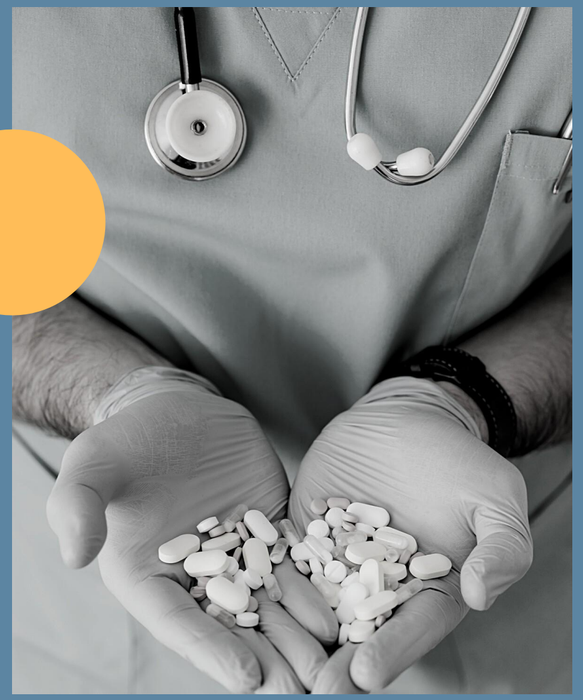

DISSERTATION PRESENTATION

ASSESSING QUALITY OF LIFE AMONG FEMALE CANCER PATIENTS AT BMCHRC THROUGH PATIENT REPORTED OUTCOME MEASURES (PROMS)- A PILOT STUDY

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INTRODUCTION :

• Cancer accounts for 9.6 million deaths in 2018. In 2018, India recorded 1,157,294 cancer cases and 784,821 cancer deaths. The number of cancer patients in India is expected to rise to 29.8 million in 2025.

• In India, a total of 3,71,302 women died of cancer in 2018. Incidence rates begin to grow in the early forties and peak between the ages of 50 and 64. There is a 9.42 percent chance of developing cancer before the age of 75 for women. Breast cancer is the most frequent cancer in Indian women, accounting for 14% of all cancers. It affects one out of every 28 women at some point in their lives.

• The diagnosis of cancer comes with several unpleasant repercussions, particularly for women. The impact of a cancer diagnosis on a patient's quality of life is one of the drawbacks. Patients with cancer experience a wide range of symptoms. Cancer-related morbidity is also believed to be very high. Hence input from patients is useful for clinical research as well as for determining the influence of a specific treatment on a patient's quality of life.

• Patient-reported outcome measures are critical for determining whether healthcare interventions and procedures improve patients' health and quality of life. It can be used to manage health services, improve quality, and monitor performance. A coordinated approach to PROM's data-collecting could provide enormous potential benefits. Given the variety of potential uses for PROMs data, a coordinated approach to PROMs data collecting, which would make this information available to doctors, health system administrators, policymakers, researchers, and the public, could provide enormous potential benefits.

LITERATURE REVIEW :

• Ali Dehkordi, M. Saeed Heydarnejad, and Daryoush Fatehi (2009) conducted a study to describe the quality of life in solid tumor 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 utilized to assess QoL in the student patients. There was no link between QoL and characteristics including age, sex, marital status, sickness duration, economic situations, or occupational function. Furthermore, no link was discovered between QoL and the educational level of the patients. Nonetheless, there was a substantial improvement with every succeeding chemotherapy cycle, which suggests that encouraging cancer patients to finish a CT course has a significant impact on treatment outcomes and quality of life in cancer patients who undergo CT.

- Harminder Singh et al. (2014) used the EORTC QLQ- C30 questionnaire in a prospective, non-interventional, observational study at a tertiary care hospital in Punjab to assess QOL and physical/ psychological stress among 131 cancer patients during their chemotherapy 10 sessions. Analysis of variance (ANOVA) was used to compare the different groups, and 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 on, the patients' quality of life increased dramatically.

- Ajeet Kumar Gandhi et al. (2014) used the EORTC- HN35 and EORTC QLQ- C15- PAL questionnaires to assess the symptom burden and QOL among advanced incurable HNCa patients who were administered palliative radiations in observational research on 100 advanced head and neck cancer patients. Pain, sleeplessness, lack of appetite, and fatigue were the top four most prevalent symptoms. Physical functioning was found to be impaired by 23%, while emotional functioning and QOL were affected by 50%.

• Guru Karthikeyan et al (2012) conducted a cross-sectional observational study on 121 cancer patients receiving various anti-cancer therapies such as chemotherapy, radiotherapy, and concurrent chemo radiation with the goal of determining the prevalence of fatigue and the relative impact of fatigue on QOL using the FACT- G scale and SPSS 110 version of the software. The researchers discovered that individuals getting chemotherapy and concurrent chemo-radiotherapy experienced severe fatigue, while those receiving radiation therapy experienced a greater impact of fatigue on QOL.

RESEARCH RATIONALE:

While patient reported Experience Measures (PREMs) were being collected at BMCHRC, but Patient reported Outcome measures (PROMs) collection was still to be bought in action. Capturing PROMs has been labelled as an element of excellence by NABH 5th edition under patient safety and quality improvement standard (PSQ-3). PROMs collection is seen to have ability to improve quality of care and is of value to understand the health experience of patient. The study will help in tracking the outcome of treatment and promoting patient participation in their care, which will aid in identifying the barriers that may result in poor quality of life among cancer patients.

METHODOLOGY:

Study Design: Descriptive Cross-Sectional study
Study Location: Day Care at BMCHRC
Study Duration: 2 months (May & June 2022)
Study Tools: Semi–Structured Questionnaire (EORTC – QLQ -C30 version 3.0 Questionnaire).

STUDY POPULATION:

Inclusion criteria:

- Female cancer patients between the ages of 18 to 65 years who are admitted for chemotherapy at BMCHRC.

Exclusion criteria:

- Patients who are unwilling to participate.
- Patient with speech impairment due to cancer of the oral cavity
- Patients who are getting chemotherapy for the first time.

Sample size: 155 female cancer patients undergoing chemotherapy.
Sampling Techniques: Convenient sampling

RESEARCH QUESTION:

What is the Patient Reported Outcome for female Cancer patients undergoing Chemotherapy at BMCHRC?

RESEARCH OBJECTIVE:

Broad Objective:

To study patient reported outcome for female Cancer patients undergoing Chemotherapy at BMCHRC.

Specific Objective:

- To assess health related quality of life among female cancer patients admitted to Day care unit at BMCHRC using EORTC QOL –C30 version 3.0 tool.
- To give suggestions for future PROMs collection and its uses at BMCHRC.

EORTC – QLQ -C30 VERSION 3.0 QUESTIONNAIRE

The EORTC quality of life questionnaire (QLQ) is a comprehensive approach for assessing cancer patients' health-related quality of. life (HRQoL) in international clinical trials. The QLQ-C30 contains 30 questions of which the first 28 are scored 1 to 4, namely "Not at all", "A little", "Quite a bit" and "Very much" And the 29 & 30 question is scored on 1 to 7 scale. Both multi-item scales and single item measurements make up the QLQ-C30. The scales and single-item measurements all have a score range of 0 to 100. A high scale score indicates a higher level of responsiveness. Thus, a high score on a functional scale and GHS scale is considered good as it indicates a healthy level of functioning and a high level of QoL. However, a high score on a symptom scale indicates a high level of symptomatology/difficulties.

Value of PROMs:

- PROMs complement traditional, clinical-based outcomes, enabling a more comprehensive understanding of outcomes and effectiveness.
- PROMs support service delivery improvements by allowing the effectiveness of services to be evaluated, identifying patients who would benefit from interventions and encouraging the sharing of best practices.
- PROMS can be incorporated into the evaluation of performance and effectiveness of care to enable a potential shift in health system resource management from a volume-based to a value-based model.
- PROMs are especially important in elective surgeries and chronic illness management, where the predominant goal is to enhance patients' quality of life
- PROMs can also inform decisions regarding resource allocation to ensure investments support improvements in population health.

•Data Collection Method: Data was collected through personal interview with individual respondents using EORTC QLQ – C30 Questionnaire which was converted into a google form. Questions were translated to the respondents in Hindi language.

•Scoring Method for Analysis: 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:**

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

Further, SPSS version 13 was used to calculate Pearson's correlation of GHS with Functional scale items & Symptom scale items.

RESULTS

Table.1 Distribution of Female Respondents (N=155)

Characteristics	% Of participants
Age	
18-24	3%
25-45	26%
46-65	71%
No of chemo sessions	
less than 5	43%
5 to 15	52%
more than 15	6%
Category	
Bhamashah/Chiranjeevi	11%
BPL	5%
Cash	44%
CGHS	2%
Empanelled	10%
Others	6%
RGHS	23%
Diagnosis / Disease	
Head & Neck. C	1%
Breast. C	50%
Ovarian. C	21%
Cervix. C	8%
Uterus. C	1%
Blood & Bone marrow. C	2%
Lung. C	4%
Rectum. C	3%
Colon. C	1%
Gall bladder. C	3%
HL & NHL	1%
Oesophageal. C	3%
Sarcoma	1%
Vaginal. C	1%
Periampullary Carcinoma	1%
Total Participants	100%

A total of 155 female cancer patients were interviewed on 30 items while being treated for cancer and undergoing chemotherapy. The Functional scale consisted of 15 items and was separated into five categories: Physical functioning, Role functioning, Emotional functioning, Cognitive functioning, and social functioning. The Symptom scale was divided into 9 symptom categories based on 13 questions: Fatigue, Nausea& vomiting, Pain, Dyspnea, Insomnia, Appetite loss, constipation, diarrhea, and financial troubles. The final category, Global Health Status, had two questions about health status and quality of life (QOL).

Table. 2 Quality of life scores for all participants (N=155)

EORTC Item	MEAN	SD
FUNCTIONAL SCALE		
Physical functioning	87.3	14.9
Role functioning	76.6	28.4
Emotional functioning	83.1	15.3
Cognitive functioning	88.5	15.9
Social functioning	95.9	8.9
SYMPTOM SCALE		
Fatigue	30.8	20.8
Nausea and vomiting	16.8	19.6
Pain	16.2	19.9
Dyspnoea	9.9	19.0
Insomnia	15.9	24.3
Appetite loss	15.5	21.5
Constipation	25.8	31.3
Diarrhoea	11.2	21.8
Financial difficulties	12.7	23.4
Total Functional Score	86.7	10.1
Total Symptom Score	19.1	10.3
GLOBAL HEALTH STATUS	70.2	12.1

According to Fig. 1, the respondents had a good quality of life scores on the functional scale. The highest quality of life was found in all areas of the functional measures, with the maximum score of 95.9 in social functioning which includes questions about relations with family and society, followed by 88.5 in cognitive functioning which includes questions about concentration and memory, 87.3 in physical functioning which includes 5 questions about physical activities, 83.1 in emotional functioning which includes 4 questions about emotional status of respondents, and the lowest score of 76.6 in role functioning which includes 2 questions about their daily activities.

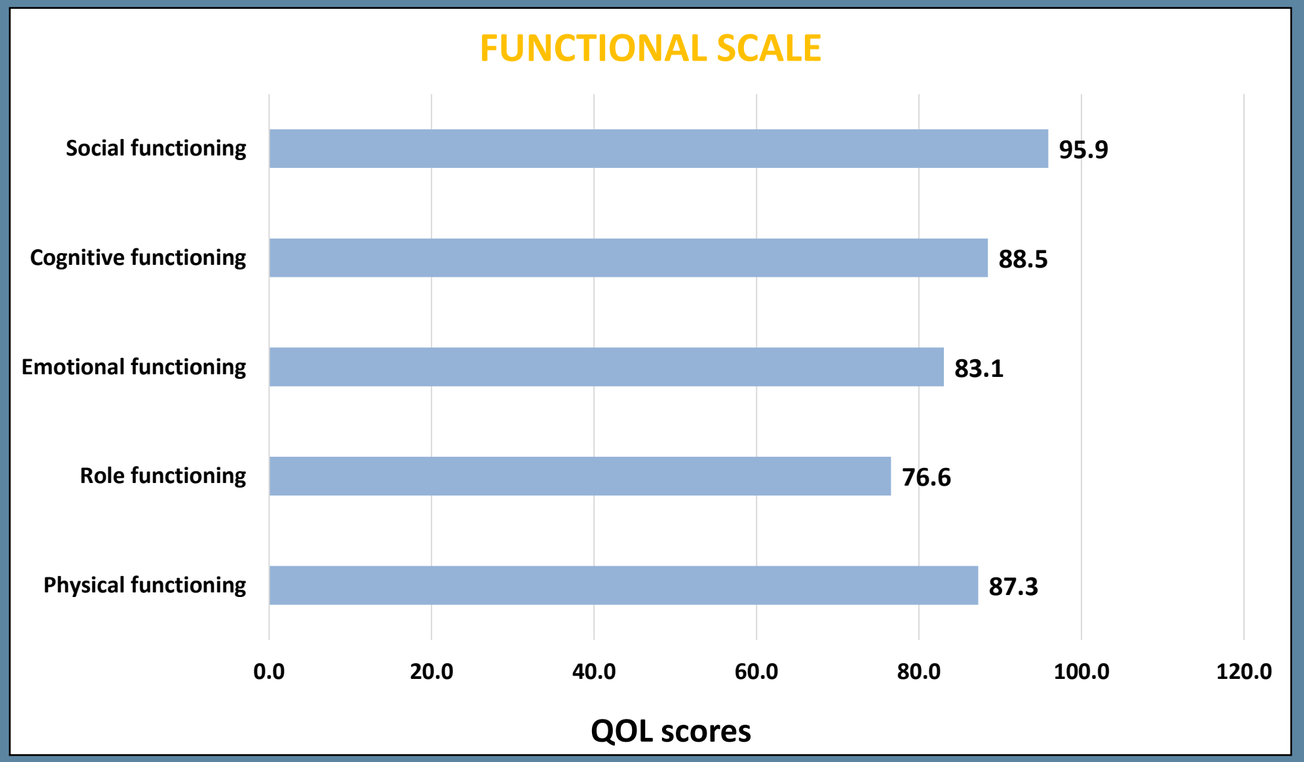


Figure. 1. Functional scale scoring.

The mean symptom scale score according to Fig.2. was highest at 30.8 for fatigue followed by 25.8 for constipation, 16.8 for nausea and vomiting, 16.2 for pain, 15.9 for insomnia, 15.5 for loss of appetite, 12.7 for financial troubles, 11.2 for diarrhoea, and least at 9.9 for dyspnoea. The mean GHS score was 70.2 indicating a decent health status among respondents.
Among the 16 patients that rated 3 or 4 on their financial difficulties around 9 respondents belonged to cash category, of which 8 patients showed a GHS score and emotional score below the mean GHS and emotional functioning score suggesting that financial burden of the treatment affected the quality of life and emotional functioning among patients.

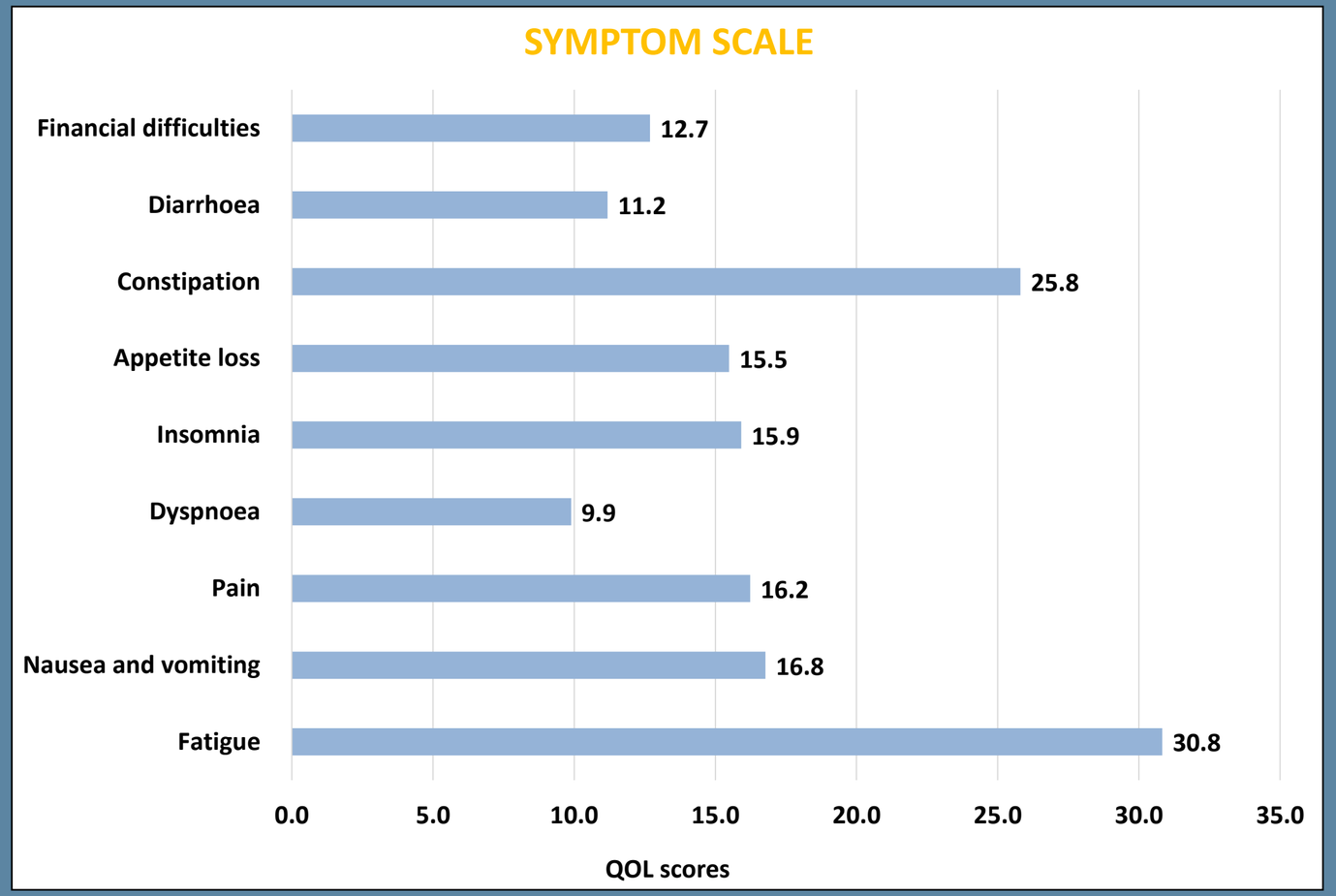


Figure. 2. Symptom scale scores.

Functional scale Items	Correlation Value [R]	Significance level (2- tailed)
Physical functioning	0.349	0.01
Role functioning	0.435	0.01
Emotional functioning	0.374	0.01
Cognitive functioning	0.077	0.01
Social functioning	0.233	0.01
Total functional Score	0.498	0.01

Table.3 Correlation between GHS and Functional scale items

Table.4 Correlation between GHS and Symptom scale items.

Symptom scale Items	Correlation Value [R]	Significance level (2- tailed)
Fatigue	-0.441	0.01
Nausea and vomiting	-0.152	0.01
Pain	-0.184	0.01
Dyspnoea	-0.137	0.01
Insomnia	-0.143	0.01
Appetite loss	-0.273	0.01
Constipation	-0.104	0.01
Diarrhoea	-0.008	0.01
Financial difficulties	-0.165	0.01
Total Symptom Scale	-0.445	0.01

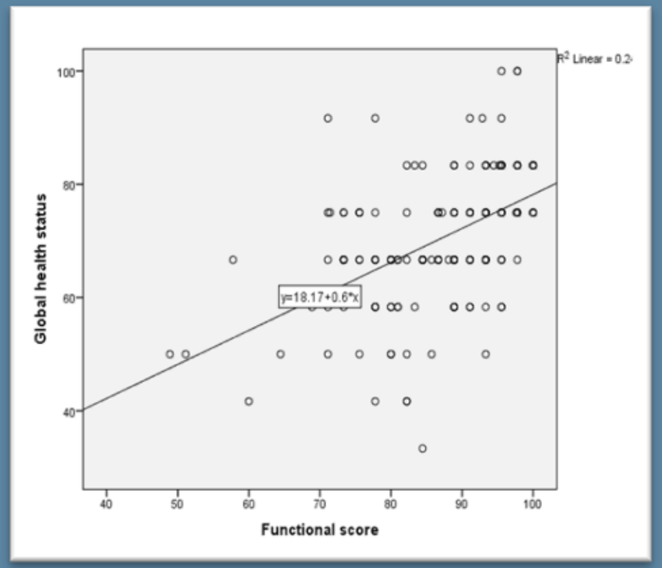


Figure.3. Correlation between GHS and Functional scores

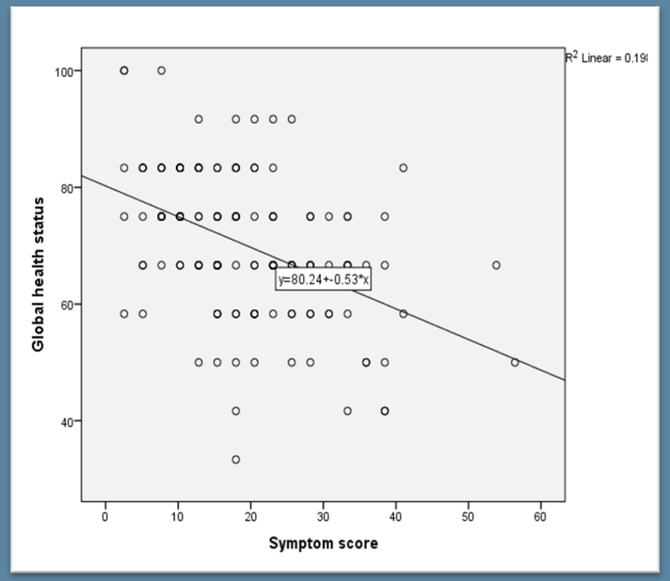


Figure.4. Correlation between GHS and Symptom Scores

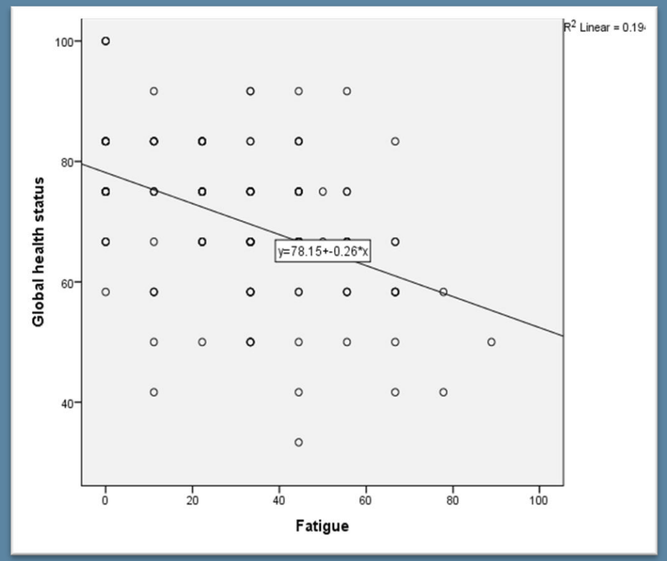


Figure.5. Correlation between GHS and Fatigue

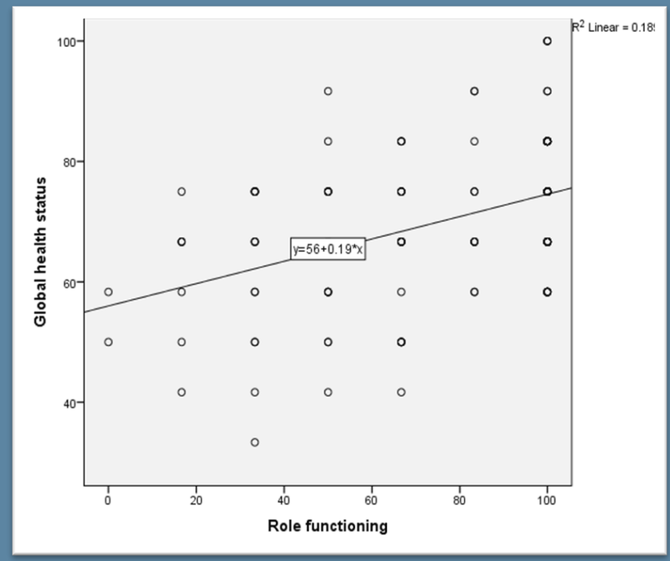


Figure.6. Correlation between GHS and Role Functioning

DISCUSSION

•"Quality of life" refers to a person's overall well-being, which includes physical, emotional, mental, social, and behavioral aspects. The EORTC QLQ-C30 is the most extensively used instrument for assessing QoL in cancer patients. The current PROMs study at the BMCHRC provides an insight into the influence of treatment intervention on patient's health-related quality of life.

•Our research revealed that the majority of study participants at BMCHRC were over the age of 40 and that the majority of them had breast cancer, with roughly 50% of study respondents having breast cancer. According to studies undertaken by Nancy. E. Avis et al., Zahra Sheikhalipour et al., and national level data, breast cancer is the most common malignancy among Indian women, with one out of every 28 women diagnosed dying from it.

•A high social functioning score indicates that the cancer sickness is becoming more accepted in society. Patients reported a good quality of life on the functional scales. The highest score went to the social domain, which includes questions concerning patients' post-diagnosis relations with family and society. While we received the lowest scores in emotional and role functioning, this suggests that most cancer patients may be suffering from mental and emotional disorders. The connection between functional scores and global health status (GHS) And quality of life was shown to be moderately positive (QOL).

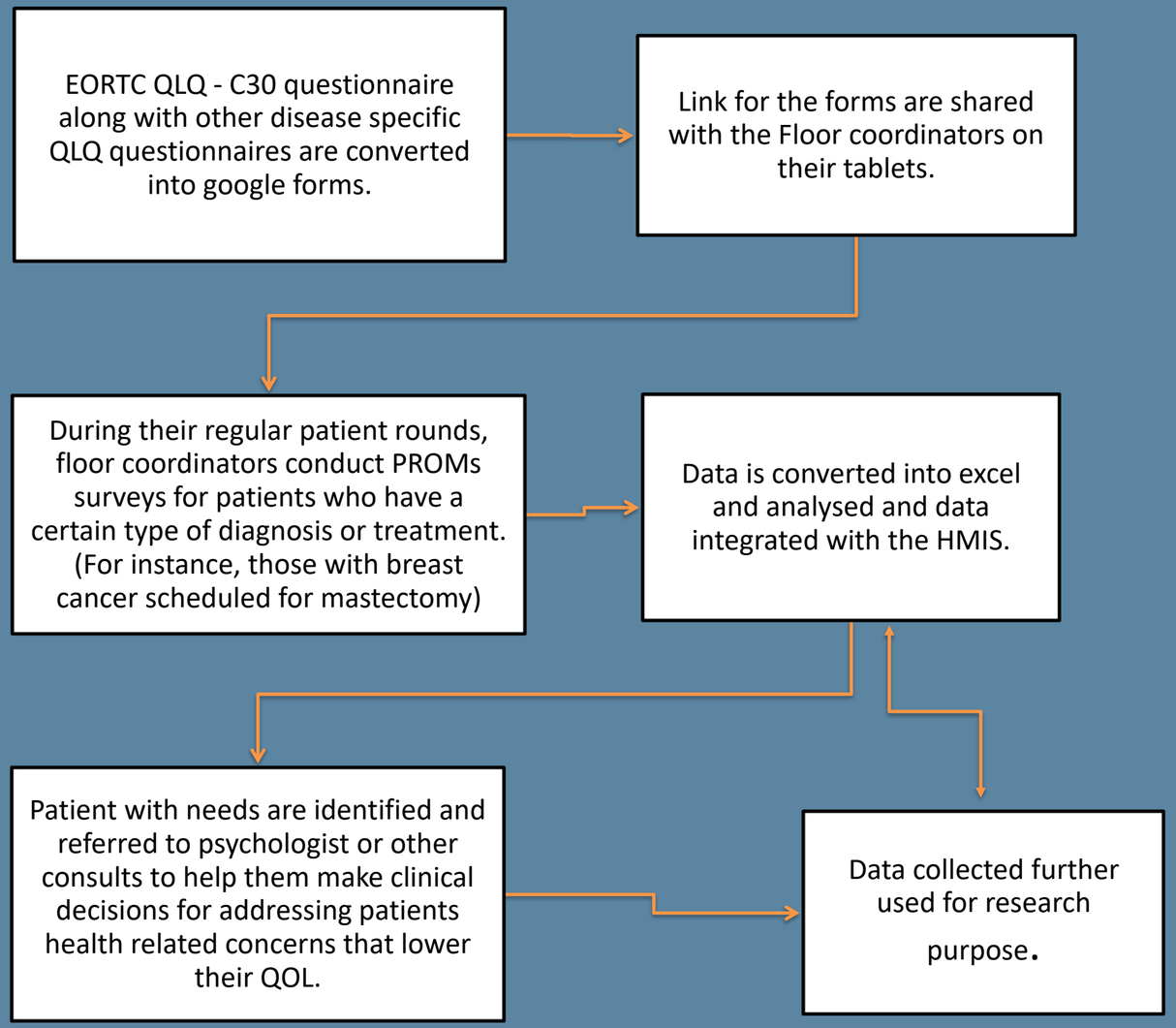
•Fatigue, constipation, nausea & vomiting, pain, and insomnia were the top five poorest performing symptoms on the symptom scale, in decreasing order of scores collected. Our study found that fatigue was the most common symptom, which is consistent with Guru Karthikeyan et al findings, which found a significant frequency of severe fatigue among cancer patients receiving chemotherapy.

•Nearly half of the female respondents scored above 70 on the Global health status scale, indicating that chemotherapy has a good impact on quality of life. Other research investigations have found that typical cancer symptoms result in a considerable decline in QOL. Women are often given a lot of information about treatment options and procedures, but they aren't always prepared for how they'll feel about themselves or how a cancer diagnosis will affect their daily lives, so it's important to pay attention to these symptoms and educate patients about the possible side effects of chemotherapy before they begin treatment.

CONCLUSION

Cancer is a chronic disease that can continue a long time, it is critical to not only reduce mortality but also to recognize the disease's morbidity in order to maintain a healthy, high-quality life for all cancer patients until they are disease-free. It can be concluded from the study that most female patients with cancer are more prone to symptoms such as fatigue, constipation, and pain because of the disease, all of which negatively impact their quality of life. Chemotherapy-related fatigue management is an important issue in the care of cancer patients which may also hamper their pursuit of daily routine activities. As a result, it is critical to educate and keep patients informed about potential health issues and treatment-related adverse effects that they may encounter throughout therapy. PROMs are a fantastic tool for keeping track of the outcome of the treatment they are receiving and for encouraging patient participation in their care, which will aid in discovering the roadblocks that are causing poor quality of life.

SUGGESTIONS FOR FUTURE PROMs COLLECTION AND USE AT BMCHRC:



- A new HMIS system will shortly be implemented at BMCHRC, allowing for the integration of PROM data with the EMR for clinical decision-making and self-care management.

- Data from PROMs can be used for additional oncology-related research at the BMCHRC's approved research centre, where several clinical trials and studies are conducted.

- PROMs data can be used to identify individuals who exhibit lower emotional functioning, In order to recommend these patients to psychologists who can give them the assistance they need.

- Several welfare programmes for female cancer patients are already in place at the BMCHRC, such as "Annual Surveillance and Early Detection of Breast Cancer" and "Breast Cancer Recurrence Prevention." We can use PROMs to identify priority patients, such as needy widows and women over 60 with cancer who lack a source of income or family support, and we can expand the scope of these programmes to include these patients in order to provide them with physiological as well as welfare support.

LIMITATION OF STUDY:

As the study was a pilot study to implement PROMs at BMCHRC and due to limited time for data collection patients were enrolled by convenience at their respective chemotherapy sessions. Several exclusion criteria in our study and repetition of patients as most had their chemotherapy sessions on every 7th , 15th or 21st day, were major reason which led to a smaller sample size available for my study.

ETHICAL CONSIDERATIONS:

As the study is done as part of a process for patient safety and quality improvement as suggested under NABH 5th edition. Administrative permission was taken for carrying out the study. The objective of the study was explained to the study participants in brief and post which an informed consent was obtained.

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Thanks!