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Clinical Verification of Rauwolfia Serpntina 6C Potency on the Patients of Essential Hypertension

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ABSTRACT

Background: Essential Hypertension is one of the major causes of morbidity and mortality. However, treatment and control of essential hypertension remain major challenges worldwide. Homoeopathy is said to be effective in essential hypertension. A homoeopathic drug, Rauwolfia serpentina is said to be effective against essential hypertension. This study was undertaken to determine the efficacy of Rauwolfia serpentina in Essential hypertension in National Institute of Homoeopathy, Kolkata.

Methods: A randomized, double blind, placebo-controlled, and parallel design was adopted for the study. The study included 30 patients, age between second to eight decade, of both sexes and religions, represented with signs and symptoms of Essential hypertension, and characteristics of Rauwolfia serpentina. The potency used was 6 CH. The outcome measures were assessed by different attributes.

Results: The highest prevalence of essential hypertension was seen in 33-80 years of age and in lower middle class population. Hindu male subjects showed a higher frequency among all. The chi-square test revealed that Rauwolfia serpentina 6CH is more efficacious in essential hypertension than placebo at the 5% significance level. Those who suffered for less than 2 years showed more improvement. A retrospective study of subjects who exhibited positive effects reconfirmed the characteristic symptoms of Rauwolfia serpentina in Essential hypertension.

Conclusion: Rauwolfia serpentina in 6 CH potency possessed positive effect against Essential hypertension significant reduction of hypertension in that study population, who presented with symptoms and signs of hypertension, as well as characteristics of Rauwolfia serpentina.

Keywords: Essential hypertension; Rauwolfia serpentina; Homoeopathy.

1. Introduction

In the present era, information technology has forced the world into a closed circuit; as a result, man can visualize everything modern and its usefulness. As a result, the demand has increased, but the resources are limited. Thus, it creates a condition of stress both to achieve and maintain his own position. He is not free even at his home, and his ego gets constantly injured in his social and occupational environment, which makes him a competitor of his own relatives, child or even life partner. This condition ceases his mental peace. This disturbed state involves all the biochemical processes in his body, making the adrenaline gland hyperactive, a stressed vascular system and raised blood pressure. Persistent stress can lead to increased activity of the adrenal system and vascular strain, which are closely associated with the development of elevated arterial blood pressure. Consequently, hypertension has become a major risk factor for several serious health complications, including stroke, coronary heart disease, and renal failure. The scientific understanding of blood pressure developed gradually through the contributions of early researchers such as Stephen Hales, who conducted the first experimental measurements of arterial pressure in animals, and Scipione Riva-Rocci, who introduced the sphygmomanometer for clinical measurement. Over time, medical research established hypertension as a critical precursor of cardiovascular morbidity, particularly from the mid-twentieth century onward. Essential hypertension, in which the underlying cause remains largely unknown, accounts for more than 90% of hypertensive cases, while the remaining cases are categorized as secondary hypertension associated with identifiable pathological conditions such as renal or endocrine disorders.

Epidemiological studies indicate that hypertension affects a significant proportion of the global population. It is often described as an “iceberg disease” because a large number of affected individuals remain unaware of their condition. Estimates suggest that approximately 25% of adults in developed countries and 10–20% in developing countries suffer from elevated blood pressure. Because the risk of cardiovascular complications increases proportionally with blood pressure levels, early detection and effective management remain essential to reduce morbidity and mortality.

Conventional medicine has developed numerous pharmacological agents capable of reducing blood pressure; however, these treatments may be associated with adverse effects, high costs, and limitations in addressing the holistic aspects of disease. In contrast, the principles of Homeopathy emphasize the treatment of the individual as a whole, viewing disease as a disturbance of the vital force manifested through characteristic signs and symptoms. This holistic perspective provides an alternative approach to the management of chronic conditions such as hypertension.

Among the medicinal plants explored for the management of hypertension, Rauwolfia serpentina has attracted considerable attention. This evergreen shrub of the family Apocynaceae, commonly known as Sarpagandha or Indian snakeroot, has long been used in traditional Indian medicine. Ancient Ayurvedic texts, including the Charaka Samhita, describe the therapeutic use of its roots for various ailments. The plant contains several biologically active indole alkaloids such as reserpine, rescinnamine, ajmaline, and yohimbine, which exert significant effects on the cardiovascular and nervous systems. Modern clinical use of Rauwolfia for the treatment of hypertension and certain psychiatric conditions was first documented in Indian medical literature in the early twentieth century.

Although Rauwolfia serpentina has been widely used in crude or mother tincture form in homoeopathic practice for the management of hypertension, relatively limited information is available regarding the effectiveness of its potentised preparations. Therefore, further exploration of the therapeutic role of potentised Rauwolfia in hypertensive patients is warranted. The present study seeks to evaluate the

potential efficacy of potentised Rauwolfia serpentina in the management of hypertension and to contribute to a better understanding of its therapeutic applications within homoeopathic practice.

2. Literature Review

2.1 Essential Hypertension: Definition and Epidemiology

Hypertension is one of the most common chronic disorders affecting the cardiovascular system and represents a major public health concern worldwide. It is characterized by a persistent elevation of arterial blood pressure above the normal physiological range. The diagnosis of hypertension is generally established when the systolic blood pressure exceeds 140 mmHg and/or the diastolic blood pressure exceeds 90 mmHg, measured on multiple occasions under standardized conditions. This operational definition is widely accepted by international health organizations and clinical guidelines.

Blood pressure values within a population typically follow a continuous distribution rather than a clear distinction between normal and abnormal values. Therefore, the threshold for diagnosing hypertension is somewhat arbitrary and is determined based on the level of blood pressure associated with increased cardiovascular risk and the benefits of therapeutic intervention. Hypertension may be classified into different categories including normal blood pressure, prehypertension, stage I hypertension, stage II hypertension, and isolated systolic hypertension, depending on the measured systolic and diastolic values.

Hypertension can be broadly categorized into primary (essential) hypertension and secondary hypertension. Secondary hypertension occurs when elevated blood pressure is caused by identifiable pathological conditions such as renal disease, endocrine disorders, or vascular abnormalities. In contrast, essential hypertension has no clearly identifiable cause and accounts for approximately 80–90% of all cases of hypertension. The development of essential hypertension is believed to result from a complex interaction of genetic predisposition, environmental influences, and physiological regulatory mechanisms.

Epidemiological studies have shown that hypertension affects a substantial proportion of the global population. Its prevalence increases with age and varies across different geographic regions and ethnic groups. In many developed countries, approximately one-quarter of the adult population is affected by hypertension, while in developing countries the prevalence ranges between 10% and 20%. The condition is often referred to as a “silent killer” because many individuals remain asymptomatic until complications develop.

Hypertension is also a major risk factor for several serious cardiovascular and systemic complications including coronary artery disease, stroke, heart failure, renal insufficiency, and peripheral vascular disease. Persistent elevation of blood pressure leads to structural and functional changes in blood vessels and vital organs, thereby significantly increasing morbidity and mortality. Early diagnosis and effective management are therefore essential to prevent long-term complications associated with this condition.

2.2 Risk Factors and Pathophysiology of Essential Hypertension

The development of essential hypertension is multifactorial and involves a complex interplay between genetic, environmental, and lifestyle factors. Several epidemiological investigations have identified both non-modifiable and modifiable risk factors contributing to the development of elevated blood pressure.

a. Non-modifiable Risk Factors

Among the non-modifiable risk factors, age plays a crucial role in the development of hypertension. Blood pressure tends to increase progressively with advancing age due to structural and functional changes in blood vessels. These changes include reduced elasticity of the arterial wall, increased vascular stiffness, and accumulation of environmental influences over time.

Genetic predisposition is another important factor influencing the development of hypertension. Twin and family studies have demonstrated a strong hereditary component in blood pressure regulation. Individuals with hypertensive parents have a significantly higher risk of developing hypertension compared to those whose parents are normotensive. These findings suggest that blood pressure regulation is influenced by multiple genes, although the exact genetic mechanisms remain incompletely understood.

Sex and ethnicity also influence the prevalence and severity of hypertension. Studies have shown that males generally exhibit higher blood pressure levels during early and middle adulthood, whereas after menopause women may experience a greater increase in blood pressure. Certain ethnic populations have also been observed to have a higher prevalence of hypertension compared with others.

b. Modifiable Risk Factors

Several lifestyle and environmental factors contribute significantly to the development of hypertension. Obesity has been consistently identified as one of the most important modifiable risk factors. Increased body weight is associated with increased cardiac output and peripheral vascular resistance, both of which contribute to elevated blood pressure. Epidemiological evidence suggests that weight reduction is often accompanied by a corresponding decrease in blood pressure levels.

Dietary sodium intake also plays an important role in the pathogenesis of hypertension. Excessive salt consumption can lead to expansion of extracellular fluid volume, increased cardiac output, and elevated blood pressure. Populations consuming high-salt diets have been found to have a higher prevalence of hypertension compared with populations with lower sodium intake.

Other dietary factors such as high saturated fat intake, low dietary fibre consumption, and alcohol consumption have also been associated with increased risk of hypertension. Alcohol, in particular, has been shown to elevate systolic blood pressure through mechanisms involving sympathetic nervous system stimulation and vascular effects.

Physical inactivity is another contributing factor. Regular physical activity has been shown to improve cardiovascular function and reduce blood pressure levels by enhancing vascular elasticity and improving metabolic regulation.

Psychosocial stress is also considered an important factor in the development of hypertension. Chronic stress can lead to sustained activation of the sympathetic nervous system and increased secretion of catecholamines, which in turn raise blood pressure levels.

c. Physiological Mechanisms of Hypertension

From a physiological perspective, arterial blood pressure is determined by two primary factors: cardiac output and peripheral vascular resistance. Various regulatory systems maintain blood pressure within normal limits under physiological conditions. However, disturbances in these regulatory mechanisms can lead to sustained elevation of blood pressure.

One important mechanism involved in hypertension is intravascular volume expansion, which is primarily regulated by sodium balance and renal function. Excessive sodium retention leads to increased extracellular fluid volume and increased cardiac output, ultimately contributing to elevated arterial pressure.

The autonomic nervous system also plays an important role in the regulation of blood pressure. Increased sympathetic nervous activity leads to vasoconstriction, increased heart rate, and increased cardiac output, all of which contribute to hypertension.

Another important regulatory mechanism is the renin–angiotensin–aldosterone system (RAAS). Activation of this system results in the production of angiotensin II, a potent vasoconstrictor that increases

peripheral resistance and stimulates the secretion of aldosterone. Aldosterone promotes sodium and water retention, further contributing to increased blood pressure.

Structural changes in blood vessels also contribute to hypertension. Chronic elevation of blood pressure leads to vascular remodelling, characterized by thickening of the arterial wall, reduced vascular elasticity, and narrowing of the vascular lumen. These changes increase peripheral resistance and further exacerbate hypertension.

2.3 Homoeopathic Concept of Essential Hypertension

Homoeopathy approaches disease from a fundamentally different perspective compared to conventional medicine. According to homoeopathic philosophy, health represents a harmonious state of the vital force, while disease arises from disturbances in this vital force. These disturbances manifest as characteristic symptoms that reflect the body's attempt to restore equilibrium.

In the homoeopathic approach, the focus is not merely on the pathological condition but on the individual patient as a whole. Essential hypertension is therefore considered not merely as elevated blood pressure but as a manifestation of deeper constitutional and functional disturbances within the organism. Treatment is based on the principle of similia similibus curentur, whereby a remedy capable of producing symptoms similar to those of the patient is selected to stimulate the body's self-healing mechanisms.

2.3.1 Miasmatic Interpretation

The concept of miasms plays an important role in the homoeopathic understanding of chronic diseases. Miasms represent underlying constitutional predispositions that influence the development and progression of disease.

Essential hypertension is considered a multi-miasmatic disorder. The psoric miasm is often associated with functional disturbances such as emotional stress, anxiety, and nervous irritability that may lead to labile hypertension. The sycotic miasm is associated with structural changes such as hypertrophy of the heart and vascular thickening. The syphilitic miasm is associated with destructive pathological changes including vascular degeneration and severe complications such as stroke or myocardial infarction.

The tubercular or pseudo-psoric miasm may produce fluctuating blood pressure levels and hemorrhagic tendencies. The relative predominance of these miasmatic influences determines the clinical presentation and progression of hypertension in individual patients.

Homoeopathic management of essential hypertension, therefore involves individualized treatment based on the totality of symptoms, constitutional characteristics, and miasmatic background of the patient.

2.4 Rauwolfia serpentina in Traditional and Modern Medicine

Rauwolfia serpentina, commonly known as Sarpagandha or Indian snakeroot, is a medicinal plant belonging to the family Apocynaceae. The plant has been used for centuries in traditional Indian medicine for the treatment of various ailments including insomnia, mental disorders, snake bites, and gastrointestinal disturbances.

Historical references to the medicinal use of Rauwolfia serpentina appear in ancient Ayurvedic texts such as the Charaka Samhita. The plant gained international attention in the twentieth century following the discovery of its potent antihypertensive properties.

Phytochemical investigations have revealed that Rauwolfia serpentina contains more than sixty indole alkaloids. Among these, reserpine, rescinnamine, and ajmaline are considered the most pharmacologically active constituents. These alkaloids exert significant effects on the cardiovascular and nervous systems.

The antihypertensive action of Rauwolfia serpentina is primarily attributed to the ability of its alkaloids to deplete catecholamines such as norepinephrine from sympathetic nerve endings. This mechanism reduces sympathetic nervous activity and lowers peripheral vascular resistance, resulting in decreased blood pressure.

In addition to its antihypertensive effects, Rauwolfia serpentina also exhibits sedative and tranquilizing properties, making it useful in conditions associated with anxiety, insomnia, and nervous tension.

2.5 Rauwolfia serpentina in Homoeopathic Practice

The homoeopathic application of Rauwolfia serpentina has been explored through provings and clinical observations. The first Hahnemannian proving was conducted by Otto Leeser and R. Schrenk in 1954 at the Robert Bosch Hospital in Stuttgart. The proving involved twenty-four volunteers and utilized various dynamisations of the drug.

Subsequent provings conducted by W. L. Templeton and other researchers expanded the understanding of the remedy's symptomatology. These studies revealed that Rauwolfia serpentina produces a wide range of symptoms affecting the mental, neurological, cardiovascular, gastrointestinal, and endocrine systems.

Clinical observations have also demonstrated the therapeutic usefulness of Rauwolfia preparations in the treatment of hypertension and certain neuropsychiatric conditions. Early investigations by Sen and Bose reported significant reductions in blood pressure following administration of Rauwolfia extracts in patients with hypertension.

Later studies conducted by Gupta and colleagues demonstrated improvements in patients suffering from insomnia, agitation, and certain mental disorders following treatment with Rauwolfia preparations.

However, prolonged use of crude Rauwolfia preparations or reserpine has been associated with adverse effects including sedation, depression, and impaired concentration. These limitations have stimulated interest in exploring potentised preparations within homoeopathic therapeutics.

2.6 Research Gap

Although Rauwolfia serpentina has been widely used in traditional medicine and modern pharmacology for the treatment of hypertension, most studies have focused on crude extracts or isolated alkaloids. In homoeopathic practice, the mother tincture of Rauwolfia serpentina has been frequently used for managing hypertension.

However, there remains limited scientific evidence regarding the clinical effectiveness of potentised forms, particularly the 6C potency, in patients suffering from essential hypertension. Therefore, there is a need for systematic clinical studies to evaluate the therapeutic potential of potentised Rauwolfia preparations.

The present study aims to address this gap by conducting a clinical verification of Rauwolfia serpentina 6C potency in patients with essential hypertension, thereby contributing to the scientific understanding of its role in homoeopathic therapeutics.

3. Objectives of the study

- To assess the efficacy of Rauwolfia serpentina 6C potency on patients of Essential hypertension.
- To assess the clinical pattern of Essential hypertension.
- Analysis of demographic data of Essential hypertensive patients.
- Analysis of different effects of Rauwolfia serpentina in Essential hypertensive patients.

4. Materials and Methods

1. Study design:

Prospective, Randomized, Double blind, placebo control parallel design study.

2. Study period:

From May 2008 to September 2009

3. Study population:

3.1.Study site: National Institute of Homoeopathy, Block GE, Sector III, Salt Lake, Kolkata-106, West Bengal, India.

3.2.Study setting: Outpatient Department and Indoor Patient Department.

3.3.Defining the population: Target population is preferably from Kolkata and surrounding districts.

3.4.Sample size: n = 30

3.5.Sample selection:

3.5.1. Inclusion criteria:

- Subjects with hypertension (systolic blood pressure ≥140 mmhg and/or diastolic blood pressure ≥90 mmhg).
- Subjects agree to give consent for participating in the study.
- Subjects agree to comply with the protocol.

3.5.2. Exclusion criteria:

- Subjects having major complications of hypertension i.e. hypertensive encephalopathy, severe coronary artery disease, left ventricular failure, stroke and severe nephropathy.
- Subjects with age below 12 years.
- Blood pressure >200/140 mmhg.
- Any other associated major systemic diseases e.g. diabetes, thyroid dysfunction etc.
- Subjects who are under long term anti-hypertensive therapy
- Subject does not agree to give consent for participating in the study.
- Patients unlikely to comply with the trial protocol.

3.5.3. Factors considered during the study:

- Instructions regarding exercise, nutritional supplement, salt restricted diet, etc.
- Any new homoeopathic medicines as intermittent, complementary or emergency therapy.

4. Study treatment:

4.1 Medicine:

4.1.1 Medicine for experimental group: Rauwolfia serpentina.

Potency: 6 CH.

Quantity: 30 ml sealed phial.

Manufacturing pharmaceuticals: Hahnemann Publishing Co. Pvt Ltd (HAPCO), 165 BB Ganguly St., Kolkata –19.

Manufacturing date: September 2009.

4.1.2 Medicine for control group (Placebo): Dispensing alcohol.

Quantity: 30 ml sealed phial.

Manufacturing pharmaceuticals: HAPCO, 165 BB Ganguly St., Kolkata –19.
Manufacturing date: September 2009.
4.1.3 Vehicle (Dispensing media): Vehicle was used during manufacturation of medicine. No dispensing media was used during our study.
4.2 Sample categorization: The study population was categorized into two groups, experimental and placebo group.
4.3 Randomization: In order to maintain the nature of the study design, both experimental and placebo groups were coded appropriately. The investigator was provided with the randomization code in a sealed phial of "code no.1", "code no.2",.. which was only, be opened, prior to enrollment of subjects in the study. Randomization was done in lottery method.

5. **Interrogation:** As per the "Case Report Form" (CRF) listed in Appendix A.
6. **Prescription and follow up:** Blood pressure was measured in selective cases randomly according to the facility available in the infrastructure and with patient's consent. The patients were prescribed "Code no.1", "Code no.2".. and doses as 5 drops twice a day for 10 days, thus doses were same in every case. Follow up was aimed between 10 days to 15 days of time from the period of active interference. On reporting, the cases were followed up properly and results assessed.
7. **Safety variables:** Any undesired / untoward event experienced by the subject recruited in the study is noted and assessed at the end of the study.
8. **Outcome measures**: The various outcome measures have been listed in **Table 3**.
9. **Statistical analysis**: Chi-Square Test was used for the estimation, as the data was attributes. Pictorial representation of the data was done for the observations. For the frequency distribution table, Class interval (CI) was determined by the formula CI = 1+ 3.3222 $\log_{10}$ N (where N = the total no. of the variables) and Class width (CW) was determined by CW = $X_n - X_1$ / C.I (where X_n = highest value, X_1 = lowest value of the data).

Table 3. POST TREATMENT OUTCOME MEASURES

The outcome measures	Interpretation	Grade
Continuous improvement of 'Headache, Vertigo, Dizziness and Palpitation' including reduction of 'Blood pressure' even after ≥ 2 months.	Positive effect	I
Improvement of 'Headache, Vertigo, Dizziness and Palpitation' or reduction of 'Blood pressure'.	Palliative effect	II
Clinical assessment indicating status quo condition or positive qualitative deterioration of the patients' condition.	No effect	III

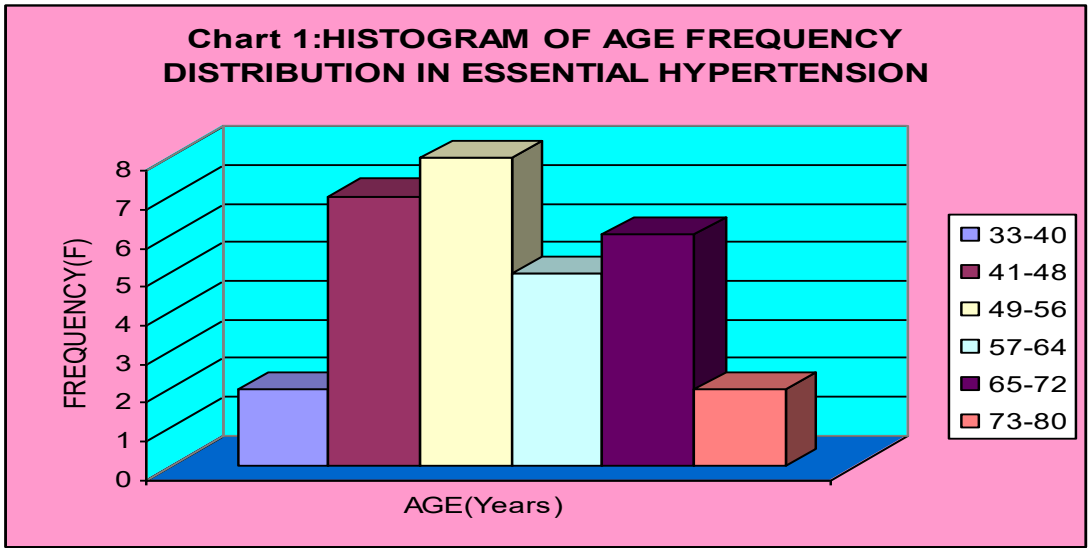
5. Case Observations and Summary of Selected Cases (A, B, C, D, E)

The present study aimed to evaluate the clinical effect of Rauwolfia serpentina 6CH potency in patients suffering from essential hypertension. In total, 30 patients were included in the study and were divided

equally into experimental and placebo groups. For detailed clinical understanding, five representative cases (Cases A, B, C, D, E) were selected and analyzed individually. These cases illustrate the clinical presentation, response to treatment, and therapeutic outcomes observed during the study period.

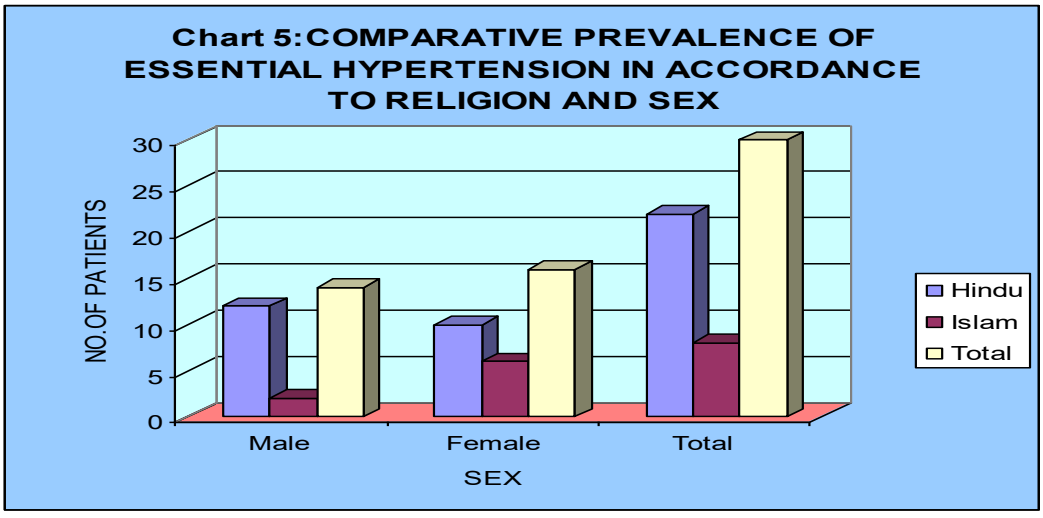
5.1 Age Distribution of Patients

Analysis of the age distribution of the study population revealed that essential hypertension was most prevalent among individuals in the 49–56 years age group, which accounted for the highest frequency of cases. In contrast, the lowest prevalence was observed in the 33–40 years and 73–80 years age groups. These findings indicate that individuals in the fourth to sixth decades of life are more susceptible to developing essential hypertension.



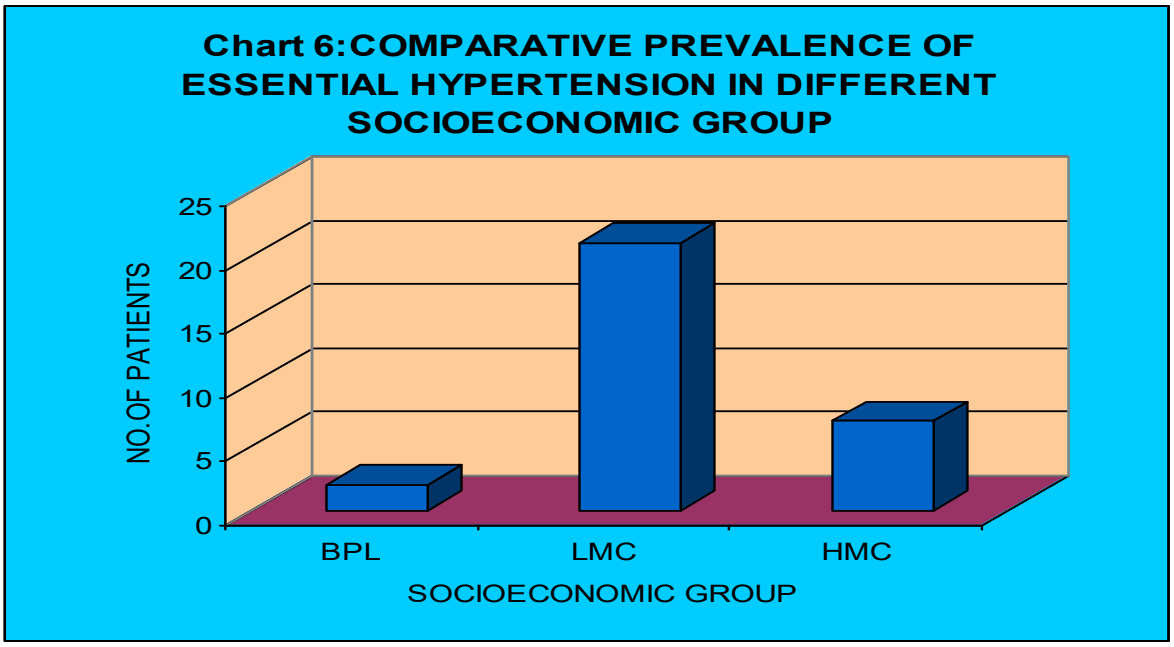
5.2 Distribution According to Religion and Sex

The distribution of patients according to religion and sex showed that Hindu patients constituted the majority of the study population, accounting for 22 out of the 30 patients, while 8 patients belonged to the Muslim community. Among males, the prevalence was higher in the Hindu population, whereas among females a comparatively higher proportion was observed in the Muslim community. Overall, male patients constituted 46.67% and female patients constituted 53.33% of the study population.



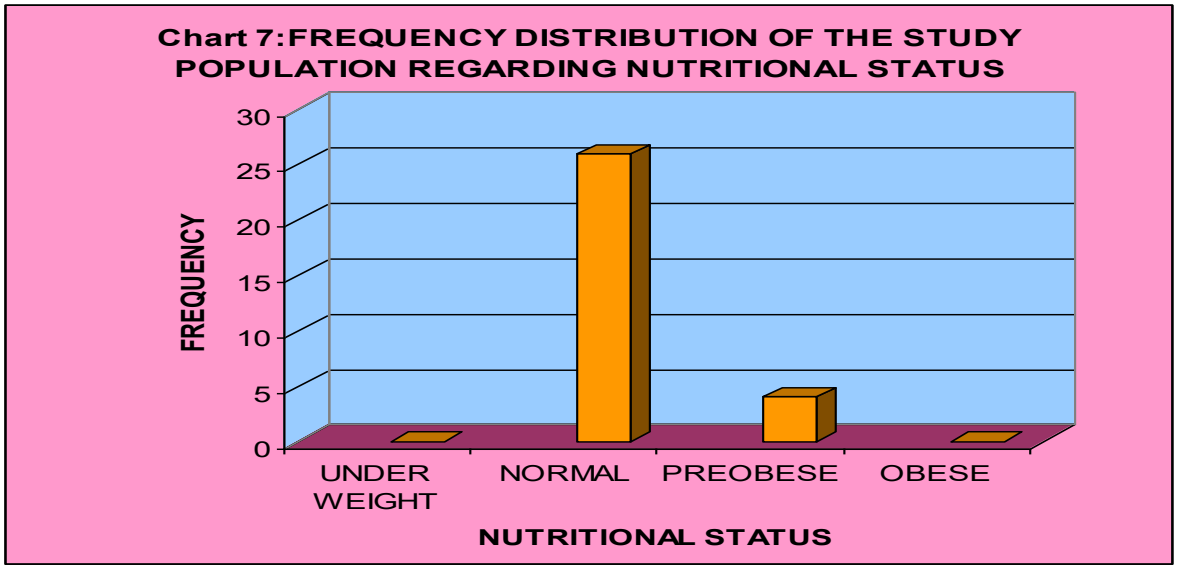
5.3 Distribution According to Socioeconomic Status

The analysis of socioeconomic status revealed that 70% of the patients belonged to the lower middle-class group, followed by 23.33% from the higher middle-class group and 6.67% from the below-poverty-line group. The higher prevalence in the lower middle-class population may be attributed to factors such as lifestyle changes, dietary habits, and stress associated with urbanization.



5.4 Nutritional Status of the Patients

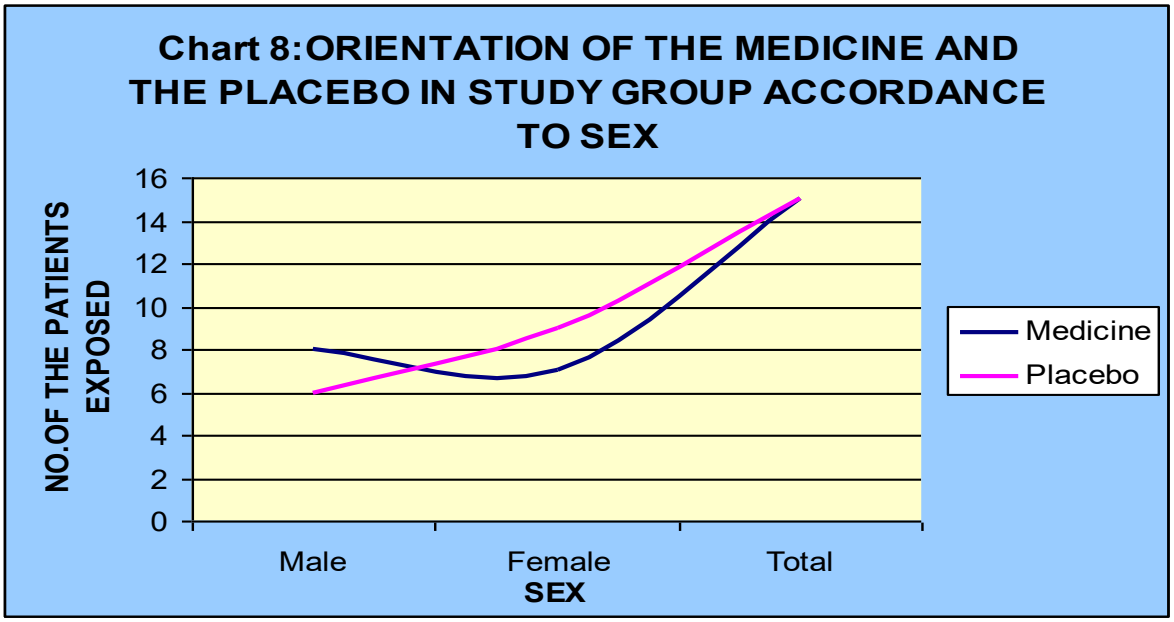
The nutritional status of the study population was assessed using Body Mass Index (BMI). The majority of the patients (86.67%) were found to have BMI within the normal range (18.50–24.99), while 13.33% were classified as pre-obese. No cases of underweight or obesity were observed in the study population. These findings suggest that hypertension may occur even among individuals with normal BMI and is not exclusively associated with obesity.



5.5 Distribution of Medicine and Placebo According to Sex

After decoding the study groups, it was observed that 15 patients received Rauwolfia serpentina 6CH, while the remaining 15 patients received placebo. Among the experimental group, 53.33% were males

and 46.67% were females, whereas in the placebo group 40% were males and 60% were females. Thus, the exposure to the experimental medicine was slightly higher among male participants compared to females.



5.6 Outcome Measures

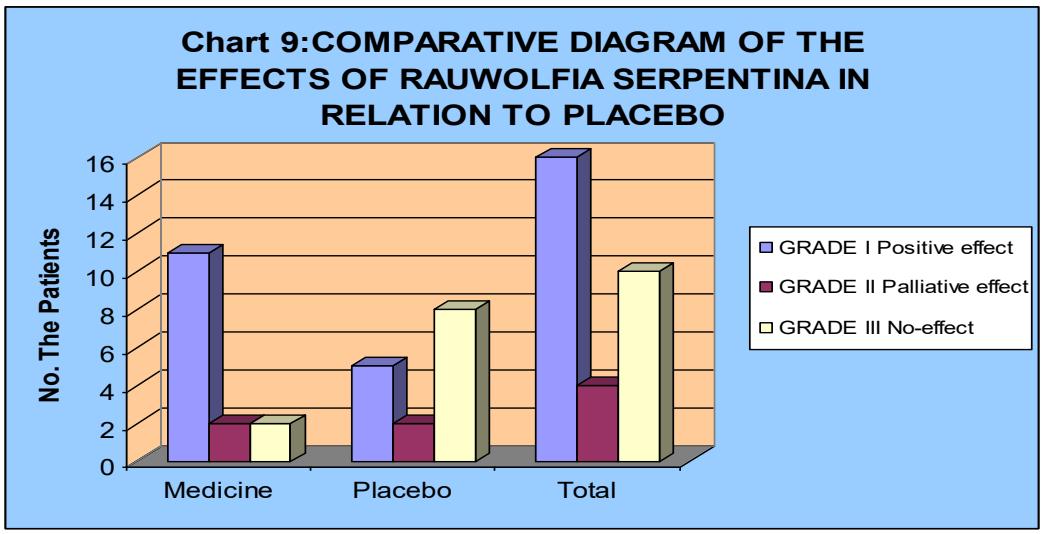
The therapeutic outcomes of the study were categorized into three grades:

- Grade I – Positive Effect
- Grade II – Palliative Effect
- Grade III – No Effect

Out of the 30 patients included in the study:

- 16 patients showed Grade I (positive effect)
- 4 patients showed Grade II (palliative effect)
- 10 patients showed Grade III (no effect)

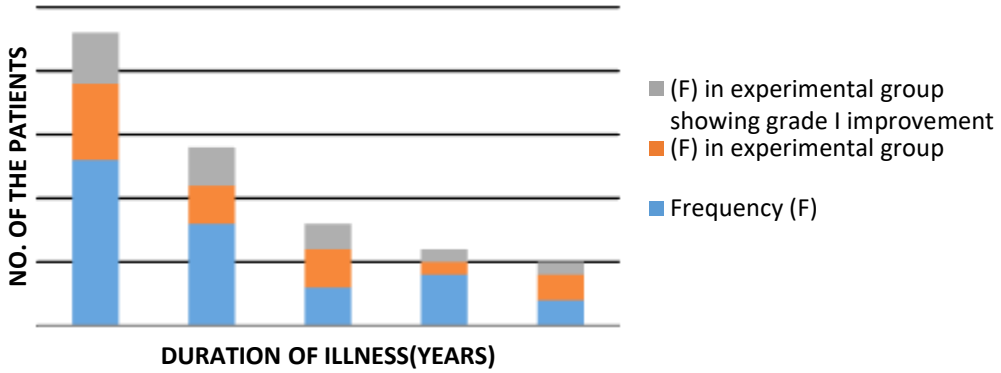
Among the patients showing Grade I improvement, 73.33% belonged to the experimental group treated with Rauwolfia serpentina 6CH, while the remaining cases were observed in the placebo group. These findings indicate a greater therapeutic response in the experimental group compared to the placebo group.



5.7 Duration of Illness

The duration of illness among the study population varied from less than two years to ten years. The majority of patients had been suffering from hypertension for two years or less. Patients with shorter duration of illness demonstrated better clinical improvement following treatment with Rauwolfia serpentina 6CH. Conversely, patients with longer duration of illness showed comparatively lesser improvement.

Chart 10: COMPARISON OF DURATION OF ILLNESS IN THE STUDY GROUP, EXPERIMENTAL GROUP AND AND SUBJECT SHOWING POSITIVE EFFECT OF RAUWOLFIA SERPENTINA 6CH



5.8 Summary of Selected Cases (A, B, C, D, E)

Five representative cases were selected for detailed observation in order to illustrate the clinical response to treatment. Across these cases, the common presenting complaints included headache, dizziness, vertigo, palpitations, and elevated blood pressure levels. Following administration of Rauwolfia serpentina 6CH and appropriate lifestyle modifications such as dietary regulation and salt restriction, most cases demonstrated gradual improvement in both subjective symptoms and blood pressure readings.

Among the five cases:

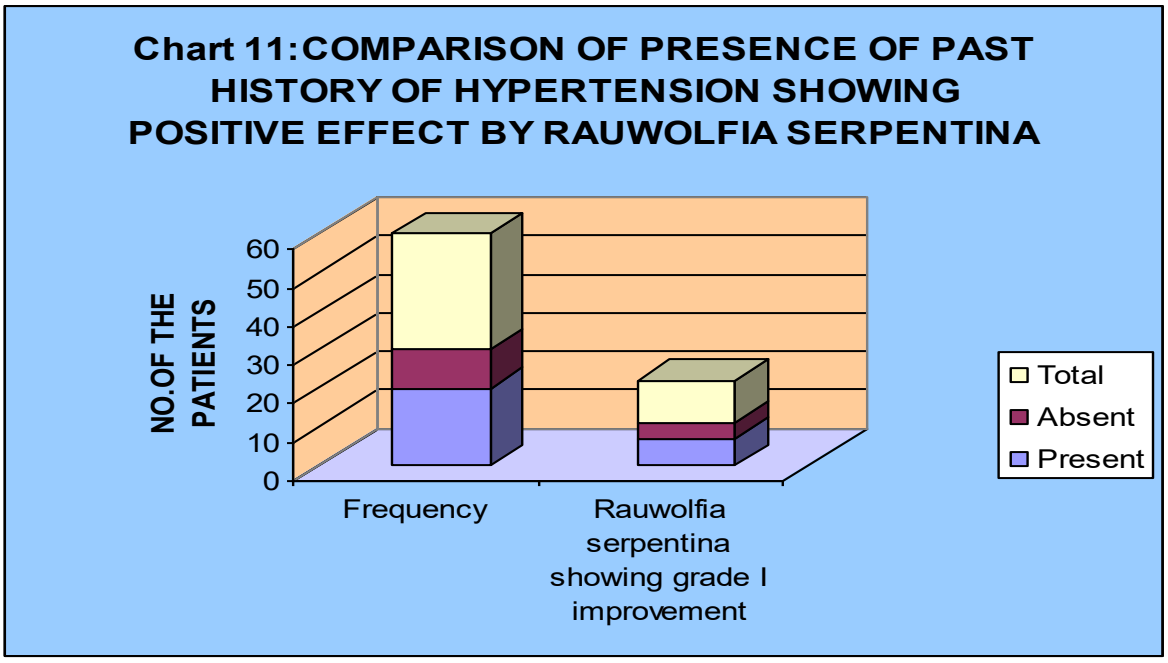
- Three cases showed marked improvement (Grade I) with significant reduction in blood pressure and associated symptoms.
- One case showed partial improvement (Grade II) with moderate reduction of symptoms.
- One case showed minimal or no improvement, possibly due to longer disease duration, genetic predisposition, or individual constitutional factors.

These case observations highlight the potential therapeutic role of Rauwolfia serpentina 6CH in managing essential hypertension when prescribed based on appropriate clinical indications.

5.9 Overall Interpretation

The findings from the selected cases, along with the statistical observations from the entire study population, suggest that Rauwolfia serpentina 6CH demonstrates a notable therapeutic effect in patients with essential hypertension, particularly in cases with shorter duration of illness and less severe pathological changes.

However, individual variability in response to treatment was observed, emphasizing the importance of individualized homoeopathic prescribing and consideration of constitutional factors in the management of chronic diseases such as hypertension.



6. Discussions

The present study evaluated the comparative efficacy of Rauwolfia serpentina 6CH potency and placebo in patients suffering from essential hypertension. The study included 30 patients aged between 33 and 80 years, selected randomly from the OPD and IPD of the National Institute of Homoeopathy, Kolkata. A prospective, randomized, double-blind, placebo-controlled parallel study design was adopted. The study population was divided into two equal groups, consisting of 15 patients in the experimental group and 15 patients in the placebo group.

The treatment was administered using coded vials to maintain blinding of both the investigator and the patients. The participants were followed up at intervals of 10–15 days, and the mean duration of treatment was approximately 55 days. During the study period, all participants were advised to follow lifestyle modifications including salt restriction, dietary control, and regular exercise in order to minimize observational bias.

The demographic analysis of the study population showed that essential hypertension was most prevalent among individuals aged 49–56 years (26.67%), while the lowest prevalence was observed in the 33–40 years and 73–80 years age groups (6.67%). The findings suggest that individuals between the fourth and sixth decades of life are more vulnerable to essential hypertension. The study also showed a relatively higher prevalence among the lower middle-class socioeconomic group (70%), which may be associated with lifestyle changes and the effects of urbanization.

Statistical analysis using the Chi-square test was performed to evaluate the significance of the therapeutic effects. The results demonstrated that 13 out of 15 patients (86.67%) in the experimental group showed effective outcomes (positive or palliative effects), compared to 7 out of 15 patients (46.67%) in the placebo group. The calculated Chi-square value ($\chi^2 = 5.4$) was greater than the tabulated value ($\chi^2 = 3.84$) at the 5% level of significance, indicating that the null hypothesis was rejected. Therefore, a significant difference was observed between the effects of Rauwolfia serpentina 6CH and placebo, suggesting that Rauwolfia serpentina 6CH is more effective than placebo in the management of essential hypertension.

Approximately 73.33% of the patients in the experimental group showed positive improvement, while 13.33% exhibited palliative improvement. In contrast, the placebo group demonstrated 33.33% positive improvement and 13.33% palliative effect. Two patients in the experimental group showed no improvement, which might be attributed to factors such as strong genetic predisposition, severity of disease, or the possibility that a different potency or individualized homoeopathic remedy might have been required.

Improvement observed in some placebo cases may be explained by psychological factors, reduction of stress, and adherence to lifestyle modifications, which are known to influence blood pressure regulation.

Overall, the findings of this study suggest that Rauwolfia serpentina 6CH possesses therapeutic potential in the management of essential hypertension, although further studies with larger sample sizes and longer follow-up periods are necessary to confirm these results.

7. Main Findings

Patients with arterial hypertension and no definable cause are said to have primary, essential, or idiopathic hypertension. Individuals in whom a specific structural organ or gene defect is responsible for hypertension are defined as having a secondary form of hypertension. In contrast, individuals in whom generalized or functional abnormalities may be the cause of hypertension, even if the abnormalities are discrete, are defined as having essential hypertension. The majority (80-90%) of patients with hypertension have primary elevation of blood pressure (i.e. cause not known – essential hypertension), which can be ameliorated only by life-long pharmacological therapy.

Essential hypertension is one of the leading causes of death for which mortality rates are still rising worldwide resulting in major health and economic burden. Certain limitations, significant adverse effects as well as the cost of pharmacotherapy necessitated development of a new and alternate approach. A homoeopathic medicine prepared from an annual herb Rauwolfia serpentina, is known to possess significant effect in essential hypertension as claimed in the literatures of homoeopathy. Despite the claim authentication via rigorous and methodological evaluation is inadequate. This study was therefore intended to assess the efficacy of Rauwolfia serpentina in essential hypertension by maintaining the gold standard of modern day research methodology.

The study comprised of 30 patients, collected from the OPD and IPD of National Institute of Homoeopathy. The study population was of both sexes and religions with an age range of 33-80 years. The target population was preferably from Kolkata and surrounding districts. For the study, a prospective, randomized, double blind, placebo controlled and parallel design was adopted. The study included the patients representing with clinical manifestation of essential hypertension and possess the ‘totality’ of Rauwolfia serpentina. Patients who received modern drug therapy for last one month or those who presented with significant disorder, put the subject at risk and who did not give written consent to participate in the study were excluded. All study subjects were instructed to follow life style modification for hypertension. Those who are at life risk, rescue treatment were done to save the patients. The patients were categorized into the experimental and control group according to randomization. The interrogation was done as per CRF. The coded drug was prescribed on first day after the participants fulfilled inclusion/ exclusion criteria, agreed to give consent and was repeated on every subsequent feedback when necessary. The feedbacks from the patients were not uniform, but the span of the study treatment was 30 to 55 days with a minimum of 2 follow-ups.

The potency used was 6 CH. Both the placebo and the specific potency of the medicine were collected from HAPCO. The outcome measures were assessed depending on clinical parameters including blood pressure measurement. The highest prevalence of essential hypertension seen in an age group of 49-56 years and in lower middle class population. Hindu male subjects showed a higher frequency among all. Most of the patients having normal range of BMI and represented with manifestations of essential hypertension. Chi square test was used for testing the significance, which revealed that Rauwolfia serpentina 6CH is more efficacious in the treatment of essential hypertension than placebo at 5% level of significance. A retrospective study of the experimental group exhibited positive effect reconfirmed the characteristic symptoms suggestive of Rauwolfia serpentina in essential hypertension.

8. Limitations of the Study

- Despite the sincerest approach, the study of efficacy of the medicine in Essential hypertension has some lacunae as evident from the study. This study therefore demands reconfirmation. Due to the small sample size, it would be difficult to generalize the results from this study.
- The study duration was three months, and hence the study does not reflect the efficacy of Homoeopathic treatment in the long term. Both of these factors may possibly confound the results obtained.
- Most of the hypertensive complications and concomitant illnesses are excluded from this study, and one cannot assume the efficacy of homoeopathic treatment in such cases. Such cases may also warrant the use of many partially proved or smaller remedies, and the efficacy of such remedies has not been assessed in this study.
- Miasmatic analysis was not included in this study. Miasmatic analysis of the study could be a fertile field for the forthcoming researches. The other potencies of Rauwolfia serpentina should also be tested in the future study.
- Nevertheless, it is worth mentioning that this type of broad-spectrum study is of lesser importance in the field of research. Therefore a more specific approach is required for the accurate estimation. For confirmation of the positive effect cross over trials were extremely necessary, which was not done here due to limited time. To estimate the positive effect of Rauwolfia serpentina in context to the increased limitations and adverse effects of the drug therapy, comparative study should be done with proper cross over design and with estimation of risk/ benefit ratio.
- Last but not the least, in homoeopathy the efficacy of a particular drug to a particular disease condition, which is chronic in nature may not be feasible. Instead of that efficacy of homoeopathic treatment in a particular disease condition is more acceptable, though methodology should be reviewed and if necessary re-devised to exclude observation bias in this type of study.

9. Conclusion

The study of the efficacy of Rauwolfia serpentina in essential hypertension, comprising of 30 patients of an age range of 33-80 years and of both sexes and bothreligions, concludes that Rauwolfia serpentina in 6 CH potency possessed positive effect against essential hypertension including significant reduction of blood pressure in that study population, who represented with occipital headache, neck pain, vertigo, dizziness and generalized weakness.

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