

JOURNAL OF HEALTH SCIENCES

ACCEPTED ARTICLE

SUBMITTED: 25 June 2017

ACCEPTED: 1 December 2017

DOI: <https://doi.org/10.17532/jhsci.2017.442>

Running title: Ilievová et al. Quality of life of colorectal cancer patients

RESEARCH ARTICLE

Evaluation of quality of life in patients treated for colorectal cancer at the University Hospital Trnava

Lubica Ilievová^{1,*}, Daniel Jirkovský², Gabriela Vöröšová³, Monika Strádalová⁴

¹Department of Nursing, Faculty of Health and Social Work, Trnava University, Trnava, Slovak Republic

²Department of Nursing, Charles University Medical Faculty, Prague, Czech Republic

³Department of Nursing, Constantine the Philosopher University in Nitra, Slovak Republic

⁴Department of Surgery, University hospital Trnava, Trnava, Slovak Republic

*Corresponding author

Lubica Ilievová, PhD. Department of Nursing, Faculty of Health and Social Work, Trnava University in Trnava, University square 1, 917 01 Trnava, Slovak Republic. Email: lubica.ilievova@truni.sk.

ABSTRACT

Introduction: The aim of the study was to evaluate quality of life (QoL) in patients with colorectal cancer during complex treatment using the EORTC QLQ-C30 and QLQ-CR29 questionnaires and to implement routine QoL assessment into our practice.

Methods: Thirty patients diagnosed with colorectal cancer at the Department of Surgery, Faculty Hospital Trnava, Slovakia were included in the study between May 2014 and April 2015. QoL was assessed using EORTC QLQ-C30 and QLQ-CR29 questionnaires before surgery and 1 month after surgery. Data are presented as means, and a paired t-test and independent t-test were used for statistical analysis.

Results: A significant correlation between the type of treatment and QoL was identified in the cohort. A trend to lower QoL was observed in patients with completed neoadjuvant chemoradiotherapy and after surgery with stoma formation. The QoL was also affected by the age and gender of the patients.

Conclusion: QoL assessment provides important outcomes reflecting the consequences of particular therapeutic modality in patients with colorectal cancer. The worse effect of neoadjuvant chemoradiotherapy and stoma formation was shown in our study in comparison to radical resection with adjuvant chemotherapy.

Keywords: quality of life, questionnaire, EORTC, QLQ-C30, QLQ-CR29, colorectal cancer

INTRODUCTION

The growing incidence of colorectal cancer (CRC) is alarming. There are 940 000 new cases diagnosed and a mortality of approximately 500 000 patients annually worldwide [1]. Slovakia remains in the top five countries with the highest incidence and mortality, with 3000 new cases of CRC annually.

CRC is the most frequent malignancy of the gastrointestinal tract. Management of patients with CRC usually combines a multimodal causal treatment with symptomatic therapy and management of side effects [2]. Surgery remains the first treatment option, commonly in combination with neoadjuvant or adjuvant therapy with regards to disease staging and location.

The diagnosis of CRC and the following treatment lead to complex psychomotor, functional, and social impairment, which all affect quality of life (QoL) [3]. Recently, QoL has been considered to be an important component of treatment outcomes. Therefore, research became more focused on psychosomatic and physical well-being [4].

The QLQ-CR29 questionnaire was developed by the EORTC (European Organization for Research and Treatment of Cancer) and is widely used in CRC patients within Europe.

Slovak validation of QLQ-CR29 was completed at the Department of Surgery, Faculty Hospital Trnava in collaboration with EORTC.

The aim of the study was to evaluate QoL in patients with CRC during complex treatment using EORTC QLQ-C30 and QLQ-CR29 questionnaires and to implement routine QoL assessment into practice.

METHODS

The observational study was performed and data are presented using descriptive statistics.

Forty-six patients with CRC were considered eligible for the study. The participation in the trial was voluntary. From a total of 46 patients, 30 (65.2%) patients were included: 20 (67%) men and 10 (33%) women. The average age was 63.7 years with a range of 42 – 81 years. In total, 12 (40%) patients were <65 and 18 (60%) were ≥65 years of age. With respect to tumour location, 19 (63%) patients were diagnosed with colon cancer and 11 patients (37%) were diagnosed with rectal cancer. Resection with and without primary stoma formation was performed in 14 (46%) and 5 (17%) patients with colon cancer and in 6 (20%) and 5 (17%) with rectal cancer, respectively (Table 1). Of 11 (100%) patients with rectal cancer, 9 patients (82%) underwent neoadjuvant chemoradiotherapy (CRT).

QoL questionnaire

Data collection was performed using the EORTC QoL Questionnaire C30 (EORTC QLQ-C30) and the EORTC QLQ-CR29 module at the Department of Surgery, Faculty Hospital Trnava, Slovakia, from May 2014 until April 2015.

All patients with CRC included in the study completed a validated questionnaire in the Slovak language before the initiation of treatment and 1 month after surgery.

Each patient was informed by a clinician about the diagnosis before the first assessment. The patients completed the questionnaire independently with adequate time provided.

The cohort of 46 patients was divided into two groups depending on the tumour location: group 1 included patients with colon cancer and group 2 included patients with rectal cancer (tumour located within 15 cm from linea dentata). Data from the questionnaires were processed using the original software provided by the EORTC.

Statistical analysis

Data were analysed with Statistical software SPSS 22.0.01 using means with standard deviations, a paired t-test and independent t-test. Both groups were compared using an independent t-test. The difference between pre and postoperative QoL outcomes was assessed with a paired t-test. P value ≤ 0.05 was statistically significant.

RESULTS

The comparison of QoL in patients with colon cancer (group 1) and rectal cancer (group 2) is presented in Table 2 (table 2).

The mean global health status of the cohort was 42.4–43.4 preoperatively and these values increased to 47.7–52.6 one month after the procedure. The patients with colon and rectal cancer differed significantly in the score of buttock pain 1 month after surgery ($p=0.001$).

A significant difference was also observed between these two groups in mouth dryness ($p=0.042$), impotence ($p=0.035$) and sore skin around the anus in patients without stoma ($p=0.039$).

The outcomes of QoL assessment in patients with CRC stratified by age are presented in Table 3 (table 3).

The mean global health status was 30.6–52.8 within the whole cohort. A significant difference between the two age groups was found before the surgery ($p=0.007$). The score of sexual interest in the group of men differed significantly between these groups before ($p=0.020$) and after surgery ($p=0.007$). The fatigue score and the constipation score showed significant differences ($p=0.019$ and $p=0.028$, respectively) before the operation. One month after surgery a statistically significant difference was observed in financial difficulties ($p=0.020$).

The outcomes of QoL evaluation in patients with CRC stratified by gender is shown in Table 4 (table 4).

The mean global health status was preoperatively less than 50.0 in both genders. In the second assessment, 1 month after surgery, the scores for men and women were 47.1 and 58.3, respectively. A significant difference was found between men and women for body image ($p=0.031$) and constipation scores ($p=0.007$) one month after surgery. There was also a significant difference identified for anxiety before surgery ($p=0.023$).

The evaluation of QoL in patients with and without stoma is presented in Table 5.

The mean global health status of the studied sample was 36.7–51.7. A significant difference was identified in the physical functioning domain between patients with and without stoma 1 month after surgery (48.0 versus 70.7; $p=0.024$). A statistically significant difference was found in the fatigue score preoperatively ($p=0.045$) and 1 month after surgery ($p=0.047$).

The evaluation of QoL in patients with rectal cancer with and without neoadjuvant CRT is presented in Table 6.

The mean global health status of patients in the studied cohort was 41.7–50.0. A significant difference between patients who were not treated with neoadjuvant CRT and who completed neoadjuvant treatment was observed in the cognitive functioning domain in the time before surgery ($p=0.010$). The presence of blood and mucus in stool was more frequent in the group with completed neoadjuvant CRT one month after surgery ($p=0.023$).

DISCUSSION

CRC represents the most common malignant tumour of the gastrointestinal tract and the second most frequent malignancy after lung cancer in men and breast and ovarian cancer in women [5]. Loss of health integrity due to presence of CRC or the consequences of its treatment can lead to psychomotor, functional and social disability, which all affect QoL [3]. QoL is an important treatment outcome for overall survival in each individual patient and the concept of QoL gained a specific place in nursing. This is closely related to human needs, health, self-sufficiency, well-being, and daily activities [6]. The QoL is influenced by various spheres of life, individual expectations and perception of needs. The importance of particular dimensions can vary during the disease and during life itself [3].

The variability of symptoms, which depend on tumour localization, the strategy of neoadjuvant treatment, the extent of surgery, and adjuvant therapy can lead to different and individual QoL outcomes in patients with CRC.

The mean global health status score varied in our sample between 42.4–52.6. Statistically significant differences between patients with colon and rectal cancer was found 1 month after surgery for ratings of buttock pain ($p=0.001$), mouth dryness ($p=0.042$), impotence ($p=0.035$) and sore skin around the anus in patients without stoma ($p=0.039$).

The outcomes from our research differ from Ramsey et al. [7], who studied 227 patients with CRC and observed high scores of QoL, regardless of tumour localization, staging, and disease duration. Comorbidities and financial problems were of significantly higher negative impact.

Our findings are, on the other hand, supported by Bernadic and Pechan [8] who reported postoperative QoL correlating with the site of surgery and its complexity. The technique of radical colon cancer resection is less demanding than rectal surgery for multiple reasons such as different mesentery, easier manipulation with the colon and better visualization of constructed anastomosis.

The incidence of CRC increases with age. For example, in the U.S.A., the incidence in 45, 55, 65, and 75 years old patients is 10, 30, 90, and 200/100 000 respectively. The peak of CRC incidence is at 65–70 years of age. However, a patient's higher age is not a contraindication for therapeutic interventions including biological treatment. In older patients, the indication is modified by lower levels of fitness, comorbidities, and poor social background [9, 10].

Marventano states the outcomes of QoL assessment in patients with CRC are controversial regarding age. Some studies showed that QoL improves with age, while the others report a lower QoL in older patients [11].

In our cohort of CRC patients with ≥ 65 and < 65 years of age, the mean global health score varied between 30.6–52.8 and a statistically significant difference was observed between these groups preoperatively ($p=0.007$). A significant difference between these groups was also found for sexual interest in subgroups of men preoperatively ($p=0.020$) and 1 month postoperatively ($p=0.007$). Preoperatively, these two groups of ≥ 65 and < 65 years old showed a significant difference in the fatigue score ($p=0.019$) and constipation score ($p=0.028$). One month after surgery, there was a statistically significant difference in financial problems ($p=0.020$).

Similar outcomes were published by Arndt et al., who found a difference between two age groups (≥ 60 and < 60 years old). They found that the group below 60 had more financial problems. A lower score in the physical functioning domain was observed in patients who returned to work after completing treatment [12]. On the other hand, Forsberg et. al. (1996) did not confirm age as an indicator of QoL in patients with CRC [13].

Gender affects the incidence of CRC. Men have significantly higher incidence of CRC especially in rectal cancer. The ratio between colon and rectal cancer varies in different countries [9]. Natrah et al. performed a study in 2011 on a group of 100 patients in Malaysia. The authors reported

a statistically significant difference in cognitive functions between male and female patients. Men showed better cognitive functions in comparison with women. Mean scores of symptoms (fatigue, pain, nausea and vomiting, constipation, diarrhoea, insomnia, shortness of breath, loss of appetite) varied between 4.00 and 20.7. Women showed worse symptoms for pain, fatigue and shortness of breath [14].

In our research, the gender adjusted mean global health status score varied between 40.8 and 58.3. A statistically significant difference between men and women was observed one month after the surgical procedure for body image ($p=0.031$) and constipation ($p=0.007$). Preoperatively, a significant difference was found for anxiety ($p=0.023$).

Similar results were published in a German study by Arndt et al. who assessed 439 patients with CRC one year from diagnosis using QLQ-C30 questionnaire. The most significant differences were gender related. Men reported better outcomes in emotional and cognitive components of QoL than women. On the other hand, the female patient achieved the worst results for pain, insomnia, tiredness, constipation and loss of appetite [4].

Hendren et al. performed a trial on sexual dysfunction in male and female patients after rectal cancer surgery. In total, 81 women and 99 men were included. Of the sexual problems evaluated by the EORTC questionnaire, women reported changes in libido, and pain and discomfort during intercourse. Male patients reported changes in libido, impotence, and partial impotence. Both genders perceived their body image negatively. The authors suggested that the risk of sexual dysfunction is rarely discussed prior to rectal cancer surgery and little attention is paid to the treatment of these complications [15].

Patients with stoma experience a number of losses, such as the loss of ability to control defecation and passage of gas, which can affect normal social life and lead to negative feelings and social and

psychological isolation. Patients lose dignity, have feelings of inferiority, and their body image and self-esteem suffer. Many times they are not able to face these situations and are self-disgusted [16].

In our study, the stoma adjusted mean global health status was 36.7–51.7. In physical functioning, a significant difference was observed 1 month after surgery between patients with and without stoma ($p=0.024$). Moreover, a statistical difference was found before ($p=0.045$) and one month after surgery ($p=0.047$) for the fatigue score.

Bossema et al. studied rectal cancer patients with and without stoma with regards to global health status, and emotional and cognitive functioning. The EORTC-C30 questionnaire was completed by a total of 122 patients. Of these, 62 had abdominoperineal resection with permanent stoma and 60 had low anterior resection without stoma. No significant differences were found between patients with and without stoma for any of the parameters. A stronger correlation between disease acceptance and QoL in relation to health was observed in non-stoma patients [17].

Sprangers et al. published a meta-analysis focused on QoL in CRC patients with and without stoma. Of all searched papers published between 1969 and 1992, 17 studies were identified, which evaluated at least one of four aspects of patient functioning (physical, psychical, social, and sexual) and compared the groups with and without stoma. The study concluded that both groups of patients suffer from frequent irregular bowel motions and diarrhoea. However, patients with stoma reported higher psychical distress. Both groups reported deterioration in social functioning. However, these problems are more common in patients with colostomy [18].

Radiotherapy remains a part of a multimodal approach and is currently applied either as a neoadjuvant or adjuvant treatment [19]. According to Büchler, radiotherapy plays an important

role in reduction of local recurrence and palliative therapy of both symptomatic and high risk metastatic lesions [10].

In our research, the rectal cancer patients with and without complete CRT were compared. The mean global health status of these patients was 41.7–50.0. A significant difference between the above mentioned groups was found in cognitive functioning ($p=0.010$) and in blood and mucus in stool 1 month after surgery ($p=0.023$).

Arndt et al. presented QoL outcomes one year after diagnosis and after treatment (surgery, chemotherapy, and/or radiotherapy). Higher scores for physical and cognitive functioning, but lower scores for emotional functioning were observed while 80% of patients felt depressed, irritated, nervous and fearful [12].

A Norwegian prospective study including 42 patients with rectal cancer was published by Guren et al. in 2003 that evaluated symptoms and QoL during neoadjuvant radiotherapy. QLQ-CR38 was completed at the beginning, at the end of radiotherapy and 4–6 weeks afterwards. The scores for diarrhoea, fatigue, and loss of appetite were higher after radiation compared to initial values. The authors found 64% of patients felt fatigue and 52% had worsened diarrhoea during the treatment. However, the overall QoL assessed 4–6 weeks after radiotherapy was comparable with values measured before the treatment [20].

The limitation of our study was that the first QoL assessment was scheduled relatively shortly after surgery. Nevertheless, our primary aim was to determine the suitability of QoL evaluation in a homogenous group of patients with CRC and implement this method into practice. Thus, we created conditions for long-term follow-up and QoL evaluation as a component of complex care of patients with CRC.

CONCLUSION

In addition to routinely monitored data during complex treatment of patients with CRC (length of stay, blood loss, early and late complications, overall survival, disease free interval etc.), QoL is an equally important outcome of medical, surgical, and nursing interventions. The QoL reflects the individual postoperative limitations of everyday activities and provides a feedback on how the treatment affects patients' lives. Currently, non-physician health care professionals are getting more involved in data collection and evaluation.

A significant correlation between the QoL score and the type of treatment was found in our study. Neoadjuvant CRT and surgery with stoma seemed to have a negative effect on overall QoL.

REFERENCES

- 1 - Nadacia na pomoc onkologickým pacientom. <http://www.npop.sk/>. Accessed on April 14, 2016.
- 2 - Cancer.Net. <http://www.cancer.net/>. Accessed on November 12, 2015.
- 3 - Angelovicova K, Argayova I, Cuperova J. Hodnotenie a vyskum kvality zivota v urologii. *Presov: Univerzitna Kniznica Presovskej Univerzity*; 2010,12-19.
- 4 - Svehlikova L, Heretik A. Kvalita zivota - o com to hovorme? *Psychiatria - Psychoterapia - Psychosomatika*. 2008;15:194-198.
- 5 - Kroupa K. Zasady a moznosti chirurgickej liecby kolorektálneho karcinomu. *Onkologia* (Bratisl). 2006;1(1):42-50.

- 6 - Gurkova E. Hodnoceni kvality zivota. *Praha: Grada Publishing*; 2011:224.
- 7 - Ramsey SD, Berry K, Moinpour C et al. Quality of life in long term survivors of colorectal cancer. *Am J Gastroenterol.* 2002;97(5):1228-1234.
- 8 - Bernadic M, Pechan J. Chirurgicka liecba kolorektalneho karcinomu. *Kolorektalny Karcinom.* <www.farm-servis.cz/ext/files/article/3499/35_42.pdf>. Accessed on May 15, 2016.
- 9 - Vavrecka A. Epidemiologia, etiologia, klinicky obraz a prevencia kolorektalneho karcinomu. *Via Practica.* 2010;7:10 -13.
- 10 - Buchler, T. Strategie a cile lecby nemocnych s kolorektalnim karcinomem. *Kolorektalni Karcinom.* 2009;5:31-37.
- 11 - Marventano S, Forjaz M, Grosso G et al. Health related quality of life in colorectal cancer patients: state of the art. *BMC Surg.* 2013;13(2):S15.
- 12 - Arndt V, Merx H, Stegmaier C et al. Quality of life in patients with colorectal cancer 1 year after diagnosis compared with the general population: a population-based study. *J Clin Oncol.* 2004;22(23):4829-4836.
- 13 - Forsberg C, Bjorvell H, Cedermark B. Well-being and its relation to coping ability in patients with colo-rectal and gastric cancer before and after surgery. *Scand J Caring Sci.* 1996;10(1):35-44.
- 14 - Natrah MS, Ezat S, Syed MA et al. Quality of life in Malaysian colorectal cancer patients: a preliminary result. *Asian Pac J Cancer Prev.* 2012;13(3):957-962.
- 15 - Hendren SK, O'Connor BI, Liu M et al. Prevalence of male and female sexual dysfunction is high following surgery for rectal cancer. *Ann Surg.* 2005;242(2):212-223.
- 16 - Michelone Ade P, Santos VL. Quality of life of cancer patients with and without an ostomy. *Rev Lat Am Enfermagem.* 2004;12(6):875-883.

- 17 - Bossema ER, Seuntjens MW, Marijnen CA et al. The relation between illness cognitions and quality of life in people with and without a stoma following rectal cancer treatment. *Psychooncology*. 2011;20(4):428-434.
- 18 - Sprangers MA, Taal BG, Aaronson NK et al. Quality of life in colorectal cancer. Stoma vs. nonstoma patients. *Dis Colon Rectum*. 1995;38(4):361-369.
- 19 - Zanova, M. Problematika malnutricie u pacientov s kolorektalnym karcinomom (z pohladu onkologa). *Onkologia (Bratisl)*. 2008;3(5):324-330.
- 20 - Guren MG, Dueland S, Skovlund E et al. Quality of life during radiotherapy for rectal cancer. *Eur J Cancer*. 2003;39(5):587-594.

Table 1 – General characteristics of study cohort

Gender		Age		Surgical procedure		Colon cancer		Rectal cancer	
Men	Women	≥ 65	< 65	Colon cancer	Rectal cancer	Without stoma	With stoma	Without stoma	With stoma
20	10	18	12	19	11	14	5	6	5

Table 2 - Evaluation of quality of life in patients with colon cancer (group 1) and rectal cancer (group 2)

score ¹	Time point	Group 1 (N = 19) ^{4,5}	Group 2 (N = 11) ^{4,5}	p ²
QL2 Global health status	At entry	43.4 (23.7)	42.4 (23.7)	0.912
	1 month	52.6 (24.5)	47.7 (16.7)	0.562
	Difference	9.2 (-5.4; 23.9)	5.3 (-17.7; 28.3)	
	p ³	0.203	0.618	
BP Buttock pain	At entry	17.5 (23.2)	27.3 (32.7)	0.350
	1 month	7.0 (17.8)	45.5 (27.0)	0.001
	Difference	-10.5 (-21.3; 0.3)	18.2 (-5.0; 41.4)	
	p ³	0.055	0.111	
DM Dry mouth	At entry	31.6 (30.4)	33.3 (33.3)	0.884
	1 month	19.3 (25.6)	36.4 (18.0)	0.042
	Difference	-12.3 (-29.4; 4.8)	3.0 (-20.4; 26.4)	
	p ³	0.149	0.779	
IMP ⁴ Impotence	At entry	20.5 (32.0)	9.5 (16.3)	0.41
	1 month	25.6 (38.9)	0.0 (0.0)	0.035
	Difference	5.1 (-13.0; 23.2)	-9.5 (-24.6; 5.5)	
	p ³	0.549	0.172	
SS Sore skin without stoma	At entry	15.7 (23.9)	20.0 (28.1)	0.675
	1 month	11.9 (21.1)	38.9 (32.8)	0.039
	Difference	-5.1 (-16.3; 6.0)	22.2 (-6.3; 50.8)	
	p ³	0.337	0.102	

1 - Data are presented as means with standard deviation and mean difference with a 95% confidence interval

2 - Results from independent t-test

3 - Results from paired t-test

4 - Group 1: men N = 13, women N = 6; group 2: men N = 7, women N = 4

5 - Group 1: with stoma at entry N = 2, without stoma at entry N = 17

with stoma in 1 month N = 5, without stoma in 1 month N = 14

Group 2: with stoma at entry N = 1, without stoma at entry N = 10

with stoma in 1 month N = 5, without stoma in 1 month N = 6

Table 3 – The quality of life stratified by age groups (≥ 65 years and < 65 years)

score ¹	Time point	≥ 65 (N = 18) ^{4,5}	< 65 (N = 12) ^{4,5}	p ²
QL2 Global health status	At entry	51.4 (24.5)	30.6 (14.8)	0.007
	1 month	52.8 (26.4)	47.9 (12.9)	0.508
	Difference	1.4 (-16.0; 18.8)	17.4 (2.8; 31.9)	
	p ³	0.868	0.023	
SEXM ⁴ Sexual interest (men)	At entry	33.3 (20.1)	8.3 (23.6)	0.020
	1 month	30.6 (22.3)	4.2 (11.8)	0.007
	Difference	-2.8 (-13.7; 8.1)	-4.2 (-14.0; 5.7)	
	p ³	0.586	0.351	
FA Fatigue	At entry	24.7 (22.7)	50.0 (33.0)	0.019
	1 month	40.1 (23.8)	47.2 (20.7)	0.408
	Difference	15.4 (4.4; 26.5)	-2.8 (-21.8; 16.3)	
	p ³	0.009	0.754	
CO Constipation	At entry	24.1 (35.8)	58.3 (45.2)	0.028
	1 month	16.7 (30.8)	8.3 (15.1)	0.334
	Difference	-7.4 (-25.9; 11.1)	-50.0 (-81.9; -18.1)	
	p ³	0.409	0.005	
FI Financial difficulties	At entry	18.5 (28.5)	16.7 (26.6)	0.859
	1 month	42.6 (35.8)	13.9 (22.3)	0.020
	Difference	24.1 (10.4; 37.8)	-2.8 (-13.7; 8.1)	
	p ³	0.002	0.586	

1 - Data are presented as means with standard deviation and mean difference with 95% confidence interval

2 - Results from independent t-test

3 - Results from paired t-test

4 - Group 1: men N = 12, women N = 6; group 2: men N = 8, women N = 4

5 - Group 1: with stoma at entry N = 1, without stoma at entry N = 17
with stoma in 1 month N = 4, without stoma in 1 month N = 14

Group 2: with stoma at entry N = 2, without stoma at entry N = 10
with stoma in 1 month N = 6, without stoma in 1 month N = 6

Table 4 – The outcomes of quality of life evaluation in patients with CRC stratified by gender

score ¹	Time point	Men (N = 20) ⁴	Women (N = 10) ⁵	p ²
QL2 Global health status	At entry	40.8 (19.7)	47.5 (29.9)	0.469
	1 month	47.1 (22.3)	58.3 (19.6)	0.188
	Difference	6.3 (-7.4; 19.9)	10.8 (-15.5; 37.2)	
	p ³	0.349	0.377	
BI Body image	At entry	75.6 (26.4)	61.1 (29.3)	0.184
	1 month	72.2 (23.5)	48.9 (31.9)	0.031
	Difference	-3.3 (-14.0; 7.4)	-12.2 (-32.9; 8.5)	
	p ³	0.522	0.214	
ANX Anxiety	At entry	63.3 (28.4)	36.7 (29.2)	0.023
	1 month	58.3 (32.2)	46.7 (23.3)	0.318
	Difference	-5.0 (-14.2; 4.2)	10.0 (-12.6; 32.6)	
	p ³	0.267	0.343	
CO Constipation	At entry	40.0 (41.3)	33.3 (47.1)	0.694
	1 month	20.0 (29.4)	0.0 (0.0)	0.007
	Difference	-20.0 (-42.3; 2.3)	-33.3 (-67.1; 0.4)	
	p ³	0.076	0.052	

1 - Data are presented as means with standard deviation and mean difference with 95% confidence interval

2 - Results from independent t-test

3 - Results from paired t-test

4 - Men: with stoma at entry N = 1, without stoma at entry N = 19
with stoma in 1 month N = 7, without stoma in 1 month N = 13

5 - Women: with stoma at entry N = 2, without stoma at entry N = 8
with stoma in 1 month N = 3, without stoma in 1 month N = 7

Table 5 - Evaluation of quality of life in patients with and without stoma

score ¹	Time point	With stoma ^{4,5} (N = 10)	Without stoma ^{4,5} (N = 20)	p ²
QL2 Global health status	At entry	36.7 (17.7)	46.3 (25.4)	0.296
	1 month	49.2 (15.4)	51,7 (24.7)	0.773
	Difference	12.5 (-3.0; 28.0)	5,4 (-11.2; 22.0)	
	p ³	0.101	0.503	
PF2 Physical functioning	At entry	75.3 (21.1)	87.0 (15.8)	0.100
	1 month	48.0 (22.8)	70.7 (25.2)	0.024
	Difference	-27.3 (-47.9; -6.8)	-16.3 (-26.2; -6.5)	
	p ³	0.015	0.003	
FA Fatigue	At entry	50.0 (31.5)	27.2 (26.1)	0.045
	1 month	54.4 (18.5)	37.2 (22.6)	0.047
	Difference	4.4 (-13.2; 22.1)	10.0 (-3.2; 23.2)	
	p ³	0.583	0.128	

1 - Data are presented as means with standard deviation and mean difference with 95% confidence interval

2 - Results from independent t-test

3 - Results from paired t-test

4 - Group 1: men N = 7, women N = 3; group 2: men N = 13, women N = 7

5 - Group 1: with stoma at entry N = 2, without stoma at entry N = 8
with stoma in 1 month N = 10, without stoma in 1 month N = 0

Group 2: with stoma at entry N = 1, without stoma at entry N = 19
with stoma in 1 month N = 0, without stoma in 1 month N = 20

Table 6 - Evaluation of quality of life in rectal cancer patients without (group 1) and with completed neoadjuvant chemoradiotherapy (group 2)

score ¹	Time point	Group 1 (N = 2) ^{4,5}	Group 2 (N = 9) ^{4,5}	p ²
QL2 Global health status	At entry	45.8 (5.9)	41.7 (26.4)	0.835
	1 month	50.0 (23.6)	47.2 (16.7)	0.844
	Difference p ³	4.2 (-260.5; 268.9) 0.874	5.6 (-22.7; 33.8) 0.663	
CF Cognitive functioning	At entry	100.0 (0.0)	79.6 (18.2)	0.010
	1 month	91.7 (11.8)	81.5 (17.6)	0.464
	Difference p ³	-8.3 (-114.2; 97.6) 0.500	1.9 (-17.8; 21.5) 0.999	
BMS Blood and mucus in stool	At entry	58.3 (58.9)	20.4 (18.2)	0.528
	1 month	0.0 (0.0)	13.0 (13.9)	0.023
	Difference p ³	-58.3 (-587.8; 471.1) 0.395	-7.4 (-27.8; 13.0) 0.426	

1 - Data are presented as means with standard deviation and mean difference with 95% confidence interval

2 - Results from independent t-test

3 - Results from paired t-test

4 - Group 1: men N = 1, women N = 1; Group 2: men N = 6, women N = 3

5 - Group 1: with stoma at entry N = 0, without stoma at entry N = 2
with stoma in 1 month N = 1, without stoma in 1 month N = 1
Group 2: with stoma at entry N = 1, without stoma at entry N = 8
with stoma in 1 month N = 4, without stoma in 1 month N = 5