ORIGINAL ARTICLE

Factors Affecting Health Related Quality of Life of Rectal Cancer Patients Undergoing Surgery

C. Krishnan Nair • P. S. George • K. S. Rethnamma • R. Bhargavan • S. Abdul Rahman • A. P. Mathew • M. Muralee • K. Cherian • P. Augustine • M. I. Ahamed

Received: 14 December 2013 / Accepted: 5 August 2014 / Published online: 16 October 2014 © Indian Association of Surgical Oncology 2014

Abstract Maintaining quality of life (OOL) is one of the important aims of cancer treatment. Quality of life of a cancer patient is affected by various factors, which may be disease related, patient related, or treatment related. To study changes in health-related quality of life (HRQOL) brought about by treatment of rectal cancer and factors affecting the changes using Malayalam translation of FACT-C (Functional Assessment of Cancer Therapy—Colorectal) Questionnaire. Also to detect the minimally important clinical changes (MICC) in health-related quality of life of patients with carcinoma rectum, who have undergone surgery. Forty-five patients diagnosed with carcinoma rectum, who have undergone curative surgery, were studied. HRQOL was assessed at baseline 2 weeks after surgery and 3 months after surgery. The changes in scores were correlated with various demographic factors like age, sex, marital status, number of children, number of married children, and education and occupation of the patient and spouse. Also the treatment-related factors like presence of stoma, presence of morbidity, previous treatment, stage of disease, and administration of chemotherapy before and after surgery were correlated. All the subscales of FACT-C tool, except emotional well-being, were significantly reduced 2 weeks after surgery and increased slightly above pretreatment level 3 months after surgery. The Chronbach α values were 0.88, 0.89 and 0.86 on three occasions, respectively, establishing internal validity of the test. Baseline HRQOL scores were better in males compared to females. Among the various subscales, the drops in SWB, FWB, FACT-G, total Score and TOI were significant (P < .05). There were no significant differences in scores between patients who have undergone open surgery and minimally invasive surgery or patients who had permanent colostomy versus no colostomy. The HRQOL scores after surgery reduced 2 weeks after surgery and improved above pre-surgical levels 3 months after surgery. The approach of surgery (minimally invasive versus open) or presence or absence of permanent colostomy didn't make any significant change in HRQOL. But since the sample size of the study was small, we need further larger studies to arrive at definite conclusions.

Keywords Quality of life · Rectal cancer · Minimally important clinical change

Introduction

According to Globocan 2008, out of 12.7 million cancers occurring annually, 1.23 million (9.7 %) were colorectal cancers. Colorectal cancer is the third most common cancer in men (663 000 new cases annually, 10.0 % of the total annual cancer incidence) and the second in women (571 000 cases, 9.4 % of the total) worldwide [9]. Even though the incidence rates in developing countries like India are less compared to western countries, the rates are increasing year after year. Surgery is one of the most important treatment modalities of rectal cancer. As other modalities, surgery is associated with drop in HRQOL. The reasons, in general, are post-operative pain, anxiety, hospital stay, etc. The more specific reasons for the drop in HRQOL in rectal cancer treatment are thought to

C. K. Nair ((() · K. S. Rethnamma · R. Bhargavan · A. P. Mathew · M. Muralee · K. Cherian · P. Augustine · M. I. Ahamed Department of Surgical Oncology, Regional Cancer Centre, Trivandrum, India e-mail: drchandramohan@gmail.com

P.S. George

Department of Bio-Statistics, Regional Cancer Centre, Trivandrum, India

S. Abdul Rahman

Department of Radiotherapy, Regional Cancer Centre, Trivandrum, India



be formation of stoma (permanent or temporary) and damage to autonomic nerves of pelvis with the resultant problems in defecation, urination, and sexual activity. In rectal cancer the tri-modality therapy, comprising surgery, chemotherapy and radiotherapy, contributes to the damage to the neural plexus [7, 12]. In ultra-low anterior resection, which is done for very low lying rectal cancers, damage or weakness of rectal sphincter also contributes to the poor continence thus leading to drop in QOL. We now know that it is very important to preserve the QOL of the patients undergoing treatment of cancer. To achieve this, changes should be objectively quantified and recorded during the course of treatment; but unfortunately, unlike clinical parameters of effectiveness of cancer cure (like recurrence rates and survival), QOL is not routinely measured frequently and accurately. A variety of tools is available to measure changes in QOL: EORTC QOL Questionnaire, FACT QOL Questionnaire, Short forms 36, etc. FACT-C [16] is a part of FACIT ((Functional Assessment of Chronic Illness Therapy) measurement system, which is a collection of QOL questionnaires. FACT Questionnaires are one of the most important clinically validated tools available today to assess the OOL of colorectal cancer patients. The FACT questionnaires have both general tools and disease-specific tools for various diseases. FACT-C is the questionnaire used for colorectal cancer. This has been translated and validated in local language Malayalam with the concurrence of FACIT group [4]. In our validation study we have confirmed the reliability of the questionnaire. Fact-C Version 4 is a 36 item quality of life questionnaire with five subscales: Physical wellbeing (PWB), Social well-being (SWB), Functional wellbeing (FBW), Emotional Well-being (EWB) and Colorectal Cancer Specific additional concerns (CCS). EWB has six and all remaining (PWB, SWB, FWB, and CCS) has seven parameters. PWB, SWB, EWB and FWB scales were added to get FACT-G score, which had 27 items. FACT-G and CCS scores were added to get FACT-C score, which is having 34 items. Similarly Trial Outcome Index [TOI] (21 items) score obtained after adding up PWB, FWB and CCS scores. Participants responded how they felt during last 1 week on a scale 0 (not at all) to 4 (very much). These scores are added together using a special scoring manual so that each domain is summed up to provide an overall quality of life score. The total scores can vary from 0 to 136. Higher the score, better the quality of life. Each domain except emotional well-being has a maximum score of 28.

Methods

Forty-five patients with rectal cancer were prospectively followed up, and HRQOL was assessed at baseline (prior to surgery) 2 weeks after surgery and 3 months after surgery. All these patients had biopsy-proven operable rectal cancers, were

Table 1 Demographic characteristics

		Total (45)	Percentage
Gender	Male	25	55.56
	Female	20	44.44
Religion	Hindu	24	53.33
	Christian	10	22.22
	Muslim	11	24.44
Marital status	Unmarried	4	8.89
	Married	33	73.33
	Widowed	8	17.78
Education	Pre-School	21	42.22
	School	6	13.33
	Pree degree	7	15.55
	Graduate	8	11.11
	Post graduate	3	6.66

aged 18 and more, and were able to read and speak Malayalam, the local language. The patients who were unwilling to participate and too ill to fill up the questionnaires were excluded. The study was approved by Institutional Review Board and Human Ethics Committee of the institute.

HRQOL data were prospectively collected by interviewer. The questionnaires used were FACT-C, which was translated to Malayalam and validated. The translation process was forward-backward-forward technique as stipulated by the Center on Outcomes, Research, and Education (CORE) [16]. The interviewer also collected demographic information and information about disease and its treatment. Demographic

Table 2 Disease and treatment related characteristics

		Total (45)	Percentage
Stoma	No	18	40
	Yes	27	60
Surgical Approach	Laparoscopic	18	40
	Open	27	60
Morbidity	No	40	88.89
	Yes	5	11.11
Neo-adjuvant treatment	No	15	33.33
	Yes	30	66.67
TNM stage[13]	0	1	2.22
	1	4	8.89
	2	13	28.89
	3	27	60
Chemotherapy before surgery	No	17	37.78
	Yes	28	62.22
Chemotherapy after surgery	No	1	2.22
	Yes	44	97.78

Abbreviations: TNM, Tumour Node Metastasis



Table 3 Reliability of the FACT-C Questionnaire

Scale	Baseline	2 weeks post-operative	3 months post-operative
PWB	0.87	0.86	0.88
SWB	0.88	0.88	0.90
EWB	0.86	0.87	0.89
FWB	0.89	0.92	0.90
FACT-G	0.88	0.90	0.88
CCS	0.92	0.91	0.89
TOTAL	0.91	0.95	0.89
TOI	0.86	0.94	0.90

Abbreviations: *PWB*, physical well-being; *SWB*, social well-being; *FBW*, functional well-being; *EWB*, emotional well-being; and *CCS*, colorectal cancer specific; *FACT-C*, Functional Assessment of Cancer Therapy — Colorectal; *FACT-G*, Functional Assessment of Cancer Therapy — General; *TOI*, Trial Outcome index.

factors were recorded in the whole group. The changes in score from baseline at 2 weeks and 3 months were noted. The changes in scores were correlated with various demographic factors like age, sex, marital status, number of children, number of married children, and education and occupation of the patient and spouse (Table 1). Also the treatment related factors like presence of stoma, presence of morbidity, previous treatment, stage of disease, administration of chemotherapy before and after surgery were correlated (Table 2).

Statistical Analysis

FACT-C subscores were determined by converting the original values to a range of 0 (worst QOL) to 136 (best QOL). For the internal consistency test, Cronbach's Alpha, was used to test the instrument reliability. The reliability of each scale (i.e. internal consistency) was assessed by Cronbach's alpha coefficient [6]. A value of 0.70 or greater was considered as acceptable for group comparison [14].

QOL scores were expressed as mean and standard deviation. Descriptive statistics were used to summarize the data.

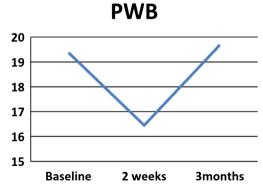


Fig. 1 Changes in Physical Well-being





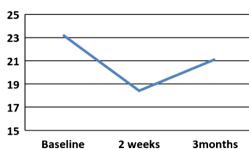


Fig. 2 Changes in Social Well-being

Since measurements of QOL made repeatedly on the same patients, we conducted repeated measures analysis of variance (ANOVA) over time using data from both the initial response (baseline) and follow-up surveys to assess the significance of change over time in QOL scores. Post-hoc pairwise comparisons with Bonferroni correction were performed for each subscale across the three time points (baseline, 2 weeks, and 3 months). When there are only two groups, independent sample t test was used. (eg. Laprascopy and open surgery). Both group-by-time interaction effects and between-subjects and within-subjects effects were assessed. The threshold for statistical significance after analysis was considered to be at p < 0.05. For the data analysis, software Statistical Package for Social Science (SPSS11.5 for Windows) was used. Minimally important clinical difference (MID) was calculated by distribution based method. Standard deviations of FACT- C scores were divided by 3 and 2 and established 1/3 and 1/2 SD estimates. The Standard Error of Mean (SEM)for the FACT-C scores were calculated using the following formula: SEM= $\sigma \times \sqrt{1}$ -relx where $\sigma \times =$ the SD of the scale or subscale and relx=the reliability of the scale or subscale (internal consistency)[18].

Result

Forty-five patients were included in the study. There were 25 males and 20 females. Mean age of the study group was

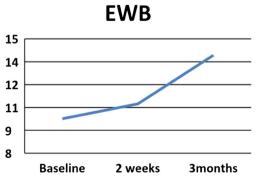


Fig. 3 Changes in Emotional Well-being

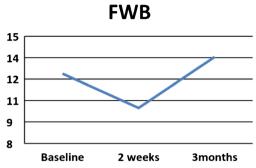


Fig. 4 Changes in Functional Well-being

54.82 years (28–77). First internal consistency of the questionnaire was tested. Internal consistency for each of the subscales at baseline (pre-treatment), and at 2 weeks and 3 months' follow-up was found to be adequate (all Cronbach αs >0.85). At baseline the Cronbach αs ranged from 0.86 to 0.92. At 2 weeks follow-up the Cronbach αs ranged from 0.86 to 0.95 and at 3-months follow-up the αs ranged from 0.88 to 0.90(Table 3).

The demographic, disease-related and treatment-related factors were given in Tables 1 and 2, respectively. At 2 weeks, global score and all subscales dipped, except EMB which was better after surgery, though not statistically significant (p= 0.09) showing a fall in HRQOL (Figs. 1, 2, 3, 4, 5, 6, 7 and 8). Among the various subscales, the drops in SWB, FACT-G, total Score and TOI were significant (P<.02) (Table 4).

Among the 45 patients, five had some or other perioperative morbidity (two had anastomotic leaks and three had pneumonia). However, there were no correlation between morbidity and change in HRQOL. Out of 45 patients, 27 (60 %) had permanent stoma following abdomino-perineal resection. All the patients had undergone preoperative chemo radiotherapy. After chemo radiation, the stage groups were stage 0 for one, stage 1 for four, stage 2 for 13 and stage 3 for 27. All but one patient received post-operative chemotherapy.

Changes in QOL scores were analysed with independent sample t-tests to know whether demographic factors like age, gender, marital status, education of the patient, education of spouse, number of children, number of married children, approach of surgical procedures (minimally invasive versus

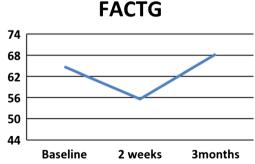


Fig. 5 Changes in FACT-G scores

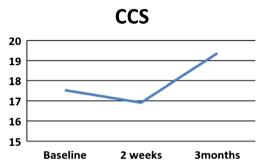


Fig. 6 Changes in Colorectal Cancer Specific Scores

open) or presence or absence of stoma were associated with changes in scores of QOL. When independent sample T test was done on FACT subscales, men had better baseline OOL in subscales of PWB, SWB, FACT-G and Total Score, but as far as changes in HRQOL is concerned, there were no significant differences in changes based on gender either at 2 weeks or at 3 months (Tables 5 and 6). Similarly the stage of disease has not affected the changes in QOL (Tables 5 and 6). When drop in HRQOL was compared in open and laparoscopic group, there was no significant difference but changes in FACT-G scores at 2 weeks were much worse in open group compared to laparoscopic group (p=.067), which was of near significance. Similarly the drop in scores of HRQOL was not much different in ostomates versus non ostomates either at 2 weeks or at 3 months. When the four factors (gender, stage, surgery, stoma) analysed with ANOVA for the 45 patients who completed 3 months of assessment, none was significant in influencing the QOL outcome over time (i.e. there was no overall positive or negative trend in quality of life scores in the patient group). Minimally important clinical differences (MID) which were calculated by distribution based method is given in Table 7.

Discussion

Maintenance of HRQOL is one of the important aims of treatment of cancer because cancer and it's treatment

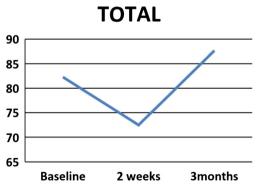


Fig. 7 Changes in Total scores



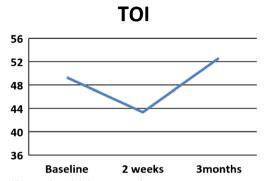


Fig. 8 Changes in Trial Outcome Index scores

negatively affect it. Here we used Malayalam translation of FACT-C questionnaire, which was translated and validated by us. In the initial validation study of the questionnaire, we have found out that out of the four primary QOL domains the alpha values ranged from 0.82 to 0.92 indicating satisfactory internal consistency within each domain(5). We used the questionnaire again and the validation is reconfirmed with acceptable chronbach-alpha values above 0.85. It is evident from our study that as a result of surgical treatment HRQOL scores drops down at 2 weeks and rises up after 3 months (Figs. 1, 2, 3, 4, 5, 6, 7 and 8). In our study, even though most of the patients were receiving post-operative adjuvant chemotherapy at the time of third interview, the HRQOL sores were higher than baseline.

Rectal cancer and its treatment affect at least three different areas of functioning, Physical functioning (e.g., urgency to defecate/ urinate, frequent/irregular bowel movements, gas, faecal leakage, altered bowel and urinary habits etc.), social functioning (e.g., due to urgency and/or frequency of their bowel/urinary movements), and sexual functioning (in men

due to erectile dysfunction, failure of eiaculation, and incapability of orgasm and in females due to dyspareunia, diminished orgasm and less frequent intercourse). Moreover colorectal cancer patients who also have a colostomy are particularly at-risk for high levels of distress and suffer from the "double stigma" of cancer and colostomy. When both genders were compared males were having slightly better HRQOL scores at baseline. This may be due to gender bias existing in society and better copping mechanism of male gender at the time of diagnosis of cancer, but this difference was nullified later on after commencement of treatment. In most patients 2 weeks after surgery the scores dipped low, may be because of immediate post-operative fatigue and pain associated with surgery, but after 3 months scores were better than baseline, may be because of recovery and disease free status. Even after 2 weeks, though most scores dipped down, emotional wellbeing was better, which continued to increase at 3 months. This may be because of the enhanced confidence level brought about by surgical treatment. Similarly after 3 months after surgery social wellbeing scores were low, may be because failure of coping with the society after cancer treatment.

The minimally important difference (MID) has been defined as smallest change in patient reported outcome that is perceived as beneficial or that would lead the clinician to consider a change in treatment [3]. There are two methods to assess the MID, anchor-based and distribution based [18]. The MID by distribution based methods were calculated as 1/3rd or 1/2 Standard Deviation (SD), and 1 standard error of means (SEM). Here we calculated MID using distribution based method. This is given in Table 7. The distribution based method was employed here because it is less samples dependent and it has greater generalizability. Wyrwich et al. suggested that SEM corresponds to anchor based approaches

Table 4 Anova-tests on FACT-C scores

Scale	Mean Score±Standard Deviation					
	Before treatment	Two weeks after surgery	Three months after surgery	pvalue		
PWB	19.4±6.5	16.4±5.7	19.7±4.1	0.085		
$SWB^{(a,b)}$	23.2±5.5	18.4 ± 6.7	21.1±5.9	0.001		
EWB	9.8±5.7	10.7 ± 6.5	13.9±5.1	0.092		
FWB	12.4±5.5	10±5.7	13.5±5.6	0.024		
FACTG ^(a,b)	64.7 ± 15.2	55.6±17.8	68.3 ± 11.8	0.004		
CCS	17.5±3.8	16.9±4.2	19.4±3	0.373		
$TOTAL^{(a,b)}$	82.3 ± 17	72.5 ± 20.4	87.7±13.2	0.004		
$TOI^{(a,b)}$	49.3 ± 10.6	43.3 ± 11.9	52.6±8.9	0.004		

Abbreviations: *PWB*, physical well-being; *SWB*, social well-being; *FBW*, functional well-being; *EWB*, emotional well-being; and *CCS*, colorectal cancer specific; *FACT-C*, Functional Assessment of Cancer Therapy – General; *TOI*, Trial Outcome index.

^a Bonferroni post hoc test significant at P < 0.02 between patients in initial response and two weeks after surgery; ^b Bonferroni post hoc test significant at < 0.02 between patients in two weeks after surgery and three months after Surgery.



Table 5 Change in score (baseline to two weeks) -FACT- C subscales at for patients

	Change in score(baseline to two weeks)							
	PWB	SWB	EWB	FWB	FACTG	CCS	TOTAL	TOI
Gender								
Male	4.4 ± 8.9	6.1 + 7.4	-1.9 ± 9.6	2.6+6.7	11.2±21.6	0.0 ± 4.5	11.2±22.7	7 ± 13.0
Female	1.1 ± 7.0	3.2 ± 7.7	0.2 ± 6.3	2.2 ± 7.3	6.6 ± 18.0	1.4±4.8	8.0 ± 21.3	4.7 ± 13.9
P_Value	0.170	0.206	0.421	0.864	0.449	0.319	0.630	0.562
Stage								
Stage I	10.9 ± 5.0	15.4 ± 5.4	17.8 ± 4.3	15.3 ± 3.7	52.2±7.7	16.4 ± 16.0	5.2 ± 10.1	3.2 ± 28.5
Stage II	13.9 ± 5.9	16.3 ± 6.4	15.8 ± 3.8	14.0 ± 5.2	51.8±9.4	8.8 ± 19.8	1.9 ± 7.3	-5.9 ± 23.2
Stage III	10.1 ± 3.8	19.0 ± 3.6	19.0 ± 4.5	11.0 ± 6.5	55.9+9.7	-4.2 ± 23.5	-0.4 ± 7.6	-8.1 ± 11.6
P_Value	0.132	0.407	0.126	0.199	0.576	0.080	0.301	0.449
Surgery								
Laproscopy	1.3 ± 6.0	2.5 ± 6.6	-2.7 ± 8.9	1.4 ± 5.4	2.5 ± 17.4	0.1 ± 4.3	2.5 ± 20.2	2.7±9.9
Open	4.0 ± 9.3	6.3 ± 7.9	0.2 ± 7.3	3.1 ± 7.8	13.6 ± 20.7	1.0±4.9	14.6 ± 22.0	8.1 ± 14.9
P_Value	0.272	0.100	0.254	0.428	0.067	0.509	0.069	0.186
Stoma								
No	2.9 ± 8.3	4.4 ± 9.2	1.7 ± 7.5	2.3 ± 7.8	11.3 ± 19.7	0.7 ± 5.3	12.1 ± 21.3	6.0 ± 13.5
Yes	2.9 ± 8.2	5.1 ± 6.5	-2.7 ± 8.5	2.4 ± 6.4	7.7 ± 20.5	0.6 ± 4.2	8.3 ± 22.5	5.9 ± 13.5
P_Value	0.994	0.760	0.080	0.959	0.561	0.907	0.578	0.986

Abbreviations: *PWB*, Physical Well-being; *SWB*, Social Well-being; *FBW*, Functional Well-being; *EWB*, Emotional Well-being; and *CCS*, Colorectal Cancer Specific; *FACT-C*, Functional Assessment of Cancer Therapy – Colorectal; *FACT-G*, Functional Assessment of Cancer Therapy – General; *TOI*, Trial Outcome index; *SD*, Standard Deviation

Table 6 Change in score (baseline to three months) = FACT-C subscales at for patients

	Change in score(baseline to three months)							
	PWB	SWB	EWB	FWB	FACTG	CCS	TOTAL	TOI
Gender								
Male	2.1 ± 6.9	3.5 ± 7.2	-4.0 ± 6.9	-0.8 ± 8.2	0.8 ± 17.3	-1.0 ± 5.2	-0.1 ± 19.6	0.4 ± 13.7
Female	-2.3 ± 9.3	1.4 ± 9.6	-3.7 ± 7.1	-1.0 ± 7.6	-5.6 ± 22.8	-2.0 ± 6.5	-7.5 ± 28.0	-5.3 ± 17.7
P_Value	0.076	0.392	0.853	0.920	0.290	0.576	0.304	0.238
Stage								
Stage I	65.8 ± 14.9	17.1±7.5	67.5 ± 15.5	13.3 ± 6.3	6.2 ± 7.5	1.2 ± 5.4	-5.0 ± 8.7	3.0 ± 16.9
Stage II	64.8 ± 16.6	18.0 ± 6.3	71.7 ± 22.1	13.3 ± 5.1	1.7 ± 8.4	0.2 ± 3.7	-3.9 ± 6.1	-4.0 ± 16.0
Stage III	62.5 ± 12.1	22.6 ± 5.8	85.7 ± 19.8	14.7 ± 6.3	0.7 ± 7.8	0.9 ± 6.4	-1.6 ± 6.1	-6.1 ± 10.7
P-Value	0.0.899	0.193	0.140	0.839	0.190	0.810	0.574	0.328
Surgery								
Laparoscopy	-2.0 ± 8.1	0.3 ± 7.7	-4.3 ± 6.9	-0.4 ± 5.9	-6.4 ± 17.0	-2.1 ± 4.0	-8.5 ± 19.6	-4.5±11.5
Open	1.6 ± 8.2	4.1 ± 8.5	-3.6 ± 7.1	-1.9 ± 9.0	0.9 ± 21.5	-1.0 ± 6.8	0.0 ± 25.8	-0.6 ± 18.0
P_Value	0.159	0.143	0.716	0.772	0.229	0.543	0.245	0.415
Stoma								
No	1.1 ± 7.9	3.2 ± 8.5	-2.7 ± 8.1	-0.8 ± 10.1	0.8 ± 22.3	-0.1 ± 7.7	0.7 ± 27.7	0.2 ± 19.0
Yes	-0.5 ± 8.6	2.2 ± 8.4	-4.7 ± 6.1	-0.9 ± 6.2	-3.9 ± 18.4	-2.3 ± 4.1	-6.2 ± 20.7	-3.7 ± 13.2
P_Value	0.522	0.704	0.348	0.982	0.448	0.229	0.350	0.429

Abbreviations: *PWB*, Physical Well-being; *SWB*, Social Well-being; *FBW*, Functional Well-being; *EWB*, Emotional Well-being; and *CCS*, Colorectal Cancer Specific; *FACT-C*, Functional Assessment of Cancer Therapy – General; *TOI*, Trial Outcome index; *SD*, Standard Deviation



Table 7 Minimally important difference estimates: distribution-based

	SD	1/3 SD	1/2SD	SEM
PWB				
Baseline	6.5	2.2	3.3	1.0
2 weeks post-operative	5.7	1.9	2.9	0.9
3 months post-operative	4.1	1.4	2.1	0.6
SWB				
Baseline	5.5	1.8	2.8	0.8
2 weeks post-operative	6.7	2.2	3.4	1.0
3 months post-operative	5.9	2.0	2.9	0.9
EWB				
Baseline	5.7	1.9	2.8	0.8
2 weeks post-operative	6.5	2.2	3.2	1.0
3 months post-operative	5.1	1.7	2.6	0.8
FWB				
Baseline	5.5	1.8	2.8	0.8
2 weeks post-operative	5.7	1.9	2.9	0.9
3 months post-operative	5.6	1.9	2.8	0.8
FACT-G				
Baseline	15.2	5.1	7.6	2.3
2 weeks post-operative	17.8	5.9	8.9	2.6
3 months post-operative	11.8	3.9	5.9	1.8
CCS				
Baseline	3.8	1.3	1.9	0.6
2 weeks post-operative	4.2	1.4	2.1	0.6
3 months post-operative	3.0	1.0	1.5	0.5
TOTAL				
Baseline	17.0	5.7	8.5	2.5
2 weeks post-operative	20.4	6.8	10.2	3.0
3 months post-operative	13.2	4.4	6.6	2.0
TOI				
Baseline	10.6	3.5	5.3	1.6
2 weeks post-operative	11.9	4.0	6.0	1.8
3 months post-operative	8.9	3.0	4.4	1.3

Abbreviations: *PWB*, Physical Well-being; *SWB*, Social Well-being; *FBW*, Functional Well-being; *EWB*, Emotional Well-being; and *CCS*, Colorectal Cancer Specific; *FACT-G*, Functional Assessment of Cancer Therapy – General; *TOI*, Trial Outcome index; *SD*, Standard Deviation; *SEM*, Standard Error of Mean.

[17]. The important observation from the study is that change QOL was not affected approach of surgery (minimally invasive versus open). This is similar to the results of Quality of Life of COLORII (multicentre randomized trial comparing laparoscopic and open surgery for rectal cancer) study. This was a study done with 385 rectal cancer patients participated in COLOR II Trial. Similar to our study, this study showed deterioration of HRQOL immediately after surgery which improved over time. There was no difference in QOL in different surgical approaches (Minimally invasive versus open) [1]. Laparoscopic rectal surgery is accepted as standard

of care with more and more evidence coming up about oncologic safety and preservation of HRQOL by laparoscopy. The MRC CLASSIC TRIAL has shown that laparoscopy and open surgery have equipoise of HRQOL, but for unknown reasons men had loss of sexual scores compared to women in laparoscopic group, which was not statistically significant [10], but there are studies showing superiority of laparoscopy over open surgery. The study by Braga et al. showed better general health status, physical and social function with laparoscopy compared to open surgery [2]. In COREAN trial sleep and physical wellbeing were better, and fatigue was less after laparoscopic surgery compared to open surgery [11]. Most of studies showed superiority of laparoscopy in preserving HRQOL in immediate post-operative period while few showed during long term also. Recently, the study by Ng SS et al. did a study to compare quality of life (QOL) outcomes in Chinese patients after curative laparoscopic vs open surgery for rectal cancer. They have used EORTC QLQ C30 and QLQC38 to assess the QOL at 4 months, 8 months and 12 months. This study showed that laparoscopic sphincterpreserving resection for rectal cancer is associated with better preservation of OOL and fewer male sexual problems when compared with open surgery (15). But we know that the benefit of laparoscopy was more evident in immediate postoperative period and this study evaluated HRQOL only during late post-operative period. This was a limitation of the study, which was rectified in our study. Similarly study by Sprangers et al. showed that there is significant reduction in HRQOL in patients who had undergone a sphincter saving procedure compared to procedures involving permanent stoma [15]. Even though it is believed that abdomino-perineal resection (APR) results in poor QOL, it is not substantiated by evidence. Though patients, after APR, had lower body image scores and reduction in sexual function in male patients, they had better scores of physical function, future perspective and global QOL. The meta-analysis by Cornish JA et al. showed that though sexual function and physical function scores were less with APR, global health scores were similar. Cognitive and emotional function scores were high in APR patients [5]. Smilarly In a study done recently, QOL in patients with permanent stoma and in those after colo-anal anastomosis (CAA) did not differ significantly. APR patients had worse sexual function, while most CAA patients had faecal incontinence and sometime obstructed defecation, with important impact on their QOL [8].

According to our study, the HRQOL scores after surgery reduced 2 weeks after surgery and improved to pre surgical levels 3 months after surgery. But due to a small sample size of the present study, what we can best say is that the approach of surgery (minimally invasive versus open) or presence or absence colostomy didn't make any significant changes in HRQOL. There was a trend for change in HRQOL with time, this may have been influenced by



extraneous factors. Since preservation of HRQOL is one important goal of cancer treatment, changes in QOL should be documented and considered as a quality index of treatment. Further studies with larger number of patients are much needed.

Acknowledgement Ms Rekha Jayasankar, Research Assistant

References

- Andersson J, Angenete E, Gellerstedt M, Angeras U, Jess P, Rosenberg J, Furst A, Bonjer J, Haglind E (2013) Health-related quality of life after laparoscopic and open surgery for rectalcancer in a randomized trial. The Br j of surg 100(7):941–949
- Braga M, Frasson M, Vignali A, Zuliani W, Civelli V, Di Carlo V (2005) Laparoscopic vs. opencolectomy in cancer patients: long-term complications, quality of life, and survival. Dis Colon Rectum 48(12):2217–2223
- Cella D, Hahn EA, Dineen K (2002) Meaningful change in cancerspecific quality of life scores: differences between improvement and worsening. Qual of life res: an int j of qual of life aspects of treat, care and rehabil 11(3):207–221
- Chandramohan K, Pandey M, Sreerekha KR, Sebastian P, Bejoy CT (2012) Reliability of the Malayalam FACT-colorectal and predictors of QOL in patients with colorectal carcinoma. World J of Psycho-Soc Oncol 1(1):1–4
- Cornish JA, Tilney HS, Heriot AG, Lavery IC, Fazio VW, Tekkis PP (2007) A meta-analysis of quality of life for abdominoperineal excision of rectum versus anterior resection for rectal cancer. Ann Surg Oncol 14(7):2056–2068
- Cronbach LJ (1951) Coefficient alpha and the internal structure of tests. Psychmnemka 16:297
- Da Silva GM, Berho M, Wexner SD, Efron J, Weiss EG, Nogueras JJ, Vernava AM, Connor JT 3rd, Gervaz P (2003) Histologic analysis of the irradiated anal sphincter. Dis of the colon and rectum 46(11): 1492–1497
- Digennaro R, Tondo M, Cuccia F, Giannini I, Pezzolla F, Rinaldi M, Scala D, Romano G, Altomare DF (2013) Coloanal anastomosis or

- abdominoperineal resection for very low rectal cancer: what will benefit, the surgeon's pride or the patient's quality of life? Int J Colorectal Dis 28(7):949–957
- Ferlay J, Shin HR, Bray F, Forman D, Mathers C, Parkin DM (2010)
 Estimates of worldwide burdenof cancer in 2008: GLOBOCAN 2008. Int i of cancer J int ducancer 127(12):2893–2917
- Jayne DG, Guillou PJ, Thorpe H, Quirke P, Copeland J, Smith AM, Heath RM, Brown JM (2007) Randomized trial of laparoscopicassisted resection of colorectal carcinoma: 3-year results of the UK MRC CLASICC Trial Group. J of clin oncol: off j of the Am Soc of Clin Oncol 25(21):3061–3068
- 11. Kang SB, Park JW, Jeong SY, Nam BH, Choi HS, Kim DW, Lim SB, Lee TG, Kim DY, Kim JS et al (2010) Open versus laparoscopic surgery for mid or low rectal cancer after neoadjuvantchemoradiotherapy (COREAN trial): short-term outcomes of an open-label randomised controlled trial. The lancet oncol 11(7):637–645
- Lim JF, Tjandra JJ, Hiscock R, Chao MW, Gibbs P (2006) Preoperative chemoradiation for rectalcancer causes prolonged pudendal nerve terminal motor latency. Dis of the colon and rectum 49(1):12–19
- Ng SS, Leung WW, Wong CY, Hon SS, Mak TW, Ngo DK, Lee JF (2013) Quality of life after laparoscopic vs open sphincter-preserving resection for rectal cancer. World J Gastroenterol 19(29):4764–4773. doi:10.3748/wjg.v19.i29.4764
- Nunnally JC, Bernstein IH (1994) Psychometric theory, 3rd edn. McGraw-Hill, New York
- Sprangers MA, Taal BG, Aaronson NK, te Velde A (1995) Quality of life in colorectal cancer. Stoma vs. nonstoma patients. Dis Colon Rectum 38(4):361–369
- Ward WL, Hahn EA, Mo F, Hernandez L, Tulsky DS, Cella D (1999) Reliability and validity of the Functional assessment of cancer therapycolorectal (FACT-C) quality of life instrument. Qual of life res: an int j of qual of life aspects of treat, care and rehabil 8(3):181–195
- Wyrwich KW, Tierney WM, Wolinsky FD (1999) Further evidence supporting an SEM-based criterion for identifying meaningful intraindividual changes in health-related quality of life. J Clin Epidemiol 52(9):861–873
- Yost KJ, Sorensen MV, Hahn EA, Glendenning GA, Gnanasakthy A, Cella D (2005) Using multipleanchor- and distribution-based estimates to evaluate clinically meaningful change on the functional assessment of cancer therapy-biologic response modifiers (FACT-BRM)instrument. Value Health 8(2):117–127

