037 Efficacy and safety of tirabrutinib, highly selective Bruton’s tyrosine kinase inhibitor, for oral treatment of pemphigus: a multicenter, open-label, uncontrolled, and extension study
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Tirabrutinib, a highly selective oral BTK inhibitor that is expected to inhibit the immunoglobulin G autoantibody-mediated mechanism that plays a central role in the pathophysiology of pemphigus. The aim of this study was to investigate the efficacy and safety of tirabrutinib in patients with refractory pemphigus. In this multicenter, open-label, extension phase 2 study, patients received post-marketing oral tirabrutinib 80 mg once daily for 52 weeks. In total, 16 patients were evaluated. The complete remission (CR) rate after 24 weeks of treatment (primary endpoint) was 18.6% (3/16 patients). The cumulative CR rate and cumulative remission rate at 52 weeks of treatment were 50.0% and 62.5%, respectively. Control of disease activity rates were 37.5%, 60%, 78.6%, and 92.0% at weeks 4, 12, 24, and 52, respectively. During the 52 weeks of tirabrutinib administration, decreases in pemphigus disease area index score, anti-desmoglein 1 and 3 autoantibody levels, and oral corticosteroid exposure were observed. One patient (6.3%) relapsed. The incidence of adverse events (AEs) and serious AEs were 87.5% and 18.8%, respectively. No grade ≥4 AEs were reported. The patients in this study showed favorable outcomes in response to the treatment with tirabrutinib and did not result in any major safety concerns. Thus, tirabrutinib may be a new treatment option for patients with refractory pemphigus.

038 Differences in clinical features and comorbid burden between HALA-C06:02 carrier groups in more than 9,000 people with psoriasis
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Dipeptidyl peptidase 4 (DPP-4) - inhibitors used for type 2 diabetes mellitus (DM) have been associated with significantly increased risk for bullous pemphigoid (BP). The purpose of the present study was to investigate the association of other DM drugs and the risk of BP in large national register data. We conducted a case-control study of 5078 BP patients aged over 40 years (mean age 77.6 years) and 19663 matched controls with basal cell carcinoma. Data on diagnoses and purchased reimbursed drugs were obtained from Finnish national registers. Associations between DM drugs usage and BP were evaluated using a conditional logistic regression model. After adjusting with several neurological diseases, DM and aldosterone antagonists, anticholinergics, antipsychotics and dopaminergic drugs, only DPP-4 inhibitors in monotherapy or as combination regimens were associated with the increased BP risk. Vildagliptin and linagliptin were associated with the highest risk for BP in monotherapy (Adjusted Odds Ratios 4.5 [95% CI 2.3-8.8] and 4.2 [95% CI 2.0-8.7], respectively) as well as in combination with metformin. Neither metformin mono-therapy, sulfonylurias, sodium-glucose co-transporter 2 (SGLT2) inhibitors, glucagon-like peptide-1 (GLP-1) analogues nor thiazolidinediones were associated with increased risk for BP. The present study strengthens the view of DPP-4 inhibitors being the most evident risk factor for BP among DM drugs. Also, it offers novel data showing GLP-1 analogues and SGLT2 inhibitors not being associated with increased risk of BP.

041 Efficacy with continuous dosing, down-triatment, or treatment withdrawal after successful treatment with baricitinib in patients with moderate-to-severe atopic dermatitis
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Baricitinib (BAR), an oral, selective Janus kinase (JAK)1/2 inhibitor, demonstrated long-term efficacy in moderate-to-severe atopic dermatitis (AD) in an ongoing, double-blind, phase 3 long-term extension study, BREEZE-AD3 (NCT03134435). We describe a sub-study on the efficacy of down treatment, either by reducing the dose of BAR or temporarily discontinuing BAR for a short period of time, in adult patients with moderate-to-severe AD. Ad was significantly higher in patients (n=526) treated with BAR 4mg or 2mg at entry into BREEZE-AD1 who achieved a vIGA-AD score of 0 (clear)/1 (almost clear)/2 (mild) at Week (wk) 52. BAR 4mg pts were rerandomized to BAR 4mg, BAR 2mg, or placebo (PBO) (BAR 4mg to BAR 4mg 40%, BAR 4mg to BAR 2mg 40%, PBO 20%). BAR 2mg pts were rerandomized to BAR 2mg, BAR 1mg, or PBO (BAR 2mg cohort). After 16 ws, we assessed the proportion of pts with vIGA-AD 0/1, vIGA-AD 0/1/2, vIGA-AD ≥1 (retreatment criteria) and retreatment pts recapturing vIGA-AD 0/1/2. In the BAR 4mg cohort, BAR 4mg, BAR 2mg, and PBO, respectively, the proportions were 51%, 45% and 30% for vIGA-AD 0/1 (P<0.001, P<0.001 vs BAR 4mg); 87%, 61% and 50% for vIGA-AD 0/1/2 (P<0.001, P<0.001, and PBO vs BAR 4mg); 39% (continuous 4mg), 49% and 56% of pts were retreated and of these, 67%, 78% and 83% recaptured efficacy. In the BAR 2mg cohort, BAR 2mg, BAR 1mg, and PBO, respectively, the proportions were 51%, 48%, 42%, and 40% for vIGA-AD 0/1 (P<0.001, P<0.001, P<0.001 vs BAR 2mg); 92%, 71%, and 45% for vIGA-AD 0/1/2 (P<0.001, P<0.001, and PBO vs BAR 2mg); 41% (continuous 2mg), 41%, and 64% of pts were retreated of these, 63%, 51% and 80% recaptured efficacy. BAR allows for pts to down titrate or stop treatment, with many pts maintaining clinically relevant efficacy levels after 16 ws and most pts regaining efficacy on retreatment.

042 Atopic dermatitis and the risk of eating disorders
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Evaluation of psychiatric morbidity in atopic dermatitis (AD) patients is essential for comprehensive care. AD is known to be associated with multiple mental disorders. Until now, there is a limited association between AD and eating disorders research. The aim of this study was to investigate the relationship between AD, eating disorders (ED) and food allergies. This retrospective epidemiological Finnish hospital registry-based study was conducted using all cases of AD under the age of 18 at the time of diagnosis between 1987 and 2018. Preselected ED diagnoses at the age of 18 and 10 years were searched for AD cases and for age- and sex-matched controls derived from a random sample of 500,000 Finnish residents in the Finnish Population Register Center database. In this study of 70,584 AD cases and 270,763 controls, AD patients significantly associated with all ED diagnoses compared to controls. At the age of 18 years, AD was most strongly associated with bulimia (adjusted OR 4.01, 95% CI 2.01-8.41) and binge-eating disorder (adjusted OR 2.25, 95% CI 1.75-3.23), the highest significant ED. Both EDs are clinically significantly between age 10-40. The found associations are not influenced by age, sex or food allergy. We conclude that this retrospective hospital registry-based study revealed significant associations between AD and eating disorders.