

Factors associated with non-completion of TB preventive treatment in Brazil

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SUMMARY

BACKGROUND: Among Brazilian initiatives to scale up TB preventive therapy (TPT) are the adoption of the 3HP regimen (12 weekly doses of rifapentine and isoniazid [INH]) in 2021 and the implementation in 2018 of the TPT surveillance information system. Since then, 63% of the 76,000 eligible individuals notified completed TPT. Recommended regimens in this period were 6H, 9H (6 or 9 months of INH) and 4R (4 months of rifampicin).

OBJECTIVE: To analyse the factors associated with TPT non-completion.

METHODS: We analysed the cohort of TPT notifications from 2018 to 2020. Robust variance Poisson regression model was used to verify the association of

TPT non-completion with sociodemographic, clinical and epidemiological variables.

RESULTS: Of the 39,973 TPT notified in the study period, 8,534 (21.5%) were non-completed, of which 7,858 (92.1%) were lost to follow-up. Age 15–60 years (relative risk [RR] 1.27, 95% confidence interval [95% CI] 1.20–1.35), TPT with isoniazid (RR 1.40, 95% CI 1.19–1.64) and Black/mixed race (RR 1.17, 95% CI 1.09–1.25) were associated with a higher risk of non-completion.

CONCLUSION: Individuals in situations of social and financial vulnerability such as being Black/*pardo* race, younger and on longer TPT regimens were more likely to be associated with TPT incompleteness.

KEY WORDS: latent tuberculosis; TPT; *Mycobacterium tuberculosis*; loss to follow-up; patient dropouts

TB preventive treatment (TPT) is an effective strategy for reducing TB incidence and a vital and necessary strategy if TB elimination is to be achieved.¹ The WHO currently recommends TPT for people living with HIV (PLWHIV) and close contacts of people with pulmonary TB. Accordingly, a commitment was made to provide TPT to six million PLWHIV, four million contacts under 5 years of age and 20 million other contacts by the end of 2022 by over 100 countries during the UN High-Level Meeting held in 2018.² Much progress has been made with regards to TPT provision for PLWHIV worldwide, but contacts are still neglected. One of the drivers of TPT scale-up in recent years is the implementation of shorter TPT regimens recently recommended by the WHO and by several pulmonology societies and public health institutions.^{3–5}

In the last 5 years, the Brazilian Ministry of Health, one of the UN political document signatories, has engaged in efforts to scale up TPT in Brazil. A new TPT surveillance system was implemented in 2018,

and states and municipalities were successively trained on TB infection (TBI) management and surveillance.⁶ Furthermore, more recently, interferon-gamma release assays (IGRAs) and the 3HP regimen (12 weekly doses of 900 mg of rifapentine [RPT] + 900 mg of isoniazid [INH]) were incorporated into the public health system.⁶ Notification of TPT is not compulsory in Brazil, but, according to the Ministry of Health, the system had registered over 76,507 TPT notifications, with a mean completion rate of 63% up to the end of 2021.⁷ The aim of the present study is to understand the factors associated with the lack of TPT completion in order to inform future interventions to improve the proportion of people completing TPT.

STUDY POPULATION AND METHODS

Setting

Since 2014, notification and registration of TBI treatment have been recommended throughout Bra-

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zil. As of 2017, the intensification of TB prevention became one of the goals of the National Plan to End TB as a Public Health Problem (National Plan). Between 2018 and 2021, 76,507 eligible TPT cases were notified in Brazil.⁷

According to the national recommendations, people are diagnosed as having TBI based on either a positive tuberculin skin test (TST), i.e., induration ≥ 5 mm, or a positive IGRA, followed by a chest radiogram to rule out TB disease. For PLWHIV, TPT should be provided if CD4⁺ cell counts are $< 350/\text{mm}^3$, while those with an unknown CD4⁺ count or $\geq 350/\text{mm}^3$ should receive TPT only after a positive test for TBI. People initiating TPT are followed up for medical consultation at regular intervals of 30 days. For those who have good adherence and low risk of hepatotoxicity, this interval may be increased to 60 days.^{6,7}

INH was the recommended drug for TPT in Brazil, and up to 2020, treatment with INH could last for 6 or 9 months. TPT with rifampicin (RIF) is indicated for patients over 50 years of age, those under 10 years of age, those with liver disease, contacts of mono-resistant patients and those with INH intolerance. In 2021, Brazil recommended a regimen comprising RPT associated with INH, and this has been the treatment of choice since then.⁶

Assessment of TPT adherence and completion is based on self-reported number of doses taken and treatment duration. For INH, 270 doses taken in 9–12 months (9H) or 180 doses taken in 6–9 months (6H) are considered treatment completion. For treatment with RIF, 120 doses taken in 4–6 months (4R) is the criterion for TPT completion. The regimen RPT associated with INH, 12 weekly doses (3HP) was not available during the study period.⁶

Study design and data source

This was an observational retrospective cohort study based on secondary data. TPT notified to the Brazilian TBI Information System (*Sistema de informação para notificação das pessoas em tratamento de ILTB*, or “IL-TB”) were eligible. The IL-TB contains socio-demographic data, TBI test results, chest radiogram results, indication for TPT, associated health conditions (comorbidities) and clinical data on TPT follow-up of all persons who started TPT where the IL-TB was available.⁶

Inclusion and exclusion criteria

Individuals initiating TPT between January 2018 and December 2020 were included in the current analysis. Individuals with current or past TB disease, deaths and those who moved to another country were excluded.

Variables and outcome

The outcome was TPT non-completion for the following reasons: loss of follow-up (LTFU) and

adverse reaction. The following exposure variables were analysed: sex, age, race/skin colour, whether an immigrant, geographic region of Brazil, diabetes mellitus, immunosuppressive therapy, neoplasms, HIV infection/aids, contact of patients with pulmonary TB, bacille Calmette-Guérin (BCG) vaccination status, chest radiogram, TST result and drug used in TPT (no information on which regimen, 6H or 9H, was available). Data were obtained from IL-TB, available from the Ministry of Health. The variables ‘IGRA’ and ‘immigrant status’ were not included in the multiple analyses. IGRAs were not available in the Brazilian public health system during the study period, which may have introduced bias in the analysis. As the proportion of immigrants in the notifications was too small proportion (0.9%), the variable was removed from the multiple analyses.

Analyses

Pearson’s χ^2 test was performed to verify the association between treatment outcome and covariates. Variables with a $P \leq 0.20$ were included in a robust Poisson regression model, where TPT non-completion was the reference unit. Variables with a $P \leq 0.05$ in the unadjusted analysis were included one by one in the final model, and retained in the model as an adjustment if $P \leq 0.05$. The Hosmer–Lemeshow test was used after each Poisson regression for assessing model fit.

Results of the multivariate analysis were interpreted in terms of relative risk (RR) with 95% confidence intervals (95% CIs). All analyses were performed in Stata v14.0 (Stata Corp, College Station, TX, USA).

Ethics

The Federal University of Espírito Santo (UFES) Institutional Review Board, Vitória, ES, Brazil, approved the study (registration no: 5,311.108).

RESULTS

Between January 2018 and December 2020, 39,973 TPT cases were notified to the TPT information system in Brazil. We excluded 406 notifications: 197 (0.5%) for active TB, 159 (0.4%) deaths and 50 (0.6%) transferred to another country. The final population consisted of 39,567 people, of whom 31,033 (78.4%) completed TPT and 8,534 (21.6%) did not complete. Among those who did not complete TPT, 7,858 (92.1%) were reported as lost to follow-up and 676 (7.9%) as treatment discontinued due to adverse events.

Sociodemographic characteristics, comorbidities and diagnosis of patients who initiated TPT are given in Table 1. Age < 15 years was associated with 19.2% non-completion, which declined with increasing age, from 23.0% among 15–60-year olds to 17.0%

Table 1 Distribution of sociodemographic characteristics, comorbidities and clinical characteristics of patients who initiated TPT, Brazil, January 2018–December 2020 (*n* = 39,567)

Variables	TPT		<i>P</i> value*
	Completion <i>n</i> (%)	Non-completion <i>n</i> (%)	
Age, years			<0.001
<15	7,112 (80.98)	1,670 (19.02)	
15–60	20,573 (76.91)	6,177 (23.09)	
>60	3,348 (82.97)	687 (17.03)	
Sex			0.002
Female	16,592 (79.03)	4,403 (20.97)	
Male	14,441 (77.76)	4,131 (22.24)	
Race/skin colour			<0.001
White	11,181 (79.41)	2,899 (20.59)	
Black	2,832 (75.46)	921 (24.54)	
Brown/ <i>pardo</i>	14,089 (78.02)	3,970 (21.98)	
Asian and indigenous	694 (86.21)	111 (13.79)	
Immigrants			<0.001
No	30,650 (78.52)	8,386 (21.48)	
Yes	229 (67.55)	110 (32.45)	
Geographic region of Brazil			<0.001
South	3,336 (78.85)	895 (21.15)	
Northeast	5,937 (80.47)	1,441 (19.53)	
Midwest	1,180 (75.11)	391 (24.89)	
Southeast	17,852 (78.08)	5,013 (21.92)	
North	2,728 (77.46)	794 (22.54)	
Diabetes mellitus			0.132
No	30,890 (78.41)	8,505 (21.59)	
Yes	143 (83.14)	29 (16.86)	
Immunosuppressive therapy			<0.001
No	26,365 (77.62)	7,600 (22.38)	
Yes	4,668 (83.33)	934 (16.67)	
Neoplasms			0.388
No	30,931 (78.42)	8,511 (21.58)	
Yes	102 (81.60)	23 (18.40)	
HIV			<0.001
No	26,290 (79.26)	6,879 (20.74)	
Yes	4,743 (74.13)	1,655 (25.87)	
Contact of patients with TB			0.001
No/not known	10,871 (79.47)	2,808 (20.53)	
Yes	19,169 (78.00)	5,407 (22.00)	
BCG vaccination performed			<0.729
No	2,342 (79.20)	615 (20.80)	
Yes	24,098 (78.93)	6,433 (21.07)	
Chest X-ray			<0.019
Normal	27,128 (78.62)	7,376 (21.38)	
Not suggestive of TB	1,875 (80.92)	442 (19.08)	
Suspected TB	38 (73.08)	14 (26.92)	
IGRA			0.014
Negative	147 (85.96)	24 (14.04)	
Positive	388 (74.90)	130 (25.10)	
Undetermined	78 (74.29)	27 (25.71)	
Not performed	30,420 (78.46)	8,353 (21.54)	
TST, mm			0.017
<5	824 (76.08)	259 (23.92)	
≥5	27,508 (79.10)	7,270 (20.90)	
Medication			<0.001
Rifampicin	954 (86.26)	152 (13.74)	
Isoniazid	30,079 (78.21)	8,382 (21.79)	

* Pearson's χ^2 test.

TPT = TB preventive treatment; BCG = bacille Calmette-Guérin; IGRA = interferon-gamma release assay; TST = tuberculin skin test.

among those over 60. There was little difference in non-completion rates between the sexes, while Asian and indigenous race had the lowest non-completion rate. People with HIV had greater LTFU rates

(25.8%) than those without the virus (20.7%). There was little difference between those who were TB contacts and those who were not, although those with a positive TST had a modestly higher LTFU rate.

Table 2 RRs of treatment incompleteness of TPT by sociodemographic, comorbidities and clinical characteristics of patients who initiated treatment, Brazil, January 2018–December 2020 ($n = 39,567$)

Variables	RR (95% CI)	<i>P</i> value	aRR (95% CI)	<i>P</i> value
Age, years		<0.001		<0.001
<15	1.00		1.00	
15–60	1.21 (1.15–1.27)		1.27 (1.20–1.35)	
>60	0.89 (0.82–0.97)		0.99 (0.90–1.09)	
Sex		0.002		0.129
Female	1.00		1.00	
Male	1.06 (1.02–1.10)		1.03 (0.98–1.08)	
Race/skin colour		< 0.001		<0.001
White	1.00		1.00	
Black	1.19 (1.11–1.27)		1.17 (1.09–1.25)	
Brown/ <i>pardo</i>	1.06 (1.02–1.11)		1.06 (1.01–1.12)	
Asian and indigenous	0.66 (0.56–0.79)		0.58 (0.48–0.71)	
Geographic region of Brazil		<0.001		<0.001
South	1.00		1.00	
Northeast	0.92 (0.85–0.99)		0.85 (0.78–0.92)	
Midwest	1.17 (1.06–1.30)		1.16 (1.03–1.30)	
Southeast	1.03 (0.97–1.10)		1.01 (0.94–1.08)	
North	1.06 (0.97–1.15)		0.95 (0.86–1.05)	
Immunosuppressive therapy		<0.001		<0.001
No	1.00		1.00	
Yes	0.74 (0.70–0.79)		0.82 (0.75–0.89)	
HIV		<0.001		0.244
No	1.00		1.00	
Yes	1.24 (1.19–1.30)		1.05 (0.96–1.15)	
Contact of patients with TB		0.001		0.001
No/not known	1.00		1.00	
Yes	1.07 (1.02–1.11)		1.15 (1.01–1.23)	
Chest X-ray		0.020		0.130
Normal	1.00		1.00	
Not suggestive of TB	0.89 (0.81–0.97)		0.90 (0.82–1.00)	
Suspected TB	1.25 (0.80–1.97)		1.18 (0.67–2.09)	
TST, mm		0.014		0.022
<5	1.00		1.00	
≥5	0.87 (0.78–0.97)		0.87 (0.78–0.98)	
Medication		<0.001		<0.001
Rifampicin	1.00		1.00	
Isoniazid	1.58 (1.36–1.84)		1.40 (1.19–1.64)	

RR = risk ratio; TPT = TB preventive treatment; CI = confidence interval; aRR = adjusted RR; TST = tuberculin skin test.

Those receiving RIF had a markedly lower (13.7%) LTFU rate than those receiving INH (21.7%).

Results of the multivariate analyses are shown in Table 2. The following variables were associated with a higher risk of TPT non-completion: age 15–60 (RR 1.27, 95% CI 1.20–1.35), TPT with INH (RR 1.40, 95% CI 1.19–1.64), being Black (RR 1.17, 95% CI 1.09–1.25) or *pardo* race (RR 1.06, 95% CI 1.01–1.12) and living in the midwest region of Brazil (RR 1.16, 95% CI 1.03–1.30). The following variables were associated with a lower risk of TPT non-completion: individuals with a TST result ≥ 5 mm (RR 0.87, 95% CI 0.78–0.98) as opposed to individuals with a TST < 5 mm and individuals on immunosuppressive therapy (RR 0.82, 95% CI 0.77–0.88).

DISCUSSION

Under programmatic conditions, we report high TPT completion. The completion rate found is compatible

with a meta-analysis that described completion rates of 45–95% in the general population.⁸ Our results identified sociodemographic and clinical factors associated with TPT non-completion. On one hand, protection was associated with a positive TST and the use of immunosuppressive treatment. On the other, being an young adult, use of INH regimens, being Black and brown/*pardo*, and living in the midwest region of the country were associated with a higher risk for TPT non-completion. Most of these characteristics are also the social determinants of TB.⁹

Our results indicate a TPT completion rate of 78.3%, which is relatively high when compared to other studies.^{8,10} The fact that the patients were followed up by health teams from a reference centre for the care of patients with TB may have contributed to the high rate of completion. Another point to be highlighted is that the IT-TB system helps in monitoring patients undergoing TPT; as notifications are made at treatment initiation and the database

updated during follow-up, it is possible to actively search for those who are lost to follow-up. To note, the national recommendation is for follow-up medical consultations to take place at a maximum interval of 60 days.⁶ We emphasise that, in Brazil, notification to this system is not mandatory, which may have led to underreporting of cases. However, we believe that this affect our results, as notifications were distributed throughout the country.⁷

Individuals in situations of social and economic vulnerability were more likely to become infected with *Mycobacterium tuberculosis* and to LTFU from TB treatment and TPT. As observed in studies with individuals undergoing TB treatment, we believe that the guarantee of social support and economic security for individuals undergoing TBI treatment can ensure adherence to treatment.^{11–13}

We found out that Black and brown/pardo patients had the highest risk of TPT non-completion. A prospective study carried out in Brazil that evaluated TPT LTFU corroborates our results as it found that people of colour were 71 times more likely to be lost to follow-up.^{13,14} These findings can be explained by the fact that race is often a proxy marker for socio-economic status in Brazil. The more precarious living conditions of these populations, lower access to education, lower income and greater difficulty in accessing health services make them more likely to have TPT non-completion.^{13,14}

Better adherence to shorter RIF-based regimens is widely reported in the literature, both in clinical trials^{15–17} and in programmatic experience.^{18,19} Besides treatment duration, the frequency of adverse events and the number of pills to be ingested with INH may contribute to the increased LTFU.^{18–22} The introduction of short-term treatment regimens in Brazilian public health services will likely reduce TPT LTFU.

We found that individuals using immunosuppressive drugs and TST-positive individuals had lower risks of TPT non-completion. We believe that, in real-life conditions, individuals who are at higher risk of developing TB and who test positive are more likely to be followed up longitudinally by health professionals and may thus have greater adherence to treatment.^{23,24} Furthermore, we hypothesised that individuals known to have a positive test are more likely to adhere to treatment because they know they are infected.

This is the first study to assess TPT non-completion in Brazil at the national level using IL-TB data. The major strength of this analysis is the large population size and the inclusion of the majority of people initiating TPT in Brazil. The study has, however, some limitations. First, TPT reporting is not mandatory in Brazil. The definition of ‘completion’ may have been inconsistent, as it was registered by hundreds of different healthcare professionals across the country.

However, data were monitored and were subjected to a hierarchical sequence of data quality assessment. Finally, additional factors that may affect TPT completion, such as homelessness, income data, tobacco use, alcohol consumption, drug use and other comorbidities, were not available.

In conclusion, individuals in situations of social and financial vulnerability such as being Black, a young adult and on longer TPT regimens were more likely to be associated with TPT non-completion. Investing in social and health policies that minimise these vulnerabilities and the introduction of shorter TPT regimens are essential to reduce TPT LTFU.

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RÉSUMÉ

CONTEXTE : Parmi les initiatives brésiliennes visant à élargir la prise du TPT figurent l'adoption du schéma 3HP en 2021 et la mise en œuvre en 2018 du système de surveillance des données du TPT. Depuis, parmi les 76 000 cas de patients sous TPT notifiés, 63% ont achevé leur traitement. Les schémas recommandés étaient alors les 6H, 9H et 4R.

OBJECTIF : Analyser les facteurs associés au non-achèvement du TPT.

MÉTHODES : Nous avons analysé la cohorte des notifications de patients sous TPT de 2018 à 2020. Un modèle de régression de Poisson à variance robuste a été utilisé pour vérifier l'association entre le non-achèvement du TPT et les variables sociodémographiques, cliniques et épidémiologiques.

RÉSULTATS : Sur 39 973 cas de patients sous TPT notifiés pendant la période de l'étude, 8 534 (21,5%) n'ont pas achevé leur traitement, dont 7 858 (92.1%) ont été perdus de vue. Être âgé entre 15 et 60 ans (risque relatif [RR] 1,27 ; 95% CI 1,20–1,35), prendre un TPT à base d'isoniazide (RR 1,40 ; 1,19–1,64) et être noir ou métisse (RR 1,17 ; 1,09–1,25) étaient associés à un risque plus élevé de non-achèvement du TPT.

CONCLUSION : Les personnes vulnérables sur le plan social et financier (telles que les personnes noires ou appartenant au groupe ethnique *pardo*, et les jeunes adultes) et les personnes sous schéma TPT plus long étaient davantage susceptibles de ne pas achever le TPT.

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