COMPARISON OF NEBIVOLOL AND ATENOLOL ON BLOOD PRESSURE, BLOOD SUGAR AND LIPID PROFILE IN PATIENTS WITH ESSENTIAL HYPERTENSION

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ABSTRACT

BACKGROUND

Beta-blocker is considered to be a very effective antihypertensive drug to control hypertension. But National Institute for Health and Clinical Excellence (NICE) recommended that it should no longer be used as first-line drug as the treatment of uncomplicated hypertension. This recommendation was based on the various studies showing increased risk of new onset Diabetes Mellitus and derangement of lipid metabolism with the use of beta-blocker. These studies were mainly based on Atenolol with or without diuretics. We are in need of a beta-blocker that has effective antihypertensive properties without altering the metabolic profile like blood sugar level and lipid metabolism. Nebivolol, a b1-selective blocker, has got more or less the similar properties. It increases insulin sensitivity in patients with insulin resistance due to its vasodilator properties. Also, antioxidant properties of nebivolol, and increase in nitric oxide properties by reducing its oxidative inactivation may be responsible for beneficial lipid and carbohydrate metabolic profile.

MATERIALS AND METHOD

A prospective study was conducted between December 2011 to August 2013 on 60 patients at medicine outpatient department (OPD) of Katihar Medical College, Katihar, after getting approval from the Institutional Ethics Committee. The patients meeting the inclusion criteria were explained in detail about the nature of the trial, its purpose, procedures, and followup. They were provided with detailed trial information sheet. Written informed consent was obtained from those who volunteered to participate in the trial.

RESULTS

In our study, the mean difference of systolic blood pressure from baseline and at 24 weeks was 40.20±1.74 in the Atenolol group and 43.80±1.405 in the Nebivolol group. Similarly, in Atenolol group, diastolic blood pressure is decreased by 17±1.3 and 19.4±1.223 in Nebivolol group.

In our study, the mean difference of blood sugar level from baseline and at 24 weeks was 18.43 ±1.216 in the Atenolol group and 1.08±1.134 in the Nebivolol group.

In this study, the mean difference of Total cholesterol, Triglycerides, VLDL, HDL, and LDL from baseline and at 24 weeks is 20.83±1.034, 15.96±1.784, 3.20±0.297, -2.97±0.203, and 21.46±1.04 respectively in the Atenolol group and 0.63±0.758, 0.17±0.667, 0.00±0.200, 0.12±0.302, and 0.44±0.684, in the Nebivolol group.

CONCLUSION

Our study clearly shows that Nebivolol is highly effective antihypertensive therapy as Atenolol and very minimal or no derangement observed in forms of blood sugar, TG, VLDL, HDL, and LDL level after successful therapy with Nebivolol. Hence Nebivolol, a selective beta-blocker with vasodilator properties should be considered to be a first line antihypertensive therapy.

KEYWORDS

Nebivolol, Atenolol, Antihypertensive Efficacy, Adverse lipid Profile, Blood sugar.

HOW TO CITE THIS ARTICLE: Dev A, Pandit SK, Singh VK, et al. Comparison of nebivolol and atenolol on blood pressure, blood sugar and lipid profile in patients with essential hypertension. J. Evid. Based Med. Healthc. 2016; 3(70), 3783-3789. DOI: 10.18410/jebmh/2016/810

Financial or Other, Competing Interest: None.
Submission 27-07-2016, Peer Review 05-08-2016,
Acceptance 20-08-2016, Published 31-08-2016.
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DOI: 10.18410/jebmh/2016/810

INTRODUCTION: Hypertension is a very common and important disease related to modern civilised life and its complications pose a major health problem in populations world-wide. Its prevalence is quite high in India, and affects both rural and urban populations.[1]

Hypertension is a widely prevalent asymptomatic condition of elevated blood pressure (BP). It is a major risk factor for the development of cardiovascular disease (CVD) and is the leading cause of the global mortality.[2]

According to a World Health Organization survey, the prevalence of hypertension in India is 23.10% in male and 22.60% in female over 25 years of age (WHO 2012).[3]

It has also been predicted that the total number of adults with hypertension will increase to 1.56 billion people by 2025.[4]

The current European Society of Hypertension (ESH) and European Society of Cardiology (ESC) guidelines define hypertension as BP>140/90 mmHg and recommend a treatment target of <140/90 mmHg and <130/80 mmHg in the general hypertensive population and in patients with diabetes mellitus (DM) respectively.[5]

Guidelines also emphasise that hypertension diagnosis and management should be based on the assessment of total cardiovascular (CV) risk, since only a small proportion of the hypertensive population displays elevated BP alone. The majority of patients have additional CV risk factors such as type 2 DM in these subjects.

Both randomised clinical trials and observational studies have confirmed the effect of uncontrolled hypertension on cardiovascular morbidity and mortality.[6]

Early treatment can reverse and retard the complications associated with hypertension.

The classes of antihypertensive therapy available for the clinical management of hypertension include thiazide diuretics, beta-blockers, calcium channel blockers (CCBs), angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs).

Blockers are widely used in the clinical management of hypertension. β-blockers have long been considered as first line antihypertensive drugs. A number of clinical trials such as STOP, CAPP, NORDIL and JNC 7 recommend β blockers in the initial management of hypertension.[7,8,9]

Atenolol, a β1-blocker, is a commonly used antihypertensive agent, and has often been used as a reference drug in a number of clinical trials.[10] However, the question arises about the status of this drug as a reference drug in comparison with other antihypertensive drugs, because of its undesirable effects on lipid profile, blood sugar, and heart rate of patients.[11,12]

The newer 3rd generation β -blocker, nebivolol, is found to be more cardioselective, and has a vasodilating effect on resistance arteries.[13] This drug is endowed with peripheral vasodilating properties mediated by endogenous production of nitric oxide.[14] Recently, it has been well studied that pharmacogenomics has a greater impact on the therapeutic effect of the drug.

It has been shown improved tolerability profile with respect to adverse effects commonly associated with other β-blockers.[15]

Not much work has been done in our setup to compare the efficacy and safety of atenolol and nebivolol on the cardiovascular system; hence, keeping in mind the promising utility of nebivolol, it is thought of interest to elucidate the effects of nebivolol on blood pressure and on other metabolic profile in patients with hypertension.

AIMS AND OBJECTIVES: Atenolol, a selective beta-blocker has fewer side-effects than the usual non-selective beta-blocker. But the deleterious effect caused by Atenolol like raised blood sugar level and dyslipidaemia made this drug undesirable as first-line treatment of hypertension, as recommended by National Institute for Health and Clinical Excellence (NICE) and the British Hypertension Society (BHS). So there is a need to select more selective beta-blocker with all the benefit of selective beta-blocker without any side effect. So as to be considered as first line antihypertensive therapy.

Hence, the aim of the study is to compare effects of Nebivolol and Atenolol on Blood Pressure, Blood Sugar, and Lipid Profile in patients of essential hypertension.

MATERIALS AND METHOD: A prospective study was conducted between December 2011 to August 2013 on 60 patients at medicine outpatient department (OPD) of Katihar Medical College, Katihar after getting approval from the Institutional Ethics Committee. The patients meeting the inclusion criteria were explained in detail about the nature of the trial, its purpose, procedures, and followup. They were provided with detailed trial information sheet. Written informed consent was obtained from those who volunteered to participate in the trial.

Inclusion Criteria: Patients of either gender in the age group of 20-70 years with blood pressure >140/90 mmHg, newly diagnosed cases were included in the study.

Exclusion Criteria:

1. Diabetic mellitus, bronchial asthma, chronic obstructive pulmonary disease, hepatic or renal diseases, sinus bradycardia, sick sinus syndrome, Prinzmetal's angina, heart block, chronic heart failure, myocardial infarction, and peripheral vascular disease were excluded.
2. Pregnant and lactating women and patients with history of hypersensitivity or allergy to atenolol/nebivolol were also excluded.
3. Cases of secondary hypertension.

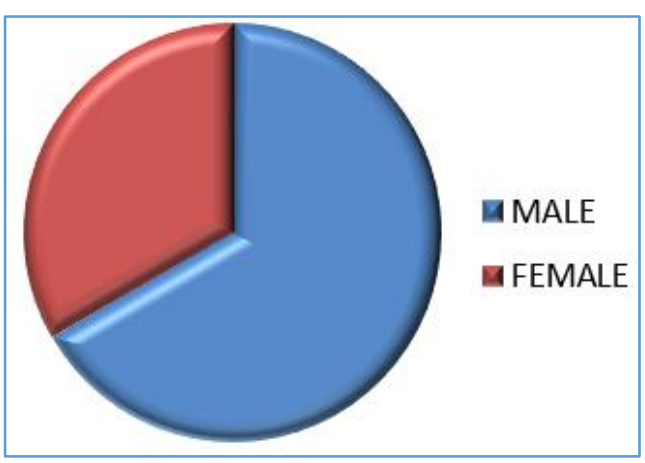
Systolic and diastolic blood pressure was measured in right arm, sitting posture by auscultatory method using standard mercury sphygmomanometer. Two recordings of blood pressure were taken at an interval of 15 min. After initial screening, the demographic data, past medical history, family history, findings of physical examination, and clinical examination were recorded in the case report form. Diagnosed cases of essential hypertension were randomly allocated using random number table to either Group A (to receive tablet atenolol 50 mg) or Group B (to receive tablet nebivolol 5 mg).

All patients were instructed to take the tablet orally once a day with glass of water in the morning. After allocating the patients to respective group, blood samples were drawn by taking all aseptic precaution in fasting state. Baseline fasting blood sugar, serum cholesterol, serum triglyceride, serum very low-density lipoproteins (VLDL), serum low-density lipoproteins (LDL), serum high-density lipoproteins (HDL), and electrocardiography (ECG) were done. Estimation of fasting blood sugar and serum lipids were done by using calibrated semiautomated analyser. Glucose oxidase/peroxidase (GOD/POD) method for the estimation of fasting blood sugar, Cholesterol oxidase peroxidase method for serum cholesterol, Precipitation method for HDL, Glycerol phosphate oxidase method for TG, Friedewald's formula for calculation of VLDL and LDL. Heart rate was calculated from ECG. The patients were recalled for review with filled and empty blisters of the tablets after 12 weeks and 24 weeks for evaluation by the physician and repeat investigations. Compliance to study medicines was measured by pill count during each followup.

RESULTS:

OBSERVATION:

Sex	Number of Patients
Male	40
Female	20
Table 1: Shows Sex Ratio of the Study	



This table shows that among 60 patients in the study 40 are male and 20 are female

Blood Pressure	Number of Patients
141-150	7
151-160	10
161-170	6
171-180	4
181-190	3
Table 2: Number of Patients Taking Nebivolol in Different Blood Pressure Groups	

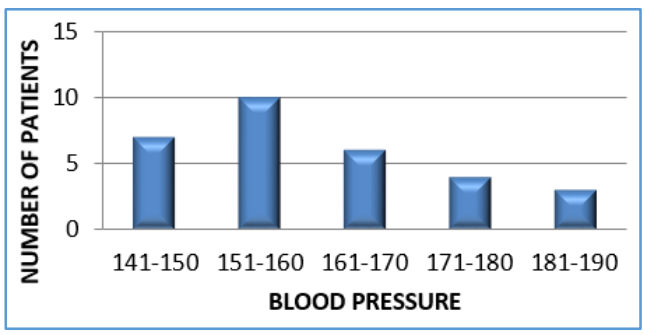


Table 1 Shows distribution of patients in different blood pressure groups; number of patients in between 141-150 mmHg are 7. Ten patients are in range of 151-160. Six patients are of blood pressure group 161-170 mmHg. 4 are in between 171-180 and 3 are in between 181-190.

Blood Pressure	Number of Patients
141-150	6
151-160	7
161-170	8
171-180	6
181-190	3
Table 3: Number of Patients Taking Atenolol in Different Blood Pressure Groups	

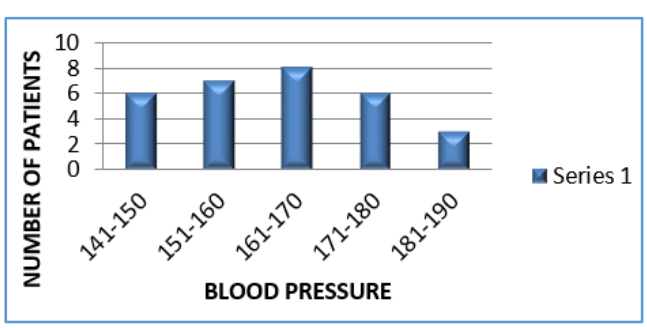


Table 2 Shows distribution of patients in different blood pressure groups; number of patients in between 141-150 mmHg are 6. Seven patients are in range of 151-160. Eight patients are of blood pressure group 161-170 mmHg. Six are in between 171-180 and 3 are in between 181-190.

Parameters	Group-a= atenolol 50 mg/day (n=30)		
	Baseline	12 weeks	24 weeks
SBP	162.16±1.61	142.13±0.56	131.92±0.87
DBP	96.45±1.12	88.32±1.56	80.11±0.78

Table 4: Effects of Atenolol on Systolic and Diastolic Blood Pressure of Patients at 12 and 24 Weeks of Treatment

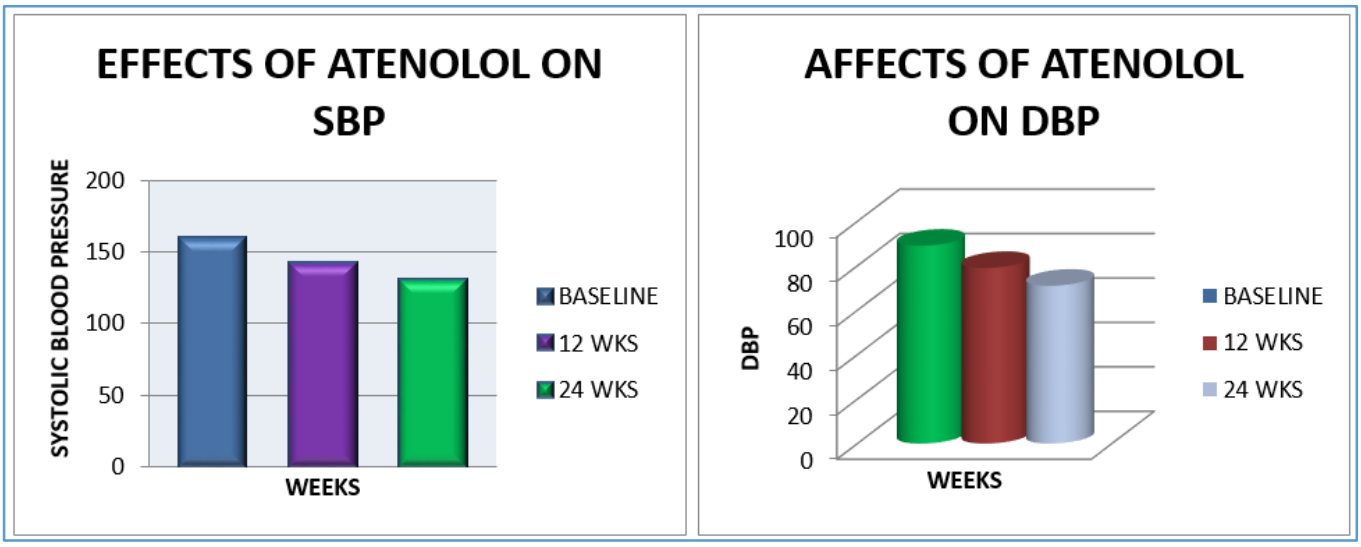


Table 3: Shows effect of atenolol on systolic and diastolic blood pressure at 12 and 24 weeks of treatment. Systolic blood pressure decreases from baseline 162.16 ±1.61 to 142.13±0.56 at 12 weeks and 131.92±0.87 at 24 weeks. Similarly, the diastolic blood pressure decreases from baseline 96.45±1.12 to 88.32±1.56 at 12 weeks and 80.11±0.78 at 24 weeks.

Parameters	Group- b=nebivolol 5 mg/day (n=30)		
	Baseline	12 weeks	24 weeks
SBP	161.16±1.71	146.13±0.56	126.72±0.82
DBP	97.45±1.13	87.32±1.56	79.91±0.98

Table 5: Effects of Nebivolol on Systolic and Diastolic Blood Pressure of Patients at 12 and 24 Weeks of Treatment

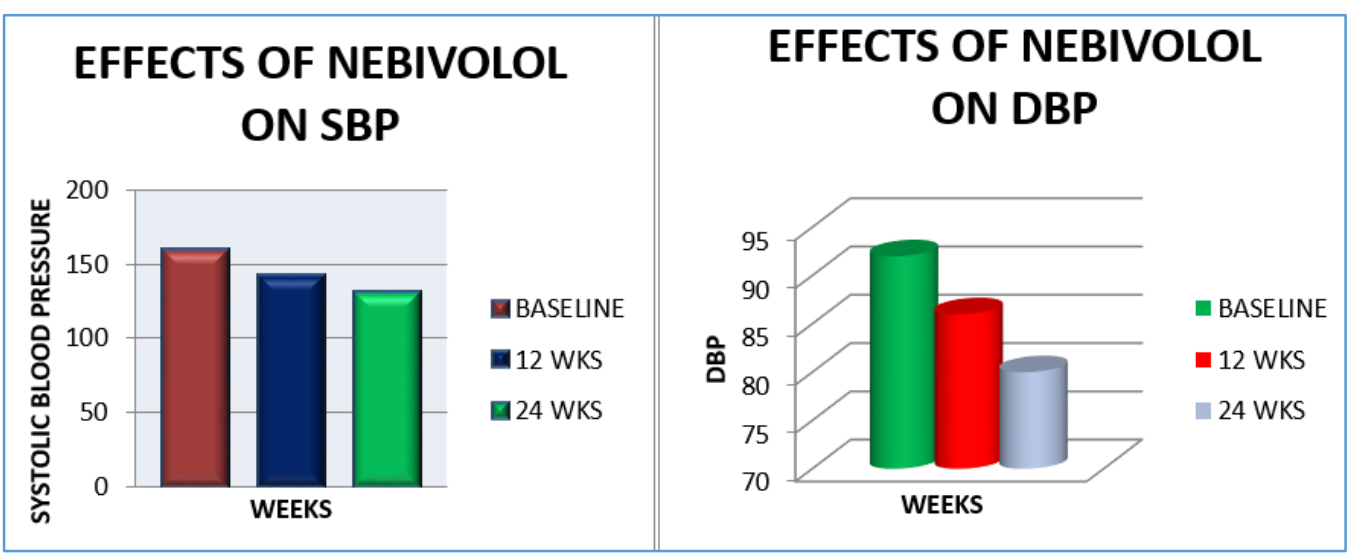


Table 4: Shows effect of nebivolol on systolic and diastolic blood pressure at 12 and 24 weeks of treatment. Systolic blood pressure decreases from baseline 161.16 ±1.71 to 146.13±0.56 at 12 weeks and 126.72±0.82 at 24 weeks. Similarly, the diastolic blood pressure decreases from baseline 97.45±1.13 to 87.32±1.56 at 12 weeks and 79.91±0.98 at 24 weeks.

Parameters	Group-b=nebivolol 5 mg/day (n=30)		
	Baseline	12 weeks	24 weeks
BSL	87.32±1.56	89.45±0.63	93.56±0.75

Table 6: Effects of Nebivolol on Blood Sugar Level of Patients at 12 and 24 Weeks of Treatment

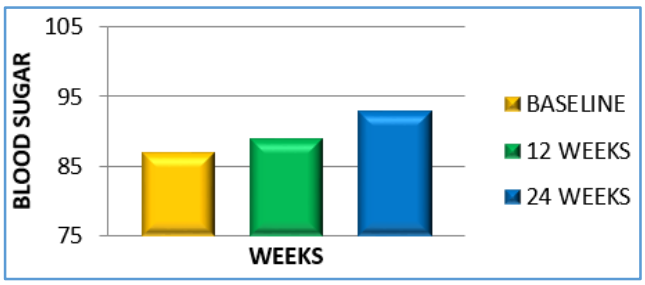


Table 5: Shows effects of nebivolol on blood sugar level of patients at 12 and 24 weeks of treatment. The baseline was 87.32±1.56 mg/dL. The blood sugar level increases slightly to 89.45±0.63 mg/dL at 12 weeks and 93.56±0.75 mg/dL at 24 weeks.

Parameters	Group-a= atenolol 50 mg/day (n=30)		
	Baseline	12 weeks	24 weeks
BSL	86.32±1.56	93.56±0.89	103.56±0.45

Table 7: Effects of Atenolol on Blood Sugar Level of Patients at 12 and 24 Weeks of Treatment

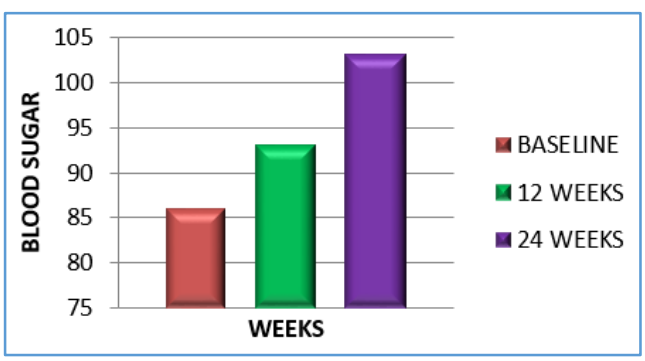


Table 6: Shows effects of atenolol on blood sugar level of patients at 12 and 24 weeks of treatment. The baseline was 86.32±1.56 mg/dL. The blood sugar level increases to 93.56±0.89 mg/dL at 12 weeks and 103.56±0.45 mg/dL at 24 weeks.

Parameters	Group-a= atenolol 50 mg/day (n=30)		
(Mg/dL)	Baseline	12 weeks	24 weeks
TC	160.43±2.67	171±1.61	183.30±0.34
TG	120.43±3.67	126.72±0.82	136.7±0.63
VLDL	25.89±0.89	25.91±0.98	26.78±0.23
HDL	43.76±0.43	41.45±1.13	40.98±0.98
LDL	93.89±3.23	103.45±0.63	115.67±0.27

Table 8: Effects of Atenolol on Lipid Profile of Patients at 12 and 24 Weeks of Treatment

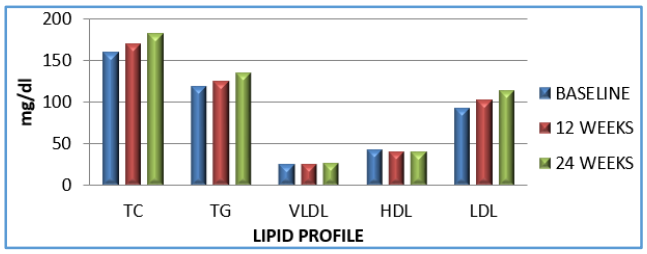


Table 7: Shows effects of atenolol on lipid profile of patients at 12 and 24 weeks of treatment. Total cholesterol (tc) increases from baseline 160.43±2.67 to 171±1.61 at 12 weeks and 183.30±0.34 at 24 weeks. Triglycerides (tg) level are 120.43±3.67 at baseline 126.72±0.82 at 12 weeks and 136.7±0.63 at 24 weeks. VLDL levels are 25.89±0.89 at the start of study, 25.91±0.98 at 12 weeks and 26.78±0.23 at 24 weeks. HDL level was 43.76±0.43 at baseline. At 12 weeks, it is 41.45±1.13 and at 24 weeks its level is 40.98±0.98. LDL values change from baseline 93.89±3.23 to 103.45±0.63 at 12 weeks and 115.67±0.27 at 24 weeks.

Parameters	Group-B= atenolol 5 mg/day (n=30)		
	Baseline	12 weeks	24 weeks
TC	162.43±1.77	162.98±0.63	163.30±0.84
TG	118.83±3.67	124.87±0.45	136.7±0.93
VLDL	23.89±0.89	23.83±0.45	23.78±0.63
HDL	44.76±0.93	44.86±1.56	44.98±0.08
LDL	93.59±3.25	93.62±3.67	93.67±0.97

Table 9: Effects of Nebivolol on Lipid Profile of Patients at 12 and 24 Weeks of Treatment

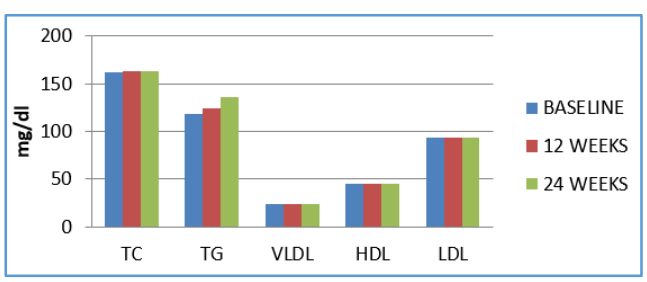


Table 8: Shows effects of atenolol on lipid profile of patients at 12 and 24 weeks of treatment. Total cholesterol (tc) increases from baseline 162.43±1.77 to 162.98±0.63 at 12 weeks and 163.30±0.84 at 24 weeks. Triglyceride (tg) levels are 118.83±3.67 at baseline, 124.87±0.45 at 12 weeks and 136.7±0.93 at 24 weeks. VLDL levels are 23.89±0.89 at the start of study, 23.83 ±0.45 at 12 weeks and 23.78±0.63 at 24 weeks. HDL level was 44.76±0.93 at baseline, at 12 weeks 44.86 ±1.56, and at 24 weeks 44.98±0.08. LDL values change from baseline 93.59±3.25 to 93.62±3.67 at 12 weeks and 93.67±0.97 at 24 weeks.

Parameters	Mean difference from baseline at 24 weeks	
	Atenolol (n=30)	Nebivolol (n=30)
SBP	40.2±1.74	43.8±1.405
DBP	17±1.3	19.4±1.223
BSL	18.43±1.216	1.08±1.134
TC(mg/dL)	20.83±1.034	0.63±0.758
TG(mg/dL)	15.96±1.784	0.17±0.667
VLDL(mg/dL)	3.20±0.297	0.00±0.200
HDL(mg/dL)	-2.97±0.203	0.12±0.302
LDL(mg/dL)	21.46±1.04	0.44±0.684

Table 10: Comparison of Effect of Atenolol and Nebivolol on Cardiovascular and Metabolic Parameters in Patients of Essential Hypertension

Table 10: This table shows the mean difference of SBP and DBP is 40.2±1.74 and 17±1.3 in patients on atenolol and 43.8±1.405 and 19.4±1.223 in nebivolol group in 24 weeks of treatment. The mean difference of blood sugar level is 18.43±1.216 and 1.08±1.134 in nebivolol and atenolol group respectively. In 24 weeks of treatment, the mean difference in TC, TG, VLDL, HDL, and LDL is 20.83±1.034, 15.96±1.784, 3.20±0.297, -2.97±0.203, and 21.46±1.04, respectively in atenolol group. And in nebivolol group, the mean difference is 0.63±0.758, 0.17±0.667, 0.00±0.200, 0.12±0.302 and 0.44±0.684 respectively.

DISCUSSION: There is a strong relationship between hypertension and cardiovascular, cerebrovascular and renovascular diseases. The main goal of hypertensive treatment is to prevent/arrest cardiovascular damage as well as preventing hypertensive complications such as stroke and renal failure. Beta-blockers are recommended as first-line treatment in essential hypertension (JNC 7). However, the newer hypertension treatment guidelines from National Institute for Health and Clinical Excellence (NICE) and the British Hypertension Society (BHS) recommend that "β blockers should no longer be used as first-line drugs for the treatment of uncomplicated hypertension." This recommendation is based on the evidence of various studies of atenolol alone or in addition diuretics increases the risk of new onset diabetes mellitus than other medicines such as ACE inhibitors, angiotensin receptor blockers and calcium channel blockers, due to its adverse effect on carbohydrate and lipid metabolism. Hence, β-blockers are now reserved as third- or fourth-line medicines unless there are compelling indications otherwise. Patients treated with atenolol (±diuretics) have 30% higher chances of new onset diabetes compared to those receiving calcium channel blockers (±ACE inhibitors).

In our study, the mean difference of systolic blood pressure from baseline and at 24 weeks was 40.20 ±1.74 in the Atenolol group and 43.80±1.405 in the Nebivolol group. Similarly, in Atenolol group, diastolic blood pressure is decreased by 17±1.3 and 19.4±1.223 in Nebivolol group. In the study conducted by Badar VA et al on essential hypertension published in Indian Journal of Pharmacology, 2011 Jul-Aug, the mean difference of systolic blood pressure from baseline and at 24 weeks was 41.20 ±1.75 in the Atenolol group and 43.20±1.50 in the Nebivolol group. Similarly, in Atenolol group diastolic blood pressure decreased by 16±1.29, and 18.6±1.33 in Nebivolol group. Similar findings were observed in study done by Van Nueten L, Taylor FR, Robertson JI. (1998), in his double blind randomised trial. Similar observation was found in study done by Sawhney V, Kapoor B et al in study on Effects of atenolol and nebivolol on blood pressure and ECG, published in Journal of Clinical and Diagnostic Research. 2008 Dhakam Z, Yasmin, McEniery CM, Burton T, Brown MJ, Wilkinson IB, in their study, A comparison of atenolol and nebivolol in isolated systolic hypertension, 2008, found the same.

In our study, the mean difference of blood sugar level from baseline and at 24 weeks was 18.43±1.216 in the Atenolol group and 1.08±1.134 in the Nebivolol group. Study conducted by Badar VA, et al, on essential hypertension published in Indian Journal of Pharmacology, 2011 Jul-Aug, the mean difference of blood sugar level from baseline and at 24 weeks was 17.43±1.31 in the Atenolol group and 1.03±1.23 in the Nebivolol group. Similar observation was found in study done by Sawhney V, Kapoor B et al, in study on Effects of atenolol and nebivolol on blood pressure and ECG, published in Journal of Clinical and Diagnostic Research, 2008 Aug, Poirier L, Cléroux J, Nadeau A, Lacourcière Y, (2001) Effects of nebivolol and atenolol on insulin sensitivity and haemodynamics in hypertensive patients, indicate that insulin sensitivity was not modified significantly by nebivolol, whereas it was reduced by atenolol, although blood pressure was decreased to the same extent by both drugs. Neither drug induced systemic or forearm vasodilatation but the inverse relationship between cardiac output and insulin sensitivity was preserved with nebivolol but not with atenolol. Dunne F, Kendall MJ, Martin U, (2001) in their study Beta-blockers in the management of hypertension in patients with type 2 diabetes mellitus: Is there a role? Showed that the development of newer and more selective beta-blockers has overcome many of these problems. In addition, some of the newer agents have novel properties such as release of nitric oxide, which theoretically would make them more attractive in patients with diabetes mellitus.

In this study, the mean difference of Total cholesterol, Triglycerides, VLDL, HDL, and LDL from baseline and at 24 weeks is 20.83±1.034, 15.96±1.784, 3.20±0.297, -2.97±0.203, and 21.46±1.04 respectively in the Atenolol group and 0.63±0.758, 0.17±0.667, 0.00±0.200, 0.12±0.302, and 0.44±0.684 in the Nebivolol group. Similarly, Kalavathi D et al found that there were non-significant differences in case of TG, HDL, LDL with treatment of Nebivolol. Similar study by Pesant, Marc Aurele et al found no significant changes in lipid metabolism. Fogari R et al in their study showed that in hypertensive patients with NIDDM, on treatment with Nebivolol, there was no adverse effect on lipid profile. Fallois el al (2001), in a 6-week observational study, showed that nebivolol reduced both systolic and diastolic blood pressures and unlike first

generation beta-blockers, there were significant reductions in cholesterol, triglycerides, and blood sugar. Grassi G, Trevano FQ, Facchini A, Toutouzas T, Chanu B, Mancia G, (2003), provided evidence that for the same antihypertensive effects, nebivolol shows a better tolerability profile than atenolol and a lower incidence of adverse effects. The β receptors mediate activation of hormone sensitive lipase in fat cells leading to release of free fatty acids into the circulation. Beta receptor antagonists modify the metabolism of carbohydrates and lipids by attenuating the release of free fatty acids from adipose tissue. The vasodilator β-blockers increase insulin sensitivity in patients with insulin resistance as compared to classical β-blockers which decrease insulin sensitivity. Antioxidant property of nebivolol and increase in NO by reducing its oxidative inactivation may be responsible for beneficial lipid and carbohydrate metabolic profile. Thus, Nebivolol may be a better therapeutic option for the patients requiring beta-blocker due to its favourable metabolic properties.

SUMMARY AND CONCLUSION: Beta-blocker is considered to be very effective antihypertensive drug to control hypertension. But National Institute for Health and Clinical Excellence (NICE) recommended that it should no longer be used as first-line drug as the treatment of uncomplicated hypertension. This recommendation was based on the various studies showing increased risk of new onset Diabetes Mellitus and derangement of lipid metabolism with the use of beta-blocker. These studies were mainly based on Atenolol with or without diuretics. We are in need of a beta-blocker that has effective antihypertensive properties without altering the metabolic profile like blood sugar level and lipid metabolism. Nebivolol, a b1-selective blocker, has got more or less the similar properties. It increases insulin sensitivity in patients with insulin resistance due to its vasodilator properties. Also, antioxidant properties of Nebivolol, and increase in nitric oxide properties by reducing its oxidative inactivation may be responsible for beneficial lipid and carbohydrate metabolic profile.

Our study clearly shows that Nebivolol is a highly effective antihypertensive as Atenolol and very minimal or no derangement observed in forms of blood sugar, TG, VLDL, HDL, and LDL level after successful therapy with Nebivolol. Hence Nebivolol, a selective beta-blocker with vasodilator properties should be considered to be a first line antihypertensive therapy.

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