

Tuberculosis incidence among contacts of active pulmonary tuberculosis

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SUMMARY

BACKGROUND: Treatment of latent tuberculosis (TB) infection (LTBI) in Brazil is recommended only in the case of contacts of pulmonary smear-positive TB patients aged ≤ 15 years with a tuberculin skin test (TST) ≥ 10 mm and no previous bacille Calmette-Guérin (BCG) vaccination or with a TST ≥ 15 mm regardless of previous BCG vaccination.

OBJECTIVE: To evaluate the 2-year incidence and predictors of TB among contacts who did not meet the Brazilian criteria for LTBI treatment.

DESIGN: Retrospective cohort study. Contacts aged between 12 and 15 years and those aged >15 years who did not meet the Brazilian criteria for LTBI treatment were enrolled in the study.

RESULTS: TB incidence was 3.2% (22/667), with an estimated TB rate of 1649 per 100 000 population. Risk of TB was greater among the 349 contacts with TST ≥ 5 mm (5.4%) compared to the 318 contacts with TST < 5 mm (0.9%; RR 6.04, 95% CI 1.7–20.6).

CONCLUSION: The high incidence of TB among contacts who did not meet the Brazilian criteria for LTBI treatment strongly suggests that these criteria should be reviewed. Furthermore, even among BCG-vaccinated contacts, TST induration ≥ 5 mm was the only variable that predicted the development of TB disease within 2 years.

KEY WORDS: pulmonary tuberculosis; LTBI; tuberculin test

THE EVALUATION and treatment of individuals at greatest risk for developing active pulmonary tuberculosis (TB) is an essential component of TB control programmes in countries with low TB incidence rates, a term used when the incidence of all forms of active TB is below 10 per 100 000 population.^{1–3} In these settings, contacts of active pulmonary TB cases presenting with a tuberculin skin test (TST) reaction of ≥ 5 mm are treated with 6–9 months of isoniazid (INH) for latent TB infection (LTBI). Only contacts who would be recommended to receive treatment for LTBI are to be tested.^{1,2} In high-incidence TB settings (≥ 100 cases/100 000), however, contact evaluations are not a priority of TB control programmes, where the maximum effort is devoted to the detection and treatment of individuals with active TB.^{2,3}

The overall burden of TB cases in Brazil was estimated at 95 000 in 2006, the highest in Latin America and the fifteenth worldwide.⁴ Overall TB incidence in 2006 was 50/100 000. Approximately 10 000 new TB cases are reported annually to the City of Rio de Janeiro Health Secretariat, for an incidence of 175 cases/100 000.⁵ In 2005, Rio de Janeiro state showed the

highest TB incidence in Brazil (80.5/100 000), with 12 384 new cases.⁶ The incidence rate of the jurisdiction in which the study was conducted ranged from 119.7/100 000 in 2000 to 97.5/100 000 in 2003.⁵

The Brazilian National TB Programme (NTP) recommends investigating only childhood household contacts (aged ≤ 15 years) of pulmonary smear-positive TB index patients. The routine evaluation of asymptomatic human immunodeficiency virus (HIV) seronegative/unknown contacts includes a TST and follow-up chest X-ray (CXR) if the TST induration is ≥ 10 mm with no previous bacille Calmette-Guérin (BCG) vaccination or if the TST is ≥ 15 mm with previous BCG vaccination.⁵ For those contacts with a positive TST and normal CXR, preventive treatment with daily INH for 6 months is recommended. Asymptomatic contacts aged ≤ 15 years with a negative or unknown TST are advised to return to the Health Unit if respiratory symptoms develop. All symptomatic contacts are investigated for TB diagnosis through CXR and sputum smear. HIV-infected contacts are referred to the AIDS Clinic of the hospital and receive specific evaluation and treatment.⁵

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The aim of this study was to evaluate the 2-year incidence and predictors of pulmonary TB disease among contacts of active pulmonary TB cases who did not receive treatment for LTBI as they did not meet the Brazilian government's criteria for LTBI treatment.

METHODS

We performed a retrospective cohort study at the Institute of Thoracic Diseases (ITD) of the Federal University of Rio de Janeiro (FURJ), located at the Clementino Fraga Filho University Hospital (CFFUH) in Brazil.

Contact evaluation

The contact evaluation in our hospital differs slightly from the Brazilian government's recommendations. In our setting, the Hospital TB Programme staff attempt to evaluate all contacts aged ≥ 12 years of confirmed pulmonary TB cases. The hospital where the study was conducted cares only for adults (defined as subjects aged ≥ 12 years). Patients and contacts aged < 12 years are referred to another hospital, where children are treated.

During the study period, a source TB case was defined as an individual with respiratory symptoms and positive sputum culture for *Mycobacterium tuberculosis*, and contacts were defined as those who have shared ≥ 100 h in a closed space with a pulmonary TB source case during the infectious period. Household contact was defined as living in the same house with the source case. Contacts were interviewed, screened for respiratory symptoms and underwent a CXR.

After ruling out past and current TB and past *M. tuberculosis* infection, contacts underwent a TST. Contacts with a TST induration ≤ 10 mm were asked to return for a second TST 8–12 weeks after the first TST. An increase of ≥ 10 mm in the second TST was classified as a TST conversion.

Treatment with INH was recommended for TST converters and for those contacts who fulfilled the Brazilian criteria for LTBI treatment, as previously described.⁵ Contacts who did not meet Brazilian criteria for LTBI treatment were advised to return to the hospital to be evaluated 1 and 2 years later or whenever respiratory symptoms developed.

All subjects with respiratory symptoms underwent a physical examination, had a CXR performed and were instructed to provide three unsupervised sputum specimens for smear and culture testing. Subjects with abnormal CXRs who were unable to provide a spontaneous sputum specimen underwent sputum induction with hypertonic saline solution. HIV serology was not offered to contacts as routine procedure but only to those diagnosed with pulmonary active TB during the follow-up evaluation. For initial treatment of active TB in persons without prior TB treatment, the NTP in Brazil recommends the standard regimen

of rifampicin (RMP, R) and INH (H) for 6 months, plus pyrazinamide (Z, PZA) during the first 2 months (2RHZ/4RH) for both HIV-seropositive and HIV-seronegative subjects.

Subject selection and definitions

The names of contacts of all TB source cases diagnosed between 1 July 2000 and 31 December 2002 were obtained from the TB Control Programme registry. We retrospectively evaluated the smear and culture results of index cases at the TB laboratory registry and the charts of their contacts. Contacts who did not return to the hospital for the 24-month evaluation were interviewed by a member of the research team through home visit or phone call to determine if TB had been diagnosed. Included in this study were contacts who did not receive treatment for LTBI regardless of age or TST status. Contacts were excluded from the study if they had active TB at the beginning of the study, if the chart was not available for review, if the TST results were not recorded in the chart, or if the contact was lost to follow-up 2 years after the first TST and was therefore not interviewed by a member of the team.

We defined subjects as not infected (TST < 5 mm) or infected (TST ≥ 5 mm). A TB diagnosis was defined when: 1) TB diagnosis and drug regimen were described in the chart, or 2) the patient reported the diagnosis and described the anti-tuberculosis standard drug regimen during the interview conducted by the research team member.

Statistical analysis

The results were analysed using SPSS programme version 11.0 (SPSS Inc, Chicago, IL, USA). The outcome variable was TB diagnosis and we calculated the proportion of TB cases within 24 months following the first TST among infected and non-infected contacts. χ^2 tests and Fisher's exact were used to analyse dichotomous variables. The relative risk (RR) of TB in non-infected and infected subjects was calculated.

The Ethics Committee of the CFFUH/FURJ approved this study in September 2005.

RESULTS

Between July 2000 and December 2002, 276 culture-positive active pulmonary TB patients were diagnosed and 1178 contacts (mean 4.2 contacts per index case) attended the hospital to be evaluated. The flowchart of screened contacts, including losses to follow-up, is shown in the Figure. One hundred and eighty contacts were excluded and 998 had a TST at baseline. Of these, 431 (43%) were positive and 567 (57%) were negative. Twenty-nine (6%) converted their TST on retesting. Of 460 patients with LTBI, 111 were lost to follow-up, as were 129 of 447 non-infected contacts. Among the 667 contacts enrolled in the study with available TST results and known TB outcome

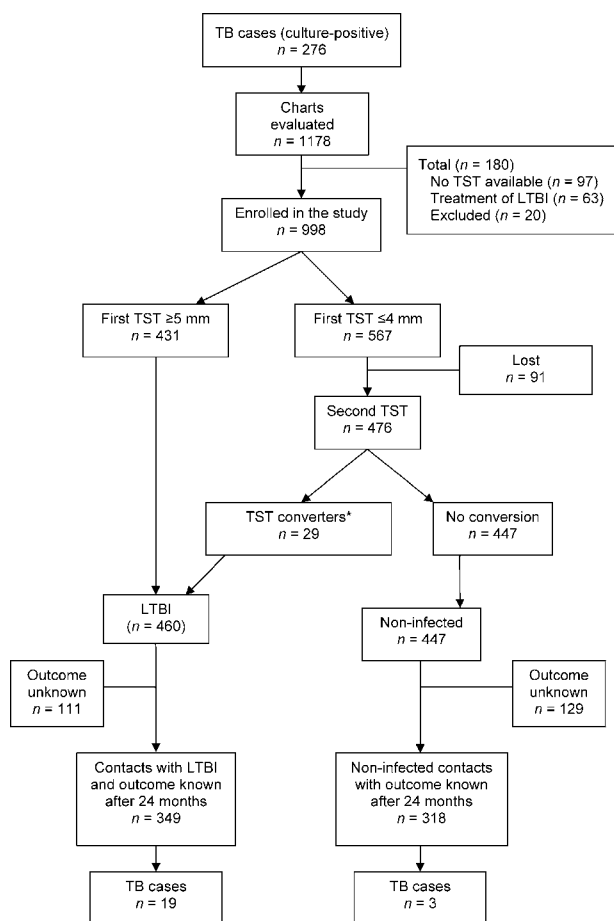


Figure Flowchart of contacts evaluated. *Contacts who did not accept treatment for LTBI despite TST conversion. TST = tuberculin skin test; TB = tuberculosis; LTBI = latent tuberculosis infection.

within 24 months, 22 (3.2%) were diagnosed with TB, with an estimated TB rate of 1649/100 000.

HIV serostatus was known for 208/276 (75%) source cases: 148 (71%) had a negative result and 20 (10%) were positive. As shown in Table 1, TST positivity was similar among contacts of HIV-positive and -negative TB source cases. HIV test results were available for 40% (9/22) of contacts who developed TB: one case was positive. The characteristics of the 667 contacts stratified by TST status are presented in Table 1. The median age among infected contacts was higher than among non-infected contacts (35 vs. 23 years, $P = 0.001$).

During follow-up, 22 individuals developed active TB, 19 of whom had a positive TST and three were TST-negative. Table 2 shows that the risk of TB was significantly higher among 349 contacts with TST ≥ 5 mm (5.4%) compared to the 318 contacts with TST < 5 mm (0.9%, RR 6.04, 95% confidence interval [CI] 1.7–20.6). The estimated yearly TB cumulative incidence among contacts with LTBI was 2722/100 000; among non-infected contacts it was 472/100 000. The size of the TST reaction did not predict TB risk (Table 2). When further stratified, there was

Table 1 Characteristics of 667 contacts enrolled in the study with available tuberculin skin test results and known tuberculosis outcome

Contact characteristic	Non-infected contacts (n = 318) n/N (%)	Contacts with LTBI (n = 349) n/N (%)	P value
Sex			
Male	122 (38)	133 (38)	1.00
Female	196 (62)	216 (62)	
BCG vaccination*			
Yes	216 (70)	227 (67)	0.4
No	94 (30)	113 (33)	
Median age, years [IQR]	23 [11–45]	35 [18–49]	0.001
Age, years			
12–15	113/318 (35)	60/349 (17)	0.001
≥ 16	205/318 (64)	289/349 (83)	
Household contact [†]			
Yes	252/315 (80)	284/347 (82)	0.6
No	63/315 (20)	63/347 (18)	
Smear-positive source			
Yes	224/318 (70)	266/349 (76)	0.1
No	94/318 (30)	83/349 (34)	
HIV-positive source case [‡]			
Yes	57/280 (20)	53/310 (17)	0.3
No	223/280 (80)	257/310 (83)	
Presence of comorbidities [§]			
Yes	50/308 (16)	74/338 (22)	0.07
No	259/308 (84)	263/338 (78)	

* BCG status of 17 contacts not available.

[†] Contact who lives in the same house as the source case. Exposure of contact (household or otherwise) not available for five contacts.

[‡] HIV status of 20 index cases not available.

[§] Includes diabetes mellitus, silicosis, liver disease, alcohol abuse, tobacco smoke. Comorbidities of 21 contacts not available.

LTBI = latent tuberculosis infection; BCG = bacille Calmette-Guérin; IQR = interquartile range; HIV = human immunodeficiency virus.

no difference in proportion with TB among infected patients with indurations of 5–9 mm (5.2%) compared to those with indurations of ≥ 10 mm (5.9%).

TST induration ≥ 5 mm was the only variable that predicted the development of TB disease within 2 years among contacts (Table 3). There was no significant association between the smear status of the source case and household contact status.

DISCUSSION

Forty-six per cent of contacts of TB cases enrolled in our study were classified as infected with *M. tuberculosis*.

Table 2 Incidence of tuberculosis within 2 years among 667 contacts

TST result	TB diagnosis (n = 22) n/N (%)	RR (95%CI)
TST 0–4 mm (n = 318)	3/315 (0.9)	Reference
TST ≥ 5 mm (n = 349)	19/330 (5.4)	6.0 (1.7–20.6)
TST 5–9 mm (n = 80)	4/76 (5)	Reference
TST ≥ 10 mm (n = 269)	15/254 (5.6)	1.1 (0.3–3.4)

TST = tuberculin skin test; TB = tuberculosis; RR = relative risk; CI = confidence interval.

Table 3 Possible predictive variables and the outcome 'active tuberculosis disease within 2 years'

Characteristic	No TB (n = 645) n/N (%)	TB (n = 22) n/N (%)	P value
Reactive TST (≥ 5 mm)	330/645 (51)	19/22 (86)	0.002
Male sex	248/645 (38)	7/22 (32)	0.6
Age, years			
12–15	166/642 (26)	5/22 (23)	0.7
≥ 16	476/642 (74)	17/22 (77)	
Median age, years [Q1–Q3]*	29 [15–48]	22 [15–38.7]	0.3
BCG vaccination†			
Yes	429/629 (68)	14/21 (64)	1.0
No	200/629 (32)	7/21 (32)	
Household contact‡			
Yes	519/640 (81)	17/22 (77)	0.8
No	121/640 (19)	5/22 (23)	
Sputum of source case			
Smear-positive	471/645 (73)	19/22 (86)	0.2
Smear-negative	174/645 (27)	3/22 (14)	
Contacts of			
HIV-positive source-case§	105/573 (18)	5/17 (29)	0.4
HIV-negative source-case§	468/573 (82)	12/17 (71)	
Comorbidities¶			
Yes	122/628 (19)	2/18 (11)	0.5
No	506/628 (81)	16/18 (89)	

* Q1 = percentile 25%; Q3 = percentile 75%.

† BCG status of 17 contacts not available.

‡ Contact who lives in the same house as the source case. Exposure of contact (household or otherwise) not available for five contacts.

§ HIV status of 77 index cases not available.

¶ Includes diabetes mellitus, silicosis, liver disease, alcohol abuse, tobacco smoke. Comorbidities of 21 contacts not available.

TB = tuberculosis; TST = tuberculin skin test; BCG = bacille Calmette-Guérin; HIV = human immunodeficiency virus.

losis, and 19 (5.4%) of the 349 subjects with known outcome developed active TB within 2 years. TB rates were similar in those with TST reactions of 5–9 mm and ≥ 10 mm, suggesting that the 5 mm cut-off point for TST positivity in contacts is appropriate. None of the patients received treatment for LTBI because they did not meet the Brazilian criteria for LTBI treatment or because they refused to be treated (29 contacts with TST conversion).

The rate of 5.4% active TB disease within 2 years among contacts is similar to that found in the literature, and underscores the importance of preventive treatment for infected contacts.^{1–3,7–12} In settings with high TB prevalence, this rate might have a strong impact on the absolute number of new TB cases.

In our control group of non-infected contacts, the rate of TB was only 0.9%, while the incidence of disease was six times higher among infected contacts. This strongly suggests that TB cases among infected contacts are related to their index cases. Our findings are consistent with previous reports demonstrating that the risk for developing active TB among subjects recently infected by the *M. tuberculosis* in the first year of follow-up is eight times higher than in subsequent years and that 82% of TB cases developed active disease within 2 years of infection.^{2,13}

The Brazilian NTP recommends investigation and treatment of LTBI among childhood contacts (aged ≤ 15 years) of smear-positive active pulmonary TB. The decision to focus on this specific age group is based on the considerably increased incidence of TB in infants and adolescents infected by *M. tuberculosis*.¹⁴ In our study, the median age of the infected contacts (35 years, range 18–49) was higher than that of the non-infected contacts (23 years, range 11–45, $P = 0.001$). Furthermore, 77% (17/22) of the contacts who developed active pulmonary TB within 2 years were aged > 15 years (median 22 years). Sixty-seven per cent of the pulmonary TB patients notified to the TB Programme of Rio de Janeiro City during 2003 were aged between 20 and 49 years, corresponding to the age range of 75% of TB cases (15–54 years) according to the World Health Organization.^{15,16} Only contacts aged ≥ 12 years were evaluated by the TB Control Programme of the ITD/CFFUH during the study period; it is therefore not possible to make any inferences about the risk of developing TB in infants in this study. However, our findings clearly show the higher risk for developing active TB among contacts aged > 15 years within 2 years after presumed infection by *M. tuberculosis*; this group of individuals should therefore not be excluded from contact tracing.

The only variable significantly associated with the development of active TB among contacts was LTBI defined by a TST induration of ≥ 5 mm. The TST induration cut-off point to define the presence of *M. tuberculosis* infection depends on many factors and is strongly influenced by the prevalence of infection in the clinical context studied. Although the Brazilian NTP recommends LTBI treatment for contacts aged ≤ 15 years with TST ≥ 10 mm (no history of BCG vaccination) or TST ≥ 15 mm (past history of BCG vaccination), the American Thoracic Society (ATS) has recommended treatment for contacts with TST induration ≥ 5 mm since 1974.¹⁷ The ATS recommendation is based on the fact that as the prevalence of *M. tuberculosis* infection is presumably higher among contacts of pulmonary TB cases, the reduction of the cut-off point increases the sensitivity of the TST and consequently its positive predictive value.¹⁸ Our findings support that even in a setting with a high prevalence of TB, using a TST induration cut-off point of 5 mm to define LTBI among contacts of infectious TB for preventive treatment could prevent a significant number of new active TB cases, with no significant increase in the number of contacts evaluated.

The present study has some limitations, including losses to follow-up and missing TST results due to the retrospective design of the study, and unknown HIV status for 60% of the contacts who developed TB. Furthermore, we did not have data on the timing of TB disease among contacts, but rather a yes/no response with regard to TB within 2 years, such that the actual timing within the 2-year interval cannot be determined.

Despite these limitations, these data provide important information on the impact of LTBI treatment among infected adults on TB control.

CONCLUSIONS

This study suggests that the risk of developing active TB is 30 times higher among contacts of active TB than among the general population of Rio de Janeiro, Brazil and that a TST induration of ≥ 5 mm was the only variable that predicted the development of TB disease within 2 years among contacts. Current guidelines in Brazil state that childhood household contacts (aged ≤ 15 years) of smear-positive active pulmonary TB should be screened for LTBI. However, our findings suggest that a significant number of new TB cases might be prevented if all contacts of confirmed pulmonary TB cases, independently of age and of the smear status of the index case, are tested and treated for LTBI.

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RÉSUMÉ

CADRE : Au Brésil, le traitement de l'infection tuberculeuse latente (LTBI) est recommandé uniquement pour les sujets âgés de ≤ 15 ans au contact de patients tuberculeux (TB) pulmonaires à bacilloscopie positive dont le test cutané à la tuberculine (TST) est ≥ 10 mm et qui n'ont pas eu de vaccination bacille Calmette-Guérin (BCG) antérieure ou dont le test est ≥ 15 mm qu'il y ait eu ou non vaccination BCG antérieure.

OBJECTIF : Evaluer l'incidence de la TB à 2 ans et ses facteurs prédictifs chez les contacts qui ne répondaient pas aux critères brésiliens de traitement de la LTBI.

SCHÉMA : Etude rétrospective de cohorte. Les sujets-contact d'un âge de 12 à 15 ans et ceux âgés de > 15 ans qui ne répondaient pas aux critères brésiliens du traitement de la LTBI ont été enrôlés dans l'étude.

RÉSULTATS : L'incidence de la TB a été de 3,2% (22/667) avec un taux estimé de TB de 1649/100 000. Le risque de TB est plus élevé parmi les 349 contacts dont le TST est ≥ 5 mm (5,4%) par comparaison avec les 318 contacts dont le TST est < 5 mm (0,9% ; RR 6,04 ; IC95% 1,7–20,6).

CONCLUSION : L'incidence élevée de la TB parmi les contacts ne répondant pas aux critères brésiliens de traitement de la LTBI suggère fortement que ces critères devraient être révisés. De plus, même chez les contacts vaccinés par le BCG, une induration du TST ≥ 5 mm est la seule variable prédictive du développement d'une maladie TB dans les 2 années à venir.

RESUMEN

MARCO DE REFERENCIA : El tratamiento de la infección tuberculosa latente (LTBI) de los contactos de casos de tuberculosis (TB) pulmonar bacilífera se recomienda en Brasil únicamente a los contactos hasta la edad de 15 años y que presentan una reacción tuberculínica (TST) de ≥ 10 mm, sin antecedente de vacunación antituberculosa (BCG) o aquellos con una reacción de ≥ 15 mm, independientemente del antecedente de vacunación.

OBJETIVOS : Evaluar la incidencia a 2 años y los factores de predicción de enfermedad tuberculosa en los contactos que no cumplen con los criterios de tratamiento de la LTBI aplicados en Brasil.

MÉTODOS : Fue este un estudio retrospectivo de cohortes de contactos entre los 12 y los 15 años de edad y de contactos > 15 años que no cumplían con los criterios del tratamiento de la LTBI vigentes en Brasil.

RESULTADOS : La incidencia de TB fue 3,2% (22/667), con una tasa de TB calculada de 1649 por 100 000. El riesgo de TB fue mayor en los 349 contactos con una reacción tuberculínica ≥ 5 mm (5,4%), comparado con el riesgo de los 318 contactos con reacciones cutáneas < 5 mm (0,9% ; riesgo relativo 6,04 ; IC95% 1,7–20,6).

CONCLUSIÓN : La alta incidencia de TB en los contactos que no cumplen con los criterios brasileños de tratamiento de la LTBI indica claramente la necesidad de revisar dichos criterios. Además, en los contactos vacunados con el BCG, una induración tuberculínica de ≥ 5 mm fue la única variable que permitió predecir la aparición de enfermedad tuberculosa en los siguientes 2 años.
