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Assessment of the Effect of *Raga* Therapy & *Nisha Amalaki Churna* on Prehypertension - A clinical study

Research Article

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Abstract

Background: Prehypertension is classified as elevated blood pressure above normal by American medical classification. JNC 7 suggested systolic between 120 to 139 mmHg or diastolic 80 to 89 mmHg should be consider as Pre-hypertension. Oxidative stress develops due to stress and anxiety is recognized as main risk factor for initiation of hypertension. The *Nada Yoga* (sound based yoga) practices has been reported to decreases stress and anxiety. *Nisha Amalaki Churna* the combination of *Amalaki* (Indian gooseberry) and *Haridra* (turmeric) powder also reported to effectively reduces oxidative stress. Aim - To assess the combined effect of Indian Classical *Raga Ahirbhairav* and *Hindol* along with *Nisha Amalaki Churna* on Prehypertension. Material and method- It was clinical study. Total 48 patients selected by purposive sample technique and then divided into 2 groups (n = 24 each) randomly. Assessment was done by criteria of pre hypertension given by JNC 7. Result - In present study group A (*Raga Ahirbhairav*, *Raga Hindol* and *Nisha Amalki Churna*) patients the mean score of Systolic B.P. had decreased from 135.50 to 120.76 (Mean difference 14.74) with extremely significance ($p < 0.0001$) compare to group B (only *Nisha Amalki Churna* orally) and mean score of Diastolic B.P. had decreased from 88.61 to 79.706 (Mean difference 8.904) with extremely significant ($p < 0.0001$) compare to group B. Relief in mild headache 31.94% ($p<0.01$), relief in Anxiety 52.67% ($p<0.0001$) and relief on stress was reported 34.56% ($p<0.0001$) in Group A were reported, compare to Group B. Conclusion- result of study indicating that *Raga therapy* with *Nisha Amalaki Churna* had potential in the management of pre hypertension.

Key Words: *Raga Therapy, Nada Yoga, Prehypertension, Nisha Amalaki Churna.*

Introduction

Hypertension is a serious health threat. It is a major health issue as well as one of the prominent health challenges in developed and developing countries. It is a major risk factor for the development of cardiovascular disease (CVD) and coronary heart disease (CHD). Systematic review indicating that overall prevalence for hypertension in India was 29.8% (95% confidence interval: 26.7–33.0). Approximately 27.6% prevalence of Hypertension were recorded in rural population and 33.8% in urban population in India.(1) The prevalence of Prehypertension is also reported high. In North India large cross-sectional survey study indicating prevalence of pre-hypertension were 40.8% in North India. (2)

The Seventh Report of the Joint National Committee suggested Systolic <120 mmHg and diastolic <80 mmHg should be consider as Normal blood pressure, systolic between 120 to 139 mmHg or diastolic 80 to 89 mmHg should be consider as Pre-hypertension and readings greater than or equal to 140/90 mmHg should be consider as hypertension, based upon two or more readings at two or more separate occasions separated by at least one week. (3)

Pre-hypertension is often asymptomatic at the time of diagnosis. Family history of hypertension, a sedentary lifestyle, stress and anxiety, eating high sodium foods, smoking and excessive alcohol intake are considered as risk factors of Pre-hypertension and Hypertension. Oxidative stress has important role in the pathogenesis of hypertension. (4)

Need of the Study

Prehypertension has been found strongly linked with oxidative stress thus in early hypertension stage i.e. in prehypertensive stage with effective traditional methods it can manage effectively without any adverse effect. Researches have been shown significant cardio-protective effects of various Indian classical *Ragas* such as *Raga Ahirbhairav* (5) and *Raga Hindol* (6). Studies indicating that increased vascular oxidative stress is linked with hypertension. (7) Hence, reduction in oxidative load with the help of powerful anti-oxidant

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might be helpful in the management of hypertension. An Ayurvedic formulation *'Nishamalaki'* is a preparation of Amla (*Emblica officinalis*) and Turmeric (*Curcuma longa*) had been identified as strong anti-oxidant formulation and also reduces lipid perioxidation.(8) Hence, this study was planned with *Raga Ahirbhairav and Hindol* along with *Nisha Amalaki churna* in the management of Prehypertension.

Aim & Objectives

To assess the combined effect of Indian Classical *Raga Ahirbhairav* and *Hindol* along with *Nisha Amalaki Churna.*

Material & Methods

Study Design: The study was Clinical study.

Selection of the Patients

Study was designed with 60 patients (n=30 in each group). But only 48 patients were registered for study. Patients were selected by purposive sample technique from the OPD of Department of *Swasthavritta* and *Kayachikitsa* of Pt. Khushilal Sharma Govt. Ayurveda College, Bhopal and then divided in two group in equal number.

Ethical Clearance

The proposed clinical study was presented in the form of a synopsis before the Institutional Ethics Committee dated on 28/05/ 2016. The clinical trial started after the approval from Chairman of Institutional Ethics Committee.

Diagnostic Criteria

Blood pressure level Systolic Blood Pressure between 120-139 mmHg or Diastolic Blood Pressure between 80-89 mmHg based on the average of two or more blood pressure readings taken on separate occasions as recommended by JNC VII. (9)

Inclusion Criteria

- The Male patients between the age 18 years to 45 years.
- The patient's those blood pressure level found between Systolic blood pressure- 120-139 mm of Hg and Diastolic blood pressure-80-89 mm of Hg as recommended by JNC VII.

Exclusion Criteria

- Patient having BMI more than 35
- Patients having any type of hearing and speech defect.
- Patient having any severe mental and physical ailment.

Grouping and Posology

Study was designed with 60 patients (n=30 in each group). But only 48 patients were registered by purposive sample technique in study. All registered 48 patients then were randomly divided into two groups (*n* = 24 each). An informed consent from each patient was obtained before starting the treatment. 41 patients were completed the course of treatment and 7 patients of group A were discontinued the study because 04 patients were moved to other city for long period and 2 patients got transfer to long distance area from research centre so was not able to attend daily raga session and 01 patient got serious accident.

Group A - group A patients were treated with 2 *Ragas, Raga Ahirbhairav* and *Raga Hindol* and *Nisha Amalki Churna* orally. Patients were advice to do *sukshma vyayama* for 10 mints before *Raga* therapy. Then were advised to lie down in *Shavasana* position. After that, in a peaceful room daily in the morning *Raga Ahirbhairav* and *Hindol* simultaneously each for 15 mints in soft volume were played through headphone. *Nisha Amalki Churna* was given orally with luke warm water in the dose of 6 gm bid daily.

Group B - this group Patients were advised to take 6 gm *Nisha Amalki Churna* orally in bid dose with luke warm water daily.

Study Duration: 45 days for both groups.

Drug Preparation: *Nisha Amalaki Churna* was prepared in the college pharmacy of Pt. K.L.S. Govt. Ayurvedic College, Bhopal.

Criteria for assessment

Blood pressure level (SBP 120-139 mmHg or DBP 80-89 mmHg) was assessed by as recommended by JNC VII. And associated symptoms Headache was self-assessed by Numeric Rating Scale (NRS) (10) and associated risk factors such as stress was assessed by Perceived Stress Scale (11), Anxiety was assessed by GAD-7. (12) The observations were recorded and presented in tabulation form and results were analyzed statistically by applying Paired t test, Unpaired t test, Wilcoxon matched-pairs signed-ranks test, Mann- Witney U-statistic test.

Observations

In the present study total 48 patients of pre-hypertension were registered, out of which 41 patients completed the course of treatment and 7 patients in group A were discontinued before completion of treatment course due to their personal cause. In study maximum 50% patients were found prehypertensive between the age group of 32-38 years. 100% male were registered because this study was planned with only male subjects. 52.08% patients were doing clerical work. 66.66% of patients had positive family history of hypertension, 41.66% patients had disturbed sleep, 58.33% of patients were found to be Alcohol addicted. 47.91% of patients were found addicted to smoking, while 27.08% of patients were found addicted with tobacco chewing, 43.75% patients were having *Vishama Agni,* 47.91% patients were taking mixed diet, 62.5% patients were insufficiently active and 31.25% patients were leading completely inactive life, 62.5% patients were having 25.0-29.9 range of BMI. Waist hip ratio of maximum 45.83% patients were belongs to between 0.91-0.95, Abdominal girth of 43.75% patients were found between 100-120 cm, 52% patients were complaining only mild headache whereas 29% patients were complaining of body ache. 75% patients were expressing anxiety while 81% were expressing stress.

Results

Table No.1 - Effect of the Therapy on Blood Pressure

B.P.	Group	Mean		MD	SD	SE	Paired t test	p value
		BT	AT					
Systolic B.P.	**A** (n=17)	135.50	120.76	14.74	5.495	1.333	t=11.432	p<0.0001, ES
	B (n=24)	135.38	131.25	4.125	1.676	0.3422	t=12.056	p<0.0001, ES
	Unpaired t test, t= 9.353 , p <0.0001 ES							
Diastolic B.P.	**A (n=17)**	88.61	79.706	8.904	4.280	1.038	9.047	p<0.0001, ES
	B (n=24)	88.292	84.542	3.750	1.824	0.3723	t=10.073	p<0.0001, ES
	Unpaired t test, t = 5.781, p <0.0001 ES							

BT: Before Treatment, AT: After Treatment, MD: Mean difference, SD: Standard Deviation, SE: Standard Error, n: Number of patients, ES: Extremely Significance.

Effect on Systolic B.P.- In group 'A' the mean score of Systolic B.P. had decreased from 135.50 to 120.76 whereas in group B the mean score of Systolic B.P. was decreased from 135.38 to 131.25 that was statistically found extremely significant (p <0.0001) in both groups.
Effect on Diastolic B.P.- In group 'A' the mean score of Diastolic B.P. had decreased from 88.61 to 79.706 whereas in group B the mean score of Diastolic B.P. had decreased from 88.292 to 84.542 that was statistically found extremely significant (p <0.0001) in both groups.

Effect on Associated Symptoms-Headache was self-assessed by Numeric Rating Scale (NRS).

Table No.2 - Effect of the therapy on the Mild Headache

Symptom	Group	Mean		% Relief	MD	SD	SE	Wilcoxon matched-pairs signed-ranks test	p value
		BT	AT						
Headache	**A** (n=17)	1.647	1.118	0.5294	31.94	0.5145	0.1248	w=45.000 n=9	p=0.0039
	B (n=24)	1.708	1.417	0.2917	17.07	0.04643	0.09478	w=28.00 n=7	p=0.0156
	Mann- Witney U-statistic= 167.50, p=0.3285 p>0.05 NS								

BT: Before Treatment, AT: After Treatment, MD: Mean difference, SD: Standard Deviation, SE: Standard Error, W: Wilcoxon matched-pairs signed ranks test, n: Number of patients.
Relief observed in Group A on mild headache was 31.94% with p<0.01 whereas in Group B relief was 17.07% with p=0.05.

Effect of therapy on Associated Risk Factor

Table No. 3 Effect of therapy on Anxiety- (Anxiety was assessed by GAD 7)

Risk factor	Group	Mean		% Relief	MD	SD	SE	Wilcoxon matched-pairs signed-ranks test	p value
		BT	AT						
Anxiety	**A** (n=17)	2.083	1.176	1.118	52.67	0.4851	0.1176	W=136.00 n=16	p=0.0001 ES
	B (n=24)	1.750	1.625	0.1250	7.14	0.3378	0.06896	w=6.000 n=3	p=0.250 NS
	Mann- Witney U-statistic = 33.50, p <0.0001 ES								

BT: Before Treatment, AT: After Treatment, MD: Mean difference, SD: Standard Deviation, SE: Standard Error, W: Wilcoxon matched-pairs signed ranks test, n: Number of patients, ES: Extremely Significance, NS: Not significant.

Relief observed in group A on Anxiety was 52.67% with p<0.0001, whereas in group B relief was 7.14% (p>0.05).

Table No. 4 Effect of Therapy on Stress - (assessed by Perceived Stress Scale)

Risk factor	Group	Mean		MD	% Relief	SD	SE	Wilcoxon matched-pairs signed-ranks test	p value
		BT	AT						
Stress	**A (n=17)**	2.042	1.294	0.7059	34.56	0.4697	0.1139	W=78.000 n=12	p=0.0005 ES
	B (n=24)	1.833	1.708	0.1250	6.81	0.3378	0.06896	w=6.000 n=3	p=0.250 NS
	Mann- Witney U-statistic = 85.500, p =0.0015 p<0.01 VS								

BT: Before Treatment, AT: After Treatment, MD: Mean difference, SD: Standard Deviation, SE: Standard Error, W: Wilcoxon matched-pairs signed ranks test, n: Number of patients, ES: Extremely Significance, NS: not significant.
Relief on stress in Group A was reported 34.56% with p<0.0001, and in Group B relief was 6.81% (p>0.05).

Comparative effect of therapy

The Mean difference in Systolic B.P. in Group A was recorded 14.74 And in group B was recorded 4.13 while, and difference in Diastolic B.P. in group A was reported 8.904 and in group B, 3.750 respectively. This result indicating the decrease in Systolic and Diastolic B.P. in Group A was more than Group B.

Discussion

Prehypertension reported in those were in stress, anxiety and had insufficient sleep because of increased sympathetic drive. In present study 75% patients were expressing anxiety, while 81% patients were expressing stress and 41.66% patients had disturbed sleep. Normally, sympathetic nervous system increased the heart rate and parasympathetic nervous system decreases the heart rate and stroke volume. Hence, by controlling the sympathetic stimulation and uplifting the parasympathetic stimulation, cardiac output and blood pressure can be decreased. Studies reported listening to soft music is an effective method of relaxation as it shifts the autonomic balance toward parasympathetic activity. (13)

Probable Mode of Action of *Raga* Therapy

Various studies indicating that practicing *Nada Yoga* (use of music, vocal toning and verbal or silent repetition of sacred *Mantra)* increases inner peace and decreases stress because the energy of sound that helps to heal physical, mental, emotional and spiritual bodies. Indian classical music which is based on *ragas* are arranged in specific notes have specific pitch and tone hence, each *raga* produces a specific frequency sound and generates particular vibration which shows significant effect on diseases, improve mental health, do relaxation as alpha waves which develop during early meditation also observed during *raga* therapy. (14)

Might be because of these effect of *Raga* on body, in present study group A (*Raga Ahirbhairav*, *Raga Hindol* and *Nisha Amalki Churna*) prehypertensive patients were got more significant effect on Systolic and diastolic blood pressure, anxiety and stress compare to drug group alone. The mean score of Systolic B.P. had decreased from 135.50 to 120.76 (Mean difference 14.74) with extremely significance ($p < 0.0001$) compare to group B (only *Nisha Amalki Churna* orally) and mean score of Diastolic B.P. had decreased from 88.61 to 79.706 (Mean difference 8.904) with extremely significant ($p < 0.0001$) compared to group B. Also, relief in mild headache was observed 31.94% with $p<0.01$ in Group A while only17.07% relief ($p=0.05$) reported in Group B, relief in Anxiety was reported 52.67% with $p<0.0001$ in group A while in group B relief was reported 7.14% ($p>0.05$). Relief on stress was reported 34.56% ($p<0.0001$) in Group A, while only 6.81% ($p>0.05$) relief in Group B.

Similar effect was reported in study conducted with 20 minutes instrumental session of *Raga Todi* of Hindustani Classical Music for 30 days duration by lowering in systolic blood pressure by 6.1 mmHg and diastolic blood pressure by 5.7 mmHg and, pulse rate and respiratory rate showed significant ($p < 0.001$) decrement in healthy/ asymptomatic subjects exposed to music therapy. (Samarpita Chatterjee et al., 2020).(15) Jawaharlal Nehru Medical College, Belgaum, showed that 20 minutes daily *Raga Todi* for 30 days along with their regular medication was effective in lowering the blood pressure in adults (age > 40 years) of both sexes having essential hypertension (Kamat-Nadkarni, 2013). (16) Kulkarni and Chittapur, (2017) also recorded significant lowering of blood pressure on exposure to long term raga therapy in chronic hypertensive patients. (17) Kunikullaya et al., (2016) conducted a three month study with raga *Bhimpalas* among prehypertensives or stage I hypertensives, along with lifestyle modification and reported decrement in blood pressure.(18) A Sri Lankan study found that listening Hindustani Classical Music for certain duration in healthy individuals (between 45 and 65 years aged male and females) effectively improved cardiovascular and respiratory health, evaluated in terms of SBP, DBP, Pulse rate and Breathing rate (Siritunga et al., 2013).(19) Lakshmi and Bhushan (2015) conduct a study on elderly adults of Chennai, Tamil Nadu , administered music therapy using *Raga Malkauns* for a time period of 22 minutes, in the evening for 30 days. Result of the study was found to be significantly effective in lowering blood pressure.(20) Sobna et al., (2013) conducted study with music therapy intervention (listening *Ahir Bhairav* using earphones for 20 minutes per day) for 40 days, among pre-hypertensive male (aged 35-40) adults and reported significant reduction in the blood pressure.(21) Nagarjan et al., (2015) reported, *Raga Bhupali*, found to be useful for lowering heart rate and modulating other cardiac regulation factors by lowering the sympathetic activity and raising the vagal tone.(22)

Baumgartner T, Lutz K, Schmidt CF, in the study indicating that music very efficiently arouse and modulate emotions as well as moods. (23,24,25) This impact of music on emotions and heart activity are due to several pathways transmitting information into the cardiac nerve plexus, such as autonomic and endocrine pathways, blood pressure, and blood gases. (26) Also, cardiovascular afferent neurons provide information about blood pressure as well as the mechanical and chemical situation of the heart to autonomic nervous system.(27) Such sensory information modulates autonomic outflow and regulate the heart rate, blood pressure and respiratory rate. Study also indicating that listening to pleasant music specially provokes parasympathetic activity compared with a resting condition. (28) The significant decrease in Systolic and Diastolic blood pressure in Group "A" prehypertensive patients indicating the marked increase in parasympathetic activity after the raga therapy in the present study.

Probable Mode of Action of *Nisha Amalaki Churna* Therapy

It is established that Hypertension is associated with increased vascular oxidative stress because of vascular smooth muscle cell proliferation and hypertrophy and collagen deposition, leading to thickening of the vascular media and narrowing of the

vascular lumen. Increased oxidative stress may damage the endothelium and impair endothelium-dependent vascular relaxation and increases vascular contractile activity. (29)

Studies indicating that higher consumption of nutrients with antioxidant capabilities has been reduced the frequency of morbidities or mortalities associated with oxidative stress. Thus, the use of antioxidant can prevent or control prehypertension. In *Ayurvedic* classics combination of equal quantity of *Haridra* and *Amalki* called *Nishaamalki churna*. (30) *Haridra* (turmeric) and *Amalaki* (*Emblica officinalis*) are having potent anti-oxidant activity due to phytochemicals compounds like Gallic acid, ellagic acid, emblicanin A & B, phyllembein, quercetin and ascorbic acid. Curcumin a natural polyphenol is found in the rhizome of turmeric (*Curcuma longa L.*). Experimental studies suggested that Curcumin has been shown to improve systemic markers of oxidative stress including plasma activities of SOD and catalase, as well as serum concentrations of glutathione peroxidase (GSH) and lipid peroxides. (31) It also prevent from various free radicals, such as reactive oxygen and nitrogen species (ROS and RNS, respectively). (32) In vitro study also revealed that an aqueous extract of *Amla* fruit in hepatocyte cell line (HepG2) reduced oxidative stress by attenuating level of lipid hydroperoxide, ROS, increasing the levels of antioxidant enzymes such as GSH, glutathione reductase, glutathione S-transferase, glutathione peroxidase. (33).

Conclusion

Group A, *Raga Ahir Bhairav and Hindole* along with *Nisha Amalaki Churna* were found more effective compare to group B treated with alone *Nisha Amalki Churna* in the management of pre-hypertensive patients. It may be because the combined effort of Raga therapy along with *Nisha Amalaki Churna* were able to reduce the oxidative stress and marked increased in Parasympathetic activity by affecting autonomous nervous system in the Prehypertensive patients. Thus, in Raga Therapy could be established alone or with combination of certain rejuvenate drugs as preventive tool and as therapeutic in the treatment of Hypertension which could be safe and cost effective also.

Conflict of Interest --- Nil

Acknowledgment- Nil

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