Postmenopausal Hypertension and Blood Pressure Target Achievements using Monotherapy in a Tertiary Care Teaching Hospital, South India

Thangamani Subramani^{1,*}, Saravanan Kunchithapatham², Sajeeth Chadappully Ismail¹

¹Department of Pharmacy Practice, Grace College of Pharmacy, Palakkad, Kerala, INDIA. ²Department of Pharmacy, Annamalai University, Chidambaram, Tamil Nadu, INDIA.

ABSTRACT

Background: Prevalence of hypertension and scanty of evidences related to the clinical efficacy and safety of antihypertensive regimens among post menopausal women were almost negligible in India. So, the aim of the present study was aimed to evaluate the efficacy of antihypertensive as monotherapy in hypertensive postmenopausal women. **Materials and Methods:** A prospective observational study was conducted in Department of General Medicine at Karuna Medical College Hospital, Palakkad, Kerala for a period of November 2019 to October 2020. The patients were divided in to four groups according to the class (Angitensin Receptor Blockers) (ARBs) or Calcium Channel Blockers (CCBs) or Diuretics or Beta Blockers) as monotherapy and their BP values were noted. **Results:** A total of 250 post menopausal hypertensive women were enrolled in this study. The patients achieved the goal on ARBs with 78% and CCBs with 69.5% was higher compared than BB (54.3%) and Diuretics (45.7%). ARBs and CCBs

treated patients showed statistically significant differences in reduction of systolic blood pressure, Diastolic blood pressure, Pulse Pressure and Mean Arterial Pressure in hypertensive women. **Conclusion:** The twothirds of hypertensive post menopausal women are not being achieved the BP goal; those have more risk for cardiovascular disease and stroke. **Keywords:** Postmenopausal women, Hypertension, Pulse Pressure, Beta Blockers, Angiotensin Receptor Blockers.

Correspondence

Mrs. Thangamani Subramani

Associate Professor, Department of Pharmacy Practice, Grace College of Pharmacy, Palakkad-678004, Kerala, INDIA.

Email id: thangamph@gmail.com **DOI:** 10.5530/ijpi.2022.2.41

INTRODUCTION

Hypertension is a public health challenge worldwide and the prevalence of hypertension increases with age and is more common in men as compared to women but they loose this advantage after menopause. Data showed changes in blood pressure across the menopausal transition in female.¹⁻² Menopause is the permanent end of menstruation due to the depletion of functional and viable ovarian follicles and it is a physiological part of ageing that is said to occur 12 months after a woman's last menstrual period and it happens between 45-50 years of age, the mean age of menopause was 47 years.³

Studies showed a lower BP control and a higher pulse pressure in women as compared with men because of higher Systolic BP levels in women at the age of \geq 55 years.⁴ Drug utilization studies showed in monotherapy calcium channel blockers were used in 16%, angiotensin-converting enzyme inhibitors in 14%, Beta blockers in 9%, and diuretics in 14% of the post-menopausal hypertensive women.⁵

BP goal target rates remain unacceptably low and patients may fail to attain the target for a variety of reasons like medication nonadherence and clinical inertia that is, failure to intensify or initiate of therapy based on evidence of failure to attain BP goals with existing therapy.⁶ BP control is inadequate worldwide and it is not satisfactorily controlled using monotherapy in most patients.⁷ So the management of hypertension is an important intervention to minimize the risk of future cardiovascular events in women.⁸

Hypertension is also more common in diabetics than in non-diabetics but the antihypertensive therapy which was most appropriate for the treatment of hypertensive diabetics is also unclear.⁹ The higher prevalence of hypertension among post menopausal women with risk of cardiovascular disease, scanty of evidence related to the clinical efficacy of antihypertensive regimens in hypertensive post menopausal were almost negligible from South Asian region. So, the aim of the present study was aimed to evaluate the efficacy of antihypertensive as monotherapy in hypertensive postmenopausal women.

MATERIALS AND METHODS

A prospective cross sectional observational study is conducted in Department of General Medicine at Karuna Medical College Hospital, Palakkad, Kerala for a period of one year (November 2019 to October 2020). Ethical approval and informed consent Approval were obtained from the Institutional Ethics Committee prior to the data collection and Ethical Clearance number was KMC/IHEC/10/2019.

Post-menopausal hypertensive women with self-reported cessation of menstruation for >12 consecutive months with or without comorbid diseases and post-menopausal hypertensive women treated with ARBs or CCBs or Diuretics or Beta Blockers were included in the study. Postmenopausal women who were done hysterectomy, oophorectomy, women with indeterminate menopausal status, patients with Systolic Blood Pressure (SBP) >210 and/or Diastolic Blood Pressure (DBP) >120 mm Hg requiring emergency care, patients treated with combination therapy of antihypertensive and patients were not willing to participate were excluded from the study. The study procedure was explained in detail to all the patients and informed consent was obtained before the data collection.

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Study Procedure

A data entry form was prepared for the collection of patient's demographic details, lab investigations and treatment chart. Patients were subjected to thorough history, clinical examination, and biochemical investigations. During screening at visit, patients were examined completely and collected the data like medical history, family history, socio economic history, past medical history and past medication history. Patients were examined physically to record the SBP, DBP, body weight, and vital signs. The hypertensive postmenopausal women under treatment were monitored and entire the study period BP <140/90 mm Hg was targeted. The study population was divided in to four groups according to their treatment with class (ARBs or CCBs or Diuretics or Beta Blockers) and the BP values were noted. The Pulse Pressure and Mean Arterial Pressure were calculated by using the mentioned formula.

Pulse Pressure (PP)

The difference between the systolic and diastolic pressure is called the pulse pressure. It is the most important component of pressure associated with severe coronary heart disease.

Pulse Pressure = Systolic BP- Diastolic BP.

Mean Arterial Pressure (MAP)

It is the perfusion pressure experienced by end organs such as the kidney, the liver and bones.

$$Mean Arterial Pressure (MAP) = \frac{Systolic BP + 2(Diastolic BP)}{3}$$

Statistical Analysis

The values of SBP, DBP, PP and MAP were evaluated by intra group comparisons made between the values obtained from the data collection. These values were statistically evaluated by a one-way ANOVA by using SPSS version 28. Results of changes in SBP, DBP, PP and MAP were expressed as mean \pm standard deviation. The categorical variables were analysed by using chi square test. The statistically significant was considered as p < 0.05.

RESULTS

A total of 250 Post menopausal hypertensive patients were enrolled in this study as per the inclusion criteria. The study population was divided in to four groups (ARBs or CCBs or Diuretics or Beta Blockers). Table 1 was showed the baseline characteristics of study population. Distribution of age, family history, body weight, occupation and comorbid conditions were analysed. The age \leq 65 years (*n*=182) was higher compare than > 65 years (*n*=68). The distribution of body weight showed the >65 kg (*n*=164) was predominant among the study population. The frequency of distribution was significant difference among the patients with regards to in family history, number of children, occupation and comorbid conditions.

Table 2 showed that mean \pm SD of SBP, DBP, PP and MAP in the four groups. The ARB group (137.60 \pm 13.36 mmHg, 85.86 \pm 9.32 mmHg) and CCBs group (141.21 \pm 11.7 mmHg, 87.07 \pm 7.45 mmHg) tended to have lower SBP and DBP compare than BB (143.80 \pm 12.75 mmHg, 90.47 \pm 7.71 mmHg) and Diuretic group (147.11 \pm 12.18 mmHg, 87.96 \pm 8.66 mmHg). There was statistically difference have seen in SBP (p< 0.01) and DBP (p<0.05) between the four groups. The PP was lower in ARBs (47.60 \pm 7.05 mmHg) and CCBs (51.61 \pm 8.34 mmHg) and comparatively higher in BB (51.61 \pm 8.34 mmHg) and Diuretics (51.61 \pm 8.34 mmHg) groups.

The MAP was also lower in ARBs (103.71±8.14 mmHg) and CCBs (106.83±6.01 mmHg) and comparatively higher in BB

Gable 1: Clinical Characteristic of Study Population.					
S. No	Parameters	n=250 (%)	<i>p</i> -value		
1	Age in years				
	≤ 65	182	.0.01**		
	>65	68	< 0.01		
2	Body Weight				
	≤ 65	86	. 0. 01**		
	>65	164	< 0.01^^		
3	Number of Children				
	≤ 2	207	. 0. 01 **		
	>2	43	< 0.01^^		
4	Family History				
	Yes	188	. 0. 01 **		
	No	62	< 0.01^^		
5	Occupation				
	Housewife	154			
	Employed	96	< 0.01**		
6	Comorbid Diseases				
	Yes	185	. 0. 01**		
	No	65	< 0.01^~		

(110.03±8.18 mmHg) and Diuretics (110.44±8.51 mmHg) groups. There was statistically difference seen in PP (p< 0.01) and MAP (p<0.05) in the four groups. The clinical efficacy of ARBs and CCBs were showed higher therapeutic outcome compared than BB and Diuretics. The hypertensive postmenopausal women achieved the goal on ARBs (78%) and CCBs (66.6%) was higher compare than BB (54.3%) and Diuretics (45.7%). There was statistically difference have seen in the four groups (p< 0.01). It was also showed the greater number of study population achieved the goal under ARBs and CCBs therapy.

Table 3 showed that mean \pm SD of SBP, DBP, PP and MAP of hypertensive post menopausal women with diabetes mellitus in the four groups. The ARBs group (135.8 \pm 09.00 mmHg, 85.8 \pm 09.42 mmHg) and CCBs group (142.64 \pm 13.09 mmHg, 87.94 \pm 5.38 mmHg) tended to have lower SBP and DBP compare than BB (142.63 \pm 13.08 mmHg, 89.73 \pm 8.21 mmHg) and Diuretic group (145.13 \pm 11.69 mmHg, 86.45 \pm 9.11 mmHg). There was no statistically difference have seen in SBP (p>0.05) and DBP (p>0.05) in the four groups. The lower PP was also lower in ARBs (49.28 \pm 6.15 mmHg) and CCBs (53.91 \pm 7.73 mmHg) and comparatively higher in BB (54.15 \pm 8.41 mmHg) and Diuretics (57.77 \pm 10.25 mmHg) groups. The MAP was also lower in ARBs (103.05 \pm 7.77 mmHg) and CCBs (106.55 \pm 5.27 mmHg) and comparatively higher in BB (107.85 \pm 8.58 mmHg) and Diuretics (110.58 \pm 8.79mmHg) groups.

There was statistically difference seen in PP (p< 0.05) and MAP (p<0.05) in the four groups. The clinical efficacy of ARBs and CCBs was showed higher therapeutic outcome compared than BB and Diuretics among the hypertensive postmenopausal women with Diabetes Mellitus. The hypertensive postmenopausal women with Diabetes Mellitus achieved the goal on treatment with CCBs (71%) and ARBs (70.5%) was higher compare than BB (61.5%) and Diuretics (54%). There was no statistically difference have seen in the four groups (p> 0.05). It was also showed the more number of study population achieved the goal under BB and ARBs therapy.

S.No	Parameters	ARB (<i>n</i> = 82)	CCB (<i>n</i> =63)	BB (<i>n</i> = 46)	DI (<i>n</i> = 59)	<i>p</i> -value	
1	SBP mmHg (mean ± SD)	137.60± 13.36	141.21 ± 11.7	143.80± 12.75	147.11±12.18	< 0.01**	
2	DBP mmHg (mean± SD)	85.86±9.32	87.07±7.45	90.47±7.71	87.96 ± 8.66	< 0.05*	
3	Pulse Pressure mmHg (mean± SD)	47.60±7.05	51.61±8.34	53.80±7.49	56.77± 9.90	< 0.01**	
4	Mean Arterial Pressure mmHg (mean± SD)	103.71 ± 8.14	106.83 ± 6.01	110.03 ± 8.18	110.44±8.51	< 0.01**	
5	Patients reached the target BP n (%)						
	Yes	64 (78 %)	42 (66.6 %)	25 (54.3 %)	27 (45.7 %)		
	No	18 (21.9 %)	21 (33.3 %)	21 (45.6 %)	32 (54.2 %)	< 0.01**	

Table 2: Impact of Antihypertensive as Monotherapy and its BP Control Rate among Study Population.

Table 3: Impact of Antihypertensive as Monotherapy and its BP Control Rate among Hypertensive Postmenopausal Women with Diabetes Mellitus.

S. No	Parameters	ARB (<i>n</i> = 82)	CCB (<i>n</i> =63)	BB (<i>n</i> = 46)	DI (<i>n</i> = 59)	<i>p-</i> value	
1	SBP mmHg (mean ± SD)	135.8± 09.00	142.64 ± 13.09	142.63 ± 13.08	145.13±11.69	0.143	
2	DBP mmHg (mean± SD)	$85.8{\pm}~09.42$	87.94±5.38	89.73±8.21	86.45±9.11	0.255	
3	Pulse Pressure mmHg (mean± SD)	49.28±6.15	53.91±7.73	54.15 ± 8.41	57.77±10.25	< 0.05*	
4	Mean Arterial Pressure mmHg (mean± SD)	103.05±7.77	106.55±5.27	107.85 ± 8.58	110.58±8.79	< 0.05*	
5	Patients reached the target BP n (%)						
	Yes	24(70.5 %)	27(71 %)	8(61.5 %)	20(54 %)		
	No	10(29.5 %)	11(29 %)	5(38.4 %)	17(45.9%)	0.0634	

DISCUSSION

Post menopausal women comprise more than 30% of the females, affected with CVDs which was considered to be the primary case of mortality in India and hypertension is a major risk factor for CVDs.^{10,11} Hypertension was higher in postmenopausal women compare than men and with 41% of postmenopausal women becoming hypertensive.¹² Our study resulted that, frequency of hypertensive post menopausal women with age \leq 65 years and >65 kg body weight was higher compare than > 65 years and <65kg. But both systolic and diastolic blood pressure increased with advancing age.¹³

Prevalence of hypertension in obese postmenopausal women was 1.38 times higher compared with who had normal weight (95% CI is 0.92-2.07) and Framingham study showed that the 15% of weight gain increase SBP by 18% compared with average weight and 20% were at eight times more risk to suffer from hypertension.¹⁴ Hypertensive postmenopausal women get more affected with diabetes mellitus in our study. Late menopause was associated with increased risk of development of DM in postmenopausal women.¹⁵ Studies have found that lowering BP in patients with DM has led to sizable reductions in mortality.¹⁶

Despite of increasing burden CVDs, hypertensive women need much attention when compared to men and they need more stringent efforts to achieve BP goals than the men. A cross-sectional study showed that though women are significantly more to receive antihypertensive regimen (61.4% in women as compared to 56.8% in men), only 44.8% of these women were likely to achieve target BP control as compared to 51.1% of treated men.¹⁷

A study was resulted, mean SBP was higher in the female versus the male patients (160.0 \pm 12.71 versus 159.3 \pm 12.31 mm Hg; p = 0.003), and mean DBP was higher in the male versus the female patients (96.4 \pm 10.65 versus 94.5 \pm 10.72 mm Hg; p < 0.001). After 4 weeks and 8 weeks of Val/Aml treatment, women not achieving the target BP was less than that of men (57.41% versus 59.59%; p < 0.05) at 4 weeks and (22.22% versus 23.78%; p < 0.05) at 8 weeks. Among both men and women, the proportion of patients not achieving the target SBP increased with age;

and changes in SBP were closely related to gender, indicating that the SBP-lowering effect after Val/Aml treatment might be better in women.¹⁸ DBP starts to increase earlier and SBP starts to increase after 50 years of age which is a higher health risk.¹⁹ In general one-fourth of hypertensive patients failed to achieve goal BP and considering the consequences of poor control, cost-effective, context specific interventions are needed.²⁰

Our study reported that ARBs and CCBs were more effective BP control rates and BB and Diuretics in less effective to control the BP. But previous studies showed that 45–64 years females using Diuretics showed best control rates, while CCBs were least effective and the age \geq 65 years also attained a better control rate in females with Diuretics. CCBs were the most popular drugs but the control rate was comparatively low in all age groups.² ARBs may be an appropriate first line agent for postmenopausal women with hypertension because the activation of renin–angiotensin–aldosterone system is suggested as one possible mechanism of postmenopausal hypertension.²¹

An increased PP and a decreased DBP, in association with an elevated SBP, are the potent risk markers of hypertensive CVD in middle-aged and older subjects.²² A study was compared the short- and long-term effects on changes in PP of a diuretic (hydrochlorothiazide), a b-blocker (atenolol), a CCB (diltiazem sustained release [SR]), an ACE inhibitor (captopril), an a1-blocker (prazosin), and a central a2-agonist (clonidine) in a retrospective analysis of the Department of Veterans Affairs (VA) Single-Drug Therapy for Hypertension Study. They resulted reductions in PP during titration were greater with clonidine (6.7 mm Hg) and hydrochlorothiazide (6.2 mm Hg) than with captopril (2.5 mm Hg), diltiazem (1.6 mm Hg), and atenolol (1.4 mm Hg).²³

Recent meta-analyses reported that in uncomplicated hypertensive patients, first-line therapy with beta-blockers compared with other antihypertensive agents was associated with an increased risk of stroke, especially in the elderly.²⁴ Even though the BP reduction with BB was more, it is not recommended to use in older adults as first line agent for hypertension due to a risk of stroke and CVDs.²⁵

Postmenopausal hypertension is a complex disease with multiple contributing mechanisms involved. In our study resulted that one third of patients not achieved the goal and ARBs and CCBs as a monotherapy have given the better therapeutic outcome among hypertensive postmenopausal women.

CONCLUSION

The effect of ARBs and CCBs in postmenopausal women was greater reduction of BP compare than the other antihypertensive drugs for the prevention of stroke and CVDs. The hypertensive women who were not achieved the BP goal are needed combination therapy for better therapeutic outcome. The longitudinal studies are needed to investigate the potent antihypertensive for the management of hypertension among the postmenopausal women.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ARBs: Angitensin Receptor Blockers; **CCBs:** Calcium Channel Blockers; **BB:** Beta Blockers; **BP:** Blood Pressure; **SBP:** systolic blood pressure; **DBP:** Diastolic blood pressure; **PP:** Pulse Pressure; **MAP:** Mean Arterial Pressure; **CVDs:** Cardio Vascular Diseases; **ACE:** inhibitor Angiotensin Converting Enzyme inhibitors.

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