

Post–Autologous Immune Cell Therapy Quality of Life in Cancer Patients: A Retrospective Study

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Abstract:

Objective: Patients with advanced cancer are treated palliatively, with a focus on quality-of-life improvements through the amelioration of symptoms and functional status. This study aimed to evaluate the quality of life of cancer patients post–autologous immune cell therapy (ICT), as it is known for its ability to replace defective immune cells, which reduces cancer–related symptoms and may improve patient quality of life.

Material and Methods: The patients' whole blood was processed to obtain activated immune cells. Treatment consisted of 6 autologous intravenous ICT infusions with an interval of 2 weeks. Patient quality of life was evaluated with the EORTC–QLQ–C30 questionnaire before and after 6 autologous ICT treatments.

Results: Quality of life score increased in global health status, physical functioning, role functioning, cognitive functioning, and social functioning. There was a reduction in scores on the symptom scales for fatigue and pain components.

Conclusion: Improvements in quality of life, function, and symptoms in cancer patients were observed after 6 autologous ICT treatments.

Keywords: cancer, immune cell therapy, quality of life

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Introduction

Cancer is the leading cause of premature death in 177 of 183 countries. Beyond being a leading cause of mortality, cancer also imposes significant morbidity and substantial societal and macroeconomic burdens¹. For solid tumors, the TNM (Tumor, Nodes, Metastasis) classification is most commonly used and can aid in determining prognosis. It is based on the anatomic extent of the disease and can be grouped into stages^{2,3}. Advanced cancer stage is associated with disease severity and decreased survival rates. Hence, treatment in patients with metastatic disease is characterized by palliative and supportive care in order to preserve quality of life (QoL)⁴.

Immunotherapy and cellular therapy have emerged as promising treatment options for cancer patients. Advances in understanding the complex interactions between cancer cells and the host immune system have paved the way for these innovative approaches⁵. Several studies have shown that these modalities can significantly alleviate cancer-related symptoms and enhance patient quality of life^{6,7}. To this extent, many studies continue to optimize these modalities to maximize patient quality of life with the hope of one day curing cancer.

Immune cell therapy (ICT) is a cellular therapy that aims to enhance patients' immune systems, especially in cancer patients with a defective immune system. Consequently, the improvement of a patient's immune status results in a reduction of cancer-related symptoms. Thus, cancer patients undergoing ICT are likely to experience improvements in quality of life⁸. However, data are still lacking regarding the quality of life in cancer patients undergoing ICT. Therefore, this study aimed to evaluate the quality of life in post-ICT stage I to stage IV cancer patients.

Material and Methods

Study design

This study was a retrospective study assessing cancer patients' quality of life post-immune cell therapy in Hayandra Clinic from 2018 to 2021. The data were obtained from medical records documented in Hayandra Clinic with informed consent from each patient enrolled in the study. Ethical approval was obtained from the Ethics Committee of the Faculty of Medicine Universitas Kristen Indonesia, with ethical approval no. 13/Etik Penelitian/FKUKI/2024.

Sample size estimation used the "difference between two paired means" formula. The significance level (α) was set at 0.05 for a two-tailed test, with 80% power ($1-\beta=0.80$). The standard deviation of the mean difference was assumed to be 20, based on the GARNET trial⁹, and the clinically important mean change was set at 10 (per Cocks et al.)¹⁰. The calculation yielded a minimum required sample size of 32, which we exceeded to account for potential dropouts.

Patient selection

The inclusion criteria for the patients in this study were: (1) adult patients (>18 years) with stage I, II, III, and IV cancer; and (2) patients who have undergone 6 immune cell therapies. Patients fulfilling the following criteria were excluded from the study: (1) undergoing pregnancy or breastfeeding; (2) having pre-existing mental illness; and (3) experiencing conditions that affect consciousness (e.g., a brain metastasis causing a decreased level of consciousness).

Immune cell therapy isolation, preparation, and infusion

Peripheral blood mononuclear cells (PBMC) were isolated from the patients' whole blood. PBMC was obtained from buffy coats by Ficoll-Paque density centrifugation and washed three times with phosphate buffer saline (PBS).

The PBMC was then re-suspended at 1×10^6 cells/mL in Lymphomedia (GC LYMPHOTEC Inc., Tokyo, Japan) and cultured with immobilized anti-CD3 antibody (5 mg/mL, BD Pharmingen, NJ, USA) and recombinant human IL-2 (700 U/mL, R&D Systems, MN, USA) for 5 days. Further incubation was done for 9 days in Lymphomedia containing recombinant human IL-2 only (170 U/mL). The medium and IL-2 were replenished every 3 days¹¹. The ICT in the form of cytokine-induced killer cells was then obtained and infused intravenously to the patients. Six infusions of ICT were given with an interval of 2 weeks.

Quality of life assessment

Patients' quality of life was assessed with the translated and validated Indonesian version of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30. The questionnaire consisted of 30 questions, which comprised

global health status, functional scales, and symptom scales. The details of the questionnaire are available in Table 1. The interpretation of the questionnaire followed the EORTC QLQ-C30 scoring manual¹². A higher score in global health status and functional scales indicated a better quality of life. As for the symptom scales, the lower the score, the better the quality of life. The authors used the Indonesian version of the EORTC QLQ-C30, which had been previously translated and validated¹³.

Statistical analysis

The questionnaires were filled in by the patients during appointments at the clinic. The answers were then typed into a spreadsheet and exported to SPSS version 24 (IBM Corp., Armonk, NY, USA) (RRID: SCR_002865), which was also used to conduct statistical analyses. Comparison between baseline and post-ICT scores for quality of life was statistically analyzed using a paired T-test or Wilcoxon

Table 1 Parameters of the EORTC QLQ-C30

Parameter	Abbreviation	Number of items	Range*	Item numbers
Global health status/Quality of life (QoL)				
Global health status/QoL	QL	2	6	29, 30
Functional items				
Physical functioning	PF	5	3	1-5
Role functioning	RF	2	3	6, 7
Emotional functioning	EF	4	3	21-24
Cognitive functioning	CF	2	3	20, 25
Social functioning	SF	2	3	26, 27
Symptom items				
Fatigue	FA	3	3	10, 12, 18
Nausea and vomiting	NV	2	3	14, 15
Pain	PA	2	3	9, 19
Dyspnea	DY	1	3	8
Insomnia	SL	1	3	11
Appetite loss	AP	1	3	13
Constipation	CO	1	3	16
Diarrhea	DI	1	3	17
Financial difficulties	FI	1	3	28

*Range is the difference between the possible maximum and the minimum response

test, accordingly. Statistical significance was determined by a two-tailed p-value<0.05.

Results

Demography of patients

A total of 18 cancer patients, 11 male and 7 female, from Hayandra Clinic, Hayandra Peduli Foundation, were included in the analysis (Figure 1). One patient had stage I cancer, two patients had stage II cancer, two patients had

stage III cancer, and 13 patients had stage IV cancer. The mean age of the patients was 56±15 years (Table 2). For variables with only two data points, the central tendency is described using the median without interquartile range.

The mean cell number of all patients for ICT 1 was 1.39×10^9 cells and ICT 6 was 1.34×10^9 cells. The average viability of all patients for ICT 1 was 95.64% and ICT 6 was 95.34%. The mean cell number based on cancer staging is shown in Table 2.

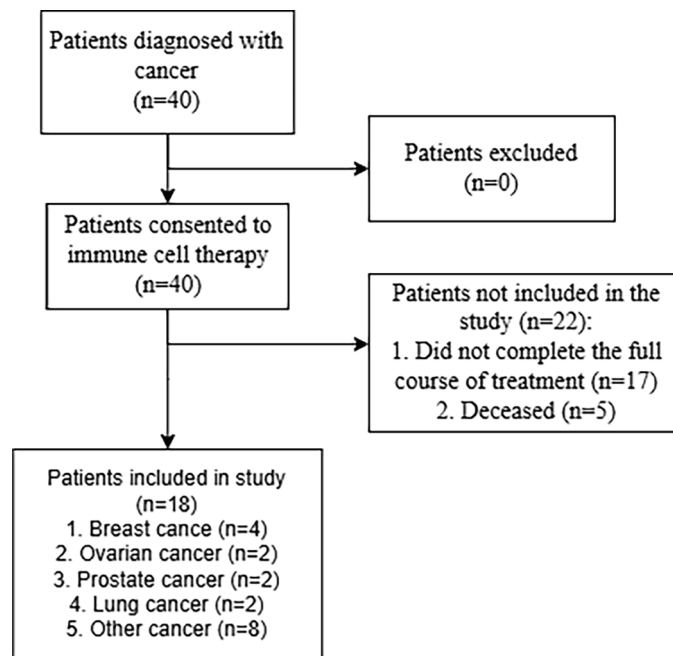


Figure 1 Flowchart of patient recruitment

Table 2 Demography of cancer patients and ICT cell number

Stage	Age (years)	Sex (%)	Cell ($\times 10^9$ cells)	Viability (%)
I (n=1)	75	Male: 1 (100)	1.18	96.23
II (n=2)	39	Male: 1 (50) Female: 1 (50)	1.95	94.41
III (n=2)	39.5	Female: 2 (100)	1.45	95.18
IV (n=13)	59.31±12.8	Male: 9 (69.23) Female: 4 (30.77)	1.32	95.88

ICT=immune cell therapy

Patients' quality of life before and after immune cell therapy

Quality of life and functional scale

The data showed an overall trend of improvement in global health status and the functioning aspects of the patients (Table 3). Median quality of life (QoL), physical functioning (PF), role functioning (RF), cognitive functioning (CF), and social functioning (SF) scores improved after treatment with ICT. There was a slight decrease in the median emotional functioning (EF) score. However, data in all the variables were not normally distributed, and statistical analyses showed non-statistically significant differences in QoL and functional scores before and after 6 doses of ICT.

Symptom scales

All patients showed improvements on the symptom scales. Notable improvements in symptom scoring were found in the fatigue and pain components. Fatigue score improved from 33.33 (27.78) to 22.22 (33.33) (p -value=0.24). Pain score improved from 8.33 (16.67) to 0 (16.67) (p -value=0.055). Other components in symptom scoring did not deteriorate and remained 0.

Patients' quality of life before and after immune cell therapy by staging

Quality of life and functional scale

Overall, patient quality of life showed an improvement from 70 (22.5) before ICT treatment to 80 (40) after the 6th ICT, although the difference observed was not statistically significant. Improvement in QoL score was also seen in the subgroup analysis of stage IV cancer patients. The mean QoL score increased from 63.85 ± 19.81 to 73.08 ± 20.57 , albeit insignificantly. Due to the limited number of subjects with stage I, II, and III cancer, subgroup statistical analysis was only conducted for patients with stage IV cancer.

Symptom scales

Trends of improvements were found in stage II and IV cancer. In stage II cancer, improvements were found in fatigue score from 5.55 (11.11) to 0; insomnia score from 16.67 (33.33) to 0; and constipation from 16.67 (33.33) to 0. No deterioration of score was found in the other scales. Stage IV cancer showed improvements in fatigue score from 33.33 (16.67) to 27.35 (24.27) (p -value=0.24); pain score from 24.36 (31.63) to 11.54 (19.70); dyspnea score from 5.13 (12.52) to 2.56 (9.25) (p -value=0.331); appetite score from 17.95 (32.25) to 15.38 (22.01) (p -value=0.772); constipation score from 12.82 (28.99) to 7.69 (19.97) (p -value=0.083); diarrhea score from 5.13 (12.52) to 2.56 (9.25) (p -value=0.579); and financial difficulty score from 15.38 (22.01) to 12.82 (21.68) (p -value=0.717).

Adverse events

The reported adverse events after ICT treatment for the patients are shown in Table 5. Almost half of the patients experienced fatigue ($n=8$, 44.4%), followed by fever and chills ($n=5$, 27.8%), and only one patient experienced nausea (5.6%) after ICT treatment. All reported adverse events subsided, with the longest duration being two days. Table 5. Adverse events after ICT treatment.

Discussion

Immune cell therapy (ICT) has been studied and utilized to boost immune responses externally by supplying desired functional anti-cancer immune cells. This occurs through the reinvigoration of pre-existing immune responses and also activates new immune responses for anti-tumor activity. The current ICT utilized in this study is considered a low-risk ICT, as described by Han et al (2024). It is considered a low-risk ICT due to the use of autologous immune cells to eliminate cancer cells with safer and fewer adverse effects¹⁴.

Table 3 Cancer patients' quality of life scoring components

QoL Score	Start of ICT treatment	Endpoint	p-value
	Median (IQR)	Median (IQR)	
Global health status	70 (22.5)	80 (40)	0.126 ^a
Physical functioning	76.67 (43.33)	83.33 (26.67)	0.213 ^a
Role functioning	66.67 (54.17)	91.67 (37.5)	0.141 ^a
Emotional functioning	100 (8.33)	91.67 (16.67)	0.87 ^a
Cognitive functioning	100 (20.83)	100 (16.67)	0.916 ^a
Social functioning	100 (33.33)	100 (33.33)	0.766 ^a
Fatigue	33.33 (27.78)	22.22 (33.33)	0.24 ^a
Nausea and vomiting	0 (4.17)	0 (16.67)	0.655 ^a
Pain	8.33 (16.67)	0 (16.67)	0.055 ^a
Dyspnea	0 (0)	0 (0)	0.317 ^a
Insomnia	0 (33.33)	0 (41.67)	0.732 ^a
Appetite loss	0 (8.33)	0 (33.33)	1 ^a
Constipation	0 (8.33)	0 (0)	0.083 ^a
Diarrhea	0 (0)	0 (0)	0.564 ^a
Financial difficulties	0 (33.33)	0 (33.33)	0.792 ^a

^aWilcoxon W test, ICT=immune cell therapy

Comparison of the ICT cell number in every cancer stage

Patients with stage IV cancer had a lower mean cell number compared to patients with stage II and stage III cancers. In stage IV cancer, the metastasis of cancer cells suppressed the production and activity of immune cells, as reported by Fernandez et al (2020)¹⁵. Moreover, patients with advanced metastatic tumors experienced lymphopenia, which produced a lower immune cell number for ICT. Therefore, a lower immune cell number was obtained in stage IV cancer patients¹⁶. A notable finding in our study is that the mean cell number of stage IV cancer was higher compared to our stage I cancer patient. Although our stage I cancer patient was only one patient compared to 13 stage IV cancer patients, the stage I cancer patient had chronic lymphocytic leukemia (CLL), which explains the low cell number for ICT. It has been well-established that patients with CLL experience autoimmune cytopenia and autoreactive leukemic cells due to the defective

immune cells¹⁷. Thus, the processing of immune cells for ICT produces lower cell numbers in the patient with CLL compared to other cancer types.

Quality of life and functional scale comparison of cancer patients

A QoL Saudi Arabian study conducted in 2019, which also used EORTC QLQ-C30, found that QoL did not differ significantly between stage A (stage 0–2) and stage B (stage III and IV) breast cancer. However, the mean QoL scores were low compared to our patients at all cancer stages after the ICT regimen¹⁸. Furthermore, the difference in mean QoL score of stage IV cancer patients in this study was around 10 points. It was suggested that a ≥ 10 -point difference in EORTC-QLQ-C30 should be evaluated, as it may be clinically important¹⁹. However, this finding should also take into account the limited number of subjects.

Among the components of the functional scale, trends of improvements were seen in physical and role functioning, while a downtrend was seen in the emotional

Table 4 Cancer patients’ quality of life scoring components based on staging

QoL score	Staging								p-value
	I (n=1)		II (n=2)		III (n=2)		IV (n=13)		
	Start of ICT treatment	Endpoint	Start of ICT treatment	Endpoint	Start of ICT treatment	Endpoint	Start of ICT treatment	Endpoint	
Global health status	70	80	90	100	90	90	63.85±19.81	73.08±20.57	0.224 ^a
Physical functioning	100	100	100	100	100	1010	60 (33.33)	73.33 (23.33)	0.213 ^b
Role functioning	66.67	83.33	100	100	100	100	56.41±24.09	69.23±35.52	0.183 ^b
Emotional functioning	100	100	83.33	100	87.5	87.5	100 (8.33)	91.67 (12.5)	0.027 ^b
Cognitive functioning	100	100	91.67	100	83.33	83.33	100 (25)	83.33 (16.67)	0.684 ^b
Social functioning	100	100	100	100	100	83.33	83.33 (41.67)	83.33 (33.33)	0.778 ^b
Fatigue	33.33	33.33	5.55 (11.11)	0 (0)	16.67 (33.33)	16.67 (33.33)	33.33 (16.67)	27.35 (24.27)	0.24 ^b
Nausea and vomiting	0	0	0 (0)	0 (0)	0 (0)	0 (0)	11.54 (23.94)	12.82 (20.59)	0.668 ^b
Pain	0	0	0 (0)	0 (0)	0 (0)	0 (0)	24.36 (31.63)	11.54 (19.7)	0.106 ^b
Dyspnea	0	0	0 (0)	0 (0)	0 (0)	0 (0)	5.13 (12.52)	2.56 (9.25)	0.331 ^b
Insomnia	0	0	16.67 (33.33)	0 (0)	33.33 (0)	50 (33.33)	15.38 (25.88)	15.38 (29.24)	1 ^b
Appetite loss	0	0	0 (0)	0 (0)	0 (0)	0 (0)	17.95 (32.25)	15.38 (22.01)	0.772 ^b
Constipation	0	0	16.67 (33.33)	0 (0)	0 (0)	0 (0)	12.82 (28.99)	7.69 (19.97)	0.083 ^b
Diarrhea	0	0	0 (0)	0 (0)	0 (0)	0 (0)	5.13 (12.52)	2.56 (9.25)	0.579 ^b
Financial difficulties	0	0	0 (0)	0 (0)	50 (33.33)	50 (33.33)	15.38 (22.01)	12.82 (21.68)	0.717 ^b

^apaired t- test, ^bWilcoxon W test, ICT=immune cell therapy

^cComparative statistics were only performed for stage IV cancer patients due to limitations in sample size

and cognitive functioning aspects, though the differences observed were statistically insignificant. The results are similar when compared to the scores of the Saudi Arabian study, wherein there were no significant differences in mean scores of the functional scales between stage A and stage B breast cancer patients¹⁸. Again, the mean scores of the functional scales in the Arabian study were relatively lower compared to our patients. Instead of cancer stage, the Arabian study found that QoL and functioning scores were affected by age. Patients aged ≤50 years old had

better scores in the QoL and functioning scales, which were statistically significant.

Table 5 Adverse events after ICT treatment

Adverse events	n (%)
Fatigue	8 (44.4)
Fever and chills	5 (27.8)
Nausea	1 (5.6)

ICT=immune cell therapy

Symptom scale comparison of cancer patients

Our data reported overall improvements in the symptom scales of all stages in cancer patients. Trends of improvement were observed in stage IV cancer patients' quality of life post-ICT, although not statistically significant. It has been reported in several studies that post-ICT advanced cancer patients' quality of life improved despite the lower cell number in ICT of advanced cancer patients. The rationale behind the improvement of the symptom scale in the advanced cancer patients is the ability of ICT to replenish the low number of CD4+ T cells, as cancer patients are known to experience lymphopenia, with a particularly low number in the CD4+ subtype²⁰. Another rationale is the ability of ICT to replace defective immune cells in cancer patients. Thus, improvements in the immune system reduced cancer-related fatigue, due to defective inflammation in cancer patients, and helped reduce the risk of infections¹⁴.

Possible mechanisms

ICT primarily targets solid tumor cells via non-MHC-restricted killing, mediated by perforin and Fas ligand. ICT can also enhance the effects of chemotherapy by eliminating residual or drug-resistant tumor cells. Additionally, ICT may also reestablish immune system function by secreting cytokines, such as IL-2, IFN- γ , and TNF- α ^{21,22}.

Similarly, ICT demonstrates direct cytotoxicity and modulation of immune molecules in hematological malignancies, such as CLL. Remarkably, the killing of CLL cells appears independent of the Fas/CD95 pathway. The secretion of interferon- γ by ICT cells also upregulates adhesion molecules (CD54 or ICAM-1), which is helpful in targeting CLL, as CLL cells typically express the molecules at low levels²³.

However, expansion-based ICT also faces several limitations. First, the time required to expand the cells to

achieve a therapeutic amount of lymphocytes renders it unsuitable for patients with rapidly worsening conditions. The cells may also degrade in quality, with poor cytotoxicity and lifespan being observed with prolonged in-vitro expansion. Furthermore, TIL may not be suitable for all types of solid tumors. These constraints may be found with other modalities that also utilize cellular expansion, such as tumor-infiltrating lymphocytes (TIL)^{24,25}. Clinical evidence supporting ICT in certain malignancies, such as CLL, also remains limited. Notably, no TIL therapy has yet received FDA approval.

Limitations of the study

Our study still has limitations, mainly in the small sample size, especially in stage I, II, and III cancers. Moreover, our study did not control for any confounding factors, such as patients' diet, lifestyle, and exercise. Thus, further studies with larger sample sizes, distributed samples among stages, and controlled confounding factors are needed.

Conclusion

Patients showed improvements in global health status, functional outcomes, and symptom scores following six ICT treatments. However, these findings are not statistically significant, presumably due to the small sample size. Therefore, these findings should be interpreted cautiously. Further studies with larger sample sizes are needed to confirm the current findings.

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Conflict of interest

The authors declare that they have no conflicts of interest to declare.

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