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## **Original Research Article**

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# Quality of life assessment in patients who have undergone oncologic resection of rectum: a retrospective, three arms, single centre, observational study

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#### ABSTRACT

**Background:** Quality of life (QOL) analysis following cancer surgery is a sensitive issue among patients. The present study tried to find the status of these QOL parameters in patients who had undergone oncogenic resection of rectum. **Methods:** Patients were given the short form 36 (SF-36), The European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and the EORTC QLQ-C29 questionnaires to fill at three time points in their treatment (prior to surgery, 3 months and 6 months following surgery). The prospectively collected questionnaires were analysed retrospectively.

**Results:** On comparing SF-36 questionnaire, there was significant improvement as we proceeded from baseline to first and second visit except for the energy level. On EORTC-30 questionnaire, there was significant improvement in all scales as we proceeded from baseline to first visit and then to second visit. On comparing EORTC-29 questionnaire, among all visits of abdominoperineal resection (APR), symptoms like pain and blood or mucus in stools significantly improved, low anterior resection (LAR) showed significant improvement in all 4 scales, high anterior resection (HAR) patients showed worst micturition complaints during first visit and gradually improving scores for other scales from baseline to first and second visit.

**Conclusions:** The three-questionnaire used in the study comprehensively included all issues from general health after cancer surgery to problems faced by the patients specifically after various modalities of rectal surgery. Such studies should be planned routinely to assess comprehensive outcome of oncogenic surgeries.

Keywords: EORTC questionnaire, Quality of life, Rectal cancer surgery

#### **INTRODUCTION**

Quality of life (QOL) measurement plays an important role in the field of oncology as it aims to include the patient as well as disease outcomes in the assessment of treatment. The term QOL is used to describe factors that influence the living condition of the society or the individual. The WHO defines QOL as, "the individual perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations standards and concerns".<sup>1,2</sup> It is a multidimensional global construction introduced as a keyword in the United States National Library of Medicine in 1977.<sup>3</sup>

OOL also includes physical health, personal circumstances (wealth, living conditions), social relationships, functional activities and pursuits, as well as wider societal and economic influence. It has been introduced as an outcome parameter in the present medical practice according to the contemporary holistic approach to the patient and over the past 15 years Health Related Quality of Life (HRQOL) has been progressively more accepted as an important patient outcome result in oncology along with the other conventional outcomes that used before such as treatment success, mean survival, disease free survival or cancer control survival.<sup>4-6</sup>

Quality of life analysis following rectal cancer surgery is a sensitive issue among patients in view of the implications of treatment on physical, sexual and psychological status of patients. Therefore, in present study authors tried to finds the status of these QOL parameters in patients who had undergone oncogenic resection of rectum in our setup.

#### **METHODS**

In present study, the study period was from September 2010 to September 2012, total of 176 patients were operated in TMH for carcinoma rectum. QOL questionnaires filled by total of 75 patients were retrospectively audited with aim to find out QOL outcomes in patients following oncologic resection of rectum with retrospective analysis of prospectively collected QOL questionnaires.

Patients undergoing surgery for rectal cancer at Tata Memorial Hospital (TMH) were given the Short Form 36 (SF-36), The European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and the EORTC QLQ-C29 questionnaires to fill at three time points in their treatment (prior to surgery, 3 months and 6 months following surgery).<sup>7</sup> The forms were submitted and collected prospectively during hospital stay and subsequently at each follow-up visit. The collected questionnaires were retrospectively analyzed. The questionnaires were self-administered in three languages Hindi, Marathi and English.

The analysis of QOL data included all patients with localized non metastatic rectal cancer who were operated either upfront or post neo-adjuvant chemo radiation at TMH.

The excluded patients were who had two or more uncontrolled comorbidities falling the American Society of Anesthesiologists (ASA) category 3 or 4, whose disease was invading other pelvic or abdominal organs even after completion of neoadjuvant therapy (T4 tumors), who underwent simultaneous resection of metastatic disease, who were not able to fulfill regular follow-up schedule or undergoing surgery for recurrent disease and illiterate patients who were not able to read and understand the questionnaires.

#### Statistical analysis

The main outcome will be QOL was assessed using the EORTC QLQ-C30 and QLQ - C 29 and QLQ SF-36 questionnaire for comparison of study for improvement in Physical, intellectual/cognitive, emotional, and social domains scores.

Scales were computed for each domain score were presented as mean (S.D), median. Change in scores from base line to follow up visit was compared using Paired T test or Wilcoxon signed rank sum test as per distribution of data. Categorical variables were analyzed using Chisquare test or Fisher's exact test. The change in the outcome variable recorded at different time points was analyzed using repeated measures ANOVA (with Bonferroni correction) or Friedman test for non-normal data. P value<0.05 will be considered statistically significant.

#### RESULTS

During the study period from September 2010 to September 2012, a total of 176 patients were operated in TMH for carcinoma rectum.

QOL questionnaires filled by 75 patients were retrospectively audited, wherein mean age of patients who had undergone APR (Abdominoperineal Resection) was 49, LAR (Low Anterior Resection) was 54 and HAR (High Anterior Resection) were 55. Male to female ratio on an average for all the arms was around 7-8. Out of 25 patients in APR arm 84% were stage 3 and 16% stage 2. In LAR arm, 76% were stage 3 and 24% stage 2 and in the HAR arm 92% were stage 3 and 8% were stage 2. Thus, on an average 75 to 90% of patients belonged to stage 3 and 10 to 25% to stage 2. Mean follow up of patients was around 13 months. In the LAR arm 16% of patient underwent pre op stoma, 36% of patients had stoma at first and 20% at second visit. In the HAR arm 4% had pre op stoma and 20% had stoma at first and 12% second visit (Table 1).

#### Table 1: Baseline characteristics of study population.

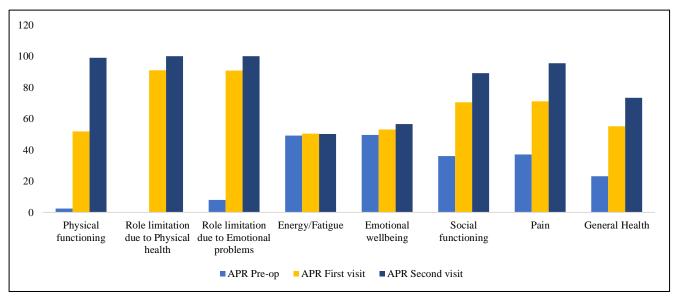
Baseline characteristics	APR	LAR	HAR
Total patients	25	25	25
Age (mean)	49	54	55
Sex			
Male (%)	19 (76)	18 (72)	20 (80)
Female (%)	6 (24)	7 (28)	5 (20)
UICC classification			
Stage 2 (%)	4 (16)	6 (24)	2 (8)
Stage 3 (%)	21 (84)	19 (76)	23 (92)
Mean follow –up (months)	9	14	16
Preop stoma (%)	20 (80)	4 (16)	1 (4)
Postop stoma (first visit) (%)	11 (44)	9 (36)	5 (20)
Postop stoma (second visit) (%)	17 (68)	5 (20)	3 (12)

#### SF 36 Questionnaire

SF 36 questionnaire was divided into 8 health domains, each domain containing certain number of questions and a two-step statistical analysis was done with calculation of P value. Intragroup comparison was done for all three arms from preoperative to first and second visit.

On comparing improvement in all health domains among all the three arms for each visit there was significant improvement as we proceeded from baseline to first and second visit except for the energy level which showed improvement from baseline to first visit but no significant improvement between first and second visit (Figure 1, 2, 3). EORTC 30 questionnaire was evaluated with 17 domains, again each containing certain number of questions and P value was calculated. Intra group comparison was done from preoperative to first and second visit.

While comparing between baseline to first and second visit in patients operated for APR there was significant improvement in all scales as we proceeded from baseline to first visit and then to second visit. A similar improvement was observed for patients undergoing high AR from baseline to first and then to second visit and results were similar for patients operated for low AR as well. (Figure 4-6).



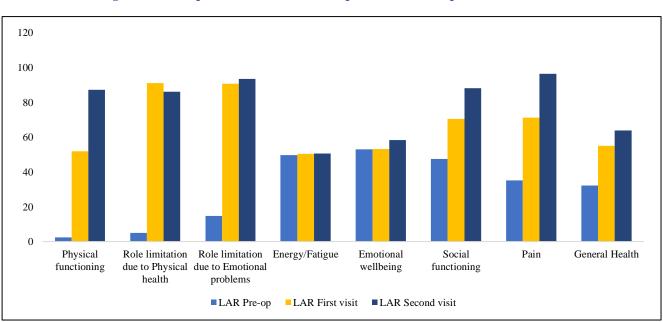
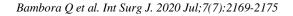


Figure 1: SF-36 questionnaire in abdominoperineal resection patients in all visits.

Figure 2: SF-36 questionnaire in low anterior resection patients in all visits.



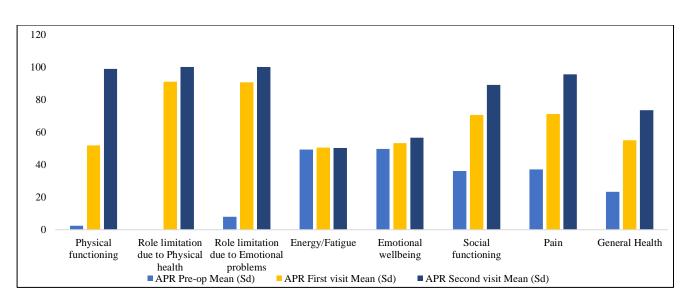


Figure 3: SF-36 questionnaire in high anterior resection patients in all visit.

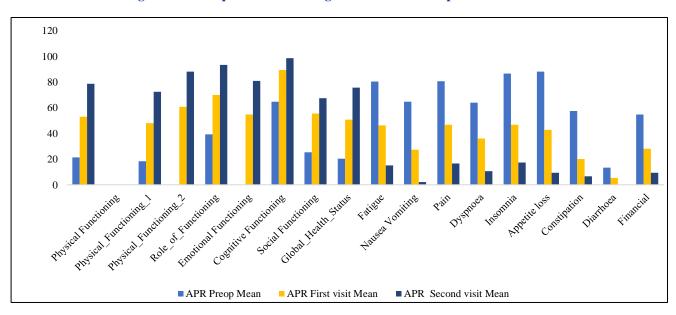


Figure 4: EORTC 30 questionnaire in abdominoperineal resection patients in all visits.

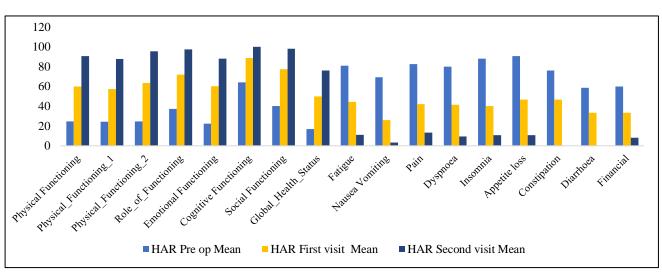


Figure 5: EORTC 30 questionnaire in high anterior resection patients in all visits.

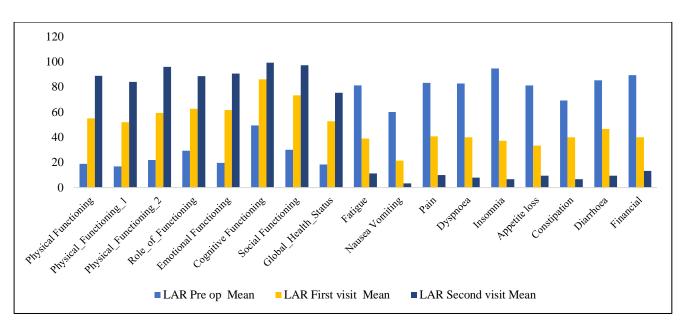
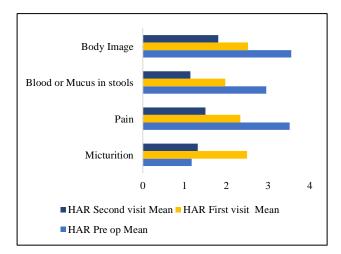


Figure 6: EORTC 30 questionnaire in low anterior resection patients in all visits.

EORTC29 questionnaire was divided into 4 domains, with 15 questions considered as single items. Out of single items 7 questions were specific for complications regarding stoma and two regarding sexual dysfunction. Again, comparisons were made intragroup from pre op to first and second visit.

Comparing among all visits of APR, symptoms like pain and blood or mucus in stools significantly improved from baseline to first and second visit. Complications regarding micturition were worst at first visit which gradually improved during second visit and patients had worst perception of body image during first visit which again improved at second visit. Patients undergoing LAR showed significant improvement in all 4 scales from baseline to first and second visit. Patients undergoing HAR again showed worst micturition complaints during first visit and gradually improving scores for other scales from baseline to first and second visit (Figure 7-9).





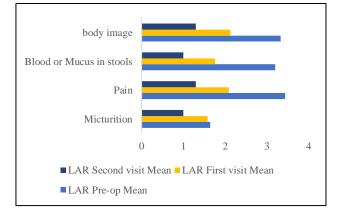
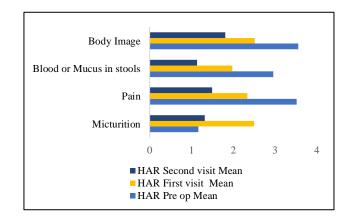


Figure 8: EORTC 29 questionnaire in low anterior resection patients in all visits.



# Figure 9: EORTC 29 questionnaire in high anterior resection patients in all visits.

#### DISCUSSION

Though all patients were offered to fill the QOL forms, the compliance rate was 42%. This probably is due to

lack of better understanding by the patients regarding value of such an audit or shyness on the part of patient for not giving answers to certain questions related to sexual problems. Quite a few patients were unwilling to discuss issues regarding their financial and social problems. Particularly questions regarding sexual dysfunction were largely avoided, however low response rates to sexual questions, have also been observed elsewhere for rest of the questionnaire patient didn't find much difficulty filling questionnaire.<sup>8,9</sup>

While comparing all 8 domains of generic heath measure (SF 36 physical functioning, health, emotional wellbeing, energy level, social functioning, pain and general health) there was definitive improvement in all groups when compared from baseline visit to second visit. Regarding the other two standard questionnaires used in our study, A Chinese study by Peng et al supplemented that EORTC QLQ-C30 and QLQ-CR29 is a useful questionnaire in evaluating curatively treated patients with rectal cancer.<sup>10</sup>

A study by Carlsson et al concerns and quality of life before surgery and during the recovery period in patients with rectal cancer and an ostomy concluded that participants in the study expressed concerns associated with developing cancer, being a burden on others, and related to the uncertain nature of disease.<sup>11</sup> Health-related quality of life scores dropped significantly in 6 of 8 domains when preoperative scores were compared to those obtained 1 month postoperatively, but scores improved at 6 months. There were significant differences between preoperative study group scores and population norms on physical and emotional role function, social function, and for mental health domains. Significant differences persisted when population norms were compared to study group scores 6 months following surgery on all these domains except mental health. Participants identified good relations with significant others, social and leisure activities, psychological issues, and health as important for maintaining QOL. Obstacles to maintaining QOL included fatigue, pain, illnessinduced limitations in life and worries over what their new life would entail.

Compared with responses to the EORTC QLQ-30 from a general German population sample rectal cancer patients in our study showed significant improvement in all heath domains from baseline to second visit for patients operated for either of three types of surgeries.<sup>12</sup> After undergoing such major surgical procedures for rectal cancer, patients and their relatives are under immense mental pressure regarding future prospects and chances of disease recurring.<sup>13</sup> Under such circumstances doctors play an important role by assuring patients that many aspects of quality of life will improve over time, because there is some evidence that a positive approach from the doctor can reduce the symptomatic burden.<sup>14</sup>

While comparing EORTC 29 scales of symptoms like problems related to micturition, pain, blood or mucus in the stool and perception of body image, there was significant improvement in all scales over progressing from baseline to second visit for all types of surgeries except for the micturition symptoms which were worst during first visit for patients undergoing high AR. Regarding problems like dry mouth, sense of taste, bloated feeling and worries regarding future and weight, all showed improvement from baseline to subsequent visit irrespective of surgery type.

Separate studies highlighting just sexual dysfunction had also been published. Such a study done by Schmidt et al concluded that there were significant differences between men and women on scales of function and symptoms. Women had worse scores for physical function and overall quality of life and higher values for fatigue. Sexual life was impaired in both men and women, but the impairment was significantly more severe in men, and men felt more distressed by it than women did. Physical function and overall quality of life were better in patients aged 69 and younger, while patients aged 70 and older suffered from fatigue. Younger patients had a more severe impairment of sexuality, which, over the time period of the study, led to severe emotional symptoms.

A study done regarding sexual function, incontinence, and wellbeing in women after rectal cancer by Panjari et al concluded that there is a gap in our knowledge of the effects of rectal cancer and its treatment on urinary and fecal continence, sexual function and QOL in women.<sup>15</sup> There is a need for studies of sufficient size and duration to gain a better understanding of the disease and its management and the long-term effects on these parameters. This information is needed to develop preventative health care plans for women treated for rectal cancer that target those most at risk for these adverse outcomes.

#### CONCLUSION

Quality of life issues in operated cases of rectal cancer patients is a largely unattended issue in the Indian population. The three-questionnaire used in the study comprehensively included all issues from general health after cancer surgery to problems faced by the patients specifically after various modalities of rectal surgery. Compliance to the questionnaire was observed to be less compared to western counterparts. A further larger study would be required to give an exact knowledge of sexual dysfunction in our population because of reluctance on part of the Indian population to discuss such issues when compared to western population.

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