A longitudinal study to assess quality of life in cervical cancer patients before and after cancer-directed treatment

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ABSTRACT

Background: Cervical cancer is world's one of the most deadly but easily preventable cancers of women. Diagnosis and treatment is emotionally traumatic and results in psychosexual sequelae-affecting quality of life (QoL). The present study was conceptualized as Department of Community Medicine, Government Medical College, Jammu is already reporting these cancers to Indian Council of Medical Research (ICMR) and it was thought that a QoL study would help us in getting fair idea about their QoL as well. **Objectives:** To assess and compare QoL of cervical cancer patients before and after completion of cancer-directed treatment (CDT). **Materials and Methods:** The present longitudinal study was conducted in Government Medical College which is a tertiary care hospital in Jammu. All newly diagnosed cases of cervical cancer over a period of 6 months were included in the study. European Organization for Research and Treatment of Cancer (EORTC) QoL questionnaire (QLQ) C-30 (general) and EORTC CX-24 (specific) questionnaires were used to assess QoL. The data was analyzed using computer software Microsoft Excel and SPSS version 17. A scoring algorithm recommended by EORTC was used. Pre- and post-mean scores were compared by the use of paired *t*-test. Pre- and post-Cronbach's alpha reliability coefficient was also calculated. **Results:** Stage III was the most common stage diagnosed followed by Stage II. Regarding QLQ C-30, the mean scores across all domains showed statistically significant worsening of QoL from baseline. The worsening was more severe in emotional and social functioning. Regarding, Global health status and EORTC QLQ CX-24 questionnaire all items also showed worsening of QoL from their baseline values. **Conclusion:** QoL of cervical cancer patients showed worsening after CDT in all domains due to acute and subacute adverse effects of radiotherapy and chemotherapy in the course of treatment.

KEY WORDS: Quality of Life; Cervical Cancer; European Organization for Research and Treatment of Cancer Quality of Life Questionnaire CX-24; Quality of Life Questionnaire C-30

INTRODUCTION

Cancers figure among the leading causes of morbidity and mortality worldwide. The global annual incidence of cervical cancer is around 5,29,800 new case with 2,75,100 deaths[1,2] with rising population and aging, number of cervical cancer cases is expected to increase 1.5 fold by 2030.[2] The situation in India is alarming. India reports high incidence of oral cancer, carcinoma breast, and carcinoma cervix.[3,4] According to the World Health Organization (WHO) cancer country profiles, 2014, in India there are an estimated 1,22,844 new cases of cervical cancer in females.[5] For cervical cancer, human papilloma virus, high-risk sexual activity, high parity, smoking, oral contraceptives, family history, etc., are known risk factors.[2] Cancers have devastating effect on the lives of those afflicted with it. It instills a dreary sense of fear and panic in the mind of those suffering from it and those receiving treatment as well. It shatters the patients physically and psychologically affecting their quality of life (QOL). The burden of cancers and its impact on the patient justify that the

QOL of such patients is evaluated properly and suitable steps initiated to mitigate their suffering.[2,6]

The WHO defines "QoL as an individual's 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."[7]

The measurement of such phenomenon is complicated as the underlying issues have strong cultural basis and therefore no single instrument capably determines health-related QoL in different settings. The European Organization for Research and Treatment of Cancer (EORTC), QoL questionnaire (QLQ) C-30 is a cross-culturally accepted and widely used generic instrument for assessing the health-related QoL (HR QOL) of cancer patients.[8,9] EORTC QLQ CX-24 is specific instrument that focus on problems associated with cervical cancer, respectively.[9]

Cervical cancer diagnosis lead to emotional and psychosexual sequalae[10-12] and its treatments, such as surgery, chemotherapy (CT), and radiation, can result in a distortion of body image, nausea, vomiting, diarrhea, constipation, mucositis, weight changes, psychological factors, hormonal changes, and economic burden.[13-15] QoL is increasingly being used as a primary outcome measure in evaluating treatment effectiveness. Thus, clinicians and policymakers are recognizing health-related QoL importance for better patient management and policy decisions.

Thus, there is a clear need to evaluate QOL and factors that affect it. QoL studies provide data regarding cancer treatment-related side effects, its related effectiveness, thus helping cancer patients in their decision-making and QoL improvement and also in prognosis.[16] Since health-related QoL measure in medical research is common in the west, but there is paucity of literature on longitudinal studies on QoL from India. Further, QoL varies with cancer site, time since diagnosis, pre- and post-treatment.[15,17]

Thus, the present study was conducted to assess and compare QoL in cervical cancer patients before and after completion of cancer-directed treatment (CDT) in tertiary care hospital of Jammu city.

MATERIALS AND METHODS

The study was conducted in the Department of Radiotherapy, Government Medical College Jammu. The department is a part of Regional Cancer Center and caters to nearly 2000 cancer patients yearly and serves as a referral center for entire Jammu province while drawing many patients from neighboring states as well. The department houses facilities for external radiotherapy (RT), brachytherapy, and other modalities for diagnosis and management of cancer patients.

The department is collaborating with the Department of Community Medicine in implementing National Cancer Registry Project of Indian Council of Medical Research (Hospital Based Cancer Registry-Pattern of Care and Survival Studies) project since 2014.

The present study was conducted in patients of carcinoma cervix registered with Department of Radiotherapy and Gynecology with effect from 1st October 2015 to 31 March 2016. Sensitization meetings with the faculty of these departments were convened before the initiation of the study. The study was initiated after seeking clearance from Institutional Ethical Committee GMC Jammu.

The study design was longitudinal in nature. All patients of cervix carcinoma registered with the department and being treated on outpatient or inpatient basis were eligible to participate.

Inclusion Criteria

All newly diagnosed cases of cervical cancer with all stages and all sites, irrespective of age, sex were included in the study.

Exclusion Criteria

- Gross psychopathology (functional status sufficiently impaired to prevent answering the questionnaire
- Terminally ill and ambulatory patients
- Pregnant women
- Patient unable to understand language
- Patients not consented to participate
- Already receiving CDT.

The investigator on daily basis visited newly registered cases in Department of Radiotherapy and contacted them. All such patients were requested to participate in the present study. After seeking written consent from them, the general sociodemographic data were collected, and then, the patients were subjected to personal interviews using predesigned validated cancer-specific QOL questionnaires.

Attempt was made to capture all patients of carcinoma cervix who reported to gynecology outpatient department. To capture all such patients, a close liaison with the departments was made and information was collected on regular basis.

Upon getting information from any of the department regarding admission of patient with the cancer, the investigator approached the patients and seeks his or her consent to participate. The patients thereafter were interviewed in a similar manner and using similar tools.

Information regarding cancer specific QoL was obtained using cancer-specific QoL questionnaire. EORTC QLQ C-30[8]

(generic questionnaire) and EORTC QLQ CX-24[9] (specific questionnaire) was used. These standard questionnaires are validated cancer-specific measures of health-related QoL.

Salient features of these questionnaires are given below.

- EORTC QLQ-C 30: Is a30 item generic validated questionnaire formulated to assess QOL during the previous week for assessing three symptom scales, five functioning scales, a global health status/QoL scale, one assessing financial impact, and six single items.[8]
- EORTC QLQ CX-24: It consists of 24 questions (4-likert scale) including three multi-item scales on symptom experience, body image, and sexual/vaginal functioning and six single-item scales covering statements on lymph-edema, peripheral neuropathy, menopausal symptoms, sexual worry, sexual activity, and sexual enjoyment.[11]

All the patients thus recruited were followed up as per the management protocol followed by the Department of Radiotherapy. All the patients thus registered were interviewed after completion of CDT (within 4-6 weeks) using similar questionnaire to the one used to collect data before the initiation of treatment. In case the patients got registered after getting treatment from other institution in or outside the state, such patients were only subjected to QoL interview after the completion of CDT.

Loss to follow-up was minimized by making telephone calls if the patient misses scheduled visit.

Classification of Smokers, Smokeless Tobacco Users, Alcohol Users[16,18]

Current smoker

Respondents who reported smoking at least 100 cigarettes in their lifetime and who, at the time of survey, smoked either every day or some days.

Former smoker

Respondents, who reported smoking at least 100 cigarettes in their lifetime and who, at the time of survey, did not smoke at all.

Never smoker

Respondents who have never smoked a cigarette or who smoked fewer than 100 cigarettes in their entire lifetime.

Current smokeless tobacco user

Respondents currently using smokeless tobacco and who, at the time of survey, used smokeless tobacco either every day or some days.

Former smokeless tobacco user

Respondents who are ever daily smokeless tobacco users and currently do not use smokeless tobacco.

Never user

Who has never consumed smokeless tobacco.

Current drinker

Current drinking was defined as consumption of alcohol in the past year. Among current drinkers, low in take was defined as up to 7 drinks per week; moderate intake was defined as 7-14 drinks per week for women or 7-21 drinks per week for men; and high intake was defined as more than 14 drinks per week for women and more than 21 drinks per week for men.

Former drinker

Former drinking was defined as having ceased alcohol consumption for 1 year or more.

Never drinker

Who has never consumed alcohol.

Statistical Analysis

The data were analyzed using computer software Microsoft Excel and SPSS version 17 for windows (Chicago Inc.). Data was entered in Microsoft Excel for windows and double checked for accuracy. The scores recorded on each item of respective QOL question was linearly transformed to provide a score ranging from 0 to 100; A scoring algorithm recommended by EORTC was used.[19] A problematic group was defined as one with a Global QoL or functional scale score of 33 or less and symptom scale score of 66 or more on the QLQ C-30 and QLQ CX-24.[20,21] Qualitative data were reported as percentages whereas mean ± SD was reported for quantitative variables. Pre- and post-mean scores were compared by the use of paired *t*-test. A $P < 0.05$ was considered as significant. All P values reported were two tailed.

RESULTS

58 cervical cancer patients were enrolled. Pre- and post-QoL was available for 39 of the patients. The predominant reason for noncompletion of pre- and post-QoL assessment in all patients was reception of any form of CDT before enrolment (12), recurrent cancers (4), followed by discontinuation of treatment (3) (Figure 1).

Table 1 depicts that out of 58 cases, maximum cases 35 (nearly 61%) were in age group of 36-57 years. The mean age of patients was 51.6 ± 11.1 years with range of 29-75 years. As per Figure 2, most (32.8%) of the patients belonged to Jammu district followed by Kathua district (15.5%). Least number of patients (1.7%) belonged to Ladakh and Leh district as they are geographically hard to reach areas. Regarding sociodemographic profile of patients (Table 2), nearly 48 (82.8%) cervical cancer patients belonged to

Hindu religion followed by Muslim cases. Maximum cases were married, illiterate, and moderate workers. Regarding personal characteristics of patients, 43 (74.1%) patients were vegetarian, and 15 (25.9%) were nonvegetarian. Majority of cases 51 (88%) were never smokers followed by former smokers 7 cases (12%). There was no current smoker in the present study. Maximum cases 49 (84.5%) were never users of smokeless tobacco, 9 cases were former users, and there was no current smoker. There was no patient who had history of alcohol intake.

Gynecological and obstetrics history revealed that only 7% of the cervical cancer patients had a history of early menarche. Most (64%) of the patients were postmenopausal and 36% were premenopausal. 76% of patients had more than 2 children. Majority of patients (64%) were not using any methods of contraception, 21% had history of tubectomy, 10% of the patients were having history of

usage of oral contraceptives and 5% were using barrier method (Table 3). About 22.4% of cervical cancer patients were suffering from comorbidities. Among comorbidities, one patient was suffering from HIV infection and about 20.7% were suffering from non-communicable disease (Table 4).

Table 5 depicts that Stage III (48%) was the most common cervical cancer stage diagnosed followed by Stage II in 38% cases, 9% had metastatic stage, 5% had Stage IVA, and none of the patients were diagnosed as Stage I. 91% of the patients were treated with curative/radical intention and 9% were treated with palliative intent. Majority (86%) of the patients were treated with concurrent chemoradiation followed by brachytherapy, and 9% were treated with palliative (RT ± CT).

As evident in Table 6, the mean scores across all domains showed worsening of QoL from baseline. The worsening was more severe in emotional and social functioning while physical, role, and cognitive functioning were comparatively less affected. None of the patients had nausea, vomiting, and diarrhea before CDT. 71% however had diarrhea of varying severity. Fatigue, pain, and dyspnea also showed worsening after CDT with fatigue most affected and dyspnea being affecting least number of patients. Insomnia which was widely seen before CDT persisted after. Similarly, appetite loss was observed

Table 1: Age distributsion of cervical cancers (*n*=58)

Age (years)	Females *n* (%)
25-35	4 (6.9)
36-46	17 (29.4)
47-57	18 (31)
58-68	14 (24.1)
69-79	5 (8.6)
Total	58

Table 2: Sociodemographic characteristics of cervical cancers (*n*=58)

Characteristics	*n* (%)
Religion	
Hindu	48 (82.8)
Muslim	9 (15.5)
Others	1 (1.7)
Marital status	
Married	54 (93.1)
Unmarried	1 (1.7)
Widow/divorced/separated	3 (5.2)
Education	
Illiterate	46 (79.3)
Primary	6 (10.4)
Middle	1 (1.7)
High school	5 (8.6)
Occupation	
Labor class	11 (19)
Service class	1 (1.7)
Homemaker	46 (79.3)
Lifestyle	
Sedentary	1 (1.7)
Moderate	47 (81)
Heavy	10 (17.3)
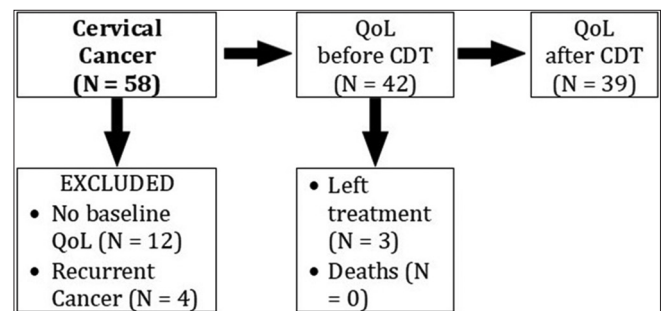
Figure 1: Flow chart depicting recruitment of patients
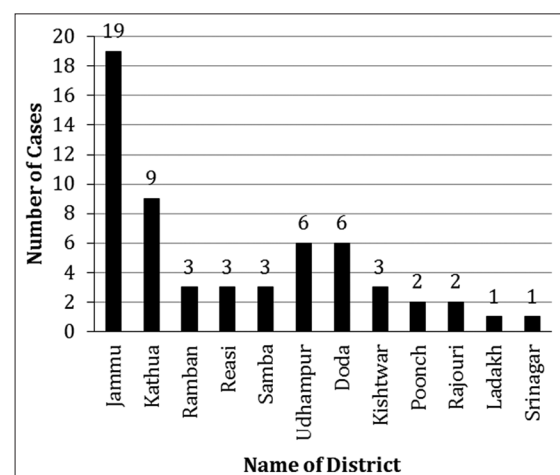
Figure 2: District-wise distribution of cervical cancers

Table 3: Gynecological/obstetrics history of cervical cancer patients (*n*=58)

Parameters	n (%)
Menarche	
Early menarche	4 (7)
Normal menarche	54 (93)
Menopausal status	
Premenopausal	21 (36)
Perimenopausal	0 (0)
Postmenopausal	37 (64)
Parity	
Unmarried	1 (2)
Nulliparous	0 (0)
Primiparous	0 (0)
2 child	13 (22)
>2 child	44 (76)
Family planning	
Oral contraceptives	6 (10)
Barrier method	3 (5)
Tubectomy	12 (21)
No method	37 (64)
Cohabitants	
Living alone	8 (14)
Living with partner	28 (48)
Living with others	22 (38)

Table 4: Personal characteristics of cervical patients (*n*=58)

Characteristics	n (%)
Diet	
Vegetarian	43 (74.1)
Nonvegetarian	15 (25.9)
Smoking status	
Current smoker	0 (0)
Former smoker	7 (12)
Never smoker	51 (88)
Smokeless tobacco	
Current user	0 (0)
Former user	9 (15.5)
Never user	49 (84.5)
Alcohol status	
Current user	0 (0)
Former user	0 (0)
Never user	0 (0)
Co-morbidities	
Heart disease	3 (5.2)
Hypothyroidism	1 (1.7)
Hypertension	6 (10.3)
Severe anemia	1 (1.7)
Kidney disease	1 (1.7)
HIV positive	1 (1.7)
Total	13 (22.4)

with more severity and in comparatively more number of patients. The patients had higher levels of financial difficulties after CDT. Global health status also showed worsening after CDT. All pre- and post-differences were statistically significant.

Mean scores of multi-item scales and single items are presented in Table 7. All items showed worsening of QoL from their baseline values. As far as multi-item scales are concerned, the worsening was more severe in body image. Symptom experience remained similar in pre- and post-CDT phase. Menopausal symptoms and sexual worry showed worst worsening of QoL among all domains after CDT. Lymphedema and peripheral neuropathy were comparatively less affected after CDT. As the patients were not sexually active, therefore sexual/vaginal functioning and sexual enjoyment could not be elucidated. Statistical significance was observed except peripheral neuropathy, lymphedema, and symptom experience.

Table 8 presents the reliability coefficients of generic and specific cervical cancer EORTC questionnaire (global- and domain-wise). It is clearly evident that pre- and post-Cronbach alpha coefficients for generic and cervical cancer specific QoL is acceptable for most domains.

Psychometric evaluation for cervical cancer tool yielded good reliability coefficients.

Table 5: Clinical characteristics of cervical cancer patients (*n*=58)

Characteristic	n (%)
Stage	
FIGO Ib	0 (0)
FIGO IIa	3 (5)
FIGO IIb	19 (33)
FIGO IIIa	6 (10)
FIGO IIIb	22 (38)
FIGO IVA	3 (5)
FIGO IVB (metastatic)	5 (9)
Intention to treat	
Radical/curative	53 (91)
Palliative	5 (9)
Treatment plan	
Concurrent chemoradiation followed by brachytherapy	50 (86)
Palliative (RT±CT)	5 (9)
Surgery+RT	3 (5)

RT: Radiotherapy, CT: Chemotherapy

DISCUSSION

In the present study, 58 Cervical Cancer patients were enrolled. Pre- and post-QoL was available for 39 of the

Table 6: EORTC QLQ C-30 of cervical cancer patients assessed before and after CDT (*n*=39)

Parameters	Mean±SD		Statistical inference	
	Before CDT	After CDT	*t* valve	*P* valve
Functional scale				
Physical functioning	85.6±17.5	68.7±16.1	13.2	<0.001
Role functioning	87.1±18.9	55.2±19.7	12.1	<0.001
Emotional functioning	29.9±8.97	12.9±11.5	23.4	<0.001
Cognitive functioning	89.7±12.9	64.5±21.0	9.5	<0.001
Social functioning	82.9±12.3	26.1±16.9	33.7	<0.001
Symptom scales				
Fatigue	15.2±12.8	88.5±8.1	58.9	<0.001
Nausea and vomiting	0	51.6±25.8	12.5	<0.001
Pain	17.4±23.9	38.6±25.7	5.3	<0.001
Single items				
Dyspnea	11.2±26.9	6.9±19.1	1.9	0.057
Insomnia	71.0±24.5	89.9±15.4	6.4	<0.001
Appetite loss	21.3±23.6	67.5±32.1	12.7	<0.001
Constipation	39.3±37.4	12.7±16.3	5.8	<0.001
Diarrhoea	0	39.3±33.3	7.4	<0.001
Financial difficulties	16.2±21.4	74.4±35.5	8.3	<0.001
Global health status	61.4±18.0	50.9±14.9	9.7	<0.001

P<0.001 (highly significant), *P*>0.05 (not significant). CDT: Cancer directed treatment, SD: Standard deviation, EORTC: European Organization for Research and Treatment of Cancer, QLQ: Quality of life questionnaire

Table 7: EORTC QLQ CX-24 of cervical patients assessed before and after CDT (*n*=39)

Parameters	Mean±SD		Statistical inference	
	Before CDT	After CDT	*t* value	*P* valve
Multi-item scales				
Symptom experience	43.9±26.3	46.1±13.9	0.6	0.584
Body image	46.7±20.6	81.7±14.9	16.2	<0.001
Sexual/vaginal functioning	X	X	-	-
Single item scales				
Lymphedema	7.7±19.5	17.0±21.4	2.1	0.041
Peripheral neuropathy	8.5±18.3	17.2±29.6	2.5	0.016
Menopausal symptoms	17.0±21.4	100±0.0	24.2	<0.001
Sexual worry	71.1±20.5	100±0.0	8.8	<0.001
Sexual activity	0	0	-	-
Sexual enjoyment	X	X	-	-

t: Paired t-test, *P*<0.001 (highly significant), *P*>0.05 (not significant). CDT: Cancer directed treatment, SD: Standard deviation, EORTC: European Organization for Research and Treatment of Cancer, QLQ: Quality of life questionnaire

patients. Maximum cases were in age group of 36-57 years. Majority of patients in our study presented in Stage (IIb, III).

Comparatively lesser proportion of patients had comorbidities. In a study conducted by Satwe et al., in Maharashtra similar sociodemographic distribution was observed.[22] We chose to study patients of cervical cancers primarily because we were already reporting these cancers to Indian Council of Medical Research as part of project titled "pattern of care and survival studies" and we thought a QoL study would help us in understanding the impact on their QoL before and after treatment which may further help in improving outcome in such patients.

Our QoL deteriorated in all domains after treatment because our questionnaire was answered within 4-6 weeks of CDT and QoL got worsened due to acute and subacute adverse effects of RT and CT in the course of treatment. The worsening was more severe in emotional and social functioning while physical, role, and cognitive functioning were comparatively less affected. Satwe et al.[22] also found deterioration in all domains immediately after completion of RT. Similar results are reported by Barker et al.[23] Greimel et al.,[24] Klee and Machin[25] Klee et al.,[26,27] Distefano et al.[28] There was increase in physical symptoms and impaired level of functioning directly after RT. While some workers reported emotional worsening after treatment[15,24,29] others reported deterioration in physical and role functioning.[23,24,27,28] On the contrary, Ljuca and Marosevic reported improvements in emotional, role, social, and cognitive domains at 12 months after treatment.[30] We observed worsening in social

Table 8: Cronbach's alpha coefficient

QLQ C-30	Items	Before CDT	After CDT
Functional scale			
Physical functioning	1-5	0.897	0.779
Role functioning	6,7	0.830	0.802
Emotional functioning	21-24	0.795	0.788
Cognitive functioning	20,25	0.680	0.609
Social functioning	26,27	0.740	0.798
Global QoL	29,30	0.908	0.773
Symptom scales			
Fatigue	10,12,18	0.965	0.718
Nausea and vomiting	14,15	0.523	0.893
Pain	9,19	0.911	0.891
QLQ CX-24			
Symptom experience	31-37,39,41-43	0.877	0.882
Body image	45,46,47	0.900	0.809
Sexual/vaginal functioning	X	X	

QoL: Quality of life, CDT: Cancer directed treatment, QLQ: Quality of life questionnaire

functioning probably because of strong social stigma attached to the disease. Many investigators however reported low global health status.[22-25] As far as symptoms are concerned, fatigue, nausea and vomiting, diarrhea, and appetite loss got worsened after treatment[23,31-33] as known side effects of RT. Sexual activity was reported to be absent before and after treatment. Low sexual willingness, husband's fear they might hurt their partners, and cultural background possibly explains this phenomenon. Worse sexual functioning after treatment has been reported by many other workers.[34,35] The QoL investigation is challenging both for the clinicians and researchers alike. Measurement of QoL poses several problems. While clinicians may not find sufficient time to record QoL routinely, the research communities face huge challenges in evolving tools that measure it validly and reliably. Further, the tools for measurement of QoL were initially developed by western researchers. Although psychometric evaluation of the tools has been undertaken in Indian setting, yet the QoL assessment studies are infrequent.[17,36] Therefore, we thought it pertinent to report reliability coefficients to see how the tool performs in our setting. Pre- and post-Cronbach's alpha coefficients for generic and cervical cancer specific QoL is acceptable for most domains. Psychometric evaluation for cervical cancer tool yielded good reliability coefficients. In our setting, Cronbach's alpha coefficient for EORTC QLQ C-30 and EORTC QLQ CX-24 ranged from 0.52 to 0.90. However, Crohnbac s alpha reliability coefficient for EORTC QLQ C-30 and EORTC QLQ CX-24 was >0.7 in cervical cancers as per Indian study by Damodar et al.[17] and as per other study done in Sri Lanka by Jayasekara et al.,[37] Crohnbach alpha ranged from 0.63 to 0.79.

Strengths and Limitations

- Strengths: There was 97% follow-up of participants. Validated questionnaires EORTC QLQ C-30 and EORTC-QLQ CX-24 were used. Cronbach alpha as a measure of reliability coefficient was calculated.
- Limitation: There is possibility of selection bias as the cervical cancer patients with advanced stage are more likely to report as compared to patients in initial stages which could have affected our estimates of QoL.

Recommendation

Multifaceted systematic changes need to be incorporated in patient care and management so that we not only add "years to life" but also succeed in adding "life to years." Some of the suggestions are as follows: QoL assessment be done for each and every patient registered in Department of radiotherapy which will allow the clinicians to devise patient-specific interventions. High-quality information should be made available to all patients attending the Department of Radiotherapy regarding all aspects of cancers including prevention, management, supportive care and finances etc. Trained counsellors be made available in the department so that requisite psychosocial support is available at all times. Adequate support and management of conditions unduly affecting QoL be made available such as diet counseling, sexual counseling, and pain management. Further, research is needed to develop shortened and easier yet valid version of QoL so as assessment of QoL in routine care is easily incorporated.

CONCLUSIONS

EORTC QLQ C-30 (generic) revealed worsening of QoL across all domains after CDT. QoL showed severe deterioration in Emotional and social domain while physical, role, and cognitive functioning were comparatively less affected. EORTC QLQ C-24 (specific) revealed worsening of all symptom scales/items after CDT. Body image and menopausal symptoms and insomnia got worsened post CDT. Pain, lymphedema, and peripheral neuropathy got increased after CDT.

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