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Impact of Autologous Hematopoietic Stem Cell Transplantation on the Quality of Life of Type 1 Diabetes Mellitus Patients

Impacto do Transplante de Células-Tronco Hematopoéticas sobre a Qualidade de Vida de Pacientes com Diabetes Mellitus Tipo 1

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Abstract

The present study aimed at assessing the health-related quality of life (HRQoL) of patients with type 1 diabetes mellitus (DM1) submitted to autologous hematopoietic stem cell transplantation (HSCT). This study is part of a pioneering research protocol which tests the applicability of autologous hematopoietic stem cell transplantation as a new therapeutic approach to DM1. The study was conducted on 14 patients admitted to the ward of the Bone Marrow Transplantation Unit of a university hospital during the period from October 2006 to December 2007. The patients were evaluated at admission and on the occasion of the ambulatory return visit 100 days after transplantation. They answered the SF-36 quality of life questionnaire and the data were analyzed according to literature recommendations. The results showed that 100 days after transplantation the value of the patients' quality of life was higher compared to the pre-HSCT value, with significant differences in the Physical Domains (Role Limitations due to Physical Problems) ($p = .009$), Vitality ($p = .02$) and Mental Health ($p = .04$), demonstrating significant appreciation of those domains after the procedure. The results indicate an improvement in HRQoL after HSCT. The SF-36 proved to be a useful instrument for the assessment of quality of life in patients with DM1 submitted to HSCT.

Keywords: Type 1 Diabetes Mellitus; Quality of Life; Bone Marrow Transplantation; Hematopoietic Stem Cells.

Resumo

Este estudo teve como objetivo avaliar a qualidade de vida relacionada à saúde (QVRS) de pacientes com diabetes mellitus tipo 1 (DM1) submetidos ao Transplante de Células-Tronco Hematopoéticas (TCTH). O estudo é parte de um protocolo de pesquisa pioneiro no mundo, que testa a aplicabilidade do TCTH como nova abordagem terapêutica no DM1. Foram investigados 14 pacientes, que constituíram a população de pessoas internadas na enfermaria da Unidade de Transplante de Medula Óssea de um hospital universitário, no período de outubro de 2006 a dezembro de 2007. Os pacientes foram avaliados na admissão e no retorno ambulatorial 100 dias pós-transplante com o questionário de qualidade de vida SF-36. Os resultados mostraram que, 100 dias após o transplante, a qualidade de vida apresentou valores superiores ao pré-TCTH, com diferenças significantes nos Aspectos Físicos ($p = 0,009$), Vitalidade ($p = 0,02$) e Saúde Mental ($p = 0,04$), evidenciando significativa apreciação nesses domínios após o procedimento. Os resultados sugerem que houve melhora na QVRS pós-TCTH.

Palavras-chave: Diabetes Mellitus Tipo 1; Qualidade de Vida; Transplante de Medula Óssea; Células-Tronco Hematopoéticas.

The Multiple Facets of Diabetes Mellitus: Etiopathogeny, Symptomatology and Epidemiology

Diabetes mellitus (DM) is diagnosed in the presence of a reduction or alteration of the insulin produced by the pancreas and is characterized by chronic hyperglycemia

with disorders of carbohydrate, lipid and protein metabolism (Santos & Enumo, 2003), and is classified according to its etiology. Type 1 diabetes mellitus (DM1) is characterized by the destruction of beta cells, with absolute insulin deficiency. Type 2 diabetes mellitus (DM2) varies between insulin deficiency and a secretory defect (F. P. M. Guimarães & Takayanagui, 2002).

The signs and symptoms of DM are: polydipsia (excessive thirst), polyuria (excessive urine volume), polyphagia (excessive hunger), rapid weight loss and elevated hyperglycemia or glycosuria detected by routine blood tests. Fasting glycemia between 100 and 125 mg/dl is considered to represent glucose intolerance and two

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tests above 126 mg/dl are a criterion for the diagnosis of DM. The most frequent complications of the disease are: hypoglycemia, diabetic ketoacidosis, proteinuria, peripheral neuropathy, retinopathy, and nephropathy, among others (American Diabetes Association, 2005).

The World Health Organization ([WHO], 2004) estimates at 143 million the number of persons with DM worldwide and the projection for the year 2025 is that the disease will reach 300 million individuals. In Brazil, according to Health Ministry estimates, there are approximately five million people with DM, 90% of them with type 2 and 5-10% with type 1 DM (Lojudice & Sogayar, 2008).

According to the Brazilian Diabetes Society (2007), the lack of effective forms of prevention of DM1 cause this disease to be one of the most important public health problems, affecting people when they are completely unprepared for the possibility of being diagnosed. This element of surprise regarding the diagnosis of DM1, which is a serious disease of chronic and degenerative course, generates an initial commotion not only in the affected person, but also in his family network, requiring a rearrangement of eating habits and life style. A rearrangement of family relationships frequently occurs in order to provide the necessary care to the patient (Zanetti, Biaggi, Santos, Peres, & Teixeira, 2008).

Long-term complications usually arouse the greatest fear in patients who receive a diagnosis of DM1, since they know that, even if they rigorously follow the conventional treatment, they will not be free from these complications, which may arise sooner or later. It should be remembered that 12 to 13% of patients are estimated to die 20 years after the diagnosis, this being the fourth cause of death in Brazil (Santos & Enumo, 2003).

The belief that treatment may be ineffective, allied to the side effects of the disease and the almost total absence of symptoms, impairs adhesion to treatment, which in many cases only occurs due to the threat of future complications (Gimenes, Zanetti, & Haas, 2009; Marcelino & Carvalho, 2005). Among adolescents the question is even more complex since DM1 may cause limitations of interpersonal relationships, with consequent difficulties of socialization and insertion in the peer group, a fundamental task for individual development in this age range (Imoniana, 2006). During adolescence, metabolic control tends to deteriorate due to the decline in insulin production that occurs because of the hormonal changes typical of this age range, associated with insulin resistance, a greater risk of hypoglycemia and difficulty in complying with the treatment recommended by health professionals (Damião & Pinto, 2007).

The treatment of DM, both type 1 and type 2, is quite demanding because it imposes on the patient a full restructuring of life habits (Zanetti et al., 2006). The necessary care is based on three major factors, i.e., a balanced diet, physical exercises, and insulin therapy

(Grupo de Estudos em Endocrinologia e Diabetes, 2001). Because of the countless impositions of treatment, DM is characterized as one of the most demanding chronic diseases both at the physical and psychological level (Apóstolo, Viveiros, Nunes, & Domingues, 2007; Péres, Santos, Zanetti, & Ferronato, 2007).

In view of the many challenges imposed by the management of the disease, over the years DM1 has stimulated the discovery of many innovations related to treatment modality (Voltarelli, 2004). In this respect, among the treatments available, Hematopoietic Stem Cell Transplantation (HSCT) – also known as Bone Marrow Transplantation (BMT) – has recently arisen as one of the most promising and bold resources and is being tested as an experimental alternative to conventional therapy (Couri, Foss, & Voltarelli, 2006; Couri & Voltarelli, 2008; Voltarelli et al., 2007).

HSCT as a Treatment Strategy for Type 1 Diabetes Mellitus

Autologous hematopoietic stem cell transplantation (HSCT) is used in DM1, with the donor being the patient himself. His bone marrow is removed during the process of disease remission and is preserved for later infusion. Evidence suggests that in DM1, immunosuppression at high doses associated with infusion of hematopoietic stem cells can potentially prevent the total destruction of insulin-producing pancreatic cells, promoting their preservation. On this basis, pancreatic beta cells would start again to produce insulin in an efficient manner (Couri et al., 2006).

At the end of 2002, Brazilian and North American researchers elaborated a pilot protocol of autologous HSCT for DM1. According to this protocol, patients younger than 35 years who have been diagnosed with DM1 for less than six weeks or who are in the asymptomatic phase of the disease are eligible for HSCT (Voltarelli, 2004).

The procedure consists of various phases. The present study focused on two of them: pre-HSCT and immediate post-HSCT period (100 days after HSCT). Phase 1, or pre-HSCT, involves the pre-admission period, medical evaluation and patient admission to the ward under protective isolation. In phase 2, immediate post-HSCT period (D+100), the patient is seen on an outpatient basis, with weekly return visits. It is known that the intense restrictions imposed by treatment have an impact on the quality of life of patients with neoplasias and other hematologic diseases – the main indications of HSCT – but these restrictions are gradually reduced with time (Mastropietro, Oliveira, Santos, & Voltarelli, 2007).

During the HSCT procedure, the patients are subjected to stressful events such as chemotherapy, catheter implantation, waiting for bone marrow to “take” (time when production of bone marrow cells starts) and the fear of

contracting infections due to immunosuppression, facts that contribute to an important impairment of their quality of life (Riul, 1995). This damage, however, is consistently attenuated when the patient is discharged from the ward, with a feeling of optimism after overcoming the critical period of highest risk of the procedure (Mastropietro et al., 2007).

Health-Related Quality of Life (HRQoL)

According to Oliveira-Cardoso, Santos, Mastropietro, and Voltarelli (2009), WHO specialists in quality of life consider that there are three consensual characteristics in the construct of quality of life: *subjectivity* (a person's estimate about his quality of life is not pure, since there are external conditions present in the environment and in the living and working conditions that influence it), *bipolarity* (the construct has positive dimensions such as performing social roles, mobility, and autonomy, and negative ones such as pain, fatigue and dependence, with emphasis on the perceptions each individual has regarding these dimensions), and *multidimensionality* (which includes at least three dimensions, i.e., physical, psychological and social ones, always in the direction of subjectivity; in other words, what is important is to know how an individual perceives his physical and affective status and the interpersonal relations and the social roles he plays in his life).

In the present investigation, the HRQoL concept was used, which can be understood as the Perceived Health Status. This refers to the perception a person has of his health status when affected or not by some disease (Ashing-Giwa, 2005; Fayers & Machini, 2007).

As a multidimensional concept, quality of life can be measured in an objective manner by means of instruments whose properties of reproducibility, validity and susceptibility to changes are satisfactory (Kovács, Andrade, & Sgorlon, 1998). In the HRQoL concept, quality of life is interpreted as a continuum within the well-being scale that covers domains such as satisfaction, perception of one's general health, psychological well-being and limitations due to the disease itself until death, with emphasis on the assessment of the subjective well-being of the patient within the context of his disease, accident or treatment (Bullinger, Anderson, Cella, & Aaronson, 1993).

Among the various procedures used to evaluate HRQoL are generic instruments developed in order to reflect the impact of a disease on the life of the patients in wide variety of populations (Ciconelli, 2003). The Generic Questionnaire for the Assessment of Quality of Life (Medical Outcomes Study 36 Item Short-Form Health Survey – SF-36) is one of the instruments most frequently used in the health area all over the world.

This instrument was used in a longitudinal assessment of HRQoL in 17 patients with serious hematologic disea-

ses submitted to HSCT. The study considered three stages: pre-HSCT, immediate post-HSCT and late post-HSCT. The results demonstrated that there was a significant depreciation of the quality of life of the patients when they left the ward, especially regarding social domains (Social Functioning) and physical domains (Role Limitations due to Physical Problems). However, a recovery of these domains and an improvement of others such as Physical Functioning were observed during the late post-HSCT period. No significant differences were observed between the values obtained during the phase preceding the transplant and those obtained one year after the procedure (Oliveira-Cardoso et al., 2009)

Within the context of the evaluation of autoimmune diseases, F. A. B. Guimarães, Santos e Oliveira (2008) assessed 19 patients with autoimmune diseases before and immediately after HSCT using the generic quality of life questionnaire SF-36 and detected impairment of HRQoL domains in patients before HSCT and a recovery of these indices 100 days after transplantation.

Regarding patients with DM, Aguiar, Vieira, Carvalho, and Montenegro-Junior (2008) carried out a review of the literature in order to describe and analyze the generic and specific instruments for the assessment of quality of life applied to this population and observed, among other findings, that the SF-36 is the generic instrument most frequently used in the various investigations. The validity and reliability of this scale have been demonstrated in patients with DM. This is one of the few instruments that have been formally validated in Brazil. Another advantage of the SF-36 is that, when compared to specific instruments, it has also been considered appropriate for the assessment of quality of life in patients with DM.

The conventional treatment of DM delays, but does not prevent the chronic complications of the disease and requires a rigorous and repeated control of glycemia along the day. In addition to being difficult to perform, it is associated with frequent episodes of hypoglycemia. These daily restrictions are responsible for a significant impairment of the quality of life of the patients, a fact that makes it difficult to adhere to treatment, with a consequent worsening of glycemia control and an increase in the number of complications due to the disease (Aguiar et al., 2008; Couri & Voltarelli, 2008; Rodrigues et al., 2009).

A study conducted on 316 patients with DM1 and DM2 showed that 59.8% of them suffer from the chronic complications of the disease. Patients with complications are less satisfied with friends, indicating impairment of the quality of social interaction (I. Silva et al., 2003).

In view of this evidence and of the lack of Brazilian as well as international investigations focusing on the impact of HSCT/BMT on the perception of quality of life, the objective of the present study was to assess the health-related quality of life of patients with DM1 submitted to HSCT.

Method

Type of Study

The present study can be characterized as a clinical investigation in which the personal experience of the investigator is essential for the choice of research subject and for the execution of the work (Brewer & Hunter, 1989; Diers, 1979; Miller & Crabtree, 1999, Souza, Cavalcante, Makdisse, & Avezum, 2003).

This is a prospective follow-up study in which the patients were assessed at two times: pre-HSCT (time

preceding the transplant) and post-HSCT (100 days after bone marrow infusion).

Participants

The population consisted of 14 patients with DM1 of both sexes submitted to autologous HSCT at a public university hospital in the interior of the State of São Paulo, Brazil, during the period from October 2006 to December 2007. Inclusion criteria were: being attended at the outpatient clinics of the BMT Unit before and after HSCT during the period of evaluation, to be able and available to collaborate voluntarily with the research, and to have preservation of cognitive skills.

Table 1

Sample Characterization by Sex, Age, Schooling, Marital Status, and Profession/Occupation

Participant	Sex*	Age	Schooling	Marital status	Profession/Occupation
1	M	16	High Schoolincomplete	Single	Student
2	M	20	Higher Educationincomplete	Single	Military man
3	M	17	High School incomplete	Single	Student
4	M	27	Higher Educationcomplete	Casado	Nursing Technician
5	M	16	High Schoolincomplete	Single	Student
6	F	24	Higher Educationincomplete	Single	Secretary
7	M	16	High School incomplete	Single	Student
8	F	18	Higher Educationincomplete	Single	Student
9	F	17	High Schoolcomplete	Single	Student
10	M	16	High Schoolincomplete	Single	Student
11	F	14	High Schoolincomplete	Single	Student
12	M	24	Higher Education complete	Single	Biologist
13	M	31	Higher Educationcomplete	Married	Dentist
14	M	16	High School incomplete	Single	Student

Note. * M: Male; F: Female.

Table 1 shows that 10 of the 14 patients were males. Age ranged from 14 to 31 years (mean = 19.43 years; standard deviation = 5.07). Eight participants were High School students at the time of assessment; 12 were single and two were married. Most participants were students, a fact compatible with the juvenile range of the population investigated and with the time in the life cycle when the diagnosis is established. The older participants had professions or occupations such as military man, nursing technician, secretary, biologist, and dentist.

Instrument

Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The SF-36 is a multidimensional instrument for the generic assessment of health originally elaborated in the English language, which is easy to administer and to understand. It consists of 36 questions covering eight domains that can be grouped into Physical Components and Mental Components (Ware, Kosinski, & Keller, 1994).

According to Ciconelli (2003), the results of each dimension range from 0 to 100. In this continuum, 0 corresponds

to the worst health status and 100 to the best health status. Internal consistency was determined according to the Cronbach alpha, which exceeded .90 for all domains. In addition to having appropriate psychometric properties, the SF-36 is an instrument widely used all over the world, permitting comparison with results obtained in other studies with similar samples.

A version of this scale for the Portuguese language was developed after a translation and transcultural adaptation process, which confirmed its measuring properties, i.e., reproducibility and validity. The study concluded that this instrument is a reproducible and valid parameter to be used for the evaluation of the HRQoL of Brazilian patients with chronic diseases (Ciconelli, 2003).

The SF-36 measures the basic human necessities and the emotional and functional well-being (Ware & Sherbourne, 1992). Like all quality of life scales, it provides an estimate of subjective satisfaction in different domains. Several studies using this instrument have been published in the specific literature about HSCT (Hann, Jacobsen, Martin, Kronish, & Azzarello, 1997; Mastropietro, Car-

dosso-Oliveira, Santos, & Voltarelli, 2009; Mastropietro et al., 2007; L. M. G. Silva, 2000; Sutherland et al., 1997).

Data Collection

Ethical Considerations. The research Project was approved by the Research Ethics Committee of the University Hospital (protocol nº 7673/2006). The study insured the ethical care that guarantees the integrity of the participant according to the directives and norms defined by Resolution nº 196/96 to regulate research involving human beings (Conselho Nacional de Saúde, 1996) and by Resolution nº 196 of the Federal Council of Psychology (2000).

Application of the Instrument. The instrument was applied individually to each patient upon admission and reapplied on the occasion of the ambulatory return visit 100 days after HSCT. The instrument was applied with the help of the investigator, who only read the questions individually, without the presence of the parents or persons responsible. The first application occurred on

the ward of the HSCT Unit and the second in a room of the outpatient clinic. The mean time of application was 40 minutes.

Data Analysis. The instrument was evaluated according to the directions of Ciconelli (2003). After application, a score was attributed to each question and later transformed on a scale from 0 to 100. As mentioned earlier, zero corresponds to a worse health condition and 100 to a better condition, with each dimension being analyzed separately. Purposely, there is no general value in view of the multidimensional character of the HRQoL construct.

Data were analyzed statistically by the Wilcoxon test for paired samples, with the level of significance set at $p < .05$.

Results and Discussion

The mean values of the results obtained with the application of the quality of life questionnaire (SF-36) before and after transplantation are summarized in Table 2.

Table 2
Means, Standard Deviations and Probability of the SF-36 Variables Determined by the Wilcoxon Test in the Group (N = 14) Before and After HSCT

Physical and Mental Components of SF-36	Pre-BMT	SD	Post-BMT	SD	p
Physical Functioning	93.57	11.34	95.71	8.52	.40
Role Limitations due to Physical Problems	41.07	36.17	81.93	17.58	.009*
Bodily Pain	68.50	26.60	82.64	12.40	.16
General Health Perceptions	75.07	12.17	84.79	12.08	.10
Vitality	63.57	18.23	76.07	11.30	.02*
Social Functioning	59.82	34.03	80.00	22.45	.12
Role Limitations due to Emotional Problems	71.43	43.10	84.57	23.08	.31
General Mental Health	66.86	9.34	74.57	13.28	.04*

Note. * $p < .05$.

The domains most affected during the period before HSCT were the Role Limitations due to Physical Problems and Social Functioning. The Role Limitations due to Physical Problems were evaluated with items of the questionnaire that score difficulties in executing physical activities due to the transplant, i.e. “vigorous activities that require great effort such as running, lifting heavy objects, participating in strenuous sports” and “moderate activities such as moving a table, vacuuming the floor, playing ball, sweeping the house”. At the first evaluation, the physical health of all participants was compromised not only by the restriction of the environment due to hospitalization, but also by the metabolic changes due to the lack of stabilization of the disease a short time after the diagnosis (Damião & Pinto, 2007). At the second evaluation, the improvement of these indicators of quality of life reflected the restoration of the physical conditions, one of the objectives of HSCT.

The Mental Health component estimates the perception the patient has of his own emotional equilibrium and his resistance over time, with items such as: “how long have you felt like a very nervous person?”, “how long have you felt so depressed that nothing could cheer you up?”. The significant increase in the score attributed to this component suggests a better emotional control, with a reduction of the signs and symptoms of anxiety and depression. It is possible to postulate that there was a recovery of psychological stability, which had been temporarily affected by the orders received after learning about the diagnosis (Zanetti et al., 2008), by the daily limitations caused by the disease (Santos & Enumo, 2003), and especially by the perspective of having to face the challenges of HSCT (Oliveira-Cardoso et al., 2009).

Statistical analysis of the data revealed a significant increase in the scores of the following domains related to the quality of life of the participants 100 days after the

HSCT: Role Limitations due to Physical Problems ($p = .009$), Mental Health ($p = .04$), and Vitality ($p = .02$).

The Vitality domain is assessed by items such as: “how long have you felt full of vigor, full of desire, full of strength?”, “how long have you felt a lot of energy?”. The better appreciation of this domain during the post-HSCT phase reflects the gradual recovery of the patient, who had to go through a stressful period both from a physical and psychological viewpoint (F. A. B. Guimarães et al., 2008). During the transplant the patients are exposed to various stressful events which contribute to a marked impairment of their quality of life (Riul, 1995). Discharge from the ward favors the recovery of optimism on the part of the patient by having overcome the critical and highest risk stage of the procedure and by the perspective of leaving the protective isolation (Mastropietro et al., 2007). This increases the sensation of well-being and of control of the events of one’s life, which had been seriously compromised during the experience of admission, with invasive procedures and serious immunosuppression.

To understand why an improvement in quality of life occurs 100 days after transplantation, i.e. at the second time of assessment, it is important to consider that the patients had already returned home and their ambulatory return visits for medical follow-up were being increasingly spaced, a fact that possibly reduced the sensation of dependence on the hospital and on the health multidisciplinary team.

An improvement of quality of life immediately after HSCT was observed by F. A. B. Guimarães et al. (2008). These authors evaluated patients with autoimmune diseases before and immediately after HSCT and detected impairment of quality of life domains in the patients before the transplant, followed by a recovery of these indices 100 days after the procedure.

An encouraging result is the rapid recovery of HRQoL by patients with DM compared to patients with other diseases also submitted to HSCT. According to Oliveira-Cardoso et al. (2009), a significant depreciation of quality of life is observed in the patients during the immediate post-HSCT period, especially in social domains (Social Functioning) and in physical domains (Role Limitations due to Physical Problems). According to the cited study, the recovery of these domains of the HRQoL and the improvement of others such as Physical Functioning occurred during the late post-HSCT period, i.e., one year after the procedure.

It should be pointed out that, in the present investigation, the patients had been living, even for a short time, with the limitations of a chronic disease such as DM1 and had the opportunity to intervene early in the course of the condition. This possibility of controlling a progressive and debilitating morbid condition opened entirely new perspectives for these patients, a fact that appeared to be essential for the improvement of the patterns of quality of life assessed with the instrument used.

Final Considerations

The SF-36, the instrument used to measure the quality of life of patients with DM1, proved to be appropriate for the purposes of the present investigation. Easily and rapidly applied, the instrument was well accepted by the participants, providing data that were consistent with the objectives of the present study.

On the basis of the present results, we perceive that, despite all the difficulties faced by these young patients over such a short period of time, the hope for a resolving treatment of DM1 and the perspective of a future free of the disease or with attenuated disease manifestations reduces the fear of future complications. Thus, favorable expectations regarding the outcome of the procedure may, of themselves, contribute to improving the quality of life.

Despite the limitation of the present study in terms of generalization of the data due to the small sample size, the originality of the investigation and its innovative nature at the international level endorse the dissemination of the results. It should be remembered that the treatment in question is a pioneer one in the world and is regulated by an experimental protocol that is being tested, a fact that explains the reduced number of cases evaluated up to now.

Due to the recent beginning of hematopoietic stem cell transplantation for patients with DM1 and to the small number of subjects transplanted thus far, it is essential to conduct more investigations that will compare the quality of life of those who live with the disease to the quality of life of those who receive the transplant, so that the effects of the procedure on the recipients may be estimated. In addition, follow-up studies of greater amplitude are desirable in order to examine whether the improvement in quality of life observed on a short-term basis will tend to persist over time. Thus, it will be possible to monitor the course of this innovative treatment and to examine the evolution of the patients starting from promising initial results.

By dealing with a multidimensional construct, investigation with the HRQoL may contribute to the enrichment of various disciplines in the health field, including Psychology, Medicine and Nursing. Since the research protocol regarding the applicability of HSCT to DM1 is part of a multicenter study in which Brazil is one of the participating countries, this study may represent a significant advance for Brazilian Psychology.

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