

## The role of clinical pharmacist in enhancing the health-related quality of life in patients with pulmonary tuberculosis

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### ABSTRACT

Tuberculosis (TB) is potentially airborne severe infectious disease which requires long term treatment. It considerably affects the physical and mental health quality of the patient's life. Appropriate patient counselling with the help of Patient Information Leaflet will help to improve the patient's quality of life and overall treatment outcome. To enhance the health related quality of life in pulmonary tuberculosis patients by providing patient counselling with the aid of patient information leaflet. An interventional study was carried out for six months in 80 patients diagnosed with pulmonary tuberculosis from the OP & IP of Tuberculosis and Chest Department of a medical college hospital. The HRQoL was assessed using the SF-36 questionnaire. Appropriate patient counselling was provided with the help of Patient Information Leaflet. In our study, a total of 80 patients were enrolled, out of which 49[61%] were Out-patients, and 31[39%] were In-patients. All the 8 sub domains of the SF-36 survey show statistical significance with improvement in 2<sup>nd</sup> Visit (after counselling) when compared with the baseline visit. The demographic variables like smoking, low socioeconomic status, allergies, family history show statistically significant association with overall HRQoL. The HRQoL of the pulmonary tuberculosis patients were initially low before the start of Anti-TB therapy, after providing proper patient counselling using patient information leaflet the HRQoL scores were found to be increased on the subsequent revisits, which implies the need of proper patient counselling and follow-up in PTB for the better quality of life.

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### INTRODUCTION

Tuberculosis (TB) is a significant public health concern globally and the world's second most common cause of death from infectious disease after

HIV/AIDS [1, 2]. Tuberculosis is an airborne disease caused by Mycobacterium tuberculosis (MTB) that usually affects the lungs leading to severe cough, fever, and chest pains. The other symptoms include unintentional weight loss, fatigue, night sweats and chills [3]. If the infection is confined only to the lungs, it is called Pulmonary Tuberculosis, and if the infection spreads out of the lungs, it is called Extra Pulmonary Tuberculosis [4]. Fixed-dose combination (FDC) is when two or more drugs are combined in a single pill or tablet. Fixed-dose combinations of four drugs (Isoniazid, Rifampicin, Pyrazinamide and Ethambutol), three-drug combination (Isoniazid, Rifampicin, Ethambutol) and two-drug combination (Isoniazid and Rifampicin) are currently available [5]. Since TB requires long term treatment, it considerably affects the physical and men-

tal health quality of the patient's life. HRQoL is defined as the extent to which patient's subjective perception of physical, mental and social wellbeing is affected on a day to day basis by disease and its treatment. HRQoL was assessed using the SF-36 questionnaire. Appropriate patient counselling with the help of Patient Information Leaflet will help to improve the patient's quality of life and overall treatment outcome [6].

## MATERIALS & METHODS

A prospective study was conducted over six months among patients who visited and were admitted in the department of Pulmonology ward. Ethical approval was obtained from the Institutional Ethics Committee before the commencement of the study. (Letter Reference no.: IEC/TOMCHRC/ 091/ 18-19)

Patients of adult age group (18 -65years) of both genders, who were willing to participate in the study were included after taking patient consent through the informed consent form. In contrast, patients of the special population like paediatrics, geriatrics and pregnant, patients with extra-PTB and co-morbid diseases (HTN, DM, HIV, Alzheimer's and Epilepsy) were excluded. All the documents used in the study were translated to the local language (Kannada) and based on the convincing of the patient preferred was language accordingly. A total of 80 patients who were admitted and visited the department were assessed for their health-related Quality of Life using SF-36 questionnaire on the First Visit, and they were counselled about the cause, signs and symptoms, complications and need of lifestyle changes using Patient Information Leaflet. Demographic details of the patient (Name, Age, Sex, Nikshay ID etc.) and the date regarding past medical history, past medication history, diagnosis, prescribed drugs, etc. through data entry form are collected. The patients were followed up for one month, and their Health-Related Quality of Life was reassessed (1<sup>st</sup> re-visit). Counselling was given again, and the follow up was done for another month. On the 2<sup>nd</sup> re-visit, their Health-Related Quality of Life was again reassessed. The obtained data were subjected for suitable statistical method.

## RESULTS

### Demographic details of patients

In our study, a total of 80 patients were enrolled, out of which 49[61%] were Out-patients, and 31[39%] were In-patients. Based on their Gender, 48[60%] were males, and 32[40%] were females. The maximum number of patients enrolled belongs to the

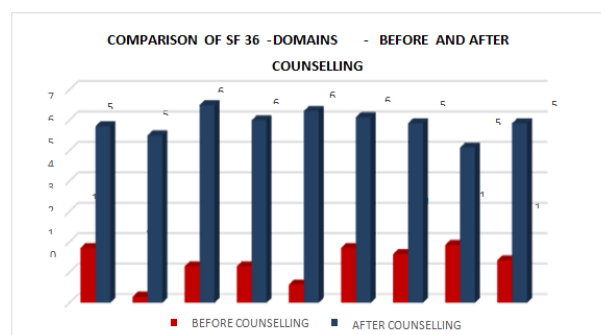
age group of 55-64 years (24%) and 25-34 years [24%]. Demographic details of patients involved in the study are given in [Table 1].

### HRQOL Assessment Using SF 36 Questionnaires

All the 8 domains of SF-36 survey (HRQoL scores) show statistically significant improvement in 2<sup>nd</sup> Visit when compared with the baseline visit after counselling. Distribution of patients based on SF-36 scores during different visits is given in table 2.

### Comparison of SF 36 subdomains - before and after counselling

Assessment of SF-36 subdomains from baseline to I follows up. II follow up and showed an increase in HRQoL scores, all the 8 domains of SF-36 survey (physical functioning, role physical, bodily pain, general health, energy, social functioning, role emotional and mental health) show statistical significance with improvement in 2nd Visit (after counselling) when compared with the baseline visit. Table 3 and Graph 1 show the comparison of 36 subdomains - before and after counselling.



**Figure 1: Impact of patient counselling on HRQoL Scores**

### Association HRQoL Scores with Patient Demographics

The demographic variables like smoking, low SES, allergies, family history shows statistically significant association with overall HRQoL scores, whereas the other demographic characteristics show no association. It was observed that SES ( $p=0.0019$ ), smoking, ( $p=0.013$ ) Hx of allergies ( $p=0.016$ ) and Family Hx ( $p=0.022$ ) were found to be statistically significant with the overall score in pulmonary tuberculosis which is given in Table 4.

## DISCUSSION

The prime objective of this study was to assess the HRQoL in patients with PTB visiting the TBCD department. The Demographics and clinical characteristics of our study population were similar to the reports of other studies on the HRQoL of PTB

**Table 1: Demographic details of patients**

Variables	No of participants (N=80)	Percentage (%)
<b>Sex</b>		
Male	48	60%
Female	32	40%
<b>Age</b>		
18-34	32	40%
35-54	21	26%
55-65	24	30%
<b>Education</b>		
Illiterate	31	39%
Literate	49	61%
<b>Occupation</b>		
Unemployed	26	33%
Employed	54	67%
<b>Socioeconomic Status</b>		
Middle Class	36	42%
Low Class	44	58%
<b>Residential Area</b>		
Urban	39	49%
Rural	41	51%
<b>Allergies</b>		
Yes	50	62%
No	30	38%
<b>Family History Of Tb</b>		
Yes	52	65%
No	28	35%
<b>Smoker</b>		
Yes	45	56%
No	35	44%
<b>Alcoholic</b>		
Yes	17	21%
No	63	79%
<b>Tobacco</b>		
Yes	65	81%
No	15	19%

patients. A study conducted by the Baskaran Dhanaraja et al., [7] also have similar age characteristics, i.e. the highest no of patients having PTB is between the age group of 55-64 years [8, 9]. Demographic characteristics were similar to the reports of other studies, where male predominance [60%] was observed, and 75% were employed under various jobs [10, 11]. Studies conducted by Madeeha Malik et al., [12] and Cheng-Ting Li et al., [11] have similarities with our study such that more patients have high literacy level [61.25%]. Studies by Atif et al., [8] Madeeha Malik et al., [12] and Stevens M.B. Kisaka et al., [7] had shown similarity with our study

in terms of marital status, with those married [70%] coming under the majority population. The proportion of subjects living in a rural area was found to be more [51%], than subjects living in an urban area, and shows similarity with the study conducted by Stevens M.B. Kisaka et al., [10] and Tesfahuneygn G et al., [13]. In the study conducted by Carlo A Marra, [14] it was found that the number of out-patients was more than in-patients admitted. This was similar to our study, where 61% of patients were out-patients. In our study, 56.45% of patients were found to be smokers. This is supported by the study conducted by AlaviNaini R et al., [15] where

**Table 2: Distribution of patients based on SF-36 scores during different visits**

Sf-36 Domains	Total no. of patients					
	1 <sup>st</sup> Visit		1 <sup>st</sup> Revisit (counselling done )		2 <sup>nd</sup> Revisit (counselling done )	
	SF-36 Score >50(n=80)	SF-36 Score <50(n=80)	SF-36 Score >50(n=80)	SF-36 Score <50(n=80)	SF-36 Score >50(n=43)	SF-36 Score <50 (n=43)
PF	1	79	60	20	42	0
RP	0	80	56	24	42	0
MH	1	79	56	24	42	0
Vitality	1	79	58	22	42	0
RE	3	77	48	32	42	0
SF	3	77	67	13	42	0
BP	0	80	55	25	42	0
GH	10	70	54	26	42	0
Overall	0	80	60	20	42	0

**Table 3: Comparison of SF 36 subdomains - before and after counselling**

Sl. no	Sf - 36 Subdomains	1 <sup>st</sup> Visit Before Counseling (Mean ± SD)	2 <sup>nd</sup> Visit After Counseling (Mean ± SD)	P-Value
1	Physical functioning	18 ± 0.113	58 ± 0.218	<0.00001*
2	Role physical	2 ± 0.059	55 ± 0.249	<0.00001*
3	Mental health	12 ± 0.102	65 ± 0.199	<0.00001*
4	Vitality	12 ± 0.086	60 ± 0.228	<0.00001*
5	Role emotional	6 ± 0.176	63 ± 0.333	<0.00001*
6	Social functioning	18 ± 0.134	61 ± 0.197	<0.00001*
7	Bodily pain	16 ± 0.123	59 ± 0.207	<0.00001*
8	General health	19 ± 0.150	51 ± 0.173	<0.00001*
9	Overall	14 ± 0.070	59 ± 0.164	<0.00001*

the majority of patients were found to be smokers.

In HRQoL, the study was conducted over 6 months; the patients were reviewed every two months, twice during the period of study. The values obtained during the first Visit of study shown that patients had low overall SF-36 scores. Then the treatment was started and was provided counselling with the help of Patient Information Leaflet. The HRQoL was reassessed after 2 months. Most of the patients shown significant improvement in their HRQoL scores. The patients were reassessed after another two months. The scores obtained during 2<sup>nd</sup> re-visit shows that the patient's HRQoL has improved significantly which is similar to the conclusion of the studies conducted by both Chamla

D et al., [16] and Atif et al., [8], i.e., low HRQoL scores were observed before the start of treatment. Throughout therapy, these scores will eventually improve, indicating an improvement in HRQoL.

The mean scores obtained during 1<sup>st</sup> and 2<sup>nd</sup> visits for all domains of SF-36 are found to be significantly associated with improvement in mean scores.e. The SF-36 scores after 2 months of treatment have significantly improved scores than those obtained before the start of treatment. This is supported by the study conducted by Stevens M.B. Kisaka et al., [10] The highest mean score in our study was found in the MH domain[65%] followed by RE domain[63%] and SF domain[61%]. While in the study conducted by Stevens M.B. Kisaka et al., [10] the highest mean

**Table 4: Association HRQoL Overall Scores with Patient Demographics**

Patient demographics		SF-36 score		Chi-square statistic	P-value
		<50	≥50		
Gender	Male	39	9	2.5	0.113
	Female	21	11		
Age	≥ 40 years	29	8	0.419	0.517
	<40 years	31	12		
Marital status	Single/Widow/ Divorced	20	4	1.269	0.259
	Married	40	16		
Educational status	Literate	38	11	0.438	0.507
	Illiterate	22	9		
Occupational status	Employed	45	15	0	1
	Unemployed	15	5		
Socioeconomic status	Low class	24	16	9.6	0.001**
	Middle class	36	4		
Residential status	Urban	29	10	0.016	0.897
	Rural	31	10		
I.P/O.P	In-patient	22	9	0.438	0.507
	Out-patient	38	11		
Smoking habit	Smoker	29	16	6.112	0.013*
	Non-smoker	31	4		
Alcohol consumption	Alcoholic	13	4	0.027	0.868
	Non-alcoholic	45	18		
Tobacco Consumption	Tobacco user	11	4	0.027	0.868
	Non-user	49	16		
History of Allergies	Yes	33	17	5.76	0.016*
	No	27	3		
Family history Of PTB	Yes	42	19	5.176	0.022*
	No	18	1		

score is observed in PF domain [53 %] followed by MH domain[52.8%].

Our study shows that patients who had low SF-36 scores before the start of therapy had significantly improved after patient counselling which was provided with the help of PIL. All the eight subdomains of SF 36 scores had improved significantly after counselling This result is supported by the study conducted by Prabhakar K. et al., [17] which shows significant improvement in physical and mental status which implies a positive impact of patient counselling. In another study conducted by Veintra-muthSankar et al., [18] proves that pictograms play an essential role in patient counselling and it can be used as a useful counselling tool to make the patients better understand their disease and ways to improve their HRQoL in a simplified language.

The individual patient demographics were assessed

for risk factors causing PTB with the overall HRQoL scores by using the Chi-square test. The results of the chi-square test showed a statistically significant relationship with smoking, low SES, Hx of Allergies and Family Hx of PTB. In this study, 56.45% patients were found to be smokers; this is supported by the study conducted by Alavi Naini R et al., [15] where the majority of patients were found to be smokers which found to be a significant factor .Raj-pal.Kashyap et al., [2] have conducted a study that reveals low SES status as a significant risk factor for tuberculosis which supports our study.

ShahriarSalehitali et al., [19] and Patel PG et al., [20] had conducted a similar study but obtained different results. Shariarconcluded that Gender and residential area were significant in causing PTB, whereas, Patel concluded that Gender, SES and age were not a significant association in causing PTB. A study conducted by Laurent Abelet al., [21] reveals



that family history is a significant factor in tuberculosis patients, which is similar to this study. In our study, it is found to be a high degree of allergic sensation in TB patients which is concluded in the study conducted by Linda K Ellertsen et al., [22] The study findings revealed that many risk factors influence the HRQoL of TB patients. Overall HRQoL was relatively lower in patients with a family history of TB, allergies, low SES and smoking habit. The result from the study confirms the need to conduct patient education and counselling as an essential part of the tuberculosis care that can result in the improvement of patient's quality of life and improvement in all 8 subdomains of SF 36.

## CONCLUSION

According to our study findings, the overall HRQoL found to be lower before the onset of the treatment, which shows significant enhancement after the provision of each counselling. Counselling, with the aid of Patient Information Leaflets (PIL) to the patient, has improved the overall HRQoL, with mental health domain showing the most significant improvement. By enhancing the HRQoL, the pharmacists and clinicians can understand the functioning and well-being of TB patients so that individual patient-specific needs can attain the best clinical or treatment outcome. Prolonged duration of time, patient's lack of interest in re-visiting the physician and refilling the medicines, lack of knowledge regarding the disease and its treatment are considered as the challenges which may often discontinue the treatment. So, particular strategies to strengthen treatment support that include specific, close monitoring of patients, as well as increase the awareness in public on the importance of the disease and timely interventions may help to improve the overall HRQoL of TB patients to a greater extent.

## LIMITATIONS

The study was conducted for a short period in a single institution; therefore, the result cannot be generalized. All the prognostic features, such as co-morbidities, were not included in the analysis. Proper follow up of the patients seems to be challenging which might have potential impacts on the results.

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## Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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