

Prospective evaluation of the quality of life of oral cancer patients undergoing post-operative radiotherapy in a Regional Cancer Centre of central India

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Received: April 16, 2019; Accepted: May 30, 2019

ABSTRACT


Background: The assessment of the quality of life (QOL) has become an important aspect of oral cancer research. It has allowed the evaluation of the impacts of the disease as well as the treatment from the patient's perspective. **Objectives:** The objective of this study is to assess the QOL of oral cancer patients undergoing post-operative radiotherapy (PORT) during treatment as well as after the completion of treatment. **Materials and Methods:** It is a hospital-based prospective observational study. It was carried out in Regional Cancer Centre, Dr. Bhim Rao Ambedkar Hospital, Raipur, India. A total of 108 oral cancer patients with cancer-free survival after surgery who satisfied the study criteria and got registered for PORT were included as study participants. The data with regard to their QOL were collected using the European Organization for Research and Treatment of Cancer QOL Core Questionnaire-C30 and the European Organization for Research and Treatment of Cancer Head and Neck Module (QLQ-H and N35) at three time-points, i.e., just before initiation, just after completion, and 6 months after completion of PORT. Mean, median, standard deviation, standard error, and 95% confidence intervals were calculated. Statistical significance was set at $P < 0.05$. The association between QOL at various time points was analyzed using Wilcoxon signed-rank test and Friedman's ANOVA. **Results:** It was elicited that various scales of functional and symptomatic domains of QOL were significantly impaired at the end of RT and either restored to or improved from pre-RT level, at 6 months after completion of PORT. However, social functioning, nausea vomiting, appetite loss, dry mouth, and sticky saliva remained significantly deteriorated at the final assessment as compared to pre-RT level. **Conclusions:** This study concludes that QOL alters significantly over a short period of time from pre-RT to subsequent post-treatment period. However, it emphasizes the all-important need for psycho-social support in addition to disease cure for oral cancer patients during their treatment as well as a later period.

KEY WORDS: Oral Cancer; Quality of Life; Post-operative Radiotherapy

INTRODUCTION

Oral cancer is turning out to be a major public health problem in India. Around 77,000 new cases occurred in the country

with around 52,000 deaths due to oral cancer during the year 2012. It accounts for over 30% of all cancers in the country.^[1] The age-standardized incidence and mortality rate of oral cancer in India are 9.1 and 5.6 per 100,000 population, respectively, which is much higher than that of the world.^[2] With a multi-factorial etiology (i.e., genetic, environmental, social, and behavioral) and tobacco as one of the most common risk factors associated, oral cancer is causing significant mortality and morbidity worldwide, including India.^[3] It has been estimated that 42.4% of men, 14.2% of women, and 28.6% (266.8 million) of all adults currently use

Access this article online	
Website: http://www.ijmsph.com	Quick Response code 
DOI: 10.5455/ijmsph.2019.0409530052019	

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tobacco (smoked and/or smokeless tobacco) in India, which explains the increasing burden of oral cancer in the country.^[4]

In general, the value that has been used to measure success or failure in cancer treatment has been survival, inferred as a period free of disease. However, currently, in clinical research, quality of life (QOL) is perceived as an important endpoint in addition to the conventional endpoints such as response rate, disease-free survival, and longevity.^[5] QOL is a multidimensional formulation that consists of physical, psychological, social, and emotional functional domains. It has been explained as the value assigned to the duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy.^[6] Long-time survival of oral cancer patients due to screening methods and its early diagnosis followed by treatment indicates that a considerable number of patients cope with the after-effects of the treatment (i.e., surgery or the habitual combination of surgery, radiotherapy (RT), and chemotherapy) in addition to the disease process itself. Therefore, possibly in no other group of cancer patients does QOL play a crucial role as in oral cancer.^[7,8]

RT constitutes an essential component of various treatment modalities of oral cancer. To improve on loco-regional control and forestall recurrence in oral cancer, post-operative radiation therapy (PORT) is frequently recommended in the presence of adverse clinical characteristics. Although augmentation of treatment with PORT has a positive impact on the conventional treatment endpoints, the effect of RT-associated morbidity on oral cancer patients' QOL is still ill-understood.^[9-11] Over the past decade, various advances of RT techniques for treating oral cancer have emerged, but complications associated with irradiation of sensitive normal structures around the oral cavity in the pathway of the irradiation, are still remarkable and often for a lifetime.^[12] As therapeutic radical surgery with or without reconstruction followed by RT, can cause an inevitable functional deterioration, it is important to study its effect on QOL outcomes in addition to treatment outcomes. On the other hand, it is in the short-term (6–12 months) that many changes in QOL are reported and the period from diagnosis to 1 year should be further investigated as there is such a significant change in QOL scoring. However, limited studies have been performed to evaluate the QOL among oral cancer survivors in India. Therefore, the present study was planned to assess the change in QOL of oral cancer patients following PORT.

MATERIALS AND METHODS

Patient Characteristics

The present study was carried out as a prospective observational study designed to evaluate the QOL of oral cancer patients seeking PORT at Regional Cancer Centre

(RCC), Dr. Bhim Rao Ambedkar Hospital, Raipur, India. In this study, oral cancer is considered as primary mucosal carcinoma originating at six locations in the oral cavity, as defined in the Union for International Cancer Control classification: (1) Tongue cancer, (2) upper gingival and alveolar cancer, (3) lower gingival and alveolar cancer, (4) buccal mucosal cancer, (5) floor of mouth cancer, and (6) hard palate cancer.^[13] Patients eligible for this study were those having undergone radical surgery for newly diagnosed oral cancer while registered at RCC for PORT and age >18 years. Patients revealing a history of RT or chemotherapy, previous or synchronous malignancies or metastasis, critically ill and/or a level of cognitive impairment were excluded from participation in this study.

A total of 151 oral cancer patients met the study criteria and gave their consent to participate in the study before the initiation of PORT during the period from June 2016 to October 2016. Data of 43 patients were excluded from the analysis due to dropping out of treatment due to radiation-related side effects ($n = 15$), incomplete data ($n = 8$), and non-compliance to follow-up ($n = 20$). Finally, 108 fully evaluable patients were considered for analysis in the study. There were no significant differences with regard to sex, age, site, stage, or treatment distribution between patients who were included in the study and patients who were excluded from the study.

Methodology

Institutional Ethics Committee granted approval for the study after proper screening for adherence to ethical guidelines. Participants who accepted to be part of the study signed an informed consent form and received formal assurance about the confidentiality of the data. Data were collected through interviews with the help of study tools in the form of questionnaires. Interviews of female participants were done in the presence of a female medico-social worker so that they feel comfortable during the process. Patient information form to obtain personal, socio-demographic and disease-related data, European Organization for Research and Treatment of Cancer (EORTC) QOL Questionnaire (QLQ-C30), and head and neck module (H and N 35) scales to measure QOL were used as study tools. The EORTC core quality of life questionnaire (EORTC QLQ-C30) and H and N35 have been translated and validated into several languages including Hindi and are used in numerous studies worldwide. In the present study, validated Hindi version of EORTC QLQ-C30 and H and N35 has been used. The tools were utilized at three different times, i.e., at the start of PORT(T1), at the end of PORT(T2), and 6 months after completion of PORT(T3).

The EORTC QLQ-C30 is a cancer-specific questionnaire for the assessment of QOL, developed by the EORTC and validated in large cross-cultural settings. It consists of a global QOL domain, five functional scales (physical, role, emotional, cognitive, and social) and nine symptom scales

(fatigue, pain, nausea/vomiting, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). On the other hand, the EORTC QLQ-H and N35 is a head and neck cancer-specific questionnaire consisting of 35 items and is designed to be used together with the EORTCQLQ-C30. This module incorporates seven multi-item symptom scales (pain, swallowing, senses, speech, social eating, social contact, and sexuality) and 11 single item symptom scales (problems with teeth, problems opening the mouth, dry mouth, sticky saliva, cough, feeling ill, pain killers, nutritional supplements, feeding tube, weight loss, and weight gain). Each scale is transformed into a 0–100 point score. In the five functional scales and the global QOL scale, a high score indicates a “high level of functioning or global QOL.” In the case of symptom scales, a higher score implies a “higher level of symptoms or morbidity.”

Statistical Analysis

Data were analyzed using IBM-SPSS 20 statistics software. The mean scores and standard deviation (SD) of the QOL scales were calculated according to the EORTC QLQ scoring manual.^[14] The Kolmogorov–Smirnov normality test was applied, and the data showed a skewed distribution, so data were then analyzed using a non-parametric test. Mean, SD, standard error, 95% confidence intervals were calculated, and statistical significance was set at $P < 0.05$. The association between QOL at various time points was analyzed using Wilcoxon signed-rank test and Friedman’s ANOVA.

RESULTS

Table 1 summarizes the characteristics of the patient cohort of the present study. Majority of subjects were in the age group of 41–50 years (31.48%) and the mean age of the study participants was 47.05 ± 11.25 years. Three-fourth of the study subjects were male patients. Half of the study subjects were from lower socio-economic status (Class IV and V). Majority of patients were having a lesion at buccal mucosa (43.71%) and most of the patients were diagnosed at Stage II (46.36%) and Stage III (37.75%).

Tables 2 and 3 depict the pattern of QOL over time while considering the pre-RT recording (T1) as the baseline. The worst performing functional domain in all the three assessments was a social function for EORTC QLQ-C30. Among symptom scales worst symptom was for “financial difficulties” at T1 (42.28 ± 29.04) whereas “fatigue” scored as a highest symptom at T2 (62.35 ± 17.18) and T3 (41.77 ± 15.63). Further, the highest mean score in Global health status (51.93 ± 16.18) was reported at T1.

Among the three assessments of EORTC QLQ-C-30, it is evident that a trajectory of maximal impairment at T2 (immediately after completion of PORT) followed by

Table 1: Characteristics of study participants

Variable	Category	n (%)
Gender	Male	81 (75.0)
	Female	27 (25.0)
Age group	<30 years	12 (11.12)
	31–40 years	30 (27.78)
	41–50 years	34 (31.48)
	51–60 years	22 (20.95)
	>60 years	10 (9.25)
Residence	Rural	45 (41.67)
	Urban	63 (58.33)
Marital status	Married	102 (94.45)
	Unmarried	4 (3.70)
	Widowed/Separated/Divorced	2 (1.85)
Employment	Employed	78 (72.23)
	Unemployed	30 (27.77)
SES (Modified Prasad classification)	Class I	7 (6.48)
	Class II	21 (19.45)
	Class III	26 (24.07)
	Class IV	44 (40.75)
	Class V	10 (9.25)
Site of lesion of oral cancer	Buccal Mucosa	66 (43.71)
	Tongue	51 (33.77)
	Alveolus	27 (17.88)
	Lip	5 (3.31)
	Palate	2 (1.32)
Stage	Stage I	24 (15.89)
	Stage II	70 (46.36)
	Stage III	57 (37.75)

improvement thereafter till T3 (6 months after completion of PORT) exists. Repeated measure analysis of variance was applied to know the significance of change over three QOL assessments done over the study period and it was found that statistically highly significant ($P < < < 0.01$) difference over time existed in global health status as well as all the domains of functional scales. In symptom scales, all the items except dyspnea ($P = 0.131$) and constipation ($P = 0.145$) showed highly significant ($P < < < 0.01$) change over time.

However, to know the significance in change at each follow-up, Wilcoxon signed-rank test was applied. A highly significant positive change was observed in cognitive functioning when compared between pre-RT (T1) and final QOL assessment (T3), whereas emotional and social functioning showed a negative change. Physical and role functioning also showed improvement, but the difference was found insignificant. In symptom scales, significant deterioration was observed from baseline pre-RT (T1) to first follow-up after RT in all items of core questionnaire except dyspnea ($P = 0.549$) and constipation ($P = 0.064$). On the other hand, nausea and vomiting, pain, appetite loss, financial difficulties remained

Table 2: Comparison of domains of EORTC QLQ-C30 during three assessments

Domains	Before	After	6 months after completion of PORT (T3) [#]	Wilcoxin signed rank test (<i>P</i> -value)			Friedman's ANOVA (<i>P</i> value)
	PORT (T1) [#]	PORT (T2) [#]		T1-T2	T2-T3	T1-T3	
	Mean±SD	Mean±SD	Mean±SD				
Global health status							
Global health status	51.93±16.18	40.66±12.15	50.46±12.47	HSF*	HSF	0.309	HSF*
Functional scales							
Physical functioning	83.27±14.13	70.00±14.63	85.37±11.03	HSF	HSF	0.530	HSF
Role functioning	96.14±10.09	91.97±11.73	96.30±8.00	HSF	HSF	0.980	HSF
Emotional functioning	81.48±16.91	73.69±13.20	90.05±9.56	HSF	HSF	HSF	HSF
Cognitive functioning	96.45±7.23	88.73±13.25	92.75±11.90	HSF	HSF	HSF	HSF
Social functioning	69.75±19.22	49.85±20.95	77.01±15.57	HSF	HSF	HSF	HSF
Symptom scales/items							
Fatigue	38.48±17.68	62.35±17.18	41.77±15.63	HSF	HSF	0.910	HSF
Nausea and vomiting	3.40±10.63	17.28±17.34	8.18±9.80	HSF	HSF	HSF	HSF
Pain	9.57±13.13	24.23±18.42	6.02±10.56	HSF	HSF	0.008	HSF
Dyspnea	4.63±11.58	5.56±12.48	2.78±9.25	0.549	0.039	0.157	0.131
Insomnia	7.72±16.18	20.37±23.61	8.02±15.02	HSF	HSF	0.986	HSF
Appetite loss	24.38±24.37	55.56±27.72	32.10±22.75	HSF	HSF	0.01	HSF
Constipation	7.72±16.18	12.04±21.11	8.95±14.84	0.064	0.167	0.786	0.145
Diarrhea	0.62±4.51	3.70±10.52	1.23±6.32	0.004	0.046	0.414	HSF
Financial difficulties	42.28±29.04	57.72±31.11	37.34±24.42	HSF	HSF	0.014	HSF

*HSF: Highly significant <<<0.01. [#]T1-Before post-operative radiotherapy/baseline. [#]T2-After post-operative radiotherapy (1st follow-up). [#]T3-After 6 months of post-operative radiotherapy (2nd follow up), EORTC QLQ-C30: European Organization for Research and Treatment of Cancer quality of life-C30, PORT: Post-operative radiotherapy, SD: Standard deviation

significantly deteriorated at T3 when compared with the baseline (T1).

Similarly, as explained Table-3, all most all the items of QLQ-H and N 35 indicate distinct change over time. Among all symptom of EORTC QLQ-H and N 35 scales, worst one was “opening mouth” at T1 (30.86±23.55) whereas “weight loss” scored highest at T2 (81.48 ± 39.02) and T3 (31.48 ±46.66). All the symptoms manifested with maximum severity at T2, i.e., post-RT except “feeding tube” and “weight gain.” This is since none of the study subjects reported the use of feeding tube or weight gain during any of the three QOL assessments.

Repeated measure ANOVA found that statistically significant difference over time existed in all the symptoms of EORTCQLQ-H and N 35 barring “feeding tube” and “weight gain.” Within the three assessments of EORTCQLQ-H and N 35, all the symptoms except “feeding tube” and “weight gain” showed an increase in severity between T1 and T2 and decrease in severity thereafter between T2 and T3. To know the significance in change at each follow-up as compared to baseline (T1), Wilcoxon signed-rank test was applied. Almost all the symptoms (except weight loss, weight gain, and feeding tube) significantly worsened from T1 to T2. On the other hand, 7 out of 18 symptoms (“pain” “sexuality” “opening mouth” “coughing” “felt ill” “pain killers” “weight loss”) found significantly improved at 6 months (T3) when compared to pre-RT status (T1). However, “dry mouth” (*P* = 0.016) and

“sticky saliva” (*P* = 0.007) remained significantly deteriorated at the final assessment (T3) as compared to baseline (T1).

DISCUSSION

Based on study results, it can be summarized that there is a significant change in QOL of subjects during different time points following PORT. Statistically significant deterioration was found after RT during second QOL assessment with maximum impairment for social followed by emotional and physical functioning scales among the majority of study subjects. After completion of RT, when subjects went back to their family environment and further QOL assessment was done after 6 months, it was found that majority of study subjects showed improvement in almost all functional as well as symptom scales.

With the heterogeneous nature of oral cancer and the diverse treatment modalities applied in studies, the influence of radiation complications on the QOL outcome for oral cancer patients appears to be unclear. In contrast with other studies, only those treated with PORT were eligible in this study, thereby excluding the possible effects of an existing gross tumor on the patient's QOL. This helped to assess changes in QOL related to radiation complications among post-operative patients more clearly as RT is one of the most important parameters affecting the QOL of oral cancer patients.^[15]

Table 3: Comparison of domains of EORTC QLQ-H and N 35 during three assessments

Domains	Before PORT (T1) [#]	After PORT (T2) [#]	6 months after completion of PORT (T3) [#]	Wilcoxin signed-rank test (P-value)			Friedman's ANOVA (P value) SD
	Mean±SD	Mean±SD	Mean±SD	Mean	SD	Mean	
Pain	8.71±11.18	30.63±14.97	5.16±5.77	HSF*	HSF	HSF	HSF
Swallowing	6.14±10.67	16.94±13.10	5.47±4.98	HSF	HSF	0.966	HSF
Senses problems	10.80±15.33	14.50±16.75	11.88±36.67	HSF	HSF	0.472	0.003
Speech problems	25.25±12.80	42.07±15.71	27.98±11.41	HSF	HSF	0.139	HSF
Trouble with social eating	28.85±15.47	41.51±18.61	29.86±16.27	HSF	HSF	0.887	HSF
Trouble with social contact	13.39±11.97	21.72±14.04	11.17±11.23	HSF	HSF	0.086	HSF
Sexuality	20.15±19.77	51.94±24.45	13.57±17.15	HSF	HSF	0.053	HSF
Teeth	23.76±26.20	28.70±30.04	20.67±22.19	0.023	HSF	0.095	0.021
Opening mouth	30.86±23.55	50.92±23.44	26.85±16.71	HSF	HSF	0.017	HSF
Dry mouth	11.72±18.40	56.48±20.61	18.20±17.28	HSF	HSF	0.016	HSF
Sticky saliva	7.098±15.14	62.34±18.84	13.57±17.07	HSF	HSF	0.007	HSF
Coughing	2.160±8.24	7.71±18.00	1.54±7.03	0.005	HSF	HSF	HSF
Felt ill	25.30±24.05	40.12±26.48	8.02±15.02	HSF	HSF	HSF	HSF
Pain killers	19.44±39.76	38.88±48.97	8.33±27.76	0.001	HSF	0.014	HSF
Nutritional supplements	19.44±39.76	28.70±45.44	11.11±31.57	0.033	0.002	0.095	0.002
Feeding tube	0.00±0.00	0.00±0.00	0.00±0.00	1.000	1.000	1.000	1.000
Weight loss	69.44±46.27	81.48±39.02	31.48±46.66	0.063	HSF	HSF	HSF
Weight gain	0.00±0.000	0.00±0.00	0.00±0.00	1.000	1.000	1.000	1.000

*HSF-Highly significant <<<0.01. [#]T1-Before post-operative radiotherapy/Baseline. [#]T2-After post-operative radiotherapy (1st follow up). [#]T3-After 6 months of post-operative radiotherapy (2nd follow-up), EORTC QLQ-C30: European Organization for the Research and Treatment of Cancer quality of life-C30, PORT: Post-operative radiotherapy, SD: Standard deviation

Throughout the EORTC QLQ C30 assessments in the present study, among functional scales, the worst one was social functioning. This was in accordance with Oates *et al.*, which reported the worst function at the end of the RT as social and role functioning.^[16] As per the current study, among functional scales, physical and role functioning reached baseline values after a significant drop following RT. On the other hand, emotional and social functioning improved from the baseline pre-PORT phase (T1) to 6 months after RT (T3), whereas only cognitive functioning degraded. These observations are in contradiction to study findings of Braam *et al.* as all the functional scale items improved after RT (except cognitive functioning) but without any significant change.^[17] Several studies have shown that degradation of cognitive function may be attributed to various factors such as inactivity depression/anxiety, psychological and emotional stress, nutritional factors and deficiencies, and direct neurotoxic effects of RT.^[18] Among symptom scales, fatigue, appetite loss, weight loss, nausea vomiting, and financial difficulties had the worst mean scores, which is comparable with other studies.^[19-21]

Most of the participants from the study reported post-surgical disfigurement of faces. This may be a crucial factor affecting the emotional and social domain of the patients. The emotional domain of QOL had been described as an important

predictor of the overall burden of oral cancer patients by Onakoya *et al.*^[22] Meanwhile, the social function degraded significantly during the PORT period. This may be since most of the patients in our study were coming from distant areas for RT. They had to come at least 2–4 times/week to undergo RT for 1–2 months. During this period, it may have kept them isolated from various social events which prevented their social integration. Once the discharged (after completion of RT) subjects returned home, the improvement in the physical condition and the continuous support from families and friends improved the emotional as well as social status of subjects. Thus, the subjects may have reported a significantly better social and emotional functioning of the QOL during the past follow-up. With regard to the financial status, most subjects in the present study were with lower socio-economic status. Although RT was provided free of cost, the economic cost of being out of work and the indirect costs of treatment (especially travel and stay) increased the financial burden on these subjects. Patients who had undergone surgery at private healthcare facilities were already with higher out of the pocket expenditure. Thus, subjects reported more financial difficulties at each to follow-up.

In the EORTC QLQ-H and N35 assessments, most subjects reported more serious problems (i.e., speech, taste/smell, sticky saliva, dry mouth, coughing, weight loss, opening

mouth, and sexuality) just after completing PORT. Opening mouth was reported as a problem due to post-surgical stricture at the first assessment, which improved significantly at second follow-up. Loss of weight was a common complaint throughout the study duration, which may be due to both nutritional as well as psychological factors. When compared to other studies, it was observed that specific symptoms in the head-neck-area (e.g., problems with swallowing and speech) presented the most difficulties to patients.^[23,24] At T2 most of the patients were on liquid or semi-solid food (e.g., Dalia) due to sore throat, local inflammation due to RT and teeth problems after surgery. After 6 months of PORT (T3) also there were complaints of difficulties as complete dental rehabilitation although possible, is not available to all patients due to the health system and financial reasons. None of the patients were on a feeding tube during the study period. There were also apparently consistent results in the social domains of the two questionnaire modules. Social functioning in the core questionnaire showed significant improvement after last QOL assessment. Social functioning (trouble with social contact) as explored in the H and N 35 modules, which exhibited a significant decrease after PORT (T2) also improved at T3. The trouble with social eating, however, persisted, which is in accordance with the study results of Fang *et al.*^[25]

Even though the mean age of the patients is quite high in this study, sexuality still remains an important aspect for many of them as the perception on the sexuality change quite a lot during treatment and follow-ups.^[26] Most of the female subjects skipped this part of the questionnaire as they consider themselves as a part of conservative society and preferred to remain silent on this issue. However, scores on sexuality scale improved significantly 6 m after PORT. This may be linked to the pattern of the emotional domain of QOL to some extent.

Xerostomia, one of the most common complications from RT to affect oral cancer patients, has been broadly studied. It results in tooth decay, periodontal disease, taste loss, and dysphagia.^[27] One study of 75 patients reported that more than 90% of patients were found to have decreased saliva production, causing wide range of secondary emotional and social problems, including increased tension and worry, depression, impaired speech, and heightened consciousness while eating with other people.^[28] As per the present study, xerostomia and dry mouth still persisted at 6 m after PORT but relatively less as compared to a similar study by Braam *et al.*^[17] This may be attributed to the fact that all of the patients received intensely modulated RT (IMRT) as methods for PORT. A randomized trial on IMRT's parotid sparing effect in head and neck cancers confirms that xerostomia is significantly reduced among those cancer patients which are treated through this modality.^[29]

The present study also elicited that the disease and treatment-induced symptomatic problems lead to a diversity of functional

impairments, which can subsequently transfer into a poorer global QOL and that global QOL trend grossly correlates well with other domains of EORTC QLQ-C30, as explained by List and Stracks.^[30] This is in contradiction to a similar study done by Fang *et al.* which had a longer follow-up period, and the symptoms did not sensitively translate into poorer global QOL score.^[25] In accordance with other longitudinal studies, it was found that a temporary deterioration in several physical symptoms and functioning scales occurred during the study period.^[31-35] PORT led to deterioration of most of the QOL component in the present study (which were already being affected by surgery) followed by gradual improvement but after 6 month most of the domains reached the baseline level (T1) with some exceptions.

The whole pattern of restoration of QOL domains may be largely ascribed to the effect of "response shift" phenomenon on the interpretation of longitudinal QOL changes for cancer patients. The concept of response shift refers to a change of a person's internal standard for determining his or her level of functioning on a given dimension.^[36,37] This is believed to be due to a combination of various factors, including time required to recover from treatment side effects and to adapt to a new lifestyle, and perhaps eventually increasing optimism in the absence of recurrent disease. Although the effect of response shift has not been measured in this study, it is important to understand that it is the patient's perception and experience that decides the QOL rather than the absolute numerical score of QOL. Present study also suggests that those patients who survived to receive PORT after the catastrophic experience of being diagnosed with cancer and then receiving radical cancer surgery might have developed a somewhat tougher enduring capability to deal with the side effects of RT in its physical-psychosocial functioning aspects during the PORT as well as during subsequent time periods. However, Rapoport *et al.* observed a deterioration after 18 months and Bjordal *et al.* found that QOL deteriorated significantly during treatment, followed by a gradual recovery until the 12-month follow-up. In contrast, the present study found an improvement during 6 months period.^[38,39] This pattern may be explained by the fact that maximum proportion (>50%) of patients in our study belongs to lower socio-economic status and there may be a positive change in their perception regarding QOL more rapidly than expected. On the other hand, in the present study, there were a relatively high proportion of patients with limited disease and free from recurrence or metastasis, which may have also led to limited long-term psychosocial morbidity and could have contributed to early restoration of QOL.

Our study has the following limitations. First, we have not included the patients with recurrences or metastasis, thereby making the results applicable only to oral cancer patients with better survival characteristics leading to a limited generalization of findings. Second, this study does not have any indications of whether the QOL of dropouts was differing

from that of the study participants or was without any distinction, although the socio-demographic characteristics were matching largely. Finally, the current study tries to analyze the QOL changes during a short-term post-treatment period, thereby failing to follow-up the patients for a longer duration due to time and resource constraints.

CONCLUSIONS

This study showed that RT had a substantially negative impact on the QOL of patients with oral cancer. Our results confirmed that QOL deteriorated during treatment, with maximum deterioration just after the RT and progressively improved after the treatment was completed. It is recommended that before the start of RT, patient as well as their family members should be well informed and counseled about the process and side effects of the therapy for reduction of physical and psychological sufferings. During therapy, peer support groups among oral cancer patients should be formed and motivational cum spiritual talk sessions should be arranged for the promotion of their social and emotional well-being at the institutional level. There is a further need to study the association between QOL domains, the clinical significance of QOL, and survival of oral cancer patients to provide more insight into the effect of disease and its treatment on them. Assessing the QOL is a complex, yet a crucial tool to understand and support recommended changes to attain more effective patient care for oral cancer patients. Therefore, QOL should be used as an integral component for the comprehensive assessment of oral cancer therapy and its outcome. After all, somebody has truly quoted – “a good physician treats the disease; the great physician treats the patient who has the disease.”

REFERENCES

1. Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, *et al.* GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC Cancer Base No. 11. Lyon, France: International Agency for Research on Cancer; 2013.
2. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A, *et al.* Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin* 2018;68:394-424.
3. Manoharan N, Tyagi BB, Raina V. Cancer incidences in rural Delhi 2004-05. *Asian Pac J Cancer Prev* 2010;11:73-8.
4. Tata Institute of Social Sciences (TISS), Mumbai and Ministry of Health and Family Welfare, Government of India. Global Adult Tobacco Survey GATS 2. India: Tata Institute of Social Sciences; 2016-17.
5. Slevin ML. Quality of life: Philosophical question or clinical reality? *BMJ* 1992;305:466-9.
6. Patrick DL, Erickson P. Health Status and Health Policy: Quality of Life in Health Care Evaluation and Resource Allocation. New York: Oxford University Press; 1993.
7. Bjordal K, Kaasa S. Psychological distress in head and neck cancer patients 7-11 years after curative treatment. *Br J Cancer* 1995;71:592-7.
8. Hassan SJ, Weymuller EA Jr. Assessment of quality of life in head and neck cancer patients. *Head Neck* 1993;15:485-96.
9. Ang KK, Trotti A, Brown BW, Garden AS, Foote RL, Morrison WH, *et al.* Randomized trial addressing risk features and time factors of surgery plus radiotherapy in advanced head-and-neck cancer. *Int J Radiat Oncol Biol Phys* 2001;51:571-8.
10. Hinerman RW, Mendenhall WM, Morris CG, Amdur RJ, Werning JW, Villaret DB, *et al.* Postoperative irradiation for squamous cell carcinoma of the oral cavity: 35-year experience. *Head Neck* 2004;26:984-94.
11. Shrimme MG, Gullane PJ, Dawson L, Kim J, Gilbert RW, Irish JC, *et al.* The impact of adjuvant radiotherapy on survival in T1-2N1 squamous cell carcinoma of the oral cavity. *Arch Otolaryngol Head Neck Surg* 2010;136:225-8.
12. Wan Leung S, Lee TF, Chien CY, Chao PJ, Tsai WL, Fang FM, *et al.* Health-related quality of life in 640 head and neck cancer survivors after radiotherapy using EORTC QLQ-C30 and QLQ-H&N35 questionnaires. *BMC Cancer* 2011;11:128.
13. Izumo T. Surgical pathology of oral cancer. In: Kirita T, Omura K, editors. *Oral Cancer Diagnosis and Therapy*. Japan: Springer; 2015. p. 23-4.
14. Fayers P, Aaronson NK, Bjordal K, Curran D, Gronvold M. EORTC QLQ-C30 Scoring Manual. 2nd ed. Brussels: EORTC Data Center; 1999.
15. Van Cann EM, Dom M, Koole R, Merckx MA, Stoeltinga PJ. Health related quality of life after mandibular resection for oral and oropharyngeal squamous cell carcinoma. *Oral Oncol* 2005;41:687-93.
16. Oates JE, Clark JR, Read J, Reeves N, Gao K, Jackson M, *et al.* Prospective evaluation of quality of life and nutrition before and after treatment for nasopharyngeal carcinoma. *Arch Otolaryngol Head Neck Surg* 2007;133:533-40.
17. Braam PM, Roesink JM, Raaijmakers CP, Busschers WB, Terhaard CH. Quality of life and salivary output in patients with head-and-neck cancer five years after radiotherapy. *Radiat Oncol* 2007;2:3.
18. Asher A, Myers JS. The effect of cancer treatment on cognitive function. *Clin Adv Hematol Oncol* 2015;13:441-50.
19. Citak E, Tulek Z. Longitudinal quality of life in Turkish patients with head and neck cancer undergoing radiotherapy. *Support Care Cancer* 2013;21:2171-83.
20. De Graeff A, de Leeuw JR, Ros WJ, Hordijk GJ, Blijham GH, Winnubst JA, *et al.* Long-term quality of life of patients with head and neck cancer. *Laryngoscope* 2000;110:98-106.
21. Al-Mamgani A, van Rooij P, Tans L, Verduijn GM, Sewnaik A, Baatenburg de Jong RJ, *et al.* A prospective evaluation of patient-reported quality-of-life after (chemo) radiation for oropharyngeal cancer: Which patients are at risk of significant quality-of-life deterioration? *Radiation Oncol* 2013;106:359-63.
22. Onakoya PA, Nwaorgu OG, Adenipekun AO, Aluko AA, Ibekwe TS. Quality of life in patients with head and neck cancers. *J Natl Med Assoc* 2006;98:765-70.
23. Bjordal K, Kaasa S, Mastekaasa A. Quality of life in patients treated for head and neck cancer: A follow-up study 7 to 11 years after radiotherapy. *Int J Radiat Oncol Biol Phys* 1994;28:847-56.
24. Konstantinović VS. Quality of life after surgical excision followed by radiotherapy for cancer of the tongue and floor of the mouth: Evaluation of 78 patients. *J Craniomaxillofac Surg*

- 1999;27:192-7.
25. Fang FM, Chien CY, Kuo SC, Chiu HC, Wang CJ. Changes in quality of life of head-and-neck cancer patients following postoperative radiotherapy. *Acta Oncol* 2004;43:571-8.
 26. Bjordal K, Ahlner-Elmqvist M, Tolleson E, Jensen AB, Razavi D, Maher EJ, *et al.* Development of a European organization for research and treatment of cancer (EORTC) questionnaire module to be used in quality of life assessments in head and neck cancer patients. EORTC quality of life study group. *Acta Oncol* 1994;33:879-85.
 27. Bomeli SR, Desai SC, Johnson JT, Walvekar RR. Management of salivary flow in head and neck cancer patients a systematic review. *Oral Oncol* 2008;44:1000-8.
 28. Dirix P, Nuyts S, VanderPoorten V, Delaere P, Vanden Bogaert W. The influence of xerostomia after radiotherapy on quality of life: Results of a questionnaire in head and neck cancer. *Support Care Cancer* 2008;16:171-9.
 29. Nutting CM, Morden JP, Harrington KJ, Urbano TG, Bhide SA, Clark C, *et al.* Parotid-sparing intensity modulated versus conventional radiotherapy in head and neck cancer (PARSPORT): A phase 3 multicentre randomised controlled trial. *Lancet Oncol* 2011;12:127-36.
 30. List MA, Stracks J. Evaluation of quality of life in patients definitively treated for squamous carcinoma of the head and neck. *Curr Opin Oncol* 2000;12:215-20.
 31. Deleyiannis FW, Weymuller EA Jr, Coltrera MD. Quality of life of disease-free survivors of advanced (stage III or IV) oropharyngeal cancer. *Head Neck* 1997;19:466-73.
 32. List MA, Siston A, Haraf D, Schumm P, Kies M, Stenson K, *et al.* Quality of life and performance in advanced head and neck cancer patients on concomitant chemoradiotherapy: A prospective examination. *J Clin Oncol* 1999;17:1020-8.
 33. Hammerlid E, Bjordal K, Ahlner-Elmqvist M, Jannert M, Kaasa S, Sullivan M, *et al.* Prospective, longitudinal quality-of-life study of patients with head and neck cancer: A feasibility study including the EORTC QLQ-C30. *Otolaryngol Head Neck Surg* 1997;116:666-73.
 34. Hammerlid E, Mercke C, Sullivan M, Westin T. A prospective quality of life study of patients with oral or pharyngeal carcinoma treated with external beam irradiation with or without brachytherapy. *Oral Oncol* 1997;33:189-96.
 35. Rogers SN, Humphris G, Lowe D, Brown JS, Vaughan ED. The impact of surgery for oral cancer on quality of life as measured by the medical outcomes short form 36. *Oral Oncol* 1998;34:171-9.
 36. Sprangers MA. Quality-of-life assessment in oncology. Achievements and challenges. *Acta Oncol* 2002;41:229-37.
 37. Sprangers MA, Schwartz CE. Integrating response shift into health-related quality of life research: A theoretical model. *Soc Sci Med* 1999;48:1507-15.
 38. Rapoport Y, Kreitler S, Chaitchik S, Algor R, Weissler K. Psychosocial problems in head-and-neck cancer patients and their change with time since diagnosis. *Ann Oncol* 1993;4:69-73.
 39. Bjordal K, Ahlner-Elmqvist M, Hammerlid E, Boysen M, Evensen JF, Björklund A, *et al.* A prospective study of quality of life in head and neck cancer patients. Part II: Longitudinal data. *Laryngoscope* 2001;111:1440-52.

How to cite this article: Pradhan SK, Gupta SA, Shrivastava N, Sinha A, Agrawal S. Prospective evaluation of the quality of life of oral cancer patients undergoing post-operative radiotherapy in a Regional Cancer Centre of central India. *Int J Med Sci Public Health* 2019;8(8):640-647.

Source of Support: Nil, **Conflict of Interest:** None declared.