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QUASI-EXPERIMENTAL STUDY OF THE EFFECT OF PATIENT COUNSELLING ON QUALITY OF LIFE AMONG TUBERCULOSIS PATIENTS

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ABSTRACT: Objectives: Tuberculosis (TB) remains one of the most substantial infectious causes of death in the world. Studies focusing on the quality of life (QOL) among TB patients are limited and the effect of counselling on patients QOL has not been well-studied. The aim of this study was to assess the effect of patient counselling on QOL among patients with Tuberculosis. **Methods:** A quasi-experimental study was conducted over 6 months at a tertiary care hospital after permission from the Institutional Ethics Committee. Tuberculosis patients between 18 and 65 years and were taking anti-tubercular therapy were included. Their physical component scoring (PCS) and mental component scoring (MCS) were assessed using SF-12®questionnaire. Counselling was provided to all the patients and PCS and MCS were assessed again after 14 days. **Results:** A total of 109 patients were taken for the study. There was an improvement in physical and mental status of TB patients. **Conclusion:** Improved physical and mental status implies the positive impact of patient counselling.

INTRODUCTION: Tuberculosis (TB) is one of the oldest infections known to affect humans and in spite of the new treatment strategies and observations; it remains one of the major causes of death in the world. It is estimated that about one third of the world population has *Mycobacterium tuberculosis* infection [1]. In 2010, there were 8.8 million new cases and 1.1 million deaths caused by TB in developing and industrialized countries [2].

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The World Health Organization (WHO) has developed the Global Plan to Stop TB by 2015 and 2050, which is defined as 50% reduction in the prevalence and mortality rates by 2015 and achieving towards less than 1 case per 1 million populations per year by 2050. It indicates that TB control should be more effective than it is currently [3]. Besides the burden of disease and mortality, the long duration of treatment and the combination of treatment lead to changes in life structure. In spite of the most focus directed towards mortality and incidence rate, the changes in health status parameters have not been well considered [4].

Progression from TB infection to overt TB disease occurs when the bacilli overcome the immune system defences and begin to multiply.

In primary TB disease (some 1 - 5% of cases), this occurs soon after the initial infection. However, in the majority of cases, a latent infection occurs with no obvious symptoms [5]. These dormant bacilli produce active tuberculosis in 5 - 10% of these latent cases, often many years after infection [6]. There are several methods for health status and disease management evaluation. The assessment of patient reported outcomes is a valuable method for this purpose and the quality of life (QOL) instruments have been developed to measure patients' outcome in clinical research and practice [7]. The QOL is defined as individuals' perception of their physical and mental health in their daily lives which cover physical, psychological, economic, spiritual, and social functioning [8]. It can reflect the impact of diseases and related morbidities on daily activities and functioning. This measurement is very much necessary among patients with chronic diseases whose mental and social well-being as well as pure physical health are affected by the disease and its related long-term treatment [4]. 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.

In addition, just the diagnosis of TB alone may lead to depression and anxiety or contribute to the worsening and persistence of disease symptoms, which follows with fear, frustration, and disappointment [9]. Furthermore, most TB patients have no knowledge of disease progress and treatment which can cause more anxiety and feelings of frustration and decreases the QOL among the patients [10]. Studies focusing on the QOL among TB patients are limited and no such investigation has been considering the fact that improvement in health-related QOL is an important factor for better response to treatment among TB patients, which may lead to better outcome in patients' mental health, infection surveillance and prevention programs.

MATERIALS AND METHODS: A quasi-experimental study without controls was carried out for a period of 6 months at a tertiary care hospital after getting approval from the Institutional Ethics Committee, School of Pharmaceutical Sciences, Vels University [IEC/DOPI/2015/06]. Sample size was calculated based on the target population that could show an estimated increase (Estimated 10% increase) from the baseline survey scores (200 patients) with a confidence interval of 95% with a 5% margin of error. The estimated sample size was found to be 109 and hence 109 patients were recruited in this study. Tuberculosis patients of both sexes, aged between 18 - 65 years and who are on anti-tubercular therapy were included. Children, pregnant women and mentally incompetent patients and records which have incomplete data were excluded. Their physical component scoring (PCS) and mental component scoring (MCS) were assessed using SF-12® questionnaire. SF-12® questionnaire contains 7 questions which help to track of patients' feelings and the ability to do their usual activities. The SF-12® was translated and retranslated and validated with a Cron Bach alpha score of 0.84. Physical and Mental Health Composite Scores (PCS and MCS) are computed using the scores of twelve questions and range from 0 to 100, where a zero score indicates the lowest level of health measured by the scales and 100 indicates the highest level of health. A score of below 30 is usually considered poor. A score below 50 is considered below average. A score of above 70 is considered good quality of life [11].

Detailed counselling was provided to all the patients in two sessions on 1st day and 14th day and PCS and MCS were assessed again after 14 days (28th day). The questionnaire was administered by the investigator on 2 occasions (1st day of enrolment and 28th day). One investigator was assigned for administration of the questionnaire and counselling of the patients. The same investigator had counselled 109 patients on both occasions. The improvement in physical and mental component scoring was assessed. All descriptive statistics were analyzed using SPSS version 22. The quality of life scores were directly noted from the results on the day of administration of questionnaire. Student 't' test was used to analyse the null hypothesis and a 'p' value of $p<0.05$ was considered significant with a 95% confidence interval.

RESULTS: Of the 125 patients, 109 patients met inclusion and exclusion criteria. Majority of the patients were male (61%). More patients were in the age group of 60-70 years (n = 30; 27.5%) followed by 30 - 40 years (n = 28; 26%) and 50 - 60 years (n = 28; 26%). Majority of the patients in

our study were smoker but non-alcoholic. Majority of the patients had no family history of tuberculosis (n = 85, 78%). About 21% of the patients had extra-pulmonary TB (n = 23). The distribution of TB based on the category was shown in **Table 1**.

Table 2 depicts the comparison of PCS and MCS before and after counselling. There was a statistically significant improvement in PCS and MCS after counselling.

TABLE 1: DISTRIBUTION OF TB BASED ON CATEGORIES

Categories	No. of patients (n=109)	Percentage (%)
DOTS	57	53
DOTS + Streptomycin	43	39
MDR	9	8

DOTS – Directly Observed Treatment, Short-course
MDR – Multidrug resistance

TABLE 2: PCS AND MCS BEFORE AND AFTER COUNSELLING

PCS (Mean ± SD)		p value	MCS (Mean ± SD)		p value
Before counselling	After counselling		Before counselling	After counselling	
44±5.12	54±4.13	<0.0001*	39±5.21	54±5.13	< 0.0001*

* P< 0.05 is statistically significant

The impact of counselling based on gender was shown in **Table 3**. A statistically significant improvement was observed in PCS and MCS after counselling irrespective of gender.

TABLE 3: IMPACT OF COUNSELLING BASED ON GENDER

Gender	PCS (Mean ± SD)		p value	MCS (Mean ± SD)		p value
	Before counselling	After counselling		Before counselling	After counselling	
Male (n=67)	44.6±5.04	53.2±3.82	<0.0001*	39.08±5.13	54±4.92	<0.0001*
Female (n=42)	43.5±5.18	55±4.46	<0.0001*	39.5±5.32	54±5.44	<0.0001*

* P< 0.05 is statistically significant

PCS and MCS for pulmonary and extra-pulmonary TB before and after counselling were compared and the same was depicted in **Table 4**. A statistically significant improvement in PCS and MCS was seen after counselling irrespective of types of TB.

TABLE 4: COMPARISON OF PCS AND MCS FOR PULMONARY AND EXTRA-PULMONARY TB BEFORE AND AFTER COUNSELLING

Types	PCS (Mean ± SD)		p value	MCS (Mean ± SD)		p value
	Before counselling	After counselling		Before counselling	After counselling	
Extra-pulmonary(n=23)	43.5±5.22	53.16±4.89	<0.0001*	40.7±5.36	53.16±5.95	<0.0001*
Pulmonary(n=86)	44.3±5.13	54±3.90	<0.0001*	38.7±5.10	54±5.42	<0.0001*

*P < 0.05 is statistically significant

Table 5 depicts the comparison of PCS and MCS for various categories of TB before and after counselling. There was a statistically significant improvement in PCS and MCS among all the categories of TB.

TABLE 5: COMPARISON OF PCS AND MCS FOR VARIOUS CATEGORIES OF TB BEFORE AND AFTER COUNSELLING

Categories	PCS (Mean ± SD)		p value	MCS (Mean ± SD)		p value
	Before counselling	After counselling		Before counselling	After counselling	
DOTS	44±5.22	53±3.9	<0.0001*	39.4±5.57	53.4±5.7	<0.0001*
DOTS + Streptomycin	44.5±4.96	54.2±4.45	<0.0001*	38.3±4.83	54±5.41	<0.0001*
MDR	43.4±4.22	55.8±3.45	<0.0001*	40.5±4.43	53.6±8.34	<0.0001*

*P< 0.05 is statistically significant

Table 6 shows the comparison of PCS and MCS between male and female after counselling. The p value shows that there was no difference in PCS and MCS score among male and female after counselling.

TABLE 6: COMPARISON OF PCS AND MCS BETWEEN MALE AND FEMALE AFTER COUNSELLING

	PCS (Mean ± SD)		MCS (Mean ± SD)	
Gender	**After counselling**	**p value**	**After counselling**	**p value**
Male(n=67)	53.2±3.82	0.1088	54±4.92	0.9650
Female(n=42)	54.5±4.46		54±5.44	

DISCUSSION: Health related quality of life (HRQOL) is a relatively new index for TB patients. The QOL assessed for the cases when compared with that of the control group helped in the evaluation of the impact of TB on QOL of patients. QOL is needed, as a person's perception of his or her physical and mental health covers broad domains including physical, psychological, economic, spiritual and social well being. Health care to be comprehensive in true sense must include not only the indicators of changes in frequency and severity of disease but also an estimation of well -being.

Our study included assessment of physical component and mental component parameters (SF-12® Questionnaire) to evaluate the health status in patients.

HRQOL scoring was sensitive to changes in the quality of life of patients as demonstrated by statistically significant differences in physical and mental component scoring observed among the patients. Several studies reported that quality of life of patients with tuberculosis is negatively affected [12-14].

In our study females were more affected by TB compared to male. It is contrast to the study conducted by Onifade DA *et al*., 2010 [15].

The present study revealed that there was a significant difference between the physical component scoring (PCS) and mental component scoring (MCS) among the patients before and after counselling. The scores of the men were significantly higher than those of the women in the dimensions of SF 12 in active cases. In several studies performed in England, it has been suggested that the negative effects of TB on QOL are greater in women than in men [16]. The fact that QOL scores appeared to be low in the women of both the TB and control groups, in the present study could be explained by social roles and restrictions regarding sex, and could also be related to the physiological structure and hormonal differences of the women.

CONCLUSION: This study illustrated that the quality of life of TB patients were improved after giving counselling and this should be made mandatory for all TB patients during their treatment course which would help the patients for the betterment of their treatment. Improved physical and mental status implies the positive impact of regular patient counselling, among tuberculosis patients.

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