Effect of DOTS on quality of life among tuberculosis patients: A follow-up study in a health district of Kolkata

Sitikantha Banerjee¹, Kajari Bandypadhyay¹, Pranita Taraphdar², Aparajita Dasgupta³

¹Department of Community Medicine, All India Institute of Medical Sciences, Nagpur, Maharashtra. ²Department of Community Medicine, NRS Medical College, ³Department of Preventive and Social Medicine, All India Institute of Hygiene and Public Health, Kolkata, West Bengal, India

ABSTRACT

Context and Aims: This study was carried out to assess quality of life (QoL) of tuberculosis patients receiving treatment from DOTS centres, to find out its change with treatment, and to ascertain its determinants. Materials and Methods: An institution based follow-up study was conducted in Bagbazar Urban Health District (UHD), Kolkata where all the tuberculosis patients registered within 1st 4 months of data collection were followed up for their current course of treatment. Quality of Life (QoL) was assessed using SF36v2 questionnaire at the start of treatment and after continuation phase (CP) (within 14 days). Statistical Analysis Used: General Linear Model was used to assess the predictors of change of QoL with treatment. Results: 61.4% and 16.4% patients were at the risk of depression at the start and end of their TB treatment respectively. Patient’s per-capita monthly Income (PCI) and current smoking status interacted with time to predict trends in the Physical component scores. Similarly, PCI and educational status interacted with time to predict trends in the mental component scores. PCI and unemployment were found to be predictor of differences of Physical and mental component scores (between subject effects) respectively. Conclusions: QoL assessment in different stages of treatment should be incorporated in the ongoing RNTCP to make the programme more client-oriented and comprehensive, and to provide social support to those who need it most. Directly observed treatment should be supplemented with economic support, de-addiction campaign and Inter-personal counselling by the DOTS providers.

Keywords: Directly Observed Therapy Short Course, general linear model, quality of life, Revised National Tuberculosis Control Programme

Introduction

Tuberculosis, a chronic communicable bacterial disease, has varied clinical profile, chemotherapeutic responses, and social implications. Despite being curable and having structured treatment regimen for many years, it continues to be one of the most important public health problems worldwide. In 2017, there were an estimated 10 million TB cases and 1.3 million death worldwide."³"¹ Tuberculosis has become a menace in India, accounting for about one-fourth of the global TB burden, that is, 2.74 million new cases annually."³"¹ In India, more than 6000 people develop tuberculosis every day and 2 deaths occur because of it in every 5 min."³"¹ This is the scenario despite the ongoing robust program, Revised National Tuberculosis Control Programme (RNTCP), for the prevention and control of the disease."³"¹ Government of India launched RNTCP in 1993, where the World Health Organization (WHO) recommended that

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Directly Observed Therapy Short Course (DOTS) strategy was implemented. Good-quality diagnosis by sputum smear microscopy assures uninterrupted supply of high-quality drugs and directly observed treatment that were the key components of DOTS. Though RNTCP has consistently been progressing to achieve global benchmarks of case detection and treatment success, it mainly focuses on clinical and microbiological cure, and unfortunately, little attention has been paid to the impact of the burden of illness and its therapy on their psychological, emotional, and social well-being.

For comprehensive evaluation of health status, it is essential to consider the overall impact of TB on health and patient's well-being which can be assessed by quality of life (QoL). “Health-related quality of life”, as proposed by Kaplan and Bush, constitutes a complex, multidimensional construct, representing the functional effects of an illness and its therapy on a patient, as perceived by them. So, rationale of studying QoL among tuberculosis patients is thinking beyond clinical and microbiological cure. Acceptance and success of RNTCP will improve if effect of the disease on different health domains is taken into account and strategies are adopted to make the program more client-oriented and comprehensive. With this background, the study was conducted to assess the QoL of tuberculosis patients receiving treatment from the DOTS centers of an urban health district (UHD) in Kolkata, to find out the change of QoL with treatment and to ascertain its determinants.

Materials and Methods

Study setting
An institution-based prospective study of longitudinal design was conducted in all the 10 DOTS centers of Bagbazar UHD, Kolkata. RNTCP is implemented in Kolkata through 10 UHDS (operational units of RNTCP for Kolkata city), and Bagbazar UHD is one of them. It is located in the northern part of Kolkata, covering 432,000 people. There are 4 designated microscopic centers (DMCs), 1 drug-sensitivity testing center, and 10 DOTS centers under Bagbazar UHD.

Patients complaining of chest symptomatics from different public and private sector are referred to the DMCs for sputum microscopy. After diagnosis of sputum-positive pulmonary tuberculosis in DMCs, patients are referred to the DOTS centers nearest to their home. Sputum negative or extrapulmonary tuberculosis are directly referred to DOTS centers after diagnosis, where they get supervised antitubercular drugs.

Study population
This was a follow-up study, which continued for a period of 2 years. All adult (≥18 years) new (Cat-I) and previously treated (Cat-II) tuberculosis patients, registered in the DOTS centers of Bagbazar UHD and started DOTS between May 2015 and August 2015, were included in the study. This cohort of patients was followed up until they completed their current course of DOTS treatment. Multidrug resistant (MDR) or extensively drug resistant (XDR) tuberculosis patients and unwilling patients were excluded from the study. Study variables include background information such as demographic, socioeconomic, and behavioral characteristics, treatment-related information such as category of disease, associated comorbidity, and treatment outcome. The outcome variable was QoL.

Study tools and techniques
A schedule or interviewer administered questionnaire was prepared, according to the objectives and after discussion with specialists of All India Institute of Hygiene and Public Health, Kolkata. Several generic and disease-specific instruments are now available for quantifying QoL, but till date, no validated questionnaire is available specific for tuberculosis. In this study, for assessment of QoL, Short Form 36 (SF36) v2 questionnaire was adapted. This is a widely used, generic health-status measure comprising 36 questions, providing scores on 2 broad areas of subjective well-being – physical and mental health (represented by component summary scores). The standard norm-based scoring (NBS) of summary components was obtained using the standard scoring algorithms. The scores on component summary measures (Physical QoL score was assessed by Physical Component Summary (PCS) and Mental QoL by Mental Component Summary (MCS)), ranging from 47 to 53, were considered equivalent to the general population norms. Whenever a group mean scale score is below 47, health status is considered as below the average of general population. An individual having MCS score ≤42 NBS point was considered to be at the risk of depression. The questionnaire was translated to Bengali language and then translated back again in English by separate persons. Then, it was pretested on 20 tuberculosis patients under DOTS treatment in separate UHD of Kolkata (Tangra UHD). Emphasis was given on comprehensibility of the language and social acceptance of items. Necessary modifications were done in terms of replacing some words with locally relevant words. Face validity of all items and content validity of all the domains were ascertained by two reviewers, who were experts in this field. Internal consistency of individual domains was calculated (Chronbach’s alpha ranges from 0.65 to 0.73).

Study techniques include interview, review of records (DOTS treatment card, DOTS register), and prescriptions.

Method of data collection

Baseline data collection
All patients from 10 DOTS centers, fulfilling the inclusion criteria, were approached within 14 days of start of treatment at the DOTS centers when they come to take the medication. Patients unable to come to DOTS centers were approached to their home. After explaining the importance of this study, informed written consent was obtained. Patient's treatment card, Out-patient Department (OPD) ticket, doctor's prescriptions, and investigation reports in relation to current illness were reviewed.
Follow-up

The patients were approached within 14 days of completion of continuation phase (CP) at the DOTS centers (in case where MDR/treatment failure was diagnosed before completion of treatment, the patient was interviewed within 14 days of diagnosis of MDR/treatment failure). In case the patient was not available at DOTS centers, home visits of the patients were made for those patients. Throughout the study period, for the data collection, comfortable places were allotted in the DOTS centers.

Ethics

This research work was a part of postgraduate thesis (dissertation). Ethical clearance for the thesis work was obtained from institute ethics committee. The study was conducted after obtaining written permission from district tuberculosis officer, Bagbazar UHD.

Statistics

Data were analyzed using SPSS software, version 19.0 (Statistical Package for the Social Sciences Inc., Chicago, IL, USA). Changes of QoL with treatment were carried out by using paired t-test. General linear model (GLM) repeated measures ANOVA analysis was used to determine which independent variables were predictive of variability in the PCS and MCS over time.

Results

Total 140 tuberculosis patients had been included in the study. Background information revealed that participants from both sexes were almost equally distributed (male 50.7% vs. female 49.3%). Most of the participants were young (almost 45% belong to 18–27 years age group), currently married (46.4%), had literacy up to primary school completion (26.4%), and Muslim (57.9%). About 28.2% male and 15.9% female were illiterate. Majority of the male participants were manual laborer (53.4%) and female were homemakers (62.4%). Almost half of the participants belong to nuclear family. Majority belonged to Class III (35%) followed by Class IV (33.6%) socioeconomic status according to modified BG Prasad Classification. Use of smoking tobacco, smokeless tobacco, and alcohol were found out to be 31.4%, 25.7%, and 30.7% [Table 1].

Among the total 140 tuberculosis patients, majority (68.6%) were Cat-I (new) and the remaining were Cat-II (previously treated). About 60.7% were found to be suffering from pulmonary tuberculosis, and the remaining 39.3% had extrapulmonary tuberculosis. Associated comorbidities include diabetes (13.6%) and HIV (4.2%). Majority of the male participants were manual laborer (53.4%) and female were homemakers (62.4%) at baseline. Eight male participants were unemployed at the beginning of the study. Among the 62 participants who were earning before diagnosis of disease, 22 (35.5%) patients had lost their job and became unemployed any time during diagnosis and current treatment process.

Overall, 79.3% patients had favorable outcome, and out of them, 50 (37.5%) and 61 (43.6%) patients were diagnosed as “cured” and “treatment completed,” respectively. Out of the 29 patients with unfavorable outcome, 11 patients were converted to MDR, 12 failed to be converted to MDR, 2 were defaulted (lost to follow-up), and 4 patients died. So among 140 participants included in the study, 134 could be followed up.

QoL, assessed using SF36v2 questionnaire, was kept as continuous variable, maximum, and minimum attainable scores for each domain being 100 and 0, respectively. Total overall QoL score ranged from 5 to 86, with mean (SD) and median (IQR) of 42.42 (18.18) and 40.42 (28.54–55.49), respectively. At the initiation of treatment, mean physical, mental, and total summary score were 46.5, 37.6, and 43.1, respectively, which increased to 70.1, 65.9, and 69.6, respectively after CP [Figure 1]. The differences were found to be statistically significant (using paired t-test). But when the total study participants were stratified based on their treatment outcome, it was observed that improvement of total summary QoL score of patients with favorable treatment outcome increased significantly with treatment (P = 0.001), whereas the change was very little among patients with unfavorable treatment outcome, and it was not statistically significant (P = 0.19) [Table 2]. Moreover, it was observed that among patients with unfavorable treatment outcome, total summary score was below 47, that is, below the average for general population, both during the initiation of treatment and the completion of treatment [Table 2]. MCS score was found to be below 42 points in 61.4% and 16.4% of the patients at the start and end of their TB treatment, respectively, which implies that they are at a higher risk of depression at those stages.

GLM repeated measures ANOVA analysis was run to identify the variables predicting the variability in the PCS and mental QoL scores over time. Both within-subject and between-subject effects of variation of PCS and MCS were calculated after adjusting with the potential confounders. Variables with P ≤ 0.2 in bivariate analysis were included in final model. Smoking status,
presence of diabetes, and category of disease were included in the model considering their biological plausibility. Within-subject effect revealed that patient's per-capita income \( (F = 8.805, P = 0.004) \) and current smoking status \( (F = 4.031, P = 0.047) \) interacted with time to predict trends in the PCS. Similarly, per-capita monthly income \( (F = 8.159, P = 0.005) \) and educational status \( (F = 5.917, P = 0.016) \) interacted with time to predict trends in the Mental Component summary score (MCS) [Table 3]. In adjusted model, per-capita income \( (F = 5.836, P = 0.017) \) and unemployment \( (F = 4.017, P = 0.047) \) were found to be predictor of differences of PCS and MCS scores (between-subject effect), respectively [Table 4].
In the present study, patient's per-capita income interacts with time to predict the trend of both PCS and mental QoL scores. Differences in PCS and mental QoL scores (between-subject effect) were predicted by per-capita income and employment status, respectively. Many TB patients were unable to work due to the travel distance between DOTS centers and their workplace. Disease-induced worsening of their physical condition also contributed to their limited work capacity. Often family members need to get involved as caregivers leading to their loss of income through reducing their own work or by providing financial support to the patients. This may lead to financial and economic deterioration for TB patients. On the other hand, people with higher monthly income face low economic constraints. Consequently, they are expected to get better nutrition, leading to improvement in physical QoL as well as mental satisfaction leading to improvement of mental QoL. So, improvement of TB-related QoL at the end of treatment was much less among the poorer TB patients than their richer counterparts.

In a study among new smear-positive pulmonary TB patients at Malaysia, Atif et al. observed that monthly income along with smoking and TB-related symptoms at the start of the treatment were predictive of differences in the Mental QoL scores. In contrast, in this study, smoking was found to be interacting with time to predict the trend of physical health. Smoking is known to adversely affect the immune system, leading to higher bacillary loads, which can augment the severity of disease and adversely affect the improvement of physical health with treatment. The present study findings added weight to this argument. In a cohort study conducted at South Africa, it was observed that higher educational qualification had a significant positive effect on the mental QOL, which was not found in this study.

The main strength of this study was its longitudinal design. A recent systematic review identified only 17 published studies worldwide, and not a single one in this study setting, where QoL of tuberculosis patients was studied for the total duration of treatment. This study was conducted taking in account that research gap. Another strength was that all the 134 patients who were continuing treatment for the total course of treatment could be followed up that leads to minimum data loss.

The findings of our study need to be interpreted in the light of certain limitations. The study only included new (Cat-I) and previously treated (Cat-II) patients. Therefore, the study’s results could not be generalized for all types of TB patients. MDR and XDR patients could not be included in this study. Though social security, housing condition, level of depression, and some laboratory investigations (WBC count, Serum Alanine Aminotransferase (ALT)) have been considered as significant predictors of change in QoL, they have not been taken into account in this study.

**Conclusion**

Poor QoL among the patients at the start of treatment, and even at the end of treatment among patients with unfavorable
outcome, call upon urgent attention of care providers of all categories to address QoL at various stages of the treatment. This strategy will enable them to take timely actions for improving mental health, which is equally important as physical well-being of the patients. Till date, the treatment of TB solely concentrates on introduction of some drugs in patient’s body to kill the bacilli, but is it sufficient to take into account for the physical, mental, and social impact of the disease? The answer is “no.” Directly observed treatment should be supplemented with social and economic rehabilitation, smoking cessation activities, psychosocial support, and interpersonal counseling by the health-care providers. Such initiatives will make the program more client-oriented and comprehensive, and thus, the acceptance of RNTCP will be enhanced in long run.

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Conflicts of interest

There are no conflicts of interest.

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