Transanal endoscopic microsurgery in rectal cancer

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CHAPTER 5

Impact of transanal endoscopic microsurgery on quality of life and functional outcome

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INTRODUCTION

Local excision of benign rectal tumors is safer compared to radical surgery and considered treatment of choice. [1-3] Several techniques have been developed for local excision, with the transanal technique according to Parks as the most frequently used. [1, 4] Other techniques used are the dorsal trans-sacral approach (Kraske) and the dorsal trans-sphincteric approach (York-Mason). [5-9] Each procedure has its own (dis-) advantages, and none of the procedures mentioned is able to achieve local excision of tumors throughout the entire rectum. Transanal endoscopic microsurgery (TEM) demonstrated to be a safe procedure capable of overcoming this shortcoming. In early publications even distal sigmoid tumors could be locally excised with excellent results. Moreover, recurrence rates are minimal compared to other local techniques. As a result the indication for local excision of rectal tumors has expanded dramatically. [10-13]

Few studies have addressed functional outcome following TEM, and with the operation rectoscope with a length of 12 or 20 centimetres and a diameter of 40 mm, scepticism towards postoperative faecal continence remains. In manometric studies after TEM there seems to be a temporary detrimental impact on internal sphincter functioning, although without clinical significance. [14-16]

Cataldo et al. recently performed a prospective study on faecal continence and incontinence-specific quality of life after TEM, using standardized surveys. [17] They stated TEM does not result in significant alterations. These results are promising, especially with a relative short duration of follow-up of six weeks in this study. As known from other types of rectal surgery, incidence of faecal incontinence diminishes with time. [18] This could imply results after TEM may even improve with longer follow-up.

Quality of life is increasingly recognised as the ultimate endpoint when assessing clinical outcomes after different surgical interventions because it measures the patient's perspective. The precise impact of the TEM procedure on quality of life has not been well studied. This prospective study was set out to provide a comprehensive insight into the impact of TEM on functional outcome and quality of life.

PATIENTS AND METHODS

Between January 2004 and January 2006, a consecutive series of fifty patients were referred for a TEM procedure. All patients were evaluated preoperatively according to a standard protocol including rigid rectoscopy, tumor biopsy and endorectal ultrasound. If TEM was considered feasible patients were eligible for this study. Informed consent had to be given before inclusion. Local medical ethical committees approved this study. Always a full-thickness excision was performed. The portion of the tumor located within the sphincter musculature was excised partial thickness. Before and at least six months after the TEM procedure patients were asked to fill out

a questionnaire to assess anorectal functioning and quality of life. All data were collected by an independent research coordinator, not previously involved in the patients' care. We recorded the demographics, operative details, postoperative length of stay, postoperative complications and functional outcome for each participant. We evaluated functional outcome by means of a detailed questionnaire based on the Faecal Incontinence Severity Index (FISI) [19]. This system, developed by Rockwood, uses two basic components: the type of incontinence and its frequency. FISI scores range from zero (total continence) to 61 (complete incontinence to solid stool on a daily basis). We used the validated weighting scores that are based on patients input. Quality of life was evaluated using both the EuroQol EQ-5D and the Faecal Incontinence Quality of Life (FIQL) score. The EuroQol EQ-5D consists of a so-called Index score representing the societal value of the health state, and has a scale ranging from 0 (no quality of life) to 100 (optimal quality of life). The EuroQol EQ-5D also uses a visual analogue scale, the EQ-VAS, representing the patient perspective. This scale ranges from 0 (no quality of life) to 100 (optimal quality of life). The EuroQoL EQ-5D scores were compared with a sex- and age-matched, community based sample of healthy persons without co-morbidity.[20] The FIQL score as described by Rockwood et al. measures specific quality of life issues, expected to affect patients with faecal incontinence. [21] This instrument is composed of 29 questions within 4 domains: lifestyle issues, coping/behavior, depression and self-perception, and embarrassment. The scores in the FIQL range from a minimum score of 1 to a maximum of 4, for all of the scales (1= quality of life alteration present most of the time, 4= none of the time). Data are presented as medians and standard deviations. Changes within groups were evaluated using the nonparametric one-sample Wilcoxon's signed-rank test. Comparison of these changes between groups was conducted using the Mann-Witney U test. The Spearman`s correlation coefficient was used for correlation between the different findings. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

Fifty patients were eligible and informed consent was obtained. Three patients were excluded. In two patients TEM could not be performed because of bulky tumor or technical problems. An additional patient underwent low anterior resection for locally recurrent disease within six months of the TEM. The remaining forty-seven patients completed both questionnaires and were included for analysis. All of these patients were alive without evidence of recurrent disease. The group consisted of 22 males and 25 females. Median age was 67 years (range 40-84). Preoperative diagnosis was villous adenoma in all patients. Median distance from the distal tumor margin to the dentate line was 7 (range 0–15) cm and median tumor size 20 (range 4–53) cm^2. The median rate of captured circumference of the rectal wall was 40 percent (range 5-80). (Table 1) Median operative time, defined as beginning when the rectoscope was inserted and ending when it was removed, was 55 minutes (range 10–140). Complications developed in 4 of 47 (8.5 percent)

Table 1. Patient, tumor and procedure related characteristics.

Number of patients	47
Male/female	22/25
Median age in years (range)	67 (40-84)
Median distance from dentate line in cm`s (range)	7 (0-15)
Median tumor size in cm^2 (range)	20 (4-53)
Median capture of circumference of rectal wall in % (range)	40 (5-80)
Median duration of operation in minutes (range)	55 (10-140)
Complications	4/47 (8,5%)
Urinary retention	2
Urinary tract infection	1
Bloodtransfusion	1
Reoperations	None
Length of hospital stay in days (range)	4 (3-9)

patients. Two patients had urinary retention, one patient a urinary tract infection and one suffered from a low hemoglobin rate requiring blood transfusion. No reoperations were necessary and mortality rate was zero. Median length of stay was 4 days (range 3-9). (Table 1)

Definite histopathological examination of the resected specimens revealed an adenoma in 44 patients and an invasive carcinoma in 3 patients (pT1 in two patients and pT2 in one patient). These three patients were reluctant to major surgery and were observed with rectoscopy and endorectal ultrasound every three months without signs of recurrence at six months after TEM. In three adenomas excisional margin was considered microscopic irradical, resulting in 94% of tumors being radically excised. Six months after surgery, mean FISI scores were found to be decreased (pre-operative: 10, post-operative: 7, $p < 0.01$; Figure 1), depicting an improvement in faecal continence. Overall when preoperative and postoperative FISI scores were compared, 24 patients improved, 16 patients were unchanged and seven deteriorated. Operation time or tumor size did not influence the change in FISI score. There was a significant correlation between the decrease in FISI score and tumor height ($p = 0.02$). Reduction of FISI was significantly greater in patients with a tumor location within seven centimetres from the dentate line ($p = 0.01$). (Table 2) Mean scores and ranges of the EuroQol EQ-5D are presented in Table 3. Mean general quality of life score from the patients` perspective (EQ-VAS) was found to be significantly higher six months after TEM ($p < 0.02$). The observed changes in EQ-VAS showed no correlation with the postoperative alterations in FISI scores or tumor characteristics. Mean pre-operative EQ-VAS score in our group was lower compared to the mean EQ-VAS score of the sex- and age-matched general population ($p = 0.02$). Postoperative EQ-VAS score was comparable with the general population. Mean Index score (social perspective) remained the same ($p = 0.09$). Both pre- and postoperative EQ-5D index scores were similar to those of the sex-age matched general population. Comparing the change from baseline in FIQL scores, a statistically significant improvement was observed in two of the four domains (embarrassment; $p = 0.03$

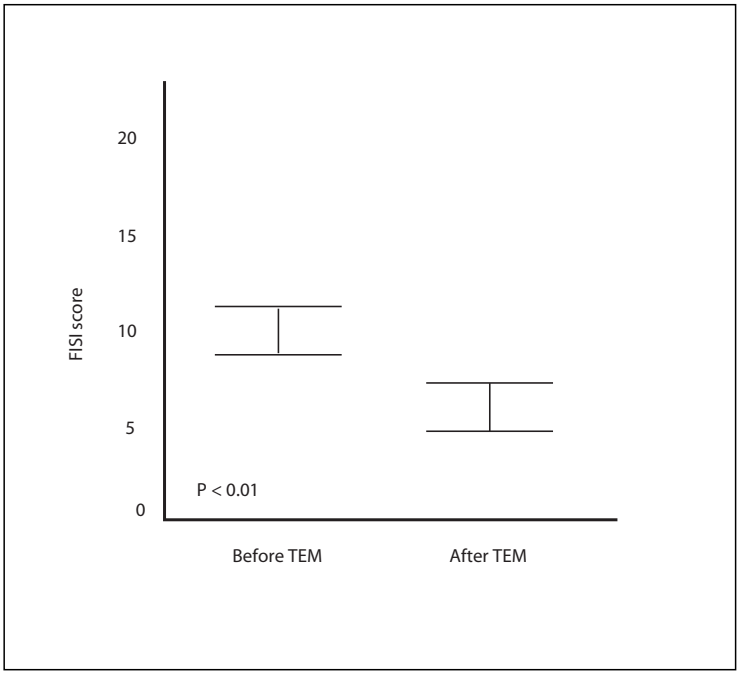

Figure 1. Mean Faecal Incontinence Severity Index (FISI) scores (±SEM) before and after transanal endoscopic microsurgery (TEM)

Table 2. Mean Faecal Incontinence Severity Index (FISI)-scores.

FISI-score	Preoperative	Postoperative	Statistical Significance
Overall	10 (2)	6 (2)	p < 0.01
Duration of operation < 55 minutes (N=24)	9 (4)	7 (3)	p = 0.24
Duration of operation > 55 minutes (N=23)	12 (3)	4 (2)	p = 0.17
Tumors < 7 cm from dentate line (N=21)	16 (5)	5 (2)	p = 0.01
Tumors > 7 cm from dentate line (N=26)	6 (2)	7 (3)	p = 0.43
Median tumor size < 20 cm^2 (N=27)	12 (4)	6 (3)	p = 0.12
Median tumor size > 20 cm^2 (N=20)	8 (3)	6 (3)	p = 0.32

Numbers in parentheses are standard deviations. Lower values indicate better anorectal functioning.

Table 3. Mean EuroQoL EQ-5D scores.

	Control group	Preoperative	Postoperative	Statistical Significance
EQ-VAS	82 (7)	77 (14)	82 (11)	p = 0.02
Index score	86 (6)	84 (11)	89 (9)	p = 0.09

Numbers in parentheses are standard deviations. EQ-VAS represents the patients` perspective on quality of life, Index score represents the societal value on quality of life. Higher scores indicate higher quality of life. Both scores are compared with a healthy sex- and age matched control group.

Table 4. Mean Faecal Incontinence Quality of Life (FIQL) scores.

	Preoperative	Postoperative	Statistical Significance
FIQLS			
Lifestyle	3.7 (0.3)	3.9 (0.3)	p = 0.05
Coping	3.6 (0.5)	3.8 (0.4)	p = 0.10
Depression	3.7 (0.3)	3.9 (0.4)	p = 0.08
Embarrassment	3.1 (0.3)	3.7 (0.4)	p = 0.03

Numbers in parentheses are standard deviations. Higher scores indicate higher quality of life.

and lifestyle; p = 0.05). The domains of lifestyle, coping and behaviour, and embarrassment were correlated with the FISI (all p < 0.05). (Table 4) Overall, EQ-5D and FIQL scores were not affected by age and gender of the patients. Surgical aspects and tumor characteristics did not influence the outcome.

DISCUSSION

In rectal adenomas, TEM has emerged as the procedure of choice, because of its safety and low local recurrence rates. Especially compared to radical surgery TEM has proven its safety.[22, 23] However, possible adverse effects of TEM have to be addressed. The use of a rectoscope with a four centimetres diameter, introduced transanal, has lead to substantial scepticism regarding impact on anorectal functioning. In earlier studies we already showed TEM to be superior to total mesorectal excision regarding postoperative defecation disorders, although this did not result in improved quality of life. [24] In the present study TEM resulted in improved faecal continence as measured by the Faecal Incontinence Severity Index (FISI). This apparent paradox may be attributed to preoperative tumor symptoms as mucinous or bloody discharge, prolapse, tenesmi and/or urge, giving rise to incontinence-like symptoms. Postoperative improvement of continence was most significant in tumors within seven centimetres from the dentate line but disappeared in our study in tumors above seven centimetres from the dentate line. Kreis et al. performed manometric studies after TEM and found a significant reduction in anal resting pressure one year postoperative and a temporary reduction in anal squeezing pressure, resulting in a temporary rise in urge-incontinence. [25] Kennedy et al. found a significant reduction in anal resting pressure six weeks after TEM. [26] This reduction was significantly correlated with duration of the procedure, but mean continence score was not changed after TEM. Both of the above studies however did not use validated questionnaires on faecal continence, and therefore comparison with our study is difficult. Cataldo et al. reported on the impact of TEM on functional outcome and incontinence specific quality of life, using the same questionnaires. [17] No significant alteration was found in faecal continence after TEM. The discrepancy between both studies may be explained by the relative short interval between the TEM procedure and postoperative questioning of six weeks in the Cataldo series. Also in his study, indications for

TEM were heterogeneous which may have influenced results. The positive effect of TEM on faecal continence in our series may be explained by the differences in preoperative FISI score between both studies (10 versus 2.4), depicting more continence problems among the patients in our series. Another explanation may be the differences in tumor distance from the dentate line (present series median seven centimetres, Cataldo series 11 centimetres). Also in our series tumors were larger (median 20 cm^2 versus 8.75 cm^2). Because tumors were larger in our series more extensive resections were performed, not seldom in tumors located within the sphincter apparatus. These latter were already shown to influence recto-inhibitory reflex, reflex sphincter contraction, rectal sensitivity and compliance. [16] Further analysis within our series upon this issue showed only tumor distance from the dentate line less than seven centimetres to be a significant contributing factor. These results however are based upon low number of patients and therefore solid conclusions cannot be drawn. Although in our study TEM resulted in a significant improve in continence, the postoperative FISI was still worse compared to the Cataldo series (7 versus 2.4). Regarding quality of life, Cataldo found TEM was of no significant influence. In our series mean general quality of life score from the patients' perspective, EQ-VAS, was significantly higher after TEM. This improvement could not be explained by improved FISI-scores, but probably to lower pre-operative EQ-VAS scores as compared to healthy controls. Another explanation may be the rejoice phenomena, that is patients are relieved the tumor has been excised, and in most cases an adenoma was found. [27] However, because of the low number of invasive carcinomas in our series this is purely theoretical. The societal value of general quality of life, EQ-5D, remained unchanged. Measuring quality of life using the Faecal Incontinence Quality of Life (FIQL) questionnaires, resulted in a significant improve in two of the four FIQL domains (embarrassment and lifestyle). Moreover the domains of lifestyle, coping and behaviour, and embarrassment were all significantly correlated with the FISI.In conclusion, how are these results to be interpreted? This study supports the hypothesis rectal tumors give rise to incontinence-like symptoms, especially in low-lying rectal tumors. After the tumor is excised using the TEM technique, faecal continence improves. TEM itself does not improve continence, but also does not deteriorate faecal continence. Mean quality of life from the patients` perspective following TEM is improved.

Based on, as we know, the only two studies addressing anorectal functioning and quality of life after TEM in one study, it can be concluded TEM does not impair faecal continence. Also, quality of life is not negatively influenced by the TEM procedure itself, and therefore TEM is the procedure of choice in all rectal adenomas.

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