International Journal Dental and Medical Sciences Research
Volume 4, Issue 4, July-Aug 2022 pp 619-923 www.ijdmsrjournal.com ISSN: 2582-6018

To Study the Effect of Withania Somnifera (Ashwagandha) Supplementation on Biochemical and Hematological Parameters in Type 2 Diabetes Mellitus

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Submitted: 05-08-2022 Accepted: 16-08-2022

ABSTRACT: Diabetes mellitus is a persevering condition that happens when there are brought levels of glucose up in the blood in light of the fact that the body cannot convey any or enough of the compound insulin or use insulin feasibly. World ethno-plant statistics about therapeutic plants reports that very nearly 800 herbs might be utilized to control diabetes mellitus. Various flavors and plants have been portrayed as having hypoglycaemic movement when taken orally extricates. Various withanolide steroidal lactones were secluded from the leaves of Ashwagandha. There are various reports clarifying the compound and medicinal properties of W. Somnifera. A total 200 subjects of middle age group 36-55yrs were selected for the study and were divided in two groups. Group- I-These patients were taking conventional treatment and served as the control group. Group-II-These patients besides conventional treatment were given powder of WITHANIA SOMNIFERA (ASHWAGANDHA) root and served as study group. Fasting Blood sugar, Glycosylated haemoglobin, Serum Lipid profile, Complete Blood Count was done in both the groups at baseline and after three months of Withania Somnifera Supplmentation. All Biochemical & Haemtological parameters had shown a significant improvement in study group after three months supplementation.

KEYWORDS: Type 2 Diabetes Mellitus, Withania Somnifera, systolic blood pressure and diastolic blood pressure.

I. INTRODUCTION

Diabetes mellitus prevalence in the general population has reached epidemic levels and is rapidly rising. According to the International Diabetes Federation, there were 285 million persons with diabetes mellitus in the globe in 2010. Up to 438 million people will develop diabetes by 2030, according to the federation. Type 2 diabetes mellitus now accounts for 90% of cases, and type 2 will most likely grow in prevalence at a rate that is in line with the rise in obesity.[1]

As per Diabetes Mellitus Diagnostic Criteria[2](World Health Organization., American Diabetes Association)

Fasting plasma glucose: 126 mg/dL or ≥7.0 mmol/L.

Following a 75g oral glucose load, two-hour plasma glucose was ≥11.1 mmol/L (200 mg/dL).A patient who exhibits the typical signs of hyperglycemia or a hyperglycemia crisis and has a random plasma glucose level of 200 mg/dl (11.1 mmol/L) or greater. A HbA1c level of at least ≥6.5 percent (48 mmol/mol).

Plants have been the significant wellspring of remedy for the management of diabetes mellitus in Indian medication and other antiquated frameworks on the planet, and to a certain extent, Diabetes mellitus has been dealt with orally with natural drugs or their concentrates[3], since plant items are occasionally viewed as not so much harmful but rather more liberated from results than engineered ones[4] . iWithania isomnifera (L.) Dunal, regularly referred as "Ashwagandha" in Sanskrit language, is a lasting plant having a place with the family iSolanaceae. The ipharmacological impacts of the underlying foundations of W. somnifera are credited to the existence of iwithanolides, a gathering of isteroidal ilactones[5]. There are various reports clarifying the compound and medicinal properties of W. Somnifera[6,7]. Ashwagandha, also known as Withania somnifera, is a herb that has been utilised in traditional Indian medicine since the time of Ayurveda. The plant's dried roots are used to treat neurological and sexual issues. The medication is chemically composed of a class of physiologically active substances called withanolides. Withanolides have been examined for their chemical makeup and are found in large quantities in the Solanacae family. According to reports, leaves contain withaferin-A, a withanolide that is therapeutically effective. The

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Volume 4, Issue 4, July-Aug 2022 pp 619-923 www.ijdmsrjournal.com ISSN: 2582-6018

fundamental motivation behind present investigation is to contemplate the impacts of Herbal supplementation of Withania somnifera on hematological and biochemical parameters of Type 2 diabetes mellitus subjects.

II. MATERIAL & METHOD

Data Collection

A randomised control trial study was designed to evaluate the effect of Withania Somnifera that include a total of 200 subjects of middle age group 36-55yrs and were divided in two groups. Group- I-These patients were taking conventional treatment and served as the control group. Group-II-These patients besides conventional treatment were given powder of WITHANIA SOMNIFERA (ASHWAGANDHA) root and served as study group. The research excluded individuals with liver illness, arthritis, lung TB, malabsorption, alcoholism, asthma, history of coronary heart disease, an acute myocardial infarction, valvular heart disorders, and non-cooperative patients.

Methodology

Dose:5gm of ASHWAGANDHA churna was prescribed by Ayurvedic physician twice a day (2.5gm in morning and 2.5gm in evening) along with lukewarm water on empty stomach. Dried root powder of ASHWAGANDHA (WITHANIA SOMNIFERA) churna was purchased from Patanjali chikitsalya, Bikaner. Subjects in study group was given 5 gm of Ashwagandha root powder twice a day for three months regularly.

Before starting Ashwagandha root powder ,patients were instructed about the procedure. Baseline parameters were taken of every patient that is BMI, glycosylated hemoglobin, blood pressure, lipid profile, fasting blood sugar, complete blood count. After three months, above all mentioned tests for subjects were repeated. All subjects were also enquired about any adverse effects.Patients were also urged to let their treating physician know if they had any negative side effects.

Following Parameters were accessed:

A. BMI
B. Blood Pressure
C. Fasting Blood Sugar
D. Glycosylated Haemoglobin
E. Serum Lipid Profile
F. Complete Blood count

Statistical Analysis

The observations and results were analysed using standard statistical procedures .In order to compare the means ,the student's paired 't' test was applied. In all cases, p values were calculated with two tails ,and a value of less than 0.05 was taken to be statistically significant.

III. OBSERVATION TABLE AND RESULT

Table 1

Age and Sex wise distribution into control and study group

Age Group (years)	Sex											
	Control Group						Study Group					
	Female		Male		Total		Female		Male		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
35-40	10	27.0	20	31.7	30	30.0	4	11.1	20	31.3	24	24.0
41-45	0	-	7	11.1	7	7.0	7	19.4	13	20.3	20	20.0
46-50	4	10.8	24	38.1	28	28.0	18	50.0	5	7.8	23	23.0
51-55	23	62.2	12	19.0	35	35.0	7	19.4	26	40.6	33	33.0
Total	37	37.0	63	63.0	100	100	36	36.0	64	64.0	100	100.0

Table 2

Mean±SD age of subjects under both the groups

	Female		Male		Total	
	Control Group	Study Group	Control Group	Study Group	Control Group	Study Group
Mean	50.08	47.36	45.65	46.58	47.29	46.86
SD	6.59	4.12	5.89	6.56	6.49	5.81
SE	0.82	0.68	0.74	1.08	0.65	0.58
t	2.113		0.835		0.494	
p	0.038		0.405		0.622	

International Journal Dental and Medical Sciences Research
Volume 4, Issue 4, July-Aug 2022 pp 619-923 www.ijdmsrjournal.com ISSN: 2582-6018

Table 3
Effect of Ashwagandha on anthropometric ,biochemical & Hematological parameters in Control Group

Parameters		Base Line		Post Treatment		t	p
		Mean	SD	Mean	SD		
BMI (Kg/m^2)		29.79	5.15	29.59	5.35	1.810	0.073#
Blood Pressure (mmHg)	Systolic	138.36	8.26	135.74	7.73	9.095	<0.001*
	Diastolic	91.08	8.81	86.76	8.16	4.117	<0.001*
Glycemic Control mg/dl %	FBS	144.52	16.97	138.27	18.49	6.286	<0.001*
	HbA_1C	7.24	1.18	6.81	0.91	5.857	<0.001*
Lipid Profile (mg/dl)	TC	194.20	21.02	191.29	21.35	4.251	<0.001*
	TG	151.01	28.16	149.46	30.08	2.420	0.017*
	HDL	42.34	7.27	43.58	7.22	7.768	<0.001*
	LDL	121.97	25.17	117.82	24.99	5.677	<0.001*
	VLDL	30.20	5.63	29.89	6.01	2.420	0.017*
Blood Parameters	RBC	4.96	0.55	4.98	0.38	0.481	0.631#
	WBC	8.09	2.14	8.19	2.09	1.524	0.131#
	Platelet	3.19	0.9	3.20	0.60	10.899	<0.001*
	Hb	13.13	2.35	13.46	2.28	7.541	<0.001*

Table 4
Effect of Ashwagandha on anthropometric,biochemical &hematological parameters in Study Group

Parameters		Base Line		Post Treatment		t	p
		Mean	SD	Mean	SD		
BMI(Kg/m^2)		27.73	5.44	27.05	5.57	6.297	<0.001*
Blood Pressure (mmHg)	Systolic	138.26	7.45	133.96	7.07	13.564	<0.001*
	Diastolic	95.98	5.92	88.86	6.83	13.104	<0.001*
Glycemic Control mg/dl %	FBS	140.15	21.51	131.43	17.72	7.833	<0.001*
	HbA_1C	7.42	1.13	6.66	0.94	17.931	<0.001*
Lipid Profile (mg/dl)	TC	194.01	22.57	178.65	15.31	12.488	<0.001*
	TG	208.94	83.29	192.69	74.77	8.342	<0.001*
	HDL	42.13	6.71	47.57	6.53	21.904	<0.001*
	LDL	110.09	19.49	92.54	16.23	14.893	<0.001*
	VLDL	41.78	16.66	38.54	14.95	8.342	<0.001*
Blood Parameters	RBC	4.44	0.52	4.51	0.54	12.499	<0.001*
	WBC	7.88	1.15	7.98	1.13	6.718	<0.001*
	Platelet	2.91	0.97	2.92	0.97	14.100	<0.001*
	Hb	12.33	2.08	12.81	2.041	18.604	<0.001*

Table 5
Comparison of different parameters between Control & Study group at pre-treatment

Parameters		Control Group		Study Group		t	p
		Mean	SD	Mean	SD		
BMI (Kg/m^2)		29.79	5.15	27.73	5.44	2.747	0.007
Blood Pressure mmHg	Systolic	138.36	8.26	138.26	7.45	0.090	0.928
	Diastolic	91.08	8.81	95.98	5.92	4.619	<0.001
Glycemic Control mg/dl %	FBS	144.52	16.97	140.15	21.51	1.595	0.112
	HbA_1C	7.24	1.18	7.42	1.13	1.080	0.281
Lipid Profile (mg/dl)	TC	194.20	21.02	194.01	22.57	0.62	0.951#
	TG	151.01	28.16	208.94	83.29	6.589	<0.001*
	HDL	42.34	7.27	42.13	6.71	0.212	0.832#
	LDL	121.97	25.17	110.09	19.49	3.730	<0.001*
	VLDL	30.20	5.63	41.78	16.66	6.589	<0.001*

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Volume 4, Issue 4, July-Aug 2022 pp 619-923 www.ijdmsrjournal.com ISSN: 2582-6018

Blood Parameters	RBC	4.96	0.55	4.44	0.52	6.930	<0.001*
	WBC	8.09	2.14	7.88	1.15	0.836	0.404#
	Platelet	3.19	0.9	2.91	0.97	2.418	0.017*
	Hb	13.13	2.35	12.33	2.08	2.557	0.011*

Table 6
Comparison of different parameters between Control & Study group at post-treatment

Parameters		Control Group		Study Group		t	p
		Mean	SD	Mean	SD		
BMI (Kg/m^2)		29.59	5.35	27.05	5.57	3.286	0.001*
Blood Pressure (mmHg)	Systolic	135.74	7.73	133.96	7.07	1.699	0.091#
	Diastolic	86.76	8.16	88.86	6.83	1.974	0.050*
Glycemic Control mg/dl %	FBS	138.27	18.49	131.43	17.72	2.671	0.008*
	HbA_1C	6.81	0.91	6.66	0.94	1.126	0.262#
Lipid Profile (mg/dl)	TC	191.29	21.35	178.65	15.31	4.811	<0.001*
	TG	149.46	30.08	192.69	74.77	5.364	<0.001*
	HDL	43.58	7.22	47.57	6.53	4.098	<0.001*
	LDL	117.82	24.99	92.54	16.23	8.480	<0.002*
	VLDL	29.89	6.01	38.54	14.95	5.364	<0.001*
Blood Parameters	RBC	4.51	0.54	4.44	0.52	7.091	<0.001*
	WBC	7.98	1.13	7.88	1.15	0.917	0.361#
	Platelet	2.92	0.97	2.91	0.97	2.435	0.016*
	Hb	12.81	2.041	12.33	2.08	2.124	0.035*

* $P < 0.05$ (Significant) # $P > 0.05$ (Not significant)

IV. DISCUSSION

The aim of the current research was to determine the impact of Withania somnifera (ASHWAGANDHA) on diabetic patients in the middle age range, 36-55 years, at the Sardar Patel Medical College and Diabetic Care & Research Centre, Bikaner.

In our study, after three months of treatment, Withania Somnifera root powder iproduce ihighly isignificant ireduction in blood sugar and HbA_1C,and RBC,WBC, Haemoglobin and Platelet count had shown a statistically significant improvement in study group.

In our investigation, withania somnifera powder produced a very significant decrease in itotal icholesterol, triglyceride, LDL cholesterol, and VLDL cholesterol after three imonths of itherapy. The HDL-cholesterol level increased significantly.

In our study, after three month of treatment, Withania Somnifera had shown a statistically significant improvement in SBP & DBP.

One study conducted by Andallu & Radhika (2000)[8] on six mild iNIDDM subjects and six imild ihypercholesterolemic subjects who were given root powder of iWithania iSomnifera for 30days, and their blood and urine samples were collected before and after treatment period. Their results demonstrated a 12% decrease in blood sugar of withania somnifera treated NIDDM subjects which is similar to decrease in blood sugar of control subjects who were taking oral hypoglycaemic drug. The hypoglycaemic effect of Withania somnifera may be due to its property to increase iserum iinsulin ilevels, and or ithe iactivities iof icatalase, isuperoxide dismutase and glutathione peroxidise, indicative of its antioxidant properties. This study also revealed a reduction of 10,15,6 & 15% reduction in iserum icholesterol, itriglycerides, iLDL, VLDL and a slight iincrease in iHDL.

In our study too, in study group due to Ashwagandha supplementation significant reduction occurred in Blood sugar,HbA_1C,TC,LDL,VLDL,TG and a increament in HDL was found.

According to a few of the studies that were reviewed, ashwagandha not only has immunostimulatory activity but also has been shown to prevent myelosuppression in mice given immunosuppressive medications and to significantly increase haemoglobin concentration, RBC count, WBC count, iplatelet icount, and ibody iweight[9]. In our study , in study group significant improvement in RBC Count,WBC Count,Platelet count was found.

Some of the research we considered have demonstrated hypolipidemic action of Withania somnifera[10], who observed the antihyperlipidemic activity of Withania somnifera extract in Triton X-100 produced hyperlipidemic rats, which is consistent with our results. Rats receiving triton-X-100 (100 mg/kg) saw an increase in total cholesterol, total triglycerides, VLDL and LDL, as well as a decrease in HDL levels. Rats that had been given Triton to induce hyperlipidemia were given withania somnifera at different dosages of 200 and 400 mg/kg per day (p.o.). The reference standard was atorvastatin. Plant extract therapy resulted in a substantially (p0.05) lower level of TG, TC, VLDL, and LDL. Furthermore, it was discovered that the extract raised HDL levels in a manner that was significant (p 0.05).

Steroid alkaloids and steroidal lactones, which belong to a group of substances termed withanolides, are the main biochemical components of Ashwagandha root. Currently recognised anti-hyperlipidemic effects of this plant include 12 alkaloids, 35 withanolides, and many sitoindosides.

Withaferin A and withanolide D, which have antihyperlipidemic effect, are the two primary withanolides that make up the majority of the plant's chemical composition. The effectiveness of Withania Somnifera as an antihypertensive.[11] Purposive sampling was used to choose 51 stress-oriented hypertensive patients between the ages of 40 and 70 for the investigation. Group I and Group II of subjects were separated. Two grammes of Ashwagandha root powder were added to the morning beverages of milk and water for groups I and II, respectively. Over a three-month period, blood pressure was also monitored. Despite being non-significant, a general decline in isystolic iblood ipressure was seen. Additionally, group I showed a substantial reduction in isystolic iblood ipressure, whereas both groups showed significant reductions in diastolic blood pressure. As a result, supplementing with Ashwagandha and milk is advised for the treatment of stress-related hypertension.

In our investigation, Withania Somnifera therapy for three months resulted in a statistically significant change in SBP and DBP in study groups.

V. CONCLUSION

As Ashwagandha possess infinite properties like it is antidiabetic,hypolipidemic, immumodulatory ,antihypertensive ,thus it may be utilised as an Adjuvant therapy in addition to the standard care for Diabetes mellitus. As the mainstay of traditional medical treatment across the globe, medicinal herbs should be studied further.

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