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ORIGINAL ARTICLE

Impact of Pharmacist Assisted Patient Counseling for Improving Medication Adherence and Quality of Life in Pulmonary Tuberculosis Patients - An Educational Interventional Study

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ABSTRACT

Objectives: This study aimed to assess the impact of pharmacist-assisted patient counselling for improving medication adherence and quality of life in patients with pulmonary tuberculosis.

Methodology : This prospective educational interventional study was conducted in Bangalore's TB Units/DOTS centers to educate patients about TB and medication adherence. Patients were educated, and baseline QOL was measured using the WHO-BREF scale. High-risk patients were identified, and pharmacist counselling was implemented. The impact of counselling on adherence and QOL was also assessed.

Findings: A total of 164 individuals participated in the study, with 2 deaths and 5 dropouts, resulting in a final sample size of 157 patients. Among these 157 patients, 37 (23%) demonstrated adherence to the prescribed treatment, 20 (13%) were at risk of nonadherence, and 100 (64%) were classified as nonadherent. The impact of patient counselling on medication adherence was found to be significant (p < 0.0001). Additionally, patients' quality of life scores were affected, particularly in the physical domain, followed by the psychological domain. Following counseling, there was a statistically significant improvement in QOL scores, with a p-value of <0.0001*.

Novelty: Pharmacist-assisted patient counselling has a statistically significant impact on improving medication adherence and QOL in patients with pulmonary TB.

Keywords: Pulmonary Tuberculosis; Nonadherence; DOTS; QOL

INTRODUCTION

Tuberculosis (TB) continues to be a significant global infectious disease responsible for numerous deaths. Mycobacterium tuberculosis, which primarily affects the lungs, is the primary cause of TB infections. If left untreated or inadequately treated, TB can lead to progressive tissue damage, ultimately resulting in death[1]. In India, TB claims more adult life than any other disease[2]. In India, the highest prevalence of TB cases and deaths occurs among individuals between the ages of 15 and 60 years, encompassing the most economically active segment of the population. TB tends to affect a larger proportion of men than of women. While children have a lower incidence of TB than adults, they are at a higher risk of developing severe manifestations of the disease and may face fatal consequences if not provided with appropriate treatment[2].

Patients diagnosed with tuberculosis encounter a range of challenges, including physical, psychological, financial, and social issues. These difficulties significantly impact patients' overall well-being and can diminish their quality of life[3]. It is crucial for individuals with pulmonary TB to have a thorough understanding of the disease to facilitate recovery. This understanding should encompass the importance of consistent and complete adherence to the prescribed treatment regimen. Failure to comply with treatment poses a substantial risk as it can lead to the development of multidrug-resistant tuberculosis (MDR-TB). In fact, nonadherence increases the likelihood of MDR by 7.75 times when compared to patients who diligently follow their

treatment plan[4].

Currently, much focus in tuberculosis management is directed towards achieving microbiological cure, while the influence of this cure on the quality of life (QOL) is often overlooked or rarely taken into account. It is important to recognize that tuberculosis has a profound and comprehensive impact on the QOL of infected individuals[5]. QOL is an outcome parameter reported by patients, encompassing various dimensions of health, as perceived by the patients themselves, including physical, social, and psychological well-being. TB patients often experience both physical and mental distress, which can negatively impact disease prognosis and treatment effectiveness[4]. In the case of pulmonary tuberculosis, individuals typically exhibit a medical history that includes chest symptoms, such as cough (productive or non-productive), chest pain, and haemoptysis. These specific symptoms of pulmonary tuberculosis can further restrict a patient's ability to engage in work and social activities. In certain communities, patients with TB are viewed as a potential source of infection for healthy individuals, leading to social rejection and isolation. Social stigma and negative emotions associated with the illness can have a lasting impact on patients' psychological and social wellbeing. Consequently, this may result in prolonged absence from work, leading to decreased productivity and a reduction in monthly income[6].

Poor adherence to treatment increases the likelihood of drug resistance, treatment ineffectiveness, disease recurrence, fatalities, and prolonged contagiousness, all of which pose challenges for the effectiveness of tuberculosis initiatives. Factors such as therapy duration, medication side effects, alcohol limitations, perceived expenses, and access to healthcare facilities are acknowledged as obstacles that can influence adherence to medication[7]. Several reports and studies indicate that the primary reason for treatment failure in patients with pulmonary tuberculosis (PTB) is non-adherence to and lack of knowledge about anti-TB therapy. Pharmacists have the potential to contribute significantly to enhancing patient knowledge and compliance with anti-TB treatment. By focusing on improving the personal, interpersonal, and social systems of patients, adherence among patients with pulmonary TB can be effectively achieved[8]. Efforts such as providing health education to patients or their families are essential in mitigating the factors that impact adherence and treatment success rates, ultimately leading to higher rates of adherence and treatment success. QOL has emerged as a crucial tool for comprehending health outcomes through a patient-centered approach to care and treatment. Enhancing QOL requires the provision of comprehensive care and support to patients with tuberculosis (TB) during the initial two months of treatment, known as the Intensive Phase[9].

To improve treatment adherence, comprehensive health education, especially for patients at treatment sites, must be addressed. Pharmacist counselling leads to improved patients adherence[5,10–13]. Improving patients' knowledge can enhance their awareness of the illness and its potential complications, leading to greater compliance. It is inappropriate to generalize the results of counselling studies conducted in different diseases and countries in the local context because of cultural variations. Therefore, this study aimed to evaluate the influence of pharmacist-assisted patient counselling on medication adherence and Quality of Life in patients with Pulmonary Tuberculosis.

METHODOLOGY

This prospective educational interventional study involved 164 patients aged 18-80 years for a period of 1 year from September 2016 to April 2017 from Bangalore's TB/DOTS centers who received Category-I and Category-II anti-TB drug therapy for one month. The study was approved by the ethics committee and included demographic details, such as age, gender, marital status, family history, social history, locality, and educational status. Patients with TB who were unwilling to participate in the study were also excluded.

Case Report Form

A Case Report Form was created using the RNTCP DOTS-Plus guidelines, including patient demographics, contact information, diagnostic tests, medication details, and QOL measurements using the WHO-BREF scale, generating four domain scores: physical, psychological, Social Relationships, and environment.

Selection of DOTS Centres

Randomly selected TB Units from Bangalore- Rural (Hoskote), Urban (Varthur), and BBMP (Adugodi, Taverekare, and CoxTown) were included in the study.

Records from DOTS Centres

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

Procedure

The study was approved by the Institutional Ethical Committee at MVJ Medical College and Research Hospital, which educated patients about TB and medication adherence in each TB Unit. 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 revised national TB control program (RNTCP) treatment card for each patient. Medication adherence was assessed, and baseline QOL was measured using the WHO-BREF scale. The WHOQOL-BREF produces four domain scores: physical, psychological,

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social relationship, and environment. 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/her health. Domain scores are scaled in a positive direction (i.e. higher scores denote a higher quality of life). The mean score of items within each domain was used to calculate the domain score. Mean scores were then multiplied by 4 to make domain scores comparable with the scores used in the WHOQOL-100 and subsequently transformed to a 0-100 scale using a formula.

Patients who did not adhere to treatment and those who were at a high risk of nonadherence were identified. (The operational definition for Non-adherence: Those Patients who missed more than one dose of the anti-TB treatment; the patients at high risk of Non-adherence: Those following characteristics: Forgetfulness, Social stigma, Social Habits, Physical difficulty, comorbidities, inadequate knowledge, transportation cost, lack of support, and side effects). Factors and reasons affecting non-compliance were determined. Patient-centered pharmacist counselling was provided in their regional language to prevent non-adherence, both verbally and using educational aids and leaflets, and contact information was collected for follow-up purposes. Patients were reviewed and followed up for medication adherence, and QOL was assessed at the end of the Intensive Phase and two months after the Continuous Phase. Follow-up was performed either by visiting the DOTS center or by telephone. The impact of patient counselling on improving QOL and medication adherence was assessed using baseline and follow-up data. The results of the study were statistically analyzed using the JMP^{TM} 8.0. The inferential statistics comprised the paired t-test, Wilcoxon signed-rank test, and sign test.

RESULTS

This study included 164 patients from various TB Centres. Among them, 112 were patients with CAT-I and 52 were patients with CAT-II. Seven patients dropped out, with 2 of them passing away during the study. The remaining 157 patients were included in the study. (Table 1).

Socio demographic characteristics (n=157)

The study included 157 patients, from whom comprehensive demographic information, including age, gender, marital status, educational background, and social behaviours, was gathered. Of the total patients, 65% (n=102) were male and 35% (n=55) were female. (Table 1).

Age groups

Among 157 patients, majority were in the age group 25-44 years (n=79) 50 %, followed by the age group 45-64 years (n=38) 24%. Males were found to be more non-adherent

Table 1: Distribution of patients based on CAT-I and CAT- II, gender, medication adherence, marital status

Number of patients in CAT-I and CAT-II			
CAT-I	**CAT-II**	**Drop Outs**	**Total**
112	52	7	157
Distribution of patients based on gender (n=157)			
Gender	**n**	**%**	
Male	102	65%	
Female	55	35%	
Medication adherence in among males and females (n=157)			
Adherent Males	27	26%	
Non-adherent Males	75	74%	
Adherent Females	30	55%	
Non-adherent Females	25	45%	
Distribution of patients based on marital status			
Married	**Single**	**Widows**	**Divorced**
102 (65%)	42 (27%)	10 (6%)	2 (2%)

than females (Table 1).

QOL among males and females

Similarly, QOL was impaired in males when compared to females. The worst affected domain was physical domain. The most non-adherent age group was found to be 45-64 years and had a poor QOL in physical domain. However, the physical domain was most affected in the age group 5-14 years (Figure 1).
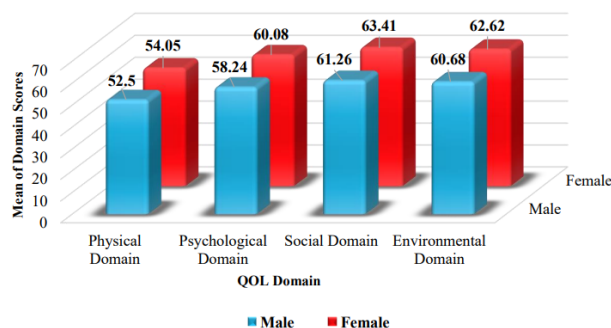

Fig. 1: QOL in male and female patients (n=157)

Marital status (n=157)

Of the enrolled 157 patients, 102 (65%) were married, 42 (27%) were single, 10 (6%) patients were widows, and 2 (2%) were divorced. Divorced patients were 100% non-adherent and had poor QOL in the psychological and physical domains (Table 1 and Figure 2).
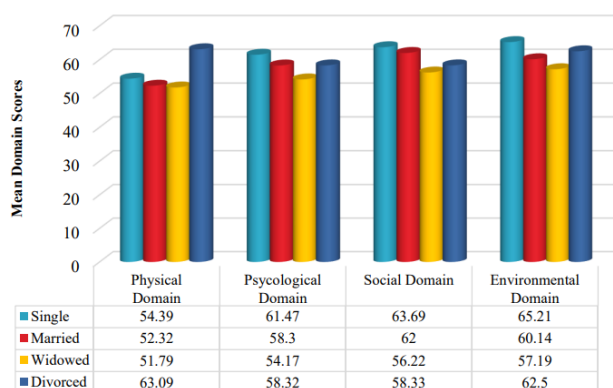

Fig. 2: QOL based on marital status

	Physical Domain	Psycological Domain	Social Domain	Environmental Domain
Single	54.39	61.47	63.69	65.21
Married	52.32	58.3	62	60.14
Widowed	51.79	54.17	56.22	57.19
Divorced	63.09	58.32	58.33	62.5

Educational status

From the study, we observed that the level of education was secondary in 40% of patients, followed by tertiary in 25%, primary school in 23%, and none in 12%. Non-adherence rates were higher in patients with tertiary education, followed by those who had no formal education. The most affected domain was the physical domain, which was highly affected in patients with primary education (Table 2).

Medication adherence based on social habits

Of the 157 patients, 23% were smokers, 15% were alcoholics, and 7% were both smokers and alcoholics. 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 had poor QOL (Table 2).

Sputum examination

Of the 157 patients, 92% were sputum positive, and the remaining 8% were sputum negative (Table 2).

Cat-I and Cat-II treatment

Among the 157 enrolled patients, the vast majority were undergoing CAT-I therapy and remained under CAT-II therapy. Among the patients, the majority were new cases, followed by relapse, default, and failure cases. Patients with CAT-II were found to be more non-adherent and had a poor QOL in the physical domain (Table 3).

Table 3: Distribution of patients based on type, co-morbidities, ADR, risk factors for medical adherence

Distribution of patients based on type

New	Relapse	Failure	Treatment after default	Others
108 (69%)	32 (20%)	5 (3%)	9 (6%)	3 (2%)

Distribution of patients based on co-morbidities

Co-morbidities	Number of patients (n=157)	Percentage (%)
Diabetes	24	15.29
Hypertension	11	7
Asthma	5	3.18
HIV	4	2.55
Thyroid disorder	2	1.27
Seizure	1	0.64
Psoriasis	1	0.64
None	109	69.43
Total	157	100

Distribution of patients based on ADR

ADR	No. of Patients (n=42)	Percentage %
Nausea	17	40.5
Vomiting	11	26.2
Diminished vision	5	11.9
Dizziness	9	21.4
Total	42	100

Distribution of patients based on risk factors for medical adherence

Factors (n=157)	Yes	No
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%)
Co-morbidity	48 (30.57%)	119 (69.43%)
Side effects	43 (27.39%)	114 (72.61%)
Forgetfulness	25 (15.92%)	132 (84.08%)

Table 2: QOL based on educational status, social habits, medication adherence based on social habits and sputum examination

QOL based on educational status				
Educational status	Physical Domain	Physiological Domain	Social Domain	Environmental Domain
None	53.79	56.29	55.99	59.03
Primary	50.60	56.57	59.28	59.29
Secondary	53.85	61.68	66.14	63.43
Tertiary	53.60	57.49	60.36	60.82
QOL based on social habits				
Social Habits	Number of patients (n=157)	Percentage (%)		
Alcoholic	26	16		
Smoker	36	23		
Both smoker and alcoholic	9	6		
Non-smoker Non-alcoholic	86	55		
Total	157	100		
Medication adherence based on social habits (n=157)				
	Adherent	Non-adherent		
Social habits	16 (23%)	55 (77%)		
None	41 (48%)	45 (52%)		
Distribution of patients based on sputum examination				
Sputum results	No. of patients (n=157)	%	Total (n / %)	
Smear positive	144	92 %	157 (100%)	
Smear negative	13	8 %		

QOL based on CAT-I and CAT-II with respect to co-morbidities

Various comorbidities were observed in 48 (30.57%) of the 157 enrolled patients. Diabetes, hypertension, and asthma were the most common comorbidities, with low incidences of HIV infection, thyroid disorders, seizures, and psoriasis. Patients with comorbidities had a poor QOL, particularly in the physical domain (Table 3).

Side-effects (n=42)
A few side effects were observed. The most common adverse drug reaction (ADR) was nausea and vomiting, followed by diminished vision and dizziness (Table 3).

Adherence status (n=157)

Of the 157 enrolled patients, the majority were non-adherent, a few were at risk of non-adherence, and the remaining patients were adherent (Table 3).

Risk Factors for Medication Adherence (n=157)

The study identified social stigma as the most common risk factor for nonadherence, followed by physical difficulty, social habits, transportation costs, lack of support, inadequate knowledge, side effects, and forgetfulness (Table 3).

Overall adherence status (n=157)

Of the 157 patients enrolled, 69% were found to be nonadherent and 31% were adherent at baseline. After patient counselling, there was an improvement in adherence status, and 69% of patients became adherent.

Medication adherence in cat-I patients (n=107)

This study analyzed medication adherence in patients with CAT-I and found a significant improvement after counselling (Table 4).

Medication adherence in cat-II patients (n=50)

The adherence status of patients with CAT-II was statistically analyzed separately. The results showed a statistically significant improvement in medication adherence after counselling (p-value in Table 4).

Table 4: p value calculated within pairs and among pairs

P Value	Within Pairs	Among Pairs
Medical adherence in CAT-I patients (n=107)	0.4152	< 0.0001
Medical adherence in CAT-I patients (n=50)	0.6208	0.3433
Overall QOL scores (n=157)	0.1289	<0.0001
QOL – Physical Domain (n=157)	0.0021	<0.0001
QOL – Psychological Domain (n=157)	0.0782	<0.0001
QOL – Social Domain	0.0019	<0.0001
QOL – Environmental Domain (n=157)	0.0327	<0.0001

Overall QOL score (n=157)

The overall QOL of the patients was impaired at baseline; after counselling, there was a statistically significant difference in the overall QOL (Table 4).

QOL scores of each domain (n=157)

This study assessed QOL scores in various domains, with the physical domain being the most affected, followed by the psychological domain, showing greater improvement after counselling (Table 4).

DISCUSSION

The outcome of treatment for tuberculosis is greatly influenced by adherence to anti-TB medication. In the current study, we examined how pharmacist-assisted patient counselling can enhance medication adherence and improve the quality of life of patients with pulmonary TB. Adherence was measured based on the number of missed doses using a method similar to that employed by Suparna B et al.[14]. However, they utilized a distinct operational definition for nonadherence. Among patients with TB, adherence rates were relatively low, with approximately 69% of the patients enrolled in the study being classified as non-adherent at the beginning.

The majority of tuberculosis research has focused on clinical results, with only a limited number of studies examining the effect of TB on a patient's QOL. Given that health is a fundamental human right and a global societal objective crucial for meeting basic human needs, enhancing the QOL of individuals affected by disease is of utmost significance.

The Short Form Survey (SF-36) has been extensively used as a primary tool for assessing quality of life in various communities and clinical settings across different countries. Its reliability and validity as a measure of QOL have been consistently demonstrated. In our study, we opted for the WHO BREF scale owing to its inclusion of the impact of disease on environmental factors, which is particularly crucial for diseases requiring long-term treatment. This scale was also employed by Nasara et al.[8], who compared QOL scores between patients with tuberculosis and the general population.

In the investigation, the most affected domains were the physical domain, which evaluates the effects of the disease on independence, daily activities, pain, reliance on medication, energy levels, sleep, mobility, and work capacity. This was followed by the psychological domain, which evaluated self-esteem, positive and negative emotions, physical appearance, and spirituality. This contrasts with previous studies by Olayinka OO et al.[15] and Abdullateef AG et al.[3], in which the environmental domain was found to be the most affected. Following counselling, there was a statistically significant improvement in these two domains (p<0.0001). However, the improvement in the psychological domain among patients was not as significant as that in the physical domain. This could be attributed to varying psychological factors among patients. Despite the intervention, there was no substantial improvement in the social and environmental domains compared to the other two domains. The environmental health domain evaluates financial resources, physical safety, quality of the home environment, access to health and social care, transportation, and leisure opportunities. The social relationship domain assesses social support, personal relationships, and sexuality. Therefore, patients facing travel-related and financial issues as well as those with poor home environments require special attention. Counselling of family members is also crucial for enhancing personal relationships.

In this study, women showed higher adherence levels than men. This finding is consistent with that of a study conducted at the Mumbai Municipal Corporation by Kulkarni PY et al.[16]. A possible explanation for this could be that women tend to be less inclined to take risks, leading to a higher likelihood of following the treatment guidelines. Moreover, quality of life (QOL) was reported to be better among females because of their higher adherence levels compared to males. This finding aligns with those of Olayinka et al.[15].

The age group most affected in this study consisted of patients aged 25-44 years. This aligns with a study conducted by Chukuma et al., in which the most affected age group was also 25-44 years[17]. Non-adherence to medication was found to be higher among those age group–45-64 years, followed by those aged 65 years or above. This finding differed from that of Chukuma et al's study, where there was a decreasing trend in medication non-adherence as the age of respondents increased, with the lowest proportion of missed drugs observed among patients above 65 years of age[17]. Additionally, the quality of life (QOL) domain scores were negatively impacted in these two age groups, particularly in the physical domain. However, among patients aged

5-14 years, the physical domain was the most severely affected. This could be attributed to disease-causing fatigue in children, preventing them from attending school or engaging in play with their friends. Consequently, their physical health is significantly affected.

According to a study conducted in Nigeria by Chukuma et al.[17], divorced and widowed populations showed a low adherence status. Furthermore, another study conducted by Abdullateef et al. found that this population had a lower quality of life score in the psychological domain than the single and married population[3].

In this study, it was observed that patients with tertiary education had higher levels of nonadherence. This finding contrasts with the results of a study conducted in Nigeria by Chukuma et al.[17], which showed that patients with tertiary education displayed better adherence. One possible explanation for this difference could be that individuals with tertiary education are part of the working population, making it challenging for them to visit DOTS centers three times a week because of their work commitments. On the other hand, patients with no formal education and those with primary education experienced an impaired quality of life. This could be attributed to the fact that many elderly patients fall into these educational categories, which leads to a decline in their quality of life. These results suggest that there is no significant correlation between educational status and adherence rates.

Alcohol consumption and smoking are considered risk factors for tuberculosis. Our research also revealed that individuals who engage in these behaviors tend to have low adherence to treatment, which is supported by a study conducted by Kulkarni et al.[17]. Additionally, these patients tend to have poor quality of life scores, particularly in the physical domain which is significantly affected.

In this study, patients had various comorbidities. The most prevalent comorbidity was diabetes, which affected 15.29% of the subjects. Hypertension was the second most common, affecting 7% of the subjects, followed by asthma (3.18%), and HIV (2.55%). Diabetes has been linked to higher rates of tuberculosis (TB), potentially owing to a weakened immune response mediated by T cells. At the individual level, HIV poses the greatest risk for TB, but at the population level, diabetes may be the most significant factor. A study conducted by Adane et al. revealed that HIV-coinfected patients face a high risk of non-adherence. Our own studies also indicated that nonadherence is prevalent among patients with comorbidities [20]. Additionally, TB patients with other comorbidities experience impaired quality of life (QOL) owing to the need for long-term treatment. The physical domain is the most severely affected, as patients' physical health is greatly compromised by multiple diseases. This is followed by the psychological domain, particularly in HIV-infected patients.

Most patients fell under the CAT-I classification. This study involved a statistical analysis of adherence levels among patients with CAT-I and CAT-II, separately. Patients with CAT-I exhibited higher adherence rates. Following counselling, there was a statistically significant improvement in adherence rates among patients with CAT-I. In contrast, patients with CAT-II showed lower adherence levels owing to a higher proportion of relapse and failure cases. Consequently, they may experience negative emotions, questioning the effectiveness of their treatment despite their medication intake. These patients displayed lower quality of life scores in the physical domain, followed by the psychological domain.

During the course of our investigation, patients reported experiencing certain side effects. The predominant symptoms are nausea, vomiting, dizziness, and diminished vision. A study carried out in Ethiopia by Adane AA et al. revealed that patients reported side effects, such as headache, dizziness, vomiting, skin rash, yellowing of the eyes, and changes in urine colouration[18].

We also investigated the group of patients who were more likely to not adhere to their treatment even though they were initially adherent. We also analyzed various factors that contributed to nonadherence. The primary risk factor we identified was social stigma, which was supported by a study conducted in Indonesia by Bagoes et al.[19]. Additionally, we observed other risk factors such as physical challenges, social habits, transportation expenses, lack of support from family and friends, insufficient knowledge, comorbidity, side effects, and forgetfulness.

The quality of life (QOL) of tuberculosis (TB) patients was also found to be compromised. QOL encompasses two questions regarding an individual's general view of their quality of life and their general view of their health. Following counselling, there was a statistically significant enhancement in overall QOL (p<0.0001). This outcome is consistent with that of the research conducted by Abhishek et al.[20]. This study underscores the significance of anti-TB therapy in enhancing QOL among patients with TB. Assessing the QOL of patients with TB is crucial to obtain a comprehensive understanding of the impact of the disease on various aspects of health.

This research indicates that patient counselling provided by pharmacists has a substantial impact on enhancing patients' understanding of their disease and medication as well as their adherence to prescribed therapy. This, in turn, contributes to the improvement of clinical outcomes in tuberculosis patients.

Furthermore, research indicates that pharmacists' involvement is crucial in the management of chronic illnesses. Clinical pharmacists can educate patients about their specific diseases and prescribed medications. The provision of patient education by pharmacists aids in enhancing patients' comprehension of their condition and

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medications, ultimately leading to improved healthcare outcomes.

In terms of the study's limitations, it should be noted that the sample size was relatively small to conduct a correlation study. Additionally, we encountered challenges related to study dropouts owing to factors such as migration and death. Medication adherence was assessed by reviewing the treatment cards at the DOTS center. However, we did identify discrepancies in the records of a few patients, as sometimes the medication would be marked as received, even if the patient had not actually taken it. Another limitation is the possibility that some patients may not have fully disclosed the truth, potentially impacting the findings of the study.

CONCLUSION

Pharmacist-assisted patient counselling significantly enhanced medication adherence and quality of life in individuals with pulmonary tuberculosis. Nevertheless, a more holistic strategy should be embraced to tackle travel-related issues, enhance patient education, involve the patient's family members in counselling, establish appropriate time intervals for patients consuming multiple medications, and offer specialized care for geriatric and paediatric patients.

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