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A clinical Investigation on the management of Stress-induced by T2DM with Withania Somnifera (Ashwaganda)

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ABSTRACT:

Diabetes slowly and silently deteriorates practically all body organs, including the central and peripheral nerve systems and circulating fluids. The stress induced hormones can influence glycaemic control. Ayurveda takes a holistic approach to treating and managing diabetes related stress. Ashwagandha,a herbal plant shows adaptogenic and anti-stress properties. The present study is based on clinical trial, 60 patients were divided in two groups (30 each), where control was given diabetic allopathic medicine (Metformin 250 mg + Glimepiride 1 mg) and experimental were given Ashwagandha powder (300 mg) + (Metformin 250 mg + Glimepiride 1 mg) for six weeks. Blood was taken pre and post treatment to assess blood glucose and stress hormone parameters. The findings suggest that parameters relative to experimental blood sugar FBS (p=0.001), PPBS (p=0.001) and HbA1 (p=0.001) show clinically high significant differences between pre and post treatments relative to the control group. In study experimental and control pre-test exhibit greater levels of the stress hormone, supporting the connection between stress and T2DM. The values for stress hormone cortisol (p=0.001) and Dehydro-epi-androsterone DHEA (p=0.01) compared for pre and post treatment declined significantly for the experimental group than the control group. Based on the findings, the study supports that *Ashwagandha (Withania somnifera)* offers notable improvement in management of stress level and blood glucose level in T2DM patients.

Keywords*: Withania Somnifera (Ashwagandha), Type 2 Diabetes Mellitus, Stress Hormone, Clinical Trail*

Introduction

Diabetes slowly and silently deteriorates practically all body organs, including the central and peripheral nerve systems and circulating fluids. Stress, and diet quality may account for 60% of type 2 diabetes illness risk. Over 85% of diabetic patients, reside in developing nations like India, China, etc., where most of their people still rely solely on herbal remedies .Thus herbal medicine is also used to treat T2DM through its anti-inflammatory, anti-glucose and anti- stress properties. Diabetes patients experience co-morbidities of stress-related anxiety, depression, and other mental health issues more frequently than the general population (Bhattacharya et al.,2019).

The phrase "stress" refers to the whole of a person's bodily, mental, and emotional stresses or tensions. When under stress, the liver's gluconeogenesis process uses protein reserves to produce glucose for the body. This process is mediated by the stress hormones cortisol and DHAE. An individual may use this energy to flee or combat a stressful situation. On the other hand, chronically raised amounts of stress hormone continually create glucose, raising blood sugar levels (Bone et al.,2016). One of the crucial therapeutic fields where Ayurveda has made significant progress is stress

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management. Many plants show adaptogenic and anti-stress applications. Ashwagandha belongs to a group of herbs known as adaptogens, which are used in the form of teas, powders, tinctures, supplements, or in its raw state for their health advantages. Ashwagandha is a plant with herbal roots and berries that is often called Indian ginseng, winter cherry, or Withania Somnifera, its scientific name. Ayurvedic doctors frequently use ashwagandha (Withania somnifera) as a Rasayana medication to treat stress brought on by diabetes. Numerous experimental and clinical studies have demonstrated Ashwagandha's adaptogenic and anti-stress capabilities. Here, the herbal supplement Ashwagandha is being studied to see if it can help manage stress induced in T2DM patients.

MATERIALS & METHODS

Study Design

Ayurveda is one of the complementary and alternative medical systems that requires high-quality evidence for therapeutic application. The investigation was conducted on clinical trials that were registered for observational studies, in which selected respondents were administered Ayurvedic medicine Withania Somnifera in form of herbal powder. i. Participants with T2DM were randomly selected for sample collection from the OPD of the Government Ayurveda Hospital in Delhi . The study included 60 patients for the study.

Clinical Investigation:

- All of the study participants gave their informed, written permission. Following enrollment, all patients had a primary screening, systemic examination, and laboratory tests according to the study's protocol. The patients were briefed on the further steps to be taken.
- Selection criteria includes participants already having medical history Type II Diabetics treated with fixed Oral Hypoglycaemic allopathic drugs (Metformin 250 mg + Glimepride 1 mg) inside 40 – 55 years, FBS $\geq$ 126 & $\leq$ 180 mg/dl and PPBS $\leq$ 240 mg/dl, HbA1C $\geq$ 7% whereas exclusion criteria includes: Diabetics on insulin, occurrence of major diabetic complications such as ulcers, nephropathy, neuropathy, retinopathy, gestational DM, women planning pregnancy in next six months.
- Random allotment to Control Group (C) and Experimental Group (E). Also, the investigation finished with 30 subjects in (C) and 30 subjects in (E).
- **Control Group:** Patients taking medication (Metformin 250 mg + Glimepride 1 mg)
- **Experimental:** Patients taking medication (Metformin 250 mg + Glimepride 1 mg) and 300 mg herbal powder (Withania Somnifersa)

Herbal Product, Dosage & Duration

Ashwagandha (Withania somnifera) powder was made from the plant's roots. Therefore, the study participant received roughly 300 mg of root extract powder. Patients underwent an observational follow-up phase for nearly six weeks. The patients in the experimental group were administered Ashwagandha powder having 300 mg of root extract for 6 weeks, followed by an anti-diabetic treatment (Metformin 250 mg + Glimepride 1 mg;1 tablet).

Duration of the study and follow up schedule

ISSN PRINT 2319 1775 Online 2320 7876

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The trial lasted for a total of six weeks. The first three weeks were spent actively treating patients, while the subsequent three weeks were spent monitoring their progress.

Laboratory Investigations

3 mL blood was withdrawn from all patients for estimation of clinical parameters which includes diabetes parameters FBS, PPBS, HbA1C, and stress parameters including serum cortisol, and DHEA. Thus, clinical tests were done at the beginning and after the treatment of the study.

Statistical Analysis

For each objective metric, we determined the mean ± SD both before and after therapy. When the p-value was less than 0.05, we concluded that the herbal medicine was effective.

RESULTS:

Male patients between the ages of 41 and 50 made up the vast majority of the sample. It was also observed participant weight was 65.1±2.11 suffering from diabetes under stress.

Table1: Participants baseline demographic data

Parameter	**Participants (N=60) (mean ±SD)**
Age (yrs.)	43 ±2.51
Gender **Male** **Female**	 48±2.33 12±1.11
Weight (kg)	65.1±2.11

Table2: Effectiveness of herbal drug on stress parameters and diabetes parameters

Parameter	**Group**	**n**	**Pre-Treatment (mean ±SD)**	**Post-Treatment (mean ±SD)**	**P value**
Fasting Blood Sugar	**Control**	**30**	167±1.33	140±1.13	0.01
	Experimental	**30**	164.4±1.20	1.26±1.03	0.001
Post Prandial Blood Sugar	**Control**	**30**	210±2.12	180±2.09	0.01
	Experimental	**30**	200±2.11	160±1.12	0.001
HbA1	**Control**	**30**	7.73±1.6	7.12±1.12	0.7
	Experimental	**30**	7.72±1.54	6.2±0.7	0.001

ISSN PRINT 2319 1775 Online 2320 7876

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Stress Hormone					
Cortisol (mcg/dl)	**Control**	**30**	15.16±0.41	14.6±0.39	0.6
	Experimental	**30**	15.17±0.39	10.22±0.1	0.001
DHEA (mcg/dl)	**Control**	**30**	247±2.44	239±2.41	0.6
	Experimental	**30**	246±2.41	190±1.64	0.001

As shown in Table 2 comparison between control and experimental group finding suggest that, parameters related to experimental blood sugar FBS (p=0.001), PPBS (p=0.001) and HbA1 (p=0.001) show clinically high significant differences between before and post-treatments in comparison with control group. As can be observed in Table 2, both the experimental pre-test and the control pre-test exhibit greater levels of the stress hormone, supporting the connection between stress and T2DM, whereas stress hormone parameters cortisol (p=0.001) & DHEA (p=0.001) declined notably in the experimental group when compared between pre and post-treatment on other hand no notable changes were seen in cortisol and DHEA in control group between pre and post treatment.

Discussion

The substantial, controlled, direct effect of stress on diabetes may affect glucose metabolism through dysregulating the hypothalamic-pituitary-adrenal and sympathetic-adrenal-medullary axes, according to Joshua et al. (2018). When there are actual or perceived risks to homeostasis, the acute stress response stimulates the immunological, autonomic, neuroendocrine, and central nervous systems as well as motor responses. Cortisol and DHEA are specifically released by the sympathetic-adrenal-medullary axis, and glucocorticoids are secreted by the hypothalamic-pituitary-adrenal axis, which activates the "fight or flight" response. According to Prakash et al. (2017), chronic activation of the sympathetic-adrenal-medullary and hypothalamic-pituitary-adrenal axes and related mechanisms, as well as the resulting amplification of pro-inflammatory cytokines (through increased tumour necrosis factor- and interleukin-6 production), all work against insulin and may lead to insulin resistance and beta-cell dysfunction, which elevate blood glucose levels. Here in this report, the benefits of Withania Somnifera (Ashwagandha) in managing stress brought on by diabetes is discussed in the current study. Perhaps, the most well-known benefit of ashwagandha is its capacity to reduce stress. This benefit is also highlighted by numerous research that show how considerably ashwagandha can reduce participants' levels of stress and anxiety (Bhattacharya et al., 2019)

Table 2 results indicate that the experimental blood sugar parameters FBS (p=0.001), PPBS (p=0.001), and HbA1 (p=0.001) demonstrate clinically high significant differences between before and after treatment relative to the control group. Another finding (Bhattacharya et al.,2018) suggested that people with diabetes exhibit a correlation between stress hormone and blood sugar levels, which results in increased stress hormone levels. As shown in table 2, the stress hormone parameters cortisol (p=0.001) and DHEA (p=0.001) decreased notably in the experimental group when compared between before and after treatment, while Cortisol and DHEA in the control group showed no noteworthy changes between pre and post treatment. According to a study by Sundaram et al. (2016), fructose-fed rats had considerably higher blood glucose concentrations than control rats, demonstrating the impact of Withania Somnifera (WS) on blood sugar parameters. Blood glucose levels were considerably lower in WS + fructose-fed rats compared to fructose-alone-fed rats, demonstrating WS's anti-hyperglycaemic activity and demonstrating the ability to lower blood sugar. W. somnifera could serve as an antidiabetic plant having anti-hyperlipidemic effects, according to the

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results of another trial in which capsules containing powdered root were given to individuals with moderate, non-insulin-dependent diabetes for 30 days straight (Balaji et al., 2016). The study also found that regularly consuming W. somnifera root powder can significantly lower FBS and HbA1 levels.

Based on other finding of these study according to (Frans et al.,2018) cortisol and DHEA anxiety and stress levels decreased by 41% in participants utilising ashwagandha, which compared favourably to the 24% decrease experienced in placebo-taking participants. Changes in cortisol, a stress hormone, and DHEA-S, a steroidal hormone, were examined in another research (Bone et al., 2016) to better comprehend ashwagandha's therapeutic processes in stressed adults. Fasting cortisol was shown to drop by 23% and morning cortisol by 5%, while DHEA-S increased by 2.5% and decreased by 8.2% after taking ashwagandha compared to taking a placebo. As it can be observed in Table 2, both the experimental pre-test and the control pre-test exhibit greater levels of the stress hormone, supporting the connection between stress and T2DM. In summary of this discussion, stress was a factor in the development of diabetes in patients. Thus, patients with T2DM who take herbal powder made from the roots of ashwagandha (Withania somnifera) exhibit excellent improvement in managing stress hormone and blood glucose parameters. As a result, Ashwagandha can be a part of Rasayana Dravyas in Ayurveda, which may combat sickness and restore health, vigour, and vitality.

CONCLUSION:

This study finding highlight the parameters related to experimental blood sugar FBS (p=0.001), PPBS (p=0.001) and HbA1 (p=0.001) show clinically high significant differences between pre and post treatment in comparison with control group. Diabetes mellitus patients in both groups demonstrate a connection with stress (which is higher stress hormone) prior to treatment, whereas significant decrease was seen in Cortisol (p=0.001) and DHEA (p=0.001) with T2DM in the experimental group post-treatment. In conclusion, the study supports the association of stress induced by T2DM in patients and investigation proved stress negatively impacts diabetes. The results of this research suggest that *Ashwagandha (Withania somnifera)* may help T2DM patients control their stress levels.

References

1. Joshua Cowa, Shoba Raja, Amali Naik and Gregory Armstrong, Knowledge and attitudes of doctors regarding the provision of mental health care in Doddaballapur Taluk, Bangalore Rural district, Karnataka, International Journal of Mental Health System, 2018, 6:21.
2. Prakash B Behere, Anweshak Das, Richa Yadav, Aniruddh P BehereAyurvedic concepts related to psychotherapy, IJP, 55 (6), 2017, 310-314.
3. Sundaram, K. Dr, Manoroga Chikitsa Ayurvedathil, in Ayurveda seminar Text, 2016, Aryavaidyasala, Kottakkal, P.10.
4. Balaji Deekshitulu P.V. Dr, Stress Relaxation Through Ayurveda, International journal of Ayurvedic & Herbal medicine 3(3) Jul-Aug, 2016,1246-1252.
5. Frans Pouwer, Nina Kupper, Marcel C Adriaanse, Does Emotional Stress Cause Type 2 Diabetes Mellitus? A Review from the European Depression in Diabetes (EDID) Research Consortium, Discovery Medicine, February 2018, 9(45), 112-118.
6. Bone K. Clinical Applications of Ayurvedic and Chinese Herbs. Monographs for the Western Herbal Practitioner. Australia: Phytotherapy Press, 2016, 137-141.

ISSN PRINT 2319 1775 Online 2320 7876

Research paper UGC CARE Listed (Group -I) Journal Volume 10, Iss 1, Jan 2021

7. Bhattarcharya SK, Muruganandam AV. Adaptogenic activity of Withania somnifera: an experimental study using a rat model of chronic stress. Pharmacol Biochem Behav, 2019, 75, 547-555.