REAL LIFE SAFETY IN RHEUMATOLOGICAL PATIENTS TREATED WITH JANUS KINASE INHIBITORS: BEFORE AND AFTER AN INTERNATIONAL SAFETY WARNING

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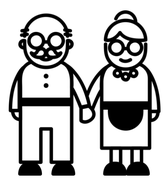
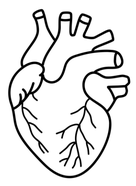
BACKGROUND AND IMPORTANCE

October 2022: EMA published measures to minimise the risk of serious adverse events (AE) linked to Janus kinase inhibitors (iJAK) application, including restrictions for:


≥ 65 years


Smokers


Risk of cardiovascular events


Cancer

OBJECTIVES

To identify the reason of treatment withdrawal in patients with rheumatoid diseases treated with a iJak, describe the AE profile developed and analyse the impact on their safety after the risk minimization measures announcement.

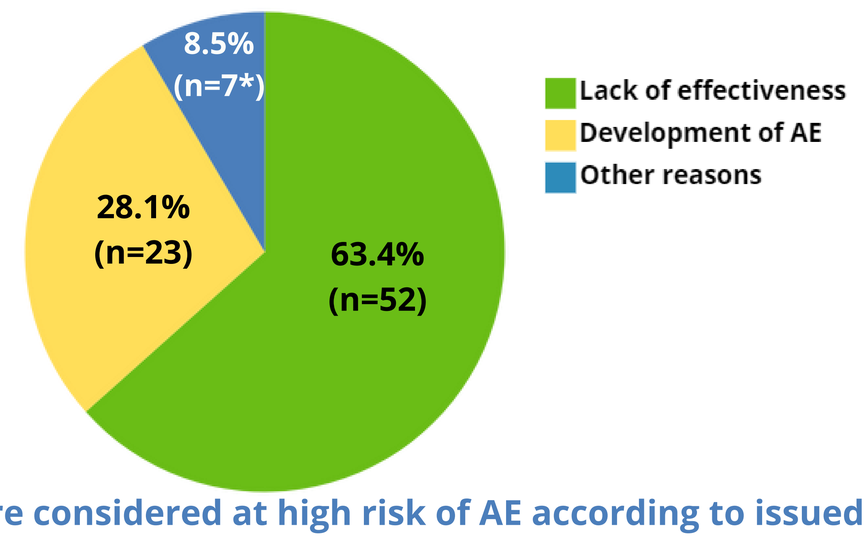
MATERIALS AND METHODS

Retrospective, observational study included all patients with rheumatoid diseases treated with an iJak since their market launch in 2018 to September 2024. Data were extracted from the electronic medical record. The patients' risk profile for developing AE was analysed according to the published safety signals.

RESULTS

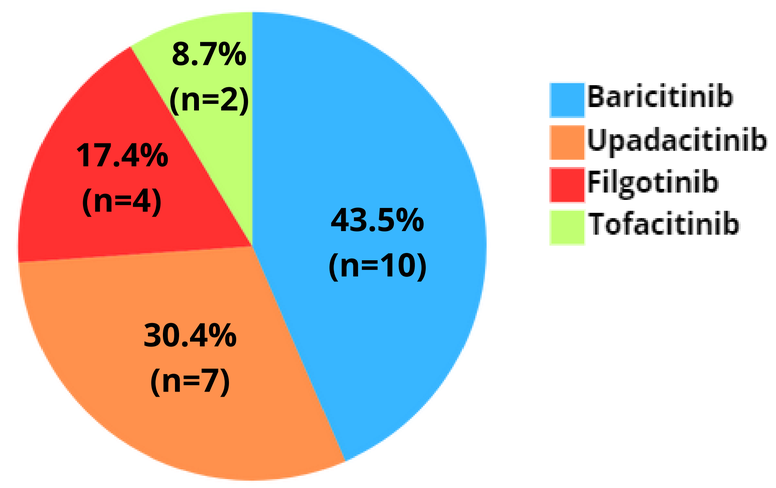
N = 160 patients ⟶ 66.3% (n=106) started the treatment before October 2022

Among the 160 patients, 51.3% (n=82) interrupted the treatment.
Reasons for withdrawn:



*3 patients were considered at high risk of AE according to issued safety measures, and the iJAK treatment was discontinued.

28.1% of the patients discontinued treatment for safety reasons (n=23).
Analysed by active ingredients:



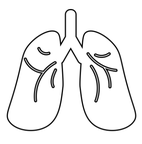
Most frequent AEs:


Asthenia


Herpes zoster


Headache

Most serious AEs:


1 fatal pneumonia (upadacitinib)


1 prostate carcinoma (upadacitinib)


1 deep venus thrombosis (baricitinib)

Major AE, analysed before and after October 2022, showed that **they occurred among patients > 65** and the treatments were initiated before the safety warning announcement.

CONCLUSIONS

A high percentage of drug withdrawals observed in patients treated with iJAK, was due to ineffectiveness. The serious AE associated with iJAK application were related to the patient's risk profile. However, no serious AE were described among patients who started with iJAK after the safety measures were issued, underlining the importance of an adequate selection of patients to start treatment with iJAK.

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