From trials to treatment: real-world vericiguat initiation and residual risk in Germany

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Background and Purpose

- Vericiguat reduced the risk of cardiovascular death or hospitalisation for heart failure (HHF) in patients with heart failure with reduced ejection fraction (HFrEF) and a recent worsening heart failure (WHF) event in the VICTORIA trial (NCT02861534).[1]
- In patients with HFrEF but no recent WHF, the VICTOR trial (NCT05093933) showed no statistically significant benefit with vericiguat versus placebo in the primary endpoint.[2]
- We investigated clinical characteristics and outcomes in a real-world cohort of patients treated with vericiguat in routine care.

Methods

- This retrospective cohort study used anonymised claims data from the German InGef Health Research Database (approximately 10 million insured individuals).
- All patients with a new prescription of vericiguat between September 2021 and June 2024 were included.
- In line with trial definitions, patients were classified as 'VICTORIA-like' if HHF occurred within 6 months before the index date (time of initiation of vericiguat) or intravenous (IV) diuretics were used within 3 months before the index date; patients with a less recent or no prior WHF event were considered 'VICTOR-like'.
- Guideline-directed medical therapy (GDMT) use was assessed during the 3 months before the index date.
- Outcomes were: death, HHF, and their composite; Kaplan–Meier curves were generated and event rates per 100 patient-years (py) were calculated.
- Associations between HHF within 6 months before the index date, or IV diuretics or oral diuretic intensification (ODI) within 3 months pre-index, and post-index mortality risk were assessed using multivariable Cox regression adjusted for sociodemographics, HHF, ODI, IV diuretics, and comorbidities.

Results

- Among 732 patients initiating vericiguat (mean age 70 years, 22% female), 71% were classified as VICTORIA-like and 29% as VICTOR-like (**Table 1**); 11% of VICTOR-like patients had experienced an ODI during the 3 months prior to initiation.
- GDMT use during the 3 months prior to vericiguat initiation included beta-blockers (66%), renin–angiotensin system inhibitors (61%), mineralocorticoid receptor antagonists (40%) and sodium–glucose co-transporter 2 inhibitors (48%), with no major differences between the VICTORIA-like and VICTOR-like subgroups, with 18% receiving all four foundational drug classes.
- Outcomes in VICTOR-like and VICTORIA-like patients are shown in **Figure 1**. The overall rate of death during follow-up was 20 per 100 py in all patients (VICTORIA-like: 24/100 py; VICTOR-like: 12/100 py). Corresponding rates for HHF and the composite of death or HHF were 46/100 py (VICTORIA-like: 61/100 py; VICTOR-like: 23/100 py) and 57/100 py (VICTORIA-like: 74/100 py; VICTOR-like: 30/100 py), respectively.
- In multivariable regression models, the impact of pre-index ODI (hazard ratio [HR] 1.52; 95% confidence interval [CI] 1.11–2.07) on mortality risk was comparable to that of HHF within 6 months before the index date (HR 1.59; 95% CI 1.11–2.28), whereas pre-index IV diuretics had no effect (HR 0.93; 95% CI 0.69–1.25).

Conclusions

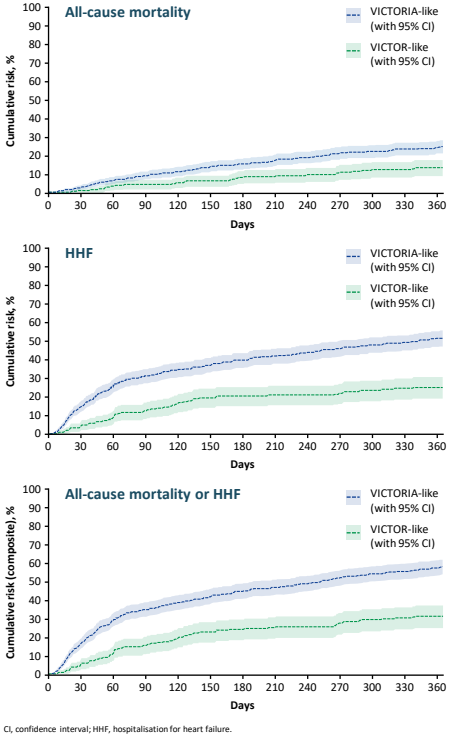
- In German routine care, vericiguat is initiated predominantly in VICTORIA-like patients but also in a substantial VICTOR-like minority, including patients with recent ODI.
- Residual risk for death and HHF remains high, particularly after recent WHF, and implementation of foundational GDMT remains incomplete.
- ODI may represent an outpatient marker of WHF risk comparable to recent HHF, even among ostensibly stable patients.

Table 1. Patient characteristics at the time of initiation of vericiguat

	All patients (n=732)	'VICTORIA-like' (n=519)	'VICTOR-like' (n=213)
Age			
Mean (SD)	69.9 (12.7)	70.3 (12.3)	69.1 (13.4)
Sex			
Female	163 (22.3%)	108 (20.8%)	43 (25.8%)
Male	569 (77.7%)	411 (70.2%)	158 (74.2%)
NYHA class†			
I	<5	–	<5
II	26 (3.5%)	7 (1.4%)	19 (8.9%)
III	263 (35.9%)	166 (32.0%)	97 (45.5%)
IV	402 (54.9%)	335 (64.6%)	67 (31.5%)
Comorbidities			
Anaemia	167 (22.8%)	130 (25.1%)	37 (17.4%)
Atrial fibrillation	444 (60.7%)	328 (63.2%)	116 (54.5%)
COPD	230 (31.4%)	170 (32.8%)	60 (28.2%)
Renal impairment	454 (62.0%)	349 (67.2%)	105 (49.3%)
Diabetes mellitus	425 (58.1%)	320 (61.7%)	105 (49.3%)
Hypertension	681 (93.0%)	489 (94.2%)	192 (90.1%)
Myocardial infarction	311 (42.5%)	214 (41.2%)	97 (45.5%)
Sleep apnoea	142 (19.4%)	107 (20.6%)	35 (16.4%)
Hypotension	147 (20.1%)	108 (20.8%)	39 (18.3%)
Hyperkalaemia	117 (16.0%)	94 (18.1%)	23 (10.8%)
Other HF medication			
Beta-blocker	481 (65.7%)	352 (67.8%)	129 (60.6%)
RASi	446 (60.9%)	316 (60.9%)	130 (61.0%)
MRA	293 (40.0%)	207 (39.9%)	86 (40.3%)
SGLT2i	354 (48.4%)	257 (49.5%)	97 (45.5%)
ODI	114 (15.6%)	91 (17.5%)	23 (10.8%)
IV diuretics	178 (24.3%)	178 (34.3%)	0 (0.0%)
Number of GDMT classes			
≤1	242 (33.1%)	166 (32.0%)	75 (35.2%)
2	173 (23.6%)	126 (24.3%)	47 (22.1%)
3	182 (24.9%)	132 (25.4%)	50 (23.5%)
4	135 (18.4%)	95 (18.3%)	40 (18.8%)

Data are n (%), unless indicated otherwise.
†Information on NYHA class was missing in n=37 patients.
COPD, chronic obstructive pulmonary disease; GDMT, guideline-directed medical therapy; HF, heart failure; IV, intravenous; MRA, mineralocorticoid receptor antagonist; NYHA, New York Heart Association; ODI, oral diuretic intensification; RASi, renin–angiotensin system inhibitor; SD, standard deviation; SGLT2i, sodium–glucose co-transporter 2 inhibitor.

Figure 1. Clinical outcomes with vericiguat in VICTORIA-like and VICTOR-like patients (unadjusted Kaplan–Meier curves)



CI, confidence interval; HHF, hospitalisation for heart failure.

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1. Armstrong PW, et al. *N Engl J Med*. 2020;382:1883–1893.
2. Butler J, et al. *Lancet*. 2025;406:1341–1350.

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