To Study the Blood Pressure Response to Benidipine in Hypertension Patients

Mallikarjuna Shetty*1, Nageswar Rao Modugu2, Lavanya Mandli3, Jumana Hussain4, Rinita Ajey5, Nishanth Madela6

1Associate Professor, Department of General medicine, M.D General medicine
2Professor, Department of General medicine, M.D General medicine
3Assistant Professor, Department of General medicine, M.D General medicine
4Assistant Professor, Department of General medicine, M.D General medicine
5Junior Resident, Department of General medicine, M.D General medicine
6Junior Resident, Department of General medicine, M.D General medicine

The Department of General Medicine, Nizam’s Institute of Medical Sciences – Hyderabad

*Corresponding author
Mallikarjuna Shetty

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Abstract: Hypertension is most important cause for morbidity and mortality worldwide, most of the hypertension patients are not aware of disease and most of them are not under control. To study the clinical features, of blood pressure response, side effects of patients treated with Benidipine. We retrospectively collected data of all patients presenting to out patient department over 3 months, the parameters studied were Age, symptoms, signs, investigations if any, with main focus on patients with Hypertension (Diagnosed according to JNCVII guidelines) treated with Benidipine 4mg along with blood pressure response from day1, day 8 and day 30 were noted.

Total number of patients was 40 patients, with Male to Female ratio of 60%:40% and the age ranging from 34 years to 72 years with mean age of .50.72 years. The commonest symptom was headache in 55% followed by giddiness and body pains in 41.5%, neck pain in 20% and body pains in 17.5%, weakness in 10%. Day 1 mean Systolic Blood pressure was 162.5 mm Hg and mean Diastolic Blood pressure was 97.54 mm Hg, after treatment with Benidipine the mean Systolic Blood Pressure on day 8 was 140.6 mm Hg and Diastolic Blood pressure was 88.16 mm Hg, and day 30 mean systolic Blood pressure was 132.5 mm Hg and mean Diastolic Blood pressure was  86.53 mm Hg. 87.5 % patients reached target blood pressure, 12.5% did not reach the target. 2(10%) patients had pedal oedema. Benidipine has better Blood pressure lowering effects with good tolerance in hypertensive patients.

Keywords: Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Hypertension, Calcium channel blocker (CCB), Benidipine.

INTRODUCTION

Hypertension is one of the main causes of mortality and morbidity globally, and major cause of cardiovascular diseases [1-3] and about 25% of rural and 33% of urban populations in India are hypertensive [4]. Among them only 10% in rural and 20% in urban have their hypertension under control [5]. Since there are many drugs used to treat hypertension, according to JNC-8 guidelines calcium channel blockers are the primary antihypertensive drugs [6].

Benidipine is a dihydropyridine-derived newer calcium channel blocker developed in Japan, with several unique mechanisms of action, that is, triple calcium channels (L, N, and T) blocking action with a membrane approach [7], and it has shown good antihypertensive effects and lesser side effects[8].this drug has been in India since few years and there are very few studies in Indian patients regarding efficacy and side effects which made us to collect data on Benidipine on blood pressure response and its side effects.

MATERIAL AND METHODS

Out patient records of patients with diagnosis of Hypertension treated with Benidipine, in Nizams Institute of Medical sciences hospital which is a multispeciality, tertiary care referral hospital were collected over a period of three months.

Inclusion criteria was

• All patients diagnosed with Hypertension treated with Benidipine 4mg.
• Age above 18 years. Exclusion criteria was
• Patients Age below 18 years. Information from out patient records of all patients recruited for analysis was reviewed. In the history, demographic details, symptoms with the duration, risk factors if any were noted.

**Laboratory investigations**

Hemogram, complete urine examination, Liver function test, renal function test, Lipid profile Chest radiograph, Ultrasound Abdomen (carried with MYLAB60 model, ESaote Company from Ahmedabad), Electrocardiography, 2D Echcardiography. Were ever done were noted.

**Diagnosis**

The diagnosis of Hypertension was done according to JNC VII th guidelines [9]. Hypertension was diagnosed when Systolic Blood Pressure (SBP) was >140mmHg and/or mean Diastolic Blood Pressure (DBP) > 90mmHg. Isolated systolic hypertension was defined as a Systolic Blood Pressure 140mmHg and a Diastolic Blood Pressure <90mmHg [9].

**Follow up**

Those patients who were on Benidipine 4mg dose, and their initial Blood pressure on day 1 was noted, then subsequently the Blood pressure was noted on day 8 and day 30 were also noted, along with any side effects.

The above data from all the patients was tabulated and analysed retrospectively with main focus on symptoms, Blood pressure response to Benidipine 4mg on day8 and day30 and any side effects were noted.

The study was retrospective audit with no patient direct identifiers; hence consent was not taken. Hospital ethics committee was informed of the study.

**STATISTICAL ANALYSIS**

Microsoft office 2007 was used for the statistical analysis. Descriptive statistics like mean and percentages were used to interpret the data.

**RESULTS**

Total 40 patients (Table-1) data was collected. with age ranging from 34 years to 72 years, with mean age being 50.72 years, Male to Female ratio of 24:16 (60%-40%). The commonest symptom being headache in 55%, next symptom was giddiness in 41.5%, neck pain in 20%, body pain in 17.5% and weakness in 10%.

Total 40 patients of Hypertension who received Benidipine 4mg (Benidipine) and who came for review on day 8 and day 30 were included. The maximum Systolic blood pressure (SBP) (Table-2) noted on day1 was 194 mm of hg with mean systolic blood pressure of 162.5 mm of Hg,and maximum Diastolic blood pressure(DBP) on day 1 was 106 mm of Hg ,with mean diastolic blood pressure of 97.54 mm Hg. All the patients received Benidipine4 mg, after 8 days the mean systolic blood pressure was 140.6 mm Hg and mean diastolic blood pressure was 88.16 mm Hg. On follow up on day 30 (Figure-1) the mean systolic blood pressures was 132.5 mm Hg, and mean diastolic blood pressure was 86.53 mm Hg. That is on day 8and day 30 Mean systolic Blood pressure came down by -21.9 mmHg and -30 mmHg respectively and mean Diastolic blood pressure came down by day 8 by 9.38 and by day 30 -11.01mm Hg from day 1 blood pressure reading. All patients reached the goal blood pressure of <140mm of Hg systolic and<90 mm Hg diastolic blood pressure, except 5 (12.5%) patients,who required Benidipine 8mg to control the blood pressure. The side effects of pedal oedema were seen in 4(10%) patients.

**Table-1: shows clinical findings**

<table>
<thead>
<tr>
<th>Numbers (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Sex Male : Female</td>
</tr>
<tr>
<td>Symptoms</td>
</tr>
<tr>
<td>Head ache</td>
</tr>
<tr>
<td>Giddiness</td>
</tr>
<tr>
<td>Neck pain</td>
</tr>
<tr>
<td>Body pains</td>
</tr>
<tr>
<td>Weakness</td>
</tr>
<tr>
<td>Side effects while on Benidipine</td>
</tr>
</tbody>
</table>
Table-2: Showing Blood Pressure response to Benidipine 4mg

<table>
<thead>
<tr>
<th>Blood pressure Day</th>
<th>Blood Pressure in mm Hg</th>
<th>Mean change in Blood pressure in mm Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic Blood pressure Day 1</td>
<td>Mean-162.5</td>
<td>-</td>
</tr>
<tr>
<td>Diastolic Blood pressure Day 1</td>
<td>Mean-97.54</td>
<td>-</td>
</tr>
<tr>
<td>Day 8 on Benidipine 4mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic Blood pressure</td>
<td>Mean-140.6</td>
<td>-21.9</td>
</tr>
<tr>
<td>Diastolic Blood pressure</td>
<td>Mean-88.16</td>
<td>-9.38</td>
</tr>
<tr>
<td>Day 30 on Benidipine 4mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic Blood pressure</td>
<td>Mean-132.50</td>
<td>-30</td>
</tr>
<tr>
<td>Diastolic Blood pressure</td>
<td>Mean-86.53</td>
<td>-11.01</td>
</tr>
<tr>
<td>Not reaching target Blood pressure by day 30</td>
<td>5(12.5%)</td>
<td></td>
</tr>
</tbody>
</table>

**DISCUSSION**

Hypertension is one of the leading causes of coronary arterial disease and deaths from it in India [10]. In our study we had 40 patients of Hypertension who were treated with Benidipine (Benidin) 4mg. Among them 24(60%) were male and 16(40%) were females which is similarly reported by Shetty [11] et al. and M K Singh [12] et al. Of 59% to 41%, but William [13] et al. reported 54% to 46% respectively. The age of the patients was 34 years to 72 years but M K Singh [12] et al. had patients age ranging from 20 years to 70 years and the mean age was 50.72 years in our study which is similarly reported by Shetty [11] et al. 51.72 years but William [13] et al. Reported mean age of 56 years in their study group.

The commonest symptom at presentation was headache in 55% followed by giddiness in 41.5%, neck pain in 20% which is similarly reported by Shetty [11] et al. and William [13] et al.

The Mean Systolic blood pressure at presentation was 162.5 mm Hg and Mean Diastolic blood pressure was 97.54 mm of Hg which is similarly reported by Shetty [11] et al. but more than Gupta [14] et al. reported systolic blood pressure of 128.8+17 mm of Hg. After these patients were treated daily with Benidipine 4 mg (Benidin) the Mean Systolic Blood pressure on day 8 was 140.6 mm of Hg and Mean Diastolic pressure was 88.16 mm of Hg and on day 30 the Mean Systolic blood pressure was 132.5 mm of Hg and Mean Diastolic blood pressure were 86.53 mm Hg, that is on day 8 and day 30 Mean Systolic blood pressure came down by 21.9 mm of Hg and -30 mm of Hg and Mean Diastolic blood pressure came down by -9.38 mm of Hg and -11.01 mm of Hg respectively. (FIG –1).

Similarly Nakajimo [8] et al. reported a Mean SBP reduction from 173 mm of Hg to 135 mm of Hg and Mean DBP from 104 mm of Hg to 88 mm of Hg, but Seino [15] et al. reported Mean SBP decreased from 155.8+13.7 mm of Hg to 145.9+17 mm of Hg and Mean DBP decreased from 76.5+13.3 mm of Hg to 71.4+13.7 mm of Hg after Benidipine 4 mg treatment.

Available online at http://saspublisher.com/sjams/
and Sasaki H et al. [16] showed Mean SBP decreased from 154 mm of Hg to 139 mm of Hg and Mean DBP decreased from 91 mm of Hg to 78 mm of Hg in their study.

In our study the Mean SBP reduction with Benidipine 4 mg was -30 mm of Hg and Mean DBP was -11.01 which is better than clindipine as reported by Seino [15] et al. But Shetty [11] et al. and Bakris [17] et al. reported similar decrease in Mean SBP and Mean DBP with Azilsartan 40 mg. The Mean SBP and Mean DBP reduction was more with Benidipine in our study compared to candesartan reported by Rakugi [18] et al. of Mean SBP reduction of -17.5 mm of Hg and Mean DBP reduction of -9.8 mm of Hg. But Ihm [19] et al. reported similar Mean SBP and Mean DBP reduction when benidipine was compared with losartan in there study.

All the patients 87.5% reached the goal Blood Pressure of SBP of < 140 mm of Hg and DBP of < 90 mm of Hg except 12.5% patients who required Benidipine 8 mg to control Blood Pressure which is similarly reported by Nakajima [8] et al. and kalke s [20] et al. The major side effect was pedal oedema in 10 % patients.

CONCLUSION

Benidipine a new calcium channel blocker has better clinical Blood Pressure lowering effects than other calcium channel blockers, ACE inhibitors and Angiotensin receptor blockers with good tolerance. Hence it is more useful in Blood Pressure control in Hypertension patients.

Limitations

This study has very small sample size, it’s a retrospective study, and does not mention about major side effects and cardiovascular mortality and about benefits over other calcium channel blockers.

ACKNOWLEDGEMENTS

To my Wife keerthi, Daughter Saanvi, Lloyd Healthcare, My patients.

REFERENCES


