Quality of life and anorectal function after transanal surgery for rectal cancer.
A literature review

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AIM: *The aim of the study is analyze the results after Transanal Endoscopic Microsurgery (TEM) and Trans-Anal Minimally Invasive Surgery (TAMIS) for rectal cancer in terms of Quality of Life (QoL) and anorectal function.*
MATERIAL OF STUDY: *The authors have conducted a review of the literature through the PubMed database using the following keywords: "quality of life", "rectal cancer", "transanal surgery", "TEM" and "TAMIS".*
RESULTS: *Six and five studies were included on TEM and TAMIS, respectively, for a total of 619 patients with a follow up of up to five years. QoL and anorectal function were evaluated by questionnaires and anorectal manometry in four out of eleven studies. At postoperative evaluation, patients reported temporary changes (from 3 weeks to 36 months) but no long-term effects on anorectal function and QoL. There were no differences in the postoperative functional outcome between surgery with rigid (TEM) or soft (TAMIS) devices. Some of the studies reported postoperative changes at manometry that were not clinically confirmed by the questionnaires.*
DISCUSSION: *During TEM and TAMIS the risk of pelvic autonomic nerves damage, that may compromise urinary and sexual function and the risk of permanent sphincter damage with the need to perform a stoma, are very low.*
CONCLUSIONS: *Quality of life and anorectal function after TEM or TAMIS for the treatment of rectal tumors are good with no postoperative sequelae at mid-term follow up.*

KEY WORDS: Quality of Life (QoL), Rectal cancer, Transanal surgery, Transanal Endoscopic Microsurgery (TEM), Trans-Anal Minimally Invasive Surgery (TAMIS)

Introduction

In the last three decades, several technological improvements were achieved in transanal surgery that eventually led to an increasing number of minimally invasive procedures performed worldwide for the management of rectal lesions [1].

In 1983, Gerard Buess proposed Transanal Endoscopic Microsurgery (TEM) as the first alternative to conventional Trans Anal Excision (TAE) or anterior resection of the rectum [1-3]. Initially, TEM was proposed for the management of sessile rectal polyps and early rectal cancer, with better results in terms of radicality (R0) and local recurrence rate as compared to TAE, due to the TEM advantages such as 3D vision, image magnification and lighting [1,2,4]. With increased experience, this device was proposed in selected patients also for the treatment of T2-T3 rectal cancer after neoadjuvant chemoradiotherapy (n-CRT) and in some dedicated centers it included the excision of the adjacent mesorectal fat with enclosed lymph-nodes [5-13].
More recently, Atallah et al. reported the use of Trans-Anal Minimally Invasive Surgery (TAMIS) as an alternative to TEA and TEM [14]. Several disposable devices

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are available to perform TAMIS (SILS Port, Covidien, Mansfield, MA, USA, GelPath Trans-anal Access Platform, Applied Medical, Inc., CA, USA, Keyport, Wolf Company, Knittlingen, Germany) using standard laparoscopic instruments [1,14,15]. The main difference between these devices in terms of the functional results is that TEM employs a rigid platform while the other ones use soft platforms [1]. The aim of the transanal approach is a reduction of the surgical invasiveness and of the postoperative functional sequelae after low anterior resection [16-22]. These may occur from possible damage of the pelvic autonomic nerves and of the sphincter function which may require creation of a temporary or permanent stoma, thereby affecting the patients' quality of life (QoL) [16-22].

The aim of the present literature review is to report the results, in terms of QoL and anorectal function, after TEM and TAMIS for rectal cancer.

Materials and Methods

Search Strategy

The authors conducted a literature review of published papers through PubMed database using the following keywords: "quality of life", "rectal cancer", "transanal surgery", "TEM" and "TAMIS".

Inclusion Criteria

Inclusion criteria were: 1) articles written in English or in Italian; 2) study in which data regarding postoperative patients' quality of life or anal function data after TEM or TAMIS were reported; and 3) articles involving human subjects.

Exclusion Criteria

Exclusion criteria were: 1) articles in languages other than English or Italian; 2) meta-analysis, reviews, correspondence, letters to authors or editors, editorials, technical surgical notes, and imaging studies; and 3) articles involving animals.

Data were extracted by three reviewers (L.P., D.C. and F.M.) from the full text, after screening the titles and abstracts, and identifying the articles that fulfilled the eligibility criteria. Eleven papers were included in the study for a total of 619 patients [23-33].

Results

Transanal Endoscopic Microsurgery - Tem

Several articles reported on QoL and anal function after TEM [23-29]. Lezoche et al. reported a series of 17 patients who underwent TEM for T1 rectal cancer [23]. QoL was assessed by the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-C38 questionnaires, preoperatively and at 1, 6, and 12 months after surgery [23]. A significant worsening of gastrointestinal symptoms and of defecation problems at QLQ-CR38 questionnaire, and of global health status, physical functioning, role functioning, fatigue and pain at QLQ-C30 questionnaire were observed 1 month after surgery, in comparison to the preoperative evaluation [23]. However, no functional sequelae were reported at 6 and 12 months [23]. Similarly, D'Ambrosio et al. evaluated patients with T1-T2-T3 rectal cancer by QLQ-C30 and QLQ-CR38 questionnaires, before and 1, 6 12 months after TEM [24]. In this study, patients with T2-T3 rectal cancer underwent n-CRT before surgery [24]. Statistically significant differences were observed 1 month after surgery, in comparison to the preoperative status, while at 6 and 12 months of follow up no differences were observed [24]. Another study by Hompes et al., showed temporary and reversible worsening of QoL and anal function after TEM, without affecting the urinary function [25]. One-hundred-two patients were evaluated by questionnaires: EORTC QLQ-C30 and QLQ-CR29, EuroQol (EQ-5D), Colo-Rectal Functional Outcome (COREFO) and the International Prostate Symptom Score (I-PSS) before and 6, 12, 26, 52 weeks after surgery [25]. QoL and anorectal function returned to baseline at 26 and 12 weeks after surgery, respectively (Table I) [25].

Some studies evaluated the patients' anal function by manometry [26-28]. Allaix et al. evaluated patients by the Wexner score, EORTC QLQ-C30 and QLQ-CR38, EQ-5D and EQ-VAS (visual analogue scale) questionnaires and anorectal manometry on a sample of 93 patients who underwent TEM [26]. They found that TEM did not affect the anorectal function and the QoL at long term follow up (60 months) [26]. Mora López et al. reported statistically significant decreases in Voluntary Contraction Pressure (VCP) and Baseline Pressure (BP) at manometry 4 months after surgery, but the Wexner score did not show clinical incontinence [27]. Biviano et al. reported the functional data of patients who underwent n-CRT and TEM, showing that radiation therapy causes modifications of the anorectal function without significantly affecting anal continence at 4 months after surgery, and that at 12 months of follow up, the risk of major anal incontinence is low (Table I) [28].

Trans-Anal Minimally Invasive Surgery - Tamis

Verseveld et al. reported on functional results before and 6 months after surgery in a sample of 24 patients who underwent TAMIS [29]. QoL and functional outcomes were evaluated by the Fecal Incontinence Severity Index (FISI), the Fecal Incontinence Quality of Life (FIQL) and the EQ-5D questionnaires [29]. FIQL and FISI ques-

Table I - *Functional data after Transanal Endoscopic Microsurgery (TEM). EORTC: European Organization for Research and Treatment of Cancer. EQ-5D: EuroQol. COREFO: Colo-Rectal Functional Outcome. I-PSS: International Prostate Symptom Score. QoL: Quality of Life. VAS: visual analogue scale. n-CRT: neoadjuvant chemoradiotherapy.*

Authors, years	Type of study	Number of patients	Evaluation instrument	Time of evaluation	Conclusions
Lezoche, 2014 [23]	Retrospective	17	EORTC QLQ-C30 EORTC QLQ-CR38	Preoperative and 1, 6, 12 months after surgery	No differences 6 months after surgery
D'Ambrosio, 2015 [24]	Retrospective	31	EORTC QLQ-C30 EORTC QLQ-CR38	Preoperative and 1, 6, 12 months after surgery	No differences 6 months after surgery
Hompes, 2015 [25]	Prospective	102	EORTC QLQ-C30 EORTC QLQ-CR29 EQ-5D COREFO I-PSS	Preoperative and 6, 12, 26, 52 weeks after surgery	Temporary and reversible impact on QoL and anorectal function
Allaix, 2011 [26]	Prospective	93	Wexner score EORTC QLQ-C30 EORTC QLQ-CR38 EQ-5D EQ-VAS Manometry	Preoperative and 3, 12, 60 months after surgery	TEM had no long-term effect on anorectal function and QoL
Mora López, 2015 [27]	Prospective	201	Wexner score Manometry	Preoperative and 1, 4 months after surgery	TEM does not affect anal continence
Biviano, 2017 [28]	Retrospective	37	Wexner score Manometry	Baseline, after n-CRT and 4, 12 months after surgery	TEM does not affect anal function. n-CRT does affect anal function without causing major anal incontinence

tionnaires showed no differences after surgery in comparison to baseline, while EQ-5D showed an improvement at 6 months [29]. Garcia-Florez et al. reported on clinical outcomes after TAMIS, without the use of questionnaires [30]. In a sample of 32 patients who were all continent before surgery, 5 patients reported minor episodes of fecal incontinence (15.6%) 4 weeks after TAMIS, but at 8 weeks after surgery these had resolved [30]. Moreover, urinary and sexual functions were not affected in any case [30]. Clermonts et al. compared the postoperative results of 37 patients who underwent TAMIS with those of 37 healthy controls paired for age, sex, and socio-economic status [31]. Employing the Short-Form 36 (SF-36) and FISI questionnaires at a median follow up of 36 months, they found that the postoperative QoL is similar to the healthy control group [31]. However, statistically significant differences were observed regarding Bodily Pain in the surgical group and Social Functioning in the control group [31]. Schiphorst et al. prospectively evaluated the functional results by the FISI questionnaire before and after TAMIS in 35 patients [32]. Overall, the FISI score after surgery was improved in 15 patients, unchanged in 18 patients and worsened in 4 patients [32]. Finally, Karakayali et al. reported functional results in a series of ten patients, who were evaluated by the Cleveland Clinic Incontinence Score questionnaire and anorectal manometry, before and 3 weeks after surgery [33]. The only statistically significant difference that was observed between the preoperative and postoperative manometric evaluation was the minimum rectal sensory volume ($p = 0.004$) (Table II) [33].

Discussion

The present study was conducted with the aim to analyze the functional results after trasnsanal procedures by TEM and TAMIS for the management of rectal tumors. Based on the results reported by the articles included in the study, for a total of 481 patients who underwent TEM and 138 patients who underwent TAMIS, transanal surgery provided excellent postoperative results as evaluated by the questionnaires and anorectal manometry data in 4 studies.

TEM was specifically developed for transanal surgery [2]. It is a rigid platform held in position by a self-retaining arm and it employs a dedicated instrumentation and insufflator [1,2,5,8]. To be safe and effective, TEM requires a prolonged learning curve and extensive experience [1,2,5,8]. Together with the added cost, this probably explains the

Table II - *Functional data after Trans-Anal Minimally Invasive Surgery (TAMIS). FISI: Fecal Incontinence Severity Index. FIQL: Fecal Incontinence Quality of Life. EQ-5D: EuroQol. SF-36: Short-Form 36.*

Authors, years	Type of study	Number of patients	Evaluation instrument	Time of evaluation	Conclusions
Verseveld, 2016 [29]	Prospective	24	FISI FIQL EQ-5D	Preoperative and 6 months after surgery	After TAMIS there was no detrimental effect on anorectal function and overall QoL was improved
Garcia-Florez, 2017 [30]	Prospective	32	Clinical interview	Preoperative and 4 weeks after surgery	TAMIS provides good functional outcomes
Clermonts, 2018 [31]	Prospective	37	SF-36 FISI	Preoperative and at 36 months median follow up	TAMIS has a postoperative QoL scores similar to that of healthy case matched controls
Schiphorst, 2014 [32]	Prospective	35	FISI	Preoperative and 6 months after surgery	Short-term functional results after TAMIS are excellent
Karakayali, 2015 [33]	Prospective	10	Cleveland Clinic Incontinence Score Manometry	Preoperative and 3 weeks after surgery	TAMIS does not damage the anal sphincter and does not impair anorectal function.

lack of a wide diffusion of this technique [1,2]. On the contrary, the devices employed for TAMIS were devised for single-port laparoscopic surgery and employ standard laparoscopic instruments [34]. TAMIS is performed with a soft platform and without the need for a dedicated instrumentation [1,35]. This explains its rapidly growing popularity [1,35].

With increased surgeons' experience in the use of these devices, it is now possible to perform transanal loco-regional excision in selected patients with T2-T3rectal tumors after n-CRT, but also TransAnal Total Mesorectal Excision (TATME) [5,7,8,36-40]. Other indications include restoring intestinal continuity after Hartmann procedure, the treatment of recto-urinary or recto-vaginal fistulas and the treatment of anastomotic stenosis after anterior resection [36-43].

Based on the present data, it seems that transanal surgery for the management of rectal tumors is associated with good functional results avoiding the so called "anterior resection syndrome" [44]. In fact, with the transanal approach the risk of pelvic autonomic nerves damage that may compromise the urinary and sexual functions and the risk of sphincter damage with the need to perform a temporary or a definitive stoma, are very low, with a better postoperative QoL [16,17,23,34,45]. Based on the published results, urinary and sexual postoperative alterations are not observed, and the sphincter modifications are reported to be temporary [23-33]. Moreover, it is interesting to note that there are no differences in the postoperative functional outcomes between surgery using the rigid (TEM) or the soft (TAMIS) platforms [23-33]. Some authors hypothesized that the TEM rigid proctoscope might affect the anal sphincter due to its diameter (4 cm) and the consequent stretch exercised on the sphincter muscle fibers [27,28,47,48], but this finding was not confirmed by the present study. Another important issue is the relation between the manometric evaluation and the questionnaires [27,28,33]. The studies included in the present review do report some postoperative changes at manometry which, however, were not confirmed by the questionnaires [27,28,33]. So probably the anatomical alterations caused by the procedures are subclinical and not relevant enough to be perceived by the patients, although detected by manometry.

Despite the good functional results obtained with the transanal approach, in case of rectal cancer the main object of treatment is oncologic control of the disease with adequate negative margins. Therefore, in case of advanced rectal tumors, open or laparoscopic anterior rectal resection or abdominoperineal excision still remain the standard treatment strategy with a curative intent [46,49].

The main limitations of the present review are the lack of randomized controlled trials comparing the functional outcomes after TEM or TAMIS and comparing the transanal surgery with low anterior resection, and the absence of a statistical analysis.

Conclusions

Quality of life and anorectal function after TEM or TAMIS for the treatment of rectal tumors are good with no functional sequelae at mid-term follow up. Further studies and randomized controlled trials design with larger patient samples are required to better define the impact of transanal surgery on the patients' QoL.

Riassunto

L'obiettivo della presente revisione della letteratura è quello di analizzare i risultati in termini di qualità di

vita e funzione anorettale dopo Transanal Endoscopic Microsurgery (TEM) e Trans-Anal Minimally Invasive Surgery (TAMIS) nel trattamento dei tumori del retto. Gli autori hanno condotto una revisione della letteratura attraverso il database PubMed usando le seguenti parole chiave: "quality of life", "rectal cancer", "transanal surgery", "TEM" e "TAMIS".
RISULTATI: Sei e cinque studi, rispettivamente, sono stati inclusi riguardanti la TEM a la TAMIS per un totale di 619 pazienti con un follow up fino a 5 anni. La qualità di vita e la funzione anorettale sono state valutate mediante questionari e manometria anorettale in quattro studi su undici. Nella valutazione postoperatoria della funzione anorettale e della qualità di vita i pazienti hanno riportato modificazioni temporanee (da 3 settimane fino a 36 mesi) ma non effetti a lungo termine. Non ci sono state differenze nei risultati funzionali postoperatori tra la chirurgia con piattaforma rigida (TEM) o morbida (TAMIS). Alcuni studi riportano qualche alterazione alla manometria postoperatoria che comunque non viene confermata dai questionari.
DISCUSSIONE: Durante la TEM e la TAMIS, il rischio di danno dei nervi pelvici autonomi, che può compromettere le funzioni urinarie e sessuali, e il rischio di danni allo sfintere con la necessità di confezionare una stomia, sono molto bassi.
CONCLUSIONE: La qualità di vita e la funzione anorettale dopo TEM e TAMIS per il trattamento dei tumori del retto sono buoni, senza sequele postoperatorie ad un follow up a medio termine.

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