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Open randomised controlled study to evaluate the efficacy of *Karsha Vati* and Telmisartan in the management of Essential Hypertension: A Pilot Study

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ABSTRACT

Hypertension appears to be the important risk factor of the modern society; the cause behind this is busy and stressful life, absence or less physical activities. A clinical study was conducted on patients, to evaluate the efficacy of *Karsha Vati* and Telmisartan in the management of essential Hypertension. The present study was designed on newly diagnosed cases of Hypertension. The Aim and Objective of this study was to evaluate the efficacy of *Karsha Vati* and Telmisartan in the management of Hypertension. This study was planned on 60 diagnosed cases of Hypertension in each Trial and Controlled group who were orally administered with *Karsha Vati* and Telmisartan respectively. Result obtained from study revealed that *Karsha Vati* (Trial group) shows good effect in relieving the subjective criteria's viz, *Shiroruka, Bhrama, Klama, Nidra-vikruti, Hrud-dravata* than controlled group. There was no significant difference seen between the two groups.

Key words: *Karsha Vati, Telmisartan, Essential Hypertension.*

INTRODUCTION

In Ayurveda, there is no disease, which can directly co-related with Hypertension. As per Ayurveda principle, in case of unknown disease, physician should try to understand the nature of disease through *Dosha*, *Dushya* and *Samprapti*; then should initiate the treatment.[1] *Rakta Dhatu* explained in Ayurveda (inclusive of *Rasa Dhatu*) can be compared to the blood tissue. *Vyana Vayu* is responsible for the heart function including the output (Systole) and input (Diastole) of the blood and the circulation. As per Ayurveda, hypertension can be correlate with *Vataj Hrudroga*.[2] Hypertension is often called the silent killer because it shows no early symptoms and, simultaneously, is the single most significant risk factor for atherosclerosis and all clinical manifestation of atherosclerosis. Currently available anti-hypertensive drugs are either too expensive for long term use or often related with side effect like renal impairment, headache, oedema etc. hence there has been pursuit for new safe and effective drug for hypertension. Hence it is necessary to find out some human health friendly and cost wise cheap formulation to control and eradicate this disease. The entire above scenario encouraged to invent a new and safe Polyherbal drug *Karsha Vati* as mentioned in Bhavaprakasha Madhyam Khanda for eradication of *Hrudaygat Vata*.[3] According to ancient Ayurvedic text and Nighantus all the contains of *Karsha Vati* [i.e. *Ashwagandha* (*W. somnifera*),[4] *Bibhitaki* (*Embilica officinalis*)[5] and *Gud* (jaggery)],[6] these drugs are *Hrudya* means good for heart and purifies blood and enhances blood circulation thus *Rasayana* and increase life expectancy, hence thought to be useful in hypertension.

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Aim and Objective

To study the clinical efficacy of *Karsha Vati* in the management of Essential Hypertension.

Materials and Methods

During this study of "*Karsha Vati*" in essential hypertension, pre-decided methodology was adopted. 60 patients were selected (By Simple Random method) for the study and divided into 2 groups. Ingroup (I), called as 'Trial Group', 30 patients were included to whom '*Karsha Vati*' (2 gm) given twice a day before meals for 6 weeks. Another group, called as 'Control Group', 30 patients were included who were given a tablet of 'Telmisartan' (20 mg) once daily after breakfast for 6 weeks.

Type of Study - Open Randomized Controlled Study.[7]

Method of Preparation

Karsha Vati was prepared under the guidance of Bhaishajya Kalpana Department of Smt. K. G. Mittal P. Ayurveda College, Mumbai, India as per classical text reference.

Fine powders (*Churna*) of *Ashwagandha, Bibhitaki* and (*Purana* & *Shuddha*) *Gud* were taken in 1:1:2 proportion (According to Sharangadhara Samhita).[8]

Sufficient water was added in above mentioned ingredients in a big pan over low fire, which make a semisolid matter (i.e. suitable form for preparation of tablets) after some time.

- Matter was stirred till end of the recipe; and Then, it was dried in a shadow to make the tablets each of 500 mg weight; with the help of Tablet-Preparing-Machine and kept in small plastic bottles.
- The drug is given in *Vati* form for the following purposes.

1. To administer the correct dose.
2. To palatability of patient.

Standardization of drugs

Tablet analysis of *Karsha Vati* was done at Alarsin pharmaceutical Lab. Andheri, Mumbai.

Dose

- *Karsha Vati* 2 gm. twice a day before food [*Aushadha Sevana Kala 'Pragbhakta'*] given according to Ayurvedic principles for more accurate results to Trial Group.
- Telmisartan had been given in dose of 20 mg after breakfast once a day to Control Group.

Anupana

Ushnodaka (warm water) to increase the efficacy of the drug.[9]

Duration - 6 weeks.

Diet and Exercises (*Aahara* and *Vihara*)

They were as per patient's previous schedule; but not with too much oily, fried, non-veg food. Also, too much exercises (like Yoga) not permitted during trial for 6 weeks.

Follow-up

Clinically patients were screened every day for first week thenafter weekly screening is done.

Study Centre - OPD and IPD; Dept. of Kayachikitsa of our Institution.

Criteria of Diagnosis

Patient with pre-hypertension stage i.e. SBP (120-139mmHg) and DBP (80-89 mmHg) also Stage 1 hypertension i.e. SBP (140-180 mmHg) and DBP (90-99 mmHg) was diagnosed.

Inclusion criteria

- Both sexes are equally involved in study.
- Age group 30 to 70 years age.
- Newly diagnosed patient of hypertension OR patient Known to be Hypertensive but yet not approached any system of medication.
- Blood pressure >/= 130 (systolic) & >/= 85 (diastolic) or specific medication. (130-180 systolic & 85-100 diastolic pre hypertension & Stage I (7th JNC Criteria & WHO criteria for diagnosis of HTN)

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Exclusion criteria

- Severe essential hypertension (SBP/DBP is >/= 180/100 mmHg). Significant Renal insufficiency.
- H/O cerebral Vascular Disease, HIV, AIDS, Hep-B, Hep-C, or any other Immunosuppressive disorder.
- Current Diagnosis or H/O of malignancy and any Mental Disorder.
- Pregnant or breastfeeding women.

Withdrawal criteria

1. Left Against Medical Advice (LAMA)
2. Aggravation of Symptoms
3. Development of complications due to presenting illness or otherwise
4. Any adverse drug effects

Investigations

1) Blood - CBC, ESR, Liver Function and Renal Function Tests, Lipid Profile before treatment as routine and to exclude complications said in Exclusion Criteria as per requirement.
2) Blood Sugar (Fasting and Post-Prandial) before treatment as routine and to avoid Diabetes Mellitus as per requirement.
3) X – Ray (Chest) PA view before treatment as routine to avoid Respiratory Diseases as per requirement.
4) ECG before treatment as routine to avoid Cardiac Diseases Complications as per requirement.

Criteria of assessment

Assessment was done subjectively as well as objectively.

Subjective criteria

Symptoms of Hypertension mentioned in the text or practically observed was assessed at each follow- up and presence or absence of them was registered. All symptoms were graded into five grade scales (0-4) on the basis of severity to assess the changes and this study in gradation was done at each follow up.

Gradation of symptoms[10]

These gradations are given by CCRAS and also practically observed in essential hypertension.

Table 1: Gradation of symptoms

SN	Criteria	Detail	Score
1.	Headache (*Shiroruk*)	Absent	0
		Headache relieves without medication.	1
		Frequent headache relieves with rest doesn't disturb daily routine.	2
		Frequent headache disturbs daily routine requires medication	3
		Continuous or severe headache disturbs sleep and daily activities and also not managed by the medication.	4
2.	Giddiness (*Bhrama*)	Absent.	0
		Rarely for some movement during change of posture.	1
		Often for some movement during change of posture.	2
		Often for each movement even in lying down position.	3
		Patient unable to hold himself without any support.	4
3.	Tiredness (*Klama*)	Absent.	0
		Rarely feeling of tiredness without any exertion.	1
		Rarely feeling of tiredness without any exertion with inability in concentration.	2
		Frequently feeling of tiredness without any exertion with inability in Concentration.	3
		Continuous feeling of tiredness without any exertion with inability	4

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		in Concentration.	
4.	Disturbance of sleep (*Nidra-Vikruti*)	Absent	0
		Disturbed sleep wakes up1-2 times.	1
		Difficult to onset of sleep remains disturbed all night.	3
		Very less sleeping small intervals makes patient irritable.	4
		Not getting sleep without medication.	5
5.	Palpitations (*Hrud-dravatva*)	Absent.	0
		Palpitation rarely	1
		Palpitation sometimes.	2
		Palpitation on exertion	3
		Palpitation at rest	4

Table 2: Effect on symptoms of 30 patients of Trial group - Subjective Parameters (Intra-Group Comparison) by Wilcoxon-Matched-Pairs Signed-Ranks Test.

SN	Symptom		Mean ± SD	SEd	Sum of all signed ranks (W)	No. of pairs (n)	P value
1.	*Shiroruk*	BT	1.87 ± 0.63	0.11	378.00	27	< 0.0001
		AT	0.80 ± 0.61	0.11			
		Diff.	0.07 ± 0.52	0.10			
2.	*Bhrama*	BT	1.47 ± 0.73	0.13	300.00	24	< 0.0001
		AT	0.50 ± 0.57	0.10			
		Diff.	0.97 ± 0.61	0.11			
3.	*Klama*	BT	1.30 ± 0.65	0.12	325.00	25	< 0.0001
		AT	0.23 ± 0.50	0.09			
		Diff.	1.07 ± 0.64	0.12			
4.	*Nidra Vikruti*	BT	1.87 ± 0.82	0.15	253.00	22	0.0001
		AT	0.30 ± 0.53	0.10			
		Diff.	1.57 ± 0.53	0.13			
5.	*Hrud-Dravatva*	BT	1.03 ± 0.72	0.13	**78.00**	**12**	0.0005
		AT	0.57 ± 0.50	0.09			
		Diff.	0.47 ± 0.63	0.11			

Table 3: Effect on symptoms of 30 patients Of Control group by Wilcoxon-Matched-Pairs Signed-Ranks Test.

SN	Symptom		Mean ± SD	SEd	Sum of all signed ranks (W)	No. of pairs (n)	P value
1.	*Shiroruk*	BT	1.77 ± 0.68	0.12	325.00	25	< 0.0001
		AT	0.90 ± 0.61	0.11			
		Diff.	0.87 ± 0.43	0.08			
2.	*Bhrama*	BT	1.83 ± 0.70	0.13	300.00	24	< 0.0001

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		AT	0.83 ± 0.59	0.10			
		Diff.	1.00 ± 0.64	0.12			
3.	*Klama*	BT	1.87 ± 0.86	0.16	276.00	23	< 0.0001
		AT	1.00 ± 0.69	0.13			
		Diff.	0.87 ± 0.57	0.10			
4.	*Nidra Vikruti*	BT	1.77 ± 0.77	0.14	253.00	22	< 0.0001
		AT	1.03 ± 0.72	0.13			
		Diff.	0.73 ± 0.45	0.08			
5.	*Hrud-Dravatva*	BT	1.20 ± 0.81	0.15	300.00	24	< 0.0001
		AT	0.40 ± 0.56	0.10			
		Diff.	0.80 ± 0.55	0.10			

Table 4: Showing comparison between two groups before treatment with respect to symptoms score by Mann-Whitney Test.

SN	Symptom	Group	Mean ± SD	Confidence Interval		P value
				Lower 95%	Upper 95%	
1.	*Shiroruk*	Trial	1.87 ± 0.63	1.63	2.10	0.6793, Not Significa
		Control	1.77 ± 0.68	1.51	2.02	nt
2.	*Bhrama*	Trial	1.47 ± 0.73	1.19	1.74	0.0833, Not quite significant
		Control	1.83 ± 0.70	1.57	2.09	
3.	*Klama*	Trial	1.30 ± 0.65	1.06	1.54	0.0148, Significant
		Control	1.87 ± 0.86	1.55	2.19	
4.	*Nidra Vikruti*	Trial	1.87 ± 0.82	1.56	2.17	0.4880, Not Significant
		Control	1.77 ± 0.77	1.48	2.06	
5.	*Hrud-Dravatva*	Trial	1.03 ± 0.72	0.76	1.03	0.5841, Not Significant
		Control	1.20 ± 0.81	0.90	1.50	

This test was performed to show homogeneity of the data between two groups. The test was applied to symptom score. The value of P>0.05 (except *Klama*) which was statistically insignificant. Hence, gradations of symptoms in both groups were at same level which means that data was homogenous in nature.

Table 5: Showing comparison between two groups After treatment with respect to symptoms score by Mann-Whitney Test.

SN	Symptom	Group	Mean ± SD	Confidence Interval		P value
				Lower 95%	Upper 95%	
1.	*Shiroruk*	Trial	0.80 ± 0.61	0.57	1.03	0.5774, Not Significant
		Control	0.90 ±	0.67	1.13	

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			0.61			
2.	*Bhrama*	Trial	0.50 ± 0.57	0.29	0.71	0.0520, Not quite significant
		Control	0.83 ± 0.59	0.61	1.05	
3.	*Klama*	Trial	0.23 ± 0.50	0.045	0.42	< 0.0001, Extremely significant
		Control	1.00 ± 0.69	0.74	1.26	
4.	*Nidra Vikruti*	Trial	0.30 ± 0.53	0.10	0.50	0.0003, Extremely Significant
		Control	1.03 ± 0.72	0.77	1.30	
5.	*Hrud-Dravatva*	Trial	0.57 ± 0.50	0.38	0.75	0.2232, Not Significant
		Control	0.40 ± 0.56	0.19	0.61	

There was no significant difference found between Trial and Control group in all symptoms. The P value is >0.05 (except *Klama* and *Nidra Vikruti*), which means the drug in Trial group was equally effective as in control group with respect to above symptoms. In case of '*Klama* and *Nidra Vikruti',* the trial drug showed more improvement as compared to controlled drug with P value less than 0.05.

Table 6: Showing effect on objective Parameters of 60 patients of Essential hypertension by paired 't' test.

Trial Group – Objective Parameters (Intra – Group Comparison): (Paired t test)

SN	Symptom		Mean ± SD	SEd	t value	P value
1.	SBP	BT	149.33 ± 8.14	1.49	9.997	< 0.0001
		AT	143.2 ± 7.89	1.44		
		Diff.	6.13 ± 3.30	0.61		
2.	DBP	BT	89.73 ± 3.14	0.57	11.164	< 0.0001
		AT	85.20 ± 3.04	0.56		
		Diff.	4.53 ± 2.22	0.41		

Control Group – Objective Parameters (Intra – Group Comparison): (Paired t test)

SN	Symptom		Mean ± SD	SEd	t value	P value
1.	SBP	BT	152.27 ± 10.75	1.96	15.168	< 0.0001
		AT	140.07 ± 10.11	1.84		
		Diff.	12.20 ± 4.41	0.80		
2.	DBP	BT	89.20 ± 3.35	0.61	19.568	< 0.0001
		AT	80.53 ± 3.52	0.64		
		Diff.	8.67 ± 2.43	0.44		

Showing effect on Objective Parameters of 60 patients of Essential hypertension by paired 't' test.

- Systolic blood pressure values were decreased in Trial group by 6.13 ± 3.30. Paired t was 15.168. P < 0.0001, which was statistically extremely significant.
- In case of Control group, systolic blood pressure was decreased by 12.20 ± 4.41. Paired t was 15.168. P< 0.0001, which was statistically extremely significant.
- Diastolic blood pressure values were decreased in Trial group by 4.53 ± 2.22. Paired t was 11.164. P < 0.0001, which was statistically extremely significant.
- In case of Control group, diastolic blood pressure was decreased by 8.67 ± 2.43. Paired t was

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19.568. P< 0.0001, which was statistically extremely significant.

Table 7: Showing comparison between two groups by Unpaired 't' Test on objective parameters.

Inter – Group Comparison – Objective Parameters – BT Values: (Unpaired t test)

SN	Symptom	Group	Mean ± SD	Confidence Interval		t Value	P Value
				Lower 95%	Upper 95%		
1.	SBP	Trial	149.33 ± 8.14	146.29	152.37	1.192	0.2383, Not Significant
		Control	152.27 ± 10.75	148.25	156.28		
2.	DBP	Trial	89.73 ± 3.14	88.56	90.91	0.6366	0.5269, Not Significant
		Control	89.20 ± 3.35	87.95	90.45		

Inter – Group Comparison – Objective Parameters – AT Values: (Unpaired t test)

SN	Symptom	Group	Mean ± SD	Confidence Interval		t value	P value
				Lower 95%	Upper 95%		
1.	SBP	Trial	143.20± 7.89	140.25	146.15	1.338	0.1860, Not Significant
		Control	140.07 ± 10.11	136.29	143.84		
2.	DBP	Trial	85.20 ± 3.04	84.06	86.34	5.492	< 0.0001, Extremely Significant
		Control	80.53 ± 3.52	79.22	81.85		

Statistical Analysis of the effect of therapy on Objective parameters of 60 patients of Essential hypertension by Unpaired 't' test:

Before treatment

- Systolic blood pressure Mean of difference in Trial group was 149.33 ± 8.14, which was compared with that of mean of difference in Control group. It was 152.27 ± 10.75. Unpaired t was 1.192; P > 0.05 not significant, which suggests that difference of mean exhibited by Control group was insignificant.
- Diastolic blood pressure Mean of difference in Trial group was 89.73 ± 3.14, which was compared with that of mean of difference in Control group. It was 89.20 ± 3.35. Unpaired t was 0.6366; P > 0.05, which suggests that difference of mean exhibited by Control group was insignificant.

After treatment

- Systolic blood pressure Mean of difference in Trial group was 143.20 ± 7.89, which was compared with that of mean of difference in Control group. It was 140.07 ± 10.11. Unpaired t was1.338; P > 0.05, which suggests that difference of mean exhibited by Control group was insignificant.
- Diastolic blood pressure Mean of difference in Trial group 85.20 ± 3.04, which was compared with that of mean of difference in Control group. It was 80.53 ± 3.52. Unpaired t was 5.492; P <0.05, which suggests that difference of mean exhibited by Trial group was significant difference.

Table 8: Showing effect on symptoms score of 60 Patients of essential hypertensions

SN	Subjective Parameter	Trial Group				Control Group			
		Total Score - BT	Total Score - AT	Diff.	% Relief	Total Score - BT	Total Score - AT	Diff.	% Relief
1.	*Shiroruk*	56	24	32	57.14%	53	27	26	49.06%
2.	*Bhrama*	44	15	29	65.91%	55	25	30	54.55%
3.	*Klama*	39	07	32	82.05%	56	30	26	46.43%

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4.	*Nidra Vikruti*	56	09	47	83.93%	53	31	22	41.51%
5.	*Hrud-dravatva*	31	17	14	45.16%	36	12	24	66.67%
	Average score	45.2	14.4	30.8	66.84%	50.56	25	25.6	51.75%

Effect of therapy on symptom score: It was observed that overall percentage of relief was more in Trial group (66.84%) than in Control group (51.75%). The symptoms such as Shiroruk, Bhrama, Klama, Nidra-Vikruti, and Hrud-dravatva were studied in this trial as described here before in table. Percentage of relief for all the symptoms is more in Trial group (except *Hrud-dravatva*).

Effect of therapy on blood pressure: It was observed that overall percentage of relief was more in control group (8.864%) than in trial group (4.573%). Telmisartan is more accurate on management of hypertension from initial dose.

DISCUSSION

Diet and lifestyle are major factors to influence susceptibility to many diseases. Man has adapted himself to the fast-paced life by modifying dietary and lifestyle preferences to suit this modern era. This has resulted in a state of discrepancy between the external environment and internal mechanism causing many diseases which are popularly referred as 'lifestyle-diseases' and "essential hypertension" is one of them.

There is no precise terminology for Essential hypertension mentioned in the Ayurveda Classics. Causative factors of *Vyana Vayu, Rasa-Rakta Dhatu, Hrudaya Roga* and Essential hypertension are having direct relation with *Vata Dosha,* hence being close resemblance in terms of *Nidanas* the disease Essential hypertension can be correlated with *Vataja Hrudroga.*

Essential hypertension requires long term treatment and no drug in modern science is able to treat the basic pathology of the disease completely and prevent progression without complications. Hence, the world is looking towards Ayurveda the ray of hope. The present scenario regarding essential hypertension has encouraged me to work on this disease with the help of a Polyherbal Combination *Karsha Vati*.

Discussion on mode of action of *Karsha Vati*

In the pathogenesis of Essential Hypertension main factors are *Vata Vrddhi, Rasa - Rakta Dhatwagnimandya* and vitiated *Kapha* with *Pitta*. So here '*Karsha Vati*" had been selected to breakdown its Samprapti. The '*Karsha Vati*', due to its *Laghu Guna* and *Ushna Virya* may conquer the *Dhatwagnimandya* and do strengthening of *Hrudaya*.

Discussion on Total Effect of Therapy

Comparison of Ordinal Data between two groups was statistically evaluated by "Mann-Whitney test". The value of Mann Whitney 'U' Static is 311.5 and P-value is more than 0.05 (except *Klama* and *Nidra Vikruti*), which was statistically insignificant suggestive of no significant difference between two groups with respect to effect of therapy on Subjective Criteria. In case of '*Klama* and *Nidra Vikruti'*, the trial drug showed more improvement as compared to controlled drug with P value less than 0.05.

Comparison of Numerical Data between two groups was statistically evaluated by "Unpaired-t test". The value of 't' is 1.338 and P-value is more than 0.05, which was statistically insignificant suggestive of no significant difference between two groups with respect to effect of therapy on Objective Criteria.

CONCLUSION

In this trial patients had shown better results in both the groups i.e. Trial group (*Karsha Vati*) and Control group (Telmisartan). There is a significant reduction in diastolic blood pressure in trail group, while not so significant difference in systolic blood pressure levels in both the groups is noted. It was observed that overall percentage of relief in symptoms is more in Trial (66.84%) than in Control group (51.75%). It was observed that overall percentage of relief in managing raised blood pressure was more in control group (8.864%) than in trial group (4.573%). Telmisartan is more accurate on management of hypertension from

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initial dose. Hence it can be stated that, *Karsha Vati* has less effect than telmisartan in management of essential hypertension.

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