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An Assessment of Knowledge, Attitude, Practices of Sacubitril/Valsartan Among Physicians in The Department of Cardiology and Clinical Pharmacists in Southern India



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ABSTRACT

Background: Sacubitril/valsartan is the first of its kind under the classification angiotensin receptor neprilysin inhibitor which is now a class I recommendation in the management of heart failure. Physicians and clinical pharmacists must be thoroughly knowledgeable about this drug. This study was done to assess the knowledge, attitude and practices towards sacubitril/valsartan among physicians in the department of cardiology and clinical pharmacists in Southern India. **Methods:** An observational cross-sectional study was conducted through both online forms and face-to-face interviews of physicians in the department of cardiology and clinical pharmacists in Southern India. The study included 66 participants (34-physicians & 32-clinical pharmacists) whose responses were collected through a self-prepared questionnaire from October 2020 to January 2021. The questionnaire included 25 questions based on both qualitative and quantitative research variables and analyzed significance using Microsoft Excel v.2019. **Results:** Study participants were broadly classified as physicians and clinical pharmacists and their knowledge, attitude and practices regarding sacubitril/valsartan were assessed. Among physicians, 26.4% (9) had high, 52.9% (18) medium and 20.5% (7) received low scores. 3.1% (1) had high, 50% (16) medium and 46.8% (15) had low scores. The median score was more among physicians ($p=0.009$). Comparing the score of the knowledge module with the experience of physicians and CPs did not show a linear relationship. **Conclusion:** There exists gap in knowledge about sacubitril/valsartan regarding when dosage needs to be modified and when the drug is contraindicated among physicians and clinical pharmacists. The median score of physicians is higher. This may be due to their increased exposure to drugs used in the cardiology department. Despite having a good attitude toward the drug, its acceptability has been poor in patients of low socioeconomic status as it is unaffordable.



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INTRODUCTION

Heart failure is a major cause of mortality and morbidity in India and all over the world. It is approximated that 50% of heart failure patients have an estimated 5 - year mortality ^[1-3]. The lack of survey systems makes it difficult to estimate the incidence and prevalence of heart failure in India. Regardless, the prevalence of HF is possibly high as India continues to be doubly burdened by the rise in risk factors of traditional cardiovascular disease and pre-transitional diseases such as rheumatic heart disease, endomyocardial fibrosis, tuberculous pericardial disease and anemia ^[4].

Pharmacotherapy remains the primary treatment option as the availability of resources like cardiac resynchronization therapy and heart transplant programs are limited. Sacubitril-valsartan is turning up to be revolutionary in the treatment of heart failure with reduced ejection fraction (HFrEF) ^[5,6].

Sacubitril/Valsartan is an angiotensin receptor neprilysin inhibitor (ARNI), the first of its class that has been approved in the treatment of heart failure. It is a combination of angiotensin receptor (valsartan) and a neprilysin inhibitor (sacubitril) in a 1:1 by molecule count ^[7]. The U.S. Food and Drug Administration has approved sacubitril/valsartan combination based on the results of the PARADIGM-HF trial for the treatment of New York Heart Association class II – IV with reduced ejection fraction. Those who were randomized to receive sacubitril/valsartan experienced a 20% relative risk reduction in cardiovascular death or hospitalization for HF and a 16% relative risk reduction in all-cause mortality compared with those randomized to receive enalapril^[7,8]. It is now a class I-B recommendation in 2016 ESC and ACC/AHA/HFSA guidelines ^[9,10,11].

India is one of the 57 countries with the approval for marketing this combination. Despite the drug showing significant benefits and being a class I – B recommendation, its acceptance into clinical practice has been poor. Data from the Change the Management of Patients with Heart Failure (CHAMP-HF) Registry shows that of the currently eligible 13.9% of outpatients with HFrEF are prescribed an ARNI, and only 14% of those treated received target doses ^[12]. It has even been suggested to initiate this combination in patients with heart failure with reduced ejection fraction admitted for acute decompensated heart failure so that the patient can be monitored closely on initiation. Treatment with sacubitril/valsartan has an incremental cost-effectiveness ratio of \$45 017 per quality-adjusted life-year (only available data). This is on par with other high-value accepted cardiovascular interventions^[13].

Clinical pharmacists play a crucial role in the management of heart failure by optimizing the transition of care from the hospital to the community/home. This is crucial for improving outcomes and decreasing high rates of hospital readmissions, which are associated with increased morbidity, mortality, and costs. Pharmacists' participation on both inpatient and outpatient teams can provide a variety of services that have been shown to reduce hospital readmission rates and benefit patient management and treatment. In addition, as new pharmacologic treatments for HF become available, pharmacists can raise awareness of optimal drug use by maximizing education related to efficacy (e.g., adherence) and safety (e.g., potential side effects and drug interactions) [14]. This study aims to depict the current understanding about this new drug (sacubitril/valsartan) among physicians with heart failure patients and clinical pharmacists.

MATERIALS AND METHODS

Data were collected during 3 months (October 2020-January 2021) from 66 participants including physicians working in the department of cardiology and clinical pharmacists in Southern India through online forms and face-to-face interviews. The knowledge, attitude and practices regarding the drug sacubitril-valsartan was assessed using a questionnaire made in English.

Questionnaire design and data analysis

A set of 2 questionnaires were prepared as hard copy and as an online form to collect data from physicians and clinical pharmacists. The idea of this questionnaire was obtained from the prescribing information provided by Novartis for the tablet Entresto (Sacubitril/Valsartan). To measure the levels of various aspects of Knowledge, Attitude and Practice (KAP), the questionnaire was divided into three distinct modules. To assess knowledge, attitude and practices, 14, 7 and 4 questions were asked respectively. The analysis of the knowledge was done based on a scalar-scoring method. The attitude & practice module here is to understand the physician's and CP's attitude towards the drug & their practices in prescribing sacubitril/valsartan.

In the knowledge section, those questions having two possible answers were given 1 point for correct response and zero point for wrong or uncertain response. The other type of questions had 4 levels of scores, 0, 1, 2, 3 representing incorrect response, Poor, Fair and Good level of Knowledge. The total score of the knowledge module is used to rank the level of knowledge.

If a person answered all questions correctly, 20 scoring points were awarded. Those who scored more than or equal to 75 % (score ≥ 15) were high score, those between 50 to 74.9% came under medium score (score ≥ 10 and < 15) and scores below 50% (score < 10) were considered low level. The responses for attitude and practices are categorized and presented in frequency and percentage.

Statistical Analysis

Continuous variables with normal distribution were presented as means \pm SD. Scores were presented as medians and range. To compare the level of significance of knowledge score between physicians and clinical pharmacists Chi-square test was performed using Microsoft Excel v.2019 and p-value < 0.01 was considered statistically significant.

RESULTS AND DISCUSSION

RESULTS

Demographic details of the study participants

The study participants were classified into physicians (n=34) working in the department of cardiology and clinical pharmacists (CPs), n=32. Physicians were further subclassified as: cardiologists 70.58% (24), cardiac surgeons 2.94% (1), MBBS, MD physicians 5.88% (2) & PG Registrars 20.58% (7) working in the department of cardiology. Mean duration of practice of physicians is 15.23 ± 11.65 years with a minimum duration of 1 and a maximum of 50. The mean duration of practice of CPs is 1.89 ± 1.33 years with a minimum duration of 0.083 and maximum of 4.5. Figure 1 shows the distribution of physicians and clinical pharmacists by location.

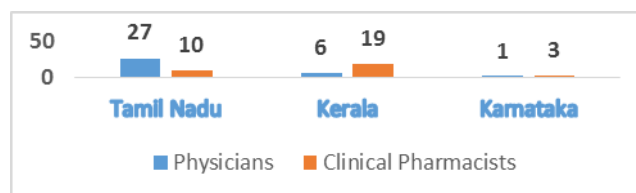


Figure No. 1: Distribution of physicians & clinical pharmacists (N=66)

Knowledge on Sacubitril/Valsartan

The median score of physicians was 12 (03, 19) and CPs was 10 (02, 16) out of a total score of 20. 95% of physicians & 94% of CPs were aware about the existence of sacubitril/valsartan.

About 68% of physicians and 69% of CPs correctly classified the drug as an angiotensin receptor neprilysin inhibitor (ARNI). While majority of study participants generically stated that the drug is used to treat heart failure, 9% of physicians and 6% of CPs mentioned that it is used in the treatment of chronic heart failure with reduced ejection fraction NYHA class II-IV. About 94% of both physicians and CPs correctly identified the major adverse effects of the drug. Around 50% of physicians & 29% of CPs were aware that sacubitril/valsartan can be used to treat paediatric heart failure. Majority of physicians and CPs (71%, 78%) were incorrect about the starting dose of the drug to the blood pressure values of the patients. 12% of the physicians and none of the clinical pharmacists were aware of all the conditions in which the drug is initiated at a reduced dose. About 68% physicians & 66% clinical pharmacists were aware of the strengths in which sacubitril/valsartan is available. 68% of the physicians and 31% of the CPs correctly stated the frequency of dose titration of the drug. Around 50% of the physicians and 6% of the clinical pharmacists gave completely correct answers regarding the conditions in which the use of the drug is contraindicated. 62% of physicians and 72% of CPs correctly answered the washout period between ACE inhibitors and ARNI as 36 hours \approx 2 days. Around 88% CPs and 100% of physicians were aware that the drug is not safe during pregnancy & lactation. About 53% of physicians and 31% of CPs were aware of the cost of a single dose of sacubitril/valsartan in India. Comparing the score of the knowledge module with the experience of physicians and CPs did not yield a linear relationship. Table 1 shows the comparison of a score of knowledge module among physicians and clinical pharmacists.

Table No. 1: Comparison of score of knowledge module among physicians and CP's (N=66)

Score	Frequency		Mean Score	Standard Deviation	χ^2 (p < 0.01)
	Physician (n=34)	CP (n=32)			
High (≥ 15)	9 (26.47%)	1 (3.125%)	10.74	+/- 3.69	0.009211
Medium (10 - 14)	18 (52.94%)	16 (50%)			
Low (<10)	7 (20.58%)	15 (46.875%)			

Attitude towards Sacubitril/Valsartan

The questions assessed the beliefs of physicians and clinical pharmacists towards sacubitril/valsartan as it is a relatively new drug launched in India and were not scored as correct or incorrect. Around 91% of physicians and 81% of CPs disagree that sacubitril/valsartan can only be used in the United States of America as it is a new drug. The majority of physician’s (92%) & CP’s (78%) agree that the drug is highly effective in the treatment of heart failure. 70 % of the study participants believe that ARNI is superior to ACEI or ARB in treating heart failure. Around 52% of the study participants agree that sacubitril/valsartan should only be used in severe cases of heart failure and 77% of them agree that patients to whom sacubitril/valsartan is prescribed require close monitoring. 76% of the physicians disagree and clinical pharmacists remain split (34% neutral & 34% agree) on their opinion that the adverse effects of sacubitril/valsartan make it risky to prescribe to the Indian population. About 63 % of the study participants disagree that sacubitril/valsartan is marketed solely for the profit of pharmaceutical companies. Table -2 shows the responses given by the study participants to questions meant to assess their attitude towards sacubitril/valsartan.

Table No. 2: Attitude towards sacubitril/valsartan (N=66)

Statements	Strongly Disagree/ Disagree (%)		Neutral (%)		Strongly Agree/ Agree (%)	
	Phy	CP	Phy	CP	Phy	CP
Sacubitril/valsartan can only be used in the United States of America as it is a new drug	91	81	6	0	3	19
Sacubitril/valsartan is a highly effective drug in the treatment of heart failure	0	0	9	22	91	78
Sacubitril/valsartan is superior to ACEI or ARBs in treating HF	0	3	21	38	79	59
Sacubitril/valsartan is prescribed only in severe cases of heart failure	53	9	9	25	38	66
Patients to whom sacubitril/valsartan is prescribed require close monitoring	6	0	12	28	82	72
The adverse effects of sacubitril/valsartan make it risky to prescribe to the Indian population	76	32	15	34	9	34
Sacubitril/valsartan exists solely for the profit of pharmaceutical companies	79	49	21	32	0	19

Practices regarding Sacubitril/Valsartan

Around 82% of physicians have prescribed sacubitril/valsartan and it has been prescribed in the workplace of 78% of CPs. Around 25% of physicians and 24% of CPs responded that it is used as a last line of treatment in heart failure & 28 % of CPs responded that they don't know when to use the drug. 56% of physicians and 91% of clinical pharmacists agreed that they require more information regarding the drug. When asked what in their opinion is the reason for decreased prescribing of sacubitril/valsartan in India, around 88% of physicians and 60% of CPs responded that it is a very expensive treatment. Table 3 shows the reasons for the decreased prescribing of sacubitril/valsartan.

Table No. 3: Reasons for decreased prescribing of sacubitril/valsartan (N=66)

RESPONSE	PHYSICIAN (%)	CP (%)
It is a very expensive treatment.	88.2	59.4
The long-term effects of this drug are unknown.	11.8	31.3
It is not part of the hospital formulary that I work in.	8.8	15.6
It requires close monitoring and I do not have sufficient time for it.	11.8	21.9
The adverse effects are severe in contrast to the efficacy of the drug.	2.9	15.6
It is not easily available in India.	5.9	3.1
Several doctors are not aware of its benefits.	2.9	0
No idea	2.9	6.3

DISCUSSION

Our study shows that there is a significant gap in knowledge regarding sacubitril/valsartan among physician's and clinical pharmacists. When we considered the total score of knowledge module, 15.15% (10) had high score, 51.51% (34) had medium score & 33.33% (22) had low score. Overall mean score of knowledge regarding sacubitril/valsartan was found to be 10.74 ± 3.69 . It was higher in physicians 12 ± 3.57 when compared to clinical pharmacists 9.40 ± 3.87 with a significant statistical difference ($p=0.009211$). Physicians and clinical pharmacists should have thorough knowledge about a drug, especially one that has been newly approved for marketing. Inadequate knowledge on the drug may lead to sub-optimal therapy, increased risk of adverse effects, cost of therapy and ultimately providing no benefit to the patient. Our study shows that both the physicians and clinical pharmacists have a basic knowledge

regarding sacubitril/valsartan. Gap exists in knowledge on effect of food, starting dose of drug among varied blood pressure ranges, need in reduction of starting dose, conditions in which sacubitril/valsartan is contraindicated. Over 80% heart failure patients are ≥ 65 years & most of these patients suffer from one or more co-morbidities. Chronic kidney disease, liver failure, diabetes mellitus and hypertension are seen commonly in patients with CHF [15]. Exhaustive knowledge about this drug is essential to ensure that the patients would experience its highest benefits. In the Indian scenario as of 2021, the right to prescribing drugs lies only with the physicians and the pharmacists cannot practice or prescribe drugs and must ensure that the prescription is rationale and ethical [16]. Hence in a country like India, the physicians must be sure when to start & stop the drug, when to reduce the dose and when the use of the drug is contraindicated. Clinical pharmacists need to upskill themselves to be able to participate in improving patient care. Comparing the mean score of the knowledge module with the experience of physicians and CPs did not show a linear relationship. This shows that experience does not automatically equate to superior knowledge, rather the constant practice of educating themselves about the latest treatment options is vital to ensure that patients receive proper treatment. Figure 2 & 3 shows the association of mean knowledge score with physicians and CPs experience respectively.

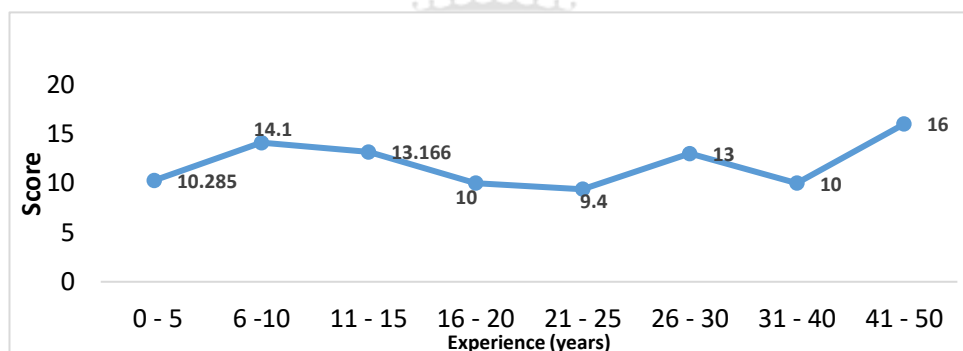


Figure No. 2: Association of mean knowledge score with physician's experience (n =34)

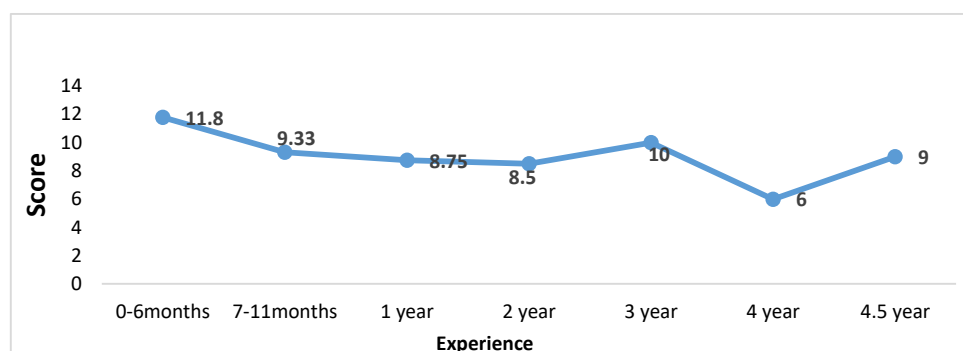


Figure No. 3: Association of mean knowledge score with CPs experience (n =34)

Although the attitude of the study participants regarding sacubitril/valsartan was found to be good, 15% remain neutral on its efficacy. 29% of the study participants remain neutral in their belief on its superiority to ACEI/ARBs despite of the results of the clinical trial conducted by *McMurray et al*, (PARADIGM-HF trial) [8]. The study also showed that there is a lack of clarity among physicians and CPs on when to use sacubitril/valsartan as 16.67% of study participants believe that it should be used in severe cases of heart failure despite its class I-b recommendation in treatment guidelines (ACC/ESC/AHA/HFSA) [9,10,11].

82.35% of the physicians have prescribed sacubitril/valsartan, indicating that the drug has been widely accepted and prescribed by the physicians. 19.69% of the study population have stated that they prescribe the drug as a last-line treatment. While it was clear that the drug was being prescribed, the study also showed that not all physicians were giving it as a first-line treatment. Unanimously, both physicians and clinical pharmacists (74%) have stated that the cost of therapy is the major reason for reduced prescribing (Average cost of a single tablet Rs.60-80 or Rs. 35-50)^[17]. Lack of knowledge on long-term effects (21.21%) of the drug and its requirement of close monitoring (16.67%) are also reasons leading to decreased prescription. Even though most physicians have prescribed sacubitril/valsartan, 56% stated that they would like more information regarding the drug. Adequate knowledge about the drug will improve its usage and help improve patient outcomes. Any new therapy for HF will need good patient counseling before prescription which can only be done by a specialist HF nurse (or) a clinical pharmacist, busy physicians do not have the time do this. The study also highlights the lack of sufficient skilled clinical pharmacists in the medical setting in Southern India. With an increase in CPs in the patient management teams, the quality of patient care received would be vastly improved. Only with sufficient knowledge, clinical pharmacists will be able to aid in the transition of care in heart failure patients especially with newly released drugs which require prompt monitoring and detailed patient counseling.

CONCLUSION

The study analyzed the baseline knowledge, attitude and practices regarding sacubitril/valsartan among physicians working in the department of cardiology and clinical pharmacists. There exists gap in knowledge about sacubitril/valsartan regarding when dosage need to be modified and when the drug is contraindicated (for RAAS blockers naïve patients, blood pressure values, renal & hepatic function, and previous use of ACEI/ARBs). Both physicians and clinical pharmacist have a good attitude towards the drug. Most of the

physicians have prescribed the drug but have stated that prescription frequency is extremely low which the clinical pharmacists concur. Despite having a good attitude toward the drug, its acceptability has been poor in patients of low socioeconomic status due to high cost. Sacubitril/valsartan is a valuable drug that could be used in increasing frequency, provided that it is available at a more affordable cost. The loss of revenue will be made up easily by increased use.

LIMITATIONS

The study was conducted with only a limited number of participants. As most physicians who participated in this study work both at hospitals and have individual practices, we were unable to determine the differences in the prescribing practices of sacubitril/valsartan between physicians working in hospitals and individual practitioners. This study is the first of its kind, hence the questionnaire prepared may need further modification and validation process with extended study participants. The study procedure involved the collection of data through online and paper format forms. Online forms may provide biased responses.

FUTURE RECOMMENDATIONS

A national registry should be maintained to determine the prescription pattern of the drug, its appropriate usage, unexpected and serious adverse effects whose results should be published annually. A cost-effective analysis study should be performed in India, to establish a suitable cost of therapy especially as it is a medication used in chronic treatment plans. Clinical pharmacists can conduct a drug utilization evaluation (DUE) study to determine the causes of inappropriate use of this medication as it is expensive and used in chronic treatment.






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