Effectiveness of Knowledge Based Approach for the Provement of Patient Adherence and Reducing the Severity of Adverse Drug Reaction in Anti Tubercular Therapy

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Research Article

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Abstract

To study the effectiveness of knowledge based approach for the improvement of patient adherence and reducing the severity of adverse drug reaction in anti tubercular therapy in the pulmonology department of an 800 bedded hospital at Coimbatore.

Both in patients and outpatients who received the treatment for Tuberculosis (TB) aged between 16 to 75 years was included in this study. A prospective observational study was conducted over a period of 6 month from July-December 2011. Patients were informed to check their LFT, once every 15 days of two months and to come for three reviews during the intensive phase of the therapy.

A total of 60 patients were enrolled, out of which 50 males and 10 females. And it was evident that males were more prone to TB than females. Most prominent age group was '46-60' comprising of 27 (45%) patients, with 58% patients having smoking habit. 95 % of patients diagnosed with PTB. All the patients were having the cardinal signs of TB and got counselling by the clinical pharmacist using patient information pamphlet. 12% of patients who couldn't answer the scheduled questionnaire were re-counseled. 1st review by 100% patients, 2nd review by 96.60% and 3rd review by 90% of total patients. Most of the subjects were uneducated and with a poor living standard. All the 100% of patients with high living standard came for all the review. Occurrence of ADR influences the patients from stopping the ATT. Hepatotoxicity was found to be the major ADR. Distance to the study clinic was also found to be influencing the adherence of the patient. From our study it was concluded that the clinical pharmacist can exhibit a vital role during the

TB therapy in TB centers, pulmonology departments and DOTS centers to guarantee a better patient therapeutic outcome.

Introduction

Tuberculosis (TB) is the most prevalent human infections and causes more deaths worldwide than any other infectious disease. Tuberculosis (TB) is the leading communicable disease among the ten cause of global mortality. It is caused by Tubercle bacillus, known as *Mycobacterium tuberculosis*, and more rarely Mycobacterium bovis whose host is human.[1] Tuberculosis is on the rise throughout the world. Better understanding and knowledge about TB remains an important tool in its control. [2]

Estimates show that approximately one third of the global population is infected and 8 million new cases of TB occur each year, leading to nearly 3 million deaths annually. The World Health Organization (WHO) reported that, TB is almost exclusively a disease of the developing countries.[3] The direct and indirect cost of TB to India amounts to an estimated $23.7 billion annually. Studies suggest that on an average three months of work time is lost as a result of TB.[4]

The shortest duration of treatment is generally 6 months, and 2 to 3 years of treatment is necessary for cases of multi drug resistance TB (MDR TB). As it is a long term treatment vigilant follow up is required to improve the treatment outcome. [5] The female: male ratio is 2:5 among new smear-positive cases registered for treatment.[3]

A single patient can infect 10-15 people in a year.[6] Despite the availability of effective treatment, TB is still a major health problem in most of countries. The poor out-come was accredited to **poor patient adherence**, and to interruption partly due to **adverse drug reaction** (WHO, 1997).[3] Non-compliance is cited as a major obstacle to the control of tuberculosis at the level of public health. It is also a serious problem in the treatment of individual patients and in the development of drug resistant strains**.**[7]

After several decades of research, we have learned that medication non-adherence is due to many factors including lack of adequate knowledge about medication and treatment goals, beliefs about the medication, complex regimens that are difficult to manage, side effects, and costs associated with medications.[8] Also more patient centered interventions and superior concentration to structural barriers are needed to improve treatment adherence.[9]

The failure to take prescribed medication is a universal perplexing phenomenon.[10]

Disease characteristics have also been shown to influence adherence. Non adherence may be more common among patients with:•Chronic illness rather than acute illness•Greater disability created by the disease• Resolution of disease symptoms, because patients who are no longer symptomatic feel that they don't have to continue the medications .[11]

The influence of side effects – real, anticipated or interpreted on compliance to treatment was mentioned in a number of studies. Some patients reported stopping medication due to adverse effects while others complained that they were not educated about side effects and what to do to counter those.[12]Counseling of patients for timely hindrance, revealing and management of ADRs was also highly suggestive.[13]

ROLE OF PHARMACIST IN ATT- AS A PART OF HEALTH CARE TEAM

Patients understanding of their treatment regimen can influence their adherence behavior. Therefore, patient education can be awfully effectual response to many of the difficulties in getting patients to adhere to a complete course of TB therapy Adherence to treatment may be best understood as a set of interrelated behaviors that includes cognitive formulation of a personal understanding of why pharmacotherapy is prescribed; interpersonal skills to communicate effectively with health care providers; and practical skills related to medication taking.[14]

The pharmacist should educate patients on the importance of continuing their chemotherapy despite symptomatic improvement. Pharmacists should become a part of multidisciplinary band (with nurses, physicians, social workers) devoted to successful chemotherapy of TB patients and their families.[5]

Patients counseled by pharmacists were more likely to be very satisfied with information provided about adverse effects As well, patients found the written information provided by pharmacists more meaningful when used in conjunction with the pharmacist's counseling.

Considering all the above aspects, a patient information pamphlet was introduced in the Pulmonology department and the study entitled "Effectiveness of Knowledge based approach for the improvement of patient adherence and reducing the severity of Adverse Drug Reaction in Anti Tubercular Therapy" was carried out. Both the physician and clinical pharmacist were equally participated to improve the enhanced therapeutic outcome in TB therapy by aiming the complete patient care. A thorough education by the pharmacist regarding the treatment and drugs and the possible adverse drug reactions were given.

Material and Method

STUDY DESIGN: It is a prospective observational study
STUDY CRITERA:-
INCLUSION CRITERIA:-Both in patients and outpatients who received the treatment for Anti Tubercular Therapy and aged between 16 to 75 years.
EXCLUSION CREITERIA:-
• Patients who referred to their nearest clinic or physician for continuation of the treatment after diagnosing from the present study site.
• Patient with MDR TB.
• Psychologically ill patients.
• Patient with co-morbidity.
DURATION OF STUDY:-
• Six months.
STUDY SITE:-Department of Pulmonology, Kovai Medical Center and Hospital, Coimbatore.
STUDY POPULATION:-
• All Patients who are diagnosed with TB and aged between 16 to 75 years.
STUDY PERIOD: Study conducted over a period of 6 month from July-December 2011.
STUDY TOOLS USED:
• A self prepared data entry form of the patient.
• A patient information pamphlet which was evaluated and validated by the physicians. This is the main study tool for this study, which is particularly prepared for understanding the seriousness of the ADR by the patient. The pamphlet provide the information's on TB, possible ADR during therapy and the emergency contact number of both the physician and pharmacist to report ADR by the patient itself once if they suspect the ADR.
• A knowledge evaluating questionnaire prepared on the basis of patient information pamphlet.

Results and Discussion

The study was carried out in the pulmonology department of Kovai Medical Center and Hospital at Coimbatore, over a period of 6 months from July to December 2011. A total of 60 patients were incorporated in the study. Of the whole population 50 (83%) were inpatients and 10 (17%) were outpatients. Among the total population, 50 (83%) were male and 10 (17%) were females. It is found that males were more prone to tuberculosis when compared to females with a ratio of 8:2. A study conducted by Mahmood I et al., reveals that the pervasiveness of tuberculosis is more in males than females with a ratio of 5:1. Also the NTP summarized as the ratio of the occurrence of TB between the male and female were 5:2.[3] One of the study performed by Jaggarajamma K

et al., has the identical outcome alike to ours in case of the gender wise occurrence of the TB, which contributes that a 7:2.5 ratio of male and female incidence of TB.[10] Not only these studies some other studies also point out that the TB is more prone to male gender.[13,15,16,17] According to RNTCP status report (TB India 2006) TB affects habitually in young adults with an age range of 25-34.[18] A descriptive study executed by Habib-ullah K et al., reveals that the mean age group for TB occurrence is 42.10±20.38.[16] The mean age of the TB patients from the study population of Marra F et al., were also found to be 49.9±20.[19] Both of these two studies were supporting to the current study outcome. Out of the study population, 35(58%) patients were having the smoking habits. Out of the total study population, all the 60 (100%) patients showed the symptom of persistent cough for many days followed by fever for 25 (41.66%) patients; haemoptysis for 17(28.33%) patients, weight lose for 13(21.66%) patients, cold for 4 (6.66%) patients, chest pain for 3(5%) patients and breathlessness for 2 (3.33%) patients.

Some of these are the cardinal clinical features of PTB such as chronic cough, weight lose, haemoptysis and night sweat. About 83.6% of patients were having cough and weight lose in the study done by Bello SI and Itiola O A.[1] Evaluation of the knowledge concerning the information's in pamphlet after the primary counseling shows that out of 60 patients, 53 (88%) patients were answered correctly . Remaining 7 (12%) patients were not answered correctly and who were re-counseled. The patients demonstrated a high level of knowledge of their medication regimens, which illustrates the benefit of additional support provided by pharmacists.[20]

Among the full population 60(100%) patients came for the first review 58(96.60%) patients came for the second review and 54(90%) patients came for the third review. According to study by Susanne Moadebi etal.,[18] the reasons for poor adherence are multifaceted and complex, and include lack of knowledge about medications and their side effects. No association of review pattern and the literacy levels of the patients in our study. A study conducted by Anupa K C etal.,[15] also shows the similar result where there is no significant relation between the educational level of the patients and review patterns. Among the full population 15 (25.00%) patients experienced at least one ADR during the time of study period. Out of 16 ADRs 6(37.50%) were elevated liver enzyme/vomiting, which is most prominent followed by chest pain with 3(18.75%) patients. At the end of two month follow up of the study it was found that total 6 (10%) patients were dropped out of the study during the intensive phase of ATT due to non compliance.

It was observed that 54 (90%) patients were adhered to treatment till the completion of intensive phase, which is a great level of adherence and this is directly related to the knowledge based approach and the good communicative patient care system in our study.

Conclusion

A patient information pamphlet named as "THINGS TO BE NOTICED WHILE TAKING MEDICINES FOR TUBERCULOSIS" was already prepared which was used in the current study which includes the essential information regarding therapy, possible ADRs during the ATT and the emergency number to contact in case of any emergency due to adverse drug reactions or to take prior booking for the next review. A well experienced and skilled pharmacist counseled the patients with the help of scheduled pamphlet and enables the patients to adhere with the ATT and deal with the possible ADRs.

Entirely 60 patients were included in our study. Tuberculosis was predominant in males. Our study found that TB occurred chiefly in age group of "46-60". Majority of them had PTB. Most of the patients needed hospitalization (83%) during the initial phase of the study. A total of 58% patients had smoking habit which could be a result of increasing the risk of infection with TB mycobacteria in these individuals. Smoking can decrease the immunity or damage the functioning of cilia in the airways which may increase the risk of getting infected easily.

Most of the patients were presented with cardinal signs of TB such as cough, haemoptysis and weight lose. In our study all the patients got the counselling from the well experienced clinical pharmacist with the help of a pamphlet and the knowledge was assessed by giving them a knowledge evaluation questionnaire. And 7 patients who failed to answer properly were re-counseled by the clinical pharmacist. So that they could understand the treatment properly and adhere to ATT.

A total of 60 patients that is entire population came for the first review and 50 (90%) patients came for the third review which is a very good response from the patients still to achieve full adherence further possible steps should be taken. Out of 60 patients 40 were having no education or a primary education where as rest of the patients were well educated. However no significance was found between education and review pattern of the patients in our study.

Living standard of the majority of the patients were found to be poor or average which could be a reason for getting infected by the TB mycobacterium as they may be undernourished, increasing the rate of active TB. Where as when comparing the review pattern by these patients it was found that the patients with high living standard have 100% adherence with ATT who came for all the three review during the intensive phase of treatment.

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A total number of 16 ADRs were reported by 15(25%) patients with one patient reported with two ADRs. It was found that hepatic biliary system were the major spot for the incidence of ADR. It showed that 67% of ADRs occurred within the 15 days of ATT and day by day the incidence of ADRs was decreasing. Occurrence of adverse effects or unawareness about how to deal with the ADRs may influence the patients from stopping the ATT and finally the occurrence of drug resistance. There plays the role of a pharmacist where he can implement a good patient care by providing information about the treatment and possible ADRs and what to do if any of them is suspecting. As a pharmacist, we have the liability to support the patients during the periods of ATT, while they were suffering these kinds of unwanted effects of the drug. Amplified healthcare cost. If a proper educational system is implemented like our study, most of the patients were ready to adhere with the treatment with 90% of adherence and there by increasing the therapeutic outcome.

In our study totally 6(10%) patients were dropped out of intensive phase of the ATT out of which majority were living very far from the study center. So it is clear that that patient who stays near to the clinic shows more compliance with ATT.

A good constitutional system of communicational approach to the patient by group effort of the pharmacist and physician with the aim of complete patient care will aid for early detection of the ADRs of any drug and can trim down the incidence and severity of the same. Since DR is the major emerging problem during ATT, implementation of well communicated system like pharmacist counselling will help to hoist the patient's self-assurance in the treatment and reduced incidence of DR.

One recommendation of this study is to implement a new-fangled call system along with knowledge based approach by a pharmacist, which alarms the patient to come for the next review in right time for a better adherence.
In this prospective observational study, it is suggested that the clinical pharmacist should exhibit their vital role during TB therapy in TB centers, pulmonology departments and DOTS centers to guarantee a better patient therapeutic outcome.

Acknowledgement

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AUTHORS' CONTRIBUTIONS

Authors contributed equally to all aspects of the study.

PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests