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IMPACT OF PHARMACIST ASSISTED PATIENT COUNSELING FOR IMPROVING MEDICATION ADHERENCE AND QUALITY OF LIFE IN PULMONARY TUBERCULOSIS PATIENTS- AN EDUCATIONAL INTERVENTIONAL STUDY

Aarsha Joby¹, Allu Jaya George¹, Anjali A. Nair¹, Prannoy Shanker P.V.¹, Rajeswari Ramasamy², N.S. Mahesh³, Shashidhar G.⁴, Teena Nazeem⁵

¹Department of Pharmacy Practice, Krupanidhi College of Pharmacy, affiliated with Rajiv Gandhi University of Health and Sciences, Bangalore-560035, India.

²Department of Pharmacy Practice, Krupanidhi College of Pharmacy, Bangalore- 560035, India.

³Department of Tuberculosis and Respiratory Medicine, MVJ Medical College & Research Hospital, Bangalore, India.

⁴Department of General Medicine, MVJ Medical College & Research Hospital, Bangalore, India.

⁵Department of Pharmacy Practice, Krupanidhi College of Pharmacy, Bangalore- 560035, India.

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ABSTRACT

Medication Adherence to the long course of tuberculosis treatment is a complex, dynamic phenomenon. The assessment of an association between both, HRQOL and medication adherence in TB, would provide valuable information on treatment effectiveness, optimal disease management and health policy making. In Pulmonary tuberculosis (PTB), the patients usually present themselves with a history of chest symptoms (cough, chest pain and hemoptysis) which further limit the patient's role in work and social activities. Social stigmatization and negative emotions resulting from the illness could result in a long-term impairment of patient's psychosocial well-being. This study aimed to assess the impact of pharmacist assisted patient counseling for improving medication adherence and quality of life in pulmonary tuberculosis patients. A prospective-educational interventional study was conducted from September 2016 to April 2017 in various Tuberculosis units across Bangalore. Medication adherence was assessed and measurement of QOL was done using WHO-BREF scale. Of the 164 patients enrolled, there were 2 deaths and 5 drop-outs. Among the 157 patients, 37(23%) were found to be adherent, 20(13%) were at the risk of non-adherence and 100(64%) were found to be non-adherent. There was significant impact of patient counselling in improving the medication adherence ($p < 0.0001^*$). QOL scores were also affected in these patients. The worst affected domain was physical domain followed by psychological domain. After the counseling there was a statistically significant improvement in QOL scores ($p < 0.0001^*$). Pharmacist assisted patient counseling had a statistically significant impact in improving medication adherence and QOL in pulmonary TB patients.

Corresponding author

Anjali A. Nair

VARSA CAMELIA APARTMENTS, Green Domain Layout, B/H RMZ,
Off ITPL Road, Kundanahalli,
Bangalore- 560 048, Karnataka, India
anjalinair94@gmail.com,
+918050973433, +919972671801.

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INTRODUCTION

Globally Tuberculosis (TB) remains a leading infectious killer disease. TB infection is caused by *Mycobacterium tuberculosis* (*M. Tuberculosis*). If left untreated or improperly treated, TB causes progressive tissue destruction and, eventually, death [1].

Revised National Tuberculosis Control Programme (RNTCP) uses the World Health Organisation (WHO) recommended Directly Observed Treatment Short Course (DOTS) strategy and it reaches over a billion people in 632 districts/reporting units. Both diagnosis and treatment of TB are free with the RNTCP.

As per Times of India, March 27, 2017, between 2012 to 2017, more than 42 million people were screened as part of the RNTCP, while more than seven million patients received treatment across the country. [2] Now TB ranks alongside Human Immunodeficiency Virus (HIV) as a leading cause of death worldwide. In India, TB kills more adults than any other disease. [4]

As per the Global TB report 2015, India has the highest burden of both TB and Multi-Drug Resistant TB (MDR-TB) and has the second highest of HIV associated TB in the world. [4] In India, the greatest burden of TB incidence and mortality is in adults aged 15 to 60 years, which include the most productive members of society. TB affects more men than women. The incidence of TB in children is less when compared to adults, but they are likely to suffer from more serious forms of TB and may die if they are not treated properly. [3]

A patient with TB faces various physical, psychological, financial and social problems. These problems have a great impact on the well-being of the patient and can impair the quality of life of the patient suffering from TB [12].

Much of the attention within tuberculosis management at present is spent on microbiological cure, and its impact on HRQOL is either undervalued or seldom considered. TB has substantial and encompassing impact on HRQOL of infected patient. [10] HRQOL is a patient-reported outcome (PRO) parameter which refers to the multi-dimensional nature of health, directly from the patient perspective of well-being in physical, social and psychological aspects. Physical and mental distress is found to be common in TB patients and it may lead to poor disease outcome or poor treatment outcome. [5] In case of pulmonary tuberculosis, the patients usually present themselves with a history of chest symptoms such as cough (productive or non-productive), chest pain and haemoptysis. These PTB specific symptoms can further limit the patient's role in work as well as social activities. In some communities, TB patients are considered to be a source of infection for the healthy individuals, so they have to face social rejection and isolation. Social stigmatization and negative emotions resulting from the illness could result in a long-term impairment of patient's psychosocial well-being. This may lead to work absenteeism resulting in loss of productivity and reduced monthly income. [11]

Poor treatment adherence increases the risk of drug resistance, treatment failures, relapses, deaths and prolonged infectiousness which remains a hurdle to the success of tuberculosis programmes. Therapy duration, the side effects of the medication, the restriction of alcohol, perceived cost and access to healthcare clinics are all recognized as barriers that can impact medication adherence rates. Countries which are implementing DOTS to ensure treatment adherence have shown impressive results along with increasing treatment success and low default rates. [13]

Several reports and studies suggest that the treatment failure in PTB patients is mainly due to non-adherence and lack of knowledge towards the anti-TB therapy. The pharmacist can play a major role in improving the patient knowledge and compliance towards the anti-TB therapy. Hence, in this project titled "Impact of Pharmacist Assisted Patient Counseling For Improving Medication Adherence and Quality of Life in Pulmonary Tuberculosis Patients" an attempt is made to improve the patient adherence towards the PTB by counseling the patients, which will help to improve health care outcomes [10].

Adherence among pulmonary TB patients can be achieved by improving personal, interpersonal, and social system of patients. [7] Efforts like health education to patients or their family is needed to reduce those factors which affect adherence and treatment success rates, in order to ensure higher rates of adherence and treatment success. HRQOL has become an important tool for the understanding of health outcomes by adopting a patient-centered approach to care and treatment. To improve HRQOL, extensive care and support should be given to TB patients in the first two months of treatment that is, during Intensive Phase. [6]

OBJECTIVES:

1. To assess Medication Adherence and assess the QOL - Pulmonary Tubercular patients
2. To identify the patients who are not adhering to anti-TB treatments, and also the patients at high risk of non-adherence
3. To prevent and manage non-adherence by patient centered pharmacist care/counseling
4. To determine the impact of pharmacist's counseling in improving QOL and medication adherence

METHODOLOGY

STUDY DESIGN: Prospective observational study

STUDY SITE: Randomly selected TU/DOTS centers in Bangalore

SAMPLE SIZE: 164 patients

STUDY PERIOD: The study was performed over a period of eight months from September 2016 –April 2017

STUDY APPROVAL:

1. Human ethical clearance was obtained for carrying out the research work from Ethical Committee of MVJ Medical College & Research Hospital, Hoskote, Bangalore with ethical clearance number MVJ MC & RH/05/2017.
2. Permission letter from the Office of the Joint Director State TB Centre.

SOURCE OF DATA:**Case Report Form**

A specially designed Case Report Form was prepared as per the format given in RNTCP DOTS-Plus Guidelines for incorporating patient's details. The format contains the basic demographics, contact details, sputum and other diagnostic tests and medication related details and measurement of QOL was done using WHO-BREF scale containing 26 questions. The WHOQOL-BREF produces four domain scores which are Physical domain, Psychological domain, Social Relationships domain, and Environment domain.

Selection of DOTS centres

Randomly selected TB Units from Bangalore- Rural, Urban and BBMP were included for the study.

Records from DOTS centres

Information of TB patients on CAT-I and CAT-II treatment was retrieved as per inclusion criteria from the RNTCP treatment cards from respective TB Units.

Informed Consent

The subjects who met the inclusion criteria were enrolled for the study after obtaining informed consent

INCLUSION CRITERIA:

All Pulmonary Tubercular patients of various age groups, receiving Category I and II anti-TB drug therapy for one month.

EXCLUSION CRITERIA:

The TB patients unwilling to participate in the study

PROCEDURE

- A Prospective- Educational Interventional study was conducted in the randomly selected TB Units/DOTS centers in Bangalore.
- The study was conducted on gaining approval from the Institutional Ethical Committee.
- Patients were called for the meeting in each TB Units with the help of Treatment Supervisors/Laboratory Supervisors.
- All the patients were educated about TB and importance of medication adherence.
- All patients who met the inclusion criteria were enrolled in the study after taking Informed Consent (IC) before commencing the study.
- The basic demographics, contact details, sputum and other diagnostic tests and medication related details were collected by the researchers personally using the Case Report Form (CRF) from the RNTCP treatment card for each patient.
- Medication adherence was assessed and baseline measurement of QOL was done using WHO-BREF scale. The WHOQOL-BREF produces four domain scores which are Physical domain, Psychological domain, Social Relationships domain, and Environment domain. There are also two items that are examined separately: Question 1 asks about an individual's overall perception of quality of life and Question 2 asks about an individual's overall perception of his or her health. Domain scores are scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100, and subsequently transformed to a 0-100 scale using a formula.
- The patients who were not adhering to treatment and the patients who were at high risk of non- adherence were identified. {The operational definition for Non-adherence: Those patients who missed more than one dose of the anti-TB treatment; the patient at high risk of Non-Adherence were those with the following characteristics – Forgetfulness, Social stigma, Social Habits, Physical difficulty, Co-morbidities, Inadequate knowledge, Transportation cost, Lack of support and Side-effects}
- The factors and reasons affecting non-compliance were determined.
- To prevent and manage non-adherence, patient centered pharmacist counseling was given on the disease condition and treatment in their regional language both verbally and with the help of various counseling/educational aids like leaflets. The contact number and address was taken from each subject after the counseling for follow-up purpose.
- Patients were reviewed and follow up for their medication adherence and QOL was done after the end of Intensive Phase and two months of Continuous Phase.
- The follow-up was done either by visiting the DOTS center or through telephone.
- The impact of patient counseling in improving QOL and medication adherence was assessed using baseline and follow up data.

The results of the study were analyzed statistically using statistical software using JMP™ 8.0. The inferential statistics comprised of Paired t test, Wilcoxon Signed Rank Test and Sign Test.

RESULT

A total of 164 patients were enrolled for the study in the study period of 8 months from different TB centres. Out of 164 patients, 112 were CAT-I and 52 were CAT-II patients. Of this there were 7 drop-outs, out of which 2 died during the study period. The study was carried out for the remaining 157 patients.

A total of 157 patients were enrolled into the study, whose complete demographic details such as age, gender, marital status, educational status and social habits were collected. Of the 157 patients enrolled, 65 % (N=102) were male and 35 % (N=55) were female. Majority were in the age group 25-44 years(N=79) 50 %, followed by the age group 45-64 years(N=38) 24%. The males were found to be more non-adherent than females. Similarly, QOL was impaired in males when compared to females. The worst affected domain was physical domain (Table 1).

Out of the enrolled 157 patients 102(65%) patients were married, 42(27%) patients were single, 10 (6%)patients were widows and 2 (2%) were divorced. Divorced patients were found to be 100% non-adherent and they had a poor QOL in psychological domain and physical domain (Table 1).

From the study, we could observe that the level of education was secondary for 40%, followed by tertiary 25%, primary school 23% and none 12% patients. Non-adherence rates were found to be higher in patients with tertiary education followed by patients who had no formal education. Most affected domain was physical domain and this domain was highly affected in patients with primary education (Table 1).

Of the 157 patients, 23% were smokers, 15% were alcoholics and 7% were both smoker and alcoholic. 55% did not have any social habits. Patients with social habits were found to be more non-adherent than those without any social habits and they had a poor QOL (Table 1).

Out of the 157 patients, 92% were sputum positive and remaining 8% were sputum negative. A vast majority were under CAT I therapy and remaining under CAT II therapy. Among the type of patients, majority were new cases, followed by relapse cases, default cases, failure cases and others. CAT II patients were found to be more non-adherent and they had a poor QOL in physical domain (Table 1).

Various co-morbidities were seen in 48(30.57%) patients out of the 157 enrolled subjects. The most common was diabetes (15.29%), followed by hypertension (7%) and asthma (3.18%). Other co-morbidities were also seen in low incidence like HIV (2.55%), thyroid disorder (1.27%), seizure (0.64%) and psoriasis (0.64%). Patients with co-morbidities were found to be more non-adherent than those without. They had a poor QOL in which worst affected was physical domain (Table 1).

Table 1: Medication adherence and QOL based on Patient characteristics (N=157).

Patient characteristics	Number & Percentage	Adherence Status (Number & Percentage)		QOL (mean value)			
		Adherent	Non-adherent	Physical Domain	Psychological Domain	Social Domain	Environmental Domain
Gender							
Male	102(65%)	27(26%)	75(74%)	52.5	58.24	61.26	60.68
Female	55(35%)	30(55%)	25(45%)	54.05	60.08	63.41	62.62
Age Distribution(years)							
0-4	3(2%)	3(100%)	0(0%)	57.14	57.75	57.29	59.48
5-14	6(4%)	25(16%)	6(100%)	41.06	56.94	52.78	58.56
15-24	79(50%)	16(64%)	9(36%)	55.3	60.9	65.54	64.9
25-44	38(24%)	25(32%)	54(68%)	55.23	61.98	64.37	64.7
45-64	6(4%)	6(16%)	32(84%)	48.36	51.38	56.84	53.13
≥65		1(17%)	5(83%)	50.08	58.69	58.33	58.48
Marital Status							
Single	42(27%)	29(69%)	13(31%)	54.39	61.47	63.69	65.21
Married	102(67%)	24(24%)	78(76%)	52.32	58.33	62	60.14
Divorced	3(2%)	0(0%)	3(100%)	51.79	54.17	56.22	57.19
Widowed	10(6%)	4(40%)	6(60%)	63.09	58.33	58.33	62.5
Educational Status							
Tertiary School	39(25%)	13(33%)	26(67%)	53.60	57.49	60.36	60.82
Secondary School	63(40%)	24(38%)	39(62%)	53.85	61.68	66.14	63.43
Primary School	36(23%)	13(36%)	23(64%)	50.60	56.57	59.28	59.29
None	20(12%)	7(35%)	13(65%)	53.79	56.29	55.99	59.03
Social Habits							
With	71(45%)	16(23%)	55(77%)	52.36	57.56	59.92	59.55
Without	86(55%)	41(48%)	45(52%)	53.68	59.96	63.67	62.69

Co-morbidities							
With	48(30.57%)	14(29%)	34(71%)	53.52	60.28	63.22	63.25
Without	109(69.43%)	43(39%)	66(61%)	52.11	55.72	59.28	57.05
Treatment							
Category	107(68%)	49(46%)	58(54%)	54.83	60.39	63.16	62.69
CAT -I	50(32%)	8(16%)	42(84%)	49.28	55.73	59.62	58.56
CAT-II							

A few side-effects were observed. The most common was nausea and vomiting, followed by diminished vision and dizziness (Table 2).

Table 2: DISTRIBUTION OF SIDE-EFFECTS (N=42).

SIDE-EFFECTS	NUMBER	PERCENTAGE
Nausea	17	40.5%
Vomiting	11	26.2%
Diminished vision	05	11.9%
Dizziness	09	21.4%
Total	42	100%

Of the 157 enrolled patients, majority were non-adherent, few very at the risk of non-adherence and the remaining patients were adherent. (Figure 1).

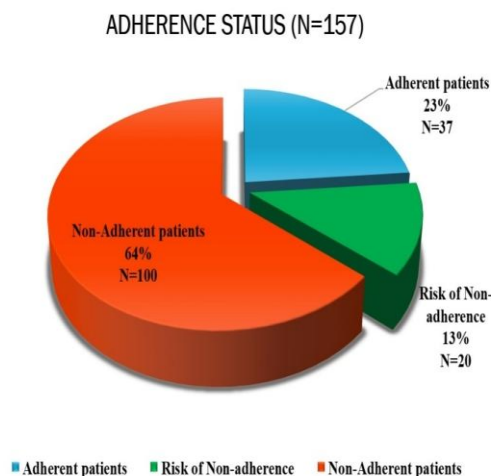


Figure 1: ADHERENCE STATUS (N=157).

Risk Factors for Medication Adherence

The study also determined the factors that may lead to non-adherence. The most common risk factor was social stigma followed by physical difficulty, social habits, transportation cost, lack of support, inadequate knowledge, side-effects and forgetfulness (Table 3).

Table 3: RISK FACTORS OF MEDICATION ADHERENCE (N=157).

RISK FACTORS	YES (Number & Percentage)	NO (Number & Percentage)
Social stigma	118 (75.16%)	39 (24.84%)
Physical difficulty	98 (62.42%)	59 (37.58%)
Social Habits	71 (45.22%)	86 (54.78%)
Transportation cost	70 (44.59%)	87 (55.41%)
Lack of support	68 (43.31%)	89 (56.69%)
Inadequate knowledge	63 (40.13%)	94 (59.87%)
C0-morbidity	48 (30.57%)	119 (69.43%)
Side effects	43 (27.39%)	114 (72.61%)
Forgetfulness	25 (15.92%)	132 (84.08%)

Medication Adherence in CAT-I Patients

The adherence status in CAT-I patients was statistically analyzed separately. The result showed that there was a statistically significant improvement in medication adherence after counseling ($p < 0.0001$) (Figure 2, Table 4).

Medication Adherence in CAT-II Patients

The adherence status in CAT-II patients was statistically analyzed separately. The result showed that there was not much statistically significant improvement in medication adherence after counseling ($p < 0.3433$) (Figure 2, Table 4).

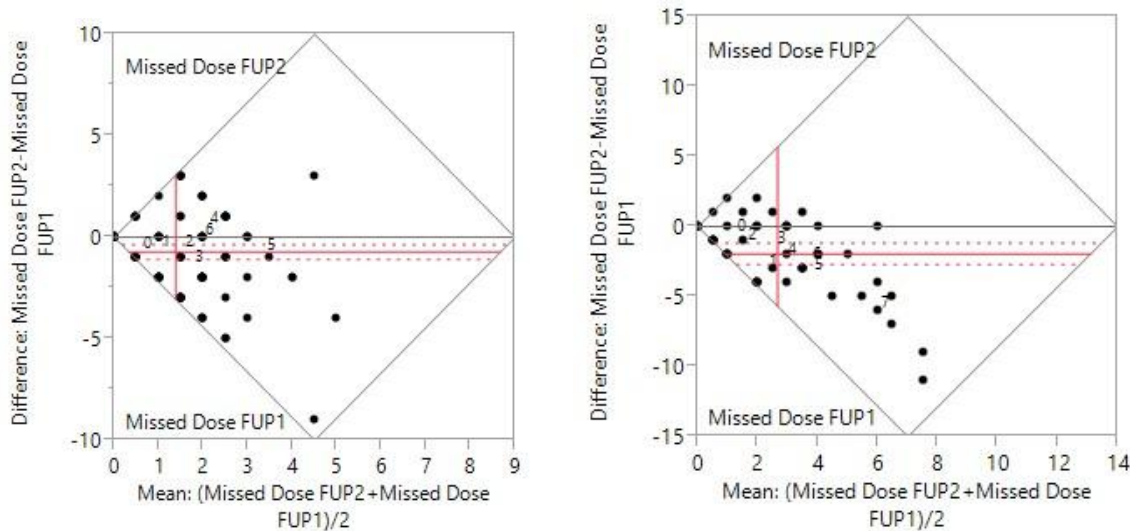


Figure 2: MEDICATION ADHERENCE IN CAT-I AND CAT-II PATIENTS (N=157).

QOL Scores of Each Domain

QOL scores in each domain were assessed. The worst affected domain was Physical domain followed by Psychological domain. After the counseling, more improvement was seen in Psychological domain followed by Physical domain ($p < 0.0001$) (Table 4, Figure 4).

Table 4: MEDICATION ADHERENCE AND QOL DOMAINS IN PTB PATIENTS (N=157).

	Adherence Status (Number & Percentage)		Overall QOL (Mean value)	QOL Domains (Mean value)			
	Adherent	Non-adherent		Physical Domain	Psychological Domain	Social Domain	Environmental Domain
Baseline	57(69%)	100(31%)	60.51	53.09	58.88	62.01	62.36
Follow up-1	67(36%)	90(64%)	67.59	62.01	66.05	66.36	66.95
Follow up-2	98(31%)	59(69%)	75.79	73.63	75.83	71.39	72.91

The Over-all QOL of the patients were impaired during the baseline and after counselling there was a statistically significant in the over-all QOL ($p < 0.0001$) (Figure 3, 4).

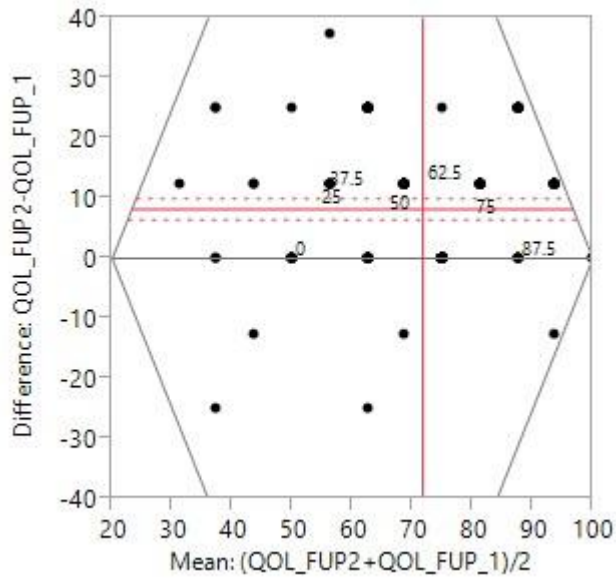


Figure 3: OVER-ALL QOL SCORE (N=157).

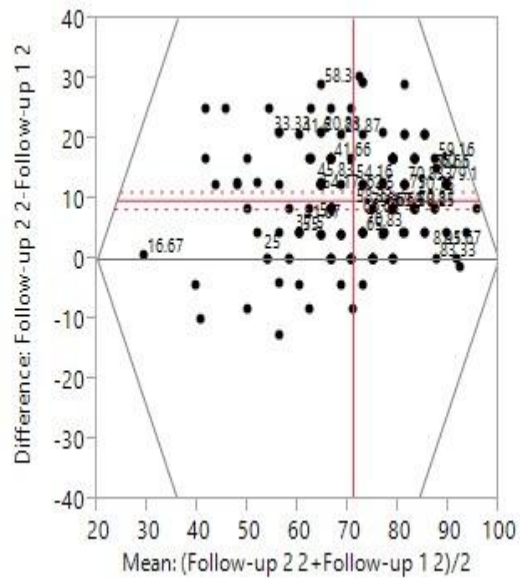
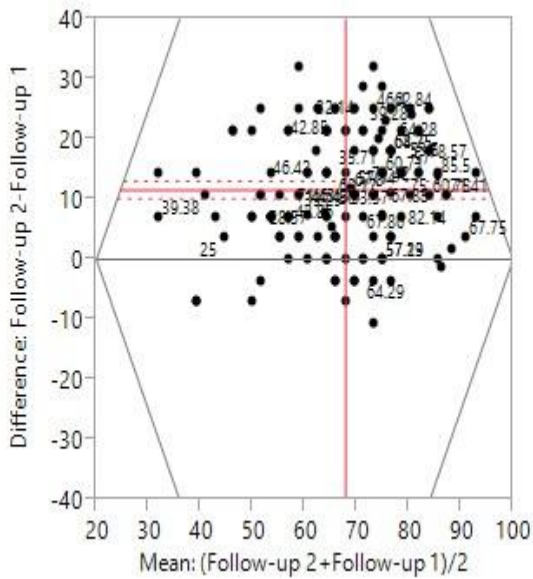


Figure 4(a): PHYSICAL DOMAIN

Figure 4(b): PSYCHOLOGICAL DOMAIN.

Figure 4: QOL SCORES IN EACH DOMAIN (N=157).

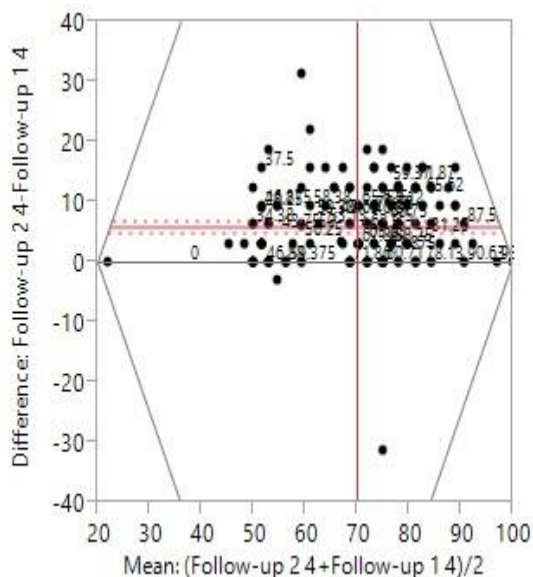


Figure 4(c): ENVIRONMENTAL DOMAIN

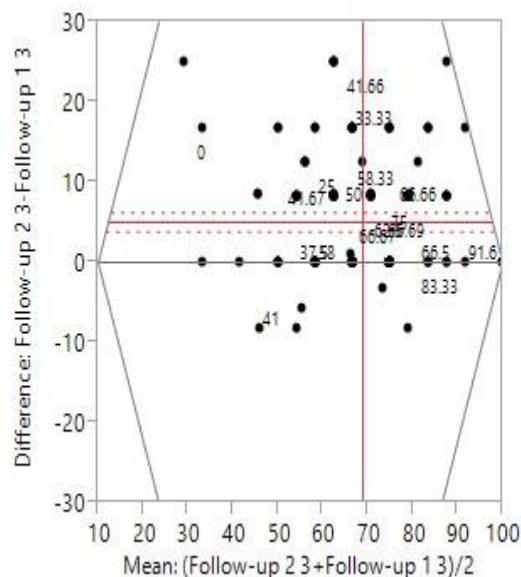


Figure 4(d): SOCIAL DOMAIN.

DISCUSSION

Medication adherence to anti-TB treatment is a major determinant of treatment outcome. [8] Our present study assessed the impact of pharmacist assisted patient counseling in improving medication adherence and QOL in pulmonary TB patients. Adherence was measured on the basis of missed doses. The similar method was used by Suparna B et al., [14] but they used a different operational definition for non-adherence. Adherence rates were less among TB patients. Nearly 69% of the enrolled patients were found to be non-adherent in the baseline.

Most of the TB studies have concentrated on clinical outcomes, only a few studies have assessed the impact of TB on patient's QOL. Since health is a fundamental human right and a worldwide social goal that is essential to the satisfaction of basic human need, it is therefore very important to improve QOL even in diseased states. [15]

SF-36 was the most widely used tool for measuring QOL in communities and clinical settings in different countries. [9] We selected WHO BREF scale since it also considers the impact of disease on environmental factors which is very important in case of diseases that requires long term treatment. The same scale has been used by Nasara R et al., [7] where they compared the QOL scores in patients of TB with that in the normal population.

In the present study, the most affected domains were physical domain followed by psychological domain. This study is contrary to those of the previous studies by Olayinka OO et al., [15] and Sule AG et al., [12] in which the worst affected domain was environmental domain. After the counseling, there was a statistically significant improvement in these two domains ($p < 0.0001$). However, after the intervention, not much improvement was seen in social and environmental domains when compared to the other two domains. So special attention should be given to the patients with travel related and financial problems and having poor quality of home environment and also counseling to family members is essential to improve personal relationships.

In this study, various co-morbidities were seen in some of the subjects. The most common was diabetes (15.29%), followed by hypertension (7%), asthma (3.18%) and HIV (2.55%). DM has been associated with increased rates of TB, which may be partially explained by a decreased T cell-mediated immune response. HIV is by far the strongest risk factor for TB at an individual level, but DM may be the most important at the population level. [17] A study conducted by Adane AA et al., showed that HIV co-infected patients are at high risk of non-adherence. [8] Our studies also showed that non-adherence is high among patients with co morbidities. Similarly, QOL was also impaired in TB patients with other co-morbidities which requires long term treatment.

Majority of the patients were CAT I patients. In this study, the adherence status among CAT I and CAT II patients were statistically analyzed separately. Higher rates of adherence were seen among CAT I patients. Statistically significant improvement in adherence rates was seen among CAT I patients after the counseling. CAT II patients were less adherent. These patients had a poor QOL score in physical domain followed by psychological domain.

During our study, some side effects were reported by the patients. Among these the most common were nausea and vomiting followed by dizziness, diminished vision. In a study conducted in Ethiopia by Adane AA et al., the side effects reported by the patients included headache and dizziness, vomiting, skin rash, yellow eyes, urine discoloration. [8]

In this study, we also examined the patients who were at higher risk of non-adherence among the already adherent patients. The factors affecting non-adherence were also studied. The major risk factor identified was social stigma which is supported by a study conducted in Indonesia by Widjanarko et al. [16] Other risk factors observed were physical difficulty, social habits, transportation cost, lack of support from family and friends, inadequate knowledge, co-morbidity, side effect and forgetfulness.

The overall QOL of TB patients were also impaired. Overall QOL includes two questions related to an individual's overall perception of quality of life and an individual's overall perception of his or her health. There was a statistically significant improvement in overall QOL after the counseling ($p < 0.0001$). This result is consistent with a study conducted by Abhishek B et al., [9].

The study concludes that pharmacist provided patient counseling found to have significant influence on improvement in the patient's knowledge towards their disease and medication, and adherence to prescribed therapy which helps to improve the clinical outcome of TB patients. Further the study suggests that, the pharmacist intervention is essential in the management of chronic diseases. Clinical pharmacist can educate the patients regarding their disease and medication.

CONCLUSION

Pharmacist assisted patient counseling had a statistically significant impact in improving medication adherence and QOL in pulmonary TB patients. However, a more comprehensive approach should be adopted addressing solutions for travel related concerns, providing better patient education, counseling the patient's family members, scheduling proper time interval for patients taking multiple drugs, providing special care for geriatric and pediatric patients.

In the study we observed that there is a lack of knowledge about TB among study population. So, in future research we would like to focus on public awareness program providing more information regarding TB transmission, prevention and treatment in the form of leaflets, videos and mass communication, particularly among the illiterates.

Less awareness about adherence with therapy is the major cause of non-compliance to tuberculosis therapy. So, patients' education and awareness relating to side effects of therapy and importance of complete adherence with therapy is mandatory to get TB free zone nationally. For this, workshops should be organized for healthcare professionals who are in close contact with TB patients such as TB outreach workers, nurses, pharmacists etc.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

ABBREVIATIONS

BBMP	: Bruhat Bengaluru Mahagara Palike
CAT I	: Category I Anti-Tubercular drugs
CAT II	: Category II Anti-Tubercular drugs
CRF	: Case Report Form
DOTS	: Directly Observed Treatment Short-course
FUP	: Follow-up
HRQOL	: Health Related Quality Of Life
IC	: Informed Consent
IP	: Intensive Phase
MDR-TB	: Multi-Drug Resistant Tuberculosis
PTB	: Pulmonary Tuberculosis
PRO	: Patient Reported Outcome
RNTCP	: Revised National Tuberculosis Control Programme
STS	: Senior Treatment Supervisor
STLS	: Senior Tuberculosis Laboratory Supervisor
WHO	: World Health Organization

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