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Vericiguat In Decompensated Cardiac Failure: Clinical Insights on Addition to Guidelines-Derived Medical Therapy

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ABSTRACT

Objective: To assess the efficacy of vericiguat compared to placebo in patients with decompensated heart failure, focusing on key outcomes such as hospitalisation rates, cardiovascular death, and side effects like gastrointestinal disturbances and hypotension.

Methodology: A total of 130 patients were enrolled in a randomised controlled trial conducted at the Armed Forces Institute of Cardiology, Rawalpindi, from January 2026 to April 2026. Participants were randomly assigned to receive either vericiguat (n = 64) or placebo (n = 66). The primary outcomes were hospitalisation, cardiovascular death, and side effects, which were assessed through chi-square tests, t-tests, and descriptive statistics.

Results: The study demonstrated no statistically significant differences between the vericiguat and placebo groups. Heart failure hospitalisation occurred in 60.94% (n = 39) of the vericiguat group compared with 45.45% (n = 30) in the placebo group (p = 0.111). Cardiovascular death was observed in 46.88% (n = 30) of patients receiving vericiguat versus 59.09% (n = 39) in the placebo group (p = 0.223). Gastrointestinal disturbances were reported in 59.38% (n = 38) of the vericiguat group and 56.06% (n = 37) of the placebo group (p = 0.838), while hypotension occurred in 51.56% (n = 33) and 56.06% (n = 37), respectively (p = 0.735).

Conclusion: This randomised controlled trial compared vericiguat with placebo in heart failure with reduced ejection fraction, assessing hospitalisation, cardiovascular mortality, and safety outcomes. Vericiguat showed a numerical reduction in heart failure hospitalisation and a favourable trend in the composite outcome and cardiovascular death, but none of these differences were statistically significant.

Keywords: Cardiovascular Death, Heart Failure, Hospitalisation, Side Effects, Vericiguat

Authors' Contribution:
[1,2]Conception; Literature research; manuscript design and drafting; [3,4]Critical analysis and manuscript review; [5,6]Data analysis; Manuscript Editing.

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Introduction

Heart Failure (HF) is a progressive condition in which the heart cannot pump blood effectively, leading to inadequate oxygen and nutrient supply to tissues. Decompensated Heart Failure (DHF) is a severe form of HF characterized by worsening symptoms that often require urgent medical intervention and are associated with high morbidity and mortality rates.[1,2] Management of DHF, particularly in patients with reduced ejection fraction (HFrEF), has been widely studied, with emerging therapies such as vericiguat offering new treatment options. [3,4]

Vericiguat is a soluble guanylate cyclase (sGC) stimulator that enhances cyclic guanosine monophosphate (cGMP) levels, promoting vasodilation and reducing cardiac stress [5]. By

improving vascular function, vericiguat may enhance clinical outcomes in DHF, particularly when added to guideline-directed medical therapy (GDMT). Recent studies indicate that vericiguat, in combination with standard HF therapies, can reduce cardiovascular mortality and hospitalisations, especially in patients who respond inadequately to conventional treatments [6].

Hospital admissions due to HF exacerbations are common and often result in prolonged hospitalization and poor long-term outcomes. Vericiguat has been shown to reduce such hospitalisations, potentially improving patient quality of life and lowering healthcare costs.[7] Additionally, it may support beneficial cardiac remodeling, a key determinant of HF progression .[8]

The VICTORIA trial demonstrated that vericiguat significantly decreased cardiovascular mortality and HF-related hospitalisation in patients with HFrEF, establishing its efficacy in controlled clinical settings .[9] Ongoing studies continue to explore its effects on symptom management and patient outcomes in real-world populations.[10] However, vericiguat is associated with side effects such as gastrointestinal disturbances and hypotension, which may limit its use in certain patients .[11],[12] These considerations highlight the need for further studies to determine optimal dosing and identify patient populations most likely to benefit.

Introducing vericiguat to GDMT may represent a significant advance in DHF management, potentially reducing hospitalisations, mortality, and complications while improving quality of life. This study compares vericiguat and placebo in patients with DHF, focusing on primary outcomes of hospitalisation and gastrointestinal disturbances and secondary outcomes of mortality and hypotension.[5] The aim is to provide robust evidence on the safety and efficacy of vericiguat as an adjunct therapy for DHF.[13]

The aim of this study is to make a comparison of results of vericiguat and placebo in individuals with DHF, with the primary aim of comparing hospitalisation rate and gastrointestinal disturbances and secondary aims of comparing death and hypotension. It is on the basis of this comparison that we seek to present stronger evidence as to the safety and efficacy of vericiguat as an adjunct to GDMT in the treatment of DHF.

Methodology

It was a Randomised Controlled Trial (RCT), with the subject of study being in the Department of Cardiology, Armed Forces Institute of Cardiology (AFIC), Rawalpindi, Pakistan, from 3rd January 2026 to 3rd April 2026.

The overall sample size of 130 patients was computed with the help of the WHO calculator. This sample was divided into two groups, with each having 65 participants. This was calculated using a significance level of 5% and a power of 80% of the study and an anticipated percentage of hospitalisation of 12% and a placebo of 29.6 (similar to previous studies on HF treatment).[9] The sample size was considered sufficient to identify significant differences in the outcomes of interest in the two groups.

The study involved patients between the ages of 25 and 65 years of either sex diagnosed with DHF according to the operational definition. The operational definition of DHF was limited to individuals whose left ventricular ejection fraction (LVEF) was 45 or less, whose symptoms exhibited NYHA functional class III-IV or worsening functional class II and whose natriuretic peptides were increased. Instead, these patients had to possess an NT-proBNP of more than 1000 pg/mL in sinus rhythm or an NT-proBNP of more than 1600 pg/mL in atrial fibrillation and no other reasons explaining their high levels of biomarkers.

Patients with blood pressure under 100 mmHg, on long-acting nitrates, sGC stimulators, phosphodiesterase type 5 inhibitors, inotropes given intravenously or implantable left ventricular assist devices (LVADs) were excluded. Patients who were

severely comorbid and thus would confound the measurement of HF outcomes were also excluded.

Patients that satisfied the inclusion criteria were grouped randomly and in two groups using a random lottery process. In Group A, the patients were given vericiguat along with the regular therapy (sacubitrilvalsartan), increasing doses of 2.5 to 10 mg per day. Group B involved patients who were treated only with sacubitrol-valsartan. In this study, blinding was not used because the patients were allocated to treatment groups without knowing the outcomes of the other patients in the study; thus, there was no bias during the treatment allocation.

The research was launched following the consent of the IERB. Non-probability consecutive sampling was used to enrol seventy patients. Data collection entailed getting specific patient history (age, gender, HF duration, medical history (alcoholism, smoking, diabetes, and hypertension), baseline LVEF and NYHA class)). The patient was enrolled with informed consent of the person who attended him.

The follow-up was carried out within three months (3rd January 2026 – 3rd April 2026) in the outpatient department (OPD). The following outcomes were assessed at every follow-up visit: hospitalisation due to HF (hospitalisation was reported when symptoms increased and intravenous diuretic treatment was necessary), cardiovascular death, and side effects like gastrointestinal discomfort (nausea, vomiting, and abdominal pain) and hypotension (BP ≥ 100/60 mmHg). Any potential negative occurrences were noted on a structured performa that was kept during the study.

The main outcome was HF hospitalisation, which was identified by either the necessity to be hospitalised because of the increase in the symptoms of HF or the necessity to have intravenous diuretic treatment. The major outcomes were death related to cardiovascular events at the three-month follow-up and the side effects, gastrointestinal problems (nausea, vomiting and abdominal pain) and hypotension (BP 100/60 mmHg).

The data was keyed into SPSS version 26, and statistical analysis was carried out. The Shapiro-Wilk test was used to check the normality of data. The mean and the standard deviation were calculated in cases of numeric variables such as age, duration of HF, and EF. The categorical variables, including gender, smoking history, alcoholism, diabetes, hypertension and outcomes (hospitalisation, death and side effects), were presented as frequencies and percentages. The chi-square test was used to compare the results of Group A and Group B. The p-value was established at p 0.05. The stratification based on age, gender, smoking, alcoholism, diabetes, hypertension, EF at baseline, and NYHA class was conducted, and the Chi-square test was used to compare the outcome difference in each stratum after stratification.

The study was started after the AFIC Institutional **Ethical and Research Board** (IERB Ref#,9/29R&D/2025/372, dated 24 July 2025 and **RCT registration ClinicalTrials.gov ID: NCT07444398**, dated 02/26/2026) gave its ethical approval. Detailed information on the study was given to all the patients or their attendants, and informed consent was taken by the attendants of all the participants.

Results

A total of 130 patients were included in the study and analysed in accordance with the intention-to-treat principle, with 64(49.2%) allocated to the vericiguat group and 66(50.8%) to the placebo group. No patients were lost to follow-up or excluded from the final analysis. The overall demographic profile of the study population and baseline clinical characteristics are summarised in Table 1, while the distribution of NYHA functional class and laboratory parameters is presented in Table 2.

The mean age of the study population was 46.2±11.6 years, with a predominance of female patients 76(58.5%). The mean left ventricular ejection

fraction was 34.2±6.0%, consistent with heart failure with reduced ejection fraction. The mean NT-proBNP level was 1986.6±583.9 pg/mL, reflecting a moderately to severely symptomatic cohort. Hypertension was present in 63(48.5%) patients and diabetes mellitus in 76(58.5%) patients.

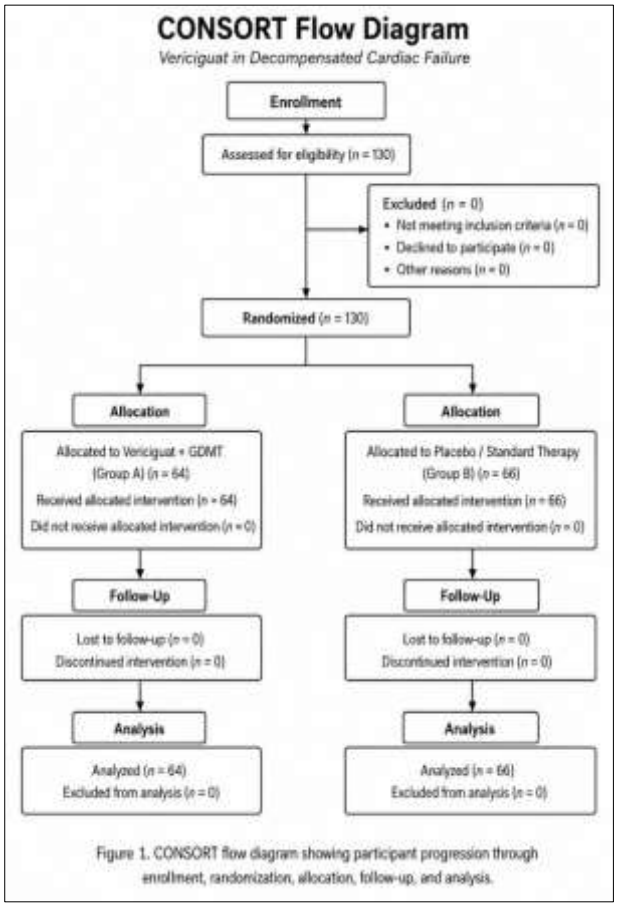

Figure 1. CONSORT flow diagram showing participant progression through enrollment, randomization, allocation, follow-up, and analysis.

Figure 1: CONSORT flow diagram

Table I shows the baseline demographic characteristics stratified by treatment group, including age, sex distribution, hypertension, diabetes mellitus, smoking status, and alcohol use. The groups were comparable at baseline, with no statistically significant differences observed in demographic variables. Age was 45.2±10.8 years in the vericiguat group and 47.1±12.3 years in the placebo group (p=0.421). Male sex was observed in 28(43.8%) and 26(39.4%) patients in the vericiguat and placebo groups respectively (p=0.621).

Table I: Baseline demographic characteristics of the study population

Variable	Vericiguat group n=64	Placebo group n=66	Total n=130	p-value
Age (years)	45.2±10.8	47.1±12.3	46.2±11.6	0.421
Male sex	28(43.8%)	26(39.4%)	54(41.5%)	0.621
Female sex	36(56.3%)	40(60.6%)	76(58.5%)	0.588
Hypertension	31(48.4%)	32(48.5%)	63(48.5%)	0.991
Diabetes mellitus	39(60.9%)	37(56.1%)	76(58.5%)	0.573
Smoking	32(50.0%)	33(50.0%)	65(50.0%)	1.000
Alcohol use	34(53.1%)	33(50.0%)	67(51.5%)	0.723

Table II: NYHA classification and baseline clinical parameters

Variable	Vericiguat group n=64	Placebo group n=66	Total n=130	p-value
NYHA Class I	17(26.6%)	14(21.2%)	31(23.8%)	0.642
NYHA Class II	16(25.0%)	19(28.8%)	35(26.9%)	0.688
NYHA Class III	19(29.7%)	19(28.8%)	38(29.2%)	0.931
NYHA Class IV	12(18.7%)	14(21.2%)	26(20.0%)	0.714
LVEF (%)	34.1±5.9	34.2±6.2	34.2±6.0	0.912
NT-proBNP (pg/mL)	1985.4±610.5	1987.6±550.8	1986.6±583.9	0.988

Table III: Clinical outcomes in the study population

Outcome	Vericiguat group n=64	Placebo group n=66	Total n=130	p-value
HF hospitalisation	15(23.4%)	23(34.8%)	38(29.2%)	0.140
Cardiovascular death	5(7.8%)	7(10.6%)	12(9.2%)	0.620
Composite endpoint	19(29.7%)	27(40.9%)	46(35.4%)	0.180

Table II presents the NYHA functional class distribution and baseline echocardiographic and biomarker profiles. NYHA Class III was the most frequent functional class, observed in 38(29.2%) patients overall. The distribution of NYHA class was similar between groups with no statistically significant differences. The mean LVEF was 34.1±5.9% in the vericiguat group and 34.2±6.2% in

the placebo group (p=0.912). NT-proBNP levels were also comparable between groups.

The primary outcome was a composite of heart failure hospitalisation or cardiovascular death. Table 3 summarises the clinical outcomes observed during follow-up. The composite endpoint occurred in 19(29.7%) patients in the vericiguat group compared with 27(40.9%) in the placebo group (p=0.180). Heart failure hospitalisation occurred in 15(23.4%) and 23(34.8%) patients in the vericiguat and placebo groups respectively (p=0.140). Cardiovascular death was observed in 5(7.8%) patients in the vericiguat group compared with 7(10.6%) in the placebo group (p=0.620).

Safety outcomes are presented in Table 4. Gastrointestinal disturbances were reported in 18(28.1%) patients in the vericiguat group and 17(25.8%) in the placebo group (p=0.780). Hypotension occurred in 12(18.8%) patients receiving vericiguat compared with 9(13.6%) in the placebo group (p=0.421). No statistically significant differences in adverse events were observed between the two groups.

Figures 1 and 2 illustrate the distribution of heart failure hospitalisation and cardiovascular death between the treatment groups. Figure 1 demonstrates a lower number of HF hospitalisations in the vericiguat group compared with placebo. Figure 2 shows a slightly lower number of cardiovascular deaths in the vericiguat group, although the difference was not statistically significant. The observed numerical reduction in the composite endpoint in the vericiguat group suggests a clinically favourable trend in line with evidence from the VICTORIA trial, which demonstrated modest reductions in HF hospitalisation in patients receiving vericiguat on top of guideline-directed medical therapy. However, the absence of statistical significance in this study is likely attributable to the limited sample size and short follow-up duration, indicating that the findings should be interpreted as exploratory and hypothesis-generating rather than confirmatory.

Table IV: Safety outcomes

Outcome	Vericiguat group n=64	Placebo group n=66	Total n=130	p-value
Gastrointestinal disturbances	18(28.1%)	17(25.8%)	35(26.9%)	0.780
Hypotension	12(18.8%)	9(13.6%)	21(16.2%)	0.421

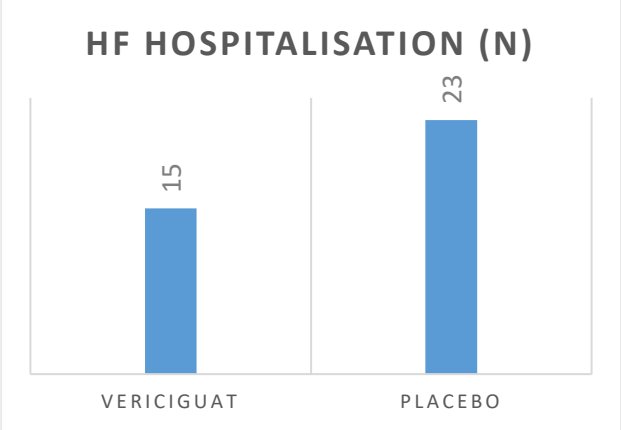

Figure 2: Heart Failure Hospitalisation

Discussion

The purpose of the study was to evaluate the effectiveness of vericiguat in the therapy of decompensated heart failure (DHF) and, in comparison with placebo, assess its impact on hospitalisation rates, cardiovascular mortality, and side effects such as gastrointestinal disturbances and hypotension. In our study, all key outcomes showed no statistically significant difference between the vericiguat and placebo groups. Specifically, hospitalisation rates, cardiovascular death, gastrointestinal disturbances, and hypotension did not differ significantly, suggesting that vericiguat did not confer measurable clinical benefits in this Pakistani cohort.

This research provides important insights into the local clinical practice of vericiguat in Pakistan, where data on its use and effectiveness are limited. As one of the first studies evaluating vericiguat outcomes in a South Asian population, it fills a gap in the literature and contributes to understanding whether findings from Western populations can be

generalized to countries with distinct demographics, healthcare access, and comorbidity profiles.

Previous international trials have shown differing results. The VICTORIA trial demonstrated a 10% reduction in the risk of cardiovascular death or HF-related hospitalisation in patients with HFrEF treated with vericiguat versus placebo.[4] Similarly, meta-analyses and systematic reviews have suggested that vericiguat may improve composite outcomes in HF, although benefits on cardiovascular mortality alone remain inconsistent.[14,15]

The discrepancy between our findings and international studies may reflect differences in patient demographics, comorbidity burden, and healthcare system constraints in Pakistan. Real-world studies have shown that outcomes with vericiguat can vary significantly depending on patient selection, disease severity, and adherence to guideline-directed medical therapy.[16,17] Moreover, the timing of vericiguat initiation may influence outcomes, with early initiation after initial HF hospitalisation showing better improvements in biomarkers and functional status.[18]

Despite these differences, vericiguat remains a promising adjunct to guideline-directed therapy. Studies combining vericiguat with "new quadruple" therapy (ARNI/ACE inhibitors, beta-blockers, MRAs, and SGLT2 inhibitors) have demonstrated improvements in ejection fraction, NT-proBNP levels, and quality of life in HFrEF patients.[19,20] Real-world registries also highlight that patients with higher comorbidity burdens and more severe HF may experience attenuated benefits, emphasizing the importance of local patient profiling and context-specific treatment strategies.[21]

In Pakistan, limited studies have explored newer HF therapies beyond conventional medications such as ACE inhibitors, beta-blockers, and sacubitril-valsartan.[4] Our findings highlight the necessity of additional region-specific clinical trials to determine whether vericiguat and other novel pharmacologic agents can deliver comparable benefits in South Asian populations. Such research could inform patient selection, optimize treatment timing, and improve adherence, ultimately tailoring therapy to the local context.

While vericiguat has shown efficacy in international trials and real-world studies, our results suggest limited benefits in a Pakistani cohort with decompensated HFrEF. This underscores the critical need for local clinical trials to evaluate the applicability of global findings and optimize heart failure management strategies in South Asia.

Limitations of the Study and Future Research: Even though this study will make a novel contribution, there are a number of limitations that should be discussed. The first was that it was a relatively small sample size, and the follow-up time was only three months. To tell what the real clinical benefits of Vericiguat are, bigger sample sizes and longer-term studies are required. Also, the response of the patients to the medication and hospital resources could have affected the outcome, and the subsequent research should take these variables into account in order to present a more accurate analysis.

Further studies are needed on multi-centre trials in Pakistan to determine what effect Vericiguat has on a larger and more diverse population, including other ethnicities and socioeconomic statuses. More research might also be done to investigate the use of Vericiguat as a combination therapy with other HF drugs in order to enhance patient outcomes.

Conclusion

This randomised controlled trial compared vericiguat with placebo in heart failure with reduced ejection fraction, assessing hospitalisation, cardiovascular mortality, and safety outcomes. Vericiguat showed a numerical reduction in heart failure hospitalisation and a favourable trend in the composite outcome and cardiovascular death, but none of these differences were statistically significant. Safety outcomes were comparable between groups. Overall, vericiguat demonstrated a

non-significant reduction in hospitalisation, suggesting potential benefit without confirmed superiority in this population, and further larger multicentre studies are required to establish its clinical role.

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