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Assessment of Health-Related Quality of Life and Medication Adherence In Tuberculosis Patients

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ABSTRACT

Tuberculosis (TB) is an infectious disease caused by bacteria called Mycobacterium tuberculosis. The disease mainly affects lungs and causes pulmonary tuberculosis. It can also affect intestine, meninges, skin, bones and other tissues of the body. Although the drugs alone can cure TB, it still remains a major public health problem worldwide. The aim of the study was to assess the quality of life and medication adherence in TB patients. The Quality of life was assessed using SF-36 in patients receiving DOTS treatment in initial or continuous phase while the medication adherence was analyzed using Morisky Green Levine Scale. Subjects were also counselled about their disease during their first visit and a follow up was done after a month. A total of 152 subjects were enrolled in the study of which majority of the subjects had Pulmonary TB (55.26%). Diabetes was found to be the most common comorbidity followed by HTN. The average Physical Component Summary (PCS) and Mental component summary (MCS) were found to be 44.34 and 39.60 respectively. Females had a better quality of life scores compared to males. High adherence was seen in 32.24% of patients while 28.29% had low adherence. Follow up was done for 135 subjects. 15 subjects defaulted and 2 of them died. There was a significant increase in the QoL scores and medication adherence after one month. A significant association was found between the Physical functioning (p=0.001) and emotional wellbeing (p=0.01) with Duration of treatment indicating that subjects who had completed more than one month of their treatment had marked improvement in Physical functioning and emotional wellbeing scores.

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INTRODUCTION

Tuberculosis (TB) is a chronic infectious disease caused by Mycobacterium tuberculosis. It primarily affects the lungs but can affect other organ systems as well such as intestine, meninges, bones and joints, skin and other tissues of the body (Ernst *et al.*, 2007). According to the WHO Global Tuberculosis Report 2019, 10 million people developed TB disease in the year 2018 itself. About 1.7 billion people that is around 23% of the world population are estimated to have latent TB infection. India alone

accounts for about 27% of the world's annual incidence of TB making it the highest contributor of TB burden (Global tuberculosis report, 2019). The government has been making a lot of efforts by improving DOTS therapy, implementing standard diagnosis and treatment guidelines and providing free medications. But still the decrease in the TB incidence has been slow and mortality rates are high. Also, due to drug resistance TB has become a major public health concern. Both physical and mental distress is common in TB patients. While drugs alone can cure TB, living with this chronic disease can be debilitating. Health-related quality of life (HRQOL) of TB patients is important because it directly influences the outcomes of the treatment. Adherence is a key factor associated with the effectiveness of the treatment but is particularly critical for medications prescribed for chronic conditions. Medication adherence is a huge burden to the world's health care system, so it is necessary to know how much percentage of the patient adhere to the pharmacologic therapy and to aware the patient regarding the disease and medication (Jimmy and Jose, 2011).

MATERIALS AND METHODS

The study was conducted in outpatient wards of department of Chest and TB of 500 bedded teaching hospital. This was an observational study which was conducted for 6-month period. The subjects who were of age 18 years and above, those with confirmed diagnosis of tuberculosis by sputum test or X-ray or FNAC with or without co-morbidities, subjects with active /inactive TB taking anti TB medications and subjects who were willing to participate in the study and signed written informed consent were included. Lactating and pregnant women up to 12 weeks after partum and subjects with psychiatric disorders and those who were unable to answer the questions were excluded.

Data was collected from the selected subjects with the help of structured questionnaire. Subjects were also counselled about their disease during their first visit and a follow up was done after a month. Collected data were entered in Microsoft Excel and appropriate statistical analysis was done to evaluate the objectives of the study.

Study Tools

Data was collected using a self-designed data collection form, which contains details like demography, chief complaints, history of present illness, medication and medical history. WHO QOL SF-36 was used to assess the HRQOL. This scale consists of 8 multi item sections (vitality, physical functioning, bodily pain, general health, physical role functioning, emotional role functioning, social role functioning and mental health). The lower the score the more is the disability. Morisky Green Levine Scale is a self-reported scale comprises of four questions with yes/no response that assesses the patient's medication taking behavior. A yes response to a question is given zero score and no response is given one. The scoring ranges from 0-4 and the three levels of medication non-adherence based on this score is high, moderate and low adherence with 0, 1-2 and 3-4 points respectively.

Ethical Clearance

The study was approved by the Institutional Ethical Committee of ESIC MC-PGMSR & Model Hospital, Rajajinagar.

Statistical Analysis

Statistical analysis was performed using the Chi-Square Test to find the association between quality of life and duration of treatment. Mann Whitney U test was used to find the association between quality of life with Type of TB and Treatment Phase. The data collected for this study was analyzed statistically by computing proportion for all qualitative data and mean, standard deviation, median, interquartile range for quantitative data. The results were expressed in terms of 95% of confidence interval. The results were also presented in the form of frequency format and diagrammatic representation whenever necessary. For inferential statistics the relationship between quality of life and variables (treatment stage, duration and type of TB), the results were considered statistically significant whenever P is less than 0.05.

RESULTS AND DISCUSSION
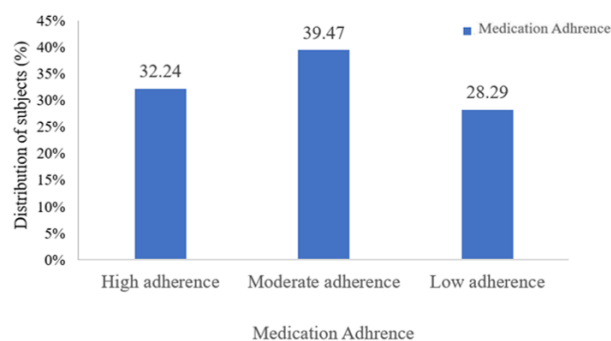
Figure 1: Medication Adherence

This study included a total of 152 subjects whose average age was found to be 41.37 ± 14.72 years. Age group 35-44 years were in majority accounting for 26.97% of the total population and age group 55-64 years were minimal in number i.e. 6.57%.

Table 1: Type of TB and mean scores of SF-36

Type of TB	Physical Functioning	RLPH*	PAIN	Health Changes	Social Functioning	RLEP*	Energy	Emotional well-being
Pulmonary	56.36	27.97	44.82	53.27	51.22	25.35	38.21	39.27
Extra pulmonary	54.63	28.83	44.47	49.44	51.89	26.56	40.69	39.28
P-value	0.181	0.421	0.91	0.078	0.25	0.673	0.031*	0.704

*RLPH= Role Limitation due to Physical Health,RLEP= Role Limitations due to Emotional Problems
*For inferential statistics the relationship between quality of life and variables, the results were considered statistically significant whenever P is less than 0.05

Table 2: Duration of TB and mean scores of SF-36

| Duration of Treatment	Physical Functioning	RLPH*	PAIN	Health Changes	Social Functioning	RLEP*	Energy	Emotional well-being
<1 month	54.05	27.33	48.85	49.52	51.87	24	39.68	38.57
>1 month	57.6	28.13	47.6	49.65	51.98	27.07	45.8	42.88
P-value	0.001*	0.51	0.27	0.92	0.51	0.28	0.12	0.01*

*RLPH= Role Limitation due to Physical Health,RLEP= Role Limitations due to Emotional Problems
*Forinferential statistics the relationship between quality of life and variables,the results were considered statistically significant whenever P is less than0.05

Table 3: Comparison of Gender Differences in Quality of Life Scores

Gender	Physical Component Summary				
	Physical Functioning	RLPH	Pain	Health Changes	Mean
Male	52.97	25.57	42.99	48.76	42.57
Female	57.94	35.29	47.401	50.78	47.85
Gender	Mental Component Summary				
	Social Functioning	RLEP	Energy	Emotional Well-being	Mean
Male	52	25.57	39.35	38.44	38.84
Female	51.67	28.52	43.33	40.94	41.11

RLPH=Role Limitation due to Physical Health, RLEP= Role Limitations due to Emotional Problems
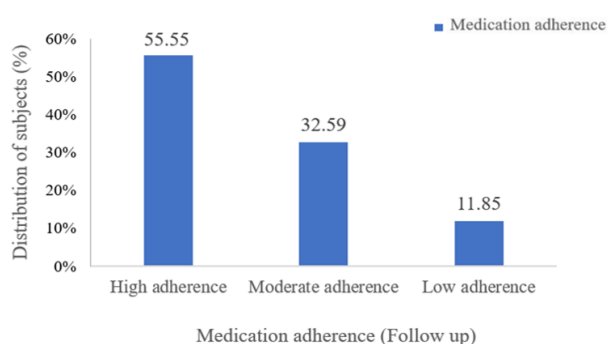
Figure 2: Medication Adherence (Follow up)

Out of 152 subjects in the study 101 were male (66.45%) and 51 were female (33.55%). Habits such as Smoking and Alcoholism was seen in 56 subjects i.e. 36.84%. The data revealed that 31 subjects (20.39%) were found to be illiterate. The highest number of patients received Pre-university College education (33.55%) followed by high school education (24.34%) and graduate (21.17%). The most commonly seen co-morbidity was T2DM with 32.23% followed by HTN.

Among the 152 subjects, 131 (86.18%) were new cases, 20 (13.15%) were relapsed cases and 1 (0.66%) were subjects who had a history of treatment failure. About 82 subjects (55.26%) suffered from Pulmonary TB while 70 (44.74%) had Extra-

Table 4: Mean PCS and MCS scores during first visit and follow-up

PCS	First visit		Follow-up		Mean difference
	Mean	SD	Mean	SD	
Physical Functioning	58	22	73.6	17.16	15.6
Role limitation due to physical health	30.44	39.57	83.45	15.03	53.01
Pain	45.18	18.56	75.25	14.84	30.07
Health Changes	47.43	30.18	72.76	19.97	25.33
MCS	First visit		Follow-up		Mean difference
	Mean	SD	Mean	SD	
Social Functioning	52.58	15.71	76.73	18.33	52.58
Role limitation due to emotional problems	28.41	39.22	78.08	26.69	28.41
Energy	40.41	17.15	76.66	13.98	40.41
Emotional wellbeing	40.35	16.03	71.74	12.89	40.35

pulmonary TB. Out of which 92.76% were in initial phase of the treatment while 7.24% were in continuous phase. All the new subjects received an internationally accepted first line treatment regimen. The initial phase consisted of 2 months of Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), and Ethambutol (E). The continuation phase consists of three drugs i.e. Isoniazid, Rifampicin and Ethambutol given for at least 4 months. Streptomycin (S) was used as a first line TB medicine in patients who have been previously treated for TB. Dose was given according to the body weight depending on the standard weight bands.

The majority of the subjects belonged to the initial phase due to which 134 (88.16%) patients were prescribed with HERZ while 9 (6.58%) were on RHE, 7 (4.61%) on HERZS and 1 (0.66%) on RH. About 82.89% of the study population were in their first month of treatment when they were first interviewed. Out of the 152 subjects interviewed, 6.57% had been treated for more than 6 months, 4.60% had been treated for 2 months, 1.31% for 3 months, 0.65% for 4 months, 0.65% for 5 months and 3.68% for 6 months.

Analysis of HRQOL in the study population using SF-36 revealed the average physical functioning (PF), role limitation due to physical health (RLPH), pain and health changes to be 54.63±21.43, 28.83±37.05, 44.47±17.99 and 49.44±29.55 respectively. Analysis of mental component revealed the average of social functioning, role limitation due to emotional problems (RLEP), energy and emotional well-being to be 51.89±15.20, 26.56±38.12, 40.69±16.86 and 39.28±15.75 respectively. Social functioning had the highest average i.e. 51.89 and role limitation due to emotional problems had the least average i.e. 26.56.

The total average of four dimensions each under PCS and MCS was found to be 44.34 and 39.6 respectively and the overall average of both PCS and MCS was 41.97. Mann Whitney U test was performed between the Type of TB and all the 8 domains. The test indicated that the decrease in HRQOL in the Energy domain was greater for subjects with Pulmonary TB, p=0.031, as shown in Table 1.

The test results also showed that Type of TB had no significant effect on rest of the domain. Chi-square test was performed to find the association between the duration of treatment and HRQOL. A significant association was found between the Physical functioning and Duration of treatment (p=0.001) indicating that subjects who had completed more than one month of their treatment had marked improvement in Physical functioning scores. Similarly, there was found to be a significant association between the emotional well-being and duration of treatment (p=0.01) indicating that subjects who had completed more than one month of their treatment had marked improvement in emotional well-being scores, as shown in Table 2.

Comparison of gender differences in quality of life scores revealed that in all the eight domains of the physical component summary and mental component summary, the average QOL scores in females was found to be more than that of males. The average scores of each domain is mentioned in Table 3. Out of 152 subjects enrolled in the study, 15 subjects defaulted and 2 of them died. The mean SF-36 scores

of all the 135 patients during their first visit and follow up are mentioned in Table 4. There was a significant increase in the QOL scores after one month in all the 8 domains.

Among the 152 subjects, majority of the subjects i.e. 39.47% had moderate adherence and 28.29% had low adherence to the TB medications, as shown in Figure 1.

A total of 135 subjects were interviewed again after a month and the follow-up results of medication adherence are shown in Figure 2. About 55.55% had high adherence, 32.59% had moderate adherence and 11.85% had low adherence to TB medication.

The social behavior with regard to alcohol consumption and smoking in the present study reveals that 36.84% were indulged in habits such as smoking and alcoholism. Contrary to this is a study conducted by Hilka TK et al., which reveals that majority of their subjects were prone to smoking and alcoholism (Kastien-Hilka *et al.*, 2017). Diabetes was found to be the most common comorbid condition with about 32.28% of patients suffering from it followed by hypertension with 11.18%. The study by Hilka TK et al., also had diabetes as the most common comorbid condition (48.1%). The mean age of the subjects was found to be 41.37 ± 14.72 years. Similar to this, a study conducted by Mamani M et al., the mean age was found to be 55 ± 20 years (Mamani *et al.*, 2014).

The average PCS and MCS scores were 44.34 and 39.6 indicating an average HRQOL as 41.97 when the patients were first interviewed. The study showed that the subjects had difficulty in performing vigorous activities like running, lifting heavy objects, climbing several flights of the stairs etc. TB can have an impact on social functioning due to social stigma that is associated with it. This study showed that the lowest MCS score was seen in role limitation due to emotional problems. In a similar study conducted by Masoon S et al., the average PCS and MCS scores were found to be 31.67 and 45.8 respectively indicating an overall average HRQOL as 39.18 (Masoon *et al.*, 2012).

Comparison of the QOL scores in both males and females in the study revealed that males had slightly lower scores than females in all the 8 domains with RLPH being the lowest (25.57 ± 17.15 for males, 35.29 ± 31.5 for females) but there was no statistically significant differences in the QOL among the study subjects based on gender. In another study by Jankowska BK et al., the analysis of QOL was carried out and the respondents gave the lowest assessment to their QOL in physical domain (12.9 ± 30 by males, 12.4 ± 31 by females). Men had obtained slightly lower rating in QOL in each domain but it was not statistically significant (Jankowska-Polanska *et al.*, 2015).

Comparison of the mean SF-36 scores of all the 135 patients during their first visit and follow up was done and significant increase in the QOL scores after one month in all the 8 domains was found. The mean PCS scores during their first visit and at the follow up was 44.34 and 76.26 respectively. Similarly, the mean MCS scores during the first visit and follow up was found to be 39.6 and 76.91 respectively. A similar study was conducted by Malik Met al., and the mean PCS scores at the start of the treatment was found to be 41.9 ± 5.1 and during follow up was 46.0 ± 6.9. The mean MCS scores at the start of the treatment was 39.9 ± 7.3 and during follow up was 46.8 ± 7.8 (Malik *et al.*, 2018). Assessment of medication adherence revealed that 32.24% were having high adherence, 39.47% were having moderate adherence and 28.29% were having low adherence during their first interview. Patients were counselled regarding their disease condition and medication adherence and follow up was done after a month via personal interview or telephonic conversation. According to another study conducted by Bagchi S et al., out of 588 subjects, 81% were adherent to TB medications and 16% were non-adherent (Bagchi *et al.*, 2010). Another study conducted by Geetha K et al., had a study population of 73 patients which revealed that 56% were highly adherent, 39% were moderately adherent and 5% of the patients had low adherence (Geetha *et al.*, 2016).

In a country like India which has dual burden of both TB and Diabetes, it is necessary to manage both the diseases simultaneously. Proper DM screening in all the DOTS Centers and PHCs could be made mandatory along with proper patient counselling (Volmink and Garner, 2009).

CONCLUSIONS

The study found that the HRQoL in TB patients was significantly low and the most affected domain in majority of the patients was role limitation due to emotional problems. TB can have a negative impact on social functioning due to the social stigma associated with it. Majority of the subjects had moderate adherence. Assessing medication adherence along with patient counselling can improve responses to the treatment and improve the physical and mental functioning.

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