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Impact of chronic GVHD on quality of life after allogeneic HSCT

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The aim of this work was to identify possible relationships between chronic Graft versus host disease (GVHD), quality of life and psychosocial adjustment in patients submitted to hematopoietic stem cell transplantation (HSCT). A cross-sectional correlation study was performed of a sample of 62 patients submitted to HSCT. To collect data we used the following instruments: Questionnaire for post-HSCT data, SF-36, FACT-BMT, HAD and LSSI. The standardized instruments were applied individually and the results listed according to the recommendations made in the literature for each technique, with the exception of the Post-HSCT questionnaire; this was recorded and later the contents accurately transcribed in full and the replies were submitted to thematic content analysis. The results obtained in other instruments were statistically analyzed to assess associations between variables and their respective degrees of statistical significance. The variable GVHD is predictive of a poorer quality of life and greater susceptibility to anxiety ($\chi^2 = 4.56$; $p = 0.03$) as patients suffering from GVHD had lower rates in most domains of the quality of life. This finding of a drop in the quality of life after HSCT is an indicator that should be taken into account by the healthcare team, as HSCT is becoming more and more important as a therapeutic option for many serious diseases.

Keywords: *Hematopoietic stem cell transplantation; Quality of life; Graft versus host disease*

Introduction

Hematopoietic stem cell Transplantation (HSCT) is a procedure used to treat different types of cancers and hematologic malignant and nonmalignant diseases.(1)

With the technological advances and breakthroughs in the application of therapy over the last decade, the number of survivors of this technique has increased, which has resulted in more attention being paid to the quality of life of patients.(2)

Studies in Brazil(3-6) show the complexity and intensity of emotional, physical and occupational demands associated with HSCT and highlight the concern of the post-HSCT period, in particular in respect to potential deleterious effects in patients' lives that may result from this procedure. These changes may include worse psychiatric comorbidities (depression, anxiety), sexual dysfunction, negative effects on interpersonal relationships, limitations in recreation and leisure activities, changes in lifestyle, loss or impairment of productive capacity, unemployment, and loss of autonomy and some social roles. (7,8)

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After HSCT, complications linked to treatment, including chronic GvHD (Graft versus Host disease), may appear.(9)

Studies show that some aspects of the quality of life of patients who evolve with GvHD become significantly worse.(10-13) The greatest impairment is observed in patients with the chronic disease(14-16) even though this type of GvHD is associated with increased survival rates.(17)

This study aims to identify possible relationships between the onset of chronic GvHD, the quality of life and psychosocial adjustment of patients submitted to HSCT.

Methods

This clinical research was carried out using an exploratory correlational cross-sectional design, in which possible associations between different variables were investigated. This model stipulates that the start and the end of the data collection period of the study must be pre-established. In the current investigation the data collection period was set from January 1 to December 31 2005.

Sample

All patients who returned to the day hospital and outpatient clinic in the predetermined time interval and who met the inclusion criteria of the study were evaluated. The sample comprised 62 adults submitted to allogeneic HSCT at least one year prior to their interview and who were being attended in the day hospital or outpatient clinic of the HSCT Unit of Hospital das Clínicas of the Medical School in Ribeirão Preto, Universidade de São Paulo (HCFMRP-USP).

All patients submitted to related donor HSCT who were 21 years old or over and who had had at least three years of formal education were included in the survey if they accepted. Inclusion was considered irrespective of the type of graft employed (bone marrow, peripheral blood etc.) and whether they had chronic GvHD or not. All candidates had been conditioned in the unit itself (by myeloablative or non-myeloablative chemotherapy), had been followed up since transplant and were being attended in the day hospital and outpatient clinic during the data collection period. Patients were excluded if they had psychiatric disorders that affected their critical understanding of reality and/or cognitive abilities, thus impairing the application and comprehension of the assessment tools.

Instruments employed in data collection

Five instruments were utilized for data collection:

- Post-HSCT Recovery Questionnaire: This was translated and adapted to the Brazilian reality(6) and evaluated in a previous study.(17) It addresses issues related to general health and occupational and social adaptation, and aims to understand the resumption of daily life activities, demands experienced during this period, coping strategies, limitations acquired after HSCT, health problems and plans for the future.

- Generic Questionnaire on Quality of Life Related to Health (Medical Outcomes Study Short-Form Health Survey - SF-36): This is a generic tool that assesses the quality of life related to health. It is multidimensional, easy to administer and to understand. The instrument was validated in the Portuguese language.(18) It is composed of 36 questions that address the domains: physical functioning (10 items), physical aspects (4 items), pain (2 items), general health status (5 items), vitality (4 items), social aspects (2 items), emotional aspects (3 items) and mental health (5 items). The last question that compares the health at the time of the interview with one year before. Each domain is scored from 0-100; the higher the score the better the quality of life is preserved.

- Specific questionnaire to assess the quality of life of patients undergoing BMT (Functional Assessment Cancer Therapy - Bone Marrow Transplantation - FACT-BMT): This instrument consists of six domains: physical wellbeing, social/family wellbeing, relationship with doctor, emotional wellbeing, functional wellbeing and additional concerns. It is one of the most commonly used instruments to measure the functioning of patients submitted to HSCT. Cronbach's alpha internal consistency reliability estimate for the Portuguese version was 0.8816.(19) As in the previous questionnaire, the closer the score is to 100, the better the aspects of the domain are preserved.

- Hospital Anxiety and Depression Scale - HAD: Created with the aim of assessing symptoms of anxiety and depression, this scale consists of 14 multiple-choice questions divided into two subscales with seven items each: one for anxiety and the other for depression. The Portuguese version was validated among patients hospitalized on a general ward.(20) This scale measures emotional distress in hospitalized patients. Total scores range from 0 to 21 with the cutoff point identifying established anxiety and depression being seven.

- The Lipp Stress Symptoms Inventory for Adults - LSSI: This tool, validated for the Brazilian context, is fast to apply (about 10 minutes) and has been used in several clinical trials. It enables a precise diagnosis of the presence or absence of stress, at which stage the individual is (alert, resistant, near-exhaustion and exhausted) and whether the stress is manifested as physical or psychological symptoms.(21) It considers a maximum number of symptoms for each stage of stress (alert: six; resistant: three; near-exhaustion: nine, exhausted: eight), with scores above this value being considered indicative of the level of stress established.

A thorough review of hospital records was also carried out to collect clinical information relevant to this study. These clinical data included diagnosis, time after HSCT, complications and diseases associated with HSCT, such as chronic GvHD. The standardized instruments were applied individually. The order of application was randomly alternated to avoid bias resulting from the effects of fatigue.

Statistical analysis

Statistical tests (Fisher's exact test, Mann-Whitney test, Spearman's linear correlation coefficient and multivariate logistic regression analysis) were applied to assess associations between variables and their degree of statistical significance. The selected variables were: chronic GvHD (yes or no), stress (yes or no), anxiety (yes or no), depression (yes or no), the eight domains of the SF-36 (emotional aspect, mental health, vitality , social aspects, pain, physical appearance, general health, functional capacity), the six domains of FACT-BMT (physical wellbeing, social/family wellbeing, relationship with doctor, emotional wellbeing, functional wellbeing, additional concerns) and total score, as well as the variables of the Post-BMT Recovery Questionnaire (feeling capable, experiencing limitations, satisfaction with life, changes, occupational projects, health project, work). The level of significance was set for a p-value ≤ 0.05.

Ethical considerations

All ethical guidelines were adopted for the inclusion of participants in this study. First, the basic principles of respect for volunteers and the institution were considered. The project was approved by the Research Ethics Committee of the Hospital das Clínicas of the Medical School in Ribeirão Preto (USP-HCFMRP Protocol No. 10700/2004). The objectives of the study were discussed with each candidate before starting the study including the conditions of professional secrecy to protect the identity of participants. Only individuals who signed written consent forms were included in the study. It was also made clear that refusal to participate in the study would not prejudice the care provided to patients.

Results

Study participants were predominantly female (56.45%), aged between 21-30 years old (51.61%), married or cohabiting (75.81%) and with dependent children (61.29%). Most of the patients had had more than eight years of schooling (54.84%). The majority of participants (56.45%) had household incomes of more than two minimum wages (approximately US $ 600.00). Most of the participants had performed HSCT within the 18 months leading up to this study (38.71%). Patients with tumors predominated (87.10%) in the study and most patients (38.71%) were interviewed within 18 months after HSCT. The majority of the patients underwent myeloablative conditioning (87.10%) and the bone marrow was the most common source of cells (87.10%). All donors were related. Most patients did not evolve with chronic GvHD (59.68% - Table 1).

Of the variables that comprise the SF-36 questionnaire, three showed significant correlations with chronic GvHD: the emotional aspect (p = 0.05), mental health (p = 0.005) and general health (p = 0.039 - Table 2).

Table 1. Sociodemographic and clinical profile of patients

Demographic and clinical variables	f	Total %
Gender		
Female	35	56.45
Male	27	43.54
Age range		
21 to 30 years	32	51.61
> 30 years	30	48.39
Marital status		
With partner	47	75.81
Without partner	15	24.19
Children		
With dependent	38	61.29
Without dependent	24	38.71
Schooling		
1 to 8 years	28	45.16
> 8 years	34	54.84
Income		
1 to 2 minimum salaries	27	43.54
> 2 minimum salaries	35	56.45
Time after TCTH		
Up to 18 months	24	38.71
19 to 48 months	18	29.03
49 to 120 months	20	32.26
Diagnosis		
Neoplasia	54	87.10
Non-neoplasia	8	12.90
Conditioning		
Myeloablative	54	87.10
Non-myeloablative	8	12.90
Donor		
Related	62	100.00
Non-related	-	-
Source of graft		
Bone marrow	59	95.16
Peripheral Stem cells	3	4.84
Chronic GvHD		
Had	25	40.32
Did not have	37	59.68

Table 2. Means, medians, standard deviations and associations between SF-36 and chronic GvHD

Variables of SF-36	Without chronic GvHD (n=37)			With chronic GvHD (n=25)			Total (n=62)				
	M	SD	Median	M	SD	Median	M	SD	Median	z	p
Emotional aspect	72.58	32.75	80.00	54.80	38.86	66.00	65.41	36,12	66,25	-1,963	0,050*
Mental health	80.11	5.32	84.00	66.48	20.14	72.00	74.94	18,53	80,00	-2,819	0,005*
Vitality	74.86	14.69	75.00	67.56	18.50	72.00	71.94	16,59	73,00	-1,381	0,167
Social aspect	73.60	28.30	87.00	61.80	24.70	62.00	68.80	27,30	73,00	-1,865	0,062
Pain	78.57	22.50	84.00	71.20	24.83	74.00	75.60	23,55	83,50	-1,225	0,220
Physical aspect	57.03	39.96	75.00	42.88	38.67	50.00	51.32	39,74	50,00	-1,271	0,204
General healthe	76.05	16.03	77.00	63.24	22.31	66.00	70.89	19,69	75,50	-2,062	0,039*
Functional capacity	77.14	18.03	80.00	71.20	20.72	75.00	74.74	19,22	80,00	-1,102	0,270

$^{*}p \leq 0.05$

Table 3. Means, medians, standard deviations and associations between FACT-BMT and chronic GvHD

Variables of FACT-BMT	Without chronic GvHD (n=37)			With chronic GvHD (n=25)			Total (n=62)				
	M	SD	Median	M	SD	Median	M	SD	Median	z	p
Physical wellbeing	24.03	3.20	24.00	20.48	4.02	21.00	22.60	3.94	23.00	-3.588	0.001*
Social/familiar wellbeing	22.30	4.20	22.00	15.52	4.08	16.00	19.56	5.31	20.00	-4.959	0.001*
Relationship with doctor	7.11	1.35	8.00	6.32	1.55	6.00	6.79	1.47	7.00	-2.452	0.014*
Emotional wellbeing	21.92	1.96	22.00	17.76	3.43	19.00	20.24	3.34	21.00	-4.797	0.001*
Functional wellbeing	20.86	4.61	20.00	15.20	3.69	15.00	18.58	5.07	18.50	-4.264	0.001*
Additional concerns	35.24	5.86	35.00	29.60	5.42	30.00	32.97	6.31	33.00	-3.294	0.001*
Total score	131.46	15.00	127.00	104.88	13.50	107.00	120.74	19.42	118.00	-5.663	0.001*

$^{*}p \leq 0.05$

Table 4. Percentages and Associations between Post-HSCT Recovery Questionnaire and Chronic GvHD

Questionnaire variables	Without chronic GvHD		With chronic GvHD		Total		χ^2	p
	n	%	n	%	n	%		
Feeling capable								
Yes	33	89.20	5	20.00	38	61.30	30.10	
No	4	10.80	20	80.00	24	38.70		< 0.001*
Total	37	100.00	25	100.00	62	100.00		
Experiencing limitations								
Yes	17	45.60	25	100.00	42	67.70	19.95	< 0.001*
No	20	54.10	-	-	20	32.30		
Total	37	100.00	25	100.00	62	100.00		
Satisfaction with life								
Yes	17	45.90	2	8.00	19	30.60	10.11	< 0.001*
No	20	54.10	23	92.00	43	69.40		
Total	37	100.00	25	100.00	62	100.00		
Changes								
Positive	32	86.50	12	48.00	44	71.00	10.73	< 0.001*
Negative	5	13.50	13	52.00	18	29.00		
Total	37	100.00	25	100.00	62	100.00		
Occupational projects								
Yes	25	67.60	19	76.00	44	71.00	0.52	0.47
Não	12	32.40	6	24.00	18	29.00		
Total	37	100.00	25	100.00	62	100.00		
Health projects								
Yes	12	32.40	6	24.00	18	29.00	0.52	0.47
No	25	67.60	19	76.00	44	71.00		
Total	37	100.00	25	100.00	62	100.00		
Currently working								
Yes	16	43.20	5	20.00	21	33.90	3.60	0.005*
No	21	56.90	20	80.00	41	66.10		
Total	37	100.00	25	100.00	62	100.00		

$^{*}p \leq 0.05$

Table 5. Percentages and Associations between LSSI, HAD and chronic GvHD

psychological Variables	Without chronic GvHD		With chronic GvHD		Total		χ^2	p
	n	%	n	%	n	%		
LSSI / stress								
Yes	15	40.50	13	52.00	28	45.20		
No	22	59.50	12	48.00	34	45.20	0.79	
Total	37	100.00	25	100.00	62	100.00		0,37
HAD / anxiety								
Yes	7	18.90	11	44.00	18	29.00		
No	30	81.10	14	56.00	44	29.00	4.56	0,03*
Total	37	100.00	25	100.00	62	100.00		
HAD / depression								
Yes	6	16.20	8	32.00	14	22.60		
No	31	83.80	17	68.00	48	77.40	2.13	0,15
Total	37	100.00	25	100.00	62	100.00		

*p ≤ 0,05

All six domains and total score of the FACT-BMT showed statistically significant correlations with the dependent variable, chronic GvHD (Table 3): physical wellbeing ($p < 0.001$), social/family wellbeing ($p < 0.001$), relationship with doctor ($p = 0.014$), emotional wellbeing ($p < 0.001$), functional wellbeing ($p < 0.001$), additional concerns ($p = 0.001$) and total score ($p < 0.001$).

Table 4 illustrates the variables of the Post-HSCT Recovery Questionnaire that showed significant relationships with chronic GvHD: feeling capable ($p < 0.001$), experiencing limitations ($p = 0.001$), satisfaction with life ($p = 0.001$), changes ($p = 0.001$), currently working ($p = 0.005$). Of the variables of the LSSI and HAD instruments, only anxiety (HAD) showed a significant relationship with chronic GvHD ($p = 0.03$ - Table 5).

Discussion

This study shows that there was impairment in the physical well-being ($p < 0.001$), social/family well-being ($p < 0.001$), relationship with the doctor ($p = 0.014$), emotional well-being ($p < 0.001$), functional wellbeing ($p < 0.001$), additional concerns ($p = 0.001$) and total score ($p < 0.001$), emotional aspect ($p = 0.05$), mental health ($p = 0.005$) and overall health ($p = 0.039$) of patients with chronic GvHD.

The involvement of various domains of quality of life of patients with both acute and chronic GvHD was also reported by recent studies.(22,23)

With regards to psychosocial adjustment, it was found that stress and depression do not appear to be correlated with chronic GvHD, but there was a statistically significant relationship between clinical complications and symptoms of anxiety ($p = 0.03$).

These findings are partially in agreement with a study conducted to evaluate the relationship between chronic GvHD and psychological variables, which concluded that chronic GvHD is accompanied by increased anxiety, stress and hopelessness.(23)

The finding that patients have few signs of psychological morbidity, such as stress and depression, despite the limitations imposed by chronic GvHD may be related to the care provided by the multidisciplinary team throughout the treatment process. The importance of dealing with mental health as a key element in the maintenance of quality of life is well known in view of the importance of emotional factors in restoring well-being.(24) It is believed that care of the patient's psychosocial aspects can help to relieve the symptoms of psychological maladjustment after HSCT.

This study shows that subjects who suffer from chronic GvHD experience more limitations when performing everyday activities ($p < 0.001$) and have less satisfaction in their day-to-day lives ($p = 0.001$) as they reported feeling less capable to perform every day activities ($p < 0.001$), reported negative changes in their lives after HSCT ($p = 0.001$) and showed greater difficulty to return to the labor market ($p = 0.005$).

These limitations in terms of functionality are directly related to the manifestation of GvHD, particularly in patients with the chronic form of the disease.(25) Since acute GvHD affects the functionality of patients during the first six months post-HSCT, one year after the quality of life has improved to a level similar to that presented by patients who did not suffer from acute GvHD.(26)

The results of this investigation corroborate the findings of several studies(27-29) that also reported that chronic GvHD is predictive of more difficult psychosocial adjustment, greater limitations and worse quality of life of transplant patients.

Conclusions

It was found that chronic GvHD is predictive of a poorer quality of life and greater susceptibility to anxiety after allogeneic HSCT, as patients who presented with this complication had lower scores in most quality of life domains.

Resumo

O objetivo deste trabalho foi identificar possíveis relações entre o acometimento pela doença do enxerto contra o hospedeiro (DECH) crônica, qualidade de vida e ajustamento psicossocial em pacientes submetidos ao transplante de células-tronco hematopoéticas (TCTH). Foi realizado estudo transversal correlacional, com amostra composta por 62 pacientes na fase pós-TCTH. Para a coleta de dados foram utilizados os seguintes instrumentos: Questionário de Recuperação Pós-TCTH, SF-36, FACT-BMT, HAD e ISSL. Os instrumentos padronizados foram aplicados individualmente e seus resultados cotados segundo as recomendações preconizadas pela literatura para cada técnica, à exceção do Questionário de Recuperação Pós-TCTH, cuja aplicação foi gravada e seu conteúdo transcrito de modo literal e na íntegra; posteriormente, as respostas foram submetidas à análise de conteúdo temático. Os resultados obtidos nos demais instrumentos foram analisados estatisticamente para aferir as associações existentes entre as variáveis e seus respectivos graus de significância estatística. A variável DECH crônica é preditiva de pior qualidade de vida e maior suscetibilidade à ansiedade ($\chi 2=4,56$, $p=0,03$), uma vez que os pacientes que cursaram com DECH crônica apresentaram índices inferiores, na maioria dos domínios, de qualidade de vida. O achado de depreciação da qualidade de vida pós-TCTH é um indicador a ser levado em consideração pela equipe de saúde, pois cada vez mais o TCTH tem se firmado como importante opção terapêutica para diversas enfermidades graves.

Descritores: *Transplante de células-tronco hematopoéticas; Qualidade de vida; Doença enxerto-hospedeiro*

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