



# Health-related quality of life among cervical cancer patients in India

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## HIGHLIGHTS

- Measurement of health-related quality of life should be an integral component of effectiveness of interventions.
- Efforts to improve quality of life of cervical cancer patients should focus upon ameliorating pain and anxiety.
- Cervical cancer patients with higher economic status report lower quality of life for the same health state as compared to the poor patients because of 'positional objectivity'.

## ABSTRACT

**Introduction** Estimation of health-related quality of life of cervical cancer patients in India is important in assessing the well-being of patients, monitor treatment outcomes, and conduct health technology assessments. However, health-related quality of life estimates for different stages of cervical cancer are not available for the Indian population. This study aims to generate stage-specific quality of life scores for cervical cancer patients in India.

**Methods** A cross-sectional study using the EQ-5D (EuroQol 5-dimensions) instrument, that consists of the EQ-5D-5L descriptive system and the EuroQol Visual Analog Scale (EQ-VAS) was conducted. A total of 159 cervical cancer patients were interviewed. Mean EQ-5D-5L quality of life scores (utility scores) were calculated using the EQ-5D-5L index value calculator across different stages of cervical cancer. The proportion of patients reporting problems in different attributes of EQ-5D-5L was assessed. The impact of socio-economic determinants on health-related quality of life was evaluated using multiple linear regression.

**Results** The mean EQ-5D-5L and EQ-VAS utility scores among patients of cervical cancer were 0.64 [95% CI=0.61–0.67] and 67.6 [95% CI=65.17–70.03], respectively. The most frequently reported problem among cervical cancer patients was pain/discomfort (61.88%), followed by difficulty in performing usual activities (53.81%), and anxiety/depression (41.26%).

**Conclusion** Cervical cancer significantly impacts the health-related quality of life of the patients in India. Clinical interventions should focus on the control of pain and relief of anxiety. The measurement of health-related quality of life should be an integral component of the effectiveness of interventions as well as health technology assessment.

## INTRODUCTION

Cancer of the uterine cervix is the second most common cancer among women worldwide.<sup>1</sup> India constitutes the largest burden of global cervical cancer patients.<sup>1</sup> In diseases like cancer, both the disease and the treatment have a negative impact on the health-related quality of life of cancer patient.

As a result, not only the quantity, but the quality of life is equally important for such patients. The health-related quality of life becomes even more important when the overall survival of patients with cervical cancer has improved due to the early detection and availability of comprehensive treatments.<sup>2</sup>

Health-related quality of life encompasses the physical, psychological, and social domains of health, which are influenced by an individual's experiences, beliefs, expectations, and perceptions.<sup>3,4</sup> Evaluation of health-related quality of life in cervical cancer patients is important to monitor and evaluate the effectiveness of treatment and intervention, overall functioning, and well-being of the patient, as well as for facilitating clinical decision-making and undertaking health technology assessment studies and for designing the intervention for improving patients' outcome.<sup>5</sup> Moreover, the measurement of quality of life becomes important to capture the broadened definition of health which goes beyond accounting for just the traditional measures of mortality and morbidity.<sup>6</sup>

The measurement of health-related quality of life among cervical cancer patients comprehensively evaluates how the disease and its treatment impact the patient in terms of symptoms, side effects, patient functional status, and financial impact, as it is a multifaceted and complex paradigm.<sup>7,8</sup> Some functional disorders occur following therapies such as surgery and radiotherapy, which adversely impact the quality of life. It involves surgical alteration of female genital anatomy affecting directly their perception of body image and sexual functions; radiotherapy which could damage the vaginal mucosa and epithelium; and chemotherapy which could induce various adverse effects such as nausea, vomiting, diarrhea, constipation, mucositis, weight changes, and hormonal changes.<sup>9,10</sup> In addition, various psychological factors including low self-esteem, changes in self-image, beliefs about the origin of cancer, marital tensions, fears, and worries can substantially affect the quality of life of cervical cancer patients.<sup>9,10</sup>

## Original research

Two types of instrument are used to measure health-related quality of life among cancer patients, namely the generic instrument and disease-specific instrument.<sup>11</sup> The generic instruments are used to collect information on healthy as well as those with any illness, in the community or clinical practice. This allows for the comparison of health-related quality of life across different conditions and settings, and between healthy and ill patients.<sup>12</sup> On the other hand, disease-specific instruments aim to collect information on symptoms or disease-specific health problems from more specific populations with a given disease or symptom.<sup>12</sup> The generic preference-based measures are commonly used in the health technology assessments, as they provide a multidimensional description of health that is combined with survival to generate quality-adjusted life-years,<sup>13</sup> often a measure to value health outcomes in the economic evaluation studies.<sup>14</sup>

Barring a few examples from Thailand and Indonesia, there is scant literature on health-related quality of life of cervical cancer patients in the developing countries, including India.<sup>7 15 16</sup> Whatever studies have been done in India to assess the health-related quality of life of cervical cancer patients, they have used disease-specific instruments.<sup>9 16</sup> However, the EQ-5D is a preferred instrument for assessing quality of life in health technology assessments.<sup>17 18</sup> As a result, there is a lack of India-specific studies that provide information about the generic preference-based quality of life status of cervical cancer patients. This study aims to measure the health-related quality of life of cervical cancer patients using the EQ-5D-5L questionnaire consisting of a descriptive system and Visual Analog Scale (VAS), which has not been performed in India so far.

## METHODS

### Study settings

A cross-sectional study was carried out to recruit study participants from the department of radiation oncology of a tertiary care hospital in North India. Cervical cancer patients, whose radiotherapy treatment had been completed at least 4 months ago, were recruited in the out-patient department during their follow-up visit. A gap of 4 months since the completion of treatment was considered appropriate, so that the immediate deterioration in health-related quality of life because of side effects of radiotherapy wears off and the patient achieves a stable quality of life.<sup>19 20</sup> The study was approved by the Institute Ethics Committee and written informed consent was obtained from all participants or a legal surrogate.

### Data collection

A total of 159 patients of cervical cancer were recruited. Considering the mean utility score of cervical cancer as 0.76 with the SD of 0.2, the anticipated difference in the utility score from the known population as 6%, type-I error as 0.05, and power of the study as 80%, a sample size of 148 was estimated to be appropriate.<sup>7</sup> All the patients, whose radiotherapy treatment had been completed between 4 months and 2 years prior to the date of recruitment in the study, were considered eligible to participate. The final sample comprised patients with a median period of 9 months since the completion of radiotherapy (range of 4 to 23 months). Consecutive sampling was done by appropriately qualified and trained research assistants to recruit patients. Eligible participants were identified

by trained research staff and out-patient department registers were reviewed daily. All baseline interviews were administered face-to-face at the hospital. In case of an illiterate participant, each question of the descriptive system was read to the participant, the printed EQ-VAS scale was shown, and the participant was asked to say and point out the answer.

### Quality of life tools

To measure health-related quality of life, the EQ-5D-5L descriptive system and EQ-VAS were used. The EQ-5D-5L descriptive system covers five dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression, and each dimension has five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems.<sup>21</sup> An EQ-5D-5L health state is a set of responses to the five dimensions and is represented as a five-digit number (11 111, 11 112 etc.), with each digit representing the level of problem in the respective dimension. EQ-5D-5L was used to produce a single utility score between <0 and 1 based on individuals' responses to questions regarding the impact of cervical cancer on their lives. Utility score of 1 means perfect health and 0 implies death. Since the tariff values for the Indian population are not available, we used the reference population value-set of Thailand to determine the quality of life index value of individual health states.<sup>22</sup> The choice of the Thailand value-set to calculate quality of life index scores was based on the recommendations of the draft Indian reference case for undertaking health technology assessments.<sup>23</sup>

In addition, all the patients were also asked to rate their present health state between 0–100 through the EuroQoL VAS.<sup>24</sup> It consists of a 20 cm vertical line with clearly defined endpoints. The scores represent the ordinal rankings of the health outcomes, where '0' denotes the worst health state and '100' denotes the best health state from the patients' perspective. Stage-specific mean utility scores were estimated for patients according to FIGO classification Stage I, II, III, and IV.<sup>25</sup> Descriptive analysis in terms of the proportion of patients reporting individual problems, were estimated for each attribute of EQ-5D-5L.

### Association of health-related quality of life with socio-demographic characteristics

Socio-demographic data regarding age in years, religion (Hindu, Muslim, Sikh, Christian, or others), residential status (urban or rural), educational status (illiterate, primary, middle, matric, senior secondary, graduation, and post-graduation or above), marital status (married, never married, widowed, separated, or divorced), and annual household income (in Indian National Rupees) was collected. ANOVA was used to assess the statistical significance between the mean quality of life scores among patients of different age, religion, education, and annual household income, whereas the independent samples *t*-test was used to see the difference in mean quality of life scores among patients of different residences and marital status. Multiple linear regression was used to assess the determinants of health-related quality of life among cervical cancer patients. The regression equation so formed can be written as:

$$y = \alpha + \beta_1\alpha_1 + \beta_2\alpha_2 + \beta_3\alpha_3 + \beta_4\alpha_4 + \beta_5\alpha_5 + \beta_6\alpha_6$$

Where  $\alpha$  is constant,  $\alpha_1$ – $\alpha_6$  denotes annual household income, stage of cancer, residence, education, marital status, and

age (independent variables),  $\beta_1$ – $\beta_6$  are regression coefficients for all the independent variables, and  $y$  is EQ-5D-5L score (independent variable).

## RESULTS

### Sample characteristics

Out of the total of 159 patients, over one-third of patients (35.8%) were 41–50 years' old and 44% of the patients were illiterate. The majority (63.5%) of the recruited patients were diagnosed with stage II cervical cancer, belonged to rural areas (64.8%), and were married (74.8%). Among the study participants, the majority of patients (67.9%) have received radiotherapy, chemotherapy, and brachytherapy, followed by radiotherapy and brachytherapy (13.2%), radiotherapy and chemotherapy (11.3%), radiotherapy alone (5%), surgery, radiotherapy, and brachytherapy (1.26%), surgery, radiotherapy, and chemotherapy (0.63%), and surgery, radiotherapy, chemotherapy, and brachytherapy (0.63%). Detailed sample characteristics are presented in Table 1.

### Health-related quality of life

A total of 106 health states were reported by the patients of cervical cancer, among which the most commonly reported health states were 11111 (15.7%), 11121 (6.9%), 11122 (4.4%), 11112 (3.8%), and 21121 (3.1%). Among all the perceived health states, the state corresponding with the worst quality of life was 55 511, which was reported by one patient. The findings of the study show that the most commonly faced problem by the patients of cervical cancer in India is of pain/discomfort, which was reported by 61.9% of patients (Table 2). It was followed by problems in performing usual activities (eg, work, study, housework, family or leisure activities), which was reported by 53.8% of the patients. While 41.3% of the cervical cancer patients in India reported to have anxiety/depression, 39.9% reported to have problems in walking about (mobility). Only 2.7% of cervical cancer patients reported to have difficulties in activities pertaining to self-care (bathing or dressing oneself).

The mean EQ-5D-5L utility score among cervical cancer patients was 0.64 [95% CI=0.61–0.67]. Similarly, the mean EQ-VAS score was estimated as 67.6 (95% CI=65.17–70.03). The stage-specific mean EQ-5D-5L and EQ-VAS scores along with CIs are presented in Table 3. As the number of patients in stage IV is fewer, a pooled estimate of the health-related quality of life for the patients in stage III and stage IV of cervical cancer has been generated. The mean EQ-5D-5L utility score among cervical cancer patients in stage III and stage IV was 0.635 [95% CI=0.56–0.71]. Similarly, the mean EQ-VAS score for these patients was estimated as 67.2 (95% CI=60.67–73.69).

The health-related quality of life of cervical cancer patients decreased significantly with an increase in their annual household income ( $P=0.019$ ). Patients having annual household income less than 50000 INR reported the highest EQ5D score (0.7107), followed by those in the income group of 50000–1 lac INR (0.6893), 1 lac–2 lac INR (0.6849), and more than 2 lac INR (0.5756), respectively (Table 1).

Better health-related quality of life was observed among cervical cancer patients in rural area (mean EQ-5D-5L score 0.6466) as compared with those in urban areas (0.6302). Furthermore, literate patients showed better quality of life score (0.6506) as compared

**Table 1** EQ5D scores among different socio-demographic groups

Characteristics	Number of patients* (n=159)	Mean EQ5D score	P-value
Age in years			
Less than 40	14 (8.8)	0.6230	0.318
41–50	57 (35.8)	0.6597	
51–60	46 (28.9)	0.6715	
61–70	32 (20.1)	0.6087	
More than 70	10 (6.3)	0.5198	
FIGO stages			
Stage I	19 (11.9)	0.6984	0.698
Stage II	101 (63.5)	0.6323	
Stage III	37 (23.3)	0.6371	
Stage IV	2 (1.3)	0.591	
Religion†			
Hindu	116 (73)	0.6344	0.779
Muslim	2 (1.3)	0.7216	
Sikh	41 (25.8)	0.6553	
Residential status			
Urban	56 (35.2)	0.6302	0.071
Rural	103 (64.8)	0.6466	
Educational status			
Illiterate	70 (44.0)	0.6284	0.77
Primary	31 (19.5)	0.6346	
Middle	21 (13.2)	0.7086	
Matric	14 (8.8)	0.6032	
Senior secondary	12 (7.5)	0.6371	
Graduate and post-graduate	11 (6.9)	0.6602	
Marital status‡			
Married	119 (74.8)	0.6366	0.82
Widow/separated/divorced	40 (25.2)	0.6536	
Annual household income (INR)			
Less than 50000	10 (6.3)	0.7107	0.019
50000–1 lac	38 (23.9)	0.6893	
1 lac–2 lac	43 (27.0)	0.6849	
More than 2 lacs	68 (42.8)	0.5756	

\*Values in parentheses represent percentage.

†None of the study participants belonged to any other religion.

‡None of the study participants were unmarried.

with illiterate patients (0.6284). Poor quality of life was observed among married cervical cancer patients (0.6366), as compared with those who were widowed, divorced, or separated (0.6536). Patients in the 51–60 years age group reported the highest mean EQ-5D-5L score (0.6715), followed by 41–50 years (0.6597), less

**Table 2** Problems reported by cervical cancer patients in different dimensions of EQ5D

	Mobility N (%)	Self-care N (%)	Usual activities N (%)	Pain/discomfort N (%)	Anxiety/depression N (%)
No problem	134 (60.1%)	217 (97.3%)	103 (46.2%)	85 (38.1%)	131 (58.7%)
Slight problem	39 (17.5%)	1 (0.4%)	28 (12.6%)	84 (37.7%)	50 (22.4%)
Moderate problem	23 (10.3%)	0 (0%)	30 (13.4%)	31 (13.9%)	26 (11.7%)
Severe problem	26 (11.7%)	2 (0.9%)	27 (12.1%)	14 (6.3%)	11 (4.9%)
Extreme problem	1 (0.4%)	3 (1.4%)	35 (15.7%)	9 (4.0%)	5 (2.2%)

than 40 years (0.6230), 61–70 years (0.6087), and more than 70 years (0.5198) age group, respectively. However, these observed differences among the mean EQ-5D-5L scores within these groups (residence, education, marital status, and age) were not found to be statistically significant. (Table 1)

The results of multiple linear regression implied that even after controlling for the stage of cervical cancer and other socio-demographic variables, the quality of life of the patients decreases with the increase in their annual household income. However, the other independent variables considered in the regression model were not found to be the significant predictors for health-related quality of life of cervical cancer patients (Table 4).

## DISCUSSION

We consider that this is the first study from India to measure summary health-related quality of life scores of cervical cancer patients using the EQ-5D-5L instrument. While the average health-related quality of life was found to be 0.643, pain/discomfort was reported to be the most common problem. We also found a declining gradient in EQ-5D-5L and EQ-VAS utility scores of cervical cancer patients from stage I to stage IV. These findings are in line with those of other studies,<sup>26</sup> as well as the general biological plausibility of health-related quality of life and disease progression.<sup>2,16</sup>

The utility scores for cervical cancer patients using the EQ5D instrument has been undertaken in a few other Asian countries. A study undertaken in Indonesia found the mean utility score to be 0.76.<sup>7</sup> The utility scores of Chinese cervical cancer patients at 1, 3, and 6 months after therapy, using the EQ-5D-3L tool, was reported to be 0.68, 0.75, and 0.86, respectively.<sup>2</sup> Similarly, the mean utility scores of cervical cancer patients in Taiwan was found to be 0.84.<sup>27</sup> Studies done in Italy and Argentina, however, observed comparatively lower quality of life – 0.58 and 0.40, respectively.<sup>28,29</sup> These differences in utility scores may be attributed to the use of

the EQ-5D-3L questionnaire, in contrast with the EQ-5D-5L questionnaire used by us, and the differences in health perception across different population ethnicities.<sup>7,28,29</sup> Ethnicity has also been reported to influence the valuation of quality of life.<sup>30,31</sup> Methodological differences in valuation of utility scores, such as differences in value-sets used in converting health states into utility scores, could also explain differences in ultimate utility scores in different studies.<sup>7,28</sup> A comparison of stage-specific utility scores as observed in various regional studies is presented in Table 3.

The results of our study imply that health-related quality of life of cervical cancer patients decreases with the increase in their annual household income. A previous study from India also reported a rising gradient in the odds of self-reported morbidity across increasing socio-economic strata.<sup>32</sup> This implies that the rich tend to report lower quality of life for the same health state, a concept which has been termed as positional objectivity.<sup>33</sup> The rich could possibly be more conscious about their health, and thus in a better position to appraise their quality of life relative to the poor. On the other hand, the poor are afflicted by the unmet basic needs of life which pushes ‘health’ further down in their priority valuation. As a result, the rich are reporting themselves to be in worse quality of life as compared with their poorer counterparts.

Pain/discomfort was found to be the most commonly reported problem (61.9%) faced by cervical cancer patients in India. These findings are in line with the similar study conducted in Indonesia, wherein 67.8% of the patients reported to have problems of pain/discomfort.<sup>7</sup> Moreover, Gao et al<sup>34</sup> conducted a similar study in Singapore using the EQ5D instrument and found that 54.6% of the patients reported to have problems of pain/discomfort. Gao et al also found the proportion of patients reporting anxiety/depression as 41.2%, which is similar to the findings of our study. Our study also found that 53.8% of cervical cancer patients face problems in performing usual activities (eg, work, study, housework, family or leisure activities), which may be a sequel to pain/discomfort. This

**Table 3** EQ-5D and EQ-VAS score classified by cancer stages

FIGO staging	Current study		(EQ5D) scores in other regional studies			
	Mean EQ-5D-5L score (95% CI)	Mean EQ-VAS score (95% CI)	Endarti <sup>7</sup> (Indonesia)	Goldie <sup>26</sup> (USA)	Praditsitthikorn <sup>15</sup> (Thailand)	Khemapech <sup>40</sup> (Thailand)
Stage I	0.6984 (0.6158 to 0.7809)	69.74 (64.1 to 75.37)	0.85	0.65	0.74	0.784
Stage II	0.6323 (0.5881 to 0.6766)	69.01 (65.46 to 72.56)	0.76	0.56	0.76	0.788
Stage III	0.6371 (0.5535 to 0.7208)	67.57 (60.77 to 74.37)	0.71	0.56	0.72	0.776
Stage IV	0.591 (0.4127 to 0.7684)	60.00 (40.4 to 79.6)	0.77	0.48	0.63	0.814
All stages	0.6437 (0.6135 to 0.6738)	67.6 (65.17 to 70.03)	–	–	–	–

**Table 4** Determinants of health-related quality of life (EQ5D score) among cervical cancer patients

Variable	Beta	P-value	95% CI
Annual household income	−0.055	0.004	−0.094 to −0.015
Stage	−0.026	0.372	−0.085 to 0.032
Residence	0.009	0.825	−0.068 to 0.085
Education	0.009	0.470	−0.016 to 0.033
Marital status	0.025	0.559	−0.059 to 0.109
Age	−0.011	0.560	−0.048 to 0.026

shows that there is internal consistency between the findings for individual domains. Moreover, it implies that interventions aiming to improve quality of life of cervical cancer patients should focus on these aspects in order to achieve better patient-centric outcomes.

Unlike some of the previous studies which interviewed healthy respondents for perceived quality of life of hypothesized health states resembling cervical cancer, we valued the quality of life as reported by actual cervical cancer patients.<sup>28 35</sup> Since the general population is likely to over-emphasize the perceived deterioration in health status of such a disease scenario, the utility scores of the hypothesized sample tends to be lower than that of cervical cancer patients.<sup>7 36</sup>

Our study had methodological limitations. First, our sample of patients was drawn from a single center. Although the valuation of health-related quality of life is determined by culture, ethnicity, region, and other socio-demographic characteristics, yet, the hospital from which the cases were recruited caters to a large population from more than six Indian states. Therefore, the patient population which was selected using a consecutive sampling were representative of the Indian population. Moreover, the sample characteristics are similar to the overall characteristics of the Census population in terms of the caste, occupation, region, and education. Second, utility scores were calculated using a value-set from another country. However, it is worthwhile to mention here that the value-set for the Indian population has not been prepared thus far,<sup>22 37</sup> necessitating the use of a value-set from another country. As per standard recommendations in selecting another country value-set to be used for converting local health states to utility scores, Thailand appears most appropriate among the countries with a value-set.<sup>38 39</sup> Moreover, the draft Indian reference case for undertaking health technology assessments in India recommends using the Thailand value-set to calculate quality of life index scores, until the Indian value-set is prepared.<sup>23</sup> Finally, since the valuation for quality of life using the Thai value-set is not significantly different from what was reported by Indian women when interviewed using the VAS tool, we can assume that the findings of quality of life found in our study is not too sensitive to the use of the tariff values from Thailand.

As the study generated utility scores for cervical cancer patients in the local population, its results may be used for conducting India-specific economic evaluations. However, further studies are needed to develop a local EQ-5D value-set in order to facilitate the evidence that informed decision-making in India. Efforts to improve

health-related quality of life of cervical cancer patients should focus on ameliorating pain and anxiety.

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**Contributors** GJ: methodology, software, formal analysis, data curation, writing original draft. ASC: methodology, software, formal analysis, data curation, writing review, editing. BR: validation, resources, writing review, editing. SG: validation, resources, writing review, editing, supervision. RS: validation, resources, writing review, editing. SP: conceptualization, methodology, validation, formal analysis, resources, writing review, editing, supervision.

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