



A CLINICAL STUDY OF A POLYHERBAL COMPOUND IN THE MANAGEMENT OF MALE SEXUAL DYSFUNCTION

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ABSTRACT

Healthy sexual functioning plays pivotal role in maintaining the harmony and happiness in marital life. It provides a media to express love, strength, happiness of mind and it is the base for all activities. In Kama Sutra, Acharya Vatsayana has given more importance to fore play, before actual sexual intercourse. The success of happy sex life in males depends on a desire to indulge into an act that cultivates into sexual arousal, penile erection and effective foreplay, followed by the sexual congress for a considerably long satisfactory duration. If all sequenced well the act ultimately results into the ejaculation coupled with organism that gives an individual a sense of physical as well as emotional wellbeing. A man who is full of stresses of life and lost his manhood is accepting his failure and undergone depression resulting into divorce. Man is surrounded by various types of diseases as a result of industrialization and modernization. If these conditions coupled with disturbed sleep and habits like cigarette smoking and tobacco chewing are identified as risk factors for sex related disorders and unhealthy conditions which are becoming more and more common now-a days. Male sexual dysfunction affects 10-25% of middle-aged and elderly men. It is estimated that in 1995 there were over 152 million men worldwide who had Erectile Dysfunction and in 2025 the number of men will be approximately 322 million, an increase of nearly 170 million men. Demographical changes, the popularity of newer treatments and greater awareness of sexual dysfunction by patients and society have led to increased diagnosis and associated health care expenditures for the management of this common disorder. The search for a perfect aphrodisiac drug specially a herbal formulation mentioned in Bhaysajya Ratnawali, an Ayurvedic Samhita was prepared, which consist of Aswagandha (*Withenia somnifera* Linn), Vidarikanda (*Pueraria tuberosa* DC) and Shatavari (*Asperagus racemosus* Wild) churna mixed with equal quantity to evaluate the clinical effect in 68 male diagnosed pateints of klaibya (Group A) and Placebo was given to 32 male diagnosed patients of Klaibya (Group B). Total 100 patients Klaibya completed the full course both Group A & Group B. The result of this herbal formulation showed statistically significant improvement in sexual symptoms (by IIEF Questionnaires) and hormonal parameters in randomized double blind placebo control study.

KEYWORDS : Klaibya, Erectile Dysfunction, IIEF Questionnaires.

INTRODUCTION:

The well-known and ancient authoritative text of Indian erotic literature Kama Sutra considers Kama (love and sex) as an art. Sexuality has fascinated the people in all walks of life from ancient times to present. This literature deals with all the aspects of love and sex, with its personal, social, cultural and medical importance. It has been mentioned about 64 art forms of sex. In Kama Sutra, Acharya Vatsayana has given more importance to fore play, before actual sexual intercourse.

Male sexual dysfunction affects 10-25% of middle-aged and elderly men. It is estimated that in 1995 there were over 152 million men worldwide who had erectile Dysfunction and in 2025 the number of men will be approximately 322 million, an increase of nearly 170 million men. Demographical changes, the popularity of newer treatments and greater awareness of sexual dysfunction by patients and society have led to increased diagnosis and associated health care expenditures for the management of this common disorder.

The common cause which prevents man from enjoying the act of sexual interplay with his female partner is referred to as "Klaibya". A male suffering from Klaibya is unable to maintain the sufficient rigid erection during the lovemaking process required for pleasure or fertilization therefore Klaibya is creating problems to males directly and indirectly to female. The sign and symptoms of Klaibya is most nearer with impotence or erectile dysfunction and Chakrapani Dutta also narrates that "*klabyam iti dhawjaanusrya*" it means erectile dysfunction. It is very humiliating for a person to find himself ineffective before his female partner while performing sexual

intercourse, since on the other part the female partner expects the male partner to give her immense sexual pleasure and gratification during the full period of sex. Klaibya can be temporary or permanent and it can be total or partial too. Generally Klaibya considered as a disorder of old age but it can also affect men at any age of puberty. In such cases Ayurveda is very beneficial because Ayurveda has a hidden treasure to solve the various sex and infertility related problems of mankind.

After knowing the burning nature with higher incidence of the problem and the limitations of the available medication, the search for an effective, safe and affordable aphrodisiac to manage this troublesome problem.

Erectile dysfunction has been described elaborately along with its management under the name of klaibya in the brihatrayees and Laghutrayees as well. Apart from which several effective preparation have been prescribed in Vajikarana chapter to improve the sexual health.

In Ayurveda practice, Aswagandha, Shatavari and Vidarikanda finds a place in the treatment of klaibya, as an aphrodisiac herb. It is emphasized for the treatment of disorders such as Klaibya (Male sexual Dysfunction), Shukrkshaya (semen loss) and Napumsakata (Impotency). The Vrishya, Rasayana, Balya, Sukrala magical effect of Aswagandha, Shatavari and Vidarikanda are also well documented in the treatises of Ayurveda.

Research on these ingredients to support the classical

literature have also shown excellent results, Based on these references, the herbal compound containing Aswagandha, Shatavari and Vidarikanda, which was coded as AVS Vajikaran.

CLINICAL STUDY

- Consultation of both the patient and his sexual partner are very much essential regarding sexual history. Life style factors such as sexual orientation, the patient's distress from ED, performance anxiety and details of sexual techniques should be addressed.
- Erectile dysfunctions have been described elaborately along with its management

AIM

- To evaluate the efficacy of "AVS Vajikarna" in the management of Klaibya (Male sexual dysfunction)

OBJECTIVES

- The objective of this study was to establish and reassess the effect of "AVS Vajikaran"

MATERIAL & METHOD

Selection of the patient

For the present study, 100 patients fulfilling the clinical criteria for diagnosis of Klaibya (Male sexual dysfunction) were selected from the Kayachikitsa O.P.D, Govt. Ayurvedic College and hospital, Jalukbari, Guwahati irrespective of religion, cast, occupation etc. the study was conducted after getting the approval from Institutional ethical committee

Type of study:

Randomized double blind placebo control study

Inclusion Criteria:

- Patients having a marked reduction in sexual function over past 4 weeks.
- Unable to consummate the sexual act due to lack of erection or lack of rigidity.
- Patients are more than 21 years and less than 55 years of age.

Exclusion criteria

1. Patients are less than 21 years and above 55 years of age.
2. Patients who have suffering from other systematic diseases such as
 - Cardiac disease
 - Hypertension
 - Hypothyroidism
 - Syphilis
 - Gonorrhoea
 - Inflammatory disease of genitalia
 - Spinal cord injury
 - Pelvic trauma
 - Diabetes Mellitus
 - STD
 - Carcinoma
 - Phimosi
 - Hydrocele
 - Congenital abnormality of genital organs

Criteria for assessment

The assessment of the patients was done based on subjective as well as objective criteria as mentioned below during the course of trial treatment in two follow-up. The final assessment was done on the basis of the both parameters and by comparing the laboratorial investigation before and after treatment.

Subjective Criteria

- Relief in the subjective parameters of erectile dysfunction

mainly

- Relief in the subjective parameters as per International index of erectile function (IIEF) questionnaire
- Relief in the subjective parameters of associated Sexual dysfunctions and the other symptoms were also considered, to support the main finding and to assess the total effect of the therapy

Objective criteria

- The special scoring system for sexual parameters in male, with some changes was adopted for the statistical analysis of the overall effect of the therapy on different sexual parameters. The assessment was made at the start of the trial, during follow up and at the end of the trial (4 weeks).

Investigations

- Routine hematological investigation : Haemoglobin (Hb), Total Leukocyte count (TLC), Different leukocyte count (DLC), Erythrocyte sedimentation Rate (ESR).
- Biochemical investigation : Fasting blood sugar (FBS), PPBS, Lipid profile, Blood urea, Sr. creatinine
- Bio markers : serum testosterone
- The study was cleared by the institutional Ethics Committee. 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. A detailed proforma was prepared incorporating Ayurvedic as well as modern points.
- A total of 100 patients were registered in the present study where Group A (Trial group) having 68 no patients and Group B (Placebo) having 32 no. of patients.). Total 100 patients completed the research course. The investigation were carried out before the treatment to exclude any organic pathology and to assess the general condition of the patient. If any abnormalities were found in the investigation reports, those patients were found in the investigation reports, those patients were excluded from this study.

Concept of management

- The selected patients recruited into clinical trial were given AVS Vajikaran

(Aswagandha-Vidarikanda-ShatavariChurna), in the dose of 3 gm twice daily with milk after meal for a period of 4 weeks with 3 follow ups of 1 week interval

Table 1: Effect of AVS Vajikaran on Penile Erection (Erectile Function, IIEF Questionaries' 1,2,3,4,5 & 15) of 100 patients

GROUP	MEAN X		SD (+-)		SE (+-)	Z	P	Remark
	BT	AT	BT	AT				
Group A	8.82	20.14	2.61	3.26	.506	-22.37	< .00001	Highly Significant
Group B	9.56	10.22	2.16	1.99	.656	-1.00	> .01	Not Significant

Comment : The oral administration of AVS Vajikaran with lukewarm milk in Group A provided improvement in Penile Erection within 60 days which was statistically significant at p <.00001 .where Group B placebo group found to be no improvement which was statistically not significant

Table 2: Showing the Comparative Effect on Penile Erection

MEAN A	MEAN B	SEM A	SEM B	Unpaired t	P
20.14	10.22	.506	.656	11.47	<.0001

The two-tailed p value is less than 0.0001. The observed difference of mean in both groups is considered to be extremely significant. Thus the trial drug used in Group A have more efficacy in improving Penile Erection.

Table 3: Effect of AVS Vajikaran on Penile Rigidity during intercourse (Erectile Function, IIEF Questionaries' 3 & 4) of 100 patients

GROUP	MEAN X		SD(+/-)		SE (+/-)	Z	P	Remark
	BT	AT	BT	AT				
Group A	3.38	6.27	.907	.788	.145	-19.93	<.00001	Highly Significant
Group B	3.37	3.71	0.751	.683	.179	-1.89	>.01	Not Significant

Comment: The oral administration of AVS Vajikaran with lukewarm milk in Group A provided improvement in Penile Rigidity during intercourse within 60 days which was statistically significant at p <.00001 .where Group B placebo group found to be no improvement which was statistically not significant

Table 4: Showing the Comparative Effect on Penile Rigidity during intercourse

MEAN A	MEAN B	SEM A	SEM B	Unpaired t	P
6.27	3.71	.145	.179	10.46	<.0001

The two-tailed p value is less than 0.0001. The observed difference of mean in both groups is considered to be extremely significant. Thus the trial drug used in Group A have more efficacy in improving Penile Rigidity during intercourse.

Table 5: Effect of AVS Vajikaran on Orgasmic Function with Ejaculatory control (IIEF Questionaries 9 & 10) of 100 patients of Klaibya

GROUP	MEAN X		SD(+/-)		SE (+/-)	Z	P	Remark
	BT	AT	BT	AT				
Group A	4.88	6.98	1.77	1.05	.249	-12.61	<.00001	Highly Significant
Group B	4.00	4.56	1.36	1.60	.370	-2.07	> .01	Not Significant

Comment: The oral administration of AVS Vajikaran with lukewarm milk in Group A provided improvement in Orgasmic Function with ejaculatory function during intercourse within 60 days which was statistically significant at p <.00001 .where Group B placebo group found to be no improvement which was statistically not significant

Table 6: Showing the Comparative Effect on Orgasmic Function with Ejaculatory control

MEAN A	MEAN B	SEM A	SEM B	Unpaired t	P
6.98	4.56	.249	.370	10.46	<.0001

The two-tailed p value is less than 0.0001. The observed difference of mean in both groups is considered to be extremely significant. Thus the trial drug used in Group A have more efficacy in improving Orgasmic Function with Ejaculatory control.

Table 7: Effect of AVS Vajikaran on Sexual Desire (IIEF Questionaries 9 & 10) of 100 patients of Klaibya

GROUP	MEAN X		SD(+/-)		SE (+/-)	Z	P	Remark
	BT	AT	BT	AT				
Group A	4.58	6.80	1.12	1.096	.190	-11.68	<.00001	Highly Significant
Group B	4.5	5.15	1.13	.883	.253	-2.56	<.0105234	Significant

Comment: The oral administration of AVS Vajikaran with lukewarm milk in Group A provided improvement in Sexual Desire within 60 days which was highly statistically significant at p <.00001 .where Group B placebo group also found to be moderate improvement which was statistically significant.

Table 8: Showing the Comparative Effect on Sexual Desire

MEAN A	MEAN B	SEM A	SEM B	Unpaired t	P
6.80	5.15	.190	.253	5.0465	<.0001

The two-tailed p value is less than 0.0001. The observed difference of mean in both groups is considered to be extremely significant. Thus the trial drug used in Group A have more efficacy in improving Sexual Desire than Group B.

Table 9: Effect of AVS Vajikaran on Intercourse Satisfaction (IIEF Questionaries 6,7 & 8) of 100 patients of Klaibya

GROUP	MEAN X		SD(+/-)		SE (+/-)	Z	P	Remark
	BT	AT	BT	AT				
Group A	5.25	8.36	.835	1.19	.176	-17.67	< .00001	Highly Significant
Group B	5.37	5.60	.832	.863	.211	1.09	.137857 P < .01	Significant

Comment: The oral administration of AVS Vajikaran with lukewarm milk in Group A provided improvement in Intercourse Satisfaction within 60 days which was statistically significant at p <.00001 .where Group B placebo group found to be no improvement which was statistically not significant

Table 10: Showing the Comparative Effect on Intercourse Satisfaction

MEAN A	MEAN B	SEM A	SEM B	Unpaired t	P
8.36	5.60	.176	.211	5.0465	<.0001

The two-tailed p value is less than 0.0001. The observed difference of mean in both groups is considered to be extremely significant. Thus the trial drug used in Group A have more efficacy in improving Intercourse Satisfaction than Group B.

Table 11: Effect of AVS Vajikaran on Serum Free testosterone level in blood of 31 patients of Klaibya

GROUP	MEAN X		SD(+/-)		SE (+/-)	Z	P	Remark
	BT	AT	BT	AT				
Group A	3.39	4.38	1.03	.645	.218	-4.54	<.00001	Significant
Group B	-	-	-	-	-	-	-	

Comment: The oral administration of AVS Vajikaran with lukewarm milk in Group A provided improvement on Sr. Free Testosterone Level in 60 days which was highly statistically significant at p <.00001.

Table 12: Effect of AVS Vajikaran on Overall Satisfaction (Confidence Level) (IIEF Questionaries 9 & 10) of 100 patients of Klaibya

GROUP	MEAN X		SD(+/-)		SE (+/-)	Z	P	Remark
	BT	AT	BT	AT				
Group A	3.41	6.02	.980	1.51	.218	-11.97	< .00001	Significant
Group B	2.81	3.15	.859	1.01	.234	-1.45	.073529	

Comment: The oral administration of AVS Vajikaran with lukewarm milk in Group A provided improvement in Intercourse Satisfaction within 60 days which was statistically significant at p <.00001 .where Group B placebo group found to be no improvement which was statistically not significant.

Table 13: Showing the Comparative Effect on Overall Satisfaction (Confidence Level)

MEAN A	MEAN B	SEM A	SEM B	Unpaired t	P
6.02	3.15	.176	.211	5.0465	<.0001

The two-tailed p value is less than 0.0001. The observed difference of mean in both groups is considered to be extremely significant. Thus the trial drug used in Group A have more efficacy in improving Intercourse Satisfaction than

Group B.

DISCUSSION & CONCLUSION:

Erectile dysfunction (ED) is not considered normal part of the ageing process. Nonetheless, it is associated with certain physiologic and psychological changes related to age.

The main ingredients of my drug are namely Aswagandha, Vidarikanda, Shatavari which having Madhur, Snigdha and sheet quality and the Guna of Sukra is also homologues with the drugs on the basis of qualitative aspect.

Without clinical trial to human subject the study of a theory or a medicine is incomplete and impracticable. On my research work AVS Vajikaran was selected as a trial drug in the management of Klaihya. By virtue of its vrisya quality.

A series of 100 patient of Klaihya were selected for the present clinical study from the clinics of Kayachikitsa department O.P.D. and causality department; Govt. Ayurvedic College and hospital, Guwahati 14 fulfilling the inclusion criteria. After diagnose of the patient, AVS vajikaran was prescribed in a dose of 3gm twice daily, morning and evening with lukewarm milk for a period of 4 weeks. They are advised to come after 7 days of interval for the assessment of the therapeutic response.

In my present study, the maximum no. of Klaihya is seen in the age group of 21-30 years i.e. 36% followed 30-40 years is 34%, 40-50 (22%) respectively. It may be due to unhealthy lifestyle, stress.

In my research study, it has seen that the incidence of Klaihya are more prevalent in people doing private service which is 35% the Business which is 31% followed by service and farming. This is probably due to the occupational stress full condition.

In my study, it has seen that the maximum patients were married 64% where as 21% people are divorced due to Erectile dysfunction and 15% unmarried but they are having the regular sex partner. According to WHO Erectile dysfunction can be diagnosed only when problem persist minimum for three months. Secondly married person can express their problem on the basis of sexual experience with their life partners.

People having addicted towards the smoking, alcohol, tobacco, betel nut etc. are more sufferer in this disease, People having abnormal sleep are found more prone to develop Klaihya, may be due to imbalance of vatadi doshas which help for the manifestation of the disease. Present study reveals that maximum patient having the sedentary lifestyle i.e. 62%. This comes under Manas Klaihya. Present study reveals maximum patients have habit of premarital sex. 64 in no. (64%). Perhaps this type of habit produce a guilty feeling which augmenting impotence as psychological factor.

Possible mode of Action of the drugs:

- The ingredients of my trial drugs are Aswagandha, Vidarikanda and Shatavari. They possess the quality of Madhur, Snigdha and Sheeta, (Aswagandha- Ushna) which is similar to that of Sukra.
- Vidarikanda which having madhura, shita, guru, snigdha is mentioned as vrisya and various therapeutic formulation mentioned in Bhaisya Ratnawali.
- Aswagandha having madhura, tikta katu rasa and ushna virya as mentioned as a Vajikaran, mastisklasamak, vlyya, brimhan, rasayan is very much effective in erectile dysfunction due to stress factor, because stress is the main culprit of erectile dysfunction.
- Shatavari having madhura tikta rasa, shita virya, guru,

snigdha guna which increases sukra dhatu and mentioned as blyya, rasayan and Vrisya, Sukrala and also used in mastiska durvlyya. And it is very much effective in increase of serum testosterone level in male sexual dysfunction patient.

- The therapies are effective in sexual parameter that is erection, desire, satisfaction ejaculation etc.

It has seen probably due to the increase of jalamahabhoot

which is the main constituent of both sukra and qualities of ingredients of the drug i.e. Madhur, Snigdha and Sheeta. On the other hand we can say that Pancha Mahabhoot are produced from the panchatanmatra; Sabda; Sparsha, Roop. Rae and gandha which are under bisistha guna. The Mahabhoot which are formed from the tanmatras are so to speak equal to the qualities in its primordial state though they bear some micro substratum. Gradually from this only later on when it takes the shape of gross form it becomes substratum or substance harboring qualities. The Panchamahabhoot are the basic element of all dravyas.

My drug increases the quality of sukra and thereby simultaneously responsible for the increment of panchamahabhoot and as a result quantities of sukra are increased and Aswagandha and Shatavari having mastiskasamak guna which is very much important in psychological changes Erectile dysfunction.

At last we can say that the Sexual potency was increased by AVS Vajikaran by physiological and psychological changes. The selected formulation counteracts the aggravated Vata in Erectile Dysfunction, clears the sukrawahaSrotadusti and improves sexual arousal and it is also very useful in psychogenic erectile dysfunction and thus can be used as a good remedy in treating the disease.

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