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A Double Blind, Randomized, Placebo-Controlled Clinical Study of the Nutraceutical Ashwagandha in the Form of Vedaan Ashwagandha KSM 66 Capsules as an Antioxidant, Energy Booster, Nervine Tonic, Anti-Stress and Aphrodisiac in General and Specific Chronic Ailments

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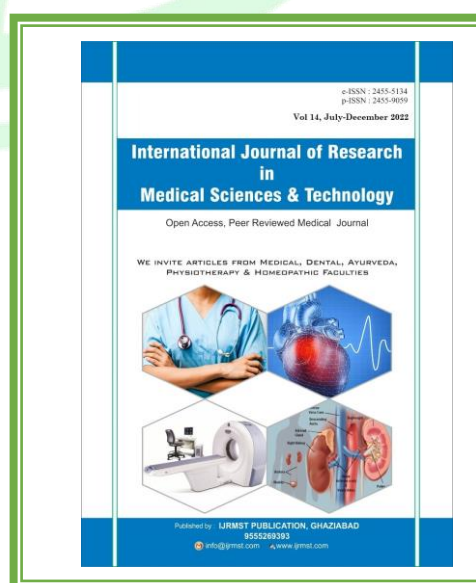
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ABSTRACT

In the modern world, numerous ailments like Tuberculosis and Diabetes Mellitus are common health problems. They can generate a loss of energy in the body, and develop neuropathies which can further generate stress, insomnia, loss of libido and early ageing. In this modern era, stress can disturb an individual's normal physical and mental health. It causes the perturbation of the body's homeostasis and leads to various physical and psychological health problems. The state of accumulated stress can increase the risk of both acute and chronic psychosomatic illness and weaken immune system of the body. Stress can cause many things such as headaches, anorexia, insomnia, fatigue, or diseases such as hypertension, diabetes mellitus etc.

Withania Somnifera is commonly known as Ashwagandha in Ayurvedic medicine, Indian ginseng, poison gooseberry or winter cherry. Well-known antioxidant or Rasayana drug has been chosen and selected for the management of chronic ailments like Tuberculosis and Diabetes mellitus associated with stress, anxiety, headache, insomnia, loss of energy, fatigue, loss of libido. It is used as an antioxidant, diuretic, sedative, anti-inflammatory and aphrodisiac for many ages.

Many studies have shown that *Withania Somnifera* roots have several effects on the central nervous system, including modulation of acetylcholinesterase activity and serotonin receptors, as well as GABA activity (NPD, 2017). Ahmad et al. (2010) described a significant increase ($P < 0.01$) in sperm concentration and motility in men with normozoospermia, oligozoospermia, and azoospermia treated with Ashwagandha root extract. Results showed a decrease in seminal LPO levels, stress and serum cortisol levels, ROS production, elevated antioxidant levels and overall improvement in sperm quality (concentration and motility), testosterone and LH levels.

The current study evaluates the efficacy of Ashwagandha as an antioxidant. Ashwagandha (*Withania Somnifera*) is already been clinically tried as an adjuvant in the patient with Tuberculosis and Diabetes mellitus. We have given Vedaan Ashwagandha, KSM 66 capsules in our OPD and IPD.

Keywords: *ASHWAGANDHA (Withania Somnifera), Vedaan Ashwagandha, KSM 66 capsules, Tuberculosis, Diabetes Mellitus, Madhumeha, Rajyakshma, Insomnia, Rasayan.*

INTRODUCTION

According to our classical texts, *Madhumeha* is a type of *Vataja* being *Vata dosha* predominant and is mainly associated with *Dhatukshaya* and *Ojokshaya*. *Rasayana (Antioxidant)* Drugs mainly nourishes—all *Dhatu* and hence *Ojas*. It also improves the quality of *Ojas*. Various types of free radicals are implicated in the pathophysiology of IDDM. Free radicals are mainly causing retinopathy and nephropathy. Many *Rasayana (Antioxidant)* drugs like *Ashwagandha (Withania Somnifera)* act as an antioxidant which scavenges the free radicals. So, there is the role of *Ashwagandha (Withania Somnifera)* in Diabetes mellitus as an antioxidant. *Ashwagandha (Withania Somnifera)* also has a neuroprotective role. It is helpful in relieving symptoms like the burning sensation and numbness in hands and feet.

Similarly, Tuberculosis is also a major leading cause of death in developing countries. In Ayurveda it is considered as *Rajyakshma*. It leads to the depletion of *Dhatu*. So, it is also called *Kshya* or *ShoshaRoga*. In *Rajyakshma* there is obstruction of channels of circulation. *Antioxidant* drugs improve the quality of *Rasa* so that good quality of *Rakta*, *Mansa*, *Meda*, *Asthi*, *MajaaSukra* and good quality

of *ojas* are formed. So, the excellence of all *Dhatu* is achieved. It also improving the microcirculation hence improving tissue nourishment¹.

AIMS AND OBJECTIVES

- To study the efficacy of Vedaan Ashwagandha (*Withania Somnifera*) KSM 66 capsules as *Rasayana (Antioxidant)* in specific chronic ailments on various subjective and objective criteria associated with sign and symptoms.
- To review the literature regarding *Rasayana* and *Ashwagandha*.
- To study the safety profile of the trial drug Vedaan Ashwagandha KSM 66 capsules.

MATERIAL AND METHODS

Vedaan Ashwagandha KSM 66 capsules were taken as a clinical trial drug which is prepared with Ashwagandha KSM 66 from Ixoreal Biomed, an herbal extracts and pharmaceuticals company based in Los Angeles, California USA, and Hyderabad, India. It has adopted the highly revered traditional herb *Ashwagandha (Withania Somnifera)* through The American Botanical Council (ABC).

Vedaan Ashwagandha KSM 66 capsules is composed of 500mg of Ashwagandha, KSM 66, manufactured at VEDAAN INDIA PHARMACEUTICALS 136-A, CIRCUIT HOUSE CROSSING, CIVIL LINES, Bareilly (Uttar Pradesh), - 243001.

After taking Vedaan Ashwagandha KSM 66 capsules to standardize the drug 45,000 capsules of 500 mg were taken from a said batch number which was having a batch size of 50,000 capsules through analytical test reports were done in a well intact and sealed packing. A proper dossier of the drug with special reference to Ayurvedic Pharmacopoeia of India was obtained from the manufacturer.

Patients were selected from OPD and IPD of *Rasa Shastra Evum Bhaishajya Kalpana* Department of Shri. Krishna Govt. Ayurvedic College Kurukshetra, 136118 Haryana India. Had selected the fulfilling criteria irrespective of age, sex, religion etc. Patients were selected between the age group of 20 to 60 years. A routine blood examination was carried out order to rule out any other pathology & monitor the normal values of blood.

INCLUSION CRITERIA:

- All the patients suffering from ailments like Tuberculosis and Diabetes mellitus

were selected.

- All patients in the age group of 20-60 were selected.
- The patients feature that was selected in the clinical study had symptoms such as stress, weight loss, numb-hand & feet, insomnia, lethargies, easy fatigability, and loss of libido.

EXCLUSION CRITERIA

- Patients not willing for trial
- Patients below age 20 and above age 60
- Patients with complications of the disease.
- Alcohol and drug abuse.

DURATION OF THE TRIAL

The total duration of the trial was 6 Months.

METHOD OF STUDY

Took written consent of patients' inclusion in the trial. 300 patients were registered and put into the clinical trial. Out of 300 patients, 285 completed the trial and 15 dropped out the trial. Recorded the complete subjective and objective criteria in the research history Proforma. All the patients were divided into two major group i.e., Trial Group I, Sub Trial Group I, Trail

Group II and Sub Trial Group II. A total of 300 patients were registered.

Trial Group I - (75 Patients of Diabetes Mellitus)

All 75 patients were included in this group to see the effect of the Ashwagandha capsule in the form of Vedaan Ashwagandha, KSM 66 as an Antioxidant on few selected signs and symptoms present in diseases combinedly.

Sub Trial Group I - (75 Patients of Diabetes Mellitus)

All 75 patients were included into this group to see the effect of *Placebo* as *Rasayana (Antioxidant)* on a few selected signs and symptoms present in diseases combinedly. All the patients suffering from

Diabetes Mellitus were placed in the Sub Trial group I and given Placebo therapy, and the treatment was advised for managing Diabetes Mellitus. All 75 patients were included in this group to see the effect of Placebo as antioxidant on a few selected signs and symptoms present in diseases combinedly. Out of which 70 patients completed the trial, 5 dropped out in this group.

Drug and Dose:

The assessment was done and reviewed for statistical analysis, recorded all the signs and symptoms according to severity based on improvements reported by the patients. Based on cardinal signs and the disease symptoms and their gradation.

1	GENERAL FEELING OF WELL BEING	Grade
	Normal	G0
	Not completely fit	G1
	Low	G2
	Very low	G3
2	FATIGUE – Lethargic (Loss of Energy in the Body)	
	Normal	G0
	Only in evening	G1
	Always tired	G2
3	SLEEP	
	Normal	G0
	Disturbed	G1
	Insomnia	G2

4	BURNING SENSATION (Neuropathy)	
	No burning sensation	G0
	Occasional burning sensation	G1
	Intermittent burning sensation throughout the day	G2
	Continuous burning sensation throughout the day	G3
5	TINGLING SENSATION (Neuropathy)	
	No Tingling sensation	G0
	Intermittent tingling sensation throughout the day in upper & lower extremities	G1
	Continuous tingling sensation throughout the day in upper & lower extremities.	G2
	Continuous tingling sensation throughout the day in whole body	G3
6	STRESS	
	Normal	G0
	Not completely fit	G1
	High	G2
	Very high	G3
7	ANXIETY	
	Normal	G0
	Not completely fit	G1
	High	G2
	Very high	G3
8	HEADACHE	
	Normal	G0
	Not completely fit	G1
	High	G2
	Very high	G3
9	LOSS OF LIBIDO	
	Normal	G0
	Not completely fit	G1
	Low	G2
	Very low	G3

OBJECTIVE CRITERIA

Objective criteria for the assessment were based on laboratory test such as Hematological tests;

Biochemical Tests:

- Fasting blood sugar
- Total serum protein
- Total serum albumin
- Total serum globulin

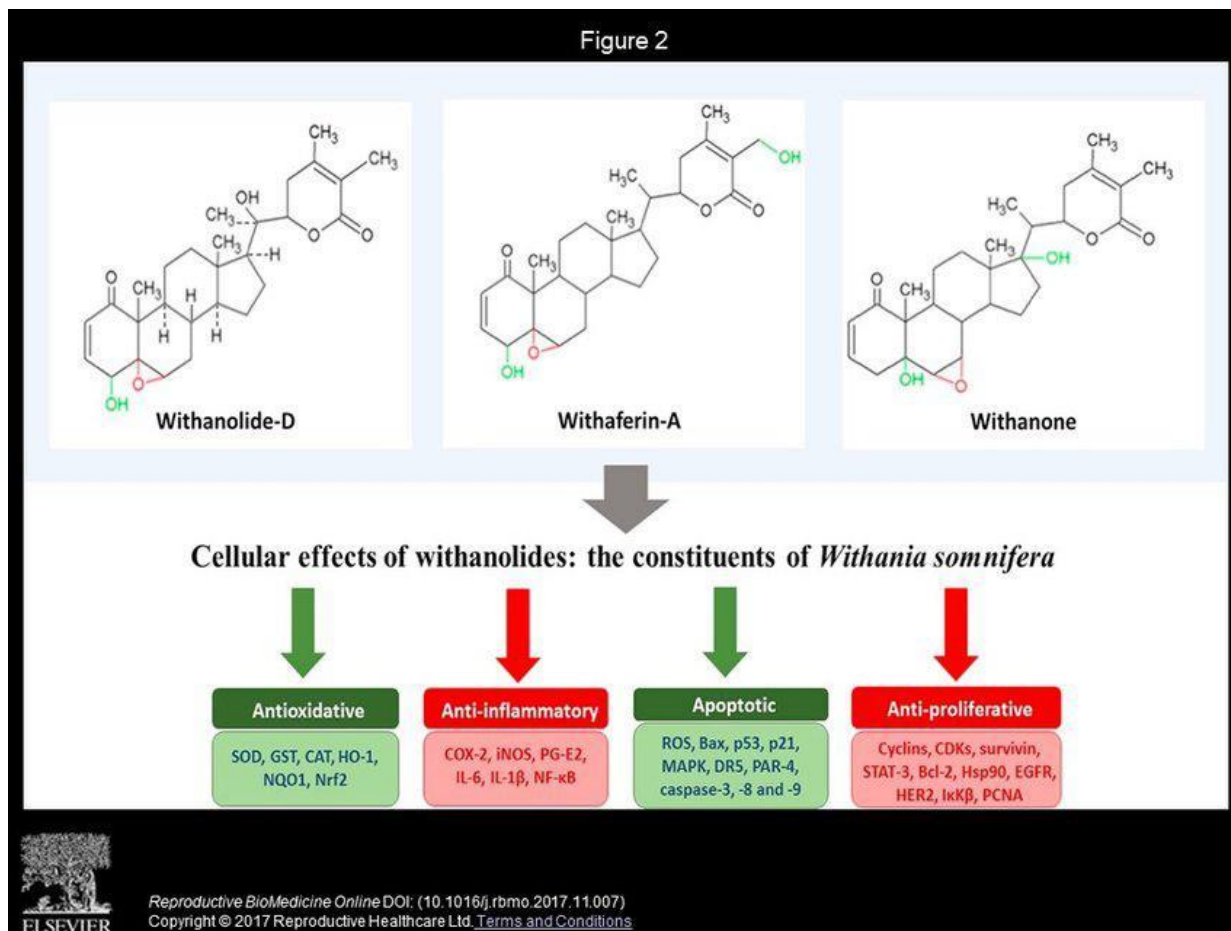
Data collected from the Clinical Study was compiled and statistically analyzed. In the present research work, a total of 300 patients were registered from OPD and IPD of Shri Krishna Govt. Ayurvedic College Kurukshetra, Haryana 136118 India. Out of which 286 patients completed the trial. 14 patients dropped out from the trial.

In the **Trial Group I** total 75 patients were registered. All 75 patients were suffering from Diabetes mellitus, 71 patients successfully completed the trial and only 4 patients were dropped out. All the 75 patients were suffering from Diabetes mellitus. Each group was given Vedaan Ashwagandha KSM 66 capsules along with the treatment which was advised for the management of Diabetes mellitus.

In the **Sub Trial Group, I** total 75 patients were registered. All 75 patients were suffering from Diabetes mellitus, 70 patients successfully completed the trial and only 5 patients were dropped out. All the 75 patients were suffering from Diabetes mellitus. Each group was given one Placebo capsule B.D along with the treatment which was advised for the management of Diabetes mellitus.

In the **Trial Group II** total 75 patients were registered. All 75 patients were suffering from Diabetes Mellitus, 73 patients successfully completed the trial and only 2 patients were dropped out. All the 75 patients were suffering from Tuberculosis. Each group was given Vedaan Ashwagandha KSM 66 capsules along with the treatment which was advised for the management of Tuberculosis.

In the **Sub Trial Group II** total 75 patients were registered. All 75 patients were suffering from Diabetes Mellitus, 72 patients successfully completed the trial and only 3 patients were dropped out. All the 75 patients were suffering from Tuberculosis. Each group was given one Placebo capsule B.D along with the treatment which was advised for the management of Tuberculosis.



The root of *Withania Somnifera* has more than 35 chemical constituents (Rastogi and Mehrotra, 1998). Steroidal alkaloids and lactones (Withanolides, Withaferins): chlorogenic acid, beta-Sisterol, fruitcysteine, iron, scopoletin, somniferinine, somniferiene, tropanol, withananine, withanoside IV, withanolides A-Y (Steroidal lactones) and sitoindosides and acylsteryl glucosides⁷. Thesitoindosides VII-X and with a ferin-A are anti-stress agents which

Anaferine alkaloid, anahygrine, isopelletierine, cuseohygrine, Ash Ashwagandha (*Withania Somnifera*) nolide (dimerichthio withanolide), support immunomodulatory actions and have antifungal properties also (Abraham *et al.*, 19^o 5; Choudhary *et al.*, 1995; Singh *et al.*, 2006).

Most of the pharmacological activities of Ashwaganda have been attributed to two main withanolides, withaferin A and withanolide D (Singh *et al.*, 2010).

Five-dehydroxywithanolide-R and with a somniferin-A are obtained from the aerial parts of *Ashwagandha* (*Withania Somnifera*) and effect of withaferin-A has been also seen on human blood lymphocytes. *Withania Somnifera* is a rich source of iron (Davis and Kuttan, 2000a; Kuboyam *et al.*, 2006; Subbaraju *et al.* 2006; Mirja lili *et al.*, 2009).

Major withanolides present in *Withania Somnifera* are withaferin-A, withanolide-D and withanone antioxidative property by increasing the activities of cellular antioxidant enzymes (superoxide dismutase [SOD]; catalase [CAT]; glutathione S-transferase [GST]; heme oxygenase 1 [HO-1]; NADPH dehydrogenase, quinone 1 [NQO1]; nuclear factor E2-related factor 2 [Nrf2,]) as well as possess anti-inflammatory effects by inhibiting prostaglandin (PGE2) synthesis by cyclooxygenase-2 (COX-2) and nitric oxide production by inhibiting nitric oxide synthase (iNOS) Withanoids also having apoptosis-inducing activity by stimulating reactive oxygen species, BCL2-associated X protein (Bax), Death receptor 5 (DR5) Withanoides inhibits cellular proliferation by regulating cellular division through cyclin-dependent kinases (CDKs), signal transducer and activator of

transcription 3 (STAT3), B-cell lymphoma 2 (Bcl2), heat shock protein 90 (Hsp90), epidermal growth factor receptor (EGFR), human epidermal growth factor receptor 2 (HER2) ⁹.

This herb improves both quality of sperm as well as the reproductive hormonal profile by acting through direct and indirect pathways, respectively.

Withania Somnifera reduces oxidative stress and improves the antioxidant potential of seminal plasma, whereas through the indirect antioxidant defence pathway. *Withania Somnifera* prevents the stress induced cortisol-mediated decrease in testosterone level, as well as exerts an inhibitory action on prolactin for sperm production.

In direct effect oxidative mechanism SOD, CAT activities, Vitamin A, E and C, essential metal ions level like of Copper Zinc, Iron, silver, and antioxidant defence mechanism is increased rather ROS generation, lipid Peroxidation and oxidative Stress is reduced.

In indirect effect known of ceded to mechanism CRHACTH and go to soul level or reduced GNRH gonadotropin LH and FSH and testosterone or increased.

RESULTS: -

FBS:

In Trial Group I - 52.6% decrease was observed in FBS

In Sub Trial Group I - 27.6% decrease was observed in FBS

In Trial Group II - 51.0% decrease was observed in FBS

In Sub Trial Group II - 10.0 % decrease was observed in FBS

Ashwagandha (Withania Somnifera) acts as a *Vatahara*. *Ashwagandha (Withania Somnifera)* also acts as an antioxidant so helpful in preventing complications of Diabetes Mellitus. *Ashwagandha (Withania Somnifera)* also reduces blood sugar². It is a commercial preparation which contains active ingredient of *Ashwagandha* and other components. It decreases streptozotocin in (STZ) induced hyperglycemia in rats due to its pancreatitis let free radical scavenging activity (Bhattacharya *etal.* 2001).

A1C:

In Trial Group I - 41.7 % decrease was observed

In Sub Trial Group I - 20.7% decrease was observed

Tingling and burning sensation:

In Trial Group I - 57. 4% decrease was observed

In Sub Trial Group I - 20.8% decrease was observed

In Trial Group II - 52.4% decrease was observed

In Sub Trial Group II - 15.4% decrease was observed

Neuropathy is one of the common and major complication of Diabetes Mellitus (Madhumeha). According to ayurvedic samprapti, there is involvement of vata and pitta dosha in neuropathy. It causes burning sensation, tingling and numbness in hand and feet. Madhumeha is type of vataprameha, *Ashwagandha (Withania Somnifera)* also act as *vatahara*. *Ashwagandha* also exerts antioxidant action. Thus, help fight the disease and reduce numbness and tingling sensation. Root extract enhances the level of interferon gamma (IFN- γ), interleukin-2 (IL-2) and granulocyte macrophage colony stimulating factor¹⁰.

IMMUNITY:

In Trial Group I - 4.4% increase was observed

In Sub Trial Group I - no significant increase was observed

In Trial Group II - 5.4% increase was observed

In Sub Trial Group II - no significant increase was observed

Ashwagandha (Withania Somnifera) is a potent immunomodulator drug, which potentiates the immune system of the human body and with its other pharmacological activities it helps in Pulmonary Tuberculosis because root extract up regulates Th1 -dominant polarization due to the presence of withanolide-A and hence supports the humoral immunity (HI) and Cell-mediated Immune. Suggestive of an immune potentiating and myeloid protective effect. *Ashwagandha* enhances nitric oxide synthase activity of the macrophages, which in turn increases the microbial killing power of these immune cells (Iuvone *etal*, 2003). *Ashwagandha (Withania Somnifera)* has been reported to induce helper T-lymphocyte (Th1) polarized cell

mediated immune response. A glycoprotein Glycowithanolides (WSG), commonly known as *Withania Somnifera* glycoprotein, 28 kDa isolated from the IN *somnifera* root has demonstrated potent antimicrobial activity against the pathogenic fungi and bacteria. *Ashwagandha (Withania Somnifera)* plant has potent antibacterial property even against multi-drug resistant (MDR) strains of microbes as withaferin and withanolides are the chief compounds. *Withania* has been found to be effective inhibiting the growth of several bacteria viz., *Neisseriagonorrhoea*, *Escherichiacoli*, *Salmonella*, *Pseudomonas fluorescens*, *P.aeruginosa*, *Bacillussubtilis*, *Listeria monocytogenes*, *Staphylococcus aureus* and methicillin-resistant *Staphylococcus aureus* or Oxacillin resistant *S.aureus* ⁹.

ANTIOXIDANT PROPERTIES:

In Trial Group I - 6.4% increase was observed

In Sub Trial Group I - 4.8% increase was observed

In Trial Group II - 6.4% increase was observed

In Sub Trial Group II - 4.4% increase was observed

Ashwagandha (*Withania Somnifera*) having antioxidant property and removes the free radical from the body, act as a rejuvenator³. *Withania Somnifera* has powerful antioxidants. It increases the levels of three natural antioxidant enzymes like superoxidases mutase, catalase and glutathione peroxidase in the brain. Root powder of Ashwagandha prevents Cadmium-induced oxidative stress in chicken and lead-induced oxidative damage. Active principles of *Withania Somnifera* root have antioxidant effects like anti-stress, cognition-facilitating, anti-inflammatory and anti-aging effects. Double-blind clinical trial was conducted to test the anti-aging properties of Ashwagandha in a group of 101 healthy males, ageing about 50-59 years were given at a dosage of 3 grams daily for one year. The volunteers showed significant improvement in hemoglobin, red blood cell count, hair melanin, seated stature, improve maintain sexual performance, decrease in serum cholesterol, and nail calcium

was preserved (Bone,1996; Ilayperumaetal.,2002).

TESTOSTERONE LEVEL (RELATED TO LOSS OF LIBIDO)

In Trial Group I - 7.4% increase was observed

In Sub Trial Group I - no significant increase was observed

In Trial Group II - 6.4% increase was observed

In Sub Trial Group II - 4.4% no significant increase was observed

Ashwagandha enhances the level of testosterone production and reduces the stress induced reproductive issues, maintain libido and sexual performance, sexual vigour as well as dysfunction in penile erection can be corrected by root extract of *W. somnifera*. The roots contain Fe, K, Mg and Ni which plays significant role in the diuretic, aphrodisiac activity and in the treatment of spermatophyte and seminal depletion. Once cessation of treatment, these effects are partially Gamma Amino Butyric Acid (GABA), serotonergic or sedative activities of the extract instead of changes in levels of testosterone.

Male sexual competence is detrimentally affected by roots of *W.somnifera* and thereby is contradictory⁷.

STRESS:

In Trial Group I - 15.4% decrease was observed

In Sub Trial Group I - no significant decrease was observed

In Trial Group II 11.4% - decrease was observed

In Sub Trial Group II - no significant decrease was observed

Withanolides I-II and IV-V isolated from *W.Somnifera* inhibited cholinesterase, acetyl cholinesterase and butyrylcholinesterase, toxic phospholipase enzymes and therefore, are under consideration to be among the potent therapeutic candidate for treatment of Alzheimer's disease (*Choudhary et al.*, 2004, 2005; *Johri et al.*, 2005; *Kambizi et al.*, 2006). Ashwagandha is a potent anti-stress agent. It checks stress induced changes in adrenal function and augments protein synthesis. Ashwagandha with anti-stress activity is effective in increase in the physical endurance, plasma

corticosterone level, sexual vigour, more sperm count, phagocytic index, cardiac activity, augmenting level of Th-1 cytokines, rising lymphocytes proliferation and preventing stress induced ulcer, carbon tetra chloride (CCI₄) induced hepatotoxicity and mortality (*Ilayperuma et al.*, 2002; *Tomi et al.*, 2005; *Khan et al.*, 2006; *Al-Qirim et al.*, 2009).

ANXIETY:

In Trial Group I - 17.4% decrease was observed

In Sub Trial Group I - no significant decrease was observed

In Trial Group II - 16.4% decrease was observed

In Sub Trial Group II - no significant decrease was observed

The anti-anxiety effect of Ashwagandha was due to GABA-like activity, inhibitory neurotransmitter in the brain. It decreases the neuron activity and inhibits nerve cells from over firing, results in calming effect (*Mehta et al.* 1991). It has an anti-depressant and anti-anxiety effect and used as widespread tranquillizers used in India (*Singh et al.*, 2010).

HEADACHE:

In Trial Group I - 50.4% decrease was observed

In Sub Trial Group I -25.8% decrease was observed

In Trial Group II - 46.4% decrease was observed

In Sub Trial Group II - 44.4% decrease was observed

Withanolide obtained from the plant possess analgesic and anti-inflammatory activity due to its cyclooxygenase-2 inhibition property (Nair and Jayaprakasam, 200°).

Peroxidases enzyme have been purified from this herb.

ABILITY TO DO WORK:

In Trial Group I - 74% increase was observed

In Sub Trial Group I - 42% increase was observed

In Trial Group II - 67% increase was observed

In Sub Trial Group II - 45% increase was observed

Ashwagandha reduces stress and anxiety which enhances the energy in the well-

being, leads to activeness in the body ⁴. Milk supplemented with Ashwagandha has been reported to increase total proteins and body weight (Venkata raghavan *et al.*, 1980). It has a rejuvenate effect on the body mainly on their productive and nervous systems and is used to improve vitality and aid in recovery after chronic illness (Bhattacharya *et al.*, 198°). Aphale *et al.* (1998) reported that the combination of Ashwagandha and Ginseng (Panax ginseng) was significantly increased the body weight, food consumption, liver weight and improved hematopoiesis.

FATIGUE:

In Trial Group I - 74% decrease was observed

In Sub Trial Group I - 22% decrease was observed

In Trial Group II - 67% decrease was observed

In Sub Trial Group II - 25% decrease was observed

Ashwagandha is known as energy booster and enhances the stamina of human being which leads to reduce in lethargicness in the body. Alkaloids of Ashwagandha have muscle relaxant and antispasmodic effects

against several spasmogens on bronchial, blood vascular, intestinal, uterine, and tracheal muscles. This smooth muscle relaxant activity of the alkaloids was like that of papaverine which is a direct Musculo tropic agent (*Anonymous, 1982*).

SLEEP:

In Trial Group I - 74% increase was observed

In Sub Trial Group I - 35% increase was observed **In Trial Group II** - 67% increase was observed

In sub-Trial Group II - 67% increase was observed

Ashwagandha contains alkaloids like sitoindosides, having anxiolytic effect that was comparable to sedative drugs of modern. In Sub Trial Group II 45% decrease was observed so results of Vedaan Ashwagandha KSM 66 capsules as an antioxidants in pulmonary tuberculosis and Diabetes mellitus are satisfactory both in selected subjective and objective criteria. Use of Vedaan Ashwagandha KSM 66 capsules as adjuvant therapy along with Anti-Tubercular Therapy and Anti-Diabetic Therapy in Pulmonary Tuberculosis and Diabetes Mellitus respectively, is fully justified¹.

DISCUSSION

The present study stated that the science dealing with an *Antioxidant* effect are supposed to appropriately influence the body as well as the mind and improvement in the mental faculties is an essential part of the Antioxidant *chikitsa* or Antioxidant treatment. In the changing concept of health and disease, the *Rasayana* (*Antioxidant*) drugs like *Ashwagandha* (*Withania Somnifera*) appear to be of great value in view of the growing incidence of psychosomatic stress. *Ashwagandha* (*Withania Somnifera*) is a drug widely used in *Ayurveda* as *Rasayana*. So we choose Vedaan Ashwagandha KSM 66 capsules for this clinical research work.

CONCLUSION

We have studied the efficacy of Vedaan Ashwagandha KSM 66 capsules as *Rasayana* in chronic ailments like Pulmonary Tuberculosis and Diabetes mellitus.

Antioxidant refers to providing a good nourishment to the *Dhatu*s of the Body. So, the person becomes physically and mentally healthy and strong. By the *Rasayana* one gets the excellence of all *Dhatu*s like blood, muscles, bones, bone marrow, semen, and every system of the body. *Rasayana* drugs

act in the body by antioxidant action, immunomodulatory action, hematopoietic effect, nutritive function and neuroprotective action, anti-ageing, stress removing (anxiolytic) and energy generation.

Ashwagandha (Withania Somnifera) is a drug widely used as *Rasayana (Antioxidant)*. *Ashwagandha Vrishya (increasing volume and consistency of semen)*, *Balya (Energy Provider)*, *Vishaghana (Toxins remover from the body)* and *Nidrajanana (Sleep Generator)*.

Ashwagandha is also having antistress properties, antioxidant action, and antianxiety action. It acts as an immunomodulator, useful in chronic fatigue syndrome and helps in delaying ageing. It is a cognition enhancer and memory improving, *Ashwagandha can* reduce blood sugar level.

Tuberculosis (*Rajyakshma*) and Diabetes Mellitus are disease where restorative therapy is required. In Tuberculosis (*Rajyakshma*) there is loss of all *Dhatus (Dhatukshya)*. There is generalized muscle wasting and loss of strength is seen in Tuberculosis. *Ashwagandha (Withania Somnifera)* acts by improving the quality of all *Dhatus like Blood, Muscles, Bones, Bone Marrow, and Semen* which is very useful in

treatment of Tuberculosis. It acts at the level of *Rasa, Agni* and *srotasagani (Metabolic Level)* hence improving microcirculation. So, it improves tissue nourishment at micro level. *Ashwagandha (Withania Somnifera)* is a potent immunomodulator drug, which potentiates the immune system of the human body and with its other pharmacological activities it helps in Tuberculosis and Diabetes Mellitus.

Antistress effect of *Ashwagandha* is also beneficial in stress induced Diabetes mellitus. *Ashwagandha* also acts as an antioxidant so helpful in preventing complications of Diabetes mellitus. *Ashwagandha* can reduce Blood sugars also.

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Conflict of Interest: None

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