### IJPSR (2012), Vol. 3, Issue 07





# INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH



Received on 24 March, 2012; received in revised form 23 April, 2012; accepted 21 June, 2012

# A COMPARATIVE STUDY OF DOT AND SAT IN RURAL TERTIARY CARE HOSPITAL: A TWO YEARS RETROSPECTIVE STUDY

Jagadish Babu D.\* and K. Jyothi

Department of Clinical Pharmacy, SAC College of Pharmacy, Karnataka, India

#### **ABSTRACT**

#### Keywords:

DOT,

SAT,

**Tuberculosis** patients

#### **Correspondence to Author:**

#### Jagadish Babu D.

Sri Adichunchanagari College of Pharmacy, Department of Clinical Pharmacy, B.G.nagara-571 448, Mandaya District, Karnataka, India Directly observed therapy (DOT) of tuberculosis patients talking their drugs is supposed to improve treatment completion and outcome .we compared DOT and Self Administered therapy (SAT), in which patients on the same drug regimen are not, observed taking their pills, to assess the effect of each on the success of tuberculosis treatment. This was the two year (2010 and 2011) retrospective study of tuberculosis patients admitted to the AH and RC.A total of 308 patients cases were analyzed. The majority of the cases were within 21-40 years TB patients were 38.96% of the total. Among the all TB patients with chronic illness others were 18(58.44%) more. Among 308 patients TB patients 131(42.53%) TB patients undergone DOT and 177 (57.46%) TB patient's undergone SAT therapy. The comparative outcome between DOT and SAT were 110(86.61%) of cure and in SAT were 90 (57.32%). Only 5(03.93%) treatment failure, acquired drug resistance 01(00.78%), follow up lost were 11(08.66%) in DOT as compared to SAT 23(14.64%), 06(03.82%), 23(14.64%) respectively. There is no relapse and death in DOT therapy but in SAT therapy relapse were 10(06.36%) and deaths were 05(03.18%). There were large and significant difference in the cure, treatment failure, relapse and death rates between TB patient who receive DOT and SAT therapy respectively.

**INTRODUCTION:** Directly observed treatment, shortcourse (DOTS) was introduced in India in 1993 as part of the revised national tuberculosis control programme (RNTCP), following a review of India's National Tuberculosis Programme (NTP) a year earlier. The dots strategy has five components: political will, diagnosis by microscopy, regular supply of drugs for short-course treatment, direct observation of treatment (dot), and systematic monitoring <sup>1</sup>.

Tuberculosis (TB) is a global health concern, with an estimated 8.9 million new cases worldwide in 2004. It is a major contributor to the burden of disease, especially in low- and middle-income countries <sup>2</sup>.

The world health organization (who, 2008), has estimated that 8 to 10 million people catch the disease every year, with 3 million dying from it. It causes more deaths worldwide than aids and malaria combined, and it is the world's biggest killer of women.

TB 'blackspots' include Eastern Europe, with 250,000 cases a year, south East Asia, with 3 million cases a year, and sub predicts that if left unchecked TB will kill 35 million people in the world by 2025 <sup>3</sup>. The introductory article by Zwarenstein *et al.*, is the first randomized trial of dot against self-administered therapy to compare adherence and outcome <sup>4</sup>.

Dot was defined as ingestion of anti-tuberculosis medications that was directly supervised by a healthcare worker. Dot took place at either the tuberculosis clinic, or the patient's residence or workplace. Self-administered therapy (sat) was defined as unsupervised administration of anti-tuberculosis medications by patients as prescribed by their provider

Dot seeks to improve the adherence of people to tuberculosis treatment through health workers, family members, or community members directly observing them taking their anti-tuberculous drugs. This approach was first adopted in studies in madras, India, and Hong Kong as early as the 1960s and a number of specialists now widely recommend dot for the control of tuberculosis <sup>6</sup>.

The principal objective of Directly Observed Therapy (DOT) is to cure the individual patient and to minimize the risk of transmission of TB to other people.

# **Objective:**

- To compare therapeutic outcome of DOT and SAT.
- To assess the frequency of DOT ad SAT.
- To minimize the risk of transmission of TB to other people.

## Methodology:

**Study Site:** DOT center of Sri Adichunchanagiri Hospital and Research Center, B.G. Nagara, Karnataka, India.

**Study Type:** A retrospective study was carried out using hospital records for cases of pulmonary TB.

**Study Period:** This study was conducted for a period of two years from 2010 to 2011.

**Study Population:** The study population comprises patients screened for pulmonary TB within the two year period (2010 to 2011).

**Study Analysis:** Descriptive statistics such as mean, tables, graphs and charts were used to analyze the data.

**Study procedure**: This study is carried out in DOT center of Adichunchanagiri Hospital and Research Center, B.G. Nagara, Karnataka, India. Before conducting the study we took Ethical Committee Clearance and collected the patient data from the medical records of DOT center. We collected the cases of past two years from 2010 to 2011 and we assessed the therapy outcomes in both DOT and SAT patients. We collected the required information from the SAT patients by regular follow ups in between the treatments.

RESULTS AND DISCUSSION: According to Figure 1, which showed that steady decrease in the number of admissions during 2010-2011, the number of TB admissions during the year 2010 (193 cases) followed by 2011 (115 cases). There was a steady decrease in the number of admissions from 2010 to 2011. The year 2010 had the highest number of admissions with 193 cases followed by 2011 with 115 cases. This decrease in TB cases is due to awareness about DOT program, Proper treatment regimens and following of proper hygienic conditions like personal hygienic as well as surroundings.

In 2010 more number of TB cases were due to very easily spreading of TB due to spitting of sputum and contamination with sputum, lack of awareness regarding vaccines, lack of treatment adherence, lack of knowledge regarding DOT, crowding, which leads to various sanitation and health problems. A dirty environment and malnutrition can both make a person more susceptible to TB infection. The larger number of admissions could also be due to increased awareness of TB among patients and their health seeking behavior.

The most common age group infected was 21-40 years old (n=120; 38.96%), followed by the 41-60 year old age group (n=79; 25.64%). The age group with the fewest cases was age 0-20 years old (n=18; 5.84%). As shown in the **table 2 and figure 2**. The majority of cases (64.6%) were in the 21-60 year old age group. The reason for this could be the patients who were working were exposed to infections from their work environment. Similar findings were found in the study conducted by Jetan CA *et al.*, that the age groups between 21-60 years were having TB.

**Fig. 3 and table 3** show the types of illnesses suffered by patients with tuberculosis. The majority (58.44%) suffered from other illnesses like chronic obstructive airway disease, pneumonia, cancer, HIV and patients with TB, followed by hypertension (16.55%) and 3.24% suffered from hypertension with diabetes mellitus with ischemic heart disease. Whereas, in study conducted by Jetan CA *et al.*, shows that more number of patients was having hypertension, diabetes mellitus and ischemic heart disease <sup>7</sup>.

According to the **table 4 and figure 4** shows that among 308 patients, 131(42.53%) patients undergone Directly Observed Therapy and 177(57.46%) patients undergone self administered therapy.

We found that a substantial proportion of patients in a DOTS programme more than 40% did not actually receive treatment under observation. Unawareness regarding DOT, illetaracy, advanced age/infirmity and fear of social stigma were the primary reasons given for not participating in DOT. Patients not receiving DOT were strikingly more likely to have treatment failure, relapse and deaths as compared to the patients on DOT.

The overall outcomes in DOT was favorable in 110 patients (cured) 86.61% of cases. There were 3 unfavorable outcomes (5 treatment failure, one acquired resistance to drugs, 11 lost follow-up) 13.39% of cases. There were no deaths and relapse of the disease found. As in SAT, was favorable in 90 patients (cured) 57.32% of cases. There were 5 unfavorable outcomes (23 treatment failure, 6 acquired resistance to drugs, 23 lost follow-up, 5 deaths and 10 relapse of the disease ) 42.68% of cases found as shown in table 5 and figure 5.

Similar findings found in the study conducted by Balasubramanian VN *et al.*, showed that Patients treated without direct observation have a substantially higher risk of adverse outcome than those treated under direct observation <sup>1</sup>.

This study shows that patients with tuberculosis treated by DOT at the start of therapy had significantly higher cure rates compared with those treated by SAT at the start. Patients treated by DOT were not having tuberculosis-related mortality.

TABLE 1: NUMBER OF TB ADMISSIONS DURING THE YEAR 2010-2011 (n=308)

Year	Frequency	Percentage		
2010	193	62.66		
2011	115	37.33		

**TABLE 2: NUMBER OF TB ADMISSIONS BY AGE GROUP** 

Age group	Frequency	Percentage			
00-20	18	05.84			
21-40	120	38.96			
41-60	79	25.64			
61-80	61	19.80			
81-100	30	09.74			

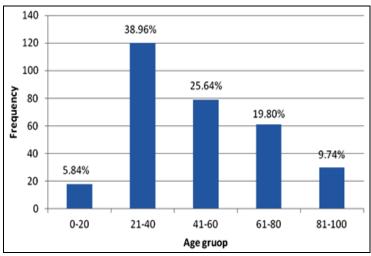


FIGURE 2: NUMBER OF TB ADMISSIONS BY AGE GROUP

**TABLE 3: TYPE OF CHRONIC ILLNESS PATIENTS WITH TB** 

Chronic illness	Frequency	Percentage
HTN	51	16.55
DM	40	13.00
HTN+DM	27	08.76
HTN+DM+IHD	10	03.24
Others	180	58.44

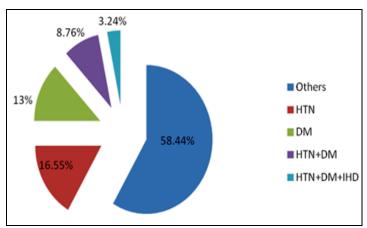
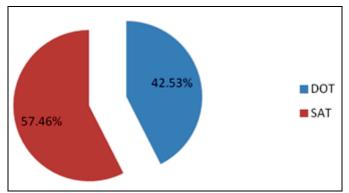


FIGURE 3: TYPE OF CHRONIC ILLNESS PATIENTS WITH TB

**TABLE 4: TYPE OF THERAPY** 

Type	Frequency	Percentage		
DOT	131	42.53		
SAT	177	57.46		



**FIGURE 4: TYPE OF THERAPY** 

TABLE 5: DIRECTLY OBSERVED THERAPY AGAINST SELF ADMINISTERED THERAPY OUTCOMES

Outcome	DOT	Percentage	SAT	Percentage
Cure	110	86.61	90	57.32
Treatment failure	05	03.93	23	14.64
Acquired resistance to drugs	01	00.78	06	03.82
Follow-up lost	11	08.66	23	14.64
Relapse	00	00.00	10	06.36
Death	00	00.00	05	03.18

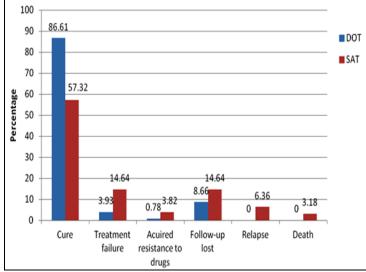


FIGURE 5: DIRECT OBSERVATION THERAPY AGAINST SELF ADMINISTRATION THERAPY OUTCOMES

**ACKNOWLEDGEMENTS:** Authors are very thankful to Doctors of Adichunchanagari Hospital & Research center (AH&RC), B.G. Nagara, for their kind support. Our sincere thanks to Dr. B. Ramesh, Principal of Sri Adhichunchanagiri College of Pharmacy, B.G. Nagara, Staff and students of Clinical Pharmacy Department.

**CONCLUSION**: We conclude that the directly Observed therapy from start of therapy have greatest success in improving TB treatment outcomes as compared to self administered therapy and there were no relapse and death in DOT therapy as compared to SAT therapy. The limitation of our study is that Sputum smear test was not undergone in TB patients. And we did not randomly assign patients to DOT or SAT.

#### REFERENCES:

- Balasubramanian VN, Oommen K, Samuel R. DOT or Not? Direct Observation of Anti-Tuberculosis Treatment and Patient Outcomes. Int J Tuberc Lung Dis 2000; 4(5):409-13.
- Munro SA, Lewin SA, Smith HJ, Engel ME, Fretheim A, Volmink J. Patient Adherence to Tuberculosis Treatment: A Systematic Review of Qualitative Research. PLoS Medicine 2007; 4(7):1230-45.
- Imam TS, Oyeyi TI. A Retrospective Study of Pulmonary Tuberculosis (PTB) Prevalence amongst Patients Attending Infectious Diseases Hospital (IDH) In Kano, Nigeria. Bajopas 2008; 1(1):10-15.
- 4. Ormerod LP. Directly observed therapy (DOT) for tuberculosis: why, when, how and if. Thorax 1999; 54(Suppl 2):S42–S45.
- Jasmer RM, Seaman CB, Gonzalez LC, Kawamura LM, Osmond DH, Daley CL. Tuberculosis Treatment Outcomes Directly Observed Therapy Compared with Self-Administered Therapy. Am J Respire Crib Care Med 2004; 170: 561-66.
- Volmink J, Garner P. Directly observed therapy for treating tuberculosis. Cochrane Database of Systematic Reviews 2007, Issue 4. Art. No.:CD003343. DOI:10.1002/14651858.CD003343. nub3.
- 7. Tuberculosis: An Eight Year (2000-2007) Retrospective Study At The University of Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia. Southeast Asian J Trop Med Public Health. 2010 Mar; 41(2):378-85.

#### How to cite this article:

Babu J.D. and Jyothi K.: A Comparative Study of DOT and SAT in Rural Tertiary Care Hospital: A Two Years Retrospective Study. *Int J Pharm Sci Res*, 2012; Vol. 3(7): 2283-2286.

\*\*\*\*\*\*\*\*\*\*