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Socio-Demographic Profile, Treatment Outcome & Factors Influencing Outcome among Tuberculosis Cases Treated On Daily Regimen: A Cross-Sectional Study at District Tuberculosis Centre, Uttarakannada

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ABSTRACT

Introduction: Tuberculosis is one of the leading causes of mortality in India. Measuring, monitoring and evaluating ending tuberculosis outcomes is central to the success of the National Programme.

Methodology: Retrospective Cross-sectional Descriptive study involving all registered tuberculosis cases treated on daily regimen using Fixed Dose Combination from period of 1st Jan to 31st Dec 2018 was conducted. Questionnaire derived from patient treatment card was used to collect data from the patient records. Incomplete/missing data were excluded from analysis. Frequency, proportions, mean and chi-square test were used to present and analyze the data.

Results: Of the 1243 tuberculosis cases notified, 50.2% were between 15-44years. 64.36% were males. 89.14% & 10.86% of cases were notified from public & private sectors respectively. 3.54% were Drug Resistant Tuberculosis cases. Overall treatment success rate was 87%. Treatment success rate among HIV reactive cases was 64.44%. Statistically significant association was observed between age, gender and the outcome of treatment success.

Conclusion: A good treatment success rate of 87% was observed. Strategy to improve notification of cases from private sector and among females needs to be strengthened.

Key words: Tuberculosis, treatment outcome, Fixed Dose Combination, treatment success rate.

INTRODUCTION

Tuberculosis (TB) remains a world-wide public health problem despite the fact that highly effective drugs and vaccine are available.[1] TB is one of the leading causes of mortality in India.[2] It has killed more persons than any other infectious diseases.[3] India contributes 27% of global burden with estimated 27.5 lakhs patients.[4]

In the journey of TB control in India, National Tuberculosis Program (NTP) was initiated in 1962. A combined review of the program in 1992 led to Revised National Tuberculosis Control Program (RNTCP) in 1997.[5] National AIDS Control Program and RNTCP have developed a "National framework of joint TB/HIV Collaborative activities" to articulate the policy for strengthening TB/HIV collaborative activities.[6] National strategic Plan (NSP) for Tuberculosis elimination 2017-2025 was launched for working towards achieving the goals of eliminating TB by 2025.[5] Sustainable Development Goals (SDG's) Target 3.3 includes ending the TB epidemic by 2030.[7]

Major path-breaking measure of switching from thrice weekly regimen being followed since program inception to daily regimen using Fixed Dose Combination (FDC's) drugs for treatment of all TB

patients is initiated.[5] Treatment outcome is one of the key determinants to evaluate the effectiveness of TB control program.[8]

Uttarakannada is a border district between the States of Karnataka and Goa. There are hardly any studies done to assess the treatment outcome and factors influencing the outcome after the initiation of daily regimen by RNTCP. Hence this study was taken up to assist the effective program management.

OBJECTIVES

The research was conducted to study the socio-demographic profile of tuberculosis cases registered at District Tuberculosis Centre (DTC), Uttarakannada and treated on daily regimen; and also to assess the treatment outcome and the factors influencing the outcome among cases on daily regimen at DTC, Uttarakannada.

MATERIALS AND METHODS

A retrospective Cross-sectional Descriptive study was conducted using data available from District Tuberculosis Centre (DTC), Uttarakannada district. This study was conducted from 1st June 2019 to 31st July 2019.

All TB cases registered at DTC Uttarakannada district and treated on daily regimen using FDC's from period of 1st January 2018 to 31st December 2018 were included in the study.

Written consent was obtained from the office of District Tuberculosis Centre (DTC), Uttarakannada, Dept of Health and Family Welfare, Government of Karnataka for conducting the study. A pretested and adopted questionnaire derived from RNTCP treatment card was used to collect the data. Required data was obtained from the patient records maintained at DTC. The identity of the patient was delinked with the data and confidentiality of the data collected was maintained.

Since this study involved secondary data and did not include direct patient involvement, permission for wavier of informed consent form was obtained from the Institutional Ethical Committee.

Definitions of treatment outcome: Was based on the Technical and Operational Guidelines for Tuberculosis Control in India 2016 which includes cured, treatment completed, treatment success, failure, lost to follow-up, not evaluated, treatment regimen changed and died.[13]

Statistical Analysis: Data collected was entered into excel sheet and analyzed using SPSS version 18 statistical software. Frequency, percentage and means were used to present the data. Chi square test was used to find association between different factors and treatment outcome (treatment success and outcomes other than treatment success). For all the tests p value of < 0.05 was considered for statistical significance. Incomplete/ missing data were excluded from analysis.

ETHICAL CLEARANCE

Ethical clearance was obtained from Institutional Ethical Committee of Karwar Institute of Medical Sciences, Karwar before starting the study.

RESULTS

During the period of one year from 1st January to 31st December 2018, a total of 1243 cases were registered at District TB Centre of Uttarakannada district (3 cases of "Duplicate record" and 2 cases of "wrong diagnosis" were excluded).

Table 1 shows that, more than half of the cases were reported in the age group of 15-44 years (50.2%), pediatric cases (<15 years age[4]) accounted for 6.60%. Mean age was 40.1 Years. 64.36% were males, 35.56% were females and 0.08% were transgender. Male to female ratio in TB notification was 1.8:1.

Table 2 & Figure 1 shows that among 12 TB units (current facility TBU) at Uttarakannada district, maximum cases i.e. 14% were reported from Mundgod TB Unit followed by Sirsi (12.55%) and Karwar (12.15%). Least number of cases were reported from Joida (3.3%) followed by Siddapur (3.86%) and Yellapur (4.1%). 89.14% of cases were notified from the public sector while private sector contributed 10.86% of notified cases. No cases were reporting from private sector from the TB units of Ankola, Haliyal, Siddapur and Yellapur. Prevalence of Drug Resistant TB cases was 3.54%.

Table 3 shows that 86.97% of cases knew their HIV status and among the tested, 4.26% were HIV positive. 77.15% of the cases were tested for their blood sugar status and among the tested, 10.32% were having diabetes mellitus.

Table 1: Age and sex wise distribution of registered cases (N=1243)

Age (Years)	Male (%)	Female (%)	Transgender (%)	Total (%)
< 15	41 (3.3)	40 (3.22)	1 (0.08)	82 (6.6)
15-29	162 (13.03)	171 (13.76)	0 (0)	333 (26.79)
30-44	200 (16.09)	91 (7.32)	0 (0)	291 (23.41)
45-59	215 (17.3)	83 (6.68)	0 (0)	298 (23.97)
60-74	147 (11.83)	51 (4.1)	0 (0)	198 (15.93)
>75	35 (2.82)	6 (0.48)	0 (0)	41 (3.3)
Total	800 (64.36)	442 (35.56)	1 (0.08)	1243 (100)

Table 2: Distribution of TB cases Notified based on current facility TB Unit (N=1243)

Current facility TB unit	TB cases Notified (%)	Sector wise		Pediatric TB cases (%)	Drug Resistant TB cases (%)
		Public (%)	Private (%)		
Ankola	111 (8.93)	111 (8.93)	0 (0.00)	3 (0.24)	5 (0.40)
Bhatkal	96 (7.72)	90 (7.24)	6 (0.48)	9 (0.72)	3 (0.24)
Dandeli	56 (4.51)	52 (4.18)	4 (0.32)	5 (0.40)	5 (0.40)
Haliyal	87 (7.00)	87 (7.00)	0 (0.00)	5 (0.40)	3 (0.24)
Honnavar	144 (11.58)	140 (11.26)	4 (0.32)	8 (0.64)	6 (0.48)
Joida	41 (3.30)	33 (2.65)	8 (0.64)	1 (0.08)	1 (0.08)
Karwar	151 (12.15)	143 (11.50)	8 (0.64)	4 (0.32)	6 (0.48)
Kumta	128 (10.30)	105 (8.45)	23 (1.85)	15 (1.21)	1 (0.08)
Mundgod	174 (14.00)	143 (11.50)	31 (2.49)	17 (1.37)	4 (0.32)
Siddapur	48 (3.86)	48 (3.86)	0 (0.00)	2 (0.16)	1 (0.08)
Sirsi	156 (12.55)	105 (8.45)	51 (4.10)	11 (0.88)	5 (0.40)
Yellapur	51 (4.10)	51 (4.10)	0 (0.00)	2 (0.16)	4 (0.32)
Total	**1243 (100)**	**1108 (89.14)**	**135 (10.86)**	**82 (6.60)**	**44 (3.54)**

Table 3: Distribution of cases as per TB Co-morbidities (N=1243)

TB Co-morbidities	Cases (%)
HIV	
TB cases with known HIV status (tested)	1081 (86.97)
HIV positive cases among tested	46 (4.26)
Diabetes Mellitus	
TB cases with known blood sugar (tested)	959 (77.15)
TB-DM Co-morbid cases among tested	99 (10.32)

Table 4: Distribution of cases as per the treatment outcome (N=1108)

Treatment outcome	Cases (%)
Cured	474 (42.78)
Treatment completed	490 (44.22)
Died	74 (6.68)
Treatment failure	12 (1.08)
Lost to follow up	40 (3.61)
Treatment regimen changed	14 (1.26)
Not evaluated	4 (0.36)
Total	1108 (100)
Treatment success (Cured + treatment completed)	964 (87)

Out of 1243 notified TB cases, 1108 cases were assigned treatment outcome as per the Technical and Operational Guidelines for Tuberculosis Control in India 2016. **Table 4** shows treatment outcome among the notified cases. The treatment success rate (Cured + treatment completed) of 87% was observed. **Table No. 5** shows the distribution of cases as per the various factors observed and treatment outcome. Chi square test was performed which showed a significant association between age ($\chi2$ = 23.03, p<0.0003), gender ($\chi2$ = 12.69, p<0.0018) and the treatment outcome (treatment success and outcomes other than treatment success). No significant association was observed between the public and private cases and treatment outcome ($\chi2$ = 0.02, p=0.88)

Among the 46 HIV reactive cases, 45 had documented treatment outcome. **Table 6** shows treatment outcome among HIV reactive cases. The treatment success rate of 64.44% was observed among HIV reactive cases.

Table 5: Distribution of cases as per the various factors and treatment outcome

Parameter	Treatment Outcome (N=1108)							Grand Total	P value
	Treatment success (Cured or Complete(%)	Outcome other than treatment success							
		Died (%)	Treatment Failure (%)	Lost to Follow-up (%)	Treatment Regimen Changed(%)	Not Evaluated (%)	Sub total (%)		
n	**964 (87.00)**	74 (6.68)	12(1.08)	40(3.61)	14(1.26)	4(0.36)	**144(13.00)**	1108	
Age in yrs									
< 15	**77 (97.47)**	0 (0)	0 (0)	2 (2.53)	0 (0)	0 (0)	**2 (2.53)**	79	**<0.0003**
15-29	**270 (91.53)**	5 (1.69)	4 (1.36)	11 (3.73)	5 (1.69)	0 (0)	**25 (8.47)**	295	
30-44	**224 (86.82)**	17 (6.59)	3 (1.16)	7 (2.71)	6 (2.33)	1 (0.39)	**34 (13.18)**	258	
45-59	**220 (82.09)**	30 (11.19)	4 (1.49)	10 (3.73)	2 (0.75)	2 (0.75)	**48 (17.91)**	268	
60-74	**147 (84.48)**	15 (8.62)	1 (0.57)	9 (5.17)	1 (0.57)	1 (0.57)	**27 (15.52)**	174	
>75	**26 (76.47)**	7 (20.59)	0 (0)	1 (2.94)	0 (0)	0 (0)	**8 (23.53)**	34	
Gender									
Male	**596 (84.3)**	64 (9.05)	9 (1.27)	25 (3.54)	12 (1.70)	1 (0.14)	**111 (15.70)**	707	**<0.0018**
Female	**367 (91.75)**	10 (2.5)	3 (0.75)	15 (3.75)	2 (0.5)	3 (0.75)	**33 (8.25)**	400	
Transgender	**1 (100)**	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0 (0)**	1	
Place of treatment									
Public sector	**887 (87.05)**	71 (6.97)	12 (1.18)	32 (3.14)	13 (1.28)	4 (0.39)	**132 (12.95)**	1019	**0.88**
Private sector	**77 (86.52)**	3 (3.37)	0 (0)	8 (8.99)	1 (1.12)	0 (0)	**12 (13.48)**	89	

Table 6: Treatment outcome among HIV reactive cases

Treatment outcome	HIV reactive (%)
Cured	11 (24.4)
Treatment completed	18 (40)
Died	12 (26.7)
Lost to follow up	2 (4.4)
Treatment regimen changed	1 (2.2)
Not evaluated	1 (2.2)
Total	45 (100)
Treatment success (Cured + treatment completed**)**	29 (64.44)

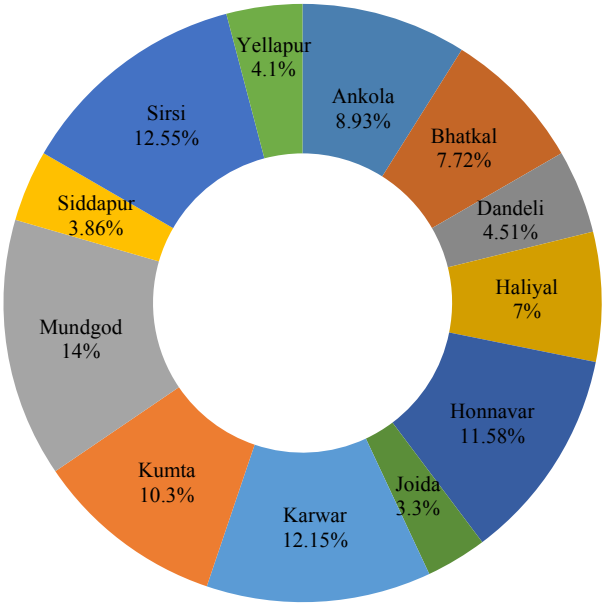

Figure 1: TB cases notified based on current facility TB Unit

DISCUSSION

Among the 1243 cases notified, more than half of the cases were reported in the age group of 15 to 44 years (50.2%) & mean age of presentation was 40.1 years. Similar observations are reported in India TB report 2019 (58.9% among age group 15-44 years), Kashyap R et al (mean age 38.2 years), Mohandas B et al, Sahyog et al and Bisoi et al at West Bengal (64.4% of cases in age group of 15-44 years).[4,9,10,11,12] This shows that majority of the TB burden is among the working age group and this can affect the socio-economic status of the families.

Our study observed 6.6% of TB cases among paediatric population (< 15 years of age[4]) which was similar to the Global TB report 2019 (8%) and India TB report 2019 (6.2%).[4,7] Improved screening of household contacts and other close contacts for active TB, screening for TB in Nutritional Rehabilitation Centres and Anganwadi Centres, encouraging and involving the paediatric professional bodies for notifying all diagnosed TB patients could yield more number of paediatric TB cases.[5]

In our study 64.36% were males, 35.56% were females and 0.08% were transgender. Overall male to female ratio was 1.8:1. Similar findings are reported in Global TB report 2019 (male: female ratio 1.7:1).[7] India TB report 2019 reports 63.67% males, 36.25% females and 0.08% transgender.[4] Similarly, in studies conducted by Mekonnen et al, Kashyap R et al, Mohandas B et al, Sahyog et al, Bisoi et al, and reports less cases being notified among females when compared to males.[3,9,10,11,12]

The steep decrease in the number of cases of TB notifications among females in age group of 30 years and above might be because of probable lower status of women in society at large and gender based in-equality within the family. Fear of lower likelihood of marriage among un-married females, fear of divorse /abandonment among married females and harassment by husband's family might be some of the other reasons.[5]

Along with public health care sector, the private sector also plays a major role in health care delivery system of our country. In our study, the notification of TB cases from public and private sectors are 89.14% and 10.86% respectively. India TB report 2019 also reports similar differential reporting from public sector (74.5%) and private sector (25.5%).[4] This gap needs to be addressed.

Newer challenge in the fight against TB control activity is the emergence of drug resistance for anti-tubercular drugs. In our study 3.54% of the notified cases were drug resistant TB. Highest cases were reported from the TB units of Honnavar and Karwar. India TB report 2019 also reports 3.1% of drug resistance TB cases at National level.[4]

Associated co-morbid conditions, mainly HIV and diabetes mellitus play an important role in the final outcome of tuberculosis.[5] In our study, 86.97% of notified cases knew their HIV status which is a better when compared to India TB report 2019 (67% knew their HIV status) and Global TB report 2019 (64% knew their HIV status).[4,7] Better achievement was observed in our study when compared to NSP 2017-2025 indicator of achieving "proportion of TB cases with known HIV status (Including private sector) of 80%" by 2018.[5] In our study, among the cases tested for HIV, 4.26% were HIV positive while India TB report 2019 reports 3.4% of HIV positivity among cases tested.[4]

76.84% of the cases in our study were tested for their blood sugar status and among the tested, 10.32% were having diabetes mellitus which was good achievement when compared to the India TB report which reports that 29% of the notified cases knew about their blood sugar status and among

the tested 8% were having diabetes mellitus.[4] Early detection and prompt treatment can help improve care and control of both diseases

The overall treatment success rate that was observed in our study was 87% which is encouraging when compared to NSP 2017-2025 indicator of achieving "Treatment success rate of 80% among DSTB cases" by 2018.[5] Since studies analysing the treatment outcome after the initiation of daily FDC regimen in India were hardly available, our study results were compared with the latest available treatment outcome data. India TB report 2019 reports a treatment success rate of 79% among TB cases notified in 2017.[4] A higher treatment success rate was observed in study done by Kashyap R et al (89.7%) and Mohandas B et al (89%).[9,10]

Our study reported treatment success rate of 64.44% among HIV reactive cases while India TB report 2019 & Global TB report 2019 reports success rates of 70% & 71% respectively.[4,7]

Upon analyzing the association of various factors with the treatment outcomes (treatment success and outcomes other than treatment success), statistically significant association was observed among age and gender.

CONCLUSION

Majority of the TB burden in our study is among working age group (50.2% among 15-44years of age). There is a need to address about the issue of differential reporting of cases among males and females. Notification of TB cases from private sector needs to be encouraged. 3.54% of the notified cases were drug resistant TB. The overall treatment success rate that was observed in our study was 87% which is an encouraging fact. Statistically significant association was observed among age, gender and the treatment outcome.

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Ethical approval: Taken from the Institutional Ethical Committee of Karwar Institute of Medical Sciences, Karwar before starting the study.

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