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ORIGINAL ARTICLE

Quality of Life After "Total Mesorectal Excision (TME)" for Rectal Carcinoma: a Study from a Tertiary Care Hospital in Northern India

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Abstract Quality of life (QoL) is a key element in rectal cancer (RC) patients. There is not much data regarding this from North India. This study assesses QoL following low anterior resection (LAR) and abdominoperineal resection (APR), operated for low rectal tumors at a high-volume center in northern India. One-hundred-thirty patients of rectal carcinoma were prospectively assessed for quality of life using the European Organization for Cancer QLQ-30 and CR29 questionnaires and compared with reference data population. There was no significant difference in the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 functional or symptom score between the study group and reference data population. Specific functional and symptom QoL scores of the study group were comparable to that of reference data population. There was no significant difference in the EORTC QLQ-C30 functional or symptom score between APR and LAR groups, except for the symptom of nausea and vomiting which was reported significantly more by the LAR group patients than APR group ($p = 0.001$). LAR patients had significantly higher scores with regard to nausea and vomiting than patients with an APR ($p < 0.05$). APR patients had significantly higher scores with regards to urinary frequency ($p = 0.0001$), abdominal pain ($p = 0.0001$), and embarrassment ($p = 0.0001$) than LAR patients. Quality of life after APR and LAR for rectal carcinoma was found to be comparable to the reference data population, and the QoL after APR was similar to that after LAR barring a few symptoms.

Keywords Total mesorectal excision · Quality of life · Rectal carcinoma

Introduction

Colorectal cancer is the second leading cause of cancer-related mortality and the fourth most prevalent malignant disease in many developed countries. It affects men and women almost equally. Almost 1 million new incident cases and 250,000 deaths occur worldwide each year [1]. Survival rates have increased throughout the last decades; approximately 80% of patients now survive the first year after diagnosis, and approximately 62% survive 5 years and more [2]. However, its prevalence in developing countries is still not clear.

Total mesorectal excision (TME) has become the gold standard for the treatment of cancer for the middle or lower third of the rectum. It has been shown worldwide that local recurrence rates have declined since the introduction of TME [3]. TME with pelvic autonomic nerve preservation (PANP) has been reported to be an ideal surgery for rectal carcinoma, as it minimizes local recurrence and sexual and bladder dysfunction [4, 5].

Urinary and sexual dysfunction is a well-known complication of colorectal surgeries. Increased understanding of anatomical and physiological background and improved surgical techniques have led to a reduction of such complication rate [6].

Colorectal cancer and its treatment also have adverse effects on various social activities, including work and productive life and relationships with friends, relatives, and partners. Patients with colorectal cancer, with or without stoma, are

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troubled by frequent or irregular bowel movements, diarrhea, flatulence, and fatigue, and often have to follow dietary restrictions [7, 8].

Thus, the high quality of TME should fulfill two clinical measurements: absence of impotence or incontinence and at least single digit, i.e., less than 10%, 5-year cumulative recurrence rate regardless of adjuvant therapy [9].

Besides disease-free and overall survival time, quality of life (QoL) has become an important outcome measure for cancer patients. The term quality of life refers to a multidimensional concept, which includes, at least, the dimensions of physical, emotional, and social functioning.

Assessment of QoL is equally important and it has been shown that there is a poor correlation between doctor and nurse assessment of the patient's quality of life and patient's own assessment, and there is wide variability between quality of life scores produced by doctors and different health professionals consecutively; hence, there is variability regarding quality of life scores post-operatively [10, 11].

Proper assessment of QoL in patients with cancer may improve our understanding of how cancer and therapy influence the patient's lives and how to adapt treatment strategies [12].

Material and Methods

Patients with rectal cancer, who underwent primary surgery at a high-volume center in North India over a period of 2 years, were prospectively observed.

The inclusion criteria were adults (aged 18 years and above), with a histologically confirmed primary rectal carcinoma presenting to or referred to our department and treated with radical resection with or without neoadjuvant therapy.

Patients underwent one of two surgical modalities:

a) LAR and
b) APR.

All patients provided written informed consent.

Data Collection

Patients, who had completed 1 year after surgery, without evidence of metastasis or recurrence on follow-up were interviewed and invited to participate in the study. They were given oral and written information concerning the research and told that they could withdraw from the study whenever they wished. Those patients who provided informed consent completed the questionnaires once during the follow-up period.

The European Organization for Research and Treatment of Cancer (EORTC) QLQ questionnaires were sent to patients or handed over personally and a demographic questionnaire for completion. To maximize the questionnaire response rate, subjects received a telephone call reminder if they did not respond within 30 days, and a new questionnaire was sent if needed. All aspects of the questionnaire survey and telephone interview were administered by a single person.

The data collected from the institutional colorectal cancer database and demographic questionnaire included age, sex, surgery type (LAR or APR), CRT before surgery, and stoma.

HRQoL was assessed by use of the validated EORTC core (QLQ-C30) [13] and colorectal cancer (QLQ-CR29) questionnaires [14].

The QLQ-C30 has 30 items and includes five functional scales (physical, emotional, cognitive, social, and role functioning), three symptom scales (fatigue, nausea/vomiting, and pain), global health status, and six single-item measures (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties).

The QLQ-CR29 has 29 items and includes four functional scales (body image, future perspective, sexual function, and sexual enjoyment) and eight symptom scales (micturation problems, gastrointestinal tract symptoms, chemotherapy side effects, defecation problems, stoma-related problems, male and female sexual problems, and weight loss).

QLQ-C30 evaluates areas common to different tumor sites and treatments, whereas QLQ-CR29 evaluates the areas associated with colorectal cancer and its treatments. The EORTC QLQ-CR29 is an updated version of the EORTC QLQ-C38.

These two versions share two similar scales, whereas other areas have a related or different content. The QLQ-CR29 allows for a better comparison between surgical modalities than the QLQ-C38 by including five separate scales for patients with or without stoma which can then be compared.

By recommended EORTC procedures [15], patient responses were converted to a scale from 0 to 100. High functional scores represented good function and high symptom scores represented more disease.

For items missing within a scale, the score was calculated by using only the items for which values were available, provided that at least half of the items in the scale were completed. The scales in which less than half of the items were completed were treated as missing data, which could not be analyzed.

Sample characteristics and the scores of the QoL and the functional evaluations were described using frequencies and percentages for the categorical variables, and means and standard deviations for the continuous ones.

Inter-group comparisons were made on the basis of surgical modality (LAR versus APR).

The QLQ-C30 and QLQ-CR29 scores were compared for the two surgical modality groups, as well as with a reference data (colorectal cancer patient group) from the EORTC reference manual.

Table 1 Comparison of the specific functional QoL scores between the study group and the reference population

Functional scale	Score in sample (mean ± SD)	Score in reference data (mean ± SD)	*t* value	*p* value
Global health status/QoL (QL)	61.15 ± 23.35	60.7 ± 23.4	0.2117	0.8324
Physical functioning (PF)	78.67 ± 23.69	79.2 ± 21.1	0.2740	0.7841
Role functioning (RF)	69.23 ± 34.38	70.4 ± 32.8	0.3913	0.6956
Emotional functioning (EF)	69.42 ± 15.16	68.9 ± 24.5	0.2386	0.8114
Cognitive functioning (CF)	84.87 ± 18.96	85.2 ± 20.4	0.1789	0.8581
Social functioning (SF)	77.05 ± 23.32	76.0 ± 28.6	0.4087	0.6828

Statistical Package for Social Sciences (SPSS) version 16 was used for data analysis. The data was first keyed in MS Excel ©2007 before converting it into SPSS for analysis. The results were expressed as percentages, mean ± SD, or median (IQR) as specified. Pearson's chi-squared method was used for comparing proportions and percentages. ANOVA was used wherever needed. A two-tailed *p* value was used for calculating statistical significance; a value of <0.05 was taken as significant.

Results

This prospective study has been conducted in the Division of Colorectal Surgery, Sheri-I-Kashmir Institute of Medical Sciences, Srinagar, India, and included 130 patients. Results were subjected to statistical analysis and following observations were made.

Versions of the EORTC Quality of Life Questionnaire (QLQ) used are QLQ-C30 version 3.0 and QLQ-CR29 version 2.1.

One-hundred-thirty patients from 143 candidates were evaluated between May 2014 and June 2016. The reasons for not filling in the questionnaires were patient refusal (11 cases) and death (2 cases). All patients had received surgery between January 2014 and March 2016.

Out of total 130 patients, APR was performed in 28 patients (21.54%) and LAR in 102 patients (78.46%).

The mean age was 48.59 ± 15.73 years with range of 18–75 years. There were 58 males and 72 females. Thirty-nine (30%) patients received NACRT.

There was no significant difference in the EORTC QLQ-C30 functional or symptom score between the study group and reference data population. Study group patients had slightly higher score with regards to financial difficulties than reference population that was not significant. Specific functional and symptom QoL scores of the study group were comparable to that of reference population (Tables 1 and 2).

There was no significant difference in the EORTC QLQ-C30 functional or symptom score between APR and LAR group except for the symptom of nausea and vomiting, which was reported significantly more by the LAR group patients than APR group ($p = 0.001$) (Tables 3 and 4).

Scores of the EORTC QLQ-CR30 and the QLQ-CR29 for the patient groups were analyzed.

Univariate analysis showed differences between the two groups on five scales.

LAR patients had significantly higher scores with regard to nausea and vomiting than patients with an APR ($p < 0.05$).

Table 2 Comparison of the symptom QoL scores between the study group and the reference population

Symptom scale	Mean score in sample (mean ± SD)	Score in reference population (mean ± SD)	*t* value	*p* value
Fatigue (FA)	34.53 ± 29.84	34.7 ± 28.4	0.0656	0.9477
Nausea and vomiting (NV)	8.08 ± 18.11	7.3 ± 17.2	0.4973	0.6191
Pain (PA)	24.62 ± 28.47	24.0 ± 29.6	0.2311	0.8173
Dyspnea (DY)	18.21 ± 27.57	17.4 ± 26.3	0.3378	0.7355
Insomnia (SL)	31.28 ± 32.35	30.5 ± 32.6	0.2635	0.7922
Appetite loss (AP)	20 ± 30.95	19.1 ± 30.2	0.3274	0.7434
Constipation (CO)	15.38 ± 27.26	15.8 ± 27.9	0.1659	0.8682
Diarrhea (DI)	15.38 ± 26.63	16.6 ± 27.6	0.4876	0.6259
Financial difficulties (FI)	17.18 ± 29.71	13.6 ± 26.3	1.4842	0.1379

Table 3 Comparison of the specific functional QoL (QLQ-CR30) scores between the APR group and LAR group

Functional scale	Score (APR), $n = 28$ (mean ± SD)	Score (LAR), $n = 102$ (mean ± SD)	t value	p value
Physical functioning	81.90 ± 20.60	77.78 ± 24.49	0.90	0.373
Role functioning	72.62 ± 32.46	68.30 ± 34.98	0.61	0.543
Emotional functioning	72.92 ± 14.63	68.46 ± 15.23	1.42	0.164
Cognitive functioning	86.31 ± 15.08	84.48 ± 19.94	0.53	0.600
Social functioning	75 ± 24.64	77.61 ± 23.04	−0.50	0.617
Global health status	67.85 ± 21.24	59.31 ± 23.66	1.84	0.072

APR patients had significantly higher scores with regards to urinary frequency ($p = 0.0001$), abdominal pain ($p = 0.0001$), and embarrassment ($p = 0.0001$) than LAR patients (Tables 5 and 6).

Discussion

The purpose of this study was to provide a comprehensive over view of the functional outcome and quality of life of patients with cancer of rectum. All these patients underwent APR or LAR. The quality of life among disease-free survivors was good, with scores that were comparable to those of the population-based reference group. This study shows that the quality of life was similar in patients with LAR and APR. It is remarkable that most of our patients ranked their quality of life comparable as that in the population-based reference group.

Most follow-up studies with RC have administered the previous version of the EORTC colorectal module (QLQ-CR38). As noted previously, not all areas of the two EORTC questionnaires (QLQ-CR38, QLQ-CR29) can be compared.

The present study is limited by its short duration, the relatively small number of patients.

Nevertheless, good arguments exist for the validity of the expressed values and our finding is consistent with other reports on quality of life in cancer survivors [16, 17].

Scores in the functional evaluation of LAR patients indicate that patients have good functional scores and the QoL results are comparable to those of other studies [18].

The relatively good quality of life, observed among our patients, might be explained by the fact that the measurement followed their earlier diagnosis of a life-threatening disease, which changed their perceptions of the length of life, thereby shifting their expectations and priorities with regard to life fulfillment. Successful treatment therefore might result in a higher quality of life as reported by the patient. This effect, known as "rejoice," has been noted from the beginning of quality of life research [19]. An additional contributing factor might be the adaptation of the patients to their morbidity over time, a phenomenon that is also referred to as coping or "response shift." Adaptation is defined as a change in the meaning of a respondent's self-evaluation of quality of life that results from changes in his or her internal standards, values, or conceptualization of quality of life [20]. In other words, to accommodate deteriorating function, patients may lower their internal standards, alter their values, and change their ideas about what constitutes a good quality of life. Response shift is related to the subjective value of morbidity. This explains why the morbidity may be only weakly correlated with the more subjective measure of quality of life. To test the use of coping strategies, Boyd and co-workers posted a treatment preference questionnaire to patients with rectal cancer treated by APR or by radiotherapy without colostomy. The questionnaire was also sent to physicians and healthy volunteers. All

Table 4 Comparison of the symptom QoL (QLQ-CR30) scores between the APR and the LAR group

Symptom scale	Score APR (mean ± SD)	Score LAR (mean ± SD)	t value	p value
Fatigue	31.35 ± 25.13	35.40 ± 31.06	−0.72	0.477
Nausea and vomiting	1.79 ± 6.94	9.80 ± 19.81	−3.39	0.001
Pain	18.45 ± 21.91	26.31 ± 29.89	−1.54	0.128
Dyspnea	15.48 ± 23.10	18.95 ± 28.73	−0.67	0.508
Insomnia	23.81 ± 25.43	33.33 ± 33.82	−1.63	0.110
Appetite loss	14.29 ± 23.00	21.57 ± 32.72	−1.34	0.184
Constipation	15.48 ± 27.94	15.36 ± 27.22	0.02	0.984
Diarrhea	15.03 ± 25.10	16.67 ± 32.08	0.25	0.804
Financial difficulties	14.29 ± 26.34	17.97 ± 30.64	−0.63	0.531

Table 5 Comparison of the specific functional scores between the APR group and LAR group (EORTC QLQ-CR29)

Functional scale	General sample (mean ± SD)	Score APR (mean ± SD), $n = 28$	Score LAR (mean ± SD), $n = 102$	t value	p value
Body image	83.68 ± 15.03	84.13 ± 14.95	83.55 ± 13.87	0.1927	0.8475
Anxiety	82.82 ± 29.71	85.71 ± 26.34	82.03 ± 30.64	0.5791	0.5635
Weight	95.38 ± 15.94	100 ± 0	94.11 ± 17.80	1.7460	0.082
Sexual interest (men)	59.77 ± 34.63	45.24 ± 24.83	64.40 ± 36.23	1.8405	0.0710
Sexual interest (women)	53.62 ± 32.95	41.02 ± 19.97	56.55 ± 34.77	1.6030	0.1134

subjects were asked to imagine living the rest of their lives with a colostomy [21]. Healthy volunteers and patients with rectal cancer, treated by radiotherapy, without the need of a colostomy, were the most averse to treatment that involved a colostomy. Physicians and patients who had a colostomy were the most ready to accept living the rest of their life with a colostomy.

Although the overall quality of life among all our patients was good, significant differences were observed between the groups. This study showed that the quality of life was almost similar in patients with LAR and APR, except for nausea-vomiting, urinary frequency, abdominal pain, and embarrassment, the variation being statistically significant.

The few QoL differences between LAR and APR patients are in line with other studies. We would like to note that the previous version of the colorectal module, QLQ-CR38, which has been applied in most studies performed with the EORTC instruments, does not allow stool frequency between the two surgical modalities to be compared, thereby possibly preventing results similar to ours in this dimension from being found. Furthermore, QLQ-CR29 allows more comparisons between surgical modalities to be carried out in specific areas than the QLQ-CR38, thereby supporting our conclusion that there are few differences between two surgical modalities studied.

In a meta-analysis of 11 studies (eight of which applied the EORTC instruments, and a further eight of which were performed in the follow-up period), Cornish et al. [22] found no differences in general QoL between APR or LAR, although few differences were detected in specific areas. Furthermore, and similar to the results of our study, these authors found no differences in body image, although differences in this area were found in some of the individual studies [23].

Most surgeons try to avoid an APR by performing LAR, frequently without a pouch. This policy is based mainly on the assumption that the quality of life after such LAR is better than after APR. This is not confirmed by the present study in which quality of life after LAR was similar to that after APR.

Table 6 Comparison of the specific symptom scores between the APR group and LAR group (EORTC QLQ-CR29)

Symptom scale	General sample (mean ± SD)	Score APR (mean ± SD)	Score LAR (mean ± SD)	t value	p value
Urinary frequency	28.85 ± 22.81	43.45 ± 22.38	24.84 ± 21.33	4.1249	0.0001
Blood and mucus in stools	17.82 ± 16.10	17.86 ± 15.67	17.81 ± 16.29	0.0145	0.9885
Stool frequency	29.06 ± 25.59	29.76 ± 26.59	28.43 ± 24.32	0.2512	0.8021
Urinary incontinence	20 ± 23.33	26.20 ± 24.61	18.30 ± 22.80	1.5965	0.1128
Dysuria	10.77 ± 18.66	16.67 ± 19.25	9.15 ± 18.26	1.9080	0.0586
Abdominal pain	22.05 ± 23.68	32.14 ± 26.42	9.28 ± 22.22	4.6245	0.0001
Buttock pain	14.87 ± 21.19	25 ± 28.15	12.10 ± 18.04	2.9366	0.0039
Bloating	16.67 ± 22.06	13.10 ± 20.96	17.65 ± 22.35	0.9666	0.3356
Dry mouth	15.64 ± 22.80	15.48 ± 19.21	15.69 ± 23.78	0.0430	0.9658
Hair loss	48.72 ± 28.20	47.62 ± 30.67	49.02 ± 27.63	0.2319	0.8170
Taste	18.97 ± 21.14	16.67 ± 16.97	16.61 ± 22.18	0.0133	0.9894
Flatulence (FL)	–	32.14 ± 27.94	33.66 ± 28.34	0.2521	0.8013
Fecal incontinence (FI)	–	26.19 ± 27.75	30.06 ± 25.91	0.6895	0.4918
Sore skin (SS)	–	28.57 ± 26.79	27.78 ± 24.41	0.1485	0.8822
Embarrassment (EMB)	–	47.62 ± 26.34	23.86 ± 24.54	4.4671	0.0001
Stoma care problems (STO)	–	30.95 ± 28.59	–	–	–
Impotence	21.84 ± 28.99	28.57 ± 25.68	19.70 ± 29.92	1.4298	0.1552
Dyspareunia	33.33 ± 32.62	40.48 ± 29.75	31.61 ± 33.29	1.2763	0.2042

Camilleri-Brennan et al. [24] and Rauch et al. [25] also did not find any differences between the quality of life after APR and LAR.

In a prospective study, Grumann et al. [26] showed that following LAR patients had a lower quality of life than those who underwent an APR. In contrast, However, Engel et al. [27] and Sprangers et al. [28] observed that APR patients experienced a poorer quality of life. Four of the eight studies included in a recent Cochrane Database Systemic Review revealed no difference with regard to quality of life between LAR and APR [29].

In one study, it was shown that the quality of life in patients with a colostomy was only slightly affected. The three other studies revealed that formation of a stoma significantly affected the patients' quality of life [29]. These conflicting results and the data obtained from our own study do not provide substantial evidence for to the assumption that the quality of life after LAR is better than APR.

The functional outcome after a LAR without a pouch is not as good as first thought [30]. Moreover, pre-operative radiotherapy has significant adverse effects on anorectal function [31]. A poor functional outcome after LAR without a pouch is characterized by high frequency, urgency, and impaired continence, especially during the first 2 years after the operation. It has been shown that pre-operative radiotherapy increases urgency, defecation frequency, usage of pads, and rectal blood loss [32].

In case of a disappointing functional outcome, the patient is confronted with a lack of control, which adversely affects quality of life [33]. The experience of lack of bowel control and uncertainty probably explains our observation that the quality of life after LAR was as good as that after APR. When a colostomy becomes necessary, modern stoma appliances are so effective that most patients with a colostomy enjoy normal lives. Engel et al. [27] who reported that APR patients have a consistently lower quality of life stated that 60% of the patients in their sample were poorly informed about stoma irrigation techniques. This underlines the importance of instruction by stoma therapists on colostomy care and washout, enabling more bowel control. The quality of life among LAR patients might be improved by a better control of their bowel function. Recently, it has been shown that colonic irrigation is beneficial for patients with a low anastomosis in controlling their bowel function [34].

In the present study, we found a lower perception of body image in APR patients as compared to LAR patients, which is in agreement with other studies [33]. However, despite this poorer body image perception, the social and psychological functioning of APR patients were similar to those of LAR patients.

In the present study, other factors such as gender, urinary problems, and sexual dysfunction were found to be independently associated with quality of life. Our male patients ranked their quality of life higher than our female patients. This is in accordance with other population-based studies revealing a higher quality of life among men [35]. Post-operatively sexual dysfunction and urinary problems were experienced by 24 and 19% of the patients, respectively. These figures are similar to those reported by other studies [36]. In the present study, a higher incidence of sexual dysfunction was observed after APR than LAR. Urinary problems were more frequently encountered after APR than after LAR. These differences are difficult to explain, and are probably surgeon dependent.

Our observation that the quality of life after APR is equal to the quality of life after LAR might have implications for current clinical practice. Most surgeons are convinced that the construction of a double-stapled LAR results in a higher quality of life than an APR with permanent colostomy.

In the treatment of patients with cancer located in the middle or lower third of the rectum, total mesorectal excision is established as the therapeutic golden standard. After this procedure, a transanally double-stapled anastomosis can only be constructed at the level of or just above the pelvic floor. Most surgeons believe that the preservation of a short rectal remnant is beneficial for the patient. However, it has been shown that this does not offer any functional advances [37].

Moreover, most surgeons underestimate the high risk of anastomotic leakage after the construction of such a low anastomosis. Recently, a population-based study from Sweden revealed that the incidence of this serious complication was 24% when the anastomosis was located within 6 cm from the anal verge [38]. Such an anastomotic leakage in this region is associated not only with a high morbidity but also with a significant mortality [39]. It has been also been reported that an anastomotic leakage adversely effects disease-free survival [40].

It would be useful to perform prospective studies involving long-term follow-up in order to study the evolution of the differences between various surgical modalities for rectal carcinoma.

Quality of life data should be used to improve treatment and care, to assist intervention planning, and to help patients anticipate side effects.

Conclusion LAR may not be superior to APR for low rectal cancer. The quality of life after permanent stoma is equal or better than the quality of life after LAR in some cases. This fact should be taken into consideration while dealing with low rectal cancers.

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