Effectiveness of a community-based observation of anti-tuberculosis treatment in Bangalore City, India, 2010–2011

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<http://dx.doi.org/10.5588/pha.13.0043>

Setting: The Revised National Tuberculosis Control Programme in an urban setting of Bangalore City, India.

Objectives: To compare treatment outcomes and smear conversion rates among new smear-positive tuberculosis (TB) patients undergoing treatment administered by community directly observed treatment (DOT) providers with those undergoing treatment administered by institutional DOT providers in Bangalore City in 2010–2011.

Method: Cohort study of routine data recorded from treatment cards of TB patients undergoing treatment under the public health services from 1 October 2010 to 30 September 2011.

Result: Treatment records of 1864 new smear-positive TB patients registered during this period were evaluated. Among those evaluated, 604 (32%) had been administered treatment by community DOT providers and the remainder by institutional DOT providers. The treatment success rate in those undergoing community DOT was 93% ($n = 564$) and that of those undergoing institutional DOT was 75% ($n = 951$; RR 1.23, 95%CI 1.19–1.28). The sputum smear conversion rate of patients who underwent community DOT was 92% and that of those who underwent institutional DOT was 71% at the end of 2 months.

Conclusion: We conclude that community DOT for treatment supervision of TB patients is more effective than institutional DOT and that it should be reinforced.

The policy of directly observed treatment (DOT) has been adopted by India's Revised National Tuberculosis Control Programme (RNTCP).¹ Community DOT was introduced in India after a number of studies were conducted on its feasibility and acceptability.^{2–5} A DOT provider is an individual who is accessible, acceptable to the individual and to the community, and accountable to the health system, but not a family member, who supervises and supports the tuberculosis (TB) patient.⁶ The RNTCP recommends the decentralisation of DOT for effective supervision and provision of customised treatment near the patient's residence through the use of community DOT providers.

Many TB patients prefer to undergo DOT in an institutional setting (peripheral health institutions [PHIs] or designated microscopy centres [DMCs]).⁴ However, these facilities are not always convenient and accessible for the patient, and the majority of these facilities have high workloads, resulting in suboptimal patient supervision and support.⁷

The effectiveness of community DOT in comparison

to institutional DOT has not been assessed in India since its implementation several years ago. The objective of the present study was to find out 1) whether community DOT is associated with equally favourable treatment outcomes in comparison to institutional DOT, and 2) the profile of community DOT providers in an urban setting in Bangalore.

MATERIAL AND METHODS

Study design

This was a cohort study of routinely collected information.

Study setting

Bangalore is the third most populous city in India, with a population of 9.5 million.⁸ Public sector TB services have been managed by the municipality of Bangalore under the RNTCP. TB services are provided by nine tuberculosis units and 50 DMCs. All newly diagnosed TB patients are offered human immunodeficiency virus (HIV) counselling and testing. The study treatment regimen for drug-susceptible TB followed RNTCP guidelines, consisting of rifampicin-based intermittent treatment (thrice weekly on alternate days), with provision of individual patient boxes standardised for specific weight groups. Each dose of treatment during the initial intensive phase and at least the first of the three weekly doses during the continuation phase were given under direct observation. The patient chose the type of DOT provider in consultation with the medical officer. All DOT providers, including community volunteers, were trained in providing DOT. Treatment details, type of DOT provider and treatment outcomes were recorded in a standard routine treatment card for each TB patient.

Definitions

Definitions of new smear-positive TB patient, sputum smear conversion and treatment outcome were those used routinely in the RNTCP.⁶ A 'community DOT provider', defined as per the RNTCP definition,⁶ was a person who volunteered to administer DOT per programme guidelines and who belonged to the community where the patient resided, but was not a government health worker or a member of the family. An 'institutional DOT provider' was defined as any government health worker in the institution (either PHI or DMC) who was trained by the RNTCP and administered DOT. Delayed completion of treatment was defined as completion of treatment beyond 1 month of

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KEY WORDS

DOT providers; community volunteers; DOTS

Received 11 June 2013
Accepted 21 August 2013

PHA 2013; 3(3): 230–234
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the RNTCP norm for treatment completion for either the intensive or the continuation phase.

Sample size

The sample size was calculated based on the assumption that 25% of TB patients undergo treatment under community volunteers and 75% choose institutional DOT; there was a difference of 5% in treatment success rates between the two groups. A sample size of 1895 TB patients was calculated for 95% confidence intervals (CIs) and a power of 80% using Open Epi software, version 2.3 (Emory University, Atlanta, GA, USA).

Data collection

The treatment cards of consecutive new smear-positive TB patients registered from 1 October 2010 to 30 September 2011 with the public health services of Bangalore City were reviewed. Relevant data were extracted into a data collection form designed for the study. This included age, sex, HIV status, sputum smear grade, sputum smear conversion, treatment duration and treatment outcome. Data were verified using the TB Register. Information on the type of DOT provider was recorded from the list in the DMC/PHI responsible for the treatment of the patient.

Data management

Data were double-entered into an electronic database using EpiData Entry software Version 3.1 (The EpiData Association, Odense, Denmark) and validated. Analyses were performed using EpiData Analysis software. Crude

relative risk (RR) was used for calculating associations. Two-tailed χ^2 and Yates' correction were used for determining significance.

Ethics approval

Ethics approval for the study was obtained from the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France, and from the Ethics Committee of the National Tuberculosis Institute, Bangalore, India.

RESULTS

A total of 2099 new smear-positive TB patients were registered from 1 October 2010 to 30 September 2011 in public health facilities of Bangalore City. The treatment cards of 1864 (89%) patients were available for evaluation (Figure), of whom 1222 (66%) were male. The mean age of the male patients was 40 years (standard deviation [SD] 15) and that of the female patients was 32 years (SD 15). A minority ($n = 604$, 32%) of patients chose to undergo treatment under the supervision of a community DOT provider. There was no significant difference in age group, sex or initial sputum smear grade between patients who chose institutional DOT and those who chose community DOT. The HIV status of 1624 (87%) TB patients was known, of whom 57 (4%) were HIV-positive. Of the 57 HIV-positive patients, 13 (23%) underwent community DOT.

Table 1 shows that favourable treatment outcomes were significantly more frequent among those under

ACKNOWLEDGEMENTS

The authors thank G Puttaswamy, B A Shivasankar, N Prasad and Venkatachallappa of the National Tuberculosis Institute, Bangalore, for data collection and entry. The support and help provided by the Revised National Tuberculosis Control Programme Project Coordinator and the staff of all tuberculosis units of Bangalore Corporation is highly appreciated. This research was supported by an Operational Research course jointly developed and run by the International Union Against Tuberculosis and Lung Disease, South-East Asia Regional Office, New Delhi, India; the National Institute for Research in Tuberculosis, Chennai, India; and the Desmond Tutu TB Centre, Stellenbosch University, Cape Town, South Africa. Funding for the Operational Research course was made possible by the support of the American people through the United States Agency for International Development (USAID). The funders had no role in study design, data collection, analysis or interpretation. The contents of this article do not necessarily reflect the views of the USAID or the Government of the United States. Conflict of interest: none declared.

FIGURE Flow chart of new smear-positive TB patients undergoing DOT and their outcomes, Bangalore City, 1 October 2010–30 September 2011. TB = tuberculosis; DOT = directly observed treatment.

TABLE 1 Treatment outcome by type of treatment provider, demographic characteristics and sputum grade of new smear-positive tuberculosis patients in Bangalore City, 2010–2011

Characteristic	Community volunteers		Institutional providers		RR (95%CI)	P value
	Total cases	Favourable outcomes n (%)	Total cases	Favourable outcomes n (%)		
All	604	564 (93)	1260	951 (75)	1.23 (1.19–1.28)	<0.0001
Age group, years						
0–14	7	7 (100)	23	22 (96)	1.04 (0.95–1.14)	0.5
15–24	168	165 (98)	304	256 (84)	1.16 (1.10–1.22)	<0.0001
25–34	121	112 (93)	282	222 (79)	1.17 (1.08–1.27)	<0.01
35–44	106	96 (91)	258	180 (70)	1.29 (1.17–1.43)	<0.0001
45–54	101	95 (94)	191	137 (72)	1.31 (1.18–1.45)	<0.0001
55–64	53	47 (89)	123	86 (70)	1.26 (1.09–1.34)	<0.01
≥65	48	42 (88)	79	48 (61)	1.44 (1.17–1.77)	<0.01
Sex						
Male	384	350 (91)	838	595 (71)	1.28 (1.21–1.35)	<0.0001
Female	220	214 (97)	422	356 (84)	1.15 (1.10–1.20)	<0.0001
Sputum grade						
Scanty	56	54 (96)	119	92 (77)	1.14 (1.03–1.25)	<0.05
1+	213	203 (95)	444	340 (77)	1.24 (1.17–1.32)	<0.0001
2+	163	149 (91)	301	234 (78)	1.17 (1.84–1.26)	<0.001
3+	172	158 (92)	396	285 (72)	1.27 (1.18–1.37)	<0.0001

RR = relative risk; CI = confidence interval.

the supervision of a community DOT provider (RR 1.23, 95%CI 1.19–1.28). A higher rate of favourable outcome in most subsets (age, sex and sputum grade) of this population was observed in this group. A significant difference in unfavourable outcomes between the two groups was noted for default (2.6% vs. 7%) and for failure (0.8% vs. 4.1%). Transfer out outcomes were more frequent in the institutional DOT group than in the community DOT group (7.4% vs. 0.7%).

Failure to examine sputum smears at the end of the initial intensive phase of treatment was less likely in the community DOT group (RR 0.15, 95%CI 0.08–0.25). In those examined, patients under the supervision of community DOT providers were less likely to remain smear-positive (RR 0.69, 95%CI 0.53–0.90); the differences did not vary by sex or sputum smear grade subgroups.

Delayed treatment completion during the initial phase was noted in 63 TB patients, of whom 14 underwent treatment under

the supervision of community DOT providers and 49 under institutional DOT providers. During the continuation phase, 184 patients had delayed treatment completion, of whom 60 were from the community DOT group and 124 from the institutional DOT group. There was no significant difference between the two groups in delayed treatment completion.

The categories of community DOT volunteers by the number of patients treated were as follows: trained local non-governmental health workers ($n = 430$), physicians ($n = 95$), neighbours, colleagues or other community members ($n = 49$), shopkeepers ($n = 16$), alternative medicine practitioners ($n = 12$) and teachers ($n = 2$). The categories of institutional DOT providers recorded were as follows: TB health visitors ($n = 1008$), auxiliary nurse midwives ($n = 15$), staff nurses ($n = 8$) and others, including laboratory technicians and attendants ($n = 229$).

Table 2 shows the subset analysis of treatment outcomes in the

TABLE 2 Treatment outcome of new smear-positive TB patients undergoing DOT, Bangalore City, October 2010–September 2011

DOT provider	Total n (column %)	Favourable outcomes		Unfavourable outcomes			
		Cured n (row %)	Treatment completed n (row %)	Failure n (row %)	Defaulted n (row %)	Died n (row %)	Transferred out n (row %)
Community volunteers							
Community health workers	430 (71)	400 (93)	1 (0.2)	5 (1.2)	11 (2.5)	11 (2.5)	2 (0.6)
Physicians	95 (16)	89 (94)	0	0	3 (3)	1 (1)	2 (2)
Alternative medicine providers	12 (1.7)	10 (83.4)	0	0	1 (8.3)	1 (8.3)	0
Shopkeepers	16 (3)	16 (100)	0	0	0	0	0
Teachers	2 (0.3)	2 (100)	0	0	0	0	0
Others	49 (8)	46 (94)	0	0	1 (2)	2 (4)	0
Total	604 (100)	563 (93.2)	1 (0.2)	5 (0.8)	16 (2.6)	15 (2.5)	4 (0.7)
Institutional DOT providers							
TB health visitors	1008 (80)	751 (74.5)	11 (1)	45 (4.5)	65 (6.5)	58 (5.8)	78 (7.7)
Staff nurses	8 (0.6)	6 (75)	0	1 (12.5)	1 (12.5)	0	0
Auxiliary nurse midwives	15 (1.2)	12 (80)	0	0	0	3 (20)	0
Others	229 (18.2)	167 (73)	4 (1.8)	6 (2.6)	22 (9.6)	15 (6.5)	15 (6.5)
Total	1260 (100)	936 (74.3)	15 (1.2)	52 (4.1)	88 (7)	76 (6)	93 (7.4)

TB = tuberculosis; DOT = directly observed treatment.

different types of community volunteers and institutional DOT providers. There were no significant differences in treatment success rates (RR 0.97, 95%CI 0.92–1.03, $P > 0.05$) between trained non-governmental community health workers and non-health workers such as shopkeepers, teachers and others. Among the institutional DOT providers, no significant difference in favourable outcomes was observed between patients undergoing treatment under the supervision of TB health visitors (RR 1.0, 95%CI 0.93–1.09, $P > 0.05$) and those administered treatment by all other DOT providers.

DISCUSSION

This study demonstrates that a favourable treatment outcome is more likely among new smear-positive TB patients undergoing community DOT than in those undergoing institutional DOT. Similar findings have been reported in a meta-analysis from China⁹ and studies in African countries.^{10–12} These benefits were also seen in sputum smear conversion at the end of the intensive phase of treatment.

The most striking unfavourable outcomes among institutional DOT providers were the default, failure and transfer out rates. Previous studies have shown that due to the heavy workload in institutional facilities, retrieval activity is poor and the health facilities are often far from the patient's residence.^{13,14} The community provider is often closer to the patient's residence, which makes it more convenient to track patients who delay taking their daily doses. Other factors reported to be responsible for high default rates in urban settings are a lack of knowledge about the full duration of anti-tuberculosis treatment and dissatisfaction with health providers.^{14,15} Less time devoted to counselling before the start of treatment, long waiting periods and uncooperative staff may cause increased default, and perhaps also a higher failure rate, in patients undergoing institutional DOT. The large number of institutions in urban areas attracts TB patients from remote places and nearby villages,¹⁶ who undergo treatment in in-patient or out-patient departments under the supervision of institutional DOT providers. These patients usually return to their place of residence after feeling well after their symptoms have resolved; the treatment outcome of the majority of these patients is therefore not reported to the health facility where treatment was started. On the other hand, most TB patients who undergo community DOT are generally from the local area. The transfer out rate is thus higher in the institutional DOT group than in the community DOT group.

In this study, the highest proportion of community DOT providers was from among community health workers. A substantial number of TB patients were also supervised by private practitioners (physicians or alternative medicine providers). The default rate was <2% among non-health worker community DOT providers, whereas it was higher (2.5–8%) among non-governmental community health workers, physicians and alternative medicine providers.

Among institutional DOT providers, the majority of TB patients underwent treatment under the supervision of TB health visitors who are appointed as contractual health workers in urban health facilities by the RNTCP for carrying out field TB control work; this is in line with another study in an urban setting in India.¹⁷ No significant difference in treatment outcomes was observed among TB patients supervised by TB health visitors compared to other types of institutional DOT providers.

Our study had a few limitations. First, this is a study based on a review of past records of TB patients maintained by public health facilities, which are not always free from errors; the reliability of the records therefore cannot be assured. Second, treatment outcome may be affected by confounding factors other than those studied here to decide an association. Third, some of the TB patients may have changed DOT providers while on treatment, which was not captured in the records.

CONCLUSION

Our study findings show that community DOT was more effective than institutional DOT in terms of favourable treatment outcomes. The decentralisation of treatment observation with the help of community volunteers therefore needs to be encouraged.

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Contexte : Programme National de Lutte contre la Tuberculose (TB) dans un contexte urbain de la ville de Bangalore, Inde.

Objectifs : Comparer les résultats du traitement et du taux de négativation des frottis chez les nouveaux cas de patients TB à frottis positif prenant leur traitement avec l'aide d'un pourvoyeur de traitement directement observé (DOT) de la collectivité avec ceux qui le prennent avec l'aide d'un pourvoyeur de DOT institutionnel dans la ville de Bangalore en 2010–2011.

Méthode : Etude de cohorte des données recueillies en routine à partir des cartes de traitement des patients TB traités dans les services de santé publique de la ville de Bangalore du 1er octobre 2010 au 30 septembre 2011.

Résultat : On a évalué les dossiers de traitement de 1864 nouveaux patients TB à frottis positif enregistrés au cours de la période. Parmi

ceux évalués, 604 (32%) avaient bénéficié du traitement avec l'aide des pourvoyeurs DOT de la collectivité et le reste avec l'aide des pourvoyeurs DOT institutionnels. Le taux de succès du traitement chez ceux recevant le DOT grâce à un pourvoyeur DOT de la collectivité a été de 93% ($n = 564$) et avec l'aide d'un pourvoyeur DOT institutionnel de 75% ($n = 951$; $RR = 1,23$; $IC\ 95\% 1,19-1,28$). Le taux de négativation des frottis de crachats à la fin de 2 mois chez les patients prenant leur traitement avec l'aide d'un pourvoyeur DOT de la collectivité a été de 92% et celui de ceux le prenant avec l'aide d'un pourvoyeur DOT institutionnel a été de 71%.

Conclusion : Nous concluons que le DOT soutenu par la collectivité pour la supervision du traitement TB est plus efficace que le DOT institutionnel, et qu'il devrait être renforcé.

Marco de referencia: El Programa Nacional contra la Tuberculosis (TB) en un entorno urbano de la ciudad de Bangalore en la India.

Objetivos: Comparar el desenlace terapéutico y la tasa de conversión de la baciloscopia del esputo de los casos nuevos de TB con baciloscopia positiva, entre los pacientes que recibían el apoyo de un miembro de la comunidad que suministraba el tratamiento directamente observado (DOT) y los pacientes supervisados por el personal institucional en la ciudad de Bangalore del 2010 al 2011.

Método: Fue este un estudio de cohortes, realizado a partir de los datos registrados de manera sistemática en las tarjetas de tratamiento antituberculoso de los pacientes tratados en los servicios de salud del sector público de la ciudad de Bangalore entre el 1° de octubre del 2010 y el 30 de septiembre del 2011.

Resultados: Se evaluaron los expedientes clínicos de 1864 pacientes

con diagnóstico reciente de TB y baciloscopia positiva registrados durante el periodo del estudio. De estos, 604 habían recibido el tratamiento de un dispensador de DOT en la comunidad (32%) y el resto de los pacientes de un profesional de salud institucional. La tasa de éxito terapéutico de los pacientes supervisados en la comunidad fue 93% ($n = 564$) y la tasa de éxito en la supervisión institucional fue 75% ($n = 951$; $RR = 1,23$; $IC95\% 1,19$ a $1,28$). La tasa de conversión de la baciloscopia al final del segundo mes en los pacientes que recibieron el DOT en la comunidad fue 92 % y el 71% de los pacientes que recibieron el DOT en una institución convirtió su baciloscopia en este lapso.

Conclusión: Los resultados del estudio permiten concluir que la supervisión comunitaria del DOT es más eficaz que la supervisión institucional y que es preciso reforzar la ejecución de esta estrategia.