Cardiology Research and Cardiovascular Medicine
Dedhia A, et al. Cardiolog Res Cardiovasc Med 11: 296.
www.doi.org/10.29011/2575-7083.100296
www.gavinpublishers.com

OPEN ACCESS

GAVIN PUBLISHERS

Research Article

A Cross-Sectional Study on the Drug Utilization of Sacubitril-Valsartan (Sacu V) in Patients with Heart Failure with Reduced Ejection Fraction Across Various Clinics in India

Ankeet Dedhia[1], Anuj Bhasin[2], Sathish Babu[3], Pankaj Jariwala[4], Aditya Daruka[5], Sumit Bhushan[6*], Sanjay Chaudhari[6], Rahee Borulkar[6], Kiransing Pawar[6], Rujuta Gadkari[6], Saiprasad Patil[6]

[1]Holy Family Hospital, Mumbai, India

[2]ICON hospital, Mumbai, India

[3]Sathish clinic, Chennai, India

[4]Yashodha Hospital, Hyderabad, India

[5]Sree Health Care, Kolkata, India

[6]Glenmark Pharmaceuticals Ltd., Mumbai, India

***Corresponding author:** Sumit Bhushan, Glenmark Pharmaceuticals Ltd., Mumbai, India

Citation: Dedhia A, Bhasin A, Babu S, Jariwala P, Daruka A, et al. (2026) A Cross-Sectional Study on the Drug Utilization of Sacubitril-Valsartan (Sacu V) in Patients with Heart Failure with Reduced Ejection Fraction Across Various Clinics in India. Cardiol Res Cardio vasc Med 11:296. DOI:https://doi.org/10.29011/2575-7083.100296

Received Date: 28 February, 2026; **Accepted Date:** 05 March, 2026; **Published Date:** 06 March, 2026

Abstract

Background: Sacubitril-valsartan, an angiotensin receptor neprilysin inhibitor (ARNI), has demonstrated significant cardiovascular benefits in heart failure with reduced ejection fraction (HFrEF). However, real-world utilization patterns in Indian clinical practice remain poorly characterized. **Objective:** To evaluate the real-world drug utilization pattern of sacubitril-valsartan in patients with HFrEF across multiple clinical centers in India and characterize the demographic and clinical profiles of patients receiving this therapy. **Methods:** This multicenter, cross-sectional, observational study was conducted across 319 sites in India from October 2023 to April 2024. Medical records of patients prescribed sacubitril-valsartan for HFrEF management were analyzed using electronic data capture. Data included demographics, clinical parameters, medical history, laboratory values, comorbidities, and concomitant medications. Descriptive statistical analysis was performed. Independent ethics committee approval was obtained prior to study initiation. **Results:** A total of 3,260 patients were analyzed with mean age 60.82 ± 10.11 years and 74.14% males. New York Heart Association (NYHA) functional class distribution showed Class I (24.57%), Class II (47.21%), Class III (22.02%), and Class IV (6.20%). Mean ejection fraction was 39.65±10.67%. Common comorbidities included hypertension (78.83%), diabetes (50.12%), and ischemic heart disease (45.89%). Treatment-naïve patients comprised 79.82% while 20.18% switched from other therapies. Mean NT-proBNP levels were 1969.88 pg/mL Beta-blockers (19.60%), sodium–glucose cotransporter-2 inhibitors (SGLT2i; 10.09%), and mineralocorticoid receptor antagonists (MRA; 4.02%) were the most common concomitant cardiovascular medications for HFrEF. Angiotensin II receptor blockers (ARBs) were prescribed

only in patients prior to switching to ARNI therapy and were not co-administered with sacubitril–valsartan. **Conclusions:** This large-scale real-world study demonstrates widespread utilization of sacubitril-valsartan across diverse HFrEF patient populations in India. Most patients were in NYHA Class II with predominant HTN as comorbidity and received sacubitril–valsartan in combination with other GDMT pillars, including beta-blockers, SGLT2 inhibitors, and mineralocorticoid receptor antagonists. The high proportion of treatment-naïve patients indicates increasing adoption of guideline-directed medical therapy as first-line treatment, providing valuable insights into contemporary heart failure management patterns in Indian clinical practice.

Keywords: Heart failure; Sacubitril-valsartan; ARNI; Real-world evidence; Drug utilization; India

Introduction

Heart failure (HF) represents a major global health challenge, characterized by dyspnea, limited exercise tolerance, and impaired cardiac ventricular filling and/or blood ejection [1]. The condition affects millions worldwide and poses significant health and economic burdens, particularly in India where prevalence continues to rise due to demographic transitions and increasing cardiovascular risk factors [2].

The pathophysiology of HF involves complex mechanisms including over-activation of the renin-angiotensin-aldosterone system (RAAS), leading to vasoconstriction, hypertension, elevated aldosterone levels, increased sympathetic tone, and eventual cardiac remodeling [3]. Simultaneously, the endogenous natriuretic peptide (NP) system activates as a compensatory mechanism, though insufficiently to counteract the deleterious RAAS effects. Since natriuretic peptides are degraded by the enzyme neprilysin, its inhibition emerged as an important therapeutic target [4].

Sacubitril-valsartan represents the first-in-class dual angiotensin receptor neprilysin inhibitor (ARNI), combining neprilysin inhibition with angiotensin II receptor blockade [5]. The landmark PARADIGM-HF trial demonstrated that sacubitril-valsartan significantly reduced cardiovascular mortality and HF hospitalizations compared to enalapril in patients with HF with reduced ejection fraction (HFrEF) [6]. Subsequently, major international guidelines have recommended ARNI as first-line therapy for eligible HFrEF patients [7,8].

Despite robust clinical trial evidence, real-world implementation and utilization patterns of sacubitril-valsartan vary considerably across different healthcare systems and populations. Understanding these patterns is crucial for optimizing clinical outcomes and healthcare resource allocation. In the Indian context, where healthcare delivery faces unique challenges including diverse socioeconomic factors, varying access to specialized care, and different disease presentations, comprehensive real-world evidence regarding ARNI utilization remains limited.

This study aims to bridge this knowledge gap by evaluating the real-world drug utilization pattern of sacubitril-valsartan in patients with HFrEF across multiple clinical centers in India, providing insights into demographic characteristics, clinical profiles, treatment patterns, and prescribing practices in contemporary Indian cardiology practice.

Materials and Methods

This was a multicentre, cross-sectional, observational study conducted across 319 clinical sites in India to evaluate the real-world utilization pattern of sacubitril–valsartan in patients with heart failure with reduced ejection fraction (HFrEF). The study was conducted from October 2023 to April 2024. The study was carried out in accordance with the New Drugs and Clinical Trials Rules, 2019 issued by the Government of India, the ethical principles outlined in the Declaration of Helsinki, the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, and all applicable local regulatory requirements. Ethics committee approval was obtained from the Suraksha Ethics Committee, Institute of Medical Science (AIMS) Hospital (EC Registration: ECR/644/Inst/MH/2014/RR-20).

Medical records of patients prescribed sacubitril–valsartan by their treating physician for the management of HFrEF were included in the study. Patients with incomplete medical records or missing key data were excluded. As this was a descriptive observational study without a predefined hypothesis, no formal sample size calculation was performed. A total of 3,260 patients were included in the final analysis. Data were captured retrospectively using a validated electronic data capture (EDC) system. A predesigned structured proforma was used to collect information from medical records, and only completely filled case record forms were included in the analysis.

Collected data included demographic characteristics (age, gender, height, weight, and vital signs), medical history (shortness of breath, chest pain, peripheral edema, heart failure–related hospitalizations, and smoking status), and comorbid conditions such as ischemic heart disease, hypertension, diabetes mellitus, obesity, dyslipidemia, and chronic kidney disease. Laboratory parameters recorded included NT-proBNP levels, HbA1c, serum creatinine, blood urea nitrogen, and left ventricular ejection

fraction, where available. Clinical severity was assessed using the New York Heart Association (NYHA) functional classification. Treatment-related variables included initiation of sacubitril–valsartan as first-line therapy or switching from prior heart failure medications. Concomitant medications prescribed during sacubitril–valsartan therapy were also documented.

Descriptive statistics were employed for all analyses. Continuous variables are presented as mean ± standard deviation, median, and range with 95% confidence intervals where appropriate. Categorical variables are presented as frequencies and percentages.

Results

A total of 3,260 patients with HFrEF receiving sacubitril-valsartan therapy were analyzed from 319 participating centers across India. The study population had a mean age of 60.82 ± 10.11 years (95% CI: 60.47-61.16), from 23 to 91 years with a median age of 60 years. Male patients predominated, comprising 2,417 (74.14%) of the study population, while females accounted for 843 (25.86%). Patients had mean weight of 71.16 ± 11.27 kg The mean systolic blood pressure was 139.33 ± 16.77 mmHg (while diastolic blood pressure averaged 90.64 ± 14.59 mmHg The mean pulse rate was 83.24 ± 11.21 beats per minute). The distribution of patients across NYHA functional classes was: Class I - 801 patients (24.57%), Class II - 1,539 patients (47.21%), Class III - 718 patients (22.02%), and Class IV - 202 patients (6.20%). The majority of patients (47.21%) belonged to NYHA Class II, indicating mild to moderate symptomatic HF. Among 1,857 patients with available data, the mean left ventricular ejection fraction was 39.65 ± 10.67%.

The study population demonstrated a high burden of cardiovascular comorbidities. Hypertension was the most prevalent comorbidity, affecting 2,570 patients (78.83%), followed by diabetes mellitus in 1,634 patients (50.12%). Ischemic heart disease was present in 1,496 patients (45.89%), while dyslipidemia affected 1,100 patients (33.74%). Obesity was documented in 781 patients (23.96%), other cardiovascular diseases in 616 patients (18.90%), and chronic kidney disease in 230 patients (7.06%).

Among 1,484 patients with available data, the mean HbA1c was 7.28 ± 1.20%.Serum creatinine data was available for 959 patients, showing a mean of 1.25 ± 0.41 mg/dL.. Among the study population, 1,345 patients (41.26%) reported a history of shortness of breath, with those affected experiencing a mean of 2.49 ± 2.61 episodes in the past year. Chest pain history was documented in 1,351 patients (41.44%). Peripheral edema was reported by 738 patients (22.64%). A history of heart failure-related hospitalizations in the past year was documented in 817 patients (25.06%). Smoking or tobacco use was reported by 892 patients (27.36%) in the study population.

NT-proBNP levels were available for 911 patients, with a mean value of 1,969.88 ± 2,192.84 pg/mL.. Of the 3,260 patients analyzed, 2,602 (79.82%) were treatment-naïve to HF therapy and initiated directly on sacubitril-valsartan, while 658 patients (20.18%) had switched to sacubitril-valsartan from other HF medications. The analysis revealed complex polypharmacy patterns. The most commonly prescribed concomitant cardiovascular medications included beta-blockers in 639 patients (19.60%). SGLT2 inhibitors were used in 329 patients (10.09%). mineralocorticoid receptor antagonists combined with or without diuretics were prescribed in 131 patients (4.02%). Proton pump inhibitors were commonly prescribed (143 patients, 4.39%).

Discussion

This large-scale, multicenter observational study provides comprehensive insights into the real-world utilization patterns of sacubitril-valsartan in Indian patients with HFrEF. The findings demonstrate important trends in contemporary HF management and reveal characteristics of patients receiving ARNI therapy in routine clinical practice across India. The study population's demographic profile reflects the typical HFrEF population in India, with a predominance of elderly male patients (mean age 60.82 years, 74.14% males). This gender distribution aligns with global HF epidemiology, where males demonstrate higher prevalence of HFrEF, particularly in the setting of ischemic heart disease [9, 10].The high burden of comorbidities observed in this study population is characteristic of contemporary HF patients. Hypertension (78.83%) and diabetes (50.12%) were the most prevalent comorbidities, reflecting the major cardiovascular risk factors driving HF development in the Indian population [11]. The prevalence of ischemic heart disease (45.89%) underscores the significant contribution of coronary artery disease to HFrEF in India [12].The predominance of NYHA Class II patients (47.21%) suggests that sacubitril-valsartan is being initiated in patients with mild to moderate symptomatic HF , aligning with guideline recommendations for early intervention [13]. The mean ejection fraction of 39.65% confirms appropriate patient selection for ARNI therapy, as guidelines recommend sacubitril-valsartan for patients with HFrEF (typically EF ≤40%) [14].

A particularly significant finding was that 79.82% of patients were treatment-naïve, indicating increasing adoption of sacubitril-valsartan as first-line therapy for HFrEF. This represents a paradigm shift from traditional stepwise approaches to HF management and suggests better implementation of contemporary guideline recommendations in Indian clinical practice [15].The elevated NT-proBNP levels (mean 1,969.88 pg/mL) confirm the presence of significant HF in the study population, as these levels are well above normal ranges and consistent with

symptomatic HF [16].The metabolic profile, including mean HbA1c of 7.28%, indicates suboptimal glycemic control in the diabetic subpopulation, highlighting the need for comprehensive cardiovascular risk factor management [17]. The complex polypharmacy patterns observed reflect the multi-morbid nature of contemporary HFrEF patients and the need for comprehensive cardiovascular risk management. The high usage of beta-blockers (19.60%) as concomitant therapy demonstrates good adherence to guideline-recommended combination therapy for HFrEF [18].The substantial use of SGLT2 inhibitors (10.09%) reflects emerging evidence for their cardiovascular benefits in HF [19]. These findings have important implications for HF care in India. The predominant use as first-line therapy suggests good guideline implementation but raises questions about healthcare resource allocation and cost-effectiveness in resource-constrained settings. The complex medication regimens observed highlight the need for comprehensive pharmaceutical care and medication management programs.

Conclusions

This comprehensive multicentre study provides valuable insights into the real-world utilization patterns of sacubitril–valsartan in Indian patients with heart failure with reduced ejection fraction (HFrEF). The findings demonstrate that sacubitril–valsartan is being appropriately prescribed across varying disease severity, with a predominant pattern of first-line usage indicating increasing adoption of guideline-directed medical therapy in routine clinical practice. The high burden of comorbidities and use of sacubitril–valsartan in combination with other guideline-directed medical therapies, including beta-blockers, SGLT2 inhibitors, and mineralocorticoid receptor antagonists, reflect contemporary management of HFrEF in India. These real-world data contribute to understanding current prescribing patterns of sacubitril–valsartan in routine clinical care.

Study Limitations

The cross-sectional design precludes assessment of temporal relationships and clinical outcomes. The retrospective data collection may have introduced selection bias. The study was sponsored by the manufacturer of the studied medication, which could potentially influence site selection and data interpretation. The absence of a control group limits comparative effectiveness assessments. Mention about short duration, less number of participant.

Acknowledgments

We would like to extend our thanks to all the institutes and respective investigators and team members for their support. We also appreciate the CRO support by IR Innovate Research for clinical trial management. We also thank Auriga Research for medical writing support in the study.

Ethical standards

The work presented in this study was in accordance with the study protocol, the New Drugs and Clinical Trials Rules 2019 issued by the Government of India, the ethical principles that have their origin in the Declaration of Helsinki, International Council for Harmonisation (ICH) Good Clinical Practice (GCP), and all applicable local regulatory requirements. Independent Ethics committee approval was obtained prior to study initiation and data collection.

Funding

This study was funded by Glenmark Pharmaceuticals Limited. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of Interest

Dr. Sumit Bhushan, Dr. Sanjay Chaudhari, Dr. Rahee Borulkar, Mr. Kiransing Pawar, Ms. Rujuta Gadkari and Dr. Saiprasad Patil are employees of Glenmark. All other investigators/authors have no conflicts of interest that are directly relevant to the content of this article.

References

1. Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JGF, et al. (2016) 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J. 37: 2129-2200.
2. Savarese G, Lund LH (2017) Global public health burden of heart failure. Card Fail Rev. 3:7-11.
3. Pascual-Figal D, Bayés-Genis A, Beltrán-Troncoso P, Caravaca-Pérez P, Conde-Martel A, et al. (2021) Sacubitril-valsartan, clinical benefits and related mechanisms of action in heart failure with reduced ejection fraction. A review. Front Cardiovasc Med. 8:754499.
4. D'Elia E, Iacovoni A, Vaduganathan M, Lorini FL, Perlini S, et al. (2017) Neprilysin inhibition in heart failure: mechanisms and substrates beyond modulating natriuretic peptides. Eur J Heart Fail. 19:710-717.
5. Campbell DJ (2017) Long-term neprilysin inhibition—implications for ARNIs. Nat Rev Cardiol. 14:171-186.
6. McMurray JJV, Packer M, Desai AS, Gong J, Lefkowitz MP, et al. (2014) Angiotensin-neprilysin inhibition versus enalapril in heart failure. N Engl J Med. 371:993-1004.
7. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey Jr DE, et al. (2017) 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure. : A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 136: e137-e161.
8. McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, et al.

(2021) 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur Heart J. 42:3599-3726.

9. Savarese G, Becher PM, Lund LH, Seferovic P, Rosano GMC, et al. (2023) Global burden of heart failure: a comprehensive and updated review of epidemiology. Cardiovasc Res. 118:3272-3287.

10. Benjamin EJ, Muntner P, Alonso A, Bittencourt MS, Callaway CW, et al. (2019) Heart disease and stroke statistics—2019 update: a report from the American Heart Association. Circulation. 139:e56-e528.

11. Prabhakaran D, Jeemon P, Roy A (2016) Cardiovascular diseases in India: current epidemiology and future directions. Circulation. 133:1605-1620.

12. Gupta R, Mohan I, Narula J (2016) Trends in coronary heart disease epidemiology in India. Ann Glob Health. 82:307-315.

13. Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, et al. (2022) 2022 AHA/ACC/HFSA guideline for the management of heart failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 79: e263-e421.

14. Solomon SD, McMurray JJ, Anand IS, Ge J, Lam CSP, et al. (2019) Angiotensin–neprilysin inhibition in heart failure with preserved ejection fraction. N Engl J Med. 381:1609-1620.

15. Greene SJ, Butler J, Albert NM, DeVore AD, Sharma PP, et al. (2018) Medical therapy for heart failure with reduced ejection fraction: the CHAMP-HF registry. J Am Coll Cardiol. 72:351-366.

16. Mueller C, McDonald K, de Boer RA, Maisel A, Cleland JGF, et al. (2019) Heart Failure Association of the European Society of Cardiology practical guidance on the use of natriuretic peptide concentrations. Eur J Heart Fail. 21:715-731.

17. Kenny HC, Abel ED (2019) Heart failure in type 2 diabetes mellitus. Circ Res. 124:121-141.

18. Fiuzat M, Wojdyla D, Kitzman D, Fleg J, Keteyian SJ, et al. (2012) Relationship between beta-blocker dose and outcomes in ambulatory heart failure patients with systolic dysfunction: results from the HF-ACTION trial. J Am Coll Cardiol. 60:208-215.

19. McMurray JJV, Solomon SD, Inzucchi SE, Køber L, Kosiborod MN, et al. (2019) Dapagliflozin in patients with heart failure and reduced ejection fraction. N Engl J Med. 381:1995-2008.