



# Health-related quality of life as a predictor of tuberculosis treatment outcomes in Iraq



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## ARTICLE INFO

### Article history:

Received 23 August 2014

Received in revised form 27 November 2014

Accepted 1 December 2014

### Keywords:

Tuberculosis  
Treatment  
Outcome  
HRQL  
FACIT  
FACT-G

## SUMMARY

**Objectives:** To determine how tuberculosis (TB) treatment affects the health-related quality of life (HRQL) of patients with pulmonary TB and to identify the predictors of favourable TB treatment outcomes in Baghdad, Iraq.

**Methods:** The Functional Assessment of Chronic Illness Therapy – Tuberculosis (FACIT-TB), a new TB-specific quality of life instrument derived from the internationally recognized FACIT measurement system for the assessment of HRQL, was administered. The mean total and subscale scores of the FACIT-TB at baseline, end of the intensive phase, and end of TB treatment were compared.

**Results:** After the 2-month intensive phase, physical well-being, functional well-being, and the overall total scores were significantly increased ( $p < 0.01$ ). Furthermore, at completion of TB treatment, there were significant improvements in the overall HRQL as indicated by the FACIT-TB total score and all subscales, except social and economic well-being and spiritual well-being. In a direct logistic regression model, only the FACIT-TB total score made a statistically significant contribution towards predicting the likelihood that a patient would have a favourable TB treatment outcome.

**Conclusions:** Therapeutic intervention had a positive impact on patient HRQL. We conclude that FACIT-TB is a reliable tool to monitor HRQL during the course of TB treatment.

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## 1. Introduction

The evaluation of therapeutic interventions is no longer limited to clinical outcomes such as curing diseases, reducing associated morbidity or symptoms, preventing mortality, and normalizing biomedical markers that have been measured traditionally, but it is now also focused on humanistic outcomes such as patient satisfaction and quality of life (QoL). Hence, health-related quality of life (HRQL) assessments are being used in direct patient care processes, clinical trials, program evaluations, and for monitoring health status in populations.<sup>1</sup>

Until recently, no psychometrically robust, concise instrument existed to assess HRQL in patients with tuberculosis (TB) that was of

practical use in clinical practice and clinical trials.<sup>2,3</sup> Therefore, we developed a multi-dimensional HRQL measure specific for pulmonary TB (PTB) patients in Iraq called the Functional Assessment of Chronic Illness Therapy – Tuberculosis (FACIT-TB). Building on the conceptual and methodological framework for the assessment of health status proposed by Cella and colleagues in the USA<sup>4</sup> and Aaronson and colleagues in Europe,<sup>5,6</sup> a modular approach was adopted for the development of this instrument. The intent was to construct a core questionnaire covering broad domains of QoL, such as physical well-being, emotional well-being, and social well-being, relevant to a broad range of patients regardless of their specific diagnosis, supplemented by disease and treatment-specific (i.e. PTB) modules. The core, general HRQL questionnaire is comprised of the Functional Assessment of Cancer Therapy – General (FACT-G) items.<sup>4</sup> FACT-G was selected because of its established psychometrics and history in measuring HRQL symptoms in patients with a variety of chronic illnesses as well as in the general population.<sup>7</sup>

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Over the past several years, a growing number of studies assessing the impact of TB and TB-associated treatment on patient HRQL have been conducted in many regions.<sup>8–13</sup> However, such studies were lacking in Iraq. Therefore, the current study was conducted to determine how TB treatment affects HRQL of patients with PTB attending the Thoracic and Respiratory Disease Specialist Centre in Baghdad, Iraq, and to assess the impact of a number of factors on the likelihood that a patient would have a favourable TB treatment outcome (i.e., cured or completed treatment).

## 2. Methods

### 2.1. Study design, setting, and population

A prospective cohort study was conducted in Baghdad, Iraq between September 1, 2012 and July 31, 2013, among consecutive patients with PTB who received treatment at the Thoracic and Respiratory Disease Specialist Centre, the largest centre for the diagnosis, treatment, and recording of all new and previously treated TB cases in Iraq. Patients aged 18 years or older at the time of PTB diagnosis were included in the study. Patients with any associated pulmonary diseases such as lung cancer, chronic obstructive pulmonary disease, and asthma, and other chronic diseases likely to affect HRQL including diabetes mellitus and cardiovascular diseases, as well as hospitalized patients and patients with underlying immune suppression, were excluded from the study.

### 2.2. Quality of life and data collection instruments

A standardized data collection tool was designed to collect the following data: (1) socio-demographic information including age, gender, marital status, occupation, and educational level; (2) environmental variables including habitat and number of household contacts; (3) financial status using a measure rating this as poor, intermediate, or good; and (4) FACIT-TB questionnaire items.

FACIT-TB is a disease-specific instrument designed to assess HRQL in patients diagnosed with PTB and is a part of the FACIT measurement system.<sup>14</sup> We followed a modular approach to develop the FACIT-TB questionnaire. In this approach, a set of items assessing QoL issues considered to be relevant and specific to the target population of TB patients, but not sufficiently covered in the original FACT-G instrument, were added. Furthermore, the new subscale structure of the questionnaire was determined through principal component analysis. It comprises 45 items: 17 items covering physical well-being (possible score range 0–68), seven items covering social and economic well-being (possible score range 0–28), 11 items covering emotional well-being/living with TB (possible score range 0–44), seven items covering functional well-being (possible score range 0–28), and three items covering spiritual well-being (possible score range 0–12). A 5-point Likert-type scale ranging from 0 (not at all) to 4 (very much) is assigned to each item. Two different total scores in addition to each individual subscale score can be obtained (FACT-G total score and FACT-G plus disease-specific domain scores). The FACT-G total score provides a useful summary of overall QoL across a diverse group of patients. The disease-specific questionnaire total scores (i.e., FACT-G plus disease-specific subscale score) may further refine the FACT-G summary score. The FACIT-TB total score ranges from 0 to 180, with a higher score corresponding to a better HRQL. Using a classical psychometric approach, FACIT-TB has demonstrated excellent reliability, constructs validity, and is a sensitive instrument to set clinically significant differences in longitudinal studies of TB treatment. The internal consistency estimate was 0.92 and the Cronbach's alpha coefficients for the FACIT-TB subscales were uniformly high across all of the subscales, ranging

from 0.81 to 0.93. Item intra-class correlation coefficients for test–re-test reliability analysis ranged from 0.72 to 0.92.

### 2.3. Data collection

When eligible cases were identified, the FACIT-TB was administered and completed by the patient him/herself or through face-to-face interview for those who were illiterate or who had other difficulties. The interviews were conducted by a medical social worker who was trained prior to the study to standardize the interview procedure. Subsequently, the interviewer conducted a structured interview using a data collection form to collect information on demographics and socio-economic status. The FACIT-TB HRQL instrument was administered before the respondent was asked about socio-demographic characteristics so that any discussion did not affect their answers to the questionnaire.

Moreover, the interviews were conducted in a quiet, distraction-free area at the study centre after informed consent had been obtained from the individual patient. Additionally, patients were informed about the aim of the study, the confidentiality of the data to be collected, and their right to withdraw from the study at any time. The principal investigator accompanied the interviewer during the first 2 months of the data collection for the purpose of quality control.

### 2.4. Statistical analysis

Data were analysed using SPSS version 18 software (SPSS Inc., Chicago, IL, USA). Descriptive statistics, such as percentages, mean, and standard deviation, were calculated. To analyse the significance of the continuous data, the independent samples *t*-test and Mann–Whitney *U*-test were applied, as appropriate. Furthermore, direct logistic regression analysis was performed to assess the impact of a number of factors on the likelihood that a patient would have a favourable TB treatment outcome. Statistical significance was set at  $p < 0.05$  for all analyses.

### 2.5. Ethical considerations

The study protocol, informed consent, and other relevant documents were reviewed and approved by the Research and Teaching Aids Division, Training and Development Centre, Ministry of Health, Iraq.

## 3. Results

### 3.1. Demographic characteristics of the study participants

Three hundred five participants were recruited consecutively over a period of 11 months. Participants ranged in age from 18 to 91 years, with a mean age of 41.6 years; 64.6% were male and 28.2% were illiterate. Furthermore, poor financial status was predominant in our cohort and 50.8% of the patients in the sample were the breadwinners for their families (Table 1).

### 3.2. The effect of TB treatment on patient health-related quality of life

To investigate the effect of TB treatment on HRQL of patients with PTB, the mean of the FACIT-TB total score and its subscale scores at different stages of treatment were compared. Participants completed the FACIT-TB questionnaire at baseline, after 2 months of treatment, and at completion of treatment during their regularly scheduled follow-up visits. After the 2-month intensive phase, physical well-being, functional well-being, and FACIT-TB total scores were significantly increased ( $p < 0.01$ ). Furthermore, there was a significant improvement in overall HRQL as indicated by the

**Table 1**  
Demographic characteristics of patients with pulmonary tuberculosis in Iraq (N=305)

| Characteristics             | n (%), or mean ± SD |
|-----------------------------|---------------------|
| Age, years                  | 41.59 ± 15.43       |
| Sex                         |                     |
| Male                        | 197 (64.6)          |
| Female                      | 108 (35.4)          |
| Education status            |                     |
| No formal education         | 86 (28.2)           |
| Primary school              | 132 (43.3)          |
| Secondary school            | 57 (18.7)           |
| University                  | 30 (9.8)            |
| Marital status              |                     |
| Single                      | 71 (23.3)           |
| Married                     | 208 (68.2)          |
| Divorced                    | 4 (1.3)             |
| Widow/widower               | 22 (7.2)            |
| Number of household members | 7.72 ± 4.08         |
| Type of the job             |                     |
| Salaried                    | 60 (19.7)           |
| Waged                       | 18 (5.9)            |
| Self-employed               | 93 (30.5)           |
| Other                       | 134 (43.9)          |
| Breadwinner                 |                     |
| No                          | 150 (49.2)          |
| Yes                         | 155 (50.8)          |
| Financial status            |                     |
| Poor                        | 115 (37.8)          |
| Intermediate                | 88 (28.9)           |
| Good                        | 102 (33.3)          |
| Smoking status              |                     |
| Never smoker                | 135 (44.3)          |
| Ever smoker                 | 170 (55.7)          |

FACIT-TB total score and all subscales, except social and economic well-being and spiritual well-being at completion of TB treatment (Table 2).

### 3.3. Factors predicting the likelihood of a favourable TB treatment outcome

Direct logistic regression was performed to assess the impact of a number of factors on the likelihood that a patient would have a favourable TB treatment outcome (i.e., cured or completed

treatment). Preliminary analysis confirmed that poor educational status, poor financial status, and being a smoker, were independent determinants of poor HRQL as indicated by the FACIT-TB total score. Therefore, four independent variables (FACIT-TB total score at baseline, smoking status, education level, and financial status) were included in the model. The full model containing all predictors was statistically significant (Chi-square (4,  $n = 129$ ) = 10.49,  $p = 0.033$ ), indicating that the model was able to distinguish between subjects who had favourable TB treatment outcomes and those who did not. The model as a whole explained between 7.8% (Cox and Snell R-square) and 11% (Nagelkerke R-square) of the variance in treatment outcome, and correctly classified 69% of the cases. As shown in Table 3, of the independent variables, only the FACIT-TB total score at baseline made a unique statistically significant contribution to the model. The FACIT-TB total score at baseline recorded an odds ratio of 1.02. This indicates that the higher the FACIT-TB total score at baseline, the more likely that a PTB patient will have a more favourable outcome at the completion of treatment, while controlling for the other factors in the model.

## 4. Discussion

A study of the impact of PTB on various aspects of QoL is possible by using a disease-specific HRQL measure. QoL has become an instrumental outcome measure in clinical research, and advances have been made in assessing the impact of many diseases on QoL.<sup>10</sup> Different generic HRQL instruments and health utility measures such as SF-36, SF-12, EQ-5D, WHOQOL-100, and WHOQOL-BREF, have been used among the studies that have quantitatively assessed health for patients with TB.<sup>2</sup> Although these instruments have been applied successfully to measure QoL in patients with TB, perhaps the most significant drawback has been the absence of a widely accepted psychometrically robust TB-specific instrument for carrying out such assessments in the context of TB.<sup>2,3,15</sup>

In the current study, the gradual increase in physical well-being, functional well-being, and emotional well-being/TB subscale scores over the course of TB treatment indicates the positive impact of therapeutic interventions on patient QoL. However, the emotional well-being/TB subscale score at 2 months of TB

**Table 2**  
Health-related quality of life determination over the course of tuberculosis treatment using the FACIT-TB instrument; FACIT-TB total and subscale scores (mean ± SD)

|  | PWB                          | SEWB         | EWB/TB                       | FWB                         | SpWB         | Total score                   |
|--|------------------------------|--------------|------------------------------|-----------------------------|--------------|-------------------------------|
| At baseline<br>( $n = 136$ )                 | 31.93 ± 17.62                | 22.45 ± 5.11 | 20.54 ± 9.65                 | 12.97 ± 7.17                | 9.67 ± 2.75  | 97.56 ± 30.14                 |
| After 2 months of treatment<br>( $n = 136$ ) | 38.30 ± 18.04 <sup>a</sup>   | 22.50 ± 5.27 | 20.78 ± 11.04                | 13.89 ± 7.67 <sup>a</sup>   | 9.61 ± 2.80  | 105.10 ± 30.20 <sup>a</sup>   |
| At completion of treatment<br>( $n = 109$ )  | 49.75 ± 14.58 <sup>a,b</sup> | 22.57 ± 4.70 | 28.43 ± 10.50 <sup>a,b</sup> | 17.41 ± 6.74 <sup>a,b</sup> | 10.56 ± 7.88 | 128.72 ± 25.28 <sup>a,b</sup> |

EWB/TB, emotional well-being/stigma of having TB; FACIT-TB, Functional Assessment of Chronic Illness Therapy – Tuberculosis; FWB, functional well-being; PWB, physical well-being; SD, standard deviation; SEWB, social and economic well-being; SpWB, spiritual well-being.

<sup>a</sup>  $p < 0.01$  compared to baseline.

<sup>b</sup>  $p < 0.001$  compared to score after 2 months of treatment.

**Table 3**  
Logistic regression analysis for predicting the likelihood of a favourable TB treatment outcome

|                                  | B      | SE    | Wald  | df | p-Value | OR    | 95% CI for OR |
|----------------------------------|--------|-------|-------|----|---------|-------|---------------|
| FACIT-TB total score at baseline | 0.019  | 0.008 | 6.280 | 1  | 0.012   | 1.020 | 1.004–1.035   |
| Smoking status                   | −0.222 | 0.411 | 0.292 | 1  | 0.589   | 0.801 | 0.358–1.792   |
| Education status                 | 0.153  | 0.237 | 0.416 | 1  | 0.519   | 1.165 | 0.732–1.856   |
| Financial status                 | −0.044 | 0.257 | 0.029 | 1  | 0.865   | 0.957 | 0.579–1.584   |
| Constant                         | −1.024 | 0.728 | 1.975 | 1  | 0.160   | 0.359 |               |

SE, standard error; OR, odds ratio; 95% CI, 95% confidence interval; FACIT-TB, Functional Assessment of Chronic Illness Therapy – Tuberculosis.

treatment did not significantly differ from baseline. Studies have demonstrated that emotional stress is associated with immunological responsiveness and reactivation of bacillus.<sup>16</sup> Moreover, the psychiatric complications as adverse effects of anti-TB medications are also a matter of concern.<sup>17</sup> These factors are viewed as a major barrier to treatment adherence.<sup>17</sup> The risk of treatment default is high during the first 2 months of TB treatment,<sup>18</sup> suggesting that better management of emotional stress could improve treatment outcomes and will serve as a framework for effective TB control. International health agencies are considering strategies to integrate mental health services into the existing health systems for the purpose of increasing responsiveness to patient needs.<sup>19</sup>

A study carried out to identify how TB affects the QoL of patients attending two directly observed therapy (DOTS) centres in an urban area of Delhi using the Hindi version of the WHOQOL-BREF questionnaire also reported similar results.<sup>10</sup> The final findings demonstrated that there was a significant increase in the overall QoL and in all domains except social after 3 months and at completion of treatment under DOTS, and that the maximum improvement was seen in the physical domain followed by the psychological domain. Moreover, our results are consistent with the pattern observed in a study conducted in China using the SF-36 questionnaire,<sup>8</sup> in which all physical scales including physical functioning, bodily pain, role-physical, and general health scores showed a significant increase over the course of TB treatment ( $p < 0.05$ ), while the improvement in vitality and mental health was statistically not significant.

Previous findings from the literature support the notion that there is a significant relationship between educational level, financial status and the QoL of patients with TB.<sup>20–22</sup> Financial strains are exacerbated during illness, and this difficulty results in an additional burden for TB patients.<sup>23</sup> Moreover, smoking was significantly associated with poor HRQL as indicated by the FACIT-TB total score. Research demonstrates the negative association between smoking and HRQL, and the magnitude of this association is determined by the number of cigarettes smoked.<sup>24–26</sup> Furthermore, a study conducted in Malaysia demonstrated that tobacco smoking is a predictor of poor TB treatment outcomes,<sup>27</sup> and that an integration of DOTS with smoking cessation intervention potentially improves overall HRQL outcomes among TB patients who are smokers.<sup>28,29</sup> Therefore, smoking cessation interventions should be offered to all TB patients who are smokers when they are undergoing TB treatment. The National Tuberculosis Program (NTP) in Iraq should vigorously integrate tobacco dependence treatment into the management of TB and should provide capacity building for healthcare providers caring for TB patients.

A study conducted in Delhi using the DR-12 questionnaire reported that TB patients who had favourable outcomes at completion of TB treatment also had higher scores on the DR-12 questionnaire when compared to those who had unfavourable outcomes.<sup>30</sup> This is consistent with our findings, which demonstrate that the higher the FACIT-TB total score at baseline, the more likely it is for the patient to have a favourable outcome at completion of TB treatment, controlling for other socio-demographic factors including educational level, financial status, and smoking status. Thus, the FACIT-TB questionnaire could be used for the comprehensive assessment of HRQL for PTB patients during the course of TB treatment where the assessment is generally based on clinical parameters. The evaluation of patients using the FACIT-TB instrument would also minimize misleading assumptions and conclusions about the effect of TB treatment on health status as a result of using generic QoL instruments.<sup>31</sup>

In conclusion, the newly developed FACIT-TB instrument could potentially be used to monitor HRQL during the course of TB treatment. Overall, the current study has managed to contribute additional information regarding the utility of a disease-specific

QoL instrument as a prognostic variable beyond established predictors in patients with PTB in Iraq and suggests that such an instrument could reliably be used to monitor patient QoL progression. Understanding QoL trends according to specific domains will provide a basis for relating patient reported outcomes with drug therapy and identifying domains that require other interventions such as social support. Further research is needed to provide more insight into the predictive validity and sensitivity of the instrument. Research is also needed to replicate these findings and to confirm them in other patient populations.

## Acknowledgements

The authors would like to thank the investigators of the Thoracic and Respiratory Diseases Specialist Centre in Iraq for their help and support in the collection of the required data. We also greatly acknowledge the support provided by the FACIT measurement system and FACT-G developers for granting permission to use the FACT-G and for their input during the FACIT-TB development process. This research project was sponsored in part by a grant from Universiti Sains Malaysia, Research University Postgraduate Research Grant Scheme (USM-RU-PRGS; grant number 1001/PFARMASI/845040).

**Conflict of interest:** The authors declare that no conflicts of interest exist.

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