

A CLINICAL STUDY ON THE ROLE OF GOKSHURADI YOGA IN THE MANAGEMENT OF KLAIBYA (ERECTILE DYSFUNCTION)

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Abstract: The rich heritage of Indian culture considered 'kâma' as one among the purushârthas, the objectives of life. The concept of 'kâma' reveals that the recreational aspects like enjoyment of pleasure is equally important to its procreational aspects. An apparent disparity between the subjective sense of pleasure and objective performance was always present. The present media culture additionally impacts unsatisfied inquisitiveness lead them to various misconceptions and sexual dysfunctions. The male sexual dysfunction includes all sort of disturbances of coital performance and sexual congress in male. Among the various phases of sexual response the most essential is the achieving of normal erection with sufficient rigidity for penetrative intercourse, the absence of which ends into failure and dissatisfaction. This condition has been elaborately described as 'Klaibya' in Ayurvedic classics and 'Erectile dysfunction' in modern texts. The disease klaibya is a multifactorial condition, mainly involving Bahu Dosavasthaas a whole and Sukraksaya in specific, Mano Dosa, and Sukravaha Sroto Dusti. Considering the grave nature of the disease though it does not reduce the life expectancy, it has been selected for the present study to find out a better cure. *Materials and Methods:* 30 diagnosed patients of, aged between 20 – 50 years attending Opd of N.I.A Jaipur, 30 patients of, aged between 20 – 50 years, fulfilling the clinical criteria for diagnosis of Klaibya (Erectile dysfunction) were randomly selected irrespective of their caste, and religion from the OPD & IPD of Maulik Siddhant department of National Institute of Ayurveda Jaipur. were randomly selected and assigned into two groups. In Group A Gokshuradi yoga in the dose of 5gm/twice daily with water, for 45 days. and in Group B – Patients of this group received placebo capsule containing soybean powder (500 mg) in the dose of 2 capsule /twice daily with water, for 45 days. Follow up was done for 2 month. Assessment done on the basis of self scoring symptoms / subjective and objective parameters of Klaibya (Erectile Dysfunction). The study clearly showed that there is an improvement in both group with added effect in group A Patients of Klaibya (Erectile Dysfunction)

Keywords: Purushârthas, 'Klaibya', Erectile Dysfunction, Bahu Dosavasthaas.

Introduction

The disease klaibya is a multifactorial condition, mainly involving Bahu Dosavasthaas a whole and Sukraksaya in specific, Mano Dosa, and Sukravaha Sroto Dusti. It is commonly observed in the society, owing to the feeling of inadequacy less commonly reported, even than Master and Johnson reported a fear of impotence in all men above 40 years. Considering the grave nature of the disease though it does not reduce the life expectancy, it has been selected for the present study to find out a better cure.

Vajikarana has been described specially to improve the sexual health to enhance the status of Sukra and to please the mind. The amount of sexual dysfunction prevalent in the society is difficult to estimate if not impossible. About half of the married couples experience sexual difficulties in one or the other way at various stages of their married life (MC carthy *et al.* says that, The percentage of all men treated for sexual disorders who have impotence (erectile dysfunction) as the chief complaint ranges from 35 to 50 percent.

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According to Acharya Charak Klaibya is defined as inability to perform sexual act¹ and in sutra sthana 28th chapter, he says klaibya means lack of penile erection.² According to Acharya Dalhana, klaibya means impotent,³ According to Acharya Vagbhata, it means inability to perform sexual intercourse with female partner,⁴ According to Astanga Sangraha, it means lack of penile rigidity,⁵ and According to Yoga Ratnakara, it means incapability of a person to perform sexual act and its form is Klaibya.^{6,7}

Aim and objects

(1) To study the patients of male sexual dysfunction in general and the erectile dysfunction in particular from Ayurvedic point of view and its correlation with various types of Klaibya.

(2) To study the efficacy of the gokshuradi yoga administered orally in the management of Klaibya.

(4) To compare the effects of gokshuradi yoga With Placebo Drug.

Materials and methods

For the present study, 30 patients fulfilling the clinical criteria for diagnosis of Klaibya (Erectile dysfunction) were randomly selected irrespective of their caste, and religion from the OPD & IPD of Maulik Siddhant department of National Institute of Ayurveda Jaipur.

Plan of the study:

1. Patients were selected randomly. It is a comparative study with Pre-test – post-test design.
2. The selected patients were assigned into 2 groups, each consisting of 15 patients.
3. Group A: Patients received test drug in the dose of 5 gm/twice daily with water, for 45 days.
4. Group B: Patients of this group received placebo capsule containing soybean powder (500 mg) in the dose of 2 capsule /twice daily with water, for 45 days.

Inclusion criteria

The following was the main clinical criteria for the selection of the patients:-

- 1) All Married men (age 20-50 years)
- 2) Incapability to perform sexual act.
- 3) Premature Ejaculation
- 4) Flaccidity of the penis even after psychic or physical stimulation

Exclusion criteria

Patients suffering from mental retardation, Unmarried persons (more than 50 years of age), congenital anomalies, infectious diseases of brain, vascular causes, toxic causes, metabolic causes of seizures were excluded from the study.

Assessment criteria

Subjective criteria

1. Sexual desire,
2. Breathlessness during coitus,
3. Excessive perspiration during coitus,
4. Premature ejaculation,
5. Erectile dysfunction,
6. Pain during ejaculation.

Objective criteria

Investigations

Routine haematological Biochemical and urine investigations like Hb, Tc, Dc,ESR, Random Blood Sugar and Serum Cholesterol were carried to rule out other pathologies before starting the treatment, and after the completion of treatment to assess the overall effect of the therapy.

Semen examinations

To see the effect of the drug on the seminal parameters, the semen examination was done. The samples were collected by masturbation.

The semen analysis was carried out by physical, chemical and microscopic examination to assess it qualitatively and quantitatively both, before and after the treatment in the all patients.

Preparation of medicine

The drug Kapikacchu was purified by boiling with milk and then dried and powdered, after that this was mixed with other drugs powder which are taken in equal quantity and prepared 150 gms pack.

Grading of both Subjective criteria and Objective criteria

1. Sexual desire

Sexual desire	Grading		
	Score	B.T	A.T
Normal desire	0		
Lack of desire	1		
Desire only on demand of partner	2		
No desire at all	3		

2. Breathlessness

Breathlessness	Grading		
	Score	B.T	A.T
No Breathlessness	0		
Mild Breathlessness which does not disturb the act	1		
Moderate Breathlessness sometimes disturb the act	2		
Severe Breathlessness which hamper every act	3		

3. Excessive perspiration

Excessive perspiration	Grading		
	Score	B.T	A.T
No perspiration	0		
Mild perspiration	1		
Moderate perspiration	2		
Severe perspiration which disturbs the act	3		

4. Premature Ejaculation

Premature Ejaculation	Grading		
	Score	B.T	A.T
Every time can control ejaculation till both get satisfied	0		
Can control ejaculation till He get satisfaction	1		
Ejaculation before penetration	2		
Ejaculation during foreplay	3		

5. Erectile Dysfunction

Erectile Dysfunction	Grading		
	Score	B.T	A.T
Proper stiffness to maintain erection and to continue the sexual intercourse till last.	0		
Some loss of stiffness but can maintain the erection and continue the act till last	1		
Some loss of stiffness, able to maintain erection, but unable to continue act till last	2		
Total loss of stiffness and unable to initiate the sexual intercourse	3		

6. Pain during ejaculation

Pain during ejaculation	Grading		
	Score	B.T	A.T
No Pain during ejaculation	0		
Occasionally Mild Pain during ejaculation	1		
Usually Moderate Pain during ejaculation	2		
Sever Pain during ejaculation	3		

(A) Volume of semen (in ml)

Volume of semen	Score	B.T	A.T
> 3-0 ml	0		
upto 2&3 ml	1		
upto 1&2 ml	2		
<1 ml	3		
0 ml	4		

(B) Sperm Count Million/ml

Sperm Count	Score	B.T	A.T
>40 million/ml	0		
30&39 million/ml	1		
20&29 million/ml	2		
10&19 million/ml	3		
0&9 million/ml	4		

In the present clinical study Group A was administered with gokshuradi yoga powder with a dosage of 5 gms bd with water, Group B was administered with 2 placebo capsules bd with water.

Review of the different components of the formulations.

Gokshura⁸:- Oral administration of 100 mg/kg of test drug has proven anabolic effect as evidenced by body weight gain in the body and reproductive organs. Improvement in sexual

Drugs of the Gokshuradi Yoga

Sl. No.	Drugs ^[7]	Latin names	Part used
1.	Gokshura	Tribulus terrestris	Fruit
2.	kokilaksha	Asteracanth longifolia	Root
3.	Black gram	Phaseolus mungo	Seed
4.	Kapikacchu	Mucuna prurita	Seed
5.	Shatavari	Asparagus racemosus	Rizome

behavior of male rats was characterized by increased amount and intromission frequency. Penile erection index (PEI) was also considerably enhanced without any noticeable toxicity, and the testosterone level and sperm count also significantly increased, and the results are comparable to that of standard drug, sildenafil citrate. Findings of the present study validate the traditional use of *Tribulus terrestris* for its role in enhancing sexual behavior and potential to be used in the treatment of Erectile Dysfunction (ED).

Kokilaksha^{9,10,12} :- *Asteracantha longifolia* (L.) Nees, Acanthaceae, is a source of the ayurvedic drug, 'Kokilaaksha' and the Unani drug, Talimakhana. The seeds are acrid, bitter, aphrodisiac, tonic, sedative, used for diseases of the blood. The plant is known to possess antitumor, hypoglycemic, aphrodisiac, antibacterial, free radical scavenging and lipid peroxidation, hepatoprotective and haematopoietic activity. It contains lupeol, stigmaterol, butelin, fatty acids, and alkaloids.

Black gram¹¹:- Nutritional Value of Black Gram (vigna mungo, urad, black lentil)

Black gram is black colored bean of a plant. It is nutritious bean commonly cooked for healthy diet.

Nutrition Facts and Information about Black Gram: Black gram is rich in potassium, phosphorus and calcium with good amount of sodium. It also has small amount of iron in it.

Vitamin Content of Black Gram: Black gram is rich in Vitamin A, B1 and B3 and has small amount of thiamine, riboflavin, niacin and Vitamin C in it.

Calorie Content of Black Gram: 100g of Black Gram has 347 calories. Calories from fat are 5.

Health Benefits of Black Gram: Black Gram cures **diabetes, sexual dysfunction, nervous disorders, hair disorders, digestive system disorders and rheumatic afflictions.**

Kapikacchu^{9,10,12} :- A long history of traditional use in Brazil and India as an aphrodisiac. Clinical studies in India have validated that the plant does indeed have aphrodisiac activity. It also has reported with anabolic and growth hormone stimulant properties. The anabolic effect of the seed is due to its ability to increase testosterone. In 2002, a U.S. patent was filed on the use of velvet bean to stimulate the release of growth hormone in humans. Research cited in the patent indicated that the high levels of L-dopa in mucuna seed were converted to dopamine which stimulated the release of growth hormone by the pituitary gland. L-dopa and dopamine are also effective inhibitors of prolactin. Prolactin is a hormone released by the pituitary gland; increased levels are considered to cause erection failure in males. In one study, oral intake of the seeds in 56 human males was able to improve erection, duration of coitus, and post-coital satisfaction after only four weeks of treatment. The seed also has documented fertility promoting and sperm producing effects in human males (being able to improve sperm count and motility).

Discussion

In the present clinical study, after analyzing etiological factors of klaibya it was found that aharaja, viharaja, and manasika factors play a role in the manifestation of this. Quality and quantity of shukra has direct relation with klaibya.

Acharya Charaka considered klaibya as lakshana under shukra kshya but klaibya will manifest both as a disease and a symptom, current parallel science has also supported the same.

Assessment was done on the basis of, sexual desire, breathlessness during coitus,

Observation and Result

Table 1. Assessment of sexual desire in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	11	1.90	0.72	1.18	62.10	0.60	0.18	6.55	<.001	HS
Group B	10	1.80	1.30	0.50	27.77	0.52	0.16	3.125	<.025	S

1 Sexual desire (Table 1)

In group A, out of 15 patients, 11 patients that is 62.10% found relief, statistically it is highly significant ($P < .001$). In group B 10 patients out of 15 patients that is 27.77% found relief, statistically it is significant ($p < .025$).

Table 2. Assessment of Breathlessness during coitus in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	09	1.88	0.66	1.22	64.89	0.65	0.21	5.80	<.001	HS
Group B	11	1.81	1.36	0.45	24.86	0.52	0.15	3.00	<.025	S

2 Breathlessness during coitus (Table 2) &

In group A, out of 15 patients, 9 patients that is 64.89% found relief, statistically it is highly significant ($P < .001$). In group B 11 patients out of 15 patients that is 24.86% found relief, statistically it is significant ($p < .025$).

Table 3. Assessment of Excessive perspiration during coitus in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	13	1.92	0.69	1.23	64.06	0.70	0.19	6.47	<.001	HS
Group B	14	1.92	1.57	0.35	18.22	0.49	0.13	2.69	<.02	S

3 Breathlessness during coitus (Table 3)

In group A, out of 15 patients, 13 patients that is 64.06% found relief, statistically it is highly significant ($P < .001$). In group B 14 patients out of 15 patients that is 18.62% found relief, statistically it is significant ($p < .025$).

Table 4. Assessment of Premature Ejaculation in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	13	2.30	1.23	1.07	46.52	0.90	0.25	4.28	<.01	S
Group B	15	1.86	1.46	0.40	21.50	0.63	0.16	2.44	<.05	S

4 Premature ejaculation (Table 4)

In group A, out of 15 patients, 13 patients that is 46.52% found relief, statistically it is significant ($P < .010$). In group B 14 patients out of 15 patients that is 46.52% found relief, statistically it is significant ($p < .050$).

Table 5. Assessment of Erectile Dysfunction in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	11	2.09	0.72	1.37	65.55	0.16	0.20	6.8	<.001	HS
Group B	12	2.0	1.41	0.59	29.50	0.66	0.19	3.02	<.02	S

5 Erectile dysfunction (Table 5)

In group A, out of 15 patients, 11 patients that is 65.55% found relief, stasticaly it is highly significant (P<.001). In group B 12 patients out of 15 patients that is 18.62% found relief, stasticaly it is significant (p<.025).

Table 6. Assessment of Pain during ejaculation in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	10	1.50	1.0	0.50	33.33	0.52	0.16	3.00	<.02	S
Group B	11	1.54	1.18	0.36	23.37	0.50	0.15	2.39	<.05	S

6 Pain during ejaculation (Table 6)

In group A, out of 15 patients, 10 patients that is 33.33% found relief, stasticaly it is highly significant (P<.001). In group B 11 patients out of 15 patients that is 23.37% found relief, stasticaly it is significant (p<.050).

Table 7. Assessment of Volume of Sperm in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	15	2.57	3.10	-0.53	-20.62	0.55	0.14	3.70	<.01	S
Group B	15	2.90	2.86	0.04	1.37	0.14	0.03	1.103	>.10	IS

7 Volume of the semen (Table 7)

After the treatment all the patients of group A found 20.62% benefit, stasticaly it is significant (P<.010). Were as in group B 1.37% of benefit was found, stasticaly it is non-significant (p<.10).

Table 8. Assessment of Sperm count in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	15	46.33	55.20	-8.86	-19.12	8.44	2.18	4.068	<.01	S
Group B	15	51.33	50.53	0.80	1.55	2.04	0.52	1.517	>.10	IS

8 Sperm count (Table 8)

After the treatment all the patients of group A found 19.12% benefit, stasticaly it is significant (P<.01). Were as in group B 1.55% of benefit was found, stasticaly it is non-significant (p<.10).

Table 9. Assessment of Motility of sperm in both groups

	N	Mean		Dif	% of Change	S.D.	S.E.	t	P	R
		B.T.	A.T.							
Group A	15	51.33	61.66	-10.33	-20.12	10.93	2.82	3.66	<.01	S
Group B	15	52.33	51.66	0.67	1.28	2.85	0.66	1.00	>.10	IS

9 Motility of Sperm (Table 9)

After the treatment all the patients of group A found 20.12% benefit, stasticaly it is significant (P<.01). Were as in group B 1.28% of benefit was found, stasticaly it is non-significant (p<.10).

excessive perspiration during coitus, premature ejaculation, erectile dysfunction, pain during ejaculation.

Probable Mode of action of Gokshuradi yoga

1. Sexual desire

In the present clinical study *Gokshuradi yoga* containing gokshura, black gram, kapikacchu seed, shatavari, etc does nourishment, nourine tonic, increases sexual vigor and increases sexual stamina, along with this satvavajaya treatment will boost the effect.

2. Breathlessness during coitus

As *Gokshuradi yoga* does nourishment of dhatus, vata shaman and increases the strength of the body mind, so it helps in the relieving this symptom.

3. Excessive perspiration during coitus

To combat this symptom along with this *yoga satvavajaya* treatment is beneficial.

4. Premature ejaculation

Due to premature ejaculation dhatu kshaya will be the effect to enrich shukra dhatu *Gokshuradi yoga* is beneficial because combination of drugs having properties like shnigdha guna, seeta veerya etc.

5. Erectile dysfunction

The drugs of the *Gokshuradi yoga* having properties nourishing, neuron tonic, which it helps in the Erectile dysfunction which is leading cause for *klaibya*.

6. Pain during ejaculation

Vitiating of vata dosha due to nidana sevans it manifests in the form of pain during ejaculation. The *Gokshuradi yoga* containing drugs, having properties like guru, snigdha, ushana veerya, madhura rasa helps in pain during ejaculation.

Discussion on tables

Discussion on the symptoms of *klaibya* (which shows statistically highly significant Value)

1) Breathlessness during coitus (Table 2)

— In group A, out of 15 patients, 9 patients that is 64.89 % found relief, statistically it is highly significant ($P < .001$).

In group B 11 patients out of 15 patients that is 24.86% found relief, statistically it is significant ($p < .025$).

2) Breathlessness during coitus (Table 3)

— In group A, out of 15 patients, 13 patients that is 64.06% found relief, statistically it is highly significant ($P < .001$).

In group B 14 patients out of 15 patients that is 18.62% found relief, statistically it is significant ($p < .025$).

3) Erectile dysfunction (Table 5)

— In group A, out of 15 patients, 11 patients that is 65.55% found relief, statistically it is highly significant ($P < .001$).

In group B 12 patients out of 15 patients that is 18.62% found relief, statistically it is significant ($p < .025$).

Discussion on laboratory investigations

1. **Volume of the semen (Table 7)** after the treatment all the patients of group A found 20.62% benefit, statistically it is significant ($P < .010$). Whereas in group B 1.37% of benefit was found, statistically it is non-significant ($p < .10$).

Summary

In the present clinical study entitled “**A Clinical Study on the Role of Gokshuradi Yoga in the Management of Klaibya Roga**”

Description regarding causative factors, symptoms, pathogenesis of *klaibya*, and mode of action of *Gokshuradi yoga* seen.

1. Regarding the principle (siddhant) of the study

The combination of all the drugs in this *Gokshuradi yoga*, nourishes all the 7 dhatus, because of quality of drugs having snigdha, guru, seeta, which are similar to shukra dhatu. Based on the concept samanaguna bhuhista and samanyam ektvakara, this supports the principle of this study.

2. Regarding klaibya

By taking different kind of vata doshakara ahara, vihara, manasika causes, by vyadhi karshana etc causes vitiats vatadi doshas, which intern vitiats agni ,because of this their will be uttarottar dhatu kshaya which leads to klaibya roga.

Conclusion

In the present study patients were divided into two groups, namely group A and group B. Group A :- subjects were administered with gokshuradi yoga. The relief found in the symptoms are as follows, sexual desire (62.10%), breathlessness during coitus(64.89%), excessive perspiration during coitus (64.06%), premature ejaculation (65.55%), erectile dysfunction (46.52%), pain during ejaculation (33.33%). stastically it is significant ($p < .05$).

Group B :- subjects were administered with placebo cap containg soybean powder. The reliefs found in the symptoms are as follows, sexual desire (27.77%), breathlessness during coitus (24.86%), excessive perspiration during coitus (18.62%), premature ejaculation (46.52%), erectile dysfunction (29.50%) and pain during ejaculation (23.37%).

Compairing both Groups the over all 56.99 % improment in group A and were as in group B is 24.17% found

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