



Original Research Article

A prospective study to determine the efficacy and tolerability of antihypertensive drugs in diabetic and non-Diabetic patients at a tertiary care centre in Ganjam, Odisha

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ABSTRACT

Background: Hypertension and Type 2 diabetes are the two factors having a great impact on the mortality and morbidity of a substantial amount of population over the globe. It has also been identified that Hypertension and Type 2 diabetes co-exist in the majority of the patients. There is a wide range of antihypertensive drugs available for the management of hypertension namely, enzyme inhibitors (ACEIs), diuretics (D), beta-blockers (β Bs), calcium-channel blockers (CCBs), and angiotensin receptor blockers (ARBs).

Aim: To study the Efficacy and tolerability of antihypertensive drugs in Diabetic and Non-Diabetic patients at a tertiary care centre in Ganjam, Odisha

Materials and Methods: A prospective study with 400 patients was conducted in which 200 were included in the non-diabetic group, and 200 were included in the diabetic group. The study period was six months, from June 2019 to November 2019, and it was conducted at the MKCG Medical College Berhampur, Ganjam Odisha. Patients with Type 1 diabetes were excluded from the study. All the patients suffering from mild and moderate hypertension were included in the study. Also, the patients with and without type 2 diabetes were included in the study.

Results: Fifty of the non-diabetics with hypertension belonged to 51-70 years of age group. Similarly, 52.5% of the patient in the Diabetics with Hypertension group belonged to 51-70 years. There was no statistically significant difference among the different mean values among the diabetic and non-diabetic patients except the mean values of diabetic and non-diabetic patients under AST when given $\beta\text{B} + \text{CCB} + \text{D} + \text{ACEI}$. There was no statistically significant difference among the renal function of various drugs among the diabetic and non-diabetic group. More people were given two drugs combination as compared to monotherapy, three drugs combination and four drugs combination. There was no statistically significant difference among the various drug combinations on the systolic blood pressure. It was identified various mean urea, mean creatinine and mean uric acid values for different drug combinations. There was no statistically significant difference among the renal function of various drugs among the diabetic and non-diabetic group.

Conclusion: The study concluded that antihypertensive drugs were significantly helpful in treating systolic blood pressure. The BP was controlled substantially in the diabetics and non-diabetics using the ACEI drug.

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1. Introduction

Hypertension and Type 2 diabetes are the two factors having a great impact on the mortality and morbidity of a substantial amount of population over the globe.¹

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Talking of hypertension, it has been ranked third highest risk factor responsible for causing disability in developed as well as developing countries.² It has also been identified that Hypertension and Type 2 diabetes co-exist in the majority of the patients.

The prevalence clearly depicts nearly 90% of the population worldwide is at risk of developing hypertension due to factors like obesity, lifestyle changes, lack of proper nutrients in the diet and much more.³ Furthermore, it has been estimated that nearly 14% of the population has experienced premature deaths due to hypertension. Also, it has been found 6% of the disability and 50% of glucose intolerance are generated as a result of hypertension.⁴ The incidence of both hypertension and Type 2 Diabetes has been found to be increasing owing to the unhealthy lifestyle changes and with an increase in the various pharmacological changes as well.⁵

There is a wide range of antihypertensive drugs available for the management of hypertension namely, enzyme inhibitors (ACEIs), diuretics (D), beta-blockers (β Bs), calcium-channel blockers (CCBs), and angiotensin receptor blockers (ARBs).⁶ It has been found in the various clinical trials that the antihypertensive drugs used to lower the Systolic BP within the range of 9-11 mmHg and the Diastolic BP within the range of 2-9 mmHg are greatly helpful in reducing the chances of cardiovascular diseases by 30%-60%.⁷ Also, antihypertensive medicines help in reducing the microvascular complication by 20%-50% in different cases.⁸

However, it has been identified that patients with hypertension and Type 2 diabetes have difficulty in achieving the targeted BP. Therefore, in the majority of the patients with normalized renal functioning and hepatic functions need to be treated with a combination of antihypertensive drugs from different classes.⁹ However, the combination of antihypertensive drugs is known to be associated with the reduction of different adverse effects on glucose levels and reducing the advancement towards cardiac and renal malfunctioning.¹⁰

2. Aim

To study the Efficacy and tolerability of antihypertensive drugs in Diabetic and Non-Diabetic patients at a tertiary care centre in Ganjam, Odisha

3. Material and Methods

A prospective study with 400 patients was conducted in which 200 were included in the non-diabetic group, and 200 were included in the diabetic group. The study period was six months, from June 2019 to November 2019, and it was conducted at the MKCG Medical College Berhampur, Ganjam Odisha. Patients with Type 1 diabetes were excluded from the study. All the patients suffering

from mild and moderate hypertension were included in the study. Also, the patients with and without type 2 diabetes were included in the study.

4. Results

Table 1: Age Distribution

Age	Non-diabetics with Hypertension	Diabetics with Hypertension
30-50	80 (40%)	20 (10%)
51-70	100 (50%)	105 (52.5%)
71-90	20 (10%)	75 (37.5%)

The above table depicts that 50% of the non-diabetics with hypertension belonged to 51-70 years of age group. Similarly, 52.5% of the patient in the Diabetics with Hypertension group belonged to 51-70 years.

Table 2: Gender Distribution

Gender	Non-diabetics with Hypertension	Diabetics with Hypertension
Male	90(45%)	99 (49.5%)
Female	110 (55%)	101 (50.9%)
Total	200 (100%)	200 (100%)

The above table depicts that the number of female patients was slightly more as compared to male patients.

From the above table, it was identified various mean urea, mean creatinine and mean uric acid values for different drug combinations. There was no statistically significant difference among the renal function of various drugs among the diabetic and non-diabetic group.

The above table shows the mean values of Bilirubin, ALP, ALT, and AST across various drug combinations. There was no statistically significant difference among the different mean values among the diabetic and non-diabetic patients except the mean values of diabetic and non-diabetic patients under AST when given β B + CCB + D + ACEI.

From the above table, different values of cholesterol, Triglycerides, HDL, and LDL values for different drug combinations were observed. There was no statistically significant difference among the renal function of various drugs among the diabetic and non-diabetic group.

The above table shows that more people were given two drugs combination as compared to monotherapy, three drugs combination and four drugs combination.

The above table shows the mean values for SBP. It was observed that there was no statistically significant difference among the various drug combinations on the systolic blood pressure.

5. Discussion

In the current study, ACEI was considered to be the most prominent drug among the monotherapy and all the other

Table 3: Safety assessment by the effect on renal function

Drugs	Urea		Creatinine		Uric Acid	
	Diabetics	Non-Diabetics	Diabetics	Non-Diabetics	Diabetics	Non-Diabetics
Monotherapy						
ACEI	35.9±2 (25)	32.2±1.7 (23)	1.5±0.08 (25)	1.2±0.08 (25)	5.5±0.537 (6)	6.0±0.34 (6)
Two drug therapy						
βB+ACEI	34±1.4 (61)	36±1.6 (50)	1.0±0.045 (61)	1.0±0.0616 (50)	5.35±0.22 (17)	5.4±0.35 (12)
Three drug combination						
βB+CCB+ACEI	31.2±1.33 (46)	32.8±1.73 (43)	0.2±0.0396 (46)	0.6±0.04 (43)	5.5±0.609 (6)	5.3±0.35 (9)
Four Drug Combination						
βB + CCB + D + ACEI	24.6±1.97 (6) <0.005 >0.3	37.89±1.7 (12)	0.89±0.76 (6)	0.5±0.06 (12)	5.1±0.42 (6)	4.7±0.32 (6) >0.3

Table 4: Safety assessment by the effect on liver function

Drugs	Bilirubin		ALP		ALT		AST	
	Diabetic	Non-Diabetic	Diabetic	Non-Diabetic	Diabetic	Non-Diabetic	Diabetic	Non-Diabetic
Monotherapy								
ACEI	0.66±0.06 (16)	0.64±0.53 (17)	155±18 (16)	161.5±20 (20)	34.6±3.77 (16)	28.6±1.65 (19)	38±4 (16)	36.4±3.03 (17)
Two drug therapy								
βB+ACEI	0.76±0.067 (27)	0.6±0.027 (20)	159.7±7.51 (15)	242±12.3 (09)	40±2.8 (26)	36±2.21 (20)	39±3.3 (27)	34±2.6 (20)
Three drug combination								
βB+CCB+ACEI	0.9±0.048 (41)	0.63±0.026 (25)	186.5±11 (45)	195.7±18 (22)	30±1.61 (45)	35±3.7 (25)	28.6±1.82 (41)	31.8±2.0 (25)
Four Drug Combination								
βB + CCB + D + ACEI	0.63±0.0422 (6)	0.7±0.06 (7)	166±28.7 (6)	156±25 (7)	22.5±2.3 (6)	40±4.10 (7)	23.5±1.607 (6)	36±2.4 (7)

Table 5: Safety assessment by the effect on lipid profile

Drugs	Cholesterol		Triglycerides		HDL		LDL	
	Diabetic	Non-Diabetic	Diabetic	Non-Diabetic	Diabetic	Non-Diabetic	Diabetic	Non-Diabetic
Monotherapy								
ACEI	175.6±10.2 (6)	153±23.3 (6)	168.6±10.14 (6)	149±44.5 (6)	36±2.38 (6)	37±4.02 (6)	107±9.01 (6)	92±21.1 (6)
Two drug therapy								
βB+ACEI	182±5.9 (25)	191±8.8 (12)	175±8.9 (25)	185±9.16 (12)	41.8±1.24 (25)	42±1.7 (12)	107±4.64 (25)	114±6 (12)
Three drug combination								
βB+CCB+ACEI	163±7.6 (6)	168±12.7 (8)	162±20.49 (6)	197±21.6 (8)	43±2.9 (6)	37±2.2 (6)	83±7.78 (6)	102±8.9 (6)
Four Drug Combination								
βB + CCB + D + ACEI	184.5±4.992 (4)	168±5 (4)	164.5±24.3 (4)	138±39 (4)	45.7±1.315 (4)	41±5.4 (5)	105.7±7.09 (4)	102±2.7 (6)

Table 6: Distribution of patients based upon drug prescribed

Drug	Monotherapy		Two drug combination			Three drug combination			Four drug combination		
	Non-diabetic	Diabetic	Drug	Non-diabetic	Diabetic	Drug	Non-diabetic	Diabetic	Drug	Non-diabetic	Diabetic
ACEI	60	55	BB+ACEI	90	80	βB + CCB + ACEI	55	55	BB + CCB + D + ACEI	5	10

Table 7: Effects of drugs on systolic blood pressure

Drugs	Baseline SBP	SBP (mmHg) NDP	DP
Monotherapy			
ACEI	184.5±33.9 >0.2	120.3±1.556 (60)	119.6±2.25 (42)
Two Drugs Combination			
βB+ACEI	173.7±19	111±1.4 (100)	120±1.53 (73)
Three Drugs Combination			
βB+CCB+ACEI	152.5±18	123±1.44 (70)	120±1.42 (70)
Four Drugs Combination			
βB + CCB + D + ACEI	190±33 (20)	122.5±2.66	113±2.04 (27)

combination treatment mechanisms. As per the present study, it was identified that both in case of diabetic and non-diabetic patients ACEI was the most commonly prescribed drug. According to the study of Beulah et al. (2011)⁷ ACEI was considered to be the most effective drug for the treatment of hypertension. However, according to the study of Lee et al., (2012),¹¹ only ACEI was solely responsible for the treatment of hypertension as compared to the combination of drugs. Furthermore, according to the study of Yasmeen et al. (2011), similar results were found.¹² In the current study, other drugs such as βB, CCB, and D were found to be equally effective in treating hypertension among diabetic and non-diabetic patients. Similarly, results were obtained as per the study of Yasmeen et al., (2011).¹¹ The current study also identified that the ACEI and other antihypertensive drugs proved to be effective in lowering the systolic blood pressure. Petrella et al. (2011) found similar readings in their study.⁸

6. Conclusion

The study concluded that antihypertensive drugs were significantly helpful in treating systolic blood pressure. The BP was controlled substantially in the diabetics and non-diabetics using the ACEI drug. It was also identified in the study that various combinations of different anti hypertensive drugs were equally beneficial and provided better BP control. Furthermore, there was no substantial difference among the diabetics and the non-diabetics regarding the effects of antihypertensive drugs.

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8. Conflict of Interest

The authors declare they have no conflict of interest.

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