Exploration of the Quality of Life in patients with malignancy and their primary caregivers: A Study in a Rural Tertiary Care Hospital.

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ABSTRACT

Quality of Life is a multidimensional construct encompassing perceptions of both positive and negative aspects of the dimensions, such as physical, emotional, social, and cognitive functions, as well as the negative aspects of the somatic discomfort and other symptoms produced by disease or its treatment. The impact of cancer is far more significant than the number of cases alone would suggest. A caregiver contributes the benefits of medical, social, economic, or environmental resources to a dependent or partially dependent individual such as a critically ill patient.

Methods: A cross-sectional exploratory study was conducted among 190 malignancy cases, and their respective primary caregivers were admitted to a tertiary care center in the Wardha district. Data were collected using the WHOQOL-BREF questionnaire to assess QoL across four domains: physical, psychological, social, and environmental. Sociodemographic and health-related information was obtained through structured interviews. Descriptive statistics and appropriate statistical tests were used to analyze the data.

Results: Among the two groups of patients with malignancy and their primary caregivers, the mean age for caregivers was approximately 5 years younger and was significant. The number of male caregivers was almost double that of female caregivers. The difference in Quality of Life was significantly different in the group receiving different treatment modalities. Patients who received a combination of chemotherapy and surgery had more impairment in Quality of Life than those with Chemotherapy and Surgery alone. Breast cancer and Oral cancer have significantly different impaired Quality of Life when they are compared to other cancers. The correlation between various domains of quality of life was significant and strongly correlated with each other. In patients with malignancy, the quality-of-life score in the social and general well-being domains correlated positively with the score in the physical domain and negatively with the psychological domain. The score on the psychological domain correlated negatively with the physical domain, environmental domain, and general well-being. However, the Quality-of-Life score in the social domain correlated positively with physical and psychological dimensions and general well-being. Quality of life in the domain of general well-being was correlated positively with all other domains except for the psychological domain, which was negatively correlated. These correlations mentioned above were significant.

Conclusion: This study has shown that the Quality of Life of patients with malignancy and primary caregivers is impaired, but the difference is insignificant. The intra- and inter-individual differences exist concerning circumstances, events, resources, and health outcomes. Also, positive and negative care experiences and health outcomes may coexist, but not necessarily at the same moment. Moreover, these experiences and *circumstances will likely shift throughout the day and during caregiving. Informal caregivers need to be recognized as equivalent healthcare team members.*

Keywords: *Quality of Life, Malignancy, Primary Care Giver, WHOQOL-BREF, General wellbeing.*

INTRODUCTION

Non-communicable diseases (NCDs) are the leading causes of death, causing more deaths than all other causes combined globally, and they strike hardest at the world's low- and middle-income populations. Malignancy/cancer is a term for a group of diseases in which abnormal cells divide without control and can invade nearby / distant tissues, as defined by the National Cancer Institute (Thakur et al. 2020). The impact of cancer is far more significant than the number of cases alone would suggest. The initial diagnosis of cancer is perceived by many patients as a grave event, with more than one-third of them suffering from anxiety and depression. Cancer is equally distressing for the family (Page and Adler NE 2008). It could significantly affect both daily functioning and economic situation of the families. The financial shock often includes the loss of income and the increase of expenses because of the treatment and health care.

The World Health Organization defines quality of Life as individuals' perceptions of their position in life in the context of the culture and value systems in which they live and to their goals, expectations, standards, and concerns. This definition reflects the view that Quality of Life refers to a subjective evaluation embedded in a cultural, social, and environmental context. Because this definition of Quality of Life focuses upon respondents' "perceived" Quality of Life, it is not expected to provide a means of measuring in any detailed fashion symptoms, diseases, or conditions, but rather the effects of disease and health interventions on Quality of Life (Cai et al. 2021).

A Caregiver contributes the benefits of medical, social, economic, or environmental resources to a dependent or partially dependent individual, such as a critically ill patient (Haris et al. 2018). Invariably, the overall Quality of Life decreases in cancer patients and their primary caregivers (defined as the person giving care to the patient, primarily, not necessarily blood relative or close relative).

Despite such huge implications and the need, studies on the assessment of Quality of Life in this subset of the population are scanty, particularly in India. The present study is intended to be an exploratory effort in the above direction and provide a stimulus for further research. Hence, there is a need for the study. This will direct us to develop an effective model for intervention in the hospital and the community.

Materials and Methods

Study Design

This is a hospital-based cross-sectional Exploratory study designed to assess the Quality of Life (QoL) among the patients with a confirmed diagnosis of malignancy admitted to the Sharad Pawar Dental College and Acharya Vinoba Bhave Rural Hospital of Wardha and their respective Primary Care Givers.

Study Duration

The study was conducted over twelve months.

Study Population:

The target population for this study included the patients with a confirmed diagnosis of malignancy admitted under the Oral Surgery Department of Sharad Pawar Dental College and Surgery, ENT, Obstetrics and Gynaecology, Skin, Orthopaedics, Pulmonary Medicine and Medicine Departments of Acharya Vinoba Bhave Rural Hospital in Wardha and their Primary Care Givers.

Primary Care Giver:

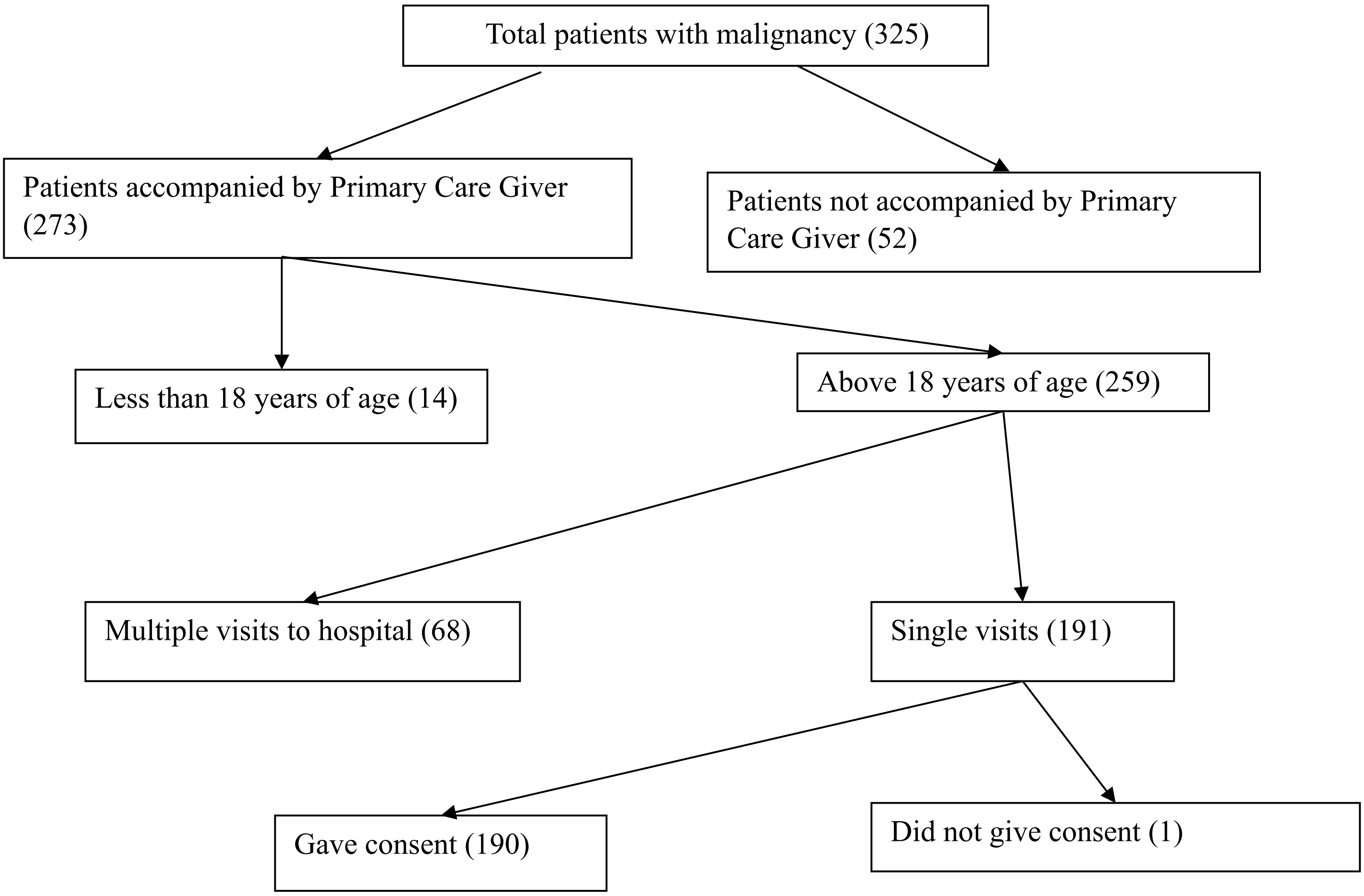
Caregivers (the person giving care to the patient, primarily, not necessarily a blood relative or close relative) of the respective in-patient with malignancy who were willing to participate in the study were considered primary caregivers for the survey.

Sample Size Calculation

All the patients who are above 18 years of age with a confirmed diagnosis of malignancy admitted under the Oral Surgery Department of Sharad Pawar Dental College and Surgery, ENT, Obstetrics and

Gynaecology, Skin, Orthopaedics, Pulmonary Medicine and Medicine Departments of Acharya Vinoba Bhave Rural Hospital and accompanied by their primary caregiver were included as cases. A total of 190 cases, i.e., patients with a confirmed diagnosis of malignancy and who fulfilled the inclusion criteria, were identified. Similarly, 190 primary caregivers of the respective cases were assessed.

Selection of Participants



Informed Consent

Written informed consent in the local language was obtained from participants selected for the study.

Data Collection tool:

1. **Socio-demographic Profile Sheet**

A structured format was developed to record variables like age, sex, religion, residential area, marital status, education, occupation, and socio-economic status.

2. **Clinical Profile Sheet**

This contains relevant clinical information like site of malignancy, stage of malignancy, treatment history, and family history. This was constructed specially for the present study.

3. **WHO Quality of Life Brief (WHO Quality of Life - BREF):**

The World Health Organization Quality of Life-Brief instrument is a self-administered instrument. It emphasizes the subjective evaluation of respondent's health and living conditions rather than objective functional status. The four domains of Quality of Life are measured: physical health, psychological health, social relationships, and environmental health based on the past two weeks. The scale has good discriminate validity, internal consistency, and test-retest reliability (Saxena et al. 1998; WHOQUALITY OF LIFE 1995; Gill and Feinstein 1994). The WHOQOL-BREF contains a total of 26 questions. One item from each of the 24 facets of the WHO QOL-100 has been included to provide a broad assessment. In addition, two items from the Overall Quality of Life and General Health facet have been included. The English and Hindi versions of WHO Quality of Life – BREF were used in this study to assess the quality of life of patients with malignancy and their primary caregivers.

Data collection

All the patients who are above 18 years of age with a confirmed diagnosis of malignancy admitted under the Oral Surgery Department of Sharad Pawar Dental College and Surgery, ENT, Obstetrics and Gynaecology, Skin, Orthopaedics, Pulmonary Medicine and Medicine Departments of Acharya Vinoba Bhave Rural Hospital for one year and accompanied by their primary caregiver were included as cases. A total of 190 cases and their respective primary caregivers were considered as study participants. The participants were interviewed after building a rapport and ensuring confidentiality regarding the use of data for research purposes only. All the study participants were administered the following instruments: Socio-demographic Profile Sheet, Clinical Profile Sheet, and WHO Quality of Life (WHO QOL -BREF). The survey was undertaken by employing face-to-face interviews. Detailed histories of the patients were recorded on the pretested proforma. No change in the treatment was done to facilitate intake into the study.

Data analysis

Descriptive statistics (frequency, percentage, mean, and standard deviation) were used for sociodemographic and clinical data. Domain scores, scaled positively (higher scores indicate better Quality of Life), were calculated as the mean of items within each domain. Quality-of-life scores for patients with malignancy and their caregivers were compared using Analysis of Covariance with post-hoc tests, accounting for group differences in age, sex, marital status, education, and occupation. Statistical tests, including Student's t-test, Chi-square, Mann-Whitney U, Kruskal-Wallis, and Pearson's correlation, analyzed the relationship between sociodemographic/clinical variables and Quality-of-Life scores.

Scoring the WHOQOL-BREF

The four domain scores denote an individual's perception of Quality of Life in each domain. Domain scores are scaled positively (i.e., higher scores denote higher Quality of Life). The mean score of items within each domain is used to calculate the domain score. An SPSS Version 26.0 file that automatically checks and recodes data and computes domain scores is used for the analysis.

Ethical Considerations

The Institutional Ethical Committee, Datta Meghe Institute of Medical Sciences, Nagpur, Maharashtra approved the protocol for the current study with ref. No. DMIMS (DU)/IEC/2010-11/95. Informed consent was taken from all the study participants before data collection. Patients and their primary caregivers retained the right to withdraw consent at any stage that did not harm the treatment. Confidentiality was maintained. No invasive procedures were carried out as a part of the study.

A) Descriptive statistics

Table 1 Age and sex-wise distribution of study participants: -

Age (in years)	**Participants with malignancy (n=190)**			**Primary Care Givers (n=190)**		
	Male	Female	Total	Male	Female	Total
18-27 yrs	6 (6.45%)	7(7.215%)	13(6.84%)	0(0)	2(3.64%)	2(1.05%)
28 – 37yrs	12(12.90%)	21(21.65%)	33(17.37%)	15(11.11%)	9(16.36%)	24(12.63%)
38 – 47yrs	18(19.36%)	26(26.8%)	44(23.16%)	52(38.52%)	26(47.27%)	78(41.05%)
48 – 57yrs	16(17.20%)	18(18.56%)	34(17.9%)	42(31.11%)	18(32.73%)	60(31.58%)
58 – 67yrs	26(27.96%)	18(18.56%)	44(23.16%)	21(15.55%)	0(0)	21(11.06%)
> 68 yrs	15(16.13%)	7(7.215%)	22(11.57%)	5(3.71%)	0(0)	5(2.63%)
Total	93(100%)	97(100%)	190(100%)	135(100%)	55(100%)	190(100%)
Mean Age:	49.31 +-14.54			46.72+-9.46		
Male	93 ± 11.20			135 ± 9.80		
Female	97 ± 15.28			55 ± 11.02		

For age: p = 0.04 *, df = 378, t-value = 2.06; For Sex: p = 0.001 **, df = 1, x ^{2} - value = 19.31

($p < 0.05$ * significant, $p<0.01$ ** highly significant)

As shown in Table no. I, the mean age for patients with malignancy was 49.3 years, which is higher than that for caregivers, which was 46.7. Among caregivers, males 135(71.05%) outnumbered compared to females 55 (28.95%) in contrast to 93(48.95%) males and 97(51.05%) females in the group with patients with malignancy. Both in the patient group and the primary caregiver group, the majority (more than 2/3 rd) belonged to the age group of 28 years to 67 years. The number of cancer patients increased as the age increased for males and females. In the givers group, no such increment or decrement trend was noticed. The number of cancer patients aged 38 to 47 years was 44 compared to the number of caregivers in the corresponding age group, which was 78. That means the ratio of caregivers to patients was nearing 2 1. The difference in age and sex among both groups was significant, with p-values of 0.04 and 0.001, respectively.

Table 2 Distribution of study participants according to religion.

Religion	**Participants with malignancy (n=190)**		**Primary Care Givers (n=190)**		**Total**
	Number	Percentage	Number	Percentage	
Hindu	181	95.26%	182	95.79%	363(95.53%)
Muslim	7	3.69%	6	3.16%	13(3.42%)
Buddhist	1	0.525%	1	0.525%	2(0.525%)
Sheikh	1	0.525%	1	0.525%	2(0.525%)
Total	190	100%	190	100	380(100%)

***p* = 0.994, df = 3, x^2 - value = 0.08**

As shown in Table no.2, the predominant religion of patients with malignancy (95.26%) and their caregivers (95.79%) was Hindu, followed by Muslims (3.7% versus 3.16%) respectively.

Table 3 Distribution of study participants according to residential area.

Residential area	**Participants with malignancy (n=190)**		**Primary Care Givers (n=190)**		**Total**
	Number	Percentage	Number	Percentage	
Rural	114	60%	114	60%	228(60%)
Urban	76	40%	76	40%	152(40%)
Total	190	100%	190	100%	380(100%)

***p* = 1.00, df = 1, x^2 - value = 0.00**

*The current study found that in both the patients and primary caregiver groups, 60% belonged to rural areas, compared to 40% in urban areas. Though this hospital caters to rural areas predominantly, 40% of patients belonging to urban areas, as patients from nearby urban areas like Hinganghat, Amravati, Yavatmal, and Pulgaon, come to this hospital (**Table 3**).*

Table 4 Distribution of study participants according to marital status.

Marital Status	Participants with malignancy		Primary Care Givers		Total
	Number	Percentage	Number	Percentage	
Married	156	82.1%	185	97.37%	341(89.74%)
Single	13	6.85%	0	0	13(3.42%)
Widower	13	6.85%	02	01.05%	15(3.95%)
Widow	08	4.2%	03	1.58%	11(2.89%)
Total	190	100%	190	100	380(100%)

***p* = 0.001 **, df = 3, x^2 -value = 25.80 (p<0.01 ** highly significant)**

A fraction of 97.4% of caregivers were married compared to 82.1%in the patient group. This shows that married individuals are more likely to give care to their family members. The percentage of single marital statuses was only 6.85% in the patient group, whereas no single person was in the primary caregiver group (Table 4).

***Table 5** Distribution of study participants according to educational status*

Educational status	Participants with malignancy (n=190)		Primary Care Givers (n=190)		Total
	Number	Percentage	Number	Percentage	
Graduate and above	02	01.05%	01	0.5%	03(0.79%)
Intermediate	06	03.15%	08	04.2%	14(03.68%)
High School	37	19.5%	37	19.5%	74(19.5%)
Middle	26	13.7%	48	25.2%	74(19.5%)
Primary	66	34.7%	71	37.4%	137(36.0%)
Illiterate	53	27.9%	25	13.2%	78(20.53%)
Total	190	100%	190	100%	380(100%)

***p* = 0.04 *, df = 5, x^2 - value = 17.39 (p < 0.05 * significant)**

*Furthermore, it was shown that the educational status of patients with malignancy in descending order were 34.7%, 27.9%, 19.5%, and 13.7% for primary, illiterate, high school, and middle class, respectively. The educational status for the caregiver group in descending order was 37.4%, 25.2%, 19.5%, and 13.2% for primary, middle, high school, and illiterate, respectively. That means a major chunk (more than 95%) of patients and their caregivers did not have education beyond high school (**Table 5**).*

Table 6: - Distribution of study participants according to socioeconomic status

Socioeconomic status of participants according to* modified B.G.	Participants with malignancy (n=190)		Primary Care Givers (n=190)		Total
	Number	Percentage	Number	Percentage	

Prasad's classification					
Class I	03	1.6%	03	1.6%	06(1.6%)
Class II	41	21.6%	42	22.1%	83(21.8%)
Class III	104	54.7%	103	54.2%	207(54.5%)
Class IV	39	20.5%	39	20.5%	78(20.5%)
Class V	03	1.6%	03	1.6%	06(1.6%)
Total	190	100%	190	100%	380(100%)

*A fraction of 90% of patients with malignancy were from the middle class (class II, III, and IV) as that for the giver group. The number of cancer patients in low and high socioeconomic status was equal. Among all, class III had the majority of cancer and caregivers, i.e., more than 50%. Interestingly, the no. of cancers showed an increasing trend with an increase in SES to class III socioeconomic status (**Table 6**).*

Table 7 Distribution of study participants with malignancy according to the site of malignancy

Site of malignancy	**Participants with malignancy (n=190)**	
	Number	Percentage
Breast	50	26.31%
Oral Cavity	48	25.26%
Head and Neck	27	14.21%
Gastro-Intestinal	16	8.42%
Genito-Urinary	15	7.9%
Others	34	17.9%
Total	190	100%

*The majority sites of malignancy were in the Breast (26.31%), followed by the Oral cavity (25.26%) and Head and Neck (14.21%) out of 190 patients with malignancy (**Table 7**). The Gastrointestinal and Genito-urinary malignancies were of almost equal prevalence. The other categories included cancers of the Skin, Eye, and Endocrine glands.*

Table 8 Distribution of study participants with malignancy according to the mode of treatment.

Mode of treatment.	**Participants with malignancy (n=190)**	
	Number	Percentage
Chemotherapy	117	61.58%
Surgery	09	4.74%
Surgery + Chemotherapy	64	33.68%
Total	190	100%

The majority, nearly 62%, were on chemotherapy, followed by 34% on a combination of surgery and chemotherapy, followed by 5% who underwent surgery alone out of 190 patients with malignancy (Table 8).

B) Inferential Statistics

The WHO QUALITY OF LIFE-BREF scale assesses the quality of life in five domains: general well-being domain, physical domain, psychological domain, social domain, and environmental domain. The general well-being domain comprised two item questions. The physical domain contained seven items, the psychological domain contained six items, the social domain contained three items, and the environmental domain contained 8 item questions. We have assessed the Quality of Life across each item and each domain.

Quality of life scores in patients with malignancy

The mean scores on Quality-of-Life domains in patients with malignancy were 3.5, 10.7, 18.3, 19.1, and 20.9 for general well-being, social domains, psychological domains, physical domains, and environmental domains in that order. The lower the score, the more the impairment in the Quality of Life in that domain. The difference between minimum and maximum scores was narrow in all domains except for the environmental domain, indicating the possibility that the extent to which Quality of Life is impaired in all domains is neither too high nor too low (except for the environmental domain). The mean score on items 3, 4, 6, 8, 11, 20, 21, 25, and 26 were above 3, indicating that the Quality of Life in these items was less impaired than "moderate impairment". The mean score on items 1, 2, 5, 12, 16, and 18 were below or equal to 2, which means the Quality of Life was impaired more in these items, worse than or equal to that of "a little well-being". The mean score on item no. 20 was 4, indicating that perhaps the impairment in personal relationships was not affected much.

Quality of life scores in primary caregivers of patients with malignancy

The mean score on quality-of-life domains in patients with malignancy and caregivers was like each other except for items 3 and 4, as well as the physical domain. That means the quality-of-life score in care-givers psychological, social, environmental, and general well-being domains is equally impaired to that of patients with malignancy.

Table 9 scores on various dimensions of who quality of life-bref scale of patients with malignancy and their primary caregivers

Group	Patients with malignancy (n = 190)		Caregivers (n = 190)	
	Mean ± S. D	Range	Mean ± S. D	Range
Physical domain	19.18 ±1.47	**18-21**	24.07±1.80	**12-17**
Psychological	18.37 ± .54	**18-21**	22.37±.64	**17-24**
Social	10.75 ±0.45	**10-12**	14.75±.55	**11-13**
Environmental	20.91±3.47	**17-25**	25.91±4.23	**18-26**
General well being	3.55±.83	**2-5**	5.55±1.83	**3-6**

Table 10: Comparison of WHO QOL-BREF Scores among cancer patients by treatment modality

Items	Chi-Square	df	Asymp. Sig.
Physical domain	31.677	2	<.001**
Psychological	126.485	2	<.001**
Social	42.897	2	<.001**
Environmental	83.723	2	<.001**
General wellbeing	31.458	2	<.001**

(*p*<0.01 ** highly significant)

If we compare the Quality of Life between patients with malignancy who are taking different modalities of treatment, then each group differed highly significantly (p < 0.001) from each other in all domains and all items except for items 3, 4, and 5, 16, 18, 20 and 22. That means the type of treatment the patient receives is an important point in terms of cancer patients' quality of life. When the group that received a combination (surgery plus chemotherapy) was compared with the group that underwent surgery, the difference in Quality of Life was highly significant except for items 3, 4, 5, 20, and 21. No significant difference in quality of life was noticed when the group undergoing chemotherapy was compared with the group that underwent surgery alone.

Type of cancer and quality of life:

The Quality of Life in types of cancer category (breast cancer, oral cancer group, head and neck cancer group, others) differed from each other significantly on various domains of Quality of Life when compared to each other as below:

a) *Breast cancer people had a better Quality of Life than the oral cancer group in all domains of Quality of Life except in the social domain. The difference is significant with p-value of 0.01, 0.02, 0.01, and 0.01 for physical, psychological, environmental, and general well-being domains*
b) *A similar significant difference in Quality of Life in similar domains was observed so far as the comparison of oral cancer and head & neck cancer was concerned with a p-value ranging from .01 to .001 except for the social dimension*
c) *Breast cancer had more impaired Quality of Life than other categories of cancer significantly in all domains of Quality of Life except in the psychological domain (p values as mentioned in table)*
d) *Compared to other categories, The category of oral cancers had poor Quality of Life in all domains except in the psychological domain, which is poor for another category. All differences were significant, with p-values of .001 for all differences*
e) *In contrast, the comparison between permutation and combination of other possible groups did not show any significant differences in any domain of quality of life.*

Table 11: -Correlation between different dimensions of quality of life

Group		Physical domain	Psychological	social	environmental	General wellbeing
Patients with malignancy	**Physical domain**	1.000	-.541(**)	.486(**)	.900(**)	.949(**)
	Psychological	-.541(**)	1.000	.464(**)	-.847(**)	-.534(**)
	Social	.486(**)	.464(**)	1.000	.057	.433(**)
	Environmental	.900(**)	-.847(**)	.057	1.000	.869(**)
	General wellbeing	.949(**)	-.534(**)	.433(**)	.869(**)	1.000
Primary caregiver	**Physical domain**	1.000	-.449(**)	.451(**)	.781(**)	.842(**)
	Psychological	-.449(**)	1.000	.464(**)	-.847(**)	-.534(**)
	Social	.451(**)	.464(**)	1.000	.057	.433(**)
	Environmental	.781(**)	-.847(**)	.057	1.000	.869(**)
	General wellbeing	.842(**)	-.534(**)	.433(**)	.869(**)	1.000

(*p*<0.01 ** highly significant); - value indicates negative correlation, + value indicates positive correlation

In patients with malignancy, the Quality-of-Life score in the social and general well-being domains correlated positively with the score in the physical domain and negatively with the psychological domain. The score on the psychological domain correlated negatively with the physical domain, environmental dimension, and general well-being. However, the Quality-of-Life score on the social dimension correlated positively with physical and psychological dimensions and general well-being. Quality of life in general well-being was correlated positively with all other domains except for the psychological domain, which was negatively correlated. These correlations mentioned above were significant. The correlation coefficient is noted in **Table 11**. A similar trend in correlation between different domains of Quality of Life was observed in caregivers, too.

DISCUSSION

Very few studies have been done on the Quality of Life of the caregivers of cancer patients, and only two of them systematically investigated and compared the Quality of Life in cancer patients and their principal caregivers in a hospital setting (Grunfeld et al. 2004; Ioannis et al. 2012).

The present study assessed Quality of Life in patients with malignancy and their primary caregivers. To meet this, patients who are above 18 years of age with a confirmed diagnosis of malignancy admitted under Oral Surgery Department of Sharad Pawar Dental College and Surgery, ENT, Obstetrics and Gynaecology, Skin, Orthopaedics, Pulmonary Medicine and Medicine Departments of Acharya Vinoba Bhave Rural Hospital in Wardha district of Nagpur division of central India for one year and accompanied by their primary caregiver were included as cases or patients with malignancy. During this period, 325 patients were diagnosed to have cancer. Out of these, 52 patients were not accompanied by their primary caregivers.14 patients were less than 18 years of age.68 patients were multiple visitors to the hospital for chemotherapy cycles. One patient admitted to the ICU could not consent to the study. So, a total of 190 cases, i.e., patients with a confirmed diagnosis of malignancy and who fulfilled the inclusion criteria, were identified during this period. Similarly, 190 primary caregivers of the respective cases were assessed.

Socio-demographic characteristics of Study Participants:

The mean age for patients with malignancy was 49.3 years, which is higher than that for caregivers, which was 46.7. Among caregivers, males 135 (71.05%) outnumbered compared to females 55(48.95%) in contrast to 93(48.95%) males and 97(51.05%) females in the group with patients with malignancy. Both in the patient group and the primary caregiver group, the majority (more than 2/3 rd) belonged to the age group of 28 years to 67 years. The number of cancer patients increased as the age increased for males and females. In the givers group, no such increment or decrement trend was noticed. The number of cancer patients aged 38 to 47 years was 44 compared to the number of caregivers in the corresponding age group, which was 78. That means the ratio of caregivers to patients was nearing 2:1. The difference in age and sex among both groups was significant, with p-values of 0.04 and 0.001, respectively. These findings align with; however, the other study has a contrast finding (Grunfeld et al. 2004); Ioannis Vrettos et al. **2012**).

According to residential areas, 60% were from rural areas. This may be because the sample was taken from a rural hospital. This makes the study unique because, to our knowledge, no study from India has compared cancer patients and caregivers so far as Quality of Life is concerned.

The predominant religion of patients with malignancy (95.26%) and their caregivers (95.79%) were Hindu, followed by Muslims (3.7% versus 3.16%) respectively.

According to marital status, 97.4% of caregivers were married compared to 82.1% of patients in the group. This shows that maybe married individuals are more likely to give care to their family members. The percentage in the single marital status was only 6.8%. This means that single people either do not come for treatment or there is no one to bring them to the hospital. This can be explained by the fact that in India, particularly in rural culture, the emotional bond, family structure, and function are intimately related, where one depends on the other for emotional reasons and day-to-day needs. Whereas in the West, too much independence, broken families, and the preponderance of social service NGOs are the reasons not to have a married family member as a primary caregiver.

In descending order, the educational status of patients with malignancy was 34.7%, 27.9%, 19.5%, and 13.7% for primary, illiterate, high school, and middle class, respectively. The educational status for the caregiver group in descending order was 37.4%, 25.2%, 19.5%, and 13.2% for primary, middle, high school, and illiterate, respectively. That means a major chunk (more than 95%) of patients and their caregivers did not have education beyond high school.

In the present study, according to the subjective state of health recorded, male and lower education caregivers had higher Quality of Life scores. Interestingly, married caregivers had lower quality of life scores than single ones, contrasting with the general population's observations. This can be explained by the fact that the higher proportion of caregivers in the current study were spouses of the patients *with whom they were living in the same house and caring for them. According to another study, being a partner of the care recipient, as compared to other caregivers, is associated with experiencing more strain, potentially becoming ill, and experiencing higher levels of psychiatric symptoms. This may be an alternative explanation applicable to our sample, too (Nijboer et al.1998).*

Homemakers and farmers constituted nearly 70% and 55% of patients with malignancy and caregiver groups, respectively. Contrary to the expectation, homemakers as caregivers were almost half of that in the patient group.

More than 90% of patients with malignancy were from class III as the caregiver group. The number of cancer patients in class I and class V was equal. Among all, class III had the majority of cancer and caregivers, i.e., more than 50%. Interestingly, the number of cancers showed an increase in trend with an increase in socioeconomic status till class III.

The mean rank for Quality-of-Life scores in increasing order were 58, 93, 94, 102, and 121 for classes I, III, IV, II, and V for patients with malignancy along the physical domain. For the psychological domain, figures were 88, 92, 102, 104, and 124 for classes III, V, IV, II, and I, respectively. The social domain rank was 87.37, 87.67, 102, 108, and 119 for classes III, IV, II, and V, respectively. For the environmental domain, the scores were 52, 90, 96, 98, and 113 for classes I, IV, II, III, and V, respectively. The higher the rank, the better the Quality of Life. Though there was a difference in Quality of Life among different social classes, the difference was not significant amongst each other except for social domain for social class I and III ($p < 0.004$) (impaired Quality of Life in the patient group compared to primary caregiver group, mean rank 87.67, 87.97, 102.13, 106.69 and 119 for social class I, III, IV, II and V respectively). However, a comparison between class I and II revealed a worse Quality of Life in class I caregivers than in patients with malignancy; the reverse for class II concerns the physical domain. And this difference was statistically significant ($p < 0.028$). Other domain comparisons between classes one and II were insignificant between caregiver and patient groups. When Quality of Life is compared between classes I and IV, class I had worse Quality of Life than class IV along the physical domain but not in any other domain. And this difference was significant ($p<0.039$). Other intra-social class/domains and inter-social class/domains were not significant.

Clinical Correlates of Study Participants:

According to the site of malignancy, out of 190 patients with malignancy, the majority of sites of malignancy were Breast (26.31%), followed by the Oral cavity (25.26%) and Head and Neck (14.21%). The Gastrointestinal and Genito-urinary malignancies were of almost equal prevalence. The Others category included cancer of the Skin, Eye, and Endocrine glands. This value is in line with the recent statistics from a survey funded by WHO conducted in all the districts of India in 2005, which suggested Wardha district has the highest incidence of oral cancer in the world.

*According to the mode of treatment, out of 190 patients with malignancy, the majority, nearing 62%, were on chemotherapy, followed by 34% on a combination of surgery and chemotherapy, followed by 5% who underwent surgery alone. When Quality of Life was assessed, it was more impaired in the group who were on combination therapy, i.e., Surgery + Chemotherapy in comparison to Surgery or Chemotherapy alone, which is in contrast to the study previous study (**Ganz et al. in 2004**). If in the present study we compare the Quality of Life between patients with malignancy who are taking different modalities of treatment, then, each group differed highly significantly ($p < 0.001$) from each other in all domains and all items except for item 3, 4, 5, 16, 18, 20 and 22. That means the type of treatment the patient receives is an essential factor in the Quality of Life of cancer patients. When the group that received combination therapy (surgery plus chemotherapy) was compared with the group that underwent surgery, the difference in Quality of Life was highly significant except for items 3, 4, 5, 20, and 21. No significant difference in quality of life was noticed when the group undergoing chemotherapy was compared with the group that underwent surgery alone.*

Domains of Quality of Life and its Comparison:

The mean scores on Quality-of-Life domains in patients with malignancy were 3.5, 10.7, 18.3, 19.1, and 20.9 for general well-being, social domain, psychological domain, physical domain, and environmental domain in that order. The lower the score, the more the impairment in the Quality of Life in that domain. The difference between minimum and maximum scores was narrow in all domains except for the environmental domain, indicating the possibility that the extent to which Quality of Life is impaired in all domains is neither too high nor too low (except for the environmental domain). The mean score on items 3, 4, 6, 8, 11, 20, 21, 25, and 26 were above 3, indicating that the Quality of Life in these items was less impaired than "moderate impairment". The mean score on items 1, 2, 5, 12, 16, and 18 were below or equal to 2, which means the Quality of Life was impaired more in these items, worse than or equal to that of "a little well-being." The mean score on item no. 20 was 4, indicating that perhaps the impairment in personal relationships was not affected much.

The study revealed significant differences in sociodemographic characteristics, treatment modalities, and Quality-of-Life (QOL) scores among participants with malignancy and their primary caregivers. Most participants were middle-aged, with a mean age of 49.31 years for patients and 46.72 years for caregivers. Male caregivers predominated, while patients showed a balanced gender distribution. Most participants belonged to rural areas, were married, and adhered to Hinduism. Educational and socioeconomic profiles showed limited higher education, with most participants in middle or lower socioeconomic classes. These findings align with previous studies, which highlight the challenges faced by rural caregivers in managing the burden of care, and the other one which documented similar demographic trends in cancer patients (Kulkarni et al. 202; Dahar et al. 2024).

QOL scores demonstrated significant differences between patients and caregivers across physical, psychological, social, and environmental domains, with caregivers generally reporting higher scores. Patients undergoing combined surgery and chemotherapy had better QOL scores than those receiving only chemotherapy or surgery, consistent with the previous findings (Khazi et al. 2024). Correlation analyses revealed inter-domain relationships, emphasizing the multidimensional impact of cancer on QOL. Similar patterns were observed in a couple of studies which has underscored role of sociodemographic and clinical factors in shaping QOL outcomes (Islam et al. 2023; Qadir et al. 2024). These results highlight the need for targeted interventions to address the specific challenges patients and caregivers face in rural settings.

The study highlights significant disparities in QOL between patients with malignancy and their primary caregivers, influenced by sociodemographic and clinical factors. Caregivers reported higher QOL scores across all domains, reflecting their adaptive resilience despite the burden of care. Patients undergoing combined treatment modalities exhibited better QOL, emphasizing the benefits of comprehensive care approaches. The findings underscore the need for tailored interventions to improve QOL for patients and caregivers, particularly in rural settings, aligning with evidence from similar regional studies. Addressing the multifaceted challenges faced by these groups remains critical to enhancing their overall well-being.

LIMITATIONS

There is a limitation associated with the WHOQOL-BREF itself. Quality of Life measurement in cancer patients is usually assessed using cancer-specific instruments that are likely to be more responsive than generic instruments. However, in this case, a disease-specific instrument would not have allowed us to compare two different populations, like cancer patients and their caregivers. The present study included Primary Caregivers who provided palliative care but not to the sickest ones in the terminal phase. There is also a risk of selection bias towards pairs of Primary caregivers and patients with close attachment and high commitment. The cross-sectional design precludes the interpretation of any causal relationship but enables some hypotheses about gender differences.

CONCLUISON

Cancer is characterized as a chronic disease with considerable, continuing, and fluctuating specific needs and problems for patients as well as their caregivers. Contextual factors, personal characteristics, and perceptions related to caregiver health outcomes. Specific types of care may lead to health outcomes. Patient care and support may be expected to be burdensome and lead to a more substantial negative effect on the caregiver's health. However, because people may have an increased risk for poor health, this does not mean they cannot experience positive health outcomes.

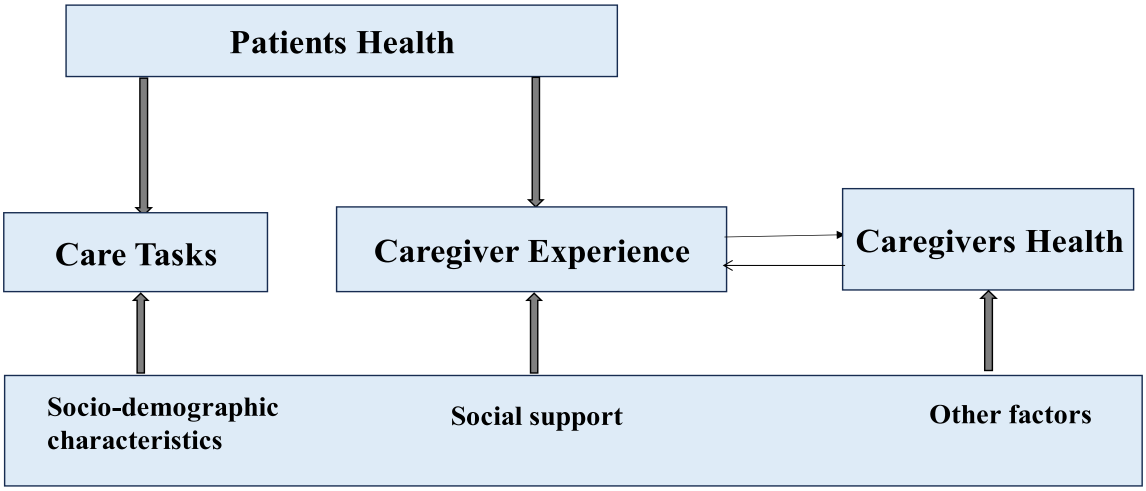
The present study attempts to understand the complicated interaction between cancer patients undergoing treatment and their primary caregivers regarding their Quality of Life.

This study has shown that the Quality of Life of patients with malignancy and primary caregivers is impaired, but the difference is insignificant. The intra- and inter-individual differences exist concerning circumstances, events, resources, and health outcomes. Also, positive and negative care experiences and health outcomes may coexist, but not necessarily at the same moment. Moreover, these experiences and circumstances will likely shift throughout the day and during caregiving. Informal caregivers need to be recognized as equivalent healthcare team members.

We conclude by saying that body and mind are married to each other, and when one suffers, the other sympathizes.

Recommendations

In modern medicine, the evaluation of a patient’s health problem is based not only on clinical or laboratory markers but also on a holistic approach of the patient that includes the evaluation of the *consequences of diagnosis or therapy of the health condition. Interventions that can improve the Quality of Life, especially in the domain of mental health, of both cancer patients and caregivers should be recommended. Further research should study larger samples and try to improve the participation rate of patients to avoid biases. Healthcare personnel should be observant of the emotional problems of Primary Caregivers caring for patients with cancer. Strategies to support caregivers would reduce caregiver burden, potentially prevent psychosocial distress, and allow caregivers to focus on their most immediate concern, caring for the dying patient. The home care needs of cancer patients receiving chemotherapy caregivers must be emphasized and reemphasized, and their Quality-of-Life scores must be evaluated periodically. There is a need for role allocation for different family members to take a specific role and responsibility in a family where one family member is suffering from cancer. This will help reduce the burden and improve the quality of life of caregivers, which might affect the patient positively (they need assistance for one or more daily living activities). Universalizing home care programs as a policy can reduce the burden on caregivers and the overall outcome for patients. The aim of the oncologist should be not only to treat the disease but to increase the Quality of Life of the patient and caregiver. Longitudinal studies that carefully follow patients and caregivers throughout the illness can shed light on the effects of long-term caregiving. We propose a conceptual model for intervention in rural areas. This model can be implemented at three levels: 1. At tertiary care, rural hospitals like ours need to be implemented by a multidisciplinary team of oncologists, psychiatrists, and social workers; 2. At the community level under the leadership of the Department of Community Medicine, 3. Integrating such services with primary health centers and health workers.*



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