

A RANDOMIZED CLINICAL STUDY ON THE EFFECT OF TRIPHALADI VIRECHANA KARMA WITH ARJUNA PUNARNAVADI GHANAVATI IN THE MANAGEMENT OF ESSENTIAL HYPERTENSION

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ABSTRACT

Hypertension one of the grave condition accounts 6% of death of world-wide. Increased blood pressure is the cause of 50% of heart disease, stroke and heart failure. Long term use of antihypertensive drugs is associated with adverse effect. According to Ayurveda hypertension is *Tridoshaja Vata-Pitta Pradhana* disorder with *Dusthi* of *Rasa, Rakta, Meda*. Ayurveda radical treatment like *Panchakarma*, corrects the basic pathology by eliminating the chief causative factors. *Virechana Karma* is best for the elimination of vitiated *Pitta Dosha* and it regulate movement of *VataDosha*. Thus present study has been conducted on 15 patient to evaluate Effect of *Triphaladi Virechana karma* followed by oral administration of *ArjunaPunarnavadiGhanavati* in the management of Essential Hypertension. The blood pressure was recorded after *Deepan-Pachana*, after *Snehapan*, on the day of *Virechana Karma*, after *Virechana Karma*, after administration of *ArjunaPunarnavadiGhanavati* for 30 days and one month follow up, The result have been analysed statistically, *Virechana karma* with *ArjunaPunarnavadiGhanavati* was highly effective in reducing both systolic and diastolic blood pressure level which was statistically extremely significant ($P < 0.001$)

Keywords: *Virechana karma, Triphala Taila, ArjunaPunarnavadiGhanavati.*

INTRODUCTION

It has been estimated that hypertension accounts 6% of death of worldwide^[1]. About 800 million people in the world are suffering from hypertension; more than 95% cases of hypertension are of essential hypertension. The most devastating aspect of this disorder is that it is not characterized by any of the cardinal symptoms and causes damage to vital organ over a period time. Persistent hypertension doubles the risk of cardiovascular disease, including coronary heart disease (CHD), congestive heart failure (CHF), ischemic and haemorrhagic stroke, renal failure and peripheral arterial disease^[2]. **National Health and**

Nutrition Examination Survey (NHANES) reported that, about 16 million take medicine, but still don't have their blood pressure under control. Increased blood pressure was the cause of an estimated 9.4 million deaths and 162 million years of life lost in 2010 and the cause of 50% of heart disease. stroke and heart failure, 13% of deaths overall. Although anti-hypertensive therapy clearly reduces the risk of cardiovascular and renal disease, large segment of the hypertensive population are either untreated or inadequately treated. Long term use of antihypertensive

drugs associated with adverse effect like, insomnia, slow heart rate, kidney failure^[3]. According to *Ayurveda* hypertension is *Tridoshaja Vata-Pitta Pradhana* disorder with *Dusthi* of *Rasa, Rakta, Meda*. *Ayurveda* through its holistic approach and radical treatment like *Panchakarma*, corrects the basic pathology by eliminating the chief causative factors. Among the *Panchakarma* treatments *Virechana Karma* is best for the elimination of excessively vitiated *Pitta Dosha* and to correct *Agni*. It regulates movement of *Vata Dosha*, which are the basic factors involved in the etiopathogenesis of hypertension. *Virechana Karma* followed by oral administration of herbs which are basically *Rasayana, Medhya, Mutrala, Deepana* and *Hridya* in nature.

AIMS & OBJECTIVES

To evaluate the effect of *Triphaladi-Virechana karma with Arjuna Punarnavadi Ghanavati* in the management of Essential Hypertension

MATERIALS AND METHODS:

Clinical study materials: 15 patients

Source of data:

15 patients were selected randomly from OPD & IPD of Panchakarma, National Institute of Ayurveda, Jaipur which were diagnosed of essential hypertension as per 7th JNC & WHO criteria for Diagnosis of Hypertension. The present study has been done with Registration no.

RAU/ACa/622/12-13,

Dr. Sarvapalli Radhakrishnan Rajasthan Ayurveda University Jodhapur.

Inclusion criteria:

1. Patients of both sex between the age group 20 to 60 yrs.
2. Patients who already diagnosed as essential hypertension were selected.
3. Mild and moderate grade patients of hypertension as per 7th JNC & WHO criteria were included.
4. Patients fit for clinical trial.

Exclusion Criteria

1. Secondary hypertension.
2. Pregnancy induced hypertension
3. Patient on Oral Contraceptive Pills, steroids.
4. Patient associated with serious illness like malignancy, HIV and Tuberculosis.

CRITERIA FOR ASSESSMENT

a) Subjective parameters:

- 1] *Shirshool* (Headache)
- 2] *Bhrama* (Giddiness)
- 3] *Klama* (Fatigue)
- 4] *Hrutdravata* (Palpitation)
- 5] *Swedhadhikyata* (Excessive sweating)
- 6] *Anidra* (Insomnia)

Assessment of above subjective parameters was done according to grading pattern.

b) Objective parameters: Assessment of change in both systolic and diastolic blood pressure level in supine position.

Table No. 1: 7th JNC & WHO criteria for Diagnosis Hypertension

Category of HTN	Systolic BP (mmHg)	Diastolic BP (mmHg)
Normal	<120	and <80
Pre hypertension	120-139	or 80-89
Stage 1 hypertension	140-159	or 90-99
Stage 2 hypertension	160	or 100
Isolated systolic hypertension	140	and <90

(Harrison's Principles of Internal Medicine, 17th Edition, Page No.1553)

Scoring pattern for the subjective parameters:

Table No.2: Showing the scoring pattern of subjective parameters:

Parameters		Score
1. <i>Shirshoola</i>	Nil	00
	Rarely Headache relieves without medication	01
	Frequently Headache relives by rest doesn't disturb daily activities	02
	Frequently severe Headache disturbs daily activities requires medication.	03
	Continuous / severe Headache disturbs sleep and daily activities and also not managed by the medication.	04
2. <i>Bhrama</i>	Nil.	00
	Rarely Bhrama for some movement during change of posture.	01
	Often for some movement during change of posture.	02
	Often for each movement even in lying condition also.	03
	Patient unable to hold himself without any support.	04
3. <i>Klama</i>	Nil	00
	Rarely feeling of tiredness without any exertion.	01
	Rarely feeling of tiredness without any exertion with inability in concentration.	02
	Frequently feeling of tiredness without any exertion with inability in concentration	03
	Continuous feeling of tiredness without any exertion with inability in concentration	04
4. <i>Svedadhikya</i>	Able to do both routine and special activities without discomfort	00
	Mild sweating by heavy work	01
	Sweating with moderate work relieves soon	02
	Severe sweating with mild work but no disturbance to the routine	03
	Severe sweating with mild work disturbs the routine	04
5. <i>Hrutdravata</i>	No Palpitation.	00
	Palpitation occasionally	01
	Palpitation sometime.	02
	Palpitation frequently.	03
	Palpitation almost common.	04
6. <i>Anidra</i>	Palpitation at rest	05
	Sound Sleep.	00
	Disturbed Sleep wake up 1-2 times a night.	01
	Difficult to onset Sleep remains disturbed in night .	02

	Very less Sleep in small intervals makes patient irritable.	03
	Not getting sleep without medicine.	04

Methodology:

15 patients received *Virechana Karma*.

Virechana Karma.

Classical *Virechana Karma* was administered in the following steps.

Poorvakarma

1. *Deepanaand Paachana:*

Drug: *Panchakola Choorna*

Dose: 3 grams three times a day orally after food.

Duration: 3 to 7 days i.e., till *Nirama-Lakshana* achieved.

Anupaana: SukoshnaJala.

2. *Snehapana*

Drug: *TriphalaTaila*

Dose : In an increasing order started with small dose on first day between 30 to 50 ml depending upon appetite (*Agni Stithi*) , second day onwards the dose of *Taila* was increased according to *Agnideepti* (increased power of digestion).

Time of administration: Between 6.30am to 7 am.

Duration: 3 to 7 days i.e., till *Samyak-SnigdhaLakshana* were obtained.

Anupaana: UshnaJala

Advise: Advised to take hot water for drinking and to avoid exposure to excessive wind, sunlight, emotional exacerbations etc.

Diet: Liquid, warm light diet like rice gruel, green gram soup with little vegetables. Advised to avoid junk food, fast food, fat, spicy, heavy, bakery items, snacks and cold items.

3. *SarvangaAbhyanga and Svedana:*

SarvangaAbhyanga with *DashamoolaTaila* done for 25 to 30 minutes followed by *MriduBashpaSvedana* for 5 to 10 minutes, carried out for 4 days including the day of *Virechana Karma*.

4. Diet during three days gap: Diet including rice gruel, green gram soup, sour fruits like grapes, sweet lemon, orange and pomegranate was advised.

Pradhanakarma

1. Preparation of *Virechana Yoga*

Virechana Yoga contains:

TriphalaKvatha(25gm): 100 ml

TrivriithChoorna: 15 grams

Aragwadhaphalamajja 15gm

ErandaTaila 30ml

Draksha 50gm

2. Administration of *Virechana Yoga*

After *Sarvanga Abhyanga* and *Mridu Svedana* patients were examined for the vitals like pulse, blood pressure then above mentioned *Virechana Yoga* was administered in between 9.30 to 10.00 am with warm water.

Advise: Patients were instructed to take warm water repeatedly, not to sleep in the afternoon, not to sit under fan or near the window, not to come outside in the flowing winds, sunlight, have a rest on the bed and to attend the urge of defecation.

3. Observations of the patient

The observations like the time of initiation of *Virechana Vega* (urge of defecation), total number of *Virechana Vega*, time of completion, nature of *Vega* , *Kshudhapravritti*, examination of vitals , *Lainghiki Lakshana*, *Antiki Lakshana*, *Vyapad* if any were noted.

Pashchatkarma

1. *Samsarjana Krama* was advised for 3, 5 and 7 days depending upon *Avara*, *Madhyama* and *Pravara Shuddhi* respectively.

2. Avoid: Excessive speech, travelling, exercise, sitting and lying in improper posture, exposure to wind, and suppression of natural urges.

3. In general advised to take luke warm water.

Shamana Yoga- ArjunaPunar- navadiGhanavati

ArjunaPunarnavadiGhanavati

After Virechana Karma a new compound ArjunaPunarnavadiGhanavati was prepared by using Arjuna, Punarnava, Guduchi, Gokshur, Shankhapuhspi, Draksha, Haritaki, Pushkarmoola, Shunti. ArjunaPunarnavadiGhanavati 2 tabs twice a day was administered for 30 days in both the group (Each tab of 500mg).Then Follow up of the patients was done weekly up to 1 month.

Follow up: Follow up of the patients was done weekly up to 1 month.

Clinical observations and Result:

Data related to Demographic data

Maximum 33.33% of patients were from the age group of 41-50 years, 53.33% were female, 66.66% married , 93.33% were of Hindu religion,33.33% were house wife, 73.33% were from middle class, 60% were of vegetarian , 53.33% were having Mandagni, 73.33% were having Madhyama Koshtha, 46.66% belonged toPitta Kapha Prakriti, 46.66% each were having Madhyama Satva and MadhyamaSamhanana .Vyayama Shakti was Avara in 46.66%, 40 %were taking Madhura Rasa PradhanaAhara, 46.66% patients were having addiction to tea alone.

Data related to disease:60% Patients were having the positive family history, 53.33% each patients were having chronicity history of in between 4 to 10 year,66.66 % patients were giving history

of day sleep, 23.33% of patient were having history of anxiety and tension , 56.66% of patient were taking antihypertensive drugs regularly, 26.66% of patient were not on antihypertensive therapy.

Data related to treatment: Out of 15 patients, in 53.33%of patients DeepanaPachana was given for 5 days, maximum 46.66% of each patient was administered Snehapana for 4 and 5 days, maximum 53.33% of patients had between 11 to 20 Virechana Vega, Kaphanta Shuddhi was observed in 60 % of the patients.Lainghiki Shuddhi like Shareera Laghuta was observed in 86.66% of patient, IndriyaPrasadana were observed in 80%, Agni Deepti in 73.33% of patient maximum 83.33% followed Samsarjana Krama for 5 days, Virechana Vyapad like vomitingwas observed in 13.33% of patients and 6.66% each complained headache and pain abdomen.

Results: The data obtained in clinical study is subjected to statistical tests and analyzed in two parts:

- 1) Objective Parameter
- 2) Subjective Parameter

Statistical Methods:

- Student paired t test (two tailed, dependent) has been used to find the significance of objective parameters.
- Wilcoxon test was used for the assessment of subjective parameters.

Table no. 3] Effect of Virechana karma in Subjective Parameters

(Wilcoxon match paired signed rank test)

Chief complaint	com-	BT	Mean Diff.	%Relief	S.D.	S.E.	'w'	'p'
		After Vir.						
		After Arj-						

		Pun. Vati						
Hrutdravatva	3.800	2.333	1.467	38.60	0.7432	0.1919	120.	<0.0001
		1.067	2.733	71.92	1.280	0.3305	120.	<0.0001
Bhrama	1.800	0.8000	1.000	55.55	0.3780	0.09759	105.	0.0001
		0.4667	1.333	74.05	0.7237	0.1869	105.00	0.0001
Klama	2.067	1.267	0.8000	38.703	0.4140	0.1069	78.00	0.0005
		0.9333	1.133	54.81	0.3519	0.09085	120.00	<0.0001
Shirashoola	1.400	0.5333	0.8667	61.90	0.3519	0.09085	91.000	0.0002
		0.2667	1.133	80.92	0.6399	0.1652	91.000	0.0002
Anidra	2.133	0.9333	1.200	56.25	0.8619	0.2225	105.00	0.0001
		0.5333	1.600	75.01	0.8281	0.2138	120.00	<0.0001
Swedadhikyata	2.200	1.333	0.8667	39.39	0.5164	0.1333	78.00	0.0005
		0.8667	1.333	60.45	0.7237	0.1869	105.00	0.0001

(Vir.-Virechana, Arj Pun Vati - Arjuna-PunarnavadiGhanavati)
VirechanaKarma with ArjunaPunarnavadiGhanavati was effective on Hrutdravatva, Bhrama, Klama, Anidra,)

Shirahshoola&Swedadhikyata shown statistically significant result

Table no.4: Effect of VirechanaKarma on systolic blood pressure (PAIRED‘t’ TEST

BP	Mean mmhg	BP in	mean diff.	%Relif	S.D.	S.E.	‘t’	‘p’
	BT	After DP						
		After SN						
		On the day of Vir						
		After Vir.						
		After SH						
		F- up						
Systolic Pressure	160.67	147.27	13.400	8.3400	10.377	2.679	5.001	0.0002
		134.00	26.667	16.18	14.960	3.863	6.904	< 0.0001
		141.73	18.933	11.78	16.298	4.208	4.499	0.0005
		132.00	28.667	17.84	17.674	4.563	6.282	< 0.0001
		139.33	21.333	13.27	16.847	4.350	4.904	0.0002
		132	28.667	17.84	17.674	4.563	6.282	< 0.0001

(DP- Deepana, Pachana, SN- Snehapana, Vir.-Virechana, SH- Shamana yoga, F-up- Follow up)
In Virechana group, the initial mean of systolic blood pressure was 160.67. It was

reduced to 147.27 after *deepana pachana* ,134 after *Snehapana* , It was increased to 141 on the day of *Virechanabut* after *Virechana* it was again reduced to 132, then increased to 139 after *shaman* (Ar-

junaPunarnavadiGhanavati)and reduced to 132 after follow up. The relief was 8.3%, 16.18%,11.78%,17.84%, 13.27%,17.84% respectively which is statistically extremely significant with corre-

sponding 'P' value of 0.0002, P<0.0001, P 0.0005, P<0.0001, P 0.0002, P<0.0001.

Tab No.5] Effect of Virechana karma on diastolic pressure (PAIRED 't' TEST)

BP	Mean BP in mmhg	Mean diff.	%Relief	S.D.	S.E.	't'	'p'	
	BT	After DP						
		After SN						
		On the day of Vir.						
		After Vir.						
		After SH						
		F- up						
Diastolic Pressure	105.3	94.667	10.667	10.67	7.037	1.817	5.870	< 0.0001
		91.33	14.00	13.33	15.024	3.879	3.609	0.0028,
		92.000	13.333	12.69	21.931	5.662	2.355	0.0337
		86.00	19.333	18.40	12.228	3.157	6.123	<0.0001
		90.00	15.333	14.6	15.055	3.887	3.944	0.0015
		86.667	18.667	17.77	11.255	2.906	6.424	<0.0001

The initial mean of Diastolic blood pressure before treatment was 105.33. It was reduced to 94.66 after *Deepan-Pachana*, 91.33 after *Snehapana*, slightly increased to 92 on the day of *Virechana* then reduced to 86 after *Virechana* increased to 90 after *Shamana Yoga*, reduced to 86.67 after follow- up ,with relief of 10.67%, 13.33%, 12.69%, 18.40%, 14.6%, 17.77% respectively. The corresponding P value <0.0001 is statistically extremely significant,(P0.0028) is statistically very significant, (P 0.0337) is considered as significant, (P <0.0001) extremely significant, (P0.0015) considered as very significant.

DISCUSSION

The *Virechana* Karma eliminate the *morbid Doshas* in general and *Pitta* in particular their by having its effect on *Rakta* and regulate activity & movement of *Vata* by its *Anulomana* action. Thus it corrects the *Rasa-RaktaSamvahan* and helps to regulate the activity of heart and help to reduce systolic blood pressure and diastolic blood pressure .*Virechana* by means of inducing purgation helps to decrease fluid volume which may help to reduce cardiac overload and subsequently reduces blood pressure.

Virechana remove the *Margavarodha* (obstruction) and eliminate the morbid

Doshas and regulate movement of *Vata*, the cleansing effect of *Virechanakarma*, which might have improved the functioning of Heart. Thus *virechana karma* is highly effective in *hrutdravata*, *Bhrama*, *Klama*, *Shirashoola*, *Swedadhikyata* and *Anidra*.

In hypertension or in the complications of hypertension there is involvement of vital organ Brain, heart and kidney, *Arjuna-Punarnavadi Ghanavati* contains herbs which are organ specific and basically *Rasayana*, *Medhya*, *Mutrala*, *Deepana* and *Hridya* in nature provided a better and long lasting relief.

Purpose behind taking this *Shamana Yoga* is to alleviate remaining amount of *Doshas* after *Shodhana*.

1 *Arjuna* having *Hridya* property.

2 *Guduchi* is the drug known for its *V-P Shamaka* and *Rasayana* property. Recent research work on *Guduchi* had proved that it repairs the damaged cells and rejuvenates the whole body. Aqueous extract of the stem showed immunomodulatory, anti-inflammatory, analgesic anti pyretic activity and antioxidant activity.^[4]

3 *Shankhpushpi* was used because of its *Medhya*, *Tridoshaja*, *Nidrajanana* property. *Convolvulus pluricaulis* (The chloroform fraction of the total ethanolic extract) elicited a significant antidepressant-like effect in mice by interaction with the adrenergic, dopaminergic, and serotonergic systems.^[5]

4 *Haritaki* *Haritaki* is *Tridoshahara*, It is *smriduvirechaka*, Study was done on aqueous extract of *T. cheubla*, it inhibits the development of age-induced damages by protecting against oxidative stress and enhanced antioxidant status in the liver and kidney of aged rats.^[6]

Shunthi *Shunthi* is *Sama Pitta nashaka*, *Shothaghna*, *Hrutashoolanashaka*.

Recent Study on *Zingiber officinalis*, In spontaneously hypertensive rats (SHR), it reduces systolic blood pressure, atherogenic index (AI) and TG levels, more potent in reversing endothelial dysfunction while was devoid of cardiac stimulatory effect^[7].

Punarnava

Research on *Boerhaaviadiffusa* reveals that, medicinal plants might be potent and novel therapeutic agents for scavenging of NO and the regulation of pathological conditions caused by excessive generation of NO and its oxidation product, peroxynitrite^[8].

CONCLUSION

It can be concluded from present study that,

- The hypertension is prolonged and excess of tension and stress caused by blood on arteries. It is an elevated arterial pressure level >140/90 mmHg. Essential hypertension affecting 90-95% of hypertensive patients..
- As hypertension is *Tridoshaja vyadhi* with the dominance of *Pitta* and *Vatadosha*.
- *Agni dushti* with *Apkwa Dhatu Utpatti*.
- *Dushti* of *Rasa*, *Rakta* and *Meda* with *Sroto-rodha* and *Sira Shaithilyata*.
- The *Virechana Karma* eliminates the morbid *Pitta Dosh* in particular their by having its effect on *Rakta* and regulate activity & movement of *Vata* by its *Anulomana* action. Thus it corrects the *Rasa-Rakta Samvahan* and helps to regulate the activity of heart and help to reduce blood pressure.
- *Virechana* by means of inducing purgation helps to decrease fluid volume which may help to reduce cardiac overload and subsequently reduces blood pressure which is statistically highly significant.

- *ArjunaPunarnavadiGhanavati* contains herbs which are organ specific acts on heart, brain, kidney maintain blood pressure within normal limits which is statistically highly significant.

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Source of support: Nil
Conflict of interest: None Declared