Original Article :

Complications and patient quality of life after hematopoietic stem cell transplantation

Roai Gassas[1*], Mohamed Eldigire Ahmed[2]

1. Faculty of Applied Medical Sciences, Nursing Department, King Abdulaziz University, Rabigh, Saudi Arabia
2. King Saud bin Abdulaziz University for Health Sciences. Kingdome of Saudi Arabia, Jeddah City

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Corresponding Author:
Roai Gassas, Faculty of Applied Medical Sciences, Nursing Department, King Abdulaziz University, Rabigh; Saudi Arabia, E-mail : rgassas@kau.edu.sa

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Abstract

Background and Aims:
Hematopoietic stem cell transplantation (HSCT) is a potential cure for genetic disorders, leukaemia, and lymphoma. Nevertheless, the transplant process is difficult and exposes the patient to significant toxicity, which can lead to early and late transplant complications in both autologous and allogeneic transplants. Thus, the transplant process affects the patients' physical and psychological quality of life. The study aimed to investigate the quality of life of patients following HSCT and pinpoint the most prevalent complications

Methods:
A cross-sectional descriptive design was utilized. The study included 45 adult patients who underwent HSCT in 2023. Data were collected with the Functional Assessment of Cancer Therapy—Bone Marrow Transplant (FACT-BMT) quality of life instrument (Arabic version).

Result:
Most patients (73.3%) had autologous transplants, and 26.7% had allogeneic transplants. Refractory disease was the main indication (46.7%) for HSCT. Social/family well-being was the highest-rated domain, and physical well-being was rated the lowest. Having pain and needing to stay in bed were perceived as the most critical problems in the physical well-being domain.

Conclusion:
This research describes patients' quality of life after HSCT and the types of complications they experienced. Transplant is a major procedure that requires excellent preparation and follow-up, including input from different specialties to optimize patients' quality of life. This study assists in identifying patient perspectives on complications, enabling leaders to advance the current system of follow-up.

Keywords:
Fact-BMT, Quality of life, Arabic patients, Bone marrow transplant, Stem cell transplantation

Introduction:

Hematopoietic stem cell transplantation (HSCT) has been the standard treatment for malignant and non-malignant disorders for many years. HSCT can be either autologous, in which patients receive their own stem cells, or allogeneic, in which the patient receives stem cells from a donor. Despite advances in treatment and post-transplant follow-up, HSCT (especially allogeneic transplants) is still associated with many complications [1]. HSCT is considered the only cure for relapsed/refractory leukemia and lymphoma. Nonetheless, patients must undergo a long treatment course and risk complications that leave them psychologically vulnerable. This leads to poor outcomes, especially in the first years after the transplant [2]. Although the survival of patients who receive autologous and allogeneic transplants continues to increase, the mortality and morbidity rates remain high because of long-term complications. These include secondary cancer, late infections, psychosocial issues, sexual and fertility concerns, financial hardship, issues around returning to work or school, and a decrease in quality of life (QOL) [3].

QOL became an essential aspect for patients and treating physicians before proceeding with the transplant decision. Graft-versus-host disease (GVHD), the conditioning regimen, female sex, young age, receiving less social support, and pre-transplant psychological distress are predictors of various aspects of health-related QOL following HSCT [4]. The World Health Organization (2024) [5] defines QOL as an individual's perception of their position in life in the context of their culture and value system and in relation to their goals, expectations, standards, and concerns. In a prospective cohort study, Pasyar et al. [6] found that participants with higher pain and fatigue scores, as well as those with more nausea and vomiting, had higher anxiety levels, indicating that fatigue, pain, the severity and frequency of nausea, and the type of transplant are predictors of trait anxiety. In addition, the findings revealed a correlation between anxiety and pain, fatigue, nausea, and vomiting among the patients who survived. Fenech et al. [7] examined post-traumatic stress disorder (PTSD) symptoms in patients who underwent transplant for six months; they found that 92.3% experienced hypervigilance and avoidance symptoms and 76.9% experienced intrusion. Thus, QOL information is critical for the assessment of treatment effectiveness because improved overall survival is not the only criterion relevant to evaluating whether medical outcomes are successful [8]. Transplant counseling should begin as soon

as the decision is made to use this treatment to allow the patient to make choices without time pressure. This counseling should cover all transplant indications and potential risks, such as infertility, organ failure, and psychological issues. The counseling should not be limited to this information, as other risks may be involved depending on the patient's condition [9]. A report from four leading tertiary care HSCT centers in Saudi Arabia indicated that 6,184 HSCTs were performed between 1984 and 2016; 3,586 HSCTs were performed in adults, and 2,598 were performed in pediatric patients. Malignancy was the primary indication for transplantation. Limited bed capacity was the primary factor contributing to the low number of transplant cases despite Saudi Arabia being the largest Arabian Gulf country [10]. Furthermore, the demand for HCST is high. A recent systematic review showed that sickle cell disease (SCD) prevalence ranged from 0.24% to 5.8% across the Gulf Cooperation Council (GCC), whereas the sickle cell trait ranged from 1.02% to 45.8% [11]. Saudi Arabia has one of the world's highest rates of SCD, an inherited hemoglobinopathy, with up to 2.6% of the population affected [12]. This indicates the high need for transplants for malignant and benign disorders. Therefore, such a study is essential, especially in Saudi Arabia, where bone marrow transplantation is still developing, and baseline data on the Saudi population is needed.

Aim: This study explored patients' post-transplant QOL to identify the most common types of complications.

Methods:

Design: A cross-sectional, descriptive design was adopted because it provides data about the phenomena at a single time.

Sample: Purposive sampling was used to specifically select participants who fit the inclusion criteria, achieve the study's goal, and ensure that each participant's unique features are relevant to the study. The study encompasses adult patients who have undergone autologous or allogeneic transplants at Princess Norah Oncology Centre within the past 12 months. Patients must have completed a minimum of 100 days prior to enrolling. The study precluded pediatric patients and patients with diagnosed mental disorders to guarantee that the data accurately represented the experiences of participants without the potential confounding effects of developmental differences between children and adults and underlying psychiatric disorders. A total of 50 adults received autologous and allogeneic transplants in 2023. The statistical power level was set at 0.80 with an alpha of 0.05, and the sample size was calculated using G*Power 3.1. Assuming a significance level of 0.05, a

power of 0.80, and an effect size of 0.15 (medium), the minimum required sample size was 45 patients.

Instrument: The first part of the questionnaire concerned patients' demographic data, such as age, gender, and marital status. The second part measured patient QOL through the Functional Assessment of Cancer Therapy—Bone Marrow Transplantation (FACT-BMT) version 4 QOL instrument translated into Arabic. This scale is specifically created to evaluate health-related quality of life in patients undergoing bone marrow transplantation, addressing all concerns pertinent to the procedure. It is suitable for both autologous and allogeneic transplant recipients. It is extensively validated and universally utilized across various languages and cultures. The FACT-BMT has a total of 50 questions divided into four domains: physical well-being (PWB; 7 items), social/family well-being (SWB; 7 items), emotional well-being (EWB; 6 items); and functional well-being (FWB; 7 items). It also contains a section about additional concerns (23 items). Each item is rated on a 5-point Likert scale,0 = Not at all to 4 = Very much. Higher scores indicate better quality of life. The tool is valid and reliable, with a Cronbach's alpha range of 0.67 to 0.91 [13].

Data collection: Data was collected between December 2023 and March 2024. Patients were contacted for data collection 100 days after the transplant. Every eligible patient was contacted and requested to participate in the study. The researcher described the purpose of the study to each patient, emphasizing the significance of answering all questions, and then patients were given questionnaires in sealed envelopes. Patients were informed that questionnaires take approximately 10-15 minutes to complete. Some patients requested to take the questionnaire home to read and complete it at their convenience, and some completed the questionnaire on the spot. These patients who completed the survey did so in a private, quiet room, and if they had any questions, a researcher was available to clarify them. To ensure privacy and secrecy, patients were requested not to put their names or file numbers on the questionnaire and to place it in an envelope and seal it.

Setting: The research was conducted at the Princess Norah Oncology Center of King Abdulaziz Medical City. The center was established in 2001 and is located in Jeddah City. A variety of services are offered, including outpatient's clinic, daycare for chemotherapy administration, and inpatient treatment. The adult leukemia/BMT ward, established in September 2008, specializes in the treatment of adult patients with

benign and malignant hematological disorders. The BMT program initiated in March 2014 with autologous BMT, while allogenic transplantation commenced in 2016.

Data analysis: The mean score for each item and subscale on the FACT-BMT scale (Physical, Social/Family, Emotional, Functional Well-being, and Bone Marrow Transplant subscales) was calculated. Each item was evaluated using a five-point Likert scale, with scores ranging from 0 (not at all) to 4 (very much). Higher scores were indicative of an improved quality of life. A lower percentage of the mean score (%) indicated a worse quality of life, while a greater percentage indicated a better quality of life. The subscale's missing values were filled in by averaging the completed items. The questionnaire was excluded from the total score if more than half of the items on a subscale were absent. All data are displayed in tables.

Ethical approval: Data were collected from patients who agreed to participate in the study and signed an informed consent form. All participants were assured that they could withdraw from the study at any time without penalty or any effect on their treatment protocols. They were also informed that the study would pose no harm to them and that their information would be used solely for research purposes. Only the primary investigator had access to the data, which were stored in a locked cabinet after collection. The primary investigator will retain the data for five years, after which they will be destroyed. To ensure confidentiality, patients' names were replaced with identification numbers. The study was approved by the King Abdullah International Medical Research Centre Institutional Review Board (approval number: NRJ21J/060/03).

Results:

Table 1: Basic characteristics of participants.

Variable	N=45
Age[1]	41.0 (27.5-51.5)
Diagnosis	
HL	12 (26.7)
None HL	10 (22.2)
MM	13 (28.9)
Others	10 (22.2)
BMT Type	
Auto	33 (73.3)
Allo	12 (26.7)
Marital status	
Not married	14 (31.1)
Married	31 (68.9)
Number of children[1]	3.0 (0-4.0)
Disease status	
Relapsed	8 (17.8)
Refractory	21 (46.7)
Transplant up front	16 (35.6)
Education	
High school	11 (24.4)
College degree	27 (60.0)
Still in school	7 (15.6)
TBI based conditioning	
Yes	4 (8.9)

No	32 (71.1)
NA	9 (20.0)
Employment status	
Employed	15 (33.3)
Unemployed	19 (42.2)
Retired due to illness	4 (8.9)
Housewife	3 (6.7)
Retired	4 (8.9)

The median age of patients was 41 years. Approximately 48.9% of the patients had Hodgkin lymphoma (HL) and non-Hodgkin lymphoma. The sample mainly comprised patients who received autologous transplants (73.3%). Thirty-one patients were married, the population had an average of three children, and 60% of patients had a college education. Approximately half (46.7%) were refractory cases, and most did not require total body irradiation (TBI)-based conditioning.

Table 2: Physical well-being.

Item	Mean Score	% of Mean Score
PWB_1	1.44	36.11
PWB_2	2.02	50.57
PWB_3	2.04	51.11
PWB_4	2.43	60.80
PWB_5	1.84	46.11
PWB_6	2.20	55.00
PWB_7	2.42	60.56
Overall	2.05	51.25

Table 2 presents the patients' responses regarding physical well-being. The highest means were for the statements "I have pain" and "I am forced to spend time in bed" (60.80% and 60.56%, respectively). The statement "I have a lack of energy" had the lowest mean (1.44), followed by "I am bothered by side effects of treatment" (1.84).

Table 3: Social/family well-being.

Item	Mean Score	% of Mean Score
SWB_1	2.49	62.22
SWB_2	3.73	93.33
SWB_3	2.84	71.11
SWB_4	3.40	84.88
SWB_5	3.40	84.88
SWB_6	2.71	67.74
SWB_7	1.42	35.48
Overall	3.19	79.75

Table 3 describes the results for the social well-being of patients; the highest score was 93.33% for "I get emotional support from my family", and the lowest mean score was 1.42 for "I am satisfied with my sex life".

Table 4 Emotional well-being.

Item	Mean Score	% of Mean Score
EWB_1	2.24	56.11
EWB_2	3.23	80.68
EWB_3	3.36	84.09
EWB_4	2.86	71.59
EWB_5	3.42	85.56
EWB_6	2.87	71.67
Overall	2.92	73.00

The results for emotional well-being are displayed in Table 4. The statement "I worry about dying" was rated the highest, with a mean score of 3.42, followed by "I am losing hope in the fight against my illness", with a mean score of 3.36. "Feeling

sad" had the lowest mean (2.24).

Table 5 Functional well-being.

Item	Mean Score	% of Mean Score
EWB_1	2.24	56.11
EWB_2	3.23	80.68
EWB_3	3.36	84.09
EWB_4	2.86	71.59
EWB_5	3.42	85.56
EWB_6	2.87	71.67
Overall	2.92	73.00

Table 5 shows the result for functional well-being, which indicated that "I have accepted my illness" had the highest score (80.56%), whereas the lowest score (43.52) was related to "My work (including work at home) is fulfilling."

Table 6 Additional Concerns.

Item	Mean Score	% of Mean Score
BMT_1	3.17	79.17
BMT_2	2.04	51.11
BMT_3	2.73	68.33
BMT_4	1.78	44.44
C6	1.80	45.00
C7	2.11	52.78
BMT_5	2.53	63.33
BMT_6	1.50	37.50
BL4	1.45	36.21
BMT_7	1.02	25.61
BMT_8	3.39	84.66
BMT_9	0.29	7.22
BMT_10	2.98	74.43
Br1	3.04	76.11
BMT_11	0.98	24.44
BMT_12	1.11	27.84
BMT_13	1.89	47.22
BMT_14	0.68	17.05
B1	0.82	20.56
BMT_15	1.04	26.11
BMT_16	1.69	42.22
BMT_17	1.60	40.00
BMT_18	0.91	22.78
Overall	1.53	38.25

Regarding additional concerns, "I have confidence in my nurses" was ranked the highest (84.66%), whereas "I regret having the bone marrow transplant" was ranked the lowest (0.29).

Overall, social/family well-being was the highest-rated domain (3.19), whereas physical well-being was the lowest-rated domain (2.05).

Discussion:

This research describes patients' QOL after HSCT. Social/family well-being was the highest-rated domain, and physical well-being was rated the lowest. Regarding physical well-being, having pain and being forced to stay in bed were perceived as the most critical problems. In a similar context, Shanklin et al. [14] found that patients who received allogeneic transplants reported pain and fatigue as the top long-term complications, even 6 years after the transplant. Different from our study, Galvin et al. [15] followed patients with autologous and allogeneic transplants for 9 months and reported an increase in reported neuropathic symptoms for autologous

HSCT (P = 0.02). However, we believe that both groups reported high levels of pain due to the effects of conditioning chemotherapy. Conditioning regimens are used to create space in the bone marrow (BM) niches for the durable engraftment of stem cells/ hematopoietic stem cells. The toxicity of this regimen affects extramedullary tissues[16]. Most cases of conditioning-associated toxicity result from off-target effects, in which the agents harm cells that are not present in the BM [17]. Pain related to cancer or cancer treatment is a serious negative outcome. Among 12,019 cancer survivor respondents, 9.5% reported feeling pain, and it was significantly higher for survivors with poor physical or mental health [18].

The second domain showed high social well-being, and this can be explained by the classification of Saudi culture as collectivist[19]. Additionally, the influence of Islamic values, which promote interdependence and care among relatives, makes the family the primary source of emotional and social support. Therefore, the patients had good family support. Although social well-being was high, patients reported dissatisfaction with sexual function. Georges et al. [20] conducted a study that addressed late effects and QOL among patients with lymphoma and myeloma; among 389 patients, the most reported problem was sexual dysfunction.

Patients reported worries about dying and losing hope in fighting their disease. HSCT commonly affects psychological health, and patients can experience psychological challenges. Prior to transplantation, patients are evaluated by a psychiatric consultant for any preexisting mental illnesses. Nevertheless, unless the patient verbalizes or manifests symptoms, there is a lack of periodic follow-up by psychologists or psychiatrists' post-transplant. Patients may lack the requisite skills to effectively manage such prolonged and stressful situations, which can necessitate several months of partial recovery. Amonoo et al. [21] conducted a qualitative review that focused on negative emotional experiences after HSCT and found that feeling trapped, fear, guilt, discouragement, and powerlessness were frequently expressed; additionally, patients stated that their desire to engage in healthy behaviors crucial to their transplant recovery was hampered by negative emotional states. Furthermore, according to a systematic review by Di Giuseppe et al. [22], the rate of anxiety and depression was high among pediatric survivors compared with healthy children of the same age. All patients in this study were Muslims, and 80.56% stated that they had accepted their illness. Islam is an authentic religion that transcends all facets of existence, and the principles of Islam contribute to the treatment and prevention of despair. A devout Muslim holds the

belief in the unity of Allah as well as the conviction that the entirety of the universe is governed by Allah Almighty. They perceive life as a realm filled with trials and afflictions, exhibit patience in the face of life's challenges, find solace in remembering Allah, and place their complete trust in Allah Almighty [23].

Regarding additional concerns, only a few patients had regrets about undergoing the transplant. This finding is congruent with the patients' conditions, as transplantation is the only potential cure for several malignant conditions, such as lymphoma and leukemia[24].

The patients denied symptoms such as skin problems, tremors, shortness of breath, and frequent infections. This can be attributed to the fact that most patients had autologous transplants, and these types of problems are more common with allogeneic transplants. Furthermore, the data were collected within 1 year of transplantation, which illustrates the need for patient follow-up. Shanklin et al. [14] reported that the increasing cohort of HSCT survivors has raised the awareness of long-term and late effects. Comprehending potential complications facilitates the development of a post-transplant follow-up program and equips patients with the necessary knowledge to anticipate their experiences, thereby improving their decision-making abilities. Additionally, it allows the organization to adjust policies and procedures to meet the needs of patients, such as increasing the number of beds or offering mobile clinics to identify latent complications.

Limitation:

The generalizability of this study is mainly limited to patients with autologous transplants, as these patients were the predominant group in this cohort. Furthermore, this study is limited to one center located in the western region, and many of the patients treated in this center lived in other regions of the kingdom. In addition, because of the nature of the research design, the data were collected at a single time point; however, these patients might experience additional complications in the future, which necessitates the need for a longitudinal cohort.

Conclusion:

The study highlights patients' experiences and their perceptions of post-transplant complications within 1 year of their transplant. Transplantation is a life-saving procedure, but complications are unavoidable; balancing between the necessity of the transplant and the potential effect on patient QOL is a difficult decision for the patient and the treating physician. However, knowing about the expected outcomes is helpful for proper management

and establishing a multidisciplinary approach for follow-up and early detection of potential complications.

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Conflicts of interest: There are no conflicts of interest.

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