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Case Control Study



Effectiveness of treatment on quality of life among tuberculosis patients- A case-control study

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ABSTRACT:

Introduction: Tuberculosis (TB) is a prominent infection prevalent worldwide. Although there are effective treatment modalities, it does not address the issues that TB patients experience. In addition to the physical symptoms, people frequently see a reduction in their general quality of life (QoL). The SF-36 instrument was used to compare QoL of tuberculosis patients at the start and end of therapy and compare with non-TB controls. Methods: The casecontrol study was carried out in the Department of General Medicine, at SRIHER in Chennai, India. Tuberculosis patients (n=28) and non-tuberculous patients (controls) (n=28) were recruited. The SF-36 questionnaire (eight categories) was administered to evaluate QoL. Ethics approval and informed consent were obtained. SPSS software (version 16) was used and p-value ≤ 0.05 was considered significant. Results: Total QoL score of TB patients at the start of treatment (49.5 ± 29.8) was lower than that of non-TB controls (77.8 ± 27.3) with p<0.001. HR-QoL score of TB patients at start of treatment was compared with the end of treatment (p<0.001). At the end of treatment of cases, there was no significant difference in the scores (p<0.76) with non-TB controls. Conclusion: Patients with TB had a substantially worse healthrelated QoL; deficiencies were seen in every SF-36 questionnaire domain. HR-QoL improved by DOTS treatment, which helped it approach the levels of non-TB controls. Counselling TB patients on the advantages of DOTS therapy and highlighting its contribution to enhancing their QoL is crucial.

<u>KEYWORDS</u>: attitude, diagnosis, lung tuberculosis, quality of life, treatment.

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1. INTRODUCTION

Tuberculosis (TB) remains a significant worldwide infection, contributing significantly to illness and death. In 2017, out of 10 million TB cases, 1.6 million cases resulted in death. Additionally, about onequarter of the global population carries a latent TB infection, increasing their risk of developing active disease later. [1] Current TB control efforts primarily focus on achieving microbiological cure, using it as the key measure of treatment success. While this is essential for public health, it does not fully address the broader challenges faced by TB patients. [2] Beyond the physical symptoms, patients also undergo a decreased effect in quality of life (QoL), yet their perspectives on the disease and its effects remain largely unexplored. [2] The 36-item short-form (SF-36) has been utilized to assess the health status in health and disease. [3] Using the SF-36 tool, QoL was compared at the initiation with the completion of treatment in tuberculosis patients.

2. METHODS

Selection and Description of Participants:

The prospective case-control study was carried out in the Department of General Medicine, at a tertiary care hospital in the southern region of India.

Study Participants

Cases: One method for treating TB is called DOTS (Directly Observed Treatment, Short-course), which makes sure patients take their drugs as directed. Individuals aged 18 years and older (n=28) diagnosed with sputum positive pulmonary TB and were registered for DOTS.

Controls: Non-tuberculous individuals from the same communities as the TB patients were selected as controls. Around 28 controls were enrolled.

Technical Information:

Study Tool - QoL questionnaire - 36-item Short Form Survey (SF-36):

The study participants were subjected to SF-36 to measure quality of life (QoL). The instrument evaluates eight different aspects of health: physical and social functioning, energy, role limitations, somatic pain, general health perceptions, and mental well-being. The results are displayed on a 0–100 scale for each category, and each item is scored in accordance with a defined procedure. A more positive view of one's own health is reflected in higher ratings.

Data Collection Procedure:

The research was carried out from January to December of 2023. After gaining their agreement, TB patients who were enrolled in the DOTS program were added to the trial. The study included 28 non-TB controls and patients with sputum-positive PTB, either cavitatory or non-cavitatory. An overview of the questionnaire's items and replies was provided to the study participants prior to the questionnaire's introduction. All recruited individuals, both controls and those starting treatment for tuberculosis, were given the SF-36 questionnaire. At the end of treatment, the cases were given the same questionnaire to reevaluate their quality of life. The answers were tallied and examined.

Ethics:

The Institutional Ethics Committee gave its approval for the study to be carried out (IEC/21/UN/163/43). The methods used were compliant with the Helsinki

Declaration of 1975, as amended in 2000, and the institutional ethics committee on human experimentation's ethical guidelines. Prior to their enrolment in the trial, all individuals provided written informed consent.

Statistics:

Categorical data were presented as frequency and compared by Fisher Exact test. Continuous variables were presented as mean \pm standard deviation and was compared by student 't' test. P-value was deemed statistically significant if it was less than 0.05. Software SPSS version 16.0 was used.

3. RESULTS

There were 56 patients, 28 in each group. With ages ranging from 19 to 86, the mean age of TB patients was 49.6 ± 18.9 years, whereas it was 50.2 ± 14.6 years in controls with p=0.89. The distribution of genders and marital status was comparable in both groups. Approximately 95% of the individuals in both groups were men. (Table 1)

Among the literary status, in the TB-case group most of them were either illiterate or studied till primary education alone. Whereas among the control group, most of them were in secondary or higher-secondary level of education and it was statistically significant (p=0.008). Among the TB patients, 35.7% were unemployed, compared to 14.3% in the non-TB control group, (p=0.12). Socio-economic status was classified as per the Kuppuswamy scale updated for the year 2024. [4] Additionally, income levels, socio-economic status and dietary patterns did not vary between the groups (p=0.99). (Table 1)

Table1: Demographic profile of the study participants

Parameter		ТВ	Control	p-value
		patient	group	
		s (n=28)	(n=28)	
Age (years)#		49.6 ±	50.2 ±	0.89
		18.9	14.6	
Sex	Male	27	26	0.99
n (%)		(96.4)	(92.8)	
	Female	1 (3.6)	2 (7.2)	
Marital	Married	26	27	0.99
Status		(92.8)	(96.4)	
n (%)	Unmarried	2 (7.2)	1 (3.6)	
Employmen	Employed	18	24	0.12
t status		(64.2)	(85.71)	
n (%)	Unemploye	10	4	
	d	(35.7)	(14.28)	
Literacy	Illiterate	8 (28.5)	1 (3.57)	0.008*
status	Primary	9 (32.1)	3	*
n (%)			(10.71)	
	Secondary	5 (17.8)	9	
			(32.14)	
	Higher	4 (14.3)	10	
	Secondary		(35.71)	
	Graduate	3 (10.7)	5	
			(17.85)	
Socio-	Higher Class	4 (14.3)	3 (10.7)	0.99
economic	(1 & 11)			
status	Lower Class	24	25	
n (%)	(III - V)	(85.7)	(89.3)	
Urban/rural	Urban	25	26	0.99
n (%)		(89.2)	(92.8)	
	Rural	3 (10.8)	2 (7.2)	
Dietary	Vegetarian	2 (7.2)	3 (10.7)	0.99
pattern	Non-	26	25	
n (%)	Vegetarian	(92.8)	(89.3)	

expressed as mean \pm SD; compared using Student 't' test. Other variables expressed as frequency; compared using Fisher exact test. p-value \leq 0.05 was considered statistically significant. **: statistically highly significant

The health-related quality of life (HR-QoL) of TB patients and non-TB controls was assessed using the SF-36 questionnaire. [5] The scores of TB patients and non-TB controls at the start of DOTS treatment are shown in Table 2.

Table 2: SF-36 questionnaire items in TB cases (initiation- and completion of treatment) and non-TB Controls

SI	SF-36 items	Cases (n=28)		Non-TB	Comparison between		
No		Initiation of	Completion of	Control	treatment	treatment	treatment
		treatment	treatment	(n=28)	initiation &	initiation &	completion &
					control # (p-	completion	control
					value)	\$ (p-value)	# (p-value)
1	Physical functionality	55.3±24.2	86.9±20.4	87.5±16.8	<0.001**	<0.001**	0.90
2	Role limitation due to	50.4±38.4	87.1±25.2	85.2±29.1	<0.001**	<0.001**	0.79
	Physical Health						
3	Role limitation due to	49.6±40.1	88.8±22.6	86.5±29.2	<0.001**	<0.001**	0.74
	emotional health						
4	Energy / Fatigue	41.2±24.6	73.1±17.2	69.6±29.2	<0.001**	<0.001**	0.58
5	Emotional Well Being	45.4±24.1	73.5±16.8	72.2±26.4	<0.001**	<0.001**	0.82
	(Mental Health)						
6	Social Functioning	51.1±24.8	79.2±20.1	78.1±28.6	<0.001**	<0.001**	0.86
7	Body Pain	60.2±30.3	84.6±19.6	75.3±30.9	<0.001**	<0.001**	0.18
8	General Health	45.5±23.9	72.8±20.3	72.4±26.2	<0.001**	<0.001**	0.94
9	Total Score (HR-QoL)	49.5±29.8	79.8±21.4	77.8±27.3	<0.001**	<0.001**	0.76

Expressed as mean \pm SD. #: compared by unpaired student 't' test, \$: compared by paired student 't' test, p-value ≤ 0.05 was considered statistically significant. **: statistically highly significant

The results showed that total HR-QoL score in TB patients at the start of treatment (49.5 \pm 29.8) was lower than that of non-TB controls (77.8 \pm 27.3) with p<0.001. The total scores of TB patients at the beginning and end of the DOTS regimen revealed p<0.001 between the scores at the beginning of therapy (49.5 \pm 29.8) and scores at the end of the treatment (79.8 \pm 21.4). The scores were almost the same in TB patients (end of treatment) and non-TB controls (p<0.76). (Table 2)

In the case group, there were notable differences between the beginning and end of treatment for individual items like physical functionality, role limitation due to physical, mental and emotional health, energy, social functioning, body pain, and general health (p<0.001). All of the items in the questionnaire showed significant differences between TB cases (start of treatment) and non-TB controls (p<0.001). There were no statistically significant changes in the individual items of the questionnaire,

between the TB cases (end of treatment) and controls. (Table 2)

4. DISCUSSION

Health is more than just the absence of disease; it includes whole physical, mental, and social well-being. [6] According to this viewpoint, tuberculosis (TB), particularly when it is a chronic illness, has a variety of effects on people, affecting not just their physical health but also their social, psychological, and financial stability. [7] India's National Tuberculosis Elimination Programme (NTEP), formerly known as the Revised National Tuberculosis Control Programme (RNTCP), uses the DOTS technique to diagnose and treat tuberculosis. [8] In order to evaluate therapy response, the program mainly monitors bacteriological markers, concentrating on outcomes like cure rates, death, and treatment failure or default. [9] However, health-related quality of life (HR-QoL) will be adversely affected by a number of circumstances. Social and economic stigma are common among TB patients, which can cause them to feel alone and rejected by their communities and family. [10] In addition to the disease itself, TB treatment can have an impact on quality of life. The typical course of treatment is taking several drugs for at least six months, which may result in short-term negative effects even when they are beneficial. Furthermore, slum residents in both rural and urban regions may feel even more helpless and anxious if they are ignorant of tuberculosis and how to handle it. [11]

A complicated and multifaceted notion, quality of life (QoL) encompasses characteristics related to the physical, social, psychological, economic, and spiritual

domains. A person's cultural background, values, and life circumstances all influence it. [12] In contrast to clinical evaluations that concentrate on quantifiable symptoms, QoL takes into account individual experiences and preferences. Adult TB patients' quality of life (QoL) is lower than that of healthy people in the majority of domains, with physical functioning being the most severely impacted, according to several studies that have evaluated QoL in TB patients. [13] People with active TB frequently believe that their health is worse than that of people with latent or previously treated TB. [2] Self-reported HR-QoL is a useful instrument for determining the true effects of tuberculosis on patients.

Measuring the impact of a disease and its treatment on day-to-day functioning from the patient's point of view is necessary to objectively evaluate their quality of life. [14] A number of instruments, such as rating scales and questionnaires, have been created to evaluate self-reported quality of life in people with active tuberculosis. [2] While some of these tools concentrate on particular elements like physical health or psychological impact, others offer a more comprehensive assessment of total well-being. Since several of these evaluation instruments are generalpurpose, they can be used with people in good health as well as with people who have different medical issues. It is meant to be used in research, clinical practice, evaluations of health policies, and demographic surveys.

The Short Form 36 (SF-36) is frequently used to assess quality of life in TB research. [3] It also offers two total ratings, the Physical and Mental Component Scores, which provide a comprehensive assessment of

physical as well as psychological health. In the intensive period of directly observed treatment, HR-QoL is especially important for TB treatment adherence. In India, there aren't many community-based studies that use the SF-36 score to evaluate HR-QoL in TB patients. In a tertiary care hospital in South India, we used the SF-36 tool to compare their HR-QoL at the start and end of treatment with a non-TB control group. [15]

In the present study, the mean age of TB patients was 49.6 ± 18.9 years, while that of controls was 50.2 ± 14.6 years, with age ranging between 19-86 years. Both groups had similar gender distribution and marital status. In both the around 95% of them were males. Among the literary status, in the TB-case group most of them were either illiterate or studied till primary education alone. Whereas among the control group, most of them were in secondary or highersecondary level of education and it was significant (p=0.008). Around 35.7% were unemployed in cases, compared to 14.3% in the case group. Socio-economic status was classified as per the Kuppuswamy scale updated for the year 2024. [4] Income levels, socioeconomic status and dietary patterns did not vary between cases and controls. (Table 1)

Given that many patients also have concomitant diseases or socioeconomic challenges, it can be difficult to determine the degree to which TB contributes to QoL impairment. [2] Although QoL seems to be generally unaffected by age or gender, some research indicates that becoming older has a detrimental effect on QoL, while other studies show that women have lower QoL. [16] It's interesting to note that women have higher QoL scores in both the

psychological and physical domains, according to one Indian study. [17] This could be a sign of greater coping mechanisms. Furthermore, there may be a correlation between increased QoL impairment and lower socioeconomic position and education levels. [18] The most notable declines in QoL typically occur in patients going through retreatment or relapsing. [19]

The results showed that TB patients' overall scores at the start of therapy (49.5 \pm 29.8) was lower than that of controls (77.8 \pm 27.3), p<0.001. Comparison of the scores of TB patients at the beginning of therapy (49.5 \pm 29.8) with end of the DOTS regimen (79.8 \pm 21.4) was significant p<0.001. Following the completion of the DOTS, the scores of TB patients was almost the same as that of non-TB controls. (Table 2)

There were prominent alterations in the outcomes and scores across both general and specialized QoL measures, with variations by country and patient profile. The included studies assessed the impact of sociodemographic, economical, psycho-social, coinfection or comorbidity, and adverse drug reaction variables on HR-QoL in TB patients. [14] The HR-QoL scores of the control group and TB patients after DOTS completion were examined in this study. The results demonstrated that there was no alteration between the control group and the TB patients' overall mean score following therapy completion. Despite having poorer HR-QoL at first, TB patients' ratings improved with anti-TB treatment, and by the end of six months, they were on par with the general population. The findings of Ramkumar S. et al. [15] were comparable to this. On the other hand, studies by Mamani M et al. and Othman GQ et al. found that a QoL of TB patient even after completing DOTS is lesser than the healthy individuals. [20, 21]

In the case group, there were notable differences between the beginning and end of treatment for individual items like physical functionality, role limitation due to physical, mental and emotional health, energy, social functioning, body pain, and general health (p<0.001). All of the SF-36 questionnaire items showed statistically significant differences between TB cases at the start of treatment and non-TB controls (p<0.001). There were no statistically significant changes between the TB cases and controls at the end of treatment for any of the SF-36 questionnaire's components. (Table 2)

At the initial assessment, the energy domain had the lowest mean score (41.2 ± 24.6), followed by emotional well-being (45.4 ± 24.1) and general health (45.5 ± 23.9). However, after completing TB treatment, QoL scores improved significantly, demonstrating the beneficial effects of TB treatment on overall wellbeing. (Table 2) Ramkumar S et al. and Awan MS et al reported QoL scores similar to the findings of this study. [15,22] In the present study, the scores for physical function domain among TB patients were 55.3 ± 24.2 during treatment and 86.9 ± 20.4 on completion of the treatment. Across all the measured domains showed significant improvement following treatment, as presented in Table 2. These results are consistent with previous research by Ramkumar S et al; [15] but, Othman et al. and Marra CA et al. studies observed lower scores than those reported here. This suggests that social stigma may contribute to variations in HR-QoL outcomes. [21, 23]

Comprehensive evaluation, identification of asymptomatic and co-occurring illnesses, precise diagnosis, prompt and appropriate treatment, referral for hospitalisation and surgery when necessary, and the capacity to monitor the patient and modify the treatment plan as necessary are all components of high-quality care. With growing recognition of health as a basic human right, there is increasing demand for improved HR-QoL. Understanding how diseases affect HR-QoL is essential for shaping healthcare policies. As a result, global efforts are focused on enhancing HR-QoL by strengthening primary healthcare services. [24]

5. LIMITATIONS

The sample size was small. It did not involve different stages of TB presentation. The presence co-morbid conditions should be included. It can be done in multiple centres to facilitate generalizability.

6. CONCLUSIONS

Compared to healthy people, patients with tuberculosis have a substantially worse health-related quality of life (HR-QoL), with deficiencies seen in every SF-36 questionnaire component. However, significant improvements were observed in every HR-QoL category following six months of medication therapy. After receiving effective TB therapy, HR-QoL scores of patients were on level with the population as a whole. Counseling TB patients on the advantages of DOTS therapy and highlighting its contribution to enhancing their quality of life is crucial going ahead. In order to improve treatment adherence and the general wellbeing of TB patients, efforts should also be made to inform and encourage family members to offer continuous support over the course of therapy.

Abbreviations

DOTS : Directly Observed Treatment, Short-course

HR-QoL : health-related quality of life

NTEP : National Tuberculosis Elimination Programme

QoL : quality of life

RNTCP : Revised National Tuberculosis Control Programme

SF-36 : 36-item short-form survey

SPSS : Statistical Package for Social Sciences

SRIHER: Sri Ramachandra Institute of Higher Education and

Research

TB: tuberculosis

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