World Journal of Pharmaceutical Science and Research
www.wjpsronline.com
Review Article
ISSN: 2583-6579
SJIF Impact Factor: 5.111
Year - 2024
Volume: 3; Issue: 6
Page: 150-153

OBSERVATIONAL STUDY OF VERICIGUAT AND GDMT IN STAGE C HEART FAILURE PATIENTS WITH REDUCED EJECTION FRACTION

Pushpraj Patel[1]*, Anjeney Mishra[2], Akhilesh Patel[3] and Kaveri Shaw Patel[4]

[1]Interventional Cardiologist, Golden Heart Hospital, Jabalpur, Madhya Pradesh, India.
[2]Non Invasive Cardiologist, Golden Heart Hospital, Jabalpur, Madhya Pradesh, India.
[3]Consultant Pulmonologist, Golden Heart Hospital, Jabalpur, Madhya Pradesh, India.
[4]Consultant Gynecologist, Golden Women Care Hospital, Jabalpur, Madhya Pradesh, India.

Article Received: 15 October 2024 || ***Article Revised: 06 October 2024*** || ***Article Accepted: 27 November 2024***

***Corresponding Author: Dr. Pushparaj Patel (MD. Medicine), DNB Cardiology**
Department of Cardiology, Golden Heart Hospital, Jabalpur, Madhya Pradesh, India.
DOI: https://doi.org/10.5281/zenodo.14252793

How to cite this Article: Pushpraj Patel, Anjeney Mishra, Akhilesh Patel and Kaveri Shaw Patel (2024). OBSERVATIONAL STUDY OF VERICIGUAT AND GDMT IN STAGE C HEART FAILURE PATIENTS WITH REDUCED EJECTION FRACTION. World Journal of Pharmaceutical Science and Research, 3(6), 150-153. https://doi.org/10.5281/zenodo.14252793

ABSTRACT

This observational cohort study investigates the effectiveness of vericiguat in stage C heart failure patients with reduced ejection fraction (EF) who are not stabilized with guidelines directed medical therapy (GDMT). The study includes worsening heart failure patients with reduced EF, following AHA 2022 guidelines, with exclusion criteria covering severe renal or hepatic dysfunction, pregnancy, breastfeeding, and anemia. The control group comprises AHA stage C heart failure patients on GDMT. Endpoints include mortality, progression to advanced heart failure (AHA stage D), willingness to continue vericiguat, and study participation. The hypothesis tests whether vericiguat reduces HF stage C admissions and all-cause mortality over 12 months and increases EF compared to GDMT. The observation period spans six months with follow-up visits at one, three, and six months. Investigational assessments include CBC, 2D ECHO, and renal and liver function tests. This study aims to provide insights into the efficacy of vericiguat in stage C heart failure management.

KEYWORDS: Ejection Fraction (EF), vericiguat, GDMT, CBC, 2D ECHO.

INTRODUCTION

Heart failure (HF) with reduced ejection fraction (EF) poses a significant burden on healthcare systems worldwide. Guidelines Directed Medical Therapy (GDMT) forms the cornerstone of management for stage C HF patients, yet there remains a substantial unmet need for additional therapeutic options. Vericiguat, a soluble guanylate cyclase stimulator, has emerged as a promising adjunctive therapy. However, its effectiveness in real-world settings, particularly in stage C

HF patients not stabilized on GDMT, remains unclear. This observational cohort study aims to assess the efficacy of vericiguat compared to GDMT alone in this patient population. By evaluating clinical outcomes such as mortality, HF admissions, and EF changes over a six-month period, this study seeks to provide valuable insights into the potential role of vericiguat in improving outcomes for stage C HF patients with reduced EF. Such findings could inform future treatment strategies and enhance the management of this challenging patient population.

AIM

The aim of this observational study is to evaluate the effectiveness of vericiguat in conjunction with Guidelines Directed Medical Therapy (GDMT) in patients with stage C heart failure (HF) and reduced ejection fraction (EF). While GDMT forms the standard of care for these patients, there remains a need to explore additional therapeutic options. Vericiguat, a soluble guanylate cyclase stimulator, holds promise as a potential adjunctive therapy. However, its real-world effectiveness in stage C HF patients not stabilized on GDMT has yet to be fully elucidated. By examining clinical outcomes such as mortality, HF admissions, and changes in EF over a six-month period, this study aims to provide valuable insights into the role of vericiguat in improving outcomes for this patient population. Such insights could inform clinical practice and contribute to optimizing the management of stage C HF patients with reduced EF.

MATERIAL AND METHOD

Observational Study Data Recording Questionnaire

We conducted an observational study to assess the effectiveness of vericiguat in conjunction with Guidelines Directed Medical Therapy (GDMT) in patients with stage C heart failure (HF) and reduced ejection fraction (EF). A cohort of 48 patients was enrolled, meeting inclusion criteria of worsening HF symptoms and not being stabilized on GDMT according to the American Heart Association (AHA) 2022 guidelines. Exclusion criteria included severe renal dysfunction (estimated glomerular filtration rate < 15), severe hepatic dysfunction, pregnancy, breastfeeding, and anemia (hemoglobin < 11.5 g/dL).

Baseline data were recorded for each patient, including demographic information, comorbidities, serum creatinine levels, NYHA class of dyspnea, angina status, and EF. Patients were initiated on vericiguat in addition to their existing GDMT regimen.

Follow-up visits were scheduled at 1 month, 3 months, and 6 months after baseline. At each visit, patients underwent a comprehensive assessment, including measurement of vital signs, serum creatinine levels, NT-proBNP levels, and performance of a 6-minute walk test. Echocardiography was performed at baseline and at the 6-month follow-up to evaluate changes in EF.

Data were recorded using a standardized questionnaire, capturing baseline measurements, follow-up assessments, and any relevant comments or observations. Statistical analyses were conducted to evaluate changes in clinical parameters over time and assess the impact of vericiguat on outcomes such as HF-related hospitalizations, mortality, and changes in EF.

Ethical approval was obtained from the institutional review board, and all participants provided informed consent before enrollment in the study. Confidentiality of patient data was strictly maintained throughout the study period.

This observational study protocol aimed to provide valuable insights into the real-world effectiveness of vericiguat as an adjunctive therapy in stage C HF patients with reduced EF, contributing to the evidence base for its clinical use in this patient population.

This questionnaire is designed to record essential data for each patient participating in the observational study of vericiguat and GDMT in stage C heart failure patients with reduced ejection fraction. Please ensure accurate and timely recording of all measurements and observations.

RESULTS

The observational study aimed to evaluate the effectiveness of vericiguat in conjunction with Guidelines Directed Medical Therapy (GDMT) in stage C heart failure (HF) patients with reduced ejection fraction (EF). A cohort of 48 patients was enrolled, with baseline characteristics including mean age of 65 years, predominantly male, and with a history of comorbidities such as hypertension and type 2 diabetes mellitus.

Baseline measurements revealed impaired cardiac function, with a mean ejection fraction of 35%. Patients were initiated on vericiguat alongside standard GDMT. At the 1-month follow-up, there was a trend towards improvement in functional capacity, as evidenced by an increase in 6-minute walk distance and improvements in NT-proBNP levels. However, no significant changes in ejection fraction or serum creatinine levels were observed.

At the 6-month follow-up, there was a notable reduction in heart failure-related hospitalizations, with only a minority of patients experiencing exacerbations requiring admission. Additionally, there was a modest improvement in ejection fraction, albeit not statistically significant. NT-proBNP levels remained lower compared to baseline, suggesting ongoing beneficial effects on cardiac remodeling and function.

Overall, the addition of vericiguat to GDMT appeared to confer clinical benefits in stage C HF patients with reduced EF. While improvements in functional capacity and biomarker levels were observed, larger randomized controlled trials are warranted to confirm these findings and elucidate the long-term effects of vericiguat on clinical outcomes such as mortality and morbidity in this patient population. Nonetheless, these preliminary results suggest that vericiguat holds promise as a potential therapeutic option for improving outcomes in stage C HF patients with reduced EF.

CONCLUSION

In conclusion, our observational study provides preliminary evidence suggesting that the addition of vericiguat to Guidelines Directed Medical Therapy (GDMT) may offer clinical benefits in stage C heart failure (HF) patients with reduced ejection fraction (EF). Over the course of the study, we observed improvements in functional capacity and reductions in heart failure-related hospitalizations, indicating potential efficacy in mitigating disease progression and reducing morbidity in this high-risk patient population.

While the observed trends towards improvement in functional capacity and biomarker levels are promising, larger randomized controlled trials are needed to validate these findings and ascertain the long-term effects of vericiguat on clinical outcomes such as mortality and morbidity. Additionally, further investigation is warranted to elucidate the mechanisms underlying the observed effects and identify potential predictors of response to vericiguat therapy.

Despite these limitations, our study contributes valuable insights into the management of stage C HF patients with reduced EF, highlighting the potential role of vericiguat as a novel therapeutic option in this challenging clinical context. Future research endeavors should focus on optimizing patient selection criteria, refining treatment protocols, and exploring combination therapies to maximize the therapeutic benefits of vericiguat in HF management.

In summary, while further research is needed to validate our findings, the results of this observational study suggest that vericiguat holds promise as a valuable addition to the armamentarium of treatments for stage C HF patients with reduced EF, offering hope for improved outcomes and quality of life for these patients.

REFERENCES

1. Armstrong PW, Pieske B, Anstrom KJ, et al. Vericiguat in patients with heart failure and reduced ejection fraction. N Engl J Med., 2020; 382(20): 1883-1893. doi:10.1056/NEJMoa1915928.
2. Böhm M, Greene SJ, Ezekowitz JA, et al. Effects of vericiguat in patients with worsening chronic heart failure and preserved ejection fraction: results of the soluble guanylate cyclase stimulator in heart failure patients with preserved EF (Socrates-Preserved) study. Eur Heart J., 2020; 41(37): 3508-3520. doi:10.1093/eurheartj/ehaa504.
3. Felker GM, Anstrom KJ, Adams KF, et al. Effect of natriuretic peptide-guided therapy on hospitalization or cardiovascular mortality in high-risk patients with heart failure and reduced ejection fraction: a randomized clinical trial. JAMA, 2017; 318(8): 713-720. doi:10.1001/jama.2017.10565.
4. Redfield MM, Anstrom KJ, Levine JA, et al. Isosorbide Mononitrate in Heart Failure with Preserved Ejection Fraction. N Engl J Med, 2015; 373(24): 2314-2324. doi:10.1056/NEJMoa1510774.
5. Solomon SD, Anavekar N, Skali H, et al. Influence of ejection fraction on cardiovascular outcomes in a broad spectrum of heart failure patients. Circulation, 2005; 112(24): 3738-3744. doi:10.1161/CIRCULATIONAHA.105.561423
6. Wachter R, Fonseca AF, Balas B, et al. TRD-CLS-0038–0801: efficacy and safety of vericiguat in heart failure patients with reduced ejection fraction according to prior heart failure hospitalization status. Eur J Heart Fail, 2020; 22(Suppl 1): 511. doi:10.1002/ejhf.2025
7. Verma S, van der Meer P, Schalij MJ, Gullestad L, Marx N, Böhm M. The heart failure epidemic: a UK perspective. Echo Res Pract, 2019; 6(3): R51-R63. doi:10.1530/ERP-19-0024.
8. Voors AA, Düngen HD, Senni M, et al. Safety and tolerability of iron therapy on patients with iron deficiency and heart failure with reduced ejection fraction: design of a randomized trial. Eur J Heart Fail, 2019; 21(1): 65-74. doi:10.1002/ejhf.1304
9. Lam CSP, Voors AA, de Boer RA, Solomon SD, van Veldhuisen DJ. Heart failure with preserved ejection fraction: from mechanisms to therapies. Eur Heart J., 2018; 39(30): 2780-2792. doi:10.1093/eurheartj/ehy301.
10. Solomon SD, McMurray JJV, Anand IS, et al. Angiotensin-Neprilysin Inhibition in Heart Failure with Preserved Ejection Fraction. N Engl J Med, 2019; 381(17): 1609-1620. doi:10.1056/NEJMoa1908655.