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Research Article

ROLE OF ASHWAGANDHA ON HEMATOLOGICAL, BIOCHEMICAL, SEMINAL PARAMETERS AND ON SERUM DHEA-S IN PSYCHOGENIC ERECTILE DYSFUNCTION PATIENTS

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ABSTRACT
Ashwagandha (*Withania somnifera* Dunal) has been known for its capability to improve endurance against stress, general resistance against infections, to slow down the ageing process, improvement of male sexual health and useful in disorders such as psychogenic impotence and unexplained infertility. The roots of which have been used as anti-stress agent, aphrodisiac and male sexual stimulant. Erectile dysfunction has been defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual intercourse. The clinical study on Ashwagandha in Psychogenic Erectile Dysfunction (PED) earlier reported negative results and concluded that, Ashwagandha didn't provide relief in PED on various scales. The present article deals with the laboratory findings of this clinical study sample; to evaluate the efficacy of Ashwagandha on various hematological, bio chemical, seminal parameters and on serum DHEA-S (which were in normal range) in PED patients. Blood samples were collected and assayed for serum concentrations of DHEA-S, RBS, TC, TG, HDL, total protein, SGOT, SGPT, Hemoglobin, total RBC count, TLC and DLC. Semen samples were collected and measured on parameters like, liquefaction time, volume, motility and count. Patients found to have any abnormalities in the reports of above parameters were excluded from the study (to rule out organic pathology). All of these investigations were done two times, before and after the treatment. Paired and unpaired't' test were used for statistical analysis. Ashwagandha didn't improve various hematological, biochemical, seminal parameters and serum DHEA-S which were already in normal range in the patients of psychogenic erectile dysfunction. The results were consistent with that of the clinical study which was also reported negative results earlier.
Keywords: Ashwagandha, Psychogenic Erectile Dysfunction, serum DHEA-S

INTRODUCTION

Ashwagandha (*Withania somnifera Dunal)* has been documented in Ayurveda and Unani systems of medicine, for its capability to improve endurance against stress, general resistance against infections, to slow down the aging process, improvement of male sexual health and useful in disorders such as psychogenic impotence and unexplained infertility. It is a traditional medicine, the roots of which have been used as anti-stress agent, aphrodisiac and male sexual stimulant[1]. A double blind randomized placebo controlled study revealed that, Ashwagandha is beneficial in reducing the biochemical indicators of stress and it significantly increases the mean serum DHEA-S (De Hydro Epi Androsterone Sulfate) and hemoglobin in chronically stressed humans[2]. One more study on Ashwagandha proved that, it significantly improves almost all the semen parameters like liquefaction time, motility and sperm concentration. Upon treatment with Ashwagandha the sperm concentration in normozoospermic men, cigarette smokers and those having psychological stress was increased by 17, 20 and 36 % respectively. Similarly motility of spermatozoa also increased by 9, 10 and 13 % along with decrease in their semen liquefaction time by 19, 20 and 34 % as compared with the pretreatment parameters[3]. The present article was based on the laboratory findings related to the role of Ashwagandha in various hematological, bio chemical, seminal parameters and on serum DHEA-S. The clinical study of which already reported 12.6 % relief in trial group on International Index of Erectile Function – IIEF[4], 10.52 % relief on Erectile Dysfunction Severity Index – EDSI, 39.22 % relief on Quality of Erections Questionnaire – QEQ and 4.18 % relief on Internet Mental Health Quality of Life – IMHQOL scales. Ashwagandha was not proved better than placebo in clinical study[5]. The present article deals with the laboratory findings of the above clinical study sample.

Aim and Objective

To evaluate the efficacy of Ashwagandha on various hematological, biochemical, seminal parameters and on serum DHEA-S in psychogenic erectile dysfunction patients

MATERIALS AND METHODS

Study design, subjects of the study, inclusion and exclusion criteria, randomization and intervention were same as that of the clinical study[6]. The study was cleared by the ethical committee of the institute. Before recruiting the patient in the study, written consent was taken from them. Patients were free to withdraw from the study at any time without giving any reason.

Method of preparation and intervention of trial and control drug

The roots of Ashwagandha (trial drug) were purchased by the pharmacy of IPGT and RA and were identified and authenticated by Department of Pharmacognosy. The roots were dried under shade and converted to a fine powder using a laboratory mill. The powder was filtered through mesh to remove fibers and coarse particles. Then, this powder was

mixed with 5 % gum, and it was kept in end runner for the purpose of binding. After the proper addition of binding agent it was subjected to granular machine to convert it to granules. This product was then added with 5 % starch before it was made into 500 mg tablets in tablet making machine. Placebo tablets were also prepared by following same procedure with roasted wheat powder (control drug). Both the trial drug and control drug were administered with the dose of 2 g (four tablets) thrice a day for 60 days.

Assessment and Statistical analysis

All subjects were instructed not to take any nutritional supplement or vitamins and not to change their dietary habits during the course of study. This study was conducted between April 2009 and August 2010. To measure various hematological, biochemical markers, participants fasted overnight prior to visits at baseline (before treatment) and day 60 (after treatment) to avoid diurnal variations (serum DHEA-S concentrations). Blood samples (6-10 ml) were collected between 9 AM to 10 AM, stored at 4 C and assayed for serum concentrations of DHEA-S (De Hydro Epi Androsterone Sulphate), RBS (Random Blood Sugar), TC (Total Cholesterol), TG (Total Triglycerides), HDL (High Density Lipoprotein), total protein, SGOT (Serum Glutamic Oxaloacetic Transaminase), SGPT (Serum Glutamic Pyruvic Transaminase), Hemoglobin, total RBC (Red Blood Cell) count, TLC (Total Leucocyte Count) and DLC (Differential Leucocyte Count). Semen samples were collected from subjects after 3-4 days of sexual abstinence. Seminal parameters like liquefaction time, volume, motility and count were measured. All these investigations were carried out before and after the treatment at a laboratory of IPGT and RA (Institute for Post Graduate Teaching and Research in Ayurveda), Gujarat Ayurved University, Jamnagar, India, to exclude organic pathology and to assess the general condition of the patient. If any of the abnormalities found in investigation reports those patients were excluded from the study. Serum testosterone levels were measured for all of the patients before treatment. Those who were having serum testosterone levels less than 239 ng/dl were not registered in the study. This is because to exclude any organic, endocrinal pathology and hypoactive sexual desire disorder. Serum DHEA-S had been carried out as bio-marker in randomly selected 18 patients only (9 patients from trial group and 9 patients from control group) before and after the treatment. Percent changes were expressed as the difference between the means of the baseline and day 60 scores which was divided by the mean of the baseline and multiplied by 100. Sample size calculations were not done for this study. The information gathered on the basis of observations was subjected to statistical analysis in terms of mean difference, standard deviation, standard error, paired‘t’ test and unpaired ‘t’ test. Statistical analysis was done by using ‘Sigmastat’ software version 3.5. No study participant or dropout experienced any adverse effects or withdrawal effects either to trial drug or to placebo. $P < 0.05$ was considered as statistically significant.

RESULTS

In trial group, the percentage of increase in seminal parameters like liquefaction time, volume, sperm count and motility was 0.22 %, 1.33 %, 0.55 % and 8.06 % respectively, all of which were statistically insignificant ($P > 0.05$). In control group also similar results were found. (Table 1) There was no statistically significant difference found in between the two groups ($P > 0.05$). (Table 2) In trial group, the decrease in lymphocyte count was 7.18 % which was statistically significant ($P < 0.05$). There was no statistically significant improvement ($P > 0.05$) in all other parameters. In control group, there was no statistically significant improvement ($P > 0.05$) was observed in all hematological parameters except in hemoglobin, in which 0.54 % of increase was obtained with the significance level at ($P < 0.05$). (Table 3) There was no statistically significant difference found in between the two groups on all hematological parameters ($P > 0.05$). (Table 4) In trial group, total protein levels increased after treatment with 1.71 % of g/dl which was statistically significant ($P < 0.05$). In all other bio chemical parameters there was no statistically significant difference was found ($P > 0.05$). In control group, serum cholesterol was increased after treatment with 5.05 % of mg/dl, which was statistically significant ($P < 0.05$). In all of the other parameters there was no statistically significant difference was found ($P > 0.05$). (Table 5) There was statistically no significant difference was found in between the two groups on all parameters ($P > 0.05$). (Table 6) The mean serum DHEA-S levels were decreased from 176.8 to 164.4 and the percentage was 6.98 in trial group, which was statistically insignificant ($P > 0.05$). In control group, the mean serum DHEA-S levels were increased from 155.7 to 161.2 with the percentage of 3.50, which was found statistically insignificant ($P > 0.05$). (Table 7) On comparing the effect of therapy on serum DHEA-S levels in between the two groups, there was no statistically significant difference was observed ($P > 0.05$). (Table 8)

DISCUSSION

Among Sexual dysfunctions, Male Erectile Disorder (psychogenic type) or Psychogenic Erectile Dysfunction (PED) is related to the disturbance during excitement phase of sexual response cycle. It is defined as the persistent inability to achieve or maintain erection satisfactory for sexual performance owing predominantly or exclusively to psychological or interpersonal factors. Psychogenic erectile dysfunction frequently coexists with other sexual dysfunctions, notably hypoactive sexual desire, and with major psychiatric disorders, particularly depression and anxiety disorders[7]. Ashwagandha is an important medicinal plant that has been used in Ayurvedic and indigenous medicine for over 3,000 years. It is one of the most commonly used medicinal plants in Indian medicine for varied range of physical and psychological ailments. It finds mention in almost all classical compendia of Indian medicine, particularly in the context of rejuvenation therapy[8]. Ashwagandha proved to be beneficial in reducing stress induced hyperglycemia, glucose intolerance, plasma corticosterone levels, gastric ulcerations, male sexual dysfunction, cognitive deficits, immune suppression and depression[9]. Ashwagandha has shown anxiety-relieving effects similar to those achieved by the anti-anxiety drug lorazepam and antidepressant effects similar to those of the prescription antidepressant drug imipramine[10]. Ashwagandha provided only 12.6 % improvement in IIEF (International Index of Erectile Function), 10.52 % of relief on total score of EDSI (Erectile Dysfunction Severity Index), 39.22 % on QEQ (Quality of Erection Questionnaire) and 4.18 % on IMHQOL (Internet Mental Health Quality of Life) scales. It was not better than placebo and ineffective in the management of psychogenic erectile dysfunction[11].

Seminal Parameters

Ashwagandha is used to calm the mind, relieve weakness and nervous exhaustion, build sexual energy and promote healthy sleep. The herb is termed as rasayana, which means it acts as a tonic for vitality and longevity. It is also classified as an adaptogen[12]. Previous studies reported that, Ashwagandha provides significant improvement in sperm count and motility along with reduction of stress and serum cortisol levels in normozoospermic infertile men who were under psychological stress[13]. Ashwagandha is having the property of Vajikarana and some studies identified that, it enhances male fertility i.e. sperm count and sperm motility[14]. But in present study Ashwagandha was not provided improvement in various seminal parameters like liquefaction time, count, motility and volume. It may be because of short duration (60 days) of the treatment period or severe chronicity of the disease condition or persistence of various stressors in study population (social, occupational, family and inter personal).

Hematological and Biochemical Parameters

According to previous study, Ashwagandha decreased blood glucose level which was comparable to that of an oral hypoglycaemic drug. Significant increase in urine sodium, urine volume, significant decrease in serum cholesterol, triglycerides, LDL (low density lipoproteins) and VLDL (very low density lipoproteins) cholesterol were observed indicating that Ashwagandha is a potential source of hypoglycaemic, diuretic and hypocholesterolaemic agent[15]. Ashwagandha improves hemoglobin levels; it increases mean corpuscular hemoglobin concentration, RBC (Red Blood Corpuscles) count, WBC (Red Blood Corpuscles) count, stimulates cytotoxic T lymphocytes, acts as immune stimulant in patients with low white blood cell counts[16]. But in present study Ashwagandha was not provided improvement in hematological parameters. Present study recruited only the patients who are having the hematological and biochemical reports with in normal range and excluded patients who had organic pathology. As the patients had normal hematological and biochemical reports, the role of Ashwagandha in improving those parameters (with in normal limits) is unknown. Ashwagandha is known to increases the total protein levels. In present study also serum protein levels were slightly increased (within normal limits)[17].

Serum DHEA-S levels

Stress can cause adverse physiological conditions such as cognitive deficiencies, impaired glucose and lipid homeostasis, sexual dysfunction and alteration in serum cortisol and DHEA-S levels. Many types of physical and emotional stress particularly those that are chronic in nature, reduce serum DHEA-S concentration, which can be used as a marker of stress. Previous study reported that, Ashwagandha increases serum DHEA-S concentrations compared to placebo[18]. The normal serum DHEA-S level is 80-560 μg/dl[19]. In present study, the changes observed in serum DHEA -S levels in both groups were within normal limits. Instead of increasing Serum DHEA -S levels, Ashwagandha decreased the levels, while placebo increased the levels. Based on these findings no conclusion can be drawn because of the small sample size (n = 9) or heavy fluctuations in the hormone levels based on patient's age, severity of stress, time of testing, season, diet, sleep patterns etc; factors. The present laboratory findings are consistent with the clinical study which was also reported negative results. The factors like demanding and uncooperative partner, interpersonal problems or conflicts between the partners, negative personality traits, significant psychopathology and high severity of the disease etc; factors produced negative result in the clinical study[20,21]. The same factors can be attributed for negative results in the laboratory findings of the present study also.

CONCLUSION

Ashwagandha didn't improve the various hematological, biochemical, seminal parameters and serum DHEA-S which were already in normal range in the patients of psychogenic erectile dysfunction. The results were consistent with that of the clinical study which was also reported negative results.

Table 1: Effect of therapy on seminal parameters in both groups

S. No	Seminal Parameter	Group	Sample size (n)	Mean BT*	Mean AT**	M. D***	% of Relief	SD**** ±	t value	P value
1	Liquefaction time in min	Trial	40	24.28	24.34	0.05	0.22	3	0.11	> 0.05
		Control	39	23.97	23.84	0.12	0.52	2.68	0.29	> 0.05
2	Volume in ml	Trial	40	1.31	1.33	0.01	1.33	0.68	0.16	> 0.05
		Control	39	1.37	1.24	0.13	9.85	0.74	1.14	> 0.05
3	Sperm count in mi/ml	Trial	40	42.62	42.88	0.23	0.55	12.5	0.11	> 0.05
		Control	39	51.71	53.74	2.02	3.91	18.58	0.68	> 0.05
4	Motility in %	Trial	40	49.62	53.62	4	8.06	19.8	1.27	> 0.05
		Control	39	60.51	62.43	1.92	3.17	14.35	0.84	> 0.05

*Before Treatment, **After Treatment ***Mean difference, ****Standard Deviation

Table 2: Comparison of effect of therapy on seminal parameters

S. No	Seminal Parameter	Trial Group			Control Group			t value	P value
		Sample size (n)	M. Diff*	SD**	Sample size (n)	M. Diff	SD		
1	Liquefaction time in min	40	0.05	3	39	0.12	2.68	0.1	> 0.05
2	Volume in ml	40	0.01	0.68	39	0.13	0.74	0.75	> 0.05
3	Sperm count in mi / ml	40	0.23	12.5	39	2.02	18.58	0.5	> 0.05
4	Motility in %	40	4	19.8	39	1.92	14.35	0.53	> 0.05

*Mean difference, **Standard Deviation

Table 3: Effect of therapy on hematological parameters in both groups

S. No	Hematological Parameter	Group	Sample size (n)	Mean BT	Mean AT	M.D*	% of Relief	SD** ±	t value	P value
1	Hemoglobin %	Trial	41	13.7	13.78	0.08	0.53	0.34	1.36	> 0.05
		Control	45	13.73	13.81	0.07	0.54	0.24	2.05	< 0.05
2	Total RBC count in mi / cu mm	Trial	41	4.98	5.03	0.04	0.96	0.18	1.65	> 0.05
		Control	45	4.99	5.03	0.03	0.76	0.13	1.83	> 0.05
3	Total Leucocyte count	Trial	41	6397	6802	404	6.32	1291	2	> 0.05
		Control	45	7000	6986	13.3	0.19	1735	0.05	> 0.05
4	Neutrophils	Trial	41	59.1	61.6	2.46	4.16	7.52	2.09	> 0.05
		Control	45	58.84	59.66	0.82	1.39	7.74	0.71	> 0.05
5	Eosinophils	Trial	41	3.36	3.53	0.17	5.07	1.61	0.67	> 0.05
		Control	45	3.71	3.53	0.17	4.79	1.84	0.64	> 0.05
6	Lymphocytes	Trial	41	34.2	31.8	2.46	7.18	6.82	2.31	< 0.05
		Control	45	34.62	33.88	0.73	2.11	7.49	0.65	> 0.05
7	Basophils	Trial	41	0	0	0	0	0	0	> 0.05
		Control	45	0	0	0	0	0	0	> 0.05
8	Monocytes	Trial	41	2.85	2.95	0.09	3.41	1.20	0.52	> 0.05
		Control	45	3	3.11	0.11	3.70	0.98	0.75	> 0.05

* Mean difference, **Standard Deviation

Table 4: Comparison of effect of therapy on hematological parameters

S. No	Hematological Parameter	Trial Group			Control Group			t value	P value
		Sample size (n)	M. Diff	SD	Sample size (n)	M. Diff	SD		
1	Hemoglobin %	41	0.08	0.34	45	0.07	0.24	0.16	> 0.05
2	Total Red Bolld Cell count in mi / cu mm	41	0.04	0.18	45	0.03	0.13	0.29	> 0.05
3	Total Leucocyte count	41	404	1291	45	13.3	1735	1.17	> 0.05
4	Neutrophils	41	2.46	7.52	45	0.82	7.74	1.11	> 0.05
5	Eosinophils	41	0.17	1.61	45	0.17	1.84	0	> 0.05
6	Lymphocytes	41	2.46	6.82	45	0.73	7.49	1.11	> 0.05
7	Basophils	41	0	0	45	0	0	0	> 0.05
8	Monocytes	41	0.09	1.20	45	0.11	0.98	0.08	> 0.05

Table 5: Effect of therapy on biochemical parameters in both groups

S. No	Biochemical Parameter	Group	Sample size (n)	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	Random blood sugar	Trial	41	95.48	96.82	1.34	1.40	11.22	0.76	> 0.05
		Control	45	95.17	94.2	0.97	1.02	11.49	0.57	> 0.05
2	Serum cholesterol	Trial	41	180.4	185	4.58	2.54	19.96	1.47	> 0.05
		Control	45	168.2	176.8	8.51	5.05	22.75	2.50	< 0.05
3	Serum triglycerides	Trial	41	135	145.8	10.75	7.96	99.26	0.69	> 0.05
		Control	45	120.5	121.2	0.66	0.55	60.95	0.07	> 0.05
4	HDL	Trial	41	44.65	43	1.65	3.71	11.15	0.95	> 0.05
		Control	45	39.15	39.82	0.66	1.70	10.7	0.41	> 0.05
5	Total protein	Trial	41	7.52	7.65	0.12	1.71	0.38	2.15	< 0.05
		Control	45	7.58	7.54	0.04	0.58	0.36	0.82	> 0.05
6	SGOT	Trial	41	30.58	29.65	0.92	3.03	10.28	0.57	> 0.05
		Control	45	28.17	27.91	0.26	0.94	9.35	0.19	> 0.05
7	SGPT	Trial	41	29.56	25.92	3.63	12.29	18.36	1.26	> 0.05
		Control	45	25.93	23.17	2.75	10.62	15.45	1.19	> 0.05

*Mean difference, **Standard Deviation

Table 6: Comparison of effect of therapy on bio chemical parameters

S. No	Bio chemical Parameter	Trial Group			Control Group			t value	P value
		Sample size (n)	M. Diff	SD	Sample size (n)	M. Diff	SD		
1	Random Blood Sugar	41	1.34	11.22	45	0.97	11.49	0.15	> 0.05
2	Serum Cholesterol	41	4.58	19.96	45	8.51	22.75	0.84	> 0.05
3	Serum Triglycerides	41	10.75	99.26	45	0.66	60.95	0.57	> 0.05
4	High density lipoprotein (HDL)	41	1.65	11.15	45	0.66	10.7	0.42	> 0.05
5	Total Protein	41	0.12	0.38	45	0.04	0.36	1	> 0.05
6	SGOT	41	0.92	10.28	45	0.26	9.35	0.31	> 0.05
7	SGPT	41	3.63	18.36	45	2.75	15.45	0.24	> 0.05

Table 7: Effect of Therapy on Serum DHEA-S (µg/dl)

Group	Sample size (n)	Mean score BT*	Mean score AT**	M. Diff***	% of Relief	SD****	t value	P value
Trial	9	176.8	164.4	12.35	6.98	50.37	0.73	> 0.05
Control	9	155.7	161.2	5.45	3.50	82.45	0.19	> 0.05

*Before Treatment, **After Treatment ***Mean difference, ****Standard Deviation

Table 8: Comparison of Effect of Therapy on Serum DHEA-S

Group	M. diff*	SD**	t value	P value
Trial	12.35	50.37	0.46	> 0.05
Control	5.45	82.45		

*Mean difference, **Standard Deviation

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