Public Health Section

Pre and Post Chemoradiotherapy Assessment of Quality of Life in Individuals Diagnosed with Cervical Cancer in Tripura, India: A Cross-sectional Study

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ABSTRACT

Introduction: Cervical cancer is among the most common malignancies affecting women in India. Assessment of Quality of Life (QoL) has become a vital part of patient care, extending beyond traditional survival outcomes. Despite the high disease burden in Tripura, India limited evidence exists on QoL changes before and after treatment.

Aim: To compare the QoL of women with cervical cancer before and after treatment, identify variables influencing QoL, and evaluate the impact of treatment modalities.

Materials and Methods: The present cross-sectional study was conducted at the Atal Bihari Vajpayee Regional Cancer Centre, Agartala, Tripura, India, from March 2022 to December 2024. A total of 384 patients were enrolled and reassessed six months after therapy using validated European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-CX24 questionnaires. The data were analysed using Statistical Package for Social Sciences (SPSS) version 24. Paired sample t-tests and Chi-square tests were employed to compare pre and post-treatment EORTC QLQ-C30 and QLQ-CX24 scores, with a significance threshold set at $p<0.05$. Baseline characteristics were summarised using descriptive statistics.

Results: The mean age at diagnosis was 50.38 ± 11.66 years. Overall health status improved significantly after treatment (64.67 ± 2.68 vs. 45.32 ± 4.59; $p<0.001$). Post-treatment, significant gains were observed in physical, cognitive, and emotional functioning. Conversely, symptom experience worsened (23.42 ± 3.36 vs 3.36 vs 10.44 ± 4.23; $p=0.037$), and both sexual satisfaction and functioning declined. Patients who received combined chemoradiotherapy showed greater improvements in QoL and overall health scores compared with those receiving radiotherapy alone.

Conclusion: Cervical cancer survivors in Tripura experienced significant improvement in overall health scores following therapy, particularly in functional domains. However, persistent challenges, including sexual dysfunction and treatment-related toxicities, underscore the need for integrated survivorship care focusing on counselling, rehabilitation, and supportive interventions.

Keywords: Cervical cancer survivor, Chemotherapy, European organisation for research and treatment of cancer

INTRODUCTION

Out of all the gynaecological cancers that affect women in India, cervical cancer is the second most frequent. In India, a total of 122,844 new instances of cervical cancer are reported every year, with 67,477 women losing their lives soon after diagnosis [1]. Cancer and its treatments have a significant influence on survivors' QoL, which in turn affects their health. The characteristics of the disease and the therapeutic measures implemented to manage it can significantly influence both patients and their families [1]. In Tripura this specific type of cancer is most commonly found among women. The 2021 report from the Indian Council of Medical Research (ICMR) indicates that the Northeast region has the highest incidence rate of cancer [2]. The survey indicated that only 21% of participants were aware of cervical cancer. Within this cohort, around 77% demonstrated awareness that all women qualify for the PAP smear test, while roughly 9% showed a lack of understanding regarding the test. Patients who have survived often demonstrate a lack of awareness about their lifestyle choices, and there has been no appropriate protocol assessed to improve their QoL after undergoing radio-chemotherapy [3]. Cervical cancer survivors frequently encounter a range of enduring side effects that may persist for an extended duration, demonstrating minimal signs of improvement. A comprehensive review suggests the occurrence of symptoms such as sexual difficulties, discomfort, premature menopause, fatigue, and reduced physical function. The negative impacts of cancer treatment can greatly reduce the QoL for individuals who have triumphed over cancer [4].

The established cervical cancer treatment procedure varies by stage {International Federation of Gynaecology and Obstetrics (FIGO) I,II,II,IV}; however, the post-treatment experiences and side-effects of survivors remain inadequately understood. Therapeutic approaches influence an individual's sexual health. Treatments such as radiation, chemotherapy, and surgery can significantly impact a woman's sexual health by altering her body image, vaginal elasticity, lubrication, and hormonal balance. Changes may adversely affect an individual's sexual wellbeing and QoL by resulting in reduced sexual desire, discomfort, and emotional distress. The integration of surgery with chemoradiotherapy enhances patient QoL. Ongoing counselling is essential for ensuring a secure and healthy life [5-7]. Patients diagnosed with advanced-stage cervical cancer (FIGO stages IIB-IVB) may present with pelvic, lower back, or abdomen pain, oedema in the legs, and alterations in bowel or urinary function [8]. The present study seeked to explore the obstacles faced by women concerning their physical, emotional, financial and cognitive processes. The survival rate for individuals diagnosed with cervical cancer is steadily increasing over time, resulting in a heightened focus on the QoL experienced by these patients. QoL assessments before, during, and after radiation and chemotherapy have the potential to enhance patients' health [9-11]. As a result, it is essential for healthcare professionals to consistently engage with this issue throughout and following the treatment process [12,13]. The present study aimed to evaluate the QoL of cervical cancer patients before and after therapy, identify the factors influencing QoL, and examine the impact of different treatment methods on QoL.

MATERIALS AND METHODS

The present cross-sectional study, was carried out at the Atal Bihari Vajpayee Regional Cancer Centre in Agartala, Tripura, India, from March 2022 to December 2024. Patients diagnosed with cervical cancer visited the Outpatient Department (OPD) of the respective hospital and who fulfilled the inclusion criteria were enrolled in the study. Approval for ethical considerations was obtained from the institutional review board of Agartala Govt. Medical College (Ref. No.F.4(6-13)/AGMC/Medical Education/IEC Approval/2022/17320) and University Research Ethics Committee, DIT University, Dehradun (DITU/UREC/2022/04/05). Being the only cancer hospital in Tripura, the research centre offers extensive cancer treatment options.

Sample size calculation: The required sample size was calculated using the single-population proportion formula:

$$n = \frac{Z^2 \, p(1-p)}{d^2},$$

assuming a 95% confidence interval (Z=1.96), a 5% margin of error (d=0.05), and an estimated proportion (p=0.5) to ensure maximum variability. The calculated sample size was 384 participants. The primary criterion is to enrol patients diagnosed with cervical cancer who have not yet commenced therapy. The same participants were subsequently followed-up for six months following the completion of treatment. All registered patients-maintained communication by telephone and in person during their hospital visits for therapy. The treatment comprised surgery, chemotherapy, and radiation therapy. All patients were selected after receiving their written informed consent.

Inclusion criteria: A total of 384 individuals diagnosed with cervical cancer visiting OPD were selected for the study via face-to-face interview.

Exclusion criteria: Exclusion criteria included patients in a critical condition, those who were unwilling to provide informed consent, and those who had surgery but did not require radiation or chemotherapy. The patients who were enrolled but died or left hospital before completion of 6 months treatment were excluded from the study. Individuals under 18 years of age or those who expressed disinterest in participating in the interview are excluded.

Study Procedure

Section A and Section B were the two sections of a standardised questionnaire that was administered by an interviewer. Part A contains the patient's socioeconomic profile, cancer stage, treatment method, comorbidities, and other relevant medical information. Part B has concentrated on structured questionnaire QLQ-C30 and QLQ-CX24 modules of the EORTC. Both the English and Bengali versions of these modules were made available [14]. Bengali version of the questionnaire was collected from EORTC portal. https://qol.eortc. org/questionnaire/eortc-qlq-c30/?utm_source. To assess QoL, the EORTC-general cancer QoL score questionnaire (QLQ C-30) and its cervical cancer module (QLQ CX-24), which is specifically designed for cervical cancer, were utilised. The reliability and validity of these surveys have been validated by extensive testing in multicultural and multidisciplinary contexts [14-16].

EORTC QLQ C-30: There is a total of thirty questions in the EORTC QLQ C-30 questionnaire. These questions cover five different functional areas: physical, role, cognitive, emotional, and social. There are also three symptom areas to measure pain, fatigue, nausea, and vomiting. Additionally, there are six individual items to measure dyspnoea, insomnia, appetite loss, constipation, diarrhoea, financial impact, and global health status, which looks at overall QoL. Every one of the multiple-item scales uses a unique set of items; no item appears on more than one scale.

EORTC QLQ CX-24: The EORTC QLQ CX-24 contains 24 questions that evaluate both functioning (body image, sexual satisfaction, and sexual/vaginal functioning) and symptoms (symptoms experience, lymphedema, peripheral neuropathy, menopausal symptoms, and sexual worry) [15]. A four-point scale ranging from "not at all" to "quite a bit" is used in both questionnaires to evaluate functional or symptom items.

A seven-point scale ranging from "very poor" to "excellent" is employed to evaluate global health status. The raw category scores were translated into a score between 0 and 100 using the EORTC scoring manual, which was then used for model construction [17]. One of the first steps in scoring was determining a rough average of the scale's components; this was known as the raw score. A stronger reaction is indicated by a higher score. More dysfunction is indicated by higher scores on the symptom/item scales, but higher scores on the functional or global health status/QoL scales suggest a higher degree of functioning or QoL. The calculation for missing values was based on the assumption that if half of the items on the scale had been filled out, the missing items will have had average values [17].

STATISTICAL ANALYSIS

The study population's demographic and clinical features were summarised using descriptive statistics. Mean±standard deviation was used to represent continuous data like age and functional scores, whereas percentages were used to express categorical variables like education level, marital status, and cancer stage. Using a paired sample t-test, we compared patients' QoL before and after chemoradiation. Scores on the EORTC QLQ-C30 and QLQ-CX24 were compared before and after therapy in this test. Statistical significance was defined as a p-value below 0.05. To evaluate statistical differences in QoL scores according to FIGO stages and treatment modalities, a Chi-square test with Yate's correction was employed for subgroup analysis. Data analysis was carried out using SPSS version 24.

RESULTS

[Table/Fig-1] shows the population's sociodemographic and clinical characteristics. The majority of 259 patients (67.5%) were diagnosed between 40-60-year-old, with a mean age of 50.38±11.66. The results showed that 271 (70.6%) of the sample had only completed elementary school. Overall, 63.8% of study patients were from rural locations. According to [Table/Fig-1], 197 (51.3%) of the population was middle-class. The [Table/Fig-1] shows that 271 (56.5 %) patients married before 20 years. Half of patients had their first baby before 20, the most frequent age of first pregnancy. A total of

Variables	N (%)
Total patients	**384 (100%)**
Age in years (mean±SD)	**50.38±11.66**
20-40	55 (14.3%)
40-60	259 (67.5%)
60-80	68 (17.7%)
>80	2 (0.5%)
Education	
Primary	271 (70.6%)
Secondary	89 (23.2%)
Higher	15 (3.9%)
Illiterate	9 (2.3%)
Economic status*	
Lower class	173 (45.1%)
Middle class	197 (51.3%)
Upper class	14 (3.6%)
Residence	
Urban	139 (36.2%)
Rural	245 (63.8%)

Age at marriage (years)	
≤20	217 (56.5%)
21-30	128 (33.3%)
31-40	32 (8.3%)
>40	4 (1.1%)
Never married	3 (0.8%)
Tobacco use	
Yes	273 (71%)
No	111 (29%)
FIGO Stage	
IA	4 (1.1%)
IB	7 (1.8%)
IIA	57 (14.8%)
IIB	93 (24.2%)
IIIA	137 (35.7%)
IIIB	52 (13.5%)
IVA	27 (7%)
IVB	7 (1.8%)
Treatment modality	
CT+RT	299 (78%)
RT	46 (12%)
Surgery+RT	39 (10%)
Cell type	
Squamous cell carcinoma	322 (84%)
Adenocarcinoma	57 (15)
Others	5 (1%)

[Table/Fig-1]: Sociodemographic and clinical characteristics of the patients.
*It pertains to socioeconomic classification (SES) predicated on income. The BG Prasad scale is a widely utilised instrument for categorising socioeconomic level in India.
FIGO: International Federation of Gynaecology and Obstetrics;
CT+RT: Chemotherapy+Radiotherapy

273 numbers (71%) patients used tobacco, 322 numbers (84%) of cases were squamous cell carcinoma followed by adenocarcinoma. Most patients 299 (78%) had a course of treatment that included both radiation and chemotherapy. Around 12% of those who participated only underwent radiation treatment, and an additional 10% had radiation administered following surgery. A total of 137 numbers (35.7%) of patients were diagnosed at stage IIIA upon their initial hospital report.

The results of the EORTC QLQ-C30 in [Table/Fig-2], showed a notable improvement in overall health status after therapy (p<0.001). Functionalities related to behaviour, cognition, roles, social interactions, and emotions all showed improvement. In the examination of symptom scores, there was a notable decrease in nausea and vomiting (p=0.041), but no significant reduction in appetite loss or exhaustion. In addition, there was a notable improvement in insomnia (p<0.001). After the therapy, there was a noticeable rise in pain levels (p<0.001) and an intensification of financial problems (p<0.001), indicating that the economy was negatively impacted. Dyspnoea and diarrhoea did not show any statistically significant changes.

EORTC QLQ-C30 scale	Pretreatment	Post-treatment	p-value
Global health score/QLQ scale	45.32±4.59	64.67±2.68	<0.001*
Functional scale			
Physical functioning	63.14±6.25	76.26±3.27	0.019*
Cognitive functioning	73.17±4.32	77.51±5.35	0.049*
Role functioning	67.31±4.86	76.51±3.65	<0.001*
Social functioning	50.16±3.10	66.09±2.73	<0.001*
Emotional functioning	59.74±7.41	70.92±2.97	<0.001*

Symptom scale			
Fatigue	39.78±7.16	25.35±3.2	0.056
Nausea and vomiting	38.12±9.40	28.63±3.0	0.041*
Pain	39.86±14.37	42.87±2.4	<0.001*
Single item			
Dyspnoea	34.52±9.51	18.90 ±3.4	0.098
Insomnia	49.67±3.8	41.83±3.2	<0.001*
Appetite loss	40.10±10.76	37.49±2.6	0.056
Diarrhoea	32.82±1.36	41.31±3.6	0.072
Financial difficulties	8.67±9.62	20.11±3.5	<0.001*

[Table/Fig-2]: Evaluation of Quality of Life (QoL) of cervical cancer patients before and after therapy using the EORTC QLQ C 30.
• Independent t-test was used to compare the two groups

The results of the cervical cancer patients' EORTC QLQ CX-24 modules before and after therapy are shown in [Table/Fig-3]. A significant reduction in body image (p<0.001), sex satisfaction (p<0.001), and sexual/vaginal functioning (p=0.001) was observed in post-treatment QLQ-CX24 scores, indicating a correlation between treatment and a decline in sexual wellbeing and self-perception. A significant rise in treatment-related toxicities was evidenced by an increase in symptoms, such as lymphoedema (p=0.005), peripheral neuropathy (p=0.025), and menopausal symptoms (p<0.001). Conversely, there was a significant reduction in sexual anxiety (p<0.001), suggesting an inverse relationship whereby patients exhibited diminished sexual performance yet reported decreased concern for their sexual health.

EORTC QLQ-CX24 scale	Pretreatment	Post-treatment	p-value
Functional scale			
Body image	51.36±6.32	30.87±4.83	<0.001
Sexual activity	19.54±5.67	15.15±3.83	0.42
Sexual enjoyment	36.56±6.21	17.33±4.81	<0.001
Sexual/vaginal functioning	31.42±4.89	18.98±4.76	0.001
Symptom scale			
Symptom experience	10.44±4.23	23.42±3.36	0.037
Lymphoedema	16.33±2.65	29.33±4.0	0.005
Peripheral neuropathy	10.61±6.43	23.22±3.26	0.025
Menopausal symptom	21.65±6.88	24.03±3.32	<0.001
Sexual worry	61.88±5.32	32.43±5.46	<0.001

[Table/Fig-3]: Evaluation of Quality of Life (QoL) of cervical cancer patients before and after therapy using the EORTC QLQ CX-24.
*t-test was used to compare the two groups

[Table/Fig-4] presented that in stages I-IIB of cervical cancer, there was a substantial improvement in overall health and QoL scores after therapy (p<0.039). However, in stages III and IV, there was no significant improvement. Individuals who underwent both radiation and chemotherapy showed a statistically significant improvement in their QoL and overall health scores (p=0.043 and 0.021, respectively), whereas individuals who underwent radiation therapy alone did not.

DISCUSSION

An essential element of therapeutic criteria in clinical practice is the degree of health-related QoL. The QoL of cervical cancer patients in Tripura was assessed pre and post-therapy. Alterations in women's QoL following a cervical cancer diagnosis are attributable to various factors. Pelvic surgery can result in both impairment of the female genital tract's functionality. Radiation therapy also induces many side effects, including alterations in weight and hormone levels, mucositis, nausea, vomiting, diarrhoea, and constipation. The evidence indicates that treatment enhances QoL, as the global health score showed a significant increase following treatment, corroborated by similar findings in recent studies [11,18,19].

Variables	Pretreatment 1 2 3 4 5 6 7	Post-treatment 1 2 3 4 5 6 7	p-value (df=1)	Yate's Corrected Chi-sqaure
FIGO Stage I-IIB (N=161)				
Overall Health Score	0 7 13 87 54 0 0	0 0 0 47 107 7 0	0.039	4.542
Quality of Life (QoL) score	0 7 13 87 54 0 0	0 0 0 47 107 7 0	0.039	4.542
FIGO Stage IIIA-IVB (N=223)				
Overall Health Score	0 7 56 112 48 0 0	0 0 14 111 84 0 0	0.21	3.55
Quality of Life (QoL) score	0 7 70 90 56 0 0	0 0 14 111 84 0 0	0.29	2.73
Treatment Modality: Radiotherapy/surgery+RT (N=85)				
Overall Health Score	0 2 14 48 21 0 0	0 0 0 28 42 7 0	0.32	2.45
Quality of Life (QoL) score	0 2 14 48 21 0 0	0 0 0 28 42 7 0	0.32	2.45
Treatment Modality: Radiotherapy+Chemotherapy (N=299)				
Overall Health Score	0 14 54 150 82 0 0	0 0 7 129 150 14 0	0.021	4.68
Quality of Life (QoL) score	0 15 68 128 88 0 0	0 0 7 129 150 14 0	0.043	3.67

[Table/Fig-4]: Overall health and Quality of Life (QoL) of patients assessment based on FIGO stage and treatment type.
*1 is very poor and 7 is excellent
Chi-square test is used with yate's correction to compare the groups

Over a six-month period, all items on the functional scales- physical, role, emotional, cognitive, and social functioning demonstrated significant improvement. This contradicts the findings of another study that reported diminished global QoL, emotional wellbeing, and role performance even after the conclusion of therapy [20]. Analyses of symptom scales showed that therapy significantly reduced tiredness, discomfort, sleeplessness, and lack of appetite. This went against the results of a different study that found an increase in discomfort, lack of appetite, nausea, and vomiting following three months of treatment [21]. Potential cause of this difference including discrepancies in the duration between the initiation of treatment and the assessment of quality-of-life post-therapy. The present study indicates that radiation may have intensified episodes of diarrhea. Radiation treatment, according to can cause diarrhoea, in contrast to surgical procedures that can damage the parasympathetic neurons and leading to constipation [21,22]. An additional study found an inverse correlation between scores and symptoms such as dyspnoea, nausea, vomiting, disturbed sleep, peripheral neuropathy, and menopausal symptoms [23]. Statistical analysis of the effects of treatment on financial difficulty showed little change Patients QoL may be negatively impacted by financial issues that worsen following therapy, according to other research [24]. The respondents out-of-pocket expenses may have been negligible due to their treatment in a government-funded institution. In underdeveloped countries such as India, where resources are limited, this aspect of assessment has greater importance. This is particularly significant for developing nations, as the economic burden profoundly affects individuals QoL. This is likely a result of the cancer experience or the treatment as stated on the EORTCQLQCX-24 scale [25]. But the present research showed that survivors had a poorer "body image" after treatment than before. Because of its central role in determining QoL, sexuality is an important component of gynaecological cancer. Both the "sexual activity" and the "sexual and vaginal functioning" scores dropped significantly in the current research.

There was an alarming increase in the "menopausal symptoms" according to the survivors. A prior study found that individuals were more likely to experience severe menopausal symptoms when surgical oophorectomy was used to mark the transition to menopause compared to when radiation therapy was used to mark the climacteric transition. This confirms that radiation therapy exacerbates menopausal symptoms [12,18]. Overall QoL data has been reported from several studies in nations like China, Iran, Tanzania, and Ethiopia, with values of 64.4, 65.3, 48.3, and 46.9, respectively [12,23,26]. In Tripura, a global health status value of 64.67±2.68, which is consistent with this earlier research was found.

Radiation therapy and major surgical interventions may negatively affect the sexual functioning of cervical cancer survivors, with impacts that can persist from several months to many years after treatment and major surgery. There was statistically significant change in sexual or vaginal function between the pre- and post-treatment times (p=0.001). Several studies have found the same thing [3,4,26-29]. Although newer forms of radiation may have less of an impact on sexual function, the unfavourable effects of radiation on sexual function are still higher than those of radical hysterectomy with pelvic lymphadenectomy. Combination radiation therapy (external and brachytherapy) can significantly lessen sexual worry, boost sexual engagement, and enhance body image, according to a comprehensive review and a Tanzanian study [30,31].

Previous studies identified age, duration since diagnosis, marital status, presence of comorbidities, cervical cancer stage, and post-treatment QoL as significant factors. Published research indicates that there was no statistically significant difference in QoL evaluations among different age groups and stages of cervical cancer [27,28,32]. Research and treatments in the future should prioritise improving survivors' QoL. Despite a high QoL for cervical cancer survivors after treatment, it might be much higher with effective management of sequelae. It is possible to lessen or eliminate some of the negative effects of cervical cancer treatment by recognising problems with patients' QoL after treatment and then implementing intervention programs. Psychosocial support and financial aid are essential to alleviate economic strain. Future research must encompass longitudinal studies with extended follow-up durations to evaluate long-term QoL, assess the impact of specific treatment modalities on sexual functioning and psychological wellbeing, and explore culturally tailored interventions to enhance awareness, coping strategies, and follow-up care. Multicentre studies involving larger populations would enhance generalisability and facilitate the development of more effective, evidence-based criteria for the QoL of cervical cancer survivors.

Limitation(s)

The study was performed at a single regional cancer centre in Tripura, potentially restricting the applicability of the results to wider populations in various areas of northeast India. The long-term effects following this period remain unexamined. A qualitative study exploring sexual concerns and experiences is recommended. Integrating sexual counselling into all cervical cancer treatment pathways is essential. Given that the present study was observational in nature, future research should adopt more rigorous designs to evaluate pre- and post-treatment effects.

CONCLUSION(S)

From the results of the present study, it can be concluded that survivorship care programs for cervical cancer patients should not only focus on improving overall health-related QoL, which was observed to improve in domains such as physical, emotional, role, and social functioning six months after chemoradiotherapy- but also specifically address persisting concerns related to sexual activity, body image, and menopausal symptoms. Survivorship care programs should integrate targeted counselling, rehabilitation, and sexual health education as essential elements of routine post-treatment care to effectively address these concerns.

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