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Cost-effectiveness of QuantiFERON testing prior to initiation of biologic therapy in inflammatory bowel disease

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Abstract

Background—Anti-TNF α drugs are known to reactivate latent tuberculosis (TB). Current guidelines recommend screening for latent TB infection (LTBI), with either tuberculin skin test (TST) or interferon gamma release assays (IGRA) such as QuantiFERON-TB Gold (QFT-G). Given the high rates of anergy to TST among immunosuppressed IBD patients, there is considerable interest in evaluating the superiority of IGRAs over TST in this patient population to diagnose LTBI. We compared the performance of TST and QFT-G for screening latent TB among immunosuppressed IBD patients based on prevalence, mortality risk from reactivation TB, and costs.

Methods—A decision analytic model was constructed to compare one-year outcomes and costs of using TST or IGRA in an immunosuppressed IBD population.

Results—Under the base case scenario, for every 1000 patients screened, the QFT-G strategy resulted in 0.53 deaths from TB reactivation compared to 1.92 deaths using TST. The QFT-G strategy results in 1.85 TB reactivations vs. 6.7 TB reactivations using TST. The model was not sensitive to background prevalence of latent TB. The cost of QFT-G would have to more than double for the TST strategy to become more cost-effective. QFT-G also remains the cost-effective option unless the sensitivity of the TST improves by 400%.

Conclusion—Under a broad range of parameter values, the QFT-G strategy dominates the TST strategy in cost-effectiveness. Consideration should be given to QFT-G as the preferred method of identifying latent TB in all immunosuppressed IBD patients.

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Arun Swaminath is responsible for the study question. All authors were equally involved in study design, data analysis, and authorship of the manuscript.

Keywords

interferon gamma release assay; cost-effectiveness; latent tuberculosis reactivation; IBD

Background

Patients with moderate to severe inflammatory bowel diseases (IBD), Crohn's disease or ulcerative colitis, require immunosuppression in order to maintain long term disease remission. Anti-tumor necrosis factor (TNF) α antibodies were approved for the management of Crohn's disease in 1998 and for ulcerative colitis in 2005. Up to 5 fold higher incidence of latent tuberculosis reactivation has been observed in this population, secondary to inhibition of TNF α and related chemokine networks.^{1, 2} Keane et al., reported that the majority of patients developed disseminated or extra pulmonary disease within 3 months of exposure to anti-TNF α drugs. Tuberculosis was attributed as the direct cause of 4 deaths among 70 patients (5.7%) with TB reactivation.³

As a result, clinical and manufacturers guidelines now recommend screening patients for LTBI prior to anti-TNF α use. In routine clinical practice within the U.S., LTBI testing in IBD patients prior to anti-TNF α exposure involves a thorough history taking focused on TB risk factors, tuberculin skin test (TST) and chest x-ray in patients with positive TST or negative TST with high suspicion prior to treatment.^{4, 5} About 20% of all persons with known active tuberculosis can have lack of response to TST.⁶ False negative TSTs can also be the result of anergy as well as observer error. The sensitivity of TST testing in immunocompromised patients is limited due to high levels of anergy.

Mow et al. found that 83% of IBD patients already on treatment with steroids or immunomodulators were anergic to the TST.⁷ In another study of immunocompromised patients, out of 32 patients with TB, only 50% had a positive TST.⁸ This high rate of anergy has been demonstrated by various studies of patients with chronic immunosuppression.^{9, 10} Conversely, the specificity of the tuberculin test is also reduced due to false positives secondary to cross reactivity among patients exposed to environmental mycobacteria or prior vaccination with bacille Calmette–Guérin (BCG).¹¹

In 2001, the FDA approved the first interferon gamma release assay, which measured the level of interferon gamma release from peripheral blood lymphocytes after *in vitro* exposure to mycobacterium tuberculosis antigens. Subsequent improvements to the assay incorporated synthetic peptides, which mimicked ESAT-6 and CFP-10, antigens specific to *M. tuberculosis* but absent from BCG vaccine strains and non-tuberculosis bacteria. In 2005, the CDC supported Quantiferon-Gold (QFT-G) (Cellestis Ltd, Carnegie, Victoria, Australia) to be interchangeable with TST.¹² Most studies comparing TST to IGRA performance in immune suppressed populations suggest sensitivity and specificity of IGRA is superior to TST,^{9, 13–15} but not all.^{16, 17} Additionally, IGRA positivity has been shown to be more closely related to TB risk than positive TST results.^{18, 19} However, the lack of a gold standard test for the diagnosis of LTBI makes the direct evaluation of the sensitivities and specificities of TST and IGRAs difficult.¹¹ The drawbacks of IGRA testing include the higher cost of the test and the high rate of indeterminate results in patients on long term corticosteroids and immune modulators, reported to be between 2 to 15.6% in literature.^{8, 20, 21}

Reflecting the inconclusive evidence, the U.S., U.K., and Canadian guidelines on LTBI testing do not offer consensus on the best practice.^{22–24} There are currently no cost effectiveness studies comparing the efficacy of either TST or IGRA testing in reducing TB reactivation specifically among the inflammatory bowel disease patients about to initiate

biologic treatment. We sought to compare the costs and benefits of these two strategies in via decision analytic modeling.

Methods

Base Case Population

In our base case analysis, we modeled 1000 US born, 35 year old patients with moderately to severely active Crohn's disease, currently being treated with immunomodulators or prednisone (>15mg/d). According to the literature, the prevalence of TB in the general US population is approximately 4%.²⁵ We varied this assumption in the sensitivity analysis to account for higher rates of LTBI among foreign-born US residents.

Model Structure

A decision tree model was constructed to compare TST and QFT-G in order to identify LTBI in the population of interest (Figure 1). The main outcome measure is the reduction of reactivation of tuberculosis in patients within the first year of treatment with biologic agents. Additional outcome measures included death from TB reactivation, false positive test results and cost. The model adopts a healthcare payer, rather than societal, perspective. In each screening arm, patients could be identified as true positive, true negative, false positive, or false negative. Test characteristics for TST were determined based on a tuberculin positivity cutoff at 5mm.^{6, 26} Patients who are treated are at risk of adverse drug reaction from treatment with 9 months of isoniazid therapy. Adverse effects modeled included hepatitis and death from hepatitis. False negative patients, who had LTBI but not treated, were at a higher risk of reactivation TB from which they could recover or die. The time frame was one year from date of initiation of anti-TNF α therapy. The model was constructed using TreeAge Pro Suite 2011 (Williamstown, MA).

Assumptions

While reactivation of tuberculosis is possible any time after anti-TNF α exposure, the majority occur within the first 12 months.^{3, 24} We chose to model only the first 12 months of treatment with the assumption that if the model proved to show superiority of a testing strategy within the first year, these benefits would only increase over longer periods of time. We did not model the following outcomes because they are extremely rare: secondary cases of TB from reactivation, especially since most reactivations appear to be extra pulmonary; TB reactivation despite successful treatment with INH; and outcomes resulting from indeterminate tests or noncompliance with LTBI prophylaxis, given that these patients would not be initiated on biologic therapy. Given the relatively low rates of multidrug resistant tuberculosis in the US,²⁷ we did not include these cases in the model. Additionally, we assumed that indeterminate tests would lead to repeat testing one time. A second indeterminate test was assumed to lead to further consultation rather than treatment with anti-TNF medication. We also did not model patients who did not return to have their PPD tests interpreted during a second visit as these patients would not be started on Anti-TNF therapy. Hence, the cost of TST includes *all* visits required to have an interpretable result. Although there are multiple FDA approved IGRAs, our model incorporates data specific to QFT-G only.

Parameter Inputs

Where available, we used data specific to IBD populations. When this information was lacking, we used data obtained from immunosuppressed autoimmune (i.e. rheumatoid arthritis) populations as a surrogate. Table 1 summarizes the base case inputs.

World Health Organization data was used to determine the 4% prevalence of LTBI in the US.²⁸ Sensitivity analysis for LTBI prevalence ranged from 1–70%. Cost of TST, QFT-G, LTBI prophylaxis with isoniazid for 9 months, cost of treatment of reactivation TB including need for hospitalization, cost of death from reactivation TB, cost of reversible hepatitis, and cost of fatal hepatitis were obtained from Linas et al.²⁹ We varied the costs of the TST and QFT-G to determine the prices at which the two strategies are equally cost-effective. Probability of death from reactivation from TB was obtained from the infliximab package insert. One-way sensitivity analyses was used to incorporate the lower bound of the probabilities of death from reactivation identified by Denis et al.³⁰

The sensitivity of the TST and QFT-G in immunosuppressed populations had a large variation within the literature. We started with the most recent data by Linas to establish pooled TST sensitivity of 0.89 and QFT-G sensitivity of 0.83.²⁹ By assuming that anergy was the only reason for false negative TSTs in this population, we estimated an 83% false negative rate based on Mow et al.⁷ Of the remaining 17% LTBI patients, 89% would be correctly diagnosed resulting in a sensitivity of 15.13%.

Published data suggest IGRA is indeterminate 12% of the time in autoimmune immunosuppressed populations.¹⁴ Approximately 7.5% of results remain indeterminate after 2 repeat studies.¹⁶ Of the remaining 92.5% patients, 83% would be properly identified as LTBI+, giving a QFT-G sensitivity of 76.78% among immunosuppressed IBD patients.

The one way sensitivity analysis included the full range of values from multiple sources in the literature.^{7, 9, 13, 15} For example, recalculating sensitivity for both tests using pooled sensitivities from Pai et al.³¹, resulted in TST sensitivity of 11.88% and QFT-G sensitivity of 89.73%.

Results

Under base case assumptions, for every 1000 immunosuppressed IBD patients screened for LTBI, the choice of QFT-G over TST would avoid 30 false negative cases of LTBI, 4.92 TB reactivations, 1.4 deaths, and \$71,520 in costs (Table 2). The QFT-G strategy dominates the TST strategy by producing greater health gains with lower cost.

Worldwide, MTB infection among adults ranges from 14–46%, with certain outliers such as Cambodia with 76% population prevalence.²⁸ One-way sensitivity analysis was performed to include a range of LTBI prevalence of 1% to 76% in the base case estimate and the QFT-G strategy dominated across all of the ranges (Fig 2, panel A). The probability of death from reactivation of TB ranges from 4.8%³⁰ to 28.75% (infliximab insert). One-way sensitivity analysis was performed across this range and the QFT-G strategy, again, dominated (Fig 2, panel B).

The sensitivity of QFT-G would have to decrease by 71% of the base case value in order to have TST as the preferred strategy (Fig 3, panel A). Alternatively, the sensitivity of the TST would have to increase by 462% of the base case value in order to be the preferred strategy (Fig 3, panel B). These are extreme deviations from the baseline value and unlikely to be true in reality, hence the QFT-G strategy appears dominant across any reasonable deviation from the base case sensitivity values.

The base case conclusion was not sensitive to the cost of the TST (data not shown). The cost of the QFT-G test would have to more than double in order for the TST to be the preferred strategy (Fig 4). Two way sensitivity analysis for both cost and sensitivity parameters are provided (Figs., Supplemental Digital Content 1 and 2, <http://links.lww.com/IBD/A236> and

<http://links.lww.com/IBD/A237>) and demonstrate the degree of change in either parameter that would be required in order to change the preferred testing strategy.

Discussion

This study marks the first decision analysis model comparing the efficacy of IGRA and TST in IBD patients on long-term immunosuppressive therapy. Screening for LTBI in immunosuppressed populations is complicated by the lack of gold standard diagnostics as well as the decreased performance characteristics in this group of patients. Patients on prednisone doses >15mg/d or on long term immunosuppression with azathioprine/6-mercaptopurine are likely to have suppressed T-cell responses. Both TST and IGRA tests are dependent upon T-cell responses in order to identify patients with LTBI.

This decision analysis illustrates that despite highly varying sensitivities of these tests in immunosuppressed IBD patients, QFT-G testing is dominant to TST when outcomes of interest are avoidance of false negative LTBI designation, reactivation of MTB, death due to reactivation MTB, and direct costs of the tests.

We assigned the rate of reactivation of latent TB as our main outcome both due to its clinical relevance and because this event is likely to occur at higher frequency than death from reactivated tuberculosis. Aside from overall costs, we highlighted the rate of false positives as an important outcome because it serves as a marker for additional costs to society through public health contact investigations and outpatient follow up, as well as patient important outcomes such as anxiety and emotional trauma resulting from false diagnosis, neither of which are integrated in this model.

One of the major limitations of this study is inherent to decision sciences overall. The accuracy of models in reflecting reality is based on the accuracy of the inputs utilized and hence the quality of the studies these inputs originate from. The lack of gold standard in LTBI diagnosis yields a range of values for test parameters for both IGRA and TST use. Additionally, the costs are specific to the US. The range of costs and sensitivities at which our conclusions remain true for other countries are delineated in Figs., Supplemental Digital Content 1 and 2, <http://links.lww.com/IBD/A236> and <http://links.lww.com/IBD/A237>.

Under broad assumptions of sensitivity, cost, and LTBI prevalence, the QFT-G strategy dominated the TST strategy to identify true LTBI among immunosuppressed IBD populations. Our decision analysis supports a call by others^{9, 32} to make QFT-G testing to be preferred method, rather than an interchangeable method, of identifying LTBI among the immunosuppressed IBD population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

IBD inflammatory bowel disease

IGRA	interferon gamma release assay
LTBI	latent tuberculosis infection
QFT-G	QuantiFERON Gold
TB	tuberculosis
TNF	tumor necrosis factor
TST	Tuberculin Skin Testing

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Figure 1.
Decision tree of the two testing strategies and possible outcomes.

Figure 2.

One way sensitivity analysis to determine if change in testing strategy is recommended based on variance of LTBI risk (panel 2A) or the risk of death from reactivation TB (panel 2B).

Figure 3.

One way sensitivity analysis to identify threshold at which TST equals QFT-G by variation in the LTBI detection sensitivity of QFT-G (panel 3A) and TST (panel 3b).

Figure 4. One way sensitivity analysis to determine cost-equivalence between TST and QFT-G by varying cost of QFT-G.

Table 1

Variable *	Value	Range for Sensitivity Analysis	Reference
Latent TB prevalence	4.2%	1–76%	WHO Data (2000)
Anergy TST in immunosuppression	82%		Mow (2004), Papay (2011), Schoepfer (2008).
Sensitivity TST	15.13%	11–90%	Calculation based on anergy and pooled sensitivity (see sample calculation in text) Linas (2011), Pai (2008), Mow (2004), Schoepfer (2008), Qumsey (2011),
Sensitivity QuantiFERON	76.78%	5–90%	Calculation based on anergy and pooled sensitivity (see sample calculation in text), Linas (2011), Pai (2008), Mow (2004), Schoepfer (2008), Qumsey (2011), Sellam (2007),
TB Reactivation risk with biologic exposure	19%	10–30%	Keane (2001), Brassard(2006),
Probability of death from reactivation TB	28.57%	4.8–30%	Infliximab Package Insert, Denis (2008)
Cost TST	\$41.80	\$10–80	Linas (2011)
Cost QuantiFERON	\$51.77	\$40–150	Linas (2011)
Cost isoniazid Prophylaxis	\$51.34		Linas (2011)
Cost of hepatitis from isoniazid	\$182.61		Linas (2011)
Cost of survival of reactivation TB	\$14307		Linas (2011)
Cost of death from reactivation TB	\$22464		Linas (2011)

* Variables are referenced for immunosuppressed IBD patients when available.

Table 2

<i>Base case x 1000 patients</i>	TST	QuantiFERON
<i>False negatives</i>	40	10
<i>TB Reactivations</i>	6.77	1.85
<i>TB deaths</i>	1.93	0.53
<i>Cost</i>	\$156,370	\$84,850

* Preferred strategy in bold.