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Expert Opinion on the use of Bisoprolol-Telmisartan Combination in Indian Patients with Hypertension

Research Article

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Abstract

Background: The combination of bisoprolol and telmisartan has been recognized as a viable treatment option for hypertension management in India. However, there was a dearth of information available on the preference of antihypertensives in the actual clinical practice among clinicians.

Objective: To assess the prescription pattern of antihypertensive medications and evaluate the real-world practice of bisoprolol + telmisartan combination therapy for hypertension management in the Indian context.

Methodology: A cross-sectional, multiple-response questionnaire-based survey was conducted among clinicians with expertise in treating hypertension. The survey consisted of 25 items and focused on the prescription practices of antihypertensive medications, as well as the utilization of bisoprolol + telmisartan combination therapy for hypertension treatment. Descriptive statistics were used to analyze the data, and categorical variables were represented as percentages.

Results: The study analyzed the responses of 647 participants. It was found that 47% of the respondents followed the American Hypertension Guidelines for hypertension management. Telmisartan was the preferred choice of angiotensin receptor blocker for approximately 95% of the respondents. Among the participants, 73% favored bisoprolol as the beta-blocker of choice for newly diagnosed hypertension patients, and 57% preferred a dosage of 5 mg for patients at risk for cardiovascular disease. Furthermore, 44% of the respondents believed that 20-40% of hypertension patients required a dual antihypertensive drug combination. Nearly 70% of the participants reported improvements in organ function, specifically in target organs affected by hypertension such as the heart, kidneys, and blood vessels, when using the bisoprolol + telmisartan combination.

Conclusion: It was observed that telmisartan was the preferred choice as an angiotensin receptor blocker, while bisoprolol was favored as the beta-blocker for newly diagnosed hypertension patients. The combination of bisoprolol + telmisartan has been shown to be effective in managing hypertension, reducing cardiovascular risk, and improving organ function.

Keywords: Bisoprolol; Telmisartan; Hypertension; Blood Pressure; Antihypertensive Treatment

Introduction

Of the 1.28 billion people with hypertension worldwide, two-thirds are from low- and middle-income countries and they range in age from 30 to 79. The reduction of hypertension prevalence by 33% between 2010 and 2030 is one of the global targets for non-communicable diseases [1]. Office blood pressure (BP) values of at least 130 mm Hg systolic and 80 mm Hg diastolic were considered to be indicative of hypertension, while 24-hour ambulatory BP readings were 125 mm Hg systolic and 75 mm Hg, respectively [2]. For the optimal management of patients over 65 years of age, the most recent European and US Guidelines recommend targeting systolic blood pressure (SBP) between 120 and 130 mmHg, and diastolic blood pressure (DBP) between 70 and 80 mmHg [2]. Around 46% of adults with hypertension were unaware of their condition, indicating a lack of awareness. Additionally, less than half (42%) of adults diagnosed with hypertension received appropriate diagnosis and treatment. Moreover, approximately 1 in 5 adults (21%) with hypertension successfully managed to keep their BP under control [1].

According to Indian guidelines on hypertension-IV, the diagnosis of hypertension in India was based on office BP reaching 140/90 mm Hg, and ambulatory BP exceeding 130/80 mm Hg [3]. It was undiagnosed or untreated hypertension that increases the risk of death or lifelong disability and it was a stand-alone risk factor for myocardial infarction, stroke, chronic renal disease, and coronary heart disease [4]. However, hypertension remained a modifiable risk factor, and both non-pharmacological and pharmaceutical interventions can effectively reduce the associated risks. Therefore, regular monitoring of BP was crucial for the diagnosis and management of hypertension [5]. Ambulatory BP monitoring (ABPM) enabled automatic measurement of the diurnal variation in BP as well as continuous therapy efficacy assessment [6]. The long-term prognosis was improved by ABPM's accurate prediction of cardiovascular (CV) risk and ability to manage BP during the times of increased risk [7].

Beta-blockers, angiotensin II receptor blockers (ARBs), angiotensin-converting enzyme inhibitors (ACEi), calcium channel blockers, and diuretics (including thiazides and thiazide-like diuretics) are the five medication classes currently used for the management of hypertension [8]. Studies have revealed that up to 75% of patients treated with a single antihypertensive medication experience inadequate BP management [9]. Fixed-dose combination was recommended by the majority of hypertension management guidelines, as it helps to improve patient compliance and convenience while achieving better BP control [10-12].The combination therapy of bisoprolol + telmisartan has been recognized as a viable treatment option for hypertension management in India. Bisoprolol, a beta-blocker, and telmisartan, an angiotensin II receptor blocker, have complementary mechanisms of action that can effectively lower BP. Bisoprolol acts by reducing heart rate and contractility, whereas telmisartan works by blocking the effects of angiotensin II, resulting in vasodilation and decreased fluid retention. By combining these two medications, clinicians can target multiple pathways involved in BP regulation, leading to improved control of hypertension [13].

The present study was intended to evaluate the prescription pattern of antihypertensive medications and the real-world practice of bisoprolol + telmisartan combination therapy for hypertension management in the Indian context.

Methodology

A cross sectional, questionnaire based survey was carried out among clinicians with expertise in treating hypertension in the major Indian cities from June 2022 to December 2022.

Questionnaire

The questionnaire booklet titled HEART (The Experts Opinion on HypertEnsion And its TReatmenT) study was sent to the physicians who were interested to participate in the study. The HEART study questionnaire included questions on the current practices, preferences, clinical observations, and experiences related to the use of antihypertensives in routine settings, particularly bisoprolol + telmisartan for the management of hypertension. The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

Participants

An invitation was sent to leading clinicians in managing hypertension in the month of March 2022 for participation in this Indian survey. 647 doctors from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provide necessary data. Physicians were asked to complete the questionnaire without discussing with peers. A written informed consent was obtained from each physician prior initiation of the study.

Statistical Analysis

The data were analyzed using descriptive statistics and percentage was used to represent categorical variables. In order to represent each variable's distribution, we used a frequency distribution and a percentage distribution. Using Excel 2013 (16.0.13901.20400), pie and bar charts were made.

Results

The study analyzed the responses of 647 participants. Analysis of data on clinicians' compliance with guidelines for the management of hypertension revealed that 47% of the respondents followed the American Hypertension Guidelines, while 31% of the respondents adhered to the European Hypertension Guidelines. Indian Hypertension Guidelines were followed by 19% of the respondents. Combining recommendations from multiple sources or considering the overall consensus (0.77%) was performed by a small proportion of clinicians [Table 1].

Diabetes was the most common comorbid condition noted in newly diagnosed hypertensive subjects, as reported by 52% of the participants. While 32% of the respondents reported dyslipidemia as a commonly noted comorbid condition, 9% of them observed chronic kidney disease and only 5.5% highlighted hypothyroidism. Furthermore, the majority of respondents (87.32%) agreed that aortic

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Table 1: Guidelines compliance by the clinicians for the management of hypertension in clinical practice

Guidelines followed for the management of hypertension	Response rate (n=647)
American hypertension guidelines	307 (47.45%)
European hypertension guidelines	198 (30.60%)
Indian hypertension guidelines	126 (19.47%)
All the above	5 (0.77%)
Depends on situation	1 (0.15%)
Guidelines published by Joint National Committee	2 (0.30%)
Clinicians customized the guidelines according to patient requirement	1 (0.15%)
Others	7 (1.07%)

stiffness and pulse wave velocity are newer indices that can be used to assess uncontrolled hypertension and CV risk but 5% of them denied it and 6% of physicians require more data to support it.

Majority of respondents (71.40%) preferred the prescription of once-daily anti-hypertensive medications in the morning. On the other hand, approximately 25% of the clinicians preferred prescribing the medication in the evening. Regarding the use of dual combination antihypertensive medications, a significant percentage of respondents (44.2%) noted that 20-40% of hypertensive patients would require such a combination. Nearly 40% of the respondents estimated that 10-20% of hypertensive patients would benefit from a dual combination, while approximately 13% believed that <10% of hypertensive patients would require this type of combination therapy. Around 47% of the respondents believed that 25-50% of newly diagnosed hypertensive patients achieve BP control within the first year of treatment using monotherapy, while 41% of the respondents noted only <25% and 8.34% of them observed 50-75% reduction in BP.

The findings on the commonly preferred angiotensin receptor blockers (ARBs) showed that around 95% of the respondents expressed a preference for telmisartan as the ARB of choice. A small percentage of respondents (3.24%) indicated a preference for olmesartan as the ARB alternative [Figure 1].

Approximately 73% expressed a preference for bisoprolol as the beta-blocker of choice for newly diagnosed hypertensive patients, while 21% indicated a preference for metoprolol. A small percentage of respondents (5.10%) preferred carvedilol as the beta-blocker for newly diagnosed hypertensive patients [Table 2].

Out of 647 respondents, 72% identified the high beta-1 selectivity of bisoprolol as one of its advantages. Approximately 16% recognized that bisoprolol's ability to reduce heart rate and cardiac output contributes to its antihypertensive properties and 6% of clinicians observed all such effects. A smaller proportion of respondents (3.70%) indicated that bisoprolol has a minimal impact on libido. Around 57% of the clinicians selected 5 mg as the preferred dosage for bisoprolol in hypertensive patients with CV risk, while 40% indicated that a dosage of 2.5 mg of bisoprolol might be appropriate [Table 3].

A major proportion of respondents (71%) indicated that they encounter patients who have both hypertension and CV disease, whereas 16% reported encountering patients with uncontrolled hypertension and nearly 6% of them preferred in younger patients with hypertension. Approximately 55% noted that patients between the ages of 40 and 50 years are typically diagnosed with hypertension. While around 32% reported encountering patients under the age of 40 with newly diagnosed hypertension. A smaller percentage of

Table 2: Preferred beta-blocker in newly diagnosed hypertensive patients

Preferred beta-blocker in newly diagnosed hypertensive patients	Response rate (n=647)
Carvedilol	33 (5.10%)
Bisoprolol	474 (73.26%)
Metoprolol	130 (20.09%)
Nebivolol	2 (0.30%)
All the above	1 (0.15%)
Avoid in young males	1 (0.15%)
Others	6 (0.92%)

Table 3: Dosage of bisoprolol for the management of hypertension with CV risk

Dosage of bisoprolol	Response rate (n=647)
2.5 mg	260 (40.18%)
5 mg	367 (56.72%)
10 mg	5 (0.77%)
Both 5 and 10 mg	9 (1.39%)
Others	6 (0.92%)

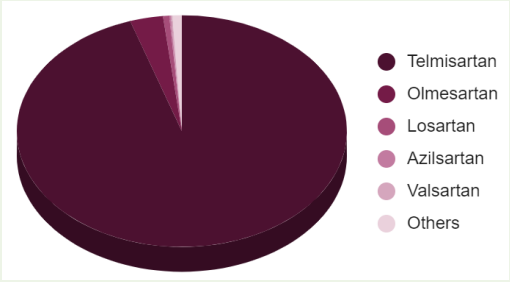

Figure 1: Commonly preferred ARBs in clinical practice

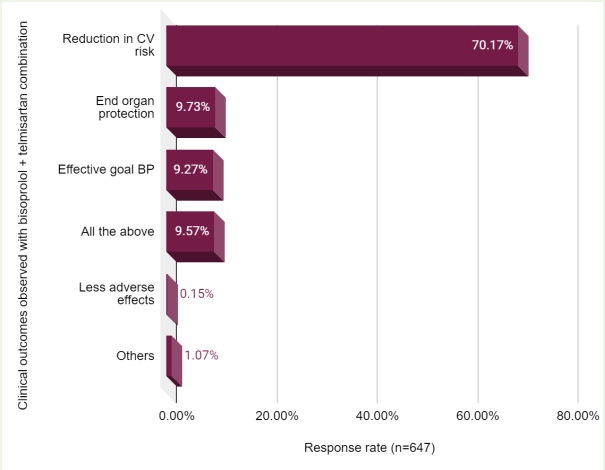

Figure 2: Clinical outcomes observed with bisoprolol + telmisartan combination

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respondents (10.97%) reported managing patients between the ages of 50 and 60 years.

Approximately 70% reported a reduction in CV risk in patients receiving the bisoprolol + telmisartan combination. Additionally, 10% observed that the treatment confers end-organ protection, particularly in target organs affected by hypertension such as the heart, kidneys, and blood vessels. Furthermore, 9% of respondents reported achieving effective BP control in patients treated with the bisoprolol + telmisartan combination. Lastly, 10% indicated that they observed multiple positive outcomes with the bisoprolol + telmisartan combination including a reduction in CV risk, end-organ protection, and effective goal BP control [Figure 2].

Discussion

The current study emphasized the importance of medication adherence as a critical factor in achieving successful therapeutic outcomes for hypertensive patients. By providing individualized treatment options, it was possible to maximize the therapeutic effects and improve patient satisfaction in controlling hypertension. To enhance adherence and maximize treatment effectiveness, simplifying treatment algorithms and favoring single-pill combinations can be employed to attain BP goals [13]. The most recent revision of the European Society of Cardiology/European Society of Hypertension guidelines for the diagnosis and treatment of hypertension recommend streamlined drug treatment algorithms. The preferred approach involves using an ACEi or ARB combined with a calcium-channel blocker and/or a thiazide/thiazide-like diuretic as the core treatment strategy for most patients. This strategy was based on evidence demonstrating the ability of these medication classes to reduce CV events and improve patients' prognoses [9].

The current data also highlighted the diversity in guideline adherence among clinicians participating in the study, with a significant number following either the American or European Hypertension Guidelines. The inclusion of the Indian Hypertension Guidelines as another notable reference demonstrated the global variation in hypertension management practices. The presence of a small proportion combining recommendations from multiple sources indicated potential flexibility and open-mindedness in incorporating different guidelines.

The European Society of Cardiology/European Society of Hypertension Guidelines and the American Heart Association/ American College of Cardiology 2017 guidelines emphasized the important role of beta-blockers in the management of hypertension [2]. The majority of respondents in the current study expressed a preference for bisoprolol as the beta-blocker of choice for newly diagnosed hypertensive patients, while a significant percentage indicated a preference for metoprolol. The recommended dosages of bisoprolol identified by the respondents were 5 mg and 2.5 mg, which are considered appropriate for hypertensive patients with CV risk. Bisoprolol's selectivity for beta-1 adrenergic receptors, primarily found in the heart, was believed to contribute to its effectiveness in reducing heart rate and blood pressure. This selectivity allowed it to target specific receptors, potentially leading to better outcomes [14].

The respondents also recognized the effectiveness of bisoprolol in reducing heart rate and cardiac output, which contributes to its antihypertensive properties [15]. Carvedilol, a non-selective beta-blocker with additional alpha-blocking properties, was often prescribed for specific indications such as heart failure. It was worth noting that other beta-blockers, including metoprolol and bisoprolol, were widely used in various European countries and were considered safe during pregnancy [16]. A significant percentage of the current respondents indicated that 20-40% of hypertensive patients require a dual combination of antihypertensive medications. The percentage of patients requiring dual combination therapy can vary based on several factors. Disease severity, the presence of comorbidities, individual patient characteristics, and treatment guidelines all play a role in determining the appropriate treatment approach. Many hypertension management guidelines recommended initiating antihypertensive therapy with a medication combination, preferably in the form of a fixed-dose combination. This approach offered several advantages, including convenience for patients and improved medication adherence [9, 12].

In the current study, the majority of the respondents favored telmisartan as the preferred ARB in the management of hypertension. Telmisartan has been shown to have several advantages compared to other antihypertensive drugs. It has greater tolerability and fewer side effects, making it a favorable choice for many patients [17]. The findings from the another trial further support the efficacy of telmisartan in controlling the morning increase in blood pressure, which was a significant concern for hypertensive individuals [18]. Additionally, Gosse et al. demonstrated that telmisartan 80 mg was superior to ramipril 10 mg in lowering early morning mean systolic and diastolic blood pressure compared to baseline measurements[19]. This suggested that telmisartan can effectively reduce blood pressure levels, especially during critical periods such as the early morning. One notable aspect contributing to the superiority of telmisartan was its longer half-life of approximately 24 hours. This extended duration of action allows for sustained blood pressure control throughout the day, enhancing its effectiveness compared to other drugs with shorter half-lives[20].

Despite the widespread preference for telmisartan, a small percentage of respondents in the study expressed a preference for olmesartan as an alternative ARB. Nakayama et al. found that olmesartan significantly reduced mean systolic and diastolic blood pressure compared to telmisartan after 8 weeks of treatment [21]. The preference for olmesartan by a subset of respondents indicated the need for individualized treatment approaches and consideration of alternative ARBs based on patient-specific factors.

As per the recent updates on hypertension management, the combination of the beta blocker, bisoprolol and the ARB, telmisartan has garnered attention. According to the majority of respondents in the current study, the bisoprolol + telmisartan combination demonstrated a reduction in CV risk [22, 23]. Furthermore, a notable percentage of respondents reported observing end-organ protection, indicating that the combination therapy preserved and improved organ function, especially in target organs affected by hypertension,

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such as the heart, kidneys, and blood vessels. Additionally, a small proportion of respondents mentioned achieving effective BP control with the bisoprolol + telmisartan combination, indicating its efficacy in helping patients reach their target BP levels.

Sawhney et al. conducted a study in Indian settings and highlighted the combination of bisoprolol + telmisartan as a valuable treatment approach for patients with concomitant hypertension[23]. The authors observed that the use of bisoprolol had significant clinical implications in various patient populations, including those with left ventricular dysfunction post myocardial infarction, coronary artery disease, hemodialysis, and heart failure. Bisoprolol demonstrated its effectiveness by modulating resting heart rate in these conditions. On the other hand, telmisartan was found to provide a distinct pharmacological approach to the management of hypertension. Its unique properties made it a valuable tool for controlling blood pressure and addressing hypertension-related issues[23].

The multicentric, double-blind, parallel-group, comparative, prospective, phase-III clinical study established the efficacy, tolerability, and safety of the fixed dose combination tablet of Telmisartan 40 mg + Bisoprolol 5mg tablets for the management of stage 1 and stage 2 hypertension[24]. The mean change in SeSBP and SeDBP at weeks 2/6/12 as compared to the prior visit was statistically significant ($p<0.001$) in all cases (i.e., baseline to week 2, week 2 to week 6, and week 6 to week 12) in both test and control arms. The mean difference in SeSBP from baseline to study end was significantly higher in Telmisartan 40 mg + Bisoprolol 5mg than the Telmisartan 40 mg + Metoprolol Succinate ER 50 mg ($p = 0.029$). Rated as 'excellent' by 93.75% subjects in test arm and 91.40% subjects in control arm. This study showed that Telmisartan 40 mg + Bisoprolol 5mg combination was non-inferior to Telmisartan 40 mg + Metoprolol Succinate ER 50 mg and was significantly superior with respect to a few end points [24].

Telmisartan's long-lasting blood pressure-lowering effects and cardioprotective properties is due to its strongest AT1 receptor antagonistic ability and corresponding slower dissociation from the receptor. Several Landmark trials (ONTARGET, TRANSCEND, DETAIL, AMADEO, VIVALDI etc.) have shown the effectiveness of Telmisartan in the management of Hypertension. The 2019 Indian hypertension-IV guideline recommends telmisartan as one of the drugs of choice to treat hypertension [25]. The BRIGHT study has shown the effectiveness of Bisoprolol in Indian patients with Hypertension [26]. The BISOCAD study [27], CREATIVE study [28] have shown that Bisoprolol is superior in dynamic HR reduction and BP reduction than Metoprolol.

Further to the Phase III study, the present study offers valuable expert opinions on the clinical use of this combination therapy. This contributes to the existing body of knowledge supporting the effectiveness of bisoprolol + telmisartan in helping patients manage their hypertension and achieve their BP targets. The study's strength and significance in the field of hypertension research and clinical practice are further enhanced by its rigorous methodology, providing reliable and accurate insights. Moreover, the emphasis on individualized therapy in the study adds value by recognizing the importance of tailoring treatment approaches to meet the specific needs of patients.

One major drawback of the current study was its small sample size, which may limit the generalizability of the findings to a larger population of hypertensive individuals. A larger and more representative sample would provide a more accurate understanding of the topic. Additionally, the study's reliance on expert judgment introduces the possibility of bias, as various perspectives and preferences might have influenced the reported results. It was important to consider these limitations when interpreting the findings and to conduct further research to confirm and expand upon the conclusions.

Conclusion

It was found that telmisartan was the preferred ARB and bisoprolol was the favored beta-blocker for newly diagnosed hypertension patients. Combining bisoprolol + telmisartan has demonstrated effectiveness in the management of hypertension, along with benefits such as reducing cardiovascular risk and improving organ function.

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