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Trend in the incidence of smear-positive tuberculosis in a district in South India after DOTS implementation

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SUMMARY

SETTING: One baseline and three repeat surveys of the prevalence of tuberculosis (TB) disease were conducted in 1999–2008 in rural South India, where the DOTS strategy was implemented in 1999. The impact of DOTS on prevalence was documented, but not its impact on incidence.

OBJECTIVE: To ascertain epidemiological trends in the incidence of smear-positive TB.

DESIGN: All persons aged ⩾15 years (range 83 000–92 000) were examined using chest radiography (CXR); chest symptoms and history of anti-tuberculosis chemotherapy were noted in all four surveys. Sputum was collected from eligible participants and tested using direct smear and culture, and for drug susceptibility. As follow-up surveys were not frequent, survey cases and cases directly notified under DOTS were combined to estimate the incidence of smear-positive TB.

RESULTS: Coverage was consistently high in all the repeat surveys, at ⩾80% for CXR and symptom recording, and at ⩾95% for sputum examination. The annual incidence of smear-positive TB was respectively 112, 80 and 76 per 100 000 population in 2001–2003, 2004–2006 and 2006–2008. The overall decline observed was 7.5% per annum.

CONCLUSION: A well-implemented DOTS strategy can lead to a reduction in the TB burden in the community.

KEY WORDS: epidemiology; survey; sputum; prevalence; treatment success

BETWEEN 1995 AND 2009, 41 of 49 million patients with tuberculosis (TB) worldwide were treated successfully under the DOTS strategy.[1] The United Nations Millennium Development Goals target for TB control was to stop and reverse the incidence of TB disease by 2015.[2] In India, a Revised National Tuberculosis Control Programme (RNTCP) was initiated in 1993.[3] The World Health Organization (WHO) recommended DOTS strategy for TB control was subsequently introduced as part of the RNTCP by the Government of Tamil Nadu in a semi-urban population in Tiruvallur District, South India in 1999. To evaluate the impact of DOTS implementation, the National Institute for Research in Tuberculosis (NIRT), Chennai, South India, was given the task of closely monitoring the programme in one Tuberculosis Unit for a period of 5 years since its implementation. The performance of the public health facilities serving as DOTS centres in the area (1999–2003) has been reported elsewhere.[4]

During the period 1999–2008, the NIRT conducted one baseline and three repeat prevalence surveys at 2.5-year intervals, which showed a decline in TB prevalence due to the DOTS strategy.[5] It was also shown that repeated TB prevalence surveys conducted in the study area did not influence the observed decline in prevalence.[6] The effect of a well-implemented TB control programme is also reflected in a reduction in TB incidence in the community. The limitations of conducting community surveys to assess the epidemiological impact of TB control programmes on TB incidence have been reported elsewhere.[7]

To study the impact of the DOTS strategy on the incidence of TB, a retrospective study of new smear-positive cases reporting with chest symptoms to DOTS centres between the surveys was conducted.[8]

MATERIALS AND METHODS

The required sample size for the prevalence survey was 82 000. A simple random sample of 53 villages was selected from the five blocks/urban areas of Tiruvallur District, South India.[9] The study design followed in all four surveys conducted in 1999–2001, 2001–2003, 2004–2006 and 2006–2008 was similar.[5] All persons aged ⩾15 years (range 83 000–92 000) were registered by door-to-door census. The repeat survey activity consists of the registration of new entrants in the study population (new-borns, new residents and persons missed in the previous survey). All participants were also asked about chest

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symptoms/history of anti-tuberculosis treatment, and underwent chest radiograph (CXR). In those with chest symptoms, history of anti-tuberculosis treatment or an abnormal CXR, two sputum samples (one spot and one overnight) were collected and underwent smear and culture; all patients diagnosed with TB were referred to a health facility for DOTS-based treatment.[5]

Data collection

As there was no follow-up of the population between surveys, we included new smear-positive cases using the TB register maintained by the TB Unit of the area.[8] Patients' addresses from the TB register were used by field staff for identification. The field staff also visited the homes of survey participants who presented with a history of anti-tuberculosis treatment during the survey periods and collected information on smear status and date of TB diagnosis using the TB register or the patients' medical records after confirming their identity. All such patients were allotted a unique number according to the survey records, coded by survey period based on the date of diagnosis and checked for duplicates. These records were later merged with the survey records. Smear-positive cases identified from notification data and from the surveys were used to estimate incidence; these were taken into account only once at the time of first registration as a smear-positive case.

The institutional ethics committee of the NIRT, Indian Council of Medical Research, Chennai, India, approved the project. All the study subjects were informed of the purpose of the survey and provided written consent.

Definition of incident case

All individuals with negative sputum or normal chest symptoms and CXR in the earlier prevalence survey, but smear-positive based on prevalence or routine notification data during the subsequent survey period, were defined as incident cases.

Estimation of TB cases

If X_i is the number of eligible persons in the i^{th} subgroup (by sex and by age), x_i the number examined using CXR and chest symptoms, S_i the number eligible for sputum collection based on abnormal CXR and/or chest symptoms, s_i the number with a sputum test and f_i the number with a smear-positive result, the total number of positives in the i^{th} subgroup was estimated by the following equation:

$$(f_i/s_i) \times (S_i/x_i) \times X_i = C_i,$$

assuming that results in those not examined would be similar to results in those tested. In this study, however, the number of smear-positive cases among those who did not undergo sputum testing was estimated from the nature of the CXR abnormality, using the probability of a positive CXR and/or chest symptom. To estimate the number of cases among those with no CXR in each survey, the relative risk (RR) of a person having chest symptoms (compared with that of a person with a CXR) was taken as proxy for the RR of a person without CXR having TB (compared with a person with CXR).[9,10] The estimated number of missed cases due to missing CXR and/or sputum examination was added to the observed number of cases in each subgroup; overall estimates of smear-positive TB were obtained (for both sexes and all ages combined) by pooling appropriate categories. The survey and analytical methods have been described in detail elsewhere.[5,9,11,12]

Data analysis and statistical methods

The study population was stratified by age (15–34, 35–54, $\geqslant$55 years) and sex. To allow for changes in age distribution and sex ratio during the study period, the incidence rate was estimated from the first, second and third repeat surveys, and age-sex distribution standardised using the 'direct' method[13] based on the at-risk population in the first repeat survey. The rate of decline over time was then determined by linear regression of log incidence on time using SPSS, version 14.0 (Statistical Package for the Social Sciences, Chicago, IL, USA).

RESULTS

Number of eligible persons in the prevalence surveys

Persons eligible for examination in the four surveys varied between 83 000 and 92 000. Males constituted 49% of the study sample in all the surveys. Changes in age distribution (15–34, 35–54 and $\geqslant$55 years) observed over the study period were statistically significant ($P < 0.0001$) (Table 1).

Screening coverage and incidence of smear-positive cases

The number of eligible participants covered by investigations was consistently high in all the surveys, at $\geqslant$80% for CXR and recording of symptoms, and at $\geqslant$95% for sputum testing. The proportion of incident cases diagnosed through the prevalence survey was 60.7%, 47.6% and 61.8%, respectively, in the 2001–2003, 2004–2006 and 2006–2008 repeat surveys; the proportion of new cases diagnosed by the health facilities was respectively 39.3%, 52.4% and 38.2% (Table 2).

Incidence rate of smear-positive cases

The estimated standardised annual incidence rate at the first, second and third repeat survey periods was respectively 112, 80 and 76 per 100 000 population, with a decline of 7.5% per annum (Table 3). The

Table 1 Number of persons eligible for examination during the prevalence surveys

	Population in the prevalence survey period			
	Baseline survey (1999–2001) *n* (%)	First repeat survey (2001–2003) *n* (%)	Second repeat survey (2004–2006) *n* (%)	Third repeat survey (2006–2008) *n* (%)
Total	83 425 (100)	85 474 (100)	89 413 (100)	92 255 (100)
Sex				
Male	40 848 (49)	41 607 (48.7)	43 477 (48.6)	44 996 (48.8)
Female	42 577 (51)	43 867 (51.3)	45 936 (51.4)	47 259 (51.2)
Age, years*				
15–34	42 118 (50.5)	43 138 (50.5)	43 044 (48.1)	43 702 (47.4)
35–54	27 141 (32.5)	28 199 (33)	30 567 (34.2)	32 480 (35.2)
⩾55	14 166 (17)	14 137 (16.5)	15 802 (17.7)	16 073 (17.4)

* The differences are statistically significant for all age groups among the survey periods ($P < 0.0001$).

estimated annual decline rate was respectively 7.7% and 6.8% in males and females. A higher annual decline rate was observed in persons aged 15–34 and ⩾55 years (8.8% and 11.6%, respectively; Table 3). The estimated incidence rate without adding the estimated number of missed cases at the first, second and third repeat surveys was respectively 119, 83 and 81/100 000, with an annual decline of 7.4%. Similarly, the estimated incidence rates using only survey cases were respectively 69, 40 and 48/100 000, with a decline of 7.0% per annum (data not tabulated).

The ratio of the estimated prevalence of smear-positive TB to the calculated incidence of smear-positive TB from the respective prevalence surveys and the calculated incidence provided a ratio of 2 (259/112, 168/80, 180/76), i.e., the duration of disease would be 2 years. The estimated national burden for the prevalence and incidence of all forms of TB were respectively 399 and 214, 347 and 205, and 308 and 196 in 2003, 2006 and 2008, at a ratio of 1.6:1.9 (data not tabulated, Figure).

Routinely notified cases under the RNTCP in the study area

The performance of the RNTCP recorded during 2001–2003 showed average annual rates of conversion, treatment success, default, failure and death of respectively 85%, 77%, 13%, 6% and 4%. The case notification rate (CNR) decreased from 82/100 000 in 2001 to 53/100 000 in 2008 (data not shown).

DISCUSSION

Following the implementation of the DOTS strategy in 1999, one baseline and three repeat surveys (1999–2008) were conducted at 2½-year intervals to assess its impact on TB disease burden.[5] As it is difficult to conduct frequent follow-up surveys,[7] it was later decided to use survey data and notification data from the study area to estimate the incidence of smear-positive TB.[8] After combining survey data and routine notification data, it was observed that the high proportion of incident cases diagnosed through surveys (averaging more than half of total incident cases) was due to the use of chest symptoms and CXR as screening tools. Furthermore, patients diagnosed under survey were less infectious and were more likely to be lost to follow-up ('initial defaulters').[14] The study showed that the proportion of new smear-positive TB cases was higher in all the repeat surveys, except the second repeat survey, than the proportion of new smear-positive TB cases diagnosed by the health facilities. The proportion of smear-positive cases diagnosed by the health facilities increased from 39.3% in 2001–2003 to 52.4% in 2004–2006, and then fell to 38.2% in 2006–2008. This showed that the rate of cases diagnosed was not consistent over the entire period under the DOTS strategy.

The overall annual incidence of smear-positive TB was 112/100 000 at the first repeat survey (2001–2003), and decreased by 7.5% per annum over 5 years to 76/100 000 in the third repeat survey (2006–2008). In the first repeat survey, the incidence of

Table 2 Screening coverage and new smear-positive cases

Repeat survey period	Persons eligible for examination *n*	Persons asked about symptoms and who underwent CXR *n* (%)	Eligible for sputum testing based on: Symptoms *n*	CXR *n*	Both *n*	Sputum examined *n* (%)	New smear-positive cases diagnosed by: Survey *n* (%)	Health facility* *n* (%)
2001–2003	74 342	60 201 (81)	6 134	1 198	939	7 934 (96)	108 (60.7)	70 (39.3)
2004–2006	75 961	61 245 (81)	5 674	1 460	884	7 650 (95)	60 (47.6)	66 (52.4)
2006–2008	79 434	63 520 (80)	5 272	1 144	698	6 894 (97)	81 (61.8)	50 (38.2)

* Cases diagnosed by health facilities were considered eligible for sputum testing based on chest symptoms only.
CXR = chest X-ray.

Table 3 Annual incidence rates of smear-positive TB (/100 000 population) during the survey periods*

	Repeat survey period			Decline in TB incidence/year
	2001–2003 *n* (95%CI)	2004–2006 *n* (95%CI)	2006–2008 *n* (95%CI)	%
Total	112 (95–129)	80 (66–93)	76 (61–91)	7.5
Sex				
Male	190 (161–218)	128 (107–150)	127 (101–153)	7.7
Female	44 (28–59)	36 (24–49)	31 (17–44)	6.8
Age, years				
15–34	68 (50–86)	54 (39–69)	43 (26–61)	8.8
35–54	131 (101–160)	78 (57–99)	107 (80–134)	4.0
⩾55	208 (158–258)	158 (116–200)	112 (77–147)	11.6

* The incidence for the 2004–2006 and 2006–2008 repeat surveys was standardised against the at-risk population of the 2001–2003 repeat survey.
TB = tuberculosis; CI = confidence interval.

smear-positive TB was high (112/100 000), essentially due to the detection of more TB cases that had accumulated over the years, and also because most individuals who had not received anti-tuberculosis treatment earlier were later treated under the new programme, leading to a reduction in the incidence of smear-positive TB in the second repeat survey (80/100 000) and showing a larger decline in TB. Furthermore, approximately the same number of new TB patients emerged from among those who were already infected with TB. The incidence rate therefore decreased from 80 to 76/100 000, with a decline of 2.0% per annum between the second and third repeat surveys; as expected, the decline in incidence rate was slower. This explains the slow decline in TB incidence and our findings corroborate this. The study showed that significantly more males had TB; the difference in the rate of annual decline in TB incidence between males and females was not statistically significant (7.7% vs. 6.8%, $P = 0.69$).

An annual rate of decline of 8.8% observed in the younger age group (15–34 years) suggests a reduction in the transmission of tuberculous infection due to successful treatment under the DOTS strategy. This reduction was also evident from the series of studies on the prevalence of tuberculous infection conducted in the same area among children aged 1–9 years from 1999 to 2010 (non-bacille Calmette-Guérin [BCG] vaccinated group—5.2% per annum, BCG-vaccinated group—5.4% per annum).[15] The estimated incidence rates in persons aged 35–54 years were not consistent with this pattern, with a decline of 4.0% per annum. This may have been because the risk of contracting TB disease remains high in this age group. A significantly higher annual reduction of 11.6% ($P = 0.04$) was observed in the older group aged ⩾55 years, possibly due to cases not being identified, death before diagnosis, treatment in the private sector without notification or migration. When the case detection rate, cure rate and profile of patients referred by the private sector from the survey area to DOTS centres were compared with those of self-reporting patients, the cure rate was found to be comparable.[16] Trends in incidence and conclusion were therefore not affected. Based on the data on national estimates of the TB burden and from survey data, the observed average duration of disease was respectively 1.7 and 2 years. The average duration of disease in the same study area during the pre-DOTS era (1968–1986) was reported to have

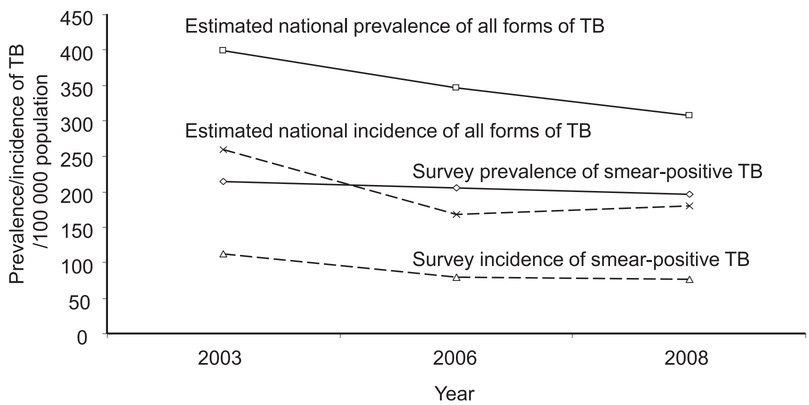

Figure Estimated national prevalence/incidence of all forms of TB and estimated survey findings of prevalence/incidence of smear-positive TB in 2003, 2006 and 2008. TB = tuberculosis.

been 3.6 years.[10] The observed reduction in the duration of disease may have been due to the implementation of the DOTS strategy.

The 2011 RNTCP status report showed annualised cure and success rates of respectively 89% (WHO global target $\geqslant$85%) and 77% (WHO global target $\geqslant$70%) during 1999–2010 for the study area.[17] Furthermore, the CNR decreased from 82/100 000 in 2001 to 53/100 000 in 2008. The decrease in CNR in the later years of the study period suggests that some cases have remained undetected under the DOTS strategy. Epidemiological data from a BCG trial (1968–1986) conducted in our study area showed that the annual incidence of smear-positive TB among persons aged $\geqslant$10 years with normal CXR varied from 48 to 90/100 000 over a 15-year period, with nil decline.[10] It therefore appears plausible that the decrease observed over the 5-year period was due to implementation of the DOTS strategy.

Limitations

The decline in TB incidence might be attributable to many other unobserved factors, including improvements in socio-economic position and nutrition,[18] reduced crowding[19] and segregation of infectious cases in workhouses or sanatoria.[20] As information on these factors in the community was not available, their possible impact could not be assessed. Finally, as human immunodeficiency virus (HIV) infection and multidrug-resistant TB (MDR-TB) were not highly prevalent in the study area, our conclusions cannot be generalised to all areas, especially to those with a high prevalence of HIV infection or MDR-TB.[5]

In conclusion, although data on many important factors related to the disease burden were absent, we believe that the DOTS strategy, if well-implemented, can reduce TB disease in the community. Our study findings will be useful in providing information on the epidemiological impact of the DOTS strategy, and for planning future studies to measure true TB incidence.

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Conflicts of interest: none declared.

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RESUME

CONTEXTE : Une enquête de départ et trois enquêtes répétées de prévalence de la tuberculose (TB) réalisées en 1999–2008 en Inde du Sud rurale, où la stratégie DOTS a été mise en œuvre en 1999. L'impact de DOTS a été documenté en ce qui concerne la prévalence, mais pas l'incidence.

OBJECTIF : Vérifier la tendance épidémiologique de l'incidence de la TB à frottis positif.

SCHÉMA : Toutes les personnes âgées de ⩾15 ans (fourchette 83 000–92 000) ont eu une radiographie pulmonaire (CXR) et ont été interrogées sur leurs symptômes respiratoires éventuels et leurs antécédents de traitement antituberculeux lors des quatre enquêtes. Les crachats ont été recueillis auprès des participants éligibles et examinés par frottis direct et culture et testés pour leur pharmacosensibilité. Comme il n'y a pas eu d'enquêtes de suivi fréquentes, les cas identifiés par les enquêtes et les cas directement déclarés sous DOTS ont été combinés pour l'estimation de l'incidence de TB à frottis positif.

RÉSULTATS : La couverture a été régulièrement élevée dans les enquêtes répétées, de ⩾80% pour la CXR et la recherche de symptômes et ⩾95% pour l'examen des crachats. Le taux d'incidence annuel de TB à frottis positif a été respectivement de 112, 80 et 76 par 100 000 personnes lors des enquêtes répétées de 2001–2003, 2004–2006 et 2006–2008. Le déclin total observé a été de 7,5% par an.

CONCLUSION : Une stratégie DOTS bien mise en place peut réduire le fardeau de la TB au sein des communautés.

RESUMEN

MARCO DE REFERENCIA: De 1999 al 2008 se realizaron encuestas de prevalencia de tuberculosis (TB), una de referencia y tres repeticiones, en una zona rural del sur de la India donde se introdujo la estrategia DOTS en 1999. Se documentó la repercusión de la introducción de DOTS sobre la prevalencia de TB, mas no sobre su incidencia.

OBJETIVO: Verificar la evolución epidemiológica de la incidencia de TB con baciloscopia positiva.

MÉTODOS: En las cuatro encuestas, todas las personas de edad ⩾15 años (intervalo 83 000–92 000) se sometieron a una radiografía de tórax (CXR) y se interrogaron sobre la presencia de síntomas respiratorios y antecedentes de tratamiento antituberculoso. Se recogieron muestras de esputo de los participantes que reunían las condiciones, con el propósito de realizar la baciloscopia, el cultivo y las pruebas de sensibilidad a los medicamentos. Dado que no se realizaron encuestas frecuentes de seguimiento, se agruparon los casos detectados en las encuestas y los casos notificados directamente en el marco del programa DOTS, con el fin de estimar la incidencia de TB con baciloscopia positiva.

RESULTADOS: Se logró una alta cobertura constante en todas las encuestas repetidas, de ⩾80% con la CXR y el interrogatorio sobre los síntomas y de ⩾95% con el examen del esputo. La incidencia anual de TB con baciloscopia positiva fue 112/100 000 habitantes según la repetición de la encuesta del 2001 al 2003, 80/100 000 en la repetición del 2004 al 2006 y 76/100 000 en la encuesta del 2006 al 2008. La disminución global observada fue de 7,5% por año.

CONCLUSIÓN: Un programa DOTS bien ejecutado puede disminuir la carga de morbilidad por TB en la comunidad.