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Incidence of angioedema after initiation of angiotensin-converting enzyme inhibitors in adults with heart failure

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(0.43-0.46), n=4,530, PPV 92% IV. New on statins regardless of substance 13.71 (13.64-13.79), n=140,288, PPV 62%

Conclusions: When defining new users of a drug, it is important not only to differentiate between first-ever use and recurrent treatment episode but also to consider the earlier use of other substances that can be considered substitutes within the same group of substances.

Incidence of angioedema after initiation of angiotensin-converting enzyme inhibitors in adults with heart failure

Track: Safety End Points

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Background: Angioedema, a potentially life-threatening adverse event associated with angiotensin-converting enzyme inhibitor (ACEI) use, occurs more often among Black patients than non-Black patients. Specific angioedema incidence rates (IRs) among heart failure (HF) patients initiating an ACEI are limited.

Objectives: To provide estimates of angioedema incidence among HF patients initiating an ACEI, particularly among Black patients.

Methods: We conducted a retrospective cohort study among adult (≥18 years) patients with HF who initiated ACEI use at 5 healthcare delivery systems within the Cardiovascular Research Network between July 2015 and May 2019. We required patients to have ≥12 months of continuous medical and prescription drug coverage and no ACEI dispensings in the 1 year before treatment initiation. Our primary outcome was serious angioedema, defined as a primary or secondary diagnosis of ICD-9 code 995.1 ('Angioneurotic edema not elsewhere classified') or ICD-10 codes in the T78.3 series ('Angioneurotic edema') during hospitalization. Our secondary outcome was 'any angioedema', which included serious angioedema and non-serious angioedema that was diagnosed in the outpatient setting. We followed patients from ACEI initiation until first angioedema diagnosis or a censoring event (treatment discontinuation, initiation of another renin-angiotensin-aldosterone system blocking agent, disenrollment, death, or end of 365-day follow-up or study). We calculated crude IRs and exact 95% confidence intervals (CI) for angioedema among HF patients initiating an ACEI.

Results: We identified 14,241 ACEI users, of which 6,156 (43.2%) were women and 2,105 (15%) were self-reported Black. Mean age was 70 ± 14 years. We observed 6 serious angioedema events overall (IR: 0.8/1,000 person-years (PYs), 95% CI: 0.3-1.7), with 2 events occurring among Black patients (IR: 1.8/1,000 PYs, 95% CI: 0.2-6.5) and 4 events among non-Black patients (IR: 0.6/1,000 PYs, 95% CI: 0.2-1.5). We observed 43 angioedema events overall (IR: 5.4/1,000 PYs, 95% CI: 3.9-7.3), with 21 events occurring among Black patients (IR: 19/1,000 PYs, 95% CI: 11.8-29.1) and 22 events among non-Black patients (IR: 3.2/1,000 PYs, 95% CI: 2.0-4.9).

Conclusions: Our estimate of angioedema incidence among HF patients who initiated an ACEI (5.4 events/1,000 PYs) is slightly higher than a previously published estimate (3.3/1,000 PYs) among a similarly defined population identified through administrative claims data. Similar to prior reports, we found a higher incidence of angioedema, both serious and non-serious, among Black ACEI users than among non-black ACEI users.

Incidence of inpatient constipation among migraine patients treated with erenumab: A retrospective cohort study in a US electronic health record database

Track: Safety End Points

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Background: Erenumab was approved in the US in May 2018 as a first in class treatment for migraine prevention in adults. Constipation with serious complications has been observed among erenumab users in the post-marketing setting.

Objectives: This study describes the incidence of inpatient (IP) constipation among new erenumab users, overall and by baseline characteristics.

Methods: New erenumab users age ≥ 18 years were identified using prescription orders from May 2018 – March 2019 in the Optum Electronic Health Record Database. Patients were required to have at least 1 migraine diagnosis (ICD-10-CM G43.-) or prescription for a triptan/ergot in the prior year, and at least 1 outpatient (OP) visit at least 1 year prior to erenumab start to establish a 1-year period for assessing baseline characteristics. IP constipation events were identified with ICD-10-CM K59.0- in an emergency department (ED) or IP visit, and the 90-day incidence proportion (95% CI) was calculated.

Results: The study included 9,994 new erenumab users (87% female; mean age [standard deviation]: 46.6 (12.7) years). Fifty-five IP constipation events were identified (incidence: 0.6%, 95% confidence interval [CI]: 0.4–0.7). The incidence was 0.6% (95% CI: 0.4–0.8) in females, 0.3% (95% CI: 0.1–0.8) in males, 0.5% (95% CI: 0.4–0.7) in patients 18–64 years, and 1.0% (95% CI: 0.5–2.0) in patients ≥ 65 years. In patients with prescription drug use to treat constipation during baseline, incidence was 2.7% (95% CI:1.6–4.6) and for over-