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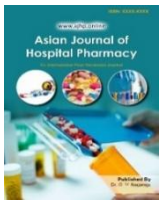

A PROSPECTIVE OBSERVATIONAL STUDY ON THE CLINICAL SAFETY AND EFFICACY OF SACUBITRIL AND VALSARTAN IN HEART FAILURE MANAGEMENT

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Abstract

Heart failure is a major cardiovascular disorder affecting millions of people worldwide and is associated with high morbidity, mortality, and frequent hospitalisation. Reduced ejection fraction (EF) is a significant indicator of disease severity and poor prognosis. The combination of Sacubitril and Valsartan has emerged as an effective therapeutic option for improving cardiac function and reducing hospitalisation in heart failure patients. The present prospective observational study was conducted to evaluate the safety and efficacy of sacubitril/valsartan in heart failure management over a period of six months at Gleneagles Hospitals. A total of 60 patients diagnosed with heart failure and reduced ejection fraction were included in the study. Patient data were collected from case records, prescriptions, laboratory reports, and medication history. Demographic distribution showed a higher prevalence among males (62%) compared to females (38%), with the majority of patients belonging to the age group of 61–70 years (33.33%). Out of 60 patients, 52 (87%) showed improvement in ejection fraction after initiation of sacubitril/valsartan therapy, indicating significant therapeutic efficacy. Furthermore, 50 patients (83.33%) demonstrated reduced frequent hospitalisation and improved quality of life. Safety evaluation revealed that 50 patients experienced no adverse drug reactions, while only 10 patients reported mild adverse effects such as hyperkalemia, angioedema, hypotension, and renal impairment. The findings conclude that sacubitril/valsartan therapy significantly improves ejection fraction, reduces hospital admissions, and provides a favourable safety profile in heart failure patients.

Keywords: Heart failure, Sacubitril, Valsartan, Ejection fraction, Hospitalisation, Safety, Therapeutic efficacy.

INTRODUCTION

Heart Failure is a complex clinical syndrome characterised by the inability of the heart to pump sufficient blood to meet the metabolic demands of the body. It remains one of the leading causes of morbidity and mortality worldwide, affecting nearly 64 million people globally and posing a significant burden on healthcare systems [1]. The prevalence of heart failure increases progressively with age, particularly in individuals above 60 years, and is commonly associated with underlying cardiovascular conditions such as hypertension, coronary artery disease, diabetes mellitus, and valvular heart diseases [2]. Despite advances in medical treatment, heart failure continues to be a major cause of repeated hospital admissions and reduced quality of life.Heart failure is broadly classified into heart failure with reduced ejection fraction (HFrEF) and heart failure with preserved ejection fraction (HFpEF). Among these, HFrEF is characterized by impaired systolic function and reduced left ventricular ejection fraction, which significantly increases the risk of mortality and hospitalization [3]. Ejection fraction (EF) is an important clinical parameter used to assess cardiac pumping efficiency, with values below 40% indicating severe left ventricular dysfunction. Reduced EF is associated with poor prognosis and progressive deterioration of cardiac function [4]. Conventional pharmacological management of heart failure includes angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), beta-blockers, diuretics, and

mineralocorticoid receptor antagonists. Although these therapies have improved survival rates, many patients continue to experience persistent symptoms and frequent exacerbations [5]. Recent therapeutic developments have introduced angiotensin receptor-neprilysin inhibitors (ARNIs) as a promising approach in heart failure management.

The combination of Sacubitril and Valsartan is the first approved ARNI for the treatment of HFrEF. Sacubitril inhibits neprilysin, leading to increased levels of natriuretic peptides, while valsartan blocks angiotensin II receptors, reducing vasoconstriction and aldosterone secretion [6]. Together, this dual mechanism enhances vasodilation, natriuresis, and cardiac remodelling while reducing myocardial stress and fluid overload [7].Clinical trials such as the PARADIGM-HF study demonstrated that sacubitril/valsartan significantly reduced cardiovascular mortality and hospitalisation compared to enalapril in HFrEF patients [8]. In addition, real-world studies have shown improvements in ejection fraction, symptom control, and overall quality of life among patients receiving this therapy [9]. However, adverse effects such as hypotension, hyperkalemia, renal impairment, and angioedema remain concerns requiring careful monitoring [10-12].

Therefore, the present study was undertaken to evaluate the clinical safety and efficacy of sacubitril and valsartan in heart failure management by assessing improvements in ejection fraction, reduction in hospitalisation frequency, and occurrence of adverse drug reactions in routine clinical practice.

MATERIALS AND METHODS

Study Design

The present study was designed as a prospective observational study to evaluate the clinical safety and efficacy of the combination therapy of Sacubitril and Valsartan in the management of patients diagnosed with heart failure. The study focused on assessing improvement in ejection fraction, reduction in hospitalization frequency, and monitoring adverse drug reactions during the treatment period.

Study Site

The study was conducted in the Department of Cardiology at Gleneagles Hospitals, a tertiary care multispecialty hospital located at Lakdikapul, Hyderabad, Telangana, India.

Study Duration

The study was carried out over a period of six months.

Sample Size

A total of 60 patients diagnosed with heart failure and receiving sacubitril/valsartan therapy were enrolled in the study.

Source of Data Collection

Data were collected from multiple sources to ensure comprehensive patient evaluation, including:

- Patient data collection forms
- Patient case notes and prescription records
- Laboratory investigation reports
- Patient medication history
- Follow-up clinical reports
- Patient interviews

Study Procedure

The study was initiated after obtaining approval from the Institutional Ethics Committee. A detailed literature survey was conducted to understand the current therapeutic role of sacubitril/valsartan in heart failure management. A structured patient data collection form was prepared to record all relevant clinical and demographic details.

Eligible patients diagnosed with heart failure and prescribed sacubitril/valsartan were included in the study. Baseline parameters such as age, gender, body mass index (BMI), co-morbidities, ejection fraction, hospitalization history, and medication history were documented. Patients were monitored during the study period to evaluate changes in ejection fraction, clinical improvement, and occurrence of adverse drug reactions[13-16].

Inclusion Criteria

Patients fulfilling the following criteria were included:

- Patients of all age groups diagnosed with heart failure
- Patients with confirmed severe left ventricular dysfunction
- Patients with ejection fraction <35%
- Patients receiving sacubitril/valsartan therapy
- Patients willing to participate and provide necessary information

Exclusion Criteria

The following patients were excluded:

- Patients with ejection fraction >50%
- Patients with chronic renal disease (Serum creatinine >2 mg/dL)
- Pregnant and lactating women
- Non-cooperative patients
- Patients with frequent hypotension or decreased eGFR

Assessment of Efficacy

Therapeutic efficacy was assessed based on:

- Improvement in ejection fraction after drug administration
- Reduction in frequent hospitalization
- Improvement in patient clinical condition
- Better symptom control and quality of life

Safety Assessment

Safety evaluation was performed by documenting adverse drug reactions such as:

- Hypotension
- Hyperkalemia
- Angioedema
- Renal impairment

Statistical Analysis

The collected data were compiled and analyzed using appropriate statistical methods. Results were expressed in the form of frequencies, percentages, and comparative observations to determine the efficacy and safety outcomes of sacubitril/valsartan therapy[17-19].

Ethical Clearance

Prior to the initiation of the study, ethical clearance was obtained from the Institutional Ethics Committee of Gleneagles Hospital. Written informed consent was obtained from all participants, and patient confidentiality was maintained throughout the study.

RESULTS AND DISCUSSION

Gender-wise Distribution of Patients

The gender-wise distribution of the study population showed that out of 60 patients, **37 (62%) were male** and **23 (38%) were female**, as presented in Table 01. This indicates a higher prevalence of heart failure among male patients. The increased male predominance may be associated with higher cardiovascular risk factors such as smoking, hypertension, and sedentary lifestyle.

Table 01: Gender-wise distribution of patients

Gender	Total Number of Patients	Percentage (%)
Male	37	62
Female	23	38

Age-wise Distribution of Patients

The age-wise distribution revealed that the majority of patients belonged to the 61–70 years age group (33.33%), followed by 51–60 years (26.66%), as shown in Table 02 and Figure 01. This indicates that heart failure is more common among elderly patients due to progressive cardiac dysfunction and associated co-morbidities.

Table 02: Age-wise distribution of patients

Age Group (Years)	Male	Female
10–20	0	0
21–30	0	0
31–40	2	1
41–50	4	3
51–60	10	6
61–70	12	8
71–80	7	3
81–90	2	2

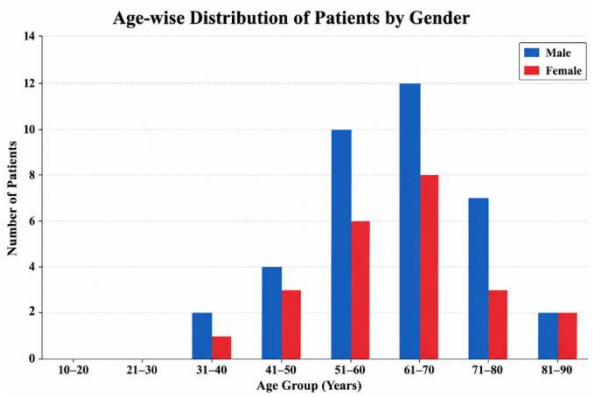

Figure 01: Distribution of Patients According to Age and Gender

Age-wise Percentage Distribution

The percentage-wise age distribution shown in Table 03 and Figure 02 demonstrated that the highest proportion of patients was in the 61–70 years age group (33.33%), indicating increased susceptibility to heart failure with advancing age.

Table 03: Age-wise percentage distribution of patients

Age Group	Total Patients	Percentage (%)
10–20	0	0
21–30	0	0
31–40	3	5
41–50	7	11.67
51–60	16	26.66
61–70	20	33.33
71–80	10	16.67
81–90	4	6.67

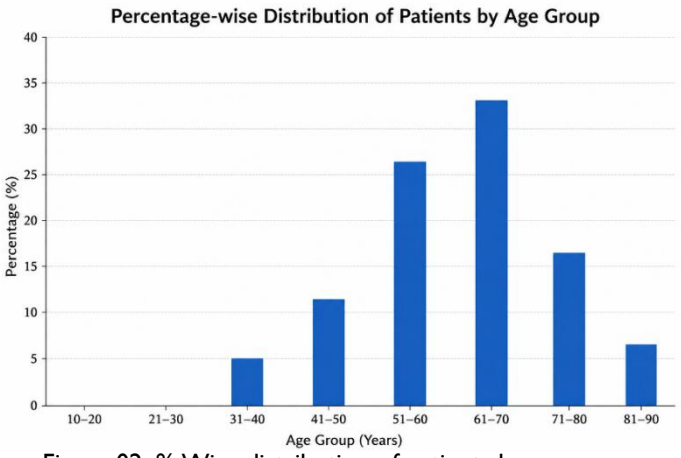

Figure 02: % Wise distribution of patients by age group

Body Mass Index (BMI) Distribution

BMI analysis demonstrated that 31.67% of patients were overweight, followed by 28.33% normal weight, 26.66% underweight, and 13.34% obese, as shown in Table 04 and Figure 03. Overweight and obesity may increase cardiovascular burden and worsen heart failure outcomes.

Table 04: Distribution of patients based on BMI

BMI Category	Number of Patients	Percentage (%)
Underweight	16	26.66
Normal	17	28.33
Overweight	19	31.67
Obese	8	13.34

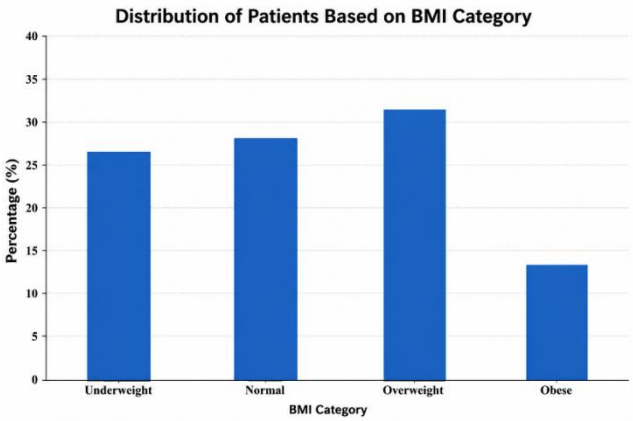

Figure 03: Distribution of patients based on BMI

Distribution Based on Co-morbidities

Out of 60 patients, 42 (70%) had co-morbidities and 18 (30%) had no co-morbidities. This suggests that co-existing illnesses significantly contribute to heart failure progression.

Distribution of Multiple Co-morbidities

The most common co-morbidity was hypertension (12 cases) followed by renal impairment (10 cases) and pulmonary disease (7 cases), as shown in Table 05 and Figure 04. Hypertension remains a major contributor to left ventricular dysfunction.

Table 05: Distribution based on multiple co-morbidities

Diseases	Male	Female	Total
Diabetes Mellitus	2	4	6
Hypertension	5	7	12
Hepatic Impairment	5	1	6
Renal Impairment	6	4	10
Hyperlipidaemia	1	0	1
Pulmonary Disease	3	4	7

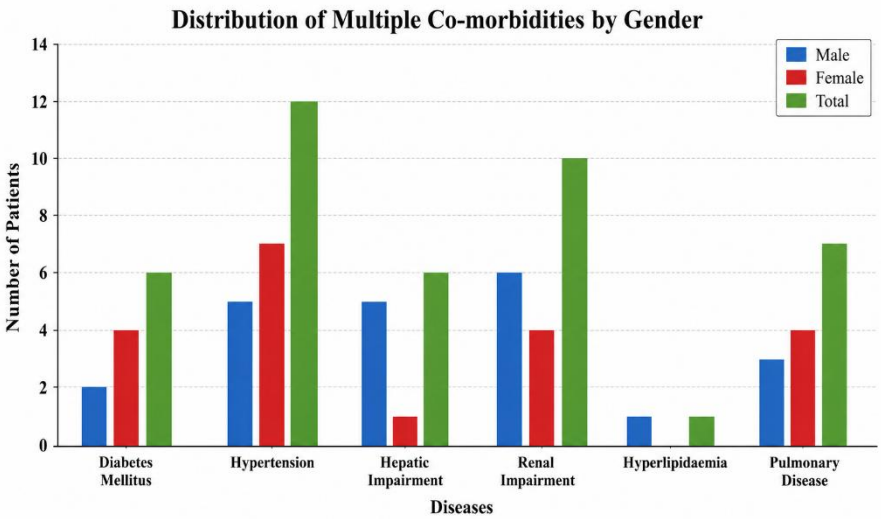

Figure 04: Comparative Analysis of Co-morbid Conditions in Male and Female Patients

Improvement in Ejection Fraction (EF)

The assessment of therapeutic efficacy revealed that out of 60 patients, 52 patients (87%) showed a significant improvement in ejection fraction (EF) after administration of Sacubitril and Valsartan, while only 8 patients (13%) showed no improvement. The marked increase in EF indicates enhanced left ventricular function and improved cardiac performance following treatment. These findings support the clinical effectiveness of sacubitril/valsartan in managing heart failure with reduced ejection fraction and suggest its beneficial role in improving overall cardiovascular outcomes.

Reduction in Frequent Hospitalisation

A total of 50 patients (83.33%) showed reduced frequent hospitalisation after treatment, as shown in Table 6 and Figure 5. This demonstrates better symptom management and improved quality of life.

Table 06: Distribution based on reduced frequent hospitalisation

Age Group	Heart Failure Patients	Reduced Hospitalization
31–40	3	3
41–50	7	7
51–60	16	15
61–70	20	18
71–80	10	5
81–90	4	2

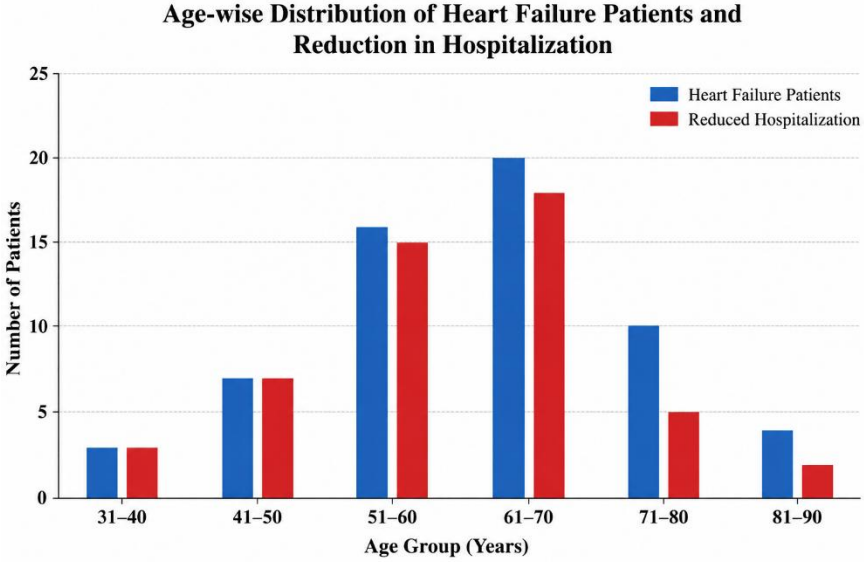

Figure 05: Age-wise Distribution of Heart Failure Patients with Reduced Frequent Hospitalisation

Distribution of Adverse Drug Reactions

Among 60 patients, 10 patients reported ADRs. The most common ADR was hyperkalemia (40%), followed by angioedema (30%), as shown in Table 07.

Table 07: Distribution of adverse drug reactions

Adverse Effects	Number of Patients	Percentage (%)
Hypotension	2	20
Hyperkalemia	4	40
Angioedema	3	30
Renal Impairment	1	10

Safety Profile of Sacubitril/Valsartan

The safety assessment of Sacubitril and Valsartan therapy demonstrated a favorable tolerability profile among the study population. Out of 60 patients, 50 patients (83%) did not experience any adverse effects during the treatment period, while only 10 patients (17%) reported mild adverse drug reactions, as illustrated in Figure 10. Among the reported adverse effects, hyperkalemia was the most frequently observed, followed by angioedema, hypotension, and renal impairment. These findings indicate that sacubitril/valsartan therapy is generally safe and well tolerated in heart failure patients, with manageable adverse effects under proper clinical monitoring.

Efficacy Based on Patient Condition

The therapeutic efficacy of sacubitril/valsartan was further evaluated based on the severity of baseline ejection fraction (EF), as presented in Figure 11. Patients with mild (30–35%) and moderate (26–30%) EF showed complete improvement following treatment. Similarly, a high percentage of patients with severe EF (20–25%) and chronic EF (<20%) also demonstrated significant improvement after therapy. These findings suggest that sacubitril/valsartan is effective across varying degrees of heart failure severity and may contribute substantially to improving cardiac performance irrespective of disease stage.

Comparison of Ejection Fraction Before and After Drug Administration

The comparative evaluation of ejection fraction before and after administration of sacubitril/valsartan showed marked clinical improvement, as illustrated in Figure 12. Before initiation of therapy, none of the patients showed improved ejection fraction, whereas after treatment, 50 out of 60 patients demonstrated a significant increase in EF. This improvement reflects enhanced left ventricular function and better hemodynamic stability. The results strongly support the clinical efficacy of sacubitril/valsartan in improving cardiac output, reducing disease progression, and enhancing overall patient prognosis in heart failure management.

CONCLUSION

The present study demonstrated that sacubitril/valsartan therapy is an effective and safe treatment option in the management of heart failure patients with reduced ejection fraction. The majority of patients showed significant improvement in ejection fraction after drug administration, which reflects improved cardiac function and better clinical outcomes. Additionally, the treatment contributed to a reduction in frequent hospitalization and enhanced patient quality of life. The adverse drug reactions observed during the study were minimal and manageable, indicating a favorable safety profile. Hyperkalemia was the most commonly reported adverse effect, followed by angioedema, hypotension, and renal impairment. Overall, the study provides strong clinical evidence supporting the use of sacubitril/valsartan as an important therapeutic approach in heart failure management, particularly in patients with severe left ventricular dysfunction. Further long-term studies with larger sample sizes are recommended to validate these findings.

FUNDING

Nil

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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AUTHOR CONTRIBUTIONS

B. Manjula conceived and designed the study, supervised the research work, and critically reviewed the manuscript. G. Suraj Kumar, G. Dharma Raju, B. Rama Krishna, and G. Sridhar contributed to data collection, data analysis, literature review, manuscript preparation, and revision. All authors read and approved the final version of the manuscript.

ETHICAL STATEMENT

The ethical committee clearance was obtained from Gleneagles Global Hospital before initiating the study. Reference number: AIPS/ 04/ IEC/05

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