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The effect of Shirodhara on essential hypertension: Systematic review and meta-analysis

Meenakshi Khapre, Dhanlika Dhanlika, Sriloy Mohanty, Amrita Mehndiratta

Abstract:

Essential hypertension, a common multifactorial condition, is a significant public health concern. In India, the prevalence of hypertension is high, with estimates indicating a rising trend. Shirodhara, an Ayurvedic therapy, has exhibited the potential for stress reduction and relaxation. Thus, the review investigates the effect of Shirodhara on systolic and diastolic blood pressure and its impact on clinical symptoms like palpitation, insomnia, giddiness, fatigue, and headache in essential hypertensive patients. We searched PubMed, Embase, Scopus, Google Scholar, and Shodhganga, Web of Science search for this systematic review and meta-analysis from inception to June 2023. Evidence from RCTs was synthesized as a standardized mean difference (SMDs) for systolic and diastolic blood pressure, comparing participants who received Shirodhara intervention along with Ayurveda medication and those who received only Ayurveda medication. The Revised Cochrane Risk of Bias tool for randomized control trials (RoB-2) was used for the quality assessment of randomized control trials. Analysis was done using Medcalc software. The comparison table is provided for the percentage of relief in clinical symptoms in both groups. Out of four RCTs, only three were included for quantitative analysis, which mentioned the mean and standard deviation of systolic and diastolic blood pressure. Meta-analyses revealed the effects of Shirodhara on systolic blood pressure (n = 100), the mean difference (MD) was – 1.257 mmHg, (2.660–0.145), I^2 = 89.3%, and diastolic blood pressure (n = 100) MD was – 0.40 mmHg, (–0.79–0.01) I^2 = 0. The percentage of relief in clinical symptoms was notably higher in the Shirodhara and Ayurveda groups than in the Ayurvedic drug group. Shirodhara lowered diastolic blood pressure significantly, but it has low clinical value. Shirodhara's effect on systolic blood pressure remained unclear. Relief in clinical symptom score was notable. Larger, well-designed research is needed to prove Shirodhara's effectiveness in hypertension management and optimize therapy methods.

Keywords:

Ayurveda, blood pressure, essential hypertension, meta-analysis, Shirodhara

Introduction

Essential, primary, or idiopathic hypertension is a multifactorial disorder caused by persistent chronic elevation of blood pressure in the arteries.[1] It is a chronic condition of a public health concern, as it is associated with the causation of coronary heart disease, stroke, and chronic heart disease.[2] According to WHO estimates, one in every eight deaths was caused by high blood pressure. Raised blood pressure accounts for 7.5 billion deaths of the total all causes of mortality annually around the globe.[3] It is anticipated to be increased to 1.56 billion adult hypertensive cases.[3] According to estimates, 17.6% of all people with hypertension live in India, which indicates that the burden of cardiovascular diseases will likely rise significantly in the near future.[4]

Essential hypertension is the most prevalent type, accounting for 95% of all hypertensive cases. Factors associated with increased blood pressure are obesity, high salt intake,

Additional Professor, Department of Community and Family Medicine, AIIMS, Rishikesh, Uttarakhand, India

Address for correspondence:
Ms. Dhanlika Dhanlika, MPH, Department of Community and Family Medicine, AIIMS, Rishikesh, Uttarakhand, India.
E-mail: dhanlika786@gmail.com

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stress, low potassium intake, low calcium intake, high alcohol consumption, aging, and insulin resistance.[5]

Modern society's leading silence killer is hypertension, along with its repercussions. Hypertension is a risk factor for a variety of disorders, including cardiovascular disease, stroke, heart failure, chronic renal disease, dementia, cancer, and osteoporosis.[6-8] Considering the idiopathic nature and chronicity of hypertension, both diagnosis and its management have a lot of impediments. Currently, the only successful management method for hypertension is antihypertensive medication therapy. Polytherapy has become the mainstay of treatment.[9]

Psychological stress may not be directly linked to hypertension; it does eventually lead to its development.[10] The effects of global urbanization, lifestyles that are sedentary, and a lack of physical activity and social support lead to anxiety, uncertainty, and eventually chronic mental stress. The main pathogenic mechanisms associating psychological stress with hypertension are changes in the neuroendocrine and immune systems.[11]

Shirodhara, a term from Sanskrit, joins "shira," meaning "head," and "dhar," representing "continuous flow." This traditional Ayurvedic therapy involves a gradual and steady stream of therapeutic oil directed onto the forehead of patients while they lie comfortably in the supine position.[12,13] Various liquids other than oil, like coconut water, buttermilk, or milk, as well as herbal concoctions, may be employed as needed. There are various kinds of Shirodhara, including Taildhara, Jaladhara, Thakradhara, and Ksheeradhara.[14] The precise duration of a full Shirodhara treatment was not stated in Indian Ayurvedic texts. However, different practices in India suggested that it was given for 3, 7, 14, or 28 days.[15] A constant stream of warm liquid applied to the forehead over an extended period may result in local peripheral vasodilatation.[16] Shirodhara enhances blood flow to various locations and aids in regulating the brain's blood supply. Combining vibration and warmth may improve thalamus and basal forebrain function, restoring normal serotonin and catecholamine levels.[12,17]

Shirodhara may have potential benefits for reducing stress and anxiety and promoting sleep.[16,18] An increase in alpha rhythm and a decrease in beta activity were observed in previous EEG investigations on Shirodhara, which is equivalent to deep meditation.[16] Shirodhara's calming effect may be attributed to the continuous flow of oil over the forehead, which sends afferent signals to the cerebral cortex, causing an altered state of consciousness and anxiolysis.[19]

Shirodhara may reduce hypertension through a variety of physiological methods. Active arterial vasoconstriction increases essential hypertension.[20] Shirodhara may cause a state of relaxation and concentration because of the continuous and rhythmic liquid pouring, which may promote the release of neurotransmitters like serotonin and acetylcholine. Even in trace levels, acetylcholine release may help lower blood pressure.[17]

Evidence on the effectiveness of Shirodhara intervention for essential hypertension management is still being determined. Less research has been done till now on how Shirodhara affects hypertension. Moreover, many of these trials had small sample sizes, making it challenging to reach firm conclusions about the therapy's effectiveness. The current investigation intended to provide a single, pooled estimate of the treatment's benefit. A comprehensive synthesis of existing studies could provide a more robust understanding of Shirodhara's effects on hypertension. Further, we included a broader range of study designs. This review could identify gaps in the current literature, paving the way for future research directions.

This systematic review aims to comprehensively examine existing scientific literature to evaluate the potential impact of Shirodhara (an ancient Ayurvedic therapeutic technique) on systolic and diastolic blood pressure in patients diagnosed with essential hypertension.

Study objectives

Among two groups of essential hypertensive patients receiving Shirodhara along with Ayurveda medication and only Ayurveda medication

1. To measure and compare systolic and diastolic blood pressure
2. To compare the percentage relief in clinical symptoms like palpitation, insomnia, giddiness, fatigue, and headache of essential hypertensive patients.

Materials and Methods

The study was registered on PROSPERO (CRD42020159533).

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines[21] to ensure a high level of evidence.

Data sources and strategy

We searched PubMed, Embase, Scopus, Google Scholar, Shodhganga, Web of Science, and Dhara (Digital Helpline for Ayurveda Research Articles) for this systematic review and meta-analysis from inception to December 2023. The brief search strategy consisted of intersecting keywords related to the intervention (Shirodhara) and main outcome (Blood pressure) [Table 1].

Table 1: Search terms for Shirodhara and hypertension

Keywords	Search term
Shirodhara	Shirodhara or shirodhar* OR shirothara OR shiroparisheka OR ayurvedic oil dripping therapy OR panchakarma OR tailadhara OR ksheerdhara OR takradhara OR kwatha dhara OR dugdha dhara OR jala dhara.
Hypertension	Essential hypertension OR Hypertension OR blood pressure OR high blood pressure OR raised blood pressure

The following Search strategy was employed

(((((((((primary hypertension) OR essential hypertension) OR high blood pressure) OR hypertensive) OR persistent high blood pressure) OR systolic blood pressure) OR diastolic blood pressure) OR raised blood pressure)) AND ((((((((((Shirodhara) OR Shiro dhar) OR Shirothara) OR Shiro seka) OR Shirodhara massage) OR Dhara) OR Parisheka) OR Shiro-paresheka) OR Panchakarma therapy) OR Ayurveda oil dripping therapy) OR Pancha Karma)

Selecting the studies

After removing duplicate records, titles, and abstracts from the database, the results were screened, followed by a full-text examination of possibly relevant abstracts against inclusion and exclusion criteria. Screening and full-text review were carried out separately in duplicate by two independent research authors (MK and DD) and then concluded by consensus of all authors.

Inclusion criteria

Randomized and non-randomized control trials, experimental studies, pre-post single group design, case studies or series and observational studies with Shirodhara as an intervention or as an adjunct therapy for essential hypertensive patients of age group 18–80 years with no other comorbidities were included. Language is restricted to English. No restrictions were made on eligible control groups. If two types of Shirodhara were used in the trial, then the results of both groups were pooled.

Exclusion criteria

Ayurvedic review articles on hypertension, studies on secondary hypertension with other comorbidities, and relevant animal studies were also eliminated. Duplicated publications reporting the same groups of participants were excluded.

Data extraction

Two independent authors MK and DD extracted the data from the paper based on characteristics of included studies and clinical outcomes (Systolic and diastolic blood pressure, clinical symptoms like palpitation, insomnia, giddiness, fatigue, and headache assessed using subjective severity scoring).

Quality assessment

The Revised Cochrane risk of bias tool for randomized trials (RoB-2) for randomized trials.[22] The risk of bias was assessed for observational study-pre-posttest design, using the tool by the National Heart, Lung, and Blood Institute (NHLBI), National Institute of Health (NIH), developed a set of specialized quality evaluation tools in 2013 to assist reviewers in focusing on aspects that are essential to the internal validity of a study.[23]

Statistical analysis

The primary outcome was to assess the effect of Shirodhara on systolic and diastolic blood pressure in hypertensive patients. Using the baseline and post-treatment sample sizes, means (M) and standard deviations (SD), standardized mean difference (SMD), and 95% confidence intervals (95% CI) were calculated to assess the difference in change in systolic and diastolic blood pressure between the Shirodhara intervention and comparison group. The I^2 consistency score was employed to characterize heterogeneity and assessed using the inverse variance model. High I^2 values (more than 75%) indicate high trial variability. Scores above 50% are deemed moderate, and scores above 75% indicate that random-effects model estimates should be considered.[24] The decision to report fixed or random effects data was based on I^2 heterogeneity. MedCalc® Statistical Software version 22.001 was used for the analysis. Percentage relief was calculated using a change in mean symptom severity scoring from baseline to after treatment in both groups.

Results

The review of the literature yielded 311 articles. Figure 1 depicts a full description of the selection procedure for the included articles using a P.R.I.S.M.A. flow diagram. The following are the results of studies conducted on hypertensive patients:

Characteristics of the studies

From the initial 475 identified studies, 459 were excluded based on removing duplicates. Based on the title and abstract, six studies were excluded as the studies were not relevant to the research question's aims and objectives. Additional studies were rejected after full-text review for the following reasons: review ($n = 1$) and conducted before 2012 ($n = 1$). Study designs varied with four randomized studies and one pre-post interventional study.

A total of five articles were included in the final review Table 2. Four of them were RCTs (160 Participants), and one was a pre-posttest study (30 participants). Out of four RCTs, only 3 RCTs were included for quantitative analysis as it mentioned the mean and standard deviation of systolic and diastolic blood pressure. One randomized

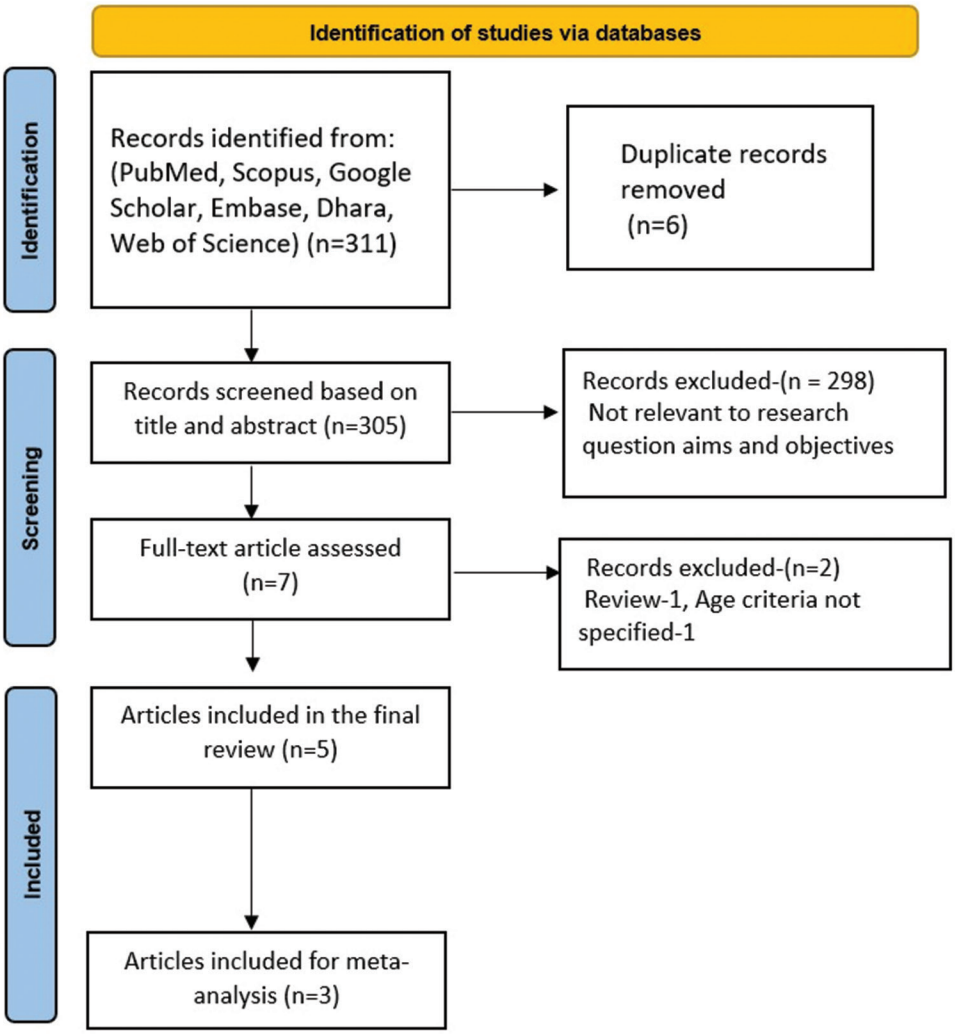

Figure 1: PRISMA flow diagram

control trial was excluded for sub-categorizing in mild, moderate, and severe hypertensive groups, and placebo and enalapril treatment were used for the control group. Pre- and post-comparable data on the effects of Shirodhara on systolic and diastolic blood pressure for both the comparison and intervention groups were used to determine inclusion. The meta-analysis investigated the effect of Shirodhara on blood pressure in three randomized controlled studies with 100 individuals.

Intervention

Table 2 depicts the main characteristics of the proposed Shirodhara interventions. No substantial differences were found in the administration of Shirodhara treatment. However, the duration varied from 10 to 14 days. The concoction used in Shirodhara treatment in five different studies were Takra amalaka, Triphala siddha jala, Mansayadi kwath, and Ksheerabala taila (oil), respectively.[25-29] Also, both the intervention group and control group received different Ayurveda medications Tagaradi Kwatha, Jatamansyadi Kwatha, Mansyadi Yoga, and Tab Arjin for 30–45 days. The follow-up was done on 15th, 30th, and 45th day.[26,27]

Quality assessment

For the randomized control trial, ROB-2 depicted an overall higher concern for the quality of the studies [Table 3]. For the pre-posttest study design, the assessment revealed fair quality [Table 4].

The forest plot of the three included studies illustrates the range of systolic and diastolic blood pressure observed in the analysis [Figures 2 and 3].

Meta-analyses revealed evidence for the effects of Shirodhara on systolic blood pressure (3RCTs, n = 100; the mean difference (MD) = −1.257 mmHg, confidence interval (CI) −2.660 to 0.145, P = 0.07; heterogeneity: $I^{(2)}$ =89.3%, $\chi^{(2)}$ =18.69, P < 0.00) and diastolic blood pressure (3RCTs, n = 100; mean difference (MD) = −0.40 mmHg, confidence interval (CI) = −0.79 to – 0.01, P = 0.04; heterogeneity: $I^{(2)}$ =0.00%, $\chi^{(2)}$ =1.33, P < 0.51).

Table 2: Characteristics of the included studies

Author/year	Study design	Sample size	Study population	Intervention description		Clinical outcomes and lab investigation
				Study	Control	
Preeti P *et al*. (2021)[25]	RCT	40	Clinically diagnosed hypertensive patients aged 18–70 years	Tagaradi Kwatha 10 gm BD for 30 days + Takra-Amalaki Shirodhara for 10 days	Tagaradi Kwatha 10 gm BD for 30 days	Headache, Fatigue, Giddiness, Insomnia, Palpitation, Systolic Blood Pressure and Diastolic Blood Pressure
C Vijay *et al*. (2021)[26]	RCT	20	Patients diagnosed with primary hypertension aged 20–80 years	Jatamansyadi Kwatha 50 ml (15 g) BD for 30 days + Shirodhara with Triphala Siddha Jalafor 10 days	Jatamansyadi Kwatha 50 ml (15 g) BD for 30 days	Systolic Blood Pressure Diastolic Blood Pressure
Gajraj V *et al*. (2020)[27]	Open-label RCT	40	Patient-diagnosed and confirmed cases of essential hypertension aged 18–60 years	Group B: Mansyadi Yoga 500 mg BD 45 days along with Mansyadi Kwath Shirodhara for 14 days.	Group A: Mansyadi Yoga 500 mg BD for 45 days.	Headache, Fatigue, Giddiness, Insomnia Palpitation, Systolic Blood Pressure, and Diastolic Blood Pressure
Author/year	**Study design**	**Sample size**	**Study population**	**Intervention description**		**Clinical outcomes and Lab investigation**
				Study	**Study**	
Bajaj G. *et al*. (2016)[28]	RCT	60	Essential hypertensive patients aged 20–70 years	Group I B: Mild HT Shirodhara Group II B: Mod HT Shirodhara (for 15 days) and Tagaradi with for two months Group III B: Severe HT Shirodhara (for 15 days) and Tagaradikwath with Enalapril for two months.	Group I A: placebo Group II A: placebo Group III A: Enalapril-5 mg (the dose titration was done as per the need of the patient)	Headache Fatigue Dizziness Systolic Blood Pressure Diastolic Blood Pressure
Pradeep BC *et al*. (2014)[29]	Pre-post test study	30	Essential hypertensive patients aged 30–70	Shirodhara (ksheerabala tail) for seven days, along with Tab Arjin for 30 days	NA	Systolic Blood Pressure Diastolic Blood Pressure

Table 3: Risk of bias using ROB 2

Study ID	D1	D2	D3	D4	D5	Overall
Preeti P *et al*. (2021)[25]	!	-	+	!	!	-
C Vijay *et al*. (2021)[26]	!	-	+	!	!	!
Gajraj V *et al*. (2020)[27]	!	+	!	+	!	-
Bajaj G. *et al*. (2016)[28]	!	+	!	!	!	!

D1: Randomization process, D2: Deviations from the intended interventions, D3: Missing outcome data, D4: Measurement of the outcome, D5: Selection of the reported result, +: Low risk, !: Some concerns, -: High risk

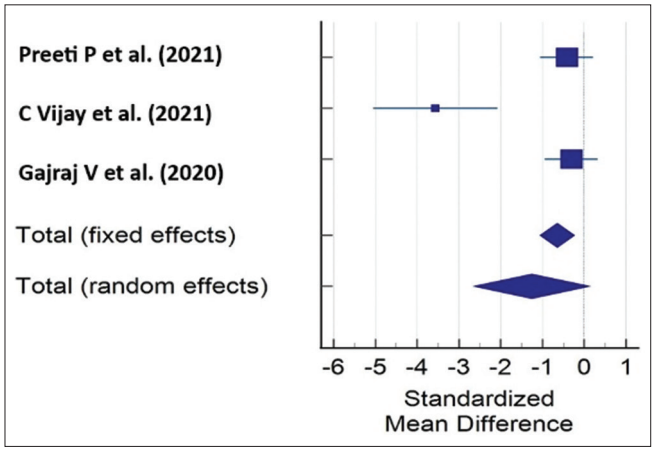

Figure 2: SMD for systolic blood pressure

The systolic and diastolic blood pressure of the two studies were not included in the meta-analysis.

Table 4: Quality assessment for observational study pre-posttest design study using NIH

Quality Assessment	1	2	3	4	5	6	7	8	9	10	11	12	Total
Pradeep BC *et al*. (2014)[29]	Y	Y	CD	NR	Y	Y	Y	N	N	Y	CD	CD	6/12 Fair

Y-YES, N-NO, CD-Can't Determine, NR-Not Reported. Quality Rating: Poor <50%, Fair 50–75%, Good ≥75%

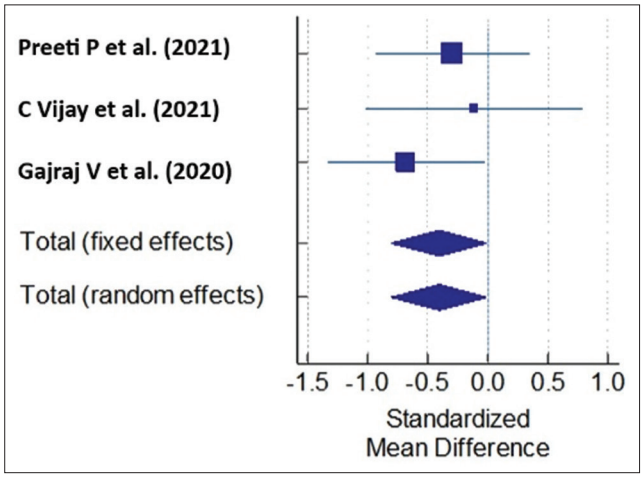

Figure 3: SMD for diastolic blood pressure

Pradeep BC *et al*.[29] conducted a pre-post study in 2014, revealing a significant decrease in systolic blood pressure by 14 mmHg on the 7th day, 22 mmHg on the 15th day,

and 24 mmHg after the treatment. Additionally, they observed a reduction in diastolic blood pressure by 9 mmHg on the 7th day, 12 mmHg on the 15th day, and 15 mmHg after the treatment. In a separate study by Bajaj G. *et al*. in 2020,[28] the application of Shirodhara intervention was associated with a substantial reduction in systolic blood pressure by 12 mmHg and a reduction in diastolic blood pressure by 7.14 mmHg.

Out of five [Table 5], three studies reported that the percentage of relief in headaches in the Shirodhara group was 60–75% compared to 26–53% in the control group. The percentage of relief in fatigue was 55–73%, compared to 53% in Shirodhara and the control group, respectively. Percentage relief in fatigue, insomnia, and palpitation was comparatively higher in the Shirodhara group compared to the Ayurveda group.

Discussion

The present meta-analysis investigated the effect of Shirodhara on blood pressure in three randomized controlled studies with 100 individuals. Systolic blood pressure dropped by about − 1.257 mmHg. However, there was no statistical significance (P = 0.07) and significant heterogeneity (I^2 = 89.3%) among studies. One study by C Vijay *et al*.[26] showed considerable deviation in Systolic BP due to heterogeneity. This deviation could be due to a smaller sample size and difference in methodology. Conversely, Shirodhara demonstrated a statistically significant reduction in diastolic blood pressure of about − 0.40 mmHg (P = 0.04) and low heterogeneity (I^2 = 0.00%). The results were backed up by Dhuri KD *et al*.;[16] their findings demonstrated a considerable drop in diastolic blood pressure alone with heart rate and breathing rate after Shirodhara intervention in healthy adults. However, another study found that Shirodhara treatment significantly lowered systolic and diastolic blood pressure.[30] The study by C Vijay *et al*. (2021),[26] compared to the other two RCTs, showed better improvement in systolic and diastolic blood pressure and reduced headache, fatigue, giddiness, and insomnia. However, it showed a larger deviation in systolic blood pressure, resulting in heterogeneity. The possible reasons could be the small sample size (n = 10, each group) and the difference in the age group that is 30% of the participants fell in the age group above 40 years, whereas in the other two RCTs, around 50% of participants were along to 40–60 years age group. Shirodhara may benefit young and middle-aged adults more than older adults. Arterial stiffness is a condition marked by decreased arterial wall flexibility and increased arterial wall rigidity. It results from degenerative cellular and structural changes brought on by aging. Because of the impaired artery's capacity to dilate and constrict in response to variations in blood flow, this increased arterial stiffness further complicates the efficient control of blood pressure. The complicated interactions between arterial stiffness and age-related degenerative changes highlight how sophisticated blood pressure regulation systems are as we age.

According to Xu F *et al*.,[31] the physiological impact of Shirodhara is caused by the somatic-autonomic reflex through thermos sensors and pressure sensors in the skin or hair follicles via the trigeminal cranial nerve. Shirodhara may affect adrenergic neurons by changing the processes connected to noradrenaline synthesis, storage, and absorption, according to the possibility of its alpha-adrenergic inhibiting impact.[32] Uebaba K. and colleagues saw Shirodhara treatment to cause a decrease in noradrenaline levels, which is suggestive of a known sympatholytic action. The correlation between the induction of an altered state of consciousness and the observed reduction in anxiety strengthens the association between the calming impact of Shirodhara and the modulation of anxiety through changes in consciousness states (r = 0.52, P < 0.05, N = 16).[19] Also, Shirodhara significantly increased alpha-wave activity in the frontal and parietal lobes of the brain, promoting relaxation and reducing anxiety.[16]

Many Studies showed significant improvement in clinical symptoms like giddiness, fatigue, insomnia, palpitations, headache, and breathlessness.[25-29] Shirodhara showed psycho-neuro-immunological benefits such as lowering noradrenaline levels, endorphin release, increased parasympathetic activity, stimulating circulation in

Table 5: Percentage (%) relief in clinical outcomes in participants who received Shirodhara along with Ayurvedic and Ayurveda medication

Studies	Headache (%)		Fatigue (%)		Giddiness (%)		Insomnia (%)		Palpitation (%)	
	Ayurvedic drug + Shirodhara	Ayurvedic drug only	Ayurvedic drug + Shirodhara	Ayurvedic drug only	Ayurvedic drug + Shirodhara	Ayurvedic drug only	Ayurvedic drug + Shirodhara	Ayurvedic drug only	Ayurvedic drug + Shirodhara	Ayurvedic drug only
Preeti P *et al*. (2021)[25]	65.9	53.3	55.5	52	54.5	50	66.6	56.6	52.6	50
Gajraj V *et al*. (2020)[27]	60.5	53.6	57.5	53.8	54.1	50	63.8	54	56.8	52.3
Bajaj G. *et al*. (2016)[28]	75.8	26.46	73	0	68.1	24.1	-	-	82.5	34.43

the skin's periphery, and enhancing natural killer cell numbers that is reducing inflammation.[19] According to case study findings, Shirodhara and BBT-I (brief behavioral therapy) have shown potential anti-stress, anxiolytic, and sleep-inducing benefits.[33]

Recent studies have incorporated a variety of herbal mixtures in Shirodhara therapy, a traditional Ayurvedic treatment. These mixtures include amalaka, Triphala siddha jala, mansayadi kwath, and ksheerabala oil, which has been used alongside other treatments to help control high blood pressure. Specifically, Shirodhara therapy was complemented with Tagara (Valeriana wallichii DC.) and Jatamansi (Nardostachys jatamansi DC.), both known for their calming properties by inhibiting GABA transaminase. This enzyme breaks down GABA neurotransmitters in the brain.[34,35] Additionally, Mamsyadi Kwatha, a blend of Jatamamsi (*Nardostachys jatamansi* DC.), Ashwagandha (*Withania somnifera* Linn.), and Parasika Yavani (*Hyocymus niger* Linn.).[36] has been recognized for its potential psychoactive and antidepressant benefits.[37] Another concoction, Ksheerabala, made from Sida cordifolia, cow's milk, and sesame oil, is noted for its antioxidant properties.[38]

Limitations and recommendation

The limited research on Shirodhara's impact on hypertension, characterized by small studies, potential biases, and brief follow-ups, highlights the need for a more rigorous investigation. The inconsistency in study designs, participant age, treatment protocols (duration, dosage, and Herbal concoctions), and outcome measures further complicates the evidence synthesis. Comprehensive research involving large-scale randomized controlled trials and extensive observational studies are essential to determine its clinical efficacy and safety.

Conclusion

We conclude that Shirodhara significantly reduces diastolic blood pressure by 0.40 mm (−0.01 to 0.79 mmHg), but not a clinically meaningful difference. We did not find a significant reduction in Systolic blood pressure in the Shirodhara group. There was more percentage relief of clinical symptoms that is headache, fatigue, insomnia, palpitation, and giddiness in Shirodhara adjunct to the Ayurveda drug compared to only the Ayurveda drug group.

This review offers insightful information on the effect of Shirodhara on hypertension. However, more thorough randomized controlled studies with bigger sample sizes are required to establish Shirodhara's effectiveness in the treatment of hypertension. Further research into the precise herbal mixtures and dosages used in Shirodhara treatments may aid in optimizing their effects.

Author contribution

Conceptualization: MK; Methodology: MK; Data curation: MK; Data Analysis MK, DD, SM, AM; Supervision: MK; Original draft DD, SM, AM; Editing and approval final draft: MK.

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Conflicts of interest

There are no conflicts of interest.

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