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## Comparative study on efficacy of Amlodipine versus Atenolol with Hypertensive Patients in a Tertiary Care Teaching Hospital, Nellore

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### ABSTRACT

Hypertension is currently affects, approximately one billion adults globally. It is a major risk factor for cardiovascular diseases (CV) and stroke. The high prevalence of hypertension has contributed to the present pandemic of CV disease, which now accounts for 30% of all deaths worldwide. As the population ages and the prevalence of contributing factors such as obesity, sedentary lifestyle and smoking rise, this figure is projected to increase by 60% to 1.56 billion by the year 2025. The present study was to compare the efficacy of Amlodipine vs. Atenolol, both are belongs to the above mentioned classes of channel blocker and beta adrenergic blocker above Amlodipine has antioxidant properties and an ability to enhance the production of nitric oxide (NO), an important vasodilator that decreases blood pressure and Atenolol will reduce the heart rate, blood pressure and decreases myocardial contractility. Treatment of hypertension with two study drugs Amlodipine 5 mg and Atenolol 25 mg were carried out in a population of 50 patients. They were instructed to follow a healthy diet with proper exercise. After 3 months study it is observed that, both of the study drugs have good impact on blood pressure lowering. But the Atenolol 25 mg showed superior reduction in blood pressure when compared to Amlodipine 5 mg.

**Keywords:** Hypertension, Myocardial contractility, Atenolol, Family history

### ARTICLE INFO

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## 1. Introduction

### Definition

Hypertension (or HTN) or high blood pressure is defined as abnormally high arterial blood pressure. According to the

Joint National Committee 7 (JNC7), normal blood pressure is a systolic BP < 120 mmHg and diastolic BP < 80 mm Hg. Hypertension is defined as systolic BP level of ≥140 mmHg

and/or diastolic BP level  $m \geq 90$  mmHg. The grey area falling between 120–139 mmHg systolic BP and 80–89 mmHg diastolic BP is defined as “pre hypertension”<sup>6,7</sup>. Although pre hypertension is not a medical condition in itself, pre hypertensive subjects are at more risk of developing HTN<sup>8</sup>.

### Etiology

More than 90% of the patients having essential hypertension, it is a disorder of unknown origin effect the BP regulating mechanism. A subject with family history of hypertension is likelihood to develop hypertensive disease. Primary hypertension is four times more frequently in blacks than in whites. Likely it observed more often in middle aged male subjects than middle aged females. Many environmental factors like stressful life style, unhealthy diet, obesity, smoking and alcoholism, lack of proper exercise and usage of drugs such as NSAID are predisposing factors to develop hypertension<sup>9</sup>.

### Causes of Hypertension

90-95% of hypertension is primary \essential hypertension and 5-10% of hypertension belongs to Secondary hypertension<sup>10</sup>.

### Primary Hypertension

It is an elevation in BP without an identified cause.

### Secondary Hypertension

- It is an elevation in BP with an exact cause. This type is account for 5-10% total cases. The causes of secondary HTN includes
- Congenital narrowing of aorta
- Renal disease
- Endocrine disorders like brain tumours and head injury
- Sleep apnoea
- Medications like oral contraceptive pills
- NSAID and cocaine
- Cirrhosis of liver
- RISK FACTORS
- Age: chance of CAD after 50 years of age
- Alcohol, smoking and DM
- Excessive dietary intake of sodium
- Gender
- Family history
- Obesity
- Sedentary life style
- Stress<sup>11</sup>

### Complications of Hypertension

- Myocardial infraction
- Stroke
- Malignant hypertension
- Dissecting aortic aneurysm
- Hypertensive Nephrosclerosis
- Peripheral vascular disease

### Drug Profile Amlodipine

**Name:** Amlodipine

**Brand Name:** Aml-5mg

### Description:

Amlodipine, initially approved by the FDA in 1987, is a popular antihypertensive drug belonging to the group of drugs called dihydropyridine calcium channel blockers. Due to their selectivity for the peripheral blood vessels, dihydropyridine calcium channel blockers are associated with a lower incidence of myocardial depression and cardiac conduction abnormalities than other calcium channel blockers. Amlodipine is commonly used in the treatment of high blood pressure and angina. Amlodipine has antioxidant properties and an ability to enhance the production of nitric oxide (NO), an important vasodilator that decreases blood pressure. The option for single daily dosing of amlodipine is an attractive feature of this drug. Therapeutic category: Antihypertensive (calcium channel blocker)

Table 1: Classification of Blood Pressure

| Classification of bloodpressure | Systolic (mm Hg) | Diastolic (mm Hg) |
|---------------------------------|------------------|-------------------|
| Normal                          | <120             | and <80           |
| Prehypertension                 | 120–139          | or 80–89          |
| Stage 1Hypertension             | 140–159          | or 90–99          |
| Stage 2Hypertension             | $\geq 160$       | or $\geq 100$     |

### Interaction:

#### Drug – Drug:

**1-benzylimidazole:** 1-benzylimidazole may decrease the antihypertensive activities of Amlodipine.

**2,4-thiazolidinedione:** The risk or severity of hypoglycemia can be increased when Amlodipine is combined with 2,4-thiazolidinedione.

#### 2,5-Dimethoxy-4-ethylthioamphetamine:

2,5-Dimethoxy-4-ethylthioamphetamine may decrease the antihypertensive activities of Amlodipine.

#### 4-Methoxyamphetamine:

4-Methoxyamphetamine may decrease the antihypertensive activities of Amlodipine.

**Abediterol:** Abediterol may decrease the antihypertensive activities of Amlodipine.

#### Food-Drug:

- Avoid grapefruit products.
- Avoid natural licorice.
- Take with or without food. The absorption is unaffected by food

### Atenolol

**Name:** Atenolol

**Brand Names:** Aten-100mg

**Description:** Atenolol is a cardio selective beta-blocker used in a variety of cardiovascular conditions. Sir James Black, a Scottish pharmacologist, pioneered the use of beta-blockers for the management of angina pectoris in 1958 for which he received the Nobel Prize. Beta-blockers quickly became popular in clinical use and where subsequently investigated for use in myocardial infarction,

arrhythmias, and hypertension during the 1960s. Later they continued to be investigated for use in heart failure throughout the 1970-1980s. Atenolol itself was developed early on in this history by Alvogen Malta under the trade name Tenormin and received FDA approval in September, 1981.

**Therapeutic category:** Antihypertensive (Beta adrenergic blocker)

**Drug – Drug:**

- 1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine: The metabolism of Atenolol can be decreased when combined with 1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine.
- 1-benzylimidazole: 1-benzylimidazole may decrease the antihypertensive activities of Atenolol.
- 2,5-Dimethoxy-4-ethylamphetamine: The therapeutic efficacy of Atenolol can be decreased when used in combination with 2,5-Dimethoxy-4-ethylamphetamine.
- 25-desacetylirifapentine: The metabolism of Atenolol can be increased when combined with 25-desacetylirifapentine.
- 4-Bromo-2,5-dimethoxyamphetamine: The therapeutic efficacy of Atenolol can be decreased when used in combination with 4-Bromo-2,5-dimethoxyamphetamine.

**Food-Drug:**

- Avoid foods rich in vitamin K. Vitamin K in foods such as green leafy vegetables can reduce warfarin efficacy.
- Take at the same time every day.
- Take before a meal. Take 30-60 minutes before meals<sup>63</sup>.

## 2. Methodology

**Study Site:** ACSR GOVT Hospital, (750 bedded), Nellore – AP

**Study Design:** Prospective observational study.

**Duration of Study:** 3 months.

**Dosage:** Amlodipine 5mg, Atenolol 25 mg.

- A total of 50 patients were enrolled in the treatment program.
- A prospective and observational study was carried out to compare efficacy of Amlodipine 5mg versus Atenolol 25 mg in patients with hypertension.
- The selected patients were divided into two groups. Group A, Group B
- Group A (25 patients) were to be treated with Amlodipine 5mg.
- Group B (25 patients) were to be treated with Atenolol 25 mg.

### Study criteria

#### Inclusion criteria

- **Patients aged between 30 -59 years and** Patient's who having sustained diastolic blood pressure >90 mm Hg accompanied by elevated systolic blood pressure > 140 mm Hg.
- Patient's who agreed with prescribed consent form.
- Patients who are able to participate in the study.

#### Exclusion Criteria

**Patient with secondary hyper tension and other medication with known effects**

- Patient who refuse to participate in study or withdrawing prescribed consent.
- Pregnant and lactating women
- Patients who are not able to participate in the study

#### Parameters

- Primary parameters
- Systolic blood pressure
- Diastolic blood pressure

#### Secondary Parameters

- Height
- Weight
- BMI

#### Statistical Analysis

- The information collected regarding all the selected cases were recorded in a Master Chart.
- Data analysis was done with the help of computer (Microsoft excel 2007) Using this software range, frequencies, percentages, means, standard deviations, and 'p' values were calculated.
- The Students T test was used to test the significant difference of quantitative variables; chi square test was used to test the significant difference of qualitative variables.
- A 'p' value less than 0.05 is taken to denote significant relationship.

#### Method of Study

- Based on the inclusion criteria and exclusion criteria patients were enrolled in the study
- Patient data such as demographic details and medical history should be collected from data collection form.
- The inclusion criteria patients were divided into two groups are: Group: A & Group: B
- The drug Amlodipine 5mg should be given to the Group A subjects and Atenolol 25mg should be given to the Group B subjects because to comparing the two drugs in hypertensive patients.
- Follow up should be done for every 15 days intervals during their treatment of hypertension.
- For every visit of all primary and secondary parameters were recorded in the initial visit to

final visit.

- Assessing the efficacy of between a two drugs by systolic and diastolic parameters.
- To monitor the drug's efficacy and its effect in hypertensive patients
- Outcomes for the Amlodipine 5 mg and Atenolol

25 mg is observed for comparing the two drugs hypertensive patients and patient blood pressure controlled is assessed.

- The comparison of efficacy between two drugs to control blood pressure should be achieved.

### 3. Results and Discussion

The work entitled comparative study of efficacy of Amlodipine 5 mg versus Atenolol 25 mg in patients with hypertension was carried out in Department of General Medicine at ACSR GOVT hospital, Nellore, AP. A total number of 50 patients were enrolled in this study. These patients were divided into two groups (A&B). Group A (25 patients) were treated with Amlodipine 5 mg and Group B (25 patients) Atenolol 25 mg. All primary and secondary parameters were recorded in the initial visit, systolic and diastolic blood pressure recorded at each follow up of 15 days interval and weight, height and body mass index were recorded at the end of the study. All the recorded parameters were compared to assess the efficacy.

Group A: Amlodipine 5 mg

Group B: Atenolol 25 mg

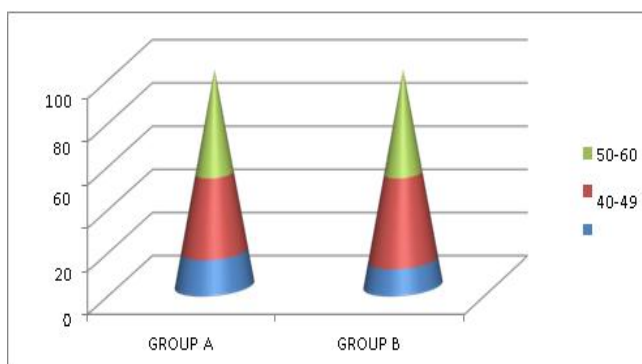


Figure 1 Age Distribution

The mean age of group A was  $50.17 \pm 6.62$  years and group B was  $50.47 \pm 6.25$  years.

Table 2: Age Distribution

| Age group (in years ) | Group A |     | Group B |     |
|-----------------------|---------|-----|---------|-----|
|                       | No      | %   | No      | %   |
| 30 – 39 years         | 4       | 16  | 3       | 12  |
| 40 – 49 years         | 9       | 36  | 10      | 40  |
| 50 – 60 years         | 12      | 48  | 12      | 48  |
| Total                 | 25      | 100 | 25      | 100 |
| Range                 | 38 –59  |     | 30 – 60 |     |
| Mean                  |         |     |         |     |
| SD                    | 5.62    |     | 5.25    |     |

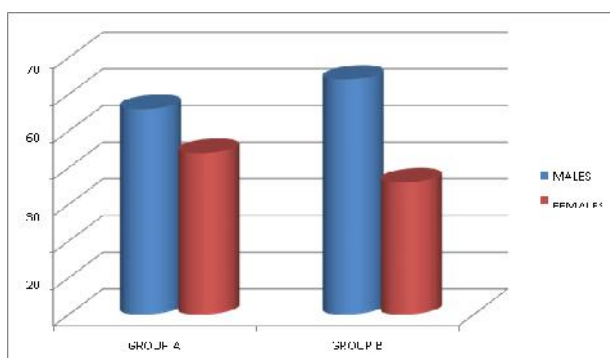


Figure 2 Sex Distribution

Table 3: Sex Distribution

| SEX    | Group A |     | Group B |     |
|--------|---------|-----|---------|-----|
|        | No      | %   | No      | %   |
| Male   | 14      | 56  | 16      | 64  |
| Female | 11      | 44  | 9       | 36  |
| Total  | 25      | 100 | 25      | 100 |

Table 4: Physiological Parameters

| Variable       | Group A |      | Group B |      | 'p' value |
|----------------|---------|------|---------|------|-----------|
|                | Mean    | SD   | Mean    | SD   |           |
| Weight (in kg) | 76.1    | 7.97 | 72.3    | 7.82 | 0.1823    |
| Height (in cm) | 164.52  | 7.56 | 162.66  | 7.95 |           |
| BMI            | 28.65   | 2.75 | 27.99   | 2.92 |           |

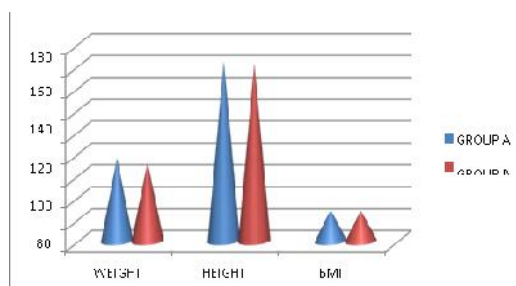


Figure 3 Physiological Parameters

Table 5: Change in BMI

| BMI  | GROUP A    |            |            | GROUP B    |            |            |
|------|------------|------------|------------|------------|------------|------------|
|      | Firstvisit | Finalvalue | Difference | Firstvisit | Finalvalue | Difference |
| MEAN | 28.59      | 27.14      | 1.45       | 27.84      | 26.33      | 1.51       |
| SD   | ±2.70      | ±2.72      | ±1.36      | ±2.89      | ±2.68      | ±1.68      |

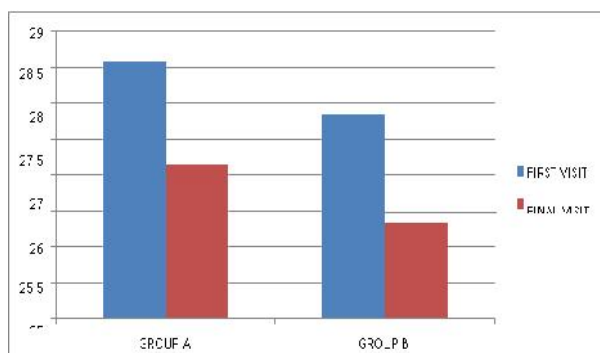


Figure 4: Change in BMI

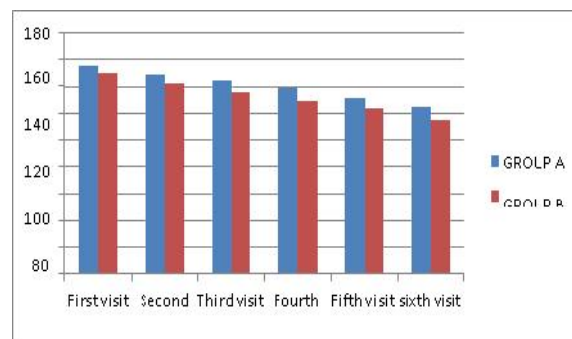


Figure 6: Change in Diastolic Blood Pressure in 2 Week Interval

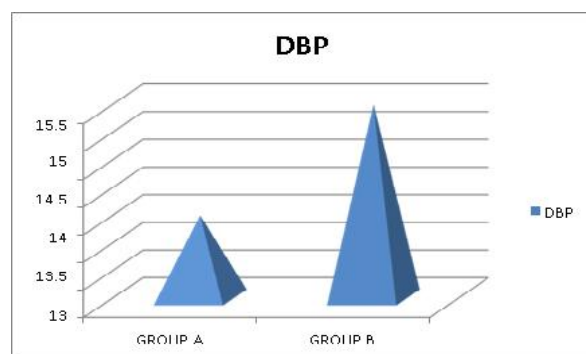


Figure 5: Change in Diastolic Blood Pressure (DBP)

## Discussion

### Age Distribution:

A number of 50 patients, 25 patients were of group A, out of these 4 patients (16%) between the age group of 30-39 years, 9 patients (36%) between the age group of 40-49 years, 12 patients (48%) between the age group of 50-60 years and 25 patients were of group B, out of these 3 patients (12%) between the age group of 30-39 years, 10 patients (40%) between the age group of 40-49 years, 12 patients (48%) between the age group of 50-60 years. The age group A was  $48.12 \pm 5.62$  years and group B was  $48.53 \pm 5.25$  years. A total number of 24 patients come under the age category 50-60 years i.e., 53.33% of total

study population this will cement the age correlation of hypertension "As the age increases the risk for hypertension also increases".

### Sex Distribution

A total of 50 patients were screened and randomized into two treatment group. Out of which 25 patients were of GROUP A, 14 patients (56%) were males, 11 patients (44%) were females. In case of 25 patients of GROUP B, 16 patients (64%) were males, 9 patients (36%) were females. In our study population, numbers of males with hypertension were higher than the females, this may be due to the life style difference between the males and females, especially using of tobacco and alcohol.

### Physiological parameters:

The average weights of patients were  $76.1 \pm 7.97$  in GROUP A and  $72.3 \pm 7.82$  in GROUP B. The average height of patients was  $164.52 \pm 7.56$  in GROUP A and  $162.66 \pm 7.95$  in GROUP B. The average BMI of patients were  $28.65 \pm 2.75$  in GROUP A and  $27.99 \pm 2.92$  in GROUP B.

### Systolic Blood Pressure:

The mean systolic blood pressure of Group A and Group B were  $(154.91 \pm 7.51 \text{ mm Hg})$  &  $(149.80 \pm 8.28 \text{ mm Hg})$  respectively, at the base line (First visit). The group A who were treated with Amlodipine 5 mg showed a mean reduction of  $(124.11 \pm 6.99 \text{ mm Hg})$  but that was lower than that produced by the Atenolol in Group B  $(33.27 \pm 3.42 \text{ mm Hg})$ . Both of the study drug produced reduction in the systolic blood pressure during the study time and of that, the Atenolol 25 mg is found to be superior in SBP reduction which is statistically significant when compare to Amlodipine 5 mg with a p value  $< 0.05$ .

### Diastolic Blood Pressure

The mean Diastolic blood pressure of Group A and Group B were  $(94.69 \pm 4.32 \text{ mm Hg})$  &  $(94.60 \pm 3.70 \text{ mm Hg})$  respectively, at the base line (First visit). The group A who were treated with Amlodipine 5 mg showed a mean reduction of  $(13.49 \pm 3.08 \text{ mm Hg})$  but that was lower than that produced by the Atenolol 25 mg in Group B  $(15.49 \pm 3.22 \text{ mm Hg})$ . Both of the study drug produced reduction in the systolic blood pressure during the study time and of that the Atenolol 25 mg is found to be superior in SBP reduction which is statistically significant when compare to Amlodipine 5mg with a p value  $< 0.05$ .

## 4. Conclusion

In this present prospective observational study, treatment of hypertension with two study drugs Amlodipine 5 mg and Atenolol 25 mg were carried out in a population of 50 patients. They were instructed to follow a healthy diet with proper exercise. After 3 months study it is observed that, both of the study drugs have good impact on blood pressure lowering. But the Atenolol 25 mg showed superior reduction in blood pressure when compared to Amlodipine 5 mg.

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