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Assessment of PPD Conversion Rate in Patients Receiving Tumor Necrosis Factor-alpha Inhibitor Drugs

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ABSTRACT

Background & Objective: Tumor necrosis factor-alpha (TNF-α) inhibitors are widely used in rheumatologic diseases but may increase the risk of primary tuberculosis (TB) infection or reactivation. Purified protein derivative (PPD) conversion is an important indicator of latent TB in immunosuppressed patients. This study aimed to determine the rate of PPD conversion and associated factors in patients receiving anti-TNF therapy.

Methods: This prospective study included adults with rheumatologic diseases who initiated anti-TNF therapy between March 2021 and September 2023. Patients with prior TB, previous anti-TNF exposure, or a positive baseline PPD were excluded. A PPD test was performed before treatment and repeated one year later. An induration ≥5 mm at follow-up was considered conversion.

Results: Sixty patients completed the study (mean age 44.29 ± 14.70 years; 56.7% male). Six patients (10.0%) demonstrated PPD conversion after one year of anti-TNF therapy. Most conversions occurred in individuals with psoriatic arthritis (66.6%). No cases of active TB were detected clinically or radiologically. Statistical analysis showed no significant association between PPD conversion and age, sex, disease duration, anti-TNF type, methotrexate or corticosteroid use, diabetes mellitus, or hypertension. Psoriatic arthritis was the only factor significantly associated with conversion (P = 0.03).

Conclusion: Ten percent of patients receiving anti-TNF therapy developed PPD conversion, indicating new latent TB infection. Psoriatic arthritis was significantly associated with conversion, while medication type and other clinical factors were not. These findings support routine annual TB screening in anti-TNF recipients, particularly in regions with moderate or high TB prevalence.

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Introduction

Biological drugs revolutionize the treatment of various diseases, including autoimmune and malignancies (1). Recent studies have been focused on novel therapeutic targets to help in drug design (2). One of the most potent drugs in this group is anti-TNFs, which include monoclonal antibodies (Adalimumab and Infliximab) and soluble TNF receptors (Etanercept) (3). These drugs play a significant role in disrupting the body's defense mechanisms, including granuloma formation, and therefore, early and long-term control of tuberculosis (TB) infection through the inhibition of TNF-alpha function. As a result, despite their significant efficacy, these drugs can expose their user to primary infection or reactivation of TB (4).

TB, an infectious disease caused by Mycobacterium tuberculosis, is one of the most common causes of death from infectious diseases in adults worldwide. According to the World Health Organization, in 2020 and 2021, respectively, about 10.1 and 10.6 million people around the world were infected with TB, and about 1.6 million people died due to TB in 2021 worldwide (5). In 2015, in Iran, an endemic area for TB, the incidence rate of smear-positive TB was 6.3 per 100 thousand people, and the incidence rate of all types of

TB was 12.6 per 100 thousand people. Also, 757 patients died from this disease in the same year (6).

Due to the significant role of TNF-alpha in the prevention of primary infection or reactivation of tuberculosis bacillus, patients treated with this class of drugs should be monitored for primary infection or reactivation of TB (7). Active TB in these patients causes various complications, including complications caused by TB itself, complications caused by the use of anti-TB drugs, as well as complications caused by the impossibility of continuing treatment with biological drugs and, as a result, insufficient treatment of rheumatic disease (8, 9). This study investigates the PPD conversion (latent TB) rate in anti-TNF recipients.

Materials and Methods

Study population

This study was conducted on patients referred to the rheumatology clinic of Imam Khomeini Hospital in Tehran, who were candidates for receiving an anti-TNF due to their rheumatological disease from Mar 2021 to Sep 2023. The inclusion criteria were age over 18 years, confirmation of anti-TNF initiation by two rheumatologists, and lack of previous anti-TNF consumption. On the other hand, the exclusion criteria were a history of TB or positive PPD test, history of isoniazid consumption, history of recent viral or bacterial infection, or history of recent live virus vaccination (e.g., MMR and polio) in the last 4 weeks, history of surgery or burns in the last 4 weeks, positive test HIV, chronic kidney failure, severe malnutrition, or malignancy.

Study setting

After checking the inclusion and exclusion criteria, two rheumatologists independently evaluated the patients regarding the need to prescribe anti-TNFs. Informed consent was obtained from all patients, and their demographic information, including age, gender, type of rheumatological disease, type of anti-TNF or other medication, history of hypertension and diabetes mellitus (DM), and history of contact with a TB patient, was recorded, and PPD test was performed on patients. In order to do the test, an experienced person, after disinfecting the injection site with alcohol, intradermally injected 10 units (0.1cc, equivalent to 5 international units of tuberculin) of PPD solution into the patient's forearm between the upper third and lower two-thirds. After the injection, a small papule with a diameter of less than 1 cm was created on the skin. If there was no papule, the injection was worthless and repeated. A line was drawn around the injection site with a pen, and the patient was advised to return to the clinic 48-72 hours later for the test analysis. At follow-up, if swelling and induration were present at the injection site, the diameter was measured perpendicular to the arm axis with a ruler and recorded in millimeters. At baseline, patients with a PPD induration ≥10 mm were excluded from the study. Because anti-TNF recipients are considered immunosuppressed, an induration of ≥5 mm at follow-up was regarded as clinically significant according to CDC guidelines for high-risk groups. Traditional definitions requiring a ≥10-mm increase was not applied, as these criteria do not align with immunosuppressed host recommendations (10). Then, the medicine considered was prescribed for each patient, and it was recommended that the patient visit the clinic every three months. In each visit, the patient's general condition, drug side effects, and signs of disease progress were examined, and paraclinical tests were ordered according to the rheumatologist's opinion. Patients with severe adverse drug reactions like thrombocytopenia, leukopenia, or pancytopenia were excluded from the study and were treated accordingly. Finally, a year after the primary PPD, this test was performed on the patients again. Due to patients' immune system condition, patients whose induration diameter was greater than 5 mm were subjected to chest radiography to check for lung involvement, abdominopelvic ultrasound to check for lymphadenopathy, and urine analysis and culture to check for urinary tract TB. In the case of normal results, prophylactic treatment with 300 mg of Isoniazid a day was started for 9 months, and the anti-TNF drug was stopped for two weeks to one month, depending on the patient's condition and the severity of the disease.

Sample size

Based on the study of Hapark et al. (11), considering $\alpha = 0.05$ and $\beta = 0.2$ and according to the estimation formula and ratio calculated bypass 2021 sample size software. The sample size was 60.

Statistical methods

Data were analyzed using SPSS software version 24. Chi-square or Fisher’s exact tests were used for categorical variables, depending on cell size. Fisher’s exact test was selected when expected cell counts were small. The Kolmogorov-Smirnov test was used to determine quantitative data distribution. An Independent T-test was applied to compare the mean of data with normal distribution. Moreover, qualitative data were compared using the Chi-square and Fisher's exact tests. P-value<0.05 was considered significant.

Results

Demographic information of patients

During the period of data collection, 80 patients were examined. 7 patients were excluded from the study due to CKD, 2 due to receiving prophylactic isoniazid, 4 due to viral infection in the last 4 weeks, and 1 patient due to surgery in the last 4 weeks, and a total of 65 patients met the criteria. Among the patients included in the study, 3 were excluded from the study due to unwillingness to continue treatment and 2 due to neutropenia. Both of these patients had rheumatoid arthritis (RA), and Adalimumab was prescribed for them. Among the 60 patients who completed the study,

34 (56.7%) were male, and 26 (43.3%) were female. The average age of the study participants was 44.29 ± 14.70 years. The youngest participating patient was 18 years old, and the oldest patient was 79 years old. None of the patients who developed PPD conversion reported a history of close contact with individuals with active TB.

In terms of the type of rheumatological disease, 17 patients (28.3%) had RA, 16 (26.7%) had psoriatic arthritis, 17 (28.3%) had ankylosing spondylitis (AS), 7 (11.7%) had Behcet's disease, and 3 (5.0%) had other rheumatological diseases (2 cases of Takayasu arteritis and 1 case of Juvenile ankylosing spondylitis). In terms of underlying diseases, 5 patients (8.3%) had DM, 5 (8.3%) had hypertension, and 53 patients (88.3%) reported no comorbidities other than their rheumatological disease. Also, three patients (5.0%) had concurrent DM and hypertension. No patient mentioned a history of malignancy. Regarding the type of anti-TNF drug, 13 patients (21.7%) were treated with Infliximab, 35 patients (58.3%) were treated with Adalimumab, and 12 patients (20.0%) were treated with Etanercept.

The drug history of our patients revealed that 27(45.0%) had used corticosteroids, 2 patients (3.3%) hydroxychloroquine, 4 (6.7%) sulfasalazine, 33 (55.0%), 6 (10.0%) azathioprine, and two patients (3.3%) were treated with leflunomide. Neither of them mentioned a history of using rituximab, cyclophosphamide, or mycophenolate mofetil or higher than 12.5 mg prednisolone per day (Table 1).

Table 1. Demographic information of included people.

		N (Total:60)	%
Age (mean ± sd)		14.70± 44.29	
Gender	Male	34	56.7%
	Female	26	43.3%
Rheumatologic diagnosis	Psoriatic Arthritis	16	26.7%
	Ankylosing Spondylitis	17	28.3%
	Behcet	7	11.7%
	Rheumatoid Arthritis	17	28.3%
	Takayasu's arteritis	2	3.3%
	Juvenile Ankylosing Spondylitis	1	1.6%
Underlying disease	Diabetes mellitus	5	8.3%
	Hypertension	5	8.3%
	Both	3	5%
	Neither	53	88.3%
Type of anti-TNFa	Adalimumab	35	58.3%
	Infliximab	13	21.7%
	Etanercept	12	20%
Other prescribed drugs	Methotrexate	33	55%
	Prednisolone	27	45%
	Azathioprine	6	10%
	Sulfasalazine	4	6.7%
	Hydroxychloroquine	2	3.3%
	Leflunomide	2	3.3%

This table presents the baseline demographic variables, rheumatologic diagnoses, comorbid conditions, types of TNF-α inhibitor administered, and concomitant medications among the 60 patients who completed the study. Values are reported as frequencies and percentages unless otherwise indicated.

PPD test

The present study included 60 patients suffering from rheumatological disease receiving anti-TNFs. One year after treatment initiation, six patients (10.0%) developed PPD conversion, defined as an induration ≥5 mm at follow-up. Among the patients with positive PPD test, 4 (66.6%) were female, and two (33.3%) were male. The average age of people with positive PPD was 49.00 ± 13.74. Among them, four patients (66.6%) had psoriatic arthritis, one (16.6%) had AS, and one (16.6%) had RA. Four of them (66.6%) had no underlying non-rheumatological disease, but one

(16.6%) had DM, and one (16.6%) had hypertension. four patients (66.6%) received adalimumab and two (33.3%) received etanercept. Concomitant therapies included methotrexate in four patients (66.6%) and prednisolone in two (33.3%). Two patients (33.3%) received no additional medication. Table 2 shows the summary of demographic information related to these six patients. Among the six patients with PPD conversion, four had an initial PPD induration <5 mm that later increased to 5–10 mm at follow-up.

Neither of the positive PPD patients had clinical symptoms of TB, and their chest radiography, abdominopelvic ultrasound, urine analysis, and culture revealed no pathological findings. Patients with positive PPD were treated for latent TB, and depending on the conditions and severity of the rheumatological disease, their anti-TNF medication was paused for two to four weeks.

Factors affecting PPD conversion

Our data suggest no significant relationship between latent TB with gender (P-value = 0.38), age (P-value = 0.41), duration of rheumatic disease (P-value = 0.99), AS (P-value = 0.66), RA (P-value = 0.66), use of Infliximab (P-value = 0.32), Adalimumab (P-value = 1.00), Etanercept (P-value = 0.59), glucocorticosteroid (P-value = 0.68), Methotrexate (P-value = 0.68), DM (P-value = 0.42) or hypertension (P-value = 0.42). The only significant relationship observed in this study was the relationship between latent TB and psoriatic arthritis (P-value = 0.03).

Table 2. Characteristics of patients with PPD conversion

	Sex	Age (year)	Rheumatologic disease	Underlying Disease	Type of anti-TNF	Other drugs
1	Female	42	PSA	DM	Adalimumab	MTX
2	Male	35	AS	-	Etanercept	-
3	Male	56	PSA	-	Etanercept	PDN + MTX
4	Female	62	PSA	HTN	Adalimumab	MTX
5	Female	34	PSA	-	Adalimumab	-
6	Female	65	RA	-	Adalimumab	PDN + MTX

PSA: Psoriatic Arthritis, AS: Ankylosing Spondylitis, RA: Rheumatoid Arthritis, DM: Diabetes mellitus, HTN: Hypertension, MTX: Methotrexate, PDN: Prednisolone

Table 3. Baseline and follow-up tuberculin skin test (TST) induration measurements among patients with PPD conversion.

Patient	Baseline TST (mm)	Follow-up TST (mm)	Absolute Increase (mm)	Meets Conversion Criteria?
1	2	7	+5	Yes (≥5 mm in anti-TNF users)
2	0	6	+6	Yes
3	3	9	+6	Yes
4	1	8	+7	Yes
5	4	10	+6	Yes
6	0	5	+5	Yes

Discussion

This study aimed to investigate the rate of PPD conversion in patients receiving anti-TNFs and its related factors. In our study, 10.0% of patients had PPD conversion, of which 66.6% were treated with Adalimumab and 33.3% were treated with Etanercept. 66.6% of patients had psoriatic arthritis, 16.6% had AS, and 16.6% had RA. None of the patients had clinical evidence of active TB. Our study found no significant relationship between PPD conversion and gender, age, duration of rheumatological disease, AS, RA, use of Infliximab, Adalimumab, Etanercept, glucocorticosteroids, Methotrexate, DM, or hypertension and only psoriatic arthritis and PPD conversion were found to have a significant relationship.

A notable point is the occurrence of PPD conversion and the presence of latent TB in anti-TNF consumers, which highlights the importance of annual TB screening in patients taking these drugs (12). According to the findings of our study, no significant cause-and-effect relationship was found between certain types of these drugs and latent TB. Various studies have also been conducted in this field, in which efforts have been made to obtain the prevalence of conversion and its associated risk factors (13-15). Several studies conducted in low-prevalence regions reported correspondingly low rates of PPD conversion. For example, Pattanaik et al. investigated the rate of TB conversion among 123 patients with rheumatological diseases who were treated with biological drugs between 2004 and 2013 (16). They reported that only

one case out of 123 patients (0.8%) was infected with latent TB, which suggests that in areas where the prevalence of TB is low, PPD conversion will not occur frequently. Therefore, there is no need for annual screening for TB. Meanwhile, our study obtained a relatively high prevalence of PPD conversion compared to the prevalence of TB in Iran. We did not observe any cases of active TB among our patients. This finding is most likely attributable to the limited sample size and relatively short follow-up duration, which may have reduced the likelihood of detecting active TB cases.

Our results align with research from other regions where the burden of tuberculosis is a concern among patients receiving anti-TNF therapy. For example, a recent study in Mexico by Zavala and colleagues (2023) found that patients with rheumatoid arthritis had a considerable prevalence of latent TB infection. Their work highlights how underlying rheumatologic conditions, coupled with the use of biologic agents, may create a setting in which TB surveillance becomes critical. The parallels between their findings and ours underscore that this is not merely a local problem but a broader issue affecting diverse populations(17). Similar observations have been reported in East Asia. Song et al. (2021) conducted a prospective study in South Korea and showed that individuals with rheumatoid arthritis receiving targeted therapies, including anti-TNFs, had a notable risk of developing tuberculosis. Their study adds weight to the idea that the combination of host factors, local TB epidemiology, and immunosuppressive treatment together increase vulnerability. Taken together, these international findings suggest that careful and ongoing TB screening should be viewed as an integral component of patient safety strategies wherever anti-TNF drugs are prescribed. The incidence rate of TB in South Korea is higher than in Iran, with about 77 cases per 100,000 people in 2018. Although the incidence rate in South Korea is decreasing, still in 2022, the incidence rate of TB is 35 people per 100,000. Studies on the association of anti-TNFs and the underlying rheumatological or inflammatory disease type have not reached a single result in this field(18). In 2023, Coşkunol et al. conducted a study in Turkey on 520 patients receiving anti-TNF who had a history of receiving TB chemoprophylaxis with isoniazid between 2011 and 2014; they reported a significant correlation between TB conversion and Infliximab (19). This finding was contrary to the findings of our study, in which none of the patients with conversion were treated with Infliximab. Also, Hai et.al. investigated the incidence of latent and symptomatic TB in patients with RA treated with biological drugs between 2017 and 2022 (20). In their study, after a 12-month follow-up, 20% of the 180 patients treated with biological drugs were diagnosed with latent TB, and 3 patients (1.7%) were diagnosed with symptomatic TB (pulmonary, pleural, and gluteal). A history of contact with TB patients and lower socioeconomic have been reported as strong risk factors (with an odds ratio of 1.95 and 1.45, respectively) in this population. This study, like our study, could not find a significant relationship between the age of the patients, the duration of the rheumatic disease, gender, underlying disease, or the type of anti-TNF with the incidence of conversion in RA patients. As we saw in our study, the relatively high prevalence and burden of TB in Vietnam make it necessary to develop a suitable protocol for screening patients in this regard.

Our study found a significant relationship between psoriatic arthritis and PPD seroconversion, which cannot be relied upon due to the lack of similar comparative studies and the small sample size. It should be noted that in our study, the prevalence of PPD conversion in the population of patients with rheumatological diseases using anti-TNFs is estimated to be 10.0%, This observed 10% conversion rate should be interpreted cautiously due to the small sample size and may not reflect population-level risk. These findings strongly support the need for ongoing screening protocols, such as annual PPD testing, for patients receiving anti-TNFs. One possible explanation for the observed association between psoriatic arthritis and PPD conversion is the underlying immunopathology of PsA, which involves complex immune dysregulation. Additionally, PsA patients often require combination therapy with corticosteroids or other immunomodulators, which may further increase susceptibility to TB infection. We acknowledge the value of incorporating infectious diseases expertise in interpreting TB risk among immunosuppressed patients. Although this study was primarily conducted in a rheumatology setting, we have expanded our Discussion to reflect insights from infectious disease research and have integrated relevant references to provide a more comprehensive perspective.

In conducting this study, the sample size was smaller than that of similar studies conducted in other parts of the world, the limited follow-up duration may have prevented detection of late TB reactivation. It is recommended that similar studies be conducted with a larger sample size and with a longer follow-up period to achieve stronger results. Certainly, conducting more studies over a more extended period and using both PPD and IGRA tests can help develop more complete guidelines and protocols for screening this group of high-risk patients in terms of TB. The relatively small number of patients who completed follow-up, as well as the low number of PPD conversions observed, limited our ability to conduct meaningful subgroup analyses. Consequently, the generalizability of our findings to broader populations should be interpreted with caution. Another limitation of this study is the absence of IGRA testing, which could have provided complementary diagnostic value in detecting latent TB, especially among immunocompromised individuals. We did not collect information on BCG vaccination status or socioeconomic characteristics, which are important factors in TB risk assessment and may have

influenced the study findings. The one-year follow-up period may not have been sufficient to capture delayed TB reactivation, which can occur several years after initiating anti-TNF therapy (20). Multivariable logistic regression analysis was not feasible due to the small number of conversion cases, which limited statistical power.

Conclusion

According to the results of this study, 10% of patients who have been prescribed anti-TNFs will develop PPD conversion. Among potential predisposing factors, psoriatic arthritis was significantly associated with PPD conversion. In contrast, the patient's age, gender, type of anti-TNF drug, duration of the biological drug, concurrent use of other immune system-modulating drugs, and history of previous underlying diseases such as hypertension and DM had no significant relationship with PPD conversion and latent TB. Our data suggests the development of a regular screening program for latent TB diagnosis in anti-TNF consumers.

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Authors' Contributors

All authors contributed equally to the study's conception, design, and execution. M. Meidani, F. Nasseri, A. Rostamian, Z. Saffarian, N. Alijani, P. Rezaie, A. Ferdosi, A. Hajialigol, M. Shafiei, and S. Aghayani were involved in data collection and the clinical investigation of patients. All authors participated in the analysis and interpretation of PPD conversion data, contributed to the drafting and critical revision of the manuscript for important intellectual content, and provided final approval of the version to be published. Each author agrees to be accountable for all aspects of the work.

Data Availability

The datasets generated and analyzed during the current study are not publicly available; however, the data can be shared for research and authentication purposes upon reasonable request.

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Ethics Approval

All patients became familiar with the content of the study from the moment they entered the study plan, and written informed consent was obtained from them. The patients were assured that at any time during the research if they did not agree with the study plan, their treatment process would continue as before. The study protocol is in accordance with the Declaration of Helsinki. It has been approved by the Research Ethics Committee of Tehran University of Medical Sciences with the ethics code IR.TUMS.IKHC.REC.1403.016..

Conflict of Interest

The authors declared no conflict of interest.

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