



Research Article

www.ijrap.net



ASHWAGANDHA IN PSYCHOGENIC ERECTILE DYSFUNCTION: ANCILLARY FINDINGS

Prasad Mamidi^{1*}, Kshama Gupta², Anup B Thakar³

¹Assistant Professor, Department of Kayachikitsa, Parul Institute of Ayurved, P.O. Limda, Vadodara, Gujarat, India

²Assistant Professor, Department of Kayachikitsa, Parul Institute of Ayurved, P.O. Limda, Vadodara, Gujarat, India

³Associate professor and HOD, Department of Panchakarma, I.P.G.T and R.A, Gujarat Ayurved University, Jamnagar, Gujarat, India

Received on: 09/12/13 Revised on: 07/01/14 Accepted on: 12/02/14

*Corresponding author

Dr. Prasad Mamidi PhD, Assistant Professor, Dept of Kayachikitsa, Parul Institute of Ayurveda, Vadodara, Gujarat, India

Email: drprasadmamidi@gmail.com

DOI: 10.7897/2277-4343.05108

ABSTRACT

Erectile dysfunction has been defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance. The present study was based on the ancillary findings of the main study (which was based on scoring of International Index of Erectile Function - IIEF) in Psychogenic Erectile Dysfunction (PED). The study main findings based on IIEF scoring reported, 12.6 % improvement in trial group (Ashwagandha - *Withania somnifera*) and 19.11 % improvement in control group (Placebo) ($P < 0.001$). Ashwagandha didn't provide relief in PED on IIEF scoring. The present ancillary findings are based on the measurement tools like, Erectile Dysfunction Severity Index (EDSI), Quality of Erections Questionnaire (QE) and Quality of Internet Mental Health Quality of Life scale (IMHQOL) on same sample, with same materials and methods and intervention as of the main study. The aim of this study is to evaluate the efficacy of Ashwagandha on EDSI, QE and IMHQOL. Two assessments were done before and after treatment, based on the scorings of EDSI, QE and IMHQOL. Paired and unpaired 't' test were used for statistical analysis. In trial group ($n = 41$), 10.52 % improvement on EDSI, 4.18 % on IMHQOL and 39.22 % on QE and in control group ($n = 45$), 11.20 % of improvement on EDSI, 5.95 % on IMHQOL and 45.74 % on QE was observed ($P < 0.001$). No statistically significant difference ($P > 0.05$) found in between the two groups on all the scales. Ashwagandha did not prove better than placebo on EDSI, QE and IMHQOL scales.

Keywords: Psychogenic Erectile Dysfunction, Ashwagandha, Placebo, EDSI, QE, IMHQOL, IIEF

INTRODUCTION

The essential feature of Male Erectile Disorder (MED) or Erectile Dysfunction (ED) is a persistent or recurrent inability to attain or maintain an adequate erection until completion of sexual activity. The disturbance will cause marked distress / interpersonal difficulty. It can disrupt existing marital or sexual relationship and may be the cause of unconsummated marriages and infertility.¹ The present work was the ancillary one to the main study which was conducted on Ashwagandha (*Withania somnifera* Linn) by using the assessment tool, International Index of Erectile Function – IIEF; this trial reported 12.6 % improvement in trial group, whereas in control group 19.11 % of improvement was observed. Ashwagandha was not proved better than placebo on IIEF in this main study.² The present article deals with the findings on the measurement tools like, Erectile Dysfunction Severity Index – EDSI, Quality of Erections Questionnaire – QE and Internet Mental Health Quality of Life – IMHQOL scales but on the same sample with same materials and methods and intervention as that of main study.

Aim and Objective

To evaluate the efficacy of Ashwagandha on EDSI, QE and IMHQOL scales in PED patients

MATERIALS AND METHODS

Study design, subjects of the study, inclusion and exclusion criteria, randomization and intervention were same as that of the main study. The study was cleared by the ethical committee of the institute. Written consent was taken from each patient willing to participate before the

start of the study. Patients were free to withdraw from the study at any time without giving any reason.

Intervention

The trial drug (Ashwagandha) was collected from the pharmacy of I.P.G.T and R.A, Gujarat Ayurveda University, Jamnagar, India. The root powder of Ashwagandha was made in tablet form and it was given with the dose of four tablets (500 mg each) thrice a day (i.e. 6 g / day) through oral route after intake of food for 60 days in trial group. Placebo (wheat powder) in tablet form with the dose of four tablets (500 mg each) thrice a day (i.e. 6 g / day) has been given in control group through oral route after food for 60 days.

Assessment

Before and after treatment total two assessments were carried out. Criteria of assessment were based on the scoring of Erectile Dysfunction Severity Index (EDSI), Quality of Erections Questionnaire (QE) and Internet Mental Health Quality of Life scale (IMHQOL). The EDSI is composed of 10 Items (Questions). Each question is rated on 11 point (0-10) scale. The EDSI has been used in clinical trials of men with ED who had been in a stable relationship, so these men had opportunities to engage in sexual activity and sexual intercourse. The 10 Questions of EDSI asks about the frequency, obtaining, maintenance, duration of erections and impact of loss of erections on patient and his partner.³ The QE is composed of 6 items (Questions). Each question is rated on a five point (1-5) scale. The QE has been used in clinical trials of men with ED who had been in a stable relationship, so these men had opportunities to engage in

sexual activity and sexual intercourse. The six questions of QEQ ask about the hardness, maintenance, duration and overall quality of erections one has had in their sex life over the last 4 weeks.⁴ The IMHQOL is composed of 78 Items (Questions) which are divided in to 15 categories.⁵ In the present study slight modifications were done to the original scale; among 15 categories of the scale, seven categories (impulsive/anti social behavior – items 19-21, substance abuse – items 22-24, hyperactivity/excitement – items 34-36, reality testing - items 37-39, intellectual functioning – items 40-48, need for institutional care – item 49 and lack of insight – item 50) containing of total 23 items were not included in the assessment because these items are related to mania or psychotic disorders or substance abuse or various organic pathologies which were excluded in the present study. This scale measures the quality of life of the patient in various domains especially focused on mental health.

Statistical Analysis

The information gathered on the basis of observations was subjected to statistical analysis in terms of Mean difference, Standard deviation (S.D), Standard error (S.E), Paired 't' test and Unpaired 't' test. In present study there were no drop outs. Statistical analysis was done by using 'Sigmatat' software version 3.5. The obtained results were interpreted as Insignificant if value $P > 0.05$, $P < 0.05$ and significant if value $P < 0.01$, $P < 0.001$.

Observations and Results

The average length of penis in both groups was 11.73 cm and circumference was 9.36 cm in trial group and 9.82 cm in control group. In trial group there was no change observed in penis length and circumference after treatment. In control group the mean difference in penis length was 0.04 cm (> 0.05) and circumference was 0.02 cm (> 0.05). There was statistically no significant difference in between the two groups in these parameters. The mean change in angle of erection was from 95.36° to 89.26° and the relief was 6.4° % in trial group, in control group mean change was from 95.3° to 88.4° and the relief was 7.22° %, in both groups the change was statistically highly significant ($P < 0.001$). The difference in between the two groups was insignificant (> 0.05). As the sample size was less in the symptoms like semen discharge in urine (n = 5), night emissions (n = 8) and sleeplessness (n = 6), no conclusions can be drawn in the relief on these symptoms. In penile buckling, 2.44 % relief observed in trial group and 4.44 % observed in control group.

Effect of therapy on EDSI

In trial group, maximum relief was found i.e. 25.21 % in EDSI 10 (co morbid conditions like premature ejaculation, low sexual desire etc ;) and 22.5 % in EDSI 4 (duration of hardness of erection in intercourse) which were statistically significant ($P < 0.001$) (Table 1). All of these percentages were calculated by using the formula, BT (Before Treatment) – AT (After Treatment) / $BT \times$

100. In control group, maximum relief was found i.e. 29.21 % in EDSI 10 (co morbid conditions like premature ejaculation, low sexual desire etc) followed by 24.76 % in EDSI 4 (duration of hardness of erection in intercourse) which were statistically significant ($P < 0.001$) (Table 1). Except these in all other EDSI questions very poor outcome was found in both the groups (Table 1). On comparing the effect of therapy on all ten questions (individually) of the EDSI in between the two groups, there was no statistically significant difference was found between these two groups ($P > 0.05$). In trial group, 10.52 % of improvement was observed on the total score of EDSI whereas in control group 11.20 % of improvement was observed ($P < 0.001$) (Table 4). On comparing the effect of therapy on the total score of EDSI in between the two groups, there was no statistically significant difference found ($P > 0.05$).

Effect of therapy on QEQ

In trial group, maximum relief was found i.e. 57.1 % in QEQ 5 (hardness of erection) followed by 56.3 % in QEQ 6 (overall quality of erections), 53.5 % in QEQ 4 (length of the time able to be erect during intercourse) and 50 % in QEQ 3 (length of the time until the erection was hard enough to participate in sexual intercourse); which were statistically highly significant ($P < 0.001$) (Table 2). In control group, maximum relief was found i.e. 64.6 % in QEQ 4 (length of the time able to be erect during intercourse) followed by 63.6 % in QEQ 5 (hardness of erections), 61.5 % in QEQ 6 (overall quality of erections) and 56.7 % in QEQ 3 (length of the time until the erection was hard enough to participate in sexual intercourse); which were statistically highly significant ($P < 0.001$) (Table 2). In trial group, 39.22 % of improvement was observed on the total score of QEQ whereas in control group 45.74 % of increase was observed ($P < 0.001$) (Table 4). On comparing the effect of therapy on the total score of QEQ as well as individual six items of QEQ, there was no significant difference found ($P > 0.05$).

Effect of therapy on IMHQOL

In trial group, relief was observed only on two categories i.e., in physical functioning and dysphoric mood with the percentage of relief 9.92, 13.06 respectively ($P < 0.01$). There was no change observed in all other items (Table 3). In control group also relief was observed only on two categories i.e., in physical functioning and dysphoric mood with the percentage of relief 9.09 ($P < 0.01$) and 18.7 respectively ($P < 0.001$). There was no change observed in all other items (Table 3). On comparing the effect of therapy on IMHQOL scale in between the two groups, there was no statistically significant difference found in all items ($P > 0.05$). In trial group 3.75 % improvement was noticed whereas in control group 6.03 % of improvement was observed on total score of IMHQOL scale. (Table 4) There was no statistically significant difference found ($P > 0.05$) on total score of the IMHQOL scale in between the two groups.

Table 1: Effect of Therapy on Erectile Dysfunction Severity Index (EDSI) in both groups

S. No	EDSI	Group	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	EDSI-1	Trial	4.80	4.78	0.02	0.51	0.16	1	> 0.05
		Control	5.2	5.2	0	0	0	0	> 0.05
2	EDSI-2	Trial	7.09	5.90	1.19	16.83	0.55	13.72	< 0.001
		Control	7	5.8	1.17	16.82	0.68	11.5	< 0.001
3	EDSI-3	Trial	5.31	4.48	0.82	15.59	0.91	5.77	< 0.001
		Control	5.46	4.53	0.93	17.07	0.80	7.73	< 0.001
4	EDSI-4	Trial	4.87	3.78	1.09	22.5	0.66	10.59	< 0.001
		Control	4.75	3.57	1.17	24.76	0.77	10.16	< 0.001
5	EDSI-5	Trial	7.17	6.17	1	13.94	1.04	6.10	< 0.001
		Control	7.64	6.46	1.17	15.4	1.49	5.27	< 0.001
6	EDSI-6	Trial	4.82	4.04	0.78	16.16	1.12	4.42	< 0.001
		Control	4.84	4	0.84	17.43	1.16	4.85	< 0.001
7	EDSI-7	Trial	5.21	5.21	0	0	0	0	> 0.05
		Control	5.97	5.93	0.04	0.74	0.29	1	> 0.05
8	EDSI-8	Trial	9.12	9.04	0.07	0.8	0.34	1.35	> 0.05
		Control	9.22	9.11	0.11	1.20	0.38	1.94	< 0.05
9	EDSI-9	Trial	7.26	7.24	0.02	0.33	0.15	1	> 0.05
		Control	7.35	7.35	0	0	0	0	> 0.05
10	EDSI-10	Trial	5.70	4.26	1.43	25.21	1.07	8.58	< 0.001
		Control	5.4	3.82	1.57	29.21	1.17	8.99	< 0.001

*Mean difference, **Standard Deviation

Table 2: Effect of Therapy on Quality of Erections Questionnaire (QE) in both groups

S. No	QE	Group	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	QE-1	Trial	3.09	3.41	0.31	10.23	0.56	3.57	< 0.001
		Control	3.08	3.44	0.35	11.51	0.64	3.69	< 0.001
2	QE-2	Trial	1.48	2.14	0.65	44.2	0.61	6.83	< 0.001
		Control	1.51	2.33	0.82	54.4	0.80	6.84	< 0.001
3	QE-3	Trial	1.41	2.12	0.70	50	0.60	7.52	< 0.001
		Control	1.48	2.33	0.84	56.7	0.70	8.02	< 0.001
4	QE-4	Trial	1.36	2.09	0.73	53.5	0.59	7.90	< 0.001
		Control	1.44	2.37	0.93	64.6	0.61	10.1	< 0.001
5	QE-5	Trial	1.36	2.14	0.78	57.1	0.52	9.51	< 0.001
		Control	1.46	2.4	0.93	63.6	0.65	9.57	< 0.001
6	QE-6	Trial	1.34	2.09	0.75	56.3	0.79	6.05	< 0.001
		Control	1.44	2.33	0.88	61.5	0.68	8.74	< 0.001

*Mean difference, **Standard Deviation

Table 3: Effect of Therapy on Internet Mental Health Quality of Life scale (IMHQOL) in both groups

S. No	IMHQOL	Group	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	Physical Functioning (1-9)	Trial	3.43	3.09	0.34	9.92	0.72	3	< 0.01
		Control	3.17	2.88	0.28	9.09	0.58	3.29	< 0.01
2	Social Functioning (10-13)	Trial	0.31	0.31	0	0	0	0	> 0.05
		Control	0.17	0.17	0	0	0	0	> 0.05
3	Employment / Economic Functioning (14-18)	Trial	4.19	4.19	0	0	0	0	> 0.05
		Control	3.51	3.51	0	0	0	0	> 0.05
4	Anxiety (25-28)	Trial	0.04	0.04	0	0	0	0	> 0.05
		Control	0	0	0	0	0	0	> 0.05
5	Dysphoric Mood (29-33)	Trial	4.85	4.21	0.63	13.06	1.21	3.32	< 0.01
		Control	4.73	3.84	0.88	18.7	1.38	4.30	< 0.001
6	Overall Psychosocial Functioning (51)	Trial	2.63	2.63	0	0	0	0	> 0.05
		Control	1.86	1.86	0	0	0	0	> 0.05
7	Cluster A + C Personality Traits (52-66)	Trial	6.29	6.29	0	0	0	0	> 0.05
		Control	5.24	5.24	0	0	0	0	> 0.05
8	Cluster B Personality Traits (67-78)	Trial	2.04	2.04	0	0	0	0	> 0.05
		Control	2.17	2.17	0	0	0	0	> 0.05

*Mean difference, **Standard Deviation

Table 4: Effect of Therapy on Total Scores of EDSI, QE and IMHQOL

S. No	Scale	Group	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	EDSI	Trial	61.41	54.95	6.46	10.52	3.78	10.92	< 0.001
		Control	62.86	55.82	7.04	11.20	5.08	9.29	< 0.001
2	QE	Trial	10.07	14.02	3.95	39.22	2.81	8.97	< 0.001
		Control	10.44	15.22	4.77	45.74	3.64	8.78	< 0.001
3	IMHQOL	Trial	23.87	22.87	1	4.18	1.81	3.52	< 0.01
		Control	20.91	19.66	1.24	5.95	1.58	5.27	< 0.001

*Mean difference, **Standard Deviation

DISCUSSION

Ashwagandha has been used extensively for many years in treating various psychosomatic condition and sexual dysfunction. Ashwagandha is a proved anxiolytic, anti depressant, anti stress adaptogen and found effective in stress induced sexual dysfunctions in rat models;⁶ may be because of this effects good improvement was noticed in present study on individual items like EDSI 10, EDSI 4, QEQ 5, QEQ 6, QEQ 4 and QEQ 3. But Ashwagandha was proved ineffective (EDSI) and not better than placebo (QEQ) on total scores of the both scales (QEQ and EDSI). According to the main study (based on IIEF scoring), 82.9 % of the patients in trial group came under no relief category and only 14.01 % improvement was noticed on total score of IIEF. These present ancillary findings are consistent with the results of the main study (trial drug ineffective).⁷ ED impairs the quality of life of affected men and their partners. It is strongly associated with unsatisfying personal experiences and relationships. ED can produce a strong negative effect on interpersonal relationships, well being, quality of life and sexual life dissatisfaction. Improved erectile function is accompanied by improved quality of life and decrease in general psychiatric symptoms.⁸ In present study, Ashwagandha was not effective in improving the quality of life on all items of IMHQOL (Table 3). Placebo also provided similar results like Ashwagandha in all the three scales (EDSI, QEQ and IMHQOL). The mode of action of placebo may be by conditioning or learning or by anticipation or positive expectancy effects or by altering central nervous system activities and autonomic nervous system activities or by altering neurotransmitter release such as dopamine, serotonin or by altering hypothalamic pituitary adrenal axis or immune system activity or by changing mood, motivation/effort or by cognitive set shifting or by various psychoneuroimmunological changes.⁹ All these actions can be considered as placebo effects. The improvement in EDSI 4, EDSI 10 (Table 1) and QEQ 4, QEQ 5, QEQ 6 and QEQ 3 (Table 2) were may be due to these placebo effects.

Probable reasons for poor outcome in present study

Maximum number of the patients (91.86 %) in the present study belongs to moderate to high severity category. It was observed that maximum number of the patients in present study didn't get proper treatment at proper time and proper duration. This leads to persistence of the sexual dysfunction and chronicity of the condition. Most of the patients, after getting treatment from various other systems of medicine finally came to Ayurvedic treatment. These factors like severity, chronicity and patient's high expectations from treatment may be one of the causes for poor outcome. 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 worsen the erectile problems and leads to poor prognosis.¹⁰ This may be the cause for very poor relief. In present study maximum number of the patients (66.32 % were having chronicity of erectile dysfunction more than two years). The patients who have the best prognosis in psychogenic impotence was in whom the

disorder has lasted less than two years, who have a strong motivation for therapy, persisting sexual desire and who are without significant psychopathology.¹¹ In psychogenic erectile dysfunction, to be effective, a treatment should produce improvement within one year.¹² In present the short duration of the treatment (60 days) was also one of the factors for poor outcome. Acharya Susruta mentioned bhaya (fear), dvesha (hatred) and krodha (anger) etc; factors lead to a condition called "manasika klaibya" (psychogenic erectile dysfunction) and he suggested to avoid these manasika factors (nidana parivarjana) in the treatment of klaibya.¹³ According to some studies, hostility and resentment toward the partner is associated with erectile difficulties. Unconscious hatred of the spouse also acts as an etiological factor for erectile dysfunction and leads to recurrence.¹⁴ In present study, 81 % of the patients were having interpersonal difficulties with their partners. Present study was conducted at OPD level without any psychosocial or psychological intervention. This also may be one of the causes for negative outcome. In present study for us it was not possible to involve the female partners of the patients in treatment as well as in assessments. Most of them were not ready to come to hospital because of shyness, stigma associated with sexual problems or lack of interest or motivation or awareness regarding their partner's sexual problems. Further studies should consider the involvement of female partner in treatment and assessment schedule if possible.

CONCLUSION

Ashwagandha provided only 10.52 % of relief on total score of EDSI, 39.22 % on QEQ and 4.18 % on IMHQOL scale. It was not better than placebo and ineffective in the management of psychogenic erectile dysfunction. The results were consistent with that of the main study.

REFERENCES

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders – Text Revision (DSM-IV-TR). Sexual and gender identity disorders – Male erectile disorder. 4th edition. New Delhi: Jaypee Publications; 2000. p. 545.
2. Mamidi P, Thakar AB. Efficacy of Ashwagandha (*Withania somnifera* Dunal. Linn.) in the management of psychogenic erectile dysfunction. AYU 2011; 32: 322-328. <http://dx.doi.org/10.4103/0974-8520.93907>
3. Michaelmetzphd.com. Erectile Dysfunction Severity Index (EDSI) – version; 2004.
4. Porst H, Gilbert C, Collins S, Huang X, Symonds T et al. Development and Validation of the Quality of Erection Questionnaire. J Sex Med 2007; 4: 372 – 381. <http://dx.doi.org/10.1111/j.1743-6109.2006.00422.x>
5. Internet mental health. Internet Mental Health Quality of Life scale (IMHQOL) – version; 2008.
6. Bhattacharya SK, Bhattacharya A, Sairam K and Ghosal S. Anxiolytic-antidepressant activity of *Withania somnifera* glycowithanolides: an experimental study. Phytomedicine 2000; 7: 463-469. [http://dx.doi.org/10.1016/S0944-7113\(00\)80030-6](http://dx.doi.org/10.1016/S0944-7113(00)80030-6)
7. Mamidi P, Thakar AB. Efficacy of Ashwagandha (*Withania somnifera* Dunal. Linn.) in the management of psychogenic erectile dysfunction. AYU 2011; 32: 322-328. <http://dx.doi.org/10.4103/0974-8520.93907>
8. Rehman S. Erectile Dysfunction: Prevalence, Incidence and Risk Factors. University of Tampere; 2004. p. 10.
9. Oken BS. Placebo Effects: Clinical Aspects and Neurobiology. Brain 2008; 131: 2812-2823. <http://dx.doi.org/10.1093/brain/awn116>
10. James MT, Paul CW. Psychological factors involved in impotence: A review of the literature. J Androl 1983; 4: 59-66.

11. James MT, Paul CW. Psychological factors involved in impotence: A review of the literature. *J Androl* 1983; 4: 59.
12. James MT, Paul CW. Psychological factors involved in impotence: A review of the literature. *J Androl* 1983; 4: 62.
13. Susruta, Susruta samhita, Chikitsa sthana, Ksheena baleeya vajeekaraneeya adhyaya, 26/9-10, edited by Vaidya Yadavji Trikamji Acharya and Narayan Ram Acharya Kavyatirtha. Varanasi: Chaukhambha orientalia; 2005. p. 497.
14. James MT, Paul CW. Psychological factors involved in impotence: A review of the literature. *J Androl* 1983; 4: 60.

Cite this article as:

Prasad Mamidi, Kshama Gupta, Anup B Thakar. Ashwagandha in psychogenic erectile dysfunction: Ancillary findings. *Int. J. Res. Ayurveda Pharm.* 2014;5(1):36-40 <http://dx.doi.org/10.7897/2277-4343.05108>

Source of support: Nil, Conflict of interest: None Declared