Quality of Life after Endoluminal Loco-Regional Resection (ELRR) by Transanal Endoscopic Microsurgery (TEM)

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AIM: *Endoluminal Loco-Regional Resection (ELRR) by Transanal Endoscopic Microsurgery (TEM) may be considered a valid alternative surgical treatment in patients with rectal cancer. Aim of this study is to evaluate the short and medium term Quality of Life (QoL) from prospectively collected data in patients who underwent ELRR by TEM.*
MATERIAL OF STUDY: *From May 2010 to June 2013, 31 patients with iT1-iT2-iT3N0 rectal cancer were enrolled in this study. Patients with T1 rectal cancer underwent ELRR by TEM. Patients with iT2-iT3 rectal cancer underwent neoadjuvant radio-chemoterapy (n-RCT) before surgery. QoL was evaluated by EORTC QLQ-C30 and QLQ-CR38 questionnaires before surgery and 1, 6, and 12 months after surgery.*
RESULTS: *Mean distance from the anal verge was 5.4 cm (range 1-10). Mean operative time was 145.8 minutes (range 60-300). Pathological staging was as follows: pT0N0 (6), pT1N0 (18), pT2N0 (7). At 1 month after surgery, in QLQ-C30 questionnaire, significant worsening was observed in Global Health Status (p=0.0028), Physical Functioning (p=0.0016), Role Functioning (p=0.0004), Fatigue (p=0.0024), Pain (p=0.0003) and Dyspnoea (p=0.0192). In QLQ-CR38 questionnaire significant worsening at 1 month was observed in Defecation Problems (p=0.0005) and Weight Loss (p=0.0008). At six and twelve months after surgery, no significant differences were observed* in QLQ-C30 and in QLQ-CR38 questionnaires.
DISCUSSION: *QoL evaluation showed worsening results at 1 month after ELRR by TEM, in QLQ-C30 and in QLQ-CR38 questionnaires.*
CONCLUSIONS: *At 6 and 12 months after surgery, no significant differences in QoL as compared to preoperative status were observed.*

KEY WORDS: Endoluminal Loco-Regional Resection (ELRR), Quality of Life (QoL), Rectal cancer, Neoadjuvant Radio-Chemoterapy (n-RCT), Transanal Endoscopic Microsurgery (TEM)

Introduction

Transanal Endoscopic Microsurgery (TEM) was proposed for the first time by Buess in 1983 [1] for adenoma or T1 rectal cancer. This technique provides an excellent view of the rectal cavity due to image magnification, lighting and 3D vision. Authors have previously described an original surgical technique, named Endoluminal Loco-Regional Resection (ELRR) by TEM

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[2,3], for the treatment of iT1-iT2-iT3N0 low rectal cancer in selected patients, with similar long term oncological results as compared to traditional Laparoscopic Total Mesorectal Excision (LTME) [4,5]. In the last years several studies on Quality of Life (QoL) in patients with rectal cancer after surgery have been published [6-9].
Aim of the present study was to evaluate the short and medium term Quality of Life in patients with low rectal cancer (iT1-iT2-iT3N0) who underwent ELRR by TEM.

Materials and Methods

Preoperative assessment included clinical examination, total colonoscopy with biopsies, endoscopic ultrasound (EUS), pelvic magnetic resonance (MRI) and total body computed tomography (CT), as previously reported [4]. Patients were classified according to the 6th edition of the UICC classification [10].
Inclusion criteria were: cancer staged as iT1-iT2-iT3N0 at admission imaging, preoperative n-RCT for iT2-iT3 rectal cancer, American Society of Anesthesiologists (ASA) grade I-II and comprehension and acceptance of the specific and informed consent to the administration and use of questionnaires. Exclusion criteria were: iT4 rectal cancer, N+ or M+ at imaging, previous ano-rectal and abdominal surgery, local recurrence, patients who underwent ileostomy, American Society of Anesthesiologists (ASA) grade III-IV and patients with associated pathology that can compromise the Quality of Life.
Patients with iT1 and patients with iT2-iT3 N0 rectal cancer responder to n-RCT (downsizing > 50 % and/or downstaging), underwent ELRR by TEM. Patients with T2-T3 rectal cancer no responders to n-RCT were excluded and underwent LTME.
From May 2010 to June 2013, 31 patients (18 female, 13 male, mean age 67.5, range 37-86) were enrolled in this study. Patients were asked to sign a specific informed consent form and to complete the questionnaires the week before the operation and at 1, 6 and 12 months after surgery. All patients completed and returned questionnaires up to 12 months after surgery.
Patients were followed up after operation by digital rectal examination, tumor markers' assay, colonoscopy, pelvic MRI and total body CT every three months for the first 3 years and every six months for the next 2 years.

Surgical Technique

Endoluminal Loco-Regional Resection (ELRR) by TEM was performed under general anesthesia, as previously reported [2,3], using the instrumentation described by Buess [11] (Wolf Company, Germany).

Questionnaires

Assessment of disease-specific quality of life was performed using two validated questionnaires developed by the QoL Study Group of the European Organization for Research and Treatment of Cancer (EORTC). One questionnaire assessed cancer-specific QoL (EORTC QLQ-C30) and the other site-specific (colorectal) QoL (EORTC QLQ-CR38) [12,13].
The EORTC QLQ-C30 is a patient self-rating questionnaire that comprises six multi-item function scales measuring physical, role, social, emotional and cognitive functions and overall QoL. Separate symptom scales are included to assess pain, fatigue, and emesis and five single items to measure GI symptoms, dyspnea, appetite loss and insomnia. A single item evaluates the perceived economic consequences of the disease.
The EORTC QLQ-CR38 is a patient self-rating questionnaire that comprises 38 questions, of which 19 are completed by all patients and the remaining by subsets of patients (example: men or women). The general structure comprises 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 on micturition, chemotherapy side effects, GI general symptoms, defecation problems, stoma-related problems and sexual dysfunction in men or women. The single symptom item assesses weight loss. A higher score indicates better functioning for all functioning scales and for two of the single items including sexual enjoyment and future perspective. A higher scale on all symptom scales and the remaining single item (weight loss) indicate a lower level of well-being.

Statistical analysis

Data are presented as mean. Statistical study was done through the T-Student. The probability value of less than 0.05 was considered to define statistical significance. All computations were carried out with SPSS software 13.0 (SPSS Inc.).

Results

Mean distance from the anal verge was 5.4 cm (range 1-10). Mean operative time was 145.8 minutes (range 60-300). Pathological staging was as follows: pT0N0 (6), pT1N0 (18), pT2N0 (7).
At 1 month after surgery, in QLQ-C30, significant worsening was observed in Global Health Status (p=0.0028), Physical Functioning (p=0.0016), Role Functioning (p=0.0004), Fatigue (p=0.0024), Pain (p=0.0003) and Dyspnoea (p=0.0192) (Fig. 1).

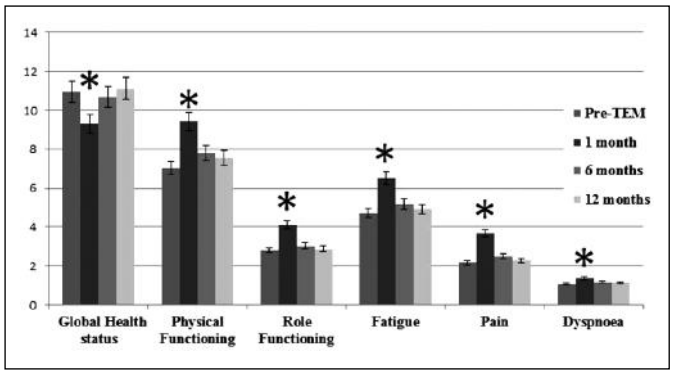

Fig. 1: QLQ-C30 questionnaire results. *P < 0.05

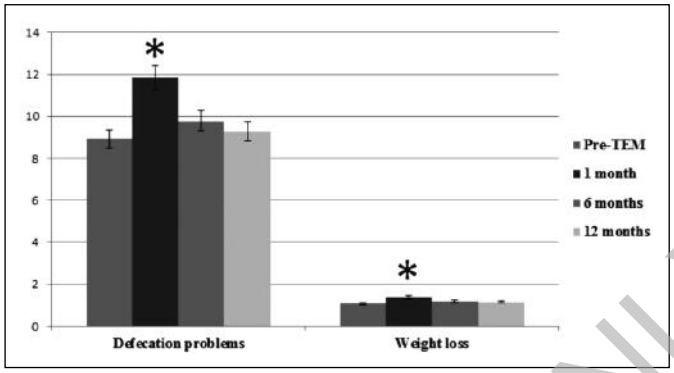

Fig. 2: QLQ-CR38 questionnaire results. *P < 0.05

In QLQ-CR38 significant worsening at 1 month was observed in Defecation Problems (p=0.0005) and Weight Loss (p=0.0008) (Fig. 2).
At six and twelve months after surgery, no significant differences were observed in QLQ-C30 and QLQ-CR38.
At mean follow up of 24 months (range 12-38) all patients are disease free.

Discussion

Abdominoperineal resection (APR) is been considered the standard surgical treatment for rectal cancer for many years [14]. This very invasive technique requires a permanent stoma creation and an important worsening of quality of life due to psychological problems related to body image [15-18], sexual and urinary dysfunction [18,19]. In 1982, Heald introduced the concept of Total Mesorectal Excision (TME), to preserve the sphincter apparatus and to remove all perirectal fat to improve oncological results and QoL [20]. Quickly with the introduction of laparoscopic approach, technical improvements and circular stapling, TME with pelvic autonomic nerve preservation [14] became the gold standard in the treatment of rectal cancer. Finally the introduction of radio-chemotherapy before surgery caused improvement in terms of local recurrence, distant metastases rates and disease free survival [21-23].
Transanal Endoscopic Microsurgery was introduced in 1983 by Buess [11], as an alternative to major surgery for the treatment of sessile rectal polyps and early rectal cancer. In order to obtain better functional results and quality of life without compromising the oncological outcome, authors have developed ELRR by TEM. This technique combined with n-RCT showed equivalent results to LTME even for treatment of T2-T3N0 rectal tumors [4,5,8].
According to several studies on quality of life after TEM [6,9,24-28] this study shows that the functional sequelae after TEM are only temporary.
In Allaix's study patients completed questionnaires at 3,12 and 60 months [9]. In QLQ-C30 questionnaire, was observed worsening in Role Functioning, Physical and Social Functioning and in QLQ-CR38 questionnaire in Defecation Problems like at 3 months after surgery. In this study the same problems are observed at 1 month after TEM but with a complete functional restore at 6 months. According to present data, Allaix's study, shows that TEM had no long term effect on patients' anorectal function or QoL [9].
Other authors confirm that quality of life in patients undergoing TEM, worsens only temporarily. Doornerbosch et al., in a series of 47 patients, using Faecal Incontinence Severity Index (FISI) and EuroQoL EQ-5D questionnaires, reported an improvement of fecal incontinence and a significant improvement of QoL at six months after TEM [6]. Also Planting et al., using EORTC QLQ-C30, EORTC QLQ-CR38, FISI and Fecal Incontinence Quality of Life (FIQL) questionnaires, showed that there is no worsening on fecal incontinence in a series of 30 patients underwent TEM [24]. In Hermann et al.'s series of 33 patients, anorectal function is evaluated by manometric score, and it is demonstrate that fecal incontinence after TEM is only temporary [25].
Also in case of repeated TEM excisions, at six months after surgery, QoL and anorectal function are fully restored [26]. In this study n-RCT seems not to influence QoL after ELLR by TEM. In literature are reported two studies in patients with locally advanced low rectal cancer, who underwent n-RCT before TEM and worsening of QoL or defecation were not observed [27,28].

Conclusions

The present study shows that the impact on the Quality of Life after ELRR by TEM is limited to the first postoperative month. After six and twelve months, worsening of QoL was not observed. Also in patients who underwent n-RCT worsening of QoL was observed only one month after surgery with complete restore at six months.

Oncological results of ELRR by TEM seems to be overlapping to LTME in this series with the same QoL at six months after surgery to preoperatively. Randomized clinical controlled trials and a larger series of patients are required to confirm these conclusions.

Riassunto

OBIETTIVO: Endoluminal Loco-Regional Resection (ELRR) mediante Transanal Endoscopic Microsurgery (TEM) può essere considerata come una valida alternativa chirurgica al trattamento dei pazienti con cancro del retto. Scopo di questo studio è valutare la Qualità di vita a breve e medio termine nei pazienti sottoposti a ELRR mediante TEM con dati raccolti in modo prospettico.
MATERIALE DELLO STUDIO: Da Maggio 2010 a Giugno 2013, 31 pazienti con cancro del retto iT1-iT2-iT3N0 sono stati arruolati in questo studio. I pazienti affetti da cancro del retto iT1 sono stati sottoposti a ELRR mediante TEM. I pazienti con cancro del retto iT2-iT3 sono stati sottoposti a radio-chemioterapia neoadiuvante prima dell'intervento chirurgico. La Qualità di vita è stata valutata mediante i questionari EORTC QLQ-C30 e QLQ-CR38 prima della chirurgia e a 1, 6, e 12 mesi dopo l'intervento.
RISULTATI: La distanza media dal margine anale era di 5.4 cm (range 1-10). Il tempo operatorio medio è stato di 145.8 minuti (range 60-300). La stadiazione istologica definitiva era: pT0N0 (6), pT1N0 (18), pT2N0 (7). Ad 1 mese dopo la chirurgia, nel questionario QLQ-C30, un peggioramento significativo è stato osservato in Global Health Status (p=0.0028), Physical Functioning (p=0.0016), Role Functioning (p=0.0004), Fatigue (p=0.0024), Pain (p=0.0003) e Dyspnoea (p=0.0192). Nel questionario QLQ-CR38 un peggioramento significativo è stato osservato ad 1 mese in Defecation Problems (p=0.0005) e Weight Loss (p=0.0008). A 6 e 12 mesi dopo chirurgia, non sono state osservate differenze statisticamente significative in entrambi i questionari QLQ-C30 e QLQ-CR38.
DISCUSSIONE: La valutazione della Qualità di vita mostrava un peggioramento dei risultati ad 1 mese dopo ELRR mediante TEM, nei questionari QLQ-C30 e QLQ-CR38.
CONCLUSIONI: A 6 e 12 mesi dopo chirurgia, non sono state osservate differenze statisticamente significative nella Qualità di vita se comparate con lo stato preoperatorio dei pazienti.

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