

Health-related quality of life assessment in patients with rectal cancer treated with curative intent

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ABSTRACT – Background – The treatment of median and distal rectal cancer has evolved a lot in the last decades due to the dissemination of the technique of total mesorectal excision and the use of neoadjuvant chemotherapy and radiotherapy. However, this multidisciplinary approach can affect patients' quality of life in a number of ways that deserve to be adequately assessed. **Objective** – To evaluate immediate and late health related quality of life in patients with rectal cancer treated with curative intent. **Methods** – Prospective study including patients with non-metastatic mid or low rectal cancer. EORTC QLQ-C30 and EORTC-CR38 questionnaires were applied before, 3 months and 12 months after treatment. The mean scores of the questionnaires were stratified into 4 categories for the purpose of comparing the results at different moments. **Results** – Twenty nine patients completed the 1st and 2nd questionnaires and 12 completed the three questionnaires. Patient's mean age was 50.8 years and 62% were female. Sphincter preservation was possible in 89.6%. Overall health scores and quality of life improved after three months after 12 months. After three months, sexual satisfaction, female sexual problems and future perspective were worsen, but gastrointestinal symptoms, sphincter problems, and weight loss were improved. After 12 months the Future Perspective deteriorated, but there was improvement of the problems related to stoma, sphincter problems and body image. **Conclusion** – Despite the complexity of the treatment of rectal cancer within a specialized service, quality of life was preserved and was satisfactory in most of the studied aspects.

HEADINGS – Quality of life. Rectal neoplasms. Health related quality of life. Colorectal neoplasms.

INTRODUCTION

Mid and distal rectal cancer (RC) treatment has evolved a lot in the last decades due to the dissemination of total mesorectal excision technique and the use of neoadjuvant chemotherapy and radiotherapy. Although this multidisciplinary treatment improves local control and survival rates, there are still a number of problems that affect patients' quality of life (QoL) since the time of diagnosis. Patients need to adjust to an illness that threatens life expectancy, need diagnostic procedures and therapeutic interventions, and can cause symptoms such as inappetence, nausea, vomiting, abdominal discomfort, diarrhea, and constipation. While patients undergoing abdominoperineal resection should adapt to a definitive colostomy, those undergoing anal sphincter-preserving surgeries should adapt to a situation in which there may be urgency to evacuate, episodes of incontinence and increased evacuation frequency⁽¹⁻³⁾.

A review of 54 published studies on quality of life after surgical treatment of RC showed that the patients presented a series of physical problems, mainly related to sexual performance and to the urinary and intestinal functions⁽⁴⁾. Several other studies have shown important changes in quality of life in relation to physical, psychological and social limitations, among others⁽¹⁻¹¹⁾.

Understanding that for many reasons the quality of life can be significantly altered in the treatment of rectal cancer, we propose to study the quality of life in a specialized cancer center in order to increase knowledge about the characteristics of these patients and the immediate and late consequences of their treatment.

METHODS

This study was approved by Committee of Ethics in Research of the Institute of Cancer of the State of São Paulo on n. 035/13 and all patients have signed an Informed Consent term.

A prospective unicentric cohort study was conducted between January 2015 and January 2017. We included patients older than 18 years with a diagnosis of locally advanced mid or low rectal cancer (T3, T4 or N+) treated with curative intent. We excluded patients who could not understand the quality of life questionnaires, patients with previous treatment for colorectal cancer in another service, who had a second primary tumor, previous intestinal resections regardless of the cause, recurrent tumors, and disabling health conditions.

The neoadjuvant treatment consisted of 5-Fluoracil at the dose of 350mg/m² in intravenous bolus in the first and last five days concomitant with radiotherapy. The total dose of pelvic radiation was 5040 cGys applied in 28 consecutive sessions of 180 cGys each. After the end of the neoadjuvant treatment, the patients were re-staged between 8 and 10 weeks, and then underwent surgical treatment.

The surgical treatment consisted of rectosigmoidectomy with total mesorectum excision and high ligation of the inferior mesenteric vessels. Surgical options included low anterior resection with preservation of the sphincter or abdominoperineal resection, depending on the sphincter invasion at re-staging.

For quality of life assessment, we used a cancer generic questionnaire EORTC (European Organization for Research and

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Treatment of Cancer), QLQ C30⁽¹²⁾ validated for Brazil⁽¹³⁾ and a questionnaire specific for colorectal cancer, the EORTC CR 38^(14,15).

The EORTC QLQ C30⁽¹²⁾ consists of 30 questions, five of which are functional scales (physical function, role performance, cognitive function, emotional function and social function); three scales of symptoms (fatigue, nausea and vomiting, and pain); items that evaluate symptoms (dyspnoea, anorexia, insomnia, constipation and diarrhea); assessment of the financial impact of the disease and treatment; and a global health measure and quality of life. The questions are considered for events that occurred in the last week.

Similarly, EORTC CR 38⁽¹⁴⁾ has 38 questions, of which 19 are applied to all, and 19 are applied to specific subgroups such as men and women, with or without stoma. The instrument has two functional scales (body image and sexual function) and seven scales of symptoms/problems (urination problems, chemotherapy effects, gastrointestinal tract symptoms, female sexual problems, male sexual problems, sphincter problems, and stoma related problems). The items on Sexual Satisfaction, Weight Loss and Future Perspective are analyzed separately.

The answers follow a Likert scale score: 1= no, 2= little, 3= moderately, and 4= a lot. Global Health and Quality of Life scale requests scores from 1 to 7, being 1-bad and 7-optimal⁽¹²⁾. The scales and items are transformed into scores from 0 to 100. A high score for Functional Scales represents a healthy functional level, while a high score for Symptoms/Problems, represents a high level of symptomatology or problem.

In order to compare the mean scores between the questionnaires carried out at different moments, we adopted the following classification suggested by Akhondi-Meybodi et al.⁽¹⁶⁾ with respect to the functional scales: score 0-25= very poor, 26-50 = poor, 51-75= good, 76-100= very good. In relation to the scales of symptoms / problems were considered the values in the inverse way (score from 0-25= very good, 26-50= good, 51-75= poor, 76-100= very poor).

Data were collected through interviews at three moments: the first before treatment, the second 3 months after surgery, and the third 12 months after surgery.

RESULTS

Fifty-eight consecutive patients meet the inclusion criteria. Among them, only 29 answered the 1st and 2nd interviews, and only 12 answered the three interviews.

Eighteen (62%) patients were female and the mean age was 50.8±11.4 years. The majority lived with partners (69%), 58.6% were white, 69% had dependents, 86.2% had income of up to 4 minimum wages, and 62.5% had primary or secondary education. Seventy-six percent underwent laparoscopic surgery, and sphincter preservation was possible in 89.6% of the cases.

TABLES 1 and 2 show the results of the HRQoL (mean, standard deviation) before (1st interview), 3 months after treatment (2nd interview) and 12 months after treatment (3rd interview) respectively for EORTC QLQ- C30 and EORTC CR-38.

We can verify that the initial scores of the patients' functional scales (ie, before any treatment) were all classified as "good" (score of 51 to 75) or "very good" (score of 76 to 100), according to established criteria. And at the same time, most of the mean scores for the symptoms were below 50 points, which in terms of symptoms means "good" or "very good."

Regarding the differences in the scores between the 1st, 2nd and 3rd interviews we can note that:

- General Health Status and Global quality of life (GHS/GQL) improved with treatment after 3 months and 12 months.
- There was no deterioration of any scale. In addition, all scales after 12 months were at least equal (good) or better (very good), most of which were categorized as "very good" (TABLE 1).

TABLE 1. Descriptive analysis of HRQOL scores (means, standard deviation) of EORTC QLQ-C30 before (1st interview), 3 months after treatment (2nd interview) and 12 months after treatment (3rd interview). São Paulo, 2017.

	1st interview Mean (SD) n=29	2nd interview Mean (SD) n=29	3rd interview Mean (SD) n=12
Scales			
GHS/GQL*	73.0 (23.3) Good	78.1 (16.9) Very good	79.8 (13.5) Very good
Functional			
Physical function	89.7 (16.1) Very good	93.6 (11.2) Very good	91.7 (15.3) Very good
Role function	76.1 (32.8) Very good	81.0 (22.1) Very good	78.1 (29.4) Very good
Emotional function	66.4 (26.4) Good	75 (19.9) Good	70.8 (26.2) Good
Cognitive function	71.9 (31.1) Good	82.2 (20.9) Very good	83.3 (28.4) Very good
Social function	90.2 (19.2) Very good	85.1 (24.9) Very good	97.2 (6.5) Very good
Symptoms			
Fatigue	21.8 (33.2) Very good	1.2 (4.3) Very good	7.4 (15.2) Very good
Nausea and vomiting	13.2 (28.3) Very good	8.5 (13.5) Very good	1.4 (4.8) Very good
Pain	32.2 (34.8) Good	13.2 (21.1) Very good	13.9 (29.16) Very good
Symptoms (items)			
Dyspnoea	1.2 (6.2) Very good	5.7 (15.6) Very good	5.5(13.0) Very good
Insomnia	34.5 (40.3) Good	23.0 (31.0) Very good	16.7 (33.3) Very good
Appetite loss	20.7 (35.0) Very good	5.7 (15.6) Very good	11.1 (29.6) Very good
Constipation	34.5 (37.3) Good	5.7 (18.0) Very good	5.5 (13.0) Very good
Diarrhoea	13.8 (28.9) Very good	14.9 (29.0) Very good	22.2 (38.5) Very good
Financial difficulties	23.0 (36.8) Very good	27.6 (36.8) Good	19.4 (30.0) Very good

* General Health Status and Global quality of life.

TABLE 2. Descriptive analysis of HRQOL scores (means, standard deviation) of EORTC CR-38 before (1st interview), 3 months after treatment (2nd interview) and 12 months after treatment (3rd interview). São Paulo, 2017.

	1st interview Mean (SD) n=29	2nd interview Mean (SD) n=29	3rd interview Mean (SD) n=12
Functionals scales			
Body image	87.8 (19.6) Very good	87.7 (21.3) Very good	95.4 (12.9) Very good
Sexual function	54.6 (29.2) Good	63.8(29.2) Good	59.7 (28.8) Good
Symptoms/problems			
Voiding problems	8.5 (12.1) Very good	4.4 (6.5) Very good	3.0 (7.2) Very good
Chemotherapy side-effects	Not applicable	13.0 (16.8) Very good	12.9 (13.5) Very good
Gastrointestinal symptoms	29.2 (23.7) Good	10.3 (11.1) Very good	10.3 (15.4) Very good
Male sexual problems	6.5 (14.2) Very good	35.4 (37.4) Good	35.7 (39) Good
Female sexual problems	21.4 (32.9) Very good	50 (31.2) Poor	Not applicable
Sphincter problems	52.9 (24.4) Poor	14.8 (12.8) Very good	26.5 (22.5) Good
Stoma-related problems	Not applicable	30.0 (22.6) Good	14.3 (8.9) Very good
Symptoms			
Weight loss	37.9 (34.2) Good	14.9 (31.6) Very good	2.8 (9.6) Very good
Items			
Sexual satisfaction	69.8 (27.7) Good	48.3 (38.2) Poor	51.8 (41.2) Good
Future perspective	54.0 (28.8) Good	46.0 (36.1) Poor	36.1 (43.7) Poor

The results of a descriptive analysis of the HRQOL scores (means, standard deviation) of the EORTC CR-38 before (1st interview), 3 months after treatment (2nd interview) and 12 months after treatment (3rd interview), in relation to the scale for the classification of scores, showed that:

- All variables except “sphincter problems” were considered “good” or “very good” in the initial evaluation.
- There was “very good” maintenance of the functional scales “body image”, “sexual function”, and “voiding problems”. Similarly, there was no worsening of chemotherapy-related symptoms (keeping in the “very good” range in the three moments of the interviews).
- There was improvement in gastrointestinal symptoms and weight loss, but there was worsening of sexual problems in both men and women. There was no information regarding the women sexual problems in the third interview due to their sexual inactivity during this period.
- There was improvement of the stoma-related symptoms in the late period when compared to the period after three months of surgery.

- Sexual satisfaction worsened after three months of surgery, but improved again at 12 months.
- The future perspective worsened in the 2nd interview and did not improve again in the 3rd interview.

DISCUSSION

Our study allowed a broad view of the characteristics of patients with rectal cancer treated in our institution.

Regarding our sample size, we can verify that it is inferior to most of the other published studies, whose samples ranged from 21 to 575 cases^(1,2,6,7,16-18). However, it is worth emphasizing that the studies with the largest number of cases were multicentric, with one involving up to 30 services from eight different nationalities⁽¹⁸⁾, which could even be criticized for including people from different cultures, religions and nationality that would certainly make the sample very heterogeneous and with different perceptions about quality of life. Corroborating with this idea, How et al.⁽²⁾, in 2012, similarly performed QOL investigation in a multicenter study in the United Kingdom and another European center with modest sample size to the proportion of the study, emphasizing on the importance of the prospective study and that the retrospectives, even with larger sample sizes, are subject to greater bias in relation to the selection of the participants and the results obtained from the object itself.

When we evaluated the unicentric studies we noticed that the samples ranged from 21 to 120 patients, most of them being less than 60 patients^(1,2,17,19). Our study was initially conducted with 58 patients diagnosed with cancer were at the beginning of treatment, but unfortunately only 29 were within the criteria for analysis and could then be used. The reason for the limited size of our sample may be justified by the fact that some metastatic patients were excluded at the time of their initial diagnosis. This is due to the poor access of the population to good health services with good professionals and well equipped enough for the early diagnosis of this condition. In addition, we had to exclude some patients from other services where they were forced to undergo emergency surgery due to intestinal obstruction, and some stoma was made prior to the start of definitive treatment of rectal cancer in our institution. This could cause some bias in our sample since this could obviously negatively affect the individual's perception of their quality of life even before the start of their treatment. In addition, we had to exclude patients who had difficulty understanding and responding to questionnaires, or who were simply not sufficiently motivated to participate in the study because they did not envisage any benefit or for any other personal reason. In a way, it is observed that older individuals who already have some degree of deterioration in their quality of life due to other conditions, or because they no longer have sexual partners or active sex life, feel less motivated to participate in studies like this one. Likewise, it is known that there is a greater difficulty for women to participate mainly because of their embarrassment in the questioning of their sex life, even when the questionnaires are applied individually without the presence of the researcher⁽³⁾. Despite this possible constraint on women in research participation, the female sex was predominant (18:11) in the present study, which is in agreement with other national studies^(19,20), but contrary to what happens in most international studies^(16,23).

The mean age of our patients was 50.8 years. As in this study, in the other studies age was not used as an exclusion criterion^(1,2,4,6,15-19). It was observed that the average age found in the literature ranged from 60-79 years. These values may vary from country to country⁽²⁴⁾.

Cancer is a chronic degenerative disease associated with aging, and is most often manifested in individuals over 50 years of age⁽²⁰⁾, so the evaluation of the impact of RC on HRQoL should consider the incidence of this age group due to its epidemiological relevance. However, in our study we did not aim to analyze whether age would be a relevant factor in the evaluation of quality of life.

It is worth noting that in our study we used EORTC QLQ-C30^(12,13) and CR38^(14,15), as well as most of the other studies as instruments. However, some studies have used other validated instruments that may lead to difficulties in comparing the results between the studies due to their different methodology. Michelone & Santos⁽¹⁾ chose to use WHOQOL-bref, while other studies used additional specific questionnaires such as St Marks's Bowel Function, Coloplast stol QOL15⁽²⁾, Beck Depression and Anxiety Inventory⁽¹⁹⁾, EuroQol 5D⁽¹⁸⁾.

Studies of HRQoL in patients with rectal cancer appear conflicting. However, it remains implicit that there are changes in the habitual way of living after the treatment of rectal cancer. In the presence or absence of a stoma, which certainly alters the body image⁽⁷⁾, the surgical procedure itself will bring about physiological changes, of body image that can clearly be felt by the patients, especially at first moment. The preparation of a stoma may bring about perceptions of physical and emotional limitation, due to the alterations in the body image with the exteriorization of the intestinal loop, absence of control of feces and gas. The adaptation to the use of the stoma bag can cause dependence to the care of others and feeling of social rejection, consequently impairing the social conviviality and its leisure activities. In addition, excludent feelings may be present due to the feeling of being "dirty" exacerbating social exclusion and may be linked to daily coping with this impairment in paper performance.

Michelone & Santos⁽¹⁾, evaluating colorectal cancer patients comparing the presence and absence of stomies, used the World Health Organization generic questionnaire for quality of life of the WHOQOL-bref, in which the non-stomized patients presented better scores for all domains compared to the stomates, even though there was no significant difference between groups. Sun et al.⁽⁷⁾ in a US study found that women with stoma had difficulties with self-image and were more likely to be rejected by their partners.

In the study by How et al.⁽²⁾, specifically designed to answer the questions about the impact of abdominoperineal resection on QoL, it was not possible to demonstrate evident differences between patients with or without sphincter preservation⁽²⁾. In addition, one of the most important studies in this area, a *Cochrane* review⁽⁵⁾ published in 2012, challenges the perception that HRQoL would be worse in the long term stomized patients and highlights the need for better prospective studies to actually substantiate this idea. Our study was not designed to respond specifically to this question. In fact, because we are a very specialized center for the treatment of rectal cancer, and because we have highly trained surgeons in sphincter preservation techniques, we can explain our high rate of sphincter preservation in this population (89.6%). On the other hand, despite our high index of sphincter preservation, it is worth mentioning that 13.7% of the patients underwent an interphincteric resection with a colo-anal hand-sewn anastomosis, which is already known in the literature to present poorer functional results when compared to a colorectal anastomosis by double stapling, even more in patients who were previously treated with chemoradiotherapy⁽²¹⁾. We know from literature that a poorer functional outcome of this colo-anal hand-sewn anastomosis may

translate into a quality of life comparable to that of individuals with a definitive colostomy, as well demonstrated in the *Cochrane* review⁽⁵⁾. Although our study was not specifically designed to answer these questions, it is worth mentioning that in our experience the mean score for "stoma problems", whether definite or temporary, improved from the 2nd to the 3rd interview, in agreement with the literature when the individual at a later stage has already learned and adapted better the presence of the stoma, and has already overcome all the fears of the initial period.

It is also worth mentioning that 75.8% of our surgical procedures were performed through the laparoscopic access route, which can be considered a high rate in comparison to the largest centers in the world, indicating that our Service is highly qualified for the minimally invasive treatment of cancer, despite the fact that the surgical access was not evaluated as an impact factor in the quality of life in the present study. Interestingly, Andersson et al.⁽¹⁸⁾ in a multicenter randomized study using the EORTC QLQ-C30 and EORTC QLQ-CR38 and EuroQol-5D instruments found that HRQL after rectal cancer surgery was not affected by surgical approach.

The religious component was not investigated in this study, but was very latent in the affirmations and justifications of the patients. This helps us in understanding the subjectivity of the subject who experiences such changes and that QoL is about the influence of culture, values and personal satisfaction^(1,22), and also on the issue of the person's difficulties in expressing their perceptions through a structured questionnaire. The verbalization with their own words possibly translates the experience better and points to suggestions for both quantitative and qualitative studies⁽²³⁾.

In the present study, it was possible to observe that patients experienced changes that limited habitual living during the treatment. Although rectal cancer treatment is complex and challenging, we would like to emphasize that the overall quality of life score improved after treatment in the earlier and later stages. In the same way, role, physical, emotional, cognitive and social functions, and body image were also preserved at a good level. This serves as a stimulus and a reward for the intense multidisciplinary work required treating this condition. As aggressive this treatment may be, the relief and improvement of the symptoms caused by rectal cancer justify its treatment. In the study of Machado and Sawada⁽¹⁷⁾ performed in Ribeirão Preto with 21 patients applying the same questionnaires of our study, both cognitive function and social function had their means decreased after three months of treatment. However, they commented that even in the case of changes in scales scores the overall health status/QoL score showed that the quality of life remained the same compared to the beginning and three months after. Still in the same study⁽¹⁷⁾, both cognitive function and social function worsened after three months of treatment. However, they commented that even with changes in scales scores, the overall health status/QoL score showed that quality of life remained the same when compared to the beginning and three months after.

Regarding financial difficulties, the subjects evaluated in our study presented a worsening in the 2nd interview. Removal from work due to limitations imposed by therapy (chemo/radiotherapy) and the use of stoma devices may be determinant factors for return to work. Activities can be affected as the subject is faced with the role they are assigned to play. However, in the 3rd interview, there was a recovery of this score, which may be attributed to the possibility of returning to work, even if the stoma is still present 1 year after surgery, when the individual is already better physically, psychologically and better recovered from post trauma surgery.

We know that chemotherapy is a systemic treatment that has a large impact on the division of tumor cells, causes toxicity by the deleterious effect on the division of normal cells of the body such as bone marrow or gastrointestinal tract⁽²²⁾. Similarly, radiation therapy causes changes as a result of local radiation that may compromise the patient's functionality⁽²¹⁾. Curiously in our study the problems of the effects of chemotherapy have always remained low. Machado and Sawada⁽¹⁷⁾, however, found a decrease in the physical function of patients who underwent chemotherapy, although it did not have a negative impact on overall quality of life due to elevated general health/quality of life scores.

Our study has some limitations. Among them we must mention the relative small number of the sample. In addition, the fact that most patients have not yet responded to the 3rd interview to date may have impaired the analysis of quality of life data in the late postoperative period.

CONCLUSION

Based on our data, we can conclude that despite the complexity

of the multidisciplinary treatment of rectal cancer within a specialized service, the quality of life was preserved and was satisfactory in most of the studied escales.

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Authors' contribution

Souza JLCA contributed to data collection, data analysis, interpretation of results and drafted the manuscript. Nahas CSR designed the study, contributed to data analysis, interpretation of results, preparation and review of the manuscript. Nahas SC contributed to the design of the study, data analysis and revision of the manuscript. Marques CFS, Ribeiro Júnior U and Ceconello I contributed to the interpretation of the results and the revision of the manuscript. All authors have read and approved the article for publication.

Souza JLCA, Nahas CSR, Nahas SC, Marques CFS, Ribeiro Júnior U, Ceconello I. Avaliação sobre qualidade de vida relacionada à saúde em pacientes com câncer retal tratados com intenção curativa. *Arq Gastroenterol.* 2018;55(2):154-9.

RESUMO – Contexto – O tratamento do câncer de reto médio e distal evoluiu muito nas últimas décadas devido à disseminação da técnica de excisão total do mesorretal e ao uso de quimioterapia e radioterapia neoadjuvantes. No entanto, essa abordagem multidisciplinar pode afetar a qualidade de vida dos pacientes de várias maneiras que merecem ser adequadamente avaliadas. **Objetivo** – Avaliar a qualidade de vida imediata e tardia relacionada à saúde em pacientes tratados de câncer retal com intenção curativa. **Métodos** – Estudo prospectivo que incluiu pacientes com câncer primário de reto médio ou baixo não metastático. Foram aplicados os questionários EORTC QLQ-C30 e EORTC-CR38 antes, 3 meses e 12 meses após o tratamento. As médias dos escores dos questionários foram estratificadas em quatro categorias para fins de comparação dos resultados nos diferentes momentos. **Resultados** – Vinte e nove pacientes responderam aos 1º e 2º questionários e 12 responderam os três questionários. A idade média foi de 50,8 anos e 62% do sexo feminino. Preservação esfinteriana foi possível em 89,6%. As médias de escores globais de saúde e qualidade de vida melhoraram tanto após 3 meses quanto após 12 meses. Função cognitiva, dor, insônia, constipação, sintomas gastrointestinais, problemas esfinterianos, perda de peso melhoraram tanto no período imediato quanto tardio. Problemas sexuais masculinos e femininos e perspectiva futura pioraram tanto no período precoce quanto tardio. As demais funções ou sintomas ou itens não se alteraram. **Conclusão** – Apesar da complexidade do tratamento do câncer de reto dentro de um serviço especializado, a qualidade de vida ficou preservada ou melhor na maioria das características estudadas.

DESCRITORES – Qualidade de vida. Perfil de impacto da doença. Neoplasias retais. Qualidade de vida relacionada à saúde. Estudos de coorte. Neoplasias colorretais.

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