



Incidence of active tuberculosis in Korean patients with rheumatoid arthritis: a comparison between tumor necrosis factor inhibitors and tofacitinib

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Objective: This study aims to compare the incidence of active tuberculosis (TB) among Korean patients with rheumatoid arthritis (RA) initiating treatment with tumor necrosis factor inhibitors (TNFi) or tofacitinib.

Methods: Using the Korean National Health Insurance database, we conducted a nationwide, retrospective cohort study of RA patients who started TNFi or tofacitinib therapy between 2015 and 2018. We calculated the incidence rates of active TB based on the treatment type and results from latent tuberculosis infection (LTBI) screening tests. A multivariable Cox proportional hazards model was employed to evaluate the risk of active TB in RA patients beginning TNFi or tofacitinib treatment.

Results: Among 3,382 RA patients (596 on tofacitinib and 2,786 on TNFi), LTBI screening was predominantly conducted using the IGRA (interferon-gamma release assays) test. Of these patients, 624 (18.5%) with a positive LTBI test received prophylactic treatment. No cases of active TB occurred in tofacitinib users, while 32 cases were observed in TNFi users. The adjusted hazard ratio for active TB in LTBI-positive patients was 5.47 (95% confidence interval 2.74 to 10.92) compared to LTBI-negative patients. In subgroup analyses, TB incidence was significantly higher among individuals aged over 65 years.

Conclusion: Despite LTBI treatment, active TB remains prevalent among RA patients on TNFi therapy and in those with positive LTBI tests.

Keywords: Latent tuberculosis infection, Rheumatoid arthritis, Janus kinase inhibitors, Tumor necrosis factor inhibitors

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic inflammatory disease that affects the joints and is associated with progressive disability [1]. The development of therapeutic agents and treatment guidelines for RA has significantly reduced disability and improved the quality of life for patients [2,3]. A major contributor to these advances has been the introduction of targeted therapies,

which have revolutionized RA management. Among these, tumor necrosis factor inhibitors (TNFi), non-TNFi biologics, and more recently, Janus kinase inhibitors (JAKi), have played a crucial role in controlling disease activity and slowing progression [1,4].

However, despite their effectiveness, a common concern with these agents is the increased risk of infections [5]. These infections range from pneumonia, *Pneumocystis jirovecii* pneu-

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monia, and herpes zoster, to more serious infections such as tuberculosis (TB) and non-tuberculous mycobacteria [5-7]. TB remains a major concern for RA patients, particularly in Korea, where TB incidence was 49.4 per 100,000 in 2020 [8]. The use of TNFi in RA patients has been associated with a significantly increased risk of TB reactivation, as TNF plays a critical role in containing latent TB within granulomas. Studies in Korean RA patients have shown a higher prevalence of latent tuberculosis infection (LTBI), around 30%, which is significantly higher than in Western countries, emphasizing the need for strict LTBI screening and management in this population [6,9,10].

The American College of Rheumatology (ACR) and European Alliance of Associations for Rheumatology (EULAR) guidelines recommend that patients with RA receiving targeted therapy should be screened for LTBI and undergo treatment if positive [3,4]. In 2017, Korean government has also implemented national LTBI screening programs for high-risk groups, including patients receiving targeted therapies for RA, with mandatory LTBI screening for reimbursement eligibility of targeted therapy under national insurance policies. Patients with a history of successfully treated TB do not require additional LTBI treatment before starting TNFi, even if they test positive for LTBI [11,12].

While TNFi are known to increase the risk of TB reactivation, less is known about the risk associated with JAKi. This study was performed to assess whether tofacitinib carry a similar risk of LTBI reactivation compared to TNFi and to determine whether LTBI treatment reduces the risk of TB reactivation in LTBI-positive patients, bringing their risk level closer to that of LTBI-negative patients.

MATERIALS AND METHODS

Data source

We used the National Health Insurance Service (NHIS) database, analysing records from January 2015 to December 2019. The database covers more than 50 million individuals in Korea and includes detailed information on healthcare utilization, medical diagnoses, and treatments. These data enabled us to identify patients with RA and ascertain their LTBI screening and treatment histories.

Study population and design

This retrospective cohort study utilized the NHIS database to

analyze LTBI screening, treatment, and active TB incidence in RA patients receiving either tofacitinib or TNFi (e.g., infliximab, adalimumab, etanercept, and golimumab). Although the exposure assessment period of this study covered the period from January 2015 to December 2018, following the introduction of tofacitinib and baricitinib reimbursement in Korea in March 2015 and November 2018, respectively, only tofacitinib users were identified as JAKi users in this study population.

We included patients with RA identified by diagnosis codes (ICD-10: M05, M060, M062, M063, M064, M068, M069) and prescriptions for disease-modifying antirheumatic drugs (DMARDs)—methotrexate, hydroxychloroquine, sulfasalazine, leflunomide, tacrolimus, azathioprine, cyclosporine, minocycline, mizoribine, D-penicillamine, and bucillamine—and targeted therapies (etanercept, adalimumab, infliximab, golimumab, abatacept, tocilizumab, rituximab, tofacitinib, baricitinib) [13]. We excluded individuals aged under 18 years and those with ankylosing spondylitis (M45), psoriatic arthritis (M070, M072, M073), inflammatory bowel disease (M074, M075, K50, K51), or juvenile rheumatoid arthritis (M08). We also excluded patients with any prior targeted therapy use or active TB. Active TB was defined by diagnostic codes (A15-A19), insurance codes (V206, V246, V000) or treatment records indicating a regimen comprising ethambutol or pyrazinamide with isoniazid and rifampicin, irrespective of duration, to accommodate regimen changes or suboptimal adherence. These criteria ensured inclusion of only new users of TNFi or tofacitinib. The index date was the first tofacitinib or TNFi dispensing, with a minimum follow-up of 1 year.

The Institutional Review Board (IRB) of Hanyang University Hospital exempted this study from review due to the use of publicly available data without direct subject identification (IRB no. HYUH 2020-06-042).

Latent tuberculosis infection screening and treatment

LTBI screening was performed with tuberculin skin tests (TST; E7113) or interferon-gamma release assays (IGRA; CZ393), in accordance with Korean guidelines [12]. Patients who received isoniazid, rifampicin, or the combination within 1 year of an LTBI screening claim were classified as LTBI positive [9,14]. We evaluated LTBI screening and treatment patterns during previous 1 year and within 1 year after the date of tofacitinib or TNFi initiation.

Active tuberculosis incidence and follow-up

Active TB was defined by specific diagnostic codes or treatment regimens for TB. Follow-up started on the index date and continued until active TB occurrence, death, or study end (December 31, 2019).

Statistical analysis

Descriptive statistics summarized LTBI screening and treatment patterns. Baseline characteristics were presented as counts and means. Cumulative incidence function (CIF) curves for TB incidence between groups were estimated, and Log-rank test was used to compare the groups. A multivariable Cox proportional hazards model estimated hazard ratios (HRs) and 95% confidence intervals (CIs) for active TB risk in LTBI-treated versus untreated patients, adjusting for age group, sex, insurance type, geographic regions, institution type, Charlson comorbidity score, dyslipidemia, previous use of nonsteroidal anti-inflammatory drugs, and concurrent use of corticosteroids and methotrexate. Subgroup analyses evaluated the effect of LTBI treatment by age, LTBI positivity, hypertension, diabetes, and body mass index (BMI). Statistical significance was set at $p < 0.05$, with analyses conducted using SAS version 9.4 (SAS Institute, Cary, NC, USA) and R software version 4.2.1.

RESULTS

A total of 3,382 RA patients who started either tofacitinib or TNFi were included in the study, comprising 596 tofacitinib users and 2,786 TNFi users (Figure 1). The average age was 54.1 (± 13.1) years, with 81.5% of patients being female. All tofacitinib users received tofacitinib, while the TNFi group received

adalimumab (34.3%), golimumab (25.7%), etanercept (25.0%), or infliximab (15.0%). Additional demographics and baseline characteristics for both groups are detailed in Table 1.

A total of 2,912 (86.1%) patients received at least one LTBI screening test, including IGRA and TST. Of the study population, 18.5% (624 patients) were subsequently received LTBI treatment, and the majority completed treatment. The most common regimen was 9 months of isoniazid therapy, received by 71.8% of patients, followed by 3 months of isoniazid/rifampin therapy (21.2%) and 4 months of rifampin therapy (7.0%).

Of the 3,382 RA patients, 32 (0.9%) developed TB, and all patients with TB were TNFi users. The median follow-up for these TNFi users was 2.93 years (interquartile range 1.92 to 3.95 years) after the index date (Figure 2A). The CIF curve of TB were also significantly different between group with LTBI positive and negative group ($p = 0.006$) (Figure 2B). TB incidence rate was 1.01/100 person-years (PYs) (95% CI 0.64 to 1.58) in LTBI-positive and 0.18/100 PYs (95% CI 0.10 to 0.30) in LTBI-negative group.

Multivariable Cox proportional hazards model analysis demonstrated a significantly increased risk of TB in the LTBI-positive group compared to the LTBI-negative group (adjusted HR 5.21, 95% CI 2.59 to 10.50). Subgroup analysis highlighted that age was a critical factor; in individuals aged ≥ 65 years, the incidence rate of TB was 2.97/100 PYs (95% CI 1.68 to 5.22), significantly higher than 0.26/100 PYs (95% CI 0.10 to 0.70) in the LTBI-negative group, with an adjusted HR of 9.88 (95% CI 3.13 to 3.97). Conversely, in those under 65 years of age, although the incidence rate in LTBI-positive individuals was higher (0.60/100 PYs, 95% CI 0.22 to 0.99) compared to the LTBI-negative group (0.15/100 PYs, 95% CI 0.07 to 0.29), the adjusted HR (2.78, 95%

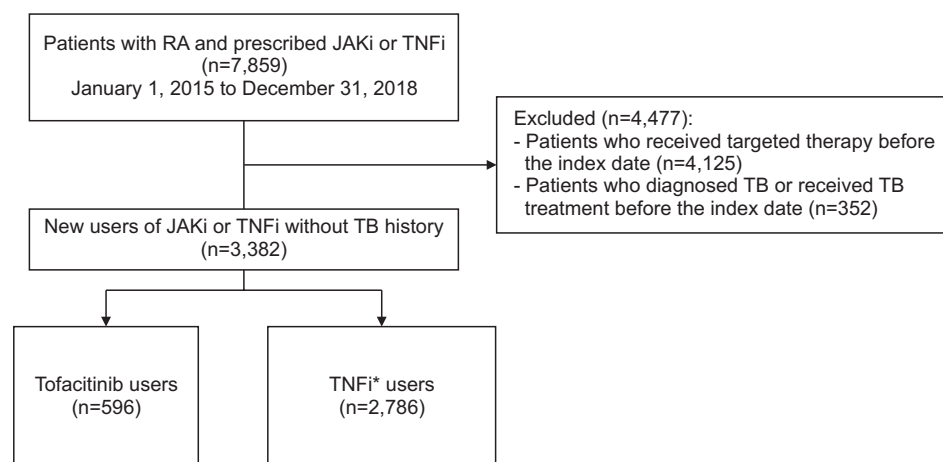


Figure 1. Flow chart of patient selection. RA: rheumatoid arthritis, JAKi: Janus kinase inhibitors, TNFi: tumor necrosis factor inhibitors, TB: tuberculosis. *Infliximab, adalimumab, etanercept, and golimumab.

Table 1. Baseline characteristics of study population (n=3,382)

Variable	Value
Type of targeted therapy	
TNFi	2,786 (82.4)
Tofacitinib	596 (17.6)
Age (yr)	54.1±13.1
Sex, female	2,756 (81.5)
Initiation of targeted therapy	
2015	712 (21.1)
2016	738 (21.8)
2017	810 (24.0)
2018	1,122 (33.2)
Type of insurance	
National Health Insurance	3,201 (94.6)
Medical aid	181 (5.4)
Geographic region	
Seoul or metropolitan city	1,503 (44.4)
Others	1,769 (52.3)
Type of hospital	
Tertiary referral hospital	1,999 (59.1)
General hospital	929 (27.5)
Community hospital/clinic	454 (13.4)
Income level	
Quartile 1 (lowest)	812 (24.0)
Quartile 2	652 (19.3)
Quartile 3	833 (24.6)
Quartile 4 (highest)	1,085 (32.1)
RA seropositive	3,191 (94.4)
Concomitant medication	
MTX	2,699 (79.8)
Oral corticosteroid	2,809 (83.1)
Comorbidities and medications*	
CCI score	2.63±1.66
Hypertension	1,112 (32.9)
Diabetes	662 (19.6)
NSAIDs	3,297 (97.5)
COX-2 inhibitor	2,064 (61.0)
Oral corticosteroid	3,192 (94.4)
Number of previous csDMARDs	2.5±0.6

Values are presented as number (%) or mean±standard deviation. TNFi: tumor necrosis factor inhibitors, RA: rheumatoid arthritis, MTX, methotrexate, CCI: Charlson Comorbidity Index, NSAIDs: nonsteroidal anti-inflammatory drugs, COX-2: cyclooxygenase-2, csDMARDs: conventional synthetic disease-modifying antirheumatic drugs. *Comorbidities and medications within the previous year.

CI 0.94 to 8.24) did not reach statistical significance. Other variables such as BMI, hypertension, and diabetes were associated with higher TB incidence in LTBI-positive individuals, but the differences in adjusted HRs between subgroups were not statistically significant (Table 2).

DISCUSSION

In this population-based study, 2,912 (86.1%) patients received at least one LTBI screening test, including IGRA and TST, and 624 patients (18.5%) who were considered LTBI-positive were prescribed LTBI treatment. Despite appropriate LTBI diagnosis and treatment, active TB was diagnosed in 32 (0.9%) patients; all the TB cases were TNFi users. The LTBI-positive group showed a higher risk of active TB, especially in the patients with ≥65 years of age.

Since the 2017 Korean reimbursement updates, IGRA has become more commonly used [15]. However, cases of active TB have still occurred in some patients who tested negative for LTBI and did not receive LTBI treatment. Given that RA patients may experience false-negative TST or IGRA results due to immunosuppression, a negative test result should not be viewed as definitive evidence for excluding LTBI. Regular monitoring for signs and symptoms of TB reactivation is essential, yet there remains a lack of sufficient evidence to support the need for repeated LTBI screening. Further research is warranted to clarify the role and frequency of follow-up screening in this population.

Although the incidence of TB in Korea has shown a gradual decline during the study period [9], it remains considerably higher among high risk groups such as patients with RA compared to the general population (35.7 per 100,000 population) [16]. Additionally, a higher incidence of active TB was observed among TNFi users. Our study revealed that older patients are at a higher risk of developing active TB despite undergoing LTBI treatments. This increased risk maybe related with immunosenescence associated with aging. While studies have not conclusively demonstrated a reduced effectiveness of LTBI treatment in the elderly, this population often experiences lower treatment completion rates [17] and greater susceptibility to adverse drug reactions, potentially undermining the overall effectiveness of LTBI management. Although recent safety concerns with JAKi have led to recommendations prioritizing TNFi as the first-line agent for patients over 65 due to increased risks of malignancy and cardiovascular disease, careful consideration of TB risk may

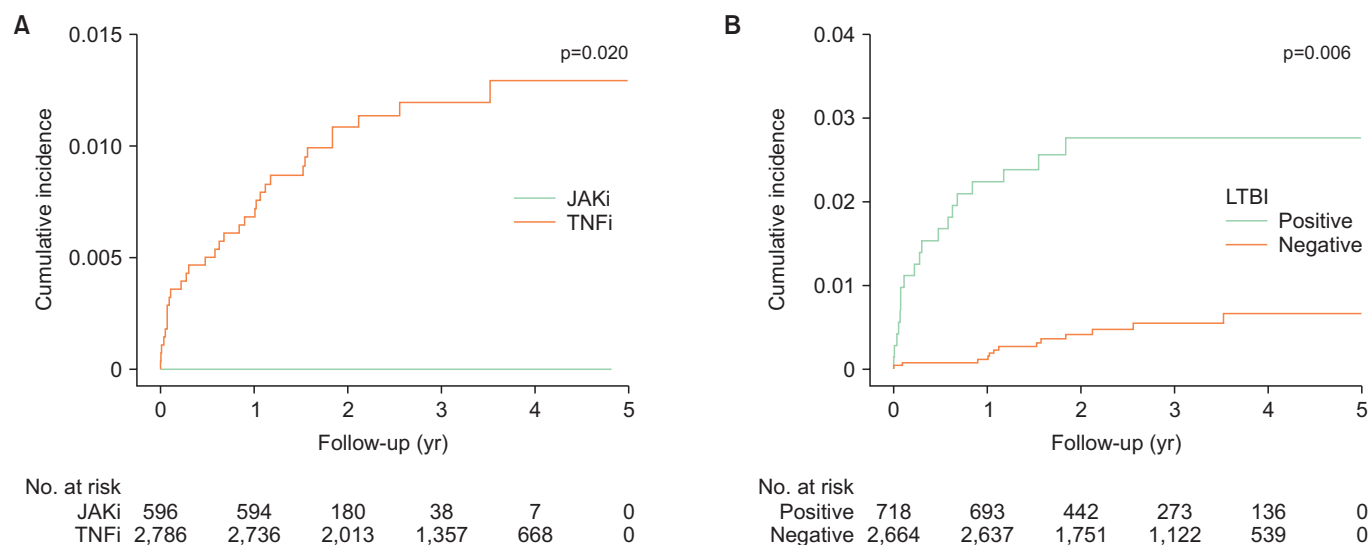


Figure 2. Cumulative incidence of active tuberculosis in the study population. Cumulative incidence analysis of patients (A) receiving TNFi or JAKi and (B) stratified by LTBI positivity. JAKi: Janus kinase inhibitors, TNFi: tumor necrosis factor inhibitors, LTBI: latent tuberculosis infection.

Table 2. Overall and subgroup analysis on LTBI positivity and the risk of TB

Variable	Positive LTBI			Negative LTBI			Adjusted HR* (95% CI)	p-value for interaction
	No. of patients	No. of events	Incidence rate per 100 PYs (95% CI)	No. of patients	No. of events	Incidence rate per 100 PYs (95% CI)		
Overall	718	19	1.01 (0.64 to 1.58)	2,664	13	0.18 (0.10 to 0.30)	5.21 (2.59 to 10.50)	
Subgroup analysis								
Age (yr)								0.001
≥65	166	12	2.97 (1.68 to 5.22)	578	4	0.26 (0.10 to 0.70)	9.88 (3.13 to 3.97)	
<65	552	7	0.60 (0.22 to 0.99)	2,086	9	0.15 (0.07 to 0.29)	2.78 (0.94 to 8.24)	
Hypertension								0.080
Yes	265	11	1.70 (0.94 to 3.06)	847	3	0.13 (0.04 to 0.40)	12.16 (3.39 to 43.55)	
No	453	8	0.64 (0.32 to 1.29)	1,817	10	0.20 (0.11 to 0.37)	3.38 (1.33 to 8.58)	
Diabetes								0.330
Yes	169	7	1.61 (0.77 to 3.38)	493	6	0.45 (0.20 to 1.00)	3.64 (1.15 to 11.47)	
No	549	12	0.83 (0.47 to 1.45)	2,171	7	0.12 (0.06 to 0.24)	6.64 (2.80 to 15.74)	
BMI (kg/m ²)								0.433
≥25.0	182	5	1.01 (0.42 to 2.42)	543	3	0.21 (0.07 to 0.64)	5.00 (1.20 to 20.92)	
<25.0	418	5	0.46 (0.19 to 1.10)	1,587	8	0.18 (0.09 to 0.36)	2.97 (1.02 to 8.67)	

LTBI: latent tuberculosis infection, TB: tuberculosis, PYs: person-years, CI: confidence interval, HR: hazard ratio, BMI: body mass index, NSAIDs: nonsteroidal anti-inflammatory drugs. *Adjusted for age group, sex, insurance type, geographic regions, institution type, Charlson comorbidity score, dyslipidemia, previous use of NSAIDs, and concurrent use of corticosteroids and methotrexate.

still support JAKi use in LTBI-positive individuals. Considering the lower relative risk of malignancy and cardiovascular disease in Koreans compared to Western populations, and Korea's high TB burden, such an approach warrants further discussion.

In our study, there were no cases of active TB were observed

in tofacitinib users. A previous single-center study in Korea also observed no active TB in JAKi users [6], and a Taiwan study also reported no significant difference in TB incidence between JAKi and TNFi users (HR 0.60, 95% CI 0.22 to 1.62) [18]. On the other hand, an increased risk of opportunistic infections,

including TB, was observed in RA patients treated with tofacitinib, particularly at higher doses in a phase three study [19], and a long-term extension trial further highlighted TB as the most common opportunistic infection associated with JAKi use [20]. Therefore, further studies with longer observation periods in JAKi users are needed.

Our study has several strengths. First, we comprehensively identified LTBI screening, LTBI treatment, and incidence of active TB, including both tofacitinib and TNFi. Second, using nationwide health insurance claims data covering the entire population of South Korea to minimize selection and recall biases. Third, this study provides important evidence on the risk of TB in patients with RA treated with tofacitinib and TNFi in Korea, a country with an intermediate TB burden. However, there are several potential limitations to consider. First, due to the inherent limitations of claims data, residual confounding may persist despite adjustment for age, sex, comorbidities, and medication, because variables such as socioeconomic status, smoking history, and prior TB exposure were unavailable. Therefore, the associations observed in this study should not be interpreted as causal. Second, because the NHIS database does not provide information on medication adherence, it was not possible to confirm whether patients were adherent to each LTBI treatment regimen. The database also lacks LTBI screening results, so LTBI positivity was inferred indirectly from chemoprophylaxis prescriptions. Nevertheless, under Korean national TB control guidelines, patients who test positive for LTBI must receive chemoprophylaxis before initiating biologic DMARDs or JAKi, supporting the validity of this operational definition. Third, the study period, spanning 2015 to 2018, was selected to align with the approval of tofacitinib, the first JAKi in Korea. The inclusion of only tofacitinib, together with the relatively small sample size, limits the generalisability of our findings. Currently, four JAKi are approved for RA in Korea, enabling more comprehensive analyses in future studies. However, starting from September 2022, their use as a first-line therapy may be restricted for patients aged 65 or older, which could influence future study outcomes. Therefore, further studies with longer follow-up periods are warranted, with careful interpretation needed to better elucidate the association between LTBI treatment and various risk factors in RA patients initiating targeted therapy.

CONCLUSION

In conclusion, despite prior LTBI screening and treatment, patients treated with TNFi had an increased risk of active TB, whereas no active TB occurred in tofacitinib users. Given the relatively short follow-up among tofacitinib users and the evaluation of only tofacitinib, further studies with larger JAKi cohorts and longer follow-up are warranted. The LTBI-positive group showed a higher risk of active TB, particularly among patients aged ≥ 65 years. To further reduce TB incidence, it is essential to evaluate treatment adherence and efficacy. Moreover, shared decision-making is warranted when considering JAKi for older, LTBI-positive patients, given limited but suggestive evidence of safety and effectiveness.

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CONFLICT OF INTEREST

S.K.C. has served as an editorial board member of the Journal of Rheumatic Diseases since June 2020 but had no role in the decision to publish this article. The other authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

JYK, SYJ, and SKC conceptualised the study. JYK, SHY, and SYJ curated the data. JYK and SHY performed the formal analysis. SKC obtained funding and supervised the study. All authors contributed to methodology and validation. JYK drafted the original manuscript. All authors reviewed and edited the manuscript for important intellectual content.

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