

SAFETY PROFILE OF APREMILAST IN PSORIASIS AND PSORIATIC ARTHRITIS

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BACKGROUND

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 appearance of side effects (ASE).

METHODS

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

Data analysed:

- Demographic characteristics, diagnosis and previous treatment.
- ASE
- Dose reductions
- Reason for drug discontinuation
- 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

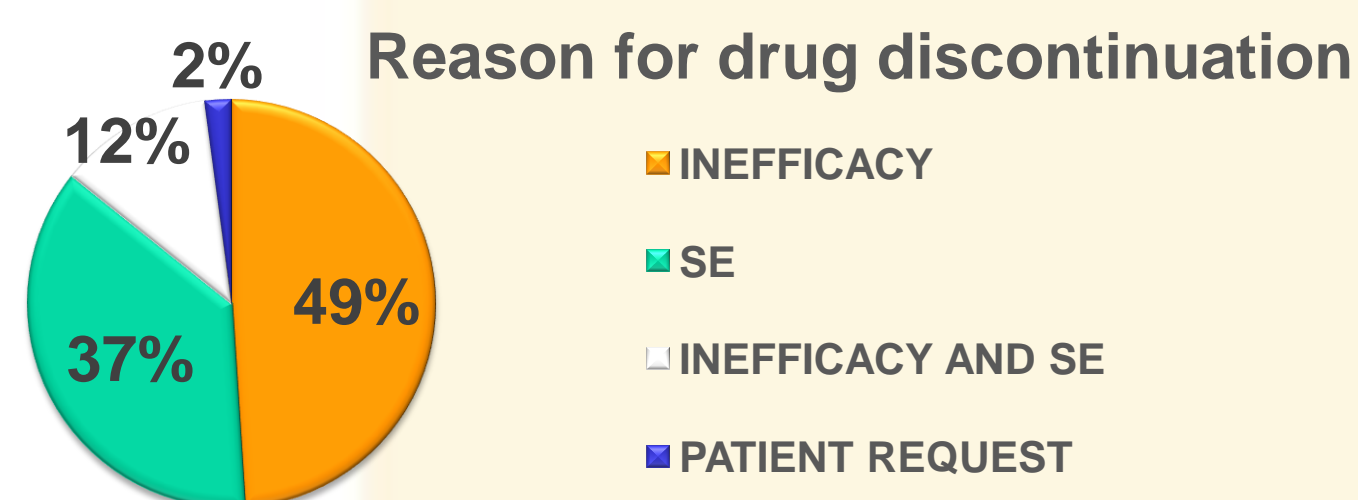
50 patients, median age 55,1 years (IQR:45,5-61,8), 52% women. 66% diagnosed with Ps, 32% with PsA and 2% were on off-label use.

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%; 24% had also been treated with biologic agents: adalimumab 58%, etanercept 50% and others 42%.

- Medium duration until ASE was 1,3 (IQR:0-9,5) months
- Dosage reductions of 50% were observed in 14% of patients.

Half of the patients discontinued apremilast.



| MOST FREQUENT SE | |
|---------------------|----|
| SE | % |
| Diarrhea | 72 |
| Headache | 42 |
| Nausea and vomiting | 36 |
| Acid reflux | 32 |
| Decreased appetite | 18 |
| Abdominal pain | 18 |
| Depression | 12 |

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 ($p=0,044$).

CONCLUSIONS

- A high percentage of patients presented SE to apremilast, being diarrhea the most frequent.
- Patients demographic characteristics and diagnosis were not related to the ASE except 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 this type of patients.

