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Research Article

A CLINICAL EVALUATION OF ANTISTRESS ACTIVITY OF *ASHWAGANDHA* (*WITHANIA SOMNIFERA* DUNAL) ON EMPLOYEES EXPERIENCING MENTAL STRESS AT WORK PLACE

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ABSTRACT

According to various surveys, the stress is the major problem for many diseases ranging from psychiatric disorders to endocrine disorders. In national capital regions like Mumbai, Chennai, Kolkata and Pune. As per the survey over 76% of senior and middle level executives working endure the highest levels of stress resulting into mental and physical fatigue. Pertaining to the stress, modern medicine can provide some curable results but they are complicated and unsatisfactory. So the answer is hidden in *Ayurveda* i.e. *Rasayana Chikitsa* (Rejuvenation therapy). As similar to the modern concept of adaptogenic agents which gives the protection to the human physiological system against diverse stressor, recent studies shows that the *Rasayana Dravyas* having adaptogens which could induce a state of non-specific increase of resistance to affect internal homeostasis. The adaptogens improve the response to stress and help the body to adapt by normal physiological processes in times of increased stress. Therefore, *Ashwagandha* which is the best in *Rasayana Karma*, identified as *Withania somnifera* Dunal, is selected for the study. The present research work has been undertaken with the main objective as the clinical evaluation of antistress effect of *Ashwagandha* (*Withania somnifera* Dunal) on employees at different work places by various scientific parameters.

KEYWORDS: *Ashwagandha,* Withania Somnifera, Antistress Activity, *Rasayana,* Adaptogens.

INTRODUCTION

Rasayana is one of the eight branches of *Ayurveda*. This *Dravya's* are claimed to contribute in revitalising the tissues and even the psyche thereby maintaining mental health of the human being. These are stated to possess rejuvenation power which enhance the *Ojas* of the body i.e. vitality.[1] *Ayurveda* has very vividly classified various sources of stress in terms of *Asatmyendriyartha samyoga, Pragyaparadha* and *Parinama.* As modern man is living in the perpetual state of ever increasing stressful situations arising from the development of science and technology, environmental pollution, highly ambitious and competitive life styles, over population, monotony and boredom of complex interpersonal relationships, jobs responsibilities and many other associated mental and emotional causes. All socio-economic groups of population including high pressure executives, businessman, working women and even students are affected by a variety of stresses. The growing stress and strain of modern life has attributed to the development of an undesired body response, which if continues result into the development of a variety of stress disorders.

The stress disorder is a psychosomatic disease. The latest research by Workplace Provider Faculty shows that Indian workers are getting more stressed. The survey reveals that work (51%) and personal finance (49%) are the contributing factors for the increased stress level of the Indian employees. Half (51%) of Indian respondents say their stress level have raised over the past year.[2] In conventional medicine the long-term, stress-related changes in brain structure can be altered by multiple pharmacologic interventions. The major drugs to be used for the treatment of stress are benzodiazepines, the serotonin-specific reuptake inhibitors (SSRIs), Buspirone (BuSpar) and Venlafaxine (Effexor). Other drugs that may be useful are tricyclic drugs e.g. Imipramine, antihistamines, and β-adrenergic antagonists. Benzodiazepines have a relatively favourable

adverse effect profile. Adverse effect of these drugs is well known which can hamper brain cognitive function on longer administration. The only treatment of stress in modern medicine is anxiolytics or antidepressant etc. while the basic cause of any psychological disorders is the physiological pathways that connect the mind and body demonstrating a strong relationship between them and emphasize the mind's effect on the body. Thus at this level, *Ayurveda* holds a holistic approach in management of any disease by modification of diet, drug and lifestyle, specifically according to *Prakruti* of the individual may provide better results. There are so many somatic diseases in which psychological symptoms have been described whereas in the description of *Manasika Roga*, somatic characters are also mentioned. In *Ayurveda*, avoidance of the causative factors is described as the first line of treatment of any disease whether it is *Sharira* or *Manasa Roga*.

The *Medhya Rasayana Dravyas* described in *Ayurveda* have better effect on the mind and body which helps to alleviate the symptoms of stress and increase day to day performance and cognitive functions. The *Rasayana Dravyas* acts through the mechanism of specific molecular nutrition to the target organ at fault in the true sense of the concept, the *Rasayana* therapy is not only a single drug treatment, but it is a comprehensive and specialized regimen capable of causing healthful longevity and improved mental faculties by acting at the level of *Rasa* (Nutrition), *Agni* (Digestion and Metabolism) and *Strotasaa* (Microcirculatory Channels), thus enabling the organism to procure best qualities of different *Dhatus*.[3] *Ashwagandha* increased peritoneal macrophage activity as it has an advantage over *Panax ginseng* that it does not appear to result in Ginseng abuse syndrome, Also *Ashwagandha* appearing to stimulate stem cell proliferation and improve red blood cell, white blood cell and platelet parameters.[4] Two new glycowithanolides, sitoindoside IX (1) and sitoindoside X (2), isolated from *Withania somnifera Dunal*, were evaluated for their immunomodulatory and CNS effects like antistress, memory and learning in laboratory animals. Both these compounds produced significant anti stress activity in albino mice and rats, augmented learning acquisition and memory retention in both young and old rats. These findings are consistent with the use of *Withania somnifera* in *Ayurveda* to attenuate cerebral function deficits in the geriatrics population.[5]

An alcoholic extract from roots & seeds of *Ashwagandha* dissolved in normal saline was given (100mg/kg intra peritoneal as a single dose) to 20-25 gm mice in a swimming performance test in water at 28'-30' C. It is seen that the extracts approximately double the swimming time when compared to control. It suggested that *Withania somnifera* induced a stage of nonspecific increased resistance during stress. Glycosides of *Withania somnifera* exhibited significant antistress activity in forced swimming induced immobility in mice, restraint stress induced gastric ulcer & auto analgesia in rats.[6]

The antioxidant action of *Withania somnifera* could be attributed to withanolides (sitoindosides VII-X) & withaferin-A (glycowithanolides) present in *Withania somnifera* extract. Besides the presence of other potential sources of antioxidant compound such as polyphenols, flavonoids & alkaloids, vitamin-C can attribute to the antioxidant efficacy of *Withania somnifera* as In-vitro exposure of goat blood to 1, 4-dioxane & Trichloro ethylene can alter the biochemical parameters, induce oxidative imbalance by reducing antioxidant dioxane or Trichloro ethylene induced oxidative stress.[7] From all above reasons, *Ashwagandha* was selected for evaluation of its antistress effect.

AIM AND OBJECTIVES

To study the antistress activity of *Ashwagandha* (*Withania somnifera Dunal*) Granules on employees experiencing mental stress at different work places.

MATERIALS AND METHODS

1. Collection of sample of *Ashwagandha* root (*Withania somnifera Dunal*).
2. *Ashwagandha* granules will be prepared as per standard procedure.
3. Standardisation of *Ashwagandha* granules will be done by following parameters
   a) Organoleptic characters
   b) Physio-chemical parameters like Ph value, solubility, sugar estimation (Total, Reducing, Non-reducing)
4. All questioner scales were translated in Devanagari language for better interpretation.

Sample size

Considering risk factor 1, Odd's ratio 1, efficacy 95%, prevalence 50%, drop out 10%, the calculated sample size was n=40

Trial design

A prospective, simple, randomized, open labelled study was conducted on 40 patients of stress (n=40). Patients will be randomly selected based on scores obtained from work place stress scale

Ethical clearance

1. No objection certificate was obtained from the Institutional Ethics Committee (IEC) prior to initiation of the project. Entire work reports was recorded by IEC (GAC/IEC-NO./178/2014)

2. Bilingual patient information sheets were prepared.

3. Informed consent was taken from all 40 patients before initiation of the trials.

Inclusive criteria

1) Patients of age group between 35 to 65 years.

2) Patients with workplace stress scale score more than 15.

Exclusive criteria

1. Patients of age group less than 35 and more than 65 years
2. Pregnant or nursing women
3. Metabolic, Systemic disorders e.g. Anaemia, Hypertension, etc.
4. Patients taking sedative drugs, hormonal therapy, natural health products

Withdrawal of subjects

1. Patient following the treatment very irregularly.
2. Patient willing to discontinue from trial.
3. Occurrence of severe adverse effects.

Baseline assessment

All the selected subjects were screened initially (on 0 day) on the following baseline parameters.

1. Patients showing signs and symptoms of stress.
2. Patients having Workplace stress scale score more than 15.
3. Patients having comparatively high score of PSS- 14 scale by Sheldon Cohen.
4. Patients having comparatively high score of *Manasa Pariksha Bhava*.
5. Patients having comparatively high value of Serum cortisol of blood.
6. Clinical examination and case record form (CRF).

Thorough assessment of each patient was done by clinical examination.

Study period

Total study period was of 60 days i.e. baseline screening on day 0 and follow up was taken on 60th day.

Standard drug preparation

Formulation of *Ashwagandha* Granules (*Treebhavita*) by approved drug manufacturing pharmacy company. Preparation is made according to standard operating procedure (S.O.P.). The text followed for standardizing the procedure is '*Sharangdhara Samhita'*. [Fig.1]

Raw Material : *Ashwagandha (Withania somnifera Dunal)*

Part used : Roots

Dose Determination Study

The recommended dose of *Ashwagandha* granules is 10 gm. Dose variation study was conducted for determination of suitable, effective therapeutic dose. For this purpose, *Ashwagandha* granules was given to individuals with the starting dose of 5 gm in two divided doses for 7 days. The maximum effective dose without producing any adverse effect was found 10 gm in two divided doses which was administered to every individual. The dose of *Anupana* has not been mentioned in texts. It is said that it should be used accordingly as needed.

Drug delivery system

All the 40 subjects registered for the trail were recommended *Ashwagandha* granules through oral route in the dose of 10gms twice a day i.e. *Prataha Bhojanpurva* (Before lunch) and *Ratrau Bhojanpurva* (Before dinner) with luke warm water for the duration of 60 days with dietary restriction as per the descriptions available in the *Ayurvedic* classics during the therapy. Follow up was taken after 60 days.

Criteria for assessment of efficacy

A. Subjective Parameter:

Quality of life questionnaire given by WHO for health assessment was evaluated before and after treatment.

1) The workplace stress scale [by American Institute of Stress, New York]

Total score of 15 or lower: Chilled out

16 to 20 : Fairly low stress
21 to 25 : Moderately stress
26 to 30 : Severe stress
31 to 40 : Stress level is potentially dangerous

2) Perceived stress scale (PSS-14) by Sheldon Cohen

- Total scores of PSS-14 ranges from 0-56.
- A higher score indicates greater stress.
- PSS-14 exhibited satisfactory psychometric properties & their used for research & health care practice is warranted.

3) *Manasa Pariksha Bhava*[8]

***Nidra* (Sleep)**

Sound sleep	:	0
Sound Sleep when interrupted, can sleep again	:	1
Sound Sleep when interrupted, can't again	:	2
Disturbed sleep but can sleep for few hrs.	:	3

***Krodha Abhidrohena*. (Anger) (I.e. *Parapidartha pravrittihi_Chakrapani*)**

No violent tendencies	:	0
Violent thoughts very rarely	:	1
Violent, sadistic functions oftenly	:	2
Frequent thoughts & functions of violence & sadistic	:	3

***Shok Dainyena* (Sadness) (i.e. *Rodanadi_ Chakrapani*)**

No feeling of sorrowness	:	0
Feels inferiority & sorrow at occasion	:	1
Inferiority complexes & greedy oftenly	:	2
Weeps & feels inferior very frequently		3

***Vignyanam Vyavasayena* (Routine work)**

Normal functioning in routine	:	0
Gradual hampered performance in functioning	:	1
Impaired motivation towards functioning often	:	2
Loss of pace & motivation in functioning	:	3

***Veeryam Uthhanena/Kriyarambhakatva* (Encouragement) (i.e. *Kriyarambhena Chakrapani*)**

Starts & works very quickly	:	0
Work with less interest	:	1
Delayed & decreased in working capacity	:	2
Not able to start any work	:	3

B. Objective Parameter:

Serum Cortisol Level

Normal values are 6 to 23 micrograms per deciliter (mcg/dL), may vary slightly among different laboratories. Physical and emotional stress, as well as illness, can increase cortisol levels because during the normal stress response, the pituitary gland releases more ACTH which may be within the normal range. But still patient feeling stressed, first he was evaluated according to subjective parameters.

OBSERVATIONS AND RESULTS

The study of demographic profile of 40 registered patients of stress having age between 35-65 years, visiting O.P.D. of Government Ayurved Hospital, Nanded for different ailments and problems, revealed following interesting information.

The study of age and sex revealed that there was predominance of the patients of 35-45 years 77.5% of age and the predominance of males 28 (70%) respectively in the present series of patients registered for the trial. Near the age of 40 years, the persons are considered to be more active in this phase of life to achieve something and to make carrier for better tomorrow. In addition, today's competitive life style as well as strong will power of youth to get top most position complicate the picture. Because of this factors, the persons are prone to suffer from the stress that is why the incidence of stress was high in this age group. The predominance of males may be because of the male dominant society, whose problems are given more importance, while the problems of female are often ignored. The study of the incidence of occupation revealed that the majority of patients 45% were having sedentary work. The patients of middle economic status dominated the series of patients registered for the present trial.

In India, the people belonging to middle economic status have face to a stressful life in all aspects. As regards the marital status, most of the patients registered were married. The reason is, as mentioned earlier that the patients between the ages of 35-65 years were taken for the present trial. Most of the patients registered for the present trial were vegetarian 55% without family history of psychiatric illness.

Some found to be addicted to tobacco, smoking and caffeine. These findings correspond

with the culture and status of the Indian patients. The disease witnessed chronic onset in all the patients which corresponds with the nature of disease and delay in the awareness towards this ailment. One of the feature in the present series of patients of stress was *Malavashtambha* (constipation) which corresponds with predominance of *Dosha* i.e. *Vata*. The study of *Agni* revealed that the disease has victimized almost patients of all types of impaired *Agni* in good numbers.

The study of the incidence of the *Deha Prakruti* revealed the predominance of *Kapha-Pitta Prakruti* 35%. As regards the *Manasa Prakruti*, the *Rajasa Prakruti* were predominant in this type of patients according to their way of talking, their attitude, behaviour, day to day activities etc. It may be because the *Rajasa* persons are very active in all types of social work and easily become exited and violent, so they have to face much stress and conflicts in life.

In Workplace stress scale score, 57.5% of patients were having score between 21 to 25 i.e. moderately stressed before treatment and after treatment 50% of patients were found in the range between 16-20 i.e. fairly low stressed.

In Perceived stress scale, before treatment, 40% of patients having score range of 26-30 and after treatment, 42.5% patients were having score range of 21-25 as higher score indicates greater stress. PSS-14 exhibited satisfactory psychometric properties and their used for research and health care practice is warranted.

In *Manasa Pariksha Bhava* scale

- For *Nidra* score, majority of patients (47.5%) were having disturbed sleep but can sleep for few hours and after treatment 70% of patients were having sound sleep.
- For *Krodha* (i.e. *Parapidartha pravrittihi Chakrapani*), majority of patients (60%) were having violent thoughts very rarely and after treatment 80% were having the same results.
- For *Shoka* (i.e. *Rodanadi Chakrapani*), majority of patients (62.5%) were having feels inferiority and sorrow at occasion and after treatment 75% were having the same results.
- For *Vigyana*, 35% were having impaired motivation towards functioning often and after treatment 37.5% were having gradual hampered performance in functioning.
- For *Veeryam Uthanena* (i.e. *Kriyarambhena Chakrapani*), 37.5% were having tendency to starts and works very quickly and after treatment 57.5% were having tendency to starts and works very quickly.

In objective parameter, before treatment, maximum number (52.5%) of patients were having Serum cortisol level in blood ranges between 15.6-18.6 µg/dL and after treatment 40% were having the range between 12.6-15.5 µg/dL, which is better. [Table No.1]

Table 1: Frequency Distribution of Subjects According To Blood Serum Cortisol Level

S. cortisol levels	No. of pt before treatment	Percentage	No. of pt after treatment	Percentage
6.6-9.5	1	2.5%	5	12.5%
9.6-12.5	2	5%	13	32.5%
12.6-15.5	7	17.5%	16	40%
15.6-18.5	21	52.5%	6	15%
18.6-21.5	9	22.5%	0	0%
TOTAL	40	100%	40	100%

As per weight reading, there is weight gain found in majority of patients. Before treatment patients were having weight range between 32.6-36.6 to 76.6-80.5 kg and after treatment patients were having weight range between 36.6-40.5 to 80.6-84.5 kg. The minute change that occurred by the treatment in systolic and diastolic blood pressure which was not great enough significant as the range of blood pressure was nearly unchangeable.

DISCUSSION

All the 40 patients of stress registered for the present trial were assessed for the subjective and clinical improvement after the *Ashwagandha* therapy. It was observed that there was a considerable improvement in feeling of well-being with significant improvement in mental and physical functions after the therapy

confirming the *Rasayana Prabhava* of *Ashwagandha*.

The *Prabhava* of *Ashwagandha* was also worked out in terms of *Nidra, Krodha, Shoka, Vigyana, Viryam Uthanena (Kriyarambhakatva)*. Also Workplace stress scale and Perceived stress scale [PSS14] evaluated as per modern subjective parameters. All the patients have revealed a highly significant improvement in Workplace stress scale (p = <0.001), perceived stress scale [PSS 14] (p = <0.001), *Nidra* (p = <0.001), Serum cortisol level of blood (p = <0.001) and significant improvement in *Kriyarambhakatva* (p= 0.020).

Rasayana Prabhava was also worked out in terms of various physiological parameters. The observations revealed that there was considerable improvement in Body weight (p = <0.001) confirming the anabolic i.e. *Rasayana Prabhava* of *Ashwagandha*.

On the other hand, there was no significant improvement in *Krodha* (p = 0.109), *Shoka* (p = 0.118), *Vigyanam* (p = 0.067). [Table No.2]

TABLE NO.2: STATISTICAL EVALUATION OF SUBJECTIVE AND OBJECTIVE PARAMETERS

S. No.	Parameter	N	Mean diff.	S.D diff.	S.E.M diff.	t value	p value
1	Workplace Stress Scale Score	40	4.15	3.239	0.512	8.104	< 0.001
2	PSS 14 Scale Score	40	5.425	5.093	0.805	6.736	< 0.001
3	***Manas Pariksh Bhava* Score**						
	Nidra	40	1.925	0.997	0.158	12.21	< 0.001
	Krodha	40	0.175	0.675	0.107	1.639	0.109
	Shoka	40	0.2	0.791	0.125	1.599	0.118
	Vigyana	40	0.25	0.84	0.133	1.883	0.067
	Kriyarambhakatva	40	0.425	1.107	0.175	2.429	0.02
4	Serum cortisol	40	3.651	2.484	0.393	9.297	< 0.001
5	Weight	40	-1.125	1.234	0.195	-5.767	< 0.001

[N= *Sample size*, S.D. *= Standard Deviation,* S.E.M. *= Standard Error Mean,* diff. *=Difference*]

Hence the clinical and statistical improvement in the scale of psychological parameters after *Ashwagandha* therapy confirms the *Medhya* effect of *Rasayana Dravya Ashwagandha*.

It is very difficult to pinpoint, how actually the *Dravya* acts according to modern, but it can be understood only by *Aptapramana* (Novel). The *Rasayana* having *Medhya Karma* which act as brain tonics in following way,

a) Increase of *Sattva Guna*.

b) Re-establishment of *Dhee, Dhrti, Dhairya*.

c) Eliminates *Pragyaparadha*.

d) Suppression of *Raja, Tama*.

e) Normality of *Vata Dosha*, causative factor of producing disturbed *Manasa Bhava.*

f) Formation of *Rasa Dhatu*: Selectivity and adaptability to brain tissue.

g) Attainment of *Prakrita Avalambaka* and *Tarpak Kapha*.

h) Normality of *Pranavayu* and *Sadhakaagni*, *Pitta Dosha.*

i) Eliminates *Strotorodha*.

j) Nutritional ingredients; Nourishment of brain tissues.

k) Medicinal ingredient stimulate of function of brain.

Also *Rasayana Dravya* may produce its beneficial effects by acting through one or more of the following three modes of actions,

1. By enriching the nutritional value of Rasa and helping directly in the better nourishment of *Dhatus* in the body leading to the final *Rasayana* effects.

2. By improving the digestion, absorption and metabolism by acting at level of *Agni*. This

improved digestion, absorption and metabolism also ultimately leads to improved tissue nourishment.

3. Acting at the level of *Strotasa* i.e. at the microcirculatory channels carrying nutrition to improved tissue nourishment.

The *Dravya, Ashwagandha* appears to influence the organism partly on all the three levels as indicated above and thus it affords the *Rasayana* effects and is a good remedy for the treatment of stress because of producing the tranquillity of mind.

No side or toxic effects was noticed in any patients after administration of *Ashwagandha* Granules and all the subjects registered for the present trail tolerated them very well.

Ashwagandha possesses various pharmacodynamics properties which include *Tikta, Kashaya Rasa* and *Madhur Vipaka, Ushna Veerya, Laghu* and *Snigdha Guna, Rasayana, Vrishya, Balya, Vishaghna* and *Nidra Janana* in *Prabhava*.[9] A drug with such pharmacodynamics properties is expected to improve quality of life, reduce the amount of stress and improve mental functions and physical strength of the individual. Being a *Rasayana*, immunomodulator and antioxidant drug, *Ashwagandha* seems to strengthen the immune system of human body, there by proving to be potent antistress agent.

The *Ashwagandha* also have proven pharmacological actions like Immuno-stimulant, estrogenic, restorative, hypotensive, hypoglycaemic, antimicrobial, CNS depressant, diuretic, antineoplastic, anti-anxiety and tonic for brain. These properties also check the whole etio-pathogenesis of ageing process and provide efficacy towards the signs and symptoms of stress.

From this, it is seen that it will be used in *Vata Dosha Pradhana Samprapti* (pathogenesis). Clinical trials using *Ashwagandha* for a variety of conditions should also be conducted. Some animal study on *Ashwagandha* in context of its adaptogenic effect was also carried out worldwide which is helpful to support its adaptogenic action in human being.

CONSLUSION

1. *Ashwagandha* (*Withania somnifera Dunal*) is the best *Rasayana Dravya*, which can be used for improving the quality of life in term of improved mental function and improved physical strength.
2. *Ashwagandha* possesses potent anti-stress activity as it improves the mental faculties due to its psychotropic and tranquillizing effects over mind. Therefore, it can be used effectively in the management of stress.
3. *Ashwagandha* is a potent immunumodulator and antioxidant drug, which potentiates the immune system of human body. So it works as adaptogenic agent in the management of stress.
4. When *Rasayana Dravya* like *Ashwagandha* was administrated, the improvement rate of disturbed *Manasa Bhava* was increased remarkably because of its mental and physical health promoting effect.
5. The research study has shown remarkable results, however it was carried out in less number of patients and short time span because of limited study duration. Therefore it is recommended to carry out the study in large number of patients and for longer duration.

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Fig.1: *Ashwagandha Churna* Granulation Process

Pulvarization

Mixing

Granule formation

Packing

Air tight jar

***Ashwagandha* granules**