

An Open Label Single Arm Clinical Study on Gokshurakadi Churna in the management of Klaibya (Erectile Dysfunction)

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Background: Erectile dysfunction (ED) has been defined as the inability to achieve/ maintain penile erection which leads to unsatisfactory sexual intercourse. Its incidence increases drastically from about 6% in the age group 20-29 years, to 50-70% in the age group 40-79 years. Its incidence has been projected to increase significantly to over 320 million by the year 2025. Erectile dysfunction (ED) affects physical and psychosocial health and has a significant impact on the quality of life of sufferers and their partners and families. Thus, it can be considered that management of ED is of significant importance. Considering the above facts, the present clinical study on the effectiveness of Gokshurakadi Churna Granules in the management of Klaibya (Erectile Dysfunction) was undertaken.


Objectives: To study the effect of Gokshurakadi Churna Granules with milk in subjects diagnosed with Klaibya (Erectile dysfunction).

Methodology: Among the 22 registered patients, 20 of them completed the course of the treatment. They were administered with Gokshurakadi Churna Granules 6gms BD morning and night after food with milk for a period of 30 days. Subjective parameter was analysed using paired sample t test.

Result: There was statistically significant improvement in subjective parameter of Klaibya (Erectile Dysfunction) (P <0.05).

Conclusion: Gokshurakadi Churna Granules is effective in the management of Klaibya.

Keywords: Erectile Dysfunction, Klaibya, Gokshurakadi Churna Granules

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Introduction

Important pillars of healthy life are *Ahara*, *Nidra* and *Abramcharya*.^[1] Sexual health and functions are important determinants of quality of life. Sexual disorders affect physical and psychosocial health and may have a significant impact on the quality of life of sufferers and their partners. Erectile dysfunction (ED) is a common medical problem affecting approximately 15% of men each year.^[2]

Incidence increases drastically from about 6% in the age group 20-29 years, to 50-70% in the age group 40-79 years. Its incidence has been projected to increase significantly to over 320 million by the year 2025.^[3] A study in southern Indian rural population showed 21.15% of the male subjects were diagnosed to have one or more sexual disorder and in that prevalence of erectile dysfunction was found to be 15.77%.^[4]

Although lifestyle modifications and psychotherapy are considered as the first-line of treatment in ED, pharmacotherapy along with psychotherapy gives better results. Thus, medical management of ED is of significant importance. *Ayurveda* recommends the usage of drugs with *Vrushya* property in the management of *Klaibya* (ED).

Gokshurakadi Churna^[5] is one such *Vrushya* Yoga with *Madhura*, *Snigdha*, *Jeevaniya*, *Brihmana* and *Manoharshana* properties. *Gokshurakadi Churna* was made into granules form for better palatability. The subjects of *Klaibya* is said to regain the capacity of indulging in the sexual activity by administration of this *Yoga*. Hence *Gokshurakadi Churna* was selected for the study.

Materials and Methods

Method of collection of data: Data was collected using specially prepared case report form.

Screening of the patient: A screening form was prepared with all the aspects of history, signs, and symptoms of *Klaibya* (Erectile Dysfunction)

Diagnostic Criteria: Among Screened Subjects, *Klaibya* was diagnosed based on the *Lakshana's* such as *Linga Shaitilya* (flaccidity of penis), *Mogasankalpachesta* (futile sexual activity), *Mlana Shishna* (lack of erection due to loss of rigidity).^[6] Erectile dysfunction diagnosed as per International Index of Erectile Dysfunction (IIEF).^[7]

Inclusion Criteria

1. Minimum 3 months history of erectile dysfunction who are in a stable, monogamous relationship with a female partner.
2. Age-21 to 60 years.
3. Fairly good glycaemic condition HbA1C < 8%
4. Those subjects ready to participate and follow the instruction and sign the informed consent form

Exclusion Criteria

Subjects with,

1. Any systemic disease with impaired cardiac, hepatic and renal functions that may interfere with the course of treatment.
2. Significant anatomical penile deformity requiring surgical correction.
3. Failure to achieve erection after radical prostatectomy or pelvic surgery.
4. Penile Implants.

Sampling Technique: Convenient Sampling

Sample size: 20

Statistical Method: Paired Sample T test is used to analyze the significance of change in Scale data

Ethical clearance and CTRI registration: The ethics clearance certificate from the Institutional Ethics Committee of Sri Dharmasthala Manjunatheshwara College of *Ayurveda* and Hospital, Hassan was obtained, with, **IEC No: SDM/IEC/43/2022**. Trial was registered on Indian clinical trial registry, **CTRI/2023/07/055562**.

Study design: Open label single arm prospective clinical study with pre and post-test design, from outpatient department of a tertiary *Ayurveda* hospital attached to *Ayurveda* medical college located in district headquarters in Southern India.

Intervention

Dose: 6 gms twice daily (Morning and night), After food

Route of administration: Oral

Anupana: Warm Milk (100ml)

Duration: 30 days

Source of medicine and authentication: Raw drug was procured from the vendor and authenticated at *Dravya Guna* department at Sri Dharmasthala Manjunatheshwara College of *Ayurveda* and Hospital, Hassan.

Gokshurakadi Churna Granules

SN	Name of the drug	Botanical Name	Part used	Proportions
1.	Gokshuraka	Tribulus terrestris Linn.	Fruit	1 Part
2.	Ikshuraka	Asteracantha longifolia Linn.	Seed	1 Part
3.	Sathavari	Asparagus racemosus Linn.	Root	1 Part
4.	Kapikacchu	Mucuna pruriens Linn.	Seed	1 Part
5.	Nagabala Mula	Sida veronicaefolia Linn.	Root	1 Part
6.	Atibala mula	Abutilon indicum Linn.	Root	1 Part
7.	Sarkara			2 Parts
8.	Go-Grita			Q.S

Assessment Criteria

Study parameters include International Index of Erectile Dysfunction Questionnaire (IIEF-15) with domains Erectile Function, Orgasmic Function, Sexual Desire, Intercourse Satisfaction.

Overall Satisfaction were assessed giving suitable scoring at three intervals namely 1st, 15th and 30th day of treatment.

Table 1: International Index of Erectile Dysfunction (IIEF-15)

Q. no.	Questionaries	Response
Q1	How often were you able to get an erection during sexual activity?	0 No sexual activity 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
Q2	When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	0 No sexual activity 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
Q3	When you attempted intercourse, how often were you able to penetrate (enter) your partner?	0 No sexual activity 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
Q4	During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	0 No sexual activity 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
Q5	During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	0 Did not attempt intercourse 1 Extremely difficult 2 Very difficult 3 Difficult 4 Slightly difficult 5 Not difficult
Q6	How many times have you attempted sexual intercourse?	0 No attempts 1 One to two attempts 2 Three to four attempts 3 Five to six attempts 4 Seven to ten attempts 5 Eleven or more attempts
Q7	When you attempted sexual intercourse, how often was it satisfactory for you?	0 Did not attempt intercourse 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
Q8	How much have you enjoyed sexual intercourse?	0 No intercourse 1 No enjoyment at all 2 Not very enjoyable 3 Fairly enjoyable 4 Highly enjoyable 5 Very highly enjoyable

Q. no.	Questionaries	Response
Q9	When you had sexual stimulation or intercourse, how often did you ejaculate?	0 No sexual stimulation or intercourse 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always

Observations

Table 2: Demographic profile of 22 patients of *Klaibya* (Erectile Dysfunction)

Age group	Frequency	Percent
21-25	1	4.5
26-30	5	22.7
31-35	5	22.7
36-40	3	13.6
41-45	4	18.2
46-50	2	9.1
51-55	2	9.1
Total	22	100.0

Table 3: Distribution of subjects based on symptom Lingashaitilya and Mogasankalpachesta

Lingashaitilya and Mogasankalpachesta	Frequency	Percent
Present	22	100.0

Table 4: Distribution of subjects based on symptom Mlanashishna

Mlanashishna	Frequency	Percent
Absent	15	68.2
Present	7	31.8
Total	22	100.0

Results

Table 5: Paired Samples T test for Erectile function

		Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Pair 1	Erectile Function BT - Erectile Function D15	.500	.513	.115	.260	.740	4.359	19	< 0.05	S
Pair 2	Erectile Function D15 - Erectile Function AT	.500	.513	.115	.260	.740	4.359	19	< 0.05	S
Pair 3	Erectile Function BT - Erectile Function AT	1.000	.562	.126	.737	1.263	7.958	19	< 0.05	S

Table 6: Paired Samples T test for Orgasmic Function

		Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Pair 1	Orgasmic Function BT - Orgasmic Function D15	-.250	.444	.099	-.458	-.042	-2.517	19	< 0.05	S
Pair 2	Orgasmic Function D15 - Orgasmic Function AT	-.200	.523	.117	-.445	.045	-1.710	19	< 0.05	S
Pair 3	Orgasmic Function BT - Orgasmic Function AT	-.450	.605	.135	-.733	-.167	-3.327	19	< 0.05	S

Table 7: Paired Samples T test for Sexual Desire

		Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Pair 1	Sexual Desire BT - Sexual Desire D15	-.400	.598	.134	-.680	-.120	-2.990	19	< 0.05	S
Pair 2	Sexual Desire D15 - Sexual Total AT	-.350	.671	.150	-.664	-.036	-2.333	19	< 0.05	S
Pair 3	Sexual Desire BT - Sexual Desire AT	-.750	.786	.176	-1.118	-.382	-4.265	19	< 0.05	S

Table 8: Paired Samples T test for Intercourse Satisfaction

		Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Pair 1	Intercourse Satisfaction BT - Intercourse Satisfaction D15	-1.550	1.191	.266	-2.107	-.993	-5.820	19	< 0.05	S
Pair 2	Intercourse Satisfaction D15 - Intercourse Satisfaction AT	-.900	1.021	.228	-1.378	-.422	-3.943	19	< 0.05	S
Pair 3	Intercourse Satisfaction BT - Intercourse Satisfaction AT	-2.450	1.099	.246	-2.964	-1.936	-9.969	19	< 0.05	S

Table 9: Paired Samples T test for Overall Satisfaction

		Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Pair 1	Overall Satisfaction BT - Overall Satisfaction D15	-.250	.550	.123	-.507	.007	-2.032	19	< 0.05	S
Pair 2	Overall Satisfaction D15 - Overall Satisfaction AT	-.450	.759	.170	-.805	-.095	-2.651	19	< 0.05	S
Pair 3	Overall Satisfaction BT - Overall Satisfaction AT	-.700	.923	.206	-1.132	-.268	-3.390	19	< 0.05	S

Discussion

The paired samples t-tests evaluate changes in various sexual health domains across baseline (BT), day 15 (D15), and after treatment (AT). Significant improvements were observed in **Erectile function**, with mean differences of **0.500** (BT to D15, D15 to AT) and **1.000** (BT to AT), demonstrating the treatment's efficacy in addressing the issues ($p < 0.05$).

In **Orgasmic function** showed improvement. The improvements were statistically significant across all pairs, with a cumulative mean difference of **0.450** (BT to AT, $p < 0.05$). Similarly, **Sexual desire** experienced a significant improvement (**0.750**, BT to AT), similar improvement was noted from D15 to AT.

The most substantial reductions occurred in **Intercourse satisfaction** (**-2.450**, BT to AT), indicating persistent dissatisfaction despite physiological improvements. This may reflect psychological or relational challenges. **Overall satisfaction** demonstrated modest changes, with early-phase results not significant (BT to D15), but later improvements (D15 to AT and BT to AT) were significant, with a total reduction of **-0.700**.

Probable effect of Gokshuradi Churna Granules on *Klaibya*

The trial drug has shown significant improvement in patients with *Klaibya*. Its probable mode of action can be attributed to its *Madhura Rasa*, *Guru* and *Snigdha Guna*, *Madhura Vipaka*, and *Sheeta Veerya*. According to classical texts, *Acharya Charaka* highlights *Guru* and *Snigdha Guna* as key characteristics of *Vrishya Dravya*'s. These properties are similar to those of *Shukra*. The drug effectively addresses sexual dysfunction by alleviating *Vata Dosha* - the root cause of *Klaibya* - through its *Guru* and *Snigdha Guna*. Furthermore, due to its *Vrishya*, *Balya*, *Brimhana*, and *Vajikara*, *Manoharsana* properties, the formulation strengthens and improves erectile function.

Role of Gokshurakadi Churna Granules on Erectile Function

Steroidal saponins, such as protodioscin, furostanol, neotigogenin, tigogenin, gitogenin, neogitogenin and diosgenin, are considered to be the main active component of *T. Terrestris*. The saponins fraction has positive influence on testosterone production and improves libido and erectile function.[8] *T. terrestris* was shown to support hormonal function via the conversion of protodioscine to dehydroepiandrosterone (DEHA), which is the base molecule for the synthesis of testosterone.[9] Furthermore, diosgenin exerts a well-known protective effect on micro-circulation, and therefore, chronically using *Tribulus* could improve erectile function[10] *Mucuna pruriens*, has a long history of use in traditional medicine. Its seed extract has been extensively studied for the treatment of erectile dysfunction (ED). The ethanolic extract of *M. pruriens* seeds has been found to improve sexual performance in both healthy animal models and in models of diabetes-induced ED. Additionally, the extract has demonstrated effectiveness in protecting and restoring penile tissue from oxidative stress in animal models. There are also reports of *M. pruriens* extract stimulating aphrodisiac activity and potentially reversing spermatogenic loss in infertile men.[9]

There is highly significant result in erectile function. The relation between brain Dopamine and sexual behaviour are also well established. This drug contains L-Dopa, so the effect on Erectile Dysfunction may be due to its above chemical constitution. The drug enhances the blood circulation and produce general wellbeing by toning up the mental and physical functions. This might be the probable reason that there is significant improvement in Erection.[11]

Effect of Gokshurakadi Churna Granules on Sexual Desire, Orgasmic Function, Intercourse Satisfaction & Overall Satisfaction

Sexual desire is controlled by brain systems involved in sexual excitation and inhibition.

Hypoactive sexual desire disorder may result from hypo functional excitation, hyper functional inhibition, or some mix of the two. Brain dopamine systems that link the hypothalamus and limbic system appear to form the core of the excitatory system.

The multi-drug formulation helps to stimulate the activation of hypothalamic dopamine may be effective in stimulating sexual desire in animals and humans. Dopamine is involved in sexual gratification and mood elevation. Thus, it may help the Sexual Desire, Orgasm factor, Intercourse Satisfaction and overall satisfaction.[12]

Ghritha

Ghritha's Madhura Rasa and Madhura Vipaka makes it *Shukravardhaka* and also effective in balancing *Vata*. Its *Guru* and *Snigdha* qualities further promote *Shukra* through the principle of *Gunasamanya*.

As *Ghritha* balances both *Vata* and *Pitta*, it supports the neurological and vascular aspects of erection. Additionally, it plays a key role in the emission and ejaculation phases. Being *Agnideepana* in nature, it stimulates *Agni*, improving metabolism at the levels of *Rasa*, *Rakta*, *Majja*, and *Shukra*. [13]

Ksheera

Ksheera, with its *Madhura* and *Snigdha Guna*, is *Shukrala* and *Vrshya*. It has a direct influence on *Shukradhatu*, increasing its volume through *Dravyasamanya*. Being *Ojasyam* in nature, it boosts *Veerya* and *Bala*.

As a *Dhatuvardhaka*, it enhances both *rasa* and *Shukradhatu* due to its *Saumya bhava*. Its *Vatapittahara* properties helps in neurological and vascular aspects of erection and ejaculation. [14]

Conclusion

Gokshurakadi Churna granules has shown significant improvement with $p < 0.05$ in Erectile function, Orgasmic function, Sexual Desire, Intercourse Satisfaction and Overall satisfaction domains in International Index of Erectile Function in 20 patients of *Klaibya* when given 6 gm twice a day with *Ksheera* (100ml) for a period of 30 days. Thus, Research hypothesis was accepted.

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