Original Article

Assessment of Quality of Life in Treated Patients of Cancer Cervix

Zakia Rahman, Uma Singh, Sabuhi Qureshi[1], Nisha, Kirti Srivastav[2], Anil Nishchal[3]

Departments of Obstetrics and Gynaecology, [2]Radiotherapy and [3]Psychiatry, King George's Medical University, [1]Department of Gynaecological Oncology, Super Speciality Cancer Institute, Lucknow, Uttar Pradesh, India

ABSTRACT

Aim: The aim of the study was to assess the quality of life (QoL) in women suffering from cancer cervix before and after the treatment, to study various factors affecting the QoL in these women, and to evaluate the impact of treatment modalities on the QoL. **Materials and Methods:** Women with cervical cancer attending Department of Obstetrics and Gynecology and Department of Radiotherapy who met the eligibility criteria were interviewed with a structured questionnaire of QoL, the European Organization for Research and Treatment of Cancer QLQ30, and its Cervical Cancer Module (Cx24). The baseline observations were recorded when the patient first reported, second evaluation was done at 3 months posttreatment, and the third evaluation at 6 months posttreatment. QoL domains along with sociodemographic and clinicopathological variables were analyzed. **Results:** A total of ninety patients were included for analysis, of which 5 were lost to follow up. A statistically significant improvement was found in physical, emotional function, pain, fatigue, and vaginal symptoms of the participants; however, there was no significant improvement in social, cognitive, or role functioning, body image, sexual activity, or sexual enjoyment. Vaginal and sexual function worsened significantly. Multivariate analysis showed that young women and those with a higher level of education had better QoL. Stage and type of cancer had little impact on the general QoL, but participants with earlier stage and well-differentiated cancer had better cancer cervix-specific QoL. **Conclusion:** The QoL of the participants in terms of physical (P = 0.04) and emotional functioning (P = 0.001) improved with treatment. Women with a higher level of education and early stage of disease had better QoL.

KEYWORDS: *Cancer cervix, gynecological cancer, quality of life, treated patients*

INTRODUCTION

Cervical cancer is the second most common gynecological malignancy and fourth most common cancer overall in women. Every year in India, 122,844 women are diagnosed with cervical cancer and 67,477 die from the disease.[1,2] There are important consequences from the disease and its treatment among survivors, especially the impact on quality of life (QOL). The nature of the disease and its treatment can affect the QOL of these patients and their families.

QoL is a multifaceted and complex paradigm that reflects patients' experiences with disease, treatment, and accompanying long-term sequelae.[3,4] Cancer survivors who have overcome the immediate effects of cancer and side effects of cancer treatment need a more comprehensive follow-up program that includes monitoring of multidimensional health problems such as physical, psychological, social, and spiritual health issues. In this respect, QoL data can be used as measures of the overall well-being and functioning of the patients and as complementary monitoring tools in routine follow-up practice of cancer survivors.[5] In addition to their utility in assessing patient well-being and facilitating clinician decision-making, recent studies have suggested that QoL

Access this article online

Quick Response Code:

Website: www.jmidlifehealth.org

DOI: 10.4103/jmh.JMH_40_17

data can also provide distinct prognostic information.[6] Besides clinical variables, the QoL should be considered in the planning and monitoring of the therapeutic process in patients with cancer.

Not many studies have been done on QoL of cancer cervix survivors in the developing world including India and hence there is less literature on this subject. Moreover, the few studies available on QoL of cancer survivors have compared the QoL of the cancer survivors with the general populations as controls. With this pretext, the present study was designed to evaluate the QoL issues in women of cervical cancer.

Aim

The aim of the study was to assess the QoL in patients of cancer cervix before and after the treatment.

Objectives

1. To study various factors affecting the QoL in these women
2. To evaluate the impact of treatment modalities on the QoL.

MATERIALS AND METHODS

The study was a prospective cohort study, conducted in the Department of Obstetrics and Gynaecology and Department of Radiotherapy of King George's Medical University, Lucknow from May 2015 to July 2016.

Sample size

Sample size was calculated using the formula: SS = Z^2 (P) (1 − P)/C^2

Where, Z = Z value (1.96 for 95% confidence level), P = percentage picking a choice, expressed as decimal (0.5 used for sample size needed), C = confidence interval, expressed as decimal (0.95). Using above formula, sample size was 80. Ninety patients were recruited.

Ethical consideration

Ethical consideration was obtained from Institution Ethical Committee.

Inclusion criteria

Patients of cancer cervix before the start of treatment and the same patient 3 months from completion of treatment and at 6 months posttreatment, who have been treated with either surgery or chemoradiation, with no recurrence, who have the ability to understand and communicate in Hindi or English and who gave consent to participate in the study.

Exclusion criteria

Patients not willing to participate, those having major systemic illness such as cardiac failure, renal failure, or pulmonary edema, patient with psychiatric disorders, patients who are in immediate posttreatment phase, patients with stage 4 disease, or patient treated with both chemoradiation and surgery.

Methodology

Patients were selected from Gynaecology Cancer Clinic of OBGYN and Radiation Oncology Department. Written and informed consent was obtained from the recruited patients in a specially designed consent form. Detailed history about epidemiological factors and obstetric details was taken. All the history, examination findings, relevant investigation, and imaging findings were recorded. QoL questionnaire was filled which included two sections: Section A and section B described below.

Section A includes sociodemographic profile, stage and grade of cancer, imaging findings, treatment method, and comorbidities. Women's characteristics consist of questions related to demographic features (age, education, marital status, and income level) and disease-related information (cancer stage and histological type).

Section B has European Organization for Research and Treatment of Cancer (EORTC) QLQ C30 and EORTC QLQ-Cx24 questionnaire.

The EORTC-general cancer QoL score questionnaire (QLQ C-30, and its cervical cancer module which is specific for cervical cancer (QLQ CX-24) were used to measure QoL. These questionnaires have been extensively tested in multicultural and multidisciplinary settings and have been confirmed to be reliable and valid.[7-9] The EORTC QLQ C-30 questionnaire comprises thirty questions which includes five functional scale (physical, role, cognitive, emotional, and social) and three symptom scale for pain, fatigue, nausea and vomiting, six single items for dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial impact, and a global health status score which assesses the overall QOL. Each of the multi-item scales includes a different set of items – no item occurs in more than one scale. The EORTC QLQ CX-24 questionnaire which consists of 24 questions assessing functioning (body image, sexual enjoyment, and sexual/vaginal functioning) and symptoms (symptoms experience, lymphedema, peripheral neuropathy, menopausal symptoms, and sexual worry).[7]

Both the questionnaires use a four-point response scale (not at all, a little, quite a bit, and very much) to assess each functional or symptom item, and a seven-point response scale is used to assess global health status (from very poor to excellent). For model development, the categorical raw scores were linearly transformed into a score of 0–100 for processing according to the

EORTC scoring manual.[10] The principle for scoring was to estimate the average of the items that contributed to the scale; this was the raw score. A high scale score represents a higher response level. The higher scale score for the functional scale or the global health status/QOL represents a higher level of functioning or higher QOL, whereas the higher level of symptoms/problems for the symptom/item scales represents a higher level of dysfunction. Missing values were calculated such that if at least one-half of the items from the scale had been completed; it was assumed that the missing items would have had values equal to the average of the items present.

Statistical analysis

Demographic and clinical data were calculated using descriptive statistics. The results are presented in mean ± standard Deviation and percentages. The continuous variables were tested for normalcy using Kolmogorov test. The nonparametric Wilcoxon signed-rank test was used to compare median scores of QOL scales between the examined groups of patients. A 5% level of statistical significance was used for variables ($P < 0.05$). Data were analyzed using SPSS for windows (version 19.0; SPSS Inc., Chicago, IL, USA).

RESULTS

Ninety patients were recruited, of which three patients expired before the completion of 3 months of treatment and one patient was lost to follow up and one developed vesicovaginal fistula, who was subsequently lost to follow up; as a result, 85 patients were included for final analysis. The sociodemographic profile of the studied population is in Table 1. Clinical and pathological characteristics are described in detail in Table 2.

Tables 3-5 show the comparison of global health score (overall health), general QoL score, and cancer cervix-specific QoL score from baseline to 3 months and 6 months after treatment.

There are two ways to evaluate QoL: Objectively and subjectively, the most frequent being the objective one. The objective way of evaluation of QoL is related to the clinical perception of the disease. This type of evaluation is mainly concerned with the state of health based on the physician's diagnosis. In the subjective approach, the patient evaluates his/her own life's circumstances. Specialists consider this method to be much more valuable than the objective one, as it addresses the health issue as perceived by the patient and his/her biological, cognitive, social, spiritual, and cultural spheres.[11]

Our study included QoL assessment (subjective approach described above) of ninety women at three instances: before treatment, 3 months after treatment

Table 1: Sociodemographic profile of the subjects (*n*=90)

Sociodemographic profile	Number of cases (%)
Age (years)	
<50	12 (14.1)
>50 and above	73 (85.9)
Mean±SD (range)	56.14±8.14 (36-70)
Marital status	
Married	68 (75.3)
Widow	22 (24.7)
Age at 1st intercourse	
<20	51 (56.5)
≥20	39 (43.5)
Mean±SD (range)	19.50±2.78 (16-25)
Income	
Low	80 (89.4)
Middle	4 (4.7)
High	6 (5.9)
Education	
Literate	26 (29.4)
Illiterate	64 (70.6)
Residence	
Rural	44 (49.4)
Urban	46 (50.6)
Religion	
Hindu	76 (84.7)
Muslim	9 (9.4)
Christian	4 (4.7)
Sikh	1 (1.2)
Menstrual status	
Pre	24 (27.1)
Post	66 (72.9)
Parity	
Nulliparous	0
<5	41 (45.9)
≥5	49 (54.1)
Tobacco use	
Yes	31 (34.1)
No	59 (65.9)

SD: Standard deviation

and 6 months after treatment (where treatment could be in the form of either chemoradiation or surgery). This allowed us to identify the changes that the participants were going through with regard to the general QoL, the general evaluation of their health, as well as their biocognitive-sociocultural function at three points of time.

The analysis of EORTC QLQ30 and QLQC-24 was done by multivariate regression model evaluating independent factors for different QOL indicators. The global health, total functional scale, and symptom scale were found to be lower among the higher age groups; however, this was statistically insignificant ($P > 0.05$). Higher the education, overall the QoL was significantly ($P < 0.05$) higher. Tobacco use was associated significantly with

Table 2: Clinical and pathological characteristics of the studied population (*n*=90)

Clinical feature	Number of cases (%)
Stage	
1a	1 (1.2)
1b	9 (10.6)
2b	38 (42.4)
3b	42 (45.9)
Degree of differentiation of tumor	
Well differentiated	21 (23.5)
Moderately differentiated	50 (55.3)
Poorly differentiated	19 (21.2)
Tumor size (cm)	
<4	68 (75.3)
≥4	22 (24.7)
Histology	
Squamous	87 (96.4)
Adenocarcinoma	3 (3.6)
Treatment modality	
Surgery	5 (5.9)
Chemoradiation	85 (94.1)

Table 3: Comparison of global health score (over-all health) from baseline to 3 months and 6 months after treatment (*n*=85)

Timing of evaluation	Global health (mean±SD)
Baseline	4.91±1.86
3 months	5.44±1.79
6 months	5.69±2.19
P [a]	
Baseline to 3 months	0.09
Baseline to 6 months	0.04*

[a]Wilcoxon test, *Significant. SD: Standard deviation

poor QoL (*P* = 0.04). Patients with well-differentiated tumor and tumor size < 4 cm had better QoL, and this was statistically significant (*P* < 0.05). Religion, parity, residence, menstrual status, stage, and histology of cancer had no significant impact on the general QoL of the participants. There was no statistically significant difference in QoL of patients treated with either surgery or radiotherapy. Evaluation of physical symptoms in study population showed pain to be the greatest before treatment. Appetite loss, lymphedema, peripheral neuropathy, and insomnia decreased but were not statistically significant.

DISCUSSION

The level of health-related QoL is recently becoming a central element within therapeutic standards in clinical practice. In our study, there was a significant improvement in the global health, representing the overall health and QoL of patients of the patient posttreatment. Similar results were found in the study by Pasek *et al*.[12] In a study done by Lutgendorf *et al*.,[13] the participants expressed a significant improvement of the QoL despite a worsening of their physical function and of their general frame of mind. Physical functioning was assessed to be the worst before the treatment, but it improved gradually throughout the follow-up period after treatment. Pasek *et al*.[12] reported a significant improvement in physical functioning of the participants which was greatest after 6 months of treatment. In another study, Bradley *et al*.[14] found no difference between their cancer patients and healthy controls with regard to physical functioning. Although there was an improvement in the role and

Table 4: Comparison of general cancer quality of life score (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire 30) from baseline to 3 months and 6 months after treatment (*n*=85)

	Baseline	3 months	6 months	*P* value baseline to 3 months[a]	*P* value baseline to 6 months[a]
Functional scale					
Physical function	8.67±2.15	10.18±2.62	12.97±3.54	0.06	0.04*
Role function	2.72±0.82	3.27±1.44	4.54±1.96	0.11	0.10
Emotional function	7.72±1.31	9.42±1.91	12.50±1.90	0.001*	0.001*
Cognitive function	2.61±0.74	2.87±1.03	3.03±0.95	0.06	0.05
Social function	6.41±1.40	7.65±0.78	6.41±1.40	0.09	0.09
Single item					
Financial difficulties	2.49±0.82	2.21±0.59	2.14±0.67	0.16	0.13
Diarrhoea	1.55±0.73	1.29±0.45	1.18±0.39	0.17	0.15
Constipation	2.44±1.01	1.95±0.57	1.90±0.60	0.11	0.10
Appetite loss	3.32±0.82	2.77±0.80	2.72±0.82	0.13	0.12
Insomnia	2.38±0.78	1.70±0.45	1.67±0.47	0.10	0.09
Dysponea	1.72±1.02	1.42±0.72	1.23±0.42	0.14	0.13
Symptom scale					
Pain	6.50±1.43	4.45±1.13	3.10±0.83	0.003*	0.002*
Nausea and vomiting	2.51±0.50	2.04±0.21	2.00±0.01	0.11	0.10
Fatigue	10.05±1.80	8.22±1.87	7.52±2.05	0.002*	0.001*

[a]Wilcoxon test, *Significant

Table 5: Comparison of cancer cervix specific quality of life score (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Cx 24) from baseline to 3 months and 6 months after treatment (*n*=85)

	Baseline	3 months	6 months	P value baseline to 3 months[a]	P value baseline to 6 months[a]
Functional					
Body image	5.57±0.91	4.52±0.70	4.31±0.75	0.10	0.09
Sexual activity	1.65±0.17	2.00±0.01	2.38±0.49	0.11	0.08
Sexual enjoyment	4.61±0.49	3.83±0.63	3.42±0.49	0.08	0.07
Vaginal/sexual function	16.05±1.68	13.65±2.20	11.98±2.28	0.07	0.001*
Symptom score					
Symptom experience	17.81±2.66	13.22±1.94	11.00±1.28	0.001*	0.0001*
Lymphoedema	1.91±1.18	1.61±0.72	1.30±0.46	0.11	0.10
Peripheral neuropathy	1.56±0.90	1.47±0.66	1.37±0.48	0.09	0.08
Menopausal symptom	1.48±0.50	1.48±0.50	1.48±0.50	-	-
Sexual worry	4.00±0.01	2.61±0.49	2.12±0.33	0.07	0.06

[a]Wilcoxon test, *Significant

social functioning during the follow-up period, it was not statistically significant. Carter *et al.*[15] also reported that role functioning was improved after the treatment.

In our study, there was a statistically significant improvement in the emotional function of the survivors of cancer cervix after treatment. This improvement in the emotional functioning may be due to decreased worry about cancer. Ljuca and Marosevic[16] and Pasek *et al.*[12] also showed significant improvement in the emotional function of the participants after treatment. In contrast to these results Kumbhaj *et al.*[17] showed that there was no statistically significant improvement in the emotional functioning of the patients treated with surgery. In our study, there was no impact of treatment on the social functioning of the participants. Worst social functioning and body image were reported by Park *et al.*[18] There was no impact on the body image of the survivors while there was a slight increase in the sexual function though it was not significant. According to Ljuca and Marosevic,[16] there was no difference in sexual function of surveyed patients since almost half of them did not have sexual activity before and after the irradiation due to issues not related to the disease itself. In our study, there was not a significant impact on financial difficulties after treatment; however, according to Kumar *et al.*,[19] financial difficulties increased in a highly significant proportion of the survivors.

When analyzing the occurrence of physical symptoms in the study population, it was noticed that diarrhea most often occurred at the end of the treatment, and rarely 5–6 months later. Radiation damages the vaginal mucosa and epithelium of the gastrointestinal tract and may induce side effects including nausea, vomiting, diarrhea, and mucositis. It almost rarely occurred before the treatment. Similar findings were reported by Klee *et al.*[20]

In our study, we could not evaluate the impact of two treatment modalities (surgery vs. radiotherapy) on the

QoL of the participants due to small size in the surgically treated group. Sexual functions are least affected by surgery as compared to radiotherapy. Out of ninety participants recruited, only five patients were treated surgically. As all the patients in the surgically treated group were sexually inactive, change in sexual functions could not be assessed. Kumbhaj *et al.*[17] showed that cervical cancer survivors treated with radiotherapy had worse sexual functioning than did those treated with radical hysterectomy and lymph node dissection. The cause of this difference is due to radiation-induced fibrosis and stenosis of the vagina.

Limitations of the study

A potential limitation of this study is the short period during which the patients were followed up. The maximum follow-up duration was 6 months which is too short for reporting late treatment side effects and for evaluation of the long-term QoL. The sample size of the study was small to generalize the significance of the study findings. Furthermore, we could not evaluate the difference in QoL between patients treated with radiotherapy and surgery because of the small size in the surgically treated group.

CONCLUSION

This study revealed that patients treated for cancer cervix had better QoL after the treatment as revealed by the global health score. Assessment of functional status showed a significant improvement in physical (*P* = 0.04) and emotional functioning (*P* = 0.001) of the participants after treatment. Symptomatically, patients fared better after treatment. However, there was no significant improvement in social, cognitive, or role functioning. Furthermore, there was no significant improvement in the body image of the patient. There was a significant worsening in vaginal and sexual function (*P* = 0.001) due to stenosis and atrophy of the vagina.

Evaluation of factors affecting QoL and treatment of these dysfunctions should be included in the standard routine approach to cancer patients. Improvement in patient doctor relationship, counselling about cancer-specific issues, and sexual education should be a major objective in the patient care.

REFERENCES

1. Siegel R, DeSantis C, Virgo K, Stein K, Mariotto A, Smith T, *et al.* Cancer treatment and survivorship statistics, 2012. CA Cancer J Clin 2012;62:220-41.
2. World Health Organisation. GLOBOCAN 2012: Estimated cancer incidence, mortality and prevalence worldwide in 2012. Lyon, France: International Agency for Research on Cancer. 2014.
3. Cella D. What do global quality-of-life questions really measure? Insights from Hobday *et al.* and the "do something" rule. J Clin Oncol 2003;21:3178-9.
4. Study protocol for the world health organization project to develop a quality of life assessment instrument (WHOQOL). Qual Life Res 1993;2:153-9.
5. Velikova G, Booth L, Smith AB, Brown PM, Lynch P, Brown JM, *et al.* Measuring quality of life in routine oncology practice improves communication and patient well-being: A randomized controlled trial. J Clin Oncol 2004;22:714-24.
6. Gotay CC, Kawamoto CT, Bottomley A, Efficace F. The prognostic significance of patient-reported outcomes in cancer clinical trials. J Clin Oncol 2008;26:1355-63.
7. Greimel ER, Kuljanic Vlasic K, Waldenstrom AC, Duric VM, Jensen PT, Singer S, *et al.* The European Organization for Research and Treatment of Cancer (EORTC) quality-of-life questionnaire cervical cancer module: EORTC QLQ-CX24. Cancer 2006;107:1812-22.
8. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, *et al.* The European Organization for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 1993;85:365-76.
9. Sprangers MA, Cull A, Bjordal K, Groenvold M, Aaronson NK. The European Organization for Research and Treatment of Cancer. Approach to quality of life assessment: Guidelines for developing questionnaire modules. EORTC study group on quality of life. Qual Life Res 1993;2:287-95.
10. Fayers P, Aaronson NK, Bjordal K, Curran D, Groenvold M. On behalf of the EORTC Quality of Life Study Group. EORTC QLQ-C30 Scoring Manual (Third edition). Brussels, EORTC Quality of Life Group, 2001. p. 86.
11. Schipper H, Clinch JJ, Olweny CL. Quality of life studies: Definitions and conceptual issues. Quality of Life and Pharmacoeconomics in clinical trials. Lippincott.Raven Publishers: Philadelphia 1996;2:11-23.
12. Pasek M, Suchocka L, Urbański K. Quality of life in cervical cancer patients treated with radiation therapy. J Clin Nurs 2013;22:690-7.
13. Lutgendorf SK, Anderson B, Ullrich P, Johnsen EL, Buller RE, Sood AK, *et al.* Quality of life and mood in women with gynecologic cancer: A one year prospective study. Cancer 2002;94:131-40.
14. Bradley S, Rose S, Lutgendorf S, Costanzo E, Anderson B. Quality of life and mental health in cervical and endometrial cancer survivors. Gynecol Oncol 2006;100:479-86.
15. Carter J, Sonoda Y, Baser RE, Raviv L, Chi DS, Barakat RR, *et al.* A 2-year prospective study assessing the emotional, sexual, and quality of life concerns of women undergoing radical trachelectomy versus radical hysterectomy for treatment of early-stage cervical cancer. Gynecol Oncol 2010;119:358-65.
16. Ljuca D, Marosevic G. Quality of life in patients with cervical cancer FIGO IIb stage after concomitant chemoradiotherapy. Radiol Oncol 2009;43:293-8.
17. Kumbhaj PR, Sharma R, Bhatnagar A, Saini PK. Sexual functioning & quality of life in cervical cancer survivors after surgery and radiotherapy. Natl J Med Res 2014;4:116-8.
18. Park SY, Bae DS, Nam JH, Park CT. Cancer. Am Cancer Soc 2007;110:2716-25.
19. Kumar S, Rana ML, Verma K, Singh N, Sharma AK, Maria AK, *et al.* PrediQt-cx: Post treatment health related quality of life prediction model for cervical cancer patients. PLoS One 2014;9:e89851.
20. Klee M, Thranov I, Machin Prof D. The patients' perspective on physical symptoms after radiotherapy for cervical cancer. Gynecol Oncol 2000;76:14-23.