Clinical Characteristics and Outcomes in a Cohort of Patients Starting Treatment

with Vericiguat in the United States

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Background and purpose

- Vericiguat is a soluble guanylate cyclase stimulator, which has been available in the United States (US) since 2021.
- ESC guidelines recommend vericiguat for patients with chronic HFrEF, NYHA class II–IV, who had a worsening event, despite receiving guideline-directed medical therapy (GDMT), to reduce the risk of cardiovascular mortality or heart failure hospitalization (HFH).
- Limited data are available about the characteristics and outcomes of vericiguat users in real-world clinical practice.

Methods

- Using two large, closed claims data sources from Health Verity in the US, we identified patients with a first ambulatory prescription for vericiguat (the index date) from 20 January 2020 to 30 June 2023.
- For inclusion, patients needed ≥1 year of continuous database enrollment, ≥1 GDMT prescription between 3 months before and 1 month after the first vericiguat prescription, and a baseline period of ≥3 months before the first vericiguat prescription.
- We evaluated patients' clinical characteristics (in the year before the index date) and other HFrEF treatments and comedications (in the 3 months before the index date).
- Outcomes during follow-up (mean 290 days, SD ±158)
 were all-cause mortality and first HFH (defined as an
 inpatient claim with a heart failure diagnosis code with a
 duration of >1 day. The two outcomes were also combined
 in a composite endpoint (all-cause mortality/first HFH).

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Results

- Among 1391 new users of vericiguat (mean age 64.7 years, 67.5% male, 23.9% smokers), 17.6% had undergone a coronary artery bypass graft and 47.1% had received an implantable cardioverter defibrillator.
- HFH before the index date occurred in 27.8% (within 3 months before) and 35.9% (within 6 months before).

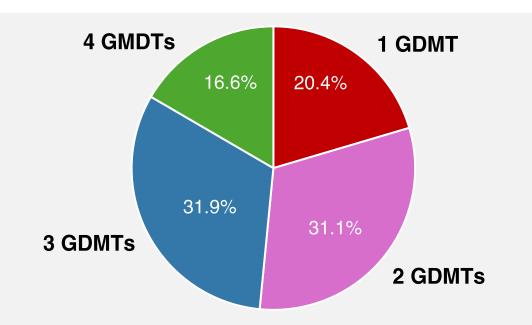


Fig 1. Number of GDMTs among the vericiguat study cohort.

- Most patients received either two or three GDMTs (Fig 1), the most common being beta blockers (80.2%; Fig 2). Oral loop diuretics and statins were other commonly used medications (Fig 3).
- Hypertension and hyperlipidemia were the most common comorbidities (Fig 4).

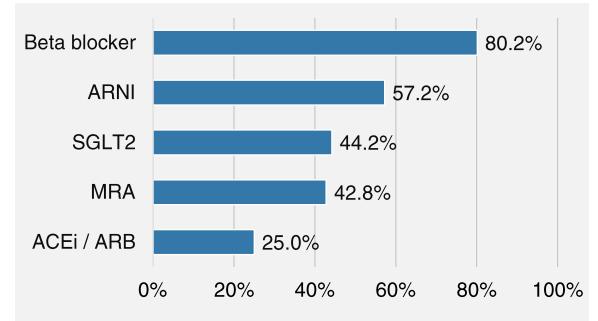


Fig 2. Type of GDMTs among the vericiguat study cohort.

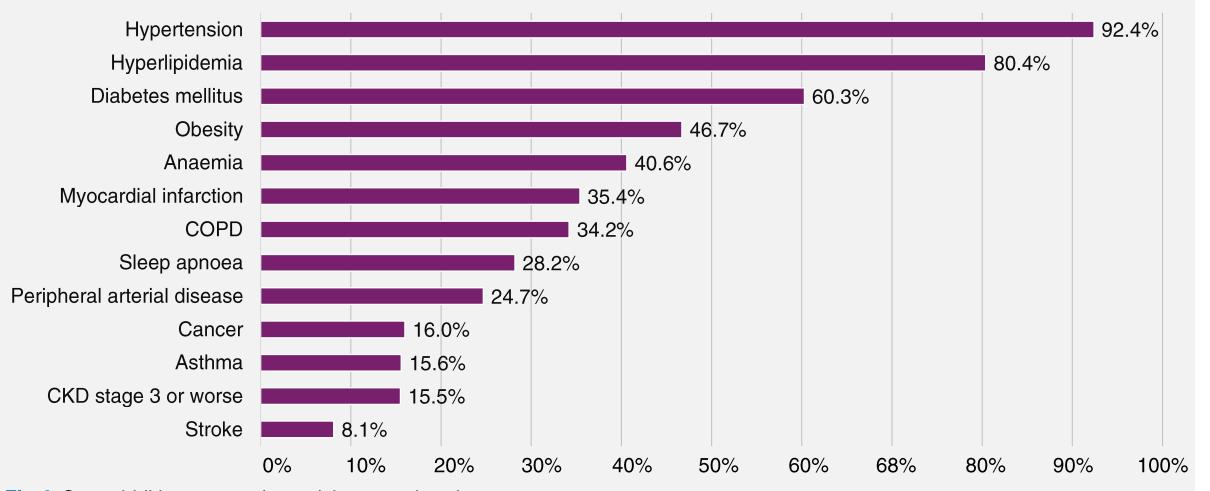


Fig 4. Comorbidities among the vericiguat study cohort.

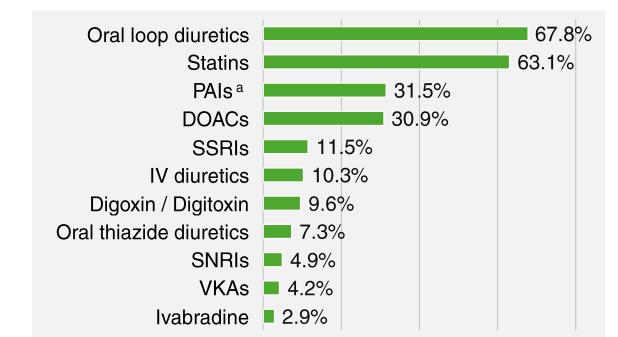


Fig 3. Other medications among the vericiguat study cohort. ^a Including aspirin. PAI, platelet aggregation inhibitor; SNRI, serotoninnorepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor

- During follow-up, 45 patients (3.2%) died; mortality rate of 4.1 per 100 person-years (95% CI: 3.0–5.5), and 382 patients (27.5%) had ≥ 1 HFH (incidence rate of 44.9 per 100 person-years, 95% CI: 40.6–49.7).
- Approximately 29% (403 patients) reached the composite endpoint (all-cause mortality/first HFH); an incidence rate of 47.4 per 100 person-years (95% CI: 42.9–52.2).

Conclusions

- Vericiguat users had a high level of comorbidities.
- Approximately half of the cohort had vericiguat added to existing triple or quadruple GDMT; the other half received only mono or dual GDMT when starting vericiguat. This could indicate intolerance to other GDMTs among these patients and/or vericiguat was added early in the treatment pathway.
- Mortality was low among vericiguat new users, and the combined endpoint was mainly driven by the HFH rate.
- Comparisons with clinical trial data should consider the broader definition of HFH used in this study.