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Management of previously treated tuberculosis patients in Kalutara district, Sri Lanka: how are we faring?

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Setting: District Chest Clinic, Kalutara, Sri Lanka.
Objectives: To determine the coverage of culture and drug susceptibility testing (CDST), delays in CDST, treatment initiation, obtaining CDST results and treatment outcomes of previously treated tuberculosis (TB) patients.
Design: Retrospective cohort study involving review of records and reports. All previously treated TB patients from January 2008 to June 2013 were included in the study.
Results: Of 160 patients, 126 (79%) samples were sent for CDST; 79 (63%) were culture-positive and no multidrug-resistant (MDR) TB cases were reported. Respectively 9% and 15% of patients experienced a delay in sending samples (median delay 21 days) and receiving CDST reports (median delay 71 days), while 20% experienced delays in initiating the retreatment regimen (median delay 11.5 days). The cohort recorded an 82% treatment success rate.
Conclusion: Of all retreatment patients, only 79% were tested for CDST and there were sizeable delays in sample transportation and treatment initiation. Possible ways forward to strengthen the programme are discussed.

According to the 2013 World Health Organization (WHO) global tuberculosis report, an estimated 8.6 million new cases of tuberculosis (TB) were diagnosed and 1.3 million people died from TB in 2012, while the number of multidrug-resistant tuberculosis (MDR-TB) notifications reached almost 450 000.[1] Globally, 3.6% of new cases and 20% of previously treated cases were estimated to have MDR-TB,[1] which represents one of the most dramatic global health challenges of the past few years.

The WHO revised definitions broadly classify smear-positive TB patients into 'new' and 'retreatment' cases. 'Retreatment' or 'previously treated' patients, defined as having previously taken anti-tuberculosis drugs for ⩾1 month, are further classified as 'relapse', 'treatment after failure', 'treatment after default (lost to follow-up)' or 'others', patients who do not fit the standard case definition.[2] Previously treated TB cases are a challenge for TB control services, as they need to be tested for drug resistance, require a longer duration of treatment and have poorer treatment outcomes.[3]

Sri Lanka is considered a low-burden TB country with low MDR-TB rates.[4] In 2012, Sri Lanka reported a total number of 9343 TB cases (48 cases per 100 000 population, estimated by the WHO at 66/100 000) and 433 were retreatment cases. Also in 2012, 1329 patients were tested and five were confirmed as MDR-TB.[5] According to the national TB control guidelines, all sputum samples of smear-positive retreatment cases are investigated for resistance to first-line drugs, namely isoniazid (INH), rifampicin (RMP), streptomycin (SM) and ethambutol (EMB), through culture and drug susceptibility testing (CDST) using solid culture Löwenstein-Jensen medium, and are initiated on a TB retreatment regimen without waiting for the CDST results.[5] Programme reviews and field visits have suggested operational issues in the management of such cases in terms of timely investigation for first-line drug resistance and initiation of resistant patients on MDR-TB treatment. There is a concern that any lapse in this implementation strategy would affect the outcome of TB patients and lead to increased MDR-TB prevalence in the country.

We therefore conducted a study to determine the proportion of patients whose samples were sent for CDST, the delays encountered during the process, the CDST results describing the culture positivity rates and type of drug resistance and the treatment outcomes of these patients.

METHODS

Study design

This was a retrospective cohort study.

Setting

Sri Lanka is an island divided in 26 health districts, with a population of about 20 million.[6] Kalutara district, with a mainly rural population of 1.2 million, is among the districts with the highest TB prevalence in Sri Lanka. The population has three main ethnicities; Sinhalese (87.1%), Tamil (3.9%) and Moor (8.7%).[7] The District Chest Clinic (DCC) in Kalutara, the only institution catering for TB patients in the district, has a caseload of approximately 700 per annum. The district has six peripheral microscopy centres and a main centre at the DCC, all of which are involved in sputum smear microscopy for screening and follow-up.

All CDST of sputum and other specimens is performed through the National Tuberculosis Reference Laboratory (NTRL), which is located on the premises of Welisara Chest Hospital, 65 km from the district TB centre. The NTRL undergoes quality control for drug susceptibility testing (DST) by the Supranational Laboratory, Chennai, India, and the University of Antwerp

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Laboratory, in Antwerp, Belgium, a WHO Collaborating Centre.

Two samples are collected for culture from each patient over two consecutive days. They are refrigerated at the district chest clinic and sent to the NTRL twice a week in a cold box with a messenger, who travels by bus. Appropriate measures, such as sealing the cap with adhesive tape and covering the sealed bottle, are taken to prevent spillage and contamination during transportation. The results are sent to the respective districts by the laboratory by messenger sent from the districts or by post. Patients resistant to INH and RMP are initiated on an MDR-TB regimen; otherwise they are continued on the retreatment regimen which includes 2SHRZE/1HRZE/5HRE* for a period of 8 months. The drugs are provided under daily directly observed treatment (DOT), as per the WHO recommended strategy adopted in 2006.

Operationally, the following were considered as delays in our study: 1) >5 days for sending the samples to CDST (5 days was taken as the operational norm, as samples are sent to the NTRL twice a week); 2) >65 days for receiving the CDST report from the Central Reference Laboratory, as it takes 8 weeks of incubation to report a negative culture; and 3) >5 days for initiating a Category II treatment regimen, as it takes a few days for patients who are diagnosed at the peripheral microscopy centres to attend the DCC, and two samples for CDST are taken over two consecutive days from each patient before initiating the retreatment regimen.

Study population

All retreatment smear-positive pulmonary TB patients registered in the district TB register, Kalutara district, during the period from 1 January 2008 to 30 June 2013 were included in the study.

Variables, data collection and validation

The variables included in the study were type of retreatment, CDST results, treatment outcomes and days taken to establish diagnosis, treatment initiation, sample sending and declaration of results. All the data were collected from the existing district TB register and laboratory CDST registers and double-checked with the original patient treatment cards. The data were collected in a customised data collection proforma, double-entered into EpiData (version 3.1, EpiData Association, Odense, Denmark) and cross-validated.

Analysis and statistics

Relative proportions and incurred delays were assessed through simple summary statistics using EpiData Analysis (v.2.2.1.171).

Ethics issues

Ethics clearance was obtained from the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France; the National TB Control Programme (NPTCCD), Sri Lanka; and the Ethics Approval Committee of Sri Jayawardenapura University, Sri Lanka.

*S = streptomycin; H = isoniazid; R = rifampicin; Z = pyrazinamide; E = ethambutol. Numbers before the letters indicate the duration of the phase of treatment in months.

RESULTS

During the study period, 160 previously treated TB patients were registered under the programme; 39 of these were failures, 95 were relapses and 25 were treatment after default. Of the 79% of patient sputum samples sent for CDST, 63% were culture-positive, none was resistant to INH and RMP, four were non-tuberculosis mycobacteria, and results were missing for 18 (Figure). The DST results showed sizeable rates of monoresistance (12%) and polyresistance (7%) among the cultures. Monoresistance was mainly found to EMB or SM, while polyresistance was mainly found to INH+SM, or EMB+SM (Table 1).

Of all the samples sent for CDST, delays occurred in sending for 9% and in receiving the reports from the NTRL for 15%. A delay was experienced by 20% of patients in initiating Category II treatment; this was more marked among treatment after failure patients (36%) (Table 2). The median delay for sending samples was 21 days (range 8–262), for receiving reports 71 days (range 66–161) and for treatment initiation 11.5 days (range 6–185).

The overall treatment success for the cohort that completed treatment was 82%, with eight patients still on treatment irrespective of their culture results. Four patients with contaminated or unreported culture results had unfavourable outcomes (Table 3).

DISCUSSION

This is the first study conducted in Sri Lanka in a programme setting to describe the delays in investigating drug resistance and treatment outcomes among previously treated TB patients. We found that about 80% of the patient samples reached the NTRL, which is better than in similar studies conducted in India (69%), Cambodia (46%) and China (42%).[8–10] This illustrates the commitment of the programme in managing previously treated TB patients. There were no MDR-TB cases among the cohort. Twenty per cent of the previously treated TB patients experienced delay in initiating their Category II regimen.

The study finding has the following programme implications. First, although Sri Lanka is a small country

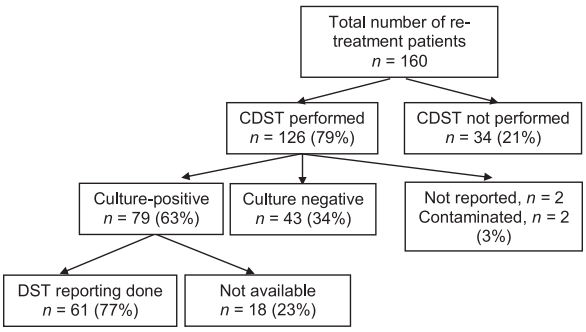

FIGURE Flow chart showing previously treated patients registered in Kalutara District, Sri Lanka, January 2008–June 2013. CDST = culture and drug susceptibility testing; DST = drug susceptibility testing.

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Conflict of interest: none declared.

TABLE 1 Culture and DST results of previously treated TB patients from Kalutara District, Sri Lanka, 2008–2013

	Failure *n* (%)	Relapse *n* (%)	Treatment after default *n* (%)	Total *n* (%)
Culture result				
Negative	29 (85)	12 (16)	2 (10)	43 (34)
Positive	5 (15)	59 (81)	15 (79)	79 (63)
Contaminated	0 (0)	2 (3)	0 (0)	2 (2)
Not reported	0 (0)	0 (0)	2 (10)	2 (2)
Total	34 (100)	73 (100)	19 (100)	126 (100)
DST results				
Susceptible to all drugs	1 (33)	31 (52)	11 (73)	43 (54)
Monoresistance	0 (0)	7 (12)	2 (13)	9 (11)
EMB	0 (0)	2 (3)	2 (13)	4 (5)
SM	0 (0)	5 (8)	0 (0)	5 (6)
Polyresistance	0 (0)	5 (8)	0 (0)	5 (6)
INH+SM	0 (0)	2 (3)	0 (0)	2 (2)
INH+EMB	0 (0)	1 (2)	0 (0)	1 (1)
EMB+SM	0 (0)	2 (3)	0 (0)	2 (2)
NTM	0 (0)	4 (7)	0 (0)	4 (5)
Not available	2 (67)	12 (20)	2 (13)	18 (23)
Total	3 (100)	59 (100)	15 (100)	79 (100)

DST = drug susceptibility testing; EMB = ethambutol; SM = streptomycin; INH = isoniazid; NTM = non-tuberculous mycobacteria.

TABLE 2 Delays in sending samples, receiving reports and initiating treatment among previously treated TB patients in Kalutara District, Sri Lanka, 2008–2013

	n (%)
Delays in sending samples for CDST	
No delay (⩽5 days)	111 (91)
Delay (>5 days)	10 (9)
Total	121* (100)
Delay in receiving reports of CDST	
No delay (⩽65 days)	88 (85)
Delay (>65 days)	15 (15)
Total	103† (100)
Delay in initiating Category II regimen	
No delay (⩽5 days)	98 (80)
Delay (>5 days)	24 (20)
Total	122‡ (100)

*Of 126 patients for whom CDST results were sent, 5 were excluded as the CDST sent dates were not available.
†Of 121 patients for whom CDST sent dates were available, 18 were excluded as the CDST result receiving dates were not available.
‡36 patients were excluded as the date of diagnostic smear microscopy was not recorded.
TB = tuberculosis; CDST = culture and drug susceptibility testing.

with a low burden of TB and a well-established national TB control programme, and TB patients are low in number, nearly 20% of patient samples had not reached the CDST laboratory, and 23% of the DST reports were not available in the patient records or registers in the clinic. There is scope and an immediate need for the programme to strengthen its supervision and monitoring system so as to identify previously treated TB patients effectively, establish mechanisms for rapid transport of sputum samples from the field, and enhance accurate record keeping. Continued involvement and coordination is needed from the general health system to monitor the process. Creation of a post for a mid-level programme officer at sub-district level would be a feasible strategy for strengthening the system.

Second, 34% of samples were culture-negative, which could be a consequence of storage and twice-weekly transport of samples to the NTRL. Such issues could be addressed by finding ways either to implement a daily sample transport or to decentralise the facility, although the latter option is unlikely to be cost-effective. However, culture results among patients treated after relapse and after default (culture negativity 16% and 10%, respectively) suggest that poor storage and transport conditions are unlikely to fully explain the overall 34% negativity rate. The cohort of treatment after failure patients was the main contributor to overall culture negativity, with 85% of this group culture-negative, probably due to high rates of false treatment failures resulting from erroneous detection of dead bacilli in the laboratory. Further studies are required to identify more effective ways of diagnosing and ruling out such patients, such as by introducing tests such as fluorescein diacetate vital staining (FDA).[11]

Third, no MDR-TB cases were detected in this cohort. In contrast, neighbouring South-East Asian countries such as India and Bangladesh have a high prevalence of MDR-TB.[12–14] However, our findings were similar to those of other drug resistance studies conducted in Sri Lanka.[15] While the culture positivity rate was similar to those in other studies in the world, there was no INH and RMP resistance.[8,12] This raises speculation about the quality of the sputum samples collected, transported and processed at the laboratory. It is essential that the operating procedures of the CDST laboratory be certified and closely monitored by a WHO-identified Supranational Reference Laboratory. Considerable mono- and polyresistance was observed in the study. To address these, the programme should create effective collaboration with the private sector and emphasise the International Standards of TB Care (ISTC) for diagnosis and treatment,[16] possibly by rolling out rapid molecular tests such as Xpert® MTB/RIF (Cepheid, Inc, Sunnyvale, CA, USA), which was introduced only recently and remains limited to a small proportion of patients, and by strengthening DOT in the country.[15]

Fourth, the delays in initiation of Category II treatment in 20% of the patients and in 36% of failure patients is of concern, as these are cases with a high potential for developing drug resistance. Under the programme, although there are no specific guidelines on when treatment should be started, patients are conventionally initiated on treatment within the first 5 days. Immediate measures need to be taken by the programme to identify the operational issues and provide feasible solutions.

Fifth, the treatment success rate of previously treated TB cases, reported as 82%, with a death rate of 6%, is relatively satisfactory when compared to studies conducted in Malawi, for example, where the treatment success rate and death rate were 75% and 14%, respectively.[17] This high success rate could be due to the lower prevalence and the well-established programme, and managers should not be complacent. The death rate may be due to the association of TB with other co-morbidities. The prevalence of human immunodeficiency virus (HIV) infection is low in the country and there is no established TB-HIV co-infection. After 2012, the programme nevertheless established a policy of routinely screening all TB patients for HIV at chest clinics. The prevalence of diabetes is high in the general population, and the programme needs to conduct operational feasibility studies for a routine screening policy for TB patients for diabetes.[18]

The strengths of the study are that it was conducted in a pro-

TABLE 3 Treatment outcomes among previously treated TB patients in Kalutara District, Sri Lanka, 2008–2013

	Cured *n* (%)	Treatment completed *n* (%)	Default *n* (%)	Died *n* (%)	Other *n* (%)	Total *n*
Patients without a positive culture result						
CDST not performed	28 (88)	1 (3)	1 (3)	2 (6)	0 (0)	32
Culture not reported or contaminated	0 (0)	0 (0)	2 (50)	2 (50)	0 (0)	4
Culture-negative	39 (91)	0 (0)	0 (0)	4 (9)	0 (0)	43
Patients with a positive culture result						
Susceptible to all drugs	32 (86)	0 (0)	5 (14)	0 (0)	0 (0)	37
Monoresistance	9 (100)	0 (0)	0 (0)	0 (0)	0 (0)	9
Polyresistance	3 (75)	1 (25)	0 (0)	0 (0)	0 (0)	4
NTM	0 (0)	3 (75)	0 (0)	1 (25)	0 (0)	4
DST reports not available	15 (88)	0 (0)	0 (0)	1 (6)	1 (6)	17
Total	126 (84)	5 (3)	8 (5)	10 (7)	1 (1)	150*

*10 patients excluded as outcome was not stated for 2 and 8 were still on treatment.
TB = tuberculosis; CDST = culture and drug susceptibility testing; NTM = non-tuberculous mycobacteria; DST = drug susceptibility testing.

TABLE 4 Revised WHO definitions of previously treated TB cases and treatment outcomes

Definitions
Previously treated TB cases
Relapse
Patients previously treated for TB and declared cured or treatment completed at the end of their most recent treatment episode and now diagnosed with a recurrent episode of TB (either true relapse or new episode of TB caused by re-infection)
Treatment after failure
Patients previously treated for TB and whose treatment failed at the end of their most recent treatment episode
Treatment after default (treatment after loss to follow-up)
Patients previously treated for TB and declared lost to follow-up at the end of their most recent treatment episode. (Previously known as treatment after default)
Other
Patients previously treated for TB but with an unknown or undocumented outcome for their most recent treatment episode
Treatment outcomes
Cured
A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment and smear- or culture-negative in the last month of treatment and on at least one previous occasion
Treatment completed
A TB patient who completed treatment without evidence of failure BUT no records to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion are negative, either because they were not performed or because results were not available
Treatment failed
A TB patient whose sputum smear or culture is positive at month 5 or later during treatment
Died
A TB patient who dies for any reason before starting treatment or during the course of treatment
Default (lost to follow-up)
A TB patient who did not start treatment or whose treatment was interrupted for ⩾2 consecutive months
Not evaluated
A TB patient for whom no treatment outcome is assigned. (Includes cases transferred out to another treatment unit and where the treatment outcome is unknown to the reporting unit)

WHO = World Health Organization; TB = tuberculosis.

gramme setting and reflects the reality in the field, a large number of records were verified from the past 5 years and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were adhered to. The study has a number of limitations: as in any record-based review, there is always incomplete data recording and inaccuracies, and the CDST results and TB treatment outcome were not available for a number of patients. In addition, the relatively high number of culture-positive patients with drug resistance patterns other than INH and RMP remains unexplained.

To conclude, in the national TB control programme of Sri Lanka, substantial numbers of previously treated TB patients are not tested for drug resistance, and there is a sizeable delay in initiation of the Category II treatment regimen. The programme must implement measures to enhance monitoring and supervision, such as creating a post for a mid-level programme officer at sub-district level, transporting specimens in a timely fashion and adopting new diagnostic measures to overcome these challenges.

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Contexte : Dispensaire de pneumologie du district de Kalutara, Sri Lanka.
Objectif : Déterminer la couverture du test de culture et de sensibilité aux médicaments (CDST), les délais des tests de résistance aux médicaments, de mise en œuvre du traitement et d'obtention des résultats du CDST ainsi que les résultats du traitement chez des patients tuberculeux déjà traités auparavant.
Schéma : Etude rétrospective de cohorte par revue de dossiers et de rapports. Tous les patients tuberculeux de janvier 2008 à juin 2013 déjà traités ont été inclus dans l'étude.
Résultats : Sur 160 patients, 126 (79%) ont été référés pour un CDST ; 79 (63%) avaient une culture positive et il n'y a eu aucun cas de TB-MDR. Environ 9% et 15% des patients, respectivement, ont eu un retard d'expédition des échantillons (retard médian 21 jours) et de réception du rapport du CDST (retard médian 71 jours), tandis que 20% ont subi un retard de mise en œuvre de la reprise du traitement (retard médian 11,5 jours). Le taux de succès thérapeutique de la cohorte atteignait 82%.
Conclusion : Parmi tous les patients en retraitement, seulement 79% ont bénéficié d'un CDST et il y a eu des retards considérables dans le transport des échantillons et la mise en œuvre du traitement. Des discussions sont en cours afin de renforcer le programme.

Marco de referencia: El consultorio distrital de neumología de Kalutara, en Sri Lanka.
Objetivos: Determinar la cobertura con la culture y las pruebas de sensibilidad a los medicamentos antituberculosos (CDST), el retraso en el análisis de la farmacorresistencia, el comienzo del tratamiento y la obtención del resultado del CDST y los desenlaces terapéuticos de los pacientes con diagnóstico de tuberculosis (TB) y antecedente de tratamiento previo.
Método: Se llevó a cabo un estudio retrospectivo de cohortes con análisis de las historias clínicas y los informes de laboratorio. Se incluyeron en el estudio todos los pacientes tuberculosos atendidos entre enero del 2008 y junio del 2013 que habían recibido tratamiento antituberculoso.
Resultados: De los 160 pacientes incluidos en el estudio se enviaron 126 muestras para CDST (79%); en 79 muestras se obtuvo un cultivo positivo para TB (63%) y no se notificaron casos de multidrogorresistencia. Se observó retraso en el envío de las muestras en el 9% de los casos (mediana del retraso 21 días) y en el 15% de los pacientes hubo retraso en la obtención de los resultados del CDST (mediana del retraso 71 días); en 20% de los pacientes se retrasó el comienzo del régimen de retratamiento (mediana del retraso 11,5 días). La tasa de éxito terapéutico en la cohorte estudiada fue 82%.
Conclusión: De todos los pacientes en retratamiento, se practicaron CDST solo en 79% de los casos y se observaron retrasos considerables en el transporte de las muestras y el comienzo del tratamiento. En el artículo se proponen métodos encaminados a fortalecer el programa.

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