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Transanal endoscopic microsurgery after neoadjuvant radiochemotherapy for locally advanced extraperitoneal rectal cancer: short-term morbidity and functional outcome

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Abstract
Background Transanal endoscopic microsurgery (TEM) after radiochemotherapy (RCT) has been reported in selected cases of locally advanced rectal cancer as an alternative to traditional radical resection with total mesorectal excision with a curative intent or as diagnostic tool to confirm a pathological complete response of the primary tumor. No study has evaluated functional outcome after TEM in preoperatively irradiated patients.
Methods This study was designed to evaluate short-term morbidity (according to Clavien's classifications) and establish (by a questionnaire) continence and evacuative function after RCT and TEM, at 1 year from surgery, analyzing the impact of RCT on postoperative outcomes. Patients with locally advanced rectal cancer treated by RCT and TEM (group 1) or with early T1 or adenomas treated only by TEM (group 2) entered this cohort comparative study.
Results Twenty-two patients entered the study as group 1 and 25 as group 2. No postoperative mortality occurred. The morbidity rate was 36.4 % in group 1 vs. 16 % in group 2 ($p = 0.114$). The rate of suture dehiscence was 22.7 % in group 1 vs. 4 % in group 2 ($p = 0.068$). No grade III complications, reoperation, or hospital readmission within 30 days was recorded in either group. One year after surgery, continence and evacuative scores in group 1 were 1.05 ± 1.25 and 24.72 ± 2.79, respectively, which were similar to group 2 ($p = 0.081$ and 0.288, respectively).
Conclusions TEM after RCT in selected rectal cancer patients has an acceptable morbidity and functional results at 1 year from surgery. Preoperative irradiation could increase postoperative short-term morbidity, but it does not seem to influence evacuative or sphincter function after 1 year from surgery.

Keywords Rectal cancer · Radiochemotherapy · Transanal endoscopic microsurgery · Pathological complete response · Postoperative morbidity · Functional outcome

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Large, randomized, controlled trials have established radiotherapy (RT) or radiochemotherapy (RCT) followed by total mesorectal excision (TME) as the "gold standard" for the treatment of locally advanced rectal cancer [1, 2]. Neoadjuvant RCT plays an important role in local disease control and tumor regression by significantly reducing tumor size (downsizing), the depth of tumor penetration, and the risk of nodal metastases (downstaging) [1].

TME, since its introduction in 1982, has significantly reduced the rate of local recurrences and improved overall survival compared to surgery without TME [3, 4]. However, it is associated with significant postoperative short-term morbidity (range 20–35 %) and mortality (range

1–4 %) [5, 6]. Moreover, patients who undergo TME frequently experience evacuative dysfunction, commonly known as "anterior resection syndrome," including gas and fecal incontinence, urgency, a sensation of incomplete rectal emptying, inability to defer defecation, and clustering of bowel movements [7]. Randomized, clinical trials have shown a significant increase of these disorders after neoadjuvant treatment, and it is not clear how important radiation treatment is in these symptoms [8, 9].

For these reasons and because of the increasing incidence of pathological complete response after RCT [10–13], local excision after RCT, especially using transanal endoscopic microsurgery (TEM), has been recently reported in the literature in selected cases as a valid alternative treatment to TME [14, 15]. Our group reported the use of TEM as an essential diagnostic step in clinical complete response to offer a more conservative treatment rather than radical resection to patients with pathological complete response of the primary tumor [16]. The selection of patients is essential in both cases.

The main advantage after local excision by TEM is to preserve the anatomical and functional integrity of the rectum to avoid the functional disorders that are frequent after radical surgery. Authors who have analyzed functional outcome after TEM have reported no change in evacuative function or sphincter parameters between the preoperative and postoperative periods [17–19]. However, in these series, no patients were preoperatively treated with RCT, and to the best of our knowledge, no studies have evaluated functional outcome in patients submitted to TEM after preoperative RCT. Moreover, recent studies evaluated postoperative outcome of patients submitted to TEM after neoadjuvant RT or RCT and reported a significantly higher rate of postoperative morbidity, especially suture dehiscence, compared with patients who underwent TEM without preoperative pelvic irradiation [20, 21].

The purpose of the current study was to evaluate and analyze postoperative mortality, short-term (within 30 days) morbidity, and evacuation and continence function at 1 year from surgery in patients submitted to TEM after RCT, quantifying the influence of preoperative irradiation on postoperative outcomes.

Materials and methods

From 2000 to 2010, all patients affected by extraperitoneal rectal cancer were enrolled in a pretreatment workup, including digital examination, colonoscopy with biopsy, endorectal ultrasound, abdominal computed tomography scan, pelvic magnetic resonance imaging, positron emission tomography (PET) scan, and chest x-ray. Patients with early (cT1-2 N0 M0) extraperitoneal (up to 12 cm from the anal margin) rectal cancer were submitted directly to surgery with a TME or with a local excision by TEM (in selected cT1 cases). If pretreatment workup staged the cancer as nonmetastatic locally advanced (T3-4 N0 M0/any T N + M0), the patients were treated with neoadjuvant long-term RCT. Radiation therapy consisted of 50.4 Gy of external-beam radiation therapy delivered by a 3-field approach with daily doses of 1.8 Gy on weekdays to the pelvis. During the study, different protocols of chemotherapy were adopted: cisplatin and 5-fluorouracil (5-FU PVI protocol) [22], raltitrexed and oxaliplatin (TOMOX protocol) [23], or oxaliplatin and capecitabine (CAPOX [24] and XELOX protocols [25]).

Six weeks after the end of RCT, the patients underwent restaging examinations (endoscopy, endorectal ultrasound, pelvic magnetic resonance, PET scan) to estimate the tumor response to RCT. The clinical response to RCT was assessed according to the World Health Organization score [26] using a reference index (IND) defined as the product of the quarter of the circumference of the rectal wall involved (categorized 1–4) multiplied by the craniocaudal length of the tumor in mm [27]. This index was calculated at the time of initial diagnosis (IND-pre) and 6 weeks after radiation (IND-post). Patients with a complete (absence of residual disease) or partial (IND-post < 50 % IND-pre) response were considered responders to RCT; all others (no change or progression) were considered nonresponders. We defined a clinical complete response, at restaging, as there was a negative pelvic magnetic resonance and PET scan and, at endoscopy, the absence of macroscopic intraluminal tumor residue or the presence of only a small scar at the site of the tumor.

Standard surgical treatment was radical resection with TME, anterior resection, or abdominoperineal resection (APR), performed 8 weeks after the completion of RCT. TEM was performed in selected cases: patients unfit for or refusing radical surgery with TME or patients in whom a clinical complete response to RCT was obtained, to assess the pathological complete response of the primary tumor. All patients preoperatively signed an informed consent. TEM was performed under general anesthesia, using Richard Wolf's (Knittlingen, Germany) TEM equipment, according to the standard technique described by Buess et al. [28]. The patients were positioned in the lithotomy, prone or lateral position, depending on the location of the lesion. Only one surgeon (C.C.) performed TEM. In all patients, a full-thickness excision was performed and the wound was closed with one or more running sutures (Biosyn 3/0) secured with silver clips. All patients had a urinary catheter in place at the time of surgery, which was removed 24 h after operation.

All patients were given antibiotics with gram-negative, aerobic and anaerobic coverage, e.v., ½ hour before and for

2 days after surgery and orally for the next 4 days. Narcotics were prescribed on demand and included ketorolac 10 mg or paracetamol 1,000 mg. The specimens were staged according to TNM system [29], and tumor response after neoadjuvant RCT was evaluated according to Mandard's tumor regression grade [30]. When specimen examination confirmed a complete (ypT0 and TRG1) or nearly complete (ypT1 and TRG2) pathological response with margins free of tumors, no adjunctive radical surgery was proposed to the patient. This group of patients were enrolled in an intensive follow-up program, including digital examination, assessment of blood carcinoembryonic antigen, endoscopy, pelvic magnetic resonance, and PET/computed tomography scan. In all other cases (pT >1 or pT1 TRG >2), immediate (within 1 month) radical surgery with TME was suggested. Short-term (within 30 days) postoperative morbidity and mortality were recorded, and complications were graded according to the classification proposed by Clavien and colleagues [31].

At follow-up visit 1 year after surgery, the study population was asked to answer a pool of questions to evaluate the anorectal function and quantify evacuative and sphincter disorders. Seven questions were intended to define the evacuative function and considered the following parameters: number of bowel movements/day; sensation of incomplete evacuation, defined as the need, after leaving the toilet, to return within a few minutes for second or multiple evacuations; the necessity to return to the bathroom less than 15 min after evacuation; the ability to evacuate completely in less than 15 min; the ability to defer evacuation more than 15 min; the use of laxatives and/or enemas; and the use of medications for retarding transit. Five questions were used to define continence status: incontinence to gas, liquid, or solid stools; need to wear a pad; and modification of lifestyle.

The answers were subsequently evaluated to establish the frequency of each symptom, defining an evacuation and continence score according to those proposed by Gervaz et al. [32] and Jorge and Wexner [33]. The former evaluates the frequency of each of the seven evacuative parameters on a scale varying from never to always. Each degree of the scale corresponds to a score, varying from 4, the most desirable option, to 0. This allowed us to calculate an evacuation score varying from 0 to 28, with the highest value corresponding to the best function [32]. The Jorge and Wexner continence score evaluates the frequency of each of the five continence parameters that we considered in our questionnaire by the same grading scale as described above. In this index, each degree of the scale corresponds to a score, varying from 0, the most desirable option, to 4 [33]. The calculated continence score can vary from 0 to 20 points, with the lowest value corresponding to the best function. To quantify the incidence of each functional disturbance in the study population, we considered only those patients who complained of the symptom at least once a week to be affected (often/usually or always in the grading scale). Strict adherence to validated questionnaires guaranteed maximally from questioner's personal interpretation. Apart from the scores, evacuation also was studied by asking questions regarding the patient's ability to distinguish flatus from stools and pain at defecation.

The inclusion criteria for this study were preoperative radiation therapy dose of almost 50.4 Gy, local full-thickness excision of the tumor residue or scar by TEM, no other surgical rectal procedure performed after TEM, no adjunctive postoperative radiation dose, no history of inflammatory bowel disease, no rectal comorbidities, and the absence of local or distant relapses at the time of the questionnaire. Patients operated on by TEM after RCT observing these inclusion criteria entered in the study as group 1.

During the same period (2000–2010), patients with clinically early rectal cancer (pTis, pT1sm1) or with villous adenomas were managed only by TEM, performed by the same surgeon (C.C.). This group of patients were analyzed about short-term postoperative morbidity and investigated, at 1 year from surgery, about long-term functional outcome with the same methods of group 1 patients. The inclusion criteria were local full-thickness excision of the tumor by TEM, no other surgical rectal procedure performed after TEM, no preoperative or postoperative radiation dose, and no history of inflammatory bowel disease. Patients operated only by TEM observing these inclusion criteria entered in the study as group 2. The short-term postoperative morbidity and long-term functional results of group 1 were compared with the results recorded in group 2.

Statistical analysis was performed using the χ^2 and Fisher's exact probability tests for categorical variables and Student's t test for continuous variables. $p < 0.05$ was considered statistically significant. This study was approved by the institutional review board.

Results

From Jan 2000 to Dec 2010, a total of 178 patients with locally advanced extraperitoneal rectal cancer were treated with preoperative long-term RCT, were restaged 6 weeks after the end of RCT, and, after 6–8 weeks, underwent surgery. One hundred twenty-five had an anterior resection, 24 had an abdominoperineal resection, 3 had palliative stoma, and 1 patient had a Hartmann resection. Twenty-five patients underwent TEM after neoadjuvant RCT: 22 had a clinical complete response, 2 refused radical surgery with TME after partial clinical tumor response, and 1 was unfit for radical resection. Pathological complete response

(ypT0; TRG1) was found in 17 patients (the ratio between pathological complete response and clinical complete response was 77.27 %), and pathological major response (ypT1-TRG2) was found in 3. In the remaining five cases, pathological examination showed one ypT2-TRG2, one ypT2-TRG4, and three ypT3- TRG2, all with clear margins. Two patients with (ypT3-TRG2) agreed to radical resection and, consequently, were excluded from the study: one (ypT3-TRG 2) patient, who previously refused surgery with TME, was submitted to postoperative RT and was excluded from the study; two patients (1 ypT2-TRG2 and 1 ypT2-TRG4) refused radical surgery with TME and were not submitted to postoperative RT. Thus, 22 patients (15 males; median age 63 (range 41–78) years) entered the study as group 1. Neither intraoperative nor short-term (within 30 days) postoperative mortality occurred. Short-term complications occurred in eight patients (36.4 %). Five patients (22.7 %) had a dehiscence of the suture line, all of whom were conservatively treated (2 required prolonged antibiotic therapy, and 3, reporting only rectal pain, required only occasional oral analgesic drugs). One patient had persistent rectal pain, without evidence of dehiscence of the suture line, requiring chronic use of oral analgesic drugs. One patient developed pneumonia, which was treated with antibiotics, and one case had an unspecific fever that required antibiotics. According to Clavien's classification, grade I complications occurred in four patients (18.2 %), and grade II complications occurred in four patients (18.2 %); no grade III complications occurred. Particularly, dehiscence of the suture line caused grade II postoperative complications in two cases, and no patients who experienced a wound dehiscence required a reoperation or a hospital readmission. None of the eight patients with complications required surgical reintervention. The median hospital stay was 4 days (range 3–12 days), and no hospital readmission within 30 days was recorded.

During the same period, 27 patients (15 male) were operated on by TEM for adenomas (14 patients) or early adenocarcinomas (13 patients: 3 in situ adenocarcinomas, 9 pT1 sm1 adenocarcinomas, and 1 pT2 adenocarcinoma). One patient with low rectal pT1 sm1 adenocarcinoma, after 1 month, was operated on by anterior resection for a synchronous sigmoid adenocarcinoma; the pT2 patient was unfit for radical surgery and was submitted to postoperative radiation therapy. So, 25 patients entered the study as group 2. They had undergone no other rectal surgical procedures or any type of adjuvant treatment. No intraoperative or short-term (within 30 days) postoperative mortality occurred. Short-term postoperative complications occurred in four patients (16 %): one patient had a dehiscence of the suture line, which was conservatively treated with antibiotics; two patients reported occasional rectal pain, which was treated with oral analgesic drugs; and one patient had a urinary tract infection, which was treated with antibiotics. According to Clavien's classification, grade I complications occurred in two patients (8 %), and grade II complications occurred in two patients (8 %). The median hospital stay was 4 (range 2–14) days, and no hospital readmission within 30 days was recorded.

Table 1 shows a comparative analysis of the patient characteristics and short-term postoperative outcomes recorded in group 1 and group 2. Tumor and defect size were significantly greater in group 2 (respectively, 40 mm vs. 12.5 mm, $p < 0.001$; and 57.5 mm vs. 32.5 mm, $p < 0.001$). The rate of grade II postoperative complications was slightly but not significantly higher in group 1. The rate of suture line dehiscence was higher in group 1, but this difference also was not statistically significant (22.7 vs. 4 %; $p = 0.068$).

Patients of both groups were interviewed about their functional status during the follow-up evaluation 12 months (median value; range 11–14 months) after surgery (Table 2). In group 1, the mean evacuation score was 24.72 ± 2.79, and the only evacuation disorder reported was urgency, in one case (4.5 %). The mean continence score was 1.05 ± 1.25, and incontinence to flatus was reported in two cases (9.1 %); no patients reported soiling, incontinence to solid stools, or the necessity of wearing a pad. In group 2, the mean evacuation score was 25.6 ± 2.24 (not significantly different from group 1; $p = 0.288$), and the only evacuation disorder reported was urgency, in three cases (12 %; not significantly different from group 1; $p = 0.354$). The mean continence score was 0.84 ± 1.43 (not significantly different from group 1; $p = 0.081$), and no patients reported incontinence to flatus (not significantly different from group 1; $p = 0.213$), soiling, incontinence to solid stools, or the necessity of wearing a pad. One year after surgery, no patients reported difficulty in distinguishing gas from liquid stools or painful evacuation.

Discussion

In selected groups of extraperitoneal rectal cancer patients, local excision by TEM after RCT is increasingly common as an alternative to traditional radical resection with TME. The only prospective, randomized study comparing these modalities was published by Lezoche in 2008, who compared the oncologic results obtained after TEM (35 patients) and after laparoscopic TME resection (35 patients) for T2N0 rectal cancer after neoadjuvant RCT. At a follow-up of 84 months, they found no significant differences between the two approaches, and the probability of survival for rectal cancer was the same (94 %) after TEM as after TME [14]. In our previous study, in response

Table 1 Patient characteristics and short-term (within 30 days) post-operative (p.o.) outcome: comparative analysis between group 1 and group 2

Variables	Group 1	Group 2	*p* Value
No. of patients	22	25	–
Median age (range)	63 (41–78) years	64 (44–82) years	0.773
Sex (M/F)	15/7	14/11	0.396
Site of tumor (middle/low)	4/18	10/15	0.106
Tumor size (median diameter)	12.5 (0–25) mm	40 (15–50) mm	<0.001
Defect size	32.5 (25–45) mm	57.5 (25–70) mm	<0.001
No. of running stitches	2 (2–3)	2 (2–3)	0.765
Median hospital stay (days)	4 (3–12)	4 (2–14)	0.23
P.O. mortality	0 %	0 %	–
Overall P.O. morbidity	8 (36.3 %)	4 (16 %)	0.114
Grade I P.O. morbidity	4 (18.2 %)	2 (8 %)	0.301[a]
Grade II P.O. morbidity	4 (18.2 %)	2 (8 %)	0.301[a]
Grade III P.O. morbidity	0 %	0 %	–
Suture line dehiscence	5 (22.7 %)	1 (4 %)	0.068[a]
Readmission rate within 30 days	0 %	0 %	–

[a] Fisher's exact test

Table 2 Long-term (1 year after surgery) functional outcome: comparative analysis between group 1 and group 2

Parameters	Group 1	Group 2	*p* Value
No. of patients	22	25	–
Evacuation score (mean ± SD)	24.73 ± 2.79	25.6 ± 2.24	0.288
Daily evacuation > 3	0 %	0 %	–
Sensation of incomplete evacuation	0 %	0 %	–
Necessity to return to bathroom < 15 min	0 %	0 %	–
Inability to completely evacuate < 15 min	0 %	0 %	–
Urgency	1 (4.5 %)	3 (12 %)	0.354[a]
Continence score (mean ± SD)	1.05 ± 1.25	0.84 ± 1.43	0.081
Incontinence to flatus	2 (9.1 %)	0 %	0.214[a]
Soiling	0 %	0 %	–
Incontinence to solid stools	0 %	0 %	–
Necessity of wearing a pad	0 %	0 %	–
Modification of lifestyle	0 %	0 %	–

SD standard deviation

[a] Fisher's exact test

to the reported increasing rate (8–35 %) of pathological complete response after RCT [10–13], we proposed TEM as an essential diagnostic step to identify patients in whom clinical complete response corresponds to a true pathological complete response of the primary tumor and a radical resection can be avoided [16]. Full-thickness excision of the rectal wall disc previously containing a tumor allows the surgeon to assess the grade of pathologic response (ypT) of the primary tumor with high accuracy. The major criticism of this approach is the impossibility of radically removing the mesorectum and, consequently, obtaining direct pathological information regarding mesorectal lymph-node status [34]. Nevertheless, a direct correlation between ypT status and mesorectal lymph node involvement has been observed and the rate of positive nodes is very low when a complete response (ypT0) is found [10, 13, 16, 34].

Short-term postoperative complications after TEM occur at a rate of approximately 4 % and include suture line dehiscence, bleeding, abscess formation, transient incontinence, and stenosis [19, 35–37]. Studies of TEM after RCT are scant but have reported short-term postoperative complication rates from 11 to 61 % [14, 20, 21, 38]. In 2009, an American prospective study from Thomas

Jefferson University analysed the postoperative outcome of 43 patients operated on by TEM after RT, comparing these results with a group of 19 patients treated by TEM alone. In the irradiated group, the overall rates of morbidity and dehiscence of the suture line were significantly higher than among nonirradiated cases (respectively, 33 vs. 5.3 and 25.6 vs. 0 %) [20]. Along the same lines, in 2011, a Brazilian prospective study analysed 23 irradiated patients and 13 nonirradiated patients treated by TEM. Patients undergoing neoadjuvant RCT were more likely to develop grade II/III complications (56 vs. 23 %) and wound dehiscence (70 vs. 23 %) with a consequently higher readmission rate within 30 days (43 vs. 7 %) [21]. In our prospective study, overall morbidity in the irradiated group was 36.4 %, but it was only 18.2 % if only grade II complications were considered; this morbidity rate was slightly but not significantly higher than that in nonirradiated cases. We found a tendency toward a higher rate of suture dehiscence in previously irradiated patients, but also in this case the difference was not statistically significant. The absence of statistical significance is probably due to the small size of the sample. The high rate of postoperative short-term complications and, in particular, suture dehiscence could be a consequence of the detrimental effects of RCT on the tissue, e.g., free radical formation, DNA damage and vascular injury, with a consequently higher risk of suture line dehiscence and infection [39]. Moreover, when TEM is performed on irradiated tissue, both wound edges used for the suture were previously irradiated, which carries a higher hypothetical risk of wound healing [20]. However, in our series of irradiated patients, the occurrence of postoperative complications did not give rise to a significantly prolonged hospital stay or to any hospital readmissions.

Two studies have evaluated long-term functional outcome after TEM, reporting very good results [17, 19]. In 2004, Cataldo and colleagues [17] reported the results of a prospective, comparative study based on interviews of 41 patients (using the Faecal Incontinence Severity Index [FISI] and the Faecal Incontinence Quality of Life [FIQL] score) 6 weeks after TEM. The number of bowel movements per 24 h, urgency, FISI and FIQL were unchanged when preoperative and postoperative data were compared. A recent large (93 patients) Italian study published the long-term (60 months) functional results and quality of life results after TEM, based on clinical scores (Wexner score, FIQL score, EORTC QLQ-C30, EORTC QLQ-CR38, EuroQoL EQ-5D, and EQ-VAS) and manometry. Three months after TEM, postoperative continence (evaluated with Wexner's score) became worse than that preoperatively (but without statistical significance), improved at 12 months, and returned to the preoperative status at 60 months. Urgency occurred in 65 % at 3 months, 30 % at 12 months, and 5 % at 60 months after TEM. The same trend was noted in QoL scores and in postoperative manometry values, which were significantly lower than those at baseline at 3 months but returned to preoperative values at 12 months (no significant difference between results at 12 and 60 months) [19]. One explanation for these results could be that the effects of prolonged insertion of the 40-mm-diameter operating proctoscope during the procedure or that the necessity of performing a large full-thickness excision impairs (although not permanently) evacuative function, and evacuative and sphincter functions usually return to physiological status within 12 months [40, 41].

However, no published studies have evaluated long-term functional outcome after TEM in patients previously treated with RCT. Therefore, ours is the first such study. In our study, long-term functional results recorded 1 year after TEM in previously irradiated patients were excellent, with near-optimal continence and evacuative scores that were not significantly different from those of nonirradiated patients and with a low rate of weekly or daily occurring functional disorders. The absence of statistically significant differences between irradiated and nonirradiated patients could represent the marginal impact of neoadjuvant treatments in determining long-term evacuative and sphincter disorders when the rectum is spared. Moreover, if preoperative RCT could increase the short-term postoperative complication rate, these events do not seem to affect functional outcome after 1 year from TEM, with similar low rate of functional disorders between irradiated and not irradiated patients.

It is our opinion that the type of surgery plays a major role in determining functional disorders after integrated treatment for rectal cancer. It seems obvious to assume that evacuative and continence functions after TEM are better than after anterior resection with TME. However, only one study has investigated this aspect, and it only concerned patients not previously treated with RCT. In that study, 31 patients operated on by TEM (for T1 rectal cancers) were compared with 31 patients treated with radical surgery and TME (for more advanced rectal cancers). The evaluation, performed after a median interval of 28 (range 5–91) months using four cancer-specific questionnaires (EuroQoL EQ-5D, EQ-VAS, EORTC QLQ-C30, and QLQ-CR38) showed that TEM patients had fewer defecation problems than TME patients [18]. In the setting of irradiated patients, in 2007, we published the functional results of 100 patients preoperatively irradiated (long-term RCT) treated by anterior resection with TME and evaluated the same length of time after surgery and with the same questionnaire reported in the current study [7]. Although these series are not comparable because of the dissimilar numbers of cases analyzed, it is clearly evident from

Table 3 Long-term functional outcome of irradiated patients treated by TEM (group 1) and patients operated on by radical surgery with TME [7]

Parameters	TEM series	TME series [7]
No. of patients	22 (15 M; 7 F)	100 (58 M; 42 F)
Median age (range)	63 (41–78) years	67.5 (43–83) years
Evacuation score (mean ± SD)	24.73 ± 2.79	16.12 ± 5.12
Daily evacuation > 3	0 %	23 %
Sensation of incomplete evacuation	0 %	58 %
Necessity to return to bathroom < 15 min	0 %	37 %
Inability to completely evacuate < 15 min	0 %	35 %
Urgency	4.5 %	31 %
Continence score (mean ± SD)	1.05 ± 1.25	6.3 ± 4.79
Incontinence to flatus	9.1 %	46 %
Soiling	0 %	19 %
Incontinence to solid stools	0 %	5 %
Necessity of wearing a pad	0 %	14 %
Modification in lifestyle	0 %	29 %

SD standard deviation

Table 3 that patients who underwent TME had more functional disorders than patients treated by TEM.

The main limitation of this study was the small number of cases analyzed due to the strict selection criteria for performing TEM after neoadjuvant RCT. We did not compare functional status before neoadjuvant treatment or TEM with postprocedure status. We believe that because our study population was affected by locally advanced rectal cancers, located in the middle or lower rectum, pretreatment evaluation of the evacuation and continence functions could have been impaired by the presence of the rectal mass itself. Moreover, we did not perform a manometric evaluation, because we wanted to evaluate what patients felt independently of objective measurements.

Conclusions

In highly select locally advanced extraperitoneal rectal cancer patients previously treated with RCT, TEM is increasingly reported as a therapeutic option or as a valid diagnostic tool to assess whether a pathological complete response of a primary tumor has been obtained. Our study shows, contrary to a recent report [21], that the short-term postoperative morbidity rate in this group of patients is acceptable, especially considering that no grade III complications were reported and no reoperations or readmissions were needed, even if a relatively high rate of suture dehiscence is reported. Another important aspect, unique to this study, is the rate of evacuative and continence disorders in patients treated with preoperative long-term radiochemotherapy and TEM. Our results indicate that, in both group treated by TEM, a very low rate of functional disorders after 1 year from surgery was reported, probably due to rectum preservation, without differences between not irradiated and irradiated patients. In particular, for irradiated patients, the not statistically significant higher rate of suture dehiscence and higher rate of postoperative complications do not seem to affect functional outcome at 1 year from surgery.

Disclosures C. Coco, G. Rizzo, C. Mattana, M.A. Gambacorta, A. Verbo, B. Barbaro, F.M. Vecchio, D.P. Pafundi, M.G. Mastromarino, and V. Valentini have no conflict of interest or financial ties to disclose.

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