SAFETY ASSESSMENT OF JANUS KINASE INHIBITORS IN CLINICAL PRACTICE

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BACKGROUND AND IMPORTANCE

- Janus kinase inhibitors (JAKi) tofacitinib, baricitinib, upadacitinib and filgotinib are immunosuppressants indicated for the treatment of chronic inflammatory disorders.
- Concern regarding their safety has recently arisen since new data have been published in the last years.

AIM AND OBJECTIVES

- To assess the safety of JAKi for the treatment of chronic inflammatory disorders in real clinical practice.
- To compare it with the clinical trials (CT) results.

MATERIALS AND METHODS

- Observational restrospective study including patients treated with JAKi from January 2019 to August 2023.
- Data were obtained by review of electronic medical records and laboratory database.
- Variables studied were: patient demographics, prescribing units, adverse reactions (AR), treatment duration and motive of interruption.

RESULTS

N= 271 (74,5% women)
Median age= 55 years (18-92)

	BARICITINIB	TOFACITINIB	UPADACITINIB	FILGOTINIB
Total patients n	142	105	20	4
Toxicity n patients (%)	66 (46,5)	49 (46,6)	5 (25)	2 (50)
Total AR	101	65	5	4
Gastrointestinal disorders (GD)	9	13	0	2
Infections	18	7	0	0
Blood test parameters	44	22	3	1
Hypertriglyceridaemia	5	4	1	0
Hypercholesterolaemia	21	15	1	1
Others	18	3	1	0
Cardiovascular disorders (%)	9	2	1	0
Headache	5	6	0	0
Dyspnea	4	3	0	0
Skin disorders	1	1	1	0
Others	11	11	0	1

- Treatment interruption due to toxicity in 43 patients (tofacitinib>baricitinib>upadacitinib>filgotinib) and due to neoplasm diagnosis in 5 patients (barcitinib>tofacitinib)

CONCLUSION AND RELEVANCE

- For tofacitinib and baricitinib, the toxicity profile is similar to the one described in CT. All AR are described in the literature.
- Infections and hypercholesterolaemia are among the most frequent AR in our study and in CT.
- Although most of the AR were tolerable, there were several cases of severe AR led to treatment interruption.
- In contrast to recent CT results, no major adverse cardiovascular events were registered in our study.
- A bigger sample is needed to make conclusions about upadacitinib and filgotinib safety.