is quite new surgical approach for rectal cancer treatment that seems to solve some of the associated technical issues. The aim of the study was to present our experience in laparoscopy-assisted transanal total mesorectal excision.

Materials and methods: After obtaining approval from the local Ethics Committee, a single centre prospective double-arm comparative non-randomized trial was initiated. With recruiting still in progress at present, between 27.02.2017 and 01.10.2017 four laparoscopy-assisted transanal total mesorectal excision procedures and two laparoscopic total mesorectal excisions were performed in the department of Endoscopic Endocrine Surgery and Coloproctology at the Military Medical Academy in Sofia.

Results: There is no conversion in both groups. No postoperative mortality 30 days after surgery. The quality of total mesorectal excision was satisfactory in all patients estimated by the Quirque classification. There was no distal or proximal tumor involvement of surgical margins. In one of the cases, we reported positive circumferential resection margin. We had two cases with postoperative morbidity.

Conclusion: Transanal total mesorectal excision with laparoscopic assistance is quite new minimally invasive surgical approach for rectal cancer treatment. Avoiding the procedure-related complications during the learning curve is essential before applying the method to every patient. Multicenter randomized control trial is needed so that we could answer the questions raised in this study.

BACKGROUND
The aim of medicine and surgery in the last decades has been to reduce the impact of the surgical trauma. The rectal carcinoma is no exception and in the last few years the number of sphincter-preserving surgical interventions has been on the rise. Despite the advantages of the laparoscopic rectal surgery over the conventional, clear evidence of improvement in the oncologic results is lacking. The introduction of laparoscopy-assisted transanal total mesorectal excision (LappAssTaTME) in 2009 aroused considerable interest in the surgical community. The aim of the method is to improve the oncologic, functional and early post-operative results in rectal carcinoma located in the lower and middle third of the rectum.2 Approximately two years after the initiation of the first randomized control trial COLOR III, the method continues to validate itself. The natural orifice surgery and LapAssTaTME in particular appears to be the next revolutionary change in the rectal cancer surgery. A number of issues could be solved by its application.3 The aim of the present paper was to share the results of our initial experience with LapAssTaTME.

MATERIALS AND METHODS
After a hearing of the local Ethics Committee the startup protocol for a single-centre prospective non-randomized comparative study in Military Medical Academy in Sofia was approved. At the moment recruiting continues and between February 27, 2017 and October 1, 2017, six patients were enrolled in the Clinic of Endoscopic Endocrine Surgery and Coloproctology in Military Medical Academy, Sofia. On two of the patients a laparoscopic TME (LapTME) was performed. The experimental approach was used on the other four after obtaining informed consent from the patients. The patient selection was rotational — two transanal, followed by two laparoscopic interventions. The study goal
was to compare the early and late results between the groups. Primary outcomes were safety, feasibility, morbidity and mortality. Secondary outcomes were functional results, early and late oncological outcomes. All values of interest are listed in details in the study protocol. The study inclusion and exclusion criteria are shown in Table 1.

All patients indicated for neoadjuvant radiochemotherapy according to the ESMO criteria were referred to preoperative long course radiochemotherapy. Assessment of the functional results and the quality of life via Wexner, LARS and EORTC QLQ questionnaires were included in the study protocol. We used the Clavien & Dindo (C&D) classification for the assessment of the early postoperative complications, the complications up to day 30 after the surgical intervention are considered as such. Study-independent pathologists assessed the TME quality according to the Quirke classification, the presence of tumor infiltration in the resection margin, the presence of tumor infiltration in the circumferential resection margin in up to 1 mm of it, local tumor progression and the presence of lymph node metastases. We used the ESMO follow-up protocol in all patients up to the first remission - defined as lack of recurrence at month 60. The GoldMann, ASA, APACHE and Cr-Possum perioperative risk assessment protocols were utilized. Conversion in the TaTME group was defined as completion of the surgical interven-

**Table 1. Inclusion and exclusion criteria of the study**

**Inclusion Criteria**

- Patients over 18 years old
- Rectal adenocarcinoma verified histologically after colonoscopy and biopsy
- Tumor located in middle and lower third of the rectum, at a distance of at least 1 cm from the anorectal line (1-10 cm from the anorectal line)
- Tumors in stages cT1-T4a, N0-2, M0 (post MRI, abdominal ultrasound and chest X-ray)
- Patients with post neoadjuvant treatment can be included
- Patients with previous surgical interventions or overweight can be included

**Exclusion Criteria**

- Patients under 18 years old
- Other type of rectal neoplasm (sarcoma, lymphoma, melanoma, etc.)
- Benign rectal lesions
- Rectal carcinoma treated by local excision (endoscopic submucosal excision, TEM with local excision, etc.)
- Pregnancy
- Previous rectal surgery
- Presence of distant synchronous metastases, determined by: abdominal ultrasound, CT and chest X-ray
- Patients with absolute contraindications for general anesthesia and/or pneumoperitoneum
- Surgical interventions in emergency – bowel obstruction, perforation, peritonitis, etc.
- Synchronous abdominal surgery
- Family history and/or familial form of colorectal carcinoma (FAP, Lynch I&II, etc.)
- Crohn’s disease and/or ulcerative colitis
- Synchronously neoplastic disease
- Locally advanced T4b carcinomas or T3b with sphincter involvement
tion by a conventional or laparoscopic approach. Conversion in the laparoscopic group was defined as the transit of the surgical intervention into an open approach. After the standard clinical laboratory tests, every patient enrolled in the study was diagnostically verified by colonoscopy with biopsy and was staged according to the AJCC TNM classification, latest edition. Pelvic MRI and CT scan were performed for staging purposes. All patients underwent preoperative bowel preparation, thromboembolic prophylaxis and antibiotic prophylaxis. Standardized protocols (ERAS) were used during the postoperative period.

**Surgical technique:** We used a synchronous technique with a delayed transanal part.

**Abdominal part:** 12-mm-Hg pneumoperitoneum was achieved by a Veress needle placed around the umbilicus or using the open Hasson approach. A four trocars technique in a diamond shape fashion was used with two 12-mm and two 5-mm ports. A 30-degree 12-mm Hopkins Carl Storz® scope was used for the abdominal part. The surgical intervention began with abdominal exploration, after which it continued with high ligation of the inferior mesenteric artery and vein, mobilization of the descending colon, the sigmoid and the rectum up to the pelvic peritoneal reflection, utilizing a lateral to medial or medial to lateral approach. If necessary, the splenic flexure was mobilized in order to accomplish an anastomosis along with freedom of tension. The SILS Covidien® platform was used for transanal approach. The Carl Storz UI400® insufflator was used to achieve pneumorectum, in maximum flow up to 1 l/min and pressure between 8-12 mm Hg. The scope used for the transanal part was 5-mm 0-degree Hopkins Carl Storz®. The distant resection margin was determined based on the distance between the tumor and the ARL. A purse-string suture was applied and the rectum was interrupted distally manually or endoscopically, at a distance of 2-4 cm from the lower edge of the tumor. Dissection followed: posterior – in the areolar ‘holy’ plane (based on the principles for total mesorectal excision), anteriorly in the avascular plane (between the vagina or the prostate and the rectal wall) and laterally – preserving the autonomic pelvic innervation. The dissection was performed symmetrically circumferentially and the lateral parts were dissected after adequate mobilization in the anterior and posterior plane. Using this approach, the rotation of the rectum and the loss of the anatomical plane was avoided. The specimen was extracted transanally or, if not possible (large tumor and/or narrow pelvis), via a mini laparotomy. The proximal resection margin was determined and a hand-sewn or mechanical coloanal anastomosis was performed. PDS 3/0 was used for the manual and EEA PPH 33 mm Covidien® circular stapler for the mechanical anastomosis. A protective ileostomy was made in all patients after neoadjuvant chemoradiotherapy (NACRT) or when there was evidence for anastomotic leakage.

**RESULTS**

Baseline characteristics of the patients included are listed in Table 2. No cases of conversion were observed in the sample. Splenic flexure mobilization was necessary in two patients in the LapAssTaTME group and in one of the laparoscopic group.

Family history was observed in only one patient from the transanal group. In all patients the values of the tumor markers (CEA & CA 19.9) were within the reference ranges. The main postoperative, clinical and pathological characteristics of the operated patients are presented in Table 3.

Longer operative time was observed in the transanal group compared to the laparoscopic. An infection of the operative wound was a complication which occurred in the postoperative period in one of the patients and was classified as IIIa according to C&D classification and led to an increase of the hospital stay. In the transanal group, the second patient was administered into a cardiology department on the fifth postoperative day for further treatment due to a rhythm and conduction disorder. Manual coloanal anastomoses were performed in three of the patients of the transanal group and stapled anastomosis in the rest of the patients in the group. According to the local protocols, the patients take fluids on the first postoperative day and solid food at tolerance. Active rehabilitation in all patients begins on the first postoperative day. One late complication was registered in the follow-up period in the LapAssTaTME group, which was managed by conservative treatment. The blood loss due to the surgical intervention in all patients was less than 100 ml. According to the pathological report, tumor infiltration in the proximal and distant resection margin was not observed in any patient. No recurrences have been registered yet. There was no perioperative mortality.

**DISCUSSION**

**Advantages of the method:** Barcelona Clinic mentioned many advantages of the method as reduction...
of the surgical trauma and the direct visual control over the tumor during the placement of the distal resection margin which provides the opportunity of increasing the number of organ-sparing rectal resections. The lack of an additional incision for the specimen extraction would lead to a reduction of the post-operative hernias and infections. The extraction of the specimen under laparoscopic guidance leads to less frequent rotation of the specimen. The difficulties related to the distal stapling of the rectum are avoided and reducing of the “double stapling” technique could lead to a reduction of the postoperative anastomotic leaks. The reduction of the operative time and the technical convenience, especially in male patients with narrow pelvis and large tumors, are essential advantages of the method. Helbach reports an operative time of 204 minutes when the intervention is performed in non-synchronous fashion by one team, in 80 patients. In the largest series published so far, 140 patients followed-up for 3 years, the average operative time is 166 minutes and the fastest procedure lasts 60 minutes. In the last results of the international TaTME register of 720 patients, the average operative time is 277±83 minutes. Other advantages include the higher quality of TME due to the better anatomical dissection, especially in the distal rectum, and the reduction of the positive circumferential resection margin. Precisely these two factors would lead to the improvement of the early and the late oncologic results. The good visualization and the preservation of the autonomic pelvic innervation would lead to better functional results. The reduction of the number of surgical conversions is often mentioned as an advantage of the method compared to the laparoscopic surgery. A number of authors consider that the method could lead to a reduction of the laparoscopic conversions due to the better visualization for dissection in male patients with narrow pelvis and large tumors.

### Table 2. Baseline characteristics

| Case | Operation     | Age (years) | Sex | BMI kg/m² | Tumor (distance from the ARL, cm) | mriCRM | cTcN |
|------|---------------|-------------|-----|-----------|-----------------------------------|--------|------|
| 1    | LapAssTaTME   | 36          | Female | 23        | 6                                 | +      | T4N1b|
| 2    | LapAssTaTME   | 76          | Male  | 24        | 4                                 | -      | T2N0 |
| 3    | LapTME        | 69          | Male  | 25        | 8                                 | -      | T1N0 |
| 4    | LapTME        | 58          | Female | 23        | 4                                 | -      | T2N0 |
| 5    | LapAssTaTME   | 60          | Male  | 26        | 9                                 | -      | T1N0 |
| 6    | LapAssTaTME   | 72          | Female | 27        | 3                                 | -      | TisN0|

BMI: body mass index; ARL: anorectal line; mriCRM: circumferential resection margin from the magnetic resonance imaging; cTcN - clinical tumor stage clinical nodal stage from TNM AJCC Classification

| Case | Intervention type | Duration (min) | Complications | POS | CRM | cTcN | LN | TME Quality |
|------|-------------------|----------------|---------------|-----|-----|------|----|-------------|
| 1    | LapAssTaTME       | 290            | No            | 5   | +   | T3-4N0 | 38 | Almost complete |
| 2    | LapAssTaTME       | 185            | II            | 6   | -   | T2N1  | 12 | Complete     |
| 3    | LapTME            | 150            | No            | 25  | -   | T2N0  | 4  | Almost complete |
| 4    | LapTME            | 130            | IIIa          | 23  | -   | T1N0  | 12 | Complete     |
| 5    | LapAssTaTME       | 225            | No            | 6   | -   | T2N0  | 5  | Complete     |
| 6    | LapAssTaTME       | 240            | No            | 4   | -   | T2N0  | 13 | Complete     |

POS: postoperative stay; CRM: circumferential resection margin; LN: number of isolated lymph nodes; cTcN - clinical tumor stage clinical nodal stage from TNM AJCC Classification
The conversion in the laparoscopic surgery is around 17-29%. After the introduction of LapAssTaTME, professor Lacy does not report any conversions. According to the summarized international register data, the TaTME conversion frequencies are 6.3% for abdominal and 2.8% for perineal part. Last and least is the superior cosmetic effect. Some authors conclude that the method is much easier and faster compared to the standard laparoscopic anterior rectal resection. Most centres do not reach the desired results at the beginning because of the lack of experience and the necessity of reaching a plateau in the learning curve. All of these advantages need to be based on high level of evidence which is not available to date.

Disadvantages: The main disadvantages are related to the technical difficulties and the lack of a specific transanal platform and instrumentation. The lack of triangulation, the small size of the operational field, the maintenance of stable pneumorectum, the rectal wall spasms provoked by the carbon dioxide flow and the smothering of the operational field are the main technical challenges during the procedure. During the last few years, the industry has been trying to solve some of these problems. Some surgeons raise the question about potential functional complications due to the application of the transanal platform and the fecal incontinence, assessing the Wexner score in patients after LapAssTaTME, and in 1 of 20 patients late severe fecal incontinence is observed with average Wexner score – 16, thus limiting the quality of life, which has not improved after the first year. Other functional results which the same authors report, are anastomotic strictures in 4 patients, treated by dilatation. A specific disadvantage of LapAssTaTME is the need of two teams for the performance of one surgical intervention, which is a technical and an organizational problem. The approach to perform TME from below requires knowledge of new anatomical landmarks and a significantly long period in the learning curve with background experience in the transanal and laparoscopic surgery. Some authors alert about the emergence of so-called new complications such as the increasing frequency of urethral and bladder lesions, falling into a different anatomical planes such as retrococcygeal plane, etc. In relation to the increase of the frequency of the urethral lesions, the industry finds the solution by applying fluorescent or lighting urethral catheters. The main intraoperative complications in 720 patients reported in a paper in Annals of Surgery are technical problems in 39.3%, falling into an incorrect anatomical plane in 7.8%, bleeding in 6.9%, urethral lesions in 0.7%, urinary bladder lesions in 0.3%, vaginal injury in 0.1%, lesion of the autonomic innervations and specimen penetration in 0.3% of the interventions.

Complications: The most common complication in LapAssTaTME is urine retention, with frequency between 6% and 40%. A Dutch team reported complications in 39 out of 80 patients, and in 11 of them a surgical intervention was necessary. The same author reported the first mortality case in a patient with anastomotic leakage and pelvic sepsis. Other procedure related complications in literature include ischemia in the proximal anastomotic stump, intestinal deserosation, stoma revision as a result of ischemia and necrosis, intestinal ileus due to internal herniation, etc. According to the data from the largest multicenter sample so far, the postoperative complications are up to 32.6%, and 21.7% are classified as class I and II according to the C&D classification. The frequency of anastomotic leaks from the same database amount to 5.4%, The specific complication related to the procedure in the complete mucosal necrosis in the distal anastomotic stump 10 days after the surgery. This is probably related to the application of the transanal platform (for a prolonged time). In his paper, Chouillard does not report any postoperative complications in strictly selected patients. Italian authors report a single lethal outcome in a patient with myocardial infarction, and complications up to 26.9%, two of them being anastomotic leaks. No mortality is observed in the largest series so far and the postoperative morbidity amounts to 34.2%. Complications reported by a Barcelona Clinic are postoperative anastomotic strictures in 6 patients, recto-vaginal fistula in one patient and anastomotic leaks in 8.6%. The team defines 20% of the complications as classes I and II according to the C&D classification. A multicenter study with the participation of 2 centres reports a single conversion due to uncontrolled bleeding. The authors also report anastomotic leaks in 2 of 20 patients.

Oncologic results: The laparoscopic method could not improve the oncologic results in the treatment of rectal carcinoma. Multiple surgeons hope the innovative method will reduce the recurrences to a minimum and will prolong the disease-free period in patients with rectal carcinoma. The improvement of the survival and the quality of life are the main variables in the oncological surgery. Again,
CONCLUSIONS

The laparoscopy-assisted transanal total mesorectal excision in patients with middle-low rectal carcinoma is a feasible and safe surgical technique when a significant amount of experience in laparoscopic and transanal rectal surgery is achieved. In the era of the evidence-based medicine, unconditional data for the advantages, disadvantages, indications and contraindications is necessary until the method is applied routinely. The key to better results is the selection of the patients until the plateau in the learning curve is reached.

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Введение: Ректальный рак прямой кишки, локализованный в дистальной трети, все еще остается технической проблемой для хирургов. Трансанальное тотальное мезоректальное иссечение с использованием лапароскопической ассистенции является сравнительно новым хирургическим подходом к лечению ректального рака, которое, похоже, решает некоторые технические проблемы, связанные с лечением. Цель исследования состояла в том, чтобы представить наш опыт лапароскопического ассистирования трансанального тотального мезоректального иссечения.

Материалы и методы: Как только мы получили одобрение местной Комиссии по этике, было проведено одноцентровое проспективное, сравнительно нерандомизированное, двойное исследование. Набор кандидатов всё еще продолжается, но в период с 27.02.2017 по 01.10.2017 на кафедре эндоскопической эндокринной хирургии и колопроктологии Военно-медицинской академии в Софии были выполнены четыре лапароскопических трансанальных тотальных мезоректальных иссечения и два полных мезоректальных иссечения.

Результаты: В обеих группах не было отклонений от процедуры. На 30-е сутки после операции послеоперационной смертности не отмечено. Качество общего мезоректального иссечения оказалось удовлетворительным у всех пациентов в соответствии с классификацией Quirke. Не было установлено поражения дистального или проксимального края опухоли в хирургической линии. В одном случае мы сообщили о положительной линии периферической резекции. В нашем исследовании было два случая послеоперационной заболеваемости.

Вывод: Трансанальное тотальное мезоректальное иссечение с лапароскопической ассистенцией является довольно новым минимально инвазивным хирургическим подходом к лечению ректального рака. До применения данного метода в отношении каждого пациента исключительное значение имеет предотвращение процедурных осложнений во время кривой обучения. Многоцентровое рандомизированное контролируемое исследование необходимо, чтобы иметь возможность ответить на вопросы, поднятые в этом исследовании.