

EFFICACY OF VIDARIKANDA (PUERARIA TUBEROSE) CHURNA IN KLAIBYA (ERECTILE DYSFUNCTION): A DOUBLE BLIND, PLACEBO CONTROLLED, CLINICAL TRIAL

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ABSTRACT

Introduction: Sexual health and function are important determinants of quality of life. *Klaibya* is mentioned as one among the *shukrapradoshaja vikara* in Ayurveda. This concept is arbitrarily accepted as Erectile Dysfunction (ED). The drugs used to treat ED in Contemporary Medicine have been reported unsuccessful and it has many side effects, there is always a quest for newer drug, in this regard, the *Vidarikanda* (*Pueraria tuberosa*) a well-known ayurvedic Vajikarana drug was selected for the study. **Materials and Methods:** Institutional ethics committee approved protocol was carried out. 31 patients diagnosed as *Klaibya* were randomly recruited in to two groups. Randomization was done using numbered, identical containers. Sexual parameters were considered for the assessment of the treatment.

Drug and placebo were administered at a dose of 6 grams in two divided dose after food, administered orally for a period of 30 days. **Results and Discussion:** Vidarikanda churna showed statistically significant results in parameters such as “sexual desire”, “Erection”, and “Penile rigidity” with P value is 0.038, 0.008, and 0.006 respectively. Patients receiving placebo showed statistically insignificant results on sexual parameters. As Vidarikanda possess madhura rasa, madhura vipaka, guru, snighda guna, the efficacy can be attributed to vrushya, balya, Rasayana karma of Vidarikanda **Conclusion:** *Vidarikanda Churna* used in this study was effective in Erectile Dysfunction.

KEYWORDS: *Klaibya*, Erectile dysfunction, *Vidarikanda churna*.

INTRODUCTION

Sex is the integral part of one's life. It is considered as the basic instinct of all the creatures particularly human beings thereby considered purushartha of life. Procreation is responsibility of every animal and hence primary intention of sexual intercourse is to continue the species. Sex also serves as a bond of love and passion between two partners psychologically, leading to a healthy status of family. Ability to perform the act of sex is compromised in a disease *klaibya vis-a-vis* Erectile Dysfunction (ED). Erectile dysfunction has seen rise in its prevalence worldwide. In the Massachusetts Male Aging Study (MMAS),^[1] a community based survey of men between the ages of 40 and 72, 52% of respondents reported some degree of erectile dysfunction, complete ED in 10% of respondents, moderate in 25% and minimal ED in 17%. In a national and social life survey (NHSL) on samples of men age 18 to 59 years, 19% of men reported being unable to maintain an erection. Incidence was highest among men in the 50 to 59 age group (21%) and among men who were poor (14%), divorced (14%), and less educated (13%). The incidence of ED is also higher among men with certain medical disorders such as diabetes mellitus, heart disease, hypertension and decreased HDL levels. Smoking is a risk factor in the development of ED. Medications used to treat diabetes or cardiovascular diseases are additional risk factors. There is a higher incidence of ED among men who have undergone radiation or surgery for prostate cancer and in those with a lower spinal cord injury; Psychological causes of ED include depression, anger or stress from unemployment or other causes. Further incidence of erectile dysfunction is increasing day by day with the increase in the incidence of diabetes, hypertension, peripheral vascular disorders, peripheral neuropathy, anxiety, stress, depression and their medications. It is also increasing due to the change in the life style and the increased addictions particularly smoking. *Vajikarana* is a branch of Ayurveda which is prescribed to improve sex life. *Vajikara dravyas* are highlighted and praised in the context of *Klaibya* to overcome the aggravated *Vata*. Hence *Vidarikanda*, a *Vajikara dravya* was chosen to evaluate its efficacy in *Klaibya vis-à-vis* Erectile Dysfunction (ED).

MATERIALS AND METHODS

The study was a single center, parallel group, placebo compared clinical trial. The study protocol was approved by the institutional ethics committee. 31 patients fulfilling the diagnostic criteria of *Klaibya* with respect to age, sex and irrespective of caste, religion & socio-economic status approaching the OPD & IPD of Government Ayurveda Medical

College and Hospital, Mysore were selected for the study. They were assigned in to two groups for the interventional study.

Inclusion Criteria

1. Willing male patients between the age group 21 to 50 years.
2. Patients coming under diagnostic criteria.

Exclusion criteria

1. Patients with Psychiatric illness.
2. Patients with Sexually transmitted diseases.
3. Patients with Spinal injury and major pelvic surgeries.
4. Patients having any systemic diseases, which interfere with the course of treatment

Diagnostic Criteria

The presence of any of the following *Klaibya Lakshana*^[2]

Linga shaithilya (Flaccidity of penis), *Mlana shishnata* (lack of rigidity), *Nirbija* (Lack of Ejaculation/Semen), *Moghasankalpa chesta* (Futile sexual activity), *Dhwaja anucchraya* (Loss of erection), *Suratasaktata* (Inability to perform sexual intercourse)
Svinna Gatrata ((Profuse sweating)

Erectile Dysfunction was diagnosed as per F 52.2, ICD-10-CM Guidelines.^[3]

- Inability to attain penile erection.
- Inability to maintain penile erection until completion of the sexual activity.

Assessment Parameters

The parameters are Sexual Desire (SD), Penile Erection(PE), Penile Rigidity(PR), Performance Anxiety(PA), Ejaculation(Ej) and Orgasm(Or). These were graded and assigned a score of 0 to 5. Assessment was done on before treatment (0 day), After Treatment (30th day). Shown in table 1 and 2.

Drug

Vidarikanda churna was procured from Govindaraj Chetty and sons Shop, Devraj Urs Road, Mysore, and Rice powder (placebo drug) was collected from Mohana Bhandar shop, sayyajirao Road, Mysore. Both were identified with the help of Dept. of Dravya Guna, Govt. Ayurveda medical College, Mysuru.

The drug and the placebo were prepared with identical physical appearance (gelatin capsules) and were packaged in identical containers, identifiable only by their numbers.

Statistical analysis

The result of the present study was analyzed statistically using descriptive statistics, chi-square test, and contingency table analysis using SPSS for windows software. After the completion of trial, observation and results it was revealed that Group A patients received trial drug, and Group B patients received placebo. Group A was having 15 patients were given with the *Vidarikanda churna* and Groups B had 16 patients who received the Placebo drug (Rice powder). Dose was 6grams bid with milk as *anupana* for both group.

RESULTS AND DISCUSSION

Sexual Desire

Sexual desire is a motivational state and an interest in “sexual objects or activities, or as a wish, need, or drive to seek out sexual objects or to engage in sexual activities.”^[4]

The therapy with *Vidarikanda churna* provided 73.3% improvement on this parameter and the drug effect was statistically significant. The P value is being 0.038. The placebo Group provided 62.5% improvement on this parameter and the drug effect was statistically not significant.

Erection

An erection (clinically: penile erection or penile tumescence) is a physiological phenomenon in which the penis becomes firmer, engorged and enlarged. *Vidarikanda churna* provided 86.7% improvement on this parameter and the drug effect was statistically significant. The P value is being 0.008. The placebo Group provided 43.3% improvement on this parameter and the drug effect was statistically not significant.

Rigidity

The ability of the erect penis to resist bending or buckling forces applied to its long axis. The greater its resistance, the more effectively the penis can penetrate during intercourse. *Vidarikanda churna* provided 46.7% improvement on this parameter and the drug effect was statistically significant. The P value is being 0.006. The placebo Group provided 37.5% improvement on this parameter and the drug effect was statistically not significant.

Performance Anxiety

It is a state or condition of nervousness or fear which prevents or adversely affects the sexual activity. Vidarikanda churna provided 46.7% improvement on this parameter and the drug effect was statistically not significant. The P value is being 0.069. The placebo Group provided 37.5% improvement on this parameter and the drug effect was statistically insignificant.

Ejaculation

Ejaculation is the discharge of semen (usually carrying sperm) from the male reproductive tract. It is usually the final stage and natural objective of male sexual stimulation, and an essential component of natural conception. Vidarikanda churna provided 46.7% improvement on this parameter and the drug effect was statistically not significant. The P value is being 0.066. The placebo Group provided 25% improvement on this parameter and the drug effect was statistically not significant. The P value is being 0.317. When compared to both Groups, Vidarikanda has better result than placebo.

Orgasm

Orgasm (from Greek orgasmos "excitement, swelling"; is the sudden discharge of accumulated sexual excitement during the sexual response cycle, resulting in rhythmic muscular contractions in the pelvic region characterized by sexual pleasure.^[5] Vidarikanda churna provided 33.3% improvement on this parameter and the drug effect was statistically not significant. The P value is being 0.178. The placebo Group provided 25% improvement on this parameter and the drug effect was statistically not significant. The P value is being 0.477.

Mode of Action of Vidarikanda

Recent chemical analysis of *Vidarikanda* indicates following active constituents are present in *Vidari* plant viz, Beeta-Sitosterol, Stigmasterol, Diadzein, Puerarin, Tuberosin, Steroid saponin (disogenin), Genistein. Traditionally Vidarikanda is used as a reproductive herb. The scientific analysis of reproductive activity analyses is reveals that Diazein, Puerarin, and Genistein present in Vidarikanda interact with androgen receptors and helps in the secretion of Testosterone hormone. Vidarikanda contains Diazein, Puerarin, and Genistein which acts as Antioxidants^[6], Nueroprotector, Antidepressant and Anxiolytic activity.^[7] Puerarin also have the Antimicrobial property.^[8] Vidarikanda contains beeta-Sitosterol and Stigmasterol which acts as Androgenic^[9] and Hypolipidimic effect respectively.^[10] Vidarikanda contains

Steroid saponin (disogenin) it reduces the level of serum cholesterol. Vidarikanda contains Tuberosin which acts as Antioxidant. By its antioxidant property of Tuberosin it secretes the Nitric oxide in penile tissue.^[11] Nitric oxide is chemical compound that plays a major role in male sexual function. An abundance of nitric oxide can improve circulation and lead to more frequent erections. Nitric oxide's mechanism of action is very simple. The inner-lining of blood vessels use nitric oxide to signal the surrounding smooth muscle to relax. This leads to vasodilation (blood vessel dilation), and therefore increased blood flow. Increased blood flow can lead to more frequent erections.

Table 1: Assessment Parameters before treatment, After Treatment (30th day) Group A

	SD0	SD1	SD2	SD3	SD4	SD5	Total
BT	1	3	0	1	3	7	15
AT	0	0	0	0	11	4	15
	PE0	PE1	PE2	PE3	PE4	PE5	
BT	1	6	0	2	3	3	15
AT	0	1	0	1	0	13	15
	PR0	PR1	PR2	PR3	PR4	PR 5	
BT	1	6	7	1	0	0	15
AT	0	0	6	2	7	0	15
	PA0	PA1	PA2	PA3	PA4	PA5	
BT	0	2	1	8	3	1	15
AT	7	3	0	4	0	1	15
	Ej0	Ej1	Ej2	Ej3	Ej4	Ej5	
BT	0	0	1	14	0	0	15
AT	0	0	1	7	6	1	15
	Or0	Or1	Or2	Or3	Or4	Or5	
BT	0	2	3	5	5	0	15
AT	0	0	1	3	6	5	15

Table 2: Assessment Parameters before treatment, After Treatment (30th day) Group B

	SD0	SD1	SD2	SD3	SD4	SD5	Total
BT	2	0	0	0	5	9	16
AT	0	0	0	0	10	6	16
	PE0	PE1	PE2	PE3	PE4	PE5	
BT	3	9	0	2	2	2	16
AT	1	6	0	0	7	7	16
	PR0	PR1	PR2	PR3	PR4	PR 5	
BT	3	3	9	1	0	0	16
AT	1	1	4	3	7	0	16
	PA0	PA1	PA2	PA3	PA4	PA5	
BT	0	1	5	5	5	0	16
AT	6	1	4	3	2	0	16

	Ej0	Ej1	Ej2	Ej3	Ej4	Ej5	
BT	2	0	1	13	0	0	16
AT	1	0	0	9	4	2	16
	Or0	Or1	Or2	Or3	Or4	Or5	
BT	1	0	1	9	5	0	16
AT	2	0	1	4	4	5	16

CONCLUSION

Vidarikanda churna in the dose of 6grams per day for 30 days showed statistically significant results in Sexual desire, penile erection and Penile Rigidity. Hence the *Vidarikanda* is a worthy choice of drug in treating Klaibya (Erectile Dysfunction)

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