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Research Article

CLINICAL EVALUATION OF A NEW AYURVEDIC HERBO-MINERAL FORMULATION (NIA/DG/2020/01) IN STAGE -1 PRIMARY HYPERTENSION

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ABSTRACT

Hypertension, also known as high or raised blood pressure, is a multifactorial disease with multiple causes and multiple treatments. In India, the prevalence of hypertension was estimated to be 40.8% in urban areas and 17.9% in rural areas. Though there are multiple treatment of disease still it is a challenge to manage this disease effectively with lower side effects as all available treatments are full of side effects and toxic effects. New Ayurvedic herbo-mineral formulation NIA/DG/2020/01 is a new anti-hypertensive Ayurvedic *Ghan* formulation, containing *Arjuna (Terminalia arjuna* Roxb.), *Ashwagandha (Withania somnifera* Linn.), *Jatamansi (Nordostachys jatamansi* DC.), *Shankhpushpi (Convolvulus pluricaulis* Chois.), *Punarnava (Boerhavia diffusa* Linn.), *Gojihwa (Onosma Bracteatum Wall.), Guduchi (Tinospora cordifolia Willd.), Mukta Shukti (Margarita)* and *Praval Pisti (Corrallium Rubrum)*. **Aim and Objective:** To assess role of a new Ayurvedic herbo-mineral formulation NIA/DG/2020/01 in Stage-1 primary hypertension. **Material and Methods:** Initially, the formulations were prepared by the instructions mentioned as per classical text. Then clinical trial was proceeded after ethical clearance and CTRI registration on 60 patients from NIA Arogyashala as per inclusion-exclusion criteria and other said parameters. **Observation and Results:** Recorded systolic and diastolic blood pressure was tabulated and analysed statistically by SPSS in both the trial groups. **Discussion:** The result of systolic and diastolic blood pressure changes and percentage of relief was discussed thoroughly. **Conclusion:** The trial drugs showed highly significant reduction in Blood pressure of stage -01 Hypertension when given at a dose of 1 capsule twice a day before meal for 90 days.

INTRODUCTION

Blood arteries have elevated pressure in hypertension, commonly referred to as high or rising blood pressure. As blood is pumped by the heart, it pushes against the walls of blood vessels (arteries), creating blood pressure. The heart has to work more to pump when the pressure is higher.[1]

Hypertension is classified as either primary (essential) or secondary.[2]

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Primary - About 90 to 95% of cases are termed Primary Hypertension, which refers to high BP for which no medical cause can be found.

Secondary - The remaining 5 to 10% of cases, called Secondary Hypertension, are caused by other conditions that affect the kidneys, arteries, heart, or endocrine system.

Globally, an estimated 26% of the world's population (972 million people) has hypertension, and the prevalence is expected to increase to 29% by 2025, driven largely by increases in economically developing nations. [4] About 12.8% of all fatalities worldwide, or 7.5 million, are attributed to hypertension. It is reported to be the fourth contributor to premature death in developed countries and the seventh in developing countries.[5]

Table1: 8th JNC criteria for diagnosis of Hypertension[3]

Category of HT	Systolic BP (mm of HG)	Diastolic BP (mm of HG)
Normal	</=120	</=80
Prehypertensive	120-139	80-89
Stage 1	140-159	90-99
Stage 2	>/=160	>/=100

Despite the fact that the antihypertensive medication class was identified more than 60 years ago, the multifactorial character of hypertension provides a severe difficulty in its management. Modern antihypertensive drugs poses some of the major issues.[6] which are lifelong dependence on drugs, associated adverse drug reaction of anti-hypertensive drugs, development of resistance to anti-hypertensives and failure to bring normotensive despite multiple anti-hypertensives, etc. Hence there is the need for resurgence of the use of traditional medicines by switching onto the older systems of Ayurveda from current therapies.[7] In the present context, the Ayurvedic system of medicine is widely accepted and practiced not only in Indian peninsula but also in developed countries.[8]

The holistic approach used by Ayurveda makes sense for complex conditions like hypertension. Traditional medical practises like Ayurveda are gaining popularity again as people look for more comprehensive remedies to this health problem. Ayurveda generally uses herbs with *Vata-pitta Shamaka* activity and affinities to the central nervous system and circulatory system to treat hypertension. To manage this condition, herbs with antihypertensive, stress-reduction, cardio tonic, diuretic, and antioxidant properties are employed.

Therefore, it is necessary to develop a body of data that is methodically created to support this antihypertensive management strategy. Although practically adopted, there is very little scientific and systemic data available for the role and efficacy of Ayurvedic medicines in hypertension. Although many Ayurvedic herbs are used for hypertension management, a holistic formulation containing ingredients that can address all possible pathways of hypertension is not available in the market.

Hence, in the proposed study, a new Ayurvedic herbo-mineral formulation (NIA/DG/2020/01) is a hypothetical Ayurvedic formulation which contains aqueous extract of *Arjuna* bark, *Ashwagandha* root, *Jatamansi* rhizome, *Punarnava* whole plant, *Shankhapushpi* whole plant, *Gojihwa* whole plant, *Guduchi* stem, *Mukta Shukti* and *Praval Pisti* (Table-4) along with an Ayurvedic formulation NIA/DG/2015/01, which was constituted in 2015 containing *Arjuna, Ashwagandha, Jatamansi, Shankhpushpi* and *Punaava.* Each of the aforementioned medications is known to have an individual hypotensive or antihypertensive impact and work via a distinct mechanism (Table-5).

The main objective of the present study is to assess role of a new Ayurvedic herbo-mineral formulation NIA/DG/2020/01 in Stage-1 Primary Hypertension.

MATERIAL AND METHODS

Ethical Clearance: Ethical clearance was taken from Institutional ethical committee before the commencement of the trail (IEC/ACA/2020/3-22 dated 30-06-20).

CTRI Registration: The registration number for this trial is CTRI/2021/04/033231.

Site of Study- Arogyashala OPD and other hospitals of National Institute of Ayurveda, Jaipur.

Selection of Patients: 66 patients have been selected randomly, out of which 60 have completed the trial, all were well diagnosed as Stage-01 Primary Hypertension as per 8th JNC criteria for diagnosis hypertension and symptoms described in Ayurvedic classical text. Clinical history has been taken in a specially prepared proforma.

Inclusion Criteria

1. Patients belonging to male and female between the age group 18 to 60 years.
2. Patients of Stage 1 Primary Hypertension.
3. Mild to moderate grade patients of hypertension as per 8th JNC & WHO criteria has been included.
4. Isolated grade-1 systolic or diastolic hypertension.

Exclusion Criteria

1. Known cases of secondary hypertension.
2. Known cases of renal diseases, diabetic mellitus.
3. Known cases of pregnancy induced hypertension.
4. Known cases of ventricular hypertrophy, coarctation of aorta.
5. Known cases of portal hypertension.
6. Known cases of renal artery stenosis induced hypertension.
7. Patients using other antihypertensive medicines of conventional biomedicine/AYUSH systems/any other system.
8. Patients using drugs like oral contraceptive pills, steroids.
9. Patient not taking any previous anti-hypertensive medication.
10. Patient with no evidence of any target organ damage.

Criteria for Withdrawal

1. During the course of trial, if any clinical or health condition arose which required discontinuation from the trial.
2. Patients developed any serious adverse effect which required withdrawal from the trial.
3. Patient himself/herself wanted to withdraw from clinical trial.
4. The records of the withdrawn cases were kept and mentioned in the dissertation.

Grouping, Randomization & Blinding

After the screening through complete examination and investigation, selected patients had been enrolled for the trial by double blinding & SNOSE method of randomization.

Administration of Drug

Table 2: Groups of Drug Administration

Group-1	Group-2
30 patients have been received NIA/DG/2020/01 with DASH Diet	30 patients have been received NIA/DG/2015/01 with DASH Diet

Pathya Apathya: The DASH Diet (Dietary Approaches to Stop Hypertension) format has been kept as *Pathya Apathya* in all patients during the treatment period which was provided in written form.

Mode of Administration

- Drug- NIA/DG/2020/01 and NIA/DG/2015/01
- Dose- 01 capsules twice a day
- Dose form- Capsule
- *Anupana*- Lukewarm water
- Route of administration- Oral
- Time of administration- Before meal
- Duration of therapy- 90 days

Duration of Clinical Trial and Follow Up Study

Duration of clinical trial has been of 3 months intervention and 1 month follow up (±2 Days).

Table 3: Duration of Clinical Trial and Follow Up

Days of Follow Up	For All Groups
Day 0	Protocol explanation and informed consent, clinical assessment and lab investigations, randomization
Day 1	Start of drug intervention
Day 15	Measurement of blood pressure
Day 30	Measurement of blood pressure
Day 45	Measurement of blood pressure
Day 60	Measurement of blood pressure
Day 75	Measurement of blood pressure
Day 90	Clinical and self-assessment of patient with lab investigations, stoppage of drug intervention
Day 120	Follow up with blood pressure measurement

Preparation of Test Drugs

Table 4: Preparation of new Ayurvedic Herbo-mineral formulation NIA/DG/2020/01

S.No.	Ingredient	Family	Part Used	Quantity
1.	*Convolvulus pluricaulis* Chois.	Convolvulaceae	Whole plant	3 parts
2.	*Withania somnifera* Linn.	Solanaceae	Root	3 parts
3.	*Terminalia arjuna* Roxb.	Combretaceae	Bark	3 parts
4.	*Boerhavia diffusa* Linn.	Nyctaginaceae	Whole Plant	3 parts
5.	*Tinospora cordifolia* Willd.	Menispermaceae	Stem	3parts
6.	*Nordostachys jatamansi* DC.	Valerianaceae	Rhizome	2 parts
7.	*Onosma bracteatum* Wall.	Boraginaceae	Aerial Part	3 parts
8.	*Margarita/Pearl oyster*	-	-	1/8 part
9.	*Corrallium rubrum*	-	-	1/4 part

Dried aqueous extract of first six ingredients mentioned in the above table has been obtained by crude extraction method. The aqueous extract of *Gojihva* has been also obtained but separately (as after *Kwath* preparation it is heated by direct heat upto a particular stage than heated by dry heat). The two mineral contents i.e., *Mukta shukti* and *Praval* has been added to this dried extract and filled in to capsules.

Table 5: Preparation of new Ayurvedic polyherbal formulation[9-15] *NIA/DG/2015/01*

S. No.	Ingredient	Family	Part Used	Quantity
1.	*Convolvulus pluricaulis* Chois.	Convolvulaceae	Whole plant	1 part
2.	*Withania somnifera* Linn.	Solanaceae	Root	1 part
3.	*Terminalia arjuna* Roxb.	Combretaceae	Bark	1 part
4.	*Boerhavia diffusa* Linn.	Nyctaginaceae	Whole Plant	1 part
5.	*Nordostachys jatamansi* DC.	Valerianaceae	Rhizome	1 part

Dried aqueous extract of all ingredients mentioned in the above table has been obtained by crude extraction method. The obtained medicine has been dried and filled in to capsules.

Statistical Analysis

- Intragroup comparison for non-parametric data has been done by Wilcoxon Matched Pairs Signed Ranks Test and intragroup comparison for parametric data has been done by Paired T Test and results have been calculated accordingly.
- Intergroup comparison for non-parametric data has been done by Mann Whitney Test and intragroup comparison for parametric data has been done by Unpaired T Test and results have been calculated accordingly.

OBSERVATIONS AND RESULTS

Intra Group Comparison of Systolic and Diastolic Blood Pressure – Group Wise

Table 6: Showing effect of Therapy on Systolic Blood Pressure (Visit Wise- Group-A)

Variable	Day	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
Systolic BP (mm of Hg)	15	145.4667	138.1337	-7.333	05.04	2.796	0.5104	14.37	<0.0001	HS
	30	145.4667	128.1967	-17.27	11.87	3.342	0.6101	28.30	<0.0001	HS
	45	145.4667	125.1367	-20.33	13.97	3.155	0.5760	35.30	<0.0001	HS
	60	145.4667	123.8667	-21.60	14.85	3.460	0.6317	34.19	<0.0001	HS
	75	145.4667	123.3367	-22.13	15.21	4.607	0.8411	26.32	<0.0001	HS
	90	145.4667	121.6000	-23.86667	19.15	4.32900	0.79036	30.197	<0.0001	HS

Table 7: Showing effect of Therapy on Diastolic Blood Pressure (Visit Wise- Group-A)

Variable	Day	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
Diastolic BP (mm of Hg)	15	93.5333	84.8663	-8.667	09.26	3.209	0.5859	14.79	<0.0001	HS
	30	93.5333	82.2633	-11.27	12.05	2.490	0.4547	24.78	<0.0001	HS
	45	93.5333	82.3333	-11.20	11.97	2.605	0.4756	23.55	<0.0001	HS
	60	93.5333	82.1333	-11.40	12.19	2.737	0.4997	22.82	<0.0001	HS
	75	93.5333	82.5333	-11.47	12.26	2.569	0.4691	24.44	<0.0001	HS
	90	93.5333	81.7333	-11.80	12.61	2.18774	0.39942	29.542	<0.0001	HS

Table 8: Showing effect of Therapy on Systolic Blood Pressure (Visit Wise- Group-B)

Variable	Day	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
Systolic BP (mm of Hg)	15	146.40	141.4667	-4.933	03.37	2.612	0.4769	10.34	<0.0001	HS
	30	146.40	126.60	-19.80	13.52	2.483	0.4533	43.68	<0.0001	HS
	45	146.40	124.2	-22.20	15.16	3.123	0.5701	38.94	<0.0001	HS
	60	146.40	123.00	-23.40	15.98	3.900	0.7121	32.86	<0.0001	HS
	75	146.40	122.33	-24.07	16.44	4.185	0.7640	31.50	<0.0001	HS
	90	146.40	122.40	-24.00	16.39	4.84234	0.88409	27.147	<0.0001	HS

Table 9: Showing effect of Therapy on Diastolic Blood Pressure (Visit Wise- Group-B)

Variable	Day	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
Diastolic BP (mm of Hg)	15	93.7333	85.2003	-8.533	09.10	3.192	0.5828	14.64	<0.0001	HS
	30	93.7333	84.6663	-9.067	09.67	3.005	0.5486	16.53	<0.0001	HS
	45	93.7333	83.5333	-10.20	10.88	2.696	0.4922	20.72	<0.0001	HS
	60	93.7333	82.8033	-10.93	11.66	2.504	0.4572	23.91	<0.0001	HS
	75	93.7333	82.0033	-11.73	12.51	2.612	0.4769	24.60	<0.0001	HS
	90	93.7333	81.6000	-12.133	12.94	2.22421	0.40608	29.879	<0.0001	HS

Intra Group Comparison of Systolic and Diastolic Blood Pressure - (before and after treatment)

Table 10: Showing effect of Therapy on Systolic and Diastolic Blood Pressure (before and after treatment)

Variable	Gr.	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
Systolic BP	A	145.4667	121.6000	23.86667	19.15	4.32900	0.79036	30.197	<0.0001	HS
	B	146.40	122.40	24.00	16.39	4.84234	0.88409	27.147	<0.0001	HS
Diastolic BP	A	93.5333	81.7333	11.8000	12.61	2.18774	0.39942	29.542	<0.0001	HS
	B	93.7333	81.6000	12.13333	12.94	2.22421	0.40608	29.879	<0.0001	HS

Inter Group Comparison of Systolic and Diastolic Blood Pressure - (before and after treatment)

Table 11: Showing Intergroup Comparison for Systolic and Diastolic Blood Pressure (Unpaired t Test)

Variable	Gr.	Mean	SD±	SE±	T	P	S
Systolic BP	A	121.6000	1.42877	0.26086	2.562	<0.05	S
	B	122.4000	1.10172	0.20115			
Diastolic BP	A	81.7333	1.14269	1.14269	0.494	>0.05	NS
	B	81.6000	0.81368	0.14856			

Figure 1: *Ghan* of NIA/DG/2020/01 & NIA/DG/2015/01

Figure 2: *Ghan* Capsules of NIA/DG/2020/01 & NIA/DG/2015/01

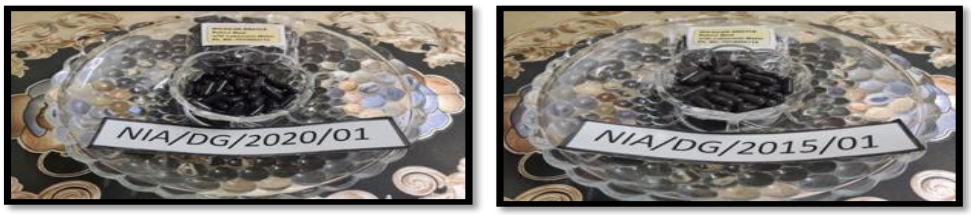


Figure 3: Showing effect of Therapy on Blood Pressure (Group-A)

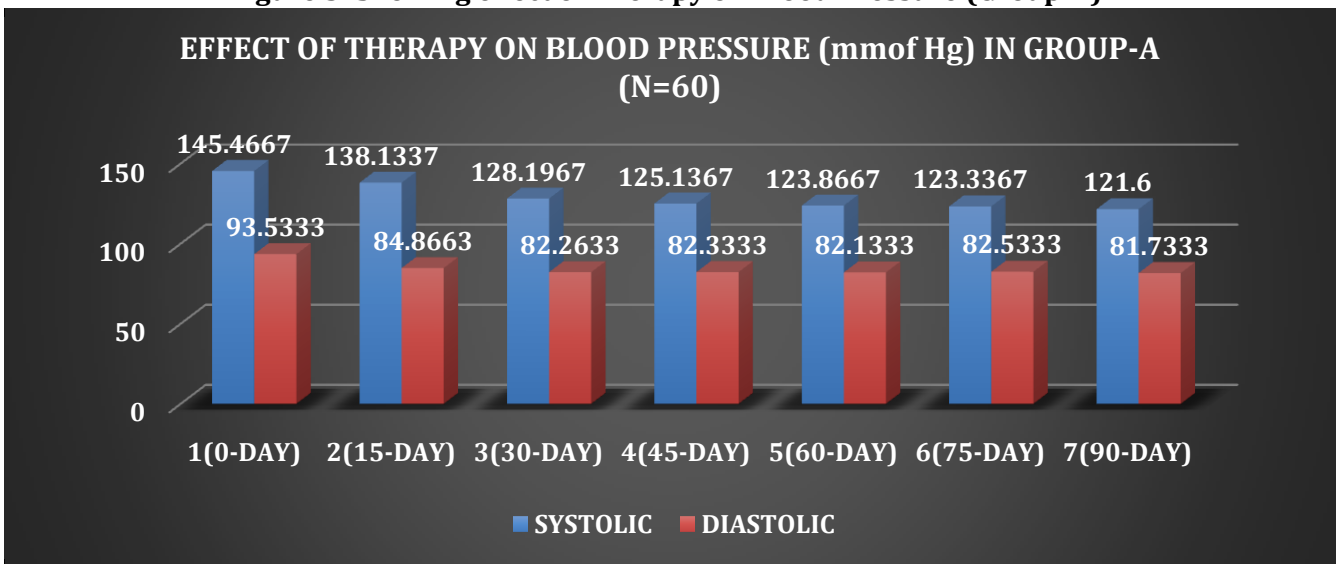


Figure 4: % Relief of Therapy on Group-A

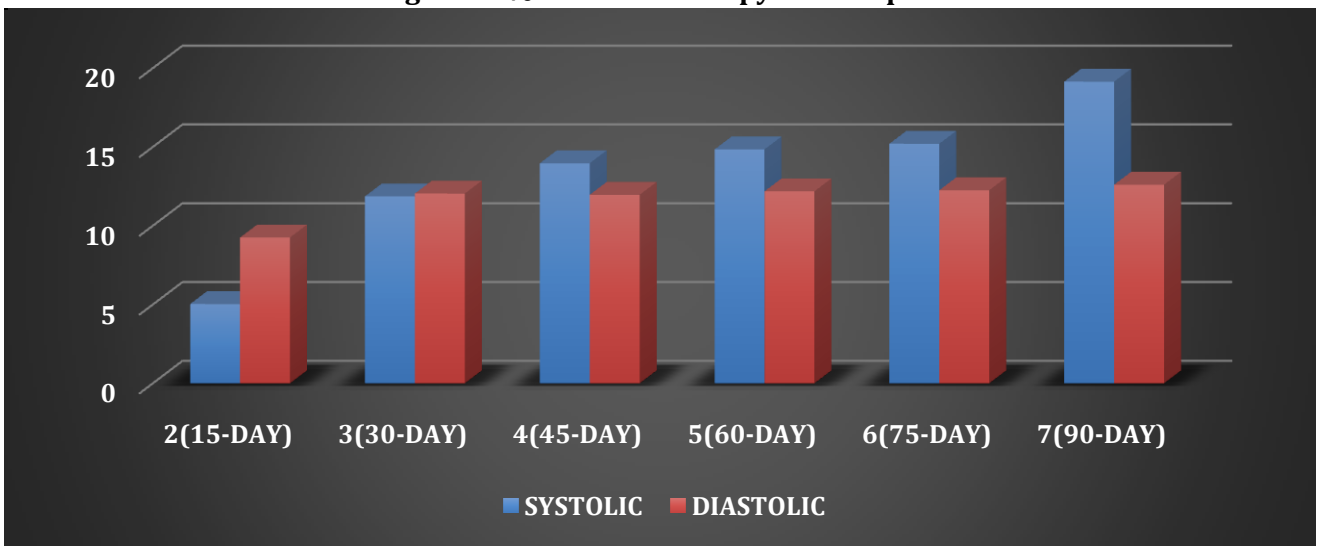


Figure 5: Showing effect of Therapy on Blood Pressure (Group-B)

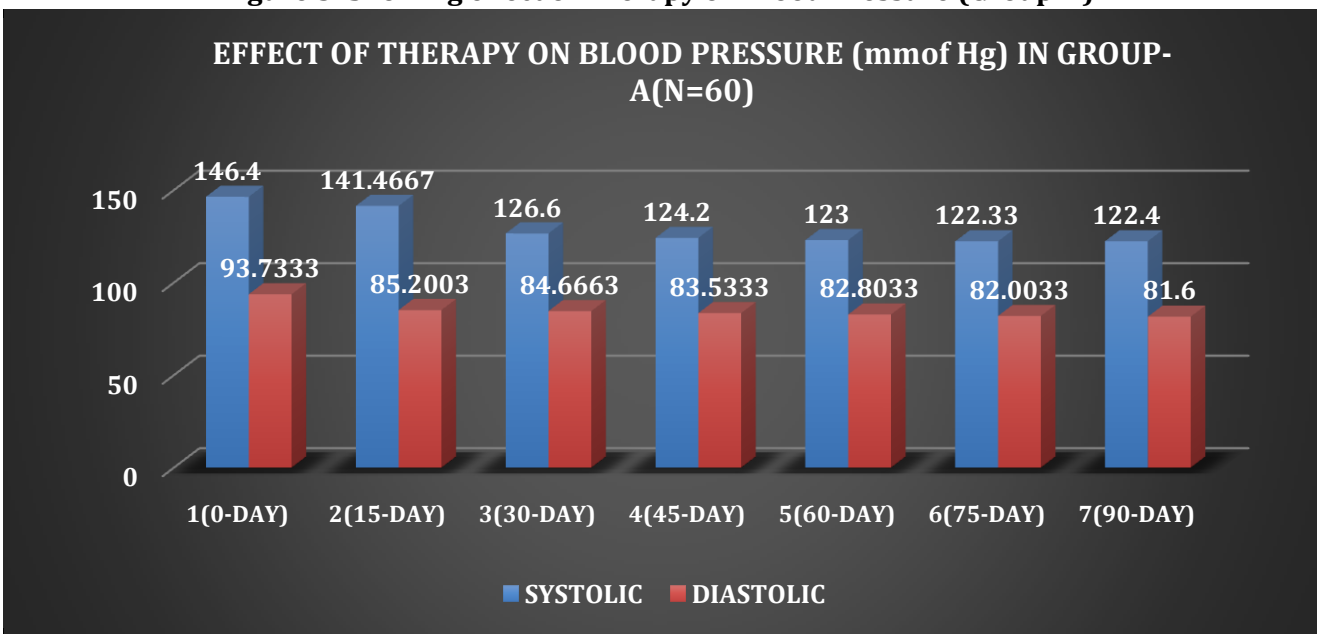


Figure 6: % Relief of Therapy on Group-B

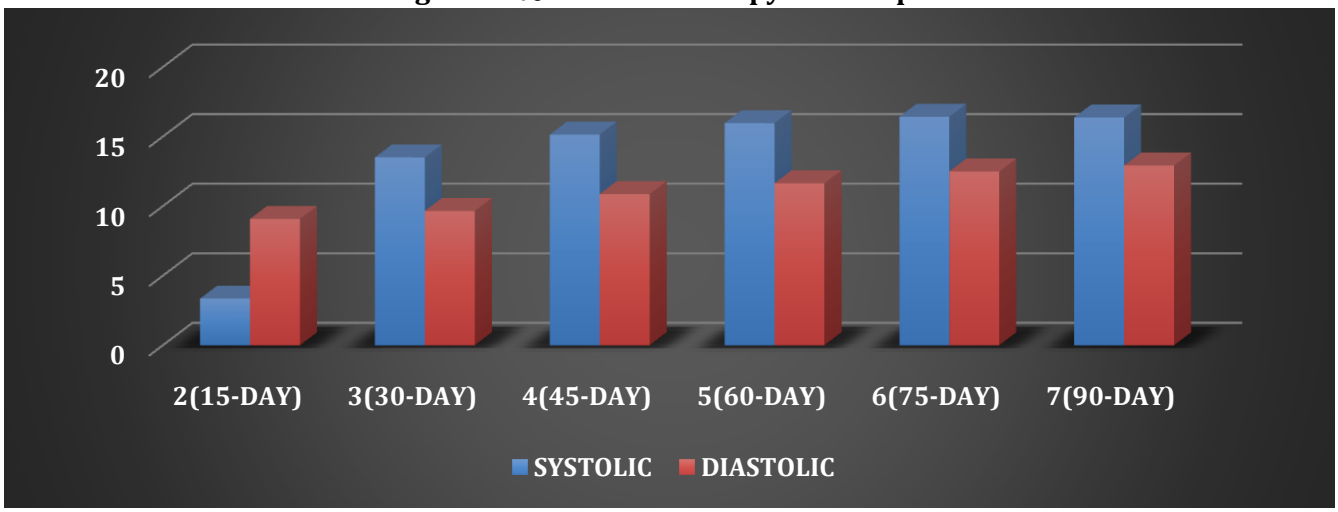


Figure 7: Showing Relief in Both Groups in Objective parameters (B.P.)

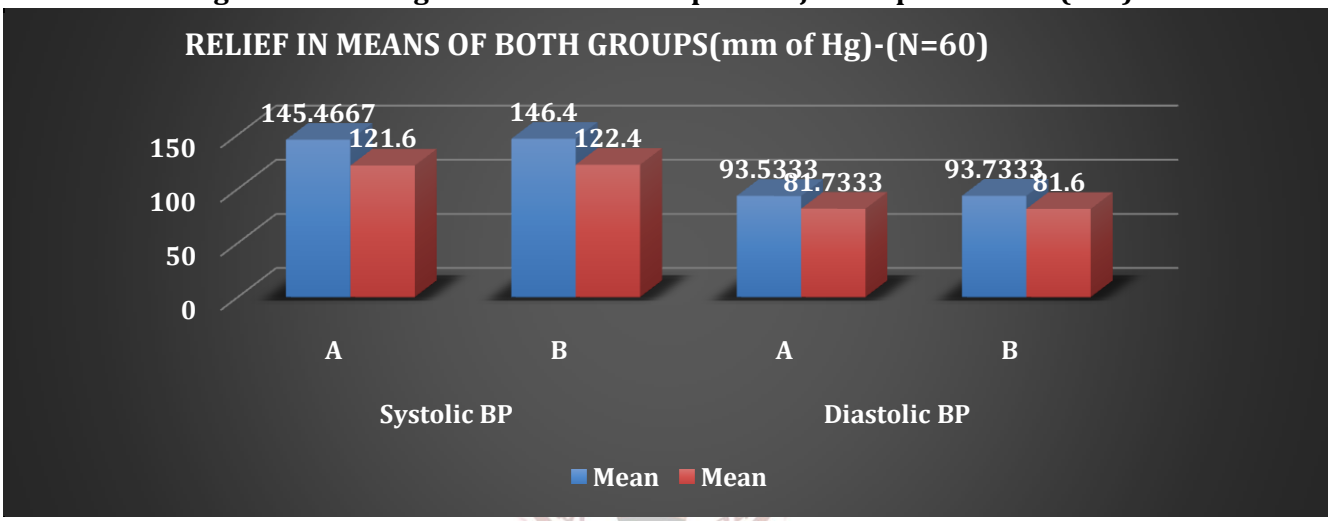
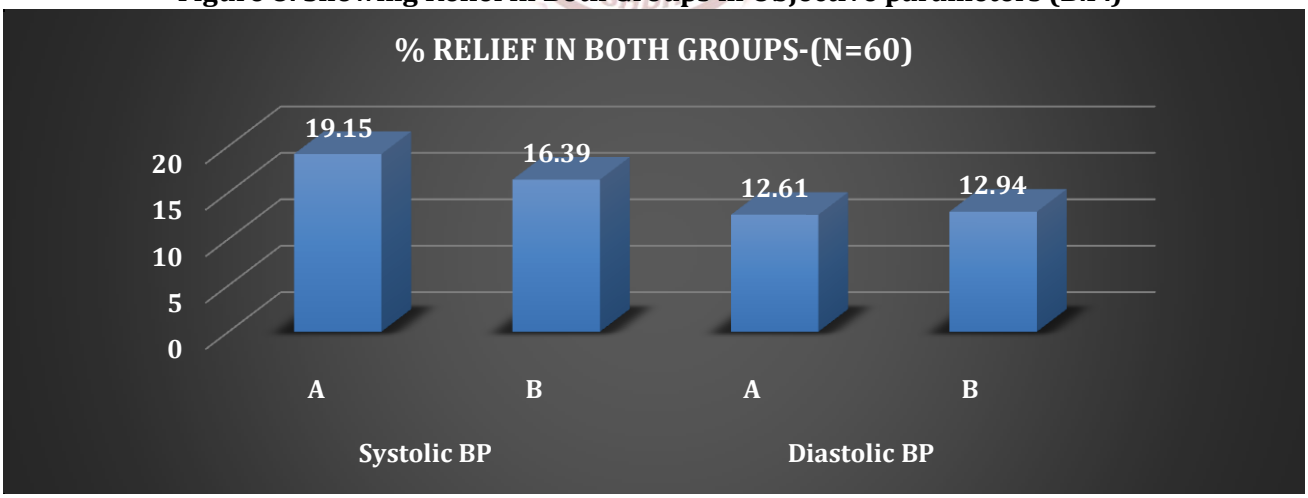


Figure 8: Showing Relief in Both Groups in Objective parameters (B.P.)



DISCUSSION

Discussion on Systolic B.P.

- As per Table No-6, in Group A the mean score before treatment was 145.47mm of Hg which lowered down to 138.13 at 15th day, 125.14 at 30th day, 123.34 at 45th day, 121.60 at 60th day, 121.34 at 75th day and 120.87 at 90th day after treatment, with giving (percentage of decrease in BP in mm of Hg) an improvement of 5.04%, 13.97%, 15.21%, 16.41%, 16.59% and 16.91% respectively which was statistically, highly significant (P<0.0001).
- As per Table No-8, in Group B the mean score before treatment was 146.40mm of Hg which lowered down to 141.47 at 15th day, 126.60 at 30th day, 124.2 at 45th day, 123 at 60th day, 122.33 at 75th day and

122.40 at 90th day after treatment, with giving (percentage of decrease in BP in mm of Hg) an improvement of 3.37%, 13.52%. 15.16%, 15.98%. 16.44% and 16.39% respectively which was statistically, highly significant (P<0.0001).

This is clear from the above discussion that in the two group therapies, group-A & group-B reduced Systolic BP, but it was more in Group A in comparison to Group B.

Discussion on Diastolic B.P.

- As per table No-7, in Group A the mean score before treatment was 93.53mm of Hg which lowered down to 84.87 at 15th day, 82.26 at 30th day, 82.13 at 45th day, 82.53 at 60th day, 81.73 at 75th day and 81.06 at 90th day after treatment, with giving (percentage of decrease in BP in mm of Hg) an improvement of 9.26%, 12.05%. 12.19%, 12.26%. 12.61% and 13.33% respectively which was statistically, highly significant (P<0.0001).
- As per Table No-9, in Group B the mean score before treatment was 93.73mm of Hg which lowered down to 85.20 at 15th day, 84.67 at 30th day, 83.53 at 45th day, 82.80 at 60th day, 82.00 at 75th day and 81.60 at 90th day after treatment, with giving (percentage of decrease in BP in mm of Hg) an improvement of 9.10%, 9.67%. 10.88%, 11.66%. 12.51% and 12.94% respectively which was statistically, highly significant (P<0.0001).

This is clear from the above discussion that in the two group therapies, group A and group B reduced Diastolic BP, but it was more in Group A in comparison to Group B.

Effect of Therapy on Systolic and Diastolic Blood Pressure (Before and After Treatment- Intra-Group)

- **As per Table No-10. Systolic pressure-** In Group A the mean score before treatment was 145.4667 which lowered down to 121.6000 after treatment, with SD±4.32900 giving (percentage of decreased) an improvement of 19.15% which was statistically highly significant (P<0.0001). In Group B the mean score before treatment was 146.40 which lowered down to 122.40 after treatment, with SD±4.84234 giving an improvement of 16.39% which was statistically highly significant (P<0.0001).
- **As per Table No-10. Diastolic pressure-** In Group A the mean score before treatment was 93.5333 which lowered down to 81.7333 after treatment, with SD± 2.18774 giving (percentage of decreased) an improvement of 12.61% which was statistically highly significant (P<0.0001). In Group B the mean score before treatment was 93.7333 which lowered down to 81.6000 after treatment, with SD±2.22421 giving (percentage of decreased) an improvement of 12.94% which was statistically highly significant (P<0.0001).

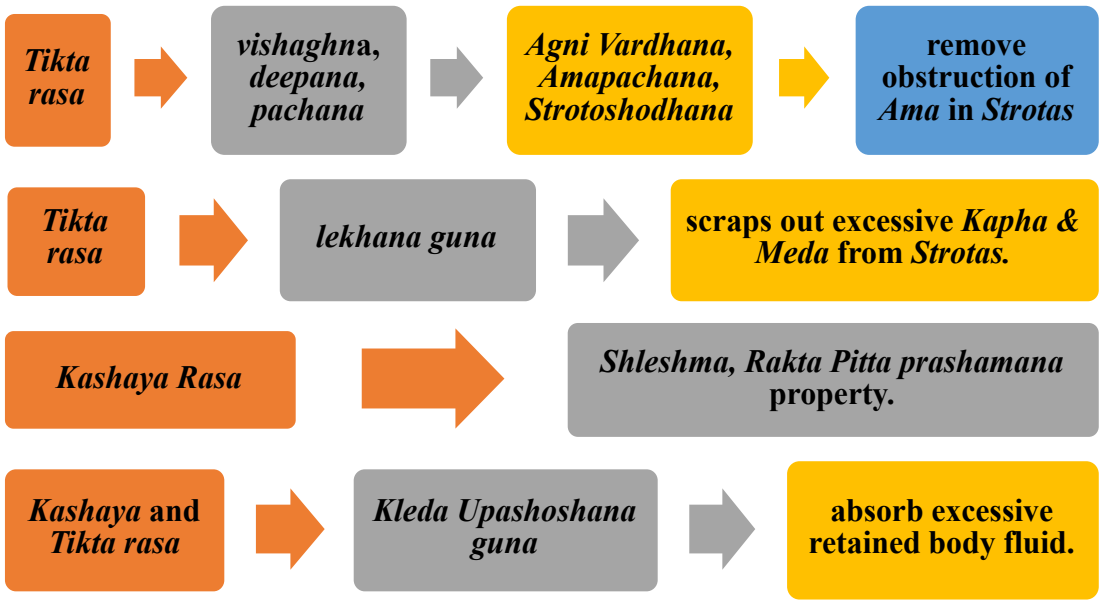
Effect of Therapy on Systolic and Diastolic Blood Pressure (before and after treatment- Intra-Group)

- **As per Table No-11. Effect of Therapy on Systolic BP:** The P<0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments.
- **Effect of Therapy on Diastolic BP:** The P>0.05 which is statistically not significant which shows that there is no statistical difference in efficacy of both treatments.

Discussion on Probable Mode of Action

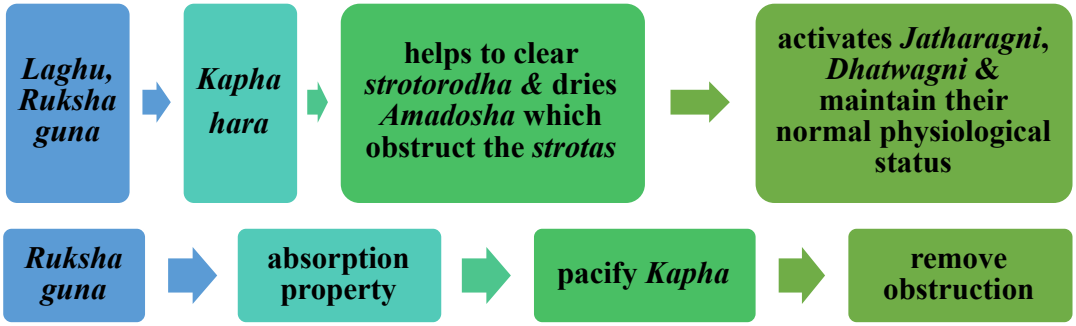
***Rasa* -** It has been observed that most of drugs in trial drug possess *Madhur, Tikta* and *Kashaya Rasa.*

Figure- 09: Mode of Action by *Rasa*



Guna- When we study predominant *Guna* present in trial drug it is evident that majority are possessing *Laghu, Ruksha guna*.

Figure- 10: Mode of Action by *Guna*



Virya- As regard to *Virya* some of the drugs of trial drug.

Figure-11: Mode of Action by *Virya*

Vipaka- *Related to Vipaka* majority of these drugs have.

Figure-12: Mode of Action by *Vipaka*

***Samprapti Vighatan* (as per individual *Dravya* effect)**

- ***Rasayana* Property:** *Punarnava, Ashwagandha, Shankhapushpi, Guduchi* and *Jatamansi* possesses *Rasayana* property. *Rasayana* drugs also possess the property of *Srotoshodhana* which makes them useful where the *Samprapti* of disease due to *Avarana* i.e., due to *Margavarodha. Rasayana* also works where vitiation of *Vata* is due to *Dhatushayajanya*. Thereby they act as antioxidant and immunomodulator. By these properties they normalize the process of *Dhatu* formation producing the *Prashasta Dhatus* and purify vitiated *Dhatus.*
- ***Mutrala* Property:** *Punarnava, Gojihva, Mukta Shukti pisti & Praval pisti* may reduce the blood volume resulting into decreased blood pressure due to their *Mutrala* property. Its stress lowering effect adds to its antihypertensive action.
- ***Medhya* Property:** *Medhya* property of *Shankhapushpi* and *Jatamansi* calms the mind and maintain equilibrium of autonomous nervous system which acts on vasomotor centre which creates vasodilation and may be helpful to decrease the blood pressure.
- ***Hhridya* Property:** *Arjuna, Gojihva, Mukta Shukti pisti & Praval pisti* is very beneficial as a cardioprotective by its *Hridya prabhava* and increases stroke volume which decreases heart rate and decreases blood pressure.
- ***Pitta shamaka* property:** *Mukta Shukti pisti & Praval pisti* have *Pitta shamaka* effect by doing *Drava-pitta avashoshana*. They both balances the Na^+, K^+ & Cl^- by increasing excretion of Na^+ & Cl^- and decreasing excretion of K^+ in urine, and thus finally decreasing blood pressure.
- **Antidepressant and anti-stress effects:** *Ashwagandha, Shankhapushpi, Guduchi* and *Jatamansi* produces antidepressant and antistress effects through *Vatahara* property which helps in pacification of *Raja Dosha* of *Mana*. *Shankhapushpi* is a *Medhya rasayana*, which controls the production of stress hormones.
- **Antioxidant, anxiolytic and Antidepressant action:** *Jatamansi & Guduchi* have antioxidant, anxiolytic and antidepressant action has an antihypertensive effect as anxiety and depression are significant contributory factors in hypertension.

CONCLUSION

- The trial drugs showed highly significant reduction in Blood pressure of Stage -01 Hypertension when given at a dose of 1 capsule twice a day before meal for 90 days.
- Since both NIA/DG/2020/01 and NIA/DG/2015 /01 showed highly significant results, it can be concluded that NIA/DG/2020/01 showed more percentage of relief in objective parameter (systolic & diastolic blood pressure).
- The trial drug was well tolerated by all the patients and no toxic or unwanted effects were observed in any patient.

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