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Full Length Research Paper

Health related quality of life of pulmonary and extrapulmonary tuberculosis patients in Yemen

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To compare the health related quality of life (HRQoL) between pulmonary and extrapulmonary tuberculosis (PTB and EPTB) patients at pre- and post-intensive phases of treatment. A total of 173 PTB and 160 EPTB patients were selected from the TB centers in Sana'a, Yemen. The patients were given DR-12 questionnaire, measuring three domains: symptoms, life activities and social activities. DR-12 was subjected for internal consistency, reliability and linguistic validation. Quality of life was measured at onset, after one month, and at the end of intensive phase of treatment. Patients with PTB had significantly worse HRQoL score compared to EPTB ($P < 0.05$). The greatest difference was observed in the dimension reflecting symptoms, during the intensive phase. The improvement in HRQoL for both PTB and EPTB patients for the three domains, after one month and at the end of intensive phase compared to the baseline were statistically significant ($P < 0.001$). The HRQoL did not improve in PTB patients who failed to convert at the end of the intensive phase compared to the first month. At baseline, PTB patients have significantly lower HRQoL than EPTB. Both PTB and EPTB patients significantly improved after onset of treatment. The converted PTB patients improved in symptoms as compared to the non converted PTB patients.

Key words: Yemen, DR-12 questionnaire, health-related quality of life, tuberculosis.

INTRODUCTION

The World Health Organization defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, 1948). According to Khanna and Tsevat (2007), HRQoL is a concept of multi- dimensions which connect the physical, emotional and social components of the individual with his medical conditions. HRQoL can be measured by two instruments; either disease specific tools or generic measurement tools. The generic instrument allows comparison to be made between groups of patients with different diagnosis while the disease specific tools give information about one disease and its effect on the health.

Disease specific tools are more sensitive for measuring the important differences in the health situation, hence it is used successfully to measure the outcomes from a specific treatment. A well-known example of a disease-specific instrument is the questionnaire of TB quality of life, SF-12 questionnaire by Dhingra and Rajpal (2003).

SF 12 (short form health survey) Jenkinson and Layte (1997) said that short form health survey, SF-12, is a tool of choice which allows summary of information about the physical, mental and health state. Such instrument is able to produce two summary scales which are shortened from SF-36 with accuracy and less effect on the patients. Three studies in India (Dhingra and Rajpal, 2003, 2005; Singh et al., 2006) used short form (DR- 12) to evaluate the impairment of HRQoL with TB during the treatment (DR-12 questionnaire was considered as a new TB-specific instrument, which was developed by Dhingra and Rajpal in India and first published in 2003). A study which was conducted in India (Dhingra and Rajpal, 2003, 2005), using short form DR- 12 at baseline, four weeks and eight weeks of treatment for the first study, while the second study conducted at base line. After the intensive phase and at the end of treatment, both studies revealed that there was a gradual improvement on DR-12 scores in active TB

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patients over the course of the treatment. In general, the symptoms scores showed better improvement than socio psychological and exercise adaptation scores. They added that there was a significant difference between the scores of pulmonary and extrapulmonary TB patients (higher in extrapulmonary TB cases) both in symptom scores and in total HRQoL scores at the beginning of treatment. Moreover, sputum negative patients showed a higher symptom score than the sputum positive patients. The first study which was conducted for two months, showed comparable findings of HRQoL compared with the second study which was conducted till the end of treatments.

Other study by Singh et al. (2006) confirmed the usefulness of DR-12 to evaluate the impairment of HRQoL for 100 patients (of age 15 years and older) with TB during their treatment at 0, 4 and 8 weeks by using a HRQoL questionnaire. The questionnaire was based on symptoms (score I), physiological, psychological, and social interaction of the patients (score II). The study observed that there was a perceptible increase in the HRQoL score at weeks 4 and 8 in all categories of patients and in patients who did not convert sputum negative at the end of the intensive phase though the latter's increase was low as compared to those who turned sputum negative. Finally, an improvement was also noticed in both male and female patients with pulmonary TB or extrapulmonary TB diseases. Intensive phase (IP) defined as an initial treatment for 2-3 months. During this phase, the treatment is given under observation (Rajeswari et al., 2005).

The prevalence rate of TB in Yemen is significant and upsetting. No study evaluating the quality of life was ever done in Yemen. The aim of this study was to compare the health related quality of life between pulmonary and extrapulmonary TB patients pre- and post-intensive phase of treatment.

MATERIALS AND METHODS

The study protocol was approved by the local Ethical Committee in the Ministry of Public Health and Population of Yemen, and informed consent was obtained from all patients. We conducted a prospective cohort study of pulmonary and extrapulmonary, matched on the basis of variables (gender, age, marital status, smoking, educational level, and occupation) that have been demonstrated in previous studies (Duyan et al., 2005; Chamla, 2004). For the purposes of our study, the following patients were excluded from the study: patients transferred from the Sana'a TB centers to complete their treatment in other health centers outside Sana'a city; defaulted patients; relapsed patients; subjects with major comorbidity (HIV, malignancy, diabetes, underlying cardiorespiratory disease, rheumatic disease, psychiatric disease); or if the patient died.

HRQoL was assessed by means of the 12-item short form questionnaire (DR-12), adapted for use in Arabic language. The 12 items in the questionnaire evaluate three different dimensions of health: symptoms (symptoms associated with TB (for both PTB and EPTB) such as cough, hemoptysis, loss appetite, loss weight, fever, breathlessness and chest pain); life activities (such as interest in work, household activities, and exercise activities); social activities (such as emotional symptoms and social adaptability). The items for each dimension of the DR-12 were coded and aggregated, then transformed on a scale ranging from 0 (reflecting the poorest state of health) to 100 (reflecting the best state of health).

Sample size and sampling

A total of 333 patients were met in the TB center and health facilities in Sana'a. 173 of them were pulmonary TB patients and were followed up for interview during the expected time of treatment of 8 months, while 160 extra pulmonary TB patients were followed up for 12 months. The study included all patients with suspected or confirmed pulmonary and extrapulmonary TB, who were investigated and recorded in medical records during March 2008 until August 2009.

$$n = \frac{(u+z)^2 P1(100-P1) + P2(100-P2)}{(P1-P2)^2}$$

Mustafa et al. (2000)

$$n = \frac{(1.28+1.96)^2 (30\times 70) + (15\times 85)}{(30-15)^2}$$

=157 patients in each group
n= the sample size
For the 95% confidence level, the u value is 1.96
70% = HRQoL scores expected for pulmonary TB patients
85% = HRQoL scores expected for extra pulmonary TB patients

The above percentage that is 70 and 85% resulted from the measurement of HRQoL scores of the first 60 pulmonary and extra pulmonary TB patients.

The total number of subjects to be evaluated was 390 pulmonary and extra pulmonary TB patients, based on several parameters. According to the exclusion and inclusion criteria, only 4.7% were transferred to other health facilities, 7.5% patients defaulted, and 2.5% patients died and the rest of them not wished to complete the HRQoL questionnaire for the following months. Cases fulfilled the inclusion criteria were interviewed at the TB centre using a pre-designed and pre-tested questionnaire.

Reliability properties and content validity

The questionnaire was pre-tested and showed a good reliability measure (Reliability = 0.71). After a linguistic translation to Arabic language, the scale was subjected to content validity in Yemen by distributing it among social scientists, doctors and nurses to assess whether the scale is sensible and covered all the relevant issues. After the development of a scoring method, various parameters of HRQoL questionnaire and scores were adopted. The individual parameters were equally weighted and patients were asked to evaluate their symptoms and activities on a scale from 1-3 (Score I).

HRQoL was measured with 12 questions at a base line repeatedly for one and two months of the follow-up; the score ranges from 0 (maximum impairment) to 100 (representing an optimal functioning of well-being). These scores were then combined and the composite scores were expressed as total HRQoL score. The DR-12 scale consists of 12 questions, which were given scores from 1-3. Scoring of items was based on a Likert-type scale.

Linguistic validation process

Linguistic translation and validation ensure that the same meaning of the original concepts existed in all translations. The questionnaire for instance, was adapted to a new language methodologically by using forward, backward, and independent forward translations of an

Table 1. Clinical characteristics of the study population (n=333).

Type of TB	Age group		Sex		Employment status		Marital status		
	15-54 years old	>54-70 years old	M	F	Employed	Not employed	Single	Married	Others
Pulmonary TB (n = 173)	158	15	81	92	28	145	57	100	16
Extra-Pulmonary TB (n = 160)	149	11	61	99	21	139	57	95	8

original questionnaire done by professional translators, native speakers of the target language and by those fluent in the source language. A backward translation was also done by other professional translators, native speakers of the source language and by persons who are fluent in the target language. Finally, the backward and original translations were compared and report by the independent translator to ensure that the forward-backward and the original versions are identical in both meaning and content. However, in some items equivalent words and phrases were used (Fayers and Machin, 2007).

Statistical analysis

Statistical package for the social sciences (SPSS) version 12 was employed for data analysis. Descriptive statistics and t-test were carried out to compare HRQoL between pulmonary and extrapulmonary patients. Paired t-test and Wilcoxon's nonparametric rank sum test were used appropriately according to data distribution pattern to assess differences within groups of subjects on follow-up that is, in the first day of treatment, at the end of first month, and at the end of second month. Statistical significance level used was 0.05.

RESULTS

The age of the TB patients was between 15 to 70 years, with a median of 29 years for pulmonary TB patients and 30 years for extra pulmonary TB patients. Out of 390 patients in the study, only 333 (173 pulmonary TB patients and 160 extra pulmonary TB patients) were available for follow up analysis. Registered males with pulmonary TB were 81 (47.2%), while the females were 92 (52.8%). In extra pulmonary TB, the males were 61 (38%), while females were 99 (62%) as shown in Table 1.

The HRQoL score of pulmonary and extrapulmonary TB patients improved significantly at the end of the first month of follow-up and at the end of the intensive phase. Significant differences were noticed for the dimension of symptoms at baseline, after the first month of follow-up and at the end of intensive phase ($P < 0.001$) for each group. Further, there was a significant difference in total score of the first and at the end of intensive phase ($P = 0.007$ and $P = 0.010$). Nevertheless, there was no significant difference between pulmonary and extrapulmonary TB in life activity and social activity scores as shown in Tables 2, 3 and 4. A number of 173 pulmonary TB patients started with the first treatment step; at the baseline, symptoms score was 52.1, social activities score was 28.3, life activities score was 39.5 and total score was 39.9. The improvement in HRQoL, for three domains, after the first month and at the end of intensive phase in addition to the total scores was statistically significant ($P = 0.000$) for each group as compared to the base line score (Table 5).

A number of 160 patients with extrapulmonary TB started their first treatment; at baseline, score I was 64.9, score II was 32.8, score III was 39.8 and total score was 45.8. The progression in HRQoL, for the three domains, after the end of first and second month was statistically significant ($P < 0.001$), for each group compared to the baseline (Table 6).

The study showed that HRQoL scores at the end of second month was significantly higher in pulmonary TB patients who converted at the end of the intensive phase in symptoms domain, compared to those who did not convert (Table 7). The study showed that HRQoL score of positive and negative pulmonary tuberculosis patients weren't significant differences at the onset of treatment as illustrated at Table 8.

The study also showed that HRQoL of negative pulmonary TB was significantly better than positive pulmonary TB at the end of second month follow-up, of the score I, ($P = 0.021$) as illustrated in Table 10. On the other hand, referring to score II (life activities), there was a significantly higher in HRQoL of positive pulmonary TB than negative pulmonary TB at the end of first month follow-up ($P =0.013$) as shown in Table 9.

DISCUSSION

The findings of the study indicated that at the onset of treatment and at the end of intensive phase, patients with pulmonary TB have significantly lower mean scores than extrapulmonary TB as far as symptoms scores and the total scores are concerned. That is because pulmonary TB affects the process of respiration and has more systemic manifestation due to inadequate tissue oxygenation (Ganong, 2005; Gyton, 2000). This finding coincides with the findings reported by other studies (Dhingra and Rajpal, 2003, 2005; Singh et al., 2006; Dhuria et al., 2009).

Table 2. HRQoL scores in TB patients according to site of involvement at onset of treatment.

Score	Pulmonary TB (n = 173) mean ± SD (median)	Extra pulmonary TB (n = 160) mean ± SD (median)	P-value
Symptoms score	52.1 ± 18.3 (56.0)	64.9 ± 15.3 (64.0)	< 0.001*
Social activities score	28.3 ± 25.8 (25.0)	32.8 ± 29.0 (25.0)	0.268*
Life activities score	39.5 ± 32.6 (25.0)	39.8 ± 37.2 (25.0)	0.793*
Total score	39.9 ± 17.7 (39.0)	45.8 ± 21.3 (44.0)	0.007**

Note: * Mann-Whitney U test and **t- test at = 0.05.

Table 3. HRQoL scores in TB patients according to site of involvement after first month of treatment.

Score	Pulmonary TB (n = 173) mean ± SD (median)	Extra pulmonary TB (n = 160) mean ± SD (median)	P-value
Symptoms score	76.5 ± 14.7 (78.0)	84.6 ± 14.3 (86.0)	< 0.001*
Social activities score	42.2 ± 28.7 (50.0)	46.9 ± 28.2 (50.0)	0.171*
Life activities score	64.7 ± 31.4 (75.0)	61.7 ± 36.7 (75.0)	0.658*
Total score	61.1 ± 18.4 (61.0)	64.5 ± 19.8 (66.0)	0.113**

Note: * Mann-Whitney U test and **t- test at = 0.05.

Table 4. HRQoL scores in TB patients according to site of involvement after intensive phase treatment.

Score	Pulmonary TB (n =173) mean ± SD (median)	Extra Pulmonary TB (n = 160) mean ± SD (median)	P-value
Symptoms score	87.3 ± 12.5 (89.0)	93.0 ± 11.1 (100.0)	< 0.001*
Social activities score	55.0 ± 28.3 (50.0)	59.2 ± 30.7 (50.0)	0.251*
Life activities score	74.7 ± 28.4 (75.0)	76.6 ± 31.4 (100.0)	0.306*
Total score	72.3 ± 16.8(74.0)	76.0 ± 19.4 (80.0)	0.010*

Note: * Mann-Whitney U test at = 0.05.

The HRQoL score of pulmonary TB and extrapulmonary TB patients improved significantly during the treatment period (Table 8); a matter that indicates the positive effect of medical intervention on patients' quality of life. In this study, and specifically, at the onset of the course of treatment, participants with pulmonary TB had bigger deficits in HRQoL than extrapulmonary TB. However, after one month of drug therapy participants with pulmonary TB and extrapulmonary TB displayed clear marks of improvements in most HRQoL domains. The domains that improved in pulmonary TB and extra pulmonary TB participants were symptoms, life activity, and social activity scores. Both pulmonary TB and extrapulmonary TB improved significantly and comparatively when looked at the onset of treatment till the completion of the intensive phase of treatment. This implies that treatment would improve HRQoL significantly irrespective of the type of TB. It also implies that ensuring patients received

Table 5. Pulmonary TB during the period of treatment (n = 173).

Score	At onset of treatment mean ± SD (median)	After first month mean ± SD (median)	P-value	At onset of treatment mean ±SD (median)	After intensive phase mean ± SD (median)	P-value
Symptoms score	52.1 ± 18.3 (56.0)	76.5 ± 14.7 (78.0)	< 0.001*	52.1 ± 18.3 (56.0)	87.3 ± 12.5 (89.0)	< 0.001*
Social activities score	28.3 ± 25.8 (25.0)	42.2 ± 28.7 (50.0)	< 0.001*	28.3 ± 25.8 (25.0)	55.0 ± 28.3 (50.0)	< 0.001*
Life activities score	39.5 ± 32.6 (25)	64.7 ± 31.4 (75.0)	< 0.001*	39.5 ± 32.6 (25)	74.7 ± 28.4 (75.0)	< 0.001*
Total score	39.9 ± 17.7 (39.0)	61.1 ± 18.4 (61.0)	< 0.001**	39.9 ± 17.7 (39.0)	72.3 ± 16.8 (74.0)	< 0.001**

*Wilcoxon's test and * * Paired t-test at = 0.05.

Table 6. Extrapulmonary TB during the period of treatment (n = 160).

Score	At onset of treatment mean ± SD (median)	After first month mean ± SD (median)	P-value	At onset of treatment mean ± SD (median)	After intensive phase mean ± SD (median)	P-value
Symptoms score	64.9 ±15.3 (64.0)	84.6 ± 14.3 (86.0)	< 0.001*	64.9 ± 15.3 (64.0)	93.0 ± 11.1 (100.0)	< 0.001*
Social activities score	32.8 ± 29.0 (25.0)	46.9 ± 28.2 (50.0)	< 0.001*	32.8 ± 29.0 (25.0)	59.2 ± 30.7 (50.0)	< 0.001*
Life activities score	39.8 ± 37.2 (25.0)	61.7 ± 36.7 (75.0)	< 0.001*	39.8 ± 37.2 (25.0)	76.6 ± 31.4 (100.0)	< 0.001*
Total score	45.8 ± 21.3 (44.0)	64.5 ± 19.8 (66.0)	< 0.001**	45.8 ± 21.3 (44.0)	76.0 ± 19.4 (80.0)	< 0.001**

*Wilcoxon's test and ** Paired T-test at = 0.05.

Table 7. HRQoL scores in pulmonary TB converted patients and non-converted patients at the end of intensive phase.

Score	Pulmonary TB converted patients (n=173) mean ± SD (median)	Pulmonary TB non converted patients (n=9) mean ± SD (median)	P-value
Symptoms score	87.7±12.5 (89.0)	79.3 ±10.1 (79.0)	0.022
Social activities score	55.5 ± 28.3 (50.0)	45.3 ±26.7 (50.0)	0.280
Life activities score	75.2 ±28.8 (100.0)	66.6 ±17.6 (75.0)	0.193
Total score	72.7 ±16.8 (75.0)	63.8 ±14.8 (62.2)	0.119

Note: Mann-Whitney U test at = 0.05

proper treatment is of great value and there- fore, treatment should be made affordable to the patients. We assessed HRQoL at the onset and at the completion of the intensive phase only because the symptoms disappear mostly after completing the intensive phase, therefore it is not expected to get extra improvement after completing the intensive phase of treatment. Similar results were found in the different studies after a year of successful treatment of TB (Dhingra and Rajpal, 2005; Chamla, 2004; Muniyandi et al., 2009).

The study revealed that there was an association between HRQoL scores at the end of the second month in pulmonary TB patients, who converted from sputum positive to sputum negative at the end of the intensive phase in all domains of HRQoL. This study showed that the patients who converted from sputum positive to sputum negative had higher scores than patients who did not convert, at the end of the intensive

Table 8. HRQoL scores in TB patients according to sputum status at onset of treatment.

Score	Positive pulmonary TB (n = 144) mean ± SD (median)	Negative pulmonary TB (n = 29) mean ± SD (median)	P-value
Symptoms score	52.4 ± 18.7 (56.0)	50.0 ± 15.9 (50.0)	0.609**
Social activities score	41.5 ± 33.5 (25.0)	29.30 ± 25.9 (25.0)	0.096*
Life activities score	29.3 ± 26.0 (25.0)	23.30 ± 24.5 (25.0)	0.233*
Total score	41.0 ± 18.0 (40.0)	34.30 ± 15.4 (33.0)	0.064**

Note: * Mann-Whitney U test and **t- test at = 0.05.

Table 9. HRQoL scores in TB patients according to sputum status after first month of treatment.

Score	Positive pulmonary TB (n = 144) mean ± SD (median)	Negative pulmonary TB (n = 29) mean ± SD (median)	P-value
Symptoms score	76.2 ± 14.5 (78.0)	77.9 ± 15.8 (79.0)	0.561**
Social activities score	63.4 ± 32.5 (75.0)	71.6 ± 24.8 (75.0)	0.291*
Life activities scores	44.8 ± 29.1 (50.0)	29.6 ± 23.5 (25.0)	0.013*
Total score	61.4 ± 19.3 (62.5)	59.8 ± 12.9 (57.0)	0.571**

Note: * Mann-Whitney U test and **t- test at = 0.05.

Table 10. HRQoL scores in TB patients according to sputum status after intensive Phase Treatment.

Score	Positive pulmonary TB (n = 144) mean ± SD (median)	Negative pulmonary TB (n = 29) mean ± SD (median)	P-value
Symptoms score	86.3 ± 12.8 (89.0)	92.2 ± 9.6 (93.0)	0.021*
Social activities score	73.60 ± 28.60 (75.00)	80.2 ± 27.0 (100.0)	0.242*
Life activities score	54.1 ± 27.8 (50.0)	59.5 ± 30.3 (50.0)	0.483*
Total score	71.2 ± 17.0 (73.5)	77.4 ± 14.8 (75.0)	0.073**

Note: * Mann-Whitney U test and **t- test at = 0.05.

phase. This is because the bacteria of converted patients are reduced (that is the bacteria which caused the symptoms). However, some noticeable symptoms were still exiting. Similar findings were found in studies that was conducted in India (Dhingra and Rajpal, 2003; 2005).

The study showed there was a higher score of HRQoL in negative pulmonary TB than in positive pulmonary TB at the end of the second month of the follow-up, negative pulmonary TB patients at the end of the first month of the follow-up of score II (life activities), and at the total HRQoL scores of the first day. Dinghra and Rajpal (2003 and 2005) explicated that the sputum negative patients showed a higher symptom score than the sputum

of positive patients, because the symptoms of negative TB patient were non-serious, so the impact of TB on their physical health status was not high.

IMPLICATION ON PHARMACY PRACTICE

The study results highlighted that the HRQoL scores are lesser in pulmonary TB as compared to extra pulmonary TB in Yemen. HRQoL should be one of the targeted outcomes in TB management. These highlights that the physicians treating pulmonary TB should be more concern in terms of the quality of life of the patients.

STUDY LIMITATIONS

The study compared only between two categories of TB (pulmonary TB and extra pulmonary TB), and therefore we recommend to look into all categories of TB in future studies. This will help to see problem from a broader perspective, and will provide a clear picture about this problem in Yemeni society.

STUDY RECOMMENDATIONS

In-depth interviews with patients and close family members and qualitative study method may supply more comprehensive information about the patients' QoL. Further research is needed to find out whether the results reported here may be replicated in another dimension.

Conclusions

At the beginning of therapy, pulmonary TB patients have significantly lower HRQoL than extra pulmonary TB patients. The HRQoL of both pulmonary TB patients and extra pulmonary TB patients significantly improved after the onset of treatment. The pulmonary TB converted patients improved significantly in symptoms as compared to the pulmonary TB non converted patients.

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