spacing dupilumab to 300 mg/3 weeks. One of them debuted with facial erythema a year after starting with dupilumab, the dose spacing was made the same month as the appearance of erythema. The other one presented erythema one month after the start of dupilumab, starting the dosing schedule 5 months after the onset of erythema. The third patient reported erythema one month after the start of dupilumab. Three months after the onset of erythema, she discontinued treatment due to primary inefficacy. One month after discontinuation of dupilumab, the erythema completely subsided. All three patients also experienced ocular adverse effects (dryness, irritation and/or conjunctivitis episodes), which resolved completely with dosage adjustment or discontinuation of dupilumab. A possible trigger for dupilumab-associated erythema is alcohol consumption. Two of the three patients confirmed worsening of erythema after alcohol consumption.

Conclusion and Relevance Head and neck erythema appears to be associated with the use of dupilumab, as an adverse effect not described in the data sheet. Extension of the experimental dosing interval to 300 mg/3 weeks or discontinuation of dupilumab partially or completely resolves the erythema in the patients in this case series.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-115 EVALUATION OF HYPOTHYROIDISM ASSOCIATED WITH APALUTAMIDE AND ENZALUTAMIDE TREATMENT IN METASTATIC PROSTATE CANCER USING THE EUROPEAN ADVERSE EFFECT DATABASE (EUDRAVIGILANCE)

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Background and Importance Hypothyroidism is a limiting and underestimated adverse effect of metastatic prostate cancer treatments, the impact of which in elderly patients is more significant. Apalutamide and enzalutamide are drugs with similar chemical structure, but differ in terms of adverse effect profile. Hypothyroidism is described as a common adverse reaction for apalutamide, but has not been evaluated in pivotal trials of enzalutamide.

Aim and Objectives To compare the incidence of hypothyroidism with apalutamide and enzalutamide by analysing spontaneous real-life reports obtained from EudraVigilance database.

Material and Methods Spontaneous notifications concerning the evaluated drugs were obtained from EudraVigilance, the European Medicines Agency's database for suspected adverse drug reactions. For each drug-event combination, the following were calculated as measures of disproportionality: the proportional reporting ratio (PRR), the 95% confidence interval (CI95%), the Chi-square (χ^2) and the number of reported cases. Among all reported adverse reactions, only those classified as hypothyroidism (event) were considered. The analysis periods were 2019–2023 for apalutamide and 2013–2023 for enzalutamide (from the date of authorisation). For the generation of an alert signal, the following 3 criteria must be met: PRR$\geq$2, $\chi^2\geq$4 and the number of new cases reported $\geq$3 (1).

Results In the period studied, for both drugs, a total of 26.077 adverse reaction reports were collected. Of these, 4.274 (16%) were for apalutamide and 21.803 (84%) for enzalutamide, of which 74 (1.7%) and 14 (0.06%) corresponded to hypothyroidism, respectively. The values of the disproportionality measures of apalutamide with respect to enzalutamide calculated were: PRR= 26.96 (15.24–47.69), χ^2=295.32 and number of hypothyroidism cases for apalutamide=74. According to these values, when all three criteria are met, a hypothyroidism alert for apalutamide would be generated.

Abstract 5PSQ-115 Figure 1

Conclusion and Relevance Our analysis performed on the EudraVigilance real-life database confirms the high incidence of hypothyroidism in patients treated with apalutamide, according to the SPARTAN and TITAN pivotal trials, compared to enzalutamide. On the other hand, a much lower incidence of hypothyroidism is evident for enzalutamide. The importance of monitoring for signs of hypothyroidism in patients treated with apalutamide is highlighted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Rothman KJ. The reporting odds ratio and its advantages over the proportional reporting ratio. *Pharmacoepidemiol Drug Saf*. 2004 Aug;**13**(8):519–23.

Conflict of Interest No conflict of interest.

5PSQ-116 REAL-WORLD PERSISTENCE WITH GUSELKUMAB AMONG ADULTS WITH PSORIATIC ARTHRITIS

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Background and Importance Guselkumab is a monoclonal antibody that selectively binds to interleukin 23 protein with a label indication in plaque psoriasis and psoriatic arthritis (PsA). Little information about real-world persistence with guselkumab therapy for PsA is known.

Aim and Objectives The aim was to evaluate persistence with guselkumab therapy in PsA.

Material and Methods Retrospective observational study was conducted in a tertiary level hospital. Patients who started treatment with guselkumab between 01/05/2020–01/09/2023 were included. Those with less than 9 months' treatment duration were excluded. The variables collected were sex, age, underlying pathology and comorbidities, previous treatments, and start-end date of treatment. Data analysis was performed using SPSS® version 24 statistical software. A descriptive analysis of the data was performed, comparative statistical tests, as well as a Kaplan-Meier survival analysis.

Results Among the 69 patients in the database who initiated guselkumab during the study period, 50 met the study inclusion criteria. The mean (SD) age was 53.3 (12.7) years and 58% were female. 44% (22/50) had been treated with four or

more PsA drugs before guselkumab and 74% used an anti-TNF drug.

The median drug survival (SD) was 20.6 (2.7) months. 52% of patients experienced the event (discontinuation of treatment) within 30 months of treatment. Persistence was 69.3% (ES:0.07) at 1 year of treatment and it decreased to 43.7% (ES:0.08) at 2 years of treatment.

There were no statistical differences between patients who had been treated with more or less than four previous treatments nor patients with and without comorbidities. However, we found some differences between patients with previous anti-TNF treatments and the ones who didn't use them. 30.8% of patients without Anti-TNF discontinued treatment vs 59.5% who used Anti-TNF before (p=0,075), mean drug survival in the first group (no anti-TNF) (SD) was 26.0(2.0) vs 16.4 (1.8) in the second group (p=0.02). The reason for these results may be because guselkumab is used in initial stages of the disease due to contraindications to anti-TNF.

Conclusion and Relevance As in clinical trials and another real-world study, high persistence rates were observed with guselkumab during the first year. Further real-world research should be conducted to correlate the differences found between patients with previous anti-TNF treatment, as no such differences were found in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-117 TRACEABILITY OF IMPLANTABLE MEDICAL DEVICES/ PATIENT INFORMATION: WHERE DO WE STAND?

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Background and Importance Health traceability of implantable medical devices (IMD) is a major public health issue. In the event of materiovigilance, this information can be used to trace patients who have received an IMD. Legal information relating to IMD is included in the patient file and must be transmitted to the patient on an implant card (Article R5212–42, French Public Health Code).

Aim and Objectives To assess the compliance of this traceability in our facility to comply with the new version of the Contract for the Improvement of Quality and Efficiency of Care (CAQES).

Material and Methods Ten IMD representative of the facility's activity, with different management and financing modes were selected and 50 interventions were analysed. Twenty-seven items were evaluated divided into four areas: traceability by pharmacy (9), by user service (6), traceability of patient information in the electronic patient record (EPR – 9) and transmission to the patients (3). This retrospective analysis was compared to a similar audit conducted in 2020.

Results Compliance rates are 86% for pharmacy traceability, 84% for service traceability, 52% for patient information traceability in the EPR and 96% for information transmission to the patient. There is a loss of information observed between traceability in business software and information recorded as transmitted to the patient, especially for IMD denomination, manufacturer name, lot and serial numbers. Practices vary depending on surgical specialties. The main non-compliances concern the provision of the implant card, the Unique Device Identifier (UDI), and the Individual Healthcare Identifiers (IHI) number, which are not tracked. Since 2020, practices have improved, especially in terms of patient information traceability, which has increased by 43%.

Conclusion and Relevance Despite the positive results for pharmacy and service traceability, the target set by CAQES for 2022–2024 (>75%) is not met for all criteria. Improvement areas include UDI traceability upon receipt and use, integration of the IHI number into the business software, and harmonising processes across different operating rooms. Improvement avenues for patient information traceability involve standardising liaison letters between surgical specialties, interoperability of business software, and traceability of the delivery of the operative report and implant card to the patient, all to maintain a high level of care quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-118 NON-ACTIVE PRESCRIPTIONS IN AMBULATORY PATIENTS: ANALYSIS AND EFFECT IN CONSULTATION WAITING TIME

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Background and Importance The optimisation of time within the Hospital Outpatient Pharmacy has become an urgent challenge in light of the remarkable surge in activity over recent years. A substantial number of patients arrive without an active prescription, rendering it impossible to dispense their medications promptly, consequently resulting in consultation delays and patient inconvenience.

Aim and Objectives The primary aim of this study is to delineate the chief causes of non-active prescriptions at the point of dispensation and to assess their impact on patient waiting times when attending the Hospital Outpatient Pharmacy.

Material and Methods Between January 2022 and September 2023, we conducted a prospective registration of patients lacking active prescriptions and subsequently selected a random sample for analysis. This investigation encompassed an assessment of the clinical service to which patients were affiliated, the reasons underpinning prescription unavailability, and the temporal discrepancy between the scheduled appointment time and the actual consultation conclusion time. It is essential to emphasise that we considered the appointment time as the moment of consultation entry, assuming zero delays. Data were meticulously gathered from the electronic prescribing software.

Results Our study encompassed a cohort of 81 patients. Among the patients who presented with non-active prescriptions, the implicated Clinical Services comprised Nephrology (21.0%), Rheumatology (21.0%), Neurology (16.0%), Pulmonology (11.1%), Internal Medicine (9.9%), Urology (7.4%), Dermatology (3.7%), Gastroenterology (3.7%), Endocrinology and Nutrition (2.5%), Allergy (1.2%), Haematology (1.2%), and Paediatrics (1.2%).

The rationales behind non-active prescriptions were multifarious: failure to renew prescriptions during the previous