

**Conclusion** Almost all patients had received prior systemic therapy with conventional agents and/or biologics. The use of prenilast has some advantages including oral administration, being well tolerated and with a safer profile. It will likely be of value to these patients and those who may not be candidates for biologics.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 4CPS-034 USE OF USTEKINUMAB IN REFRACTORY PATIENTS OF PSORIASIS

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**Background** Ustekinumab is indicated for moderate to severe psoriasis (msPs) in patients who have had an inadequate response to systemic treatments.

**Purpose** To assess the effectiveness and safety of ustekinumab in our hospital patients with msPs refractory to tumour necrosis factor inhibitors (anti-TNF $\alpha$ ).

**Material and methods** Descriptive retrospective study from January 2010 to September 2018 was developed. Patients with msPs had previously been treated with  $\geq 2$  anti-TNF $\alpha$  and received ustekinumab were selected. Farmatools application and digital clinical history were used to record variables: age, gender, previous treatment, therapy duration, treatment regimen and Psoriasis Area and Severity Index (PASI). Patients with weight  $\leq 100$  kg received subcutaneous ustekinumab 45 mg at week 0, 4 and 16, followed by 45 mg every 12 weeks, and patients with weight  $> 100$  kg received ustekinumab 90 mg. Effectiveness endpoint was PASI90 ( $\geq 90\%$  reduction from baseline in PASI) and PASI75 ( $\geq 75\%$  reduction from baseline in PASI) at 24, 48 and 96 weeks. Adverse reactions (AR) were collected to analyse safety.

**Results** In the study period, 36 patients with mean age 47.2 (24–78) years were included: 22 (61.1%) men and 14 (38.9%) women. Previous anti-TNF $\alpha$  treatments were: 28 (77.7%) patients with etanercept+adalimumab, four (11.1%) infliximab+etanercept+adalimumab, two (5.6%) infliximab+adalimumab, one (2.8%) infliximab+etanercept and one (2.8%) efalizumab+infliximab. Mean therapy duration was 30.7 (6–85) months. Thirty-four (94.4%) patients received ustekinumab 45 mg and two (5.6%) ustekinumab 90 mg. At baseline: 29 (80.5%) patients had PASI  $\geq 12$ , two (5.6%) PASI=6, two (5.6%) PASI=4 and three (8.3%) PASI=2. At week 24 and 48: 24 (66.7%) patients achieved PASI90 and seven (19.4%) PASI75. At week 96, 35 patients were assessed (one withdrew from treatment for pregnancy): 20 (57.1%) patients achieved PASI90 and seven (20%) PASI75. No AR were reported.

**Conclusion** Ustekinumab was an effective treatment in more than half of our study patients with msPs refractory to  $\geq 2$  anti-TNF $\alpha$ , showing a response maintained for long periods of time (96 weeks). No patients recorded AR, so ustekinumab was safe in our hospital patients. Studies with a larger sample size and duration are necessary to

assess the effectiveness and security of ustekinumab. The main limitation of our research was the limited number of patients.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

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#### 4CPS-035 PERSISTENCE AND SAFETY OF APREMILAST IN PSORIASIS

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**Background** Psoriasis is a disease that requires long-term treatment. Apremilast is indicated in the treatment of psoriasis in patients who have not responded or have contraindicated or cannot tolerate other treatment systemics. This drug has a lower accumulated specific organ toxicity, so it seems that it is the first oral systemic drug with which long-term treatments can be planned.

**Purpose** To estimate the persistence and safety of treatment with apremilast in patients diagnosed with psoriasis.

**Material and methods** Retrospective observational study of all patients with psoriasis who were treated with apremilast (January 2016 to September 2018). Demographic variables (age, sex) and variables related to the drug were collected (treatment start and discontinuation date, adverse reactions, causes of suspension and previous treatment). Persistence was defined as time (months) from the start of treatment until its discontinuation due to toxicity or inefficiency. Persistence was calculated with Kaplan–Meier survival curves (log rank test).

**Results** Forty-two patients (54.8% women) were included. Mean age was 46.5 years (SD=13,2). Previous therapies: topical (100%), methotrexate (38.1%), acycrin (30.9%), cyclosporin (23.8%) and etanercept (7.2%). Average of previous treatments/patient: 2 (1–3). Mean persistence was 19.4 months (95% CI 14.9 to 23.9). At the end of the study period, 69% (n=29) of patients continued with apremilast and 31% (n=13) were discontinued. The causes of suspension were inefficacy in 62% (n=8) and toxicity in 38% (n=5). The severe adverse reactions that required the suspension of treatment were: diarrhoea (one), migraine (one), low back pain (one) and psychiatric disorder (two). Two patients required dose reduction (30 mg/24 hour). The estimated median time of treatment until discontinuation due to toxicity is 3 months compared to 4 months for patients who leave treatment due to inefficiency. There are no statistically significant differences between the survival curves of the causes of abandonment of treatment with apremilast (p=0.532). After 15 months of treatment the probability of discontinuing treatment for any of the causes is maintained over time.

**Conclusion** The role of the pharmacist is essential in detecting the symptoms and signs of toxicity and ineffectiveness in the first year of treatment. Even so it would be of interest to extend the study time to analyse the long-term persistence.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.