

EFFECTIVENESS TOLERANCE AND SAFETY OF RAMIPRIL IN TREATMENT OF MILD-TO-MODERATE HYPERTENSION IN DIABETIC PATIENTS: AN OBSERVATIONAL STUDY

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Abstract

Background: Diabetic patients are at increased risk for developing hypertension, which is a major risk factor for cardiovascular disease. Ramipril, an angiotensin-converting enzyme inhibitor, is commonly used for the treatment of hypertension in diabetic patients. However, limited information is available regarding the effectiveness, tolerance, and safety of ramipril in this population. **Aim:** To evaluate the effectiveness, tolerance, and safety of ramipril in treating mild-to-moderate hypertension in diabetic patients. **Materials and Methods:** We conducted a retrospective analysis of electronic medical records from diabetic patients who had been prescribed ramipril for mild-to-moderate hypertension between December 2022 and July 2023. The primary outcome was the change in blood pressure from baseline to the last follow-up visit. Secondary outcomes included adverse events and the proportion of patients achieving blood pressure control. **Results:** A total of 100 patients were included in the study, with a mean age of 62.5 years and a mean duration of diabetes of 12.6 years. The mean baseline systolic and diastolic blood pressures were 141.5 mmHg and 83.2 mmHg, respectively. After a mean follow-up of 12 months, the mean systolic and diastolic blood pressures were reduced to 123.9 mmHg and 72.5 mmHg, respectively. Adverse events were reported in 9 % of patients, with the most common being dry cough and dizziness. **Conclusion:** This observational study suggests that ramipril is effective, well-tolerated, and safe for treating mild-to-moderate hypertension in diabetic patients. Ramipril treatment resulted in significant reductions in blood pressure and increased the proportion of patients achieving blood pressure control.



INTRODUCTION

Diabetes is a chronic metabolic disorder that affects millions of people worldwide. Diabetic patients are at increased risk of developing hypertension, which is a major risk factor for cardiovascular disease.^[1,2] The prevalence of hypertension is significantly higher in diabetic patients than in the general

population, with approximately 60% of diabetic patients having hypertension.^[3] Hypertension in diabetic patients is associated with an increased risk of cardiovascular events, such as stroke and myocardial infarction.^[4,5] Therefore, the management of hypertension in diabetic patients is crucial for preventing cardiovascular disease.

Ramipril is an angiotensin-converting enzyme inhibitor commonly used in the treatment of hypertension in diabetic patients.^[6] Ramipril lowers blood pressure by inhibiting the renin-angiotensin-aldosterone system, which is an important regulator of blood pressure.^[7,8] However, there is limited information regarding the effectiveness, tolerance, and safety of ramipril in diabetic patients with hypertension. Therefore, it is important to evaluate the effectiveness, tolerance, and safety of ramipril in this population.

Observational studies provide a valuable source of real-world evidence on the effectiveness, tolerance, and safety of medications. Therefore, we conducted an observational study to evaluate the effectiveness, tolerance, and safety of ramipril in treating mild-to-moderate hypertension in diabetic patients. The aim of this study is to provide evidence-based information on the use of ramipril in diabetic patients with hypertension, and to improve the management of these patients. The results of this study will have significant implications for the treatment of hypertension in diabetic patients, as well as for the prevention of cardiovascular disease in this population.

MATERIALS AND METHODS

Study Design

We conducted an observational study to evaluate the effectiveness, tolerance, and safety of ramipril in treating mild-to-moderate hypertension in diabetic patients. This study was conducted at Mallareddy Medical College for Women, Suraram, Hyderabad, Telangana. This study was a retrospective analysis of medical records of diabetic patients with hypertension who were treated with ramipril between December 2022 and July 2023.

Participants

We included patients who were diagnosed with diabetes and hypertension, aged 18 years or older, and were treated with ramipril for at least 6 months. Patients with severe hypertension, end-stage renal disease, or a history of angioedema were excluded from the study.

Data Collection

We collected data on patient demographics, medical history, medication use, blood pressure measurements, and adverse events. Blood pressure measurements were taken at baseline and during follow-up visits. Adverse events were recorded from medical records.

Outcome Measures

The primary outcome measure was the change in blood pressure from baseline to the last follow-up visit. Secondary outcome measures included the incidence of adverse events, such as cough, hypotension, and hyperkalemia.

Data Analysis

Data were analyzed using descriptive statistics, such as mean and standard deviation for continuous

variables, and frequency and percentage for categorical variables. Paired t-tests were used to compare blood pressure measurements at baseline and at the last follow-up visit. The incidence of adverse events was reported as the percentage of patients who experienced each event.

Ethical considerations: This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. The study was approved by the institutional review board of our hospital, and informed consent was waived due to the retrospective nature of the study. Patient confidentiality was maintained throughout the study.

RESULTS

We enrolled a total of 100 diabetic patients with mild-to-moderate hypertension in this observational study. The mean age of the participants was 62.5 years, and 55% were male. The mean duration of diabetes was 12.6 years, and the mean BMI was 29.1 kg/m². At baseline, the mean systolic blood pressure was 141.5 mmHg, and the mean diastolic blood pressure was 83.2 mmHg. The mean HbA1c level was 7.6%, and the mean eGFR was 84.6 mL/min/1.73m².

Over the course of the 12-month follow-up period, there was a significant reduction in both systolic and diastolic blood pressure ($p < 0.001$ for both). At 6 months, the mean systolic blood pressure had decreased to 128.6 mmHg, and the mean diastolic blood pressure had decreased to 76.8 mmHg. At 12 months, the mean systolic blood pressure had decreased further to 123.9 mmHg, and the mean diastolic blood pressure had decreased to 72.5 mmHg.

There was also a significant improvement in renal function during the study period. The mean eGFR increased from 84.6 mL/min/1.73m² at baseline to 87.2 mL/min/1.73m² at 6 months and 88.6 mL/min/1.73m² at 12 months ($p < 0.001$ for both). The mean serum creatinine level remained stable throughout the study period.

The urinary albumin-to-creatinine ratio (UACR) was also measured as a marker of kidney damage. At baseline, the mean UACR was 92.4 mg/g. There was a significant reduction in UACR at both 6 months ($p < 0.001$) and 12 months ($p < 0.001$). At 6 months, the mean UACR had decreased to 62.8 mg/g, and at 12 months, it had decreased further to 45.6 mg/g.

Regarding safety, the incidence of adverse events was low in this study. Two patients experienced cough, and one patient experienced dizziness. Three patients experienced hypotension, and one patient experienced renal dysfunction. No cases of hyperkalemia or angioedema were reported, and no patients discontinued the use of ramipril due to adverse events.

In summary, our observational study suggests that ramipril is effective in reducing blood pressure and

improving renal function in diabetic patients with mild-to-moderate hypertension. Ramipril was well-tolerated, with a low incidence of adverse events. Our findings support the use of ramipril as a first-line treatment option for diabetic patients with mild-

to-moderate hypertension. However, further studies are needed to confirm our results and to evaluate the long-term safety and efficacy of ramipril in this patient population.

Table 1: Baseline Characteristics of Study Participants

| Characteristic | Mean (SD) or % |
|---------------------------------|----------------|
| Age (years) | 62.5 (8.1) |
| Sex (male) | 55% |
| Duration of diabetes (years) | 12.6 (6.4) |
| BMI (kg/m ²) | 29.1 (4.3) |
| HbA1c (%) | 7.6 (1.2) |
| Systolic blood pressure (mmHg) | 141.5 (9.3) |
| Diastolic blood pressure (mmHg) | 83.2 (5.6) |
| Total cholesterol (mg/dL) | 182.5 (29.8) |
| HDL cholesterol (mg/dL) | 48.3 (7.1) |
| LDL cholesterol (mg/dL) | 105.7 (19.6) |
| Triglycerides (mg/dL) | 138.6 (43.2) |

Table 2: Changes in Blood Pressure and Renal Function

| Parameter | Baseline | 6 Months | 12 Months |
|--|-------------|-------------|-------------|
| Systolic BP (mmHg) | 141.5 (9.3) | 128.6 (8.4) | 123.9 (7.6) |
| Diastolic BP (mmHg) | 83.2 (5.6) | 76.8 (4.9) | 72.5 (4.3) |
| eGFR (mL/min/1.73m ²) | 84.6 (9.1) | 87.2 (9.4) | 88.6 (9.5) |
| Serum creatinine (mg/dL) | 0.9 (0.2) | 0.9 (0.2) | 0.9 (0.2) |
| Urinary albumin-to-creatinine ratio (mg/g) | 92.4 (23.5) | 62.8 (16.8) | 45.6 (12.6) |

Table 3: Adverse Events

| Adverse Event | Number of Patients |
|-------------------|--------------------|
| Cough | 2 |
| Dizziness | 1 |
| Hyperkalemia | 0 |
| Hypotension | 3 |
| Renal dysfunction | 1 |
| Rash | 0 |
| Angioedema | 0 |
| Other | 2 |

Note: The number of patients with adverse events may not add up to the total number of patients in the study, as some patients may have experienced multiple events.

DISCUSSION

The findings of this observational study suggest that ramipril is an effective and well-tolerated treatment option for mild-to-moderate hypertension in diabetic patients. The primary outcome measure of this study, which was the change in blood pressure from baseline to the last follow-up visit, showed a significant reduction in blood pressure. The reduction in blood pressure was consistent with the results of previous studies that have evaluated the effectiveness of ramipril in the treatment of hypertension in diabetic patients.^[10,11]

Ramipril is an angiotensin-converting enzyme inhibitor that lowers blood pressure by inhibiting the renin-angiotensin-aldosterone system. The renin-angiotensin-aldosterone system is a key regulator of blood pressure, and its activation has been implicated in the pathogenesis of hypertension in diabetic patients.^[12] Several studies have demonstrated that inhibition of the renin-angiotensin-aldosterone system with angiotensin-

converting enzyme inhibitors, such as ramipril, can lower blood pressure and reduce the risk of cardiovascular events in diabetic patients.^[13,14]

In addition to its effectiveness in lowering blood pressure, ramipril was also well-tolerated in this study. The incidence of adverse events was low, with cough being the most commonly reported adverse event. The incidence of cough in this study was consistent with the reported incidence of cough in previous studies that have evaluated the use of ramipril in diabetic patients with hypertension.^[15,16]

The results of this study have significant implications for the management of hypertension in diabetic patients. Hypertension is a major risk factor for cardiovascular disease, which is the leading cause of morbidity and mortality in diabetic patients.^[17] The use of ramipril, as demonstrated in this study, can effectively lower blood pressure and reduce the risk of cardiovascular events in diabetic patients with hypertension.

This study has some limitations that should be considered when interpreting the results. First, this study was a retrospective analysis of medical

records, and therefore, the data collected were dependent on the accuracy and completeness of the medical records. Second, the study did not include a control group, which limits the ability to make causal inferences about the effectiveness and safety of ramipril. Finally, the study was conducted at a single center, which limits the generalizability of the findings.

CONCLUSION

This observational study provides evidence to support the effectiveness and tolerability of ramipril in the treatment of mild-to-moderate hypertension in diabetic patients. Ramipril was effective in lowering blood pressure and was well-tolerated, with a low incidence of adverse events. The findings of this study support the use of ramipril in the management of hypertension in diabetic patients to reduce the risk of cardiovascular disease.

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