

Cost-effectiveness of tuberculosis screening and isoniazid treatment in the TB/HIV in Rio (THRio) Study

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SUMMARY

OBJECTIVE: To estimate the incremental cost-effectiveness of tuberculosis (TB) screening and isoniazid preventive therapy (IPT) among human immunodeficiency virus (HIV) infected adults in Rio de Janeiro, Brazil.

DESIGN: We used decision analysis, populated by data from a cluster-randomized trial, to project the costs (in 2010 USD) and effectiveness (in disability-adjusted life years [DALYs] averted) of training health care workers to implement the tuberculin skin test (TST), followed by IPT for TST-positive patients with no evidence of active TB. This intervention was compared to a baseline of usual care. We used time horizons of 1 year for the intervention and 20 years for disease outcomes, with all

future DALYs and medical costs discounted at 3% per year.

RESULTS: Providing this intervention to 100 people would avert 1.14 discounted DALYs (1.57 undiscounted DALYs). The median estimated incremental cost-effectiveness ratio was \$2273 (IQR \$1779–\$3135) per DALY averted, less than Brazil's 2010 per capita gross domestic product (GDP) of \$11 700. Results were most sensitive to the cost of providing the training.

CONCLUSION: Training health care workers to screen HIV-infected adults with TST and provide IPT to those with latent tuberculous infection can be considered cost-effective relative to the Brazilian GDP per capita.

KEY WORDS: Brazil; TB-HIV co-infection; economic analysis; IPT; skin tests

DESPITE the World Health Organization (WHO) recommendations for isoniazid preventive therapy (IPT) for human immunodeficiency virus (HIV) infected patients,¹ and recent evidence that IPT reduces tuberculosis (TB) incidence among persons living with HIV/AIDS (acquired immune-deficiency syndrome),^{2–4} few countries have prioritized IPT in their HIV strategy.⁵ HIV and TB programs are rarely integrated; the responsibility for IPT implementation and associated costs is thus a complicated issue that should be considered before implementing preventive therapy.

In Brazil, TB remains an important public health problem, and 14% of new adult TB patients in Brazil are also estimated to be HIV-infected.⁶ The tuberculin skin test (TST) and IPT for those testing positive have been recommended for persons living with HIV/AIDS in Brazil since 1995, but few HIV-infected patients

had been tested before 2005. The Tuberculosis/HIV in Rio de Janeiro (THRio) study was conducted between 2005 and 2009, providing TST and IPT to HIV-infected patients in 29 clinics. The study showed that it is possible to markedly increase the number of patients receiving TST and IPT in this setting, and that this increase can reduce TB incidence and mortality.^{3,7} The impact of THRio on TB incidence may not be able to be generalized to other settings where there are higher rates of transmission, such as South African gold mines, where TST and IPT were not able to reduce TB disease rates.⁸

If the THRio intervention is to be scaled up in Brazil, or implemented in a similar setting, a better understanding of the resources allocated and the cost-effectiveness of the intervention is necessary. The costs of such a program include training staff, reorganizing clinic services as well as paying addi-

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Table 1 Effectiveness outcomes of training to provide tuberculin skin test and isoniazid preventive therapy in 100 HIV-infected patients

Items	TB deaths	TB cases	DALYs lost by 100 people over 20 years	Discounted lost DALYs
Without intervention	1.3	11.5	822	582
With intervention	1.1	10.0	821	581
Incremental	0.1	1.5	1.6	1.1
Incremental with discounting			1.1	

HIV = human immunodeficiency virus; TB = tuberculosis; DALY = disability-adjusted life-years.

tional costs for the medical care associated with administering TST and IPT. This report analyzes the costs, impact on disability-adjusted life years (DALYs) and cost-effectiveness of the THRio study.

METHODS

Study design, intervention, and population

We used decision analysis with Markov methods to compare costs and health outcomes (i.e., DALYs) at public clinics in Rio de Janeiro, RJ, Brazil. Our primary outcome was the incremental cost-effectiveness ratio (ICER), comparing facilities exposed to a program designed to increase the rate of TST and IPT delivery among HIV patients in Rio de Janeiro to a baseline of similar facilities not exposed to this program. We expressed the outcome as the cost in 2010 US dollars (USD) per DALY averted among adults treated at exposed and non-exposed facilities. Data to populate the model were drawn from the THRio study, the design and primary results of which have been described elsewhere.³ Briefly, the THRio study was a cluster-randomized trial in which 29 public HIV clinics were randomly assigned, in stepped-wedge fashion, dates on which to receive training in using TST and IPT. Health care workers receiving the intervention were trained on the proper use of TST and to provide IPT to eligible individuals with a positive TST and no evidence of active TB. Eligible patients were those with no history of previous TB or receipt of IPT; active TB was ruled out by sputum smear and chest X-ray (CXR), according to Brazilian guidelines, in all individuals with a positive TST (≥ 5 mm induration) before receiving IPT (6 months of isoniazid 300 mg and pyridoxine 25 mg daily).⁹ Prescriptions were refilled every 30 or 90 days, depending on the clinic.⁹ Patients were followed to primary endpoints of incident TB or death from any cause. The median size of the training sessions in each clinic required 4 physicians, 5 nurses and 4 health assistants, with a total average of 30 person-hours required per clinic.

We projected costs and outcomes for 100 eligible patients (i.e., no evidence of active TB on presentation) receiving the THRio intervention vs. usual care. We considered all activities related to the intervention

over a time horizon of 1 year, and followed patients for outcomes (i.e., TB cases and deaths) for a time horizon of 20 years. The incidence of TB and the protective effect of IPT were taken from the THRio trial.³ We assumed that the effect of IPT would last at least 20 years in this population, the majority of whom were on antiretroviral therapy (ART) and at low annual risk of TB re-infection. We conservatively assumed that the only effect of IPT would be through a reduction in TB incidence (i.e., no ancillary benefits on mortality beyond a reduction in strictly measured incident TB cases). We thus adopted as our primary measure of effect the reduction in TB incidence alone; this conservative assumption provides the estimate of cost-effectiveness that is least favorable to IPT. In a sensitivity analysis, we considered the more liberal assumption that IPT had wider benefits on both TB incidence and mortality, as seen in the THRio trial.

Cost calculation

Costs were calculated using an ingredients approach, as shown in the top panel of Table 1. We adopted the perspective of the medical sector as the primary party responsible for financing this intervention. We used actual program costs reflecting local market prices and wages.^{10,11} We surveyed the trainers responsible for implementing the program at each of the 29 clinics to determine the job titles and salaries of clinic attendees who had to cancel their clinical operations to attend training. The survey also included information on logistics required to conduct each training session. Unit cost estimates were derived from personnel payrolls, financial records and consultations with staff. All costs are reported in 2010 USD. Cost data from other years in Brazilian Reals were inflated to 2010 using the Brazilian inflation rate, and then converted to USD using the 2010 exchange rate. Medical care costs were confined to the costs of treating TB cases. Some would argue that the incremental medical costs of antiretrovirals for TB patients whose lives are saved should have been included as well. Including these costs would make the intervention more costly per DALY averted. We discounted future costs and effectiveness outcomes at 3% per year.

Table 2 Static version of cost-effectiveness modeling per 100 patients over 20 years; costs as of 2010

Cost model	Items	Price per unit 2010 US\$	Number needed for 100 patients	Total cost US\$
	PPD costs (includes patient waiting time)	28.12	58	1 631
	IPT			
	Sputum AFB	28.12	58	1 631
	Chest X-ray	39.43	7	276
	INH	30.85	7	216
	Clinic start up	6 654.54	0.22	1464
Minimum cost per 100 patients followed for 20 years				
	Items	Price per unit	Intervention	Without intervention
	Training cost (0.22 training courses)	6 655	1 464	0
	TST cost (58 TSTs)	28	1 631	0
	IPT cost (7 IPTs)	91	640	0
	Anti-tuberculosis treatment cost	653	523	601
	Total		10 248	7 477
	Total discounted		8 992	6 034
ICER in 100 patients followed for 20 years				
	Items	Discounted DALYS	Minimum discounted costs US\$	ICER (ΔUS\$/ΔDALY)
	Without intervention	582.02	6 034	
	With intervention	580.88	8 992	
	Difference	1.14	2 958	
	Difference per patient	0.0114	29.58	
	ICER			2 594

PPD = purified protein derivative; IPT = INH preventive therapy; AFB = acid-fast bacilli; INH = isoniazid; TST = tuberculin skin test; ICER = incremental cost-effectiveness ratio; DALY = disability-adjusted life-year.

Effectiveness calculation

Mortality outcomes have been estimated and published based on study data collected from September 2005 to August 2009.³ We computed years of life lost per TB death relative to the average survival of HIV-infected, non-TB-infected patients in the THRio trial. To estimate the disability weight for TB-HIV-coinfected individuals in Brazil, we used data drawn from 98 of the patients in this trial who reported on their disability using a visual analog scale.¹² This survey supported our estimate of disability weights of respectively 72.78, 74.09 and 77.4 among TB-HIV-coinfected, TB-infected and HIV-infected individuals.¹² We assumed that the state of TB-HIV disability lasted for 1 year before reverting to the disability state of chronic stable HIV.

Sensitivity and uncertainty analysis

We conducted both one-way sensitivity analyses on selected model parameters and a probabilistic Monte Carlo uncertainty analysis in which we varied the hazard ratio (HR) of TB death associated with the intervention among all eligible patients (i.e., regardless of TST or IPT status) from a low of 0.7 to a high of 0.97, using a point estimate HR for TB disease in the THRio trial of 0.87 and a normal distribution. The probabilistic sensitivity analysis also varied the cost using a log normal distribution with the minimum costs shown in Table 2. This is another conservative assumption that gives extra consider-

ation to the possibility that future costs will be higher than those observed in the study. The probabilistic analysis was programmed in @Risk™ (Palisade Corp, Ithaca, NY, USA) and generated distributions around costs, DALYs and the incremental cost-effectiveness ratio. We summarize this uncertainty range using median and interquartile ranges (IQRs).

Ethics

This study was approved by the institutional review boards of the Johns Hopkins Medical Institutions, Baltimore, MD, USA, and the Municipal Health Secretariat of Rio de Janeiro, Rio de Janeiro, RJ, Brazil.

RESULTS

Cost and cost-effectiveness

To carry out the intervention for 100 patients, we estimated a requirement of 0.22 clinic trainings, 58 TSTs placed, and 7 courses of IPT delivered. The cost of carrying out the training intervention was \$6655 per clinic (454 patients). The cost per 100 patients was calculated as follows: $100/454 = 0.22$, and $[(0.22) \times \$6655] = \1464 per 100 patients. The median discounted cost including intervention implementation, diagnosis, follow-up and treatment in 100 patients followed for 20 years was \$9748 (IQR \$9530–\$10 078) with the intervention and \$6461 (IQR \$6278–\$6783) in the baseline condition; the

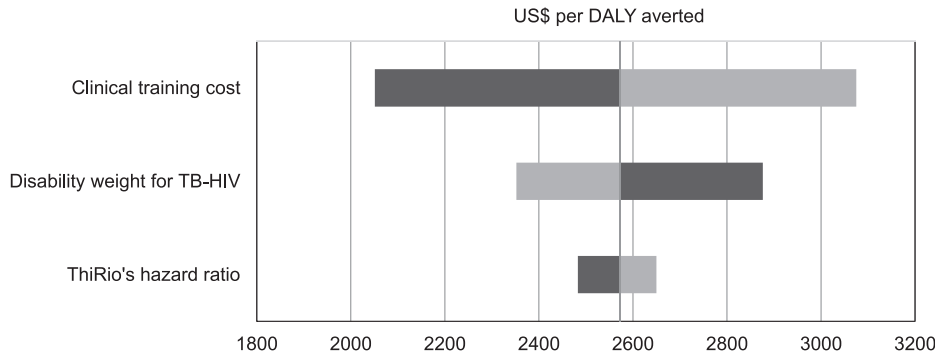


Figure Results of the sensitivity analysis on parameters used in the cost-effectiveness model. DALY = disability-adjusted life-year; TB = tuberculosis; HIV = human immunodeficiency virus.

median of the cost differences across 10 000 iterations was \$3208 (IQR \$3108–\$3355), or \$32.08 per patient.

Intervention effects

The results of the impact evaluation of the trial are available elsewhere.³ Key values derived from the trial include a crude HR for incident active TB (comparing the intervention to no intervention) of 0.87 and 58% TST coverage among the eligible population, of whom 20% tested positive, with 82% of TST-positive people receiving IPT. Crude rates of TB and TB or death, respectively, were 1.31 and 3.64/100 person-years (py) in the control population vs. 1.10 and 3.04/100 py in the intervention population. We projected that the THRio intervention would avert 0.17 TB deaths and 1.48 cases of active TB over a 20-year horizon (Table 1). These averted deaths and TB cases are estimated to account for 1.14 discounted DALYs averted in 100 people over 20 years. We estimate that 96% of the DALY burden averted is due to disability, with the remainder due to premature death. The bottom of Table 1 lists one estimate of the ICER, obtained by dividing the minimum cost by the mean estimate of discounted DALYs, at \$2594. The ICER estimate based on the median of 10 000 iterations of the Monte Carlo model was \$2273 per DALY averted (IQR \$1779–\$3135).

Sensitivity analysis

Among the parameters used in the model, those most likely to affect the results were chosen for univariate sensitivity analysis. We chose to examine the efficacy of the intervention because all estimates of benefit hinge on it. Similarly, the disability weight on TB-HIV could have a large impact, as 96% of the DALY burden is from disability. Among the cost parameters, as training costs accounted for approximately 22% of the total cost of the intervention, we varied that as well. The results of two-way sensitivity analysis (Figure) show that the cost-effectiveness of the intervention was robust to variations in the efficacy

of IPT, cost of clinical training and disability weight for TB-HIV. If the disability weight for TB-HIV was 10 points worse than HIV, it would make the intervention appear more cost-effective and would lower the ICER to \$2352 per DALY averted. Other factors associated with variation in the cost-effectiveness ratio included the cost of start-up clinics.

DISCUSSION

This decision model, based on data from a pragmatic cluster-randomized trial, suggests that training to perform TST and deliver IPT to HIV-infected adults is likely to be cost-effective in medium-burden, middle-income settings. For every 100 individuals exposed to this intervention, we project that 1.5 cases and 0.2 TB deaths could be averted, at a median cost of \$2273 (IQR \$1779–\$3135) per DALY averted. Thus, although the gains from this feasible intervention may be relatively small in absolute terms, they are likely to present good ‘value for money’ in comparison with other health interventions that may be available in middle-income settings such as urban Brazil. The incremental cost per DALY averted for this intervention was less than one quarter of Brazil’s 2010 per capita gross domestic product (GDP) of \$11 700. This thus meets the criteria to be classified as highly cost-effective in the context of Brazil.

This is one of the first analyses to estimate the cost-effectiveness of preventive treatment for TB among HIV-infected individuals with an assumption of constant incidence of TB. Other analyses among non-HIV-infected low-prevalence populations suggest that IPT may also be cost-effective in selected settings.¹³ Relative to these studies, the ICER of providing IPT to HIV-infected adults in Brazil is somewhat more cost-effective. This supports current WHO guidelines to provide IPT to people living with HIV.¹⁴ Importantly, the THRio trial was designed to test a pragmatic intervention at the clinic level; this intervention remains cost-effective despite our effectiveness measures inherently accounting for program-

matic realities, including incomplete coverage (e.g., only 58% of eligible individuals receiving TST). If the intervention could be delivered at even higher coverage (e.g., through provision of nurses or other personnel to administer TSTs), its cost-effectiveness might be enhanced further. However, if IPT efficacy or TB incidence were lower, then the cost per DALY averted would be higher.

As with any modeling analysis, our study has important limitations. While we found that this intervention was cost-effective against the threshold of Brazil's GDP, it would not meet this same threshold in other lower-income countries unless its cost was proportional to GDP. Compared to many other TB interventions—even some considered to be very expensive (e.g., treatment of multidrug-resistant TB¹⁵)—this intervention is less cost-effective, although it may be more affordable due to its lower per-patient cost. Our findings—which assume long-term effectiveness of IPT—may not be able to be generalized to higher-burden settings where the long-term efficacy of 6 months of IPT is known to be lower.^{16,17}

The majority (67%) of the participants were on ART at the time of IPT initiation. Of those who were not, many (35%) started ART at some point after IPT initiation. Thus, our findings may not generalize to populations that are largely ART-naïve; however, many existing programs for IPT delivery are integrated with ART, as was the case here.

We took as our study population the population of THRio, which was largely ART-exposed at the time of IPT initiation. Providing IPT to a population with little ART exposure may augment the impact of IPT (e.g., if TB risk is higher as a result), but it is more likely that ART and IPT have synergistic effects.¹⁸ Epidemiological models of the Brazilian HIV-infected population estimated an annual risk of infection of 0.8% per year, which was consistent with observed TB incidence in this population.¹⁹

Finally, the costs and effectiveness of this intervention as measured in urban Brazil may not be reflective of those in rural settings, or in areas with lower ART coverage or general public health infrastructure; also, our estimates of cost-effectiveness may overestimate the benefit of IPT, to the extent that TST-positive individuals may have living conditions that put them at greater risk of reinfection. In summary, this decision analysis suggests that an intervention aimed at training health care workers to provide TST-guided IPT to people accessing HIV care is likely to be cost-effective in urban Brazil settings. Further study is required to see if these findings can be generalized to higher-burden or lower-income settings. In the interim, these findings support existing guidelines to provide IPT in this population, suggesting that preventive therapy is not only effective but likely to provide good value for money as well.

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Conflict of interest: none declared.

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RESUME

OBJECTIF : Estimer le rapport coût-efficacité différentiel du dépistage de la tuberculose (TB) et du traitement préventif par isoniazide (IPT) chez les adultes infectés par le virus de l'immunodéficience humaine (VIH) à Rio de Janeiro, Brésil.

SCHEMA : Nous avons utilisé l'analyse de décision, grâce aux données d'un essai randomisé par groupes, afin de projeter les coûts (en dollars US de 2010) et l'efficacité (en années de vie ajustées à l'incapacité évitées [DALY]) de la formation des travailleurs de santé pour mettre en œuvre le test cutané à la tuberculine (TST) suivi par l'IPT pour les patients dont le TST s'est avéré positif sans signe de TB active. Cette intervention a été comparée au traitement de routine. Nous avons utilisé des échéances d'une année pour l'intervention et

de 20 années pour les résultats, avec tous les DALY et coûts médicaux futurs actualisés de 3% par an.

RÉSULTATS : Offrir cette intervention à 100 personnes éviterait 1,14 DALY actualisés (1,57 DALY non-actualisés). Le ratio coût-efficacité différentiel médian estimé était de \$2273 (IQR \$1779-\$3135) par DALY évitée, moins que le produit national brut (PNB) per capita du Brésil en 2010, soit \$11 700. Les résultats n'ont pas été sensibles au coût de la formation.

CONCLUSION : La formation du personnel de santé au dépistage des adultes infectés par le VIH par le TST et la fourniture d'IPT à ceux qui ont une infection tuberculeuse latente peut être considérée comme rentable relativement au PNB per capita du Brésil.

RESUMEN

OBJETIVO: Calcular la rentabilidad progresiva de la estrategia de detección sistemática de la tuberculosis (TB) y tratamiento preventivo con isoniazida (IPT) en los adultos infectados por el virus de la inmunodeficiencia humana (VIH) en Río de Janeiro, Brasil.

MÉTODO: Con el propósito de prever los costos (en USD en el 2010) y evaluar la eficacia (medida en años de vida ajustados en función de la discapacidad [DALY]) de la intervención se utilizó un análisis decisional alimentado con los datos de un ensayo clínico por conglomerados. La estrategia consistía en la capacitación de profesionales de salud en materia de aplicación de la prueba cutánea tuberculínica (TST), seguida del suministro del IPT a los pacientes con resultados positivos que no presentaban signos de TB activa. El resultado de esta intervención se comparó con la atención corriente como punto de referencia. Se aplicaron perspectivas temporales de 1 año de

intervención y 20 años de desenlaces de la enfermedad con una tasa de descuento de 3% anual de todos los DALY y los costos médicos futuros.

RESULTADOS: La ejecución de esta intervención en una población de 100 personas evitaría la pérdida de 1,14 DALY si se aplica la tasa de descuento (1,57 DALY sin descuento). La mediana del costo por cada DALY evitado fue 2273 USD (IQR 1779-3135); esta cifra es inferior al producto interno bruto (PIB) por habitante del Brasil que en el 2010 fue 11 700 USD. La mayor sensibilidad correspondió a los costos de prestación de la capacitación.

CONCLUSIÓN: La capacitación de los profesionales de salud en materia de detección sistemática de la TB en los adultos infectados por el VIH mediante la TST, aunada a la provisión de IPT a las personas con infección tuberculosa latente, se puede considerar como una intervención rentable con respecto al PIB por habitante del Brasil.
