

Original Research Article

Assessing cilnidipine and its combination usage in Indian settings: a knowledge, attitude, and practice survey

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Received: 26 July 2024

Revised: 03 September 2024

Accepted: 04 September 2024

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ABSTRACT

Background: Hypertension, affecting 31% of the Indian population, is a major risk factor for cardiovascular diseases. Cilnidipine is used in its management, alone or in combination with ARB. The objective of the current KAP survey was to assess the knowledge of healthcare professionals (HCPs) regarding hypertension management, their attitudes toward its treatment, and the application of this knowledge in clinical practice.

Method: A pan-India cross-sectional KAP survey was conducted from April 2022 to March 2023. The survey utilized a specially designed questionnaire focusing on various aspects of using cilnidipine and its combination with telmisartan in hypertension management. A total of 1,254 HCPs with recognized qualifications participated. Descriptive statistics were employed for data analysis.

Results: Around 56% of HCPs initiated monotherapy of an antihypertensive drug at an SBP level of 140 mmHg, while 57% initiated combination therapy at an SBP > 160 mmHg. Nearly 43% reported initiating combination therapy in 20-30% of patients as initial treatment. Cilnidipine was preferred over amlodipine mainly due to decreased pedal edema. Cilnidipine monotherapy benefits young hypertensive patients (46%) and those with chronic kidney disease (CKD, 44%). Cilnidipine and telmisartan combination benefits patients with uncontrolled hypertension (46%), diabetes (43%), and CKD (41%). Advantages of this combination include less fluid retention, better compliance and tolerability, and less pedal edema.

Conclusion: This KAP survey highlights current practices in hypertension management, emphasizing the use of cilnidipine and its combination, attributed to their favorable tolerability and suitability for diverse patient profiles.

Keywords: Hypertension, Cilnidipine, Telmisartan, KAP survey, India

INTRODUCTION

Hypertension is a major risk factor for cardiovascular (CV) morbidity and mortality.¹ The American college of cardiology (ACC)/American heart association (AHA) 2017 guideline redefined hypertension as a persistent

average systolic blood pressure (SBP) ≥ 130 mmHg and/or diastolic blood pressure (DBP) ≥ 80 mmHg.^{1,2} The World Health Organization reported that hypertension affects 33% of adults aged 30-79 globally.³ According to the 2023 WHO report, the prevalence of hypertension is similar across groups of countries i.e., 32% in high-income

countries to 34% in low-income countries.³ According to the recent ICMR-INDIAB study, the overall prevalence of hypertension was 35.5%.⁴ Given its increasing prevalence, particularly in correlation with aging populations, lifestyle changes, exposure to risk factors, and comorbidities, the importance of optimal hypertension management cannot be overstated.³ Lifestyle modifications form the cornerstone of hypertension prevention and management.¹ Guidelines recommend different drug classes, such as thiazide or thiazide-like diuretics, calcium channel blockers (CCBs), angiotensin-converting enzyme inhibitors (ACEIs), and angiotensin receptor blockers (ARBs) as primary treatment options.^{1,2} Within this extensive array of antihypertensive agents available, CCBs have been the mainstay of antihypertensive therapy for years and are among the most used antihypertensive agents in the market currently.^{5,6}

Cilnidipine, a fourth-generation calcium channel blocker, exhibits a dual L/N-type Ca²⁺ channel-blocking action.⁵ It suppresses the neurohumoral control of the CV system, including the sympathetic nervous system and the renin-angiotensin-aldosterone system (RAAS) through N-type Ca²⁺ channel blockade, and is beneficial in different complications of hypertension.⁵ It also exhibits reno protective effects.^{5,6} Cilnidipine is used in the management of hypertension either as a monotherapy or as a combination therapy with ARB.^{6,7}

Considering the increasing prevalence of hypertension worldwide and the evolving landscape of hypertension management, it is important to assess the attitude and practices of healthcare professionals (HCPs) in its management. Clinical evidence highlights the importance of cilnidipine and its combination with telmisartan in managing hypertension. Gaining insight into how cilnidipine is utilized in clinical settings can facilitate an understanding of the factors affecting its preference, applicability, and usage, ultimately improving hypertension management. Knowledge, attitude, and practice (KAP) surveys are focused evaluations that evaluate changes in knowledge, attitudes, and practices in response to a specific intervention.⁸ The present KAP survey aimed at understanding the knowledge of HCPs about managing hypertension, their attitudes toward its treatment, and translating this knowledge into clinical practice.

METHODS

Survey design

This was a cross-sectional, observational, questionnaire-based survey conducted across India.

Study duration

The study was conducted from 25th April 2022 to 15th March 2023. The flow of the study was: administration of the questionnaire to participants who gave consent,

followed by filling of the questionnaire based on their experience and knowledge, collection of questionnaires, compilation, analysis, and presentation of data.

Survey participants

Survey participants were registered medical practitioners with recognized qualifications in cardiology (MD/DM), nephrology (MD/DM), general medicine (MD), and internal medicine (MD/MBBS, DNB), and hereafter all participants have been referred as HCPs, working in outpatient departments of privately run clinics/hospitals in a tertiary care setting.

Survey instrument

It was a specially designed, structured, and self-completion questionnaire. It was used to assess the knowledge, perception/attitude, and practices toward the use of antihypertensive drugs, particularly cilnidipine, and its combinations in routine clinical practice. These included four knowledge, four attitude-based, and three practice-based questions. Nine questions were open-ended, while two were multiple-choice questions.

Knowledge-based questions were as follows

At what level of SBP do you initiate monotherapy of an anti-hypertensive drug? At what level of SBP do you initiate a combination therapy of anti-hypertensive drugs? At what level of SBP do you initiate a combination therapy of three anti-hypertensive drugs? In how many hypertensive patients do you start an antihypertensive drug combination as an initial therapy?

Attitude-based questions were as follows

Do you prefer cilnidipine over amlodipine along with telmisartan in the management of hypertension? On what parameters cilnidipine is better than amlodipine? Which patient type would benefit from cilnidipine monotherapy? Which patient type do you prescribe cilnidipine and telmisartan combination?

Practice-based questions were as follows

How much SBP/DBP reduction happens with the cilnidipine and telmisartan combination? Will you replace amlodipine and telmisartan with cilnidipine and telmisartan? If yes then in which patient profile? What are the benefits of the cilnidipine and telmisartan combination?

Ethical consideration

This was a survey through which no patient-related data was captured and therefore ethics committee approval was not necessary and hence not obtained. As this was not a clinical trial, no clinical trial registration was required.

Statistical analysis

Categorical values were summarized by using frequencies and percentages. A comparison of variables representing categorical data was assessed.

RESULTS

Baseline demographics

A total of 1254 HCPs participated from different zones across India (Figure 1). All the participants completed the survey.

Knowledge about hypertension management

Among the HCPs participating in the survey, more than half of HCPs (56%) reported that they initiated monotherapy of an antihypertensive drug at an SBP level of 140 mmHg. Some (21%) reported initiating monotherapy of an antihypertensive drug >150 mmHg (Table 1).

When asked about initiating the combination therapy of antihypertensive drugs, more than half of them (57%) reported initiating it at SBP above 160 mmHg (Table 1). Lastly, one-third of the respondents (33%) reported initiating triple combination therapy of antihypertensive drugs at SBP above 170 mmHg, while another third indicated initiating at levels above 180 mmHg (Table 1). Among the HCPs participating in the survey, 43% reported that they initiated an antihypertensive drug combination in 20-30% of patients as initial therapy, while 35% reported that they started an antihypertensive drug combination in 30-40% of patients (Table 1).

Attitude or perception about the management of hypertension and cilnidipine

Most HCPs (95%) reported that they preferred cilnidipine over amlodipine with telmisartan to manage hypertension (Table 2). When asked about their preference for cilnidipine over amlodipine, the majority of HCPs (76%) reported less pedal edema as a reason, while some (35%) reported that better uric acid reduction effect as the reason (Table 2). Among the HCPs participating in the survey, one segment (46%) reported that young hypertensive

patients benefitted from cilnidipine monotherapy, while another segment (44%) reported that hypertensive patients with CKD benefitted from cilnidipine monotherapy (Table 2). When questioned about the patient profiles who are prescribed cilnidipine and telmisartan combination, HCPs reported various groups. Specifically, 46% reported patients with uncontrolled hypertension, while 43% reported those with hypertension and diabetes. Additionally, 41% of HCPs reported prescribing it to individuals with CKD hypertension (Table 2).

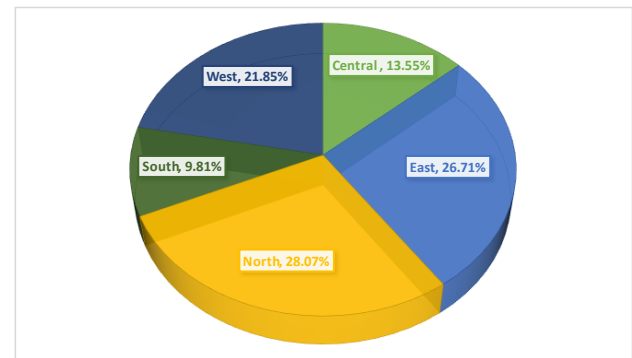


Figure 1: Regional distribution of HCP participation.

Practice assessment for cilnidipine

Among the HCPs participating in the survey, the response for the reduction in SBP/DBP with cilnidipine and telmisartan combination was varied. Some (31%) reported a 20/10 mmHg reduction with the cilnidipine and telmisartan combination, while some others (25%) reported a 30/20 mmHg reduction (Table 3). One segment of HCPs (46%) reported that they would replace the amlodipine and telmisartan combination with the cilnidipine and telmisartan in CKD patients with hypertension. Another segment (45%) reported that they would replace the amlodipine and telmisartan combination with the cilnidipine and telmisartan in patients with pedal edema (Table 3). The response was varied when asked about the benefits of the cilnidipine and telmisartan combination. Some HCPs (37%) reported less fluid retention, and better compliance and tolerability as the benefits of this combination. Some others (26%) reported that better pedal edema control is the benefit of the cilnidipine and telmisartan combination (Table 3).

Table 1: Knowledge among HCPs about the management of hypertension.

S. no.	Response statements	Percentage of HCPs
1.	Level of SBP at which monotherapy of an antihypertensive drug is initiated	
	130 mmHg	19
	140 mmHg	56
	160 mmHg	5
	>150 mmHg	21
2.	Level of SBP at which a combination therapy of antihypertensive drugs is initiated	
	>140 mmHg	9

Continued.

S. no.	Response statements	Percentage of HCPs
	>150 mmHg	23
	>160 mmHg	57
	>170 mmHg	6
	>180 mmHg	6
	Level of SBP at which a combination therapy of three antihypertensive drugs is initiated	
	>165 mmHg	17
	>170 mmHg	33
	>180 mmHg	33
	>190 mmHg	12
	>200 mmHg	5
	Percentage of hypertensive patients in whom antihypertensive drug combination is started as an initial therapy	
	10 – 20%	11
	>20 – 30%	43
	>30 – 40%	35
	>40 – 50%	11

Note: SBP, systolic blood pressure

Table 2: Perceptions of HCPs about the use of cilnidipine in routine clinical practice.

S. no.	Response statements	Percentage of HCPs
	Preference for Cilnidipine over Amlodipine along with Telmisartan in the management of hypertension	
	Yes	95
	No	0
	Both	5
	Reasons for Cilnidipine being better than Amlodipine	
	Better pedal edema	76
	Uric acid reduction	35
	Better renal protection	20
	Cardiac safety is better	17
	CKD	15
	Patient type benefited from Cilnidipine monotherapy	
	Elderly patient	13
	Hypertension with CKD	44
	Hypertension with diabetes	17
	Hypertension with pedal edema	16
	Young hypertensive patients	46
	Patient profiles for Cilnidipine and Telmisartan Combination	
	Cardiac patients	9
	CKD with hypertension	41
	High heart rate	9
	Hypertension with diabetes	43
	Moderate-to-severe hypertension	9
	Uncontrolled hypertension	46

Note: CKD, chronic kidney disease

Table 3. Approaches or practices in the use of cilnidipine and telmisartan combination.

S. no.	Response statements	Percentage of HCPs
	SBP/DBP reduction with the Cilnidipine and Telmisartan combination	
	10/6 mmHg	21
	20/10 mmHg	31
	30/20 mmHg	25
	40/30 mmHg	16

Continued.

S. no.	Response statements	Percentage of HCPs
2.	Patient profile in which Amlodipine and Telmisartan combination would be replaced with Cilnidipine and Telmisartan combination	
	Hypertension with CKD	46
	High proteinuria patients	11
	Hypertension with diabetes	22
	Moderate-to-severe hypertension	6
3	Pedal edema	45
	Benefits of the Cilnidipine and Telmisartan combination	
	Better compliance and well-tolerated	37
	T2DM with CKD	16
	Less fluid retention	37
	Less pedal edema	26
	Renal protection	21

Note: CKD, chronic kidney disease; DBP, diastolic blood pressure; SBP, systolic blood pressure; T2DM, type 2 diabetes mellitus.

DISCUSSION

Hypertension, a common CV condition, is a leading cause of death globally.^{5,9} Different drug classes are used in the management of hypertension either alone or in combination. CCBs are widely used for managing hypertension.^{5,6} Cilnidipine, a dihydropyridine calcium antagonist, has prolonged antihypertensive properties and is one of the primary antihypertensive agents used today.⁶ We conducted a KAP survey to understand the management of hypertension, with an emphasis on various aspects of the use of cilnidipine in routine clinical practice.

Knowledge about hypertension

Hypertension treatment is typically initiated based on various factors, including blood pressure (BP) levels and the presence of other CV risk factors.⁹ Guidelines often recommend initiation of treatment if the SBP is at or above 140 mmHg or if the DBP is at or above 90 mmHg.^{2,9} Specifically, the ESH 2023 guideline recommends initiating monotherapy in patients with grade 1 hypertension i.e., SBP 140–159 mmHg and/or DBP 90–99 mmHg. For most hypertensive patients, initiation of therapy with a two-drug combination is recommended. If BP control is not achieved with the initial two-drug combination, despite using the maximum recommended and tolerated dose, treatment escalation to a three-drug combination is advised. In the present survey, more than half of HCPs reported that they initiated monotherapy of an antihypertensive drug at an SBP level of 140 mm Hg, and combination therapy above 160 mmHg. These findings align with established guidelines.⁹

Attitude or perception about the management of hypertension and cilnidipine

The present survey highlights that most HCPs preferred cilnidipine over amlodipine with telmisartan in managing hypertension due to benefits in decreasing pedal edema and lowering uric acid levels. Clinical studies have demonstrated the superiority of cilnidipine in decreasing pedal edema and reducing uric acid levels over

amlodipine.^{5,10-13} Cilnidipine monotherapy was reported to benefit hypertensive patients with CKD and young hypertensive patients in this survey. This aligns with clinical evidence indicating the efficacy of cilnidipine in reducing urinary albumin excretion without affecting serum creatinine levels, thereby exhibiting a reno protective effect.¹⁴⁻¹⁶ Additionally, the superiority of cilnidipine in renal protection, particularly when compared to CCBs targeting solely L-type calcium channels, further supports its utility in managing hypertensive patients with CKD.¹⁷

Some studies have also demonstrated the efficacy and safety of cilnidipine in young hypertensive patients.^{18,19} One study involving Indian patients aged over 25 years compared the efficacy of cilnidipine (mean age: 46.37 years) to amlodipine (mean age: 45.51 years). Cilnidipine was found to be equally effective as amlodipine in reducing SBP and DBP in patients with mild to moderate essential hypertension.¹⁹

Cilnidipine and telmisartan were reported to be usually prescribed for hypertension in patients with diabetes as well as those with CKD. Literature corroborates this finding as this combination is reported to be effective in managing hypertension and its associated complications.^{20,21} Furthermore, Research Society for the Study of Diabetes in India (RSSDI) guidelines recommend newer medications like cilnidipine in combination with ARBs to enhance CV and renal protection in diabetic patients with hypertension.²¹ Additionally, clinical evidence indicates the synergistic effect of cilnidipine and renin-angiotensin system inhibitors in preventing the progression of proteinuria among hypertensive patients with CKD.¹⁷

Practice assessment for cilnidipine

The survey findings reveal variability in responses regarding the reduction in SBP and DBP reduction with the cilnidipine and telmisartan combination. However, a significant proportion of HCPs reported a reduction of 20/10 mm Hg with this combination, consistent with

clinical study results by Ram S et al, which demonstrated a similar SBP reduction.²¹ The survey also highlights that the cilnidipine and telmisartan combination would replace the amlodipine and telmisartan combination mainly in hypertensive patients with CKD and those experiencing pedal edema. This preference is supported by studies indicating that cilnidipine when substituted for amlodipine, improves urinary protein excretion and results in better renal outcomes in hypertensive CKD patients already receiving RAAS inhibitors.²² Furthermore, clinical studies highlight its efficacy in reducing edema induced by amlodipine due to a reduction in ankle circumference and body weight.^{23,24}

Lastly, the combination of cilnidipine and telmisartan was associated with significant benefits, including improved compliance, reduced fluid retention, less pedal edema, and renal protection. The combination exhibits synergistic effects and may also be advantageous in controlling cardiovascular disease and hyperglycemic conditions.²⁰ The lower incidence of pedal edema can be attributed to the action of cilnidipine on both N-type and L-type calcium channels compared to amlodipine, which solely blocks the L-type channel.¹² Cilnidipine reduces the activity of the sympathetic nervous system and the release of norepinephrine from sympathetic nerve endings, mitigating reflex tachycardia and stress-induced elevation in BP.⁶ These effects contribute to improved compliance.^{5,12,21}

Pan-India coverage and participation of a large number of participants are some of the strengths of our study. However, there are some limitations, such as the cross-sectional study design and the potential for selection bias. The questionnaire was based on a subjective opinion and respondents may interpret open-ended questions differently, resulting in variability in responses to some questions. Additionally, the questions were not validated. Nevertheless, this was an attempt to understand the knowledge, attitude, and practice of HCPs towards the use of cilnidipine and its combination in routine clinical practice.

CONCLUSION

This study provides a comprehensive perspective on the approach of HCPs in the management of hypertension, revealing the adoption of an evidence-based approach. It also highlights the use of cilnidipine and its combination with telmisartan in hypertension management considering its good tolerability and applicability across different patient profiles.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge and thank the 1, 254 healthcare professionals across India who participated in this survey.

Funding: This study was funded and sponsored by Alembic Pharmaceuticals Ltd

Conflict of interest: Dr. Dinesh Jiwane and Dr. Heena Bhojwani are full-time employees of Alembic Pharmaceuticals Ltd, which actively markets Cilnidipine and its combination

Ethical approval: Not required

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Cite this article as: Shete M, Saxena A, Nakrani A, Shah C, Bhojwani H, Jiwane D. Assessing cilnidipine and its combination usage in Indian settings: a knowledge, attitude, and practice survey. *Int J Adv Med* 2024;11:559-65.