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Functional Assessment of Cancer Therapy Bone Marrow Transplantation: Portuguese translation and validation

ABSTRACT

OBJECTIVE: To translate into Portuguese and validate the "Functional Assessment of Cancer Therapy – Bone Marrow Transplantation" (FACT-BMT) quality-of-life questionnaire, among bone marrow transplantation patients.

METHODS: The study was carried out in Ribeirão Preto, Southeastern Brazil in 2005. After translating FACT-BMT (version 3) into Portuguese, it was applied to 55 consecutive leukemia patients simultaneously with the Portuguese version of the Short Form-36 Health Survey (SF-36). These patients had undergone transplantation and were being followed up. Two clinical parameters were used for testing the sensitivity of the questionnaire: time elapsed since transplantation and presence or absence of graft-versus-host disease. Analysis of variance with the post-hoc Tukey test was used. Cronbach's alpha coefficient was applied, standardized for all the questions, final scores and domains.

RESULTS: The patients' mean age was 34.8±8.1 years and mean schooling was 10.8±4.7 years, and 78.1% of the patients were female. The mean time since transplantation was 29.8±32.19 months. At the end of the translation and cultural adaptation process, it was seen that there had not been any alteration to the original format of the questionnaire. The internal consistency was high (0.88). The correlation between the translated questionnaire and SF-36 ranged from 0.35 to 0.57 and was considered to be moderate to good for most quality-of-life domains. The evaluation of the construct and concurrent validities was satisfactory and statistically significant.

CONCLUSIONS: The Portuguese version of FACT-BMT was satisfactorily validated for application to Brazilian patients of both sexes undergoing bone marrow transplantation.

KEYWORDS: Bone marrow transplantation, rehabilitation. Quality of life. Questionnaires. Translation (product). Validity of tests. Reproducibility of tests.

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INTRODUCTION

Bone marrow transplantation (BMT) is a procedure of high complexity. Its development over recent decades has made it possible for diseases that previously were invariably fatal to be treated.[1]

Several studies on the quality of life among patients who underwent BMT have emphasized the need to correlate the clinical variables, such as time since BMT and existence of graft-versus-host disease (GVHD), and the demographic variables, such as sex and age.[5,8,10,11]

According to the literature, there are several instruments or indices for eva-

luating and measuring quality of life among patients who underwent BMT. These can be divided into two groups: generic and specific. They supply complementary information, in such a way that they can be used concomitantly.[13]

From this perspective, the need for quality-of-life evaluations to be carried out by means of instruments that are sensitive, specific and easily reproducible has been highlighted.[13] It is fundamentally important for such instruments to be adapted to the cultural conditions and to be validated for the language of the country in which it will be used.[3]

In Brazil, studies have been carried out using the Short Form-36 Health Survey (SF-36) questionnaire. This is a general instrument for evaluating quality of life by means of 36 questions and was validated in Brazil by Ciconelli et al in 1999.[6] In this country, there are no quality-of-life questionnaires that are specific for BMT, and this justifies conducting a study to validate an instrument with this purpose.

Among the several specific questionnaires available for quality-of-life evaluations on patients who underwent BMT the Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (FACT-BMT) is prominent. This includes functional characteristics and quality-of-life variables.[9,11,12,16,18] FACT-BMT is a simple, brief and self-administrable questionnaire that was originally developed and validated in the English language by McQuellon et al.[15]

The objective of the present study was to translate the Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (version 3) into the Portuguese language, taking into consideration its cultural adaptation and validation for use in research in Brazil.

METHODS

An observational study of cross-sectional type was carried out on 55 consecutive patients of both sexes who were being followed up at the outpatient clinic of the BMT unit of a university hospital in Ribeirão Preto between November 2004 and June 2005. The study included patients aged over 21 years who had had at least three years of formal schooling and were available to collaborate voluntarily with the research; they had undergone BMT in this hospital and were being followed up with day-hospital and outpatient clinic care during the study period. The study excluded patients with psychiatric disturbances and mental diseases in which their critical judgment of reality and/or cognitive capacity were compromised, thus impairing the application and understanding of the instruments.

All the data were collected at a single meeting. These consisted of sociodemographic data on age (up to 30 years and over 30 years), sex, schooling (up to eight years and over eight years), marital status, family income (up to two minimum salaries and over two minimum salaries) and the clinical variables of time since BMT (<1 year - G1, from 1 to 2 years - G2, >4 years - G3) and diagnosis of GVHD (yes or no).

The FACT-BMT (version 3) is composed of 47 questions, of which 41 are used to obtain the score and the remaining six questions left are presented to supply synthesis information but must not be used for obtaining the final score. The questions are distributed in six domains. FACT-BMT is scored according to its domains, as the sum of the scores for its questions. The Likert format of the responses allows scores from zero to four for each question, after taking into account reverse scores for questions constructed in a negative form. The final score for FACT-BMT ranges from zero to 164.

Two translations were made by Brazilians who were fluent in the English language and aware of the research objectives. After their harmonization, this translation (given the name version 1) was back-translated into English by two people native to the United States who were fluent in Portuguese and not aware of the research objectives. After harmonization of the back-translations with the original in English (to give version 2), the Portuguese translation version 1 was considered to be grammatically and semantically equivalent to the original version in English and fit for submission to a committee of five bilingual judges who were all health-sector professionals. After their suggestions had been considered, the Portuguese version of FACT-BMT (version 1) was pretested on 27 patients who had undergone BMT.[14]

The only alteration to the translation in relation to the original text occurred in question number 44: "I have concerns about my ability to have children". The initial translation was: "*Tenho consciência da minha capacidade de ter filhos*" [I am aware of my capacity to have children]. The version in Portuguese was considered to be grammatically and semantically correct, on the basis of the translation and back-translation. However, during the pretest phase, it was observed that most patients had difficulty in understanding the question. For this reason, question 44 was modified to "*Estou preocupado(a) com a minha capacidade de ter filhos*" [I am concerned about my capacity to have children]. With this sentence, in the second pretest, there was a comprehension rate of 91%. Thus, the final version of FACT-BMT was then considered ready for application to the sample of 55 patients.

The patients were asked to fill out the Portuguese versions of the FACT-BMT and SF-36 questionnaires. The order of the instruments was alternated so as to control the presentation effects. The SF-36 questionnaire is composed of 36 questions, distributed into

seven domains: functional capacity, physical aspects, pain, general health state, vitality, emotional aspects and mental health. It presents the final score between zero and 100, in which zero corresponds to the worst general health state and 100 to the best health state.

The construct validity was evaluated by comparison between the version of SF-36 already validated in Portuguese and the Portuguese version of FACT-BMT. The concurrent validity was evaluated by determining the capacity of FACT-BMT to discriminate between patient subgroups with different lengths of time since BMT and with or without a diagnosis of GVHD.

The descriptive analysis was performed by means of frequencies of categorical variables and measurements of central positions and continuous variable dispersions.

As a reliability measurement, the internal consistency of the instrument and the correlation coefficient were evaluated. To estimate the internal consistency, Cronbach's alpha coefficient was applied, standardized for all questions, final scores and domains. To investigate the correlations between all the FACT-BMT domains and the final score, the non-parametric Spearman correlation coefficient was used.

To compare the FACT-BMT domains among the different levels of the variable of length of time since BMT, variance analysis (ANOVA) was used with the *post hoc* Tukey test. The normality of the variables was tested by the Kolmogorov-Smirnov method.

For comparing the FACT-BMT domains among the levels of the GVHD variable, the t test for independent samples was used.

To study the correlations between the variables (domains) of FACT-BMT and the variables (domains) of SF-36, and between each other, the non-parametric Spearman correlation coefficient was used.

The calculations were performed using the SPSS 10.0 program.

The project was approved by the Research Ethics Committee of Hospital das Clínicas, Ribeirão Preto Medical School, University of São Paulo, HCRP case No. 10700/2004. The patients signed a statement of free and informed consent for their participation.

RESULTS

The 55 patients studied had the following characteristics: mean age of 34.8 ± 8.1 years; mean schooling of 10.8±4.7 years; 78.1% were female; and mean time since BMT of 29.8 ± 32.2 months. The subdivided mean times since BMT were: G1, 1.9 ± 1.0 months; G2, 14.4 ± 3.2 months; and G3, 70.7 ± 17.8 months. In relation to the presence of GVHD, 34.5% of the patients had this diagnosis.

Study of the associations between the questionnaire scores and the sociodemographic variable categories indicated significant differences in the correlations with the FACT-BMT domains. Correlation between the variables of schooling and family income (p<0,0001) indicated that patients with schooling of more than eight years and family income of more than two minimum salaries had higher quality-of-life scores. Correlation of the variable of sex with the domains of additional worries (p=0.02), social aspects (p=0.02) and pain (p<0.0001) showed that men presented higher scores than women. For the correlation between the variables of age and social aspects (p=0.04), it was seen that adults obtained higher scores than young adults.

Cronbach's alpha, which was used to evaluate the accuracy of the instrument, was considered satisfactory (0.88); the domain values ranged from 0.65 to 0.88, and the lowest value was generated by item 44. After excluding this question, a small increase in the alpha value was seen (to 0.70), which suggested that this question had a weak correlation with the domain of additional worries (Table 1).

The correlation coefficients for internal consistency ranged from 0.29 to 0.88, and all the domains had significant correlations between each other (p<0.0001). The best correlations occurred especially between functional wellbeing and the total score (0.88) and between additional worries and the total score (0.80) (Table 2).

The construct validity was analyzed by measuring the correlations between the FACT-BMT domains and the SF-36 domains. Significant correlations were observed between the final FACT-BMT score and all the SF-36 domains (p<0.0001). The "mental health" and "absence

Table 1. Internal consistency analysis for the domains of the Functional Assessment of Cancer Therapy - Bone Marrow Transplantation questionnaire, applied to bone marrow transplantation patients. Ribeirão Preto, Southeastern Brazil, 2005. (N=55)

Domain	Cronbach's alpha coefficient
Physical wellbeing	0.73
Family/social wellbeing	0.70
Relationship with the doctor	0.80
Emotional wellbeing	0.70
Functional wellbeing	0.78
Additional worries	0.65
Total	0.88

Table 2. Spearman's coefficient correlation among the domains of the Functional Assessment of Cancer Therapy - Bone Marrow Transplantation questionnaire, applied to bone marrow transplantation patients. Ribeirão Preto, Southeastern Brazil, 2005. (N=55)

Domain	Physical well-being	Family/social wellbeing	Relationship with the doctor	Emotional wellbeing	Functional wellbeing	Additional worries
Family/social wellbeing	0.29 0.03	- -	- -	- -	- -	- -
Relationship with the doctor	0.39 0.003	0.47 <0.001	- -	- -	- -	- -
Emotional wellbeing	0.55 <0.001	0.50 <0.001	0.44 0.001	- -	- -	- -
Functional wellbeing	0.56 <0.001	0.62 <0.001	0.53 <0.001	0.67 <0.001	- -	- -
Additional worries	0.58 <0.001	0.34 0.01	0.40 0.003	0.54 <0.001	0.65 <0.001	- -
Total	0.69 <0.001	0.70 <0.001	0.63 <0.001	0.79 <0.001	0.88 <0.001	0.80 <0.001

Table 3. Variance analysis on the domains of the Functional Assessment of Cancer Therapy - Bone Marrow Transplantation questionnaire as a function of the time since bone marrow transplantation. Ribeirão Preto, Southeastern Brazil, 2005. (N=55)

Domain	G1 Mean ± SD	G2 Mean ± SD	G3 Mean ± SD	p
Physical wellbeing	20.05±4.07	23.38±3.79	25.15±2.43	<0.001
Family/social wellbeing	18.00±6.32	20.00±4.99	21.15±4.59	0.20
Relationship with the doctor	6.61±1.53	6.72±1.22	7.47±0.90	0.05
Emotional wellbeing	19.83±2.74	20.27±3.47	21.36±3.46	0.34
Functional wellbeing	14.38±3.82	19.11±4.18	22.47±4.32	<0.001
Additional worries	29.22±5.07	32.72±6.08	37.78±5.52	<0.001
Total	108.11±17.50	122.22±15.64	135.42±16.45	<0.001

G1: less than one year after bone marrow transplantation
G2: from one to two years after bone marrow transplantation
G3: more than four years after bone marrow transplantation

Table 4. Variance analysis on the domains of the Functional Assessment of Cancer Therapy - Bone Marrow Transplantation as a function of diagnoses of graft-versus-host disease (GVHD). Ribeirão Preto, Southeastern Brazil, 2005. (N=55)

Domain	With GVHD (N=19) Mean ± SD	Without GVHD (N=36) Mean ± SD	p
Physical wellbeing	20.78±4.18	24.02±3.52	<0.001
Family/social wellbeing	14.84±3.96	22.33±4.13	<0.001
Relationship with the doctor	7.41±0.87	6.05±1.47	<0.001
Emotional wellbeing	17.73±3.70	21.97±1.71	<0.001
Functional wellbeing	14.57±3.74	20.91±4.59	<0.001
Additional worries	28.94±5.20	35.63±6.00	<0.001
Total	102.94±12.27	132.30±14.84	<0.001

of pain" domains presented the lowest correlations (0.35). The highest correlations were with the "general health state" and "physical aspect" domains, for which the correlations were 0.52. The concurrent validity was evaluated by the correlation between some sociodemographic and clinical variables and the domains and final score of the FACT-BMT questionnaire.

All the means and standard deviations showed that the patients with short times since BMT presented lower scores than did the patients whose BMT was one to two years ago. Moreover, the latter patients had lower scores than those whose BMT was more than four years ago. This difference can also be seen from the significance (p<0.001) in most domains (Table 3).

Having a diagnosis of GVHD interfered negatively in the quality of life of the sample (p<0.0001). It was observed that in all the domains there was a statistical difference between the groups with and without GVHD (Table 4).

DISCUSSION

The lack of quality-of-life evaluation instruments with translation and validation for use in Portuguese within the field of bone marrow transplantation has restricted the research in this field in Brazil. In this clinical segment, the Portuguese version of SF-36 has been proven reliable, through analysis of its measurement properties.[6] Its construct, however, was devised for evaluating generic quality of life within healthcare. The decision to develop the translation, cultural adaptation and validation of FACT-BMT was made because it is an instrument that specifically evaluates the impact of BMT on patients' lives.

One of the limitations of this study related to the schooling level of the population sample. Although it is self-applicable, the questionnaire had to be read out by the interviewer to 13 (23%) of the patients studied. This technique is commonly resorted to, for including patients with low levels of or no schooling.[6]

The results regarding length of time since BMT and its direct relationship with quality of life were similar to findings from studies in other countries.[4,5,9,11,18,19] This can be explained by the expected gradual improvement in the patient's organic condition and by the reduction in the limitations resulting from the treatment itself, such as the impossibility of performing activities that involve physical effort, need for regular use of medications, frequent outpatient returns and possibility of disease recurrence, among others.

One explication for the worse quality of life among patients with GVHD in its chronic or acute form would be the need to return to treatment using immunosuppressive drugs, thereby extending the limitations. This finding is corroborated by results from studies performed in other countries.[5,8]

The results from the present study indicating better quality of life among patients with higher income and schooling levels are consistent with findings in the international literature.[2,17]

The internal consistency of FACT-BMT, as measured by the correlation between the domains and their questions, was satisfactory. A general rate of 0.88 was obtained, and the internal consistency of its domains ranged from 0.65 to 0.88.

Comparing these results with those from SF-36 and FACT-BMT in the English language, SF-36 has presented correlation coefficients ranging from 0.1481 to 0.6189, thus demonstrating moderate correlation between them.[7] Cronbach's alpha found for FACT-BMT in the English language is within a range from 0.85 to 0.92.[15]

The hypotheses raised previously have been confirmed, because worse quality of life measured by FACT-BMT was related to the clinical and sociodemographic parameters investigated. Thus, it was found that the highest quality-of-life values were among the adult male patients with more than eight years of schooling, family income of more than two minimum salaries and without GVHD.

Concluding, FACT-BMT was successfully translated and validated as a Portuguese version, according to the results from the final analysis of its measurement proprieties. Through its simplicity and speed of application, this questionnaire becomes a practical instrument available for use in clinical research in Brazil.

Today, FACT-BMT is now available translated into Portuguese as version 4, which is still awaiting validated. It can be obtained through the Functional Assessment of Chronic Illness Therapy (FACIT) Multilingual Translations Project.

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ANNEX

Functional Assessment Cancer Therapy – Bone Marrow Transplantation   (versão 3)

NOME:

LOCAL DE APLICAÇÃO:

DATA: _____ / _____ / _____   INÍCIO: _____h_____min   TÉRMINO: _____h_____min

Abaixo você encontrará uma lista de declarações, que outras pessoas com a sua doença disseram ser importantes. Fazendo <u>um círculo em um número por linha</u>, favor indicar até que ponto cada declaração foi verdadeira para você <u>durante os últimos sete dias.</u>

BEM-ESTAR FÍSICO	Nem um pouco	Um pouco	Mais ou menos	Bastante	Muito
1- Estou sem energia	0	1	2	3	4
2- Fico enjoado(a)	0	1	2	3	4
3- Por causa da minha condição física, tenho dificuldade em atender às necessidades de minha família.	0	1	2	3	4
4- Tenho dores	0	1	2	3	4
5- Os efeitos colaterais do tratamento me incomodam	0	1	2	3	4
6- Sinto-me doente	0	1	2	3	4
7- Tenho que me deitar durante o dia	0	1	2	3	4
8- Olhando para as 7 questões, quanto você diria que seu bem-estar físico interferiu em sua qualidade de vida					

Nem um pouco	0	1	2	3	4	5	6	7	8	9	10	muito

BEM-ESTAR SOCIAL / FAMILIAR	Nem um pouco	Um pouco	Mais ou menos	Bastante	Muito
9- Sinto que tenho um relacionamento distante com os meus amigos	0	1	2	3	4
10- Recebo apoio emocional da minha família	0	1	2	3	4
11- Recebo apoio dos meus amigos	0	1	2	3	4
12- A minha família aceita a minha doença	0	1	2	3	4
13- Estou insatisfeito(a) com a comunicação da família sobre a minha doença	0	1	2	3	4
14- Sinto-me próximo(a) do(a) meu(minha) parceiro(a) (ou pessoa que me dá maior apoio)	0	1	2	3	4
15- Você teve relação sexual durante o ano passado? NÃO___SIM___. Se **SIM**: Eu estou satisfeito com minha vida sexual	0	1	2	3	4
16- Olhando para as 7 questões, quanto você diria que sua vida social/familiar interferiu em sua qualidade de vida					

Nem um pouco	0	1	2	3	4	5	6	7	8	9	10	muito

RELACIONAMENTO COM O MÉDICO	Nem um pouco	Um pouco	Mais ou menos	Bastante	Muito
17- Tenho confiança no(s) meu(s) médico(s)	0	1	2	3	4
18- Meu(s) médico(s) é(são) capaz de responder minhas questões	0	1	2	3	4
19- Olhando para as 2 questões, quanto você diria que seu relacionamento com o médico interferiu em sua qualidade de vida					

8

Translation and validation of FACT-BMT   Mastropietro AP et al.

Nem um pouco	0	1	2	3	4	5	6	7	8	9	10	muito

BEM-ESTAR EMOCIONAL	Nem um pouco	Um pouco	Mais ou menos	Bastante	Muito
20- Sinto-me triste	0	1	2	3	4
21- Estou satisfeito(a) com a maneira com que enfrento a minha doença	0	1	2	3	4
22- Estou perdendo a esperança na luta contra minha doença	0	1	2	3	4
23- Sinto-me nervoso	0	1	2	3	4
24- Estou preocupado(a) com a idéia de morrer	0	1	2	3	4
25- Estou preocupado(a) que a minha condição venha a piorar	0	1	2	3	4
26- Olhando para as 6 questões, quanto você diria que seu bem-estar emocional interferiu em sua qualidade de vida					

Nem um pouco	0	1	2	3	4	5	6	7	8	9	10	muito

BEM-ESTAR FUNCIONAL	Nem um pouco	Um pouco	Mais ou menos	Bastante	Muito
27- Sou capaz de trabalhar (inclusive em casa)	0	1	2	3	4
28- Sinto-me realizado(a) com meu trabalho (inclusive em casa)	0	1	2	3	4
29- Sou capaz de sentir prazer em viver	0	1	2	3	4
30- Aceito minha doença	0	1	2	3	4
31- Durmo bem	0	1	2	3	4
32- Gosto das coisas que normalmente faço para me divertir	0	1	2	3	4
33- Estou satisfeito(a) com a qualidade da minha vida neste momento	0	1	2	3	4
34- Olhando para as 7 questões, quanto você diria que seu bem-estar funcional interferiu em sua qualidade de vida					

Nem um pouco	0	1	2	3	4	5	6	7	8	9	10	muito

PREOCUPAÇÕES ADICIONAIS	Nem um pouco	Um pouco	Mais ou menos	Bastante	Muito
35- Tenho pensado em retornar meu trabalho (incluído trabalho em casa)	0	1	2	3	4
36- Sinto-me distante de outras pessoas	0	1	2	3	4
37- Tenho medo que o transplante não irá funcionar	0	1	2	3	4
38- Os efeitos do tratamento são piores que eu tinha imaginado	0	1	2	3	4
39- Tenho bom apetite	0	1	2	3	4
40- Gosto da aparência do meu corpo	0	1	2	3	4
41- Sou capaz de fazer as coisas que estão ao meu redor	0	1	2	3	4
42- Fico cansado(a) fácil	0	1	2	3	4
43- Tenho interesse em ter relação sexual	0	1	2	3	4
44- Tenho consciência da minha capacidade de ter filhos	0	1	2	3	4
45- Tenho confiança em minha(s) enfermeira(s)	0	1	2	3	4
46- Regredi fazendo transplante de medula óssea	0	1	2	3	4
47- Olhando para as 12 questões, quanto você diria que essas preocupações adicionais interferiram em sua qualidade de vida					

Nem um pouco	0	1	2	3	4	5	6	7	8	9	10	muito