ASSESSING MARKET ACCESS STRATEGIES FOR (SACUBITRIL AND VALSARTAN) A COMPARATIVE ANALYSIS OF DOMESTIC MARKET AND HOSPITAL SURVEY FOR MEDICINE USED FOR HEART FAILURE PATIENT.

THE EVALUATION OF THE FINANCIAL TOLL THAT HEART FAILURE TAKES ON HEALTHCARE SYASTEM.

[It entails analysing the direct and indirect expenses of heart failure, including hospital stays, drug expenditures (available treatment regime in India), and lost productivity. The goal would be to create a comprehensive plan for a specialised HF clinic for people living with heart failure in India]

Dissertation Submitted to

The IIHMR University, Jaipur

For the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

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Under the supervision and Guidance of

Prof. Saurabh Kumar

Associate Professor and Dean SPM

2023

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **"Assessing Market Access Strategies for (sacubitril and valsartan) A Comparative Analysis of Domestic Market and Hospital Survey for Medicine used for Heart Failure Patient. The evaluation of the financial toll that the heart failure takes on healthcare system."** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Sankalp Tanaji Sapkal

Date:

Completion Certification

CERTIFICATE

This is to certify that **Sankalp Tanaji Sapkal** in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed his internship at **MSN Laboratories, Hyderabad** during April 1st to May 30, 2023.

Preceptor/Head of the Organization

MSN Laboratories, Hyderabad

Place:

Date:

Certificate from Faculty Guide and School Dean

CERTIFICATE

This is to certify that dissertation titled "**Assessing Market Access Strategies for (sacubitril and valsartan) A Comparative Analysis of Domestic Market and Hospital Survey for Medicine used for Heart Failure Patient. The evaluation of the financial toll that the heart failure takes on healthcare system.**" is a record of the research work undertaken by Sankalp Tanaji Sapkal in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

Prof. Saurabh Kumar Banerjee	Prof. Saurabh Kumar Banerjee
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ABSTRACT

This thesis examines the market entry methods used for the combination medication of sacubitril and HFrEF (heart failure with reduced ejection fraction) is treated with valsartan. The goal is to assess the efficacy of the company's tactics in different markets, identify significant factors affecting market access, and analyse the domestic and foreign market access strategies for Sacubitril and Valsartan. This research will offer useful insights towards maximizing market access and enhancing patient outcomes by looking at pricing, reimbursement practices, legal requirements, and market dynamics.

Worldwide, especially in India, the burden of heart failure (HF) on healthcare systems is substantial. This thesis examines the financial burden that HF places on healthcare systems, highlighting the direct and indirect costs related to the illness. The research considers a number of factors, including hospital stays, medicine costs, and missed productivity, with the ultimate goal of creating a detailed strategy for a specialised HF clinic in India.

The study starts with a detailed analysis of the home market for HF drugs already available, with a focus on Sacubitril and Valsartan, a popular therapy option. In order to ensure that sacubitril and valsartan is accessible, affordable, and available to heart failure patients in India, various market access tactics are examined.

The study examines the direct costs related to hospital stays in order to gauge the financial burden of HF. This entails examining the typical length and expense of hospital stays for HF patients in India. The study also examines the pharmacological costs related to treating HF, taking into account the therapy options available in India. This research evaluates the accessibility and affordability of alternative medicines for patients while also accounting for the price of sacubitril and valsartan.

The thesis examines the indirect costs of HF, such as lost productivity, in addition to direct expenditures. The study shows the financial effects of HF by looking at how it affects people's capacity to work. This assessment helps to clarify the overall financial impact of HF on patients and the healthcare system.

The thesis comes to a conclusion by developing a thorough strategy for a specialised HF clinic in India based on the outcomes of the market access study, hospital survey, and evaluation of financial consequences. This strategy intends to address the problems with sacubitril and valsartan cost, accessibility, and availability as well as those with other HF medicines, ultimately leading to an improvement in the treatment and care of individuals with HF in India.

For healthcare regulators, pharmaceutical firms, and healthcare practitioners involved in the management of HF, the knowledge collected from this study will be a significant resource. This study helps design efficient interventions and policies to lessen the cost of HF on India's healthcare systems and improve patient outcomes by finding market access tactics and comprehending the financial toll of HF.

ACKNOLEDGEMENT:

I would like to sincerely thank and appreciate the following people and organisations for their assistance in finishing this thesis.:

My Marketing manager, Mr. Alok Bajpai sir and my Product manager, Mr. Pradip Chadalavada Sir, for their guidance, patience, and expertise throughout this research. Their invaluable advice and constructive feedback have been instrumental in shaping the direction and quality of this work.

The faculty and staff of IIHMR University, Jaipur, for providing a conductive environment for academic growth and research. I am grateful for the resources, facilities, and opportunities they have provided to further my knowledge and skills.

Secondly, I would like to express my gratitude to Dr. Prahlad Rai Sodani, President of IHMR University, Jaipur for encouraging me to take this dissertation. Also, I am extremely thankful to my faculty guide Dr. Saurabh Kumar Banerjee, (Dean and Associate professor, School of Pharmaceutical Management) for his valuable guidance, keen interest and encouragement throughout the completion of this project.

This internship has not only enriched me professionally but Also on a personal level.

Additionally, I would like to thank the organisations that have supported this research, I'm extremely thankful to MSN Laboratories, Hyderabad to give me honour in this study which has played a significant role in its successful completion.

Also, I would like to thank a few friends & family who encouraged me throughout this time and helped me on every obstacle. I would like to thank Mrunali, Prince and Prem for being my stress busters, motivators and proof-readers.

Lastly, I would want to express my sincere gratitude to everyone who has helped with this work in any way, whether through discussions, reviews, or encouragement. Your contributions have been truly valuable and have shaped this thesis for the better.

TABLE OF CONTENT:

ABBREVATIONS:

HF - Heart Failure

ACE - Angiotensin-Converting Enzyme

ARB - Angiotensin Receptor Blocker

HFrEF - Heart Failure with Reduced Ejection Fraction

HFpEF - Heart Failure with Preserved Ejection Fraction

NT-proBNP - N-terminal pro-B-type natriuretic peptide

HRQoL - Health-Related Quality of Life

QALY - Quality-Adjusted Life Year

HES - Hospital Episode Statistics

LOS - Length of Stay

ICU - Intensive Care Unit

DAPT - Dual Antiplatelet Therapy

MI - Myocardial Infarction

COPD - Chronic Obstructive Pulmonary Disease

RCT - Randomized Controlled Trial

LVEF - Left Ventricular Ejection Fraction

NYHA - New York Heart Association

CV - Cardiovascular

BMI - Body Mass Index

CAD - coronary artery disease

BP - Blood Pressure

HbA1c - Glycated Hemoglobin

CKD - chronic kidney disease

CVD - cardiovascular disease

PVD - Peripheral Vascular Disease

CHAPTER 1

INTRODUCTION

1.1Background

Heart failure with a low ejection fraction should be treated with, a medication combination known as sacubitril, and valsartan is employed. It is promoted under the Entresto brand name. ARBs (angiotensin receptor blockers) include valsartan. while sacubitril is a neprilysin inhibitor. Together, these two medications enhance heart health and lower the possibility of hospitalizations regarding cardiac failure.

Usually, the drugs sacubitril and valsartan are used to treat adults with heart failure and a low ejection fraction, which contains both sacubitril and valsartan. Typically, they are offered under the Entresto brand name. Sacubitril is a member of a group of medicines known as neprilysin inhibitors, which function by raising the levels of specific hormones in the body to lessen the strain on the heart and enhance blood flow. ARBs like valsartan, which relax blood vessels and lower blood pressure to lessen stress on the heart, help to lower blood pressure. Valsartan and sacubitril together increase heart function and lower the number of hospitalizations for heart failure. They are often given by a medical professional, and close supervision is needed to ensure the right dosage and effectiveness. It is crucial to speak with a healthcare provider before taking any medication because there could be potential adverse effects or drug interactions.

Here is detailed information about valsartan with sacubitril:

- **Action Mechanism**:

  The enzyme neprilysin, which is in charge of breaking down compounds including natriuretic peptides, bradykinin, and adrenomedullin, is inhibited by sacubitril. Sacubitril raises the amounts of these helpful compounds, which aid in promoting vasodilation, sodium excretion, and lowering fluid retention by blocking neprilysin.

  Angiotensin II receptor type 1 (AT1 receptor) is specifically inhibited by the angiotensin II receptor blocker (ARB) valsartan. Valsartan prevents angiotensin II's vasoconstrictive and aldosterone-secreting effects, causing vasodilation and a reduction in fluid retention.

- **Indications**:

  Valsartan and sacubitril are used to treat adult patients with heart failure with a decreased ejection fraction (HFrEF) are recommended. HFrEF is a disorder where the left ventricle of the heart struggles to adequately pump blood, resulting in symptoms like fatigue, fluid retention, and shortness of breath.

- **Dosage:**

  49/51 mg twice daily is the normal beginning dose for sacubitril/valsartan. After two to four weeks, depending on the patient's tolerance, this can be raised to the goal maintenance dose of 97/103 mg twice day.

- **Contraindications:**

  Patients with genetic or idiopathic angioedema, as well as those who have previously received ACE inhibitor or ARB medication, should not take sacubitril/valsartan.

  It shouldn't be provided along with ACE inhibitors because doing so could make angioedema more likely.

- **Adverse Reactions:**

  Low blood pressure (hypotension), lightheadedness, hyperkalemia (elevated blood potassium levels), cough, and renal impairment are the most frequent adverse reactions to sacubitril/valsartan.

  A rare but serious adverse effect associated with the use of sacubitril/valsartan is angioedema, a potentially fatal allergic reaction characterised by throat, tongue, face, or lip swelling.

- **Drug interactions:**

  Sacubitril/valsartan usage concurrently with ACE inhibitors, potassium-sparing diuretics, potassium supplements, or other medications that raise potassium levels may increase the risk of hyperkalaemia. The efficacy of sacubitril/valsartan may be decreased by NSAIDs (Non-Steroid Anti-Inflammatory Drugs) and specific COX-2 Inhibitors.

1.2 RESEARCH OBJECTIVES

i. This study aims to analyse the efficiency of sacubitril and valsartan market access tactics in domestic and international markets, evaluate the company's market access methods, and identify the major market access influencing factors.

ii. In addition to making suggestions for enhancing sacubitril and valsartan market access in both domestic and international markets, the study intends to provide light on the parallels and discrepancies between these tactics.

iii. A financial assessment of heart failure's financial toll on healthcare systems. (This involves looking at the direct and secondary expenses resulting from heart failure, such as hospital stays, drug costs (there are therapeutic options available in India), and lost productivity. The objective would be to develop a thorough plan for a specialised heart failure clinic for patients in India.)

1.3 SIGNIFICANCE OF STUDY

Improved Treatment Access:

In order to guarantee that patients have timely and cost-effective access to this important treatment, it is essential to understand market access methods for the heart failure medication sacubitril and valsartan. The study can shed light on potential impediments, pricing tactics, regulatory requirements, and reimbursement mechanisms by contrasting domestic and international markets. Using this data, politicians, healthcare professionals, and pharmaceutical businesses can create plans to increase sacubitril and valsartan access in India and enhance patient outcomes.

Comparative Analysis:

Comparison of domestic and foreign sacubitril and valsartan markets might show variations in pricing, supply, and market dynamics. Potential gaps in the Indian market can be identified using this study, and ways to close them are suggested. It can also reveal effective strategies used in other countries that can be modified to improve sacubitril and valsartan access in India.

Hospital Survey:

Insights about current prescribing trends, treatment modalities, and pharmaceutical accessibility can be gained by conducting a survey at hospitals to assess how often people with heart failure take medicines. With the aid of this knowledge, potential problems with the treatment of heart failure may be identified, and steps to enhance patient care may be guided. It may also help in making decisions on whether to include sacubitril and valsartan in prescription drug guidelines or formularies.

Financial Impact of Heart Failure:

Understanding the economic impact that heart failure places on healthcare systems depends on how much money it costs. The study can offer a thorough evaluation of the financial impact by analysing direct costs like hospital stays and medicine costs as well as indirect costs like missed productivity. Policymakers and healthcare executives can use this

data to distribute resources wisely, create cost-effective interventions, and promote the opening of specialised heart failure clinics.

Specialized Heart Failure Clinic:

The study's objective of developing a thorough strategy for a specialised heart failure clinic in India addresses the requirement for special medical facilities for people with heart failure. The study can provide a financially viable clinic model by taking into account the cost load and difficulties in getting access to therapy. By offering specialised care, boosting patient outcomes, lowering hospital readmission rates, and maximising resource use, such a clinic can improve the quality of life for Indians who have heart failure.

Overall, the importance of this study can be attributed to its potential to expand consumer access to sacubitril and valsartan, build specialised clinics to assist Indian patients with heart failure and improve our understanding of the financial effects of heart failure.

1.4 RESEARCH QUESTION

i. What are the similarities and differences between sacubitril and valsartan market access strategies in domestic and international markets, and how do these strategies affect the company's market performance in each market?

ii. What are the main challenges faced by sacubitril and valsartan in accessing domestic and international markets, and what recommendations can be made to improve the company's market access strategies and overcome these challenges?

1.5 RESEARCH METHODOLOGY:

• To analyse sacubitril and valsartan market access strategies in domestic and foreign markets, It will use a comparative case study approach.

•Data collection and analysis will be done using a mixed-methods methodology (Marketing and sales)

Data Collection:

Secondary data sources, such as annual reports, business websites, market studies, and academic articles, will be used to learn more about sacubitril and valsartan and its market access initiatives. Surveys and interviews with pertinent stakeholders, including company executives, marketing managers, and industry experts, will be used to gather primary data

Data Analysis:

• To find patterns and relationships in the data, quantitative data will be studied statistically using techniques like descriptive statistics and regression analysis.

• To find themes and patterns in qualitative data, content analysis will be used to analyse it.

• To discover the similarities and variations in market entry methods across domestic and international markets, the data will be compared.

CHAPTER 2

LITERATURE REVIEW

2.1Heart Failure and HFrEF Treatment

STUDY TITLE: Heart failure disease management: a systematic review of effectiveness in heart failure with preserved ejection fraction.

AUTHOR : Fotini Kalogirou Faye Forsyth Martha Kyriakou Rhys Mantle , Christi Deaton

Methods and results: Using CINAHL, Cochrane, MEDLINE, and Embase, a systematic review of DMPs involving patients with HFpEF published between 2008 and 2023 in English or Greek was carried out. In order to assess interventions and rate their complexity and intensity, a DMP taxonomy was employed. Using the Cochrane Collaboration technique, bias was evaluated. Both the initial search and the amended search produced 6089 titles after duplicates were removed. 1866 patients (34 percent; study ranges 18-100%) indicated possible HFpEF (limited by conflicting classifications) among the 5435 HF patients from 18 trials who were included in the final analysis. Due to the substantial variability in the population, intervention, comparisons, and outcomes, meta-analysis was not feasible. Despite statistically significant or positive trends in mortality, hospitalisation rates, self-care skills, quality of life, anxiety, depression, and sleep, the results were equivocal.

KEY LEARNINGS: The interpretation of results is significantly constrained by the various HFpEF criteria employed in investigations. Recent HF DMP trials have demonstrated a decreasing efficacy, It may be linked to advancements in standard medical care as well as the inclusion of diverse people with HFpEF or HF with mid-range EF who might not respond to certain components in the same way as HFrEF. Treatment for individuals with HFpEF should target both the underlying and presenting phenotypes and follow the fundamentals of a full geriatric assessment and does not merely focus on one disease because they are older and multi-morbid. Instead of only continuing the current strategy, additional elements that are more specifically targeted to HFpEF could include changing lifestyle factors for which there is growing evidence.[1].

2.2 Sacubitril and Valsartan Combination Therapy. [2]

Trial Acronym [Ref], Setting	Study Design Patients' no./Inclusion Criteria Period	Results
PARADIGM-HF [25], ambulatory preceded	S/V (target dose 97/103 mg × 2/day) vs. enalapril; a multicenter, prospective, randomized clinical trial 8442/NYHA II–IV (EF ≤ 40%) follow-up of 27 months	• CVD mortality ↓20% • HF hospitalization ↓21%
TITRATION [104], ambulatory	S/V clinical trial, multicenter, prospective, randomized/ 498/NYHA II–IV (EF ≤ 35%)/ 16-week study period	• 76% of patients achieved and maintained S/V without modifying the dose • 77.8% of patients reached the appropriate S/V dosage, • 84.3% with a prolonged titration • Safety was equal
PRIME HF [84], ambulatory	S/V vs. valsartan in a multicenter, prospective, randomized clinical study 118/HFrEF (EF < 50%) 12-month study period	• reduction in EROA • significant changes in regurgitant volume and LVEDV • no significant changes in LVESV and inadequate mitral leaflet closure area.
EVALUATE-HF [106], ambulatory	S/V vs. enalapril in a multicenter, prospective, randomized clinical trial	• difference in aortic characteristic impedance—not substantial
	464/ HFrEF (EF ≤ 40%) S/V or enalapril were assigned at random. 12-week study period	• changes in LAVI, LVEDV, LVESV, mitral E/e' ratio • EF increased by 1.9% in S/V group
PROVE-HF [105], ambulatory	S/V clinical trial, multicenter, prospective, open label 794/HFrEF (EF ≤ 40%) 12-month study period	• reduction in NT-proBNP • changes in LVEDV, LVESV, LAVI and E/e' ration • reversal cardiac remodeling • low NT-proBNP, not attain target dose, new-onset HF, or not taking an ACEI/ARB at the time of enrolling—similar outcomes.
PIONEER-HF [107], in-hospital	S/V was compared to enalapril in a multicenter, prospective, randomized clinical trial 881/NYHA II–IV (EF ≤ 40%) 8-week study period	• 47% against a 25% drop in NT-proBNP • S/V is safe in AHF or new-onset HF • recurrent HF hospitalizations—reduced • no significant difference between the two groups regarding renal function, hypotension, and hyperkalemia
TRANSITION [108], in-hospital	A multicenter, prospective, randomized clinical trial 1.002/HFrEF (EF ≤ 40%)	• patients who reached the target dose of S/V was similar • S/V safe and well-tolerated in patients with AHF and new-onset HF

Relative results of different comparisons in terms of different outcome SAC/VAL

Comparison (continuous outcomes)	Number of patients	MD with 95%CI, mmHg
msSBP		
sac/vals*200 mg vs. sac/vals*100 mg	1748 vs. 156	− 21.46 (− 47.78 to 4.86)
sac/vals*400 mg vs. sac/vals*100 mg	1264 vs. 156	− 8.44 (− 33.84 to 16.96)
sac/vals*400 mg vs. sac/vals*200 mg	1264 vs. 1748	13.02 (− 2.55 to 28.59)
sac/vals*100 mg vs. Valsartan 80 mg	156 vs. 163	− 1.30 (− 30.71 to 28.11)
sac/vals*200 mg vs. Olmesartan 20 mg	1579 vs. 1577	− 2.63 (− 15.50 to 10.24)
sac/vals*200 mg vs. Valsartan 160 mg	169 vs. 166	− 14.06 (− 40.38 to 12.26)
sac/vals*400 mg vs. Olmesartan 40 mg	57 vs. 57	− 2.59 (− 32.25 to 27.06)
sac/vals*400 mg vs. Valsartan 320 mg	350 vs. 343	− 3.37 (− 19.92 to 13.17)
msDBP		
sac/vals*200 mg vs. sac/vals*100 mg	1748 vs. 156	5.93 (− 8.29 to 20.16)
sac/vals*400 mg vs. sac/vals*100 mg	1264 vs. 156	− 3.45 (− 17.18 to 10.27)
sac/vals*400 mg vs. sac/vals*200 mg	1264 vs. 1748	− 9.38 (− 17.79 to − 0.97)
sac/vals*100 mg vs. Valsartan 80 mg	156 vs. 163	− 0.83 (− 16.72 to 15.06)
sac/vals*200 mg vs. Olmesartan 20 mg	1579 vs. 1577	0.04 (− 6.90 to 6.98)
sac/vals*200 mg vs. Valsartan 160 mg	169 vs. 166	12.69 (− 1.53 to 26.92)
sac/vals*400 mg vs. Olmesartan 40 mg	57 vs. 57	− 0.10 (− 16.21 to 16.00)
sac/vals*400 mg vs. Valsartan 320 mg	350 vs. 343	1.10 (− 7.88 to 10.07)
maSBP		
sac/vals*200 mg vs. sac/vals*100 mg	1748 vs. 156	− 3.70 (− 6.22 to − 1.18)
sac/vals*400 mg vs. sac/vals*100 mg	1264 vs. 156	− 1.96 (− 5.08 to 1.16)
sac/vals*400 mg vs. sac/vals*200 mg	879 vs. 1361	1.74 (− 0.10 to 3.58)
sac/vals*100 mg vs. Valsartan 80 mg	156 vs. 163	− 0.60 (− 3.50 to 2.30)
sac/vals*200 mg vs. Olmesartan 20 mg	1192 vs. 1188	− 0.54 (− 3.29 to 2.22)
sac/vals*200 mg vs. Valsartan 160 mg	169 vs. 166	− 3.23 (− 5.25 to − 1.21)
sac/vals*400 mg vs. Olmesartan 40 mg	n.a	n.a
sac/vals*400 mg vs. Valsartan 320 mg	314 vs. 307	− 0.34 (− 3.08 to 2.40)
maDBP		
sac/vals*200 mg vs. sac/vals*100 mg	1748 vs. 156	− 2.98 (− 5.11 to − 0.85)
sac/vals*400 mg vs. sac/vals*100 mg	1264 vs. 156	− 1.67 (− 3.91 to 0.57)
sac/vals*400 mg vs. sac/vals*200 mg	879 vs. 1361	1.31 (0.61 to 2.01)
sac/vals*100 mg vs. Valsartan 80 mg	156 vs. 163	1.00 (− 1.83 to 3.83)
sac/vals*200 mg vs. Olmesartan 20 mg	1192 vs. 1188	0.76 (− 1.42 to 2.94)
sac/vals*200 mg vs. Valsartan 160 mg	169 vs. 166	− 0.53 (− 1.54 to 0.48)
sac/vals*400 mg vs. Olmesartan 40 mg	n.a	n.a
sac/vals*400 mg vs. Valsartan 320 mg	314 vs. 307	1.66 (0.43 to 2.89)

Comparison (dichotomous outcome)	Number of patients	OR with 95% CI
Trial-specified AEs		
sac/vals*200 mg vs. sac/vals*100 mg	1748 vs. 156	1.03 (0.62–1.73)
sac/vals*400 mg vs. sac/vals*100 mg	1264 vs. 156	0.76 (0.42–1.38)
sac/vals*400 mg vs. sac/vals*200 mg	1264 vs. 1748	0.74 (0.55–0.99)
sac/vals*100 mg vs. Valsartan 80 mg	156 vs. 163	1.06 (0.63–1.79)
sac/vals*200 mg vs. Olmesartan 20 mg	1579 vs. 1577	1.22 (0.70–2.14)
sac/vals*200 mg vs. Valsartan 160 mg	169 vs. 166	1.20 (0.72–2.02)
sac/vals*400 mg vs. Olmesartan 40 mg	n.a	n.a
sac/vals*400 mg vs. Valsartan 320 mg	208 vs. 200	0.76 (0.42–1.36)

msSBP mean sitting systolic blood pressure, *msDBP* mean sitting diastolic blood pressure, *maSBP* mean ambulatory SBP, *maDBP* mean ambulatory DBP, *MD* mean difference, *CI* confidence interval, *n.a.* not applicable

2.3 MARKET ACCESS STRATEGIES IN THE PHARMACEUTICAL INDUSTRY:

It's crucial to take into account a number of aspects when developing market access strategies for medications like sacubitril and valsartan. The following are some crucial tactics that pharmaceutical corporations may use:

1. **Clinical Trial Design**:
   It is essential to create solid clinical trials that show the drug's effectiveness and safety. Performing well-controlled research that produce high-quality data can aid in obtaining regulatory clearances and financial support.

2. **Regulatory Approval:**
   The right organisations, such as the American Food and Drug Administration (FDA) or the European Medicines Agency (EMA)., must be contacted in order to obtain regulatory approval. Successful market access will depend on adhering to regulatory standards and delivering thorough data on the drug's safety, effectiveness, and quality.

3. **Health Economic Data:**
   It is crucial to produce health economic evidence that backs up the benefits of sacubitril and valsartan. This entails performing comparative effectiveness research and cost-effectiveness evaluations to show the drug's advantages over current treatment options.

4. **Pricing and Reimbursement Strategies:**
   It is essential to create sensible pricing plans and negotiate with payers and health technology assessment (HTA) organisations. Positive reimbursement choices may be attained by proving the drug's value, including its therapeutic advantages and prospective cost reductions in the long run.

5. **Market Education and Awareness:**
   It is essential to carry out educational programmes to increase awareness of the advantages of sacubitril and valsartan among healthcare providers, patients, and payers. Promoting the drug's mechanism of action, scientific proof, and patient results can help it gain market acceptance.

6. **Key Opinion Leader Engagement:**

   Working together with powerful key opinion leaders (KOLs) from the cardiology and medical sectors can help the drug become more well-known and credible. KOLs can promote the usage of the drug and offer knowledgeable commentary, which may have a favourable effect on market access.

7. **Real-World Evidence:**

   Post-marketing studies and registries can be used to gather data from the actual world to support market access claims. These studies may offer further information about the medication's efficiency, security, and patient outcomes in actual clinical settings.

8. **Patient Assistance Programs**:

   It may be advantageous to implement patient assistance programmes to support qualified patients' access to sacubitril and valsartan despite potential financial obstacles. These initiatives can improve patient adherence to therapy while addressing difficulties with affordability.

It's crucial to remember that market access methods may change depending on local laws, healthcare systems, and market dynamics. Pharmaceutical businesses should adjust their tactics accordingly, while also making sure that they are in accordance with local laws and regulations.

CHAPTER 3

METHODOLOGY

3.1 Research design: Data (sales and marketing) will be gathered and analysed using a mixed-methods approach.

Quantitative data collection:

Background:

Despite the fact that heart failure is on the rise, shockingly little is known about the struggles and journeys that patients and healthcare professionals face. The purpose of this study is to outline the symptoms that people with heart failure experience, how those symptoms affect their careers, and how those symptoms affect their lives in general.

Methods:

Focus groups were held in person for this Hyderabad-based investigation. Groups were audio recorded, Data was evaluated utilising a content-analysis technique after their discussions were recorded and transcribed.

Results:

The study included 90 participants—64 patients and 26 caretakers. The patients were 59.3 8 years old on average, with 52.0% of them being female, and 55.6% of them being from KIMS SECUNDERABAD. The symptoms that were reported most commonly were difficulties breathing (81.3%), exhaustion/fatigue (76.6%), edoema of the legs and ankles (57.8%), and sleeping problems (50.0%).

Patients reported that difficulties stair climbing and walking (56.3%), food changes (64.1%), and decreased social/family connections were the most frequent unfavorable impacts of the disease. Mental-health repercussions were anxiety (32.8%), dread of dying (32.8%), and depression and despair (43.8%). Reduced social/family contacts (50.0%), feeling restless, nervous, and fearful (46.2%), and needing to keep an eye on their "patience" level (42.3%) were also reported by those who give care (mean age, 55.5 11.2 years, and 52.0% female).

Conclusions:

Significant unmet requirements exist for both HF patients and carers. Further study is required to better understand these requirements and the effects of HF, as well as to develop and assess illness management toolkits that can benefit patients and their jobs.

Qualitative data collection:

Objective:

Heart failure (HF) must be diagnosed and treated as soon as possible, but identifying individuals who may have the condition can be difficult, particularly in primary care. We outline the steps primary care patients with HF must take, starting with presentation, diagnosis, and first therapy.

Methods:

We described the investigation and referral pathways taken by patients from the initial presentation with relevant symptoms to the diagnosis of HF using the Clinical Practise Research Datalink (primary care consultations linked to hospital admissions data and national death registrations for patients registered with participating primary care practises in HYDERABAD), paying particular attention to alignment with recommendations of the National Institute for Health and Clinical Excellence.

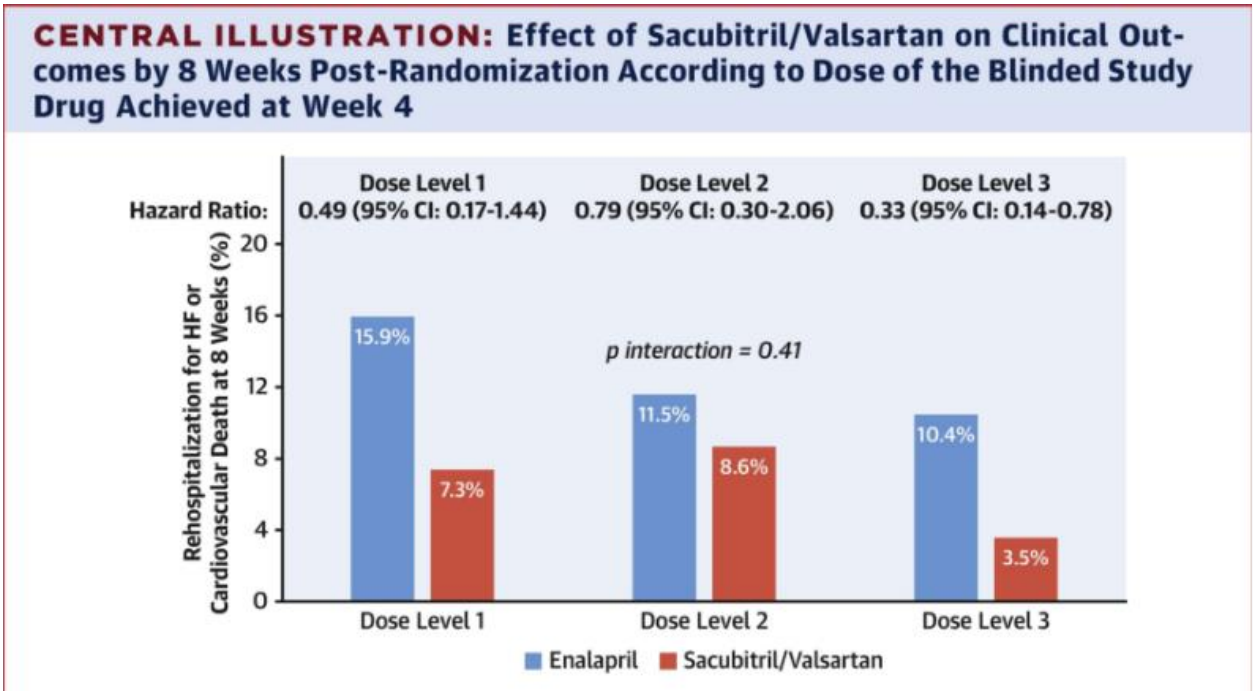
Results:

A diagnosis of HF that met the inclusion criteria was reported for 36 748 individuals between 1 January 2020 and 31 March 2023. This was initially noticed while inpatient for 29 113 (792%) patients. In the five years before to diagnosis, 3967 patients (10.8%) did not see their general practitioner, while 17 724 patients (48.2%) went in for another reason and 15 057 patients (41.0%) had a single of the three main HF symptoms identified. A recommended course of action, which comprised an echocardiogram, a serum natriuretic peptide examination, and a specialist referral, was only taken by 24% of persons with known HF symptoms, while 44% did not.

Conclusions:

Different patient journeys lead to the diagnosis of HF. Few people, nevertheless, seem to take the recommended course of investigation and referral. In primary care, there are probably unrealized chances for earlier HF diagnosis.

3.2 DATA COLLECTION



Methods:

In the 881 patients stable during hospitalisation for ADHF who were enrolled in the PIONEER-HF trial, sacubitril/valsartan was compared to enalapril in a randomised, double-blind, active-controlled study. The initial dosage was determined by an algorithm based on systolic blood pressure and the investigator's evaluation of tolerability, and it was then titrated towards a target of sacubitril/valsartan 97/103 mg twice day, or enalapril 10 mg twice daily. The research drug was given for 8 weeks in a blinded manner.

Results

At 4 weeks, the target dose was administered to 211 patients (60%) getting enalapril and 199 patients (55%) receiving sacubitril/valsartan. At every dose level, baseline characteristics were comparable between the two treatment groups. Through 8 weeks, neither the pre-specified adverse events of special interest nor the decline in NT-proBNP (pinteraction = 0.69), the decline in cardiovascular mortality or rehospitalization for heart failure (pinteraction = 0.42), nor the decline

in cardiovascular death or rehospitalization through 8 weeks showed any heterogeneity across dose levels.

Pre & post covid effect on use of Sacubitril and valsartan:

Healthcare procedures and patient treatment, particularly the administration of drugs like sacubitril and valsartan (ARNI therapy), have been impacted by the COVID-19 pandemic. While information on the effects of sacubitril and valsartan use before and after COVID may not be easily accessible, the following basic points should be kept in mind:

1. **Treatment Recommendations:**
   Throughout the epidemic, the recommendations for treating heart failure, including the administration of sacubitril and valsartan, have not changed. ARNI therapy is still advised for patients who qualify by organisations including the American College of Cardiology (ACC), the American Heart Association (AHA), and the European Society of Cardiology (ESC).
2. **Access to medicine:**
   Disruptions in healthcare systems, supply chains, and drug distribution networks may have had an impact on patients' access to medications during the COVID-19 pandemic. Some people might have had trouble getting their prescription medicines, like sacubitril and valsartan.
3. **Telemedicine and remote monitoring**:
   Technology use has risen as a result of the pandemic. Virtual consultations are being used more frequently by healthcare professionals to evaluate patients' conditions, modify drug schedules, and offer follow-up treatment. Tools for remote monitoring have made it easier to track patients' vital signs and how they are responding to treatment, including the usage of sacubitril and valsartan.
4. **Adherence to medication:**
   The COVID-19 epidemic has brought forth further stresses and difficulties for people, which could have an impact on drug adherence. Changes in socioeconomic situations, anxiety of visiting medical institutions, and disruptions in daily routines could have affected patients' adherence to ARNI therapy, including sacubitril and valsartan.

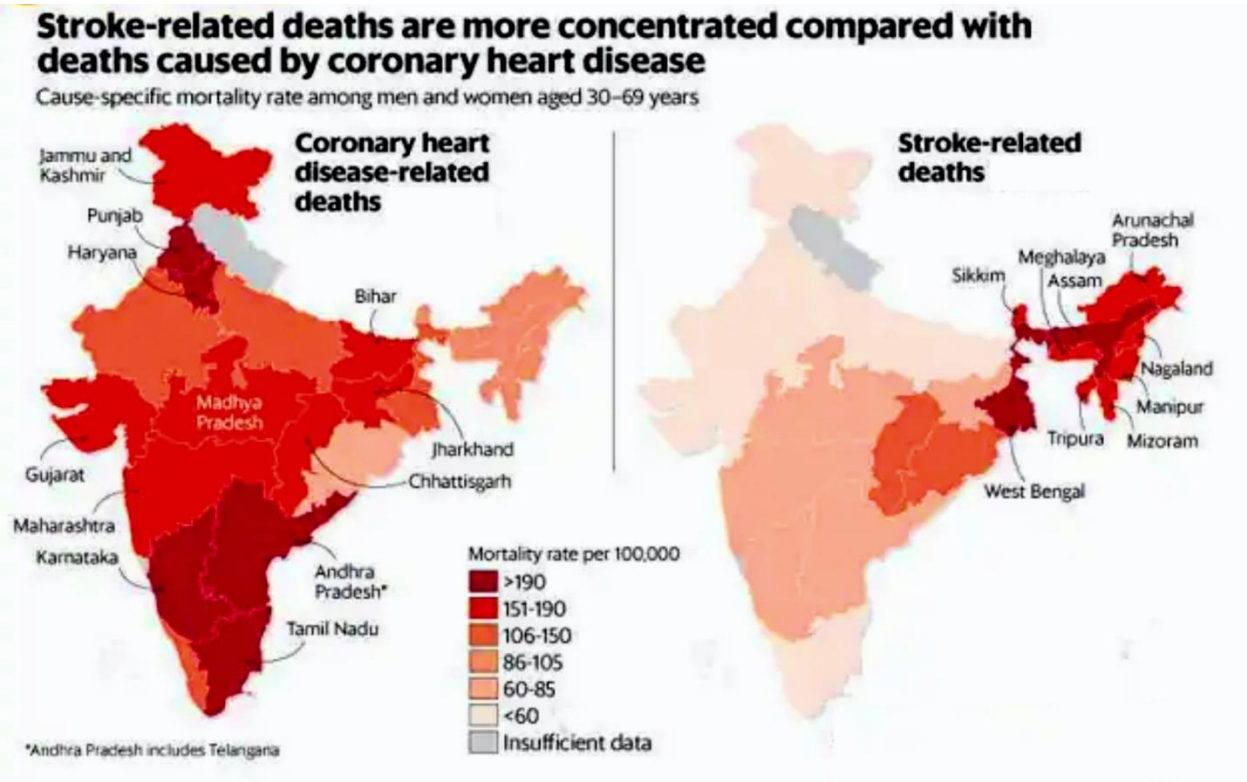
5. **Impact of covid 19 infection:**

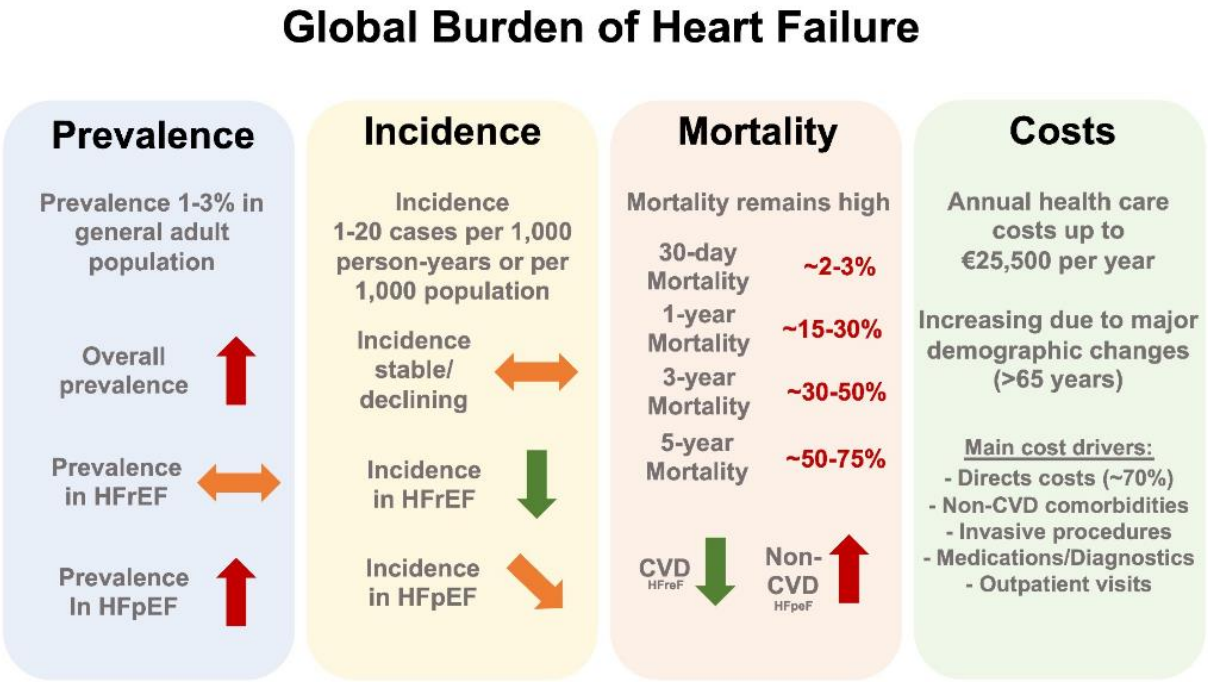
The COVID-19 epidemic has brought forth further stresses and difficulties for people, which could have an impact on drug adherence. Changes in socioeconomic situations, anxiety of visiting medical institutions, and disruptions in daily routines could have affected patients' adherence to ARNI therapy, including sacubitril and valsartan.

CHAPTER 4

COMPREHENSIVE PLAN:

4.1 HEART FAILURE IN INDIA





EPIDEMIOLOGICAL DATA

Since there is no surveillance scheme in place to track incidence, prevalence, outcomes, and the primary causes of heart failure, accurate heart failure statistics are not available for India. We argue that population, epidemiological, and health trends are to blame for the rising incidence and prevalence rates of heart failure. We provide a conservative estimate of the prevalence and incidence rates for various diseases that there are between 1.3 and 4.6 million cases of heart failure in India every year, caused by rheumatic heart disease, obesity, diabetes, high blood pressure, and coronary artery disease. The prevalence of the condition is also estimated to range between 491 600 and 1.8 million cases annually. These projections are influenced by social inequality, a limited healthcare infrastructure, and the twin burdens of persistent "pre-transition" disorders like rheumatic heart disease and rising cardiovascular risk factors. The classification of heart failure into four stages—stages A, B, C, and D—was introduced in 2005 and provides a framework for focusing prevention interventions on patients with heart failure risk factors Heart failure symptoms are stage C, structural disease alone is stage B, and end-stage illness is stage D. Interventions at the policy level, including restrictions on salt and cigarette use, are advantageous for avoiding heart failure and would have a greater impact. Treatment for acute decompensated heart failure, atherosclerosis, diabetes, and hypertension are a few examples of clinical interventions that are beneficial for primary, secondary, and even tertiary prevention.

The cardiovascular disease health transition that results from population and epidemiological transitions in many societies

Health transition: Cardiovascular disease example				
Stage	**I**	**II**	**III**	**IV**
Life expectancy (years)	35	50	60	>70
Dominant diseases	Infections, nutritional	Mixed (receding communicable and rising non-communicable)	Chronic (mid-life)	Chronic (elderly)
Contribution of cardiovascular disease to mortality (%)	5–10	15–35	>50	<50
Pattern of cardiovascular disease	Rheumatic, nutritional	Rheumatic, nutritional and stroke (ICH)	Coronary, stroke (both)	Coronary, stroke (THR)
Primary victims	Higher class	All classes	Lower classes	Lower classes

PREVALANCE RATE

Due to the country's continuous double burden of pre-transitional illnesses such RHD, endomyocardial fibrosis, tuberculous pericardial disease, and anaemia as well as the rising risk factors for conventional cardiovascular disease (CVD), the prevalence of HF may be rising in India. The goal of HF prevention, which is occasionally overlooked in clinical practise, offers physicians and patients a lot of beneficial options. In this review, we discuss interventions for HF prevention in India, the epidemiology of heart failure in India today and potential causes, and the staging of heart failure as a model for preventing heart failure, according to the heart failure recommendations of the American Heart Association and American College of Cardiology.

- 14.9% OVER 50 YEARS
- 22.5% UNDER 30 YEARS

MORTALITY RATE

Heart failure (HF) has become a significant and growing health concern in India. We outline the 5-year results for HF hospital patients in India.

Methods

In 2023, patients who had received acute heart failure treatment at 16 hospitals in Trivandrum, Kerala, were added to the Trivandrum Heart Failure Registry (THFR). The term "guideline-directed medical therapy" (GDMT) refers to the use of a combination of beta-blockers (BB), renin-angiotensin system blockers (RAS), and mineralocorticoid receptor antagonists (MRA) in patients with heart failure with reduced ejection fraction (HFrEF, EF 40%) at discharge.. For analysis, we employed Kaplan-Meier survival graphs and Cox proportional hazards models. The exposure variables also included the components of the MAGGIC risk score.

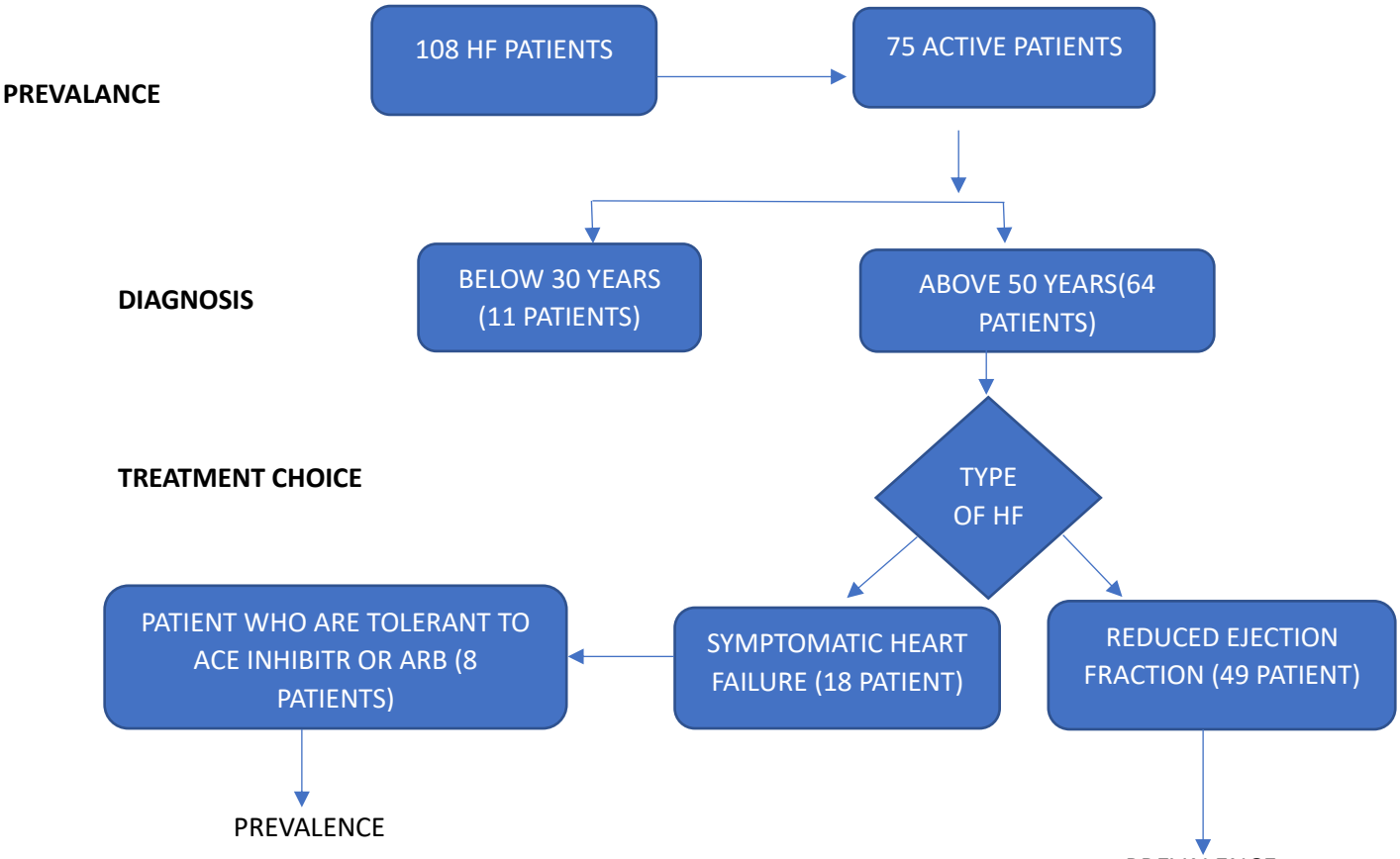
Results

69% of patients, and a mean (SD) age of 61.2 (13.7) years having HFrEF, the group of 1205 patients received 25% of the GDMT. The median lifespan was 3.1 years, and 59% of people died within five years (n = 709 deaths). 46% and 49% of the fatalities were attributed, respectively, to pump failure and abrupt cardiac death. Discharge prescriptions for BB, RAS blockers, and MRA were associated with decreased 5-year mortality rates according to the multivariate Cox model. Older age, lower systolic blood pressure, NYHA classes III or IV, and greater serum creatinine were also linked to an increase in 5-year mortality.

Conclusions

During a 5-year period of follow-up, 3 out of every 5 patients had died, with a three-year median survival. Frequent readmissions and a lack of GDMT in HFrEF patients were linked to a higher 5-year mortality rate. Programmes for quality improvement that focus on GDMT adherence and readmission prevention may enhance HF outcomes in this area.

4.2 Patient survey of HF patient treatment:



FINAL OUTPUT

TYPES HF	ACTIVE PATIENT TAKING TREATMENT	PATIENT NOT FOLLOWING TREATMENT REGIMEN.
SYMPTOMATIC HF	19	7
REDUCED EJECTION FRACTION	38	11

4.3 Treatment Regimen:

We have collected some data by preparing questionnaire for cardiologists, some of the questions are mentioned in following table

Questions	Answer
When and why doctor prescribe ARNI treatment?	Patients with heart failure are routinely given the ARNI (Angiotensin Receptor-Neprilysin Inhibitor) treatment. Heart failure patients with decreased ejection fraction, also known as HFrEF, are specifically advised to take it. a disease in which the heart's capacity to pump blood is compromised.
Which is the right time to shift patient to ARNI treatment?	A healthcare provider, usually a cardiologist, should decide whether to switch a patient to ARNI (Angiotensin Receptor-Neprilysin Inhibitor) a medication like sacubitril/valsartan, based on the patient's unique clinical state and other variables.
How do you determine the appropriate duration for switching patient from ARB to ARNI / ACE to ARNI?	The timing of the switch will depend on several variables, including the patient's reaction to the current treatment, the stability of their condition, and how well they tolerate the medications.
Can you explain the process of a complete washout of medication before starting ARNIs?	Before beginning ARNIs (Angiotensin Receptor-Neprilysin Inhibitors), the preceding medication must be stopped to allow the body to eliminate it from the system. ACE inhibitors or ARBs are frequently used in this process. The exact medication and its half-life will determine how long the washout period will last. The medical practitioner has the option of suddenly stopping the medicine or tapering it off gradually. Throughout the washout phase, it's critical to keep a close eye on the patient's clinical condition. A healthcare provider should decide whether to do a washout and how long it should last based on each patient's clinical situation.
What is the recommended starting dosage of ARNI for Heart failure patients?	Patients with heart failure should often start with 49 mg/51 mg twice daily of an ARNI (Angiotensin Receptor-Neprilysin Inhibitor), more precisely sacubitril/valsartan (trade name: Entresto). The dosage, however, may change based on the patient's unique clinical state and tolerance. To identify the ideal ARNI starting dosage for each patient, it is

	crucial to speak with a medical expert, usually a cardiologist.
What is the frequency at which monitoring and follow ups are required for this treatment?	Depending on the specific condition and treatment response of the patient, the frequency of monitoring and follow-up visits may change. Nevertheless, in the majority of situations, medical professionals, often cardiologists, may plan follow-up appointments at first every one to three months to evaluate the patient's clinical response, keep an eye out for any potential side effects, and alter the dosage as necessary.
What are the Specific precautions that the doctor advices ARNI patients to take?	• following the recommended dosage schedule • Avoiding Potassium Supplements • Avoid Pregnancy • Monitoring Heart Rate and Blood Pressure • Reporting Symptoms • Dehydration Prevention • Regular Visits for Follow-Up Patients should speak with their doctor to get specific advice and precautions based on their unique medical situation and treatment regimen.

As per suggested by some doctors of KIMS Sunshine hospital,

1.Dr. S Vijay kumar Reddy

2. Dr. Vivek Narasimha V

3.Dr. Rajaram

4. Dr. Aparna

And the doctors of Apollo Hospital,

1. Dr. Sajid Pavitram

2. Dr. Vamshi Krishna Mamidala

3. Dr. Rajiv Garg

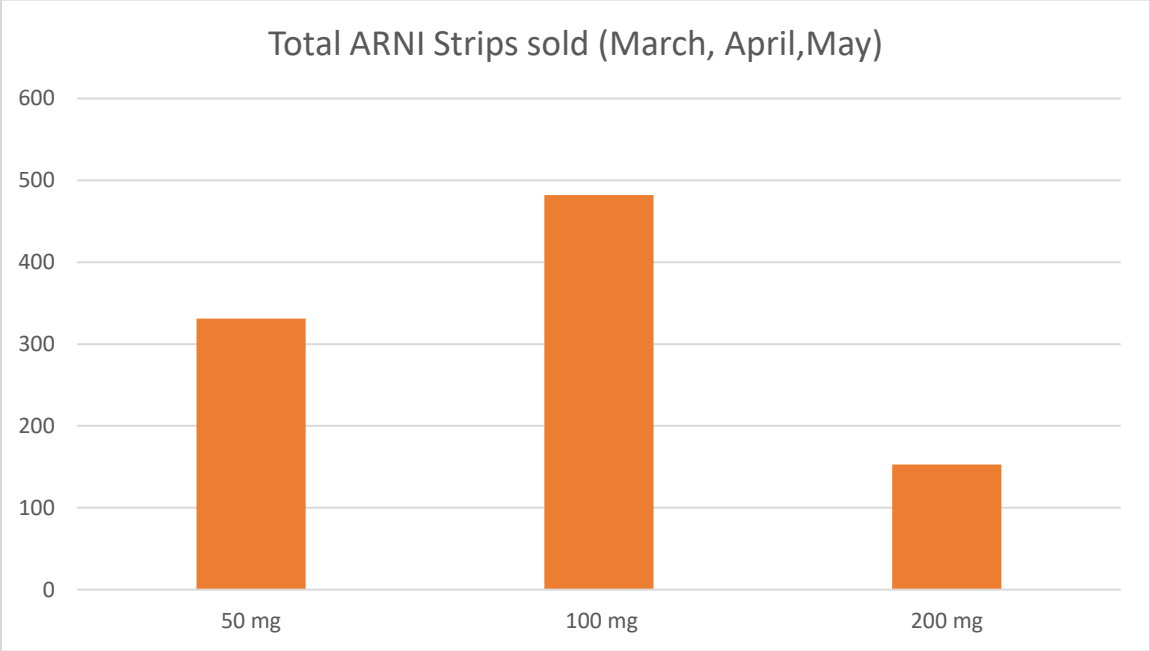
4. Dr. Mukesh Rao

The **treatment regimen** plan for heart failure patient is as follows,

Step 1	**Diagnosis**	• Physical evaluation • Blood test • Echocardiogram etc.
Step 2	**Medication** [on the basis of type of severity of HF Patient]	• Ace inhibitor • ARB • Beta blocker • Diuretics • Aldosterone • ARNI
Step 3	**Lifestyle Modification**	Patient should have: • Healthy Diet (Low Sodium & Saturated fats) • Physical Exercise • Should quit smoking, Alcohol consumption, stress management activities, And Maintain BMI (Body Mass Index).
Step 4	**Regular Monitoring** [Check for medication effectiveness and any possible complications]	• Periodic check-up • Blood test to assess kidney function. • Electrolyte level • Imaging test to evaluate heart function and structure
Step 5	**Symptom management**	Patients need to report physical changes to the doctor if occur any, Such as, • Shortness of breath • Fatigue • Weight gain/loss
Step 6	**Adjustment & Intervention**	• Medication Adjustment [Addition or removal of medicine] • Consideration of device therapy or surgical intervention
Step 7	**Support and continuous education**	Regarding necessary lifestyle changes and cope with emotions.

- **Sacubitril and valsartan 50 mg ,100mg and 200mg preferences of doctors of 3 months [March, April and May]**

Total ARNI Sale(Total Strips sold) (March, April, May)	
50 mg	331
100 mg	482
200 mg	153



4.4 Financial Analysis of HF Patient:

- Some sample of average measured financial analysis of heart failure patient are as below.
- **Note:** The values/ pricing mentioned in billing are not actual/real they are hypothetical.

KIMS Sunshine Hospital, Hyderabad **Patient Details:** **Patient Name: Mrs. Jaya Reddy** **Date: 5th May 2023** **Sex: Female** **Place: Hyderabad** **Age: 55**		
Direct Healthcare Cost	Expenses related to Hospital. (Considering any Private Hospital)	25,000/-
Diagnostic tests:	Echocardiogram	4000/-
	Electrocardiogram (ECG)	550/-
	Chest Xray	900/-
	Cardiac MRI	10,500/-
	Cardiac CT	15,000/-
	Cardiac Catheterization	27,000/-
	Blood test	900/-
Medication & Medical Procedure		
Medication:	Ace inhibitor (per tab)	80/-
	β -blocker (per tab)	75/-
	Diuretics (per tab)	30/-
	Aldosterone antagonist (per tab)	120/-
	Digoxin (per tab)	25/-
	ARNI	39/-
Medical Procedure:	Coronary Angioplasty	1,60,000/-
	Implantable cardioverter	4,70,000/-
Follow-up Visit	Cost per Visit including consultation. (Private hospital)	700/-
TOTAL COST		7,14,919/-

Apollo Hospital, Secunderabad **Patient Details:** **Patient Name: MR. Vijay Patil** **Date: 13th May 2023** **Sex: Male** **Place: Hyderabad** **Age: 58**		
Direct Healthcare Cost	Expenses related to Hospital. (Considering any Private Hospital)	22,000/-
Diagnostic tests:	Echocardiogram	3700/-
	Electrocardiogram (ECG)	580/-
	Chest Xray	750/-
	Cardiac MRI	9,800/-
	Cardiac CT	13,999/-
	Cardiac Catheterization	25,475/-
	Blood test	950/-
Medication & Medical Procedure		
Medication:	Ace inhibitor (per tab)	69/-
	β -blocker (per tab)	60/-
	Diuretics (per tab)	27/-
	Aldosterone antagonist (per tab)	115/-
	Digoxin (per tab)	20/-
	ARNI	37/-
Medical Procedure:	Coronary Angioplasty	1,45,000/-
	Implantable cardioverter	4,49,000/-
Follow-up Visit	Cost per Visit including consultation. (Private hospital)	650/-
TOTAL COST		6,72,230/-

CHAPTER 5

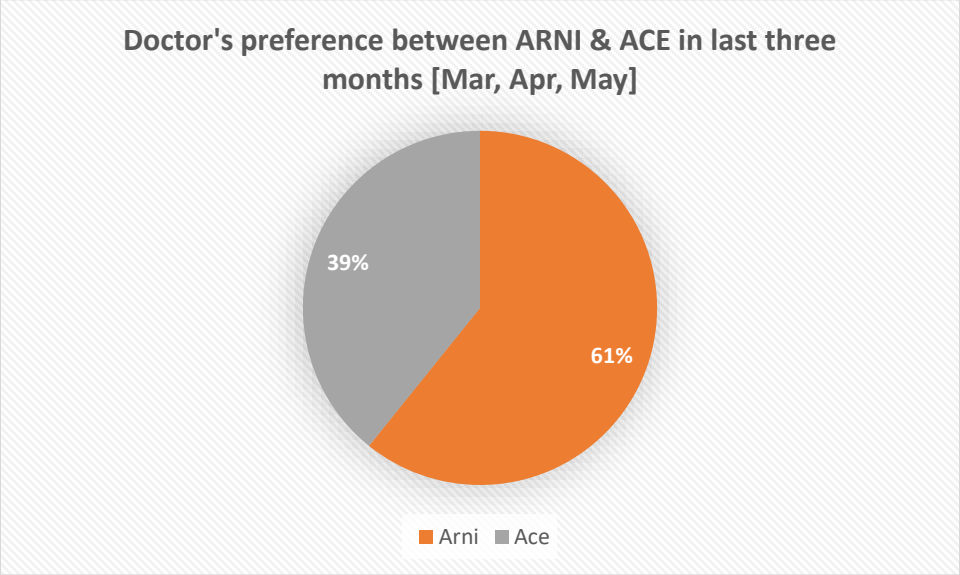
COMPARATIVE ANALYSIS OF DOMESTIC MARKET

5.1 Data Collection:

- The market of sacubitril and valsartan is estimated to be INR 630 crore with an annual growth of 36% and CAGR of 50%.
- Sacubitril and valsartan is available under 23 brand names in India. Out of 23 brands the revenue of top 3 brands is around INR 100 crore.

BRANDS	COMPANY	PROD_LNCH	TOTAL	RANKING
VYMADA	NOVARTIS INTL.*	201702	246.0	1
CIDMUS	DR REDDYS LABS	201705	195.9	2
AZMARDA	JB PHARMA*	201703	114.2	3
NEPTAZ	MANKIND	202205	34.8	4
ZAYO	ERIS LIFESCIENCES*	202012	19.8	5
VALENTAS	LUPIN LIMITED	202301	4.0	6
ARNEY	INTAS PHARMA*	202301	2.9	7
SACURISE	SUN*	202301	2.1	8
ARNICOR	CIPLA	202301	1.9	9
HEFCARD	TORRENT PHARMA*	202301	1.3	10
ARNIPIN	LUPIN LIMITED	202301	1.3	11
ARNOZA	TORRENT PHARMA*	202301	1.2	12
EXDUO	EMCURE*	202301	1.1	13
SACUTAN	MSN LABS	202012	1.0	14
SACUVAL	ALKEM*	202301	0.9	15
SACU-V	GLENMARK PHARMA	202301	0.8	16
SACUMADA	IPCA LABS	202301	0.7	17
REFSAV	ABBOTT*	202301	0.2	18
ARNIV	MICRO LABS*	202301	0.2	19
MYMARDA	MACLEODS PHARMA	202302	0.2	20
SACUHART	MACLEODS PHARMA	202302	0.1	21

- After collection of data for 3 months [March, April and May], we observed that,
- Most of the cardiologist / cardiac surgeons prefer to prescribe ARNI over ACE inhibitors.



CHAPTER 6

CONCLUSION:

6.1 Summary of findings:

"Assessing Market Access Strategies for (sacubitril and valsartan) A Comparative Analysis of Domestic Markets and Hospital Survey for Medicine Used for Heart Failure Patient" is the title of the dissertation.

Analysing the heart failure's direct and indirect costs, such as hospital stays, medicine costs, and lost productivity, is necessary to assess the financial impact that heart failure has on healthcare systems. The objective would be to develop a thorough strategy for a dedicated heart failure clinic for patients in India.

This thesis examines the market entry methods utilised for the combination medication of sacubitril and valsartan, a medication for HFrEF, or heart failure with poor ejection fraction. The goal is to assess the efficacy of the company's tactics in different areas, identify significant variables affecting market access, and analyse the local and foreign market access strategies for Sacubitril and Valsartan. This research will offer useful insights towards maximising market access and enhancing patient outcomes by looking at pricing, reimbursement practises, legal requirements, and market dynamics. Valsartan and sacubitril are two drugs that are combined to treat heart failure with a low ejection fraction. Valsartan is an angiotensin receptor blocker (ARB), whereas sacubitril is a neprilysin inhibitor.

They complement one another to enhance heart function and lessen hospitalisations for heart failure. Angiotensin II receptor blocker (ARB) valsartan aids in blood vessel relaxation and blood pressure reduction, which lessens the burden on the heart. Sacubitril and valsartan are advised adult treatment for heart failure with a lower ejection fraction (HFrEF).

Dosage: twice-daily 49/51 mg.

Contraindications: Sacubitril/valsartan should not be taken by those with hereditary or idiopathic angioedema, as well as those who have already taken ACE inhibitors or ARB medications.

This study intends to examine the efficiency of sacubitril and valsartan market access tactics in local and foreign markets, evaluate the company's market access methods, and identify the major

market access influencing variables. In addition to making suggestions for enhancing sacubitril and valsartan market access in both local and foreign markets, the research intends to provide light on the parallels and discrepancies between these tactics. The financial impact of heart failure on healthcare systems, including hospital stays, prescription costs, and lost productivity, will also be assessed. The study will also assess how much heart failure costs the healthcare system. Sacubitril/valsartan should not be taken by those with hereditary or idiopathic angioedema, as well as those who have already taken ACE inhibitors or ARB medications.

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6.2 Contribution of Learning:

- Valuable insights have been gained for the development of a thorough plan for a specialised heart failure clinic in India through the evaluation of market access strategies for (sacubitril and valsartan) and the assessment of the financial toll that heart failure takes on healthcare systems. The present treatment regimen and its expenses have been clarified by comparing the domestic market and hospital survey for drugs used in heart failure care.

Understanding Market Access Strategies:

- The evaluation of sacubitril and valsartan market access strategy has helped us better understand the potential and difficulties associated with bringing a novel heart failure medicine to market. It has emphasized the need of taking into account elements including price, reimbursement, regulatory frameworks, and local market competitiveness. The formulation of a successful market entry strategy for sacubitril and valsartan in India will be aided by this information.

Financial Toll of Heart Failure:

The considerable direct and indirect costs linked to the condition have been emphasised by the assessment of the financial impact of heart failure on healthcare systems. The three biggest cost factors have been identified as hospital stays, prescription costs, and lost productivity. This knowledge underlines the necessity of an integrated strategy that not only emphasises efficient medical management but also takes into account the financial burden of heart failure on people, healthcare providers, and society at large.

Tailoring Treatment Regimes:

The examination of the therapeutic options that are accessible in India has shed light on the preferences and practises that are currently used to manage heart failure. The creation of a specialised heart failure clinic that caters to the requirements of patients in India would be greatly helped by the information provided. The clinic can improve patient happiness,

optimise patient outcomes, and perhaps save healthcare costs associated with managing heart failure by customising therapy regimens to the local environment.

Comprehensive Plan for a Specialized HF Clinic:

The overall benefit of this knowledge is the development of a thorough strategy for an Indian heart failure clinic. The strategy will include several aspects of heart failure management by merging the knowledge gathered through market access strategies, financial toll evaluation, and the study of the treatment regime. It will take into account elements including ease of access to medications, cost, level of treatment, patient education, and long-term monitoring. A strategy like this may enhance patient outcomes, lower hospital stays, and lessen the financial burden that heart failure places on healthcare systems.

In conclusion, the examination of sacubitril and valsartan market entry methods and the cost of heart failure have offered useful insights for the creation of a thorough strategy for a specialised heart failure clinic in India. The insights gained from this study help to create a comprehensive strategy for managing heart failure that considers both the clinical and financial elements. Healthcare professionals in India may seek to raise the standard of care and outcomes for while lessening the cost burden, treat individuals with heart failure on both the individual patient and the healthcare system by putting the suggested method into practise.

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Thank You