INCIDENCE OF SERIOUS GASTROINTESTINAL EVENTS AND INFLAMMATORY BOWEL DISEASE AMONG TILDRAKIZUMAB-TREATED PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS: DATA FROM 3 LARGE RANDOMISED CLINICAL TRIALS

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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 1191 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 14 (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 saliary 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.

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DIAGNOSTIC EXPERIENCES OF PATIENTS WITH PSORIATIC ARTHRITIS: MISDIAGNOSIS IS COMMON

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Background: Psoriatic arthritis (PsA) is a heterogeneous, chronic, immune-mediated disease characterised by a range of musculoskeletal conditions including joint pain, swelling, enthesitis and dactylytis as well as skin and nail manifestations. Early diagnosis of PsA is important as shorter time to treatment may improves outcomes. However, PsA is often undiagnosed or misdiagnosed. There is limited information on the diagnostic experiences of patients with PsA, including medical care sought and potential barriers to diagnosis.

Objectives: To determine patients’ experiences related to the diagnosis of PsA including initial symptoms experienced, medical care sought, and time to diagnosis.

Methods: US patients aged ≥18 years with a self-reported diagnosis of PsA were recruited through CreakyJoints (www.Creakyjoints.org), an online patient support community comprising patients with arthritis and arthritis-related diseases and their caregivers, and outreach through social media. Participants completed an online survey designed to collect data on socio-demographics, clinical symptoms, disease burden, and diagnosis history, including initial PsA symptoms experienced, types of health care providers seen, misdiagnoses received before a diagnosis of PsA, and time to PsA diagnosis. Survey questions were developed following analysis of qualitative interviews of patients with PsA and clinical experts, as well as a targeted literature review.

Results: Of the 203 patients included in the study, 172 (85%) were female, with a mean (SD) age of 51.6 (10.8) years; 132 patients (65%) had private insurance, 61 (30%) Medicare, and 25 (12%) Medicaid. The most common initial symptoms that led patients to seek medical attention were joint pain (142 patients [70%]), stiffness (109 [54%]), swollen joints (101 [50%]), skin rash/psoriasis (97 [48%]), and fatigue (96 [47%]). Most patients (153 [75%]) sought medical treatment within 2 years of symptom onset. During the diagnosis process, patients most commonly sought care from a general practitioner (162 [80%]), rheumatologist (135 [66%]), dermatologist (67 [33%], orthopaedist (44 [22%]), and/or podiatrist (25 [12%]). Only 8 patients (4%) reported that they had never received a misdiagnosis; common misdiagnoses were psychosomatic disease, osteoarthritis, and anxiety/ depression (figure 1). Patients reported median (IQR) time since diagnosis of 6.0 (2–11.5) years. Many patients (94 [51%]) received a diagnosis of PsA ≤1 year after seeking medical attention; however, 25 (17%) and 31 (15%) patients received a PsA diagnosis ≤5 and 10 years after seeking medical attention for the first time, respectively.
THE TRAJECTORY OF RADIOGRAPHIC PROGRESSION SLOWS AMONGST PATIENTS WITH PSORIATIC ARTHRITIS TREATED WITH ANTI-TNF

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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. Radiographs were taken at approximately 3 time points: 5 years before T0, at the time of T1 and 5 years post T0 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 Ratingen 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 (T0 to T1) compared with subsequent anti-TNF treatment (T1 to T2). 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 detect the smallest detectable difference of the VDH (6.25) to 5% significance level.

Results: Of the 28 patients 15 were male, the mean age was 61 years (SD 13.4) and mean disease duration at T0 was 11.2 years (SD 11.14). The mean study follow up period was 10.2 years (SD 2.76). Inter- and intra-rater reliability was >0.9. The median VDH score at baseline was 8.5 (IQR 1.75–27.5). The median scores for erosions, joint space narrowing and proliferation at baseline were 1.5 (IQR 0–8.5), 4.5 (IQR 1–15) and 7 (SD 13.5) respectively. The median change in VDH score on csDMARDs was 11.00 (IQR 9–19.5) and on anti-TNF was 4.00 (IQR 0.75–11.5). The median rate of change in VDH score per year was 2.29 (IQR 0.85–3.81) on csDMARDs and on anti-TNF was 1.04 (IQR 0.16–0.016). These scores correlate with observed improvements in clinical disease outcome measures including tender joint count, swollen joint count and nail score (data not shown).

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: