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IGRA Testing in Suriname, an Intermediate Tuberculosis Incidence Country

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Abstract

Background: Latent tuberculosis can progress to active TB. To diagnose LTBI the TST is used, which shows cross reactivity with NTM and BCG, giving way to overdiagnosis of LTBI. The sophisticated QFT is also used to diagnose LTBI and hardly has cross reactivity. Based on previous findings we assumed overdiagnosis of LTBI in Suriname because of false positive TST results due to NTM. Method: To evaluate our premise, we conducted a prospective study comparing the TST and QFT results of patients who had undergone both tests. Results: 64.1% of patients with a positive deemed TST had a negative QFT result, of which 64% were not prescribed TPT or did not complete TPT. At one year follow up no cases of active TB were encountered. Conclusion: False positive TST results lead to overestimation of LTBI incidence. Whenever an unexpected positive TST result is encountered it is advisable to perform a QFT for a more accurate diagnosis.

Keywords

QFT, TST, LTBI, NTM, BCG

1. Introduction

To eliminate TB worldwide it is important to identify and treat patients with latent tuberculosis infection (LTBI) [1], and as such preventing progress to active TB disease. However, LTBI is a clinical diagnosis and there are no laboratory tests to diagnose LTBI with certainty. For more than a century [2] the not so specific Tuberculin Skin Test (TST) is used to aid in the diagnosis of LTBI and for about 2 decades [3] the more specific [4] Interferon Gamma Release Assay (IGRA) test is

used in the diagnosis of LTBI. Latent tuberculosis infection is defined by the World Health Organization (WHO) as a state of persistent immune response to stimulation by *Mycobacterium tuberculosis* antigens with no evidence of clinically manifest active tuberculosis [1]. Tuberculosis (TB) is an airborne infectious disease caused by the tuberculosis bacteria, which is spread by infectious TB patients in droplet nuclei through coughing, speaking, singing and sneezing [5]. After exposure to tuberculosis bacteria, about 20% - 25% of individuals can be infected, of whom 5% may develop active disease in the ensuing 2 years and the remaining 95% enter a state of LTBI, because of the host immune response [6]. Within 2 to 5 years about 5% to 15% of LTBI people progress to active tuberculosis, which is designated as reactivation [7] [8]. The phenomenon of reactivation depends on bacterial, host and environmental factors [9], such as HIV infection, organ transplantation, silicosis, use of tumor necrosis factor alpha blockers and kidney dialysis [10]. Accordingly, individuals with LTBI can be considered to be a reservoir for new active TB cases [11] [12]. To tackle the global TB epidemic the End TB Strategy was devised by the WHO, which envisions a world free of TB, with zero deaths, disease and suffering due to TB by the year 2035. A very important aspect of this strategy is to identify and treat people with LTBI [13], vulnerable populations being people living with HIV, household contacts of TB patients, children, people with diabetes mellitus, prisoners, homeless people, workers exposed to silica, migrants and refugees [14]. Based on local epidemiology and the health system, high risk groups for LTBI should be identified and interventions tailored to their needs, minimizing the risk of adverse events during preventative treatment [1].

It is estimated that about a quarter of the global population has LTBI [15]. As there is no gold standard method to diagnose LTBI, the TST and IGRA are used in the diagnostic process, both dependent on a competent host immune system [1]. The TST is performed by intradermal injection of purified protein derivative, a mixture of several mycobacterial antigens found in tuberculosis bacteria, Bacille Calmette-Guérin (BCG) vaccines and in the environmentally abundant non tuberculous mycobacteria (NTM) [16]. The interpretation and classification of the dermal reaction is according to the American Thoracic Society (ATS) guidelines, with cut off values for TST positivity set at 5, 10 and 15 mm depending on the patients a priori chance of being infected with TB [17]. As such interpretation of the TST result is deemed positive depending on the local incidence of TB, the anamnesis and chest x ray of the patient [17]. On the contrary, IGRA is a cell mediated in vitro blood test which measures interferon gamma released by T lymphocytes, after stimulation by mycobacterium tuberculosis complex specific antigens ESAT-6 and CFP-10 [18]. This cell mediated in vitro diagnostic blood test has cross reactivity with a few NTM like *M. kansasii*, *M. szulgai, M. flavescens* and *M. marinum,* but not with BCG [19]. Both the TST and IGRA are used in the diagnostic process of LTBI, with the choice of test method being based on affordability and availability [1], while the TST is an inexpensive test, IGRA tests require a

laboratory for processing [16] [18]. Suriname, a South American nation with an upper-middle income [20] with a tropical climate and a population of approximately 610.000, had an intermediate TB incidence of 180 (130 - 220) patients in 2021, resulting in a rate of 29 (22 - 36) per 100.000 [21]. For decades the TST is used in the detection of LTBI [22], but because NTM is widely present in Suriname [23], there is concern about TST results which could be unjustly classified as positive and as such a patient being diagnosed with LTBI. Recently IGRA testing was made available in Suriname, making it possible to diagnose LTBI with more certainty and make implausible NTM [18] [24] [25] cross reactivity. To gain insight in probable misdiagnosis of LTBI, we conducted a prospective comparative study between TST and IGRA.

2. Method

A descriptive study comparing the TST results to IGRA testing was set up, the IGRA test results being considered the definitive diagnostic result. In Suriname the TST is done at the offices of the National Tuberculosis Program (NTP), with the cutoff values for positivity set at 5 mm for children and people living with HIV, 10 mm for other contacts of TB patients and 15 mm for the general population [22]. IGRA testing was done at a private laboratory who would provide 50 QuantiFERON-TB Gold (QFT®) ELISA tests (QIAGEN GmbH) free of charge as an introductory promotion. From May 1st to July 31st 2023, a TST and the QFT was done in patients with a medical condition suggestive of tuberculosis, drug abusers who would take part in an institutionalized rehab program, and Surinamese students who would study abroad and needed an obligatory TST result (requested by the host country). Patients were seen by pulmonologist, internal medicine specialist or pediatrician, where a thorough patient history was taken, a chest x ray made, and depending on the anamnesis sputum analysis by smear and PCR test was done. HIV testing was not done. The TST results were available within 1 week, whereas the QFT results were available 6 - 8 weeks after testing. It was at the discretion of the treating medical specialist, based on the ATS guidelines [17], to start tuberculosis preventative treatment (TPT) while waiting for the QFT result. Patients with a TST deemed positive, were given follow up appointments at the treating physician. Patients who had a negative deemed TST and a negative QFT were evaluated by telephone consult 1 year after initial testing, the main questions being chronic cough, weight loss, persistent fever, night sweats and their overall wellbeing.

3. Results

Our study recruited 54 patients, 3 were excluded from evaluation because 2 did not have a TST result and 1 had no QFT result, moreover these patients were lost to follow up early in the evaluation process, for not attending their scheduled appointment with the treating medical specialist and they also could not be reached by telephone. Analysis was thus done for 51 patients, 33 being male, the youngest

patient being 3 years of age and the oldest 82 years. A total of 9 patients were lost to follow up (LTFU). Patient demographics, TST result/classification, QFT result, BCG vaccination status, the interventions applied as well as follow up results at 1 year after QFT testing are shown in Table 1.

Table 1. Overview of results and intervention.

		N
Sex	Male	33
	Female	18
Tuberculin Skin Test	Negative	12
	Positive	39
Quantiferon Gold Test	Negative	36
	Positive	11
	Indetermined	4
Intervention	TPT	15
	no TPT/BCG	5
	HREZ	4
	no TPT	27

TPT: tuberculosis prophylaxis therapy; BCG: bacille Calmet Guerin vaccination; HREZ: isoniazid/rifampicin/ethambutol/pyrazinamide.

The TST was deemed positive for 39 patients, of whom 11 had a positive QFT result, 25 a negative QFT result and 3 an indeterminate QFT result. Six patients with a positive QFT result completed treatment with TPT, 3 patients completed treatment with first line tuberculostatics, 1 (who claimed to have been BCG vaccinated in Guyana) never attended follow up visit at the pulmonologist and 1 patient with uveitis had to stop TPT (isoniazid and rifampicin respectively) because of elevated liver enzymes, ASAT and ALAT, well above 200 IU/L. At 1 year follow up this patient had no signs of active tuberculosis. Of the 3 patients with a positive deemed TST and an indeterminate QFT result, 1 with recurrent pleural fluid was presumptively treated with first line tuberculostatics, resulting in normalization of the chest x ray. The 2 other patients were not prescribed TPT and they had no signs of active tuberculosis 1 year after initial testing. Of the 25 patients with a positive TST but a negative QFT, 4 were lost to follow up at an early stage, 8 were prescribed TPT based on the diagnosis of referral of whom 5 completed TPT before the QFT result was available and 3 discontinued TPT within a month of initiation once the QFT result was known to be negative. 13 patients had a wait and see policy. None of these 16 patients had signs of active TB at 1 year after initial evaluation.

Of the 12 patients with a negative deemed TST result, 11 had a negative QFT

and 1 had an intermediate QFT result. None of these patients were prescribed TPT. At 1 year after initial evaluation, 8 had no signs of active TB ant the other 4 were LTFU. Four MDRTB contact patients with a positive TST, who were BCG vaccinated in their country of birth (Malaysia), had a negative QFT. The 4 patients with an intermediate QFT result had no repeat QuantiFERON-TB Gold ELISA test done due to shortage of tests.

See Supplement S1 for complete results.

4. Discussion

The TST and QFT are both used in the diagnosis of LTBI, with the TST being much more susceptible to cross reactivity with NTM and BCG. In Suriname the TST is used, but when the QFT was available we conducted a study to compare the results of these 2 tests, the QFT regarded as the more specific test to diagnose tuberculosis infection. In our cohort of the 39 patients with a positive deemed TST, 25 patients had a negative QFT result, which is in line with our surmise of TST mostly being falsely considered positive in Suriname. Follow up was possible for 21 (84%) of these 25 patients of which 16 (64%) had no TPT, but none of them showed signs of active tuberculosis at 1 year after the first consult at the pulmonologist. A false positive TST could be the result of an allergy to (repeat) PPD intradermal injection [26] or BCG vaccination, but this is not a likely cause for a positive TST in Suriname. The last mass BCG vaccination of the local population was in 1955 and 1956 [27] and because of the elapsed time, the effect of BCG on the TST can be expected to have waned [28]. Also, a reading error of the TST seems unlikely because the skin induration is measured by 2 certified nurses.

In our opinion these findings support our thought that the discrepancy between the positive deemed TST and the subsequent negative QFT result is probably attributable to NTM [16] [29], which is abundant present in Suriname [23] [26]. As a consequence overdiagnosis of LTBI and subsequent treatment as well as overestimation of LTBI incidence is possible.

The omission of a HIV test is a limitation of our study, because both the TST and the QFT require a competent host immune system to provoke a response at skin level or in blood [1]. Also, the 1 year follow up period of our study can be considered as a limitation, because up to 97% of active TB cases in TB contacts occur within 2 years of exposure to the index case [30]. The QFT was regarded as the reference test in our study, where 64.1% of the positive TST results turned out to be negative according to the QFT. However, ESAT-6 and CFP-10 antigen detection can be erroneous resulting in false negative or false positive test results [31]. In case of a false negative QFT, there will be underestimation of LTBI incidence. The TST is a cheap test with no need for a laboratory, but cross reactivity with NTM and BCG. Cross reactivity with BCG and NTM could be suspected when a patient is BCG vaccinated or when a patient has no risk factors for TB but has a positive TST and a normal chest x ray. In this case we recommend an IGRA test which renders a TB infection less likely when the IGRA test result is negative

[32]. We also recommend an IGRA test to be performed whenever an unexpected positive TST result is encountered. We have seen this phenomenon in persons who had no risk factors for tuberculosis but had to do a TST because of emigration procedures. In countries with an intermediate incidence of tuberculosis and a high prevalence of NTM, a positive deemed TST in a person with no risk factors for TB, should have follow up with an IGRA test to make less likely a false positive TST result. Alike, a TB contact with a negative deemed TST should be reassessed with an IGRA test to exclude a false negative TST, assuming the TB contact has a competent immune system.

5. Conclusion

LTBI is a clinical diagnosis based on the anamnesis, findings on the chest x ray and a positive TST or QFT, with the QFT being a more accurate diagnostic tool in the diagnosis of LTBI while the TST has cross reactivity with BCG and NTM.

Credit Author Statement

Fitzgerald Gopie: conceptualization, methodology, investigation, data curation, original draft preparation. Jayant Kalpoe: conceptualization, methodology, resources, reviewing, funding acquisition. Sheila Kort: conceptualization, methodology, resources, data curation, reviewing, funding acquisition.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Supplement

Table S1. Complete results.

sex	age (yr)	TST (mm)	TB risk factor	TST cutoff*	TST codification	QFT result	intervention	Follow Up at 1 year
M	15	10	contact RRTB	10	pos	pos	TPT	TPT completed
F	61	15	uveitis	10	pos	pos	TPT	TPT stopped, no complaints
M	49	11	drug abuse	10	pos	pos	TPT	TPT completed
M	20	12	contact MDRTB	10	pos	pos	no TPT/BCG	LTFU
M	41	15	uveitis/TB contact	10	pos	pos	HREZ	completed EPTB treatment
M	28	17	study abroad	15	pos	pos	TPT	TPT completed
M	69	15	contact TB	10	pos	pos	TPT	TPT completed
M	65	22	drug abuse	10	pos	pos	TPT	TPT completed
F	55	15	uveitis	10	pos	pos	TPT	TPT completed
M	53	18	cervical lymphnodes	15	pos	pos	HREZ	completed EPTB treatment
F	57	11	tumor in right lung	10	pos	pos	HREZ	PTB treatment, CXR normalised
F	34	13	contact RRTB	10	pos	neg	TPT	TPT completed
M	47	11	contact RRTB	10	pos	neg	TPT	TPT stopped, no complaints
M	39	15	drug abuse	10	pos	neg	no TPT	no complaints
M	61	11	uveitis	10	pos	neg	TPT	TPT completed
M	44	10	contact MDRTB	10	pos	neg	no TPT / BCG	no complaints
M	48	18	contact MDRTB	10	pos	neg	no TPT / BCG	no complaints
M	47	17	contact MDRTB	10	pos	neg	no TPT / BCG	LTFU
F	36	19	contact MDRTB	10	pos	neg	no TPT / BCG	no complaints
M	24	19	contact TB	10	pos	neg	TPT	TPT stopped, no complaints
F	33	20	study abroad	15	pos	neg	TPT	TPT completed
F	21	10	contact TB	10	pos	neg	no TPT	no complaints
F	31	17	study abroad	15	pos	neg	TPT	TPT stopped, no complaints
M	49	15	etra pulm TB?	10	pos	neg	no TPT	no complaints
M	13	12	contact RRTB	10	pos	neg	TPT	TPT completed
M	46	15	study abroad	15	pos	neg	no TPT	LTFU
M	57	18	drug abuse	18	pos	neg	no TPT	no complaints
F	66	18	contact TB	10	pos	neg	no TPT	no complaints
F	31	10	contact TB	10	pos	neg	no TPT	LTFU
M	47	10	contact TB	10	pos	neg	no TPT	no complaints
M	31	11	contact TB	10	pos	neg	no TPT	LTFU

Continued

F	56	10	contact TB	10	pos	neg	no TPT	no complaints
M	62	10	contact TB	10	pos	neg	no TPT	no complaints
F	54	10	contact TB	10	pos	neg	no TPT	no complaints
F	32	10	uveitis	10	pos	neg	TPT	TPT completed
M	22	11	drug abuse	10	pos	indeterm	no TPT	no complaints
M	56	16	study abroad/jailed	10	pos	indeterm	no TPT	no complaints
M	45	10	skin granuloma	10	pos	neg	no TPT	no complaints
M	19	13	recurrent pleural fluid	10	pos	indeterm	HREZ	PTB treatment, CXR normalised
M	41	10	coughing	15	neg	neg	no TPT	no complaints
M	60	7	contact RRTB	10	neg	neg	no TPT	no complaints
M	50	0	contact TB	10	neg	neg	no TPT	LTFU
M	7	0	contact TB	10	neg	neg	no TPT	LTFU
F	3	0	contact TB	5	neg	neg	no TPT	LTFU
M	36	13	study abroad	15	neg	neg	no TPT	no complaints
F	66	0	recurrent pleural fluid	10	neg	neg	no TPT	heart failure
M	82	5	recurrent pleural fluid	10	neg	neg	no TPT	died, pleuritis eci
F	18	0	study abroad	15	neg	neg	no TPT	LTFU
F	64	11	haemoptoe	15	neg	neg	no TPT	no complaints
M	48	5	thoracic spine tumor	15	neg	neg	no TPT	died, lungcancer
F	74	0	pulmonary nodule	10	neg	indeterm	no TPT	no complaints

DM: diabetes mellitus; CKD: chronic kidney disease; HCW: health care worker; TST: tuberculin skin test; QFT: quantiferon gold test; TPT: tuberculosis prophylaxis therapy; BCG: bacille Calmet Guerin vaccination; LTFU: lost to follow up; pos: positive; neg: negative; indeterm: indeterminate; CXR: chest x ray; (E)PTB: (extra) pulmonary TB.