SAFETY PROFILE OF APREMILAST IN PSORIASIS AND PSORIATIC ARTHRITIS

Apremilast is an oral selective inhibitor of phosphodiesterase-4 with active psoriatic arthritis (PsA) and moderate to severe psoriasis (Ps). Apremilast is on the European list of medicinal products under additional monitoring.

Purpose
To assess the safety profile of apremilast and identify patient risk factors associated with the appearance of side effects (ASE).

Material and methods
A descriptive, retrospective study was carried out in patients with Ps and PsA who initiated apremilast between 2016–2018. Data were collected from clinical history and the pharmacy program (Farmatools).

Data analysed: demographic characteristics, diagnosis, previous treatment, ASE, dose reductions, reason for drug discontinuation and duration of treatment in those patients who discontinued apremilast.

The relationship between factors related to the patient and the ASE was evaluated using SPSS15.0.

Results
Fifty patients were analysed, median age 55.1 years (IQR: 45.5–61.8), 52% females. Sixty-six per cent were diagnosed with Ps, 32% with PsA and 2% were on off-label use.

The median of previous treatments received was 2 (IQR: 1–3). All patients had previously been treated with, at least, one conventional systemic therapy: methotrexate 86%, acitretin 46%, cyclosporine 26% and others 20%; and 24% had also been treated with biologic agents: adalimumab 58%, etanercept 50% and others 42%.

Side effects (SE) were observed in 78% of patients (median of SE: 1 (IQR: 1–3)). Most frequent were: diarrhoea 72%, headache 42%, nausea and vomiting 36%, acid reflux 32%, decreased appetite 18%, abdominal pain 18% and depression 12%. Dosage reductions of 50% were observed in 14% of patients.

Medium duration until ASE was 1.3 (IQR: 0–9.5) months. Half of the patients discontinued apremilast, 48% due to inefficacy, 36% SE, 12% both and 2% patients’ request.

There were not statistically significant differences in ASE in terms of sex (p=0.167) or diagnosis (p=0.062). However, significant differences were found according to age (p=0.044).

Conclusion
A high percentage of patients presented SE to apremilast, with diarrhoea the most frequent.

Patients’ demographic characteristics and diagnosis were not related to the ASE, apart from age.

For future research, it would be interesting to determine the effect of age on the ASE and to evaluate the tolerance and the effectiveness of reduced doses of apremilast in these type of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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