

Clinical Evaluation of the effect of *Nigella sativa* and *Rauwolfia serpentina* L. on the patients with High Blood Pressure.

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Summary

In the system of Ayurveda, various drugs are being used to control High Blood Pressure. The blood pressure is controlled by various ratios by these drugs. *Rauwolfia serpentina* is one such plant which is used in manufacturing of drugs used to control High Blood pressure. To increase the effect of this plant, black seed (*Nigella sativa*) is mixed with it and administered to the patients with the intention of studying its effect on high blood pressure. Liver function tests were done to examine whether there will be any side effect due to this combination of drugs. Symptoms of side effect would not be found and SGPT and SGOT levels were not changed significantly. Blood Pressure was reduced within the period of 3 weeks of treatments.

Introduction

Majority of the patients who come to the Ayurvedic hospitals for treatments suffer from paralysis, frozen shoulder, sciatica, back pain, arthritis, rheumatoid arthritis and gout (arthritis). During the examination it is found that a majority of these patients have a value of blood pressure out of the normal range.

In a healthy adult, when the blood is being pumped from the heart, during the systole the pressure takes a value of 115-130mmHg and during the diastole it is about 70-80mmHg. High Blood pressure can occur as a result of liver diseases, kidney diseases, heart problems and also as a result of obesity, high cholesterol levels in blood, irritable mental conditions and even without a particular cause. The high blood pressure caused by the latter reasons is known as Essential Hypertension.

To control this Essential Hypertension several drug types are prescribed by the Ayurvedic physicians. Among these drugs “Ekaveriya vati” or “Sarpagandha vati” takes a key position. The root of the plant *Rauvolfia serpentina* is used as the main ingredient of this drug.

When this drug is administered on patients suffering from Essential Hypertension some of them responded well and some did not. And in some patients the blood pressure fell more than expected. According to these results it is very important for a physician to have a clear understanding about these conditions, in the practice.

Through this study, the Ayurvedic Physicians are given a thorough understanding about the administration of the drug in right dose according to the age of the patient and the range within the blood pressure could be controlled and like wise they get the ability to use the drug in a safer manner.

Among the various chemical components which are included in the root of the *Rauvolfia serpentina* plant, a chemical called “Reserpine” plays the key role in controlling the blood pressure. This chemical has been subjected to many researches.

The whole root of the plant is being used for Ekaveriya vati. But, no research has been conducted to find the effectiveness of using the whole root in controlling the high blood pressure.

According to that it is wished to study the effect on high blood pressure by a drug consisted of the powder of *Rauvolfia serpentina* mixed with black seed powder (*Nigella sativa*) in this clinical research. *Nigella sativa* increases the action of this drug and enhances its ability to get absorbed into the body. Hence the objective of this research was to find out the ability of this drug consisting of *Rauvolfia serpentina* root powder and black seed powder, to control the condition of Essential Hypertension.

Methodology and Materials

Selecting the patients

- Patients were selected from the general clinics of the out door patients departments of three ayurveda hospitals and one private ayurveda clinic.
- They were divided in to two groups randomly. Each group was consisted of 32 patients.
- Both males and females were selected within the age limit of 30-70 years
- Who suffer from Essential Hypertension as the main disease and show no other major illnesses
- Only the patients who show a value of blood pressure within the ranges shown below are chosen:
 - Diastolic pressure- 90-99mmHg (Mild hypertension)
 - Systolic pressure140-160mmHg
- Among the selected patients, there were patients who use other drugs without a further reduction of blood pressure..
- All of the subjected were suffering from Essential Hypertension.
- Patients using other drugs for hypertension were given permission to continue those while using the research drugs.

Preparing the drug

All the drugs were dried and powdered maintaining a maximum cleanliness and made into capsules using machinery. One such capsule contains,

Rauwolfia serpentina root powder 125mg

Nigella sativa seed powder 125mg

Dosage

- Each patient was given 1 or 2 capsules twice a day
- Like wise the patients were given the drug during a period of 4 weeks.
- The blood pressure of each patient was checked once a week

Application of the drug

The drug was given orally with water.

Calculation of the change of the blood pressure due to the drug

The blood pressure of the patient was checked before the drug is given. And it was checked repeatedly once a week during the time period where the drug is given. For this purpose, a mercury column sphygmo manometer was used.

Looking for the side effects caused by the drug.

To a group of patients who were selected randomly from the patients who are using the above mentioned drug was subjected to 4 tests given below before and after taking the drug and the results were analyzed.

1. S.G.O.T
2. S.G.P.T
3. Alkaline Phosphate
4. Serum creatinine

Results and Analysis

When administering the drug to the patients they were divided into 2 separate groups. One group was given 1 capsule at a time and the other was given 2.

The changing pattern of blood pressure of the patients who received 1 capsule twice a day, against the period. (The average of the blood pressure is used)

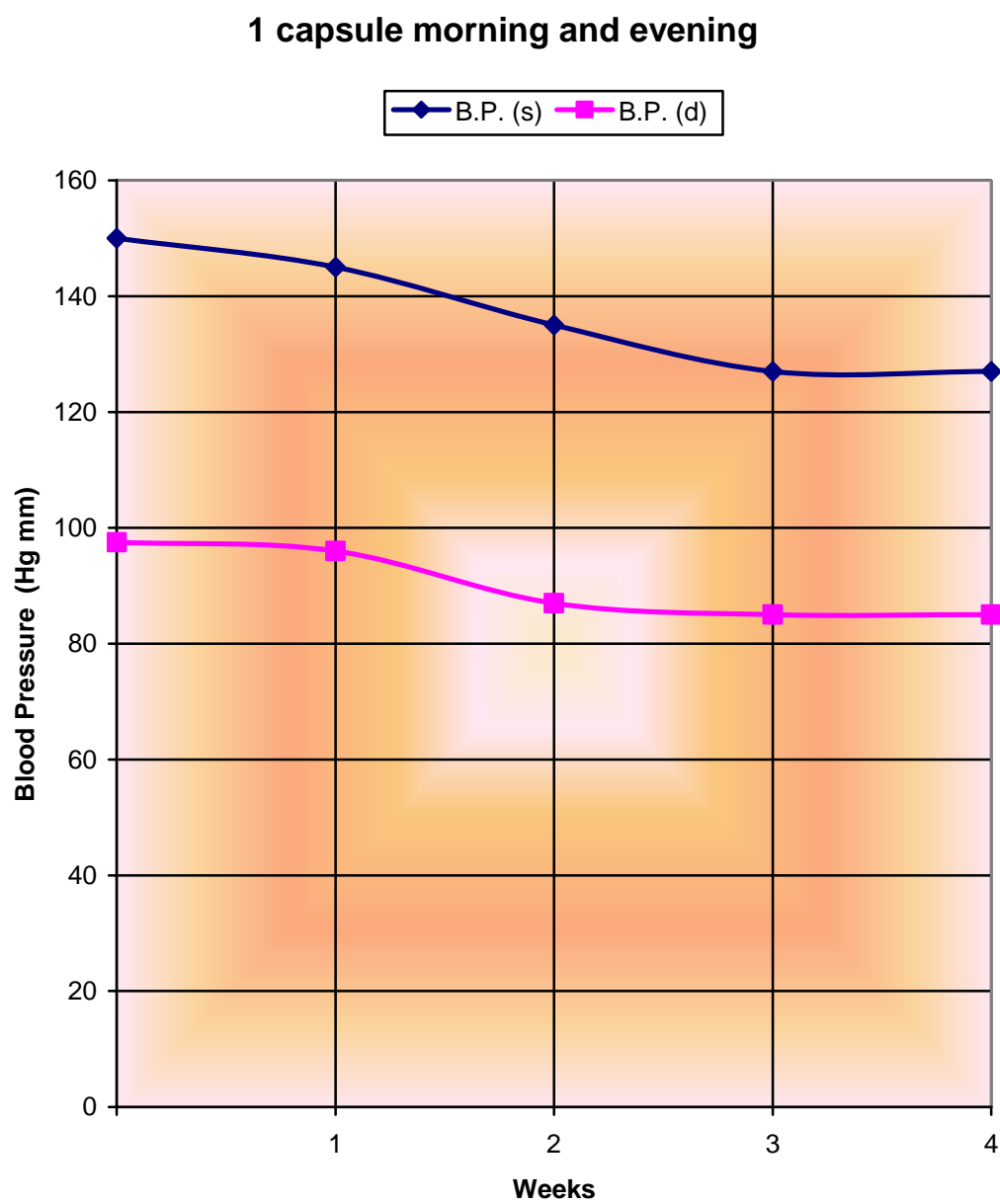


Fig. 1

The changing pattern of blood pressure of the patients who received 2 capsules per day is shown below. (The average of the blood pressure of 32 patients is used)

2 capsules morning and evening

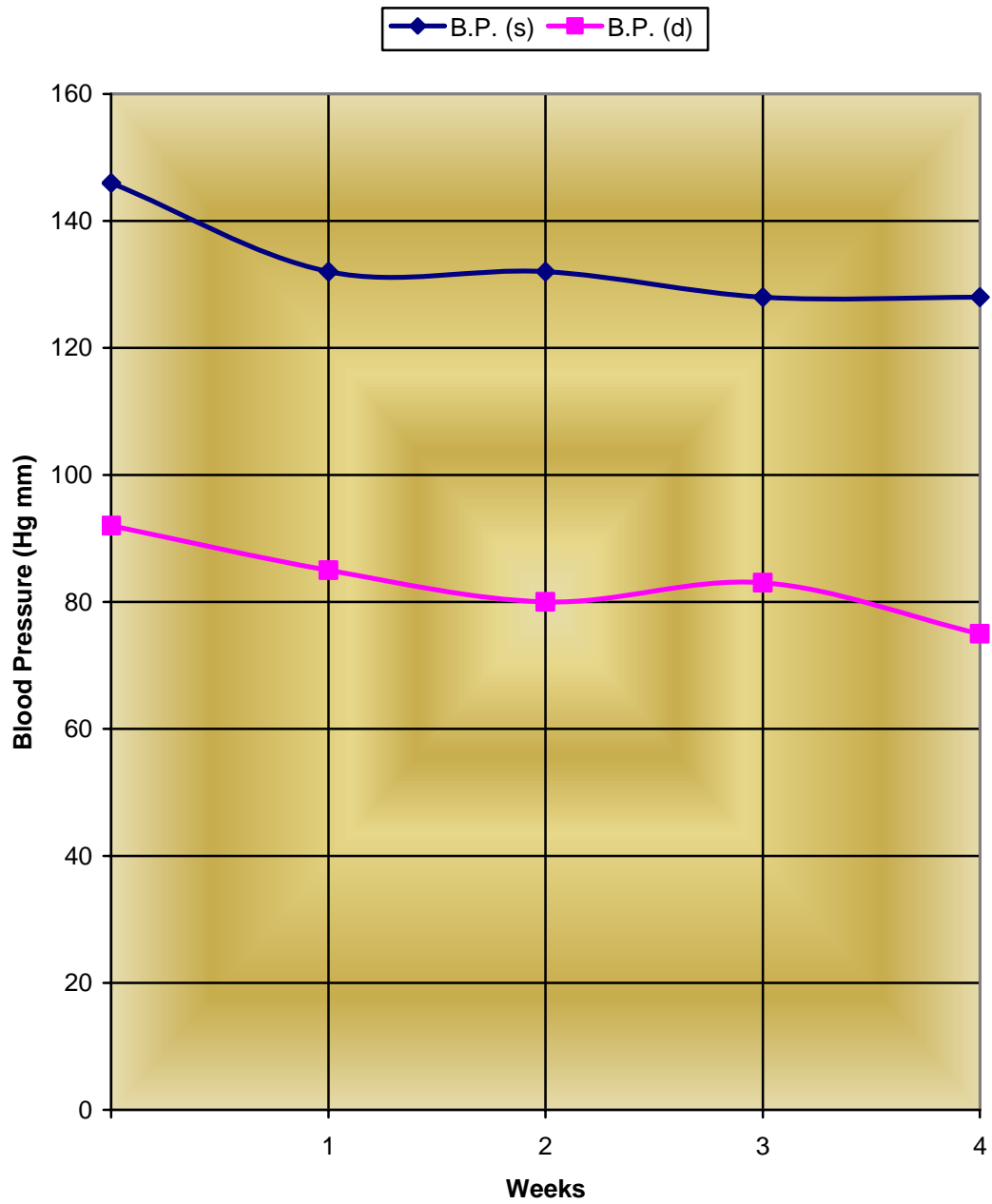


Fig. 2

The dose of the drug and the reduction of the blood pressure of the 2 groups which received 1 capsule and 2 capsules per day are compared below

Dose – 1 capsule

Week	Capsule /s	Doses per day	Systolic Pressur mmHg	Change of Blood Pressure mmHg	Diastolic Pressur mmHg	Change of Blood Pressure mmHg
01	01	02	150 to 145	05	97.5 to 96	1.5
02	01	02	145 to 135	10	96 to 87	09
03	01	02	135 to 127	8	87 to 85	2
04	01	02	127 to 127	0	85 to 85	0
Total change at the end of 4th week			150 to 127	23	97.5 to 85	12.5

Table 1

Dose – 2 capsules

Week	Capsules	Doses per day	Systolic Pressur mmHg	Change of Blood Pressure mmHg	Diastolic Pressur mmHg	Change of Blood Pressure mmHg
01	02	02	146 to 132	14	92 to 85	07
02	02	02	132 to 132	0	85 to 80	05
03	02	02	132 to 128	04	80 to 83	-03
04	02	02	128 to 128	0	83 to 75	08
Total change at the end of 4th week			146 to 128	18	92 to 75	17

Table 2

According to the data and graphs shown above it is seen that the mixture of root powder of *Rauwolfia serpentina* and black seed powder possesses the ability of

reducing the Essential Hypertension and the dose can reduce the hypertension in various magnitudes.

Occurring of Side effects

The patients are observed to see whether the expected side effects of Rauwolfia serpentina is being shown in the patients within the month it was administrated.

The results are as follows,

Symptoms	No of Patients out of 64 patients	
	Before treatment	After treatment
Dizziness	6	0
Drowsiness	5	1
Headache	11	2
Loss of appetite	2	1
Nasal congestion	0	0
Gastro-intestinal upsets	0	0
Impotence	0	0
Nervousness	2	0
Rash	0	0
Itching	0	0
Vertigo	7	2
Flushing	0	0
Mental depression	0	0
Parkinson like syndrome	0	0
Bradycardia	0	0
Lethargy	12	5

Table 3

Testing the toxicity of the drug

The following 4 tests were carried out to find whether there are any toxic effects on the body. The tests were carried out on a group of 27 patients selected randomly from the patients who receive the drug, before and after taking the drug.

The analysis of the results are shown below,

Test	Before treatment	After treatment
SGPT	52.866	43.26
SGOT	43.6	32.4
ALKALINE PHOSPHATA	125.86	108.55
SERAM CREATININE	0.966	0.933

Table 4

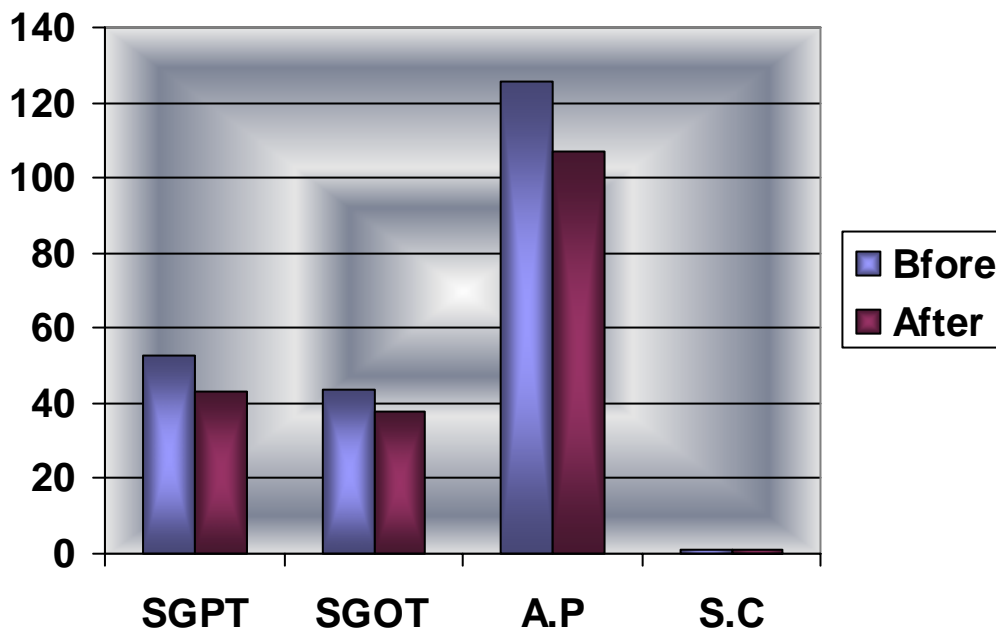


Fig. 3
(Average of the results are used)

Discussion and Conclusion

After the analysis of the data, according to Table 3 it is seen that none of the patients have shown any side effect after using the drug.

Fig. 3 confirm that the using of this drug does not cause any increment in the components of the blood. If the drug has caused any harmful condition to the body, these blood component levels should increase. Hence it can be concluded that this drug is not harmful to the body.

According to the fig 1 and 2 it is seen that the effectiveness of the drug goes up with respect to the quantity. In both situations it has taken a time period of 3 weeks for the blood pressure to reach a constant level. Though a high dose of the drug reduced the blood pressure rapidly it has not been regular. Therefore it is concluded that giving an amount of 250mg of drug twice a day for a period of 3 weeks is more suitable. After the 3rd week the dose has to be reduced gradually.