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Evaluation of Health Related Quality of Life Using Short-Form 36 Among Allogeneic Stem Cell Transplant Patients After at Least Two Years of Recovery: A Cross Sectional Observational Study

En Az İki Yıllık İyileşme Dönemi Ardından Allojenik Kök Hücre Nakli Hastalarında Kısa-Form 36 Kullanılarak Sağlıkla İlgili Yaşam Kalitesinin Değerlendirilmesi: Bir Kesitsel Gözlem Çalışması

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ABSTRACT Objective: The use of allogeneic stem cell transplantation (allo-SCT) is increasing and patients are facing physical and mental problems during and after this process. In this study, it was aimed to evaluate the quality of life (QoL) of the patients after at least two or more years from allo-SCT. **Material and Methods:** 51 transplant patients (TxPs) and 54 healthy controls included in the study. Participants were asked to fill Short Form-36 survey which evaluates QoL in eight main domains. Comparison between TxPs and healthy controls, correlation analyses between remission duration and well being, ROC analysis to find a cut-off value for returning to healthy days were performed. **Results:** TxPs reported worse QoL than healthy controls. In terms of sex only mental health domain was significantly different where female pariticipants showed better results (p=0.01). Acute or chronic graft versus host disease were not found to have an effect on QoL (p>0.05). Relapsed disease formation had a reducing effect in QoL. Transplant related complications, cytomegalovirus reactivation, conditioning regimen type did not show statistically significant effect on QoL. As the results of the ROC analyses, post-transplant 46th month is found to be a turning point for recovery to healthy status with 68.6% sensitivity and 62.5% spesificity when patients start to realize they regain their health. **Conclusion:** Allo-SCT has negative effects on patients' physical and social life. In this study it was found that patients start to report similar results to healthy controls in health change approximately after two years from transplantation and the negative effects of transplant were almost completely ceased by 3.5 years.

Keywords: Allogeneic stem cell transplantation; quality of life; surveys and questionnaries

ÖZET Amaç: Allojenik kök hücre nakli [allogeneic stem cell transplantation (allo-SCT)] kullanımı giderek artmaktadır. Hastalar bu süreç boyunca ve sonrasında, fiziksel ve ruhsal sorunlarla karşı karşıya kalmaktadır. Bu çalışmada, allo-SCT'den en az 2 yıl sonra hastaların yaşam kalitesinin [quality of life (QoL)] değerlendirilmesi amaçlanmıştır. **Gereç ve Yöntemler:** Çalışmaya 51 nakil hastası [transplant patients (TxPs)] ve 54 sağlıklı kontrol dâhil edildi. Katılımcılardan QoL'yi 8 ana alanda değerlendiren Kısa Form-36 anketini doldurmaları istendi. TxPs ve sağlıklı kontroller arasında karşılaştırma, remisyon süresi ile iyilik hâli arasında korelasyon analizleri, sağlıklı günlere dönüş için bir eşik değeri bulmak için ROC analizi yapıldı. **Bulgular:** Çoğunlukla TxPs, sağlıklı kontrollerden daha kötü QoL bildirdi. Cinsiyet açısından tek fark ruh sağlığı karşılaştırmasında bulundu ve kadın katılımcıların daha iyi sonuçlar verdiği gözlemlendi (p=0,01). Akut veya kronik graft versus host hastalığının QoL üzerinde bir etkisi bulunmamıştır (p>0,05). Nükseden hastalık oluşumu QoL'de azaltıcı bir etkiye sahip olarak bulundu. Nakil ile ilgili komplikasyonlar, sitomegalovirüs reaktivasyonu, hazırlık rejimi tipi, QoL üzerinde istatistiksel olarak anlamlı bir etki göstermedi. ROC analizlerinin sonuçlarına göre %68,6 sensitivite ve %62,5 spesifite ile transplant sonrası 46. ay, hastaların sağlıklarına kavuştuklarını fark etmeye başlamaları açısından eşik değeri olarak bulunmuştur. **Sonuç:** allo-SCT'nin hastaların fiziksel ve sosyal yaşamları üzerinde olumsuz etkileri vardır. Bu çalışmada, hastaların nakilden yaklaşık 2 yıl sonra sağlık değişikliğinde sağlıklı kontrollere benzer sonuçlar vermeye başladıkları ve 3,5 yıl sonra naklin olumsuz etkilerinin neredeyse tamamen ortadan kalktığı bulunmuştur.

Anahtar Kelimeler: Allojenik kök hücre nakli; yaşam kalitesi; sörveyler ve anketler

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The use of allogeneic stem cell transplantation (allo-SCT) in hematologic disorders is increasing day by day with the ease of finding unrelated donors, the increase in haploidentical transplantations, and the application of the reduced intensity conditioning (RIC) regimen which makes allo-SCT suitable for all age groups. Considering that the conditions of care after allo-SCT have improved greatly today, it has become easier to convince patients for transplantation. Patients should be fully aware of the early and late complications that may develop after transplantation, at the decision stage before transplantation.[1] Early-period complications that negatively affect post-transplant (Tx) life are acute graft versus host disease (GVHD), early-stage chronic GVHD, engraftment failure, and opportunistic infections [cytomegalovirus (CMV) and Epstein-Barr virus], while late-stage chronic GVHD, complications such as aseptic necrosis due to drugs such as steroids, and psychosocial regression are late-period complications.[2]

Patients who deal with such early and late complications in the first one or two years after the Tx usually struggle to return to their normal social lives at least two years after the Tx.[3] While many patients achieve a return to social life after this effort, a small number of patients cannot pass this stage spiritually and have to deal with a number of psychological problems ranging from anxiety disorders to depression in a chronic way.

In the assessment of quality of life (QoL), Short-Form 36 (SF-36) is one of the most useful questionnaires that can be easily used in all languages, and both its application and understanding are close to ideal.[4] The use of Likert-type scaling and the simple and understandable nature of the questions allow this survey to be easily applied to all age groups. With this questionnaire which consists of eight domains, psychosocial and functional results can be obtained in the healthy population or in patients who are undergoing or have undergone a certain treatment process.

In this study, it was aimed to evaluate the QoL in Tx patients (TxPs) who spent the first 2 years without primary disease relapse after allo-SCT and also to analyze their ability to re-participate in social life physically and mentally.

MATERIAL AND METHODS

This study was conducted between January 2022 and May 2022 at a tertiary hospital. This study included 51 patients who underwent allo-SCT and had at least two years of convalescence, and 54 healthy controls. The control group was randomly selected, healthy volunteers who were able to participate in the daily activities. Patients were asked to participate in this study during their outpatient clinic visits at the hematology department. Informed consent forms were obtained from the individuals and the study protocol was approved by the İstanbul Medeniyet University Göztepe Training and Research Hospital Clinical Research Ethics Committee (date: June 29, 2022, no: 2022/0405). All reported research involving "Human beings" conducted in accordance with the principles set forth in the Helsinki Declaration 2008.

Volunteered patients and healthy controls were asked to fill the SF-36 survey which is a self-administered 36 item questionnaire that assesses the individual's health related QoL (HRQoL) in eight main domains. The original text of the SF-36 survey has been translated into Turkish by sworn translators and its reliability has been proven by studies conducted in the Turkish population.[5] Turkish version is available on numerous sources.[6] The SF-36 includes eight domains that evaluates patient-reported physical and mental health (MH): physical functioning (PF), role limitation due to physical problems (RP), role limitation due to emotional problems (RE), energy and vitality (VT), MH, social functioning (SF), bodily pain (BP), and general perception of health (GH).[7] The SF-36 also includes another item that assesses an individual's health change (HC) in the last year.[8,9] For each domain patients answers were transformed into scales scored as 0 indicates the least and 100 represents the most healthy status.

Further data about the patients' clinical condition including presence of acute or chronic GVHD, occurrence of complications, CMV reactivation status, presence of steroid treatment, applied conditioning regimen type and relapsed disease history were obtained from the hospital's electronic data system and patient files.

STATISTICAL ANALYSES

All data was collected in Excel 2010 (Microsoft Corporation, Redmond, WA, USA) 2010. Statistical analyses were performed in SPSS version 26.0 (IBM Corporation, Armonk, NY, USA). Descriptive statistics (means, standard deviation, frequency) and distribution of the data were reported using the Shapiro-Wilk Test. Student's t-test was used to estimate associations. Normality tests were performed and Spearman's correlation analysis was performed to determine the relation between two quantitative data groups. Significance level was evaluated as $p<0.05$. ROC analysis was performed to find a cut-off value in days for the domains.

RESULTS

Fifty one patients who remained in remission for at least two years after allogeneic transplantation and 54 healthy control subjects were included in the study. Fifty one patients in the study were transplanted from related or unrelated donors due to various hematological diseases (n=40 related, n=11 unrelated). Duration of remission after Tx of the patients was 54.72±20.93 months in mean value; 58.8 months in median with 25.86 months at least and 94.46 months at most. Characteristics of the study population were shown in Table 1. Sociodemographic characteristics of the TxPs and healthy controls were not different ($p>0.05$).

TABLE 1: Characteristics of the study population.

Variables			TxPs (n=51)
Mean age; years±SD	TxPs		45.94±16.96
	Healthy controls		37.52±11.26
Sex; n (%)	TxPs	Male	33 (64.7)
		Female	18 (35.3)
	Healthy controls	Male	25 (49)
		Female	26 (51)
Diagnosis; n (%)	AML		19 (37.3)
	ALL		12 (23.5)
	NHL		3 (5.9)
	AIHA		5 (9.8)
	MDS		6 (11.8)
	CIMF		2 (3.9)
	HLH		3 (5.9)
	MM		1 (2)
Donor; n (%)	Related		40 (78.4)
	Unrelated		11 (21.6)
Relapsed disease; n (%)	Yes		6 (11.8)
	No		45 (88.2)
Acute GVHD; n (%)	Yes		17 (33.3)
	No		34 (66.7)
Chronic GVHD; n (%)	Yes		20 (39.2)
	No		31 (60.8)
Complication; n (%)	Yes		23 (45)
	No		28 (55)
CMV reactivation; n (%)	Yes		30 (58.8)
	No		21 (41.2)
Conditioning regimen; n (%)	MAC		26 (51)
	RIC		25 (49)
Steroid use; n (%)	Yes		26 (51)
	No		25 (49)

TxPs: Transplant patients; SD: Standard deviation; AML: Acute myeloid leukemia; ALL: Acute lymphoblastic leukemia; NHL: Non-hodgkin lymphoma; AIHA: Autoimmune hemolytic anemia; MDS: Myelodysplastic syndromes; CIMF: Chronic idiopathic myelofibrosis, HLH: Hemophagocytic lymphohistiocytosis; MM: Multiple myeloma; GVHD: Graft versus host disease; MAC: Myeloablative conditioning; CMV: Cytomegalovirus; RIC: Reduced intensity conditioning.

Comparison of TxPs and healthy subjects in terms of SF-36 domains was demonstrated in with the mean values Table 2. Statistically significant differences were found between the two groups in PF, RP, RE, VT, MH, GH and HC domains in which TxPs patients reported worse scores than healthy controls (p values; 0.048, 0.039, 0.020, 0.002, 0.001, 0.013, 0.001 respectively). Differences in SF and somatic pain domains were not statistically significant between the groups (p values; 0.107 and 0.615 respectively).

Among TxPs, statistically siginifant difference in terms of sex was found in only MH domain (61.94±18.63 for male and 75.11±15.01 for female, $p=0.01$) (Supplement 1).

There was no significant difference between the groups in terms of acute or chronic GVHD, details of chronic GVHD is shown in Table 3. Patients in remission had statistically significantly higher PF, RP, VT, MH, SF and BP domain scores than the relapsed patients (p values; 0.004, 0.009, 0.005, 0.012, 0.030, 0.001 respectively) (Table 4).

RIC or myeloablative conditioning regimens used for allo-SCT had no significant impact on the SF-36 domains (Supplement 2). Occurence of allohematopoietic SCT (HSCT) related complications (veno-occlusive disease, thrombotic microangiopathy, hemorrhagic cystitis, aseptic necrosis of joints etc.) did not have statistically significant effect on SF-

TABLE 2: Comparison of SF-36 domain scores between the transplant patients and the control group.

SF-36 domains	Transplant patients X̄±SD	Control group X̄±SD	p*
Physical functioning	82.65±23.60	91.39±12.34	0.048
Role limitation due to physical problems	69.61±41.62	89.81±19.13	0.039
Role limitation due to emotional problems	69.92±40.14	89.49±20.31	0.020
Energy and vitality	61.08±20.31	72.41±16.12	0.002
Mental health	66.59±18.41	77.81±12.61	0.001
Social functioning	76.71±23.71	83.98±19.78	0.107
Bodily pain	78.13±28.43	83.93±17.71	0.615
General perception of health	62.91±22.81	74.25±16.35	0.013
Health change	79.41±24.34	58.33±20.02	0.001

SF-36: Short-Form 36; SD: Standard deviation. *p<0.05

SUPPLEMENT 1: Comparison of SF-36 domain scores among transplant patients in terms of sex.

SF-36 scales	Male n=33	Female n=18	p*
Physical functioning	85.76±20.88	76.94±27.66	0.228
Role limitation due to physical problems	71.21±41.51	66.67±42.87	0.637
Role limitation due to emotional problems	69.68±41.13	70.35±39.42	0.912
Energy and vitality	59.70±18.66	63.61±23.37	0.573
Mental health	61.94±18.63	75.11±15.01	0.015
Social functioning	76.89±24.43	76.38±23.04	0.807
Bodily pain	80.22±26.63	74.30±31.92	0.505
General perception of health	65.45±22.16	58.26±23.89	0.224
Health change	77.27±24.49	83.33±24.25	0.386

SF-36: Short-Form 36. *p<0.05

TABLE 3: Comparison of SF-36 domain scores between the TxPs with/without chronic GVHD.

SF-36 domains	TxPs without chronic GVHD X̄±SD	TxPs with chronic GVHD X̄±SD	p*
Physical functioning	85.32±22.83	78.50±24.76	0.319
Role limitation due to physical problems	72.58±39.45	65±45.45	0.531
Role limitation due to emotional problems	73.10±37.93	64.99±43.89	0.486
Energy and vitality	60.48±22.81	62±16.17	0.798
Mental health	67.10±18.98	65.80±17.95	0.809
Social functioning	78.62±21.21	73.75±27.47	0.479
Bodily pain	80.40±27.94	74.62±29.56	0.484
General perception of health	64.51±24.19	60.43±20.85	0.539
Health change	79.03±22.45	80±27.62	0.891

SF-36: Short-Form 36; GVHD: Graft versus host disease; TxPs: Transplant patients; SD: Standard deviation. *p<0.05

TABLE 4: Comparison of SF-36 domain scores between the transplant patients with/without relapsed disease formation.

SF-36 scales	Without relapsed disease (n=45)	With relapsed disease (n=6)	p*
Physical functioning	87.67±15.86	45±37.81	0.004
Role limitation due to physical problems	75±38.43	29.17±45.87	0.009
Role limitation due to emotional problems	74.06±37.53	38.88±49.06	0.070
Energy and vitality	64.11±18.95	38.33±16.02	0.005
Mental health	67.29±18.74	61.33±16.13	0.378
Social functioning	79.72±22.81	54.16±18.81	0.012
Bodily pain	82.38±23.87	46.25±41.10	0.030
General perception of health	67.86±19.13	25.83±10.68	0.001
Health change	79.44±24.59	79.17±24.58	0.936

SF-36: Short-Form 36. *p<0.05

SUPPLEMENT 2: Comparison of SF-36 domain scores between use of two different conditioning regimens.

SF-36 scales	Conditioning regimens RIC X̄±SD n=25	MAC X̄±SD n=26	p *
Physical functioning	84.21±19.07	81.15±27.57	0.693
Role limitation due to physical problems	72±41.65	67.31±42.29	0.691
Role limitation due to emotional problems	74.56±37.62	65.37±42.67	0.408
Energy and vitality	58.60±19.92	63.46±20.77	0.421
Mental health	61.44±20.74	71.54±14.59	0.062
Social functioning	77±24.38	76.44±23.53	0.853
Bodily pain	78.4±31.61	77.88±25.65	0.611
General perception of health	62±21.88	63.79±24.07	0.727
Health change	75±25	83.65±23.39	0.192

SF-36: Short-Form 36; RIC: Reduced intensity conditioning; MAC: Myeloablative conditioning; SD: Standard deviation. *p<0.05

36 domains (Supplement 3). Statistically significant difference between patients with or without CMV reactivation and/or CMV disease after allo-SCT was not found in any SF-36 domains (p>0.05, n=30 and 21 patients respectively).

HC domain of the SF-36 was positively correlated with days after recovery (r=0.288, p=0.04). Correlation was depicted in Figure 1. A cut-off value of HC was found to be 1,369 days after the Tx, ROC curve was shown in Figure 2. Results of ROC analysis that indicates a cut-off value of HC in days showed 68.6% sensitivity and 62.5% spesificity.

SUPPLEMENT 3: Comparison of SF-36 domain scores between the transplant patients with/without occurence of transplant related complications.

SF-36 domains	TxPs without complications X̄±SD (n=28)	TxPs with complications X̄±SD (n=23)	p*
Physical functioning	82.78±23.65	81.67±25.43	0.964
Role limitation due to physical problems	70±42.17	66.67±40.82	0.751
Role limitation due to emotional problems	68.13±41.41	83.31±29.91	0.469
Energy and vitality	60.67±20.61	64.17±19.34	0.769
Mental health	67.21±18.44	62±19.22	0.618
Social functioning	77.22±22.65	72.91±32.99	0.904
Bodily pain	79.16±27.34	70.41±37.76	0.543
General perception of health	61.63±23.31	72.5±17.24	0.326
Health change	78.89±24.39	83.33±25.82	0.630

SF-36: Short-Form 36; TxPs: Transplant patients; SD: Standard deviation. *p<0.05

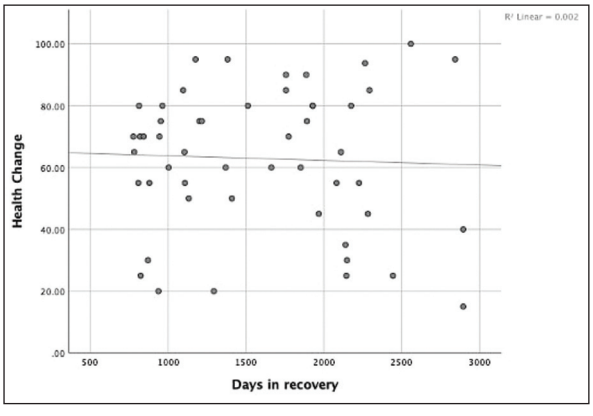

FIGURE 1: Correlation of health change domain scores and days in recovery.

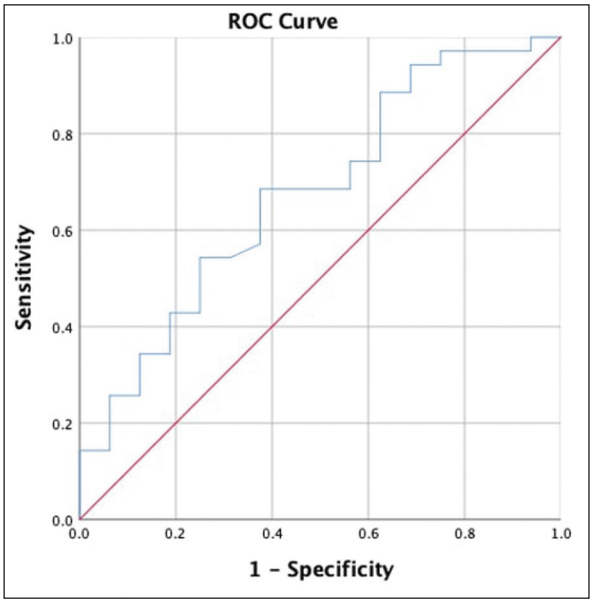

FIGURE 2: ROC curve of health change domain and days in recovery.

DISCUSSION

This study reports statistically significant differences in PF, RP, RE, VT, MH, GH and HC domains of the SF-36 between TxPs and healthy subjects. Among TxPs sociodemographic and clinical variables such as presence of acute or chronic GVHD, remission status, complication rate and CMV reactivation were evaluated in terms of their effect on the HRQoL, and none of these variables had a significant effect on QoL after Tx. A positive correlation with recovery day and HC domain was found and a quantitative cut-off value for HC domain which indicates a turning point for recovery to healthy status was demonstrated in this study.

In this study, all domains were statistically significantly different between TxPs and the control group, except SF and BP (p value; 0.107, 0.615 respectively). In a study by La Nasa et al., only difference in GH was statistically significant, while the rest of the domains showed no significant difference between the patients and the population norms (p=0.005).[10] The fact that this study gives different results than our study may be because they were conducted in different populations. Morishita et al. demonstrated that patients who are in pre-HSCT period had significantly lower SF-36 scores than mean normative values in all domains, which indicates the priorly decrease of the QoL in TxPs.[11] The results of their study also support what we obtained from our study.

In terms of sex; statistically significant difference was found in only MH domain which female participants showed better MH (p value, 0.015). In a study by Inoue et al., a similar result was found between SF-36 parameters and gender.[12] In a study by Demiral et al. which studies the SF-36 domains in Turkish population, they showed no difference of MH in general population in terms of sex and male participants reported better health except MH and VT domains, since their study can be counted as a baseline for the general Turkish population and it can be interpreted that male patients can be more prone to

get effected both physically and mentally from Tx.[5] La Nasa et al. reported no statistically significant difference of sex in terms of HRQoL outcome in their study where they used the The Functional Assesment of Cancer Therapy-Bone Marrow Transplant (FACT-BMT) Scale.[10] The positive MH status in female TxPs may be explained by maternal responsibility and also by their less participation in work life than men.

In terms of acute GVHD presence, the statistical difference was not significant between the patients, which can be comprehensible since acute GVHD is a situation that concerns approximately the first 100 days after the Tx and most probably will lose its negative effect within a period of two years. As a result of the Medical Outcomes Study Short-Form 12 (SF12) QoL questionnaire conducted by Lee et al. during the pre-Tx and post-Tx (sixth and twelfth months), no negative effect on health quality related to acute GVHD was found. The authors reported that the trial outcome index (TOI) of FACT-BMT is more sensitive for acute GVHD assessment and the TOI found that the most adverse effect of acute GVHD was 6 months after Tx.[13]

No statistical difference was observed between the SF-36 domains between TxPs with and without chronic GVHD. La Nasa et al. reported that patients who developed acute or chronic GVHD had worse GH scores.[10] Worel et al. indicated in their study that patients who have been in remission in more than two years with chronic GVHD showed impairments of role, PF and SF.[13,14] As it was aforementioned, Lee et al. suggested that SF12 was not sensitive in terms of assessing chronic GVHD either, since the SF12 and SF-36 can be homologous.[13] The reasons for the differences between the results of the mentioned studies and our results; it may be that the surveys used are different and the survey production times are different. Lee et al. also suggested that worse QoL measures after 6 months of the Tx as a consequence of chronic GVHD.[13] The reason for such a result in our study may be that the number of patients was not sufficient to infer statistical significance, and the results were affected by the time the questionnaire responses were received (at least two years after Tx).

We found that relapsed disease, which causes prolonged hospitalizations and recurrent chemotherapy processes, negatively affects SF-36 domains (except RE, MH and HC), as expected since they likely happened to have active disease formation during the time this study held. Similar to our results, in the study conducted by Sommer et al. with patient reported outcome (the European Organization for Research and Treatment of Cancer and Hospital Anxiety and Depression Scale) survey, it was shown that relapse and/or progressive disease affect HRQoL negatively.[15]

No statistically negative effect of post-Tx complications on QoL was observed. This is because; complications may be observed more frequently in the first two years after transplantation. It is obvious that serious complications such as aseptic necrosis due to steroid therapy used for GVHD will negatively affect the rest of the patients' lives. However, since only 2 cases of steroid-related aseptic necrosis were observed in the patients included in the study, statistical significance could not be determined. In a study by Dampier et al. showed that patients with sickle cell disease vaso-occlusive crisis, asthma, or avascular necrosis cause decrease in SF-36 domains.[16] The reason for the difference between the two studies may be the study populations' diseases' difference and the reversibility of the Tx complications.

CMV reactivation had no statistically significant effect on SF-36 domains. Since CMV reactivation does not cause end-organ damage like CMV disease, its negative effect on QoL is unexpected. It may cause negative effects on QoL by causing prolonged hospitalizations to receive parenteral anti-viral treatment. Decrease in CMV disease with the increase in the effectiveness of current CMV primary prophylaxis such as letermovir is a factor that ensures the QoL is not impaired in the long term. Yong et al. indicated that patients with clinically significant viremia and who received treatment have higher fatigue and lower SF scores.[17] While CMV reactivation rates were around 20-25% in the study population, almost no CMV disease was observed (end organ damage, retinitis, nephritis, colitis, etc.). Due to this decrease in the frequency of CMV disease, it is not expected to have a negative effect on HRQoL questionnaires.

HC domain assesses the perceived change in the health status over the last year. In this study the HC domain scores were positively correlated with the days after recovery. According to the result of ROC analysis, post-Tx 46th month was found as the day patients started to report health scores similar to the control group about their HC, which means TxPs regain their health at a wholesome level approximately three to four years after allo-HSCT. As we searched the literature, we were not able to find a similar report on HC however Le et al. suggested that allo-SCT patients showed excellent health and mental status after five years of Tx.[18] Also Worel et al. indicated that after two to five years after Tx 73% of the patients showed good global QoL whereas it was 79% after five years.[14] This finding on HC is unique and can guide both physicians and patients in pre- and post-Tx periods. QoL indices on SF-36 started to improve significantly from the average post-Tx two year and the level of change in health started to give almost the same results as healthy individuals on day 1,369.

LIMITATIONS

The number of participants in this study was limited to a small number, studies with a higher number of participants may provide information from more perspectives. Survey was conducted only with patients who were in remission for a minimum of 2 years after Tx, with more varied population characteristics further comparisons can be made. In this study SF-36 form was obtained from the patients at least two years after transplantation however not also right after their Tx. Therefore a comparison between the scales in two different time periods could not be performed. Also with the use of different questionnaires and the comparison between these two different scales can provide more reliable results. Patients' QoL is also affected by environmental living factors however we did not include such factors in the evaluation. Although there was a positive correlation between HC domain and days after recovery, the correlation coefficient was low.

CONCLUSION

The negative impact of allo-SCT in recipient's lives are obvious. However, considering the reason for allogeneic Tx, patients will have to endure these problems for a while. As a result of our study, it is observed that these problems, which adversely affect life after allogeneic Tx, decrease significantly as of the average post-Tx second year and almost completely cease by 3.5 years. By explaining this information to patients before the Tx and increasing their motivation, it can be more helpful in overcoming post-Tx complications.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

All authors contributed equally while this study preparing.

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