IS THERE A SAFETY DIFFERENCE?
JANUS KINASE INHIBITORS IN REAL CLINICAL PRACTICE

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BACKGROUND AND IMPORTANCE

Tofacitinib, baricitinib, upadacitinib and filgotinib are Janus kinase inhibitors (IJAKs) indicated in rheumatoid arthritis (RA).

The EMA notified that in **patients with RA who were ≥50 years with at least one cardiovascular risk factor had an increased risk of major adverse cardiovascular events (MACE), and malignancies with use of tofacitinib** relative to TNF-alpha inhibitor.

Although it is being evaluated, it is still unknown if this risk is shared by other IJAKs.

AIM AND OBJECTIVES

To describe and **compare the safety** of tofacitinib, baricitinib, upadacitinib and filgotinib in patients with RA in a real-world-setting.

Secondary objective: to analyze if there is a relationship between MACE and malignancies with a patient profile with a higher risk of developing them as established in the alert.

MATERIAL AND METHODS

Retrospective/prospective observational study of RA patients under treatment with tofacitinib, baricitinib, upadacitinib and filgotinib until September 2022

Safety was determined based on the adverse events (AEs) reported

Variables:
Sex, age at start, time-of-treatment, reason for discontinuation, risk factor´s MACE, risk factors for malignancies and AEs

Statistical analysis:
A description of characteristics and events that occurred in the cohort was carried out. Associations were later explored

RESULTS

124 patients (80.6% women); mean age 55.8 (SD 11.8) years

Treatments	Patients (N)	Median of treatment (days)
Tofacitinib	60	399 (171-884)
Upadacitinib	49	287 (130-477)
Baricitinib	21	308 (210-632)
Filgotinib	14	93 (60-171)

✓ 19 patients (15.3%) were treated with more than one IJAK sequentially

✓ **110 patients** were identified with an increased risk of MACE or malignances

AEs in 39 (31.5%) treatments	21 with tofacitinib
	9 with upadacitinib
	7 with baricitinib
	4 with filgotinib

79 end of treatment	46 for inefficacy
	22 for AE
	7 for both reasons
	4 for considered a risk patient

The most common AE was **herpes zoster**

Only 2 patients suffered a MACE in the total cohort with tofacitinib

No association could be established between risk patient and the development of adverse events, neither minor or major

CONCLUSION AND RELEVANCE

Therefore, it is still unknown if the exchange strategy between them is adequate to reduce the risk. Limitation: a larger sample size and longer follow-up time are required to detect major AEs and their association with patients at risk.

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