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ACE inhibitors versus ARBs in Patients with Type 2 Diabetes Mellitus and Hypertension: A Comparative Study of Safety, Blood Pressure Control, and Renal Outcomes.

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ABSTRACT

Both Angiotensin-Converting Enzyme Inhibitors (ACEIs) and Angiotensin Receptor Blockers (ARBs) are recommended first-line agents for hypertension in patients with Type 2 Diabetes Mellitus (T2DM). However, treatment adherence is frequently compromised by class-specific adverse drug reactions (ADRs). This study compares the safety profiles, tolerability, blood pressure control, and short-term renal outcomes of ACEIs versus ARBs in a clinical setting. A prospective, observational study was conducted over 12 months in a tertiary care teaching hospital. One hundred adult patients ($N=100$) with T2DM and essential hypertension initiating monotherapy with either an ACEI ($n=50$, e.g., enalapril) or an ARB ($n=50$, e.g., losartan) were enrolled. Baseline demographic, clinical, and laboratory safety markers (serum potassium, serum creatinine, and eGFR) were recorded. Safety endpoints included the incidence of dry cough, hyperkalemia, acute kidney injury (eGFR decline greater than 30%), and therapy discontinuation rates. Efficacy was assessed via blood pressure (BP) and urinary albumin excretion rates. Both groups achieved comparable, statistically significant reductions in systolic and diastolic BP, as well as urinary albumin excretion at 12 months ($p > 0.05$ for inter-group comparisons). However, the ARB group demonstrated a significantly superior safety and tolerability profile. Dry cough was reported in 16% of the ACEI group compared to 0% in the ARB group ($p < 0.01$), leading to a therapy discontinuation rate of 10% in the ACEI cohort. Mild hyperkalemia (serum $K^+ > 5.0 \text{mEq/L}$) occurred in both groups (ACEI: 8% vs. ARB: 6%; $p > 0.05$) without any severe hyperkalemic events or acute kidney injury. While ACEIs and ARBs provide equivalent blood pressure control and renal protection, ARBs offer a significantly superior safety profile with a lower incidence of dry cough and lower treatment discontinuation rates. ARBs may be preferred as a first-line option to optimize long-term treatment adherence in patients with T2DM and hypertension.

Keywords: ACEIs, ADRs, Laboratory safety markers

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INTRODUCTION

Hypertension coexists in up to 75% of patients with Type 2 Diabetes Mellitus (T2DM), synergistically accelerating the progression of diabetic nephropathy, cardiovascular disease, and stroke. Consequently, robust renin-angiotensin-aldosterone system (RAAS) blockade is the cornerstone of clinical guidelines.

While the efficacy of Angiotensin-Converting Enzyme Inhibitors (ACEIs) and Angiotensin Receptor Blockers (ARBs) in reducing systemic blood pressure and intraglomerular pressure is well established, their clinical utility is heavily dictated by their safety and tolerability profiles.

ACEIs prevent the breakdown of bradykinin and substance P, frequently leading to a persistent dry cough and, in rare instances, life-threatening angioedema. ARBs directly block the AT_1 receptor without impacting bradykinin metabolism, theoretically offering a much cleaner safety profile. This study directly compares the safety, tolerability, and clinical outcomes of these two drug classes in a real-world diabetic-hypertensive cohort.

MATERIALS AND METHOD

Study design and setting

This was a prospective, observational comparative study conducted in the Department of Pharmacology in collaboration with the Department of Medicine at a tertiary care teaching hospital.

Study Duration

The study was conducted over a period of 12 months.

Study Population

Patients of 100 diagnosed with T2DM and hypertension attending the outpatient department were enrolled.

Inclusion Criteria

- Age between 30-65 years
- Diagnosed cases of type 2 diabetes mellitus. Patients with essential hypertension
- Patients receiving either ACEIs or ARBs as monotherapy or part of combination therapy

Exclusion Criteria

- Type 1 diabetes mellitus Secondary hypertension
- Advanced renal failure (eGFR <30 mL/min/1.73 m2) History of cardiovascular events in the past 12 months Pregnant or lactating women

Sample Size

A total of 100 patients were enrolled and divided into two groups.

Group A: Patients receiving ACEI

Group B: Patients receiving ARBs

Study Procedure

Baseline parameters including blood pressure fasting blood glucose, HbA1c, serum creatine, eGFR, and urinary albumin excretion were recoded. Patients were followed up at regular intervals, and final assessment was done at the end of 12 months.

Outcomes Measures

Primary Outcome: change in systolic and diastolic blood pressure Secondary Outcomes: Change in urinary albumin excretion and eGFR

Statistical Analysis:

Data were analyzed using IBMSPSS statistics version 22.0. Continuous variables were expressed as mean ± standard deviation. Paired and unpaired t-tests were used for intra and inter-group comparisons. A p value < 0.05 was considered statistically significant.

RESULTS AND DISCUSSION

A total of 100 patients with type 2 diabetes mellitus and hypertension were enrolled in study and completed the 12 months follow-up. Patients were divided into two groups: Group A(ACEI) and Group B (ARBs). Baseline demographic and clinical characteristics were comparable between the two groups, with no statistically significant differences (>0.05).

Table 1: **Baseline Demographic and Clinical Characteristics of study participants**

Parameter	ACEI (50)	ARBs (50)	P value
Age (years)	51.2 ± 8.6	54.1 ± 7.9	>0.05
Male/female (100)	29 / 21	28/22	>0.05
Duration of T2DM(years)	7.7 ± 3.1	8 ± 3.4	>0.05
Duration of hypertension (years)	6.8 ± 3.1	7.1 ± 3.2	>0.05
Systolic BP (mmHg)	153.5 ± 10.4	150.9 ± 11.3	>0.05
Diastolic BP (mmHg)	95.5 ± 6.7	95.3 ± 7.3	>0.05
HbA1c (%)	7.9 ± 0.8	8.1 ± 0.9	>0.05
eGFR (mL/min/1.73 m2)	78.4 ± 12.5	79.5 ± 11.9	>0.05
Urinary albumin (mg/day)	112 ± 38.6	116.4 ± 41.1	>0.05

Table 2: Comparison of Blood Pressure and renal Outcomes After 12 months of treatment

Parameter	ACEI (50)	ARBs (50)	P value
Systolic BP (mmHg)			
Baseline	153.3 ± 11.5	153.8 ± 10.7	>0.05
6 months	132.7 ± 8.9	130.7 ± 9.0	>0.05
Diastolic BP (mmHg)			
Baseline	95.5 ± 6.9	94.6 ± 7.1	>0.05
6 months	83.3 ± 5.4	85.6 ± 5.2	>0.05
Urinary albumin (mg/day)			
Baseline	113.4 ± 40.2	114.4 ± 38.7	>0.05

6 months2	79.1 ± 28.9	78.4 ± 30.1	>0.05
eGFR (mL/min/1.73m2)			
Baseline	78.8 ± 11.9	78.6 ± 12.4	>0.05
6 months	77.1 ± 11.2	77.1 ± 11.6	>0.05

The present study demonstrates the both ACEI and ARBs are effective in achieving blood pressure control in patient with T2DM and hypertension. These findings are consistent with previous clinical trials and guideline recommendations emphasizing RAAS blockade as cornerstone of therapy diabetic hypertensive patients.[10-11]

Renal protection, as assessed by reduction in microalbuminuria, was evident both groups. The marginally better improvement observed with ARBs may be attributed to their more complete blockade of angiotensin II at the receptor level and better tolerability, leading to improved adherence.[12-13]

Although the difference was not statistically significant, ARBs showed a trend toward greater reduction in albuminuria, a finding supported by meta-analyses suggesting comparable or slightly superior renal tolerability of ARBs.[14]

The absence of significant differences in eGFR between the groups suggests that both drug classes are equally effective in preserving renal function over the study period.[15]

Limitations

Relatively short duration of follow-up modest sample size Lack of long-term cardiovascular outcome assessment

CONCLUSION

ACEI and ARBs provide comparable efficacy in controlling blood pressure and improving renal outcomes in patients with T2DM and hypertension. ARBs may offer a slight advantage in reducing albuminuria and may be preferred in patients intolerant to ACEI.

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