Trans R Soc Trop Med Hyg 2025; **0**: 1–6
https://doi.org/10.1093/trstmh/traf046 Advance Access publication 0 2025

Drug-resistant tuberculosis treatment outcomes among Saharia: a marginalized community of Madhya Pradesh, India

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Received 13 December 2024; revised 4 April 2025; editorial decision 8 April 2025; accepted 11 April 2025

Background: Few attempts have been made to explore the drug-resistant tuberculosis (DR-TB) outcomes and associated factors among underprivileged communities. This study aimed to determine DR-TB treatment outcomes and associated factors in the Saharia tribal group (TGs), a community with a high TB burden in Madhya Pradesh, India.

Methods: TB cases were detected through active case finding and were treated under the National Tuberculosis Elimination Programme. All the patients who were initiated on DR-TB treatment and had outcomes at the end of treatment were included in the study. The DR-TB treatment outcomes and associated factors were recorded.

Findings: Of 323 patients included in the analysis, 216 patients (66.8%) had successful treatment outcomes, including 70 (21.7%) who were cured and another 146 (45.2%) who completed treatment. Among the rest, 36 (11.1%) died, 66 (20.4%) were lost to follow-up and 5 (1.5%) had treatment failure. A total of 83% of patients were rifampicin resistant (RR)/multidrug resistant (MDR).

Conclusions: Although the program's recommended target of >75% could not be achieved, the treatment success rate in the study is still admirable in a hard-to-reach high-TB-risk tribal area. The findings show that with community-based approaches, favourable treatment outcomes can be achieved in DR-TB patients from resource-poor settings.

Introduction

Tuberculosis (TB) control and elimination is a major public health challenge globally, with an estimated 10.6 million people globally (134 cases per 100 000 population) with TB in 2021. The most TB cases in 2021 were in the World Health Organization (WHO) South-East Asia region (45%), and India alone shared 28% of all forms of TB.[1] The problem of drug-resistant TB (DR-TB) is increasing globally, with an increased number of 450 000 new cases of rifampicin-resistant (RR)/multidrug-resistant (MDR) TB.[1] However, in India the projected cases of MDR and extensively drug-resistant TB (XDR-TB) in 2021 was 4 and 1 for every 100 000 population, respectively, showing a significant reduction of 14% and 9%, respectively, compared with 2019 and 2020. Also, a significant decrease was seen in XDR-TB patients who were initiated on TB treatment in 2020 and 2021.[2] In India, currently, the classes for DR-TB are isoniazid (INH)-resistant TB, RR-TB and MDR-TB (RR and INH resistant), pre-extensively drug-resistant TB (pre-XDR-TB) and XDR-TB.[2]

The projected incidence of MDR-/RR-TB in 2021 for the country was 119 000 (range 93 000–145 000). A significant reduction was observed in the number of detected DR-TB patients under the National Tuberculosis Elimination Programme (NTEP) when compared with 2019. That was the year of the coronavirus disease 2019 pandemic. In 2022 there was an increase of 32% in MDR-/RR-TB cases detected compared with 2021.

In India, the management of DR-TB is challenging in terms of program implementation and could cause poor treatment outcomes. A treatment success rate of only 57% was reported among DR-TB patients who were initiated on treatment in 2019.[2] The information on DR-TB management, including treatment outcomes, is sparsely available from hard-to-reach tribal areas in India. Saharia is one of the particularly vulnerable tribal groups in Gwalior and the Chambal division of Madhya Pradesh, in central India, with an extremely high prevalence of TB that ranges from 1270 to 3294 per 100 000 population.[3–5] Hence DR-TB is a seri-

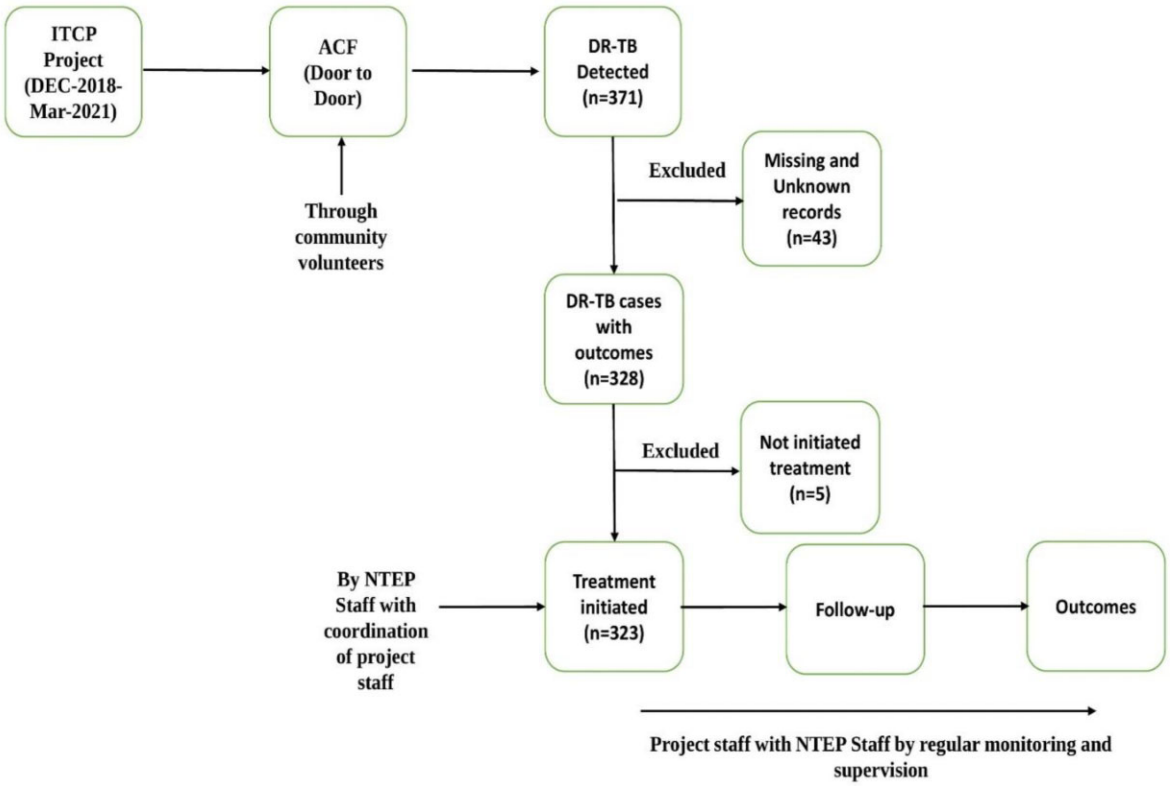

Figure 1: Study flow chart.

ous concern in the Saharia tribe.[6] The study on DR-TB conducted in this community reported that most of the RR-MDR cases had a previous TB history.[7] There is, however, no information available on the DR-TB treatment outcomes and associated factors in this community. We present here the findings of the DR-TB treatment outcomes and associated factors in this disadvantaged community.

Methods

Study design and setting

An observational study was carried out under the Intensified Tuberculosis Control Project (ITCP) among the Saharia population in seven districts of Gwalior and the Chambal division (Sheopur, Shivpuri, Gwalior, Ashoknagar, Bhind, Datia and Morena) of Madhya Pradesh in central India from November 2018 to March 2021. It was undertaken to enhance case detection and outcomes for treatment through the engagement of community volunteers using baseline, intervention and end-line survey strategies. The present study on MDR-TB is a part of this larger study in this marginalised community.[8] These districts are linked to the DR-TB centres in Gwalior under the NTEP. The detected DR-TB patients during the survey were treated at their respective district TB centre (DTC) and the cough-to-cure pathway of patients was completed by the project team through regular monitoring and supervision in the field with direct coordination of the concerned NTEP staff of the TB units and DTC.

Study population

All Saharia patients detected through active case finding in the ITCP and those who were initiated on DR-TB treatment under the NTEP[9] and had treatment outcomes were included in the study. The patients not started on treatment and those without outcome records were omitted from the study (Figure 1).

Drug susceptibility testing (DST) and treatment

Sputum samples were first tested for detection of *Mycobacterium tuberculosis* (MTB) and rifampicin resistance by smear microscopy using Ziehl–Neelsen stain and the Xpert MTB/RIF test (Cepheid, Sunnyvale, CA, USA), respectively. The specimens having resistance were sent to the intermediate reference laboratory and the national TB reference laboratory located in Jabalpur and Bhopal, Madhya Pradesh, India for the first- and second-line probe assay. As per the DST results, the project staff facilitated treatment initiation with active support of the NTEP staff. Later, treatment adherence, follow-up and outcomes were recorded by community volunteers engaged in the project under the direct supervision and monitoring of the project and NTEP staff. The volunteers who were selected from the same area, preferably from the same community, were constantly following up the patients for adherence and acted as a bridge between the patient and NTEP

staff. Sensitization and involvement of Panchayati Raj Institutions in the study area was also ensured. These members motivated the community to participate in the project activities.

Operational definitions

For DR-TB profiles, the standard NTEP definitions were used. As per program guidelines, treatment outcomes (i.e. cured, treatment completed, treatment failed, died and lost to follow-up [LTFU]) were recorded.[9] Treatment success referred to cured and treatment completed, while the others were classified as unsuccessful treatment outcomes.

Data collection and management

A central data management unit was established at the Indian Council of Medical Research (ICMR) – National Institute of Research in Tribal Health (NIRTH), in Jabalpur. All the data for the ITCP were sent monthly by field staff in predesigned formats (presumptive, TB case and outcome). The information was verified by district coordinators and project scientists before forwarding it to the central data management unit at the institute. The data management team developed a predesigned data entry application using CSPro software that reflects the various variables under study for further analysis.

Results

Patient characteristics

Of the total 323 DR-TB cases, 5 (1.5%) were in the paediatric age group (≤14 y). The median age of the cases was 40 y (range 4–70). A total of 248 cases (76.7%) were males and the male:female ratio was 35:1. Among 323 patients, 270 (83.5%) had a body mass index (BMI) ≤18.5. Two patients were coinfected with human immunodeficiency virus (HIV) and six patients were found to be diabetic. The proportion of isoniazid (H)-mono, MDR-TB, pre-XDR-TB and XDR-TB was 13%, 82.6%, 2.4% and 1.8%, respectively. About 31% of patients were new and 69% had previous TB episodes (Table 1).

Table 1: Demographic and clinical characteristics of DR-TB patients (n=323).

Characteristics	n (%)
Sex	
Male	248 (76.7)
Female	75 (23.2)
Age (years)	
0–14	5 (1.5)
15–24	18 (5.5)
25–34	74 (22.9)
35–44	92 (28.4)
45–54	78 (24.1)
≥55	56 (17.3)
Patient type	
New	101 (31.2)
Previously treated	222 (68.7)
HIV status	
Reactive	2 (0.6)
Non-reactive	321 (99.3)
Diabetic status	
Diabetic	6 (1.8)
Non-diabetic	317 (98.1)
BMI	
≤18.5	270 (83.5)
≥18.5	48 (14.8)
Unknown	5 (1.5)
Drug-resistance profile	
H-mono, 6-month regimen	42 (13.0)
RR-MDR, shorter regimen (9–11 months)	267 (82.6)
Pre-XDR (18–20 months)	8 (2.4)
XDR bedaquiline-containing regimen (18–20 months)	6 (1.8)

Treatment outcomes

Of 323 patients, 216 (66.8%) had successful treatment outcomes: 70 (21.7%) were cured and 146 (45.2%) completed treatment (Figure 2). Of the remaining, 36 (11.1%) died, 66 (20.4%) were LTFU and 5 (1.5%) were treatment failure cases.

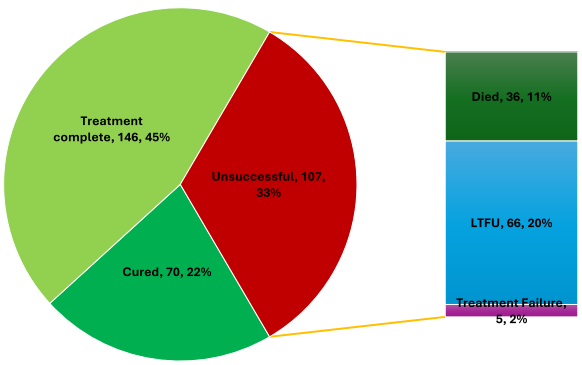

Figure 2: Treatment outcomes of DR-TB patients (n=323).

Factors associated with unsuccessful outcomes

Among all the cases, children (≤14 y) had the most unsuccessful outcomes. The patients with a previous history of TB treatment had relatively higher chances of having unsuccessful treatment outcomes (odds ratio [OR] 1.26). Similarly, RR-MDR and XDR (pre-XDR/XDR) patients had higher chances of having unsuccessful outcomes (OR 2.16 and 7.65, respectively) compared with H-mono patients. However, these differences were not statistically significant, except in the case of XDR, where the difference was statistically significant (Table 2).

Discussion

The present study is the first on treatment outcomes of DR-TB and factors associated with it among the high-TB-burden Saharia

Table 2: Factors associated with the unsuccessful treatment outcome among DR-TB patients (n=323).

Characteristics	Unsuccessful outcomes	Successful outcomes	OR (95% CI)	n
Sex				
Male	79 (31.8)	169 (68.2)	–	248
Female	28 (37.3)	47 (62.7)	1.27 (0.74 to 2.18)	75
Age (years)				
≤14	3 (60.0)	2 (40.0)	–	5
15–24	4 (22.2)	14 (77.8)	0.19 (0.01 to 1.56)	18
25–34	27 (36.5)	47 (63.5)	0.38 (0.06 to 2.44)	74
35–44	27 (29.3)	65 (70.7)	0.27 (0.04 to 1.75)	92
45–54	28 (35.9)	50 (64.1)	0.37 (0.06 to 2.37)	78
≥55	18 (14.3)	38 (85.7)	0.32 (0.05 to 2.06)	56
Patient type				
New	30 (29.7)	71 (70.3)	–	101
Previously treated	77 (34.7)	145 (65.3)	1.26 (0.76 to 2.09)	222
HIV status				
Reactive	0 (0)	2 (100)		2
Non-reactive	107 (33.3)	214 (66.7)		321
Diabetic status				
Diabetic	3 (50.0)	3 (50.0)	–	6
Non-diabetic	104 (32.8)	213 (67.1)	2.05 (0.41 to 10.32)	317
BMI				
≤18.5	86 (31.8)	184 (68.2)	–	270
≥18.5	17 (35.4)	31 (64.6)	1.17 (0.62 to 2.23)	48
Unknown	4 (80.0)	1 (20.0)	8.56 (0.94 to 77.7)	5
Drug-resistance profile				
H-mono	8 (19.0)	34 (81.0)	–	42
RR-MDR	90 (33.7)	177 (66.3)	2.16 (0.96 to 4.86)	267
Pre-XDR/XDR	9 (64.3)	5 (35.7)	7.65 (2.01 to 29.13)	14
Total	107 (33.2)	216 (66.8)		323

tribal community. The study showed that 66.8% (n=216) of patients had successful DR-TB treatment outcomes while 33.3% (n=107) had unsuccessful treatment outcomes. The treatment success rate among Saharia was higher compared with the WHO-reported global estimate of 60% and the national figure of 57% for India.[1,2] The success rate was higher than the reported rates in other studies in different settings in India and abroad.[10–14] This could be due to the active participation of community volunteers, who were mostly from the same communities/villages as the cases. The findings suggest that a community-based approach to TB treatment is another model for the delivery of TB services to people living in areas with difficult-to-access health services and resource-poor settings. The possible reason for unfavourable treatment outcomes in this community could be the higher prevalence of undernutrition, with 83.5% cases having a BMI ≤18.5. In the present study, LTFU was the major contributor (20.4%) in the 33.1% of cases with unsuccessful treatment outcomes. El Hamdouni et al.[15] and Agarwal et al.[10] found a higher rate of unsuccessful treatment outcomes of 46.5% and 57%, respectively, with a high rate of LTFU (34.6% and 28%, respectively). Our findings are consistent with the findings of Patel et al.,[11] who reported 21% LTFU in their study. Mishra et al.[16] and Nigam et al.[17] conducted qualitative studies on the reasons for LTFU and experiences of MDR/XDR patients of the Saharia tribe and found various factors associated with unfavourable treatment outcomes, including work constraints, high pill burden, myths and misbeliefs, stigma and adverse events in different phases of the treatments.

The majority of cases in the present study were male (76.7%). This finding agrees with other studies across the globe that have found a male preponderance in TB cases.[18] However, more women had higher unsuccessful treatment outcomes compared with men. The possible reason for this could be the smaller number of women in the sample size of the current study. The unsuccessful treatment outcomes increased with age. Similar findings are also reported by other studies conducted in different settings.[19,20] We found an 11.1% mortality rate and 1.5% treatment failure in our study. Patel et al.[11] and Datta et al.[21] also reported high mortality rates of 29.7% and 21.1%, respectively. Hamdouni et al.[15] and Patel et al.[11] found treatment failure in 6.9% and 6.2% of cases, respectively. TB comorbidities such as diabetes and HIV increase the risk of poor treatment outcomes.[22] In the present study, HIV-reactive patients had a 100% success rate. However, among the TB–diabetes patients, only 3 of 6 (50%) experienced successful treatment outcomes. This could be due to fewer patients with TB–HIV and TB–diabetes. Most of the DR-TB

cases were previously treated (68.7%) patients and had higher rates of unfavourable outcomes (34.7%; Tables 1 and 2). This finding is consistent with the findings of the other studies.[23,24]

In India, DR-TB poses a great challenge to TB elimination due to the high incidence and mortality of TB in the country. Our findings demonstrate that in patients with DR-TB, favourable treatment outcomes can be achieved in a resource-poor setting with community-based approaches. Although the recommended WHO target[25] was not achieved in the study, the findings need to be considered in view of the difficulties associated with treatment of TB among Saharia, a marginalised community in remote tribal areas. The study provides useful information for policy decisions to improve DR-TB management in hard-to-reach tribal areas. Further studies are required to generate data on DR-TB treatment outcomes and factors associated with it in marginalised communities.

Author's contributions: RKS, RY, MM, VGR and JB contributed to the concept, design and implementation of the study. PM, SN and MAL contributed to the study's execution, collection of data and monitoring. PM, RKS and MM were responsible for data analysis. PM, RKS, RY, MM, VGR and JB drafted and revised the manuscript. RKS and JB verified the data. JB, RKS, MM, VGR and RY decided to submit the manuscript.

Acknowledgement: Authors are grateful to Balram Bhargava, former Secretary, Department of Health Research, Ministry of Health & Family Welfare, Government of India and Director General, ICMR for his support, insights and guidance. The authors are also thankful to the Principal Secretary of Health, Principal Secretary of Tribal Development, Health Commissioner and State Tuberculosis Officer, Government of Madhya Pradesh for their constant support in undertaking this work in the Saharia tribe. The authors acknowledge R. Gangakhedkhar, former head of the ECD Division, ICMR, for his interest and constant support of project activities. The authors are thankful to Aparup Das, former director of ICMR–NIRTH, Jabalpur for his support of the study. The contributions of the district tuberculosis officers, the WHO/NTEP consultants, district tribal welfare authorities, block medical officers and peripheral field staff are acknowledged. Sincere thanks are also due to the study participants and the field and laboratory staff, data entry operators and secretarial staff involved in the study.

Funding: The work was supported by the Government of Madhya Pradesh (budget 2210/2017–18/877, 27 January 2018).

Competing interests: None declared.

Ethical approval: The Institutional Ethics Committee of ICMR–NIRTH, Jabalpur approved the study (NIRTH/IEC/2273/2016). Informed written consent was obtained from all study participants. The study was conducted in compliance with the National Ethical Guidelines for Biomedical and Human Research involving Human Participants 2017 (Indian Council of Medical Research, New Delhi).

Data availability statement: RKS and JB have full access to the data and take responsibility for the integrity and accuracy of the results. The data used in the present study are part of a larger study and include information on personal identification, thus the data are not available in the public domain but are available upon reasonable request.

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