Original Article

Estimation of the burden of bacteriologically positive Tuberculosis among Adults in Kashmir: A baseline for future surveys in the Valley

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Abstract

Background: India has the highest burden of both Tuberculosis and MDR-Tuberculosis based on estimates reported in the Global Tuberculosis Report 2016. The estimates have been revised upwards based on the newer evidence, and the current study was done to estimate the prevalence of bacteriologically positive pulmonary Tuberculosis among the adult population and to provide baseline information for future measurements of Tuberculosis burden and trends. **Methods:** A cluster-based sampling design was adopted in 10 districts of Kashmir valley in India. Assuming a prevalence of 217 per lakh population, a design effect of 2.5, a relative precision of 0.25% and the expected participation rate of 80%, a sample size of 49,716 was achieved. A total of 67 clusters were identified where each cluster had 750 subjects aged ≥15 years, and eligible individuals were questioned for pulmonary symptoms suggestive of Tuberculosis. **Results:** Of the total 42,805 that were interviewed, 3.85% had pulmonary Tuberculosis symptoms. A total of 1539 sputum samples were collected from symptomatic and 1351 chest X- rays were done. Cartridge based nucleic acid amplification test (CBNAAT) tests were done on individuals with suspicious X-ray findings. The prevalence of bacteriologically positive pulmonary Tuberculosis was found to be 147 per 100,000 population. Females are affected more than males, and the age of female Tuberculosis patients is less than that of males. **Conclusion:** The study is the first survey of its kind providing a baseline for further research in the state. CBNAAT is going to be game-changer which surmounts the drawbacks of sputum smear microscopy.

Keywords: CBNAAT, cluster sampling, north India, prevalence, pulmonary tuberculosis, sputum examination

Introduction

Globally, India accounts for one-fourth of the global Tuberculosis (TB) burden, and around 4.8 lakh people died due to TB of the estimated 28 lakh cases in 2015.[1] Global health is considered critical for national and international security, domestic and global economic well-being.[2] A country over 1.2 billion people, with over 500 million latent infections of TB and weaknesses in the available estimates are disappointing and limit effective policy-making.[3] Achieving the global targets of 'End TB 2035' is feasible only with a dramatic decline in TB deaths and cases, and elimination of the economic and social burden of TB.[4]

The first ever Tuberculosis prevalence study in Kashmir was conducted by Mayurnath *et al*.[5] in 1978. Since then there is no relevant data from Kashmir regarding TB prevalence. National Tuberculosis Control Programme was started in Kashmir in 1964,

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and the Revised National Tuberculosis Programme (RNTCP) was implemented 40 years later, in 2004.

The study aimed to gain an understanding of the burden of TB in Kashmir and to identify ways in which TB control can be improved. The specific objectives are to measure the prevalence of bacteriologically positive pulmonary TB among the adult population and provide baseline information for future measurements of the TB burden.

Methods

After acquiring formal approval from the institutional ethical Committee of Director Health Services Kashmir, this cross-sectional study was conducted in 10 districts of Kashmir valley from June to August 2017. People who were older than 15 years were eligible to be enrolled for the study after getting due consent. The sample size of 49,716 was estimated based on World Health Organization's (WHO) guidelines[6] on the expected prevalence of pulmonary TB.

Cluster-based sampling design as per WHO guidelines[7] and a sample was designed assuming an expected prevalence of 217 per 100,000 population,[8] a design effect of 2.5, a relative precision of 0.25% and expected participation rate of 80%. Study sites, i.e. districts were selected as the primary sampling units, and the blocks within these districts were the secondary sampling units. Within each block, the villages were enumerated and finally selected and sampled. The block formed the cluster and there were 67 clusters in total, where each cluster consisted of 750 subjects.

The survey tool consists of patient's socio-demographic details, X-ray film number, sputum smear number, CBNAAT number, and their results. Any respondent having cough >2 weeks, chest pain, hemoptysis, fever more than two weeks, history of previous ATT use, diabetes and age >65 years were eligible for sputum examination and were asked to provide two sputum samples. The staff collected one spot sputum sample in a pre-numbered sterilized sputum cup. A second bottle was provided for morning sample collection. For people living in difficult terrain, two spot samples were taken one hour apart and transported to the nearest DMC. X-ray examinations were done at the nearest facility and subjects with suspicious X-rays were tested using CB-NAAT.

Patients found positive were started on treatment at the nearest Directly Observed Treatment Short-course (DOTS) provider. The flowchart showing the study population, coverage by sputum examination, X-ray and CBNAAT is shown in Figure 1.

Results

Case Definition: A case of TB for the study was defined as having a positive sputum smear microscopy or a positive CBNAAT test (Xpert MTB/RIF) with or without an abnormal X-Ray result consistent with tuberculosis.

Table 1 depicts the demographic profile of the surveyed population. Out of a total screened population of 42,805, a majority 75% of the surveyed population were from rural areas and 25% population from urban areas with 51.33% males and 48.72% females. The majority of the population screened belonged to age group 15-24 (23%), with 21.14% males and 26.03 females.

X-ray findings

In Table 2 above, active TB was reported in 42 cases (3.11%) and inactive TB in 153 cases (11.32%) on X-ray findings. Out of 1351X-Rays done, 71.8% were normal, 8.66% technically inadequate. Active TB was reported in 42 cases. Lesions other than TB were reported for 68 films and inactive TB in 153 cases.

Presenting symptoms among participants

Cough alone or with any other symptom was found in 67.41% of the symptomatic individuals. The remaining 23% of the subjects had symptoms other than cough, and hemoptysis alone was the least common presenting symptom (1.15%) [Table 3].

Participants based on smear and CBNAAT results

The distribution of patients by Smear and CBNAAT is shown in Figure 2. The Table 4 shows that a maximum number of cases were found in the age groups 15-24 years with cases spread

Table 1: Demographics of the surveyed population

Variable	Number (*n*)	Percentage	Males (*n*)	Percentage	Females (*n*)	Percentage
Rural	32104	75.01	16460	51.27	15644	48.72
Urban	10701	24.99	5487	51.27	5214	48.72
Total	42805	100.00	21974	51.33	20858	48.72
Age						
15-24	10068	23.52	4639	21.14	5429	26.03
25-34	9727	22.72	4704	21.43	5023	24.08
35-44	8893	20.78	4754	21.66	4139	19.84
45-54	6098	14.25	3313	15.10	2785	13.35
55-64	4123	9.63	2295	10.46	1828	8.76
65-74	2845	6.65	1596	7.27	1249	5.99
>75	1051	2.46	646	2.94	405	1.94
Total	42805	100.00	21947	100.00	20858	100.00

Table 2: Results of X-ray findings of the surveyed population

Total	1351	Percentage
Normal	971	71.87%
Active TB	42	3.11%
Inactive TB	153	11.32%
Other Than TB	68	5.03%
Technically inadequate	117	8.66%

Table 3: Distribution of study participants according to their presenting symptoms

Symptoms	Total	Percentage
Cough alone	481	29.13
Cough with any other symptom	632	38.28
Chest pain alone	56	3.39
Fever alone	76	4.60
Haemoptysis alone	19	1.15
Combination of symptoms other than cough	387	23.44
Total	1651	100.00

Table 4: Age & sex wise distribution of the surveyed population with positive laboratory findings (sputum smear &CBNAAT)

Age (yrs)	Male	Female	Smear positive	CBNAAT positive
15-24	1	8	5	4
25-34	2	1	0	3
35-44	0	2	1	1
45-54	2	0	2	0
55-64	1	3	1	3
65-74	1	1	2	0
Above 75	0	2	1	1
Total	7	17	12	12

almost equally in other age groups. This difference is statistically significant.

Geographical distribution of TB cases

The number of positive cases was highest in North Kashmir followed by Central and least in South Kashmir ($P = 0.41$); however, this finding is not statistically significant.

Prevalence of pulmonary TB among the study population

To account for missing cases, we doubled the cases found by sputum smear examination and CB-NAAT by culture, and the calculated prevalence was 112.13/100,000 population. To account for the cases were missing by not using X-Ray as an initial screening tool, we used a multiplication factor 1.13 to obtain a prevalence of 146.72/100,000 population.

Discussion

The current community study was the first of its kind on TB prevalence with a sample size of 49716, of which 42,805 (86%) subjects were interviewed. Among those, 1539 were symptomatic who were subjected to sputum smear examination, and 1351X-ray films were studied. The prevalence of sputum positive TB by Sputum smear examination and CBNAAT was 147 per 100,000. A study conducted by Mayurnath *et al.*[5] used PPD, bacteriological examination of sputum and X-ray as survey tools. This study which was conducted on 18,000 subjects across all age groups found the prevalence of Culture Positive TB patients as 3 per 1000, and that of bacillary X-ray positive patients was 14 per 1000.[5] The present survey shows a 50% decline in the prevalence of sputum positive TB.

Our study was an effort to look at the TB situation in Kashmir to provide an accurate and realistic picture of disease burden in a valley. In a large country like India, many sub-national surveys are required to give a practical view of the burden of disease. Different surveys have shown the prevalence varying from 311/100,000 in rural South India,[9] 255.3/100,000 in Central India (Madhya Pradesh)[10] 390/100,000 in Gujarat, Western India,[6] 254 per 100,000 in South India,[11] 101.4 per 100,000 in Haryana, North India[12] 24.5/100,000 in Mohali, North India[13] and 387 among tribal population of Central India.[14,15] Importantly, the percentage of symptomatic in the present study was 3.85%, whereas in other sites it ranged from 8.3% in Jabalpur Central India[10] to 3.4% in Mohali, North India.[13] Our estimate was less than other parts but more than urban Mohali.

The present survey has covered urban, rural as well as tribal population Kashmir – which is the most important strength of the survey covering a population of 7.1 million.[9] We utilized the RNTCP staff for the study who were well versed with the symptom screening, technique of sputum collection, microscopy and transport techniques without any additional burden on the state exchequer. The prevalence of sputum positive Tuberculosis was highest in the 15-24 age group followed by 45-54-year-olds in contrast to reports by other surveys.[9,12,15] In younger age groups, the prevalence was skewed in favor of females. The male: female ratio was 1:8 in this age group, despite the number of males and females surveyed being roughly equal. Overall, the male: female ratio is 1:2.4 in this study which is opposite to that observed in the rest of the country. It was reported that the prevalence of culture-positive cases and abacillary X-ray positive cases among males in Kashmir was similar to those seen among females, contrary to the usual experience that the prevalence of the disease is 2-4 times higher in males than females in the rest of the country.[5] Various studies have demonstrated clear-cut male preponderance in TB with a male: female ratio ranging from 6:1 in South India to 2.37:1 in Central India. In India, the RNTCP detects nearly three times more male than female TB cases, although the extra-pulmonary disease has been reported more commonly in women.[16] RNTCP data from Kashmir over the last 10 years shows a male: female ratio of nearly 1:1 (range 0.96:1 to 1.06:1).[17] The difference could be because of a different ethnicity since the same pattern of nearly equal male: female ratio is seen in neighboring Afghanistan.[18]

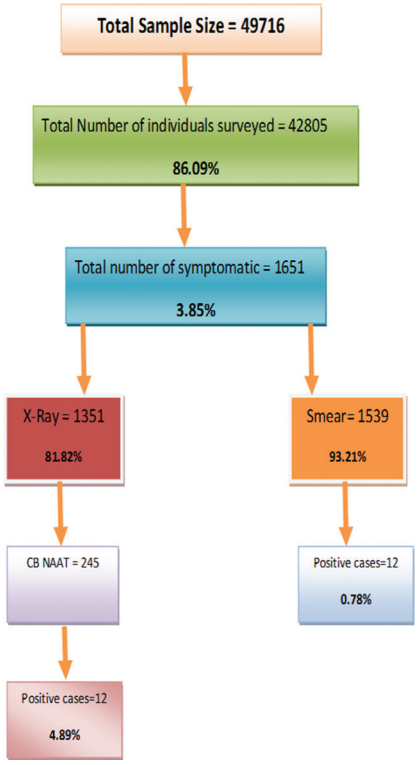

Figure 1: Flowchart depicting study population, coverage by sputum examination, X-ray and CBNAAT

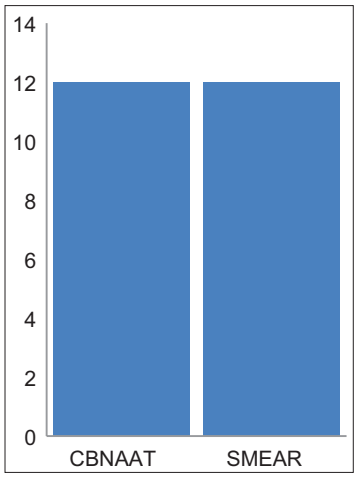

Figure 2: Distribution of cases by smear and CBNAAT results

Another significant finding was that the prevalence of TB was higher in North Kashmir (Kupwara, Baramulla) and less in South Kashmir (Anantnag, Pulwama). Although there is no statistically significant difference, the same regional difference was reported by Mayurnath *et al.*[5] in 1978.

The decline in Tuberculosis from 1978 to 2017 (present study) can be attributed to the strengthening of TB-control activities through RNTCP and implementation of Rifampicin-based DOTS regime. The programme has consistently shown a treatment success rate of more than 90% hence a reduction in case load has emerged. The India State-Level Disease Burden Initiative also documents a reduction in TB as a cause of death and disability from number 6 to number 15 over 16 years.[19] In 1990, 4% of the total DALYs were contributed by TB, and this reduced to 1.9% in 2016 for the state of Jammu and Kashmir. The same study also documents that the range of per capita disease burden due to TB among the states of India varies nine fold.[20]

Role of family physicians and general physicians

The role of family physicians and general practitioners in the control of TB in India is very significant as 50% of the population access private care, and they become the first point of care for the suspected cases. Since RNTCP is saturated with 100% coverage, the general practitioners could contribute to the success of the programme by timely referral of patients to DOTS centers, avoiding development of drug resistance due to irrational practices and by adhering to the "Standards of TB Care in India" developed by Government of India and WHO.[21] The strategies such as orienting the private practitioners, networking of private practitioners with patients and with DOTS providers, follow up and sensitization of patients by GPs on treatment adherence will have an enormous impact through these public-private partnerships.

Limitations

The major weakness in the study was the absence of a culture of sputum samples which we have tried to overcome by doubling the number of cases. X-ray was available for 82% of the eligible population, and around 8.66% which had poor quality were discarded. We used a multiplication factor of 1.3 to overcome this deficiency. At the same time, 263X-rays were suggestive of TB, but only 19% were positive on CBNAAT, hence X-ray although useful, and cannot be relied upon for diagnosis. We could not screen for extra-pulmonary or pediatric TB as it is cumbersome to carry out the same under field conditions.

Conclusion

The study highlights the importance and rationale of adding CBNAAT as an essential diagnostic tool for suspected positive Tuberculosis cases. CBNAAT is going to be game-changer in TB programme by overcoming the deficiencies of sputum smear microscopy. Accurate estimates of the TB burden at country level guides national policy-making and also improves the control efforts.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other

clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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