

Effect of *Viscum album* 30 CH on pre-diagnosed vis-a-vis diagnosed hypertensive individuals

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Article History

Received: 08July2023

Revised: 29 Sept 2023

Accepted: 12 Oct 2023

ABSTRACT

Background: The World Health Organization considers hypertension the most common health problem in today's growing population. Studies show that the rate of primary hypertension is about 85-95% and the rate of secondary hypertension is only 5%. However, homoeopathy is used as an alternative in such cases (i.e., HTN) but it has good clinical results in cases of HTN. *Viscum album* is a circulatory remedy and has been observed to lower blood pressure by acting on the circulation in many cases, but very little research has been done to prove this. This study aimed to determine whether the homoeopathic medicine *Viscum album* is effective in reducing blood pressure in participants with essential hypertension. **Methods:** This was a monocentric, Phase 2 clinical trial, single arm, single blind, and randomized, interventional study conducted in the outpatient department of Homoeopathic Hospital & Post-graduate Research Centre of Bharati Vidyapeeth (Deemed to be University), Pune. A total of 40 participants (male and female) between the ages of 20 and 75 were enrolled in this study. Blood pressure was measured in the sitting position using a sphygmomanometer according to standard procedures. **Result:** The result was a decrease in blood pressure after 10-12 weeks of outpatient care. Significant reduction in blood pressure levels of hypertensive participants before and after treatment and in participants in remission. Of the 40 cases, Mean sBP before treatment is 150, in the same vein systolic blood pressure

CCLicense CC-BY-NC-SA 4.0	after treatment is 124.4; and Mean dBp before treatment is 94.9, where as in after treatment diastolic blood pressure is reduced with 79.2. The P-value is <0.0001. Conclusion: The homoeopathic medicine Viscum album produced a significant effect on lowering blood pressure levels in participants with essential hypertension. Further studies with control groups may provide a larger source of information to demonstrate that Viscum album is effective in the treatment of essential hypertension. Keywords: Hypertension; Systolic blood pressure; Diastolic blood pressure; Viscum album; Homoeopathy.
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INTRODUCTION

The World Health Organisation estimates that 1.28 billion persons aged 30 to 79 years have hypertension today, and it is a leading cause of mortality globally. According to studies, 46% of individuals with hypertension are ignorant that they have the illness, 42% of adults are diagnosed and treated, and 1 in 5 persons (21%) with hypertension has it under control. WHO sets a global objective of 33% reduction in noncommunicable illnesses between 2010 and 2030.¹

Viscum album (mistletoe) is a semi-evergreen partial parasite that grows on the branches of deciduous trees such as oak, chestnut, black poplar, elm, pine, apple, orange, etc.² *Viscum album*, a biennial shrub found throughout Africa, Asia, and Europe.³ Mistletoe is known by various names, including European mistletoe, Birdlime, all healing, mystylde, Devil's fuge, *Phoradendron serotinum*, Golden Bough, Muerdago, visco, *Gu'mil'ioc* (meaning heal all), 'Golden Branch' and others. Its fruit produces a sticky substance, hence the other name 'bird lime.' *Tapinanthus dodoneifolius* Danser, also known as 'Kauchi' in Hausa, is a species of African mistletoe with anthraquinones, saponins, and tannins.⁴ The main chemical composition of European mistletoe plants varies depending on the host plant, but generally includes glycoproteins, polypeptides (visco toxins), flavonoids, flavanol aglycones (the methyl ether of quercetin and kaempferol), lectins such as *V. album* agglutinin I, II and III, triterpenes, related saponins, CA acetyl choline, vitamin C, lignan acids, lectins, lignan acids, and lectins, resins, thionine, cardenolides and phenolic compounds. The decoction of the leaves was historically used to treat hypertension in and relieve symptoms such as headache, dizziness, palpitations, etc.² It is one of the main medicinal plants used in traditional African medicine to treat high blood pressure. The drug significantly reduces systolic and diastolic blood pressure, possibly by a mechanism involving overexpression of nitric oxide synthase-2 and nitric oxide synthase-3 and, consequently, by increased production of circulating nitric oxide and guanosine monophosphate.^{3,5,6}

MATERIALS & METHODS

All participants received the medication in 30 size globules and at the dosage of 3 globules for BD orally, with no water intake for at least 15-20 minutes. The drug was kept in the Bharati Vidyapeeth Homoeopathic Hospital Pharmacy in Katraj, Pune, in accordance with the norms of the Homoeopathic Pharmacopoeia of India, at the right temperature. The log number and batch number were kept. All participants were also requested to continue taking their medicine as recommended for the duration of the trial.

The study included participants enrolled in the outpatient department of the Homoeopathic Hospital and the Post-graduate Research Centre of Bharati Vidyapeeth (Deemed to be University), Pune. It is a monocentric, Phase 2 clinical trial, single arm, single blind, randomized, interventional research to evaluate how *Viscum album* works in hypertensive participants.

The experiment comprised 40 participants (both male & females) based on inclusion and exclusion criteria who wished to engage voluntarily in research. Participants were enrolled in the study only after signing the informed consent form. A case form was used to document the medical history and physical examination (including vital signs and systemic examination). Standard operating procedures were followed for taking blood pressure readings on the right arm using a manual sphygmomanometer while seated. Individuals with any systemic illness, a family history of mental illness such as anxiety or depression, or secondary organ damage from hypertension were barred from participating in the study. Participants in the study who have a direct link with, or are reliant on, the sponsor or research team (students, workers of the institution, close relatives) were not included.

Case Definition

Cases of both sexes presenting with symptoms of increased blood pressure levels in resting systolic BP (sBP) to 130 mm Hg or more and diastolic BP (dBP) 90 mm Hg or more with no identified reasons, ranging in age from 20 to 75 years.

Sampling procedure and follow up

Cases of hypertension at rest with systolic blood pressure of 130 mm Hg or higher and diastolic blood pressure of 90 mm Hg or higher without identifiable cause for both sexes in the age group of 20 to 75 years with no identifiable cause. Participants were only enrolled in the study after signing an informed consent form. Each case is followed for approx. 3 months. Each patient was followed up on for around two months. First follow-up after 7 days, then after 15 days or sooner if necessary. Any concurrent symptoms that arose throughout the therapy period were handled in accordance with the acute totality of the participants.

Inclusion criteria:

- Participants of both sexes and age group between 20 to 75 yrs.
- Patient below 130 systolic B.P. and below 90 diastolic blood pressure.
- The ability to give informed consent & comply with study procedures.
- Legal capacity.

Exclusion criteria:

- Participants who require emergency medical intervention or severe co morbidities.
- Patient without written consent.
- Limited communicative ability.
- Participants with any systemic illness.
- Participants with Congenital heart disease.
- Female patient who is pregnant or lactating mother.
- Participants above 130 systolic and above 90 diastolic blood pressure.
- Consumption of sedative medications.

- Person who are on antihypertensive medications, Allopathic medicine, Ayurvedic medicine and Homoeopathic medicine or any other medications.
- Simultaneous participation in other clinical studies or completion of participation in a study less than 6 months prior (participants are explicitly asked about this).

Assessment Criteria

Improvement Marked: When the reduction of blood pressure level is more than 10-20 mmHg.

Moderate: When the patient blood pressure level reduction is more than 6-10 mmHg.

Mild: When the patient blood pressure level reduction is less than 4-6 mmHg.

No Improvement: If there is no change in reduction level even after treatment.

Statistical Analysis:

Parameters	N	Mean ± SD	SEM	Min	25% Perce ntile	75% Perce ntile	Max	Median	P value	Mean of difference	
sBP (Before treatment)	40	150 ± 8.0	1.27	130	148	157	160	150	<0.0001 *	sBP before & after Rx	dBp before & after Rx
sBP (After treatment)	40	124.4 ± 2.8	0.44	120	122	128	128	124		25.55	18.3
dBp (Before treatment)	40	94.9 ± 3.9	0.72	90	94.5	100	104	98			
dBp (After treatment)	40	79.2 ± 4.2	0.67	70	78	82	84	80			

*(P value <0.0001 = Considered to be statistically highly significant.)

Table 1: Statistical analysis by using student paired "t" test of Systolic (sBP) and Diastolic (dBp) blood pressure before and after treatment.

RESULTS

A total of 40 individuals (n=40) were selected from the age range of 20-75 years. According to the sex wise distribution, 18 were male (45%) and 22 were female (55%).

The mean age of the patient was 45.21 years (mean age of male participants is 44.5 and mean age of female participants is 45.92), with 38.23% of participants in the age range of 60-69 years of age (age wise distribution). Mean SBP before treatment=150, Mean SBP after treatment=124.4, Mean DBP before treatment=94.9, Mean DBP after treatment=79.2. The P-value is <0.0001.

DISCUSSION

Hypertension, also known as high blood pressure, is a very common health condition that affects people's daily habits and can be found all around the world. Among all the types of hypertension, essential hypertension is the most common, affecting 95% of people. If not treated promptly, it can cause complications and increase the risk of dying. This study was done

to see if the homoeopathic medicine *Viscum album* 30 CH is helpful in treating high blood pressure in people aged 20-75 years. Because this was a study with only one group, there was no other group to compare it to. Many studies have been conducted on hypertension in the field of homoeopathic medicine, but there has been limited research on the specific homoeopathic medicine, *Viscum album*. So, *Viscum album* 30 CH has been chosen for this study. It affects the heart and blood vessels in a way that lowers blood pressure. In this research, 40 people who have high blood pressure, both men and women, aged between 20 and 75 years, were selected.

No participants left the study. They received 10-12 weeks of treatment with *Viscum album* 30 CH after a thorough assessment of their condition.

The participants are received *Viscum album* 30 CH and then checked their blood pressure levels before and after the treatment. The results showed that the treatment had a positive effect on the high blood pressure of the participants. We showed that the levels of blood pressure before and after treatment are different using a statistical analysis. The findings of the statistical analysis (both systolic and diastolic levels of BP) using the student paired "t" test, which reveals that the before treatment and after treatment levels of blood pressure are in fact different, supported this impact. Thus, *Viscum album* 30 CH has a scope to lowering high blood pressure. In this study it is found the average age by adding up all the ages and dividing by the number of people. The average age is 45. 21 years, and 38.23% of participants were between the ages of 60 and 69. This means that being old increases the chances of developing high blood pressure. The number of males and females with hypertension was calculated as a percentage. Out of 40 cases, 18 were male (45%) and 22 were female (55%), which indicates that hypertension is more common in males than females. There are some limitations that need to be fixed in future research. One of the problems is that they did not include participant with malignant hypertension, so it was hard to tell if *Viscum album* 30 CH had the same beneficial effect for this with complications or not. Other problems with this study are that there was small sample size, small study duration, there was not a control group, and it included people of different ages.

Finally, this research shows that a homoeopathic medicine *Viscum album* 30 CH has suggestively promising effect in participants suffering from hypertension. It can be espoused as an alternative and complementary public health approach in limiting the high incidence of hypertension around the world.

CONCLUSION

Hypertension is a common and widespread lifestyle condition with serious consequences for individuals and the elderly. The results showed that blood pressure in people with essential hypertension decreased. Treatment with *Viscum album* resulted in an early, prolonged, and significant reduction in blood pressure, and it has also been shown to be safe and effective in the treatment of essential hypertension. Therefore, viscous is an excellent alternative as a specific therapy to control blood pressure in people with severe hypertension. Since this was a small sample size study, future research should examine a larger sample size and lengthen the study period. Further study using a randomized placebo-controlled group may provide further evidence that ultra diluted homoeopathic medicines are useful in the treatment of essential hypertension.

DECLARATION OF PATIENT CONSENT

The author confirms that he has received all appropriate consents from participants for their investigative reports and other clinical information to be reported in the journal. Participants

have been informed that their names and initials will not be published and that efforts will be made to conceal their identities, but anonymity cannot be guaranteed.

Acknowledgments

The authors are grateful to authorities of Bharati Vidyapeeth (Deemed to be University), Pune, India for providing necessary help for this study. Author thanks to Prof. Dr. Anita S. Patil, Dean - Faculty of Homoeopathy and PG-Coordinator, Bharati Vidyapeeth (Deemed to be University) HMC, Pune for kind support. In addition, the author is grateful to all members of the Department of Organon of Medicine and Homoeopathic Philosophy for providing the spiritual support needed to complete the study.

Authors' contribution

Somnath D. Pande: Concept and design of the study; Collection of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Sushama S. Manhas:** Acquisition of data; Interpretation of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Avinash R. Mhetre:** Approvals for study implementation; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Anupam Mukherjee:** Drafting the article; Analysis of data; Final approval of the version to be submitted.

Conflict of Interests

The authors declare no conflict of interest.

Financial Support

Nil

Abbreviations

Professor (Prof.); Doctor (Dr.); Doctor of Medicine (M.D.); Electronic Mail (E-mail); Hypertension (HTN); Blood Pressure (BP); Systolic Blood Pressure (sBP); Diastolic Blood Pressure (dBP); World Health Organisation (WHO); Bis in die or twice a day (BD); Total number of individuals (N); Standard Deviation (SD); Standard Error of the Mean (SEM); Minimum (Min); Maximum (Max); Probability value (P value); Recipe (Rx); Hahnemann's Centesimal-dilution (CH); Homoeopathic Medical College (HMC).

Units and Symbols

Millimeter of mercury (mmHg); Less than (<); Percentage or percent sign (%); The plus-minus sign ($\pm$); Equal sign (=).

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