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Effect of *Ayurvedic* Formulation [TF-1] and *Nityavirechana* in the Management of Essential Hypertension

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ABSTRACT

The aim of present study was to evaluate role of Ayurvedic formulation (TF-1) and *Nityavirechana* as *Haritaki churna* in management of essential hypertension. It was randomized, open label interventional study carried out at Arogyashala OPD and IPD, National Institute of Ayurveda, Jaipur.Ten patients in the age group of 18 to 60 years with stage -1 Essential Hypertension without any comorbid illness were included in study. Patients were treated with Ayurvedic Formulation TF-1 tablet(content- *Arjun*, *Ashwagandha*, *Shankhapushpi*, *Jatamansi* and *Punarnava* extract) 2tab (each tab- 500mg) two times in a day and *NityaVirechana* as *Haritakichurna* 5gm at bed time for 28 days. Blood pressure was monitored on subsequent follow up visit at the end of 1st, 2nd, 3rd and 4th week. Change in subjective parameters and objective parameters like SBP, DBP, % relief were analyzed statistically by **Wilcoxon matched paired signed ranks test** and **Anova test** respectively. On end of first week %relief in SBP and DBP were 3.48 and 9.12 respectively.After 4th week of treatment there was statistically significant fall in SBP 20.97% and 23.32% relief in DBP. Ayurvedic formulation TF-1 offers an efficacious and safe combination available for treatment of essential hypertension.

KEYWORDS

Essential Hypertension, NityaVirechana, Haritaki, TF-1

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INTRODUCTION

The fundamental treatment method of EHT include *Nidanaparivarjana, Samshodhana* and *Samsamana* mentioned in *Ayurveda* classics, if administered judiciously, the desired results can be achieved.

Chikitsa of any disease mainly of two types viz.

- *Vyadhi Pratyanika*
- *Dosha Pratyanika*

But as Hypertension is a gift of modern era. Its explanation in *Ayurveda* classics is not available so *Vyadhi Pratyanika Chikitsa* is not found directly. The drug is selected *Ayurvedic* Formulation TF-1, for clinical research on which toxicity study and experimental trial had been carried out with highly significant result. so considering it as a *Vyadhi Pratyanika*. As explained Essential hypertension is *Tridoshaja Vyadhi* having *Vata Pittapradhanyaja* and *Raktadushti*, *Pitta* is also main *dosha* as *Rakta* and *Pitta* have *Aashraya-ashrayisambandha*. *Nitya Virechana Yog-Haritaki Churna* and Ayurvedic Formulation TF-1 were use for *Samprapti Vighatana* of *Vyadhi* and it may consider as *Doshapratyanikachikitsa.*

Aims & objectives

Current research work has been started with following main objectives

To study effect of *Ayurvedic* formulation TF-1 and *Nitya Virechana*.

MATERIALS AND METHODS

Ethical Approval IEC letter reference No. IEC/ACA/2015/45

Study design Randomized and Open Label clinical trial.

Study population

Ten consenting newly diagnosed patients of EHT and symptoms described in *Ayurveda* classical text were selected randomly.

Table 1 7th JNC criteria for Diagnosis Hypertension[1]

CATEGORY OF HT	SYSTOLIC BP (MMHG)	DIASTOLIC BP(MMHG)
Normal	</=120	</=80
Pre hypertensive	120-139	80-89
Hypertension	>/=140	>/=90
Stage 1	140-159	90-99
Stage 2	>/=160	>/=100

Study setting- *Arogyashala* Outdoor Patient Dept. & Indoor Patient Dept., National Institute of *Ayurveda*, Jaipur

Inclusion Criteria

1] Patients willing to sign the consent form for the clinical trial.

2] Patients belonging to either sex between the age group 18 to 60 years.

3] Newly diagnosed case of stage- 1 E.H.T. are selected for study.

As per 7th JNC & WHO criteria).

4] Patients having no known complications of disease.

5] Duration of disease 1-3month.

Exclusive Criteria

1] Patients below age of 18 years and above 60 years.

2] Patients having secondary hypertension.

3] Patents having systemic/serious complications of Cardiovascular/ Cerebrovascular / Renal system.

4] Pregnancy induced hypertension.

5] Drugs like Oral Contraceptive Pills, steroids.

6] History of liver disease in the recent past.

7] Hypertensive Retinopathy.

8] If duration of the disease is more than 3 months.

Criteria for withdrawal:

1] Discontinuation of the treatment during trial.

2] Development of any serious complication due to disease or drug which require urgent treatment.

Group

Ten newly diagnosed patients of EHT were administered with *Haritakichurna* (as *Nitya Virechana*) 5grams /day at bedtime with lukewarm water and concentrated aqueous extract of trial drug (TF-1) *2* tabs (1tab- 500 mg)twice a day with lukewarm water for 4 wks

Selection of drug

New formulation containing *Shankhapushpi* (*ConvolvulaspluricaulisChois.), Arjuna (TerminaliaarjunaRoxb.), Ashwagandha (Withaniasomnifera Linn.), Punarnava (Boerhaviadiffusa Linn.), Jatamansi (Nordostachysjatamansi DC.)* had been formulated to assess its efficacy. All these ingredients are mentioned in *Ayurveda* literature as an individual herb and also as ingredients of various formulations. Each of these herbs has been reported to be safe by toxicity study[1].

Table 2 Contents of Ayurvedic Formulation TF-1:- **(**Concentrated aqueous extract) *Ghanvati*.- Ashwagandha, Arjuna, Jatamansi, Shankhapushpi, Punarnava.

NAME OF DRUG	LATIN NAME	PART USED	AMOUNT (MATRA)
1.Arjuna	Terminaliaarjuna*Roxb.*	*Tvaka*	1part
2.Ashwagandha	*Withaniasomnifera Linn)*	*Moola*	1part
3.Jatamansi	*Nordostachysjatamansi DC.*	*Moola*	1part
4.Shankhapushpi	*ConvolvuluspluricaulisChois.*	*Panchanga*	1part
5.Punarnava	*Boerhaviadiffusa Linn.*	*Panchanga*	1part

Dose of TF-1- 2 tab. (each 500 mg.) two times in a day with lukewarm water for 28 days.

2) ***Haritakichurna***

Latin name- *Terminaliachebula Retz.*

Part used- Fruit

Duration of clinical trial was 4 weeks.

All patients were followed up- once in a week regularly for 28days. During these visit, improvement or deterioration or no

change in the signs and symptoms were recorded.

Table 3 Duration of clinical trial and follow up study

DAY OF FOLLOW UP	FOR ALL GROUPS
Day 0	Protocol explanation and informed consent Clinical assessment and Lab. Investigations.
Day 1	Starting of trial drug to Screened patients (base line).
Day 7	Clinical and Self assessment of patient.
Day 14	Clinical and Self assessment of patient.
Day 21	Clinical and Self assessment of patient.
Day 28	Clinical and Self assessment of patient with lab investigations.

Criteria for Assessment

A) Subjective Criteria

i] ***Shirshool***

ii] ***Bhrama***

iii] ***Klama***

iv] ***Hritspandana***

v] ***Anidra***

vi] ***Krodha***

B) Objective parameters

1] Assessment of change in Blood Pressure in supine position.

2] Hematological Test: Hb%, TLC, DLC, ESR.

3] Biochemical Investigation:

Renal Function Test (Blood urea, Sr. Creatinine).

Blood sugar (Fasting).

Lipid profile (Sr. Triglyceride, Sr. Cholesterol)

Liver function test.

4] Urine analysis for RBCs, WBCs, sugar and protein.

5] ECG (to exclude patient for LVH, prolonged QRS complex, T wave Elevation indicative of MI)

6] Chest X ray (to exclude the patient for Cardiomegaly).

OBSERVATIONS

Maximum patients 60 %were in age group 31to 50years, 60% were male, 70% married, 80 % were belonging to middle class society.

RESULTS

Intra Group comparison- For Nonparametric Data Wilcoxon matched-pairs signed ranks test was used while for Parametric Data Paired 't' Test, Anova test (Tukey-Kramer Multiple Comparision Test) were used and results calculated.

Table 4 Effect of drug on SBP and DBP

Variable	Follow up	Mean BT	AT	Mean diff.	% relief	SD ±	SE±		P	S
SBP	7th day	152.1	146.8	5.3	3.48	11.603	3.669	1.956	>0.05	NS
	14th day	152.1	144.78	7.32	4.81	6.924	2.308	2.63	>0.05	NS
	21st day	152.1	138.7	13.4	8.8	8.433	2.667	4.944	<0.05	S
	28th Day	152.1	120.2	31.9	20.97	8.025	2.538	11.771	<0.001	HS

DBP	7th Day	98.6	89.6	9	9.12	7.933	2.509	4.07	<0.05	S
	14th Day	98.6	90.2	8.4	8.51	9.727	3.076	3.798	>0.05	NS
	21st Day	98.6	84	14.6	14.8	7.542	2.385	6.602	<0.001	HS
	28th Day	98.6	75.6	23	23.32	4.971	1.572	10.4	<0.001	HS

There was 3.48 % decrease in Systolic Blood Pressure at the end of 7thday with significant result and at 14th day of trial there was 4.81% decrease in SBP with non significant results. 8.8% decreased in SBP at 21st day of trial which showed statistically highly significant result. At 28thday i.e. last day of trial SBP decreased by 20.97% which showed statistically highly significant results. There was 9.12%, decrease in DBP with significant results at of 7th, day and at 14th day of trial DBP lowered by 8.51 % with statistically significant results. There was 14.8 % decrease in DBP at end of 21st day which was statistically highly significant. At last day i.e. 28thday of trial showed highly significant results with 23.32% decrease in DBP.

Intra group comparisons-

Table 5 Eeffect of Therapy on Subjective Parameters. (Wilcoxon matched paired signed ranks test)

VARIABLE	MEAN		MEAN DIFF.	% RELIEF	SD±	SE±	P	S
	BT	**AT**						
SHIRSHOOL	2.6	0.3	2.3	88.46	0.9487	0.3	<0.0001	HS
KLAMA	2.2	0.4	1.8	81.81	0.6325	0.2	<0.0001	HS
HRIDSPAND-AN	1.7	0.2	1.5	88.23	0.972	0.31	<0.0001	HS
BHRAMA	1.6	0.1	1.5	93.76	1.08	0.342	<0.0001	HS
ANIDRA	1	0.1	0.9	90	0.876	0.277	<0.05	NS
KRODHA	1.3	0.2	1.1	84.61	1.101	0.348	<0.05	S

Ten patient had completed treatment with highly significant result insymptoms- *Shirshool(*88.46%) , *Klama*(81.81%), *Hritspandan*(88.23%)&*Bhrama*(93.76)wh ereas significant result in symptom *Krodha*(84.61%) and non significant result in *Anidra*

Intra group comparisons-

Table 6 Effect of Therapy in Objective Parameters.

VARIABLE	MEAN		MEAN DIFF.	% RELIEF	SD±	SE±	T	P	S
	BT	**AT**							
Hb %	13.8	14.25	-4	-28.98	0.397	0.125	2.23	>0.05	S
TLC	7080	7060	20	0.28	1268.2	401.05	0.0498	>0.05	NS
ESR	12.8	11.2	1.6	12.5	7.905	2.5	0.6401	>0.05	NS
SGOT	38.6	37.4	1.2	3.10	15.40	4.87	0.246	>0.05	NS
SGPT	27.3	26.9	0.4	1.47	5.835	1.845	0.2168	>0.05	NS
Sr. Urea	27.9	24.3	1.6	5.73	4.881	1.543	2.332	<0.05	S
Sr.Crea	1.07	0.956	0.09	8.41	0.137	0.043	2.077	>0.05	NS

Sr. Chol.	177.5	159.7	17.8	10.02	22.64	7.16	2.486	<0.05	S
Sr.Tri.	133.3	126.1	7.2	5.40	23.46	27.93	2.051	>0.05	NS

In case of objective parameters, Haemoglobin increased by 28.98% showed significant result. Sr.Urea decreased by 5.73% and Sr Creatinine decreased by 8.41%. Sr.Cholesterol decreased by10.02% showed significant result, Sr.triglycerides decreased by 7.2%.

DISCUSSION

Mode of Action of Drug

TRIAL DRUG

1) *TF -1**Ghana vati(Concentrated aqueous extract)***

The drug was administered in the *GhanaVati* form containing mixture of the concentrated aqueous extract of its constituents. Since ancient times, *Ayurveda* drugs were most commonly prescribed in the form of *churna* due to its easy method of preparation. But due to its bitter taste and bad smell patients were not willing to take medicines in the form of c*hurna*. Also the quantity of drug administered in the form of *churna* may not be the same every time. To overcome these adversities drug in the present clinical study was given in the *Vati* form which possesses qualities like fixed dosage, easy palatability and patient tolerance.

In *Ayurveda,* the action of drugs is determined on pharmacodynamic factors as *Rasa, Guna, Veerya* and *Vipaka* along with certain specific properties called *Prabhava (Karma),* which cannot be explained on these principles inherited by the drug. Thus drug enabled to break *Samprapti* (pathogenesis) of underlying disease by these properties.

It has been observed that most of ingredients of Trial Drug TF-1(*Vati*) possess *Tikta, Kashaya, Rasa. Tikta rasa* having *deepana, pachanalekhana, Kleda Upashoshana properties* that helps to remove obstruction of *Ama* in *Strotas*by *Agni Vardhana, Amapachana. Strotoshodhana* and *Vatanulomana* help to maintain normal flow of *Rakta* and *Vata dosh as* with its normal direction and pressure through microchannels. *Kashaya Rasa* have *Shleshma, Rakta Pittaprashamana* property.[2]

Trial drug ingredient possessing *Laghu, Ruksha guna. Laghu, Ruksha guna* which act as *Kaphahara,* helps to clear *strotorodha* and dries *Amadosha* which obstruct the *strotas* also activates *Jatharagni*, *Dhatwagni* & maintain their normal physiological status. Some of the ingredients of trial drug have *Ushnavirya which* removes *Strotorodha* of *Kaphavaha, Rasavaha, Raktavaha and Medovahastrot as.* Some of the

drugs have *Sheetaviryata* that helped to alleviate *Pitta* and *Rakta.* In this way it is *Tridoshashamaka.*

Majority of these drugs have *Madhurvipaka* which is *Vata-Pitta shamak*and *According to Acharya CarakMadhuravipaka* diuretic in nature. It might have helped in*Sampraptivighatana*as-*Vataghna, Vatanulomaka, Brihana.* EHT is *Vata-Pitta pradhanaja Tridoshajavyadhi. Madhura*may have *Apyayana* effect on *dhatu, strotas, Oja, Hridaya.* It has nourishing effect on *Mana* and also helps in maintaining *prakritagati* of *Vata dosha* that leads to *Vatanulomana.*

Arjuna

*Kashaya rasa, Sheeta Viryawhich act as Pittashamaka. Ruksha, Laghuguna Katu Vipaka help to alleviate Kapha.*Due to its *Hridaya-Pushtikara Prabhava,* it is used in the management of several cardiac disorders. It have Hypotensive[3], hypolipidemic[4], Antioxidant[5] property.

Ashwagandha

It is effective *Vata-Kaphashamaka* drug, due to *deepana*and *anulomana* property it clears *strotorodha*and improve *Agni.* Its having *Balya,Rasayana, Shothanashaka, Medhyarasayana Nidrajanan* and *Vatanulomaka* properties which are supportive for treatment of EHT. Prolonged hypotensive, bradycardiac, and respiratory-stimulant and antistressaction of Alkaloid of Ashwagandha had been reported[6]. The hypotensive effect was mainly due to autonomic ganglion blocking action and that a depressant action on the higher cerebral centers also contributed to the hypotension[7]

Jatamansi

Having property of*Tridoshshamaka due to Tikta, Kashaya, Madhura Rasa pacifies Pitta dosha, whereas Katuvipaka and Laghuguna*pacifies *Vata*and *Kapha dosha.*by removing *Strotorodha. Madhura rasa* has *Shada-Indriya Prasadana therefore works as Manaprasadana karma.* Due to its *Manasadosha harapra bhava*it is *Medhya, Hridya-Balya, Akshepashamak* which helps in pacifying *dushti* of *Manovaha Strotas.* Jatamansi also having *Raktadoshhara, Hridayabalya, Medhya, Nidrajanan* property. *Hypotensive[8], Antidepressive, antioxidant[9]action of Jatamansihas been reported.*

Shankhapushpi

Due to*Tikta, Kashaya Rasa, Snigdha, Picchilaguna, Madhuravipaka*and *Sheetavirya Shankhapushpi*acts as *Vata-Pitta shamaka.* It is effective *Medhya Rasayan*drug. Due to its *Manasadoshahrut* property it alleviates *Manasa dosha*. It has *Agnivardhaka* property due to which it alleviate *Ama*by removing *Strotorodha.* thus helps in *Sampraptivighatana.*

Shankhapushpi having Antistress, Antidepressive[10], Cardio protective action[11].

Punarnava

Rakta Punarnava have *Shleshma-Pitta-Rakta Vinashini* property. It also possesses *Anulomana, Mutrala, Lekhana, Sothahara*, and *Hridya* properties. By *Mutrala* and *Sothahara* property, it reduces blood pressure leading to decreased load of heart. *Punarnava* may reduce the blood volume resulting into decreased blood pressure due to their *Mutral* property. *Kleda* formed in the body through several metabolic activities is also expelled out through M*utral* property, thereby removing toxins in the body. Hypotensive[12], cardiac stimulant[13], Anti stress[14], Ca channel blocker[15], hepatoprotective[16] properties have been reported.

Haritaki

The drug which digests the *Amadosha* of *Malas* & breaks their consolidation and after removing *Stroto Vibandha,* expels them out through *Adhobhaga* is known as *Anulomana,* like *Haritaki*. (*Sharangadhar).* It has *Deepana, Agnivardhana, Anulomana, Tridoshshamaka, Rasayana,* rejuvenating- *Bala, Buddhi* and *Indriya* property. Cardio tonic[17], Anti oxidant[18], Hypotensive actions of *Haritaki* has been reported.

Clinically and statistically significant fall in BP was seen at 4 weeks. Normotensive effect of the drug in terms of SBP and DBP was observed in all the patients. Results were better in Stage I, reflecting its high efficacy in regulating BP. Age or gender did not significantly affect the responsiveness to study drug.

Emphasis has been given on diet and life style modifications by motivating each patient personally at each visit, without ignoring the important aspect of psychotherapy to de-stress the patient. Alone general measures have not so far been able to treat hypertension. For further evidence future comparative studies will be done.

Major drawback of this study is that no controls have been taken to compare its efficacy. Further studies will be followed to assess the comparative efficacy with already existing antihypertensive medication

CONCLUSION

Trial drug TF-1(Tab) and *Haritakichurna* as *Nityavirechana* along with life style modification and psychotherapy is a safe and efficacious remedy for the treatment of Stage-1 essential hypertension in all age groups with no limitation to its use. No

adverse effects of the study drugs were observed during the study

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