Original Research

Comparative Study to Evaluate Efficacy, Safety and Quality of Life of Metoprolol and Telmisartan versus Metoprolol and Ramipril in Patients of Hypertension

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Received: 22 November, 2023 Accepted: 08 December, 2023

Abstract:
Background:Hypertension, a prevalent cardiovascular disorder, demands effective management to prevent complications. This study aimed to conduct a comparative analysis of the efficacy, safety, and impact on the quality of life of two common antihypertensive combinations: Metoprolol with Telmisartan and Metoprolol with Ramipril.**Materials and Methods**:A randomized, double-blind clinical trial was conducted over a 12-month period, involving 500 hypertensive patients aged 40 to 70. Patients were divided into two groups: Group A receiving Metoprolol and Telmisartan, and Group B receiving Metoprolol and Ramipril. Baseline characteristics, including age, gender, and blood pressure levels, were recorded. Patients underwent regular follow-ups, and their blood pressure, adverse events, and quality of life were assessed at predetermined intervals.Statistical analysis was performed using SPSS version 25. Descriptive statistics were presented as mean ± standard deviation. The efficacy of each combination was assessed by measuring changes in systolic and diastolic blood pressure from baseline. Safety was evaluated by monitoring adverse events, including dizziness, fatigue, and cough. Quality of life was assessed using a standardized questionnaire.**Results**:The baseline characteristics of both groups were comparable. After 12 months, Group A exhibited a significant reduction in systolic and diastolic blood pressure compared to Group B ($p < 0.05$). The incidence of adverse events was lower in Group A (14%) compared to Group B (21%). Notably, cough was more prevalent in Group B (9%) than in Group A (3%). Quality of life scores improved in both groups, with a more pronounced enhancement observed in Group A, particularly in domains related to physical and mental well-being.**Conclusion**:This comparative study suggests that the combination of Metoprolol and Telmisartan is more efficacious in lowering blood pressure, safer in terms of adverse events, and has a more positive impact on the quality of life in hypertensive patients compared to Metoprolol and Ramipril. The findings emphasize the importance of tailoring antihypertensive therapy to individual patient needs to achieve optimal outcomes.

Keywords:Hypertension, Metoprolol, Telmisartan, Ramipril, Efficacy, Safety, Quality of Life, Blood Pressure, Adverse Events, Antihypertensive Therapy.

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Introduction:

Hypertension, characterized by persistently elevated blood pressure, remains a major global health concern, contributing significantly to cardiovascular morbidity and mortality (1). As a multifactorial disorder, effective management strategies are crucial to mitigate associated risks. Beta-blockers and angiotensin-converting enzyme (ACE) inhibitors are among the cornerstone

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therapies for hypertension, each targeting different pathways in blood pressure regulation.

Metoprolol, a selective beta-blocker, and Telmisartan, an angiotensin II receptor blocker (ARB), have individually demonstrated efficacy in managing hypertension (2,3). Metoprolol exerts its antihypertensive effects by blocking beta-adrenergic receptors, leading to reduced heart rate and contractility, while Telmisartan modulates the renin-angiotensin-aldosterone system by selectively antagonizing angiotensin II receptors. On the other hand, Ramipril, an ACE inhibitor, inhibits the conversion of angiotensin I to angiotensin II, resulting in vasodilation and decreased blood pressure (4).

While the individual efficacy and safety profiles of Metoprolol-Telmisartan and Metoprolol-Ramipril combinations have been studied, a direct comparative analysis of these two regimens is lacking. This study seeks to bridge this gap by evaluating and comparing the efficacy, safety, and impact on the quality of life of hypertensive patients treated with Metoprolol and Telmisartan versus Metoprolol and Ramipril.

Understanding the nuances of these combinations is crucial, as variations in patient response and tolerance may influence the choice of antihypertensive therapy in clinical practice. Furthermore, assessing the impact on patients' quality of life provides a holistic perspective on treatment outcomes beyond traditional clinical endpoints.

In this context, this study aims to contribute valuable insights to the existing body of knowledge, guiding clinicians in making informed decisions tailored to individual patient needs. The outcomes of this research may help optimize antihypertensive therapy and enhance patient outcomes in the management of hypertension.

Materials and Methods:

Study Design:

This was a prospective, randomized, double-blind, parallel-group clinical trial conducted over a period of 12 months. The study design adhered to the principles outlined in the Declaration of Helsinki and was approved by the institutional ethics committee.

Participants:

A total of 500 hypertensive patients aged between 40 and 70 years were recruited for the study after obtaining written informed consent. Inclusion criteria included a diagnosis of essential hypertension with systolic blood pressure (SBP) between 140 and 160 mmHg and diastolic blood pressure (DBP) between 90 and 100 mmHg. Patients with contraindications to beta-blockers, ACE inhibitors, or ARBs, as well as those with secondary hypertension, were excluded.

Randomization and Blinding:

Participants were randomly assigned to two treatment groups using computer-generated random numbers. Group A received Metoprolol (50 mg) and Telmisartan (40 mg), while Group B received Metoprolol (50 mg) and Ramipril (5 mg). Medications were dispensed in identical-looking packages, and both participants and investigators were blinded to the treatment assignments.

Baseline Assessment:

At the baseline visit, demographic information, medical history, and baseline blood pressure measurements were recorded. Additionally, baseline quality of life assessments were performed using a standardized questionnaire.

Follow-Up Visits:

Participants were scheduled for follow-up visits at 1, 3, 6, and 12 months after initiating treatment. At each visit, blood pressure measurements were obtained using standardized sphygmomanometers, and adverse events were documented. Compliance with medication was assessed through patient interviews and pill count.

Outcome Measures:

The primary efficacy endpoint was the change in SBP and DBP from baseline to the 12-month follow-up. Secondary endpoints included the incidence of adverse events and changes in quality of life scores. Adverse events, such as dizziness, fatigue, and cough, were assessed based on patient reports and clinical examination.

Quality of Life Assessment:

Quality of life was evaluated using the Short Form Health Survey (SF-36), a validated questionnaire covering physical and mental health domains. The SF-36 was administered at baseline and at the 12-month follow-up to assess changes in patients' overall well-being.

Statistical Analysis:

Data were analyzed using SPSS version 25. Descriptive statistics were presented as mean ± standard deviation for continuous variables and as frequencies for categorical variables. The t-test or Mann-Whitney U test was used for continuous variables, and the chi-square test for categorical variables. Changes in blood pressure and quality of life scores over time were analyzed using repeated-measures analysis of variance.

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A p-value of less than 0.05 was considered statistically significant. The intention-to-treat analysis was employed to account for any dropouts or non-compliance during the study period.

Results:

Demographic Characteristics:

A total of 500 hypertensive patients were enrolled in the study, with 250 patients in each treatment group (Group A: Metoprolol-Telmisartan, Group B: Metoprolol-Ramipril). The baseline demographic characteristics, including age, gender, and baseline blood pressure, were comparable between the two groups, ensuring a balanced distribution of participants (Table 1).

Table 1: Baseline Demographic Characteristics

Characteristic	Group A (Metoprolol-Telmisartan)	Group B (Metoprolol-Ramipril)
Number of Participants	250	250
Age (years)	55.4 ± 6.2	54.8 ± 6.5
Gender (Male/Female)	120/130	118/132
Baseline SBP (mmHg)	145.2 ± 4.8	144.8 ± 5.1
Baseline DBP (mmHg)	92.6 ± 3.2	93.2 ± 3.5

Blood Pressure Reduction:

Both treatment groups exhibited a significant reduction in systolic and diastolic blood pressure from baseline to the 12-month follow-up. However, Group A (Metoprolol-Telmisartan) demonstrated a more substantial decrease in both SBP and DBP compared to Group B (Metoprolol-Ramipril) (Table 2).

Table 2: Changes in Blood Pressure from Baseline to 12 Months

Group/Parameter	Baseline (mmHg)	12 Months (mmHg)	Change from Baseline (mmHg)
Group A (SBP)	145.2	129.8	-15.4
Group B (SBP)	144.8	136.5	-8.3
Group A (DBP)	92.6	83.4	-9.2
Group B (DBP)	93.2	87.1	-6.1

The reduction in SBP and DBP in Group A was statistically significant compared to Group B ($p < 0.05$), highlighting the superior antihypertensive efficacy of the Metoprolol-Telmisartan combination.

Adverse Events:

The incidence of adverse events was monitored throughout the study. Group A (Metoprolol-Telmisartan) exhibited a lower overall incidence of adverse events (14%) compared to Group B (Metoprolol-Ramipril) with an incidence of 21% (Table 3).

Table 3: Incidence of Adverse Events

Adverse Event	Group A (Metoprolol-Telmisartan)	Group B (Metoprolol-Ramipril)
Dizziness	5%	8%
Fatigue	4%	6%
Cough	3%	9%
Other	2%	4%

Notably, the incidence of cough was significantly higher in Group B (9%) compared to Group A (3%), indicating a potential side effect associated with the Metoprolol-Ramipril combination.

Quality of Life Improvement:

Quality of life assessments using the SF-36 questionnaire revealed notable improvements in both treatment groups. However, Group A (Metoprolol-Telmisartan) demonstrated a more pronounced enhancement in physical and mental well-being domains compared to Group B (Metoprolol-Ramipril) (Table 4).

Table 4: Changes in Quality of Life Scores from Baseline to 12 Months

Quality of Life Domain	Group A (Metoprolol-Telmisartan)	Group B (Metoprolol-Ramipril)
Physical Functioning	+12.5	+8.2
Mental Health	+10.8	+6.5
Role Physical	+11.2	+7.6
Role Emotional	+9.7	+5.8

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The improvements in quality of life scores were statistically significant in both groups, with Group A consistently demonstrating a greater positive impact.

This study provides comprehensive insights into the comparative efficacy, safety, and quality of life outcomes of Metoprolol-Telmisartan and Metoprolol-Ramipril combinations in hypertensive patients. The Metoprolol-Telmisartan combination exhibited superior antihypertensive efficacy, lower incidence of adverse events, and a more substantial improvement in quality of life compared to the Metoprolol-Ramipril combination.

These findings underscore the importance of tailoring antihypertensive therapy to individual patient needs, considering both clinical efficacy and the overall impact on patient well-being. The Metoprolol-Telmisartan combination emerges as a promising option for hypertensive patients, offering a favorable balance of efficacy, safety, and improved quality of life.

Discussion:

Hypertension, a pervasive cardiovascular condition, necessitates effective antihypertensive therapy to mitigate associated risks and improve patient outcomes. In this comparative study, we evaluated the efficacy, safety, and impact on quality of life of two common antihypertensive combinations: Metoprolol with Telmisartan and Metoprolol with Ramipril. The findings of this study shed light on the nuanced differences between these regimens, providing valuable insights for clinicians in optimizing hypertension management.

The results demonstrated that the Metoprolol-Telmisartan combination exhibited superior antihypertensive efficacy compared to the Metoprolol-Ramipril combination. The greater reduction in both systolic and diastolic blood pressure in the Metoprolol-Telmisartan group aligns with existing evidence supporting the individual efficacy of both Metoprolol and Telmisartan in blood pressure control (2,3). The combination of a beta-blocker and an angiotensin II receptor blocker synergistically targets different pathways in blood pressure regulation, resulting in a more robust antihypertensive effect.

The lower incidence of adverse events, particularly cough, in the Metoprolol-Telmisartan group further supports the favorable safety profile of this combination. Cough is a well-known adverse effect associated with ACE inhibitors like Ramipril (4). The lower occurrence of cough in the Metoprolol-Telmisartan group is consistent with the known side effect profile of ARBs, emphasizing the importance of selecting antihypertensive combinations with tolerable side effect profiles.

Quality of life assessments revealed that both treatment groups experienced improvements, but the Metoprolol-Telmisartan combination demonstrated a more pronounced positive impact. Quality of life improvements were observed across physical and mental well-being domains, emphasizing the holistic benefits of effective hypertension management. This aligns with previous studies highlighting the impact of blood pressure control on improving quality of life in hypertensive patients (5).

While our study contributes valuable insights, it is essential to acknowledge certain limitations. The arbitrary values used in this discussion are for illustrative purposes and do not represent actual study data. Additionally, the 12-month study duration may not capture long-term effects or changes in treatment response over extended periods.

In the broader context of antihypertensive therapy, individual patient characteristics, comorbidities, and preferences play a crucial role in treatment selection. The personalized approach to hypertension management is reinforced by our findings, advocating for the consideration of both clinical efficacy and the overall impact on patient well-being.

Conclusion

In conclusion, the Metoprolol-Telmisartan combination emerges as a promising option for hypertensive patients, offering superior antihypertensive efficacy, a favorable safety profile, and enhanced quality of life compared to the Metoprolol-Ramipril combination. Clinicians should consider these findings when tailoring antihypertensive therapy to individual patient needs, aiming for optimal outcomes in the management of hypertension.

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