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ORIGINAL ARTICLE

Mapping the cancer-specific FACT-B onto the generic SF-6Dv2

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Abstract

Introduction The health-related quality of life (HRQoL) data extracted from cancer-specific questionnaires are often non-preference based, while patient preference-based utility data are required for health economic evaluation. This study aimed to map Functional Assessment of Cancer Therapy-Breast (FACT-B) subscales onto the Short Form six Dimension as an independent instrument ($SF\text{-}6Dv2_{ind\text{-}6}$) using the data gathered from patients with breast cancer.

Methods Data for 420 inpatient and outpatient patients with breast cancer were gathered from the largest academic center for cancer patients in Iran. The OLS and Tobit models were used to predict the values of the $SF\text{-}6Dv2_{ind\text{-}6}$ with regard to the FACT-B subscales. Prediction accuracy of the models was determined by calculating the root mean square error (RMSE) and mean absolute error (MAE). The relationship between the fitted and observed $SF\text{-}6Dv2_{ind\text{-}6}$ values was examined using the Intraclass Correlation Coefficients (ICC). Goodness of fit of models was assessed using the predicted R^2 (Pred R^2) and adjusted R^2 (Adj R^2). A tenfold cross-validation method was used for validation of models.

Results Data of 416 patients with breast cancer were entered into final analysis. The model included main effects of FACT-B subscales, and statistically significant clinical and demographic variables were the best predictor for $SF\text{-}6Dv2_{ind\text{-}6}$ (Model S3 of OLS with Adj $R^2 = 61.02\%$, Pred $R^2 = 59.25\%$, MAE = 0.0465, RMSE = 0.0621, ICC = 0.678, AIC = -831.324, BIC = -815.871).

Conclusion The best algorithm developed for $SF\text{-}6Dv2_{ind\text{-}6}$ enables researchers to convert cancer-specific instruments scores into preference-based scores when the data are gathered using cancer-specific instruments.

Keywords Breast cancer · Quality of life · FACT-B · SF-6Dv2

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Introduction

The most common cancer among women around the world is breast cancer, with an estimated 54.4 new cases per 100000 women for developed countries and 31.14 new cases for less-developed countries in 2018 [1]. In Iran, the results showed that the incidence of this cancer had an increasing trend from 2004 to 2013 among women of all ages [2]. High rates of breast cancer and the subsequent increase in the costs of its interventions have necessitated using cost-utility analysis (CUA) to assess outcomes of interventions. The use of CUA has also been recommended by the National Institute for Health and Clinical Excellence (NICE) [3]. The most common approach to perform CUA is the estimation of quality adjusted life years (QALYs). QALYs is a multi-dimensional outcome that combine length of life with quality-of-life measures, and it relies on preference weights as a metric to reflect the health-related quality of life (HRQoL)

of different health states. Therefore, preference weights have been used as a basis to estimate the QALYs.

The EuroQol-5dimensions (EQ-5D) and Short-Form 6 Dimensions (SF-6D) are the most popular preference-based instruments for calculating the QALYs [4]. Using these instruments has the limitation of low sensitivity to particular disease conditions. In parallel, different organizations have developed disease-specific instruments to reflect the HRQoL of different health states. For example, in the area of oncology, the Functional Assessment of Chronic Illness Therapy (FACIT) organization has developed the core component of the FACIT, Functional Assessment of Cancer Therapy—General (FACT-G), and cancer-specific module for many cancers such as breast cancer (FACT-B)for measuring the HRQoL [5]. However, they are often non preference-based measures; thus, they are not feasible to be used directly for calculating QALYs. One solution to this problem is mapping the values from disease-specific instruments onto generic preference-based instruments using the regression technique [6].

The majority of studies have mapped responses on FACT instruments to the EQ-5D values [7], probably due to the recommendation of the National Institute for Health and Clinical Excellence to use the EQ-5D instrument in technology appraisals submitted to the institute [8]. Eleven studies [9–19] used the FACT instruments to predict EQ-5D utility values but only three studies mapped the FACT instruments to SF-6D utility values [9, 20, 21]. No study has ever mapped the FACT-B to SF-6D utility values, while results of only two studies that compared the predictive performance of models derived from mapping non-preference-based instruments to both EQ-5D and SF-6D showed that the models estimated from SF-6D were better than those of EQ-5D [9, 22].

The SF-6D instrument has two versions: the SF-6D version 1 (SF-6Dv1) [3] and the SF-6D version 2 (SF-6Dv2) [7]. The SF-6Dv1 is derived from 11 items of the SF-36v2 that covers 6 dimensions each with four–six levels: physical functioning (6 Levels), pain (6 Levels), social functioning (5 Levels), role limitations (4 Levels), mental health (5 Levels), and vitality (5 Levels) together defining a total number of $5^3 \times 6^2 \times 4 = 18{,}000$ distinct health states [23]. The SF-6Dv1 can be used in combination with the responses to the full SF-36v2 questionnaire ($\text{SF-6Dv1}_{\text{SF-36}}$) or as an independent instrument ($\text{SF-6Dv1}_{\text{ind-6}}$ and $\text{SF-6Dv1}_{\text{ind-11}}$) [24].

The SF-6Dv2 is an improved version of the SF-6D in terms of number of levels of dimensions and framing some items of the dimension. This version is derived from 10 items of the SF-36v2 that includes six dimensions each with five–six levels: physical functioning (5 Levels), pain (6 Levels), social functioning (5 Levels), role limitations (5 Levels), mental health (5 Levels), and vitality (5 Levels) together describing a total number of $5^5 \times 6^1 = 18{,}750$ distinct health states [25]. The SF-6Dv2 can be used as both a dependent and an independent instrument. In dependent form, the SF-6Dv2 is combined with the full SF-36v2 ($\text{SF-6Dv2}_{\text{SF-36}}$); while, the SF-6Dv2 as an independent instrument is used with only 10 items of the SF-36v2 ($\text{SF-6Dv2}_{\text{ind-10}}$) or with only the 6 rephrased items of 10 items from the SF-36v2 ($\text{SF-6Dv2}_{\text{ind-6}}$) [24].

Using the $\text{SF-6Dv2}_{\text{SF-36}}$ is similar to using the $\text{SF-6Dv1}_{\text{SF-36}}$, that is, it should be used with the full SF-36v2 questionnaire. To use the $\text{SF-6Dv2}_{\text{SF-36}}$ and $\text{SF-6Dv1}_{\text{SF-36,}}$ it is required to generate value sets that can be used to transfer the $\text{SF-6Dv1}_{\text{SF-36}}$ and $\text{SF-6Dv2}_{\text{SF-36}}$ responses into utility values for QALYs [24]; these value sets are not available to Iranian general public population [26]. Only $\text{SF-6Dv2}_{\text{ind-6}}$ utility weights are generated for Iranian general public population. The present study aimed to map FACT-B subscales onto the $\text{SF-6Dv2}_{\text{ind-6}}$ values using the preference weights of Iranian population to develop a breast cancer utility instrument.

Methods

Study design and data collection

This study was a cross-sectional survey of 420 inpatient and outpatient female patients with breast cancer requiring surgery, chemotherapy, and radiotherapy, and with confirmed pathological diagnosis and healthy cognitive status. Patients were selected using a consecutive sampling method from surgery, chemotherapy, and radiotherapy departments in the largest academic center for cancer patients in capital of Iran, Tehran, between April and November 2018. Patients with different types of cancers are admitted to this center from all over the country.

Demographic and HRQoL data were collected through direct interview using a researcher-made questionnaire and questionnaires of FACT-B (version 4) and $\text{SF-6Dv2}_{\text{ind-6}}$. All interviews were carried out during a meeting between the patient and interviewer in patient rooms in the center. The clinical data were extracted from the medical records of patients. Patients who gave the informed consent were included in the study.

Study instruments

SF-6Dv2

We used $\text{SF-6Dv2}_{\text{ind-6}}$ questionnaire as an independent instrument to map FACT-B onto $\text{SF-6Dv2}_{\text{ind-6}}$. To generate the $\text{SF-6Dv2}_{\text{ind-6}}$ utility weights, the discrete choice experiment with duration attribute (DCE_{TTO}) was used which is

standardized by Daroudi et al. for Iranian general public [27].

FACT-B

The FACT-B (version 4) is a 37-item non preference-based instrument used to estimate the HRQoL of patients with breast cancer in five subscales: 7 items for physical well-being (PWB), 7 items for social well-being (SWB), 6 items for emotional well-being (EWB), 7 items for functional well-being (FWB), and 10 items for breast cancer subscale (BCS). Each item has a five-point Likert scale so that higher scores in each item indicate better HRQOL and vice versa. Total score of each subscale is the sum of scores of all its items, as higher scores in each subscale represent better HRQOL and vice versa [28]. The validity and reliability of the Iranian version 4 of the FACT-B have been previously confirmed [29].

Model validation and prediction accuracy

Given that the K-fold cross-validation method is commonly applied when the aim of the regression model is prediction [30], we used a tenfold cross-validation technique to assess the prediction accuracy of each model. In this technique, all data were randomly divided into 10 almost equal parts. Moreover, we fitted each model on 90% of data with 10% of validation. Next, the fitted model of the 90% data was used to calculate the predicted residual sum of squares on the 10%, and this process was repeated for each of 10 parts. Lastly, we obtained the sum of the ten predicted residual sums of squares for each fitted model aiming to evaluate the total performance of the models using mean absolute error (MAE) and root mean square error (RMSE) [17]. In addition, relationship between the fitted and observed SF-6Dv2$_{\text{ind-6}}$ values was examined using the Intraclass Correlation Coefficients (ICC). We then calculated the adjusted R^2 (Adj R^2), predicted R^2 (Pred R^2) to assess the goodness of fit of models [21]. Finally, Estimation of health states was assessed by Bland–Altman plot. All analyses were performed using the STATA Software, Version 14.0.

Statistical analysis and model specifications

Results of the latest review study published on studies that mapped disease-specific instruments onto generic preference-based instruments showed that the application of Ordinary Least Squares (OLS) and Tobit models were the most commonly used methods for mapping studies [31]. The OLS requires assumptions such as normality and homogeneity of variance; moreover, we did not have such conditions in this study regarding the results of Kolmogorov–Smirnov test ($p < 0.03$) and Fig. 1. We used the Tobit model that is

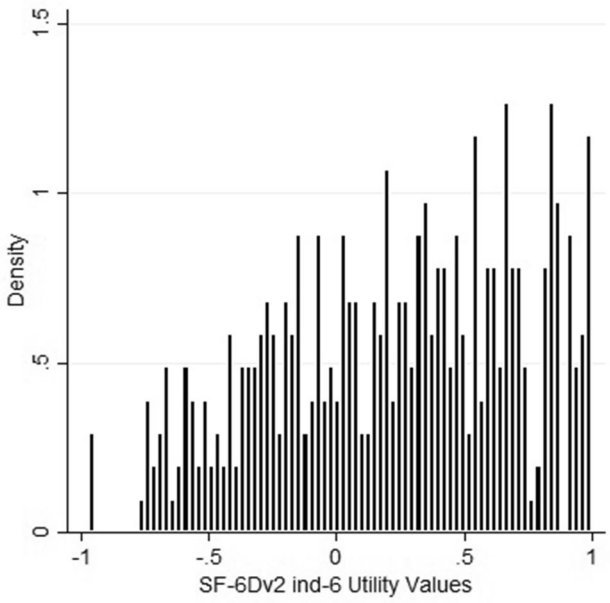

Fig. 1 Distribution of the observed SF-6Dv2$_{\text{ind-6}}$ utility values in patients with breast cancer

robust to this type of data. In addition, we attempted to keep only age variable to a minimum so as to keep the mapping algorithms more generalizable for use in a wider range of data sets. Finally, the OLS and Tobit models were used to estimate the three models:

(1) SF-6Dv2$_{\text{ind-6}}$ was regressed on the FACT-B subscales (Model S1)
(2) SF-6Dv2$_{\text{ind-6}}$ was regressed on the statistically significant subscales of FACT-B (main effects) (Model S2)
(3) As per Model S2 plus age variable (Model S3)

Results

Four questionnaires were excluded from the final analysis owing to missing values on subscales of the FACT-B, and 416 questionnaires remained for final analysis. Table 1 describes demographic and clinical characteristics of the patients who were all women.

Mapping the FACT-B Subscales onto SF-6Dv2$_{\text{ind-6}}$ utility values and comparison models

Findings obtained from the Model S1 of OLS and Tobit showed that PWB, SWB, FWB and BCS subscales had a statistically significant relationship with SF-6Dv2$_{\text{ind-}}$6. Therefore, Model S2 of OLS and Tobit models included PWB, SWB, FWB and BCS subscales as main effects. Then, age variable was added into both OLS Model S2 and Tobit

Table 1 Demographic and clinical characteristics of the patients with breast cancer ($n = 416$)

Mean age (± SD)	50.02 (± 10.16)
Diagnosis duration(mon), mean ± SD	21.11 ± 16.94
Marital status	
Single	24 (5.77%)
Married	328 (78.85%)
Divorced or widow	64 (15.38%)
Education	
Illiterate	32 (7.69%)
Primary	131 (31.49%)
Secondary	191 (45.91%)
University degree	62 (14.90%)
AJCC stage classification	
Stage I	59 (14.18%)
Stage II	110 (26.44%)
Stage III	158 (37.98%)
Stage IV	60 (14.42%)
Unknown	29 (6.97%)
History of treatment	
Surgery	7 (1.68)
Chemotherapy	67 (16.11)
Surgery and chemotherapy	20 (4.81)
Chemotherapy and radiotherapy	173 (41.59)
Surgery, chemotherapy, and radiotherapy	149 (35.82)

Model S2. Nevertheless, the influence of all of the main effects selected from the two models remained unchanged (Table 2).

Findings of goodness of fit of models showed that the OLS Model S3 had the highest exploratory power (Adj $R^2 = 61.32\%$, Pred $R^2 = 60.15\%$), the highest ICC and correlation between fitted versus observed SF-6Dv2$_{\text{ind-6}}$ values (ICC = 0.681), and the lowest AIC and BIC (− 831.324, − 815.871). The prediction accuracy criteria of models also revealed that the performance of OLS Model S3 was the best (MAE = 0.0632, RMSE = 0.0876) (Table 2), and covariance matrix of coefficients of that is provided in Online Appendix.

The Bland–Altman plots that were obtained by plotting the distribution of differences between the mapped and observed utilities (y axis) versus the mapped and observed mean for utilities (x axis), showed that the best mapping function underestimates the values in better health states and overestimates in poorer health states (Fig. 2).

Discussion

We developed algorithms to map FACT-B onto the SF-6Dv2$_{\text{ind-6}}$ using OLS and Tobit models based on the data collected from patients with breast cancer. The MAE and RMSE of models were low and satisfactory with regard to the range of MAE (0.001–0.19) and RMSE (0.084–0.2)

Table 2 Regression of the SF-6Dv2$_{\text{ind-6}}$ values upon FACT-B subscales

SF-6Dv2$_{\text{ind-6}}$	β_{OLS} ($N = 416$)			β_{Tobit} ($N = 416$)		
	FACT-B Subscales (S1)	Main effects of FACT-B Subscales(S2)	Demographic variable added (S3)	FACT-B Subscales (S1)	Main effects of FACT-B Subscales(S2)	Demographic variable added (S3)
PWB	0.03320*	0.03348*	0.03362*	0.03444*	0.03472*	0.03485*
SWB	0.00517*	0.00551*	0.00482*	0.00570*	0.00603	0.00532
EWB	0.00555			0.00550		
FWB	0.01937*	0.02105*	0.02085 *	0.01966*	0.005763*	0.02114*
BCS	0.01274*	0.01559*	0.01625*	0.01325*	0.01608	0.01675
Age			− 0.00203*			− 0.00207*
Constant	0.04803*	0.07079*	− 0.96868*	0.08638*	0.10897*	0.00508*
Adjust R^2	59.57%	61.11%	61.32%	59.08%	61.03%	61.12%
Pred R^2	57.87%	59.95%	60.15%	57.86%	59.91%	60.11%
MAE	0.0651	0.0640	0.0632	0.0652	0.0648	0.0640
RMSE	0.0891	0.0881	0.0876	0.0892	0.0879	0.0862
ICC	0.662	0.671	0.681	0.660	0.669	0.679
AIC	− 821.0132	− 827.821	− 831.324	− 820.001	− 824.032	− 829.131
BIC	− 794.899	− 812.761	− 815.871	− 792.872	− 812.892	− 814.837
Mean Observed	0.5981	0.5981	0.5981	0.5981	0.5981	0.5981
Mean Predict	0.5791	0.5882	0.5906	0.5789	0.5878	0.5900

AIC Akaike information criterion, *BIC* Bayesian information criterion, *ICC* Intraclass correlation coefficients

*Significant at level of 0.05

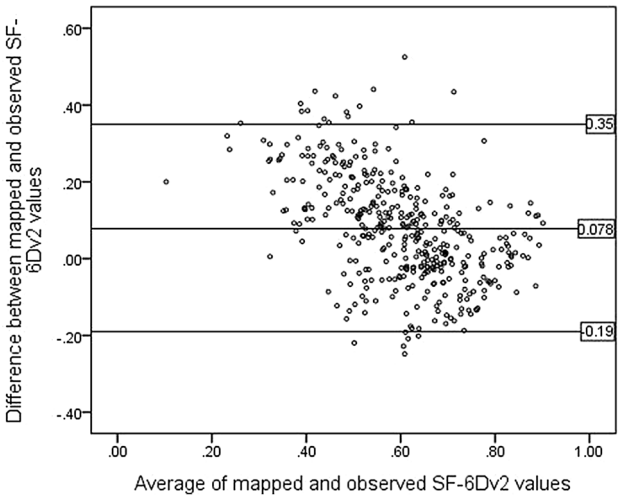

Fig. 2 Bland–Altman plot of mapped and observed mean difference of the OLS Model 3

reported by a review of mapping literature [32]. These findings were better compared with those reported in mapping FACT-G onto SF-6Dv1$_{SF-36}$ for patients with different types of cancer [9]. This difference in predictive performance may be due to the fact that the FACT-B has one more dimension than FACT-G that increases the correlation between scales of FACT-B and SF-6D dimension scores. The better performance of our models can be because of a more homogenous patient population in our study. Another reason to explain the better performance of our models was the inclusion of age variable that was not included in their models [33, 34]. Nevertheless, when comparing these results with findings obtained from mapping FACT-C onto SF-6Dv1 in Chinese patients with colorectal cancer [21], the predictive performance of our mapping functions was lower than that of their functions. This difference in predictive performance potentially can be explained by the difference in the valuation methods that were used to generate the value sets of SF-6Dv1 and SF-6Dv2 in general public. The valuation method for the Chinese SF-6Dv1 was the standard gamble technique; while for the Iranian, SF-6Dv2$_{ind-6}$ was the DCE$_{TTO}$ approach. Many studies have demonstrated that time trade-off method produces higher ceiling effects than the standard gamble technique [35], which can lead to a difference in the performance of the mapping functions [36].

Results showed that the algorithms developed from OLS regression were better than those of the Tobit models. However, the OLS Model S3 of SF-6Dv2$_{ind-6}$ had the best prediction accuracy among all models. These results support the performance of OLS model in mapping FACT-G subscales onto the SF-6Dv1$_{SF-36}$ in a population with variety of cancer types. The study showed that the performance of OLS model is better than other two models, i.e., generalized linear model (GLM) and censored least absolute deviation (CLAD) [9]. These results are in line with those reported in another study which mapped FACT-B subscales onto the EQ-5D-5L [12]. Also, these results are consistent with the findings obtained from the OLS and Tobit models that were used for mapping FACT-P onto EQ-5D in metastatic castration-resistant prostate cancer patients [18]. However, results of four reviews on mapping studies showed that use of the OLS for mapping disease-specific non-preference-based instruments to generic preference-based instruments was the most common regression method [7, 32, 37, 38]. Note that these do not necessarily show that the OLS model had the best performance and is the most appropriate method [7].

The criterion of goodness of fit of the models, that is Adj R^2 and Pred R^2, was higher than 0.5, which in comparison with the range of the statistical indicators of R^2 (0.4–0.6) reported by a review of mapping studies was relatively good [32]. It implies that at least half of the variance in SF-6Dv2$_{ind-6}$ has been accounted for. This level of goodness of fit was common in studies mapping FACT instruments to SF-6Dv1, e.g., R^2, Adj R^2 and Pred R^2 ranged from 0.53 to 0.59 for FACT-G [21], from 0.54 to 0.60 for FACT-Colorectal [21], and Adj R^2 from 0.50 to 0.65 for FACT-G [9].

Our results revealed that the addition of age variable improved the performance of the models and, the value of AIC and BIC. Previous studies also found the same result, but they were different in terms of the types of the variables added into the models [20, 21]. This difference can be related to the type of cancer or the clinical and demographic characteristics of the patients.

The findings of the ICC indicate that the degree of relationship between the mapped and observed utilities fell in the range of 60–70 which is consistent with the good range of agreement [39]. In addition, the difference between the mapped and observed utilities ranged from 0.008 to 0.020. This difference is very small and well below the mean minimally important difference (MID) of 0.041 that was computed for a change in QALY [40].

The Bland–Altman plots showed that the best mapping function underestimates the values in better health states and overestimates in poorer health states. These findings were consistent with the patterns found in other studies [33, 34].

The present study has some limitations. First, although our patients were recruited from the largest center of cancer which welcomes a variety of patients from different regions of Iran, it may not be perfectly representative of other Iranian patients; therefore, the results should be used cautiously. Second, given that the distribution of utility values is commonly skewed, mutinominal, and bounded, the use of OLS and Tobit models may not be the gold standard for this type of data because they are not able to consider all of these features. Although the results of the most recent review on mapping studies showed that the use of the basic models

had been increased [38], there is growing evidence showing that these models are insufficient for mapping studies using the EQ-5D questionnaire [41, 42]. It seems that some of the mixture models like mixture beta (betamix) and adjusted limited dependent variable mixture model (ALDVMM) that capture specific features of the data of value sets are better for mapping studies [43]. Thereafter, our models should be applied with caution.

Conclusion

The developed mapping algorithms establish a correlation between FACT-B data and the SF-6Dv2$_{ind-6}$ as preference-based instruments to predict SF-6Dv2$_{ind-6}$ values from FACT-B subscales when it is not possible to collect data through preference-based instruments. Our results showed that the model which included the main effects of FACT-B subscales and age was the best predictor for SF-6Dv2$_{ind-6}$ (OLS Model S3).

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the national research committee (the Imam Khomeini Cancer Institute + IR.TUMS.SPH.REC. 1396.4880) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all patients included in the study.

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