## 281 Real-World Effectiveness of Berotralstat in HAE With and Without C1-Inhibitor Deficiency

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**RATIONALE:** Berotralstat is a first-line, once-daily oral prophylactic treatment for hereditary angioedema (HAE). Here, we report real-world effectiveness of berotralstat in patients with HAE with and without C1-inhibitor deficiency who initiated berotralstat in the United States.

**METHODS:** Data were collected through the sole-source pharmacy and included patients with HAE with C1-inhibitor deficiency (HAE-C1INH; N=402) and physician-diagnosed HAE with normal C1-inhibitor level and function (HAE-nl-C1INH; N=302) who actively received berotralstat 110 or 150 mg between 12/16/2020–6/15/2023, for up to 540 days. Baseline attack rates were reported for the 90 days prior to berotralstat initiation and converted to a 30-day average for each patient. While on berotralstat, median($25^{th}$,$75^{th}$ percentile) attacks/month were calculated over each 90-day period by averaging each patient-reported monthly attack rate.

**RESULTS:** In patients with HAE-C1INH, the median baseline attack rate was 1.33(0.33,3.33) attacks/month (n=335). In the first 90 days, the median attack rate decreased to 0.5(0,1.50) attacks/month (n=365); median attack rates remained low with 0.5(0,1.33), 0.5(0,1.42), 0.5(0,1.50), 0.5(0,1.50), 0.5(0,1.50) attacks/month through Days 91-180 (n=289), 181-270 (n=231), 271-360 (n=200), 361-450 (n=159), and 451-540 (n=119), respectively. In patients with HAE-nl-C1INH, the median baseline attack rate was 3(1.33,>3.33) attacks/month (n=249), which decreased to 1(0.50,2.50) attacks/month in the first 90 days (n=277), and remained consistently low with median monthly attack rates of 1(0.33,2.75), 1.29(0.33,2.92), 1(0.29,2.50), 1.50(0.50,2.75), and 1.50(0.50,3) attacks/month through Days 91-180 (n=232), 181-270 (n=174), 271-360 (n=143), 361-450 (n=105), and 451-540 (n=79), respectively.

**CONCLUSIONS:** Long-term prophylaxis with berotralstat led to rapid and sustained reductions in monthly attack rates in HAE patients, regardless of C1-inhibitor function.

## 282 Burden of Illness in Female and Male Adult Patients With Hereditary Angioedema: Findings From a Multinational Survey

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**RATIONALE:** Hereditary angioedema (HAE) is a highly burdensome disease characterized by recurrent painful swelling attacks. There are limited data on the HAE disease burden described by gender.

**METHODS:** We conducted a non-interventional, cross-sectional, web-based survey of adults with HAE in 13 countries. Patient demographics and clinical characteristics reported included HAE attack rate. Patient reported outcomes included: Angioedema Control Test questionnaire (AECT; score <10 indicates patient perception of poorly controlled disease); Angioedema Quality of Life questionnaire (AE-QoL; higher score indicates higher impairment); and Hospital Anxiety and Depression Scale (HADS). Data were analyzed with descriptive statistics by gender.

**RESULTS:** 260 patients completed the survey; 189 females (mean±SD age 43.7±13.4 years) and 71 males (42.0±13.8 years). Mean±SD age at first symptoms was 12.1±8.9 and 11.9±9.1 years, while diagnosis occurred at 25.3±13.6 and 21.0±13.2 years in females and males, respectively. In the past 6 months, females experienced a higher mean±SD number of HAE attacks (12.1±14.4) than males (9.8±13.6). A lower proportion of females (57.1%) were on long-term prophylaxis than males (66.2%). Females reported greater health-related quality of life (HRQoL) impairment (AE-QoL total score [mean±SD] 46.5±23.3) than males (33.3±20.1). Perception of poorly controlled disease was observed in both genders (AECT total score [mean±SD] 7.1±3.0 females and 8.3±3.0 males). Moderate to severe anxiety and depression were reported in 33.9% and 12.2% females and in 7.0% and 5.6% males, respectively.

**CONCLUSIONS:** Females with HAE reported longer delay to diagnosis, greater burden of disease, poorer disease control and higher HRQoL impairment than males.

## 283 The UCARE Study on the Prevalence of Sleep Disorders and Nighttime Bruxism in People with Chronic Urticaria

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**RATIONALE:** Although previous studies suggest that people with chronic urticaria have poor sleep, there is little information on the prevalence of specific sleep disorders (SD) in these patients. Furthermore, it is unknown how sleep disturbances impact CU patients and if they are related to disease activity and control. As a result, we intend to discuss the sleep abnormalities found in CU patients and the distinctions between controlled and uncontrolled CU.

**METHODS:** This is a cross-sectional study using an online survey that was distributed by physicians to patients with CU from UCARE and ACARE networks. For screening SD, we used the GSAQ questionnaire and UCT for urticaria control evaluation. Descriptive analysis was performed for all questions in the questionnaire: mean and standard deviation for quantitative variables and frequency and percentage for categorical variables.

**RESULTS:** The study comprised 160 participants. In general, insomnia and OSA were the most common SD (29% and 28%, respectively). Uncontrolled urticaria patients had more cases of sleep disorders than their counterpart, the most frequent SD detected were insomnia (45%) and OSA (35%). Differences between both groups were statistically significant. Bruxism prevalence was 18%, and the majority of cases belonged to controlled urticaria.

**CONCLUSIONS:** This study shed light on the prevalence of SD among individuals with CU and provided insights into the association between disease control and SD. These findings emphasize the importance of considering SD as a significant aspect of CU patient care and management, highlighting the need for holistic approaches that address both disease control and associated sleep issues.

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