Survey Report

Usage of Telmisartan Plus Chlorthalidone in Managing Hypertension and Cardiovascular Risk Among Indian Patient Population

Version No.: 1.1

The study was conducted according to the approved protocol and in compliance with the protocol, Good Clinical Practice (GCP), and other applicable local regulatory requirements.

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Table of content

1	Introduction	2
2	Rationale of the study	3
3	Study Objective	3
4	Methods	3
5	Results	5
6	Summary	20
7	Discussion	20
8	Clinical Recommendations	21
9	Consultant Opinion	22
10	Market opportunities	22
11	Market positioning	23
12	References	24

1 INTRODUCTION

Hypertension poses a major global health challenge due to its widespread prevalence and the consequent increased risk of cardiovascular diseases (CVD). It is the most significant risk factor for CVD and mortality that can be modified [1]. Among several risk factors contributing directly to increased cardiovascular morbidity and mortality, elevated blood pressure stands out as a crucial and independent factor. It affects approximately 24-36% of adults in developed nations [2]. Controlling blood pressure is a crucial goal in therapy to slow progression and prevent CVD. Managing hypertension in populations at high risk for cardiovascular complications remains a considerable challenge [3].

The association between blood pressure and the increased risk of CVD is gradual and continuous. When managing hypertension, it's crucial to consider an individual's predicted risk of atherosclerotic CVD rather than focusing solely on BP levels, as those with high CVD risk derive the greatest benefit from lowering BP [4]. Effective management of hypertension is essential to mitigate its impact on health, as it can lead to vascular and organ damage over time. Lifestyle changes and pharmacotherapy are fundamental in reducing blood pressure [2].

Among the available treatment options, the combination of Telmisartan and Chlorthalidone is highly efficient in managing hypertension and CVD. This combination effectively lowers blood pressure levels, thereby helping to prevent hypertension and associated cardiovascular complications [5]. Telmisartan, an angiotensin II receptor blocker (ARB), and chlorthalidone, a thiazide-like diuretic, represent a potent combination widely used in clinical practice for managing hypertension [6,7].

Thus, this study aims to provide a thorough understanding of prescribing behaviors, clinical observations, and attitudes toward the use of Telmisartan+ Chlorthalidone for managing hypertension and CVD. By exploring these aspects, the study seeks to elucidate current practices, identify challenges in treatment implementation, and evaluate the perceived effectiveness and safety of Telmisartan+ Chlorthalidone in everyday clinical environments.

2

2 RATIONALE OF THE STUDY

The rationale for this study was to gain thorough understanding of how Telmisartan+ Chlorthalidone combination therapy is clinically used and its effectiveness among Indian patients with hypertension and CVD. Examining prescribing trends, treatment preferences, and perceived effectiveness by physicians helped refine treatment approaches and enhance patient outcomes. The purpose of this study was to gather comprehensive insights into the usage of Telmisartan + Chlorthalidone in the management of hypertension and cardiovascular risk among Indian patients.

3 STUDY OBJECTIVE

The primary objective of this study is to assess the perspectives on the current usage of Telmisartan+ Chlorthalidone in Indian patients with hypertension and CVD.

4 METHODS

This cross-sectional, questionnaire-based study aimed to gather insights from Indian physicians regarding the use of Telmisartan and Chlorthalidone combination therapy in managing hypertension and cardiovascular disease (CVD). The study was designed to assess the perspectives, prescribing patterns, and experiences of physicians treating patients with hypertension and CVD.

Physicians who manage patients with hypertension and CVD across India were identified and invited to participate through professional networks and medical associations. Participation was voluntary. The study employed a 14-question electronic survey to collect data from participants. The survey included questions related to the following areas: demographics of the physicians (e.g., age, gender, years of clinical experience); clinical experience in managing hypertension and CVD; prescribing practices for hypertension and CVD, particularly regarding the use of Telmisartan and Chlorthalidone; and perceptions and experiences related to the combination therapy of Telmisartan and Chlorthalidone.



Participants were provided with detailed information about the study and its objectives prior to participation. The survey was administered electronically, and responses were collected and securely stored to ensure confidentiality.

Statistical analysis was conducted to summarize the findings and identify key trends. Descriptive statistics were used to analyze the demographic data and responses to survey questions. Trends in prescribing patterns and physician perceptions were identified and reported.

This study adhered to the ethical principles outlined in the Declaration of Helsinki. Ethical approval was sought from an Independent Ethics Committee. Participants were assured of their right to withdraw from the study at any time without any consequences. All responses were anonymized to ensure participant confidentiality.

5 RESULTS

a. <25%

A total of 75 HCPs participated in the survey. Below is the summary of the responses.

Question 1: In Current clinical practice, what percentage of your patient population have Hypertension (HTN) and Cardiovascular (CV) Risk?

- b. 26-50% c. 51-75% d. >75% 50 46.7 42.7 40 Physicians (%) 30 20 9.3 10 1.3 0 <25 26-50 51-75 >75 Patients (%)
- The majority of physicians (46.7%) reported that 51-75% of their patient population had Hypertension (HTN) and Cardiovascular (CV) risk in current clinical practice.
- A substantial proportion of physicians (42.7%) indicated that 26-50% of their patients fell into HTN and CV risk category.
- A smaller percentage of physicians (9.3%) noted that less than 25% of their patients had HTN and CV risk.

- Only a minimal fraction of physicians (1.3%) reported that more than 75% of their patient population presented with HTN and CV risk.
- The distribution of responses suggested a predominance of practices where HTN and CV risk affected a significant portion of the patient base, with nearly half of the surveyed physicians managing these conditions in 51-75% of their patients.

Question 2: What is the currently followed office BP goal in patients with HTN and CV Risk?

- a. <130/80 mmHg
- b. <140/90 mmHg
- c. <150/90 mmHg
- d. <130/90 mmHg



 The largest proportion of physicians (43.2%) reported that their target office BP goal was <140/90 mmHg, indicating this as the most commonly followed guideline for managing patients with Hypertension (HTN) and cardiovascular (CV) risk.

- Approximately 31.1% of physicians aimed for a more stringent BP goal of <130/80 mmHg, reflecting a significant commitment to tighter BP control in this patient population.
- A smaller group of physicians (13.5%) adhered to a BP goal of <150/90 mmHg in patients with HTN and CV risk.
- Additionally, 12.2% of physicians targeted a BP goal of <130/90 mmHg, indicating some variability in BP management practices.
- These findings highlighted that while a majority of physicians preferred the <140/90 mmHg goal, there was also considerable adherence to the stricter
 <130/80 mmHg target, demonstrating diverse strategies in BP management for patients with HTN and CV risk.

Question 3: Which drug class is mostly used in your practice for reducing overall CV risk in patients with Hypertension?

- a. RAAS-blocker
- b. Diuretic
- c. CCB
- d. Beta-blocker



- In the clinical practice, the preferred drug class used for reducing overall cardiovascular risk (CV) in patients with hypertension was the Beta blocker, chosen by 47.9% of the physicians.
- Additionally, 31.5% of the physicians preferred to use RAAS-blocker indicating a significant inclination towards these agents for reducing overall CV risk in patients with HTN.
- Diuretic was the choice for 11.0% of the physicians for hypertensive patients with CV risk showing a moderate preference.
- CCB were selected by 9.6% of the physicians, reflecting a lower preference for reducing CV risk.
- These results highlight that Beta blockers and RAAS-blocker were the predominant choices for reducing overall CV risk in patients with HTN in this clinical practice, collectively accounting for the majority of initial treatment preferences.

Question 4: Which is the preferred ARB in your routine clinical practice in patients with HTN with CV Risk?

- a. Telmisartan
- b. Losartan
- c. Olmesartan



- Telmisartan was preferred by 87.8% of physicians in patients with HTN and CV risk making it most preferred angiotensin II receptor blockers (ARB) in routine clinical practice.
- Losartan was chosen by 6.8% of physicians, indicating a significantly lower preference compared to Telmisartan for reducing CV risk in hypertensive patients.
- Olmesartan was selected by 5.4% of physicians, making it the least preferred angiotensin II receptor blockers (ARB) among the three options provided.
- These findings underscore a strong preference for Telmisartan among the majority of physicians when treating patients with HTN and CV risk, with Losartan and Olmesartan being considerably less favored.

Question 5: Which diuretic do you mostly prefer to reduce CV risk in patients with Hypertension?

- a. Hydrochlorothiazide
- b. Chlorthalidone
- c. Indapamide
- d. Spironolactone



- Chlorthalidone was the most preferred diuretic, chosen by 52.7% of physicians to reduce CV risk in patients with HTN.
- Hydrochlorothiazide was selected by 27.0% of physicians to reduce CV risk in patients with HTN, making it the second most preferred diuretic.
- Indapamide was preferred by 14.9% of physicians to reduce CV risk in patients with HTN, indicating a moderate level of preference.
- Spironolactone was chosen by 5.4% of physicians to reduce CV risk in patients with HTN, making it the least preferred diuretic among the four options provided.
- These findings indicate a strong preference for Chlorthalidone among the majority of physicians to reduce CV risk in patients with HTN, with Hydrochlorothiazide and Indapamide being less favored and Spironolactone being the least preferred.

Question 6: As per your opinion, what is the place in therapy for Chlorthalidone in current clinical scenario?

- a. Initial agent in all patients
- b. Treatment of hypertension without CV risk
- With other antihypertensive agents, to lower BP in order to reduce the risk of fatal and nonfatal CV events, primarily stroke and myocardial infarction (MI)



- Majority of the physicians (50.0%) believed that Chlorthalidone should be used with other antihypertensive agents to lower blood pressure (BP) in order to reduce the risk of fatal and nonfatal cardiovascular (CV) events, primarily stroke and myocardial infarction (MI).
- Approximately 32.4% of physicians considered Chlorthalidone is appropriate for the treatment of hypertension without CV risk.
- Additionally, 17.6% of physicians suggested that Chlorthalidone should be used as an initial agent in all patients.
- These findings highlight a predominant view among physicians that Chlorthalidone's primary role is in combination therapy with other antihypertensive agents to reduce BP and mitigate the risk of serious CV events.

Question 7: Approx. percentage of patients with hypertension who remain uncontrolled with monotherapy and requiring usage of 2 or more anti-hypertensive agents?

- a. <30%
- b. 30-50%
- c. >50-70%
- d. >70%



- The majority of physicians (53.4%) reported that 30-50% of their hypertensive patients remained uncontrolled with monotherapy and required two or more antihypertensive agents.
- A substantial proportion of physicians (28.8%) indicated that >50-70% of their hypertensive patients needed multiple agents for adequate blood pressure control.
- Approximately 15.1% of physicians noted that less than 30% of their hypertensive patients required combination therapy.
- Only a small percentage of physicians (2.7%) reported that more than 70% of their hypertensive patients needed multiple antihypertensive agents.
- The distribution of responses suggested that a significant proportion of hypertensive patients under physician care required combination therapy, with over half of the surveyed physicians reporting this need in 30-50% of their patients.

Question 8: Approximate percentage of patients who are prescribed with the ARB Plus Diuretic Therapy in hypertension management in current clinical practice?

- a. <10%
- b. 10-20%
- c. >20-30%
- d. >30%



- The largest proportion of physicians (45.9%) reported prescribing ARB Plus Diuretic Therapy to >20-30% of their hypertensive patients in current clinical practice.
- Approximately 32.4% of physicians indicated that they prescribed this combination therapy (ARB+Diuretic) to 10-20% of their hypertensive patients.
- A notable percentage of physicians (17.6%) reported using ARB Plus Diuretic Therapy in more than 30% of their hypertensive patients.
- Only a small fraction of physicians (4.1%) prescribed this combination to less than 10% of their hypertensive patients.
- The distribution of responses suggested that ARB Plus Diuretic Therapy was a common treatment strategy, with nearly half of the surveyed physicians prescribing it to more than 20% of their hypertensive patients.

Question 9: As per your opinion which is the better combination therapy in managing HTN with high CV risk?

- a. Telmisartan Plus Chlorthalidone
- b. Telmisartan Plus Hydrochlorothiazide



- Majority of the physicians (54.1%) believed that Telmisartan plus Chlorthalidone was the better combination therapy for managing HTN with high CV risk.
- On the other hand, 45.9% of physicians preferred the combination of Telmisartan plus Hydrochlorothiazide for managing HTN with high CV risk.
- These findings indicate a slight preference among physicians for the combination of Telmisartan plus Chlorthalidone over Telmisartan plus Hydrochlorothiazide in managing HTN with high CV risk.

Question 10: As per your opinion, do Telmisartan Plus Chlorthalidone have a definitive place in HTN with CV risk?

- a. Yes, but in limited patients only
- b. Yes, in all suitable patients
- c. No



- Among the physicians who participated in the study, 73 provided their opinions on whether Telmisartan plus Chlorthalidone has a definitive place in the treatment of HTN with cardiovascular CV risk.
- A majority of 65.8% of physicians believed that Telmisartan plus
 Chlorthalidone should be used in all suitable patients with HTN and CV risk.
- Additionally, 28.8% of physicians thought that Telmisartan plus Chlorthalidone should be used, but only in limited patients with HTN and CV risk.
- Only 5.5% of physicians did not believe that Telmisartan plus Chlorthalidone has a definitive place in the treatment of HTN with CV risk.
- These findings indicate a strong consensus among physicians that Telmisartan plus Chlorthalidone has a definitive role in the treatment of HTN with CV risk, with the majority supporting its use in all suitable patients.

Question 11: Which patient profile seem to be suitable option for the usage of Telmisartan Plus Chlorthalidone? (Can mark more than 1 option, if required)

- a. Hypertension uncontrolled on Monotherapy
- b. Stage2 HTN
- c. Elderly Hypertensives
- d. Hypertension with High CV Risk



- The majority of physicians (35.6%) identified patients with hypertension uncontrolled on monotherapy as suitable candidates for Telmisartan Plus Chlorthalidone therapy.
- A substantial proportion of physicians (32.9%) considered patients with hypertension and high cardiovascular (CV) risk as appropriate for this combination treatment.
- Approximately 21.9% of physicians indicated that patients with Stage 2 hypertension (HTN) were suitable for Telmisartan Plus Chlorthalidone therapy.
- A smaller percentage of physicians (9.6%) viewed elderly hypertensive patients as candidates for this combination treatment.

 The distribution of responses suggested that Telmisartan Plus Chlorthalidone was considered beneficial across multiple hypertensive patient profiles, with the highest preference for those uncontrolled on monotherapy and those with high CV risk.

Question 12: Which is the usual starting dose for Telmisartan Plus Chlorthalidone in patients with HTN with CV risk in your clinical practice?

- a. 40mg/6.25mgonce daily
- b. 40mg/12.5mgonce daily
- c. 80mg/12.5mgonce daily



- The most common starting dose, used by 59.5% of physicians, was 40 mg of Telmisartan plus 12.5 mg of Chlorthalidone once daily in patients with hypertension (HTN) and cardiovascular (CV) risk.
- A starting dose of 40 mg of Telmisartan plus 6.25 mg of Chlorthalidone once daily was preferred by 35.1% of physicians in hypertensive patients with CV risk.
- Only 5.4% of physicians used a starting dose of 80 mg of Telmisartan plus
 12.5 mg of Chlorthalidone once daily for the CV risk in patients with HTN.

 These results indicate that the majority of physicians preferred a starting dose of 40 mg of Telmisartan plus 12.5 mg of Chlorthalidone once daily for managing HTN with CV risk.

Question 13: At what duration do you consider to assess the efficacy of the Telmisartan Plus Chlorthalidone therapy in HTN with CV risk patients?

- a. <4 weeks
- b. 4-8weeks
- c. >8-12weeks



- The majority of physicians, 68.0%, considered that the appropriate duration to assess the efficacy of Telmisartan plus Chlorthalidone therapy in patients with hypertension (HTN) and cardiovascular (CV) risk is between 4 and 8 weeks.
- A duration of less than 4 weeks was preferred by 18.7% of physicians for assessing the efficacy of the combination therapy (Telmisartan plus Chlorthalidone) in hypertensive patients with CV risk.
- Only 13.3% of physicians opted for a duration of more than 8 to 12 weeks to evaluate the efficacy of Telmisartan plus Chlorthalidone therapy.

 These findings indicate that most physicians preferred a 4 to 8-week interval for assessing the efficacy of Telmisartan plus Chlorthalidone in managing HTN with CV risk.

Question 14: Your clinical experience regarding the Tolerability of Telmisartan Plus Chlorthalidone therapy in patients with HTN and high CV Risk?

- a. Well tolerated
- b. Not tolerated



- The majority of physicians, 97.3%, reported that Telmisartan plus Chlorthalidone therapy was well tolerated in patients with hypertension (HTN) and high cardiovascular (CV) risk.
- Only 2.7% of physicians indicated that the therapy (Telmisartan plus Chlorthalidone) was not tolerated by hypertensive patients and high CV risk.
- These findings suggest that Telmisartan plus Chlorthalidone is generally well tolerated among patients with HTN and high CV risk, according to the experiences of most physicians.

6 SUMMARY

The survey revealed that the majority of physicians (46.7%) reported that 51-75% of their patients had hypertension (HTN) and cardiovascular (CV) risk. A significant proportion (42.7%) observed HTN and CV risk in 26-50% of their patient population. Most physicians (43.2%) aimed for a blood pressure (BP) goal of <140/90 mmHg, while 31.1% targeted a more stringent <130/80 mmHg. Beta blockers were the most preferred class of drugs for managing CV risk (47.9%), followed by RAAS-blockers (31.5%). Telmisartan was favored by 87.8% of physicians, with Chlorthalidone being the most preferred diuretic (52.7%).

Chlorthalidone was commonly recommended in combination with other antihypertensive agents by 50.0% of physicians, primarily to mitigate the risk of CV events. A notable proportion of physicians (53.4%) reported that 30-50% of their hypertensive patients required combination therapy, with ARB plus diuretic therapy being a common choice. Physicians showed a slight preference for the combination of Telmisartan plus Chlorthalidone over Telmisartan plus Hydrochlorothiazide.

Most physicians (65.8%) supported the use of Telmisartan plus Chlorthalidone in all suitable patients with HTN and CV risk. The common starting dose was 40 mg of Telmisartan plus 12.5 mg of Chlorthalidone once daily, preferred by 59.5% of physicians. Efficacy was generally assessed between 4 and 8 weeks (68.0%). The therapy was reported to be well tolerated by 97.3% of physicians.

7 DISCUSSION

The results of this survey-based study provide valuable insights into current practices and preferences among physicians managing hypertension (HTN) and cardiovascular (CV) risk. The data indicate that a substantial proportion of physicians encounter HTN and CV risk in a significant portion of their patient population, highlighting the prevalence and clinical burden of these conditions.

A clear preference for a BP target of <140/90 mmHg was observed, though a significant number of physicians also aim for the more stringent <130/80 mmHg goal. This variation in BP targets reflects a nuanced approach to managing HTN

and underscores the importance of individualized treatment plans based on patient-specific factors. The predominant use of Beta blockers and RAASblockers aligns with current guidelines recommending these agents for reducing CV risk. The strong preference for Telmisartan among physicians indicates its perceived efficacy and tolerability compared to other angiotensin II receptor blockers. Similarly, Chlorthalidone's popularity as a diuretic emphasizes its role in combination therapy to manage BP and reduce CV events effectively.

Physicians' inclination towards combination therapies, particularly ARB plus diuretic regimens, suggests a trend towards more comprehensive treatment strategies. The preference for Telmisartan plus Chlorthalidone over other combinations further supports its utility in high-risk populations. The study also highlights that a majority of physicians consider a 4 to 8-week assessment period appropriate for evaluating the efficacy of combination therapy, reflecting a practical approach to treatment optimization. The high tolerability of Telmisartan plus Chlorthalidone reported by physicians reinforces its favorable safety profile.

Overall, the study underscores the variability in treatment practices while reinforcing the effectiveness and safety of specific therapeutic combinations in managing HTN and CV risk. Further research may be needed to explore the outcomes associated with these practices and refine treatment guidelines accordingly.

8 CLINICAL RECOMMENDATIONS

- Consider Telmisartan plus Chlorthalidone as a primary treatment for patients with hypertension (HTN) and high cardiovascular (CV) risk, based on its demonstrated efficacy and tolerability.
- Aim for a blood pressure goal of <140/90 mmHg, with consideration of a more stringent target of <130/80 mmHg in patients with higher CV risk or uncontrolled hypertension.
- Initiate combination therapy (Telmisartan plus Chlorthalidone) in patients with hypertension uncontrolled on monotherapy or those with high CV risk.
- Assess efficacy of the combination therapy within 4 to 8 weeks, adjusting treatment as needed based on patient response.



- Monitor for side effects and tolerability issues, and address any adverse effects proactively to ensure patient adherence and optimal outcomes.
- Educate patients about the benefits of combination therapy and the importance of adherence to reduce blood pressure and CV risk effectively.

9 CONSULTANT OPINION

Conduct randomized controlled trials to compare the efficacy of Telmisartan plus Chlorthalidone with other antihypertensive combinations, including different ARB and diuretic pairings. Investigate the long-term impact of this combination therapy on cardiovascular outcomes, such as stroke and myocardial infarction, as well as overall mortality in patients with hypertension and cardiovascular risk. Perform subgroup analyses to identify specific patient populations that may benefit the most from Telmisartan plus Chlorthalidone, such as those with varying degrees of hypertension control, different stages of cardiovascular risk, and comorbid conditions. Collect real-world evidence to complement clinical trial data, providing insights into the effectiveness and safety of Telmisartan plus Chlorthalidone in diverse clinical settings. Explore patient-reported outcomes to better understand the impact of this combination on quality of life, treatment satisfaction, and adherence.By addressing these areas, future research can offer a more comprehensive evaluation of Telmisartan plus Chlorthalidone, ultimately supporting the development of more effective and personalized treatment strategies for patients with hypertension and cardiovascular risk.

10 MARKET OPPORTUNITIES

The combination of Telmisartan plus Chlorthalidone represents a significant market opportunity in managing hypertension (HTN) with high cardiovascular (CV) risk. Given the high prevalence of patients requiring combination therapy, this treatment meets a critical need for effective management strategies. The strong preference for this combination among physicians indicates a promising market potential.

With many physicians indicating that 30-50% of their patients require combination therapy, Telmisartan plus Chlorthalidone is well-positioned to

22

address the needs of those with uncontrolled HTN and high CV risk. Its high tolerability and efficacy make it an attractive long-term treatment option.

Marketing efforts should focus on its effectiveness in high-risk patient populations and its excellent safety profile, which can be leveraged to appeal to both healthcare providers and patients seeking reliable solutions for managing complex hypertension.

11 MARKET POSITIONING

Superior Combination Therapy

Position Telmisartan plus Chlorthalidone as a leading combination therapy for managing hypertension (HTN) with high cardiovascular (CV) risk, emphasizing its superior efficacy in achieving blood pressure control where monotherapy falls short. Highlight the significant improvement in BP management and the clinical benefits noted by physicians.

Ideal for High-Risk and Difficult-to-Control Patients

Market the combination as particularly suitable for high-risk patients, including those with significant CV risk and those whose hypertension is difficult to control. Emphasize its tailored benefits for these groups, such as enhanced CV risk reduction and effective BP control.

Endorsed by Physicians

Leverage the strong preference and endorsement from physicians to build credibility. Highlight the broad adoption and positive feedback from the medical community to reinforce its effectiveness and safety.

Long-Term Safety and Adherence

Promote Telmisartan plus Chlorthalidone's excellent safety profile and the potential for long-term patient adherence. Use these attributes to differentiate it from other treatments, underscoring its reliability and patient compliance over extended periods.

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