CODEN [USA]: IAJPBB ISSN: 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

http://doi.org/10.5281/zenodo.2582302

Available online at: http://www.iajps.com ***Research Article***

STUDY TO KNOW THE AMLODIPINE EFFICACY FOR THE TREATMENT OF ESSENTIAL HYPERTENTION AND ITS TOXICITY AND TOLERABILITY

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Abstract:

Objective: *To know the tolerability and efficacy of Amlodipne in the mild to moderate hypertension treatment.*

Study design: *An Observational Study.*

Location and Duration: *In the Medical Unit-1 of Allied Hospital Faisalabad for one-year duration from September 2017 to September 2018.*

Methods: *Eighty patients with ages ranging from 30 to 90 years were selected for the study. The mean age ± SD was 62.27 ± 8.19. After the history was taken, patients diagnosed with mild to moderate hypertension the antihypertensive drugs were given, but hypertension was not adequately controlled were selected. Diastolic blood pressure was defined as 90-112 mmHg in sitting position. It is based on two separate situations at least 6 days apart. A dose of 5 mg amlodipine was recommended and administered daily for at least 15 days. Two weeks later, the daily dose was adjusted to 10 mg in patients who did not show a satisfactory reduction in blood pressure in the absence of clinically significant side effects thought to be drug-related. The patients were followed-up for six weeks.*

Results: *After six weeks of treatment, 30 mmHg was the decline in systolic blood pressure and the 20 mmHg decline in diastolic blood pressure. Fifty-nine (76%) patients received 5 mg, while the remaining 19 (24%) used 10 mg amlodipine. At the end of the study, patients did not show a significant change in heart rate. Overall, efficacy assessment was excellent at 78%, good at 18%, and fair at 4%. As for tolerance, it was excellent at 81%, good at 15%, fair at 3% and weak at 1%. 80 patients (14%) had a negative effect and 2 (3%) withdrew from the study due to adverse effects, one was a male patient after 2 weeks and the other was female 4 weeks later.*

Conclusion: *This study concluded that amlodipine is effective once a day for mild to moderate hypertension.*

Key words: *Amlodipine, Efficacy, Essential Hypertension.*

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Please cite this article in press Zainab Bilal et al., ***Study To Know The Amlodipine Efficacy For The Treatment Of Essential Hypertention And Its Toxicity And Tolerability.,*** *Indo Am. J. P. Sci, 2019; 06(02).*

INTRODUCTION:

Hypertension is sometimes secondary to a different disease. However, most patients with persistent hypertension have essential hypertension. A few patients with persistent systemic hypertension have a specific etiology (eg, kidney disease, endocrine disease, heart attack and stroke). These organ insufficiencies are the main causes of morbidity and mortality. There is strong evidence that the currently accepted guideline has changed the threshold for initiating the drug treatment of the physician, changing the changes or increasing the dose by about 5 to 10 mg. Only 31% of Americans with hypertension effectively control their blood pressure. In the United States, 50 million Americans suffer from hypertension, and 600,000 paralyzed cases per year are responsible for 1.1 million heart attacks per year, 400,000 new heart failures per year, and approximately 1 million deaths a year from cardiovascular and kidney diseases. Amlodipine is a calcium channel blocker of the 1,4-dihydropyridine class proved from clinical trials in the Canada, Europe and United States. It is suggested that the drug is effective as an antihypertensive agent is amlodipine that provides better hypertention control for 24 hours without sudden drop of blood pressure and is well tolerated in combination with other antihypertensive drugs or as monotherapy. 18 total clinical studies were reviewed; amlodipine was given to 1091 patients, placebo in 805 or for comparison another drug was given. Amlodipine was effective compared to placebo and significant clinically in controlling blood pressure (23/13 mm Hg in supine position, 24/12 mmHg in the vertical position) with similar cardiac frequencies in the supine position in a representative study. Treatment of hypertension in the elderly and standing should start with lifestyle changes. Treatment with antihypertensive drugs reduces stroke, cardiovascular disease, heart failure, and related mortality. Thiazide diuretics can be used as monotherapy and well tolerated by the elderly. Diuretics cause a disproportionately greater reduction in systolic blood pressure compared to diastolic blood pressure. The amlodipine ,a long-acting dihydropyridine calcium channel blockers are ideal antihypertensive agents in the hypertension treatment in the elderly. Calcium ion plays a critical role in the contraction of vascular smooth muscle and increased peripheral vascular coronary vasodilators and is therefore useful in patients with angina.

MATERIALS AND METHODS:

This Observational Study was held in the Medical Unit-1 of Allied Hospital Faisalabad for one year duration from September 2017 to September 2018.
Eighty essential hypertension cases were included to evaluate the efficacy of amlodipine. Adults older than 30 years who have recently been diagnosed with mild or moderate hypertension or have already been diagnosed and who received antihypertensive medications and were not adequately controlled were selected. Pregnant women or the possibility of having a child and the damage to the target organs were excluded from the study. Hypertension was defined as diastolic blood pressure in the 95-114 mmHg range. The mean diastolic blood pressure will be documented in two separate cases for at least 5 days. Oral informed consent and complete medical history of each patient were obtained and physical examination was performed before starting the study. The patient's blood pressure in lying, sitting and standing was recorded. Patients were examined every week. The subjects who continued Amlodipine once a day shows a decrease in diastolic blood pressure greater than 5 mmHg after reaching the target diastolic blood pressure <90mmHg or after the first two weeks of treatment. Patients who did not show a satisfactory reduction in blood pressure after the first two weeks of treatment were increased to 10 mg / day to obtain a diastolic blood pressure of <90mmHg. Patients with diastolic blood pressure less than or equal to 5 mmHg or BPD <90 mmHg, with a maximum dose of 10 mg / day amlodipine taken over two weeks, or
Clinically significant side effects thought to be drug-related were withdrawn from the study.

Data analysis: Data was analyzed and entered in SPSS 17.0 version. Quantitative variables of the study, namely age and age presented as standard deviation. Qualitative data of gender, global amlodipine and tolerance assessment are presented as percentage and frequency.

RESULTS:

The patients mean age was 62.27 ± 8.19. Of the 80 patients, 14 (18%) were between the ages of 30-45 and 36 (45%) were between 46 and 60 years of age. Most of the patients were in the 46-60 age group. The male to female ratio was 1.16: 1 (Table 1).

Table 1: Frequency distribution of demographic variables (n=80)

Age in Years	**Frequency**	**Percentage**
30 – 45	14	18.0
46 – 60	36	45.0
61 – 75	24	30.0
76 – 90	6	7.0
Gender		
Male	43	54.0
Female	37	46.0
Total	80	100.0

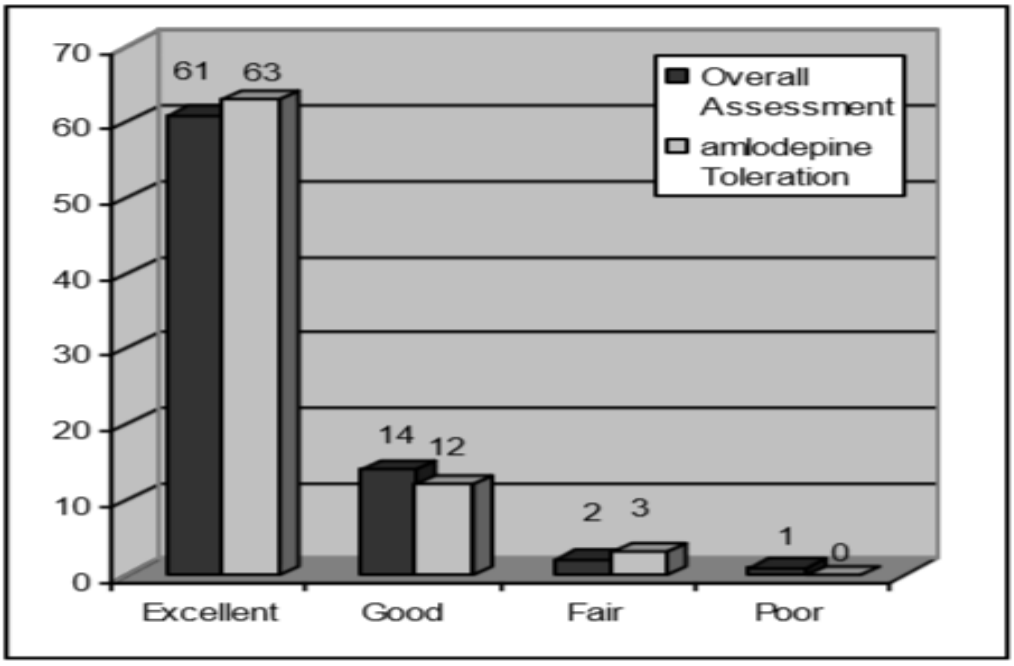
Table 2 shows that a total of 80 patients completed six weeks of amlodipine treatment. The mean reduction in B.P was 30 mmHg at systolic blood pressure and diastolic blood decrease was 20 mmHg from baseline.

Table 2: Effect of reduction in blood pressure from baseline to study end with Amlodipine

Assessment Week	**=n**	**Mean Sitting BP (mmHg)**	**Reduction (mmHg)**
Baseline	80	170/101	-
Week 1	80	155/97	16/6
Week 2	80	149/90	22/12
Week 3	79	142/89	25/16
Week 4	79	138/85	28/17
Week 5	78	134/83	29/18
Week 6	78	130/81	30/20

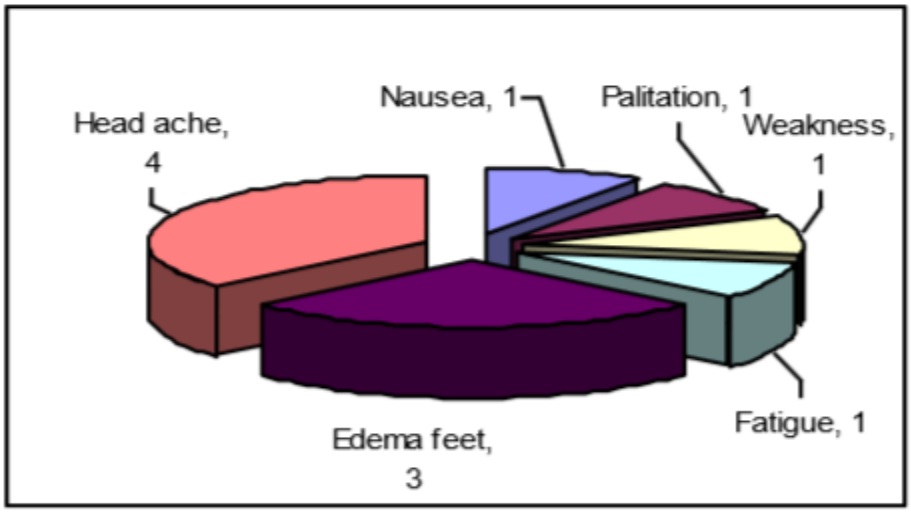
In the general evaluation of 78 patients, the efficacy of amlodipine was excellent in 61 patients (78%), good in 14 patients (18%), satisfactory in 2 patients (3%) and poor in 1 patient (1%). The overall tolerance to amlodipine was 63 (81%) excellent, 12 (15%) as good and 3 (4%) as normal (Figure 1).

Fig. 1: Overall and toleration assessment of Amlodipine efficacy of hypertensive patient



Side effects were in 11 patients (14%) with mild (moderate) hypertension, nausea 1 (1,28%), fatigue 1 (1,28%), palpitations 1 (1,28%), weakness 1 (1,28%) pain, head 4 (5%) and foot edema (4.0%) in 3 patients. Two male patients (3%) were withdrawn from the analysis due to the side effects, one was male patient (1.28%) and 1 female patient (1.28%). One patient developed weakness after two weeks of treatment and severe edema with amlodipine after 4 weeks of treatment (Figure 2).

Fig. 2: Side effects of hypertension patients



The amlodipine dose required to control blood pressure was 5 mg / day in 59 patients (76%) and 10 mg / day in 19 patients (24%).

DISCUSSION:

The most important causes of cardiovascular disease is Hypertension and hypertension treatment leads to a significant decrease in cardiovascular morbidity and mortality. Although calcium channel blockers are considered to be an important part of therapeutic armament against cardiovascular disease, concerns have been raised about these drugs, especially short-acting dihydropyridine derivatives, although they are among the most commonly prescribed antihypertensive drugs. . However, the value of long-acting dihydropyridine nifedipine should be reestablished. In a study by Gaba, the mean age was 49.8 years, she was a woman with a history of diagnosed or mild-to-moderate hypertension and had already received antihypertensive drugs but was not adequately controlled. Another study by Calhoun was mean age 53 years. The mean age of the patients in this analysis was 62.7 in hypertensive patients comparable to the other studies. In a study by Gaba, the overall efficacy assessment was excellent at 78%, good at 20% and at the remaining 2%. In terms of tolerance, 80% was excellent, 16% was 16% good at the fair and 3% was poor. Of the 100 (11%) patients, 11 had side effects and 2 (2%) were withdrawn due to side effects. In general, this study showed that the overall assessment was good in 18%, excellent in 78% and fair in 3%. Another study of Kes compared nifedipine and amlodipine once a day with moderate to mild hypertension, efficacy, safety and tolerability of treatment. This was a multicenter, randomized trial with a clear comparison of treatment with the placebo period of 2 weeks prior to 12 weeks. After 3 months of treatment, the Nifedipine and Amlodipine groups, 83.1 and 81.9 mmHg (P 0.436) was the mean diastolic blood pressure, respectively. Mean decline in systolic blood pressure (28.5 ± 11.9 mmHg and 28.2 ± 11.2 mmHg in Nifedipine and Amlodipine groups respectively) and mean decrease in diastolic blood pressure (16.47 ± 7.0 and 17.5 ± 6.9 mmHg) are comparable at the end of the study, respectively Nifedipine and Amlodipine). All international studies on the efficacy and tolerability of amlodipine indicate that amlodipine is an excellent antihypertensive agent with high efficacy and low side-effects, and provides 24-hour blood pressure control with daily dose. The results of our study can be compared with the results of international and national studies.

CONCLUSION:

We conclude that amlodipine has a significant antihypertensive effect once a day at a dosage range of 5-10 mg and is equally well tolerated as monotherapy or combination therapy in young and old patients. No significant change in heart rate was observed from the beginning until the end of the study.

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