



AMERICAN JOURNAL OF PHARMTECH RESEARCH

Journal home page: <http://www.ajptr.com/>

A Retrospective Study of Sputum Conversion Rate In New Smear Positive and Re-Treatment Cases of Pulmonary Tuberculosis In Mangalore

Akshaya Alva¹, Roopa P Nayak², RashmiR. Rao^{3*}, Mohandas Rai⁴

1. Department of Pharmacology, A.J. Institute of Medical Sciences, Mangalore.

2. Department of Pharmacology College DhanalakshmiSrinivasan Medical College, Perambalur, Tamil Nadu, India

3. Department of Pharmacology, Kasturba Medical College, Mangalore, Manipal University.

4. Department of Pharmacology, A.J. Institute of Medical Sciences, Mangalore

ABSTRACT

Tuberculosis is a major infective disease affecting Indian population with high socio-economic impact. For eradication of tuberculosis and successful implementation of Revised National Tuberculosis Control Program – Directly Observed Treatment Short Course RNTCP- DOTS program regular assessment of the condition is imperative. The aim was to determine the sputum conversion rate carried out in District Tubercular Centre (DTC), Mangalore. The data of all patients registered from January 2011 to December 2011 were examined. The study was conducted on sample population of 297 patients. Of these, 183 (61.6%) patients were NSP cases and 114 (38.4%) patients were retreatment cases. The mean age of patients in category 1 and category 2 was 40.86 ± 18.20 and 42.49 ± 13.32 respectively. Males constituted 71.2% and females were 28.8% of population. No significant difference in distribution with respect to gender ($\chi^2 = 1.327$, $p = 0.249$) and residential area ($\chi^2 = 1.290$, $p = 0.256$) in each categories. There is significant difference in distribution in category 1 and category 2 with mean age in years in different age category ($\chi^2 = 21.521$, $p = 0.001$). Of 183 patients in NSP, 137 patients converted to negative at the end of the 2 month intensive phase with conversion rate of 86.33% and 21 patients converted to negative at the end of extended intensive phase with conversion rate of 67.54%. The sputum conversion rate was comparable to other study but was less than national average. Conversion rate is less in category 2 compared to category 1 showing the importance of treatment completion in patients with TB. Majority of patients belong to a productive age group between 21-60 years indicating the impact of the disease on socio-economy of patient as well as on the country.

Keywords: Tuberculosis, new smear positive, retreatment, sputum conversion, MDR TB.

*Corresponding Author Email: dr.rao82@gmail.com

Received 21 June 2014, Accepted 04 July 2014

Please cite this article as: Rao R *et. al.*, A Retrospective Study of Sputum Conversion Rate In New Smear Positive and Re-Treatment Cases of Pulmonary Tuberculosis In Mangalore. American Journal of PharmTech Research 2014.

INTRODUCTION

Tuberculosis (TB) is an infective disease, which dates back to hundreds of years and affects major population in India. Around nine million people worldwide are diagnosed with tuberculosis annually. India is ranked 17th out of 22 high burdened countries in terms of TB incidence with an annual rate of two million cases. Despite being curable and preventable, TB represents 3.7% of India's disease burden¹. The increase in prevalence of HIV and drug resistance contributes to this disease posing a serious public health hazard with high economic burden for India in years to come.

Since the implementation of Revised National TB Control Programme (RNTCP), based on the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, the objective of achieving a cure rate of 85% in New Smear Positive (NSP) cases and detection of 70% of NSP cases has been successful. It has given good quality diagnostic and treatment services across the country¹

Sputum smear examination of acid-fast bacilli is carried out for diagnosis as well during the course of treatment as a part of DOTS strategy. This is an essential component of the follow-up of smear-positive tuberculosis patients. At 2 months follow-up, the sputum examination result is necessary to decide on whether to continue the intensive phase of treatment for 1 month if positive, or to move to the second phase of treatment if result is negative, and after completion of treatment to check whether patient is cured. Sputum conversion is an important indicator of the efficacy of the drug therapy and effectiveness of programme implementation².

Mangalore, a coastal city in the Dakshina Kannada district of Karnataka, with a total population of 615,711 around 1922 cases of TB has been reported in Dakshina Kannada in the year 2011. This is indicative of the burden the disease poses on its population and the need for effective treatment. Therefore, it is imperative that medical personnel know the extent to which the patients initially started on anti-tubercular therapy are really benefiting from it on completion of treatment and the role of influencing factors within this aspect. Hence, this study was undertaken with the objective of determining the sputum conversion rate in new smear positive (NSP) and retreatment cases of pulmonary TB and also to compare conversion rates between category 1 and category 2 in Mangalore city.

MATERIALS AND METHOD

Aretrospective record-based descriptive study was carried out in District Tubercular Centre (DTC), Mangalore. This DTC has five tubercular units (TU). This study was done on a sample from total

population of 6,15,711 covered by Mangalore TU. The data of all patients registered between January 2011 to December 2011, were studied following approval from Institutional Ethics Committee. The consent for examining the records was given by District Tubercular Officer, Bangalore.

Inclusion Criteria

Category 1 new smear positive patients and category 2 patients those who have relapsed, defaulted or those who underwent failure of previous treatment against tuberculosis were included in this study.

Exclusion Criteria

Seriously ill sputum smear negative cases and seriously ill extra pulmonary cases, coming under category 1 treatment. Data collected includes total number of patients registered in year 2011-12, number of patients in each quarter of a year (divided into four quarters), number of patients in category 1 and category 2, age, gender, residence, sputum conversion rate in category 1 and category 2.

For calculating the sputum conversion rate for NSP, all those who converted from a sputum positive state to negative state at the end of the intensive phase (IP) {at the end of two months} and at the end of the extended IP (at the end of three months) were added and divided by the number of smear-positive patients started on treatment, and the ratio was multiplied by 100 to obtain percentage values ².

$$\text{Sputum Conversion Rate} = \frac{\text{No. of sputum smear positive patients converted to sputum smear negative patients at the end of intensive phase}}{\text{Total no. of smear positive patients initiated on treatment}} \times 100$$

For other types of sputum positive cases (treated with Category II), sputum conversion is only reported at the end of the IP (at the end of three months of IP)².

Statistical analysis

Data collected was analyzed by using version 16 of the statistical package for social sciences software package (SPSS) into categories and percentages. Chi Square and t- test was used to test statistical significance.

RESULTS AND DISCUSSION

In the year 2011-2012, 716 patients with pulmonary tuberculosis were registered in Mangalore TB unit. Number of patients in each quarter of a year is mentioned in (Table 1). The study was conducted on sample population of 297 patients. Of these, 183 (61.6%) patients were NSP cases

(category 1) and 114 (38.4%) patients were retreatment cases (Table 2). The mean age of all the patients was 41.48 ± 16.50 years, the mean age of patients in category 1 and category 2 was 40.86 ± 18.20 and 42.49 ± 13.32 respectively. Males constituted 71.2 % and females were 28.8% of the sample population (Table 3). Majority of the patients belonged to urban area of the city (62.6%).

Table 1: Quarterly distribution of patient's year 2011-201

Quarter	No. of patients
1 st (Jan-Mar)	177
2 nd (Apr-June)	169
3 rd (July-Sept)	165
4 th (Oct-Dec)	185

Table 2: Distribution of patient in each category

	Category 1	Category 2
No. of patients	183	114
Percentage	61.6	38.4

Socio-demographic profile does not show any significant difference in distribution with respect to gender ($\chi^2 = 1.327$, $p = 0.249$) and residential area ($\chi^2 = 1.290$, $p = 0.256$) in each of the categories. However, there is significant difference in distribution in category 1 and category 2 with mean age in years in different age category ($\chi^2 = 21.521$, $p = 0.001$) (Table 3). Most patients in both categories belong to an age group between 21-60 years.

Table 3: Distribution of patients based on gender, age and residential area in each category

		Category		
		Category 1	Category 2	
Residence	Urban	73	38	37.4%
	Rural	110	76	62.6%
	Total	183	114	$\chi^2 = 1.290$, $p = 0.256$
Gender	Male	125	85	71.2%
	Female	57	29	28.2%
	Total	183	114	$\chi^2 = 1.327$, $p = 0.249$
Age Category	Ls 20	28	4	
	21-30	32	21	
	31-40	34	27	
	41-50	31	36	
	51-60	34	16	
	61 -70	14	9	
	70+	10	1	
	Total	183	114	Mean Age 41.48 ± 16.50
Mean age	40.86 ± 18.20	42.49 ± 13.32	($\chi^2 = 21.521$, $p = 0.001$).	

χ^2 is chi square value, p is probability value $P < 0.05$ is considered as significant

Table 4: Sputum conversion rate

Sputum conversion rate for category 1

Total no. of patients	183
Sputum converted to negative	
2 nd month	137
3 rd month	21
Total	158
Not available	25
Sputum conversion rate in percentage	86.33

Sputum conversion rate for category 2

Total no. of patients	114
Sputum converted to negative	
3 rd month	77
Not available	37
Sputum conversion rate in percentage	67.54

Out of 183 patients in category 1, 137 patients converted to negative at the end of the 2 month intensive phase and 21 patients converted to negative at the end of extended intensive phase (3rd month). The conversion rate for category 1 is 86.33%. Among 114 patients in category 2, 77 patients converted to negative at end of 3 month with the conversion rate of 67.54 %.(Table 4).

A significant progress in the fight against tuberculosis has been made since its discovery. TB mortality worldwide fell by 35 percent within 1990-2009⁽³⁾. Despite this progress, TB remains one of the leading causes of death worldwide. Sputum smear positive pulmonary tuberculosis patients are the most significant source of infection for tuberculosis. Controlling the spread of disease is highly recommended for all sputum smear positive patients and has to be maintained until non-infectiousness has been achieved⁴. The annual case notification rate is 92 % for Mangalore city and Dakshina Kannada district, which is in accordance with the objective of case detection proposed by the RNTCP⁽¹⁾. In the study, most patients belong to a productive age group of 21 - 60 years in both categories. Studies suggest that an average of 3 to 4 months work time is lost as a result of TB, resulting in an average lost potential earning of 20-30% of the annual household income. A study on the economic impact of scaling up of RNTCP in India in 2008 shows that on average each TB case incurs an economic burden of around US\$12,235 and a health burden of around 4.1 Disability Adjusted Life Years (DALY's)⁵. Incidence of TB in our study, was more in males (71.2%), irrespective of category. However, in a study conducted by Joseph N et al, there was significant difference seen in the distribution with respect to gender within the categories⁶.

The sputum conversion rates in our study, for category 1 and category 2 were 86.33% and 67.54% respectively. The findings are similar to that of other studies^{7, 8, 9}. However, it is less when

compared with the national average ¹. A comparison in the sputum conversion rate in both the groups showed that the chances of a favorable treatment outcome were significantly less in Category II compared to Category I. This highlights the importance of ensuring the successful completion of treatment among patients with TB who are put on Category I regimen to prevent them from entering a Category II treatment regimen.

Many studies have shown that initial high grade of bacilli, multi drug resistance(MDR), HIV co-infection and poor compliance could be possible reasons for continued sputum positivity ^{(10) (11)}. Programmatic Management of Drug Resistant TB (PMDT) has been implicated in Dakshina Kannada TB centre in the year 2012¹. Furthermore, Drug Susceptibility Testing (DST) should be carried out in all patients who remain positive at the end of 2 and 3-month therapy to overcome the problem of MDR TB.

CONCLUSION

To conclude, further effort and research is required to improve the treatment outcome with the help of RNTCP in Mangalore city as well at national level.

ACKNOWLEDGEMENTS

The authors acknowledge the help received from Mr. Kishore and Dr. Rama Krishna DTC, Mangalore.

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