

## INDICATION OF PROGNOSIS AND HEALTH RELATED QUALITY OF LIFE IN PATIENTS ON DOTS THERAPY AT TB UNIT IN NORTH KERALA

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Article Received on  
28 August 2018,

Revised on 18 Sept. 2018,  
Accepted on 08 October 2018

DOI: 10.20959/wjpr201818-11529

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### ABSTRACT

Direct Observation Therapy Short Term (DOTS) is a medication course initiated by WHO for treating tuberculosis across the globe. Hence it is a six month course, our study is focused on the effectiveness of the treatment in various patients who are receiving the medication at least for 2 months. **METHOD** A multicenter study was carried out over a period of six months at DOTs center of tertiary hospital and nearby Govt. Taluk Hospital. Patients who are taking the DOTs regimen were included for the study. Sputum conversion, weight gain, adverse events and treatment discomfort are taken as the main criteria to evaluate the quality of life of patients in this study.

**RESULT** Total 55 patients were enrolled out of which 44 (74.5%) are males and 11 (25.5%) were females. The maximum number of cases was seen in the age group of 41 – 50 years, about 11 (20 %) (7.3%) and the least number of patients were observed in the age category of 0 – 10 (1.8%) about 1 patient. Out of 55 patients, 44 (80%) of them shows smear negative as result and 11 (20%) shows smear positive and 36 (65.5%) of them has gained weight, 14 patients (25.5%) maintained their weight on DOTs therapy. 55 patients were ruled out and 14 (25.5%) were able to complete the course and shows complete sputum conversion and increased weigh hence improving overall quality of the life of the patients. **CONCLUSION** The study shows that men are more prevalence than women and also observed that uncomplicated side effect like skin rashes, vomiting and itching are seen in some patients. Rifampicin induced urine discoloration is the most predominant Adverse event during DOTs therapy. Overall health related quality of life of patients on DOTs therapy increases after

completing the treatment course. While considering the whole findings we attain a conclusion that with proper follow up we can improve the quality of life and patient compliance during dots therapy.

**KEYWORDS:** Tuberculosis, DOTs therapy, HRQOL, Sputum conversion, Weight gain, Adverse drug reaction.

## INTRODUCTION

Tuberculosis is an infectious disease that may affect almost any tissue of body, especially the lungs, caused by the organism mycobacterium tuberculosis, and characterized by tubercle. Tuberculosis remains a leading infectious killer globally. TB caused by Mycobacterium tuberculosis, which can produce either a silent or a progressive active disease. Untreated or improperly treated TB causes progressive tissue destruction and eventually death. A rough estimate suggest that one third of the world population is affected with TB.

Mycobacterium tuberculosis is a bacteria which is the main micro-organism causing TB in humans. Several health practices were implemented by the developed countries to control TB. Unfortunately many of these practices are not widely available in developing countries such as India. Thus the TB remains a life threatening disease in such a scenario. Globally, roughly 2 billion people are infected by *M. tuberculosis*, and roughly 2 to 3 million people die from active TB each year despite the fact that it is curable. The most pronounced symptoms of TB is weight loss and the term “wasting disease” is also used to indicate TB. Other symptoms include Coughing that lasts three or more weeks, Coughing up blood, Chest pain, or pain with breathing or coughing, Fatigue, Fever, Night sweats, Chills, Loss of appetite.

Direct Observed Therapy (DOTs) is a specific strategy, endorsed by the World Health Organization, to improve adherence by requiring health workers, community volunteers or family members to observe and record patients taking each dose. To evaluate DOTs compared to self-administered therapy in people on treatment for active TB or on prophylaxis to prevent active disease. Trials included DOTs at home by family members, community health workers (who were usually supervised); DOTs at home by health staff; and DOTs at health facilities. TB cure was low with self-administration across all studies. In four trials that compared DOTs at home by family members, or community health workers, with DOTs by

health workers at a health facility there was little or no difference in cure or treatment completion.

## REVIEW OF LITERATURE

A cross-sectional questionnaire survey was conducted by Cheng-Ting Li *et al.*<sup>[5]</sup> among 206 pulmonary TB patients who had completed DOTs and 214 individuals without TB, from July to September 2012. HRQOL was measured using the Short Form (36) Health Survey (SF-36). The patients with TB had a statistically significantly higher physical component summary (PCS) score and mental component summary (MCS) score on the SF-36 than the comparison group after adjustment for background characteristics. However, the differences did not exceed the 3-point threshold for clinically significant differences. Multiple linear regression showed that older age and presence of persistent symptoms after completion of DOTs were related to a lower PCS score in TB patients. Patients who were smear-positive before DOTs treatment had higher MCS scores than those who were smear-negative.

In-depth interviews were planned by Himanshu Negandhi *et al.*<sup>[6]</sup> across six districts of three purposively selected states of Maharashtra, Bihar and Sikkim, among health system personnel at various levels to identify their perspectives on adoption of a daily regimen for TB. These districts were sampled on the basis of TB notification rates. Thematic analysis of the qualitative data was undertaken. 62 respondents were interviewed from these 6 districts. During the analysis, it was observed that an easily accessible, patient-center and personalized outreach is an enabling factor for adherence to treatment. Lack of transportation facilities, out-of-pocket expenses and loss of wages for accessing DOTs at institutions are major identified barriers for treatment adherence at individual level. At program level, lack of trained service providers, poor administration of treatment protocols and inadequate supervision by health care providers and program managers are key factors that influence program outcomes.

## MATERIALS AND METHOD

A multi-centered study was carried out in patients, who are receiving DOTs therapy at tertiary hospital and nearby Govt. Taluk hospital. *Inclusion criteria:* All TB patients visiting TB centers for DOTs therapy are included irrespective of their age and sex. *Exclusion criteria:* Patients those who are taking TB treatment other than DOTs therapy are not selected for the study.

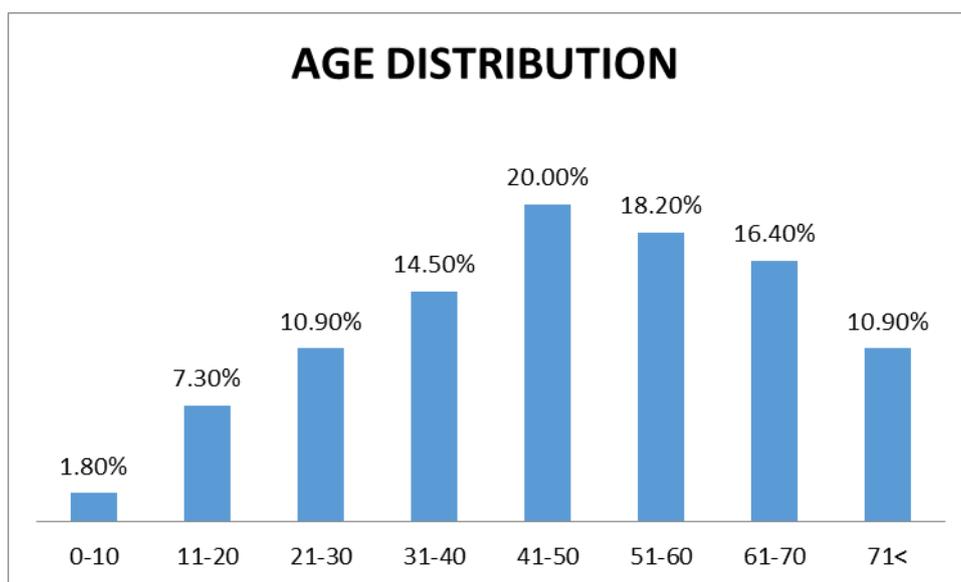
The study was approved by Institutional Human Ethics Committee of Academy of Pharmaceutical Sciences, Pariyaram Medical College. Prospective data was collected with a suitable data collection form. With the help of the form, patient demographic data such as age, gender, weight, height, past medication history will be recorded. Institutional review board and patient consent will be obtained.

## RESULT

A total of 55 patients who had satisfied the inclusion criteria were enrolled in the study.

### AGE DISTRIBUTION

The maximum number of cases was seen in the age group of 41 – 50 years, about 11 (20%) patients falls in this category, the second highest number was observed in the category 51 – 60 years about 10 patients (18.2%), the third maximum number of patients were found in the age band from 61 – 70 years which contains a frequency of 9 (16.4%), fourth maximum number of patients were in the age band of 31 – 40 years about 8 patients (14.5%), while the age band of 21 – 30 and above 70 years of age shared the same value (10.9%) which is having a frequency of 6 patients, followed by 11 – 20 years about 4 patients (7.3%) and the least number of patients were observed in the category of 0 – 10 (1.8%) about 1 patient.



### GENDER DISTRIBUTION

The study was conducted for 6 months and a sample size of 55 patients was achieved. Out of the 55 patients 41 patients (74.5%) were males and 14 (25.5%) of them were females. It is because most of the males are having daily waged job and they have to contact with multiple

persons and have more exposure to the disease and to the environment. Where females are less exposed to the disease and their frequency is also less. Life style is also a factor for the disease.

GENDER	FREQUENCY	PERCENTAGE
MALE	41	74.5 %
FEMALE	14	25.5 %

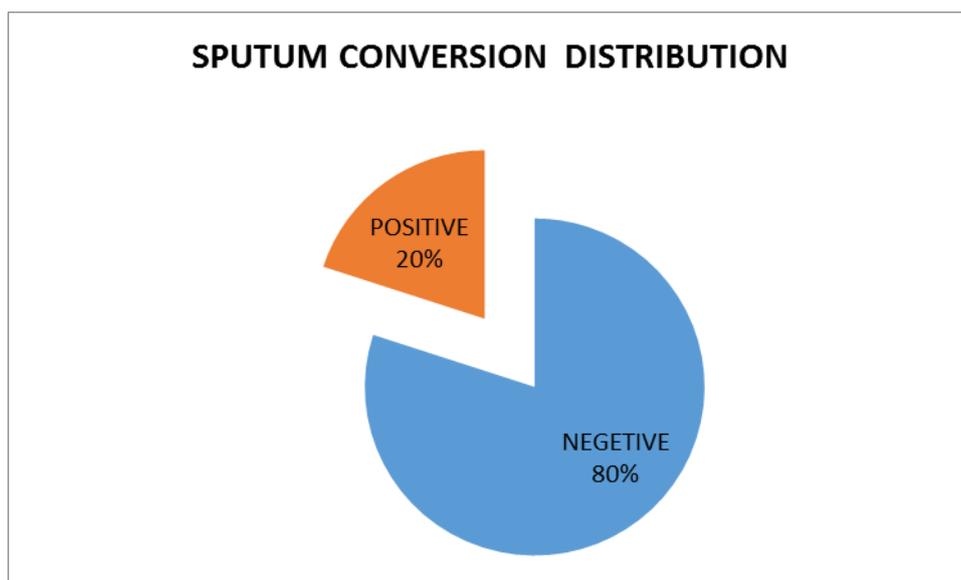
#### OTHER CRITERIA

CRITERIA	HIGHEST	LOWEST
EDUCATION	14 (25.5%) DEGREE HOLDER	1 (1.8%) DEPLOMA HOLDER
JOB	19 (34.5%) MANUAL LABOUR	1 (1.8%) CHILD
FAMILY STATUS	36 (65.5%) ABOVE POVERTY LINE	19 (34.5) BELOW POVERTY LINE
MARITAL STATUS	43 (78.2%) MARRIED	11 (20.0 %) UNMARRIED
CHILDREN	42 (76.4%) HAVE CHILDREN	13 (23.6 %) NO CHILDREN
SMOKING	32 (58.2%) NON SMOKER	23 (41.8%) SMOKERS
ALCOHOLISM	31 (56.4%) NON-ALCOHOLIC	24 (43.6) ALCHOLIC
PREGNANCY	54 (98.2%) NON-PREGNANT	1 (1.8%) PREGNANT
BREAST FEEDING	54 (98.2%) NON- BREAST FEEDING	1 (1.8%) BREAST FEEDING
PROPER PRECUATION	53 (96.4%) TAKE PRECUATIONS	2 (3.6%) NOT TAKEN ANY

#### SPUTUM CONVERSION DISTRIBUTION

Out of 55 patients, 44 (80%) of them shows smear negative as result and 11 (20%) shows smear positive after two months on DOTs therapy. The sputum conversion is an important criteria in the patients taking DOTs therapy. From this study about 80% of patients sputum converted to negative in the intensive phase itself, which is the sign of effective treatment and improvement of patients health. DOTs is a six month therapy contain 2 months of intensive phase and 4 months for the category I patient. Hence some patients take 3-4 months for the sputum conversion from positive to negative.

14 (25.5%) patients completed the course and they have the significant change in the sputum and they all attained a good margin of their body weight. Thus from these observations patients improved the quality of life during the study period.



### WEIGHT DISTRIBUTION

From the study conducted in 55 patients, 36 (65.5%) of them has gained weight, 14 patients (25.5%) maintained their weight and only 5 patients (9.1%) has mild decrease in their weight. Since weight distribution is an important factor in the DOTs treatment, it is recommended to check the weight of patients every month. In this study 65.5% of patients gained their weight, which is a sign that the DOTs therapy is effective in the patients. 25.5% of patients maintained their weight which also a good result at the current condition. In the table.5 shows the various weight band with their result.

WEIGHT	FREQUENCY	PERCENTAGE
INCREASED	36	65.5 %
SAME	14	25.5 %
DECREASED	5	9.1 %

### ADVERSE EVENT

The DOTs therapy is a six month continues administration of 4 main drugs, isoniazid, rifampicin, ethambutol and pyrazinamide. They are the first line choice of drug for TB. From the study, urine discoloration was the most prominent ADR in all patients, which means all the 55 (100%) patients observed the urine discoloration. The urine discoloration is mainly caused by the drug Rifampicin. The second common ADR which was reported by the patients is the joint pain. About 7 (12.7%) patients reported this ADR. This ADR is caused by the drug Pyrazinamide. The occurrence of vomiting is the third most reported ADR. It occurs in about 6 (10.9%) patients out of 55. It was most prominent in the intensive phase and later it was decreased. The occurrence of skin rashes and itching was found to be same. About 3

(5.5%) patients reported the ADR for each. It is caused by the Isoniazid. There was found to be zero occurrence of jaundice and ocular problems in the patients.

CONDITIONS	FREQUENCY	PERCENTAGE
VOMITING	6	10.9 %
JAUNDICE	0	0 %
OCCULAR PROBLEMS	0	0 %
JOINT PAIN	7	12.7 %
SKIN RASHES	3	5.5 %
URINE DISCOLORATION	55	100.0 %
ITCHING	3	5.5 %

## DISCUSSION

The study entitled “Indication of prognosis and health related quality of life of patients on DOTs therapy at TB unit north Kerala” was carried out in different TB centers in north Kerala. The study duration was for a period of six months from the date of approval from the Human Ethical Committee. During the study period a total of 55 patients were enrolled in the study.

## GENDER OF THE POPULATION

Hamid Salim, M. A et al in their study<sup>[23]</sup> of A total of 266189 people were surveyed, among whom 223936 (84.1%) could be interviewed. This led to the identification of 7001 tuberculosis suspects (2406 females and 4595 males) and 64 confirmed TB cases (16 females and 48 males). The female/male ratio (0.33:1).<sup>[44]</sup> Almost same result has obtained in this study more prevalence of TB disease observed in males(74.5%) than females(25.5%).It is because most of the males are having daily waged job and they have to contact with multiple persons and have more exposure to the disease and to the environment. Where females are less exposed to the disease and their frequency is also less. Life style is also a factor for the disease.

## SPUTUM CONVERSION

Bawri S et al in their study<sup>[24]</sup> shows that the overall sputum conversion rate under Directly Observe Treatment, Short Course (DOTs) chemotherapy in 100 sputum smear positive Pulmonary Tuberculosis in DOTs center, Gauhati Medical College & Hospital was 92%.<sup>[47]</sup> In our study we found out that 80% of the patient under DOTs therapy have shown negative as result in their sputum culture after the intensive phase.

### WEIGHT GAIN DURING TREATMENT

M. Vasantha et al in her study<sup>[25]</sup> shows that among 1557 smear-positive TB patients registered under DOTS programme, the changes in weight ranged from a loss of 4 Kgs to a gain of 20 Kgs at the end of TB treatment; the average change in weight was 3.22 Kgs. The gain in weight at the end of treatment was associated with age (<45 years). The findings showed that there is an association between gain in weight with DOTs at government centers and cure of patient. Almost a similar finding is arises from our study. There is an increase in the body weight of the patient under DOTs therapy. Our study shows that 65.5% populations have improvement in their body weight.

### ADVERSE DRUG REACTION

Dhingra VK et al in their study “Adverse drug reactions observed during DOTs” in EUROPE PMC<sup>[26]</sup>, DEC 2004 States that A total of 8.37% of the 1195 patients treated at NDTB Centre with DOTs under RNTCP between January 2002 to June 2003 presented with adverse drug reactions. Patients showing any sort of adverse reactions were studied in detail by personal interviews and a semi-structured questionnaire. The profile of patients presenting with adverse reactions showed that majority of the patients (53%) had gastrointestinal reactions, the commonest presenting complaint being nausea and vomiting. General aches and pains were complained by about 35% and giddiness was the presenting complaint in 27% irrespective of the use of streptomycin, although giddiness was observed more often in Category II patients (59%). Skin rash and itching was complained by about 17% of patients and 11% complained of arthralgia, while only 1% had hepatotoxicity during treatment. Majority of the adverse reactions (67%) were observed within the first four weeks of treatment and only 0.25% of patients treated with DOTs had interruption of treatment for short period. But in our study we observe that rifampicin induced urine discoloration is the most predominant Adverse event observed during DOTs therapy. Urine discoloration is seen 100% patients that we have observed. And vomiting present only around 10%, the other events such as itching (5.5%), skin rashes (5.5%) are observed very rarely. Jaundice and ocular disturbance are not observed in our study.

### CONCLUSION

The study shows that men are more prevalence than women and also observed that uncomplicated side effect like skin rashes, vomiting and itching are seen in some patients and rifampicin induced urine discoloration is the most predominant Adverse event during DOTs

therapy. Most of the patients take proper precaution such as avoiding smoking and alcohol. There is the weight gain for most of the patients and the patients are well adhere to the treatment. Overall health related quality of life of patients on DOTs therapy increases after completing the treatment course. While considering the whole findings we attain a conclusion that with proper follow up we can improve the quality of life and patient compliance during dots therapy.

### **RECOMMENDATION**

By the new medication remedy of the RNTCP, we are able to observe that the patients shows more adverse drug reaction with daily dose of anti-tubercular drugs. A large population of patients have developed serious hepatic problem. It is recommended to conduct a study on the new daily regimen of the RNTCP.

### **ACKNOWLEDGEMENT**

I would like to express my deepest gratitude to my guide Dr. N Premkumar Assistant Professor, Academy Of Pharmaceutical Science, Pariyaram. I also sincere thanks to my co guide Dr. Usha Karunakaran Assistant Professor, Academy Of Medical Science, Pariyaram who has the attitude and the substance of genius: for this ever readiness to solve the problem, to guide with valuable suggestions and constant encouragement during the work. I take this opportunity to express my heartfelt gratitude To Mr. Subair Manzil Senior Tuberculosis Supervisor, Government Taluk Hospital Payyannur for providing necessary facilities and information to carry out this work. I extent my sincere thanks to Dr. Bindu K.M District Tuberculosis Officer, Kannur for providing all the facilities to conduct the study. And special thanks to Mr. Rajeesh K Special Wing Officer District Medical Office, Kannur i express my sincere thanks To Prof. Dr. K. Premaletha Principal Academy Of Pharmaceutical Science, Pariyaram, for her constant support throughout the period of study.

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