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Original Research Article

Quality of life in drug resistant tuberculosis

Siddharth Chatterjee[1]*, Arvind S. Pandey[2]

[1]Department of Respiratory Medicine, Medanta Hospital, Gurugram, Haryana, India
[2]Department of Respiratory Medicine, Surat Municipal Institute of Medical Education and Research, Surat, Gujarat, India

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***Correspondence:**
Dr. Siddharth Chatterjee,
E-mail: Siddharth_3006@yahoo.com

ABSTRACT

Background: India has largest population of drug resistant tuberculosis, the treatment of which is long and full of adverse drug reactions. Despite the ongoing research in clinical and pharmacological aspects, quality of life in drug-resistant tuberculosis remains less explored.
Methods: This hospital based cross-sectional study done at tertiary care center in Surat, from January 2019 to February 2020, enrolling patients above 18 years, with multi-drug/ extensively drug resistant tuberculosis, who suffered >1 adverse drug reaction after commencing treatment. SF-36 was administered and QOL scores calculated in social, mental and physical domains.
Results: Among the 120 patients studied, majority (87.5%) had pulmonary tuberculosis. 92.5% and 7.2% were multi-drug resistant and extensively drug resistant respectively. The quality of life was poor in all three domains- physical (25.1), social (39.5) and mental (39.5). Gender, type of tuberculosis, past history of tuberculosis did not affect the QOL significantly.
Conclusions: Drug-resistant tuberculosis along with its associated adverse drug reactions greatly impacts the quality of life in all domains. Measures need to focus not just on treatment of disease but also the adverse drug reactions, rehabilitation and counselling measures as well.

Keywords: Adverse drug reactions, Drug-resistant tuberculosis, Quality of life

INTRODUCTION

With 10 million estimated people affected and 1.4 million deaths, tuberculosis remains to be huge burden to global heath.[1] India has the highest incidence of new and MDR-TB cases in the world, accounting to two-thirds of the global tuberculosis burden along with eight developing countries.[2,3]

Drug resistant tuberculosis (DR-TB), owing to its long treatment, need for aggressive second-line regimen which is more toxic, expensive, and painful due to need for multiple injectable poses multiple challenges in terms of treatment hurdles, adverse drug reactions and compliance.[1,5,6] Despite the complete treatment, only 57% of the DR-TB cases have been successfully treated as compared to 85% of the drug sensitive TB cases at the global level, mainly due to high rates of lost to follow-up, death, and treatment failures.[1] Additionally, MDR-TB patients often suffer various psychosocial problems due to the disease and its treatment complications, which negatively impacts patients' health-related quality of life (HRQoL).[6]

Adverse drug reactions (ADRs) associated with these drugs further complicate the picture, resulting in dropouts, insufficient treatment, and thereby affect success rate. The management of ADRs as well as the

cost of treating ADRs is an essential component and perhaps, needs to be given just as much attention as the disease itself.[7]

Despite the considerable attention given to traditional microbiological and clinical indicators, the effect of MDR-TB on the HRQoL of patients has largely been neglected.[8] There are limited studies which have evaluated the HRQoL of MDR-TB patients. Though many factors can be implicated to affect the quality of life in DR-TB, there is evidence available that shows adverse drug effects from the treatment regimen severely impacts and lowers the HRQoL of such patients. Not only that, but these adverse drug reactions also affect the adherence to the therapeutic recommendations.[9-11]

This study attempted to study the health-related quality of life (HRQoL) of patients with MDR-TB patients with adverse drug reactions.

METHODS

This was a hospital based cross-sectional study done in the Respiratory Medicine department, at tertiary care center, SMIMER Medical College, Surat, during period January 2019 to February 2020.

Inclusion criteria

Those patients above 18 years of age, diagnosed as MDR-TB and XDR TB based on drug susceptibility testing under RNTCP with 1 or more adverse drug reaction after commencing treatment for TB were included in the study.

Exclusion criteria

Pregnant women, those with adverse drug reactions from the drugs other than anti tubercular drugs, in the same patient and those not consenting for MDR and XDR TB regimen were excluded.

Aim

To study health related quality of life (HRQOL) in patients having multidrug resistant tuberculosis (MDR-TB) and extensive drug resistant tuberculosis (XDR-TB) suffering from adverse drug reactions from the treatment.

Data collection

Those patients diagnosed as MDR/XDR-TB based on CBNAAT, counselled and started under RNTCP drug regimen, were enrolled in the study, after obtaining informed consent. Data was collected using predesigned, structured and pretested questionnaire (SF-36) to enter the patient details, detailed clinical history and examination, along with previous tubercular or prior hospitalisation history. All patients who were started on treatment were asked to follow up after 1 month or earlier if occurrence of any clinical worsening or illness.

Sample size

Considering the proportion of MDR/ XDR-TB patients as per RNTCP in the month pilot survey at department of respiratory medicine at the study hospital (estimated around 17.9/month), taking the confidence level to be 95 percent, the sample size was calculated to be 120.

Study tool

The short form SF-36 health questionnaire. SF-36 consists of eight scales that measure eight domains of HRQoL, namely, physical functioning (PF, 10 items), role-physical (RP, four items), bodily pain (BP, two items), general health (GH, five items), vitality (VT, four items), social functioning (SF, two items) role-emotional (RE, three items) and mental health (MH, five items).

For sake of convenience, in our study, physical functioning, role-physical, pain, vitality and general health were clubbed as physical domain, mental health and role-emotional as mental domain and social functioning.

A maximum of 100 and a minimum of 0 is considered for each question. The scores considered for two-option, three-option and five option are (50 and 100), (0, 50 and 100), (0, 25, 50, 75 and 100) respectively.

The mean of total scores of all studied scopes was calculated to measure the total score of individuals' quality of life. The mean of every scope was calculated for every individual and, if the mean was lower than 50, the quality of related scope was considered low and if it was higher than 50, it was considered high.

The SF-36 questionnaire was filled up by the patients during first follow up at 1 month or earlier in case of occurrence of any adverse drug reaction.

Data analysis

The analysis included profiling of patients on different demographic, comorbidities, clinical findings as well as HRQOL score. Quantitative data were presented in terms of means and standard deviation. Qualitative/categorical data were presented as absolute numbers and proportions. Cross tables were generated and Chi-square test was used for testing of association. P value <0.05 was considered statistically significant.

Definitions used in the study[12]

MDR-TB (multiple drug resistance TB)

MTB resistant to both isoniazid and rifampicin with or without resistance to other drugs.

XDR-TB (extensive drug resistance TB)

A rare type of multidrug-resistant tuberculosis (MDR TB) that is resistant to isoniazid and rifampin, plus any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin).

Cured

A microbiologically confirmed patient at the beginning of treatment, who was smear negative at the end of the complete treatment and on at least one previous occasion.

Treatment failed

A patient whose biological specimen is positive by smear at 5 months or later.

Loss to follow up

A patient whose treatment was interrupted for continuous 1 month or more.

Died

A patient who has died due any reason during anti-TB treatment.

Treatment completed

A patient who has completed the treatment according to guidelines but does not meet the definition for cure or treatment failure due to lack of microbiological results.

RESULTS

Among the 120 patients studied, 77 (64.2%) were male, with male: female ratio being 1.8, with almost half the population belonging to the age group between 21 years to 40 years (44.2%). The demographic characteristics of the study are further mentioned in Table 1.

Majority were diagnosed with pulmonary tuberculosis (87.5%) and 92.5% were multi-drug resistant (MDR) Tuberculosis (Table 2). Around 5% of the patients expired by end of the study and 4.2% contributed to treatment failure.

The HRQOL was determined for all the patients with resistant Tuberculosis suffering from adverse drug reactions and was found to be low in all domains as illustrated in Table 3.

We further computed the QOL scores in sub-group of patients with pulmonary tuberculosis who were subsequently cured: physical- 25.5±4.5, mental- 39.3±2.0 and social domain- 39.7±2.2, all of which were poor. Similarly, the quality of life in subjects with extra-pulmonary tuberculosis who were subsequently cured was also poor (physical- 25.3±3.9, mental- 39.4±1.9 and social domain- 39.2±1.6).

Table 1: Socio-demographic characteristics of the study population.

Gender	Number of subjects	Percentage
Male	77	64.2
Female	43	35.8
Age group (years)		
<21	6	5
21-40	53	44.2
41-60	38	31.7
>60	23	19.2
Employment status		
Employed	55	45.8
Unemployed	65	54.2
Smoking and drinking habits		
Smoking	9	7.5
Drinking	23	19.2
Both	12	10
Associated co-morbidities		
Diabetes mellitus type 2	30	25
HIV	18	15
Both	11	9.2
None	61	50.8

Table 2: Details of the tuberculosis status in study population.

Type of tuberculosis based on site	Number of subjects	Percentage
Extra-pulmonary TB	15	12.5
Pulmonary TB	105	87.5
Site of extrapulmonary TB		
TB lymph node	7	46.7
TB pleural effusion	4	26.7
TB abdomen	2	13.3
TB Spine	2	13.3
Type of tuberculosis based on resistance		
Multidrug resistant TB	111	92.5
Extensively drug resistant TB	9	7.5
Outcomes at the end of study		
Expired	6	5
Treatment failure	5	4.2
Cured	71	59.2
Lost to follow-up	8	6.7
Still on treatment at the end of the study	30	25

*TB- Tuberculosis

When the QOL of XDR-TB patients were separately noted, the QOL scores were poor, with physical domain being worst affected (Figure 1). Similar trend was noticed

in treatment failure and patients who eventually expired (Figure 2).

Table 3: Health related quality of life (HRQOL) of study population.

Health related quality of life (HRQOL)			
	Physical	**Mental**	**Social**
Mean	25.1	39.5	39.5
Median	23.6	38.9	39.0
Std. deviation	4.2	2.1	1.9
Minimum	21.0	37.0	37.1
Maximum	35.9	44.6	44.9

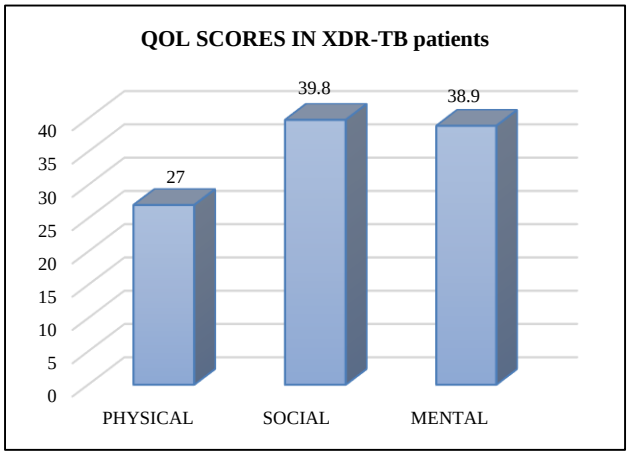

Figure 1: Quality of life in XDR-TB patients.

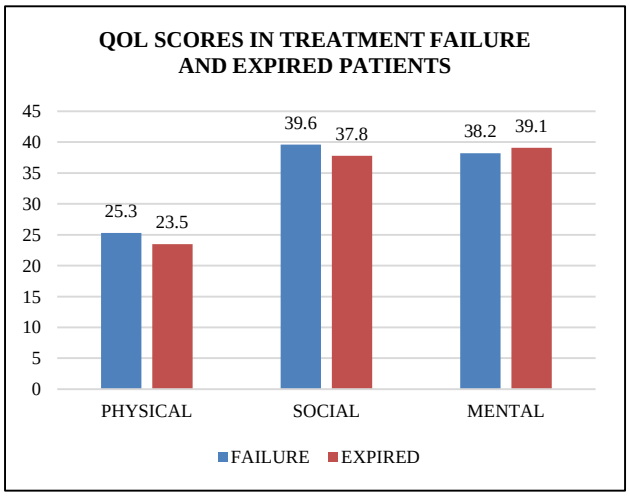

Figure 2: Quality of life in treatment failure and expired patients in study population.

Upon comparing the QOL in both genders, the scores were similar in all three domains (male: physical- 30±8.4, mental domain 27.2±7.3, social domain 25.4±6.1 whereas females: physical- 30.2±6.9, mental 27.6±5.8, social domain 26.5±5.4 with p values being 0.88, 0.78 and 0.38.

Similarly, upon comparing the QOL scores in those patients with past history of tuberculosis with those no similar past history, no significant difference was observed (past history of TB versus no past history of TB: physical domain 28.3±10.4 versus 31.2±5.5; p value-0.06, mental domain 26±8.9 versus 28.3±4.9; p value 0.09, social domain 25.3±7.6 versus 26.1±4.5; p value 0.47).

Similarly, no significant difference was seen in any domain between pulmonary tuberculosis and extra-pulmonary tuberculosis, in physical domain (28.0±10.7 versus 31.7±4.0, p value 0.19), mental domain (25.2±9.7 versus 30.3±3.3, p value 0.053) or social domain (23.8±8.9 versus 27.3±3.0, p value 0.15).

DISCUSSION

With the continuing focus on efficient methods of early and effective diagnosis in drug- resistant tuberculosis and newer better drug regimens, much of the focus of management is limited to traditional microbiological and clinical parameters. As a result, focus has seldom been dedicated to the quality of life of these patients or what reforms could be done to improve the same.

Be it the social stigma associated with disease, or the compliance to the treatment regimen for long durations along with multiple injections, health care visits or the various side-effects of the second-line or third line agents, the life of drug-resistant tuberculosis suffers from multiple reasons that could contribute to poor quality of life. In this study, an attempt has been made to assess the quality of life of patients suffering from MDR and XDR-TB with adverse drug reactions.

In our study, 120 patients with MDR and XDR-TB were enrolled, who had experienced or detected to have adverse drug reaction and their QOL scores calculated in three domains.

The quality of life in MDR-TB and XDR- TB was found to be poor, in our study, with the mean score in physical domain being 25.1, mental and social domains being 39.5 each. This was in line with studies done by Ahmad et al and Tembeka, where QOL scores were low, in all three-mental health component, social functioning and physical component summary.[13,14] A systematic review has reported that the HR-QoL of MDR-TB patients was considerably lower than DS-TB patients, especially in the first six months of therapy.[15,16] Further, Sharma et al showed the comparison of QOL scores of pulmonary TB and MDR TB, which showed a generalized worsening in MDR-TB patients, especially in the psychological domain.[11]

In our study, the physical domain score was most affected, as compared to a study in western India which showed psychological and physical health domains were the most affected among patients receiving treatment for MDR TB, and social domain worsening was a result of loss of work and isolation faced as a result of disease.[17]

DR-TB had a substantial impact on patients' quality of life, and the presence of ADR during the early months on treatment causes the QOL scores to drop even further. A study done in South Africa reported SF-36 domain scores to be lower in those who reported an ADR compared to those who did not, and both were lower than healthy adults. Compared to those who did not report an ADR, patients who reported ADRs were more likely to have a low mental domain score (aRR 2.24 95% CI 1.53-3.27) and physical domain scores (aRR 1.52 95% CI 1.07-2.18) summary score. HRQoL was lower among those on DR-TB treatment for 6 months or less.[14]

Further, QOL scores in all 3 domains remained unaffected by the site of tuberculosis (EPTB or PTB), the gender, age group or past history of TB. This was against what was anticipated by the studies by Salehitali and Jaber et al, where QOL was different based on gender and age group of the patients.[13,18]

Considering the profound impact that drug-resistant tuberculosis with adverse drug reactions has on the quality of life of patients, it is of utmost importance to detect and treat these drug reactions during the course of therapy. Treatment along with physical rehabilitation measures, social incentives and counselling for patient and family during the long duration of therapy should be emphasised, such that the long antitubercular course seems more beneficial than burden to the patient and family.

However, the study had a few limitations- the number of drug reactions and their timing of occurrence was not taken into consideration while calculating the quality of life, which may have affected the outcome. Further, this being a single centre study is likely to show a clearer picture with larger number of subjects in a multicentre study.

CONCLUSION

Drug-resistant tuberculosis along with its associated adverse drug reactions renders the quality of life in all domains to be poor. However, early detection and effective treatment of such adverse effects in systematic manner along with physical rehabilitation measures and counselling support groups, can do wonders in improving the life of these patients, such that they can contribute more to society.

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