

CLINICAL EVALUATION OF EFFICACY OF 'MANSYADI GHAN VATI' AND 'TAKRA-AMALAKI SHIRODHARA' IN THE MANAGEMENT OF HYPERTENSION

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ABSTRACT

Hypertension (Persistent high blood pressure) is not a single disease, it is a syndrome of various etiologies, multiple pathogen city, and wide range of clinical manifestations and if remains untreated will leads to several fatal complications. It is a major risk factor for the development of cardiovascular disease and cerebrovascular disease causing high rate of mortality and morbidity. Keeping in view the increasing incidence of this problem a study was conducted with following **Aims and Objectives-** To study the etiopathogenesis of *Hypertension* in *Ayurvedic context*. To study the efficacy of "*Mansyadi ghan vati*" in management of *Hypertension*. To study the efficacy of "*Mansyadi ghan vati*" along with "*Takra-amalaki shirodhara*" in the management of *Hypertension*. **Material and Methods-** The study was conducted on 40 clinically diagnosed patient of Hypertension and randomly divided into two groups. In **group-A:** 20 well diagnosed patients of *Hypertension* will be administered with *Mansyadi ghan vati* 2 tab twice a day with lukewarm water for 45days. (Each tablet of 500 mg.). In **group-B:** 20 well diagnosed patients of *Hypertension* will be administered with *Mansyadi ghan vati* 2 tab twice for 45 days along with *Takra-amalaki shirodhara* for 14 days. **Statistical Analysis-**was done with help of Instate Graph Pad software3.1 using Wilcoxon matched-pairs signed ranks test and Mann-Whitney test. **Results-** Statistically highly significant result was observed in both Groups. **Conclusion-** Therapy in the form of administration of *Mansyadi ghan vati* and *Takra-Amlaki Shirodhara* separately or in combination is a safe and effective in the management of *Uccharaktachapa* (Essential Hypertension).

KEYWORDS: *Essential Hypertension, Uccharaktachapa, Persistent high blood pressure, Mansyadi ghan vati, Takra-Amlaki Shirodhara.*

INTRODUCTION

The 21st century is described as the age of anxiety and stress. The modern man is constantly facing symbolic stress. This stress and strain of day to day life affects one's bodily organs through several psycho-physical mechanisms. The progress of medical science has helped us to conquer disease like plague, smallpox etc., but stress related diseases are rapidly increasing. Among the several psychosomatic diseases, the cardiovascular disorder like hypertension is quite significant.

In *Ayurvedic* texts, there is no straight reference of essential hypertension. But *Acharya* has described *hridaya* and process of *rasa vikshepa* by *vyana vayu* which is very closely related to the circulatory system in modern science. *Rasa vikshepa* in the body is done by *vayu* itself, as well as understanding the pathophysiology responsible for causation of essential hypertension. This vitiated *vata* gets complimentary effect with *Pitta* and

Kapha, and help in progression of disease, chief mediator of vitiation being the *rasa-rakta* (whole blood). Hence it can be concluded that, essential hypertension is a *tridoshaja* disease.

patient can perform his/her day to day activities without much difficulty i.e. like *Shirshool* (Headache), *Bhrama* (Giddiness), *Klama* (Fatigue), *Hrutspandan* (Palpitation), *Swedhadhikyata* (Excessive sweating), *Anidra* (Insomnia) was chosen as symptoms of Essential Hypertension.

Globally In terms of mortality the leading Non Communicable Disease (NCD) is Cardio-Vascular Disease) CVD which claimed 17.5 million lives in 2012 (46% of all NCD deaths) – 6 million of which were under age 70 Of the 17.5 million deaths, 7.4 million were due to CHD and 6.7 million to stroke.^[1] The prevalence of hypertension in the late nineties and early twentieth

century varied among different studies in India, ranging from 2-15% in Urban India and 2-8% in Rural India. Which has increased 25% in Urban and 10-15% in Rural India.^[2] The prevalence of hypertension ranges from 20-40% in urban adults and 12-17% among rural adults. The number of people with hypertension is projected to increase from 118 million in 2000 to 214 million in 2025, with nearly equal numbers of men and women.^[3]

The modern medical treatment of this disease requires long term use of Diuretics, Sympatholytics, Vasodilators, Angiotensin converting enzyme inhibitors and Calcium channel blockers. which may lead to the side effects. But the treatment should cure the disease without developing any other disease. So, we should search for better treatment with less complication.

Mansyadi Ghan vati (Kalpit Yoga) (Mansyadi kwath – siddha yoga samgrha – vaatrogadhikar- vinshtitam adhyay-10 was selected for trial in the present study. It contains *Jatamansi, Ashwagandha and Parsika Yawani*. Tridosha shamaka (subsides the increased bio humors) property of *Jatamansi & Kapha Vaata shamaka* (decreases) property of *Ashwagandha* corrects all the somatic ailments. Secondly, *Takra-Amlaki Shirodhara* was also selected in this research work. *Shirodhara* described in *Dhara Kalpa, Sahastrayogam. Shirodhara* is well known procedure used in *Manas Roga*.

MATERIAL AND METHODS

Minimum 40 & above patients will be selected randomly from Hospital OPD & IPD, University college of Ayurveda, Jodhpur, which will be well diagnosed of *Hypertension* as per WHO criteria for diagnosis hypertension and symptoms described in ayurvedic classical text. after obtaining informed consent from patients and randomly divided into two groups.

- 1. Study Design-** Multi centre, Open label, Randomized, Standard, Controlled, Clinical Interventional type.
- 2. Inclusion Criteria**
 - Patients of both sexes between the age group 18 to 60yrs.
 - Patients who already diagnosed as *Hypertension* will be selected.
 - Patients willing to sign the consent form for the clinical trial.
- 3. Exclusion criteria**
 - Secondary hypertension.
 - Renal diseases
 - Diabetic Mellitus
 - Pregnancy induced HTN
 - Patients of Drugs like Oral Contraceptive Pills, steroids.
 - Ventricular hypertrophies

2. Portal hypertension
3. Renal artery HTN

4. Administration of Drugs

Group-A: 20 well diagnosed patients of *Hypertension* will be administered with *Mansyadi ghan vati 2 tab twice* a day with lukewarm water for 45days. (Each tablet of 500 mg.).

Group-B: 20 well diagnosed patients of *Hypertension* will be administered with *Mansyadi ghan vati 2 tab twice for 45 days* along with *Takra-amalaki shirodhara* for 14 days.

Criteria for Assessment

The diagnosis assessment of treatment will be assessed for the patients following symptoms and signs. *Shirshool* (Headache), *Bhrama* (Giddiness), *Klama* (Fatigue), *Hritspandan* (Palpitation), *Swedhadhikyata* (Excessive sweating), *Anidra* (Insomnia). The signs and symptoms are graded as per grading scale 0,1,2,3,4 which will be developed by **Dr. Pramod Kumar Mishra**.

Shirshool (Headache)

- 1] No *shirshool* - 0
- 2] *Shiroshool* once or twice a week – 1
- 3] *Shirshool* more than twice a week- 2
- 4] Continuous *shirshool* affecting partially-3

Bhrama (Giddiness)

- 1] No *bhrama* - 0
- 2] *Bhrama* once or twice a week - 1
- 3] *Bhrama* more than twice a week -2
- 4] *Bhrama* (giddiness) daily – 3

Klama (Fatigue)

- 1] No *Klama* (fatigue) - 0
- 2] *Klama* once while during walking- 1
- 3] *Klama* during walking twice in a week - 2
- 4] *Klama* at rest once in a week - 3
- 5] *Klama* at rest more than twice in a week- 4

Hritspandan (Palpitation)

- 1] No *hritspandan* - 0
- 2] *Hritspandan* occasionally - 1
- 3] *Hritspandan* on exertion - 2
- 4] *Hritspandan* on vigorous activity - 3
- 5] *Hritspandan* daily even at rest - 4

Swedadhikyata (Excessive Sweating)

- 1] No *swedadhikyata* - 0
- 2] Excessive sweating climbing upstairs- 1
- 3] Profuse sweating with speedily walking- 2
- 4] Profuse sweating during walking - 3
- 5] Profuse sweating even at rest - 4

Anidra (Insomnia)

- 1] Sound sleep - 0
- 2] Occasionally disturbed sleep - 1
- 3] Disturbed sleep 2-3 hours - 2

- 4] Disturbed sleep 3-4 hours - 3
5] *Anidra* (insomnia) whole night - 4

b). OBJECTIVE CRITERIA

Objective Criteria were before and after findings of laboratory parameters. The parameters selected were as follows:

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)
4. Urine analysis.
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)

Diagnostic criteria^[4]

8th 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

Statistical Methods Used: Observation obtained were analyzed statistically with the help of Instate Graph pad software 3.1

1. Wilcoxon matched-pairs signed ranks test- Intra group comparison.
2. Mann-Whitney Test- For calculating the Inter group comparison.

Table 1: Showing Contents of Trial Drug.

1. Mansyadi Ghana Vati (Mansyadi kwath – siddha yoga samgrha–vaatrogadhikar- vinshtitam adhyay-10

Name of Drug	Latin name	Part Used	Amount (Matra)
1. Jatamansi ^[5]	<i>Nardostachys Jatamansi</i>	Rhizomes	1 part
2. Ashwagandha ^[6]	<i>Withania Somnifera</i>	Roots	1/4 part
3. Parsika Yawani ^[7]	<i>Hyocymus Niger</i>	Seed	1/8 part

2. Takra-Amalaki Shirodhara:- (Dhara kalpa)

Name of drug	Latin name	Part used
1. Takra	Butter milk	
2. Aamlaki ^[8]	<i>Embilica Officinelis</i>	Fruit
3. Musta ^[9]	<i>Cyperus rotundus</i>	Rhizome

OBSERVATIONS

Maximum incidences were found in between Age group 41-50 years (47.5%), Male sex (70%), Hindu Religion (95%), Married (87.5%), Middle socio-economic status (60%), illiterate (32.5%), urban area (55%). Maximum number of the patients 67.50 % were having mixed diet, maximum number of patients (60%) were of *Pitta Kapha Prakriti*, maximum number of patients (72.5%) were of *Rajasika Prakriti*, Maximum (65%) were of *Madhyama Sara*, maximum (70%) had *Madhyama* type of *Samhanana*, maximum (62.5%) were of *Avara Satva*, majority of patients 67.5%) were having *Madhyam Satmya*, Majority of the patients (52.5%) had *Madhyama Ahara Shakti*, maximum number of patients (62.5%) had *Kroora Kostha*, maximum 26 patients (65%) were having *Vishamagni*, Maximum patients of *Uccharaktachapa* having *Madhyama Abhyavaharana Shakti*.

Maximum (85%) were found to be addicted to tea, 25% patients had family history, Maximum number of the patients (52.5%) were having Negative drug history of allopathic medicines.

50% had Moderate mental stress, 95% patients had complaint of *Klama*, 90% patients had complaint of *Shirshool*, 65% patients had complaint of *Hritspandan*, 62.5% patients had complaint of *Anidra*, 57.5% patients had complaint of *Swedadhikya*, and 45% patients had complaint of *Bhrama*.

Maximum (35%) patients were having 4-8 months duration onset. Maximum i.e. 67.50% patients were recorded stage I systolic blood pressure followed by 32.5% patients was suffering from stage –II systolic blood pressure. 47.5% patients were reported stage I diastolic blood pressure while that was of stage II in 40% patients.

47.5% patients had *lavana rasa* predominantly in their diet followed by 32.5% patients were with *madhura rasa* dominance. Maximum patients were having *raktavaha* (72.5%) and *rasavaha* (62.5%) *strotodushti*.

In the *aharaja nidana*, *atilavana sevana* was found in 55.88% patients, *ati katu sevana* in 29.41%, *mamsa sevana* 52.94%, *ruksha ahara sevana* in 21.41% an *atisnigdha sevana* was observed in 47.05% patients 23.52% patients were found to have alcohol consumption.

RESULTS

Table No. 2: Showing effect of therapy on systolic and diastolic blood pressure.

Variable	Group	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
Systolic BP	Gr.A	153.30	135.0	18.300	11.9373	8.392	1.877	9.752	<0.0001	ES
	Gr.B	155.20	131.70	23.500	15.1417	7.423	1.660	14.157	<0.0001	ES
Diastolic BP	Gr.A	96.600	87.700	8.900	9.2132	4.424	0.9892	8.998	<0.0001	ES
	Gr.B	97.200	86.300	10.900	11.2139	2.936	0.6565	16.602	<0.0001	ES

Table No. 3 Effect of therapy on pulse pressure.

Variable	Group	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
Pulse Pressure	Gr.A	56.700	47.300	9.400	16.5784	5.154	1.153	8.156	<0.0001	ES
	Gr.B	58.000	45.400	12.600	21.7241	5.113	1.143	11.020	<0.0001	ES

Table No. 4: Effect of Therapy in Subjective Parameters.

Variable	Gr.	Mean		Mean Diff.	% Relief	SD±	SE±	P	S
		BT	AT						
<i>Shirshoola</i>	A	2.05	1.25	0.80	39.02	1.240	0.2772	0.0110	S
	B	2.65	0.55	2.10	79.24	1.071	0.2395	< 0.0001	ES
<i>Bhrama</i>	A	0.95	0.55	0.40	42.10	0.6806	0.1522	0.0313	S
	B	1.4	0.35	1.05	75.0	1.669	0.3733	0.0117	S
<i>Klama</i>	A	2.15	1.5	0.65	30.23	0.9333	0.2087	0.0107	S
	B	2.0	0.40	1.6	80.0	1.046	0.2340	< 0.0001	ES
<i>Hrutspadana</i>	A	2.10	1.45	0.65	30.95	1.040	0.2325	0.0166	S
	B	1.7	0.15	1.55	91.17	1.432	0.3202	0.0005	ES
<i>Swedadhikya</i>	A	1.60	1.1	0.50	31.25	1.318	0.2947	0.1099	NS
	B	1.4	0.50	0.90	64.28	1.373	0.3069	0.0137	S
<i>Anidra</i>	A	2.0	1.05	0.95	47.5	1.468	0.3283	0.0105	S
	B	1.75	0.40	1.35	77.14	1.663	0.3719	0.0024	VS

(ES: Extremely Significant VS: Very Significant S: Significant NS: Non Significant).

Table No. 5: Intergroup Comparison of Group A & Group B for Subjective Parameters (Mann-Whitney Test).

Variable	Groups	(AT) Mean	SD±	SE±	P	S
<i>Shirshoola</i>	A	1.150	0.8127	0.1817	0.0005	ES
	B	2.200	0.8335	0.1864		
<i>Bhrama</i>	A	0.4000	0.6806	0.1522	0.1079	NS
	B	1.250	1.517	0.3393		
<i>Klama</i>	A	0.8500	0.7452	0.1666	0.0018	VS
	B	1.700	0.8645	0.1933		
<i>Hrutspandana</i>	A	0.9500	0.7592	0.1698	0.2165	NS
	B	1.550	1.432	0.3202		
<i>Swedadhikya</i>	A	1.000	0.9733	0.2176	0.9886	NS
	B	1.100	1.210	0.2705		
<i>Anidra</i>	A	1.250	1.209	0.2702	0.6101	NS
	B	1.550	1.468	0.3283		

Table No. 6: Overall effect of therapy.

Effects	Group A		Group B	
	No. of Patients	Percentage	No. Of Patients	Percentage
No relief (Unchanged)	00	00	00	00
Mild relief	03	15	01	5
Moderate relief	06	30	04	20
Significant relief	08	40	10	50
Excellent relief	03	15	05	25

In group A - Excellent relief was found in 15% of patients, while significant relief in 40%, moderate relief in 30% whereas 15% were found mild relief, while in group B- Excellent relief was found in 25 % of patients, while significant relief in 50%, moderate relief in 20 % whereas 5 % were found mild relief.

DISCUSSION

- **Probable mode of action of mansyadi ghan vati**

The trial drug- *Mansyadi Ghan vati* contains *Jatamansi*, *Ashwagandha* and *Khurasani ajwain*. All the drugs mainly have *Tikta*, *Katu* and *Kashaya rasa*, *Kapha-Vata Shamak Prabhava* and *Ushna virya* properties except *Jatamansi* (which is *Shita virya*).

By the virtue of pacifies *Ushna virya*, *Ashwagandha* increased *Vata dosha* which is the causative factor of *Raktgat Vata* along with *Pitta dosha*. Due to the presence of *Tikta* and *Kashaya rasa*, *Mansyadi Ghan vati* also acts as *Pittashamaka* drug. *Jatamansi* acts by its *Prabhava* which is *Bhutaghna* i.e. having *Manasa Doshahara Prabhava*. *Khurasani Ajwain* is *Madak* and *Vedanasthapaka*.

All the constituent of *Mansyadi Ghan Vati* are having *Nadibalya*, *Mashtishkashamak*, *Nidrajanak*, and *Vatahara* properties. By combined actions of all these *Guna*, *Karma* properties and *Prabhava* the trial drug *Mansyadi Ghan vati* produced synergistic action by inducing sleep reduce *Shirashoola*, *bhrama*, *klama*, *Hrutdruv* and *swedadhikya* and produced desirable effects in the management of *Uchcha Rakt Chap* in a series of patients of *Uchcha Rakta Chap*.

Bhutaghna prabhava (Specific effect on micro organisms) of *Jatamansi* & *Maadak Prabhava* (which calms the mind) of *Khurasani Ajwain* corrects the vitiation of *Bhrama (Raja & Tama)* by penetrating into *Manovaha srotas* (channels of mind).

Medhya (promotes the intellect) & *Nidrajana* (the one which induces sleep) property of *Jatamansi* & *Rasayana* (Rejuvenation) & *Balya* (promotes the physical and mental strength) property of *Ashwagandha* corrects all *Manas Vikara* (psychiatric diseases). *Tridosha shamaka* (subsides the increased bio humors) property of *Jatamansi* & *Kapha Vaata shamaka* (decreases) property of *Ashwagandha* corrects all the somatic ailments.

So by the virtue of combined effects of all the above chemical constituents, *Mansyadi Ghan vati* acts as hypotensive, sedative and tranquillizer

- **Probable mode of action of takra-amlaki shirodhara**

The *Takra (buttermilk)* has hot effect. But the combination of *Amalaki*, *Musta* and *Takra* produces a coolant effect on the brain and the whole nervous system and hence releases the stress and anxiety stagnant in the chief controlling station of our body.

As we know that the brain controls all the functions of the body. The master gland Pituitary gland and the hypothalamus associated with many physical and mental functions are located in the head. When all these are relaxed, the body functions including the heart functions take place in a relaxed manner.

The circulation of blood and nutrients take place in a proper way. The peripheral resistance is reduced. The channels of the body open up. The cells start flushing the toxins and overall metabolism gets improved.

Takra Dhara is highly effective in relieving stress. When stress is removed the psychosomatic disorders like psoriasis etc. are subjected to an effective healing. Stubborn psoriasis which has not been relieved by any medication responds to *Takra Dhara*. Here the *dhara* is not only done for the head but also over the lesions.

CONCLUSION

Mansyadi ghan vati and *Takra-Amlaki Shirodhara* were found effective in reducing the systolic and diastolic blood pressure and also alleviates the symptoms of essential hypertension. No adverse effects of the study drugs were observed during the study.

The initial response to Ayurvedic therapies in respective groups was slow, which increased significantly as the duration of treatment steadily progressed. Though maximum duration of *Shirodhara* is 21 days as per described in texts no any untoward side effect had been observed after its administration.

During the follow up study, it was found that there was rise in systolic and diastolic pressure suggesting the palliative nature of the treatment. The plus point observed in case of Ayurvedic management is absence of any hazardous effect, which is really a great benefit to the patient and is of vital importance in view of the global acceptance of *Ayurveda*. Further extensive study is needed to authenticate the results of the present study, with larger samples and more precise diagnostic and assessment criteria.

On the basis of the various observations and results obtained after completion of the current research project, it can be concluded that, *Mansyadi ghan vati* and *Takra-Amlaki Shirodhara* may be used in the management of essential hypertension (Raktagata Vata). The clinical response in terms of improvement in blood pressure and various symptoms of essential hypertension was milder in *Mansyadi ghan vati* treated group, moderate in patients of *Mansyadi ghan vati* and *Takra-Amlaki Shirodhara* group.

Therefore, it can be concluded that, therapy in the form of administration of *Mansyadi ghan vati* and *Takra-Amlaki Shirodhara* separately or in combination is a safe and effective in the management of Uchcharaktachapa (Essential Hypertension).

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