

# Efficacy of *Nitya Virechana* with *Trivrit Churna* in the Management of Stage 1 Essential Hypertension – A Pilot Study

## Research Article

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### Abstract

**Background:** Hypertension (HTN) is a lifestyle disorder occurs due to faulty life style and stressful psychological conditions with a low rate of remission and recovery. In *Ayurveda*, Hypertension can be correlated with *Vata Pradhana Tridoshaja Vyadhi*. In *Vatapradhana Vyadhi*, *Mridu Sanshodhana* is the line of treatment and *Nitya Virechana* is a type of *Mridu Sanshodhana*. So in this study, *Trivrit Churna* was selected for *Nitya Virechana* in the management of Stage 1 Essential Hypertension. **Aim:** This clinical study was carried out to study the effect of *Nitya Virechana* with *Trivrit Churna* on Systolic and Diastolic blood pressure. **Settings and Design:** This was an open-labeled single arm interventional clinical study. **Materials and Methods:** Nine newly diagnosed cases of Stage 1 Essential Hypertension were registered from the outpatient and inpatient of Department of Panchakarma, Mahatma Gandhi Ayurved College Hospital & Research Centre, Wardha, Maharashtra, India, and *Nitya Virechana* with *Trivrit Churna* was administered for consecutive 15 days. **Statistical Analysis:** The data were statistically analyzed using Chi-square and paired *t* test. **Results:** Significant ( $p < 0.05$ ) result was found in all the assessment of subjective as well as objective parameters, namely *Shiroruk* (headache), *Klama* (fatigue), *Bhrama* (giddiness), *Anidra* (insomnia), Systolic and Diastolic blood pressure. **Conclusion:** *Nitya Virechana* with *Trivrit Churna* is highly effective to reduce Systolic and Diastolic blood pressure with significant reduction in symptoms of Stage 1 Essential Hypertension.

**Key Words:** *Essential Hypertension, Vata Pradhana Tridoshaja Vyadhi, Nitya Virechana, Trivrit Churna.*

### Introduction

Hypertension (HTN) is a lifestyle disorder occurs due to faulty lifestyle and stressful psychological conditions with a low estimate of remission and recovery. The 2017 American College of Cardiology and American Heart Association (ACC/AHA) blood pressure guidelines recommended some striking changes in the diagnosis and management of hypertension (1). Diagnostic criteria of HTN are systolic blood pressure above 130 mm Hg and diastolic above 80 mm Hg (1). Hypertension is called as a silent killer because majority patients (85%) are asymptomatic (2) and cause adverse effect to brain, kidney, heart and peripheral arteries over a period (3). Hypertension is precisely responsible for 57% of all stroke deaths and 24% of all coronary heart disease (CHD) deaths in India (4). About 26.4% of the world adult population in 2000 had hypertension and 29.2% were predicted to have this disorder by 2025 (5). In 95% cases of the hypertension, the primary etiological

factors are still unknown (6) but are presumed to be due to genetic and environmental factors (7). Although antihypertensive therapy certainly reduces the risk of cardiovascular and renal disease, but lifelong usage of antihypertensive drugs is associated with detrimental effects (8). Hence to attain and maintain good health, hypertensive patients are looking towards Ayurveda.

In Ayurveda, there is no direct reference regarding this disease which completely resembles with hypertension. Many scholars had worked on hypertension and had given various nomenclature which can be correlated with hypertension such as *Raktatvata*, *Avruta Vata*, *Siragatvata*, *Dhamani Pratichaya*, *Vyana Prakopa*, *Raktamada* etc (9) but none of these terms were universally accepted.

In Ayurveda, the regulation of blood pressure is governed by the *Tridoshas* viz *Vata* (*Prana* and *Vyana*), *Pitta* (*Sadhaka*) and *Kapha* (*Avalambaka*), *Dushya* like *Rasa*, *Rakta* and *Meda*, with the proper functioning of *Mana* (mind) and *Oja* which are situated in heart and helps in circulation of blood. On the basis of strong resemblances between etiological factors (10), symptoms (11), involvement of *Doshas* and *Dushya* in the etiopathology and complication (12), it is believed *Vata Dosha* to be the main culprit. Hence, Essential Hypertension can be correlated with *Vata Pradhana Tridoshaja Vyadhi*.

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Acharya Charaka has mentioned that if there is *Bahudosha Avastha*, then morbid toxins should be eliminated by the purificatory process (13). *Virechana* is mainly indicated in *Pitta* and *Shonita* predominant *Vyadhi* (14). As *Pitta Dosha* is having *Asharaya-ashrayi Sambandha* (mutual interdependence) with *Rakta Dhatu*, so *Virechana* is significantly beneficial in *Rakta Dushtijanya Vyadhi* (15). In *Vatapradhana Vyadhi*, *Mridu Sanshodhana* is the choice of treatment (16). *Nitya Virechana* is a type of *Mridu Sanshodhana*. There are many *Virechana* drugs described in *Samhita*. Among them, *Trivrit* is considered as *Sukhavirechaka* (17). So in this study, *Trivrit Churna* was selected for *Nitya Virechana* in the management of Stage 1 Essential Hypertension.

### Aims and Objectives

To study the effect of *Nitya Virechana* with *Trivrit Churna* on Systolic and Diastolic blood pressure in Stage 1 Essential Hypertension.

### Materials and Methods

A total 9 patients were registered for the study from the outpatient and inpatient of Department of Panchakarma, Mahatma Gandhi Ayurved College Hospital & Research Centre, Wardha, Maharashtra, India, who were newly diagnosed with Stage 1 Essential Hypertension. Informed consent was obtained from the patients before starting the intervention.

### Inclusion Criteria

Newly diagnosed patients of Stage 1 Essential Hypertension i.e. SBP (130-139 mm Hg) or DBP (80-89 mm Hg) of either sex between the age group of 30-60 years were included for the study.

### Exclusion Criteria

- Patients having Stage 2 Hypertension i.e. SBP ( $\geq 140$  mm Hg) or DBP ( $\geq 90$  mm Hg).
- Hypertension associated with cardio-vascular diseases, cerebro-vascular diseases, renal function impairment, hypothyroidism, diabetes mellitus (Type 1/ Type 2/ GDM), Pregnant and lactating women.
- Patients having Bleeding Hemorrhoids, Chronic Fissure-in-ano, Irritable Bowel Syndrome (IBS).

### Diagnostic Criteria

The diagnostic criteria of hypertension were taken from American College of Cardiology and American Heart Association (ACC/AHA) blood pressure guidelines 2017 (1) which is shown in table 1.

**Table 1: Diagnostic Criteria of Hypertension (ACC/AHA blood pressure guidelines)**

Blood Pressure Category	Systolic Blood Pressure		Diastolic Blood Pressure
Normal	< 120 mm Hg	And	< 80 mm Hg
Elevated	120-129 mm Hg	And	< 80 mm Hg
Stage 1 Hypertension	130-139 mm Hg	Or	80-89 mm Hg
Stage 2 Hypertension	$\geq 140$ mm Hg	Or	$\geq 90$ mm Hg

### Investigations for screening

All patients were screened through history and routine investigations. Hemoglobin percentage, Fasting Blood Sugar, Total Cholesterol, Triglyceride, Serum Sodium, Serum Potassium, Serum Creatinine and Electro Cardio Graph. These investigations were carried out before starting the intervention to exclude any other pathology related to exclusion criteria.

### Treatment

*Nitya Virechana* with 10 gms of *Trivrit Churna* was given with lukewarm water at empty stomach around 6 a.m. for consecutive 15 days.

### Study Duration

Initially treatment lasted for 15 days and follow up period after 15 days. The total study duration is 30 days.

### Method of administration

The patients were briefed to do their routine work. The interventional medicine is advised to take after proper digestion of previously ingested food. The dose of *Trivrit Churna* administered is 10 grams with lukewarm water at 6 am IST. Instructed them to note down the proper evacuation of mala or any complaints regarding abdominal discomfort for 15 days of the study.

### Diet and Restrictions

Patients were advised to take normal diet free from excessive salty, oily, sour items etc. and were also advised not to indulge in *Ashtamahadoshakara Varjya Vishayas* like *Uchhabhashya* (loud speech), *Rathakshobha* (travelling), *Atichakramana* (excessive walking), *Atiasana* (sedentary habit), *Ajirna* (intake of food during indigestion), *Ahitabhojana* (faulty dietary habits), *Diwaswapna* (daysleep) and *Maithuna* (sexual intercourse).

**Assessment Criteria**

**Subjective Criteria:** *Shiroruk, Klama, Bhrama* and *Anidra* were considered as subjective parameters having grades 0 to 4 are shown in table 2.

**Table 2: Assessment criteria for subjective parameters**

S.No	Subjective Criteria	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
1	<i>Shiroruk</i> (Headache)	Nil	Rarely headache relieves without medication	Headache relieves by rest; doesn't disturb daily activities	Severe headache disturbs daily activities requires medication	Continuous/ severe headache disturbs sleep and daily activities and also not managed by the medication
2	<i>Klama</i> (Fatigue)	Nil	Rarely feeling of tiredness without any exertion	Rarely feeling of tiredness without any exertion with inability in concentration	Frequently feeling of tiredness without any exertion with inability in concentration	Continuous feeling of tiredness without any exertion with inability in concentration
3	<i>Bhrama</i> (Giddiness)	Nil	Rarely Bhrama for some movement during change of posture	Often for some movement during change of posture	Often for each movement even in lying condition also	Patient unable to hold himself without any support
4	<i>Anidra</i> (Disturbed sleep/ Insomnia)	Sound sleep	Disturbed sleep, wakes-up 1-2 times a night ( <i>Khandita Nidra</i> )	Difficult onset sleep remains disturbed in night ( <i>Alpa Nidra</i> )	Very less sleep, in small intervals and makes patient irritable ( <i>Atialpa Nidra</i> )	Unable to sleep without medicine ( <i>Anidra</i> )

**Objective Criteria**

1. Systolic blood pressure
2. Diastolic blood pressure

**Assessment of Effect of Therapy**

Assessment was carried out three times, one before the treatment, second after the treatment and third after the end of follow-up period. The data were statistically analyzed using Chi-square and paired *t* test. If  $p < 0.05$  is considered as statistically significant result. Total effect of therapy was assessed on the basis of percentage of relief in subjective parameters.

1. Controlled 100% relief in complaints
2. Marked relief  $\geq 75\%$  relief in complaints
3. Moderate relief  $\geq 50-74\%$  relief in complaints
4. Mild relief  $\geq 25-49\%$  relief in complaints
5. No relief  $< 25\%$  relief in complaints

**Observations**

The maximum number of patients were males (66.6%), were belonged to 50-60 age groups (55.5%), were Hindus (77.7%), middle class category socioeconomic status (55.5%). Distribution according to occupational status, it was observed that majority patients were belonging to service class (44.4%). Mean Systolic and Diastolic blood pressure was 139.53 mm Hg and 88.33 mm Hg respectively. Majority of patients had family history (77.7%). The maximum number of patients had mixed diet (55.5%) and *Lavana Rasatmaka Ahara* (66.6%). Majority patients had *Vatapittaja Prakriti* (44.4%), *Krura Koshta* (66.6%), *Vishamagni* (77.7%), *Asamyak Malapravrutti* (88.8%) and *Saam Jivha* (77.7%). It was observed that majority of hypertensive patients were addicted to alcohol consumption (44.4%) and had stress-full lifestyle (66.6%). As per subjective parameters, it was observed that *Shiroruk* was observed in 1, 5 and 3 patients having Grade 2, 3 and 4 respectively. After follow up period, out of these 9 patients, 1 patient got relieved of the symptoms and remaining 5, 2 and 1 patient got significant reduction in the intensity of symptom with Grade 1, 2 and 3 respectively. *Klama* was observed in 1, 3 and 5 patients with Grade 2, 3 and 4. After follow up period, significant reduction was observed in the severity of symptom in 1, 4 and 4 patients having Grade 0, 1 and 2. *Bhrama* was observed in 2, 2, 3 and 2 patients having Grade 1, 2, 3 and 4 respectively. Out of these 9 patients, 3

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patients got relieved of the symptoms and remaining 4 and 2 patients got significant reduction in the intensity of symptom with Grade 1 and 2 respectively after follow-up period. On context of *Anidra*, before intervention, there were 3, 2 and 4 patients were having Grade 2, 3 and 4 which got significant reduction in the intensity of symptom with 2, 5 and 2 patients having Grade 0, 1 and 2 respectively after follow-up period [Table 3]. The mean values of SBP before treatment was  $139.53 \pm 2.83$  which got significantly reduced to  $131.14 \pm 3.05$  after intervention and after follow-up period, it again significantly reduced to  $129.58 \pm 2.96$ . The mean values of DBP before treatment was  $88.33 \pm 2.69$  which significantly reduced to  $80.17 \pm 2.75$  after intervention and after follow-up period, it again reduced to  $79.83 \pm 2.55$  [Table 4]. *Nitya Virechana* is not a proper *Shodhana* procedure, so the assessment of *Vega* is not applicable and also it was difficult to count the *Vega* of each patient for 15 days, but on average it was observed that *Krura Koshta* patients had 1-2 *Vegas*, whereas 2-3 *Vegas* was observed in *Mrudu Koshta* patients.

**Table 3: Assessment of effect of therapy on Subjective parameters**

S.No.	Assessment Parameter	Grade	Before T/t	After T/t	After Follow-up	$\chi^2$ -value After FU	P value
1	<i>Shiroruk</i>	Grade 0	0(0%)	0(0%)	1(11.1%)	16.76	<0.05, S
		Grade 1	0(0%)	3(33.4%)	5(55.6%)		
		Grade 2	1(11.1%)	4(44.4%)	2(22.2%)		
		Grade 3	5(55.5%)	2(22.2%)	1(11.1%)		
		Grade 4	3(33.4%)	0(0%)	0(0%)		
2	<i>Klama</i>	Grade 0	0(0%)	0(0%)	1(11.2%)	11.89	<0.05, S
		Grade 1	0(0%)	2(22.2%)	4(44.4%)		
		Grade 2	1(11.1%)	3(33.4%)	4(44.4%)		
		Grade 3	3(33.4%)	4(44.4%)	0(0%)		
		Grade 4	5(55.5%)	0(0%)	0(0%)		
3	<i>Bhrama</i>	Grade 0	0(0%)	2(22.2%)	3(33.4%)	10.68	<0.05, S
		Grade 1	2(22.2%)	3(33.4%)	4(44.4%)		
		Grade 2	2(22.2%)	2(22.2%)	2(22.2%)		
		Grade 3	3(33.4%)	2(22.2%)	0(0%)		
		Grade 4	2(22.2%)	0(0%)	0(0%)		
4	<i>Anidra</i>	Grade 0	0(0%)	0(0%)	2(22.2%)	15.18	<0.05, S
		Grade 1	0(0%)	3(33.3%)	5(55.6%)		
		Grade 2	3(33.4%)	3(33.3%)	2(22.2%)		
		Grade 3	2(22.2%)	3(33.3%)	0(0%)		
		Grade 4	4(44.4%)	0(0%)	0(0%)		

**Table 4: Assessment of effect of therapy on Objective parameters**

S. No.	Assessment Parameter	Before T/t (mean $\pm$ SD)	After T/t (mean $\pm$ SD)	After Follow-up (mean $\pm$ SD)	t value After FU	P value
1	Systolic Blood Pressure (SBP)	$139.53 \pm 2.83$	$131.14 \pm 3.05$	$129.58 \pm 2.96$	12.69	0.0001, HS
2	Diastolic Blood Pressure (DBP)	$88.33 \pm 2.69$	$80.17 \pm 2.75$	$79.83 \pm 2.55$	10.89	0.0001, HS

**Results**

Statistically significant results ( $p < 0.05$ ) were found which shows that *Nitya Virechana* with *Trivrit Churna* was statistically effective in reducing the intensity of symptoms of hypertension. The results obtained were highly significant ( $p < 0.0001$ ) in objective parameters which shows that *Nitya Virechana* with *Trivrit Churna* was highly effective in reducing the Systolic and Diastolic blood pressure even after follow up period. On summarizing the total effect of therapy, marked relief was found in 3 patients (33.3%) and moderate relief was found in 6 patients (66.7%) [Table 5].

**Table 5: Assessment of total effect of therapy on the basis of percentage of relief in subjective parameters**

Total effect of therapy	Range	% of relief
Controlled	100%	0(0%)
Marked Relief	$\geq 75\%$	3(33.3%)
Moderate Relief	$\geq 50-74\%$	6(66.7%)
Mild Relief	$\geq 25-49\%$	0(0%)
No Relief	$< 25\%$	0(0%)

## Discussion

Hypertension is one among the most alarming health disorder in today's time period. The lateral pressure exerted by blood on the lateral walls of blood vessels over and above the atmospheric pressure is said to be hypertension. In Ayurveda, there is no direct references regarding hypertension and as per Ayurvedic principles, in case of unknown disease, the physician should try to interpret the features of the disease through the involvement of *Dosha*, *Dushya* and its etiological factors involved in the pathogenesis of the disease and treat accordingly (18). Blood Pressure is the outcome of many physiological activities which is regulated by the *Tridoshas* viz *Vata* (*Prana* and *Vyana*), *Pitta* (*Sadhaka*), and *Kapha* (*Avalambaka*) *Doshas*, *Dushyas* like *Rasa*, *Rakta* and *Meda*, with the proper functioning of *Mana* and *Oja* which are situated in heart and helps in pumping of blood (19). On the basis of involvement of these factors, hypertension is said to be *Vata Pradhana Tridoshaja Vyadhi*.

*Trivrit Churna* predominantly has *Madhura*, *Katu*, *Tikta*, *Kashaya Rasa*, acts as *Pittakaphahara* and has *Sukhavirechaka*, *Anulomana*, *Hridya*, *Raktashodhaka*, *Amapachaka*, *Vedanasthapana* etc. properties and are indicated in *Hridroga*, *Raktavikara*, *Jwara*, *Pleeha-yakruta Vyadhi* etc (20). The chemical constituents of *Trivrit* comprises of Turpethinic acids,  $\alpha$  and  $\beta$ -turpethin, lupeol, b-sitosterol, botulin etc (21). The laxative effect of *Trivrit* is mainly due to the presence of turpethin (22). This fundamental constituent is believed to work on mysentric plexus and increase peristaltic movements in the body, thus acts as a laxative. *Operculina turpethum* exhibit analgesic, carminative, anti-inflammatory, antioxidant, hepatoprotective, immunomodulatory and hydragogue activities (23). When administered as laxative helps in alleviating the symptoms of hypertension by initiating the excretion of sodium and reducing vascular resistance.

*Mridu Sanshodhana* has been mentioned as the line of treatment of *Vata Vyadhi*. *Nitya Virechana* is a type of *Mridu Sanshodhana*. The probable mode of action of *Nitya Virechana* with *Trivrit Churna* can be understood by the dominant pharmacodynamics which helps in removing obstruction (*Margavarodha*) and eliminates the excess morbid toxic materials (*Kledamsha*) through *Adhobhaga* by the predominance of *Jala* and *Prithvi Mahabhutas*. Thereby it helps in pacifying *Kapha* and *Pitta Doshas* which altogether has its effect on *Rakta* due to *Ashraya-ashrayi Sambandha* and regulates *Vata Dosha* by its *Anulomana* action and ultimately balances the *Tridosha*. Thus *Nitya Virechana* acts either by hyper osmotic action or by reducing fluid electrolyte retention in the blood helps in expulsion of morbid *Doshas* from the body in less quantity and thereby reduces the total volume of *Rasa* and *Rakta* and maintaining the electrolyte balance and ultimately decreased blood pressure. Hence, we can conclude that *Nitya Virechana* with *Trivrit Churna* acts by *Pittakaphahara*, *Sukhavirechaka*, *Anulomana* and *Raktashodhaka* properties, which helps in maintaining

osmotic pressure, thereby regularize *Tridosha* and reduces hypertension.

## Conclusion

Hypertension is a common disorder of present era. Essential Hypertension is a psychosomatic hemodynamic disorder which is well explained in modern medicine can be correlated with *Vata Pradhana Tridoshaja Vyadhi* in Ayurveda based on the similarities in etiological factors, clinical features, complications etc. Statistically significant reduction in clinical symptomatology of hypertension and significant improvement was found in Systolic and Diastolic blood pressure. From the outcomes, we can conclude that *Nitya Virechana* with *Trivrit Churna* is effective to reduce Systolic and Diastolic blood pressure in Stage I Essential Hypertension. In this study none of the patients had developed any adverse effects during the course of treatment. The sample size was small and the study duration was too short to draw exact conclusion, thus the study with large sample and optimum duration should provide more improvement.

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