Clinical Research

A pilot study to clinically evaluate the role of herbomineral compound “Rakatchap Har” in the management of essential hypertension

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Abstract

The aim of the present study was to investigate the clinical efficacy of a herbomineral medicine Rakatchaphar (Each 500 mg cap contains Sarpgandha 150 mg, Shankhpushpi 75 mg, Jatamansi 75 mg, Jhar Mohra Khatai Pishti 75 mg, Mati Pshith 75 mg, Ras Sindoor 50 mg) in essential hypertension, an observational prospective study was done at Shri Ashutosh Maharaj (SAM) Ayurvedic Treatment and Research Centre, Noormahal. Ninety-eight patients in the age group 28–76 years with essential hypertension without any co-morbid illness were included in the study. Patients were treated with cap Rakatchaphar 500 mg twice a day. Blood pressure (BP) was monitored on subsequent follow-up visits at 2, 4, 6, and 8 weeks. Change in Diastolic BP (DBP), Systolic BP (SBP), and Mean BP (MBP) were analyzed statistically by Student’s t test, ANOVA, and Post hoc Bonferroni test. On first visit the mean SBP, DBP, and MBP was 164.16±17.27, 101.88±9.20, and 122.27±10.57 mm Hg, respectively. After 8 weeks of therapy there was a statistically significant fall in SBP (122.98±11.36), DBP (80.90±8.57), and MBP (94.86±9.24) in mmHg (P value <0.0001). Rakatchap Har offers an efficacious and safe combination of natural products available for the treatment of hypertension.

Key words: Blood pressure, hypertension, Rakatchap Har

Introduction

Hypertension is the leading member of group of so-called “noncommunicable diseases” and a leading contributory cause of death worldwide.[1] It is a major health issue affecting <10% of patients up to the age of 34 years and >50% of population after the age of 65 years.[2] High blood pressure (BP) has estimated to have caused 7.6 million premature deaths and contributed to 92 million disability adjusted life years (DALYs) worldwide in 2001.[3]

Until 1940, a majority of cardiovascular diseases were treated with traditional drugs obtained from plants, but with time, entry of conventional modern medicine has overshadowed the phytopharmaceutical products.[4] In lieu of the fact that the incidence of hypertension is still rising alarmingly, there is dire need to search for an effective and safe magical remedy because of lack of current therapies to either provide complete cure or treating the patients at the cost of adverse effects.[5-7]

Already a comprehensive search of scientific literature has identified natural health products capable of lowering BP.[8] Natural treatment of essential hypertension along with lifestyle modifications can bring down the blood pressure values into the normal range.[9,10] Hence there is the need for resurgence of the use of traditional medicines by switching onto the older systems of Ayurveda from current therapies.[11] In the present context, the Ayurvedic system of medicine is widely accepted and practiced not only in Indian peninsula but also in developed countries.[11] Ayurveda sees hypertension as imbalance of tridosha Vata, Pitta, and Kapha so treatment by Ayurveda targets on correction of these doshas.

Rakatchap Har (means which nullifies hypertensive effect) is also such an addition to the long list of current antihypertensive medications which can prove to improve BP in all grades
of hypertension effectively by synergistic effects of all the six components in it. The present study highlighted on the antihypertensive efficacy of Rakatchap Har. It is a new drug approved by Department of Ayurveda, Govt. of Punjab, showing dramatic improvement in BP in clinical practice. Reason for the selection of this drug is lack of clinical trials in spite of its dramatic efficacy as antihypertensive.

Materials and Methods

It was a prospective observational study done at Shri Ashutosh Maharaj (SAM) Ayurvedic Treatment and Research Centre, Noormahal. Approval was taken by the Ethics Committee before starting the study. Informed consent was taken from each patient for participation in the study. 110 patients of recently diagnosed essential hypertension were selected to be followed-up after giving them Rakatchap Har 500 mg twice a day. The study was completed with 98 patients, as 12 patients did not come for follow-ups. As this study was done in a charitable unit with patients coming from low socioeconomic strata with low literacy, they were not aware of the importance of follow-up visits. So those were the drop out cases of the study.

Patients were involved irrespective of their age, sex, occupation, social status, ethnicity, and grade of hypertension. All the patients who were already undergoing some antihypertensive treatment, with secondary/malignant hypertension, pregnancy, heart failure, diabetes mellitus, bronchial asthma, peripheral vascular disease, significant hepatic or renal dysfunction have been excluded from the study. For assessing their eligibility, all of them underwent complete physical examination, chest X-ray, ECG, blood biochemistry, and urine analysis. So all the patients included had investigations within normal limits.

Patients were categorized according to JNC7 classification of hypertension into prehypertensive, stage I and stage II,[11] and were prescribed Rakatchap Har 500 mg twice a day with lukewarm water. All the patients were motivated for life style modifications (adequate exercise, salt restriction in diet, smoking cessation, avoidance of alcohol intake) and given psychotherapy (through counseling sessions and orienting them toward yoga and meditation techniques) to destress them, as this aspect is equally important in the management of hypertension. All the patients attended the clinic at 2 weekly intervals at 2, 4, 6, and 8 weeks. Each time BP was measured by the same person to reduce the subjective error. BP measurements were taken uniformly after rest for at least 5 min and in sitting position in the right arm using same zero BP measurements were taken. Mean DBP was analyzed by ANOVA test and found to be statistically significant (P value <0.0001) at each visit [Table 3]. Gender was a statistically significant fall in SBP, DBP, and MBP (P value < 0.0001) using Bonferroni Post hoc test [Table 1 and Figure 1].

The Mean SBP was 138.9±17.65, 130.9±14.05, 125.1±20.51, and 122.98±11.36 mm Hg at 2, 4, 6, and 8 weeks, respectively.

The Mean DBP was 89±9.28, 83.8±7.47, 85.2±10.65, and 80.9±8.57 mm Hg at 2, 4, 6, and 8 weeks, respectively.

The Mean MBP was 105.8±11.12, 99.5±9.48, 98.1±9.79, and 94.86±9.24 mm Hg at 2, 4, 6, and 8 weeks, respectively [Table 1].

The decrease in mean SBP, DBP, and MBP was more in Stage II hypertension as compared to Stage I hypertension at all intervals of time. At the end of the study, Mean SBP was reduced by 28.1% in Stage II hypertension as compared to 13.9% reduction in patients with Stage I hypertension. Reduction in mean DBP was 23.4% in Stage II patients as compared to 9.5% in Stage I patients. Mean MBP was reduced by 25.5% in Stage II patients as compared to 11.3% reduction in Stage I patients (Student’s t test) [Table 2].

In both females and males change in mean SBP, DBP, and MBP was analyzed by ANOVA test and found to be statistically significant (P value <0.0001) at each visit [Table 3]. Gender did not appear to significantly affect the responsiveness to the drug. No clinically significant adverse drug reaction was observed in the study.

**Figure 1:** The change in blood pressure with the trial drug over observation period

### Observation and Results

Ninety-eight patients completed the study. Patients were of the age group 28–76 years. The mean age of the patients was 50.45±10.27 years with 40 (40.8%) patients <50 years and 58 (50.2%) patients >50 years. There were 54 (55.1%) males and 44 (44.9%) females. Of all the patients involved 4 (4.1%) were prehypertensive, 22 (22.4%) were with stage I hypertension, and 72 (73.5%) with stage II hypertension.

On first visit the mean SBP, DBP, and MBP was 164.16±17.27, 101.88±9.20, and 122.27±10.57 mmHg, respectively. Clinically significant improvement in BP was seen within 2 weeks after starting the therapy in 92% of patients. At each visit, there was a statistically significant fall in SBP, DBP, and MBP (P value < 0.0001) using Bonferroni Post hoc test [Table 1 and Figure 1].

The Mean SBP was 138.9±17.65, 130.9±14.05, 125.1±20.51, and 122.98±11.36 mm Hg at 2, 4, 6, and 8 weeks, respectively.

The Mean DBP was 89±9.28, 83.8±7.47, 85.2±10.65, and 80.9±8.57 mm Hg at 2, 4, 6, and 8 weeks, respectively.

The Mean MBP was 105.8±11.12, 99.5±9.48, 98.1±9.79, and 94.86±9.24 mm Hg at 2, 4, 6, and 8 weeks, respectively [Table 1].

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In both females and males change in mean SBP, DBP, and MBP was analyzed by ANOVA test and found to be statistically significant (P value <0.0001) at each visit [Table 3]. Gender did not appear to significantly affect the responsiveness to the drug. No clinically significant adverse drug reaction was observed in the study.

### Table 1: The change in blood pressure with Rakatchap Har over observation period

| Time (weeks) | Mean SBP (mm Hg) | Mean DBP (mm Hg) | Mean MBP (mm Hg) |
|--------------|------------------|------------------|------------------|
| 2            | 164.16±17.27     | 101.88±9.20      | 122.27±10.57     |
| 4            | 150.4±14.05      | 97.9±7.47        | 118.1±10.65      |
| 6            | 144.5±12.95      | 94.5±6.87        | 114.2±9.79       |
| 8            | 138.9±17.65      | 90.9±9.28        | 111±8.57         |

### Table 2: Gender wise distribution of the patients with hypertension

| Gender | Stage I | Stage II | Total |
|--------|---------|----------|-------|
| Male   | 25 (28.1) | 39 (44.9) | 64 (73.5) |
| Female | 15 (16.7) | 33 (37.5) | 48 (55.1) |

### Table 3: Gender wise comparison of blood pressure reduction

| Gender | Stage I | Stage II | Total |
|--------|---------|----------|-------|
| Male   | 15.9%   | 28.1%    | 23.9% |
| Female | 16.9%   | 25.5%    | 23.7% |
Table 1: Statistical analysis of the effect of Rakatchap Har on blood pressure

|                          | At first visit | After 2 weeks | After 4 weeks | After 6 weeks | After 8 weeks | P value |
|--------------------------|---------------|---------------|---------------|---------------|---------------|---------|
| Systolic blood pressure (mmHg) | 164.16±2.468  | 138.98±2.521  | 130.96±2.008  | 125.16±2.93   | 122.98±1.624  | <0.0001 |
| Diastolic blood pressure (mmHg) | 101.8±1.315   | 89.04±1.326   | 83.84±1.067   | 85.20±1.523   | 80.90±1.225   | <0.0001 |
| Mean blood pressure (mmHg)   | 122.27±1.511  | 105.8±1.590   | 99.59±1.356   | 98.18±1.399   | 94.86±1.321   | <0.0001 |

The Mean ± SEM values of the Systolic, Diastolic, and mean blood pressures of patients at first visit and after 2, 4, 6, and 8 weeks of treatment with 500 mg BD of Rakatchap Har

Table 2: Percentage change in blood pressure according to stage of hypertension

| Stage of hypertension | After 2 weeks | After 4 weeks | After 6 weeks | After 8 weeks |
|-----------------------|---------------|---------------|---------------|---------------|
| Percentage change in systolic blood pressure | Stage I -10.98±2.969 | -10.95±2.709 | -11.12±2.906 | -13.96±2.894 |
| Percentage change in diastolic blood pressure | Stage I -5.010±4.344 | -9.158±3.349 | -7.584±4.879 | -9.517±4.717 |
| Percentage change in mean blood pressure | Stage I -7.668±3.320 | -9.510±2.743 | -11.370±3.651 | -11.361±3.638 |

The percentage change ± SEM values of the Systolic, Diastolic, and mean blood pressures of patients in Stage I and II of hypertension (JNC7) with 500 mg BD of Rakatchap Har

Table 3: Statistical analysis of mean change in blood pressure (mm Hg) in females and males

|                  | At first visit | After 2 weeks | After 4 weeks | After 6 weeks | After 8 weeks | P value |
|------------------|---------------|---------------|---------------|---------------|---------------|---------|
| Females          |               |               |               |               |               |         |
| Mean systolic blood pressure | 164.73±3.382 | 138.09±2.836 | 131.14±2.686 | 120.64±5.622 | 120.45±2.372 | <0.0001 |
| Mean diastolic blood pressure | 101.09±1.527 | 89±2.042 | 83.82±1.367 | 85.05±2.121 | 80.18±2.182 | <0.0001 |
| Mean blood pressure | 122±1.807 | 105.41±2.105 | 99.55±1.717 | 97.82±2.122 | 93.50±2.194 | <0.0001 |
| Males            |               |               |               |               |               |         |
| Mean systolic blood pressure | 163.70±3.586 | 139.70±3.995 | 130.81±2.961 | 128.85±2.608 | 125.04±2.184 | <0.0001 |
| Mean diastolic blood pressure | 102.52±2.055 | 89.07±1.774 | 83.85±1.608 | 85.33±2.192 | 81.48±1.365 | <0.0001 |
| Mean blood pressure | 122.48±2.345 | 106.15±2.354 | 99.63±2.054 | 98.48±1.893 | 95.96±1.603 | <0.0001 |

Mean ± SEM values of the systolic, diastolic, and mean blood pressures of female and male patients at first visit and after 2, 4, 6, and 8 weeks of treatment

Discussion

Nowadays treatment of hypertension is governed by established goals given by JNC7 recommendations. In spite of it, not all the patients are having controlled hypertension irrespective of the use of antihypertensive medications. Main reasons are poor patient compliance and adverse effects by antihypertensive drugs.[13] Many phytopharmaceutical products have been proven to be successful in treating hypertension as Ayurveda enjoys the advantage of curing a disease causing minimal adverse effects. Recently, interest in herbal medicines has been rejuvenated and studies are being carried out to prove the clinical efficacy of compound preparations.[14] The trial drug Rakatchap Har is also a herbomineral preparation, which has been formulated taking into consideration the drawbacks of conventional antihypertensive medications. The trial drug contains 6 ingredients, which have been selected for their peculiar qualities to be added for the treatment of hypertension. Saripagandha (Rauwolfia serpentina), which is the main constituent, has antidiurenergic and antidepressant property and is a well-known antihypertensive.[15,16] Shankhpushpi (Convolvulus pluricaulis) is a medicinal rasayan, which controls the production of stress hormones. Its ethanolic extract has been found to reduce cholesterol, triglycerides, and phospholipids. Being an antioxidant also, its use in cardiovascular diseases (CVD), such as hypertension is known. Its stress lowering effect adds to its antihypertensive action.[16] Jatamansi (Nardostachys jatamansi) is another herb, oily extract of which has been found to have antioxidant, anti-ischemic, and antianrhythmic potential. It also increases high-density lipoprotein levels, which are protective lipids.[17] A few studies have also mentioned its anxiolytic action.[16] Jahir Mohra and Moti Pishth studies in hypertension are not too much but are known remedies for CVD.[18,19] Ras sindoor also contributes to decrease high BP by its mind calming effects.[20] Thus the synergistic action of all these is resulting in a high efficacy and high potency antihypertensive remedy “Rakatchap Har.” Treatment with Rakatchap Har has produced an early, sustained, and significant fall in BP. Clinically and statistically significant fall in BP was seen early at 2 weeks in comparison to other herbal formulations studied for their antihypertensive effect.[21,22] Normotensive effect of the drug in terms of SBP and DBP was observed in all the patients. Results were better in Stage II than in Stage I, reflecting its high efficacy in regulating BP. Age or gender did not significantly affect the responsiveness to study drug.
Emphasis has been given on life style modifications by motivating each patient personally at each visit, without ignoring the important aspect of psychotherapy to destress the patient. Along general measures have not so far been able to treat Stage I and Stage II hypertension. So such dramatic improvement in mild to the severe forms of hypertension can be attributed to the trial drug. For further evidence future comparative studies will be done.

In addition to demonstrating superior rate of blood pressure goal achievement with Rakatchap Har, this study demonstrated minimal adverse effects, such as mild headache and fatigue with treatment.

Major drawback of this study is that no controls have been taken to compare its efficacy. Explanation being the preliminary stage of research in the antihypertensive activity of Rakatchaphar Har. Further studies will be followed to assess the comparative efficacy with already existing antihypertensive medications.

**Conclusion**

Rakatchap Har along with life style modification and psychotherapy is a safe and efficacious remedy for the treatment of all grades of hypertension in all age groups with no limitation to its use.

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हिंदी सारांश

उद्दयरत्वचाप रोग में आयुर्विदिक औषधि ‘रक्तचाप हर’ के प्रभाव का अध्ययन

रुचिका नंदा, हरपाल सिंह, परमिन्दर मुदगिल, गुप्तीत कुलर

उद्दयरत्वचाप रोग में सबसे अधिक मूर्तिका का कारण है। जिमें मुख्य भूमिका रक्तचापाधिक की है। यह शास्त्रीय एवं पुश्ची देशों के लोगों का अर्थी रोग बनकर सामने आया है। इस रोग के बढ़ते प्रभाव के कारण एक ऐसी औषधि की आवश्यकता सामने आती है, जो इस रोग में अध्ययन प्रभावकारी हो तथा जिसके कुलभाव नामक हो। आयुर्विदिक चिकित्सा पद्धति (Allopathy) में वर्णित एवं उद्युक रक्तचाप को कम करने वाली (Antihypertensive) दवाओं का संदर्भ में अनुकूल प्रति सामने वाली है। इसके उपयोग से शरीर में कई प्रकार के हुस्तभाव दर्ज करना। विभिन्न औषधियों के शास्त्रीय नामक से यह बात स्वीकार है कि अन्य पद्धतियों भी इस रोग में प्रभावित हैं, उनमें से सबसे ग्राम्य है – आयुर्विदिक प्रकृतिकृत औषधियों का प्रयोग। रक्तचापहर में से एक है। यह आयुर्विदिक औषधि प्रभावशाली तरीके से रक्तचापाधिक को कम करती है। इस तौर पर इस औषधि के उन गुणों का वर्णन एवं मूर्तिका साधन सहित है, जो कि इस औषधि का इस रोग में अध्ययन प्रभावकारी, गुणकारी एवं कुप्रभावारहित बनाते हैं।