Original Article

Clinical evaluation of *Vṛṣya* effect of *Pūga Khaṇḍa* on sexual health and seminal parameters

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ABSTRACT

Background: Due to changes in life-style, the human beings are losing their *Vṛṣyatā* (virility). Bio-medicine hasn't been able to address this challenge. Hence, we see that many people seek the help of herbal medicines to get relief. In view of the above, it becomes necessary to provide potent formulations to address this ailment.

Objectives: The study was designed to evaluate the efficacy of *Pūga Khaṇḍa* on seminal parameters and sexual health.

Materials and Methods: *Pūga Khaṇḍa* has been mentioned as *Vṛṣya* (aphrodisiac) in the 30th chapter of *Bhaiśajyaratnāvalī*. A simple-randomised, single-blinded, placebo-controlled study comparing this *Pūga Khaṇḍa* preparation with a placebo was conducted in 52 patients attending O.P.D. of Department of Rasa Shastra and Bhaishajya Kalpana of Muniyal Institute of Ayurveda Medical Sciences, Manipal. An elaborative case taking Proforma was specially designed for this purpose incorporating all aspects of the disease in the *Ayurvedic* parlance. Both groups received either *Pūga Khaṇḍa* or placebo, in empty stomach in the early morning with water, as per the randomisation plan for a period of 45 days. Patients were followed-upto 4 weeks, 43 patients (84%) had completed the trial and no adverse effects were reported. The assessment was done on the basis of changes in seminal parameters and sexual health parameters.

Results: A varying degree of improvement was observed in sexual parameters viz. duration of coitus ($P<0.001$), frequency of coitus ($P<0.01$), Sexual desire ($P<0.05$), penile erection ($P<0.01$), A significant improvement was seen in duration of coitus ($P< 0.001$) in the group treated by *Pūga Khaṇḍa*.

Conclusion: The trial drug *Pūga Khaṇḍa* was superior to placebo in reducing the mean sign and symptom score of seminal parameters and sexual health.

KEY WORDS: *Klaibya*, *Puga Khanda*, seminal parameters, sexual parameters, *Vrushya*

INTRODUCTION

Today due to changes in life-style, humans are losing *Vṛṣyatā* (virility) i.e., potency physically, mentally, sexually and spiritually. Biomedicine doesn't seem to sufficiently address this problem.

Although it would seem likely that it is somewhat difficult to assess the prevalence of erectile dysfunction (ED), it is claimed to affect as much as 10% of the male population. Above the age of 40, nearly 52% of men are affected. Despite this staggering incidence, few cases come to light.[1]

The prevalence of ED across the world has a great deal of variation around 9-69% with a trend of a clear increase of this disorder at older ages. In all studies, ED has a rather high rate from 20% to 40% for the ages 60-69 years old, some increasing after the age of 65 years.[2]

This requires two kind of therapeutic approaches: one, by administering the aphrodisiac drugs with supplementation of a nutritious diet to regain vigor and virility; second, by offering counselling to dispel mis-conceptions and wrong beliefs about sexual performance.

Here in this clinical study, an attempt has been made to see the efficacy and safety of the orally administered *Pūga*

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Khaṇḍa preparation with that of a placebo in the treatment of patients with *Klaibya* (impotency).

MATERIALS AND METHODS

Study objective

- To evaluate the efficacy of *Pūga Khaṇḍa* clinically on sexual health and seminal parameters
- To ascertain if the administration of *Pūga Khaṇḍa* is associated with any side-effects.

Study design and patient selection

This was a randomised, placebo-controlled and parallel study comparing *Pūga Khaṇḍa* with placebo in married male patients aged between 21 years and 50 years, attending O.P.D of Department of Rasa Shastra and Bhaishajya Kalpana of Muniyal Institute of Ayurveda Medical Sciences., (M.I.A.M.S.) Manipal, irrespective of religion etc. who had presented the clinical symptoms of either infertility (primary/secondary) or sexual dysfunction.

An elaborative case taking proforma was specially designed for the purpose of incorporating all aspects of the disease in the *Ayurvedic* parlance.

Diagnostic criteria

All patients were diagnosed and assessed thoroughly on the basis of *Ayurvedic* classical signs and symptoms of *Klaibya* or *Vandhyātva* with detailed history.

Exclusion criteria

Unmarried patients and patients having heart disease, tuberculosis, sexual transmitted diseases and any organic defect in the penile region, taking treatment for major psychiatric problems etc., were excluded.

Study medication and dosage

All patients were divided into two groups according to the sampling method adopted,

Trial group (Group A)

In this group, 27 selected patients were studied. These patients were given *Pūga Khaṇḍa* in the dose of 6 g/q.d. in empty stomach early morning. Water was given as *Anupāna*.

Placebo group (Group B)

In this group, 25 selected patients were studied. These patients were given Placebo capsules prepared with wheat flour in the dose of 500 mg/2q.d. in empty stomach early morning. Water was given as *Anupāna*.

Irrespective of the group, all patients were subjected to *Mṛdu Śodhana* for 3 days by administering *Triphalā Chūrna* 5g with luke warm water at bed time before the administration of the medicine.

Duration of treatment

To ensure efficacy of the drug the present study advocates a minimum of 45 days medication.

Diet

Patients were kept under normal diet.

Follow-up

To confirm the result and to check for recurrence, patients were followed-up with observation once in 7 days upto 28 days, after the end of the 45 day medication.

Criteria for assessment

The assessment was performed on the basis of changes in seminal parameters and sexual health parameters observed before, during and after treatment. The obtained results were analysed statistically.

Scoring pattern

Improvement in sexual health, i.e., desire, erection, rigidity, ejaculation, orgasm were recorded and graded.[3]

Sexual desire	Score
No desire at all	0
Lack of desire	1
Desire but no activity	2
Desire only on demand of the partner	3
Normal desire	4
Excess desire	5

Erection	Score
No erection by any method	0
Erection with artificial method	1
Erection but unable to penetrate	2
Initial difficulty but able to penetrate	3
Erection with occasional failure	4
Erection when ever desired	5

Rigidity	Score
Unable to maintain erection or unable to continue sexual act	0
Some loss in erection but able to continue sexual act	1
Able to maintain erection and continue sexual act	2

Ejaculation	Score
No ejaculation	0
Delayed ejaculation without orgasm	1
Ejaculation before penetration	2
Penetration but early ejaculation	3
Ejaculation with one's own satisfaction	4
Ejaculation with both one's own and partner's satisfaction	5

Orgasm	Score
No enjoyment at all	0
Lack of enjoyment on most occasions	1
Enjoyment in 25% of sexual encounters	2
Enjoyment in 50% of sexual encounters	3
Enjoyment in 75% of sexual encounters	4
Enjoyment in every act	5

Statistical analysis

The obtained data was analysed statistically and presented as mean ± standard deviation. The data generated during the study was subjected to Mann-Whitney U-test to assess the statistical significance between the two groups.

Ethical clearance

Institutional Ethical Committee of M.I.A.M.S., Manipal approved the design of the study. Written consent was taken from each patient willing to participate before the start of the trial. Patients were free to withdraw their name from the study at any time without giving any reason.

Observations

A total of 51 patients fulfi lling the inclusion criteria were enrolled in the study. A total of 43 patients completed the 45 day study period and 8 patients dropped out prior to completion of the study, 27 patients were registered in Group A, among them 24 patients continued till end of the study and 3 patients discontinued. In group B, a total of 24 patients registered, among them, 19 patients continued till the end of the study and 5 patients discontinued [Figure 1]. The following was the demographic distribution of the patients: 27 patients (52.9%) were between 31 years and 40 years, 15 patients (29.4%) belonged to the age group of 2l-30 years. 9 patients (18%) were belonging to age group of 41-50 year. 25 patients (49%) of patients belonged to Hindu religion, 19 patients (37.2%) belonged to Muslim and 7 patients (14%) were Christians. 25 patients (49%) were labourers. 15 patients (29.5%) had *Vaāta Pitta Prakṭi*, 23 patients (45%) were addicted to smoking, followed by 18

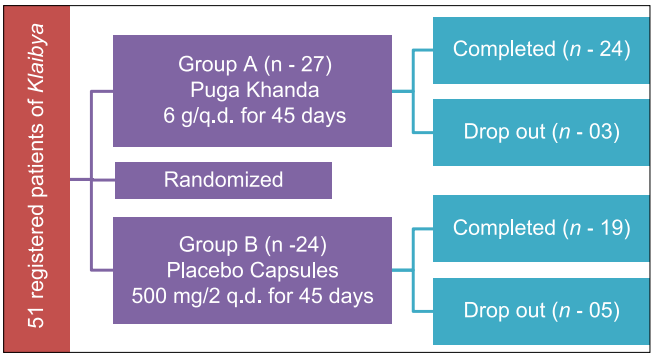

Figure 1: Trial profile of 51 patients of *Klaibya* (impotency)

patients (35%) to alcohol, 13 patients (25%) to pan-masala and 8 patients (15.6%) to tobacco. Sexual life was found unsatisfactory in 65% and satisfactory in 18 patients (35%), while 48 patients (94%) patients had normal scrotal findings and 3 patients (6%) of them had abnormal findings. 44 patients (86%) patients showed normal epididymal findings. 38 patients (74.5%) had the history of masturbation and 41 patients (80%) of reported nocturnal emissions before marriage. Nearly 18 patients (35%) indulged in *Ativyavaya* while 15 patients (30%) had *Īrṣā, Chintaā, Shoka, Bhaya* etc., and 13 patients (25.5%) had the history of taking *Asaātmya, ViruddhaAāhara*. 20 patients (39%) reported lack of erection while 15 patients (30%) patients reported primary infertility and inability to maintain erection.

RESULTS AND DISCUSSION

The present study was aimed to design an effective, safe and affordable alternative treatment of *Klaibya*. The herbal combination *Pūga Khaṇḍa* used in this study showed better improvement in sexual desire, penile erection and penile rigidity in the treated group. Such positive results were not observed in the placebo group [Table 1]. Majority of patients in the study, i.e., 49% were Hindus, which only reflects the higher population of this religion in the specific geographic area. Majority of patients, i.e., 53% were of an age group between 31 years and 40 years. Excessive sex indulgence and stress may be the reasons for this population to seek the help of the physician. About half of the patients were of labour class. More than their physical work, stressful life, life-style changes, lack of education may be the key factors here. Majority of patients were poor, lacked nutrition and led unhygienic life-style, which might have impacted their condition. About 70% of patients had one or the other addiction. Tobacco and alcohol both have adverse effects on the libido of the individual. It could be seen that the majority of patients visited were naturally having an unsatisfactory sexual life

Table 1: Effect of therapy on sexual parameters

Symptoms	*Pūga Khaṇḍa* group (n=24) $\bar{x}$ ±SD	Placebo group (n=19) $\bar{x}$ ±SD	U	*Z*	*P*
Sexual desire	3.50±0.77	2.75±0.64	332	2.5434	<0.05
Penile erection	3.58±0.72	2.87±0.53	339.5	2.726	<0.01
Penile rigidity	1.75±0.45	1.75±0.35	239	0.269014	≥0.05
Ejaculation	4.16±0.52	3.62±0.46	291	1.54	≥0.05
Orgasm	3.16±0.28	2.75±0.35	308.5	1.96869	<0.05
Duration of coitus	8.16±1.02	6.00±0.64	447	5.35582	<0.001
Frequency of coitus	3.00±0.45	2.50±0.64	337.5	2.67791	<0.01

SD=Standard deviation; U=Test statistic; *Z*=Wilcoxon signed-rank; *P*=Probability

and had led < 10 years of married life. Majority of patients were engaged in masturbation and also had nocturnal emissions. Even though these are natural and normal, mis-conceptions related with it might have had adverse effects. Majority of patients had the complaint of lack of erection. In general, this is the reason for which the patient seeks the help of a physician. Effect of therapy of the prepared sample *Pūga Khaṇḍa* was assessed by analysing the effect on sexual parameters and seminal parameters. To confirm the effect to be due to the drug, but not by chance or placebo effect, a control group with placebo administration was also selected. Considering the effect on sexual parameters, we observe statistically significant improvement on sexual desire, penile erection and orgasm in the treated group, where as placebo group did not show such positive results [Table 2].

A significant improvement $P < 0.001$ was seen in duration of coitus in the group treated by *Pūga Khaṇḍa*. This again confirms the positive effect of study drug in comparison with placebo. A significant improvement in the duration of sexual act and frequency of sexual act were other desired positive effects of *Pūga Khaṇḍa* [Table 1].

When we consider the effect on seminal parameters, the data clearly shows the therapeutic efficacy of *Pūga Khaṇḍa*. Significant improvement in seminal volume, total sperm count, rapid linear progressive motility and slow linear progressive motility were observed in the treated group. Mild reductions in the number of immotile sperms were seen in the group of *Pūga Khaṇḍa*. A marginal increase in seminal volume was observed in the treated group and an adverse effect was seen in the placebo group. Another interesting observation is that the viscosity of semen also shows an increase. When the total effect of therapy was analysed all the patients under the treated group had shown at least

Table 2: Effect of therapy on seminal parameters

Symptoms	*Pūga Khaṇḍa* group (n=24) $\bar{x}$ ±SD	Placebo group (n=19) $\bar{x}$ ±SD	U	*Z*	*P*
Semen volume	3.28±0.50	2.60±0.38	384	3.8151	<0.001
Total sperm count	38.50±5.53	37.50±2.96	378	3.66837	<0.001
RLP motility	13.81±1.22	10.25±1.51	446.5	5.3435	<0.001
SLP motility	29.16±6.90	22.62±1.66	456	5.57	<0.001
Non progressive motility	18.41±5.13	23.87±1.03	451	5.453	<0.001
Immotility	39.58±8.82	43.25±1.28	357	3.1548	<0.01
Liquefaction time	26.33±1.44	27.25±1.28	276.5	1.18611	≥0.05
Viscosity	1±0.45	0.625±0	438.5	5.1479	<0.001

SD=Standard deviation; U=Test statistic; Z=Wilcoxon signed-rank; *P*=Probability; RLP=Rapid linear progressive motility; SLP=Slow linear progressive motility

some amount of improvement. In about 58% of patients, moderate to marked improvement was observed. In the placebo group, no improvement was seen. All these observations confirm that *Pūga Khaṇḍa* has certain efficacy on both the sexual and seminal parameters [Table 2]. It also improved psychological and physical health. These effects could be due to the various ingredients present in the formulation.

Over-all effect of therapy

In Group A (*Pūga Khaṇḍa* treated group), majority of the patients, i.e., 41.66% had shown mild to moderate improvement and the remaining 16.66% patients showed marked improvement. In Group B (placebo treated group), no improvement could be seen in the selected parameters, some of the patients have even shown deterioration in their condition.

Probable mode of action of *Pūga Khaṇḍa*

Many researchers have concluded that *Areca catechu* as having aphrodisiac property,[4] anti-aging property,[5] anti-oxidant property,[6] anti-inflammatory, analgesic action.[7] *Pūga* has an alkaloid, arecoline, which has some stimulating action on the central nervous system. *Pūga* has *Kashāya, Madhura Rasa, Guru guṇa, Śīta vīrya, Kaṭu Vipāka* and is *Tridośa Śāmaka*. The ingredients like *Śatāvari (Asparagus racemosus)*[8] *Vidārīkhaṇḍa (Pueraria tuberosa)*,[9] *Godugdha* (cow's milk),[10] *Ghṛta* (ghee),[11] *Gokṣūra (Tribulus terrestris)*[12] *Āmalakī (Emblica officinalis)*,[13] *Śṛṅgāṭaka (Trapa bispinosa)*[14] have both aphrodisiac, immune adjuvant and antioxidant properties. The drugs like *Candana (Santalum album)*,[15] *Jaṭāmāṃsī (Nardostachys jatamamsi)*,[16] *Āmalakī (Emblica officinalis)*[17] have memory

enhancing, anticonvulsant properties in addition. The drugs like *Dālcīni* (*Cinnamonum zeylanica*), *Elā* (*Cinnamonum cardamom*), *Tejapatra* (*Cinnamonum tejpata*) and *Nāgakesara* (*Meusa ferrea*), *Karpūra (Cinnamomum camphora)*, *Lavaṇga (Syzegium aromaticum)*, *Pippalī (Piper longum)* etc., in addition to *Dīpana (appetizer)*, *Pācana (digestive)* properties also have a stimulant effect. This judicious composition along with the consideration of availability prompted us to select the drug.

CONCLUSION

In conclusion, the trial drug *Pūga Khaṇḍa* was superior to placebo in reducing the mean sign and symptom score of seminal parameters and sexual health over 45 days of therapy. The findings have clearly indicated that *Pūga Khaṇḍa* has very good effect as a *Vṛṣya Dravya*, which is confirmed by its action on both sexual health parameters and seminal parameters. Further, there were no clinically significant adverse reactions and the overall acceptance to the treatment was excellent.

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