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Validation of the FACT-BRM with interferon-α treated melanoma patients

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Abstract

The somatic, neurocognitive, and psychiatric side effects of biological response modifiers (BRMs) have been documented in specific patient samples. Although these side effects likely have a predictable impact on patients quality of life (QOL), no instrument currently measures the cumulative effect of the various complaints patients' report. The current study investigated the reliability and validity of the Functional Assessment of Cancer Treatment-Biological Response Modifier (FACT-BRM) scale for measuring QOL in a sample of melanoma patients receiving interferon. Measures of distress, depression, and fatigue were also obtained using standardized, well-validated instruments. Results indicate increased symptom burden, depression, and fatigue, and decreased quality of life over 4 months of IFN therapy. The FACT-BRM demonstrated good psychometrics and sensitivity to change, and thus appears to be a good instrument for measuring QOL in patients receiving BRMs.

Key words: Cancer, FACT, Interferon, Melanoma, QOL

Introduction

Recent increased interest in quality of life (QOL) for cancer patients has prompted the development of several measures of health-related quality of life, including the European organization for Research and Treatment of Cancer Quality of Life Questionnaire [1], the Functional Living Index-Cancer [2, 3], the Cancer Rehabilitation Evaluation System [4], the Medical Outcome Survey Short Form-36 [5, 6], and the Functional Assessment of Cancer Treatment (FACT) [7].

The FACT is composed of general subscales that measure physical, social/family, emotional, and functional well-being, with additional specific questions included to address concerns for the subpopulation of interest. One measure that has not yet received a great deal of study is the biological response modifier (BRM) version of the FACT (FACT-BRM). This version was designed to measure changes in quality of life associated with the use of treatments such as interferons and interleukins, which have demonstrated effectiveness in treating various conditions but remain difficult for patients to tolerate.

BRMs are associated with constitutional and neuropsychiatric side effects [8–11] which are often dose dependent [12], making higher-dose therapies (such as those used to treat melanoma) too difficult for some to tolerate, thus resulting in discontinuation of therapy [13, 14]. Many of the reports of side effects associated with BRM administration have been single case studies [15–18], used retrospective or cross-sectional designs [19], or used lower dosages of BRMs than is usually used to treat melanoma [20]. None have measured HRQOL associated with high-dose IFN administration in melanoma patients prospectively during

therapy or evaluated the utility of such a specific HRQOL instrument over the course of high-dose BRM treatments.

Having accurate information on the QOL and toxicities associated with administration of BRMs is important for consideration of these therapies for the future. Such information requires measurement with a valid, reliable instrument that is sensitive to the effects of BRMs. The varied side effects produced by these treatments suggest the need for multidimensional measures that can provide an indication of the impact they may have on QOL. Currently, little is known about the ability of the FACT-BRM to identify changes in HRQOL. Thus, the current study was designed to examine prospectively the HRQOL of a sample of melanoma patients receiving high-dose interferon-α-2b over 4 months, and to evaluate the validity, reliability, and sensitivity to change of the FACT-BRM.

Methods

Participants

This study was part of a larger project examining distress and QOL in interferon-treated melanoma patients conducted at the University of Michigan Comprehensive Cancer Center [21]. Individuals with melanoma who were planned for treatment with IFN-α-2b at the University of Michigan's Comprehensive Cancer Center between April 1999 and February 2002 were eligible for the study if they were also over the age of 18, read and understood English, and were able to give their own consent. Over this period of time, 21 patients (12 male, 9 female) with resected malignant melanoma agreed to participate. Average age of the participants was 43.67 (12.67); most were married (71.4%) and employed (57.1%); approximately half (47.6%) had a college education or higher.

Therapy involved 1 month of high dose IFN-α-2b administered daily, followed by 11 months of three times a week self-administered maintenance therapy at a lower dose. As part of the larger study, assessments were conducted at baseline (before IFN therapy was initiated), post-baseline after 1 month of high dose infusion (PoHD), and at months 1, 2, 3, 6, 9, and 12 of maintenance therapy. Since the majority of side effects associated with IFN present within the first 3 months of therapy, data from the baseline, PoHD, and the first two maintenance assessments were examined for this study. The University of Michigan IRB approved the study and all patients provided written consent.

Procedure

Initial contact and administration of baseline and PoHD questionnaires occurred in a Cancer Center examination room. Questionnaires completed after 1 and 2 months of maintenance therapy were sent to patients and returned through self-addressed stamped envelopes. Each questionnaire package consisted of the Brief Symptom Inventory, Functional Assessment of Cancer Therapy-Biological Response Modifiers, Revised Piper Fatigue Scale, and Beck Depression Inventory. The baseline package also obtained demographic and illness information. Packages took 20–30 min to complete.

Measures

Brief Symptom Inventory (BSI)

The BSI is the short version of the SCL-90-R. It contains 53 items measuring emotional distress and takes 5–10 min to complete [22, 23]. Individual items are answered on a '0' (not at all distressed) to '4' (extremely distressed) scale and are summed into one of nine clinical scales and three summary scales. Principal among these for the purpose of the current study are the somatization (as a measure of somatic complaints or symptom burden) and depression subscales, as these reflect the primary symptoms that have been identified as potentially being affected by interferon therapy. The BSI is standardized using area T-scores, each with a range from 0 to 100, mean of 50, and standard deviation of 10.

Functional Assessment of Cancer Treatment-Biological Response Modifiers (FACT-BRM)

The FACT-BRM is a 40-item questionnaire designed to assess quality of life [7]. Four general domains cover physical well-being, social/family well-being, emotional well-being, and functional well-being. A fifth, targeted domain, assesses

specific physical and cognitive/emotional concerns associated with BRM treatments. Each of the 40 items is scored on a five point Likert-type scale ranging from 0 (Not at all) to 4 (Very much). Raw subscale scores range from 0 to 24 (emotional, additional cognitive), or 0 to 28 (physical, social, functional, additional physical).

Revised Piper Fatigue Scale (RPFS)

The RPFS is a 22-item questionnaire designed to measure the presence of and interference from fatigue [24]. It is composed of four subscales: behavioral, affective, sensory, and cognitive. Each item is scored on a 0–10 Likert-type scale, with end-points representing extremes (e.g., 0 = None, 10 = A great deal). Subscale scores and a total fatigue score are obtained by calculating corresponding arithmetic means.

Beck Depression Inventory (BDI)

The BDI is a 21-item self-report questionnaire assessing the presence and severity of depressive symptoms [25]. Total scores range from 0 to 63, with higher scores indicating greater pathology.

Demographic questionnaire

A face valid demographic questionnaire obtained information on age, race, education, employment status, marital status, and number of dependents.

Statistical analyses

Descriptive statistics were computed for scales on each measure at each measurement occasion. Subscale correlations were measured using Pearson product moment correlation coefficients. Internal consistency was obtained through the use of coefficient α on the items within each subscale of the FACT-BRM. Tests of means were conducted using single sample *t*-tests. All *p* values reported are two-tailed, and all statistical analyses were performed using the Statistical Package for Social Sciences, version 10 (SPSS, Inc, Chicago, IL).

Results

Descriptives

Descriptive data are presented in Table 1. Means and standard deviations of the FACT-BRM subscales, BSI subscales, BDI, and Piper Fatigue subscales are given for the four assessment points. The physical, social/family, emotional, and functional subscales, in addition to the additional mental and additional physical scales of the FACT-BRM are provided.

Concurrent validity

In order to address the concurrent validity of the FACT-BRM, Pearson product moment correlations were conducted between the FACT and the BDI, PFS, and specific subscales of the BSI at the post-high dose assessment point. This point was chosen as it was expected that effects due to high-dose IFN administration would be greatest after 1 month of high dose therapy, relative to the

Table 1. Descriptive analyses at baseline, post high-dose, 1- and 2-months post high-dose (n = 21)

	Baseline	Post high-dose	1-Month Post high-dose	2-Month post high-dose
FACT-BRM physical	25.12 (3.80)	19.28 (4.13)	19.46 (4.29)	17.67 (4.60)
FACT-BRM social/family	23.88 (5.43)	24.22 (4.30)	24.31 (2.63)	23.10 (2.96)
FACT-BRM emotional	17.85 (4.51)	19.89 (3.08)	19.08 (5.71)	19.75 (2.67)
FACT-BRM functional	21.02 (5.95)	18.22 (5.79)	18.08 (5.76)	18.17 (5.32)
FACT-BRM additional physical	25.50 (2.28)	17.22 (4.56)	17.64 (4.85)	16.85 (5.00)
FACT-BRM additional mental	20.35 (3.42)	17.67 (4.14)	16.64 (5.26)	16.46 (4.61)
BSI somatization	50.20 (8.32)	59.22 (9.94)	58.15 (9.07)	59.17 (9.52)
BSI depression	50.90 (10.25)	51.83 (11.11)	53.62 (10.67)	54.00 (8.61)
Beck depression inventory	5.00 (4.17)	7.56 (3.85)	9.15 (7.13)	9.08 (4.74)
Piper behavior	0.77 (1.22)	3.39 (2.46)	4.00 (2.27)	3.97 (1.91)
Piper affect	1.57 (2.04)	4.03 (2.28)	4.86 (1.92)	4.82 (2.04)
Piper sensory	1.77 (1.82)	4.57 (1.95)	5.11 (1.71)	5.08 (1.44)
Piper cognitive	1.43 (1.66)	2.99 (2.01)	2.88 (1.93)	2.97 (1.67)

Table 2. Concurrent validity: post-high dose convergent correlations (n = 21)

	FACT-BRM					FACT
	Physical	Emotional	Functional	Additional physical	Additional cog/ emot	total
BSI somatization	**−0.693***	−0.667**	−0.645**	**−0.771***	−0.626**	**−0.761***
BSI depression	−0.416	−0.638**	−0.665**	−0.525**	**−0.792***	**−0.755***
Beck depression inventory	**−0.720***	−0.667**	**−0.903***	**−0.784***	**−0.839***	−0.908*
Piper fatigue behavioral	**−0.747***	−0.309	−0.490**	−0.638**	−0.524**	−0.557**
Piper fatigue affective	−0.546**	−0.298	−0.493**	−0.466**	−0.531**	−0.527**
Piper fatigue sensory	**−0.810***	−0.410	−0.589**	**−0.694***	**−0.723***	**−0.733***
Piper fatigue cognitive	−0.577**	**−0.808***	**−0.727***	−0.580**	**−0.786***	**−0.780***
Piper fatigue Total	**−0.787***	−0.539**	**−0.691***	−0.677**	**−0.762***	**−0.761***

*$p < 0.001$; **$p < 0.05$.

baseline and maintenance phase assessment points. Based on the literature, we hypothesized consistent, significant associations would demonstrate convergent validity between FACT-BRM subscale scores and scores on measures of somatic complaints, depression, and fatigue, once participants had received IFN, with discriminant validity being indicated by the absence of significant correlations [26]. Separate correlation matrices reflecting hypothesized convergent and discriminant associations are presented in Tables 2 and 3.

As expected, FACT-BRM subscales were correlated with increased depression and somatic complaints. All baseline correlations were significant at the $p < 0.05$ level except those between FACT-BRM Emotional and Piper Fatigue Affective and Behavioral. Corrected for multiple comparisons, nearly half of the correlations in Table 2 continued to be significant at the $p < 0.001$ level, demonstrating convergent validity. By comparison, only six of the correlations in Table 3 were significant at this level, demonstrating discriminant validity. Unexpected results were found when BSI Anxiety and Obsessive–Compulsive scales correlated significantly with selected FACT subscales.

Sensitivity to change

In order to assess the sensitivity to change of the FACT-BRM, baseline to PoHD scores on the FACT were subjected to *t*-tests. We hypothesized that any changes in HRQOL associated with IFN administration would be reflected in FACT-BRM changes from baseline (pre-administration) to PoHD (after 1 month of daily high dose administration). In particular, we expected changes in PWB, FWB, EWB, additional concerns, and total scores. As expected, changes on all subscales except social/family well-being were significant: PWB $t(16) = 5.91$, $p < 0.001$; S/FWB

Table 3. Concurrent validity: discriminant correlations of FACT-BRM subscales at post-high dose (n = 21)

	FACT			Additional		FACT
	Physical	Emotional	Functional	Physical	Cog/Emot	total
BSI anxiety	−0.204	**−0.724***	−0.571**	−0.539**	**−0.756***	−0.686**
BSI hostility	−0.238	−0.209	−0.187	−0.144	−0.256	−0.268
BSI psychoticism	−0.728**	−0.295	−0.464	−0.513	−0.608**	−0.615**
BSI phobic anxiety	−0.371	−0.220	−0.597**	−0.489	−0.545	−0.510
BSI obsessive-compulsive	**−0.791***	−0.633**	**−0.788***	−0.707**	**−0.834***	**−0.856***
BSI interpersonal sensitivity	−0.335	−0.255	−0.435	−0.560**	−0.329	−0.434
BSI paranoid ideation	−0.174	−0.083	−0.386	−0.029	−0.388	−0.268

*$p < 0.001$; **$p < 0.05$.

Table 4. Sensitivity to change: change score correlations baseline to post-high dose (n = 21)

	FACT-BRM					FACT
	Physical	Emotional	Functional	Additional Physical	Additional Mental	total
BSI somatization	−0.730**	−0.553**	−0.734*	−0.582**	−0.572**	−0.817***
	$p = 0.001$	$p = 0.021$	$p = 0.001$	$p = 0.014$	$p = 0.016$	0.000
BSI depression	−0.669*	−0.489**	−0.769*	−0.460	−0.478	−0.779***
	$p = 0.003$	$p = 0.046$	$p < 0.000$	$p = 0.063$	$p = 0.052$	0.000
Beck depression inventory	−0.492**	−0.661*	−0.741*	−0.196	−0.532**	−0.648*
	$p = 0.045$	$p = 0.004$	$p = 0.001$	$p = 0.451$	$p = 0.028$	0.005
Piper fatigue behavioral	−0.634*	−0.442	−0.464	−0.397	−0.490**	−0.600**
	$p = 0.006$	$p = 0.076$	$p = 0.061$	$p = 0.114$	$p = 0.046$	0.011
Piper fatigue affective	−0.274	−0.452	−0.310	−0.097	−0.416	−0.358
	$p = 0.286$	$p = 0.069$	$p = 0.225$	$p = 0.712$	$p = 0.097$	0.159
Piper fatigue sensory	−0.671*	−0.346	−0.562**	−0.433	−0.459	−0.636*
	$p = 0.003$	$p = 0.174$	$p = 0.019$	$p = 0.082$	$p = 0.064$	0.006
Piper fatigue cognitive	−0.617*	−0.500**	−0.801*	−0.245	−0.450	−0.684*
	$p = 0.008$	$p = 0.041$	$p < 0.000$	$p = 0.342$	$p = 0.070$	0.002

*$p < 0.001$; **$p < 0.05$.

$t(16) = -0.09$, ns; EWB $t(16) = -0.2786$, $p < 0.05$; FWB $t(16) = 2.27$, $p < 0.05$; AC $t(16) = 6.72$, $p < 0.001$; FACT Total $t(16) = 4.67$, $p < 0.001$.

Change scores from Baseline to PoHD were then created on the Total FACT-BRM and all its subscales. These were then correlated with change scores on the BSI somatization and depression subscales, BDI, and Piper Fatigue Scales for the same period to determine whether the changes in HRQOL measured by the FACT-BRM were associated with changes in symptom burden, depression, and fatigue. Results are presented in Table 4. Significant correlations were seen between changes in the FACT-BRM physical scale and the somatization and depression scales of the BSI (all $p < 0.005$), and the behavioral, sensory, and cognitive/affective scales of the RPFS (all $p < 0.01$). In each case, decreased physical QOL was associated with increased complaints on the other scales. Similar findings were observed for the FACT-BRM emotional, functional, and additional concerns scales with the BDI and BSI depression and somatization scales.

Internal consistency

Coefficient α,s for each subscale of the FACT-BRM were calculated at baseline and after 1 month of post-high dose administration. Baseline α,s ranged from poor to excellent: functional well-being 0.91, physical well-being 0.85, emotional well-being 0.81, additional concerns – mental 0.75, social/family well-being 0.50, additional concerns – physical 0.30. Thus, the internal consistency of the physical, functional, and emotional well-being subscales is excellent, and while it is adequate for the additional concerns – cognitive/emotional subscale, it is considerably lower for the social/family well-being and additional concerns – physical scales. α,s at the post-high dose administration assessment point are higher, reflecting improved reliability in measuring QOL once patients are on IFN: functional well-being 0.91, emotional well-being 0.83, social/family well-being 0.82, additional concerns – cognitive/emotional 0.79, physical well-being 0.73, and additional concerns – physical 0.61.

Test–retest reliability

To evaluate the stability of the FACT-BRM, 1-month test–retest reliability correlations were conducted on subscale scores from the maintenance phase of IFN administration. Scores from after 1 and 2 months of maintenance therapy were compared. Reliability for the functional subscale was in the excellent range ($r = 0.89$, $p < 0.001$), in the good range for the physical ($r = 0.79$, $p < 0.005$) and emotional subscales ($r = 0.77$,

$p < 0.01$), and in the acceptable range for the additional concerns – mental ($r = 0.68$, $p < 0.05$) and social/family subscales ($r = 0.68$, $p < 0.05$). Reliability for the additional concerns – physical subscale was not statistically significant ($r = 0.51$, $p > 0.05$). These results are consistent with the reported health of the melanoma patients, which did not change significantly during the first and second months of maintenance therapy [21]. Thus, all correlations were significant, with the exception of the additional concerns – physical subscale, which demonstrated a trend in the same direction and approached statistical significance.

Discussion

The current paper reports the results of validity and reliability analyses of a new, specific measure of QOL, the FACT-BRM, as part of a larger study measuring levels of depression, distress, and fatigue prospectively over the full 12 month course of therapy among patients taking high-dose interferon for melanoma.

The FACT-BRM demonstrated good concurrent validity when compared with the BDI, and subscales of the BSI and RPFS. All correlations were in expected directions, demonstrating good convergent and discriminant validity. FACT-BRM subscales correlated with measures of fatigue, symptom burden, and depression, as hypothesized. Although unexpected correlations were also found with measures of anxiety (as measured by the anxiety and obsessive–compulsive subcales of the BSI), they were highly significant and consistent across subscales of the FACT-BRM, making it unlikely that they are the result of chance. Also, since these correlations were from scores at the post-high dose point, participants had already been on IFN for 1 month, making anticipatory anxiety an unlikely explanation. It is possible that these correlations indicate health-related concerns and anxiety among the patients receiving interferon, which has not been a focus of previous research. It is also possible that the correlations between HRQOL dimensions and measures of anxiety reflect the occurrence of arousal symptoms (e.g., feeling shaky) precipitated by interferon, rather than anxiety. Alternatively, it may indicate the presence of other effects of high dose IFN therapy, heretofore unidentified in the literature. The results are too consistent to simply dismiss, and we would suggest that future research may elucidate this possibility further.

The FACT-BRM also demonstrated excellent sensitivity to change by measuring significant differences in mean scores on almost all subscales of the FACT from pre-administration baseline to post-high dose IFN administration. The validity of the changes noted is supported by consistent correlations with changes on other measures over the same time period.

With regard to reliability, coefficient α,s indicated adequate internal consistency at the baseline administration point, before participants were on IFN. These improved substantially after one month of high-dose therapy, indicating good internal consistency in measuring HRQOL among participants receiving high-dose IFN. One month test–retest correlations also indicated adequate stability over time.

The current study utilized data from a small, but significant group of melanoma patients who are at risk for recurrence and have few treatment alternatives. In general, scores indicated increased symptoms of depression, symptom burden, and fatigue following IFN administration, which is consistent with findings reported in the growing literature on BRMs generally. As expected, these results correlated significantly with decreased HRQOL across a number of dimensions. Results document the FACT-BRM's ability to track changes in symptoms and QOL experienced over time by patients receiving high-dose IFN. Thus, the FACT-BRM appears to be a sensitive, valid, and reliable measure of HRQOL among patients receiving high-dose IFN-α-2b.

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