

**Research Article****TO EVALUATE THE EFFICACY OF *GUDUCHYADI YOGA* IN THE MANAGEMENT OF
RAKTACHAPADHIKYATA OR ESSENTIAL HYPERTENSION-A RANDOMIZED CONTROLLED
CLINICAL TRIAL****Nitish Pathania^{1*}, Umesh C², Gopal Krishna G³, Monika Pathania⁴**¹PG Scholar, ²Professor, ³Professor and HOD, Department of Kayachikitsa, Sri Sri College of Ayurvedic Science and Research, Bengaluru, Karnataka,⁴Associate Professor, AIIMS, Rishikesh, Uttarakhand, India.**ABSTRACT**

Hypertension is the most pressing public health challenges. It is estimated that approximately 1 billion people are suffering from high blood pressure and the numbers are to increase to 2.5 billion by 2025. *Raktachaapadhikya* is the coined term for increased blood pressure given by recent authors where it can be understood as the pathology of *Vyanvayu*. The usage of *Guduchyadi Yoga* has been highlighted in the classics of Ayurveda for targeting the *Hridaya sthitha vayu*, which has not been evaluated yet. **Aim:** To evaluate and compare the efficacy of *Navahridaya Kalpa* (standard drug) and *Guduchyadi Yoga* (trial drug) for management of essential hypertension. **Materials and Methods:** A simple randomized controlled clinical study where 40 patients were equally divided as group A: *Navahridaya kalpa* (standard drug) and Group B: *Guduchyadi yoga* (trial drug) for a period of one month. **Observations and results:** The study result revealed that both the groups were beneficial in reducing high blood pressure however with no statistically significant difference found between the groups with p value being 0.339 for standard drug and 0.363 for trial drug. The group B was also found to be effective in reducing systolic blood pressure of stage I hypertension with p value .044 on comparing between the groups. **Conclusion:** The *Guduchyadi yoga* acts as *Rasayana* with the property of rejuvenation and antihypertensive which will check the high blood pressure at a very minimum cost without having any major adverse effects in the patients and hence can be advocated for use on a daily a basis.

KEYWORDS: Essential Hypertension, *Guduchyadi Yoga*, *Navahridaya Kalpa*, *Raktachaapadhikya*.**INTRODUCTION**

Hypertension is one of the most alarming health problems of the present era. It is estimated that approximately 1 billion people worldwide are suffering from high blood pressure and its number is expected to increase to 2.5 billion by the year 2025.^[1] Hypertension is known as the “Silent Killer” because typically it has no warning signs or symptoms, and many people do not know they have it even when blood pressure levels are dangerously high. Hypertension is of two types’ Essential Hypertension and Secondary Hypertension. About 90 to 95% of all people who have hypertension are said to have “Essential Hypertension” i.e. Primary or Idiopathic Hypertension.^[2] In Ayurvedic classics, there is no reference for essential hypertension. The diagnosis is totally based on signs and symptoms of the disease elucidated by the physician, hence, from time to time various correlation has been made by recent authors

and different names have been suggested for hypertension like co-relating it to *Pittavruta udana*, *Raktagata vata*, *Pittavruta vata*, *Raktavruta vata*, *Vyan vayu vaishamyata*. *Raktachapadhikya* is the coined term which translates itself to as increase in the blood pressure.^[3] Though there have been different opinions by different scholars, no one has denied the fact of essential hypertension of being psychosomatic in nature and *Vata pradhana tridoshaja vyadhi*. The ill-effects of faulty regimens like deviating from *Dinacharaya*, *Ritucharya* etc, influence the *Rajodoshha* in *Manas* thus directly bringing out the *Dosha* vitiation in the *Shareera* so as it leads to an ailment which directly predisposes hypertension.

MATERIALS AND METHODS

Research design and study population: It was a simple randomized controlled clinical study having

two parallel arms (allocation ratio 1:1). The study population was composed of subjects diagnosed with Essential Hypertension which were selected from OPD, IPD and special camps conducted in Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. The ethical clearance from the institutional ethical committee was obtained before the initiation of the research work.

Eligibility Criteria

Inclusion Criteria

1. Subjects aged between 18-70yrs of either sex.
2. Subjects falling under the category of stage-I and stage-II hypertension without underlying complications according to JNC-VIII updated guidelines of hypertension
3. Subjects involving both fresh and treated cases of essential hypertension were selected.
4. Subjects who were under Ayurvedic medicines were withdrawn for seven days and after the washout period, were included in the study.

Exclusion Criteria

1. Subjects below the age of 18 years and above 70 years of age
2. Subjects suffering from ischemic heart disease (IHD), Chronic kidney disease (CHD), Coronary artery disease (CAD), Coarctation of the aorta
3. Subjects with secondary hypertension and gestational hypertension were excluded
4. Subjects not willing to continue the treatment.

Diagnostic Criteria

The diagnosis was made on the measurement of the blood pressure using a sphygmomanometer. The criteria for normal, pre-hypertension, hypertension stage I, and hypertension stage II was accepted by the report of the updated Joint National Committee (updated JNC-VIII)^[4]. The measurement was made in all the three-position ex supine, sitting and standing. (Table no 1)

Table 1: diagnostic JNC VIII criteria

Cl. HTN	SBP (mmHg)	DBP(mmHg)
N	<120	<80
Pre	120-139	80-89
SI	140-159	90-99
SII	>160	>100

Cl*.=Classification, HTN*.=Hypertension, SBP*.= Systolic blood pressure, DBP*.= Diastolic blood pressure, N*.= Normal, Pre*.= Prehypertension, SI*.=Stage I HTN, SII*.=Stage II HTN

Intervention:

Group A: Oral administration of *Navahridaya kalpa* (standard drug) 1 tablet three times a day for stage I

HTN and 2 tablets thrice a day for stage II HTN with water as *Anupana* (drink after medication) for 30 days.

Group B: Oral administration of *Guduchyadi yoga*^[5] (trial drug) 3 tablets weighing 3.25gm^[6-7] collectively once a day for stage I HTN and twice a day for stage II HTN with hot water as *Anupana* (drink after the medication) for 30 days.

Assessment Criteria

Subjective Parameters

1. *Shiroshoola* (Headache)
2. *Anidra* (Sleeplessness)
3. *Hridravatva* (Palpitation)
4. *Klama* (Fatigue)
5. *Bhrama* (Giddiness)

Objective parameter

The disease primarily being asymptomatic, the measurement of blood pressure was considered as the primary parameter for assessment. The assessment was made with systolic, diastolic and mean arterial blood pressure. The measurement of blood pressure was made in all three postures namely, supine, sitting and standing.

The four assessments were made on the 7th, 15th, 21st and 30th day of the trial period. The assessment was done with respect to the change in the blood pressure readings in all three positions and the mean of the three readings were recorded.

Statistical Method: The results were analysed statistically, using the parametric tests like paired t-test within the group, unpaired t-test between the group for objectives parameters and non-parametric tests like Mann Whitney test within the group, Wilcoxon test between the groups for subjective parameter with the help of SPSS software version 20.

OBSERVATIONS

Among 40 patients who completed the study, maximum patients 16 in number i.e. 40% belonged to the age group 60-69 years, followed by the age group 50-59 years and 40-49 years are 27% and 15% respectively, where as in 30-39 years is 5 i.e. 12.5% and in age group 20-29 are 2 i.e. 5% patients were registered. (Table 2)

There were 11 male patients contributing to 55% and 9 female patients constituting 45% in Group A whereas there were 9 male patients constituting to 45% and 11 female patients constituting 55% in Group B (Table 3).

The observation on the distribution of occupation revealed out of 40 patients, 26 patients were homemaker which constitute 65%, 8 patients were IT professional constituting 20%, 4 patients were in business constituting 10%, 2 patients were

student and employee constituting 2.5% each (Table no.4).

The study revealed that maximum patients i.e. 14 constituting 35% weighed between 70-79kgs, followed by 60-69 kgs constituting 10 (25%), patients weighing more than 80kgs were reported to be 9 in number constituting to 22.5% and 7 patients

i.e. 17.5% in the range of 50-59 kgs. (Table no.5) Out of 40 patients majority i.e. 21 (52.5%) were freshly detected cases, 17 patients had a history from 3months to one year constituting to (42.5%), and 2 patients constituting to 5% had 1year-5years history. (Table no 6)

Table 2: Showing the Incidence of Disease With Relation to Age

Age (In years)	Group A	Group B	Total
20-29	0	2	2 (5%)
30-39	4	1	5 (12.5%)
40-49	6	0	6 (15%)
50-59	4	7	11 (27%)
60-69	6	10	16 (40%)

Table 3: Showing the Incidence of Disease With Relation to Gender

Gender	Group A	Group B	Total
Male	11	9	20 (50%)
Female	9	11	20 (50%)

Table 4: Showing the Incidence of Disease With Relation to Occupation

Occupation	Group A	Group B	Total
IT professional	7	1	8 (20%)
Homemaker	12	14	26 (65%)
Business	1	3	4 (10%)
Student	0	1	1 (2.5%)
Service	0	1	1 (2.5%)

Table 5: Showing the Incidence of Disease With Relation to Weight

Weight (Kg)	Group A	Group B	Total
50-59	1	6	7 (17.5%)
60-69	5	5	10 (25%)
70-79	7	7	14 (35%)
>80	7	2	9 (22.5%)

Table 6: Showing the Incidence of Disease With Relation to Chronicity

Chronicity	Group A	Group B	Total
Fresh	8	13	21 (52.5%)
3months - 1 year	12	5	17 (42.5%)
1 year-5year	0	2	2 (5%)
5years and above	0	0	0

RESULTS: A total of 44 subjects participated in the study. There were 4 dropouts who were lost to the followup. There were no patients in either groups with any adverse effects.

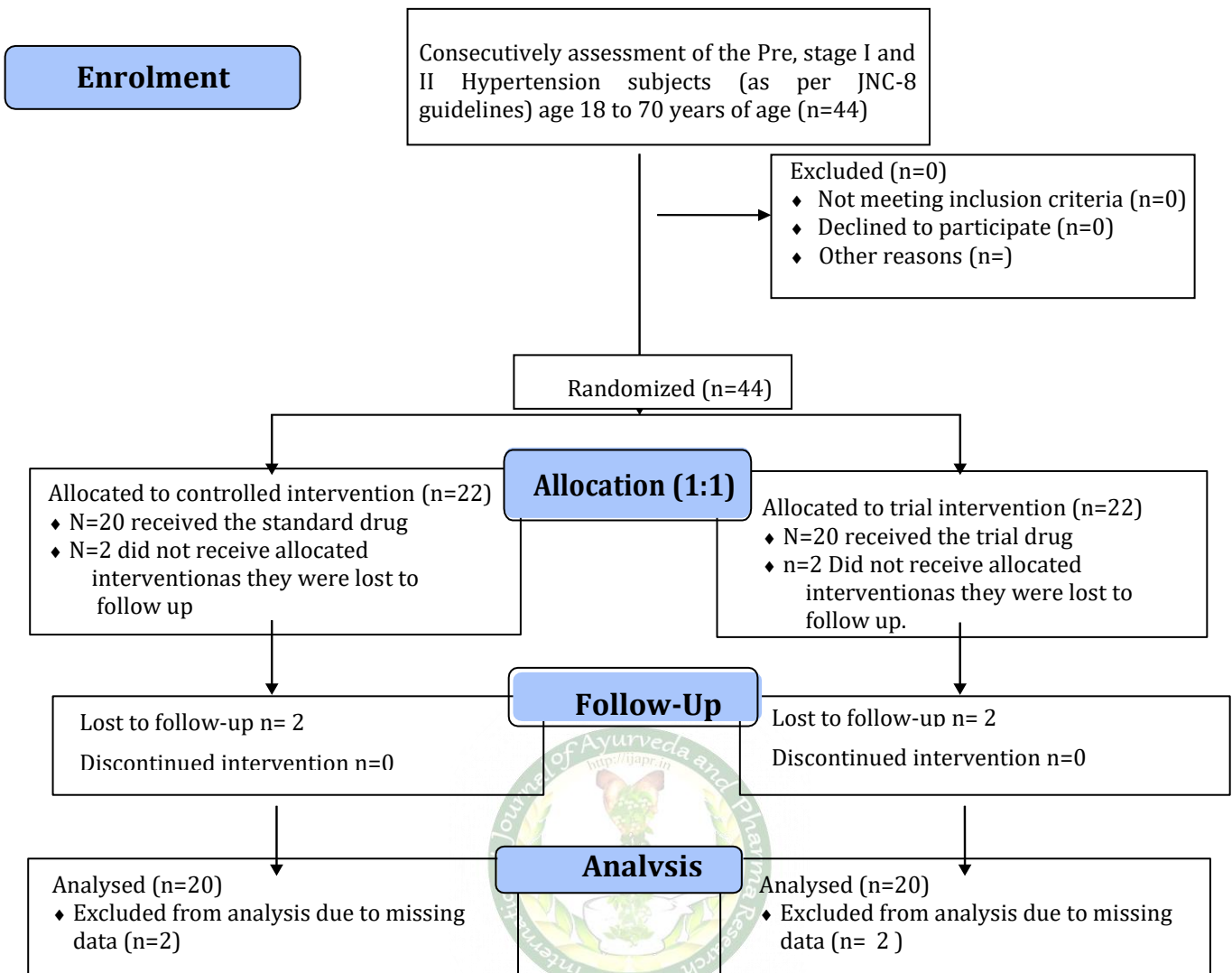


Fig.1 Consort diagram

The results obtained regarding the subjective parameters were not statistically significant within the group for headache (*Shiroshoola*), however, due to decrease in the standard error and mean rank in group B than group A, implies that group B was better in relieving headache than group A. However, there was no statistically significant difference noted between the groups with p-value .690. (Table 7)

Table 7: comparisons between groups

<i>Shiroshoola</i>	N	Mean	Sum of ranks	P value
Group A	5	6.00	30.00	.690
Group B	5	5.00	25.00	

There is no statistical significant value obtained for other subjective parameters like *Anidra* (Insomnia), *Klama* (Fatigue), *Hridravatva* (Palpitations) and *Bhrama* (Giddiness) owing to less sample size due to asymptomatic nature of the disease.

After analysing the statistical data with the help of paired t test within the group A and group B. The result was statistically found to be highly significant for systolic as well as diastolic blood pressure within the groups. (Table 8)

Table 8: Comparisons Within the Groups

Groups		N	BT	SD	AT	SD	P-value
Group A	SBP	20	153.30	10.10	136.30	8.649	.000
	DBP	20	94.95	6.013	82.90	5.964	.000
Group B	SBP	20	153.70	5.048	143.45	12.98	.006
	DBP	20	93.80	6.646	85.00	6.821	.000

The results observed on the stages of systolic and diastolic blood pressure considering the JNC VIII criteria it was found to be statistically highly significant for stage I of systolic blood pressure unlike the stage I of diastolic blood pressure within the group A and group B. (Table 9)

Table 9: Comparisons within the Groups Based on the Stage of HTN

Groups		N	BT	SD	AT	SD	P-value
Group A	SBP S1	10	149.60	2.50	140.20	9.40	.015
	DBP S1	4	93.25	3.77	90.00	.000	.184
Group B	SBP S1	10	150.40	2.50	145.60	4.76	.014
	DBP S1	4	93.25	3.77	90.75	1.50	.194

After analysing the data using unpaired t-test between the group A and group B for systolic and diastolic blood pressure, there was no significant difference found with p value as .339 for systolic blood pressure and .363 for diastolic blood pressure. However there was a significant difference observed for stage I systolic blood pressure between group A and B with p-value as 0.044.

DISCUSSION

The incidence of HTN is seen more in the old age, which can be attributed to changes in decreased baroreceptor sensitivity, increased responsiveness to sympathetic nervous system stimuli, altered renal and sodium metabolism.^[8] As already discussed about the *Vata dosha pradhanata* in the disease it can be inferred that with the increase in age, *Vata dosha* gets dominant therefore the old age people get more susceptible for *Raktachapadhikyata* or essential hypertension. In the present study, the exact ratio cannot be established due to small sample size, however, it was observed that both males and females are susceptible to essential hypertension/*Raktachapadhikyata*. Despite the gender differences in human hypertension, the treatment guidelines do not differ by gender.^[9] The study shows the majority of the patients were homemakers and IT professionals. The comprehensive reviews have concluded that the job strains, a combination of low control over the job and high psychological demands, is related to the incidence and prevalence of cardiovascular diseases. It was postulated that one of the underlying mechanisms through which job strains lead to cardiovascular disease and high blood pressure due to chronic psychological disorders.^[10] There were a majority of the patients who were overweight in the present study where it again highlights the susceptibility of such patients to HTN. It is generally thought that the accumulation of visceral and ectopic fat in tissues and organs alters the metabolic and hemodynamic pathways leading to the development of hypertension in obese patients.^[11] The main challenge in the diagnosis of essential hypertension is the absence of symptoms experienced by the patients. Hence it is termed as the 'Silent Killer' as it goes on harming the body silently. The patient with essential hypertension is usually diagnosed on regular check-ups. Due to the absence of symptoms patients tend to ignore seeking medical help; hence lots of efforts are required to educate the

mass about the incidence and prevalence of cardiovascular diseases.

Discussion on Subjective Parameters

In the present study, among 40 patients who completed the study, both symptomatic and asymptomatic patients were registered. There were 24 patients who presented with symptoms and the remaining 16 were asymptomatic (40%). The most common symptom which was observed in the patients was *Shiroshoola* (headache) with 16 patients constituting 40%. The other symptoms like *Anidra* (insomnia), *Hridravatva* (palpitation), *Bhrama* (giddiness) and *Klama* (fatigue) constituting 5% respectively.

Shiroshoola (Headache): Both groups showed some improvement in the subjects with the symptoms. The changes were seen within the 7 days. The maximum effect was found on the 15th day and by the end of the 30th day, six out of sixteen were relieved of the symptoms (Table 10-11). In group A, the drugs like *Arjuna* possess anti-spasmogenic property^[12], *Ashwagandha* has the property of CNS depressant^[13] and *Brahmi* acts as an anti-spasmodic drug which might help in relieving the headache to a considerable extent^[14]. In group B, the *Guduchi* (*Tinospora Cordifolia* Thunb) and *Maricha* (*Piper nigrum* Linn) have the *Rasayana* properties hence act on the *Vatadosha*^[15-16]. The potential therapeutic properties reported by modern scientific research includes it to have anti-oxidant, anti-stress properties.^[17]

Anidra (Insomnia): In group A, only two patients experienced moderate symptoms of *Anidra* (Insomnia). The result observed pre and post-treatment reduced the moderate symptoms to mild symptoms. The result obtained might be due to the drugs like *Sarpagandha*^[18] and *Shankhapushpi* which are *Nidrajanaka*, it also acts as a tranquilizer as studied through different researches. It acts as *Medhya*, *Vrishya*, and *Rasayana* and *Manasarogahara*.

The glycoside of *Shankhapushpi* effects on lowering the blood pressure. According to *Yogaratanakara* it acts on *Anidra* and *Bhrama*.^[19] Thus the *Anidra* (Insomnia) is relieved in the patient.

Hridratva (Palpitations): The patients in group A had a mild to moderate degree of the symptoms of *Hridratva* (palpitations). The maximum effect of the treatment was seen on the 15th day and the 30th day, there was relief observed by the patient. The drug like *Arjuna*, which is considered as *Hridya*, regulates the *Rakta vikshepana karma* of heart and *Ashwagandha* reduces *Chalaguna* of *Vata*. In group B, there was only one patient with palpitations which was relieved by the end of the treatment. The probable action may be due to *Guduchi* (*Tinospora Cordifolia* Thunb.) along with *Maricha* (*Piper nigrum* Linn) has proven to have a positive impact on cardiac conditions such as angina pectoris, myocardial infarction, ischemic heart diseases and certain arrhythmias.^[20] It might have helped clearing the obstruction in the arteries as well as in the heart and acted as cardio-protective agent. Thus *Hridratva* (palpitations) was relieved.

Bhrama (Giddiness): There was one patient in each group where the moderate symptom of *Bhrama* (giddiness) was reduced to absence of *Bhrama* (giddiness) by the end of the treatment in group A. The probable action might be due to the *Rasayana* effect of the drugs which act on *Vata dosha*. In group B the moderate symptom was reduced to mild symptom by the end of the treatment the result can be attributed to the *Vata pitta hara* and *Medhya* property^[15-16], which might have impact the *Mano dosha* like *Rajas*.

Klama (Fatigue): In group A, there was one patient where the moderate degree of *Klama* (fatigue) was reduced to absence of *Klama* (fatigue) by the end of the treatment where the action can be attributed to the various *Rasayana* and *Balya* properties of the drug in group A. In group B, the moderate symptom

of *Klama* (fatigue) was reduced to mild symptom by the end of the treatment which can be attributed to the *Rasayana* property of the drugs as well as anti-oxidant^[15] and anti-stress^[16] property.

Discussion on Objective Parameters

In group A there was significant improvement seen with respect to systolic and diastolic blood pressure, the action of the drug can be attributed to the drugs like *Sarpagandha*, which is a proven drug acting on the vasomotor center directly leading to generalized vasodilatation further causing reduction in the blood pressure.^[18] The main constituent i.e. reserpine also checks nausea. The other ingredient being *Arjuna* which acts on the *Hridaya* and is known to act as a hypotensive drug.^[21] In group B also showed significant statistical result which can be attributed to the *Guduchi* (*Tinospora Cordifolia* Thunb.) which is known to be *Tridosha shamaka* and has cardio-tonic and hematopoietic activity and is effective in cardiac debility.^[22] *Guduchi* (*Tinospora Cordifolia* Thunb.) is also known to have chromium with higher concentration of chromium in all the plants. It has been found that chromium plays a major role in ameliorating sucrose-induced blood pressure elevations and can act as antioxidant.^[23] The constituents of stem of *Guduchi* (*Tinospora Cordifolia* Thunb.) are known as diterpenoid lactones which are known to have anti-hypertensive activities.^[24] Similarly in Ayurveda it has been stated that the *Shakha* of *Guduchi* (*Tinospora Cordifolia* Thunb.) is accountable for *Vatadosha* pacification.^[25] The studies have proved that piperine content of the *Piper nigrum* possess a blood pressure lowering effect mediated possibly through calcium channel blockade, while a consistent decrease in blood pressure.^[15] It also helps in improving the bioavailability of the drug it is given along with, thus producing the synergic action of the drug over the body.

Table 10: Showing the results of intervention on a subjective parameter in Group A

	Grading	Headache	Insomania	Palpation	Fatigue	Giddiness
BT	Severe	2	0	0	0	0
	Moderate	5	0	0	1	1
	Mild	0	0	1	0	0
	Absent	0	0	0	0	0
Day 7	Severe	0	0	0	0	0
	Moderate	5	0	0	1	1
	Mild	2	0	1	0	0
	Absent	0	0	0	0	0
DT 15	Severe	0	0	0	0	0
	Moderate	0	0	0	0	0
	Mild	7	0	1	0	1
	Absent	0	0	0	1	0

Day 22	Severe	0	0	0	0	0
	Moderate	0	0	0	0	0
	Mild	4	0	0	0	1
	Absent	3	0	1	1	0
AT	Severe	0	0	0	0	0
	Moderate	0	0	0	0	0
	Mild	5	0	0	1	1
	Absent	2	0	1	0	0

Table 11: Showing the results of intervention on a subjective parameter in Group B

	Grading	Headache	Insomania	Palpation	Fatigue	Giddiness
BT	Severe	1	0	0	0	0
	Moderate	4	2	1	1	1
	Mild	4	0	1	0	0
	Absent	0	0	0	0	0
Day 7	Severe	0	0	0	0	0
	Moderate	2	2	1	1	0
	Mild	6	0	1	0	0
	Absent	1	0	0	0	1
DT 15	Severe	0	0	0	0	0
	Moderate	0	0	0	0	0
	Mild	5	2	1	1	0
	Absent	4	0	1	0	1
Day 22	Severe	0	0	0	0	0
	Moderate	2	0	0	0	0
	Mild	4	2	1	1	1
	Absent	3	0	1	0	0
AT	Severe	0	0	0	0	0
	Moderate	1	0	0	0	0
	Mild	4	2	2	0	0
	Absent	4	0	0	0	1

CONCLUSION

The study proved that both the drugs i.e. *Navahridaya Kalpa* (standard drug) and *Guduchyadiyoga* (trial drug) were beneficial in reducing the blood pressure with statistically significant values. The effect of both the drugs was found statistically significant on systolic blood pressure of the stage I hypertension. The main property mentioned for the *Guduchyadi yoga* being *Rasayana* i.e. having the property of rejuvenation and anti-hypertensive property will check the high blood pressure at a very minimum cost without having any major adverse effects in the patients. *Guduchi* (*Tinospora Cordifolia* Thunb.) and *Maricha* (*Piper nigrum* Linn) the two constituents of the *Guduchyadi yoga* are easily available and also *Maricha* (*Piper nigrum* Linn) also forms one of the main spices of every household in India. Hence the use of *Guduchyadi yoga* can be advised as alternative prescription in the daily regimen of the hypertensive patients.

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