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LETTER TO THE EDITOR

## Precautions before starting tofacitinib in persons with rheumatoid arthritis

Raktim Swarnakar, Shiv Lal Yadav

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## Abstract

Tofacitinib is an immunosuppressive and disease-modifying therapy in rheumatoid arthritis. It may result in many infections flaring up. It is important to take precautions of all kinds (cardiovascular, malignancy, infections etc.) before starting tofacitinib. In this article, we have highlighted important steps where we need to take precautions before starting tofacitinib.

Key Words: Tofacitinib; Rheumatoid arthritis; DMARDs; Disease-modifying; Precaution; Side-effects

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Core Tip: Tofacitinib is a disease-modifying drug in rheumatoid arthritis. It has many side effects, especially in susceptible people. Before starting tofacitinib we must take precautions regarding cardiovascular status, infections and malignancy.

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## TO THE EDITOR

We read with interest the article by Lin *et al*[1] where authors have reported one case report of recurrent herpes zoster (HZ) in rheumatoid arthritis (RA) patients treated with tofacitinib. We would like to highlight important aspects regarding tofacitinib,



## Table 1 Precautions before tofacitinib starting in rheumatoid arthritis

Serial No.	Precautions[4,5]	Reasons
1	Persons with moderate-severe renal impairment or moderate hepatic impairment are recommended 5 mg once daily	In RA, multiple NSAIDS (non-steroidal anti-inflammatory drugs)/DMARDs themselves can cause liver or kidney injury. Furthermore, tofacitinib is hepatotoxic. It is metabolized in the liver largely through the cytochrome P450 3A4 pathway (cytochrome P 3A4)
2	Screening of infections like latent Tuberculosis, Hepatitis, cytomegalovirus, Epstein Barr Virus (EBV), BK virus	Reactivation of TB, and hepatitis can occur
3	Screening to check immunosuppressive conditions like human immunodeficiency virus (HIV) infection, Diabetes etc.	Reactivation of latent infections can occur
4	<b>Blood investigations to be done:</b> Routine complete hemogram, Liver function and kidney function tests, lipid profile and C-reactive protein	To rule out latent infections, liver, kidney status
	Repeat complete blood count 1 to 2 mo following initiation, and every 12 wk after that	
	Lipid profile should be monitored 4 to 8 wk after initiation of treatment	
5	Mantoux test, Chest X-ray and at times Interferon gamma release assay may be required.	To rule out latent TB
6	<b>Do not start tofacitinib:</b> If haemoglobin (Hb) levels are below 9 g/dL, absolute lymphocyte count is below 500 cells/mm <sup>3</sup> , and absolute neutrophil count below 1000 cells/mm <sup>3</sup>	It may aggravate the infection
	In presence of any infection.	
7	In renal transplant recipients	Renal transplant subjects receiving tofacitinib alongside immunosuppressive therapy are at increased risk of EBV associated post-transplant lymphoproliferative disorder
8	<b>Reproductive age group:</b> Women of reproductive potential should be counselled on the risk of possible infertility from tofacitinib	Due to potential side effects of tofacitinib
	<b>Pregnancy:</b> Treatment during pregnancy may increase the potential risk to the fetus	
	<b>Lactation:</b> Discontinue breastfeeding as tofacitinib may be excreted in breast milk	
10	Screening for malignancy and cardiovascular diseases	FDA (The United States Food and Drug Administration) released an updated boxed warning in September 2021 regarding the increased risk of death, major adverse cardiovascular events, malignancies and thrombosis with Janus kinase inhibitors compared with tumor necrosis factor-alpha inhibitors[4,5]

especially all the precautions to be taken before starting tofacitinib in cases of rheumatoid arthritis. Tofacitinib is a potent, selective Janus-associated kinase (JAK) inhibitor that preferentially inhibits JAK1 and JAK3. Tofacitinib exerts its mechanism of action by inhibiting intracellular cytoplasmic nonreceptor tyrosine kinase JAK enzymes, which participate in adaptive and innate immune responses in the process of immune-mediated inflammatory diseases[2]. The incidence of herpes zoster is found to be higher with tofacitinib than in the general RA population[3]. Tofacitinib increases the risk of HZ by which mechanism is not well understood but may be related to inhibition of interferon (IFN) signaling. Antiviral defenses depend on type I and II IFN signaling via the JAK/STAT pathway and it is inhibited by tofacitinib. Tofacitinib is United States Food and Drug Administration (FDA) approved drug for RA. Oral tofacitinib 5 mg twice daily is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant of, one or more disease-modifying antirheumatic drugs (DMARDs). It can also be used in sequence with first-line therapy methotrexate or conventional DMARDS or can also be used as monotherapy for RA. Detailed precautions are listed in Table 1.

## Screening for malignancy and cardiovascular diseases

FDA released an updated boxed warning in September 2021 regarding the increased risk of death, major adverse cardiovascular events, malignancies and thrombosis with JAK inhibitors compared with tumor necrosis factor inhibitors[4,5]. Hence, before starting tofacitinib in a case of rheumatoid arthritis a doctor has to keep in mind those precautionary measures to avoid untoward adverse reactions or incidents.

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## FOOTNOTES

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