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ORIGINAL RESEARCH

A Clinical Study Examining the Impact of Transcendental Meditation and Amala Powder on Stage-1 Hypertension Patients' Systolic and Diastolic Blood Pressure

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ABSTRACT

This randomized clinical trial explores the effects of Amala powder (*Emblica officinalis*) and Transcendental Meditation (TM) on systolic and diastolic blood pressure in patients with stage 1 hypertension. Hypertension, a key risk factor for cardiovascular diseases, affects a significant portion of the global population. Non-pharmacological treatments such as herbal supplements and meditation practices offer potential alternatives to traditional antihypertensive medications. The study enrolled 90 participants and was divided into three groups: Group 1 received Amala powder, Group 2 practiced TM, and Group 3 combined both interventions over 3-months. Blood pressure, lipid profiles, and other cardiovascular markers were monitored throughout. Results demonstrated significant reductions in both systolic and diastolic blood pressure in all groups, with the most substantial improvements seen in Group 3, which combined both therapies. Additionally, Group 3 showed the greatest improvements in lipid profiles, particularly in increasing HDL cholesterol levels. These findings suggest that combining Amala powder and TM may offer a practical, holistic approach to managing hypertension and improving cardiovascular health.

KEY WORDS: Blood pressure, *Emblica officinalis*, Transcendental Meditation, Lipid profile, Non-pharmacological treatment, Cardiovascular health

INTRODUCTION

Hypertension is a significant public health and economic issue worldwide, with a high prevalence in developing and developed nations (Bromfield & Muntner, 2013; Lotfaliany *et al.,* 2015). Projections indicate that by 2025, 60% of adults will have hypertension (Kearney *et al.,* 2005). According to a systematic review conducted up to 2012, the overall prevalence of hypertension in Iran was approximately 22% (Mirzaei *et al.,* 2016). A subsequent systematic review in 2017 reported a prevalence of about 17% in Iran (Mohsenzadeh *et al.,* 2017).

Hypertension is a critical predictor of premature death and disability, significantly contributing to mortality and morbidity related to cardiovascular diseases and cerebrovascular accidents (Stamler *et al.,* 1993). In 2010, high blood pressure was identified as one of the top five or six leading risk factors for the Global Burden of Disease (GBD) worldwide, as measured by Disability-Adjusted Life Years (DALYs) (Lim *et al.,* 2010).

The World Health Organization (WHO) aims to reduce the prevalence of hypertension by 25% (Kontis *et al.,* 2015). Hypertension is the most common risk factor for cardiovascular diseases and death globally (Rosamond *et al.,* 2007). Despite the availability of various antihypertensive medications, the control of hypertension is reported to be between 6% and 30% in different populations (Kearney *et al.,* 2005). Many hypertensive patients turn to complementary medicine for various reasons (Ernst, 2005).

Several plants are used in herbal medicine and non-

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pharmacological methods to lower blood pressure; one is amala powder and transcendental meditation.

Amala *(Emblica officinalis)*

Emblica officinalis Gaertn (EO), also known as amala, belongs to the family Euphorbiaceae. It is a medium-sized tree indigenous to India and cultivated in Pakistan, Uzbekistan, Sri Lanka, Southeast Asia, China, and Malaysia. The plant is also referred to by other names, including "Phyllanthus emblica Linn", "Emblica pectinate Ridl", "Emblic myrobalan", and "Indian gooseberry" (Khan, 2009). In Iran, dried fruit is a commonly imported herbal product in herbal markets. Fresh amla fruits are green, sour, and about the size of a walnut, resembling small plums.

A systematic review by Hashem-Dabaghian *et al.* (2018) examined the cardiovascular effects of Emblica officinalis (EO). The review concluded that EO possesses several beneficial properties, including antiatherogenic, antihypertensive, anti-inflammatory, antioxidant, antiplatelet, vasodilatory, and lipid deposition inhibitory effects. Additionally, it enhances vascular endothelial function.

Bhatia *et al.* (2011) investigated the impact of EO on DOCA-salt-induced hypertension. In another study by Patel and Goyal, EO was evaluated in a rat model of diabetic-induced myocardial dysfunction, and its effect on high blood pressure was noted as a secondary outcome (Patel & Goyal, 2011).

Transcendental Meditation

It is widely accepted that attaining psychological relaxation can lead to a reduction in blood pressure in individuals with hypertension. In fact, stress reduction is frequently considered a crucial aspect of lifestyle modifications that can help lower elevated blood pressure in hypertensive patients (Patel & North, 1975). To mitigate the adverse health effects of hypertension, formal guidelines recommend lifestyle changes to safely lower blood pressure (BP) (Kjeldsen *et al.,* 2014). Effective strategies include weight loss, reduced sodium intake, limited alcohol consumption, and regular exercise. However, maintaining dietary strategies that emphasize a diet rich in fruits and vegetables and low in saturated fat can be challenging (Brook *et al.,* 2013). Beyond dietary changes, non-pharmacological treatments such as Transcendental Meditation (TM) are quickly adopted and can effectively reduce BP (Brook *et al.,* 2013).

TM is a meditation technique that focuses consciousness on repeating a word or phrase (mantra). This practice allows the typical thought process to quiet down, leading to a unique psychophysiological state known as "restful alertness" (Olex *et al.,* 2013). TM has been described as a "simple, natural, and effortless procedure," best practiced twice a day for twenty minutes while sitting comfortably with eyes closed (Nidich *et al.,* 2009; Schneider *et al.,* 2008). The standard Transcendental Meditation (TM) course the Maharishi Foundation provides includes introductory, preparatory, one-hour personal instruction and consecutive follow-up sessions over the next three days. After completing these sessions, students are expected to practice TM independently as part of their daily routine (Schneider *et al.,* 2008). The AHA scientific statement proposed that transcendental meditation (TM) could be considered to lower blood pressure in clinical practice. This suggestion comes after reviewing evidence from existing systematic reviews, meta-analyses, and recent clinical trials not included in the published reviews.

MATERIALS AND METHODS

Design of the study and inclusion, exclusion criteria

A randomized clinical trial has been selected for the study. The sample size for the present study was 90 patients, allocated in three different groups, 30 in each group. The inclusion criteria of the patients for the study were:

The age of the patients were not less than 30-years and not more than 60-years. Patients suffering from stage one hypertension without any other complications and attending the OPD of Ayurveda, Department of Kayachikitsa, SSH, IMS, BHU, Varanasi. The exclusion criteria for the present study are patients less than 30-years and more than 60-years. Patients having systolic blood pressure level <140 mm of Hg and > 159 mm of HG. Patients having diastolic blood pressure levels <90 mm of Hg and >99 mm of HG. Patients on corticosteroid therapy for other illnesses. Patients suffering from any systemic complications. Pregnant and lactating mother. The criteria for the withdrawal from the study. The chances of moving out of the location are migration and transferable jobs. Patients are already on therapy for other causes. Noncompliance of the patients. Being at high risk of possible adverse effects–Allergic to Amala powder.

Eligibility Criteria

Diagnosis of selected cases of HTN will be made based on JNC-8 criteria.

Ethical Consideration

After planning the Research plan proposal (RPP), the protocol was approved by the Institutional Ethics Committee, Institute of Medical Sciences, Banaras Hindu University, Varanasi, by order no. Dean/2022/EC/3598 on date 20/10/2022 at 3 pm. The trial was registered on the

Clinical Trials Registry- India (CTRI) website. The registration number of this trial is CTRI/2023/05/052809. Information consent was obtained from the three groups of participants in the trial.

Allocation Group

In the intervention group, the 90 diagnosed patients will get the following therapy after being randomly assigned to one of three groups-

In this clinical study, participants were divided into three intervention groups. Group A received Amala powder as the sole treatment, with a dosage of 3 grams once daily (OD) taken with normal water after meals for three months. This group focused solely on the effects of Amala powder, a well-known herbal remedy, on hypertension management. Group B underwent Transcendental Meditation (TM) as the intervention. The details of the TM practice, including the specific techniques used, are outlined in a supplementary table (Table 1). Participants in this group engaged in TM sessions for a period of three months, focusing on the relaxation and mental health benefits that TM may provide for controlling hypertension.

Group C, called the "Add-On Group," combined both interventions. Participants in this group received Amala powder at the exact dosage of 3 grams daily and practiced Transcendental Meditation for the same three-month period. This group aimed to explore the potential synergistic effects of combining a herbal intervention with a meditative practice in managing stage-1 hypertension.

The randomization method for assigning participants to these three groups was conducted using a computer-generated random allocation sequence. This ensured an equal distribution of participants across the three groups, with a ratio of 1:1:1. The randomized assignment helped to minimize bias and enhance the reliability of the study's results, allowing for a clear comparison of the effects of Amala powder, TM, and their combined use in the treatment of hypertension.

Protocol of Transcendental Meditation

The Transcendental Meditation (TM) Protocol, as outlined in Table No. 2, involves a daily routine that spans 20-minutes and is performed twice daily. The steps are as follows:

1. Preparation (01 minutes): Begin by sitting comfortably in a chair with a straight back and neck, ensuring your body is relaxed. Close your eyes gently.
2. Breathing (02 minutes): Focus on normal, relaxed breathing to ease into meditation.
3. Mantra Recitation (15 minutes): Silently recite the TM mantra, typically a meaningless vibratory word such as "Shirim." Repeat the mantra without focusing on a specific rhythm, allowing your thoughts to come and go without resistance. Don't focus on your breathing; just let the mantra guide your attention while maintaining calm.
4. Closing the Meditation (02 minutes): After 15-minutes, stop the mantra and allow yourself a few mantra-free moments to relax. Open your eyes gently and take a deep breath, easing yourself into regular consciousness.

Method

- Ensure you are seated comfortably with a straight back and neck.
- Keep your eyes closed throughout the practice.
- Choose a mantra and repeat it mentally without overthinking the process.
- Focus on the mantra, but allow any thoughts to pass without dwelling on them.
- If you experience moments of "transcendence" or restful alertness, let them occur naturally.
- After 15-minutes of meditation, spend 3-minutes slowly transitioning out of meditation before opening your eyes.
- This practice should be done twice daily for optimal results at times that suit your schedule.

This protocol aims to promote deep relaxation, mental clarity, and transcendental awareness.

Biochemical Assessment

Lipid Profile

A lipid profile, also known as a lipid panel, is a blood test that measures the levels of specific lipids in the blood. Lipids are fats and fatty substances in the blood, and their levels provide essential information about cardiovascular health and the risk of heart disease. A typical lipid profile includes the following components:

1. **Total Cholesterol:** Total cholesterol is the overall amount of cholesterol in the blood. It includes both "good" and "bad" cholesterol. High levels of total cholesterol can increase the risk of cardiovascular disease.
2. **Low-Density Lipoprotein (LDL):** Often called "bad cholesterol," LDL-C can build up in the walls of arteries, leading to atherosclerosis (hardening and narrowing of the arteries). High LDL-C levels are associated with an increased risk of heart disease and stroke.
3. **High-Density Lipoprotein (HDL):** Known as "good cholesterol," HDL-C helps remove excess cholesterol

from the bloodstream and transport it to the liver for excretion. Higher levels of HDL-C are protective against heart disease.

4. **Triglycerides (TG):** Triglycerides are fat found in the blood. Elevated levels can contribute to the hardening of arteries and increase the risk of heart disease. High triglycerides often accompany low HDL-C and/or high LDL-C levels.
5. **Very Low-Density Lipoprotein Cholesterol (VLDL-C):** VLDL-C is a type of lipoprotein that carries triglycerides through the bloodstream. It is considered another form of "bad cholesterol."

Importance of a Lipid Profile

A lipid profile helps assess an individual's risk for cardiovascular diseases such as heart disease, stroke, and peripheral artery disease. It is often used to guide decisions about lifestyle changes or medications, such as statins, to lower cholesterol levels.

Blood Pressure

A blood pressure (BP) reading consists of two numbers: systolic vs. diastolic pressure.

- **Systolic** blood pressure is the top number and refers to the amount of pressure experienced by the arteries while the **heart is beating**.
- **Diastolic** blood pressure is the bottom number and refers to the pressure in the arteries while the heart rests between heartbeats.

Table 1: JNC 8 New Hypertension Management Guidelines

Category	Systolic		Diastolic
Normal	<120	and	<80
Prehypertension	120-139	or	80-89
High Blood Pressure/ Hypertension			
Stage 1 Hypertension	140-159	or	90-99
Stage 2 Hyptertension	≥ 160	or	≥ 100

Table 2: Comparison of systolic blood pressure (SBP) before and after treatment.

GROUPS	SBP Mean ± standard deviation			
	Before treatment	F-I	F-II	F-III (after treatment)
Group 1	144.44 ± 7.673	139.93 ± 5.830	132.59 ± 24.095	136.00 ± 3.374
Group 2	147.03 ± 8.240	141.38 ± 7.984	135.72 ± 6.181	133.17 ± 4.885
Group 3	148.71 ± 8.133	140.43 ± 7.249	133.93 ± 7.149	128.50 ± 3.835
One-way ANOVA	F = 1.971 P = 0.146	F = 0.304 P = 0.739	F = 0.320 P = 0.727	F = 23.560 P = 0.000
Post hoc test				
I-II	-	-	-	p = 0.035
I-III	-	-	-	p = 0.000
II-III	-	-	-	p = .000
Within the comparison (group 1)		SBP paired t-test		
	Mean ± SD	t	p	
BT-FI	4.51 ± 4.282	5.483	0.000	
BT-FII	11.85 ± 27.366	2.250	0.033	
BT-FIII	8.44 ± 6.846	6.409	0.000	
Within the comparison (group 2)		SBP paired t-test		
	Mean ± SD	t	p	
BT-FI	5.65 ± 2.729	11.159	0.000	
BT-FII	11.31 ± 4.907	12.412	0.000	
BT-FIII	13.86 ± 6.116	12.205	0.000	
Within the comparison (group 3)		SBP paired t-test		
	Mean ± SD	t	p	
BT-FI	8.286 ± 6.365	6.889	0.000	
BT-FII	14.786 ± 7.490	10.446	0.000	
BT-FIII	20.214 ± 7.913	13.517	0.000	

Interview Technique

The consent forms were taken by the patients, and those were investigated through proforma.

Follow-ups

The follow-up was taken for 3-months. Initially, at the time of starting the intervention and at the time of ending the intervention after the treatment for 3-months, the lipid profile was noted. For systolic and diastolic blood pressure, the interventions were taken every month till the completion of three months. At the time of starting the intervention and ending it, after three months of treatment, anthropometric and biochemical were noted.

Statistical Analysis

Data analysis was done using IBM SPSS Statistics Version-21. The inter-group comparison will be done using the chi-square or Kruskal Wallis test, while the Wilcoxon signed rank test will be applied for intra-group (within the Group) comparison. For various objective clinical

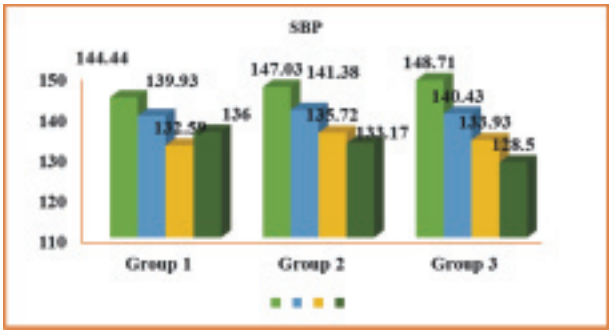

Fig. 1: Comparison of SBP before treatment and after treatment

Table 3: Comparison of diastolic blood pressure (DBP) before treatment and after treatment

GROUPS	DBP Mean ± standard deviation			
	Before treatment	F-I	F-II	F-III (after treatment)
Group 1	92.30 ± 3.495	88.59 ± 3.079	86.81 ± 2.497	85.85 ± 2.349
Group 2	94.55 ± 5.011	90.69 ± 4.080	87.03 ± 3.689	85.31 ± 2.941
Group 3	95.43 ± 4.614	89.36 ± 3.851	85.50 ± 4.168	80.43 ± 3.048
One-way ANOVA	F-3.633 P-.031	F-2.307 P-.106	F-1.552 P-.218	F-31.677 P-.000
Post hoc test				
I-II	-	-	-	p = 1.000
I-III	-	-	-	p = 0.000
II-III	-	-	-	p = 0.000

Within the comparison (group 1)		DBP paired t-test	
	Mean ± SD	t	p
BT-FI	3.70 ± 2.584	7.447	0.000
BT-FII	5.48 ± 3.215	8.859	0.000
BT-FIII	6.44 ± 3.389	9.880	0.000

Within the comparison (group 2)		DBP paired t-test	
	Mean ± SD	t	p
BT-FI	3.86 ± 3.204	6.491	0.000
BT-FII	7.51 ± 4.800	8.433	0.000
BT-FIII	9.24 ± 5.792	8.592	0.000

Within the comparison (group 3)		DBP paired t-test	
	Mean ± SD	t	p
BT-FI	6.07 ± 3.333	9.640	0.000
BT-FII	9.92 ± 5.429	9.677	0.000
BT-FIII	15.00 ± 4.505	17.618	0.000

(continuous) variables, mean and standard deviation will be determined for groups before treatment and after each follow-up. Between the groups, the comparison will be made using one-way ANOVA followed by a Post hoc test, whereas a paired t-test will be done for within-the-group comparison. A non-parametric test will be applied whenever the data do not satisfy the assumption of the corresponding parametric test. The *p-value* is considered for significance and non-significance in the statistical tests.

Observations

Out of 90 patients, 84 patients completed the study. In group A, out of 30 patients, 27 completed the study; in group B, 29 completed the study; and in group C, 28 patients were assessed for the study.

In the within-group analysis, significant reductions in systolic blood pressure (SBP) were observed across all groups throughout the different phases of the study. The t-tests for these comparisons revealed highly significant results, with most comparisons yielding a *p-value* of 0.000, indicating substantial improvements in SBP within each group after the intervention.

In the between-group analysis, the initial SBP levels (before treatment) did not show significant differences between the groups (F = 1.971, p = 0.146). However, after the treatment, a highly significant difference was found between the groups (F = 23.560, p = 0.000). This suggests that the interventions had differential effects on SBP, with certain groups experiencing more pronounced improvements than others.

In the within-group analysis, all groups demonstrated significant reductions in diastolic blood pressure (DBP) across different study phases. The t-tests for these comparisons yielded highly significant *p-values* (p = 0.000), indicating a substantial decrease in DBP within each group following the interventions.

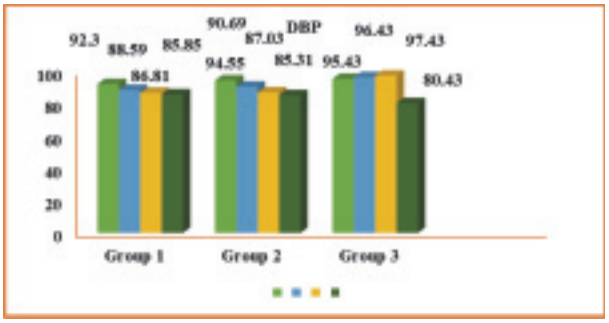

Fig. 2: Comparison of DBP before treatment and after treatment

In the between-group analysis, a significant difference in DBP was observed between the groups before treatment (F = 3.633, p = 0.031). However, this significance did not remain consistent in the later phases, suggesting that while initial differences existed, the interventions led to more uniform effects on DBP across the groups over time.

Table 4: Comparison of cholesterol before treatment and after treatment

Groups	Cholesterol		Within pair
	Mean ± standard deviation		
	Before treatment	After treatment	
Group 1	191.27±26.679	183.88±20.081	7.38±12.553 t = 3.055 p = .005
Group 2	183.50±29.871	175.51±20.981	7.98±16.006 t= 2.668 p= 0.012
Group 3	196.11±23.253	177.57±17.363	18.53±21.234 t = 4.620 p = .000
One-way ANOVA	F = 1.609 P = 206	F = 1.378 P = .258	

In the within-group analysis, all groups showed significant reductions in cholesterol levels following treatment, indicating that the interventions effectively lowered cholesterol within each group. However, in the between-group analysis, no significant differences in cholesterol levels were observed between the groups either before treatment (F = 1.609, p = 0.206) or after treatment (F = 1.378, p = 0.258). This suggests that while each group experienced improvements, the overall effect of the interventions on cholesterol was similar across the groups.

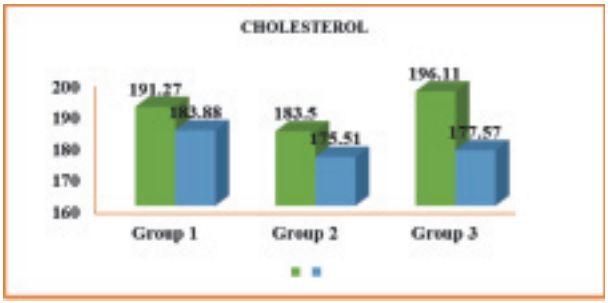

Fig. 3: Comparison of cholesterol before treatment and after treatment

Table 5: Comparison of HDL before treatment and after treatment

Groups	HDL		Within pair
	Mean ± standard deviation		
	Before treatment	After treatment	
Group 1	48.25±7.492	60.25±4.840	12.00±8.045 t = -7.755 p = 0.000
Group 2	50.70±8.094	63.53±4.206	-14.83±5.019 t= 15.640 p= 0.000
Group 3	49.66±23.253	64.50±4.392	-12.83±6.613 t = 10.454 p = 0.000
One-way ANOVA	F = 0.736 P = 0.482	F = 6.246 P = 0.003	

In the within-group analysis, all groups demonstrated significant increases in HDL levels following treatment, indicating positive outcomes in improving "good" cholesterol within each group. In the between-group analysis, significant differences emerged between the groups after treatment (F = 6.246, p = 0.003), with post hoc tests showing that Group 3 experienced significantly greater HDL levels than the other groups. This highlights a more pronounced effect of Group 3's intervention on boosting HDL levels.

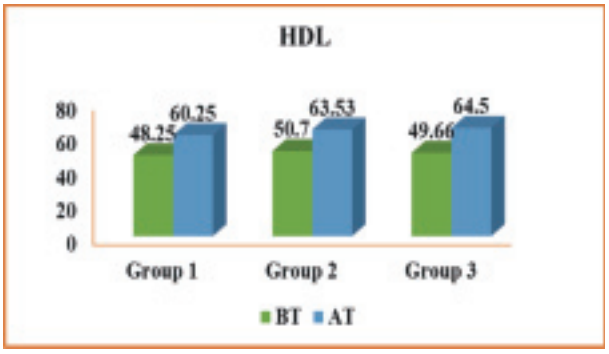

Fig. 4: Comparison of HDL before treatment and after treatment

DISCUSSION

The results of this study demonstrate the impact of different interventions—Amala powder, Transcendental Meditation (TM), and their combination—on various cardiovascular health indicators, such as systolic blood pressure (SBP), diastolic blood pressure (DBP), cholesterol, and high-density lipoprotein (HDL) levels.

In systolic blood pressure, all three groups exhibited a significant reduction in SBP following their respective interventions. This trend was consistent across the stages, particularly at the final measurement (F-III), where the reductions were most pronounced.

The interventions had varying levels of effectiveness across the groups. Group 3 demonstrated the most substantial decrease in SBP, followed by Group 2 and then Group 1. The significant differences observed between the groups after the final intervention indicate that the combination of amala powder and transcendental meditation was more effective in reducing SBP than in Groups 1 and 2.

The above findings were supported by a meta-analysis published by randomized, controlled clinical trials on the Transcendental Meditation technique's effects on blood pressure, finding a statistically significant impact in reducing systolic and diastolic blood pressure. They recommended the Transcendental Meditation technique to all cardiology patients. In NIH-sponsored research, the TM technique has been shown to reduce blood pressure as or more effectively than many conventional therapies, without side effects and with positive side benefits.

In DBP, all three groups experienced significant reductions in diastolic blood pressure (DBP) following treatment, with Group 3 showing the most substantial improvement. In Group 1, DBP steadily decreased across all phases, with significant differences observed only after the final intervention. Similarly, Group 2 showed consistent reductions, but significant differences only emerged in the last phase. Group 3, however, had the most significant reduction in DBP, especially after the final phase. Comparison between groups revealed significant differences in DBP only after the final phase, particularly between Groups 1 and 3 and Groups 2 and 3. The results suggest that 24 weeks of Transcendental Meditation practice significantly reduces DBP, a finding consistent with prior studies, including those on African Americans, and meta-analyses showing the benefits of TM on blood pressure.

As per Attique *et al.*, Previous studies have indicated that amala is highly effective in managing hypertension by helping maintain diastolic and systolic blood pressure within normal ranges and significantly reducing elevated levels. In addition to its effects on blood pressure, Indian gooseberry offers other health benefits, such as regulating blood sugar, protecting against kidney disorders, and reducing the risk of various cancers, including preventing the spread of cancer to other areas of the body. Most research on its effects involved administering the gooseberry in capsules, either in an aqueous solution or dried powder, two to three times daily after meals. Noticeable results typically appeared between the second and fourth weeks of treatment.

CONCLUSION

This study highlights the effectiveness of Amala powder, Transcendental Meditation (TM), and their combination in managing stage 1 hypertension by significantly reducing systolic and diastolic blood pressure and cholesterol and improving HDL levels. The combination of Amala powder and TM (Group 3) yielded the most substantial improvements across all parameters, indicating that these interventions work synergistically to enhance cardiovascular health.

While both Amala powder and TM were effective individually, the combined intervention led to more pronounced reductions in blood pressure and more significant improvements in lipid profiles, especially in HDL levels. These findings suggest that incorporating both Amala powder and TM into a holistic treatment plan could offer a robust, non-pharmacological approach to managing stage 1 hypertension.

RECOMMENDATION

Further studies could explore the long-term effects of these interventions and evaluate their potential for preventing more advanced stages of hypertension and cardiovascular diseases.

CONFLICT OF INTEREST

None.

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