Diagnostic Value of Two Rapid Immunochromatographic Tests for Suspected Tuberculosis Diagnosis in Clinical Practice

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Objective: *To evaluate and compare the diagnostic value of two immunochromatographic tests for tuberculosis (ICT-TB) in clinical practice.*
Material and Method: *The present extended cross-sectional study investigated suspected active TB patients at Maesai district hospital, and Lampang regional hospital between April 2009 and May 2010. Subjects underwent two commercial ICT-TB serum tests including: an endogenous ICT-TB, a local made test coated with 38 kD, 16 kD, and 6 kD antigens; and an exogenous ICT-TB, an imported test coated with 38 kD and lipoarabinomanan [LAM] antigens. All subjects received two months of follow up.*
Results: *Of 401 patients, 146 (36.4%) had active TB, and 206 (51.4%) were HIV seropositive. An endogenous ICT-TB was superior to an exogenous ICT-TB in all diagnostic values measured except for specificity. In all patients, sensitivity was low, 35.6% (95% CI: 30.9-40.3) in an endogenous ICT-TB vs. 13.7% (95% CI: 10.3-17.1) in an exogenous ICT-TB. The specificity was high and equivalent in both tests, 93.7% (95%CI: 91.4-96.1). Higher diagnostic values were found among human immunodeficiency virus (HIV) seronegatives than in HIV seropositives when unadjusted for CD4+ cell count level. The likelihood ratios (LHR) were higher in patients with CD4+ cell count over 200 cells/μL than for the HIV seronegative group (LHR+ 7.6 vs. 4.8 in an endogenous ICT-TB, and 2.5 vs. 1.9 in an exogenous ICT-TB).*
Conclusion: *For the present study setting, an endogenous ICT-TB can be a meaningful tool for first-line testing to rule in TB suspected cases. Subgroups of HIV seronegative and HIV seropositive patients with CD4+ cell count over 200 cells/μL may be expected to benefit most from the test.*

Keywords: *Tuberculosis, HIV, Diagnostic test, Serological tests, Immunochromatographic tests*

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Tuberculosis (TB) remains a major cause of morbidity and mortality worldwide. Among the 22 countries with high TB burdens in 2009, Thailand ranked 18[1]. Treatment success of Thailand lags behind the WHO target due to insufficient case evaluation, treatment default, and elevated mortality rates[1]. In Thailand, Human immunodeficiency virus (HIV) co-infection accounted for 17% of total TB incidence and ranked as the highest in the South-East Asian Region[1]; it is also a major cause of death[2]. Many HIV seropositive patients also have undiagnosed TB disease because of the reduction of sensitivity of diagnostics tests and delay the diagnosis[3].

The current laboratory standard for TB diagnosis relies upon bacteriologic methods often limited by the cost of equipment, insufficient skilled technicians, laboratory results turnaround time, or inadequacy of diagnostic validity[4]. The availability of a test that is affordable and rapidly deployable in the field would be of great benefit to TB control programs in resources limited countries. Such a test would be of potential value even if its performance was less than ideal[5]. A potential replacement test is the rapid,

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card-based immunochromatographic test for the serological diagnosis of TB (ICT-TB) detecting antibodies directed against *M. Tuberculosis* antigens in blood and serum.

Because antibody responses to *M. Tuberculosis* antigens may be heterogeneous from various factors, multiple antigens were used in ICT-TB to increase the performances of the test[6]. The performance of ICT-TB has been well established for various antigens including lipoarabinomannan (LAM), A60 and the 38 kD[7-10]. However, all of these antigens show variations in performance across changing conditions. A recent systematic review summarized that among pulmonary TB (PTB) patients, the sensitivity of ICT-TB tests from 10% to 90%, while the specificity was higher at 47% to 100%. In some studies, the range of performance was considered acceptable in first-line testing for suspected PTB[11,12]. Studies including HIV-infected patients showed delineation of several antigens that were recognized by antibodies[5,6,13,14]. Few existing studies stratify by CD4+ cell count level when reporting on the performance of diagnostic tests[13,14]. Only two previously published studies report on the diagnostic validity of LAM and 38kD recombinant antigens using pleural effusion and serum in Thai settings[13,15].

At present, test manufacturers produce dozens of different antibody detection diagnostic commercial kits with the sales volumes in developing countries ranging between 3,000 and 300,000 tests per year[9]. It is uncertain, however, whether the test is suitable for screening or diagnosing TB in clinical practice in Thailand in this era. Further evaluation ICT-TB detection performances in selected settings of Northern Thailand; which have the nation's highest rates of TB and HIV incidence[2]. Such an evaluation is of extra value amongst this vulnerable population of HIV patients. The goal of the present study was to evaluate and compare diagnostic values of two ICT-TB coated with antigens from endogenous or exogenous sources, and to identify the subgroup of patients who may benefit most from the test in clinical practice.

Material and Method

Study population

Patients suspected of having TB were eligible for the present study. They were enrolled from a TB clinic serving outpatients and inpatients, and an anti-retroviral (ARV) clinic where to recruit HIV seropositive patients who were at high risk of TB regardless the presence or absence of TB signs and symptoms. Four hundred and six patients, aged 18 years or older were investigated at Maesai district hospital, and Lampang regional hospital between April 2009 and May 2010. Patients who were receiving TB treatment or isoniazid preventive therapy (IPT) during the enrollment period or within one year prior to enrollment were excluded from participation in the present study.

Criteria for a definitive TB diagnosis were defined as positivity of smear or culture of sputum or other specimens, or a positive clinical and radiological response to specific treatment, or characteristic histology seen in biopsy specimens. Patients with non-TB mycobacterial diseases were diagnosed under the standard clinical practices.

Enrolled patients received evaluation for routine TB diagnosis and had their blood sampled for HIV testing in patients with unknown status, CD4+ cell count level, ICT-TB. Available diagnostic procedures for TB included chest radiographs, ultra sound, computed tomography (CT) scan, three consecutive collections for sputum acid fast bacilli (AFB) smear examination, and sputum culture. Additionally, baseline characteristics; age, sex, body weight at diagnosis were obtained by a physician, and a nurse using a case record form. All participants signed consent forms and were followed for two months after enrollment.

Serological immunochromatographic testing

The present study evaluated two commercial rapid ICT-TB tests, an endogenous ICT-TB, a local made test coated with antigens 38 kD, 16 kD, 6 kD, and an exogenous ICT-TB from endogenous sources, an imported test coated with antigens 38 kD and LAM from exogenous sources. The ICT-TB utilizes a unique two-site immunoassay fixed to a membrane. As the test sample flows through the membrane assembly of the device, the colored recombinant TB Ag-colloidal gold conjugate complexes with the antibodies towards TB in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant TB antigens coated on the membrane leading to formation of a colored band, which confirms a positive test results[16]. All tests were conducted on the day of specimen collection using approximately 100 μl of blood serum. Test results were indicated by the resolution of colored bands on the result window of a test strip. The presence of only one purple color band indicated a negative result. The presence of two colored bands indicated a positive result. The test was considered invalid if the reference and the control

band did not appear. Both tests were interpreted within 15 to 20 minutes of contact with the specimen.

Research staffs were trained on how to conduct the ICT-TB test prior to patient enrollment and testing. Three interpreters read the test results in accordance with manufacturer instructions. Readers were blinded on the findings of other readers, type of ICT-TB test, HIV serological status and the results of the clinical status. The result was considered "positive" when at least two readers indicated a positive result; otherwise, it was scored as a "negative" result. Indeterminate results were excluded in performance calculations.

The present study was approved by two institutional review boards: 1) Faculty of Medicine, Chiang Mai University, and 2) Lampang regional hospital.

Statistical analysis

Classical diagnostic values; *i.e.*, sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), Likelihood ratio (LHR; positive/negative), were calculated using a standard method for all patients, HIV status stratification and CD4+ cell counts different cut off points. A statistical significance level or alpha of 0.05 was selected for type I error. An estimation of sample size was based on specificity needed for the test; 90% and prevalence of TB in the study population; 17%[1]. At least 243 patients was sufficient allowing error at 5% and an additional 10% with missing data.

Results

Four hundred six eligible patients were enrolled and tested with study index tests, two ICT-TB tests, five patients were excluded due to unidentified HIV status. Four hundred and one patients were followed, diagnosed as TB or non-TB group, and included in final data analysis. Seven patients had diagnosis changed after two months of follow-up. Finally, 146 (36.4%) were diagnosed with active TB. Of whom, 134 patients (91.8%) had pulmonary TB (PTB), and 12 patients (8.2%) had extra pulmonary TB (ETB). About half, 206 (51.4%) were HIV seropositive and most of whom, 151 (73.3%) received antiretroviral therapy. Among 181 patients with a CD4+ cell count available, 19 (70.4%) in active TB group had CD4+ cell count up to 200 cells/μL (Table 1).

The non-TB group consisted of three patients with asthma, 49 with bronchitis, five with lung cancer, two with congestive heart failure, 16 with chronic obstructive pulmonary disease (COPD), one with fever of unknown origin, one with melioidosis, nine with old TB, one with Pneumocystis Carinii pneumonia (PCP), one with penniciliosis, 12 with pneumonia and 155 with the absence of chest diseases from the ARV clinic.

The results of an endogenous and an exogenous ICT-TB tests on positive and negative TB diagnosis are summarized in Table 2. Performance analysis of two ICT-TB tests revealed that an endogenous ICT-TB gave statistically significant greater diagnostic values than an exogenous ICT-TB in sensitivity, PPV, and LHR+/-. However, sensitivities of both tests were low (35.6%, 95% CI: 30.9-40.3 in an endogenous ICT-TB and 13.7%, 95% CI: 10.3-17.1 in an exogenous ICT-TB). The specificity for both tests was satisfactory high and identical (93.7%, 95% CI: 91.4-96.1). The negative predictive values (NPV) showed no statistically significant difference between tests (Table 3).

When stratified by HIV status, an endogenous ICT-TB provided better sensitivity and LHR (+/-) than an exogenous ICT-TB in every category measured. HIV seropositivity delineated performances of the test. The sensitivity of an endogenous ICT-TB was 24.3% (95% CI: 18.5-30.2) while an exogenous ICT-TB was 2.7% (95% CI: 0.5-4.9) in HIV seropositive patients. Regarding CD4+ cell count level, cut off points were determined for the best performances of both tests. CD4 counts cut off points at 200 cells/μL gave the best result (data not shown). Interestingly, it was found indifferent sensitivity value among HIV patients with CD4+ cell count over 200 cells/μL and HIV seronegative patients. The specificity for both tests was higher than 90% in every category. There was consistency of LHR results where both tests performed better in HIV seronegative patients, but only for the group of patients who CD4+ cell count up to 200 cells/μL. The likelihood ratios were higher in patients with CD4+ cell count over 200 cells/μL than for the HIV seronegative group (LHR+ 7.6 vs. 4.8 in an endogenous ICT-TB, 2.5 vs. 1.9 in an exogenous ICT-TB) (Table 4). Diagnostic parameters of each ICT-TB was pairwise tested by HIV status (seropositive vs. seronegative), CD4+ cell count level (> 200 cells/L vs. up to 200 cells/μL) and HIV seronegative vs. CD4+ count level > 200 cells/μL (Table 4).

Discussion

Diagnostic values of an endogenous ICT-TB, a local made test, were superior to those of an exogenous ICT-TB, an imported test for active TB

Table 1. Characteristics of study patients (n = 401)

Characteristic*	TB positive (n = 146)	TB negative (n = 255)
Male	79 (54.9)	124 (48.6)
Age (year), mean (SD)	43.3 (16.4)	44.4 (14.3)
BMI (kg/m^2), mean (SD)	19.4 (4.0)	20.6 (3.6)
Other nationality	99 (70.7)	96 (38.4)
Unemployment	42 (29.4)	43 (17.1)
Occupation with little skill	81 (66.9)	193 (85.4)
Any co-morbidity	16 (11.0)	38 (14.9)
History of TB diagnosis	11 (7.5)	25 (9.8)
History of TB exposure	17 (11.6)	12 (4.7)
HIV infection	37 (25.3)	169 (66.3)
Antiretroviral therapy	9 (6.16)	142 (84.0)
Abnormal chest film	113 (59.5)	77 (40.5)
Cavity	28 (21.7)	5 (2.2)
Pleural	12 (9.4)	4 (1.8)
Miliary	3 (2.3)	1 (0.4)
Mass or nodule	6 (4.7)	2 (0.9)
Hilar or paratracheal adenopathy	9 (7.0)	3 (1.3)
CD4+ cell count (/mL)		
Median (range)	100 (9-559)	397 (6-1293)
Less than 200	19 (70.4)	33 (21.4)
WBC count (1,000/dL)	8.8 (1-48)	7.0 (1-111)
Hemoglobin level (g/dL)	11.6 (3.5-16.5)	12.3 (2.1-38.8)
Hematocrit (%), median (range)	36.5(13.7-49.5)	38.4 (8.5-50.6)
Platelet count (1,000/mL), median (range)	327 (69-888)	302.5 (28-912)

* Units are n (%) unless indicated otherwise

Table 2. An endogenous ICT-TB and an exogenous ICT-TB tests results on positive and negative TB diagnosis (n = 401)

Disease status	An endogenous ICT-TB		An exogenous ICT-TB		Total
	Positive	Negative	Positive	Negative	
TB positive	52	94	20	126	146
TB negative	16	239	16	239	255
Total	68	333	36	365	401

Table 3. Diagnostic values and 95% CI of an endogenous ICT-TB test and an exogenous ICT-TB test (n = 401)

Diagnostic values	An endogenous ICT-TB	An exogenous ICT-TB	p-value
Sensitivity	35.6 (30.9-40.3)	13.7 (10.3-17.1)	<0.001
Specificity	93.7 (91.4-96.1)	93.7 (91.4-96.1)	1.000
PPV	76.5 (72.3-80.6)	55.6 (50.7-60.4)	0.043
NPV	71.2 (67.4-76.2)	65.5 (60.8-70.1)	0.087
LHR+	5.7 (3.4-9.6)	2.2 (1.2-4.1)	<0.001
LHR-	0.7 (0.6-0.8)	0.9 (0.8-1.0)	<0.001

Table 4. Diagnostic values of the two ICT-TB tests, classified by HIV status and CD4+ cell counts level (n = 401)

Diagnostic values	An endogenous ICT-TB				An exogenous ICT-TB			
	HIV+			HIV- (n = 195)	HIV+			HIV- (n = 195)
	Overall (n = 206)	CD4 ≤ 200 (n = 52)	CD4 > 200 (n = 129)		Overall (n = 206)	CD4 ≤ 200 (n = 52)	CD4 > 200 (n = 129)	
Sensitivity	24.3 (18.5-30.2)	22.1 (10.0-32.1)	37.5 (29.2-45.9)	39.5 (32.6-46.3)	2.7[d] (0.5-4.9)	0 (n/a)	12.5 (6.8-18.2)	17.4[d] (12.1-22.8)
Specificity	94.7 (91.6-97.7)	93.9 (88.7-99.8)	95.0 (91.3-98.8)	91.9 (88.0-95.7)	95.3 (92.4-98.2)	93.9 (88.7-99.8)	95.0 (91.3-98.8)	90.7 (86.6-94.8)
PPV	50.0[a] (43.2-56.8)	66.7 (53.9-79.5)	33.3[e] (25.2-41.5)	86.0[a] (81.1-90.9)	11.1[d] (6.8-15.4)	0 (n/a)	14.3[f] (8.3-20.3)	70.4[d,f] (64.0-76.8)
NPV	85.1[a] (80.2-90.0)	67.4[b] (54.7-80.1)	95.8[b,e] (92.4-99.3)	54.5[a,e] (47.5-61.5)	81.7[d] (76.5-87.0)	62.0[e] (48.8-75.2)	94.3[e,f] (90.3-98.3)	46.4[d,f] (39.4-53.4)
LHR+	4.6 (1.9-10.7)	3.5[b] (0.7-17.2)	7.6[b,e] (2.3-24.8)	4.8[e] (2.3-10.2)	0.6[d] (0.1-4.4)	n/a[+]	2.5[f] (0.3-18.5)	1.9[d] (0.9-4.1)
LHR-	0.8[a] (0.7-0.9)	0.8[b] (0.7-1.1)	0.7[b] (0.4-1.1)	0.7[a] (0.6-0.8)	1.0[d] (0.9-1.1)	1.1 (1.0-1.2)	0.9 (0.7-1.2)	0.9[d] (0.8-1.0)

[a,b,c,d,e,f] Indicated statistically pairwise differences of each diagnostic value categorized by type of ICT-TB test (p-value < 0.05)

[+] No positive test result

detection. It may be attributable to the different combination of recombinant secreted antigens and sources of antigens. Both tests comprised the 38 kD antigen claimed to be the most sensitive and specific for detecting antibodies against *M. Tuberculosis*[10]. However, sensitivities were low from both of the study tests (35.6% vs. 13.7%) due to low molecular weight of the 38 kD antigen causing a lower degree of immunogenicity and then reduce antibody production[17]. The higher sensitivity detected from an endogenous ICT-TB was attributable to two other different antigens, 16 kD and 6 kD, comparing to LAM antigen in an exogenous ICT-TB. However, the use of ICT-TB test with those two antigens has not been widely studied, they might be suitable to use for the local of *M. Tuberculosis* strains in the present study areas. Excellent specificity classified as high[17] was in concordance to many studies done previously[5,6,17,18].

When stratified by HIV status, both tests provided lower sensitivity. The greater sensitivity was presented in HIV seronegative patients comparing to ones with seropositive, which was similar to previous studies[5,6,13]. They demonstrated that the sensitivity reduces in association with HIV infection because the immune system is too weak to mount a strong antibodies response, or antibody formation was inversely associated with the severity of HIV/AIDS infection[13]. However, specificities were not affected by HIV status (over 90%).

Major findings from the present study include the performance of ICT-TB test in HIV seropositive patients whose CD4+ cell count level is > 200 cells/μL. The test results were comparable, even better in some categories, *i.e.* specificity, NPV, LHR+ to HIV seronegative patients. It is possible that antibodies to *M. Tuberculosis* antigens are still high in this group of patients to contribute as good responses as non-HIV infected patients. This finding was consistent with earlier studied in Thailand[13]. The high likelihood ratios in patients with CD4+ cell count over 200 cells/μL (LHR+ 7.6) in an endogenous ICT-TB confirmed strong evidence of active TB diagnosis in this circumstance. Therefore, when CD4+ cell count is available, the ICT-TB test, especially an endogenous ICT-TB, can be a potentially useful test to rule in patients whom CD4+ cell count level is over 200 cells/μL, and patients with HIV seronegative. However, specific ICT-TB tests require validation within a community before adoption in routine practice due to antigen-antibody reaction, the variability of diagnostic values between settings,

and the prevalence of the disease in the target population.

A limitation of the present study was using positivity either sputum smear or culture, or based on positive clinical and radiological response to specific treatment, or characteristic histology seen in biopsy specimens as the gold standard instead of cultures of *M. Tuberculosis* or biopsy results alone. However, this is the diagnosis standard for TB that is available in Thailand where accessibility to culture is limited in many areas.

Some strengths of the present study to be mentioned is that the authors evaluated and compared two types of ICT-TB rapid tests with different antigens recombinant under field conditions. Therefore, the findings can be of direct benefit to the target population in clinical practice. Moreover, the present study was conducted. All patients were followed for two months after enrollment. Thus, misclassification of TB diagnosis should be minimal.

Further ICT-TB studies should be conducted by adding a value of the test concurrent with clinical symptoms for TB to test whether the ICT-TB can improve diagnostic performances. Importantly, future research will be necessary to define whether the application of these tests results in improved patient outcomes.

Conclusion

For the present study settings, an endogenous ICT-TB performed better than an exogenous ICT-TB and can be a meaningful tool for first-line testing to rule in TB suspected cases. Subgroups of HIV seronegative and HIV seropositive patients with CD4+ cell count over 200 cells/μL may be expected to benefit most from the test. However, specific ICT-TB tests require validation within a community before adoption in routine practice due to antigen-antibody reaction, the variability of diagnostic values between settings, and the prevalence of the disease in the target population.

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Potential conflicts of interest

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คุณค่าของ immunochromatographic test สองชนิดเพื่อการวินิจฉัยวัณโรคแบบเร็วในเวชปฏิบัติ

ศิริศักดิ์ นันทะ, พัชรี ขันติพงษ์, ปานิตา ปทีปวณิช, ชิดชนก เรือนก้อน, ชไมพร ทวิชศรี, ชยันตร์ธร ปทุมานนท์

วัตถุประสงค์: *ประเมินและเปรียบเทียบคุณค่าของ immunochromatographic test สองชนิดเพื่อการวินิจฉัยวัณโรคแบบเร็ว (ICT-TB) ในเวชปฏิบัติ*

วัสดุและวิธีการ: *การศึกษาแบบภาคตัดขวางในผู้ป่วยต้องสงสัยวัณโรคที่มารับการรักษา ณ โรงพยาบาลแม่สาย และโรงพยาบาลลำปางระหว่างเดือนเมษายน พ.ศ. 2552 ถึง พฤษภาคม พ.ศ. 2553 ผู้ป่วยได้รับการตรวจซีรัมด้วย ICT-TB 2 ชนิด คือชนิดที่ผลิตในประเทศไทยเคลือบด้วย แอนติเจน 38 kD, 16kD, และ 6kD และชนิดนำเข้าจากต่างประเทศที่เคลือบด้วยแอนติเจน 38 kD และ lipoarabinomanan [LAM] จากนั้นติดตามผู้ป่วยเป็นเวลา 2 เดือน*

ผลการศึกษา: *ผู้ป่วยทั้งสิ้น 401 ราย พบวัณโรค 146 ราย (36.4%) ติดเชื้อ human immunodeficiency virus (HIV) 206 ราย (51.4%) ICT-TB ผลิตในประเทศให้คุณค่าของการวินิจฉัยสูงกว่าชนิดนำเข้าในทุกค่าการวินิจฉัยยกเว้นค่าความจำเพาะ เมื่อทดสอบในผู้ป่วยทั้งหมดได้ความไวต่ำ 35.6% (95% CI: 30.9-40.3) ใน ICT-TB ที่ผลิตในประเทศ และ 13.7% (95% CI: 10.3-17.1) ใน ICT-TB ชนิดนำเข้า แต่ได้ความจำเพาะสูงและมีค่าเท่ากัน คือ 93.7% (95% CI: 91.4-96.1) คุณค่าการวินิจฉัยในผู้ป่วยไม่ติดเชื้อ HIV สูงกว่าในกลุ่มติดเชื้อ HIV เมื่อยังไม่ได้ปรับ ด้วยระดับ CD4+ ค่า likelihood ratios (LHR) ของผู้ป่วยที่มีระดับ CD4+ มากกว่า 200 cells/μL สูงกว่าผู้ป่วย ไม่ติดเชื้อ HIV (LHR+ 7.6 vs. 4.8 ใน ICT-TB ที่ผลิตในประเทศ และ 2.5 vs. 1.9 ใน ICT-TB ชนิดนำเข้า)*

สรุป: *ผลที่ได้จากโรงพยาบาลที่ศึกษา ICT-TB ที่ผลิตในประเทศมีคุณค่าในการใช้เป็นเครื่องมือทดสอบเบื้องต้นในการคัดเข้าผู้ต้องสงสัยวัณโรค พบว่าผู้ไม่ติดเชื้อ HIV และผู้ติดเชื้อ HIV ที่มีระดับ CD4+ มากกว่า 200 cells/μL อาจได้รับประโยชน์สูงสุดจากการใช้เครื่องมือวินิจฉัยนี้*