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## Assessment of clinical pharmacist intervention to improve compliance and health care outcomes of tuberculosis patients

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### ABSTRACT

Tuberculosis is defined as "highly contagious infection caused by the bacterium called *Mycobacterium tuberculosis*". Symptoms are usually associated with a persistent cough lasting for two or more weeks with thick mucus, which may be bloody, breathlessness, unusual weight loss, lack of appetite, night sweating, fever, fatigue. Patient education helps to assist the patient, in identifying and preventing the Pulmonary Tuberculosis (PTB) and help them in using their medication appropriately. Patient education is important in Indian setup because many patients are illiterate and comes from low socio-economic background. The prime reasons identified for prognosis are inadequate education to patients, poor adherence to the medications. The nine months prospective study was conducted and enrolled patients were randomly divided in to two groups i.e. Intervention and Control groups. Out of 120 patients enrolled, 114 patients completed the study. Among 114 patients 81 (71.06%) were males and 33 (28.94%) were females. Comparatively the knowledge and drug adherence score of the Pulmonary Tuberculosis (PTB) patients of intervention group shows more improvement from baseline to I and II Follow ups which is statistically significant than the control group. Sputum examination outcomes: out of 114 patients, 46 (80.71%) were had turned sputum positive to negative in Intervention group, 25 (43.86%) were had turned sputum positive to negative in control group. The study concludes that pharmacist provided patient education found to have significant influence on patients compliance and health care outcomes.

**Key Words:** Tuberculosis, Pulmonary Tuberculosis, Knowledge, Adherence, Patient education, Patient Information Leaflet (PIL).

### INTRODUCTION

Tuberculosis (TB) is a leading communicable disease caused by Tubercle bacillus, known as *Mycobacterium tuberculosis*.<sup>1</sup> Tuberculosis is classified into Pulmonary Tuberculosis (PT) and Extra Pulmonary Tuberculosis (EPTB). According to the result of sputum smear examinations pulmonary tuberculosis is classified as:

- pulmonary tuberculosis sputum-smear positive;
- pulmonary tuberculosis sputum-smear negative.

Extra Pulmonary tuberculosis (EPTB): is a type of tuberculosis, which affects organs other than lungs such as pleura lymph nodes, abdomen, genitourinary tract, skin, joints, tubercular meningitis and tuberculoma of brain etc.<sup>2</sup>

Tuberculosis is one among most serious infectious causes of all global mortality and morbidity. It causes a great deal of ill health and enormous burden on population of most low and middle income countries.<sup>3</sup> TB remains one of the leading infectious disease causes of mortality in India, causing more than 331,000 deaths in 2007. One-third population of the world continuous to be infected with tuberculosis. There were approximately 1.96 million new TB cases in India in 2007, representing more than 21% of all TB cases worldwide India has more new tuberculosis cases annually than any other country, ranking first among the 22 high burden TB countries worldwide, according to the World Health Organization's (WHO's) Global TB report 2009.<sup>4,5</sup>

The compliance/ adherence are similar terms. Compliance is the extent to which the person's behavior in terms of taking medication, following diets or executing life style changes coincides with the medical or health advisers. The factors related to low compliance include psychiatric disorders (the more symptoms reported, the lower adherence), and treatment factors, such as the duration of the treatment, the number of medications prescribed, the cost, and the frequency of dosing. The other factors contributing to the non-compliance include patient's unresolved concerns, including diagnosis, absence of symptoms, time between drug and its effect, and the fear of adverse effects.<sup>6</sup>

Effective treatment of tuberculosis requires compliance to a minimum of 6 months treatment with multiple drugs.<sup>7</sup> The clinical pharmacist can improve the compliance by patient education including confirming the information that the patient had already received. Written instructions and/or patient information leaflets may be offered in addition to verbal counseling if there are any doubts as to the patients understanding.<sup>8</sup> An individual level of adherence include competing demands on time, knowledge of tuberculosis and preventive therapy, intention to take medication, importance of treatment related to social issues and social support. High self esteem has been associated with the improved adherence.<sup>9</sup>

A study conducted by Mohamed AI, et al. on 'Knowledge of Tuberculosis: A Survey among Tuberculosis Patients in Omdurman, Sudan' shows that the main reason for the treatment failure is mainly due to non compliance to treatment, deficient patient knowledge/ health education.<sup>10</sup>

Health care outcomes are a change in the health status of an individual, group or population which is attributable to a planned intervention or series of interventions, regardless of whether such an intervention was intended to change health status<sup>11</sup>. The broad aims of outcomes research are the assessment of disease, its effects, and its treatment from the point of view of the patient.<sup>12</sup>

Several reports and studies suggest that the treatment failure in Pulmonary Tuberculosis patients is mainly due to the lack of knowledge and non-compliance towards the prescribed therapy. The pharmacist can play a major role in improving the patient knowledge and compliance towards the TB therapy. Hence, in this project titled "Assessment of clinical pharmacist intervention to improve compliance and health care outcomes of tuberculosis patients" an attempt is made to improve the patient compliance towards the pulmonary tuberculosis by educating patients, which will help to improve health care outcomes.

**General objective:** To assess the impact of clinical pharmacist intervention to improve the compliance and healthcare outcomes of Pulmonary Tuberculosis (PTB) patients.

**Specific objective:**

- To improve the patients disease and medication knowledge.
- To minimize the default rate (non adherence).
- To improve the sputum conversion rate.

## MATERIALS AND METHODS

**Study Site:**

The study was carried out at department of medicine, HKES's Basaveshwar Teaching and General Hospital (BTGH), Gulbarga, which is a 765 bedded tertiary care hospital.

**Study design:**

A hospital based prospective study.

**Study duration:**

The study was carried out for a period of 9 months

**Study criteria:** Pulmonary tuberculosis patients admitted in department of medicine were enrolled in to the study after taking their consent and by considering following inclusion and exclusion criteria.

**Inclusion criteria:**

- Patients of either sex suffering with pulmonary tuberculosis.
- Patients with sputum positive.
- Patients willing to participate in the study.

**Exclusion criteria:**

- Patients with Extra pulmonary tuberculosis.
- Patients not willing to participate in the study.

**Source of data:**

- Case sheets of In-patients.
- Laboratory reports of Patients.

**Ethical Clearance:**

The study protocol was submitted to the Mahadevappa Rampure Medical College (MRMC) ethics committee on human subject research and applied for ethical clearance. The study was approved by institutional ethics committee and issued ethical clearance certificate.

**Informed Consent Form:**

A patient informed consent form was prepared and from the selected patients, the informed consent was obtained and enrolled into the study.

**Study materials:**

The following study materials were prepared and used for the study.

**Patient Data Collection Form:**

A suitably designed patient data collection form was prepared by referring standard text books and journals, which include information of patient demographic details such as age, gender, education, social status, duration of disease and medication history.

**➤ Knowledge Assessment Questionnaires (KAQ):**

A suitably designed KAQ were prepared by referring standard textbooks, journals articles and other internet sources. The questions were concerned to general information about disease, symptoms, etiology, purpose and adverse effects of medicines and medication usage technique.

**➤ Medication Adherence Assessment Questionnaires (MAAQ):**

A suitably designed MAAQ were prepared by referring Morisky Medication Adherence Questionnaires (MMAQ).

**Patient Information Leaflet (PIL)(English & Kannada):**

PIL on pulmonary tuberculosis were prepared by referring internet resources, textbooks and journals. PIL includes general information about etiology, signs and symptoms of PTB, management of PTB and instructions to patient regarding usage of medicines.

**Study procedure:**

After obtaining the approval from the ethical committee and from the department of medicine, the study was initiated at medicine department by selecting the patients based on inclusion and exclusion criteria of the study. The patients of pulmonary TB with sputum positive were briefed about the study and enrolled into the study after obtaining consent from the patient. All the patients enrolled in the study were randomly divided into two groups i.e. Intervention and control groups.

**Knowledge & medication adherence assessment:**

**Baseline assessment:** The baseline knowledge and adherence of the patients was assessed by means of knowledge assessment questionnaires and medication adherence questionnaires at their first visit and after this control group patients were provided PIL. Intervention group patients were educated through by video films charts and systematically counseled by one to one interaction. All the patients were advised to attend two follow up sessions, which were conducted with an interval of six weeks.

**I follow up:** During the second visit (6 weeks after baseline visit) the knowledge of the both groups patients towards disease and medication adherence was assessed by means of knowledge assessment questionnaires and medication adherence questionnaires.

After assessment of knowledge and medication adherence at I follow up, the deficit in knowledge and adherence of the intervention group was noticed and again they were systematically counseled and educated.

**II follow up:** During the third visit (6 weeks after first follow up) the knowledge of both group patients towards disease and medication adherence was reassessed by means of knowledge assessment questionnaires and medication adherence questionnaires.

After assessment of knowledge and medication adherence at II follow up, the deficit in knowledge and adherence of the intervention group were noticed and again they were systematically counseled and educated.

**Table 1: Demographic details of the Patient:**

Sr.No.	Particulars	No. of Patients (n=114)
01	<b>Gender</b> Male Female	<b>81(71.06%)</b> <b>33(28.94%)</b>
02	<b>Age (in years)</b> Bellow 10 11-20 21-30 31-40 41-50 51-60 Above 61	2 (1.75%) 12 (10.52%) 18 (15.78%) 17 (14.91%) 12 (10.52%) 27 (23.67%) 26 (22.80%)
03	<b>Education</b> Illiterate School Pre-University University	40 (35.09%) 46 (40.35%) 15 (13.16%) 13 (11.40%)
04	<b>Duration of TB</b> Newly Diagnosed Less than one year More than one year	71 (62.78%) 18 (15.21%) 25 (21.93%)
05	<b>Occupational Status</b> Agriculture House wife's Old aged Students Private Service Govt. Servants Bossiness Others	24 (21.05%) 28 (24.56%) 28 (24.56%) 07 (6.14%) 16 (14.3%) 03 (2.63%) 03 (2.63%) 05 (4.38%)
06	<b>Regional Status</b> Urban Rural	43 (37.71) 71 (62.28%)

**Pattern of scoring:** The knowledge and medication adherence assessment score were given on the basis of number of questions answered correctly and each correct answer was given 1 score.

**Sputum reports:** After 6 weeks of second follow up, sputum samples of both groups were tested by Acid Fast Bacilli (AFB) test to know sputum conversion.

**Statistical analysis:**

The data collected was analyzed by the ANOVA test.

**RESULTS**

A total of 120 pulmonary tuberculosis patients were enrolled into the study, out of which, 114 patients have completed the study of which 81 (71.05%) were male patients and 33 (28.95%) were female patients. Remaining six patients did not turn up for the follow up. The data of only those patients who completed the study were analyzed.

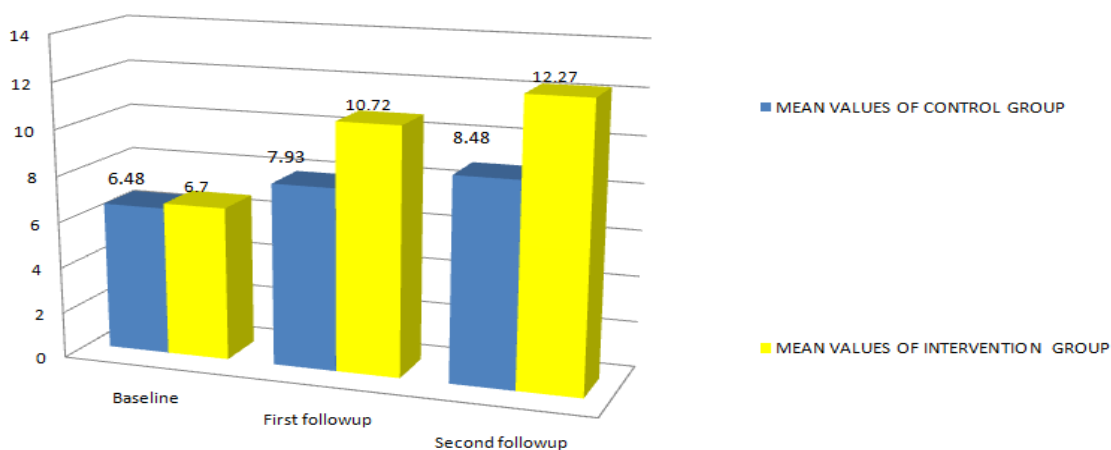
Patient's knowledge and adherence score were analyzed by using ANOVA test. From baseline, first follow up and second follow up of intervention & control groups revealed 'p' value is  $P < 0.0001$ , which is statistically significant. Patient's knowledge and adherence score of baseline, first follow up and second follow up for Control group revealed value  $P < 0.0001$ , which is statistically significant.

Patient's knowledge and adherence score of baseline, first follow up and second follow up for Control group revealed value  $P < 0.0001$ , which is statistically significant.

**Table 2: Knowledge and drug adherence score of interventional group and control group patients**

	Mean Baseline Score	Mean I follow up score	Mean II follow up score	P-Value	Significance
Intervention Group	6.7	10.72	12.27	$P < 0.0001$	Significant
Control Group	6.8	7.93	8.84	$P < 0.0001$	Significant

In intervention group improvement percentage from baseline follow up to first follow up is 10%, baseline follow up to second follow up 16%, first follow up to second follow up is 6%. In control group improvement percentage from baseline to first follow up was 9.66%, baseline follow up to second follow up was 15.73%, first follow up to second follow up was 6.07%.

**MEAN VALUES OF CONTROL & INTERVENTION**

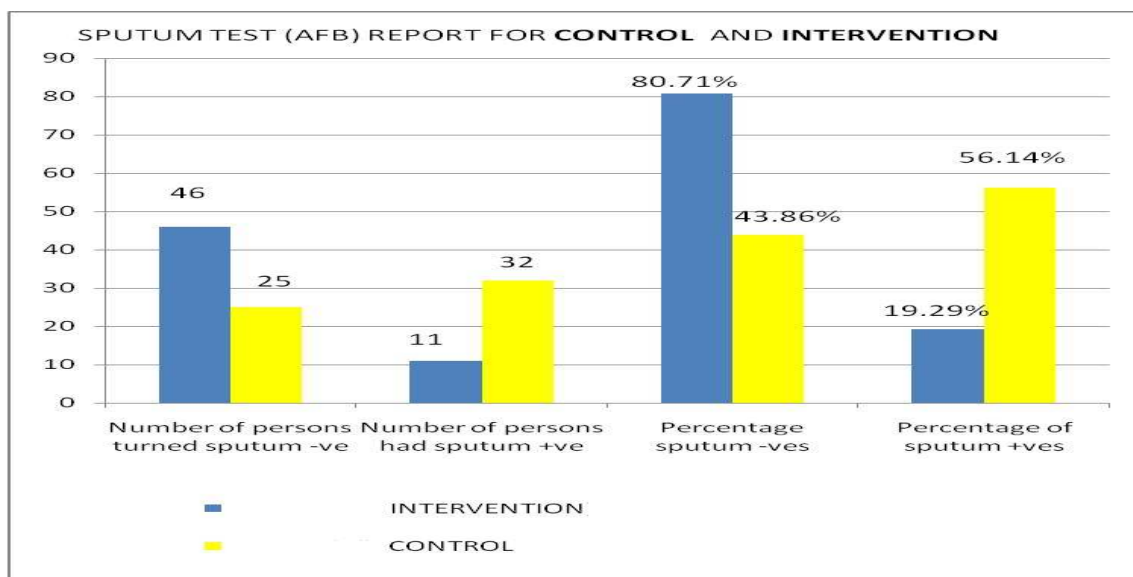
**Figure 1: Knowledge and drug adherence score of interventional and control group patients**

**SPUTUM EXAMINATION OUTCOMES:**

The sputum examination by AFB shows that in intervention group, out of 57 patients 11(19.29%) patients had sputum positive and remaining 46(80.71%) patients turned to sputum negative, where as in control group out of 57 patients 32(56.14%) patients are still sputum positive i.e more than half, remaining 25(43.86%) patients are turned to sputum negative.

**Table 3: Final sputum AFB test report for control and intervention groups**

SPUTUM EXAMINATION BY (AFB) (REPORTS)				
Group	Number of persons turned sputum+ve to -ve	Number of persons had sputum +ve	% of sputum – ves	% of sputum +ves
Group A (INTERVENTION)	46	11	80.71%	19.29%
Group B (CONTROL)	25	32	43.86%	56.14%

**Figure 2: Final sputum AFB test report for control and intervention groups**

In final sputum examination, control group sputum positive to sputum smear negative conversion accounts for 43.86%. Intervention group sputum smear positive to sputum smear negative conversion accounts for 80.71% which shows pharmacist intervention played an important role for the patients improvement and conversion rate.

## DISCUSSION

The prevalence of pulmonary tuberculosis was shown to be more in primary education and illiterate patients; this may be due to lack of knowledge about their disease, medication and support.

The study result shows counseling sessions conducted by clinical pharmacist were able to produce a statistically significant improvement in knowledge of the patient towards their disease and medication adherence. Similar study was carried out by GOVT of Iraq Tuberculosis control<sup>13</sup> in which they found intervention group patients had higher scores in Tuberculosis knowledge.

Another study conducted by Frederick AD kaona *et al*<sup>14</sup>. on Assessment of factors contributing to treatment adherence and knowledge of TB transmission among patients on TB treatment. It was concluded that the main reason for non adherence was lack of knowledge towards their medication and medication adherence.

The results of medication & adherence knowledge assessment suggest that patients at the baseline for both control and intervention possess poor knowledge of their disease and medication. This may be due to inadequate information about the disease and medication, patient's poor interest to know about their disease management and importance of medication adherence.

Both groups showed statistically significant improvement in knowledge and medication adherence from baseline assessment to I & II follow ups. Comparatively intervention group is statistically more significant because of higher improvement of patient's knowledge and medication adherence, than control group.

The results of knowledge and medication adherence assessment suggest that patients at the baseline possess poor medication adherence and this may be due to various reasons like lack of knowledge, their negligence, social status etc. In first follow up both groups showed improvement than base line but intervention group showed highly prominent improvement than the control group. In second follow up intervention group showed great improvement than control group. This is due to clinical pharmacist intervention with the intervention group.

Finally sputum examination by AFB test shows that, the conversion rate of sputum positive to negative in intervention group shows 80.71%, control group shows 43.86%. The main reason for the well improved conversion rate of intervention group may be due to clinical pharmacist intervention.

### CONCLUSION

In this study the results shows the impact of clinical pharmacist in improving the pulmonary tuberculosis patient's knowledge towards their disease and medication and also adherence to prescribed therapy by means of structured counseling.

The study concludes that pharmacist provided patient education 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 TB patient's i.e conversion rate of sputum positive to negative.

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. Pharmacist provided patient education helps in better understanding of their disease and medication, which will improve the health care outcome of the patient.

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