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Quality of life in cancer patients receiving chemotherapy vs immunotherapy in tertiary hospital settings

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SUMMARY

There are various therapies in the management of tumours. Immunotherapy is one of the most promising developed treatments included in the second line of many treatment protocols. The quality of life concept was recently evaluated in numerous RCTs to support the evidence in the selection of those therapies in treatment regimens.

Aim: To evaluate the quality of life in cancer patients and compare it in two intervention groups, first received chemotherapy alone or plus immunotherapy and second only immunotherapy.

Study design and method: Observational cross-sectional study, the study population of 92 cancer patients divided into two groups (Group A; chemo alone or with immunotherapy, and Group B Immunotherapy alone) visited Fortis Memorial Research Institute's chemo-daycare the period between September 11th, 2020 and April 28th, 2021. They evaluated QOL by administering the 3-level version of EQ-5D (EQ-5D-3L) and The Functional Assessment of Cancer Therapy - General (FACT-G) questionnaires.

Results: Of the total study population, 65.2% of patients received chemotherapy alone or with immunotherapy, and 56.5% received only immunotherapy. The VAS score and all domains of E.Q. 5D-3L were statically significant at the follow-up, and in comparison to FACT-G scores, it was highest at week 15 and in comparison of both study arm group B shows a significant P-value is<0.05.

Conclusion: Results suggest the quality of life in cancer patients receiving immunotherapy is higher than in those who receive chemotherapy alone or plus immunotherapy; the improvement is well observed in week 12. Age, gender, stage, site of tumours, and the adverse events of the treatment directly affect the QOL

Key words: Cancer, Immunotherapy, Chemotherapy, Quality of life, Patient-Reported Outcomes.

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INTRODUCTION

The concept of Quality of Life (QoL) describes and evaluates individuals' and societies' general well-being. As per the World Health Organization (WHO), Quality of Life is defined as an individual's approach to life in the culture and value systems they live in and their objectives, expectations, standards, and concerns. It is a broad-ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships, and relationship to their environment's salient features [1].

The recent advances in cancer treatments have considerably improved patients' Quality of Life (QoL), with many cancer types despite; survival rates and symptoms palliation. Despite the positive impact of recent cancer treatment protocols, cancer patients still experience many short and long-term functional and psychological problems [2].

An increasingly significant question in oncology is to evaluate QoL in cancer patients [3]. The cancer-specified QoL is related to all stages of this disease [3,4]. For all types of cancer patients, general QoL instruments can be used to assess the overall impact of patients' health status on their QoL; however, hand cancer-specific tools evaluate the implications of specific cancer on QoL [2].

Considering the QOL concept, the preferred treatment may be identified based on a variance in QOL. Quality of life has also been mainly used as the primary endpoint in studies explicitly designed to improve cancer physical or mental well-being. In these studies, Quality of life information can result in significant data about whether the intervention being evaluated should be propagated or implemented as part of routine clinical care.

Cancer immunotherapies have overturned the treatment of cancer and represent a new option for clinicians. Immune Checkpoint Inhibitors (ICIs) have garnered attention as one of the most promising types of immunotherapy. The U.S. Food and Drug Administration (FDA) approved seven ICIs for clinical use: Ipilimumab, Pembrolizumab, Nivolumab, Atezolizumab, Durvalumab, Avelumab, and Cemiplimab [5]. Despite the durable clinical benefits of the immune checkpoint blockade therapy in different cancers, ICIs use is associated with

several adverse effects related to the mechanism of action that is quite different from other systemic treatments such as cytotoxic chemotherapy.

In general, to uncover the unknown effects of immunotherapeutic agents either as single or in combination with cancer therapy, the preferred method is to perform qualitative interviewing on patients with the target disease. Another approach matches the list of irAEs associated with an immunotherapeutic agent with the symptom items from the library of widely used PROs, such as the MDASI, EORTC QLQ, and the PRO-CTCAE.

Recent cancer studies focus on chemotherapy or immunotherapy treatment's physical and psychological adverse effects or emphasize certain specific cancer sites. However, there are few studies focused on QoL comparing the effect of chemotherapy versus immunotherapy. Thus, this present study aimed to assess the QoL and compare adult patients with cancer undergoing chemotherapy and immunotherapy.

METHOD

Study design

The present study is cross-sectional, also known as a prevalence study, and examines the data on disease and exposure at one particular time point. All the patients were admitted to the chemo-daycare of Fortis Memorial Research Institute between September 11th, 2020, and April 28th, 2021. Based on the medical oncologists' referral notes, patients were screened for eligibility using the inclusion and exclusion criteria (described below). Patients who met the inclusion criteria were verbally asked by the author or the clinical nurse about their willingness to participate in the research study. Upon request, patients were provided with additional information about their participation in the study. After all, information was provided, the author's written consent was obtained. Patients meeting the following inclusion criteria were recruited; diagnosed patients with cancer of any type (≥ 18 years of age), all patients who received chemotherapy once and continuing to receive treatment, and all patients who received immunotherapy once and continuing to receive treatment. The following patients were excluded; Patients who are not willing to participate in the study, cancer patients with encephalopathy, neuromuscular diseases, severe congestive heart failure, mental problems, and cancer patients with connective tissue disorders. In this study, quality of life was the primary outcome, and sample size calculations were based on the values of the different domains that contribute to patients' quality of life. Initially, a sample size of 104 was used (G power Analysis Software 3.1 version) in two groups (A and B) per the treatment they took each 52 patients. After recruiting the patients, there was a drop out in the sample size of group B, where two subjects deceased and 10 lost the follow-up, so the final sample size was; Group A: Patients treated with either chemo alone or chemo plus immunotherapy, number 52. Group B: Patients treated with immunotherapy alone, number 40. After obtaining written informed consent from the patients, they were asked to fill in the questionnaires (the letter; 3-level version of the EQ-5D-3L version and the Functional Assessment of Cancer Therapy–General (FACT-G)) beforehand of their initial consultation with the carer and/or companion as part of the baseline assessment. Sociodemographic and clinical data were also collected by the author from clinical patient notes and patient interviews. The follow-up data collection was done at different times per the treatment cycles and was stopped after collecting four times.

Ethics

The study protocol was first approved by the Research Project Advisory Committee (RPAC), Jamia Hamdard, and the IEC Jamia Hamdard approved the study at the virtual meeting held on 10/09/2020. The same protocol was submitted to the IEC of Fortis Memorial Research Institute to obtain approval, and the same had been granted. Recruitment of participants only began after receiving approval for research conduct. The process of obtaining informed consent consists of two main components: 1) providing participants with the necessary information; 2) Sign consent forms. The Informed Consent Form (ICF) was developed in both languages (English and Hindi), and the legal translation was applied.

Statistics

All analysis was performed using SPSS Version 20. Frequencies and percentages were calculated for qualitative, and mean (SD) & Interquartile Range (IQR) were calculated for quantitative variables. An independent t-test was used to compare the two independent variables, and ANOVA was used for more than two independent samples. A paired sample t-test was used to compare the mean of two dependent variables, and repeated measure ANOVA was used for more than two dependent variables. Statistical Significance was considered as less than 0.05.

Data entry and analysis

All the sequential data thus collected were double entered into Epidata and validated. A duplicate version of the database was used for statistical analysis using Epidata software (version 3.1, Odense, Denmark). Data analysis was done to compare the sensitivity and specificity of the 2D, 3D and integrated imaging. Statistical significance was considered at 95% CI ($p<0.05$).

Ethics approval

Ethics approval was obtained from the Institutional Review Board of the Institute and The Ethical Advisory Committee of the International Union Against Tuberculosis and Lung Diseases, Paris. As the study was carried out using images already available in the hospital console and the histopathology reports available in the pathology department without the involvement of patients or active interventions, written consent was not deemed necessary. Approval to use the hospital data was obtained from the concerned authorities.

RESULTS

According to the calculated sample size, 104 patients participated in the study in two groups; group A (n=52, 65.2%) received chemotherapy alone or with immunotherapy, and group B (n=40, 56.5%) received only immunotherapy. After completing the baseline assessment, in group B, two patients deceased, and 10 lost the follow-up due to personal reasons or changes in

hospitals where they attend for treatment. The overall age of the subjects was (55.65 ± 12.77) Years. The minimum age of the subject was 22 Years, and the maximum age was 77 Years. The study population has included (34.8%) male & (65.2%) female patients (Table 1).

Most of the patients suffer from Brest cancer, and a few have Myeloma and pancreatic cancer distribution of cancer types among the study population (Figure 1). Disease Stages of the patients in the current study; most patients were on stage-2 &3, and significantly fewer patients were found in Recurrent (Table 2).

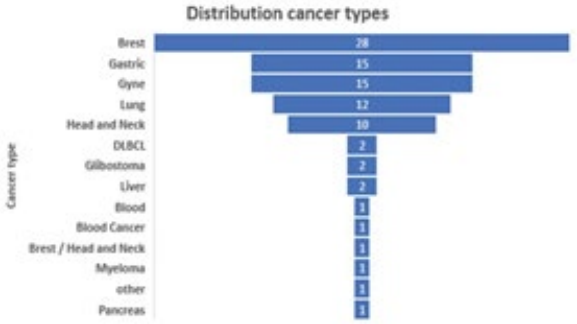


Fig. 1. Cancer types among the study population

EQ_5D-3L Questionnaire-based Analysis

The distribution of mobility and self-care at the follow-up of patients; most of the patients were found in level 1, and very few patients were found in level 3 (Figures 2&3).

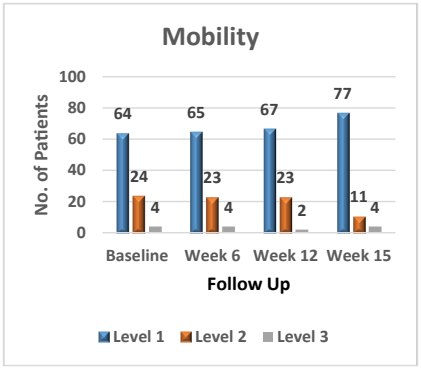


Fig. 2. Distribution of mobility at the follow-up of patients

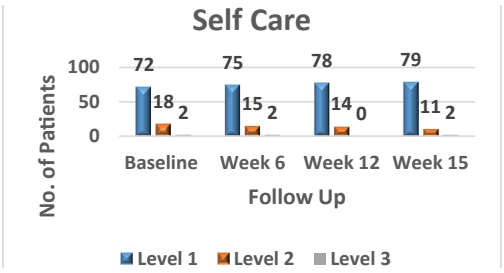


Fig. 3. Distribution of self-care at the follow-up of patients

The distribution of usual activity at the follow-up of patients, most of the patients were found in level 2, and very few patients were found in level 3 (Figure 4).

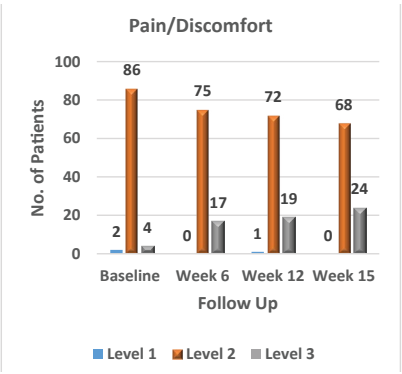


Fig. 4. Distribution of Pain/Discomfort at the follow-up of patients

The distribution of Anxiety/Depression at the Follow-up of Patients, most of the patients were found in level 2, and very few patients were found in level 1 (Figure 5).

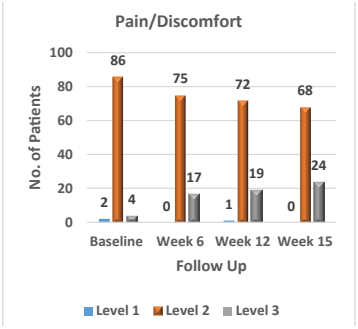


Fig. 5. Distribution of Anxiety/Depression

Tab. 1. Sociodemographic data

	Study Population		
		Frequency	Per cent
Group	Chemotherapy & Combination Therapy	52	56.50%
	Immunotherapy	40	43.50%
Gender	Female	60	0.65%
	Male	32	0.35%
Age	Maximum	22	NA
	Minimum	77	NA
	Mean	55.65	NA

Tab. 2. Distribution of disease stages among the study population

Stages	Frequency	Per cent (%)
Stage I and II	16	17.4%
Stage III and IV	43	46.7%
Metastatic	24	26.1%
Recurrent	9	9.8%

Tab. 3. Comparison of mean VAS Score at the follow-up of patients

VAS Score	Group	Mean	SD	P-Value
Baseline	Chemotherapy and Combination	59.83	5.92	0.01
	Immunotherapy	63	5.52	
Week 6	Chemotherapy and Combination	53.27	5.85	0
	Immunotherapy	58.75	4.77	
Week 12	Chemotherapy and Combination	51.15	6.76	0
	Immunotherapy	58.88	5.25	
Week 15	Chemotherapy and Combination	48.65	10.1	0
	Immunotherapy	63.88	5.72	

Tab. 4. Comparison of all domains of FACT-G scores according to intervened groups

Follow Up	Intervened Groups	Emotional Well-Being (EWB)			Functional Well-Being (FWB)			Social Well-Being (SWB)			Physical Well-Being (PWB)			FACT-G Total		
		Mean	SD	P -Value	Mean	SD	P -Value	Mean	SD	P -Value	Mean	SD	P -Value	Mean	SD	P -Value
Baseline	Chemo-therapy and Combination	12.04	2.5	0.175	15.4	2.6	0	13.83	2.8	0	17.35	3.3	0.801	52.56	16.4	0.049
	Immuno -therapy	11.38	2		18.03	2.7		11.08	1.3		17.5	2.2		57.98	5.73	
Week 6	Chemo-therapy and Combination	10.83	2.6	0.061	14.81	2.4	0	12.21	3.4	0.21	16.17	2.7	0.002	48.23	14.6	0
	Immuno-therapy	11.75	1.9		18.98	2.2		11.5	1.1		17.83	1.9		60.05	4.82	
Week 12	Chemo-therapy and Combination	9.46	3.5	0	14.1	2.4	0	11.25	4.5	0.336	15.73	3.1	0	43.75	13.4	0
	Immuno-therapy	12.65	2.2		19.15	2.4		11.95	1		18.4	2		62.4	3.77	
Week 15	Chemo-therapy and Combination	8.17	3.7	0	14.23	2.9	0	8.48	3.5	0	14.96	3.6	0	46.04	11	0
	Immuno-therapy	14.1	1.9		20.45	1.6		13.55	1.6		20.05	1.2		68.15	4.44	

The mean VAS score according to follow-up of the patients. The mean VAS score at the baseline was 61.21 ± 5.94, and 55.27 ± 11.35 was found at week-15. The trend of the mean VAS score was decreasing according to time (Figure 6).

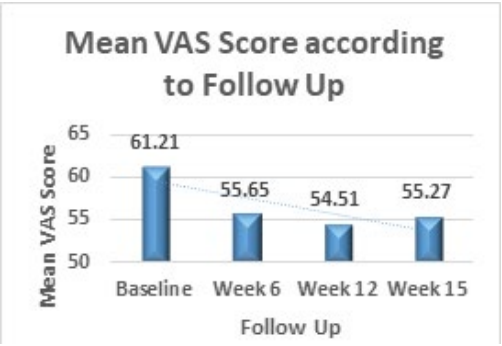


Fig. 6. Mean VAS Score according to follow-up of the patients

The comparison between the mean VAS Score in group-A and group B according to the patient's follow-up. The mean VAS score was found significant (P-value is <0.05) in our study (Table 3).

FACT-G Questionaries -Based Analysis

At the baseline, the mean physical well-being score was 17.41 ± 2.88, and 16.89 ± 2.54 was found at week 6 and week 12. The trend of mean physical well-being score was decreasing according to follow-up (Figure 7).

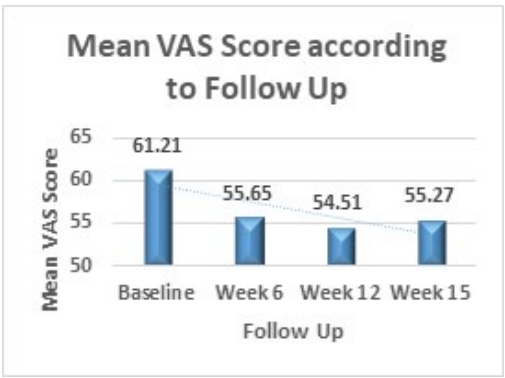
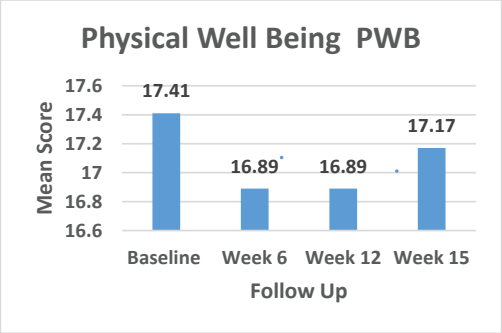


Fig. 7. Mean of Physical Well-Being Score according to follow-up of the patients.

The mean social well-being score at the baseline was 12.63 ± 2.68, and 10.68 ± 3.81 was found at week 15. The trend of

mean social well-being score was decreasing according to follow-up (Figure 8).



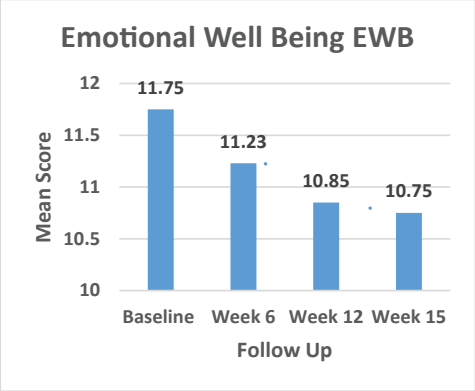


Fig. 8a and 8b. Mean of Emotional Well-Being Score according to follow-up of the patients

The mean functional well-being score at the baseline was 16.54 ± 2.94, and 10.93 ± 3.91 was found at week 15. The trend of mean functional well-being score was increasing according to follow-up (Figure 9).

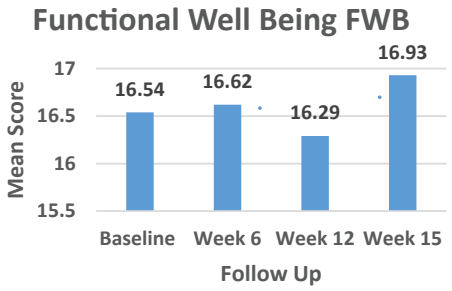


Fig. 9. Mean of Functional Well-Being Score according to follow-up of the patients

The mean FACT-G total score at the baseline was 54.91 ± 13.14, and 55.65 ± 14.07 was found at week 15. The trend of mean functional well-being score was slightly decreasing according to follow-up (Figure 10).

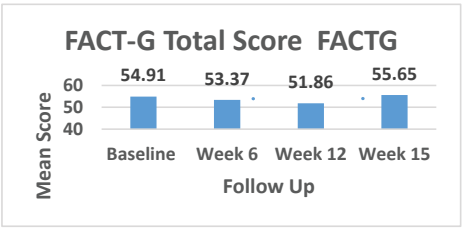


Fig. 10. Mean of FACT-G Total Score according to follow-up of the patients.

In comparing all domains of FACT-G scores according to intervened groups, the mean score was found statistically significant at week 12 and week 15 as the P-value is less than 0.05 (Table 4).

DISCUSSION

This study used a blended questionnaire-based analysis to assess the quality of life in two different groups of cancer patients. The blended questionnaires generated both efficacy and satisfaction data within a single study, providing holistic evidence. A single trial may incorporate numerous questionnaires that assess different aspects of health-related quality of life in quality-of-life outcome measures. The present study found that women appear to be more affected than men by impaired physical and social functioning after cancer development, and they reported more fatigue and pain than men, similar to other studies findings [6,7,8].

EQ 5D-3L questionnaire-based analysis classifies the QOL index into three-level 1,2,3 where 1 indicates high QOL and 3, worse, QOL with visual analogue score (VAS). The five main domain evaluated in the present study is; (Mobility, Self-care, Usual activity, Pain/ Discomfort, and Anxiety / Depression). Concerning mobility and self-care, most of the patients were in level 1, indicating patients have no problem moving and doing self-care activities while usual activity, pain/discomfort, and anxiety/depression, most of the patients were found in level 2. These findings are similar to the randomized clinical trial Check Mate–017 by Reck et al. (2017) [6]. The mean VAS score at the baseline was 61.21 ± 5.94, and 55.27 ± 11.35 was found at week 15. The trend of the mean VAS score was decreasing according to time. Similar findings were supported by Harrington et al. (2017) in the randomized clinical trial Check Mate- 141 [7] and Mayrbaurl et al. (2016) [9]. The mean VAS score was significant (P-value is <0.05) in our study while comparing the mean VAS Score in group 1 and group 2 according to the patient's follow-up. The mean VAS score was significant (P-value is <0.05) in the present study, i.e., the Immunotherapy treatment group significantly high VAS score than the chemotherapy treatment group. This indicates immunotherapy delayed the worsening of patient-reported quality-of-life outcomes compared with chemotherapy in patients with platinum-refractory. In the comparison of the different FACT-G domains according to intervened groups, the mean of the Physical Well Being score was found statistically significant at week 6, week 12, and week 15 as the P-value is less than 0.05, the mean of Social Well Being score was found statistically significant at baseline and week-15 as the P-value is less than 0.05, the mean of Emotional Well Being score was found statistically significant at week-12 and week-15 as the P-value is less than 0.05, the mean of Functional Well Being score was found statistically significant at all the follow up as the P-value is less than 0.05, the mean of FACT-G score was found statistically significant at all the follow up as the P-value is less than 0.05. These findings indicate the immunotherapy intervention has better FACT-G scores, i.e., high quality of life and statically significant at week 6, week 12, and week 15, similar to other studies findings [10-14].

CONCLUSION

Immunotherapy has a good impact on managing different tumours by improving overall survival and becoming an essential pillar in cancer therapy. Quality of life matters in cancer patients and it reflects the treatment outcomes. The present study concludes that immunotherapy has a better quality of life than different chemotherapy regimens used to treat different kinds of cancer. The improvement of QOL can be observed after 12 weeks of treatment. Side effects of both intervented groups such as nausea and vomiting, constipation and diarrhoea, pain and fatigue, loss of appetite, and dyspnea directly affect the quality of life. Age, gender, stage, and site of tumours all affect the QOL domains.

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