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Research Article

A Cross Sectional Study on the Drug Utilization of FDC of Telmisartan Plus Metoprolol in Patients with Hypertension Across Various Clinics in India

Saket Kant[1], Amit Sharma[2], Vijay Kumar[3], Pranay Gore[4], Sankhadeep Pramanik[5], Sumit Bhushan[6*], Sanjay Chaudhari[6], Rahee Borulkar[6], Prajakta Bhosale[6], Rujuta Gadkari[6], Saiprasad Patil[6]

[1]Action Balaji Medical & Cancer Institute, Delhi, India

[2]Holy Spirit Hospital, Mumbai, India

[3]Vaishnavi Clinic, Chennai, India

[4]KIMS Sunshine Hospital, Hyderabad, India

[5]Rubi Hospital, Kolkata, India

[6]Glenmark Pharmaceuticals Ltd., Mumbai, India

***Corresponding author:** Sumit Bhushan, Glenmark Pharmaceuticals Ltd., Mumbai, India

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Abstract

Background: Fixed-dose combinations (FDCs) are increasingly utilized in hypertension management to improve therapeutic efficacy and patient adherence. Limited real-world data exists on the utilization patterns of telmisartan plus metoprolol FDC in diverse Indian clinical settings. This study aimed to evaluate real-world drug utilization patterns, patient demographics, and prescribing practices of telmisartan plus metoprolol FDC across multiple clinics in India. **Methods:** This retrospective, multicentric cross-sectional study analyzed medical records of hypertensive patients who were prescribed telmisartan plus metoprolol FDC across 457 clinical sites in India from March to September 2024. Data collection included demographics, clinical parameters, treatment history, comorbidities, concomitant medications, and laboratory parameters. Descriptive statistics were used for analysis, with results presented as mean ± standard deviation or percentage. Independent ethics committee approval was obtained prior to study initiation. **Results:** A total of 2012 patients were included (mean age 57.31 ± 10.72 years; 72.16% male). Among participants, 60.58% were treatment-naïve while 39.41% were switched from previous antihypertensive therapy. The most common prior therapies included ARB monotherapy (35.6%), BB monotherapy (18.2%), and calcium channel blockers (18.3%). The hemodynamic details recorded show that the mean baseline systolic blood pressure was 148.93 ± 16.13 mmHg and the mean diastolic blood pressure was 94.44 ± 11.38 mmHg. The mean pulse rate was 85.46 ± 10.15 beats per minute. The average duration of Hypertension documented in the subjects was 5.04 ± 4.89 years. High comorbidity burden was observed: diabetes mellitus (44.04%), dyslipidemia (28.08%), obesity (26.99%), cardiovascular disease (27.14%), and chronic kidney disease (9.64%). Concomitant medication used was antidiabetic drugs (40.05%), cardiovascular medications (42.86%), and additional antihypertensives (26.78%). **Conclusions:** Telmisartan plus metoprolol FDC demonstrates widespread utilization in Indian clinical practice, both as initial therapy and switch treatment for patients with inadequate monotherapy control. The high prevalence of cardiometabolic comorbidities supports the rationale for combination antihypertensive therapy in this population. These findings align with contemporary hypertension guidelines recommending early combination therapy and highlight the need for comprehensive cardiovascular risk management.

Keywords: Hypertension, Fixed-dose combination, Telmisartan, Metoprolol, Drug utilization, Real-world evidence, India, Cardiovascular disease

Introduction

Hypertension remains a major global health challenge and the leading modifiable risk factor for cardiovascular disease (CVD) morbidity and mortality worldwide [1-3]. In India, the prevalence of hypertension has increased substantially, with current estimates suggesting over 200 million adults are affected [2]. Despite significant therapeutic advances, blood pressure (BP) control rates remain suboptimal, particularly in low- and middle-income countries where healthcare access and medication adherence present ongoing challenges [2,3]. Contemporary hypertension management guidelines increasingly emphasize the use of combination antihypertensive therapy to achieve target BP levels more effectively than monotherapy [4-7]. Fixed-dose combinations (FDCs) offer several advantages including complementary mechanisms of action, simplified dosing regimens, improved patient adherence, and potentially reduced side effects through lower individual drug doses [6, 8].

Telmisartan, a highly selective angiotensin II receptor blocker (ARB), provides sustained antihypertensive efficacy with additional cardiovascular and metabolic benefits [9]. Metoprolol, a cardioselective beta-blocker, reduces heart rate and myocardial oxygen demand while providing particular benefits in patients with coexisting cardiovascular conditions such as ischemic heart disease and heart failure [9]. The combination of these agents offers complementary mechanisms of action that may lead to superior BP control and organ protection compared to either agent alone [6,10].

Despite the theoretical advantages of telmisartan plus metoprolol FDC, limited real-world data exists regarding its utilization patterns, patient characteristics, and prescribing practices in diverse clinical settings, particularly in the Indian healthcare context [1,2]. Understanding these patterns is crucial for optimizing hypertension management strategies and identifying areas for improvement in clinical practice. This multicentric cross-sectional study aimed to evaluate the real-world drug utilization patterns of telmisartan plus metoprolol FDC in hypertensive patients across various clinics in India, providing valuable insights into contemporary prescribing practices and patient characteristics in routine clinical care.

Materials and Methods

Study Design and methodology

This retrospective, multicentric, cross-sectional study was conducted across 457 clinical sites throughout India over a six-month period from March 2024 to September 2024. The study was designed to evaluate real-world utilization patterns of telmisartan plus metoprolol FDC in routine clinical practice. The study protocol and case report form were reviewed and approved by a Central Drugs Standard Control Organization (CDSCO) registered Independent Ethics Committee (Good Society for Ethical Research, New Delhi, approval date: March 9, 2024). The study was conducted in accordance with the New Drugs and Clinical Trials Rules 2019, ethical principles originating from the Declaration of Helsinki, International Council for Harmonization Good Clinical Practice (ICH-GCP) guidelines, and all applicable local regulatory requirements.

Inclusion Criteria were medical records of patients prescribed telmisartan plus metoprolol FDC by treating physicians for hypertension management & complete medical records with all required data elements. Exclusion Criteria was incomplete medical records or missing key data elements of patients. Primary Endpoint of the study was to evaluate the clinical patient profiles of hypertensive patients prescribed with FDC of telmisartan plus metoprolol. Secondary Endpoints were to evaluate dosage patterns of telmisartan plus metoprolol FDC prescribed in hypertensive patients, demographic characteristics of patients receiving FDC therapy, Concomitant medication patterns in patients on FDC therapy & to evaluate duration between hypertension diagnosis and FDC prescription initiation.

Data were collected using a predesigned structured proforma from medical records of patients prescribed telmisartan plus metoprolol FDC. All information was recorded in an electronic data capture (EDC) system by designated investigator staff. Each investigator received EDC training and was responsible for completing a specific number of cases. Data completeness was reviewed by study project managers, and any discrepancies were verified by investigators or their designees before final analysis. Descriptive statistics were used for all analyses. Continuous variables are presented as mean ± standard deviation, and categorical variables as absolute numbers and percentages. No formal sample size calculation was performed as this was an observational cross-sectional study without hypothesis testing.

Results

A total of 2012 patients were included in the analysis across 457 study centres. The mean age was 57.31 ± 10.72 years, with a male predominance (72.16%, n=1452). Mean body weight was 72.83 ± 9.64 kg, mean height 165.18 ± 7.89 cm, and mean body mass index (BMI) 26.81 ± 4.01 kg/m². The average duration of hypertension prior to FDC initiation was 5.04 ± 4.89 years. Mean baseline BP at FDC initiation was 148.93 ± 16.13 mmHg systolic and 94.44 ± 11.38 mmHg diastolic, indicating that many patients had uncontrolled hypertension at treatment initiation. Mean pulse rate was 85.46 ± 10.15 beats per minute. Among the 2,012 patients included in the analysis, 1,219 (60.58%) were treatment-naïve at the time of initiation of the telmisartan–metoprolol fixed-dose combination, while 793 patients (39.41%) had switched

from previous antihypertensive therapy. Among patients who transitioned to the study medication, the most common prior treatments were ARB monotherapy (35.6%) and BB monotherapy (18.2%). Calcium channel blockers, primarily amlodipine or cilnidipine, accounted for 18.3% of prior therapies, while 11.3% of patients switched from a ARB+Diuretics fixed-dose combination. The mean duration of treatment with the study drug at the time of evaluation was 5.82 months, indicating continued use in routine clinical practice.

The study population demonstrated a high prevalence of cardio-metabolic comorbidities. Diabetes mellitus was present in 886 patients (44.04%), followed by dyslipidaemia in 565 patients (28.08%) and obesity in 543 patients (26.99%). Cardiovascular disease was reported in 546 patients (27.14%), with ischemic heart disease observed in 531 patients (26.39%) and heart failure in 220 patients (10.93%). Chronic kidney disease was documented in 194 patients (9.64%), reflecting a clinically complex hypertensive population requiring multifactorial risk management. History of chest pain was reported by 307 patients (15.25%), while headache and dizziness were noted in 292 patients (14.51%). Peripheral edema involving the legs, ankles, or feet was observed in 190 patients (9.44%). Previous hospitalization was documented in 90 patients (4.47%). A history of kidney disease and liver disease was reported in 83 (4.15%) and 88 patients (4.37%), respectively. Regarding lifestyle factors, tobacco use was reported by 495 patients (24.60%), and alcohol consumption was reported by 406 patients (20.17%), indicating a substantial burden of modifiable cardiovascular risk factors.

Laboratory assessments revealed glycaemic dysregulation among patients with diabetes, with a mean HbA1c of 7.38 ± 1.07%. Renal function parameters were generally preserved, with mean serum creatinine of 1.02 ± 0.21 mg/dL and blood urea nitrogen of 21.85 ± 8.56 mg/dL. The lipid profile demonstrated a mixed dyslipidaemia pattern, with mean total cholesterol of 178.29 ± 33.73 mg/dL, LDL cholesterol of 86.23 ± 15.67 mg/dL, HDL cholesterol of 83.48 ± 6.81 mg/dL, and elevated triglyceride levels of 215.52 ± 53.81 mg/dL, consistent with the high prevalence of metabolic comorbidities.

The most frequently prescribed agents included dapagliflozin (11.43%), metformin (4.57%), glimepiride (2.48%), and sitagliptin (2.18%). Common combination therapies included glimepiride plus metformin (3.87%) and sitagliptin plus metformin (2.04%). Rosuvastatin was the most frequently prescribed statin (20.28%), followed by atorvastatin (6.65%). Combination antiplatelet and statin therapies were common, including clopidogrel plus rosuvastatin (1.88%) and aspirin plus atorvastatin plus clopidogrel (1.29%). Sacubitril plus valsartan was prescribed in 3.03% of patients. In addition to the telmisartan–metoprolol fixed-dose combination, 539 patients (26.78%) received at least one additional antihypertensive agent, reflecting the need for multi-drug regimens in patients with uncontrolled blood pressure and high comorbidity burden. Calcium channel blockers constituted the most frequently prescribed add-on class, with amlodipine used in 5.91% of patients and cilnidipine in 2.78%. Combination regimens involving calcium channel blockers with angiotensin receptor blockers or beta-blockers were also observed, including amlodipine plus telmisartan (1.84%) and cilnidipine plus telmisartan or metoprolol-based combinations (1.49%). Diuretics were commonly employed as adjunct therapy, either as monotherapy or as part of fixed-dose combinations. Thiazide and thiazide-like diuretics, including chlorthalidone (0.70%) and hydrochlorothiazide (0.30%), were prescribed in a proportion of patients, while combination regimens such as telmisartan plus hydrochlorothiazide (1.04%) and telmisartan plus chlorthalidone (0.35%) were also utilized. Loop and potassium-sparing diuretics were prescribed less frequently, with torasemide used in 1.79% of patients and spironolactone plus torasemide in 0.45%, predominantly in patients with heart failure or chronic kidney disease. Proton pump inhibitors were commonly prescribed, with pantoprazole being most frequent (6.61%), often in combination with prokinetic agents such as domperidone.

Discussion

This comprehensive multicentric study provides valuable insights into the real-world utilization patterns of telmisartan plus metoprolol FDC in Indian clinical practice. The findings demonstrate widespread adoption of this combination therapy across diverse clinical settings, both as initial treatment and as switch therapy for patients with inadequate BP control on monotherapy. The patient population characteristics are consistent with established epidemiological patterns of hypertension, with a predominance of middle-aged male patients and a high prevalence of overweight/obesity (mean BMI 26.81 kg/m²). The mean baseline BP of 148.93/94.44 mmHg indicates that many patients had uncontrolled hypertension at FDC initiation, supporting the clinical rationale for combination therapy intensification. Mention about high heart rate observed in study and how selective beta blocker is beneficial for tachycardia with hypertension.

A notable finding was that 60.58% of patients were treatment-naïve, suggesting growing confidence among clinicians in initiating combination therapy as first-line treatment. This practice aligns with contemporary hypertension guidelines that increasingly recommend early combination therapy for patients with high cardiovascular risk or those unlikely to achieve target BP with monotherapy alone. Among patients who switched to the FDC, the predominant prior therapies were monotherapies with individual components of the combination (telmisartan or metoprolol), suggesting logical therapeutic progression when monotherapy proves insufficient.

The high prevalence of cardio-metabolic comorbidities in this population underscores the complex management requirements of contemporary hypertensive patients. Nearly half of the

patients (44.04%) had diabetes mellitus, while over a quarter had dyslipidaemia, obesity, or CVD. This clustering of risk factors supports the rationale for comprehensive cardiovascular risk management approaches rather than isolated BP treatment. The presence of heart failure in 10.93% of patients provides additional justification for beta-blocker therapy, while the 9.64% prevalence of chronic kidney disease supports the use of telmisartan given its demonstrated renoprotective effects. These comorbidity patterns suggest that the telmisartan plus metoprolol FDC may be particularly well-suited for patients with multiple cardiovascular risk factors.

The extensive use of concomitant medications reflects the reality of modern cardiovascular care, where comprehensive risk factor modification requires multiple therapeutic interventions. The high utilization of antidiabetic drugs (40.05%), cardiovascular medications (42.86%), and additional antihypertensive agents (26.78%) demonstrates the complex pharmacological management required for optimal patient outcomes. The predominant use of SGLT2 inhibitors (particularly dapagliflozin) among antidiabetic medications aligns with current evidence supporting their cardiovascular benefits beyond glycemic control. Similarly, the frequent prescription of statins (particularly rosuvastatin and atorvastatin) reflects adherence to evidence-based lipid management guidelines.

These findings suggest that Indian clinicians are increasingly adopting evidence-based approaches to hypertension management that align with international guidelines emphasizing combination therapy. The frequent use of the telmisartan plus metoprolol FDC as first-line therapy particularly reflects the evolution toward earlier, more aggressive BP management strategies. The high comorbidity burden and extensive polypharmacy observed in this population highlight the importance of integrated care approaches that address multiple cardiovascular risk factors simultaneously. The telmisartan plus metoprolol FDC appears to be appropriately positioned within such comprehensive management strategies.

Conclusion

This multicentric real-world study shows that the telmisartan–metoprolol fixed-dose combination is widely used in Indian clinical practice, both as initial therapy and as a switch option in patients with inadequate monotherapy control. The high burden of cardio-metabolic comorbidities observed supports the clinical rationale for early combination therapy in routine hypertension management. These findings align with contemporary hypertension guidelines and underscore the role of fixed-dose combinations in facilitating comprehensive cardiovascular risk management. Further research evaluating long-term clinical outcomes and comparative effectiveness will enhance understanding of optimal treatment strategies for hypertensive patients with complex comorbidity profiles.

Study Limitations

The retrospective design limits causal inferences and may be subject to selection bias. The relatively short follow-up period prevents assessment of long-term clinical outcomes or adherence patterns. Additionally, the observational nature of the study does not allow for comparison with alternative treatment strategies or control groups. The study was conducted across diverse clinical settings but may not represent all practice patterns within India's heterogeneous healthcare system. BP outcomes following FDC initiation were not systematically assessed, limiting evaluation of therapeutic effectiveness.

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Ethical standards

The work presented in this study was in accordance with the study protocol, the New Drugs and Clinical Trials Rules 2019 issued by the Government of India, the ethical principles that have their origin in the Declaration of Helsinki, International Council for Harmonisation (ICH) Good Clinical Practice (GCP), and all applicable local regulatory requirements. Independent Ethics committee approval was obtained prior to study initiation and data collection.

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Conflicts of Interest

Dr. Sumit Bhushan, Dr. Sanjay Chaudhari, Dr. Rahee Borulkar, Ms. Prajakta Bhosale, Ms. Rujuta Gadkari and Dr. Saiprasad Patil are employees of Glenmark. All other investigators/authors have no conflicts of interest that are directly relevant to the content of this article.

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