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Impact of Pharmacist Counselling on Knowledge, and Medication Adherence in Tuberculosis Patients: A Quasi-Experimental Design

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Abstract: Medication adherence and knowledge towards tuberculosis management are very important to cure and to prevent resistant tuberculosis. The study aims to evaluate the impact of pharmacist delivered counseling services on knowledge and medication adherence levels of tuberculosis patients. This is a quasi-experimental design without control conducted in an infectious unit of a secondary care referral hospital located in rural settings of Anantapur district, India. The study protocol was approved by the institutional review board. A suitable data collection form was used to collect the knowledge and medication adherence levels of the study participants, A total of 258 smear positive pulmonary tuberculosis patients were recruited in the study. More than half of the participants belonged to male gender with a mean age of 48.1±15.3years. Majority of the participants had smoking and alcohol consumption habits (30.6%), coolie as occupation (37.9%), and no formal education (36.4%). The mean knowledge score was significantly improved from baseline to first follow-up, and first follow-up to second follow-up, and baseline to second follow-up visits with a P <0.05. There was a significant difference in the medication adherence levels measured by pill-count method at baseline, 1st follow-up, and 2nd follow-up visits with P <0.05. The study concludes that pharmacist mediated counseling in tuberculosis patient showed a significant improvement in knowledge and medication adherence levels from baseline to 1st and 2nd follow-up visits. Knowledge regarding causes, mode of transmission, symptoms, management and prevention of tuberculosis are most important to minimize spread of infection and drug resistance.

Keywords: Counselling, Medication adherence, Knowledge, Tuberculosis,

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I.   INTRODUCTION

Tuberculosis (TB) is an infectious disease caused by the bacillus called *Mycobacterium tuberculosis*. Globally, TB is a second leading cause of death after Human Immunodeficiency Virus (HIV) Infection.[1] World Health Organization (WHO) estimates that, there were 9.0 million new TB cases and 1.5 million TB deaths in a year.[2] The primary goal of WHO is to reduce the incidence and mortality of TB, but poor adherence to the Antitubercular regimen is a major barrier to achieve this goal.[3] Treatment of tuberculosis is very difficult which requires administration of multiple antibiotics for a long duration.[4] Medication non-adherence will delay the sputum conversion from positive to negative, increases relapse rate and drug resistance.[5] So, it is very important to estimate the rate of adherence to anti-tubercular drugs, to develop interventions to improve medication adherence. Unfortunately, there was no gold standard method to estimate medication adherence accurately. Pill-count method is an economical and reliable method to estimate the rate of medication adherence.[6] The main reason for poor adherence is patient's lack of knowledge about the disease, medications and their side effects.[7] Pharmacist plays an important role in patient counseling and should be able to give basic information to the patient about the disease, dosage, side effects, drug-drug and drug-food interactions which will improve the medication adherence.[8] The aim of this study is to identify the impact of pharmacist mediated patient counseling on medication adherence and knowledge towards tuberculosis and treatment among patients.

2.   MATERIALS AND METHODS

2.1.   Study site

The study was conducted in the infectious department of a secondary care referral hospital located in resource limited settings of Anantapur District, Andhra Pradesh, India

2.2.   Study design

This is a quasi-experimental design conducted to evaluate the effect pharmacist provided counseling service on knowledge and medication adherence levels in tuberculosis.[9]

2.3.   Study criteria

2.3.1. Inclusion criteria

Patients aged 12 years and above, irrespective of gender, who are diagnosed with smear-positive pulmonary tuberculosis under Isoniazid (INH), Rifampicin (RIF), and Pyrazinamide (PZA) in their treatment regimen. Patients must be undergoing ATT for at least one week

2.3.2. Exclusion criteria

Patients who are using second-line antitubercular drugs, and having co-morbidities, using drugs (e.g. phenazopyridine, triamterene, furazolidone, etc.) that interfere with the chemical urine tests were excluded from the study.

2.4.   Study duration

The study was conducted for a period of six months from April 2019 to September 2019.

2.5.   Ethical considerations

The study was conducted after getting ethical clearance from the Institutional Review Board (RIPER/IRB/2019/035). Oral and written consent was obtained from the study participants. Confidentiality of the participants' identifiers was maintained during and after completion of the trial.

2.6.   Sample size

The sample size for the tuberculosis trial was calculated as 258 by considering the 5% of medication adherence raised after the intervention, 80% of power, 95% confidence interval, and 5% of precision.

2.7.   Study procedure

Patients who met the study criteria were enrolled and subjected to assess demographic characteristics, baseline medication adherence and knowledge towards tuberculosis by using a suitable data collection form. After getting baseline information, patients were educated about etiology, signs and symptoms, mode of transmission and complications of tuberculosis. Patients were also educated about antitubercular therapy, duration, possible side effects, and importance of medication adherence by using patient information leaflet (PIL). All the patients were advised to attend two follow up sessions which were conducted in a three months interval in order to assess the improvement of medication adherence and knowledge towards tuberculosis after counselling.[10]

2.8.   Outcome measurement

The questionnaire was adapted from the WHO template and data were collected by administering questions directly to the patients in their understandable language. The knowledge questionnaire contains 14 questions related to knowledge regarding pulmonary tuberculosis (TB), Multidrug resistant (MDR-TB) tuberculosis, extra drug resistance tuberculosis (XDR-TB), signs and symptoms, mode of transmission, risk groups, diagnostic tests, preventive measures, curability of TB, location of treatment, frequency of TB clinic visit required, approximate cost of TB treatment, duration of TB treatment, and most common side effects of anti-tubercular drugs. The knowledge of the participants was assessed at baseline, 1st, and 2nd follow-up visits.[11]

2.9.   Medication adherence assessment

Medication adherence levels were measured at baseline, 1st, and 2nd follow-up visits by using pill count method.[12]

3.   STATISTICAL ANALYSIS

Socio-demographic characteristics of the study participants were represented in descriptive statistics like frequency, mean, proportion, and standard deviation. One-way ANOVA and paired t test were used to compare the knowledge and medication adherence levels. P-value less than 0.05 was considered as statistically significant value. Epi-Info statistical software given by the Center for Disease Control (CDC) was used for data analysis.

4. RESULTS

The findings of the study revealed that, more than half of the participants belonged to male gender with a mean age of 48.1±15.3. Majority of the participants had the habit of smoking and alcohol consumption (30.6%), coolie as occupation (37.9%), and no formal education (36.4%) as shown in Table 1.

Table 1: Socio-demographic and clinical characteristics of the study population (n=258)	
Variable	Frequency (%)
Gender	
Male	143 (55.4)
Female	115 (44.6)
Age (Mean ± SD)	48.1 ± 15.3
20-29	35 (13.5)
30-39	50 (19.4)
40-49	78 (30.2)
50-59	58 (22.5)
60-69	29 (11.2)
≥ 70	8 (3.1)
Lifestyle habits	
Smoking	68 (26.3)
Alcohol consumption	25 (9.7)
Both	79 (30.6)
Tobacco chewing	22 (8.5)
None	64 (24.8)
Occupation	
Coolie	98 (37.9)
Farmer	72 (27.9)
Business	29 (11.2)
Housewife	44 (17.0)
Professional	15 (5.8)
Education	
No formal education	94 (36.4)
Primary school	78 (30.2)
Secondary school	36 (13.9)
Diploma	22 (8.5)
Degree or above	28 (10.8)

Knowledge regarding tuberculosis, transmission, symptoms, diagnosis, treatment, and prevention was greatly improved from baseline to first and second follow-up as shown in Table 2.

Table 2: Knowledge towards tuberculosis and its management (n=258)			
Question	Baseline No. (%)	First FU No. (%)	Second FU No (%)
Have you ever heard about tuberculosis before your diagnosis?	98 (37.9)	200 (77.5)	250 (96.9)
What is MDR-TB?	88 (34.1)	187 (72.5)	232 (89.9)
What is XDR-TB?	86 (33.3)	184 (71.3)	230 (89.1)
What are the signs and symptoms of TB?	92 (35.6)	197 (76.3)	243 (94.2)
How a person gets infected by the TB organism?	90 (34.9)	189 (73.2)	239 (92.6)
Who are at high risk in the development of TB?	89 (34.5)	178 (68.9)	228 (88.4)
What laboratory tests are available to diagnose TB?	92 (35.6)	183 (70.9)	234 (90.7)
What are the preventive measures for TB?	78 (30.2)	176 (68.2)	232 (89.9)
Can TB be cured?	80 (31.0)	183 (70.9)	239 (92.6)
Where can TB be cured?	74 (28.7)	167 (64.7)	254 (98.4)
What is the frequency of visit to TB clinic	78 (30.2)	176 (68.2)	236 (91.5)
What is the approximate cost of TB treatment?	64 (24.8)	178 (68.9)	233 (90.3)
What is the duration of TB treatment?	68 (26.3)	172 (66.7)	231 (89.5)
What are the most common side effects of antitubercular drugs?	70 (27.1)	178 (68.9)	234 (90.7)

The mean knowledge score was significantly improved from baseline to first follow-up, and first follow-up to second follow-up, and baseline to second follow-up visits as shown in Table 3. Paired t test was used to compare the mean knowledge scores.

Table 3: Comparison of mean knowledge level from baseline to 1st follow-up, 1st to 2nd follow-up, and baseline to 2nd follow-up visits		
Baseline to 1st follow-up		
Mean knowledge at baseline	Mean knowledge at 1st follow-up	P-value
5.22±2.37	10.32±2.53	<0.0001
1st to 2nd follow-up		
Mean knowledge at 1st follow-up	Mean knowledge at 2nd follow-up	P-value
10.32±2.53	12.43±2.59	<0.0001
Baseline to 2nd follow-up		
Mean knowledge at baseline	Mean knowledge at 2nd follow-up	P-value
5.22±2.37	12.43±2.59	<0.0001

There was a significant difference in the medication adherence levels at baseline, 1st follow-up, and 2nd follow-up visits as shown in Table 4. Medication adherence levels were measured by using pill-count methods. One-way ANOVA statistical tool was used to compare the medication adherence levels.

Table 4: Medication adherence levels at baseline and follow-up visits					
Group (BL or FU)	Avg. number of drugs prescribed per day	Average number of drugs prescribed per month	Average number of drugs remaining per month	Average number of drugs consumed per month	Mean percentage (SD) of medication adherence	*P*-value
Baseline	3.26	98.01	10.00	87.18	87.41±6.23	<0.0001
1st FU	3.40	99.12	5.58	93.31	92.83±3.77	
2nd FU	3.58	107.19	0.66	106.42	98.88±1.34	

5.   DISCUSSION

This study was designed to assess the knowledge and medication adherence in tuberculosis patients. Non adherence to the treatment is the major obstacle in the control of tuberculosis. Sometimes, patients take their medication irregularly which causes treatment failure and relapse; this can result in drug resistant tuberculosis. Drug resistant TB is more difficult to treat; it increases length of treatment, cost and adverse drug reactions. To overcome this difficulty, patient counseling by a clinical pharmacist is the effective method. In this study pill-count is used for the determination of medication adherence. This method is easy to perform and cheaper to conduct and was used to assess compliance. At 1st and 2nd follow up, the findings showed significant increase in medication compliance in tuberculosis patients. At baseline, majority of the patients were non-adherent because of fear of ADRs, this can be overcome by effective patient counseling among tuberculosis patients. The results were nearly similar to the study conducted by Sajjad et al.[11] In this study maximum numbers of patients were illiterates, and they didn't have awareness on tuberculosis. Because of lack of awareness, the disease can easily be transmissible when people have direct contact with infected persons. Hence it is very essential to educate the patients regarding the disease and its prevention. In our study, the disease is more prevalent among male patients because of their lifestyle habits like smoking, alcohol consumption and tobacco chewing. The results are nearly similar to the study conducted by Alavi-Naini et al.[13] The present study revealed that most of the participants didn't have information about tuberculosis. In the current study, some patients heard about tuberculosis from their relatives who were affected with TB in the past, some of them heard from television. Results of this study showed that many of the patients don't know the actual cause of tuberculosis, only a few patients answered the question. In that some patients correctly answered the cause of TB as being bacteria and some of them told smoking and alcohol consumption as the cause of disease and this knowledge increases after education. Most of the patients were aware of signs and symptoms and mentioned productive cough, fever, weight loss as major signs and symptoms of tuberculosis. But patients aged more than 60yrs were not able to tell at least signs and symptoms of TB which they are experiencing. In this study, more than half of people don't know how to prevent getting TB. Only some of the educated persons told about prevention and knowledge about the prevention is high after counseling by the pharmacist. Counseling was given to patients and their caretakers on prevention of disease, and observed that their knowledge increased in follow up visits. Similar findings are also observed in the study conducted by Tachfouti et al.[14] Most of the participants of the study didn't know whether TB is curable or not. A study conducted by the 'Jangobhati', reported that, most of the study participants answered that TB is curable and treatable with modern drugs. In contrast, in the present study, very few patients answered correctly during the baseline visit. However, the situation was completely opposite after patient counseling by the clinical pharmacist. In the present study, all patients got TB medicines free of cost through DOTs, so most of them were not aware about the cost of treatment. Patients who were on CAT 1 therapy were included in this study, no one knows about MDR TB and XDR TB. Awareness on MDR TB, XDR TB and cost of the treatment was increased after baseline follow up through patient education. Similar type of findings are also observed in the study conducted by Tola et al.[15] The results of medication adherence and knowledge assessment suggest that patients at baseline possess poor knowledge about disease and medication. This is due to inadequate information about the disease and management, patient's poor interest in knowing about their disease management and medication adherence. Results suggest that patients possess poor adherence at baseline, this is due to lack of knowledge, social status etc., first and second follow up shows great improvement in patient's knowledge, attitude and practice. This is due to pharmacist intervention.

5.1   Strengths and Limitations

The study provides insights for the pharmacist mediated counseling services in tuberculosis management policies to

improve knowledge and medication adherence levels. This is a quasi-experimental design without control, so the outcome may be modified by the confounders like age, prior knowledge levels, disease duration, education, and economic status. Pill-count method is an indirect measure used to assess medication adherence. Sometimes, patient may intentionally lie about reminder pills. This will introduce the bias in medication adherence estimate.

6.   CONCLUSION

Patients' knowledge and adherence towards tuberculosis management were significantly improved after providing counseling services by the pharmacist. Increased knowledge levels of patients can improve patient's awareness about disease and risk of complications, so that patients become obedient in taking medicine. A good co-operation among patient, health professionals, patient's family, community and government is needed to bring 100% adherence rate towards tuberculosis treatment. This will help in prevention of the non-adherence induced multi-drug resistant tuberculosis.

7.   ACKNOWLEDGEMENT

8.   AUTHOR CONTRIBUTION

All authors made a substantial contribution in conception and design, and/or acquisition of data, and/or analysis and interpretation of data. GN and BP are involved in manuscript writing, drafting and reviewing of the manuscript. All authors are agreed to publish revised manuscript.

9.   CONFLICT OF INTEREST

Conflict of interest declared none.

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