ASSESSING QUALITY OF LIFE THROUGH PATIENT REPORTED OUTCOME MEASURES AMONG CHEMOTHERAPY PATIENTS AT BMCHRC - A PILOT STUDY

Submitted By

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Introduction

A variety of conditions that can affect any part of the body are included under the umbrella term "cancer," which is a broad concept. Cancer is the main cause of mortality in the world, with approximately 10 million fatalities expected by 2020. Every year, 400,000 or more kids are getting diagnosed with cancer. The number of cancer patients in India is expected to rise to 29.8 million in 2025. According to the National Cancer Registry Program statistics, over 13 lakh individuals in India are diagnosed with cancer each year. The surge is attributed to sedentary lifestyles, increased urban pollution, obesity, tobacco, and alcohol usage, among other factors.

Quality of Life, for long, has been a concerning issue in oncology, particularly for those with a specific type of cancer. Cancer patients own reporting of their quality of life can be important in predicting the outcome of their disease, say researchers from the EORTC. Patient-reported outcomes have

Patient Reported Outcome Measures (PROMs)

PROMs are self-report instruments, like patient-reported experience measures (PREMs) that evaluate experience and satisfaction with care. Information is taken directly from the patient without interpretation by a physician or anyone else. In India, there are currently no noteworthy patient-centered outcome researches (PCORs).

- PROMs supplement existing data on the quality of treatment and services offered by providing insight into the effectiveness of care from the perspective of patients. Patient-reported outcomes are critical for determining whether health-care interventions and procedures improve patients' health and quality of life.
- PROMs aid in the enhancement of service delivery by allowing for the evaluation of service effectiveness, the identification of patients who would benefit from interventions, and the exchange of best practices.
- PROMS can be used to evaluate the performance and effectiveness of care, allowing for a potential transition in health care resources planning from a volume-based to a value-based paradigm.

European Organization for Research and Treatment of Cancer

- The European Organization for Research and Treatment of Cancer (EORTC) is an international non-profit institution that was created in 1962.
- There are numerous PROMs instruments available amongst which the EORTC QLQ-C30 version 3.0 is the most widely used tool for assessing QoL in cancer patients.
- It is a collection of 30 self-reported questions that assess various aspects of patient functionality, overall health, and cancer-related symptoms. It consists of five multi-item functional scales (role, physical, cognitive, emotional, and social functioning), three multi-item symptom scales (fatigue, pain, and nausea and vomiting), individual items related to common cancer symptoms (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties), and two questions assessing overall QoL.
- All multi-item scales and single-item measures have a score range of 0 to 100, with a greater score indicating a higher level of response.

Research Question

What are the Patient Reported Outcomes in patients undergoing chemotherapy in the day care of Bhagwan Mahaveer Cancer Hospital and Research Centre?

Objectives

Broad Objective: To study the Patient Reported Outcome in Cancer patients undergoing chemotherapy in the day care of the hospital.

Specific Objective:

- To examine the association of the Health-Related Quality of Life with the socio-demographic characteristics, cycle of chemotherapy etc.
- To evaluate research methods, including protocols, data gathering tools, sample recruitment techniques, and others.
- To assist in implementing of the process of PROM in the hospital as recommended by NABH (5^{th} edition).

Research Rationale

Patients share their experiences using PREMs, such as satisfaction scales, which provide insight into their experience with their health care service that already exists in the BMCHRC. PROMs can be applied and used to inform clinical practices, health services programming, planning, and policies, performance measurement, comparative effectiveness analysis, and quality improvement activities at the hospital as a result of this research.

Methodology

Study Design: Descriptive Cross-sectional

Study Location: Day care at BMCHRC

Sample Size: 250

Sampling Technique: Random Stratified

Study Duration: April and May 2022

Study Tools: Semi–Structured Questionnaire (EORTC – QLQ -C30 version 3.0

Statistical Analysis: M.S. Excel and IBM SPSS (version 28.0.1.1)

Inclusion and Exclusion Criteria

Inclusion Criteria:

1. Patients undergoing chemotherapy at the day care ward.
2. Participants aged more than 18 and less than 65.

Exclusion Criteria:

1. Those receiving chemotherapy for the first time.
2. Patients unwilling to be a part of the survey.
3. Patients unable to speak (due to mouth cancer and similar reasons).
4. Patients who were under palliative or supportive care were also not a part of the study.

Ethics Approval & Consent to participate

Prior to data collection an ethical approval was obtained from the hospital (Medical Superintendent and Quality Department). Informed consent was taken from each study participants and the purpose of the study was fully clarified.
Appropriate measures were stated to ensure data security, privacy, and confidentiality.

Scoring Method

Data were entered in Microsoft Excel and checked for consistency and completeness. For Data analysis designated formula of EORTC QLQ-C30 were used (reference). For data analysis, IBM SPSS (version 28.0.1.1) statistical package software was used. We have performed descriptive statistics based on objective. Scoring was done after transferring the data collected through google forms into MS Excel and then using the following formulas:

Table 1: Scoring the QLQ-C30 version 3.0

	Scale	Number of items	Item range*	**Version 3.0** Item numbers	Function scales
Global health status / QoL					
Global health status/QoL (revised)†	QL2	2	6	29, 30	
Functional scales					
Physical functioning (revised)†	PF2	5	3	1 to 5	F
Role functioning (revised)†	RF2	2	3	6, 7	F
Emotional functioning	EF	4	3	21 to 24	F
Cognitive functioning	CF	2	3	20, 25	F
Social functioning	SF	2	3	26, 27	F
Symptom scales / items					
Fatigue	FA	3	3	10, 12, 18	
Nausea and vomiting	NV	2	3	14, 15	
Pain	PA	2	3	9, 19	
Dyspnoea	DY	1	3	8	
Insomnia	SL	1	3	11	
Appetite loss	AP	1	3	13	
Constipation	CO	1	3	16	
Diarrhoea	DI	1	3	17	
Financial difficulties	FI	1	3	28	

* *Item range* is the difference between the possible maximum and the minimum response to individual items; most items take values from 1 to 4, giving *range* = 3.
† (revised) scales are those that have been changed since version 1.0, and their short names are indicated in this manual by a suffix "2" – for example, PF2.

For all scales, the *RawScore*, *RS*, is the mean of the component items:

$$RawScore = RS = (I_1 + I_2 + ... + I_n)/n$$

Then for **Functional scales**:

$$Score = \left\{1 - \frac{(RS-1)}{range}\right\} \times 100$$

and for **Symptom scales / items** and **Global health status / QoL:**

$$Score = \{(RS-1)/range\} \times 100$$

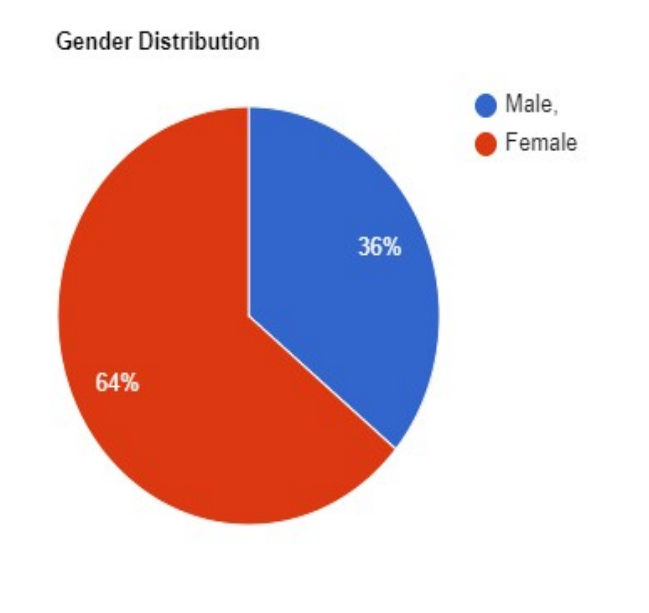
Literature Review

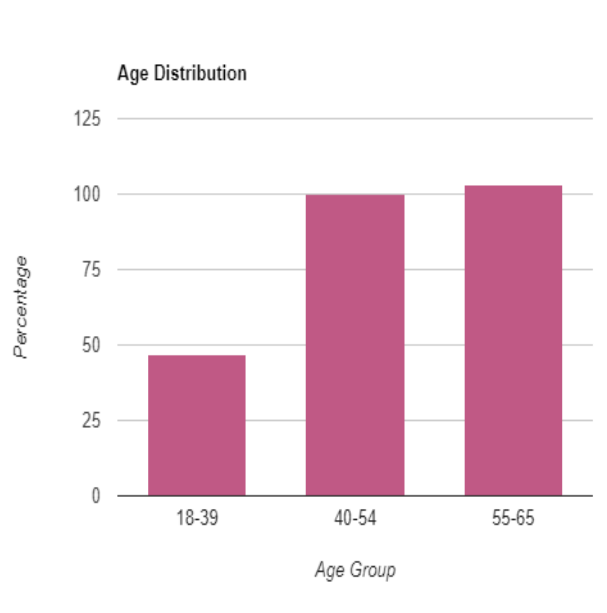
Health Related Quality of Life of Cancer Patients in Ethiopia	“Tadesse Melaku Abegaz et al. (2018) studied 150 cancer patients at the University of Gondar in Ethiopia. From January 1 to August 30, 2017, a prospective hospital-based cross-sectional study was created with the objective of assessing the health-related quality of life (HRQoL) of Cancer patients in Ethiopia. (SPSS) version 20 was used to compile all of the statistical data.”	“Emotional and cognitive functions were among the highest functional status scores that remained generally unaltered, according to the study. On the symptom scale, nausea and vomiting were by far the most frequent co mpliance, followed by fatigue. Another finding on this study indicated that surgery showed a positive impact on the global health status of patients since it could bring a radical cure of the diseases if it is followed by adequate adjuvant therapy. Health related quality of life of cancer patients was found to be low in Ethiopia.”
Quality of Life of Cancer Patients Treated with Chemotherapy	In the years 2018–2020, authors Anna Lewandowska et al. (2020) conducted a population-based, multi-area cross-sectional study among patients of the Podkarpackie Oncology Centre, Clinical Provincial Hospital in Rzeszów, with the goal of evaluating cancer patients' quality of life during oncological chemotherapy treatment. Prism 4.0 software was used to collect and analyse all of the data from the 800 patients in the trial.	The findings of this study revealed that there was no correlation between the age, gender, social status, marriage, or employment and quality of life. There was an association observed between the severity of the disease and the quality of life. The patients reported the most significant problems with self-care and feeling anxious and depressed, according to the EQ-5D-5L profile, quality of life, and psychometric properties.
Quality of Life in Cancer Patients undergoing Chemotherapy	Ali Dehkordi, M. Saeed Heydarnejad, and Daryoush Fatehi performed a study with the objective of describing the quality of life in solid tumour cancer patients during various chemotherapy cycles. The trial, which took place in a Tehran hospital, involved 200 cancer patients. The EORTC QLQ-C30 was modified and used to assess QoL in the student patients.	There was no link between QoL and characteristics including age, sex, marital status, disease duration, economic conditions, or occupational function. Furthermore, no link was discovered between QoL and the educational level of the patients. Nonetheless, there was a substantial difference in QoL between patients who had 2 Chemotherapy cycles and those who had 3-5 CT cycles. This study demonstrates that encouraging cancer patients to complete a CT course has a significant impact on treatment outcomes and quality of life in CT

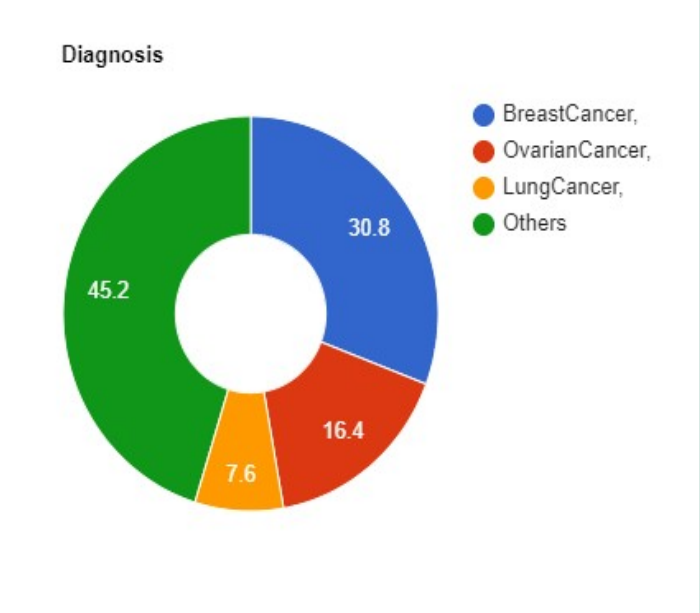
Quality of life in cancer patients undergoing chemotherapy in a tertiary care centre in Malwa region of Punjab	Harminder Singh et al. (2014) used the EORTC QOL- C30 questionnaire in a prospective, non-interventional, observational study at a tertiary care centre in Punjab to assess QOL and physical/ psychological stress among 131 cancer patients during their chemotherapy sessions. Analysis of variance (ANOVA) was used to compare the different groups.	It was discovered that GHS and four symptoms, including insomnia, pain, lack of appetite, and financial problems, were statistically significant. They also found that as the chemotherapy session went, the patients' quality of life increased dramatically.
Symptom burden and quality of life in advanced head and neck cancer patients: AIIMS study of 100 patients	Ajeet Kumar Gandhi et al. (2014) used the EORTC-HN35 and EORTC QOL- C15- PAL questionnaires to assess the symptom burden and QOL among advance incurable Head and Neck Cancer patients who were administered palliative radiations in an observational research on 100 advanced HNCa patients.	Insomnia, loss of appetite, pain and fatigue were determined to be the top four most prevalent symptoms. Physical functioning was found to be impaired by 23%, while emotional functioning and QOL were shown to be affected by 50%.
Patient-reported outcomes of	Adam W Glaser et al. (2013) conducted a study with the aim of determining the practicability of gathering population-based patient-reported	The study found that this way of assessing cancer survivors' quality of life is possible and acceptable to the majority of survivors. Systematic collection of nationwide population-based PROMs will allow for the

Results

- To calculate global QOL, the tool's items are scored in both directions. 28 of the 30 items were on a Likert 4-point scale while, the final two items were all on a seven-point semantic scale. The overall tool's Quality of Life score ranged from 100 to 33, with a maximum of 100 and a minimum of 33. . It consists of five multi-item functional scales (role, physical, cognitive, emotional, and social functioning), three multi-item symptom scales (fatigue, pain, and nausea and vomiting), individual items related to common cancer symptoms (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties), and two questions assessing overall QoL.
- The study confirms the statistics of the WHO which states that the most common cause of cancer in females were of breast cancer and men were most affected by lung cancer.

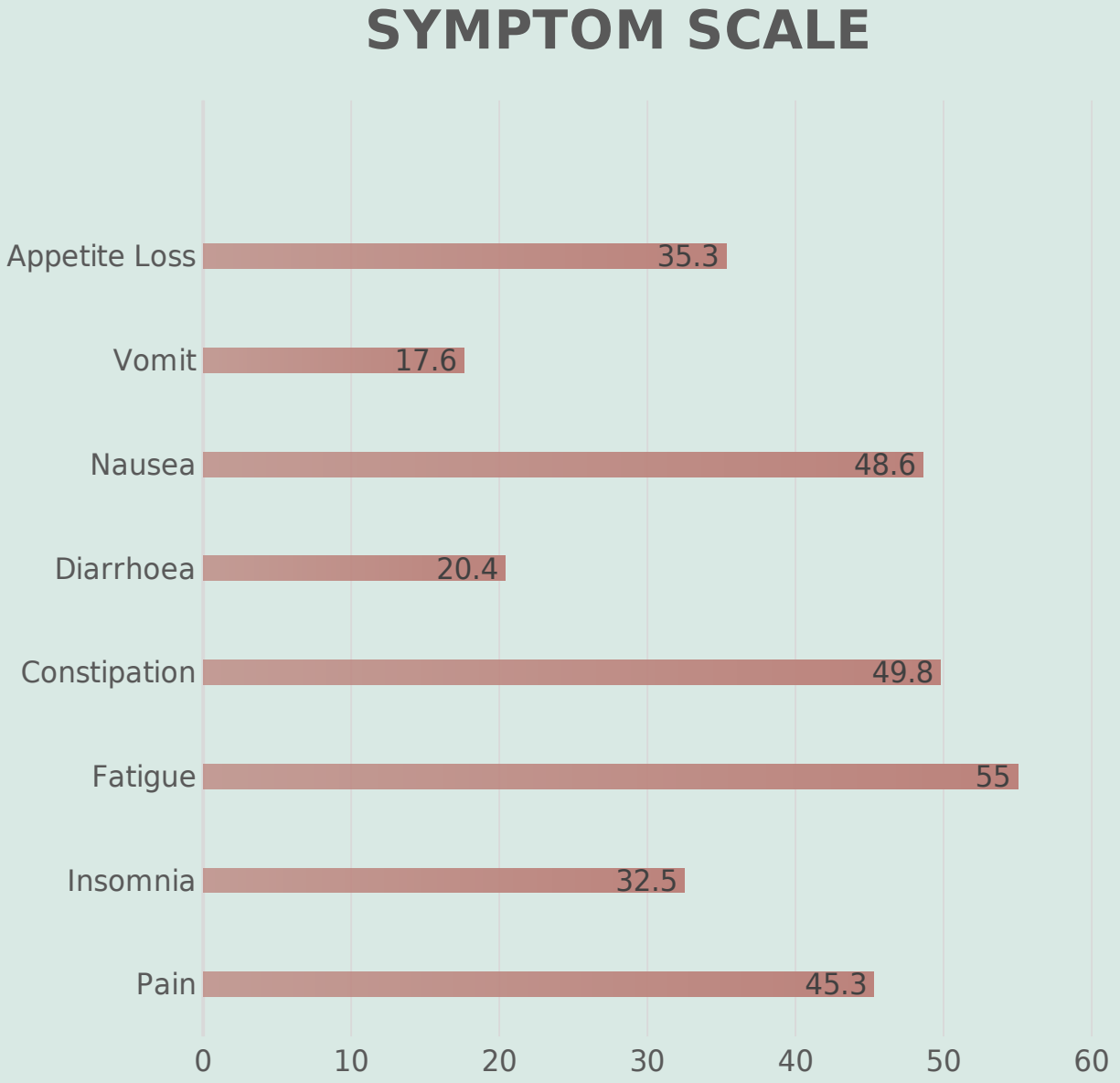






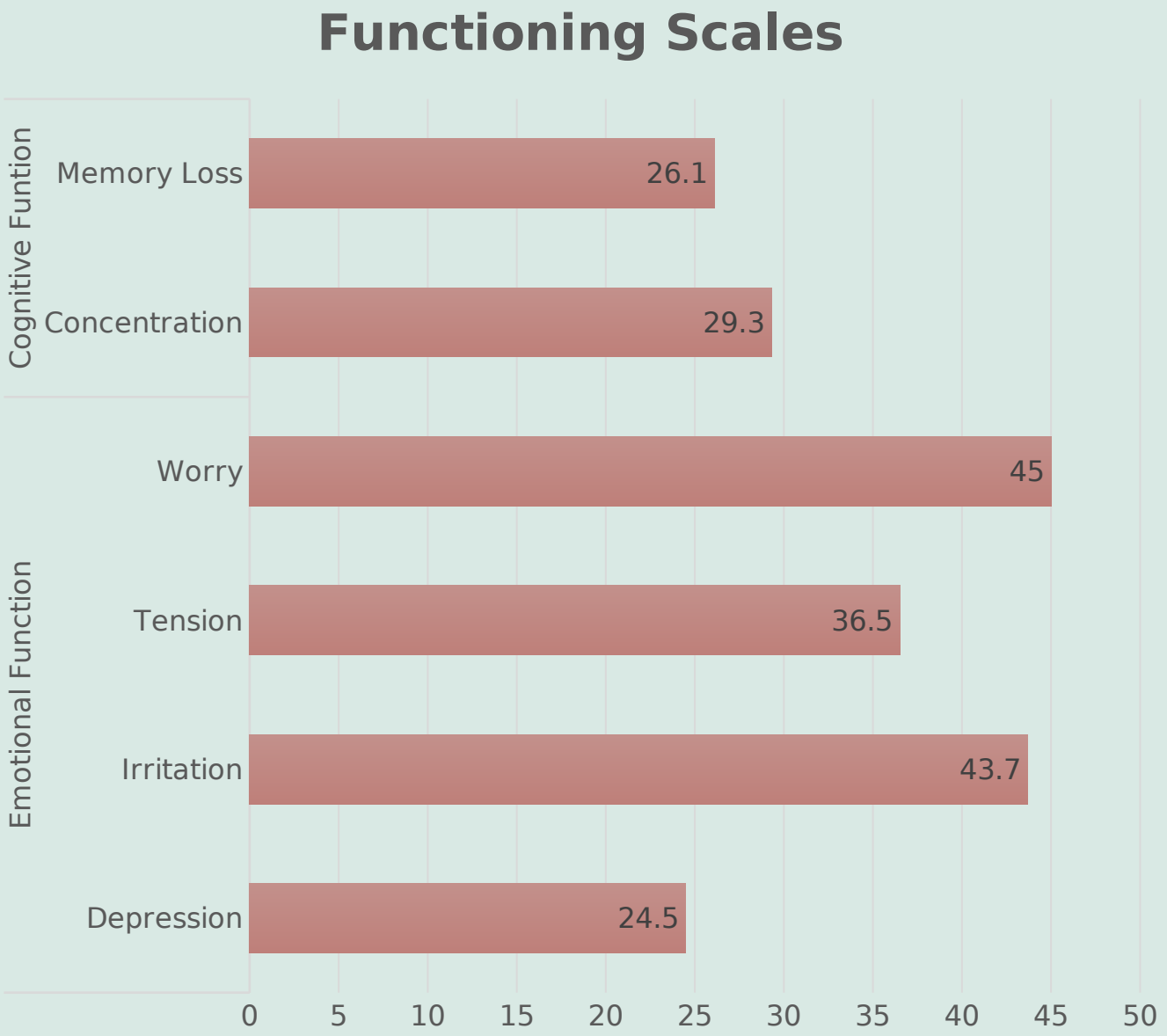
The top 4 symptoms in decreasing order of frequency in our cohort of patients are fatigue, constipation, pain, and nausea.

The mean GHS score was 71.08 indicating a decent health status among respondents. Among the 29 patients that rated 3 or 4 on the scale on their financial difficulties around 20 respondents belonged to cash category, and all 20 patients showed a GHS below the mean GHS suggesting that financial burden of the treatment



On the emotional scale, it was observed that the psychological well-being was affected by feeling very much depressed among 24.5% of the participants, and 43.7% felt they were irritable most of the time during the treatment. While receiving chemotherapy, 36.5% patients reported feeling tense and 45% reported feeling worried.

In relation to the cognitive well-being, 26.1% felt they were having difficulty in remembering things while 29.3% found it difficult to concentrate on things



- The total score of Quality of Life was categorized into four: Above 90 - very high QOL, 71–90 - high QOL, 41–70 - average QOL and 0 - 40 low QOL. The higher score indicates better QOL among the cancer patients .
- Table shows that among 250 cancer patients, 123 (49.4%) (121 + 2 = 123) were in the category of below average QOL score. While 110(16%) had a high QOL score, very few, i.e., 16 (6.4%), had very high QOL score. The overall mean QOL score was 71.08 ± 12.25.
- The study conducted by Anice George *et al*. also found that the overall mean QOL score of the study population was 105.32 ± 12.93 and similar findings also were observed in the current study.

Categories	Score	Frequency (%)	Mean±SD
Low	Below 40	2(0.8%)	71.08±12.25
Average	41-70	121(48.6%)	
High	71-90	110(16%)	
Very High	Above 90	16(6.4%)	

There was no correlation between the QoL and variables such as age, sex and payment category of patients.

The relationship between QoL and the number of CT cycles is demonstrated in the table. As shown, majority (53.2%) of the patients had fairly favorable QoL. A strong correlation was found between QoL and number of CT cycles. Most of the patients (61.2%) who had completed 3 or more cycles of CT reported a fairly favorable or favorable level of QoL. This may indicate that the CT procedure used in cancer treatment is directly associated to QoL.

	Quality of life			
Number of CT cycles	Non-favourable	Fairly Favourable	Favourable	Sum
3≤	20(27.02%)	37(50%)	17(22.9%)	74
4-5	8(12%)	44(65.7%)	15(22.4%)	67
6-10	8(11.7%)	31(45.6%)	30(42.2%)	69
≤10	7(17.5%)	21(52.5%)	12(30%)	40
Total	43(17.2%)	133(53.2%)	74(29.6%)	n=250

Discussion

Most of the questions were clearly understood and easy to answer during pilot testing of the validated sections of the generic electronic PROM. Nevertheless, feedback indicated that several enhancements and modifications were needed to implement the survey in the hospital, particularly regarding the following:

- The language barrier was one of the prime hurdles during the survey. For the survey to be filled by the patients themselves, it needs to be translated in the language most prevalent and understood by the majority in the hospital i.e., Hindi.
- The EORTC QLQ-C30 features several questions on fatigue that might be consolidated into one to make the survey easier for patients to complete.
- Sequencing of the questions can be improved to placing similar questions together.
- The survey must also include a 'Not Applicable' section because some questions do not apply to all patients.
- A remarks section could be advantageous to the survey's aim, as there are a few views expressed by patients that are not inquired about in the survey.

Strengths and Limitations of the Study

STRENGTHS

- The study's strength is its homogeneous patient cohort, which emphasizes practically upon all general symptoms that may be attributed to any type of cancer and so eliminates any bias or heterogeneity in the results.
- The scale, which encompasses the most significant components of inpatient hospital care from the patient's perspective, could be beneficial for evaluating cancer patients' experiences at BMCHRC and in similar settings across the country.

LIMITATIONS

- Because the study was confined to a particular state and BMCHRC was only selected for the study the findings cannot be applied across the country. Also, cancer patients who gave consent were only interviewed.
- It's important not to overlook communication barriers, which are especially prominent in the case of Head and Neck Cancer. Also, most patients come from low socioeconomic backgrounds and have a limited educational background.

Suggestions

- Electronically collecting PROMs may be more cost-effective and deliver more timely information than paper surveys (e.g., provide immediate feedback to clinicians).
- Self-reported PROM surveys can also help respondents feel less burdened as the responses were based on interview could have introduced a bias for patients who may have wished to respond privately.
- The EORTC QLQ – HDC29 can be used for patients undergoing chemotherapy to perceive specific chemotherapy related symptoms and problems. Multiple other disease or treatment specific questionnaire should be developed.
- In-addition, Physicians should pay close attention to prepare the patients for the acute toxicities of therapy as well as how to better deal with fatigue, constipation, pain, and loss of appetite as those were the four symptoms that were primarily observed in our cohort.
- Despite the hospital being recognised by various schemes, several patients were unable to use them and sought advice. They could receive guidance and information about this from the floor coordinators and PREs.

- Patients with significant scores in the cognitive wellbeing should be recommended to a psycho-oncologist.
- A study by Gilbar O *et al.* found significant differences indicating that the degree of adjustment and the psychosocial distress of patients who dropped out of chemotherapy treatment was worse than that of patients who completed treatment. Hence, there should be interventions to improve adherence to chemotherapy regimens.
- The interventions could include communication about the importance of adherence and the potential consequences of nonadherence, simplification of the patient's medication schedule (if possible), and inclusion of a member of the family or caregiver in the discussion. Written documents along with the verbal instructions should always be provided.
- Further research into the explanatory factors of disparities in cancer patients' healthcare experiences is recommended.

Importance of Psycho-Social Counselling

- Many cancer patients have problems in adjusting during the illness trajectory, while at the physical level, cancer and its treatment have evident repercussions for body image, with differences between “visible cancers” such as head and neck cancers as well as breast cancer and “less-visible cancers” such as lung cancer and leukaemia. Several regulatory bodies, such as the International Psycho-Oncology Society (IPOS) Standard on Quality Cancer Care, have mandated the routine assessment and treatment of distress.
- According to one study, only 40.2% of survivors said they had talked to their doctors about how cancer may have affected their emotions or relationships, and more than 90% of the barriers towards using professional counselling or support groups that survivors identified involved lack of knowledge of, or a false impression that, services were unavailable
- There are around 30 tools (Distress Thermometer or the Edmonton Symptom Assessment System), being used in BMCHRC for the screening of patients. However, the screening is limited to patients that are either referred by the doctors to the psycho-oncologist or patients that are routinely screened within the wards. Most of the patients undergoing chemotherapy within the day care wards of the hospital do not benefit from the screenings and are mostly unaware of the availability of the psycho-oncology services available in BMCHRC.

Conclusion

According to this study, cancer patients endure a wide range of symptoms that negatively impact their quality of life and it is necessary to establish methods for effective symptom management and to improve QOL. A quick screening for symptom burden and quality of life in this group of patients using a straightforward and unambiguous questionnaire, as we did in our study, would undoubtedly aid in providing better symptom-directed therapy and fulfilling the sacred objective of palliative care.

Given how poorly the chemotherapy patients performed on the symptom scales, physicians should pay close attention to how to prepare the patients for the acute toxicities of therapy. The findings demand that a psycho-oncology service be extensively used at BMCHRC to address psycho-social outcomes and to foster a better quality of life during and after treatment.

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Thank You