

Clinical Evaluation of Polyherbal Formulation in the Management of Mild Hypertension in Comparison with Tablet Abana

Eknath G. Kulkarni¹ and Jayesh B. Suryavanshi²

A.S.S Ayurved Mahavidhyalaya, Nashik.

Abstract:

In 21st century continuous changing life style, environment and dietary habits have made human victim of many diseases, Hypertension is one of them. Based on WHO definition the incidence of hypertension in urban population is around 40% and rural around 18%. The present study was carried out to investigate the efficacy and safety of Polyherbal Formulation containing extracts of Arjuna, Jatamansi, Punarnava and Pashanbheda etc. in the treatment of essential hypertension. A Randomized controlled prospective study was done at Arogyashala Rugnalaya, Panchavati, Nashik. 30 patients of either sex in experimental group in age group of 30 years to 60 years with essential systemic stage-1 hypertension without any co morbid illness were treated with Polyherbal Formulation in the dose of 1 capsule twice a day after each meal for 30 days and 30 patients in control group were treated with Tab.Abana from Himalava herbals. The clinical efficacy with respect to symptoms and changes in systolic and diastolic blood pressure were assessed using sphygmomanometer prior to and throughout the treatment. At the end of the study majority of the patients showed a highly significant response and reduction in blood pressure and various symptoms in experimental as well as control group. None of the patients showed any adverse effects with Polyherbal formulation or Tab.Abana. Changes in systolic BP and diastolic BP were analyzed statistically by Paired t- test. Before treatment in experimental group mean SBP and DBP was 151.40 and 93.60 mm Hg respectively. After 4 weeks of therapy there was a statistically significant fall in SBP to 138.73 and DBP to 86.33 mm Hg. P value (< 0.05) considered as significant.

Keywords: Hypertension, Polyherbal Formulation, Tab.Abana.

Introduction:

Hypertension is one of the leading causes of the global burden of disease. Approximately 7.6 million deaths (13-15% of the total) and 92 million disability-adjusted life years worldwide were attributable to high blood pressure in 2001. Hypertension doubles the risk of cardiovascular diseases, including coronary heart disease (CHD), congestive heart failure (CHF), ischemic and hemorrhagic stroke, renal failure, and peripheral arterial disease. It is often associated with additional cardiovascular disease risk factors, and the risk of cardiovascular disease increases with the total burden of risk factors. Although antihypertensive therapy reduces the risks of cardiovascular and renal disease, large segments of the hypertensive population are either untreated or inadequately treated. It may prove life threatening in many cases. So, hypertension is gaining more and more attention globally and due to its high prevalence in our country. India is becoming a capital of Hypertension and other metabolic disorders. Although there has been widespread dissemination of knowledge of hypertension, it is poorly treated in most of the populations including India. Among the persons identified as being hypertensive, only half are being treated and out of those receiving treatment, only half have their blood pressure normal. Along with all these problems the lifelong and palliative treatment of hypertension in modern science induces many side effects. Therefore to attain and to maintain good health, hypertensive patients are looking towards Ayurveda. So it is now prime duty of Ayurvedic research scholars and physicians to study the theory of hypertension and to search a potent and cost effective ayurvedic line of treatment. Essential hypertension is an instrumental disease which is the recent diagnostic invention of modern science. Hence there is no direct reference of hypertension available in Ayurvedic classics by name. Acharya Charaka narrates in CH.SU.18/44 that having nomenclature for each & every disease is not necessary. Such diseases without name are treated with the help of its Prakruti, Samutthan & Adhisthana.

hypertension is having role of Tridosha & dushyas rasa & rakta in its pathogenesis. Arteries are the main site of disease. Drugs which act on Tridosha & on Rasa, Rakta are used in the treatment of HYPERTENSION. Many works have been carried out on hypertension to evaluate the perfect diagnosis and mode of treatment on the basis of Ayurvedic principles. Different nomenclatures also have been adopted by Ayurvedic scholars like Uchharaktachapa, Uchharaktabhara, Raktagata Vata, Raktavrita Vata, Pranavrita Vyana, Vyanavrita Prana, Shleshmavrita Vyana etc

Various modern drugs are available as antihypertensive but they are having many side effects and they are not cost effective. As mentioned earlier many people are having resistant hypertension and their BP not controlled even after using 3-5 antihypertensive including a diuretic. Hence the search for potent, safe & cost effective Ayurvedic anti hypertensive drug is essential. Many Ayurvedic pharmacies claim that their formulations are very effective in Hypertension. Efficacy and safety of these formulations has to be verified by clinical trial. This is a comparative study of two such market preparations. Polyherbal Formulation is a preparation which contains Arjuna, Jatamansi, Punarnava and Pashanbheda and 2^{nd} formulation for control group is Tab.Abana from Himalaya herbals. It is very well known antihypertensive to all practitioners and is available in market since many years. Inspite being available since many years in market it is not so popular and practitioners prefer other modern antihypertensives over it. Hence I have selected these two medicines for this clinical trial to study their efficacy on the mild (stage – 1) hypertension.

Materials and Methods:

A single blind prospective comparative clinical study was carried out in OPD & IPD of Arogyashala Rugnalaya, Ganeshwadi, Nashik. Total 60 Patients of either sex were enrolled into clinical study, which were not taking any hypotensive drugs or agreed to discontinue the regular hypotensive drug for the period of trial.

Inclusion Criteria:

1) Newly diagnosed patients of Hypertension (stage-1 HTN.)

Systolic blood pressure < 160 mm of Hg & > or = 140 mm of Hg.

Diastolic blood pressure < 100 mm of Hg & > or = 90 mm of Hg.

2) Age between 30 yrs to 60 yrs.

3) Either sex.

Exclusion Criteria:

1) Patients <30 yrs & >60 yrs of age.

2) Pts. with Systolic blood pressure >or=160 mm of Hg<140 mm of Hg.

Diastolic blood pressure >or=100 mm of Hg<90 mm of Hg.

3) Complicated hypertensive cases with Nephropathy, LVH, Heart block, CHF, Coronary heart disease & Retinopathy.

4) Patients suffering with Diabetes mellitus.

5) Accelerated & malignant HTN.

6) Patients taking steroids, oral contraceptives pills, estrogen replacement therapy or NSAID groups of drugs.

7) Pregnant woman or planning pregnancy within six months and lactating mothers

8) Patients with severe other illness hepatic/ renal failure.

9) Gout.

Criteria for baseline screening were routine laboratory investigations to exclude any other pathology. Cardinal signs and symptoms of the disease were noted and were used for assessment of the effect of treatment. The protocol of this clinical study was approved by the Institutional Ethical Committee and conducted according to the guidelines. Written informed consent of each and every patient (in English and Marathi) obtained prior to entrance into the study. Patients and/or their attendees were fully informed about duration of the trial and overall plan of the study.

All the patients before enrollment were screened by proper history, physical examination which included blood pressure readings and laboratory investigations such as BSL® to rule out Diabetes, Sr.Creatinine to rule out renal pathology, S.G.P.T to rule out liver impairment, Sr. Uric

acid to rule out Gout, E.C.G to rule out cardiac pathology, Lipid profile at base line before they were considered for inclusion into the study. Essential or primary hypertension was diagnosed by taking measurement of blood pressure by using sphygmomanometer. Blood pressure measurements were used as an important clinical sign in the diagnosis and analyzing progress. Before taking the measurement, the patient was asked to take rest for 5 minutes. Blood pressure was measured 3 times 10 minutes apart and average is considered. On the first visit blood pressure measure in both arms and one leg and in both sitting and standing positions to rule out secondary causes such as coarctation of aorta, subclavian artery stenosis, and orthostatic hypertension.

Category	Systolic (mm of Hg)	Dystolic (mm of Hg)					
Optimum	< 120	< 80					
Normal	< 130	< 85					
High normal	130-139	85-89					
Stage 1 (mild)	140-159	90-99					
Stage 2 (mod.)	160-179	100-109					
Stage 3 (severe)	>or= 180	>or=110					
Stage 4 (very severe)	>or=210	>or=120					

J.N.C 7 Criteria considered for the clinical study was as given below:

The blood pressure measurement was done initially at day 1st and then on follow up on at day 10,20,30. The laboratory investigation and the other physiological parameters were recorded initially and at the end of the treatment. During the trial period systolic blood pressure (SBP) and diastolic blood pressures (DBP) were recorded at every follow up. The medicine Polyherbal Formulation was purchased from a GMP certified company along with that certificate of analysis also obtained. Tab.Abana for control group was purchased from the market.

Group A) Polyherbal Formulation

Contents: Each Capsule contains aqueous extract of:

Arjuna 200 mg (*Terminalia arjuna*) Jatamansi 100 mg (*Nordostachys jatamsnsi*) Punarnava 100 mg (*Boerhavia diffusa*) Pashanbheda 100 mg (*Coleus forkshill*)

Aqueous extract is prepared by evaporating a watery solution of the soluble principles of a herb. In the Polyherbal Formulation also aqueous extract of *Terminalia arjuna, Nordostachys jatamansi, Boerhavia diffusa and Coleus forkshill* are used in the proportion given above.

Group A: (Experimental group)

30 patients were treated with a polyherbal formulation.

Kala: Adhobhakta (after lunch and dinner).

Matra: 1 Capsule.

Duration: 30 days

Anupan: Koshna Jal (Lukewarm water).

Follow Up: D10, D20, D30.

Group B :(Control group)

30 patients were treated with TAB.ABANA.

Kala: Adhobhakta (after lunch and dinner).

Matra: 2 Tablets.

Duration: 30 Days.

Anupan: Koshna Jal (Lukewarm water).

Follow Up: D10, D20, D30.

Clinical parameters for assessment of results: Subjective parameters: 1) Shiroruk (Headache)

1) 5000	uk (IItaua	
Grade	Score	Feature
0	0	Rarely headache relieves without medication.
+	1	Frequently headache relieves by rest doesn't disturbs daily activities.
++	2	Frequently headache disturbs daily activities requires medication.
+++	3	Continuous severe headache disturbs sleep & daily activities also not managed by the medication.

2) Bhrama (Giddiness)

Grade	Score	Feature
0	0	Nil.
+	1	Rarely Bhrama for some movement during change of posture.
++	2	Often for some movements during change of posture.
+++	3	Often for each movement even in lying condition also.

3) Nidra-vikruti (Disturbance of sleep)

Grade	Score	Feature
0	0	Sound sleep.

+	1	Disturbed sleep wakes up 1-2 times a night.(Khandit nidra.)
++	2	Difficult to onset sleep remains disturbed in night.(Alpanidra)
+++	3	Very less sleep in small intervals makes patient irritable & requires
		medication.

Objective parameters:

1) Systolic blood pressure.

2) Diastolic blood pressure.

3) Mean arterial pressure.

All above parameters were compared statistically.

Diet and Habits Restriction

Preventive aspect is the key of this traditional medical system to treat any disease. So the patients were advised to avoid smoking and alcohol and instructed to follow the guidelines as below for both the groups:

1. Consume plenty of fruits and vegetables such as apple, banana, blackberries, broccoli, cabbage, carrot, garlic, grape fruit, green leafy vegetable, onion, pea, tomato etc.

2. Consume preferably vegetarian, low fat, low calorie diet rich in whole grain, high fiber and nuts.

3. Use of garlic and onion in regular diet.

- 4. Practice physical exercises such as brisk walking daily for 30 45 minutes
- 5. Weight reduction (in obese).
- 6. Limit use of salt (<5 gm/ day), fats and sweets.
- 7. Avoid day sleep, anger, anxiety, hyper activity, over exertion.
- 8. Avoid use of caffeine, alcohol and tobacco.

Adverse Reaction or Side Effects

At each follow up, patients were asked for occurrence of any untoward effect if any, and improvement in the signs and symptoms observed and recorded.

Case record form

The case record form contained the complete record of every patient studied. This data sheet included a brief case history, finding on physical examination, laboratory and other diagnostic studies, medications and clinical course of illness, adverse drug reactions. Any problem of interest or untoward reactions manifested by the patient at any time during or soon after drug administration were carefully evaluated and reported.

Statistical Analysis

Statistical analysis was done using the statistical test with the advice from statistical expert. Drug concentrations and all derived parameters were listed and summarized descriptively. The changes in various parameters in the post-treatment values were carried out by paired t – test for before and after values. P values ≤ 0.05 were considered statistically significant. Unpaired t – test was used for comparing the objective values in 2 groups. Chi – square test was used for comparing subjective criteria's.

Observations and Results

Charts about symptoms on follow up days in 0 to 3 grades and after applying chi square test:

(1) Headache *(shirshoola)*

Grade	Group A				Group B			
	D0	D10	D20	D30	D0	D10	D20	D30
0	7	9	21	28	10	13	17	21
+	11	18	9	2	7	13	9	7
++	10	3	0	0	9	4	3	1
+++	0	0	0	0	4	0	1	1

Gr.A vs. Gr.B at 5% level of significance

Day	χ^2	Df	Table χ^2 value	Probability	Result
D20	5.42	2	5.99	< 0.05	Non-Significant
D30	5.60	2	5.99	< 0.05	Non-Significant

(2) Giddiness (Bhrama)

Grade	Group A				Group B			
	D0	D10	D20	D30	D0	D10	D20	D30
0	17	18	21	28	7	7	10	13
+	4	10	8	1	6	19	16	12
++	9	2	0	0	14	4	4	4
+++	0	0	1	1	3	0	0	1

Gr.A vs. Gr.B at 5% level of significance

Day	χ^2	df	Table χ^2 value	Probability	Result
D20	10.042	2	5.99	< 0.05	Significant
D30	14.08	2	5.99	< 0.05	Highly Significant

(3) Disturbance of sleep (Nidra vikruti)

Grade	Group A				Group B			
	D0	D10	D20	D30	D0	D10	D20	D30
0	18	20	23	28	15	16	17	17
+	3	6	6	2	3	11	8	7
++	5	4	1	0	9	3	5	6
+++	4	0	0	0	3	0	0	0

Day	χ^2	Df	Table χ^2 value	Probability	Result
D20	5.372	2	5.99	< 0.05	Non Significant
D30	15.74	2	5.99	< 0.05	Significant

Gr.A vs. Gr.B at 5% level of significance

Paired t – test

	SBP		DBP		MAP		
	Group A	Group B	Group A	Group B	Group A	Group B	
Mean	12.67	10.46	7.26	4.26	9.06	6.26	
SD	8.52	8.60	5.92	6.11	5.39	5.62	
SE	1.56	1.58	1.08	1.115	0.978	1.026	
t 29	8.13	6.62	6.72	3.82	9.26	6.10	
t-table	2.05	2.05	2.05	2.05	2.05	2.05	
Р	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	

Unpaired t – test

	SBP	DBP	MAP
SD	8.56	6.01	5.51
SE	2.21	1.54	1.42
t 58	1	1.94	1.97
t table	2.02	2.02	2.02
Р	< 0.05	< 0.05	< 0.05

Total effect of therpy:

Relief	Upashay-anupshay	Group A	Group B
75% and above	Uttam	93.33%	56.67%
50% to < 75%	Madhyam	5.33%	28.9%
25% to < 50%	Heena	1.11%	12.22%
0% to < 25%	Anupashay	0%	1.11%
	Total	100	100

Discussion

In the present study, total number of 66 cases of essential hypertension has been registered. Only 60 patients completed the study. The remaining 6 patients were excluded from the study.

Baseline characteristics like age, sex were considered. There were 45 (75%) males and 15 (25%) females. The age group of patients ranged from 30 to 60 years with maximum 45% from 50-60 yrs, 35% from 40-50 yrs age group and 20% from 30-40 age groups. The primary factors like habit of smoking and tobacco chewing was found in 20 (33.34%) patients of the focused population. 20 (33.33%) patients had a positive family history. The patients of mild hypertension

are usually asymptomatic and symptoms appear in severe hypertension. The most common symptoms are headache, giddiness, disturbance of sleep which was considered as subjective criteria for the study purpose. The clinical features of all patients involved in the study were noted and recorded at base line and follow ups. After one month of trial and administration of drugs, there was a gradual improvement in the signs and symptoms observed in all the patients and at the end of the study, the clinical manifestations were significantly reduced which is presented in the Table. Blood pressure measurements were regularly monitored and recorded throughout the entire period of study. Initially the systolic blood pressure (SBP) and diastolic blood pressure (DBP) in experimental group were 151.4 and 93.6 mm Hg respectively. No major difference in SBP and DBP were observed after 10 days of treatment. The results after 20 days of treatment were also insignificant and after one month of treatment, the mean SBP and mean DBP were gradually decreased to 138.7 and 86.33 mm of Hg respectively. In control group SBP and DBP before treatment were 150.5 and 93.5 mm of Hg respectively. After 30 days of treatment it decreased considerably and was 140.0 and 89.26 mm of Hg respectively. The efficacy of the trial drug Polyherbal Formulation and Tab.Abana are analyzed by using statistical tests and are shown in tables above in observations. Based on the reduction in systolic and diastolic blood pressure measurements and clinical improvements, the efficacy of the trial drug on patients with essential hypertension have been assessed in terms of excellent response, marked response, moderate response, mild response and no response.

Out of the 30 patients selected for the experimental group, excellent (Uttam) response was showed in 93.33% patients, marked (Madhyam) response was showed in 5.33% patients, moderate (Heena) response was showed in 1.11% patients, poor (Anupashaya) response was showed in % which is summarized in table in observations. The overall effect of therpy on control group is also summarized in table given in observations. All the patients were carefully observed and monitored for any adverse drug reactions or side effects and there were no clinically significant adverse drug reactions and side effects noted during the course of the treatment.

Probable Mode of action (Ayurvedic view)

Hypertension is a complex disorder and we cannot get a single etiological factor causing it, many patho-physiological changes takes place in it. Similarly in ayurvedic aspect the pathophisiology involves all the 3 Dosha, 6 subtypes of the Dosha, Rasa and Rakta as Dushya, Rasavaha, Raktavaha and Manovaha Srotasa from various Sthana like Hridya, Sira, Dhamani. We need a similar drug which acts on all these components and have complex action to combat the pathophisiology. Polyherbal formulation is a complex formulation which contains 4 herbs and which acts on all the above said components and have the synergistic action hence was chosen for the trial group.

The Samprapti of Hridroga explained by Madhav Ndan is:

"दूषयित्वा रसं दोषा विगुणा झ्द्यं गता: । झ्दि बाधां प्रकुर्वन्ति झ्दरोगं तं प्रचक्षते ।"... (मा.नि. झ्दरोग २९)

Treatment for Hridroga as described by Acharya Charaka is,

"तन्महत्ता महामूला स्तच्च ओज: परिरक्षिता । परिहार्या विशेषेण मनसो दु:खहेतव: । ह्न्द्य यत् **स्यात् यदोजस्यं** स्रोतसां यत् प्रसादनं । तत् तत् सेव्यं प्रयत्नेन...... ।" (च.सु.३०/१३-१४) The medicines and diet which are useful for heart should be used so that heart, vessels originating from it i.e. Dhamani and Oja should remain in their normal state. Also the medicine should keep the Srotasa clear. Always use these types of medicine and diet to protect the heart and its constituents.

Arjuna which is there in the Polyherbal formulation as a main content is Hridya due to its Prabhav i.e. cardiotonic. Jatamansi is having Rakshoghna, Bhutaghna, Manasdoshhar action as its Prabhav it protects the heart from stressful events. Punarnava and Pashanbheda are Mutral i.e. diuretic and hence they reduce the cardiac load and protect the heart. So, entire herbs from the polyherbal formulation directly or indirectly protect the heart, which is the main aim of the Hridroga chikitsa as described above in the Shloka. Arjuna (Kashaya rasa and ruksha guna) and Jatamansi (tikshna guna and tikta, kashaya rasa) have Kaphaghna action which maintains the Avalambak kapha in normal state which is mainly present in Hridya in its natural state and thereby the normalcy of heart is maintained. Also due to Kaphaghna action Dhamaniuplepana is prevented. Jatamansi with the Snigdha guna, Madhur rasa and Pashanbheda with the Madhur rasa acts on Vata and maintains it in its normal state. Punarnava with its Tridoshghna property keeps all the Dosha in normal state. Tikta rasa of the Jatamansi, Pashanbheda stimulates the agni and thereby decreasing the Ama formation and Rasa Dushti which is considered as the main cause of Hridroga and Shaman of Pitta also takes place. Mutral action of Punarnava and Pashanbheda reduces the kleda from the body and thereby reduces the cardiac overload which is one of the causative factors of hypertension. In this manner the complex mechanism of the hypertension is treated with this formulation. All the medicines from the polyherbal formulation act by synergistic action and hence break the Samprapti i.e. Samprapti Vighatana is achieved. And hence the relief in the sympotoms achived and also the decrease in blood pressure was achived.

Probable Mode of action (Modern view)

As per the studies undergoing, the hot water infusion of *Terminalia arjuna* possesses a mild diuretic and fairly potent cardiac stimulant and cardio tonic activity. Hypotension and bradycardia were also observed following the injection of the extract into the lateral cerebral ventricles and vertebral artery. This result suggests that the hypotensive and bradycardiac effects of *Terminalia arjuna* are mainly of central origin. *Terminalia arjuna* is known to inhibit cholesterol biosynthesis and potentiate the activity of lipolytic enzymes to early clearance of lipids from the circulation. Due to this lipid lowering activity the atherosclerotic changes are reduced and hence the peripheral resistance resulting from atherosclerotic changes is reduced resulting into decrease in blood pressure.

So Arjuna by diuretic activity decreases cardiac load and decreases blood pressure, by cardiac stimulant action it increases force of contraction of heart and increases heart rate, it lowers the LDL cholesterol and thereby the atherosclerosis is decreased. Decrease in atherosclerosis decreases the peripheral resistance which is a main factor of hypertension, and hence decreases the blood pressure. The overall actions described above reduce the blood pressure.

Pashanbheda (*Coleus forkshil*) contains mainly the chemical Forskolin. The basic mechanism of action of forskolin is the activation of an enzyme, adenylate cyclase, which increases cyclic adenosine monophosphate (cAMP) in cells. Cyclic AMP is perhaps the most important cell-regulating compound and is involved in many essential metabolic processes. Once formed it activates many other enzymes involved in diverse cellular functions. Under normal situations cAMP is formed when a stimulatory hormone (e.g., epinephrine) binds to a receptor site on the cell membrane and stimulates the activation of adenylate cyclase. This enzyme is

incorporated into all cellular membranes and only the specificity of the receptor determines which hormone will activate it in a particular cell. Forskolin appears to bypass this need for direct hormonal activation of adenylate cyclase via transmembrane activation. As a result of this activation of adenylate cyclase intracellular cAMP levels rise. The physiological and biochemical effects of a raised intracellular cAMP level include:

- 1) Inhibition of platelet activation and degranulation
- 2) Inhibition of mast cell degranulation and histamine release
- 3) Increased force of contraction of heart muscle;
- 4) Relaxation of the arteries and other smooth muscles
- 5) Increased insulin secretion
- 6) Increased thyroid function
- 7) Increased lipolysis.

Forskolin relaxes the artery wall, decreasing blood pressure and preload stress on the heart muscle. All of these effects appear to be mediated via increased cAMP synthesis, which acts as a secondary messenger on various cellular processes that manifest the stated outcomes. As mentioned above, forskolin relaxes blood vessel smooth muscles via increased cAMP synthesis, helping to reduce high blood pressure by reducing resistance to blood flow. Also due to lipolysis action peripheral resistance and hence blood pressure decreased.

Punarnava contains punarnavoside, rotenoids, boeravinones A, B, C, D and E, lignans, flavones and sterols. Punarnavoside is reported to have diuretic, anti-inflammatory, antifibrinolytic and antibacterial properties. Of the two lignans liriodendrin and syringaresinol mono- β -D-glucoside found in the root extract of Punarnava, liriodendrin has a significant calcium channel blocking effect. Calcium channel blockers are drugs which relax the smooth muscle cells, thereby reducing muscle spasms. They relax blood vessels and lower blood pressure, which is useful in the treatment of cardiovascular disorders.

The alkaloidal fraction of Jatamansi exhibits a significant and sustained hypotensive action. It does not depress the vasomotor center but blocks the pro prioceptive blood pressure regulating reflex. The oil has negative inotropic and positive chronotropic effect on the heart of frog and dog. In moderate dosage the oil do not exhibits any ECG changes. The oil free aqueous extract of Jatamansi also shows a transient hypotensive effect. The hypotensive action appears to be more due to the blockade of adrenergic mechanism as evidenced by the depression of pressor response of carotid occlusion by dimethyl phenyl piperazinium iodide. Hence due to above said mechanism Jatamansi decreases the blood pressure. Thus it can be concluded that the polyherbal formulation with the unique formulation of 4 different herbs by combination of various actions keeps mild hypertension under control. No obvious side effects were observed during the trial period of 1 month, except 1 patient who developed severe giddiness after 10 days of medication. But we cannot blame the herbal medicine solely for that adverse reaction as it might be due to vertigo. No change in any general parameters and adverse effects during the course of the study suggested the safety of the drug in the prescribed dosage.

Conclusion

Thus the results of present study suggests that there was appreciable decrease in the severity of symptoms like headache, giddiness and disturbance of sleep of hypertension in control as well as experimental group. Also blood pressure in both the group was decreased considerably. Finally we conclude that both drugs are equally effective, potential and safe for the management of patients with mild hypertension along with dietary restrictions and modified lifestyle.

- 1. Associate Professor Kayachikitsa Dept. A.S.S Ayurved Mahavidhyalaya, Nashik.
- 2. PG scholar, Kayachikitsa Dept.A.S.S Ayurved Mahavidhyalaya, Nashik.

References:

1) Agnivesha.'*Charaka Samhita'*, elaborated by Charaka and Dridhbala with 'Ayurveda-Dipika' commentary,by Chakrapanidatta, by Vaidya Jadavaji Trikamaji Acharya, Chaukhmba surbharati prakashana, Gopal Mandir Lane,Varanasi -221 001, (India), reprint 2000, Ch. Su. 18/44-46.

2) Sushruta.SushrutSamhita.ayurvedatatwasandipika by KavirajAmbikadattaShastri; Chaukhamba Sanskrit sansthan, 2nd, 2007

3) MadhavNidan with Madhukosh commentary with extracts from Atankadarpana by Vd. VachaspatiVaidya; ChaukhambaOrientalia, 1st, 1986.

4) Gogate, V.M .(1997). Dravyaguna Vidnyan . Pimpalapure and publishers.

5) Bhavprakash by ShriHaridhar Prasad Pande; Chaukhamba Sanskrit sansthan, 5th 1993.

6) AshtangHridayam by Prof.K.R.Srikanta Murthy; Krishnadas academy 1st, 1991.

7) Raj Nighantu, Narahari Pandit, Hindi commentary by Indradeva Tripathi,

Chaukhamba Sanskrit series, Varanasi, 1982, 3rd edition, 2003.

8) Sharangadhara Samhita, Acharya Ramakrishna Parashara, 4th Edition, Baidyanath Ayu. Bhavan Ltd., Jhansi, 1994.

9) Shaligram nighantu- Bhushnam, Lala-Shaligramji- vaishya virachita, sanskaran- 1993, published by Khemaraj Shrikrushnadasa prakashana, Mumbai-4.

10) Nighantu Ratnakara – a compendium of system of Hindu medicine, edited by Bhishagvarya Late Krishna Shastri R. Navre collated with spacious notes by Vasudev Laxman Shastri Pansikar & Krishnaji Vitthal Soman, Part I ,Gunadosha prakarana.

11) Dash, Bhagwan And Kashyap, Lalitesh.(1980). Materiamedica Of Ayurveda. Concept Publishing Company.

12) Nicholas A Boon, Nick R.College, Brian R. Walker, John A. Hunter; Churchill.(20) (2006).Davidson's principles & practice of medicine. Livingstone,Elsevier.pg no.608.

13) Vd.Kadiwale .P.Y.AyurvedAushadhi .Vaidyakgranthabhandar.Pune.

14) Dr.Manajan.B.K.(2010). Methods in biostatics. Jaypee brother's medical publishers.

15) Dr.Sarpotdar& Dr. Bhor .(2006).Research methodology & medical statistics. Manakarnika publications.

16) Blood pressure- Take control published by WHO on world health day 2013.

17)Longo,Dan.(18th edition).(Aug 11, 2011).*Harrisons Principles of Internal Medicine*. Mc Graw Hill.

18) Clinical research protocols for traditional health sciences.(2009). CCRAS.New delhi.

19) Dr.Sabnis, Mukund. (2006). Chemistry and pharmacology of Ayurvedic Medicinal plants. Chaukhamba Amarbharti Prakashan. Varanasi.

20) Dr. Sane, Rohit.(Sept.2003).Understanding Silent killer: Hypertension- Ayurvedic and Allopathic view.

21)Madhavi Jagtap e.al. 2010; A survey of Hypertension in geriatric Population & its management with Makandi (Coleus Forskoli); M.D. (Ayu) thesis, Gujarat Ayurved University, Jamnagar.

22)M.S. Baghel (2005) (second edition), Researches in Ayurveda (A classified directory of all India P.G & Ph.D. theses of Ayurveda), Mridu Ayurvedic Publication & Sales, Jamnagar – 361 002, Gujarat (India).

23)Shaha,sidhharth.(8th ed.)(2009). 'API Textbook of MEDICINE', The association of phisicians of india., pg 531..

24) Salkar, R.G.(1987). Role of Abana in Hypertension.

25) Verma, S.K. and Bordia, A. [Probe (1992): (XXXI), 2, 177-179], A. Effect of Abana (An Indigenous Herbal Compound) in Patients of Mild and Moderate Hypertension.

26)Double-blind comparative clinical trial of Abana and Simvastatin

in Hyperlipidaemia. Venkataramaiah, H., M.D., D.M. (Cardiology),

Professor of Cardiology, Jayadeva Institute of Cardiology, Jayanagar East End, Bangalore, India. [Insertion in *Stroke*, Feb-Mar., 2002].

27) R. Balaraman, N. Hingorani, S.P. Rathod.Research Paper Studies On The Antihypertensive Effect Of Abana In Rats Indian Journal of Pharmacology 1993; 25: 209 – 214.

28) Velpandian Venkatachalapathy1*, Sathya Balakrishnan1, Mohammed Musthafa2, Anbu Natarajan2.(Research Article).A Clinical Evaluation of Nardostachys jatamansi in the Management of Essential Hypertension.International Journal of Pharmaceutical and Phytopharmacological Research.(ICV-5.09)

29) G. M. Alagu Lakshmanan*, S. Manikandan, and R. Panneerselvam.Plectranthus forskohlii (Wild) Briq. (Syn:Coleus forskohlii) – A Compendium on its Botany and Medicinal uses. International Journal of Research in Plant Science.01 oct 2013.

30)Verma *et al.*, IJPSR, 2012; Vol. 3(6): 1832-1838 Effects Of *Eclipta Alba* And *Boerhaavia Diffussa* On Normal Blood Pressure And Hypertension In Rats And Their Comparison With Amlodipine.

31)Atul kale thesis (2005)- The Clinical Study on Ayurvedic Samprapti of Essential Hypertension and the Management with Sarpagandhadi Vati, M.D. (Ayu) thesis, Gujarat Ayurved University, Jamnagar.

32)Arjuna to lower high blood pressure/Hypertension- Medindia.www.medindia.net/.../herbs-for-high-blood pressure.

33)Arjuna: comprehensive control of Hypertension. www.himalayawellness.com/product.

34) Revisiting Terminalia arjuna-An ancient cardiovascular drug.www.ncbi.nlm.nih.gov/ .../articles/PMC4220499

35) Heart Protecting Herbs & Herbal Medicines.www.geocites.ws/.../ayurveda-heartherbs.html

36) Coleus Forskohlii & high blood pressure. www.livestrong.com/article/480669-coleus -forskohlii-high-blood -pressure/

37) forskolin: Uses, Sideeffects, interactions and warnings- webmed.www.webmed.com/

38)Yegnarayan, R., Sangle, S.A., Siraskar, S.S. and Mitra .D.K., Dep.of pharmacology and Medicine. B.J. Medical college, Pune, Maharashtra, India. Regression of cardiac hypertrophy in hypertensive patients-Comparision of Abana with propranalol. (1997)(11), 3, 257.

39)Vaishali.N.Dadkar,Rajlata .R.Tahiliani,Veena.S.Jaguste,Damale .V.B. and Dhar,H.L,L.T.M Medical college sion.Bmbay,Maharashtra. .Double blind comparative trial of Abana and Methyldopa for monotherphy of Hypertension in indian patient.Japanese Heart Journal(1990) (31),2,193.

40) Agrawal,A.,Tiwari,A.K.,Dubey,M.L.and Dubey,G.P.,Department of basic principles, Institute of medical sciences.B.H.U.Varanasi,(U.P), Circadian changes in blood pressure in mild Hypertension and the effect of Abana. Indian journal of Cancer and biological research(1998) (2),1,5.

41) Aruna Agrawal, Shukla, S.S. and Dubey, G.P., Department of basic priciples, institute of medical sciences, B.H.U., Varanasi, (U.P), Abana enhances the blood pressure lowering effect of propranalol in mild to moderate Hypertension. The antiseptic (1989)(86), 9, 486.

42)Salkar,R.G.,Salkar,H.R.,(Mrs.)&Deshmukh,P.Y.,Govrnment medical college,Nagpur,Maharashtra. Role of Abana in Hypertension. The antiseptic.(1987),12,719.

43) Dravyaguna vigyan by Acharya Priyavrat Sharma; Chaukhambabharti academy; Reprint edition 2011.

44) Dravyaguna vigyan by Dr. A.P. Deshpande, Dr. R.R. Javalgekar, Dr. Subhash Ranade; Anmol prakashan; 5th edition, 2000.

45) Indian Medicinal Plants, K. R. Kirtikar, B. D Basu, M/s Bishensingh Mahendrapal Singh M/s period. Expert, 2nd, 1975.

46) Materia Medica of Ayurveda, Bhagwan Das, Lalitesh Kashyap, Concept Publishing Compony, 1st, 1980.

47) Principles of anatomy and physiology by Tortora & Derrickson; Jonh Wiley& sons; 11th edition, 2006.

48) API Textbook of Medicine, Edited in chief G.S. Sainani, API Publications, 16th edition.

49) Textbook of Medical Physiology, Guyton and Hall, Elsevier, 11th, 2006.

50) Essentials of medical pharmacology by Dr. K. D. Tripathi; Jaypee brothers medical publishers (P) Ltd.; 5th edition 2003.

51) Textbook of pathology by Dr. Harsh Mohan; Jaypee brothers medical publishers (P) Ltd.; 5th edition 2005.

52) The Effect Of Arjuna Vacadi Yoga In Vyana Bala Vaishamya- A Clinical Study , Bharti1, V.K.Shahi2 and S. Gupta3, Journal of Research in Ayurveda and Siddha , 1999, Volume : 20, 148-157.

53) Management Of Vyanabala Vaisamya With Indigenous Druges: A Comparative Study, Bharathi1 and R.K. Swamy2, Journal of Research in Ayurveda and Siddha, 2005, Volume: 26, Page: 23-24.

54) Robert E.Rakel, David P.Rakel, 9th edition, Textook of family medicine, Elsevier.

55) Vaidya. Y.G. Joshi, Kayachikitsa, 4th edition, 1st Sept 2001.

56) Ayurvedic Management Of Select Geriatric Disease Conditions Treatment Protocols -Guidelines And Costing of Select Geriatric Disorders A Ccras -Who Country Office, India Colloborative Project

Online references:

- 1) http://www.himalayastore.com/pharmaceuticals/abana-tablets.htm
- 2) http://www.jeevanrekhaayurved.com/
- 3) <u>http://ayushportal.nic.in/Default.aspx</u>.
- 4) <u>https://www.ncbi.nlm.nih.gov/pubmed</u>.
- 5) https://scholar.google.co.in/