

A Prospective Observational Study on Assessment of Quality of Life of Patients on Adjuvant and Neo-adjuvant Therapy for Lung, Breast, and Colorectal Malignancies

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Abstract– Background: Patients with malignancy undergoing chemotherapy, surgery, and radiation therapy experience a variety of symptoms that affect their quality of life (QoL). This necessitates the assessment of QoL on their subjective evidence that can be utilized in diagnosis, predicting prognosis, patient monitoring and clinical decision making. This information will help health care professionals to design interventions and recommend the appropriate treatment, thereby improving the QoL of patients. In this study we aim to assess the QoL of patients receiving adjuvant and neo-adjuvant therapy for Lung, Breast, and Colorectal cancer, in addition to making correlations according to type of treatment and disease stage. **Methods:** A prospective observational study was carried out in the radiation oncology department from March 2021 to September 2021 in Krishna Rajendra Hospital, Mysuru, India. We used the European Organization for Research and Treatment of Cancer quality of life questionnaire [EORTC QLQ – C30] Version 3.0 to assess the QoL of patients. Patients were interviewed twice, when they came to have their chemotherapy regardless of the cycle number and during the next visit. **Results:** The number of patients enrolled in the study were 107. Most of participants were female 83%. About 73.8% diagnosed with breast cancer. In patients treated with adjuvant versus neo-adjuvant treatment, the functional scores and global health status scores were statistically significant $p=0.038$ and $p=0.010$ respectively with mean scores 63.54 in favour of adjuvant therapy. These results represent a better QoL in patients received adjuvant versus neo-adjuvant therapy. The mean values of global health

status score in patients diagnosed with lung cancer during the two assessments (47.72, 51.51) were lesser than those in patients diagnosed with breast cancer (63.71, 63.50) and colorectal cancer (58.82, 58.82), indicating patients with lung cancer had poor QoL compared to breast and colorectal cancer patients. **Conclusion:** Patients received adjuvant therapy had better QoL compared to those received neo-adjuvant therapy. The QoL in lung cancer patients were majorly affected as compared to QoL in breast and colorectal cancer patients. There is a strong correlation between the type of treatment and disease stage.

Keywords: Malignancy; Quality of life (QoL); Adjuvant therapy; Neo-adjuvant therapy; Chemotherapy; EORTC QLQ – C30.

1. INTRODUCTION

Cancer is the second leading cause of death worldwide [1]. Cancer can be treated by different modalities including surgery, radiation therapy, chemotherapy, immunotherapy, targeted therapy, hormone replacement therapy, and stem cell transplantation. Treatment options will vary depending on the sort of cancer and how far it has progressed. Some cancer patients will just require one treatment. Most patients, on the other hand, receive a combination of therapies, such as surgery combined with chemotherapy and/or radiation therapy [2].

Chemotherapy has significant short- and long-term adverse effects. The specific drugs employed in the treatment regimen, as well as the dose and length of treatment, all influence the side effects [3]. Chemotherapy can cause nausea, vomiting, hair loss, cognitive dysfunction, fatigue, changes in sexual function, and a decrease in Quality of life (QoL). One-third of patients undergoing systemic chemotherapy experience cognitive dysfunction that negatively impacts their QoL [4].

Neo-adjuvant therapy refers to treatments given before the primary cancer treatment, whereas adjuvant therapy refers to treatments given after the primary treatment. The general goal of these multimodal treatment techniques is to improve the efficacy of local definitive therapy while reducing the negative

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effects that patients may suffer during primary therapies. This method is most commonly employed in patients with breast, colon, or lung malignancies to boost the chances of targeting all cancer cells [5].

According to the World Health Organization, health-related quality of life (HRQoL) is a multi-dimensional term that includes domains such as physical, mental, emotional, and social functioning [6]. It is the overall being of an individual in terms of social, physical, mental, and emotional aspects of life. It is difficult to describe and quantify the QoL. The best way to explain and quantify the QoL is to use words individually, depending on one's current lifestyle, past knowledge, future expectations, desires, and aspirations [7]. Medical advancements and the growth of evidence-based medicine (EBM) have resulted in significant improvements in both survival and treatment quality in the field of oncology. Exploring the QoL of cancer patients often necessitates an interest in their daily lives and a direct emphasis on their perspectives, which necessitates considering the QoL differently, based on the subjective experience of the patient's everyday lives, which we prefer to call the quality of daily life [8]. The wide applicability of QoL assessments includes diagnosis, predicting prognosis, evaluation, patient monitoring, clinical decision making, communication, and treatment along with designing system intervention, allocating resources and research efforts, training health care personnel, and reducing costs [9]. In this study we aim to assess the QoL of the patient receiving a djuvant and neo-adjuvant therapy for Lung, Breast, and Colorectal malignancies. In addition to making correlations between QoL and disease stage and type of treatment as well as to find out the commonest malignancies which majorly affect the QoL of cancer patients.

2. MATERIALS AND METHODS

A prospective observational study was carried out in the radiation oncology department, Krishna Rajendra Hospital, Mysuru, India for a period of six months from March 2021 to September 2021. The study was approved by the Institutional Ethical Committee, Mysore Medical College and Research Institute, Mysuru. All patients ≥ 18 years of both genders and patients diagnosed with lung, breast, and colorectal cancer who are on a djuvant or neo-adjuvant therapy were invited to participate in the study, while patients who were not willing to participate and patients with incomplete medical or medication information were excluded. The patients were enrolled after obtaining the informed consent form which was prepared both in English and the local language i.e. Kannada.

All relevant data of the enrolled patients was documented in a designed data collection form. We used the European Organization for Research and Treatment of Cancer quality of questionnaire [EORTC QLQ – C30] Version 3.0 to assess the QoL. EORTC QLQ – C30 is a valid and reliable tool that contains a 30-item cancer-specific core questionnaire that addresses various domains including functional scale (physical, cognitive, role, emotional, and social), symptom scale (fatigue, pain and nausea/vomiting) and global health status scale (overall QoL) [10]. The questionnaire was given to the patients twice (irrespective of cycle number) by interviewing them i.e. first when they came to receive their

chemotherapy cycle and second assessment was done when they came to receive their next chemotherapy cycle.

The higher scores in global health status the better QoL. Similarly, higher scores in functional scales indicate better QoL. On the other hand, higher scores in symptoms scales means the worse the QoL. For functional scales, subjects scoring <33.3% have problem, those scoring ≥ 66.7% have good functioning. For symptoms scales, subject scoring < 33.3% have good QoL and those scoring ≥ 66.7% have problems [10]. Statistical analysis was done using ANOVA test and IBM SPSS Version 22 software. A p-value of ≤ 0.05 was considered as a significant value.

3. RESULTS

We enrolled 107 subjects. Out of 107 patients, 16.82% were men and 83.17% were women in which 74.76% patients received a djuvant therapy while 25.23% patients received neo-adjuvant therapy. Majority of patients received chemotherapy 96% through the intravenous route which was followed by surgery 63.6%, radiation therapy 0.95%, and concomitant therapy 2.8%. The details of patient demographics are presented in Table 1.

Most patients diagnosed with breast cancer. The prevalence of cancer type among the patients in our study is presented in Figure 1. Majority of patients were diagnosed with Stage IV cancer.

Table 1. Patient's demographics

PATIENT CHARACTERISTICS	NUMBER OF SUBJECTS (n)	PERCENTAGE (%)
Total number of patients	107	100
Age distribution (in years)		
25-40	18	16.8
41-55	46	43
56-70	37	34.6
71-85	6	5.6
Gender distribution		
Men	18	16.8
Women	89	83.2
Stages		
I	3	2.8
II	25	23.4
III	33	30.8
IV	46	43

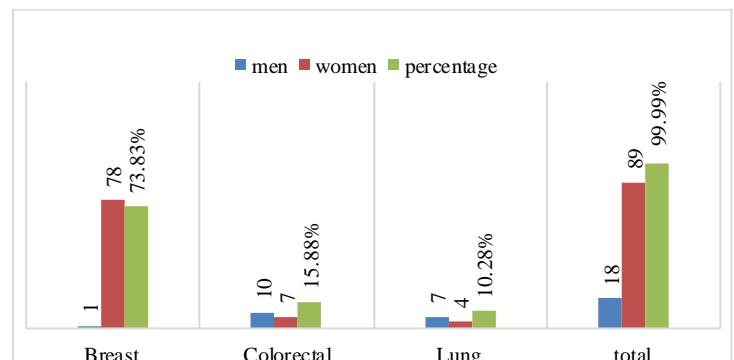


Figure 1. Types of cancer among participants

Table 2. Correlations between types of therapy & QoL domains

Type of therapy	Functional scale score 1	Functional scale score 2	Symptom scale score 1	Symptom scale score 2	Global Health Status scale score 1	Global Health Status scale score 2
Adjuvant						
Mean	68.69	70.77	26.82	23.35	63.54	62.60
N	80	80	80	80	80	80
Std. Deviation	17.22	19.45	15.35	19.54	14.24	15.00
Neo-adjuvant						
Mean	63.04	61.01	30.19	30.39	54.62	58.33
N	27	27	27	27	27	27
Std. Deviation	15.82	24.60	19.55	18.50	18.10	23.68
Sig. (p-value)	1.36	0.038	0.360	0.104	0.010	0.277

Table 3. Correlation between types of therapy & detailed QoL domains

Domain	First Assessment	P-value	Second Assessment	P-value
Functional Scale				
Physical function	AT	2.483	2.321	0.012*
	NAT	2.888	2.827	
Role function	AT	1.637	1.500	0.081
	NAT	1.836	1.844	
Emotional function	AT	2.072	2.015	0.494
	NAT	2.101	2.175	
Cognitive function	AT	1.213	1.188	0.239
	NAT	1.407	1.333	
Social function	AT	1.975	2.243	0.490
	NAT	1.982	2.444	
Symptom Scale				
Fatigue	AT	2.075	1.813	0.591
	NAT	1.852	1.926	
Nausea	AT	.400	1.387	0.585
	NAT	1.481	1.296	
Vomiting	AT	1.188	1.225	0.811
	NAT	1.407	1.259	
Pain	AT	2.213	2.000	0.187
	NAT	2.487	2.296	
Dyspnea	AT	1.150	1.125	0.084
	NAT	1.593	1.296	
Insomnia	AT	2.063	2.012	0.827
	NAT	2.000	2.074	
Appetite loss	AT	1.850	1.713	0.167
	NAT	1.815	2.037	
Constipation	AT	1.213	1.137	0.024*
	NAT	1.296	1.444	
Diarrhea	AT	1.225	1.037	0.002*
	NAT	1.296	1.333	
Financial Difficulties	AT	2.663	3.013	0.499
	NAT	2.563	3.185	

AT: Adjuvant therapy, NAT: Neo-adjuvant therapy, * statistically significant

The mean values of functional scale scores and global health status scale scores in patients received adjuvant therapy were greater than patients who received neo-adjuvant therapy in both the first response and second response. This indicate better QoL in patients who received adjuvant treatment versus those who had neo-adjuvant therapy. The symptom scale scores in patients received adjuvant therapy were lesser than in patients received neo-adjuvant therapy in both the first and second response indicating better QoL in patients received adjuvant treatment. These results confirmed with the second assessment of functional scale scores (p=0.038) and the first assessment of global health status scale scores (p=0.010). Under the symptom scale, symptoms such as constipation, diarrhea and dyspnea scores were low and p value were significant (p=0.024, p=0.002, p=0.002) respectively. Under

the functional scale, physical function score was significant in the first and second assessment, p=0.012, p=0.010) respectively. The details of the QoL assessment of different domains scores and correlation with the type of therapy are presented in Table 2 and Table 3.

The mean values of the global health status score in lung cancer patients (47.72, 51.51) were lesser than in Breast cancer patients (63.71, 63.50) and colorectal cancer patients (58.82, 58.82). Similarly, the mean values of functional scale score in lung cancer patients (56.16, 56.27) were lesser than in breast cancer patients (69.78, 70.82) and colorectal cancer patients (62.74, 64.45), whereas the mean values of the symptom scale scores in lung cancer patients (38.92, 33.60) was greater than in breast cancer patients (25.86, 22.90) and colorectal cancer patients (28.80, 30.01), indicating that patients with lung

cancer had poor QoL compared to breast and colorectal cancer patients. The first assessment of functional scale scores ($p=0.020$), the first assessment of Symptom scale score ($p=0.045$), and the first assessment for global health status scale scores ($p=0.004$) indicating the significance correlation between type of cancer and QoL. Patients with lung cancer had the least QoL (Table 3). Under the symptom scale, symptoms

such as constipation, and diarrhea, were found to be correlated with QoL and were statistically significant for the second assessment whereas dyspnea was found to be significant for both the first and second assessments. In the functional scale, physical function and cognitive functions were found to be significant but only for the first assessment. The details are presented in Table 4, Table 5 and Table 6

Table 4. Correlations between types of cancer & QoL domains' scores

Type of cancer	Functional scale score 1	Functional scale score 2	Symptom scale score 1	Symptom scale Score 2	Global Status scale score 1	Health score 1	Global Health Status scale score 2
Breast							
Mean	69.78	70.82	25.86	22.90	63.71		63.50
N	79	79	79	79	79		79
Std. Deviation	16.39	18.69	15.45	18.37	14.68		16.02
Colorectal							
Mean	62.74	64.45	28.80	30.01	58.82		58.82
N	17	17	17	17	17		17
Std. Deviation	16.75	25.01	14.40	21.74	15.15		17.54
Lung							
Mean	56.16	56.27	38.92	33.60	47.72		51.51
N	11	11	11	11	11		11
Std. Deviation	17.12	28.16	22.75	21.37	17.51		24.94
Sig. (p-value)	0.020	0.072	0.045	0.122	0.004		0.082

Table 5. Correlations between types of cancer & domains

Mean values	Breast Cancer		Lung cancer		Colorectal cancer	
	First Assessment	Second Assessment	First assessment	Second Assessment	First assessment	Second Assessment
Functional scale						
Physical function	2.409	2.341	3.393	3.000	3.042	2.588
Role function	1.607	1.470	1.909	1.981	1.848	1.755
Emotional function	2.834	2.015	2.272	2.295	2.132	2.052
Cognitive function	1.203	1.177	1.818	1.545	1.132	1.148
Social function	1.993	1.285	2.045	2.545	2.044	2.269
Symptom scale						
Fatigue	2.000	1.810	2.000	2.364	2.148	1.439
Nausea	1.456	1.392	1.455	1.182	1.169	1.222
Vomiting	1.190	1.203	1.636	1.273	1.169	1.233
Pain	2.177	1.962	3.000	2.818	2.227	1.788
Dyspnea	1.165	1.101	2.091	1.636	1.121	1.121
Insomnia	2.051	2.013	2.273	2.364	2.190	1.883
Appetite loss	1.797	1.646	1.909	2.182	1.714	1.862
Constipation	1.190	1.114	1.273	1.273	1.301	1.449
Diarrhea	1.190	1.051	1.545	1.545	1.227	1.074
Financial Difficulties	2.557	2.975	3.000	3.455	2.592	3.132

Table 6. Correlations between types of cancer & domains scores

Domain	Breast Cancer, Lung cancer, and Colorectal cancer	
	First assessment	Second assessment
Functional scale		
Physical function	0.034*	0.148
Role function	0.195	0.108
Emotional function	0.673	0.703
Cognitive function	0.004*	0.135
Social function	0.734	0.679
Symptom scale		
Fatigue	0.019*	0.230
Nausea	0.849	0.388
Vomiting	0.203	0.600
Pain	0.116	0.076
Dyspnea	0.000*	0.005*
Insomnia	0.692	0.632
Appetite loss	0.744	0.095
Constipation	0.564	0.013*
Diarrhea	0.161	0.008*
Financial difficulties	0.620	0.733

* Statistically significant

Comparing QoL in patients diagnosed with stage IV cancer to earlier stages, the mean values on symptom measures had significant correlation with QoL $p=0.05$. Patients with stage IV cancer had mean values on the global health status scale that were lower than those with the earlier stages. This demonstrates that patients who were diagnosed with a Stage IV cancer had lower quality of life. The correlation between QoL and stages of cancer is presented in Table 7.

4. DISCUSSION

In this study, we have assessed the QoL of patients receiving adjuvant and neo-adjuvant therapy. Our study findings depicted that the patients on a djuvant therapy had better QoL than the patients on neo-adjuvant therapy. This might be explained as patients undergoing adjuvant therapy already being adapted to the drugs and their side effects, or because they may have psychologically adjusted to the treatment, medications, etc., leading to better QoL.

The prevalence of breast cancer was more than that of lung cancer and colorectal cancer as most of patients enrolled in the study were female 83.17%. Different aspects, such as social history, lifestyles, familial history, or genetic predispositions, may contribute to the prevalence of specific cancer types. About 42.99% of participants had a stage IV cancer, whereas just 2.80% had a stage I. This could be a factor influencing QoL because early discovery and diagnosis aid in early treatment, which improves patients' QoL.

Breast cancer: the mean age of patients included in our study was 52.96 ± 11.99 which is consistent with the study conducted by Deshpande VP, et al. as they included patients with a mean age of 51.35 ± 12.14 [11]. The Global health status scale in our study was statistically significant which was similar to a study conducted by So WKW, Marsh G, Ling WM, Leung FY, Lo JCK, Yeung M, et al. in which the overall QoL was statistically significant [12]. Wani SQ, et al. conducted a study in which the mean value of insomnia, loss of appetite, nausea, and vomiting in the symptoms scale improved over time and the global health status scale was

statistically significant and correlated with type of cancer [13]. These findings were in consistent to the results of our study.

Colorectal cancer: our study population had the highest mean scores to financial problems, followed by symptoms as fatigue, pain, insomnia, constipation, appetite loss, nausea and vomiting, diarrhea, and dyspnea. These results were comparable to the study conducted by Laghousi D, et al. [14].

Lung cancer: dyspnea was shown to be statistically significant on the symptom scale assessment. These findings were in accordance with the study conducted by Kenny PM, et al. [15]. The mean value of dyspnea in the symptoms scale were improved from the first assessment (19) to the second assessment (12) in a study conducted by Gralla RJ, et al. [16] which was consistent to our study results in which dyspnea were improved from 2.091 to 1.636. In another study by Barwal V, et al. the patient's overall health condition remained essentially the same, and the mean scores for the emotional, role and social functioning did not significantly alter at the follow-up. Constipation, sleep, and fatigue were still statistically significant [17]. These results were compatible with our results. The cause might be explained as patients were receiving treatment, which might have stopped these symptoms from getting worse.

Adjuvant therapy: dyspnea and constipation were shown to be statistically significant symptoms in research done by Nicolussi AC and Sawada NO in individuals undergoing adjuvant therapy [18]. This result was comparable to our investigation. Our findings are consistent with those of a study by Park S, Kim IR et al. in which sleep disturbance, a ppetite loss, and constipation were found to be statistically significant [19].

Adjuvant and neo-adjuvant therapy: according to research done by Arraras JJ, Suárez J, et al. as a whole, the sample's QoL scores on the EORTC questionnaires were quite high, and only minimal changes were found for global QoL, insomnia, and constipation [20]. This was comparable to what we found in our investigation.

Strengths and limitations: Strengths of our study include evaluation of three different types (Breast, Lung, and Colorectal) of Cancer patients, health-related quality of life was measured using an open-ended questionnaire of EORTC-QLQ- C30 version 3.0 and QoL was compared according to the disease stages and type of treatment. Limitations include, enrolling limited number of patients. It was based on a single site study, so the results cannot be extrapolated with the multiple site study and imposition of lockdown due to COVID-19 pandemic during the study.

5. CONCLUSION & FUTURE DIRECTIONS

Patient receiving adjuvant therapy had better QoL compared to those who had neo-adjuvant therapy. The QoL in Lung cancer patients was the least compared to that in breast and colorectal cancer patients. There is a strong correlation between type of cancer, type of treatment, stage of disease and patients QOL. Thus, there is a need to enhance the QoL which can be achieved by undertaking the following measures:

- i) Educating health care professionals regarding the QoL measures to be taken during management.

Table 7. Correlations between stage of disease & QoL domains scores

Stages		Functional Score 1	Functional Score 2	Symptom Score 1	Symptom Score 2	Global Health Status Score 1	Global Health Status Score 2
Stage I	Mean	57.03	56.44	37.60	16.11	52.77	61.11
	SD	15.76	26.38	11.56	19.42	4.81	14.73
Stage II	Mean	63.73	67.84	30.46	24.06	60.33	60.66
	SD	18.10	18.38	15.65	19.50	16.36	16.72
Stage III	Mean	74.27	75.73	19.65	23.17	65.15	64.14
	SD	17.92	15.01	11.60	18.30	15.65	19.71
Stage IV	Mean	64.83	64.02	31.27	27.71	59.60	60.14
	SD	16.99	24.83	18.34	20.41	15.61	17.57
P - value		0.19	0.08	0.05*	0.40	0.34	0.77

- ii) Educating and counselling patients regarding the disease and treatment side effects in order to make them physically, mentally, and psychologically accept the situation and cope-up with therapy.
- iii) Encouraging patients to promptly disclose the discomfort faced during the therapy journey.
- iv) Advising non-pharmacological interventions to enhance QoL and recruiting experienced health care professionals in order to provide the best patient care.

Conflict of interest statement: The authors declare that the research was conducted without any commercial or financial relationships that can be of any potential conflict of interest.

Author contributions: Conceptualization: PLN, ABJ (both authors have equal contribution); Study design: PLN, ABJ, MS, NMS, BPL; Literature search: PLZ, ABJ, CS, MA; Data acquisition and clinical study: ABJ; PLN; Data analysis: ABJ; Manuscript drafting and editing: PLN; Manuscript review: PLN, ABJ, MS, NMS, BPL. All authors reviewed the manuscript, discussed the results, and contributed to the final manuscript.

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