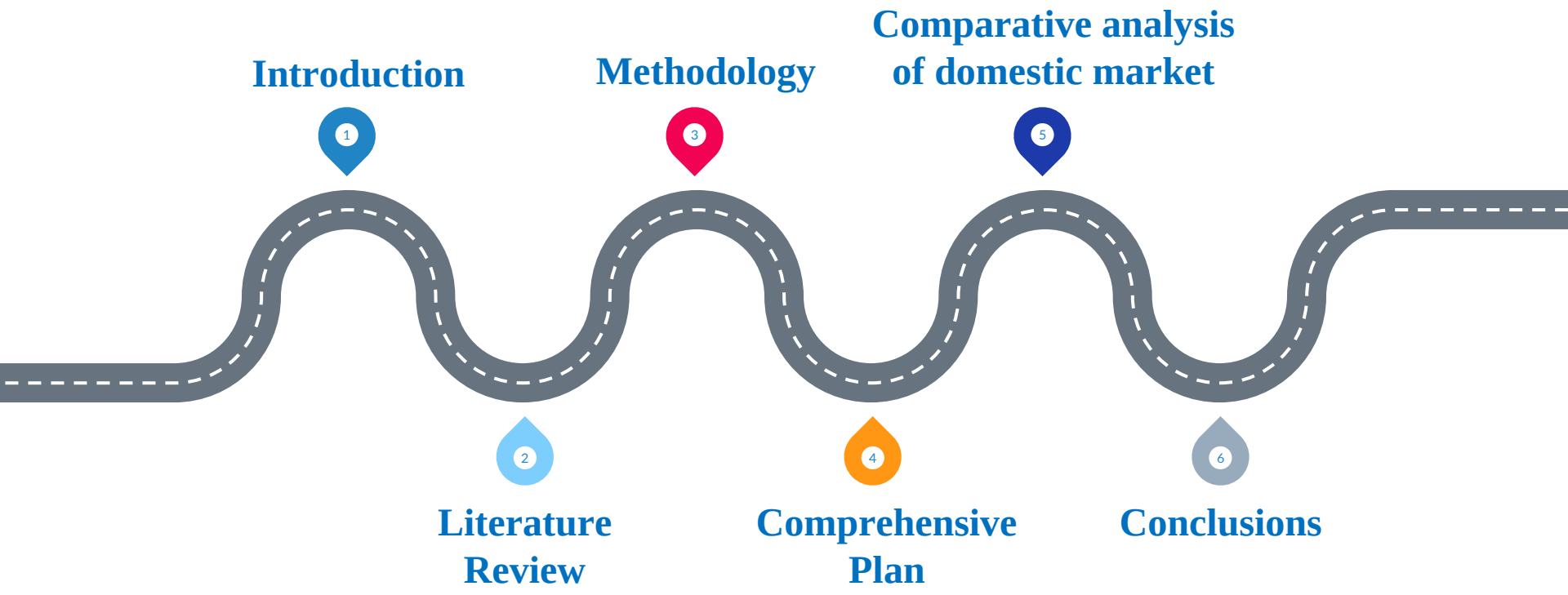
ASSESSING MARKET ACCESS STRATEGIES FOR (SACUBITRIL AND VALSARTAN) A COMPARATIVE ANALYSIS OF DOMESTIC MARKET AND HOSPITAL SURVEY FOR MEDICINE USED FOR HEART FAILURE PATIENT.

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

Prepared By : Sankalp T. Sapkal.
MBA PM 13
IIHMR-U/02/2021-23/0337

Guided By: Dr. Saurabh Kumar Banerjee
Dean & Associate Professor
School of Pharmaceutical Management.
IIHMR University , Jaipur

CONTENT


Introduction
1
Literature Review
2
Methodology
3
Comprehensive Plan
4
Comparative analysis of domestic market
5
Conclusions
6

Inspite of being the ‘pharmacy of the world’, access to essential medicines for a large majority of Indians is constrained by both physical and financial reasons.

Introduction

Let’s start with the first set of slides

STUDY ENTAILS.....

MARKET ACCESS

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

EVALUATION OF FINANCIAL TOLL

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.

LITERATURE REVIEWS

Review > JAMA. 2020 Aug 4;324(5):488-504. doi: 10.1001/jama.2020.10262.

Heart Failure With Reduced Ejection Fraction: A Review

Sean P Murphy [1], Nasrien E Ibrahim [2 3], James L Januzzi Jr [2 3 4]

Affiliations + expand

PMID: 32749493 DOI: 10.1001/jama.2020.10262

Review > Basic Clin Pharmacol Toxicol. 2018 Jan;122(1):9-18. doi: 10.1111/bcpt.12912. Epub 2017 Oct 11.

The Combination of Valsartan and Sacubitril in the Treatment of Hypertension and Heart Failure – an Update

Peter Munch Nielsen [1], Daniela Grimm [1 2], Markus Wehland [2], Ulf Simonsen [1], Marcus Krüger [2]

Affiliations + expand

PMID: 28944989 DOI: 10.1111/bcpt.12912

Rethinking market access

Delivering on the promise of therapeutic innovation

Brian Corvino
United States

John Jaeger
United States

Natasha Elsner
United States

Madhushree Wagh
India (Offices of the US)

Randomized Controlled Trial > JACC Heart Fail. 2020 Oct;8(10):789-799. doi: 10.1016/j.jchf.2020.05.005. Epub 2020 Jun 10.

Sacubitril/Valsartan in Advanced Heart Failure With Reduced Ejection Fraction: Rationale and Design of the LIFE Trial

Douglas L Mann [1], Stephen J Greene [2], Michael M Givertz [3], Justin M Vader [4], Randall C Starling [5], Andrew P Ambrosy [6], Palak Shah [7], Steven E McNulty [8], Claudius Mahr [9], Divya Gupta [10], Margaret M Redfield [11], Anuradha Lala [12], Gregory D Lewis [13], Selma F Mohammed [14], Nisha A Gilotra [15], Adam D DeVore [2], Eiran Z Gorodeski [16], Patrice Desvigne-Nickens [17], Adrian F Hernandez [2], Eugene Braunwald [3]; LIFE Investigators

Efficacy and Safety of Sacubitril/Valsartan in High-Risk Patients in the PIONEER-HF Trial

David D. Berg, M.D., M.P.H.,[1] Marc D. Samsky, M.D.,[2] Eric J. Velazquez, M.D.,[3] Carol I. Duffy, D.O.,[4] Yared Gurmu, Ph.D.,[1] Eugene Braunwald, M.D.,[1] David A. Morrow, M.D., M.P.H.,[1] and Adam D. DeVore, M.D., M.H.S.[2]

‣ Author information ‣ Copyright and License information Disclaimer

Sacubitril and Valsartan Combination Therapy.

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

Sacubitril and Valsartan Combination Therapy.

	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 (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

SIGNIFICANCE OF STUDY

- **Improved Treatment Access:**
- **Hospital Survey:**
- **Specialized Heart Failure Clinic:**
- **Comparative Analysis:**
- **Financial Impact of Heart Failure:**
- **Real-World Evidence:**

RESEARCH METHODOLOGY

Research design:

Data (sales and marketing) will be gathered and analyzed using a mixed-methods approach.

Quantitative data collection:

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.

Qualitative data collection:

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.

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

-Treatment Recommendations

-Access to medicine:

-Telemedicine and remote monitoring:

-Adherence to medication:

-Impact of covid 19 infection

Quantitative data collection:

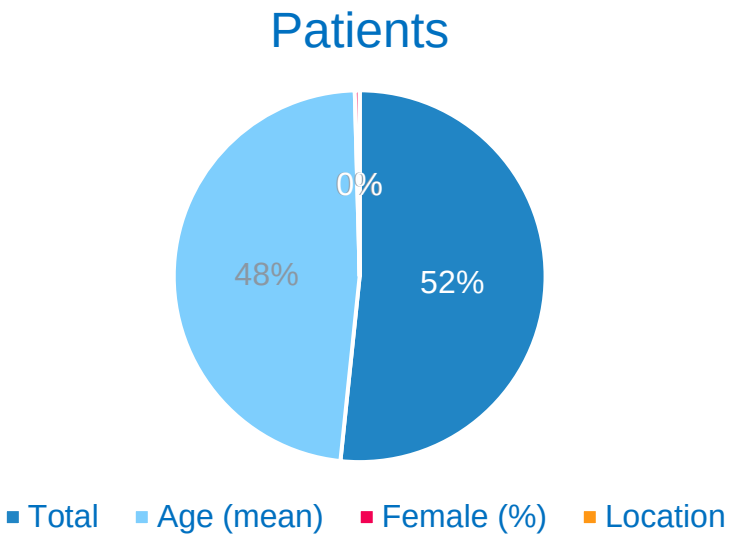
Methods:

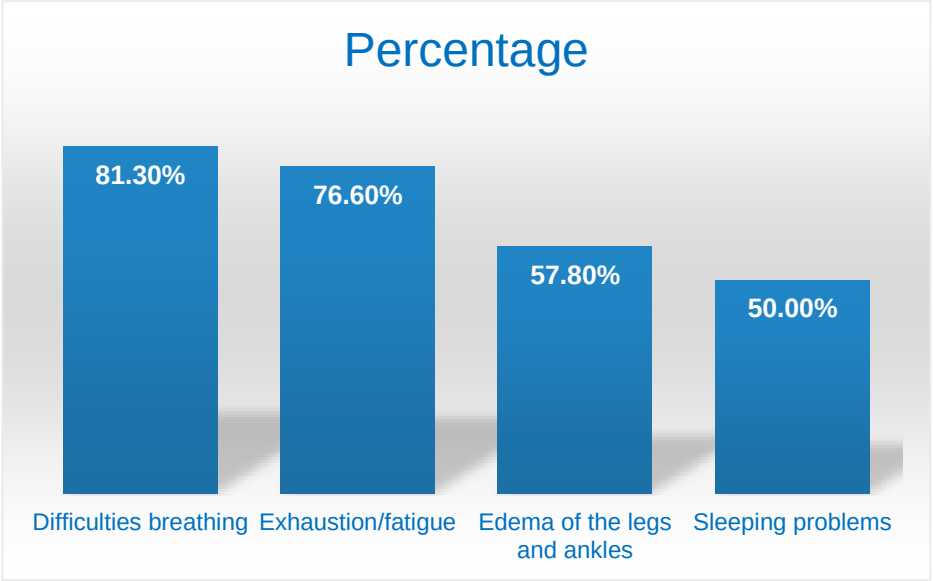
Focus groups were held in person for this Hyderabad-based investigation. Groups were audio recorded, Data was evaluated utilising a content-analysis technique after their discussions were recorded and transcribed.

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.

Most commonly reported symptoms by patients:





Quanlitative data collection:

- **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

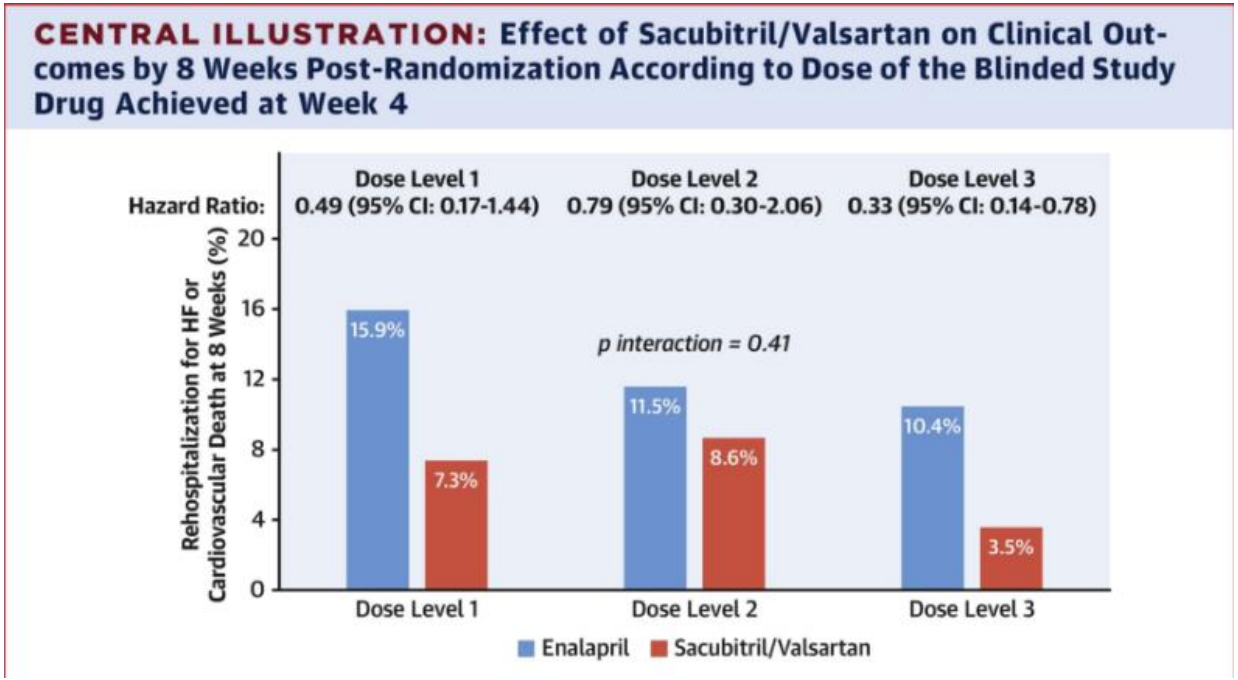
Conclusions:

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.

RESULT:

Category	Number of Patients
Total Patients with HF	36,748
Patients initially noticed inpatient	29,113 (79.2%)
Patients' General Practitioner Visits	
Did not see GP in 5 years prior	3,967 (10.8%)
Visited GP for another reason	17,724 (48.2%)
HF Symptoms	
Had a single HF symptom identified	15,057 (41.0%)
Recommended Course of Action	
Followed recommended course	8,819 (24.0%)
Did not follow recommended course	16,939 (46.0%)

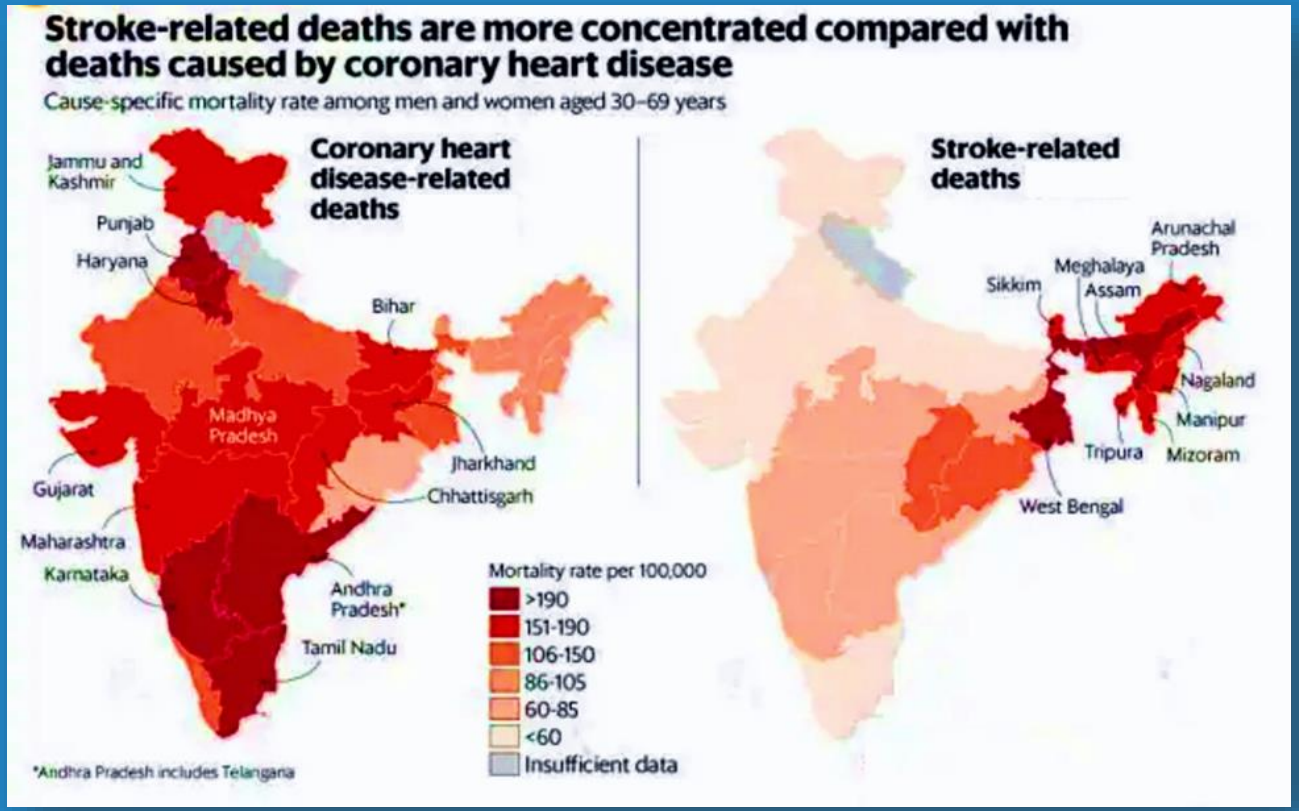
Data collection:



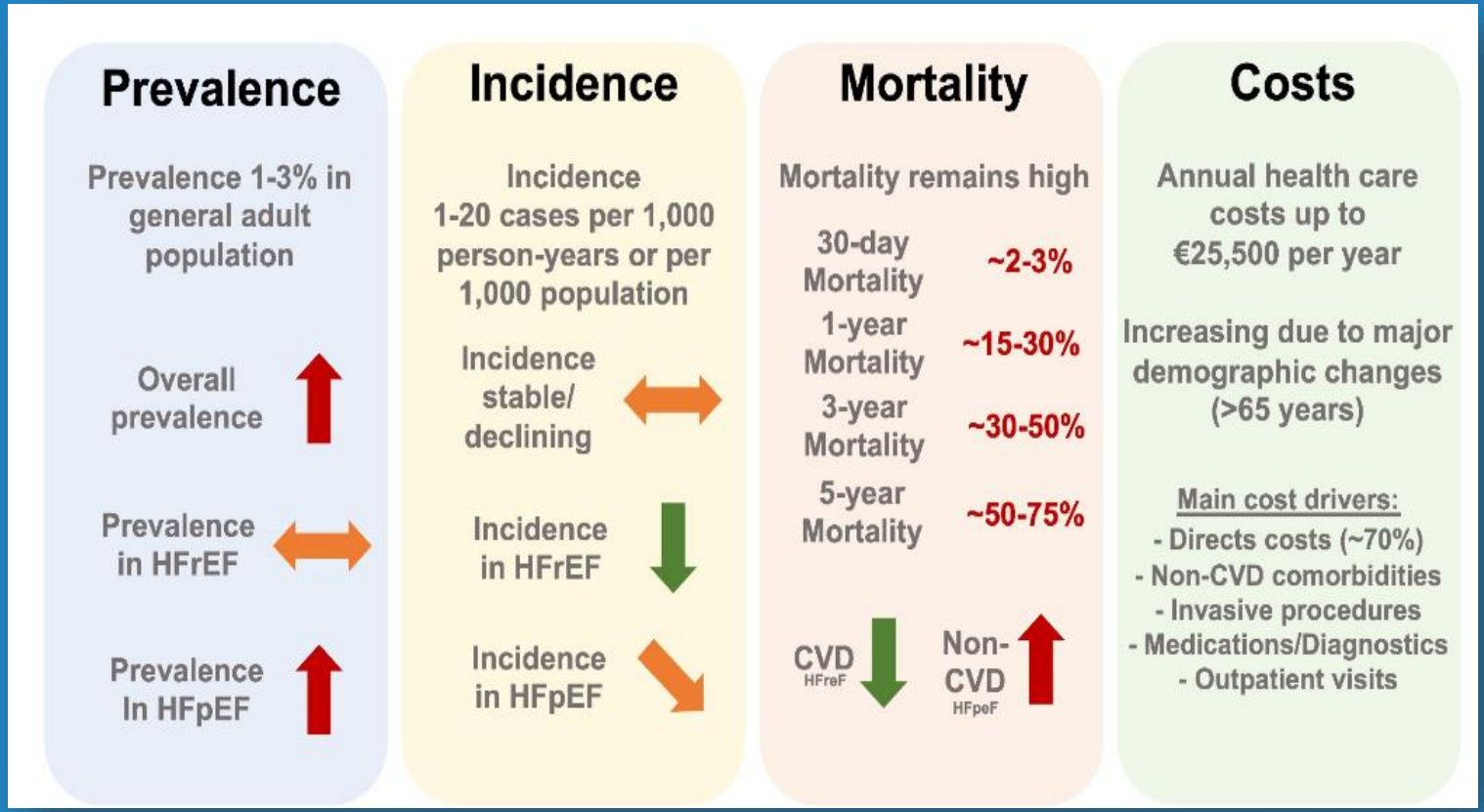
Dose Level	Enalapril Patients	Sacubitril/Valsartan Patients
4 weeks	211	199
8 weeks	250	201

COMPREHENSIVE PLAN

HEART FAILURE IN INDIA



GLOBAL BURDEN OF HEART FAILURE.



EPIDEMIOLOGICAL DATA

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

14.9% OVER 50 YEARS

22.5% UNDER 30 YEARS

MORTALITY RATE:

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.

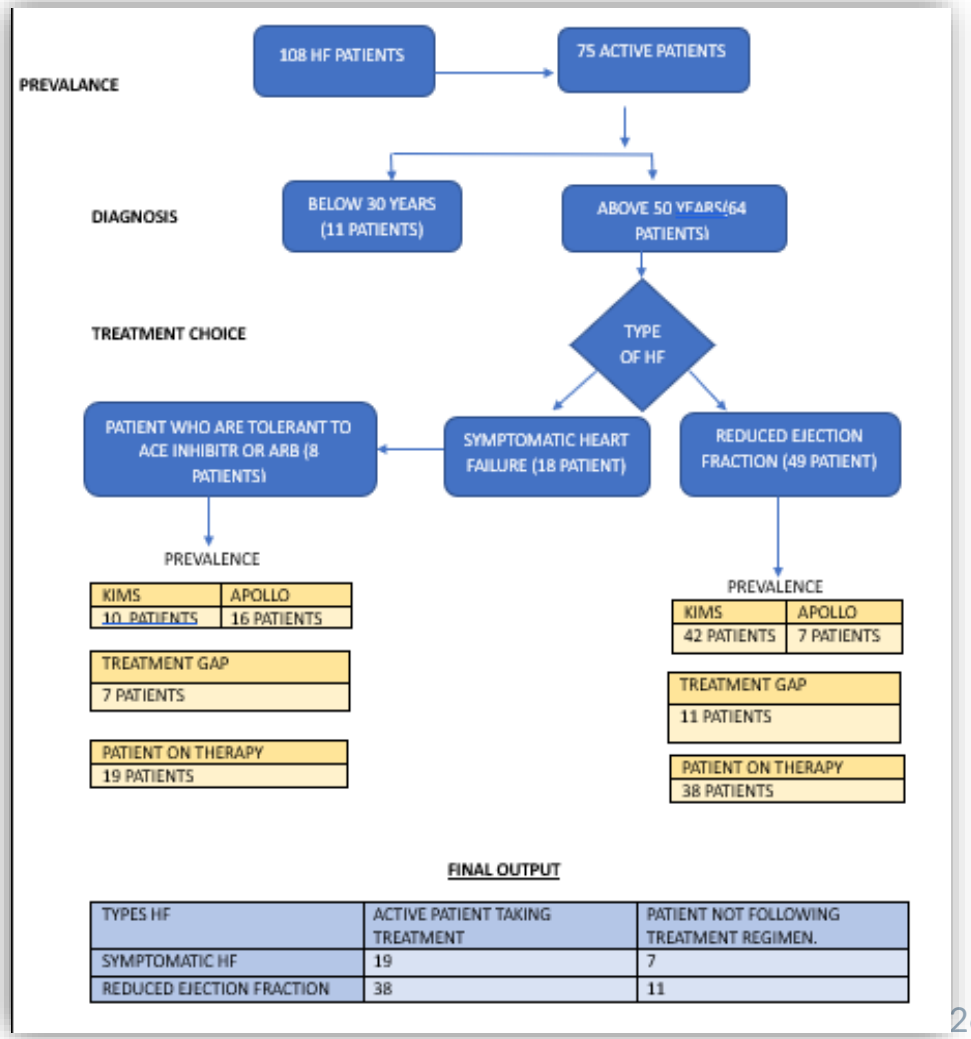
Conclusions

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.

RESULT:

Parameters	Values
Total Patients	1,205
Percentage with HFrEF	69%
Age (mean ± SD)	61.2 ± 13.7 years
GDMT Received	25%
Median Lifespan	3.1 years
5-year Mortality Rate	59%
Total Deaths (n)	709
- Pump Failure	46%
- Abrupt Cardiac Death	49%

Patient survey of HF patient treatment



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

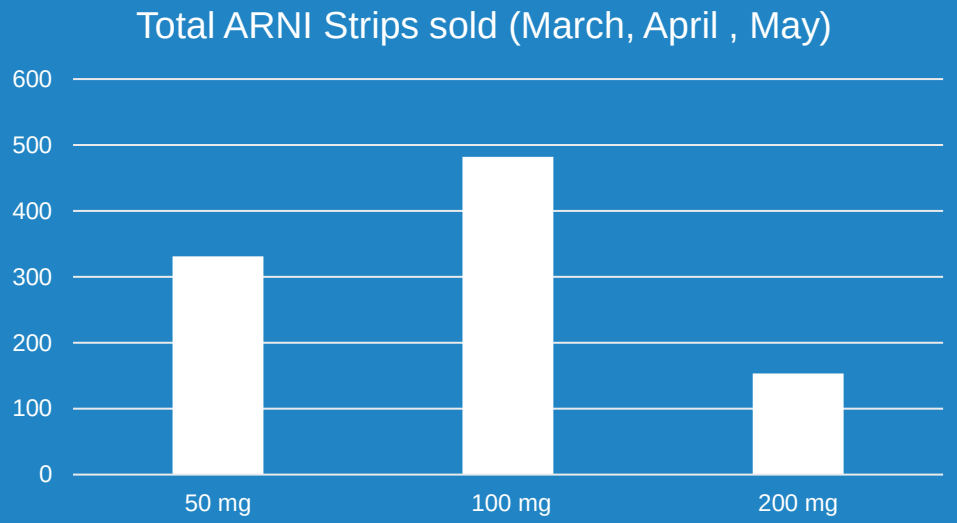
Step 1	Diagnosis	• Physical evaluation • Blood test • Echocardiogram etc.
Step 2	Medication [on the basis of type of severity of HF Patient]	• Ace inhibitor • ARB • Beta blocker • Diuretics • Aldosterone • ARNI
Step 3	Lifestyle Modification	Patient should have: • Healthy Diet (Low Sodium & Saturated 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

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

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



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/-

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.

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/-

COMPARATIVE ANALYSIS

INR 630 crore

MARKET SIZE OF SACUBITRIL AND VALSARTAN

36%

ANNUAL GROWTH

50%

CAGR (COMPOUND ANNUAL GROWTH RATE)

COMPARATIVE ANALYSIS OF DOMESTIC MARKET

Data Collection:

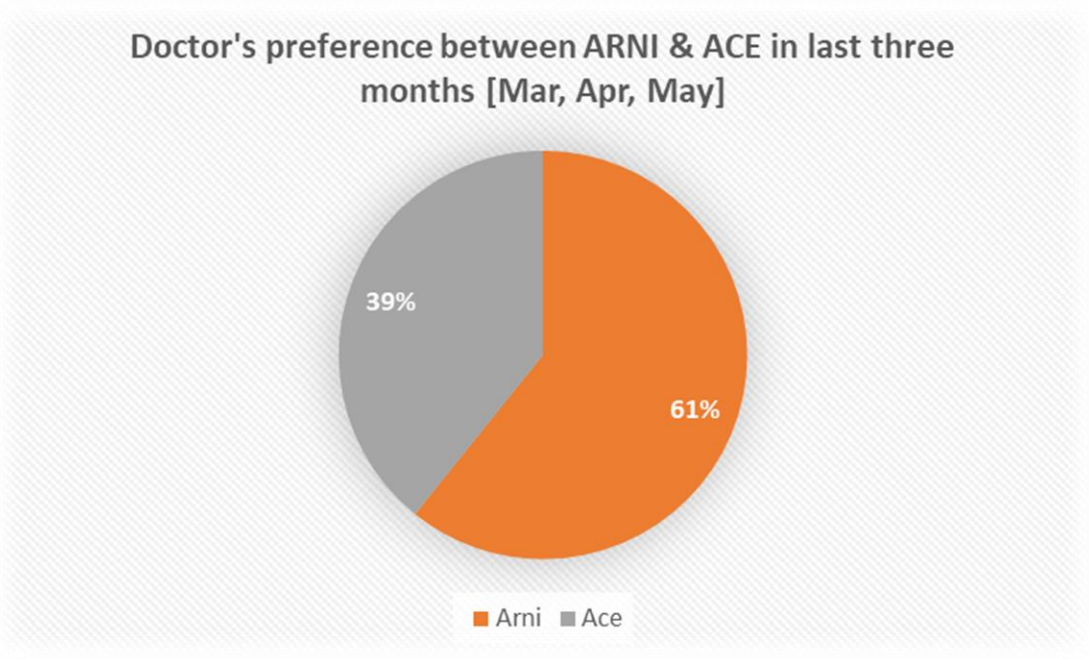
The market of sacubitril and valsartan is estimated to **be INR 630 crore** with an **annual growth of 36%** and **CAGR of 50%.**

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.**

Data Collection

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.



CONCLUSION

CONCLUSION

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.

CONCLUSION

Comprehensive Plan for a Specialized HF Clinic:

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.

Thanks!