



## **Impact of Shirodhara Treatment and Sodium and Calorie-Restricted Diet on Structural Vascular Changes in Known Hypertensive Cases**

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### **ABSTRACT :**

**Background:** One of the risk factors for cardiovascular disease that can be modified is hypertension. Prehypertension affects about 20% of the population, and hypertension affects almost 40% of the adult population. Shirodhara is an Ayurvedic treatment strategy using Panchakarma.

**Aim:** This study evaluated the effect of Shirodhara and sodium and calorie-restricted diet on elevated blood pressure and nocturnal dipping in elderly patients with Hypertension.

**Results:** The values of BMI, DBP, and SBP along with nocturnal dipping of all patients, were improved after 12 weeks of intervention. BMI, DBP, and SBP were clinically as well as statistically significant. Allopathic dependency was also reduced to a greater extent.

**Conclusion:** The findings of our study suggest that Shirodhara Panchakarma treatment and restricted diet programs were effective for patients with Hypertension. Nocturnal dipping is a proxy for structural vascular changes and our study on better nocturnal dipping points to the possibility of reversing the structural vascular abnormalities that cause high blood pressure. Also, it significantly reduces the allopathic dependency of patients, which is an added benefit.

**Keywords:** Nocturnal dipping, Blood pressure, Hypertension, Shirodhara

### **1. Introduction :**

Hypertension is one of the modifiable risk factors for cardiovascular disease (Fuchs & Whelton, 2020). The precise measurement of high blood pressure and its treatment play a critical role in managing hypertension (Yano & Kario, 2012). Blood pressure (BP) follows a circadian rhythm with being lower at night as compared to the BP during the day (Huang et al., 2021). Night-time BP can only be measured by ambulatory blood pressure monitoring (ABPM). ABPM will record the 24-hour BP thus helping us understand the diurnal BP rhythm and circadian fall in the nocturnal BP (Huang et al., 2021; Yano & Kario, 2012).

The fall in the night time blood pressure is expressed as a percentage and is calculated by measuring the difference in the mean systolic pressure during the day and night (Bloomfield & Park, 2015). This nocturnal fall in BP is known as the “dip” and was first coined by O’Brien et al in 1988 (Bloomfield & Park, 2015; Huang et al., 2021). A nocturnal dip of 10 to 20% is considered normal. However, a dip of less than 10%, also known as blunted or absent, is considered a risk factor for a cardiovascular event (Bloomfield & Park, 2015).

Lifestyle modification is an easier and more cost-effective process for the management of hypertension as compared to pharmacologic interventions. Dietary modifications form a vital part of lifestyle modification strategy. Dietary restrictions such as low sodium and high potassium, low carbohydrate, and protein-rich diet with a restricted calorie intake promote weight loss, which is further reflected in lowering blood pressure (Bazzano et al., 2013).

Ayurveda comprises treatment strategies that help restore equilibrium through several techniques such as Shirodhara, panchakarma, and diet modifications. The ayurvedic treatment acts as an add-on therapy, providing maximum benefit (Sane, 2019; Sane et al., 2017). With this backdrop, the present study demonstrated the efficacy of Shirodhara, panchakarma, and sodium and calorie-restricted diet on structural vascular changes in known hypertensive cases.

### **Material and Methods :**

#### **Ethics:**

This study was approved by the Institutional Ethics Committee. Written informed consent was obtained from all the participants. The study was registered with CTRI retrospectively. The study procedures followed are by the ICMR’s Ethical guidelines for biomedical and health research on human participants (2006 & 2017)

### 1.1. Study design and duration:

This observational study was conducted from Jan 2019 to Nov 2020 for 90 days at Madhavbaug clinics in Maharashtra, India.

**1.2. Inclusion criteria:** Patients of either gender with a clinical diagnosis of Hypertension aged 18 to 75 were recruited for the study.

**1.3. Exclusion criteria:** Patients below 18 and above 75 years were excluded from the study. No pregnant and lactating women were included in the study.

### 1.4. Study methodology:

All eligible patients underwent Shirodhara, Panchakarma therapy, and a sodium and calorie-controlled diet for 90 days. The word Shirodhara is derived from two Sanskrit words Shir-meaning head and Dhara meaning flow. It involves the process of pouring a liquid (oil/water) over a person's forehead. It provides complete mental relaxation and is often combined with a head/scalp massage. It induces calmness and helps reduce stress.

### 1.5. Restricted diet Program (Sane, 2018) –

All the patients followed a diet of high potassium, low sodium, low calorie, high fiber, moderate protein, and moderate fats. The products included in the diet kit were daal pre mix, fortified atta, stress relief herbal tea, instant soup, dehydrated sprouts, soy granules upma, and ghavan mix. Nocturnal dipping, Body mass index (BMI), systolic blood pressure (SBP), diastolic blood pressure (DBP), and concomitant medications were noted at baseline and after 90 days of treatment. SBP and DBP were also measured at night to calculate the nocturnal dipping.

### 1.6. Statistical analysis:

The study data were analyzed using descriptive and inferential statistics. The normality of the continuous data was checked using Kolmogorov – Smirnov test. Continuous data (age, weight, BMI, SBP, DBP) was presented as mean  $\pm$  standard deviation (S.D.) while categorical data (use of medications) was presented as numbers and proportions.

A between-group ANOVA was performed to determine the endpoints' change at baseline, Day 30, Day 60, and Day 90. All statistical analyses were performed using ANOVA with the help of MS Excel.

## 2. Results :

A total of n=53 hypertension patients were enrolled in the study. Of these, n=33 (62.3%) were males while n=20 (37.7%) were females. The mean age of the study population was  $50.85 \pm 10.7$  years. The baseline SBP was  $120.76 \pm 11.65$  mm of Hg and the DBP was  $75.87 \pm 8.89$  mm of Hg which improved to SBP  $120.15 \pm 10.19$  mm of Hg and DBP  $74.77 \pm 7.19$  mm of Hg after the treatment.

**Table 1: Effect of Shirodhara and Panchakarma on the study endpoints**

Variable	Before treatment	After treatment	p-value
BMI (kg/m <sup>2</sup> )	27.38 $\pm$ 3.60	25.31 $\pm$ 3.02	0.01
Day SBP (mm of Hg)	121.02 $\pm$ 11.50	121.11 $\pm$ 10.45	0.97
Day DBP (mm of Hg)	76.17 $\pm$ 9.06	75.38 $\pm$ 7.58	0.63
Night SBP (mm of Hg)	116.85 $\pm$ 13.77	113.55 $\pm$ 11.83	0.19
Night DBP (mm of Hg)	71.90 $\pm$ 9.20	69.98 $\pm$ 8.09	0.26
Nocturnal Dipping	-3.51 $\pm$ 5.62	-6.07 $\pm$ 8.03	0.004981

**BMI – Body mass index, DBP - Diastolic blood pressure, SBP - Systolic blood pressure**

**Table 2: Effect on white coat hypertension**

	Patients with White Coat Hypertension	Total Hypertensives	% White Coat Hypertensives
Before treatment	21	51	41.18
After treatment	11	51	21.57

**Table 3: Reduction of allopathic medicines**

Allopathic medicine	Before treatment	After treatment	Medicine Reduction in %
beta-blocker	21	3	-85.71
ACE inhibitor	2	0	-100.00
CCB	23	0	-100.00
hydrochlorothiazide	8	0	-100.00
ARB	58	4	-93.10
diuretic	17	0	-100.00
alpha and beta blocker	3	2	-33.33
alpha-2 agonist	1	1	0.00

ACE - Angiotensin-converting enzyme, ARB - Angiotensin receptor blockers, CCB - Calcium channel blockers

### 3. Discussion :

Worldwide, Hypertension is the major cause of cardiovascular mortality. The troubling fact is that, especially in India, its prevalence is still rising at alarming rates. This is taking place despite the availability of many common medications like beta-blockers and diuretics, as well as recommendations for the treatment of Hypertension (Halligan et al., 1993).

The efficacy of Shirodhara Panchakarma and restricted diet programs in hypertensive patients were evaluated in this study. The study was conducted for 90 days with regular follow-ups. Significant changes were observed during the treatment. BMI, HR, and SBP of all patients were found to be reduced after the treatment. Also, the p-value was smaller. A similar analysis was done for Nocturnal Dipping and the results showed an improvement in values after the treatment.

The improvement in nocturnal dipping observed here suggests structural vascular alterations that cause increased blood pressure to be corrected. Nocturnal dipping is a surrogate metric for structural vascular changes. The absolute levels of overnight blood pressure and the magnitude of the nocturnal decrease in blood pressure—typically 10% and is referred to as "dipping"—are among the measures supplied by the ABPM and are reliable indicators of future cardiovascular events (Halligan et al., 1993). Blood pressure can be reduced when structural vascular alterations are made to correct the problem.

Also, increased BMI has been related epidemiologically to a rise in several disorders, including obesity, high blood pressure, heart failure, atrial fibrillation, etc. Along with SBP, DBP, and Nocturnal Dipping Panchakarma treatment and restricted diet programs caused a considerable (high statistically significant) decrease in BMI. As a result, it combats all Hypertension-related factors.

Patients with white coat hypertension were also reduced after 12 weeks of intervention. A sign of decreased hypersympathetic activity is a decrease in the incidence of White coat hypertension.

Another benefit of Shirodhara Panchakarma treatment and restricted diet programs, which we discovered in our study, was that it lessened patients' reliance on traditional drugs. This discovery is especially significant for populations like those in India, where unfavorable side effects and higher treatment costs significantly lower compliance and adherence, raising the risk of hypertension complications (Pangtey, R; Meena, 2016).

Despite all of these noteworthy good results of Shirodhara Panchakarma treatment and restricted diet programs, we advise further research with a bigger sample size and more extended follow-up periods so that the results of our study can be confirmed and extrapolated to larger populations.

### 4. Conclusion :

The findings of our study suggest that Shirodhara Panchakarma treatment along with restricted diet programs can serve as treatment for patients with Hypertension since it significantly improves Nocturnal Dipping, BMI, SBP, and DBP. Also, it significantly reduces patients' allopathic dependency, which is an added benefit. Online license transfer

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