

Health-related Quality of Life (HRQL) in Tuberculosis Patients With and Without Diabetes Mellitus

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Abstract: We aimed to investigate describe health-related quality of life (HRQL) of tuberculosis patients with and without diabetes mellitus. Participants were diagnosed and treated at Qingdao Chest Hospital between April and August 2015. A total of 131 patients were eligible in the study and 50 of them were suffering from tuberculosis (TB) and diabetes mellitus (DM) simultaneously, 81 were TB only. Chinese version 2 of the Short Form-36 (SF-36 v2) questionnaire was used to evaluate HRQL in the patients. This survey found that most of patients in TB-DM patients group reached dietary diversification. The types of food intake results show that scores of all the eight SF-36 dimensions, and their physical and mental summary scores, were significantly lower than the Chinese general population. Except for role physical (RP) and mental health (MH), the scores of TB patients with DM (TB-DM) were lower than TB patients without DM. Multivariable analysis showed that age and occupation were the factors affecting their physical health, and the factors affecting their mental health were the situation of initial treatment, occupation and average monthly income.

Keywords Health-related quality of life (HRQL), SF-36v2, tuberculosis (TB), tuberculosis with diabetes mellitus (TB-DM)

INTRODUCTION

It has been attracted much number of attention that the complicating epidemics of pulmonary tuberculosis (TB) and diabetes mellitus (DM) and their effect on human health [Dooley *et al.*, 2009]. The prevalence of diabetes in China has an incredible increase. It was reported that the age standardized prevalence of diabetes mellitus and impaired glucose tolerance (IGT) was 9.7% and 15.5%, separately [Cheng *et al.*, 2010]. At the same time, China has a high burden, accounting for approximately seventeen percent of the world's TB burden. There are estimated 1.5 million new cases and approximately two hundred and seventy thousand deaths due to tuberculosis every year in China. A large meta-analysis reported that compared with non-diabetic controls, the DM patients were 3.1 times (95%, CI: 2.27–4.26) to have TB [Jeon *et al.*, 2008] and it has been assessed that the TB risk attributable to DM was between 15% and 25% [Pablos-Mendez *et al.*, 1997]. Similar findings with risk ratios of 3.47 (95%, CI: 2.98–4.03) and 3.80 (95%, CI: 2.30–6.10) were shown in two cohort studies from Korea and UK [Kim *et al.*, 1995, Jick *et al.*, 2006]. Therefore, the double burden and combined prevalence of tuberculosis and diabetes mellitus portray a huge health threat, making treatment failure more frequently, resulting in more community-acquired tuberculosis [Wang *et al.*, 2013].

Although tuberculosis can be cured, treatment of the disease has significant medical, social and psychological consequences, which may lead to a decline in quality of life and physical functional. It is

found that physical and mental suffering often lead to treatment failure or poor treatment outcome in TB patients [Babikako *et al.*, 2010]. Compared with the general Chinese population, active TB patients were found that Physical health was more affected than mental health [Chamla *et al.*, 2004]

Health-related quality of life (HRQL) can mirror the influence of diseases on daily activities and functions. This measurement is more necessary in patients who are undergoing a chronic disease because their mental and social health as well as physical health is affected seriously by the disease and long-term treatment [Dion *et al.*, 2004]. Patients' HRQL is known to be related to a patient's self-perceived health status, so a better comprehension of HRQL may help improve compliance of therapeutic schedule [Lertmaharit *et al.*, 2005, Marra *et al.*, 2004].

Although many HQOL studies have been performed among patients with diabetes mellitus [Grigsby *et al.*, 2002, Norris *et al.*, 2011, Rubin *et al.*, 1999, Wexler *et al.*, 2006] and among patients with tuberculosis [Babikako *et al.*, 2010, Chamla *et al.*, 2004, Marra *et al.*, 2004, Duyan *et al.*, 2005, Guo *et al.*, 2009] worldwide, there is few literatures on the HQOL among TB-DM patients. In this study, we assess the dietary patterns, nutrient intake level and HQOL among TB patients with and without DM to evaluate nutritional status and provide a scientific basis to direct their diet and observe the HRQL of the patients and investigate the influence of DM on the life quality of TB.

METHODS

Design and instrument

This is a cross-sectional study. The recruited participants were patients diagnosed and treated at Qingdao Chest Hospital between April 2015 and August 2015. A total of 131 patients were eligible in the study and 50 of them were suffering from both TB and DM, 81 of them were TB only. A two-part questionnaire including demographic data for the first part and the HRQL questionnaire for the second part was designed.

Population and participant selection

During the study period, all eligible patients were:

- 1) Diagnosed with tuberculosis. The diagnosis of TB was made within the TB prevention and control system in China, where clinical symptoms, sputum smear and chest x-ray were the principal component. As a general rule, we investigated suspected TB person by sputum smear examination. If sputum smears were positive, the patient was diagnosed as smear-positive TB; the patient was diagnosed as smear-negative TB if sputum smears were negative and chest x-ray was compatible with active TB.
 - 2) Diagnosis of DM was based on WHO criteria for the classification of glucose tolerance based on fasting plasma glucose (FPG).
 - 3) Over 16 years of age
 - 4) Who were sufficiently able to read and write Chinese characters and have the ability to complete the questionnaire by themselves
 - 5) Voluntarily participating the investigation
- Patients were removed from this study if they were:
- 6) With other serious physical and mental disorders
 - 7) Unconsciousness(Confusion) and cannot take care of themselves in daily life
 - 8) Reluctant to participate in this study.

Measures

The following demographic information of the participants was collected: gender, age, education level, marital status, occupation, income, smoking and drinking history and current situation, etc. Data collecting was conducted through reading medical records and face-to-face interview. Trained data collectors explained this study's purpose to all eligible participants in simple and clear language. We ensured that the data provided by the participants were kept confidential. The participants were informed that it was allowed to withdraw from this study whenever they want to.

Anthropometric measurements containing height and weight were measured by well-trained researcher by standard procedure. Height and weight were measured by trained investigators using standard procedure. Body mass index (BMI, kg/m^2) was calculated by using the formula: $\text{BMI} = \text{Weight (kg)} / \text{Height}^2 (\text{m}^2)$, and the cut-off value for Chinese population was used.

Lipid indexes including: hemoglobin A1C (HbA1C), albumin (ALB), pre albumin (PAB),

globulin (GLO), cholesterol (CHO), triglyceride(TG), high density lipoprotein(HDL) and low density lipoprotein(LDL) were estimated by enzymatic procedure.

HRQL was measured by using the Chinese version 2 of the Short Form-36 (SF-36v2), which enables measurement of HRQL at two levels: eight scales that gauge eight domains of health and two component scores for physical health and mental health. The eight health domains are as follows: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH). In addition, eight domains of health are used to be further summarized into two component scores: the Physical Component Summary (PCS) and the Mental Component Summary (MCS) [Ware *et al.*, 1998]. The standard norm-based scores of all subscales and physical and mental summary were account using norm-based methods (Chinese weights) that standardize to a mean of 50 in general population. Each domain and PCS and MCS score is between 0 and 100. Generally speaking, for all the domain and summary scores, higher scores indicate more favorable levels of functioning and better quality of life relevant to either mental or physical components.

The Ethics Committee of Qingdao Disease Prevention and Control Centre approved the present study, and written informed consent was obtained from each subject. The study was registered in the Chinese Clinical Trial Registry (No.ChiCTR-IPR-15006395).

Data analysis

SPSS Software program version17.0 was used for statistical analysis. All data are presented as means (\pm standard deviation [SD]) for quantitative variables and counts and percentages (%) for qualitative variables, which were calculated to describe the sample.

Patient demographic and clinical characteristics were compared using chi-squared test for qualitative variables and an independent sample *t*-test (normality distributed data) or Mann-Whitney U test (no normality distributed data) for quantitative variables. HQOL scores in the TB group were compared with the same in patients of TB-DM by *t* test (normality distributed data) or Mann-Whitney U test (no normality distributed data). Multivariable linear regression analysis was used to determine whether other variables were predictors of the PCS and MCS scores. A *p*-value of < 0.05 was considered to signify statistical significance.

RESULTS AND DISCUSSION

Social demographic, anthropometric and lipid characteristics

Totally, 131 patients were eligible in the study and 50 of them were suffering from both TB and DM (TB-DM patients group), 81 of them were TB only (TB patients group). The demographic, anthropometric and glycolipids characteristics data of the study

participants were shown in Table 1. The 81 TB cases included in the study had a mean age of 33.41 years (SD=14.13) and 61.7% were male. In TB-DM group, 66% of the patients were male, with a higher age than TB group (48.60±13.48 VS 33.41±14.13, P=0.000). Patients in TB patients group were more likely to had a lower BMI (20.39±2.51 VS 22.14±3.07, P=0.001), had a higher Education level, had less average monthly income and were more often single compared with the group with TB-DM. In the TB patients group, the smoker take a percent of 63% and this percentage was obviously higher than that in TB-DM patients group (38.0%, P=0.005). Patients in TB patients group were more likely to have a lower concentration of CHO (4.19±0.76 VS 4.82±1.16, P=0.009) and TG (0.94±0.47 VS 1.35±0.79, P=0.003) and a lower proportion of HbA1C (5.25±0.89 VS 6.81±1.02, P=0.001) than TB-DM patients. There was no significant difference in gender, concentration of ALB, PAB, GLO, HDL and LDL between the TB and the TB-DM patients (P >0.05).

As we all know, the elderly population had a higher incidence of diabetes. The age data from this study indicated that patients of TB-DM patients group older than TB patients group. This result indicated that the symptoms of pulmonary tuberculosis had occurred after diabetes in the TB-DM patients of our study.

In our study, BMI in TB-DM patients group was higher than that in TB patients group. A study showed that the proportion of overweight (BMI: 25.0 - 29.9 kg/m²) and obesity (BMI ≥30.0 kg/m²) in DM patients was higher than that in patients without DM (17.0% VS 13.4%). But the association for BMI is complex due to co-morbid DM and TB. Overweight and obesity is associated with increasing the risk of DM, and is defense against TB disease [Leung *et al.*, 2007].

Regarding education, the great majority of the participants had accomplish elementary education, which makes sure the accuracy of patients' comprehensions of the questionnaire's content and the results of the questionnaire. Concerning occupation and income, the data showed that most patients have the ability to earn money.

Our findings showed that the health system should pay greater attention to prevent TB among DM patients. The increased risk of active TB in DM patients should receive greater attention. In order to have early diagnosis and treatment, they should be informed to go to the hospital for examination in time when suspicious TB symptoms occur.

Table 1 The demographic and anthropometric and lipid characteristics data of the study participants

Demographic characteristics	TB group (N=81)	TB-DM group (N=50)	p-value
Male, n(%) ^a	50 (61.7)	33 (66.0)	0.622
Age, (years), Mean ± SD ^b	33.41±14.13	48.60±13.48	0.000
BMI, (kg/m ²), Mean ± SD ^b	20.39±2.51	22.14±3.07	0.001

Mean ± SD ^b			
Education level, n(%) ^a			0.000
Primary school	4 (4.9)	12 (24.0)	
Junior middle school	16 (19.8)	19 (38.0)	
Senior middle school	35 (43.2)	16 (32.0)	
Junior college	15 (18.5)	1 (2.0)	
University or higher	11 (13.6)	2 (4.0)	
Occupation, n(%) ^a			0.000
Farmer	2 (2.5)	16 (32.0)	
Worker	19 (23.5)	4 (8.0)	
Student	14 (17.3)	2 (4.0)	
Leadership	1 (1.2)	0	
Merchant	3 (3.7)	2 (4.0)	
Retirement	4 (4.9)	4 (8.0)	
Job-waiting	17 (21.0)	13 (26.0)	
Migrant worker	0	1 (2.0)	
Others	21 (25.9)	8 (16.0)	
Average monthly income, n(%) ^a			0.035
<1000	36 (44.4)	15 (30.0)	
1000-3000	30 (37.0)	30 (60.0)	
3000-5000	15 (18.5)	5 (10.0)	
Marital Status, n(%) ^a			0.003
Single	35 (43.2)	9 (18.0)	
Married	46 (56.8)	37 (74.0)	
Widowed	0	1 (2.0)	
Divorced	0	3 (6.0)	
Smokers, n(%) ^a	51 (63.0%)	19 (38.0%)	0.005
Alcohol drinkers, n(%) ^a	47 (58.0%)	19 (62.0%)	0.026
HbA1C (%), Mean ± SD ^b	5.25±0.89	6.81±1.02	0.001
ALB(g/L), Mean ± SD ^b	42.73±5.20	37.60±8.95	0.479
PAB(g/L), Mean ± SD ^b	192.33±105.81	174.09±108.13	0.455
GLB(g/L), Mean ± SD ^b	28.60±27.48	25.52±4.61	0.579
CHO(mmol/L), Mean ± SD ^c	4.19±0.76	4.82±1.16	0.009
TG(mmol/L), Mean ± SD ^b	0.94±0.47	1.35±0.79	0.003
HDL(mmol/L), Mean ± SD ^b	1.29±0.38	1.29±0.32	0.977
LDL(mmol/L), Mean ± SD ^b	2.53±0.66	2.86±0.91	0.094

a: chi- squared test ; b: t-test ; c: Mann-Whitney U test.

Health-related quality of life (HRQL) of Study population

Data presented in Table 2- 4 described the standard norm-based scores of all eight SF-36v2 dimensions, and their physical component summary and mental component summary in total patients group, TB patients group and TB-DM patients group, respectively. All standard norm-based scores of all groups were significantly worse than the Chinese general population norm of 50. The total patients group achieved the highest score in physical functioning (PF) (44.58 ± 10.14) and the lowest in role physical (RP) (26.71 ± 14.74). Concomitantly, role physical (RP) of TB patients group was most severely damaged (26.04 ± 14.75). In the TB-DM patients group the lowest result (26.56 ± 14.49) was observed in role emotional (RE). All differences in this comparison were found to be statistically significant ($p < 0.05$). Relevant data is presented in Table 7-9.

The findings of our study showed that the HQOL among TB patients and TB-DM patients in this study were significantly lower than Chinese general population. Between 2003 and 2004, Duyan found that TB diagnosis was associated with changes in patients' family life and social environment that lead to a negative impact on the patients' HQOL [Duyan *et al.*, 2005]. A study from UK reported that HRQL was compromised in TB patients by 8 health domain scales and 2 component summary measures [Kruijshaar *et al.*, 2010]. Our study showed that the most injured domains in health were the RE and RP, meaning that the patients had serious difficulties in their daily life activities due to emotional and physical stress. The TB patients usually have chest symptoms such as cough, chest pain and hemoptysis, and they are considered as sources of infection for the healthy people, so they have to face social exclusion and isolation from the socialization and family life, which can limit the patients' role in work and social activities. In line with our study's findings, a study in Canada also reported that RE and RP were the most affected health domains among all eight SF-36 dimensions [Marra *et al.*, 2008]. In this study, compared with PCS, lower MCS score (34.60 ± 12.75 VS 39.72 ± 9.35 , 34.78 ± 11.83 VS 41.48 ± 8.76 , 34.30 ± 14.23 VS 36.87 ± 9.66) showed that the patients underwent more psychological distress and role limitation because of emotional problems than the physical problems. In 2014, Atif's study reported almost similar findings [Atif *et al.*, 2014]. However, contrary to our findings, earlier studies [Kruijshaar *et al.*, 2010, Marra *et al.*, 2008] showed that physical health was more damaged than the mental health.

The comparison between the HRQL of TB-DM patients group and TB patients group using the SF-36 v2 questionnaire showed that except for role physical (RP) and mental health (MH), the scores of TB-DM patients group were lower than TB patients group. Only in four subscales, i.e. BP, GH, SF, and PCS, statistically significant differences between TB-DM

patients group and TB patients group were observed ($P < 0.05$) (Table 5).

The results of our study indicated that TB-DM patients experienced more serious damage in HRQL than patients with TB alone. Regarding the eight domains of the SF-36v2 investigated, it was found that domains relating to the physical component in TB-DM patients affected the HRQL more than those in patients with TB alone, while there were no distinctions of domains relating to the mental health. There is no information published regarding HRQL assessment in TB-DM patients. However, a few studies [Grigsby *et al.*, 2002, Norris *et al.*, 2011, Rubin, Peyrot *et al.*, 1999, Wexler *et al.*, 2006] that assessed HRQL in DM patients. A study applying the SF-36 to people with DM, found that the domains that obtained the lowest scores were Bodily Pain and General Health, which suggested that the subjects studied perceived impairments, such as weakness and discomfort, related to poor metabolic control [Faria *et al.*, 2013]. Due to the acute and chronic complications and the treatment demands, DM can adversely affect the physical well-being, customarily. The chronic complications in people with DM may affect the quality of life, which can be avoided through intensive control of glycaemia and arterial pressure [Faria *et al.*, 2013].

Table 2 Comparison of eight SF-36v2 category scores between the total patients and Chinese general population

SF-36v2 category	Total (N=131)	Chinese general population	p-value
PF	44.58±10.14	50±10	0.000
RP	26.71±14.74	50±10	0.000
BP	41.60±10.27	50±10	0.000
GH	35.81±10.84	50±10	0.000
VT	41.90±10.67	50±10	0.000
SF	31.33±13.86	50±10	0.000
RE	29.11±14.84	50±10	0.000
MH	37.50±11.76	50±10	0.000
PCS	39.72±9.35	50±10	0.000
MCS	34.60±12.75	50±10	0.000

All values are expressed as mean±SD. PF = physical functioning; RP= role physical; BP=bodily pain; GH =general health; VT=vitality; SF=social functioning; RE=role emotional; MH= mental health; PCS= physical component summary; MCS= mental component summary; SD= standard deviation

Table 3 Comparison of eight SF-36v2 category scores between the TB patients and Chinese general population

SF-36 category	TB (N=81)	Chinese general population	p-value
PF	46.07±8.90	50±10	0.000
RP	26.0±14.75	50±10	0.000
BP	44.51±9.55	50±10	0.000
GH	37.60±9.98	50±10	0.000
VT	42.0±10.40	50±10	0.000
SF	33.81±12.25	50±10	0.000
RE	30.6±14.93	50±10	0.000
MH	36.8±10.80	50±10	0.000
PCS	41.48±8.76	50±10	0.000
MCS	34.7±11.83	50±10	0.000

All values are expressed as mean±SD.

PF = physical functioning; RP= role physical; BP=bodily pain; GH =general health; VT=vitality; SF=social functioning; RE=role emotional; MH= mental health; PCS= physical component summary; MCS= mental component summary; SD= standard deviation

Table 4 Comparison of eight SF-36v2 category scores between the TB-DM patients and Chinese general population

SF-36 category	TB-DM (N=50)	Chinese general population	p-value
PF	42.16±11.55	50±10	0.000
RP	27.81±14.80	50±10	0.000
BP	36.90±9.70	50±10	0.000
GH	32.92±11.63	50±10	0.000
VT	41.66±11.21	50±10	0.000
SF	27.31±15.43	50±10	0.000
RE	26.56±14.49	50±10	0.000
MH	38.46±13.22	50±10	0.000
PCS	36.87±9.66	50±10	0.000
MCS	34.30±14.23	50±10	0.000

All values are expressed as mean±SD.

PF = physical functioning; RP= role physical; BP=bodily pain; GH =general health; VT=vitality; SF=social functioning; RE=role emotional; MH= mental health; PCS= physical component summary; MCS= mental component summary; SD= standard deviation

Table 5 Comparison of eight SF-36v2 category scores between the TB patients and TB-DM patients

SF-36 category	TB (N=81)	TB-DM (N=50)	p-value
PF ^b	46.07±8.90	42.16±11.55	0.064
RP ^a	26.04±14.75	27.81±14.80	0.507
BP ^a	44.51±9.55	36.90±9.70	0.000
GH ^a	37.60±9.98	32.92±11.63	0.016
VT ^a	42.06±10.40	41.66±11.21	0.837
SF ^b	33.81±12.25	27.31±15.43	0.015

RE ^a	30.68±14.93	26.56±14.49	0.123
MH ^b	36.89±10.80	38.46±13.22	0.572
PCS ^a	41.48±8.76	36.87±9.66	0.006
MCS ^a	34.78±11.83	34.30±14.23	0.617

a: t-test ; b: Mann-Whitney U test

All values are expressed as mean±SD.

PF = physical functioning; RP= role physical; BP=bodily pain; GH =general health; VT=vitality; SF=social functioning; RE=role emotional; MH= mental health; PCS= physical component summary; MCS= mental component summary; SD= standard deviation

Predictors of physical health (PCS) and mental health (MCS) in Study population

Multivariable analysis showed that age and occupation were the factors affecting all participants' physical health, and the factors affecting the mental health were the situation of initial treatment, occupation and average monthly income (Table 6) (P <0.05).

A higher possibility of lower PCS scores in the elderly was most likely to be related to their old age and the no unexpected decrements in physical health with increasing age [Demiral *et al.*, 2006, Pappa *et al.*, 2005]. Our study found a correlation between age and PCS. It is known that many participants may have begun to experience decrements in their physical capacity that is associated with increasing age. Similar to our study's results, a Chinese study reported that there were comparable association between age and HRQL scores [Chamla *et al.*, 2004], and a study found that TB patient's age was predictive of differences in the overall PCS score [Atif *et al.*, 2014]. Along the same lines, a Canadian study also reported that elderly TB patients had the lower PCS scores [Marra *et al.*, 2008].

The finding that indicators of socio-economic status (occupation, average monthly income) in this study were associated with HRQL in TB patients is in agreement with a number of studies [Duyan *et al.*, 2005, Atif *et al.*, 2014]. This is a well-known fact that people who have a higher monthly income, face low economic sufferings. Consequently, compared with the persons who fall in the low socio-economic category, rich person are expected to have better spiritual satisfaction. Other studies [Demiral *et al.*, 2006, Pappa *et al.*, 2005] also reported that patients with higher income had higher MCS scores. Unlike in some other studies [Babikako *et al.*, 2010, Chamla *et al.*, 2004, Guo *et al.*, 2008], this study did not find gender differences in relation to HQRL in TB patients.

The question of whether smoking and HRQL are associated has not been studied before in patients with TB; however, study examining the association between secondhand smoke (SHS) exposure and HRQL in TB patients was available. That study found that non-SHS exposure (P=0.033) was identified to be factors significantly associated with lower mental component summary [Masumoto *et al.*, 2014]. Our study found that smoking situation was borderline

significantly associated with mental component summary. Further study would be needed enlarge the sample size to assess our findings.

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Table 6 Predictors of physical health (PCS) and mental health (MCS) in all participants

Influence factors	PCS		MCS	
	t	p-value	t	p-value
DM	-1.268	0.207	0.484	0.629
Initial treatment or not	1.080	0.282	-2.174	0.032
Duration of TB therapy	-1.013	0.313	-0.534	0.594
Age	-2.323	0.022	-1.721	0.088
Gender	-0.668	0.506	0.061	0.951
BMI	0.778	0.438	0.224	0.823
Education level	0.228	0.820	0.273	0.785
Occupation	-2.384	0.019	-3.156	0.002
Average monthly income	-0.299	0.765	2.901	0.004
Marital Status	1.274	0.205	-0.806	0.422
Stay up late	1.358	0.177	0.238	0.813
Smoking situation	-1.182	0.240	1.937	0.055
Drinking situation	0.148	0.882	-0.826	0.410

PCS= physical component summary; MCS= mental component summary;

CONCLUSION

By the investigation, we found that patients with TB suffer from significantly diminished Health-related quality of life, and scores of TB-DM population on bodily pain (BP), general health (GH) and social functioning (SF) and their physical summary scores (PCS) were significantly worse than patients with TB alone. Age and occupation were the factors affecting their physical health, and the factors affecting the mental health were the situation of initial treatment, occupation and average monthly income.

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