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Drug Utilization and Evaluation of Vericiguat in Heart Failure Patients

P Salome Satya Vani[1]*, Sirasani Tapaswi[1], Kalavarala Battu Harshitha[1], Thodupunoori Bhuvana Chandra[1], Jitte Ashwini[1], Manoj Kumar Agarwala[2], Tripti Deb[2], Sarita Jangra[3]

[1]Department of Pharmacy Practice, Sri Venkateshwara College of Pharmacy, Madhapur, Hitech City Road-86, Hyderabad, Telangana, India, [2]Apollo hospitals, Jubilee hills, Hyderabad, India, [3]Chitkara College of Pharmacy, Chitkara University, Rajpur-Punjab, India. *Corresponding Author's Email: pssalom@gmail.com

Abstract

Drug Utilization Review (DUR) is an essential process for optimizing medication use, ensuring safety and efficacy through continuous evaluation. This study investigates the effectiveness of Vericiguat, a newly FDA-approved drug for heart failure (HF) patients. Vericiguat, a soluble guanylatecyclase stimulator, has shown promise in improving outcomes for HF patients, addressing issues related to impaired nitric oxide signaling. To evaluate the efficacy of Vericiguat, a prospective observational study was conducted in the cardiology department of a tertiary care hospital with 55 heart failure patients. Inclusion criteria included heart failure patients with reduced or preserved ejection fraction, chronic kidney disease, or type II diabetes mellitus, aged 18-75 years. The study followed patients for six months. The majority of patients were male, with most patients aged 66-75 years. The most prescribed dosage of Vericiguat was 2.5 mg OD, primarily for 3 months. Statistical analysis was performed using paired T-test via SPSS software. Significant improvements were observed in EF and SOB stages. Pre-treatment, 43 patients had HFrEF, which reduced to 22 post-treatments. Additionally, 23 patients initially in Stage III SOB improved to either Stage I or Stage II by the end of the study. Paired T-tests showed statistically significant differences in EF ($t = 13.072$, $p < 0.001$) and SOB ($t = 10.736$, $p < 0.001$) before and after treatment. These findings support the use of Vericiguat as an effective addition to existing HF treatment regimens, especially in patients with HFrEF and HFpEF, showing potential to reduce hospitalizations and cardiovascular events.

Keywords: Drug Utilization Review, Ejection Fraction (EF), Heart Failure with Preserved Ejection Fraction (HFpEF), Heart Failure with Reduced Ejection Fraction (HFrEF), Shortness of Breath (SOB), Vericiguat.

Introduction

Drug Utilization Review is a systematic and continuous evaluation of medication prescribing, dispensing, and use to ensure safety and effectiveness (1). It analyses patient data before, during, and after dispensing, promoting rational drug regimens and positive patient outcomes. DUR enhances healthcare quality by minimizing medication errors, lowering costs, and improving prescribing practices (2, 3). It is categorized into prospective, concurrent, and retrospective reviews, with pharmacists playing a pivotal role in prescription evaluation, patient monitoring, education, and interventions (4, 5). We have performed a prospective drug utilization study on a novel FDA approved drug named Vericiguat prescribed for cardiac failure patients. Heart failure (HF) is an ailment in which the heart flops to pump adequate oxygen to meet body's needs, affecting over 64 million people globally (6, 7). Heart failure is divided into left-sided, right-sided, and congestive types. Left-sided heart failure is impacted by the left ventricle, leading to two sub-types: Heart failure with reduced ejection fraction (HFrEF) and heart failure with preserved ejection fraction (HFpEF). The amount of blood the left ventricle pushes out with each contraction is measured as ejection fraction (EF) (8). A well-functioning heart's EF ranges between 55% and 70%. Taking into consideration ejection fraction as parameter, Heart Failure is classified as shown in Table 1. Common causes include coronary heart disease, heart muscle disease and high blood pressure, with risk factors like obesity, diabetes, smoking, and excessive alcohol intake (9). In HFrEF, myocardial dysfunction leads to poor contraction, ventricular remodelling, and

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activation of compensatory mechanisms, worsening the condition.

In HFpEF, the left ventricle remains stiff, impairing diastolic filling shown in the Figure 1 (10, 11). Symptoms include fatigue, shortness of breath, fluid retention, and reduced exercise tolerance, classified into NYHA stages I-IV (12, 13). Diagnosis involves tests such as NTproBNP, echocardiography, ECG, and chest X- rays (14). Management includes ACEIs or ARBs to reduce afterload, diuretics for volume overload, beta-blockers to mitigate sympathetic activation, MRAs for fluid regulation, and ARNIs or SGLT-2 inhibitors for comprehensive cardiovascular benefits (15).

Table 1: Heart Failure Conditions and their EF Percentages (8)

Heart Failure Condition	Ejection Fraction (%)
Heart failure with Reduced Ejection Fraction (HFrEF)	≤40%
Heart Failure with mildly reduced Ejection Fraction (HFmrEF)	41–49%
Heart Failure with Preserved Ejection Fraction (HFpEF)	≥50%

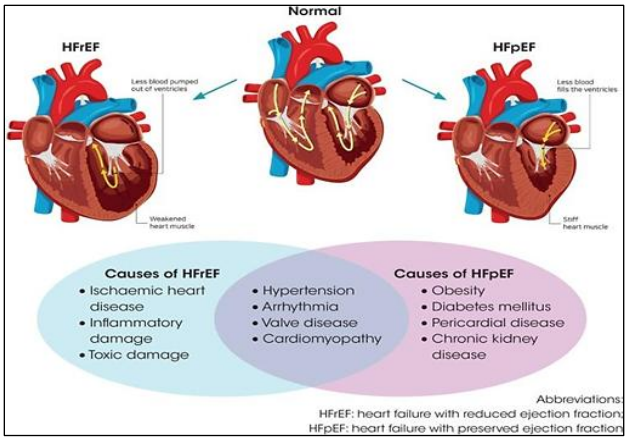

Figure 1: Differentiating Normal and a Failing Heart (11)

Despite advances, HF remains a significant cause of morbidity and mortality, necessitating continued research and innovation. In addition to existing therapies for HFrEF, HFpEF, and HFmrEF, Vericiguat emerges as a newly approved and promising treatment option, demonstrating significant potential in improving patient outcomes and addressing unmet needs in these complex heart failure conditions. Vericiguat is a ground-breaking oral soluble guanylatecyclase (sGC) stimulator approved for patients with HFrEF (EF <45%) to reduce HF hospitalizations and cardiovascular deaths (16). It works by addressing impaired nitric oxide (NO) signaling seen in HF, where reduced NO availability leads to decreased sGC function and cGMP synthesis, worsening vascular and myocardial dysfunction. Vericiguat directly stimulates sGC, increasing cGMP levels, improving myocardial contractility, vascular tone, and reducing HF progression (17). The Figure 2 shows the detailed view of mechanism of Vericiguat.

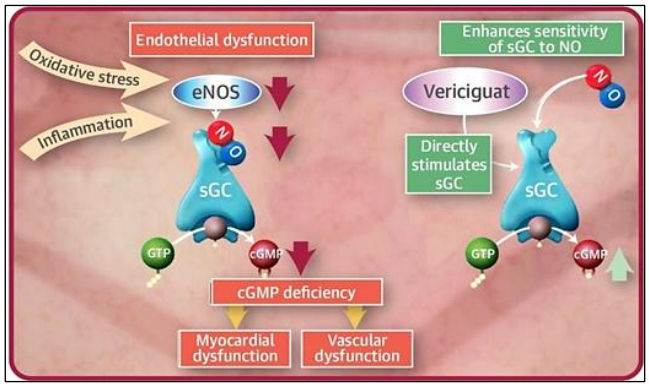

Figure 2: Mechanism of Action of Vericiguat (17)

Guidelines from the ESC, CCS, and ACC recommend Vericiguat for NYHA class II-IV HF patients who continue to be indicative contempt ideal therapy (18, 19). Benefits include improved HF symptoms, reduced fatigue, and shortness of breath, as demonstrated in trials like VICTORIA (20). It is initiated at 2.5 mg day-to- day with diet and titrated to 10 mg as tolerated. However, adverse effects like hypotension and anemia are noted, and it is contraindicated in pregnancy and with PDE-5 inhibitors due to the risk of severe hypotension. Vericiguat also holds promise as a potential therapy for HFpEF, offering improved upshots in patients with preserved EF (21, 22).

Methodology

A prospective cohort study was conducted in the section of cardiology at a super specialty hospital. The below Figure 3 denotes the outline of the procedure followed. 55 patients who were prescribed Vericiguat for cardiac failure with uncharacteristic ejection fraction percentages and SOB stages were carefully chosen based on the inclusion and exclusion standards. These 55 patients were tracked up for 6 months where the data regarding Vericiguat for HF along with co-morbidities and criteria applied was collected. The data for this study were obtained through manual chart abstraction, ensuring accurate and consistent collection of patient demographics, clinical outcomes, medication histories and other relevant clinical data. This data was analyzed using paired T test SPSS software.

Inclusion Criteria

- Cardiac failure patients with reduced, mildly reduced and preserved ejection fraction along with shortness of breath.
- Cardiac failure patients with type II diabetes mellitus and chronic kidney disease
- Age group of 18 to 75 years (inpatients and outpatients)

Exclusion Criteria

- Pregnant and lactating women
- Neonates and patients below 18 years of age
- Cancer patients
- Any other contraindication for usage of Vericiguat such as previous allergic reaction to same class modification
- The plan of work and procedure has been described in a flow chart shown in the Figure 3.

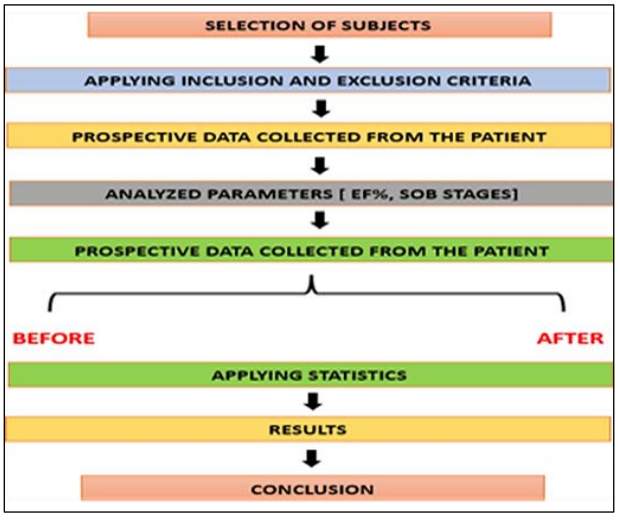

Figure 3: Summary of the Procedure

Results and Discussion

In our study, we collected 55 cases of patients who were prescribed Vericiguat for managing cardiac failure with abnormal ejection fraction percentages and SOB stages. We have followed up these patients for one to six months periodically (1,2,3,4,5,6 months). Greater number of male patients enrolled in our study than females i.e., 39 males and 16 females. A greater proportion of patients involved in the study were between the age of 66-75 years i.e., 23 patients. Type II Diabetes Mellitus is the most common comorbid condition among the patients suffering from heart failure observed in 27 patients can be seen in the Figure 4.

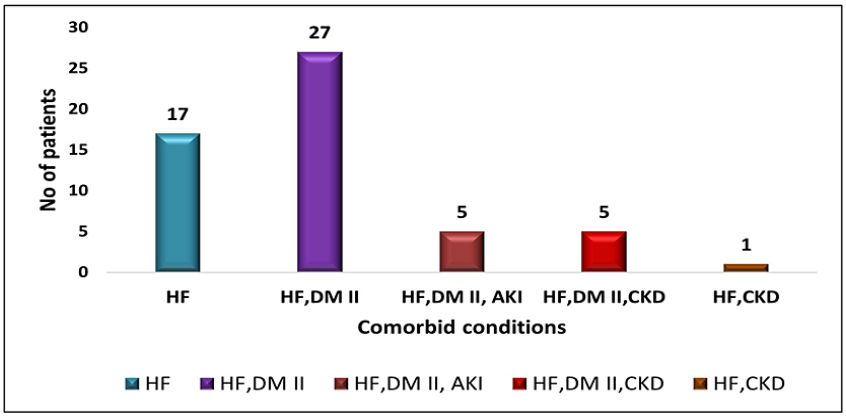

Figure 4: Distribution of Patients Based on Comorbid Condition

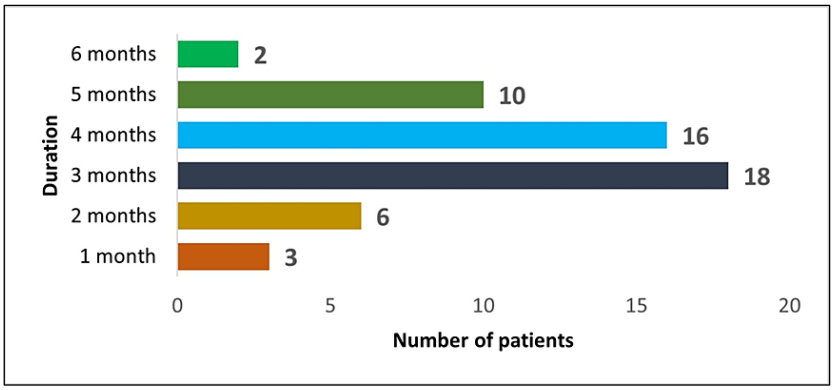

Figure 5: Number of Patients used Vericiguat for Different Durations in 6 Months

The most prescribed dose of Vericiguat was 2.5 mg OD to reduce the cardiovascular deaths given to 43 patients out of 55. Most number of patients used the Vericiguat for a period of 3 months i.e., 18 patients compared to number of patients used the Vericiguat for 1,2,4,5,6 months seen in Figure 5. Vericiguat was prescribed with other heart failure drugs in combination and the most prescribed combination was Sacubitril/Valsartan + Dapagliflozin or Empagliflozin + Vericiguat given to 25 patients shown in the below Figure 6.

The most prescribed concomitant HF drug prescribed with Vericiguat was statins, given to 45 patients. We have suspected some possible drug-drug interactions from the prescriptions. The most common possible interaction found was Vericiguat with sacubitril/valsartan which may cause low blood pressure with symptoms of chest pain, dizziness, fainting and headache in 35 patients out of 55. We also observed that 21 patients experienced hypotension and it was monitored by dietary advice.

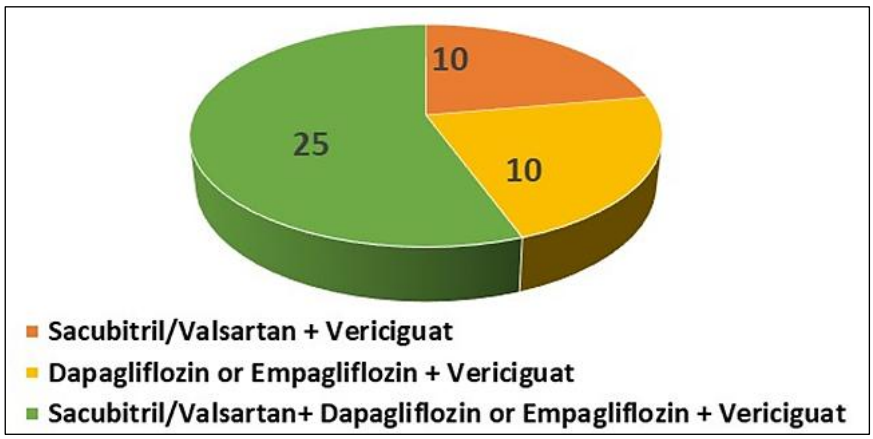

Figure 6: Combination of Drugs Prescribed Along with Vericiguat

According to the Guidelines patients with EF% ≤ 40 fall under the HFrEF stage, EF% 41-49 fall under the HFmrEF stage, and EF% ≥ 50 fall under the HFpEF stage. EF% was collected from the patient's 2D Echo reports for 1 to 6 months periodically and EF% changes were observed. The total number of patients with HFrEF out of 55 was 43 initially, before Vericiguat treatment. However, by the end of the study, i.e., following Vericiguat treatment, we were able to identify only 22 HFrEF patients. The total number of patients with HFmrEF out of 55 was 11 initially, before Vericiguat treatment. However, by the end of the study, i.e., following Vericiguat treatment, we were able to identify 22 HFmrEF patients. The total number of patients with HFpEF out of 55 was 1 initially, before Vericiguat treatment. However, by the end of the study, i.e., following Vericiguat treatment, we were able to identify 11 HFpEF patients. The below Figure 7 represents the number of patients in different stages of EF before and after Vericiguat treatment.

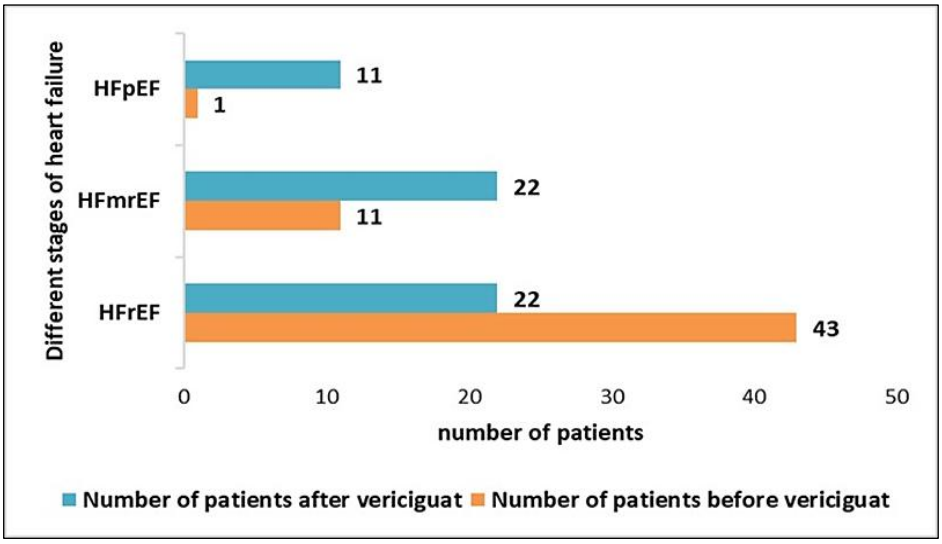

Figure 7: Number of Patients in Different Stages of HF based on EF before and after Vericiguat Treatment

In the study data was analyzed using Paired T-test. The alternative (H1) and null (H0) and hypothesis as per our assumptions in every statistical analysis were:

*H*0 = N*o significant variance observed between* EF and SOB *before and after* Vericiguat treatment.

*H*1= S*ignificant variance observed between* EF and SOB *before and after* Vericiguat treatment.

In Paired T-test value of P and T are considered for accepting or rejecting the assumptions:

If p= < 0.05 and t=> 1.96 then, H0 is rejected and vice versa

A paired sample t-test was performed on values of Ejection Fraction, pre-and post-Vericiguat treatment. According to the statistical analysis Table 2, t = 13.072 which is greater than 1.96 and p or Sig (2-tailed) was < .001. This specifies a significant variance between EF values before and after Vericiguat.

Table 2: Paired Samples t-Test Statistics - Ejection Fraction

Paired sample t-test statistics - Ejection fraction									
		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper	t	df	P or Sig (2-tailed)
Pair 1	EF before Vericiguat – EF after Vericiguat	-8.345	4.734	.638	-9.625	-7.066	-13.072	54	< .001

New York Heart Association (NHYA) classified heart failure patients with shortness of breath as Stage I to Stage IV. The data about SOB was collected from patient's reports for 1 to 6 months

periodically and SOB stage changes were observed. The overall number of patients in stage I out of 55 was 5 initially, before Vericiguat treatment. However, by the end of the study, i.e., following Vericiguat treatment, we were able to identify 27 stage I patients. The overall number of patients in stage II out of 55 was 23 initially, before Vericiguat treatment. However, by the end of the study, i.e., following Vericiguat treatment, we were able to identify 28 stage II patients. The overall number of patients in stage III out of 55 was 23 initially, before Vericiguat treatment. However, by the end of the study, i.e., following Vericiguat treatment, no patient is in stage III. The overall number of patients in stage IV out of 55 was 4 initially, before Vericiguat treatment. However, by the end of the study, i.e., following Vericiguat treatment, no patient is in stage IV. The below figure 8 represents the number of patients in different stages of SOB before and after Vericiguat treatment.

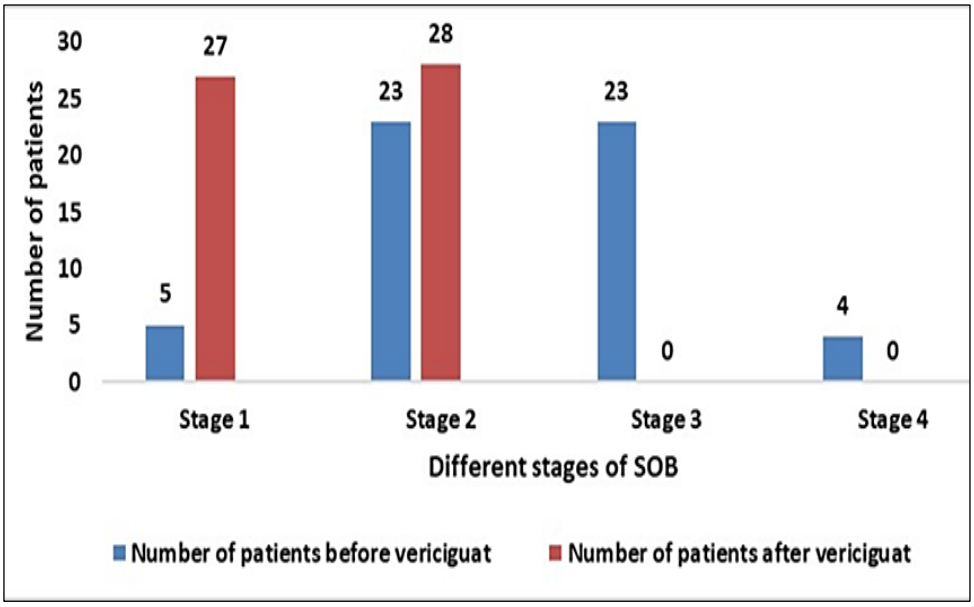

Figure 8: Number of Patients in Different Stages of SOB before and after Vericiguat Treatment

Table 3: Paired Samples t-Test Statistics- Shortness of Breath

		Paired sample t-test statistics – Shortness of breath							
		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	P or Sig (2tailed)
					Lower	Upper			
Pair 1	SOB before Vericiguat – SOB after Vericiguat	.96364	.66566	.08976	.78368	1.14359	10.736	54	< .001

A paired sample t-test was performed on stages of SOB, pre-and post-Vericiguat treatment. According to the statistical analysis Table 3, t = 10.736 which is greater than 1.96 and p or Sig (2-tailed) < .001. This specifies a significant variance between SOB stages before Vericiguat and after Vericiguat.

As shown in Figure 6, Vericiguat is prescribed in combination with ARNIs and SGLT-2 inhibitors to treat heart failure conditions. Thus, the EF and SOB changes in each combination therapy were analyzed. The table 4 shows the number of patients in different stages of HF according to ejection fraction before and after these combination treatments. A greater number of patients are there in HFrEF condition before every combination treatment and the number of patients in HFrEF condition decreased after every combination therapy.

Table 4: Combination Therapies with Vericiguat in Different EF Stages

Combination Therapies	No of Patients Before Using Combination Therapy			No of Patients after using Combination Therapy		
	HFrEF	HFmrEF	HFpEF	HFrEF	HFmrEF	HFpEF
Vericiguat along with Sacubitril/Valsartan (ARNIs)	8	1	1	4	4	2
Vericiguat along with SGLT-2 inhibitors (either Dapagliflozin or Empagliflozin	8	2	0	5	2	3
Vericiguat along with Sacubitril/Valsartan (ARNIs), SGLT-2 inhibitors (eitherDapagliflozin or Empagliflozin)	20	5	0	6	13	6

According to the statistical analysis all three combination therapies showed improvement in EF i.e, t >1.96 and p or Sig (2-tailed) < .001 which is less than 0.05 indicating a significant difference. But with higher t value of 10.320, Vericiguat along with Sacubitril/Valsartan (ARNIs) shows in Table 5, showed best results for EF parameter and may be taken as first choice of combination therapy.

Table 5: Paired Sample t-test Statistics-Combination Therapies with Vericiguat in EF Stages

Paired Sample t-test statistics – Ejection Fraction									
		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	P or Sig (2tailed)
					Lower	Upper			
Pair 1	EF before and after SGLT- 2 inhibitor + Vericiguat treatment	-7.3000	3.74314	1.1836	-9.97768	-4.62232	-6.167	9	<.001
Pair 2	EF before and after ARNIs + Vericiguat treatment	-7.70000	2.35938	.74610	-9.38780	-6.01220	-10.320	9	<.001
Pair 3	EF before and after ARNIs+ SGLT-2 inhibitor + Vericiguat treatment	-9.92000	6.14356	1.22871	-12.4559	-7.38406	-8.073	24	<.001

The Table 6 shows the number of patients in different stages of SOB before and after the combination treatments. Before each combination treatment a greater number of patients had stage III- stage IV SOB (severe SOB) and after each combination treatment no patient had severe SOB i.e., stage III and stage IV. After each combination treatment there is reduced intensity of SOB.

Table 6: Combination Therapies with Vericiguat in Different SOB Stages

Combination Therapies	No of Patients before using Combination Therapy				No of Patients after using Combination Therapy			
	Stage I	Stage II	Stage III	Stage IV	Stage I	Stage II	Stage III	Stage IV
Vericiguat along with Sacubitril/Valsartan (ARNIs)	2	5	2	1	5	5	0	0
Vericiguat along with SGLT- 2 inhibitors (either Dapagliflozin or Empagliflozin	0	4	4	2	3	7	0	0

Vericiguat along with Sacubitril/ Valsartan (ARNIs), SGLT-2 inhibitors (either Dapagliflozin or Empagliflozin)	2	12	11	0	15	10	0	0

According to our statistical analysis all three combination therapies showed reducing SOB intensity i.e, t >1.96 and p or Sig (2-tailed) < .001 which is less than 0.05 indicating a significant difference. But with higher t value of 8.048 seen I table 7, Vericiguat along with Sacubitril/Valsartan (ARNIs) and SGLT-2 inhibitors (either Dapagliflozin or Empagliflozin) showed best results for SOB parameter and may be taken as first choice of combination therapy.

Table 7: Paired Sample t-test statistics-Combination Therapies with Vericiguat in SOB Stages

		Paired Sample t-test - Shortness of breath Paired differences							
		Mean	Std. deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	P or sig (2-tailed)
					Upper	Lower			
Pair 1	EF before and after SGLT-2 inhibitor + Vericiguat treatment	1.1000	.73786	.2333	.57216	1.62784	4.714	9	<.001
Pair 2	EF before and after ARNIs + Vericiguat treatment	.70000	.67495	.21344	.21717	1.18283	3.280	9	.005
Pair 3	EF before and after ARNIs+ SGLT-2 inhibitor + Vericiguat treatment	.92000	.57155	.11431	.68408	1.15592	8.048	24	<.001

Out of 55 patients involved in our study, maximum number of patients was tracked up for a phase of 6 months as seen in graph 2. Thus, EF and SOB changes before and after Vericiguat treatment for 3 months were analyzed. Before using Vericiguat for 3 months there were 16 patients in HFrEF stage, 2 patients in HFmrEFstage and no patient in HFpEF stage. After using Vericiguat for 3 months there were 8 patients in HFrEF stage, 9 patients in HFmrEF stage and 1 patient in HFpEF stage. The figure 9 represents the number of patients in different stages of EF before and after Vericiguat treatment for 3 months.

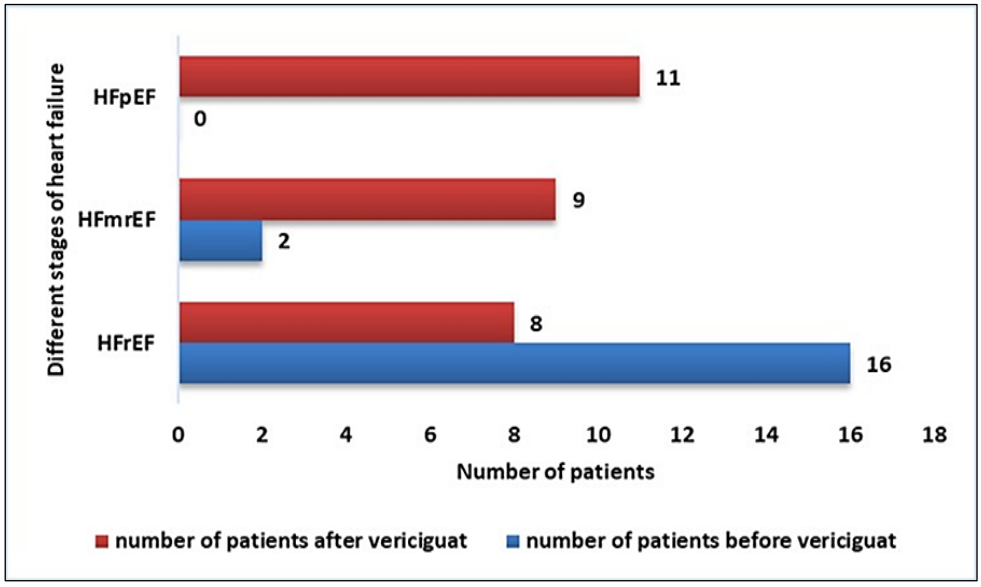

Figure 9: Number of Patients in Different Stages of EF before and after using Vericiguat for 3 Months

Table 8: Paired Sample t-test Statistics – 3 months of Ejection Fraction

Paired sample t-test statistics – 3 months of Ejection Fraction									
		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	P or Sig (2-tailed)
					Lower	Upper			
Pair 1	EF before 3 months of Vericiguat treatment – EF after 3 months of Vericiguat treatment	-8.44444	6.56391	1.54713	-11.70860	-5.18029	-5.458	17	< .001

A paired sample t-test was performed on values of Ejection Fraction, pre-and post-Vericiguat treatment for 3 months. According to the statistical analysis table 8, t = 5.458 which is greater than 1.96 and p or Sig (2-tailed) < .001. This specifies a significant variance between EF values before and after 3 months of Vericiguat treatment.

Out of 55 patients involved in our study, before using Vericiguat for 3 months, 2 patients were there in SOB stage I, 6 patients were there in SOB stage II, 7 patients were in SOB stage III and 3 patients were there in SOB stage IV. After using Vericiguat for 3 months, 8 patients were there in SOB stage I, 10 patients were there in SOB stage II, no patients were there in SOB stage III and SOB stage IV. The figure 10 represents the number of patients in different stages of EF before and after Vericiguat treatment for 3 months.

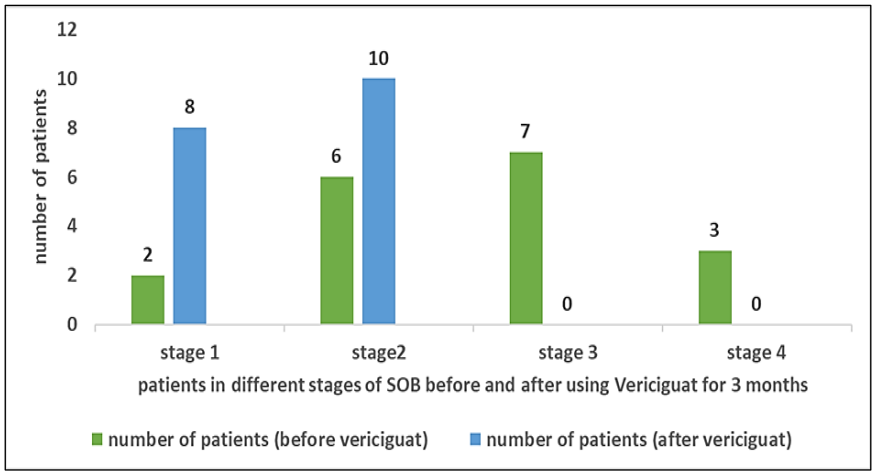

Figure 10: Number of Patients in Different Stages of SOB before and after Vericiguat Treatment

Table 9: Paired Samples T-Test Statistics – 3 Months of Shortness of Breath

Paired sample t-test statistics – 3 months of Shortness of breath									
		Paired Differences							
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	P or Sig (2-tailed)
					Lower	Upper			
Pair1	SOB before 3 months of Vericiguat treatment – SOB after 3 months of Vericiguat treatment	1.05556	.63914	.15065	.73772	1.37339	7.007	17	< .001

A paired sample t-test was performed on stages of SOB, pre-and post-Vericiguat treatment for 3 months. According to the statistical analysis table 9, t = 7.007 which is greater than 1.96 and p or Sig (2-tailed) < .001. This specifies a significant variance between SOB stages before and after 3 months of Vericiguat treatment.

Considering its clinical efficacy in Heart failure condition, Vericiguat demonstrates pharmacoeconomic value by reducing hospitalizations and improving quality of life. Despite a treatment cost of approximately ₹13,300 for 3-month duration of treatment, the associated reduction in healthcare utilization and improved patient outcomes suggest that Vericiguat is a cost-effective option for heart failure patients in real-world patient care.

Conclusion

We concluded from our study that Vericiguat was prescribed in proper dosage and properly administered as per standard guidelines to promote optimal therapy. We evaluated the drug effectiveness and identified possible drug – drug interactions. Out of 55 patients We found that, the highest number of males with Heart failure were under the age group of 66-75 and females were under the age group of 56-65. The most prescribed Concomitant drug along with Vericiguat was Statins. We found that major possible drug interactions are with clopidogrel. From standard Statistical Analysis, by using Paired t-test, we concluded that after using Vericiguat there was significant improvement in Ejection fraction and reduction in intensity of shortness of breath and Vericiguat with ARNI combination showed greater effect on improving ejection fraction values and Vericiguat with SGLT2 inhibitor and ARNI combination showed greater effect on reducing intensity of shortness of breath. Also, we have seen better improvement in patient's outcomes after using the Vericiguat for at least 3 months.

Vericiguat is pharmacoeconomically beneficial by significantly improving heart failure symptoms, reducing hospitalizations and their associated costs, and enhancing overall patient quality of life.

Hence, we conclude that Vericiguat has showed a significant positive effect in the Ejection Fraction, SOB profile and reduced the Heart failure Hospitalization when prescribed to Heart Failure patients with reduced and preserved ejection fraction.

Abbreviations

ACC: American College of Cardiology, ACEIs: Angiotensin Converting Enzyme Inhibitors, ARBs: Angiotensin Receptor Blockers, ARNIs: Angiotensin receptor-neprilysin inhibitors, CCS: Canadian Cardiovascular Society, DUR: Drug Utilization Review, ECG: Electrocardiogram, EF: Ejection Fraction, ESC: European Society of Cardiology, FDA: Food and Drug Administration, HF: Heart failure, HfpEF: Heart failure with preserved ejection fraction, HfmrEF: Heart failure with mildly reduced ejection fraction, HfrEF: Heart failure with reduced ejection fraction, MRAs: Mineralocorticoid receptor antagonists, NTproBNP: N-terminal pro-B-type natriuretic peptide, NYHA: New York Heart Association, PDE-5: Phosphodiesterase type 5, sGC: soluble guanylatecyclase, SGLT-2: Sodium-glucose transport protein 2, SOB: Shortness of Breath, SPSS: Statistical Package for the Social Sciences, VICTORIA: Vericiguat Global Study in Subjects with Heart, Failure with Reduced Ejection Fraction.

Acknowledgement

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Author Contributions

P. Salome SatyaVani and Manoj Kumar Agarwala: contributed to the methodological rigor of the paper by assisting in the selection and application of appropriate statistical tests and ensuring the accuracy of the data analysis using SPSS. All authors reviewed and approved the final manuscript.

Conflict of Interest

The authors declare that they have no conflict of interest that could have appeared to influence the work reported in this paper.

Ethics Approval

This study was conducted following ethical standards, with approval and consent obtained

from all individual participants included in the study (IEC Appl No: AHJ-ACD-028/11-23).

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None.

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