

Efficacy And Tolerability Of Different Antihypertensive Drugs In Hypertension Alone And Type II Diabetes with Hypertension Patients: A Prospective Comparative Study

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Abstract: Hypertension in diabetes is of the most widespread substantial cardiovascular risk factor of importance in clinical practice. A prospective comparative study was conducted in General Medicine (OP) Department at Rajiv Gandhi Institute of Medical Sciences (RIMS) Hospital, Kadapa in 83 patients Kadapa to study the efficacy and tolerability of different antihypertensive drugs in hypertensive alone and in type-2 diabetic with hypertension patients. Efficacy was assessed based upon the patient's reading of blood pressure and tolerability based on the patient's complaint on each follow up. By comparing the mean reduction in SBP and DBP with all class of antihypertensive drugs we observed that combination therapy showed high reduction in both SBP and DBP than monotherapy. Atenolol was more effective than Amlodipine. We noticed the underutilization of diuretics in monotherapy and in combination therapy. Although it was first line therapy for hypertension according to JNC-VI & VII report.

Keywords: Antihypertensive drugs, Diabetes Mellitus, Efficacy, Hypertension, Tolerability

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I. Introduction

Hypertension in diabetes is one of the most wide spreading cardiovascular risk factors of importance in clinical practice. Data from randomized trials have increasingly shown the benefits of tight blood pressure control in patients with type-II diabetes. ^[1] Higher prevalence of hypertension (HTN) amongst diabetics in India has been reported since 1985. ^[2] The prevalence of hypertension increases with advancing age to the point where more than half of people aged 60 to 69 years old and approximately three-fourths of those aged 70 years and older are affected. The age-related rise in SBP is primarily responsible for an increase in both incidence and prevalence of hypertension with increasing age. ^[3] It is estimated that if diabetic patients live long enough, approximately 75% will develop hypertension. ^[4]

Both diabetes and high blood pressure tend to share many predisposing factors. The same set of criteria that puts one at risk for developing high blood pressure also contributes to the development of diabetes. ^[5] Most patients with diabetes require combination therapy to attain a blood pressure of less than 130/80 mm Hg. The choice and doses of drugs used in combination therapy should be such that their synergistic effect on blood pressure is maximized, the tolerability of the drugs is maintained and side effects are minimized. Thiazide diuretics, β -blockers, or calcium channel blockers (CCBs) can be added to ACE inhibitor or ARB treatment to achieve target blood pressure, either as an individual drug component or as part of a fixed-dose combination product. ^[6] The study was aimed to compare the efficacy and tolerability of different antihypertensive drugs in hypertensive (HTN) alone patients and in Type 2 Diabetic with hypertension (T2DM with HTN) patients.

II. Materials And Methods

A. Source of data:

Alone Hypertensive and T2DM with Hypertensive patients who come for checkup in outpatient, General Medicine department, Rajiv Gandhi Institute of Medical Science (RIMS), Kadapa for the period of six months.

B. Inclusion criteria:

Patients who were diagnosed with HTN alone and Type2DM with HTN between 30-80 years old were included in the study.

C. Exclusion criteria:

Pregnant and lactating women, Patients with co-morbid conditions such as renal failure, congestive heart failure, myocardial infarction, bronchial asthma, COPD and stroke were excluded from the study.

D. Method :

This is a prospective comparative study of 83 patients who came to visit the outpatient General medicine department for a period of six months was included in the study. Data was collected on daily basis to compare the efficacy and tolerability of different antihypertensive drugs in Hypertension (HTN) alone and in T2DM with HTN(Type 2 Diabetes Mellitus with Hypertension). Inform consent form was obtained, who are willing to participate in the study. The patients were divided into two groups (HTN alone and HTN+T2DM) based on their disease status. Baseline blood pressure and demographic details was collected from their demographic and clinical data. Patient follow up was done for 5 times for a period of 5 months and the information regarding efficacy and tolerability on every follow up were recorded. Efficacy was assessed based on the patient's BP readings and tolerability based on the patient complaints on each follow up. All the results were expressed as Mean \pm SD. Parametric test was done using Student Paired 't' test. P value less than 0.05 was considered significant, less than 0.025 considered highly significant and less than 0.0001 was considered extremely significant.

III. Results

The prospective, comparative study was conducted for 6 months (September 2012- February 2013), in a South Indian Tertiary Care Teaching Hospital OP department of General Medicine at RIMS (Rajiv Gandhi Institute of Medical Sciences), Kadapa. A total of 83 patients were recruited under inclusion criteria and were followed for the present study. Out of 83 patients, 35(42.16%) were male and 48(57.84%) were female. Total distribution of patients with respect to age and gender shows that highest number of patients were found in between the age group of 51-60 (34) followed by 24 in between the age group of 61-70 and least number of patients (2) were found in between 71-80 age group.

Age group and gender wise distribution of Hypertension alone patients:

Out of 83 patients, 48patients were female (57.84%) and 35 were male (42.16%).

TABLE-1

| Age in years | No. of Patients | Male | Female |
|--------------|-----------------|--------------------|-------------------|
| 30-40 | 3 | 1 | 2 |
| 41-50 | 20 | 8 | 12 |
| 51-60 | 34 | 15 | 19 |
| 61-70 | 24 | 10 | 14 |
| 71-80 | 2 | 1 | 1 |
| Total | 83 | 35 (42.16%) | 48(57.84%) |

Age group and gender wise distribution of Hypertension with Type-2 diabetes patients:

Overall 83 patients, 32 patients have Hypertension and Type-2 Diabetes mellitus. Of these, female patients (56.25%) were more than male patients (43.75%).

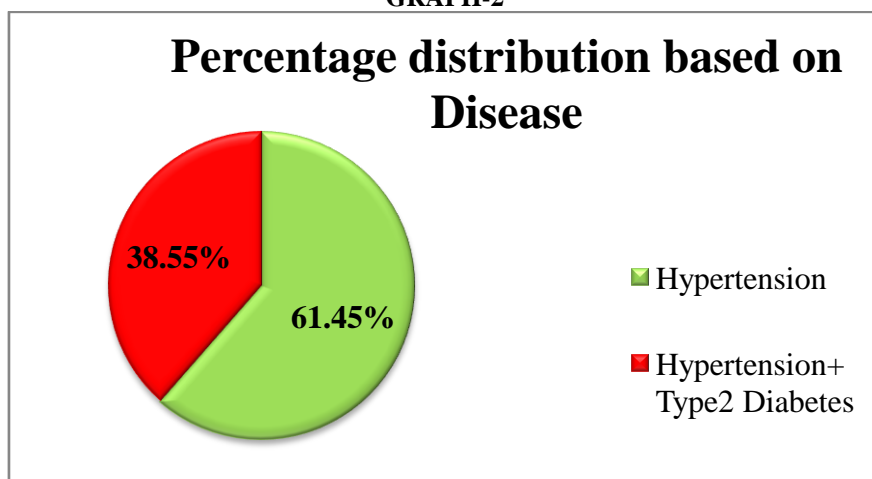
Percentage distribution based on Disease

Among 83 patients, 51 (61.44%) patients have hypertension alone and 32 (38.55%) patients have hypertension with Type-2 Diabetes mellitus which shows that majority of patients have hypertension alone than hypertension along with diabetes.

TABLE-2

| Disease | No. of Patients | Percentage |
|------------------------------|-----------------|------------|
| Hypertension | 51 | 61.45% |
| Hypertension+ Type2 Diabetes | 32 | 38.55% |

GRAPH-2



Percentage distribution based on treatment

A. Monotherapy Vs. Combination therapy

Out of 83 patients, 36 (43.37%) patients received monotherapy and 47 (56.63%) patients received combination therapy. This study revealed that highest percentage of patients was treated with combination therapy (56.62%) than monotherapy (43.37%).

TABLE-3

| Drug regimen | No. of Patients | Percentage |
|---------------------|-----------------|------------|
| Monotherapy | 36 | 43.37% |
| Combination therapy | 47 | 56.63% |

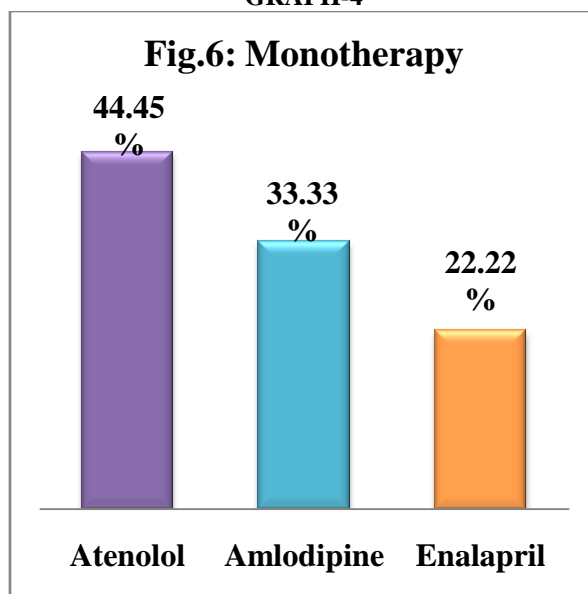
B. Monotherapy

The study revealed that in monotherapy three different antihypertensive drugs were used. These were Atenolol-50mg, Amlodipine-5mg and Enalapril-10mg. Among these drugs Atenolol was prescribed for majority of patients with 44.45% followed by Amlodipine with 33.33% and enalapril was least prescribed with 22.22%.

TABLE-4

| Drug | Hypertension | Hypertension + Type 2 Diabetes | Total | Percentage |
|------------|--------------|--------------------------------|-------|------------|
| Atenolol | 7 | 9 | 16 | 44.45% |
| Amlodipine | 6 | 6 | 12 | 33.33% |
| Enalapril | 4 | 4 | 8 | 22.22% |

GRAPH-4



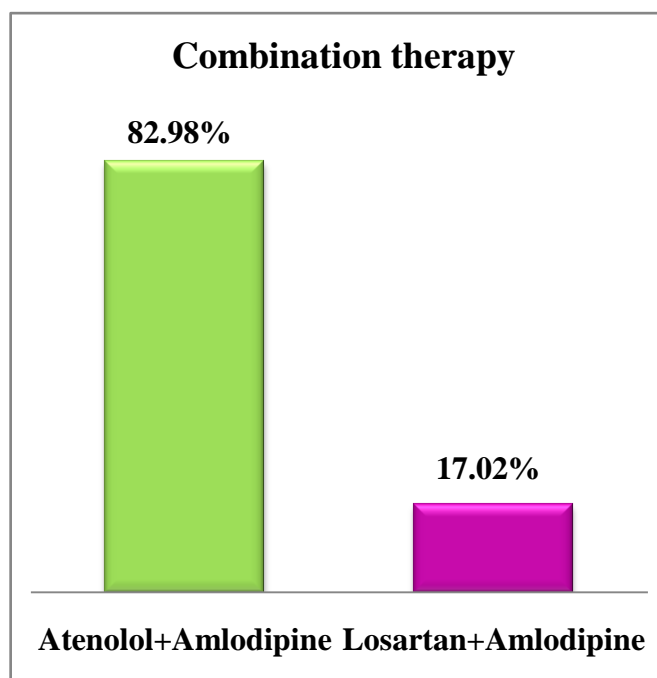
C. Combination Therapy

Out of 83 patients enrolled, 47 patients were under the 2 combination therapies (Atenolol+ Amlodipine) and (Losartan+ Amlodipine). Among those who treated with these 2 combination therapies, 82.98% received Atenolol+ Amlodipine combination followed by Losartan+ Amlodipine with 17.02%.

TABLE-5

| Drug | Hypertension | Hypertension + Type-II Diabetes | Total | Percentage |
|---------------------|--------------|---------------------------------|-------|------------|
| Atenolol+Amlodipine | 30 | 9 | 39 | 82.98% |
| Losartan+Amlodipine | 4 | 4 | 8 | 17.02% |

GRAPH-5



Effect of Drugs on Systolic Blood pressure in alone hypertensive patients:

TABLE-6

| Effect of Drugs on Systolic Blood pressure in hypertension patients | | | | | | | |
|---|--------------|-----------------|-----------------|-------------------|--------------|-----------------|---------|
| Drugs | SBP | | Decrease in SBP | % Decrease in SBP | 95% CI | | P Value |
| | Base line | After Treatment | | | Base line | After Treatment | |
| Mono Therapy | | | | | | | |
| Atenolol (n=7) | 151.1 ± 17.7 | 130 ± 10 | 21.4 ± 5.1 | 14.1 | 135 - 167.8 | 120.8-139.2 | < 0.05 |
| Amlodipine (n=6) | 148.8 ± 11.6 | 133.3 ± 5.1 | 15 ± 9.5 | 10.1 | 136.1 -160.6 | 127.9 -138.8 | < 0.025 |
| Enalapril (n=4) | 140 ± 11.6 | 127.5±5 | 12.5±2.1 | 8.9 | 127- 153 | 119.5-135.5 | < 0.025 |
| Combination therapy | | | | | | | |
| Atenolol+ Amlodipine(n=30) | 159.6 ± 20.5 | 135 ± 7.3 | 24.6±18.2 | 15.4 | 152 - 167.4 | 132.3-137.7 | <0.0001 |
| Losartan+ Amlodipine (n=4) | 152.5 ± 12.5 | 127.5± 5 | 25± 5.5 | 16.3 | 132.5 -172.5 | 119.5-135.5 | <0.05 |

CI-confidence interval (upper & lower limit), SBP-systolic blood pressure, values were expressed as mean ± SD, SD-standard deviation

A 14.1% reduction in SBP was observed with Atenolol followed by Amlodipine (10.1%), Enalapril (8.9%). In combination therapy, 16.3% reduction in SBP was observed with Losartan+Amlodipine combination followed by Atenolol + Amlodipine combination (15.4%).

Effects of drug on diastolic blood pressure in hypertension alone patients

TABLE-7

| Effect of Drugs on Diastolic Blood pressure in hypertension patients | | | | | | | |
|--|------------|-----------------|-----------------|-------------------|-------------|-----------------|---------|
| Drugs | DBP | | Decrease in DBP | % Decrease in DBP | 95% CI | | P Value |
| | Base line | After Treatment | | | Base line | After Treatment | |
| Mono Therapy | | | | | | | |
| Atenolol (n=7) | 97.4±11.1 | 81.4 ± 3.7 | 15.7± 3.9 | 16.2 | 86.8-107.4 | 77.9- 84.9 | <0.025 |
| Amlodipine (n=6) | 93.3±8.1 | 83.3 ±5.1 | 10 ±5.7 | 10.7 | 84.7 -101.9 | 77.9 -88.75 | <0.025 |
| Enalapril (n=4) | 92.5± 5 | 80± 0 | 12.5 ±2.1 | 13.5 | 84.5 -100.5 | 80 -80 | <0.025 |
| Combination therapy | | | | | | | |
| Atenolol+ Amlodipine (n=30) | 95.3± 15.2 | 84.6± 5 | 10.6 ±16.1 | 11.1 | 89.6- 101 | 82.7- 86.5 | <0.025 |
| Losartan+ Amlodipine (n=4) | 97.5± 9.5 | 82± 5 | 15± 2.5 | 15.4 | 82.2-112.7 | 74.5- 90.4 | <0.025 |

CI-confidence interval (upper & lower limit), DBP- diastolic blood pressure, values were expressed as mean ± SD, SD-standard deviation

A 16.2% reduction in DBP was observed with Atenolol followed by Enalapril (13.5%), Amlodipine (10.7%). In combination therapy, 15.4% reduction in DBP was observed with Losartan+Amlodipine combination followed by Atenolol+Amlodipine combination (11.1%).

Effect of Drugs on Systolic Blood pressure in Diabetes with hyper tension patients

TABLE-8

| Effect of Drugs on Systolic Blood pressure in Diabetes with hyper tension patients | | | | | | | |
|--|-------------|-----------------|-----------------|-------------------|--------------|-----------------|---------|
| Drugs | SBP | | Decrease in SBP | % Decrease in SBP | 95% CI | | P Value |
| | Base line | After Treatment | | | Base line | After Treatment | |
| Mono Therapy | | | | | | | |
| Atenolol (n=9) | 151.1± 12.6 | 131.1± 6 | 20 3.1 | 13.2 | 141.4-160.9 | 126.5-135.7 | <0.0005 |
| Amlodipine (n=6) | 145 ±10.4 | 131.6 ±4 | 13.33 ±1.4 | 9.2 | 134 -156 | 127.4-136 | <0.025 |
| Enalapril (n=4) | 160± 14.1 | 133.8 ±4.7 | 26.25 ±5.6 | 16.4 | 137.5 -182.5 | 126.1-141.4 | <0.05 |
| Combination therapy | | | | | | | |
| Atenolol+ Amlodipine (n=9) | 168.8 ±15.3 | 136.6± 5 | 32.2± 13.5 | 14.2 | 151.1-180.7 | 132.8-140.5 | <0.0005 |
| Losartan+ Amlodipine (n=4) | 167.5± 15 | 132.5 ±50 | 35± 6.6 | 20.9 | 143.6 -191.4 | 124.5-140.5 | <0.05 |

CI-confidence interval (upper & lower limit), SBP-systolic blood pressure, values were expressed as mean ± SD, SD-standard deviation

Enalapril showed a 16.4% reduction in SBP followed by Atenolol (13.2%) and Amlodipine (9.2%). In combination therapy, 20.9% reduction in SBP was observed with Losartan+Amlodipine combination followed by Atenolol+Amlodipine combination (14.2%).

Effect of Drugs on Diastolic Blood pressure in Diabetes with hypertension patients

TABLE-9

| Effect of Drugs on Diastolic Blood pressure in Diabetes with hypertension patients | | | | | | | |
|--|-----------|-----------------|-----------------|-------------------|-------------|-----------------|---------|
| Drugs | DBP | | Decrease in DBP | % Decrease in DBP | 95% CI | | P Value |
| | Base line | After Treatment | | | Base line | After Treatment | |
| Mono Therapy | | | | | | | |
| Atenolol (n=9) | 94.4± 8.8 | 83.3 ±5 | 11.1 ±1.8 | 5.0 | 87.6 -101.2 | 79.4 -87.1 | <0.0005 |
| Amlodipine (n=6) | 90± 8.9 | 81.6 ±4 | 8.3± 6.8 | 9.2 | 80.6 -99.3 | 77.3 -85.9 | <0.05 |
| Enalapril (n=4) | 97.5± 5 | 85± 5.7 | 12.5 ±2.1 | 12.8 | 89.5 -105.5 | 75.8 -94.1 | <0.025 |
| Combination therapy | | | | | | | |
| Atenolol+ Amlodipine (n=9) | 95.5±7.26 | 85.5 ±5.2 | 10 ±6.6 | 10.4 | 89.9- 101.1 | 81.5 -89.6 | <0.05 |
| Losartan+ Amlodipine (n=4) | 105 ±10 | 85± 5.7 | 20 ±3.5 | 19.0 | 89 -120 | 75.8- 94.1 | <0.025 |

CI-confidence interval (upper & lower limit), DBP- diastolic blood pressure, values were expressed as mean ± SD, SD-standard deviation

A 12.8% reduction in DBP was observed with Enalapril followed by Amlodipine (9.2%), Atenolol (5%). In combination therapy, 19% reduction in DBP was observed with Losartan + Amlodipine combination followed by Atenolol and Amlodipine combination (10.4%).

Effect of monotherapy and combination therapy of various antihypertensive drugs in % decrease in SBP, DBP in Hypertension alone and Type-2 Diabetes with hypertension patients

TABLE-10

| Drugs | BP Decrease in Hypertension alone patients | | BP Decrease in Type-2 Diabetes with hypertension patients | |
|---------------------|--|-------------------|---|-------------------|
| | % decrease in SBP | % decrease in DBP | % decrease in SBP | % decrease in DBP |
| Atenolol | 14.1 (p<0.05) | 16.2 (p<0.025) | 13.2 (p<0.0005) | 5.0 (p<0.0005) |
| Amlodipine | 10.1 (p<0.025) | 10.7 (p<0.025) | 9.2 (p<0.025) | 9.2 (p<0.05) |
| Enalapril | 8.9 (p<0.025) | 13.5 (p<0.025) | 16.4 (p<0.05) | 12.8 (p<0.025) |
| Atenolol+Amlodipine | 15.4 (p<0.0001) | 11.1 (p<0.025) | 14.2 (p<0.0005) | 10.4 (p<0.05) |
| Losartan+Amlodipine | 16.3 (p<0.05) | 15.4 (p<0.025) | 20.9 (p<0.05) | 19.0 (p<0.025) |

Atenolol shows high percentage decrease in SBP (14.1%) and DBP (16.2%) in hypertension alone patients than in type-2 diabetes with hypertension patients. Amlodipine also shows high % decrease in SBP (10.1%) and DBP (10.7%) than in type-2 diabetes with hypertension patients.

Whereas Enalapril shows high % decrease in SBP (16.4%) in type-2 diabetes with hypertension patients than hypertension alone patients and high % decrease in DBP (13.5%) was observed in hypertension alone patients than in type-2 diabetes with hypertension patients.

In combination therapy, Atenolol+Amlodipine shows high % decrease in SBP (15.4%) and DBP (11.1%) in hypertension alone patients than in type-2 diabetes with hypertension patients. Losartan+Amlodipine shows high percentage decrease in SBP (20.9%) and DBP (19%) in diabetes with hypertension patients than in hypertension alone patients.

IV. Discussion & Conclusion

Diabetes mellitus and hypertension are both common diseases, especially with an increasingly aged population. Hypertension accelerates the development of diabetic retinopathy, nephropathy, and peripheral vascular disease in the diabetic patient. Diabetes represents a type of premature aging and hypertension in the diabetic patient is characterized by many of the same pathophysiologic properties seen in the elderly hypertensive patient.

In our study we observed that majority of patients (61.45%) have HTN alone followed by HTN with T2DM (38.55%). It shows that the prevalence of hypertension is more than the HTN with T2DM. In this study we observed that majority of patients were in between age group of 51-60. It clearly shows that the prevalence

of HTN and T2DM with HTN increases with age. A study conducted by Keerthi Sagar et al^[7], on prescribing pattern of antihypertensives in HTN alone and HTN with T2DM patients shows that more number of patients were in age group of 61-70 years. The present study was conflict with the observations of the above study.

In the present study more predominance of females (57.84%) was observed compared to male (42.16%). Our results supported with a study conducted by H.Tiwari et al^[8] on prescription monitoring of antihypertensive drug utilization. We observed that majority of patients (54.22%) were have none of the social habits. Out of 83 patients, 38 patients have habits of Betalnut chewing (18.07%), smoking (12.04%), alcohol (8.44%) and both alcohol & smoking (7.23%). This was not supported with study conducted by Preethi et al,^[9] on prescription pattern of antihypertensives which shows that majority of study population have both habits of smoking & alcohol (43.3%).

The ultimate goal of antihypertensive therapy is to reduce cardiovascular and renal morbidity and mortality. Since most persons with hypertension, especially those >50 years old, will reach the DBP goal once the SBP goal is achieved, the primary focus should be on attaining the SBP goal. Treating SBP and DBP to targets that are <140/90 mm Hg is associated with a decrease in CVD complications. In patients with hypertension and diabetes or renal disease, the BP goal is <130/80 mm Hg. Clinical trial data have proved that, maintaining goal blood pressure with several classes of antihypertensive agents such as ACE inhibitors, ARBs, Beta-blockers, calcium channel blockers and thiazide type diuretics reduces the complications of hypertension. Most patients with hypertension require two or more antihypertensive medication to achieve the goal blood pressure.

Keerthi Sagar et al^[10], conducted a study to analyze the prescription pattern of antihypertensive drugs in HTN alone and in HTN with T2DM revealed that 107 patients received monotherapy and 103 patients - combination therapy. Our study revealed that 47 patients were prescribed 2-combination therapy and 36 patients prescribed monotherapy. Thus our study results were not consistent with the mentioned study. The reason for 2-combination therapy might be to increase antihypertensive efficacy in those patients with poor blood pressure (BP) control. We assessed different antihypertensive drugs principally by comparing their antihypertensive efficacy and tolerability In HTN alone and HTN with T2DM patients. All the drugs revealed significant reduction in BP.

In this study 44.45% of patients with HTN alone and HTN with T2DM were prescribed with Atenolol, 33.33% with Amlodipine and 22.22% with Enalapril as monotherapy. All these antihypertensives had significant reduction in both SBP and DBP. According to guidelines from the ADA, the NKF, the World Health Organization, and the JNC VII ACE inhibitors are considered preferred therapy in patients with hypertension and diabetes. Findings from the Heart Outcomes Prevention Evaluation (HOPE) study also support the above recommendations. Our study shows that ACE inhibitors were the least frequently used drug in monotherapy. It was observed that Atenolol had a significant reduction in both SBP & DBP ($p<0.05$) in HTN alone and an extremely significant reduction in HTN with T2DM patients ($p<0.0005$). Our study was consistent with Nazia Yasmeen et al,^[11] study on efficacy and tolerability of antihypertensive drugs in HTN patients and study by Beulah S et al,^[12] where Atenolol as monotherapy showed significant reduction in BP in HTN and T2DM with HTN patients. Amlodipine showed highly significant reduction in SBP & DBP ($p<0.025$) in HTN alone where as in T2DM with HTN it showed highly significant reduction in SBP ($p<0.025$) and a significant reduction in DBP ($p<0.05$).

A highly significant reduction in SBP & DBP ($p<0.025$) in HTN alone patients and DBP (<0.025) in T2DM with HTN was observed with Enalapril where as significant reduction in SBP ($p<0.05$) was observed in T2DM with HTN patients. It was observed that one of the most commonly used combination therapies were calcium channel blocker with β - blocker or ACE inhibitor in various randomized clinical trials. In our study we observed that majority of patients were on 2-combination therapy, mostly with Atenolol, Amlodipine or Losartan combination.

Losartan and Amlodipine were frequently used as first-line therapy in hypertensive patients and combining these two drugs has also been shown to be effective in lowering blood pressure. In our study there was high prevalence of Amlodipine + Atenolol combination (82.98%) usage for both HTN alone and T2DM with HTN patients followed by Losartan + Amlodipine (17.02%) this conflicts the above mentioned statement. A study by Robert A Kloner et al, concluded that Amlodipine is safe and effective when added to quinapril or losartan monotherapy to help lower BP toward therapeutic targets in patients with HTN and DM though in our study only few of HTN with T2DM patients were received amlodipine + losartan combination.

Atenolol + Amlodipine combination showed extreme significant reduction in SBP ($p<0.0005$) in both HTN alone and T2DM with HTN and highly significant reduction in DBP ($p<0.025$) in HTN alone patients where as a significant reduction in DBP ($p<0.05$) was observed in T2DM with HTN patients.

A highly significant reduction in DBP ($p<0.025$) was observed with Losartan + Amlodipine combination in both HTN alone and HTN with T2DM patients and a significant reduction in SBP ($p<0.05$) was observed in both the patients. In our study we observed that none of the patients were prescribed 3-combination

and 4-combination therapy. When comparing Atenolol with Amlodipine both the drugs have similar efficacy in HTN alone patients where as in T2DM with HTN patients Atenolol was more effective than Amlodipine. By comparing the mean reduction in SBP and DBP with all class of antihypertensive drugs we observed that combination therapy showed high reduction in both SBP and DBP than monotherapy.

No patients have reported any adverse drug reactions (ADR's) to any prescribed antihypertensive drugs in our study. It indicates that all of the patients were tolerable to the prescribed drugs & doses. Lifestyle modifications decrease BP, enhanced antihypertensive drug efficacy, decrease cardiovascular risk are generally the initial steps in managing hypertension. Along with drug therapy and life style modifications such as weight reduction, reduced salt intake, regular exercise, avoiding smoking, alcohol and avoiding stress we can control the BP effectively. At the end of our study we educated patients regarding disease and lifestyle modifications to be followed for control of high blood pressure and preventing further complication.

Based on our study results we can conclude that prescription pattern was deviated in majority of cases. We noticed the underutilization of diuretics in monotherapy and in combination therapy although it was first line therapy for hypertension according to JNC-VI & VII report. All the antihypertensive drugs were equally effective in reducing elevated blood pressure levels in both groups of patients. Monotherapy and combination therapy were also equally effective in reducing elevated blood pressure in both diseased population. Combination was used in large proportion of patients to treat hypertension than monotherapy. This may be due to inadequate control of elevated blood pressure. Although ACE inhibitors are mostly preferable for diabetes with hypertension patients but in our study Atenolol utilization was seen in most of the patients which was contraindicate in diabetes with hypertension patients. The main limitation of this study is the small sample size. This is clearly indicating the importance of clinical pharmacist role in improving drug utilization, awareness and compliance to certain accepted standards by providing specific treatment guidelines and their updates to the prescriber for effective patient care.

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