

## A CLINICAL TRIAL FOR EFFICACY OF ASHWAGANDHA EXTRACT IN STRESS RELATED DISORDERS AND GENERAL INDEX OF QUALITY OF LIFE

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### ABSTRACT

The response of human body & mind is within brain and nervous system. During it becomes intensely active leading to altered metabolic state. Hormones such as adrenaline are released into circulation along with glucose from liver. Persistent stress can lead to various health problems being associated with sustained disturbance of autonomic nervous system and poor stress adaptation. In Ayurveda one of the answer for these stress related ailments is “Rasayana chikitsa” which means “Rejuvenation therapy”. Ashwagandha is one of the most powerful medicinal plant and has been used for more than 3000 years. Ayurveda pharmacopeia considers it Rasayana and it has been found to be excellent adaptogenic natural product. It promotes sleep and normalise nervous drive, thereby restores vitality, strength, energy and reduces feeling of tiredness and fatigue. The Present study conducted at R.G.G.A.P.G.H., Paprola, H.P. is based on clinical trial of *ashwagandha* extract(1000 mg/day) in form of a capsule each containing 500 mg of drug. Total 30 patients were enrolled for present study. The analysis of pre and post trial objective and subjective criteria establish anti stress potential of the drug.

**Keywords:** *Ashwagandha*, *Rasayana*, Stress disorders, Anxiety, Depression, Adaptogens

### INTRODUCTION

In Modern Era there are various challenges to health like stress leading to anxiety, depression, insomnia and related disorders. The body & mind react to any stress factor wherein brain and nervous system became intensely active during stress and may lead to altered metabolism. Hormones such as adrenaline are released into system along with glucose from Liver. Persistent stress can lead to altered autonomic nervous drive which is root cause of stress related ailments.<sup>1</sup> Stress induced reduced immunity is also a common challenge. Reduction of natural ability of immune system to attack intruding microorganisms, and toxins

causes increase susceptibility to infection and serious illness. It is therefore important to strengthen the immune system in patients under stress.<sup>2</sup> In *Ayurveda* one of the answer for these problems is “*Rasayana chikitsa*”. *Rasayana chikitsa* means Rejuvenation therapy. It is concerned with measures that relate to physical, social and spiritual harmony. *Rasayana* is an active step toward achieving this.<sup>3</sup> *Rasayana* means the physical, mental and spiritual assistance to the human body which brings the body out of condition of natural or man made loss. *Rasayan chikitsa* basically boosts the immune system. It helps a person to maintain good

health or to establish impaired or lost physical or mental health. It provides a long disease free life to the person who undergoes this therapy. It is supposed to nourish blood, lymph, flesh, adipose tissue and semen and thus prevent degenerative changes and illness, giving freedom from chronic degenerative disorders like arthritis and senile diseases. Rasayana helps to improve metabolic processes which results in best possible biotransformation and provide the best quality of body tissues, metabolism and delays diseases of old age.<sup>4</sup> *Ashwagandha* literally means "To impart the strength of horse" is also known as Indian Gingseng or Indian Winter cherry. It is extensively used in *Ayurveda* as *Rasayana*. It is used as general tonic, adaptogen thereby helping body adapt to stress. *Ashwagandha* has been shown to possess antioxidant activity as well as ability to support a healthy immune system.<sup>5</sup> It is one of the most powerful medicinal plant and has been used for more than 3000 years. It promotes sleep and normalizes the nervous drives thereby restores vitality, strength, energy and reduce feeling of tiredness and fatigue. It is used as *Rasayana* meaning that it acts as an overall tonic for greater vitality & longevity. *Ashwagandha* nourishes the crucial mind body connection and psycho-neuro immune response. It helps coordinate the mind and senses as well, which is essential for good quality sleep. It balances the mind. This is essential for happiness in face of mental or emotional stress.<sup>6</sup> *Ashwagandha* is also having tissue building properties. It is also considered an anti-aging herb due to its Rejuvenation and longevity enhancer properties. It also act as Anti-inflammatory and pain reducing agent in Arthritis. It also enhances virility and have aphrodisiac properties. It is also well known for its powerful immune enhancing benefits. It is an effective brain tonic.<sup>7</sup> So *Ashwagandha* thus being Immunomodulatory, Anti-stress, Adaptogenic, Anti-oxidants, Anti-inflammatory, Anti-arthritis, Cytoprotective, Cardioprotective, Sedative, Anti bacterial etc. This

can be used for multiple therapeutic benefits in human body. Numerous studies suggest *Ashwagandha* can directly or indirectly prevent & treat a number of disease. Present study was conducted to explore evidence based therapeutic potential of *Ashwagandha* extract in Management of Stress related Disorders.

#### **Aims & Objectives of Present Study**

1. To evaluate the efficacy of *Ashwagandha* extract in management of Stress related Disorders especially mood disorders.
2. To evaluate the safety of Drug

**Material and Method:** The study was conducted in compliance with good clinical practice (GCP) guidelines and other applicable regulations.

**Study Subjects-** A total of 20 subjects were assessed with regard to eligibility for inclusion in study in hospital wing of Kayachikitsa, R.G.G.P.G.A.H., Paprola, H.P.

Trial patients of either sex were selected between age group of 20-60 years. Routine blood examination was carried out in order to rule out any other pathology and monitor normal values of blood during trial period. Trial Subjects were detailed about nature of trial and informed consent was obtained.

#### **Inclusion criteria-**

1. All the patients suffering from generalized weakness.
2. All the patients in age group of 20-60 years.
3. The patients having three or more features included in clinical study like weight loss, numbness of hand and feet, Wasting, Easy fatigability, Stage 1 Hypertension as per JNC-7 parameters, disturbed sleep, Stress related features like Anxiety, Depression etc.
4. Patients able to provide informed consent.

#### **Exclusion criteria-**

1. Patient not willing for trial.
2. Patient below age 20 and above age 60.
3. Patient with advanced chronic diseases.

4. Alcohol and drug abuse.
5. Patient with acute disorders.

#### **Period of clinical study:**

Start date: December 2014

Completion date- March 2015

#### **GROUP-**

The study was done in single trial group. It was open trial with voluntary participation of subjects.

**Statistical method used- t-test (IBM SPSS STATISTICS 20)**

#### **Study, Visits and Assessment-**

The subjects visited the hospital at screening and enrollment and after 30 days of trial period.

Routine investigations were done at the time of enrollment and necessary investigations done at the time of completion of trial.

The efficacy of *Ashwagandha* as *Ra-sayana* was evaluated by special proforma for assessment & evaluation which include grading for General feeling of wellbeing, Fatigue, Weight gain, Sleep, Digestion, Grip Power, Foot Thrust, QOL Questionnaire, VAS etc. improvement categorized as GOOD, MODERATE & MILD.

#### **RESULTS & OBSERVATIONS-**

20 Patients were registered and all turned for follow up after 30 days.

As per assessment criteria out of 20 patients, 3 patients showed good improvement, 13 shows moderate Improvement and 4 showed mild/no improvement. Statistical analysis shows all variables kept in Assessment and Evaluation criteria have significant positive improvement ( $p < 0.001$ ).

*Ashwagandha* has shown to exert a greater improvement in all QOL subdomains. (Dimensions of Quality of Life in SF-36) Marked improvement found in fatigue.

The patients of all ages and both the sex groups reported improvement in their complaints.

No side/adverse effect found in any patient.

#### **Symptom wise details-**

##### **1.General feeling of wellbeing**

Mean Score before treatment was 2.100 which fell to 0.7500 giving improvement

of 64% which was highly significant with t value of 12.33 and  $P < 0.001$

##### **2.Fatigue-**

Mean Score before treatment was 1.700 which fell to 0.400 giving improvement of 76.47% which was highly significant with t value of 10.17 and  $P < 0.001$

##### **3.Appetite –**

Mean Score before treatment was 2.100 which fell to 0.8500 giving improvement of 64% which was highly significant with t value of 8.753 and  $P < 0.001$

##### **4.Weight gain-**

Mean Score before treatment was 3.000 which fell to 1.6500 giving improvement of 45% which was highly significant with t value of 10.283 and  $P < 0.001$

##### **5.Ability to work-**

Mean Score before treatment was 1.900 which fell to 0.600 giving improvement of 68.42% which was highly significant with t value of 10.177 and  $P < 0.001$

##### **6.Digestion**

Mean Score before treatment was 1.300 which fell to 0.6500 giving improvement of 50% which was highly significant with t value of 5.940 and  $P < 0.001$

##### **7.Sleep-**

Mean Score before treatment was 0.9500 which fell to 0.200 giving a improvement of 78.94% which was highly significant with t value of 7.550 and  $P < 0.001$

**8.The QOL questionnaire( Dimensions of Quality of Life in SF-36)** was used to evaluate a given subjects quality of life. It comprised 8 items which measures the broad domains ;physical & psychological health. The Procedure entails each question being read out to the subject, along with response option. *Ashwagandha* has shown to improve all domains of the QOL questionnaire.

**9.VAS (Visual analogue scale )** . Patients were asked to explain their sense of wellbeing in percentage. Improvement was found in all patients.

##### **10.Grip power-**

It was checked with the help of cuff of mercury sphygmomanometer. Mean Score before treatment was 109.5 which increases to 127.65 giving a improvement of

14.93 % which was highly significant with t value of 6.0422 and P<0.001.

### 11. Foot thrust-

Measured with the help of weighing machine. Score before treatment was 35.5 which increases to 38.8 giving a improvement of 9.19% which was highly significant with t value of 9.864 and P<0.001.

### 12. Blood Investigations-

All routine investigations were done before trial to exclude pathology and only required investigations done after trial.

- Hb- Mean Score before treatment was 11.01 which increases to 11.97 giving a improvement of 2.5% with t value of - 0.766 and P= 0.456

- FBS- Mean Score before treatment was 86.33 which increases to 97.91 giving a improvement of 1.3% with t value of - 0.906 and P= 0.384, not significant

The data of study shows significant improvement (p<0.001) Except Hb and FBS. The present study was limited by small sample size. Further study with a larger sample validate the finding of this study.

**Table no 1**

S.NO	SYMPTOM	MEAN		%DIFF	S.D.	S.E.	“t”	p
		BT	AT					
1	General feeling of wellbeing	2.100	0.750	64.00	0.4893	0.1094	12.337	<0.001
2	fatigue	1.700	0.400	76.47	0.5712	0.5712	10.177	<0.001
3	Appetite	2.100	0.850	59.52	0.6386	0.1428	8.753	<0.001
4	Weight gain	3.000	1.650	45.00	0.5870	0.1312	10.283	<0.001
5	Ability to work	1.900	0.600	68.42	0.5710	0.1277	10.177	<0.001
6	Digestion	1.300	0.650	50.00	0.4890	0.1094	5.940	<0.001
7	Sleep	0.950	0.200	78.94	0.9934	0.5420	7.550	<0.001
8	Haemoglobin	11.01	11.97	2.5	1.4829	0.382	-0.766	0.456
9.	FBS	86.33	97.91	1.3	44.29	12.78	-0.906	0.384
10.	Grip power	109.5	127.65	14.93	12.11	2.7091	6.0422	<0.001
11.	Foot thrust	35.5	38.8	9.19	1.481	0.331	9.864	<0.001

## DISCUSSION

Stress is reaction to a stimulus that disturbs our physical or mental equilibrium.<sup>6</sup> Inappropriately handled stress can be devastating. It lowers our resistance and make us more vulnerable to illness and disease<sup>1</sup>. Hypertension, Diabetes mellitus, Coronary Artery Disease, Tuberculosis are common health problems. Reduced Immunity is a common challenge. Reduction in immunity fail to check natural intruding microorganism, and toxin causing increased susceptibility to infection and serious illness. It is therefore important to strengthen the immune system. Similarly aging is important part of all human society reflecting cultural and society conventions. It is a progressive change related to passage of time.<sup>7</sup> Ayurveda is concerned with measures to protect “Ayu”(age) which includes healthy living along with

therapeutic measures that relates to physical ,mental ,social and spiritual harmony. Ayurveda sees a strong connection between the mind and body. The objective of Ayurveda is to accomplish the physical, mental, social & spiritual well being by way of adopting preventive approaches as well as to treat the disease with holistic approach.<sup>8</sup>

Ashwagandha is also having Immunomodulatory activity. It also enhances virility and has aphrodisiac properties. It is also well known for its powerful Immune enhancing benefits. Ashwagandha is also used in certain ailments like digestive disorders, general debility, rheumatism ,Tuberculosis, Diabetes mellitus, Insomnia in certain stressful situation ,cough etc. It is also an effective brain tonic<sup>9</sup>.

Study from university of Leipzig in Germany has shown that it inhibits Acetyl-

cholinesterase(AchE) an enzyme responsible for breaking down of Acetylcholine. Ashwagandha is used to treat mental deficit in geriatric patients, including amnesia<sup>10</sup>

. Antioxidant researchers from B.H.U.in Varanasi have discovered that some of chemicals with in this compounds for their effects on rat brain and found on increase in level of 3 natural anti-oxidants ie. superoxide dismutase, catalase and glutathione peroxidase. These findings are consistent with therapeutic use of Somnifera as an Ayurvedic Rasayana.

A study done in Department of pharmacology (2000). Univ. of Texas health sciences indicated that extract of Ashwagandha has GABA like activity. This may account for this herb's anti-anxiety effect. Study by Pathania Sanjeev et.al 2005 , at R.G.G.P.G.A.H. 34 patients were registered and given Ashwagandha churna 5gm bd with milk in chronic ailments like Tuberculosis, Diabetes Mellitus, Rheumatoid Arthritis . Results were highly significant.<sup>11</sup>

Similar study by Hemraj et.al. 2007, at R.G.G.P.G.A.H., 38 patients were registered out of which 32 patients completed trial. This includes 16 patients of Pulmonary Tuberculosis and 16 Patients of Diabetes mellitus who completed trial. Each group was given Ashwagandha churna 5gm BD with milk. There were highly significant results in general feeling of well being, fatigue, ability of work ,sleep, cough ,fever expectoration, tingling sensation and ESR.<sup>12</sup>

Another study which was done in Dept. of Zoology Kurukshetra India and Univ. of Texas Health Sciences indicated that extract of Ashwagandha on copper induced lipid peroxidation (a cause of ageing process) and has antioxidant enzymes in aging . It was concluded that Ashwagandha might have role in delaying aging and copper induced physiological and pathological condition .

Ashwagandha improves body's ability to maintain physical effort and helps body to adopt to various types of stresses. It acts to

calm the mind & promote sound and restful sleep. It works as adaptogen ,promoting body's ability to maintain homeostasis and resist stress. Ashwagandha also has sedative effect, which calm the fuelled anxiety that accompanies stressful life style. Ashwagandha has often been used to meet primary anxiety states.<sup>13</sup>

No side/adverse effect found in any patient.

## CONCLUSION

Findings of this study suggest that Ashwagandha is effective as rasayana as it improves quality of life. Ashwagandha is also having antistress property, antioxidant action, antianxiety action. It acts as immunomodulator and is useful in chronic fatigue syndrome. It helps in delaying aging. It is cognition enhancer and memory improving. It possesses hemopoietic effect, adaptogenic action, nutritive function and neuroprotective action.

No side/adverse effect found in any patient which shows drug is safe for use.

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