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Treatment outcomes among new smear positive and retreatment cases of tuberculosis in Mangalore, South India – a descriptive study.

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RESEARCH

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Abstract

Background
India has the highest tuberculosis burden in the world. For successful implementation of the Revised National Tuberculosis Control Programme (RNTCP), treatment outcomes and factors which influence them need to be assessed on a regular basis. This study was thus done to find out the sputum conversion rates, treatment outcomes and sociodemographic factors of new smear positive cases (NSP) and retreatment cases of pulmonary tuberculosis of the Mangalore Tuberculosis Unit (TU) registered at the District Tuberculosis Centre (DTC), Mangalore.

Method
This record-based cross-sectional study was undertaken in June 2009. Information pertaining to NSP or Category I patients and retreatment patients or Category II patients between June 2008 to May 2009 (one year period) were recorded.

Results
Of 286 tuberculosis patients, 74.1% were on Category I treatment. The sputum conversion rate among Category I and II patients was 91.5% and 73% respectively. Category I patients showed a cure rate of 77.4%, a default rate of 7.5% and a failure rate of 15.1%. Category II patients showed a cure rate of 47.3%, default rate of 20.3% and failure rate of 32.4%. The differences in treatment outcomes between the two categories of treatment were found to be statistically significant (X^2=23.737, P<0.001). A favourable treatment outcome in Category I was significantly more in patients aged 30 years or less when compared to the rest (X^2=15.7, P=0.004). However, gender and place of residence did not have a significant influence on treatment outcomes among NSP patients. Among retreatment patients, age, gender and place of residence did not have a significant influence on treatment outcomes.

Conclusion
Sputum conversion rates were satisfactory but the treatment outcome rates were poorer in our study area compared to Indian national figures. Among the sociodemographic factors, age was found to significantly influence treatment outcomes in Category I patients.

Key Words
Tuberculosis, new smear positive, retreatment, sputum conversion, treatment outcome, socio demographic factors.

Background

India has the highest tuberculosis burden in the world and accounts for nearly one-fifth of the global burden of tuberculosis. Every year in India approximately 1.8 million people develop tuberculosis, of which about 0.8 million are NSP, highly infectious, cases. With the national annual risk of tuberculosis infection (ARTI) being 1.5%, the incidence of smear positive tuberculosis cases in the country is estimated as 75 NSP cases per 100,000 of the population. Today, India's RNTCP based on Directly Observed Treatment Short course (DOTS) strategy against tuberculosis is recognised as the fastest expanding programme in the world and the largest in terms of patients initiated on treatment (more than 100,000 patients on treatment every month).

DOTS, which was launched in March 1997, covered the whole country by March 2006. The RNTCP achieved its target case detection rate of 70% and treatment success rate of 85% in 2007.[1]

However, a few states such as Daman and Diu, Dadra and Nagar Haveli and Karnataka have performed poorly. The performance indicators of Karnataka state showed a sputum conversion rate of 86%, cure rate of 79%, failure rate of 3.0% and a default rate of 8.2% for Category I patients at the end of the second quarter of 2010. This performance was below par in comparison to the national average sputum conversion rate of 90%, cure rate of 85% and default rate of 5.7%.[1]

Also the performance indicators among retreatment patients in Karnataka was also dismal in comparison to national averages. The cure rate observed here was 51.1%, failure rate was 7.6% and default rate was 20.4% at the end of the second quarter of 2010.[1] Therefore this study was conducted to examine the treatment outcomes of tuberculosis and sociodemographic factors influencing them in Mangalore, Karnataka.

Methods

This cross-sectional study was undertaken in the DTC in Mangalore, a coastal city of Dakshina Kannada district of Karnataka during June 2009. The function of the DTC is to undertake tuberculosis control in the district along with with general health and medical institutions. This DTC, c five TUs namely Belthangady, Bantwal, Moodabidri, Puttur and Mangalore, covers a population of 2,114,692. One TU is established at sub-district level at the rate of 1 per 500,000 of the population. This study was undertaken from a sample taken from a total population of 615,711 covered by Mangalore TU.

This record-based descriptive study obtained ethical approval from the Institutional Ethics Committee. The consent for examining the records was given by the District Tuberculosis Officer (DTO). Following this, the treatment cards of pulmonary tuberculosis patients registered under Mangalore TU between June 2008 until May 2009 (past one year period) were examined.

Only Category I NSP patients and Category II patients i.e. relapsed, defaulted or failures of previous treatment against tuberculosis were included in this study. Seriously ill sputum smear negative cases and seriously ill extra-pulmonary cases, coming under Category I treatment, and Category III patients were excluded from this study.

The data with respect to the age, gender, category of treatment, residence of patients, sputum results of patients during various stages of treatment and treatment outcomes were recorded by the investigating team.

For calculating the sputum conversion rate for NSP, all those who converted from a sputum positivity state to negativity 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.

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]

A patient was considered to be cured of tuberculosis if the sputum smear report was negative at treatment completion. A patient was considered to have failed treatment if the patient continued to remain sputum-positive after two months of treatment under the continuation phase or at the end of treatment. A patient was considered as a defaulter if, after a minimum treatment of one month, they discontinued treatment for two or more months. Relapsed patients were those who returned sputum smear positive after being declared cured after a full course of treatment. Transfer in patients were those who were recorded in another administrative area register and transferred into the present area to continue treatment. [1, 3]

All the data collected was analysed using version 11.5 of the Statistical Package for Social Sciences software package (SPSS Inc., Chicago, IL) into categories and percentages. Chi-square and t test were used for testing statistical significance and P value less than 0.05 was considered as significant.

Results

The total number of tuberculosis patients included in our study was 286, of which 212(74.1%) were NSP cases or on Category I treatment and 74(25.9%) were retreatment cases or on Category II treatment.

Most patients belonging to Category I and II treatments were of age groups 21 to 50 years; 68.9% and 71.6% respectively. The mean age of all patients was 38.78 ±14.17 years of which mean age of Category I and II patients were 38.11±14.07 years and 40.67±14.44 years respectively.

Most of the patients were males 224 (78.3%) and the majority were from urban areas 192(67.1%) (see Table 1).

Table 1: Sociodemographic profile of patients by treatment category

Age groups (years)	***Category I no. (%)***	***Category II no. (%)***	***Total no. (%)***	***P value (* signif-icant)***
<20	19(9)	3(4.1)	22(7.7)	
21–30	51(24.1)	18(24.3)	69(24.1)	
31–40	54(25.5)	16(21.6)	70(24.5)	
41–50	41(19.3)	19(25.7)	60(21)	
51–60	29(13.7)	8(10.8)	37(12.9)	
61–70	16(7.5)	9(12.2)	25(8.7)	
>70	2(0.9)	1(1.4)	3(1)	
Mean ± SD (yrs)	38.11 ±14.07	40.67 ±14.44	38.78 ±14.17	t= 1.338 P= 0.182
Sex				
Male	160(75.5)	64(86.5)	224(78.3)	
Female	52(24.5)	10(13.5)	62(21.7)	0.048*
Residence				
Urban	146(68.9)	46(62.2)	192(67.1)	
Rural	66(31.1)	28(37.8)	84(32.9)	0.29
Total	212 (100.0)	74 (100.0)	286 (100.0)	

The Category I and II patients did not show any difference in their distribution with respect to either area of residence (urban or rural; X^2=1.118, P=0.29) or with respect to mean age (t=1.338, P=0.182). However Category I and II patients showed significant differences in their distribution with respect to gender, with the chances of ending in Category II inclined more towards males. (X^2=3.919, P=0.0477) See Table 1.

Among the Category I patients 205 (96.7%) were new and 7 (3.3%) were transferred in; among Category II patients 62 (83.8%) were new and the remaining 12 (16.2%) were transferred in. These Category II patients included 35 (47.3%) cases of relapse, 15 (20.3%) cases of failure and 24 (32.4%) cases of default.

Among the 212 NSP cases, 56 (26.4%) continued to remain sputum positive at the end of the IP (after two months of treatment). These 56 patients were then put on an extended IP of one more month (three months in total). At the end of this phase, 18 (32.1%) continued to remain sputum positive. Therefore the sputum conversion rate for Category I patients was 194 (91.5%).
Among the 74 retreatment cases, 20 (27%) continued to remain sputum positive at the end of the IP (after three months of treatment). Therefore the sputum conversion rate for Category II patients was 54(73%) (see Table 2).

Table 2: Sputum conversion rates among Category I and II patients.

Type of patients	Number of patients demonstrating sputum conversion (%)					
Month no.	2	3	4	5	6	7
Category I	156/212 (74)	NA	142/ 156 (91)	NA	132/ 138 (96)	NA
Category I*	NA	38/ 56 (68)	NA	48/ 56 (86)	NA	32/ 36 (89)
Type of patients	Number of patients demonstrating sputum conversion (%)					
Month no.	3	4	5	6	8	9
Category II	54/74 (73)	NA	42/54 (78)	NA	31/36 (86)	NA
Category II*	NA	8/20 (40)	NA	14/20 (70)	NA	4/5 (80)
NA = Not applicable, *Extended intensive phase group						

A comparison in the treatment outcomes between the two groups showed that chances of a favourable outcome were significantly less in the retreatment group (47.3%) than in the NSP group (77.4%). The default and failure rates were more than twice the retreatment group compared to the NSP group. These differences in treatment outcome were statistically significant. (X^2= 23.74, P < 0,001) (see Table 3).

Table 3: Treatment outcomes of tuberculosis patients

Type of patients	Cured (%)	Defaulted (%)	Failure (%)	Total
Category I	164(77.4)	16(7.5)	32(15.1)	212(100.0)
Category II	35(47.3)	15(20.3)	24(32.4)	74(100.0)
Total	199(69.6)	31(10.8%)	56(19.6)	286(100.0)

P<0.001*

There was no association between gender of patients and their treatment outcomes in both Category I and II groups of patients (see Table 4).

Table 4: Association between gender and treatment outcomes among patients

Gender	***Cured (%)***	***Defaulted (%)***	***Failure (%)***	***Total***	***P value***
Category I					
Males	122 (76.2)	15 (9.4)	23 (14.4)	160	
Females	42 (80.8)	1 (1.9)	9 (17.3)	52	
Total	164	16	32	212	0.200
Category II					
Male	31 (48.4)	12 (18.8)	21 (32.8)	64	
Female	4 (40)	3 (30)	3 (30)	10	
Total	35	15	24	74	0.708

Among NSP patients the cure rate was found to significantly more in the age groups below 31 years (85.3%) followed by age groups between 31 to 60 years (77.2%) and least in age groups above 60 years (52.4%). This difference was found to be statistically significant (X^2=15.7, P=0.004). However a similar association was not seen among the retreatment patients (see Table 5).

Table 5: Association between age and treatment outcome in Category I and II TB patients

Age groups	*Cure rate (%)*	*Default rate (%)*	*Failure rate (%)*	*Total*	*P value*
Category I					
≤30	58(85.3)	4(5.9)	6(8.8)	68	0.004*
30-60	95(77.2)	11(8.9)	17(13.8)	123	
>60	11(52.4)	1(4.8)	9(42.9)	21	
	164	16	32	212	
Category II					
≤30	10(47.6)	4(19)	7(33.3)	21	0.421
30-60	20(46.5)	11(25.6)	12(27.9)	43	
>60	5(50)	0(0)	5(50)	10	
	35	15	24	74	

No association was observed between place of residence and treatment outcomes among either NSP or retreatment patients (see Table 6).

Table 6: Association of area of residence with treatment outcome among TB patients

	Cured (%)	*Default (%)*	*Failure (%)*	*Total*	*P value*
Category I					
Urban	114 (78.6)	11 (7.6)	20 (13.8)	145	
Rural	50 (74.6)	5 (7.5)	12 (17.9)	67	
Total	164	16	32	212	0.737
Category II					
Urban	23 (51.1)	8 (17.8)	14 (31.1)	45	
Rural	129 (41.4)	7 (24.1)	10 (34.5)	29	
Total	35	15	24	74	0.682

Discussion

Tuberculosis remains a worldwide public health problem despite the fact that the causative organism was discovered more than 100 years ago and highly effective drugs and vaccine are available.[3] It thus becomes important for researchers to know the extent to which the patients initially put on anti-tubercular therapy are really benefiting from it on treatment completion and the role of influencing factors with this aspect. This study has brought out this information in a highly literate area in south India. Most of the tuberculosis patients in the NSP group belonged to the 31 to 40 years age group and, in the retreatment group, most belonged to the 41 to 50 years age group. In other studies most patients of Category I treatment belong to much younger age groups, 15 to 24 years[4, 5] and 21 to 40 years.[6] Similarly, most patients in Category II treatment were also reported to be in the younger age group of 15 to 24 years in a study done in Chandigarh.[4]

However the mean age of patients in Category I and II in the present study was higher than that of the Chandigarh study where it was 31.7±13.4 years for Category I patients and 32.3±14.0 years for Category II patients.[4] Another study done in West Bengal reported the mean age of Category II patients to be 41.8 years which was more than our findings.[7]

More than three-quarters of patients in our study were males. A similar observation of male preponderance among tuberculosis cases has been made in other studies too.[5, 6, 8]

This may be explained through the greater social mobility among males. Another interesting finding was that the proportion of male patients in Category II was significantly more than in Category I treatment. This meant that male patients are more likely to default, relapse or end up as failures of Category I treatment compared to females and hence need to be more closely monitored during treatment.

Most of the patients with tuberculosis in our study were from urban areas which is in contrast to observations made in a study done in West Bengal where more than 60% of patients were from rural areas. [9] This could be due to regional differences in living conditions with respect to housing conditions and population density which influence the disease transmission. Tuberculosis, which is often described as the barometer of social welfare, spreads in conditions of poor housing and overcrowding is very common in both urban and rural India.

Most patients who ended up with Category II treatment in our study were cases with relapses of tuberculosis followed by defaulters of Category I treatment. Relapse as the commonest cause of retreatment was supported by studies by Mehta and colleagues [10] and Mukherjee and colleagues [7] but these other studies found failure as the next most common cause which was different from our study. In another study done in Maharashtra, defaulters constituted the major group among patients put on Category II treatment.[11]

The sputum conversion rate is an important indicator of the efficacy of the treatment regimen and also of the effectiveness of programme implementation.[2] Sputum conversion rate at the end of the IP in Category I treatment patients in our study was greater than that found in other studies [4, 12] but was comparable to the findings of a study done in Gauhati, in which it was 92%.[6]
Among retreatment patients the sputum conversion rate at the end of the IP was similar to the observations of Mukherjee and colleagues who reported 72.8%.[7]

Favourable treatment outcomes with respect to better cure rates and lesser failure and default rates was seen significantly more in Category I patients compared to

Category II patients which was similar to the observations made by Pardeshi and colleagues.[11] This meant that treatment outcome rates in Category II is poor compared to Category I. Patients on retreatment hence pose a significant challenge to the DOTS initiative and tuberculosis control. Hence utmost care needs to be taken to minimise the default rate in Category I groups so that these patients do not end up in Category II treatment.

The cure rate of tuberculosis among Category I patients in our study was more than the cure rate reported by a study done in Bangalore (65.7%) and in Tamil Nadu (75%). [13, 14]

However a study done in Maharashtra reported a cure rate of 84.3% which was more than our results. [11]

The default rate of 7.5% among NSP cases in our study is comparable to the findings between 6 to 8% reported in several other studies. [5, 10, 11] This needs to be totally eliminated both by motivating the patient and also by effective implementation of DOTS to improve the success of the tuberculosis control programme.

However the failure rate of Category I patients in our study (15.1%) was much higher in comparison to other studies which reported failure rates between 1 and 6%. [4, 5] This difference could probably be because the representation of young tuberculosis patients between 15 to 34 years was over 65% in the other studies while it was less than 50% in our studies. The cure rate of tuberculosis is better in the younger age groups because of better body immunity. The cure rate of 47.3% was lesser than the cure rates between 55% and 67% reported among Category II patients in other studies.[4, 9, 11]

Just as in Category I, the retreatment group also showed a default rate comparable to other studies (13.5 to 17.5%) but the failure rate was much higher in comparison to others (10 to 24%).[9-11]

The favourable treatment outcome in terms of better cure rate and lesser failure and default rate was found to significantly reduce with increasing age of the patients in Category I treatment regimen. This shows the importance of early diagnosis of tuberculosis in patients and early initiation of anti-tubercular treatment in the diseased so as to get a much more favourable treatment outcome. The role of health workers becomes very vital here. During their routine house-to-house visits in their sub-centre areas they can enquire of patients with a longstanding cough of more than two weeks duration and refer them to the primary health centre to get their sputum examined for acid fast tuberculosis bacilli. Screening in the form of active surveillance is the need of the hour.

However a similar association between age and favourable treatment outcomes was not seen among patients on Category II regimen.

Conclusion

The sputum conversion rates in both the treatment categories were found to be satisfactory. The cure rate among patients on Category I treatment (77.4%) was good but not so among patients on Category II treatment (47.3%). The default rate and failure rate in both Category I and II treatment groups were high. A comparison in the treatment outcome in both the groups showed that the chances of a favourable 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.

Among NSP cases, the cure rate was found to be significantly better in patients under 31 years compared to the older age groups. This indicates the importance of screening activities for early case detection and prompt initiation of anti-tubercular treatment as per RNTCP guidelines so as to improve the chances of cure by treating at an early age. Also as drugs are supplied in patient-wise boxes containing the full course of treatment, interruption of treatment due to unavailability of drugs during the course of treatment does not arise.

A preponderance of male patients with tuberculosis was observed, this was particularly so in the retreatment group, suggesting the need for close monitoring male patients as they appear to be more prone to default and failure. Gender and place of residence did not have any significant association with treatment outcomes in both groups of patients. The factors like educational status of patients, addictions among patients, employment status and other socioeconomic factors which may have an influence on the treatment outcomes were not studied which may be a limitation of our study. From our observations we conclude that the scenario of RNTCP in Mangalore city is no different from that in Karnataka state. Hence more work is required to reduce the incidence of tuberculosis to less than one case per million population by 2050.

References

1. Performance indicators. TBC India. Accessed on December 6 2010. Available from: http://www.tbcindia.org/documents.asp.

2. Managing the Revised National Tuberculosis Control Programme in your area - A Training Course Modules 5-9. New Delhi: Ministry of Health and Family Welfare; 2005. Central TB Division, Directorate General of Health Services, 42-44.

3. Park K. Tuberculosis. Park's TextBook of Preventive and Social Medicine 20th ed. Jabalpur: M/s Banarsidas Bhanot; 2009.

4. Kaur G, Goel NK, Kumar D, Janmeja AK, Swami HM, Kalia M. Treatment outcomes of patients placed on treatment under Directly Observed Therapy Short Course. Lung India 2008; 25: 75-77.

5. Singla R, Singla N, Sarin R, Arora VK. Influence of pre-treatment bacillary load on treatment outcome of pulmonary tuberculosis patients receiving DOTS under revised national tuberculosis control programme. Indian J Chest Dis Allied Sci 2005; 47(1):19-23.
6. Bawri S, Ali S, Phukan C, Tayal B, Baruwa P. A study of sputum conversion in new smear positive pulmonary tuberculosis cases at the monthly intervals of 1st, 2nd & 3rd month under Directly Observed Treatment Short Course (DOTS) Regimen. Lung India 2008; 25(3): 118–123.
7. Mukherjee A, Sarkar A, Saha I, Biswas B, Bhattacharyya PS. Outcomes of different subgroups of smear-positive retreatment patients under RNTCP in rural West Bengal, India. Rural Remote Health 2009; 9(1): 926.
8. Vijay S, Balasangameswara VH, Jagannatha PS, Saroja VN, Kumar P. Defaults among tuberculosis patients treated under DOTS in Bangalore city: A search for solution. Indian Journal of Tuberculosis 2003; 50:185-196.
9. Mukhopadhyay S, Sarkar AP, Sarkar S. A study on factors influencing treatment outcome of failure patients receiving DOTS in a district of West Bengal. Indian J Public Health 2010; 54(1): 21-23.
10. Mehra RK, Dhingra VK, Nishi A, Vashist RP. Study of relapse and failure cases of Category I retreated with Category II under RNTCP – An eleven year follow up. Indian Journal of Tuberculosis 2008; 55: 188-191.
11. Pardeshi GS, Deshmukh D. A comparison of treatment outcome in re-treatment versus new smear positive cases of tuberculosis under RNTCP. Indian J Public Health 2007; 51(4): 237-239.
12. Rieder HL. Sputum smear conversion during directly observed treatment for tuberculosis. Tub Lung Dis 1996; 77(2): 124-129.
13. Vijay S, Balasangameswara VH, Jagannatha PS, Saroja VN, Kumar P. Treatment outcome and two & half years follow –up status of new smear positive patients treated under RNTCP. Indian Journal of Tuberculosis 2004; 51:199-208.
14. Thomas A, Gopi PG, Santha T, Chandrasekaran V, Subramani R, Selvakumar N, Eusuff SI, Sadacharam K, Narayanan PR. Predictors of relapse among pulmonary tuberculosis patients treated in a DOTS programme in South India. Int J Tuberc Lung Dis 2005; 9(5): 556–561.

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