



# Quality of life in patients with loco-regional rectal cancer after ELRR by TEM versus VLS TME after nChRT: long-term results

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Received: 10 March 2018 / Accepted: 2 November 2018 / Published online: 12 November 2018  
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## Abstract

**Background** Endoluminal loco-regional resection (ELRR) by transanal endoscopic microsurgery (TEM) may be an alternative treatment option to Laparoscopic total mesorectal excision (LTME), in selected patients with N0 rectal cancer. Post-operative quality of life (QoL) evaluation is an important parameter of outcomes related to high percentage of functional sequelae. We reported, in a previous paper, the short and medium term results of QoL in patients who underwent ELRR or LTME. The aim is to evaluate the 3 year QoL in patients with iT2–T3 N0/+ rectal cancer who underwent ELRR by TEM or LTME after neoadjuvant radio-chemotherapy (nChRT) in a retrospective analysis of prospectively collected data.

**Methods** We enrolled in this study, 39 patients with iT2–T3 rectal cancer who underwent ELRR ( $n=19$ ) or LTME ( $n=20$ ), according to predefined criteria. QoL was evaluated by EORTC QLQ-C30 and QLQ-CR38 questionnaires at admission, after n-RCT and 1, 6, 12, and 36 months after surgery.

**Results** No statistically significant differences in QoL evaluation were observed between the two groups, both at admission and after n-RCT. In short term (1–6 months) period, significantly better results were observed in ELRR group by QLQ-C30 in global health status ( $p=0.03$ ), physical functioning ( $p=0.026$ ), role functioning ( $p=0.04$ ), emotional functioning ( $p=0.04$ ), cognitive functioning, fatigue ( $p<0.05$ ), dyspnoea ( $p<0.001$ ), insomnia ( $p<0.05$ ), appetite loss ( $p<0.05$ ), constipation ( $\leq 0.05$ ), and by QLQ-CR38 in: body image ( $p=0.03$ ) and defecation ( $p=0.025$ ). At 1 year, the two groups were homogenous as assessed by QLQ-C30, whereas the QLQ-CR38 still showed better results of ELRR versus LTME in body image ( $p=0.006$ ), defecation problems ( $p=0.01$ ), and weight loss ( $p=0.005$ ). At 3 years, no statistically significant differences were observed between the two groups.

**Conclusions** In selected patients with rectal cancer, who underwent ELRR by TEM or LTME, QoL tests at 3 years do not show any statistical differences on examined items.

Despite screening programs, Colorectal cancer (CRC) is the 2nd most common cancer, accounting for 13.0% of all cancers apart from non-melanoma skin cancers and the 2nd most common cause of cancer-related deaths in Europe [1].

Surgery for rectal cancer remains the only curative treatment [2] and total mesorectal excision (TME) [3, 4] after

neoadjuvant radio-chemotherapy (nChRT) [5, 6] is currently the gold standard procedure in iT2–iT3 rectal cancer.

Since the equivalence of oncological results between Open TME (OTME) and Laparoscopic TME (LTME) approach has been proven [7, 8], the focus has shifted to the quality of life (QoL) after surgery.

Several studies have evaluated functional outcomes after OTME versus LTME. Although LTME has better outcomes than OTME, sexual dysfunction and urinary complications are, respectively, reported up to 46 and 35% of patients, underwent LTME and nChRT [9–11].

Furthermore, the presence of a stoma, either temporary or permanent, is related to a rate of psychological morbidity, such as change either in body image or depression in up to 30% of patients [12] particularly in Mediterranean and

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Middle Eastern cultures [13]. These changes may worsen the QoL [14–16].

Transanal Endoscopic Microsurgery (TEM) was proposed by Gerard Buess in 1983 [17] for the initial treatment of sessile adenomas and T1 rectal cancer.

The authors modified the original indications and technique introducing the ELRR by TEM [18], also showing its feasibility in term of oncological results even for selected patients with T2–T3 rectal cancer after nChRT [19, 20].

In two previous studies conducted by the same authors, ELRR by TEM showed better results than LTME in short- and medium-terms of QoL evaluation in patients with iT1 rectal cancer [21] and patients with iT2–T3 rectal cancer underwent nChRT [22].

The aim of this study was to compare the long-term QoL for patients with iT2–T3 rectal cancer who underwent, after nChRT, ELRR by TEM or LTME.

## Materials and methods

This study is a retrospective analysis of prospectively collected data.

As already reported in our previous study [22], patients' preoperative assessment included clinical examination, tumor markers' assay, total colonoscopy with biopsies and tattooing, Endoscopic ultrasound (EUS), pelvic magnetic resonance imaging (MRI), and total body computed tomography (CT). Tumor stage was classified according to the 7th edition of the Union for International Cancer Control (UICC) classification [23].

According to the authors' protocol, patients with iT2–T3 N0 who did not respond to nChRT (defined by downsizing > 50% or downstaging) or with iN+ rectal cancer underwent LTME. We defined as pathological the lymph nodes when demonstrating a short axis of 6 mm or greater, round shape, loss of fatty hilum, indistinct borders, heterogeneous signal on T2-weighted MR images, and signal restriction in DWI sequence [24]. On the other hand, patients with iN0 rectal cancer at pre-nChRT imaging or with iT2–T3 responding to nChRT underwent ELRR by TEM. From March 2007 to august 2012, 101 patients with T2–T3 rectal cancer

underwent surgical treatment (43 patients LTME, 58 patients ELRR). 39 patients (20 LTME, 19 ELRR) with homogeneous features fulfilled the required questionnaires, completed the 3 year follow-up, and were eligible to be included in the present study according to the following criteria:

- iT2–iT3 N0/N+ rectal cancer
- Preoperative nChRT
- Patients' acceptance to be included in the study and to fill in the required questionnaires

Exclusion criteria are summed up in Table 1.

In Table 2 are reported the major postoperative complication (evaluated according to the Clavien–Dindo classification) [25].

After surgery, patients were followed up every 3 months for the first 3 years and every 6 months for the next 2 years by digital rectal examination, tumor markers' assay, colonoscopy, pelvic MRI, PET-CT, and total body CT.

Patients' characteristics and tumor stage are shown in Table 3.

## Surgical technique and postoperative management

After preoperative colonic washout and short-term antibiotic prophylaxis, patients underwent ELRR by TEM or LTME as previously reported [20–26].

**Table 1** Exclusion criteria

Stoma at operation	8 pts
Lost in follow-up	8 pts
T4	7 pts
Conversion to open surgery	5 pts
Distant metastasis or local recurrence	12 pts
Major complication	8 pts
Adjuvant chemotherapy	14 pts

**Table 2** Major postoperative complications

LTME	ELRR
Death due to myocardial infarction on 3rd POD: 1 pt	Perirectal abscess: 2 pts
Anastomotic leakage conservative treatment: 2 pts post-operative ileostomy: 2 pts	Retropéritoneal phlegmon: 1 pt

**Table 3** Patients' characteristics and tumor stage

	LTME (20 pts)	ELRR (19 pts)
Sex ratio (M:F)	9:11	8:11
Mean age, years	63.6 (41–79)	67.4 (38–86)
Distance from the anal verge, cm	11.3 (4–16)	5.7 (2–10)
Stage		
iT2	10	14
iT3N0	5	5
iT3N1	5	–

After ELRR by TEM, patients received daily administrations of psyllium-based medications (Psyllogel Fibra<sup>®</sup>, Nathura, S.p.A., Montecchio Emilia, RE, Italy) as stool softener for at least 4 weeks.

## Questionnaires

Two validated questionnaires developed by the Quality of Life Study Group of the European Organization for Research and Treatment of Cancer (EORTC) were used to assess disease-specific quality of life, EORTC QLQ-C30 and EORTC QLQ-CR38 [27, 28]. The questionnaires were administered to patients at admission, before surgery (between 6 and 10 weeks after completion of nChRT) and then at 1, 6, and 12 months after surgery. Stoma-related problems item (QLQ-CR38) was not investigated because, in this study, stoma creation was an exclusion criterion. Aim of the authors' institutional protocol was to reduce the number of temporary or permanent stomas.

The EORTC QLQ-C30 is a patient self-rating questionnaire that measures physical, role, social, emotional, and cognitive functions as well as overall QoL. Separate symptom scales are included to assess pain, fatigue, and emesis, as well as five single items to measure gastrointestinal (GI) symptoms, dyspnoea, appetite loss, and insomnia. A single item evaluates the perceived economic consequences of the disease. A higher global health status score corresponds to better results, whereas the opposite is true for all other items. The EORTC QLQ-CR38 is a patient self-rating questionnaire structured with four multi-item/single-function scales, seven multi-item symptom scales, and one single symptom item. The functional scales assess body image, sexual functioning, sexual enjoyment, and future perspective. The symptom scales assess radiation-induced side effects at micturition, GI general symptoms, chemotherapy side effects, defecation problems, stoma-related problems, and sexual dysfunction in men or women. The single symptom item

assesses weight loss. High sexual functioning and sexual enjoyment scores are equivalent to better results, while the opposite is true for all other items.

## Statistical analysis

Statistical analysis was done using the Chi square (also known as Pearson's Chi square) test. Probability value lower than 0.05 was considered statistically significant. Data were stored and processed by means of the Microsoft Excel program (Microsoft Corporation, Redmond, Washington, USA). All statistical analyses were performed using SAS version 9.1 (SAS Institute, Cary, North Carolina, USA).

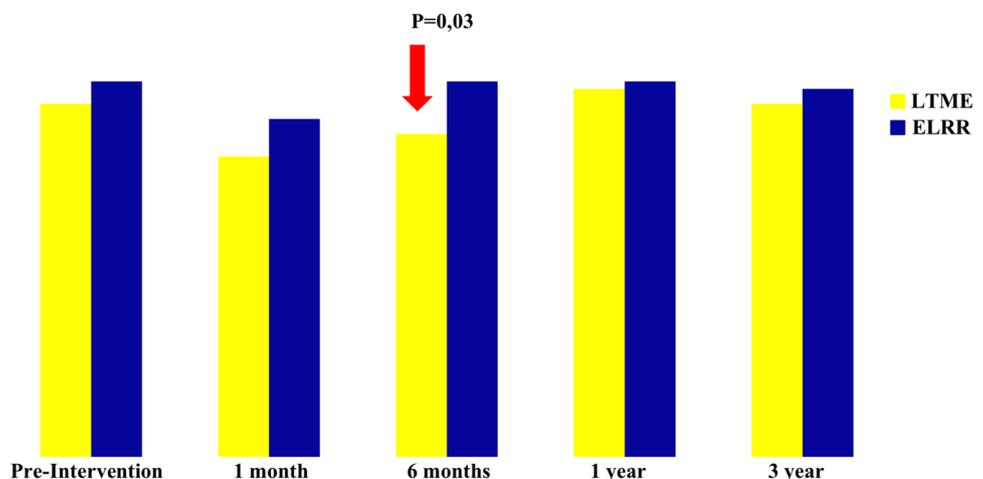
## Results

The results are valued considering each variable of QLQ-C30 and QLQ-CR38.

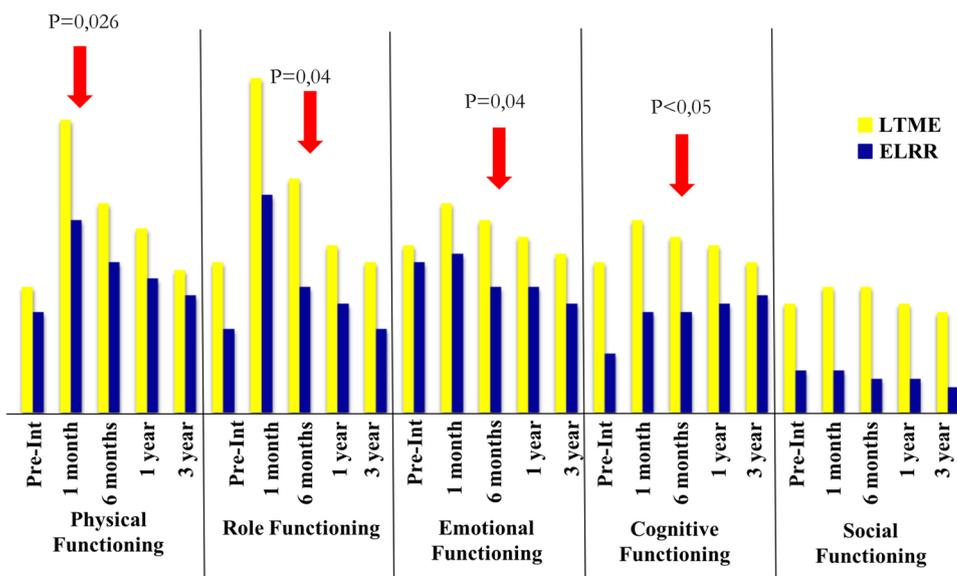
90% of patients showed a good GHS (global health status) before surgical intervention. No statistically significant difference was identified between the ELRR and LTME groups for GHS in preoperative stage. Even if ELRR group presented higher GHS's values than LTME group for each measurement (pre-intervention, at 1 month, 6 months, 1 year, and 3 years post- surgical intervention) only at 6 months, there was a significant statistical difference ( $p$  value < 0.03). At 1 and 3 years from intervention, the patients returned to similar preoperative GHS. Three years after surgery, there were no differences between two groups of patients (Fig. 1).

About the functional scales (Fig. 2), 1 month after surgical intervention, the physical functioning got worse for both surgical procedures especially in LTME group ( $p < 0.026$ ). 3 years after surgery, there were no statistically significant differences between LTME and ELRR group. Even if both groups before surgery did not have any type of role functioning limitation, ELRR patients'

**Fig. 1** QLQ-C30 global health status (GHS): only at 6 months significant statistical difference for GHS



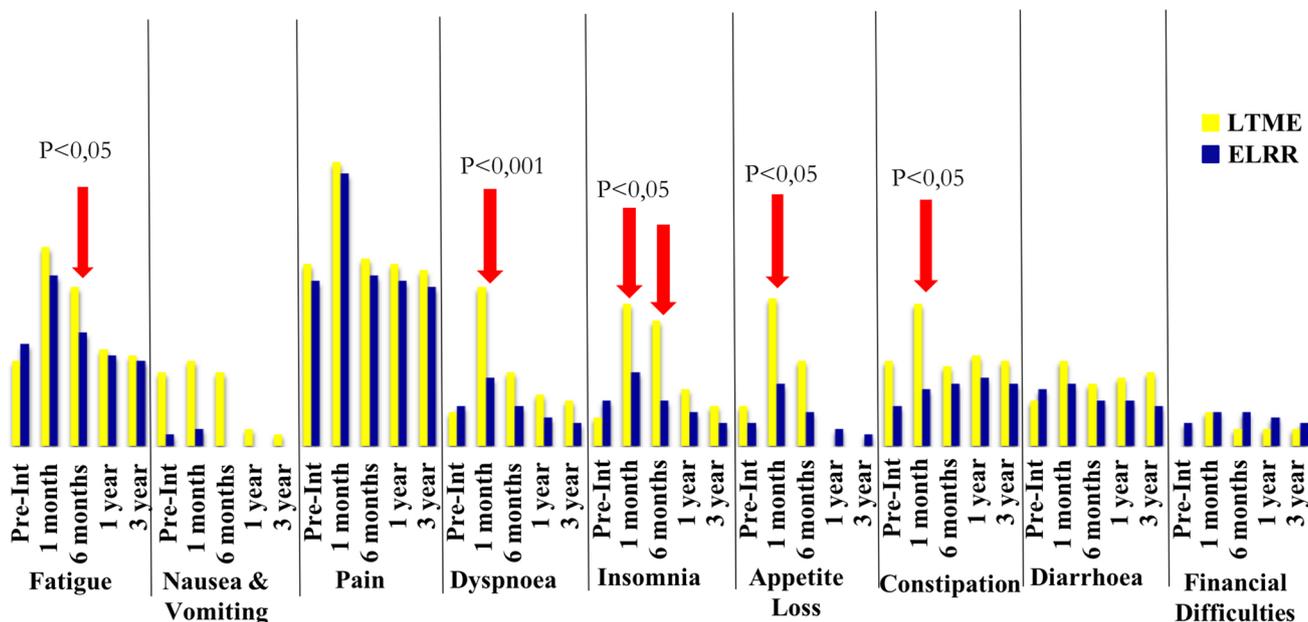
**Fig. 2** QLQ–C30 functional scales: there were statistically significant differences at 1 month for physical functioning and at 6 months for role, emotional, and cognitive functioning



role functioning higher than LTME for each measurement (1 month, 6 months, 1 and 3 years), with statistically significant difference 6 months after surgery ( $p < 0.04$ ). Regarding emotional functioning parameters, LTME patients presented a decreased emotional functioning 6 months after surgery ( $p = 0.04$ ); this difference disappeared at 1 and 3 years after surgery. LTME patients presented also a cognitive functioning parameter worse than ELRR patients 6 months after surgery ( $p < 0.05$ ), but in the following 3 years, this difference disappeared as well. Finally, although the two groups presented marked

differences regarding social functioning, these were not statistically significant.

Statistical analysis of symptom scales (Fig. 3) evidenced that fatigue was higher in LTME patients than ELRR but there was a significant statistical difference only 6 months after surgery ( $p < 0.05$ ). Whereas, after 1 and 3 years after surgery, no statistical significant difference was recorded. Pain, nausea, and vomiting were higher in LTME patients than ELRR for each period after surgery even if the values were not statistically significant. One month after surgery, dyspnoea ( $p < 0.001$ ), insomnia ( $p < 0.05$ ) and appetite loss ( $p < 0.05$ ) were higher in LTME patients than ELRR. At 6 months after surgery, fatigue ( $p < 0.05$ ) and insomnia ( $p < 0.05$ ) were higher in LTME patients than ELRR. Constipation ( $p < 0.05$ ) was higher in LTME patients than ELRR at 1 month after surgery. Diarrhoea and financial difficulties were not statistically significant.



**Fig. 3** QLQ–C30 symptom scales: there were significant statistical differences at 1 month for dyspnoea, insomnia and appetite loss and at 6 months for fatigue and insomnia

( $p < 0.05$ ), and constipation were higher ( $p < 0.05$ ) in LTME patients. These statistically significant differences remained stable only at 6 months for insomnia and fatigue. At 1 and 3 years, there were no statistically significant differences. There was not any type of difference in financial difficulties between the two groups of patients analyzed.

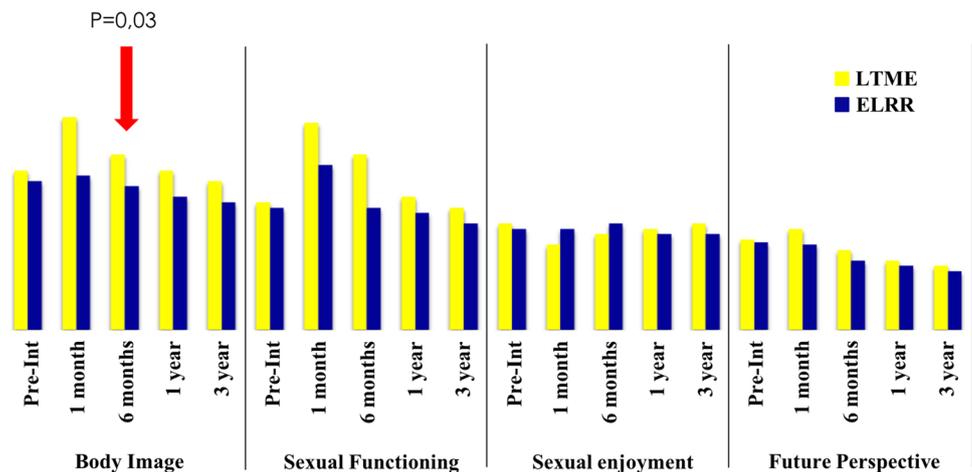
About QLQ-CR38 questionnaire (Fig. 4), 100% of patients were satisfied with their body image before surgery, but at 6 months that parameter was worse in LTME group ( $p = 0.03$ ). Other items such as sexual functioning, sexual enjoyment, future perspective (Fig. 4), nocturia, gastrointestinal, and weight loss (Fig. 5) did not have any statistically significant difference. Defecation problems (which include seven items: daily diarrhoea, nightly diarrhoea, tenesmus, stool incontinence, haematochezia, constipation, and pain during defecation) were worse in LTME groups at 1 and 6 months after surgery ( $p = 0.020$  and  $p = 0.025$ , respectively) (Fig. 5), Faecal incontinence (Fig. 6), evaluated with item 58, presented several differences between the 2 groups: at 1 month patients who underwent ELRR had more

problems than LTME ( $p = 0.04$ ), at 6 months this difference was not statistically significant any more and 3 years after surgery patients treated with ELRR by TEM showed similar results as before surgery.

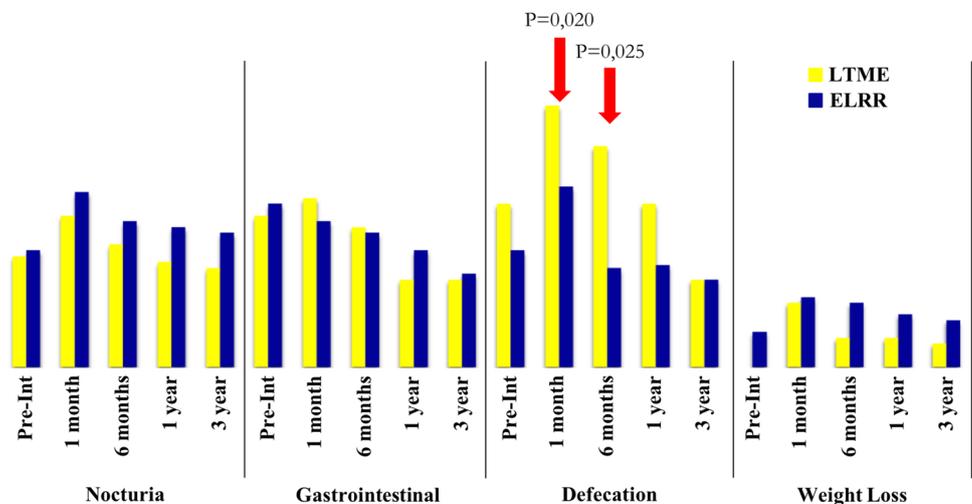
## Discussion

Abdominal perineal resection (APR) has been the most frequent surgical operation performed for the treatment of rectal cancer for many years. Although some authors reported better results in terms of QoL after APR compared to patients who underwent very-low anterior resection (VLAR) [16], nowadays this procedure is performed only in very selected patients. Anterior resection with total mesorectal excision (TME), after neoadjuvant chemo-radiotherapy, is currently the gold standard for the treatment of loco-regional rectal cancer with a decrease of local recurrence rate from 15 to 20% to about 5%.

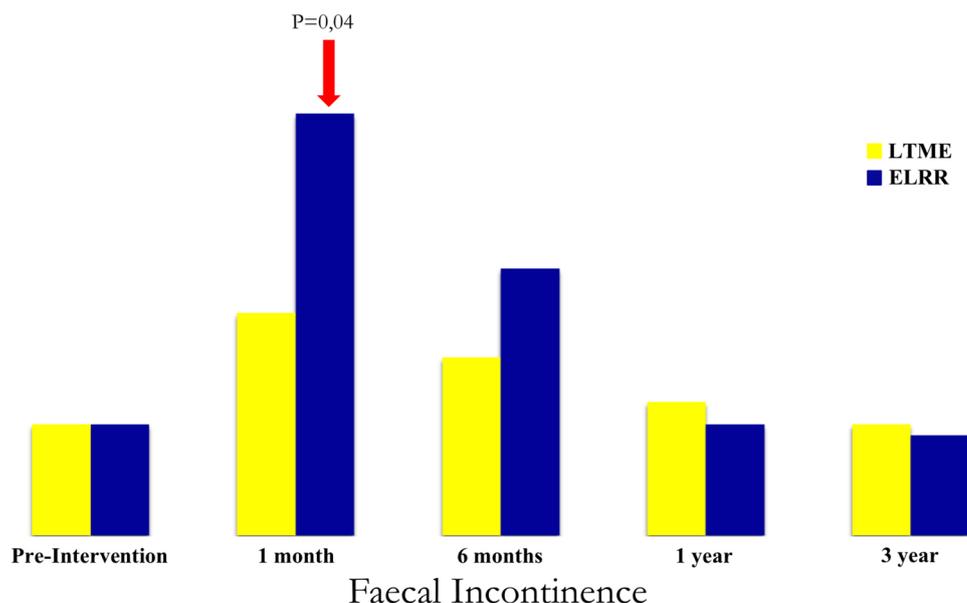
**Fig. 4** QLQ-CR38 functional scales: there was a significant statistical differences only at 6 months for body image



**Fig. 5** QLQ-CR38 symptom scales: there was a significant statistical differences only for defecation at 1 and 6 months



**Fig. 6** QLQ–CR38 faecal incontinence: there was a significant statistical differences only at 1 month



Laparoscopic TME (LTME), due to its technical advantages can facilitate the “nerve sparing” technique, improving functional results. Despite this important progress, even today, the percentage of functional sequelae in rectal surgery is still high with variable rates (35–70%) of faecal, sexual and urinary dysfunctions [9–11].

In previous studies published by the Authors, QoL was evaluated in patients with iT1 rectal cancer after ELRR by TEM and in iT2–T3 neoadjuvated after LTME at 1, 6, and 12 months after surgery [21, 22].

Some studies reported the advantages of ELRR by TEM in terms of QoL [29–31]. Doonerbosch considering a series of 47 patients with villous adenoma treated with local excision by TEM, reported no deteriorating effect on faecal continence at 6 months after surgery. Moreover, the average quality of life from the patients’ perspective following TEM was improved [29]. Allaix and Morino reported the long-term (60 months) results about QoL on 93 patients who underwent full-thickness excisions by TEM for benign neoplasia (69%) or early rectal cancer. In this study, TEM had no long term negative effects on anorectal function or QoL [31].

The proximity of the tumor from the anal verge is an independent negative prognostic factor for functional disorders and, therefore, for the QoL [32]. In our series, notwithstanding that the distance in ELRR group was lower than LTME group (5.7 vs 11.3 cm), QoL was better in the first group except in term of temporary incontinence.

The diameter and the metallic structure of the TEM operating channel, cause of anal sphincter stretching, has been considered a factor connected to temporary incontinence [30, 31]. For this reason, currently, soft devices are increasingly used in transanal surgery in order to reduce the

stretching effect [33]. In our series, patients who underwent ELRR by TEM showed a partial incontinence that disappeared completely after 6 months.

The effects of nChRT in patients with rectal cancer, in terms of functional outcomes are not well defined [34]. Only few papers compared QoL results in patients who underwent TEM after nChRT. In Valsdottir’s (57 pts) and Coco’s (47 pts) series, no statistically significant differences in QoL and defecation disorders were observed between irradiated and non-irradiated patients [35, 36]. D’Ambrosio et al. recently published a comparison of anal function between patients undergone ELRR by TEM alone (Group A 12 pts) or ELRR by TEM after nChRT (Group B 10 pts). The anal resting pressure in the Group A decreased at 4 months after surgery improving at 12 months. In the group B, the anal resting pressure decreased too, but did not improve at 12 months. The Wexner score, instead, did not show differences between the two groups. These findings show that TEM alone does not affect anal function, but when it is associated with nChRT, it may have temporary effects on sphincter functions. This could be due to the still not so well-known effects of radiotherapy and its fibrosis on the anal sphincter and presacral nerves. Other studies are needed to explain these effects [37].

In our previous paper, we reported the functional result at 1, 6, and 12 months in two groups of patients with rectal cancer submitted to ELRR by TEM and LTME [22]. To the best of our knowledge, this is the only study that reported long-term result (3 years) of QoL after nChRT and ELRR by TEM or LTME.

After a revision of the literature, only Allaix and Morino reported an analysis of QoL with a long term (5 years) follow-up on 93 patients who underwent TEM for rectal

adenoma (83%) or early rectal cancer (iT1N0). None of them received nChRT. The anal resting and squeeze pressure decreased markedly at 3 months after surgery, returning to preoperative values at 12 months. Those patients reported more frequent postoperative urgency at 3 and 12 months. Urgency returned to preoperative values at 5 years. Their multivariate analysis reported that the only two factors that may affect sphincter function in terms of anal rest pressure were the duration of the procedure and the size of the lesion. In terms of QoL, there was a slight increase in the Wexner score for faecal continence at 3 months. The QoL at 12 months statistically improved, lasting for the whole follow-up period. Although this study reports that TEM for large rectal adenomas and early rectal cancer had no long-term effects on anorectal, urological, and sexual functions or QoL, it doesn't compare TEM with abdominal surgery and, primarily, it is made on patients who didn't undergo nChRT [31].

In conclusion, QoL after ELRR by TEM is better than LTME group in the short period and become equivalent in the medium and long-term period (3 years). Faecal incontinence is higher in the ELRR group but this difference disappears at 6 months after surgery. The transanal approach with TEM is a valid tool to improve the QoL, in selected patients who underwent rectal surgery.

### Compliance with ethical standards

**Disclosures** Giancarlo D'Ambrosio, Andrea Picchetto, Salvatore Campo, Rossella Palma MD, Cristina Panetta, Francesca De Laurentis, Stefania La Rocca, Emanuele Lezoche, have no conflict of interest or financial ties to disclose.

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