ORIGINAL RESEARCH



Comparability of Interviewer-Administration Versus Self-Administration of the Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB) Health-Related Quality of Life Questionnaire in Pulmonary Tuberculosis Patients

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ABSTRACT

Objective: To investigate the extent to which two different modes of administration

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(interview by a trained interviewer versus self-administration) yielded a comparable estimate of health-related quality of life (HRQL) in patients with pulmonary tuberculosis (PTB).

Methods: The study was conducted between September 2012 and July 2013, among consecutive patients treated for PTB at the Thoracic and Respiratory Disease Specialist Centre in Baghdad, Iraq. The mode of administration of the functional assessment of chronic illness therapy-tuberculosis (FACIT-TB), a new TB-specific HRQL instrument, was recorded at baseline in 305 subjects.

Results: Although the FACIT-TB questionnaire was designed for self-administration, most patients in our sample (n = 193, 63.3 %)requested some help from an interviewer to fill out the questionnaire. Patients capable of self-administration were younger (38.2 \pm 12.9 years vs. 43.6 ± 16.4 years, p = 0.005) and required less time to complete $(14.6 \pm 3.2 \, \text{min})$ questionnaire VS. 2.6 min, p < 0.001) compared to those who were interviewed by a trained interviewer. No differences in gender were observed between the two groups. HRQL scores across all domains for those who were interviewed were slightly lower than those who answered the questionnaire by self-administration. However, the results did not reach statistical significance (p > 0.05).

Conclusions: The study demonstrates that the administration of FACIT-TB instrument using either self-administration or interviewing techniques has resulted in a comparable estimate of HRQL among patients with PTB. The FACIT-TB instrument is able to accommodate the needs of patients with diverse social, educational, and functional skills.

Keywords: FACIT-TB; Mode of administration; Quality of life; Questionnaire; Tuberculosis

INTRODUCTION

Flexibility is important in choosing the appropriate modes of questionnaire administration for health-related quality of life (HRQL) outcome and other patient-reported outcome measures [1]. Quality of life (QoL) instruments are either completed by the study participants at their own pace (self-administration) or administered by an interviewer [2]. Α self-administered questionnaire offers the advantage of being neither expensive nor requiring research personnel as an interviewer and therefore has traditionally been preferred [3]. On the other hand. interview-administration required when self-administration is not feasible, such as in those with low literacy skills or those who may be too ill to complete the questionnaire by themselves. Interviewer-administered HRQL questionnaires are more resource intensive, but offer additional control over the quality of the measurement [2–4]. In many epidemiologic studies, both modes of questionnaire administration are available to accommodate preferences and to overcome physical impairment and literacy barriers [2, 5].

The evidence of the impact of different administration techniques on HRQL scores is inconsistent. For example, some studies indicated more favorable reports of well-being when a QoL instrument is administered through an interview technique [6, 7]. A common interpretation of this phenomenon is that participants may indicate less health impairment when interviewed by a research personnel as compared to self-administration, thereby overestimating their health status [4]. Conversely, other studies have found the opposite effect [8] or no meaningful differences due to administration formats for some or all of the QoL domains [9-11]. In 2005, Bowling raised a concern about the bias effects of mode potential of administration on the quality and interpretation of the data collected [4]. The effects of different modes of administration can be evaluated in terms of psychometric measurement equivalence using responses to individual items, and in terms of classical statistical methods to compare differences in group mean scores. The primary purpose of this study was to implement classical statistical techniques to investigate the extent to which different modes two of questionnaire administration (interview versus self-administration) vielded a comparable estimate of HRQL among patients with pulmonary tuberculosis (PTB) in Iraq.

METHODS

Study Instrument

Data were collected during a cross-sectional validation study of the Arabic version of Functional Assessment of the Chronic Illness Therapy-Tuberculosis (FACIT-TB) scale. The study goals were to develop, psychometrically validate a new HRQL scale among PTB patients in Iraq, and to assess the extent to which two different modes of administration (interview versus self-administration) vielded comparable estimate of HRQL. This report addresses the validation of the two modes of administration for the FACIT-TB scale, which is a disease-specific instrument designed to assess HRQL in patients diagnosed with PTB and it is a part of the FACIT measurement system [12]. The FACIT-TB has 45 items that use a five-point categorical response scale ranging from 0 (not at all) to 4 (very much). Five subscales were derived from factor analysis of the original validation sample including physical well-being (PWB), social and economic well-being (SEWB), emotional well-being/stigma of having TB (EWB/TB), functional well-being (FWB), and spiritual well-being (SpWB). **PWB** conceptualized primarily as an aggregation of symptoms from disease and its treatment, while SEWB reflects support received from others and perceived quality of interpersonal relationships as well as the economic burden of the disease. On the other hand, EWB/TB refers to the negative affect, satisfaction with coping, and concerns about the social stigma of TB. FWB represents the impact of these symptoms and other factors upon one's capability to perform important roles and one's overall perception of life enjoyment and quality. Finally, SpWB reflects spirituality.

Since the FACIT-TB scale includes positive statements (e.g., "I am able to enjoy life") and negative statements (e.g., "I have a lack of energy"), the responses to all negative items were reverse scored according to the instruction of the FACIT measurement system for all analyses. A higher HRQL score therefore represents better HRQL. FACIT-TB instrument has demonstrated strong psychometric properties, including reliability, validity, and sensitivity to change [13, 14].

Study Participants

Participants were recruited from the Thoracic and Respiratory Disease Specialist Centre between September 1, 2012 and July 31, 2013. Interviewer training was conducted by the principal investigator. Training involved standardization of recruitment and assessment strategies, attention non-verbal communication skills (empathy, facial expressions, and body language), mock interview sessions, and observations of a sample of actual interviews during the first 2 months of data collection. Patients were eligible to participate if they had a diagnosis of PTB disease, had completed at least 2 weeks of TB treatment, were at least 18 years of age, were able to understand Arabic, and provided informed consent in accordance with institutional review board requirements. Patients with any associated pulmonary diseases such as lung cancer, chronic obstructive pulmonary disease, asthma, and other chronic diseases likely to affect HRQL including diabetes mellitus, cardiovascular diseases. hospitalized patients, and patients with underlying immune suppression were excluded from the study.

Mode of Instrument Administration and Data Collection

When eligible cases were identified, FACIT-TB was administered by self-administration—this means participants completed the questionnaires themselves using paper and pencil and they were asked to return the completed questionnaires to the researcher. The reason to switch to face-to-face interview included illiteracy and inability to read due to sight limitations. Thus, the choice of administration format depends mainly on participants' characteristics. The wording and layout of self- and interview-administered questionnaires were identical.

During interview administration, a copy of the questionnaire was given to a participant as a reference for the response option. Moreover, the interview was conducted by a trained medical social worker in a quiet, distraction-free area at the study center after informed consent was obtained from an 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. Subsequently, the interviewer conducted a structured interview using a data collection form to collect information on demographics and socio-economic status including: age, gender, marital status, occupation and educational level. Environmental variables including number of household members were also obtained. The FACIT-TB HRQL instrument was administered before the respondents were asked about socio-demographic characteristics so that any discussion did not affect their answers to the questionnaire.

Statistical Analysis

Data were analyzed using SPSS version 18 software (SPSS Inc., Chicago, IL, USA).

Mann–Whitney U test was applied for non-normally distributed continuous variables and the Pearson χ^2 statistic for nominal variables, patient characteristics were compared between the two groups. To analyze the significance of the difference in HRQL between the groups, independent sample t test and Mann–Whitney U test were applied as appropriate. Statistical significance was set at p < 0.05 for all analyses.

Ethical Approval

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. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (Thoracic and Respiratory Diseases Specialist Center, Ministry of Health Iraq) and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

RESULTS

Participants Characteristics

The mode of administration of the FACIT-TB (self-administration versus face-to-face interview) was recorded for the 305 subjects recruited for the validation study. Although the FACIT-TB was designed for self-administration, most patients in our sample (n = 193, 63.3%) requested some help from the interviewer to fill out the questionnaire. Table 1 shows the differences in socio-demographic characteristics between the two groups of patients. Patients capable of

self-administration were younger (38.2 versus 43.6 years, respectively; p = 0.005) and required less time to complete the questionnaire (14.6 versus 17.2 min; p < 0.001) compared to those who were interviewed by a trained interviewer. No differences in gender distribution were observed between the two groups.

Impact of Mode of Administration on HRQL

In terms of the mode of administration of the FACIT-TB questionnaire (self-administration versus face-to-face interview), HRQL scores were slightly lower across all domains for those who were interviewed by a trained investigator than for those who self-administered the questionnaire. However, these differences were not statistically significant for all of the QoL domains (p > 0.05). Table 2 displays the results of HRQL scores by mode of administration of the questionnaire.

In the sample of the 305 respondents, the questionnaires were completed for 77.4 % (236/305) of the subjects. All of the incomplete questionnaires had one missing item. The only quoted item was GS7 "I am satisfied with my sex life". However, there is no difference in the response rate for item GS7 between those who answered the questionnaire by interview administration and self-administration method (77.20 vs. 77.67 %, respectively).

DISCUSSION

An important issue to be considered is the technical equivalence of the FACIT-TB instrument when used in the sample of PTB patients in Iraq. As mentioned earlier, most

patients in our sample preferred the questionnaire to be administered by an interviewer instead of filling it out by themselves. It should be noted that assistance from study personnel was only to read questions on instruments to participants who had difficulty in reading. However, this may raise the issue as to whether this difference in the method of administration impacts the reporting of HRQL data that it yields.

There were no statistically significant or meaningful differences in FACIT-TB total and subscale scores between those who were interviewed by a trained investigator and those who answered the questionnaire by self-administration. Focusing on meaningful differences can enhance the interpretability of HRQL scores for researchers, clinicians, and patients [15]. Dapueto et al. and Wan et al. also found no significant effect of the mode of administration of FACT-G questionnaire on the overall QoL [16, 17]. Moreover, a large multi-center study of ambulatory cancer investigated the psychometric patients properties and statistical equivalence of the English and Spanish language versions of the FACT-G subscales between low and high literacy level patients as well as between self-administration and interview mode of administration [3]. The results demonstrated technical equivalences in high literacy group of patients and there were few differences in psychometric properties of the FACT-G scale in term of the mode of administration [3]. Subsequently, technical equivalence across different modes of administration questionnaire permits unbiased assessment of the impact of the disease and its treatments on diverse patients with backgrounds Flexibility is important in selecting methods of questionnaire administration, to accommodate

Table 1 Differences in socio-demographics with regards to mode of administration of FACIT-TB

Characteristics	Mode of administration		p value ^a
	Self-administration $n = 112$		
$\overline{\text{Age (mean} \pm \text{SD)}}$	38.16 ± 12.93	43.58 ± 16.41	0.005 ^b
Gender			0.739
Male	71 (63.4 %)	126 (65.3 %)	
Female	41 (36.6 %)	67 (34.7 %)	
Education status			< 0.001
Nothing	0 (0 %)	86 (44.6 %)	
Primary school	53 (47.3 %)	79 (40.9 %)	
Secondary school	39 (34.8 %)	18 (9.3 %)	
University	20 (17.9 %)	10 (5.2 %)	
Marital status			0.167
Single	31 (27.7 %)	40 (20.7 %)	
Married	75 (67.0 %)	133 (68.9 %)	
Divorced	2 (1.8 %)	2 (1.0 %)	
Widow/widower	4 (3.6 %)	18 (9.3 %)	
Number of household member (mean \pm SD)	6.95 ± 3.50	8.18 ± 4.33	0.018^{b}
Type of the job			0.018
Salaried	31 (27.7 %)	29 (15.0 %)	
Waged	9 (8.0 %)	9 (4.7 %)	
Self-employed	27 (24.1 %)	66 (34.2 %)	
Others	45 (40.2 %)	89 (46.1 %)	
Bread winner			0.827
No	56 (50.0 %)	94 (48.7 %)	
Yes	56 (50.0 %)	99 (51.3 %)	
Financial status			0.855°
Poor	39 (36.4 %)	72 (38.5 %)	
Intermediate	33 (30.8 %)	52 (27.8 %)	
Good	35 (32.7 %)	63 (33.7 %)	
Completion time (mean \pm SD)	14.64 ± 3.24	17.22 ± 2.61	< 0.001 ^b

p value for Chi-square test
p value for Mann–Whitney U test
Data available for 294 subjects only

Table 2 HRQL scores by mode of administration

Subscale	Mode of administration		p value ^a
	Self-administration $n = 112$	Interview $n = 193$	
PWB	32.008 ± 16.479	30.808 ± 17.588	0.424
SEWB	23.134 ± 4.461	22.196 ± 5.823	0.330
EWB/TB	20.669 ± 9.319	19.886 ± 10.117	0.503 ^b
FWB	14.062 ± 7.316	12.829 ± 7.288	0.159
SpWB	9.886 ± 2.726	9.673 ± 2.580	0.234
FACIT-TB	99.741 ± 29.397	95.394 ± 29.996	0.220^{b}

PWB physical well-being; SEWB social and economic well-being; EWB/TB emotional well-being/stigma of having TB; FWB functional well-being; SpWB spiritual well-being; FACIT-TB functional assessment of chronic illness therapy-tuberculosis

the needs of patients with diverse social, educational, and functional skills.

Data collection modes of questionnaire differ in many ways, including the methods of contacting respondents, the questionnaire delivery mode, as well as questionnaire administration [18]. However, the literature is inconclusive about different mode questionnaire administration and the quality of the data collected [18]. Some studies reported that respondents tend to give more positive (socially desirable) response in interview surveys than in self-administration surveys [19, 20], even when attempts have been made to take order and contextual effects in consideration [21]. Hence, estimates positive HRQL or health status look likely to be overstated when based on face-to-face or telephone interviews mode of questionnaire administrations, rather than self-completion mode, and socially undesirable behaviors (e.g., drug abuse) are expected to be under-estimated [21, 22]. However, some researches have reported no differences between interview

versus self-administration modes and responses type [23, 24]. Moreover, presence of interviewer can be distracting to some respondents, and again more positive or socially desirable responses were found. This could be attributable to the interviewer's characteristics or because individuals may be reluctant to disclose belief unlikely to be endorsed by the interviewer [25]. Furthermore, interviewers can differ in their capability to appear or sound neutral, to probe and listen effectively, or use technique to aid recall or record responses. In the current study, a medical social worker was carefully trained and monitored to minimize the interviewer bias. Self-administration mode obviously avoid this source of bias [18].

Ideally, respondents listen to the questions during face-to-face interviews, keep all the response options in mind, consider them, and decide then which is the most applicable to them. This is a demanding task, especially under time pressure [18]. Therefore a copy of the questionnaire was presented visually (as in

 $^{^{}a}$ p value for Mann-Whitney U test

b p value for independent sample t test

self-administration) to the participants during a face-to-face interview of our participants as a reference to the response options.

The literature demonstrates that interview administration of the questionnaire can decrease the respondents' willingness to answer sensitive questions. Moreover, the response rate is high and the reporting is more accurate when the sensitive questions are asked by more impersonal, self-administration method [26, 27]. However, Tourangeau et al.'s reviews on the topic produced conflicting results [28]. In the current study, there is no difference in the response rate for the sensitive question between those who answered the questionnaire by interview administration and self-administration method (77.20 vs. 77.67 %, respectively).

Household According to the Iraa Socio-Economic Survey of 2007, almost 23 % of Iraqis are illiterate [29]. In the current study, illiterate patients were not able to answer the questionnaire, but with the help of a trained interviewer, the FACIT-TB could be extended to this group of patients. A low literacy level may indicate an array of problems that go beyond reading ability [30]. Communication difficulties encountered by a patient may be due to differences in vocabulary as well as differences in structure and complexity of the speech used by the literate and illiterate population [30]. Investigators from three developing countries described the relationship between literacy level comprehension speech [31]. suggested that literacy builds a cognitive process that facilitates comprehension of spoken language, including health messages [16]. Furthermore, Dexter and colleagues provided insight on the link between poor and inadequate literacy health-related descriptions [32]. However, this may raise the question to which extent this could impact the reported HRQL data. Patients from our cohort

were requesting help from the interviewer not only because of illiteracy but also because of poor eyesight. Though, we do not know if some of the participants who completed the questionnaire by self-administration didn't also have limited literacy levels. Previous findings demonstrated that a low literacy level is a tremendous source of shame and that a large majority of adults did not disclose their poor literacy skill to health care providers out of embarrassment [33]. Thus, low-literacy-related stigma can seriously impair patients' interactions with health professionals and their potential to benefit from health services. Health care professionals should become more sensitive to the prevalence, significance, and management of patients with inadequate literacy levels. Thus, reliable ways to identify patients with poor literacy skills are needed to promote positive healthcare experiences and outcomes [34–36].

Every study has a limited generalizability, and ours is no exception. One might question findings from whether our research coordinators can be applied to the interviewers at other centers. Furthermore, the interviews took place in a quiet, distraction-free area at the center. However, not many centers have the luxury of having interview rooms to guarantee privacy. Nonetheless, we consider the present study useful in reflecting the real-world situation similar centers can afford. Another limitation is that we enrolled only PTB patients who were well enough to participate in the study. Results may not be generalizable to patients with other forms of TB and those with greater disease severity and poorer HRQL. In addition, FACIT-TB was developed and validated for Arabic-speaking patients in Iraq, hence, future research using FACIT-TB in samples with greater sociodemographic and clinical heterogeneity will advance

generalizability of the measure. Moreover, this sample has some intriguing sociodemographic characteristics, especially the prevalence of low literacy levels and potentially some unique cultural characteristics. Thus, further studies are required to examine the impact of poor literacy skill on the reported HRQL data using FACIT-TB instrument.

CONCLUSIONS

In conclusion, the current findings suggest that the FACIT-TB subscales can be used confidently among PTB patients with different modes of questionnaire administration. Further research is needed to replicate these findings and to confirm them in other patient populations. Studies are also needed to evaluate other modes of questionnaire administration such as telephone interviews (interactive response), computers, and Web-based testing of FACIT-TB HRQL instruments. Moreover, examining the effect of inadequate literacy skill on the reported HRQL using the FACIT-TB questionnaire are also required.

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All named authors meet the international committee of medical journal editors (ICMJE) criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval for the version to be published.

JAD, SASS, and AA conceived the research idea, participated in the design of the study, and drafted the manuscript. MAH participated in the design of the study and helped in drafting the manuscript. AQB participated in the design of the study and performed statistical analysis. JMB participated in the development of the FACIT-TB instrument and revised with important manuscript intellectual contributions. All authors read and approved the final manuscript.

Disclosures. Juman Abdulelah Dujaili, Syed Azhar Syed Sulaiman, Ahmed Awaisu, Mohamed Azmi Hassali, Ali Qais Blebil, and Jason M Bredle have nothing to disclose.

Compliance with Ethics Guidelines. The protocol, informed consent, other relevant documents were reviewed and approved by the Research and Teaching Aids Division. Training and Development Centre, Ministry of Health, Iraq. All procedures followed were accordance with the ethical standards of responsible committee on experimentation (Thoracic and Respiratory Diseases Specialist Center, Ministry of Health Iraq) and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

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