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Original Article

Multi-Centered Prospective Observational Study on Prescribing Pattern of Anti-Hypertensives in Diabetes Mellitus Type 2 and Chronic Kidney Disease Patients in Eastern Districts of Telangana

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ABSTRACT

Background: The most prevalent lifestyle diseases are Diabetes Mellitus type 2 (DM2) and Hypertension (HTN), especially in older age groups, which leads to Chronic Kidney Disease (CKD) as the most possible comorbidity. Management of HTN involves various drugs with fixed doses and combinations, while specialized regimens are implemented for patients with other comorbidities like DM2 and CKD. Treatment of blood pressure in diabetics is complicated and requires combinational therapy with regular monitoring of both blood pressure and blood glucose to prevent diabetic nephropathy. Chronic Kidney Disease (CKD) describes the gradual loss of kidney function, and it is the major complication of DM and HTN. Management of CKD involves determining the cause of disease and eliminating or controlling it, with most CKD cases intensified by HTN, DM, infections, hypovolemic conditions, and salt intake. Despite the fact that lifestyle modifications and pharmacological interventions are frequently necessary to achieve the best blood pressure goals in patients with diabetes and CKD. **Materials and Methods:** This cross-sectional study collected data on 300 patients, of whom 200 had type 2 diabetes and 100 had CKD as concomitant diseases and were regularly using anti-hypertensives. **Results:** The results of our study are astonishing because minimizing or avoiding risk factors like alcohol and smoking have improved the patient condition significantly in both DM2 and CKD, along with HTN. Starting with ACEi and ARBs initially had a great impact on achieving the blood pressure goal in DM2. Specific beta blockers are recommended in patients with CVD risk. Salt restriction, using antihypertensives like ARBs, and CCBs are used predominantly to treat blood pressure and proteinuria in CKD patients. Diuretics are implemented to treat symptoms like edema and low urine output, to reduce fluid overload on the heart, and to prevent heart failure. **Conclusion:** The clinical pharmacist plays an important role in designing the therapeutic regimen and lifestyle changes for the best patient outcome.

Keywords: Prescribing pattern, Anti-hypertensives, Diabetes type 2, Hypertension, Chronic kidney disease

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INTRODUCTION

The most prevalent lifestyle diseases are Hypertension (HTN) and Diabetes Mellitus type 2 (DM2), especially in older age groups, which leads to Chronic Kidney Disease (CKD), the most possible comorbidity. All these conditions will hamper the patient's quality of life.

Hypertension is known as persistently elevated blood pressure.[1] Most of the cases are classified as essential hypertension.[2] Studies suggest that excessive salt intake, smoking, alcohol, genetics, chronic stress, and endocrine disorders are the major risk factors for HTN.[3,4] Adults in India generally have a 30% prevalence of hypertension, with 34% in urban areas and 28% in rural areas.[5] Management of HTN has various drugs with fixed doses and combinations; specialized regimens will be implemented in patients with other comorbidities like DM2 and CKD.[6] Diabetes is a chronic, metabolic disease which is characterized by elevated blood glucose (blood sugar) levels, which leads over time to serious complications like diabetic retinopathy, diabetic nephropathy, and diabetic neuropathy. Treating blood pressure

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in diabetics is complicated, and it requires combinational therapy with regular monitoring of blood glucose.[7] Along with medicine, patient education regarding diet, exercise plays a key role in regulating and maintaining normal blood glucose levels.

The gradual decrease of kidney function is known as Chronic Kidney Disease (CKD), which is also referred to as chronic kidney failure.[8] There are many etiological factors for CKD, but it is the major complication of DM and HTN. All three diseases cause the worst complications, like end-organ damage, poor quality of life, and disability with quality-adjusted life years. CKD is categorized into different stages, from stages 1 to 5, depending on the Glomerular Filtration Rate (GFR) ranging from 15 mL/min to 120 mL/min.[9] Management of CKD involves determining the cause of the disease and eliminating or controlling it. Most of the CKD cases are intensified by HTN, DM, infections, hypovolemic conditions, and salt intake. Avoiding risk factors like smoking is important because studies demonstrate that smoking decreases the GFR by nephrosclerosing, and alcohol will also hamper the functioning of the nephrons. The risk of cardiovascular mortality is independently increased by a decreased GFR and increased albuminuria.[10,11] According to reports, 85% to 95% of people with CKD (stages 3-5) develop HTN. The relationship between HTN and CKD is cyclic because uncontrolled HTN is a risk factor for developing CKD and vice versa, HTN with CKD is the second leading cause of ESRD (End Stage Renal Disease).[12] Numerous guidelines emphasize the need to lower Blood Pressure (BP) to mitigate the progression of kidney disease and reduce cardiovascular morbidity and mortality.[13] Recent evidence has proven a role for, Advanced Glycation End products (AGEs) and microRNAs (miRNAs) and hypertension as important risk factors for diabetes-associated vascular complications (vasculopathy of diabetes), because hypertension is a disease of vascular dysfunction and injury.[14]

The recent American Diabetes Association recommendations suggest setting a treatment goal of SBP less than 140 mmHg and DBP less than 90 mmHg for most diabetic patients. Higher cardiovascular risk individuals may require more stringent blood pressure control to keep their readings under 130/80 mmHg. ACCORD BP research, which examined CVD outcomes in diabetes patients who were randomly assigned to intensive versus less intensive blood pressure management.[15] Even though lifestyle changes like salt reduction, weight loss, increased physical activity, smoking cessation, and quality sleep are known to improve metabolic health and lower blood pressure in patients with diabetes, pharmacological interventions are frequently required to meet the best blood pressure goals in these patients.[16]

MATERIALS AND METHODS

Study Design

This is a prospective observational study.

Inclusion criteria

Includes Patients using anti-hypertensive medication along with other co-morbid conditions like diabetes Type-II, and chronic kidney disease.

Exclusion criteria

Patients who are not on regular antihypertensive drugs, patients with any psychiatric illness and patients who are not willing to participate in our study.

Sample size

A total of 300 cases were collected by using prepared data collection form.

Study period

The study was performed over a period of 6 months from March 2023 to September 2023.

Study location

Selected super specialty hospitals in eastern districts of Telangana.

Study Procedure

This study was conducted after Institutional Ethics Committee (IEC) approval then the patients were selected for the study by simple random sampling. Then the patients were categorized according to their disease condition.

Source of data

Patient case sheets and patient interview about their anti-hypertensive medication, co-morbidities, lifestyle and social habits, past medical history, lab investigations.

Assessing factors

Risk factors, complications, efficacy of anti-hypertensive drugs in DM, CKD, and Stages of CKD will be assessed by using crock croft gault equation.

Statistical plan

Statistical analysis will be carried out by Microsoft Office Excel.

Monitoring Parameters

Blood Pressure, Blood Glucose, Renal Functioning test, eGFR.

RESULTS

Based on our inclusion and exclusion criteria, we collected data on 300 patients, of whom 200 had type 2 diabetes and 100 had CKD as concomitant diseases and were regularly using antihypertensives.

Assessment of prescribing pattern of anti-hypertensive drugs in DM2 patients

A total of 200 cases were collected, of which 101 (50.5%) cases were men and the remaining 99 (49.5%) cases were women. The data was depicted in Table 1.

Most of our study participants are from rural areas, most of the men are alcoholics few had smoking with alcoholism irrespective of their residential status; the data was depicted in Table 2.

As part of our study assessment, we analyzed the prescribing pattern of antihypertensives in diabetes type 2 patients the data was presented in Table 3.

Prescribing Pattern Assessment of Antihypertensives in Chronic kidney disease patients (CKD)

Out of 300 patients 100 were CKD patients who are included in this study according to inclusion and exclusion criteria. The data was depicted in Table 4.

Alcohol and smoking are the major risk factors to develop kidney disease, we assessed the alcoholics and smokers in our study with respective to their residence status, the details are presented in Table 5.

We analyzed the prescribing pattern of anti-hypertensives in chronic kidney disease patients with anticipated outcome of improved glomerular filtration rate, stable blood pressure, improved quality of life, the prescribed anti hypertensives details are presented in Table 6.

DISCUSSION

Prescribing Pattern of Antihypertensives in Diabetes type II

As we are aware alcohol and smoking are most prevailing risk factors for hypertension, diabetes, in our study we had patients from both urban and rural areas with habit of both alcohol consumption and smoking in different age groups, the most fascinating point is women with alcohol consumption had more risk to develop diabetes at early age and with more incidence.[17,18]

Hypertension is a common co-morbidity in patients with type 2 diabetes. Managing hypertension to prevent complications in patients with diabetes requires appropriate pharmacotherapy; this prospective study evaluated the real-world status of antihypertensive drug prescribing for patients with hypertension along with comorbidity of diabetes mellitus. The most common drugs prescribed for hypertension with DM2 were Angiotensin II Receptor Blockers (ARBs) in 31.2% patients, Calcium channel blockers in 30% and beta blockers in 17% of the study population.[19] The Renin Angiotensin Aldosterone System (RAAS) plays an important role in the pathology of hypertension and also it is closely linked with cardio, cerebrovascular events and chronic kidney disease, so (ACEIs), (ARBs) are the most preferred first-line drugs to control hypertension among diabetic patients to prevent diabetic complications, early use of ARBs in HTN with DM2 shows renal system protecting effect by decreasing the proteinuria and improved quality of life was depicted in few studies.[20]

Beta-blockers are effective antihypertensive agents in long-term use, studies have proven beneficial in reducing cardiovascular problems, but few physicians argue that non-selective beta

Table 1: Age and Gender wise distribution of DM2 study population.

Age	Number of cases			Percentage
	Male	Female	Total	
30-40	9	11	20	10%
41-50	47	47	94	47%
51-60	25	22	47	23.5%
61-70	16	15	31	15.5%
71-80	4	4	8	4%
TOTAL	101	99	200	100%

Table 2: Status of Residence, Social Habits of DM2 Study Population.

Residence	Number of cases			Social Habits								
	Male (M)	Female (F)	Total	Alcoholics			Smokers			Alcohol+Smoking		
				(M)	(F)	Total	(M)	(F)	Total	(M)	(F)	Total
Rural	63	61	124	27	03	30	17	02	19	14	00	14
Urban	38	38	76	22	01	23	26	03	29	09	01	10
Total	101	99	200	49	04	53	43	05	48	23	01	24

blockers are contraindicated in DM2 patients because they may create unawareness of hypoglycemic effects caused by oral hypoglycemic agents using by patient for DM2, these also instigate negative effects on lipid metabolism, but recently developed selective beta blockers like metoprolol have proven its beneficial effect at low cost. In our study, only 2 patients are using carvedilol a non-selective beta blocker and experienced masking hypoglycemic effects which are similar observations stated in studies.[21] So we suggest using selective beta-blockers is no longer contraindicated because the benefit overweighed the risk.

Table 3: Prescribing Pattern Assessment of Anti-hypertensives in DM2 Patients.

Drugs Category	Drug Name	Number of doses	Percentage
Angiotensin 2 Receptor Blocker (ARBs)	Losartan	5	31.2%
	Olmesartan	5	
	Telmisartan	87	
Total ARBs		97	
Beta Blockers	Atenolol	10	17%
	Metoprolol	41	
	Carvedilol	2	
Total β Blockers		53	
Calcium Channel Blockers (CCBs)	Amlodipine	41	30%
	Cilnidipine	46	
	Diltiazem	1	
	Nifedipine	7	
Total CCBs		95	
Diuretics	Torsemide	13	17%
Thiazides	Chlorthalidone	10	
	Hydrochlorothiazide	30	
Total Diuretics		53	
Alpha Agonist	Clonidine	3	0.009%
Alpha Blocker	Prazosin	6	0.019%
Aldosterone Receptor Antagonist	Spironolactone	2	0.006%

Table 4: Age and gender wise distribution of CKD study population.

Age	Number of Cases			Percentage
	Male	Female	Total	
30-40	13	9	22	22%
41-50	8	9	17	17%
51-60	14	6	20	20%
61-70	16	6	22	22%
71-95	14	5	19	19%
TOTAL	65	35	100	100%

Table 5: Status of residence, social habits of CKD study population.

Residence	Number of cases			Social Habits								
	Male (M)	Female (F)	Total	Alcoholics			Smokers			Alcohol + Smoking		
				(M)	(F)	Total	(M)	(F)	Total	(M)	(F)	Total
Rural	50	24	74	23	02	25	09	00	09	18	00	18
Urban	15	11	26	11	00	11	10	00	10	08	00	08
Total	65	35	100	34	02	36	19	00	19	26	00	26

Table 6: Prescribing Pattern Assessment of Antihypertensives in CKD Patients.

Drug class	Drug name	Number of doses	Percentage
Alpha-2 Agonist	Moxonidine	6	4.88%
Alpha Blockers	Clonidine	3	2.44%
ARB's	Prazosin	30	24.39%
	Telmisartan	11	8.94%
Beta blockers	Metoprolol	8	6.50%
CCB's	Amlodipine	39	31.71%
	Cilnidipine	15	12.20%
	Diltiazem	1	0.81%
Loop Diuretics	Furosemide	5	4.07%
	Torsemide	5	4.07%
TOTAL		123	100%

Calcium Channel Blockers (CCBs) are preferred in patients with pre-existing cardiovascular diseases and HTN due to vascular resistance, we found that CCBs will reduce SBP of 5 mmHg especially in older population which is almost similar observation by studies.[22] We observed 4 patients reported headache after initiating amlodipine therapy due to cerebral blood vessel vasodilation, so we advise the health care fraternity to monitor the patient for hypotension symptoms before worsening of patient condition. Clinidipine is a calcium channel blocker which had long duration of action compare to amlodipine and it also inhibit renin angiotensin aldosterone system by sympathetic inhibition, we consider clinidipine is potent, advantageous than amlodipine in treating patients with DM2 and HTN. Thiazide diuretics are most preferable first-line drugs in treating HTN but concerning to diabetes patients it may create some metabolic adverse effects thiazides will reduce the risk of heart failure in patients with HTN along with DM2. We suggest using thiazides in special-risk population of Cardio Vascular Diseases (CVD) by monitoring them cautiously. The remaining antihypertensives had no significant role in treating HTN in diabetes mellitus type 2 patients.

Prescribing Pattern of Anti-hypertensives in CKD patients

Chronic alcohol consumption is the major reason for vital organ damage including kidney, but proper mechanism of alcohol and kidney impairment was not proven yet, there is indirect effect of alcohol on kidney by many mechanisms like alcohol causes DM, HTN, metabolic disorders and many other diseases which are most important risk factors of CKD, there is still a lacuna in this area, further studies are needed to establish the proper mechanism between alcohol and CKD including what percentage of alcohol damage the kidney is still yet to be prove in different populations. Smoking is associated with high incidence of CKD; increase the mortality rate by rapid progression in stages of CKD. Hypertension is the major risk factor for developing CKD and increase the risk of Cardiovascular Diseases (CVD), HTN will complicate the patients with ESRD and who are on dialysis so it is important to treat HTN to decrease the morbidity, mortality rate and it is important to understand the underlying mechanisms of various antihypertensives in treating HTN with CKD, because HTN is the preventable and modifiable risk factor of CKD. As we all know there are various antihypertensives with different pharmacological mechanisms to treat HTN, it is important to correlate these with CKD treatment. Non-pharmacological treatment like salt intake restriction, avoiding alcohol and smoking, maintaining healthy lifestyle, taking balanced diet had significant role in treatment, delaying the progression of stages in CKD.

Out of 100 cases, majority of CKD patients are using mono drug therapy i.e., 82% and remaining patients were using dual anti-hypertensive drug regimen i.e., 18% to maintain targeted blood pressure of 140/90 mmHg. Angiotensin receptor blockers are the most preferred first line antihypertensives for treating HTN in CKD patients, using ARBs as mono therapy will slow down the renal damage progression and prevent the CVDs and its associated mortality in CKD patients; few studies also suggest that ARBs or ACEi will decrease the proteinuria a major sign of kidney damage. Risk of hyperkalemia in using ARBs needed cautious monitoring. CCBs are second choice of drugs as either mono therapy or dual therapy in CKD patients.

CCBs gives best result with when they combine with ARBs or diuretics, these combinations will reduce the CVD associated mortality. Amlodipine is the prominent CCBs its long-acting nature gives best outcomes in reducing blood pressure for 24 hr with just single dose, amlodipine along with ARBs gives better outcome in CVD related endpoints. In our study 31.7% population are on amlodipine 6 patients are on combinational therapy with losartan had better outcome in controlling blood

pressure, proteinuria, renal disease progression, these results share some similarities with other studies.[23]

Diuretics are the most preferable antihypertensives in treating blood pressure but concerning CKD patient's diuretics are used to treat edema, fluid over load which will damage kidney functioning more rapidly and lead to ESRD or CVD. Thiazides are the first choice of diuretics and loop diuretics are reserved for treating heavy fluid over load patients with CVD, thiazides will improve glucose tolerance so better are prescribed for DM2 patients with CKD and HTN. In our study loop diuretics are prescribed for 8 patients among those 4 patients had comorbidity of heart failure with decreased urine output and hyperkalemia, as we all aware the side effect of loop diuretics is hypokalemia which increases the excretion of potassium in urine and help the patient to recover rapidly. But the ADRs associated with diuretics like dehydration, electrolyte imbalance, hyperuricemia are advised to be monitored carefully. Potassium sparing diuretics will be prescribed for hypokalemic patients. In our study 2 patients on diuretics are combined with ARBs gave better outcome in reducing proteinuria.

This study is limited to only few districts of Telangana; we cannot extrapolate this to large data. But up to our knowledge the results in our study had clinical significance with the pathology of diseases and symptoms. Upon tailor made therapeutic regimen and lifestyle modifications advised by the clinical pharmacist and physician had good impact in improving patient outcome in terms of morbidity, mortality, reduced complications, improved symptoms, better quality of life with less side effects at more affordable prescription.

CONCLUSION

Prescribing antihypertensive has to be tailor made for DM2 patients with respect to their age, clinical condition, response to the therapy, we suggest using first line medicine like ACE, ARBs has to be the first priority because they improve patient outcome by several means and reduce the risk of proteinuria, CVD associated mortality. Prescribing pattern of antihypertensives in CKD patients is important to regulate both HTN and other comorbidities like CVD, stroke, heart failure, and several other diseases. ARBs are the best first line therapy to treat HTN and proteinuria to prevent CKD associated complications. Calcium channel blockers especially amlodipine is the best long acting CCBs in CKD patients along with CVD, diuretics are preferred according to the clinical condition like edema, electrolyte imbalance. Clinical pharmacist plays a major role in designing therapeutic regimen and suggesting about non pharmacological interventions to improve patient clinical outcome and optimise the quality of life at best.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DM2: Diabetes Mellitus Type II; **HTN:** Hypertension; **CKD:** Chronic Kidney Disease; **GFR:** Glomerular Filtration Rate; **ACEi:** Angiotensin converting enzyme inhibitors; **ARBs:** Angiotensin receptor blockers; **CCB:** Calcium channel blocker; **BP:** Blood pressure; **AGEs:** Advanced glycosylated end products; **miRNAs:** Micro RNA; **SBP:** Systolic blood pressure; **CVD:** Cardio vascular diseases; **IEC:** Institutional ethics committee; **RAAS:** Renin Angiotensin Aldosterone System; **ESRD:** End Stage Renal Disease.

ETHICAL APPROVAL

This study was conducted after obtaining approval from Institutional Ethics Committee.

PATIENT CONSENT

This study was conducted after explaining the study procedure and protocol details to the study participants in their local language and obtaining informed consent from them.

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