A Study on Assessment of Patients Health Related Quality of Life During Tuberculosis Treatment in a Tertiary Care Teaching Hospital

Shrishail S Patil', Aastha Rawal, Anuraj R, Sabbu Rahul, Hiremath Doddayya

Department of Pharmacy Practice, N.E.T. Pharmacy College, Raichur, Karnataka, INDIA.

ABSTRACT

Background: Tuberculosis is one of the leading causes of mortality and morbidity around the world, infecting approximately 8 billion people, with an annual death rate of close to 1 million. The present study was conducted to evaluate the impact of tuberculosis treatment on health related quality of life (HRQoL) of patients with active and inactive tuberculosis by evolving HRQoL questionnaire (SF-36v2). **Methodology:** A prospective follow-up study was conducted for total 70 patients (56 men and 14 women) diagnosed with tuberculosis (TB) in Navodaya Medical College Hospital & Research Centre, Raichur for a period of 6 months. The HRQoL of TB patients was assessed in three phases: at the onset of treatment, at one month (middle of intensive phase) and two months (end of intensive phase), after the initiation of anti-tuberculosis therapy. **Results:** A total of 70 patients completed the SF-36v2 questionnaire at the start of their treatment. Out of these, 53 and 41 completed the questionnaire at the second and third follow-ups, respectively. The mean physical component summary (PCS) scores at the start of the intensive phase were 42.09 \pm 16.77, 53.89 \pm 13.64 and 65.24 \pm 12.86, respectively. Similarly, the mean mental component summary (MCS) scores at the start of the treatment, after one month and at the intensive phase were 43 \pm 17.07, 52.19 \pm 14.12 and 62.17 \pm 15.12, respectively. **Conclusion:** The HRQoL improved with the treatment, the scores on component summary measures revealed the improvement of both physical and mental health among study patients at the end of intensive phase.

Key words: Tuberculosis, HRQoL, SF-36v2, Physical Component score, Mental Component score.

INTRODUCTION

Tuberculosis (TB) remains a major global health problem, responsible for ill health among millions of people each year. TB ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV). The latest estimate reports that there were 9.0 million new TB cases in 2013 and 1.5 million TB deaths (1.1 million among HIV negative people and 0.4 million among HIV-positive people). Tuberculosis is caused by a bacteria called Mycobacterium tuberculosis that most often affects the lungs. Tuberculosis is a curable and preventable disease. It is transmitted from person to person via droplets from the throat and lungs of people with the active tuberculosis disease.¹ Monitoring the outcome of treatment using standardized approach is essential in order to evaluate the effectiveness of the intervention and for comparison. World Health Organization in conjunction with International Union Against Tuberculosis and Lung Disease (IUATLD) provided recommendations

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Address for correspondence: *Mr. Shrishail S Patil,* Department of Pharmacy Practice, N.E.T. Pharmacy College, NMCH & RC, Mantralayam Road, Raichur-584103, Karnataka, INDIA. Phone no: +91-7795421230 E-mail: raastha57@gmail.com



on how to evaluate treatment outcomes using standardized categories.²

Early diagnosis and adequate treatment of infectious patients with pulmonary TB are necessary to reduce transmission of tuberculosis and ultimately to achieve elimination of TB. If TB is detected early and properly treated using a combination of medicines for 6 to 9 months, the patients quickly become noninfectious and are eventually cured.3 The standard anti-TB therapy consists of four medications and takes at least 6 to 9 months to complete, with serious risks of adverse reactions.4,5 In some communities, TB patients are perceived as a source of infection and the resultant social rejection and isolation leads to along-term impairment on patients' psychosocial well-being.6,7 DOTS (directly observed treatment, short course) is the internationally recommended control strategy for TB.8 In recent years Health-related quality of life (HRQoL) has become an important outcome, since the influence of the disease on everyday living is an important factor for the patients and assessment of HRQoL is essential to assess the self-perceived impact of physical and mental impairment on patients' health.9 Measurement of HRQoL is more necessary among patients with achronic disease like TB. In these patients, mental and social well-being as well as physical health are affected by the disease and its related long-termtreatment.¹⁰ Therefore, it is required to investigate the QoL of TB patients to recognize appropriate actions for improvement of health status and the QoL among the patients.¹¹ Previous reviews have found quantitative evidence,12,13 and only few studies have examined quality of life in patients with active TB.10,14 A patient with tuberculosis faces several physiological, psychological, financial and social problems. These problems have a great impact on the well-being of the patient and impair the quality of life of the patient suffering from tuberculosis. Considering the fact that improvement in HRQoL is an important factor for better response to treatment among TB patients, which may lead to better outcome in patients health.¹⁵ Measurement of the HRQoL adds a new dimension to the evaluation of TB programmes. With the development of effective treatment strategies where mortality is likely to be minimal, the focus of TB management has shifted to the reduction of illness-related morbidity.9

The present study was conducted to evaluate the impact of tuberculosis treatment on health related quality of life of patients with active and inactive tuberculosis by evolving a HRQoL questionnaire (SF 36v2).In addition the study also focuses on the relations between quality of life and demographic and social characteristics in TB patients.

MATERIALS AND METHODS

It was a prospective follow-up type of study conducted for 6 months from November 2014 to April 2015 in Navodaya Medical College Hospital and Research Centre, Raichur, a 1000 bedded tertiary care teaching hospital, in which patients receiving treatment for TB were included in study. A total of 70 patients were randomly enrolled in to the study on their visit to hospital and the study duration was 6 months.

Inclusion Criteria

- Physicians diagnosed in-patients with pulmonary tuberculosis.
- Patients between 18 years and 80 years of age.
- Patients with active or inactive tuberculosis taking anti-tuberculosis treatment.

Exclusion criteria

- Pregnant and lactating women up to 12 weeks after partum.
- Patients diagnosed with extra pulmonary TB.
- Patient with any associated pulmonary disease i.e asthma, chronic obstructive pulmonary disease and others associated disease that are likely to affect the health related quality of life namely hypertension, heart disease, diabetes mellitus, epilepsy and HIV.

Study Procedure: A standard data entry format for incorporating patient details was designed. The study was approved by Institutional Ethics Committee of Navodaya Medical College Hospital & Research Centre. The study was explained to the patients and their consent was obtained and HRQoL was assed using HRQoL questionnaire (SF-36v2 Questionnaire).

HRQOL QUESTIONNAIRES

SHORT FORM-36v2

The SF-36v2 is a standardized questionnaire derived from a larger set of questions used in the US Medical Outcomes Study in the mid-1980s. The SF-36v2 has become one of the most widely used of the healthrelated quality of life measures. These are generic, multi-dimensional measures of self-reported health status. Self-reported health measures based on individuals' own perception of their health status and functioning, are an alternative measure to the more traditional objective measures of health, such as mortality rates and hospitalization records. Self-reported health measures introduce an element of subjectivity into health status measurement. This is useful in providing a more 'consumer-centered' view of health, and places the measurement emphasis on quality of life or wellbeing. The SF-36v2 questionnaire for health status consists

of 36 questions (items) measuring physical and mental health status in relation to eight health concepts: Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE) and Mental Health (MH). These domains create a profile of the subject. Two summary scores can also be aggregated, the Physical Component Summary (PCS) and the Mental Component Summary (MCS). Scores range from 0 to 100, with higher scores representing better HRQoL.

Statistical Analysis

HRQoL of 70 patients were analyzed and interpreted by SF-36v2. Statistical analysis was performed for the obtained results using statistical Chi-square test.

RESULTS

Details of patients enrolled into the study

During the six month study period, total of 70 patients who were diagnosed for TB from the department of Pulmonary Medicine were enrolled as per our inclusion and exclusion criteria. Demographic characteristics of enrolled TB patients are shown in Table 1.

Assessment of generic HRQoL–SF-36v2: The details of the scores obtained from SF-36v2 were aggregated and averages scores are summarized in Table 2-4.

Interpretation of Physical Component Score

The details of the scores obtained were aggregated and average scores are summarized in Table 5. PCS values are between the two extremes 0 and 100, with zero indicating the lowest HRQoL and 100 indicates the better HRQoL. As the value increases from 0 to 100 it represents better health. In our study the total score of PCS is 42.09, 53.89 and 65.24 at 0 week, 4 week and 8 week simultaneously Figure 1. It shows that patient's health is improving after the treatment. This value is within the theoretical range and it shows a good correlation.

Interpretation of Mental component score

The details of the scores obtained were aggregated and average scores are summarized in Table 6. Mental component of SF-36v2 questionnaire is calculated to assess the psychological distress and wellbeing, social and role functioning, and overall vitality. MCS values are between the two extremes 0 and 100, with zero indicating the lowest HRQoL and 100 indicates the better HRQoL. As the value increases from 0 to 100 it represents better health. In our study the total score of MCS is 43.99, 52.19 and 62.17 at 0 week, 4 week and 8 week simultaneously Figure 1. It shows that patient's health is improving after the treatment. This value is within the theoretical range and it shows a good correlation.



Figure 1: Comparison of PCS and MCS for SF-36v2 at 0,4 and 8 week

Chi square test

All the variables were combined to calculate total PCS and MCS were then subjected to chi-square test to find the variation between the value at 0 week, 4 week and 8 week. The total PCS and MCS were then compared which give the result as:

- The Chi-square statistic is 1410615.8648 for PCS and MCS at 0 week and 4 week. The P value is 0.000141. This result is significant at p<0.05.
- The Chi-square statistic is -5619411.8678 for PCS and MCS at 4 week and 8 week. The P value is 0.001708. This result is significant at p<0.05.
- The Chi-square statistic is -6924486.7853 for PCS and MCS at 0 week and 8 week. The P value is 0.001675. This result is significant at p<0.05.

DISCUSSION

HRQoL has been appreciated as an important health outcome measure in clinical research. We identified original studies where multi-dimensional HRQoL was assessed among people with TB disease or infection using structured instruments around the world. We found that TB and its treatment have a significant impact on patients' quality of life from various aspects and this impact tends to persist for a long time even after the successful completion of treatment and the microbiological 'cure' of the disease. In our study a total of 70 patients were included from the pulmonary medicine department who are suffering from TB. However out of these, 53 and 41 completed the questionnaire at the second and third follow-ups, respectively. The findings for the study population demonstrate that out of

| Table 1: Demographic characteristics of enrolled TB patients | | | | |
|--|-------------|--|--|--|
| Characteristic | Data | | | |
| No of patients enrolled in study | 70 | | | |
| Male/Female n=70 | 56/14 | | | |
| Age in years n=70 | | | | |
| 20-39 | 36 (51.43%) | | | |
| 40-59 | 22 (31.43%) | | | |
| 60-79 | 12 (17.14%) | | | |
| Educational qualifications n=70 | | | | |
| Illiterate | 36 (51.43%) | | | |
| Primary | 10 (14.28%) | | | |
| Secondary | 4 (5.72%) | | | |
| Higher | 20 (28.57%) | | | |
| Alcohol Consumption n=70 | | | | |
| Alcoholic | 48 (68.57%) | | | |
| Non-alcoholic | 22 (31.43%) | | | |
| Smoking status n=70 | | | | |
| Smoker | 51 (71.6%) | | | |
| Non Smoker | 19 (28.3%) | | | |
| Sleep pattern n=70 | | | | |
| Normal | 46 (65.8%) | | | |
| Disturbed | 15 (21.6%) | | | |
| Decreased | 9 (12.5%) | | | |
| Occupational Status n=70 | | | | |
| Agriculture | 38 (54.29%) | | | |
| Industrial | 12 (17.14%) | | | |
| Clerk | 6 (8.57%) | | | |
| Housewife | 10 (14.29%) | | | |
| Student | 4 (5.71%) | | | |
| Married/Unmarried n=70 | 64/6 | | | |

| Table 2: SF-36v2 Health Domains Score at 0 week | | | | | | | | |
|---|------------------|-------------------|-------------------|----------------|------------------|-------------------|-------------------|------------------|
| | PF | RP | BP | GH | VT | SF | RE | МН |
| Avg (SD) | 51.8 (±24.22) | 29.29 (±32.96) | 50.36 (±24.04) | 36.96 (±10) | 48.9 (±18.01) | 49.29 (±21.17) | 28.57 (±30.18) | 49.2 (±20.45) |
| | | | | | | | | |

* Avg-Average, SD-Standard deviation.

| Table 3: SF-36v2 Health Domains Score at 4 week | | | | | | | | |
|---|----------|----------|---------|----------|----------|----------|----------|----------|
| | PF | RP | BP | GH | VT | SF | RE | МН |
| Avg (SD) | 61.6 | 44.34 | 62.2 | 47.48 | 52.6 | 61.56 | 42.1 | 52.5 |
| (00) | (±19.92) | (±30.47) | (±15.3) | (±10.91) | (±17.08) | (±15.27) | (±25.44) | (±18.27) |

| Table 4: SF-36v2 Health Domains Score at 8 week | | | | | | | | |
|---|-------------------|------------------|-------------------|--------------------|-------------------|-------------------|-------------------|------------------|
| | PF | RP | BP | GH | VT | SF | RE | МН |
| Avg (SD) | 74.39 (±12.95) | 62.2 (±29.11) | 71.65 (±14.51) | 52.744 (±12.31) | 59.05 (±17.25) | 67.99 (±18.12) | 61.79 (±25.34) | 59.9 (±20.16) |

| Table 5: SF-36v2 Physical Component Score | | | | |
|---|-------------------|-------------------|--|--|
| Average (SD) | | | | |
| 0 week | 4 week | 8 week | | |
| 42.09 (±16.77) | 53.89 (±13.64) | 65.24 (±12.86) | | |

| Table 6: SF-36v2 Mental Component Score | | | |
|---|----------|----------|--|
| Average | | | |
| 0 week | 4 week | 8 week | |
| 43.99 | 52.19 | 62.17 | |
| (±17.07) | (±14.12) | (±15.12) | |

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them male patients were 56 and female patients were 14 (Table 1). Similarity was observed in study of Atif M with more male patient.¹⁶ Contrary to this, a study by Marra et al showed more female patient.¹⁷ Fifty one percent of patients were in age group of 20-39, 31.43 percent were in the age group of 40-59 and 17.14 percent were in age group 60-79. So majority of the patients are from 20-39 years of age. However patients in the age group of 60-79 were considerably less (Table 1). Educational qualification for patients with primary education is 14.28%, 5.72% with secondary education and 28.57% are with higher education (Table 1). The percent of illiterate patient were the majority with 51.43%. Sleep pattern among 70 patients, are as follows: 65.8% are with disturbed sleep, 21.6% are with diminished sleep and only 12.5% are with normal sleep (Table 1). Social behavior with regard to alcohol consumption reveals that 68.57% are alcoholic and 31.43% are nonalcoholic (Table 1). Smoking habits showed that 71.6% are smoker and 28.3% are nonsmoker (Table 1). It implies that alcoholic and smoker are more prone to TB. It's also useful for counseling the patient as these both factors decline the effect of drug therapy. These findings were similar to the findings of studies from Canada (Marra CA et al) and India(Muniyandi M et al).^{17,18} However, a study from China (Chamla D) did not find any association between smoking and MCS scores.¹¹

Smoking is known to adversely affect the immune system, and can render the smokers more susceptible to infections. Similarly, smokers tend to have higher bacillary loads because of compromised immune system. A higher bacillary load can augment the severity of disease which may adversely affect the patient's perception about their mental and physical health.¹⁹ The results suggest that TB disease has a negative and encompassing impact on active TB patients' self-perceived health status in physical, psychological, and social aspects. Overall, the anti-TB treatment showed positive effect on improving patients HRQoL. It appeared that physical health seemed to be more affected by the disease but improved more quickly after the treatment, while the impairment on mental well-being tended to persist for a longer term.^{11,20} However, even after the active TB patients successfully completed the treatment and were considered microbiologically 'cured', their HRQoL remained poor as compared to the general population.^{10,11,17,21}

The relationship between TB and quality of life has been discussed in several studies. However, differences in cultures and methodologies of data collection related to HRQoL have resulted in inconsistencies and the development of multiple assessment tools. Among the tools most widely used, the SF-36v2 has been used extensively in communities and clinical settings in different countries, and has proved a reliable, valid measure of HQoL.^{22,23}

Only a few studies in the literature prospectively studied TB patients HRQoL during the whole treatment period.^{11,15,17,20,24-26} Out of these, only two studies were conducted in Asia^{20,24} one used a DR-12 questionnaire and the other used a modified version of the SF-36 health survey to quantify HRQoL in TB patients. These findings highlighted the existence of a gap in literature with regard to a follow-up study using a validated tool to gauge the impact of TB treatment on HRQoL of smear positive PTB patients. In the present study, the HRQoL of TB patients was measured in three phases: at the onset of treatment, at one month and two months, after the initiation of anti-tuberculosis therapy. In this study, 70 smear positive TB patients completed the SF-36v2 questionnaire at the start of the treatment. Out of these, 53 and 41 respondents completed the questionnaire at the 4th and 8th week of the treatment respectively. The results showed that the QoL was significantly increased after two months which indicated the positive impact of the four-drug TB regimens on the improvement of the QoL in these patients.

The findings of our study showed that there was clinically and statistically significant improvement in the scores on health domain scales and summary measures. However, despite these improvements following TB treatment, the mean PCS and MCS scores, at the end of the intensive phase, were found to be 65.24 ± 12.86 and 62.17 ± 15.12 respectively (Table 5 and 6). This indicates improvement in health after the intensive phase of treatment. Similarly, scores on all health domain scales were less than 70% (except PF 74.39 \pm 12.95 and BP 71.64 \pm 14.5 as shown in Table 4). These findings clearly suggested that although TB treatment had significantly improved the patients' perception about their health, altered HRQoL continued even after the completion of intensive phase treatment. Similar to current study's findings, Atif M and associates reported the mean PCS scores at the start of the treatment, after the intensive phase and at the end of treatment were 41.9 ± 5.1 , 45.8 ± 4.8 and 46.0 ± 6.9 , respectively. Similarly, the mean MCS scores at the start of the treatment, after the intensive phase and at the end of the treatment were 39.9 ± 7.3 , 45.0 ± 6.8 and 46.8 ± 7.8 , respectively.¹⁶ Marra and associates reported that compared with the U.S. general population norms, patients with active TB had worse scores on the SF-36 scales at the end of the treatment¹⁷ compared to latent TB. A few other studies also reported almost similar findings.11,27

With regard to HRQoL at the start of the treatment, the scores on health domain scales and summary measures

were 43.04 ± 15.91 . The RE and RP scales were the most affected health domains which meant that the patients had severe problems in performing their daily life activities due to emotional stress. Similarly, it also suggested that the patients rated their overall health as poor, and even expected it to get worse.²⁸ At the start of the treatment, compared with PCS, lower MCS scores showed that the patients experienced more psychological distress and role limitation due to emotional problems than the physical problems.²⁸ In line with the current study's findings, a study from Canada also reported lower HRQoL scores on SF-36health domain scales and component summary measures. The Canadian study also reported that, at the start of the treatment, the RE and RP were among the mostaffected health domains.17 Likewise, a study from the United Kingdom (UK) reported compromised HRQoL across SF-36 health domain scales and component summary measures.²⁹ However, contrary to the findings of our study, study from Northern Region of Malaysia by Atif M¹⁶ showed that, at the start of the treatment, mental health was more affected than the physical health.

With regard to HRQoL scores at the end of the intensive phase (8th week), the findings of this study showed gradual improvement for all health domain scales and summary measures. These findings showed that, TB treatment had significantly improved HRQoL of the patients. A similar trend in the improvement of HRQoL scores in association with TB treatment was reported elsewhere.^{25,29}

The study demonstrated the HRQoL of TB patient has been improving with the treatment, where the physical health tended to recover more quickly than the mental well-being. RE was the most affected domain and was improved drastically compared to other domains. Though this study it shows positive response with better HRQoL but complete quality was not yet achieved after the 2 month of intensive phase treatment.

CONCLUSION

The study reveals that patients with TB have an average HRQoL with wide range of disturbances in physiological wellbeing and psycho-social functioning which they experienced in daily life.Overall, the anti-tuberculosis treatment had a positive effect on improving patients' quality of life; their physical health tended to recover more quickly than the mental well-being. HRQoL and resource utilization worsening health status may lead to increased health resource utilization, which has a significant impact on the overall wellbeing of individual and also on the family. Thus, evaluating HRQoL may be useful in identifying patients at risk of steep decline for which preventive measures may be instituted. Future studies should include newer strategies to assess the adherence level and long term and large population studies.

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CONFLICT OF INTEREST

Authors declared there is no conflict of interest.

ABBREVIATION USED

| HRQoL: | Health-related quality of life |
|----------|---------------------------------------|
| SF-36v2: | Short Form 36 version 2 nd |
| PCS: | Physical Component Summary |
| MCS: | Mental Component Summary |

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