

Cost-effectiveness of routine diagnostic evaluation of pulmonary tuberculosis in a primary care unit in Brazil

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SUMMARY

SETTING: Primary health care unit in Rio de Janeiro City, Brazil.

OBJECTIVE: To estimate and compare the cost-effectiveness of strategies used for passive case finding of pulmonary tuberculosis (PTB) cases using tests available at the primary care level.

DESIGN: Data on PTB suspects were reviewed, and a decision model was developed using sputum smear microscopy and chest radiography (CXR) according to three different strategies for PTB detection. A cost-effectiveness analysis was performed to estimate the cost per correct PTB diagnosis. Mycobacterial culture was used to calculate the effectiveness of the strategies. Unit costs of health resource utilisation were obtained from the payer's perspective (the Brazilian Public Health System).

RESULTS: For the evaluation of 254 PTB suspects, the

total costs of strategies ranged from US\$5369 to US\$5944; the probability of a correct PTB diagnosis ranged from 0.66 to 0.86; the number of visits required to complete the diagnostic process ranged from two to three, and cost per PTB case identified ranged from US\$47.93 to US\$53.07. The cost-effectiveness of the three strategies studied varied between US\$56.69 and US\$72.55 per correct PTB case detected.

CONCLUSION: A strategy in which sputum smears and CXR were requested for all PTB suspects at the initial evaluation was cost-effective, had a high probability of correct PTB diagnosis and could be accomplished in two visits.

KEY WORDS: passive case finding; chest radiography; sputum microscopy

TUBERCULOSIS (TB) remains a public health problem worldwide, and diagnosis remains a major challenge for TB control.¹ Culture and rapid molecular testing have been recommended for strengthening diagnostic techniques in the laboratories.^{1–3} However, sputum smear microscopy and chest radiography (CXR) remain the standard diagnostic tools used for the investigation of pulmonary TB (PTB) at the primary care level, especially in settings with limited resources such as Brazil.^{4,5}

While sputum smear microscopy lacks sensitivity, CXR may lead to over-diagnosis in a substantial proportion of PTB suspects, even when performed only in smear-negative patients.^{6–8} The World Health Organization (WHO) recommends using CXR exclusively for smear-negative PTB suspects, but the Brazilian TB guidelines do not restrict the use of CXR in PTB cases.^{4,5,9} Despite the widespread use of these methods, the best strategy for case detection—a strategy that would be able to detect the greatest number

of TB cases at the lowest relative cost—has rarely been studied.¹⁰

The aim of the present study was to estimate and compare the cost-effectiveness of different strategies using sputum smear microscopy and CXR during passive PTB case finding among patients attending a primary health care unit in Rio de Janeiro City, Brazil.

STUDY POPULATION AND METHODS

This cost-effectiveness study was a descriptive study of secondary data using complete available information on patients included in the original study. The original study aimed to evaluate a diagnostic test for TB in sputum samples of patients attending a TB clinic at a primary health care unit in Rio de Janeiro City who met the following criteria: age ≥ 18 years, productive cough for ≥ 2 weeks plus at least one sign or symptom suggestive of TB (fever, night sweats, weight loss, haemoptysis, chest pain, appetite loss),

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Table 1 Study strategies for PTB detection at the primary care level

Strategy	First test	Second test	PTB definition
E1	CXR	Smear for those with CXR suggestive of TB	CXR suggestive of TB and 1–2 smears positive
E2	Smear	CXR for those with 1 smear positive or 2 smears negative	2 smears positive or CXR suggestive of TB (1 smear positive or 2 smears negative)
E3	Smear and CXR	Not applicable	2 smears positive or CXR suggestive of TB (1 smear positive or 2 smears negative)

PTB = pulmonary TB; CXR = chest radiography; TB = tuberculosis.

and no use of anti-tuberculosis drugs within 60 days before study inclusion. For the purposes of the original study, two spontaneous sputum samples (one on the same day and another on the following morning) and CXR were requested for all patients; other aspects of patient assessment and care were as per routine and at the discretion of the routine care clinical team.

Study sputum samples were tested using direct microscopy after Ziehl-Neelsen staining and Löwenstein-Jensen (LJ) mycobacterial culture. Specimens were processed using N-acetyl-L-cysteine (0.5% final concentration)—sodium hydroxide (2% final concentration) for decontamination. Following concentration by centrifugation, a 0.2 ml portion of the decontaminated and concentrated specimen was inoculated onto LJ slants, incubated at 37°C and examined weekly for 8 weeks. CXRs were interpreted by attending physicians not included in the study, who classified the presence of an alteration as suggestive or not of PTB according to their personal evaluation and experience, as they were not trained specifically for the study. Human immunodeficiency virus (HIV) testing was not performed for research purposes; however, about 12% of TB patients in the city are reported to be HIV-positive according to local epidemiological data.¹¹

For this cost-effectiveness study, clinical, radiological and mycobacterial data were included in the analysis. A decision model was developed using sputum smears and CXR in three strategies for PTB detection, and the definition of PTB was based on national guidelines (Table 1).^{4,5} Strategy E1 comprised CXR, followed by smear microscopy for patients with CXR suggestive of TB; strategy E2 consisted of smear microscopy, followed by CXR for patients with 1 smear-positive or 2 smear-negative results; patients on strategy E3 underwent both smear microscopy and CXR at the same visit.

A cost-effectiveness analysis was performed in terms of cost per correct diagnosis of PTB. Mycobacterial culture was used as the gold standard to calculate the effectiveness of the strategies. Costs were calculated from the payer's perspective (Brazilian Public Health System); costs such as transport costs and working hours lost were therefore not taken into consideration in the analysis. Unit costs of health resource utilisation were obtained from the standardised Management System of the Table of Procedures,

Drugs and Orthoses/Prostheses/Special Materials (SIGTAP-SUS) in reais (R\$), as of June 2012.¹² Reais values were converted to US dollars based on the Brazilian Central Bank quotation (R\$1.00 = US\$2.03 as of 8 October 2012). Costs were estimated to be US\$3.10 for a non-medical consultation, US\$4.93 for a medical consultation, US\$2.07 for direct smear microscopy and US\$4.68 for CXR. Sensitivity analysis was performed to evaluate possible changes in the results of the base case analysis when a TB prevalence of 6% was considered, which is the TB rate among patients with productive cough in a primary health unit as reported by a local prevalence study.

The original study and the cost-effectiveness study were approved by the Ethical Committee of the Federal University of Rio de Janeiro, Rio de Janeiro, Brazil.

RESULTS

Of 260 patients, data from six (2.3%) were not eligible due to incomplete information. Of the 254 patients included in the analysis, 112 (44%) were classified as TB and 140 (56%) as non-TB based on culture results. Two patients had positive cultures for non-tuberculous mycobacteria. Table 2 shows the clinical characteristics of the study patients.

Eleven patients (4.3%) did not provide a second sputum sample (three TB and eight non-TB cases),

Table 2 Patient characteristics

	TB (n = 112) n (%)	Non-TB (n = 142) n (%)	Total (N = 254) n (%)
Age, years, mean ± SD	39.1 ± 14.8	50.0 ± 15.2	45.2 ± 15.9
Sex			
Female	37 (33.0)	67 (47.2)	104 (40.9)
Male	75 (67.0)	75 (52.8)	150 (59.1)
Previous TB			
Yes	24 (21.4)	37 (26.1)	61 (24.0)
No	88 (78.6)	102 (71.8)	190 (74.8)
NA	—	3 (2.1)	3 (1.2)
Comorbidity*			
Yes	22 (19.6)	59 (41.5)	81 (31.9)
No	70 (62.5)	60 (42.3)	130 (51.2)
Unknown	20 (17.9)	23 (16.2)	43 (16.9)

* Systemic hypertension and/or diabetes mellitus 76.5%, obstructive pulmonary disease 11.1%, malignancy 7.4%, human immunodeficiency virus 2.5% and unknown 2.5%.

TB = tuberculosis; SD = standard deviation; NA = not applicable.

Table 3 CXR evaluation stratified by sputum smear results

	TB n (%)	Non-TB n (%)	Total n (%)
Smear-negative	(n = 27)	(n = 136)	(n = 163)
CXR suggestive of TB	13 (48.2)	17 (12.5)	30 (18.4)
CXR not suggestive of TB	11 (40.7)	108 (79.4)	119 (73.0)
CXR not done	3 (11.1)	11 (8.1)	14 (8.6)
Smear-positive (1 sample)	(n = 9)	(n = 4)	(n = 13)
CXR suggestive of TB	7 (77.8)	1 (25.0)	8 (61.5)
CXR not suggestive of TB	2 (22.2)	3 (75.0)	5 (38.5)
Smear-positive (2 samples)	(n = 76)	(n = 2)	(n = 78)
CXR suggestive of TB	67 (88.2)	1 (50.0)	68 (87.2)
CXR not suggestive of TB	9 (11.8)	1 (50.0)	10 (12.8)

CXR = chest radiography; TB = tuberculosis.

while 14 (5.5%) did not undergo CXR (three TB and 11 non-TB cases). CXR results stratified by sputum smear microscopy results are shown in Table 3. Radiological changes were considered suggestive of TB in 48% (13/27) of the smear-negative TB patients, while 91% (108/119) of the CXRs that were not suggestive of TB were from smear-negative non-TB patients. Among patients with one smear-positive result, 87.5% (7/8) of the CXRs compatible with TB were from TB patients, while 60% (3/5) of the CXRs classified as not suggestive of TB were from non-TB patients; 12% (9/76) of the TB patients with two smear-positive results had a CXR non-suggestive of TB, and only 10% (1/10) of the CXRs classified as not suggestive of TB were in fact from non-TB patients.

The cost of each health care component of the strategies and total costs are given in Table 4. Costs with medical consultation were higher for strategies E2 and E1, as three visits would be necessary to evaluate the second test requested for indicated patients (those with one positive or two negative smear samples in strategy E2, and those with radiological changes suggestive of TB in strategy E1). The effectiveness of the strategies and the base-case cost-effectiveness results are shown in Table 5. Effectiveness was 0.66 and 0.86 each, and the cost per correct PTB diagnosis was

Table 4 Total cost and health care component cost of the strategies for pulmonary tuberculosis detection

Health care component	Strategy E1	Strategy E2	Strategy E3
Nurse consultation			
Patients, n	254	254	254
Cost, US\$	788.28	788.28	788.28
Medical consultation			
Patients, n (2 visits)	148	78	254
Patients, n (3 visits)	106	176	—
Cost, US\$	3024.63	3369.46	2502.46
Smear microscopy			
Patients, n (1 sample)	3	11	11
Patients, n (2 samples)	103	243	243
Cost, US\$	432.41	1028.28	1028.28
Chest radiography			
Patients, n	240	162	240
Cost, US\$	1123.15	758.13	1123.15
Total cost	5368.47	5944.15	5442.17

Table 5 Cost-effectiveness of strategies for pulmonary TB detection: base-case analysis

	Strategy E1 US\$	Strategy E2 US\$	Strategy E3 US\$
Total cost	5368.47	5944.15	5442.17
Probability of correct TB diagnosis	0.66	0.86	0.86
Patients with correct TB diagnosis, n	74	96	96
Cost per evaluated patient	21.14	23.40	21.42
Cost per TB case	47.93	53.07	48.59
Cost per correct TB diagnosis	72.55	61.92	56.69

TB = tuberculosis.

respectively \$72.55, \$61.92 and \$56.69 for strategies E1, E2 and E3. As per the WHO definition of PTB cases (suspects with at least one smear-positive sample without further investigation if the smear is performed in qualified laboratories with an external quality assurance system) for strategies E2 and E3, CXR would be requested/evaluated for smear-negative suspects only and the effectiveness would be 0.87, with a cost-effectiveness of \$59.38 and \$55.53, respectively.¹³

In the sensitivity analysis, as the total number of PTB cases in the sample decreased with lower TB prevalence (6%), the cost per PTB case detected increased for all strategies (US\$596.50 for E1, US\$452.05 for E2 and US\$418.63 for E3). Strategy E3 was the most cost-effective.

DISCUSSION

Our study was based on data from adult patients undergoing routine investigation for PTB in a primary health care unit. Although two spontaneous sputum smears and CXR were requested for all patients by the study team, regardless of the advice from the attending physician, data from patients who did not perform one or more tests were not excluded in order to be able to assess the operational limitations of passive case-finding strategies.

The most cost-effective strategy for PTB detection was the one in which sputum smears and CXR were requested for all patients at initial evaluation (strategy E3): cost of US\$56.69 per PTB case detected. In this strategy, patients with two smear-positive sputum samples irrespective of CXR results, or one smear-positive or two smear-negative samples associated with CXR changes suggestive of TB, were defined as PTB cases.

Our results showed no aggregate diagnostic value of CXR in patients with two smear-positive samples; in contrast, 12% of PTB cases correctly diagnosed by smear would no longer be classified as TB if CXR was used to determine PTB case definition. Furthermore, the CXR was not useful in ruling out TB among these patients, as only 10% of those with CXR not suggestive of TB did not have TB. The role of CXR in patients

with two smear-positive sputum samples would be disease classification (miliary vs. non-miliary), assessment of disease extension (whether thoracic sites were involved) and severity, indication of another pulmonary disease and monitoring anti-tuberculosis treatment response. In patients with only one smear-positive sample, CXR would be able to rule out TB in 60% of those without the disease and confirm the diagnosis in 87.5% of PTB patients. In accordance with previously published studies, the main added value of CXR was demonstrated in patients with two smear-negative samples, detecting 48% of smear-negative PTB cases, with a total incremental yield of 11.5%, and ruling out TB in 91% of those with CXR changes non-suggestive of PTB.^{8,10,14}

Simultaneous assessment of CXR and sputum smear results allows for a reduction in the number of visits for the investigation to be completed. In our study, CXR would be indicated for further evaluation in 69% of the patients based on smear results (strategy E2). The total cost of an additional visit necessary to undergo CXR after receiving smear results was higher than the total cost of CXR for monitoring of disease in patients with two smear-positive results (strategy E3). In addition to health system costs, an additional visit also implies increased costs for the patient, such as transport costs and work days lost.¹⁵ In addition, fewer visits could also have an impact on early TB detection and better treatment outcomes. Although loss of patients and duration of investigation were not assessed in this study, previous studies have shown that initial CXR evaluation of PTB suspects may indirectly result in a 62% reduction in time to TB diagnosis if the use of empiric antibiotics can be avoided in a high proportion of TB patients, and that delay in diagnosis of ≥ 30 days may be associated with absence of cure.^{16,17}

A similar study conducted in Kenya that evaluated only two strategies showed that a strategy in which CXR was performed according to sputum smear results was more cost-effective than the opposite.¹⁰ However, if costs related to anti-tuberculosis treatment in false-positive cases are considered, a strategy in which smear is performed in case of CXR changes is more cost-effective, as its specificity is 35% higher. Unlike the scope of this study, viewing any CXR changes as an indication to investigate TB by smear microscopy is most commonly used to screen high-risk individuals (active case finding), which is not always performed by medical professionals.¹⁸ One important limitation of this study is that the cost of false-negative results was not taken into account. In our study, strategy E1 showed 17% higher specificity than strategy E3, but its sensitivity was 20% lower. Thus, direct and indirect costs associated with false-negative PTB and related symptomatic contacts/secondary TB cases (extra consultations, tests, treatments, productivity loss and death) could offset the

costs of anti-tuberculosis treatment of false-positive patients.¹⁹ Costs related to PTB diagnosis loss are more difficult to calculate due to the lack of financial data and diversity of contact definitions and tracing strategies in published studies.²⁰ However, the inclusion of costs exclusively related to incorrect anti-tuberculosis treatment leads to deficient and inaccurate conclusions about the cost-effectiveness of PTB case-finding strategies.

The main limitation of strategies using CXR is the large number of false-positive cases.¹⁰ In our study, about 13% of non-TB patients had CXR results recorded as being suggestive of TB. Cavitation and a history of TB may have been confounding factors for the physicians. In addition to the consequences of incorrect treatment for both the health care system and the individual, high rates of overdiagnosis may also represent an important challenge for settings that experience shortages in TB drug supplies. On the other hand, CXR may contribute to the diagnosis of other pulmonary diseases in non-TB patients with respiratory symptoms, as PTB represents only a very small proportion of patients seeking care for cough.²¹ In our study, 55% of patients without CXR suggestive of TB had pulmonary changes, with 56% suggestive of active disease (46% infiltrate/consolidation, 6.6% cavitation and 3.3% mass).

As this was a retrospective study of secondary data, there were important limitations related to missing information, such as HIV status, detailed clinical information and outcomes of other diseases and TB. Clinical and HIV information could contribute to the development of more specific strategies, information on the outcomes of other diseases would better determine the role of CXR in detecting respiratory diseases, and information on anti-tuberculosis treatment outcomes could have helped confirm study results. Despite these limitations, the main contribution of this study was to demonstrate, with results that reflect routine clinical practice, that the request for CXR and sputum smear microscopy at the initial stage is a cost-effective strategy for detecting PTB compared to serial examinations. However, cost-effectiveness studies on the implementation of more accurate TB diagnostic tests at the primary health care level are still needed to identify strategies that would overcome the limitations of CXR and sputum smear microscopy in the diagnosis of PTB.

CONCLUSIONS

Although the absolute cost-effectiveness values of the strategies studied did not substantially differ in the base-case scenario, the main advantage of the E3 strategy (smears and CXR for all patients) over E2 (CXR restricted to patients with one smear-positive or two smear-negative sputum samples) is the reduction in the number of visits necessary for a full investigation,

which could lead to increased TB detection and better outcomes. The use of CXR to determine which patients should undergo smear microscopy based on suggestive CXR results (strategy E1) led to a considerable loss of sensitivity in PTB detection, with the lowest cost-effectiveness results among the strategies studied.

Although sputum smear microscopy and CXR are not ideal for PTB diagnosis, they are the methods currently in use for routine passive case finding at primary health care units in lower-resource settings. The recommendation of the most cost-effective strategy to optimise the use of these tools may therefore contribute, within their limitations, to greater and earlier detection of cases, which are essential components of TB control.

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RÉSUMÉ

CONTEXTE : Une unité de soins de santé primaires dans la ville de Rio de Janeiro, Brésil.

OBJECTIF : Estimer et comparer le rapport coût-efficacité des stratégies pour le dépistage passif des cas de tuberculose pulmonaire (TBP) utilisant des tests disponibles au niveau des soins primaires.

SCHÉMA : On a analysé les données des suspects de TBP et on a développé un modèle de décision utilisant l'examen microscopique des frottis de crachats et le cliché thoracique (CXR) dans trois stratégies différentes pour la détection de la TBP. On a pratiqué une analyse de coût-efficacité pour calculer le coût par diagnostic correct de TBP. On a utilisé la culture mycobactérienne pour calculer l'efficacité des stratégies. On a obtenu le coût unitaire d'utilisation des ressources de santé selon la perspective du payeur (Système Public de Santé Brésilien).

RÉSULTATS : Pour l'évaluation de 254 suspects de TBP, les coûts totaux des stratégies se sont établis entre 5369 et 5944 US\$, et la probabilité d'un diagnostic correct s'est établie entre 0,66 et 0,86, le nombre de visites nécessaire pour l'achèvement du processus de diagnostic s'étant entre deux et trois et le coût par cas de TBP identifié s'étalant entre 47,63 et 53,07 US\$. Les rapports coût-efficacité des trois stratégies étudiées ont varié entre 56,69 et 72,55 US\$ par cas exact de TBP détecté.

CONCLUSION : Une stratégie dans laquelle les frottis de crachats et le CXR sont exigés chez tous les suspects de TBP lors de l'évaluation initiale a un bon rapport coût-efficacité et une probabilité élevée de diagnostic correct de la TBP et pourrait être réalisée en deux visites seulement.

RESUMEN

MARCO DE REFERENCIA: Una unidad de atención primaria de salud en la ciudad de Río de Janeiro en el Brasil.

OBJETIVO: Calcular la rentabilidad de las estrategias en la búsqueda pasiva de casos de tuberculosis pulmonar (TBP) que utilizan las pruebas al alcance en los centros de atención primaria, y compararlas.

MÉTODOS: Se examinaron los datos de los pacientes con presunción clínica de TBP y se formuló un modelo decisional que comportaba la baciloscopy de esputo y la radiografía de tórax (CXR) en tres estrategias diferentes de diagnóstico de la TBP. Se llevó a cabo un análisis de rentabilidad según el costo por cada diagnóstico correcto de TBP. El cultivo de micobacterias fue el criterio de referencia en el cálculo de la eficacia de las estrategias. Los costos de la unidad por la utilización de los recursos sanitarios se examinaron desde la perspectiva

del organismo pagador (el Sistema de Salud Pública del Brasil).

RESULTADOS: El costo total de las estrategias de evaluación de 254 casos de presunción clínica de TBP osciló entre USD 5369 y USD 5944; la probabilidad de un diagnóstico correcto fluctuó entre 0,66 y 0,86; se necesitó entre dos y tres consultas a fin de completar el diagnóstico y el costo por caso de TBP detectado varió entre USD 47,93 y USD 53,07. La rentabilidad de las tres estrategias analizadas osciló entre USD 56,69 y USD 72,55 por cada caso correcto diagnosticado.

CONCLUSIÓN: Una estrategia que solicita baciloscopyas de esputo y CXR a todos los pacientes con presunción clínica de TBP al comienzo de la evaluación fue rentable, ofreció una alta probabilidad de alcanzar un diagnóstico correcto y puede completarse en dos consultas.