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A CLINICAL TRIAL ON THE EFFECT OF "ARJIN" (ALARSIN) IN ESSENTIAL PRIMARY HYPERTENSION

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ABSTRACT

ARJIN (ALARSIN) Tablet both in MODERATE HYPERTENSION and MILD HYPERTENSION cases showed statistically significant reduction in both Systolic and Diastolic pressures when administered in the dose of 2 Tablets twice and three times a day respectively. ARJIN did not show any significant change in respiration or body weight. There was no significant change in the heart rate,

Though Hypercholesteremia was not recorded in any patient, it was observed that ARJIN therapy significantly reduced Cholesterol levels in the patients belonging to Mild Hypertension; i.e. Group-I.

In the present evaluation it was observed that ARJIN (ALARSIN) Tablets have improved quality of life by restoring a feeling of well-being. ARJIN was well tolerated by majority of patients.

ARJIN, a Herbal Compound preparation has been proved to be an effective and safe agent for controlling mild to moderate hypertension.

Hypertension is an important risk marker for Hemiplegia (Stroke) and Myocardial Infarction (Heart attack). This disease is often symptomless and its screening is very vital. Left ventricular failure (LVF), Retinopathy and Renal failure are some of the diseases resultant of end organ damage caused by Hypertension. In 95% of cases the cause for Hypertension is unknown. According to etiology the disease is divided into two categories; i.e. (1) Primary or Essential Hypertension (where the definite cause of 'rise" in the Blood Pressure is not known).

(2) Secondary Hypertension (due to chronic Glomerulo Nephritis, Pyelonephritis, Cushing Syndrome etc.). The World Health Organization (W.H.O.) has defined Hypertension as a state in which systolic pressure 150 mm or more and diastolic pressure is 95 mm or more.

The fifth report of the Joint National Committee on detection, education and treatment of high blood pressure framed the following classification (Table 1) and follow-up of Blood Pressure measurements and the same was adopted in the present study.

Initial Pharmacological Therapy for Primary Hypertension usually begins with low doses of Diuretics or Beta-Blocker; and angiotension converting enzyme (ACE) inhibitor or a calcium channel blocker.

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The adverse reactions of these drugs include drowsiness, headache, nightmares, mental depression, disturbances in sexual function, Tremors, Postural Hypotension, Nasal congestion, Suicidal Tendencies, Parkinsonism, fluid retention, rebound rise of Blood pressure, Urticaria, Loss of sensation of taste, Vitiligo, persistent dry cough and renal insufficiency.

TABLE - I
Grade of Hypertension

Category	Systolic Blood Pressure	Diastolic Blood Pressure	Follow Up Recommended
Normal	**130**	**85**	**Recheck in 2 years**
High Normal	**130-139**	**85-89**	**Recheck in 1 year**
Hypertension			
Stage 1 Mild	140-159	90-99	Confirm within 2 months
Stage 2 Moderate	160-179	100-109	Evaluate within 1 month
Stage 3 Severe	180-209	110-119	Evaluate within 1 week
Stage 4 Very severe	210	120	Evaluate or Refer

Keeping these adverse effects of Modern drugs in view, Scientists all over the world are making attempts to evolve anti-hypertensive drugs from herbs which can produce rapid action, act for sufficient duration, do not reduce circulation to vital organs like the brain, kidney, heart and are free from toxic effects.

In ordinary practice neither Physicians nor patients may be aware of the side effects of Anti-hypertensive drugs which can impair the patients quality of life. Ja Chuk et al (1982) surveyed a group of Hypertensive patients receiving modern hypertensive drugs for evaluating patients quality of life. It was observed that patients quality of life was worse after therapy and side effects enumerated by the patient were memory loss (33%), irritability (45%), depression (46%), Hypochondria (55%) and decreased sexual interest (64%).

Risk from Biochemical side effects of the therapy includes Hypokalemia in about one third of diuretic treated patients and elevations in serum cholesterol, triglyceride levels may accompany the use of diuretics or B-Blockers.

The following are some of the medicinal plants found to possess Hypotensive property in various research enquiries.

Hibiscus rosasinensis showed hypotensive action in intact as well as spinal dogs. In a clinical study of 20 patients of mild to moderate hypertension, powdered flowers (6-9 grams a day in divided doses) were reported to produce significant reduction in Blood pressure, the drop being more marked in diastolic than in systolic pressure (Dwivedi et al. 1977).

The Alkaloids of inula racemosa produced a fall in Blood Pressure, which could not be blocked by atropinisation or bilateral vagotomy ·(Janiwal & Anand, 1982).

The aquaeous extract of LEPTADENIA RET1CULATA (Jeevanti) stem showed highly potent and prolonged hypotensive action in anaesthetised dogs. Hypotensive activity was also reported in dogs with Leptadenia reticulata(with Leptaden Tabs. of Alarsin) (Anjaria & Gupta, 1967).

The ethanolic extract (50%) of the whole plant (excluding roots) of Mesua ferra (Nagakesar) showed Hypotensive action in cat, dog (Dhar et.al.,1973) and the effect on the diastolic pressure was significant.

The stem bark of Holarrhena antidysenterica showed Hypotensive action.
The aquaeous extract of H.lndicus (Sariba) caused a slight increase in the Urinary flow in rats but not in dogs.

The acetone extract of Lycopersicon esculentum (Tomato) leaves produced a prolonged fall in the Blood Pressure of Dogs. There was also a complete reversal of Pentobarbitone induced cardiac failure in dogs heart and lung preparation (Omchandra at a1,1968).

The alcoholic extract of Moringa olifeara leaves(Drum stick) caused an initial rise in Blood Pressure in Monrel Dogs & Cats followed by a gradual fall lasting for a considerable duration. Its action on blood pressure suggested the presence of a potent adrenergic neurone blocking substances in the alcoholic extract of M. Olifeara leaves (Singh et a1.,1976).

The extract of Mucuna pruriens (Kapicachu) seeds showed Hypotensive action in dogs.

Tulasi (Ocimum sanctum) exhibited the adaptogenic (antistress) activity in rats and mice (Bhargava & Singh, 1981). The Plant enhanced the physical endurance and survival time of swimming mice, prevented stress induced gastric ulcers in rats (Seethamahalakshmi et al.,1982), It also prevented milk induced leucocytosis in mice. Thus the plant manifested a non-specific type of protection against variety of stress induced biological changes.

The essential oil obtained from the Rhizomes of Nardostachys (Jatamansi) exerted a prolonged and pronounced hypotensive effect in dogs. Jatamansi showed a potent hypotensive activity in Normotensive and Hypertensive rats and in normotensive dogs and cats. Jatamansone was shown to exert tranquilising activity in mice and monkeys. Jatamansone was tested in double blind clinical trial covering 28 patients of moderate to severe Hypertension in an oral dose of 10 mg/per day for 16 days. Jatamansone lowered the Blood Pressure in supine as well as standing position. The hypotensive effect was manifested within 6-8 hours.

The drugs like Prosopis cineraria (Shami), Piper longum (Pippali), Phyla nodiflora (Jalapippali) have also exhibited Hypotensive action. The 50% of ethionolic extract of Rhizome of Picrorhiza kurra (Katuka) revealed significant diuretic activity in rats. (Dhar et a1,1973).

MATERIALS AND METHODS

ARJIN Tabs. (ALARSIN) was administered in the dose of 2 tabs, twice a day in Group I (mild) and 2 tabs, thrice a day in the Group-11 (Moderate).Total 25 patients belonging to Group-1 (13 Patients) and Group-II (12 patients) were included in the present study.

Patients suffering from Ventricular failure, congestive Heart failure, Malignant Hypertension, Cerebra-Vascular attack, Protenuria, Blood Urea above 60 mg or Endocrine disorders were excluded in the present study.

Blood pressure was recorded (Measured) with a standard mercury Sphygmomanometer in both lying and sitting position using constant/ routine examination to ensure as little variability as possible. The Blood pressure was recorded daily for a period of one week initially and at a weekly intervals for the rest of the period; i.e.3 months as per the proforma prepared for this study.

All the patients included in this present study were kept in "Washout period" for atleast one week for various investigations and also in order to eliminate the effect of all the previous anti-hypertensive drugs taken by them.

Each Tablet of ARJIN contains in mg.

Jatamansi	48	**Shilajit**	50
Arjunchhal	12	**Brahmi**	3
Vacha	3	**Sarpagandha**	96
Trifala	24	**Punarnava**	25
Apamarga	12	**Upersari**	12
Kaduwhite	12	**Kadublack**	12
Belmool	12	**Shatavari**	3
Harde	3	**Guduchi**	3
Bhangara	3	**Tarbujbeej**	3
Nishotar	3	**Rasana**	3
Gugul	3	**Tankanakar**	1.5
Shorkar	1.5	**Gokharu**	1.5
Sunth	1.5	**Dashamul**	1.5
Amala	1.5	**Kariyattu**	1.5
Pitapapara	1.5	**Revandchini**	1.5
Ganthoda	1.5	**Khursani Ajivayan**	1.5
Pashanabhed	1.5	**Excp. Q.** S.	

PRESERVATIVES

Sod. Benzoate I.P. - 0.3%: Nipagin I.P. - 0.15%, Nipasol I.P. - 0.3%.

The herbs namely Sarpagandha, Jatamansi, Arjun and Kutaja with proven significant hypotensive property are incorporated in this preparation of ARJIN Tablets formula. Some of the herbs also possess anxiolytic and diuretic properties which facilitate to achieve significant control of Mild to Moderate Hypertension.The herbs namely Brahmi, Vacha, Jatamansi and Khurasani Ajivayan have been proved to be possessing significant anxiolytic and sedative actions. The drugs namely Shilajit, Punarnava, Apamarga, Sariba (Upersari), Guduchi, Tarbuja, Pashanabhed and Gokshura are possessing significant diuretic action.

The drugs like Sarpagandha, Arjuna. Jatamansi and Guggulu play a pivotal role in reducing Hypertension and elevated cholesterol levels rendering cardio-protective action.

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ACTIONS & USAGE OF MAIN INGREDIENTS OF ARJIN

1. Arjin (Terminalia Arjuna) : is stimulant and tonic to heart. Action of Arjuna is noncumulative. It increases urine output and along with that some of the salts also will be excreted.
2. Apamarga (Achyranthus aspara) : is a diuretic and laxative. It acts directly on the glomeruli of the Kidneys and major portion is excreted through Kidneys. The remaining is excreted through Skin, Lungs intestines and liver, regulating the functions of all these organs. Decreases the palpitation of the heart,
3. Upersari (Hemidesmus lndicus) : Indian Sarasaperilla is excellent blood purifier, apitiser, alternative & diuretic. It increases urine output 3 to 4 times without any strain on Kidneys.
4. Bel mool (Algle Marmelos): Sedative to the nervous system. Used in the nervous disorders & Palpitation of the heart.
5. Sarpagandha (Rauwolfia Serpentina) : is a sedative & Hypotensive Extensively used in hypertension and as a mental sedative.
6. Jatamansi (Nardostachys Jatamansi) : Charak says, it is a muscular relaxant. According to Sushruta, a nervine sedative. Regulates cerebral circulation and calms the mind used in high B.P. due to excessive mental work and high blood pressure in alchohalics & headache due to H.B.P. In disorders of the brain ascribed by the modern therapeutics to hypertension and cardiovascular diseases.
7. Kadu (Picrorriza Kurrooa): An effective cholagogue and bitter tonic. Reduces high B.P. and palpitation of heart. It is also laxative.
8. Punarnava (Hoerhavia diffusa) Appitiser, stimulant and diuretic. Rich in Pottassium salts. Action is chiefly on renal epithelium. Doubles the quantity of urine output without putting strain on the kidneys. It increases contraction power of Heart.
9. Shilajit(Aspalturn Panjabinum) : A mild hypnotic, antispasmodic and nervene tonic, having general alterative properties. Used in checking various cardiacneurosis. Commonly given with Trifla (three myrobalans) to control tachycadia, palpitation and to regulate the function of the heart. Also recommended in angina pectoris. It will be most effective when used in synergistic combination.
10. Malkangani (Celastrus Paniculata) Acts on brain and nervous system causes diuresis and helps to restore memory power.
11. Trifala (Three myrobalans) : Laxative, especially increases the flow of Bile and thereby helps the normal functions of the liver,
12. Haritaki (Terminalia Chebula) : One of the ingredients of Trifala removes the sluggishness of the circulatory system, thereby helps cerebral circulation and peaceful sleep.

Thus the synergic action of ARJIN helps to rectify various factors in etiology of high B.P. and corrects the impaired cardiac problem significant at 0.05% level.

Patients included in this trial:
Table No II

Groups		Sex		Total
	Age Group	Male	Female	
Group I	40-50	8	1	9
	51-60	3	1	4
Group II	40-50	5	2	7
	51-60	3	2	5
			Total	**25**

It is evident from the above table that in the present study 13 cases in Group I and 12 cases in Group II were included. Among 25 Patients 19 were Males & 6 were Females.

Effect of Arjin in Group I Patients
Table No III

Pressure	M.D	S.D	S.F	
Systolic	3.84	2.51	0.69	5.52
Diastolic	4.8	2.55	0.7	6.07

*significant at 0.05% level

Effect of Arjin in Group II Patients
Table No IV

Pressure	M.D	S.D	S.F	
Systolic	5.58	2.39	0.69	8.08*
Diastolic	5.33	1.77	0.51	10.4

*significant at 0.05% level

Effect of Arjin on Serum Cholestrol
Table V

Groups	M.D	S.D	S.F	
Group I	2.3	1.84	0.51	4.50%
Group II	1.75	1.22	0.35	4.96%

*significant at 0.05% level

Group II insignificant at 0.00% level.

RESULTS

ARJIN was administered to 13 patients of Mild Hypertension (Group-I) in the dose of 2 tabs, twice a day and to 12 patients of Moderate hypertension (Group-II) in the dose of 2 tablets thrice a day for a period of two weeks initially and all the cases were followed up for three months.

1. In both the groups statistically significant reduction in both systolic and diastolic pressures was observed,
2. ARJIN did not show any significant change in respiration or body weight.
3. There was no significant change in the Heart rate.
4. Though hypercholesteramia was not recorded in any patient, it was observed that ARJIN significantly reduced cholesterol levels in the patients belonging to Group-I.
5. ARJIN was tolerated by the majority patients very well. Mild gastric irritation was complained by three patients and drowsiness in two cases of Group-II.

6. Increased output of urination was reported in 21 out of 25 patients which indicates that ARJIN also possesses Diuretic action.
7. All the patients reported the feeling of well being since some of the ingredients in this formula do have restorative properties
8. During the follow-up studies carried for 3 months, it was observed that ARJIN can control mild to moderate hypertension but cannot completely cure the condition.

ARJIN, a herbal compound preparation has been proved to be an effective and safe drug for controlling mild to moderate Hypertension. In the present study and evaluation, it was observed that Arjin has improved quality of life in almost all the patients by restoring confidence and feeling of well being.

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