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INCIDENCE OF SERIOUS GASTROINTESTINAL EVENTS AND INFLAMMATORY BOWEL DISEASE AMONG TILDRAKIZUMAB-TREATED PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

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Background: Tildrakizumab, is a high-affinity, humanised, anti-IL-23p19 monoclonal antibody for the treatment of chronic plaque psoriasis.

Objectives: Here, we evaluated gastrointestinal (GI) adverse events (AE) and, specifically, cases of inflammatory bowel disease (IBD; ie, Crohn’s disease or ulcerative colitis) in the clinical development program for tildrakizumab.

Methods: Patients with moderate to severe plaque psoriasis were randomised in 3 large, clinical trials: P05495 (phase 2; NCT01225731), reSURFACE 1 (phase 3; NCT01722331), and reSURFACE 2 (phase 3; NCT01729754). In this analysis, we identified serious GI AEs and new-onset or exacerbation of pre-existing IBD from a pooled dataset of tildrakizumab-treated patients from these 3 studies. Doses of tildrakizumab included 5 mg, 25 mg, 100 mg, and 200 mg in P05495 and 100 mg and 200 mg in the reSURFACE studies.

Results: In this analysis, we pooled 1911 patients from the 3 trials who received either tildrakizumab 100 or 200 mg. There were no new cases of IBD reported; among 6 patients with a history of IBD randomised to tildrakizumab, none experienced an exacerbation. The numbers (rate per 100 patient-years) of patients with serious GI AEs in the pooled dataset were 8 (0.80) for tildrakizumab 100 mg and 4 (0.43) for tildrakizumab 200 mg. These serious GI AEs included abdominal pain, constipation, diverticulum, dyspepsia, gastritis, thrombosed haemorrhoids, esophageal polyp, pancreatitis (1 patient each) among tildrakizumab 100 mg patients and abdominal hernia, upper abdominal pain, acute pancreatitis, and salivary gland enlargement (1 patient each) among tildrakizumab 200 mg patients.

Conclusions: In this post-hoc analysis of patients from 3 large randomised clinical trials, serious GI AEs were infrequent and there were no new cases of IBD or exacerbations of IBD.

REféREncES:

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Background: Radiographic damage is an important outcome in psoriatic arthritis (PsA) but the natural history of radiographic progression has not been well described. Randomised Controlled Trials (RCTs) of treatment with anti-TNF have shown reduced damage progression in the short term but long term real world data is lacking.

Objectives: We set out to describe the long term radiographic progression amongst patients with PsA who transitioned from conventional synthetic Disease Modifying Drugs (csDMARDs) to anti-Tumour Necrosis Factor Alpha inhibitors (anti-TNF) in routine care.

Methods: A retrospective sample of 28 patients (CASPAR criteria for PsA) was taken from the Bath longitudinal cohort. All patients had radiographs of the hands and feet taken at approximately 3 time points; 5 years before \( T_0 \), at the time of \( T_1 \) and 5 years post \( T_2 \) commencing anti-TNF treatment. 84 radiographs were scored using the Sharp-van der Heijde modified method (VDH) and osteoproliferation was scored using the psoriatic arthritis Rating score (PARS) method, by three assessors (AA, AA and WT). The assessors were blinded to the patient details and the order of the x-rays. Inter- and intra-rater reliability was assessed using intra-class correlation coefficients (ICC). Cumulative probability plots were used to describe radiographic progression on csDMARDs \( (T_0 \rightarrow T_1) \) compared with subsequent anti-TNF treatment \( (T_1 \rightarrow T_2) \). Change between probability plots was determined using the two-sample Kolmogorov-Smirnov test (K-S) test. This sample size was calculated to ensure 90% power to determine the smallest detectable difference of the VDH (6.25) to 5% significance level.

Conclusions: This study showed that patients often had substantial delays and misdiagnoses before they received a PsA diagnosis. Increased understanding of the diagnostic barriers may lead to earlier diagnosis and appropriate treatment that may improve outcomes.

REFERENCES:

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