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AN OBSERVATIONAL PROSPECTIVE STUDY ON EVALUATION OF PRESCRIPTION PATTERNS OF ANTIHYPERTENSIVE AGENTS IN TYPE 2 DIABETES MELLITUS ASSOCIATED WITH OR WITHOUT COMORBIDITIES

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ABSTRACT

Background: According to International Diabetes Federation- Diabetes Atlas 10th edition (2021) number of people with diabetes mellitus in south Asia are currently around 90 million and was predicted to 151.5 million by 2045. **Aim:** The main intention of the study is to evaluate the prescription patterns of antihypertensive in diabetes mellitus 2 connected with or without other disease and compute the blood pressure control and analyses the use of preferred antihypertensive therapy according to the JNC 8 guidelines. **Materials and Methods**: About 250 patients receiving antihypertensive and meeting the exclusion and inclusion criteria are assessed by observational study for 6 months. Data was collected in specially designed data collection form containing patient demographic details, past medication history, associated comorbidities. And the collected result was finally assessed with a statistical tool chi- square test by comparing the BP assessment in patients with anti- hypertensive prescriptions based on JNC8 guidelines. **Results**: Among 250 patients 150(62%) were treated with monotherapy and 92(38%) patients were prescribed with combination therapy, among 62% of patients using monotherapy 45% were on angiotensin receptor blocker, 28% were on beta blocker, 21% were on calcium channel blockers and 32% of patients were prescribed with two drug combination therapy other 6% of subjects are prescribed with more than 2 drug combination. Among the whole collected data 80% of population were treated effectively for their blood pressure management and Majority of the prescriptions were according to guidelines. **Conclusion**: 80% of population have effectively treated with antihypertensive therapy and majority of the prescriptions followed the guidelines although 20% of the population's blood pressure was not in control

KEYWORDS: Antihypertensive drugs, Monotherapy. Combination therapy, JNC8 guidelines, Blood pressure.

INTRODUCTION

Diabetes mellitus and hypertension have evolved as modern day epidemics affecting millions of people around the world. These are the two common comorbidities resulting to significant increase in cardiovascular disease, which now became the major cause of morbidity and mortality of the adult population.[1] According to International Diabetes Federation- Diabetes Atlas 10th edition (2021) number of people with diabetes mellitus in south Asia are currently around 90 million and was predicted to 151.5 million by 2045. The incidence of hypertension in patients with type 2 Diabetes mellitus is approximately two fold higher than in subjects without diseases.[2] Controlling hypertension is most important to retrieve vascular risk among diabetic hypertensive subjects.[3]

According to the eighth report of JNC hypertension can be explained as perpetual increase in arterial blood pressure (>140/90 mmhg). Elevation of blood pressure is identified as one of the most crucial risk factors for cardiovascular disease and also for the development of micro and macro vascular complications like neuropathy. nephropathy, retinopathy, coronary artery disease, stroke, peripheral vascular diseases.[4] Approximately 31% of the population have high blood pressure (>=140/90 mmhg).[5] Based on etiology factors hypertension is classified into primary and secondary hypertension. More than 90% of the individuals affected with primary

hypertension with unidentifiable cause thus called idiopathic hypertension.[6] About 10% are affected with Secondary hypertension caused by the use of drugs (NSAIDS) and diseases (CKD).[7] Pharmacological treatment of hypertension without any compelling indications is thiazide type diuretics as first choice and ACE inhibitors, ARB, CCB are second line drugs. Whereas hypertension with compelling indications like diabetes is treated with ACE or ARB, CKD with ACE or ARB and for coronary diseases beta blockers are the first choice.[8]

Thus enhancing awareness and diagnosis of hypertension and improving control of blood pressure with appropriate treatment are considered as critical public health initiatives to reduce cardiovascular morbidity and mortality*.[4] In this study we aim to evaluate the utilization of preferred antihypertensive therapy based on JNC VII guidelines as an agent to treat diabetic hypertension with or without comorbidities.

MATERIALS AND METHODS

This is an observational study of the duration of 6 months in the endocrinology department at Kamineni hospital. Patients were confirmed by physicians diagnosed with Hypertension, Diabetes mellitus type 2 and other comorbidities, were further examined consecutively for social, demographical, and clinical variables for evaluation of patterns of antihypertensive. A data collection form will be designed and approved by the hospital preceptor to collect the subject's demographic and disease specific aspects Like age, gender, past medication history, present medical history, associated comorbidities, and monitoring parameters.

Inclusion criteria were the patient's diagnosed with hypertension and Diabetes mellitus type 2 with or without associated comorbidities. Patients under 18 years or above 80 years, pregnant, lactating women are excluded from the study.

Statistical analysis

The data were statistically analysed by using MS-EXCEL and statistical package for social sciences (SPSS Version -22, IBM) software. Statistical tool chi-square test was executed to estimate the p value between the different collected data like age versus gender, bp evaluation versus following guidelines, disease associated versus gender, disease associated versus type of therapy, type of therapy versus blood pressure control P value is to estimate the statistical significance within statistical hypothesis significance for the evaluation of blood pressure control and also for the evaluation of prescription patterns according to jnc 8 guidelines. P value was set at 0.05 and confidence interval was 95%.

RESULTS

A total of 250 patients with Diabetic hypertension associated with or without comorbidities were screened according to our inclusion criteria. Among them 44% were men and 56% were women. Most of the patients were affected between the age group of 61 to 70 years with 32%. Table 1 represents the patient characteristics.

TABLE 1.

Category	Number of patients	Percentage
GENDER		
Female	144	56%
Male	106	44%
AGE		
31 -40	6	2.4%
41-50	40	16%
51-60	74	29%
61-70	80	32%
71-80	50	20%
COMORBIDITIES		
Stroke	36	14.4%
CVD	64	25.6%
CKD	18	7.2%
Other	132	52.8%

Table 2 represents the mono and combination therapy of Diabetic hypertension associated with or without comorbidities. Majority of the patients were treated with monotherapy about 62% with ARB(43%). ARB + CCB is the most used combination therapy i.e 17.6%.

TABLE 2.

Category	Number of patients	Percentage
THERAPY		
Monotherapy	156	62%
Combination therapy	92	38%
MONOTHERAPY		
ACE	4	2.6%
ARB	68	43.6%
Diuretics	8	5.1%
CCB	32	20.5%
Beta blockers	44	28.2%
COMBINATION THERAPY		
ARB + Diuretic	16	12.8%
ARB + Beta blockers	16	12.8%
ARB + CCB	22	17.6%
Diuretic + Beta blockers	6	4.8%
CCB + Diuretics	2	1.6%
CCB + Beta blockers	18	14.4%

Table 3 represents the frequently used mono and combination therapy in Diabetic hypertension associated with different diseases. In Diabetic hypertension associated with stroke, the majority of the patients were treated with ARBS. Most commonly prescribed drugs in subjects with CKD are Diuretics, in CVD are Beta blockers and Diabetic hypertension are ARB respectively.

TABLE 3.

Category	STROKE	CKD	CVD	DM & HTN
MONOTHERAPY				
ACE	4	0	0	0
CCB	12	0	0	20
Diuretics	0	**6**	0	2
Beta blockers	2	2	**30**	10
ARB	**16**	2	8	**42**
COMBINATION THERAPY				
ARB +Diuretics	**4**	0	2	10
ARB + Beta blockers	0	**2**	**12**	2
ARB +CCB	0	0	2	**20**
Diuretics+Beta blockers	0	0	6	0
CCB +Diuretics	0	0	0	2
CCB + Beta blockers	2	0	2	14

Table 4 represents the blood pressure evaluation and JNC VIII guidelines based antihypertensive prescriptions. Among 250 patients BP was in control for 80% and remaining 20% subjects BP was not in control. Majority of the antihypertensive prescriptions were followed JNC VIII guidelines i.e 73%. Whereas 27% of the patients' antihypertensive prescriptions did not follow JNC VIII guidelines.

TABLE 4.

Category	Number of patients	Percentage
BP EVALUATION		
In control	202	80%
Not in control	48	20%
JNC VIII GUIDELINES		
Followed	182	73%
Not followed	68	27%

Table 5 represents the chi square variables P value. Chi Square analysis was executed by means of SPSS software between the variables in the table 5 and the P value was clinically significant.

TABLE 5.

CHI SQUARE VARIABLES	P VALUE
Age versus Gender	0.05
BP Evaluation versus JNC VIII guidelines	0.05
Disease associated versus type of therapy	0.05
BP evaluation versus type of therapy	0.03
Gender versus disease associated	0.02

DISCUSSION

A prospective observational study on "EVALUATION OF PRESCRIPTION PATTERNS ANTIHYPERTENSIVES IN TYPE2 DIABETES MELLITUS PATIENTS ASSOCIATED WITH OR WITHOUT COMORBIDITIES" was implemented in tertiary care hospital in both inpatient and outpatient of endocrinology department.

A total of 250 subjects were included in our study meeting the inclusion criteria among them 56% were females and 44% of the population were males. Among 56% of females 1.6% of them are between the age group of 31-40 years. 8% of them are between the age group 41-50 years, 16.8% of them are between the age group 51-60 years, 19.2% are between the age group of 61-70 years.10,4% are between the age group of 71-80 years. Among 44 % of male population 0.8%, 8%, 12.8%, 12.8%, 9.6% are between the age group of 31-40 41-50 51-60 61-70,71-80 years respectively. In total 32% of the subject population are diagnosed with hypertension and diabetes mellitus type 2 are between the age group of 61-70 years. Comparatively females are mostly affected when compared to males in a range of 140,110 respectively. In our study population of 250 64 subjects were associated with cardiovascular disease i.e (25.6%) 36 subjects were affected with coronary vascular accident i.e(14.4%).18 subjects were associated with chronic kidney disease i.e(7.2%), and the other 52.8% of the population were associated with seizures. encephalopathy. cellulitis, UTI, Acute gastritis etc. Among those 52.8% of other category subjects affected only with dm2 and hypertension are 23%.

In our study we found that the majority (112) of subjects with diabetes mellitus 2 and hypertension are suffering with an average duration of 11-20 years i.e(45%) 38% of people are found to be suffering from 1-10 years.

In our study about 62% of population were prescribed with monotherapy and 38% of population were prescribed with multidrug therapy among 62% of monodrug therapy prescriptions ARB's, Beta blockers. Diuretics calcium channel blockers were prescribed 46%, 28%, 5%, 21% respectively. ARB's frequently when compared with other classes and found to be 80% effective in controlling blood pressure. Beta blockers are less prescribed when compared to ARB's i.e 28% and eventually the least prescribed class of drug was found to be diuretics(5%). Monotherapy prescriptions vary with disease associated, in our study we have found that subjects with stroke were majorly prescribed with ARB's. CCB's. Subjects with chronic kidney disease were prescribed with diuretics majorly patients with Cardiovascular diseases are treated majorly with beta blockers and diabetic hypertensive patients are majorly prescribed with angiotensin receptor blockers and calcium channel blockers.

Among 38% of multi drug therapy of the population 32% were prescribed with two drug therapy and the other 6% population were prescribed with more than two drugs. In 32% of two drug therapies two different drug class combinations were prescribed like ARB+DIURETIC, ARB+BB, ARB+CCB, DIURETIC+BB. DIURETIC+CCB, CCB+BB. Among the above mentioned drug combinations ARB+CCB are prescribed most often. Cardiovascular disease subjects are receiving ARB+BB frequently; patients with only diabetes and hypertension are prescribed ARB+DIURETIC, ARB+CCB, CCB+BB mostly. More than 2 drug combination prescriptions involve 6% of the population among them 5% of them are prescribed with three drug combinations and 1% are prescribed with four drug combinations. Three drug combinations including BB+DIURETIC+CCB, CCB+BB+ARB are found to be effective in patients with hypertensive urgency. Four drug combinations include ARB+DIURETIC+CCB+BB.In our study 80% of populations blood pressure was found to be in control and majority of the prescriptions followed jnc 8 guidelines.

CONCLUSION

Among 250 study population females (56%) are more affected with type 2 diabetes mellitus and hypertension than male ie 44%. Both female and male subjects with the age group of 51-60 years are mostly affected. Patients with diabetes and hypertension associated with cardiovascular diseases are more when compared to patients with other associated comorbidities. Majority of the patients were receiving monotherapy i.e. 62% of the population. Most commonly used antihypertensives are ARBs. BB, CCBs about 43.6% 28.2% and 20.5% respectively. About 38% of subjects are treated with combination therapy. Among ARB + BB. ARB + DIURETIC are prescribed more often. In our study we have concluded that 80% of the population's blood pressure was in control i.e 80% of population have received effective therapy following guidelines.

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