Trend of tuberculosis and performance evaluation of new sputum positive tuberculosis from Satara district, India

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ABSTRACT

Background: Tuberculosis (TB) has remained a major public health threat worldwide and considering this, Govt. of India declared TB as notifiable disease in year 2012. **Objectives:** To assess the trend of TB in Satara district, India and to evaluate outcome of new sputum positive TB cases registered under district Revised National Tuberculosis Control Programme (RNTCP). **Materials and Methods:** A retrospective record based cross-sectional study was conducted in District Tuberculosis Centre (DTC), Satara district, Maharashtra, India during March 2013. All Registered TB cases under DTC from the year 2002 to 2012 were included as study subjects. The district RNTCP records since the year 2002-2012, for all TB cases were viewed and analyzed by investigator according to RNTCP outcome evaluation indicators. The trend of TB was statistically analyzed for the period of eleven years by using chi-square trend test. **Results:** Annual the total TB case detection rate was 117.94/lakh for year 2002 which decreased to 98.30/lakh for year 2012. The proportions of pulmonary TB cases decreased from 92.23% to 81.0% since year 2002 to 2012 whereas proportions of HIV-reactive TB cases increased from 3.11% to 25.3% since year 2009 to 2011. Proportions of male TB cases were almost the double of females; however child TB cases increased continuously with maximum TB cases belonged to pulmonary type. The proportional trend of New Sputum Positive (NSP) cases showed periodic fluctuations ranging from 34% to 50% since year 2002 to 2012. The performance of outcome evaluation indicators of NSP cases during evaluation period as viz., cure rate ranging from 79.91% to 87.02% with periodic fluctuations, sputum conversion rate continuously increased from 78.5% to 93.5%, treatment success rate ranging from 82.7% to 90% with apparent difference, whereas defaulter rate decreased from 7.5% to 3.8% by year 2011, treatment failure rate continuously decreased to 2.1% whereas Death rate ranging from 5.2% to 10.4%. The proportional trends of outcome evaluation indicators of NSP-TB cases showed statistically significant difference over period of year 2002 to 2012. **Conclusion:** Data indicates that TB is still big problem in rural area of western Maharashtra, India and need to strengthen the awareness programme about TB and involvement of private health sector to control the burden of TB.

Key words: Tuberculosis, RNTCP, HIV, Evaluation

INTRODUCTION

Tuberculosis (TB) is a disease with devastating social, economic cost and has remained a major public health problem worldwide. According to World Health Organization (WHO), TB is a leading cause of death and disability among the economically active segment of the world's population. The latest global estimates of year 2012 have been shown

that the toll of new cases of tuberculosis was 8.6 million and mortality of 1.3 million.[1] It is also estimated that by year 2020, the global burden of TB may reach beyond one billion and of which more than 80% disease burden could be from the poor resourced countries.[2,3]

TB remains a major public health problem in India and accounts for one-fourth of the estimated global incident TB cases in year 2010.[4,5] Every year in the India nearly 1.5 to 1.8 million people develops TB and approximately 8 lakh is the incidence of sputum smear-positive cases. Tuberculosis is captain of deaths in India. Nearly 2.8 lakh people die of TB every year[6] mainly due to poverty, illiteracy, malnutrition, inadequate health care services, negative attitude of community, traditional medical practices and burden of HIV-AIDS infection.

Recently, the burden of resistant TB is again emerging big challenge to India and by considering this Govt. of India announces TB as a notifiable disease in year 2012. Annual risk of tuberculosis infection, the most important epidemiological indicators of disease burden in a community. Single open case of pulmonary tuberculosis can infect 10-15 persons in a year, so government mainly emphasis on early detection of new smear positive cases and immediately put them on Directly Observed Treatment Short (DOTS) course therapy. The vision of "TB free India" is adopted by Govt of India in revised RNTCP policy in 12th five year plan 2012-17 with aim of "Universal access" for quality diagnosis and treatment for all TB patients.[7]

Keeping this in view, the present study aimed to assess the trend of annual case detection of TB in Satara district, India and to assess the outcome of new sputum positive TB cases under district RNTCP.

MATERIALS AND METHODS

A retrospective record based cross-sectional study was conducted in District Tuberculosis Centre (DTC), Satara district, Maharashtra, India during March 2013. All Registered TB cases under DTC from year 2002 to 2012 were included as study subjects. The data collection was started after obtained written permission from District Tuberculosis Officer (DTO) & District Health Officer (DHO). The RNTCP records for year 2002 to 2012, i.e. the 11- year period, for all TB cases were analyzed by investigator according to RNTCP outcome evaluation indicators as follows. [8]

Annual case detection rate
It is the percentage of new confirmed TB cases per one lakh population occurring during one year.

Cure rate
Percentage of patients initially sputum smear-positive who has completed treatment and had negative sputum smears, on two occasions, one of which was at the end of treatment.

Sputum conversion rate
Percentage of sputum smear positive converted to smear negative at the end of intensive phase per total number of sputum smear positive patients initiated on treatment.

Treatment success rate
The percentage of new, registered smear positive infectious cases that were cured or in which a full course of treatment was completed.

Default rate
Percentage of patients who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment.

Treatment failure rate
Percentage of sputum smear positive cases after 5 months of treatment per total number of sputum smear positive patients initiated on treatment.

Death rate
Percentage of patients who were died during the course of treatment regardless of cause.

The data was compiled and entered into MS Excel 2007. The trend of annual case detection rate, gender and TB, outcome of New Sputum Positive cases under DOTS etc were analyzed. The trend was statistically analyzed for 2002-2012 by using chi-square test for trend. Trend was considered significant if p value is less than 0.05.

Infrastructure DTC, Satara
The DTC coverage includes 11 blocks and 1750 villages. Public health care services are rendered by one District Hospital, seventeen Rural Hospitals, seventy one Primary Health Centres and four hundred Sub-Centres. One Private Medical College also provides DOTS therapy to TB patients. DTC is run by one DTO, three Medical Officers, Laboratory Technicians(14), Senior Treatment Supervisors(10) Senior TB Lab Supervisors(10), Multi Purpose Health Supervisors (1) Multi Purpose Health Assistants (2) X-ray tech,(1) TBHV(2).
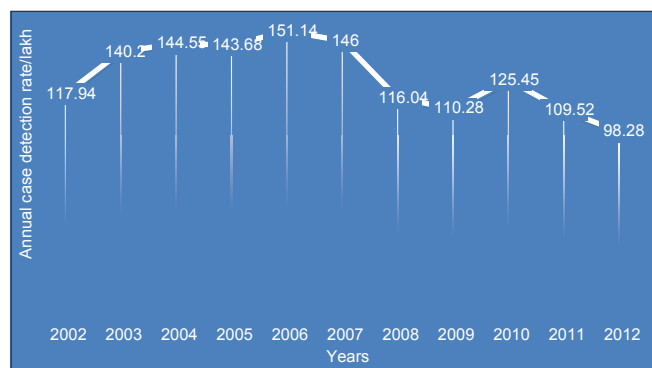
RESULTS

A total of 40,998 TB cases were registered under Satara DTC during the year 2002 to 2012.

Annual case detection rate of TB was 117.94/lakh for 2002. It was increased to 151.14/lakh for 2006 and then decreased to 98.28/lakh for 2012, with total no of TB cases

were decreased to 2991 for 2012. The trend of Annual case detection rate was studied, which was linear and was statistically significant ($\chi 2$ trend= 313.3, p < 0.0001*) (Figure 1).

Among total TB cases, proportion of pulmonary cases showed a declining trend from 92.23% to 81% since 2002 to 2012. However, proportion of extra-pulmonary cases showed steadily upward trend from 7.76% to 18.45%. The proportion of TB-HIV cases (lab confirmed) increased from 3.11% to 25.31% since 2009 to 2011 but decreased to 9.62%. for 2012. The trend of pulmonary and extra-pulmonary TB cases since 2002 to 2012 shows statistically significant difference ($\chi 2$ trend = 496.3, p < 0.0001*) (Table 1).

Among total TB cases, proportion of males were declined from 76.43% to 52.23% since 2002 to 2009 but again increased to 56.16% for 2012. The proportion of females showed upward trend from 22.84% to 37.54% with periodic fluctuating during study period. Proportion of child cases were increased from 0.71% to 8.66% since 2002 to 2011 but for 2012 decreased to 6.28%. The trend of male, female and child cases among total TB cases was

studied, which was linear and showed significant difference ($\chi 2$ trend = 225.2, p < 0.0001*) (Table 2).

Proportions of pulmonary TB cases in male and female gender were declined from 94.86% to 83.86% and 83.20% to 74.97% respectively for period of 11 years. However, proportions of extra-pulmonary TB cases were showed upward trend from 5.13% to 17.63% and 10.05% to 25.03% respectively. The trend of male and female cases for pulmonary and extra-pulmonary TB was studied and was statistically significant (@ χ^2 trend = 314.7, p < 0.0001*, # χ^2 trend = 204.2, p < 0.0001*) (Table 3).

Since year 2002 to 2007, all child TB cases were belonged to pulmonary type only but from year 2008 onwards, the proportions of pulmonary TB cases decreased to 85.10% whereas extra-pulmonary increased to 14.89% for 2012. The trend of child TB cases among pulmonary and extra-pulmonary depicts statically significant difference ($\chi 2$ trend = 11.3, p < 0.0007*) (Table 4).

Among total pulmonary TB cases, maximum, 2182 NSP cases were reported for 2004 whereas maximum, 2224

Figure 1: Annual Tuberculosis case detection rate. $\chi 2$ trend = 313.3, p < 0.0001* (* = significant statistical trend at 95% confidence interval)

Table 1: Pulmonary, extra-pulmonary and TB-HIV distribution of TB cases

Year	Annual total pulmonary TB cases, (%)	Annual total extra- pulmonary TB cases (%)	Annual total HIV-TB cases (%)
2002	3077, (92.23)	259, (7.76)	Nil
2003	3681, (92.18)	312, (7.81)	Nil
2004	3756, (90.61)	389, (9.38)	Nil
2005	3632, (87.56)	516, (12.43)	Nil
2006	3847, (87.61)	544, (12.38)	Nil
2007	3709, (86.82)	563, (13.17)	Nil
2008	2901, (84.87)	517, (15.12)	Nil
2009	2655, (81.19)	615, (18.80)	102, (3.11)
2010	3035, (81.06)	709, (18.93)	509, (13.59)
2011	2746, (83.46)	554, (16.83)	833, (25.31)
2012	2439, (81.54)	552, (18.45)	288, (9.62)

(Nil=TB-HIV reporting/record under District RNTCP was not practiced),
χ^2 trend=496.3, p<0.0001*

Table 2: Male, female and child distribution tuberculosis

Year	Annual total male TB cases, (%)	Annual total female TB cases, (%)	Annual total child TB cases, (%)
2002	2550, (76.43)	762, (22.84)	24, (0.71)
2003	2611, (65.38)	1353, (33.88)	29, (0.72)
2004	2648, (63.88)	1474, (35.56)	23, (0.55)
2005	2528, (60.94)	1579, (38.06)	41, (0.98)
2006	2857, (65.04)	1523, (34.68)	11, (0.25)
2007	2632, (61.61)	1610, (37.68)	30, (0.70)
2008	1936, (56.64)	1276, (37.33)	206, (6.02)
2009	1708, (52.23)	1307, (39.96)	255, (7.79)
2010	2172, (58.01)	1312, (35.04)	260, (6.94)
2011	1760, (53.49)	1245, (37.84)	285, (8.66)
2012	1680, (56.16)	1123, (37.54)	188, (6.28)

χ^2 trend=225.2, p<0.0001*

Table 3: Gender distribution of pulmonary and extra-pulmonary Tuberculosis

Year	Pulmonary TB cases		Extra-pulmonary TB cases	
	Male (%)@	Female (%)#	Male, (%)	Female, (%)
2002	2419, (94.86)	634, (83.20)	131, (5.13)	128, (16.79)
2003	2436, (93.29)	1217, (89.94)	175, (6.70)	136, (10.05)
2004	2383, (90.10)	1290, (87.51)	265, (10.00)	184, (12.48)
2005	2262, (89.47)	1327, (84.04)	266, (10.52)	252, (15.95)
2006	2539, (88.86)	1298, (85.22)	318, (11.13)	225, (14.77)
2007	2329, (88.48)	1350, (83.85)	303, (11.51)	260, (16.14)
2008	1669, (86.20)	1026, (80.40)	267, (13.79)	250, (19.59)
2009	1439, (84.25)	958, (73.29)	269, (15.74)	349, (26.70)
2010	1789, (82.36)	986, (75.15)	383, (17.63)	326, (24.84)
2011	1489, (84.60)	962, (77.26)	271, (15.39)	283, (22.73)
2012	1409, (83.86)	842, (74.97)	271, (17.63)	281, (25.03)

@χ^2 trend=314.7, p<0.0001*, #χ^2 trend=204.2, p<0.0001*

NSN cases were found for 2006. The proportion of NSP cases ranging from 41.3% to 58.1% with maximum and minimum cases reported in year 2006 and 2009 respectively. The trend of NSN cases showed periodic fluctuations over 11 years of study period with maximum and minimum proportion reported for 2009 & 2004 respectively. The trend of NSP and NSN was studied, and was statistically significant ($\chi 2$ trend = 290.53, p<0.0001*) (Figure 2).

Cure rate of NSP cases was in the range of 79.6% to 87% from 2002 to 2012 and was maximum in 2005 and minimum in 2009 with periodic upward and downward trend. Trend of sputum conversion rate was steadily showed upward trend from 78.5% to 93.5%. Treatment success rate was in a range of 82.7% to 90.3% and trend was almost stable during study period (Figure 3.1), however defaulter rate was decreased from 7.5% to 2.8% since 2002 to 2010 but again increased to 4.7% for 2012. Treatment failure rate was continuously decreased from 6.2% to 2.1% over period of 11 years. From 2002 to 2012, death rate among NSP cases was in a range of 5.2% to 10.4%, and was maximum in 2009 and minimum in 2007 with period little fluctuation (Figure 3.2).

Trend of cure rate, treatment success rate, treatment completion rate, sputum conversion rate, defaulter rate,

failure rate and death rate of NSP- TB cases under DOTS strategy shows significant statistical trend over study period (p <0.05)(Table 5, Figures 1 and 2).

DISCUSSION

The present record based evaluation study conducted in Satara district, India since year 2002 to 2012 has been shown the upward trend of TB from year 2002 to 2006 but thereafter linear downward by 2012. Similar findings have also been reported by Govt. of India[9] i.e. from 83/lakh to 116/lakh for period 1996 to 2004 then downward to 100/lakh by 2011. However, TB reported from Italy[10] was 17.3/lakh for year 1996 and showed further declined trend. The high difference in incidence of TB was mainly due to lack of adequate infrastructure, population explosion and poverty.

Proportions of pulmonary TB cases decreased from 92.23% to 81%, whereas extra-pulmonary increased from 7.76% to 18.45%. A similar finding also reported from South Delhi.[11] The TB-HIV case load was increased from 3.11% to 25.31% for period 2009 to 2011, Similar upward trend was also reported from Bombay,[12] but difference was high which could be due to lack of knowledge, attitude and practice about HIV-AIDS prevention in rural area.

Table 4: Trend of child tuberculosis

| Year	Pulmonary TB cases, (%)	Extra-pulmonary TB cases, (%)
2002	24, (100.00)	0, (0.00)
2003	29, (100.00)	0, (0.00)
2004	23, (100.00)	0, (0.00)
2005	41, (100.00)	0, (0.00)
2006	11, (100.00)	0, (0.00)
2007	30, (100.00)	0, (0.00)
2008	186, (90.29)	20, (9.70)
2009	211, (82.74)	44, (17.25)
2010	238, (91.53)	22, (8.46)
2011	262, (91.92)	23, (8.07)
2012	160, (85.10)	28, (14.89)

χ^2 trend=11.3, p<0.0007*
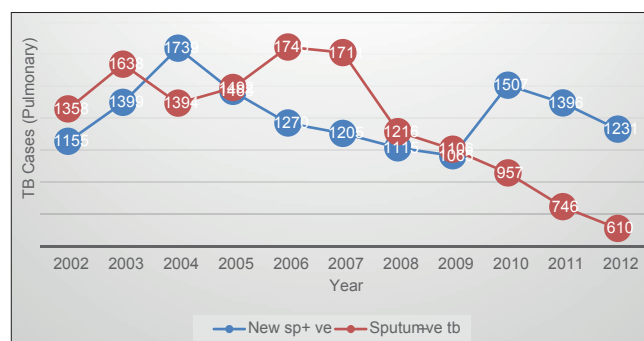
Figure 2: Trend of New sputum positive Pulmonary Tuberculosis. $\chi 2$ trend =290.53, p<0.0001*

Table 5: Outcome of new sputum positive cases under RNTCP

Year	Total NSP cases	NSP cases cured@	NSP cure rate (%)	Sputum conversion cases#	Rate (%)	Treat. Succes. Cases*	TSR (%)	DF cases**	DF rate (%)	TFL cases***	TFL rate (%)	DT cases****	DT rate (%)
2002	1271	1016	79.91	998	78.5	1096	86.23	96	7.5	80	6.2	79	6.2
2003	1774	1458	82.18	1346	75.8	1545	87.0	106	5.9	87	4.9	123	6.9
2004	2182	1865	85.47	1785	81.8	1946	89.1	89	4.0	81	3.7	147	6.7
2005	1780	1549	87.02	1589	89.8	1608	90.3	61	3.5	67	3.7	111	6.2
2006	1623	1404	86.50	1448	88.0	1442	88.8	67	4.5	31	1.9	114	7.0
2007	1791	1501	83.80	1574	87.8	1542	86.0	155	8.6	41	2.2	94	5.2
2008	1044	856	81.99	889	85.0	894	85.6	69	6.6	38	3.6	81	7.7
2009	903	719	79.62	783	86.4	747	82.7	62	6.8	28	3.1	94	10.4
2010	1423	1223	85.94	1304	91.6	1256	88.2	41	2.8	33	2.3	126	8.8
2011	1175	986	83.91	1059	91.6	1013	86.2	45	3.8	27	2.2	117	9.9
2012	1232	1049	85.14	1153	93.5	1076	87.3	58	4.7	27	2.1	98	7.9

(NSP- New sputum + ve , TSR- Treatment success rate, DF-Defaulter, TFL- Treatment failure, DT-Death). (@: χ^2 trend=64.63, p<0.0001*, #: χ^2 trend=119.91, p<0.0001*, *χ^2 trend=54.33, p<0.0001*, **: χ^2 trend=109.01, p<0.0 0001*, *** $\chi 2$ trend = 46.90, p<0.0001*, **** χ^2 trend=21.13, p<0.0001*)
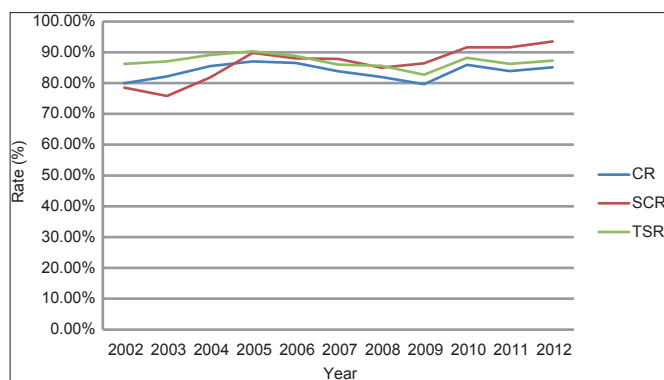
Figure 3.1: Cure rate, Sputum conversion rate and Treatment success rate. (CR=Cure rate, SCR=Sputum conversion rate, TSR= Treatment success rate)
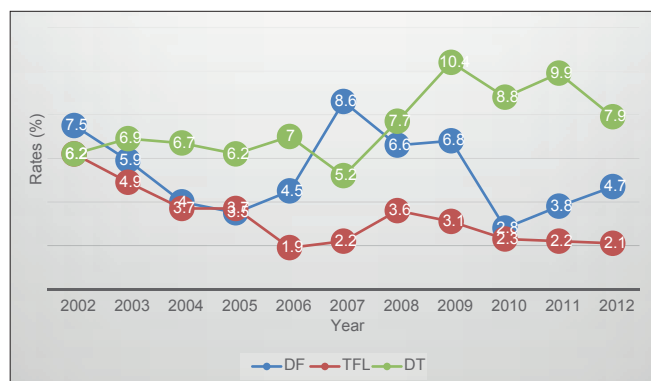
Figure 3.2: Defaulter rate, Treatment failure rate and Death rate. (DF= Defaulter rate, TFL= Treatment failure rate, DT= Death rate)

Preponderance of male TB cases over female showed trend with time usually either upward or downward, similarity in findings were reported from Serbia.[13] In present study, proportions of child TB cases increased for study period due to high prevalence of malnutrition, maternal TB and HIV infection, however proportions of child TB cases reported from Zambia[14] were so high i.e. 135% to 69% and it indicates TB is still big problem either due to neglect child TB or poor implementation of TB control programme.

Proportions of pulmonary and extra pulmonary TB in males were higher than females and showed periodic fluctuation. A similar trend was observed in Serbia[13] and South Delhi.[11] Wang J,[15] also reported that women often remain under-notified by public health authority and undiagnosed female host may serve a potential source of latent infection. Among child TB, Proportion of pulmonary TB was higher than extra-pulmonary and showed downward and upward trend respectively, however very low proportion was observed from European[16] area and difference was mainly due to quality health care services, standard of living and effective implementation of TB control activities.

In present study, proportion of NSP cases revealed increased trend from 41.3% to 50.5% for 2002 to 2012, however exact

opposite trend was reported from Dakshina Kannada district, Karnataka[17] i.e. 50% to 42%. Cure rate of NSP cases were ranged from 79.0% to 87% over study period and achieved goal of WHO-STOP TB Strategy, however rate was decreased from 85% to 79% in in Dakshina Kannada district, Karnataka.[17] A similar downward trend was also reported from Sankhuwasava district of Nepal.[18] Treatment success and sputum conversion rate was more than 86.2% and trend increased more than 90.3%, similar findings also reported by Govt. of India,[9] however it was reported low from in Sankhuwasava district of Nepal[18] may be due to inadequate health infrastructure or poor finance for TB control. Defaulter rate decreased from 7.5% to 2.8% since 2002 to 2010 but again increased to 4.7% by 2012 due to change in behavior of cases as well as may be due to workload on peripheral health care staff, however trend of defaulter rate reported by Govt of India[9] has been more than 6%. Upward trend of defaulter rate has revealed from Dakshina Kannada district, Karnataka[17] i.e. 6.8% to 10.4%.

Our study revealed declining trend of Treatment failure rate from 6.2% to 2.1%, similar trend also reported by Govt of India,[9] Dakshina Kannada district, Karnataka[17] and Bhojpur district of Nepal[18] which could be due to case adherence.

Study reported upward trend of death rate from 6.2% to 10.4% for 2002 and remains above to 7.9% for 2012, similar finding reported from Dakshina Kannada district, Karnataka.[17] Death rate reported by Govt. of India[9] was less than 5%. However, it was decreased to less than 1% in Sankhuwasava and Bhojpur district of Nepal[18] and difference observed could be due to high prevalence if TB-HIV in western Maharashtra.

CONCLUSION

The outcome evaluation of RNTCP data from Satara district showing that burden of TB in rural area of western Maharashtra is still high. To reduce burden of TB, need to improve accessibility of health care services with main emphasis on public-private partnership, early case detection, adherence with treatment as well as improvement in standard of living. Developing countries with high burden of TB need to invest more resources in TB control strategy.

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